Cerclage Passer. For minimally invasive application of cerclage cables.

Handling Technique Cable application





Table of Contents

Introduction	Cerclage Passer	
	Indications	4
	Clinical Cases	5
Surgical Technique	Preparation	6
	Surgical Steps	7
Product Information	Implants	15
	Instruments	16
	Sets	18
Bibliography		20
MRI Information		21



Image intensifier control

This description alone does not provide sufficient background for direct use of DePuy Synthes products. Instruction by a surgeon experienced in handling these products is highly recommended.

Processing, Reprocessing, Care and Maintenance

For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:

http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance For general information about reprocessing, care and maintenance of Synthes reusable devices, instrument trays and cases, as well as processing of Synthes non-sterile implants, please consult the Important Information leaflet (SE_023827) or refer to:

http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

Cerclage Passer. For minimally invasive application of cerclage cables.

Overview

Techniques for the treatment of periprosthetic fractures and other indications often include the application of cerclage cables. The Cerclage Passer Instrument Set contains the additional instruments needed for minimally invasive procedures.

Modular set configuration

The cerclage passer can be used for the minimal invasive application of cerclage cables. The modular case concept allows storage of the relevant instruments on modular instrument trays.

Note: Set does not include implants

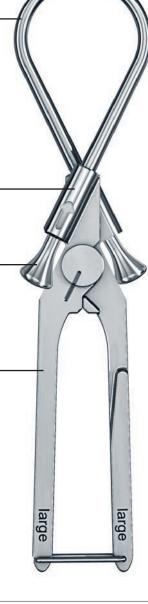
Cerclage Passer

Available in two sizes (diameter 46 mm and 60 mm) adapted to anatomy.

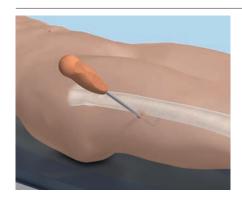
Allow passage of cable around the bone through small approach.

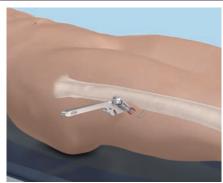
One size trocar is compatible with both cerclage passer sizes.

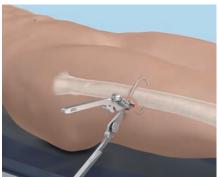
Designed as two separate halves to facilitate sequential insertion through one incision.



Quick Step Surgical Technique



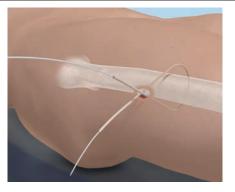


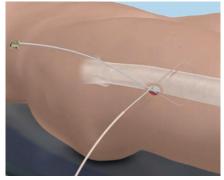


Cerclage Tunneling Device

Prepares the way and facilitates the passage of the cerclage passer. Available in two sizes that correspond with the bending diameter of the cerclage passer.







Indications

For general orthopedic trauma surgery involving the application of cerclage cables

- Periprosthetic fractures of the femur
- Subtrochanteric fractures
- Hip and knee prostheses
- Additional fixation
- Temporary reduction

Clinical Cases

78 year old female with AO 32-A1.1 fracture





Preoperative

Postoperative

72 year old female with AO 32-A1.2 fracture



Preoperative



Postoperative

Preparation

1

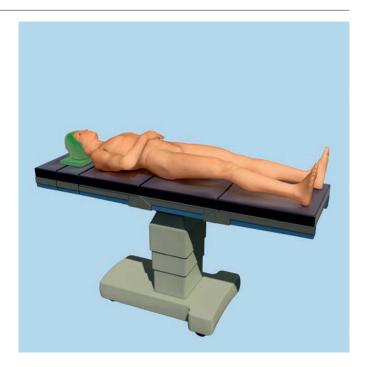
Preparation

Set	
01.221.100 Instrument Set for minimally invas Cable Cerclage	
Optional set	
188.215 Cable System in Vario Case	
Implants	
x98.80x.01	Cerclage Cables with Crimp

Precaution: Application of cerclage cables using a minimally invasive (MIS) technique requires a keen understanding of the neurovascular anatomy.

