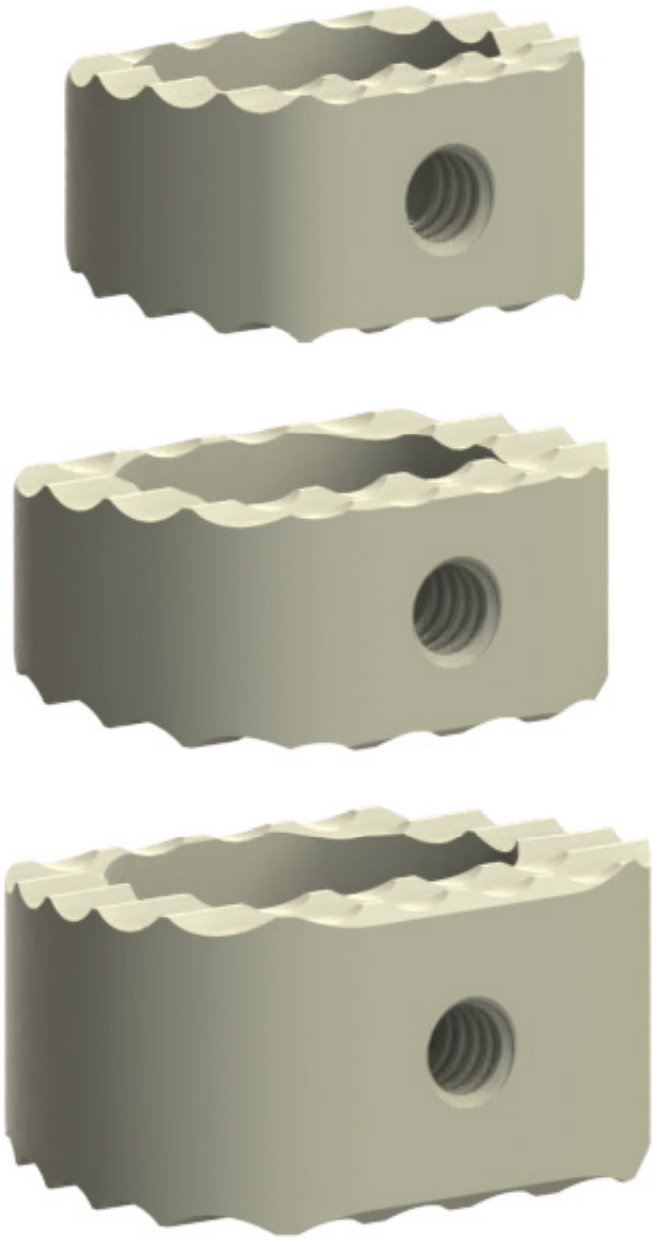
Nexxt Spine

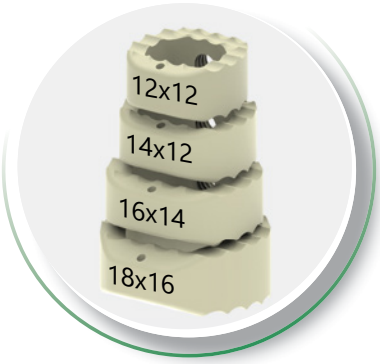
Surgical Technique Guide

HONOUR® ORB

PEEK Cervical Interbody



Simplified Instrumentation
Instruments designed to optimize procedure by reducing steps



Sizing Flexibility
Multiple footprints avaliable with wide range of heights

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70-007, Rev F

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CAUTION: Federal law (USA) restricts this device to sale and use by, or on the order of, a physician.

DISCLAIMER: This document is intended exclusively for physicians and is not intended for laypersons. Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part.

Indications for Use

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 tomaximize bone graft material volume.

INDICATIONS

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 Struxxure® 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 bone 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 lumbar spine (e.g., the Inertia® Pedicle Screw System).

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 im portant. 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.

Surgical Technique Steps

1. Patient Positioning
Following adequate general anesthesia, the patient is placed in the supine position with the head in slight extension (Fig. 1.1). The mandible is tilted out of the surgical field. The posterior cervical spine is supported to establish and maintain normal lordosis.

