Vu L•POD™ - English

Rx Only Caution: Federal Law restricts this device to sale by or on the order of physician

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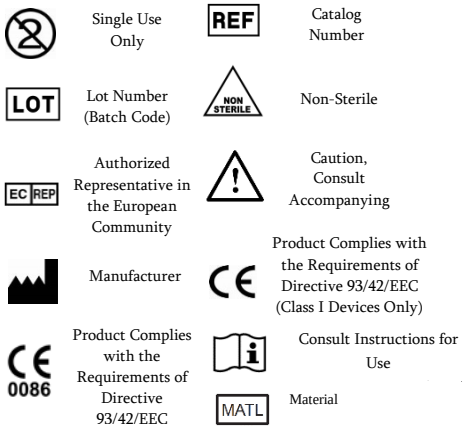

DESCRIPTION

The Vu L•POD™ Intervertebral Body Fusion Devices are comprised of PEEK-OPTIMA® LT1 cages with fenestrations and radii on all sides and toothed ridges. The toothed ridges of the concave cages engage with the superior and inferior end plates of the neighboring vertebral bodies to resist rotation and migration.

INDICATIONS FOR USE

When used as an intervertebral body fusion device, the Vu L•POD Intervertebral Body Fusion Device is indicated for use as an adjunct to fusion in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). The device is indicated for use with autograft only. The Vu L•POD Intervertebral Body Fusion Devices are intended for use with supplemental fixation. Degenerative disc disease (DDD) is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

When used as a vertebral body replacement (VBR) the Vu L•POD System is indicated for use in the thoracolumbar spine (TI-L5) to replace a collapsed, damaged or otherwise unstable vertebral body due to tumor or trauma (i.e. fracture). The Vu L•POD VBR System is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. The device is indicated for use with autograft or allograft only. The Vu L•POD VBR System is intended for use with supplemental internal spinal fixation.

IMPLANT MATERIALS

Polyetheretherketone (PEEK-OPTIMA LT1) polymer per ASTM F2026 and tantalum per ASTM F560

CONTRAINDICATIONS

Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery is a contraindication. The following conditions may reduce the chance of a successful outcome and should be taken into consideration by the surgeon. This list is not exhaustive:

- Absolute contraindications:
  - Infection in or around the operative site
  - Allergy or sensitivity to implant materials
  - Any case not described in the indication
- Relative contraindications:
  - Local inflammation
  - Morbid obesity
  - Pregnancy
  - Fever or leukocytosis
  - Prior fusion at the level(s) to be treated
  - Grossly distorted anatomy due to congenital abnormalities
  - Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis
  - Elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count
  - Any case not requiring bone graft and fusion or where fracture healing is not required
  - Patients having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition
  - Unsuitable or insufficient bone support
  - Bone immaturity
  - The patient's activity level, mental condition, occupation and/or a patient unwilling to cooperate with the postoperative instructions
  - Any case where implant utilization would interfere with anatomical structures or expected physiological performance
  - Use of incompatible components and/or materials from other systems

POSSIBLE ADVERSE EVENTS

Like other spinal system implants, the following adverse events are possible. This list is not exhaustive:

- Delayed union or nonunion (pseudarthrosis)
- Bending, disassembly or fracture of implant and components
- Loosening of spinal fixation implants may occur due to inadequate initial fixation, latent infection, and/or premature loading, possibly resulting in bone erosion, migration or pain
- Pain, discomfort, or abnormal sensations due to the presence of the device
- Pressure on skin where inadequate tissue coverage exists over the implant, with potential extrusion through the skin.
- Dural leak requiring surgical repair.
- Cessation of growth of the fused portion of the spine.
- Subsidence of the implant into adjacent bone.
- Loss of proper spinal curvature, correction, height and/or reduction.
- Increased biomechanical stress on adjacent levels.
- Improper surgical placement of the implant causing stress shielding of the graft or fusion mass.
- Intraoperative fissure, fracture, or perforation of the spine.
- Postoperative fracture due to trauma, defects, or poor bone stock.
- Serious complications associated with any surgery may occur. These include, but are not limited to: wound complications, infection, genitourinary disorders, gastrointestinal disorders, vascular disorders, including thrombus; bronchopulmonary disorders, including emboli; bursitis, hemorrhage, myocardial infarction, paralysis or death.

