DIR Report #	ARTG #	Date of Report	GMDN / UMDN Text	Device Class	Sponsor Name	Manufacturer Name	Clinical Event Information	Outcomes
27339	154912	13/07/2012	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient is experiencing heating at the IPG pocket. The reported discomfort is said to be constant and is not limited to the recharging of the IPG. The implant depth of the patient's IPG is allegedly superficial. Surgical intervention was undertaken to address this issue, and the patient's IPG was replaced. During the procedure, the physician also revised the implant depth of one of the patient's two leads alleging the device's previous position was too close to the skin and resulted in uncomfortable stimulation for the patient. No further complications have been reported following the procedure. 2012-15 June: Analysis of the returned IPG is still in progress; however, the rate of occurrence has been added to the report. 2012-09 July: Follow-up on this matter found the patient underwent another surgical procedure to revise the implant depth of the lead as the device had reportedly migrated close to the skin's surface. The physician suspects these occurrences are attributable to the anchoring technique for the lead.	Reviewed, No Further Action Required
26484	129091	16/07/2012	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient was experiencing pain and burning sensation around the IPG site. The patient was given an injection and is experiencing less pain at the IPG site and is reportedly doing well.	Reviewed, for Trending Purposes Only
27383	128775	17/07/2012	Electrode/lead, stimulator, implantable, neurological	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that during a revision for ineffective therapy the physician observed high impedances and explanted the leads and splitter. The IPG was also repositioned as the physician felt the original placement was inappropriate. The physician indicated that the leads had been damaged during the explant procedure. The patient is reportedly doing well following the revision.	Reviewed, for Trending Purposes Only
27406	132097	18/07/2012	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	The patient's SCS system included three percutaneous leads from two different lots. It was reported the patient's leads migrated. The movement was confirmed via x-ray. Surgical intervention was undertaken to address this issue. Two of the patient's three leads were successfully repositioned; however, one of the devices was inadvertently explanted; during the attempt to reimplant the lead, a CSF leak occurred. The procedure was completed with the removal of the patient's lead anchors and the relocation of the IPG pocket. These measures were undertaken to alleviate the reported discomfort alleged by the patient. The patient remains hospitalized and the CSF leak issue will continue to be monitored in case additional intervention is warranted.	Reviewed, for Trending Purposes Only
27420	154912	20/07/2012	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient suddenly lost stimulation and since that time has been unable to establish communication with the IPG via the programmer or charging system. Efforts to resolve this matter with use of a different programmer and charging system proved unsuccessful. Surgical intervention was undertaken to replace the patient's IPG. Effective stimulation was recaptured for the patient following the procedure.	Reviewed, for Trending Purposes Only
27429	127126	20/07/2012	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient is experiencing pain and discomfort at the IPG site particularly during movement. The patient's IPG is implanted in the abdomen, and the issue reportedly began after the patient bent over. Surgical intervention will be undertaken at a later date to address this issue. 22-06-2012: No new information has been provided to the manufacturer regarding this event; however the number of similar incidences has been added to the report. 20-07-2012: Follow-up on this matter found the patientâ€™s IPG was replaced on 16-05-2012 thereby resolving the reported issue. The explanted device will not be returned to the manufacturer.	Reviewed, for Trending Purposes Only
27534	131946	25/07/2012	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient is not feeling stimulation in the right leg. An x-ray was taken which revealed the lead on the right side had migrated. The patient is currently undergoing a trial for coverage of new pain areas. It is the physician's intent to address the migration issue via surgical intervention coinciding with the end of the trial. 25-07-2012: It was reported surgical intervention took place on 22-07-2012. The physician left the migrated lead in position and implanted a new lead. Effective stimulation was captured for the patient following the procedure. 25-07-2012: The physician left the migrated lead in position and implanted a new lead. Effective stimulation was captured for the patient following the procedure.	Reviewed, for Trending Purposes Only
27156	129091	27/07/2012	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Patient was experiencing discomfort at the pocket site due to the IPG being more superficial.	Reviewed, for Trending Purposes Only
27605	129091	30/07/2012	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient underwent a revision due to the IPG flipping inside the pocket. The physician wrapped the IPG in a mesh envelope and stapled the IPG in to place. The patient is recovering successfully after the procedure.	Reviewed, for Trending Purposes Only
27635	154912	30/07/2012	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient's PNS system was explanted due to infection. A culture was taken; however, the results have not been confirmed. There are no plans for reimplant. Follow-up on this matter found the physician suspects the patient has a subtle immune deficiency against Staph aureus as this was the patient's second explant due to infection. No culture results are available. 29/06/2012: No additional information has been provided to the manufacturer regarding this event.	Reviewed, for Trending Purposes Only
26696	129091	1/08/2012	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient will undergo an IPG explant/re-implant procedure due to the inability to keep a charge. The patient had previous pocket revision (mfr report # BSN520184) and since the IPG will not maintain a charge.	Reviewed, for Trending Purposes Only
27035	129091	8/08/2012	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient underwent an explant producedure due to the physician suspected malfunction of the IPG due to multiple reset counts. The patient underwent an explant procedure.	Reviewed, for Trending Purposes Only
27814	128775	8/08/2012	Electrode/lead, stimulator, implantable, neurological	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient was experiencing discomfort at the lead site due to the leads being too superficial. The patient underwent a lead revision, during which, the physician elected to replace the leads with new leads. The patient was reportedly doing well following the procedure.	Reviewed, for Trending Purposes Only
27915	132097	13/08/2012	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	The patient received an SCS system consisting of an IPG, two percutaneous leads (from the same lot) and two anchors (from the same lot). It was reported that the physician repositioned one the patient's leads deeper on 01-06-2012 in order to improve stimulation and to treat tenderness around the anchor site. During a programming session on 03-07-2012, the patient complained that her IPG site was tender while charging. She also reported an infection after the lead revision procedure. No further information is available at this time as all attempts to confirm resolution have been unsuccessful. 27/07/2012: Follow-up on the patient found the infection was confirmed within the wound where the anchor had been repositioned. The patient was treated with a course of oral antibiotics. The patient is allegedly recovering and the system remains implanted. No further patient complications were reported.	Reviewed, for Trending Purposes Only
27731	132097	23/08/2012	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	The patient received an SCS system which included two leads (from the same lot) placed in the thoracic region. It was reported the patient felt stimulation in her left arm down to her fingers. The physician reported that he feels he may not have locked the swift lock anchor however, upon reviewing the implant details it is confirmed that the patient had cinch anchors implanted. An X-ray showed that one of the leads had migrated to the cervical region. Surgical intervention will be taken at a later date to address this issue. 24/08/2012: Follow-up identified the physician repositioned the patient's migrated lead on 03 August 2012 and reported no issues as a result of the procedure. The patient's cinch anchors remain implanted.	Reviewed, No Further Action Required

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27493	131047	27/08/2012	Electrode/lead, stimulator, implantable, neurological	Class III	Aurora BioScience Pty Ltd	Cyberonics Inc	The explanted lead was returned for analysis. Paperwork with the lead indicated the lead was replaced due to a â€œlead breakâ€. The outer silicone tubing is abraded open. Dried body fluids are noted inside the outer tubing; likely due to the abraded opening in the outer tubing. Note that since the electrode array portion was not returned for analysis, an evaluation and resulting commentary cannot be made on that portion of the lead. Other than the above mentioned observations and typical wear and explant related observations, no anomalies were identified in the returned lead portion. No lead fractures were noted in the returned lead portion.	Reviewed, No Further Action Required
28210	126001	27/08/2012	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported surgical intervention was undertaken to replace the patient's neurostimulator which had previously been damaged due to a fall the patient suffered. Intraoperative testing conducted during the procedure found impedance issues with the lead when tested both independently and in conjunction with the extension. However, adequate stimulation coverage could be obtained for the patient utilizing the functioning lead contacts. The procedure was completed with the replacement of the patient's neurostimulator and extension. The lead remains implanted The explanted devices will not be returned to the manufacturer for analysis.	Reviewed, for Trending Purposes Only
28349	131947	31/08/2012	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the physician experienced difficulty implanting the lead during the trial procedure. It was the physician's intent to position the lead to the right of midline; however, each placement attempt resulted in the device steering left. The case was eventually completed with implant of a new lead. An x-ray confirmed proper lead placement. Due to the multiple implant attempts, it was reported the patient was subjected to approximately 13 minutes of radiation exposure. Despite having post operative wound pain following the procedure, the patient reported effective stimulation relief and a reduction in back pain. Further post operative testing found impedance issues with the implanted lead; however, these issues were overcome via programming.	Reviewed, for Trending Purposes Only
28422	129091	7/09/2012	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient underwent an explant procedure due to pain under the IPG site. The physician explanted the IPG and one lead, however, the other lead was left implanted due to scar tissue. The patient was reportedly doing well following the procedure.	Reviewed, for Trending Purposes Only
28467	126002	10/09/2012	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported surgical intervention was undertaken to address tightness and lead protrusion at the back of the patient's neck. Due to high impedance readings observed during a prior programming session, the physician decided to replace the patient's lead.	Reviewed, for Trending Purposes Only
28301	132097	12/09/2012	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	The patient is implanted with two leads from different lots. It was reported the patient's stimulation has changed. Efforts to rectify this matter through reprogramming yielded limited success. An x-ray was taken for further interrogation; however, no anomalies were detected. Follow-up on this matter found the patient will undergo a trial procedure to implant a peripheral nerve lead in hopes of obtaining optimal therapy coverage for his area of pain. 2012-07-20: No new information has been provided to the manufacturer regarding this event. 2012-08-17: Follow-up on this matter found the surgery is still pending. 14-09-2012: It was reported surgical intervention took place on 02-09-2012, and it was discovered the patient's leads had migrated. The physician elected to replace the leads and remove the patient's anchors. Effective stimulation was reportedly recaptured for the patient following the procedure. The explanted devices will not be returned to the manufacturer for analysis.	Reviewed, for Trending Purposes Only
28300	170450	13/09/2012	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported that the patient received an SCS system for lower back pain. She stated that she only felt stimulation down her left leg. Reprogramming efforts were allegedly unsuccessful. The physician repositioned the lead more midline during a lead revision procedure on 03-07-2012. No further information is available at this time. 07/08/2012: Follow-up found the patient was feeling stimulation from below the ribs to the ankles, with bilateral stimulation in her legs. It was reported that programming efforts were unable to achieve stimulation needed at the right hip. Diagnostic tests revealed no anomalies. The patient will be reprogrammed at a later date. No further information is available at this time. 14/09/2012: Follow-up identified the patient was recently reprogrammed and reported good stimulation coverage for her lower back and bilateral legs. It was reported that optimal coverage of the right hip may not be possible due to patient anatomy issues. It was reported the patient has scarring in her right hip area.	Reviewed, for Trending Purposes Only
28134	129091	14/09/2012	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient's IPG was repositioned due to discomfort at the IPG site. The patient is reportedly doing well.	Reviewed, for Trending Purposes Only
28634	131947	17/09/2012	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	The patient was implanted with four trial leads from different lots. During a programming session it was reported the patient felt nauseous and light headed when stimulation was initiated. The patient was reportedly standing at the time of the occurrence. The session was aborted, and medication was administered for the nausea. A subsequent programming session conducted with the patient seated resulted in adequate therapy coverage; however, the patient has elected not to proceed with a permanent implant.	Reviewed, for Trending Purposes Only
28640	131947	17/09/2012	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	The patient was implanted with four trial leads from two different lots. During programming it was reported the patient was experiencing an aching feeling from the leads instead of the intended parasthesia. The physician suspects that one or more of the trial leads may have been implanted too deep. Follow-up on this matter found the reported issue was addressed to a certain degree through reprogramming. The trial was considered successful as the patient was able to obtain 60% pain relief. The leads were removed at the conclusion of the trial.	Reviewed, No Further Action Required
28299	132097	19/09/2012	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	The patient received an SCS system for back pain and leg pain. It was reported the patient experienced ineffective stimulation in May 2012. The patient`s lead allegedly exhibited invalid impedance readings but reprogramming temporarily solved the issue. It was reported that more of the lead contacts exhibited invalid impedances and the patient subsequently lost stimulation in June 2012. X-rays were inconclusive, therefore, the patient was taken to surgery to evaluate the issue. The physician noted the lead was fractured, and the lead was explanted and replaced on 31 /07/2012. The patient reported effective stimulation as a result of the procedure. No further patient complication's were reported.	Reviewed, for Trending Purposes Only

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28679	154912	20/09/2012	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient is experiencing heating from her two IPGs. The alleged heating is said to occur intermittently and emanates through the patient's skin. Initially, the patient's SCS therapy was set to continuous programs as she reportedly utilizes the stimulation 24 hours a day, 7 days a week. Efforts to resolve this matter by changing the patient's programs to a cycling mode provided only a temporary resolution. Follow-up with the patient found the heating has returned, and the IPG sites are sore to the touch. An appointment with the physician has been scheduled for further evaluation. 01-06-2012: Follow-up on this matter found the reported discomfort has completely resolved on the patientâ€™s right side; however, the burning sensation is still felt on the left side during recharging or when pressure is applied to the site. The patient has been referred to a pain specialist for medical management of this issue. 29-06-2012: Follow-up on this matter found there is no new information to report with respect to the patientâ€™s condition. However, the manufacturer was advised the physician believes the patient has hypersensitivity in the area in question due to the formation of the pocket and does not suspect the reported issue is related to the devices implanted in this patient. 27-07-2012: Follow-up on this matter found there is no new information to report with respect to the patientâ€™s condition as she is still awaiting consultation with the pain specialist. 24-08-2012: No new information has been provided to the manufacturer regarding this matter. 20-09-2012: It was reported the patient is now experiencing a jabbing and electrical sensation at the site of the left IPG. The reported sensation is said to occur intermittently when stimulation is turned either on or off. A diagnostic test found no issues with respect to impedance. There are no immediate plans for surgical intervention; however the physician will continue to monitor this situation. If new information is provided to the manufacturer, an amended final report will be submitted.	Reviewed, for Trending Purposes Only
27978	128775	26/09/2012	Electrode/lead, stimulator, implantable, neurological	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient's leads have become superficial due to non-device related weight loss. The patient will undergo a revision procedure.	Reviewed, for Trending Purposes Only
28413	129091	26/09/2012	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient will undergo an IPG reposition due to pain at IPG pocket site.	Reviewed, for Trending Purposes Only
28508	126001	26/09/2012	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported surgical intervention was undertaken on 30-07-2012 to replace the patient's IPG as the device was no longer providing stimulation. (Reference Mfr Report # VR 2011-142790 2896/DIR 25122. for the IPG issue.) During the procedure, the physician also intended to relocate the IPG pocket. However, these plans were aborted once it was learned the patient was still taking warfarin. Intraoperative testing of the patient's extension found invalid impedance measurements for all contacts. Effective stimulation coverage was achieved through further independent testing of the lead. The case was completed with the explant of the patient's IPG and extension. The patient's lead remains in-situ. An additional surgical procedure will be undertaken to replace the IPG.	Reviewed, for Trending Purposes Only
28728	132097	26/09/2012	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	The patient was implanted with two percutaneous leads from different lots. It was reported the patient's leads were explanted and replaced with a surgical lead for the purpose of providing better pain coverage.	Reviewed, for Trending Purposes Only
28767	126001	27/09/2012	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient's pain pattern has moved, and the new indication will be treated by medication. As such, the patient requested explant of the SCS system. Upon removal of the extensions, it was reported the strain relief was missing from one of the devices. The fragment was not located following a review of the wound area. The physician indicated he was was not concerned about the possibility of the fragment remaining in-situ. No patient complications have been reported as a result.	Reviewed, for Trending Purposes Only
29228	128775	27/09/2012	Electrode/lead, stimulator, implantable, neurological	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient underwent a revision due to the lead being superficial. The physician buried the lead deeper and was satisfied with the patient's progress.	Reviewed, for Trending Purposes Only
28827	127126	1/10/2012	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient is without stimulation and is unable to establish communication with the IPG via either the programmer or charging system. Efforts to establish communication with use of a new charging system were not successful. Surgical intervention was undertaken to replace the patient's IPG, and the reported issue was resolved. The explanted device was retained by the medical facility.	Reviewed, No Further Action Required
28828	132097	1/10/2012	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported surgical intervention was undertaken to revise the patient's lead. The procedure was done at the patient's request as she alleged the original lead placement was incorrect and did not adequately address the pain in the back of her head (off-label). The patient reports satisfactory therapy coverage following the revision.	Reviewed, for Trending Purposes Only
27409	128775	3/10/2012	Electrode/lead, stimulator, implantable, neurological	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient was experiencing pain at the lead extension site and the physician has decided to proceed with a revision to remove scar tissue and bury the extensions deeper.	Reviewed, for Trending Purposes Only
28436	128775	9/10/2012	Electrode/lead, stimulator, implantable, neurological	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient's leads were starting to push out through the skin. The patient underwent a revision procedure. The physician buried the leads deeper and secured them with sutures. The patient is reportedly doing well following the procedure.	Reviewed, for Trending Purposes Only
28854	127126	9/10/2012	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported to the manufacturer the patient's IPG flipped in the pocket. The issue allegedly occurred approximately two weeks after implant. Surgical intervention was undertaken to rectify the matter.	Reviewed, No Further Action Required
28251	129091	11/10/2012	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient underwent an IPG explant due to pain at pocket site. The patient indicated that discomfort was present around IPG and buttock area. Impedances showed normal. The physician does not know if the pain is device or procedure related. The patient is reportedly doing well following the procedure.	Reviewed, for Trending Purposes Only
27977	129091	16/10/2012	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient is experiencing difficulty charging due to the IPG depth and pocket location. The patient will undergo a pocket revision procedure.	Reviewed, for Trending Purposes Only

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28934	132097	18/10/2012	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported several of the patient's lead contacts exhibited invalid impedance measurements. Reprogramming of the patientâ€™s SCS system was undertaken utilizing the functioning contacts resulting in effective stimulation. Since that time, the patient has begun experiencing difficulty communicating with the IPG via both the charging system and the patient programmer. Efforts to rectify the communication issue using various troubleshooting techniques were unsuccessful. An x-ray of the patient's SCS system was taken; however, no visible anomalies were found. Surgical intervention will be undertaken at a later date to address these issues. 2012-10-19: It was reported surgical intervention was undertaken to replace the patient's lead and IPG. It was noted the replacement lead was positioned slightly right of midline due to the presence of scar tissue. The lead was cut during explant and discarded by the medical facility. Post operative programming will be done at a later date to confirm effective therapy.	Reviewed, for Trending Purposes Only
29011	154912	23/10/2012	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported a surgical procedure has been scheduled to explant the patient's IPG. No further details were provided. 23-10-2012: Follow-up on this matter found the patientâ€™s SCS system was explanted on 06-09-2012 due to lack of efficacy. Although the patient was feeling paresthesia in the painful areas, pain relief was alledgedly not achieved. The explanted devices will not be returned to the manufacturer for analysis.	Reviewed, for Trending Purposes Only
26449	128775	26/10/2012	Electrode/lead, stimulator, implantable, neurological	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient underwent an explant due to the lead eroding through the skin. The physician does not know whether it was device or procedure related. The patient is reportedly doing well.	Reviewed, for Trending Purposes Only
29044	126002	26/10/2012	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported surgical intervention was scheduled to relocate the patient's IPG in an effort to alleviate tightness and lead protrusion at the back of the neck. Diagnostic testing conducted prior to the commencement of the procedure found an impedance issue with the patient's lead. The surgery was completed with the relocation of the patient's IPG and replacement of the lead.	Reviewed, for Trending Purposes Only
29055	129091	29/10/2012	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient underwent a pocket revision procedure due to discomfort at the pocket site. The physician repositioned the IPG and the patient was reportedly doing well following the procedure.	Reviewed, for Trending Purposes Only
28883	132097	30/10/2012	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient is not receiving effective therapy coverage. Attempts to resolve this matter via reprogramming have proven unsuccessful and resulted in positional stimulation. A diagnostic test revealed low impedance measurements for several lead contacts. Surgical intervention will be undertaken at a later date to address this issue. 2012- July 13: Follow-up on this matter found the next course of action is pending as the patient has been referred to a neurosurgeon for consultation. 2012-August 10: It was reported surgical intervention took place on 07-08-2012 to address the patientâ€™s stimulation issue. The patientâ€™s IPG was replaced. Following intraoperative testing, it was decided to replace the patientâ€™s percutaneous lead with a paddle lead to obtain adequate coverage. However, the physician experienced difficulty placing the new lead as the device was steering to the right. Additional attempts to successfully place the device resulted in discomfort for the patient. Further interrogation found the placement attempts to be hindered by the presence of scar tissue. The lead was eventually placed at spinal region T10 and connected to the IPG. Postoperative testing will be conducted at a later date to confirm stimulation coverage. 2012- September 5: Prior to the explant procedure, it was reported, the patient experienced increased urinary frequency and diarrhoea which has since resolved. 2012-October 3: Follow-up on this matter found the patient is experiencing effective therapy coverage and comfortable stimulation since the replacement procedure. The explanted products have been returned to the manufacturer for analysis.	Reviewed, for Trending Purposes Only
29062	132097	30/10/2012	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	The patient underwent a surgical procedure to implant an IPG. Intraoperative testing performed during the procedure found impedance issues with both the patient's lead and extension. As such, the lead and the extension were explanted. The procedure was completed with implantation of a new lead which was connected directly to the new IPG. Effective stimulation was captured via post-operative progamming.	Reviewed, for Trending Purposes Only
29086	132097	30/10/2012	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	The patient's SCS system includes two leads from different lots. Following a recent revision procedure, it was reported that one of the leads was exhibiting high impedance measurements. It was suspected the issue stemmed from a connection issue between the lead and IPG. An x-ray to confirm proper connection was reportedly not performed during the revision procedure. Surgical intervention was undertaken on 10-10-2012 for further interrogation, and it was found the lead in question was not properly inserted into the IPG header. As such the lead was reinserted. Proper connection was confirmed via x-ray prior to the procedure's completion.	Reviewed, for Trending Purposes Only
29167	154912	30/10/2012	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient is not receiving effective therapy coverage. Attempts to resolve this matter via reprogramming have proven unsuccessful and resulted in positional stimulation. A diagnostic test revealed low impedance measurements for several lead contacts. Surgical intervention will be undertaken at a later date to address this issue. 2012- July 13: Follow-up on this matter found the next course of action is pending as the patient has been referred to a neurosurgeon for consultation. 2012-August 10: It was reported surgical intervention took place on 07-08-2012 to address the patientâ€™s stimulation issue. The patientâ€™s IPG was replaced. Following intraoperative testing, it was decided to replace the patientâ€™s percutaneous lead with a paddle lead to obtain adequate coverage. However, the physician experienced difficulty placing the new lead as the device was steering to the right. Additional attempts to successfully place the device resulted in discomfort for the patient. Further interrogation found the placement attempts to be hindered by the presence of scar tissue. The lead was eventually placed at spinal region T10 and connected to the IPG. Postoperative testing will be conducted at a later date to confirm stimulation coverage. 2012- September 5: Prior to the explant procedure, it was reported, the patient experienced increased urinary frequency and diarrhea which has since resolved. 2012-October 3: Follow-up on this matter found the patient is experiencing effective therapy coverage and comfortable stimulation since the replacement procedure. The explanted products have been returned to the manufacturer for analysis.	Reviewed, for Trending Purposes Only
29118	154912	31/10/2012	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	The patient received two IPGs on 07/09/2009 for cluneal nerve, back and leg pain. It was reported the patient complained of being unable to turn stimulation off. It was reported the patient had mixed up her programmers and corrupted the programs. The patient allegedly reported she could still feel stimulation after her programs were deleted from the right-sided IPG which covers her cluneal leads. Reprogramming efforts were unsuccessful at resolving the issue. The physician took the patient to surgery on 24/07/2012. During the procedure, the physician disconnected the IPG from the patient's leads and the patient still reported feeling stimulation. It was reported when the physician tried to remove the lead and pull it out of the IPG port, the lead caught and the end electrode remained positioned in the IPG. The IPG (serial # 711397) was explanted. No leads were explanted. 02/10/2012: Follow-up is in progress to determine next course of action and patient status. 30/10/2012: Follow-up identified the patient underwent surgery on 26/10/2012. It was reported her exisitng original dual Octrode leads were exposed and tunnelled to the thoracic area where the patient has peripheral pain. These leads were inserted into a dual extension and the existing middle cluneal Octrode leads were also attached to a dual extension. Both of the extensions were connected to a new IPG. The patient reported effective stimulation coverage postoperative.	Reviewed, No Further Action Required

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28557	154912	5/11/2012	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient is experiencing difficulty reinitiating stimulation with use of the magnet. The reported issue is said to occur when using a cycling program and multiple attempts are needed in order for the magnet function to work properly. In addition, the patient also reports discomfort at the IPG site. Prior to these occurrences, the patient reported that the IPG was turning off without prompting. Further monitoring of that issue found the occurrence was isolated to the patientâ €™s visits to a shopping center. Surgical intervention is scheduled for 31/10/2012. At that time, the physician plans on replacing the patientâ€™s IPG and relocating the IPG pocket. The manufacturer respectfully requests permission to provide its next report following the scheduled surgical intervention. 04/11/2012: Follow-up on this matter found that the patient cancelled the procedure scheduled for 31/10/2012. There are currently no immediate plans to reschedule the surgery. As such this is the final report on this matter.	Reviewed, for Trending Purposes Only
29192	155013	7/11/2012	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported surgical intervention was undertaken to replace the patient's lead to rectify a stimulation issue (invalid impedance) previously reported in Mfr Report # VR 2011 138968 1662/ DIR 24069. The lead was reportedly difficult to explant due to the presence of scar tissue. It was also reported the physician experienced difficulty advancing the new lead into the epidural space. Trimming was allegedly needed to facilitate placement. During the surgery, a drain was inserted. In addition, blood and fluid had to be removed from the IPG header block before completion of the procedure. Post operative programming found an impedance issue with one of the contacts on the newly implanted lead. 07-11-2012: Follow-up on this matter found the previously inserted drain has since been removed.	Reviewed, for Trending Purposes Only
29210	129091	7/11/2012	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient was experiencing pocket discomfort and felt the IPG heated up, especially during charging. The physician assessed that the IPG was too shallow. The patient underwent a pocket revision and the IPG was repositioned deeper in the pocket. The patient was reportedly doing well.	Reviewed, for Trending Purposes Only
28496	126003	13/11/2012	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	The patient's SCS system consists of two surgical leads. It was reported the patient is without stimulation. X-rays showed no evidence of lead migration, and the IPG appeared intact. However, the leads at the distal end of the IPG appear twisted or frayed. In addition, the patient is allegedly experiencing intermittent pain at the implant site. Surgical intervention will be undertaken at a later date to address these issues. 27-05-2012: No new information has been provided to the manufacturer regarding this matter. 25-06-2012: No new information has been provided to the manufacturer regarding this matter. 25-07-2012: Follow-up on this matter found the patient is now under the care of a different physician. Surgical intervention is still pending. Current x-rays of the patient's SCS system will be obtained as previous images are more than 6 months old. 24-08-2012: No new information has been provided to the manufacturer regarding this matter. 21-09-2012: It was reported the patient's Lamitrode lead was explanted and replaced on 05-09-2012. Stimulation was reportedly restored for the patient; however, therapy coverage is limited. 19-10-2012: The explanted lead was returned to the manufacturer for analysis on 08-10-2012.	Reviewed, for Trending Purposes Only
29290	131944	13/11/2012	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported a surgical procedure was scheduled with the intent of replacing the patient's IPG. A diagnostic test conducted prior to the operation found impedance issues for the patient's lead. A fracture of the lead near the anchor site was confirmed during intraoperative testing. As such, the lead was replaced. Effective stimulation was recaptured for the patient following the procedure.	Reviewed, for Trending Purposes Only
29337	132097	15/11/2012	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient underwent surgical intervention on 19-10-2012 to replace a fractured lead. The device damage was previously confirmed via x-ray (Reference DIR 26093). The patient is reportedly responding well to the new device.	Reviewed, for Trending Purposes Only
28105	129091	26/11/2012	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient will undergo an IPG replacement. The patient is experiencing charging difficulties and IPG is overheating and turning off by itself. The BSN representative performed troubleshooting to all possible issues with no success. The patient had a non-device related surgery and Diathermy was used which may have damaged the IPG.	Reviewed, No Further Action Required
29102	128775	27/11/2012	Electrode/lead, stimulator, implantable, neurological	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient underwent a revision due to a lead eroding through the skin. The physician sutured the leads back in place. Nothing was implanted or explanted.	Reviewed, for Trending Purposes Only
29323	127126	6/12/2012	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	During a procedure to replace the patientâ€™s leads due to migration, it was observed the IPG had a small nick and a bubble on its surface. As such, the physician replaced the IPG as well. Effective stimulation was recaptured for the patient following the procedure. Update 7 Nav 2012: Analysis of the returned IPG is still in progress.	Reviewed, for Trending Purposes Only
28506	154912	11/12/2012	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient underwent a routine lead disconnection on 20th December 2011. Allegedly, one of the lead's distal connectors was left in the IPG, thereby blocking any future lead insertions. It was reported the IPG was not explanted and replaced until 3rd July 2012 due to the patient's health. The physician left the damaged lead in situ due to the failing health of the patient. Surgical intervention will be undertaken in the future to replace the damaged lead. No further information is available at this time. 24/08/2012: Follow-up on the patient found he had received two leads with his SCS system on 02/11/2011; a paddle lead and a percutaneous lead. It was reported the patient's IPG that was explanted and replaced on 3rd July 2012 appeared to have lead tips disconnected and stuck in both ports of the IPG. Follow-up with the physician identified that only one of the patient's leads was damaged during the 20/12/2011 disconnection procedure. The physician stated that the paddle lead was intact and able to provide stimulation with the replacement IPG; however, the percutaneous lead was left damaged in situ. The physician still plans to explant and replace the damaged lead at a later date. 21/09/2012: Follow-up is in progress. No additional information is available at this time. 19/10/2012: It was reported the damaged lead was explanted on 9/Oct/2012. It was reported the distal connector of the lead which goes into the IPG header block had broken off as expected.	Reviewed, for Trending Purposes Only

