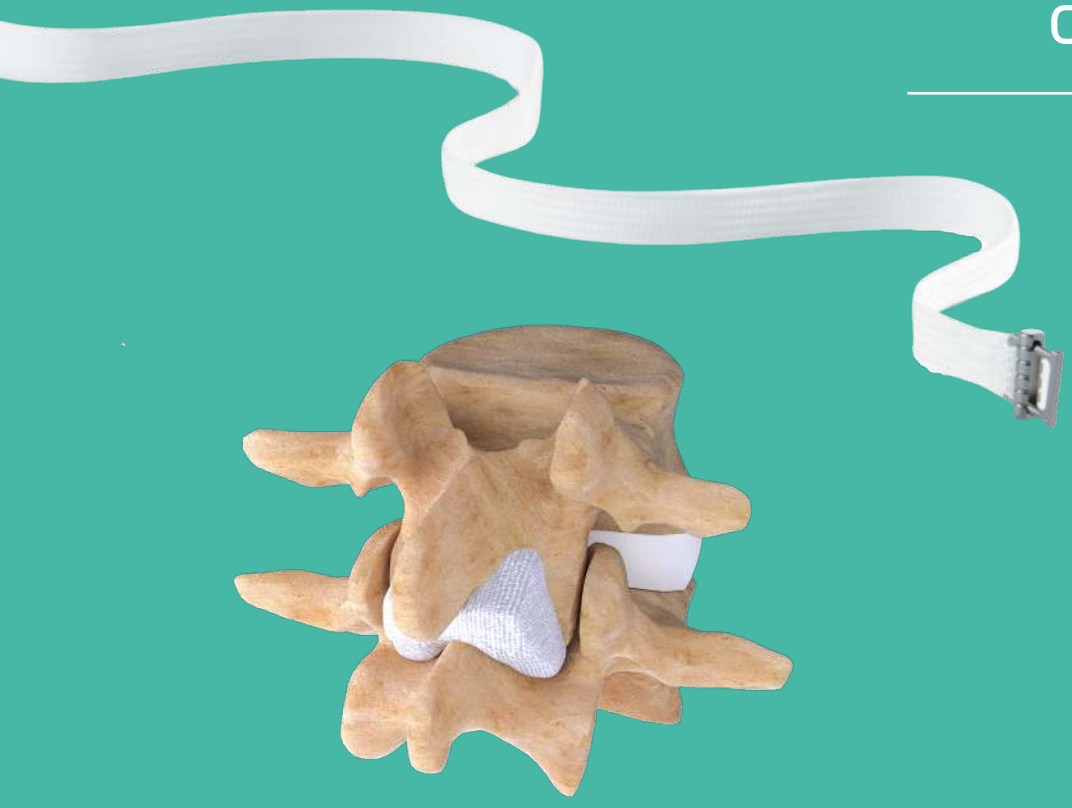
COUSIN SURGERY

IntraSPINE®

Dynamic interlaminar device



We care for Surgery

Surgical technique

IntraSPINE®

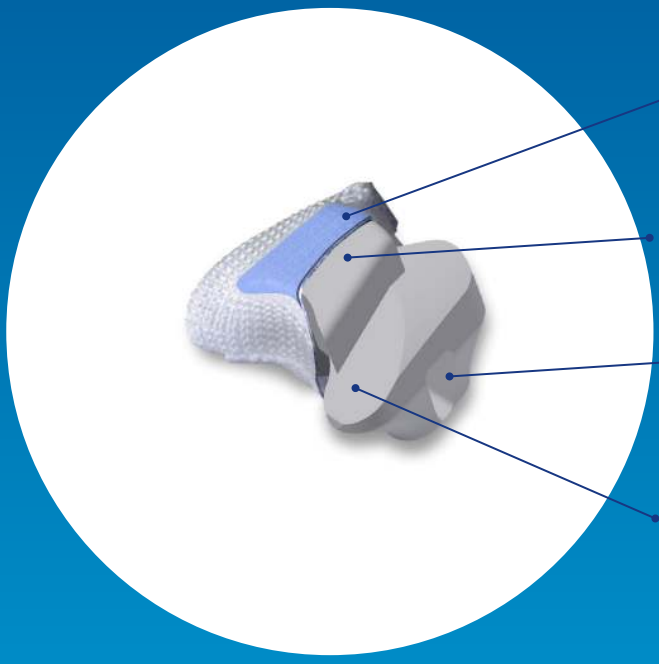
Dynamic interlaminar device

PRODUCT DESCRIPTION

The IntraSPINE® is a dynamic stalilization system which respects the physiological motion of spine. Its laminar support closer to the I.A.R* allows to decompress and to collect the lordosis better than other posteriorly devices.

The posterior surgical techniques can be done either:

- With a mini-invasive mono-lateral approach, with the device on its own (page 5).
- With a midline bilateral approach, with the device and its artificial ligament (page 11).



