TLIF and TPLIF Lumbar Spacers

Surgical Technique Guide

Honour™ Spacer System
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HONOUR™ Spacer System – TLIF and TPLIF

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 TLIF and TPLIF 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 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 and 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).
Posterior Lumbar Approach/ Decompression and Endplate Preparation – TPLIF

The HONOUR™ Spacer System straight lumbar implants may be used in a transforaminal posterior lumbar interbody fusion (TPLIF) procedure utilizing supplemental internal fixation such as the Inertia® Pedicle Screw System.

Patient Positioning

Following adequate anesthesia, the patient is placed in the prone position 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.

A transforaminal window is created by removing the inferior facet of the cranial vertebra and the superior facet of the caudal vertebra of the appropriate levels. Depending on the approach (unilateral or bilateral), a wide laminectomy is performed, decompressing the thecal sac and nerve roots above and below the target disc space. Direct decompression is completed with unilateral or bilateral near-total facetectomy and foraminotomies.

Protect the dura with a malleable nerve root retractor. A wide annulotomy is performed prior to removing disc material from the disc space. Perform a complete discectomy using preferred surgical instruments such as pituitaries, cup curettes, and thin Kerrison rongeurs. If there is significant disc space collapse, a complete discectomy may not be possible until disc space distraction is accomplished.

The main goal of this step is to provide entry to the disc space for distraction with minimal or no nerve root retraction.

Distraction

Inertia™ Pedicle Screws may be placed above and below the disc space on both sides. The screws can be utilized to distract the disc space. Distract off the screws by positioning the Inertia Distractor between the screw housings. Please refer to the Inertia Surgical Technique for additional information.

Paddle Spreaders (Fig 1.) are available for use for distraction by inserting and rotating 90°. The disc space can be sequentially distracted using the spreaders until the optimal disc height is obtained and the normal foraminal opening is restored.
When optimal disc height is obtained, insert the detachable trial spacer into the disc space. Do not over-distract the disc space or the endplates may be damaged.

**Trialing and Endplate Preparation**

Once the discectomy is completed; an HONOUR™ lumbar straight device size is determined by selecting the detachable trial spacer that most adequately fits in the prepared disc space and provides restoration of the disc height (*Fig 2.*). Overall height of the detachable trial spacers is 1mm shorter than their corresponding implants.

For the bilateral approach, a detachable trial spacer may be in place on one side. Insert the disc preparatory instruments on the contralateral side.

Final endplate preparation is carried out with straight and angled cup curettes, box chisels, shavers or other preferred disc preparatory instruments. The disc preparatory instruments will decorticate the end plates with minimal bone removal and help ensure adequate endplate preparation. Scrape medially under the midline and gradually work laterally in a repetitive sweeping motion until both cephalad and caudal endplates are cleared of soft tissue.

For a bilateral approach, repeat the previous steps on the contralateral side.
Confirm the implant size and height by reinserting the detachable trial after using the preferred disc preparatory instruments. Once the appropriate height is identified, choose the corresponding HONOUR™ TPLIF lumbar straight device.

**Implant Placement**

The thecal sac and exiting nerve root may be gently retracted with a malleable Nerve Root Retractor. Prior to inserting the implant, place autogenous bone graft material anteriorly in the disc space. For a unilateral approach, also place autograft material on the contralateral side of the disc space. Select the appropriately sized implant that corresponds to the final trial spacer. Attach the implant to the threaded inserter and pack the center cavity of the implant with autogenous bone graft material and attach it to the threaded inserter (*Fig 3*). The implant may be inserted between the vertebral bodies vertically or horizontally utilizing the tapered nose. Insert the implant making sure it is fully contained in the disc space. If inserted horizontally, then turn the implant 90° into a vertical position. Implant may be guided to final proper position using positioning tamps. When the final position is achieved for the unilateral approach, the radiographic markers will appear as shown in *Fig.4* on direct A/P and Lateral fluoroscopic images.

