ACTILIF™ C FLX

INSTRUCTIONS FOR USE

DEVICE DESCRIPTION

The ACTILIF™ C FLX is a cervical intervertebral body fusion device manufactured from Titanium Alloy (Ti6Al4V) per ASTM standard F3001 via additive manufacturing. The devices feature a combination of solid and porous, radiolucent titanium sections for reduced mechanical stiffness and improved visibility compared to solid titanium implants.

The graft containment cavity is filled with bone graft (allograft and/or autograft) material. The ACTILIF™ C FLX IBF system consists of varying heights, sagittal profiles, and footprint options to accommodate individual pathology and anatomical conditions.

INDICATIONS

The ACTILIF™ C FLX is intended for spinal fusion procedures at multiple contiguous levels from the C2-C3 disc to the C7-T1 disc 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. The ACTILIF™ C FLX is to be used in a patient who has had six weeks of non-operative treatment prior to implantation of the cage. Implants are intended to be packed with bone graft (autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft). Patients with previous non-fusion spinal surgery at the treated level may be treated. The ACTILIF™ C FLX is intended to be used with a supplemental fixation system.

CONTRAINDICATIONS

- Osteoporosis, sepsis
- Infection or inflammation at or near the operative site
- Fever of undetermined origin
- Allergy to implant materials
- Patient is unable or unwilling to follow post-operative instructions
- Disease or condition which precludes the possibility of healing
- Prior fusion at the level to be treated
- Any conditions not described in the indications

WARNINGS and PRECAUTIONS

- Patients with previous spinal surgery at the levels to be treated may not experience the same clinical outcomes as those without a previous surgery.
- Selection of an appropriately sized device for the patient is important and increases the likelihood of a satisfactory outcome.
- The implantation of the intervertebral body fusion device should be performed only by experienced spinal surgeons with specific training in the use of this type of device.
- Do not use if the package is damaged or opened. Contents may not be sterile.
- Do not use if current date exceeds label expiry date.
- Do not re-sterilize sterile implants.
- Instrumentation provided with the implants must be used in accordance with the approved surgical technique.
- Do not use excessive force when introducing and positioning the implant within the intervertebral body space to avoid damaging the implant.
- Re-usable surgical instruments must be re-sterilized prior to next use.
- Do not reuse the device even if the device shows no external signs of damage. Internal stresses from previous use may cause early failure.
- Should not be used with components of any other system or manufacturer.

- Based on fatigue testing results, when using the ACTILIF™ C FLX system, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may have an impact on the performance of this system.

POTENTIAL ADVERSE EVENTS with the ACTILIF™ C FLX

Potential risks or adverse effects identified with the use of this intervertebral body fusion device, which may require additional surgery are similar to those of other spinal systems, and include, but are not limited to:

- Dysphagia or dysphonia.
- Bending or breakage of the components
- Foreign body (allergic) reaction
- Infection
- Pseudoarthrosis (i.e., non-union)
- Bone loss due to resorption or stress shielding
- Loss of neurological function
- Neurological difficulties such as radiculopathy, paresthesia, new or continued pain, numbness/tingling, neuroma, dural tears, neuropathy and neurologic deficit
- Loss or impairment of bowel, sexual, and/or bladder function
- Vascular damage resulting in excessive blood loss
- Spinal cord impingement or damage
- Fracture, damage, degenerative changes or instability of any bone above and/or below the level of surgery
- Additional surgery
- Death

PACKAGING

Packaging of the components should be intact upon receipt. Damaged packages or products should not be used, and should be returned to Centinel Spine.

STERILITY

All components of the ACTILIF™ C FLX device are provided sterile for single use only. ACTILIF™ C FLX is supplied sterile by gamma irradiation with a SAL of 10-6. Dose mapping has been completed in accordance with ISO 11137. Sterilization validation has been completed in accordance with AAMI TIR27 (VDmax method).

System instrumentation must be sterilized per AAMI ST79. Complete instructions for cleaning and sterilization (LBL379) are available from Centinel Spine Customer Service [Call: (1) 484-887-8810 or E-mail: cs@centinelspine.com].

INSTRUCTIONS FOR USE

Use of the ACTILIF™ C FLX device should only be considered when the following pre-operative, intra-operative and post-operative conditions exist:

Pre-operative

- Patient meets the indication criteria described and does not have any contraindications.
- The surgeon should determine the construct prior to surgery to ensure that the required components in the necessary sizes are available.

Intra-operative

- The surgeon follows the surgical technique and instructions for use of the device. The surgical technique guide is available through Centinel Spine Customer Service [Call: (1) 484-887-8810 or E-mail: cs@centinelspine.com].

- All components are inspected and determined to be free of damage.
- Once the ACTILIF™ C FLX has been introduced, additional anterior or posterior instrumentation is employed if deemed appropriate by the surgeon, who should consider factors such as the stability of the spinal column and potential risk associated with a subsequent surgical procedure to remove and/or replace these surgical appliances.
- Bone graft (autograft and/or allograft) is placed in the area to be fused.

Post-operative

- The choice to administer post-operative antibiotics is at the discretion of the surgeon.
- Post-operative mobilization and rehabilitation is at the discretion of the surgeon dependent on clinical and radiological progress.
- The need for external orthotic support is not mandatory with the final choice based on surgeon preference, patient condition and intra-operative findings that might influence implant security.
- The patient is to be instructed to reduce undue stress on the implant as a precaution to avoid clinical problems that could result in fixation failure.
- The patient is to be instructed to follow the post-operative regime.

MRI SAFETY INFORMATION

Non-clinical testing demonstrated that the ACTILIF™ C FLX is MR Conditional. A patient with this device can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5 Tesla and 3-Tesla only.
- Maximum spatial gradient magnetic field of 2,000-Gauss/cm (20-T/m)
- Maximum MR System reported whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode.

Under the scan conditions defined, the ACTILIF™ C FLX implant is expected to produce a maximum temperature rise of 2.0°C after 15 minutes of continuous scanning.

- In non-clinical testing, the image artifacts caused by the STALIF® M/STALIF® M-Ti/STALIF® M FLX implant extends approximately 10-mm from this implant when imaged using gradient echo pulse sequence and a 3-Tesla MR system.

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.

STERILE R Sterilized using irradiation.

Do not re-sterilize.

Do not reuse.

Do not use if package is damaged.

Patents pending

CENTINEL SPINE®

Centinel Spine, LLC
900 Airport Road, Suite 3B
West Chester, PA 19380
Tel: +1 (484) 887-8810
www.centinelspine.com