



Precice Stryde

Antegrade Tibia Operative Technique

Contents

Introduction	3
Antegrade Tibia Operative Technique	5
Technical Details	5
Preoperative Planning	6
Limb Length Discrepancy Calculation	6
Osteotomy Calculation.....	7
Precice Stryde Antegrade Tibia Operative Technique	8
Patient Positioning	8
Antegrade Osteotomy of the Fibula	9
Soft Tissue and Nerve Release.....	10
Venting of the Tibial Intramedullary Canal	10
Syndesmotic Screws	11
Distal Syndesmotic Screw	11
Proximal Syndesmotic Screw.....	11
Extra-Articular Calcaneotibial Screw	12
Entry Point and Intramedullary Reaming	13
Tibia Guide Arm Assembly	14
Osteotomy of the Tibia	15
Proximal Locking Screws	16
Distal Locking Screws.....	17
End Cap Placement (Optional)	18
Locating the Center of the Magnet and C-arm Adjustment Guidance	18
Intraoperative External Remote Control (ERC) Distraction	19
Entering the Prescription.....	19
Precice Fast Distractor	20

Postoperative Management.....21

Final Closure21

Postoperative Management.....21

Lengthening to Consolidation 22

Consolidation Phase..... 22

Postoperative Lengthening..... **23**

External Remote Controller (ERC) Introduction 23

Features of the ERC3P 24

Implant Removal **25**

Precice Stryde Antegrade Tibia Limb Lengthening System..... **26**

Important Safety Information..... **30**

Introduction

Contributing Surgeons

Dror F. Paley

Founder and Director
Paley Orthopedic and Spine Institute
St. Mary's Hospital
West Palm Beach, FL

Shawn C. Standard, M.D.

Head of Pediatric Orthopedics
International Center for Limb Lengthening
Sinai Hospital
Baltimore, MD

John E. Herzenberg, M.D.

Director
International Center for Limb Lengthening
Sinai Hospital
Baltimore, MD

Stuart A. Green, M.D.

Clinical Professor
Department of Orthopaedic Surgery
University of California, Irvine Medical Center
Irvine, CA

The Precice Stryde System is intended for limb lengthening, open and closed fracture fixation, pseudoarthrosis, mal-unions, non-unions, or bone transport of long bones.

This Surgical Technique offers guidance but, as with any such technique guide each surgeon must consider the particular needs of each patient and make appropriate clinical decisions as required.

All non-sterile devices must be cleaned and sterilized before use. Multi-component instrument assemblies must be disassembled prior to cleaning. Please refer to the corresponding Instructions For Use.

It is the surgeon's responsibility to discuss all relevant risks with the patient prior to surgery.

The Precice Stryde System

is the latest advancement in limb lengthening utilizing distraction osteogenesis. Interaction between magnets in the device and an External Remote Controller (ERC) allow for precise, adjustable and customizable distraction throughout the lengthening phase of treatment.

Following osteotomy and during the lengthening phase, the Stryde implant is gradually lengthened based on the patient's requirements with the hand-held ERC. The physician's lengthening prescription can be entered into the ERC. When the desired length is achieved, intramedullary fixation continues to provide stability throughout the consolidation phase.

Stryde System Components

The Stryde System comprises the following components:

- Intramedullary Nail
- Proximal and Distal Locking Screws
- End Cap (optional)
- Instrument Tray
- External Remote Controller (ERC)

Intramedullary Nails

Diameter: 10.0 and 11.5mm

Sizes: 235-365mm

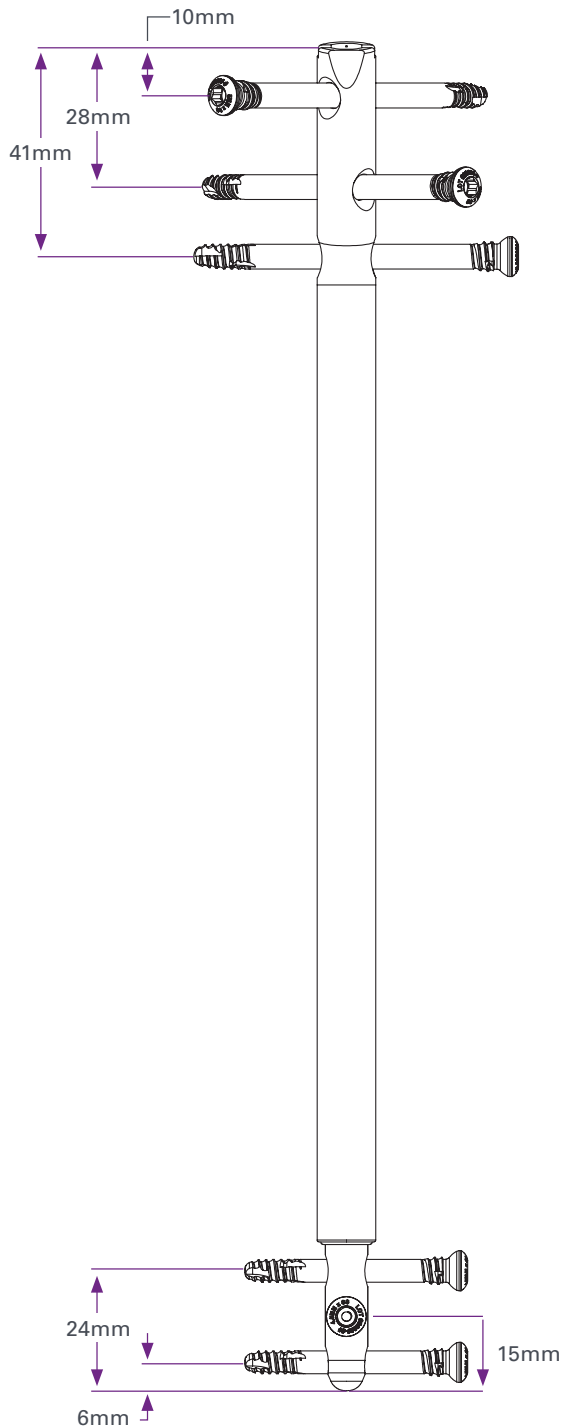


Antegrade Tibia Operative Technique

Technical Details

Antegrade Tibia

235–365mm



Telescoping Rod Diameter (Male)



10mm Nail: 7.2mm

11.5mm Nail: 8.5mm

End Cap

Diameter: 11.5mm

Note: 11.5mm end caps are compatible with the 10mm Stryde devices

Sizes:

Length

0mm

5mm

10mm

15mm

20mm



Locking Screws



4.0mm Partially Threaded Locking Screws

Length: 20–75mm



4.5mm Partially Threaded Locking Screws

Length: 20–80mm



5.0mm Partially Threaded Locking Screws

Length: 20–80mm

Antegrade Tibia Preoperative Planning

Limb Length Discrepancy Calculation

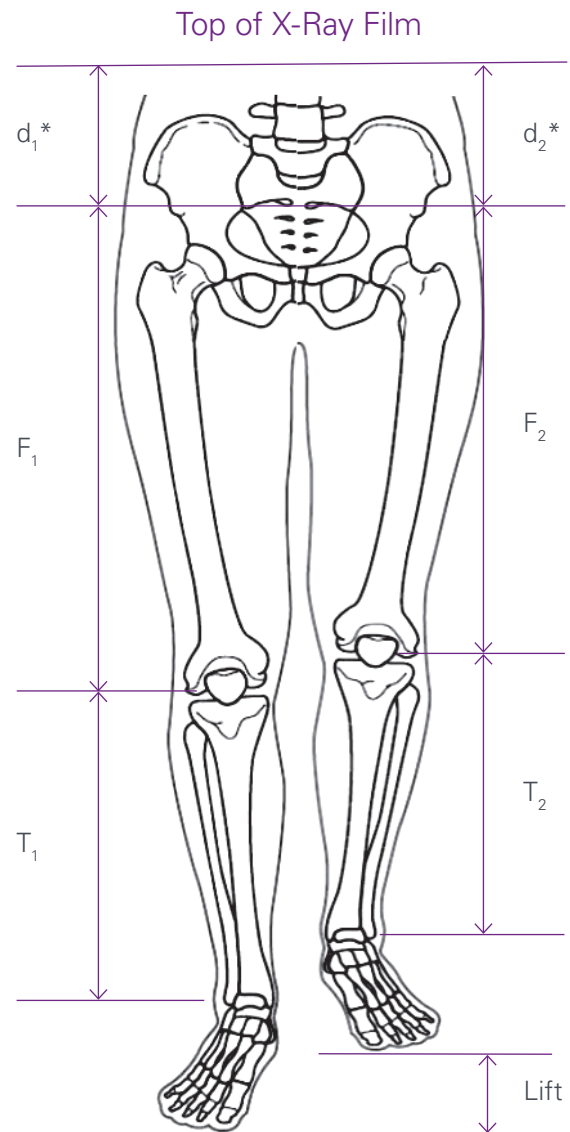
Careful preoperative evaluation and planning, proper surgical technique, and extended postoperative care are essential for success of limb lengthening procedures.

Preoperative evaluation is performed to determine:

- Limb length discrepancy
- Intramedullary diameter
- Required implant length
- Osteotomy location of tibia
- Soft tissue assessment

Diameter (mm)	10.0 and 11.5
Lengths (mm)	235, 250, 265, 280, 305, 335, 365
Maximum Distraction (mm)	50, 65, and 80
Proximal Bend	10°
Partially Threaded Locking Screws (mm)	4.0, 4.5, and 5.0

Digital templates for the Stryde implants can be found in TraumaCad software. As an alternative, the Limb Length Discrepancy Calculation can aid in calculating femoral limb length discrepancies and determine which Stryde implant is needed. Tibial and femoral lengths calculate segmental differences which helps to determine which segment to address.



$$\text{Limb Length Discrepancy} = (d_2 - d_1) + \text{Lift}$$

Contralateral Limb (mm)

$d_1 =$

$F_1 =$

$T_1 =$

Treatment Limb (mm)

$d_2 =$

$F_2 =$

$T_3 =$

* d_1 and d_2 are measured from the sacroiliac (SI) joint line reference line to the top of the x-ray image; use a magnification marker on x-ray to improve the accuracy of measurements

Antegrade Entry Osteotomy Calculation

These are general guidelines. The osteotomy level may be influenced by the presence of a sagittal or frontal plane deformity that may require correction. In all cases, it is imperative that adequate distal segment coverage be maintained at the end of lengthening for biomechanical stability.