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29370	121880	11/12/2012	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported that although the patient is receiving effective stimulation, the recharge burden for the IPG has increased. Surgical intervention will be undertaken at a later date to replace the patient's IPG as she alleges the recharge burden is becoming unmanageable. 11-12-2012: Follow-up on this matter found that the patient's IPG was explanted and replaced on 07-11-2012. Effective stimulation was recaptured for the patient following the procedure. The explanted IPG will not be returned to the manufacturer.	Reviewed, for Trending Purposes Only
28081	154866	12/12/2012	Stimulator, electrical, analgesic, spinal cord	AIMD	Medtronic Australasia Pty Ltd	Medtronic Inc	Patient was undergoing a reprogramming of her R) Motor Cortex Stimulator when she experienced what was later diagnosed as a seizure. This lasted for approximately 45 seconds where she received immediate medical treatment at the hospital. The patient underwent a range of tests and was given pain relief via a cannula. She was discharged from hospital that night. CT scan of the brain revealed no abnormalities. The patient reported that her head pain (which is on the opposite side of the lead) had returned since the event where both her mcs and sub-occipital/supra-orbital stimulators had been turned off. This pain had improved once her SON stimulation had been restarted and she was able to take her normal pain management medication. The patient asked if she could turn her MCS back on to relieve her left head pain. An appointment was arranged for this to be done with Dr at his rooms on the 3rd June which was performed without incident and with good effect on her head pain. The patient reported that she had returned to pre-event status with no residual effect. The patient stimulator was programmed back to her initial settings and limits on her amplitude and pulse width were also programmed. Implant dates: 21/04/2010 & 31/10/2007.	Reviewed, No Further Action Required
29592	127126	12/12/2012	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	Following a recent review of SJM's complaint records, it was discovered the required incident report was not filed for the below stated event. This report is being submitted to correct the oversight. It was reported the patient's IPG was explanted and replaced due to allegations of intermittent overstimulation and an increased recharge burden. It was reported the IPG had scratches on the can which were believed to have occurred during a previous surgery to address a lead migration issue.	Manufacturing process improvements
29326	127126	20/12/2012	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient is experiencing headaches and elevated blood pressure when the SCS system is in use. This has reportedly been occurring for several years. Once the stimulation is off, the issues reportedly resolve. The patient is working with his pain physician regarding this matter. 26-10-2012: A recent diagnostic test found no issues with respect to impedance. The patient is said to be receiving circulation benefits from the SCS system but limited pain relief. Investigation of the reported issue continues. 21-11-2012: There is no new information to report on this matter at this time. 20-12-2012: It was reported the implanting physician verbally addressed the patient's concerns of elevated blood pressure, headaches and ineffective stimulation during a recent appointment. The physician noted that the patient complained of headaches prior to implant and provided assurance that the reported symptoms are not device related as the patient's SCS system is functioning as intended. In addition, advisement was provided to the patient regarding the possible side effects associated with 24 hour stimulation use. To further investigate the patient's claims of increased pain, the physician ordered a CT scan. A blood pressure monitoring was also recommended. According to the patient, the results of the CT scan were normal, but he has yet to follow-up on the blood pressure monitoring referral. Impedance readings for the patient's SCS system continue to measure within specifications and system adjustments made at the patient's request during a recent programming session reportedly provided satisfactory therapy coverage.	Reviewed, for Trending Purposes Only
29822	126001	3/01/2013	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient's extension was explanted and replaced on 18-06-2007 due to functional issues. This information was discovered by the manufacturer after reviewing the patient's files. No further information is available.	Reviewed, for Trending Purposes Only
29318	154912	9/01/2013	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	The patient is implanted with two IPGs. It was reported the recharge burden for both devices had increased. In addition, it was reported the patient's IPGs were turning off without prompting. Surgical intervention was undertaken to replace both devices. The new IPGs are reportedly working well. 07-12-2012: Follow-up on this matter found the reported issue has resolved with replacement of the IPGs. Analysis of the devices is still in progress.	Field Safety Corrective Action Hazard alert
29766	160826	18/01/2013	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient was not receiving therapy from his right-side DBS lead. A diagnostic test revealed impedance issues, and it was determined that one lead contact was non-functional. X-rays were taken for further interrogation; however, no visual anomalies were observed. Effective therapy was achieved for the patient's left side via reprogramming. Follow-up on this matter found the patient has experienced a further loss of therapy. A subsequent diagnostic test revealed that the impedance issue has progressed. Recent x-rays still show no visible breaks or connection problems. Surgical intervention will be undertaken at a later date to address this issue. Additional reprogramming was conducted to provide adequate therapy relief for the patient until such time. 18-01-2013: Follow-up on this matter found that surgical intervention was undertaken to address the reported issue. Intraoperative testing found impedance issues with both the patient's right brain lead and right brain extension. Due to the complexity involved with a lead replacement, the procedure was completed with replacement of the right brain extension only. In an effort to recapture effective therapy for the patient, reprogramming will be performed at a later date utilizing the newly placed extension and the functioning contacts of the right brain lead.	Reviewed, No Further Action Required
29899	131836	18/01/2013	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient's neurostimulator was no longer providing stimulation. As such, the device was explanted and replaced on 16-08-2010 with an IPG. Due to the time that has elapsed, no further information is available regarding this event.	Product Cancelled from ARTG
28888	127126	21/01/2013	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient initially felt pain at the IPG site during charging when she was implanted. The patient stated she no longer experiences the pain when charging. However, she reported she now feels an uncomfortable "drawing" sensation at the pocket site when she charges. The patient verified the sensation is not a burning or heating sensation but instead feels like an increase in energy through the IPG towards the skin. It was reported the discomfort occasionally lasts up to two hours after charging. The patient reported she limits her recharging to 15 minute intervals twice per week. No further patient complications were reported. Nov/2012: Follow-up identified surgical intervention will be undertaken to address the issue. It was reported the patient broke her arm. As a result of the patient's broken arm, surgery has been postponed until early 2013. Consequently, the manufacturer requests permission to submit the next report in January 2013. Jan/2013: Follow-up identified there are no plans to perform surgical intervention at this time. It was reported the patient is receiving excellent pain coverage and she is managing the recharging issue.	Reviewed, for Trending Purposes Only
29657	186043	25/01/2013	Stimulator, electrical, analgesic, spinal cord	AIMD	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Nevro Corporation	It was reported that: "Patient had infection 1 month post implantation. As a result the IPG was removed." The patient has complex medical history on chronic pain and depression. No additional information was provided.	Reviewed, for Trending Purposes Only
29430	129091	29/01/2013	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient underwent an explant procedure due to the leads displayed high impedances.	Reviewed, for Trending Purposes Only

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29453	106668	29/01/2013	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient's IPG was explanted and replaced. This information was discovered by the manufacturer after reviewing the patient's billing records. The reason for the procedure is unknown. No further information is available.	Reviewed, for Trending Purposes Only
29870	132097	29/01/2013	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	The patient's therapy system includes two percutaneous leads from different lots. It was reported surgical intervention was undertaken to replace one of the devices. This information was discovered by the manufacturer after reviewing the patient's files. The reason for the procedure is unknown. Since it not known which lead was replaced, both lots are being reported.	Reviewed, for Trending Purposes Only
29871	125910	29/01/2013	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient's surgical lead was explanted and replaced with a percutaneous lead. This information was discovered by the manufacturer after reviewing the patient's files. The reason for the procedure is unknown. No further information is available.	Reviewed, for Trending Purposes Only
29872	125910	29/01/2013	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient's lead was explanted and replaced. This information was discovered by the manufacturer after reviewing the patient's files. The reason for the procedure is unknown. No further information is available.	Reviewed, for Trending Purposes Only
29873	126001	29/01/2013	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient's extension was explanted and replaced in November 2006. This information was discovered by the manufacturer after reviewing the patient's billing records. The reason for the procedure is unknown. No further information is available.	Reviewed, for Trending Purposes Only
29968	132097	31/01/2013	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	The patient was implanted with at least two percutaneous leads for thoracic pain (off-label). It was reported a surgical procedure was performed in May 2010 to implant a new lead as one of the patient's existing leads had become disconnected from the IPG header. The procedure also included the explant of one of the originally implanted leads; however, it is unknown whether this was the device affected by the connection issue. In addition, it is unclear at this time exactly how many leads the patient currently has implanted.	Reviewed, No Further Action Required
29171	129091	6/02/2013	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient is experiencing discomfort at IPG site location. The patient will undergo an IPG relocation. Additional information was received that the patient underwent a revision of the pocketsite and is reportedly doing well following the revision.	Reviewed, for Trending Purposes Only
29325	127126	7/02/2013	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient is experiencing pain at the IPG site. The reported sensation is likened to the amplitude of the stimulation being too high. Efforts to alleviate the pain through amplitude adjustments have been unsuccessful. In addition, the patient alleges the recharge burden for the IPG has increased. Reprogramming was undertaken which reportedly reduced both the pain and the recharge burden to some degree. However, surgical intervention was undertaken on 16-10-2012 to replace the patient's IPG. Since the procedure, it was reported the patient has experienced a significant reduction in pain and recharge burden.	Reviewed, No Further Action Required
29836	128679	11/02/2013	Electrode/lead, stimulator, implantable, neurological	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that during an implant procedure, the two leads would not fit into the splitters. The physician could not align the contacts. The physician spent an extra thirty minutes attempting to re-insert the leads into the splitters. A third splitter was used and worked with only one open contact. The physician noted that this deficiency could have led to a Serious Adverse Event if suitable action had not been taken, intervention had not been made, or circumstances had been less fortunate. Additional information was received clarifying that what was meant by the physician noting that the event could have led to a Serious Adverse Event was that there was no connection to the implant therefore the patient could not be programmed. Removing the splitters and replacing them with working splitters means the patient receives benefit.	Reviewed, No Further Action Required
29319	154912	26/02/2013	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient's IPG is turning off without prompting. The patient denies being near a strong magnetic field during these occurrences and claims they are happening more frequently. Surgical intervention will be undertaken at a later date to address this issue.	Reviewed, No Further Action Required
29612	127126	26/02/2013	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient is experiencing intermittent vibrations in her upper bilateral legs. The reported sensations occurred once stimulation had been turned off. As recommended, the patient ceased utilization of her SCS system for several weeks which appeared to have resolved the issue. The patient resumed therapy following the hiatus and the alleged issue returned. Surgical intervention was undertaken to address this issue.	Reviewed, No Further Action Required
30215	131944	4/03/2013	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient was without stimulation and unable to increase the amplitude for his therapy programs. Surgical intervention was undertaken to address this matter. Intraoperative testing found impedance issues for several lead contacts. Further interrogation isolated the issue to the patient's quattrode leads. As such, the devices were explanted and replaced.	Reviewed, for Trending Purposes Only
29908	126002	6/03/2013	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient's occipital lead was explanted. Neither the date of the event nor the reason for the procedure are known at this time. March 2013: It was reported the surgery to explant the patient's SCS system occurred on Sept 2012. A representative from the manufacturer was not present during the procedure. The patient reportedly was not happy with the SCS system and complained about the IPG site. No specifics were provided.	Reviewed, for Trending Purposes Only
29768	132097	13/03/2013	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient has experienced severe vomiting since being discharged following her SCS system implant. The patient also alleged the therapy being delivered was not the same as it was post-operatively. In addition, she claimed that the implant depth for one of her leads was very superficial. Efforts to address the stimulation issue via reprogramming were unsuccessful, and it was suspected the uncomfortable stimulation was the result of lead migration. Surgical intervention was scheduled with the intent of revising her leads. The patient then advised the physician that she was experiencing stimulation at the IPG site. An x-ray was taken for further interrogation and it was found lead migration had not occurred. However, the physician decided to explant the patient's SCS system as it was suspected the uncomfortable sensation was due to the IPG insertion, and the patient's thin physique. Follow-up on this matter found the reported vomiting subsided following the explant.	Reviewed, No Further Action Required
30114	131944	14/03/2013	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	The patient was implanted with two leads which were placed in the occipital region. It was reported the patient is not feeling stimulation. A diagnostic test revealed impedance issues with both leads. Following reprogramming, the patient has coverage on the right side only. X-rays of the patient's leads and IPG were performed; however the results were not disclosed to the manufacturer. Further follow-up found surgical intervention was undertaken to address matter. Intraoperative testing determined the patient's leads were faulty. As such, the devices were explanted and replaced.	Reviewed, No Further Action Required
30367	127126	18/03/2013	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	The patient was implanted with two percutaneous leads from different lots. It was reported surgical intervention was undertaken to disconnect one of the two existing 8-channel leads and implant two 4-channel leads. This was being done in an attempt to capture the patient's lower back pain. Upon opening the pocket, it was found that the lead in question had become disconnected from the IPG header.	Reviewed, No Further Action Required
26058	129091	20/03/2013	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that a patient was experiencing pain at the pocket site due to weight loss and the IPG becoming superficial.	Reviewed, for Trending Purposes Only
30419	131944	22/03/2013	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient lost effective stimulation. Surgical intervention was undertaken to reposition the patient's existing percutaneous lead. A diagnostic test taken at the beginning of the procedure found no notable impedance issues. Further intraoperative testing following repositioning of the device yielded no stimulation for the patient. The lead was again repositioned and tested for stimulation output with the same results. Subsequent diagnostic performed during the procedure again found no notable issues with respect to impedance. After testing with a trial lead produced stimulation, the physician decided to replace the patient's existing percutaneous lead. The physician also elected to replace the extension.	Reviewed, for Trending Purposes Only

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30162	170450	25/03/2013	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient was unable to increase the amplitude for his stimulation. A diagnostic test revealed impedance issues for several lead contacts. For a time period, the patient utilized other program settings which provided adequate therapy coverage. However surgical intervention was subsequently undertaken to replace the lead. 03-2013: Additional information was provided regarding the explant procedure and the patient's current status. It was reported a visible break was detected in the explanted lead with one of the wires protruding out of the polyurethane. The patient reportedly still lacks coverage of his back which was also the case prior to the lead replacement procedure.	Reviewed, No Further Action Required
30214	132097	25/03/2013	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient is unable to feel stimulation. A diagnostic test revealed low impedance readings for all lead contacts. An x-ray was taken for further interrogation, and it was found that the patient's leads were twisted. Surgical intervention will be undertaken at a later date to address this issue. 03-2013: It was reported surgical intervention was undertaken on 03-2013 to replace the patientâ€™s leads.	Reviewed, for Trending Purposes Only
30092	129091	26/03/2013	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that a patient will undergo an IPG replacement procedure due to the IPG causing discomfort.	Reviewed, for Trending Purposes Only
30058	131946	2/04/2013	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	The patient was implanted with two percutaneous leads from different lots. It was reported the patient experienced a loss of coverage. A previous diagnostic test found high impedance issues for one of the patient's leads. At that time, adequate stimulation was captured via reprogramming. Surgical intervention was subsequently undertaken as the coverage issue persisted. During the procedure, it was discovered that both of the patient's leads were fractured. As such, the devices were explanted and replaced with one percutaneous lead. Effective stimulation was recaptured for the patient following the procedure. 03-2013: Analysis still in progress. 04-2013: Analysis complete. See Section V - Results of Mfr's Investigation for details.	Reviewed, for Trending Purposes Only
30227	131944	2/04/2013	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	The patient is currently implanted with four percutaneous leads from three different lots. It was reported the patient has experienced a change in stimulation and is currently unable to utilize some of his programs. One of the patient's leads is reportedly causing painful stimulation in the buttock area. In addition, a recent diagnostic test revealed invalid impedance measurements for one of the patient's leads which inhibits stimulation coverage to his leg. Follow-up on this matter found the patient's leads have moved and the leads on the left side exhibit invalid impedance readings. Surgical intervention will be undertaken on a later date to address this issue. 04-2013: Follow-up on this matter found the physician suspects the reported issues stem from the patient's recent use of an air walker. The patient underwent a trial procedure on 02-2013 but it was unsuccessful in providing effective stimulation coverage. Surgical intervention was undertaken on 03-2013. At that time, all of the patient's leads were explanted and two of the devices were replaced. No leads will be returned to the manufacturer for analysis. Effective stimulation was recaptured for the patient following the procedure.	Reviewed, No Further Action Required
29762	154912	9/04/2013	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient's IPG is turning off without prompting. The issue reportedly began approximately three months ago. The patient still has stimulation and denies being near a magnetic field during such occurrences. Surgical intervention will be undertaken at a later date to replace the patient's IPG.	Reviewed, for Trending Purposes Only
30375	129091	11/04/2013	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient was experiencing pain at the pocket site. The physician noted that the IPG had become more superficial and has suggested a pocket revision. The patient has had recent weight loss. Additional information was received that the patient's recent weight loss was not device related. The patient underwent a pocket revision and was reportedly doing well following the procedure.	Reviewed, for Trending Purposes Only
25987	128775	13/04/2013	Electrode/lead, stimulator, implantable, neurological	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient underwent a lead revision procedure due to erosion of the lead through the skin on her buttock and the midline of her lower back region. During procedure the physician buried the lead deeper and the patient is reportedly doing well.	Reviewed, for Trending Purposes Only
30240	128775	16/04/2013	Electrode/lead, stimulator, implantable, neurological	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that following a lead revision procedure the patient was experiencing a stabbing pain in their back. The patient was admitted to the hospital for a ketamine infusion and pain medication to treat the post procedural pain. The physician assessed that the pain was due to â€œwind upâ€ as a result of the procedure.	Reviewed, No Further Action Required
30438	128775	16/04/2013	Electrode/lead, stimulator, implantable, neurological	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that a patient underwent a lead revision due to discomfort caused by the service loop being tight. The patient would feel the discomfort while turning his head to the side. The patient is no longer experiencing this issue and is receiving stimulation in his pain areas.	Reviewed, for Trending Purposes Only
24896	125910	23/04/2013	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	The patient received an SCS system including a surgical lead implanted in the chest area. The patient alleged that the stimulation was not strong enough. Surgical intervention was undertaken on 18-10-2011 to address this matter, and it was found the lead had exposed wires. As such the device was replaced. No further issues were reported.	Reviewed, for Trending Purposes Only
25047	129091	23/04/2013	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient will undergo a pocket revision due to the IPG protruding through the skin.	Reviewed, for Trending Purposes Only
30750	129091	24/04/2013	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient was experiencing a painful pocket site. The patient underwent a revision wherein the pocket site was repositioned. The patient is reportedly doing well following the revision.	Reviewed, for Trending Purposes Only
30567	126078	30/04/2013	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient lost effective stimulation. Impedance issues were noted for several lead contacts during a recent clinical visit. Surgical intervention was undertaken for further interrogation. Intraoperative testing isolated the issue to the patient's extension. As such, the device was explanted and replaced. No further impedance issues were noted, and effective stimulation was recaptured for the patient following the procedure.	Reviewed, for Trending Purposes Only
30596	158502	30/04/2013	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient is receiving a low battery warning for her IPG. In addition, the patient alleges that her stimulation turns off when attempting to increase the amplitude. Surgical intervention will be undertaken at a later date to address these issues. 30-04-2013: It was reported the procedure to replace the patient's IPG occurred on 08-04-2013. Effective stimulation was recaptured following the procedure. Based on the patient's program settings, the low battery warning previously observed appears to be indicative of normal battery depletion.	Reviewed, for Trending Purposes Only

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30608	132097	7/05/2013	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	During post-operative programming, it was reported three contacts on the patient's lead displayed invalid impedance readings. As a result, the patient was unable to utilize the affected contacts for therapy relief. The impedance issues were reportedly resolved during a 04-12-2012 programming session; however, the following day the patient claimed that she is again unable to achieve therapy from programs which utilize two of the three contacts in question. Surgical intervention was undertaken on 14-03-2013 to address the reported impedance issues. During the procedure, it was noted the patient's leads were not completely secured in the header block. One of the patient's leads was explanted and replaced. Upon visual inspection, it could not be determined whether the explanted lead was broken or fractured. The physician also decided to replace the patient's IPG. The initial intent was to relocate the device to a more convenient area for recharging; however, it was discovered that the header block of the IPG was bent. The physician was uncertain if the observed damage had any impact on the impedance issues experienced by the patient. Intraoperative testing found no impedance issues with the new IPG. The explanted IPG has been returned for analysis; however, the explanted lead was discarded. Effective stimulation was recaptured for the patient following the procedure.	Reviewed, for Trending Purposes Only
30903	126002	14/05/2013	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient experienced ineffective stimulation from the right sub occipital lead (off-label indication). A diagnostic test reveals impedance issues for several lead contacts. Surgical intervention was undertaken on 07-03-2013 to replace the patientâ€™s lead. Initial post-operative programming was not successful in capturing effective stimulation for the patient. A diagnostic test found no issues with respect to impedance. Follow-up on this matter found that effective therapy relief has yet to be achieved for the patient. The explanted lead was returned to the manufacturer for analysis and a defect was found which may have attributed to the impedance issues initially reported.	Reviewed, for Trending Purposes Only
29869	158502	21/05/2013	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported, the patient is unable to turn his IPG on via the magnet. In addition, the patient reports observing a low battery warning message for his IPG. Based on the patient's program parameters, a determination of whether the warning is related to normal battery depletion cannot be ascertained. Surgical intervention will be undertaken at a later date to address this issue. 01-02-2013: Follow-up on this matter found that the surgery to replace the patientâ€™s IPG occurred on 25-01-2013. Effective stimulation was recaptured for the patient following the procedure. 26-02-2013: The explanted IPG has been returned to the manufacturer for analysis. 28-03-2013: Analysis of the IPG is still in progress. 23-04-2013: Analysis of the IPG is still in progress. 23-05-2013: Analysis completed.	Reviewed, for Trending Purposes Only
30168	127126	21/05/2013	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient was experiencing overstimulation when therapy was initiated. Attempts to address this matter via reprogramming proved unsuccessful. Initially this issue was suspected to stem from contact between the patient's IPG and a previously disconnected lead which remained in-situ following a procedure to place an additional lead. Surgical intervention was undertaken to address the reported overstimulation. Intraoperative testing found no issues with the patient's leads. As such, the patient's IPG was explanted and replaced. Effective stimulation was recaptured for the patient following the procedure. 28-03-2013: The explanted IPG has been returned for analysis.	Reviewed, for Trending Purposes Only
30431	131944	24/05/2013	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	The patient is implanted with two percutaneous leads (different models). During a programming session, it was reported that the patient's left lead is providing effective stimulation; however, the right lead is producing a sharp sensation. The physician suspects the reported discomfort may be the result of the lead not being inserted correctly as he had to hasten to complete the implantation. Surgical intervention is scheduled for 04-2013 to revise the patient's lead. As such, the manufacturer respectfully requests permission to submit the next report on this matter following completion of the procedure. Since it is unknown from which lead the discomfort stems, both devices are being reported. 29-04-2013: No new information has been provided regarding this matter. 23-05-2013: It was reported surgical intervention was undertaken on 28-04-2013. It was discovered the patient's left lead was more lateral. As such, the device was repositioned. Since the patient is reportedly receiving adequate coverage on the right side, no adjustments were made to the right lead. Effective stimulation was recaptured for the patient following the revision procedure.	Reviewed, for Trending Purposes Only
31031	127126	24/05/2013	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient suddenly lost stimulation following a twisting movement. A diagnostic test revealed invalid impedance measurements for several lead contacts. New programs were provided to the patient utilizing the functioning contacts. Subsequent x-rays found that the lead had become disconnected from the IPG. Surgical intervention was undertaken at which time the connection was restored via the addition of new extensions. No products were explanted or replaced. Impedance issues are still present; however, the patient reports adequate therapy relief and coverage following the procedure.	Reviewed, for Trending Purposes Only
30373	128775	29/05/2013	Electrode/lead, stimulator, implantable, neurological	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that a contact of the lead eroded through the skin and was visible. The physician re-implanted the contact and administered antibiotics to the patient. Additional information was received that the patient lead had migrated superficially. It was confirmed that the patient does not have an infection. The patient is receiving comfortable stimulation in all pain areas and is reportedly doing well.	Reviewed, for Trending Purposes Only
30639	129091	3/06/2013	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient was experiencing difficulty charging the IPG. The physician assessed that the IPG had migrated. The patient will undergo a pocket revision procedure.	Reviewed, for Trending Purposes Only
31118	128775	5/06/2013	Electrode/lead, stimulator, implantable, neurological	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that following a lead revision, the lead was discovered to be fractured during analysis. The physician assessed that the lead fracture did not occur during or after the revision procedure.	Reviewed, for Trending Purposes Only
30391	128775	11/06/2013	Electrode/lead, stimulator, implantable, neurological	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that during an implant procedure following the insertion of the paddle lead the patient was experiencing severe abdominal pain post-operative and was intubated. The patient underwent an explant procedure. The patient subsequently developed a hematoma which the physician assessed was probably caused by the explant procedure. The patient remained in severe pain and the hematoma was evacuated. Additional information was received that the patient was intubated as a means to provide relief for the pain being experienced, which was due to the procedure and not the device.	Reviewed, No Further Action Required
30374	129091	12/06/2013	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that a patient was explanted due to pocket pain. The patient is reportedly doing well following the procedure.	Reviewed, for Trending Purposes Only
31222	170450	13/06/2013	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient was experiencing uncomfortable stimulation. A diagnostic test found both low and invalid impedance measurements for the patient's lead. Numerous attempts to capture effective stimulation via reprogramming proved unsuccessful. As such, the patient's SCS system was explanted. The explanted devices were discarded by the medical facility.	Reviewed, for Trending Purposes Only
30764	128775	18/06/2013	Electrode/lead, stimulator, implantable, neurological	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient was receiving inadequate stimulation. An x-ray confirmed that one lead was fractured. The patient underwent a revision and the physician replaced the lead. The patient was reportedly doing well following the procedure.	Reviewed, for Trending Purposes Only

