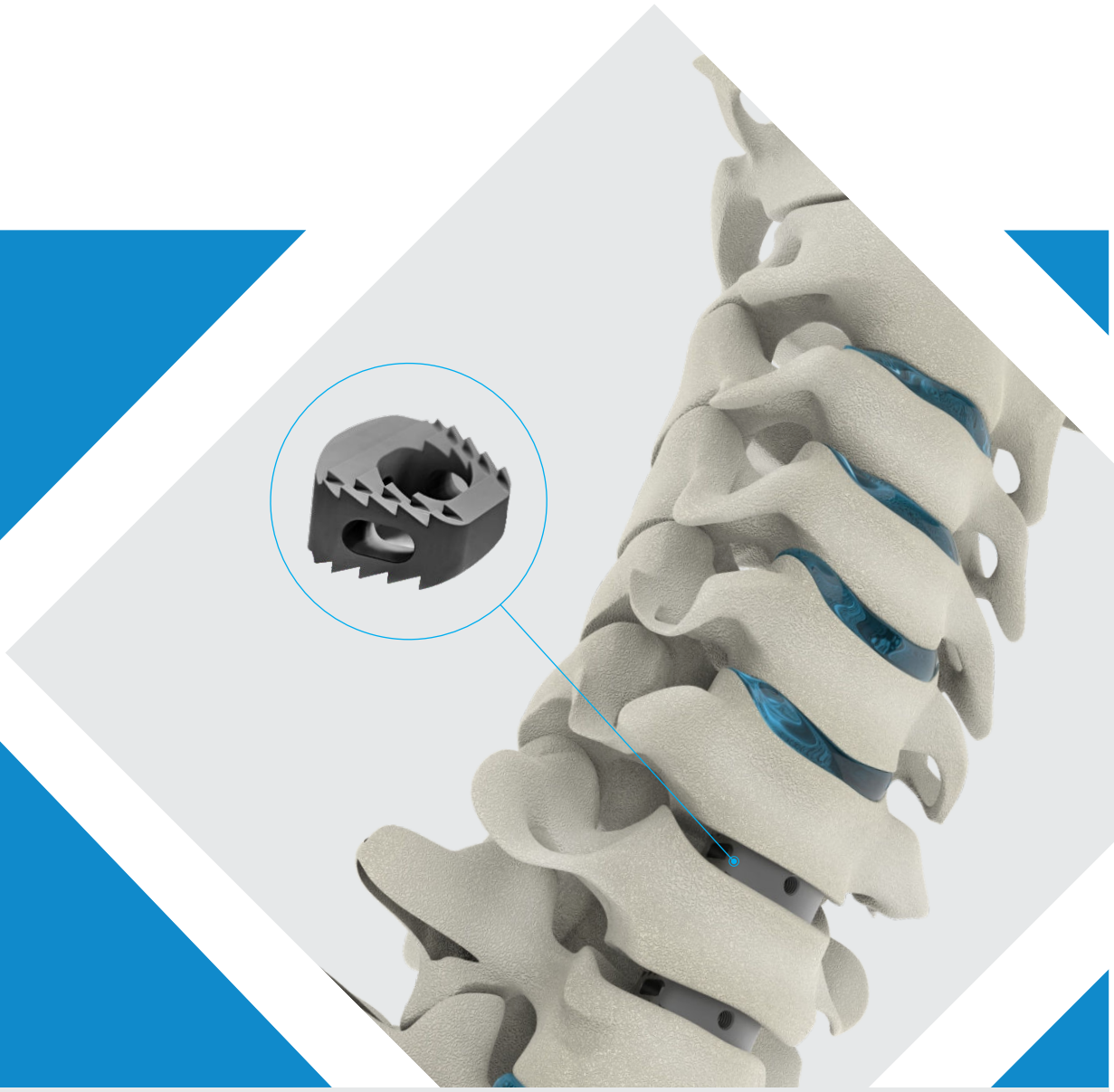
Auxein®



Surgical Technique

Cervical Cage (ACDF)

www.auxein.com

about us

Auxein Medical is an integrated, research based, orthopaedic Implants & instruments manufacturing company, producing a wide range of quality, affordable generic implants, trusted by healthcare professionals and patients across geographies. It is the Company's constant endeavor to provide a wide basket of generic and our innovator products that exceed the highest expectations of customers in term of quality and safety. The company has world-class manufacturing unit established in india and serves customers in over 75 countries worldwide.