WARNINGS AND PRECAUTIONS

- Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without previous surgery. The safety and effectiveness of spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the spine secondary to severe spondylolisthesis, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other condition is unknown.
- The implantation of this system should be performed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient.
- Based on the fatigue testing results, the surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system
- Ensure all implants, components or instruments are sterilized prior surgery. The use of non-sterile devices may lead to inflammation, infection or disease.
- Implants should never be reused under any circumstances. A used implant should be discarded. While the implant may appear undamaged, it may have small defects or internal stress patterns and if implanted, could fail to perform as intended and pose safety risks to the patient. The risks include, but are not limited to, mechanical failure, breakage, difficulty with implantation, incompatibility with mating components and infection.

MRI SAFETY

This device has 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 this device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

CLEANING AND DECONTAMINATION

All instruments and implants that have been previously taken into a sterile surgical field must be decontaminated and cleaned using established hospital methods before sterilization and reintroduction into the sterile surgical field. The following recommendations are for the manual cleaning and decontamination of surgical instruments. These recommendations are considered guidelines with the ultimate responsibility for verifying adequate cleaning remaining with the user. Automated cleaning systems differ between hospitals and therefore must be qualified by the hospital.

Manual Cleaning Procedure

1	Remove all gross visible soil with a damp gauze pad or wipe.
2	Prepare an enzymatic cleaning solution (such as Prolystica® 2X Enzymatic) per manufacturer's instructions.
3	Immerse the instruments in the cleaning solution and actuate all features so the enzymatic cleaner contacts all mated surfaces and soak for 15 minutes.
4	Transfer the instruments to fresh cleaning solution (such as Prolystica® 2X Enzymatic). Thoroughly scrub all instruments with a soft bristle cleaning brush while immersed in the enzymatic cleaning solution. Be sure that thorough scrubbing also includes any lumens with an appropriate size brush. Actuate device to allow access to hard to reach areas.
5	Thoroughly rinse all instruments with warm running water and dry with a clean cloth and/or allow to air dry.

Automated Cleaning Procedure

1	Remove all gross visible soil with a damp gauze pad or wipe. Special attention will be required to examine products with tight crevices, voids, and lumens. Lumens may require pre-cleaning with dampened soft bristle brushes and tight crevices, voids, lumens should be flushed with a syringe.
2	Prepare an enzymatic cleaning solution (such as Prolystica® 2X) per manufacturer's instructions. Immerse the instruments in the cleaning solution and actuate all features so the enzymatic cleaner contacts all mated surfaces and soak for 15 minutes.
3	Transfer items to a washer and run a cycle with the parameters listed in the following steps.
4	PRE-WASH: Cold tap water [*2 minutes*].
5	ENZYME WASH: Enzyme wash using cleaner (such as Prolystica® 2X Enzymatic) per manufacturer's recommendations, hot tap water [*4 minutes*].
6	DETERGENT WASH: Detergent wash using detergent (such as Prolystica® 2X Alkaline) per manufacturer's recommendations, hot tap water (66°C/150°F) [*2 minutes*].
7	RINSE 1: Rinse, hot tap water [*2 minutes*].
8	RINSE 2: Purified water rinse (66°C/150°F) [*15 seconds*].
9	DRYING: Hot air dry (82°C/180°F) [*12 minutes*].
10	Remove items from the washer and remove any residual moisture with a lint free clean cloth.

STERILIZATION

Vu L•POD and any instrumentation used with the implant must must be sterilized by the hospital prior to surgery.

