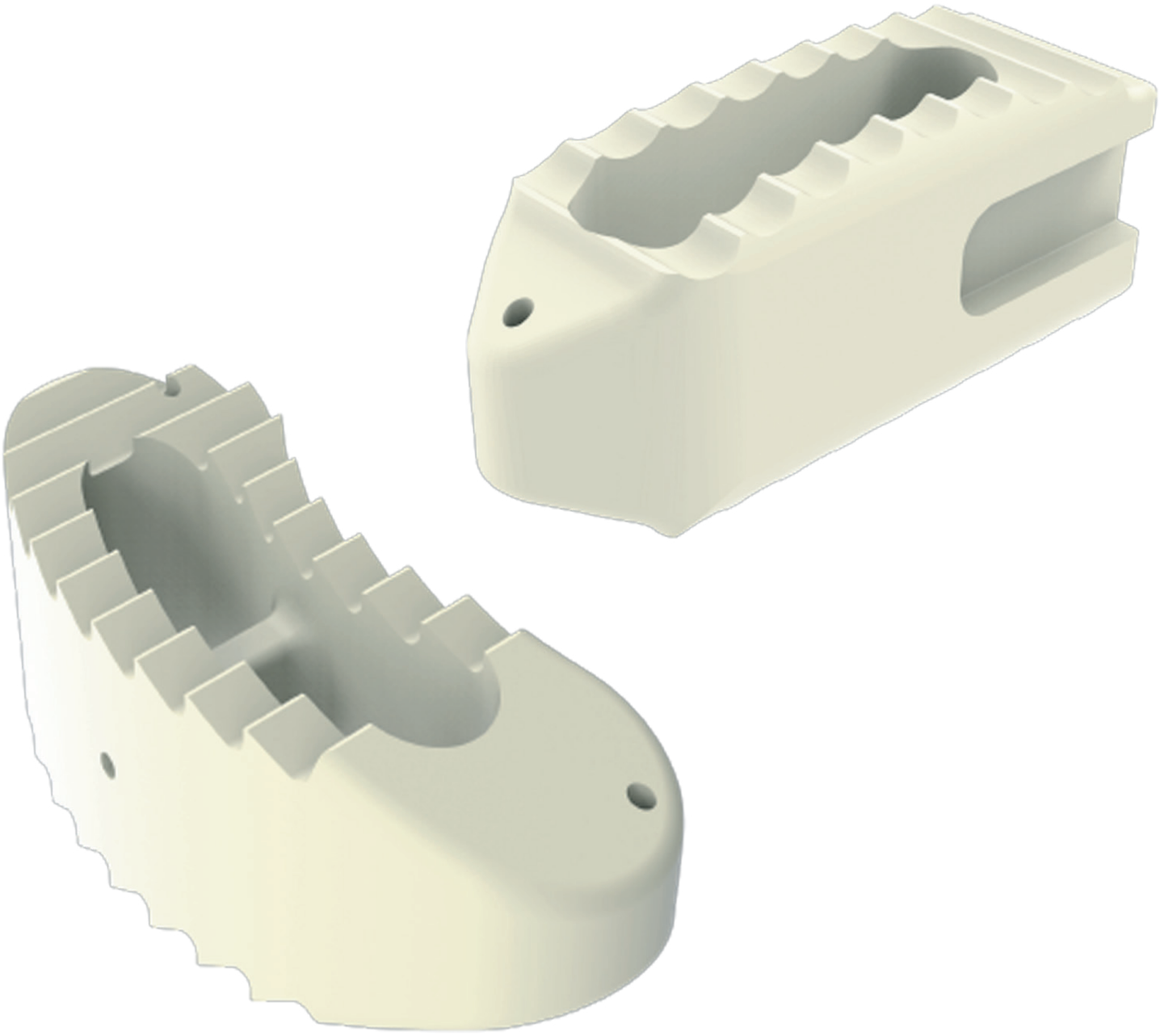
HONOUR®

tPLIF / TLIF Interbodies



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

HONOUR® Spacer System - TLIF and tPLIF

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.

Figure 1

PATIENT POSITIONING

Following adequate general anesthesia, the patient is placed in the prone position on a radiolucent spine table (Fig. 1). Particular attention is applied to the positioning of the head and extremities to lessen the risk of ocular and nerve compression.

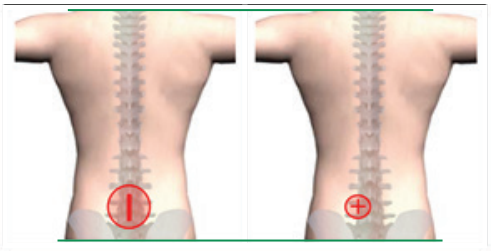


Figure 2

EXPOSURE OF OPERATIVE LEVEL(S)

Identify the affected level(s) using fluoroscopic imaging and palpation of the targeted anatomy (Fig. 2). Access the operative site using preferred instruments. Tissues should be retracted enough to allow for exposure and visualization of the targeted disc space. Insert a marker into the disc(s) to confirm the correct operative level(s) using a lateral radiograph (Fig. 3).

