CURITEVA

INSPIRE™ POROUS PEEK
LUMBAR INTERBODY FUSION SYSTEM
INSTRUCTIONS FOR USE

Carefully read all instructions and be familiar with the surgical technique(s) prior to using this product.

DESCRIPTION:

The Inspire Porous PEEK Lumbar Interbody Fusion System consists of interbody fusion cages that are generally rectangle-shaped with an open central chamber to permit packing with bone graft to facilitate fusion. The superior and inferior surfaces of the construct have a pattern of teeth to provide increased stability and to help prevent movement of the device.

The Inspire Porous PEEK Lumbar Interbody Fusion System implants are manufactured from PEEK (per ASTM F2026) with Titanium alloy markers (Ti-6Al-4V) that conform to ASTM F136. Each implant has been surface treated with a thin hydroxyapatite (HA) coating. All implants are provided sterile-packed and are intended for single use only.

INDICATIONS FOR USE:

The Inspire Porous PEEK Lumbar Interbody Fusion System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 – S1. DDD is defined as back pain of discogenic origin 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). Implants are intended to be used with autograft and/or allograft bone (comprised of cancellous and/or corticocancellous bone graft) or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion and supplemental spinal fixation systems that have been cleared for use in the lumbar spine. Patients should receive at least six (6) months of non-operative treatment prior to treatment with the device.

CONTRAINDICATIONS:

Contraindications for the Inspire Porous PEEK Lumbar Interbody Fusion System are comparable to those of other systems of similar design, and include, but are not limited to:

- Patients with probable intolerance to the materials used in the manufacture of this device.
- Patients with infection, inflammation, fever, tumors, elevated white blood count, obesity, pregnancy, substance abuse, mental illness and other medical conditions which would prohibit beneficial surgical outcome.
- Patients unwilling or unable to follow post-operative restrictions on movement, especially in athletic and occupational activities.
- Use with components from other systems, or in any case requiring the mixing of metals from different components.
- Grossly distorted anatomy caused by congenital abnormalities.
- Any neuromuscular deficit which places an unusually heavy load on the device during the healing process.
- Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
- Rapid joint disease, bone absorption, osteopenia. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, the amount of mechanical fixation, and/or the quality of the bone graft.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- 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.
- Any case not described in the indications for use.
- Reuse or multiple uses of the implants.

CAUTIONS, PRECAUTIONS, WARNINGS and POSSIBLE ADVERSE EFFECTS:

Cautions:

Mixing of dissimilar metals can accelerate the corrosion process. Do NOT use titanium and/or cobalt chromium with stainless steel in the same implant construct.

Do not use components of the Inspire Porous PEEK Lumbar Interbody Fusion System with components from any other manufacturer.

Care must be taken to protect the components from being marred, nicked or notched as a result of contact with other objects. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.

As with all orthopedic implants, none of the Inspire Porous PEEK Lumbar Interbody Fusion System components should ever be reused under any circumstances.

Precautions:

The implantation of properly selected and placed system implants and components should be performed only by experienced spinal surgeons with specific training in the use of this spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Patients who smoke have been shown to have an increased incidence of non-union. These patients should be advised of this fact and warned of the consequences. Other poor candidates for spine fusion include obese, malnourished, those with poor muscle and bone quality, and nerve paralysis patients.

Due to the presence of implants, interference with roentgenographic, CT and/or MR imaging may result. The Inspire Porous PEEK Lumbar Interbody Fusion System 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 the Inspire Porous PEEK Lumbar Interbody Fusion System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Warnings:

The safety and effectiveness of lumbar interbody fusion systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. The safety and effectiveness of these devices for any other conditions are unknown.

This device system is not intended to be the sole means of spinal support. Its use without a bone graft, for instance, or in cases that develop into a non-union may not be successful. No spinal implant can withstand the loads of the body without maturation of a solid fusion mass, and in this case, bending, loosening or fracture of the implant will eventually occur. The proper selection and compliance of the patient will greatly affect the results.

The implantation of spinal systems should be performed only by spinal surgeons fully experienced in the surgical techniques required for the use of such implants. Even with the use of spinal implants, a successful result in terms of pain, function, or fusion is not always achieved in every surgical case.

