

In-Space. Interspinous distraction through a mini-open, posterior, unilateral approach.

Technique Guide
Posterior Approach

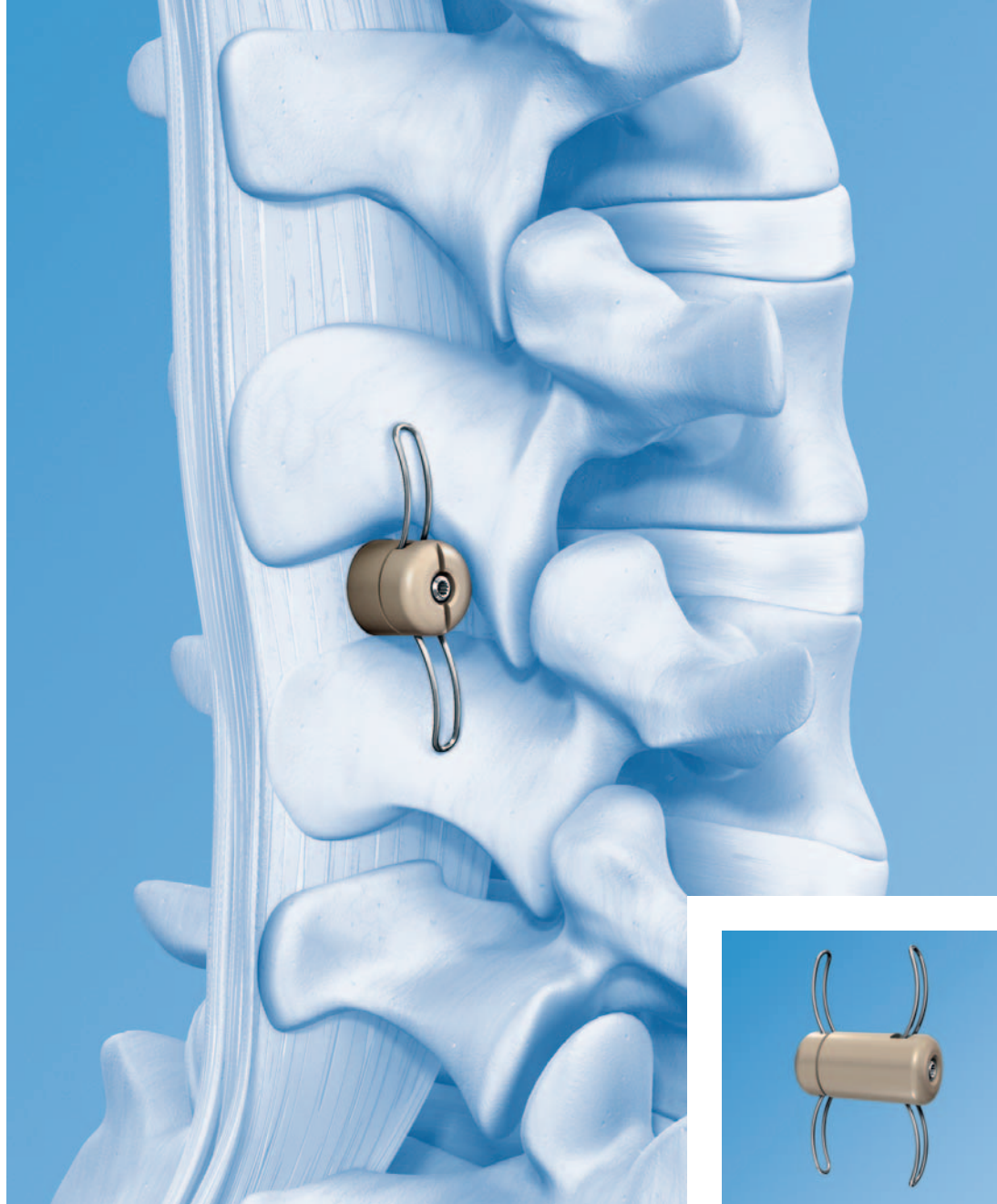


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 Image intensifier control

Warning

This description alone does not provide sufficient background for direct use of the instrument set. Instruction by a surgeon experienced in handling these instruments is highly recommended.

Reprocessing, Care and Maintenance of Synthes Instruments

For general guidelines, function control and dismantling of multi-part instruments, please refer to: www.synthes.com/reprocessing