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31241	129091	20/06/2013	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that since the patient was implanted, the charger cannot locate the IPG. An X ray was performed which found that the IPG was at an angle. The patient underwent a pocket revision where the IPG was repositioned. The patient can now charge the IPG	Reviewed, for Trending Purposes Only
30931	129091	21/06/2013	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient will undergo a pocket revision due to pocket discomfort. Additional information was received that the patient underwent a pocket revision. The IPG was repositioned and the patient was reportedly doing well following the procedure.	Reviewed, for Trending Purposes Only
31270	131947	21/06/2013	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	The patient was implanted with percutaneous leads from two different lots for an SCS trial. It was reported stimulation could not be achieved for the patient in the desired area. A diagnostic test revealed low impedance readings for several lead contacts. Although not confirmed, it was reported one of the leads appeared to be damaged near the connection point. The patient's leads were subsequently pulled, and the trial was deemed unsuccessful.	Reviewed, for Trending Purposes Only
31351	131947	28/06/2013	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	The patient was implanted with a percutaneous lead for an SCS trial. The day following implant, the patient reported having a headache that would not go away. Bed rest was ordered by the physician. Follow-up on this matter found that the patient's headache dissipated. The patient reported feeling slightly nauseated; however, that issue was later resolved with the help of an antiemetic. The trial continued without further incident.	Reviewed, for Trending Purposes Only
31390	132097	3/07/2013	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	The patient was implanted with three percutaneous leads from two different lots for an SCS trial. The patient desired therapy coverage in the hip area; however, she reported feeling stimulation down the left leg and during programming experienced tingling in both arms. A diagnostic test found low impedance measurements for several lead contacts. It was reported the treating physician is considering an alternative method of pain management for the patient.	Reviewed, for Trending Purposes Only
30929	132097	10/07/2013	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient experienced a fall and approximately four months afterwards lost the ability to increase the amplitude for her stimulation. A diagnostic test revealed impedance issues for several lead contacts. Efforts to recapture effective stimulation via reprogramming were unsuccessful. As such, surgical intervention was undertaken to replace the patient's lead. No visible anomalies were detected with the device upon explant. Therapy was restored for the patient following the procedure. 12-06-2013: Analysis is in progress. 10-07-2013: Analysis completed.	Reviewed, for Trending Purposes Only
31116	129091	12/07/2013	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that a patient underwent a pocket revision due to difficulty charging the IPG. The IPG was implanted too deep, the pocket site was found to be inflammated and the charger could not detect the IPG. The pocket site was cleaned out and moved to a more superficial location. Post operatively, the charger could connect with the IPG and the patient was sent home. Additional information was received that a culture was taken and was negative for infection.	Reviewed, for Trending Purposes Only
31247	132097	17/07/2013	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported that a recent diagnostic test of the patient's (Australia) lead found invalid impedance readings for several lead contacts. Reprogramming was undertaken utilizing the functioning electrodes resulting in marginal therapy coverage for the patient. Surgical intervention was subsequently undertaken to address the reported issue. Testing of the lead both prior to the procedure and intraoperatively found impedance issues. As such, the device was explanted and replaced. Upon removal, there was a visible break in the lead below the anchor site. Effective stimulation was recaptured for the patient following the procedure.	Reviewed, for Trending Purposes Only
31323	131944	24/07/2013	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	The patient was implanted with two percutaneous leads from different lots. It was reported the patient was not receiving adequate therapy coverage in his targeted pain areas (bilateral legs). Specifically, it was reported he was feeling unwanted stimulation in his right leg. Surgical intervention was undertaken to address this issue. The lead responsible for the patient's right leg coverage was explanted. Upon removal of the lead, a visual anomaly was noted near the location of the anchor; however no functional issues were detected with the device during intraoperative testing. A new lead was implanted to provide better coverage to the patient's left leg. Effective stimulation coverage was achieved following the surgical procedure.	Reviewed, for Trending Purposes Only
31218	128775	25/07/2013	Electrode/lead, stimulator, implantable, neurological	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient was experiencing a sensation of tightness and pressure at the lead site. The physician hopes that the lead will loosen on its own, however, a revision has been recommended. Additional information was received that the patient will not undergo a revision surgery.	Reviewed, for Trending Purposes Only
31196	132097	5/08/2013	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient experienced two episodes of overstimulation. The events reportedly lasted two to three seconds and the overstimulation could be felt throughout the patient's entire body. The second episode occurred within 24 hours of the first and was followed by a pressure sensation felt from the patient's thoracic to epigastric regions. The pressure sensation increased resulting in breathing difficulties for the patient. The symptoms resolved once stimulation was deactivated. In addition, during a recent programming session the patient reported uncomfortable rib stimulation and a stabbing sensation from several lead contacts.X-rays were taken for further interrogation. Based on the images, IPG and lead connections appear intact. Correct lead placement was confirmed, and there is no evidence of fracture. The patientâ€™s programs were adjusted to utilize contacts 5-8. The patient reports no rib stimulation on new programs during session; however, the patient continues to experience intermittent banding pressure in epigastric region. She was advised to cease use of the system for one week and then recommence therapy. The treating physician is satisfied with the x-ray results reprogramming strategy. There are no plans for invasive intervention. 11-07-2013: No new information has been provided regarding the patient's current status with the stimulation. 05-08-2013: Follow-up on this matter found the patient reported two episodes of overstimulation following recent physical activity; however, the occurrences were described as very slight compared to the initial episodes. In addition, the resulting sensation was said to be in the patientâ€™s back and not in the epigastric region. The patient is reportedly very happy with the therapy system at the present time and reports effective pain relief and coverage. There are no plans for invasive intervention.	Reviewed, for Trending Purposes Only
31205	132097	5/08/2013	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient lost stimulation. A diagnostic test revealed invalid impedance measurements for all lead contacts. Surgical intervention was undertaken to address this matter. During the procedure, a visible break was detected in the lead. As such, the device was explanted and replaced. Effective stimulation was recaptured following the surgery. 10-07-2013: Analysis still in progress. 05-08-2013: Analysis completed.	Reviewed, for Trending Purposes Only

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31686	132097	5/08/2013	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	The patient was implanted with four percutaneous trial leads from the same lot. During a programming session, all of the devices were reported as having come out of the lead holders. The markings on the leads had also come off which required reprogramming. The patient reported effective therapy coverage as a result of the session. On 15-07-2013 the patient alleged one of the leads had come out of his body. The devices were subsequently removed by the physician on 16-07-2013.	Reviewed, for Trending Purposes Only
28887	132097	21/08/2013	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	The patient received a trial system which included a lead and extension. It was reported the patient's lead exhibited high impedance readings for several contacts. In addition, it was reported there was blood between the paddle and the dura and fluid in the extension header. The extension was removed at the conclusion of the trial, and the lead remained implanted as part of the patient's permanent therapy system. The patient reported experiencing some abdominal pain; however, it was not made clear to the manufacturer if the pain was related to the recent implant of the patient's permanent therapy system. Subsequent attempts to resolve the impedance matter via reprogramming have been unsuccessful. Additional diagnostic testing will be undertaken for further evaluation. 20-07-2012; Follow-up on this matter found the patientâ€™s abdominal pain continues, and she has flank swelling on the opposite side of the IPG. The patient does not want the stimulation commenced. The physician suspects the abdominal pain is procedure related and believes there has been a pathological response to the surgery leading to Autonomic Dysfunction that has showed itself as slow wound healing, hyperesthesia and sweating. The physician maintains the possibility that a pre-procedure condition was exacerbated by the implant procedure. The doctor feels that when positioning the lead he may have irritated the dorsal root entry zone which may be a cause of the abdominal pain. The treating physician has referred the patient to a pain physician for topical nerve treatment in the abdomen. 17-08-2012: It was reported the patientâ€™s abdominal pain remains. An MRI has been ordered for further assessment. The treating physician was advised that such a procedure is contraindicated for an SCS implant and was cautioned of the risk and of the potential system damage which may result. The physician has elected to proceed with the MRI without explanting the system. 14-09-2012: No new information has been provided to the manufacturer regarding this event. 11-10-2012: The manufacturer is awaiting feedback from the physician regarding the MRI. 09-11-2012: The patient has been refered to a pain physician. Feedback from the pain physician is pending. 07-12-2012: Follow-up on this matter found new programs were added to the patient's IPG during a recent programming session. The magnet mode was disabled for the program. The patient reported she was still getting abdominal pain, and it was painful upon touch. The patient also claimed that the IPG is mobile and is catching on her clothes when dressing. The treated physician advised that an MRI is still planned; however, a date has not been scheduled. There is no planned intervention with respect to the patientâ€™s complaint of the IPG being mobile.	Reviewed, No Further Action Required
31106	155013	21/08/2013	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient's SCS system was explanted due to the need for an MRI. Upon removal of the system, a fracture was observed in one of the leads. Prior to the procedure, the patient reported experiencing a sharp pain in his back when therapy was initiated. In addition, the patient alleges an occurrence approximately six months ago in which he was unable to walk properly. 2013-06-26: Follow-up on this matter found the patient has no issues with walking. Analysis of the returned devices is still in progress. 2013-07-25: Analysis is still in progress. 21-08-2013: Analysis complete.	Reviewed, for Trending Purposes Only
31322	131944	21/08/2013	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient was experiencing inadequate stimulation coverage. An x-ray revealed both of the patient's percutaneous leads had migrated. Surgical intervention was undertaken to address this issue. During the procedure, a visible break was observed in one of the devices near the proximal end of the anchor. As such, the fractured lead was explanted and replaced; however, to facilitate extraction, the lead in question had to be cut. The remaining original lead was repositioned. Effective stimulation was recaptured for the patient following the surgery.	Reviewed, for Trending Purposes Only
31835	132097	21/08/2013	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient's SCS system was explanted due to lack of efficacy. The location of the patient's leads (same lot) was said to be lower than what was needed in order to provide optimal pain relief. Lead migration is suspected. Analysis of one of the returned lead segments identified a defect which occurred while the lead was implanted and may have attributed to the report of ineffective stimulation.	Reviewed, for Trending Purposes Only
31832	131944	23/08/2013	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	The patient was implanted with two percutaneous leads from the same lot. It was reported the patient unable to obtain coverage on the right side. Surgical intervention was undertaken for further interrogation. Intraoperative testing found invalid impedance readings for all contacts on one of the two devices. As such, the lead in question was explanted and replaced. Adequate coverage was captured for the patient following the procedure. The explanted device was discarded by the medical facility.	Reviewed, for Trending Purposes Only

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30607	132097	28/08/2013	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient experiences a surge of stimulation when manual pressure is applied to the leads at their point of entry into the spinal canal. In addition the patient reports experiencing positional stimulation. Initially, the positional simulation was said to occur with certain body movement; however more recently, the patient reports feeling the surges with every step taken. The patient reportedly has significant curvature of the spine. A previous diagnostic test revealed an impedance issue for one lead contact. Efforts to resolve these issues and provide effective therapy coverage via reprogramming have been unsuccessful. As such, surgical intervention will be undertaken at a later date to replace the patient's leads. 08-05-2013: Follow-up on this matter found the surgical procedure is still pending. 07-06-2013: Follow-up on this matter found that the patientâ€™s leads were reviewed under x-ray and the IPG site was opened but no explant was performed. On table testing showed that all connections (IPG and extension) were normal and not faulty but one of the leads still showed high and invalid impedances at electrodes 1, 3 and 6. X-ray has shown that one of the leads has migrated caudally by 2 electrodes space and both leads are now leaning more to the right side instead of midline. During the interrogation, the lead implant site was not excised as the doctor concluded that it would not be beneficial to do so. Due to the anatomy of the patient's scoliotic spine, the physician recommends that the patient proceed to a paddle lead. The physician will refer the patient to a neurosurgeon for placement of a paddle lead. 03-07-2013: Follow-up on this matter found that surgical intervention is still pending. 01-08-2013: Follow-up on this matter found that surgical intervention is still pending. 28-08-2013: No new information has been provided regarding this matter. Should additional details be obtained, an amended final report will be submitted.	Reviewed, for Trending Purposes Only
31918	131947	29/08/2013	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	The patient was implanted with two percutaneous leads from different lots for an SCS trial. The day following implant, the patient reported having a constant headache and pain through his shoulders. The reported discomfort was said to decrease when the patient was in a reclined position. The most recent diagnostic test found no issues with respect to impedance. There were no concerns of a dural puncture or leak from the physician. Bed rest and an increase in fluid intake were ordered for the patient. The trial leads were explanted on 09-08-2013. Follow-up on this matter found that the patient's headache and pain have since dissipated.	Reviewed, for Trending Purposes Only
31473	129091	2/09/2013	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient underwent an explant procedure as the physician felt the device was faulty. No additional information will be provided to BSN.	Reviewed, No Further Action Required
31562	132097	11/09/2013	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	The patient is implanted with a supraorbital percutaneous lead (off-label) as well as a surgical lead implanted in the occipital region (off-label). It was reported surgical intervention was undertaken to further interrogate the patient's therapy system. Intraoperative testing found invalid impedance readings for several lead contacts. Programming utilizing the functioning contacts yielded stimulation; however, the resulting therapy was not in correct area and was said to diminish within seconds. The procedure was completed with the revision of the supraorbital lead which reportedly is providing some stimulation; however, impedance issues remain for the surgical lead. Follow-up on this matter found the patient is not receiving therapy relief from the occipital lead and has decided to temporarily suspend use of the SCS system. There are no plans for additional surgical intervention. This issue will continue to be addressed via reprogramming. 12-09-2013: Follow-up on this matter found the patient has commenced therapy again and is receiving adequate relief from the supraorbital lead. Additional reprogramming may be needed for the occipital lead.	Reviewed, for Trending Purposes Only
31773	154912	11/09/2013	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient lost stimulation and was unable to establish communication with the IPG using either the programmer or charging system. Surgical intervention was undertaken to explant and replace the patient's IPG. Effective stimulation was recaptured following the procedure.	Reviewed, for Trending Purposes Only
31996	129091	13/09/2013	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient was experiencing pocket discomfort. The IPG was repositioned and the patient was reportedly doing well following the procedure.	Reviewed, for Trending Purposes Only
32088	129091	25/09/2013	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient underwent a pocket revision due to difficulty charging. The IPG was repositioned and the patient was able to successfully charge the IPG and was reportedly doing well following the procedure.	Reviewed, for Trending Purposes Only
31954	154912	30/09/2013	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient is experiencing pocket stimulation. The patient claims the frequency of the pocket stimulation correlates with the cycling program utilized for her left knee. As such, the reported sensation is felt only when therapy is in use. The patient reports the pocket stimulation is not uncomfortable, and she is otherwise receiving effective therapy relief. An x-ray was taken for further interrogation; however, the results were inconclusive. Surgical intervention was undertaken on 07-08-2013 to explant and replace the patient's IPG thereby resolving the reported issue.	Reviewed, for Trending Purposes Only
31579	132097	8/10/2013	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	The patient's therapy system consists of an SJM lead connected to an IPG from a different manufacturer. It was reported high impedance readings were observed. Surgical intervention was undertaken for further interrogation. X-ray images indicated the patient's lead was fractured As such, the device was explanted and replaced. Effective therapy was recaptured following post-operative programming.	Reviewed, for Trending Purposes Only
32282	131944	14/10/2013	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient was not feeling stimulation from one of her leads. A diagnostic test revealed impedance issues for the device. Surgical intervention was undertaken to address this matter. A new lead was implanted in the vicinity of the impacted device. Due to the inability to extract the lead in question, the device remains in-situ. Effective stimulation was recaptured for the patient following the procedure.	Reviewed, for Trending Purposes Only
30795	132097	16/10/2013	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient is unable to increase his stimulation to an effective level. A diagnostic test revealed impedance issues for several lead contacts. Efforts to recapture effective stimulation via reprogramming have proven unsuccessful. As such, surgical intervention will be undertaken at a later date to replace the patient's lead.	Reviewed, for Trending Purposes Only

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31114	132097	16/10/2013	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	The patient is implanted with a supra-orbital percutaneous lead (off-label). It was reported the patient is unable to increase the amplitude for any of his therapy programs and is currently without stimulation. A diagnostic test revealed impedance issues for several lead contacts. Efforts to rectify this matter via reprogramming have been unsuccessful. X-rays were taken for further interrogation; however no visible anomalies were noted. Surgical intervention will be undertaken at a later date to address this issue. 18-09-2013: Follow-up on this matter found that surgical intervention was undertaken on 30-08-2013 to explant and replace the patient's percutaneous lead. The lead was reportedly damaged during removal. Effective therapy was recaptured following the procedure. 16-10-2013: Both the patient's lead and lead extension were returned to the manufacturer for analysis inferring that the latter device was also explanted during the 30-08-2013 procedure. Analysis of the returned lead extension found a defect which may have attributed to the reported stimulation issue.	Reviewed, No Further Action Required
31859	132097	16/10/2013	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	The patient is implanted with two percutaneous leads from different lots. It was reported the patient is not getting satisfactory coverage from the SCS leads. During a recent programming session it was reported that one of the patient's programs resulted in sharp pain in the abdomen area. A diagnostic test was attempted for further interrogation but had to be abandoned due to the patient experiencing pain and shortness of breath. The pain reportedly resolved once the amplitude on the program was lowered. A subsequent diagnostic test revealed low impedance measurements for several contacts. It was reported the patient recently underwent a trial procedure using a new pain management therapy regime which reportedly resulted in effective stimulation coverage. 17-09-2013: Additional details were provided regarding the event. It was reported that reprogramming was unsuccessful in resolving the therapy coverage issue. The patient will reportedly receive epidural injections and reprogramming as needed until the new therapy regime is implemented.	Reviewed, for Trending Purposes Only
32353	155013	21/10/2013	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient's SCS system was explanted due to pain at the IPG site. The patient also alleged he did not receive therapy coverage to his feet as needed. During the surgical procedure, it was reported the physician experienced difficulty extracting the lead and had to remove a portion of bone to facilitate the explant. Pain at the IPG site is listed as a potential consequence in the IFU. However, analysis of the returned lead found a defect which may have attributed to the claim of ineffective stimulation.	Reviewed, for Trending Purposes Only
32425	126001	22/10/2013	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was report the patient experienced intermittent overstimulation from her SCS system. The reported occurrence does not appear to be positional in nature. In addition, overstimulation is said to occur if the patient touches her IPG. The functioning of the system can also be manipulated in the same manner. A diagnostic test revealed an impedance issue for one lead contact. An x-ray was taken for purposes of verifying system connections; however, the results were inconclusive. Surgical intervention was undertaken on 25-09-2013 for further interrogation. Intraoperative testing isolated the impedance issue to the patient's lead extension. As such, the device was explanted and replaced. Postoperative status for the patient found that additional reprogramming may be undertaken as needed to capture optimal therapy coverage. No further complaints of overstimulation have been reported following replacement of the patient's lead extension.	Reviewed, for Trending Purposes Only
31559	126002	24/10/2013	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient is experiencing an increased recharge burden for the IPG. The physician suspects this issue stems from increased energy requirements due to the patient's leads which are reportedly twisted. In addition, it was reported the patient is experiencing intermittent stimulation and occasional overstimulation. A diagnostic test revealed an impedance issue for one lead contact. An x-ray revealed no connection issues; however, one of the leads has allegedly migrated. Surgical intervention was undertaken to revise the devices in hopes of alleviating the twist, and the patient was issued new programs in an effort to address the recharging concerns. Follow-up on this matter found that the most recent reprogramming has improved the patient's recharge burden; however, the patient reports ineffective therapy coverage from the leads and continued intermittent stimulation. 21-08-2013: Additional details were provided to the manufacturer regarding the reported twisted leads and the surgical intervention undertaken to address this issue. It was reported the patient's leads twisted due to their implantation without the use of a strain relief loop. This resulted in the patient experiencing discomfort (tightness) above the shoulder. Surgical intervention was undertaken on 03-07-2013 to loosen the tight leads across the left collar bone. A strain relief loop was created in the area where the tightness was felt, and the patient is now able to recover full range of movement in his shoulders. With respect to the lead migration and increased recharge burden allegations, it was reported the patient's leads still remain at the original implant location. However, the devices are still slightly twisted, and the bottom of the leads veer towards patient's left shoulder resulting in more stimulation delivery to that area. Surgical intervention is scheduled for 22-09-2013 to revise patient's the leads again which will hopefully improve the patient's recharge burden. As such, the manufacturer respectfully requests permission to provide the next report on this matter by 27-09-2013. 25-09-2013: Follow-up on this matter found that the additional surgical intervention occurred as scheduled on 22-09-2013. It was reported the physician sutured one of the two leads to prevent it from twisting again; , please note that the twisting of the leads is most likely to have occurred due to the fact that a strain relief loop/anchor was not used in the initial surgery. This is recommended in the IFU. It was found that the most distal contact for one of the leads had become dislodged. No further action was taken with respect to this. At this time, only one of the two leads is said to be providing substantial coverage of the patient's painful area. The patient will continue to be monitored. It was not disclosed whether the surgical procedure improved the recharge burden. 21-10-2013: It was reported since the 22-09-2013 procedure, the patient's recharge burden has reportedly improved by a couple of hours. The patient is said to have fibrous connective tissue in the neck which could be contributing to the high amplitude requirements.	Reviewed, No Further Action Required

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31872	132097	28/10/2013	Electrode/lead, stimulator, implantable, neurological	Class III	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	The patient suffers from Failed Back Surgery Syndrome. It was reported that the patient experienced overstimulation followed by tingling in his heels and in the balls of his feet. The patient then experienced weakness in the back and numbness in the legs which resulted in him falling. This sequence initially occurred when the patient initiated stimulation following a revision procedure. However, the issue is reportedly recurring and happens regardless of the stimulation's function. Follow-up on this matter found that the reported weakness and numbness in the patient's leg is occurring more frequently. The patient has consulted a neurologist who suspects that the loss of sensation in the lower limbs is attributed to use of the SCS system. Nerve conduction tests will be performed. Surgical intervention may be undertaken at a later date to explant the patient's SCS system. 25-09-2013: Follow-up on this matter found the patient underwent an MRI procedure (contra-indication) for further interrogation. The MRI did not allude to the SCS devices impending on the patient's spinal cord. The treating physician is not convinced that the reported issue is being caused by the SCS devices and has referred the patient back to the neurologist for further investigation. 22-10-2013: No further information has been provided regarding this event.	Reviewed, for Trending Purposes Only
32776	128775	5/12/2013	Neural-tissue electrical stimulation lead	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that a patient was feeling severe stinging from the leads while the stimulation was on. Reprogramming did not resolve the symptom. The patient underwent a revision where the leads were buried deeper in the epidural space. The patient is reportedly doing well after the revision.	Reviewed, for Trending Purposes Only
32945	132097	12/12/2013	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient was admitted to the hospital due to overstimulation. In addition, it was reported the patient was not receiving effective stimulation relief. Surgical intervention was undertaken on 12-11-2013 to reposition the patient's leads. Adequate therapy coverage was recaptured for the patient following the procedure.	Reviewed, for Trending Purposes Only
32959	132097	16/12/2013	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	The patient was implanted with three percutaneous leads from different lots for purposes of a trial. During a programming session, the patient reported a change in the stimulation coverage. A diagnostic test revealed high impedance measurements for several lead contacts. Visual inspection of the connections found that the patient's lead had pulled out and four contacts were exposed. Due to these issues, the trial ended early, and the patient's leads were removed.	Reviewed, for Trending Purposes Only
32666	154912	17/12/2013	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient is experiencing intermittent stimulation. The patient is reportedly able to palpate the IPG and leads at the point of connection and in doing so can manipulate the system's functioning by applying pressure to the superior lead. X-rays have been ordered for further interrogation as it is suspected the issue stems from either a fractured lead or lead pull-out. Surgical intervention will be undertaken at a later date to address this issue. 13-12-2013: It was reported surgical intervention was undertaken on 25-11-2013 to address the reported issue. The patient's leads were disconnected from the IPG header and then reinserted. Effective stimulation was recaptured for the patient following the procedure, and the reported issue is now resolved. Based on the details of the reported issue and the method of resolution, lead pull-out is inferred.	Reviewed, for Trending Purposes Only
32673	126078	17/12/2013	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	The patient is implanted with four percutaneous leads from two lots. It was reported the patient is not receiving effective therapy coverage. Stimulation reportedly cannot be felt from the patient's lower two leads. A diagnostic test revealed an impedance issue for one lead contact. Surgical intervention was undertaken on 17-11-2013, and the patient's leads were repositioned. Intraoperative testing found that the no stimulation issue remained. The procedure was completed with the placement of two trial leads in the area of the lower leads. The following day, it was reported the patient could feel stimulation with the newly implanted trial leads. An additional surgical procedure will be conducted at a later date for further interrogation to identify the root cause of the no stimulation issue. The additional surgery has not been scheduled and is not expected to occur within the next 90 days. The manufacturer respectfully requests permission to submit its next report in this matter after the completion of the procedure.	Reviewed, for Trending Purposes Only
32387	129091	18/12/2013	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patientâ€™s IPG had migrated and was pushing against his pelvic bone at the hip causing pain. The patient underwent a procedure where the physician replaced the IPG due to preference and repositioned the pocket site. The patient was reportedly doing well following the procedure.	Reviewed, for Trending Purposes Only
33083	186043	7/02/2014	Stimulator, electrical, analgesic, spinal cord	AIMD	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Nevro Corporation	It was reported that the patient came into the emergency room with discharge from her IPG wound site. Discharge was serous and the patient was afebrile. Attempted to contact implant physician but due to holiday season, was unable to do so. The rep discussed the situation with Emergency physician and that the risk was infection & that the recommended practice was to do a swab for culture prior to starting on antibiotics. The patient was transferred from an Emergency Department to be admitted at a Private Hospital. The IPG wound was swabbed & the culture resulted stenotrophomonas matothilia. The patient was started on oral Respilin Forte & discharged on 31/12/13. The patient flew back to Queensland on 02/01/14. On the morning of 06/01/14 the patient informed the company's rep that the patientâ€™s condition was not improving. She was medically examined and was commenced on oral Clindamycin. Additional swabs and blood examination were taken. The patient responded well to antibiotic and was discharged from the hospital. She is under the care of her Pain Physician. She was to remain at home with oral antibiotics for the next 3 months. Independent evaluation of the infections was made by an infectious disease physician along with thorough investigations by the treating pain physician, that the infection was not cause by the implant device.	Reviewed, for Trending Purposes Only
32836	128775	19/02/2014	Neural-tissue electrical stimulation lead	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that during the IPG implant procedure following a permanent trial of the leads it was discovered that one of the leads was bent and broken. The physician elected to insert this lead into a new splitter and re-implant it in the patient. High impedances were noted on both leads after the procedure was completed.	Reviewed, for Trending Purposes Only
33009	154912	11/03/2014	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient is experiencing overstimulation at the IPG site. Surgical intervention will be undertaken at a later date to address this issue. 16-01-2014: After further review, it was found this event involves the same patient as VR 2013 254548 00690 DIR 32673. On 01-12-2013, the patient's lead extensions were explanted and replaced to address the stimulation issues reported in VR 2013 254548 00690 DIR 32673. However, follow-up found the overstimulation issue at the IPG site continues. An appointment with the pain specialist has been scheduled. 14-02-2014: No new information has been provided to the manufacturer regarding this event. 11-03-2014: No new information has been provided to the manufacturer regarding this event.	Reviewed, for Trending Purposes Only

