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Cat No: 9073-17-000

Revised: 07/02

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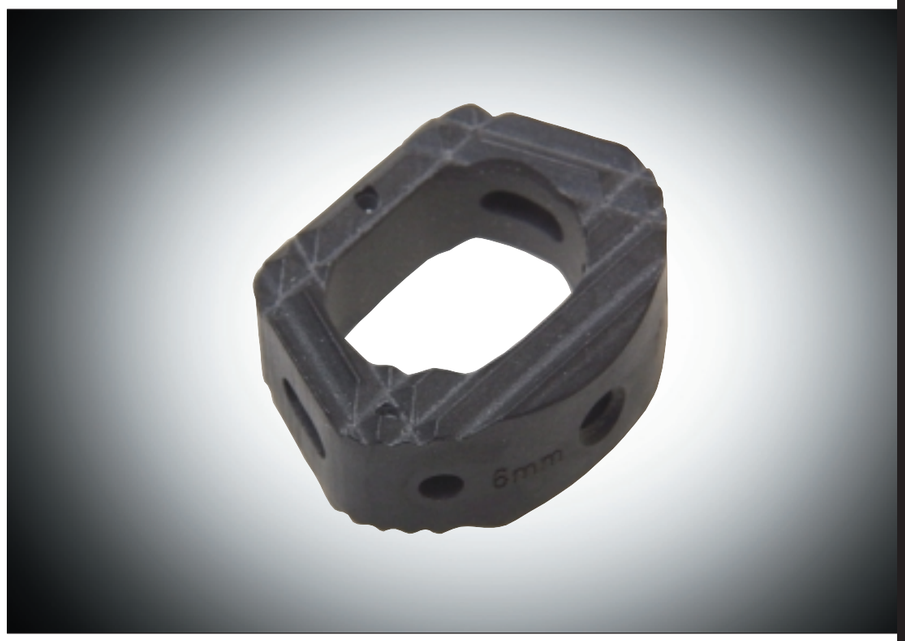
CERVICAL CFRP I/F CAGE®



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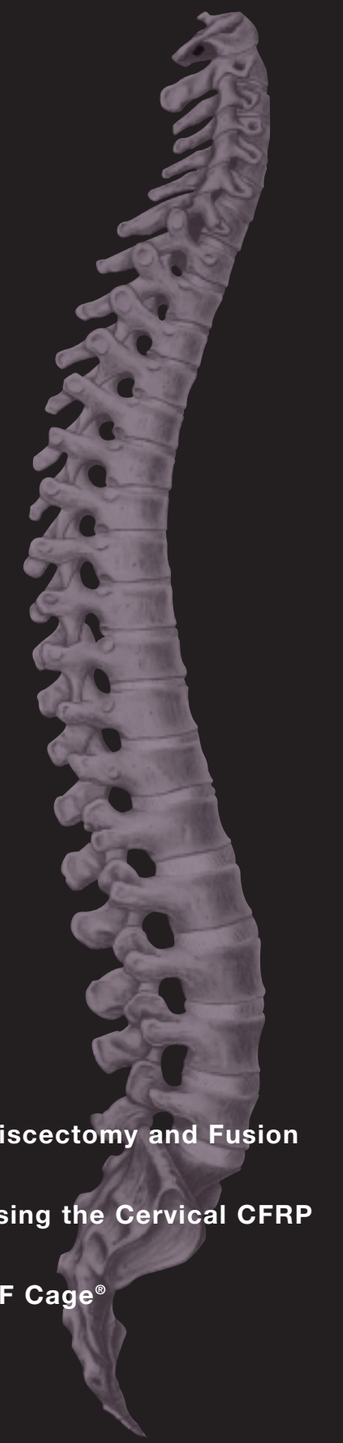
Design Rationale

Surgical Technique



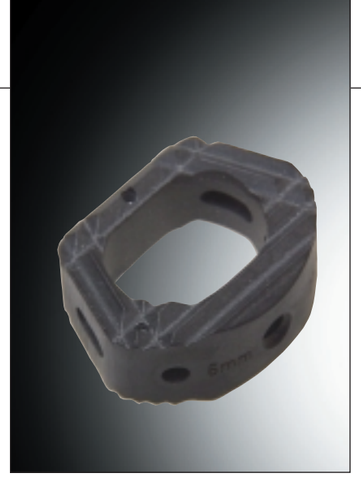
Discectomy and Fusion using the Cervical CFRP I/F Cage®

The Cervical CFRP I/F Cage® is a carbon fibre reinforced polymer (CFRP) interbody fusion device with over 5 years clinical success[1,2].