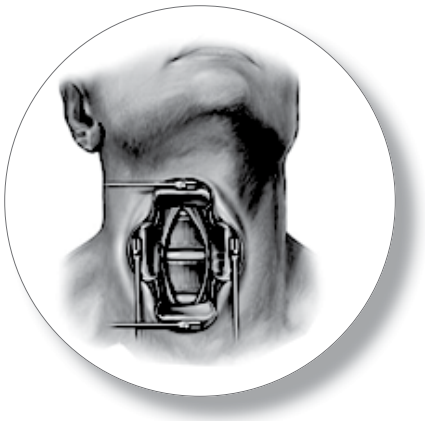


Figure 1.1

2. Exposure of the Operative Levels
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 (Fig. 2.1).

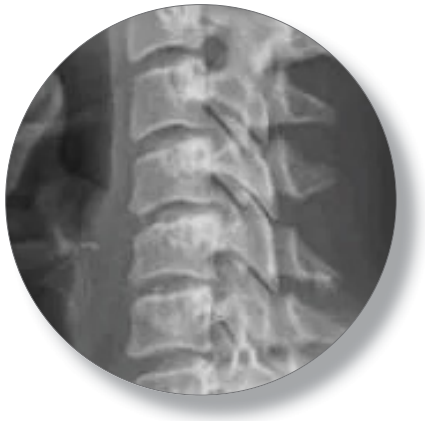


Figure 2.1

3. Discectomy
Perform a complete discectomy using preferred surgical instruments. Pituitaries, curettes, and rongeurs may be used to remove the disc material and cartilage to expose the posterior longitudinal ligament and endplates. A high-speed burr may be used for removal of posterior osteophytes to achieve neural decompression (Fig. 3.1). The posterior longitudinal ligament may be removed to access and remove any disc material that may be pressing on the neural elements.

Figure 3.1

4. Trialing and Endplate Preperation

Final end-plate preparation is carried out using a rasp correlating to the trial spacer size (Fig 4.1). A rasp maybe 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.

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 4.2.). The trial spacers are 1mm undersized for proper implant fit (Fig. 4.3). 2mm recessed shaft stops may be used to prevent over-insertion of the instrument.