NOTE: HONOUR® TLIF/tPLIF Interbodies are indicated for use at up to two contiguous levels in the lumbar spine, from L2-S1.

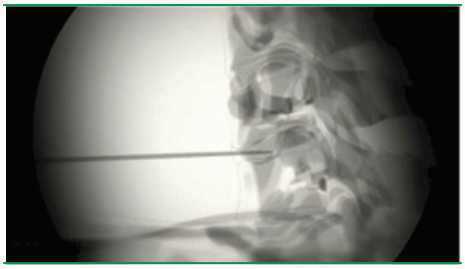


Figure 3

DISCECTOMY

Perform a complete discectomy using preferred surgical instruments. Pituitaries, cup curettes, rongeurs and interspace shavers may be used to remove the disc material (Fig. 4). 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.

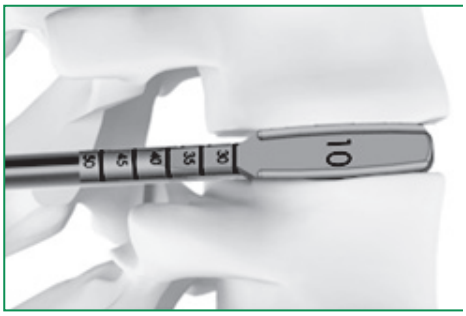


Figure 4

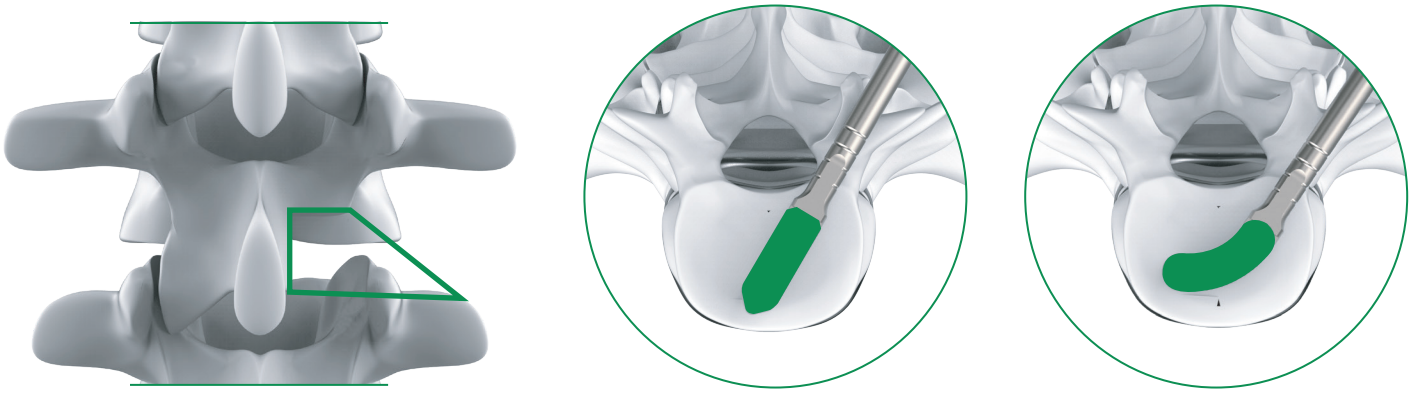
DISTRACTION

Effective distraction aids in removal of the superior articular process, decompression of the neuroforamen, preparation of the disc space and insertion of the implant. This may be accomplished through several techniques: pedicle screw distraction, distraction between boney elements, and/or distraction with Paddle Distractors (Fig. 5).

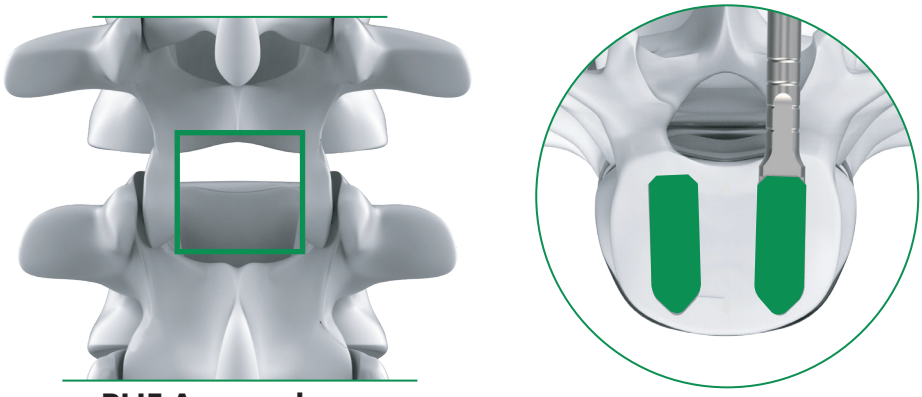
Figure 5

DECOMPRESSION

Utilizing osteotomes and rongeurs, a small section of the lamina and facet(s) should be removed to create an appropriately sized bony window for access to the targeted disc space (Fig. 6). Preserve decorticated bone to pack in or around implant prior to implantation.



