SOCORE

Miss

SURGICAL PROCEDURE

NovaSpine

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NovaSpine does not practice medicine. Each physician should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training physicians have received.

The Instructions For Use of the SOCORE device must be read carefully before using the device.

INSTRUMENTS RANGE

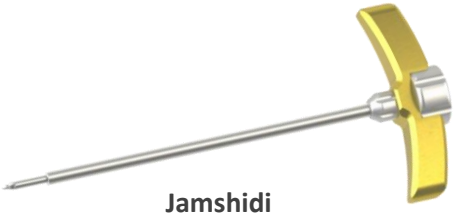
Cannulated Straight Handle
SIMDC159

Straight Ratchet Handle
SIMR153

Cannulated T handle
SIMTC178

Cannulated Ratchet T Handle
SIMTR186

Dynamometric T Handle
SIDK150



Jamshidi
SIJMI191

Wire
SIB225

Wire Holder
SIWH193

Dilators
S1 - SID201
S2 - SID202
S3 - SID203
S4 - SID204
S5 - SID205

Cannulated Taps
Ø5 - SITCA182
Ø6 - SITCB183
Ø7 - SITCC184

Cannulated Polyaxial Screwdriver
SITCL196

Screwdriver Cylinder
SICL197

Standard Persuader
SIPMI188

Tightening Screwdriver
SITS123

Lateral Opening Persuader
SIPMO189

Locking Screw Holder + Small T Handle
SIPVB119 + SIMPVB

Rod Holder
SIRHMI190

Counter Torque
SIMA199

Persuader Screwdriver
SISMI192

Compressor
SIPC210

Compression-Distraction Device
SIBCD230

Distractor
SIPD121

Persuader Releaser
SIEB200

SURGERY PREPARATION

The patient should be positioned prone, lying flat on the table. A knee-to-chest position should be avoided.

Proper C-arm set up is critical for accurate Visualization of instrument and implant positioning.

- Prepare for C-arm use that allows cephalad and caudad movement.
- Set the C-arm to capture true Anterior/Posterior and lateral views. This should be done during patient positioning and before final draping.
- As the C-arm is moved frequently, consider taping the floor to mark the best C-arm positions to eliminate variations in views during the surgery and for time efficiencies.
- Verify that adequate fluoroscopic images of the pedicles can be obtained in both an AP and lateral view before proceeding.

INDICATIONS

After meticulous clinical and radiological tests, SOCORE Implants for MISS procedures can be used for spinal stabilization, by posterior approach. Please refer to the IFU of the SOCORE device to have indications covered, contra-indications and adverse effects / possible complications. The SOCORE fixation system may be supplemented with DIVA TLIF cages.

SITE PREPARATION

The location of pedicles entry points are marked on the skin. A small incision of the skin is made to help the insertion of the Jamshidi. The Jamshidi is inserted through the incision until reaching the bone contact. Use C-arm to confirm targeted level and correct orientation of the Jamshidi. (*Figure 1*).

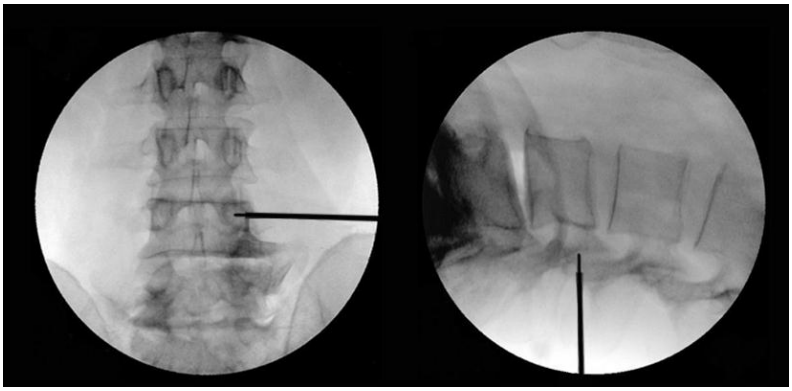


Figure 1

If position and orientation are suitable, push manually the Jamshidi into the pedicle or with slight hammering until the stop.

Hammering must be done on the inner shaft's knob and the Jamshidi must always remain in the pedicle's axis during its insertion.

Unscrew and remove the inner shaft after insertion of the Jamshidi (*Figure 2*).