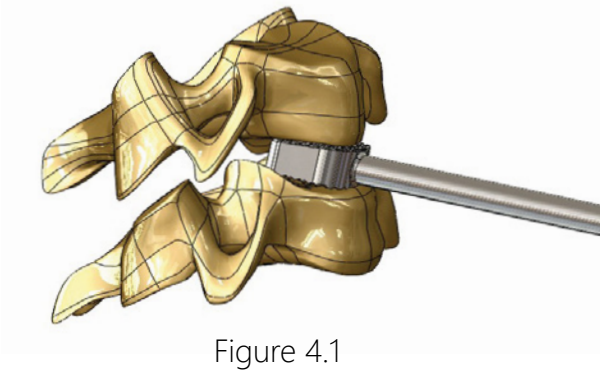


Figure 4.1

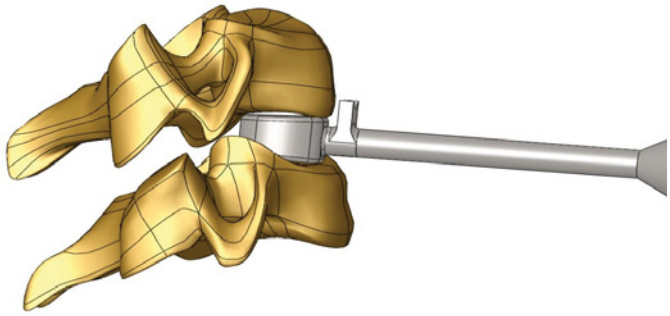
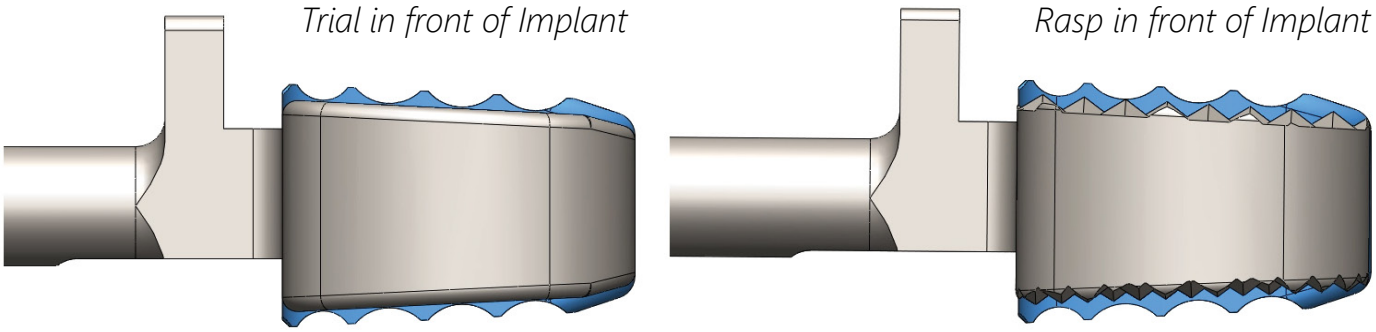


Figure 4.2

The implant has 0.5mm ridges (teeth) on superior and inferior aspects and is sized from the surface valley. Trial and rasp heights are to the implant valley (Fig. 4.3). Select the appropriately sized implant that corresponds to the final trial spacer.



Trials and Rasps are 1mm undersized from HONOUR® implants

Figure 4.3

5. Implant Placement

Attach implant to threaded inserter (Fig 5.1) 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. 5.2. and Fig. 5.3. on direct A/P and Lateral fluoroscopic images.

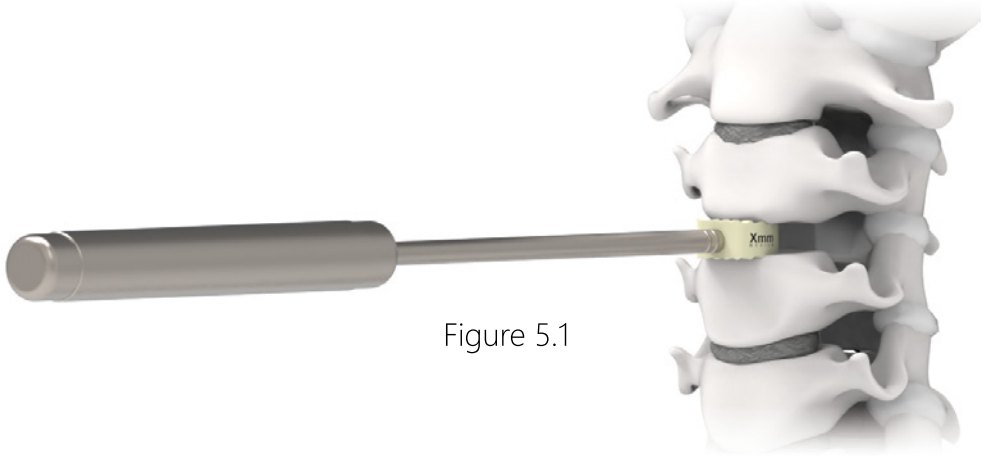
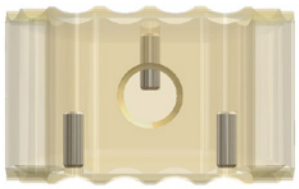
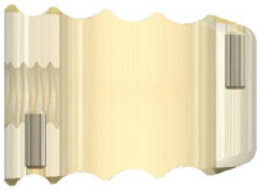


Figure 5.1



Anterior-Posterior fluoroscopic

Figure 5.2



Lateral fluoroscopic

Figure 5.3

6. Implant Removal

Removal of the implant can be accomplished by attaching the threaded removal tool into the insertion hole and gently removing the implant (Fig. 6.1). Vertebral bone overgrowth or osteophytes may be removed to facilitate implant retrieval.

