INTERVERTEBRAL BODY FUSION DEVICES

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CAUTION

Federal Law restricts this device to sale by or on the order of a Physician Please contact company for product inquiries and surgical techniques, or to report any adverse experience.

Single Use only

DESCRIPTION

The Spinal Elements intervertebral body fusion devices are used to maintain disc space distraction in skeletally mature adults requiring intervertebral body fusion. They are designed to be used in conjunction with supplemental spinal fixation instrumentation. The series is comprised of cages of various fixed heights and shapes for placement in the cervical or lumbar spine. There are different cages designed for specific regions of the spine and approaches to the spine. Each cage has a hollow center to allow placement of autograft inside of the cage. Ridges on the superior and inferior surfaces of the device help to grip the endplates and prevent expulsion.

The Spinal Elements intervertebral body fusion devices are made from the PEEK-Optima® radiolucent material with embedded tantalum x-ray markers as specified in ASTM F2026 and ASTM F560, respectively.

INDICATIONS

Stingray Cervical Cages are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Stingray Cervical Cages are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach at the C3 to T1 disc levels using autograft bone. Stingray Cervical Cages are to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

The Spinal Elements Lumbar Cages are indicated for intervertebral body spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). Spinal Elements Lumbar Cage implants are to be used with autogenous bone graft. The Spinal Elements Lumbar Cage is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage. Patients with previous non-fusion spinal surgery at involved level may be treated with the device.

PRECAUTIONS

Intervertebral body fusion should only be undertaken after the surgeon has had hands-on training in these methods of spinal fixation, and has become thoroughly knowledgeable about spinal anatomy and biomechanics. Surgical technique manuals are available for detailed instructions on the correct use of the Spinal Elements cages. The contents of these manuals alone are not adequate for complete instruction in the use of this system. Even for surgeons already experienced in spinal instrumentation and intervertebral body fusion procedures, new skills may be required that are best learned by working with an experienced surgeon or through a course of formal instruction with laboratory training. Lack of experience or expertise with these implants may result in complications. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

The Spinal Elements intervertebral body fusion devices can break during insertion if subjected to excessive force. Based on fatigue testing results, when using the Spinal Elements intervertebral body fusion devices, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this system.

CONTRAINDICATIONS

Spondylolisthesis higher than grade I (not for the use with a pedicle screw fixation system)
Reduced bone density, which does not guarantee a sufficient resting stability (e. g. osteoporosis)
Fractures
Tumors
Scoliosis
Active infection
Allergy to tantalum or PEEK
Signs of local inflammation
Fever or leukocytosis
Morbid obesity
Pregnancy
Mental illness
Suspected or documented allergy or intolerance to composite materials
Any case not needing a fusion
Any case not described in the indications
Any patient unwilling to cooperate with postoperative instructions
Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery
These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth
Spondylolisthesis unable to be reduced to Grade 1
Any case where the implant components selected for use would be too large or too small to achieve a successful result
Any case that requires the mixing of metals from two different components or systems
Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality
Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance
Prior fusion at the level to be treated
Any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count

POSSIBLE ADVERSE EFFECTS

Note: A further surgery might become necessary to correct adverse effects. This list may not include all complications caused by the surgical procedure itself.
Bending or fracture of implant. Loosening of the implant.
Implant material sensitivity, or allergic reaction to a foreign body.
Infection, early or late.
Decrease in bone density due to stress shielding.
Pain, discomfort, or abnormal sensations due to the presence of the device.
Nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, radicular pain, tethering of nerves in scar tissue, muscle weakness, and paraesthesia.
Vascular damage could result in catastrophic or fatal bleeding. Malpositioned implants adjacent to large arteries or veins could cause erosion of these vessels and catastrophic bleeding in the later postoperative period.
Dural tears experienced during surgery could result in need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis.
Bursitis.
Paralysis.
Death.
Spinal cord impingement or damage.
Fracture of bony structures.
Reflex sympathetic dystrophy.

If a pseudarthrodesis occurs coupled with the Spinal Elements cages, a mechanical grinding action could possibly occur which might generate wear debris. Most types of wear debris have shown the potential of initiating local osteolysis in articulating joints.
Degenerative changes or instability in segments adjacent to fused vertebral levels.

WARNING: An entirely satisfactory result is not always achieved in every surgical case. This particularly applies to spinal surgery, in which numerous external factors may compromise the results. Patients with previous spinal surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery. The
risk of device expulsion and migration is higher without the use of supplemental fixation. The use of dissimilar materials (e.g., titanium
and stainless steel) should not be used together because of the risk of galvanic corrosion. The components of the Spinal Elements intervertebral body fusion devices should not be used with components of other systems. The Spinal Elements intervertebral body fusion devices have not been evaluated for safety and compatibility in the MR environment. The Spinal Elements intervertebral body fusion devices have not been tested for heating or migration in the MR environment.

MAGNETIC RESONANCE ENVIRONMENT

Intervertebral Fusion Devices have not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

CLEANING OF INSTRUMENTS

Clean all instruments prior to use, and as soon as possible after use. Do not allow blood and debris to dry on the instruments. If cleaning must be delayed, place instruments in a covered container with appropriate detergent or enzymatic solution to delay drying.
Loosen and/or disassemble instruments with removable parts.
Manual cleaning is recommended using a neutral pH detergent prepared in accordance with manufacturer's

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instructions and utilizing a mechanical aid such as a brush. Particular attention should be taken to remove all debris from instruments with cannulations and holes. Pay particular attention to all crevices, recesses, pivots or threads on the devices.

If ultrasonic cleaners and/or washer decontamination equipment are used, follow equipment manufactures recommended practices. Spinal Elements recommends performing manual cleaning prior to using automated cleaning equipment. Avoid excessively acidic or alkaline solutions.

Conduct a final verification of the cleaning process by visually inspecting the device under normal room lighting conditions to verify that all of the foreign material has been removed.

STERILIZATION

Implants and instruments of the Spinal Elements intervertebral body fusion devices are supplied clean and NOT STERILE. ISO 8828 or AORN recommended practices for in-hospital sterilization should be followed for all components. In a properly functioning calibrated steam sterilizer effective sterilization may be achieved using the following parameters:

Method	Steam
Cycle	Pre-Vacuum
Temperature	270°F (132°C)
Exposure Time	6 Minutes
Pulses	4
Drying Time	N/A if unwrapped, 40 minutes if wrapped

Note: During sterilization cycles where the tray is being wrapped, the device should be used only in conjunction with FDA cleared wrap indicated for sterilization cycles.

Manufacturer: SPINAL ELEMENTS
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SYMBOL	USED FOR	SYMBOL	USED FOR
	Single Use ONLY	NON STERILE	Non-sterile
LOT	Lot Number	REF	Catalog number
	Manufacturer	QTY	Quantity
Spinalelements.com	Instruction for Use		Date of Manufacture
MAT	Material		Caution, Consult Accompanying Document