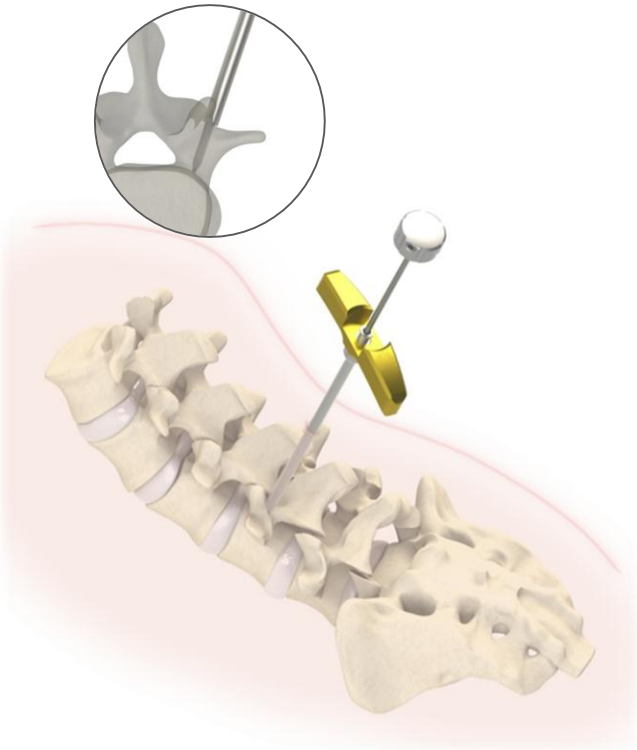


Figure 2

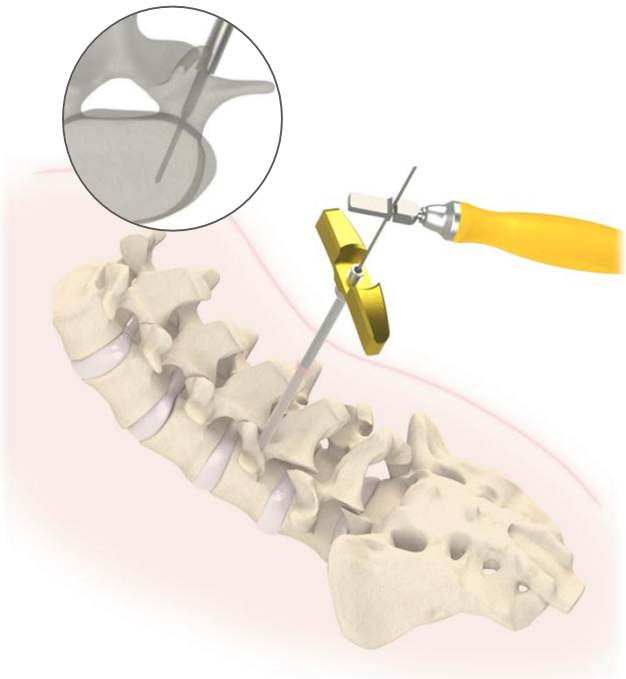


Figure 3

Insert a wire into the wire holder and screw the handle to attach it. Insert then the wire inside the Jamshidi and push it in the bone by hammering on the flat part of the wire holder until reaching the desired depth (*Figure 3*). Remove the wire holder by unscrewing the handle. The Jamshidi may now be removed. **The wire must be maintained during Jamshidi's removal.**

MUSCLES DILATION

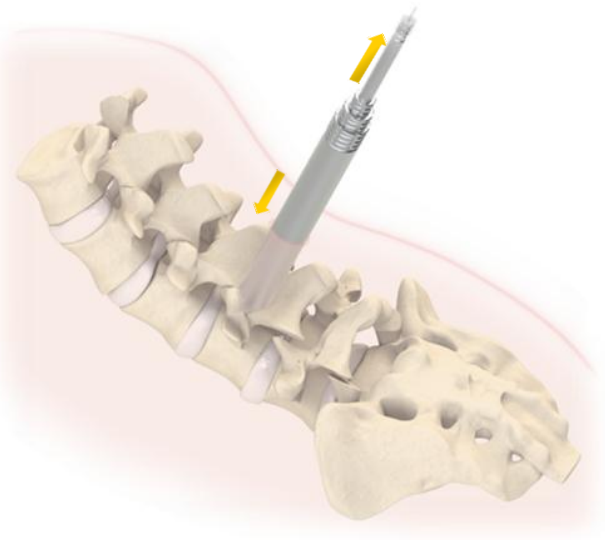


Figure 4

Slide the dilator S.1 over the wire and push it firmly until reaching a stable position. Dilator S.1 has a tip similar to the Jamshidi tip to fit the bone preparation for an optimal stability. Slide incrementally the dilators S.2, S.3 and S.4 over dilator S.1 then remove the dilator S.1 (*Figure 4*).

Assemble the tap to the handle (straight or T) and slide it over the wire, through dilator S.2, to prepare the pedicle path up to desired depth (*Figure 5*). Color-code of the taps allows to select the right diameter. Avoid lateral movements during insertion of the tap.

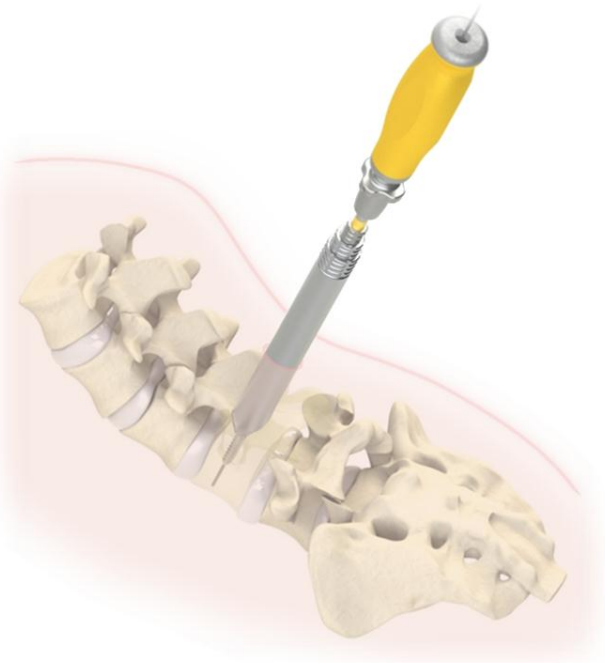


Figure 5

Remove the tap and the dilators S.2 and S.3 (*Figure 6*).

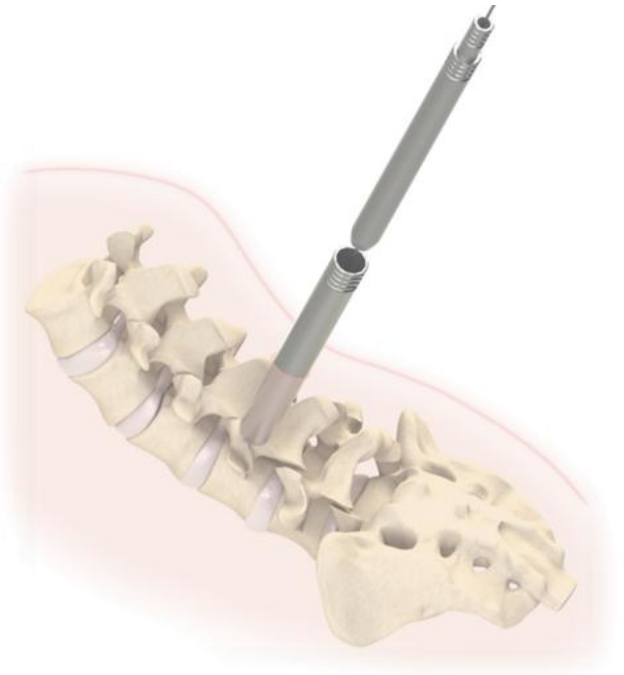


Figure 6

SCREW SETTING

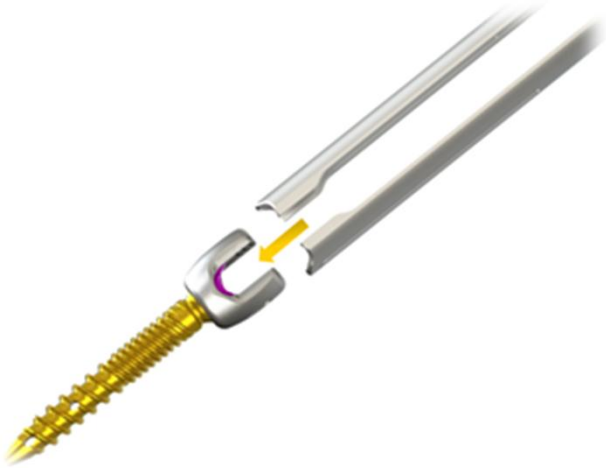


Figure 7

Assemble the Screw to the Persuader by pushing the Persuader on the Screw head until hearing the click (*Figure 7*). Insertion must be made carefully in the axis of the head.

