

StenoFix. Interspinous distraction after surgical decompression.

Technique Guide



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 Image intensifier control

Warning

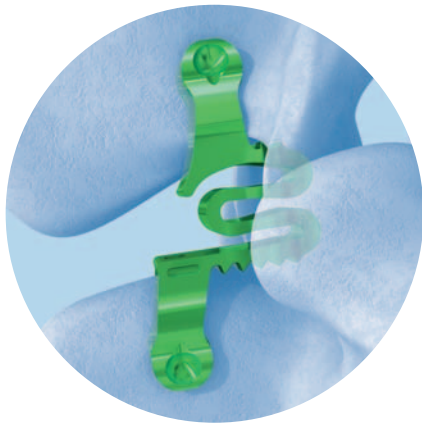
This description alone does not provide sufficient background for direct use of the product. Instruction by a surgeon experienced in handling this product is highly recommended.

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

StenoFix. Interspinous distraction after surgical decompression.

W-shaped spring allows dampening of high axial loads



Cranial radius

Caudal long flat surface

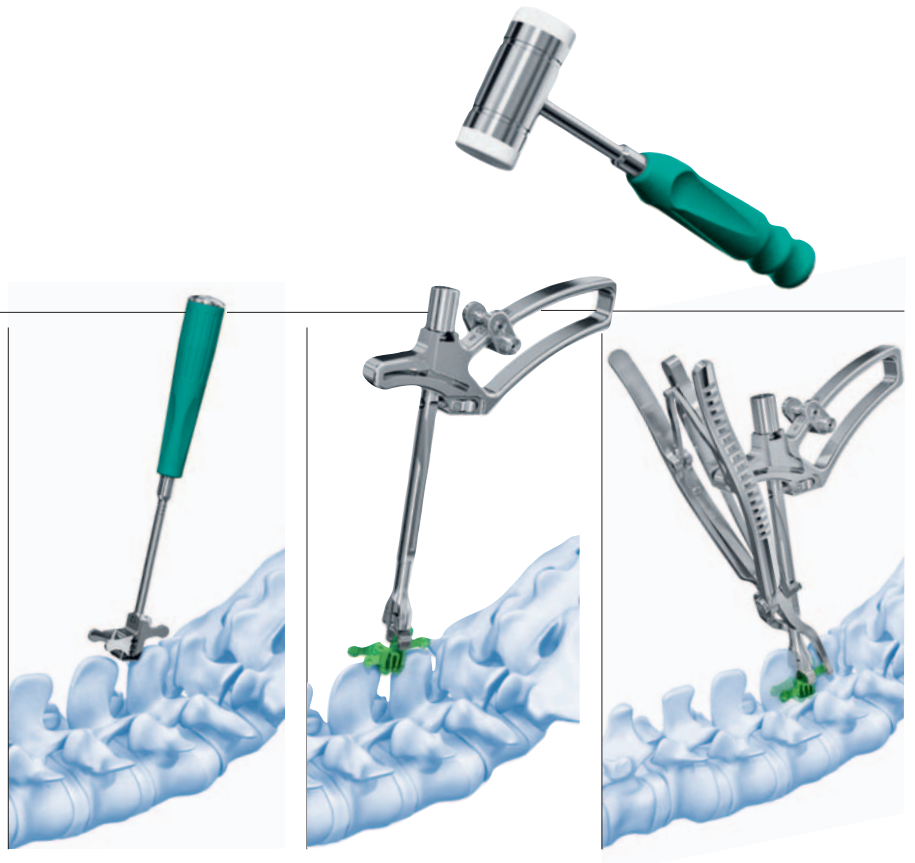
Divergent wings

Anterior taper

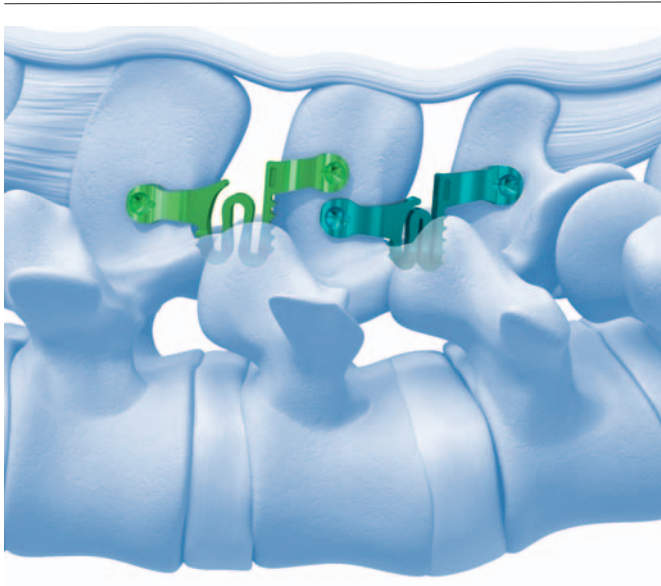


Ease of use

- Divergent wings ensure an easy implant insertion even over large spinous processes
- Wings do not need to be opened to pass the spinous process

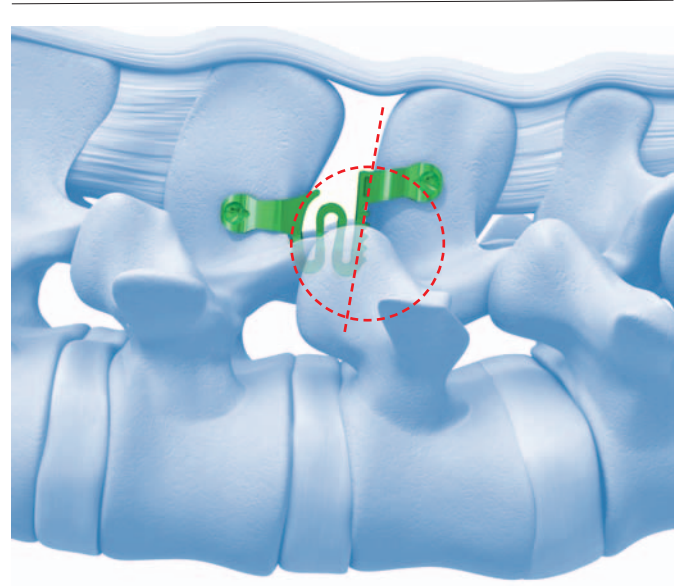


Double level implantation



- Staggered wings facilitate double level implantation

Optimized anatomical fit



- Fits into the natural concavity of the superior spinous process
- Large implant to bone contact surface with the upper rim of the inferior spinous process for good primary stability
- Anterior taper for optimal anterior positioning and load transfer

Indications and Contraindications

Intended use

StenoFix is intended for use as a space holder between the spinous processes for one or two lumbar motion segments. It controls the segmental extension and distracts the interspinous space. The intended effects on the posterior elements are:

- Preservation of the foraminal height
- Reduction of stress on the facet joints
- Reduction of pressure on the posterior annulus

It can be implanted at one or two lumbar levels from L1 to S1. For implantation at L5/S1, the presence of an S1-spinous process of adequate size is a prerequisite to fully support the implant.

Indications

StenoFix is indicated for symptomatic moderate to severe lumbar spinal stenosis with or without concomitant low back pain.

StenoFix is used after open or microsurgical decompressive surgery.

Contraindications

- Severe osteoporosis
- Morbid obesity (BMI >40)
- Conus/Cauda syndrome
- Fractures
- Spondylolysis/Isthmic spondylolisthesis
- Degenerative spondylolisthesis at index level of grade > 1
- Scoliotic deformity at index level
- Kyphosis
- Acute or chronic systemic or localized spinal infections
- Laminectomy and facetectomy

Preoperative Planning

In addition to routine preoperative investigations (X-rays AP and lateral; MRI), flexion/extension views are strongly recommended. They can rule out gross translational instability that would require a fusion procedure.

When operating at the level of L5/S1 a preoperative CT reconstruction is recommended to verify the presence and size of the S1 spinous process. The implant must have sufficient support.

Note: In patients with concomitant low back pain, StenoFix offloads the posterior elements. In patients without concomitant low back pain, the interspinous distraction maintains the foraminal height and may prevent recurrence of neural impingement over time.

