

In-Space. Percutaneous interspinous distraction.

Technique Guide

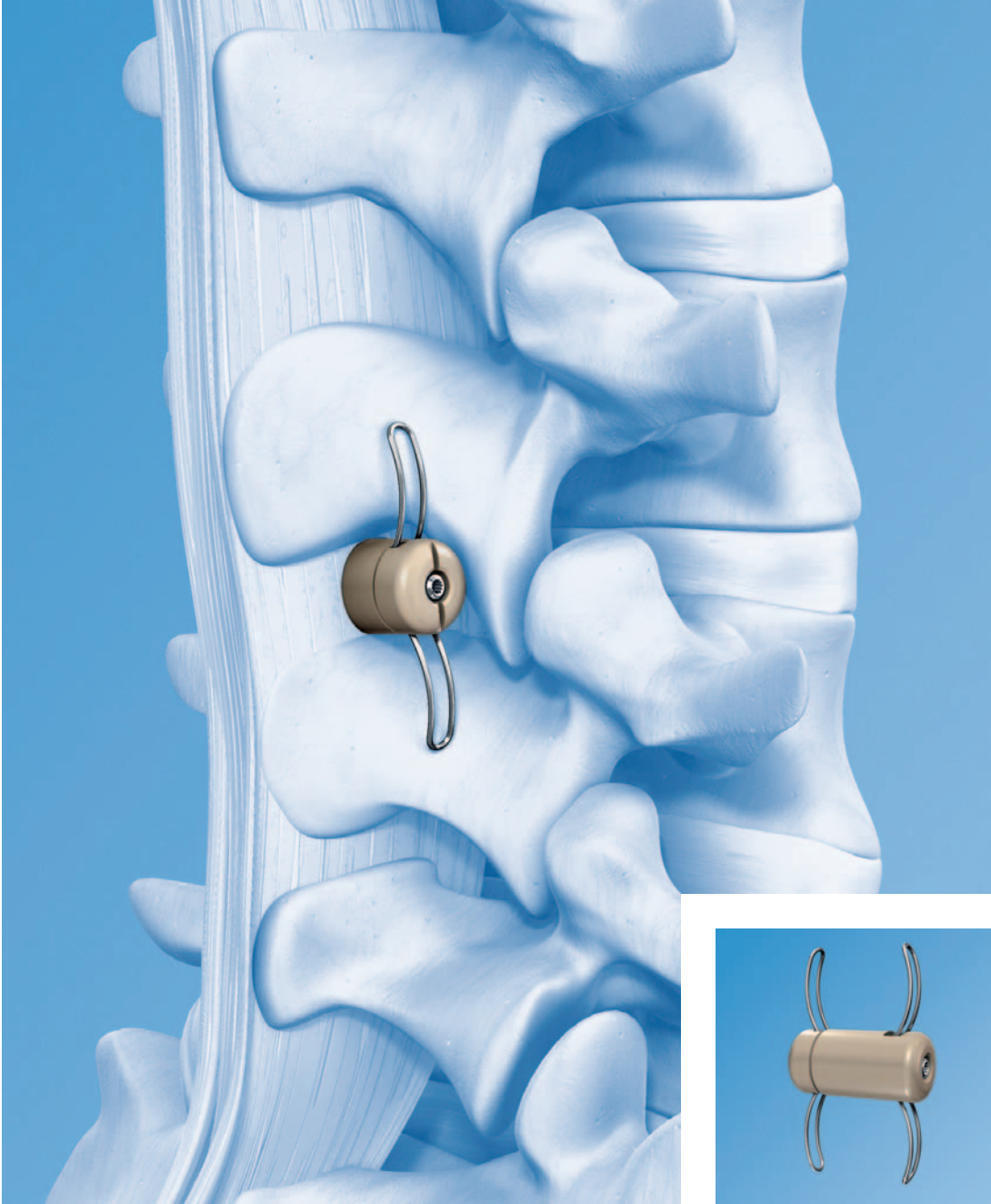


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 Image intensifier control

Warning

This description is not sufficient for immediate application of the instrumentation. Instruction by a surgeon experienced in handling this instrumentation is highly recommended.

In-Space. Percutaneous interspinous distraction.

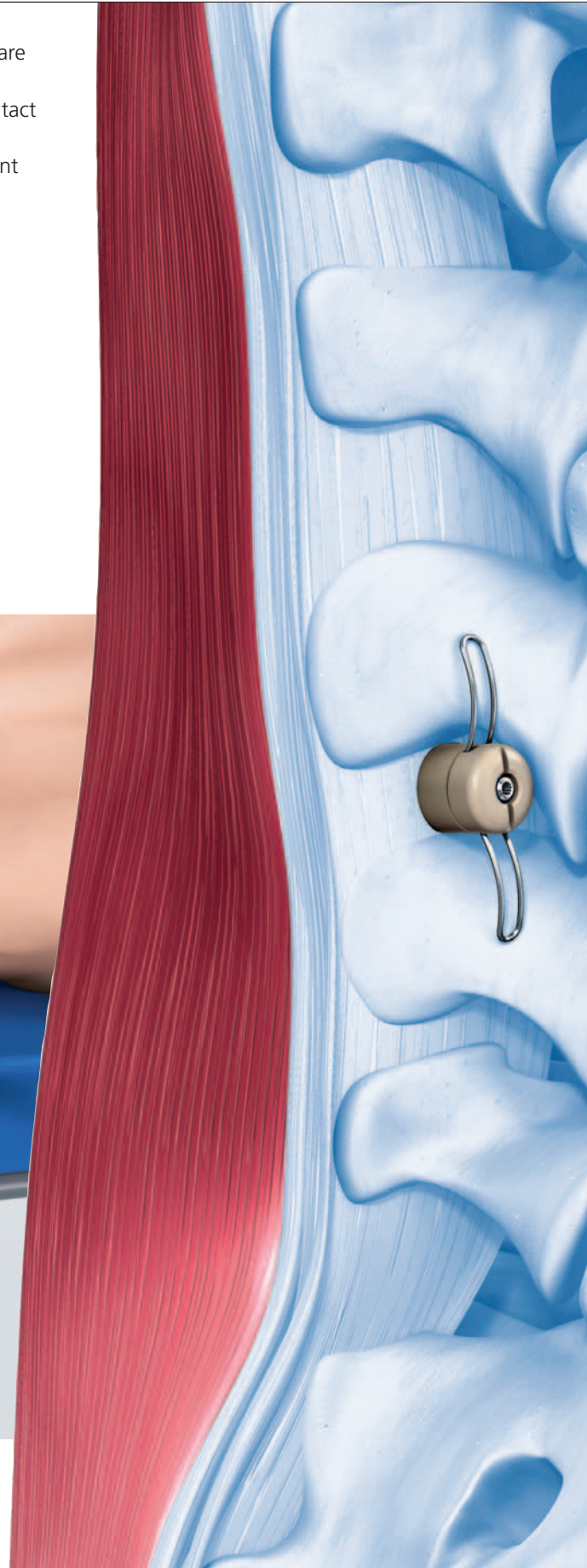
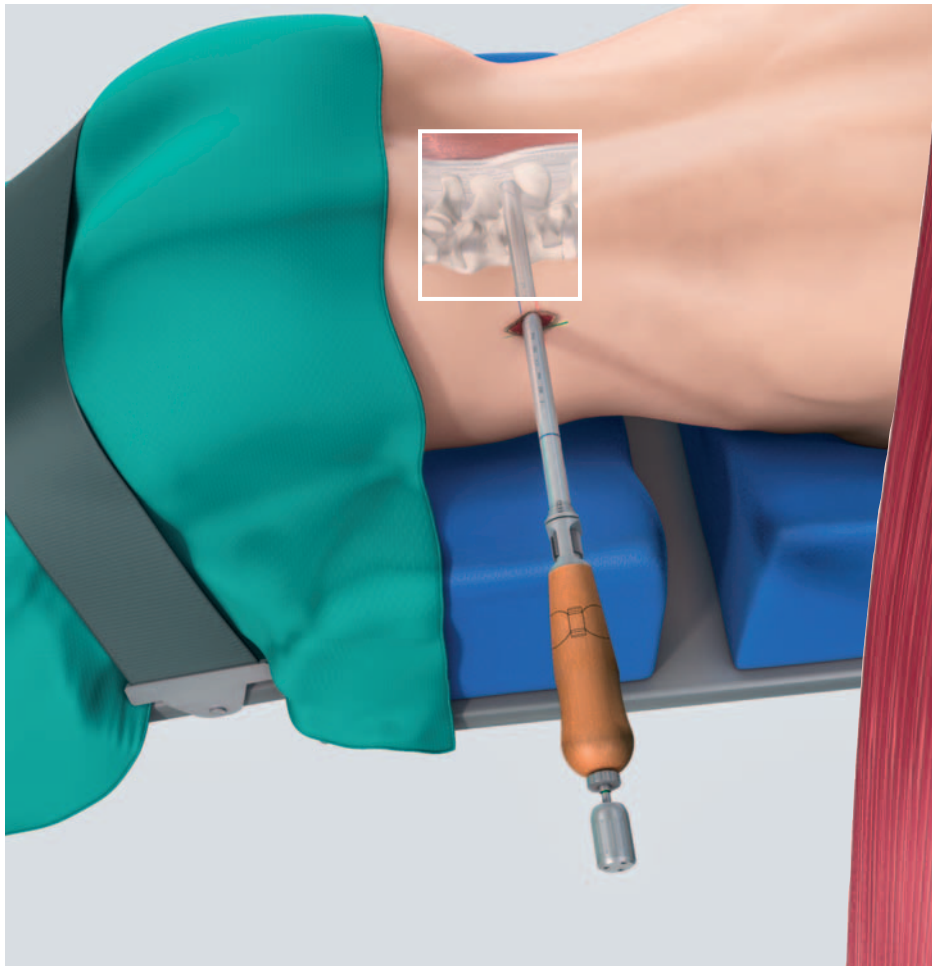
Percutaneous lateral approach

