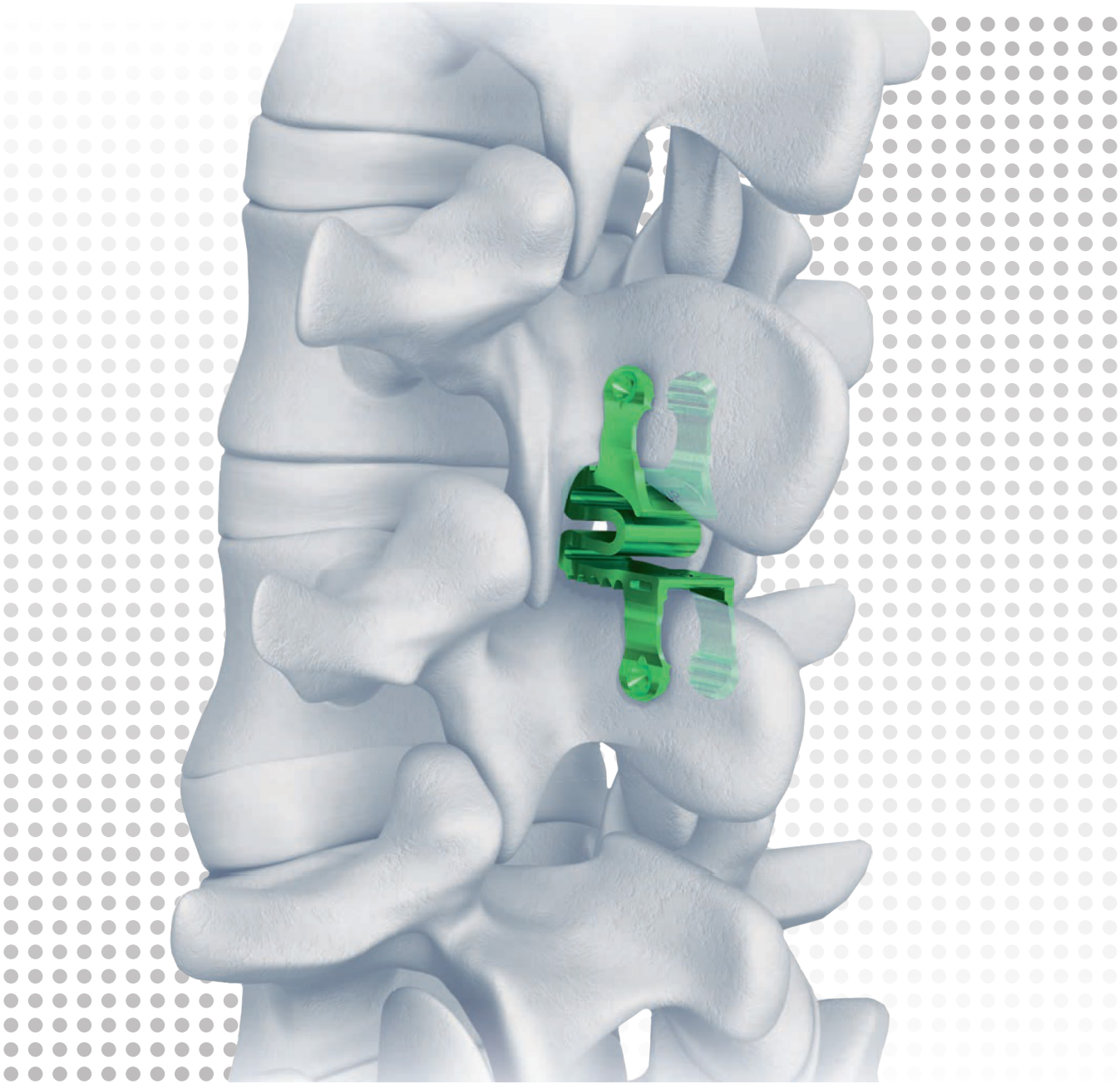
STENOFIX

Surgical Technique



DePuy Synthes
THE ORTHOPAEDICS COMPANY OF Johnson & Johnson

Image intensifier control

Warnings and Precautions

This description alone does not provide sufficient background for direct use of DePuy Synthes products. Instruction by a surgeon experienced in handling these products is highly recommended.