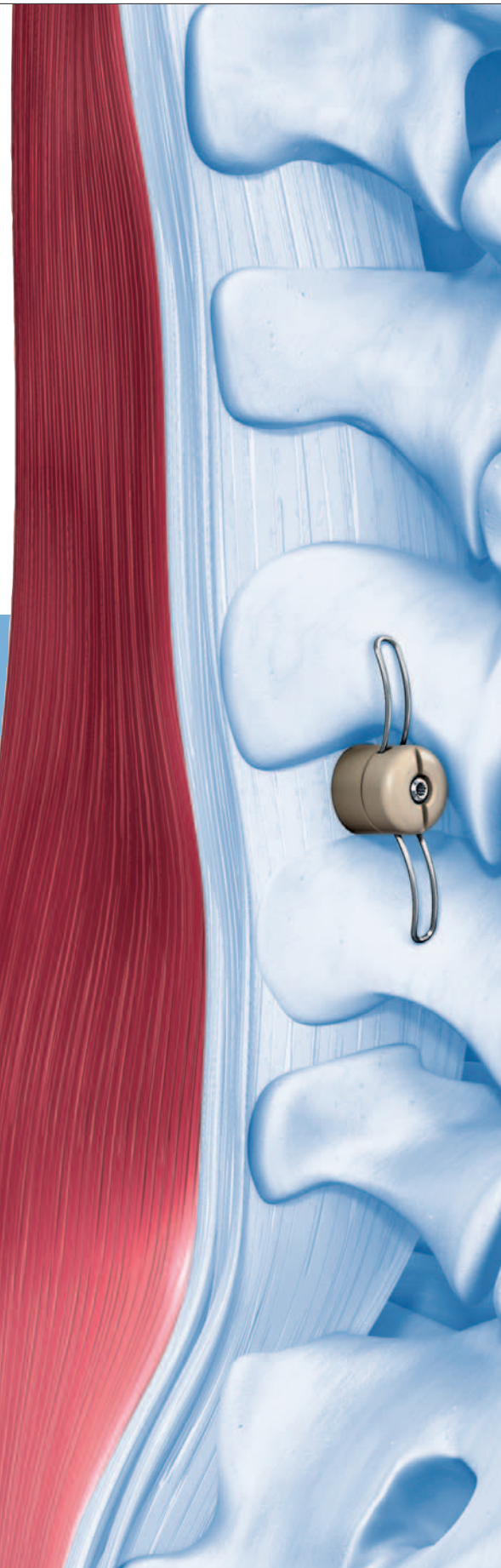
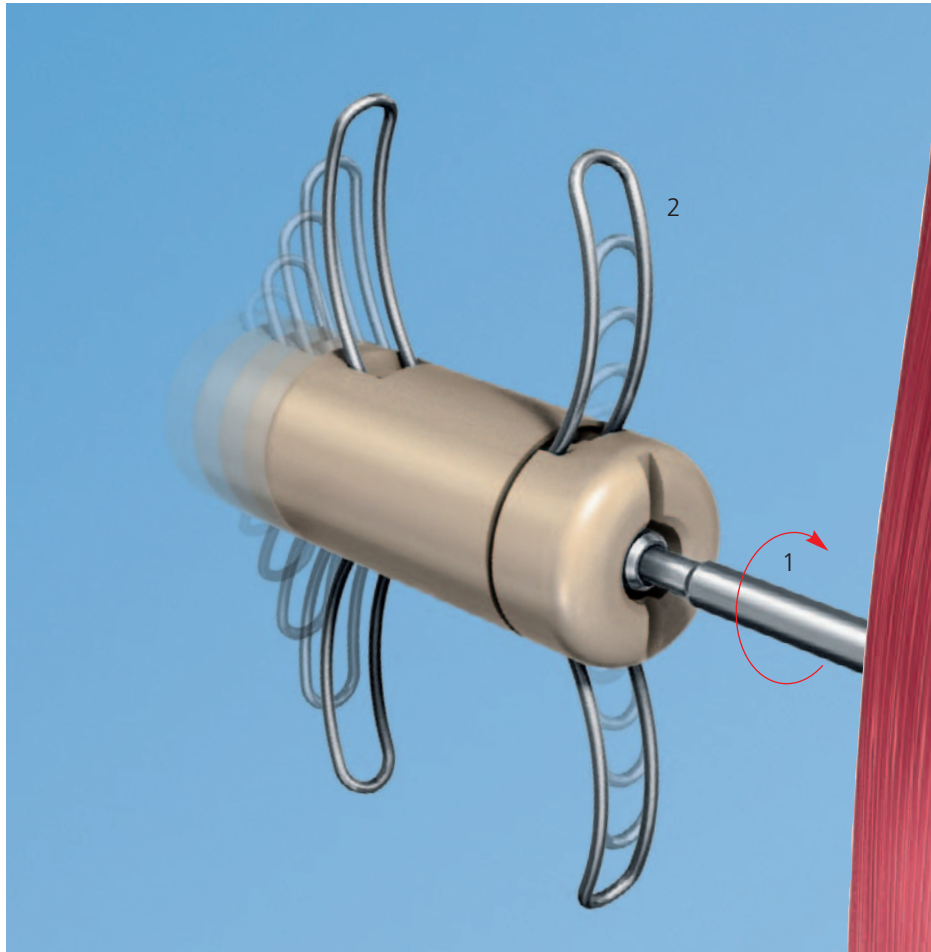
In-Space. Interspinous distraction through a mini-open, posterior, unilateral approach.

In-Situ deployment of the anchorage

When turning the screw (1), the implant closes and the wings (2) are deployed along the spinous processes

Intrinsic stability

- The wings prevent ventral and lateral migration of the implant
- The intact supraspinous ligament prevents dorsal displacement





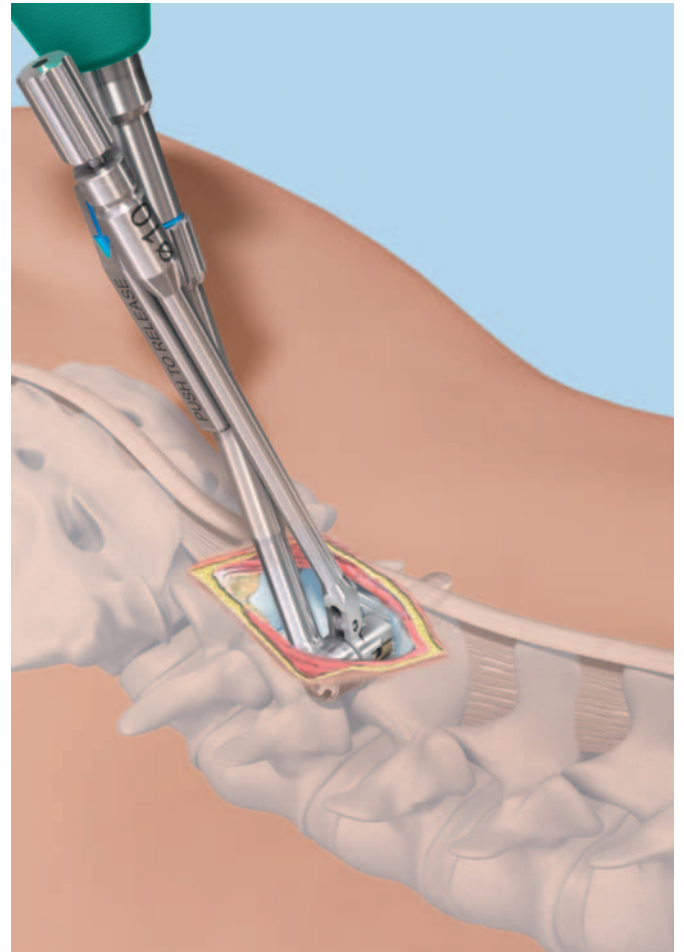
Tissue sparing procedure

Stabilizing anatomical structures are preserved:

- Supraspinous ligament is left intact
- Interspinous ligament is only pierced to the size of the implant
- No bone needs to be trimmed to facilitate the insertion of the implant

Two possibilities for muscle preserving approach

- Mini-open posterior approach:
Only unilateral stripping of the paraspinal muscles
- Percutaneous lateral approach:
No stripping of the paraspinal muscles



Indications and Contraindications

Intended use

In-Space is intended to stop the segmental extension and to distract the interspinous space at a symptomatic level between L1 to S1. In-Space acts as a space-holder and protects mainly the posterior elements by

- maintaining the foraminal height,
- opening up the area of the spinal canal,
- reducing stress on the facet joints and
- relieving pressure on the posterior annulus.

Indications

In-Space can be implanted at one or two levels from L1 to S1 for posterior approach (L1 to L5 for percutaneous approach). For implantation at L5/S1, the presence of a S1-spinous process of adequate size is a prerequisite to fully support the implant.

Based on the intended use, In-Space can be used for the following indications:

- Central, lateral and foraminal lumbar spinal stenosis with leg, buttock or groin pain, which can be relieved during flexion
- Soft disc protrusions with discogenic low back pain
- Facet syndrome due to facet osteoarthritis
- Degenerative spondylolisthesis up to grade I with hyperlordotic curve
- Degenerative Disc Disease (DDD) with retrolisthesis
- Interspinous pain arising from Bastrup syndrome (“kissing spines”)

In-Space can also be used as a temporary implant in conditions which require a temporary unloading of the disc and/or facet joints.