No stripping of the paraspinal muscles

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



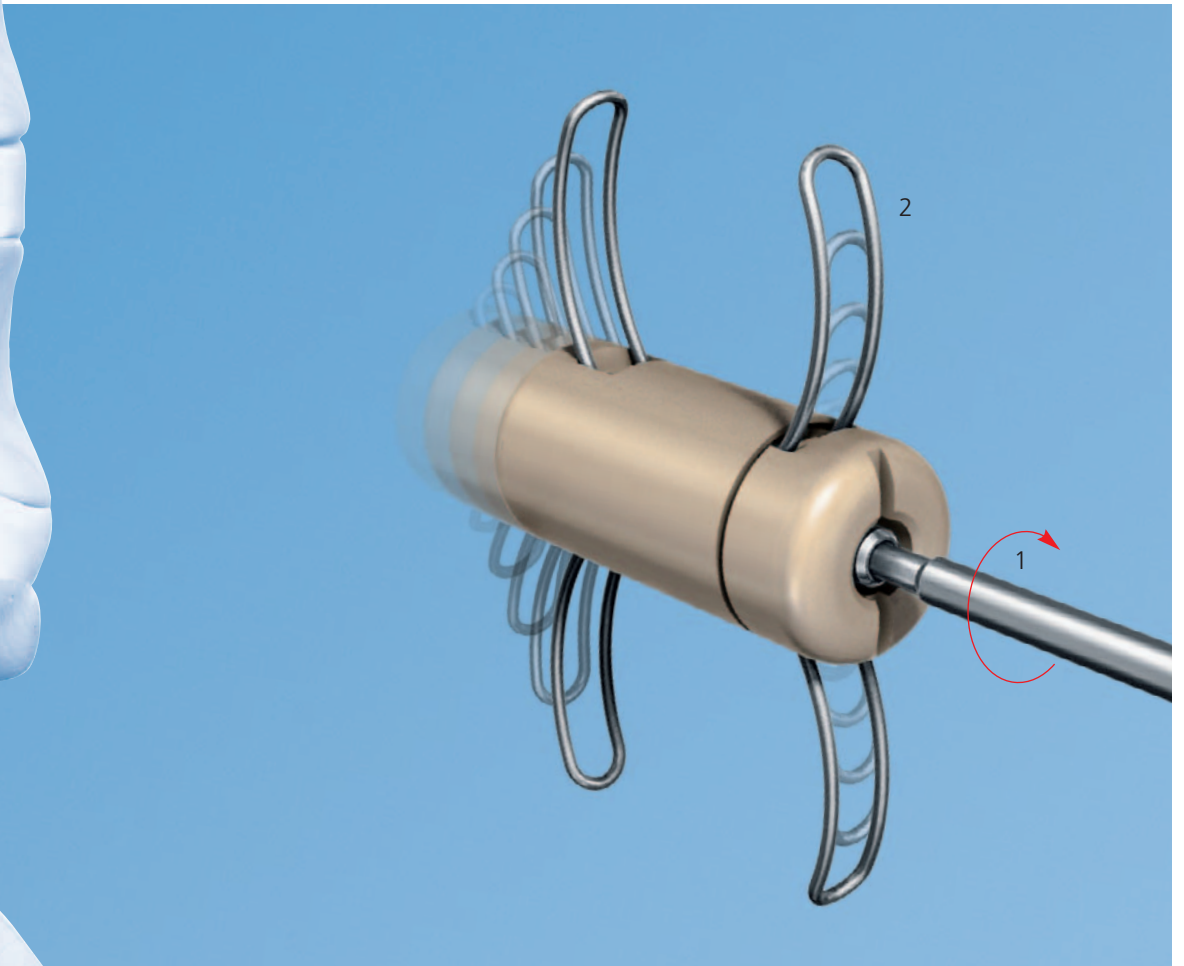


In-Situ deployment of the anchorage

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



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 L5. 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 L5.

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 Baastrup 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.

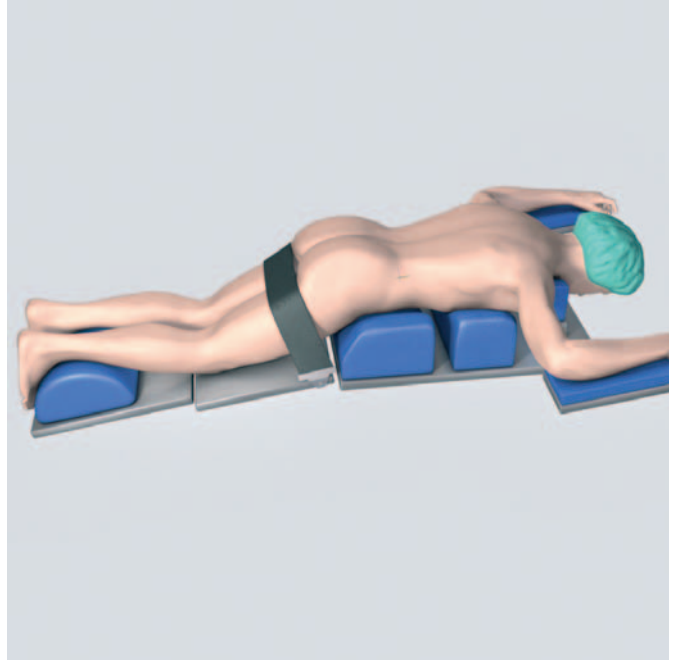
A preoperative CT reconstruction is recommended in the following situations:

- Suspicion of spinous process and/or lamina dysplasia
- At L1–L3 to exclude that abdominal contents are located posteriorly in trajectory of percutaneous approach.

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 Percutaneous Lateral Approach

1

Localize entry level

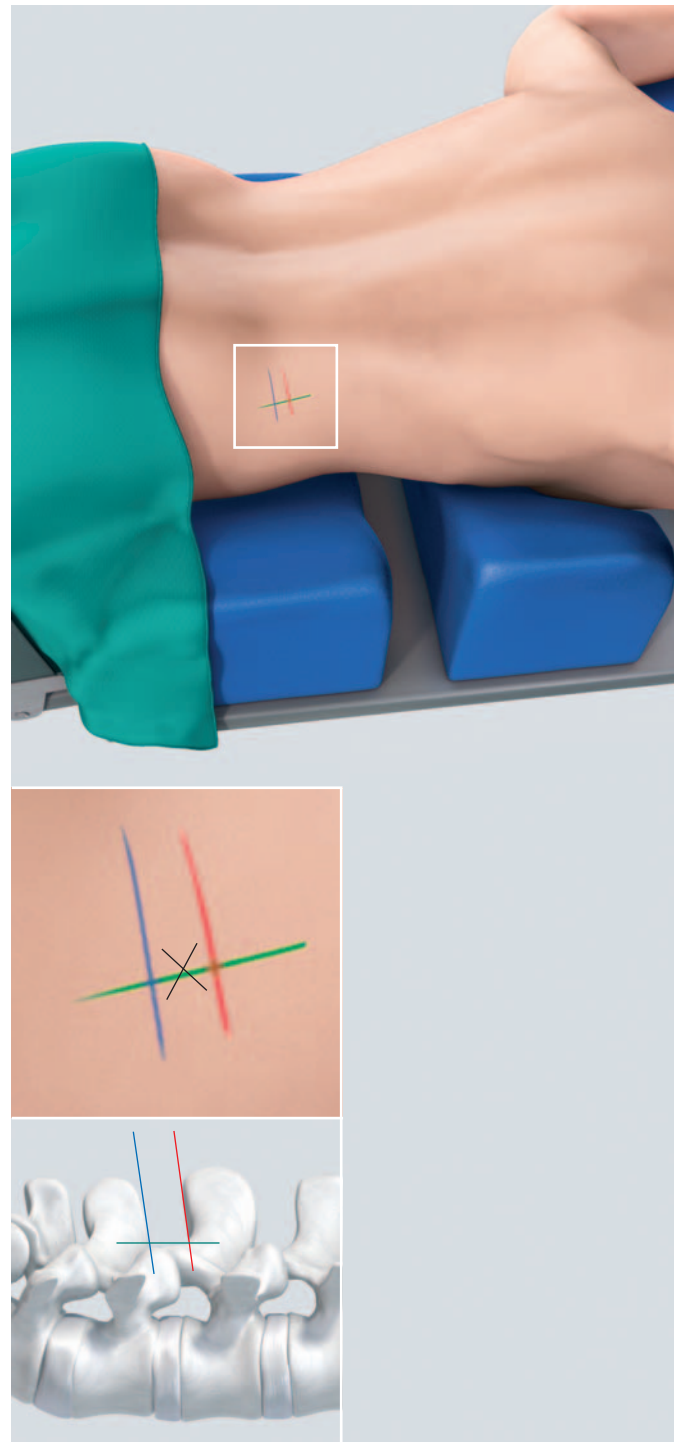
Define anatomical landmarks in projection to the skin level.

Under AP fluoroscopy, mark the midline projection of the spinous processes of the index level.

