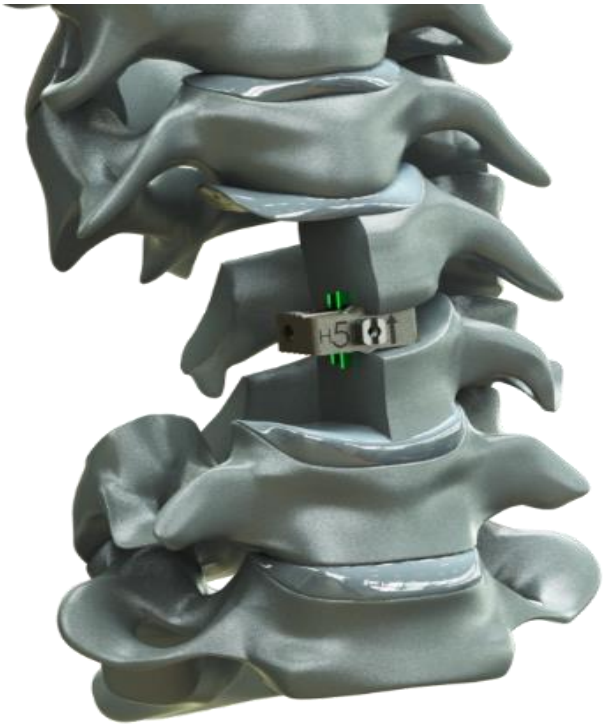
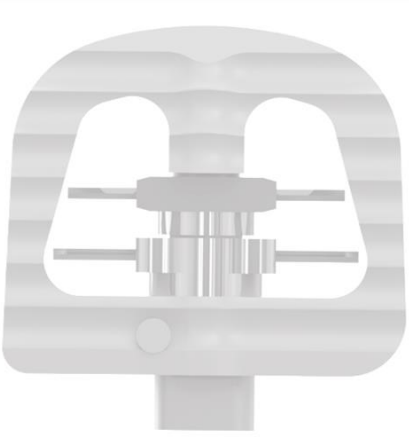
PRODORTH

Surgical Technique Guide

Anterior CERVICAL PEEK CAGE

PROYSTER ™





SURGICAL TECHNIQUE OF PRODORTH CERVICAL CAGE

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 unexperienced 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 best treatment for the patient and the results will be different according to the patient's physical and mental situation.

DEVICE DESCRIPTION

PRODORTH spinal cages are implants for long-term in order to relieve the complaints of the patients which have raised because of the pain arising from the herniation at discs, traumas or any disorders on spine.
Prodorth Cages are composed of specially machined PEEK and Titanium parts. It's aimed to inserted into the intervertebral area. The cages are introduced by posterior and anterior approaches 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 a posterior fixation. 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 spinal 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 Cage Implants are long-term implants, however they are not able to withstand the forces like healthy bone structures.

- **Current Status of the Device:** Device is already CE marked (since 2013) and has been on the market.
- **Cervical Cage GMDN No:** 38161 Spinal Cage
- **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 Assesment:**

Biological Assessment of Device According to TS EN ISO 10993-1 : 2011	
Category	**Implant Device**
Contact Level	**Bone/ Tissue**
Contact Duration	**C (Permanent - > 30days)**

- **Sterilization:**

Prodorth Cervical Cage is released to market as non-sterile.

They must be sterilized prior to surgical use. The validated sterilization method for PRODORTH implants is steam sterilization in autoclave. The implants which are intended to be sterilized should remain in autoclave at 134 C degree for 18 minutes. There is no other sterilization method PRODORTH recommends.

