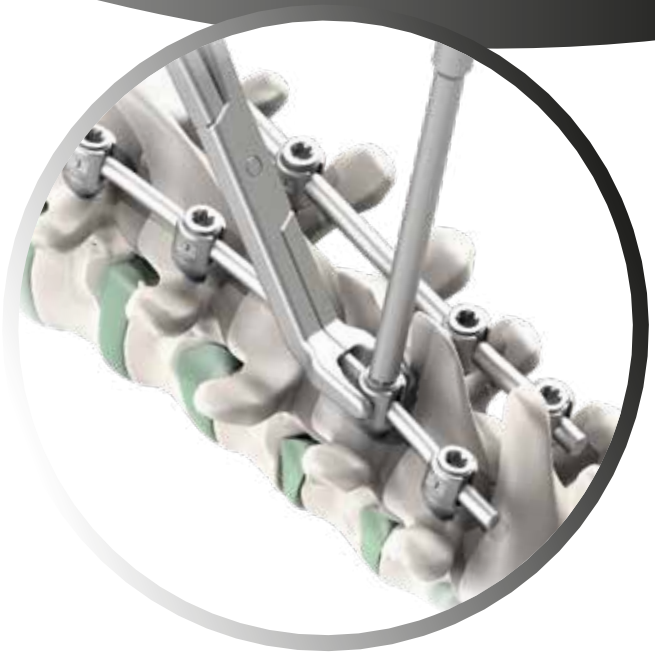
PRODORTH

PROXIPHIAS-C™



Surgical Technique Guide
Posterior Cervical Fixation System

www.prodorth.com

contents

PROXIPHIAS-C™

SURGICAL TECHNIQUE OF PRODORTH POSTERIOR CERVICAL FIXATION SYSTEMS

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 Posterior Cervical Fixation System 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.

Posterior Cervical Fixation System implants are long-term implants, however, they are not able to withstand the forces like healthy bone structures. Posterior Cervical Fixation Systems are attached to the spine with connectors and/or screws combined with rods to support the surgical area during the posterior fusion phase of the bone.

Prodorth Posterior Cervical Fixation System implants are designed and intended to be removed after the establishment of a complete fusion mass.

The raw material used for the Prodorth Posterior Cervical Fixation System is Titanium alloy (ASTM F 136 / ISO 5832-3)

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

Posterior Cervical Fixation System GMDN No: Screws GMDN code 61325, Connectors GMDN code 65114, Hooks GMDN code 65115, Rods GMDN code 65116, Occipital plate GMDN code 46653, 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 Posterior Cervical Fixation Systems are 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 Posterior Cervical Fixation System implant 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 Posterior Cervical Fixation System 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

The specific indications of the Prodorth Posterior Cervical Fixation System are as follows:

- Degeneration of the disc
- Idiopatique Scoliosis
- Deformities of the spine relating to kyphosis
- Paralytic scoliosis and oblique status of the pelvis
- Instability of deformity
- Deformities of the spine
- Oblique status of the pelvis and neuromuscular scoliosis
- Vertebral fracture or dislocation
- Tumors
- Spondylolisthesis
- Stenosis
- Pseudoarthrosis
- Non-union of the bone
- Trauma (i.e., fracture or dislocation)
- Failed previous fusion

The application area of the Prodorth Posterior Cervical Fixation System is the craniocervical junction, cervical C1-C7, and thoracic T1-T3 regions.

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

CONTRAINDICATIONS

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

- Infection history; systemic, spine or localized
- Obesity
- Mental diseases
- Alcohol or drug addiction
- Fever or unusual increase in the amount of leukocyte
- Local inflammation, with or without fever or leukocytosis
- Pregnancy
- Allergic reaction against implant materials
- Serious osteoporosis, osteopenia
- Open wounds

• Congenital abnormality, suspicious spine anatomy, tumor, or any condition, which is affecting dependable implant fixation or shortens the life cycle of the device
• Any kind of condition regarding anatomical structures or physiological performance; including the insufficiency of tissues around the surgical area
• Patients who are not obeying precautions or who are not able to
• An unhealthy shape (deformity) of the vertebrae at the level of the surgery
• Damaged vertebrae from an accident (trauma) 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:

• Bending, loosening or fracture of implants or instruments
• Tissue or nerve damage caused by improper positioning and placement of implants or instruments
• Allergic reactions to metal including possible tumor formation
• Skin or muscle sensitivity in patients with insufficient tissue
• Nonunion or delayed union of the bone
• Infection
• Nervous or vascular damages because of surgical trauma, including loss of neurological functions, paralysis and leakage of spine fluid
• Gastrointestinal, urological or systemic disorders
• Pain or illness
• Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery
• Bone loss above or below surgical limit
• Bleeding blood vessels
• Wrong alignment of anatomical structures; including loss of spine slope, reduction and/or height loss
• Bursitis
• Pain in the area of bone transplantation
• Inability to perform daily activities
• Prolongation of the operation time due to malfunction of some instruments during the operation
• 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 Posterior Cervical Fixation System. 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 Posterior Cervical Fixation System 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!

