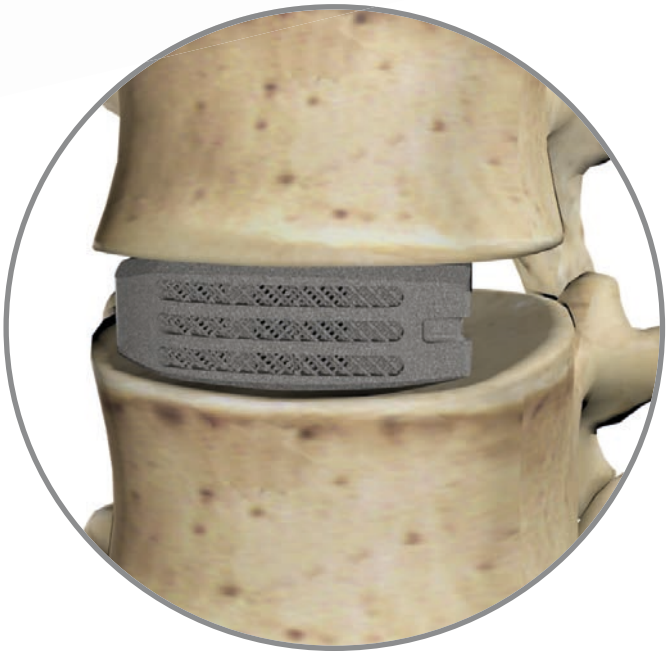
# Surgical technique

ti²b International
titanium 2 bone

## dolfyn® TLIF device
## transforaminal lumbar interbody fusion



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# General information / features and benefits

The dolfyn® device is a sterile provided intervertebral body fusion implant and has been developed for single or multi-level lumbar and/or lumbosacral intervertebral body fusion. The implant is intended for insertion between two adjacent vertebrae. The cages restore and maintain intervertebral height of the spinal segment and facilitate osteosynthesis in combination with auto-graft and a posterior rod and screw system or, if applicable, in combination with an anterior plate. The devices are used in a standard operating room environment by trained orthopedists and neurosurgeons.

Material: Ti6Al4V ELI
Manufacturing: SLM - Selective Laser Melting

Features/Design

1. Bi-convex-shaped implant is designed to fit patient's anatomy and to allow more accurate sizing.
2. Self-guiding, bulleted tip.
3. Homogenous interface between implant and endplates.
4. Spikes on the surface reduce risk of micro motion.
5. Safe lateral insertion without compromising nerve structures.
6. Straight forward surgical procedure.
7. 2 lengths, 5 heights assures an optimal patient adapted fit.

Manufactured for:

ti²b International GmbH
Große Hub 3a
65344 Eltville am Rhein
Germany

This device is not suitable for a "standalone" procedure. Supplemental fixation is required.

# Indications for use

The indications for the dolfyn® and sharx® devices include:

- Degenerative Disc Disease (DDD) at one or two levels from L2 to S1 with a specific discogenic pain pattern. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies.

- DDD patients may also have up to grade 1 spondylolisthesis or retrolisthesis at the involved levels. These patients should be skeletally mature and have had six months of non-operative treatment.

- Instability of the anterior column in association with posterior pathology.

The dolfyn® and sharx® may be implanted via an open or a minimally invasive posterior, transforaminal, oblique, or lateral technique. These implants may be used with added bone graft.

The dolfyn® devices are intended to be implanted via transforaminal or lateral approach, singly for each level.

The sharx® devices are intended to be implanted via an oblique or posterior approach, singly or in pairs for each level.

The dolfyn® and sharx® devices are intended to be used with supplemental fixation.

# Contraindications

This device is not intended for cervical spine use. Contraindications include, but are not limited to:

- Infection near the operating area.
- Reduced bone quality (e.g. osteoporosis or bone decalcification).
- Spondylolisthesis unable to be reduced to Grade 1.
- Fever or leukocytosis.
- Morbid obesity.
- Mental illness.
- Fractures.
- Tumors.
- Active infection.
- Signs of local inflammation.
- Allergy to titanium or its alloys.
- Pregnancy.
- Suspected or documented allergy or intolerance to composite materials.
- Any patient unwilling to cooperate with postoperative instructions.

- Any case where requirements for successful results are not given.

- Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery.

- These devices must not be used for pediatric cases or for patients still in skeletal growth.

- Any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of segmentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.

- Prior fusion at the level(s) to be treated.

# Implant sizing

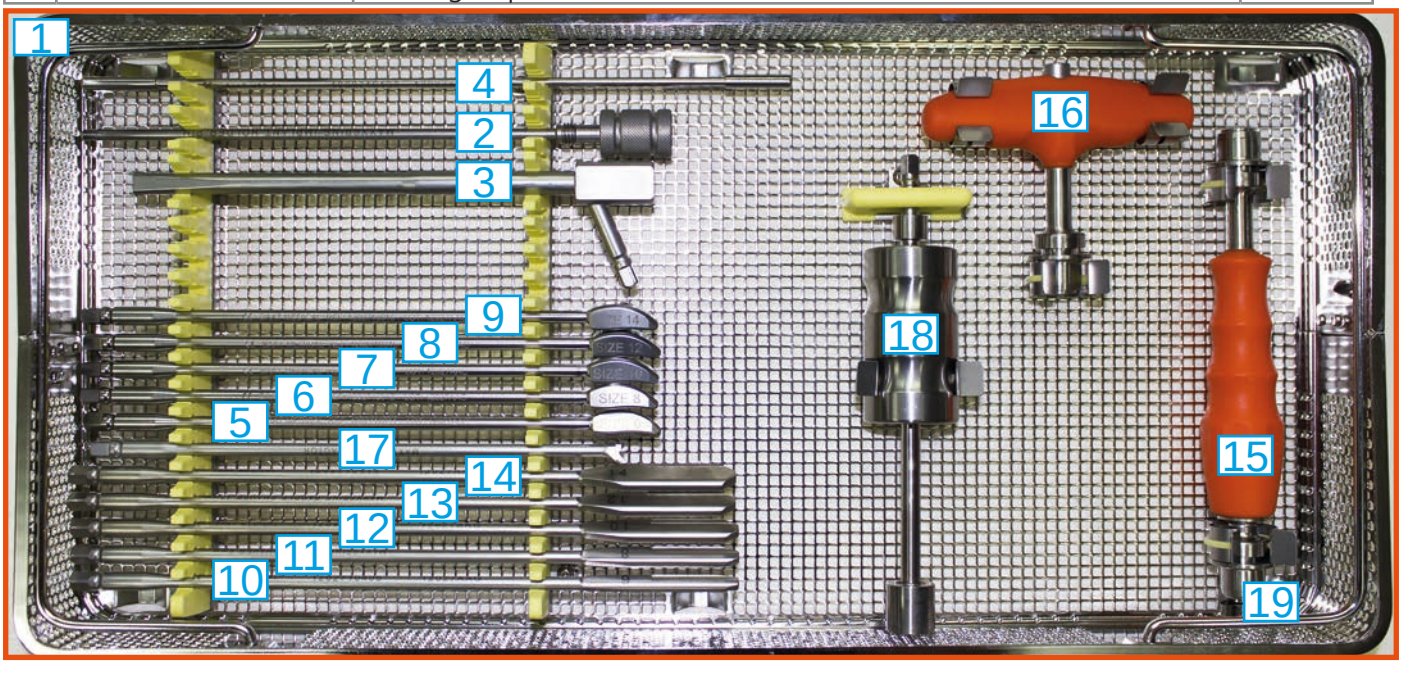
| Size | 6mm | 8mm | 10mm | 12mm | 14mm |
|---|---|---|---|---|---|
| length 28mm | BM-DTI2806 | BM-DTI2808 | BM-DTI2810 | BM-DTI2812 | BM-DTI2814 |
| length 32mm | BM-DTI3206 | BM-DTI3208 | BM-DTI3210 | BM-DTI3212 | BM-DTI3214 |