Contraindications

- Severe Osteoporosis
- Conus/Cauda syndrome
- Severe structural spinal stenosis lacking a dynamic component
- Fractures
- Spondylolysis
- Degenerative spondylolisthesis at index level of grade > I according to Meyerding
- Scoliotic deformity at index level
- DDD with fixed retrolisthesis
- Sequestered disc herniation
- Previous surgery at the operative level
- Spinous process and/or lamina dysplasia
- Infection
- Morbid obesity (BMI >40)

Caution: The stability of the In-Space relies on the presence of the following structures:

- Supraspinous ligament
- Laminae
- Spinous processes
- Facet joints

Complete or significant removal of those structures may result in device migration.

Preoperative Planning

In addition to routine preoperative investigations (X-rays AP and lateral; MRI), flexion/extension views are strongly recommended. They provide a better understanding of the active interspinous flexibility and can rule out gross translational instability (e.g spondylolisthesis > grade I) or rigid retrolisthesis.

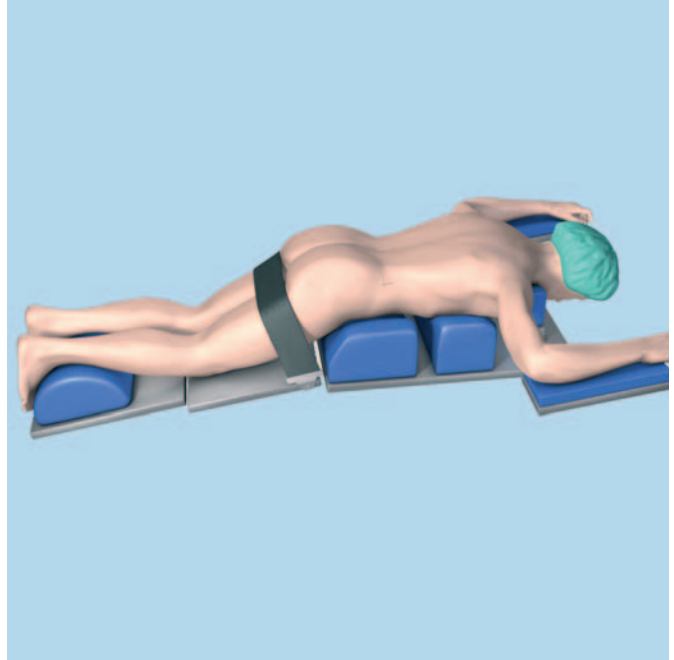
A preoperative CT reconstruction is recommended in the following situations:

- Suspicion of spinous process and/or lamina dysplasia
- At L5–S1 to control the presence of the S1 spinous process

Patient Positioning

The use of a Wilson-like frame is recommended to decrease the lordosis of the patient and to ensure that the abdomen is not put under increased pressure. The table must be tiltable and radiolucent in both planes.

Place the patient in a comfortable prone position. It is advisable to tilt the pelvis by inclining the table at the level of the pelvis. This will intraoperatively increase the segmental kyphosis and achieve natural distraction of the interspinous space.



Surgical Technique for Posterior Unilateral Approach

1

Make incision and expose muscles

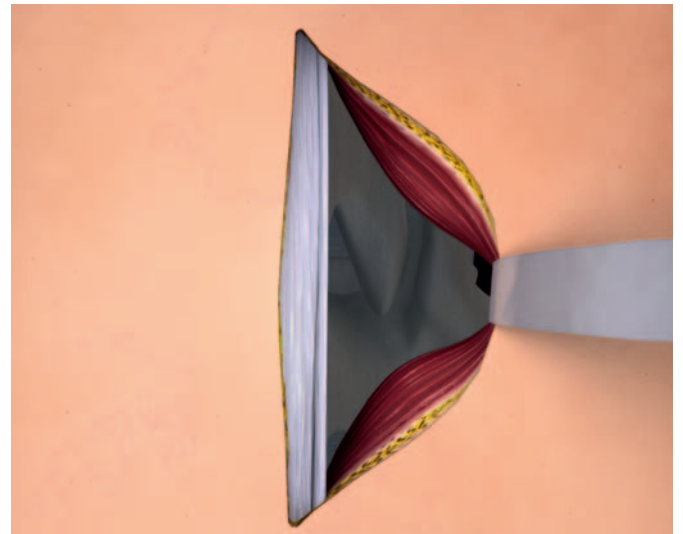
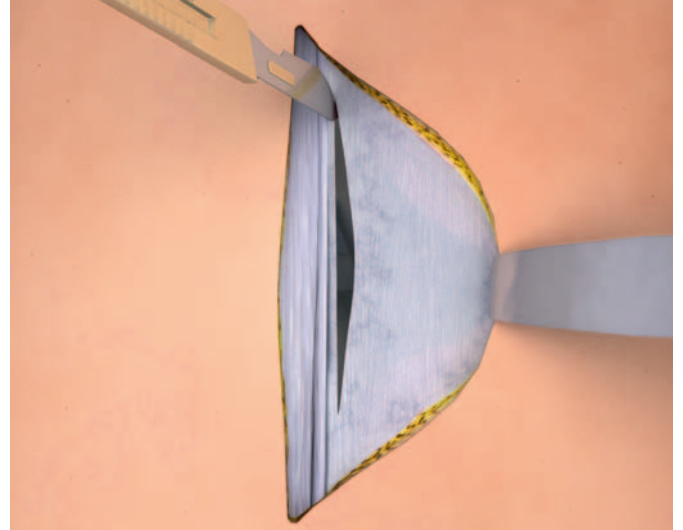
- Under fluoroscopy carefully locate the level requiring In-Space implantation.

Perform a 3 cm midline incision at the index level.

Unilaterally incise the fascia lateral to the supraspinous ligament. Dissect the paraspinal muscles from the spinous processes and lamina.

Retract the muscles laterally.

Note: Do not resect the supraspinous ligament. Take care to preserve the entire thickness of the supraspinous ligament.



2

Pierce the interspinous ligament

Instrument

03.630.025 Perforator

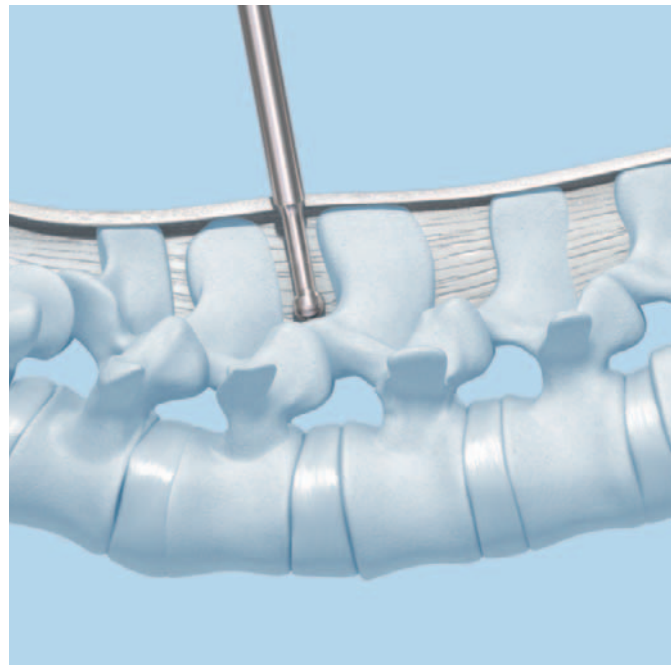
Align the tip of the perforator with the spinal column until it contacts the lamina.