Our Achievements

Guidelines

This publication sets forth detailed recommended procedures for using Auxein Medical devices and instruments.

It offers guidance that needs to be heeded. However, with any such technical guide, each surgeon must consider the unique needs of each patient and make appropriate adjustments when and as required.

A workshop training under DAIS Academy by Auxein will provide assistance prior to first surgery. It is vital to know that all non-sterile devices must be cleaned and sterilized before use.

Moreover, multi-component instruments must be disassembled for cleaning. The surgeon must discuss all relevant risks, including the finite lifetime of the device, with the patient, when necessary.

Please NOTE that all the bone screws referenced in this document here are not approved for screw attachment or fixation in the areas not mentioned in this publication.

Warning:
This description is not sufficient for immediate application of the instrumentation. Instruction by a surgeon experienced in handling this instrumentation is highly recommended.

DAIS
Division of Auxein Institute for Surgeons

Organised by: Auxein

The Cervical Cage is an interbody fusion device offering anterior column support. Its radiolucent material enables the surgeon to monitor bony fusion. The cage's mechanical structure supports loadbearing capability, restoring the natural alignment of the cervical spine, whilst load sharing the bone graft.

Positioning the Patient

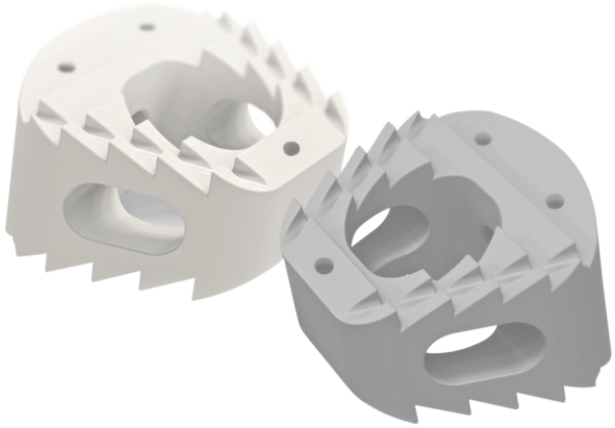
The patient is given general endotracheal anaesthesia, then placed in the supine position with the neck extended. It is helpful to place rolled blankets under the scapulae and a rolled towel under the neck to provide extension of the cervical spine. Both arms are placed at the patient's side so that X-rays can be taken with traction applied to the arms by an unscrubbed assistant at the foot of the table.

Indications:

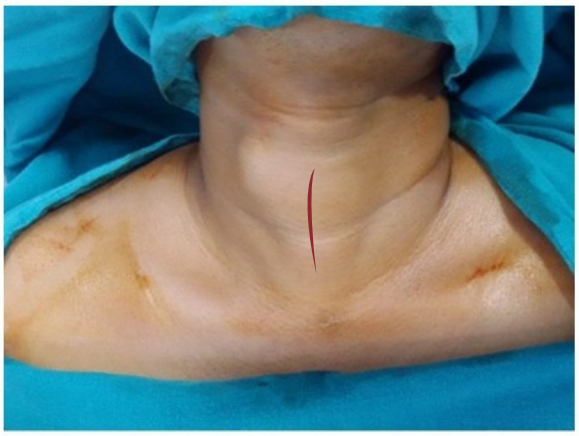
- Cervical disc herniation
- Spondylotic myelopathy
- Symptomatic cervical spondylosis
- Multiple level discogenic disease

Contraindications:

- Active systemic or localised infection
- Severe osteoporosis or osteopenia
- Conditions that reduce the likelihood of fusion



1. Exposure



The exposure can be made either on the left or right side according to surgeon preference. Although risk of retraction injury to the recurrent laryngeal nerve is higher from the right, a left sided approach has the possibility of injuring the thoracic duct and is more likely to injure the oesophagus.

