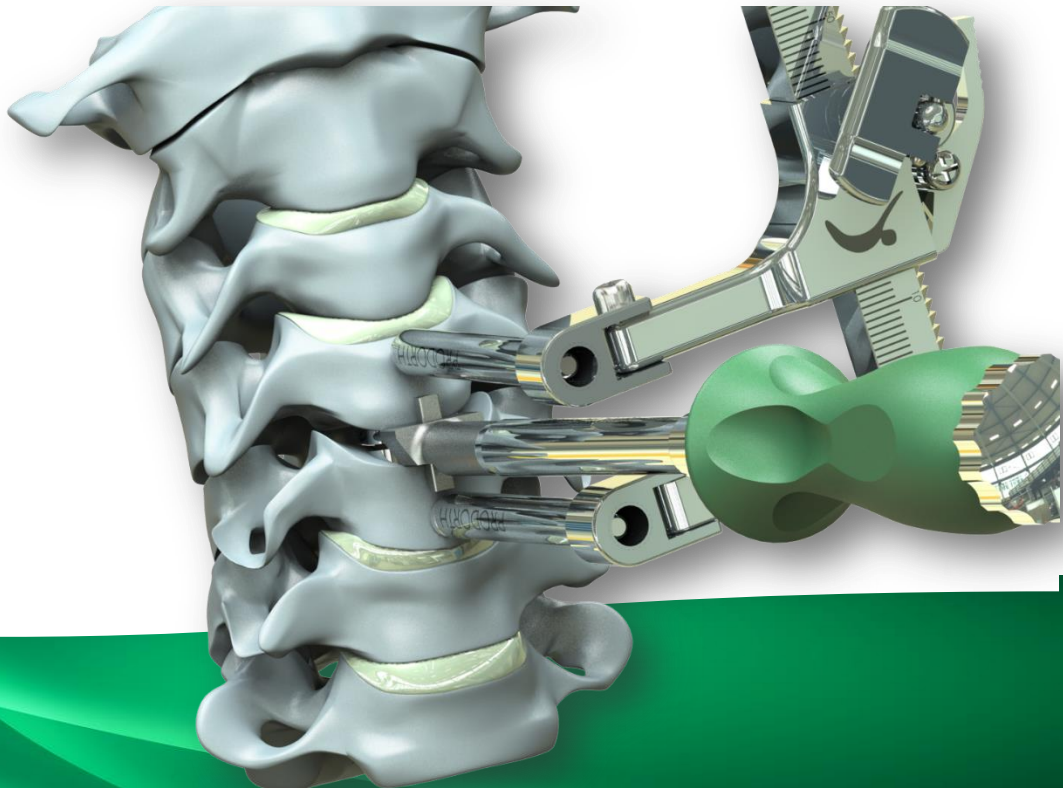
PRODORTH

Simple Techniques, Sophisticated Solutions

PROCORAL *V.2*

Surgical Technique

Cervical Disc Prosthesis



SURGICAL TECHNIQUE OF PRODORTH CERVICAL DISC PROSTHESIS

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 Cervical Disc Prosthesis is an implantation system used for disposing the complaints of the patients which are risen from the due to the herniation at discs, traumas or any disorders on cervical spine.

Prodorth Cervical Disc Prosthesis 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 Disc Prosthesis GMDN No:** 48164
- **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 Disc Prosthesis 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:**

PRODORTH Disc Prosthesis is a long-term implant in order to dispose the complaints of the patients which raised because of the pain arising from the herniation at cervical discs, traumas on cervical spine.

- 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:
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

CONTRAINDICATIONS :
Fracture, tumor
Osteoporosis. Calcium metabolism disorder
Pregnancy
Infection.
Recognized allergies to titanium or titanium alloys
Damaged cervical vertebrae from an accident (trauma) at the level of the surgery.
An unhealthy shape (deformity) of the cervical 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 Disc Prosthesis. 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 Disc implants shall be reused.

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

Prodorth Cervical Disc Prosthesis Description

Prodorth Cervical disc prosthesis is intended for single use only and restore the degenerative disc pathologies.

When a disc degenerates, the disc:

• Loses liquid. Less liquid content results in a thinner disc which has less padding. The disc might become less flexible.

