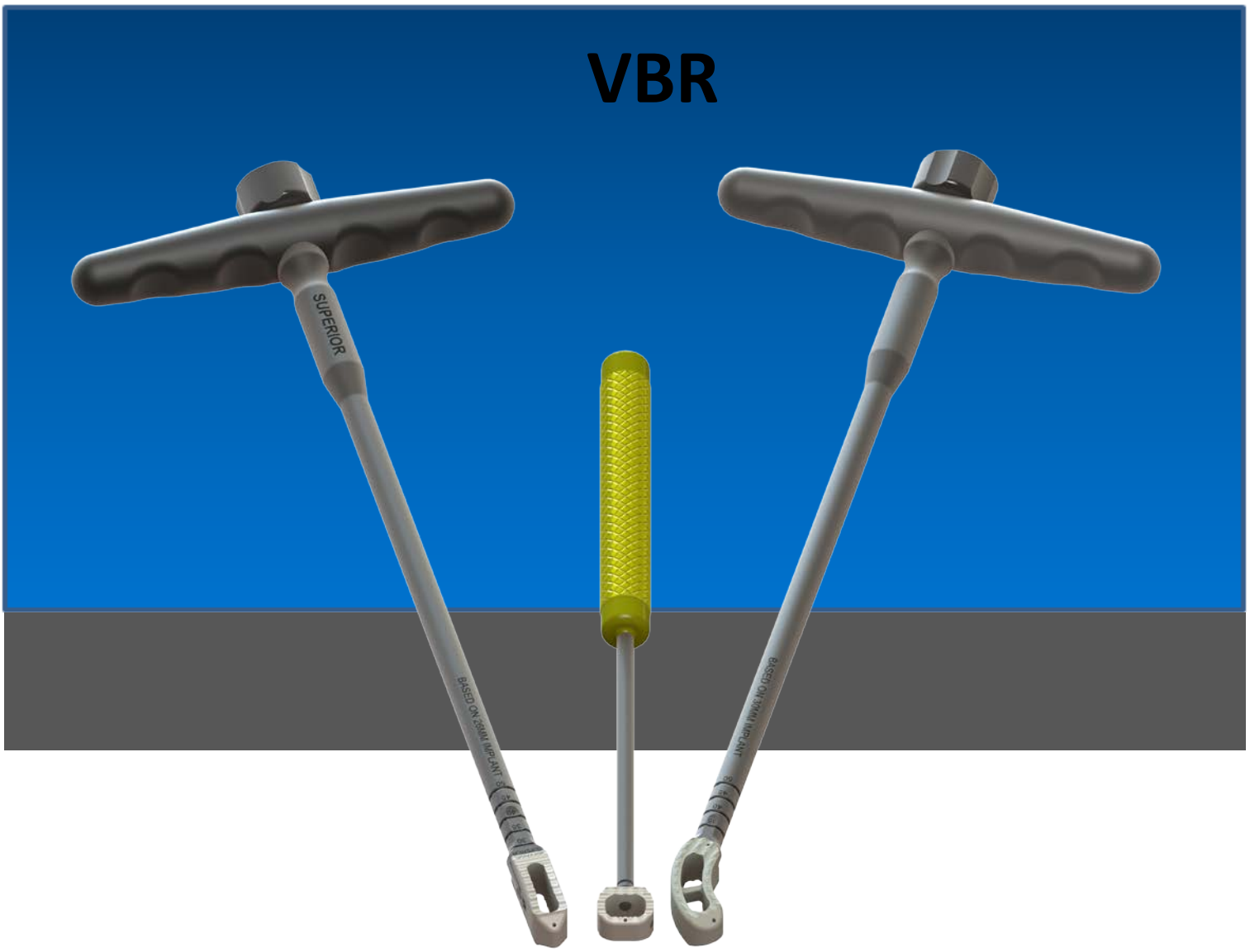
VBR



Surgical Technique Guide

Honour™ Spacer System

NEXXT Spine

70-010 Rev B

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HONOUR™ Spacer System – VBR

Surgical Technique

GENERAL DESCRIPTION

The HONOUR™ Spacer System is a collection of radiolucent cage devices constructed of medical grade polyetheretherketone with tantalum markers as described in ASTM F-2026 and ASTM F-560. The HONOUR implants are comprised of various heights and footprints to accommodate individual patient anatomy and to maximize bone graft material volume.

INDICATIONS FOR USE

When used as a cervical intervertebral fusion device, the HONOUR™ devices are indicated for use at one level in the cervical spine, from C2-T1, in skeletally mature patients who have had six weeks of non-operative treatment for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device is intended for use with autogenous bone graft and with supplemental fixation systems cleared for use in the cervical spine (e.g., the Blade® Anterior Cervical Plate System).

When used as a lumbar intervertebral fusion device, the HONOUR™ devices are indicated for use at one or two contiguous levels in the lumbar spine, from L2-S1, in skeletally mature patients who have had six months of non-operative treatment for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device is intended for use with autogenous graft and with supplemental fixation systems cleared for use in the lumbar spine (e.g., the Inertia® Pedicle Screw System).