TLIF or tPLIF Approach **tPLIF** **TLIF**



PLIF Approach

Figure 6

TRIALING AND ENDPLATE PREPARATION - LUMBAR STRAIGHT

Once the discectomy is completed; an HONOUR® lumbar straight 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. Overall height of the trial spacers is 1mm shorter than their corresponding implants.

For the bilateral approach, a 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. 7). 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. 8 on direct A/P and Lateral fluoroscopic images.

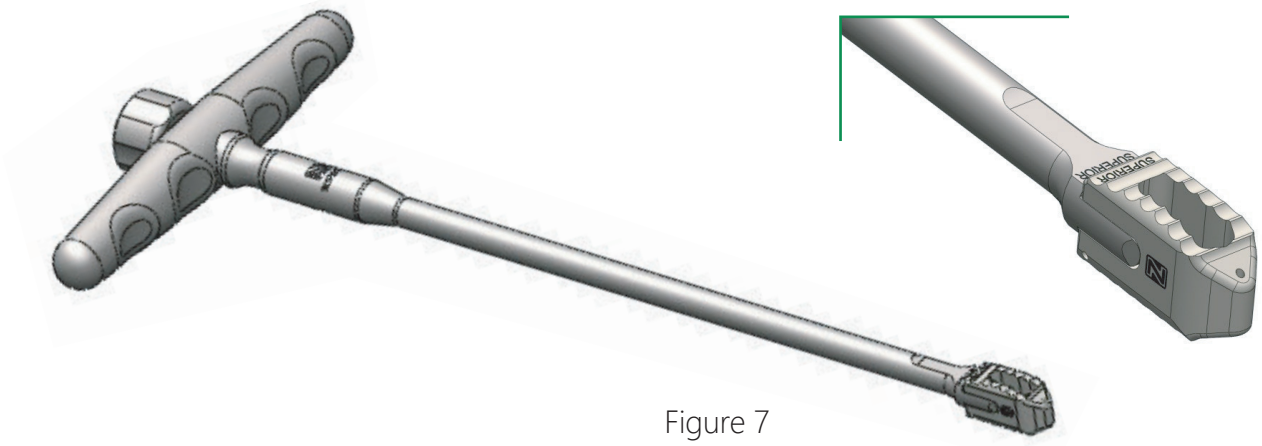


Figure 7

Unilateral AP View

Unilateral Lateral View

Figure 8

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. 9) on direct A/P and Lateral fluoroscopic images.

Bilateral AP View

Bilateral Lateral View

Figure 9

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.

TRIALING AND ENDPLATE PREPARATION - LUMBAR CURVED

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. 10).

Figure 10

Insert the implant between the vertebral bodies. 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. 11) on direct A/P and Lateral fluoroscopic images.

Figure 11

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.

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 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 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.

HONOUR® IMPLANT PRODUCT NUMBERS

HONOUR® TLIF

Standard P/N	Description
15-1030-07L	Honour, TLIF, Lordotic, 30mm L x 10mm W x 7mm H
15-1030-08L	Honour, TLIF, Lordotic, 30mm L x 10mm W x 8mm H
15-1030-09L	Honour, TLIF, Lordotic, 30mm L x 10mm W x 9mm H
15-1030-10L	Honour, TLIF, Lordotic, 30mm L x 10mm W x 10mm H
15-1030-11L	Honour, TLIF, Lordotic, 30mm L x 10mm W x 11mm H
15-1030-12L	Honour, TLIF, Lordotic, 30mm L x 10mm W x 12mm H
15-1030-13L	Honour, TLIF, Lordotic, 30mm L x 10mm W x 13mm H
15-1027-06L/15L*	Honour, TLIF, Lordotic, 30mm L x 10mm W x 6,14/15mm H
15-1030-06L,14L/15L*	Honour, TLIF, Parallel, 30mm L x 10mm W x 6/15mm H
15-1030-06P/15P*	Honour, TLIF, Lordotic, 27mm L x 10mm W x 6/15mm H
15-1033-06L/15L*	Honour, TLIF, Lordotic, 33mm L x 10mm W x 6/15mm H
15-1036-06L/15L*	Honour, TLIF, Lordotic, 36mm L x 10mm W x 6/15mm H

