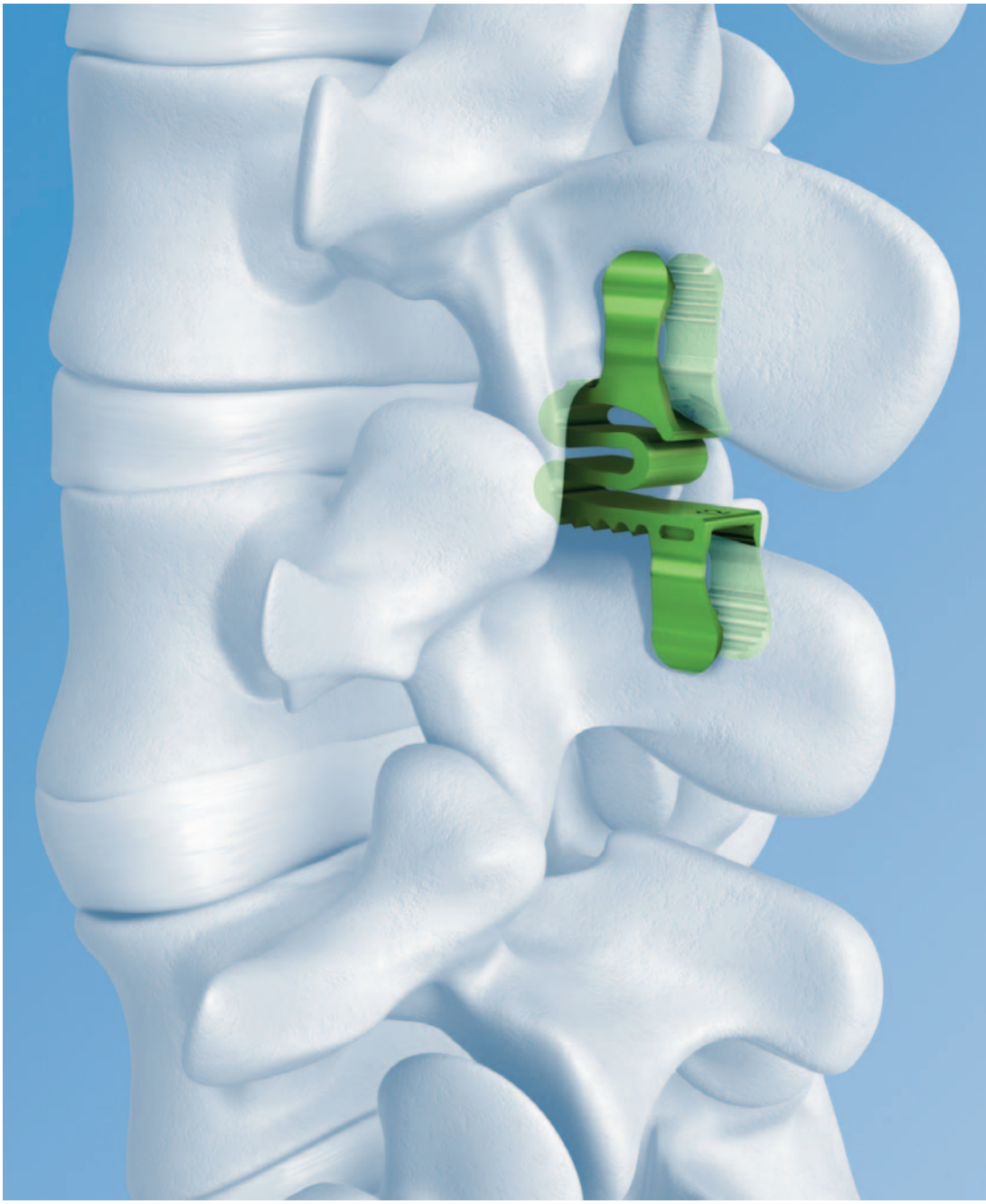
StenoFix. Interspinous distraction after surgical decompression.

