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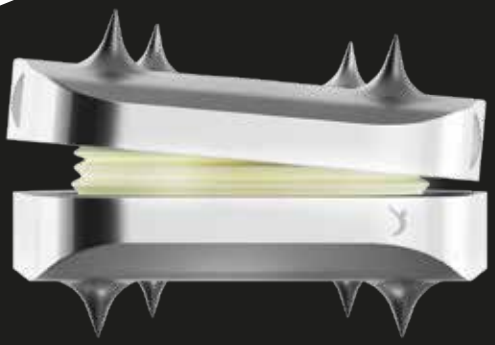

PROCORAL™

Surgical Technique Guide
Anterior Cervical Disc Prosthesis

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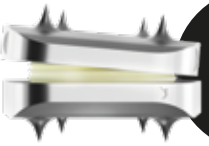

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SURGICAL TECHNIQUE OF PRODORTH CERVICAL DISC PROSTHESIS

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 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 Anterior Cervical Disc Prosthesis 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 discs, traumas, or any disorders on the cervical spine.
Prodorth Cervical Disc Prosthesis is introduced using the anterior approach by its special instruments. Prodorth Cervical Disc Prostheses 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 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 Cervical Disc Prosthesis 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 Disc Prosthesis 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

Prodorth Cervical Disc Prosthesis 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 discs, traumas, or any disorders on the cervical spine.

- 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

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

CONTRAINDICATIONS

Prodorth Cervical Disc Prosthesis should never be used in any condition not described in the indications for use. Contraindications include, but are not limited to:
- Fracture, tumor
- Osteoporosis (Calcium metabolism disorder)
- Pregnancy
- Infection
- Recognized allergies to titanium or titanium alloys and PEEK material
- Damaged 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
- Severe facet joint disease or degeneration
- Mental disability
- Any condition not described in the indications for use
- 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
- Hoarseness
- Pain or illness
- Wound infection
- HO (heterotopic ossification)
- Anterior displacement of the disc adjacent segment degeneration
- Bleeding blood vessels
- Bursitis
- Inability to perform daily activities
- Death

WARNINGS

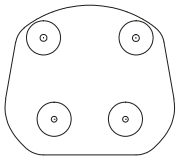
- Never re-use an implant even in a perfect state. Any implant which has been used, twisted, bent, implanted and then removed even if it appears intact, it must be discarded
- Use new implants routinely
- Similar products of competitors shall not be combined with the components of the Prodorth Cervical Disc Prosthesis. Prodorth implants and instruments should only be used with Prodorth instruments. In case 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 Prosthesis 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 CERVICAL DISC PROSTHESIS DESCRIPTION

Prodorth Cervical Disc Prosthesis is intended for single use only and to restore degenerative disc pathologies.
When a disc degenerates, the disc loses liquid. Less liquid content results in a thinner disc that has less padding. The disc might become less flexible. May have mini tears or cracks in the annulus fibrosus.
Disc degeneration might cause the:

- The inner disc (nucleus pulposus) squeezes through the outer disc (disc bulge or disc herniation)
- Spinal canal narrows and pinches the cord and nerves (spinal canal stenosis)
- The spinal cord is 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 the discectomy operation, Prodorth Cervical Disc Prosthesis is put through the vertebras in order to maintain these problems.
Cervical Disc Prosthesis is composed of 2 plates working separately and connected to each other by a kind of particular pin, besides a specially 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 in various directions and as result, it has similar behavior to a healthy disc.
Prodorth Cervical Disc Prosthesis is intended to work as an artificial disc between the vertebrae. Used in total disc replacement (TDR) surgeries which aim 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 technique as well as a great fixation with its inserter.
Furthermore, its wear resistance is pretty higher than competitors with its M-P-M design for the long-term, and better results have been obtained during the post-operative period. The Prodorth's top-notch technology "PEEK ring cover" around the inner mechanism minimizes the bone tissue growth into the disc prosthesis.



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12x14x6,0 mm	102.08 0260
12x14x6,5 mm	102.08 0265
12x14x7,0 mm	102.08 0270
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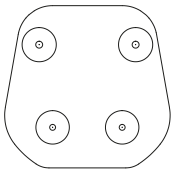

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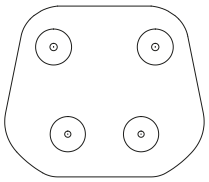

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14x16x7,0 mm	102.08 0070
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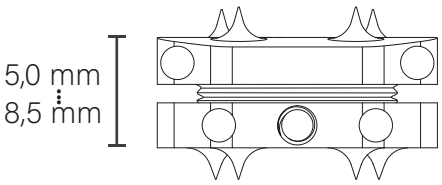
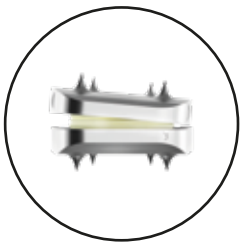
14x16x8,5 mm	102.08 0085





PRODORTH CERVICAL DISC PROSTHESIS 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.