The Cage provides mechanical stability whilst facilitating optimised conditions for fusion, which can be visualised due to the radiolucent property of the biocompatible cage material.

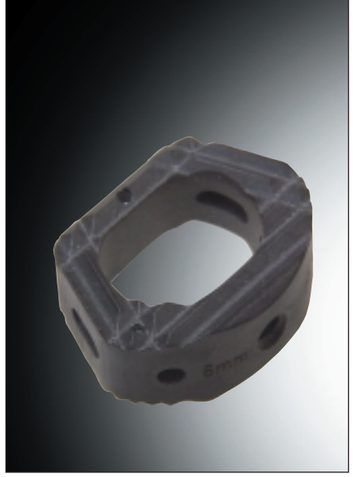
A cervical interbody fusion device offering mechanical stability whilst facilitating bony fusion.

The Cervical CFRP I/F Cage® distracts and maintains the intervertebral height, as well as providing restoration of cervical lordosis. The range of cages available is based on natural anatomical variation.



CERVICAL CFRP I/F CAGE®

Contents



CERVICAL CFRP I/F CAGE®

Design Rationale

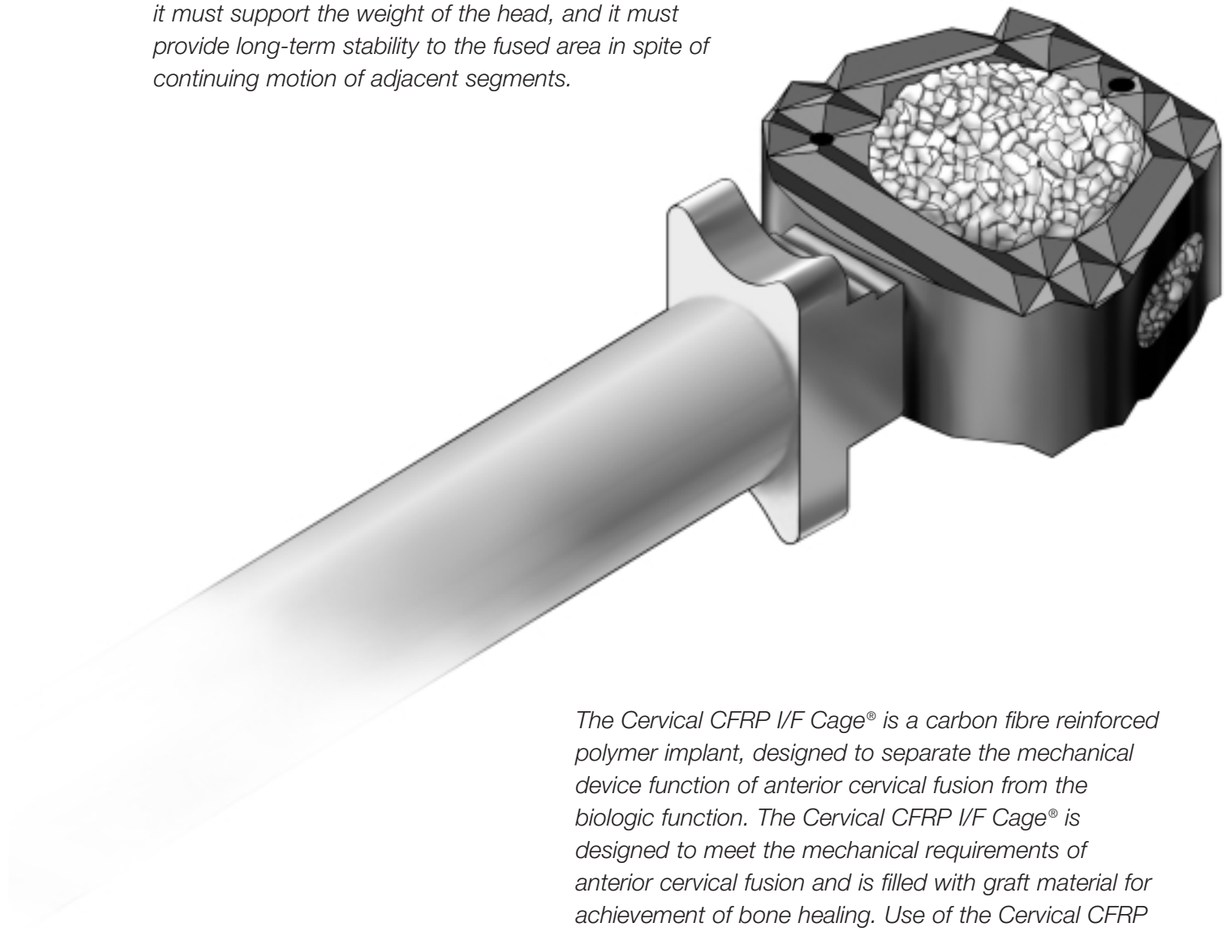
The Cervical CFRP I/F Cage® has been designed as an anterior solution to cervical interbody fusion. It is indicated for the treatment of herniated cervical discs and symptomatic cervical spondylosis. The cage has a dual function to restore disc height in a load sharing environment and to restore cervical lordosis, thus providing stability to the cervical spine.