Under lateral fluoroscopy mark the projection of

- the inferior rim of the superior spinous process (line in red),
- the superior rim of the inferior spinous process (line in blue),
- and the posterior contour of the facet joint (line in green).

The entry point for the instruments (marked by a cross on the drawing) is in the middle of the inferior and superior line and just above the posterior contour line.



2

Insert guide wire

Instruments

03.630.103	Guide Wire \varnothing 3.2 mm, length 260 mm
03.630.022	Aiming Device, radiolucent
03.630.104	Extension \varnothing 1.5 mm, length 400 mm

Make a longitudinal or transverse incision of approximately 2 cm at the previously defined entry level.

Connect the guide wire to the aiming device. Introduce the guide wire into the aiming device until it reaches the stop. Tighten the set screw.

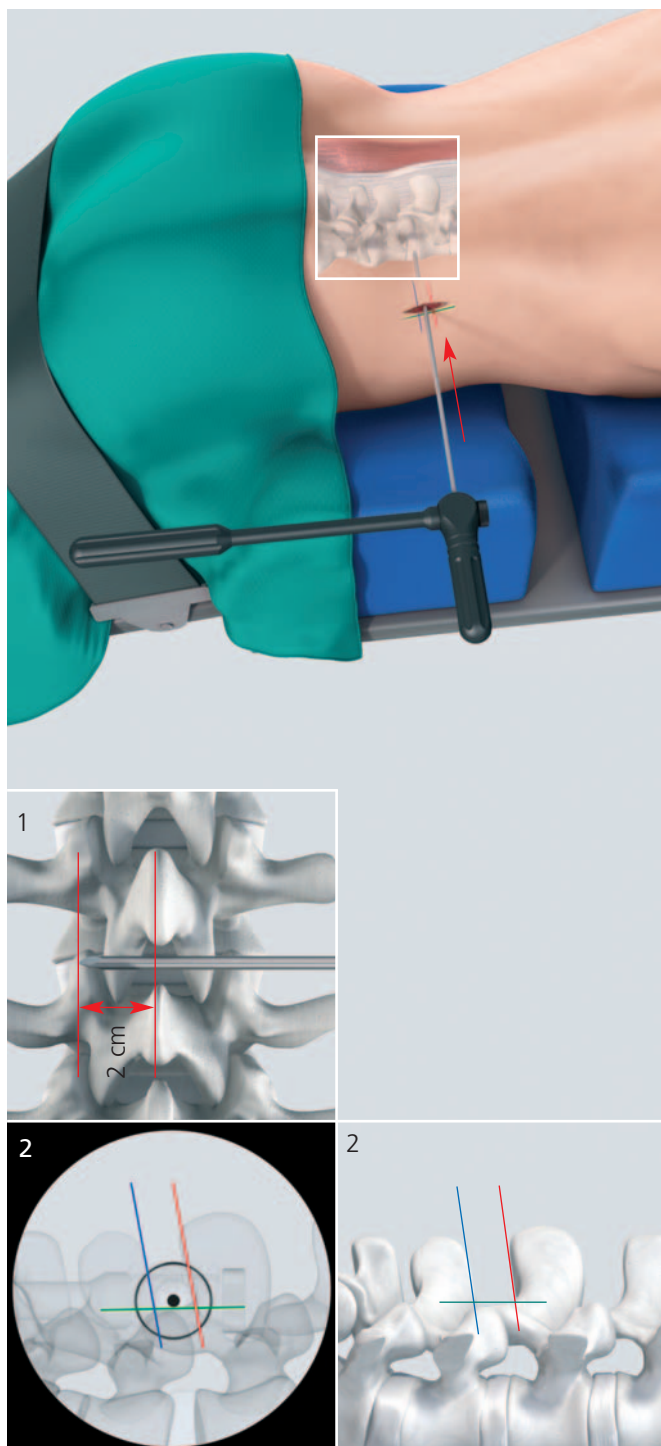
- 1 Introduce the guide wire through the incision. Under lateral fluoroscopy, carefully advance the guide wire between the spinous processes, keeping it parallel to the coronal plane. For an optimal ventral placement of the In-Space, the guide wire must be placed as far anterior as possible.

Note: The interspinous ligament gives a slightly increased resistance and must be perforated with the guide wire.

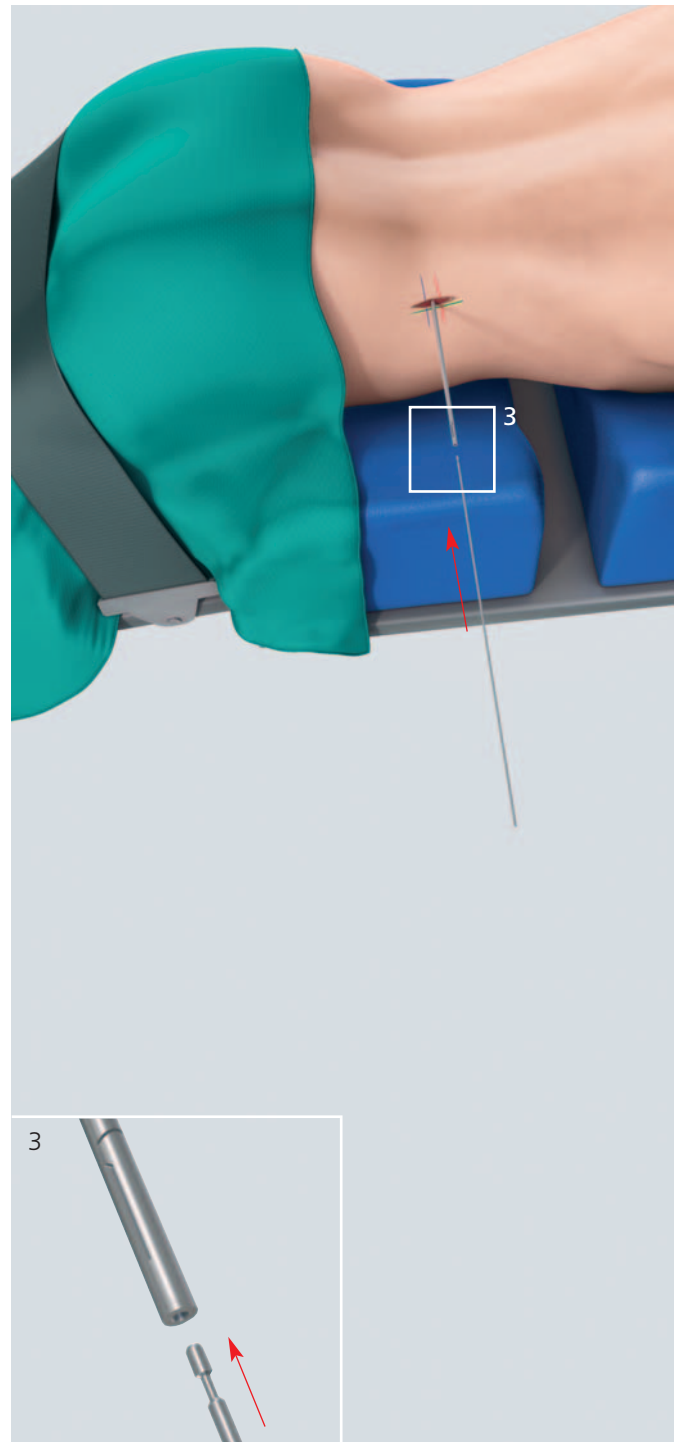
- 2 Under AP fluoroscopy, push the guide wire about 2 cm across the midline (1).

Verify its correct position in both AP and lateral view.

Note: Under lateral fluoroscopy, the radiolucent aiming device shows an aiming ring. This aiming ring can be used as a positioning guide. When the guide wire appears as a point, it is parallel to the fluoroscopy beam path (2).



Release the set screw and remove the aiming device. To extend the guide wire, push the extension for guide wire firmly all the way down into the guide wire (3). Ensure that the guide wire cannot advance any further.