When used as a vertebral body replacement device, the HONOUR™ devices are indicated for use in the thoracolumbar spine (T1-L5) for partial replacement (i.e., partial vertebrectomy) of a diseased vertebral body resected or excised for the treatment of tumors or trauma/fracture in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The device is intended for use with autograft or allograft and with supplemental internal fixation systems cleared for use in the thoracolumbar spine (e.g., the Inertia® Pedicle Screw System).

Partial VBR Indication

When used as a vertebral body replacement device, the HONOUR™ devices are indicated for use in the thoracolumbar spine (T1-L5) for partial replacement (i.e., partial vertebrectomy) of a diseased vertebral body resected or excised for the treatment of tumors or trauma/fracture in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The device is intended for use with autograft or allograft and with supplemental internal fixation systems cleared for use in the thoracolumbar spine (e.g., the Inertia® Pedicle Screw System).

Patient Positioning

Following adequate anesthesia, the patient is placed on a radiolucent spine table. Particular attention is applied to the positioning of the head and extremities to lessen the risk of ocular and nerve compression.

Exposure of Operative Level(s)

Access the operative site and retract the tissues using preferred instruments. Retract the tissues to allow for complete exposure and visualization of the target disc space. Insert a marker into the disc(s) and confirm the correct operative level(s) using a lateral radiograph.

Partial Vertebral Body Removal

The traumatized or diseased vertebral body can be exposed through the anterior approach. The affected partial vertebral body and disc material is excised and both the superior and inferior surfaces are prepared.

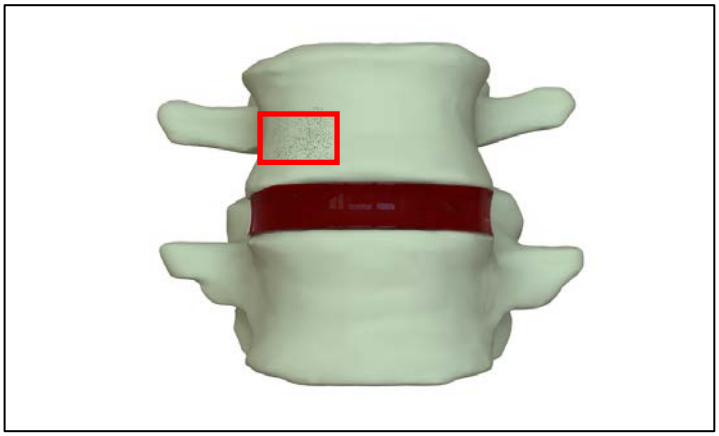

Figure 1

Implant Sizing

Attach the trial to the provided T-handle by engaging the Hudson connection into the handle and securely locking the instruments together. Place the trials sequentially into the space until the proper distraction and footprint is achieved. When the proper size trial is in the space there should be no toggling of the instrument in the affected space.

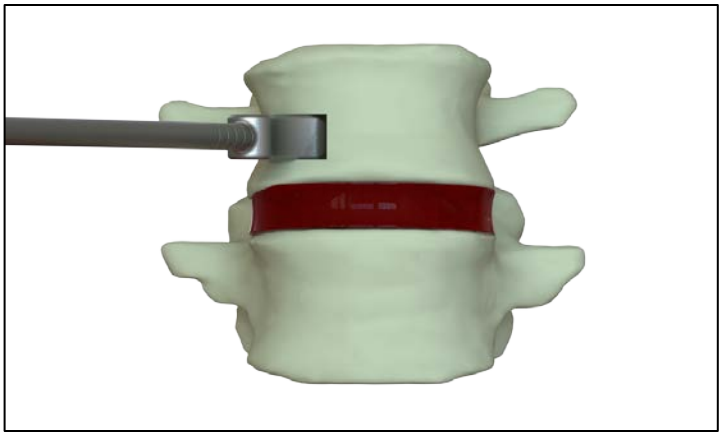

Figure 2

Loading the Implant

Figure 3, left and right: Attach the implant to the appropriate implant inserter. Rotating the thumb wheel on either instrument in the clockwise direction attaches the implant to the inserter.

Figure 3, center: Attach the implant to the implant inserter. Rotating the handle in the clockwise direction attaches the implant to the inserter.

Autograft or allograft may be packed into the implant cavity and, if possible, into the space surrounding the implant(s).

