PRODORTH

PROYSTER™

Surgical Technique Guide
Anterior Cervical
PEEK Cage

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contents

PROYSTER™

SURGICAL TECHNIQUE OF PRODORTH ANTERIOR CERVICAL PEEK CAGES

Prodorth has developed this surgical technique document for surgeons and healthcare professionals but not for unauthorized persons. This document is a supportive source but not a complete instruction for an inexperienced surgeon to perform the entire surgery, therefore the information within this surgical technique should be considered with the previous medical experiences and education of the surgeon. Surgeon's medical judgement and decisions will be the best treatment for the patient and the results will be different according to the patient's physical and mental situation.

DEVICE DESCRIPTION

Prodorth Cervical PEEK Cage is a long-term implant in order to dispose of the patients' complaints which are raised because of the pain arising from the herniation at the lumbar discs, and traumas on the lumbar spine.

Prodorth Cervical PEEK Cages are composed of specially machined PEEK and Titanium parts. It's aimed to be inserted into the intervertebral area. The cages are introduced by the anterior approach using special instruments. Single or double cages might be required per segment for an accurate fusion in order to stabilize the segment concerned. This instrumentation might be associated with anterior cervical plates. Fusion can be made between both vertebral endplates with or without using bone grafts previously introduced into the cages. The raw material used for the production of the Prodorth cervical cages is PEEK (ASTM F2026) and Titanium (ASTM F 136) as indicated by the symbol ®, as well as Titanium alloys (ASTM F 136) parts as supplementary items.

Prodorth Cervical Cages are long-term implants, however, they are not able to withstand the forces like healthy bone structures.

Current Status of the Device: The device is already CE marked (since 2013) and has been on the market.

Anterior Cervical PEEK Cage GMDN No: 60762

Product Class: (Annex II of Directive 93/42/EEC) Class IIb

Raw Materials: Ti6Al4V-ELI (ASTM F 136 / ISO 5832-3) and PEEK (ASTM F 2026)

Biological Assessment:

Biological Assessment of Device According to TS EN ISO 10993-1 : 2021	
Category	Implant Device
Contact Level	Bone / Tissue
Contact Duration	C (Permanent - > 30 days)

STERILIZATION

Prodorth Anterior Cervical PEEK Cage is released to market as non-sterile. They must be sterilized prior to surgical use. All packaging materials are removed prior to sterilization. The recommended sterilization method for Prodorth cages is steam sterilization in an autoclave. The products which are intended to be sterilized should remain in an autoclave at 134 °C for 18 minutes. There is no other sterilization method Prodorth recommends.

INTENDED PURPOSE OF THE DEVICE

This device is used in the treatment of the anatomical abnormalities of vertebrae typically due to degenerative intervertebral disks. The device can be of several different geometric forms and is implanted between the vertebrae and providing mechanical stability and sufficient space for therapeutic spinal bone fusion to occur. This process helps to relieve pressure on pinched nerves and prevents vertebral slipping. The device is made of a special polymer and metal. (PEEK and Titanium) Prodorth Anterior Cervical PEEK Cages are long-term implants, however, they are not able to withstand the forces like healthy bone structures.

- It is a single-use device
- Does not include human or animal tissue and phthalate
- Does not include any software or accessory
- The product is supplied as non-sterile
- Product does not cause any radioactive source or beam diffusing

Population: Skeletally mature male / female patients

Intended User(s): Healthcare professionals (Surgeons trained and experienced in the related field.)

INDICATIONS

General criteria and principles related to instrumented spinal surgery are applied here:

- Degenerative disc pathologies
- Herniated nucleus pulposus
- Grade 1 degenerative or isthmic spondylosis
- Visible loss of disc height compared to adjacent levels
- Cervical pseudarthrosis

Note: Patients should be skeletally mature and have had six months of non-operative treatment.

CONTRAINDICATIONS

Prodorth Anterior Cervical PEEK Cages should never be used in any condition not described in the indications for use. Contraindications include, but are not limited to:

- Fracture, tumor
- Any abnormality present which affects the normal process of bone remodeling including, but not limited to, severe osteoporosis involving the spine, bone absorption, osteopenia
- Marked local inflammation
- Pregnancy
- Infection
- Recognized allergies to titanium or titanium alloys and PEEK material
- Damaged vertebrae from an accident (trauma) at the level of the surgery
- Prior fusion at the level(s) to be treated
- An unhealthy shape (deformity) of the vertebrae at the level of the surgery
- Low bone mineral density, such as osteoporosis or osteopenia
- Mental disability
- Obesity
- Open wounds
- Fever or leukocytosis

▪ Alcohol or drug addiction
▪ Uncooperative patient or patient with neurologic disorders rendering the patient incapable of following instructions
These contraindications can be relative or absolute and should be considered when physician makes a decision. The above list does not include all possibilities. Surgeons should discuss relative contraindications with the patient.