The Stryde tibial implant is available in 10.5 and 11.5mm diameters with a proximal 10° Herzog bend. Over reaming the intramedullary tibial canal by 2.0mm is recommended to aide in implant insertion. The cortices should be at least 3mm thick at any location once reamed.

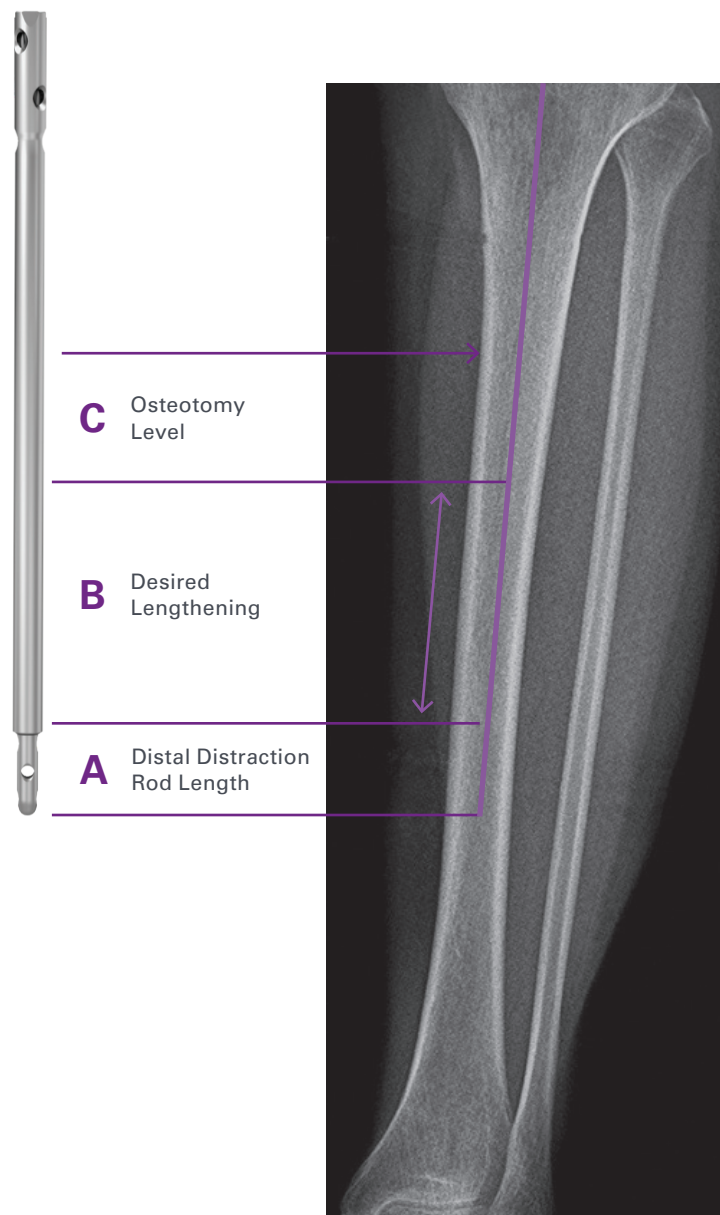
With radiographs that include a magnification marker, measure from the level of the joint line to the location of the distal end of the Stryde implant.

Calculate the following to determine the measurement from the distal end of the implant.

A	3.0cm
B	Up to 8.0cm
C	4.0-5.0cm

This measurement determines the suggested level of the osteotomy.

A + B + C = Measurement from the distal end of the implant to perform osteotomy



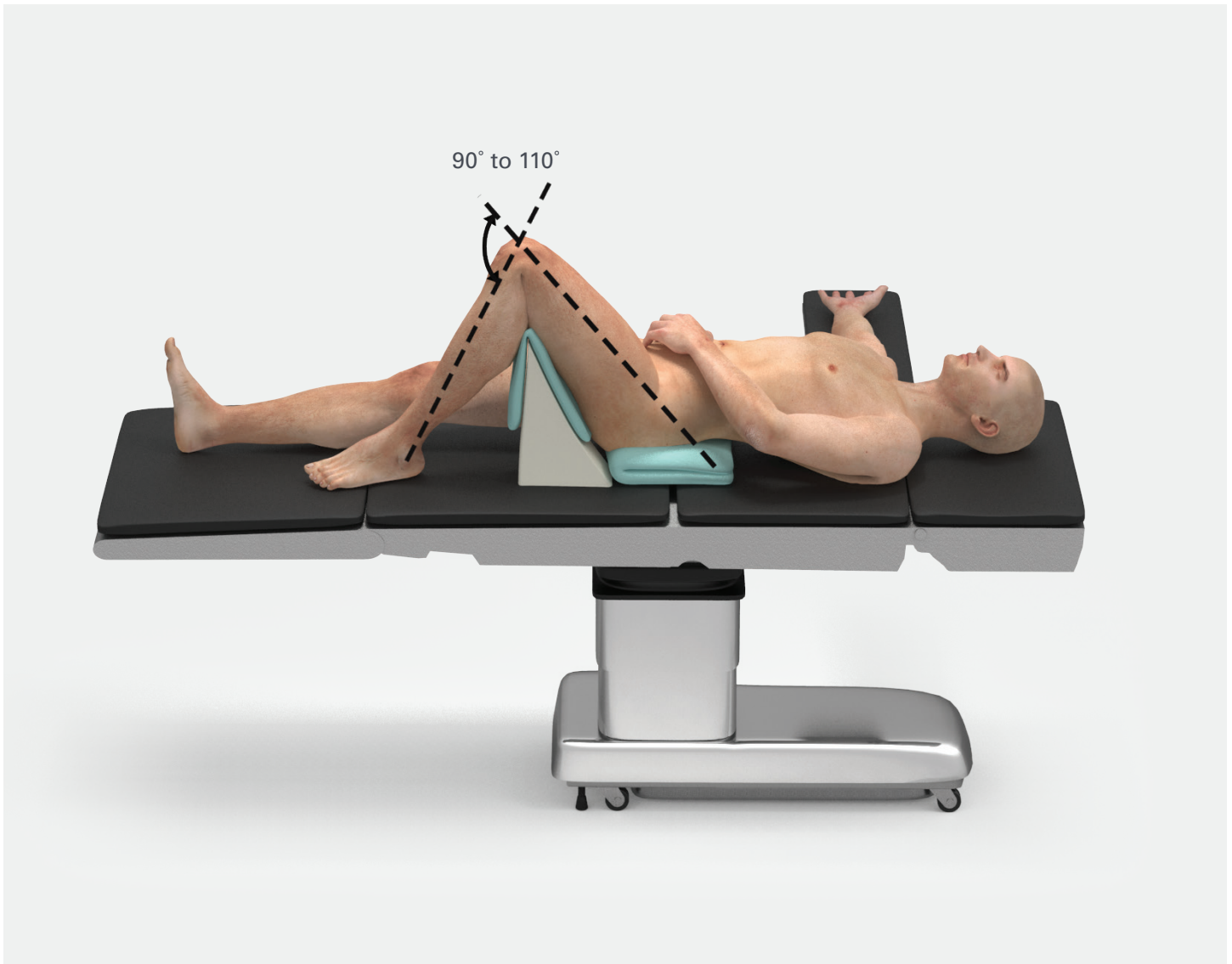
Antegrade Tibia Operative Technique

Patient Positioning

Place the patient supine on a radiolucent table and position the knee for a tibial nailing procedure. Position a small bump under the ipsilateral sacroiliac joint. A triangle may also be helpful for patient positioning and nail insertion.

Fluoroscopic visualization of the entire tibia is essential and should be confirmed prior to prepping and draping the patient's entire limb from the iliac crest to the foot/ankle.

Locate the joint line using a wire or similar technique.
Use a surgical marking pen to mark the site.



Osteotomy of the Fibula

Osteotomy of the fibula is an essential surgical step when performing tibial lengthening.