* I.A.R : Instantaneous Axis of Rotation

IntraSPINE® IMPLANTS

Size	Reference
8mm	INTRACAL08
10mm	INTRACAL10
12mm	INTRACAL12
14mm	INTRACAL14
16mm	INTRACAL16



*Implant size is defined by its nose size. All references are accompanied by an optional artificial ligament

INSTRUMENT SET



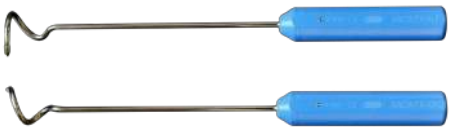
Large bone rongeur forceps
ROGNINTRAL



Distraction forceps
PINCEINTRA



Holder and trial devices (5 sizes)
FANINTRA 08, 10, 12 ,14 ,16
PRTFAINTRA



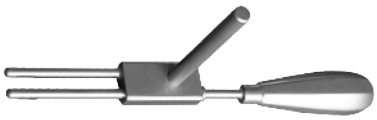
Left and right wire guides
ANCINTRALF/ANCINTRARG



Implant holder
PCALEINTRA



Impactor
IMPACINTRA



Ligament tightener
RCBANTENDU

INDICATIONS

The IntraSPINE® prosthesis is recommended in the lumbar spine and sacral area (from L1 to S1 levels) in the following cases:

- **Arthropathic facet-syndrome**
- **Foraminal stenosis**
- **Degenerative discopathy**
- **Intervertebral ligament insufficiency**

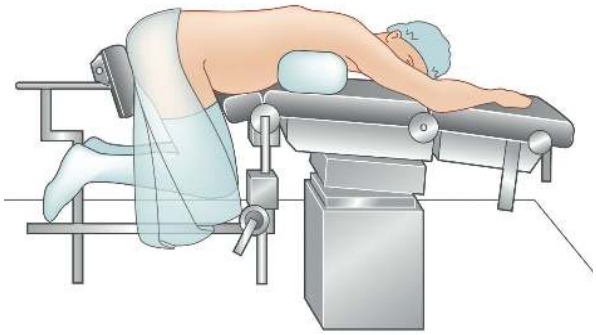
CONTRAINDICATIONS

Do not use the prosthesis in the following cases:

- Allergy to one of the components
- Growing child
- Infected site
- Pregnant woman

Factors likely to compromise successful implantation:

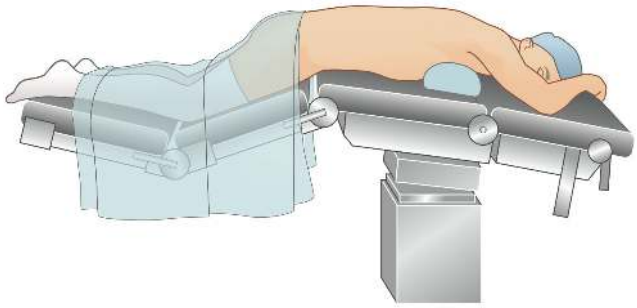
- Severe osteoporosis
- Major deformations of the spinal column
- Local bone tumors
- Systemic or metabolic disorders
- Infectious diseases
- Obesity
- Drug addictions
- Intense physical activity, for example competitive sports or hard labour
- Surgery on more than 2 levels with IntraSPINE® prosthesis



1 POSITIONING

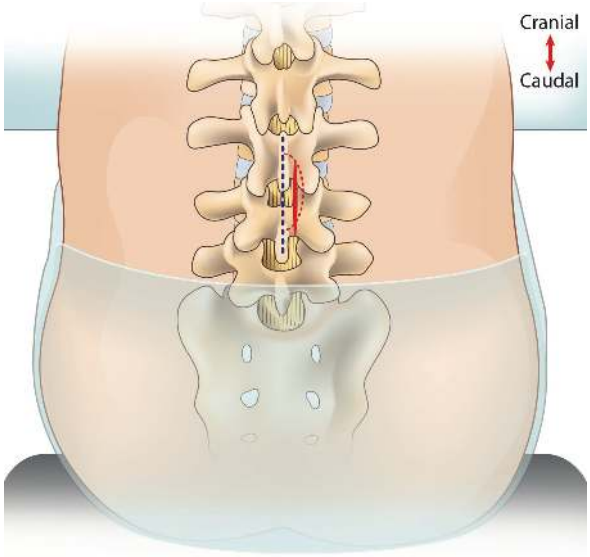
Prone knee position under general or local anaesthesia

or



Prone position

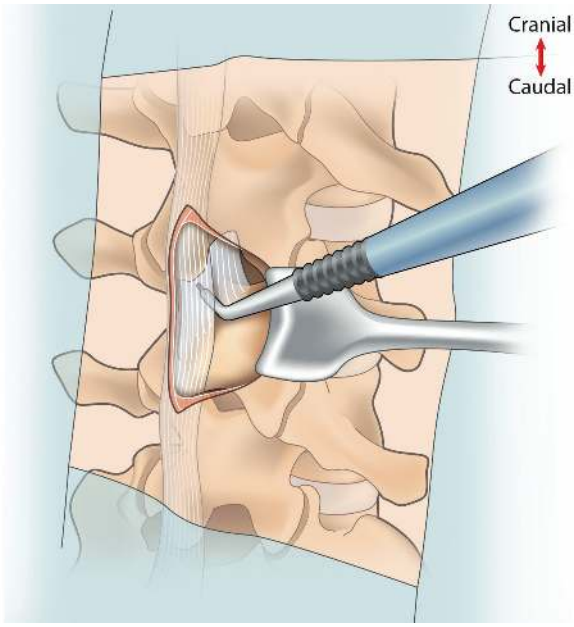
(table allowing to install patient in a lumbar kyphosis)



