

InSWing™
INTERSPINOUS SPACER



**Unilateral, Minimal Invasive
Interspinous Spacer**

INTERNATIONAL EDITION

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Orthofix Spinal Implants wishes to thank the following surgeons for their contribution to the development of the technique:

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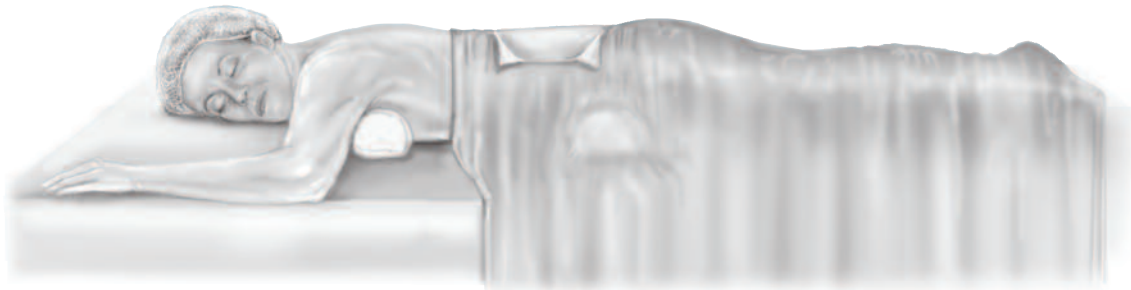
INTRODUCTION

InSWing™ Interspinous Spacers are designed to alleviate the leg and back pain suffered by individuals with lumbar spinal stenosis (LSS). This innovative device is designed for a less invasive surgical procedure involving minimal or local anesthesia, significantly less blood loss, and a shorter rehabilitation period than alternative surgical procedures.

Designed to be placed between the spinous processes of the lumbar spine, the InSWing spacer uses a unique unilateral approach. It is secured through the deployment of an innovative double-wing structure resulting in the widening of the spinal canal and decompression of the spinal nerve that was causing the patient's leg and back pain.

Acquired by Blackstone Medical and its parent Orthofix International N.V. in September 2007, InSWing was developed by a team at LfC Sp. Zo.o. that included Marek Szpalski M.D., Robert Gunzburg M.D., Ph. D. and Lechoslaw F. Ciupik, Ph.D., a bioengineer who was the team's chief designer.

InSWing technology is an important addition to Orthofix Spine's portfolio. It underscores the company's continuing commitment to make minimally invasive devices available to surgeons around the world.



1. PATIENT POSITIONING

Place the patient in the prone position.

Use padded supports under the anterior iliac crests and at the chest level. The abdomen must be free to avoid venous compression. A physiological lordotic position is thus created.