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33150	132097	17/03/2014	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient is experiencing intermittent stimulation from her therapy system. More specifically, the stimulation is said to be stopping and starting on its own. A diagnostic test revealed invalid impedance measurements for several lead contacts. Surgical intervention will be undertaken at a later date to address the issue. 19-02-2014: Follow-up on this matter found the surgical procedure to address the reported issue occurred on 29-01-2014. A diagnostic test taken prior to the surgery found impedance issues for all lead contacts; however no visual anomalies were observed via x-ray imagery. The impedance issues remained during intraoperative testing. As such, the patient's leads were explanted and replaced. Visual inspection of the devices upon extraction revealed a possible cut in the leads by the sutures. Adequate therapy coverage was achieved for the patient via intraoperative programming.	Reviewed, No Further Action Required
33389	129091	24/03/2014	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient was experiencing discomfort at the pocket site and will undergo a pocket revision procedure. Additional information was received that the patient had a successful pocket revision.	Reviewed, for Trending Purposes Only
33189	128775	26/03/2014	electrode/lead, stimulator, implantable, neurological	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient had lost stimulation. The patient underwent a lead revision procedure and the physician chose to replace the lead, due to suspected lead fracture. The patient was reportedly doing well following the procedure.	Reviewed, for Trending Purposes Only
33359	128775	2/04/2014	electrode/lead, stimulator, implantable, neurological	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that during a procedure the physician noticed the leads were bent at the proximal end when removed from the lead splitter. The leads were displaying high impedances on several contacts. The physician noticed the leads were at a 90 degree angle and the internal wires were visible where the fracture was evident. The physician elected to implant the leads, remove the splitters and implant new splitters. The patient is receiving excellent pain coverage.	Reviewed, for Trending Purposes Only
34032	131944	17/04/2014	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	The patient was implanted with four percutaneous leads from different lots for peripheral nerve stimulation. It was reported the patient was not receiving effective stimulation. Efforts to resolve this matter via reprogramming reportedly resulted in unpleasant stimulation for the patient. A diagnostic test found invalid impedance measurements for several contacts of one of the leads. Surgical intervention was undertaken to explant and replace the patient's leads. Adequate stimulation was obtained for the patient following the procedure.	Reviewed, for Trending Purposes Only
34068	128775	30/04/2014	Neural-tissue electrical stimulation lead	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient underwent an explant procedure due to high impedances on multiple contacts of the lead, thought to be caused by lead migration. Analysis of lead s/n 482897 confirmed that the lead was fractured.	Reviewed, for Trending Purposes Only
33930	128775	13/05/2014	electrode/lead, stimulator, implantable neurological	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient was experiencing cramps related to the stimulation. The patient underwent a lead revision where the physician replaced the leads due to physician's preference. However the cramping is an ongoing issue even though the stimulation has improved. Additional information was received that the patient's cramping sensation was resolved by the revision.	Reviewed, for Trending Purposes Only
34047	132097	19/05/2014	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	The patient was implanted with two percutaneous leads from the same lot. It was reported the patient experienced difficulty increasing the amplitude for stimulation and maintaining therapy once initiated. A diagnostic test found invalid impedance measurements for one of the leads. Reprogramming utilizing the functioning contacts was previously successful in providing adequate stimulation; however, surgical intervention was subsequently undertaken to explant and replace the affected lead. Effective therapy was recaptured for the patient following the procedure.	Reviewed, No Further Action Required
34095	132097	19/05/2014	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	The patient was implanted with two percutaneous leads from the same lot. It was reported the patient lost stimulation as well as the ability to increase the amplitude for her therapy. A diagnostic test found invalid impedance readings for several lead contacts. Efforts to provide effective therapy coverage via reprogramming yielded limited success. Surgical intervention was undertaken on 01-04-2014 for further interrogation. During the procedure, a broken lead was identified. As such, the affected device was explanted and replaced. 19-05-2014: It was reported the patient is receiving effective stimulation following the replacement procedure.	Reviewed, No Further Action Required
34158	131944	2/06/2014	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	The patient's therapy system included percutaneous leads from two different lots. It was reported the patient experienced difficulty initiating stimulation and was unable to increase the amplitude for one of her therapy programs. A diagnostic test found impedance issues for two lead contacts. Reprogramming utilizing the functioning contacts reportedly provided temporary therapy relief. Surgical intervention was subsequently undertaken. Intraoperative testing found the previously noted impedance issues had progressed. As such, the impacted leads were explanted and replaced. Adequate stimulation was recaptured for the patient following the procedure.	Reviewed, for Trending Purposes Only
34168	154912	2/06/2014	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient's lead extension was disconnected from the IPG header. Surgical intervention was undertaken on 2014-01-23 with the intent of restoring the connection; however, further interrogation revealed a break in the extension and an exposed wire. The procedure was completed by tethering the exposed wire and reinserting the extensions into the IPG. At that time, the patient reportedly had stimulation, but the relief was reportedly not optimal. It was reported a subsequent surgical intervention was undertaken on 10-04-2014. Intraoperative testing found impedance issues for several lead contacts. The procedure was completed with explant and replacement of the patient's IPG and lead extensions. Effective therapy was recaptured via post-operative programming.	Reviewed, for Trending Purposes Only
34222	132097	9/06/2014	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced auto-reducing and as a result was unable to initiate stimulation. A diagnostic test found invalid impedance measurements for several lead contacts and subsequent x-ray imagery confirmed lead migration. Surgical intervention was undertaken on 17-04-2014, and the patient's lead was explanted and replaced. Removal of the lead revealed a break in the device near the distal end of the anchor. Post-operative programming revealed no impedance issues with the new lead. Additionally, effective stimulation was reportedly recaptured for the patient.	Reviewed, No Further Action Required
34494	132097	17/06/2014	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient lost therapy coverage of the right foot following a non-related spinal surgery. A diagnostic test revealed no issues with respect to impedance. Efforts to resolve this matter via reprogramming yielded limited success. The patient continued to receive some therapy coverage to the right foot; however, the stimulation was reportedly not optimal. Surgical intervention was undertaken on 24-03-2014 to explant the patient's therapy system due to the reported ineffective stimulation and the need for an MRI. A tumor was reportedly evident near the placement of the lead. The explanted devices were returned to the manufacturer for analysis.	Reviewed, for Trending Purposes Only
34705	126004	16/07/2014	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	The patient's therapy system consists of an IPG and a paddle lead. It was reported the patient experienced intermittent stimulation. Diagnostic tests performed found one low impedance measurement. The patient revealed he has no feeling from his right knee downward. Initial X-Rays found no visual anomalies. Surgical intervention was undertaken on 14-05-2014 to explant and replace the patient's paddle lead. According to the physician, the patient appears to have some calcification on his dura; however, he is reportedly receiving adequate therapy relief at this time.	Reviewed, for Trending Purposes Only

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34604	127126	21/07/2014	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	The patient was implanted with three percutaneous leads from different lots. It was reported the patient is not receiving adequate stimulation coverage. Stimulation reportedly cannot be produced from her two four-channel leads. The patient reportedly feels stimulation at times; however, it is said to fade away. A diagnostic test found an impedance issue for one lead contact. An X-ray was also taken but no visual anomalies were noted. Efforts to address these issues via reprogramming yielded limited success as stimulation could only be generated from the lower lead. Surgical intervention was undertaken on 05-06-2014 to address the reported issues. Diagnostic testing taken before and during the procedure revealed an impedance issue and a no stimulation condition for one of the leads. In addition, it was noted the devices may have migrated as they were found to be on top and around the IPG. Please note that â€œimplant migrationâ€ is listed as one of the adverse events in the IFU. It was also noted on explant that one of the leads may have had possible external damage. The physician elected to explant the patient's entire therapy system, the system has been returned for analysis.	Reviewed, for Trending Purposes Only
34776	126002	11/08/2014	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient experienced ineffective stimulation. Reprogramming was unsuccessful as unintended right side stimulation occurred. Subsequently, surgical intervention took place to explant the lead. Per the physician, the lead was visibly fractured. The patient received effective therapy post-operatively.	Reviewed, for Trending Purposes Only
34944	128775	14/08/2014	Neural-tissue electrical stimulation lead	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient was experiencing a stinging sensation at her lead site. The patient underwent a revision procedure and the leads were repositioned. The patient was reportedly doing well following the procedure.	Reviewed, for Trending Purposes Only
34962	131944	15/08/2014	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	The patient's therapy system included four percutaneous leads from three different lots that were implanted peripherally. It was reported the patient's therapy system was explanted due to lack of efficacy. The physician stated the decision to explant was elective.	Reviewed, for Trending Purposes Only
35133	154912	28/08/2014	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	The patient's therapy system includes three percutaneous leads from three different lots. It was reported the patient desires to have his therapy system explanted due to lack of efficacy. Follow-up revealed surgical intervention was undertaken on 23/06/2014 to explant the SCS system. During the procedure, it was observed that the leads pulled out from the header ports with ease and without the use of the torque wrench.	Reviewed, No Further Action Required
34569	128775	8/09/2014	Neural-tissue electrical stimulation lead	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient's leads were explanted due to high impedances caused by the lead being slightly damaged by the physician during the permanent trial. The patient is reportedly doing well following the procedure.	Reviewed, for Trending Purposes Only
34955	128775	26/09/2014	electrode/lead, stimulator, implantable neurological	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that a patient's lead was displaying high impedances on multiple contacts. The patient underwent a lead revision procedure where the physician noted that the lead was broken. The lead was explanted. The patient is reportedly doing well following the procedure.	Reviewed, No Further Action Required
35478	154912	6/10/2014	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient had been without stimulation for approximately three weeks and was unable to establish communication with the IPG using either the charging system or programmer. X-ray imagery found the IPG was mobile in the pocket. In addition, based on the X-ray, the IPG appeared to be at an angle thereby prohibiting communication with the programmer. Surgical intervention was undertaken on 06/02/2014 to reposition the patient's IPG. Following the procedure communication attempts between the charging system and IPG remained unsuccessful. Follow-up identified the patient's IPG was explanted and replaced. The patient is receiving effective stimulation post-operatively and the communication issue has resolved.	Reviewed, No Further Action Required
35479	154912	9/10/2014	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	The patient's therapy system included an IPG and two percutaneous leads from different lots. It was reported the patient experienced overstimulation when pressing on the IPG with either his hand or the programmer wand. Otherwise, stimulation was said to be barely felt. A diagnostic test found low impedance readings for several lead contacts. Efforts to resolve this issue via reprogramming proved unsuccessful. Surgical intervention was undertaken on 07-08-2014 to explant the patient's therapy system. Although the intent was to replace the explanted devices, the physician encountered difficulty implanting the new leads due to scar tissue. As a result, the procedure was abandoned. The patient will undergo re-implant at a later date.	Reviewed, for Trending Purposes Only
35911	154912	24/11/2014	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient received a peripheral system. The patient has been unable to turn off stimulation using the programmer. The SJM representative was unable to establish communication with the IPG using multiple programmers. X-Rays did not identify any anomalies related to the IPG position. Subsequently, surgical intervention was undertaken to explant and replace the IPG. 24-11-2014: Follow-up on this matter identified the new IPG is functioning appropriately.	Reviewed, for Trending Purposes Only
35627	131047	18/12/2014	Neural-tissue electrical stimulation lead	Class III	LivaNova Australia Pty Ltd	LivaNova USA Inc	It was reported that during a regular patient follow up visit, a high impedance value was found. When the physician spoke to the patient, it was discovered that the patient had recently had a mole removed from her back using diathermy. Then, the generator damage was suspected. During the surgery to replace the generator, it was found that the new generator did not overcome the high impedance when the system diagnostic test was performed. The new generator was check and found to be functional; a lead breakage was then suspected. Thus the old lead was removed and a new lead inserted. After the full revision, the system diagnostic test on the new lead and new generator was successful. Both the explanted lead and generator have been sent to the manufacturer for analysis. The generator and lead analysis are completed. The explanted lead serial number is 41172, not 41179 as it was initially indicated in the previous TGA iris report on 23-10-2014.	Reviewed, for Trending Purposes Only
36172	129091	7/01/2015	Stimulator, electrical, analgesic spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient experienced seizures overnight after being implanted with a DBS. The patient is now stable and being monitored in the hospital. A Computerized Tomography (CT) scan displayed a small hemorrhage. Additional information was received that the patient was kept in the hospital for five days without a seizure and without any surgical intervention. The physicians suspected the seizures were related to the hemorrhage which was thought to be procedure related but not device related.	Reviewed, for Trending Purposes Only

DIR Report #	ARTG #	Date of Report	GMDN / UMDN Text	Device Class	Sponsor Name	Manufacturer Name	Clinical Event Information	Outcomes
36297	177594	13/01/2015	Stimulator, electrical, analgesic, spinal cord	AIMD	Medtronic Australasia Pty Ltd	Medtronic Inc	RestoreSensor Model 37714 Medtronic Neurostimulation System that is surgically implanted in my lower back 04/04/2012. I have had 3 painful surgeries to correct extreme pain caused by the electrodes after the Medtronic Neurostimulation System was in the wrong spot or not working at all. This seems to be a regular problem that Medtronic's has always known about but I was never told of these problems. I have had a lower back fusion in 2007 and back pain since than, so the Medtronic Neurostimulation System seemed to be an excellent choice. The Medtronic Neurostimulation System did work great as to relive me of my back pain and mostly to take less pain medicines such as Percocet 10/325. This is now a major setback I feel that now has False promises, in that Medtronic knows of these electrodes and leads causing major problems. I BELIEVE my problem is not just the broken leads that a recent X-Ray showed, but the main stimulation system itself failed and now sends an out of control shock and pain impulse that I was not told could happen. June 27th 2013 the Medtronic Neurostimulation System broke inside me to where it shocked me painfully and uncontrollable until I struggled to reach my remote control to turn it off. If I was not home at this time to reach the remote control this would have been a torturous pain that I could not have stopped until the device was turned off. The Medtronic Neurostimulation System will now need to be surgically removed permanently as I never want to be in this painful situation again. I am disabled on Medicare at age 49 since 2008 from Colon Cancer and back problems and cannot afford to have this painful operation. I now feel that I have been taken advantage of for there own experiment as to how these leads break. I am extremely disappointed with Medtronic sales representatives as they are concerned more about the device that what is actually going on with me. This is an update as pre request: I had my Doctor remove the Medtronic implant 10/15/2013 Tuesday the 15th. I believe these leads where moving around in me freely as much as 6 inches or more from where they were originally placed, X rays would show the severe pain this movement was causing me. The pain I am in at this time has me wondering how well the surgery went. Did the doctor cut me too much to take out the broken wires he was removing? I should mention here that Dr is not a surgeon. However, thats the least of my concerns right now. As I mentioned, I have had and am still having major pain and suffering from this implant and realize that this company was just using me. I saw a segment on Good Morning America, Monday the 14th about how it can or cannot help you. Also I feel Medtronic representatives had no concern for me and never offered any help or solutions which was very upsetting to me. When I was in the waiting room the 15th, the Medtronic Rep walked into the Doctors office and I had to address him. He would have just passed me by if I hadn't addressed	Reviewed, No Further Action Required
35453	129091	28/01/2015	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient's IPG eroded through the skin. The physician chose to remove the entire SCS system to prevent further complications. The patient was doing well post-operatively.	Reviewed, No Further Action Required
35551	128679	29/01/2015	electrode/lead, stimulator, implantable neurological	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient underwent an explant due to pain caused by the leads. During the explant the physician noted that the internal wires of one of the lead splitters was frayed and completely exposed, however no contacts had fallen off. The physician stated that the damage did not occur during the explant procedure.	Reviewed, for Trending Purposes Only
35625	129091	30/01/2015	stimulator, electrial, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient was experiencing heat and constant pain at the pocket site. The patient's pain would increase while charging. The database analysis confirmed the IPG was functioning properly. The patient will undergo an IPG replacement procedure. Additional information was received that the patient underwent an explant procedure. The patient was also experiencing difficulty charging the IPG and it was noted that the peripheral leads were causing pain. The patient is doing well postoperatively.	Reviewed, for Trending Purposes Only
34986	128775	5/02/2015	electrode/lead, stimulator, implantable neurological	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient was experiencing painful stimulation in his back. The patient's lead displayed high impedances. An x-ray confirmed lead migration. The physician noted that the lead had a kink, and he suspected the lead was fractured. Additional information was received that the patient underwent a lead replacement procedure and was doing well post-operatively.	Reviewed, for Trending Purposes Only
36620	154912	11/02/2015	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	St Jude Medical	The patient was implanted with two therapy systems consisting of two IPGs and two leads. It was reported the patient experienced abdominal stimulation which caused discomfort. Efforts to resolve this matter via reprogramming yielded limited success as the patient did not have coverage of his entire pain area. It was reported the patient's IPGs were explanted on 18-11-2014 and the patient underwent a trial using leads from a different manufacturer. A subsequent procedure was reportedly undertaken on 27-11-2014 at which time the patient's SJM leads were explanted and replaced. The newly implanted leads were externalized via an extension connection for purposes of an SJM trial.	Reviewed, No Further Action Required
35894	128775	27/02/2015	electrode/lead, stimulator, implantable neurological	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that during a trial lead pull, the lead broke, leaving seven contacts in the patient's subcutaneous area. The patient underwent a procedure wherein the physician removed the seven contacts. Additional information was received that the device analysis indicated that electrode #7 was not returned. It is not known if the missing contact was left inside the patient. Additional Information was received that the physician clarified that all contacts were removed. Numerous x-rays were performed to ensure all parts of the lead were removed. The patient attended the radiology department, the day after the lead breakage, and the radiologist attempted to remove the lead. The physician feels that this is where the missing contact is. It was requested that all parts of the lead including the contacts be returned. The radiology department discarded the contacts.	Reviewed, for Trending Purposes Only
36638	230721	2/03/2015	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	St Jude Medical	The reported event occurred at the end of the patient's trial procedure. While removing the lead from the IPG header, one of the contacts (electrodes) came apart and remained inside the IPG header block. Per the physician, the set screw was backed out all the way. The event date is unknown at this time.	Reviewed, for Trending Purposes Only
35904	129091	3/03/2015	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient underwent an explant procedure due to pain at the pocket site. The physician did not suspect malfunction.	Reviewed, for Trending Purposes Only
36515	132097	6/03/2015	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	The patient is implanted with one SCS and two PNS systems. It was reported during the patient's lead revision procedure, the physician inadvertently cut the patient's right lead resulting in loss of stimulation. The patient is receiving stimulation from the left lead. Surgical intervention will take place at a later date to address the affected lead. The device information on the other implantable leads is unknown at this time.	Reviewed, for Trending Purposes Only
36009	129091	20/03/2015	Stimulator, electrical, analgesic spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient underwent an IPG explant procedure due to intense pain around the pocket site. There was no device malfunction suspected. The patient was doing well post operatively and the pocket pain had subsided.	Reviewed, for Trending Purposes Only

DIR Report #	ARTG #	Date of Report	GMDN / UMDN Text	Device Class	Sponsor Name	Manufacturer Name	Clinical Event Information	Outcomes
36010	129091	20/03/2015	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific	A report was received that the patient underwent an explant procedure due to pain at the pocket site. The physician did not suspect malfunction.	Reviewed, for Trending Purposes Only
37233	127126	1/05/2015	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	St Jude Medical	It was reported the patient was unable to communicate with the IPG using the charging system and the programmer. The IPG was tilted in the pocket, and the patient had been experiencing difficulty charging the IPG due to this issue. The patient reportedly lost stimulation around the occurrence of this event. Subsequently, the patient underwent surgical intervention to explant the IPG. It was clarified the patient had two IPG systems, and the leads from the explanted IPG have now been connected to the second currently implanted IPG. The patient is receiving partial stimulation with the current system.	Reviewed, No Further Action Required
37305	158502	6/05/2015	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	St Jude Medical	It was reported the patient's IPG was displaying a 'Low Battery' indication which was confirmed by the SJM Representative. The patient did not lose stimulation due to the low battery indication. Subsequently, the IPG was explanted and replaced. Effective stimulation was restored post-surgery.	Reviewed, for Trending Purposes Only
37196	205793	19/05/2015	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient was experiencing pocket discomfort. The physician assessed that the IPG was too close to the skinâ €™s surface. The patient will undergo a pocket revision procedure. Additional information was received that the patient underwent the revision and now has good coverage of his pain areas.	Reviewed, for Trending Purposes Only
37475	128775	27/05/2015	Neural-tissue electrical stimulation lead	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient experienced discomfort at the lead site from the inferior implanted lead. The patient underwent a lead revision procedure wherein the lead was replaced due to physician's preference. Malfunction was not suspected.	Reviewed, for Trending Purposes Only
36681	128775	29/05/2015	electrode/lead, stimulator, implantable neurological	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient's leads eroded through the skin near the pocket site. The patient also experienced pain at the pocket site in which the physician assessed to be caused by the lead erosion. The patient underwent an explant procedure wherein all the devices were removed. The physician applied a vacuum assisted compression pump to assist in the closure of the wound and the patient was administered IV antibiotics. The patient's symptoms have resolved.	Reviewed, No Further Action Required
38028	128775	20/07/2015	Neural-tissue electrical stimulation lead	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient was experiencing discomfort with postural changes. The physician assessed that the discomfort due to the lead position in the high cervical region. The physician did not suspect device malfunction. The patient underwent an explant procedure.	Reviewed, for Trending Purposes Only
38506	132097	24/08/2015	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported during the patient's SCS IPG revision surgery the physician inadvertently cut the patient's left lead resulting in loss of stimulation. The physician removed the terminal end of the cut lead from the IPG header and placed the port plug in the IPG port. Further follow up identified a surgical intervention was taken on 08/13/2015 where the new lead was implanted. Reportedly, the patient has effective therapy postoperatively.	Reviewed, for Trending Purposes Only
38334	128679	31/08/2015	Neural-tissue electrical stimulation lead	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient was experiencing discomfort at the IPG pocket site and would undergo a revision procedure. Additional information was received that the extension header was sitting on top of another header which pushed the skin out making it uncomfortable for the patient. The patient underwent a revision procedure wherein only a minor adjustment was made to the lead extension position.	Reviewed, for Trending Purposes Only
38214	128775	14/09/2015	electrode/lead, stimulator, implantable neurological	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient's leads eroded through the skin and there was an infection at the hips. The symptoms of the infection were redness and discharge. It is unknown whether the infection at the hips was related to the device or not. The patient underwent an explant procedure. Additional information was received that the infection was Staphylococcus and antibiotics were given. It was determined that the infection was not device related.	Reviewed, for Trending Purposes Only
38586	205793	14/09/2015	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that following a non-device related fall the patient underwent a pocket revision procedure. During the procedure, the physician noticed granuloma at the pocket site around the IPG. The granuloma was removed. It is likely that the granuloma was caused by the fall but the physician was not certain. The patient was doing fine post operatively.	Reviewed, for Trending Purposes Only
37710	205793	21/09/2015	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient's stimulation was aggravating her pain and she would undergo an explant procedure. No device malfunction was suspected. Additional information was received that no further action will be taken at this time.	Reviewed, for Trending Purposes Only
38842	205793	19/10/2015	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient was experiencing pain at the pocket site. The physician assessed that the IPG did not lay flat in the pocket. The patient underwent a pocket revision procedure wherein nothing was implanted or explanted. The patient was reportedly doing well following the procedure.	Reviewed, for Trending Purposes Only
38882	127126	27/10/2015	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced loss of stimulation as the IPG was unable to establish communication with the programmer and was communicating intermittently with the charger. As a result, the patient underwent surgical intervention where the IPG was explanted and replaced which resolved the issue. Reportedly, effective stimulation was restored postoperatively.	Reviewed, for Trending Purposes Only
39182	205793	11/11/2015	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that subsequent to the patientâ€™s pocket revision procedure (TGA Dir #38586) the patient was experiencing pain at the pocket site. The patient underwent a pocket revision procedure and the IPG was repositioned to the patientâ€™s other side. The patient was doing well post-operatively.	Reviewed, for Trending Purposes Only
38505	154912	20/11/2015	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	St Jude Medical	It was reported the patient (Australia) experienced loss of stimulation due to IPG being inoperable. A SJM representative confirmed the communication issue between the IPG and multiple external devices. Consequently, surgical intervention was taken to explant and replace the IPG. Stimulation was resumed postoperatively. 10/14/2015: Date of adverse event, Date mfr aware, Implant Date, Explant Date was inadvertently reported incorrect in last follow up report. This report consists of correct information.	Reviewed, for Trending Purposes Only
38592	154912	20/11/2015	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced loss of stimulation due to IPG being inoperable. A SJM representative confirmed the communication issue between the IPG and multiple external devices. Consequently, surgical intervention was taken to explant and replace the IPG. Stimulation was resumed postoperatively. 22/09/2015: In the initial report lot number of the device was inadvertently reported incorrect. This report consists of correct data.	Reviewed, for Trending Purposes Only
38913	129091	23/11/2015	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient is unable to place the charger over the IPG to charge due to an increase in the patient's pre-existing abdominal and pocket site pain. The physician is unsure if it is the patient's normal pain responding to the sensation of having the charger belt/adhesives on the skin or if the process of charging is causing a different pain to be triggered under the skin. The patient will undergo an explant procedure. Additional information was received that the patient underwent an explant procedure. Malfunction was not suspected.	Reviewed, for Trending Purposes Only
39506	186043	8/12/2015	Stimulator, electrical, analgesic, spinal cord	AIMD	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Nevro Corporation	It was reported to Nevro that the patient went to the Emergency Room due to a weeping wound site. The physician decided to explant the devices due to infection (yellow discharge). All explanted components were disposed of by the hospital. The patient was hospitalized and prescribed IV antibiotics. The physician will re-implant next year when the patient is healed.	Reviewed, for Trending Purposes Only
34761	154912	10/12/2015	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient experienced sudden loss of stimulation and was unable to establish communication with the IPG via the charging system or patient programmer. The patient had last successfully charged the IPG on March 7, 2014; however, the patient lost stimulation on March 22, 2014. As a result, surgical intervention took place to explant and replace the IPG which resulted in restoring effective stimulation.	Reviewed, for Trending Purposes Only
38509	154912	10/12/2015	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced loss of stimulation due to IPG being inoperable. A SJM representative confirmed the communication issue between the IPG and multiple external devices. Consequently, surgical intervention was taken to explant and replace the IPG. Stimulation was resumed postoperatively.	Reviewed, for Trending Purposes Only

DIR Report #	ARTG #	Date of Report	GMDN / UMDN Text	Device Class	Sponsor Name	Manufacturer Name	Clinical Event Information	Outcomes
38631	126002	14/12/2015	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient underwent surgical intervention on 18/08/2015 due to lead migration (The patient has a competitor's SCS IPG, and it is unknown at this time if the migrated lead belongs to SJM or to a competitor). During the procedure the physician explanted the migrated lead and experienced difficulty placing the new lead due to scar tissue. The physician decided to exchange the lead with a different model. X-rays revealed the lead was placed to the right of the midline. The physician proceeded with a laminectomy at the higher level to place the lead at the midline and sutured the lead to the dura as there was no lamina to hold the lead in place. Additionally, during the procedure the patient experienced dural rupture. The physician applied a graft to the dura. Reportedly, the patient had stimulation and the impedance values were normal postoperatively.	Reviewed, for Trending Purposes Only
39585	186043	15/12/2015	Stimulator, electrical, analgesic, spinal cord	AIMD	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Nevro Corporation	It was reported to Nevro that the patient was admitted to the hospital and an ultrasound was done at the IPG site. The patient was found to have a hematoma and no infection. The patient was prescribed IV antibiotics prophylactically to ensure that he would not get an infection. The physician indicated that the IPG was not the issue and therefore it was not explanted. Follow up report indicated that the patient was discharged and he was doing well. The device was functioning and pain is under control.	Reviewed, for Trending Purposes Only
39771	131047	27/01/2016	Neural-tissue electrical stimulation lead	Class III	LivaNova Australia Pty Ltd	LivaNova USA Inc	It was reported that a VNS patient underwent generator prophylactic replacement surgery, on 03/12/2015. During the replacement, high impedance was observed when the new generator was connected to the existing lead. System diagnostics were performed prior to the surgery and the results were normal (DCDC 2). When the new generator was connected, diagnostics were performed and the DCDC was 7. A pin insertion issue or a generator issue were ruled out by performing several attempts; High impedance persisted. It was then decided to move forward with replacing the lead. It was reported that apparently patient had complained of neck pain in weeks leading up to surgery. Review of manufacturing records confirmed that the lead passed all functional tests prior to distribution. The explanted devices have been received by the manufacturer on 11-01-2016. The analysis of the explanted generator was completed but the analysis of the lead is underway and ongoing.	Reviewed, for Trending Purposes Only
39662	154912	3/02/2016	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced difficulty establishing communication with the charging system and the IPG. An SJM representative resolved the issue by using a replacement charging unit. However, follow-up identified the IPG was unable to hold charge and the communication issues persisted resulting in intermittent therapy. Subsequently, the IPG was explanted and replaced. 05-01-2016: Device analysis is pending.	Reviewed, for Trending Purposes Only
40165	205793	18/02/2016	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient underwent a pocket revision due to pocket pain. During the procedure one lead was replaced as it displayed high impedances. Update received 19/05/2016: Additional information received indicated that the leads were broken and cables were exposed at the fracture site.	Reviewed, for Trending Purposes Only
40197	154912	8/03/2016	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	St Jude Medical	It was reported the patient's (Australia) IPG was inoperable. Surgical intervention was taken where the IPG was explanted and replaced. Postoperatively the patient received effective stimulation through burst programming. Implant date unknown	Reviewed, for Trending Purposes Only
39638	129091	15/03/2016	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient's IPG was dehiscing from the right thigh. The physician believes the IPG site had only extravasated and was not infected. The patient underwent an explant procedure and was administered post operative prophylactic antibiotics.	Reviewed, for Trending Purposes Only
40491	177594	18/03/2016	Stimulator, electrical, analgesic, spinal cord	AIMD	Medtronic Australasia Pty Ltd	Medtronic Inc	I have a spinal stimulator and since I have it in I have had 6 revisions surely this can't be right or this cannot be good all these procedures the trauma and pain I have gone through I have it only 15 months what am I to do also there are recalls and problems with the device I have researched into this. My device code matches those that had recalls lately I had to have that new device put in because I had a bad fall and since then I have been suffering with incontinence each and every time I turn the stimulator on consultant said it was decompressed and let him consider what to do in the meantime. I'm here in a lot of pain down my leg with nerve damage that was the reason for the stimulator in the first place. What am I to do I don't know who to talk to or get advice. Do I need to get legal advice? Can you please help me to go to the right direction.	Reviewed, No Further Action Required
40421	186043	25/03/2016	Stimulator, electrical, analgesic, spinal cord	AIMD	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Nevro Corporation	It was reported to Nevro that a patient experienced more intraoperatively bleeding than usual during implant surgery. The patient was hospitalized when it was reported that her wound was opened and started to bleed. She was being monitored for low level infection and clotting factors. On February 25th, the IPG wound was opened in the OR and only small bleeders were observed. The wound was cauterized and closed. The wound is now healing and there are no further issues. The patient is doing well.	Reviewed, for Trending Purposes Only
40797	197909	13/04/2016	Neural-tissue electrical stimulation lead	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the loop of the patient’s lead eroded through the skin at the previous suture site. The patient underwent a revision procedure where the wound was thoroughly cleaned, the leads were re-sutured deeper and prophylactic antibiotics were administered. The physician believed the lead erosion was due to the stiffness of the lead and anchoring techniques. The issue has resolved.	Reviewed, for Trending Purposes Only
40843	186043	16/04/2016	Stimulator, electrical, analgesic, spinal cord	AIMD	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Nevro Corporation	It was reported to Nevro that a patient experienced swelling and pain at the IPG site post implant. The patient was admitted to the hospital and was treated with IV antibiotics as a precautionary measure. The patient developed a fever and blood cultures were taken. The seroma was aspirated and the fluid was collected for cultures as well. Follow-up reports indicate the blood and fluid cultures were negative for infection, the patient is no longer in pain and has been discharged from the hospital.	Reviewed, for Trending Purposes Only
40047	128775	20/04/2016	Electrode/lead, stimulator, implantable neurological	Class III	Boston Scientific Pty Ltd	Boston Scientific	A report was received that the patient's right occipital suture where the lead was located had eroded through the skin. The physician re-sited and sutured the lead. The patient is doing well following the procedure..	Reviewed, for Trending Purposes Only
40689	129091	3/05/2016	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient will undergo a pocket revision due to pain at the pocket site. Additional information was received that the patient had complained of severe ongoing pain over the pocket area. Patient had lost a significant amount of weight due to being physically active again. The physician planned to reposition the IPG deeper but after reprogramming the patient received adequate stimulation and no longer plans to be revised.	Reviewed, for Trending Purposes Only
41223	186043	18/05/2016	Stimulator, electrical, analgesic, spinal cord	AIMD	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Nevro Corporation	It was reported to Nevro that a patient acquired an infection post implant. The patient was admitted to a local hospital and was treated for infection. The device was not explanted. Follow up report indicated that the patient was discharged from the hospital and recovered without sequelae.	Reviewed, for Trending Purposes Only
40405	230721	20/05/2016	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	St Jude Medical	It was reported the patient's stimulation was unintendedly turned OFF by itself on multiple occasions. Further a SJM representative tried troubleshooting to no avail as the SCS system turned OFF in 5 minutes after the representative turned it ON. The SJM representative reported the deviceâ€™s magnetic mode was OFF. Consequently, surgical intervention was performed on the 24th February to replace the IPG.	Reviewed, for Trending Purposes Only
41370	186043	28/05/2016	Stimulator, electrical, analgesic, spinal cord	AIMD	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Nevro Corporation	It was reported to Nevro that a patient in Australia experienced swelling in lower lumbar/sacral area. The swelling was not located at the incision sites. The patient was hospitalized and was given IV antibiotics as precautionary measure. The physician believed that the inflammation was due to a seroma and not infection as the patientâ€™s blood work was negative for infection. The follow up report indicated that the patient did not experience any other complications and was discharged from the hospital.	Reviewed, for Trending Purposes Only
40452	129091	8/06/2016	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient experienced irritation at their IPG site. The patient underwent an explant procedure wherein the IPG was removed. Additional information was received that the patient experienced stimulation over the kidneys, not in the lower back where needed. The IPG was explanted due to inadequate stimulation.	Reviewed, for Trending Purposes Only