Rotate the perforator 90° until the tip of the instrument is perpendicular to the interspinous ligament. Pierce the interspinous ligament as anteriorly as possible.

- Verify correct anterior placement under lateral fluoroscopy.

Remove the perforator.

Note: Check perforator for serviceability; a blunt perforator must be replaced.



3

Choose appropriate implant size

Instruments

03.630.308	Trial Implant Ø 8 mm
03.630.310	Trial Implant Ø 10 mm
03.630.312	Trial Implant Ø 12 mm
03.630.314	Trial Implant Ø 14 mm
03.630.316	Trial Implant Ø 16 mm

Use the series of trial implants graduated in 2 mm increments to define the appropriate implant size.

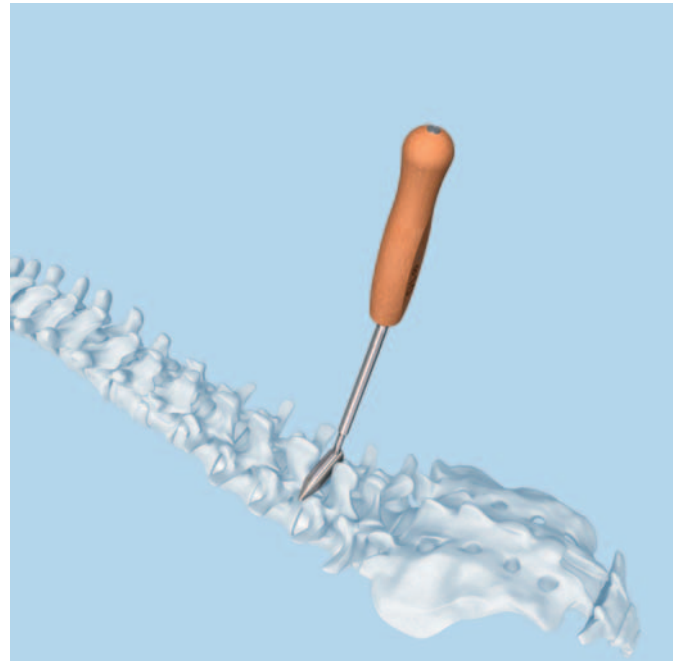
Insert the 8 mm trial implant into the pierced interspinous ligament, as far anterior as possible. Repeat with sequentially larger trial implants until the desired distraction is achieved. The correct trial implant should completely fill the interspinous space and have a press fit contact to the cranial and caudal rim of the inferior and superior spinous process.

- ① Under lateral fluoroscopy, verify that the trial implant is positioned correctly on the top of the facets in the natural concavity of the spinous processes.

Also verify the distraction. Maximum admissible distraction is reached when the vertebral endplates are parallel to each other.

Caution

- Avoid excessive distraction, as it can lead to loss of physiological lordosis and/or result in postoperative pain due to overstretching of the joint capsules.
 - If two implant sizes are possible, choose the smaller one in order to avoid over-distraction.
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4

Reassemble screwdriver

Instruments

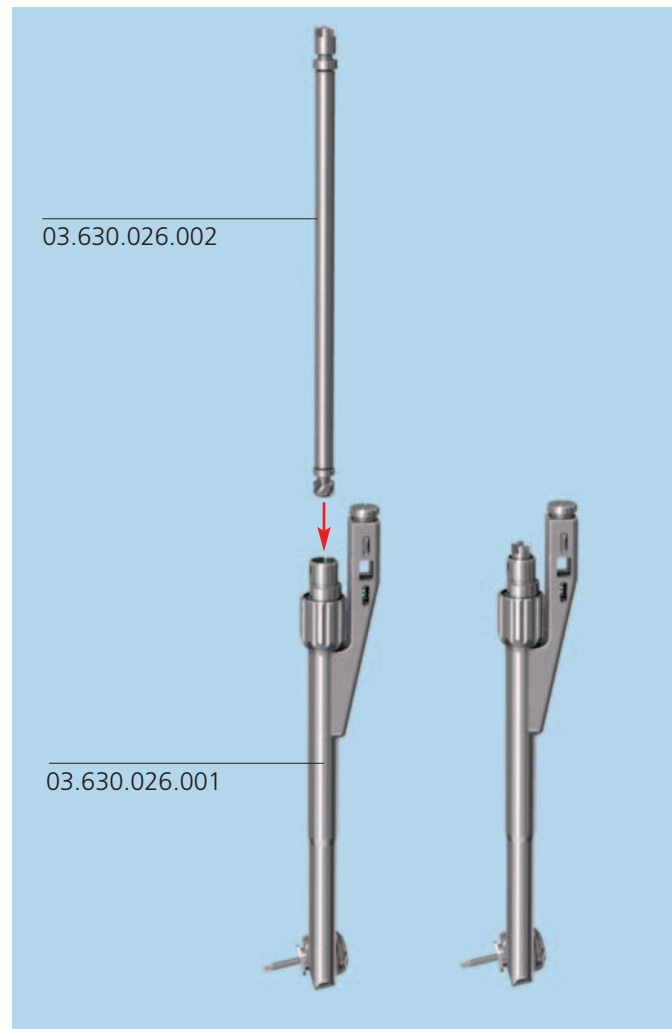
03.630.026	Screwdriver, angled
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03.630.053	Torque Limiter
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After cleaning and sterilization the screwdriver needs to be reassembled prior to use.

