

STALIF C™

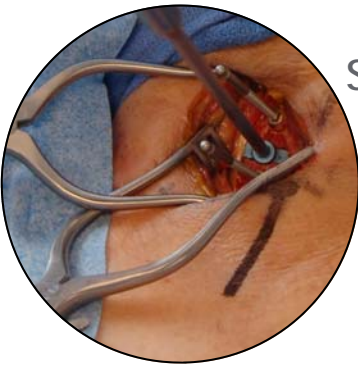
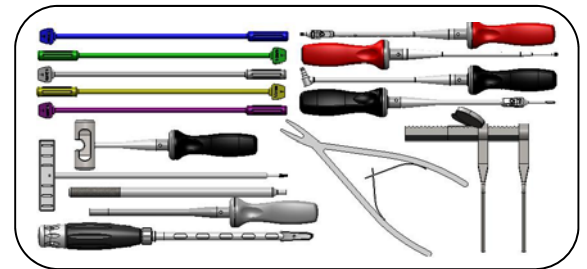
Surgical Technique

Surgical Indications

- STALIF C™ is intended to be used as an IBF cage without supplementary fixation.
- It is inserted between the vertebral bodies into the disc space 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).
- STALIF C™ is cleared in the US for single level use only.
- STALIF C™ is cleared in the US for use with autograft only.
- 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.

Device and Surgery Specific Instrumentation

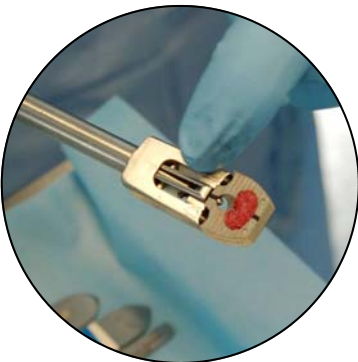
In addition to standard orthopaedic and spinal instruments, specialised instruments have been developed for use with the STALIF C™ system and are recommended for optimal implantation. These instruments include implant sizing trials, awl guide, awl, introducer, slap hammer, screwdrivers and a screw remover. All instruments are provided non-sterile designed to be sterilized by autoclave. In addition to non-sterile instruments, sterile distractor pins and a sterile midline marker are supplied as single use devices only. The Casper distractor pins are used with the Caspar distractor to open the disc space; the midline marker is used to determine the midline of the vertebral bodies by x-ray. This sight marker ensures the STALIF C™ device is implanted correctly on the midline of the vertebral body.



STALIF C™ Selection

The midline marker is taken from its sterile packaging and inserted into the marker pin screwdriver. This is inserted into the vertebral body above or below the target disc and an x-ray is taken to determine the midline of the vertebral body. It can be re-positioned until the marker pin is accurately positioned on the midline. Following excision of the cervical disc and preparation of the endplates, the correct height of device is determined using the implant sizing trials in the non-distracted disc space.

It is important that the appropriate sized STALIF C™ is selected and the device fits correctly within the intervertebral disc space. The surgeon has a choice of different anterior heights and sagittal profiles.

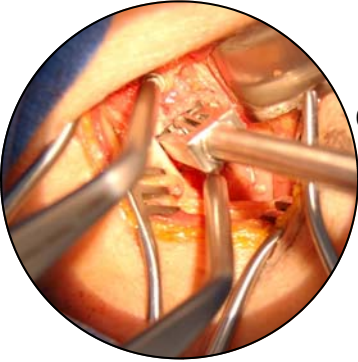


STALIF C™ Insertion

The central cavity of the device should be filled with autograft bone prior to attachment to the introducer. The bone material should be packed so that it exceeds the superior and inferior surfaces of the device by 1mm. The disc space may now be distracted slightly using the standard Caspar distractor pins and Caspar distractor.

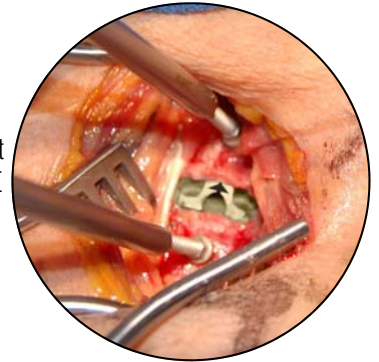
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Once assembled onto the introducer the STALIF C™ is inserted into the disc space. The black line and arrow etched onto the implant should be aligned with the midline marker pin previously inserted into the adjacent vertebral body. The device can now be inserted maintaining alignment between the midline marker pin and the etched line and arrow on the implant.