Caution

- StenoFix is designed to limit segmental extension and range of motion. If the goal of the surgical intervention is to stabilize the segment after extensive surgical decompression of the neural elements, a fusion should be considered as an alternative to this procedure.
 - Only mild instability (iatrogenic as well as degenerative instability) can be treated with StenoFix. This product is therefore intended as an alternative to fusion especially in older patients presenting with pre-existing reduced segmental mobility. It should not be used as a substitute for fusion in cases of major instability or progressive degenerative spondylolisthesis.
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Patient Positioning

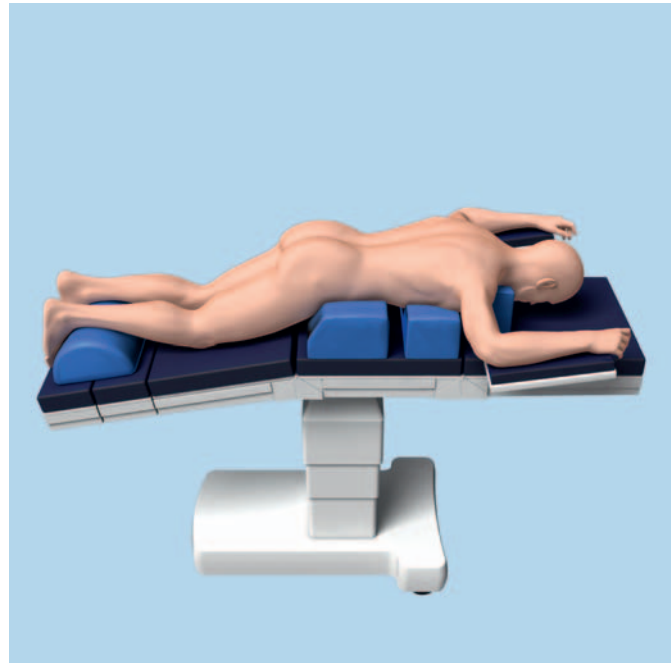
Place the patient in a decompression position using a Wilson-like frame:

- Prone position with tilted pelvis
- Knee-chest position

A neutral position of physiological lumbar lordosis should be achieved, so that the interspinous space is naturally distracted.

Notes

- Intraoperative AP fluoroscopy images cannot be recorded with the patient in the knee-chest position.
- Do not force the segment into an unphysiological kyphosis. While positioning the patient, check the position of the endplates.



Single-Level Implantation

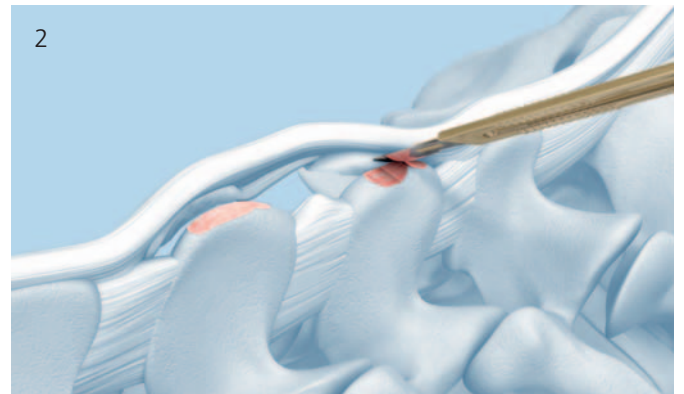
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Approach

Perform a routine midline skin incision of approximately 4 to 6 cm. Dissect the paraspinal muscles lateral to the supraspinous ligament. Strip them off the spinous processes and laminae. (1)

Preserve the supraspinous ligament. Detach the ligament from the spinous processes subperiostally or together with a bony tip of the spinous processes according to your preference. Mobilize the ligament laterally. (2)

Completely resect the interspinous ligament with a rongeur. (3)



