ChM®

CERCLAGE CABLE WITH CLAMP

- *SURGICAL TECHNIQUE*
- *IMPLANT 4.5250.600S*
- *INSTRUMENT SET 15.0506.101*

www.chm.eu

SYMBOLS DESCRIPTION

Ti	Titanium or titanium alloy
Co	Cobalt
L	Left
R	Right
L R	Available versions: left/right
Len	Length
	Torx drive
	Torx drive cannulated
	Hexagonal drive
	Hexagonal drive cannulated
	Cannulated
	Locking
	Diameter [mm]
H	H length [mm]
	Angle
88 - 340	available lengths
4-22	Available number of holes
1.8	Thickness [mm]
1:1	Scale 1:1
	Number of threaded holes in the shaft part of the plate
	Number of locking holes in the plate
VA	Variable angle
C	Cortical
	Cancellous
Ster Non Ster	Available in sterile/ non- sterile condition
	Refer to surgical technique

	Caution - pay attention to a special procedure.
	Perform the activity under X-Ray control.
	Information about the next stages of a procedure.
	Proceed to the next stage.
	Return to the specified stage and repeat the activity.
	Before using the product, carefully read the Instructions for Use. It contains, among others, indications, contraindications, side effects, recommendations and warnings related to the use of the product.
	The above description is not a detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

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The manufacturer reserves the right to introduce design changes.
Updated INSTRUCTIONS FOR USE are available at the following website: ifu.chm.eu

1. INTRODUCTION

Cerclage cable with clamp is an implant intended for stabilization of periprosthetic and long bone fractures. The presented range of implants is made of materials in accordance with ISO 5832 standards.

The set includes:
- implants (*cable with clamp*),
- instrument set used during surgery,
- surgical technique.

Indications

- Stabilization, support in injuries treatment and reconstruction of bone structures.
- Used as stand-alone devices or with bone plates.

Before using the product, carefully read the Instructions for Use. It contains, among others, indications, contraindications, side effects, recommendations and warnings related to the use of the product.

The above description is not a detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

2. IMPLANT DESCRIPTION

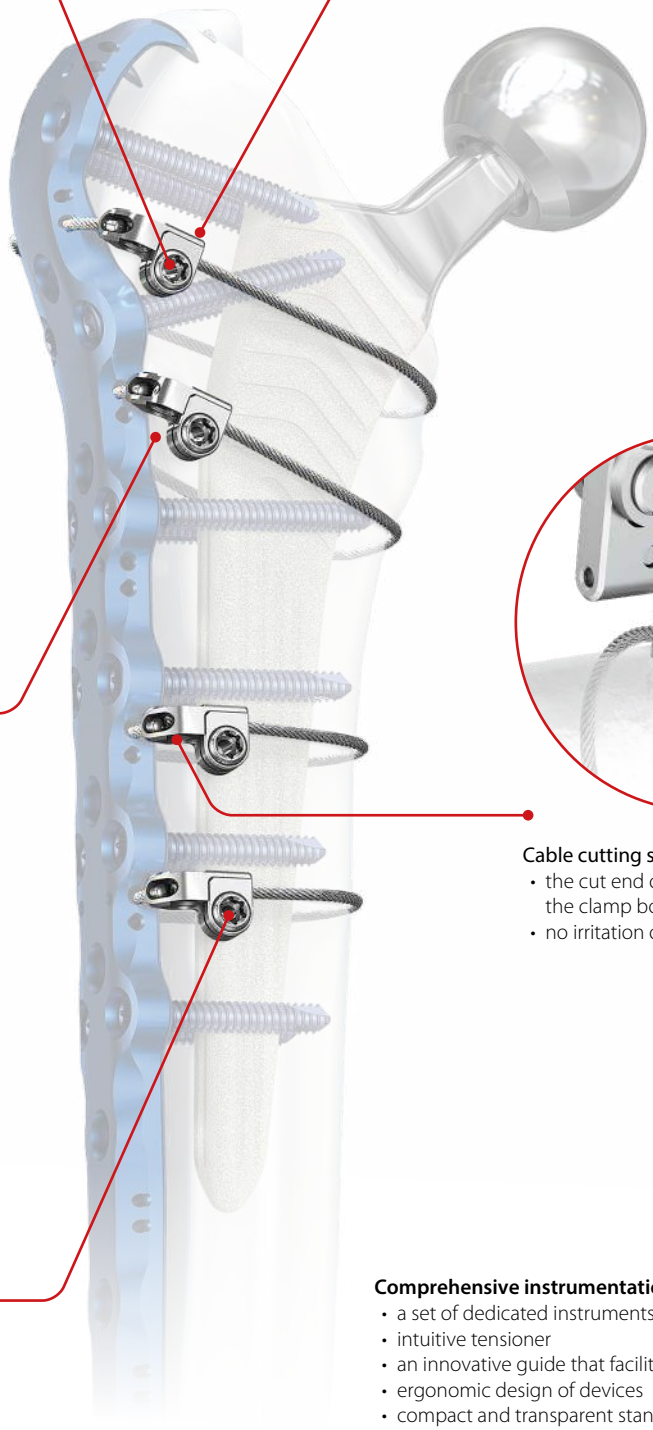
Screw clamping mechanism
- reliable cable clamping
- correction of cable tension possible
- cobalt alloy for strength increase of the implant