Cervical Disc Prosthesis Inserter PC 300.30.001

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 Disc Prosthesis. (Figure 1)

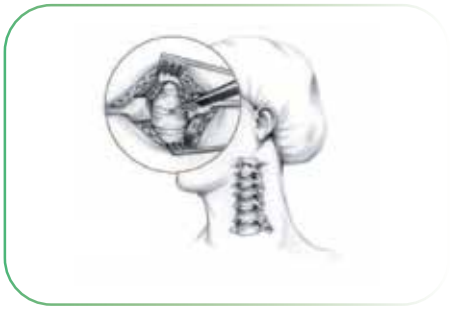


Figure 1

Step 2
Preparation of the Vertebrae

It is recommended that Disc Prosthesis be placed under distraction.

After discectomy, insert the Cervical AWL (PC 300.30.003) to create pilot holes for the caspar pins. (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 action in step-2 is repeated for the adjacent vertebra. (Figure 4)

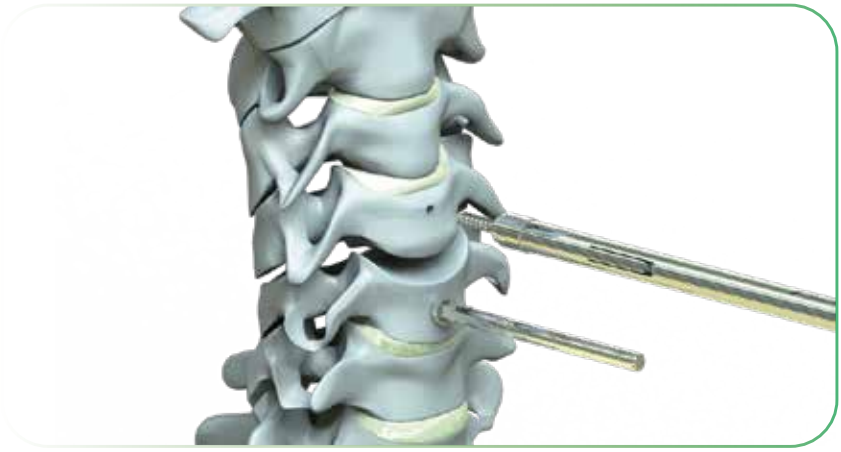


Figure 4

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)

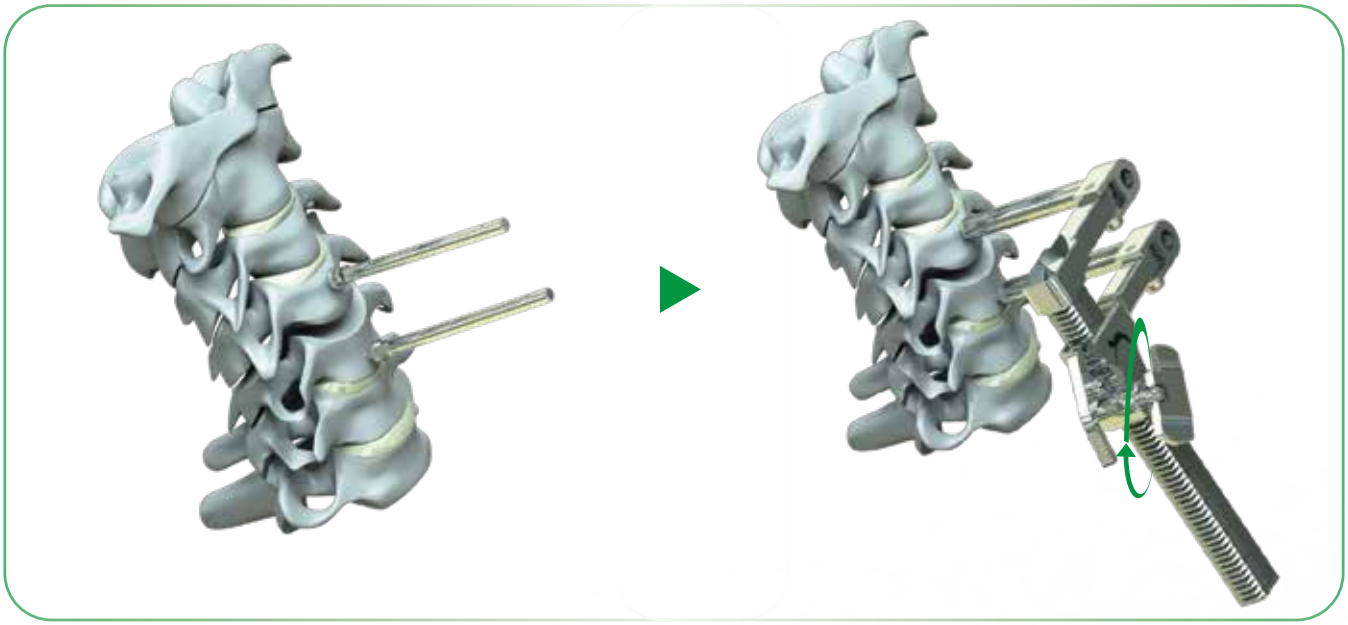


Figure 5

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

Connect the appropriate trial with the trial inserter and carefully place it into the disc space.
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 :
5-8,5 mm (by 0,5 mm increments)

