Instruction for Use (IFU052) – STALIF C® Screws Spinal Implants

Important Information – please read before use!

These Instructions for Use apply to the STALIF C Screws. Other sets of manufacturer's instructions are available containing information required for application of the systems:

- Reprocessing Instructions for Instruments (LBL379)
- Instrumentation Guide (STG017)

The system-specific product information can also be viewed at the following links:

- https://elabeling.silony-medical.com
- www.silonyspine.com

Table of Contents

1 Device Description

STALIF C® screws are to be used in conjunction with the STALIF C®, STALIF C-Ti®, and STALIF C FLX® cages. STALIF C screws can vary in diameter (3.5mm, 4mm and 4.5mm) and are cancellous, self-tapping type screws, augmented with an Anti Back-Out system (ABO®) system. STALIF C screws vary in length (13mm—17mm). 14mm, 15mm or 16mm long screws are recommended. The screws are manufactured from Titanium Alloy (Ti-6Al-4V) to ASTM F-136 & ISO 5832 Part 3 and BS 7252 Part 3.

2 Indications

Fixation of the STALIF C, STALIF C-Ti, and STALIF C FLX cages to the adjacent vertebral bodies.

3 Contraindications

- Osteoporosis, sepsis, infection or inflammation at or near the operative site.
- Fever of undetermined origin or allergy to screw material.
- Patient is unable or unwilling to follow post operative instruction.
- Disease or condition which precludes the possibility of healing.
- Any condition not described in the indications.

4 Warnings and Precautions

- Do not intermix implants of different metallic alloy types in the same construct. Premature device failure and / or infection in the patient may occur.
- Selection of an appropriately sized device for the patient is important and increases the likelihood of a satisfactory outcome.
- 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 implant 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.
- On insertion of the screw into the STALIF C/ STALIF C-Ti/ STALIF C FLX device, ensure soft tissue is not trapped between the head of the screw and the device.
- Re-usable surgical instruments must be decontaminated and sterilized prior to next use.
- Do not reuse the device even if the device shows no external signs of damage. Internal stresses from a previous use may cause early failure.
- 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.
- STALIF C 3.5mm diameter and 4mm diameter screws must only be used with STALIF C, STALIF C-Ti, and STALIF C FLX 3-hole cages. STALIF C 4.5mm screws must only be used with STALIF C 2-hole cages. 14mm, 15mm or 16mm long STALIF C screws are recommended for use with the STALIF C, STALIF C-Ti, and STALIF C FLX cages.

5 Glossary of Symbols

Symbols according to ISO 15223-1 (Recognition number: 5-134) and 21 CFR 801.109:

Symbol	Explanatory Text
	Manufacturer
	Catalog number
	Batch code
	Do not use if the packaging is damaged
	Consult instructions for use
	Caution
	Do not reuse
	Do not resterilize
	Use by date *Including the year and month in the following format: YYYY-MM-DD*
	Sterilized using irradiation
	Federal law in the USA restricts this device to sale by or on the order of a physician
	Quantity
	Contact
	Conditional MR* safe
Ø	Diameter

*The term MR is synonymous with MRI and means magnetic resonance imaging

Silony Spine Corp.
8200 NW 27th St
STE#104
Doral, FL 33122
Tel: +1 305 916 0016
www.silonyspine.com