Gentle edges and rounded head of the set screw
- reduced irritation of peri-implant tissues

Clamp shape
- optimal position of the clamp and cable on the bone

Cable cutting system
- the cut end of cable hidden inside the clamp body
- no irritation of peri-implant tissues

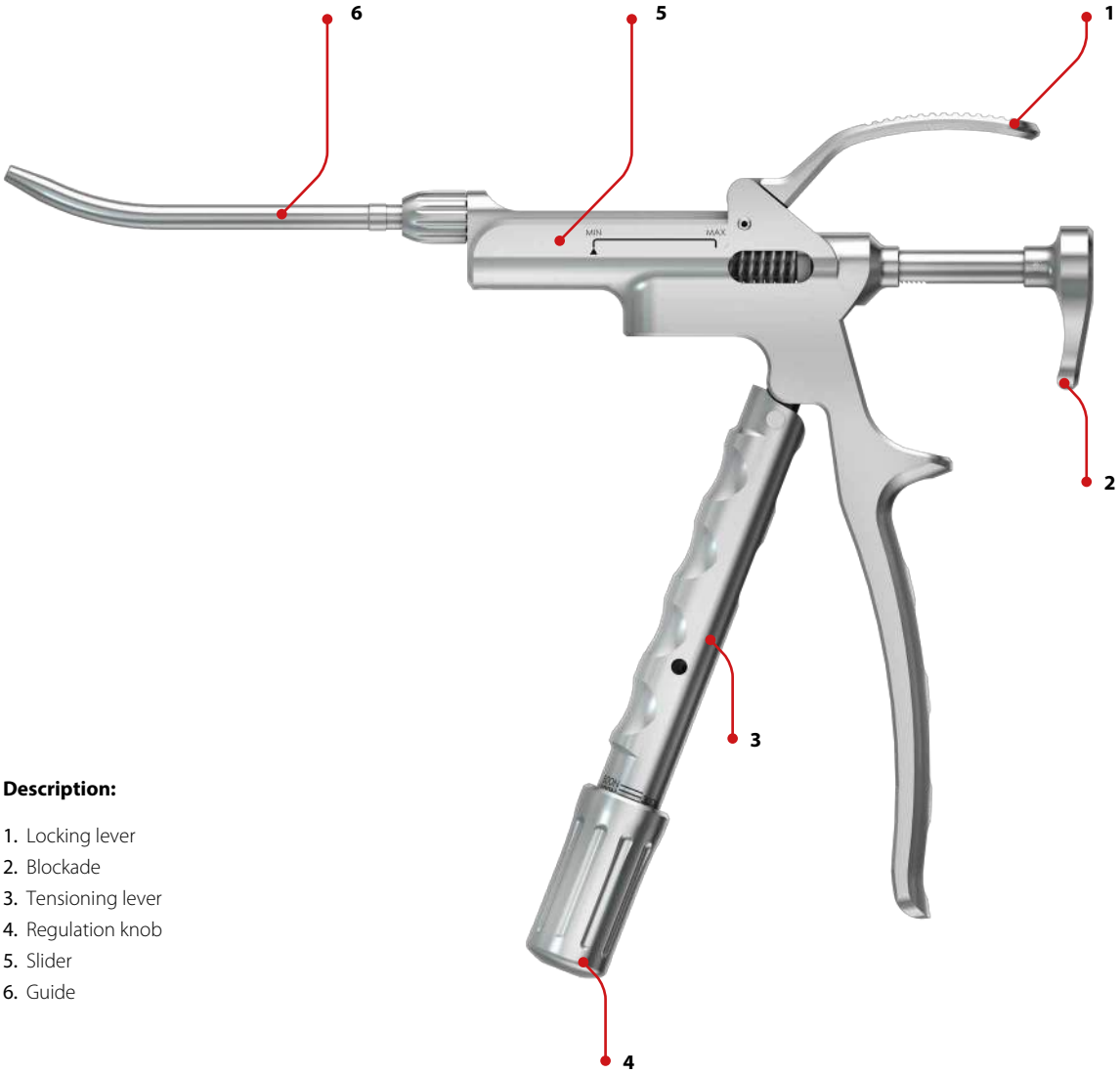
Torx socket
- improved torque transmission