Height: 6/8/10/12/14mm

# Instruments features and overview

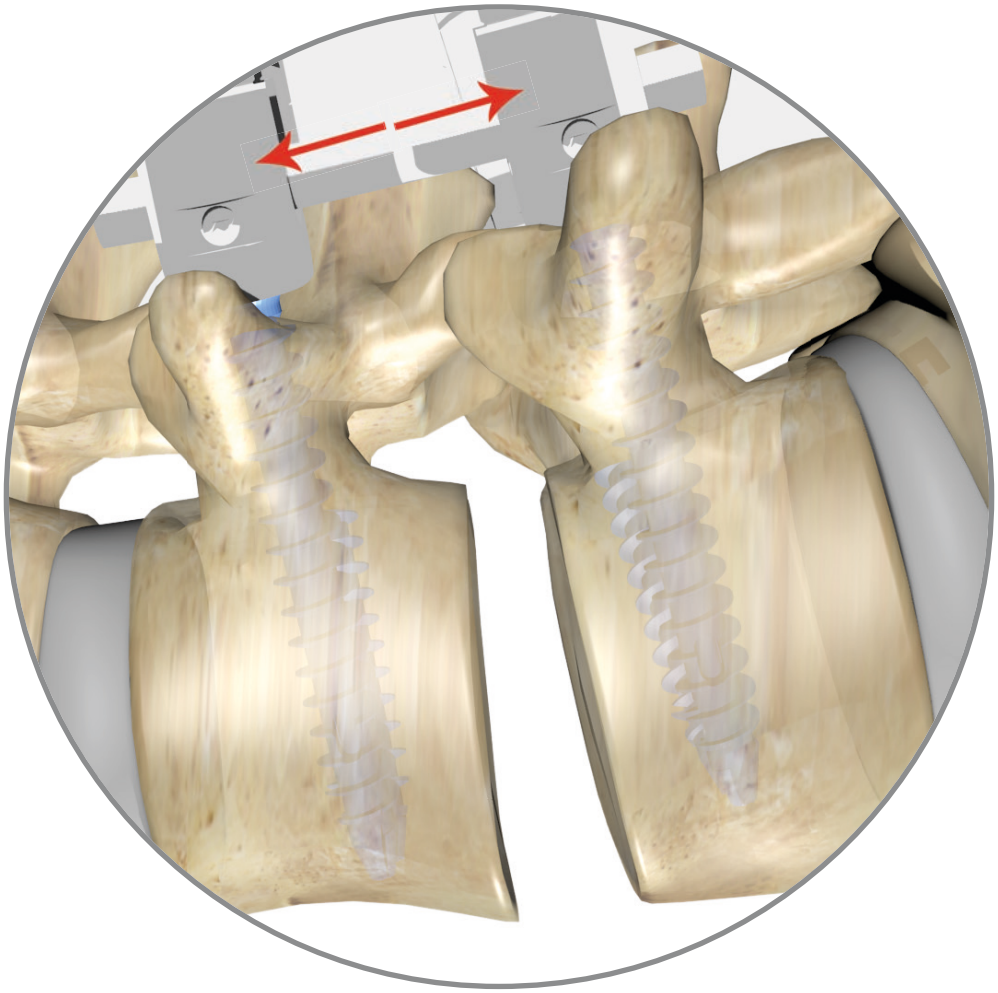
- Trials are designed with bullet-tip shape for self-guiding and easy insertion/extraction.
- Anatomical-shaped trials are designed to fit patient's anatomy and to allow more accurate sizing.

| # | Ref. | Description | Page |
|---|---|---|---|
| 1 | AE-JC223R | Tray 536x253x70mm | 7 |
| 2 | BM-1202710004A | Inner part with M5 thread implant holder sharx/dolfyn | 14-15 |
| 3 | BM-1202710004B | Outer part implant holder sharx/dolfyn | 14-15 |
| 4 | BM-1202710130 | sharx/dolfyn sizer 28/32 | 11 |
| 5 | BM-1202710011 | dolfyn Trial 6mm | 12 |
| 6 | BM-1202710012 | dolfyn Trial 8mm | 12 |
| 7 | BM-1202710014 | dolfyn Trial 10mm | 12 |
| 8 | BM-1202710015 | dolfyn Trial 12mm | 12 |
| 9 | BM-1202710016 | dolfyn Trial 14mm | 12 |
| 10 | BM-1202710406 | Paddle Shaver 6mm | 10 |
| 11 | BM-1202710408 | Paddle Shaver 8mm | 10 |
| 12 | BM-1202710410 | Paddle Shaver 10mm | 10 |
| 13 | BM-1202710412 | Paddle Shaver 12mm | 10 |
| 14 | BM-1202710414 | Paddle Shaver 14mm | 10 |
| 15 | WS15.975-RAL2004 | Silicon handle with 1/4" coupling, orange | 10-12 |
| 16 | WS16.075-RAL2004 | T-Handle with 1/4" coupling, orange | 10-12 |
| 17 | BM-1202710003 | dolfyn impactor | 16-17 |
| 18 | WS15.980 | Slap hammer | 12 |
| 19 | WS15.984 | Striking cap | |



# Distraction

When pedicle screws have been set, careful distraction should be initiated to achieve sufficient intervertebral space for discectomy.

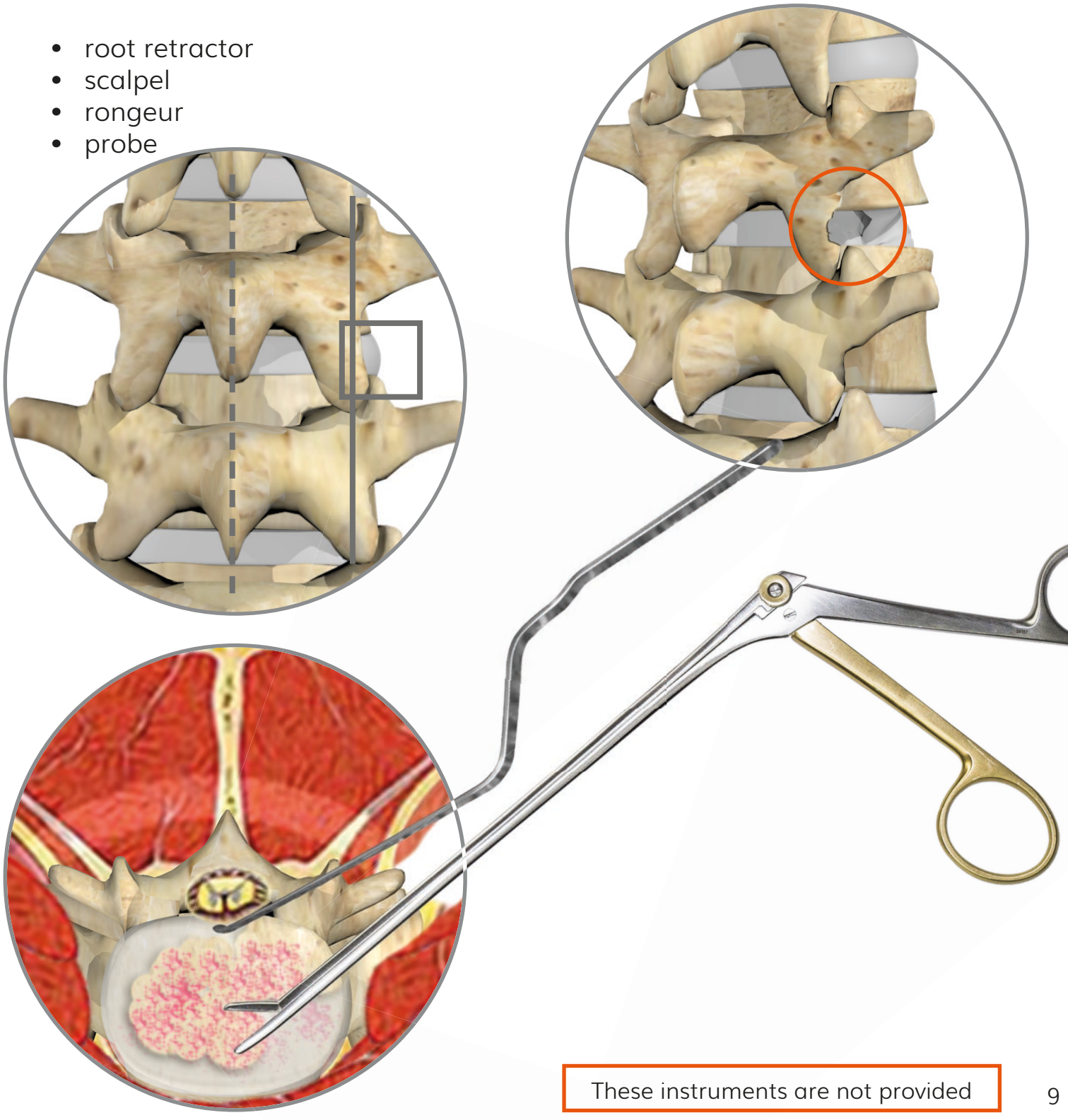


# Discectomy

Recommended instruments

- root retractor
- scalpel
- rongeur
- probe

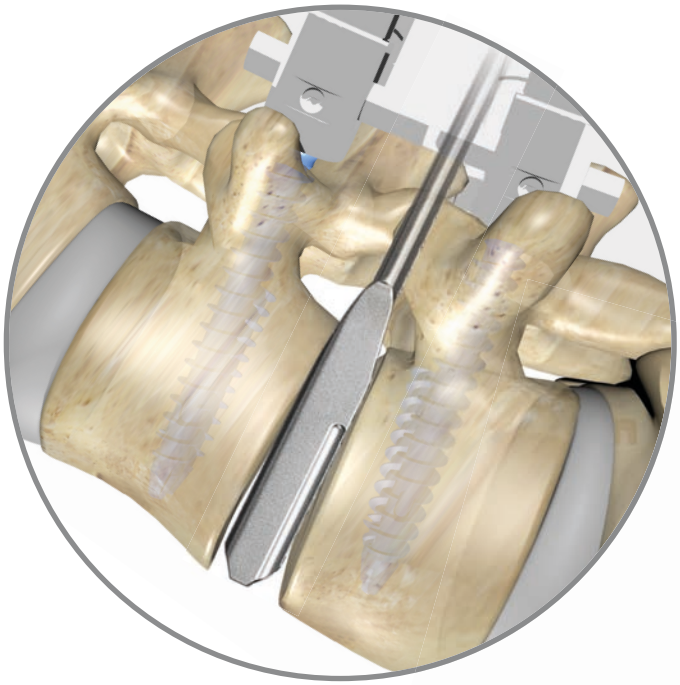
Remove disc by using the rongeur.