SIZE	REF.CODE
Ø 3,5 x 10 mm	101.01 3510
Ø 3,5 x 12 mm	101.01 3512
Ø 3,5 x 14 mm	101.01 3514
Ø 3,5 x 16 mm	101.01 3516
Ø 3,5 x 18 mm	101.01 3518
Ø 3,5 x 20 mm	101.01 3520
Ø 3,5 x 22 mm	101.01 3522
Ø 3,5 x 24 mm	101.01 3524
Ø 3,5 x 26 mm	101.01 3526
Ø 3,5 x 28 mm	101.01 3528
Ø 3,5 x 30 mm	101.01 3530
Ø 3,5 x 32 mm	101.01 3532
Ø 3,5 x 34 mm	101.01 3534

SIZE	REF.CODE
Ø 4,0 x 10 mm	101.01 4010
Ø 4,0 x 12 mm	101.01 4012
Ø 4,0 x 14 mm	101.01 4014
Ø 4,0 x 16 mm	101.01 4016
Ø 4,0 x 18 mm	101.01 4018
Ø 4,0 x 20 mm	101.01 4020
Ø 4,0 x 22 mm	101.01 4022
Ø 4,0 x 24 mm	101.01 4024
Ø 4,0 x 26 mm	101.01 4026
Ø 4,0 x 28 mm	101.01 4028
Ø 4,0 x 30 mm	101.01 4030
Ø 4,0 x 32 mm	101.01 4032
Ø 4,0 x 34 mm	101.01 4034

PROLOBSTER™

Cervical Multiaxial Connectors

SIZE	REF.CODE
20 mm - 30 mm	105.11 2030
30 mm - 40 mm	105.11 3040
40 mm - 50 mm	105.11 4050

PROLOBSTER-L™

Cervical Linear Connectors

SIZE	REF.CODE
30 mm	105.12 0030
40 mm	105.12 0040
50 mm	105.12 0050
60 mm	105.12 0060

PROWALRUS™

Laminar Narrow Blade | Laminar Wide Blade | Pedicular

SIZE	REF.CODE
Narrow Blade - Small	151.01 0017N-CS
Narrow Blade - Medium	151.01 0017N-CM
Narrow Blade - Large	151.01 0017N-CL
Wide Blade - Small	151.01 0017W-CS
Wide Blade - Medium	151.01 0017W-CM
Wide Blade - Large	151.01 0017W-CL
Pedicular - Small	151.01 0018-CS
Pedicular - Medium	151.01 0018-CM
Pedicular - Large	151.01 0018-CL