Processing, Reprocessing, Care and Maintenance

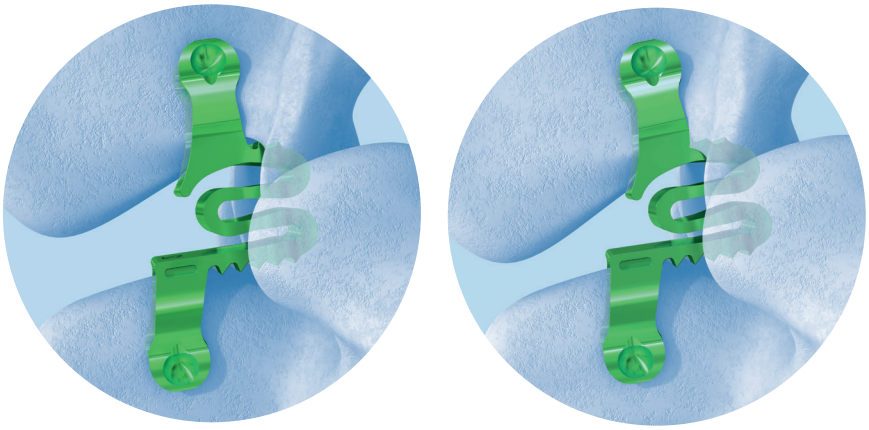
For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:

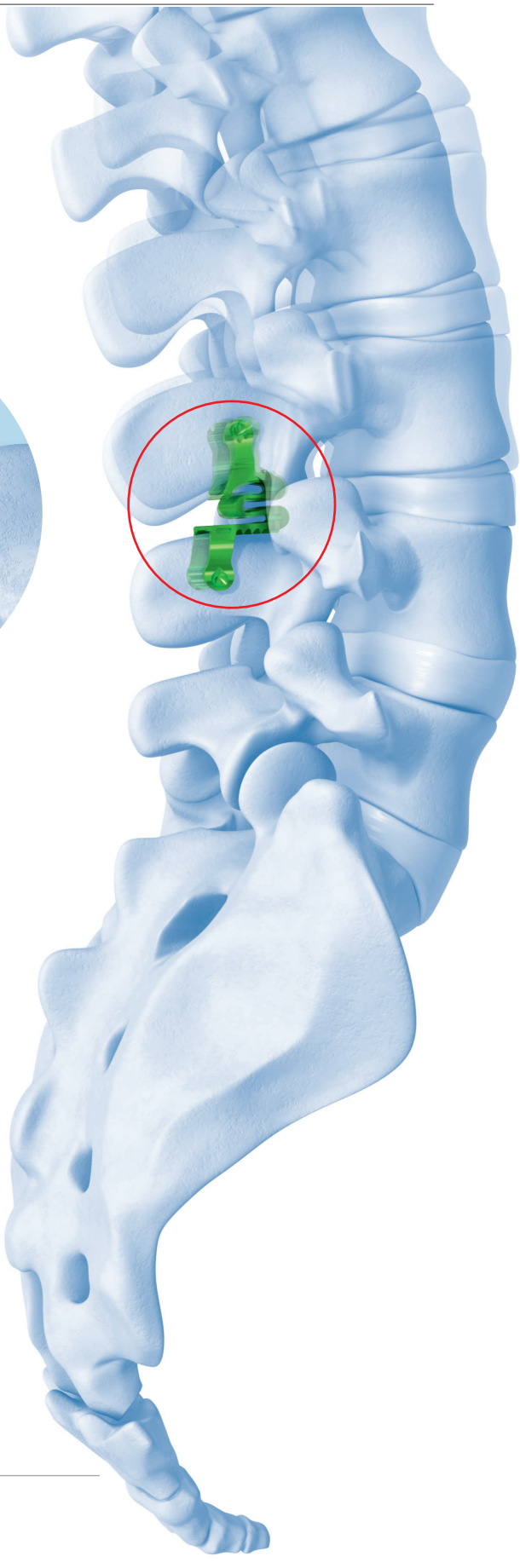
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

For general information about reprocessing, care and maintenance of Synthes reusable devices, instrument trays and cases, as well as processing of Synthes non-sterile implants, please consult the Important Information leaflet (SE_023827) or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

Table of Contents

STENOFIX. Interspinous Distraction after Surgical Decompression





Cranial radius

Caudal long flat surface

Divergent wings

Anterior taper

AO Spine Principles

The four principles to be considered as the foundation for proper spine patient management underpin the design and delivery of the Curriculum: Stability, Alignment, Biology, Function.[1,2]

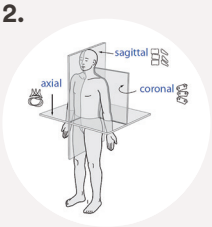
AO Principles[1,2]

1.

Stability

Stabilization to achieve a specific therapeutic outcome.

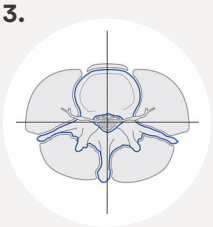
2.



Alignment

Balancing the spine in three dimensions.

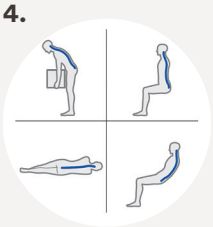
3.



Biology

Etiology, pathogenesis, neural protection, and tissue healing.

4.