1. Connect inner and outer screwdriver shaft

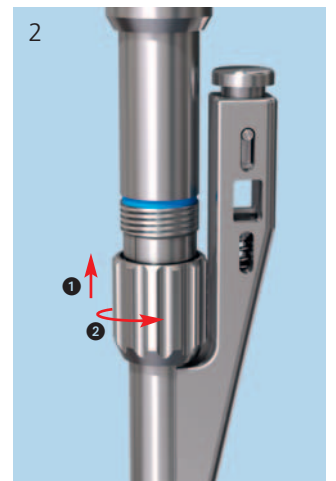
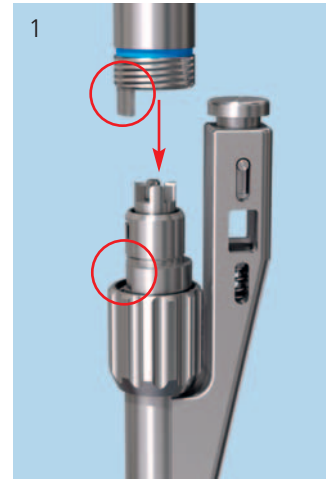
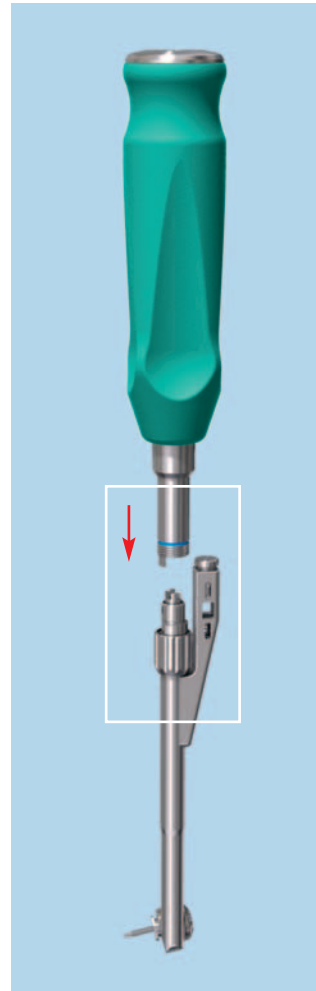
Slide the inner shaft (03.630.026.002) with the gear wheel first into the outer screwdriver shaft (03.630.026.001) until it engages.



2. Mount screwdriver handle

Introduce the outer screwdriver shaft into the screwdriver handle. Ensure that the protruding part of the screwdriver handle enters into the matching slot of the outer screwdriver shaft (1).

Pull the two parts together. Under slight, constant pressure tighten the nut (2). The blue line on the handle must be in close contact with the nut (3).



3. Mount torque limiter and deploy screwdriver insert

Mount the torque limiter on the screwdriver handle.

Fully deploy the screwdriver insert. To do so turn the knob of the torque limiter **counterclockwise** and check that the screwdriver insert turns freely. Continue turning until the insert does not advance any further.

To ensure that the screwdriver insert is fully deployed introduce the screwdriver insert into the length indicator in the Vario Case. It must at least reach the line marked with "OK".

Note: Only in this position the screwdriver is long enough to engage into the screw of the implant.

Caution: Repeated turning of the screwdriver insert in a clockwise direction can damage the instrument.



5

Attach implant to implant holder

Instruments

03.630.021	Locking Screw
03.630.208	Implant Holder Ø 8 mm
03.630.210	Implant Holder Ø 10 mm
03.630.212	Implant Holder Ø 12 mm
03.630.214	Implant Holder Ø 14 mm
03.630.216	Implant Holder Ø 16 mm

Select the implant holder that corresponds to the implant size defined in step 3.

Introduce the locking screw into the implant holder (1).

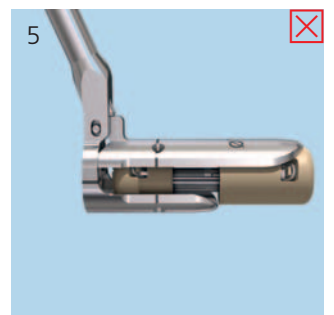
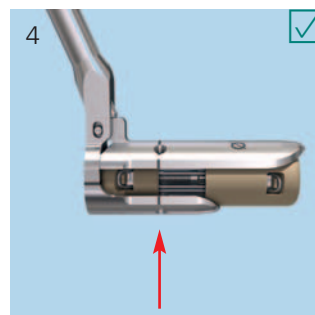
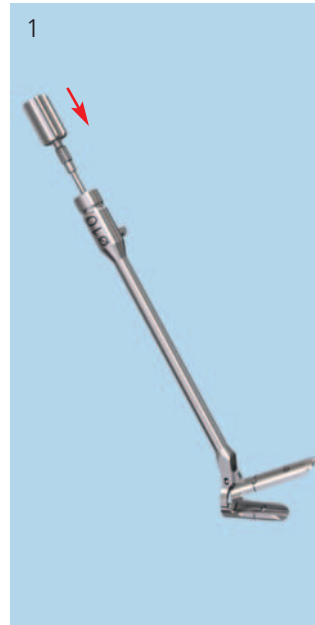
Select the implant that corresponds to the previously defined implant size.

Introduce the implant into the holder with the slots of the implant pointing into the direction of the implant holder. Ensure that the slots of the implant engage properly with the notches of the implant holder (2).

Ensure that the implant is inserted to the full depth of the implant holder.

Turn the locking screw to close the implant holder (3).

Verify that the implant is correctly attached. The lines on the shovels of the implant holder must be in line with the proximal corpus of the implant (4). Ensure that the shovels of the implant holder do not cover and block the wings of the implant for later deployment (5).



6

Attach implant holder to screwdriver

Instrument

314.070 Screwdriver, hexagonal, small

Connect the back of the implant holder to the screwdriver head in an angle of approximately 30° (1). To do so, ensure that the black line on the back of the implant holder is aligned with the black line at the side of the screwdriver head (2).

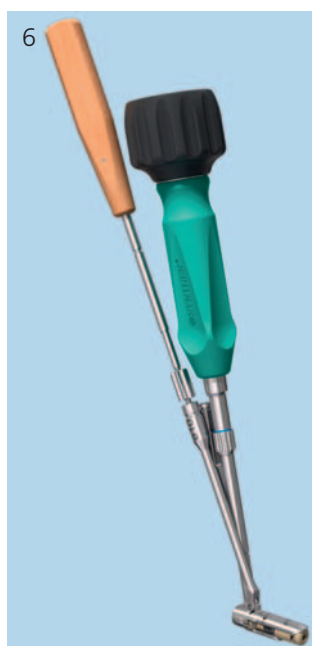
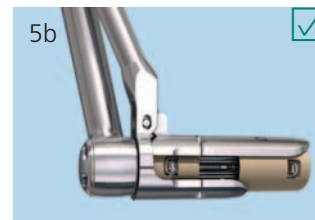
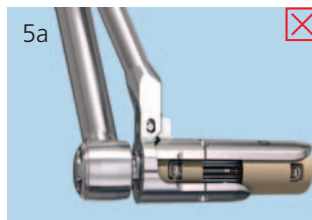
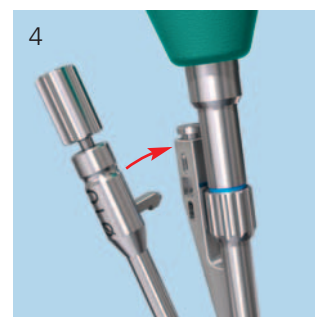
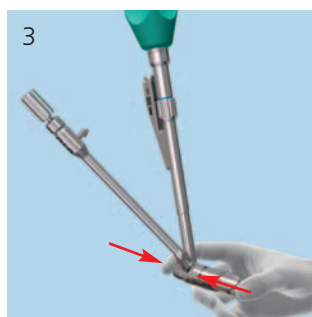
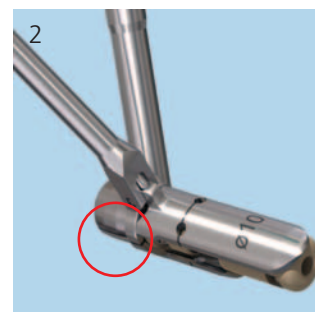
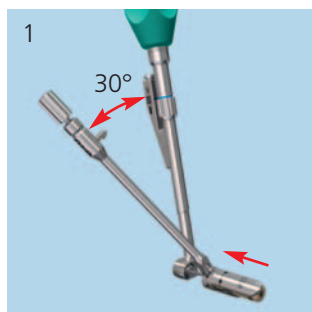
Overcome the spring resistance of the screwdriver insert by firmly pressing the implant holder against the screwdriver head (3).