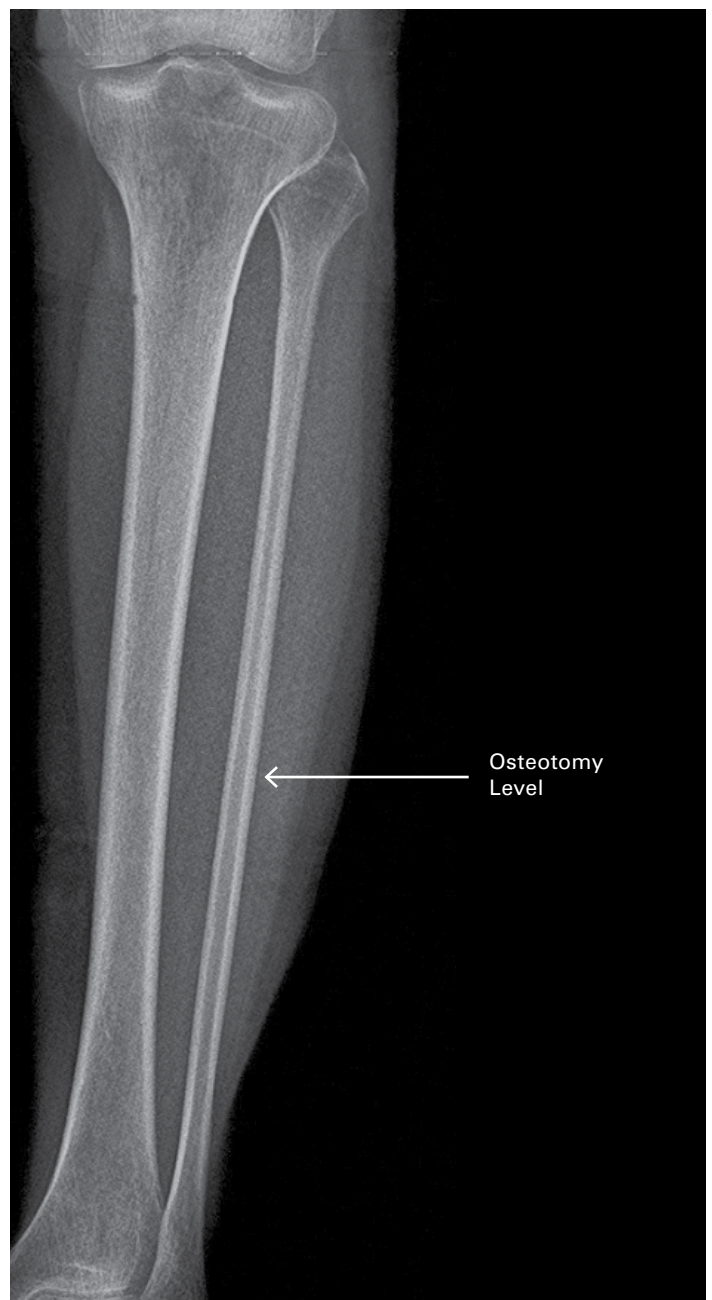
It is recommended that the fibula osteotomy be performed at a different level than the tibial osteotomy to reduce the risk of soft tissue swelling that may lead to compartment syndrome. The fibular osteotomy should not be performed within the proximal 13cm unless concurrent peroneal identification and decompression is performed.

Create a 2.5cm posterolateral incision at the junction of the middle and distal third of the fibula. Dissect the interval between the peroneal muscles and the soleus muscle along the posterolateral intramuscular septum. Lift the peroneal muscles anteriorly to expose the fibula. Using a small periosteal elevator carefully separate the periosteum from the bone of the fibula circumferentially. Insert two small retractors to protect surrounding tissues.

Using a Kirschner wire (K-wire), create multiple drill holes in the fibula at the site of the planned osteotomy.

Prior to completing the fibular osteotomy, use retractors to protect the peroneal artery and its two venae comitantes which are medial to the fibula. A small osteotome is used to complete the osteotomy.

Note: Verify and confirm completion of the fibula osteotomy.



Soft Tissue Release

Depending on clinical requirements, the surgeon may consider performing a gastrocnemius recession (Vulpus procedure), a gastrocnemius fascia release, proximal peroneal nerve release, and insert a temporary calcaneal-tibial posterior screw to help prevent equinus from developing during tibial lengthening.¹⁻³

A prophylactic percutaneous anterior and lateral compartment fasciotomy should be performed. Prophylactic antibiotics should be given prior to elevating the tourniquet.



Venting of the Tibial Intramedullary Canal

Intramedullary reaming of a closed bone generates high intramedullary pressures that have been associated with complications such as fat embolism.⁴ To avoid these potential complications, place multiple venting holes in the tibia at the planned osteotomy site prior to reaming.

Make a 1.0cm incision over the anterior tibial crest at the determined osteotomy site. Elevate the periosteum medially and laterally with a small periosteal elevator. Using the 4.0, 4.5 or 5.0mm Step Drill Bit, make one entry hole anteriorly and three exit holes posteriorly.

- Venting reduces pressure on the bone marrow during reaming and implant insertion.
- Venting creates egress for bone marrow at the osteotomy site during reaming.
- Venting drill holes will facilitate the osteotomy.
- Reamings which exit the vent holes will act as prepositioned bone graft at the distraction gap.

1. Herzenberg JE, Lamm BM, Corwin C, et al. Isolated recession of the gastrocnemius muscle: the Baumann procedure. *Foot Ankle Int* 2007;28(11):1154-9.

2. Nogueira MP, Paley D, Bhave A, et al. Nerve lesions associated with limb-lengthening. *J Bone Joint Surg Am* 2003;85-A(8):1502-10.

3. Belthur MV, Paley D, Jindal G, et al. Tibial lengthening: extraarticular calcaneotibial screw to prevent ankle equinus. *Clin Orthop Relat Res* 2008;466(12):3003-10.

4. Kröpfel A, Berger U, Neureiter H, et al. Intramedullary pressure and bone marrow fat intravasation in unreamed femoral nailing. *J Trauma* 1997;42(5):946-54.

Syndesmotic Screws

To enable the fibula to lengthen with the tibia and to provide stabilization, proximal and distal bone screws are used to secure the fibula to the tibia.

Distal Syndesmotic Screw

Care should be taken to stabilize the distal tibiofibular joint and the screw should be positioned prior to insertion of the Stryde implant.

Insert a K-wire percutaneously into the distal fibula just above the distal syndesmosis. The K-wire is driven in either an oblique or transverse fashion in a proximal/medial direction through the tibia. The K-wire should emerge from the anteromedial surface of the tibia. Make a small incision where the K-wire exits medially and then drill in a retrograde direction with a cannulated drill bit through all four cortices. An appropriate length and diameter fully-threaded cortical screw is inserted from medial to lateral securing the distal tibiofibular joint. Confirm that threads engage all four cortices.



Proximal Syndesmotic Screw

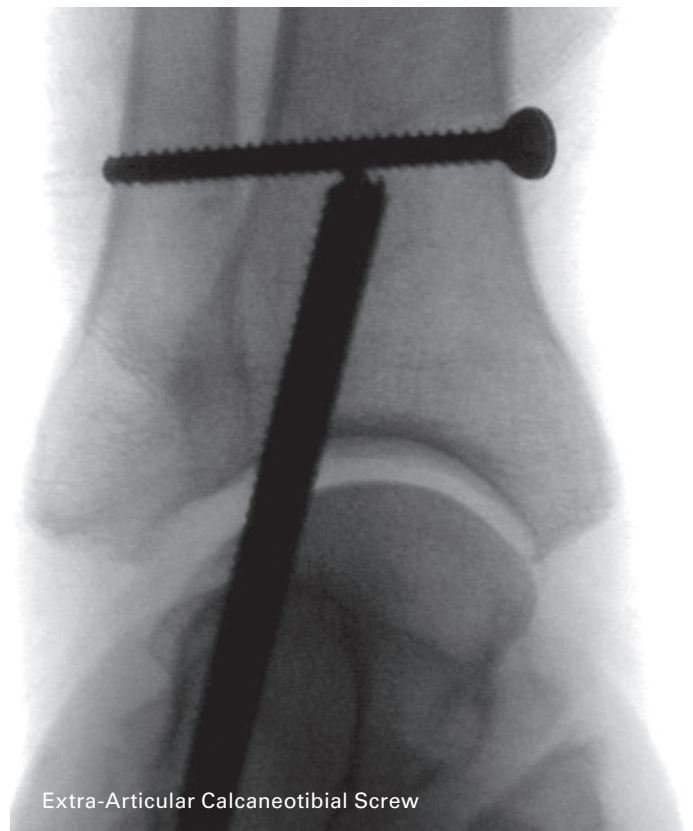
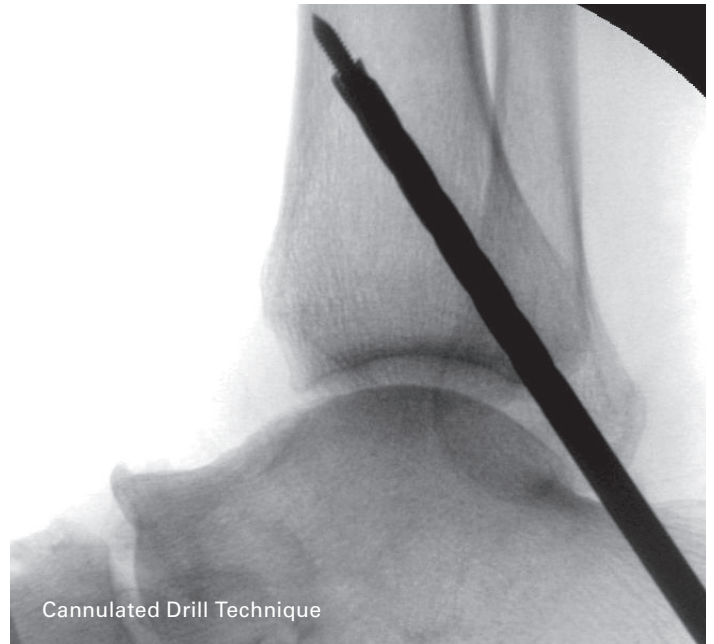
After the Stryde implant has been positioned, a proximal screw can be inserted at the level of the fibular head (see page 18). Take care to avoid the peroneal nerve as it wraps around the fibular neck.

Note: Proximal 5.0mm Partially Threaded Locking Screws positioned with the addition of a proximal fibular syndesmotic placed posterior to the nail.



Extra-Articular Calcaneotibial Screw

To help prevent equinus contracture, a temporary extra-articular screw may be used to stabilize the ankle joint during tibial lengthening. This example demonstrates the use of a cannulated fully threaded screw.



Entry Point and Intramedullary Reaming

Flex the knee to assist in finding the proximal entry point. Insert a Steinmann pin percutaneously into the proximal tibia just anterior to the joint line in-line with the tibial shaft. Verify and confirm location under biplanar fluoroscopic guidance. A more distal entry point may result in damage to the posterior cortex during nail insertion.