• May have mini tears or cracks in the annulus fibrosus. Disc degeneration might cause the:

- Inner disc (nucleus pulposus) to squeeze through the outer disc (disc bulge or disc herniation).
- Spinal canal to narrow and pinch the cord and nerves (spinal canal stenosis).
- Spinal cord to be irritated causing a loss of feeling or movement (myelopathy).
- Nerve roots to be irritated or pinched causing pain, weakness, or tingling down the arm and possibly into the hands (radiculopathy).

After discectomy operation, Prodorth Cervical Disc Prosthesis is put through vertebras in order to maintain these problems.

Cervical Disc Prosthesis is composed of 2 plates working separately and connected each other by a kind of a particular pin, besides a special designed PEEK system is used at the inner mechanism to obtain a more efficient movement capability. Using ProCoral V.2 cervical disc prosthesis instead of traditional fusion cages minimize the Heterotopic Ossification, with its capability to make motions to various directions and in result it has nearer behaviour to an healthy disc.

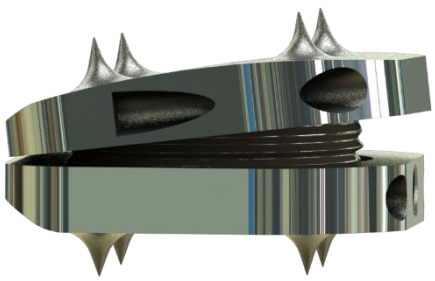
PRODORTH Cervical Disc Prosthesis is intended to work as an artificial disc between the vertebras. Used at total disc replacement (TDR) surgeries which aims to behave like the similar properties of an actual disc.

ProCoral V.2 is designed as Metal – PEEK- Metal (M-P-M) construction with various sizes and footprints. One piece design of it, provides an easier surgical tecnique as well as the great fixation with its inserter. Furthermore its wear resistance is pretty higher than competitors with its M-P-M design and for long-term, better results have been obtained on post-operative period. The Prodorth's top-notch technology "PEEK tube" cover around the inner mechanism prevent the undesired bone fusion into the disc prosthesis.

Prodorth Cervical Disc Prosthesis

Sizes & Ref. Codes

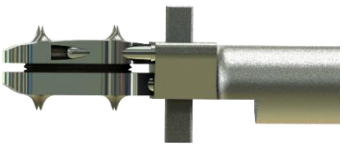
Product Name / Sizes	Ref. Code
PRODORTH CERVICAL DISC PROSTHESIS 14x16x5,5 mm	102.08 0055
PRODORTH CERVICAL DISC PROSTHESIS 14x16x6,5 mm	102.08 0065
PRODORTH CERVICAL DISC PROSTHESIS 14x16x7,5 mm	102.08 0075
PRODORTH CERVICAL DISC PROSTHESIS 14x16x8,5 mm	102.08 0085

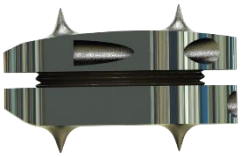


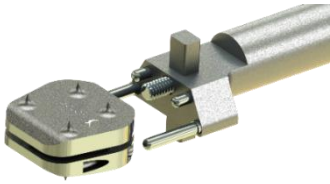
PROCORAL

The advantages of ProCoral V.2 are as follows:

- *PEEK material (ASTM F2026) used in the inner mechanism which provides a super-smooth surface for the best motion capability.*
- *Stronger&Sharper pins on the surface as well as with the new designed geometry in the most appropriate form for the anatomical structure of intervertebral area*
- *Allows axial rotations, flexion-extension and lateral bending*
- *Perfect MR visibility by the Titanium (ASTM F136) endplates*
- *One-piece Design which provides a user friendly application*
- *Stable connection with the inserter*
- *Tube-shaped PEEK material (ASTM 2026) is also used around the inner mechanism as a cover, as well as supporting the shock-absorption.*





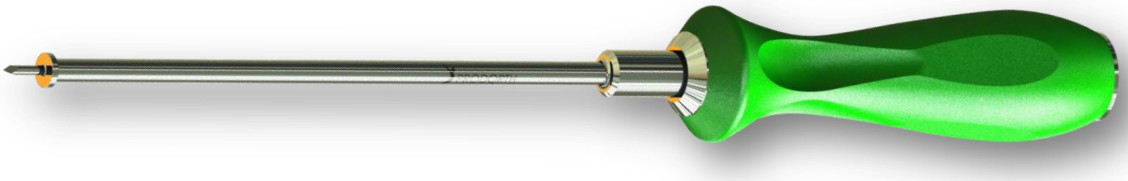


PRODORTH PROCORAL V.2 INSTRUMENTS

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 300.30.001 **Cervical Disc Prosthesis 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**