PROLOBSTER-B™

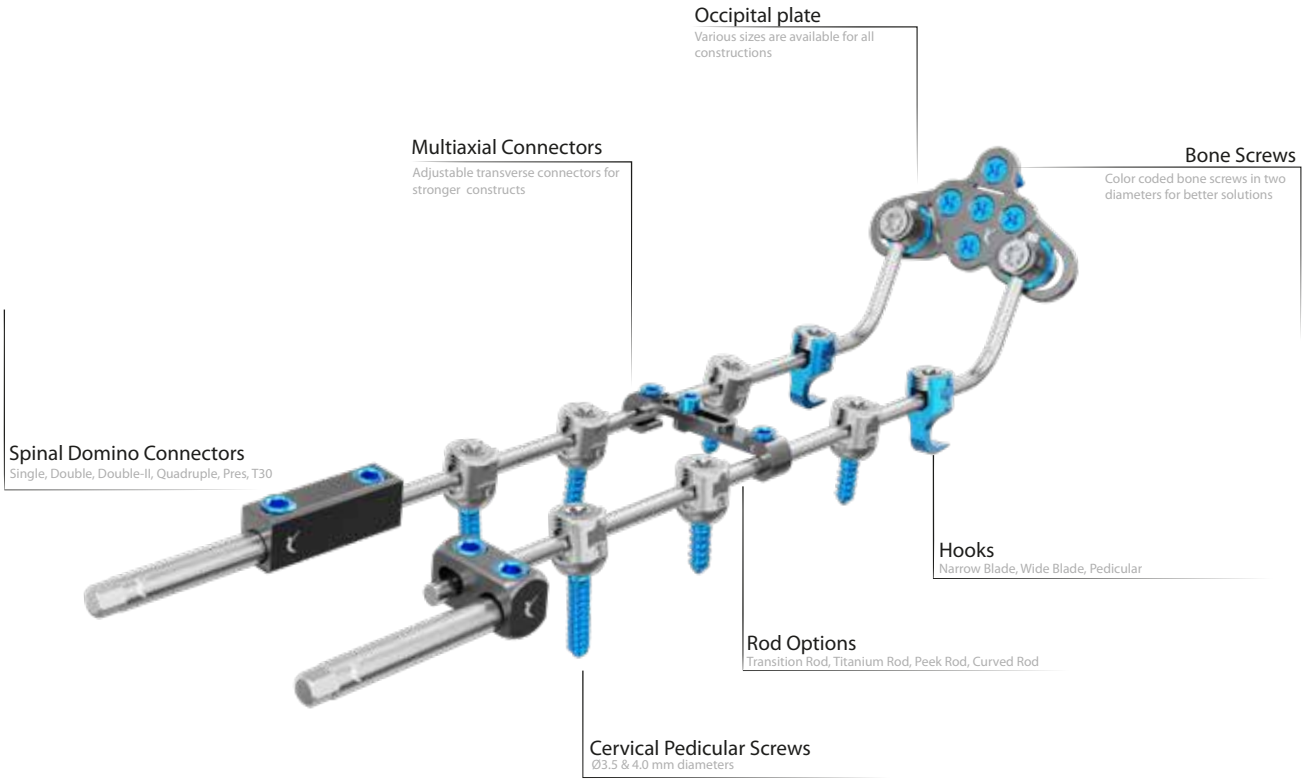
Bar Type Multiaxial Connectors

SIZE	REF.CODE
20 mm - 30 mm	105.01 2030-C
30 mm - 40 mm	105.01 3040-C

SIZE	REF.CODE
Ø 3,5 x 30 mm	104.01 3530
Ø 3,5 x 40 mm	104.01 3540
Ø 3,5 x 50 mm	104.01 3550
Ø 3,5 x 60 mm	104.01 3560
Ø 3,5 x 70 mm	104.01 3570
Ø 3,5 x 80 mm	104.01 3580
Ø 3,5 x 90 mm	104.01 3590
Ø 3,5 x 100 mm	104.01 35100
Ø 3,5 x 110 mm	104.01 35110
Ø 3,5 x 120 mm	104.01 35120
Ø 3,5 x 130 mm	104.01 35130
Ø 3,5 x 140 mm	104.01 35140
Ø 3,5 x 150 mm	104.01 35150
Ø 3,5 x 160 mm	104.01 35160
Ø 3,5 x 170 mm	104.01 35170
Ø 3,5 x 180 mm	104.01 35180
Ø 3,5 x 190 mm	104.01 35190
Ø 3,5 x 200 mm	104.01 35200

Transition Rod

SIZE	REF.CODE
Ø3,5x100 - Ø5,5x250 mm	104.01 3555-T



POSTERIOR CERVICAL FIXATION SYSTEMS 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 Anti-Torque | PPC 100.10.001

Cervical Persuader | PPC 100.10.002

Cervical AWL | PPC 100.10.003

Adjustable Drill Guide | PPC 100.10.004

Adjustable Drill Ø4,0 | PPC 100.10.005

Adjustable Drill Ø3,5 | PPC 100.10.044

Cervical Rod Pusher | PPC 100.10.006

2Nm Torque Limiting Handle | PPC 100.10.007

Cervical I-Handle Locking | PPC 100.10.008

Drill Ø3,5 | PPC 100.10.009A
Drill Ø4,0 | PPC 100.10.009B

Cervical Pedicle Probe Curved | PPC 100.10.010

Cervical Pedicle Probe Straight | PPC 100.10.011

Depth Gauge | PPC 100.10.012

Cervical Polyaxial Screw Driver | PPC 100.10.013

Cervical Screw Setscrew Driver | PPC 100.10.014

Cervical Transverse Connector Setscrew Driver | PPC 100.10.015

Cervical Transverse Connector Holder | PPC 100.10.018

Cervical Screw Pull-Out Instrument | PPC 100.10.019

Cervical Slitted Setscrew Inserter | PPC 100.10.020

Cervical Pedicle Marker Stop | PPC 100.10.021
Cervical Pedicle Marker | PPC 100.10.022