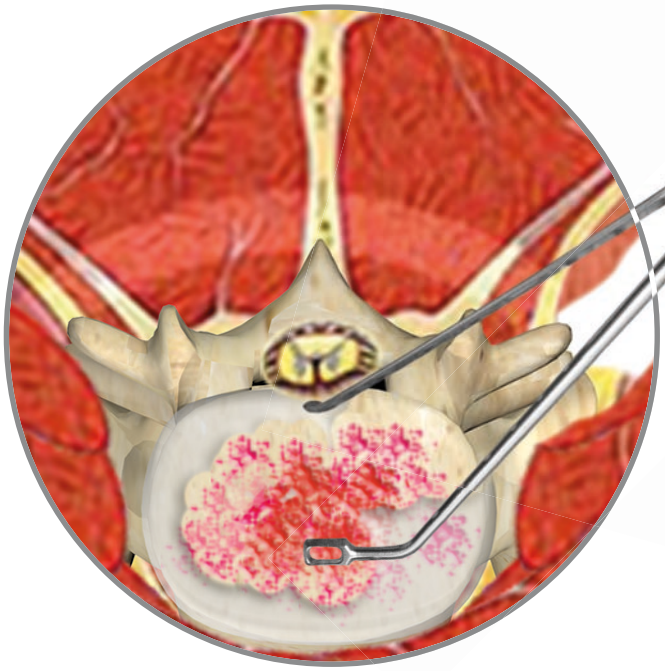


These instruments are not provided

# Curettage

- The remaining soft tissue or cartilaginous endplate should be removed with the paddle shaver and curette.
- The removal of soft tissue from the endplate surface allows joining of graft and  structure.

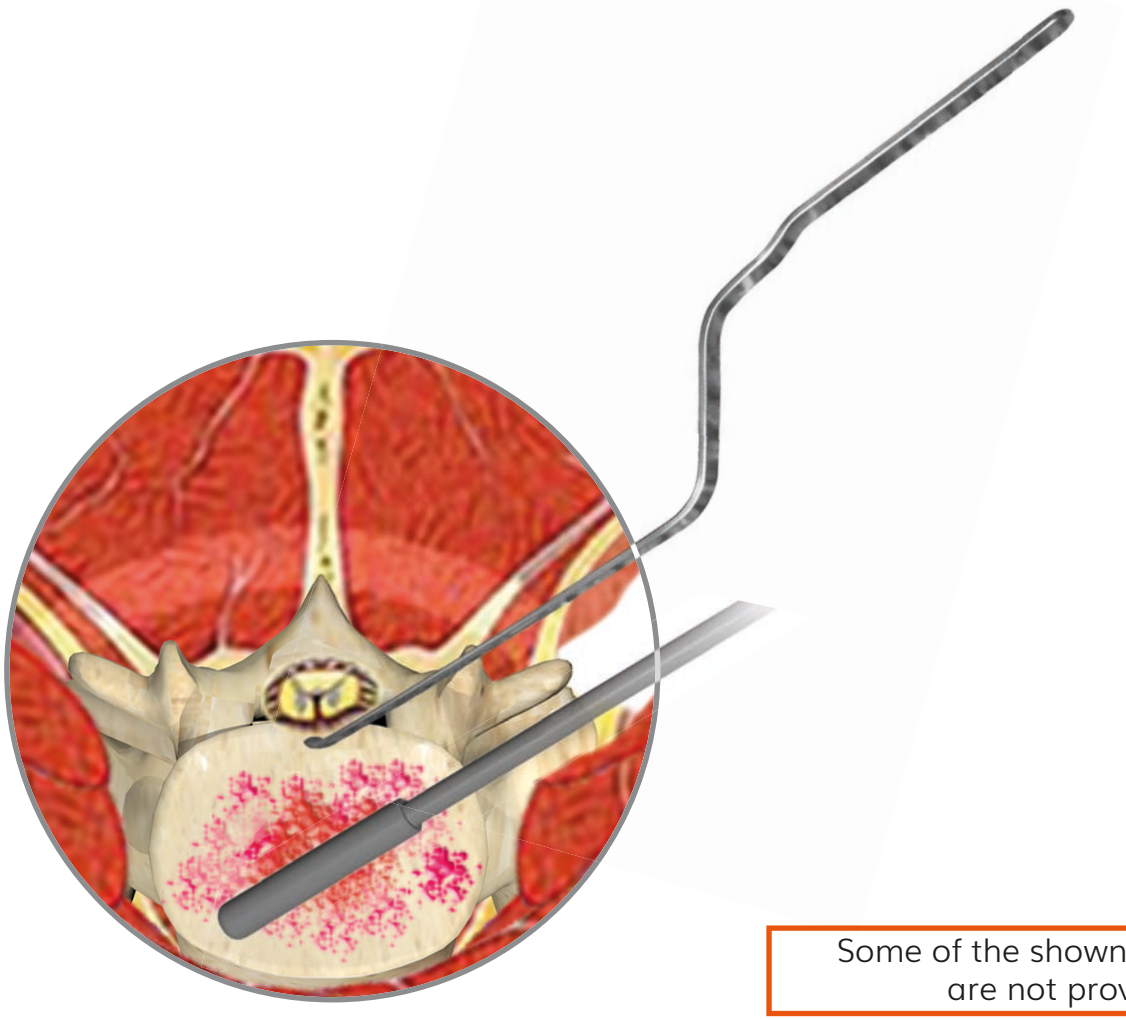




Some of the shown instruments are not provided!

# Sizer

- Sizer can help to verify the length of the implant.

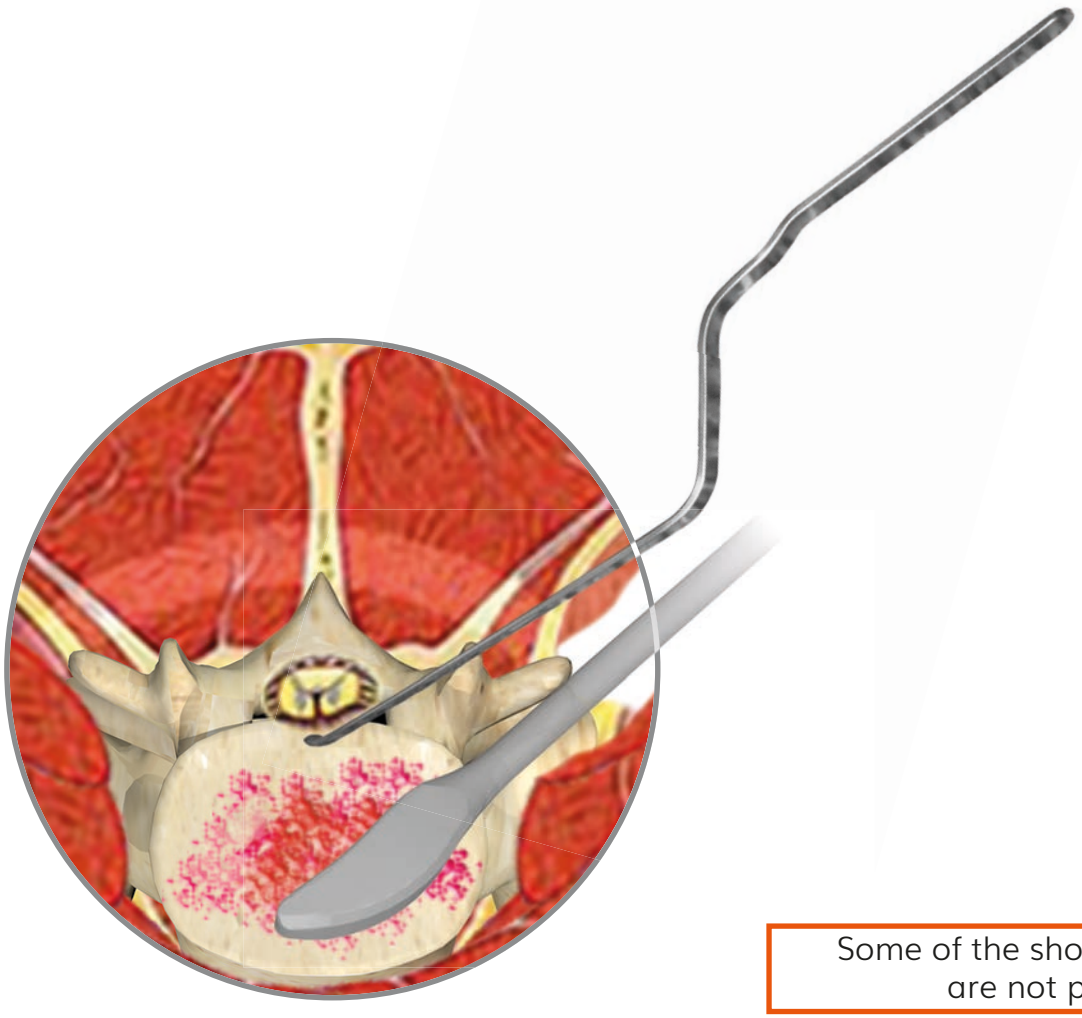


Some of the shown instruments are not provided!

# Trial insertion

- Insert trial to establish desired height for the implant.
- Use A/P and lateral fluoroscopy to confirm proper placement and trajectory.