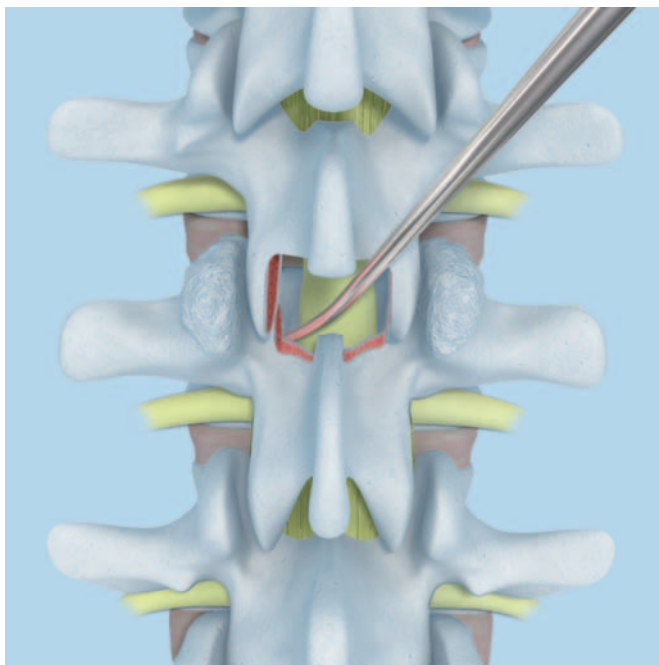
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Microsurgical decompression

Resect the ligamentum flavum to gain access to the spinal canal and perform the surgical decompression according to the patient's specific problem. Relieve all points of neural compression.

Foraminal decompression with partial laminotomy (microfenestration) can be performed. If necessary, herniated disc material can be removed. Unilateral "undercutting" or bilateral decompression can be performed.

Caution: Excessive removal of supporting laminar/bony structures may jeopardize the implantation of the StenoFix or create severe iatrogenic instability. Do not proceed to a complete laminectomy or facetectomy. Try to retain as much of the facet joints as possible since this is a motion preserving procedure.



3

Define appropriate implant size

Instruments

03.630.508	StenoFix – Trial Implant, size 8 mm
03.630.510	StenoFix – Trial Implant, size 10 mm
03.630.512	StenoFix – Trial Implant, size 12 mm
03.630.514	StenoFix – Trial Implant, size 14 mm
03.630.516	StenoFix – Trial Implant, size 16 mm
03.630.522	StenoFix – Hammer

Use the series of trial implants graduated in 2 mm increments to define the appropriate implant size. For gentle mobilization of the segment, it is advisable to perform sequential distraction of the interspinous space, starting with the smallest trial implant.

Orient the trial implant with the arrow pointing cranially and the laser etching "UP" on the head of the instrument showing on the cranial side.

Insert the trial implant as far anteriorly as possible into the interspinous space. During insertion, orient the flat caudal surface of the trial implant parallel to the cranial surface of the inferior spinous process.

Take care to introduce the trial implants gently applying light taps of the hammer, if desired. If an extremely hooked spinous process causes excessive insertion forces, a partial resection of the spinous process overhang may be required.



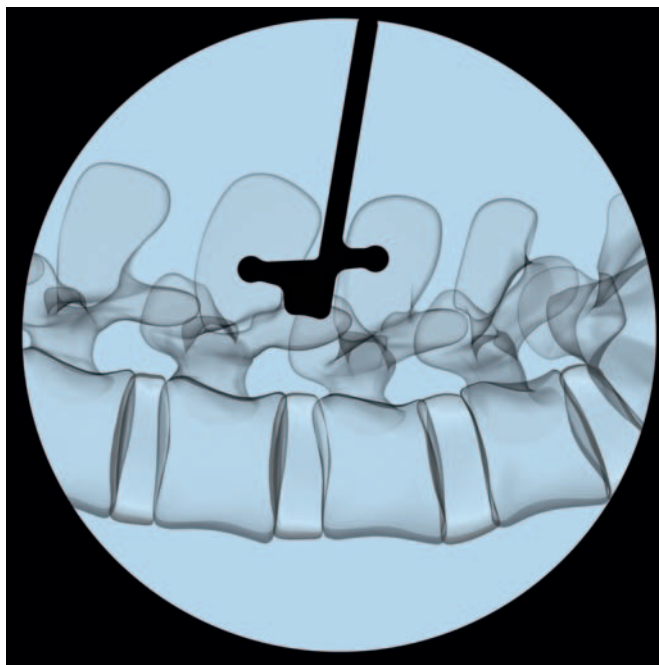
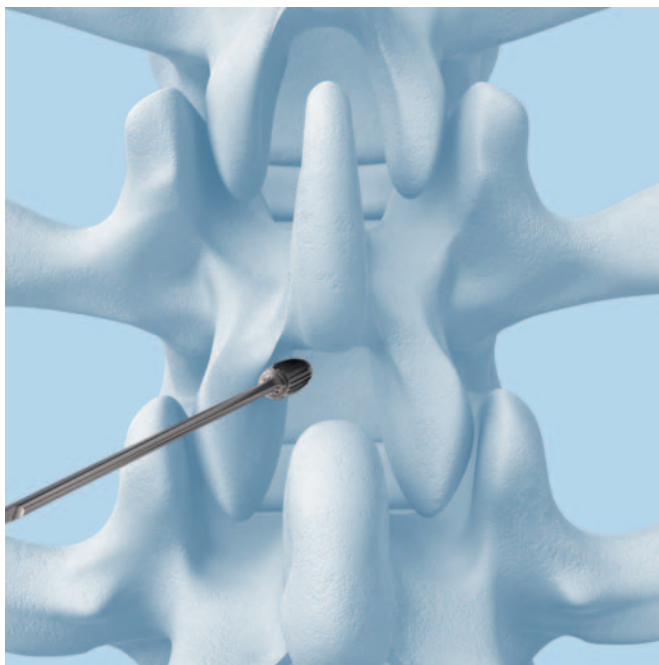
Caution: Extreme care should be taken to avoid any injury of the spinous processes and the thecal sac by heavy hammering.

