Interbody Cage

INSTRUCTIONS FOR USE

CAUTION: Federal (USA) Law restricts this device to sale by or on the order of a physician.

DEVICE DESCRIPTION
The Interbody Cage is a spinal intervertebral fusion device made from polyetheretherketone, (Zeniva PEEK ZA-500, Solvay Advanced Polymers or Vestakeep i4R, Evonik Degussa) or from titanium alloy, Titanium 6Al4V. It is provided in a variety of footprint sizes and heights in 1mm size increments. When made from PEEK, it has radiographic marker pins made from tantalum.

INDICATIONS
The Interbody Cage is indicated for use with autogenous bone graft 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 I spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain 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. These implants may be implanted via an open or minimally invasive posterior approach. Alternatively, these implants may also be implanted via an anterior and/or transforaminal approach. These devices are intended to be used with supplemental fixation instrumentation which has been cleared by the FDA for use in the lumbar spine.

CONTRAINDICATIONS
The Interbody Cage should not be implanted in patients with active systemic infection or infection localized to the site of implantation. The Interbody Cage is not indicated for prior fusion at the level to be treated.

WARNINGS
• Use as indicated. The safety and effectiveness when implanted in the spine for any other indications has not been established.

PRECAUTIONS
• Use of the Interbody Cage should only be undertaken after the surgeon has become thoroughly knowledgeable about spinal anatomy and biomechanics; has had experience with lumbar fusion procedures and lumbar fixation; and has had hands-on training in the use of this device.

• For all styles of Interbody Cage except the PLIF Cage, one Interbody Cage should be implanted at each surgical level. When using the PLIF Cage, two Interbody Cages may be implanted per level.
• The Interbody Cage should not be implanted in patients with severe osteoporosis or osteopenia.
• The surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.
• The Interbody Cage is supplied non-sterile. It must be sterilized before use.
• Implant components can break when subjected to the increased loading associated with delayed union or nonunion.
• Patients with previous spinal surgery at the level to be treated may have different outcomes compared to those without previous surgery.

The following potential adverse events (singly or in combination) could also result from the implantation of the Interbody Cage :

1. Bursitis.
2. Decrease in bone density due to stress shielding.
3. Degenerative changes or instability of segments adjacent to fused vertebral levels
4. Fracture of bony structures.
5. Implant material sensitivity, or allergic reaction to a foreign body.
6. Infection, early or late.
7. 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.
8. Nonunion, delayed union.
9. Discomfort, or abnormal sensations due to the presence of the device.
10. Paralysis.
11. Spinal cord impingement or damage.
12.Vascular damage could result in catastrophic or fatal bleeding
13. Death.

Caution: implants made from titanium and stainless steel should not be used together.

The components from this system should nto be combined with the components from any other system or manufacturer.

INFORMATION FOR PRESCRIBERS
• Correct selection of the appropriate implant size is important.
• Surgical implants must never be reused or re-implanted. Even though the device appears undamaged, it may have defects and internal stresses that may lead to early breakage.

HOW SUPPLIED
The Interbody Cage is supplied non-sterile.

RECOMMENDATIONS FOR STEAM STERILIZATION:
The individual products are recommended to be steam sterilized by the hospital in a gravity-displacement autoclave cycle at 270°F (132°C) for a minimum of 3 minutes exposure time with a 1 minute drying time.

Using a prevacuum cycle, an exposure time of 4 minutes at 132°C (270 °F) should be the minimum used, followed by a drying time of at least 20 minutes. Please note that drying times will be variable for different conditions, steam quality, total mass in the sterilizer, and varying cool down time. The user should perform inspections to confirm that products have been appropriately dried, and adjust drying time if required. Only FDA-cleared wraps should be used. Additionally the user should adhere to their standard sterilization validation procedures

The fully loaded implant and instrument trays are recommended to be steam sterilized by the hospital using an FDA cleared wrap in a gravity-displacement autoclave cycle at 270°F (132°C) for a minimum of 15 minutes of exposure with a 30 minute drying time.

These sterilization recommendations follow the guidelines for sterilization per ANSI/AAMI ST79.

Remove all packaging materials prior to sterilization.

Use only sterile products in the operating field.

CLEANING AND DECONTAMINATION
Any instruments that have been taken into a sterile field must be decontaminated and cleaned before re-sterilizing and re-introducing them into a sterile surgical field.

- Remove all gross visible soil with a damp gauze pad or wipe.
- Prepare an enzymatic cleaning solution per the manufacturer's instructions. Immerse the instruments in the cleaning solution. Instruments composed of multiple separable components should be disassembled prior to cleaning. In the PLIF Cage system, this includes the device inserter. This device may be disassembled and re-assembled by rotating the tightening knob until the thread is disengaged (disassembly) or re-engaged (assembly).

- Ultrasonically clean the instruments for while immersed in the cleaning solution for at least 15 minutes.
-Transfer the instruments to fresh enzymatic cleaning solution. Thoroughly scrub the instruments with a soft bristle cleaning brush while immersed in the solution. Scrubbing must also include any lumens with an appropriate sized round brush.
-Thoroughly clean the instruments.
-Rinse all instruments with warm running water and dry with a clean cloth and/or allow to air dry.
-Verify that all instruments are visually clean. If not, repeat the cleaning process from the beginning until they are clean.

Please note that certain cleaning solutions, such as those containing formalin, glutaraldehyde, caustic soda, bleach, or alkaline cleaners may damage some device, particularly some instruments and instrument trays. These solutions should not be used.

MRI COMPATIBILITY:
"The Interbody Cage has not been evaluated for safety and compatibility in the MR environment. The Interbody Cage has not been tested for heating or migration in the MR environment."

PACKAGING:
The implants are delivered in packages. These must be intact at the time of receipt.

The systems are sometimes supplied as a complete set: implants and instruments are arranged on trays and placed in specially-designed storage boxes.

SURGICAL TECHNIQUE MANUAL:
To view or download the surgical technique manual, please visit www.teslake.com.

MANUFACTURED BY:
Teslake, Inc.
Rochester, New York 14625
888-262-2817