ChoiceSpine™
Propelling Spinal Surgery

LUMBAR INTERBODY FUSION

HARPOON, HORNET, SABRE, SHARK

SURGICAL TECHNIQUE

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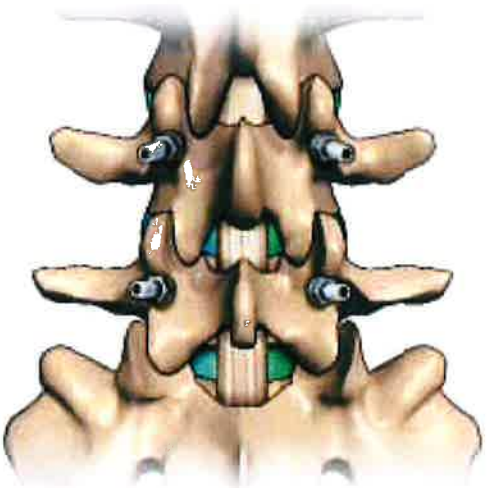
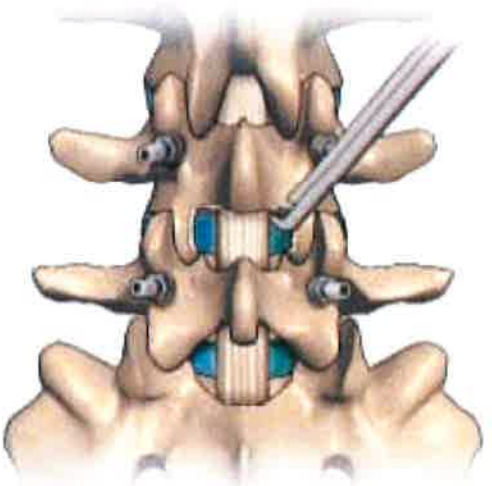
Approach and Posterior Fixation

The patient is placed on the operating table in the knee chest position or in prone position. Incision and approach are performed. The ChoiceSpine Lumbar Spacer System must be associated with a posterior fixation and a postero-lateral grafting in order to obtain a circumferential fusion and an optimal stabilization of the segment. The pedicular screws must be inserted before introducing the cages. In some cases, distraction can be facilitated by the screws in position.



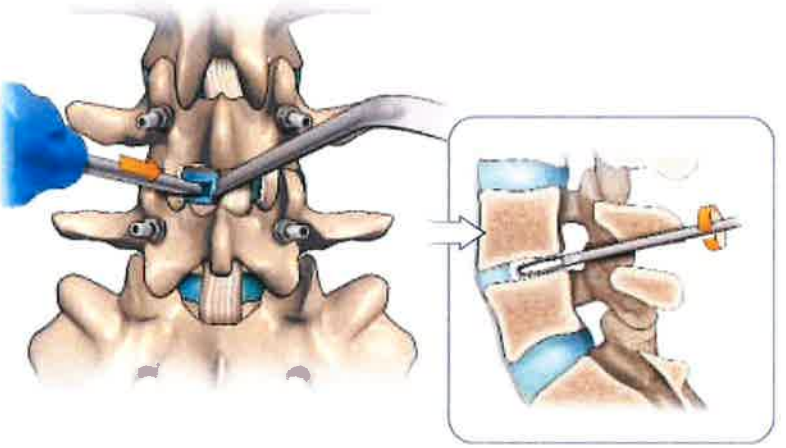
Dura and Disc Exposure

Exposure of the dura and disc is performed with a bilateral hemilaminectomy and partial facetectomy. At this stage, the nerve roots can be decompressed before the following steps.



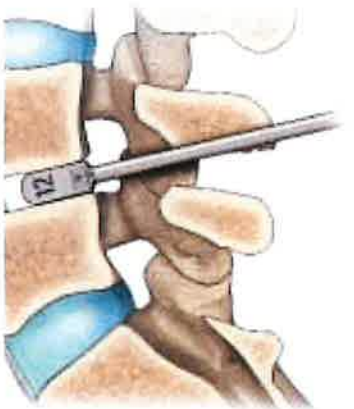
Disc Preparation

The small paddle shaver is inserted flat in the space. Rotation of the paddle shaver is carried out to remove a great volume of disc fragments. Remaining disc fragments are then removed from the disc space with the disc rongeur.



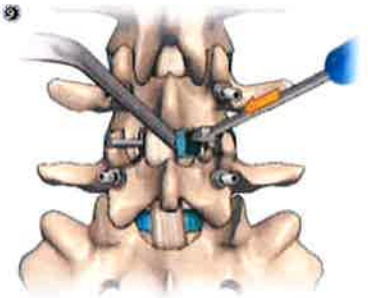
Progressive Distraction and Discectomy

Distraction goes on with the paddle starter until the adequate distraction is obtained. Care must be taken to avoid over-distraction. The medium and paddle shavers are inserted depending on the height obtained to remove remaining disc materials.