Lateral opening Persuader is usually used on the rod insertion side to allow the penetration of the Rod Holder into the persuader and ease Rod insertion.

Assemble the Screwdriver with the Cylinder to the standard or ratchet handle (straight or T; *Figure 8a*). Insert the Screwdriver inside the Persuader (*Figure 8b*). Insert the tip carefully and completely inside the bone screw head and screw the cylinder into the Screw head (*Figure 8c*).

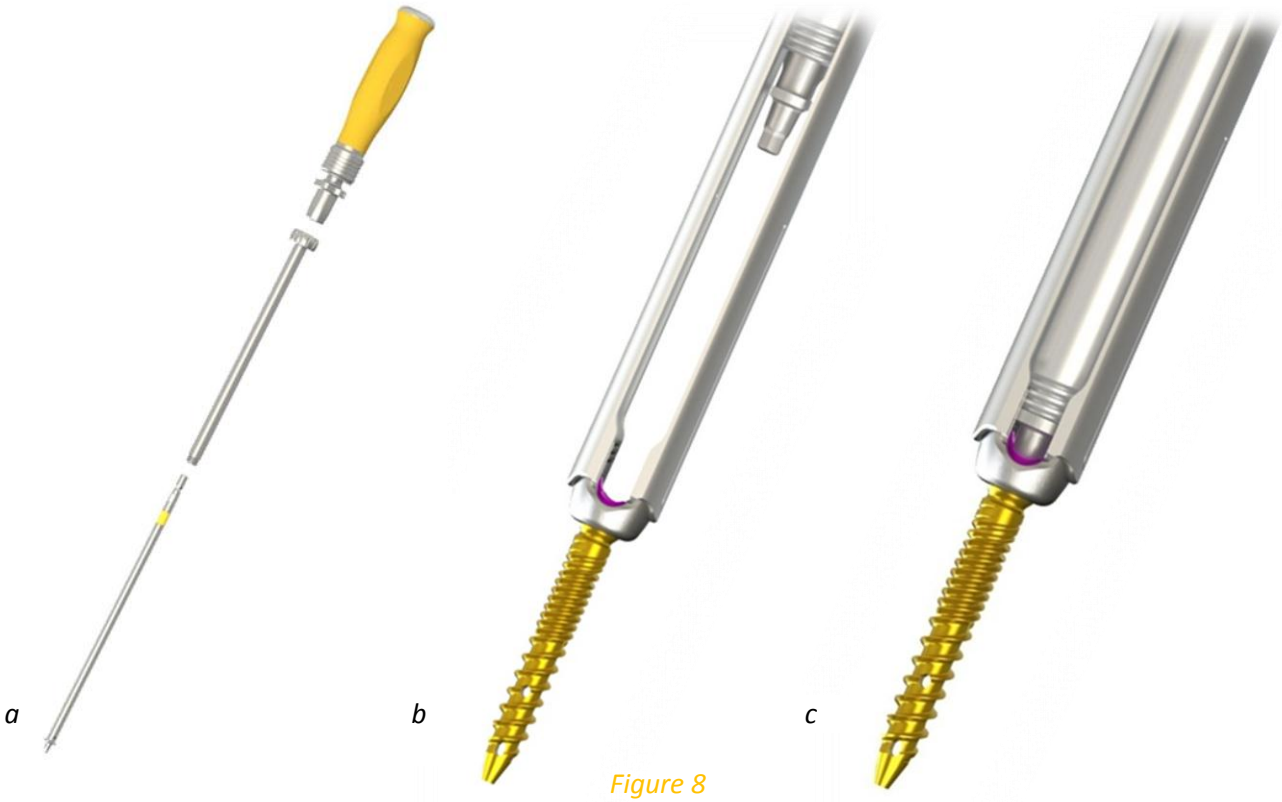


Figure 8

SCREW INSERTION

Place the screwdriver over the wire and insert the Screw through the dilator S.4 (*Figure 9*). Insert the screw carefully in the axis of the pedicle and wire, and avoid lateral movements. Insert the screw with fluoroscopic assistance to monitor screw length and head placement.

It is highly recommended to screw it until complete insertion of the threading, reaching the edge below the head shown in *Figure 9*. This aims to provide optimal stability and resistance. Remove screwdriver, dilator and wire.

The same procedure must be applied for every screw of the system.

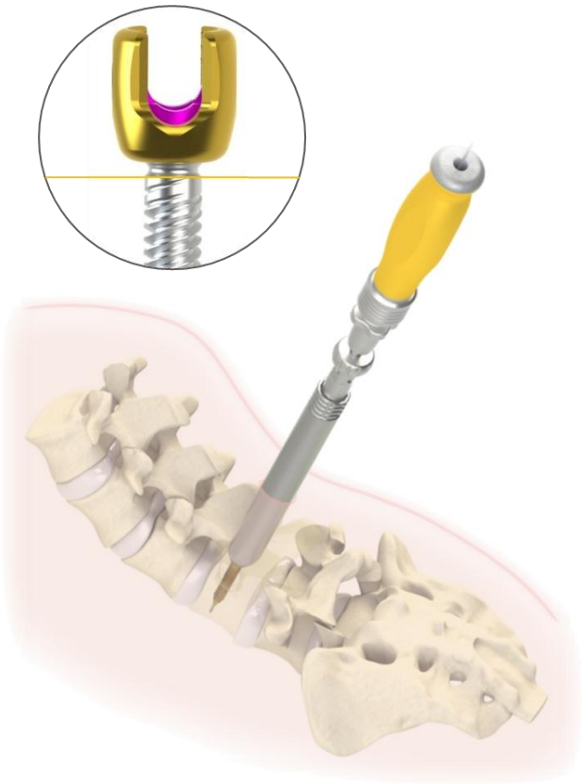


Figure 9

ROD PREPARATION AND INSERTION

Insert the Rod into the Rod Holder and tighten the inner part. During tightening, the click sound means that the rod is secured and cannot be removed without unlocking the locker.