Comprehensive instrumentation
- a set of dedicated instruments
- intuitive tensioner
- an innovative guide that facilitates cabel insertion
- ergonomic design of devices
- compact and transparent stand

3. CABLE TESNIONER DESCRIPTION

Wire instrument [40.8268.000]



Description:

1. Locking lever
2. Blockade
3. Tensioning lever
4. Regulation knob
5. Slider
6. Guide

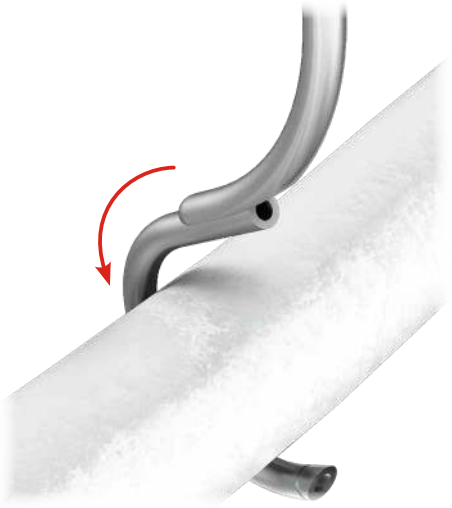
4. SURGICAL TECHNIQUE

4.1. GUIDE INSERTION

Use an appropriate guide depending on the bone size.
Insert the guide **[40.8265.060]** **[40.8265.076]** under the bone and turn to pass the blade through the tissue.

40.8265.060

40.8265.076



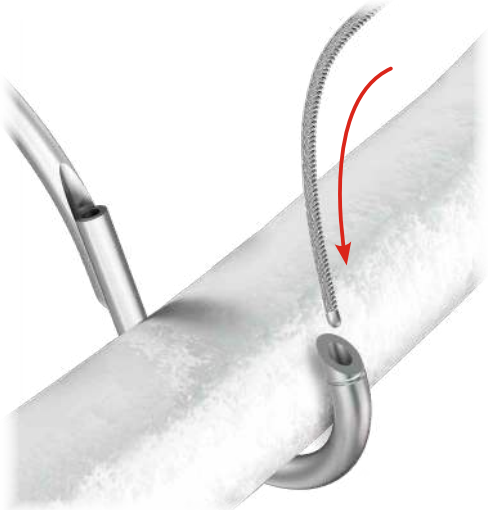
4.2. CABLE INSERTION

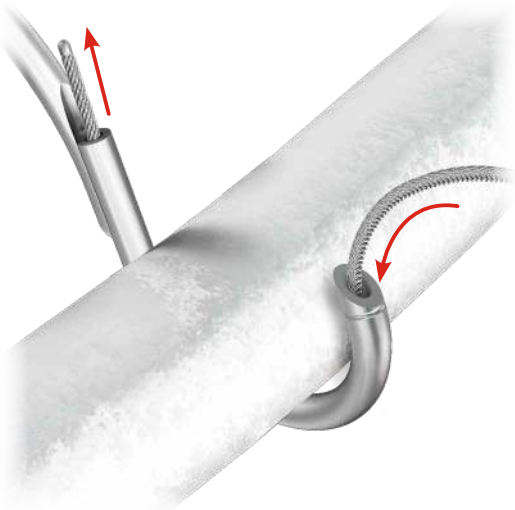
Insert the cable into the guide **[40.8265.xxx]** from the blade side.

CAUTION:
Do not insert the cable from the handle side of the guide - the removal of the guide will not be possible.

40.8265.060

40.8265.076





4.2.1. AUXILIARY TOOL USAGE

In case of difficulties with insertion of the cable into the guide hole it is recommended to use an auxiliary tool - a guide **[40.8272.000]**.

PHASE 1

Insert the cable into the guide **[40.8265.xxx]** from the handle side.