Technique Guide



SYNTHES®

Instruments and implants
approved by the AO Foundation

Table of Contents

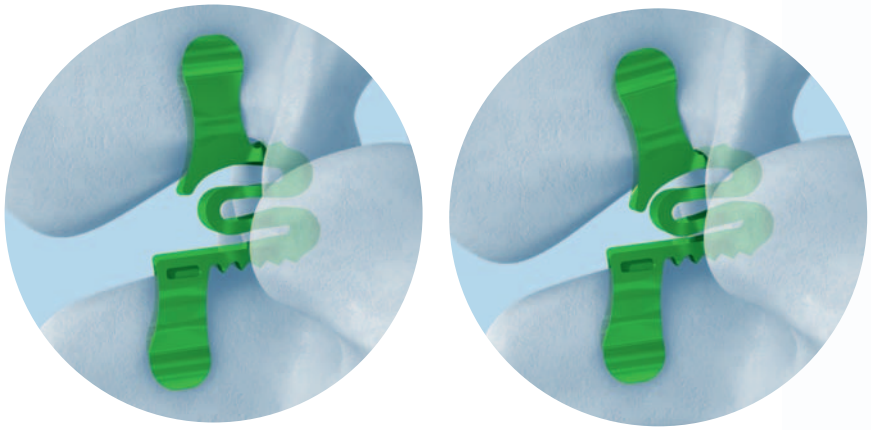
Image intensifier control

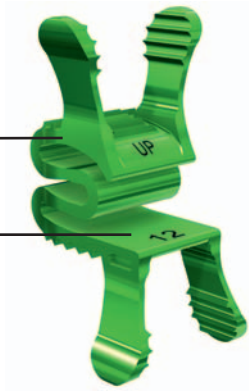
Warning
This description alone does not provide sufficient background for direct use of the product. Instruction by a surgeon experienced in handling this product is highly recommended.

