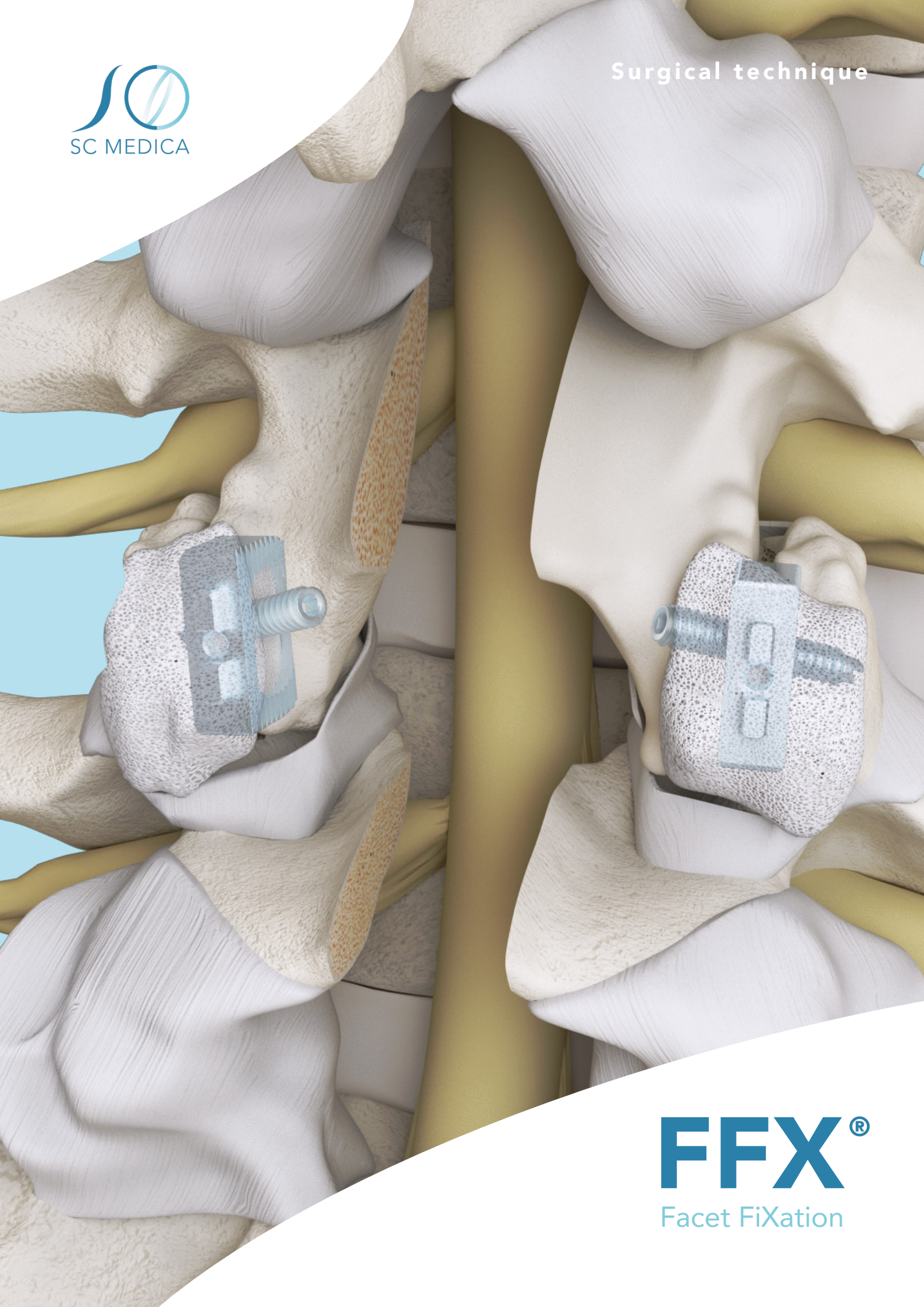
SC MEDICA

Surgical technique



FFX®

Facet FiXation

FFX®

Facet FiXation

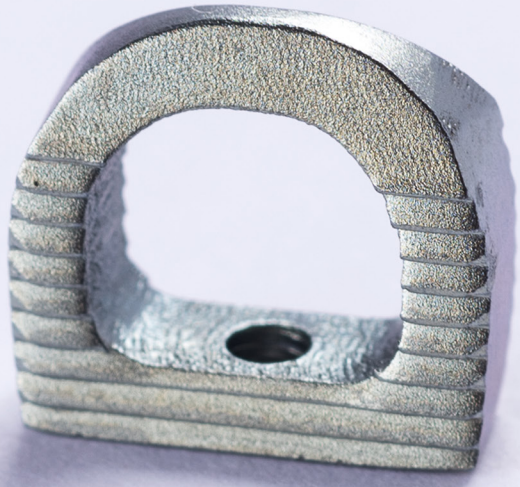
WARNING

This description alone is insufficient for immediate use of the instrumentation. Attending an introductory course on the use of this instrumentation, provided by an experienced surgeon, is highly recommended.

Instrument care and maintenance:
For general instructions, functional verification and how to disassemble multi-part instruments, contact SC MEDICA:
info@sc-medica.com

For all product-related information, including indications, contraindications, warnings, precautions, side-effects and complications, refer to the instructions provided with each implant.

SC MEDICA does not practice medicine. This surgical technique was developed in cooperation with health professionals. This document is exclusively for use by health professionals.



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FFX®: An elegant solution for facet arthrodesis

FFX® offers an alternative to standard posterior fixation systems for adult patients. The system is used to treat facet joint low back pain and prevent spinal instability after decompression by an arthrodesis of the lumbar facet joint.

FFX® system is a complete set of instruments and cages developed for posterior lumbar spine surgery.

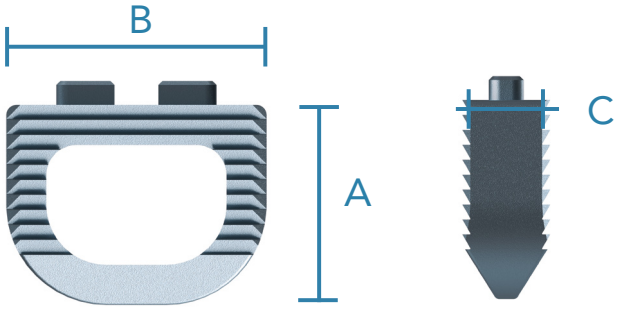
The **FFX®** cages are designed to maximize facet fusion opportunities, achieve a more anatomical distribution of the mechanical constraints that protects adjacent levels and ensures lumbar segmental stability.

List of references