*Fig. 3*

If performing a bilateral surgery, leave enough space beneath the annulotomy to allow for placement of the contralateral implant. Repeat implant autograft material packing and insertion instructions. The radiographic markers for a bilateral approach will appear according to (*Fig.5*) on direct A/P and Lateral fluoroscopic images.

*Fig. 4 Unilateral AP View*  
*Unilateral Lateral View*

*Fig. 5 Bilateral AP View*  
*Bilateral Lateral View*
Pack autogenous bone graft material into the disc space surrounding the implant(s).

**Implant Removal**

Removal of the implant can be accomplished by attaching Threaded Implant Inserter and gently removing the implant. Insert a removal hook or similar into the implant if implant removal is difficult.

**Posterior Lumbar Approach/ Decompression and Endplate Preparation – TLIF**

The HONOUR™ Spacer System Fusion curved implants are designed for a transforaminal lumbar interbody fusion (TLIF) procedure utilizing supplemental internal fixation such as the Inertia® Pedicle Screw System.

**Patient Positioning**

Following adequate anesthesia, the patient is placed in the prone position 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.

A unilateral hemilaminectomy for access to the intervertebral disc space is performed.

Protect the dura with a malleable nerve root retractor. A wide annulotomy is performed prior to removing disc material from the disc space. Perform a complete discectomy using preferred surgical instruments. Pituitaries, cup curettes, and thin Kerrison rongeurs may be used to remove the disc material. If there is significant disc space collapse, a complete discectomy may not be possible until disc space distraction is accomplished.

The main goal of this step is to provide entry to the disc space for distraction with minimal or no nerve root retraction.

**Distraction**

Inertia Pedicle Screws may be placed above and below the disc space on one side. The screws can be utilized to distract the disc space. Distract off the screws by positioning the Inertia Distractor between the screw housings. Please refer to the Inertia™ Surgical Technique for additional information.
Insert the trial spacer (Fig 6.) horizontally into the disc space and verify trial spacer depth insertion by using the depth mark etchings.

Fig. 6 Trial Spacer

Trialing and Endplate Preparation

Once the discectomy is completed; an HONOUR™ Lumbar Curved 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. The maximum height of the trial spacers are 1mm undersized when compared to the corresponding implant.

Final endplate preparation is carried out with straight and angled cup curettes, box chisels, shavers or other preferred disc preparatory instruments. The disc preparatory instruments will decorticate the end plates with minimal bone removal and help ensure adequate endplate preparation. Scrape medially under the midline and gradually work laterally in a repetitive sweeping motion until both cephalad and caudal endplates are cleared of soft tissue.

Confirm the implant size and height by reinserting the trial after using the preferred disc preparatory instruments. Once the appropriate height is identified, choose the corresponding HONOUR™ TLIF Lumbar Curved device.

Implant Placement

The thecal sac and exiting nerve root may be gently retracted with the malleable Nerve Root Retractor. Prior to inserting the implant, place autogenous bone graft material anteriorly in the disc space. Also place autograft material on the contralateral side of the disc space.

Select the appropriately sized implant that corresponds to the final trial spacer. Attach the implant to the threaded inserter and pack the center cavity of the implant with autogenous bone graft material and attach it to the threaded inserter, (Fig 7).

Fig. 7
Insert the implant between the vertebral bodies. A guided rail that corresponds to the final trial spacer height may be used to facilitate implant insertion and placement (Fig 8.).

Fig. 8

Implant may be guided to final proper position using positioning tamps. Once final implant placement is achieved, the radiographic markers will appear according to (Fig. 9) on direct A/P and Lateral fluoroscopic images.

Fig. 9  AP Fluoro View  Lateral Fluoro View

Pack autogenous bone graft material into the disc space surrounding the implant(s).

Implant Removal

Removal of the implant can be accomplished by attaching the Threaded Implant Inserter and gently removing the implant. Insert a removal hook or similar into the implant if implant removal is difficult.
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.