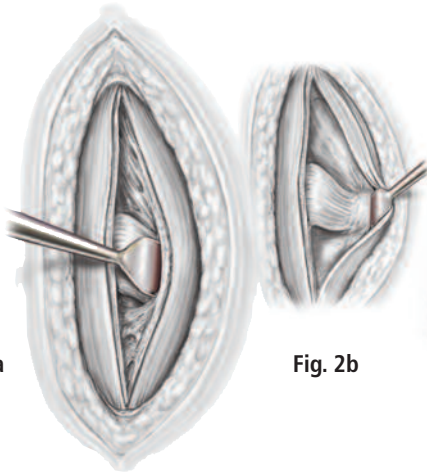


Fig. 2a

Fig. 2b

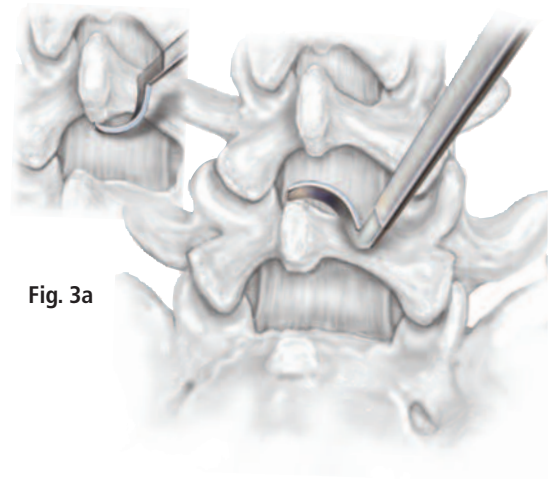


Fig. 3a

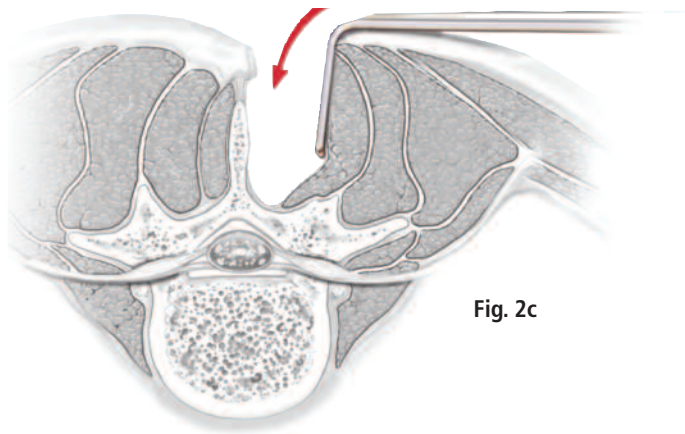


Fig. 2c



Fig. 3b

2. MIDLINE INCISION

Paraspinal muscles are detached subperiostally on **one** side with a Cobb elevator (see Figs. 2a and 2b).

A retractor is then used to expose the interspinous space (see Fig. 2c).

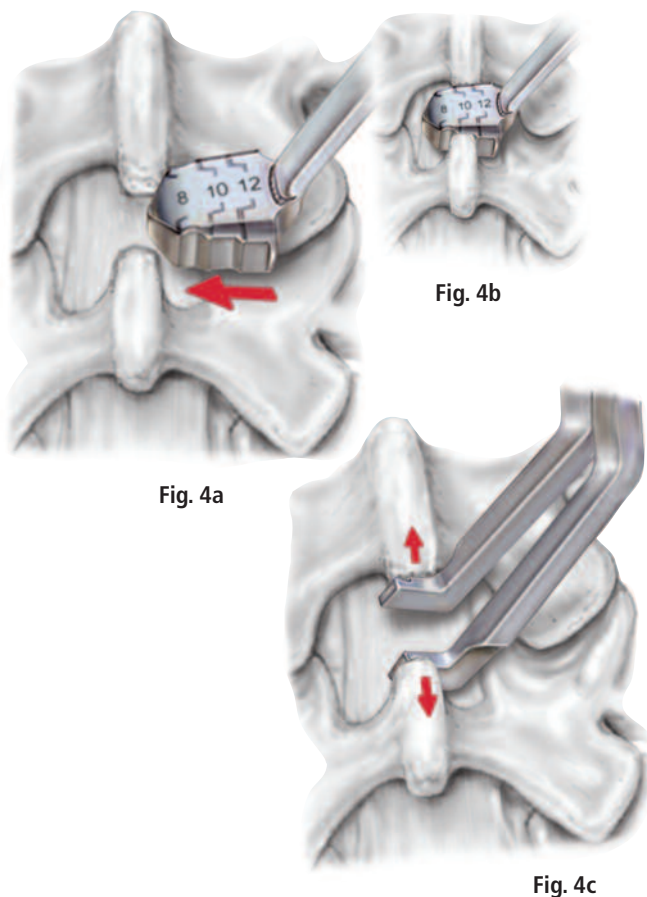
Using a scalpel or angled knife, open the interspinous ligament close to lamina in order to respect the supraspinous ligament.

Remove remains of the interspinous ligament with Kerison or knife.

3. INTERSPINOUS PREPARATION

Use a scraper to clean the remains of the interspinous ligament from the spinous process (see Fig. 3a).

NOTE: Detach the muscle on the contralateral side with the scraper to allow the wings to optimally deploy. (see Fig. 3b).



