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Surgical Technique Guide
Anterior Cervical Plate System

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contents

02
04

Surgical Technique of Prodorth Anterior Cervical Plate System

Intended Use of the Device

Secondary and Possible Side Effects

05
06

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Prodorth Anterior Cervical Plate System Instruments

07
09

Step 1
Patient Positioning and Exposure

Step 2
Plate Selection And Positioning

Step 3
Plate Bending

Step 4
Temporary Fixation Pin Insertion
(Optional)

Step 5
Guide Positioning

10

Step 6
Screw Preparation & Insertion

Step 7
Securement of Locking Mechanism

Step 8
Revision / Removal Step

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SURGICAL TECHNIQUE OF PRODORTH CERVICAL PLATES

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 Plate Systems consist of cervical plates, locking caps, bone screws, and the instruments necessary to implant this specific system. All implant components are made from a titanium alloy (Ti-6Al-4V-ELI). This system is intended for anterior interbody screw fixation of the cervical spine.

Current Status of the Device: The device is already CE marked (since 2019) and has been on the market.

Cervical Plate System GMDN No: Plates GMDN code 46653 and Plate Screws GMDN code 46651

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

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

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 Plate 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 Cervical Plate 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 Plate 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 cervical discs, and traumas 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

Prodorth Cervical Plate is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity, pseudoarthrosis, and/or failed previous fusions.

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

CONTRAINDICATIONS

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

- Local inflammation, with or without fever or leukocytosis
- Pregnancy
- Use in the posterior elements (pedicles) of the cervical, thoracic, or lumbar vertebrae
- Where attempted correction exceeds the limits of physiological conditions
- Metabolic disorders that may impair bone formation
- Inadequate bone stock to support the device
- Inability to restrict high activity level
- Obesity
- Mental disability
- Poor prognosis for good wound healing (e.g. decubitus ulcer, end-stage diabetes, severe protein deficiency and/or malnutrition)
- Any abnormality present which affects the normal process of bone remodeling including, but not limited to, severe osteoporosis involving the spine, bone absorption, osteopenia
- Recognized allergies to titanium or titanium alloys
- Alcohol or drug addiction
- An unhealthy shape (deformity) of the vertebrae at the level of the surgery
- 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

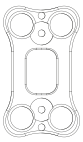
The patient shall be notified regarding the below mentioned adverse events pre-operatively. A second surgical treatment may be required:

- Paralysis
- Dural tear leading to cerebrospinal fluid fistula or pseudo meningocele
- Other spinal cord injuries not otherwise described due to the positioning of the spinal attachment device
- Laminar erosion
- Epidural bleeding
- Abnormal sensations

• Radiculopathy
• Loosening, bending, breaking, disassembly, and/or migration of the components
• Collapse of a fracture and/or fusion site
• Device failure
• Corrosion at the screw/locking cap interface contributes to breakage
• Discomfort or pain, soft tissue erosion, or protrusion due to prominent implanted hardware
• Attachment device pullout, especially with short constructs and osteoporotic bone
• Implant or graft extrusion through the skin
• Postural deformities, pain, skin breakdown, or residual neural compression due to kyphosis or lordosis occurring at the top of the segment being instrumented
• Bone loss or fracture due to stress shielding
• Foreign body reaction to the device including tumor formation, autoimmune disease, metallosis, and/or scarring
• Non-union or pseudoarthrosis
• Cessation of growth at the fusion site
• Discitis, arachnoiditis, and/or other types of inflammation
• Hemothorax
• Deep vein thrombosis, thrombophlebitis, and/or pulmonary embolism that may be fatal; may be due to patient position and/or length of the surgical procedure
• Decubitus ulcer
• Wound infection, deep or superficial, which may require implant removal and/or other medical interventions
• Wound dehiscence, delayed wound healing, or hematoma
• Pain, possibly severe in nature
• Urinary tract infection
• Blood vessel damage and/or blood loss or hemorrhage
• Fracture(s) of the bone
• Gastrointestinal, urological, and/or reproductive system compromise including sterility, impotency, and/or loss of consortium
• Bone graft donor site pain
• Inability to resume activities of normal daily living
• Tissue or nerve damage caused by improper positioning and placement of implants or instruments
• Breathing problems
• Dysphagia
• Death

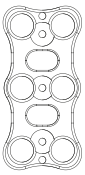
WARNINGS

• 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 Plate. 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 Plate 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!