2 APPROACH

After X-Ray monitoring of the affected level, paravertebral incision of about 4 cm (at 2 or 3 mm away from the midline on the side of the prevalent symptoms) on the outer edge of the spinous processes.

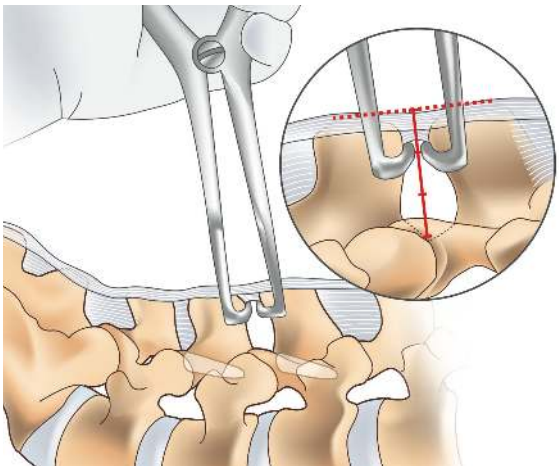
Incision of the fascia while trying to respect the most possible the midline (with special care to leave intact the supra-spinous ligament). Dissection of the multifidus to reveal the two spinous processes and the superior and inferior hemi-laminae.



3 PREPARATION

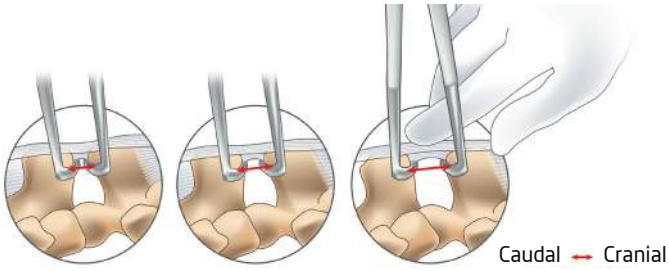
Cleaning of the interspinous space as carefully as possible, to be sure to have penetrated on the other side (with hernia forceps and Kerrison rongeur).

For a good access to the interspinous space, you can use the monopolar instrument, and fold its end as illustrated on this picture.

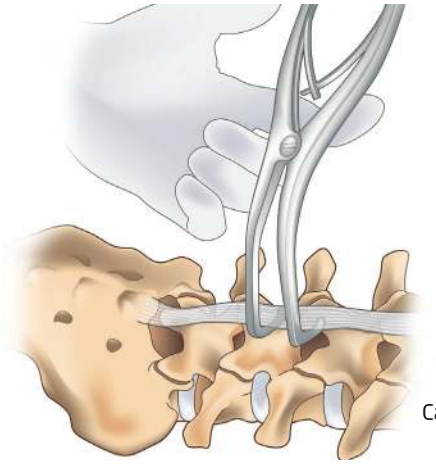


4 DISTRACTION OF THE INTER-VERTEBRAL SPACE AND SIZING OF THE PROSTHESIS

The distractor must be placed at 2/3 of the posterior height of the interspinous space in order to have a sufficient area to determine the size of the prosthesis using the appropriate instrument, which therefore must be in contact with the yellow ligament, between the laminae.

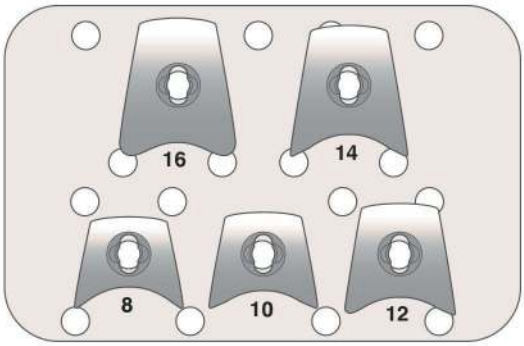


The interlaminar space must be distracted gradually and in several stages, checking visually and by manual touch the tension of the supra-spinous ligament (SSL).



Distraction should be applied until an appropriate SSL tension is achieved, as determined by surgeon.