40.8265.060

40.8265.076

Insert the auxiliary tool on the cable - guide **[40.8272.000]**

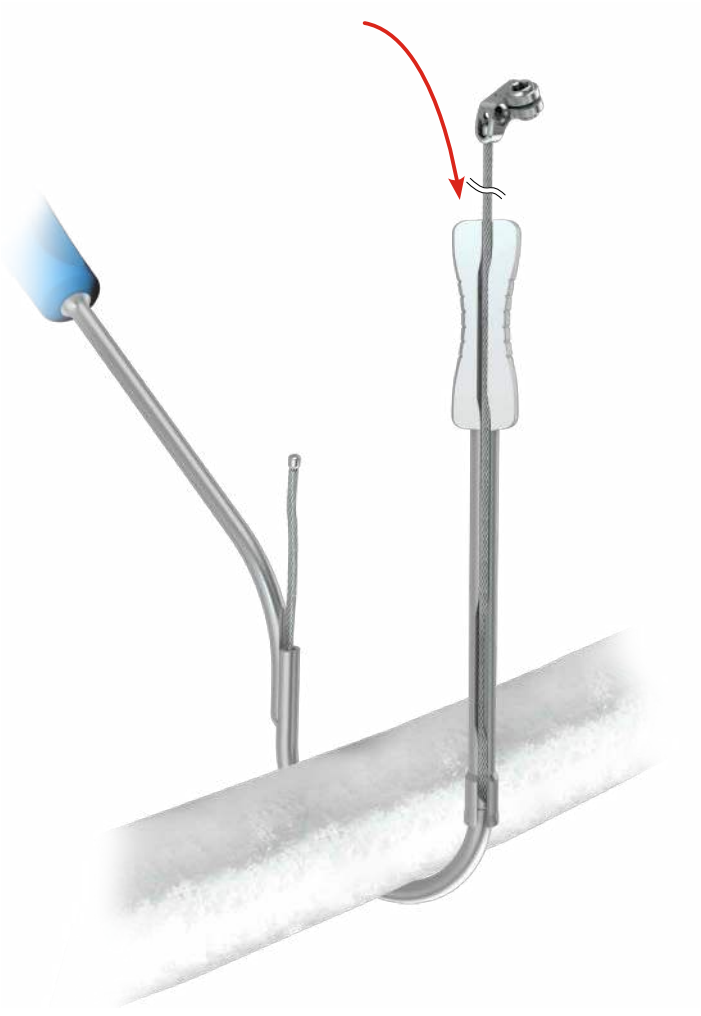
Lock the tip.

40.8272.000

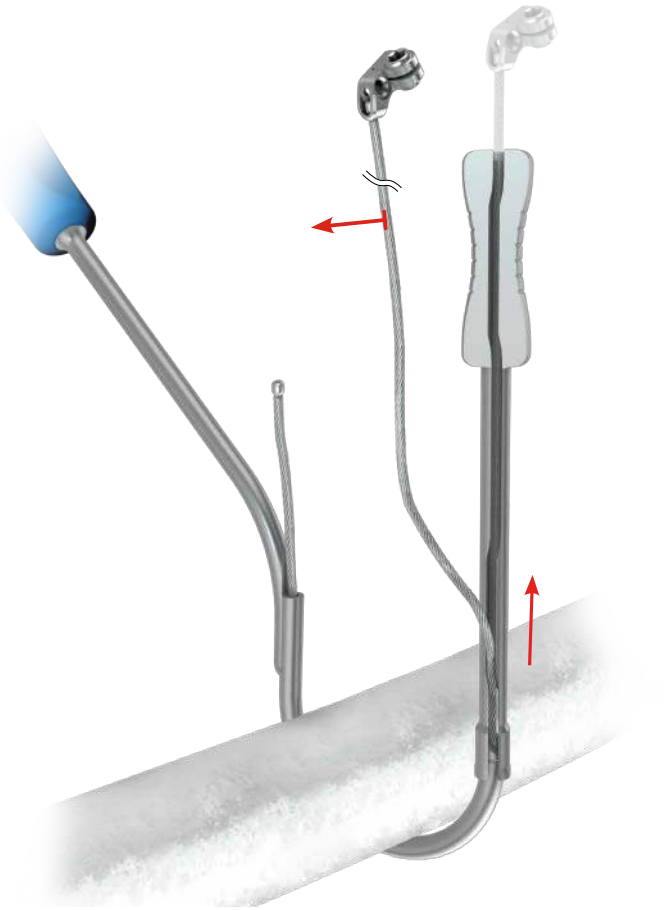
Remove the cable.

PHASE 2

Insert the cable through the auxiliary tool - guide [**40.8272.000**].

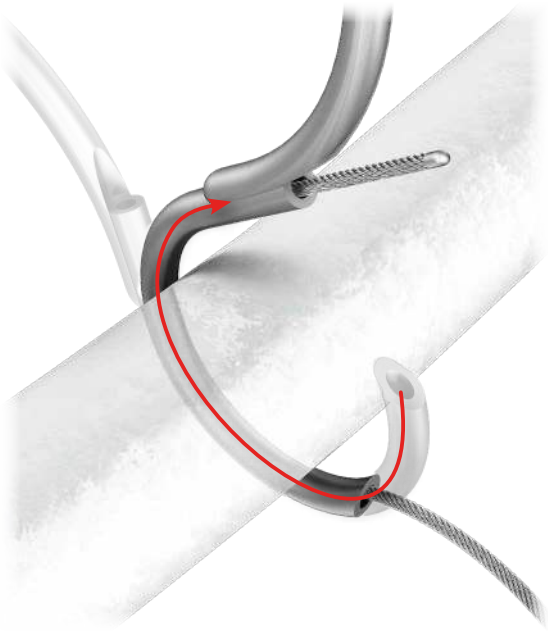


Remove the auxiliary tool - slide the cable through the side channel.