FFX® cages are made of titanium (Ti-6Al-4V, ISO 5832-3), a highly osteoconductive material that promotes facet joint fusion by generating a bone bridge.

The choice of the size of the **FFX®** cage to use depends on the patient's anatomy.

Reference	A (mm)	B (mm)	C (mm)	Color
57.000.10S	10	11	2.5	Gold
57.000.20S	10	13	2.5	Dark blue
57.000.30S	10	11	3	Green
57.000.40S	10	13	3	Light blue
57.000.50S	10	11	3.5	Brown
57.000.60S	10	13	3.5	Purple



Surgical indications

FFX® cages are intended for the treatment of the following conditions:

- Degenerative lumbar spinal stenosis
- Facet syndromes (primary or secondary)

Intended use:

FFX® cages prevent spinal instability and facet motion by enabling lumbar facet joint arthrodesis consecutive to the surgical treatment of degenerative lumbar spinal stenosis or facet syndrome.

The use of FFX® cages is contraindicated in the following situations:

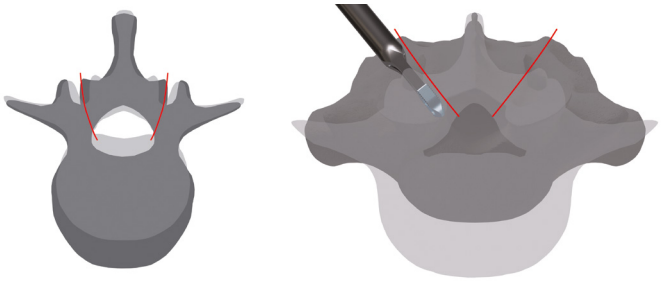
- Severe or chronic infections, local or systemic
- Sensitivity to materials
- Bone destruction or demineralization potentially affecting the fixation of the cage
- Severe muscular, neurological, or vascular deficiencies affecting the limb in question
- Any infection that could compromise the function of the cage
- Morbid obesity of the patient
- Psychiatric background
- Osteoporosis (BMD < 120 mg/cm3)
- Major spine instability (spondylolisthesis ≥ grade II)
- Fracture of the spine, isthmic lysis
- Important scoliotic deformities (>25°)
- More than 3 vertebral levels concerned
- Spondylodiscitis or spine tumor
- Wide resection of facet joints during the surgery
- Unilateral application of the cages