Most right-handed surgeons prefer to approach from the right side. A transverse “hemi-collar” incision is made parallel to the clavicle extending from the sternocleidomastoid muscle to the midline.

2. Making the incision

The crico-thyroid membrane is at the C5-6 disc level. The incision is usually two or three fingerbreadths above the clavicle, depending on vertebral level desired

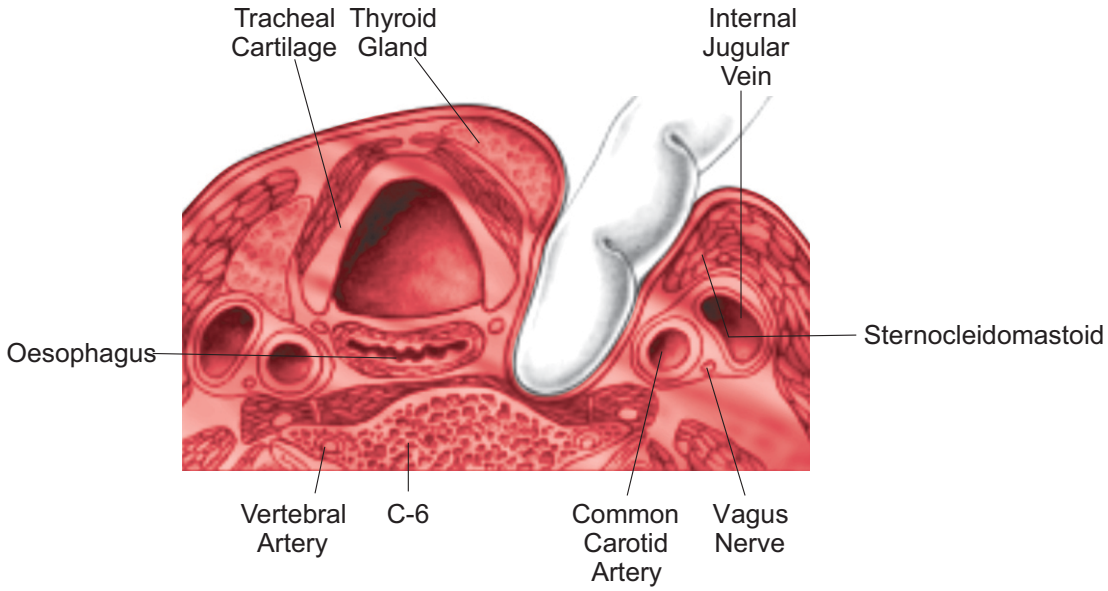
The incision is taken through the subcutaneous fat to the surface of the platysma. Although some surgeons divide the platysma in line with the skin incision, it is more cosmetic to elevate the skin a distance of two to three centimetres on either side of the skin incision and divide the platysma in the direction of its fibres.

The layer of deep cervical fascia is incised along the anterior border of the sternocleidomastoid muscle.

Blunt dissection is used to develop the interval between the carotid sheath and the midline structures, staying close to the trachea. The fascia along the lateral edge of the superior belly of the omohyoid muscle is cut with a Metzenbaum (straight blunt scissors) until the edge of the oesophagus is visible.

Note: the diagonal fibres of the muscle.

The surgeon can use either a “peanut sponge” or index finger to open the plane of cleavage between the carotid sheath laterally and the trachea and oesophagus in the midline, exposing the anterior cervical spine.