3

Distract

Instruments

03.630.108 Distraction Sleeve \varnothing 8 mm

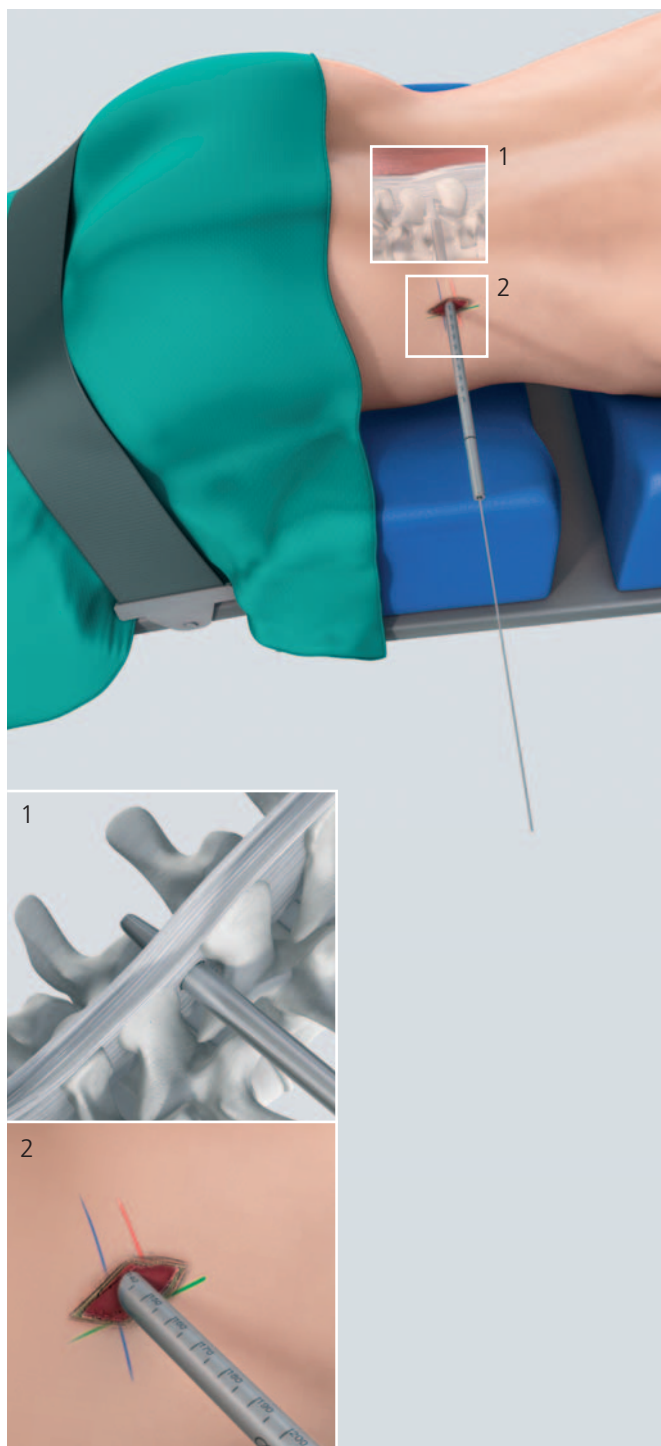
- 1 Slide the distraction sleeve over the extended guide wire while holding the guide wire in place. The distraction sleeve will stop when it reaches the tip of the wire (approximately 2 cm across the midline [1]).

If the distraction achieved with the 8 mm distraction sleeve is adequate, proceed directly to step 4, page 12.

If distraction is not yet sufficient, further distract with distraction sleeves (see "Further distraction with distraction sleeves", page 11).

Note: The scale on the distraction sleeve at skin level shows the insertion depth of the instrument (2). Later on, it can be used to match the insertion depth of the further sleeves.

Caution: When pushing the distraction sleeve into position, ensure that the guide wire does not further advance. Always hold the extended guide wire in place with one hand while introducing a distraction sleeve.



Further distraction with distraction sleeves

Instruments

03.630.080	Distraction Sleeve Ø 10 mm
03.630.082	Distraction Sleeve Ø 12 mm
03.630.084	Distraction Sleeve Ø 14 mm
03.630.086	Distraction Sleeve Ø 16 mm

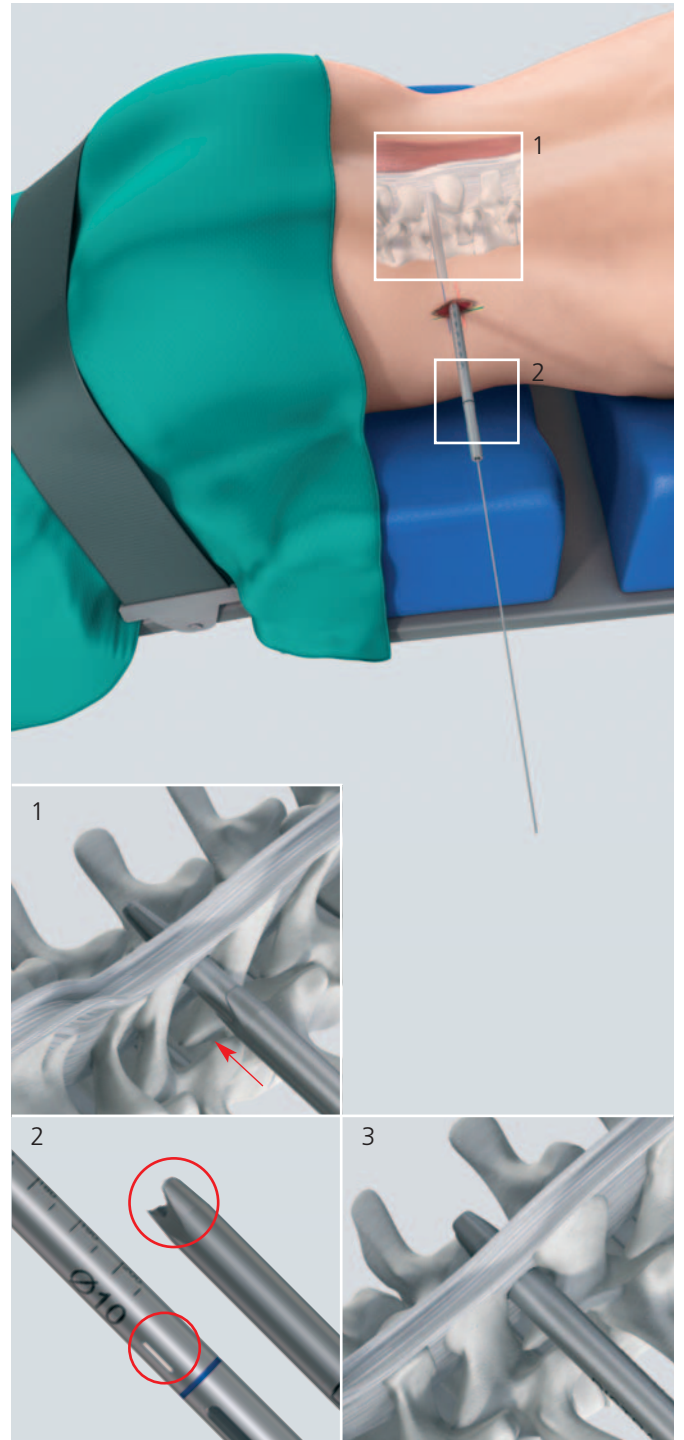
- Slide the 10 mm distraction sleeve over the 8 mm distraction sleeve while holding the extended guide wire in place.

Note: Oscillating movements may ease the insertion of the distraction sleeves through the soft tissues. However, full revolutions may wind up soft tissue around the instruments and should be avoided.

The tip of the distraction sleeve is designed to ease insertion of the sleeve between the spinous processes. When the tip of the distraction sleeve reaches the interspinous space (1), orient it in cranio-caudal direction: Rotate the sleeve until the white lines at its proximal end are parallel to the patient's coronal plane (2).

The 10 mm distraction sleeve stops when it reaches the tip of the 8 mm distraction sleeve (3).

- Repeat with sequentially larger distraction sleeves until the desired distraction is achieved. The last inserted distraction sleeve should have a press fit contact to the cranial and caudal rim of the inferior and superior spinous processes. Verify the correct amount of distraction under fluoroscopy.



In case of increased resistance during insertion of the distraction sleeves, a handle can be mounted on the sleeves for use with a hammer to aid insertion (see "Optional insertion technique in case of increased insertion forces", page 19).

Caution

- Avoid excessive distraction, as it can lead to loss of physiological lordosis. Maximum admissible distraction is reached when the vertebral endplates are parallel to each other.
- Do not hammer directly on the distraction sleeves as this may cause damage to the instruments.

4 Insert implant insertion sleeve

Instruments

03.630.008	Implant insertion sleeve Ø 8 mm
03.630.010	Implant insertion sleeve Ø 10 mm
03.630.012	Implant insertion sleeve Ø 12 mm
03.630.014	Implant insertion sleeve Ø 14 mm
03.630.016	Implant insertion sleeve Ø 16 mm

Once the desired distraction is achieved, select the corresponding implant insertion sleeve. Its coloured ring as well as the indicated diameter must correspond to the previously used distraction sleeve.

Note: The implant insertion sleeve will not distract the interspinous space further.



Distraction sleeve Implant insertion sleeve

Slide the implant insertion sleeve over the outer distraction sleeve while holding the extended guide wire in place.

Verify that the white lines at the proximal end of the implant insertion sleeve (1) are oriented in cranio-caudal direction, parallel to the patient's coronal plane. This will ease the insertion between the spinous processes (2).

