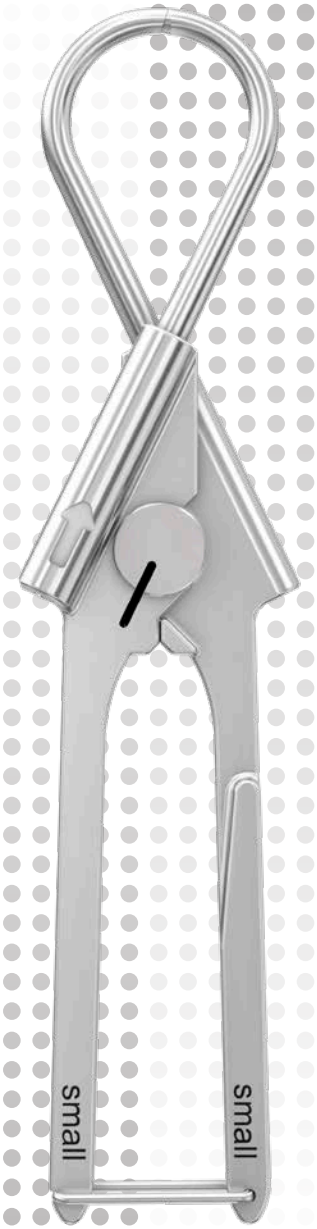
Cerclage Passer

For Minimally Invasive Application of Cerclage Wire

Surgical Technique



AO approved by AO Technical Commission

DePuy Synthes
THE ORTHOPAEDICS COMPANY OF Johnson & Johnson

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

Table of Contents

■ **Notes**
▲ **Precautions**
▲ **WARNINGS**

Cerclage Passer

For minimally invasive application of cerclage wires

Overview

Techniques for the treatment of indicated fractures often includes the application of cerclage wires. The cerclage passer instrument set contains the additional instruments needed for minimally invasive procedures.

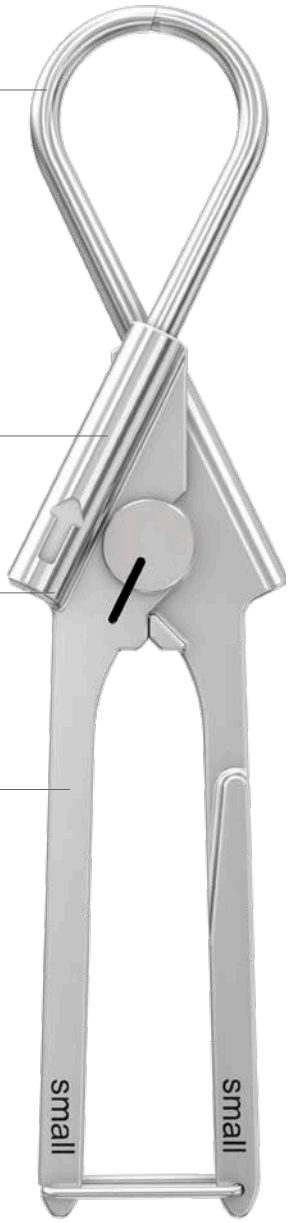
Modular set configuration

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

■ Note:

Set does not include implants.

Cerclage Passer



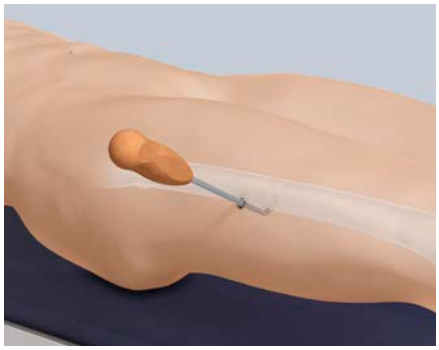
Available in two sizes (diameter 46 mm and 60 mm) adapted to anatomy.

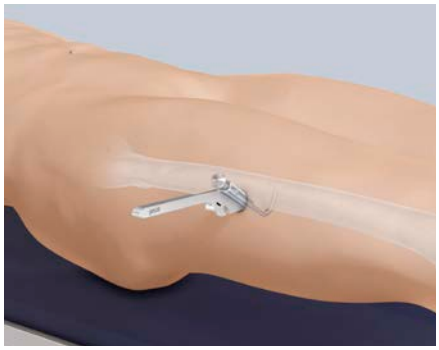
Allow passage of wire around the bone.

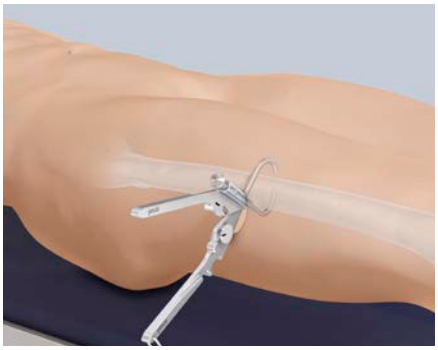
One size trocar is compatible with both cerclage passer sizes.