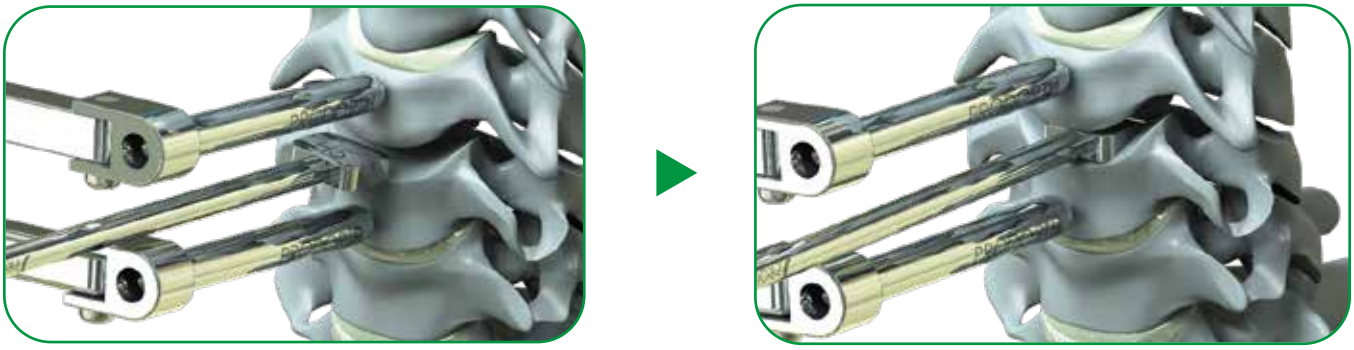


Figure 7

Step 8
Connection of the Cervical Disc Prosthesis with its Inserter

Place the internal bar inside the inserter then attach the disc prosthesis to the distal tip of the inserter by turning the internal bar knob at the back as represented in figure 8. Fully thread the disc prosthesis to the inserter. If some resistance is felt while attaching the disc prosthesis, verify that it is not cross-threaded. There is no possibility of a wrong connection due to the rails of the instrument. Rails have a special design, enabling only one right connection since the rails of the instrument havedifferent lengths suitable to the sockets of the implant. The knob behind the inserter is rotated clockwise, thus the disc prosthesis is connected. This connection provides more stable and reliable placement.

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

Figure 8

Step 9
Insertion of the Cervical Disc Prosthesis

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)
Prodorth Cervical Disc Prosthesis is introduced as the marked arrow on the implant is above. As it's represented in the figure 8.

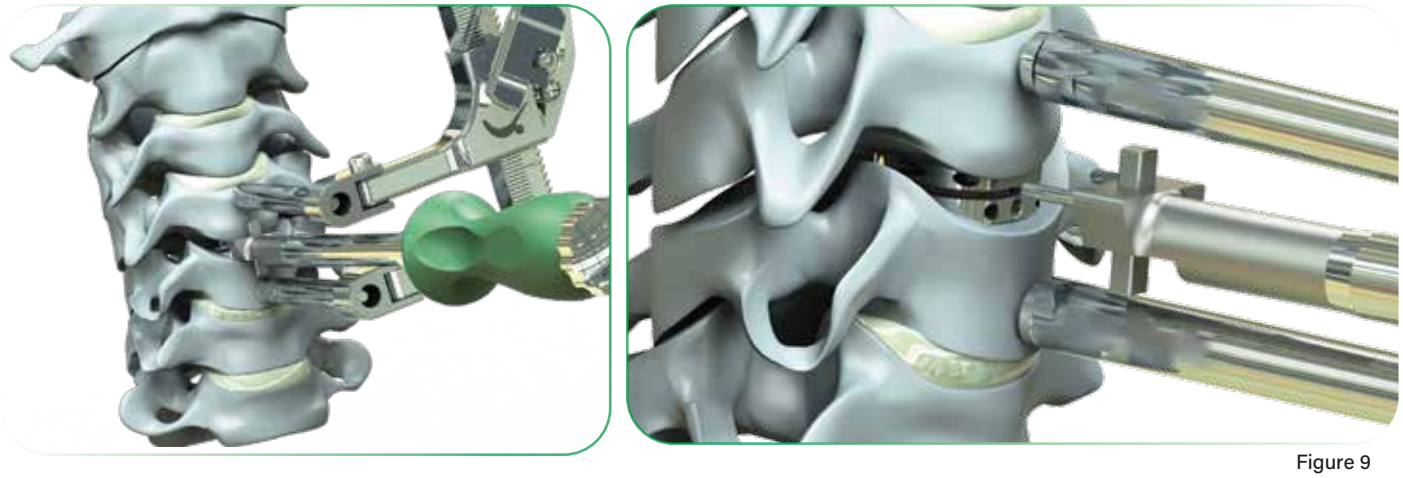


Figure 9

Surgical Technique Guide

Anterior Cervical Disc Prosthesis

PRODORTH

See the IFU prior to use for additional information.

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

CE 2292

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