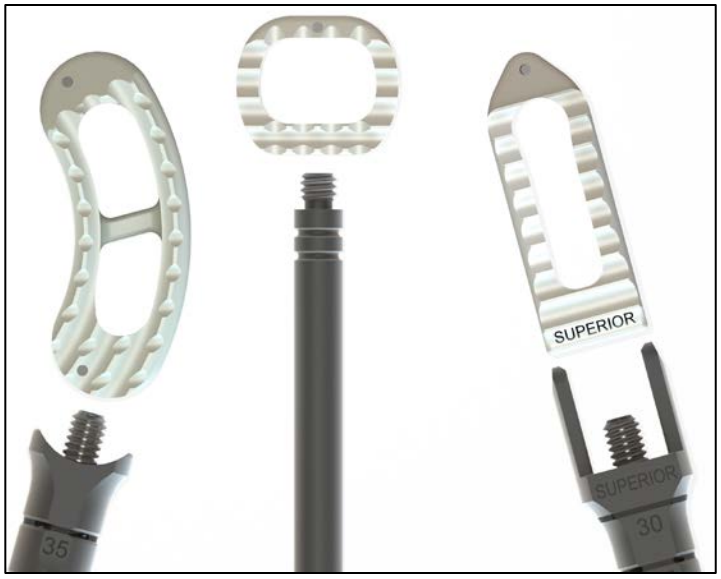

Figure 3

Implant Insertion

Insert the implant into the affected space. Using radiography, the orientation of the implant can be assessed. If reposition is need, the implant tamp may be used.

The implant must be secured using supplemental fixation (i.e., Inertia® Pedicle Screw System)

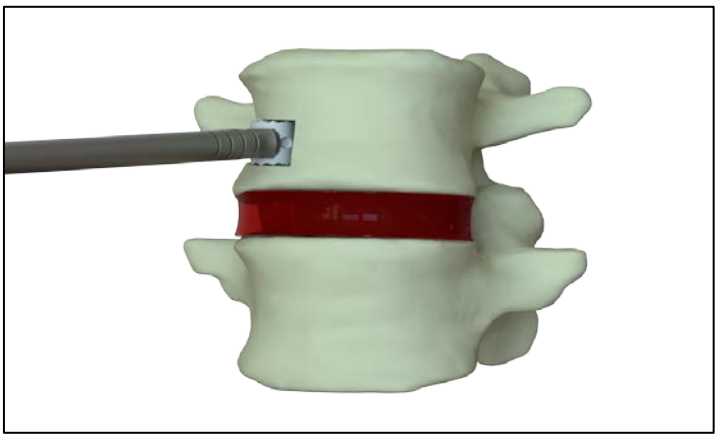

Figure 4

Implant Removal

If implant removal is required, use the implant inserter to re-engage the implant and pull the implant out of the affected space.

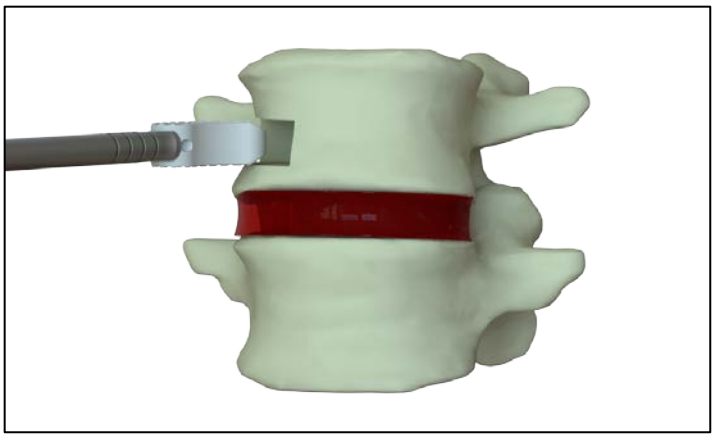

Figure 5

CONTRAINDICATIONS

The HONOUR™ Spacer System contraindications include, but are not limited to:
1. The presence of infection, pregnancy, metabolic disorders of calcified tissues, grossly distorted anatomy, inadequate tissue coverage, any demonstrated allergy or foreign body sensitivity to any of the implant materials, drugs/alcohol abuse, mental illness, general neurological conditions, immunosuppressive disorders, obesity, patients who are unwilling to restrict activities or follow medical advice, and any condition where the implants interfere with anatomical structures or precludes the benefit of spinal surgery.
2. Biological factors such as smoking, use of nonsteroidal anti-inflammatory agents, the use of anticoagulants, etc. all have a negative effect on bony union. Contraindications may be relative or absolute and must be carefully weighed against the patient's entire evaluation.
3. Any condition not described in the Indications for Use.
4. Prior fusion at the level(s) to be treated.

WARNINGS AND PRECAUTIONS

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. The HONOUR™ Spacer System devices should be implanted only by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques. Prior to use, surgeons should be trained in the surgical procedures recommended for use of these devices.
3. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape and design of the implant. Based on the dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of the device.
4. These devices are provided as single use only implants and are not to be reused or reimplanted regardless of an apparent undamaged condition.
5. The HONOUR™ Spacer System is 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.
6. The correct handling of the implant is extremely important. Use care in handling and storage of devices. Store the devices in a clean, dry area away from radiation and extreme temperatures and corrosive environments such as moisture, air, etc.
7. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
8. Components of this system should not be used with components of any other system or manufacturer.
9. The HONOUR™ Spacer System has not been evaluated for safety and compatibility in the MR environment. The HONOUR™ Spacer System has not been tested for heating or migration in the MR environment.
10. Potential risks identified with the use of this system, which may require additional surgery, include: device component breakage, loss of fixation/loosening, non-union, vertebral fracture, neurologic, vascular or visceral injury.

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