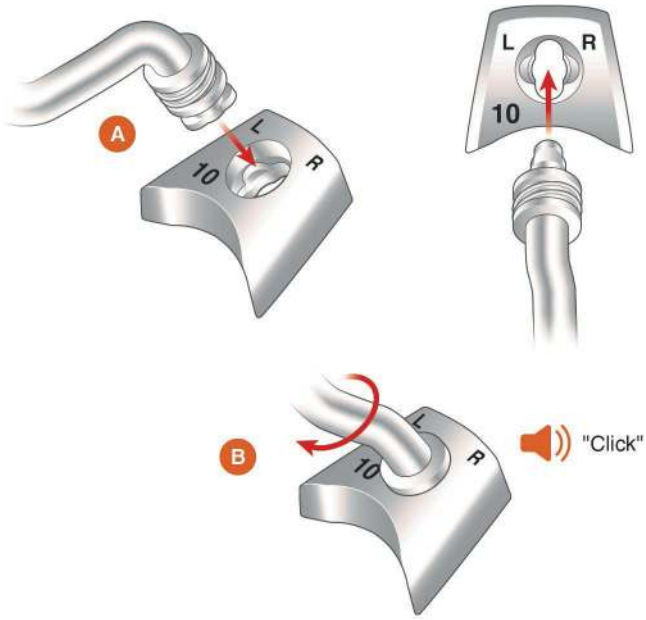
Empiric method: when the distractor is self-retaining.



5 CHOICE OF IMPLANT SIZE

The trial device are sorted in a specific box in the ancillary set.

Choose the necessary trial device and assembly it to the handle by applying a pressure (step A) and rotating the handle clock (or counter clock) wise (step B).



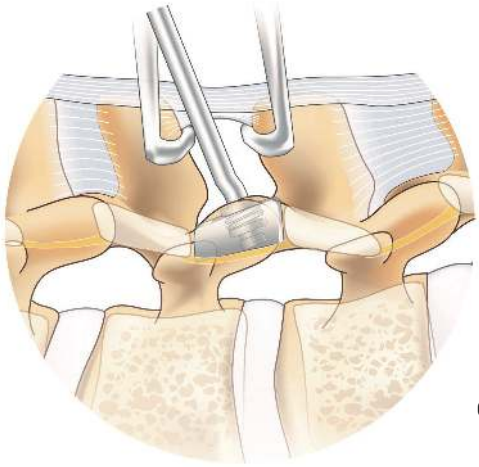
L : left side position (approaching the interspinous space by the left)

R : right side position (approaching the interspinous space by the right)

10 : size of the trial device: 08 / 10 / 12 / 14 / 16 matching the implant's size.

When inserting the tip of the trial holder into the trial device, be sure to be in the axis on the device in such way the tip is aligned to the hole of the trial.

While connecting the trial holder to the trial device to the left or right position, you must hear an audible « click ». This « click » means that the connection is secured in the appropriate position.



Caudal ⟷ Cranial

The trial device is used to determine the size of the implant which may be used.

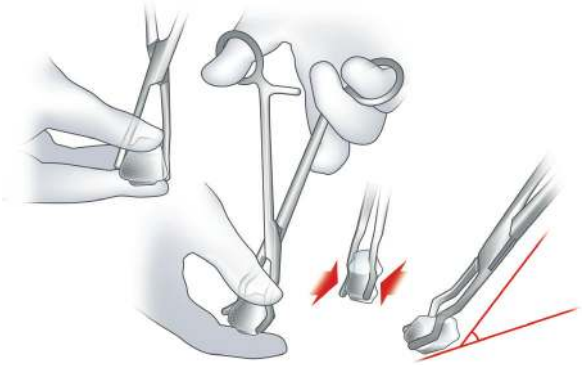
5 sizes are available:

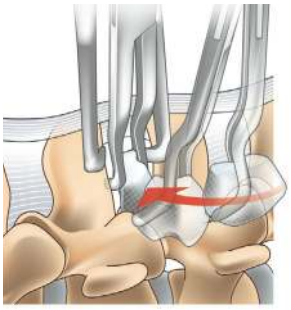
8 / 10 / 12 / 14 and 16 mm

The nose of the prosthesis must be compressed between the two laminae: if the distance measured is between two trial devices sizes, it's necessary to choose the biggest size to ensure its compression.

6 IMPLANTATION

Compression of the prosthesis, with care to place the extremities of the implant holder on the largest border of the prosthesis.

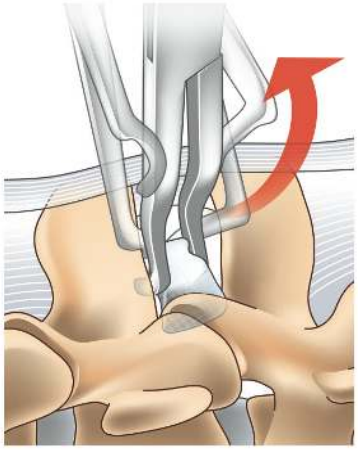




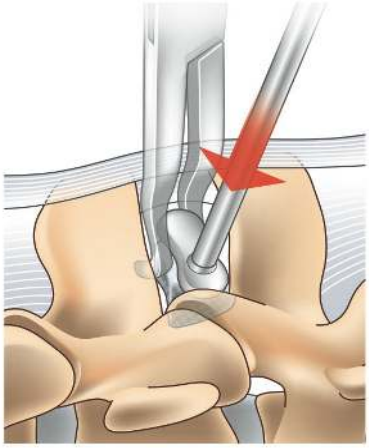
Caudal ⟷ Cranial

Dip the prosthesis into physiological liquid few secondes for an easier grip and a better compression.