DIR Report #	ARTG #	Date of Report	GMDN / UMDN Text	Device Class	Sponsor Name	Manufacturer Name	Clinical Event Information	Outcomes
40768	128775	14/06/2016	Neural-tissue electrical stimulation lead	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that following an implant procedure, the patient felt as though a stitch was still in her neck. The physician assessed that it was the suture around one of the leads and he decided to cut the electrode, and remove the protruding bit. The patient was left with a cut lead and no electrode. The remaining three leads were left intact. The physician administered an antibiotic cream for the wound site. Additional information was received that another lead was removed. The patient now has two leads implanted and is reportedly doing well post-operatively. Malfunction was not suspected.	Reviewed, for Trending Purposes Only
40809	128775	15/06/2016	Electrode/lead, stimulator, implantable, neurological	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient had discharge around the right lead site. The physician assessed that the patient had erosion/seroma of the lead with hematoma. The patient also experienced an infection around the right lead site that was external to internal. The patient was administered Vancomycin and underwent an explant procedure. The patientâ€™s symptoms have resolved. Additional information was received that culture results indicated gram negative cocci.	Reviewed, for Trending Purposes Only
35624	129091	17/06/2016	stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient was experiencing pain at the IPG site and would undergo a revision procedure to have the device re-sited.	Reviewed, for Trending Purposes Only
41131	129091	27/06/2016	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient experienced a Cerebrovascular Accident (CVA) and urinary incontinence for six to twelve months. The patient underwent an explant procedure and was stable post-operatively. The physician assessed the events to be device related.	Reviewed, for Trending Purposes Only
36256	230721	7/07/2016	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	St Jude Medical	The reported event occurred at the end of the patient's trial procedure. While removing the lead from the IPG header, one of the contacts (electrodes) came apart and remained inside the IPG header block. Per the physician, the set screw was backed out all the way. The event date is unknown at this time.	Reviewed, for Trending Purposes Only
41409	197909	15/07/2016	Neural-tissue electrical stimulation lead	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that during a lead revision procedure the physician chose to replace the leads and the lead splitters because he suspected they were damaged. The patient was reportedly doing well postoperatively. Additional information was received that one of the patient's leads had wires that broke through the outer layer of the lead. It was also noted the damage to the splitter or leads likely occurred during a number of falls the patient had prior to the revision. The falls occurred when the patient's system stopped working.	Reviewed, for Trending Purposes Only
41990	128775	15/07/2016	Stimulator, electrical, analgesic, spinal cord	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that patient was explanted due to high impedances. During the procedure the physician was unsure whether the leads were damaged because they were not properly examined before being removed.	Reviewed, for Trending Purposes Only
42069	186043	21/07/2016	Stimulator, electrical, analgesic, spinal cord	AIMD	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Nevro Corporation	It was reported to Nevro in July 2016 that a patient in Australia had developed a haematoma at the implant site shortly after the implant procedure (08 April 2014). This event was revealed recently during a conversation with the patient. The haematoma was aspirated and there was no other report of serious injury relating to this event.	Reviewed, for Trending Purposes Only
41545	127126	26/07/2016	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	St Jude Medical	It was reported the patientâ€™s IPG was unintendedly turning on and off randomly. Additionally, the patient also experienced overstimulation. As a result, surgical intervention was taken on 14th May wherein the IPG was explanted and replaced which resolved the issue. 05-07-2016: No new information available at this time. 26-07-2016: No new information available at this time.	Reviewed, for Trending Purposes Only
40732	186043	27/07/2016	Stimulator, electrical, analgesic, spinal cord	AIMD	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Nevro Corporation	It was reported to Nevro that a patient experienced a hematoma post implant at the IPG site. Follow up with the patient indicated that the physician suspected a possible infection due to patientâ€™s report of persistent pain and shocking sensation at the pocket site. The patient is currently on antibiotics.	Reviewed, for Trending Purposes Only
42148	185992	29/07/2016	Stimulator, electrical, analgesic, spinal cord	Class III	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Nevro Corporation	It was reported to Nevro that a trial patient in Australia complained of wound site pain and headache. The patient's wound was examined and no sign of infection was observed. The patient returned to the hospital for follow up examination of the site and reported slight improvement. On day 8 of the trial period, therapy was turned off due to continuing headache. The patient was readmitted to the hospital and the leads were removed. The physician was concerned about possible infection so the patient was given IV antibiotics. Follow up report indicated that the patient was discharged from the hospital and is being monitored by the hospital while completing the antibiotic course.	Reviewed, for Trending Purposes Only
41313	197909	2/08/2016	electrode/lead, stimulator, implantable neurological	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient was experiencing new pain where the splitters connect to the leads. The physician noticed that the splitters were high in profile and decided to replace the leads and splitters.	Reviewed, for Trending Purposes Only
41612	197909	10/08/2016	electrode/lead, stimulator, implantable neurological	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient experienced pain that was aggravated by stimulation. The pain caused burning and spasm from the waist down. The patient will undergo an explant procedure. Additional information was received that there was no evidence of of cutaneous burning injury. The physician did not suspect device malfunction. The patient underwent an explant procedure.	Reviewed, for Trending Purposes Only
42319	186043	10/08/2016	Stimulator, electrical, analgesic, spinal cord	AIMD	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Nevro Corporation	It was reported to Nevro that a patient in Australia had acquired an infection following a revision procedure. The patient was hospitalized and was given IV antibiotics. The device was explanted. The leads were left in-situ for future reimplant. Follow up report indicated that the infection has cleared and the patient had recovered without sequelae.	Reviewed, for Trending Purposes Only
42440	230721	22/08/2016	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	St Jude Medical	The stimulator causes electric shocks and required me to turn it off. This instruction was given to me by the St Jude medical representative.	Reviewed, No Further Action Required
41053	128775	29/08/2016	Neural-tissue electrical stimulation lead	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that during an explant procedure several contacts were dislodged from the paddle lead. Two of the contacts remained inside the patient because the physician felt like they were difficult to retrieve. The physician did not suspect malfunction of the paddle lead. Upon return of the clik anchor for analysis, pieces of silicone were missing. Additional information was received that the physician was confident the missing silicone was not left inside the patient.	Reviewed, for Trending Purposes Only
41286	197909	30/08/2016	electrode/lead, stimulator, implantable neurological	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patientâ€™s stimulation was uncomfortable and caused pain in his back and legs. The patient underwent a procedure wherein one of the two systems was explanted. The patient will undergo an explant of the second system at a later date. Additional information was received that the that the patient's second system was explanted on 06Jun2016.	Reviewed, for Trending Purposes Only
42834	205793	20/09/2016	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient underwent an IPG revision due to discomfort. The patient felt the IPG was uncomfortable, not sitting as flat as she would like, and impeded her clothing. Sponsor provided additional information (27/10/2017): Additional information was received that the IPG was revised due to the patient losing 18 kgs of weight which made the IPG more superficial. The lead position was too close to the dorsal ramus and was causing shocks so, during the revision procedure, the physician moved the lead back so that the stimulation was more comfortable.	Reviewed, for Trending Purposes Only

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42415	185992	5/10/2016	Stimulator, electrical, analgesic, spinal cord	Class III	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Nevro Corporation	It was reported to Nevro that the insertion needle detached from the hub during the removal of the needle from the epidural space. The detached needle was retrieved with the forceps and the case was completed successfully	Reviewed, for Trending Purposes Only
42165	128775	11/10/2016	electrode/lead, stimulator, implantable neurological	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that following a permanent trial procedure the patient experienced extreme leg pain postoperatively. The physician suspected that the patient had a cerebrospinal fluid leakage or that he aggravated the nerve during the positioning of a cervical lead. He did not suspect device malfunction. The patient underwent an explant procedure wherein all devices were removed. The patientâ€™s pain has improved over time.	Reviewed, for Trending Purposes Only
43339	154912	14/10/2016	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	St Jude Medical	The patient received two SCS IPGs (left side and right side). This report is for left side IPG. It was reported the patientâ€™s IPG intermittently turns off without prompting. Subsequently, surgical intervention was taken on 23/09/2016 wherein the IPG was explanted and replaced which resolved the issue.	Reviewed, for Trending Purposes Only
42391	128775	24/10/2016	electrode/lead, stimulator, implantable neurological	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patientâ€™s trial leads were pulled due to experiencing fever, chills and to decrease the risk of a suspected infection. It was later discovered that the fever and chills were not due to an infection, but were due to a sustained dural tear. No medical intervention was provided for the dural tear. The patient was in stable condition following the procedure.	Reviewed, for Trending Purposes Only
43326	154912	24/10/2016	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	St Jude Medical	The patient received two SCS IPGs (left side and right side). This report is for right side IPG. It was reported the patientâ€™s IPG intermittently turns off by itself. Subsequently, surgical intervention was taken on 23/09/2016 wherein the IPG was explanted and replaced which resolved the issue.	Reviewed, for Trending Purposes Only
43640	185992	15/11/2016	Stimulator, electrical, analgesic, spinal cord	Class III	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Nevro Corporation	It was reported to Nevro that a patient had acquired a MRSA infection at the trial incision site. The patient was hospitalized and was given IV antibiotics. The leads were removed and the patient is recovering from the infection. Follow up report indicated that the patient has a medical history of prior infections and that the trial provided good pain relief.	Reviewed, for Trending Purposes Only
42189	128775	16/11/2016	Stimulator, electrical, analgesic, spinal cord	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient underwent a revision procedure due to inadequate stimulation and high impedances. During the procedure it was discovered that one of the patient's leads had broken into three pieces, which was confirmed by x-ray. The physician was not able to confirm if there were exposed cables on the lead. He believes that the lead was broken prior to the revision procedure. The lead was replaced and all of the pieces of the broken lead were removed from the patient.	Reviewed, for Trending Purposes Only
43651	185992	16/11/2016	Stimulator, electrical, analgesic, spinal cord	Class III	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Nevro Corporation	It was reported to Nevro that a trial patient acquired an infection. The devices were removed. The patient was hospitalized and was given IV antibiotics. The trial was not successful and the permanent implant is unlikely for this patient. There was no other report of further complication.	Reviewed, for Trending Purposes Only
44008	205793	9/12/2016	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient's IPG was superficial and causing discomfort. The patient underwent a revision procedure wherein the IPG was positioned deeper into the patient's pocket. The patient was doing well post-operatively.	Reviewed, for Trending Purposes Only
44012	185992	9/12/2016	Stimulator, electrical, analgesic, spinal cord	Class III	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Nevro Corporation	It was reported to Nevro that the physician observed that the wound was not healing at the anchor site. There was no report of infection however the patient was given antibiotics prophylactically since the wound was healing slowly. Follow up report indicated that the patient was admitted to the hospital. The physician performed debridement and washout of the wound anchor site. The device was not explanted. The patient recovered well from the procedure and is currently receiving good pain relief.	Reviewed, for Trending Purposes Only
43618	218230	16/12/2016	stimulator, electrical, analgesic, spinal cord	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient's knees gave way and the patient experienced a fall due to their pain. The patient hit their head in the fall and is in an induced coma at the hospital. It is unknown if the fall was device related.	Reviewed, for Trending Purposes Only
44346	185992	7/01/2017	Stimulator, electrical, analgesic, spinal cord	Class III	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Nevro Corporation	It was reported to Nevro that a trial patient had experienced infection following implant. The patient reported pain at the lead incision site. The device was explanted. The patient was hospitalized and was given IV antibiotics due to sepsis. There was no further report of complications.	Reviewed, for Trending Purposes Only
44440	205793	13/01/2017	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient lost the use of their limbs, was unable to communicate, and became unresponsive and aphasic due to left sided brain hemorrhage following a permanent implant procedure. The physician stated that the patient was treated conservatively and assessed that the hemorrhage was not a result of the implant.	Reviewed, for Trending Purposes Only
44975	128775	24/02/2017	Stimulator, electrical, analgesic, spinal cord	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that patient developed a severe headache one day after the trial procedure. The physician suspected the headache was due to a dural puncture caused during the insertion of the tuohey needle. The patient was treated with IV fluids, analgesia, a blood patch and bed rest. The patient was stable and released from the hospital.	Reviewed, for Trending Purposes Only
44004	205793	6/03/2017	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patientâ€™s IPG was eroding and had broken through the skin. The patient underwent a revision procedure wherein the physician replaced the IPG and re-sited the new IPG. Additional information was received that the location of the skin breakage was on the patient's chest wall. The physician stated that no malfunction was suspected with the explanted IPG. The patient was doing well post-operatively.	Reviewed, for Trending Purposes Only
44474	186043	15/03/2017	Stimulator, electrical, analgesic, spinal cord	AIMD	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Nevro Corporation	It was reported to Nevro that a patient had been admitted to the hospital with an infection following the implant procedure. The patient was given IV antibiotics and the device was explanted. There was no report of further complication.	Reviewed, for Trending Purposes Only
45356	128679	23/03/2017	Neural-tissue electrical stimulation lead	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient experienced a headache due to a dural puncture. During a lead revision procedure, the patient sustained a dural tear which was treated with a blood patch. The physician stated that the dural tear was caused by the insertion of the touhey needle into the epidural space at T12. After treatment the patient is reportedly stable and has been discharged from the hospital.	Reviewed, for Trending Purposes Only
45442	128775	30/03/2017	Neural-tissue electrical stimulation lead	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient had a sore spot on the back of their head due to skin erosion. It was noted that the lead was not exposed. The patient will undergo a procedure for an exploration of the wound and a possible lead revision. Additional information was received indicating that the lead was positioned slightly superficial and the physician re-buried the lead deeper. Nothing was explanted, replaced, or added. The patient was reportedly stable postoperatively.	Reviewed, for Trending Purposes Only
45553	215750	6/04/2017	Stimulator, electrical, analgesic, spinal cord	AIMD	Medtronic Australasia Pty Ltd	Medtronic Inc	Feeling residual stimulation, severe pain in area of implant. Device not relieving lower back pain as advertised, just causing more pain.	Reviewed, for Trending Purposes Only
45329	218230	10/05/2017	Neural-tissue electrical stimulation lead	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that following epidural placement of the paddle the patient woke up unable to move their legs. The patient was taken back into surgery and a significant hematoma was found. The physician reported that the procedure took four and one-half hours, which may have caused or contributed to the issue. The physician did not suspect device malfunction. The physician explanted the system and the patient’s leg function returned. Additional information was received, that per the physician's assessment the hematoma was located in the epidural, and was caused by bleeding during the procedure.	Reviewed, for Trending Purposes Only
45170	205793	15/05/2017	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient experienced recurring electric shocks at the pocket site which were causing pain. The jolting originates from the IPG site and spreads from the patientâ€™s chest to her knees, and was more severe on the left side. The patient experiences exacerbation in her usual pain and tenderness 24-48 hours after the jolt. A database analysis revealed no anomalies.The physician was concerned about potential current leakage from the lead splitters. The patient underwent a revision procedure wherein the physician chose to replace the system. The patient is doing well postoperatively.	Reviewed, for Trending Purposes Only

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45764	205793	24/05/2017	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient was experiencing pain at the pocket site as well as inadequate therapy. High impedances were noted on the leads. The patient underwent a revision procedure wherein the physician implanted the IPG deeper within the pocket and replaced the leads. One of the leads had a broken distal tip and the physician confirmed that the damage was not done during the procedure. It was reported that post-operatively the patientâ€™s pocket pain did not resolve. Additional information was received that the patient's pocket pain has resolved and there will be no further course of action.	Reviewed, for Trending Purposes Only
45708	197909	31/05/2017	Neural-tissue electrical stimulation lead	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient had an explant procedure due to the leads eroding through the skin. All devices were explanted. All devices were explanted. The IPG and lead splitters are at BSN. The leads were discarded by the facility.	Reviewed, for Trending Purposes Only
46496	186043	14/06/2017	Stimulator, electrical, analgesic, spinal cord	AIMD	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Nevro Corporation	It was reported to Nevro that a patient had acquired an infection following a revision procedure. The patient was hospitalized and was provided IV antibiotics. The device was explanted. The patient had recovered without sequelae.	Reviewed, for Trending Purposes Only
44952	205793	19/06/2017	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient was unhappy with how the stimulation felt and the device often felt hot in her body. The patient underwent an explant procedure.	Reviewed, for Trending Purposes Only
45771	186043	24/06/2017	Stimulator, electrical, analgesic, spinal cord	AIMD	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Nevro Corporation	It was reported to Nevro that a patient had acquired an infection. The patient was hospitalized and was provided IV antibiotics. Follow up report indicated that the patient had recovered without sequelae.	Reviewed, for Trending Purposes Only
46736	186043	27/06/2017	Stimulator, electrical, analgesic, spinal cord	AIMD	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Nevro Corporation	It was reported to Nevro that a patient had acquired an infection following an implant procedure. The patient was hospitalized and was provided IV antibiotics. The report indicated that the patient had improved and is on the road to recovery. The device was not explanted.	Reviewed, for Trending Purposes Only
45622	128775	18/07/2017	Neural-tissue electrical stimulation lead	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the tip of the patient’s lead had eroded through the skin. The patient underwent a revision procedure and the physician made an incision and buried the lead deeper. The patient was doing well postoperatively. Additional information was received that the patient had occipital leads implanted.	Reviewed, for Trending Purposes Only
46133	186043	1/08/2017	Stimulator, electrical, analgesic, spinal cord	AIMD	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Nevro Corporation	It was reported to Nevro that during a lead revision procedure, one of the leads was placed lateral to spinal cord as the surgeon had difficulty placing the lead due to scar tissues. The patient reported sensory loss and severe new pain on the right leg postoperatively. The patient was brought back to the operating room and the lead that was placed lateral was explanted. Follow up report indicated that the patient had recovered with no sequelae. The initial report of sensory loss had been completely resolved.	Reviewed, for Trending Purposes Only
46258	186043	1/08/2017	Stimulator, electrical, analgesic, spinal cord	AIMD	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Nevro Corporation	It was reported to Nevro that a patient acquired an infection at the lead incision site. The wound site was drained and irrigated. The patient was provided IV and oral antibiotics. Follow up report indicated that the wound site has healed, stimulation has been turned on and patient is receiving good pain relief.	Reviewed, for Trending Purposes Only
46322	186043	1/08/2017	Stimulator, electrical, analgesic, spinal cord	AIMD	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Nevro Corporation	It was reported to Nevro that a trial patient experienced new pain in her leg following lead placement. Stimulation was never turned on and the leads were removed. CT and MRI scans were performed and did not show any abnormalities. Follow up report indicate that the patient was discharged and her leg pain has reduced.	Reviewed, for Trending Purposes Only
47225	186043	1/08/2017	Stimulator, electrical, analgesic, spinal cord	AIMD	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Nevro Corporation	During a routine follow-up, it was reported to Nevro that a patient had acquired an infection. The patient was hospitalized and treated with antibiotics. There have been no further reports of complications.	Reviewed, for Trending Purposes Only
46753	205793	7/08/2017	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient will be undergoing palliative radiation therapy for a large tumor located in the IPG pocket. The IPG pocket is located in the sub-clavicular region of the chest. It was noted that a large dose of radiation is expected to be directed to the IPG site. An explant was ruled out by the treating physician due to the risk of the cancer spreading. The tumor was assessed as being unrelated to the device. Additional information was received that the patient is now deceased. No further information can be obtained regarding the patient's tumor. Additional information was received that the patient's death was not device related.	Reviewed, for Trending Purposes Only
47346	197909	9/08/2017	Neural-tissue electrical stimulation lead	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient experienced a loss of coverage due to high impedances and lead breakage as a result of an unrelated fall. The patient underwent a lead replacement procedure and was doing well post-operatively.	Reviewed, for Trending Purposes Only
47393	197909	14/08/2017	Neural-tissue electrical stimulation lead	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient experienced some dizziness and nausea. An x-ray revealed that the patient’s leads moved too high in the flexion position and may have potentially irritated the nerve root. The physician unsuccessfully treated the patient with Platelet Rich Plasma (PRP) Injection. The patient then underwent a lead revision procedure and was doing well post-operatively. Device malfunction was not suspected.	Reviewed, for Trending Purposes Only
46590	205793	21/08/2017	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient had increasing pain at the IPG pocket site. Per the physician's examination there was erosion at the site. The IPG was not exposed. The patient underwent an explant procedure to remove the leads, clik anchor and the IPG. During the procedure a piece of silicone from the anchor was dropped and lost on the floor. The physician is confident that all the silicone was removed from the patient. Per the physician's assessment the patient's condition is stable post-operatively. Additional information was received that the patient was implanted with only Next Generation Clik anchors SC-4316 with lot number 16868695.	Reviewed, for Trending Purposes Only
47584	186043	25/08/2017	Stimulator, electrical, analgesic, spinal cord	AIMD	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Nevro Corporation	It was reported to Nevro that a patient acquired an infection during the trial. The leads were removed and the patient was hospitalized. The patient was treated with IV antibiotics. The patient is currently in stable condition and there are no reports of further complications.	Reviewed, for Trending Purposes Only
46848	279913	29/08/2017	Stimulator, electrical, analgesic, spinal cord	Class III	St Jude Medical Australia Pty Ltd	St Jude Medical	It was reported during the SCS implant procedure, high impedances were observed on the leads. The physician tried to troubleshoot to no avail. High impedances persisted postoperatively. In turn the patient experienced ineffective stimulation at the right side. The patient underwent an additional surgical intervention wherein the leads were explanted and replaced which resolved the issue. Effective stimulation was restored postoperatively. 26-07-2017: The devices were returned to the manufacturer for analysis. Analysis is pending. 22-08-2017: Analysis is closed on the device.	Reviewed, for Trending Purposes Only
47988	186043	19/09/2017	Stimulator, electrical, analgesic, spinal cord	AIMD	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Nevro Corporation	It was reported to Nevro that a trial patient developed an infection. The patient was hospitalized and was given IV antibiotics. The device was explanted. The patient was discharged and there were no reports of further complications.	Reviewed, for Trending Purposes Only
47267	186043	24/10/2017	Stimulator, electrical, analgesic, spinal cord	AIMD	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Nevro Corporation	It was reported to Nevro that a patient experienced numbness in legs and increase in blood pressure a few weeks after the implant procedure. The patient had an ECG which showed some abnormalities and is currently awaiting an appointment with the cardiologist. Device was switched off during ECG. The stimulation is currently on but only at low frequency and for a short period of time each day as suggested by pain physician. There are no reports of other complications. Follow up report indicate that patient experienced some heaviness in legs during the trial phase but did not report it to the implanting physician or Nevro.	Reviewed, for Trending Purposes Only
47544	279015	24/10/2017	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	St Jude Medical	It was reported the IPG was explanted and replaced with another model due to the device displaying premature end of life warning. 15-09-2017: No new information to report at this time. Device was returned to the manufacturer. Analysis is pending	Reviewed, for Trending Purposes Only

DIR Report #	ARTG #	Date of Report	GMDN / UMDN Text	Device Class	Sponsor Name	Manufacturer Name	Clinical Event Information	Outcomes
48023	128775	24/10/2017	Neural-tissue electrical stimulation lead	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient underwent a lead explant procedure, wherein three leads and the IPG were removed for an unknown reason. During the procedure, one of the leads was discovered to have been broken inside of the patient. The proximal to contacts broke off the lead and could not be removed from the patient. Additional information was received that the patient underwent the revision procedure due to no longer achieving adequate stimulation with their current lead configuration. Only one lead was explanted and replaced, though it is unknown which of the patient's implanted leads was removed. The IPG was not explanted.	Reviewed, for Trending Purposes Only
48603	205793	31/10/2017	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient underwent an IPG revision procedure. The IPG was repositioned, from the left buttock to the left abdomen, to make more comfortable. The patient was stable post-operatively	Reviewed, for Trending Purposes Only
47898	279015	8/11/2017	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	St Jude Medical	It was reported the patient received premature low battery warning indicator for the IPG. Subsequently, the IPG was explanted and replaced on 16-08-2017 with another model which resolved the issue. 05-10-2017: Analysis is pending on the device. 02-11-2017: Analysis is closed and reported.	Reviewed, for Trending Purposes Only
47449	205793	20/11/2017	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient experienced an increase in back pain. The patient was hospitalized and underwent a trial procedure to add leads. The event has resolved and was assessed to be related to the device and not to the procedure. Additional information was received that the event was assessed as not related to the procedure and not related to the study device system.	Reviewed, for Trending Purposes Only
47142	186043	29/11/2017	Stimulator, electrical, analgesic, spinal cord	AIMD	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Nevro Corporation	It was reported to Nevro that during a permanent procedure, the physician had difficulty accessing the epidural space in a patient with severe fibrosis in lower spine. After several attempts to insert the percutaneous lead, he retracted the lead and noted that the top contact was missing. The case was aborted and the detached contact remained in the epidural space. There was no report of further complication.	Reviewed, for Trending Purposes Only
49146	205793	14/12/2017	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient was experiencing increased pocket pain so the physician decided to revise the patient. During the revision procedure, the physician noticed that the implanter left the IPG template insitu behind the IPG which had not been visible in the X-ray results. It was observed that the IPG had flipped so the physician removed the IPG template and repositioned the IPG to a new site. The patient was stable post-operatively.	Reviewed, for Trending Purposes Only
49469	287158	22/12/2017	Stimulator, electrical, analgesic, spinal cord	AIMD	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Stimwave Technologies Inc	Stimwave Quality has investigated the details surrounding a complaint resulting from a staph infection reported to Stimwave on November 23, 2017 by a specialist in Australia. The patient was implanted on October 27, 2017 with a Freedom Receiver Stimulator (FR8A-RCV-A0) and Spare Lead (FR8A-SPR-B0). There were no complication experienced during the procedure and the patient was sent home following an overnight stay in the hospital. The patient visited a clinic on November 7, 2017 for follow up and reported no issues or illness and continued adequate coverage and pain relief. On November 17, 2017, the patient contacted a Therapy Consultant and reported that he was experiencing painful symptoms near the incision site for the original wound. The patient went to an emergency department later that evening. On November 18, 2017, the stimulator was explanted and the wound was swabbed for infectious diseases. Pathology reports showed Staph growth on the swab. The patient was therefore admitted to the hospital on November 20, 2017 and treated with IV antibiotics. The patient was discharged on November 29, 2017 and prescribed oral antibiotics for an additional 6 weeks. The patient was reviewed for incision wound healing on December 5, 2017, and December 11, 2017. Immediately following notification, Stimwave Management and Quality extensively reviewed the procedure and after care with the Therapy Specialists and the Director of the clinic. Before implantation, the patient was screened for bacterial disease with nose, groin, and back swabs. All results returned negative. During implantation, the patient received IV antibiotics (cephazolin 2g). The patientâ€™s skin was prescrubbed with chrolorhexadine, which was also applied to drying level. A square drape was used, and integueseal glue to skin to lock down any surviving bacteria. The implanting clinician changed his gloves before handling the product. The wound was copiously washed out at the end with a very dilute betadine; the exact concentration is unknown. Vancomycin powder 1g was applied inside the wounds, and collatamp G gentamicin impregnated sponge was placed in the wound. The sterile dressing is comprised of Dermabond to the skin, biopatch, and steristrips, then hyperfix. The duration of the implant procedure took less than 60 minutes. The patients are sent home with oral antibiotics (Keflex) for five days. During this investigation, a Therapy Specialist confirmed that on the day of the implant, the product packaging was not damaged, and the sterile barrier remained intact prior to the implant. In Australia, the sterile product is only handled by scrub and scout nurses in the operating theatre, the Therapy Consultants are not allowed into the sterile operating theatre. The implant was completed in accordance with the product instructions for use with the only exception being the procedure for intraoperative testing. The doctor implanted the stimulator based on pain syndrome (dermatomes) markers with the patient asleep (general anesthesia) and the incisions were closed. The patient	Reviewed, for Trending Purposes Only