A cervical interbody fusion device offering mechanical stability whilst facilitating bony fusion.

The fusion technique used in anterior cervical interbody fusion has gone through many transformations, from the use of a tricortical iliac crest graft as advocated by Smith and Robinson[3], to Cloward's bicortical dowel-shaped graft[4]. The Cervical CFRP I/F Cage® represents further advancement by adopting the benefits of a mechanical device with the use of biologic bone graft, resulting in a higher fusion success rate and increased pain relief[1,2].

Function of Anterior Cervical Fusion Graft

Any implant used for anterior cervical fusion has important mechanical functions: it must achieve disc space distraction to prevent nerve root impingement, it must support the weight of the head, and it must provide long-term stability to the fused area in spite of continuing motion of adjacent segments.

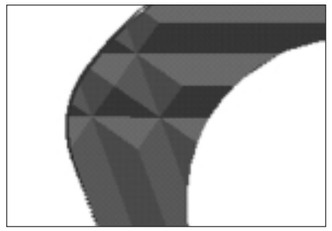


The Cervical CFRP I/F Cage® is a carbon fibre reinforced polymer implant, designed to separate the mechanical device function of anterior cervical fusion from the biologic function. The Cervical CFRP I/F Cage® is designed to meet the mechanical requirements of anterior cervical fusion and is filled with graft material for achievement of bone healing. Use of the Cervical CFRP I/F Cage® has the advantage of improved sagittal plane alignment, improved maintenance of disc space height[5] and decreased bone graft donor site morbidity.

Restoration and maintenance of disc height

Disc height restoration is achieved with the correct selection and implantation of the Cervical CFRP I/F Cage®. Once in situ, it is a combination of cage design and materials that ensures the maintenance of the disc height. The cage must be strong enough to resist the level of loading (compressive strength) as well as the cyclic nature of its application (fatigue strength).

The Cervical CFRP I/F Cage® is available in a variety of sizes.

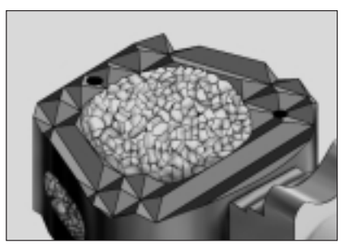


SURFACE TEETH increase stability, minimising risk of retropulsion.

Stability and fusion

Initial stability is achieved through the surface teeth that make contact with the vertebral body end plates. As the graft incorporates, leading to bony fusion, long-term stability is achieved[1,2].