Cross-sectional view of the neck demonstrates the plane of cleavage between the carotid sheath laterally and the trachea and oesophagus medially.

Cautery is used in the midline over the cervical spine, followed by a “peanut sponge” to reflect the fascia and longus coli muscles.

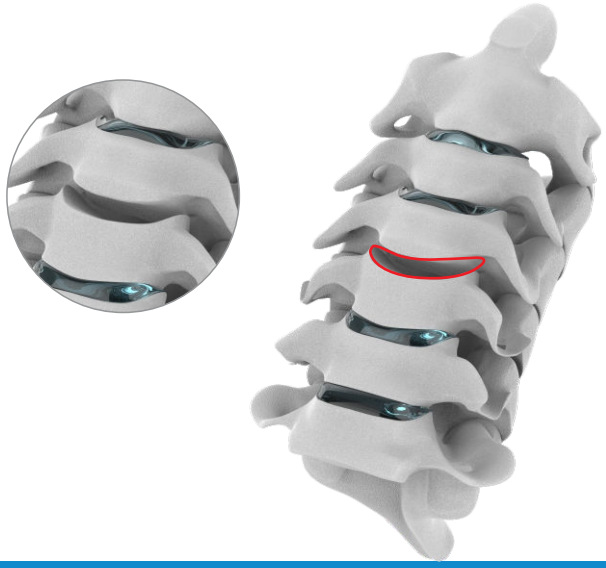
If desired, self-retaining retractors may be placed. The blunt-tooth blades are placed medial-lateral, taking care that the teeth remain within the longus coli muscle fibres. The smooth blades are placed superior-inferior.

A 22-gauge spinal needle is placed in the appropriate disc and a lateral X-ray taken to verify anatomic level. If the needle has been pre-bent to a 90o angle one centimetre from its tip, excessive penetration will be prevented.

3. Removal of the disc and preparation of the endplates

With the correct level verified, 0.5ml of indigo carmine dye is injected into the disc. This dye stains nuclear material blue and assists identification of extruded disc fragments.

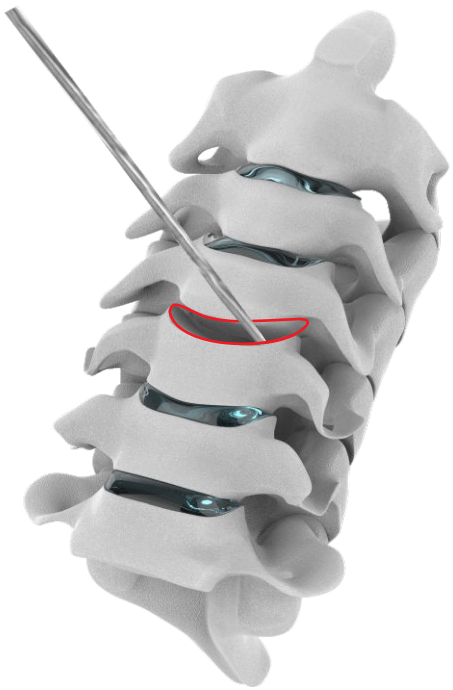
Use of a Caspar or similar vertebral distractor is recommended to distract across the disc space. Small drill holes are placed in the vertebra above and below the affected disc, just penetrating the cortex. The holes are tapped and the long shank distraction screws are inserted, making sure that the screw shanks are parallel. The distractor is applied, stretching the disc space.



Anterior osteophytes overlying the disc space may need to be removed using a rongeur or osteotome. At times, these osteophytes add substantially to the anterior-posterior dimension of the vertebral body. The anterior annulus is incised and removed. The nucleus is removed with a pituitary rongeur or curette. The cartilaginous endplate is peeled from the vertebral bodies above and below using a small periosteal elevator or curette. Dissection should not be undertaken lateral to the upslope of Lushka's joint on either side to assure protection of the vertebral arteries. After the disc has been removed, greater distraction can usually be achieved using the distractor.