Two separate halves to facilitate sequential insertion through one incision.

Quick Step Surgical Technique

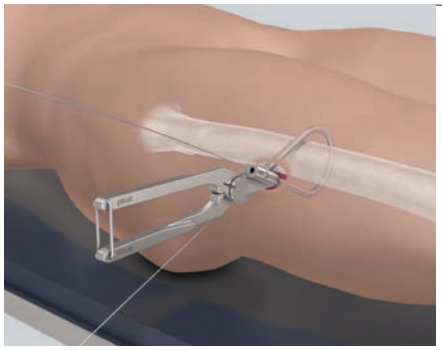


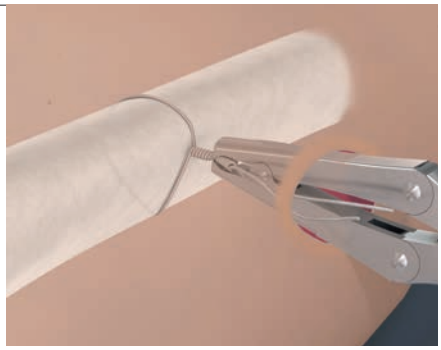




Cerclage Tunneling Device

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





The AO Principles of Fracture Management

Mission

The AO's mission is promoting excellence in patient care and outcomes in trauma and musculoskeletal disorders.

AO Principles[1,2]

1.

Fracture reduction and fixation to restore anatomical relationships.

2.

Fracture fixation providing absolute or relative stability, as required by the "personality" of the fracture, the patient, and the injury.

3.

Preservation of the blood supply to soft-tissues and bone by gentle reduction techniques and careful handling.

4.

Early and safe mobilization and rehabilitation of the injured part and the patient as a whole.

[1] Müller ME, Allgöwer M, Schneider R, Willenegger H. Manual of Internal Fixation. 3rd ed. Berlin, Heidelberg New York: Springer 1991.
[2] Buckley RE, Moran CG, Apivatthakakul T. AO Principles of Fracture Management: 3rd ed. Vol. 1: Principles, Vol. 2: Specific fractures. Thieme; 2017.

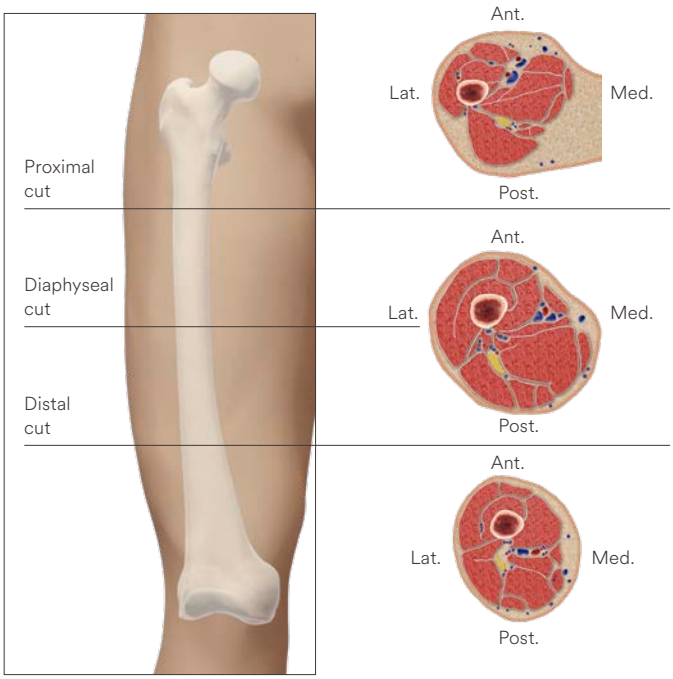
Preparation

1. Preparation

Set	
01.221.000	Instrument Set for minimally invasive Wire Cerclage
Optional set	
107.920	Wire Instrument Set in Sterilization Tray
Implants	
291.044 – 291.130	Coil with Cerclage Wire, different diameters

▲ Precaution:

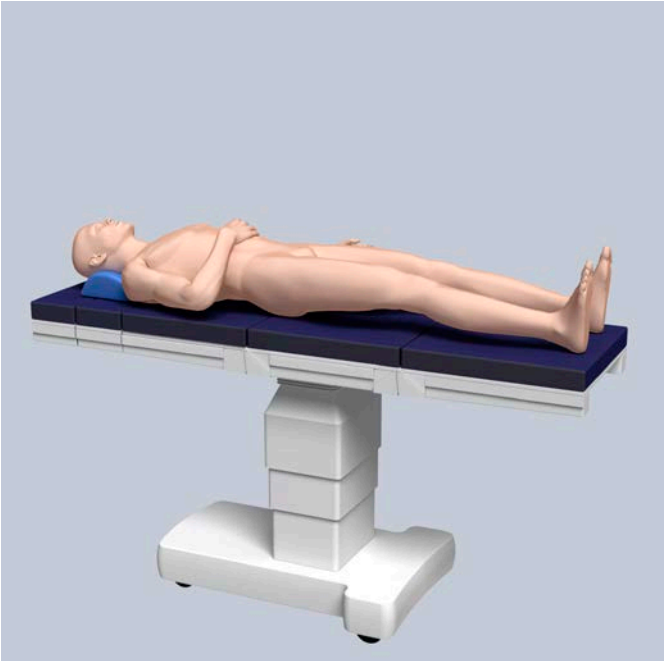
Application of cerclage wires using a minimally invasive (MIS) technique requires a keen understanding of the neurovascular anatomy.