SECONDARY AND POSSIBLE SIDE EFFECTS

The patient shall be notified regarding the below mentioned adverse events pre-operatively. A second surgical treatment may be required:

• Pseudarthrosis
• Implant penetration, migration or implant failure
• Infection
• Tissue or nerve damage caused by improper positioning and placement of implants or instruments
• Paralysis
• Allergy to materials used
• Dysphagia
• Loosening
• Increased neck pain
• Instability
• Hematoma
• c7 palsy
• Wound infection
• Hoarseness
• Pain or illness
• HO (heterotopic ossification)
• Nonunion or delayed union of the bone
• Bleeding blood vessels
• Bursitis
• Inability to perform daily activities
• Dura leak requiring a repeating surgery
• Intervertebral cages can be fractured postoperatively above or below segments of the surgical level due to trauma, the presence of any defect or weak bone structure. Re-operation may be required
• Anterior displacement of the disc adjacent segment degeneration
• Death

WARNINGS

• Never re-use an implant even in a perfect state. Any Implant which has been used, twisted, bent, implanted, and then removed even If it appears intact, must be discarded
• Use new implants routinely
• Similar products of competitors shall not be combined with the components of the Prodorth Anterior Cervical PEEK Cage. Prodorth implants and instruments should only be used with Prodorth instruments. In case of using other companie's instruments, this might result in galvanic corrosion, and incompatibility between the products as well
• No component of the Prodorth Anterior Cervical PEEK Cages shall be reused
• The restricted shelf life of the device is 10 years. It should never be used after its expiration date
▪ Correct selection of the implant is highly important!
▪ Use of provided trials is recommended

PRODORTH ANTERIOR CERVICAL PEEK CAGE DESCRIPTION

Whether the disc is herniated or bulged towards the nerves at the cervical area, the patient feels pain in his neck or arm. After the discectomy operation, this product is put through the vertebras to convert the unstable situation to stable.

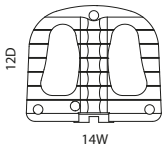
This product is manufactured from PEEK material (Polyether-ether-ketone/ ASTM F2026) which is a polymer-based composite, as well as Ti6Al4V-ELI (Grade 23).

The advantage of the Prodorth Cervical Bladed Cage is being able to be anchored with a blade that can be rotated vertically. This product ensures positioning by eliminating migration risk between vertebrae.

The Advantages of Prodorth Cervical Bladed Cages are as Follows

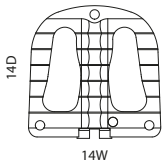
- Toothed surface is designed to prevent migration
- Anatomical geometry
- X-Ray Markers provide an easy placement
- Made of PEEK material, originated from EVONIK Industries Germany. Titanium alloy materials give an opaque image under X-Ray, however, PEEK materials are able to be seen transparently. This provides efficient following of the bone fusion through the implant at the intended periods
- Blades for a more reliable holding between the endplates
- Maximum Strong Construction / Fusion
- Space ratio
- Various sizes and footprints as well as Mono & Double Bladed versions are available

Anterior Cervical PEEK Cage



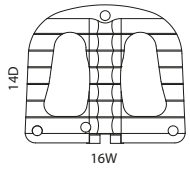
12D x 14W Interbodies

SIZE	REF.CODE
4x12x14 mm	102.06 011204
5x12x14 mm	102.06 011205
6x12x14 mm	102.06 011206
7x12x14 mm	102.06 011207
8x12x14 mm	102.06 011208



14D x 14W Interbodies

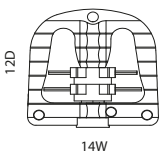
SIZE	REF.CODE
4x14x14 mm	102.06 011404
5x14x14 mm	102.06 011405
6x14x14 mm	102.06 011406
7x14x14 mm	102.06 011407
8x14x14 mm	102.06 011408



14D x 16W Interbodies

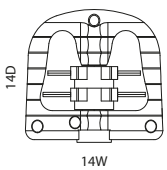
SIZE	REF.CODE
4x14x16 mm	102.06 011604
5x14x16 mm	102.06 011605
6x14x16 mm	102.06 011606
7x14x16 mm	102.06 011607
8x14x16 mm	102.06 011608