While some surgeons have recommended that posterior osteophytes not be removed due to increased risk of damage to the spinal cord 8 ,9, 10, Cloward 4, 11 and others have recommended that all posterior osteophytes be removed. In cases of cervical spondylotic myelopathy, where removal of posterior osteophyte formation is essential, performance of a corpectomy may be preferred 12, 13. A tiny up-angled curette or Kerrison rongeur can be used to remove the posterior osteophytes, if necessary. This dissection can be carried laterally until the neural foramen can be entered with a nerve hook to verify that the nerve root is free and that all blue-stained nuclear material has been removed. Vigorous probing into the foramen should be avoided to prevent penetration of the vertebral artery.

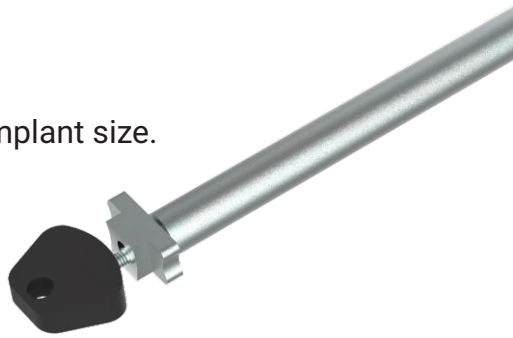
The cage specific rasps are used to flatten the endplate and ensure that all endplate cartilage has been removed. As recommended by Robinson 14, subchondral bone should be preserved as far as possible so that it can function as a bearing surface for the implant.



Note: The osteophytes have been removed on the patient's left side and a nerve hook verifies that the foramen is free. On the right side, the osteophyte has not been removed and the access to the spinal canal is limited.

Measuring for the appropriate Cervical Cage

The trials for the Cervical Cage are used to gauge the selection of implant size.



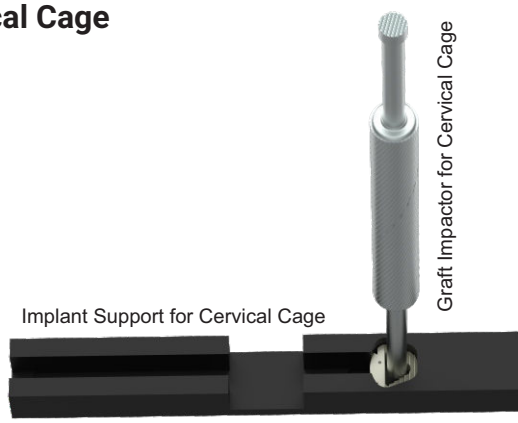
Shows the use of a trial for gauging both the height and the size of the implant required, and to assure that each surface is flat and the space is equally tapered from front to back. Each trial is slightly smaller than the actual cage implant (0.75 mm) to allow the implant a snug fit.

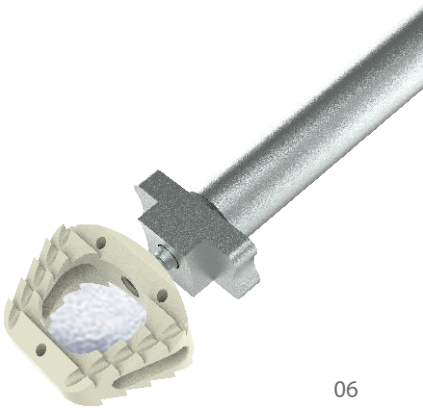
5. Harvesting, preparation and insertion of the graft into the Cervical Cage

The Cervical Cage is filled with autologous cancellous bone, harvested from the iliac crest using the following technique. A 2cm incision is made over the rim of the iliac crest. The periosteum is incised with electrocautery and elevated. An osteotome is used to remove a 1cm window of outer cortex. A curette is used to remove sufficient cancellous bone to fill the cage. The cortical window is replaced. The periosteum, subcutaneous tissue and skin layers are closed with sutures of the surgeon's choice.