Tighten firmly the inner part to lock the Rod in desired position. The position of the Rod can be changed by unscrewing slightly the inner part (*Figure 10*) then rescrewing to fix it in new position. Rod rotates only in a monoplanar direction.

Figure 10

The locker shown in *Figure 11a* secures the Rod and avoids its detachment.

To release the Rod after the final tightening, push the locker back while unscrewing the inner part (*Figure 11b*).

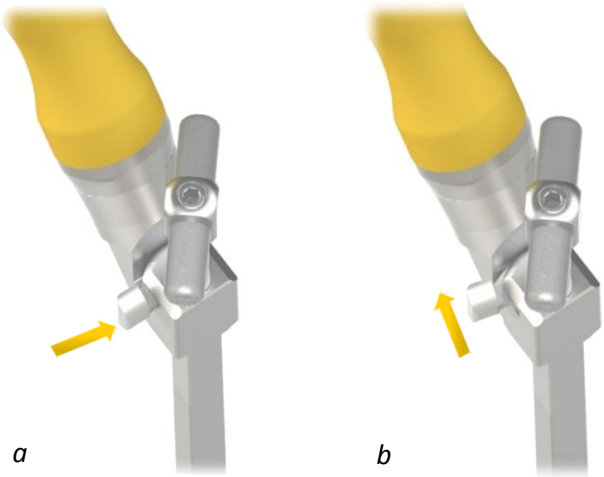


Figure 11

ROD INSERTION

Mini Open technique

In this technique the lateral incision is extended to the length of the final construct.

Set the rod in horizontal position (*Figure 12*). Tighten firmly the inner shaft of the Rod Holder, and insert the rod through the persuaders' slots.

Push the rod down with the holder until fitting the heads of screws.

Insert the external cylinders of the persuaders and screw them down to achieve the reduction of the rod inside the screws. When the rod is close to the final position, unscrew slightly the inner shaft of the Rod Holder to ease the optimal fitting of the rod into the head of screws.

Tip: For a construct with S1 level as extremity, the rod should be inserted from the cranial extremity.

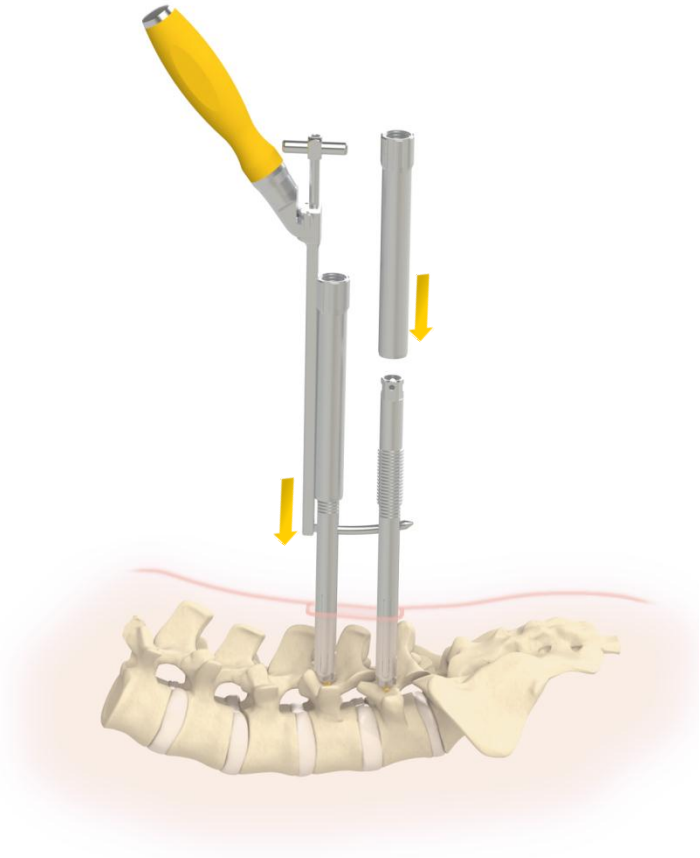


Figure 12

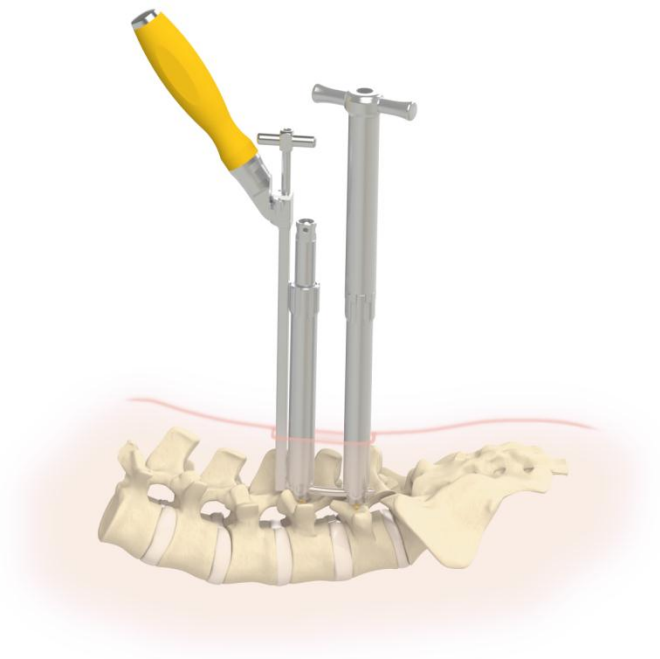


Figure 13

Use the Persuader screwdriver to ease the complete insertion of external cylinders and to put the rod in final position into the bottom of the screw head (*Figure 13*).

Percutaneous technique - option 1

Set the rod in perpendicularly to the Rod Holder and tighten the inner shaft firmly (*Figure 14*).

Put the Rod Holder in external contact with the persuader at 45° to vertical position (*Figure 14*) and insert the rod through the lateral slot of the first persuader.

Slide the tip of the rod through the incision and bring it close to the bone by pushing down.

Rotate the Rod Holder to vertical position while inserting the rod through the following persuaders.

Align the Rod Holder with the Persuaders by moving it inwards. Twist the Persuaders to make sure that the rod is inside the slot.