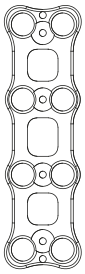
1 Level Plate

SIZE	REF.CODE
20 mm	131.01 0020
22 mm	131.01 0022
24 mm	131.01 0024
26 mm	131.01 0026
28 mm	131.01 0028
30 mm	131.01 0030
32 mm	131.01 0032



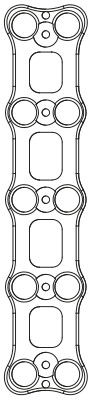
2 Level Plate

SIZE	REF.CODE
34 mm	131.01 0034
36 mm	131.01 0036
38 mm	131.01 0038
40 mm	131.01 0040
42 mm	131.01 0042
44 mm	131.01 0044
46 mm	131.01 0046
48 mm	131.01 0048



3 Level Plate

SIZE	REF.CODE
50 mm	131.01 0050
53 mm	131.01 0053
56 mm	131.01 0056
59 mm	131.01 0059
62 mm	131.01 0062
65 mm	131.01 0065
68 mm	131.01 0068
71 mm	131.01 0071
74 mm	131.01 0074



4 Level Plate

SIZE	REF.CODE
77 mm	131.01 0077
80 mm	131.01 0080
85 mm	131.01 0085
90 mm	131.01 0090
100 mm	131.01 0100

SIZE	REF.CODE
Ø 3,5 x 12 mm	131.02 3512
Ø 3,5 x 14 mm	131.02 3514
Ø 3,5 x 16 mm	131.02 3516
Ø 3,5 x 18 mm	131.02 3518
Ø 3,5 x 20 mm	131.02 3520
Ø 3,5 x 22 mm	131.02 3522
Ø 3,5 x 24 mm	131.02 3524
Ø 3,5 x 26 mm	131.02 3526

SIZE	REF.CODE
Ø 4,0 x 12 mm	131.02 4012
Ø 4,0 x 14 mm	131.02 4014
Ø 4,0 x 16 mm	131.02 4016
Ø 4,0 x 18 mm	131.02 4018
Ø 4,0 x 20 mm	131.02 4020
Ø 4,0 x 22 mm	131.02 4022
Ø 4,0 x 24 mm	131.02 4024
Ø 4,0 x 26 mm	131.02 4026

PRODORTH CERVICAL PLATE SYSTEM 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.

Plate Holder PCP 400.10.001

Plate Screw Locking Driver PCP 400.10.006

Plate Guide PCP 400.10.002

Plate AWL Quick Release PCP 400.10.007

Plate Screw Driver PCP 400.10.003

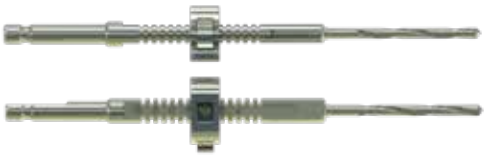


Plate Graduated Drill Quick PCP 400.10.008

Plate Primary Fixation Pin PCP 400.10.004

Plate I-Handle PCP 400.10.009

Mallet (Small) PCP 400.10.005

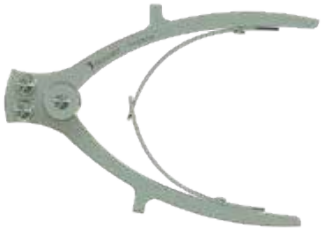


Plate Bender PCP 400.10.010

SURGICAL PROCEDURE

Step 1
Patient Positioning and Exposure

The patient is positioned supine on the operative table with a folded towel beneath the intrascapular region to maintain the head in slight extension. The standard anterior approach to the mid and lower cervical spine is utilized. After identification of the disc space through intraoperative confirmation of levels with x-ray, preparation for surgery is begun. It is critical to remove anterior osteophytes for proper plate placement. Repeat the procedure at each disc space as necessary. (Figure 1)