Anterior Cervical Bladed PEEK Cage



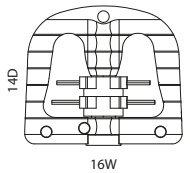
12D x 14W Interbodies

SIZE	REF.CODE
4x12x14 mm	102.06 021204
5x12x14 mm	102.06 021205
6x12x14 mm	102.06 021206
7x12x14 mm	102.06 021207
8x12x14 mm	102.06 021208



14D x 14W Interbodies

SIZE	REF.CODE
4x14x14 mm	102.06 021404
5x14x14 mm	102.06 021405
6x14x14 mm	102.06 021406
7x14x14 mm	102.06 021407
8x14x14 mm	102.06 021408



14D x 16W Interbodies

SIZE	REF.CODE
4x14x16 mm	102.06 021604
5x14x16 mm	102.06 021605
6x14x16 mm	102.06 021606
7x14x16 mm	102.06 021607
8x14x16 mm	102.06 021608

PRODORTH ANTERIOR CERVICAL PEEK CAGE INSTRUMENTS

Prodorth offers different designs of instruments for each step of the surgical procedure. They have been designed as simply as possible and user-friendly in order to provide ease of use.
Prodorth instruments are made of stainless chrome nickel steel, aluminum, and silicone.

PEEK Cage Inserter | PC 300.30.002

Mallet (Small) | PC 300.30.006

Cervical AWL | PC 300.30.003

Caspar Distractor | PC 300.30.007

Caspar Pin Driver (Distraction Screw Driver) | PC 300.30.004

Caspar Pin (Distraction Screws) | PC 300.30.008

Trial Inserter | PC 300.30.005

SURGICAL PROCEDURE

Step 1
Patient Positioning and Exposure

The patient is positioned in the supine position with the neck supported posteriorly to achieve normal segmental lordosis. In a standard anterior approach, it is recommended to open the vertebrae using Caspar Distractor (PC 300.30.007) when using Cervical PEEK Cage. (Figure 1)

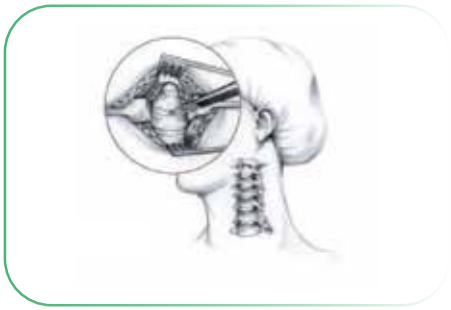


Figure 1

Step 2
Preparation of the Vertebrae

Use Prodorth Cervical AWL PC (300.30.003) to ream the vertebrae in order to make the initial holes for the distraction screws. (Figure 2)

Figure 2

Step 3
Assembly of Distractor Screws

Insert the Caspar Pin (Distraction Screws, PC 300.30.008) into the tip of the Caspar Pin Driver (Distraction Screw Driver, PC 300.30.004) and push it until assuring it's fully connected. (Figure 3)