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

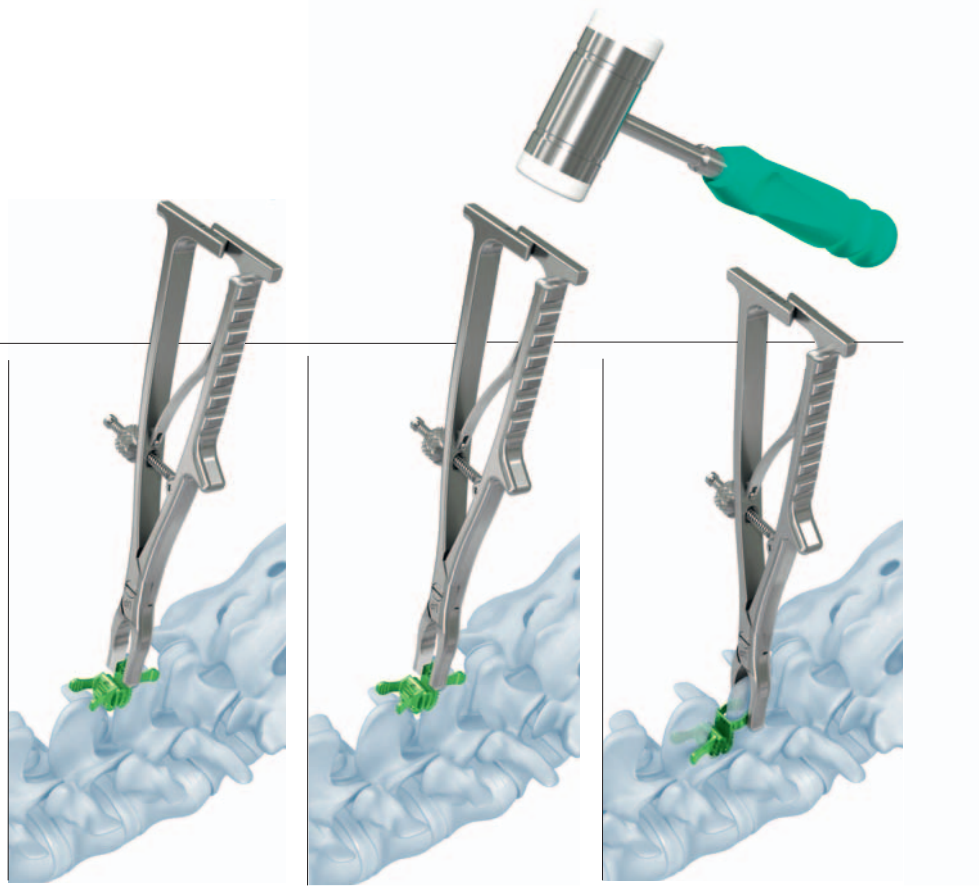
Caudal long flat surface

Divergent wings

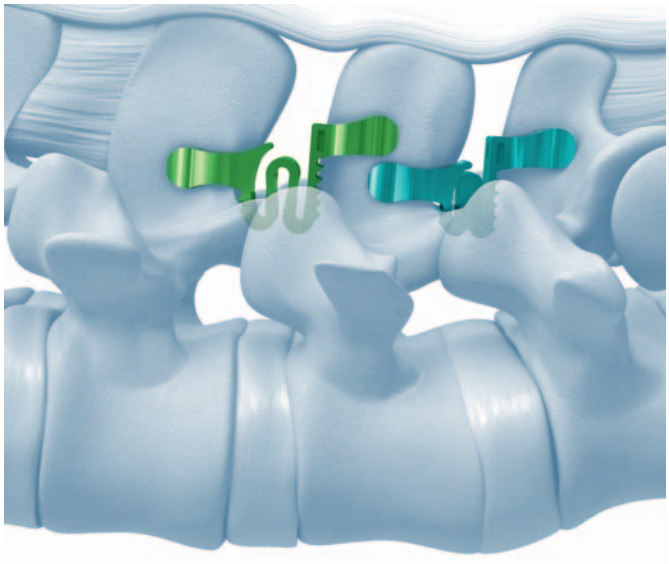
Anterior taper

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

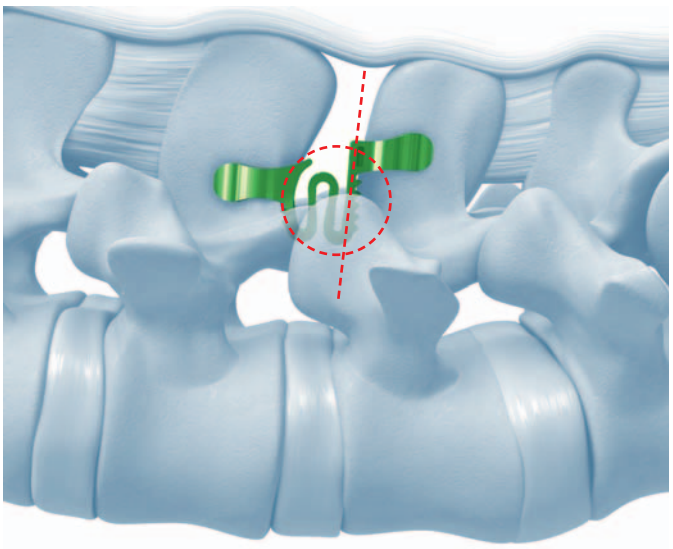


Double level implantation



- 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, the implant 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 surgically addressed neural decompression, a fusion should be envisaged as an alternative to this procedure.