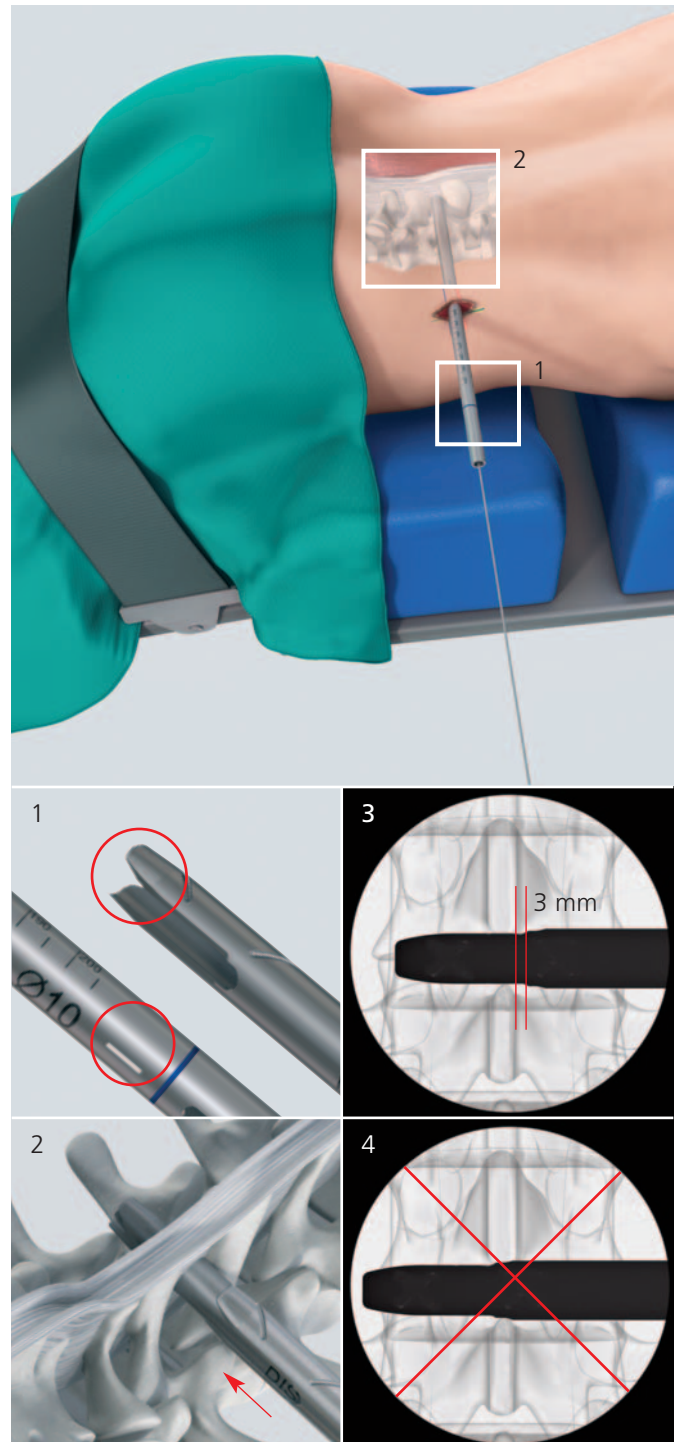
The maximal insertion depth is reached when the transition in diameter seen under AP fluoroscopy is approximately 3 mm from the border of the spinous processes (3). Do not exceed this insertion depth (4).

Remove all the inner distraction sleeves. To do so, simply pull on the extended guide wire.

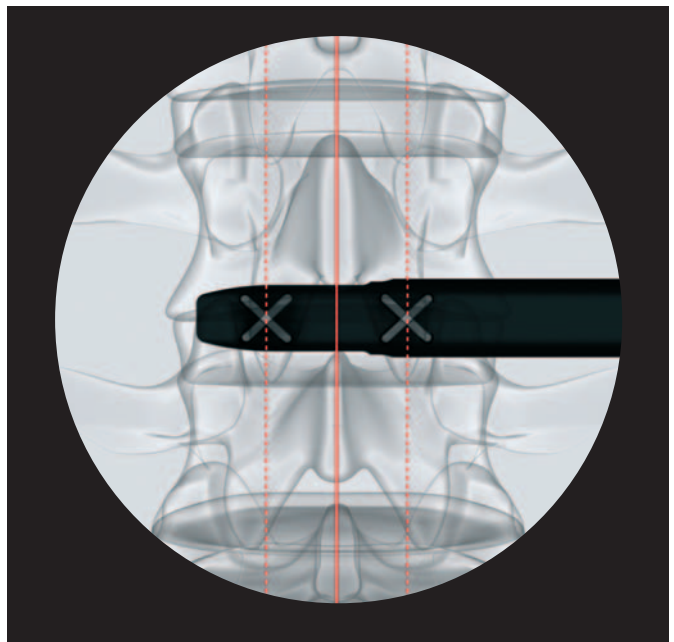
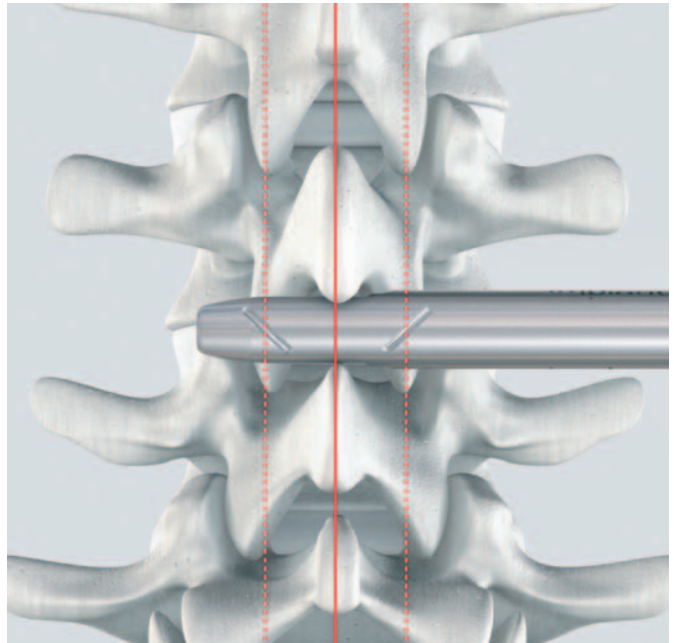
Caution

It is important to correctly orient the implant insertion sleeve in the cranio-caudal direction. Incorrect orientation may result in:

- Overdistraction of the interspinous space
- Deployment of the implant wings in antero-posterior direction.



- ① Under AP fluoroscopy, place the implant insertion sleeve in its final insertion depth. Visualize the 2 holes at the distal end of the sleeve. The virtual midpoint between these 2 points defines the midline of the In-Space implant and has to be in line with the spinous processes.



5

Insert implant

Instruments

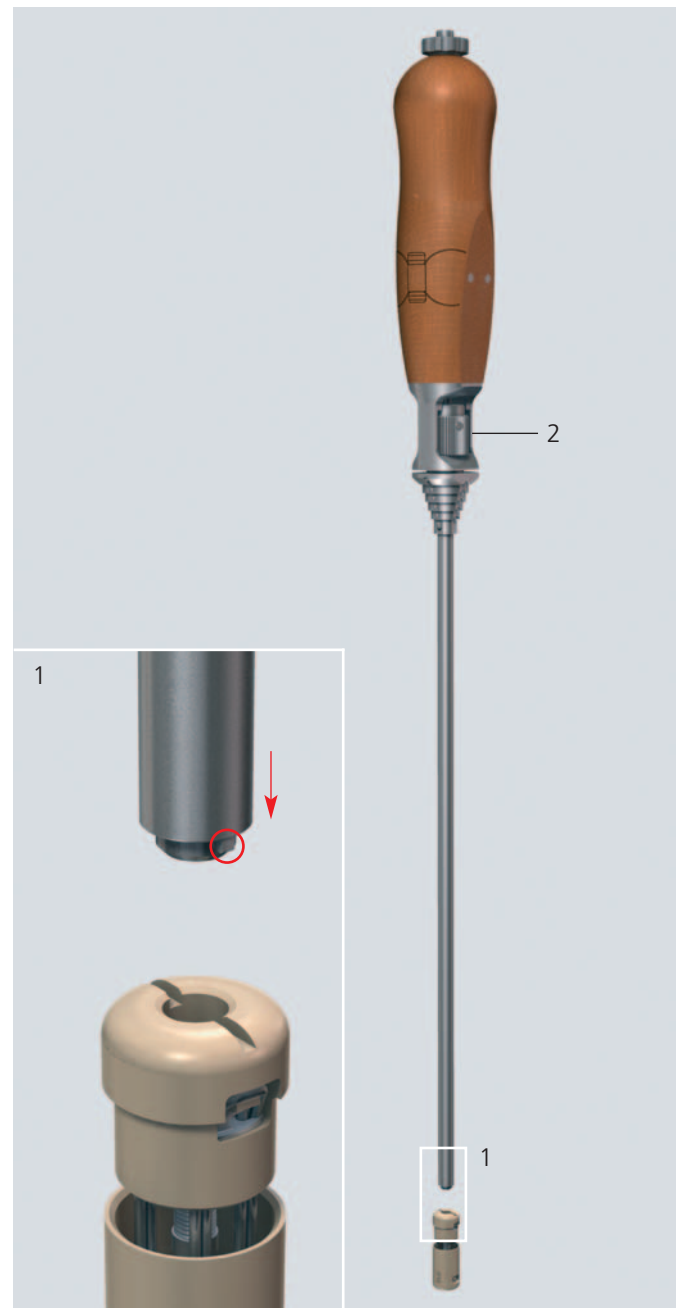
03.630.100 Implant Holder

03.630.110 Screwdriver with Torque Limiter

Select the implant size corresponding to the diameter of the implant insertion sleeve used.