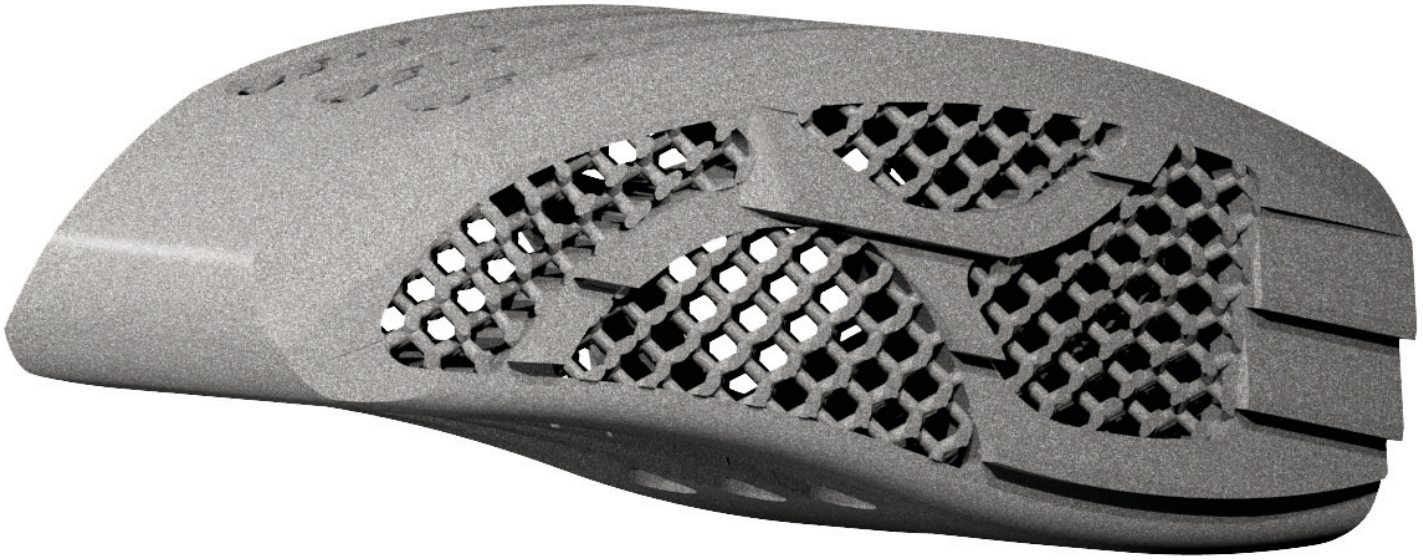
- The disc space is sequentially distracted until the adequate disc space height is obtained and the desired foraminal heights are restored. Insert the trial implant  with the curved sides touching the endplates. Insert distractors sequentially until the desired height is obtained.



Some of the shown instruments are not provided!

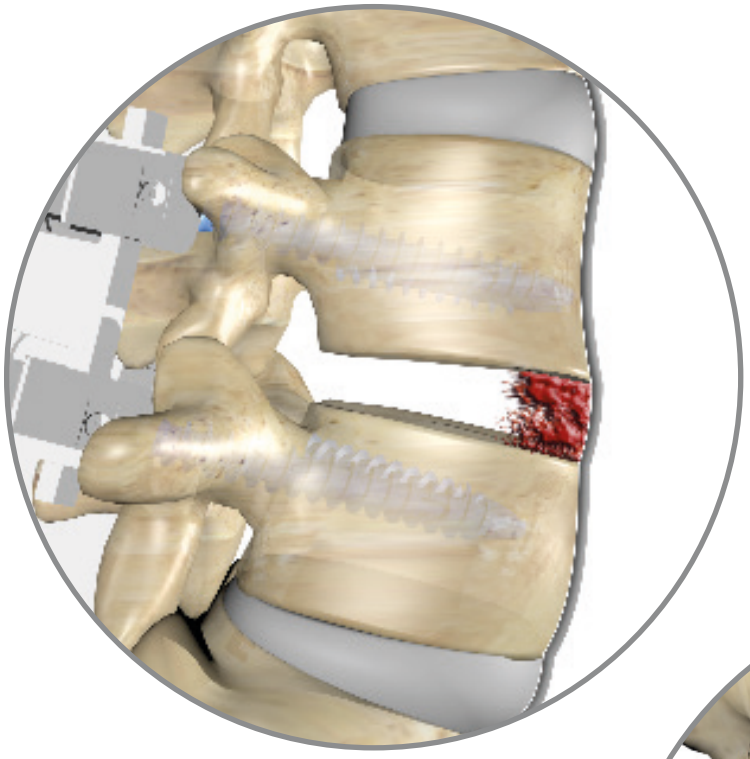
# Preparation

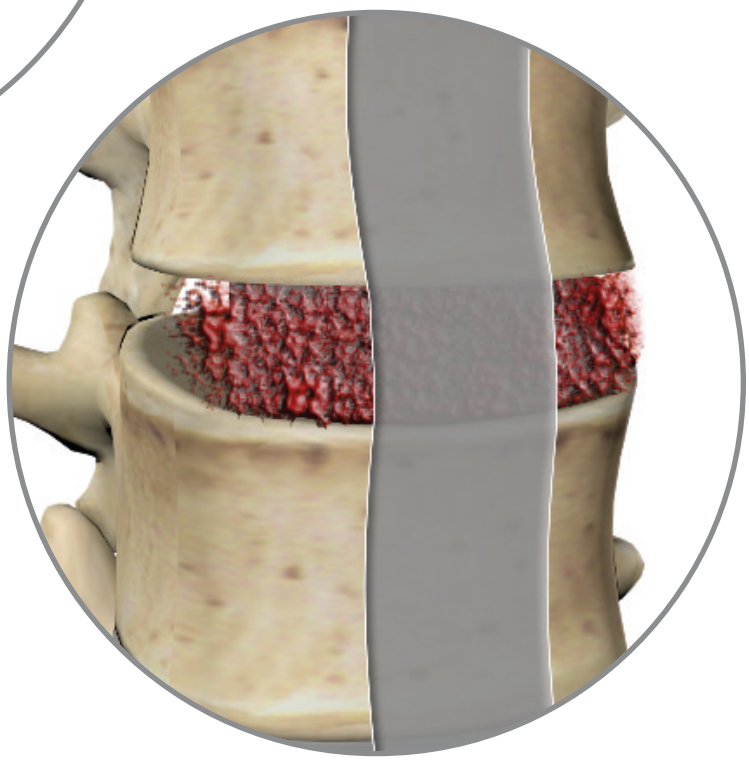
The dolfyn® cage is completely hollow, so that it can be filled with autograft at the surgeon's choice.



# Autograft

In addition to inside the cage, autogenous bone graft can also be placed in the ventral position of the vertebral disc space prior to cage insertion. After cage positioning, additional bone graft can be impacted behind the interbody fusion device.



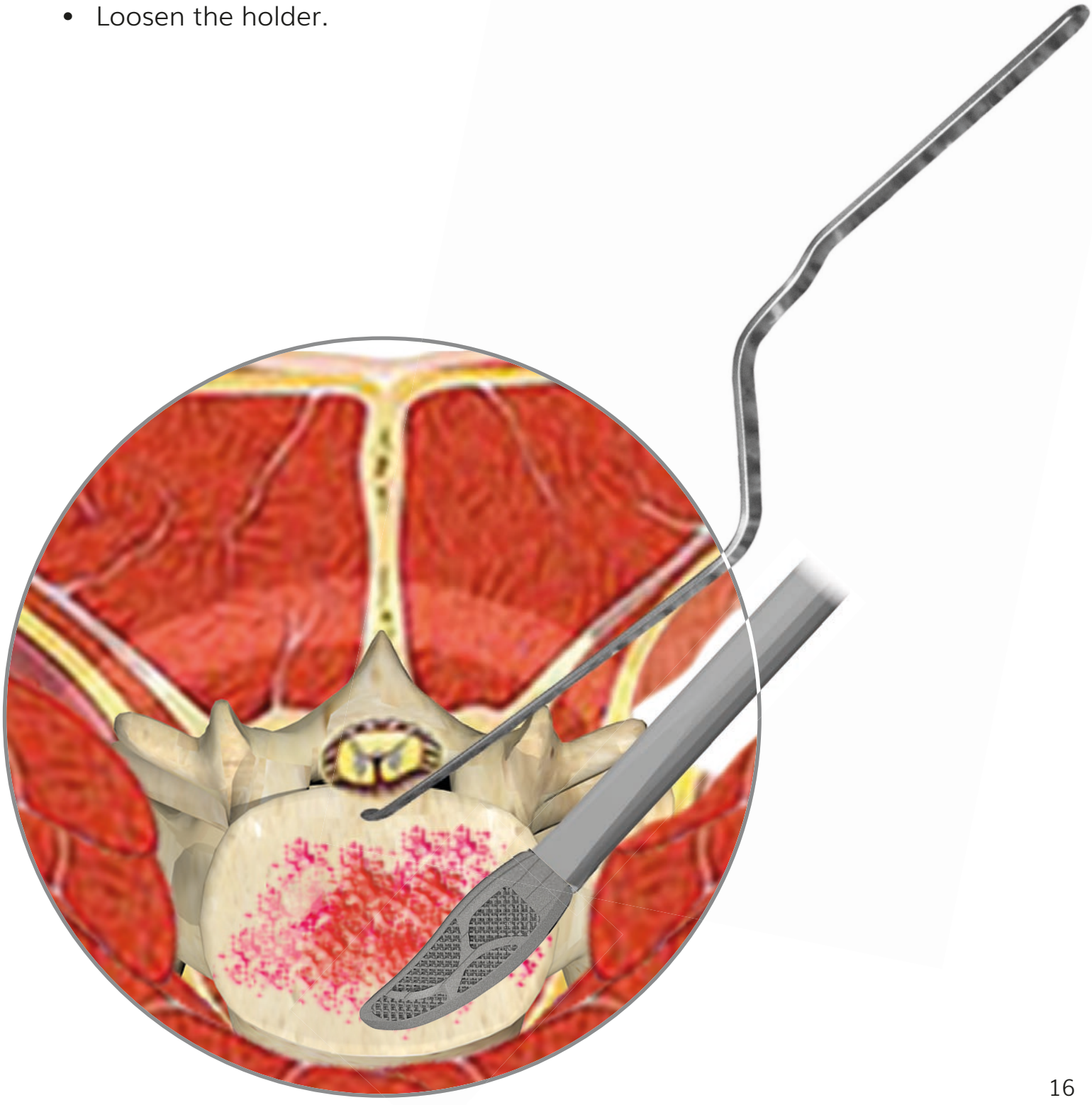


# Implant preparation

Place the implant on the implant holder and tighten by turning cylinder clock-wise.