While maintaining the pressure, close the bayonet lock by rotating the implant holder towards the shaft of the screwdriver and click it into the corresponding hole of the screwdriver (4).

Verify that the two instruments are correctly connected. The back of the implant holder must lay flush on the screwdriver (5a, 5b).

Insert the hexagonal screwdriver into the head of the locking screw and finally tighten the locking screw (6).

Note: If resistance is felt when rotating the implant holder, do not apply force. Otherwise the bayoneted lock will be damaged. Check that the implant holder has been correctly connected to the screwdriver insert and rotate again.



7

Insert implant

Technique tip on implant insertion: When working with small incisions, the space available for the insertion instruments can be critical. Approaching the interspinous space directly perpendicular to the midline might be difficult. It is recommended to apply the modified insertion technique described below.

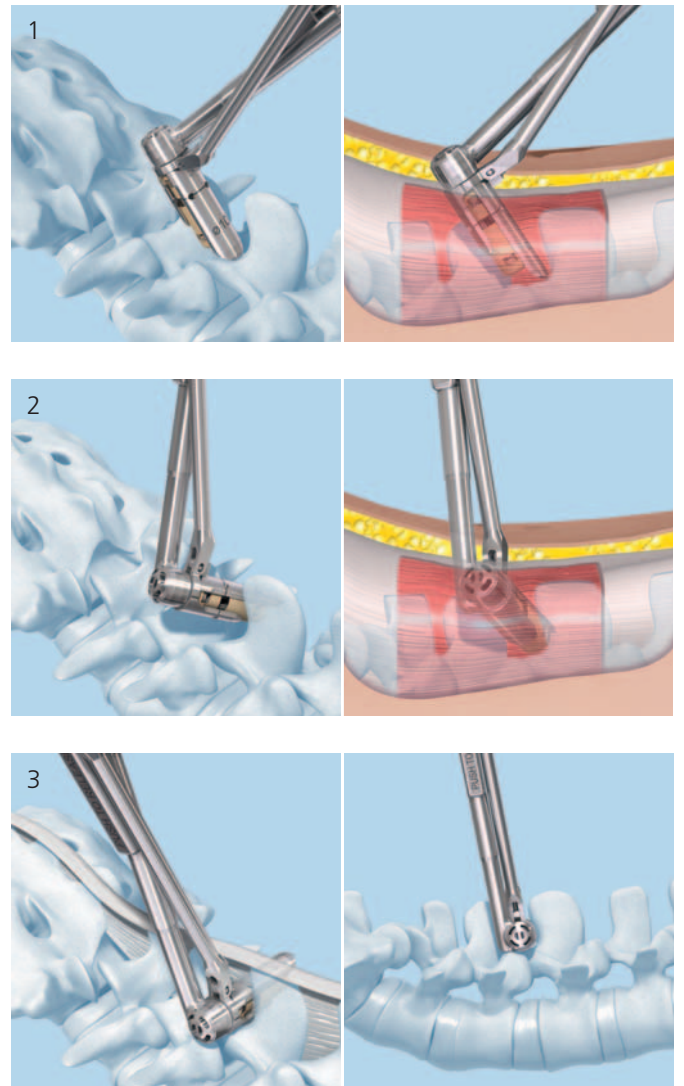
Remove the trial implant as late as possible after the implant is correctly mounted on the implant holder.

Facing from caudal to cranial align the implant holder with the spinal column. Orient the tip of the implant holder towards the perforated hole of the interspinous ligament (1).

While rotating the instrument in perpendicular direction simultaneously slide its proximal end under the fascia (2).

Slide the construct in its final position (3).

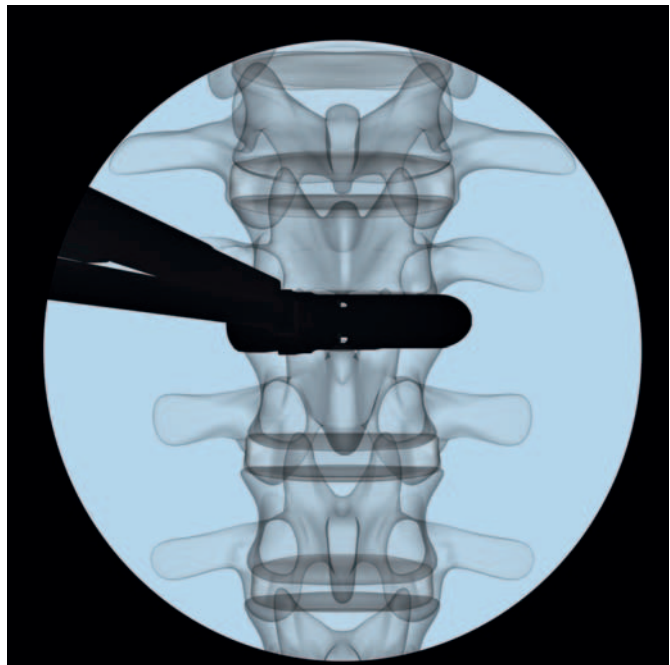
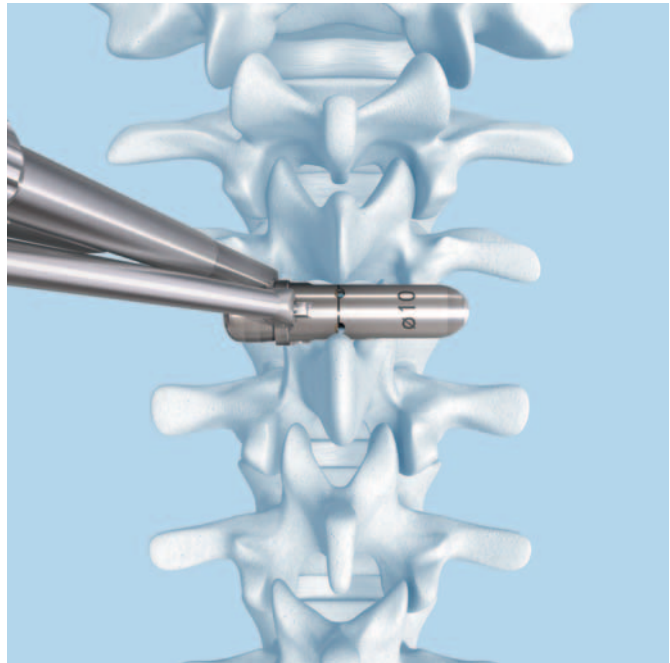
- ① Under lateral fluoroscopy verify that the instruments are positioned on top of the facets in the natural concavity of the spinous processes. Re-correct if necessary.
- ② Orient the shaft of the screwdriver parallel to the 2 rims of the spinous processes and perpendicular to the posterior contour of the facets.