The center point of the portal is located slightly medial to the lateral tibial spine as visualized on the A/P radiograph and immediately adjacent and anterior to the anterior articular margin as visualized on the true lateral radiograph. The A/P starting position can be adjusted for planned angular deformity or to target the distal tibial segment.

Make a small vertical incision around the pin and spread the soft tissues using hemostats.

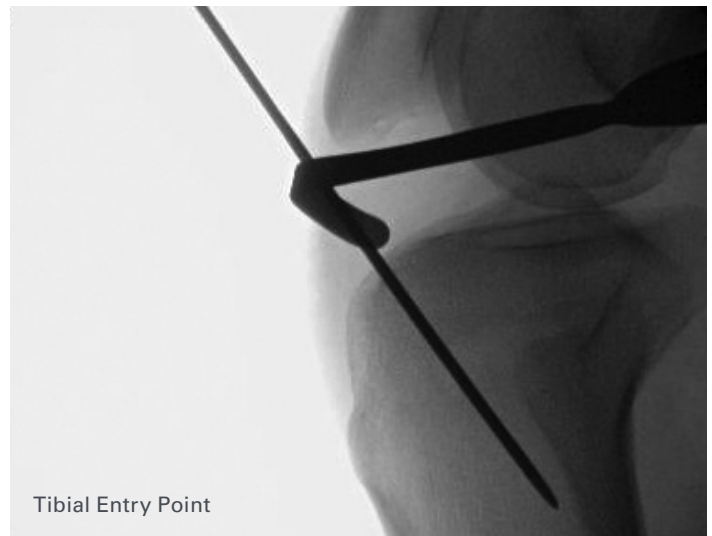
After confirming correct pin placement on A/P and lateral radiograph views, position a soft tissue protector and ream over the Steinmann pin with a rigid 8.0mm or 11.0mm entry drill (8-10mm). Protect the patellar tendon with retractors.

Using a guidewire chuck, insert a ball tip guide wire into the entry hole and down the length of the tibia about 3.0 to 4.0cm beyond the planned distal end of the nail.

Release the tourniquet if one was used for the fibular osteotomy. Blood flow through the tibia during reaming can help conduct heat away from the bone and reduce the risk of thermal injury. Close the anterior incision with a simple running suture to prevent egress of the bony reamings.

Attach an AO quick connect to the reamer prior to reaming the canal with flexible reamers beginning with 7mm. Increase by 0.5mm increments until the tibial canal is over-reamed by 2.0mm greater than the planned diameter of the Precice Stryde implant. A guidewire pusher may be used to secure the guidewire when removing the flexible reamers from the canal.

Note: There are two diameters of Stryde tibial implants available: 10.0 and 11.5mm.



Stryde Guide Arm Assembly

Attach the Stryde implant to the Guide Arm by inserting the Locking Bolt through the hollow tube of the Drill Guide Arm and aligning the arrows on the implant and guide arm. Engage the threads on the proximal end of the implant with the Locking Bolt and tighten with the 6mm Hex Driver.

Note: Do not over-tighten the Locking Bolt. Applying excessive force to the 6mm Hex Driver may affect the proximal screw targeting accuracy.

Verify correct alignment of the 5.0 x 340mm Step Drill Bit through the Guide Tube, Drill Guide, and Stryde implant. Confirm both proximal screw holes in this manner. Once the Stryde implant has been properly attached to the Tibia Guide Arm Assembly, place the construct aside in the sterile field until ready for insertion into the intramedullary canal.

Precise Instrumentation



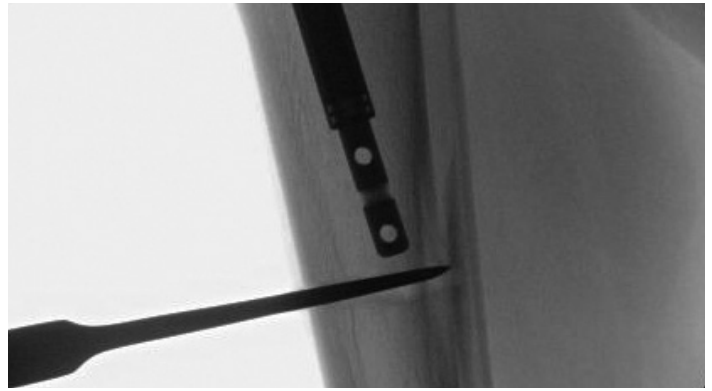
Osteotomy of the Tibia

Hyperflex the knee and insert the Stryde implant with the Tibial Guide Arm Assembly until the distal tip of the nail is just proximal to the planned osteotomy site where the vent holes were placed. Verify this location under image intensification.

Keeping the knee flexed, remove simple running suture and use an osteotome to complete the osteotomy. Use caution to avoid neurovascular injury and soft tissue damage. An irregular or comminuted osteotomy is acceptable. Ensure that the osteotomy created is completely circumferential. Verify the osteotomy is complete with multi-planar image intensification. With the knee flexed, gentle anterior pressure should be applied to the tibia during osteotomy. This will prevent acute flexion of the osteotomy site once completed.

Immediately after confirming the osteotomy, gently tap the Impactor on the Tibial Guide Arm Assembly to advance the Stryde implant across the gap and into the distal tibia. If the cut cortex of the distal segment prevents insertion, stop advancing the device, adjust the reduction, and try again. Excessive force on the Stryde nail may damage the internal mechanism. If necessary, consider reaming the canal by an additional 0.5 to 1.0mm.

Maintain rotational alignment during implant insertion and subsequent locking. Rotational alignment may be confirmed by inserting a proximal and distal half pin prior to completing the osteotomy. Alternatively, check the thigh-foot axis before the osteotomy and then again before distal locking.



Note: The use of osteotomes is always recommended as this is a low-energy osteotomy method that helps avoid an exaggerated inflammatory response and the potential for thermal necrosis.



Note: The osteotomy may be performed with the leg fully extended and manually reduced while flexing the knee for nail insertion. If maintaining control of an angular corrective osteotomy is desired, then consider the use of blocking screws.

Proximal Locking Screws

Confirm Tibial Guide Arm did not loosen during nail insertion prior to proceeding with proximal locking screws. Assemble the Guide Tube with the Drill Sleeve and Trocar (Triple Sleeve) and place through Tibia Guide Arm. Make a small stab incision where the Trocar contacts the skin. Advance the Trocar through the tissue until the tip is seated against the cortex. Verify with image intensifier that the Guide Tube is positioned on the tibial cortex.

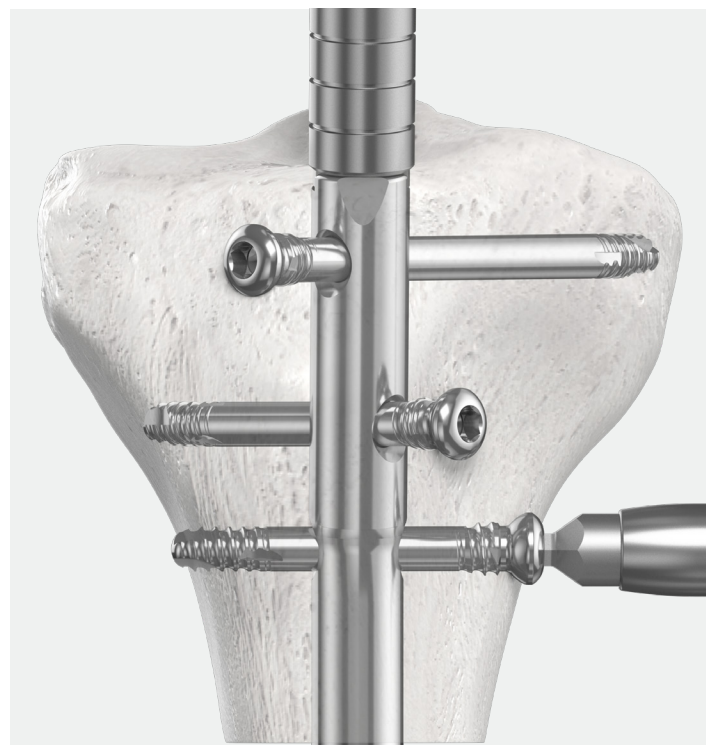
Remove the trocar leaving the Drill Guide and Guide Tube in place. Use the 5.0 x 340mm Step Drill Bit to penetrate both cortices. Confirm correct placement under image intensification.

After drilling both cortices, select the appropriate Partially Threaded Locking Screw length by reading off the calibration on the 5.0 x 340mm Step Drill Bit. 5.0mm Partially Threaded Locking Screws are available in 2.5mm increments from 20-50mm lengths and 5mm increments from 50-80 mm lengths. The screw gauge may also be used to read the calibration by sliding it down the guide tube.

Insert the Screw Capture Rod through the cannulated 3.5mm Locking Driver. Hand tighten the Screw Capture Rod to the appropriate length 5.0mm Partially Threaded Locking Screw. Attach the 3.5mm Locking Driver with the Screw Capture Rod to the Quick Connect T-handle or Teardrop Cannulated. Remove the Drill Guide and position the screw into the Guide Tube to direct it through the Stryde implant.

Hand tighten the Partially Threaded Locking Screw into the near cortex. Remove the Quick Connect T-handle and untighten the Screw Capture Rod to release the Partially Threaded Locking Screw. Repeat this sequence for the additional locking options.

Note: After securing the proximal 5.0mm Partially Threaded Locking Screws, untighten the Locking Bolt from the Stryde implant to remove the Tibial Guide Arm Assembly.



Distal Locking Screws

The free-hand technique is used to position Partially Threaded Locking Screws in the A/P and M/L distal locking holes of the Stryde implant.