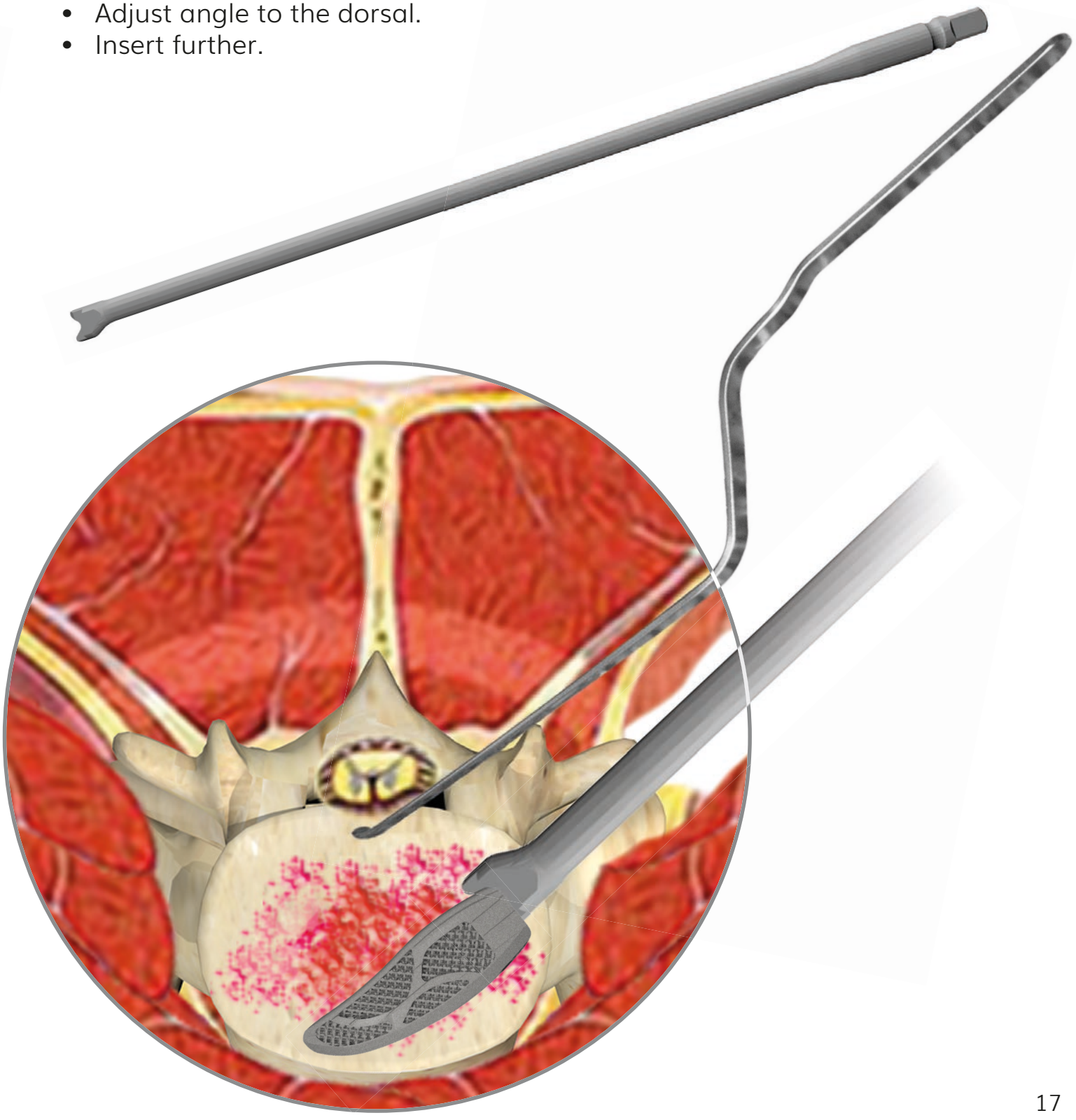
# Implantation

- Insert implant to the ventral edge (anterior longitudinal ligament).
- Lateral control.
- Loosen the holder.



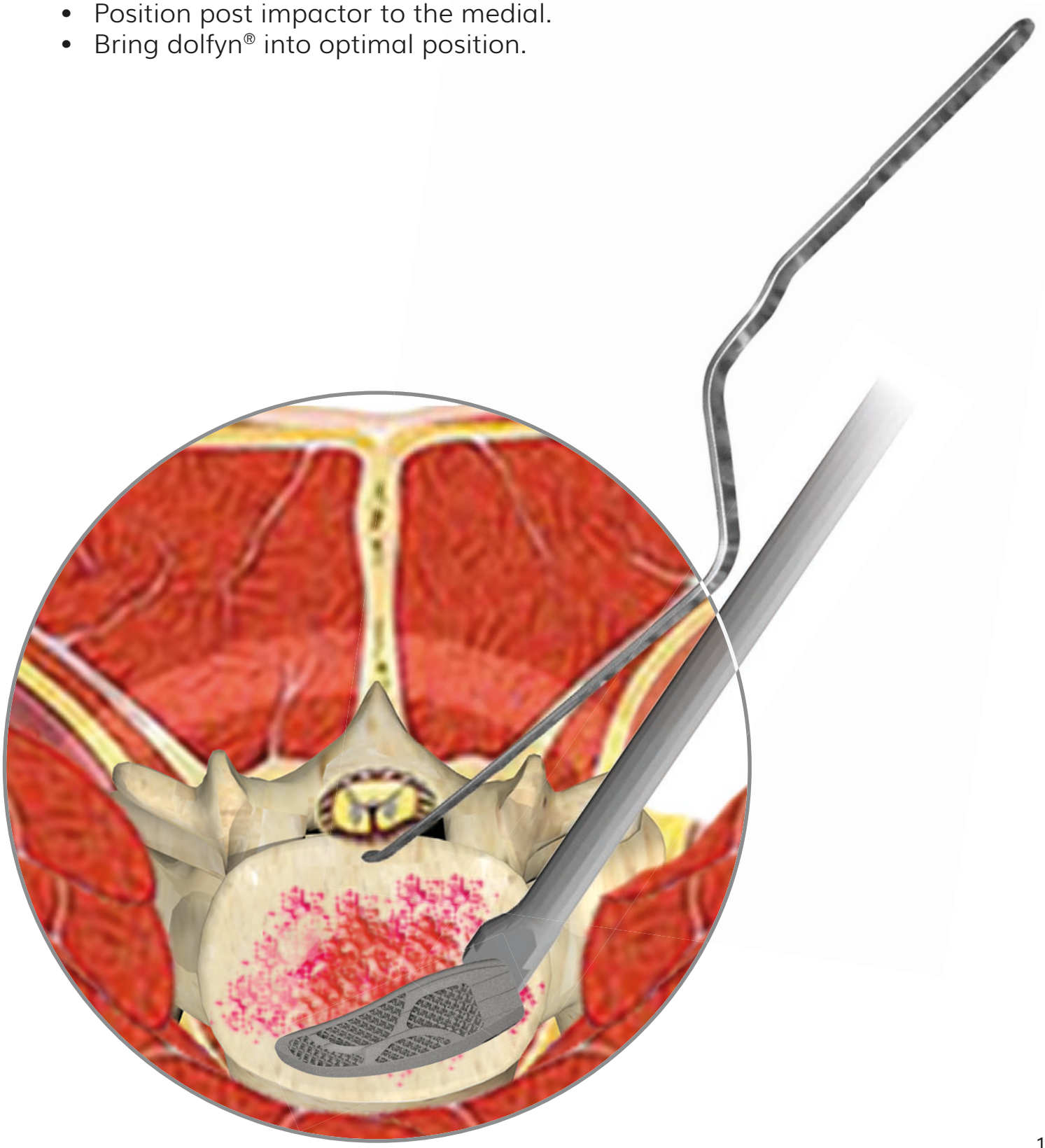
# Positioning

- Use the post impactor.
- Adjust angle to the dorsal.
- Insert further.



# Positioning

- Position post impactor to the medial.
- Bring dolfyn® into optimal position.