Cervical Feeler Straight | PPC 100.10.023

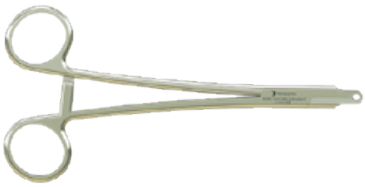
Cervical Feeler Curved | PPC 100.10.024

Cervical Rocker | PPC 100.10.025

Cervical In-Situ Bender | PPC 100.10.026

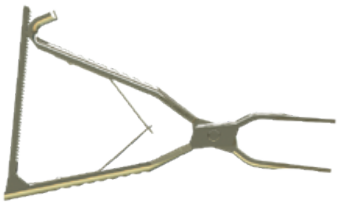
Alignment Tool | PPC 100.10.027

Cervical Rod Bender | PPC 100.10.028



Cervical Rod Holder Forceps | PC 100.10.029

Cervical Distractor | PPC 100.10.030



Cervical Compressor | PPC 100.10.031

Occipital Plate Bender | PPC 100.10.032

Cervical Rod Cutter | PPC 100.10.033

Hook Inserter | PPC 100.10.034

Hook Pusher | PPC 100.10.035

Hook Elevator Lamina | PPC 100.10.036

Rod Gauge (150mm) | PPC 100.10.037

Plate Screw Driver | PPC 100.10.045

SURGICAL PROCEDURE

Step 1
Patient Positioning and Exposure

The patient is placed on a radiolucent operating table in the prone position with the head and neck held securely in proper alignment.
Drape the patient for posterior spinal fusion.
(Figure 1)

Figure 1

Figure 2

Step 2
Preparation of the Pedicle Awl

The awl is inserted to break the cortical surface. The Cervical AWL (PPC 100.10.003) has a hard stop that limits insertion at the required level. Repeat for all screw placement regions. (Figure 2)

Step 3
Preparation of the Pedicle Drilling / Pedicle Probe

The drill can be used through the drill guide by setting it to the desired depth (as 4 mm increments) prior to use. (Figure 3) The same process can also be performed by using the pedicle probe. (PPC 100.10.010 - PPC 100.10.011) (Figure 4)

The Depth Gauge (PPC 100.10.012) is used for checking the hole depth (Figure 5)