Surgical technique

FFX® cages, screws and bone substitutes are supplied sterile and individually packaged.

1. Preoperative imaging

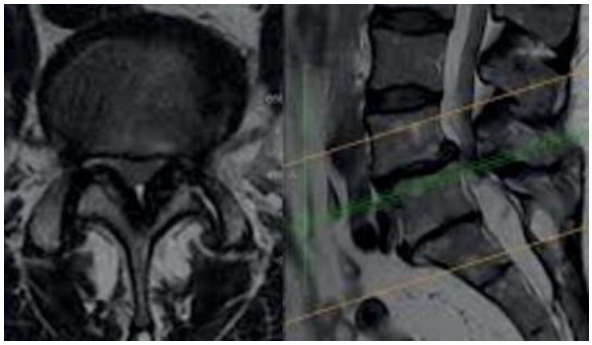
The orientation of the facet joints varies depending on the level to be instrumented.



L1 - L2 L5 - S1

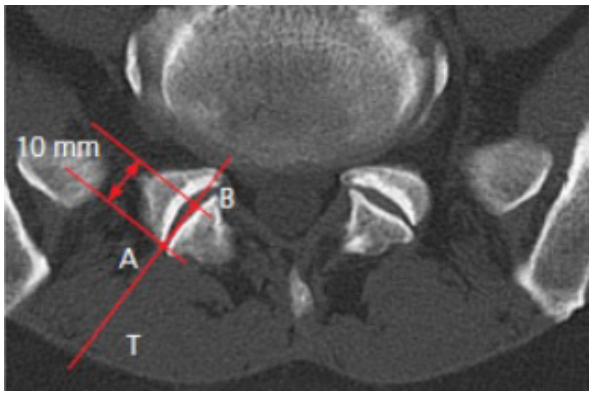
2. Surgical planning

Identify the facet joint and joint space entrance on axial images. This will guide you in choosing the size of the **FFX®** cage.

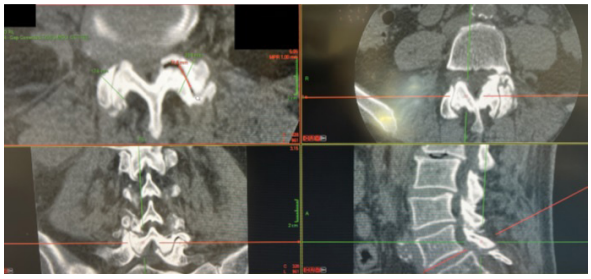


Visualize the level of the procedure in transverse view to assess the orientation of the facet joint and shape, as well as obstructive structures (osteophytes, pelvis...).

To define the correct trajectory (T) of the **FFX®** cages and instruments, identify the entrance to the facet joint (A) and the joint space to a depth of 10 mm (B) on axial images (CT or MRI).



The 10 mm length is the length of the **FFX®** cage inserted into the facet joint.



3. Position and approach

FFX® cages are designed to be inserted through a standard posterior approach to the spine. The patient is placed in the genupectoral or ventral decubitus position.

4. Incision

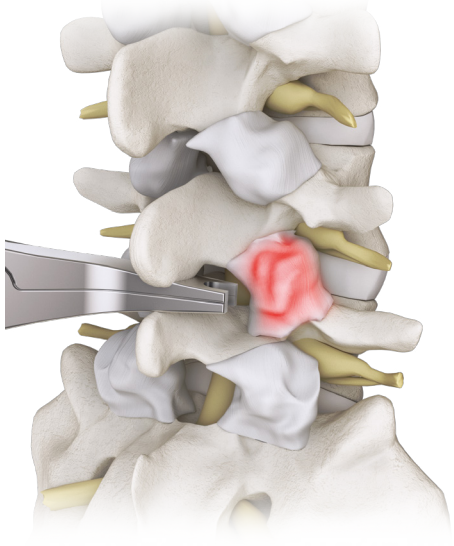
Make a middle sagittal incision with respect to the lumbar canal narrowness after fluoroscopic check.