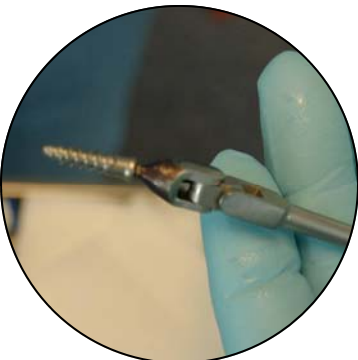
Care should be taken to prevent rotation of the implant. If required, the slap hammer can be used against the strike surface of the introducer to gently tap the device into place. **DO NOT USE EXCESSIVE FORCE WHEN STRIKING IMPLANT AS THIS MAY DAMAGE THE IMPLANT.**



If a Caspar distractor has been used, the distraction can now be released and the introducer removed from the STALIF C™. It is advisable to take A/P and lateral x-rays to ensure that the cage sits fully within the disc space and correctly orientated on the midline of the cervical spine. This can be done by checking the position of the marker pins, which will also ensure the natural spinal anatomy is restored. If necessary, the implant can be removed and/or repositioned.

STALIF C™ Screw Insertion

Once correctly positioned, the flexible awl and awl guide are used to create a pilot hole for each screw to follow. The awl guide controls the orientation of each screw and ensures they stay within the vertebral bodies. Occasionally, it may be necessary to remove a small portion of the anterior lip of the vertebral body to allow access of the awl guide into the screw holes within the device.

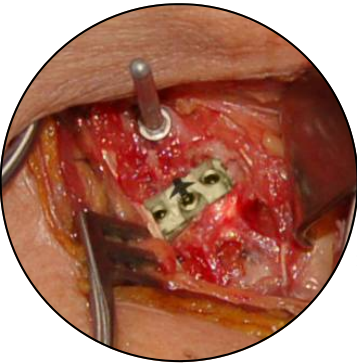
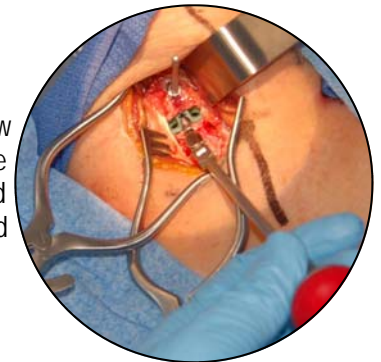


The appropriate sized STALIF C™ screw is selected based on patient anatomy and loaded onto the flexible screwdriver

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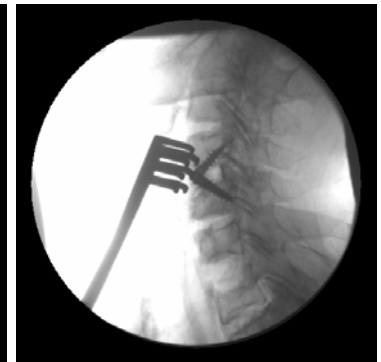
The screws used are either primary tapered (code CST) or revision parallel (code CRT). A tapered screw is generally used for primary fixation. Should a screw need to be repositioned a parallel screw can be used to replace the tapered screw. Prior to screw insertion any soft tissue around the screw hole should be removed to prevent entrapment between the head of the screw and the device. The screw is inserted through the device and screwed into the adjacent vertebral body.



It is advisable to only partially tighten down the first screw to prevent rotation of the implant during screw insertion. After the remaining two screws are inserted, they should be sequentially tightened, beginning with the central screw, as governed by vision and feel. The heads of each screw must be fully seated in the holes within the implant. Should the screwdriver prove difficult to disengage then gentle rocking of the screwdriver in the direction of the slot in the screw head will assist removal.

STALIF C™ X-Ray Check

Lateral and A/P X-rays must be taken prior to closure to ensure correct positioning of the implant by checking the two titanium marker pins.



REVISION PROCEDURE

The screwdriver can be used to remove the screws. However, occasionally it may not be possible to get adequate purchase with the tapered screw. In these circumstances it may be necessary to use the easyout screw removal instrument to remove the screw. This must be replaced with the parallel revision screw which will provide better fixation.

POSTOPERATIVE REGIME RECOMMENDATIONS

Early

- 24 hours antibiotics.
- Position with head above pelvis.
- Mobilize as comfortable.
- Regular isometric exercises.
- Optional soft collar for about 3 weeks.
- Post operative x-ray.

Intermediate (2-12 weeks)

- Radiographs at 6 and 12 weeks.
- Continue exercises.
- Patient can drive and do light work.

Late (3-12 months)

- Radiographs at 6 and 12 months.
- No special restrictions but encourage continuing exercises and can begin Isotonic exercises.
- Contact sport is at the discretion of the treating surgeon.

Postoperative external immobilization is not necessary. Isometric exercises are encouraged on a daily basis for at least 10 minutes for 2-3 months. Contact sport or vigorous activity should be avoided for approximately 3 months, until the postoperative x-rays show a satisfactory fusion. This normally occurs between 3 and 6 months after surgery.