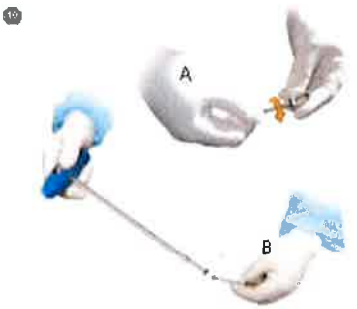
Preparation of the Opposite Side

The steps 3 to 6 are performed on the opposite side.



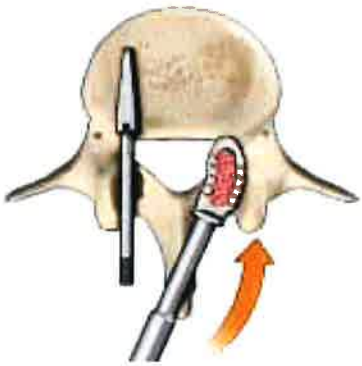
Cage Preparation

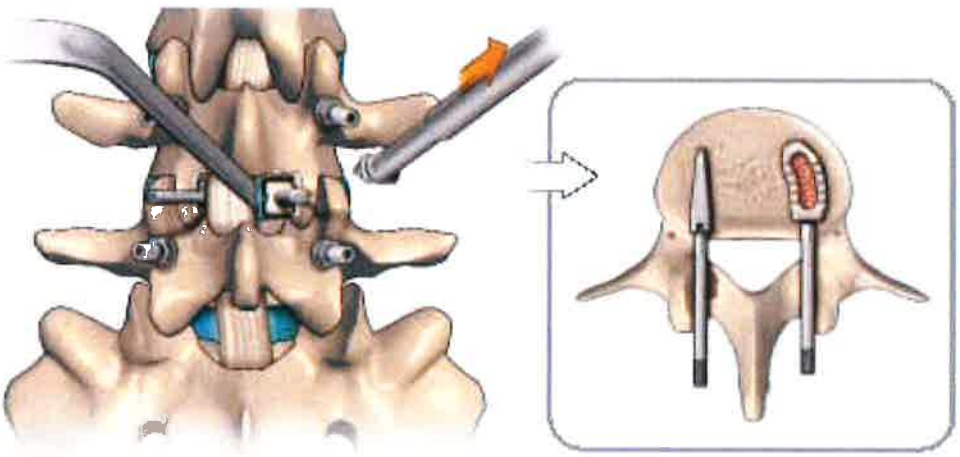
The first cage is attached to the inserter by mating the posts on the distal end of the inserter with the corresponding implant features. The center inserter drawrod is then threaded into the implant until the instrument and implant are flush with one another. This is repeated for the second implant. Both cages are carefully filled in with grafting materials (autogenous and/or allogeneic bone…).



First Cage Insertion

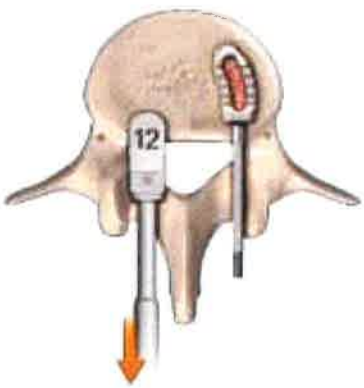
To insert the cage, the cage inserter must be inclined medially. Thus the ogival round tip of the cage will be positioned face to the entry point. During impaction, a straightening movement of the cage inserter is necessary to insert the cage lateraly. At the end, the shaft of the inserter is in contact with the facet.





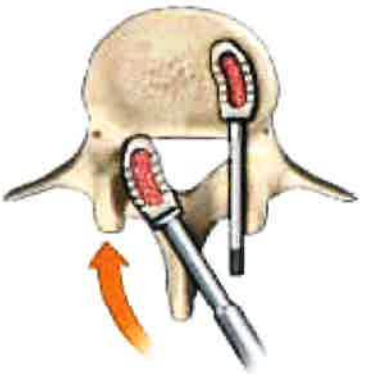
Second Cage Insertion

The paddle distractor or trial is removed on the opposite side.