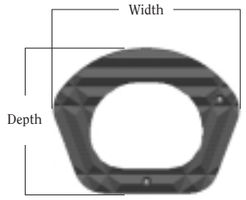
The open design of the Cervical CFRP I/F Cage® maximises the amount of bone graft that can be packed into it without compromising the cage strength. With a maximised area of contact between graft and end plate, the fusion mass is also maximised, ensuring stability.



The Cervical CFRP I/F Cage® packed with graft prior to implantation.

Implant Description

Cervical CFRP I/F Cage® implants (Figure 1) have a rounded trapezoidal shape to match the medial-lateral and anterior-posterior dimensions appropriate for anterior cervical fusion. Standard and large cages are available according to endplate size. To account for disc height variations, each size is provided in heights of 4, 5, 6, 7 and 8mm. The Cervical CFRP I/F Cage® has a shape that includes an outer support structure and a hollow inner area, which is packed with autologous bone graft, usually harvested from the iliac crest through a minimal "window" incision. Tooth-like serrations provide a stable interface when placed in the intervertebral space. The cage features a taper of seven degrees from anterior to posterior, consistent with the physiological sagittal plane alignment.



Dimensions

	Width	Depth
Standard	15mm	12mm
Large	18mm	14mm

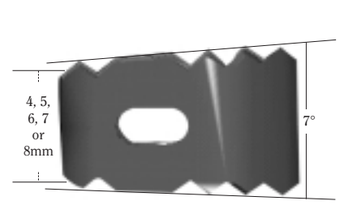
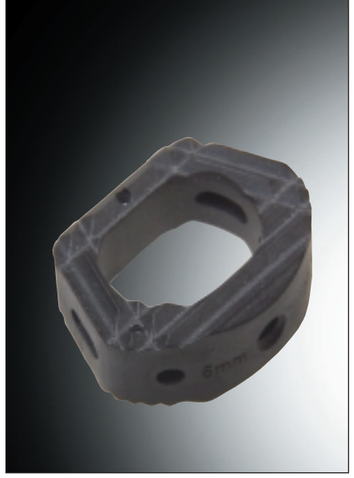


Figure 1: Cervical CFRP I/F Cage® sizing

The structure of the implant has been shown to support all anticipated loads with a modulus of elasticity approximating that of cortical bone[6]. As a result, the load is optimally shared between the cage and the graft, ensuring that the graft is not adversely stress shielded. Tests of the Cervical CFRP I/F Cage® in the calf spine have shown it to be mechanically superior to reconstruction using blocks of bone or methyl methacrylate[7]. The material is radiolucent so that bony healing can be assessed by normal radiographic methods, while tantalum marker beads show implant position.



CERVICAL CFRP I/F CAGE®

Surgical Technique

The Cervical CFRP I/F 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.

The technique of anterior cervical discectomy and fusion using the Cervical CFRP I/F Cage® is similar to the standard Smith and Robinson[3] technique utilising tricortical 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

Surgical Approach

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. *(Figure 1).*

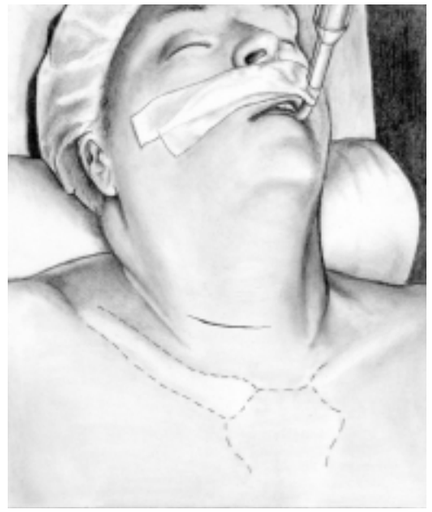


Figure 1

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, as shown in *(Figure 2a).*