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49470	287158	22/12/2017	Stimulator, electrical, analgesic, spinal cord	AIMD	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Stimwave Technologies Inc	Stimwave Quality has investigated the details surrounding a complaint of irritation at the wound resulting in explantation of the device reported to Stimwave on November 27, 2017 by a in Australia. The patient was implanted on November 6, 2017 with a Freedom Receiver Stimulator (FR8A-RCV-A0) and Spare Lead (FR8A-SPR-B0) for neuropathic leg pain associated with Multiple Sclerosis (MS). Before the procedure, the pre-screening showed a urinary tract infection (E. Coli), which was being treated with oral antibiotics. The clinician decided to proceed with the implant. There were no complication experienced during the procedure and the patient was sent home following an overnight stay in the hospital. The patient followed up at a clinic on November 20, 2017 and reported no issues or illness. On November 24, 2017, the patient contacted a Therapy Consultant and reported that she was experiencing painful symptoms and swelling over the wound. The Theraphy Consultant contacted the clinic and the cinician, who had the patient return on November 27, 2017 for evaluation. On November 27, 2017, the stimulator was explanted and the wound was swabbed for infectious diseases. Pathology reports showed a high level of leucocytes but no bacterial growth. Because the patient has Multiple Sclerosis (MS), the clinician sought advice from Infections Diseases Specialists and the patient was hospitalized starting November 27, 2017 and administered IV antibiotics. Stimwave was notified of the issue on November 27, 2017. Due to the patients pre-existing conditions, the patient was transferred to a major teaching hospital on December 1, 2017 for additional treatment. Stimwave does not know when the patient will be discharged, but as of December 18, 2017, the patient is still in the hospital. Immediately following notification, Stimwave Management and Quality extensively reviewed the procedure and after care with the Therapy Specialists and the Director of the clinic. Before implantation, the patient was screened for bacterial disease with nose, groin, and back swabs. Before the procedure, the pre-screening showed a urinary tract infection (E. Coli) treated with oral antibiotics. All other results returned negative. During implantation, the patient received IV antibiotics (cephazolin 2g). The patientâ€™s skin was prescrubbed with chrolorhexadine, which was also applied to drying level. A square drape was used, and integueseal glue to skin to lock down any surviving bacteria. The implanting clinician changed his gloves before handling the product. The wound was copiously washed out at the end with a very dilute betadine; the exact concentration is unknown. Vancomycin powder 1g was applied inside the wounds, and collatamp G gentamicin impregnated sponge was placed in the wound. The sterile dressing is comprised of Dermabond to the skin, biopatch, and steristrips, then hyperfix. The duration of the implant procedure took less than 60 minutes. The patients are sent home with oral antibiotics (Keflex) for five days. During this investigation, the Therapy Consultant confirmed that on the day of the implant, the product packaging was not damaged, and the sterile barrier remained intact	Reviewed, for Trending Purposes Only
49472	287158	22/12/2017	Stimulator, electrical, analgesic, spinal cord	AIMD	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Stimwave Technologies Inc	Stimwave Quality has investigated the details surrounding a complaint resulting from a wound that was not healing reported to Stimwave on November 27, 2017 by a Specialist. The patient was implanted on November 15, 2017 with a Freedom Receiver Stimulator (FR8A-RCV-A0) and Spare Lead (FR8A-SPR-B0). There were no complication experienced during the procedure and the patient was sent home following an overnight stay in the implanting hospital. The patient visited the clinic on November 24, 2017 for followup and reported no issues. On November 26, 2017, the patient contacted a Therapy Consultant and reported discharge from the wound. The patient was seen on November 27, 2017, and was admitted to the hospital for IV antibiotics. No pathology reports were taken. Stimwave was notified of the issue on November 27, 2017. The patient was discharged on December 2, 2017 and prescribed oral antibiotics for an additional 6 weeks. The patient was reviewed for incision wound healing on December 13, 2017 and reported no new issues or illness and continued adequate coverage and pain relief. Immediately following notification, Stimwave Management and Quality reviewed the procedure and after care with the Therapy Specialists and the Director of the clinic. Before implantation, the patient was screened for bacterial disease with nose, groin, and back swabs. All results returned negative. During implantation, the patient received IV antibiotics (cephazolin 2g). The patientâ€™s skin was prescrubbed with chrolorhexadine, which was also applied to drying level. A square drape was used, and integueseal glue to skin to lock down any surviving bacteria. The implanting clinician changed his gloves before handling the product. The wound was copiously washed out at the end with a very dilute betadine; the exact concentration is unknown. Vancomycin powder 1g was applied inside the wounds, and collatamp G gentamicin impregnated sponge was placed in the wound. The sterile dressing is comprised of Dermabond to the skin, biopatch, and steristrips, then hyperfix. The duration of the implant procedure took less than 60 minutes. The patient was sent home with oral antibiotics (Keflex) for five days. During this investigation, Therapy Consultant confirmed that on the day of the implant, the product packaging was not damaged, and the sterile barrier remained intact prior to the implant. In Australia, the sterile product is only handled by scrub and scout nurses in the operating theatre, the Therapy Consultants are not allowed into the sterile operating theatre. The implant was completed in accordance with the product instructions for use with the only exception being the procedure for intraoperative testing. Dr. Nazha implanted the stimulator based on pain syndrome (dermatomes) markers with the patient asleep (general anesthesia) and the incisions were closed. The patient was bandaged and sent to recovery for programming where the patient reported good paresthesia coverage and pain relief. There were no reported complications or issues with placement or programming. The patient was discharged the next day following mandatory overnight stay at the hospital for observation. The patient followed up eleven (11)	Reviewed, for Trending Purposes Only
49551	186043	2/01/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Nevro Corporation	It was reported to Nevro that a trial patient acquired an infection following the implant procedure. The trial was aborted and the leads were explanted.	Reviewed, for Trending Purposes Only
49631	279911	5/01/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced erosion at the IPG site below the skin. Subsequently, surgical intervention was undertaken on 09 December 2017 during which the IPG was repositioned laterally and buried deeper. The issue has since resolved.	Reviewed, for Trending Purposes Only
49665	132097	10/01/2018	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced headache and vomiting with the stimulation. Reprogramming was tried to no avail as it made the symptoms worse. As a result, surgical intervention was taken wherein the SCS system was explanted. 2018-01-08: This report concluded device analysis. Concomitant devices: Model: 3799; Prodigy IPG, Batch No: 5502399; Serial No: 15828475; Implant Date: Oct 16, 2016; Explant Date: Oct 24, 2017; Manufacturing Date: May 16, 2016; Expiration Date: May 16, 2018; GMDN No: 36007; Device ARTG: 230721 Model: 1192; Swift-Lock Anchor, Batch No: 5576108; Implant Date: Oct 16, 2016; Explant Date: Oct 24, 2017; Manufacturing Date: Jul 28, 2016; Expiration Date: Jul 28, 2018; GMDN No: 42410; Device ARTG: 129858	Reviewed, for Trending Purposes Only
49704	202323	12/01/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	Spinal Modulation Inc	It was reported the patient complained of discomfort at the Implantable Neurostimulator (INS) and lead sites with stimulation on and off. The physician indicated the issue was likely lumbar pain due to nerve irritation. Surgical intervention was undertaken and the patient's system was explanted.	Reviewed, for Trending Purposes Only

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49743	132097	16/01/2018	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported following the implant procedure, the patient experienced discomfort in her left leg (described as cramping). Subsequently the lead was explanted after 5 hours of implant. Reportedly, the issue has resolved. 2018-01-08: Device not returned as it was disposed by the facility. This report includes device analysis result.	Reviewed, for Trending Purposes Only
47853	205793	19/01/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient was experiencing a pain and discomfort at the pocket site due to IPG migration. The patient will undergo a revision procedure. Additional information was received that the IPG did not migrate. The patient was revised and stable post-operatively.	Reviewed, for Trending Purposes Only
49491	197909	22/01/2018	Neural-tissue electrical stimulation lead	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient was hospitalized 2 weeks post implant due to suspected infection at the midline incision. The patient complained of not feeling well. The patient's wounds were checked and revealed one site having surface area oozing, with no significant pus at the incision sites. Both incision sites were cleaned, new dressings were placed and antibiotics were administered. The patient became very unwell in the next 48 hours and was transferred to another facility. She was explanted, intubated and required medication to stabilize her blood pressure. There is no evidence to suggest the infection was device or procedure related. The physician assessed the patient to have critical condition sepsis and he does not expect the patient to survive. Additional information was received that the patient passed away due to multiple organ failure due to sepsis. Sponsor update received 13/03/2018: Additional information was received that the cultures taken in an effort to identify the cause of the infection failed to grow, and the source of the infection was not identified. It is unknown if the source was bacterial or fungal.	Reviewed, for Trending Purposes Only
49853	186043	24/01/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Nevro Corporation	During a routine follow-up, it was reported to Nevro that a patient acquired an infection. The patient was admitted to the hospital and received IV antibiotics. The device was explanted and there were no reports of further complications.	Reviewed, for Trending Purposes Only
48344	205793	29/01/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient felt a burning sensation at the IPG site. The patient underwent an explant procedure of the IPG. The patient is stable postoperatively. Additional information was received that during the IPG explant procedure a Clik Anchor was also removed. It was noted during the device analysis that silicone material from the eyelet was missing. The location of the missing silicone is unknown. Additional information was received that the silicone missing from the clik anchor was not left in the patients body.	Reviewed, for Trending Purposes Only
48955	128775	1/02/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient underwent a lead revision procedure due to lead migration of both leads. During the revision, the physician noticed that one of the leads had a rough edge over the end electrodes. Upon closer examination, it appeared that some of the wires were protruding. The lead was replaced and both leads were repositioned. The patient was stable post-operatively. Additional information was received that the patient experienced inadequate therapy due to lead migration.	Reviewed, for Trending Purposes Only
50013	197909	1/02/2018	Neural-tissue electrical stimulation lead	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient may have fallen, and was experiencing ineffective therapy. An impedance check revealed high impedances. The physician assessed that most likely the patient's lead have broken. The patient underwent an explant procedure. The device analysis confirmed that the lead was fractured.	Reviewed, for Trending Purposes Only
48713	205793	8/02/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient underwent a revision procedure due to increased pain. During the revision procedure, the physician noted a fluid sac in the IPG pocket. The physician assessed the fluid sac as being unrelated to device or procedure, however, he was unsure of the cause. He further clarified that the fluid sac was near a skin fold and constant rubbing. The patient was explanted of all of their devices and administered intravenous antibiotic. Cultures swabs were taken and the results were negative.	Reviewed, for Trending Purposes Only
49524	132097	8/02/2018	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient underwent an SCS trial procedure on 06 December 2017. The patient experienced numbness in the pelvic and abdominal region shortly after the procedure. Stimulation was not turned on at this time. A CT scan revealed a possible hematoma. The patient reportedly developed weakness and a heavy sensation in the left leg later in the day. As such, the leads were explanted. The patient was hospitalized and has since reported improved symptoms, however pelvic numbness persists. 2018-01-12: No additional information received at this time. The device is under investigation. 06-02-2018: Additional information received identified the pelvic numbness has improved.	Reviewed, for Trending Purposes Only
49595	279911	8/02/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced discomfort (described as heating sensation) at the IPG site. Subsequently, surgical intervention was undertaken wherein the IPG was explanted and replaced with another model to resolve the issue. 2018-01-12: The patient stated to experience heating sensation to some extent but not as before the replacement.	Reviewed, for Trending Purposes Only
50122	202323	9/02/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	Spinal Modulation Inc	It was reported the patient experienced discomfort at the Implantable Neurostimulator (INS) site. In turn, on 12January2018 surgery was undertaken and the INS was relocated from the patient's lower lumbar area to the left abdomen.	Reviewed, for Trending Purposes Only
49550	279913	13/02/2018	Stimulator, electrical, analgesic, spinal cord	Class III	St Jude Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced ineffective stimulation due to lead migration. As such, surgical intervention was undertaken during which the leads were explanted and replaced with a paddle lead. Effective stimulation was restored following the procedure. 2018-01-17: Device is under investigation. 12-02-2018: This report contains analysis results. Concomitant medical device: Model 1194; SCS Anchor; Implant Date: 28-06-2017, Explant Date: 12-12-2017, ARTG # 129858	Reviewed, for Trending Purposes Only
49598	230721	13/02/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	St Jude Medical - Neuromodulation	It was reported the patient's IPG was explanted due to infection and the need of MRI for unrelated issue. 18January2018: Device is in transit to be returned to the manufacturer. 2February2018: This report contains analysis results.	Reviewed, for Trending Purposes Only
49593	275241	16/02/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient underwent a replacement procedure of the leads and IPG due to possible fractures with the leads or a possible leakage of fluid entering into the head of the IPG, resulting in high impedances and loss of stimulation. The patient is doing well post-operatively. Additional information was received that no items or parts of items are suspected to have been left in the patient following explant procedure.	Reviewed, for Trending Purposes Only

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50243	132097	17/02/2018	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced unintended stimulation (outside of his pain area) a day post-implant. Reprogramming was attempted to no avail. X-rays showed leads migrated half a vertebral body upwards from T7-T8 to 1/2T6-1/2T8. As a result, the patient underwent lead replacement surgery. Postoperatively, the patient reported receiving 100% coverage of his pain area.	Reviewed, No Further Action Required
49998	132097	27/02/2018	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced slight erosion at the lateral tip of the left sided occipital lead. As a result, the patient underwent SCS system explant.	Reviewed, for Trending Purposes Only
50016	132097	27/02/2018	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced erosion at the site of both leads. As a result, the leads were relocated on 11 January 2018.	Reviewed, for Trending Purposes Only
50017	132097	27/02/2018	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient felt a pull while on a rowing machine. X-rays revealed the leads had both migrated. As a result, the leads were repositioned on 15 January 2018.	Reviewed, for Trending Purposes Only
49997	154912	1/03/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	St Jude Medical	It was reported the patientâ€™s IPG was unable to communicate with external devices. As a result, the patient underwent IPG explant. Details of this event is unavailable at this time. Implant date â€“ 2013 (Exact date is unknown).	Reviewed, for Trending Purposes Only
50508	279015	8/03/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced discomfort at the IPG site when lying down. As a result, the patient underwent repositioning of the IPG deeper in the left buttock pocket on 14 February 2018, resolving the issue. IPG implant date is unknown. 6 March 2018: This report contains analysis results.	Reviewed, for Trending Purposes Only
50579	186043	10/03/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Nevro Corporation	It was reported to Nevro that a patient had suffered a stroke sometime after implant. The patient has arteriovenous malformation (AVM) as a pre-existing condition. The patient had developed minor cognitive deficits post-stroke, leading to non-compliance with usage of the Nevro device. Stimulation is no longer on but the device remains implanted. There have been no further reports of medical complications related to the stroke.	Reviewed, for Trending Purposes Only
49087	205793	12/03/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient underwent an IPG replacement procedure due to discomfort at the IPG site. The patient was doing well postoperatively. Additional information was received that IPG was replaced due to physicianâ€™s preference.	Reviewed, for Trending Purposes Only
50330	205793	15/03/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient underwent a revision procedure due to discomfort at the IPG and clik anchor sites. The leads were repositioned, the IPG pocket was revised and the clik anchors were removed. No malfunction was suspected. The patient was doing well post-operatively.	Reviewed, for Trending Purposes Only
50264	132097	16/03/2018	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient presented with an infection at the lead site on 19 January 2018 and was prescribed antibiotics. The patient was admitted to the hospital on 24 February 2018 for four days and was prescribed additional antibiotics. The patient followed up with the surgeon on 1 February 2018 and was prescribed an additional course of antibiotics. 13 March 2018: The infection has reportedly resolved. This report contains analysis results.	Reviewed, for Trending Purposes Only
48623	186043	18/03/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Nevro Corporation	During a routine follow-up, it was reported to Nevro that a patient had developed a seroma. Additional follow-up indicated that the seroma developed into an infection and the patient was provided with antibiotics. The device was explanted.	Reviewed, for Trending Purposes Only
50709	186043	18/03/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Nevro Corporation	It was reported to Nevro that the patient had acquired an infection following a blunt force impact to the IPG pocket from hitting a door. The physician performed an aspiration and wound wash-out at the site and patient was given antibiotics. Nevro had attempted to obtain additional information regarding the nature of the infection but was unsuccessful.	Reviewed, for Trending Purposes Only
50295	230721	20/03/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	St Jude Medical	It was reported that the patient experienced charging difficulties and pain at the IPG site. The patient needs to lay down to charge the IPG, otherwise the paddle will not communicate with the IPG. When the patient lays down, the IPG site is painful. The physician determined by palpating the IPG site that the IPG is not flush with the skin, but instead is at an angle. As a result, the patient may be awaiting pocket site revision. 15 March 2018: Additional information received identified the surgical intervention was undertaken on 13 February 2018 to revise the IPG pocket site. No product was explanted, nor implanted. Postoperatively, the patient was able to charge the IPG, resolving the issue. This report contains analysis results.	Reviewed, for Trending Purposes Only
50782	132097	23/03/2018	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced ineffective stimulation. As a result, the physician explanted the SCS system. This report contains analysis results.	Reviewed, for Trending Purposes Only
50368	205793	26/03/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient experienced headaches when the stimulation was on, when the stimulation is off the headaches go away. During reprogramming the headaches returned. The patient and the physician have decided to have the system explanted. Malfunction is not suspected of any of the devices. Additional information was received that the patient underwent an explant procedure and all devices were explanted.	Reviewed, for Trending Purposes Only
50452	279016	27/03/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	St Jude Medical	It was reported the patient underwent IPG revision on 29 January 2018 (Reference Mfr Report#: TGA-2018-00057), but the IPG was not placed in surgery mode prior to the surgery. Monopolar electrocautery was utilized during the surgery. After the surgery, the IPG could no longer communicate with external devices. As a result, the patient underwent IPG replacement. 21 March 2018: It was reported that the patient experienced discomfort at the IPG site. As a result, the physician relocated the IPG above the right hip and on the front of the patient on 29 January 2018, resolving the issue. This report contains analysis results.	Reviewed, for Trending Purposes Only
50419	132097	28/03/2018	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced ineffective stimulation with positional changes. As a result, the patient underwent surgical intervention to explant both leads and implant a single new lead. 21 March 2018: This report contains analysis results.	Reviewed, for Trending Purposes Only
50420	154912	28/03/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	St Jude Medical	It was reported the patient stopped recharging their IPG as recommended. In turn, the patient's IPG became inoperable over time and was unable to communicate with external devices. As a result, the patient underwent surgical intervention to have their IPG replaced. Device Implant Date is unknown. 21 March 2018: This report contains analysis results.	Reviewed, for Trending Purposes Only
50473	132097	28/03/2018	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced ineffective stimulation. As a result, the patient underwent SCS system explant. 26 March 2018: This report contains analysis results.	Reviewed, for Trending Purposes Only
50887	186043	28/03/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Nevro Corporation	It was reported to Nevro that the patient acquired an infection following a recent implant of the IPG. The patient was provided IV antibiotics, the wound was washed out, and the device was explanted. Nevro had attempted to obtain additional information regarding the nature of the infection but was unsuccessful. There have been no further reports of complications.	Reviewed, for Trending Purposes Only

DIR Report #	ARTG #	Date of Report	GMDN / UMDN Text	Device Class	Sponsor Name	Manufacturer Name	Clinical Event Information	Outcomes
50498	132097	30/03/2018	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient could not place the IPG into MRI mode due to impedance issues. As the patient wished to have a spine MRI, the patient therefore underwent SCS system explant. 27 March 2018: This report contains analysis results.	Reviewed, for Trending Purposes Only
50499	131944	30/03/2018	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient fell and then began experiencing ineffective stimulation. Impedance checks showed one contact at high impedance and one contact at low impedance. Reprogramming attempts were unsuccessful. As a result, the physician explanted and replaced the patient's leads. Postoperatively, effective therapy was restored. 27 March 2018: This report contains analysis results.	Reviewed, for Trending Purposes Only
50927	186043	30/03/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Nevro Corporation	It was reported to Nevro that a patient was explanted approximately 6 months after implant. The patient reported shortness of breath and required an MRI. There have been no further reports of complications.	Reviewed, for Trending Purposes Only
50503	205793	3/04/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient felt a pulling sensation when turning over in bed that has since developed into a burning pain in his right thigh inferior to the IPG site. The physician will conduct an exploratory revision surgery to determine if the fascia has become entrapped beneath the leads and or the IPG. Additional information was received that the patient underwent an IPG revision procedure. Per the physician assessment the retaining suture on the IPG had been partially torn off the fascia which caused the burning pain, the IPG was repositioned in the same pocket and re-sutured. No device malfunction was suspected. The patient has recovered.	Reviewed, for Trending Purposes Only
50598	132097	3/04/2018	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced involuntary muscle movements throughout his body, but concentrated in his legs. The patient was hospitalized and was instructed to turn off the SCS system. The patient reported on 22 February 2018 the involuntary body movements had resolved for two days, and the patient was started on a tonic stimulation program. Further evaluation is slated to take place in several weeks. 29 March 2018 Additional information received identified the patient has not experienced any further in involuntary movements. Effective therapy has been reported. This report contains analysis results.	Reviewed, for Trending Purposes Only
50623	132097	3/04/2018	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced numbness and weakness, as well as pain and swelling at the lead site with some bleeding around the incision points. The surgeon felt the patient did not have an infection, nor dermatitis. As a result, the physician explanted both leads and replaced them. Reportedly, the patient's issue has resolved. Primary Device Implant and Explant Date is unknown, and Associated lead device information is unknown. 29 March 2018: This report contains analysis results.	Reviewed, for Trending Purposes Only
50759	289235	6/04/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced discomfort and inflammation at the IPG site. No discharge was noted. Infection was identified, and the patient was admitted to the hospital and given IV antibiotics. The physician explanted the IPG, and the patient is to be kept in the hospital for 7-10 days for observation. Reportedly, the patient is recovering well. 3 April 2018: This report contains analysis results.	Reviewed, for Trending Purposes Only
50784	170450	7/04/2018	Stimulator, electrical, analgesic, spinal cord	Class III	St Jude Medical Australia Pty Ltd	St Jude Medical	It was reported the patientâ€™s lead migrated. As a result, surgical intervention was undertaken to reposition the lead on 6 March 2018. Concomitant device implant dates are unknown. 4 April 2018: This report contains analysis results. 27 April 2018: Additional information received indicated the serial number of the lead is 17121183.	Reviewed, for Trending Purposes Only
49644	197909	9/04/2018	Neural-tissue electrical stimulation lead	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient loss stimulation. During reprogramming it was noticed that the two implanted leads exhibited high impedances. Lead breakage is suspected, however breakage was not confirmed per the x-ray results. Additional information was received that the patient underwent a lead replacement procedure. Per the physician assessment the leads were broken, however there were no exposed cables. The patient is doing well post-operatively	Reviewed, for Trending Purposes Only
51024	186043	9/04/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Nevro Corporation	It was reported to Nevro that following an implant procedure, a patient experienced temporary paralysis in his right leg. The device was explanted and the patient regained movement. During follow-up, the physician mentioned there was some difficulty advancing the leads during implant. Subsequent follow-up report indicated that the patient continued to have loss of function in his right leg after being discharged from the hospital. The patient is currently undergoing rehabilitation with a specialist and cannot walk unaided.	Reviewed, for Trending Purposes Only
50765	205793	11/04/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient experienced pain at the IPG pocket site due to migration and the IPG being loose in the pocket. The patient was hospitalized and underwent an IPG pocket revision to tighten the pocket. Device malfunction is not suspected. The patient is stable post-operatively, but still has post-operative surgical pain. Additional information was received that there was no IPG migration within the IPG pocket site. The patient was discharged from the hospital. There is no further course of action.	Reviewed, for Trending Purposes Only
50575	170450	13/04/2018	Stimulator, electrical, analgesic, spinal cord	Class III	St Jude Medical Australia Pty Ltd	St Jude Medical	It was reported the patientâ€™s lead which was disconnected and left insitu (date of intervention unknown) was explanted, and the new SCS system was implanted on 02/16/2018. Postoperatively, effective stimulation was reported. 28 March 2018: This report contains analysis results. 04-12-2018: Further review of the event identified the lead was found to be damaged during implant of the competitorâ€™s system. The manufacturer has been unable to retrieve additional information on the damaged lead	Reviewed, for Trending Purposes Only