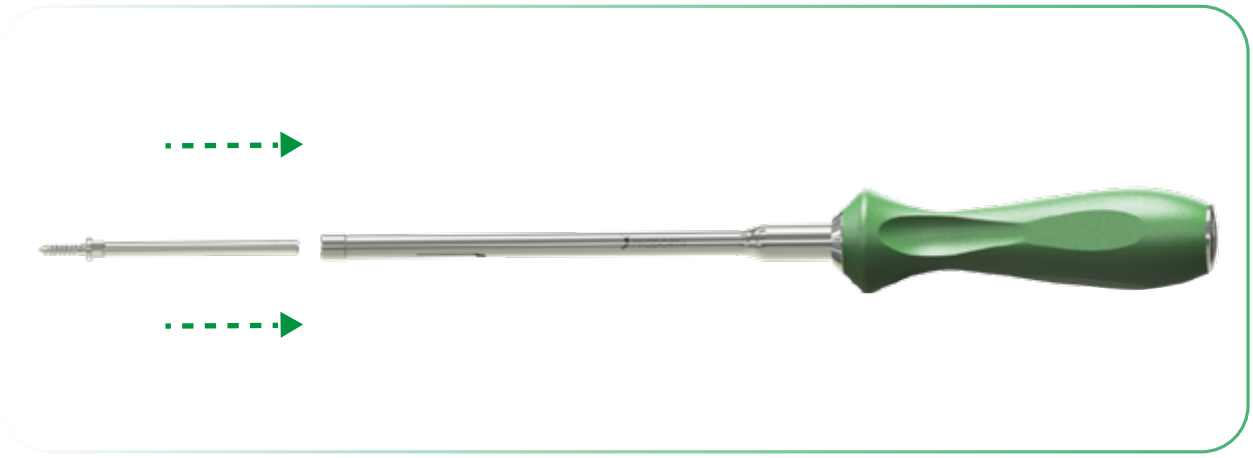


Figure 3

Step 4
Completing the Distraction

The previous actions at Step-2 is repeated for the adjacent vertebra. (Figure 4)

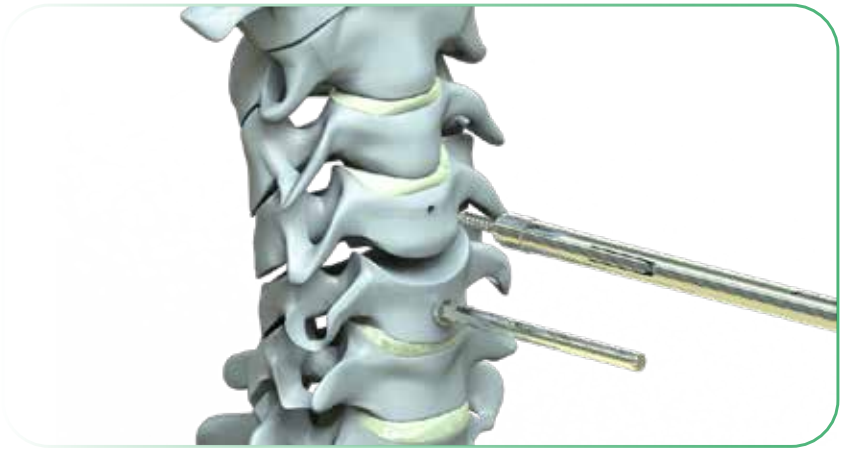


Figure 4

Step 5
Distraction

After the distraction screws are inserted properly, the Caspar Distractor's tips are connected to the screws. And the latch of the Caspar Distractor is rotated gradually until the required distance between vertebrae is obtained. (Figure 5)