Under AP fluoroscopy place the instruments in their correct insertion depth. Visualize the 2 holes on the upper shovel of the implant holder. They define the midline of the In-Space implant in its closed end position and have to be aligned with the spinous processes.

Notes

- Correct positioning of the insertion instruments is crucial. Their final position defines the final implant position. Once the wings of the implant are deployed, the position of the implant cannot be corrected anymore.
- The screwdriver shaft has an angulation of 102° in order to enhance the visualization of the interspinous space. Do not place the screwdriver shaft perpendicular to the coronal plane, since this would end in an oblique placement of the implant.



8

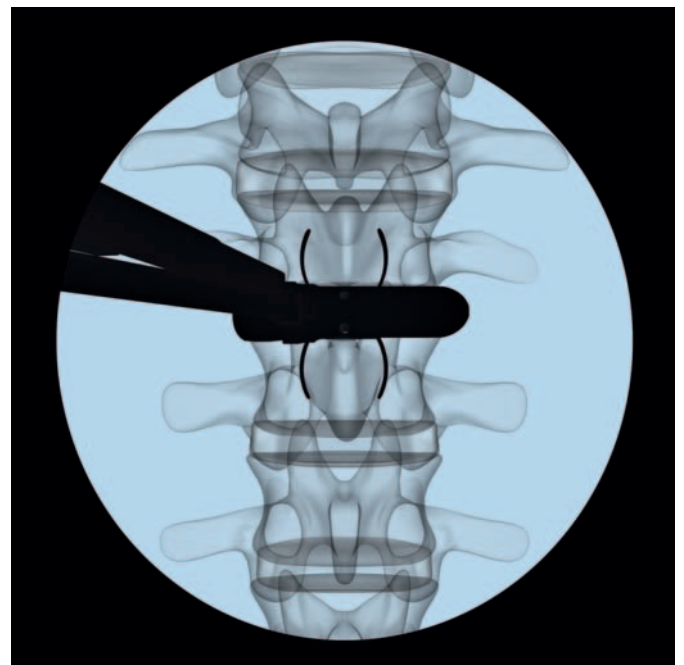
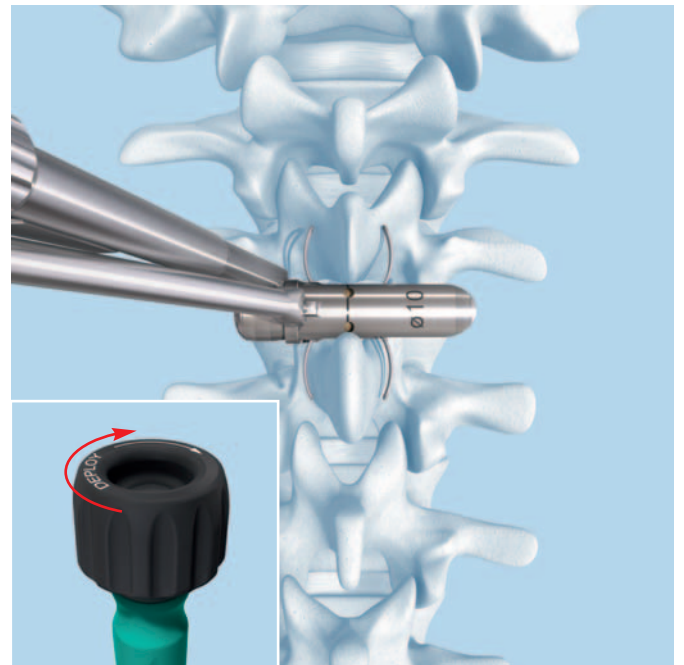
Deploy wings

Turn the knob of the screwdriver clockwise to deploy the wings of the implant.

When the wings are fully deployed, a distinctive increase in resistance is felt and the screwdriver reaches its ultimate torque.

Verify proper and complete deployment of the wings.

- ① Use AP fluoroscopy to assess the contra-lateral side.



9**Remove the instruments****Instruments**

314.070	Screwdriver, hexagonal, small
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03.630.412	Position Retainer for In-Space, size 8.0 to 12.0 mm
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03.630.416	Position Retainer for In-Space, size 14.0 to 16.0 mm
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Optional instrument

03.630.200	Handle with Quick Coupling
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Push the button on the screwdriver to loosen the clip which connects the screwdriver to the implant holder (1). Maintain the vertical position of the implant holder. Angle the screwdriver to the left side to loosen the bayonet lock (2). Retract the screwdriver.

Detach the instrument from the implant. With the hexagonal screwdriver loosen (3) and remove (4) the locking screw from the implant holder.



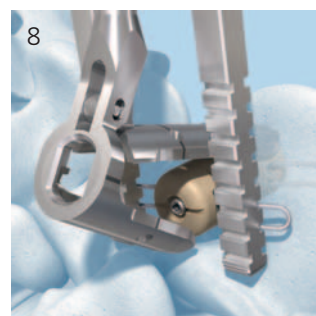
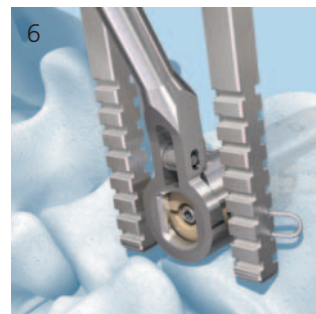
Attach the handle with quick coupling to the implant holder.

Choose the correct sized position retainer. Introduce it from the contra-lateral side to avoid conflict of space with the implant holder (5). The "ratchet" must grip the 2 ipsi-lateral wings (6). Remove the implant holder while maintaining the implant in its original position.

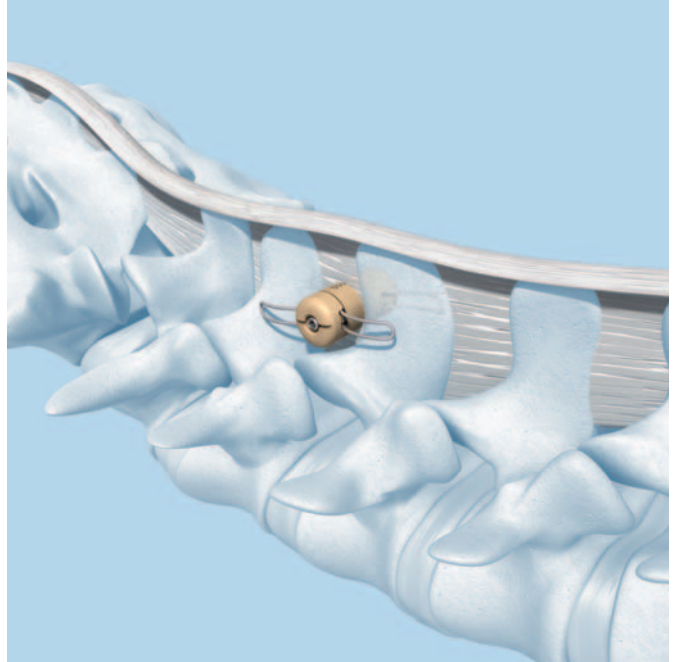
Take care to retract the implant holder strictly in lateral direction until the lower shovel of the implant holder comes out of the interspinous space (7).