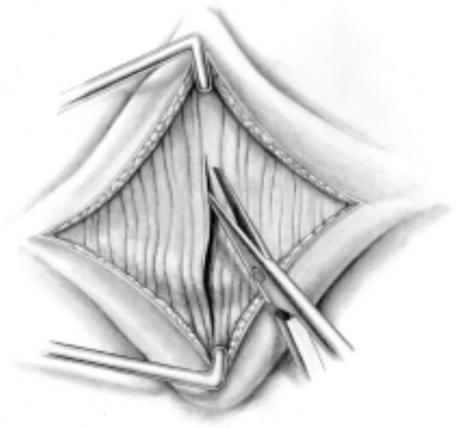


Figure 2a

Figure 2b

The layer of deep cervical fascia is incised along the anterior border of the sternocleidomastoid muscle *(Figure 2b).*

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 *(Figure 2c).*
Note: *the diagonal fibres of the muscle.*

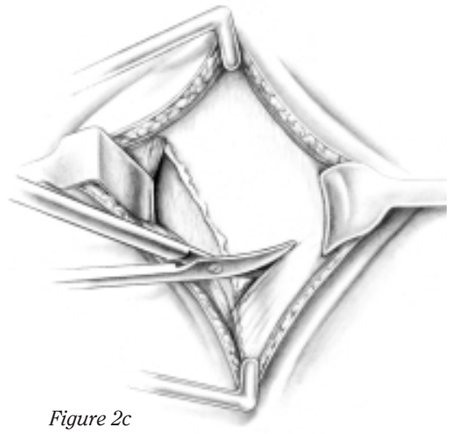


Figure 2c

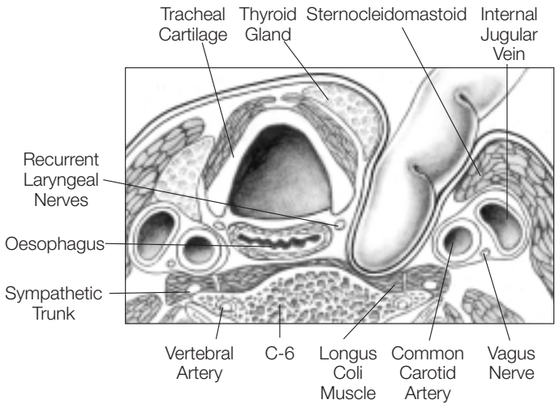


Figure 2d: Cross-sectional view of the neck demonstrates the plane of cleavage between the carotid sheath laterally and the trachea and oesophagus medially.

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 *(Figure 2d),* exposing the anterior cervical spine.

Cautery is used in the midline over the cervical spine, followed by a “peanut sponge” to reflect the fascia and longus coli muscles *(Figure 2e).*

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.