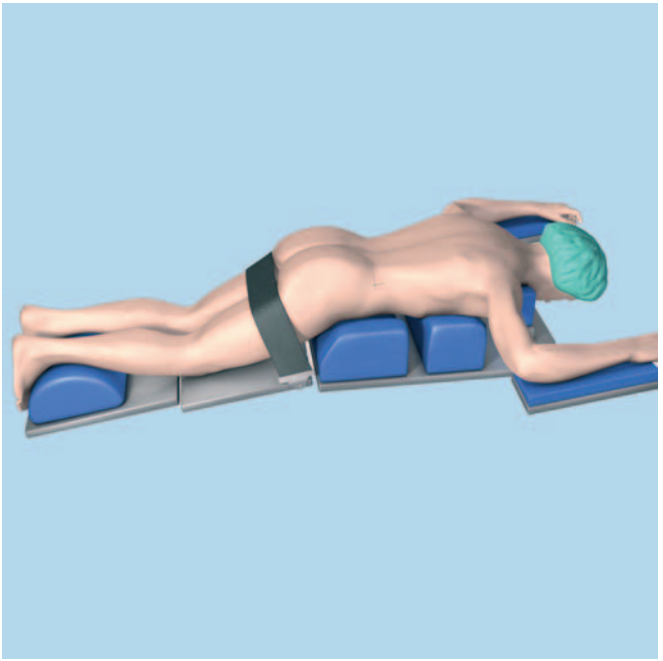
Only mild instability (iatrogenic as well as degenerative instability) can be treated with StenoFix. This product is therefore intended as an alternative to fusion especially in older patients presenting with pre-existing reduced segmental mobility. It should not be used as a substitute for fusion in cases of major instability or progressive degenerative spondylolisthesis.

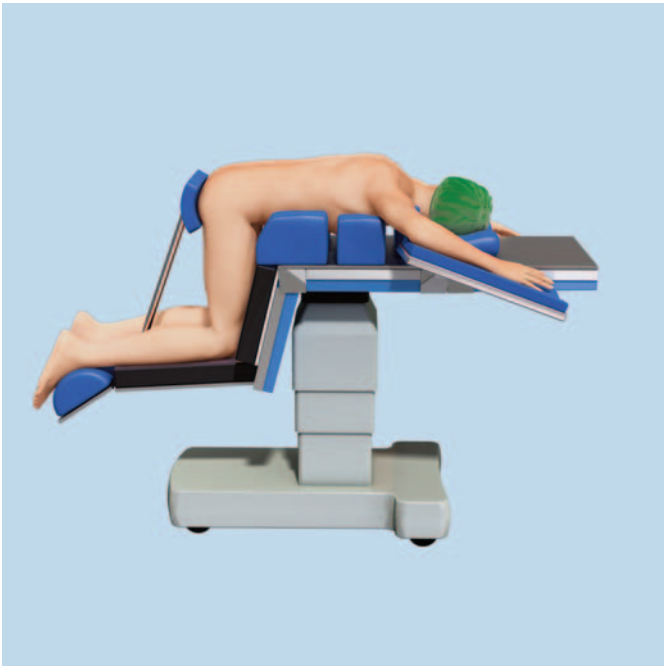
Patient Positioning

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.