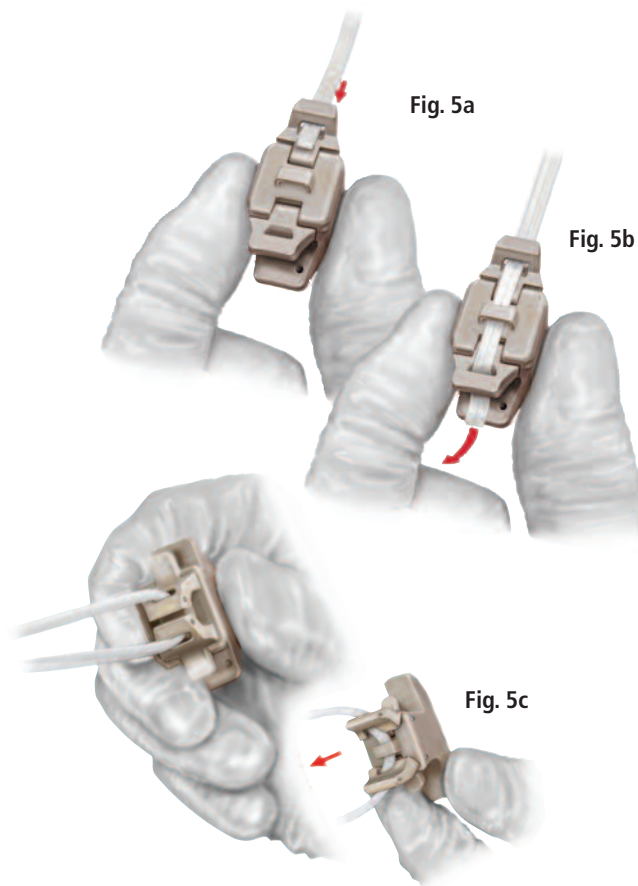
4. SIZING

Start with the smaller sizing trial and insert it into the interspinous space (**See Fig. 4a and b**). Push the trial gently into place until resistance is felt, but do not distract the spinous processes. Once resistance is found and the sizer fits tightly, read the number on the sizing trial to identify the optimal implant size.

The distractor can be used to verify the implant size (**see Fig. 4c**). The distractor has indicator marks corresponding to each implant size.

NOTE: When using the sizing trial or distractor be careful not to over distract. Too much distraction will induce kyphosis.

NOTE: If you elect not to use the band, please skip to step 8 followed by step 15.



5. IMPLANT PREPARATION

Make sure the implant wings are open.

Starting at either side of the implant, thread the band through the slot in the first wing (**see Fig. 5a**). Next, continue threading through the center slot. Finally, continue threading the band through the second wing (**see Fig. 5b**).

Close the implant wings (**see Fig. 5c**).

NOTE: Ensure the band has equal band lengths once passed through to the implant.