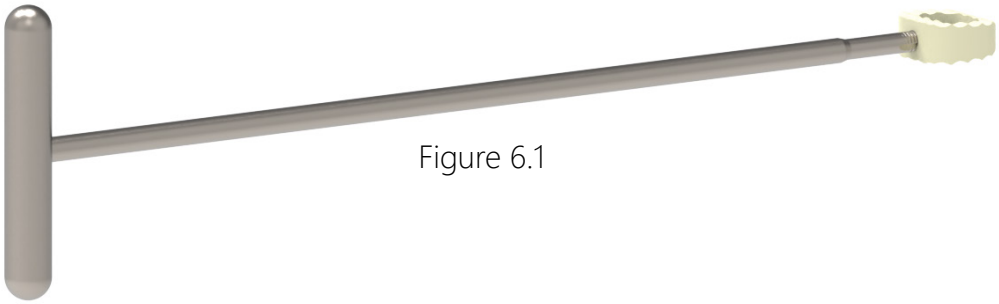


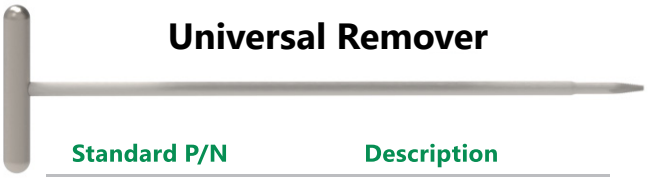
Figure 6.1

PART NUMBERS

Cervical Inserter

Standard P/N	Description
I35-30-01	Cervical, Inserter

Universal Remover



Standard P/N	Description
I35-50-01S	Universal Remover, Short

Cervical Tamps

Standard P/N	Description
I35-08-01-ML	Cervical, Graft Tamp, M/L
I35-40-01	Cervical, Tamp

Cervical Graft Block

Standard P/N	Description
I35-09-01	Cervical, Graft Block

Cervical Rasps

Standard P/N	Description
I35-20M-(05:10)	Cervical, Rasp, 6°, 12x14xHmm
I35-20L-(05:10)	Cervical, Rasp, 6°, 14x16xHmm

Cervical Trials

Standard P/N	Description
I35-10M-(05:10)	Cervical, Trial, 6°, 12x14xHmm
I35-10L-(05:10)	Cervical, Trial, 6°, 14x16xHmm

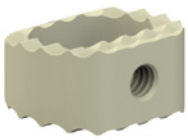
Trial-Drill Guide, Elite (Optional)

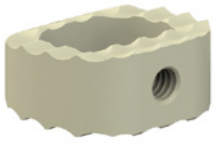
Standard P/N	Description
I35-14-XXXXE-HH	Cervical, Trial Drill Guide Elite 6°

To order this optional instrument set, ask for the *Trial Drill Guide, C35-ELITE Set.*

Not all optional offerings shown. Contact a Nexxt Spine representative to see all footprints and SKUs.

Standard Implants





Standard P/N	Description	QTY
Honour 14Wx12DxH, 6°		
35-1214-050	Cervical, 14x12x5mm	2
35-1214-060	Cervical, 14x12x6mm	3
35-1214-070	Cervical, 14x12x7mm	3
35-1214-080	Cervical, 14x12x8mm	3
35-1214-090	Cervical, 14x12x9mm	2
35-1214-100	Cervical, 14x12x10mm	2

Standard P/N	Description	QTY
Honour 16Wx14DxH, 6°		
35-1416-050	Cervical, 16x14x5mm	2
35-1416-060	Cervical, 16x14x6mm	3
35-1416-070	Cervical, 16x14x7mm	3
35-1416-080	Cervical, 16x14x8mm	3
35-1416-090	Cervical, 16x14x9mm	2
35-1416-100	Cervical, 16x14x10mm	2

Additional Cervical Offerings

SAXXONY®
Cervical Pedicle Screw System

NEXXT MATRIXX®
SA Cervical

NEXXT MATRIXX®
Corpectomy

STRUXXURE®-C & STRUXXURE® MCS
Anterior Cervical Plates

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For indications, contraindications, warnings, precautions, potential adverse effects and patient counseling information, see the package insert or contact your local representative; visit NexxtSpine.com for additional product information.

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