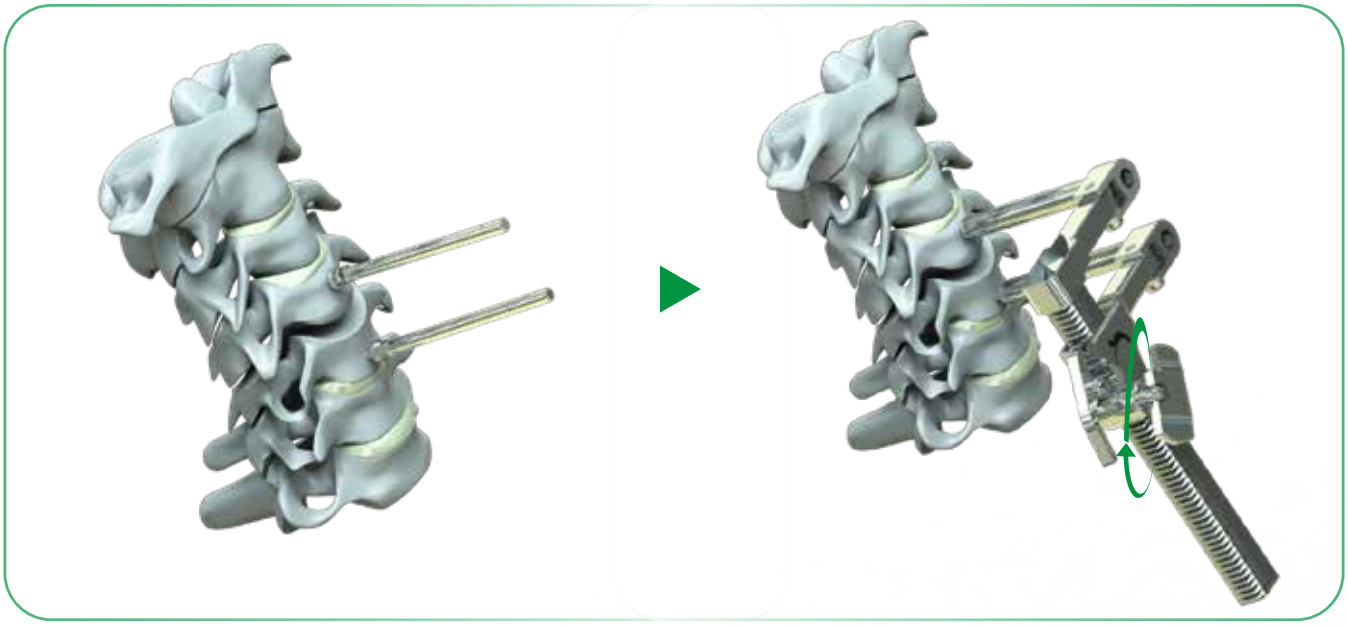


Figure 5

Step 6
Size selection

Several sizes of Trial Implants are available in the set to determine the appropriate size of the cage. They can be introduced by the Trial Inserter (PC 300.30.005). (Figure 6)

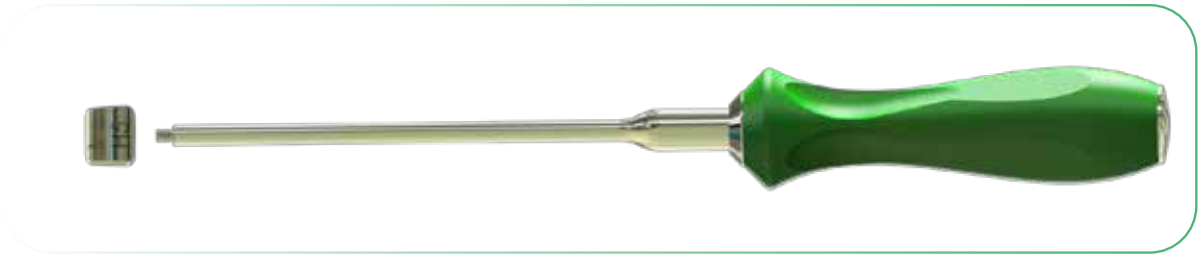


Figure 6

Step 7
Insertion of the Trial Implants

The trial implants are introduced through the vertebrae in order to determine the accurate size of the implant. It's represented at the figures below. A Mallet (Small PC 300.30.006) can be used to assist with insertion of the trial. Care should be taken not to apply excessive force during these operations. (Figure 7)

Trial Options

FOOTPRINTS :
12x14 mm , 14x14 mm , 14x16 mm
HEIGHTS :
5-8 mm (by 1 mm increments)

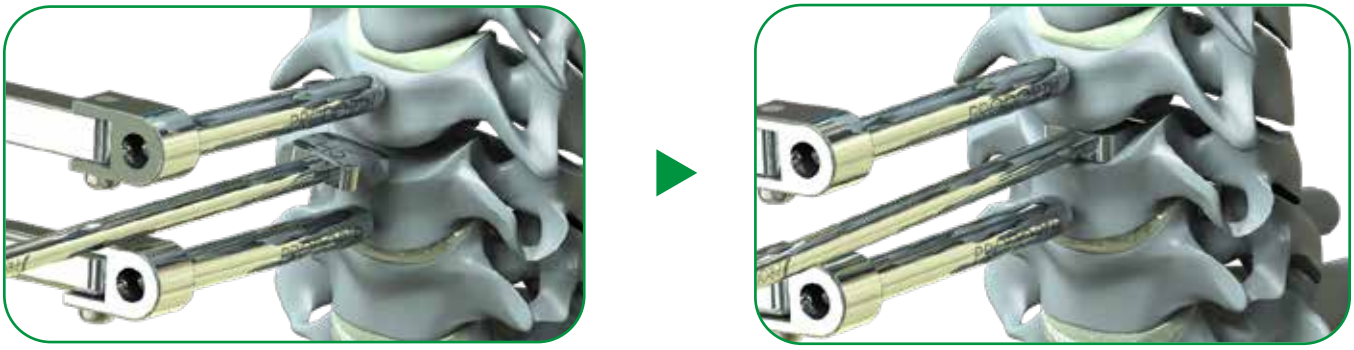


Figure 7

Step 8
Connection of the Anterior Cervical PEEK Cage with its Inserter

Place the internal bar inside the inserter then attach the cage to the distal tip of the inserter by rotating the internal bar knob at the back. Fully thread the cage to the PEEK Cage Inserter (PC 300.30.002). If some resistance is felt while attaching the cage, verify that it is not cross-threaded. Cage is introduced as the marked arrow on the implant is upside position. (Figure 8)

Note: Please make sure the cage is fully engaged with the inserter.