4.3. GUIDE REMOVAL

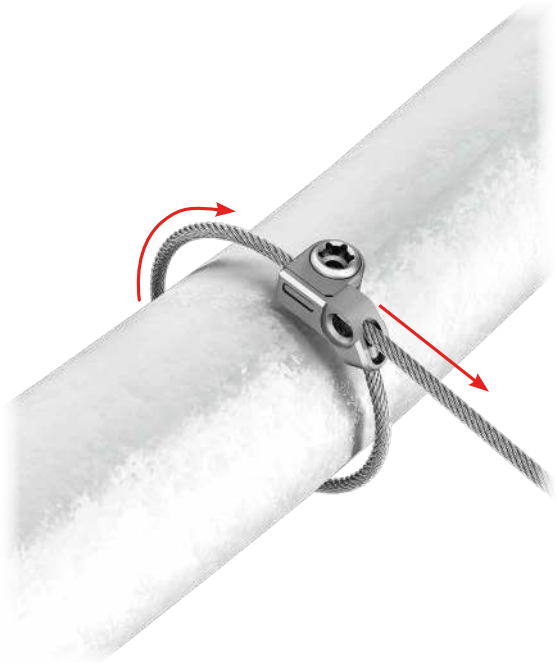
Remove the guide **[40.8265.xxx]** and leave the cable wrapped around the bone.



4.4. CLAMP POSITIONING ON THE BONE

Pass the cable through the clamp and position the latter properly. Pre-tension the cable.

CAUTION: **Position the clamp ensuring easy access to the set screw.**



4.5. SETTING THE CABLE TENSIONER

Set back the slider

If the slider (*5*) is not in MIN position:
A. Rotate the blockade (*2*) 90° clockwise to the unlocked position.
B. Pull back the slider (*5*) to the MIN position.
C. Rotate the blockade (*2*) counterclockwise to the locked position.
D. Set the required tension force with the regulation knob (*4*).
E. Set the locking lever (*1*) in open position.

4.6. CABLE TESNIONER INSERTION

Install the tensioner and push it to the clamp.

40.8268.000

4.7. INITIAL CABLE TENSIONING

Pre-tension the cable and lock it with the locking lever (*1*).

4.8. CABLE TENSIONING

Use the tension lever (*3*) to reach the set tension force.

When the tensioning force is reached, the tensioning lever "click" is felt.

4.9. CABLE CLAMP LOCKING

Position the handle **[40.8266.000]** on the cable clamp.

The tip of the handle [40.8266.000] is compatible with the clamp shape.

Use the handle **[40.8266.000]** to insert the screwdriver tip T25-1/4 **[40.5684.220]** with torque limiting ratchet handle T 4Nm **[40.6660.000]** to the clamp.

40.8266.000

40.5684.220

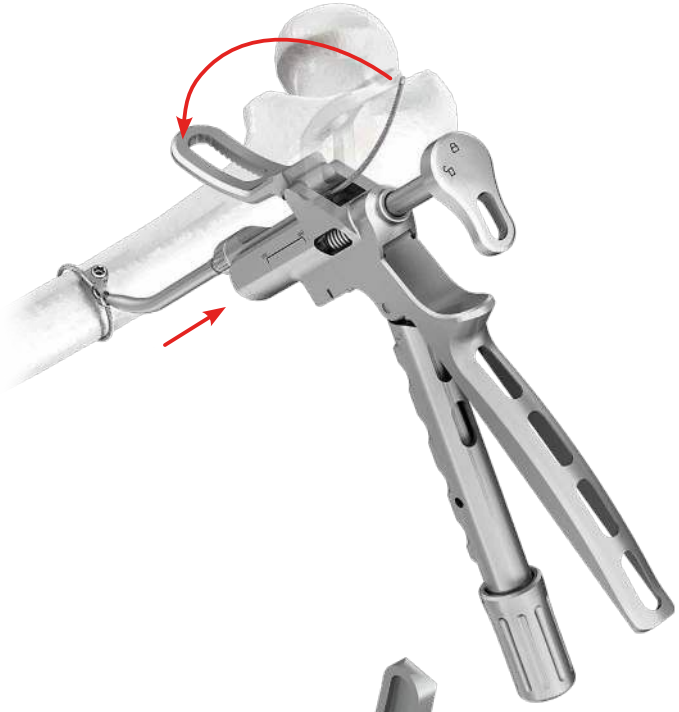
40.6660.000

Always tighten the set screw using the 4Nm torque wrench. Too low tightening torque may not clamp the cable properly and cause loosening of the cable and loss of stabilization achieved.