The trial implant should sit in the natural anterior concavity of the spinous processes. The correct size should produce a press-fit contact between the inferior and superior spinous processes. If any bony overgrowth interferes with good anterior positioning of the trial implant, perform a partial resurfacing of the bony junction between the laminae and the spinous processes.

- ① Under lateral fluoroscopy, verify the correct anterior positioning of the trial implant.

Notes

- In general, avoid excessive distraction, as this may lead to a loss of physiological lordosis. Maximum permissible distraction is reached when the vertebral endplates are parallel to each other.
 - If two trial implants show a good press-fit, choose the smaller size in order to avoid over-distraction in the standing position.
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Prepare the implant holder

Instrument

03.630.525 StenoFix Implant Holder

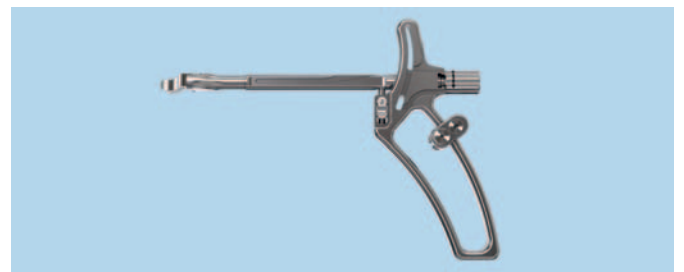
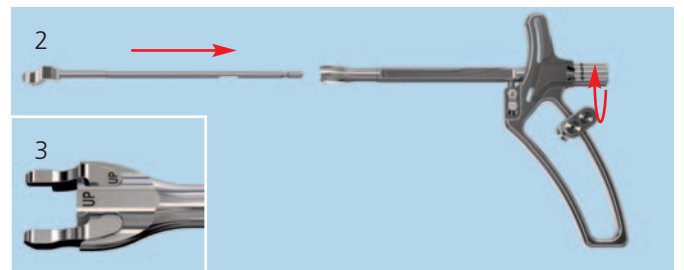
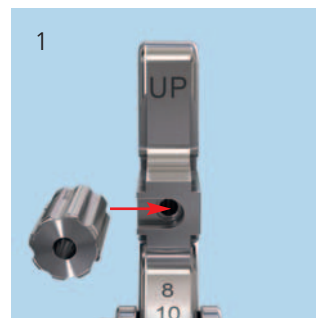
The implant holder must be assembled prior to insertion of StenoFix.

Slide in the implant holder knob into the slot at the proximal end of the implant holder. (1)

Insert the shaft (2) of the implant holder completely into the holder. Make sure that the laser etching "UP" on the shaft (3) and implant holder face the same direction.

While lightly pressing the shaft into the implant holder turn the knob clockwise to fully seat the shaft into the implant holder. Then turn the knob counter-clockwise until it stops. At this position, the implant holder is ready for loading the implant.

Note: For disassembly, turn the knob counter-clockwise while pulling the security latch down until the knob spins freely. While still holding the security latch down, slide the shaft completely out of the implant holder and remove the implant holder knob by sliding it out of the slot.