Complete a preoperative radiographic assessment and prepare the preoperative plan. Position the patient according to the respective fracture requirements on a radiolucent operating table.

Complete the closed reduction with traction to minimize anatomic distortion.



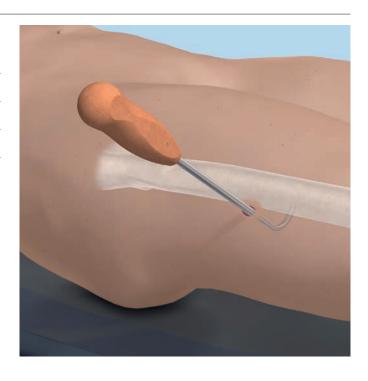
2

Incision and preparation of soft tissue tunnel

Instruments	
03.221.002	Cerclage Tunneling Device, \varnothing 46 mm
03.221.004	Cerclage Tunneling Device, ∅ 60 mm

Choose the appropriate size cerclage tunneling device for the field of application and the fracture. Make an incision and carefully insert the tunneling device over the periosteum from ventral and dorsal around the bone. Make an incision in the skin and fascia approximately $4-5\,\mathrm{cm}$ wide to avoid tension. Ensure the cerclage tunneling device perforates the fascia directly adjacent to the linea aspera on the dorsal femur.

Preparation of the tunnel is necessary to facilitate the following insertion of the cerclage passer.



Surgical Steps

1 Insertion of cerclage passer

Instruments	
03.221.010	Cerclage Passer, \varnothing 46 mm, minimally invasive
03.221.011	Cerclage Passer, \varnothing 60 mm, minimally invasive
03.221.003	Trocar, for Cerclage Passer Nos. 03.221.010 and 03.221.011

Put one trocar in each tube of the cerclage passer. This prevents soft tissue from entering the cannulated tubes of the cerclage passer. The posterior and anterior cerclage passer handles should be passed through the soft-tissue tunnel created by the cerclage tunneling device. Keep contact with the bone all the time.

Precaution: To prevent damage do not apply too much force while inserting the cerclage passer. Deformation of the tubes can result in non-closure of the instrument when connecting the halves.

Place the cerclage passer handles directly adjacent to the bone surface to connect the two handle halves. Where possible, use the smaller cerclage passer. Make sure the instrument is close to the bone.

Precaution: When the cerclage passer is in use, pay attention to the sterile field.



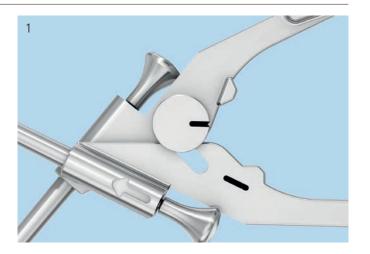


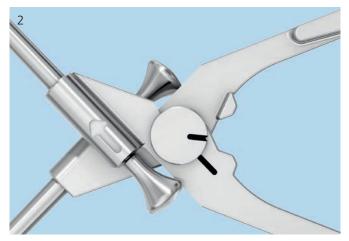
2 Connection and closure of cerclage passer

To connect the two parts of the cerclage passer, slide the notch of one half into the corresponding part of the other half (1, 2).

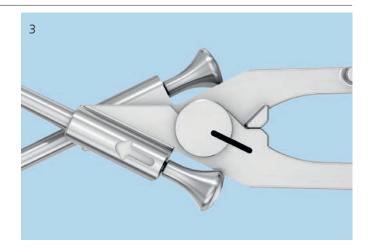
Precaution: While connecting the two parts, the tips must not meet. Do not attempt to close the forceps as long as the middle of the forceps is not connected properly.

The markings on each half ("small", "large") can be used for orientation. When the forceps are connected together, the markings will appear in the same direction.





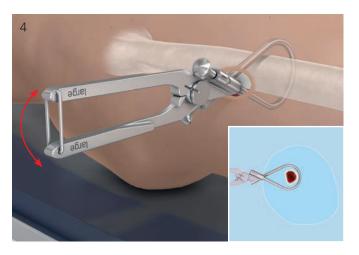
Once the two connecting parts have been brought together, close the forceps until the markings on the two halves are aligned and form a line (3). The tips of the cannulated tubes will then meet and form a passageway for the cable.