- **Intended Use 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 vertebraes 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 material. (PEEK and Titanium)

Prodorth Cervical Cage Implants 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 oraccessory,
- The product is supplied as non-sterilized,
- Product does not cause any radioactive source or beam diffusing

- **Population:** Skelatally mature male / female patients

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

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

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

CONTRAINDICATIONS :
Prodorth cages are not intended for use except as indicated.
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

SECONDARY AND POSSIBLE SIDE EFFECTS:
Pseudarthrosis
Implant penetration, migration or Implant failure
Infection
Allergy to materials used
Dysphagia
Loosening
Increased neck pain
Instability
Hematoma
c7 palsy
Wound infection
Hoarseness
HO (heterotopic ossification)
Anterior displacement of the disc
adjacent segment degeneration

WARNINGS:
Never re-use an implant even in perfect state. Any Implant which has been used, twisted, bent, implanted and then removed even If it appears intact, it must be discarded. Use new implants routinely. Similar products of competitors shall not be combined with the components of the Prodorth Cervical Cage. PRODORTH implants and instruments should only be used with PRODORTH instruments. Instruments developed by PRODORTH to be used in spinal surgeries of its spinal products. Incase of using other company's instruments, this might result in galvanic corrosion, incompatibility between the products as well. No component of the Prodorth Cervical Cages shall be reused.

The restricted shelf life of the device is 10 years. It should never be used after its expiration date.

Prodorth Cervical Cage Description

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

This product is manufactured from PEEK material (Polyether-ether-kethon/ ASTM F2026) which is a polymer based composite, as well as Ti6Al4V (grade 5) material.

The advantage of Prodorth Cervical Bladed Cage is, able to be stuck with blade which can be opened vertically, this product allows a positioning without any possibility of slip between vertebras.

Prodorth Anterior Cervical Cages

Sizes & Ref. Codes

PRODUCT NAME / SIZES	REF. CODE
PRODORTH CERVICAL PEEK CAGE 4x12x14 mm	102.06 011204
PRODORTH CERVICAL PEEK CAGE 5x12x14mm	102.06 011205
PRODORTH CERVICAL PEEK CAGE 6x12x14 mm	102.06 011206
PRODORTH CERVICAL PEEK CAGE 7x12x14 mm	102.06 011207
PRODORTH CERVICAL PEEK CAGE 8x12x14 mm	102.06 011208
PRODORTH CERVICAL PEEK CAGE 4x14X14 mm	102.06 011404
PRODORTH CERVICAL PEEK CAGE 5x14X14mm	102.06 011405
PRODORTH CERVICAL PEEK CAGE 6x14X14 mm	102.06 011406
PRODORTH CERVICAL PEEK CAGE 7x14X14 mm	102.06 011407
PRODORTH CERVICAL PEEK CAGE 8x14X14 mm	102.06 011408
PRODORTH CERVICAL PEEK CAGE 4x14x16 mm	102.06 011604
PRODORTH CERVICAL PEEK CAGE 5x14x16 mm	102.06 011605
PRODORTH CERVICAL PEEK CAGE 6x14x16 mm	102.06 011606
PRODORTH CERVICAL PEEK CAGE 7x14x16 mm	102.06 011607
PRODORTH CERVICAL PEEK CAGE 8x14x16 mm	102.06 011608
PRODORTH BLADED CERVICAL PEEK CAGE 4x12x14 mm	102.06 021204
PRODORTH BLADED CERVICAL PEEK CAGE 5x12x14mm	102.06 021205
PRODORTH BLADED CERVICAL PEEK CAGE 6x12x14 mm	102.06 021206
PRODORTH BLADED CERVICAL PEEK CAGE 7x12x14 mm	102.06 021207
PRODORTH BLADED CERVICAL PEEK CAGE 8x12x14 mm	102.06 021208
PRODORTH BLADED CERVICAL PEEK CAGE 4x14X14 mm	102.06 021404
PRODORTH BLADED CERVICAL PEEK CAGE 5x14X14mm	102.06 021405
PRODORTH BLADED CERVICAL PEEK CAGE 6x14X14 mm	102.06 021406
PRODORTH BLADED CERVICAL PEEK CAGE 7x14X14 mm	102.06 021407
PRODORTH BLADED CERVICAL PEEK CAGE 8x14X14 mm	102.06 021408
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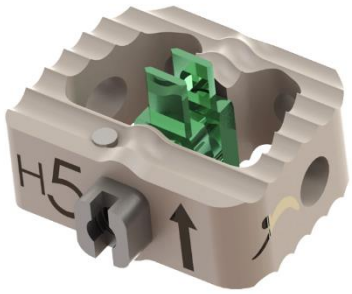