Filling the Cervical Cage with a bone graft substitute may be preferred, thus eliminating the need for bone graft harvest.

Note: Use Graft Impactor for Cervical Cage **(SP-050)** for grafting solutions using the Implant Support for Cervical Cage **(SP-049)**

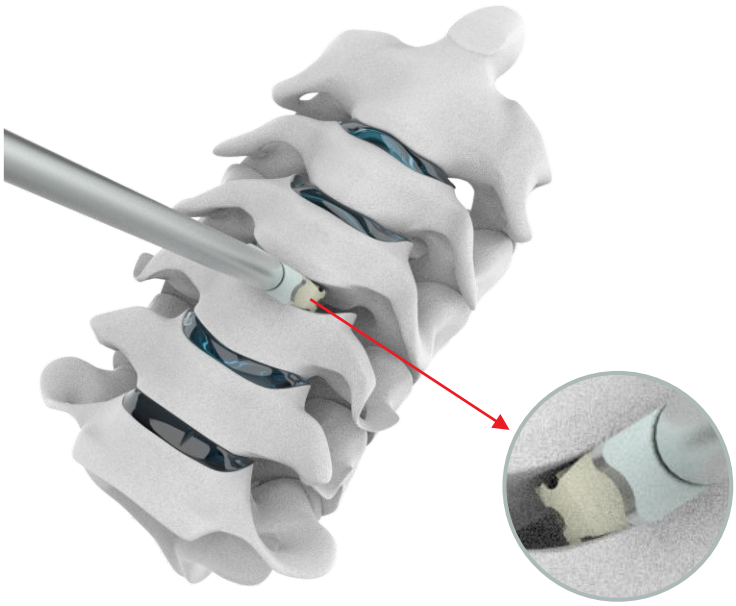




6. Insertion of the Cervical Cage

The selected cage is engaged with the threaded portion of the cage inserter and placed in the filler block.

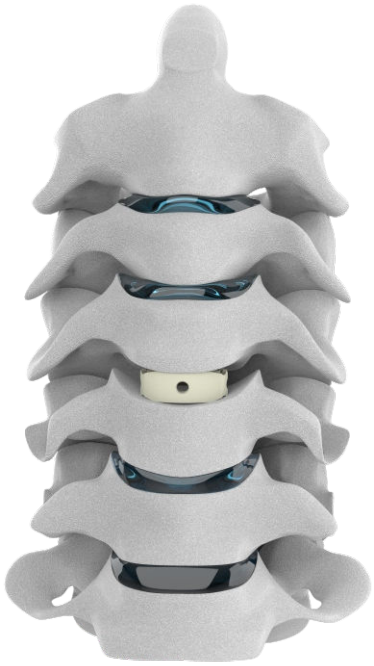
Using the cage filler block, the cancellous bone is packed firmly into the hollow area of the cage. The cage is then gently tapped into the prepared disc space using the inserter designed to prevent driving the cage too far posteriorly. Under normal circumstances, the cage should be recessed 1 to 2mm from the anterior cortex. A final xray is taken to verify position of the implant.



7. Closure of the wound

Absolute haemostasis must be achieved prior to closure. The vertebral body distractor is removed along with the long shank distraction screws. Bone wax is placed in the screw holes. The anaesthetist is asked to move the cervical spine through a range of flexion and extension positions, to insure that stability has been achieved. An anterior cervical stabilization device can be applied if less than optimum stability is observed.