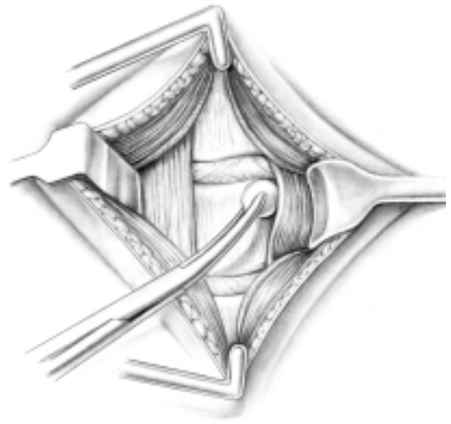


Figure 2e

3 *Removal of the disc and preparation of the endplates*

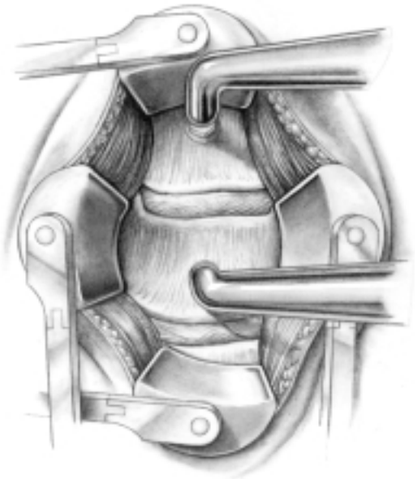


Figure 3a

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 *(Figure 3a).*

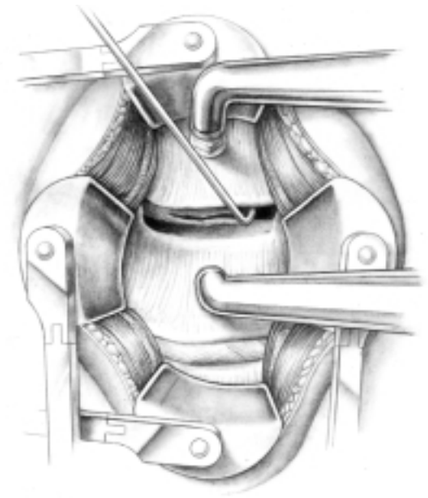


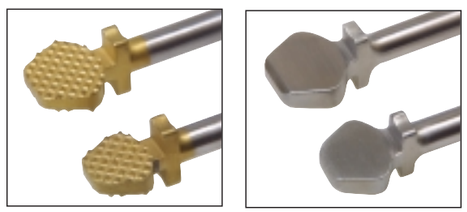
Figure 3b:
***Note:** The osteophytes have been removed on the patient's left side and a nerve hook verifies that the foramen is free. On the right side, the osteophyte has not been removed and the access to the spinal canal is limited.*

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, *(Figure 3b)*. Vigorous probing into the foramen should be avoided to prevent penetration of the vertebral artery.

The cage specific rasps *(Figure 4a)* 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.

Figure 4a



Rasps Trials

4 *Measuring for the appropriate Cervical CFRP I/F Cage®*

The trials for the Cervical CFRP I/F Cage® *(Figure 4a)* are used to gauge the selection of implant size.

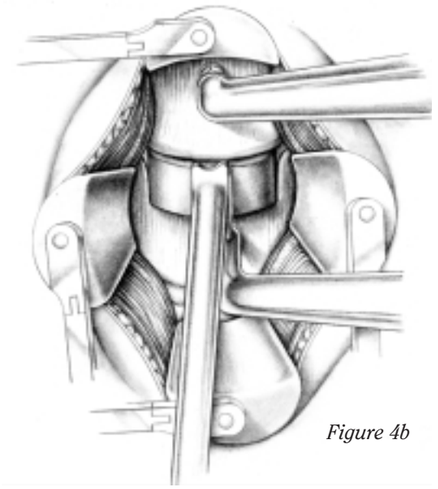


Figure 4b

Figure 4b 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 I/F Cage®*

The Cervical CFRP I/F 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 CFRP I/F Cage® with a bone graft substitute may be preferred, thus eliminating the need for bone graft harvest.

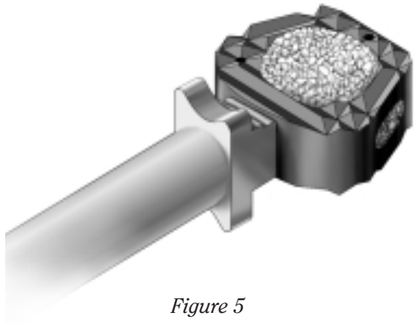


Figure 5

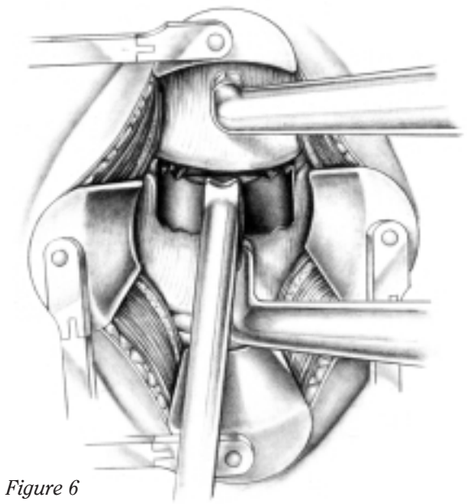


Figure 6

6 *Insertion of the I/F Cage®*

The selected cage is engaged with the threaded portion of the cage inserter *(Figure 5)* 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 *(Figure 6)* 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 x-ray 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 *(Figure 7).* 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 self-retaining 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.

