Orb™ Cervical Spacer

Surgical Technique Guide

HONOUR™ Spacer System

NEXXT Spine®

70-007 Rev D

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HONOUR™ Spacer System – Cervical

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 ORB™ 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 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

After adequate general anesthesia, the patient is placed in the supine position with the head in slight extension. The mandible is tilted out of the surgical field. The posterior cervical spine is supported to establish and maintain normal lordosis.

Exposure of Operative Level(s)

Access the operative site and retract the tissues using preferred instruments. Retract the muscles, trachea, esophagus and carotid artery to clearly see the vertebral bodies and discs. Insert a marker into the disc(s) and confirm the correct operative level(s) using a lateral radiograph.

Discectomy

Perform a complete discectomy using preferred surgical instruments. Pituitaries, curettes, and thin Kerrison rongeurs may be used to remove the disc material and cartilage to expose the posterior longitudinal ligament. A high-speed burr may be used for removal of posterior osteophytes to achieve neural decompression. The posterior longitudinal ligament may be removed to access and remove any disc material that may be pressing on the neural elements.

Trialing and Endplate Preparation

Once the discectomy is completed; an Orb™ device size is determined by selecting the trial spacer that most adequately fits in the prepared disc space and provides restoration of the disc height *(Fig 1.)*. The trial spacers are 1mm undersized for proper implant fit *(Fig. 3).* 2mm recessed shaft stops may be used to prevent over-insertion of the instrument.

Final end-plate preparation is carried out using a rasp correlating to the trial spacer size *(Fig 2.)*. A rasp may be used to decorticate the end plates with minimal bone removal and help ensure adequate end-plate preparation. 2mm recessed shaft stops may be used to prevent over-insertion of the rasp. Confirm the implant size and height by reinserting the trial after using the corresponding rasp. Once the appropriate height is identified, choose the corresponding Orb™ device.

Fig. 1.

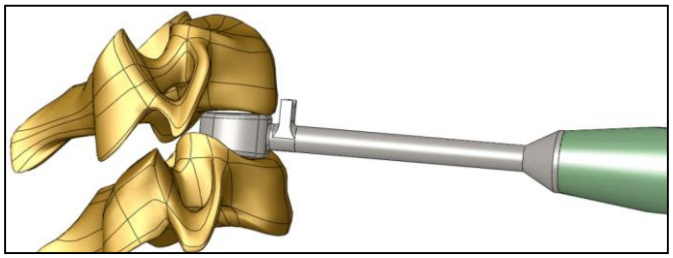
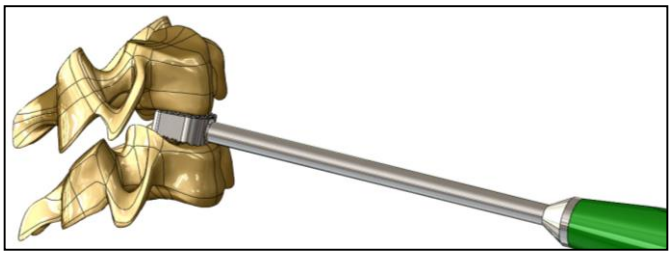


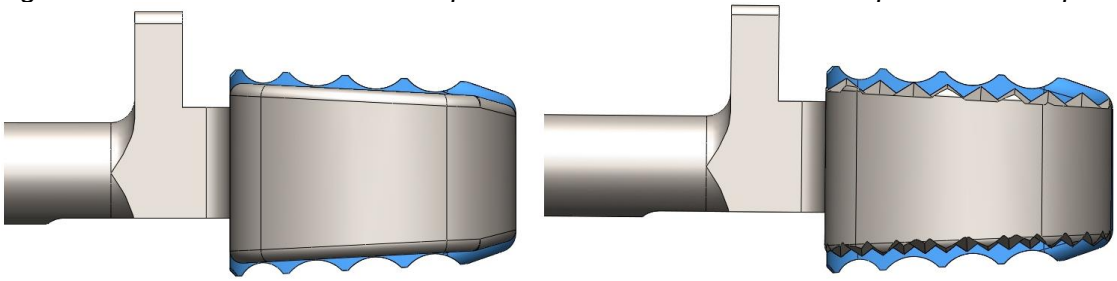
Fig.2



Implant Placement

The implant has 0.5mm ridges (teeth) on superior and inferior aspect and is sized from the surface valley. Trial and rasp heights are to the implant valley *(Fig. 3)*. Select the appropriately sized implant that corresponds to the final trial spacer.

Fig.3 *Trial in front of implant* *Rasp in front of implant*



Attach implant to threaded inserter *(Fig 4.)* and pack the center cavity of the implant with autogenous bone graft material. Insert the implant between the vertebral bodies. It is important to ensure the implant is seated in the midline of the disc space and slightly recessed (implant will be countersunk approximately 2mm). When this is achieved, the radiographic markers will appear according to *(Fig.5. and Fig.6.)* on direct A/P and Lateral fluoroscopic images.

Fig.4

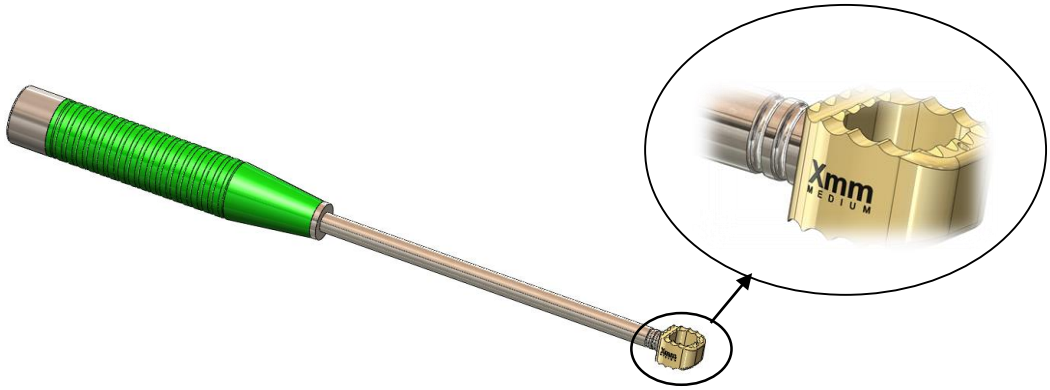


Fig. 5 *Anterior-Posterior fluoroscopic image* *Fig. 6 Lateral fluoroscopic image*

Implant Removal

Removal of the implant can be accomplished by attaching the threaded removal tool into the insertion hole and gently removing the implant. Vertebral bone overgrowth or osteophytes may be removed to facilitate implant retrieval.

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. 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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