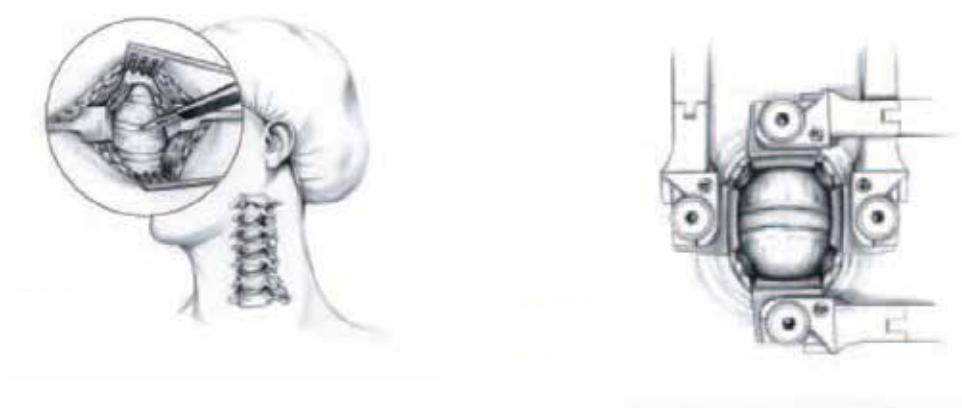


Figure 1

Step 2
Plate Selection And Positioning

Select the required plate with the appropriate length. The Plate Holder (PCP 400.10.001) is specially designed for this purpose. (Figure 2)

Figure 2

Prodorth Plate Holder (PCP 400.10.001) can hold the plate as required. The Plate Holder may be used to hold and position the plate on the anterior surface of the cervical spine.

Pay attention that the lower and upper screw holes are in the correct position on the vertebrae. (Figure 3)

Figure 3

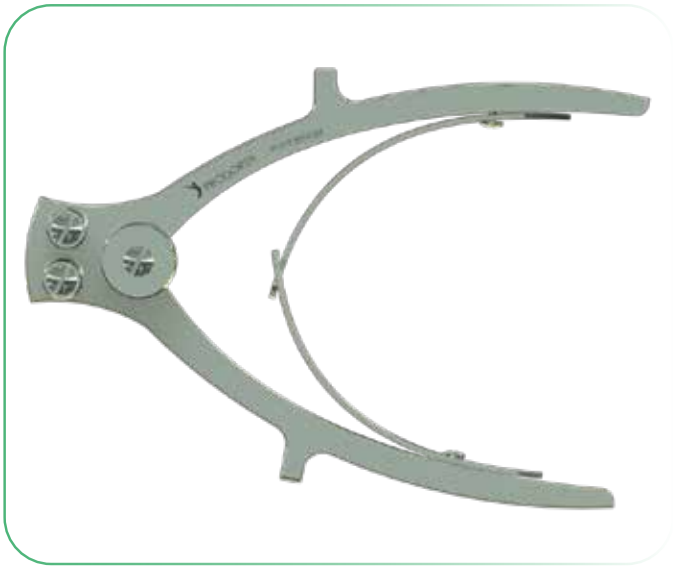


Figure 4

Step 3
Plate Bending

Although the Prodorth Cervical Plates are pre-contoured, if further contouring is necessary, use the Prodorth Plate Bender (PCP 400.10.010). Bending should be performed in small increments avoiding contact with the screw holes.

Note: Reverse bending should not be performed. Do not use the Plate Bender to bend a Prodorth plate reversely. (Figure 4)

Step 4
Temporary Fixation Pin Insertion (Optional)

After the plate has been positioned, a Temporary Fixation Pin may be inserted into the endplate notches. The Temporary Fixation Pin is positioned utilizing the Plate Screwdriver (PCP 400.10.003).