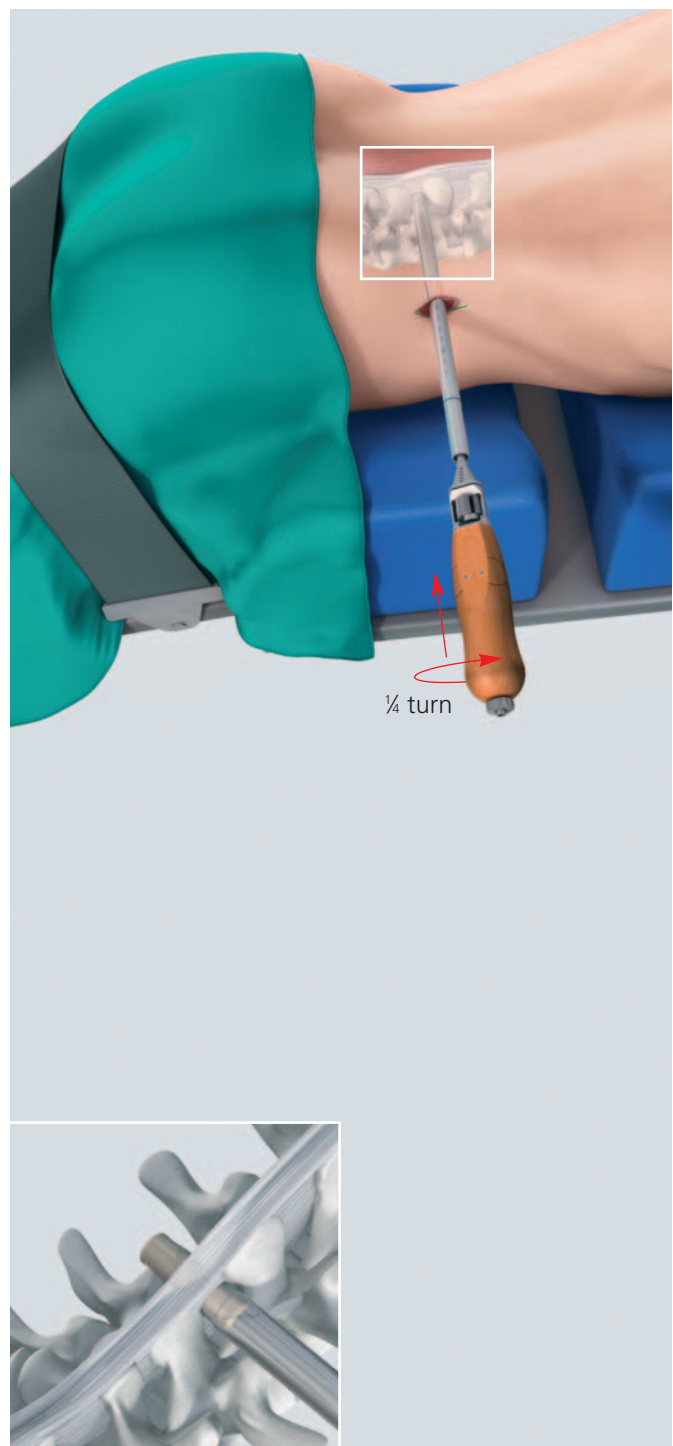
Attach the implant holder to the implant. To do so, place the 2 pins at the tip of the implant holder into the corresponding slots of the implant (1). Tighten the knurled knob (2) while simultaneously pushing it forwards to engage the thread.

Note: The implant holder can only be attached to the side of the implant where the slots are.



Insert the implant holder into the implant insertion sleeve. Turn the holder slightly until the spherules of the holder snap into the corresponding notch inside the insertion sleeve. Push the holder forwards and simultaneously rotate it by a **quarter turn**. This locks the implant holder into the sleeve.

Caution: Make sure not to adjust the insertion depth or the cranio-caudal orientation of the implant insertion sleeve while inserting the implant holder.

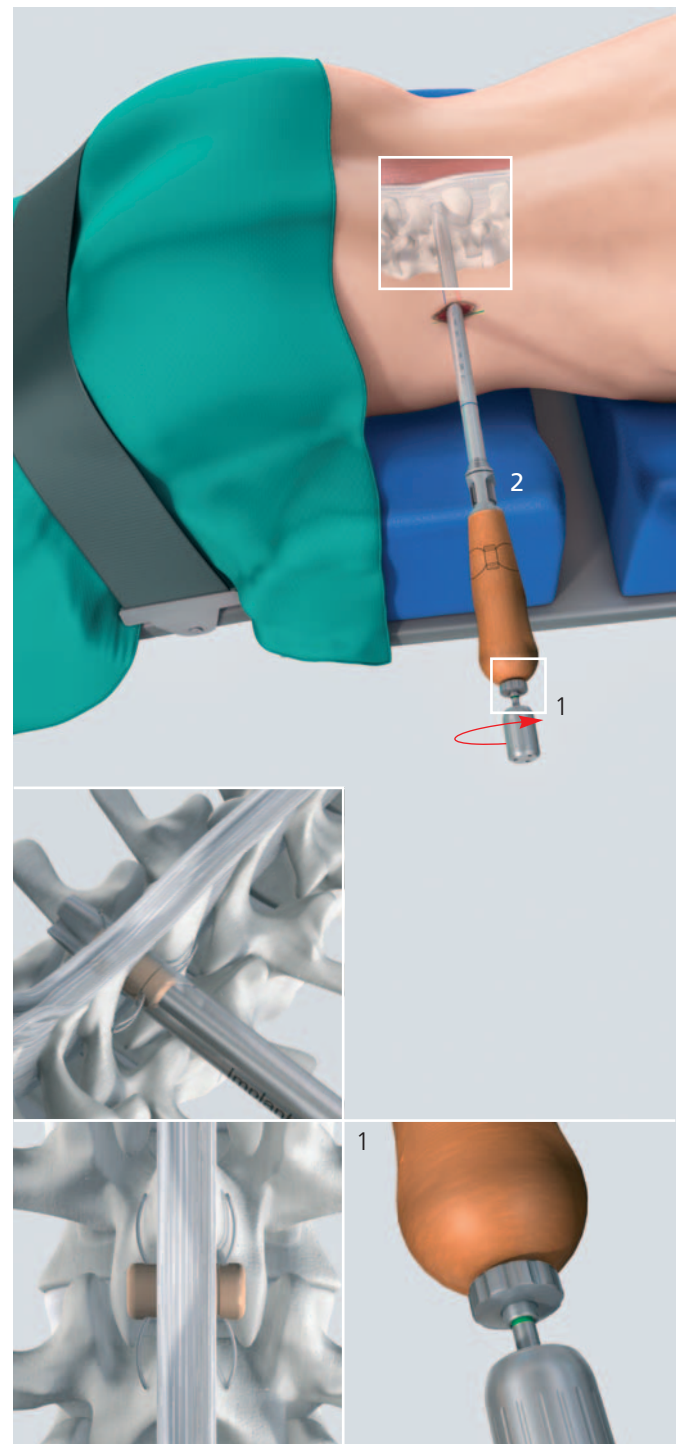


Introduce the screwdriver into the implant holder until the holding mechanism snaps in.

- Turn the screwdriver clockwise to deploy the wings of the implant. Under AP fluoroscopy, verify proper deployment of the wings. When the wings are fully deployed, a distinct increase in resistance is felt. A green coloured ring on the screwdriver shaft must appear at the proximal end of the implant holder (1).

Loosen the knurled knob (2) of the implant holder to detach it from the implant. Simultaneously remove the implant holder, the insertion sleeve and the screwdriver by pulling on the implant holder.

Note: To avoid damaging the implant do not detach the implant holder from the insertion sleeve while removing them.

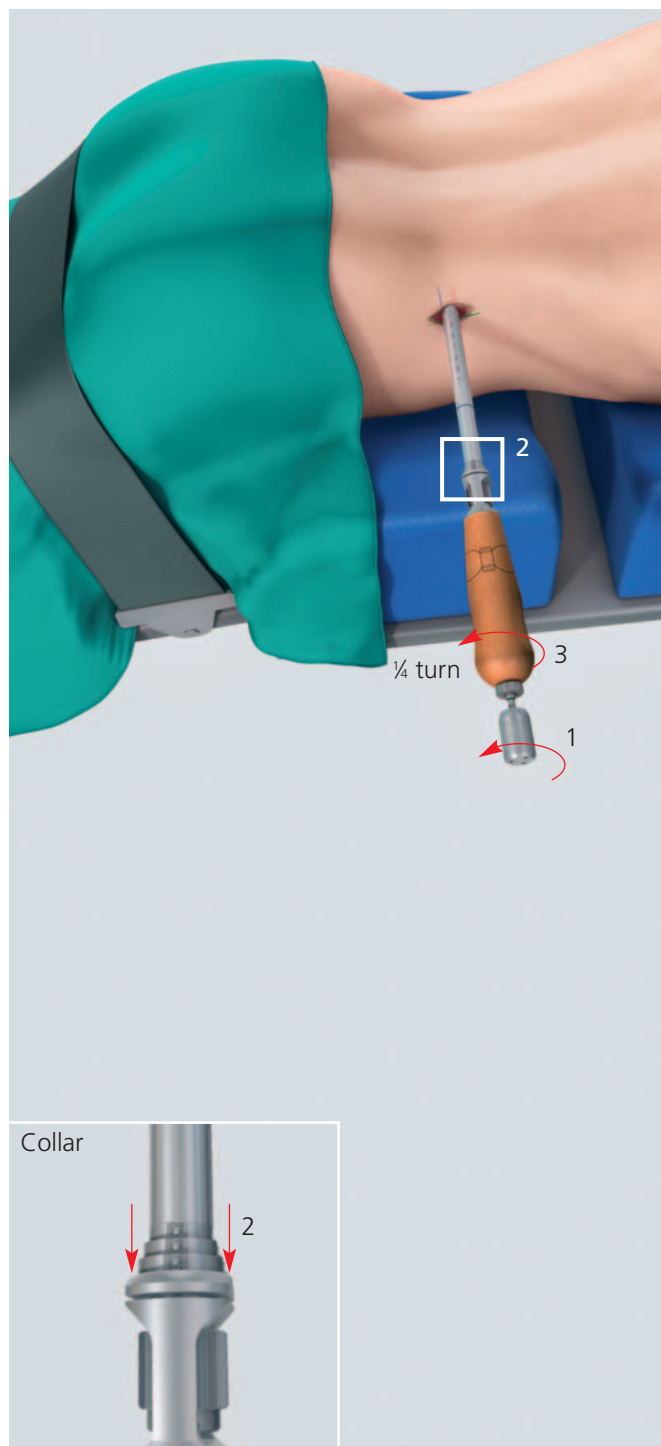


Caution:

Soft tissues or bone can hinder proper deployment of the wings. To avoid injury to these structures, a torque limiter has been integrated in the screwdriver. If the maximally achievable torque is reached before the above mentioned green coloured ring appears on the screwdriver shaft, this implies that the wings are not fully deployed and that the implant is not completely closed. The distraction effect might be lost and migration could occur.