4.10. CABLE TESNIONER REMOVAL

Unlock the locking lever (*1*).
Remove device by sliding it along the cable.

40.8268.000



4.11. CABLE CUTTING

Prior to cutting the cable the tension force may be corrected. Unlock the clamp and re-tension the cable as required (*according to the procedure described above*).

Insert the cutting pliers **[40.8267.000]** into the side notches of the cable clamp.

40.8267.000

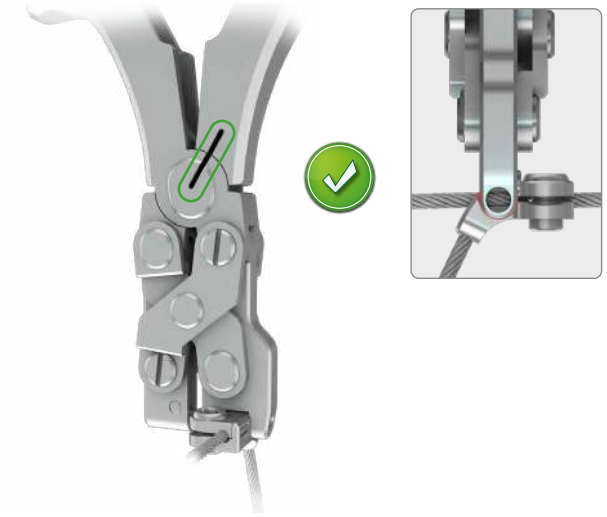
Make sure the pliers jaw is fully seated into the clamp body. Otherwise, the pliers cutting blade can be damaged.

VERIFICATION OF PLIERS POSITION

Continue squeezing the arms of the cutting pliers until a slight resistance is felt.
Verify the position of the markers on the device.

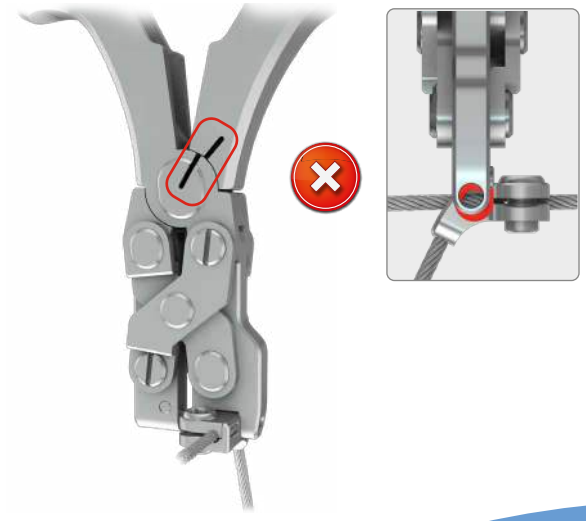
Markers lined up

Correct positioning of the pliers in the cable clamp socket – cut the cable.



Markers not aligned

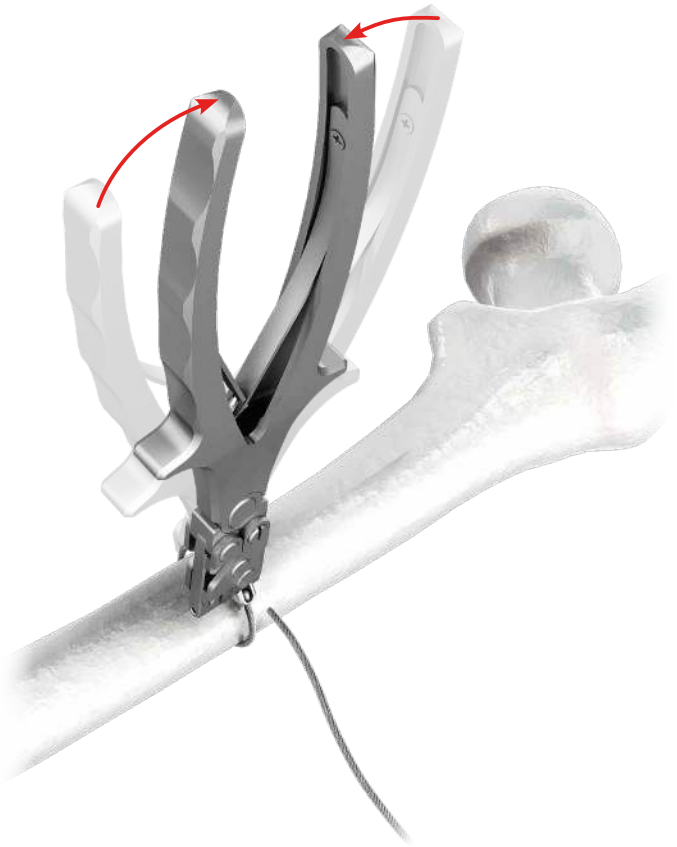
Incorrect positioning of the pliers in the cable clamp socket -reposition the device.