Note: Both Prodorth Cervical Plates Screws and Pins can be introduced by Plate Screwdriver (PCP 400.10.003) (Figure 5)

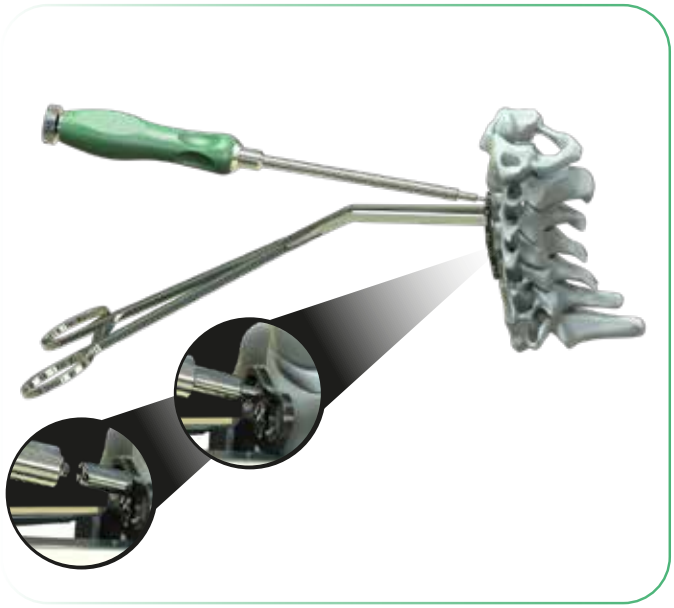


Figure 5

Step 5
Guide Positioning

Use the Plate Guide (PCP 400.10.002) for consistent screw angulations and for drill and screw placement. Prior to the drill, a cervical awl may be used for making the initial hole.(Figure 6) Plate I-Handle (PCP 400.10.009) can be connected to both cervical awl and drills.

Once the drilling is completed accurately, the holes are ready for screw introduction.(Figure 7)

Figure 6

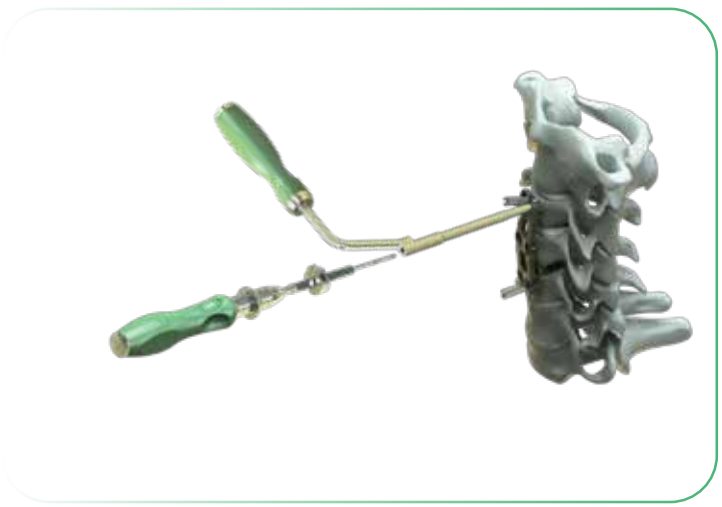


Figure 7

Step 6
Screw Preparation & Insertion

Regarding the Prodorth Cervical Plate System, the standard bone screw diameter is 3.5 mm and the recovery bone screw diameter is 4.0 mm. Using the Plate Screwdriver (PCP 400.10.003), pick up the screw from the tray and place screws in all pre-drilled screw holes. After placing the first screw, proceed with the lateral hole that is opposite and diagonal to the previously placed screw. And continue placing the screws with the same approach.
Perform the final tightening of all screws using the Plate Screw Driver. (Figure 8)
To prevent the plate from 'twisting' during screw insertion, insert a second screw contralateral to the first.