The physician is the learned intermediary between the company and the patient. The indications, contraindications, warnings, and precautions given in this document must be conveyed to the patient. If requested, additional information, including surgical technique manuals, may be obtained through Curiteva customer support representatives.

All implants are provided sterile-packed and are intended for single use only. Do not use the implant if the package is opened or damaged or if the expiration date has passed.

Possible Adverse Effects:

Pre-operatively, the patient should be made aware of the following possible adverse effects of spinal implant surgery. Additional surgery may be necessary to correct some of these effects, including but not limited to:

- Early or late loosening of any or all of the components
- Disassembly, bending, and/or breakage of any or all of the components
- Foreign body (allergic) reaction to the implants including possible tumor migration
- Skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site which may result in skin breakdown and/or wound complications
- Pressure on the skin from components where there is inadequate tissue coverage
- Loss of proper spinal curvature, correction, height, and/or reduction
- Infection
- Hemorrhage of blood vessels and/or hematomas
- Fracture, micro-fracture, resorption, damage, or penetration of any spinal bone at, above, and/or below the level of surgery
- Non-union (pseudarthrosis), mal-union or delayed union
- Loss of neurological function (e.g., bowel or bladder dysfunction), appearance of radiculopathy, and/or development of pain
- Neurovascular compromise including paralysis or other types of serious injuries
- Gastrointestinal and/or reproductive system compromise, including sterility
- Cessation of growth of the fused portion of the spine
- Death

GENERAL:

Single Use Only: Never reuse an implant. Any implant that has been twisted, bent, or implanted, then removed, even if it appears intact, must be discarded. These devices are provided as single use only.

Patient Education: It is essential to provide preoperative instructions to the patient. S/he should be made aware of the potential risks of the surgery and the implant limitations. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken or loose implant components. The patient must be made aware that implant components may bend, break, or loosen even though restrictions in activity are followed.

CLEANING OF SYSTEM COMPONENTS:

All system components, including reusable instruments and trays, must be thoroughly clean before sterilization

and introduction into a sterile surgical field. Implants are provided clean and sterile-packed. If an implant has been in contact with the patient, body fluids or tissues or is damaged, it may NOT be reprocessed and MUST be properly discarded.

Cleaning must be performed by personnel trained in the general procedures involving contaminant removal. Automated washer / disinfector systems should not be used as the sole cleaning method. An automated system may be used in addition to the following validated manual cleaning procedure.

Note: Certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or alkaline cleaners may damage some devices, particularly instruments/trays; these solutions should not be used. Also, certain instruments may require disassembly before cleaning. All products should be treated with care. Improper use and handling may lead to damage and possible improper functioning of the device.

1. Thoroughly clean all system components as soon as possible after use (within a maximum of 2 hours post-operation is recommended). Do not allow blood and debris to dry on the instruments/trays.

2. Loosen and/or disassemble instruments with movable and/or removable parts as required. Ensure that all quick-connect handles have been properly removed from all instruments, and the inserter threaded shaft has been properly unthreaded and removed from the inserter prior to cleaning.

3. The following table describes the required steps for thoroughly cleaning the system components:

Manual Cleaning Procedure:

Step	Agent	Time (mm:ss)
1. Rinse 1	Tap Water	As Needed
2. Clean 1	Enzol® Enzymatic Detergent Solution (or equivalent)	3:00
3. Rinse 2	Tap Water	1:00
4. Clean 2	Enzol® Enzymatic Detergent Solution (or equivalent)	10:00
5. Rinse 3	Deionized Water	1:00
6. Dry	Unaided Eye	As Needed
7. Inspect	Unaided Eye	As Needed

Manual Step 1 – Rinse 1
- Thoroughly rinse component(s) under cool running tap water (< 35°C) to remove gross soil for at least one (1) minute.

Manual Step 2 – Clean 1
- Add one (1) ounce (30 mL) of detergent to one (1) gallon (3.8 L) of tap water. Fully immerse component(s) for at least three (3) minutes and flush detergent through all channels no less than two (2) times until evidence of organic material is removed. While submerged, use a soft bristle brush intended for use with surgical components to gently remove visible debris. Pay close attention to threads, crevices, channels, lumens and hard to reach areas. If organic material is dried-on, extend soak time and use two (2) ounces (60 mL) of detergent per one (1) gallon (3.8 L) of warm tap water (< 55°C). Fully immerse component(s) in the detergent for at least one (1) minute.