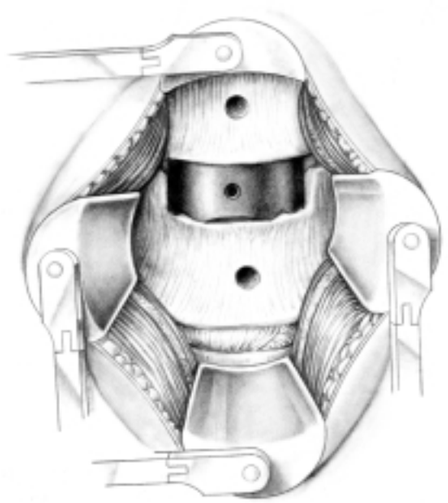
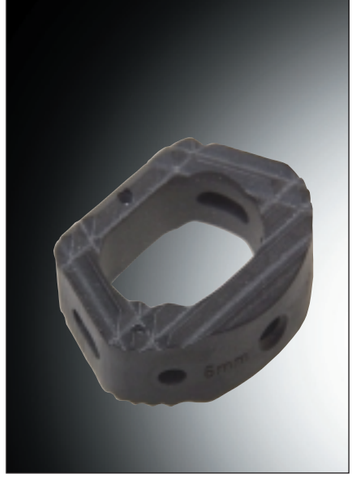


Figure 7

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 CFRP I/F CAGE®

Implants & Instrumentation

Implants

Standard Cages

Catalogue No.	*Description*	*Anterior Height*
1733-01-104	***Cervical I/F Cage®, Standard***	***4mm***
1733-01-105	***Cervical I/F Cage®, Standard***	***5mm***
1733-01-106	***Cervical I/F Cage®, Standard***	***6mm***
1733-01-107	***Cervical I/F Cage®, Standard***	***7mm***
1733-01-108	***Cervical I/F Cage®, Standard***	***8mm***

Large Cages

Catalogue No.	*Description*	*Anterior Height*
1733-01-204	***Cervical I/F Cage®, Large***	***4mm***
1733-01-205	***Cervical I/F Cage®, Large***	***5mm***
1733-01-206	***Cervical I/F Cage®, Large***	***6mm***
1733-01-207	***Cervical I/F Cage®, Large***	***7mm***
1733-01-208	***Cervical I/F Cage®, Large***	***8mm***

Standard Rasps

Catalogue No.	*Description*
2733-20-104	***Standard Rasp, Size 4***
2733-20-105	***Standard Rasp, Size 5***
2733-20-106	***Standard Rasp, Size 6***
2733-20-107	***Standard Rasp, Size 7***
2733-20-108	***Standard Rasp, Size 8***

Large Rasps

Catalogue No.	*Description*
2733-20-204	***Large Rasp, Size 4***
2733-20-205	***Large Rasp, Size 5***
2733-20-206	***Large Rasp, Size 6***
2733-20-207	***Large Rasp, Size 7***
2733-20-208	***Large Rasp, Size 8***

Instruments

Standard Trials

Catalogue No.	*Description*
2733-30-104	***Standard Trial, Size 4***
2733-30-105	***Standard Trial, Size 5***
2733-30-106	***Standard Trial, Size 6***
2733-30-107	***Standard Trial, Size 7***
2733-30-108	***Standard Trial, Size 8***

Large Trials

Catalogue No.	*Description*
2733-30-204	***Large Trial, Size 4***
2733-30-205	***Large Trial, Size 5***
2733-30-206	***Large Trial, Size 6***
2733-30-207	***Large Trial, Size 7***
2733-30-208	***Large Trial, Size 8***

Cage Impactor

Catalogue No.	*Description*
2733-10-001	***Impactor***

Cage Filler Block

Catalogue No.	*Description*
2733-10-200	***Cervical I/F Cage® Filler Block***

Cancellous Bone Tamp

Catalogue No.	*Description*
2733-10-002	***Cancellous Bone Tamp***

Cage Inserter

Catalogue No.	*Description*
2733-10-100	***Cervical I/F Cage® Inserter***

Cases and Trays

Cases and Trays

Catalogue No.	*Description*
2733-30-010	***European Cervical Instrument Tray***