Attach the implant

Instruments

68.630.500.02	Loading Station StenoFix
04.630.508S	StenoFix – Interspinous Implant, size 8 mm, Titanium Alloy (TAN), sterile
04.630.510S	StenoFix – Interspinous Implant, size 10 mm, Titanium Alloy (TAN), sterile
04.630.512S	StenoFix – Interspinous Implant, size 12 mm, Titanium Alloy (TAN), sterile
04.630.514S	StenoFix – Interspinous Implant, size 14 mm, Titanium Alloy (TAN), sterile
04.630.516S	StenoFix – Interspinous Implant, size 16 mm, Titanium Alloy (TAN), sterile
03.630.525	StenoFix Implant Holder

Select the implant size corresponding to the previously defined trial implant size. Trial implants and implants are color-coded. Check that the colors match and verify the number on the implant.

Place the implant in the loading station. The laser-etched "UP" on the implant must match the direction of the laser-etched "UP" on the loading station.

Note: Before attaching the implant to the implant holder make sure that the implant holder is ready for loading the implant. See the section titled Prepare the Implant Holder for detailed instruction.

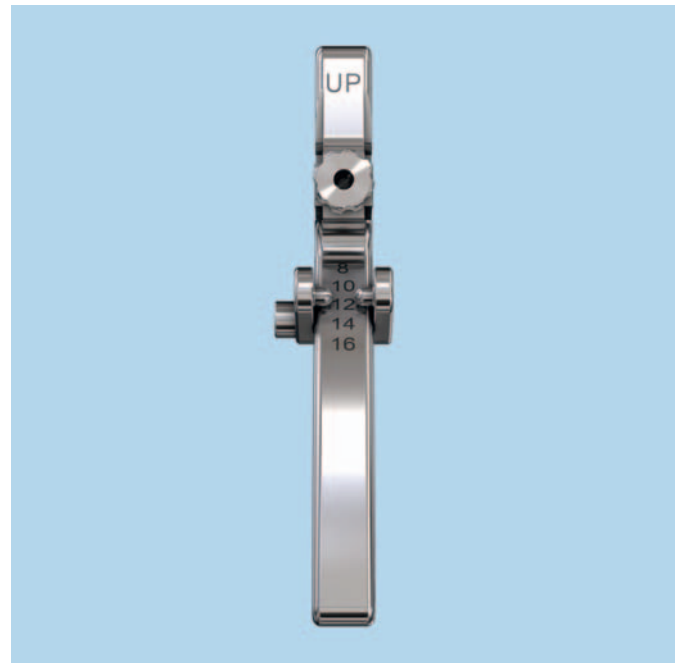


To attach the implant to the implant holder, slide the distal part of the implant holder perpendicular to the table into the loading station. Make sure the laser-etched "UP" on the implant holder matches the direction of the laser-etched "UP" on the implant.

Turn the knob of the implant holder clockwise until it is tight. This will close the implant holder jaws and secure it to the implant.

Remove the implant from the loading station. Ensure that the implant is fully and tightly connected to the implant holder. The ribs on the implant holder jaws must engage properly with the lateral slots of the implant. As long as the implant holder knob is tightened, the implant cannot move or be detached.

Once the implant has been properly attached to the implant holder, move the slider on the implant holder to the detent position corresponding to the implant size previously determined with the trial implant.



4**Insert implant****Instruments**

03.630.522	StenoFix – Hammer
03.630.525	StenoFix Implant Holder

Orient the implant so that the surface with the laser-etched "UP" on the implant and implant holder points in the cranial direction. Insert the implant into the interspinous space. If necessary apply light impaction with the hammer.

Verify the correct anterior position of the implant under lateral fluoroscopy. It should sit in the natural anterior concavity of the interspinous space.

Use a ball-topped nerve hook to verify that there is enough free space between the anterior surface of the implant body and the thecal sac. Ensure that the nerve hook can be passed freely, leaving a separation of approximately 3–4 mm.

Caution: Do not open the wings or bend them back and forth as over-manipulation can weaken the wings of the implant.