Manual Step 3 – Rinse 2
- Thoroughly rinse component(s) under cool running tap water (< 35°C) including all hard to reach areas to remove detergent for at least one (1) minute.

Manual Step 4 – Clean 2
- Prepare a fresh solution by adding one (1) ounce (30 mL) of Enzol and one (1) gallon (3.8 L) of warm tap water (< 55°C) to a sonication unit (Branson Bransonic® Ultrasonic Cleaner or equivalent). Fully immerse component(s) in the solution and sonicate for ten (10) minutes.

Manual Step 5 – Rinse 3
- Remove component(s) from sonication unit and thoroughly rinse with deionized (DI) water including all hard to reach areas to remove detergent for at least one (1) minute.

Manual Step 6 – Dry
- Dry component(s) using a clean, soft lint-free towel and/or filtered, pressurized air (20 psi).

Manual Step 7 – Inspect
- Visually inspect each component for evidence of organic material. If any contamination is present, repeat the cleaning steps as necessary.

Automated Cleaning Procedure:

Treatment Step	Time (mm:ss)	Water Temperature	Cleaning Agent
1. Pre-Wash	2:00	Unheated Tap Water	N/A
2. Enzyme Wash	**Stage 1:** 1:00	122°F (50°C)	Enzol® Enzymatic Detergent Solution (or equivalent)
	Stage 2: 2:00	150°F (65.6°C)	
3. Wash	1:00	185°F (85°C)	Steris® Prolystica Detergent Solution (or equivalent)
4. PURW Rinse	2:00	185°F (85°C)	N/A
5. Dry	5:30	N/A	N/A
6. Inspect	As Needed	N/A	N/A

Automated Steps 1 through 5 – Cycle Processing
- Process the component(s) in a washer / disinfector using the cycle parameters outlined in the table above.

Automated Step 6 – Inspect
- Visually inspect each component for evidence of organic material. If any contamination is present, repeat the cleaning steps as necessary.

Care and Handling:

Before each use, instruments should be visually inspected and function should be tested to assure instruments are functioning properly. If instruments are discolored, have loose screws/pins, are out of alignment, cracked, show excessive wear or have other irregularities, DO NOT use.

If desired, lubricate instruments to protect instruments during sterilization and storage. This should be done with a water soluble, preserved lubricant after each cleaning. The lubricant should contain a chemical preservative to prevent bacterial growth and be made with distilled water. Excess lubricant should be wiped off prior to storage and sterilization.

Refer to ASTM standard F1744, "Standard Guide for Care and Handling of Stainless Steel Surgical Instruments" for additional information.

STERILIZATION:

All Inspire Porous PEEK Lumbar Interbody Fusion System implants are provided sterile-packed. Instruments are provided non-sterile in a convenience caddy / tray(s) and must be sterilized prior to use. All instruments must be inspected for damage and free of packaging material and bio-contaminants prior to sterilization. All system components, including any caddies, must be properly placed back into the convenience tray prior to sterilization. To achieve a sterility assurance level of not less than 10^{-6}, all non-sterile instruments should be autoclave sterilized using the following validated cycle parameters:

Method: Saturated steam
Sterilizer Type: Pre-vacuum
Temperature: 270°F (132°C)
Duration: 4 minutes
Drying Time: 30 minutes

It is the end user's responsibility to use only sterilizers and sterilization packaging materials/accessories (such as sterilization wraps or pouches, chemical or biological indicators, and sterilization cassettes) that have been cleared by the FDA for the sterilization cycle specifications (time and temperature). Alternative sterilization methods or cycles may be used, but should be validated according to hospital practices and procedures. The use of an FDA cleared wrap is recommended to ensure instruments remain sterile prior to use. Do not stack trays during sterilization.

Product Complaints:

The customer or health care professional should report any dissatisfaction with the product quality, labeling, packaging or performance to Curiteva immediately. Furthermore, if any of the implanted system components "malfunction" (i.e., do not meet any of their performance specifications or otherwise do not perform as intended) and may have caused or contributed to the death or serious injury of a patient, Curiteva should be notified immediately by telephone, fax or written correspondence. When filing a complaint, the product description(s), part number(s), and lot number(s) should be provided along with the nature of the complaint, as well as the name and address of the individual filing the complaint.

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