Depending upon which Partially Threaded Locking Screw is to be inserted, align the C-arm in either the A/P or lateral position to view perfect overlapping circles. For the perfect overlapping circle technique, first find the drill hole using the finger hole of an instrument. Make a small skin incision here. Use the Soft Tissue Protector and appropriate diameter Step Drill Bit to create a pilot hole for the Partially Threaded Locking Screw.

Applies to all Stryde Nails; (235mm—365mm)
Models: SJ (Three Proximal, Three Distal Screw Holes)

Screw Sizing Chart		
10.0mm Nail	Proximal	5.0mm
	Distal	4.0mm
11.5mm Nail	Proximal	5.0mm
	Distal	4.5mm

Select the length for the first distal Partially Threaded Locking Screw by reading the measurement off the calibrated Step Drill Bit with the Soft Tissue Protector fully seated on the cortex. The Direct AO Depth Gauge may also be used. Attach the appropriate length Partially Threaded Locking Screw to the Screw Capture Rod and 3.5mm Locking Driver. Tighten the Partially Threaded Locking Screw by hand. Release the Screw Capture Rod. Repeat steps for additional distal Partially Threaded Locking Screws.



Find the drill hole by first using the finger hole of an instrument. Confirm positioning with image intensifier.



There are three distal Locking Screw options.

End Cap Placement (Optional)

If desired, an End Cap may be used to help prevent bony ingrowth into the proximal thread of the nail. Stryde Tibia End Caps are available in one diameter that is compatible with both the 10.0mm and 11.5mm implants. End Caps are also available in various lengths; 0, 5, 10, 15, 20mm options.

Secure the End Cap to the 3.5mm Locking Driver and Screw Capture Rod. Attach this assembly to the Quick Connect T-handle. Use image intensification to confirm positioning and take care not to cross-thread the End Cap.

Turn the Quick Connect T-handle clockwise until the End Cap fully sits inside the proximal portion of the nail. Untighten the Screw Capture Rod to release the End Cap.



Locating the Center of the Magnet and C-arm Adjustment Guidance

Evaluate the final implant construct under image intensification. Locate the magnet within the Stryde implant (see reference images). Be sure the C-arm is perpendicular to the implant to visualize the correct position of the central magnet.

Stryde has thick steel implant walls and visibility of the internal components may require C-arm adjustments. It is recommended to double magnification down (Mag 2), center over the magnet, and column adjust to the nail. If these steps are followed, a manual change to the kVp settings is no longer necessary and may result in better image quality.

Use a surgical skin marker to put a transverse line on the patient's skin directly over the location of the center of the Stryde magnet. Provide a surgical marker postoperatively to the patient to refresh the line as it fades.

Caution should be taken as the magnets in the ERC will attract metal objects, including surgical instruments (refer to the Operator's Manual for complete Instructions for Use prior to using the ERC).

Intraoperative External Remote Controller (ERC) Distraction

Place the ERC in a sterile bag and place it directly over the transverse mark on the skin. Make sure you have properly aligned the ERC on the patient's tibia and the magnets are pointed toward the patient's feet.

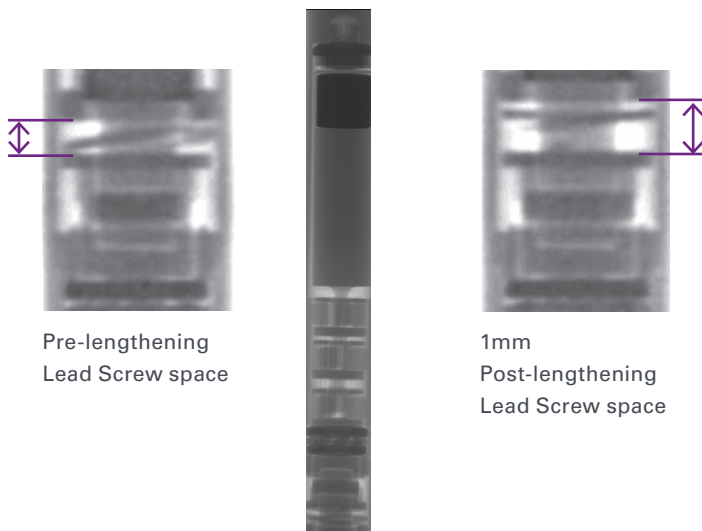
Use the implant locator window on the ERC to properly position it over the mark on the patient's skin.

Activate the ERC to distract the Stryde implant 1.0-2.0mm. This verifies correct functioning of the system. It takes six or seven minutes to achieve 1.0mm of lengthening. After functioning verification, it is not necessary to retract the Stryde implant.

Confirm under image intensification that the lengthening has occurred by comparing the pre-lengthening image to the post-lengthening image. The Lead Screw space should demonstrate distraction.

Important: Max tissue gap chart

Device diameter	ERC1, ERC2P, and ERC3P
10.0mm	13mm
11.5mm	13mm



Entering the Prescription

1. Turn on the ERC3P and type in the physician passcode
2. Choose "Prescription" from the menu
3. Select Prescription 1 (or 2 if bi-lateral)
4. Input prescription information
5. Review and confirm the prescription

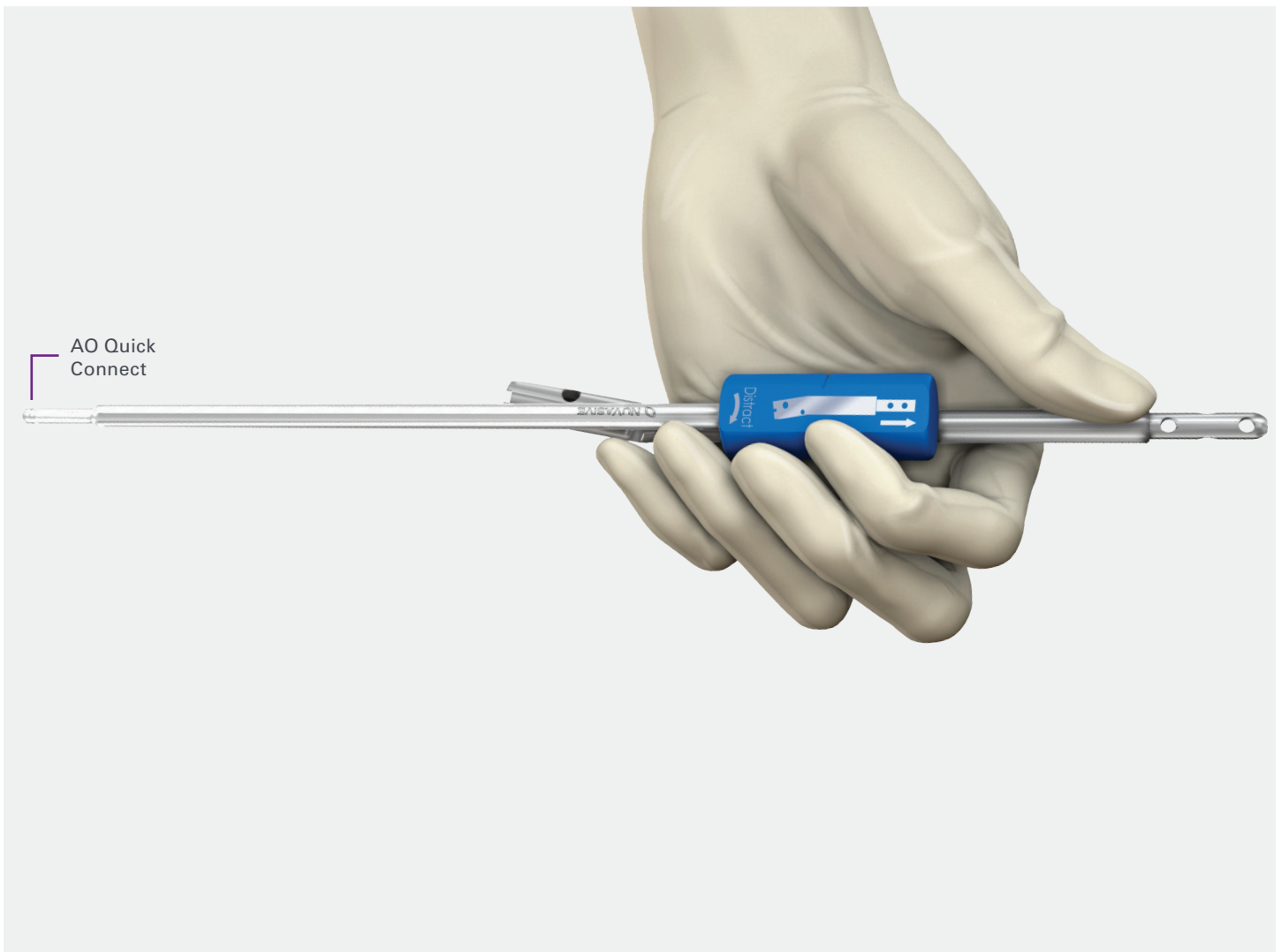
Note: Correct alignment of the ERC to the patient's tibia. Always point arrows on ERC toward patient's feet.



Precice Fast Distractor

1. Attach Fast Distractor to AO quick connect on OR Drill
2. Hold the Fast Distractor on the nail and slide it until you feel the magnet engage with the Stryde implant magnet (Stryde implant will “click” into place)
3. Ensure drill is in the forward position (Clockwise—Do not retract)
4. Cradle the fast distractor and nail in your hand
5. Start slowly and allow the drill to rotate freely (do not block it by holding too tightly)
6. Use a ruler to confirm the proper distraction amount has been achieved

Important: Do not pre-distract the Stryde device to its maximum potential distraction length (stroke). The maximum pre-distraction length must be 5mm less than the maximum Stryde nail stroke length.