PROYSTER

(Double Bladed Peek Cage)

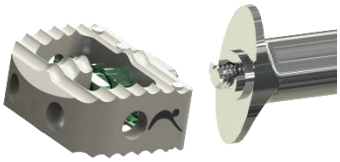
The advantages of Proyster are as follows:

- 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 opaque image under X-Ray, however PEEK materials is 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.

Regular Peek Cage

Regular Peek Cage

Mono Bladed Peek Cage

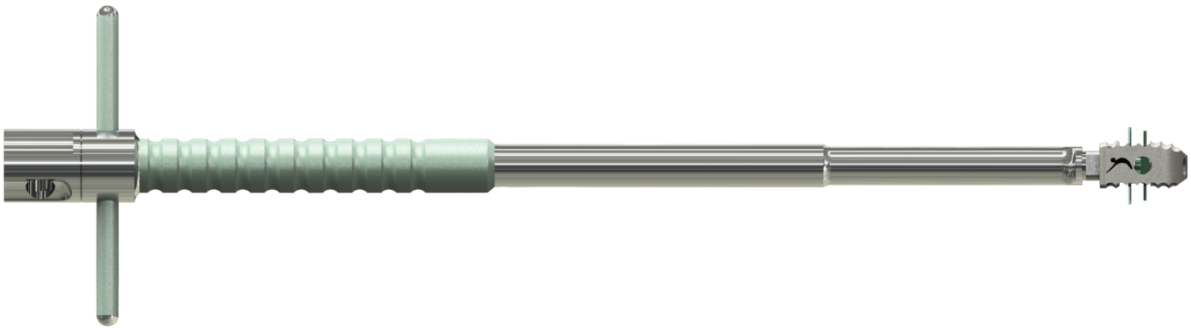


Mono Bladed Peek Cage

PRODORTH PROYSTER INSTRUMENTS

Prodorth offers different designs of instruments for each step of the surgical procedure. They have been designed as simple as possible and user-friendly in order to provide ease of use.

Prodorth instruments are made of stainless chrome nickel steel, aluminum, and silicone.



PC 300.30.002 **Cervical Cages Inserter**

PC 300.30.003 **Cervical AWL**

PC 300.30.004 **Distraction Screw Driver**

PC 300.30.005 **Cervical Trial Inserter**

PC 300.30.006 **Small Mallet**

PC 300.30.007 **Caspar Distractor**

PC 300.30.008 **Distractor Screw**

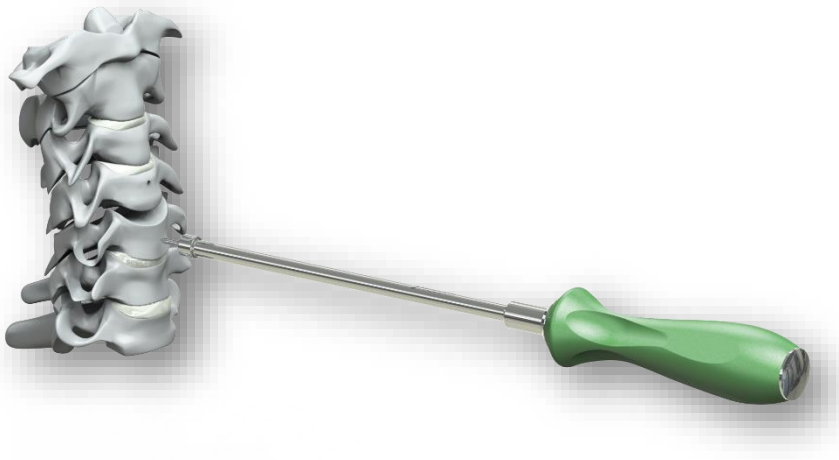
SURGICAL PROCEDURE

Step 1

The patient is positioned properly in the adequate position. The general essentials of anterior cervical surgery is applied.