Secure the closed cerclage passer by locking the bracket (4). Remove the trocars.

Note: Open and close the bracket by pressing the ends of the handles slightly together. Closed correctly, the bars of the cerclage passer forceps are parallel. The correctly closed position of the cerclage passer can be controlled by moving it up and down or using image intensifier control.

Warning: When closing the cerclage passer, be careful not to damage any soft-tissue structures. Where necessary, enlarge the approach to verify that no soft-tissue structures (mainly the neurovascular structures) are being damaged. Never push the handles medial to bring the halves together; instead, pull them towards the medial cortex. The clamping should be performed without force.



3 Insertion of cable passing tube

Instrument

03.221.012S Cable Passing Tube, length 400 mm, sterile

Push the cable passing tube through the tube of the closed cerclage passer. The only correct direction for insertion is marked by an arrow.

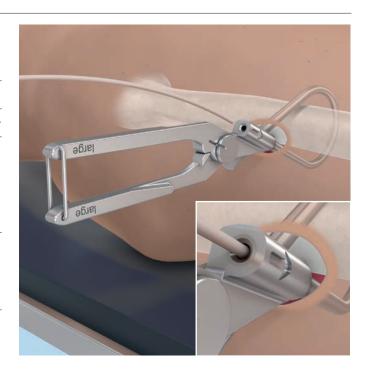
Note: It is not possible to pass a pre-assembled cerclage cable without cable passing tube. The crimp at the beaded end of the cable allows no direct passage through the cerclage passer.

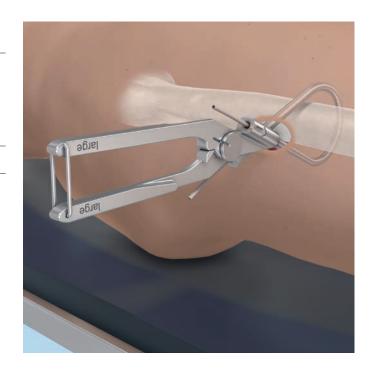
The cable passing tube is for single use only and must not be reprocessed or resterilized.

Precaution: Do not use pliers for cable passing tube insertion due to tube damages. The cable passing tube must exit the opposite part of the cerclage passer.

Do not open the cerclage passer when the cable passing tube is in use. The ends of the cerclage passer might cut the cable passing tube.

Note: For better insertion bevel the cable passing tube.





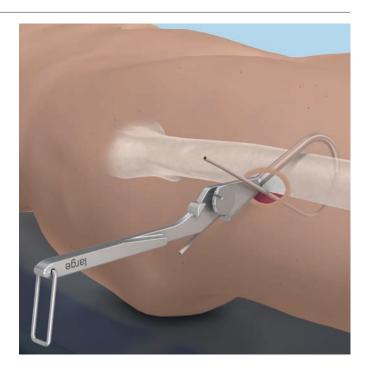
4

Remove cerclage passer forceps

Unlock the forceps by opening the bracket.

Disconnect the two halves of the cerclage passer forceps and remove the half with arrow.

Be sure that the inserted cable passing tube stays around the bone. Hold the opposite end of the cable passing tube by hand.



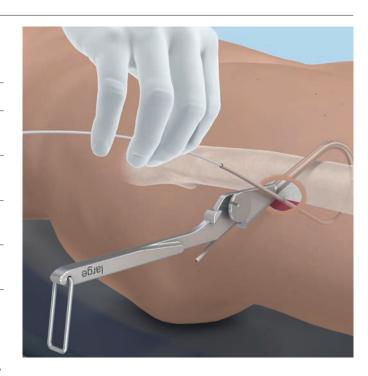
5 Insert cable through cable passing tube