Postoperative Treatment

Final Closure

After the intraoperative distraction of the Stryde implant, the surgical incisions are irrigated and closed in standard fashion.

Make certain that the skin mark noting the location of the magnet within the Stryde implant is prominent and visible. This will facilitate proper alignment and positioning of the ERC for future lengthening during the distraction phase.

Postoperative Management

Patients should be mobilized the first few days after surgery, but must follow Stryde weight bearing guidance during both the lengthening and consolidation phases. Please see chart below:

Device diameter	Max weight bearing
10.0mm	150lbs
11.5mm	200lbs

Each surgeon must prescribe a lengthening protocol for his/her patient. Factors to consider when determining daily lengthening rate include bone quality, location and trauma of the osteotomy, patient age, and comorbidities.

Daily lengthenings can range from 0.5-0.75mm divided into 2 to 3 sessions. Lengthening typically starts after a latency period of 7 days after initial implantation. Weekly clinical and radiographic evaluations by the surgeon are important to review the patient's progression. The ERC can be programmed to optimize the patient's lengthening prescription (refer to ERC Operator's Manual for complete programming instructions). During this phase, daily physiotherapy includes the following:

- Hip extension and abduction
- Full knee flexion/extension
- Ankle dorsiflexion to neutral
- Maximum ankle plantarflexion

Lengthening to Consolidation

During the lengthening phase, patient compliance to the planned lengthening prescription is important. Adherence to proper use of the ERC in addition to postoperative rehabilitation protocols must be emphasized. It is the physician's responsibility to carefully monitor the patient's progress with regular radiographs and to make any necessary change to the daily lengthening prescription. The physician may adjust or reverse a prescription to best meet the needs of the patient.

After the distraction phase has been completed, the patient's weight-bearing status must remain limited (10.0mm = 150k = lbs; 11.5mm = 200lbs) until bony healing. Once 3 out of 4 cortices have consolidated and at the physician's discretion, the patient is advanced to weight bearing as tolerated.

Consolidation Phase

The Stryde implant cannot withstand the stresses of full weight bearing. The patient should utilize external support and/or restrict activities until consolidation occurs. The consolidation phase should occur with the Stryde implant in place.

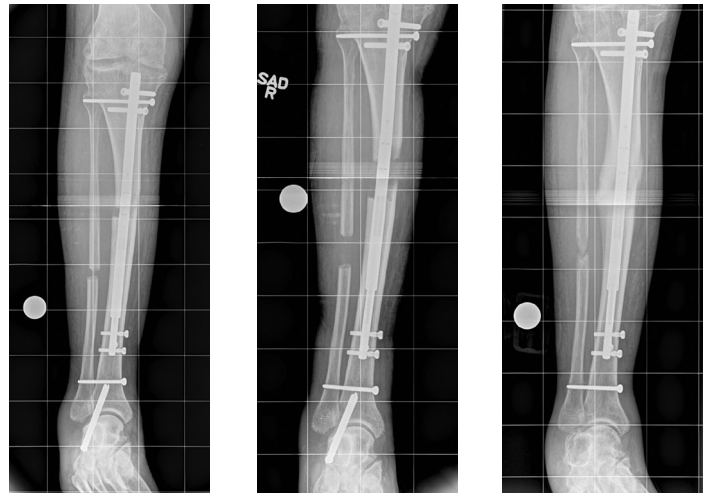
Increase to unrestricted full weight-bearing only after careful clinical and radiographic evaluation of the patient.

Full weight bearing is only permitted when there is solid healing of at least three out of four cortices on the A/P and lateral radiographs as determined by the physician.

If bone healing is delayed, consider using adjunctive measures such as ultrasound bone stimulation or bone grafting. Encourage the patient to maintain a healthy diet with adequate vitamin D and calcium. Consider measuring vitamin D levels and using supplements as needed.

Please refer to the Instructions for Use for the Stryde implant for additional information.

Antegrade Tibia



Note: The physician and his/her staff should train the patient on how to properly use the ERC. The ERC Operator's Manual (included with the ERC) may be referenced at any time for complete programming instructions.

In this example the extraarticular screw was removed at the end of the lengthening phase to allow ankle range of movement (ROM).

Postoperative Lengthening

External Remote Controller (ERC) Introduction

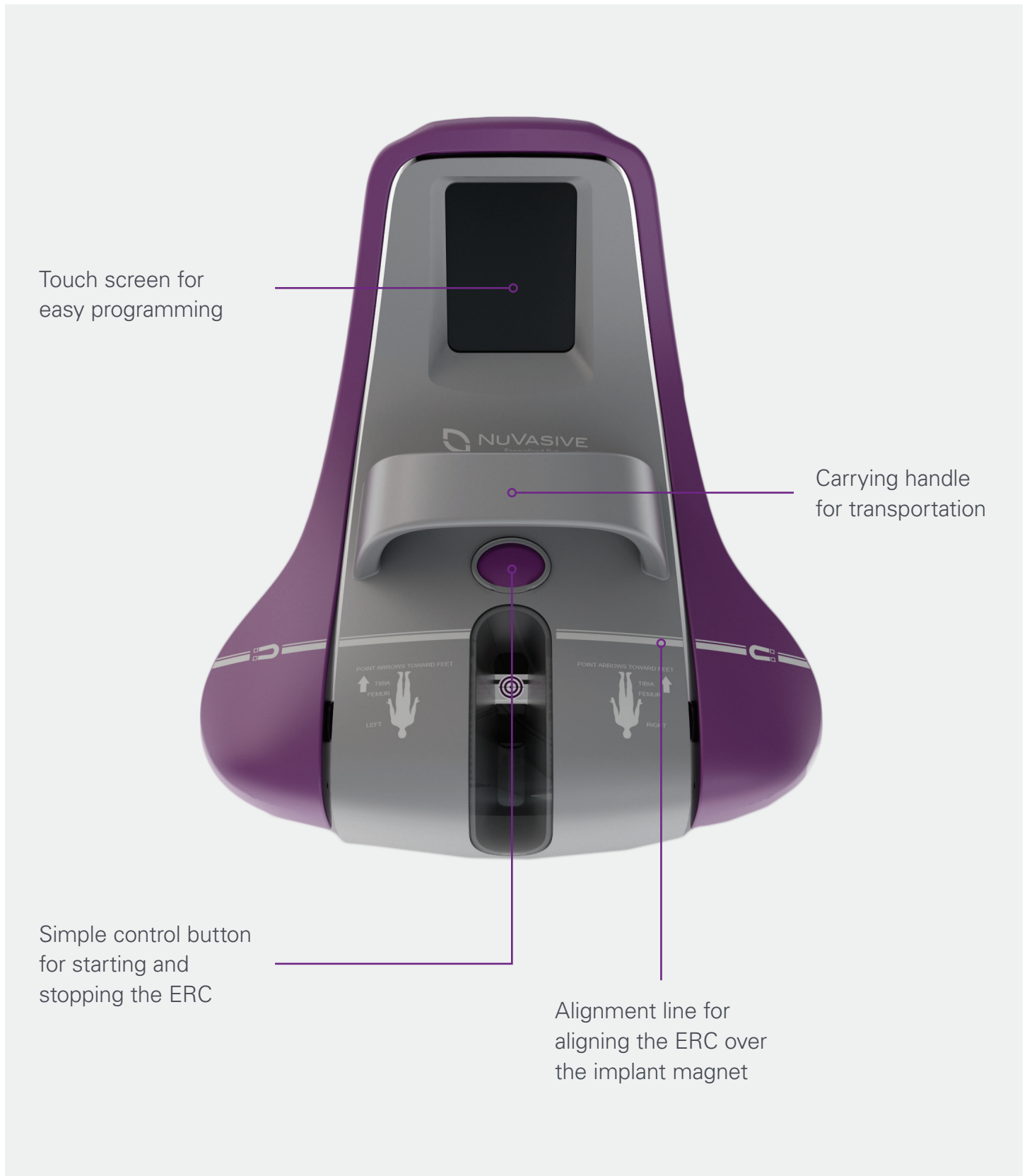
The ERC uses strong permanent magnets to distract the Stryde implant. The following are important considerations and precautions when using the ERC. For complete instructions, contraindications, warnings, and cautions please refer to the Operator's Manual.

- Weekly x-ray imaging to assess actual distraction length is recommended.
- Only use the External Remote Controller in a manner consistent with the Operator's Manual. Any alternative use may result in injury or damage to property.
- This equipment may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the External Remote Controller or shielding the location.
- Persons with a pacemaker or a similar medical aid should not handle or be exposed to the External Remote Controller. The strong magnetic fields may affect the operation of such devices.
- The External Remote Controller uses strong permanent magnets. Misuse of this system can cause serious personal injury. Make sure the work area is free of metal objects before use. This includes personal items such as jewelry, watches, keys, and cellular phones. Always return the system to its protective case when not in use.

- Only operate the External Remote Controller by holding onto both of the handles provided.
- The External Remote Controller may be pulled away from your hands if brought too close to other magnetic objects. Always maintain a firm grip on the External Remote Controller and be very aware of other objects in your work area. Also, tools or other hazardous objects may leap towards the External Remote Controller if brought too close.
- Never place the External Remote Controller near electronic media or appliances. The strong magnetic field may damage magnetic media such as floppy disks, credit cards, magnetic I.D. cards, cassette tapes, video tapes, or other such devices. It can also damage televisions, VCRs, computer monitors, and other CRT displays.
- This device has not been tested for compatibility in magnetic resonance imaging (MRI) environments and should not enter an MRI unit.