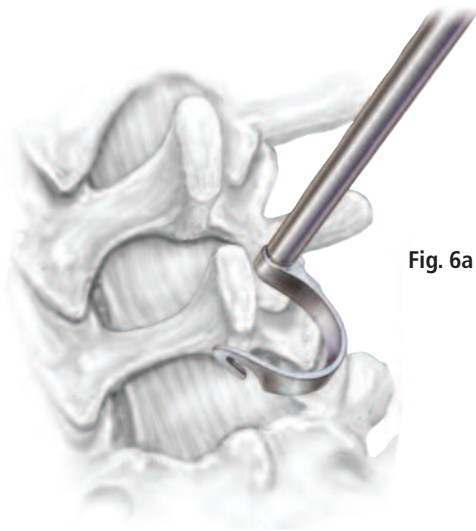


Fig. 6a

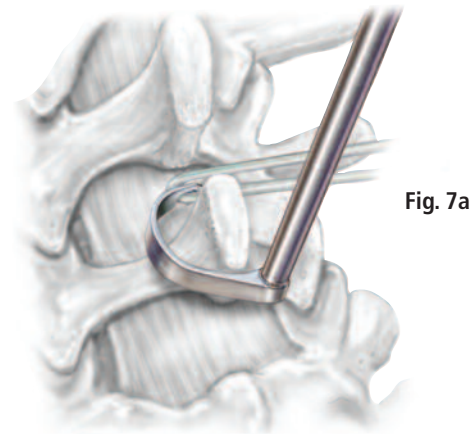


Fig. 7a

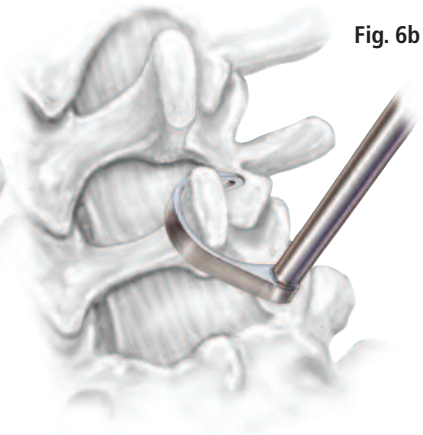


Fig. 6b

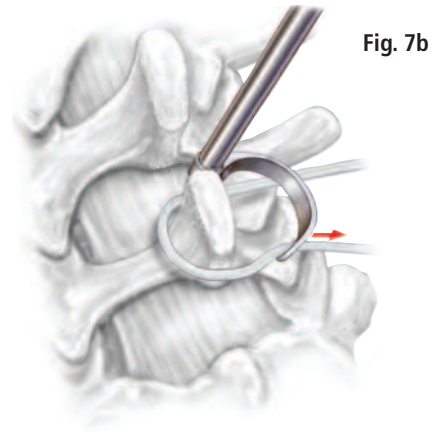


Fig. 7b

6. PREPARATION FOR BAND

Identify superior and inferior interspinous spaces. Angled forceps can be used for that purpose.

Pass an awl through the caudal interspinous space until you reach the operative interspinous space (see Figs. 6a and 6b).

Awls are available in several radii to accommodate patient anatomy.

7. BAND REEVING

With the awl passed through the caudal interspinous space, attach one band end to the eyelet on the awl tip (see Fig. 7a).

Pass the band around the spinous process by rotating the awl back through the operative interspinous space (see Fig. 7b).

Repeat steps 6 and 7 for the cephalad interspinous space using the second awl.

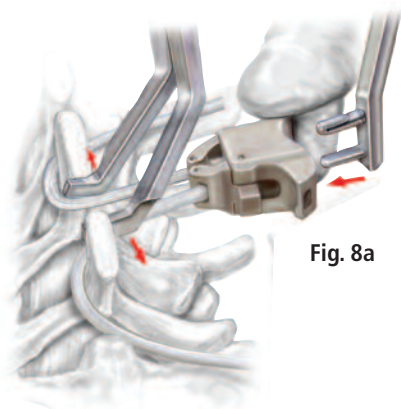


Fig. 8a

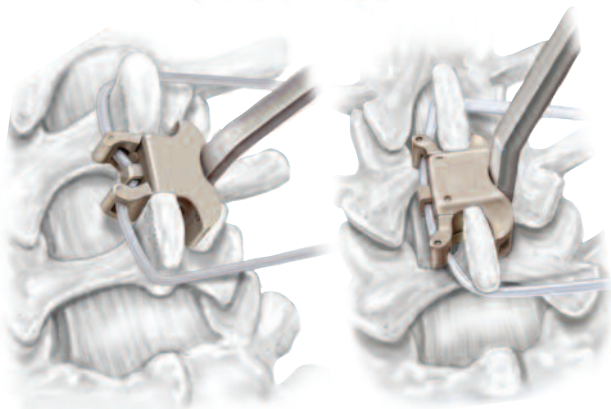


Fig. 8b

Fig. 8c

8. IMPLANT INSERTION

Insert the implant holder into implant (see Fig. 8a).

While pulling band ends, introduce the implant with closed wings into the interspinous space until wings completely open and are in contact with spinous process (see Figs. 8b and 8c).

If resistance is encountered, the distractor can be used to gently open the interspinous space.

Alternatively, introduce one wing at a time by holding the implant in a laterally skewed position and roll it into place.

CAUTION: Do not force the implant into the interspinous space as it may cause a fracture of the spinous process.

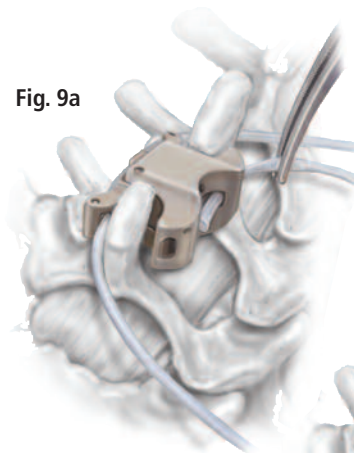


Fig. 9a

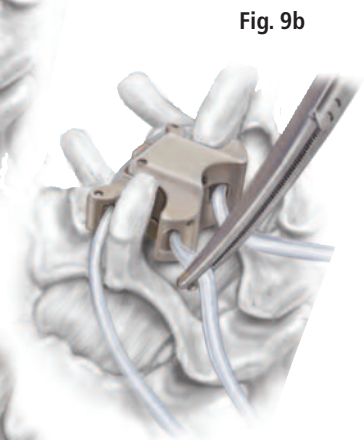


Fig. 9b

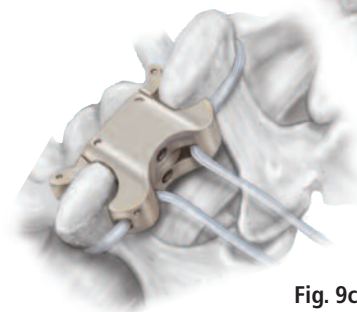


Fig. 9c

9. COMPLETE BAND REEVING

Using forceps, complete the band reeving through the slots on the fixed wings of the implant (see Figs. 9a, 9b and 9c).