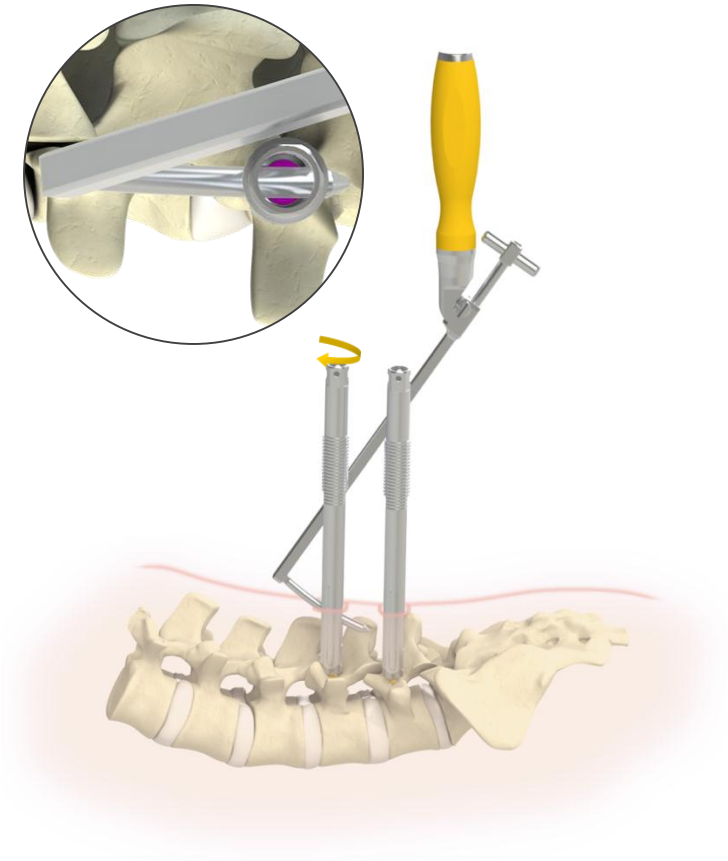


Figure 14

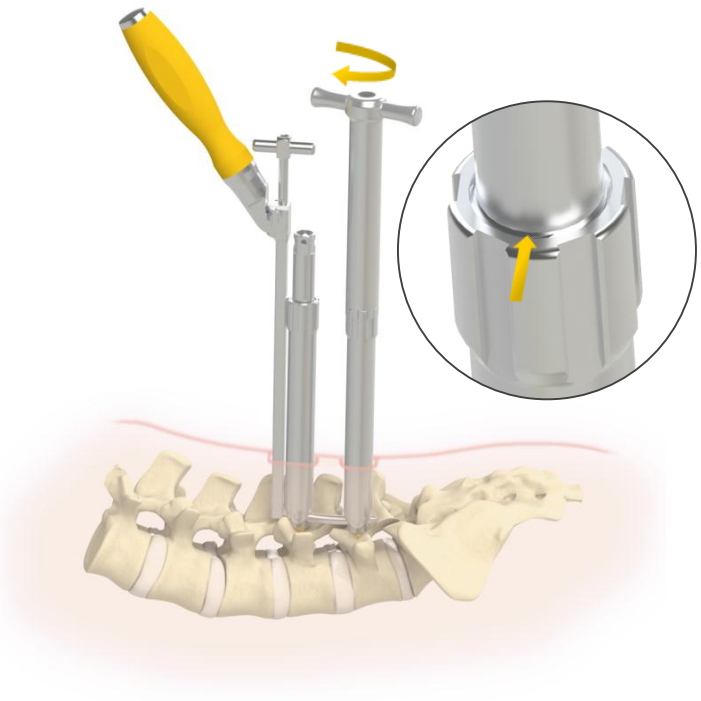


Figure 15

Push down the rod Holder to place the Rod in horizontal position inside the head of screws (*Figure 15*), then unscrew slightly the inner shaft of the Rod Holder to release the rod.

Insert the external cylinders of the persuaders and screw them down to achieve the reduction of the rod inside the screws.

Use the Persuader screwdriver to ease the complete insertion of external cylinders and to put the rod in final position into the bottom of the screw head (*Figure 15*).

When the rod is correctly inserted reduced in the screw head, the threading of the inner shaft of the Persuader becomes slightly visible (See zoomed view of *Figure 15*.

Percutaneous technique - option 2

An additional incision is required next to the screws, at the extremity of the construct, to allow the insertion of the rod (See *Figure 16*).

Set the rod in the position shown in *Figure 16* and insert it through the muscles until passing through the slot of the first persuader. Twist the Persuader to make sure that the rod is inside the slot.

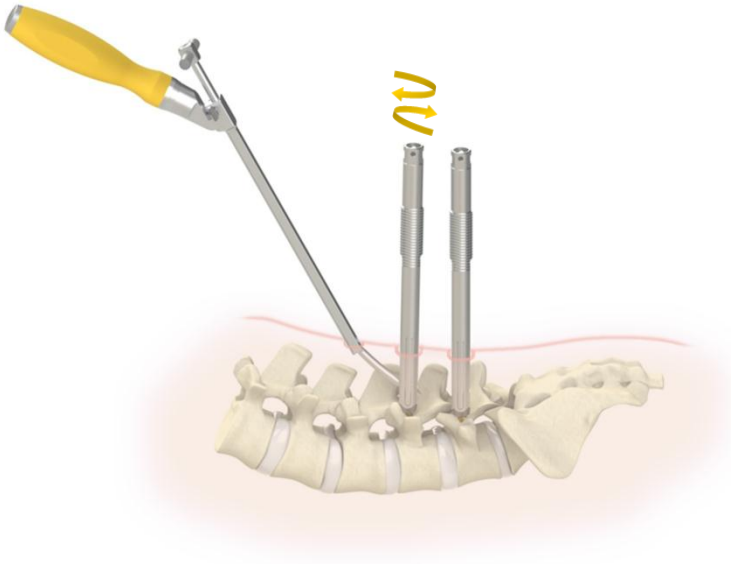


Figure 16

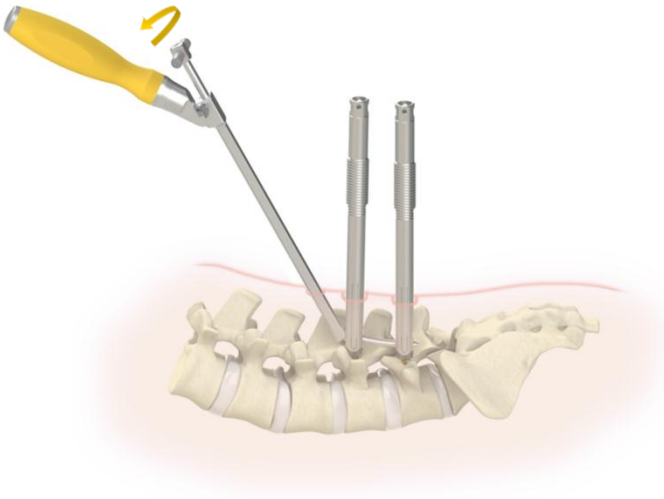


Figure 17

Unscrew slightly the inner shaft of the Rod Holder and push it down and forward in order to place the rod in horizontal position and to insert it through the slots of other persuaders (*Figure 17*).