# Final position

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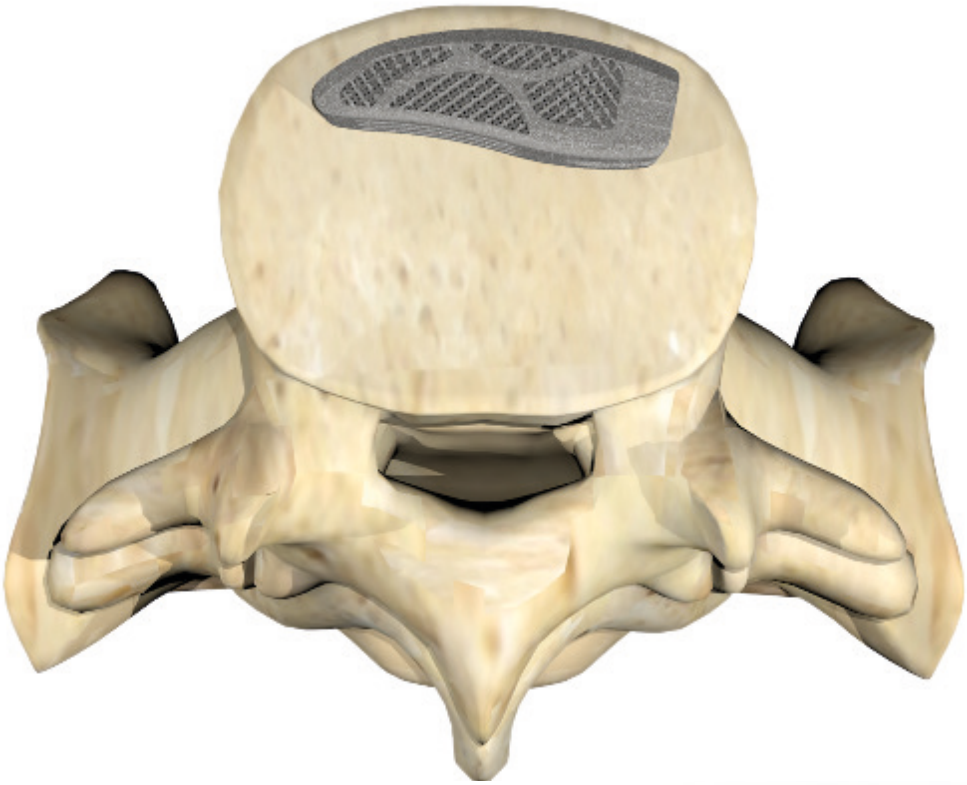
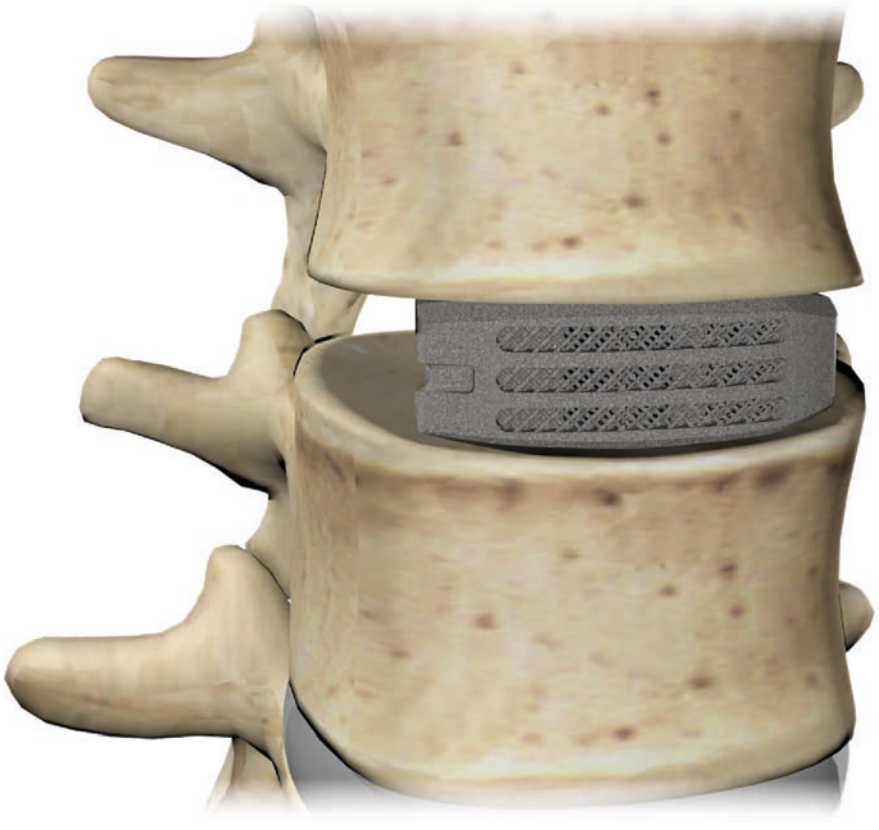
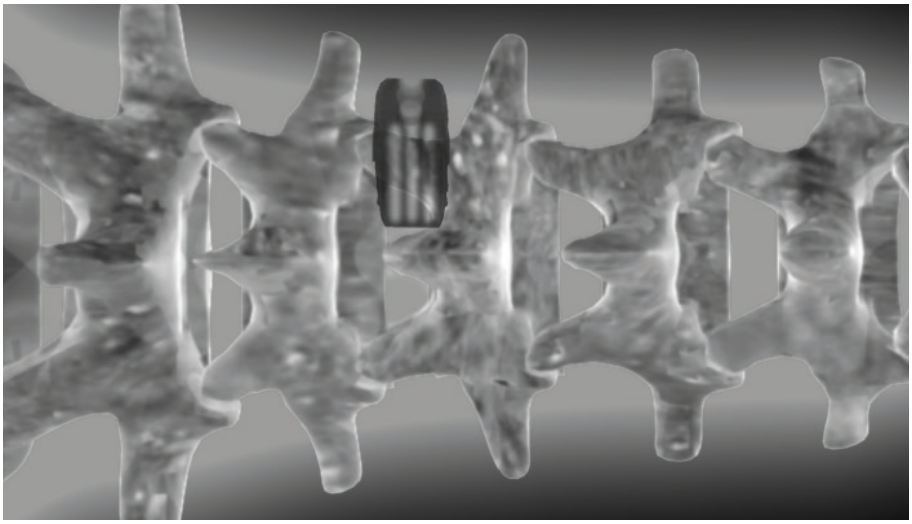
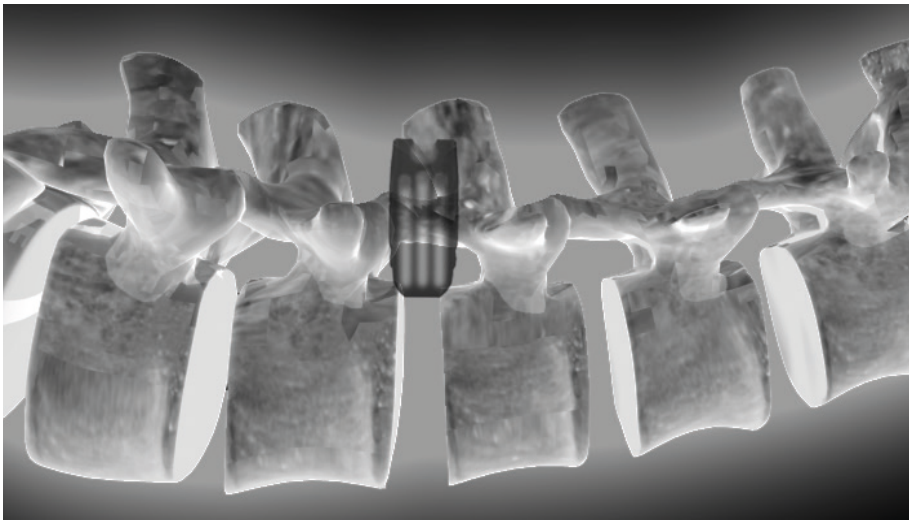




