STALIF C® Screws

INSTRUCTIONS FOR USE

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.

INDICATIONS

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

CONTRAINDICATIONS

- Osteoporosis, sepsis, infection or inflammation at or near the operative site.
- Fever of undetermined origin or allergy to screw materials.
- 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.

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™ 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.

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.

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