Visualization of the neurovascular femur anatomy

1. 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 reduce anatomic distortion.

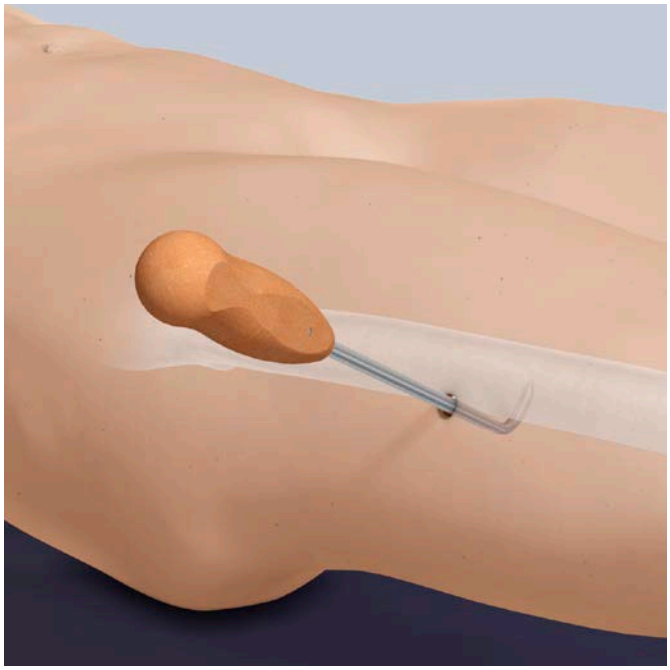


2. Incision and preparation of soft tissue tunnel

Instruments	
03.221.002	Cerclage Tunneling Device, ∅ 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 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, minimally invasive, ∅ 46 mm
03.221.011	Cerclage Passer, minimally invasive, ∅ 60 mm
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 may prevent 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:

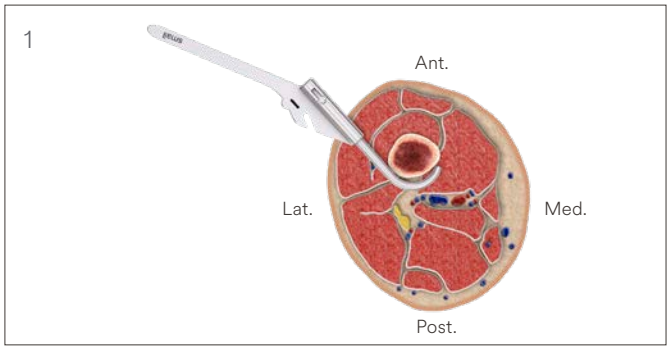
To prevent damage do not apply too much force while inserting the cerclage passer. Deformation of the tubes can result in non-closure of the instrument when connecting the halves.

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.

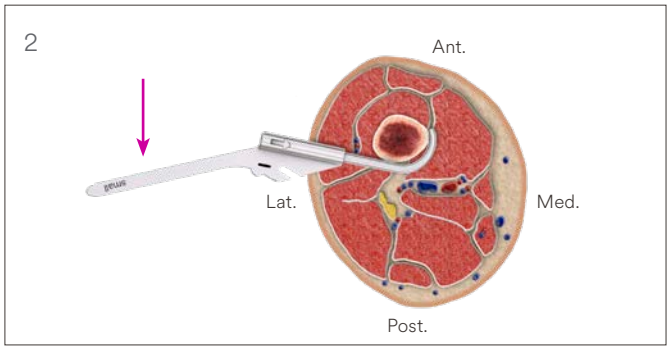
▲ Precaution:

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

Use the techniques in figures 1 and 2 to apply the cerclage passer to the distal femur. In the proximal femur the anterior handle is inserted first.



Insert posterior handle first.



Push the handle down to move the tip away from the vessels.