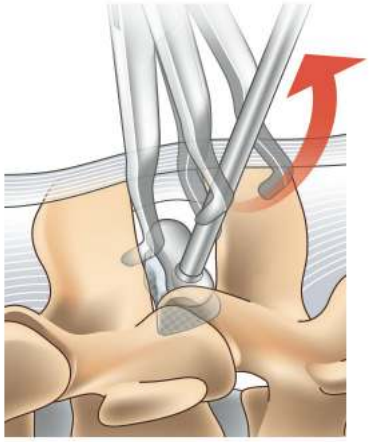
Insertion of the prosthesis with a clockwise movement.



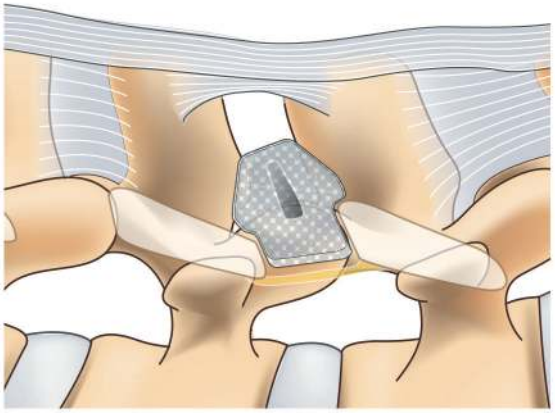
Remove the distraction forceps, with the anti-clockwise movement.



Finally, use the impactor to maintain the prosthesis...



... during the removal of the implant holders, again with a anti-clockwise movement.



If the prosthesis is implanted correctly and in the right place, it should be, remembering the anatomy of the laminae where the superior one is on one plane higher than the inferior one. The final position must be slightly oblique from cranial to caudal direction, and anteroposterior direction.

7 CLOSING

Suturing of the soft parts in layers.

Infiltration of the para-vertebral muscles with long acting anaesthesia.

8 POST-OPERATIVE CARE

According to the pathology, and to the surgeon's habit, the patient can stand-up 3 to 4 hours after surgery.

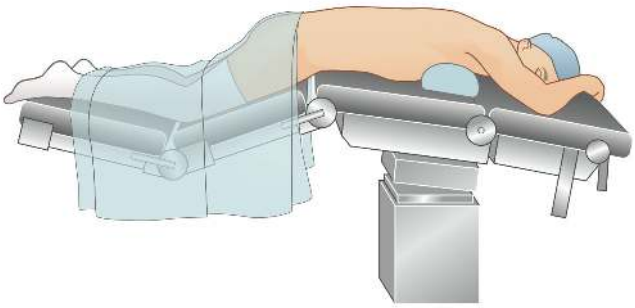
Brace according to the practice of the surgeon.

Advice to the patient:

- no flexion during 3 weeks

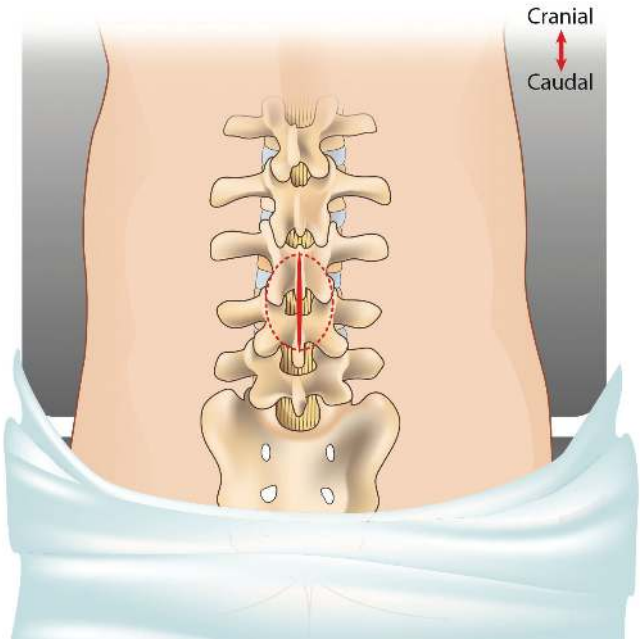
- in sitting position, it is necessary to maintain a good lumbar lordosis

Post-operative control of the prosthesis positioning one month after surgery.



1 POSITIONING OF THE PATIENT

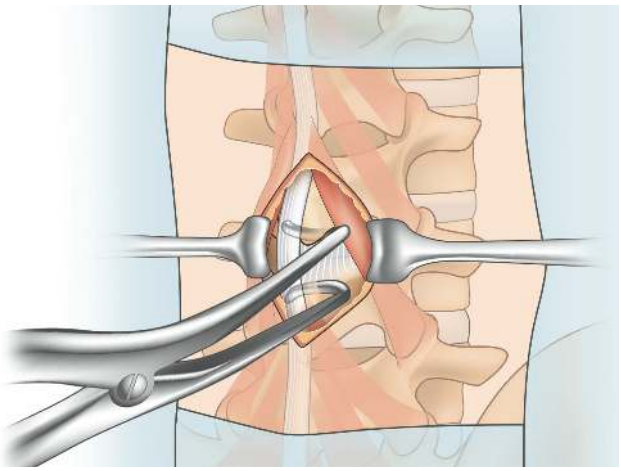
Prone position.