For cutting the cable:

- Continue squeeze the arms of the cutting pliers **[40.8267.000]** until they are fully closed.
- Remove the cut off cable from the cable clamp.
- Open the arms of the pliers and remove the instrument from the cable clamp.

40.8267.000

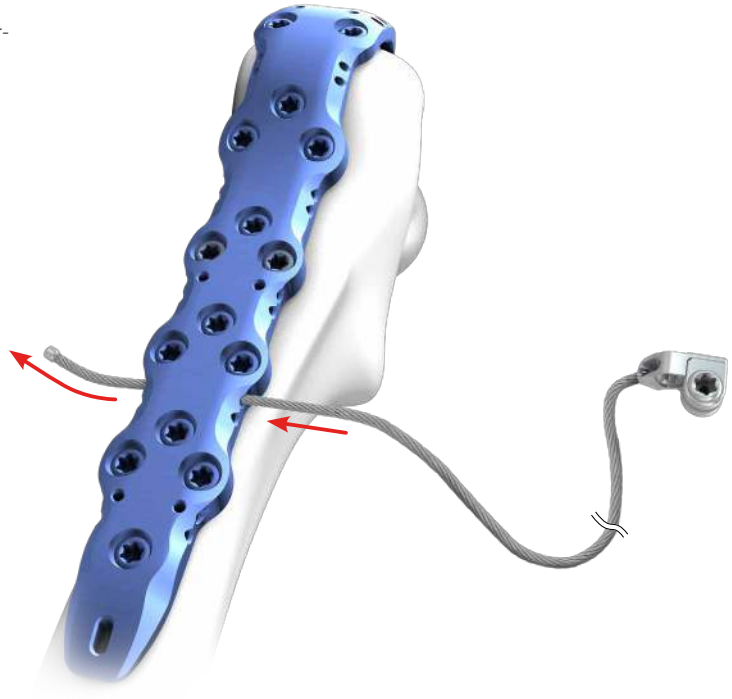


4.12. WOUND CLOSURE

Before closing the wound, take an X-Ray image in at least two positions to confirm the correct position of the implants. Use appropriate surgical technique to close the wound.

5. USE OF THE CABLE WITH A PLATE

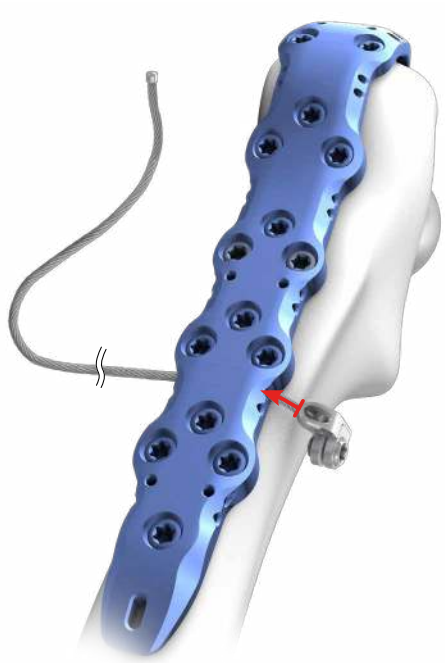
The cable may also be used with a bone plate.
Pass the cable through the wire holes in the plate or through dedicated cerclage screws.



5.1. PASSING THE CABLE THROUGH THE PLATE

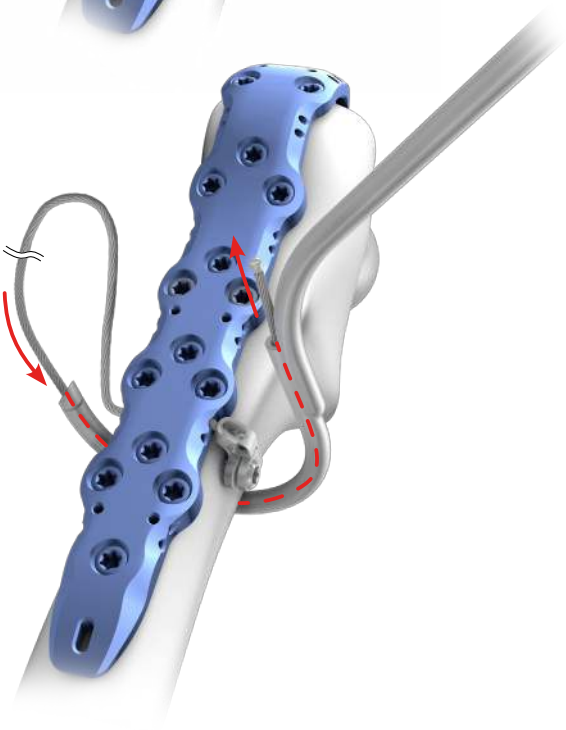
Pass the cable through the transverse holes in the bone plate.

