ACTILIF™ C

INSTRUCTIONS FOR USE

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

DEVICE DESCRIPTION
ACTILIF™ C is a spinal intervertebral fusion device made from polyetheretherketone, Zeniva PEEK (Solvay Advanced Polymers). It is provided in a variety of footprint sizes ranging from 11mm anterior-posterior x 13mm medial-lateral to 16mm anterior-posterior to 19mm medial-lateral. It is provided in heights from 4mm to 10mm in 1mm size increments. It has two radiographic marker pins made from tantalum, per ASTM F560.

INDICATIONS
ACTILIF™ C is intended for spinal fusion procedures at one level (C2 to T1) in skeletally mature patients with degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Implants are intended to be implanted via an open, anterior approach and packed with autogenous bone graft. **ACTILIF™ C** is intended to be used with a supplemental fixation system.

CONTRAINDICATIONS
ACTILIF™ C should not be implanted in patients with active systemic infection or infection localized to the site of implantation. ACTILIF™ C 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 ACTILIF™ C should only be undertaken after the surgeon has become thoroughly knowledgeable about spinal anatomy and biomechanics; has had experience with anterior cervical fusion procedures and anterior cervical fixation; and has had hands-on training in the use of this device.

- One ACTILIF™ C should be implanted at each surgical level.
- ACTILIF™ C 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.
- ACTILIF™ C 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 ACTILIF™ C:

1. Dysphagia or dysphonia.
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, 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, airway compromise or stroke.
13. Death

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
ACTILIF™ C 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 and implants that have been taken into a sterile field must be decontaminated and cleaned using established hospital methods 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.
- 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.
- Rinse all instruments with warm running water and dry with a clean cloth and/or allow to air dry.

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:
ACTILIF™ C has not been evaluated for safety and compatibility in the MR environment. ACTILIF™ C has not been tested for heating or migration in the MR environment.

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

Rx Only Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. Please refer to your sales representative for further information about this device.

Do not reuse.

CENTINEL SPINE®

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