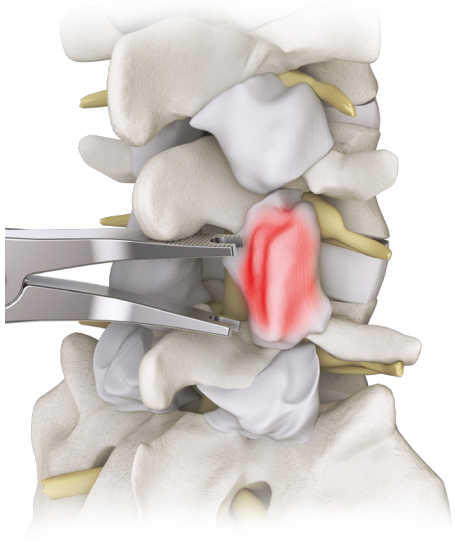
5. Tracking the articular line

Perform an intermyolamar detachment and locate the facet joints, left and right.

Mobilize the segment with the interlamar distractor to visually identify the facet joint space, left and right. The shearing motion of the distractor will help identify the facet joint space.

Tip: Place the interlamar distractor as close to the yellow ligament as possible to avoid breakage of the spinous processes.

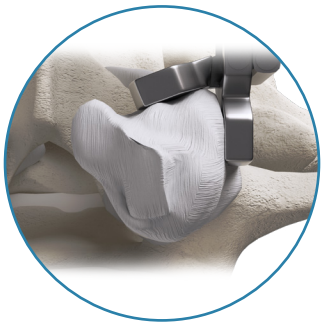


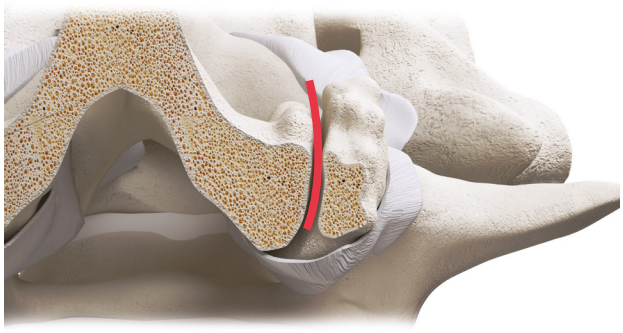


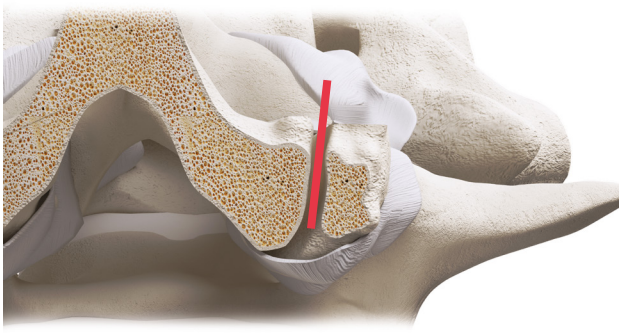
6. Resection of osteophytes

Uncap and remove osteophytes with Gouge forceps.

This step will help identify the actual articular line and help make it straighter, in accordance with the shape of the **FFX®** cage.





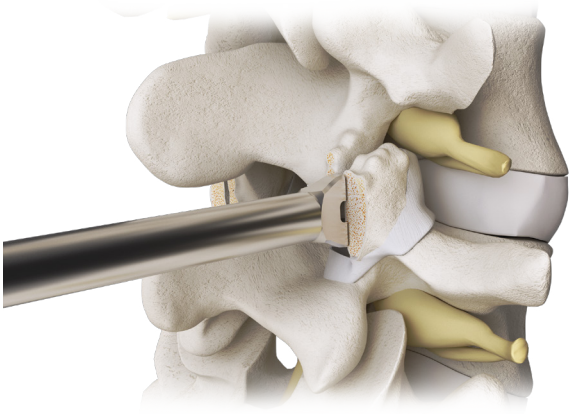


Caution: Avoid weakening the articular process when removing osteophytes.