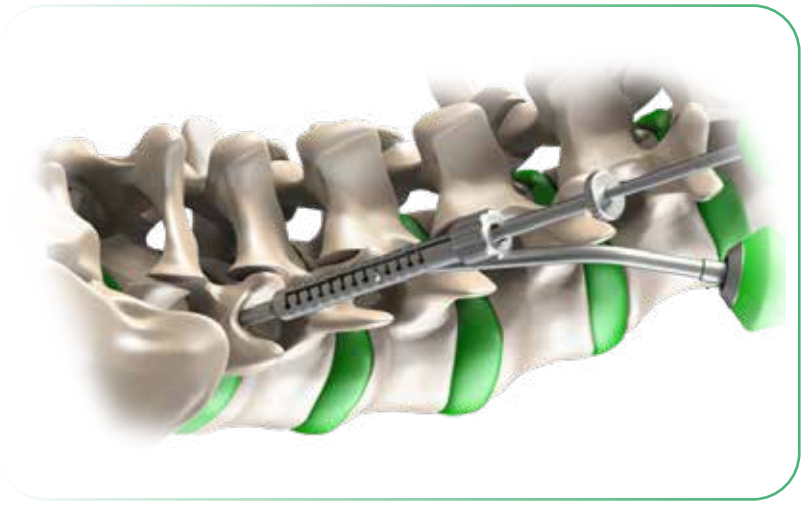


Figure 3

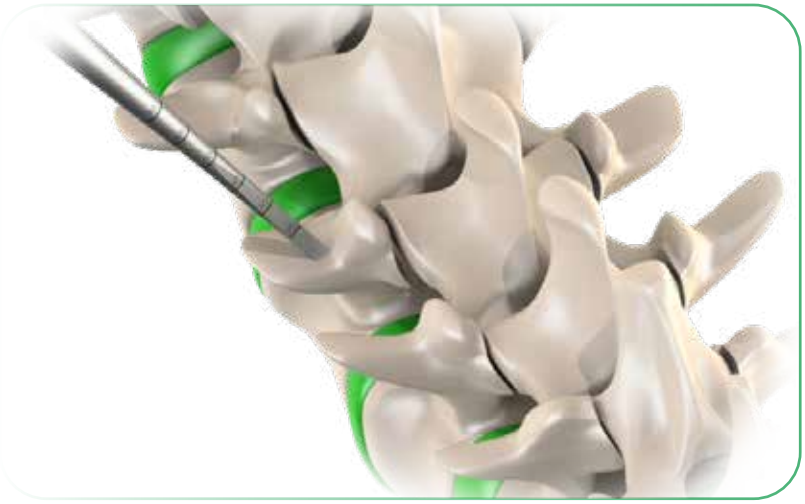


Figure 4

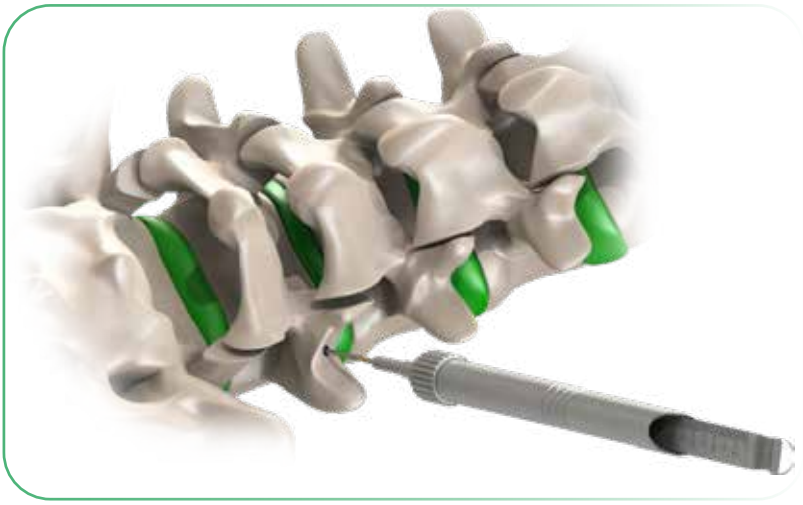


Figure 5

Step 4
Preparation of the Pedicle Verifying the Bone Integrity

You can use the Cervical Feeler(PPC 100.10.023/ PPC 100.10.024) to verify the bone integrity through the hole. It's also used to check if there's any soft tissue inside. (Figure 6)

Figure 6

Step 5
Preparation of the Pedicle Trajectory and Positioning

The Cervical Pedicle Marker Stop and/or the Cervical Pedicle Marker (PPC 100.10.021/ PPC 100.10.022) are inserted into the pedicle throughout the prepared hole, to confirm the position on fluoroscopy to manage positioning and trajectory. The hole shouldn't be too deep, caution should be taken for this. (Figure 7).

Warning: Implants and instruments can cause tissue damage. Care should be taken to minimize damage.

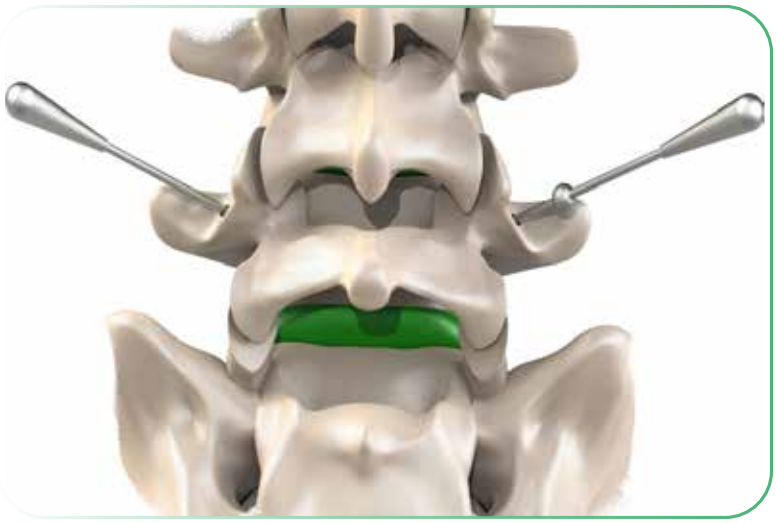


Figure 7

Step 6
Preparation of the Pedicle Drilling

Prior to introducing the screw hole, it should be drilled. Drilling process provides a more reliable advance of the screw. This decision might be different up to the surgeon's opinion and the situation of the patient.(Figure 8)

Figure 8

Screw Diameter	Appropriate Diameter Adjustable Drill
Ø 4,0 mm	Ø 3,5 mm*
Ø 3,5 mm	Ø 3,0 mm*

*Adjustable Drill (PPC 100.10.005/PPC 100.10.044) are designed 0,5 mm less diameter than diameter of the relevant screw.