*Optional

HONOUR® TLIF EZ

16-3110-07L	Honour, TLIF EZ, Lordotic, 31Lx10Wx7H mm
16-3110-08L	Honour, TLIF EZ, Lordotic, 31Lx10Wx8H mm
16-3110-09L	Honour, TLIF EZ, Lordotic, 31Lx10Wx9H mm
16-3110-10L	Honour, TLIF EZ, Lordotic, 31Lx10Wx10H mm
16-3110-11L	Honour, TLIF EZ, Lordotic, 31Lx10Wx11H mm
16-3110-12L	Honour, TLIF EZ, Lordotic, 31Lx10Wx12H mm
16-3110-13L	Honour, TLIF EZ, Lordotic, 31Lx10Wx13H mm
16-3110-06L,14L/17L*	Honour, TLIF EZ, Lordotic, 31Lx10Wx6,14/17H mm
16-3110-07P/17P*	Honour, TLIF EZ, Parallel, 31Lx10Wx7/17H mm
16-2810-07L/17L*	Honour, TLIF EZ, Lordotic, 28Lx10Wx7/17H mm
16-2810-07P/17L*	Honour, TLIF EZ, Parallel, 28Lx10Wx7/17H mm
16-3410-07L/17L*	Honour, TLIF EZ, Lordotic, 34Lx10Wx7/17H mm
16-3410-07P/17P*	Honour, TLIF EZ, Parallel, 34Lx10Wx7H/17 mm

*Optional

HONOUR® tPLIF

21-269-06*	Honour, tPLIF, Straight, 26mm L x 9mm W x 6mm H
21-269-07	Honour, tPLIF, Straight, 26mm L x 9mm W x 7mm H
21-269-08	Honour, tPLIF, Straight, 26mm L x 9mm W x 8mm H
21-269-09	Honour, tPLIF, Straight, 26mm L x 9mm W x 9mm H
21-269-10	Honour, tPLIF, Straight, 26mm L x 9mm W x 10mm H
21-269-11	Honour, tPLIF, Straight, 26mm L x 9mm W x 11mm H
21-269-12	Honour, tPLIF, Straight, 26mm L x 9mm W x 12mm H
21-269-13	Honour, tPLIF, Straight, 26mm L x 9mm W x 13mm H
21-269-14	Honour, tPLIF, Straight, 26mm L x 9mm W x 14mm H
21-269-15/17*	Honour, tPLIF, Straight, 26mm L x 9mm W x 15/17mm H
21-229-06/17*	Honour, tPLIF, Straight, 22mm L x 9mm W x 6/17mm H
21-2810-06/17*	Honour, tPLIF, Straight, 28mm L x 10mm W x 6/17mm H
21-3010-06/17*	Honour, tPLIF, Straight, 30mm L x 10mm W x 6/17mm H
21-3210-06/17*	Honour, tPLIF, Straight, 32mm L x 10mm W x 6/17mm H
21-3410-06/17*	Honour, tPLIF, Straight, 34mm L x 10mm W x 6/17mm H

*Optional

HONOUR® INSTRUMENT PRODUCT NUMBERS

I21-269-XX tPLIF Trial

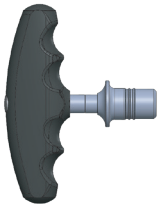
I15-XXL-XX TLIF Trial Lordotic

I15-XXP-XX TLIF Trial Parallel*

I15-01-01, TLIF, Implant Inserter

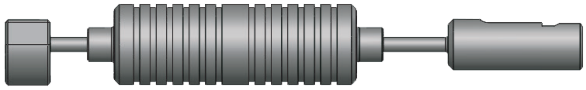
I21-01-01, Honour, tPLIF, Implant Inserter

I10-01-43, T-Handle, Silicone, Hudson Connect



I10-01-34, T-Handle, Silicone, Hudson Connect*

I21-01-02, Slap Hammer



I15-09-01, TLIF Tamp

I21-09-01, Implant Tamp, 90 degree

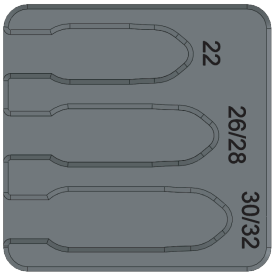
I21-09-02, Implant Tamp, Straight

I35-50-01L, Universal Remover, Long

I40-09-05, Bone Funnel: 7mm

I40-09-06, Bone Plunger: 7mm

I21-02-01, Graft Block - tPLIF



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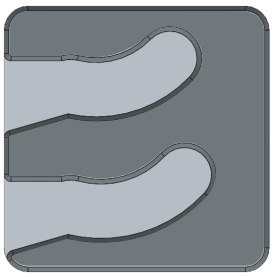

I21-08-01, Graft Packing Tool

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