7. Preparation of the facet joint

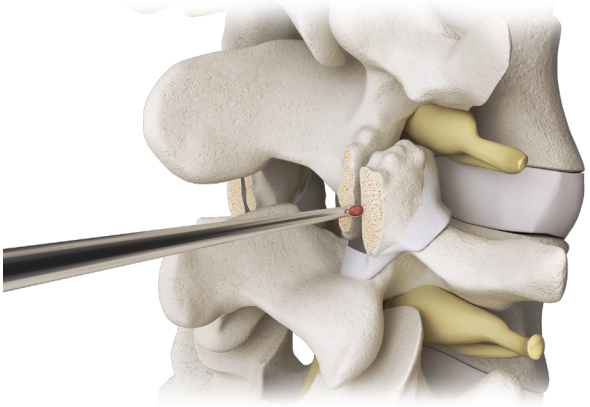
Open the facet joint space with the chisel.
Revive the facet space with the rasp until cancellous bone is reached. This step prepares for a future successful fusion of the joint.

Important: After using the rasp, use the curette to remove residual cartilage in the joint space and optimize the chances of fusion.



Facet chisel
57.002.00T

Rasp
57.003.00T



Curette
57.006.24

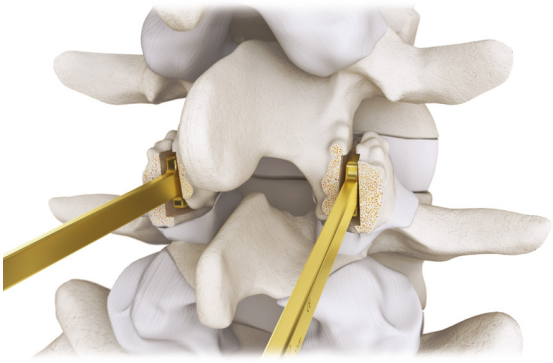
8. Choice of FFX® cages

Insert the narrowest trial implant (C=2.5 mm, gold color), simultaneously into the left and right facets. Simultaneous insertion ensures that the facet on the opposite side is not closed.

If the trial size does not sufficiently grip in the joint space, repeat the trial with the thicker model (C=3mm, green color).

Select the **FFX®** cage with the same thickness as the trial implant tested. If none provided sufficient grip, select the **FFX®** cage with the maximum thickness (C=3.5mm).
The **FFX®** cage width is chosen by comparison with the trial implants, all of which were B=11mm wide. If this width seems insufficient, select a wider **FFX®** cage (B=13mm).

Reminder: There are three FFX® cage thicknesses (C=2.5mm, 3mm, 3.5mm), two widths (B=11mm, 13mm) and only one depth (A=10mm), corresponding to a choice from a total of 6 references.

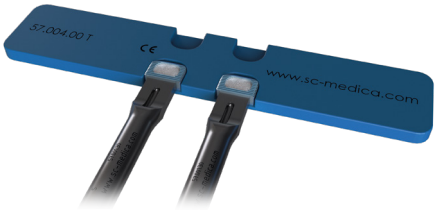


Trial implant FFX® 11 x 2.5
TRIAL- 57.000.10

Trial implant FFX® 11x3
TRIAL- 57.000.30

9. Graft insertion

Mount the **FFX®** cage on the implant holder.
Place the **FFX®** cage on the graft holder.
Insert the chosen filling material (bone graft or bone substitute) into the cavity of the **FFX®** cage.



Graft holder
57.004.00

Implant holder
57.001.30N

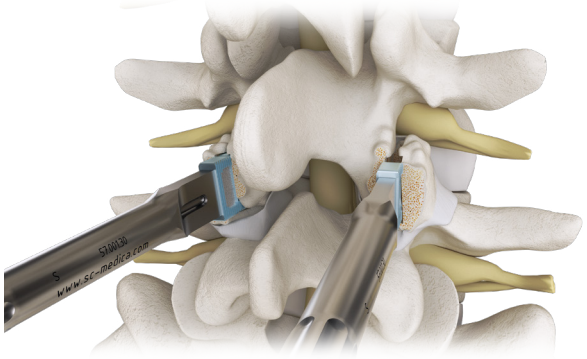
Use two implant holders, two FFX® cages per level.