NOTE: During the reeving process, ensure the band is not tangled.

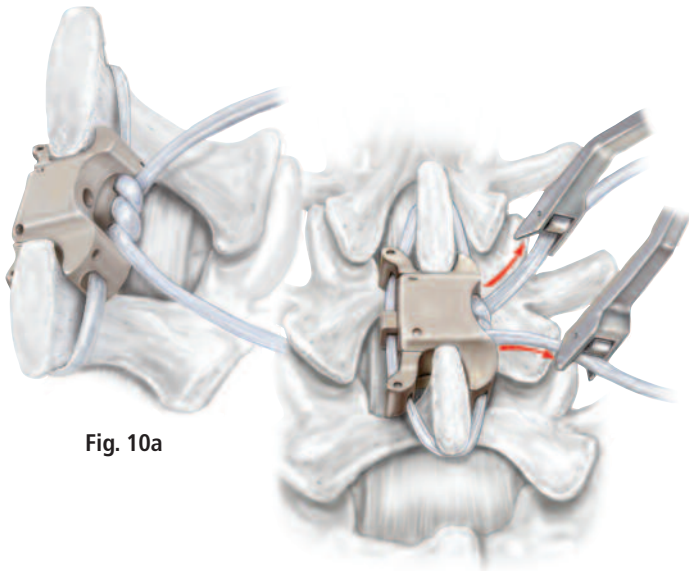


Fig. 10a

Fig. 10b

10. KNOT THE BAND

First, create an overhand knot and tighten by hand (see Fig. 10a).

Next, pass the band ends through the distal guides of tensioning instrument (see Fig. 10b).