Function

Preservations and restoration of function to prevent disability.

Preoperative Planning

In addition to routine preoperative investigations (X-rays A/P and lateral; MRI), flexion/extension views are strongly recommended to assess for gross translational instability that would require a fusion procedure instead.

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.

▲ Precautions:

- 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.

Patient Positioning

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

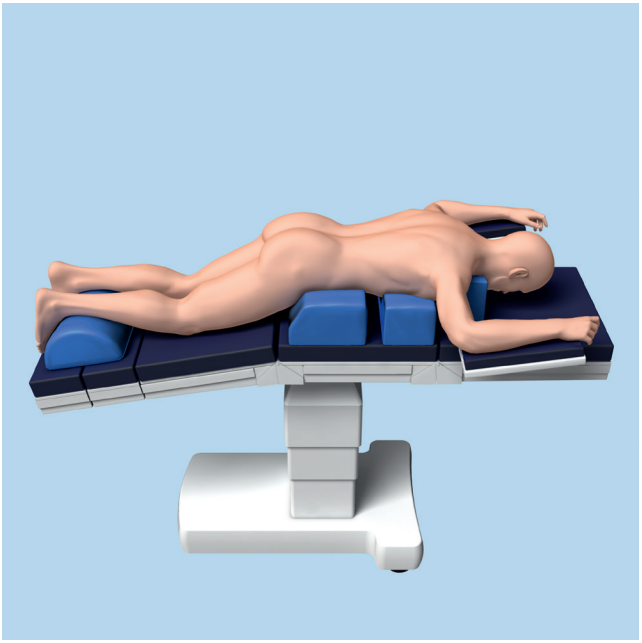
- Prone position with tilted pelvis
- Knee-chest position

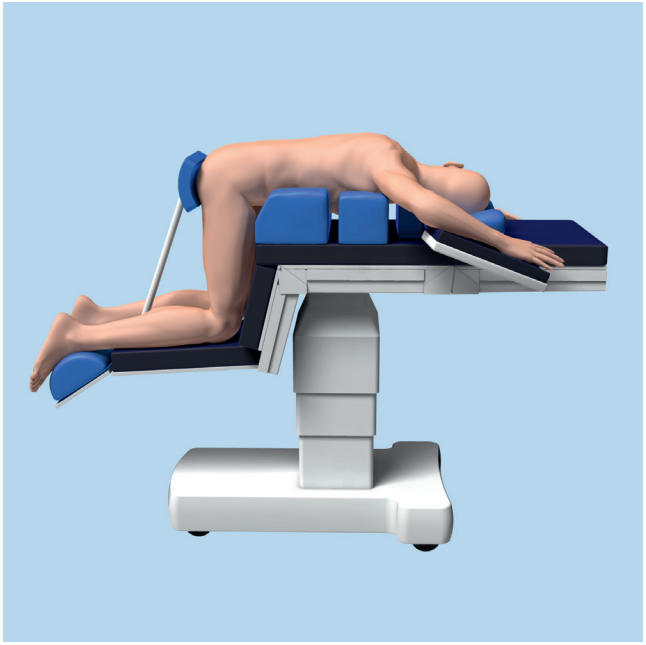
A neutral position of physiological lumbar lordosis should be achieved, so that the interspinous space is naturally distracted.

- **Intraoperative A/P fluoroscopy images cannot be recorded with the patient in the knee-chestposition.**

▲ Precaution:

- **Do not force the segment into an unphysiological kyphosis. While positioning the patient, check the position of the endplates.**