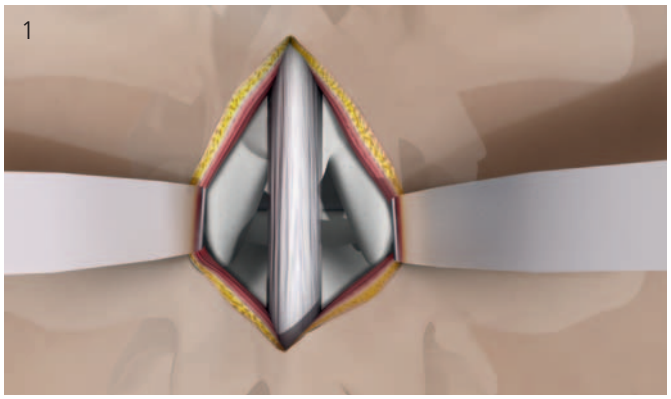


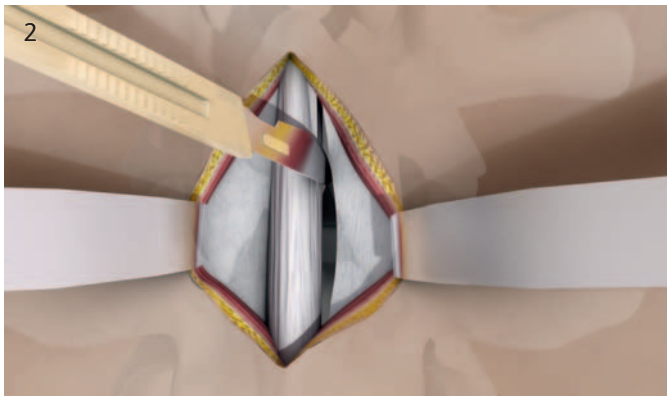
1
Approach

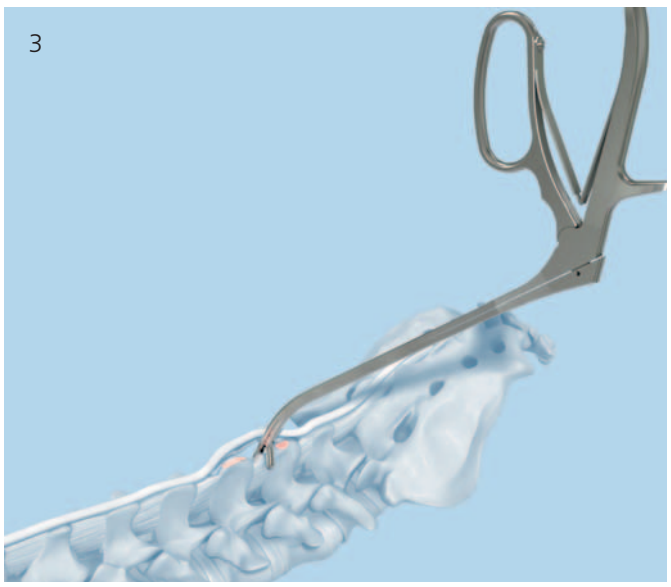
Perform a routine midline skin incision of approximately 3 to 6 cm. Dissect the paraspinal muscles lateral to the supraspinous ligament. Strip them off the spinous processes and laminae. (1)

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)





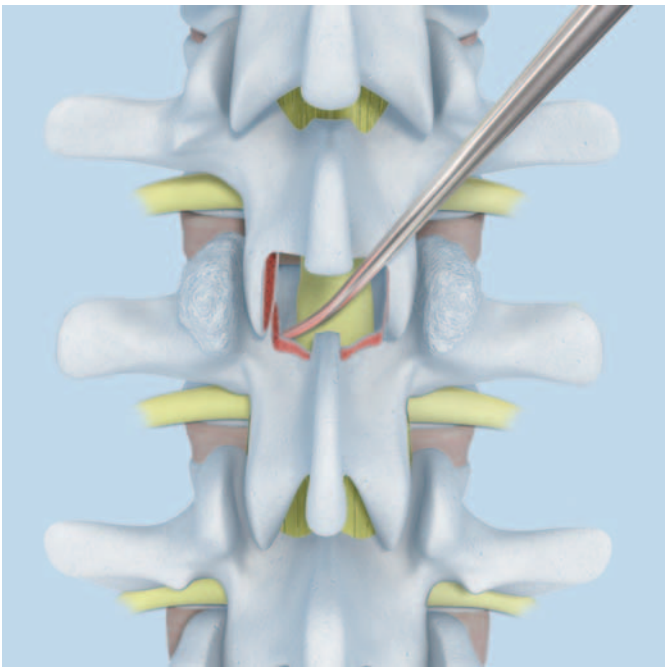


2
Microsurgical decompression

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. Try to retain as much of the facet joints as possible since this is a motion preserving procedure.