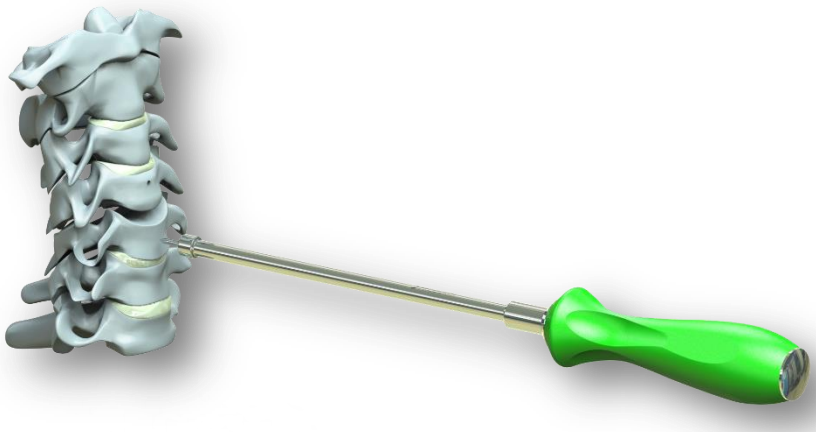
SURGICAL PROCEDURE

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.

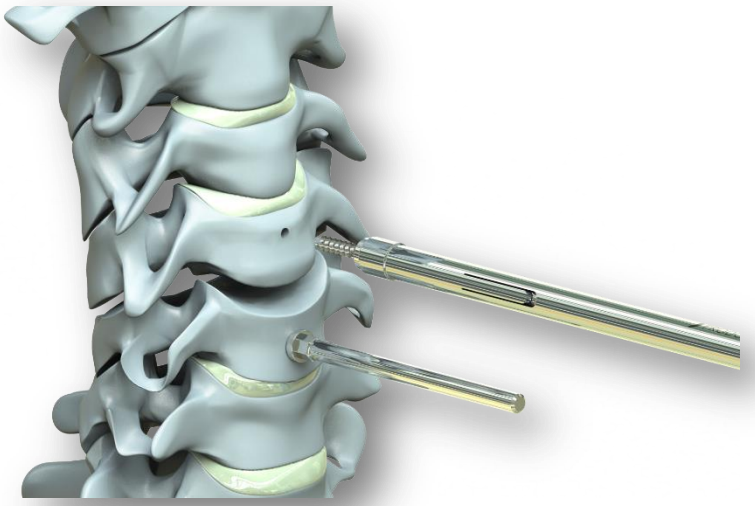


Step 3
Assembly of Distractor Screws

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

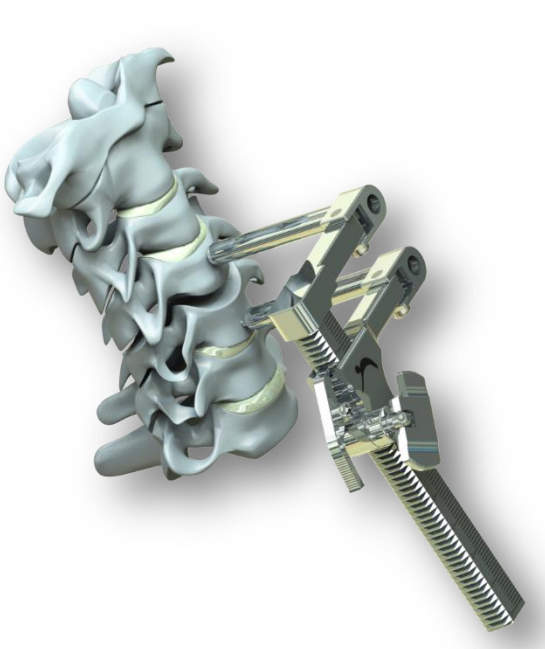
Step 4
Completing the Distraction Preparation

