Spine Innovation Interbody System INSTRUCTIONS FOR USE

DESCRIPTION

The **Interbody System** is an intervertebral body fusion device intended to stabilize the spinal segment to promote fusion. Implants are available in a variety of lengths, heights, widths, and lordotic angles to accommodate patient anatomy. The **Interbody System** implants are supplied sterile, and instruments are supplied non-sterile. For prescription use only.

TITANIUM IMPLANT MATERIALS
Commercially Pure Titanium
Titanium-6Al-4V

PEEK IMPLANT MATERIALS
Polyetheretherketone
Titanium-6Al-4V
Tantalum

INDICATIONS

The **Interbody System** is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels in the lumbar spine (L2 to S1). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. These patients may have had a previous non-fusion spinal surgery at the involved level(s). The **Interbody System** is intended for use with autograft and is intended for use with supplemental fixation. Patients must have undergone a regimen of at least six months of non-operative treatment prior to being treated with the **Interbody System**.

CONTRAINDICATIONS

Contraindications include but are not limited to:

1. Infection
2. Signs of local inflammation
3. Fever
4. Morbid obesity
5. Pregnancy
6. Patients that refuse to follow post-operative instructions
7. Spondylolisthesis unable to be reduced to Grade 1
8. Prior fusion at the treated level

POTENTIAL ADVERSE EVENTS

1. Implant migration
2. Stress shielding or bone fracture
3. Breakage of the device
4. Infection
5. Non-union or delayed union
6. Nerve damage
7. Vascular damage, hematoma or hemorrhage of blood vessels
8. Paralysis
9. Death

WARNINGS

- The **Interbody System** should not be used in patients with severe osteoporosis or osteomalacia

PRECAUTIONS

- Use of the **Interbody System** 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 sufficient training in the use of this device.
- The correct choice of the implant height, footprint and lordosis for each patient is crucial to the success of the procedure.
- The surgeon should consider the levels of implantation, patient weight, activity level, and other patient conditions, etc. which may impact the performance of the system.
- Patients with a previous spinal surgery at the affected level may have different outcomes than those without a previous surgery.
- Instruments are provided non-sterile. The user facility must sterilize them before use.
- Implants are provided sterile and must never be re-used or re-implanted.
- Physician's postoperative directions to the patient and corresponding patient compliance are extremely important. Detailed instructions on the use and limitations of the device should be given to the patient. The patient must be warned that loosening, and/or breakage of the device(s) are complications which may occur as a result of early or excessive muscular activity or sudden jolts or shock to the spine.

CLEANING AND DECONTAMINATION

All **Interbody System** 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. Contaminated devices should be wiped clean of visible soil at the point of use prior to transfer to a central processing unit for cleaning and sterilization. Contaminated devices must be cleaned promptly after use per these instructions to minimize contaminants drying and ensure an effective cleaning.

Cleaning and decontamination must include the use of neutral cleaners followed by a Critical water rinse. Instruments and cases may be processed using manual cleaning and/or automated cleaning with manual pre-cleaning using the steps listed below.

Preparation prior to cleaning:

- Instrument handles are attached to Interbody System instruments in the operating room. Ensure all **Interbody System** instrument handles are separated from the other instruments. Handles may be removed by pulling the handle trigger toward the handle in one hand and removing the instrument from the handle with a second hand. No further disassembly of handles or instruments is required. To prevent injury, separate pointed and sharp instruments and place them in a separate tray.

Manual cleaning method:

1. Rinse soiled instruments under running cold tap water. Actuate all instruments through their full range of motion. While rinsing, remove all visible soil with a damp gauze pad, wipe, or soft-bristled brush. Flush hard-to-reach areas with a syringe for at least one minute until rinse water is clear. Wrap instruments with a wet cloth soaked in Utility water.
2. Prepare an enzymatic cleaning solution at 1 oz/gallon using cold tap water. Immerse all instruments in the cleaning solution. Thoroughly scrub all instruments with a soft bristled brush while immersed in the solution to prevent aerosolization of contaminants. Scrubbing must also include any lumens with an appropriately sized round brush or flushing with a syringe and Utility water. Actuate joints, handles, and other movable instrument features to expose areas to the cleaning solution at least three times.
3. Thoroughly rinse all instruments under Utility water. Wrap all instruments in a wet cloth soaked with Utility water.
4. Prepare a fresh enzymatic cleaning solution per the manufacturer's instructions in a sonicator. Transfer all instruments to the fresh enzymatic cleaning solution in the sonicator. Actuate all instruments through their full range of motion. Flush hard-to reach areas using a syringe for at least one minute until rinse water is clear. Ultrasonically clean all instruments while immersed in the cleaning solution for at least 15 minutes.
5. Remove all instruments from the cleaning solution and rinse all instruments thoroughly with Critical water. Actuate all movable parts through their full range of motion. Flush all hard-to-reach areas with a syringe for at least one minute until rinse water is clear.
6. Verify that all instruments are visually clean; if not, repeat the cleaning process from the beginning until all instruments are clean.
7. Dry instruments with a clean, dry, and soft cloth, with clean compressed air, and/or air-dry.

Automated cleaning method (Note: the washer/disinfector should fulfill the requirements specified in ISO 15883):

1. Rinse soiled instruments under running cold tap water. Actuate all instruments through their full range of motion. While rinsing, remove all visible soil with a damp gauze pad, wipe, or soft-bristled brush (Spectrum M16). Flush hard-to-reach areas with a syringe for at least one minute until rinse water is clear. Wrap all instruments in a wet cloth soaked with Utility water.
2. Transfer all instruments into the washer for processing.
3. Pre-wash with cold Utility water for 2 minutes.
4. Wash with an enzymatic cleaning of Enzol 1 oz/gallon at "High" level motor speed for 10 minutes.
5. Rinse with hot Utility water for 2 minutes.
6. Rinse with Critical water at ≥ 66°C for 2 minutes.
7. Thermally disinfect at ≥ 94°C for 7 minutes.
8. Dry at ≥ 90°C for 7 minutes.

Note: Certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some instruments; these solutions should not be used.

STERILIZATION

All **Interbody System** implants are packaged in a double layered container and delivered sterilized through methods of ethylene oxide gas.

All **Interbody System** instruments are provided non-sterile. The implants and instruments are recommended to be steam sterilized by the hospital using an FDA cleared wrap using the following parameters:

Method	Exposure Temperature	Exposure Time	Min. Dry Time
Gravity Displacement	121°C (250°F)	30 min	40 min
Pre Vacuum	132°C (270°F)	4 min	30 min

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.

The distributor and manufacturer accept no responsibility for sterilization procedures performed by the customer that are not performed according to these recommendations.

MRI COMPATIBILITY

The **Interbody System** implant has not been evaluated for safety and compatibility in the MR environment. The **Titanium Interbody System** implant has not been tested for heating or migration in the MR environment.

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FURTHER INFORMATION

Never re-use or reprocess an **Interbody System** implant. Although the device may appear undamaged, internal stresses or other small defects may not be visible and may lead to early breakage. Discard implant after use.

The surgical technique contains further information on the **Interbody System** device and may be obtained by contacting *Spine Innovation*.

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