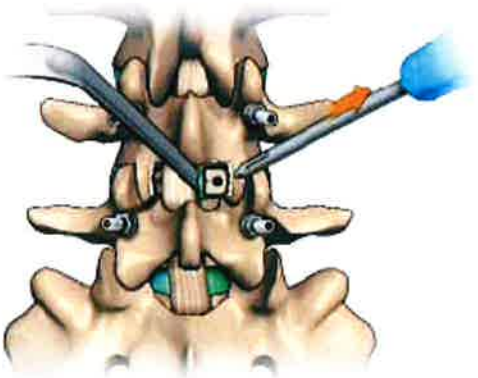


Second Cage Insertion

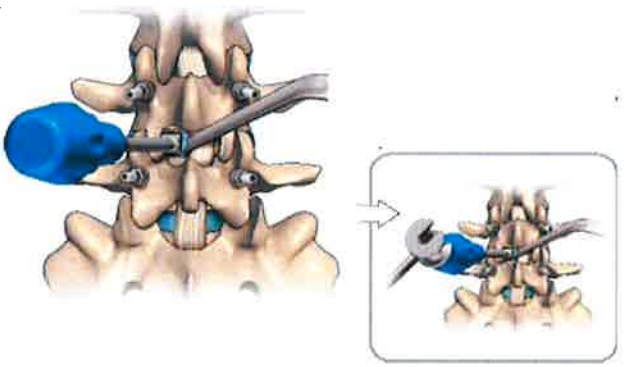
The second cage is inserted as the first one.



A counterclockwise rotation of the inserter drawrod is performed to remove the inserter from the implant.

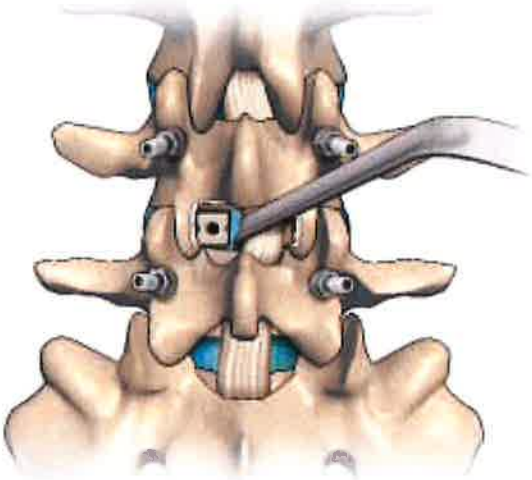


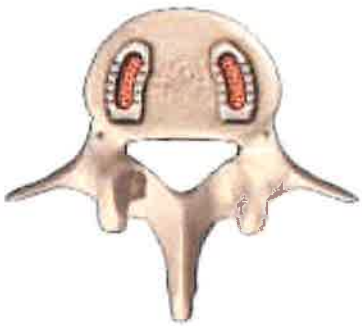
After a lateral X-ray checking, a depth adjustment can be made using the cage tamp. Light impaction is performed to position the cage beyond the posterior edge of the vertebral body.

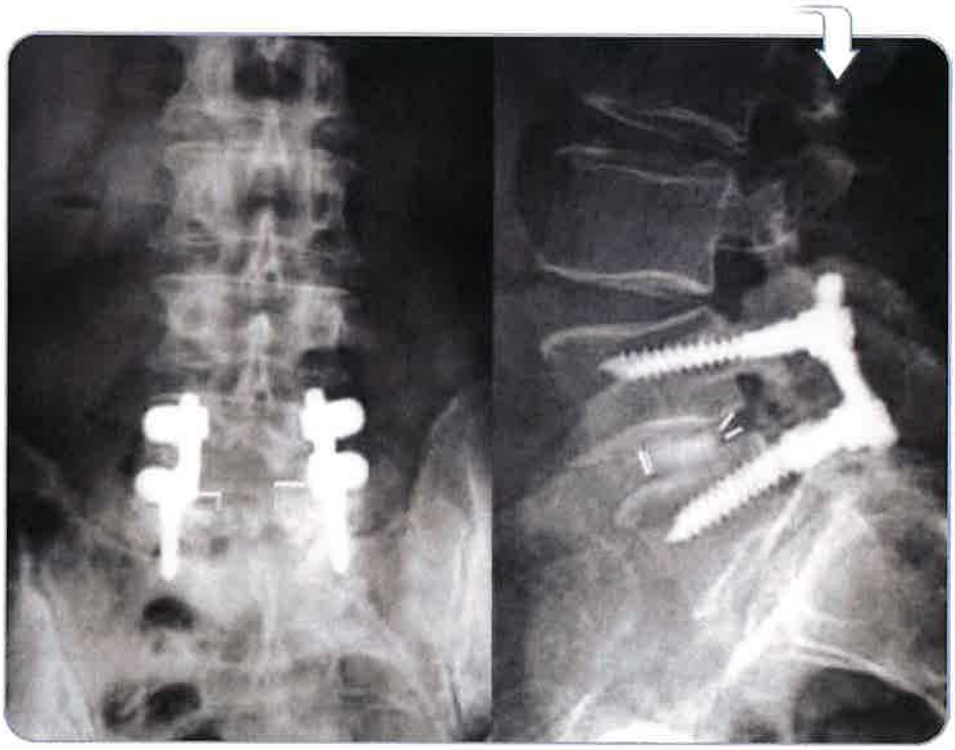


Final Checking and Completion of the Posterior Fixation

Implant position can be confirmed using X-ray.
The posterior fixation is completed to provide the adequate stability to the segment.