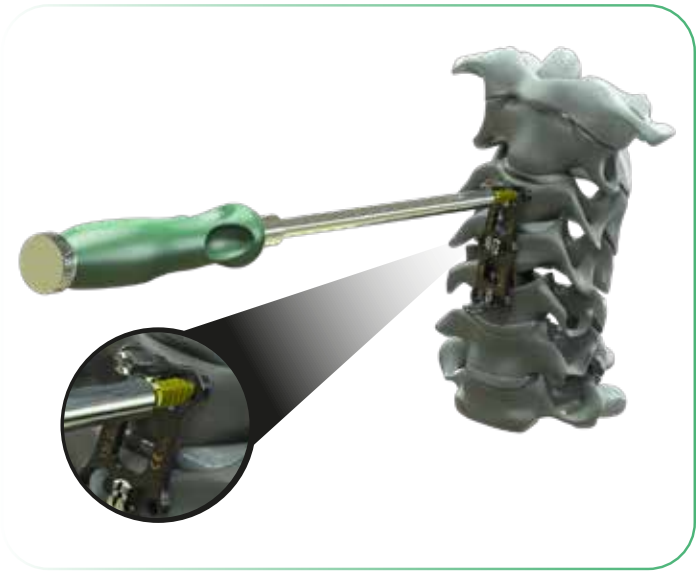


Figure 8

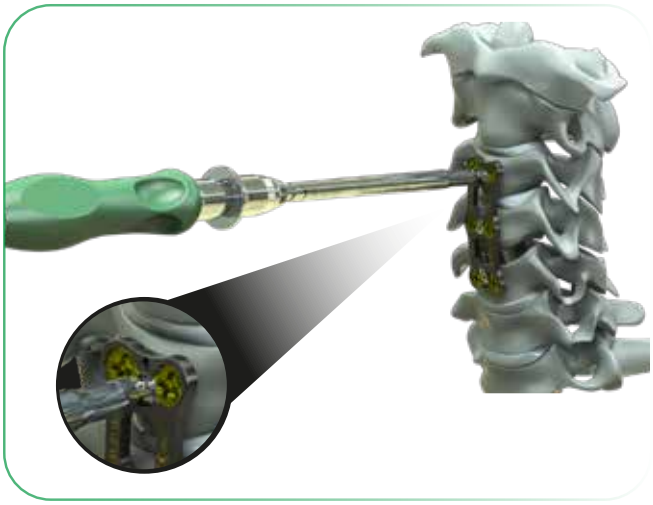


Figure 9

Step 7
Securement of Locking Mechanism

After inserting the appropriate length Bone Screw through the plate, connect the Plate Screw Locking Driver (PCP 400.10.006) to I-Handle (PCP 400.10.009) by pulling up the latch of Plate I-Handle (PCP 400.10.009) and secure the locking mechanisms. (Figure 9)

To disengage the Plate Screw Locked Driver from I-Handle, pull the I-Handle's latch upwards and release. Ensure that all screws are fully seated before securing the locking mechanism.

Step 8
Revision / Removal Step

If unlocking and removal are needed, first unlock the locking mechanisms and rotate the screws respectively anti-clockwise using the plate screwdriver. While the last 2 screws are removed, hold the plate by the plate holder to remove it safely. (Figure 10)

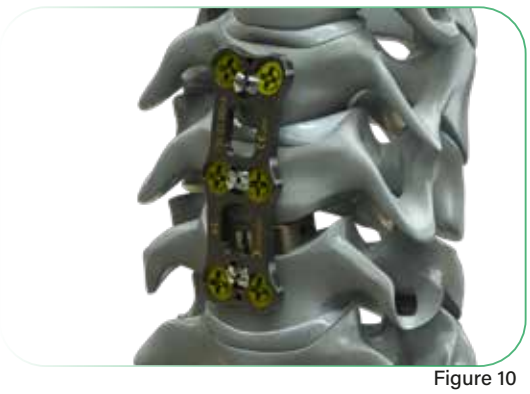


Figure 10

Surgical Technique Guide

Anterior Cervical Plate System

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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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TD.04.06.01 / Rev.05 / 25.07.2022

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