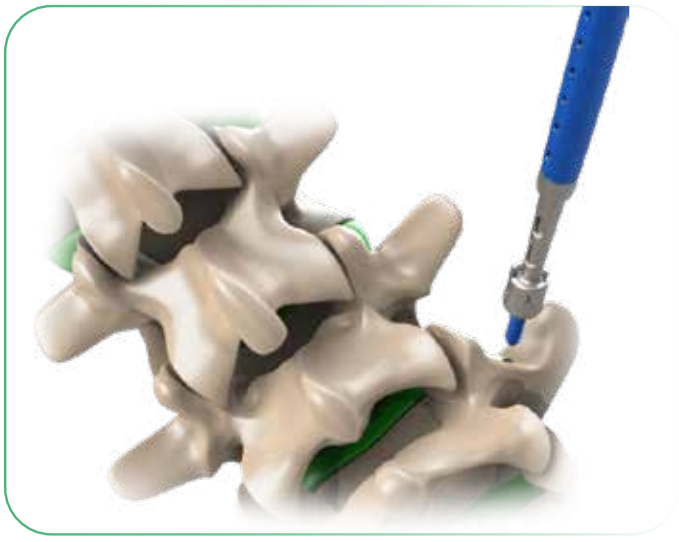


Figure 9

Step 7
Introduction of Screw

The Cervical Polyaxial Screw Driver (PPC 100.10.013) is connected with the Cervical I-Handle Locking (PPC 100.10.008) and then the selected screw is engaged to the screwdriver. (Figure 9)

While engaging the screw to the driver, the Cervical I-Handle Locking should be held constant and the rotatable knob in the middle of the driver will be rotated clockwise and the screw will be engaged in this way.

Warning

- Ensure the driver is completely engaged with the screw before insertion into the pedicle. For a proper connection, make sure that the hexagonal tip of the screwdriver is properly settled into the hex of the screw shank in the tulip
- If some resistance is felt while connecting the screw, verify that it is not cross-threaded
- Remove the screw driver by rotating the Cervical I-Handle Locking anti-clockwise until it's disengaged from the screw
- Then this process is repeated for the remaining screws in the same way

Step 8
Screw Height Adjustment (Optional)

You can reposition the screw by using the Cervical Screw Pull-Out Instrument (PPC 100.10.019). By engaging this instrument with the hex of the screw shank, you can adjust the height of the polyaxial screw more practically. It is not necessary to engage it with threads of the screw head.(Figure 10)

Figure 10

Step 9
Selection of the Appropriate Size of Rod / Rod Cutting

After the screws are placed, the appropriate rod length should be selected for the concerned levels. It's recommended to position the tips of the rod to be extended around 2-3 mm out from the first and last screw placed. The Cervical Rod Cutter (PPC 100.10.033) can be used to cut the rods in case of necessity.

Step 10
Rod Bending

Rod is placed to the screws which are already introduced into the pedicles, and the bending ratio should be determined properly to meet the necessary sagittal profile.

Then the rod is placed between the wheels of the Cervical Rod Bender (PPC 100.10.028) and it's contoured as required. A properly contoured rod should contact the bottom of each screw's saddle. (Figure 11)

Figure 11

Step 11
Rod Placement

After the pedicle screws are placed into the pedicles and the rod is contoured as required, the rod is placed into the saddles of screws by the Cervical Rod Holder Forceps (PC 100.10.029) as represented in Figure 12.

Figure 12

Step 12
Insertion of Setscrews

The setscrews will be provisionally introduced into the saddle of screws with the Cervical Slitted Setscrew Inserter (PPC 100.10.020).

Warning: The "Cervical Slitted Setscrew driver" is not a instrument for tightening but only for the initial insertion of the setscrews. Since it has a slit on its shaft, the setscrew can be attached easily and inserted smoothly without using bone wax.