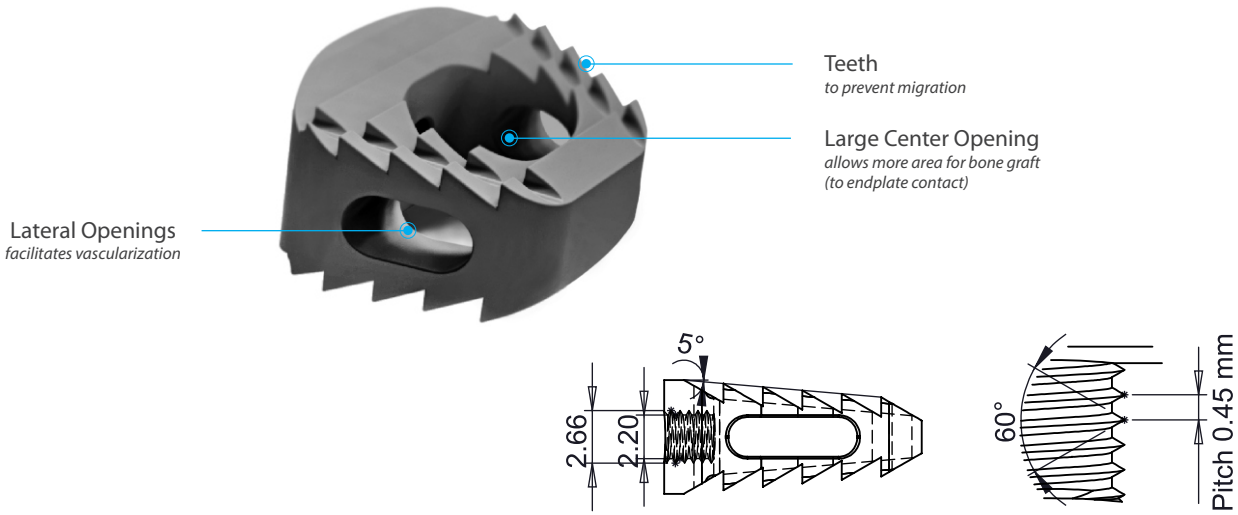
A small drain is placed deep in the wound. The selfretaining retractors are removed and the tissue layers closed. The platysma is usually the only layer requiring suture. Subcutaneous or subcuticular sutures are placed and steri-strips applied to the skin. A soft cervical collar is applied.



8. Post-operative care

The patient is usually placed in the surgical intensive care unit overnight to observe for the unlikely but dangerous possibility of airway obstruction. The patient is allowed to ambulate 24 hours post-operatively. The drain is removed and the patient discharged when comfortable usually on the second or third post-operative day. The patient is instructed to minimise motion of the cervical spine and wear the soft collar for one month post-operatively.

CERVICAL Cage (ACDF)



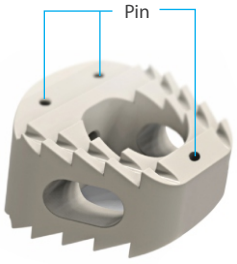
Cervical Cage (ACDF)

Code	Product Specification (mm)
SP-920	4 x 16 x 13
SP-393	5 x 16 x 13
SP-394	6 x 16 x 13
SP-395	7 x 16 x 13
SP-396	8 x 16 x 13
SP-900	9 x 16 x 13
SP-905	10 x 16 x 13
SP-906	11 x 16 x 13
SP-907	12 x 16 x 13

TITANIUM

Cervical Cage (ACDF)

Code	Product Specification (mm)
SP-404S	4 x 16 x 13
SP-405S	5 x 16 x 13
SP-406S	6 x 16 x 13
SP-407S	7 x 16 x 13
SP-408S	8 x 16 x 13
SP-922S	9 x 16 x 13
SP-923S	10 x 16 x 13
SP-933S	11 x 16 x 13
SP-948S	12 x 16 x 13