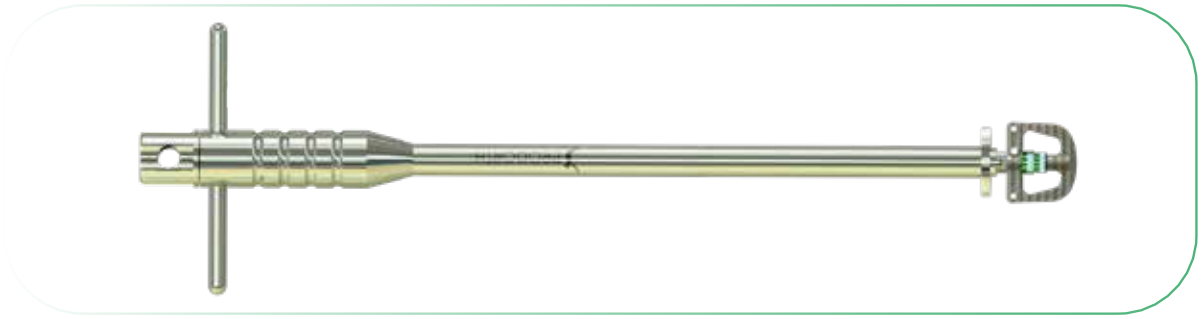


Figure 8

Once the implant is securely attached to the inserter, it should be carefully introduced into the disc space by small impacts with a Mallet (Small PC 300.30.006). The inserters have stoppers that lean on the anterior profile of the vertebral bodies for safe placement. (Figure 9)

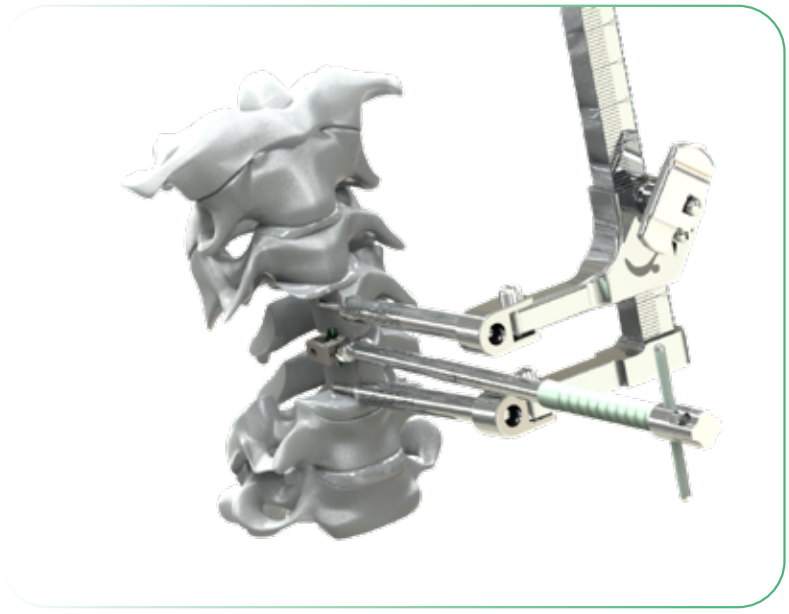
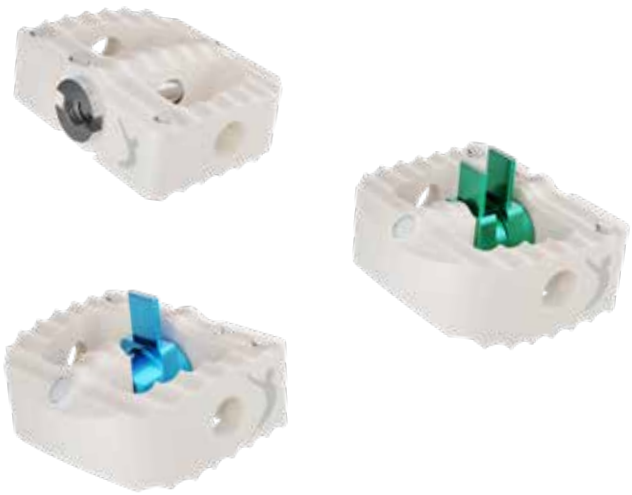


Figure 9

Surgical Technique Guide

Anterior Cervical PEEK Cage
Anterior Cervical Bladed PEEK Cage



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See the IFU prior to use for additional information.

Please check our website for the latest version of this Surgical Technique.

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