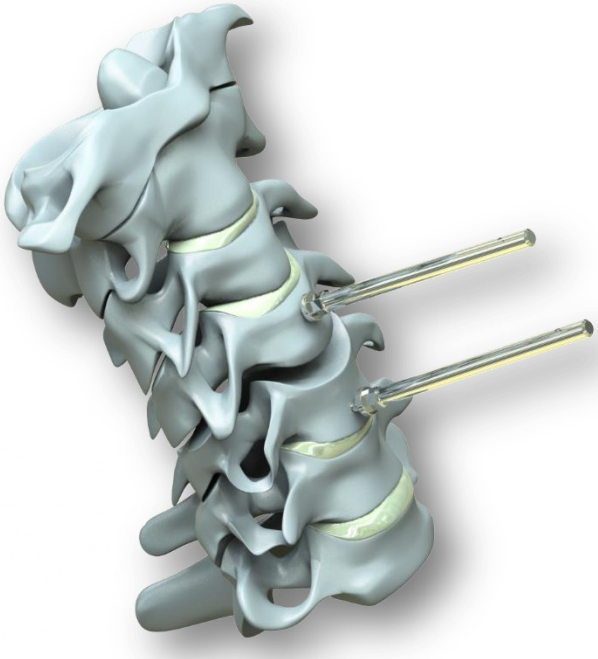
The previous actions at the step-2 and step-3 are repeated for the adjacent vertebra.



Step 5
Distraction

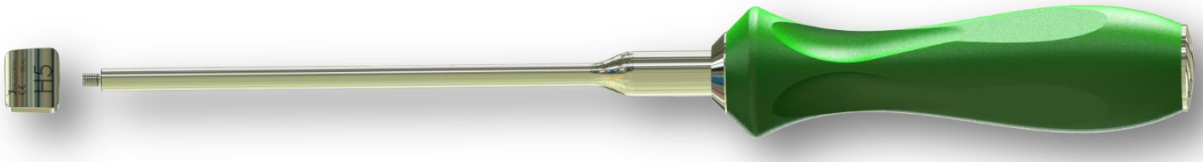
After the distraction screws are inserted properly, the Caspar Distractor's tips are assembled to the screws. And the ratchet of the Caspar Distractor is rotated gradually, until the desired distance between vertebras is obtained.





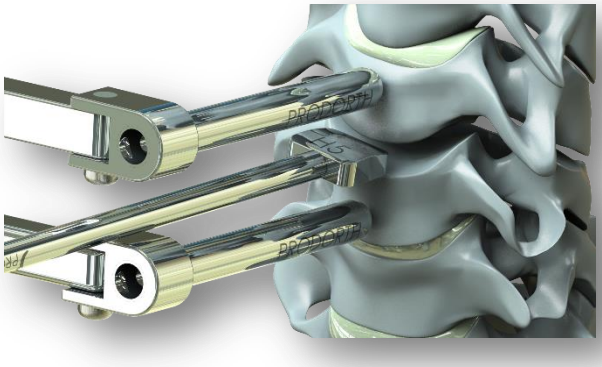
Step 6
Assembly of Trial Implant

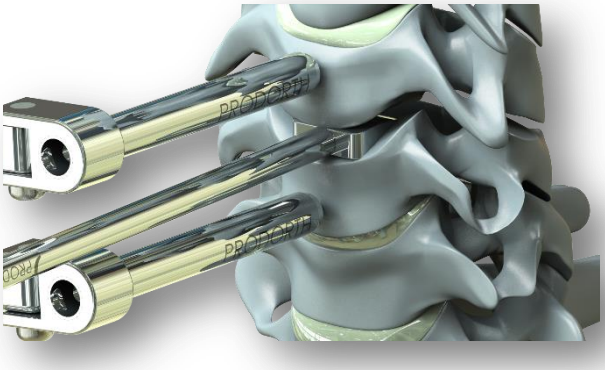
Assemble the trial implant to the trial implant driver properly.