Continue passing the cable through the plate until the clamp leans against the plate.



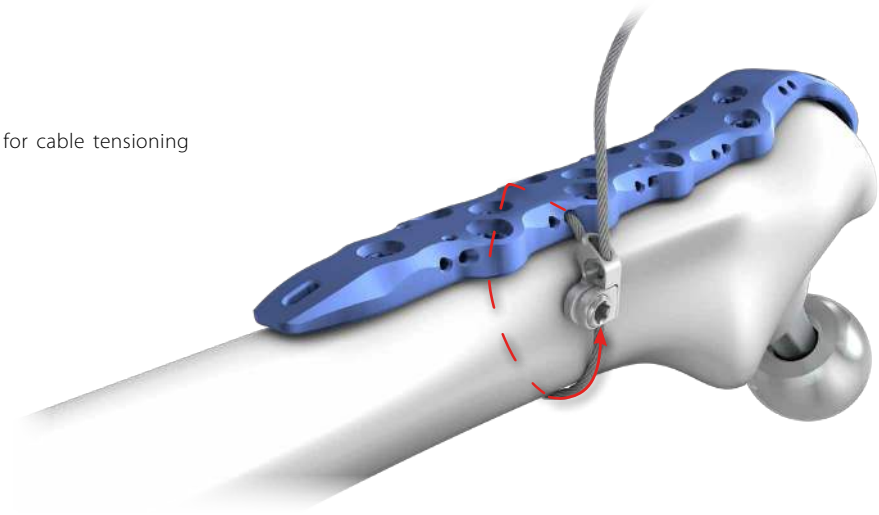
5.2. WRAPPING THE CABLE AROUND THE BONE

Wrap the cable around the bone as instructed in points 4.2-4.3 of this guide.



5.3. LOCKING THE CABLE CLAMP

Pass the cable through the clamp. Pre-tension the cable.
Follow the instructions provided in points 4.5 - 4.10 for cable tensioning and locking.



5.4. CUTTING THE CABLE

Cut the cable as instructed in point 4.11 of this guide.

6. POSTOPERATIVE PROCEDURE

Introduce appropriate post-operative treatment. The physician decides on the post-operative treatment and its conduct. In order to avoid patient's movement limitations, introduce exercises as soon after surgery as possible. However, make sure that the limb is not fully loaded before fragments osteosynthesis is complete.

7. IMPLANT REMOVAL

The physician decides about implant removal. In order to remove the implant from the body, cut the cable wrapped around the bone.

8. CATALOGUE PAGES

8a. Implants

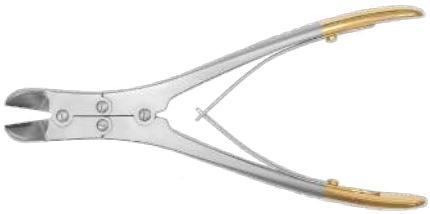
Co Ster

Cable with clamp

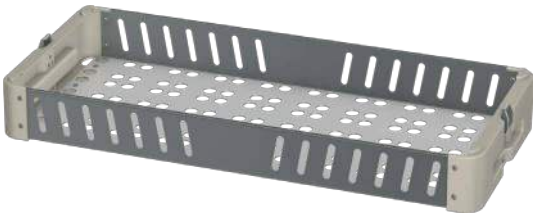
L [mm]	Name	Cat. No.
600	Cerclage cable with clamp 2x600	4.5250.600S

8b. Instrument set

Instrument set - cerclage 9x4H **15.0506.101**

	Name	Cat. No.	Pcs
	Screwdriver tip T25-1/4	40.5684.220	1
	Torque limiting ratchet handle T 4Nm	40.6660.000	1
	Guide 60	40.8265.060	1
	Guide 76	40.8265.076	1
	Handle	40.8266.000	1
	Cutting pliers	40.8267.000	1
	Wire instrument	40.8268.000	1
	Wire cutting pliers 16cm hardened	40.3176.160	1
	Guide	40.8272.000	1

Instrument set - cerclage 9x4H **15.0506.101**

	Name	Cat. No.	Pcs
	Container - cerclage 9x4H	**14.0506.101**	1
	Container lid - cerclage 9x4H	**14.0506.102**	1

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