Step 2
Preparation of the Vertebras

Use Prodorth AWL or to ream the vertebrae in order to make the initial holes for the distraction screws.

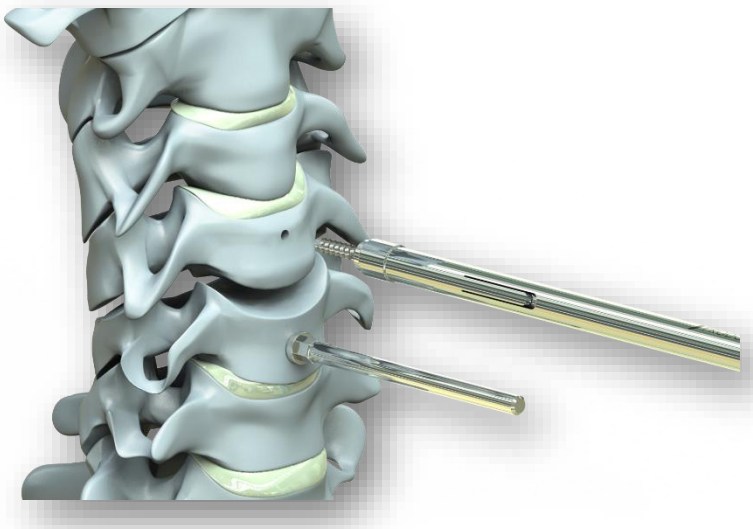


Step 3
Assembly of Distractor Screws

Insert the distractor screws into the tip of the distraction screwdriver and push it until assuring it's fully connected.

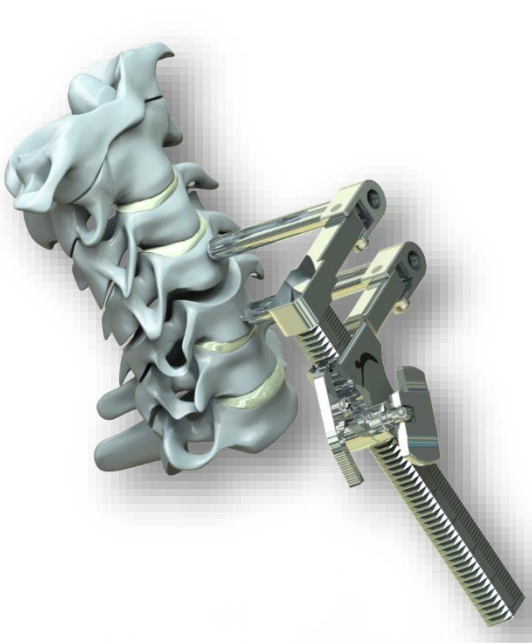
Step 4
Completing the Distraction Preparation

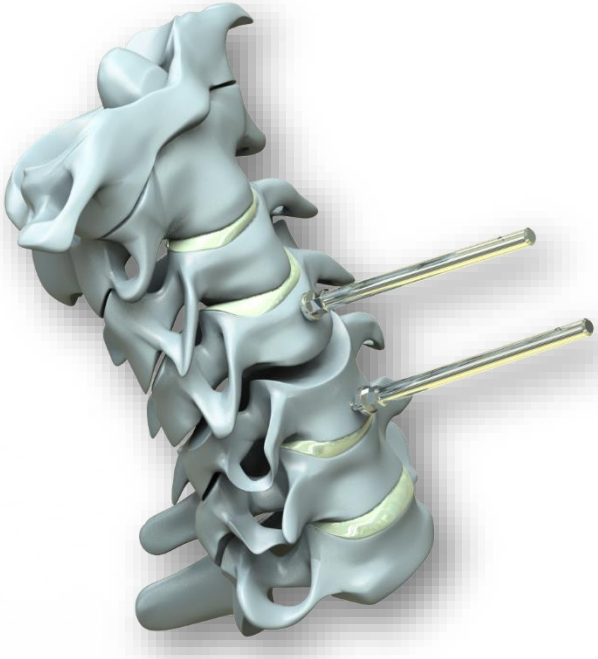
The previous actions at the step-2 and step-3 are repeated for the adjacent vertebra.



