COUSIN SURGERY

Sterile self-locking polymer cerclage system

Surgical Technique

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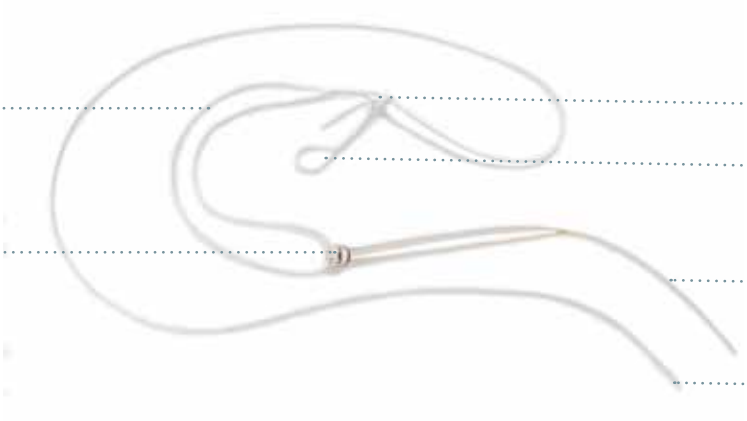
SUMMARY

PRODUCT DESCRIPTION

The sterile self-locking polymer cerclage system with splice fixation is an alternative to the metal cable traditionally used in traumatology and orthopedics.

This surgical technique describes the cerclage in the context of a femoral fracture. The technique will be identical for other long bones.

The surgeon may decide to use ostheosynthesis material complementary to the implant to reduce and help consolidation.



INDICATIONS AND CONTRAINDICATIONS

Indications

. Repair of long bone fractures due to trauma or reconstruction.

. Reattachment of the greater trochanter in total hip arthroplasty, surface replacement arthroplasty, or other procedures involving trochanteric osteotomy.

Contraindications

. Skeletally immature patients

. Active or suspected infection, either systemic or localized, in or around the implant site.

. Patient conditions, metal or neurological, that would tend to impact the patient's ability to follow the physician's instructions during the post-operative healing phase.

. Compromised vascularity that would inhibit adequate blood supply to the fracture or operative site.

. Insufficient quality or quantity of bone, which would inhibit rigid device fixation.

. Any disease affecting the support and fixation of the prothesis.

. Distant site of infection, such as genitourinary, pulmonary, skin, or other sites which may spread to the implant site. The site of infection should be treated prior to, during, and after implantation.

PRECAUTIONS FOR USE

Fracture reduction is performed with dedicated instruments (forceps, hemi forceps, reduction forceps etc.). The cerclage system can be pre-positioned before reduction but will not be tightened before reduction.

The number of cables to be positioned will be decided by the surgeon according to good practice and the intraoperative situation.

When using bone plate in addition to the cerclage, each cable should preferably be placed over the plate.

It is recommended that the cables be tightened after the screws are fastened to allow effective tensioning of the cables.

However, the surgeon may decide to place the cerclage between the bone and the bone plate in exceptional cases, provided the following criterias are met:

- Use a smooth bone plate, without sharp edges
- Avoid contact with bone screws
- Thigthen the cerclage permanantly prior to the final thigthening of the screws

When using bi-cortical screws, avoid contact between the implant and the distal end of the screws.

It is recommended to tension the cable with the tensioner developed by COUSIN SURGERY. The use of another tensioner must be approved by COUSIN SURGERY before use.

Throughout the procedure, ensure that the free ends of the cerclage remain in the sterile field.

1 CABLE SETTING

Select the correct cable-passer size for the circumference of the bone to allow the instrument to pass around it without causing soft tissue damage or periosteal detachment.

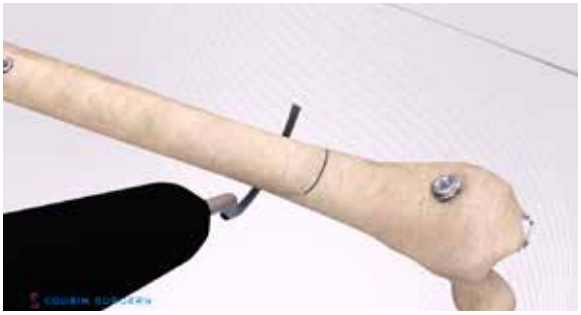
Prior to cerclage fixation, the bone must be carefully cleaned to ensure a direct hard contact between the implant and bone surface.

Use care in passing the cable-passer to avoid damage to soft tissues, bone surface and neurovascular structures (including muscle insertion line).

The distal part of the cable-passer should be on the opposite side of the surgeon.

Insert the semi-rigid end of the cable into the distal part of the cable-passer and pull it out through the other end.

Remove carefully the cable-passer leaving the semi-rigid end around the bone.