5

Fix implant

Instruments

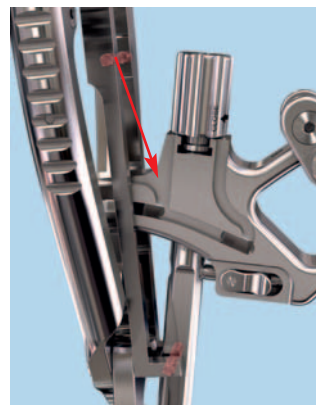
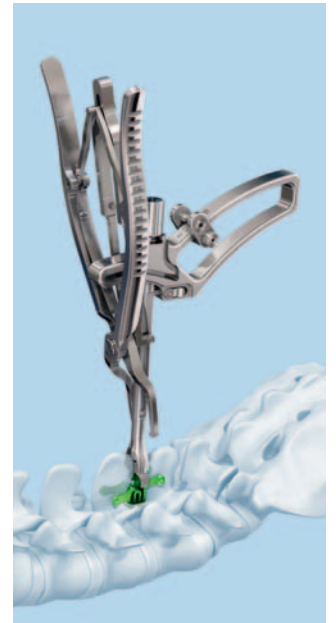
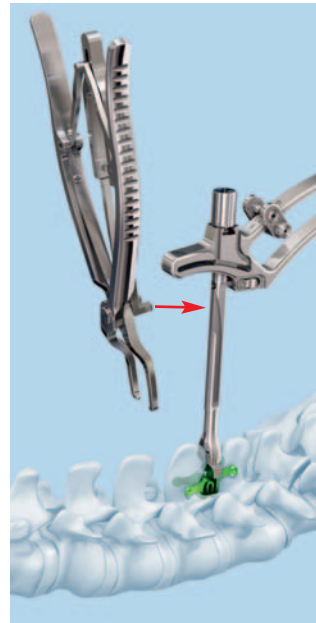
03.630.525	StenoFix Implant Holder
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03.630.526	StenoFix Crimper
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The StenoFix Crimper needs to be attached to the implant holder for proper crimping.

Note: Crimping without using the implant holder can introduce an uncontrolled force on the implant wings and damage the spinous process.

Place the crimper parallel to the implant holder shaft. Slide the crimper horizontally towards the implant holder, ensuring the upper and lower pair of pins on the crimper seat into the upper and lower grooves on the implant holder. Slide the crimper down to fully seat the crimper onto the implant holder.



Swing the crimper over the upper and lower wing tips and crimp them to the spinous processes in order to prevent the implant from migration. The ball tip of the crimper jaws must mate with the wing socket.

Notes

- To ensure that the ball tips of the crimper seat properly in the sockets, when crimping the cranial wings, the crimper must contact the slider.
- Due to anatomical variations among patients, crimping of the wings may not be fully symmetrical.

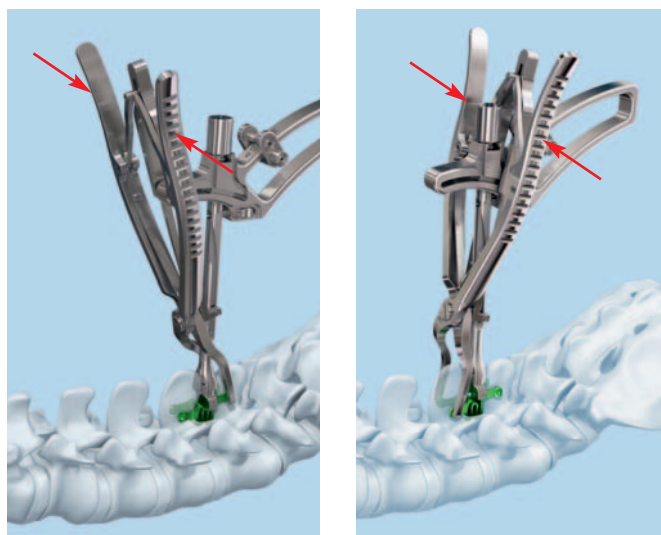
Lift the crimper up and away from the implant holder.

Turn the knob counter-clockwise until it stops. Now the implant holder can be disengaged from the implant. Remove the implant holder.

Reattach the supraspinous ligament to the spinous processes by suturing

Caution

- Do not use excessive force when crimping the wings as this can damage the spinous process.
- Do not crimp the wings past the midline of the implant.

