

STALIF C® / STALIF C-Ti®

this device may be necessary. The MR image quality of artifacts may be compromised if the area of interest is in the exact same area or relatively close to the position of the STALIF C® implant.

- MRI-related heating may occur with a highest temperature change of +1.9°C.

Symbols



Manufacturer



Catalogue number



Consult instructions for use.



Batch code



Do not reuse



Use by (Year/Month)



Do not use if package is damaged



CE-Marking in-line with EU Directive 93/42/EEC



Caution: Do not re-sterilize.



Sterilized using irradiation



MR-conditional.



Patents pending



Centinel Spine, LLC.

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



Emergo Europe

Prinsessegracht 20
2514 AP The Hague
The Netherlands
Tel: (31) (0) 70 345-8570
(Regulatory affairs only)



Centinel Spine GmbH

Gottlieb-Daimler-Str. 6
89150 Laichingen
Germany



Centinel Spine Schweiz GmbH

Grafenauweg 8
6300 Zug, Switzerland



CENTINEL SPINE®



INSTRUCTIONS FOR USE **FOR OURS ONLY**—STALIF C® / STALIF C-Ti®

General Description

The STALIF C® / STALIF C-Ti® is a radiolucent cervical intervertebral body fusion device that is fixed to the superior and inferior vertebral bodies with cancellous bone screws augmented with an anti back-out system (ABO™). The graft containment cavity is filled with bone graft-material. STALIF C® / STALIF C-Ti® is an Integrated Interbody fusion™ device and does not require supplementary fixation. The STALIF C® / STALIF C-Ti® IBF system consists of varying heights and sagittal profiles to accommodate individual pathology and anatomical conditions. The STALIF C® / STALIF C-Ti® device is manufactured from polyetheretherketone (PEEK) to ASTM F2026 with optional commercially pure titanium (CP Ti) coating to ASTM F1580. X-ray marker wires are manufactured from unalloyed Tantalum (Ta) per ASTM F-560.

Indications

The STALIF C® / STALIF C-Ti® is intended to be used as an intervertebral body fusion cage used with bone screws provided and requires no additional supplementary fixation systems. It is inserted into the disc space at one or two contiguous levels from levels C2 to T1 for the treatment of cervical degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The device system is designed for use with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft, to facilitate fusion.

The cervical cage is to be used in a skeletally mature patient who has had six weeks of non-operative treatment prior to implantation of the cage.

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

STALIF C® / STALIF C-Ti®

- 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 STALIF C® / STALIF C-Ti® 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 effects with the STALIF C® / STALIF C-Ti®

Potential adverse effects for this system are similar to those of other spinal systems, and include, but are not limited to:

- Early or late loosening of the components
- Bending or breakage of the components
- Foreign body (allergic) reaction
- Infection
- 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
- Bone graft complications including pain, fracture or wound healing problems
- Spinal cord impingement or damage
- Fracture, damage, degenerative changes or instability of any bone above and/or below the level of surgery
- Pseudoarthrosis (i.e., non-union)
- Additional surgery
- Death

Packaging

Packaging of the components should be intact upon receipt. Damaged packages or

STALIF C® / STALIF C-Ti®

products should not be used, and should be returned to Centinel Spine.

Sterility

All components of the STALIF C® / STALIF C-Ti® device are provided sterile for single use only. STALIF C® / STALIF C-Ti® is supplied sterile by gamma irradiation with a SAL of 10^{-6} . 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 STALIF C® / STALIF C-Ti® 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 STALIF C® / STALIF C-Ti® has been introduced and fixed by its screw fixation, 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 after fixation and potential risk associated with a subsequent surgical procedure to remove and/or replace these surgical appliances.
- Bone graft 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.
- The STALIF C® / STALIF C-Ti® implant is determined to be MR-conditional. A patient with this device can be scanned immediately after placement under the following conditions: Static magnetic field of 3-Tesla or less, Maximum spatial gradient magnetic field of 720-Gauss/cm or less.
- Optimization of MR imaging parameters to compensate for the presence of