3
Define appropriate implant size

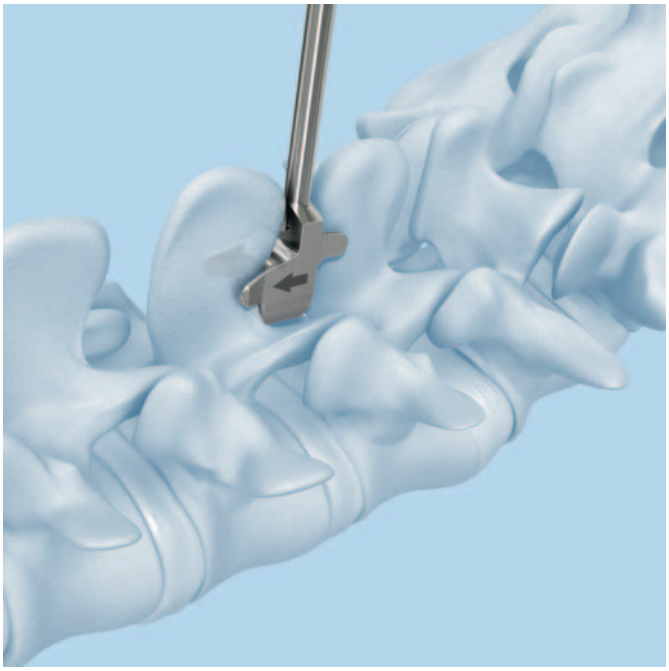
Instruments	
03.630.508	StenoFix-Trial Implant, size 8 mm
03.630.510	StenoFix-Trial Implant, size 10 mm
03.630.512	StenoFix-Trial Implant, size 12 mm
03.630.514	StenoFix-Trial Implant, size 14 mm
03.630.516	StenoFix-Trial Implant, size 16 mm
03.630.522	StenoFix-Hammer

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 caudal rim of the trial implant parallel to the upper rim of the inferior spinous process.

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.

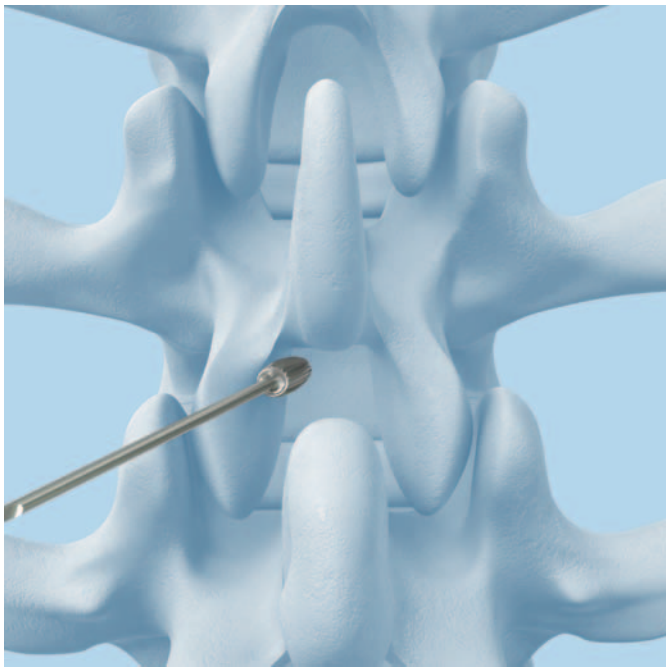
Take care to introduce the trial implants gently, applying light taps of the hammer, if desired. If an extremely hooked spinous process causes excessive insertion forces, a partial resurfacing of the spinous process overhang may be required.

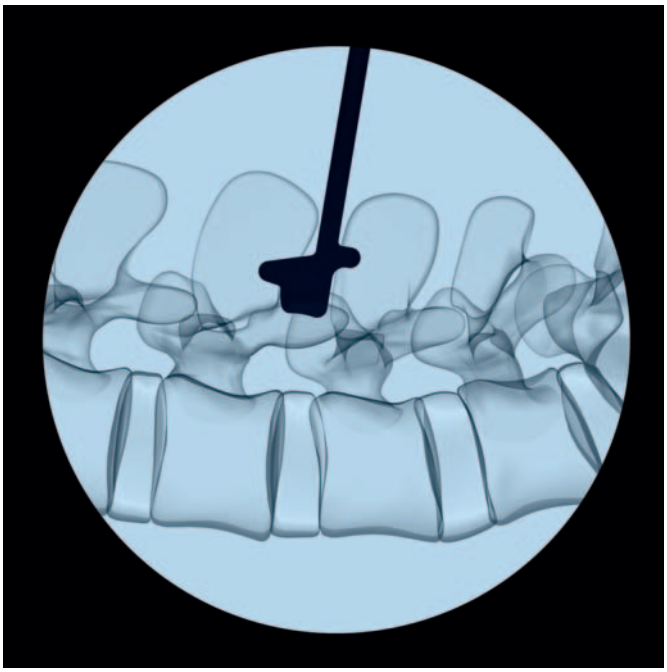
Caution: Extreme care should be taken to avoid any injury of the spinous processes by heavy hammering.