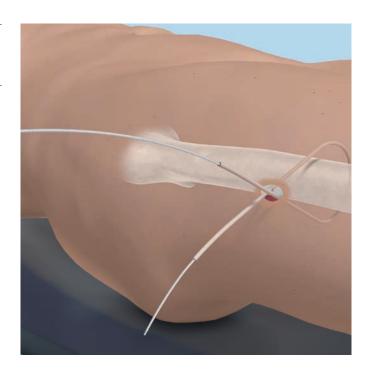
Implants	
298.800.01	Cerclage Cable with Crimp \varnothing 1.0 mm, Stainless Steel
298.801.01	Cerclage Cable with Crimp \varnothing 1.7 mm, Stainless Steel
498.800.01	Cerclage Cable with Crimp \varnothing 1.0 mm, Titanium Alloy (TAN)
498.801.01	Cable with Crimp Ø 1.7 mm, Titanium Alloy (TAN)

Select the cable according to the application and fracture.

Push the end without bead through the cable passing tube without the cerclage passer until the cable exits. Remove the other half of the cerclage passer.

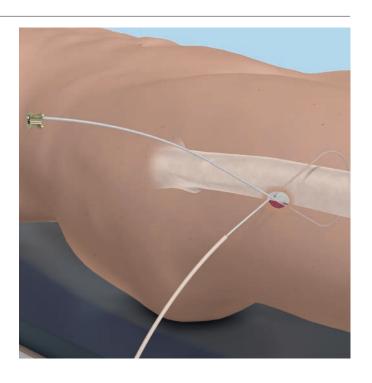
Precaution: If the cerclage cable is used in contact with other implants (e.g. LCP broad curved plate), consider the correct combination of metals.

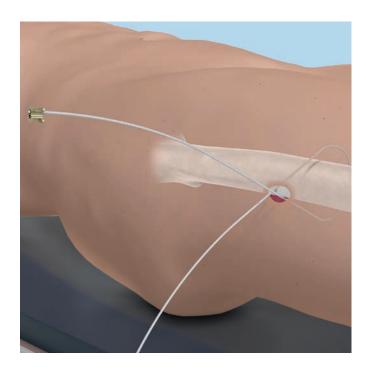




6 Remove cable passing tube

Remove the cable passing tube by pulling it over the end without bead. Take care that the inserted cable stays around the bone.





7

Tightening and fixation of cable

For further procedure, please refer to the Cable System technique guide (036.000.371) page 8, step 4A.

8

Cut cable

Instrument

03.607.513 Front Cutter

Cut the loose end of the cable using the front cutter. Position the cutting jaws very close to the crimp, and make the cut in one action to produce a clean cut. Ensure that the adjacent cerclage cables do not get damaged.

Implants

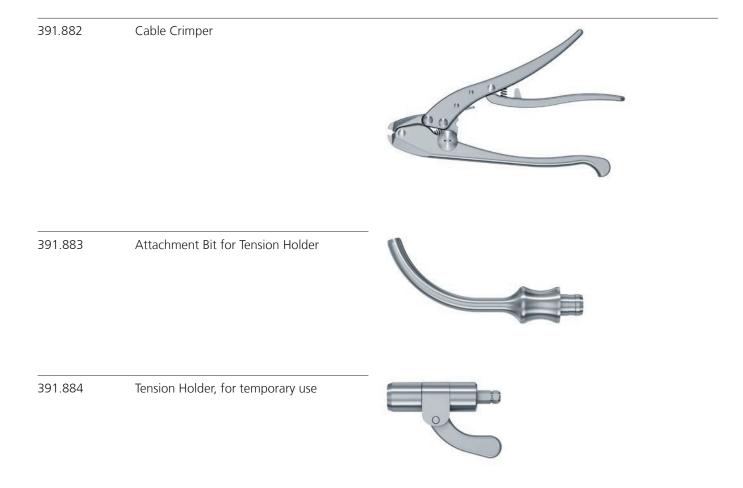
Cerclage Cable with Crimp \varnothing 1.0 mm, Stainless Steel
Cerclage Cable with Crimp \varnothing 1.7 mm, Stainless Steel
Cerclage Cable with Crimp Ø 1.0 mm, Titanium Alloy (TAN)
Cable with Crimp Ø 1.7 mm, Titanium Alloy (TAN)



For additional implants please refer to the Cable System technique guide (036.000.371), page 32.