Step 5
Distraction

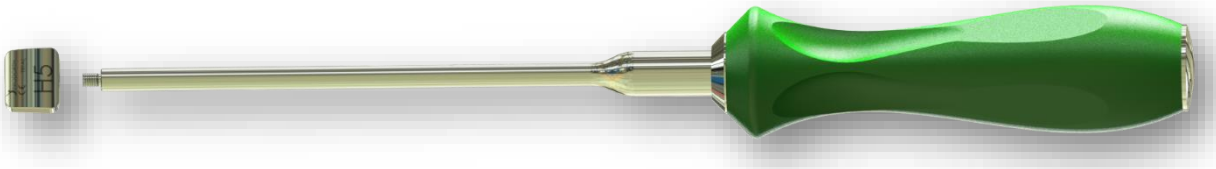
After the distraction screws are inserted properly, the Caspar Distractor's tips are assembled to the screws. And the ratchet of the Caspar Distractor is rotated gradually, until the desired distance between vertebras is obtained.





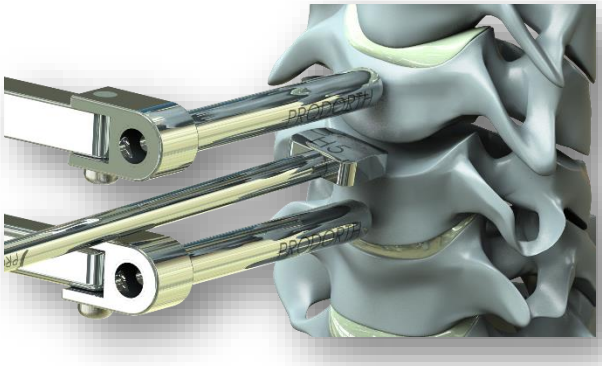
Step 6
Assembly of Trial Implant

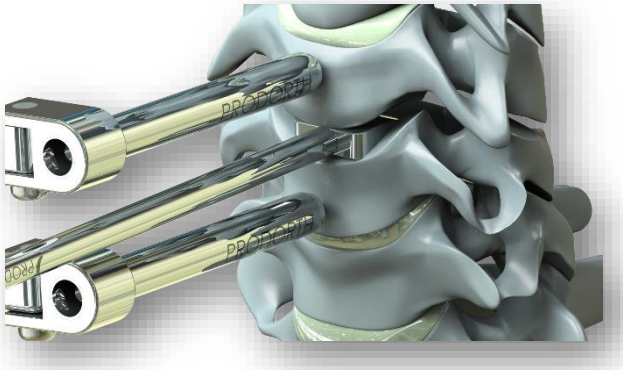
Assemble the trial implant to the trial implant driver properly.