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 admissible 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.





4
Insert implant

Instruments	
03.630.520	StenoFix-Insertion Instrument
03.630.522	StenoFix-Hammer

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

Place the implant in the loading station in the Vario Case. The laser etching "UP" on the implant must match the direction of the laser etching "UP" on the loading station.

Attach the implant holder to the implant. Slide the distal part of the insertion instrument into the loading station, close the forceps and tighten the locking screw. The correct orientation of the insertion instrument is indicated on its proximal flat surface as well as on its distal part with a laser etching marked "UP".

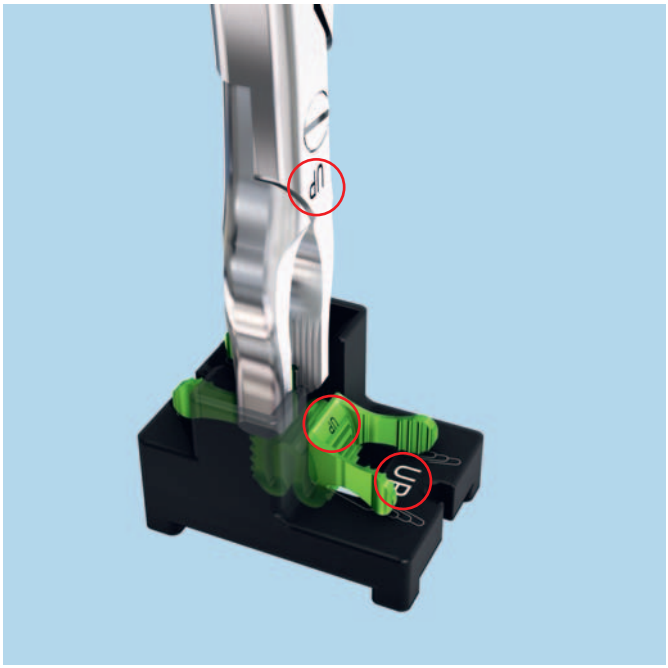
Ensure that the implant is fully connected to the insertion instrument. The notches of the implant holder must engage properly with the lateral slots of the implant.

Orient the implant with the laser etchings "UP" on the implant and insertion instrument showing cranially. Insert the implant into the interspinous space. If necessary apply gentle taps 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 beaded tip probe to verify that there is enough free space between the tip of the implant 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 overmanipulation can lead to wing fracture.



5
Fix implant

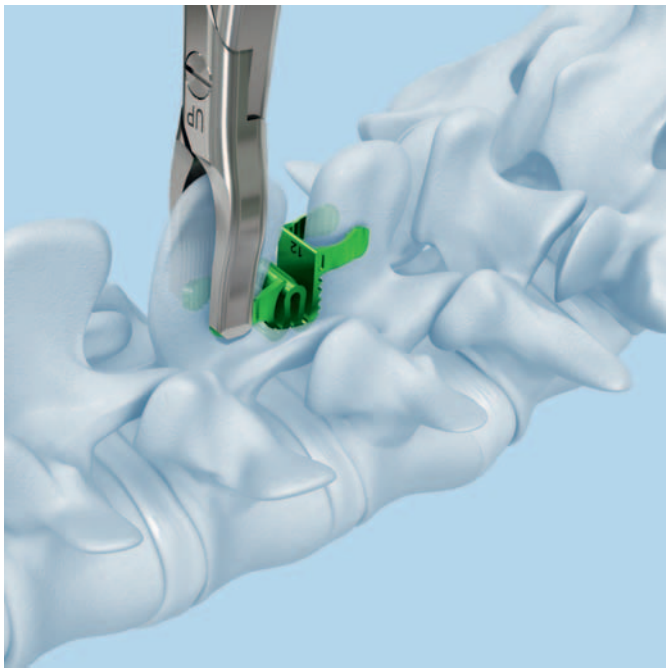
Instrument	
03.630.520	StenoFix-Insertion Instrument