PEEK OPTIMA

available in: STERILE R

IMPC-972 Cervical Cage (ACDF) Implant Set

Code	Product Specification	Qty.
SP-393	Cervical Cage, 5mm x 16mm x 13mm	1
SP-394	Cervical Cage, 6mm x 16mm x 13mm	1
SP-395	Cervical Cage, 7mm x 16mm x 13mm	1
SP-396	Cervical Cage, 8mm x 16mm x 13mm	1
SP-900	Cervical Cage, 9mm x 16mm x 13mm	1
SP-905	Cervical Cage, 10mm x 16mm x 13mm	1
SP-906	Cervical Cage, 11mm x 16mm x 13mm	1
SP-907	Cervical Cage, 12mm x 16mm x 13mm	1
4-016-01	Implant Box for Cervical Cage (ACDF) Implant Set	1

7-052-01 Trial, 4mm for Cervical Cage

SP-042 Trial, 5mm for Cervical Cage

SP-043 Trial, 6mm for Cervical Cage

SP-044 Trial, 7mm for Cervical Cage

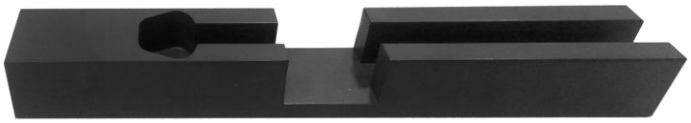
SP-045 Trial, 8mm for Cervical Cage

SP-046 Implant Inserter - Long

SP-047 Implant Inserter - Short

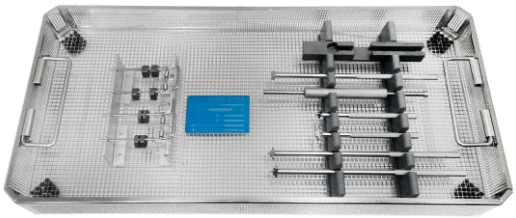
SP-048 Curve Tamp

SP-049 Implant Support for Cervical Cage

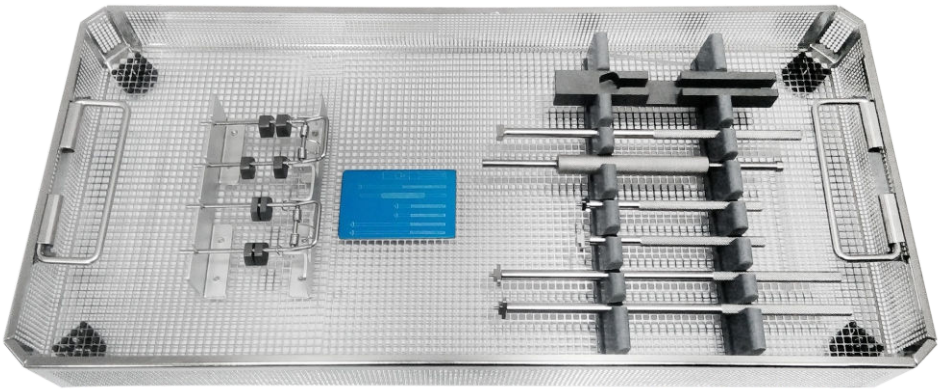


SP-050 Graft Impactor for Cervical Cage

SP-469 Mesh Tray for Cervical cage (ACDF) Instrument Set



SP-040 Cervical cage (ACDF) Instrument Set



Code	Set Consisting of	Qty.
7-052-01	Trial, 4mm for Cervical Cage	2
SP-042	Trial, 5mm for Cervical Cage	2
SP-043	Trial, 6mm for Cervical Cage	2
SP-044	Trial, 7mm for Cervical Cage	2
SP-045	Trial, 8mm for Cervical Cage	2
SP-046	Implant Inserter - Long	2
SP-047	Implant Inserter - Short	2
SP-048	Curve Tamp	1
SP-049	Implant Support for Cervical Cage	1
SP-050	Graft Impactor for Cervical Cage	1
SP-469	Mesh Tray for Cervical cage (ACDF) Instrument Set	1

AMPL-ST-122-01, Effective date - 22-07-2022

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