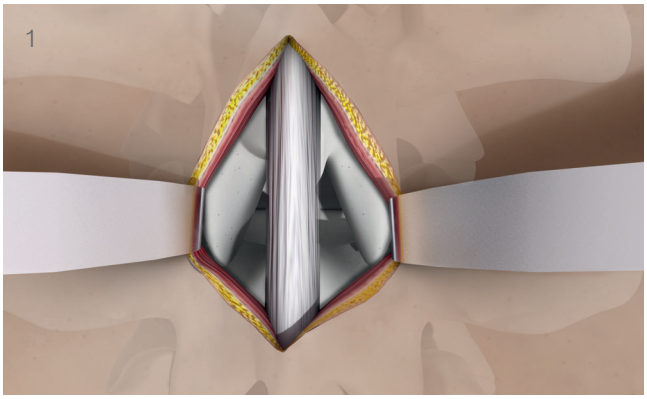
Single-Level Implantation

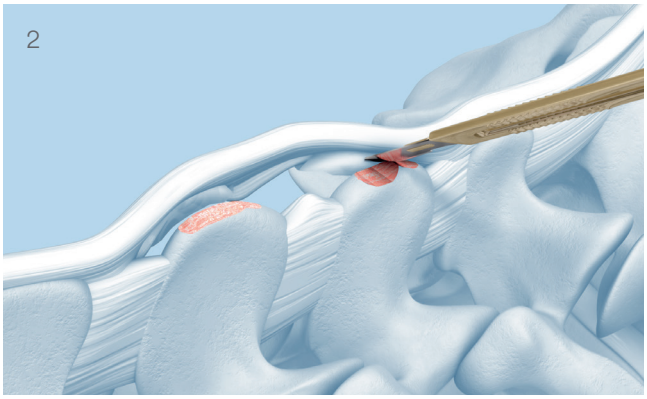
1. Approach

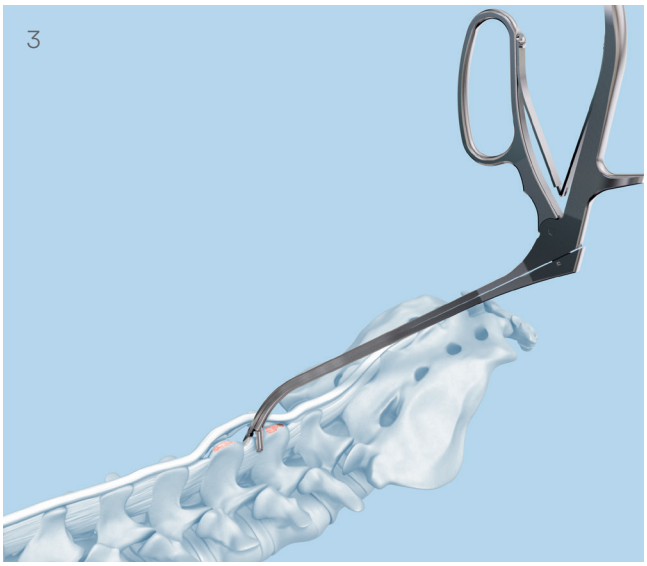
Perform a routine midline skin incision of approximately 4 to 6 cm. Dissect the paraspinal muscles lateral to the supraspinous ligament. Strip them off the spinous processes and laminae. (1)

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)



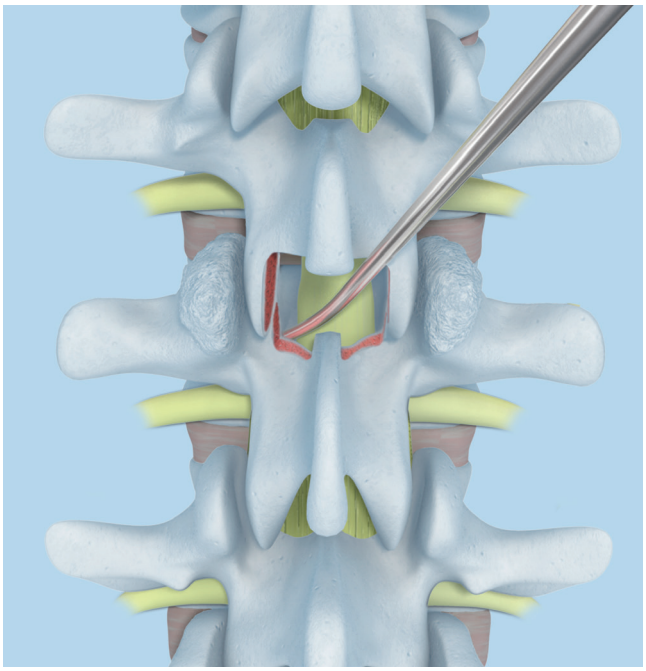




2. Microsurgical decompression

Resect the ligamentum flavum to gain access to the spinal canal and perform the microsurgical decompression according to the patient's specific problem.

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



▲ Warning:

- 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

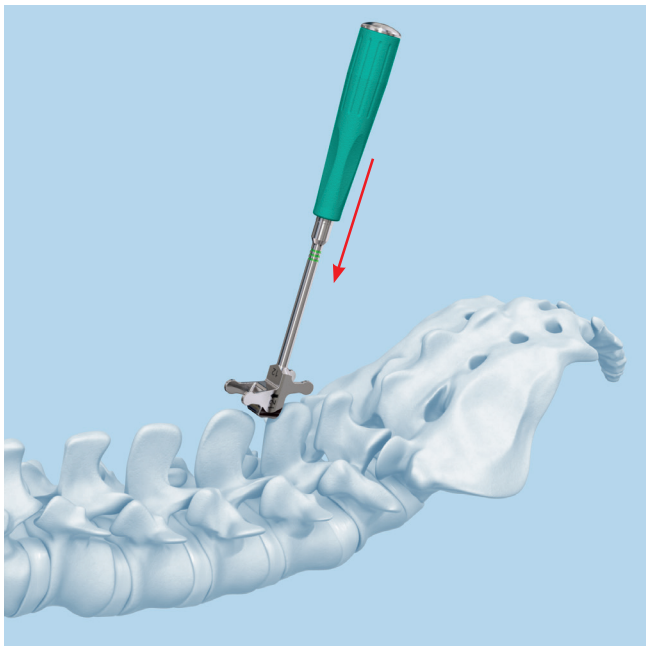
Instruments	
03.630.508	STENOFIX – Trial Implant, size 8 mm
03.630.510	STENOFIX – Trial Implant, size 10 mm
03.630.512	STENOFIX – Trial Implant, size 12 mm
03.630.514	STENOFIX – Trial Implant, size 14 mm
03.630.516	STENOFIX – Trial Implant, size 16 mm
03.630.522	STENOFIX – Hammer