Open the locking screw to detach the insertion instrument from the implant. Slide the instrument over the lower and upper wing tips and crimp them to the spinous processes to secure the implant against migration.

Note: Due to anatomical variations among patients, crimping of the wings may not be symmetrical.

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.



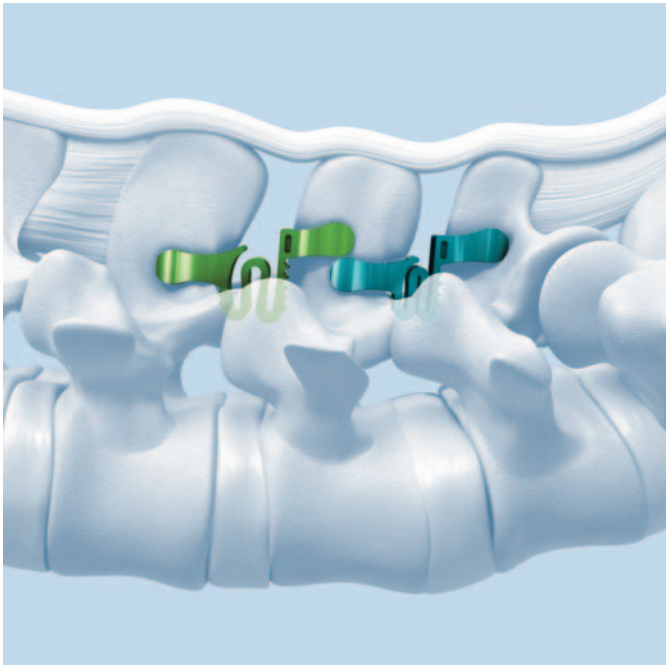
Double-level Implantation

If two implants are placed at adjacent levels, a specific implantation sequence must be respected.

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

This implantation sequence produces the best ventral positioning and avoids overlapping of the superior and inferior implant wings.

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

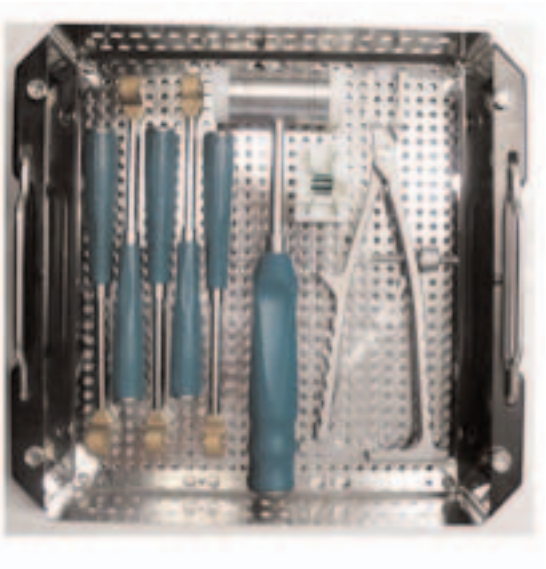
Art. No.	Size	Color
03.630.508	8 mm	Light blue
03.630.510	10 mm	Purple
03.630.512	12 mm	Green
03.630.514	14 mm	Blue
03.630.516	16 mm	Gold

03.630.520	StenoFix-Insertion Instrument

03.630.522	StenoFix-Hammer

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
03.630.520	StenoFix-Insertion Instrument
03.630.522	StenoFix-Hammer

Implants

Implants are supplied sterile and must be ordered separately.

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

All technique guides are available as PDF files at
www.synthes.com/lit

CE
0123