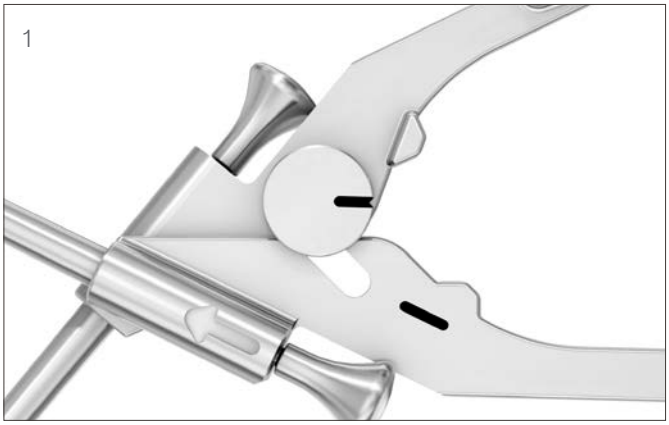
2. Connection and closure of the cerclage passer

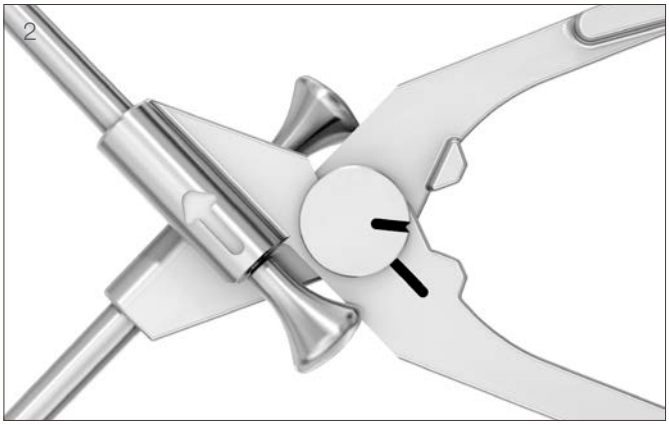
To connect the two parts of the cerclage passer, slide the notch of one half into the corresponding part of the other half. (1, 2)

▲ Precaution:

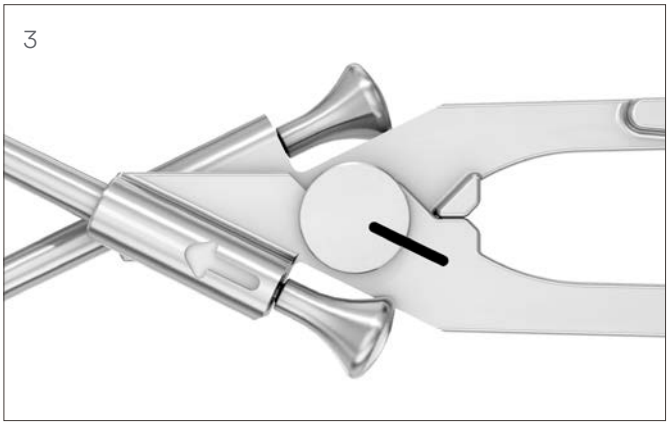
While connecting the two parts, the tips must not meet. Do not attempt to close the forceps as long as the middle of the forceps is not connected properly.

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.

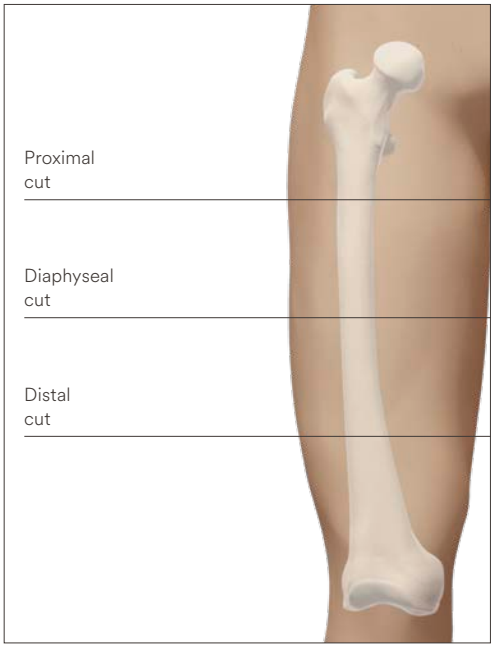




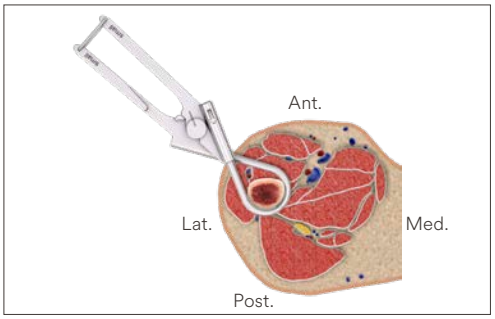
Once the two connecting parts have been brought together, close the forceps until the markings on the two halves are aligned and form a line (3). The tips of the cannulated tubes will then meet and form a passageway for the wire.



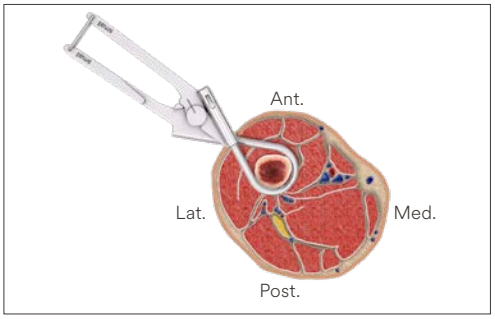
To insert the cerclage passer, use the corresponding technique per femur segment. Maintain contact with the bone throughout the procedure.