Warning: Please pay attention while introducing the setscrews, If some resistance is felt during the introduction of the setscrew, verify that it is not cross-threaded.
Once you ensure the setscrew is seated properly into the saddle of the screw, keep rotating the setscrew driver to advance the setscrew to the bottom of the saddle. (Figure 13)
Repeat the process until all setscrews are placed.

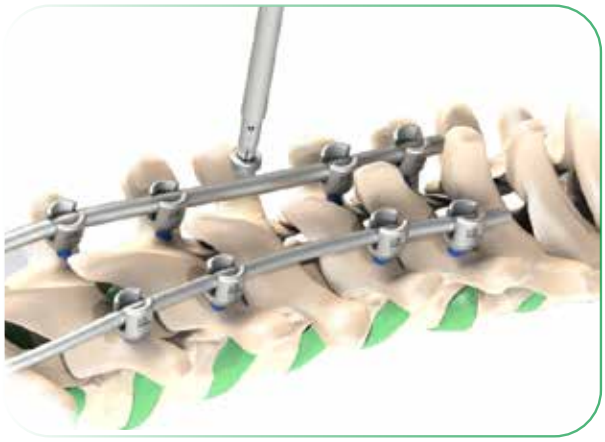


Figure 13

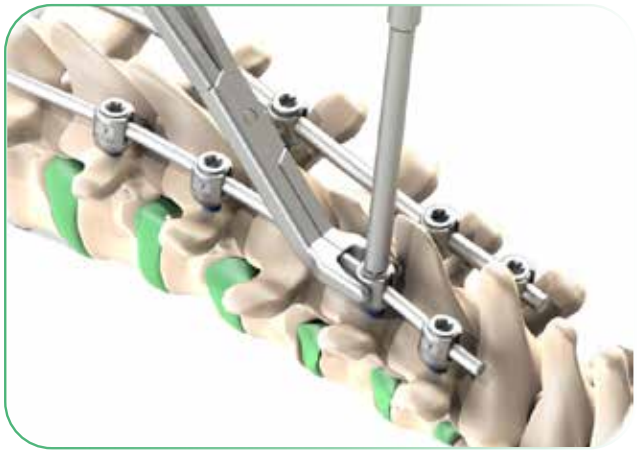


Figure 14

As it's represented at figure 14, the Cervical Rocker (PPC 100.10.025) is used for a proper insertion of setscrews with the Cervical Setscrew Driver.

Note: Cervical Persuader (PPC 100.10.002) can be used instead of rocker for the same purpose.

Step 13
Distraction-Compression

After the rod is placed into the screws, the Cervical Distractor and/or the Cervical Compressor (PPC 100.10.030/PPC 100.10.031) can be used to give the implant construct its final position.

Tighten the setscrew on one side of the level and leave the setscrew loose on the other side. Compress or distract against the provisionally tightened assembly. (Figure 15)