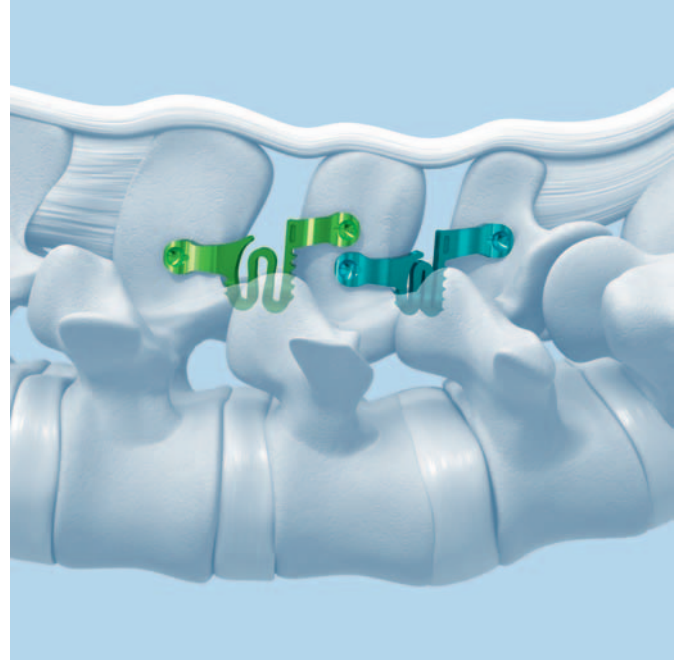


Double-Level Implantation

If two implants are placed at adjacent levels, a specific implantation sequence must be followed in order to produce the best ventral positioning and avoid overlapping of the superior and inferior implant wings.

Insert the first implant at the more caudal level. Then insert the second implant at the more cranial level.

Note: StenoFix can be implanted at a maximum of two levels.



Implants

- Five anatomical sizes in 2 mm increments
- Implant made of titanium alloy (TAN)
- Color-coded (implants and trial implants)
- Supplied in sterile package

Implants

StenoFix – Interspinous Implants, Titanium Alloy (TAN), sterile

Art. No.	Size	Color
04.630.508S	8 mm	Light blue
04.630.510S	10 mm	Purple
04.630.512S	12 mm	Green
04.630.514S	14 mm	Blue
04.630.516S	16 mm	Gold



Instruments

StenoFix-Trial Implants

Art. No.	Size	Color
03.630.508	8 mm	Light blue
03.630.510	10 mm	Purple
03.630.512	12 mm	Green
03.630.514	14 mm	Blue
03.630.516	16 mm	Gold



03.630.522 StenoFix – Hammer



03.630.525 StenoFix Implant Holder



03.630.526 StenoFix Crimper



Sets

01.630.500 Instrument Set for Insertion of StenoFix in Vario Case

68.630.500 Vario Case for StenoFix-Instrument Set, with Lid, without Contents

Instruments

03.630.508 StenoFix – Trial Implant size 8 mm

03.630.510 StenoFix – Trial Implant size 10 mm

03.630.512 StenoFix – Trial Implant size 12 mm

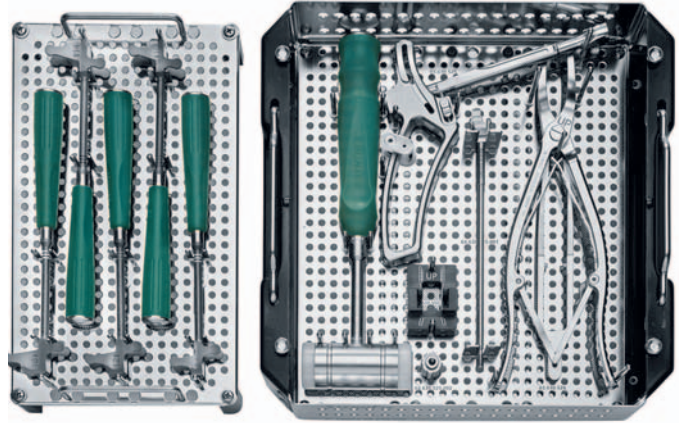
03.630.514 StenoFix – Trial Implant size 14 mm

03.630.516 StenoFix – Trial Implant size 16 mm

03.630.522 StenoFix – Hammer

03.630.525 StenoFix Implant Holder

03.630.526 StenoFix Crimper



Implants

Implants are supplied sterile and must be ordered separately.