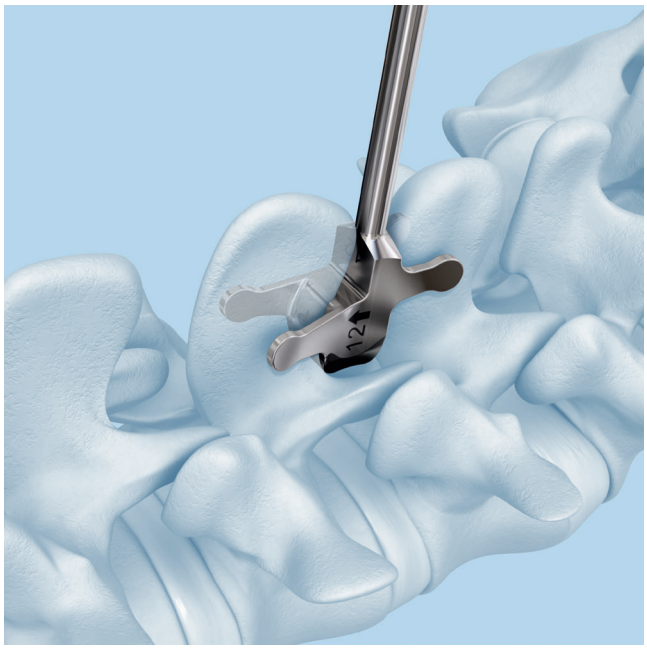
Use the series of Trial Implants graduated in 2 mm increments to define the appropriate Implant size. For gentle mobilization of the segment, it is advisable to perform sequential distraction of the interspinous space, starting with the smallest Trial Implant.

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.





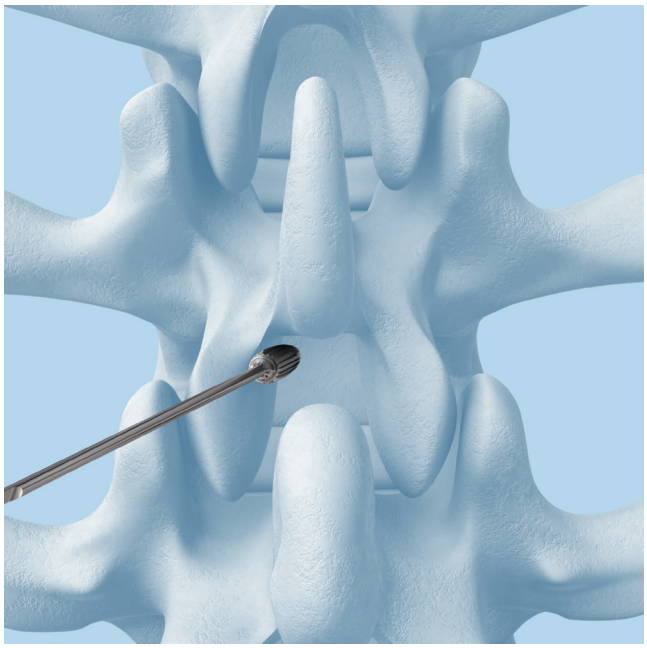
▲ Warning:

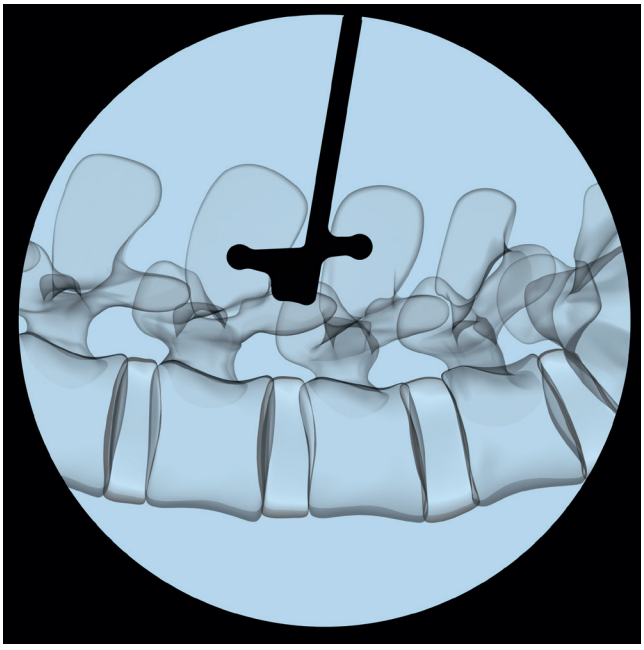
- **Extreme care should be taken to avoid any injury of the spinous processes and the thecal sac by heavy hammering.**

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.