Step 7
Insertion of the Trial Implants

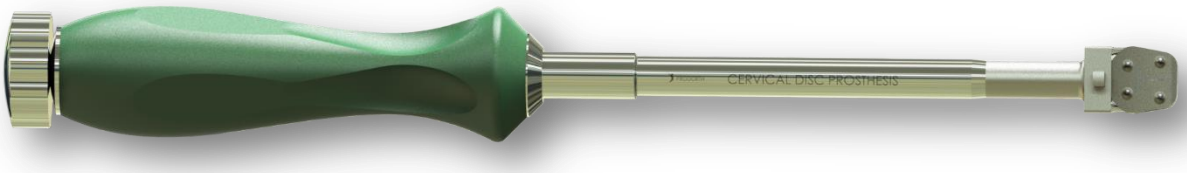
The trial implants are introduced through the vertebras in order to determine the accurate size of the implant. It's represented at the figures below





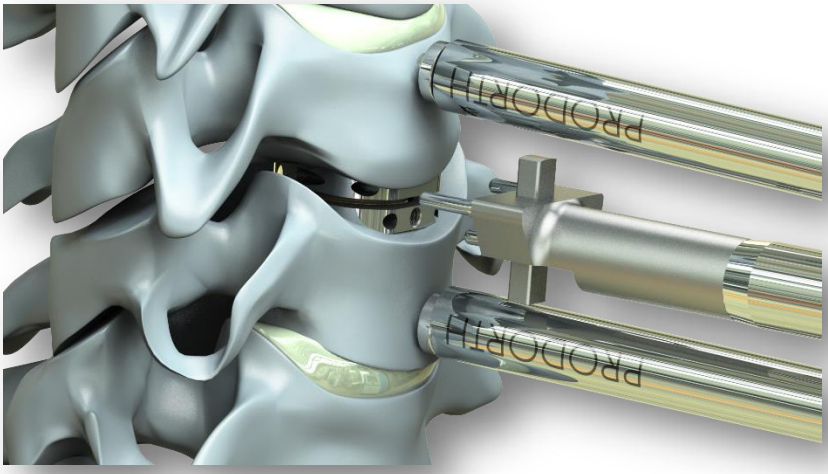
Step 8
Connection of the disc prosthesis with its inserter

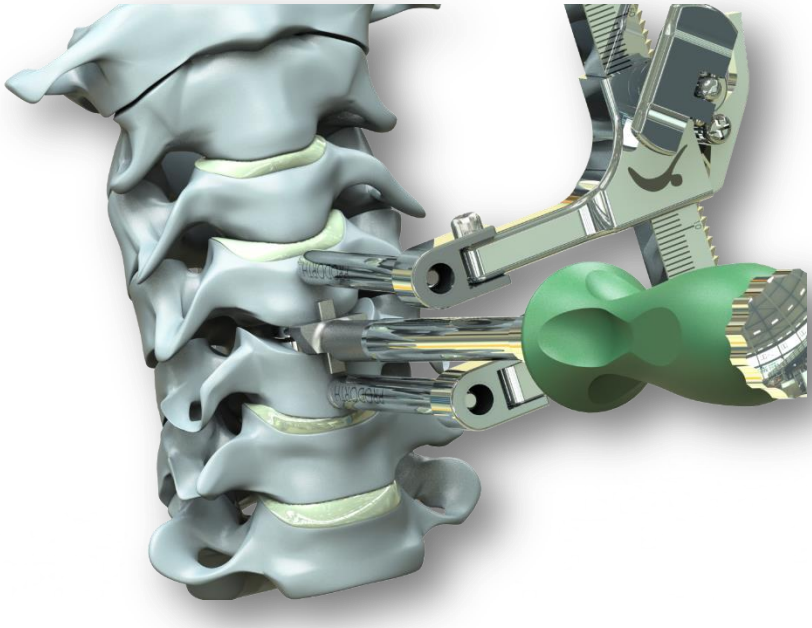
Cervical disc prosthesis is connected to the inserter as represented in figure 40. There is no possibility of a wrong connection due to rails of the instrument. Rails have a special design, enabling only one right connection. Rails of the instrument have different lengths suitable to the sockets of implant. The wheel behind the inserter is rotated clockwise, thus the disc prosthesis is fixed. This fixation provides more stable and reliable placement.



Step 9
Insertion of the Disc Prosthesis

PRODORTH cervical disc prosthesis is placed as the marked arrow on the implant is at upside . It's presented at the figures above. This arrow marked on the instrument, shows the right placement position easier





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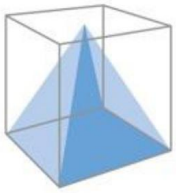

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