2 APPROACH

After X-Ray monitoring of the affected level, incision of about 5 cm on the midline.

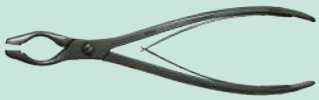
Bilateral incision of the fascia (with special care to leave intact the supra-spinous ligament) and then dissection of the multifidus to reveal the two spinous processes and the two hemi laminae bilaterally.



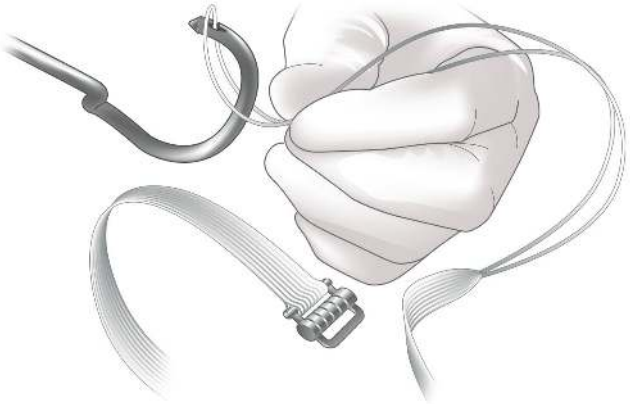
3 IMPLANTATION OF THE PROSTHESIS

Follow the instructions of the monolateral surgical technique to implant the prosthesis.

In the bilateral approach, you can use the large bone rongeur forceps to clean the interspinous space.

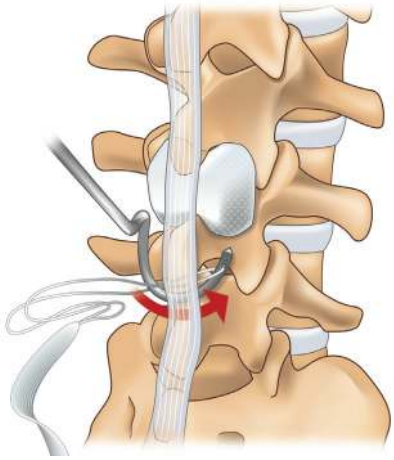


ROGNINTRAL

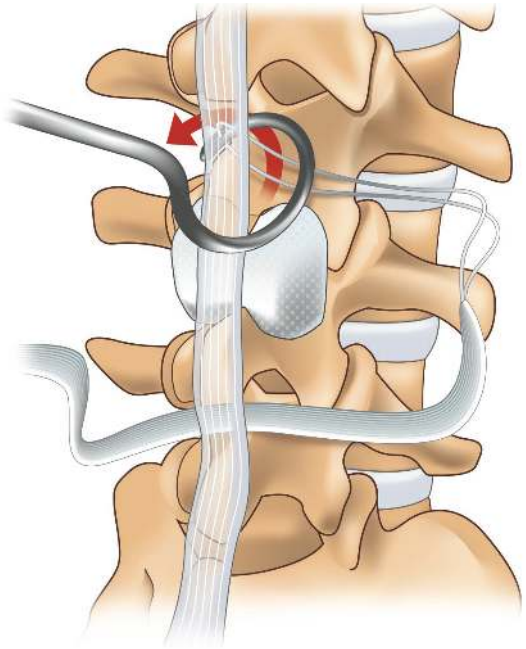


4 POSITIONING OF THE LIGAMENT

Attach the thin loop at the end of the ligament to the wire guide.



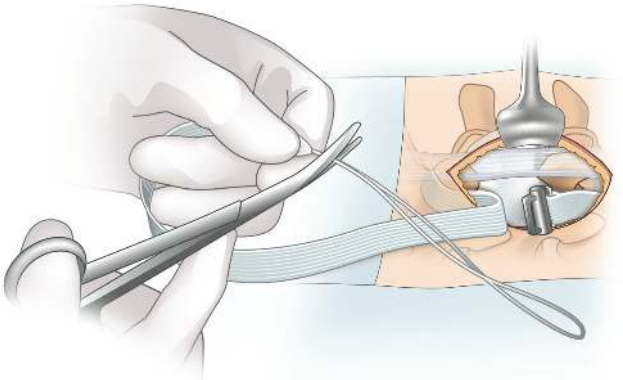
Pass the ligament under the inferior spinous process and bring it out again on the contra-lateral side.