Under lateral fluoroscopy, verify the anterior positioning of the Trial Implant.

- **In general, avoid excessive distraction, as this may lead to a loss of physiological lordosis. 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.**





Prepare the Implant Holder

Instrument	
03.630.525	STENOFIX Implant Holder

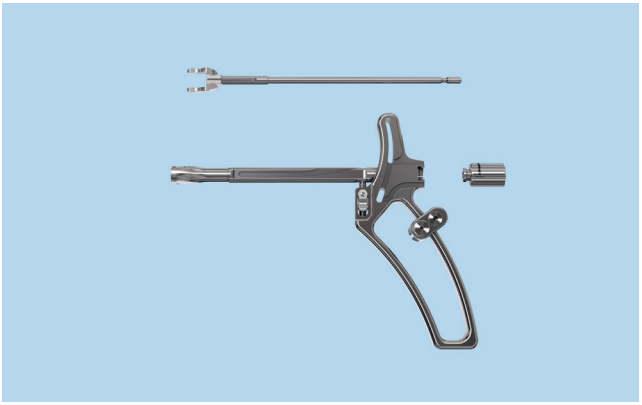
The Implant Holder must be assembled prior to insertion of STENOFIX.

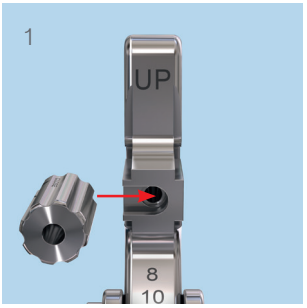
Slide in the Implant Holder knob into the slot at the proximal end of the Implant Holder. (1)

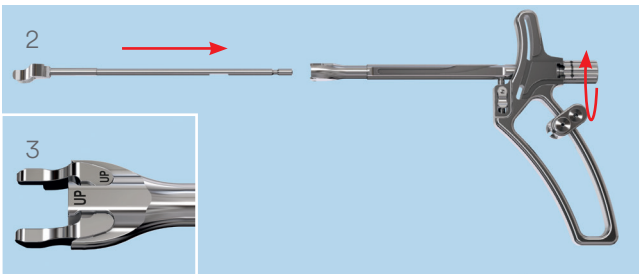
Insert the shaft (2) of the Implant Holder completely into the holder. Make sure that the laser etching “UP” on the shaft (3) and Implant Holder face the same direction.

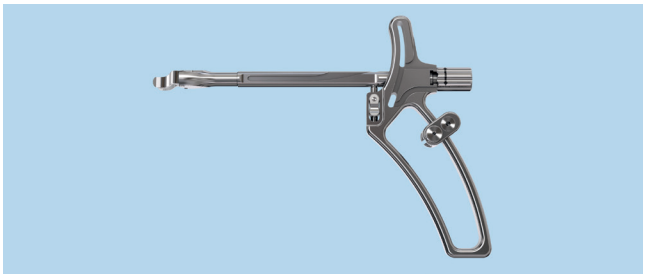
While lightly pressing the shaft into the Implant Holder turn the knob clockwise to fully seat the shaft into the Implant Holder. Then turn the knob counter-clockwise until it stops. At this position, the Implant Holder is ready for loading the Implant.

- **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	
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 (68.630.500.02). The laser-etched “UP” on the Implant must match the direction of the laser-etched “UP” on the Loading Station.

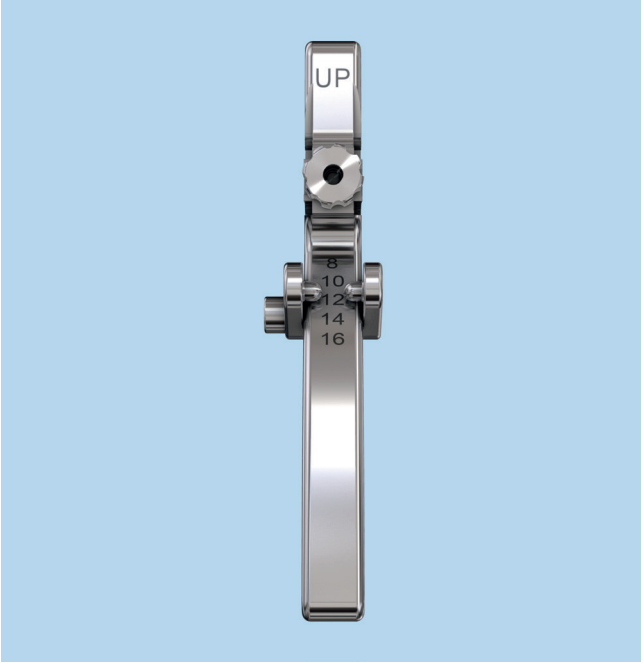
- **Before attaching the Implant to the Implant Holder make sure that the Implant Holder is ready for loading the Implant. See the section titled Prepare the Implant Holder for detailed instruction.**

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

Use a Ball Tipped 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.