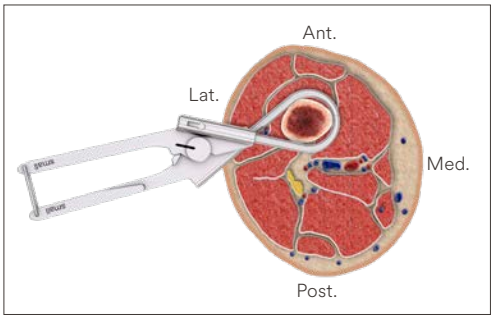
Proximal cut: Lift the handle to close instrument posteriorly.



Diaphyseal cut: Lift the handle to close instrument posteriorly.



Distal cut: Push the handle down to move the tip away from the vessels.



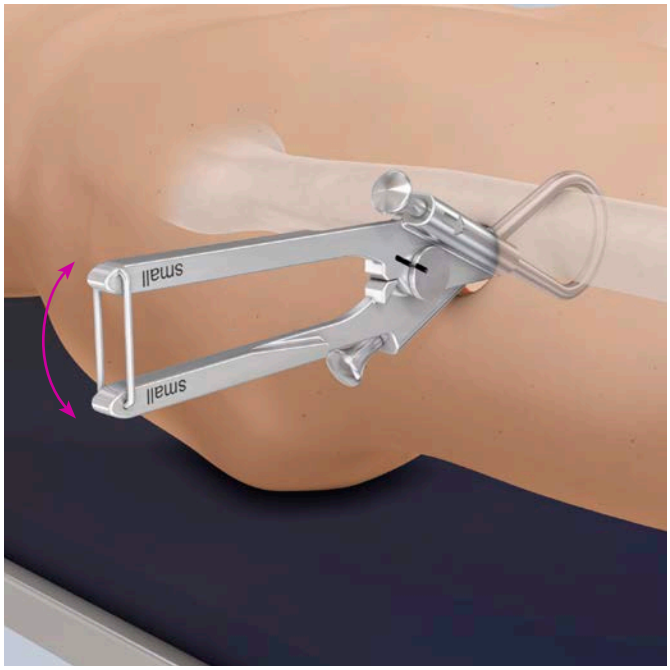
Secure the closed cerclage passer by locking the bracket. Remove the trocars.

■ 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.

▲ Precaution:

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. Close the forceps without using force.



3. Insertion of cerclage wire

Instruments	
391.963	Universal Bending Pliers

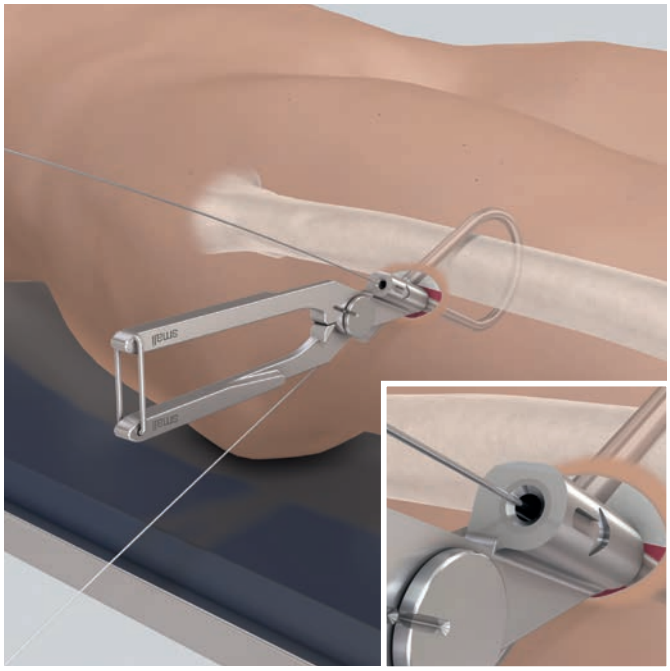
Prepare a cerclage wire in the desired length. The only correct direction for insertion is marked by an arrow.