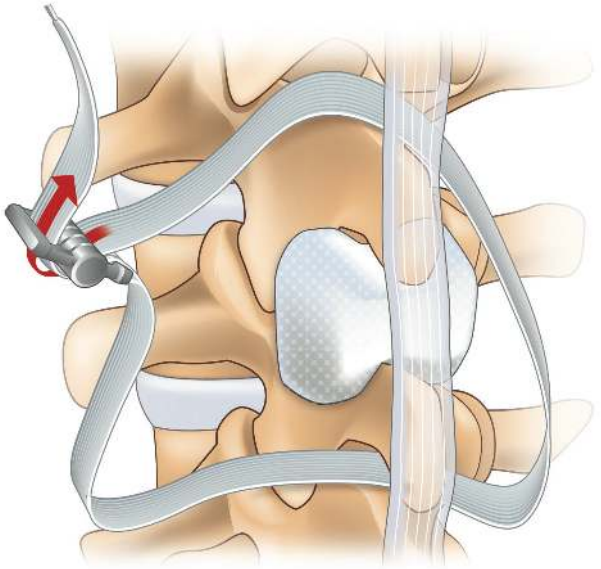
Detach the ligament from the wire guide, and attach it again on the other side.

Pass it around the superior spinous process.

Attention must be taken that the ligament is not twisted.

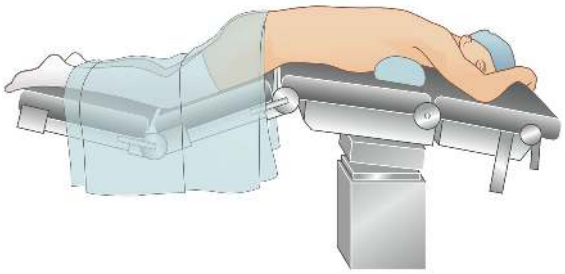


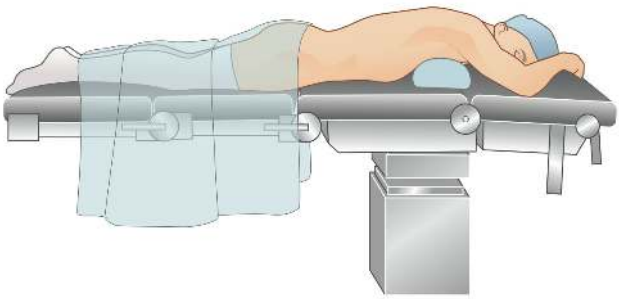
Cut the thin loop on its end.



Pull the ligament very slowly and pass its end through the titanium buckle.

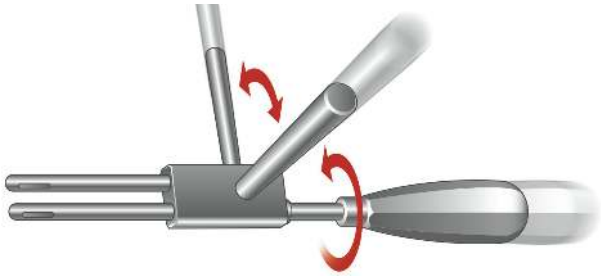
Tighten the ligament manually first.

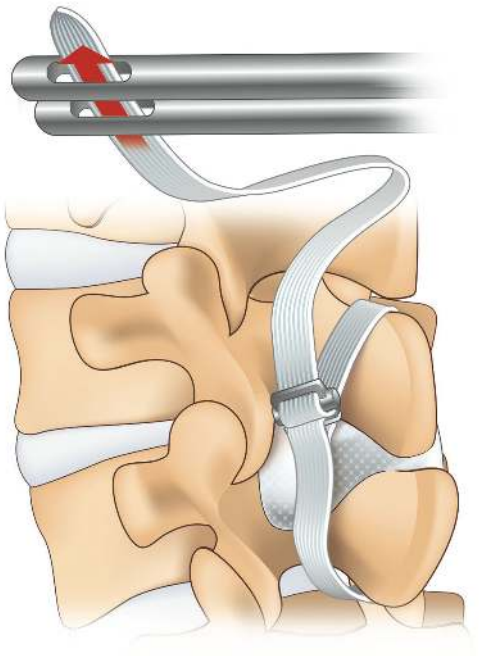




5 POSITIONNIG OF THE PATIENT BEFORE FINAL TIGHTENING OF THE LIGAMENT

As illustrated on these views, after implantation of the device and the ligament, change the position of the table to restore normal lordosis before final tightening.