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50731	289235	16/04/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	St Jude Medical	It was reported the patient underwent surgical intervention on 19 February 2018 to reposition the DRG IPG from the patient's left side to the right side. Device information and reason for IPG revision is unknown. 3 April 2018: Additional information identified the reason for the IPG repositioning was discomfort. Patientâ€™s discomfort has resolved. This report contains analysis. *Additional information received by sponsor - 04/05/2018: 16 April 2018: Additional information identified model number and serial number of INS. Device ARTG number has been updated. 27 April 2018: This report contains analysis.	Reviewed, for Trending Purposes Only
50885	230721	18/04/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced discomfort at the IPG site. As a result, the physician repositioned the IPG (date of revision is unknown). Postoperatively, effective therapy was reported. 16 April 2018: Additional information identified the IPG repositioning took place on 7 March 2018. This report contains analysis results.	Reviewed, for Trending Purposes Only
50398	205793	19/04/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient had the entire system explanted because the presence of the IPG and leads was very uncomfortable. The explanted leads were discarded by the medical facility. The IPG is at BSN.	Reviewed, for Trending Purposes Only
50886	132097	19/04/2018	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced ineffective stimulation. X-rays revealed the leads have migrated laterally. Reprogramming attempts have been unsuccessful. As a result, surgical intervention was undertaken to explant and replace one of the patient's leads. Postoperatively, effective therapy was restored. 16 April 2018: This report contains analysis results.	Reviewed, for Trending Purposes Only
50903	132097	21/04/2018	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced ineffective stimulation. Reprogramming attempts were unsuccessful, and X-rays revealed slight lead migration. As a result, the physician relocated the leads on 5 March 2018. Postoperatively, effective therapy was restored. 17 April 2018: This report contains analysis results.	Reviewed, for Trending Purposes Only
50471	230721	27/04/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	St Jude Medical	It was reported the patient stopped recharging their IPG as recommended. In turn, the patient's IPG became inoperable over time and was unable to communicate with external devices. As a result, the patient underwent surgical intervention to explant the SCS system. 29 March 2018: Device is under investigation 20 April 2018: This report contains analysis results.	Reviewed, for Trending Purposes Only
50785	170450	2/05/2018	Stimulator, electrical, analgesic, spinal cord	Class III	St Jude Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced arm weakness during a lead revision (please see Reference Mfr. Report#:1627487-2018-02852/ TGA-2018-00115). The physician opted to explant the SCS system. An MRI following the explant showed a spinal contusion. The patient continues to recover in the hospital. The patient will be transferred to a different hospital in two weeks. Concomitant device implant dates are unknown. 3 April 2018: Serial number has been corrected. 26 April 2018: Additional information received indicated the patient has continued to improve and was expected to be transferred to the spinal unit at the Princess Alexandria Hospital. The serial number of the lead has been corrected back to the originally reported number. This report contains analysis results.	Reviewed, for Trending Purposes Only
50996	205793	2/05/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient was having discomfort at their IPG pocket site an explant procedure was performed. The IPG was removed and sent to microbiology for testing, the leads remain implanted. The patient was given antibiotics during the procedure but not post-operatively.	Reviewed, for Trending Purposes Only
51015	202323	3/05/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	Spinal Modulation Inc	It was reported the patient experienced discomfort at the Implantable Neurostimulator (INS) pocket site. As a result, the physician moved the pocket site deeper on 19 March 2018. Postoperatively, effective stimulation was reported. 27 April 2018: This report contains analysis results.	Reviewed, for Trending Purposes Only
51533	132097	8/05/2018	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced ineffective stimulation with their implantable occipital neuromodulation system (ONS). Reprogramming was attempted but was unsuccessful. The patient underwent surgical intervention where in the ONS was explanted. The patient was reported to be stable post-operatively.	Reviewed, for Trending Purposes Only
51555	170450	9/05/2018	Stimulator, electrical, analgesic, spinal cord	Class III	St Jude Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced pain around the lead site. As a result, the SCS system was explanted. The patient is stable and recovering well. The pain has resolved.	Reviewed, for Trending Purposes Only
51587	128775	10/05/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient underwent an explant procedure due to the leads eroding through the skin.	Reviewed, for Trending Purposes Only
51619	279913	12/05/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the system diagnostics revealed high impedances on one of the lead. Surgical intervention was undertaken on April 16, 2018 wherein an additional lead was implanted. The alleged lead was left insitu. Therapy was restored postoperatively.	Reviewed, for Trending Purposes Only
51198	230721	16/05/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	St Jude Medical	It was reported the SCS system was explanted due to infection. Site of infection is unknown at this time.	Reviewed, for Trending Purposes Only
50924	132097	18/05/2018	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced a red and swollen area medial to the IPG site on the right buttock six weeks ago. The General Practitioner aspirated the infected fluid from the area, and the patient was prescribed oral antibiotics. The patient later saw the pain physician after completing the antibiotics, and the physician noted a continued area of broken skin where the General Practitioner had aspirated with a needle, and could see one of the implanted leads in the open wound. As a result, the physician admitted the patient to the hospital, prescribed IV antibiotics, took wound swabs and explanted the SCS system. The physician plans prescribe oral antibiotics to the patient once he is discharged from the hospital. 19 April 2018: No additional information has been received at this time. 16 May 2018: This report contains analysis.	Reviewed, for Trending Purposes Only

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51197	132097	23/05/2018	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported patient's SCS system was explanted (date unknown) due to ineffective stimulation. May 21 2018: Available device information is updated. This report includes device analysis.	Reviewed, for Trending Purposes Only
51816	128775	24/05/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient experienced a sharp zipping type of pain on the right side of the lumbar back near the end of the right cluneal lead, near the IPG. The patient states the pain around IPG site occurs only when stimulation is turned on. The pain is thought to be stimulation related as the patient required stimulation at the IPG site on the right lead. The patient underwent a revision procedure where the leads and clik anchor were replaced and the IPG pocket site was relocated to the right subcostal pocket. The physician noted there were markings on the leads and suspected lead malfunction. The patient was doing well post-operatively. Additional information was received that when the stimulation was moved from the IPG site at the right lead, the pain continued.	Reviewed, for Trending Purposes Only
51530	279913	1/06/2018	Stimulator, electrical, analgesic, spinal cord	Class III	St Jude Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced ineffective stimulation. X-rays confirmed the lead migration. The patient underwent surgical intervention where in one of the lead was explanted and replaced with another model which resolved the issue. Device information for the second lead has been requested, but has not been provided to the manufacturer.	Reviewed, for Trending Purposes Only
51013	202323	5/06/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	Spinal Modulation Inc	It was reported the patient experienced discomfort at the DRG INS site. The device was repositioned in the pocket. Device information has been requested, but has yet to be provided to the manufacturer. 2018-05-05: No further information regarding this event has been provided to the manufacturer. 2018-05-31: No further information regarding this event has been provided to the manufacturer. Should new information become available, an Amended Final Report will be submitted.	Reviewed, for Trending Purposes Only
51121	289235	5/06/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	St Jude Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced ineffective stimulation. X-rays revealed the leads had migrated and wrapped up around the IPG. Additionally, the IPG appeared to be loose in the pocket too. Reportedly, the patient has lost about 3 kilogram of weight since the implant. Surgical intervention may be taken at a later date to address the issue. 06 May, 2018: No meaningful information received at this time. 04 June, 2018: The leads were explanted and replaced on 26 May 2018 which resolved the issue. Effective stimulation was restored postoperatively	Reviewed, for Trending Purposes Only
51532	279016	5/06/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient's IPG was unable to establish communication with external devices after one day of SCS system implant. Troubleshooting was tried to no avail. The IPG was deemed inoperable. Subsequently, The IPG was explanted and replaced with another model which resolved the issue.	Field Safety Corrective Action Safety alert
51978	289236	6/06/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Abbott Medical Australia Pty Ltd	Spinal Modulation Inc	It was reported high impedances were observed on the lead. Effective stimulation was restored at the time without using the alleged lead. Subsequently, the lead was explanted and replaced which resolved the issue. Effective stimulation was restored postoperatively.	Reviewed, for Trending Purposes Only
50472	279016	14/06/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient underwent unrelated surgery where bipolar diathermy was utilized. After the surgery, the patientâ€™s IPG would no longer communicate with external devices, as confirmed by Abbott representative. As a result, the patient may be awaiting surgical intervention. 26 March 2018: No additional information received at this time. 19 April 2018: No additional information received at this time. 15 May 2018: No additional information received at this time. 11 June 2018: Additional information identified the field representative successfully recovered the patientâ€™s IPG and updated the patient controller with new software. Effective stimulation has been restored, resolving the issue. This report contains analysis.	Reviewed, for Trending Purposes Only
52087	170450	14/06/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced ineffective stimulation as the lead had migrated. The patient underwent surgical intervention on 19 May 2018, where in the lead was repositioned which resolved the issue. Effective stimulation was restored postoperatively	Reviewed, for Trending Purposes Only
51144	186043	16/06/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Nevro Corporation	It was reported to Nevro that the patient developed an infection at the implant site. The site was surgically cleaned and the patient was provided treatment for the infection. Subsequently the device was explanted. Nevro had attempted to obtain additional information regarding the nature of the infection but was unsuccessful. There have been no reports of further complications.	Reviewed, for Trending Purposes Only
51732	279913	22/06/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient never experienced effective therapy since implant. Xrays revealed the lead had migrated. The patient underwent surgical intervention on Apr 20, 2018 where in the leads were repositioned to resolve the issue.	Reviewed, for Trending Purposes Only
52232	279913	22/06/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patientâ€™s leads had migrated. As a result, surgical intervention was undertaken on March 05, 2018 where in the leads were repositioned which resolved the issue. Reportedly, effective stimulation was restored postoperatively. 04 June, 2018: Additional information received clarified during the surgery one of the leads was explanted and replaced.	Reviewed, for Trending Purposes Only
52259	279016	23/06/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced pain across the lower back. As a result, surgical intervention was undertaken to reposition the IPG on 08 June 2018, resolving the issue.	Reviewed, for Trending Purposes Only
51886	279016	26/06/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced infection at the IPG site after 3 weeks of implant. The patient was in intensive care and was treated with intravenous antibiotics. The SCS system was explanted. Reportedly, the infection has cleared.	Reviewed, for Trending Purposes Only
51887	279913	26/06/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient had an infection due to an unrelated issue which subsequently spread to the leads. Cultures taken confirmed the infection. As a result, the SCS system was explanted. The patient was treated with intravenous antibiotics while inpatient and was given oral antibiotics when discharged.	Reviewed, for Trending Purposes Only
52385	205793	1/07/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient experienced swelling at the pocket site immediately following an implant procedure and subsequently affected patient ability to charge. The patient had an ultrasound and the physician extracted fluid to help with the swelling, however the cause of the swelling could not be determined. The patient underwent a pocket revision procedure. Patient is doing well post operatively and is able to charge.	Reviewed, for Trending Purposes Only

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50574	132097	2/07/2018	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient underwent an unrelated surgical procedure (date of procedure is unknown), and postoperatively received an error message and the IPG could not connect with external devices. Troubleshooting has thus far been unsuccessful. 3 April 2018: No additional information received at this time. 25 April 2018: No additional information received at this time. 16 May 2018: No additional information received at this time. 7 June 2018: No additional information received at this time. 28 June 2018: Additional information identified the field representative successfully recovered the patient's IPG and updated the patient controller with new software. Effective stimulation has been restored, resolving the issue.	Reviewed, for Trending Purposes Only
52048	279911	11/07/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient had difficulty in charging the IPG due to the position of the IPG in the pocket. The patient underwent surgical intervention on 15 May, 2018 wherein the IPG was repositioned which resolved the issue.	Reviewed, for Trending Purposes Only
51286	205793	12/07/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient was experiencing pain at the pocket site. The patient will undergo an explant procedure. Additional information was received that the patient underwent the explant procedure. No device malfunction was suspected.	Reviewed, for Trending Purposes Only
52068	279913	12/07/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the leads were explanted as they were broken.	Reviewed, for Trending Purposes Only
52069	170450	12/07/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported following a lead implant procedure the patient experienced Pulmonary Embolism. The patient was treated with anticoagulant medications.	Reviewed, for Trending Purposes Only
52070	279913	12/07/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported after a trial procedure the patient experienced pain in the upper back. Reprogramming was tried to no avail as the patient felt tingling/ numbness in the left foot and ankle. The system was turned off at the time. Later the patient developed fever and the system was explanted. Reportedly, tingling has resolved. The physician stated the issue was not related to the device.	Reviewed, for Trending Purposes Only
52086	279016	13/07/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced infection at the IPG site. As a result the SCS system was explanted (Explant date April 2018).	Reviewed, for Trending Purposes Only
51773	289236	14/07/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Abbott Medical Australia Pty Ltd	Spinal Modulation Inc	It was reported the patient received 2 new DRG lead on 11 May 2018, following a procedure, the patient was unable to move both his legs. The physician believed the leads may have gone intra-dural and was found in the dura matar. As a result, later that day the newly implanted leads were explanted. On 13 May, 2018 the whole system was explanted. Reportedly, the patient has regained some movement in the left leg. 11 May 2018: No new information received	Reviewed, for Trending Purposes Only
52578	279913	14/07/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced ineffective stimulation due to lead migration. Surgical intervention was taken wherein one of the leads was explanted and replaced which resolved the issue. Effective stimulation was restored postoperatively.	Reviewed, for Trending Purposes Only
52681	197909	23/07/2018	Neural-tissue electrical stimulation lead	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient had intermittent pain on the left side following the insertion of the lead during the trail procedure. Per the physician assessment the led may have been lateral at the tip. The lead was explanted and discarded.	Reviewed, for Trending Purposes Only
52041	279913	24/07/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient fell and then experienced ineffective stimulation. Reprogramming attempts were unsuccessful. As a result, surgical intervention was undertaken to explant the SCS system. 27 June 2018: No additional information received at this time. 20 July 2018: This report contains analysis results.	Reviewed, for Trending Purposes Only
52331	126001	24/07/2018	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient presented at the hospital as not feeling well. Infection was determined. In turn the extensions were explanted and the leads remained insitu. The patient stayed in the hospital overnight and was treated with oral antibiotics. *Additional information received by sponsor - 21/08/2018: 20 August 2018: Additional information received identified the issue has resolved.	Reviewed, for Trending Purposes Only
51122	230721	26/07/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced pain (described as shocking sensation) at the IPG site. The patient has stopped using the system for about 12 months. Surgical intervention was undertaken wherein the SCS system was explanted. 06 May 2018: No additional reportable information received at this time. 05 June 2018: Device is in transit to be returned to the manufacturer. 29 June 2018: Device is in transit to be returned to the manufacturer. 22 July 2018: The manufacturer has not received any additional information regarding this event. Should meaningful new information become available, an amended final report will be submitted.	Reviewed, for Trending Purposes Only
51959	132097	26/07/2018	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced ineffective stimulation due to cervical lead migration. The patient underwent lead revision surgery 03 May 2018 wherein an additional lead was implanted. Therapy was restored postoperatively. It is unknown at this time if the alleged lead was explanted during the surgery. 29 June 2018: Awaiting additional information from the field. 22 July 2018: Additional information received identified only cervical lead (Model 3189) was revised during the surgery on 03 May 2018.	Reviewed, for Trending Purposes Only
51979	279913	26/07/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced ineffective stimulation due to not able to increase amplitude. System diagnostics revealed high impedances. Reprogramming resolved the issue at the time. X-rays revealed fracture on one of the leads. However, the patient underwent surgical intervention where in the leads was explanted and replaced with another model which resolved the issue.	Reviewed, for Trending Purposes Only

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52402	279911	27/07/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced break down of the wound at the IPG site, and fluid was leaking from it. Additional information has been requested, but is not yet known. 25 July 2018: Additional information identified the patient was prescribed oral antibiotics and was not hospitalized. A culture was obtained, but the results are not known at this time. The patient is being monitored and is currently doing well.	Reviewed, for Trending Purposes Only
52633	186043	31/07/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Nevro Corporation	It was reported to Nevro that one day following the implant procedure, the patient developed weakness, pain and tingling. X-rays showed a previously implanted cervical disc replacement had moved. As a consequence, the patient had a lead revision and fusion surgery. Follow-up indicated the patient is recovering and undergoing physical therapy. There have been no reports of further complications regarding this event.	Reviewed, for Trending Purposes Only
51869	186043	1/08/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Nevro Corporation	It was reported to Nevro that a patient's device was explanted and the haematoma was drained. There have been no further reports of complications.	Reviewed, for Trending Purposes Only
52823	170450	1/08/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced infection at the lead site. The patient was hospitalized for few days and was treated with intravenous antibiotics. The patient was discharged to home with oral antibiotics. Reportedly the infection has resolved. *Additional information received by sponsor - 18/10/2018: 18 October 2018: Additional information received identified the infection had reoccurred. As a result, the SCS system was explanted.	Reviewed, for Trending Purposes Only
52884	202323	7/08/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Abbott Medical Australia Pty Ltd	Spinal Modulation Inc	It was reported the patient experienced discomfort at the DRG INS site. The device was repositioned in the pocket. Device information has been requested, but has yet to be provided to the manufacturer. 2018-05-05: No further information regarding this event has been provided to the manufacturer. 2018-05-31: No further information regarding this event has been provided to the manufacturer. Should new information become available, an Amended Final Report will be submitted. 2018-08-06: Device information was provided and has been added to this submission.	Reviewed, for Trending Purposes Only
52047	279913	8/08/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced some unintended leg motor stimulation. The patient underwent surgical intervention wherein one of the lead was explanted and replaced with another model to resolve the issue. Stimulation was restored postoperatively. It cannot be determined which lead was explanted. 09 July, 2018: Additional information received clarified the issue was due to the lead migration.	Reviewed, for Trending Purposes Only
53052	279913	18/08/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient was unable to increase amplitude. Reprogramming was tried to no avail. The patient underwent surgical intervention where in the extension and lead was explanted and replaced with another model which resolved the issue. Effective therapy was restored postoperatively	Reviewed, for Trending Purposes Only
52285	132097	21/08/2018	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced discomfort at the anchor site after the anchors migrated, causing the lead loops to push up at the patient's skin which was visible via X-rays. The physician could feel the anchors through the patient’s skin. As a result, surgical intervention was undertaken on 29 May 2018 to re-suture the patient’s lead loops, resolving the anchor and lead migration. 20 July 2018: No additional information has been received at this time. 09 August 2018: No additional information has been received at this time. If additional information is received, an Amended Final will be submitted. 17 August 2018: Amended Final including similar incidents of 3189, 3186 and 1192 migration for Australia separated from the rest of the world.	Reviewed, for Trending Purposes Only
52691	170450	21/08/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported during periodic reprogramming session high impedances were observed on the lead. Reprogramming resolved the issue at the time. However, the patient underwent surgical intervention on 25 June, 2018 wherein the lead was explanted and replaced which resolved the issue. Effective therapy was restored postoperatively.	Reviewed, for Trending Purposes Only
53112	275241	22/08/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient developed an increase in back pain from the lower thoracic into the lumbar region. The patient underwent a revision procedure wherein the lead was moved from the spine to the leg. The patient has good coverage and pain relief in the foot, and the back pain has eased.	Reviewed, for Trending Purposes Only
51123	197909	30/08/2018	Neural-tissue electrical stimulation lead	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient alleged he had a stroke when the SCS was implanted. Four days prior to the implant procedure, the patient stopped taking Warfarin. The patient states that he spent five months in the hospital and now his speech is affected and he cannot spell or write a letter. Additional information was received that the physician did not believe symptoms were device related, however, the stroke may have been due to the discontinuation of anti-coagulant therapy prior to the implant procedure. The trial leads were pulled on admittance to the hospital. No further information could be obtained regarding the patient status or treatment. No further information could be obtained.	Reviewed, for Trending Purposes Only
53319	186043	6/09/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Nevro Corporation	It was reported to Nevro that the patient experienced severe migraines while using the device. The patient had one lead implanted off-label in the occipital region after a successful trial for treating headaches and a second lead in the upper thoracic region (on-label) for shoulder pain. While using the device, the patient had great pain relief in the shoulder but experienced migraines. Follow-up indicated that the physician believes the patient is highly sensitive and the lead presence in the occipital area is causing irritation and therefore has explanted the lead in the occipital region. The patient is currently using the device with one active lead for shoulder pain and there have been no reports of further complications regarding this event.	Reviewed, for Trending Purposes Only
52612	289236	8/09/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Abbott Medical Australia Pty Ltd	Spinal Modulation Inc	It was reported the patient experienced ineffective stimulation. X-rays revealed the patientâ€™s lead had migrated. The patient underwent surgical intervention where in the leads were explanted and replaced with another model which resolved the issue. 10 August 2018: No additional information received	Reviewed, for Trending Purposes Only
53359	289236	8/09/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Abbott Medical Australia Pty Ltd	Spinal Modulation Inc	It was reported the patient experienced ineffective stimulation. As a result, the leads were repositioned on 13 August 2018. Effective therapy was restored postoperatively.	Reviewed, for Trending Purposes Only
53360	132097	8/09/2018	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced ineffective stimulation. X-rays revealed one of the patient’s leads had migrated as the anchors were not locked adequately. The patient underwent surgical intervention where in the lead was explanted and replaced with another model which resolved the issue. Effective therapy was restored postoperatively.	Reviewed, for Trending Purposes Only
53374	205793	10/09/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient underwent a system explant procedure due to an infection. The physician was unsure why the infection started, however, assessed that the infection was not device related and that it was due to a non device related procedure. No further information can be obtained.	Reviewed, for Trending Purposes Only

DIR Report #	ARTG #	Date of Report	GMDN / UMDN Text	Device Class	Sponsor Name	Manufacturer Name	Clinical Event Information	Outcomes
53377	279913	11/09/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient presented to the emergency room with swelling around the lead and IPG site and had postural headaches. Blood patch was performed for suspected Dural tear (cerebral spinal fluid leak). Reportedly, the issue has resolved.	Reviewed, for Trending Purposes Only
53129	283692	14/09/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patients primary cell IPG was depleted and displayed the End of Life message. The patient underwent an IPG replacement procedure.	Reviewed, for Trending Purposes Only
53437	128775	14/09/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that a patient was experiencing discomfort at the clik anchor site. The patient underwent a revision procedure where the clik anchors were repositioned. The patient is reportedly doing well.	Reviewed, for Trending Purposes Only
53110	289235	18/09/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced pain at the IPG site. As a result, the patient underwent surgical intervention on 23 July 2018 wherein the IPG was repositioned which resolved the issue.	Reviewed, for Trending Purposes Only
53476	279913	18/09/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patientâ€™s lead had migrated. Lead migration was confirmed on X-ray. Additional information received identified the SCS system was explanted due to the need of an MRI.	Reviewed, for Trending Purposes Only
52779	132097	20/09/2018	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced loss of sensation in their left leg following an SCS implant procedure on 17 July 2018. CT scan revealed some air/fluid in the subarachnoid space. Subsequently the patient regained sensation and mobility in the leg. The physician stated the nerve fibers may have been irritated while gaining access to the epidural space during the implant and the patient's symptoms were improving. No further action taken at the time as the patient's symptoms were improving. However, the patient passed away on 20 July 2018 due to Deep Vein Thrombosis leading to a Pulmonary Embolism. The patient had co morbidities and the death was a result of these co morbidities. The reason stated was the time spent on the table during the procedure. Reportedly the issue was not related to the device. 24 August 2018: No additional information received	Reviewed, for Trending Purposes Only
53521	279913	20/09/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced overstimulation (shock like sensation) and pain at her midback incision site while bending down. The patient turned off the stimulation. X-rays taken revealed the leads had migrated. Reprogramming was tried to no avail. Additional information received identified the leads were explanted and replaced with another model which resolved the issue.	Reviewed, for Trending Purposes Only
53589	128775	24/09/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that during the follow up visit it was observed that there was dehiscence of the lead incision site and the lead was exposed. The patient was taken into surgery and the lead was removed. Per the physicians assessment there was no sign of infection, suspicion of device malfunction, or concern that the event was device related, however the lead was kept by the facility for testing. The patient was reported as doing well.	Reviewed, for Trending Purposes Only
52803	205793	28/09/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient was experiencing an unexplained burning sensation at the IPG site. The physician did not know the reason for the pain so he decided to replace the IPG. The patient was doing well post-operatively.	Reviewed, for Trending Purposes Only
53553	197909	28/09/2018	Neural-tissue electrical stimulation lead	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient no longer felt stimulation on her left side. The physician determined that the lead had migrated. A revision procedure was performed and the leads were replaced. No malfunction was suspected. Patient is doing well post operatively.	Reviewed, for Trending Purposes Only
52742	128775	3/10/2018	Neural-tissue electrical stimulation lead	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient underwent a lead explant procedure because the lead had eroded through the patient's skin and had a discharge. The explanted lead was not sent for culture and the patient was treated with antibiotics. The physician noted that the lead was cut at the base of the patient's neck and the distal portion was removed and discarded. The proximal end of the lead was left inside the patient because the physician did not want to interfere with the IPG site. The physician also noted that the cervical leads and IPG are all still implanted and functioning. The patient was doing well post-operatively.	Reviewed, for Trending Purposes Only
53587	205793	3/10/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient had difficulty charging her implanted IPG. Physician assessed that the IPG was sitting in a fold of fat and a pocket revision was performed. No device malfunction suspected. Patient is doing well post operatively.	Reviewed, for Trending Purposes Only
53341	154912	4/10/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced recharge burden as the patient had to charge the IPG daily. As a result the IPG was explanted and replaced which resolved the issue.	Reviewed, for Trending Purposes Only
53735	202323	4/10/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Abbott Medical Australia Pty Ltd	Spinal Modulation Inc	It was reported the IPG was explanted and replaced with another model due to the device not able to communicate with external devices.	Reviewed, for Trending Purposes Only
53739	205793	4/10/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient was experiencing pain and discomfort at her IPG pocket site. Patient underwent an IPG pocket revision and is doing well post operatively.	Reviewed, for Trending Purposes Only
52668	197909	5/10/2018	Neural-tissue electrical stimulation lead	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient underwent an explant procedure of two leads due to loss of therapy and high impedances. Two new leads were implanted and the patient is reportedly stable following the procedure.	Reviewed, for Trending Purposes Only
53778	132097	5/10/2018	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced headaches, which were outside of the patient's target pain area for shoulder pain. Reprogramming attempts were unsuccessful, and migration was ruled out. As a result, the physician relocated one of the patient's leads to a lower position on 10 September 2018. Note: Both of the patient's leads are being reported because it is unknown which lead is liable.	Reviewed, for Trending Purposes Only
53023	132097	6/10/2018	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced an infection at the lead and IPG wound site and was on an antibiotics course. The physician concluded the wounds were not healing properly due to scar tissue. Surgical intervention may be taken at a later date to address the issue. 10 September 2018: No new information received 02 October 2018: The manufacturer has not received any additional information regarding this event. Should new information become available, an Amended Final Report will be submitted.	Reviewed, for Trending Purposes Only
53296	205793	8/10/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient experienced inadequate pain relief and underwent an IPG explant procedure.	Reviewed, for Trending Purposes Only
53396	279016	10/10/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient received uncomfortable stimulation. Reportedly, the IPG was unintendedly turning on by itself. The issue reoccurred several times. Troubleshooting was tried to no avail. As a result, the IPG was explanted and replaced with another model which resolved the issue.	Reviewed, No Further Action Required
53843	202323	12/10/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Abbott Medical Australia Pty Ltd	Spinal Modulation Inc	It was reported the patient experienced skin irritation (redness and itching) at the IPG site. The IPG seems to be superficial. Subsequently, the patient underwent surgical intervention on 14 September 2018 to reposition the IPG. However, the physician noticed the infection at the IPG site. As a result, the SCS system was explanted. The patient was treated with Intravenous antibiotics and the wound was closed. Reportedly, the patient was discharged and the infection has resolved.	Reviewed, for Trending Purposes Only
53475	279911	16/10/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient had difficulty charging the IPG. Subsequently the IPG ran out of charge and unable to communicate with external devices. Surgical intervention was undertaken wherein the IPG was explanted and replaced with another model which resolved the issue. Therapy was restored postoperatively.	Reviewed, for Trending Purposes Only