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Removal

To remove the implant, thread the inserter onto the implant until fully seated by rotating the center rod clockwise. The posts on the end of the inserter should be captured in the pockets on each side of the implant. The slap hammer works in conjunction with the inserter to assist in the removal of implants. Place the slot of the slaphammer over the inserter shaft, slide the slaphammer along the inserter shaft and strike the shoulder of the proximal end of the inserter.

General Description

The Choice Spine Lumbar Spacer System consists of interbody fusion devices (specifically, SABRE, SHARK™, HORNET™ & HARPOON™ Lumbar Spacers) comprised of polyetheretherketone (PEEK) with tantalum markers (ASTM F2026 and ASTM F560) or Ti 6AL4V ELI (ASTM F136). The spacers have a basic rectangular shape, a hollow center for placement of bone graft and a smooth bullet-shaped anterior surface. They are available in an assortment of height, length and anteroposterior angulation combinations to accommodate many different anatomic requirements.

Indications for Use

When used as an intervertebral body fusion device, Choice Spine Lumbar Spacers are indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft to facilitate fusion. When used as a vertebral body replacement device, Choice Spine Lumbar Spacers are intended for use in the thoracic and lumbar spine, from T1 to L5, for the replacement of a collapsed or unstable vertebral body resulting from a tumor or traumatic injury. The device system is designed for use with supplemental fixation and with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft to facilitate fusion.

Contraindications

Contraindications for Choice Spine Lumbar Spacers are similar to those of other systems of similar design, and include, but are not limited to:

1. Active infectious process in the patient, particularly in or adjacent to the spine or spinal structures
2. Conditions, such as morbid obesity, which may put excessive stress on the bone and implants.
3. Severe osteopenia or osteoporosis may prevent adequate fixation.
4. Suspected or documented metal allergy.
5. Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcohol or drug abuse, occupation or life-style may interfere with their ability to follow post-operative instructions.
6. Pregnancy.

Warnings

1. Mixing of dissimilar metals can accelerate the corrosion process. Stainless steel and titanium implants must NOT be used together in building a construct.
2. A satisfactory outcome is enhanced by the selection of the appropriate device size and angle.
3. This CS.Lumbar Spacer System has not been evaluated for safety and compatibility in MR environment. It has not been tested for heating and migration in the MR environment.

Precautions

1. Choice Spine Lumbar Spacers should only be implanted by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques.
2. The implants should not be reused, even if they appear in a perfect state. Any implant that has been used, twisted, bent, implanted and then removed, even if it appears intact, must be discarded.
3. Choice Spine Lumbar Spacers are used to augment the development of a spinal fusion by providing temporary stabilization. This device is not intended to be the sole means of spinal support – supplemental internal fixation must be used. Bone grafting must be part of the spinal fusion procedure. If fusion is delayed or does not occur, material fatigue may cause breakage of the implant. Damage to the implant during surgery (i.e., scratches, notches) and loads from weight bearing and activity will affect the implant's longevity.
4. Refrain from handling Choice Spine Lumbar Spacers as much as possible before implantation and always with the utmost care. The spacers (in their original packaging) must be stored with care in a clean and dry place away from radiation or extreme temperatures. Should these requirements not be followed, reduced mechanical properties may occur which could lead to implant failure in some cases.

Potential Complications and Adverse Effects

Potential complications and adverse effects for this system are similar to those of other spinal instrumentation systems, and include, but are not limited to:

1. Early or late loosening of the components
2. Disassembly, bending or breakage of any or all of the components
3. Foreign body (allergic) reaction to the implants
4. Infection
5. Loss of neurological function, including paralysis, spinal cord impingement or damage
6. Dural tears, CSF leak or fistula or meningitis.
7. Bone graft donor complications including pain, fracture or wound healing problems.
8. Vascular damage resulting in excessive bleeding and displaced devices adjacent to large vessels could cause vessel erosion and catastrophic bleeding.
9. Loss or impairment of bowel, sexual, and/or bladder function and other types of urological compromise
10. Possible local or systemic adverse reactions from potential long-term degradation of the polymer or mechanical grinding causing wear debris
11. Bone loss due to resorption or stress shielding
12. Death

Additional surgery may be necessary to correct some of these potential adverse effects.

Single Use Only Never reuse an implant. Any implant that has been twisted, bent, or implanted, then removed, even if it appears intact, must be discarded. These devices are provided as single use only.

Patient Education It is essential to provide preoperative instructions to the patient. S/he should be made aware of the potential risks of the surgery and the implant limitations. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken or loose implant components. The patient must be made aware that implant components may bend, break, or loosen even though restrictions in activity are followed.

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