Double wrap trays using FDA-cleared sterilization wraps (2 wraps). The recommended sterilization cycle will provide a Sterility Assurance Level of (SAL 10^{-6}). Following AAMI ST79 guidelines, the validated sterilization cycle for a fully loaded tray is:

Method	Steam
Cycle	Pre-vacuum
Temperature and Exposure Time	270°F (132°C) for 4 minutes
Drying Time	30 minutes

PACKAGING

All packages containing implants should be sealed and intact upon receipt. If the package or product is damaged, the product should not be used and should be returned. The product must be handled, stored, and opened in such a way that it is protected from inadvertent damage or contamination. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components should be carefully checked for damage before use.

SURGICAL TECHNIQUE

This package insert is designed to assist in using the product and is not intended to provide information on surgical technique. Contact a SeaSpine Representative, customerservice@seaspine.com or +1-760-727-8399 for a Surgical Technique Guide.

IMPLANT SELECTION

Verify that all parts and necessary instruments are present prior to surgery, including sizes larger and smaller than those that are expected for use. The construct should be assembled prior to surgery.

PREOPERATIVE WARNINGS

- Only patients that meet the criteria described in the indications should be selected.
- Patient condition and/or predispositions such as those described in the contraindications should be avoided.
- Care should be used in the handling and storage of the implants. The implants should not be scratched or damaged. Implants and instruments should be protected during storage and from corrosive environments.
- All non-sterile parts should be cleaned and sterilized before use. Additional sterile components should be available in case of unexpected need.
- Devices should be inspected for damage prior to implantation.
- Care should be used during surgical procedures to prevent damage to the device(s) and injury to the patient.

INTRAOPERATIVE WARNINGS

- Consult Surgical Technique Guide for system specific intraoperative warnings, precautions and recommendations.
- Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological function.
- Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
- Unless otherwise described in the indications, autogenous bone graft must be placed in the area to be fused and the graft must be in contact with viable bone.
- Implants and components should not be bent, reshaped, contoured or otherwise modified.
- Use great care to ensure that the implant surfaces are not scratched or notched which may reduce the functional strength of the construct.

POSTOPERATIVE WARNINGS

- Surgeons should advise patients regarding the risks of surgery and the importance of post-operative compliance.
- The patient should be advised to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation.
- The patient should be advised that implants may bend, break or loosen despite restriction in activity.
- The patient should be advised to avoid mechanical vibrations that may loosen the device.
- The patient should be advised not to smoke or consume alcohol during recovery.

COMPLAINTS

Immediately notify SeaSpine or a SeaSpine representative by phone, fax or email regarding complaints, malfunctions or adverse events associated with this product. When possible, retain the product involved in the complaint and return to SeaSpine as instructed by SeaSpine Customer Service.

PRODUCT INFORMATION DISCLOSURE

SeaSpine has exercised reasonable care in the selection of materials and the manufacture of these products. SeaSpine warrants to the original purchaser only that each new SeaSpine product is free from manufacturing defects in material and workmanship under normal use and service for a period of six (6) months from the date of delivery by SeaSpine to the original purchaser, but in no event beyond the expiration date stated on any product labeling. SEASPINE DISCLAIMS ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, WRITTEN OR ORAL (INCLUDING BUT NOT LIMITED TO ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). Further, this warranty shall not apply to, and SeaSpine shall not be responsible for, any loss arising in connection with the purchase or use of any SeaSpine product that has been repaired by anyone other than an authorized SeaSpine service representative or altered in any way so as, in SeaSpine's judgment, to affect its stability or reliability, or which has been subject to misuse, negligence or accident, or which has been used otherwise than in accordance with these instructions. IN NO EVENT SHALL SEASPINE BE LIABLE FOR ANY SPECIAL, INCIDENTAL CONSEQUENTIAL, OR CONTINGENT LOSS, DAMAGE, OR EXPENSE, DIRECTLY OR INDIRECTLY ARISING FROM ACQUISITION OR USE OF THIS PRODUCT. SeaSpine neither assumes nor authorizes any person to assume for it any other additional liability or responsibility in connection with this product. SeaSpine intends that this device should be used only by physicians having received proper training in the use of the device. This product comprises PEEK-OPTIMA® LT1 polymer from INVIBIO®