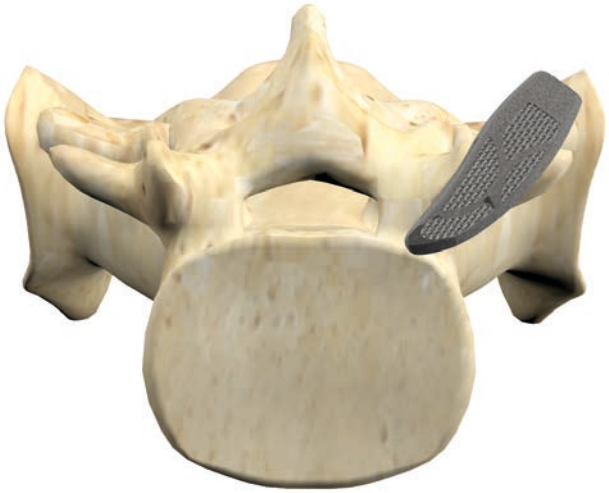
# X-Ray location control | 1



1. AP



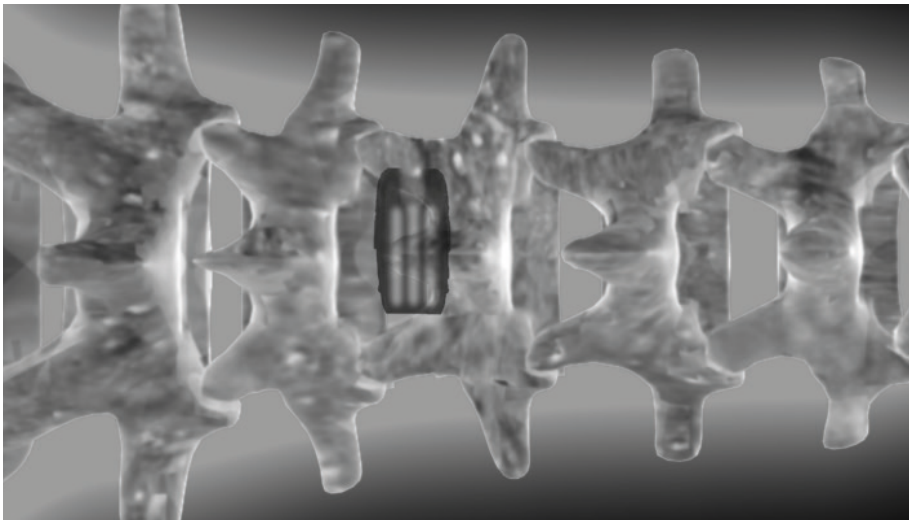
1. lateral



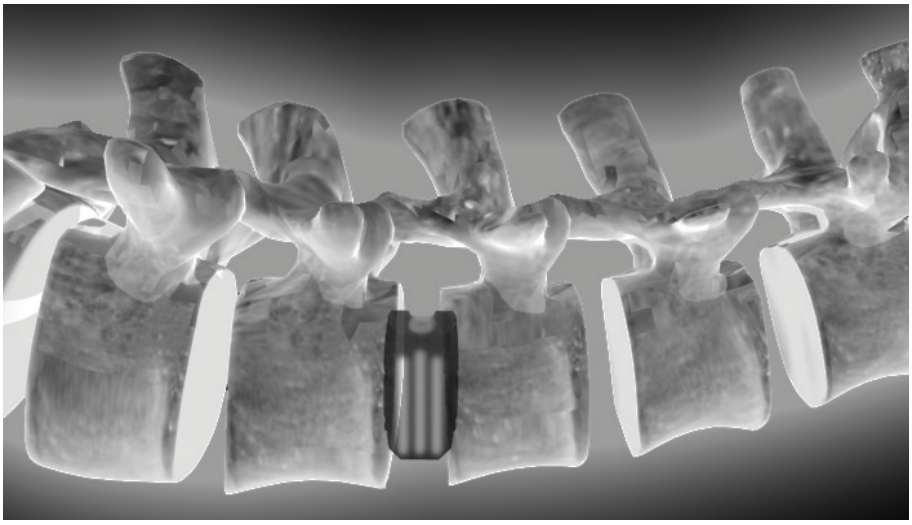
1. top view

# X-Ray location control | 2

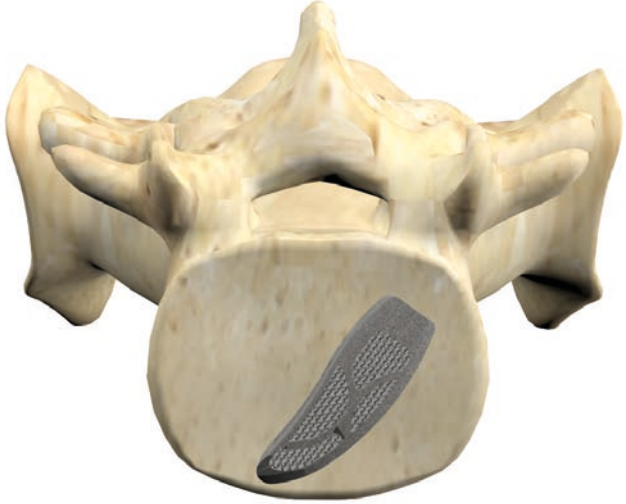
to compare, view page 16



2. AP



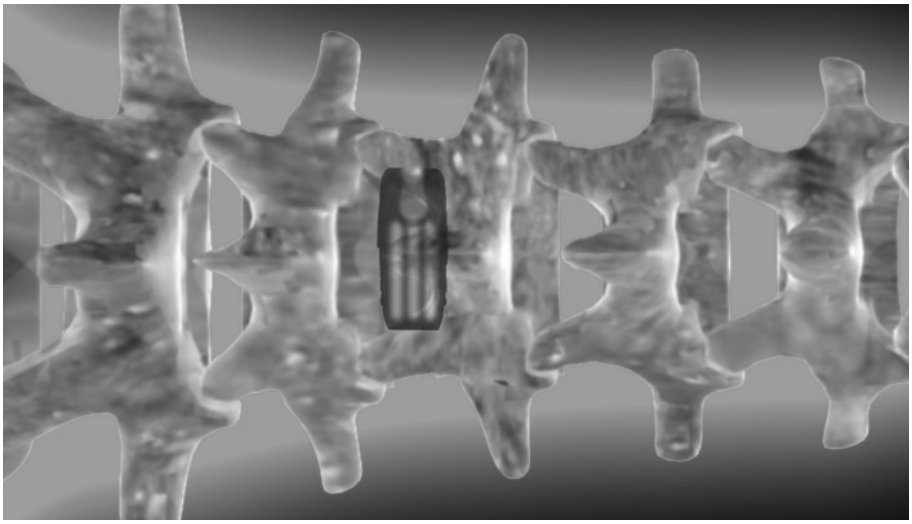
2. lateral



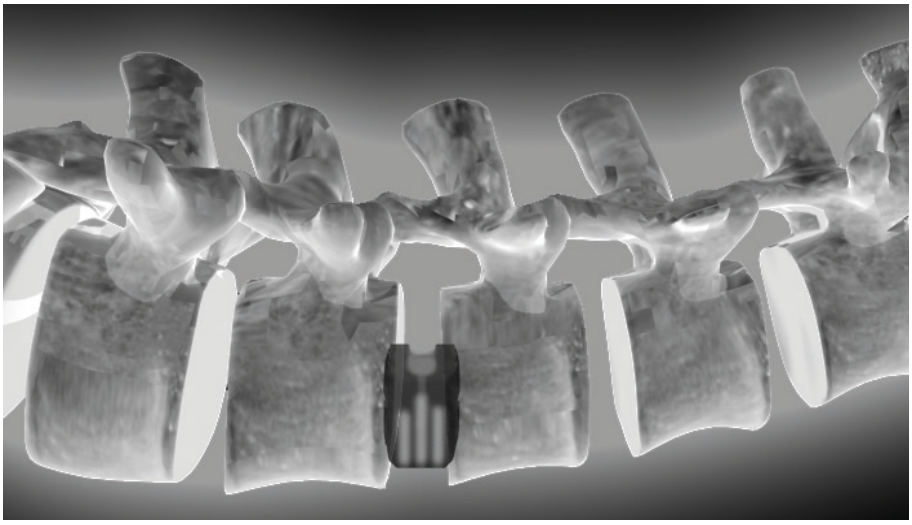
2. top view

# X-Ray location control | 3

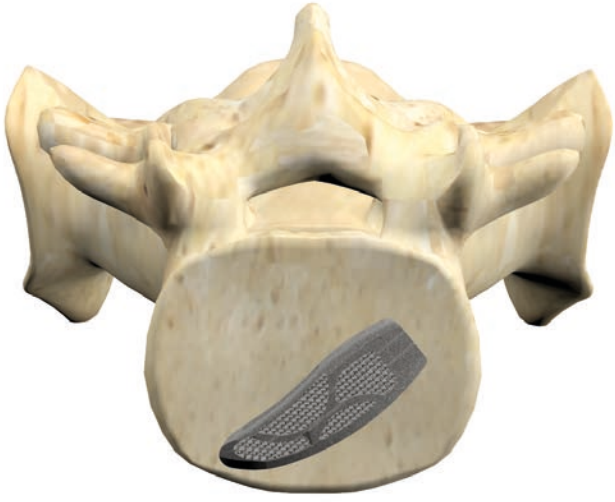
to compare, view page 17



3. AP



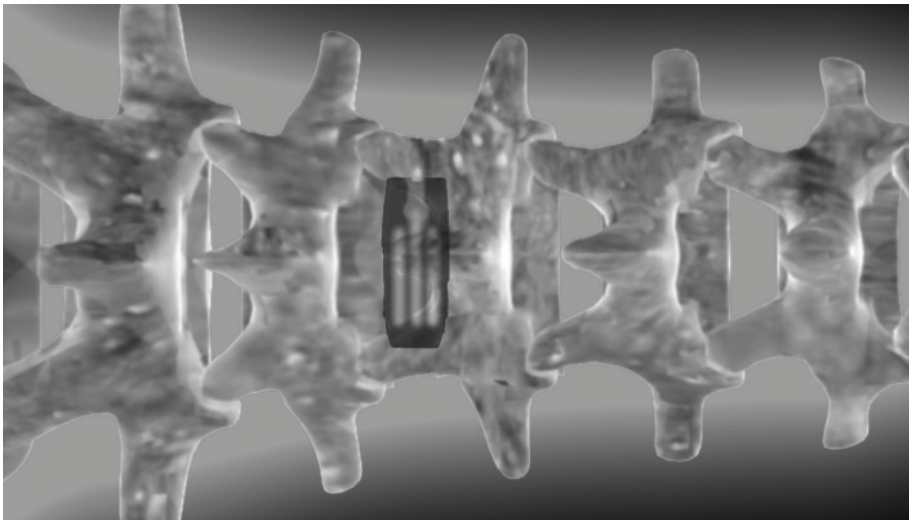
3. lateral



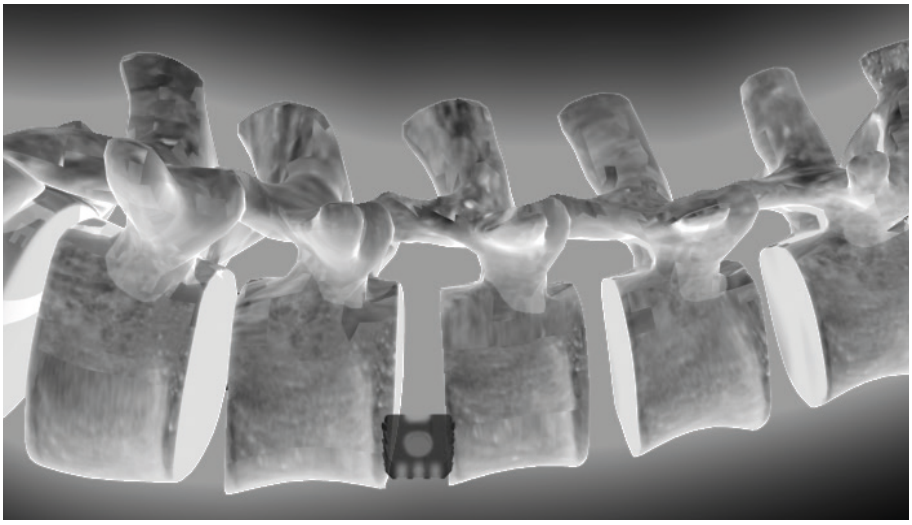
3. top view

# X-Ray location control | end

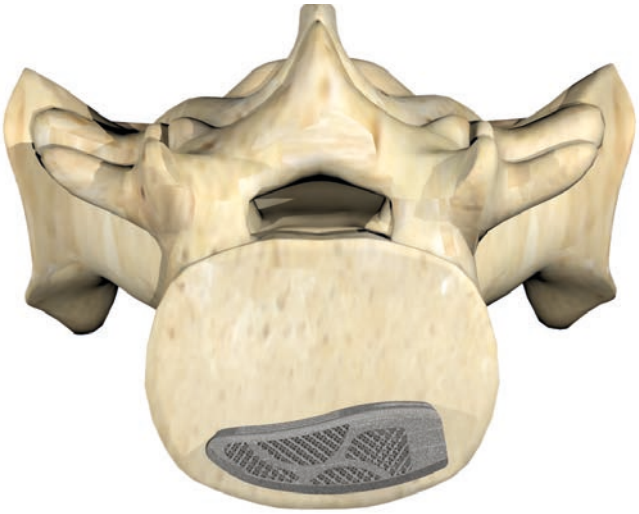
to compare, view page 18



end. AP



end. lateral



end. top view

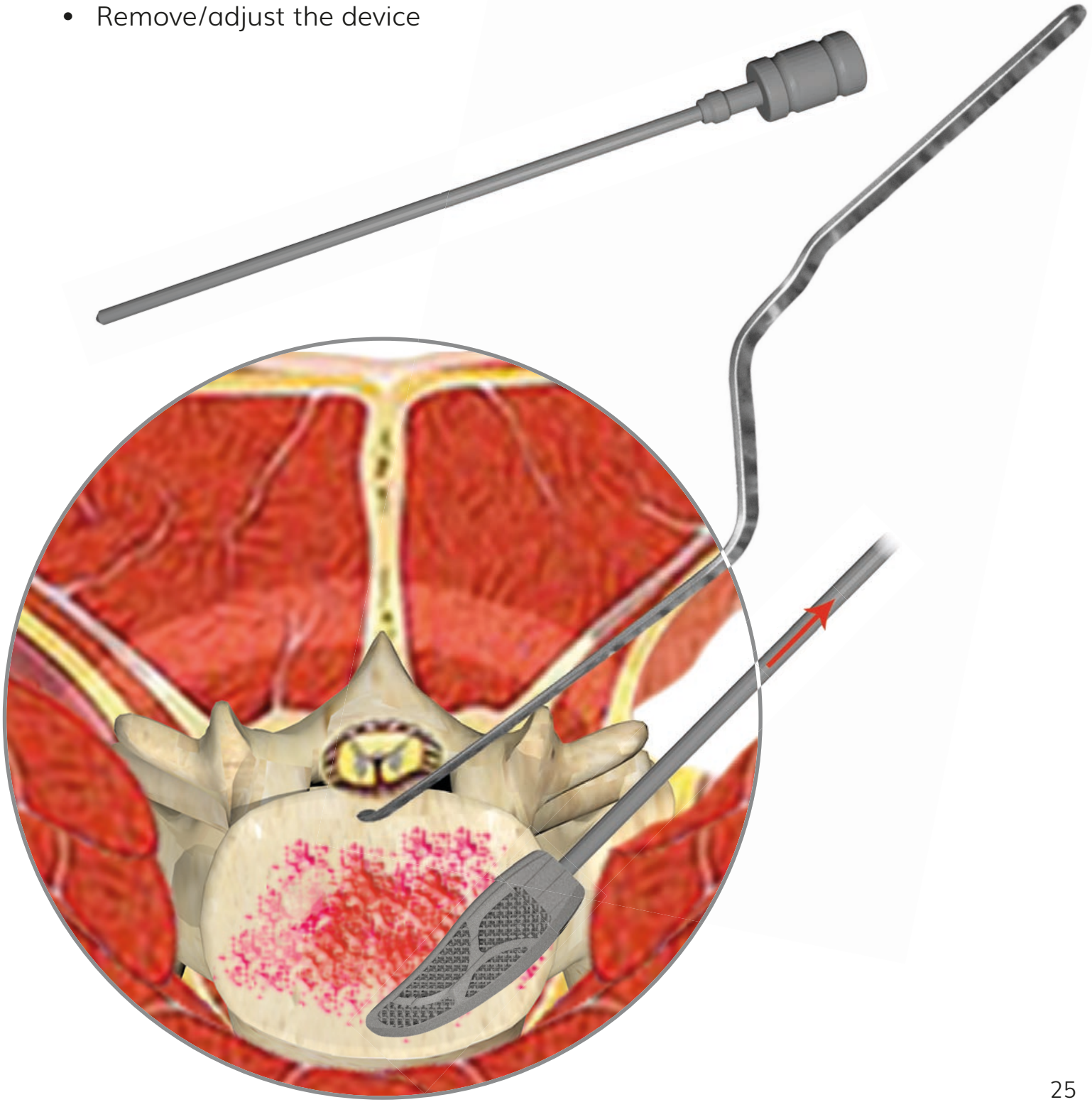
# Removal

Until dolfyn is in its final ventral position, it is still possible to remove it or to adjust its position.

- Remove the inner part of the holder by turning it counter clockwise.

# Removal

- Attach the inner part of applicator to the dolfyn® device.
- Lock it by turning clockwise
- Remove/adjust the device



# Additional information

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*Note for sterilization*

- *The instruments are not sterile upon delivery. Before use, instruments must be cleaned and sterilized according to instructions provided by the manufacturer.*

# Potential Adverse Events

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All of the potential adverse events associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of potential adverse events includes, but is not limited to:

- Early or late loosening of any or all of the components.
- Disassembly, bending, and/or breakage of any or all of the components.
- Foreign body (allergic) reaction to implants, debris, corrosion products (from crevice, fretting, and/or general corrosion), including metallosis, staining, tumor formation, and/or autoimmune disease.
- Loss of correction, height, and/or reduction.
- Infection.
- Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
- Loss of neurological function (e.g., sensory and/or motor), including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paresthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, spasms, sensory loss, tingling sensation, and/or visual deficits.
- Neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, irritation, arachnoiditis, and/or muscle loss.
- Urinary retention or loss of bladder control or other types of urological system compromise.
- Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
- Fracture, microfracture, resorption, damage, or penetration of any spinal bone (including the sacrum, pedicles, and/or vertebral body) and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery.
- Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
- Non-union (or pseudarthrosis). Delayed union. Mal-union.
- Loss of or increase in spinal mobility or function.
- Inability to perform the activities of daily living.
- Bone loss or decrease in bone density, possibly caused by stresses shielding.
- Graft donor site complications including pain, fracture, or wound healing problems.

# Potential Adverse Events, continued

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All of the potential adverse events associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of potential adverse events includes, but is not limited to:

- Ileus, gastritis, bowel obstruction or loss of bowel control or other types of gastrointestinal system compromise.
- Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.
- Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
- Development of respiratory problems, e.g., pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
- Change in mental status.
- Death.

Note: Additional surgery may be necessary to correct some of these potential adverse events.

# Warnings and Precautions

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Caution:
Federal law (USA) restricts these devices to the sale by or on the order of a physician. Implants and disposable instruments are single use only.
The device is only intended for use as indicated.
A successful result is not achieved in every spinal fusion surgery. Spinal fusion surgery should be performed only by trained orthopaedic and neurosurgeons, as it is a technically demanding procedure. Correctly performed preoperative and operating procedures are important considerations in the success of spinal fusion.
Presence of the contraindications increases the risk of failure of the procedure and may result in the adverse events described and possibly additional surgery.
The implants are single use. Never reuse the implants because this increases risk of breakage, infection and possibly other adverse events. Used implants include any implant that has come in contact with blood, bone, tissue or other body fluids.
Only install and position the implants with dedicated instruments from the instrument set (see surgical technique). Care must be taken not to distort the implants or nick, hit or score them with the instruments to reduce the risks of breakage.
The potential of success of the procedure is increased by selection of the proper size and shape of the implant for each patient. With proper implant selection the risks are minimized, however due to the limitations the size and shape of the human anatomy the implant's strength is limited. During pre- intra and postoperative procedures minimizing the stresses on the implant and optimizing circumstances for fusion is crucial. Repeated high stresses on the implant can cause the implant to break, loosen, move or experience material fatigue before fusion is achieved.
Loads on the device produced by load bearing and by the patient's activity level will dictate the longevity of the implant.

# Warnings and Precautions, continued

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Preoperative:
- Only patients that meet the criteria described in the indications should be selected.
- Patient condition and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
- Care should be used in the handling and storage of the implants. The implants should not be scratched or damaged. Implants and instruments should be protected during storage and from corrosive environments.
- All non-sterile parts should be cleaned and sterilized before use.
- Devices should be inspected for damage prior to implantation.
- Care should be taken during surgical procedures to prevent damage to the device(s) and injury to the patient.

Intraoperative:
- The instructions in the surgical technique manual should be carefully followed.
- Extreme care must be taken when the devices are used near vital organs, nerves or vessels. Damage to the nerves will cause loss of neurological functions.
- Breakage, slippage, or misuse of instruments or implants may cause injury to the patient or operative personnel.
- Use of autograft or allograft, a posterior rod and screw system and, if applicable an anterior plate is recommended.

Postoperative:
The patient should be informed about the limitations and risks of the spinal fusion and all procedures and treatments.
- The patient should be made aware of the postoperative limitations regarding weight-bearing, muscle activity and sudden movements; non-compliance with the postoperative limitations increases the risk of breakage, migration or loosening of the implant and other complications.
- The patient should be made aware of the postoperative limitations regarding smoking and alcohol consumption during union process to reduce the risk of non-union or delayed union.
- The devices must be checked periodically postoperatively to ensure the earliest possible detection of loosening, migration or breakage, using appropriate radiographic techniques. If any of this is occurs the devices should be revised and/or removed immediately before serious injury occurs.