Instruments

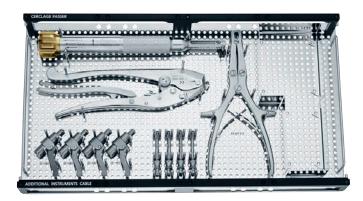
03.221.010	Cerclage Passer ∅ 46 mm, minimally invasive	small
03.221.011	Cerclage Passer Ø 60 mm, minimally invasive	large
03.221.003	Trocar, for Cerclage Passer Nos. 03.221.010 and 03.221.011	····
03.221.002	Cerclage Tunneling Device Ø 46 mm	
03.221.004	Cerclage Tunneling Device ∅ 60 mm	
03.607.513	Front Cutter	
391.201	Cable Tensioner	
03.221.0125	Cable Passing Tube, length 400 mm, sterile	



Sets

01.221.100	Instrument Set for minimally invasive Cable Cerclage		
68.221.100	Tray for Standard Instruments for minimally invasive Wire and Cable Cerclage		
03.221.002	Cerclage Tunneling Device Ø 46 mm		
03.221.010	Cerclage Passer Ø 46 mm, minimally invasive		
03.221.004	Cerclage Tunneling Device Ø 60 mm		
03.221.011	Cerclage Passer \varnothing 60 mm, minimally invasive		
03.221.003	Trocar, for Cerclage Passer Nos. 03.221.010 and 03.221.011		
68.221.130	Tray for Additional Instruments for minimally invasive Cable Cerclage		
391.201	Cable Tensioner		
391.882	Cable Crimper		
391.883	Attachment Bit for Tension Holder		
391.884	Tension Holder, for temporary use		
03.607.513	Front Cutter		
03.221.0125	Cable Passing Tube, length 400 mm, sterile		





Additionally available in sterile

03.221.012S Cable Passing Tube, length 400 mm, sterile

Additionally available

68.221.120	Labelling Plate for Instrument Set for minimally invasive Cerclage, for Vario Case
68.000.101	Lid for Modular Tray, size 1/1
519.400	Cleaning Brush, for Compact Air Drive, Power Drive and Colibri

Vario Case components

689.507	Lid (Stainless Steel), size 1/1, for Vario Case
689.510	Vario Case, Framing, size 1/1, height 126 mm

Bibliography

Schmidt AH, Kyle RF (2002) Periprosthetic fractures of the femur. Orthop Clin North Am: 143–152

Tong G, Bavonratanavech S (2006) Minimally Invasive Plate Osteosynthesis (MIPO): Concepts and cases presented by the AO East Asia

MRI Information

Torque, Displacement and Image Artifacts according to ASTM F 2213-06, ASTM F 2052-06e1 and ASTM F2119-07

Non-clinical testing of worst case scenario in a 3 T MRI system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 3.69 T/m. The largest image artifact extended approximately 169 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a 3 T MRI system.

Radio-Frequency-(RF-)induced heating according to ASTM F2182-11a

Non-clinical electromagnetic and thermal testing of worst case scenario lead to peak temperature rise of 9.5 °C with an average temperature rise of 6.6 °C (1.5 T) and a peak temperature rise of 5.9 °C (3 T) under MRI Conditions using RF Coils [whole body averaged specific absorption rate (SAR) of 2 W/kg for 6 minutes (1.5 T) and for 15 minutes (3 T)].

Precautions: The above mentioned test relies on non-clinical testing. The actual temperature rise in the patient will depend on a variety of factors beyond the SAR and time of RF application. Thus, it is recommended to pay particular attention to the following points:

- It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations.
- Patients with impaired thermo regulation or temperature sensation should be excluded from MR scanning procedures.
- Generally it is recommended to use a MR system with low field strength in the presence of conductive implants.
 The employed specific absorption rate (SAR) should be reduced as far as possible.
- Using the ventilation system may further contribute to reduce temperature increase in the body.