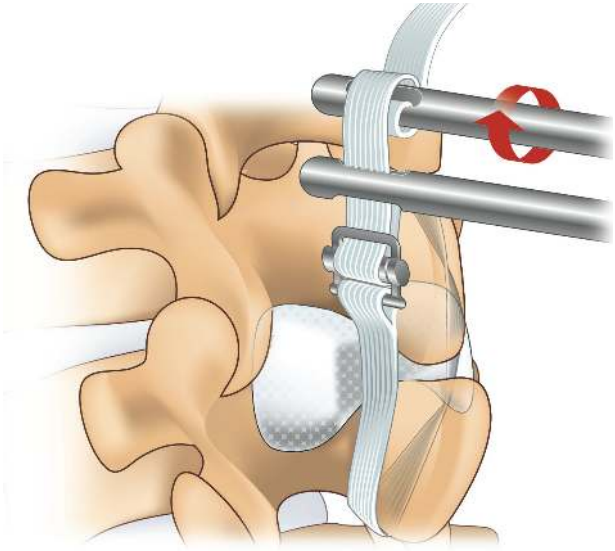




6 FINAL TIGHTENING OF THE LIGAMENT

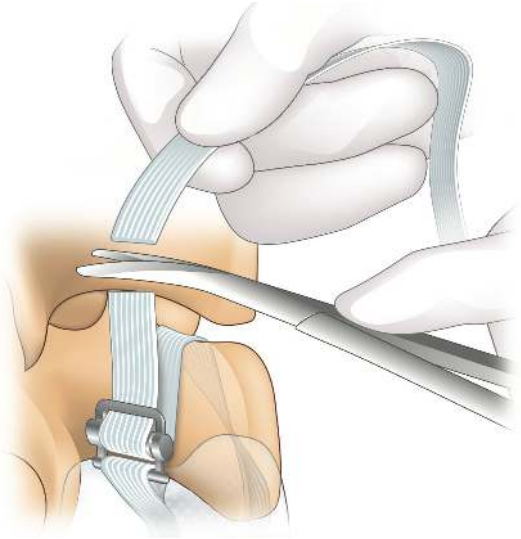
The tightener is made of 3 parts: two branches (one is fixed and the other is rotative), and a ajustable handle in 2 positions according to the surgeon's preference.

Pass the ligament through the slots, and introduce the tightener near the spinous process.

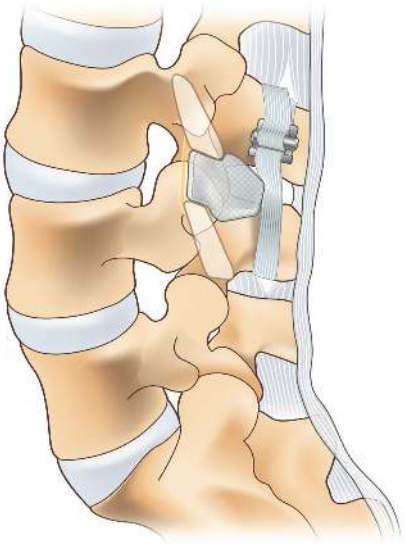


The fix part of the tightener has to be against the buckle.

Turn the main handle to tighten.

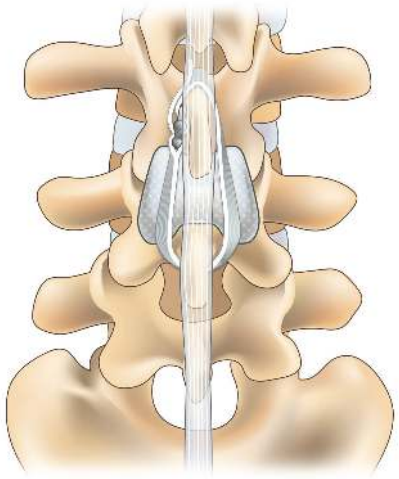


Once properly tightened, cut the ligament at least 1 cm from the buckle.



In the correct position, the ligament must be positioned exactly over the top of the device.

Be careful that the buckle must be parallel to the spinous processes to avoid any release.



Final position of posterior view.

7 CLOSING

Suturing of the soft parts in layers.

Infiltration of the para-vertebral muscles with long acting anaesthesia.

8 POST-OPERATIVE CARES

According to the pathology, and to the surgeon's habit, the patient can stand-up 3 to 4 hours after surgery.

Brace according to the practice of the surgeon.

Advice to the patient:

- no flexion during 3 weeks

- in sitting position, it is necessary to maintain a good lumbar lordosis

Post-operative control of the prosthesis positioning one month after surgery.

1. Perform a midline incision on the implantation level.

2. Locate the implant and clean the fibrotic tissue to access the polyester cover.

3. Cut the polyester cover to expose the silicon part of the implant.

4. Using forceps, pull out the silicon part out of the patient.

5. Then grab the polyester cover and twist it while pulling it out. It will slowly be detached from the fibrotic tissue from the implantation site and the silicon sheeting on the anterior part avoid adherance with the spinal cord.

After the explantation procedure, Cousin Surgery does not have the capacity to indicate the next steps in the case of a revision surgery.

A surgery video of explantation procedure is available upon request at serviceclients@cousin-surgery.com

NOTES

NOTES

COUSIN SURGERY

We care for Surgery

cousin-surgery.com

Allée des Roses • 59117 Wervicq-Sud • FRANCE

IntraSPINE® is a class IIb medical device manufactured by COUSIN BIOTECH S.A.S. The ancillaries are class I medical devices and trial devices are class IIa medical device.

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

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. The IFU is available electronically at: https://www.cousin-biotech.com/en/implant-notices

Reference: TORINTGB10 - Version: 24/03/23. Non contractual pictures and texts. Specifications likely to be modified without notice.

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.