Features of the ERC3P



Implant Removal

Implant Removal

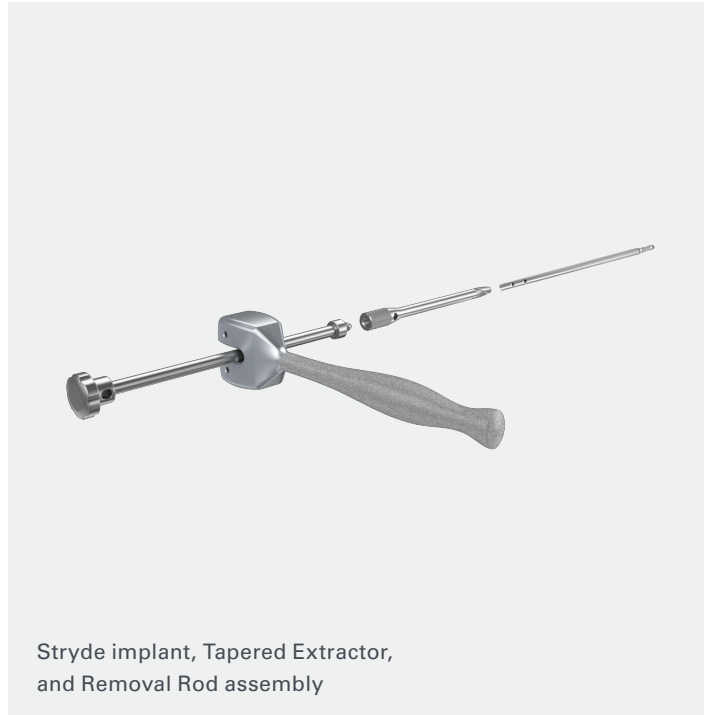
Stryde implant removal is recommended at 1 year provided radiological evidence of full bone consolidation is present. Each surgeon must determine the appropriate time for removal of the Stryde implant based upon their clinical evaluation of the patient.

Expose the proximal end of the implant by careful debridement of heterotopic bone and soft tissue.

Using the image intensifier, locate the proximal and distal locking screws. Make small incisions as required and remove the locking screws using the 3.5mm Solid Hex Driver and Quick Connect T-handle. Remove all but one of the locking screws prior to tightly threading the Tapered Extractor to the Stryde implant. If present, the End Cap must be removed prior to threading the Tapered Extractor into the Stryde implant.

Attach the Removal Rod to the Tapered Extractor, remove the final locking screw, and proceed with nail removal by gently backslapping the Slotted Mallet. Caution should be taken to avoid side loads and the mallet should always be held along the axis of force.

Perform skin closure with routine techniques.



Stryde implant, Tapered Extractor,
and Removal Rod assembly

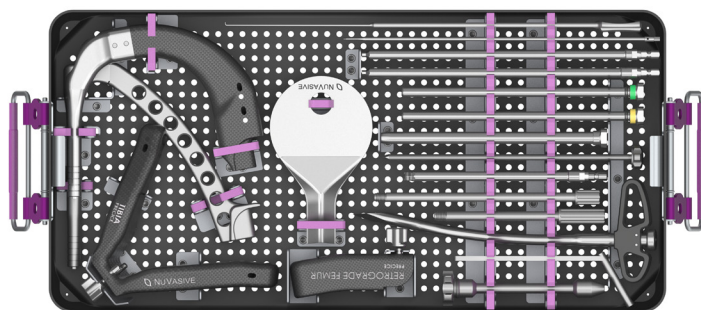
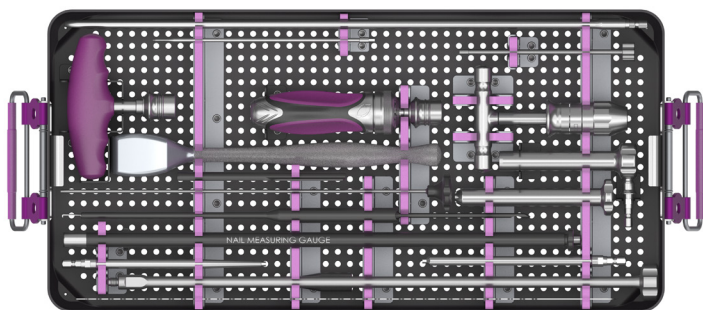
Tibial Limb Lengthening System

Approach Instrumentation (NGI2-000)

Description	Model #
Radiographic Ruler	XRR2-000
Soft Tissue Protector Tube	STS2-000
Honeycomb	HCB2-000
Mallet Null	RMB1-000
Fracture Reducer	FXR2-000
NuVa T-Handle, J-Hall	THD3-000
Guide Wire Chuck	GWC1-000
Nail Measuring Gauge	NMG1-000
Guide Wire Pusher	GWP2-000
3.5mm Screwdriver, Short Solid	SDS2-001
3.5mm Screwdriver, Short Cannulated	SDS2-000
Screw Capture Rod, Short	CRS1-000
Locking Key	LKL2-000
NuVa Handle, Straight Long Ratchet, J-Hall	HDL3-000
Direct Measuring Sleeve	DMS2-000
Screw Depth Gauge	SDG3-000
Tapered Extractor	CTA1-000
Removal Rod	RVR1-000

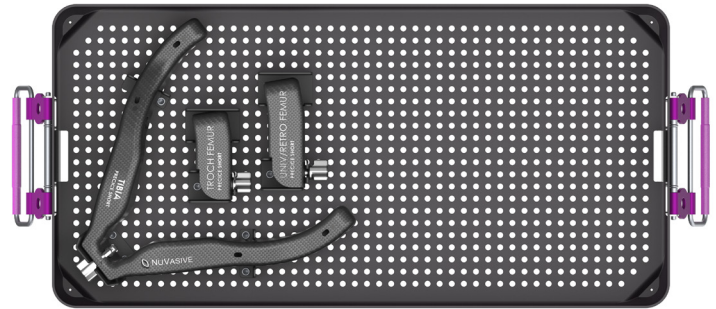
Aiming Instrumentation (NGI3-000)

Description	Model #
Guide Wire Sleeve	SET2-0001
Soft Tissue Protector - Paddle	STP1-000
Cannulated Awl	AWL2-010
Targeting Handle, Precice	PGH2-000
Locking Bolt	LBT3-000
Locking Bolt, Suprapatellar	LBT3-001
6mm Ball End Hex Driver	LBD2-001
6mm Straight Hex Driver	LBD3-001
Impactor	IMP3-000
Guide Tube	GTT2-000
Drill Sleeve	DST2-000
Drill Sleeve, 4.3mm	DST3-000
Targeting Handle, Suprapatellar	PGH2-001
Trocar	TCT2-000
Screw Depth Gauge Dipstick	DGT2-001
3.5mm Screwdriver, Long Cannulated	SDL2-000
3.5mm Screwdriver, Long Solid	SDL2-001
Capture Rod, Long	CRS2-000
Soft Tissue Protector	DSD2-035
Targeting Arm, Tibia, Precice	PGA1-000
Targeting Arm, Retro Femur, P2	PGA1-001



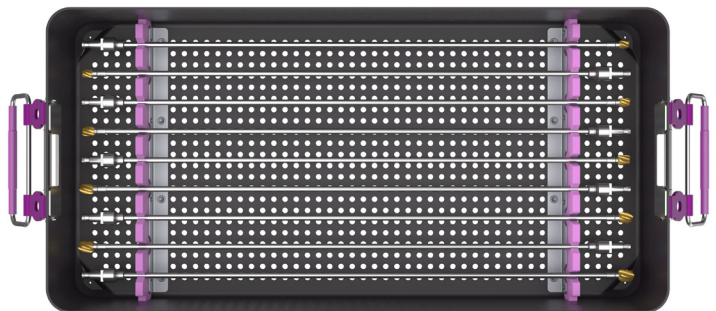
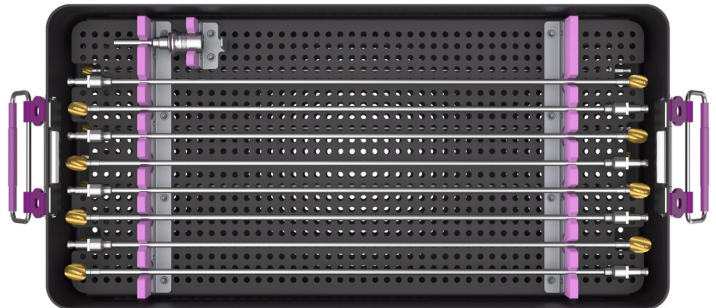
Auxiliary Instrumentation (NGI4-000)

Description	Model #
Targeting Arm Tibia Short / UNYTE	PGA1-002
Targeting Arm Femur Univ / Retro (Precice S)	PGA1-004
Targeting Arm Femur Trochanteric (Precice S)	PGA1-003



Flexible Reamer Set (SRT2-000)

Description	Model #
Flexible Reamer, 7.0mm	T18151
Flexible Reamer, 7.5mm	T18152
Flexible Reamer, 8.0mm	T18153
Flexible Reamer, 8.5mm	T18154
Flexible Reamer, 9.0mm	T18154
Flexible Reamer, 9.5mm	T12065
Flexible Reamer, 10.0mm	T12066
Flexible Reamer, 10.5mm	T12067
Flexible Reamer, 11.0mm	T12068
Flexible Reamer, 11.5mm	T12069
Flexible Reamer, 12.0mm	T12070
Flexible Reamer, 12.5mm	T12071
Flexible Reamer, 13.0mm	T12072
Flexible Reamer, 13.5mm	T18156
Flexible Reamer, 14.0mm	T18157
Flexible Reamer, 14.5mm	T18158
Flexible Reamer, 15.0mm	T18159
Hudson Quick Connect	LQC2-000