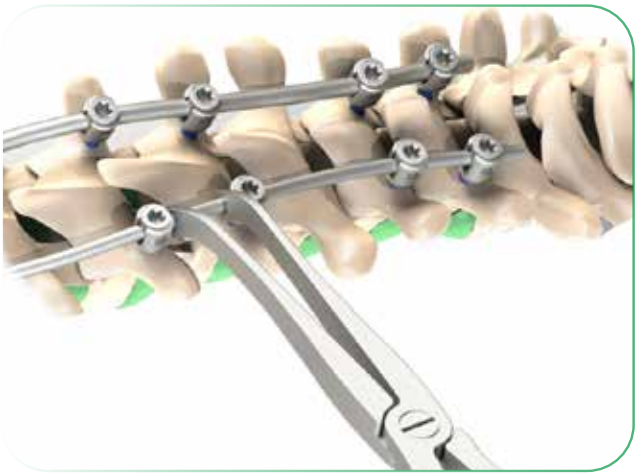


Figure 15

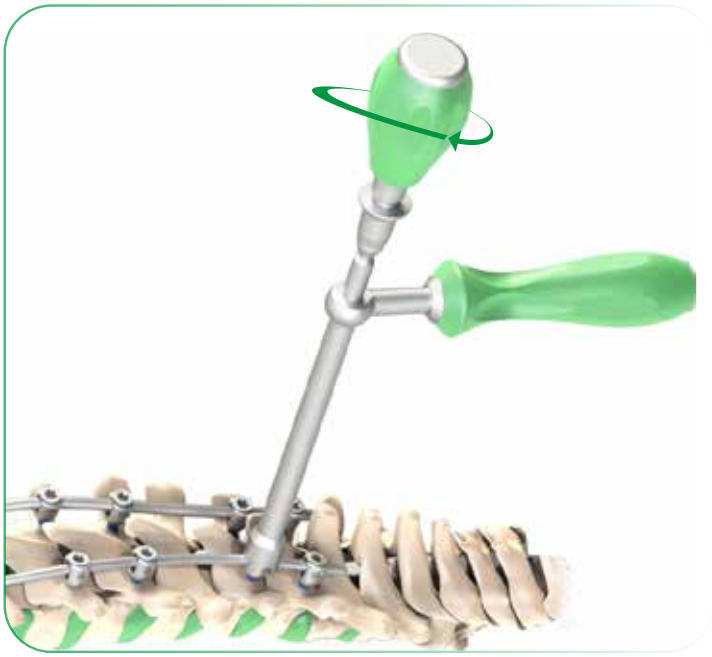


Figure 16

Step 14
Final Tightening of Setscrews

The Cervical Anti-Torque (PPC 100.10.001) instrument is placed as it's represented in Figure 16. Then the Cervical Screw Setscrew Driver (PPC 100.10.014) which is priorly connected to 2 Nm Torque Limiting Handle (PPC 100.10.007) is inserted through the Cervical Anti-Torque (PPC 100.10.001). The torquing process can be done easily in this way.

Tighten the setscrews until the "click-click" sound is heard from the 2 Nm Torque Limiting Handle (PPC 100.10.007). Repeat the process so on for the each setscrew by using the Cervical Anti-Torque (PPC 100.10.001). (Figure 16)

Step 15
Placement of the Connectors (If necessary)

Linear or multiaxial connectors may be used up to the surgeon's decision.
Both of the connectors may be placed between the rods after all the above steps are completed and the nuts on the connectors are tightened with the 2 Nm Torque Limiting Handle (PPC 100.10.007, with the spherical handle) is connected to the Cervical Transverse Connector Setscrew Driver (PPC 100.10.015) and setscrews are tightened by rotating it clockwise. When the "click-click" sound is heard, this means the tightening is completed. (Figure 17)

Note: The multiaxial connector is not only used in a linear direction but also can be positioned at different angles.

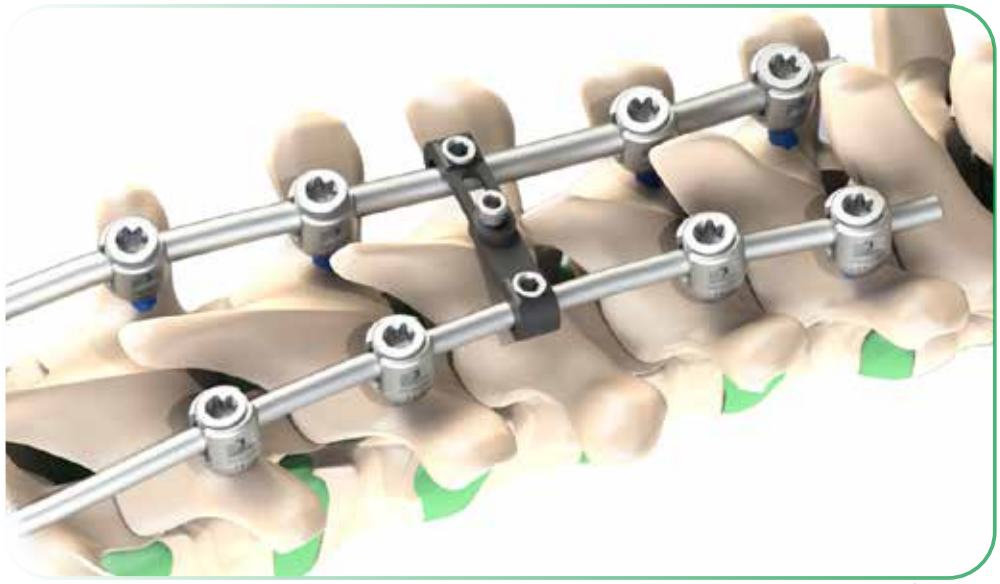


Figure 17

Surgical Technique Guide

Posterior Cervical Fixation Systems

PRODORTH

See the IFU prior to use for additional information.

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

CE 2292

TD.03.06.01 / Rev.05 / 25.07.2022

info@prodorth.com

0090 2323 48 49 50 (pbx)

Karacaoğlan Mah. Bornova Cad.
Öztim İş Merkezi No:9/G/1
Bornova - İzmir / TURKEY