Use the Persuader screwdriver to ease the complete insertion of external cylinders and to put the rod in final position into the bottom of the screw heads (*Figure 18*).

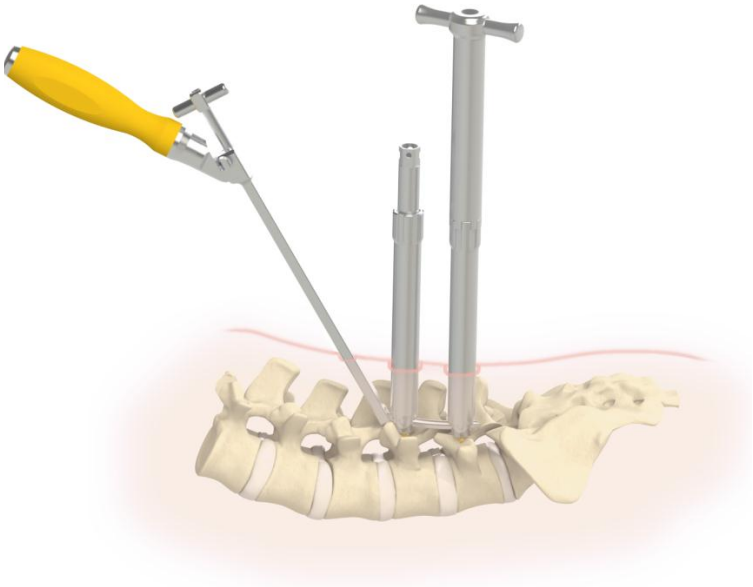


Figure 18

For each technique mentioned above, the following steps are the same.

The Locking Screw is assembled firmly to its holder by a firm pushing of the holder into the locking screw hexagon, and inserted through the Persuader (*Figure 19*). It is screwed until touching the rod without tightening.

The same operation is made for each pedicle Screw.

An X-Ray may be useful at this step to confirm the correct length and placement of the rod.

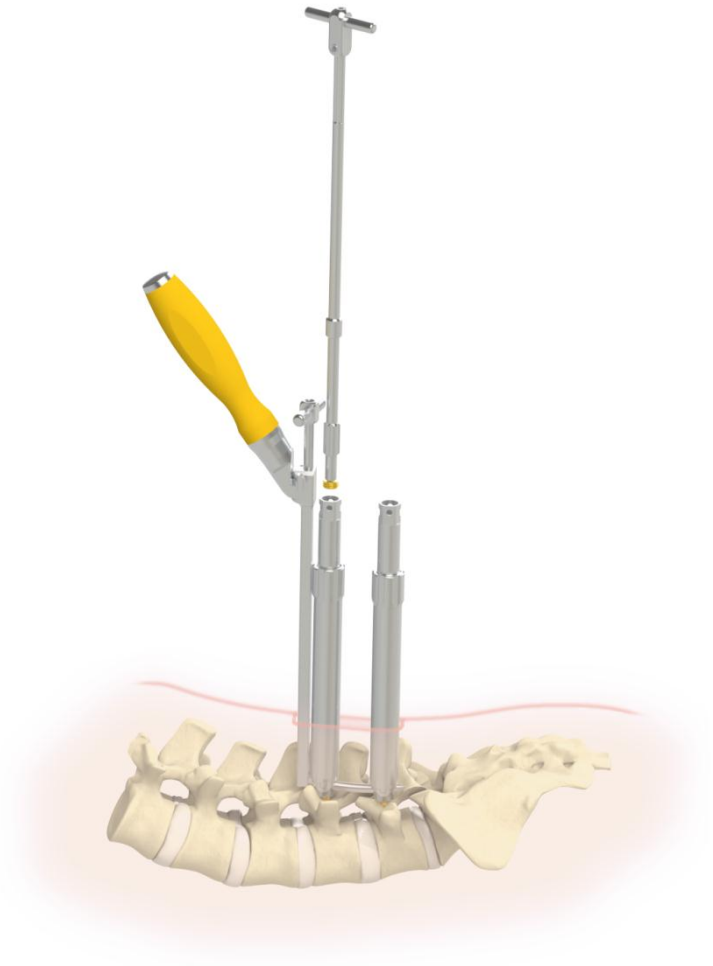


Figure 19

COMPRESSION - DISTRACTION

If a correction (compression or distraction) is needed, the Compression-Distraction Device is inserted on the top of persuaders until the stop (*Figure 20*) and fixed with the locking knobs. The length between the two tubes can be modified and fixed by screwing and unscrewing the locking knobs. Compression (*Figure 21*) or distraction (*Figure 22*) is performed using the adapted clamp, and the assembly is fixed using the locking screw holder to tighten the Rod.

For compression, the compressor can be positioned around the Rod Holder and the opposite Persuader (*Figure 21*) or around the two Persuaders directly if there is enough space.