In this case it is recommended to remove and reposition the implant. Turn the screwdriver anti-clockwise (1) until an increase in resistance is felt. Control under AP fluoroscopy that the wings are completely retracted. Pull back the collar of the implant holder (2) and turn the holder by a **quarter turn** (3) to release the implant holder from the insertion sleeve. Retract the holder together with the implant from the insertion sleeve.

Ensure that no soft tissues are entrapped in the implant obstructing proper deployment. Slightly adjust the position of the insertion sleeve. Reintroduce the holder together with the implant into the insertion sleeve and deploy the wires correctly.



Optional Technique in Case of Increased Insertion Forces

Instruments

03.630.024 Handle, for Distraction and Insertion Sleeves

03.630.031 Hammer

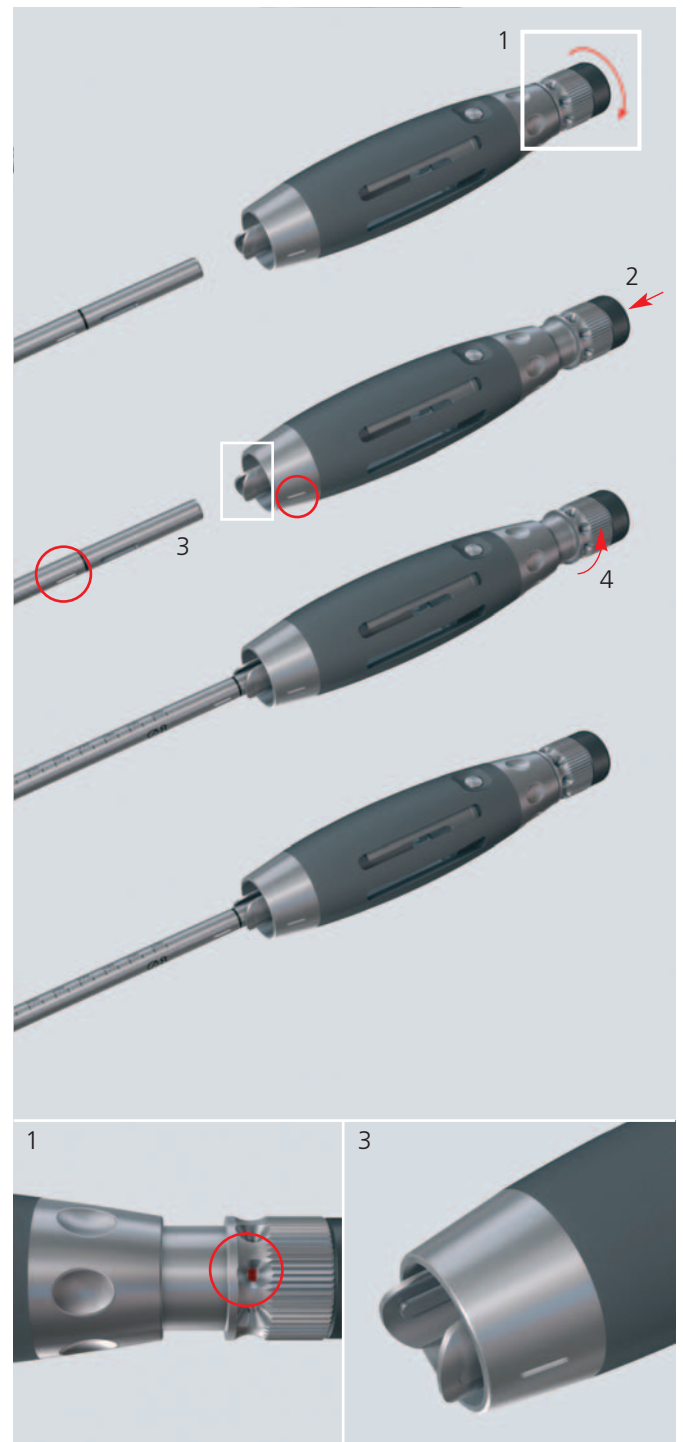
In case of increased resistance during insertion of the distraction and implant insertion sleeves a handle can be attached to ease the insertion.

Loosen the knurled knob of the handle until the red line appears in the opening (1). This is the maximum open position. Make sure not to loosen past this point or the knob will disassemble from the handle.

Press the knob (2) to open the prongs of the handle (3). Slide the handle over the sleeve and release the knob.

Note: Make sure that the ridges (3) in the handle are snapped into the corresponding slots of the instrument. Use the white lines (3) on the handle and on the sleeve for correct rotational alignment of the two instruments.

Firmly tighten the knurled knob by hand (4).



Slide the assembly over the sleeve.

Rotate the handle until the white lines are parallel to the patient's coronal plane. This will guarantee the correct cranio-caudal orientation of the instruments and ease their smooth insertion between the spinous processes.

Gentle hammering on the handle with the slotted hammer allows a controlled, step by step insertion between the spinous processes. To do so, slide the hammer from the side directly on the extension of the guide wire and rotate the instrument in the axis of the guide wire. Gently hammer.

Caution:

- Do not hammer directly on the distraction sleeves or the implant insertion sleeves (may cause damage to the instruments).
 - Extreme care should be taken to avoid any injury of the spinous processes by excessive and/or heavy hammering.
-



Technique for Removal of Outer Distraction Sleeve

Instruments

03.630.050	Holder for Adapter Nos. 03.630.062 to 03.630.066
03.630.062	Adapter for Removal of Distraction Sleeve 12 mm*
03.630.064	Adapter for Removal of Distraction Sleeve 14 mm*
03.630.066	Adapter for Removal of Distraction Sleeve 16 mm*

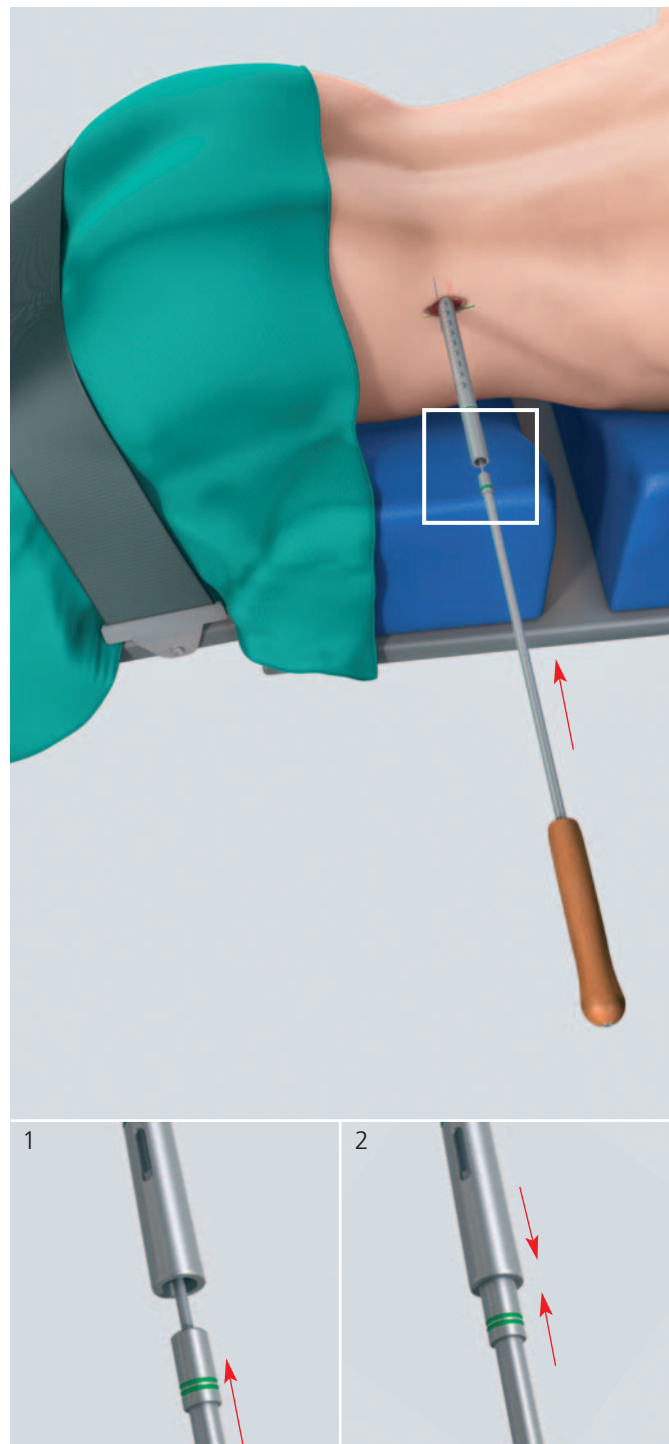
*The corresponding adapters and distraction sleeves are colour coded with a coloured ring.

If a distraction sleeve must be removed (for e.g. in case of over-distraction), use the dedicated holder with its corresponding adapter. Like this the outer sleeve can be removed while the inner sleeves remain in place.