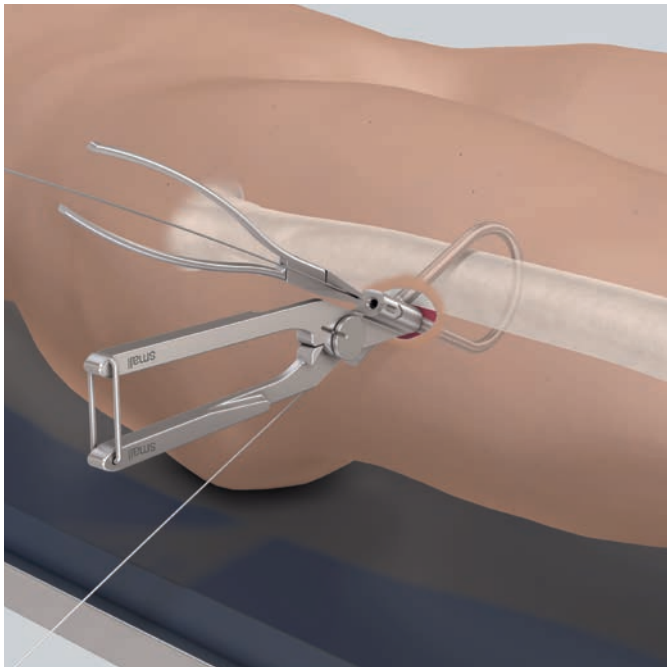
Push the cerclage wire through the tube of the closed cerclage passer.

The use of pliers (e.g. Universal Bending Pliers) can be useful for wire insertion. Insert step by step to reduce kinking of the wire. The wire must be out of the opposite part of the cerclage passer.

▲ Precaution:

The correct material composition is important. Use a Stainless Steel wire only with Stainless Steel implants.



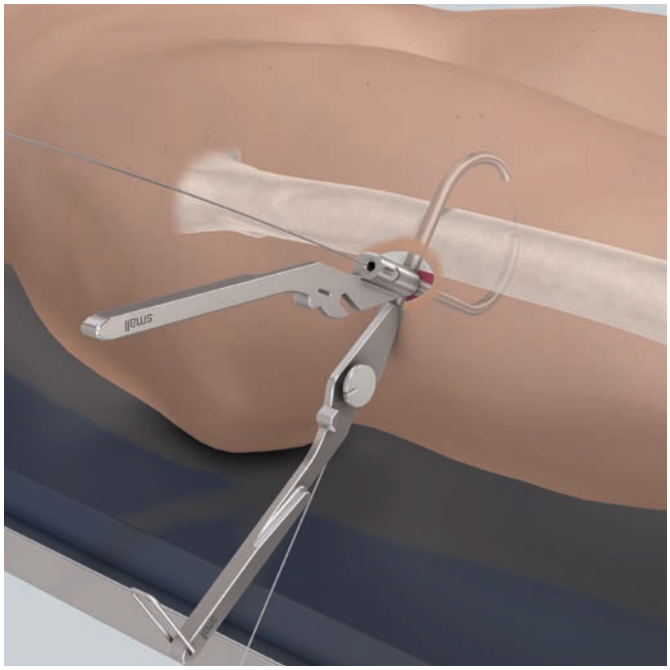


4. Removal of Cerclage Passer forceps

Unlock the forceps by opening the bracket.

Disconnect the two halves of the cerclage passer forceps and remove one half after the other.

Be sure that the inserted cerclage wire stays around the bone. Hold the opposite end of the wire.



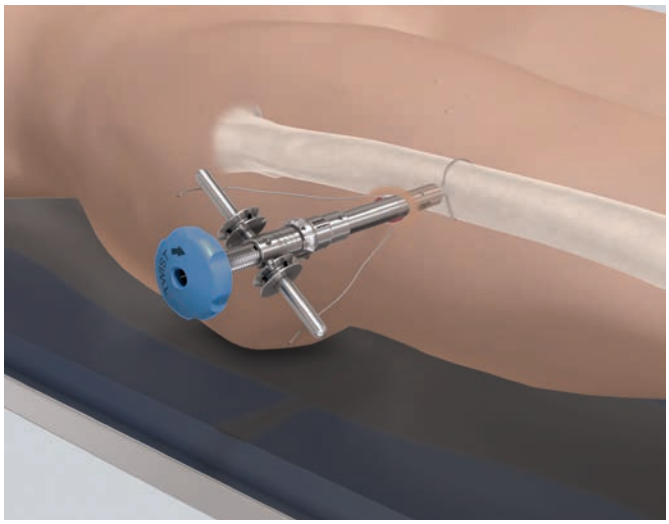
5. Tightening and fixation

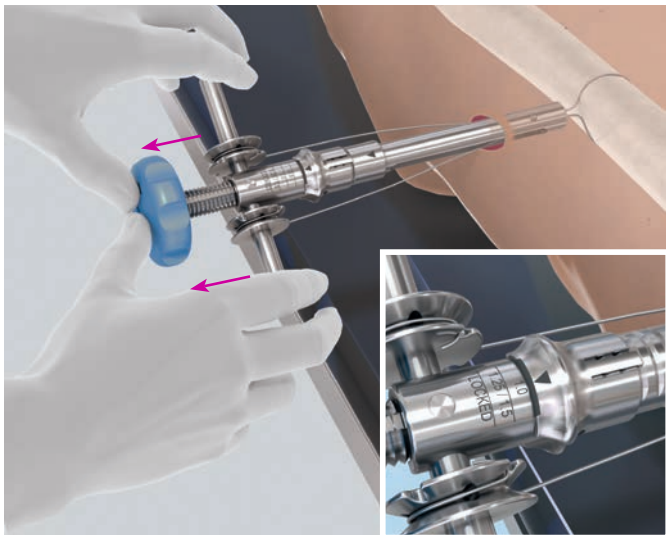
Instruments	
03.221.001	Cerclage Twister
03.607.513	Front Cutter

Insert the cerclage wire through the lower opening of the Cerclage Twister, with the bar separating the two ends of the cerclage wire.