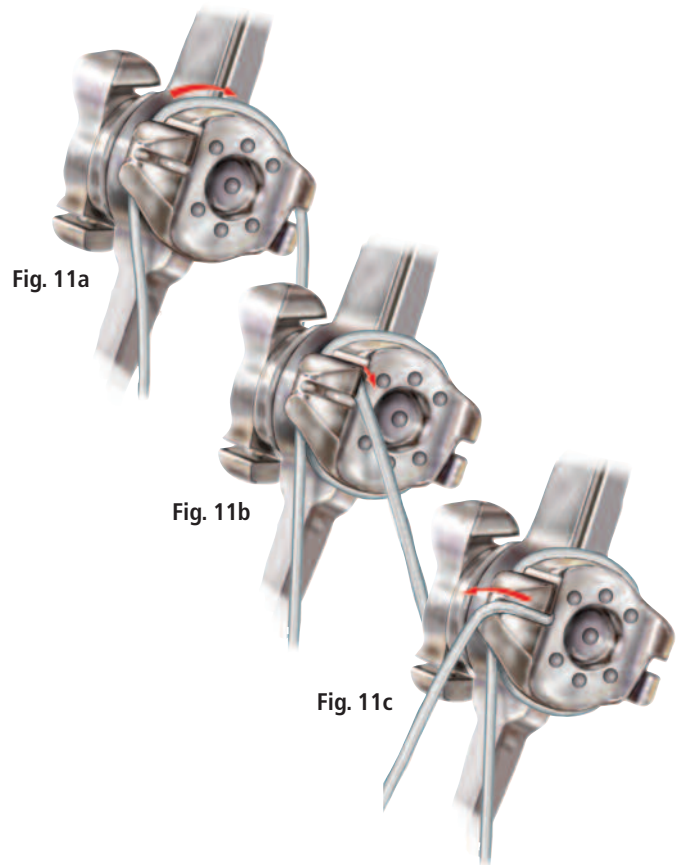


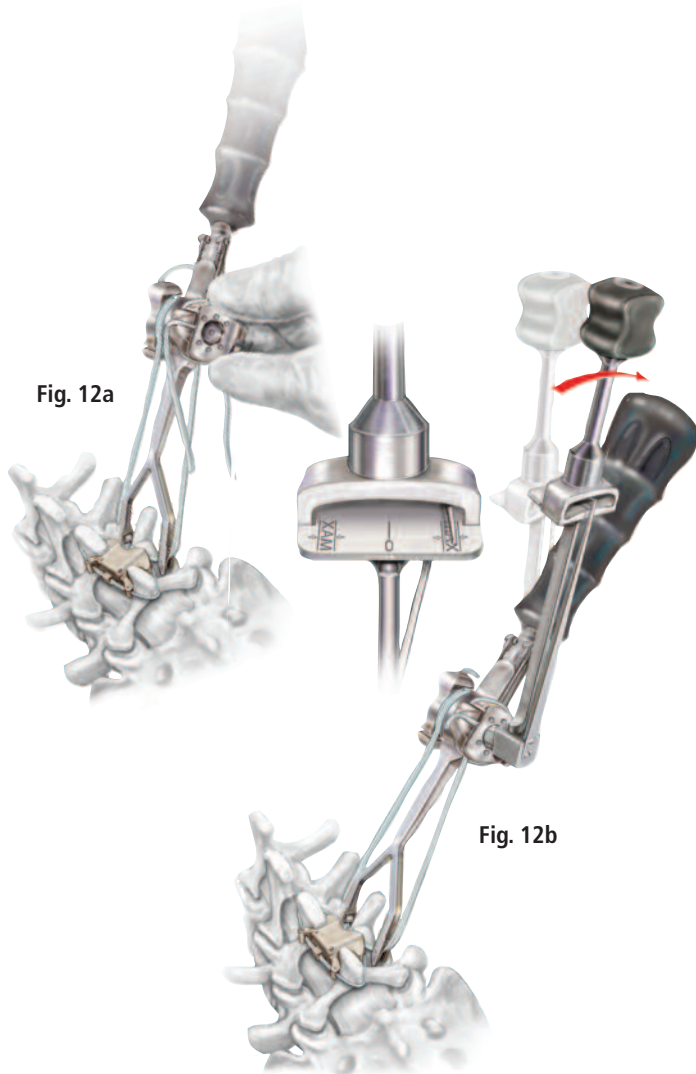
Fig. 11a

Fig. 11b

Fig. 11c

11. TENSION THE BAND

Interlace the band around ratcheting spindles of the tensioning instrument (see Fig. 11a, 11b and 11c).

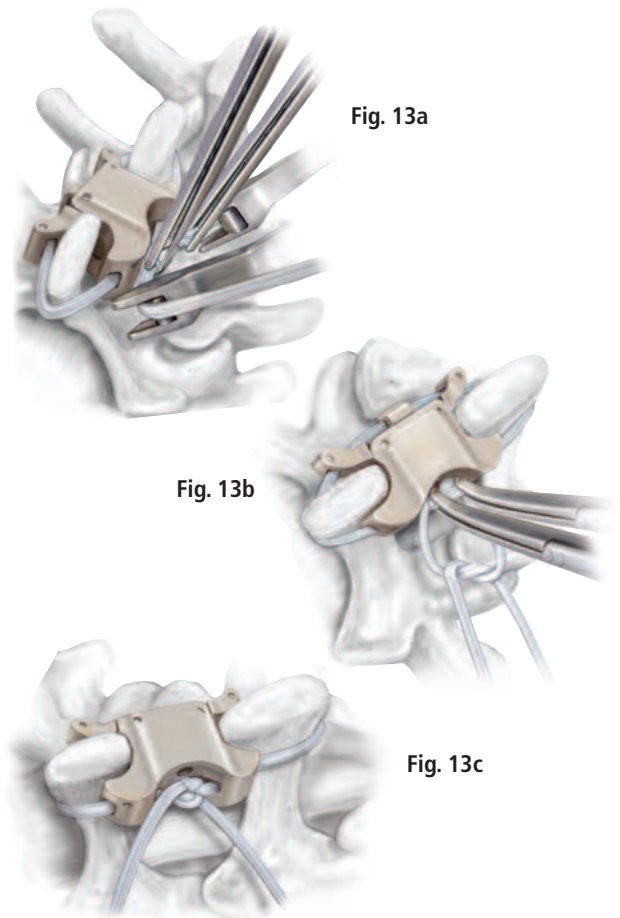


12. TENSION THE BAND

Use a torque wrench on both sides of the tensioner.