10. Insertion of FFX® cages

Simultaneously insert the **FFX®** cages mounted on their implant holders halfway into the joint space on the right and left sides.

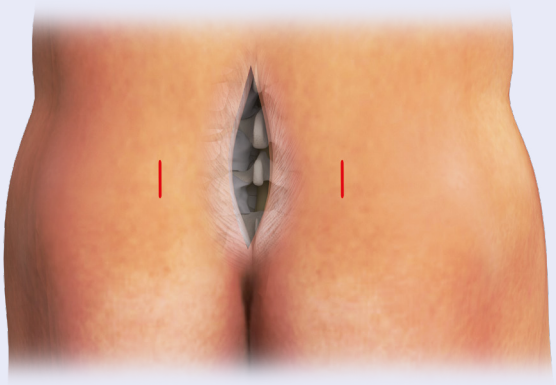
Remove the implant holders by carefully unscrewing them.

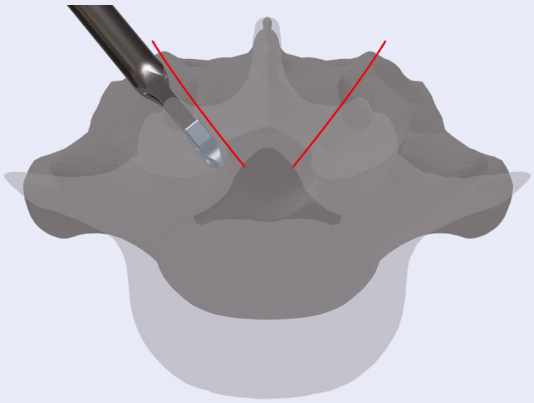
Important: Simultaneous insertion of FFX® cages avoids closure of the facet on the opposite side.



Particularities of the facet orientation of the L5-S1 level:

The orientation of the L5-S1 facet joints is horizontal in the axial plane.
Tip: If necessary, make two lateral counter-incisions to insert FFX® cages at the L5-S1 level. Alternatively, insert FFX® cages «bottom-up» (not laterally), orienting the FFX® cages along an axis parallel to the spine.





L5 - S1

11. Impaction of FFX® cages

With the impactor, push the **FFX®** cages up to 2mm below the surface of the articular mass.

Impactor
57.001.20N

12. Lumbar decompression

Perform a laminectomy and canal recalibration according to the usual technique.

Important: Decompression must be performed AFTER the FFX® cage placement, in order not to weaken the facet joints before FFX® cage placement.

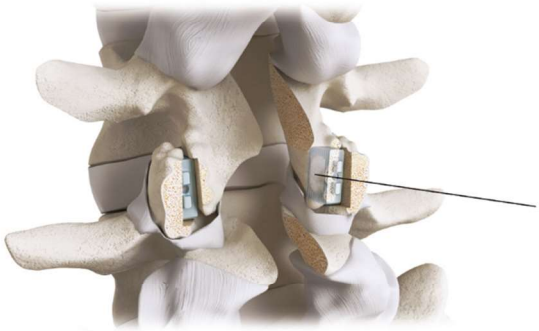
13. Preparation for facet screw fixation

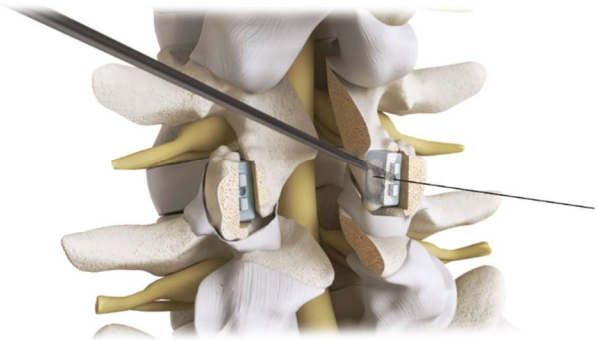
In order to ensure the successful insertion of the facet screw, it is recommended to:

1. Insert a pin (or equivalent) into the posterior fixation hole of the **FFX®** cage. This will allow visualization of the targeting axis of the facet screw

2. By projecting the axis of the pin, make a pre-hole in the IN-OUT direction with a bone awl (not provided) on the lower articular facet of the overlying vertebra, aiming at the central part of the **FFX®** cage.