Only then rotate the handle towards the midline to liberate the upper shovel of the implant holder from the interspinous space (8).

Caution: Do not apply rotational movements on the implant holder as long as the lower shovel is still contained in the interspinous space. This could cause damage to the implant wings.



- ① Confirm correct placement of the implant in AP and lateral fluoroscopy.



Implant Removal

The implant can be removed through a conventional posterior approach.

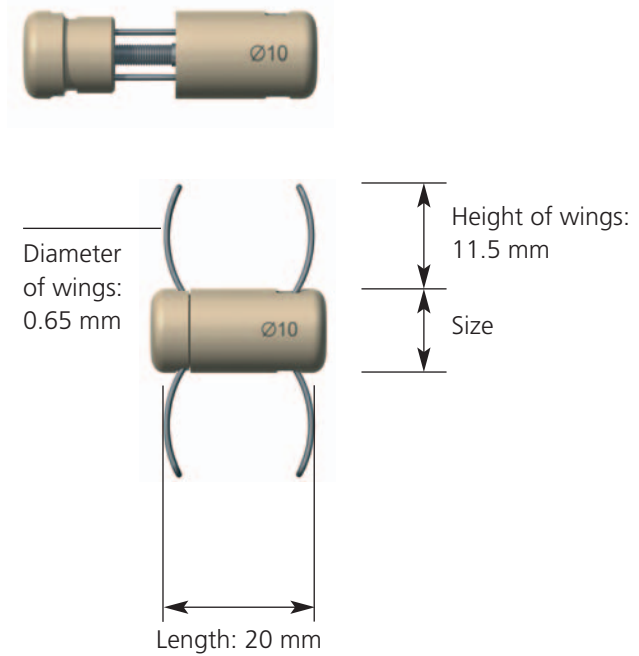
First, cut the wings and then remove the implant by pushing it to the side, displacing it from between the spinous processes.

Implants

In-Space, interspinous implant

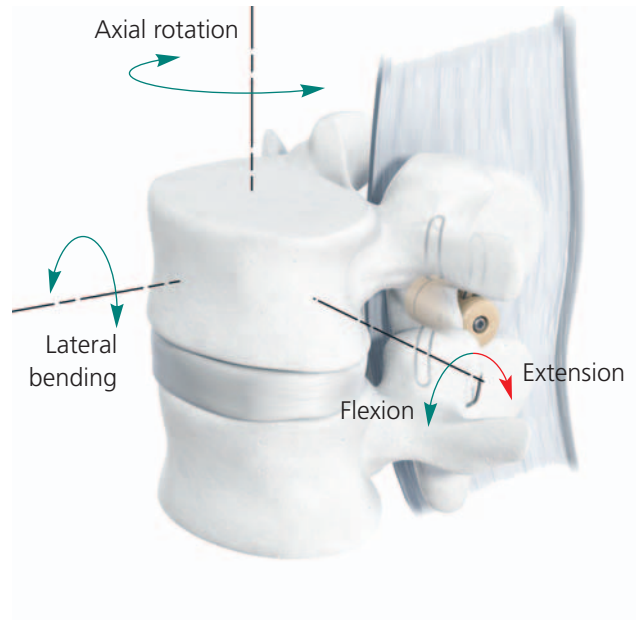
- Supplied in sterile package
- Available in 5 different sizes from 8 to 16 mm (in 2 mm increments)
- Radiolucent body in PEEK Optima for undisturbed visualization
- Screw and wings made of titanium alloy (TAV) to allow proper radiographic assessment of the correct implant position.

Art. No.	Size
04.630.008S	8 mm
04.630.010S	10 mm
04.630.012S	12 mm
04.630.014S	14 mm
04.630.016S	16 mm



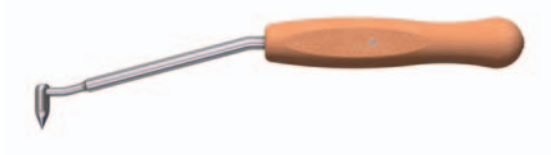
Controlled mobility

- Prevents extension at the symptomatic level
- Allows flexion, rotation and lateral bending

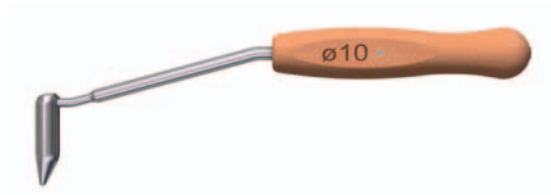


Instruments

03.630.025 Perforator, for Posterior Insertion of In-Space
Used to pierce the interspinous ligament.



03.630.308 Trial Implant Ø 8 mm, for Posterior Insertion of In-Space
03.630.310 Trial Implant Ø 10 mm, for Posterior Insertion of In-Space
03.630.312 Trial Implant Ø 12 mm, for Posterior Insertion of In-Space
03.630.314 Trial Implant Ø 14 mm, for Posterior Insertion of In-Space
03.630.316 Trial Implant Ø 16 mm, for Posterior Insertion of In-Space
Used to determine the appropriate size of the implant.



03.630.208 Implant Holder Ø 8 mm
03.630.210 Implant Holder Ø 10 mm
03.630.212 Implant Holder Ø 12 mm
03.630.214 Implant Holder Ø 14 mm
03.630.216 Implant Holder Ø 16 mm
Used to hold the implant while introducing it into the interspinous space.



03.630.021 Locking Screw, for Implant Holders Nos. 03.630.208 to 03.630.216
Used to clamp the implant on the implant holder.



03.630.026 Screwdriver, angled, for Posterior Insertion of In-Space
Allows in-situ deployment of the implant's wings.



03.630.053 Torque Limiter, for In-Space Screwdriver
No. 03.630.026

Allows controlled deployment of the implant's wings.



314.070 Screwdriver, hexagonal, small,
Ø 2.5 mm, with Groove

Used for final tightening of the locking screw.



03.630.412 Position Retainer for In-Space
size 8.0 to 12.0 mm

03.630.416 Position Retainer for In-Space
size 14.0 to 16.0 mm

Used to maintain the implants in position while removing the implant holders.



03.630.200 Handle with Quick Coupling, for
In-Space Implant Holders 03.630.208–216

Used in combination with the implant holders to facilitate their removal.





Synthes GmbH
Eimattstrasse 3
CH-4436 Oberdorf
www.synthes.com

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