Apply force on the torque wrench until the needle indicates the appropriate band tension marked as "Max" on the torque wrench.

NOTE: During the tensioning process, alternate the torque wrench to ensure the band tensioner remains centered across the implant.



13. PREPARE 2ND KNOT

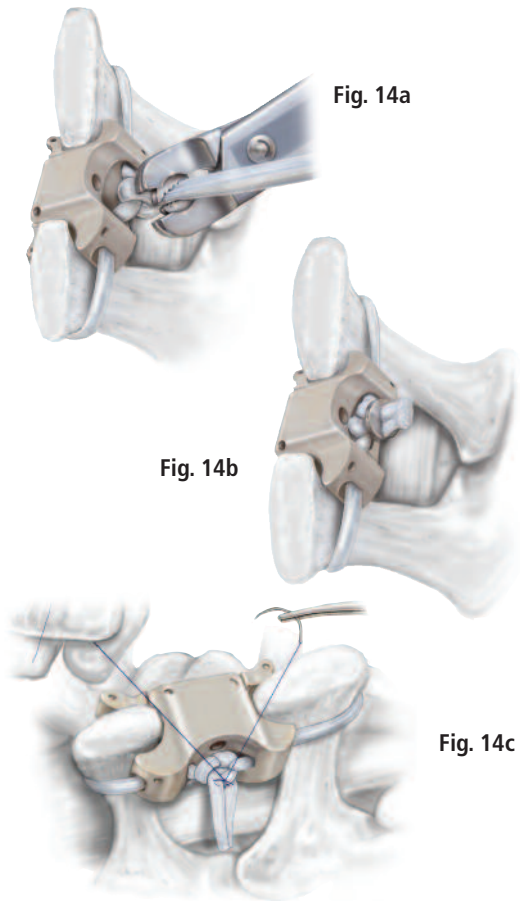
Maintain tension on the first knot using 2 forceps (see Fig. 13a).

Release the tension on the tensioning instrument by pressing the release buttons and/or unwinding.

Create a second overhand knot by hand (see Fig. 13b and 13c).

Repeat tensioning process to accurately tighten the second knot.

NOTE: Remove the forceps as the tension is applied to the second knot.



14. PROTECT THE KNOT

Protect the knot with the included clip and crimping instrument (see Figs. 14a and 14b).

Alternatively, suture the knot with non-resorbable sutures (see Fig. 14c).

Cut excess band.



15. FINAL POSITION VERIFICATION

Before closing, use fluoroscopy to verify the final implant position.

Complete the surgery using standard posterior lumbar closure procedures.

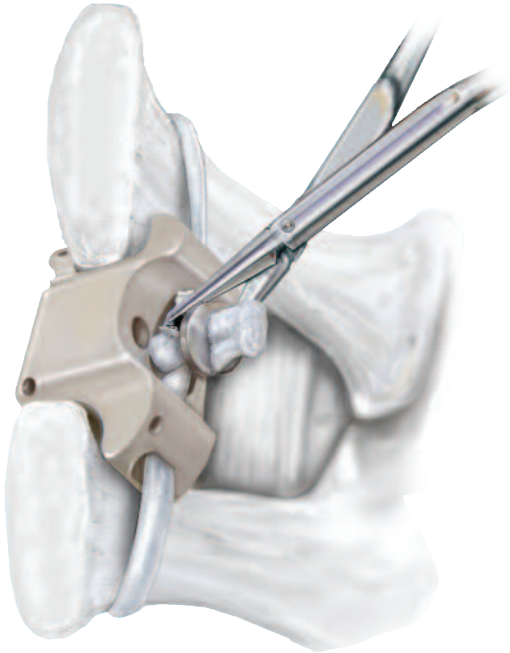


Fig. 16



Fig. 17

IMPLANT REMOVAL

In certain circumstances, removal may be necessary. Reasons for removal include but are not limited to:

- Dismantling or breakage of implant
- Fracture of spinous process with pain
- Infection
- Surgery involving spinous processes

16. CUT THE BAND

Cut the band (if present) and knot. Remove the band and clip that were used to secure the knot.

17. MAKE AN OPENING

Make a little opening in the intact fascia on the side of the opening wings.