Antegrade Tibia – 10°

Length	Distraction	10mm	11.5mm
		Catalog #	Catalog #
235mm	50mm	PS10.0-50SJ235	PS11.5-50SJ235
250mm	65mm	PS10.0-65SJ250	PS11.5-50SJ250
265mm	80mm	PS10.0-80SJ265	PS11.5-50SJ265
280mm	80mm	PS10.0-80SJ280	PS11.5-50SJ280
305mm	80mm	PS10.0-80SJ305	PS11.5-50SJ305
335mm	80mm	PS10.0-80SJ335	PS11.5-50SJ335
365mm	80mm	PS10.0-80SJ365	PS11.5-50SJ365

Partially Threaded Locking Screws



4.0mm		4.5mm		5.0mm	
Catalog #	Length	Catalog #	Length	Catalog #	Length
STP4-200	20mm	STP4.5-200	20mm	STP5-200	20mm
STP4-225	22.5mm	STP4.5-225	22.5mm	STP5-225	22.5mm
STP4-250	25mm	STP4.5-250	25mm	STP5-250	25mm
STP4-275	27.5mm	STP4.5-275	27.5mm	STP5-275	27.5mm
STP4-300	30mm	STP4.5-300	30mm	STP5-300	30mm
STP4-325	32.5mm	STP4.5-325	32.5mm	STP5-325	32.5mm
STP4-350	35mm	STP4.5-350	35mm	STP5-350	35mm
STP4-375	37.5mm	STP4.5-375	37.5mm	STP5-375	37.5mm
STP4-400	40mm	STP4.5-400	40mm	STP5-400	40mm
STP4-425	42.5mm	STP4.5-425	42.5mm	STP5-425	42.5mm
STP4-450	45mm	STP4.5-450	45mm	STP5-450	45mm
STP4-475	47.5mm	STP4.5-475	47.5mm	STP5-475	47.5mm
STP4-500	50mm	STP4.5-500	50mm	STP5-500	50mm
STP4-550	55mm	STP4.5-550	55mm	STP5-550	55mm
STP4-600	60mm	STP4.5-600	60mm	STP5-600	60mm
STP4-650	65mm	STP4.5-650	65mm	STP5-650	65mm
STP4-700	70mm	STP4.5-700	70mm	STP5-700	70mm
STP4-750	75mm	STP4.5-750	75mm	STP5-750	75mm
-	-	STP4.5-800	80mm	STP5-800	80mm

Step Drill Bits



4.0mm	
Catalog #	Length
SDST-4.0	155mm



4.5mm	
Catalog #	Length
SDST-4.5	155mm



5.0mm	
Catalog #	Length
SDST-5.0	155mm



5.0mm	
Catalog #	Length
SDLO-5.0	340mm

Cannulated Entry Drill Bits



8.0mm	
Catalog #	Length
CED1-008	260mm

11.0mm	
Catalog #	Length
CED1-011	260mm

Sterile Wires and Misc. Disposables

Catalog #	Description
0101-900S	3.0 x 900mm Ball Tip Guide Wire
NU-S0100-000	3.2 x 330mm Threaded Pin
NU-S0110-000	3.2 x 330mm Trocar-Tip Pin
12-1874-12ST1	2.5 x 900mm Ball Tip Guide Wire (EMEA Only)
PFD1-000	Precice Fast Distractor
STRLBGPRG	ERC Sterile Bag



End Caps

10.0/11.5mm	
Length	Catalog #
0mm	SST-010-000
5mm	SST-010-005
10mm	SST-010-010
15mm	SST-010-015
20mm	SST-010-020



Important Safety Information

PRODUCT DESCRIPTION

The Stryde System is composed of an implantable intramedullary nail, locking screws, reusable instruments, and a hand-held External Remote Controller (ERC). The Stryde nail is a sterile single use device that is surgically implanted using the instruments and locking screws for osteoplasty lengthening utilizing distraction osteogenesis. The ERC is used daily after implantation to non-invasively lengthen or shorten the implant to a prescribed length.

INTENDED USE

The Precice Stryde System is intended for limb lengthening, open and closed fracture fixation, pseudoarthrosis, mal-unions, non-unions, or bone transport of long bones.

CONTRAINDICATIONS


- Infection or pathologic conditions of bone such as osteopenia which would impair the ability to securely fix the device.
- Patients with Gustilo open fracture Classification Grade IIIB or IIIC fractures
- Patients with pre-existing nerve palsies
- Metal allergies and sensitivities.
- Patients with an irregular bone diameter that would prevent insertion of the Precice Stryde nail.
- Patients in which the Precice Stryde nail would cross joint spaces or open epiphyseal growth plates.
- Patients in which there is an obliterated medullary canal or other conditions that tend to retard healing such as blood supply limitations, peripheral vascular disease or evidence of inadequate vascularity.
- Patients unwilling or incapable of following postoperative care instructions.

Please refer to the table below for contraindications with regard to weight and maximum distance of the treated limb to the surface of the intramedullary canal.

Limb	Precice Stryde Model	Nail Diameter	Maximum Distance of Treated Limb Surface to IM Canal	Maximum Patient Weight
Tibia	C, SJ	10.0	13	150lbs/69kg
		11.5	13	200lbs/91kg
		13.0	13	250lbs/114kg
Femur	A,B,D,E V, X	10.0	50	150lbs/69kg
		11.5	65	200lbs/91kg
		13.0	80	250lbs/114kg

WARNINGS

- The Precice Stryde nail cannot withstand the stresses of full weight bearing. Patients should utilize external support and/or restrict activities as directed by the physician until consolidation occurs.
- Patients with an open fracture resulting in limb length discrepancy may also have soft tissue damage as a result of severe trauma. It is important that soft tissue damage is addressed prior to lengthening to minimize the risk of infection.
- Limb lengthening also involved soft tissues; it is important to allow the soft tissue to heal prior to the lengthening procedure.
- Do not use if the sterile packaging has been damaged or appears to have been previously opened.

- Metallic implants can loosen, fracture, corrode, migrate, or cause pain.
- Due to the presence of a magnet, use of the Precice Stryde System is not recommended in patients with pacemakers.
- The Precice Stryde System may not be appropriate for patients with poly-trauma.
- Use of the Precice Stryde System in patients with an active infection of the treated bone is not recommended.
- Smoking, chronic steroid use and the use of other anti-inflammatory drugs have been determined to affect bone healing and could potentially have an adverse effect of the bone regenerate during the lengthening process.
- The Precice Stryde nail is supplied sterile and is for single-use only. The nail has not been tested to be cleaned or sterilized for multiple uses. If the nail is used more than once, the device may not be sterile and could cause a serious infection.
- Patients with implanted Precice Stryde nail should not enter an MRI unit.
 - 
- The Precice Stryde System is unsafe in Magnetic Resonance Imaging environments.
- The Precice Stryde Nail should be retracted only by a physician. Retraction should be monitored and confirmed using radiography.
- There is a possibility of nerve or soft tissue damage and/or weakness related to either surgical trauma or the presence of the implant. Advise the patient to notify the surgeon of any experienced pain, numbness, or weakness while undergoing treatment.

PRECAUTIONS

- Do not use this device without proper training in both device implantation and adjustment. Refer to External Remote Controller (ERC, ERC 2P, or ERC 3P) Operator's Manual (OM0005, OM0009, or OM0016) for operation of the External Remote Controller.
- During the distraction phase, patient should not participate in contact sports or other high risk activities that will cause a load to the treated limb in excess of the maximum patient weight, as identified in the contraindications.
- Examine all Precice Stryde System components carefully prior to use to assure proper working condition. If you suspect a component to be faulty or damaged, do not use.

CAUTIONS

- The Precice Stryde System is for prescription use only by the order of a physician.
- Device should be removed after implantation time of no more than one year.
- Utilize extreme caution when handling instruments made from magnetic materials such as stainless steel in proximity of the magnet of the Precice Stryde nail, as materials will be attracted to each other.
- After the surgical procedure is complete, if retraction is needed during the lengthening or consolidation phase, retract the device no more than the amount lengthened the preceding day. Failure to follow this caution may result in pulling biologic material that may have adhered to the rod into the internal space of the Nail.
- Do not bend the Precice Stryde nail or otherwise modify or damage the implant.
- Follow the ERC Operators Manual (OM0005, OM0009, or OM0016) to assure proper alignment between the ERC and magnet of the Precice Stryde nail.

Rx Only.

The Precice Stryde System is composed of an implantable intramedullary nail, locking screws, reusable instruments, and a hand-held External Remote Controller (ERC). The Stryde nail is a sterile single use device that is surgically implanted using the instruments and locking screws. The ERC is used daily after implantation to non-invasively lengthen or shorten the implant to a prescribed length. The Precice Stryde System is intended for limb lengthening of the femur and tibia. Contraindications include infection or pathologic conditions of bone such as osteopenia which would impair the ability to securely fix the device, metal allergies and sensitivities, patients whose distance from the surface of the treated limb to the intramedullary canal is greater than 80mm for the 13.0mm diameter implant, 65 mm for the 11.5 mm implant and 50mm for the 10.0mm diameter implant, patients with an irregular bone diameter that would prevent insertion of the Stryde nail, patients in which the Stryde nail would cross joint spaces or open epiphyseal growth plates, patients in which there are conditions that tend to retard healing such as blood supply limitations, peripheral vascular disease or evidence of inadequate vascularity, patients unwilling or incapable of following postoperative care instructions, 150lbs for the 10.0mm diameter implant, 200lbs for the 11.5mm diameter implant and 250lbs for the 13.0 mm implant. The implantable device is only to be used by a trained licensed physician. Please refer to the Precice Stryde System instructions for use for complete Important Safety Information.

 **NuVasive Specialized Orthopedics, Inc.**
101 Enterprise, Suite 100, Aliso Viejo, CA 92656 USA
+1 949.837.3600

 **NuVasive UK Ltd.**
Suite B, Ground Floor, Caspian House,
The Waterfront, Elstree, Herts WD6 3BS UK
+44 (0) 208.238.7850

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