Pull the semi-rigid end and slide the adjustable loop along the bone to reach the titanium connector. Detach the semi-rigid end of the connector. This part of the implant will not be used again.

Check that the strands are parallel by moving back and forth along the bone and keep them parallel.

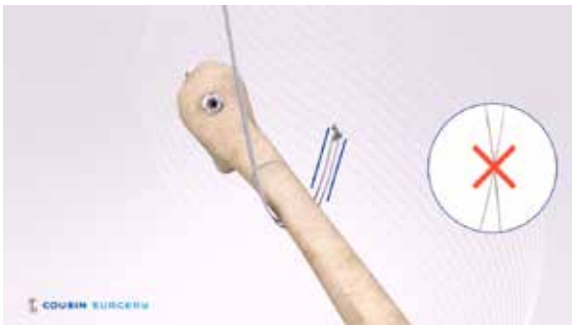
Pass the fixed loop into the titanium connector. The design of the connector allows the loop to be clipped in place and thus ensures that the assembly is maintained throughout the various subsequent operations.

Check again that the strands are still parallel by moving back and forth along the bone. If they are not, detach the connector to the adjustable loop and uncross the strands before re-attaching the adjustable loop to the connector. Keep the strands parallel.

Pull by hand the tensioning end and slide the splice loop to the bone by maintaining an equal tension on each strand.

Avoid soft tissue interpositions between the cable and the bone to ensure adequate final tension.

Avoid rubbing the cable against sharp metal or bone surfaces.



2 HAND PRE-SETTING

Depending on the fracture configuration and at the discretion of the surgeon, several cerclages can be placed.

Manual pre-tightening of the cerclage can be carried-out.

To ensure that the tension of the pre-tightening is maintained, it must be carried out with the help of the dedicated tensioner according to the procedures in step 3. The splice will maintain this temporary tension.

Be aware of sharp edge bone structure that could damage the cerclage system.

3 FINAL TIGHTENING

Insert the tensioning end into the tensioner through the front distal portion of the instrument, then pass it through the rotation axis hole of the handle.

Position the tensioner in direct contact with the splice loop to maintain stability during the tensioning phase.

The tensioner should be perpendicular to the bone.

The splicing system can only maintain the selected tension after 3 identical and successive tightenings. Therefore, the following steps are required:

1) Reach the desired tension via one or more crank turns.

Release the crank.

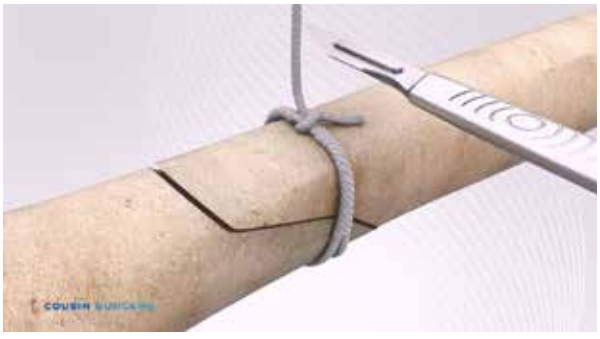
2) Repeat step 1 twice, tightening to the same tension.

After the third tightening, the surgeon can check the tension of the cerclage and retension the cable if necessary.

If multiple cerclages are placed, each cerclage will need to be re-tensioned incrementally so that each implant reaches the appropriate tension.

Do not cut the tensioning end until all the cerclages are in place and each one is checked for proper tension.

When the correct tension is reached for each implant, remove the tensioner, use an electric scalpel or scissors to cut the tensioning end to within 2 cm of the splice loop. The tension cannot be adjusted after this step.



IMPLANT AND INSTRUMENTS REFERENCES

Implant

Description	Reference
BRAIDED PET CABLE	OCBTRCER1U

Instruments

Description	Reference
TENSIONER	OCBANCER1U
SMALL CABLE-PASSER- Ø 41 mm	0105010010
LARGE CABLE-PASSER Ø 52 mm	0105030009

The sterile self-locking polymer cerclage system is a class IIb medical device manufactured by COUSIN BIOTECH S.A.S.

The CE conformity has been carried out by the notified body SGS Belgium NV (CE1639).

Instruments:The tensioner OCBANCER1U is a class I medical device (autocertification) manufactured by Cousin Biotech (CE) // The cable-passers are class I medical devices (autocertification) manufactured by SAYAN TIBBI ALETLER. The management system of COUSIN BIOTECH S.A.S is certified for compliance with ISO 13485 standard. Please read carefully the instructions for use before using the device, https://www.cousin-biotech.com/en/implant-notices.

Référence : TOOCERGB03 - 13/07/22

Cousin Biotech S.A.S capital : 340 656 € - 398 460 261 RCS Lille - N°TVA FR 34 398 460 261

Cousin Biotech is the legal manufacturer of the medical devices proposed by Cousin Surgery.