The handle has to be positioned in the middle of the threaded section. Do not set the wire diameter of the Cerclage Twister. The tip of the Cerclage Twister should be close to the bone. Tighten the Cerclage wire and wind it around the handle. Take care that the cerclage wire does not obstruct the sleeve.

Apply pre-tension by pulling the handle back to the blue knob. Adjust the wire diameter on the corresponding scale of the Cerclage Twister by sliding the tip of the arrow towards the numbers.





Turn the Cerclage Twister clockwise until the ratchet clicks 2 to 3 times or the desired tension is achieved.

■ Note:

While turning the Cerclage Twister, the whole twister device will turn.

▲ WARNING:

Be careful to apply less tension in osteoporotic bone.

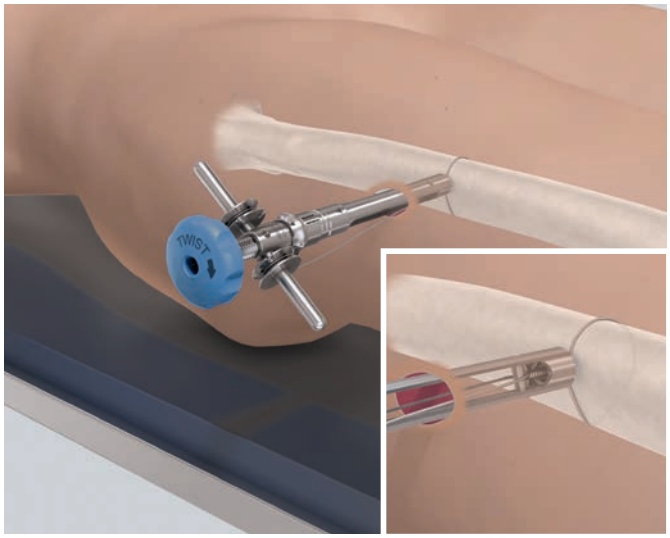
Using the Front Cutter, cut the cerclage wire near the handle and pull out the Cerclage Twister.

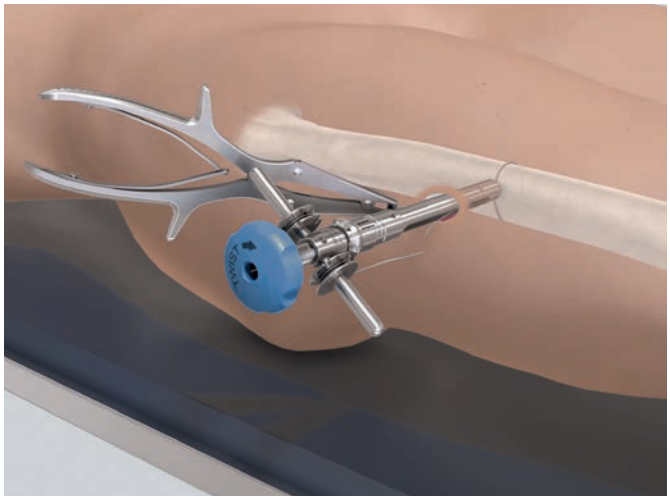
Slide with the Front Cutter along the cerclage wire and cut it near the bone. Use the front end of the Front Cutter to bend the twisted end of the cerclage wire to the bone.

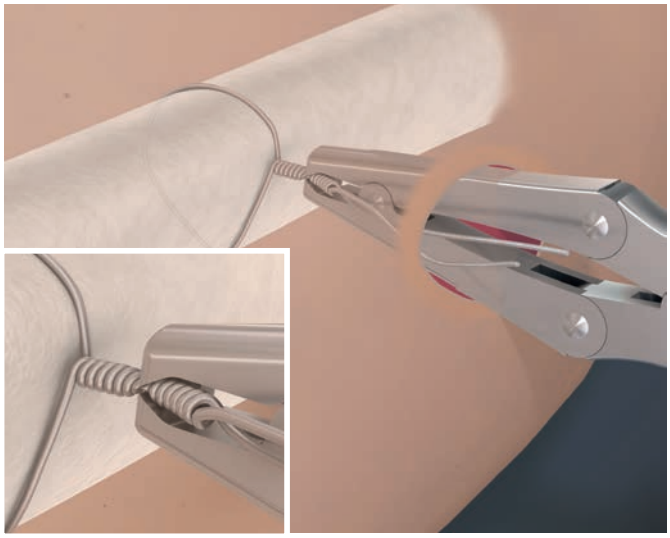
Alternative Technique: Slide with the Front Cutter along the cerclage wire and bend the twisted end to the bone. Cut the wire.