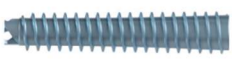
3. Using the drill bit provided, make a hole in the targeting axis.





Tip: During drilling, a feeling of crossing the two cortices of the first facet (lower facet of overlying vertebra), the center of the FFX® cage (filled with graft) and the first cortical of the second facet (upper facet of underlying vertebra) makes it possible to define the depth of drilling.

Drill bit
M004537
M004536

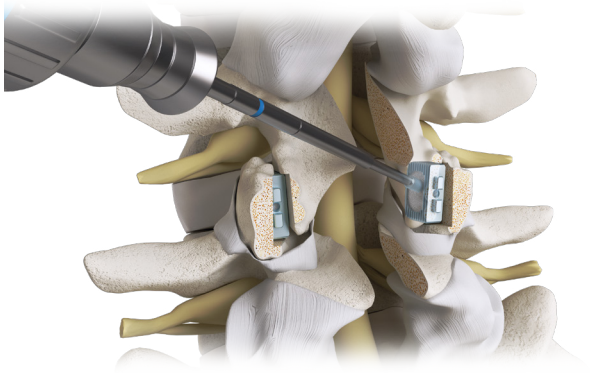


Facet screw

14. Insertion of self-compressing facet screw

Insert the self-compressing facet screw with the screwdriver supplied until the screw head is embedded in the articular mass, in the previously prepared axis.

Important: The self-compressing facet screw brings the facet joints closer together around the FFX® cage, which increases its primary anchorage and promotes bone fusion.

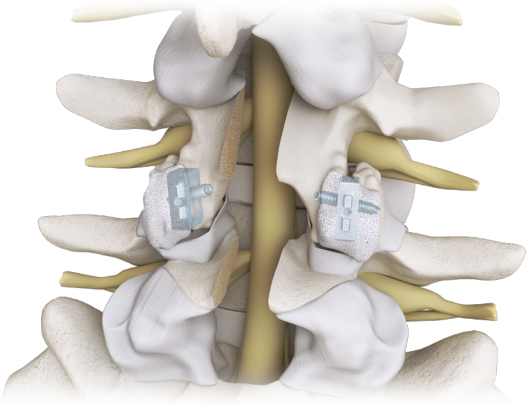


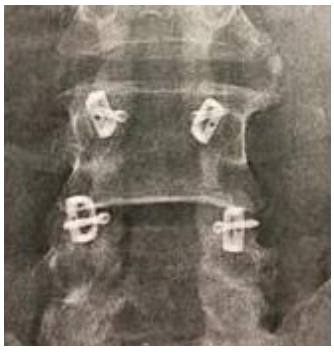
Screwdriver
HT-1120
HT-1725

15. Grafting and closure

Add graft (bone or bone substitute) posterior to the **FFX®** cage.

Close according to the usual technique.





Revision

If **FFX®** cages need to be removed during a revision surgery, please follow these steps:

- Make a direct posterior approach to the **FFX®** cages.
- Release the **FFX®** cage from the surrounding fused tissue and bones.
- Remove the **FFX®** cage axially and carefully.
- Perform a verification X-ray.

FFX® Facet FiXation

Reference	Designation	Quantity	Picture	Material
ANC.FFX	Tray with rails and engraved label	1		Stainless steel
TRIAL- 57.000.10	Trial implant FFX® 11x2.5	2		Titanium
TRIAL- 57.000.30	Trial implant FFX® 11x3	2		Titanium
57.001.20N	Impactor	1		Stainless steel
57.001.30N	Implant holder	2		Stainless steel
57.002.00T	Facet chisel	1		Stainless steel + Titanium
57.003.00T	Rasp	1		Stainless steel + Titanium
57.004.00	Graft holder	1		Titanium
57.006.24	Curette	1		Stainless steel
57.006.26	Interlaminar distractor	1		Stainless steel
57.008.00	Mallet	1		Stainless steel + Titanium
HT-1120 HT-1725	Screwdriver	1		Stainless steel + Silicone
M004537 M004536	Drill bit	1		Stainless steel

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