DIR Report #	ARTG #	Date of Report	GMDN / UMDN Text	Device Class	Sponsor Name	Manufacturer Name	Clinical Event Information	Outcomes
53178	132097	17/10/2018	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced discomfort (described as pulling sensation on the leads). As a result surgical intervention was undertaken on 29 July 2018 wherein the extension was explanted. Follow up identified the issue still persisted. 17 September 2018: Additional information received identified surgical intervention may take place at a later date to address the issue. 11 October 2018: The manufacturer has not received any additional information regarding this event. Should new information become available, an Amended Final Report will be submitted.	Reviewed, for Trending Purposes Only
53917	279913	17/10/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced ineffective stimulation. Diagnostics were unremarkable for impedances. As a result, the patient underwent explant of the SCS system.	Reviewed, for Trending Purposes Only
53144	279913	18/10/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced ineffective stimulation. In turn the patient had stopped using the SCS system. As a result, the SCS system was explanted.	Reviewed, for Trending Purposes Only
53921	197909	18/10/2018	Neural-tissue electrical stimulation lead	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient was experiencing slight discomfort at the surgical wound site following an implant procedure. Physician assessed the wound sites were not healing well and performed wound debridement whereupon necrotic tissue was found. Patient underwent an explant procedure to remove all implanted devices, and was placed on IV antibiotics. The physician believes this issue was related to the surgical procedure and not related to the device. All explanted devices were discarded by the physician. Patient is doing well post explant procedure.	Reviewed, for Trending Purposes Only
53931	186043	19/10/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Nevro Corporation	It was reported to Nevro that the patient was hospitalized for an infection. Nevro attempted to obtain additional information regarding the nature of the infection but was unsuccessful. Follow-up indicated that the patient was using the device with effective pain relief and there have been no reports of further complications regarding this event.	Reviewed, for Trending Purposes Only
53932	186043	19/10/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Nevro Corporation	It was reported to Nevro that the patient developed an infection at the anchor site. As a consequence, the anchor was removed. The patient has recovered without sequelae and there have been no reports of further complications regarding this event.	Reviewed, for Trending Purposes Only
53960	132097	20/10/2018	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported diagnostics revealed high impedances on both leads. X-rays were inconclusive in determining lead fracture. As a result, the physician explanted and replaced both of the patients leads, resolving the issue. Postoperatively, effective therapy was restored.	Reviewed, for Trending Purposes Only
53181	205793	23/10/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient experienced a painful burning sensation at the IPG site, both internally and externally and the skin would feel hot. The patient reportedly turned off the stimulation but would continue to feel the painful burning sensation for up to 24 hours, and has occurred on four separate occasions, and the sensation would spread up the spine and down to her legs. The patient reported that attempting to stand and or sit, would cause the painful burning sensation in the leg and the IPG site. The patient underwent an unrelated procedure of Thermal Radiofrequency that was not device related. The patient underwent an IPG replacement procedure per the physicians preference and is recovering post-operatively. Database analysis revealed no anomalies with the IPG.	Reviewed, for Trending Purposes Only
53993	128775	23/10/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that one of the leads was starting to protrude through the surface of the patient's skin. The patient underwent a revision procedure to bury the lead deeper into the skin.	Reviewed, for Trending Purposes Only
53695	279016	24/10/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient was presented at the hospital for potential infection (Site unknown). The patient was treated with intravenous antibiotics. Reportedly, infection has resolved.	Reviewed, for Trending Purposes Only
53696	154912	24/10/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced discomfort (stated as shocking like sensation). As a result surgical intervention was undertaken wherein the IPG was explanted and replaced. During the surgery it was found the 2 paravertebral leads implanted at L4-5 were migrated as well. As a result, the leads were also explanted and replaced to resolve the issue.	Field Safety Corrective Action Product correction
54006	205793	24/10/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient experienced difficulty charging the IPG due to the deep placement of the IPG. The patient underwent an IPG revision procedure to move the IPG more superficial. During the procedure the physician noted that 4 leads had migrated, therefore, the physician electively replaced the 4 leads. There were no symptoms due to the lead migration. The patient was doing well postoperatively.	Reviewed, for Trending Purposes Only
53719	205793	25/10/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A patient was implanted on 24 Aug 2018 and was admitted for two days following surgery as part of standard protocol. The final wound check prior to discharge was unremarkable. On 27 Sep 2018 that patient died as an inpatient in Canberra Hospital in Canberra, ACT due to septic shock, apparently secondary to infection of the IPG. Upon follow up with physician's assistant, the patient began experiencing pain in the right leg, approximately within the past 1-2 weeks prior to date of death. The patient checked into the emergency department of Canberra Hospital on 23 Sep 2018 with pain in right leg, radiating to right low back at the IPG pocket site. The physician was notified of the patient's admission on 25 Sep 2018. Patient had an explant of the SCS system on 25 Sep 2018 and died on 27 Sep 2018 due to sepsis.	Reviewed, for Trending Purposes Only
53647	132097	26/10/2018	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient was undergoing a routine trail lead pull on 06 September 2018. One of the leads lost four contacts, and the contacts remained in the patient, as verified via X-rays. There is no current plan for patient to undergo further surgical intervention to retrieve the lost contacts. Note: Both of the patient's leads are being reported because it is unknown which lead is liable. 16 October 2018: No additional information received at this time. 25 October 2018: This report contains analysis results.	Reviewed, for Trending Purposes Only
53867	205793	26/10/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient underwent a revision procedure to relocate the IPG as the positioning was too shallow. The patient experienced pain and soreness and preferred the IPG be relocated to the buttock area for more comfort. The patient was doing fine post-operatively.	Reviewed, for Trending Purposes Only
53657	275241	29/10/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient underwent a revision procedure due to lead migration. The patients leads were removed and replaced with new leads. The patient reportedly is recovering well.	Reviewed, for Trending Purposes Only
53902	230721	30/10/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient was unable to charge the IPG, as the IPG would no longer communicate with external devices. As a result, the physician explanted and replaced the patientâ€™s IPG. Postoperatively, effective therapy was restored. 26 October 2018: This report contains analysis results.	Reviewed, for Trending Purposes Only
54180	170450	1/11/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced ineffective stimulation. X-rays revealed the newly implanted lead had migrated from C2 to C3. To address the issue, the physician relocated the lead on 18 October 2018. Postoperatively, effective therapy was restored.	Reviewed, for Trending Purposes Only
54183	128775	1/11/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient was experiencing loss of stimulation. 3 of the contacts were displaying high impedances. The patient's leads were explanted and replaced with new leads.	Reviewed, for Trending Purposes Only
54185	205793	1/11/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that stimulation was not adequately covering patient pain in the groin area. Patient underwent a revision procedure to place an additional lead. Patient is doing well post operatively and pain in the groin area is now covered by stimulation.	Reviewed, for Trending Purposes Only

DIR Report #	ARTG #	Date of Report	GMDN / UMDN Text	Device Class	Sponsor Name	Manufacturer Name	Clinical Event Information	Outcomes
54210	186043	2/11/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Nevro Corporation	It was reported to Nevro that the patient developed an infection. As a result, the device was explanted. Nevro attempted to obtain additional information regarding the nature of the infection but was unsuccessful. There have been no reports of further complications regarding this event.	Reviewed, for Trending Purposes Only
54214	128775	2/11/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient experienced a loss of therapy. Imaging confirmed that the lead migrated. The patient underwent a revision procedure in which the lead was repositioned and has now regained coverage. The patient has three leads, it is unclear which of the three leads required repositioning.	Reviewed, for Trending Purposes Only
53130	128775	5/11/2018	Neural-tissue electrical stimulation lead	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that one of the leads had eroded through the patients skin. The patient will undergo either a full explant, partial explant or revision of the affected lead. Additional information was received that the patient underwent an explant procedure. The lead that had eroded was cut and removed over the Cervical spine and discarded. The IPG site was not touched.	Reviewed, for Trending Purposes Only
53207	205793	5/11/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient underwent a SCS system explant procedure due to not receiving sufficient pain relief.	Reviewed, for Trending Purposes Only
53903	128775	5/11/2018	Neural-tissue electrical stimulation lead	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient underwent a lead revision procedure due to ineffective therapy. The patient had four leads in the lumbar area that had lost effective use for management over time. Two new leads were implanted and an existing paddle lead was connected to the existing IPG.	Reviewed, for Trending Purposes Only
53971	197909	5/11/2018	Neural-tissue electrical stimulation lead	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient underwent a revision procedure due to loss of therapy and stimulation in non-target areas. High impedances were observed on one of the leads so the lead was replaced and another lead was repositioned. The patient was doing well post-operatively.	Reviewed, for Trending Purposes Only
53414	205793	8/11/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient underwent an explant procedure due to loss of therapy.	Reviewed, for Trending Purposes Only
53905	128775	8/11/2018	Neural-tissue electrical stimulation lead	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient underwent a revision procedure to reposition migrated leads. The patient experienced a reduction in pain relief due to the migration so the leads were repositioned back to their original position. The patient was doing well post-operatively.	Reviewed, for Trending Purposes Only
53965	205793	8/11/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient underwent an explant for an unknown reason.	Reviewed, for Trending Purposes Only
53522	279913	9/11/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patientâ€™s lead had eroded through the skin. As a result, the lead was cut and retracted back (date of surgery unknown). 8 Nov 2018: Additional information received identified the SCS system was explanted due to the issue.	Reviewed, for Trending Purposes Only
53918	279913	9/11/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient underwent surgical intervention on 05 September 2018 to replace two migrated leads. During the postoperative programming session the following day, the patient experienced discomfort when stimulation was turned on for the left cluneal lead. X-rays revealed the leads had migrated. As a result, the patient may be awaiting surgical intervention. 07 November 2018: Follow up information identified the physician relocated the patient's lead on 21 October 2018. Postoperatively, the patient is doing well.	Reviewed, for Trending Purposes Only
53907	131047	13/11/2018	Neural-tissue electrical stimulation lead	Class III	LivaNova Australia Pty Ltd	LivaNova USA Inc	It was reported that, prior to a generator replacement surgery planned for low battery, system diagnostics detected high impedance DCDC-7 on the patient's generator. The battery status indicator was Near End of Service (NEOS) -YES . The surgeon chose to replace the lead and generator as a result. The suspect product has not been received to date. No further relevant information has been received to date.	Reviewed, for Trending Purposes Only
54140	128775	14/11/2018	Neural-tissue electrical stimulation lead	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patients pudental lead had eroded through the skin medial to the right buttock at the original entry site of the tuohy need and incision. A loop of the lead cable was protruding from the wound. The physician did not note any infection, however the patient was administered prophylactic antibiotics. A culture was taken however the results will not be provided. The patient underwent a lead explant procedure and was doing well post-operatively.	Reviewed, for Trending Purposes Only
53893	205793	15/11/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient was unable to charge the IPG and underwent an IPG replacement procedure. The physician presumed the charging issue was due to another procedure where diathermy was used. Additional information was received that the other procedure was not device related.	Reviewed, for Trending Purposes Only
54465	129091	16/11/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that a patient's IPG was explanted because it no longer held a charge. The patient is reportedly doing well following the procedure.	Reviewed, for Trending Purposes Only
53590	197909	19/11/2018	Neural-tissue electrical stimulation lead	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient underwent a revision due to lead migration. The patient was experiencing lack of therapy and coverage. During the procedure, high impedances were observed on both leads. The physician replaced and repositioned both leads to attempt to recapture therapy in the pain areas. One of the leads was cut during the revision. Patient was stable post operatively and had coverage of all pain areas.	Reviewed, for Trending Purposes Only
54561	218230	22/11/2018	Neural-tissue electrical stimulation lead	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient experienced loss of stimulation. It was determined that the paddle lead had migrated. The patient underwent a revision procedure and the physician chose to replace the lead due to physicians preference.	Reviewed, for Trending Purposes Only
54632	128775	27/11/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient had a suspected infection on the right buttock incision site which was red. The physician prescribed antibiotics and as a precaution removed the leads. The leads were kept by the facility and cultures were taken the results are unknown. The device was not suspected to be a contributory cause for the symptoms, per the physician the patient scratched the incision site.	Reviewed, for Trending Purposes Only
53373	205793	28/11/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient presented with fever, and redness at the incision site for both the leads and IPG. The patient was placed on antibiotics and underwent an explant procedure to remove the leads and IPG. The physician does not believe the infection to be device related, but indicates the patient is a heavy smoker and thinks that this contributed to the infection. Patient is doing well post-operatively.	Reviewed, for Trending Purposes Only
53904	283692	29/11/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient underwent an explant of the IPG due to the patient high power consumption requirements. A new IPG was implanted in the patient. Additional information was received that the patients power usage requirements for therapy depleted the IPG prematurely.	Reviewed, for Trending Purposes Only
54306	205793	29/11/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient was explanted due to not getting enough relief from the stimulator.	Reviewed, for Trending Purposes Only

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53807	128775	4/12/2018	Neural-tissue electrical stimulation lead	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient underwent an explant procedure and all devices were explanted. The patient wanted the IPG and two leads explanted because the leads were migrating very close to the skin and were almost eroding out of the skin.	Reviewed, for Trending Purposes Only
54760	128775	5/12/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient underwent a revision of the leads due to lead migration. The patient experienced loss of therapy after a fall and it was observed that the leads had migrated. The physician repositioned the leads and the patient regained therapy.	Reviewed, for Trending Purposes Only
54762	128775	5/12/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	report was received that the patient underwent a revision procedure. The physician indicated that the lead migrated therefore it had to be reinserted within the sacral area. The patient regained therapy in the sacral area.	Reviewed, for Trending Purposes Only
53588	205793	6/12/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that during a revision procedure to reposition the Clik Anchors, the physician damaged an Infinion Lead and the IPG when using electro-cautery. The damaged lead and IPG were removed and replaced. Electrocautery is a known source of high voltage transient signal and current company labeling warns against the use of Electrocautery. (Physicianâ€™s implant manual 90970880-04).	Reviewed, for Trending Purposes Only
54811	128775	7/12/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient was experiencing stimulation in a non-target area. It was determined that two of the four leads had migrated, however it is not known which ones migrated. The patient underwent a lead revision procedure and the leads were repositioned. The patient was doing well post-operatively.	Reviewed, for Trending Purposes Only
54464	279913	8/12/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient was unable to set the IPG in MRI mode due to high impedances on the lead. Additional information received identified the SCS system was explanted on 25 Oct 2018.	Reviewed, for Trending Purposes Only
54810	205793	12/12/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient had increased pain at the IPG site. The patient was admitted to the hospital for pain relief and stimulation was turned off for 72 hours. The patient was given analgesia and was reprogrammed. The patient has received some pain relief following the reprogramming. Labs were taken, and the results were negative for signs of infection.	Reviewed, for Trending Purposes Only
54917	128775	13/12/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient was receiving ineffective therapy. Coverage of paraesthesia was mostly left sided, and more was needed on the right side. An x-ray confirmed that the lead migrated. The patient underwent a revision procedure and the lead was repositioned. The patient was doing fine post-operatively.	Reviewed, for Trending Purposes Only
53320	185992	17/12/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Nevro Corporation	It was reported to Nevro that the stylet tip broke off when the stylet was removed from the lead during an implant procedure. The physician was able to remove the stylet tip without incident. No injuries were sustained by the patient. The procedure was completed with no further reports of complications and the patient is currently receiving effective pain relief from the device.	Reviewed, for Trending Purposes Only
53844	205793	19/12/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient experienced ineffective therapy. Although there was no malfunction on the IPG, the patient wanted the device explanted. The IPG and two leads were explanted because the patient did not get enough relief to warrant keeping the devices implanted.	Reviewed, for Trending Purposes Only
54562	205793	20/12/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient requested an MRI because she was unable to move following a pocket revision. During the revision, the leads were disconnected from the IPG, re-sited, and then reconnected to the IPG. The physician does not believe the event was device related. The patient was admitted as an inpatient. Additional information was received that the patient's neurological symptoms were psychosomatic. All scans of the brain and spine showed no abnormalities. The physician believes the patient has fully recovered.	Reviewed, for Trending Purposes Only
54667	205793	20/12/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient was experiencing difficulty charging. The patient underwent a revision of the IPG as the IPG had flipped. The physician repositioned the IPG and the patient was doing well post-operatively.	Reviewed, for Trending Purposes Only
53884	279913	21/12/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient was unable to increase amplitude on the lead. Diagnostics revealed high impedances on all contacts. Reprogramming was unsuccessful at providing effective therapy. As a result, the patient may be awaiting surgical intervention. 30 October 2018: Additional information received identified the physician explanted and replaced the lead. 14 November 2018: No additional information received at this time. 28 November 2018: No additional information received at this time. 19 December 2018: Follow up information identified the patientâ€™s impedance issue was resolved with lead replacement. This report contains analysis.	Reviewed, for Trending Purposes Only
54538	279913	21/12/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced ineffective stimulation, as well as discomfort at the anchor site. X-rays revealed the patientâ€™s lead migrated. Reprogramming attempts were unsuccessful. To address the issue, the physician explanted both of the patientâ €™s leads and replaced it with a single lead. Postoperatively, effective therapy was restored. Note: Both of the patient's leads are being reported because it is unknown which lead migrated. 19 December 2018: Additional information received identified the patientâ€™s discomfort at the anchor site resolved following the explant on 05 November 2018.	Reviewed, for Trending Purposes Only
54558	279913	21/12/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced an infection at the thoracic incision site. To address the issue, the physician explanted the SCS system. 19 December 2018: Additional information received indicated the infection has resolved.	Reviewed, for Trending Purposes Only
54560	279913	21/12/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced ineffective stimulation, and pain when tonic stimulation was utilized. X-rays revealed the patientâ€™s lead had migrated. To address the issue, the patient is awaiting surgical intervention. 19 December 2018: Additional information received identified the patientâ€™s migrated lead was explanted and replaced. Postoperatively, effective therapy was restored.	Reviewed, for Trending Purposes Only
55134	129091	21/12/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient experienced difficulty keeping the IPG charged. It was also noted that the IPG was protruding from the lower flank and the patient felt discomfort and pain at the pocket site. Patient underwent a revision procedure to replace the IPG and allow for deeper pocket placement. Patient is doing well post operatively and is experiencing no pain at the IPG pocket site. Device is not available for return as it is against the explanting hospitals policy.	Reviewed, for Trending Purposes Only
55180	279913	28/12/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced ineffective stimulation. Surgical intervention was undertaken and the leads were explanted and replaced. Postoperatively, the patient is reportedly receiving effective therapy.	Reviewed, for Trending Purposes Only
55181	279913	28/12/2018	Stimulator, electrical, analgesic, spinal cord	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced ineffective stimulation. Diagnostics indicated high impedance readings on multiple contacts. Surgical intervention was later undertaken and the lead was explanted and replaced with a surgical lead. Postoperatively, the patient is reportedly receiving effective therapy.	Reviewed, for Trending Purposes Only

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54297	186043	29/12/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Nevro Corporation	It was reported to Nevro that the patient passed away. There were no reports of device-related issues from the patient prior to the passing and the patient had been receiving effective pain relief while using the device. Follow-up indicated that the physician believes the patientâ€™s death was not related to the device. Update 14/01/2019. The patient was implanted for back and leg pain. A review of the complaint history record shows no reported issues from the patient prior to the patientâ€™s death. The device diagnostic data shows the patient was regularly using stimulation and charging the device since implant.	Reviewed, for Trending Purposes Only
55166	287158	31/12/2018	Stimulator, electrical, analgesic, spinal cord	AIMD	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Stimwave Technologies Inc	Stimwave Quality has investigated the details surrounding a complaint resulting from an unconfirmed infection that occurred in Australia reported to Stimwave on December 17, 2018, by Stimwave Clinical Specialist. The patient had a permanent procedure performed on June 15, 2018, in which a Freedom-8A Receiver Stimulator (FR8A-RCV-A0) and Freedom-8A Spare Lead (FR8A-SPR-B0) were implanted in the patientâ€™s right leg to treat the patientâ€™s chronic leg pain (Chronic Regional Pain Syndrome). There were no complications during the implant procedure and the patient was receiving significant pain relief. On December 15, 2018, the patient contacted the Clinical Specialist and reported that her leg was sore and red around the insertion site. The patient stated that the pain and redness presented suddenly (within the last 24 hours), but the device was still providing pain relief. The Clinical Specialist instructed the patient to see out medical attention. The patient met with a physician who prescribed oral antibiotics (type, dose, and duration unknown). The Therapy Specialist sought medical advise from another pain specialist who advised that if the patient had an infection, it would be best to seek IV antibiotic treatment. The Therapy Specialist relayed this information to the patient, and as a precaution, the patient visited a local hospital for IV medical treatment. The treating hospital took cultures of the reddened site to determine the strain of infection. The results of these tests are unknown to Stimwave at this time. On December 20, 2018, the patient reported that IV treatment had ceased and was replaced with Backtroban cream on the site and is being sealed from environments to ensure finality of treatment. The patient should be discharged from the hospital on December 20, 2018. The patient continues to receive significant pain relief from the device. At this time, evaluating physicians believe the infection is superficial, and is not near the implant. Therefore, device explant is not required. The patient does not have comorbidities, pre-existing conditions, or injuries that would otherwise contraindicate her from being implanted with the Freedom SCS System. The patient reported no issues with the system before, during, or after the permanent procedure until the onset of pain and redness on December 15, 2018.	Reviewed, for Trending Purposes Only
53984	230721	3/01/2019	Stimulator, electrical, analgesic, spinal cord	AIMD	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patientâ€™s IPG would no longer communicate with external devices and became inoperable. To address the issue, the physician explanted and replaced the patientâ€™s IPG. 09 November 2018: Follow up information identified postoperatively, effective therapy was restored. 28 November 2018: No additional information received at this time. 27 December 2018: This report contains analysis results.	Reviewed, for Trending Purposes Only
53998	279913	4/01/2019	Stimulator, electrical, analgesic, spinal cord	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced migration of a lead. To address the issue, the physician opted to revise the lead. Intraoperative testing revealed high impedances on a lead. As a result, the physician explanted and replaced one lead, resolving the issue. Note: Both of the patient's leads are being reported because it is unknown which lead is liable. 09 November 2018: No additional information received at this time. 28 November 2018: No additional information received at this time. 02 January 2019: Follow up information received identified postoperatively, effective therapy was restored.	Reviewed, for Trending Purposes Only
54754	230721	5/01/2019	Stimulator, electrical, analgesic, spinal cord	AIMD	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced discomfort in the IPG pocket caused from the IPG being mobile in the pocket. To address the issue, the physician repositioned the IPG from the right lower abdomen to the right back/lower flank region. 03 January 2019: Additional information received indicated postoperatively, the patient now feels more comfortable at the IPG site.	Reviewed, for Trending Purposes Only
54814	132097	5/01/2019	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	This patient is implanted with an SCS system for off-label use. It was reported the patient experienced ineffective stimulation. Reprogramming attempts were unsuccessful, and X-rays revealed the patient's two leads migrated. To address the issue, the physician plans to perform surgical intervention. 03 January 2019: Follow up information identified the patient underwent surgical intervention to explant and replace both leads on 11 December 2018. Postoperatively, effective therapy was restored.	Reviewed, for Trending Purposes Only
53985	279913	8/01/2019	Stimulator, electrical, analgesic, spinal cord	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient was unable to get effective pain relief after implant, as stimulation was not achieved in the target area. X-rays revealed the leads were implanted slightly to the right of the midline. To address the issue, the physician explanted and replaced one of the patientâ€™s leads. Postoperatively, effective therapy was achieved. 09 November 2018: No additional information received at this time. 29 November 2018: No additional information received at this time. 04 January 2019: This report contains analysis.	Reviewed, for Trending Purposes Only
54209	279016	8/01/2019	Stimulator, electrical, analgesic, spinal cord	AIMD	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patientâ€™s IPG was unable to establish communication with external devices. The IPG was deemed inoperable. Subsequently, the IPG was explanted and replaced with another model which resolved the issue. 27 November 2018: No additional information received at this time. 04 January 2019: This report contains analysis results.	Reviewed, for Trending Purposes Only
54187	197909	11/01/2019	Neural-tissue electrical stimulation lead	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient was experiencing right sided pain, because the existing lead did not cover her pain. A fluoro exam confirmed the lead was placed too far to the left. The patient underwent a revision procedure wherein the lead was repositioned, and the pain area was covered. During the implant procedure to add an additional lead, the physician noted high impedances on the existing lead which occurred when the lead was connected to the splitter. Several attempts were made to clear the impedances by connecting and disconnected the lead from the splitters. The physician elected to replace the lead and the splitters. It is unclear which of the existing leads was replaced. The pain area was covered and the patient is doing well post-operatively. Additional information was received that device SC-2316-70 3210800 was not explanted.	Reviewed, for Trending Purposes Only

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54373	279913	11/01/2019	Stimulator, electrical, analgesic, spinal cord	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced ineffective stimulation. As a result, the physician explanted the patientâ€™s leads and replaced them with a single lead. 28 November 2018: No additional information received at this time. 09 January 2019: Additional information identified postoperatively, effective therapy was restored. This report contains analysis results.	Reviewed, for Trending Purposes Only
55245	279913	11/01/2019	Stimulator, electrical, analgesic, spinal cord	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced signs of infection at the lead site three weeks after the lead implant date. To address the issue, the physician explanted the patientâ€™s two leads, hospitalized the patient, and prescribed intravenous and oral antibiotics. The infection has improved and the patient is being monitored. 09 January 2019: Follow up information identified the patient was released from the hospital the day after the explant. The infection has since resolved.	Reviewed, for Trending Purposes Only
54123	197909	15/01/2019	Neural-tissue electrical stimulation lead	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient experienced high impedances and a loss of therapy. The patient underwent a procedure where two leads and lead anchors were explanted. The patient was doing well postoperatively.	Reviewed, for Trending Purposes Only
54809	126002	15/01/2019	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	Advanced Neuromodulation Systems Inc	It was reported the patient experienced ineffective stimulation following a heavy lifting event. X-rays revealed potential migration of the S lead. To address the issue, the physician explanted and replaced the migrated lead, resolving the issue. Postoperatively, effective therapy was restored. Device information and implant date are unknown at this time. 11 January 2019: Follow up information identified the patient’s 3286 lead was not explanted as previously reported. The surgery on 07November2018 only implanted one new lead, and no products were explanted at that time. The lead was implanted to provide greater coverage. Postoperatively, effective therapy was restored.	Reviewed, for Trending Purposes Only
54237	185992	16/01/2019	Stimulator, electrical, analgesic, spinal cord	Class III	Emergo Asia Pacific Pty Ltd T/a Emergo Australia	Nevro Corporation	It was reported to Nevro that during the lead placement, a dural tear occurred. The patient developed incontinence and left foot pain. The patient was subsequently hospitalized for a spinal cord injury and transferred to a rehabilitation center. Follow-up indicated that the patient is feeling better and is expected to make a full recovery. Further follow-up indicated that the patient is still recovering in a rehabilitation center. The patientâ€™s incontinence has improved and the patient is currently receiving effective pain relief from the device. There have been no reports of further complications regarding this event	Reviewed, for Trending Purposes Only
54935	132097	16/01/2019	Neural-tissue electrical stimulation lead	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced ineffective stimulation, as once they turned on a program, the stimulation would immediately turn back off. Diagnostics revealed 3 electrodes in 1 lead had high impedances. To address the issue, the physician explanted and replaced the patient's lead, and effective therapy was restored.	Reviewed, for Trending Purposes Only
55208	279016	16/01/2019	Stimulator, electrical, analgesic, spinal cord	AIMD	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced soreness caused by the IPG rubbing against the patient's ribs. To address the issue, the physician relocated the IPG lower on the abdomen on 17DEC2018, resolving the discomfort.	Reviewed, for Trending Purposes Only
55414	205793	16/01/2019	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient had difficulty charging the IPG. The physician assessed that the IPG was implanted at an angle. The patient underwent a revision procedure where the IPG was repositioned. The patient was doing well post operatively.	Reviewed, for Trending Purposes Only
54644	197909	18/01/2019	Neural-tissue electrical stimulation lead	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient experienced a loss of stimulation to the required areas. The patient underwent a lead explant procedure due to high impedances on damaged leads.	Reviewed, for Trending Purposes Only
55298	170450	19/01/2019	Stimulator, electrical, analgesic, spinal cord	Class III	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced ineffective stimulation. To address the issue, the physician implanted two new leads on 14 November 2018, and left the original paddle lead in place. Postoperatively, effective therapy was achieved. Device information and implant date is unknown at this time. 17 January 2019: Additional information revealed the patientâ€™s paddle lead is Model 3228.	Reviewed, for Trending Purposes Only
54421	128775	21/01/2019	Neural-tissue electrical stimulation lead	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that two leads were removed and replaced due to inadequate stimulation.	Reviewed, for Trending Purposes Only
55477	128775	21/01/2019	Stimulator, electrical, analgesic, spinal cord	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient was experiencing undesired stimulation to non target areas caused by lead migration. The patient underwent a lead revision, during which the leads were repositioned. The patient was reportedly doing well following the procedure.	Reviewed, for Trending Purposes Only
54463	279015	24/01/2019	Stimulator, electrical, analgesic, spinal cord	AIMD	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient underwent an unrelated surgical procedure (date unknown). Postoperatively, the IPG would no longer communicate with external devices, and the error message â€œCannot connect to generator. A problem was found with the generator that could not be repairedâ€ displayed. Troubleshooting was unsuccessful. To address the issue, the physician explanted the IPG and replaced it with a new model. Postoperatively, effective therapy was restored. 05 December 2018: No additional information received at this time. The IPG has been received by the manufacturer, and analysis is pending. 22 January 2019: This report contains analysis results.	Reviewed, for Trending Purposes Only
55195	128775	24/01/2019	Neural-tissue electrical stimulation lead	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient underwent a revision procedure in order to address lead migration and inadequate stimulation.	Reviewed, for Trending Purposes Only
54215	128775	30/01/2019	Neural-tissue electrical stimulation lead	Class III	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	It was reported that during the trial lead pull procedure the physician reported that one of the leads was difficult to remove. The physician applied pressure to retract the lead but the lead ended up breaking off within the patient at the proximal contact. The patient was referred to a surgeon to recover the broken end of the lead.	Reviewed, for Trending Purposes Only
55577	286709	30/01/2019	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient was experiencing soreness at the pocket site and underwent a pocket revision procedure. The patient was doing well post operatively.	Reviewed, for Trending Purposes Only
55608	129091	1/02/2019	Stimulator, electrical, analgesic, spinal cord	AIMD	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A report was received that the patient underwent an IPG replacement procedure due to the IPG no longer holding a charge. The patient was also experiencing communication difficulties.	Reviewed, for Trending Purposes Only