The 10 mm distraction sleeve can be removed using the holder for adapters without additional adapter. For removal of all other distraction sleeves an adapter must be used.

Choose the correct adapter. The coloured ring on the adapter must correspond to the coloured ring on the sleeve to be removed. Tighten the adapter to the holder.

Slide the assembly over the guide wire (1) into the outer distraction sleeve until the stop is reached. Retract the outer distraction sleeve while holding the inner instruments in place with the holder (2).



Implant Removal

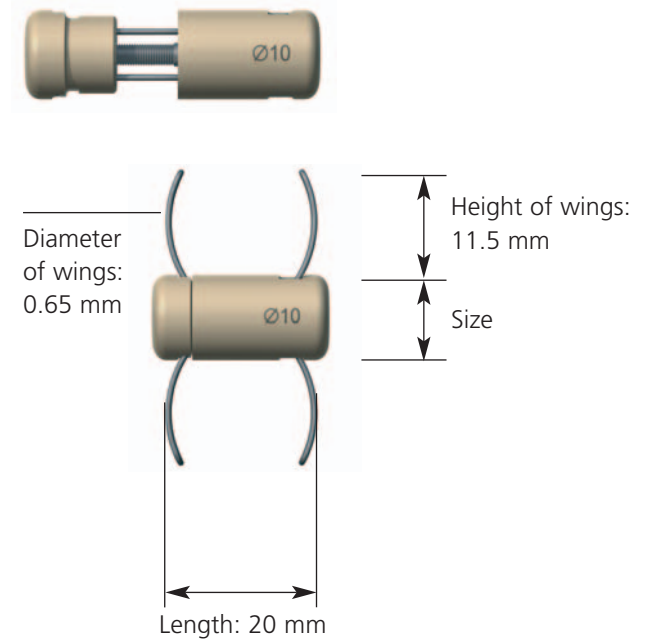
The implant can be removed through a conventional posterior approach. First, cut the wires and then remove the implant by pushing it on the side, displacing it from between the spinous processes.

Implants

In-Space, interspinous implant

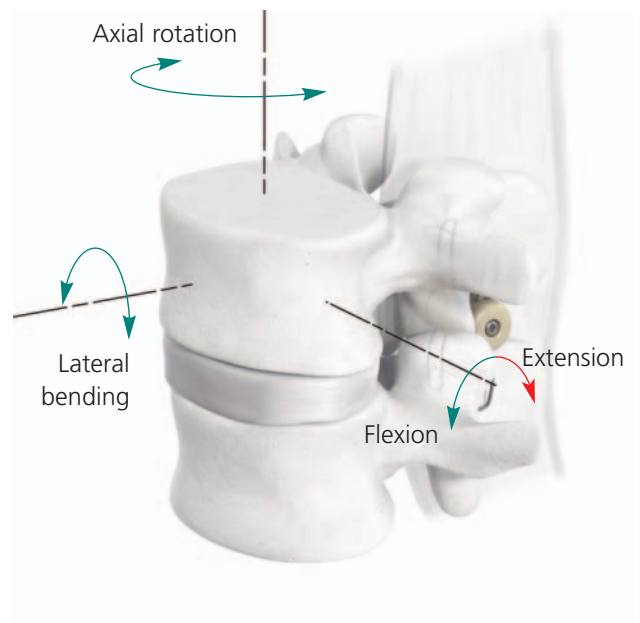
- Supplied in sterile package
- Available in 5 different sizes from 8 to 16 mm (in 2 mm increments)
- Radiolucent body in PEEK Optima for undisturbed visualization
- Screw and wings made of titanium alloy (TAV) to allow proper radiographic assessment of the correct implant position.

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 for Percutaneous Lateral Approach

Guide wire

03.630.103 Guide wire Ø 3.2 mm, length 260 mm,
for Percutaneous Insertion of In-Space

Short guide wire to avoid conflict with the image intensifier in lateral view.



03.630.104 Extension Ø 1.5 mm, length 400 mm,
for Guide Wire No. 03.630.103

Provides a pathway for secure insertion of the instruments while holding the guide wire securely in position.



03.630.022 Aiming Device, radiolucent,
for Guide Wire No. 03.630.103

Attached to the guide wire to aid in the insertion of the guide wire.



Instruments for distraction

03.630.108 Distraction sleeve \varnothing 8.0 mm, length 265 mm, for Percutaneous Insertion of In-Space

Gently dilates the soft tissues.



Distraction sleeves \varnothing 10–16 mm, for Percutaneous Insertion of In-Space

- Distract the interspinous space with the help of the conical tip.
- The nominal diameter on the sleeves corresponds to the diameter of the implant core.



Lateral view



Cranio-caudal view



Art. No.	\varnothing	Length
03.630.080	10 mm	268 mm
03.630.082	12 mm	271 mm
03.630.084	14 mm	274 mm
03.630.086	16 mm	277 mm

Instruments for implant insertion

Insertion Sleeves \varnothing 8–16 mm, for Percutaneous Insertion of In-Space

- Allow the deployment of the wires through the cranio-caudal opening at the tip of the instrument
- The slots on the side help define the midline of the implant
- The nominal diameter on the sleeves corresponds to the diameter of the implant core
- The insertion sleeves are color coded with the corresponding distraction sleeves



Art. No	\varnothing	Length
03.630.008	8 mm	265 mm
03.630.010	10 mm	268 mm
03.630.012	12 mm	271 mm
03.630.014	14 mm	274 mm
03.630.016	16 mm	277 mm

03.630.100 Implant Holder for Percutaneous Insertion of In-Space

For holding the implant and positioning it into the interspinous space through the implant insertion sleeves.



03.630.110 Screwdriver with Torque Limiter, for Percutaneous Insertion of In-Space

For a controlled in-situ deployment of the implant's wings.



Instruments in case of increased insertion resistance

03.630.024 Handle for Distraction and Insertion Sleeves, for In-Space

Used as a handle to ease the insertion of the distraction and implant insertion sleeves, if resistance is felt.



03.630.031 Hammer, for Percutaneous Insertion of In-Space

For gently hammering on the handle, if resistance is felt.



Instruments for removal of outer sleeves

In case of over-distraction; allow retracting the last distraction sleeve while holding the smaller sleeves in position.

03.630.050 Holder for Adapter
Nos. 03.630.062 to 03.630.066

For removal of distraction sleeve \varnothing 10 mm or used as a handle in connection with the adapters.



03.630.062 Adapter for removal of distraction sleeve \varnothing 12 mm



03.630.064 Adapter for removal of distraction sleeve \varnothing 14 mm



03.630.066 Adapter for removal of distraction sleeve \varnothing 16 mm



Cleaning brushes for cannulated instruments

03.630.123 Cleaning brush \varnothing 2.9 mm, length 460 mm

03.630.125 Cleaning brush \varnothing 4.7 mm, length 380 mm

Set List Instruments for Percutaneous Lateral Approach

01.630.004	Instrument Set for Percutaneous Insertion of In-Space, in Vario Case
68.630.000	Vario Case for Percutaneous Instrument Set of In-Space, with Lid, without Contents

Instruments

03.630.008	Implant Insertion Sleeve Ø 8.0 mm, length 265 mm, for Percutaneous Insertion of In-Space
03.630.010	Implant Insertion Sleeve Ø 10.0 mm, length 268 mm, for Percutaneous Insertion of In-Space
03.630.012	Implant Insertion Sleeve Ø 12.0 mm, length 271 mm, for Percutaneous Insertion of In-Space
03.630.014	Implant Insertion Sleeve Ø 14.0 mm, length 274 mm, for Percutaneous Insertion of In-Space
03.630.016	Implant Insertion Sleeve Ø 16.0 mm, length 277 mm, for Percutaneous Insertion of In-Space
03.630.022	Aiming Device, radiolucent, for Guide Wire No. 03.630.103
03.630.024	Handle for Distraction and Insertion Sleeves, for In-Space
03.630.031	Hammer, for Percutaneous Insertion of In-Space
03.630.050	Holder for Adapter Nos. 03.630.062 to 03.630.066
03.630.062	Adapter for Removal of Distraction Sleeve Ø 12.0 mm
03.630.064	Adapter for Removal of Distraction Sleeve Ø 14.0 mm
03.630.066	Adapter for Removal of Distraction Sleeve Ø 16.0 mm

03.630.080	Distraction Sleeve Ø 10.0 mm, length 268 mm, for Percutaneous Insertion of In-Space
03.630.082	Distraction Sleeve Ø 12.0 mm, length 271 mm, for Percutaneous Insertion of In-Space
03.630.084	Distraction Sleeve Ø 14.0 mm, length 274 mm, for Percutaneous Insertion of In-Space
03.630.086	Distraction Sleeve Ø 16.0 mm, length 277 mm, for Percutaneous Insertion of In-Space
03.630.100	Implant Holder for Percutaneous Insertion of In-Space
03.630.103	Guide Wire Ø 3.2 mm, length 260 mm, for Percutaneous Insertion of In-Space
03.630.104	Extension Ø 1.5 mm, length 400 mm, for Guide Wire No. 03.630.103
03.630.108	Distraction Sleeve Ø 8.0 mm, length 265 mm, for Percutaneous Insertion of In-Space
03.630.110	Torque limiting Screwdriver for Percutaneous Insertion of In-Space
03.630.123	Cleaning Brush Ø 2.9 mm, length 460 mm
03.630.125	Cleaning Brush Ø 4.7 mm, length 380 mm

Implants

Implants are supplied sterile and must be ordered separately.



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Presented by:



CE
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