▲ Precaution:

- **Do not open the wings or bend them back and forth as over-manipulation can weaken the wings of the Implant.**

5. Fix Implant

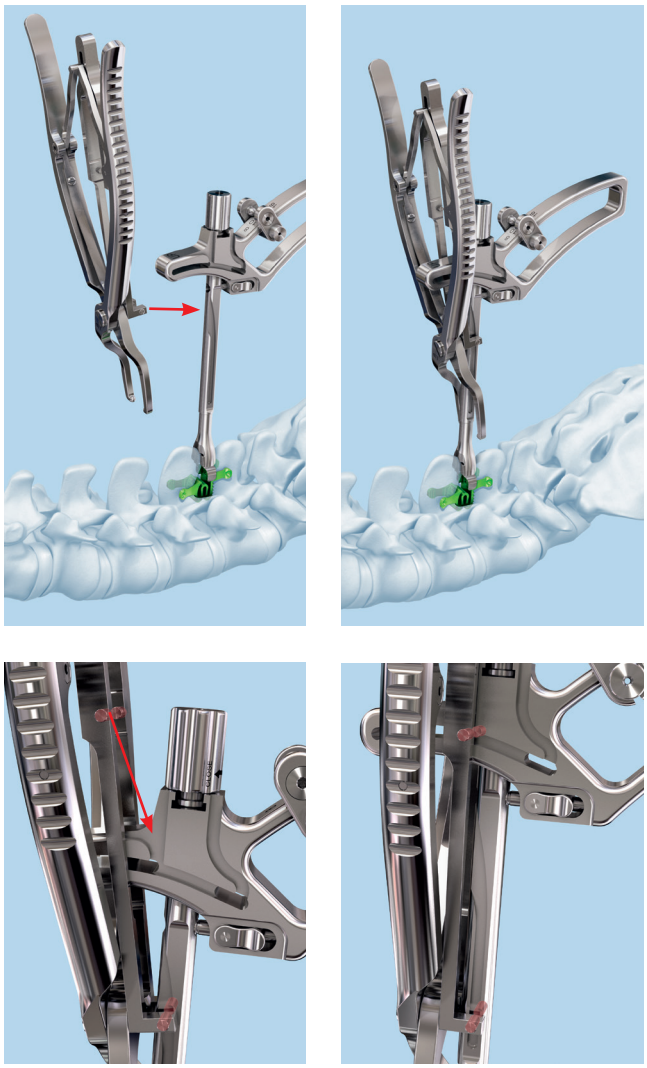
Instruments	
03.630.525	STENOFIX Implant Holder
03.630.526	STENOFIX Crimper

The STENOFIX Crimper needs to be attached to the Implant Holder for proper crimping.

▲ Warning

- **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 migrating. The ball tip of the Crimper jaws must mate with the wing socket.

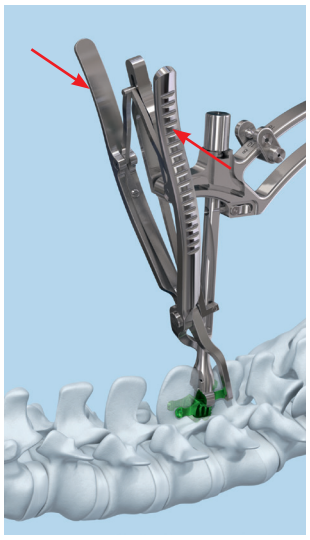
- **To ensure that the ball tips of the Crimper seat properly in the sockets, when crimping the cranial wings, the Crimper must contact the slider.**
- **Due to anatomical variations among patients, crimping of the wings may not be fully symmetrical.**

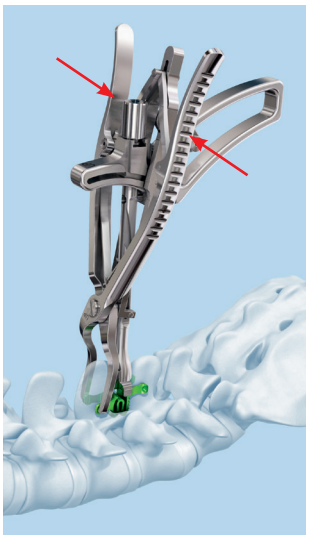
Lift the Crimper up and away from the Implant Holder. Turn the knob counter-clockwise until it stops. Now the Implant Holder can be disengaged from the Implant. Remove the Implant Holder.

