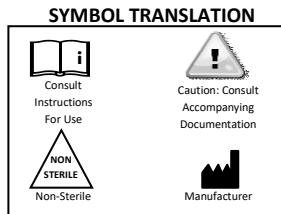


NEXXT Spine

HONOUR® SPACER SYSTEM



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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 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 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 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.
- 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.
- Any condition not described in the Indications for Use.
- Prior fusion at the level(s) to be treated.

WARNINGS AND PRECAUTIONS

- Mixing of dissimilar metals can accelerate the corrosion process. Stainless steel and titanium implants must NOT be used together in building a construct.
- 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.
- 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.
- These devices are provided as single use only implants and are not to be reused or reimplanted regardless of an apparent undamaged condition.
- 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.
- 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.
- Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
- Components of this system should not be used with components of any other system or manufacturer.
- 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.
- 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 www.NexxtSpine.com/Resources/Instructions-For-Use 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 validated steam autoclave cycle is recommended:

| Method | Cycle | Temperature | Exposure Time | Dry Time |
|--------|------------|----------------|---------------|------------|
| Steam | Pre-Vacuum | 270° F (132°C) | 4 Minutes | 30 Minutes |

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

- 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.
- Only patients that meet the criteria described in the indications should be selected.
- Correct selection of the implant is extremely important. An adequate inventory of sizes should be available at the time of surgery.
- Patient conditions and/or predispositions such as those mentioned in the Contraindications, Precautions and Warnings should be avoided.
- The surgeon should be familiar with the use and handling of all components and instruments of the system prior to surgery.
- 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

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

POSTOPERATIVE

- 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.
- 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.
- 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.
- 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.
- 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.

MANUFACTURED BY:

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