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The HONOUR® Spacer System is a collection of radiolucent implant devices constructed of medical grade polyetheretherketone with tantalum markers as described in ASTM F-2026 and ASTM F-560. TLIF 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 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).
The HONOUR® Spacer System 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.
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.

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.
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.

Endplate preparation is carried out with straight or angled cup curettes, box chisels, shavers or other preferred disc preparatory instruments. The disc preparatory instruments will decorticate the endplates 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.
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 to account for tooth height.

Insert the trial spacer (Fig 1.) horizontally into the disc space and verify trial spacer depth insertion by using the depth mark etchings.
Place autogenous bone graft material anteriorly in the disc space prior to inserting the implant. 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 2). A graft block and graft packing tool may be used to pack the implant.

Insert the implant between the vertebral bodies. Implant may be guided to final proper position using positioning tamps. An offset tamp with a pivoting knub can be used to rotate the implant to the final position (Fig 3).

Once final implant placement is achieved, the radiographic markers will appear according to (Fig 4) on direct A/P and Lateral fluoroscopic images.

Pack autogenous bone graft material into the disc space surrounding the implant(s).
Removal of the implant can be accomplished by attaching the Threaded Implant Inserter or Universal Removal Tool and gently removing the implant. Insert a removal hook or similar into the implant if implant removal is difficult.
Lordotic Trials | Universal Removal Tool

Implant Caddy | Implant Inserters (2)

Hudson Connect T-Handles (2) | Bone Funnel

Graft Block | Bone Plunger

Graft Packing Tool | Straight Tamp and Rotating Tamp
Honour® Disc Prep Tray

1. Interspace Shavers (7mm-14mm)
2. Paddle Distractors (7mm-14mm)
3. Hudson Connection T-Handles
4. Cup Curettes (selection of sizes)
When used as a lumbar intervertebral fusion device, the HONOUR®
Cervical Plate System) cleared for use in the cervical spine (e.g., the STRUXXURE® Anterior
with autogenous bone graft and with supplemental fixation systems
by history and radiographic studies. The device is intended for use
pain of discogenic origin with degeneration of the disc confirmed
operative treatment for the treatment of degenerative disc disease
C2-T1, in skeletally mature patients who have had six weeks of non-
struxure® Anterior
Cervical Plate System).

When used as a cervical intervertebral fusion device, the HONOUR®
devices are indicated for use at one level in the cervical spine, from
images, or precludes the benefit of spinal surgery. The HONOUR®
radiolucent implant 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.

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 STRUXXURE® Anterior
Cervical Plate System).

When used as a lumbar intervertebral fusion 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
nerve roots, 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).

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
nerve roots, 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).

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-
flammatory 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.

Before using product, read the following important information
This booklet is designed to assist in using the Honour Spacer System. It is not a reference for surgical techniques.

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

General description
The HONOUR Spacer System is a collection of radiolucent implant
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 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 STRUXXURE® Anterior
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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-
flammatory 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.

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. 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.

Potential adverse effects
Potential complications and adverse effects for this system are
similar to those of other spinal instrumentation systems and include,
but are not limited to: pseudarthrosis, insufficient bone stock, painful
bursa, pressure necrosis, palpable components, early or late loosening
of the components; disassembly, bending or breakage of any or all
of the components; foreign body (allergic) reaction to the implants;
infections possible requiring removal of devices; loss of neurological
function, including paralysis, spinal cord impingement or damage.
CLEANING AND DECONTAMINATION
All implants and instruments must first be cleaned using established hospital methods before sterilization and introduction into a sterile surgical field. Refer to the Nexxt Spine Reprocessing Instructions for Reusable Instruments document available at:


or by calling 317-436-7801 for the detailed cleaning instructions.

STERILIZATION
Unless specifically labeled sterile, the implants and instruments are supplied NONSTERILE and MUST be sterilized prior to use. Recommended sterilization methods include steam autoclaving after removal of all protective packaging and labeling. Prior to sterilization, verify that all instruments are in their open and unlocked position within the instrument tray(s). The use of an FDA cleared sterilization wrap is recommended. The following:

<table>
<thead>
<tr>
<th>Method</th>
<th>Steam</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cycle:</td>
<td>Prevacuum</td>
</tr>
<tr>
<td>Temperature:</td>
<td>270°F (132°C)</td>
</tr>
<tr>
<td>Exposure Time:</td>
<td>4 minutes</td>
</tr>
<tr>
<td>Drying Time:</td>
<td>30 minutes</td>
</tr>
</tbody>
</table>

INSTRUCTIONS FOR USE
The HONOUR® Spacer System should only be implanted by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques.

Refer to HONOUR® Spacer System Surgical Techniques for complete instructions for use. For product information or to obtain a copy of the surgical technique manual, please contact Nexxt Spine customer service by phone, 317-436-7801.

INSTRUCTIONS:

PREOPERATIVE
1. Preoperative instructions to the patient are essential. The adverse effects, warnings, precautions and limitations should be understood by the surgeon and explained to the patient prior to the surgery.
2. Only patients that meet the criteria described in the indications should be selected.
3. Correct selection of the implant is extremely important. An adequate inventory of sizes should be available at the time of surgery.
4. Patient conditions and/or predispositions such as those mentioned in the Contraindications, Precautions and Warnings should be avoided.
5. The surgeon should be familiar with the use and handling of all components and instruments of the system prior to surgery.
6. Proper function of the surgical instruments and components should be verified prior to every surgical procedure. All instruments and components must be sterilized before use.

INTRAOPERATIVE
1. The primary goal of this surgery is to arthodese selected vertebrae. Adequate exposure, bony preparation, and grafting are essential to this result.
2. The placement of the Nexxt Spine HONOUR® Spacer System devices should be checked radiographically.
3. Care should be taken when positioning the implants to avoid neurological damage. Extreme caution should be used around the spinal cord and nerve roots.

INTRAOPERATIVE

POSTOPERATIVE
1. Adequately instruct the patient on postoperative care, use and limitations and potential complications. Successful healing depends on postoperative care and the patient's ability and willingness to follow instructions.
2. The patient must be made aware of the limitations of the implant and that physical activity and load bearing may cause premature loosening, bending or fracture of the internal fixation device. The patient should be warned to avoid falls, sudden jolts, mechanical vibrations, and lifting, twisting motions and restrict any type of sport participation. An active, debilitated, or uncooperative patient who cannot properly restrict activities may be at particular risk during postoperative rehabilitation.
3. If a nonunion develops, or if the implants loosen, fracture, corrode, migrate, cause pain, or stress, the device(s) should be evaluated, revised and/or removed. Patients with evidence of these conditions should be closely observed, the possibilities of further deterioration evaluated, and the benefits of reduced activity, revision or removal considered.
4. Periodic X-rays for at least the first year postoperatively are recommended to detect any evidence of nonunion, changes in position, loosening, bending or cracking of components.
5. Any retrieved devices must never be reused under any circumstances.

PRODUCT COMPLAINTS
The customer or health care provider should report any dissatisfaction with the product quality, labeling, or performance to Nexxt Spine immediately. Nexxt Spine should be notified immediately of any product malfunction by telephone, fax or written correspondence. When filing a complaint, the name, part number and lot number of the part should be provided along with the name and address of the person filing the complaint.

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