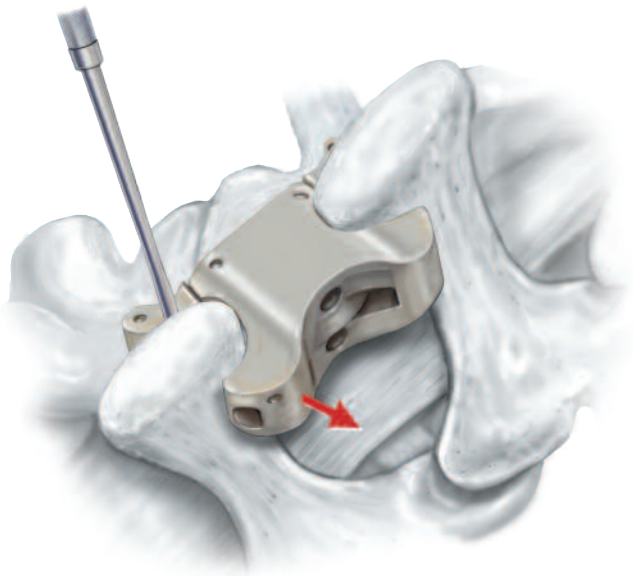


Fig. 18a

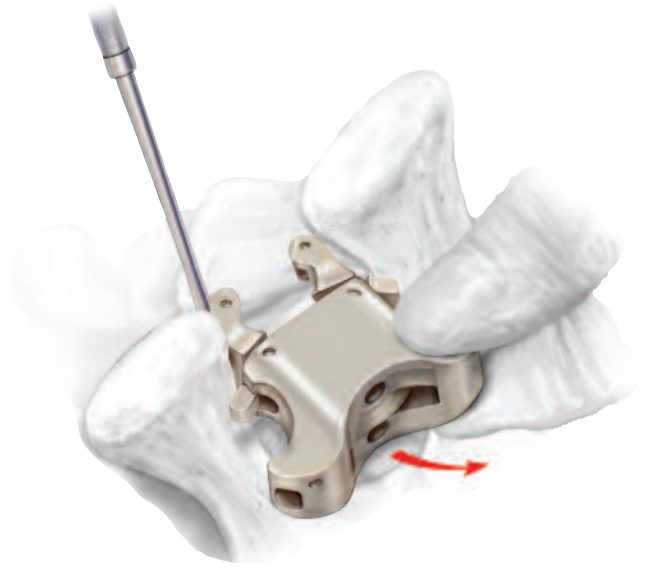


Fig. 18b

18. INSERT RASPATORY

Insert a raspatory (periosteal elevator) along a spinous process (**Fig. 18a**) and close (lift) one of the wings of the implant while pulling implant out (**Fig. 18b**). This can also be done with a finger.

CAUTION: Do not try to pull the implant out without closing a wing, as this may risk spinous process fracture.

IMPLANTS (all implants are sterile packed)**17-0001** Band (1) & Clips (2)**17-0010** 10mm InSWing Assembly**17-0014** 14mm InSWing Assembly**17-0008** 8mm InSWing Assembly**17-0012** 12mm InSWing Assembly**17-0016** 16mm InSWing Assembly**INSTRUMENTS****17-9000** Sterilization Case**17-0301** Interspinous Sizer, Large**17-0600** Band Holder**17-0100** Interspinous Scraper, Right**17-0426** Circular Awl, Left, 26mm**17-0700** InSWing Inserter**17-0101** Interspinous Scraper, Left**17-0430** Circular Awl, Left, 30mm**17-0800** Band Stretcher**17-0200** Interspinous Distractor**17-0526** Circular Awl, Right, 26mm**17-0900** Torque Wrench**17-0300** Interspinous Sizer, Small**17-0530** Circular Awl, Right, 30mm**17-1000** Clip Clamp**OPTIONAL INSTRUMENTS****17-0422** Circular Awl, Left, 22mm**17-0428** Circular Awl, Left, 28mm**17-0524** Circular Awl, Right, 24mm**17-0424** Circular Awl, Left, 24mm**17-0522** Circular Awl, Right, 22mm**17-0528** Circular Awl, Right, 28mm

Instructions for Use

See actual package insert for
Instructions for Use

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Proper surgical procedure is the responsibility of the medical professional. Operative techniques are furnished as an informative guideline. Each surgeon must evaluate the appropriateness of a technique based on his or her personal medical credentials and experience. Please refer to the "Instructions for Use" supplied with the product for specific information on indications for use, contraindications, warnings, precautions, adverse reactions information and sterilization.

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