▲ Precaution:

Make sure to cut the wire close to the crimp and in one action to avoid sharp edges.







Implant Removal

In case the physician decides to remove the implants, implants can be removed by using general surgical instruments.

Implants

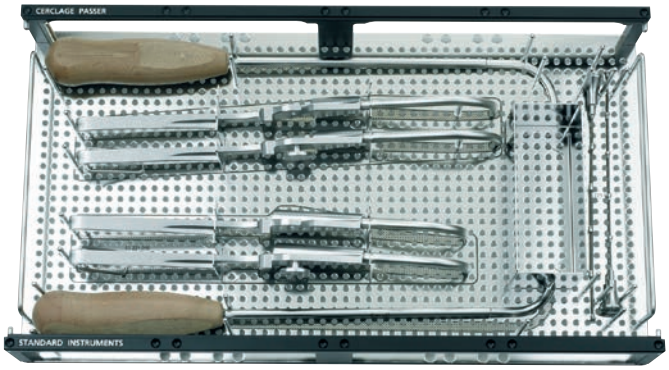
291.044	Coil with Cerclage Wire ∅ 0.4 mm, length 8 m, Stainless Steel
291.050	Coil with Cerclage Wire ∅ 1.0 mm, length 10 m, Stainless Steel
291.060	Coil with Cerclage Wire ∅ 1.25 mm, length 10 m, Stainless Steel
291.070	Coil with Cerclage Wire ∅ 0.6 mm, length 8 m, Stainless Steel
291.090	Coil with Cerclage Wire ∅ 0.8 mm, length 10 m, Stainless Steel
291.130	Coil with Cerclage Wire ∅ 1.5 mm, length 10 m, Stainless Steel

Instruments

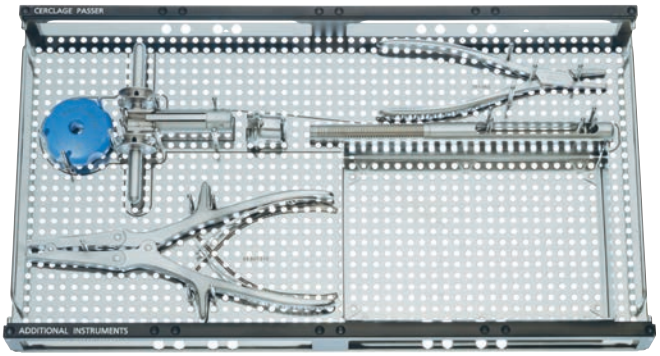
03.221.010	Cerclage Passer, minimally invasive, ∅ 46 mm	
03.221.011	Cerclage Passer, minimally invasive, ∅ 60 mm	
03.221.003	Trocar, for Cerclage Passer Nos. 03.221.010 and 03.221.011	
03.221.002	Cerclage Tunneling Device ∅ 46 mm	
03.221.004	Cerclage Tunneling Device ∅ 60 mm	
03.607.513	Front Cutter	
03.221.001	Cerclage Twister	
391.963	Universal Bending Pliers	

Sets

01.221.000	Instrument Set for minimally invasive Wire Cerclage
68.221.100	Tray for Standard Instruments for minimally invasive Wire and Cable Cerclage
03.221.002	Cerclage Tunneling Device ∅ 46 mm
03.221.010	Cerclage Passer, minimally invasive, ∅ 46 mm
03.221.004	Cerclage Tunneling Device ∅ 60 mm
03.221.011	Cerclage Passer, minimally invasive, ∅ 60 mm
03.221.003	Trocar, for Cerclage Passer



68.221.110	Tray for Additional Instruments for minimally invasive Wire Cerclage
03.221.001	Cerclage Twister
03.607.513	Front Cutter
391.963	Universal Bending Pliers



Additionally available

68.221.120	Labelling Plate for Instrument Set for minimally invasive Cerclage, for Vario Case
68.000.101	Lid for Instrument Tray, size 1/1, (without labelling)
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 88 mm

MRI Information

Torque, Displacement and Image Artifacts according to ASTM F 2213, ASTM F 2052 and ASTM F 2119

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 F 2182

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 thermoregulation 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.

Not all products are currently available in all markets.
This publication is not intended for distribution in the USA.
Intended use, Indications and Contraindications can be found in the corresponding system Instructions for Use.
All Surgical Techniques are available as PDF files at www.depuysynthes.com/ifu

DePuy Synthes
THE ORTHOPAEDICS COMPANY OF Johnson & Johnson

Synthes GmbH
Eimattstrasse 3
4436 Oberdorf
Switzerland
Tel: +41 61 965 61 11

www.depuysynthes.com

SE_819341 AB (DSEM-TRM-0115-0279) EOS: 112019-220215 02/2022

CE
0123