Reattach the supraspinous ligament to the spinous processes by suturing.

▲ Warnings:

- **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.**

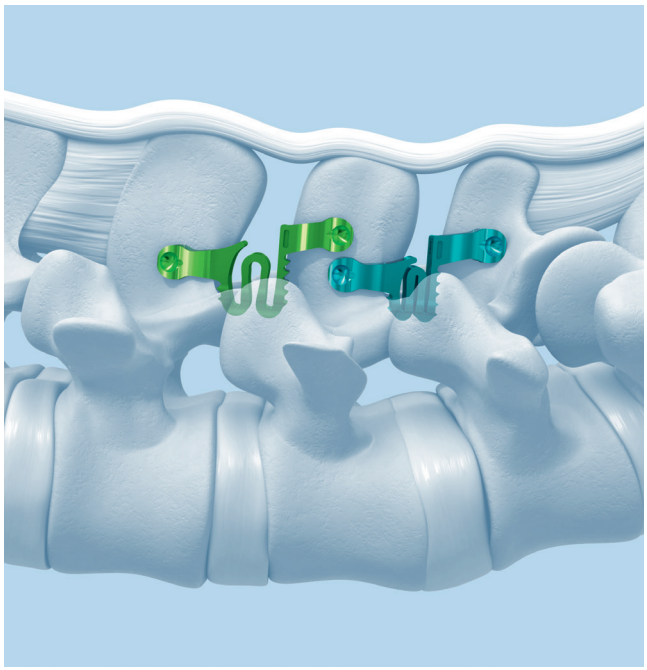




Double-Level Implantation

▲ Warnings

- If two implants are placed at adjacent levels, a specific implantation sequence must be followed in order to produce the desired 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.
- STENOFIX can be implanted at a maximum of two levels.



Implant Removal

The STENOFIX Implant is intended for permanent implantation and is not intended for removal. Any decision to remove the device must be made by the Surgeon and the patient taking into consideration the patient's general medical condition and the potential risk to the patient of a second surgical procedure.

If a STENOFIX Implant has to be removed the following technique is recommended:

- Prepare the Implant Holder Instrument according instruction on page 12.
- 03.630.525 STENOFIX Implant Holder.
- The Implant Holder must be assembled prior to attachment of STENOFIX.
- Attach Implant Holder to STENOFIXx as described on page 13.
- Open the wing tips with an appropriate tool (generic surgical spreader or forceps).
- Remove the Implant.

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

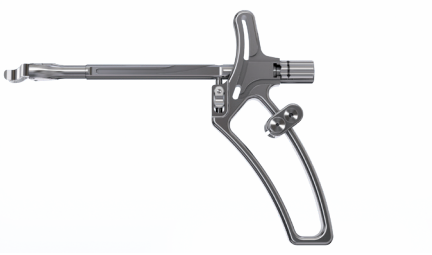
Instruments

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	

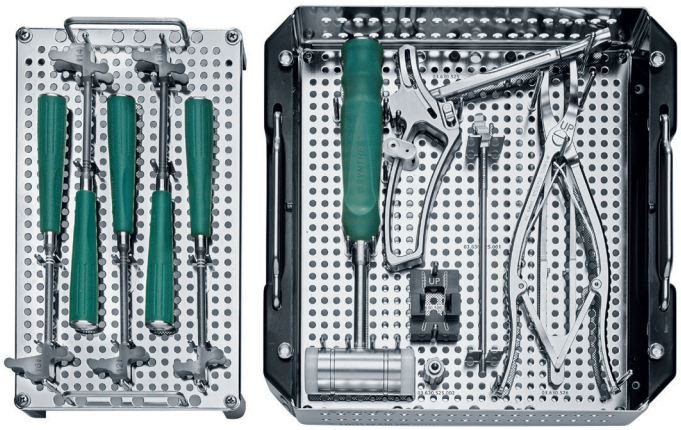


03.630.526	STENOFIX Crimper	

68.630.500.02	Loading Station for STENOFIX	

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.

Indications and Contraindications

Please refer to the corresponding Instructions for Use for specific information on Intended use, Indications, Contraindications, Warnings and Precautions, Potential Adverse Events, Undesirable Side Effects and Residual Risks. Instructions for Use are available at www.e-ifu.com and/or www.depuysynthes.com/ifu.

Bibliography

1. Aebi M, Thalgott JS, Webb JK (1998): AO ASIF Principles in Spine Surgery. Berlin: Springer.
2. Aebi M, Arlet V, Webb JK (2007) AOSPINE Manual (2 vols), Stuttgart, New York: Thieme.

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