Step 7
Insertion of the Trial Implants

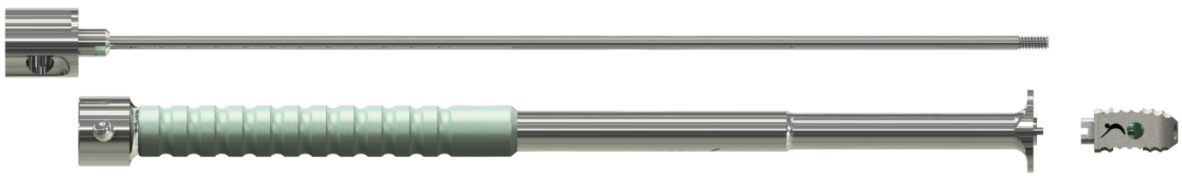
The trial implants are introduced through the vertebras in order to determine the accurate size of the implant. It's represented at the figures below





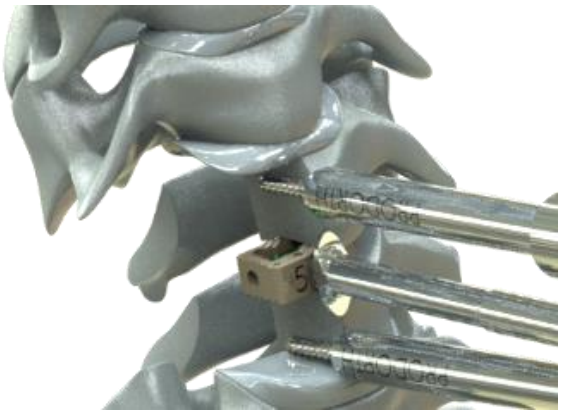
Step 8
Connection of the cervical cage with its inserter

Cervical cage is connected to the inserter as represented in figures below. There is no possibility of a wrong connection due to pins structure of the instrument. These pins at the tip of the instrument have a special design, enabling only one right connection. The wheel behind the inserter is rotated clockwise, thus the Cage is fixed. This fixation provides more stable and reliable placement.

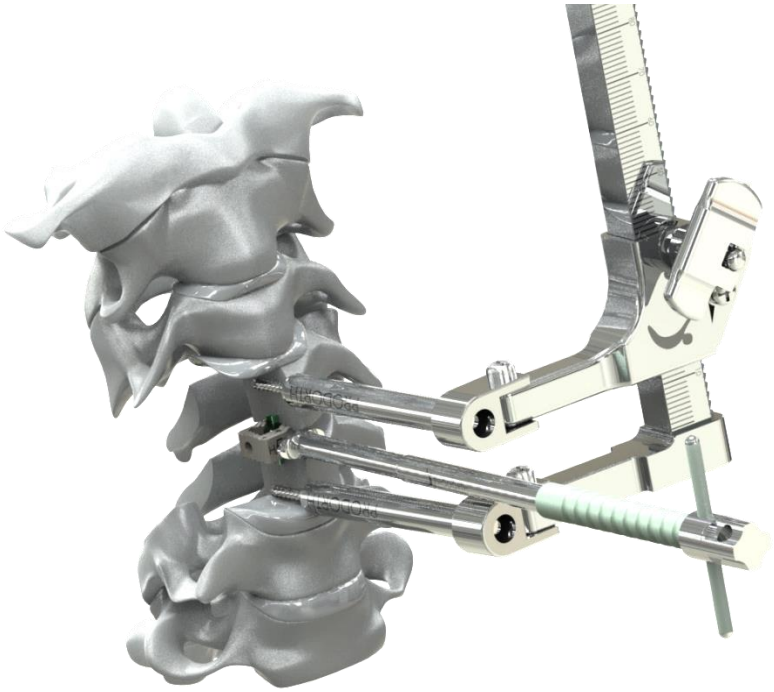


Step 9
Insertion of the Cage

PRODORTH cervicalcage is placed as the marked arrow on the implant is at upside. Instruments stopper blocks should be vertical to the peek cage while it's introduced into the intervertebral area thus the stoppers will lean on the vertebral bodies which means the cage is advanced to the accurate position. (As represented at the picture below.)



As the final action, the wheel with the stick is rotated 90° (clockwise or anti-clockwise) thereafter the wheel behind the instrument is loosened by rotating it anticlockwise and the cage released at the desired position.



PRODORTH

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See the IFU prior to use for additional information.

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