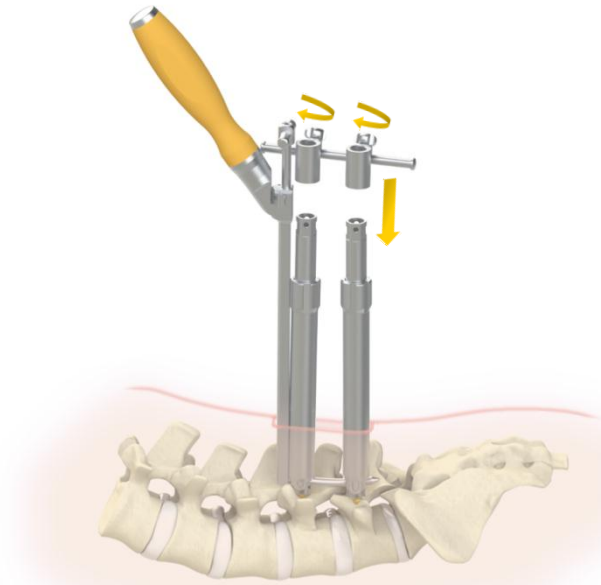


Figure 20

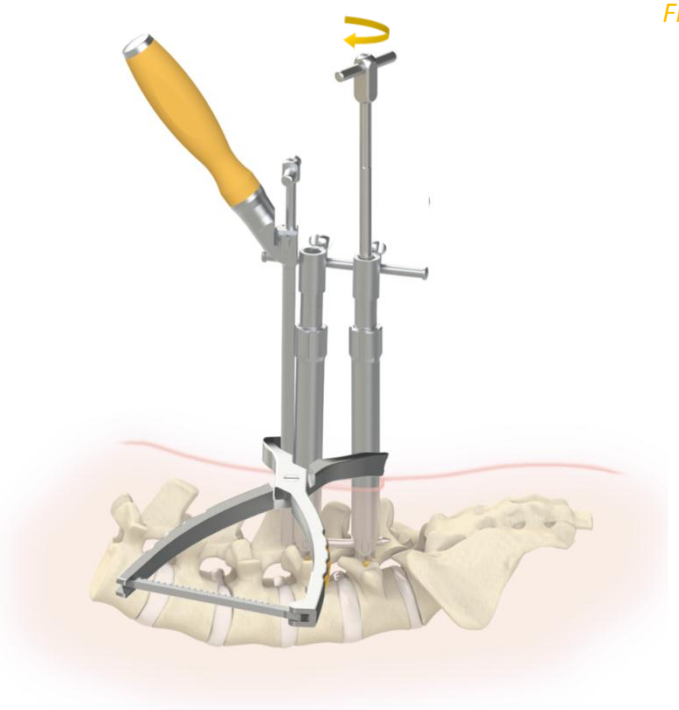


Figure 21

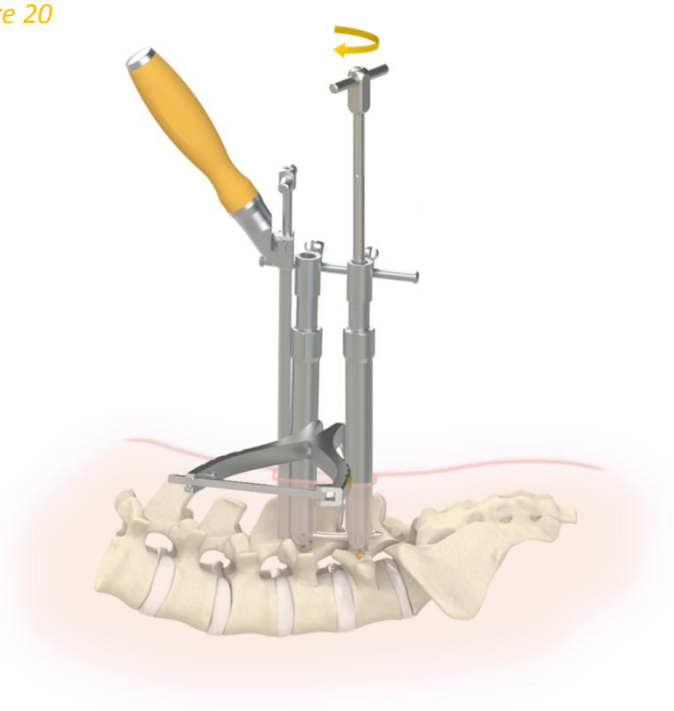


Figure 22

FINAL TIGHTENING

For each screw:

Set the Counter Torque on the top of the Persuader, until the stop, and insert the tightening screwdriver with the T dynamometric handle inside the Persuader until reaching the locking screw. (*Figure 23*). **The external cylinder of Persuaders must be in place and in contact with the rod**.

The hexagon of the tightening screwdriver shaft must be fully inserted in the female hexagon of the locking screw to avoid damaging of both hexagons and obtaining a poor fixation.

Make the final tightening until hearing the click of the dynamometric key, then remove the screwdriver and the counter torque.

When using standard T handle, hold it with the central shaft between middle and ring fingers and tighten as strong as possible (*Figure 23*).

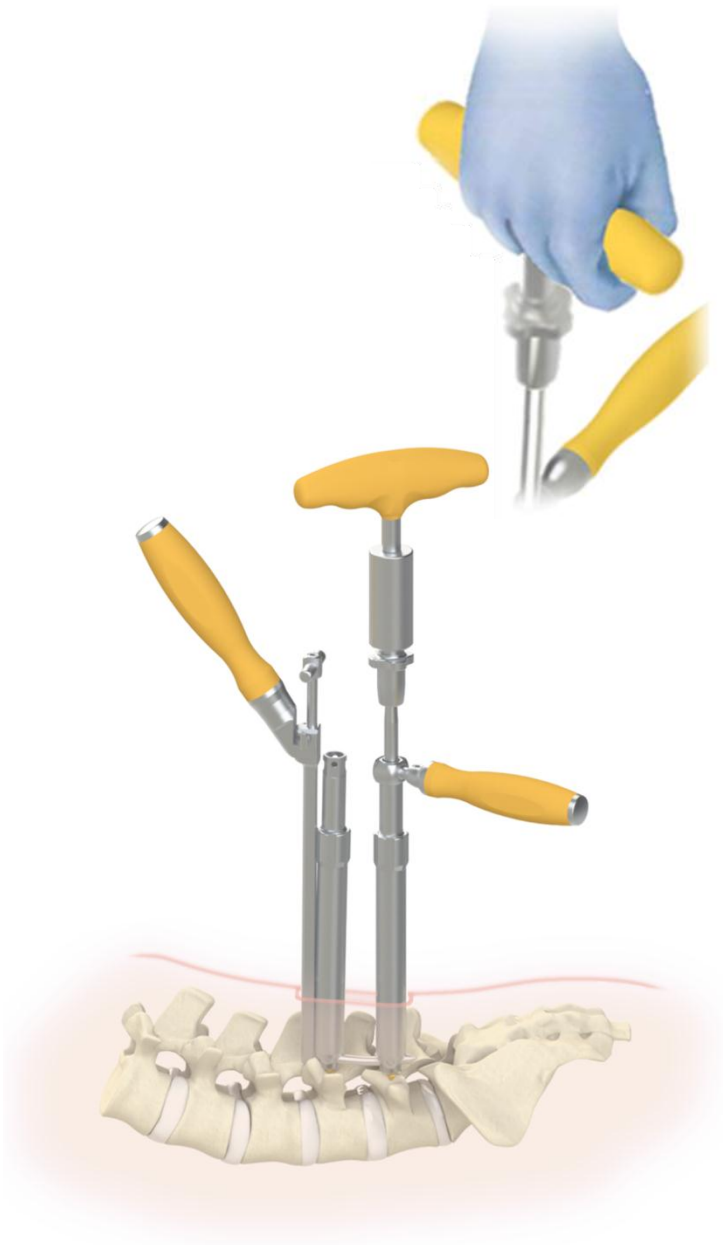


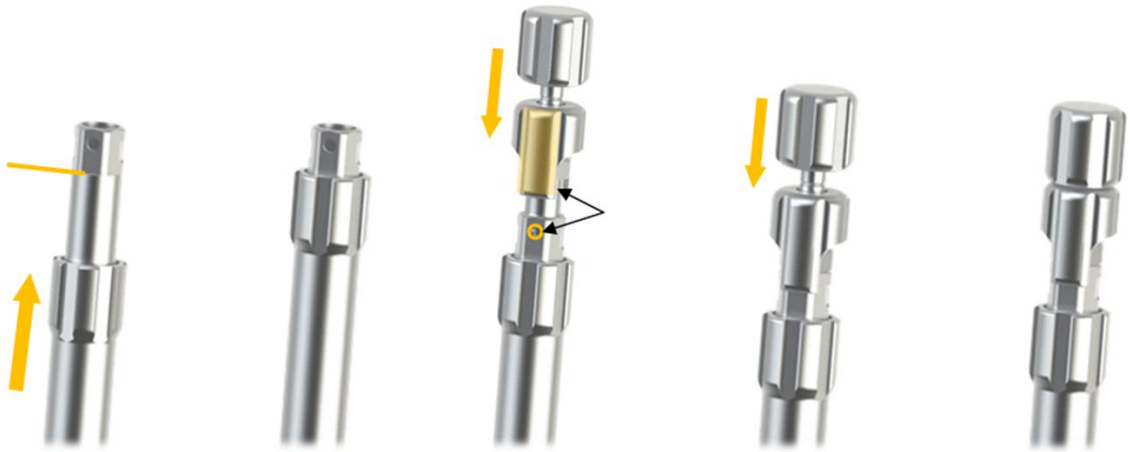
Figure 23

PERSUADER REMOVAL

Remove the Persuaders using the Persuader Releaser as shown below (*Figure 24*). Unscrew the external cylinder of the Persuader until the extremity of the hexagon limit of the internal cylinder.

Insert the Releaser through the Persuader. The tabs of the releaser must cover the lateral holes of the persuader. Screw the inner part of the Releaser until the stop. Remove both Persuader and Releaser (*Figure 25*). Unscrew the inner part of the Persuader Releaser to disassemble the Persuader and the Releaser.

The same steps are followed to remove each Persuader.



Step 1: Unscrew external cylinder of Persuader until the limit of the hexagon

Step 2: Insert the Persuader Releaser through the Persuader

Step 3: The tabs of the Releaser must cover the holes of the Persuader

Step 4: Screw the inner part of the Releaser

Step 5: Lift both Persuader and Releaser

Figure 24

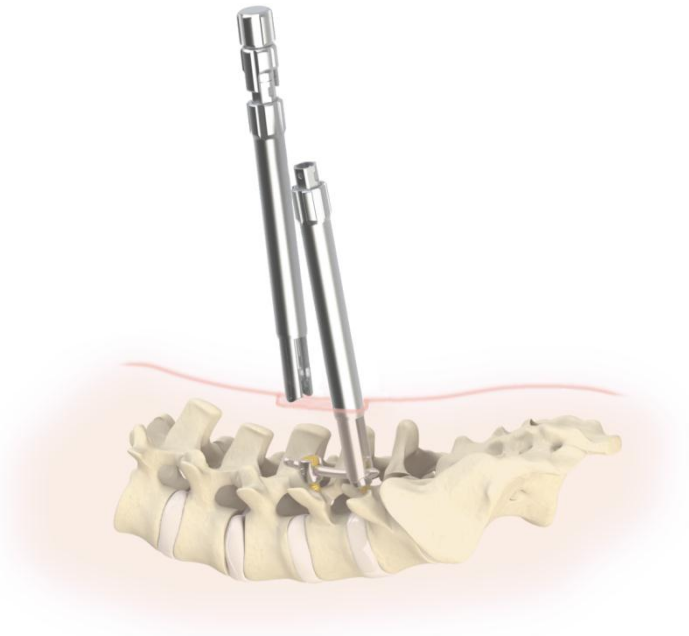


Figure 25

The whole procedure above is followed to fix the contralateral side. Bone graft must be used when implanting the construct (*Figure 26*). The final construct is shown in *Figure 27.*

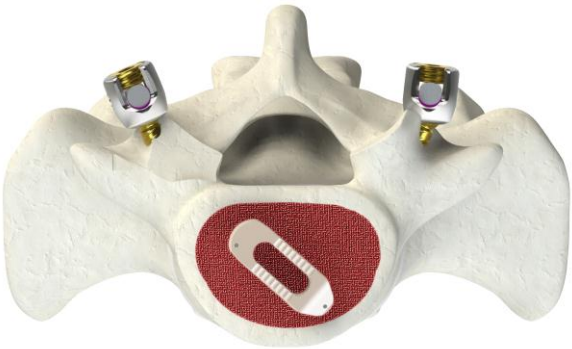


Figure 26

Figure 27

This document is intended exclusively for physician and for illustrative purpose only. The actual techniques employed will always depend on surgeons' medical judgment and can differ from one patient to another. Each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part.

IMPLANT REMOVAL

- The screwdrivers used to place the screws and their locking nuts/screws must be used for explantation.

- For locking screws removal, the final tightening screwdriver may be use to initiate the unscrewing, and the locking screw holder to complete their removal. The locking screw holder must be pushed into the locking screws to activate the gripping system.

- Any rod holder or surgical clamp can be used to remove the rods once the locking nuts are removed.

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Implantable SOCORE devices
are covered by CE 0086

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