PRODORTH

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Surgical Technique Guide
Posterior Fixation System

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contents

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SURGICAL TECHNIQUE OF PRODORTH POSTERIOR FIXATION SYSTEM

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 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 the lumbar discs, and traumas on the spine. Posterior Fixation Systems are long-term implants, however, they are not able to withstand the forces like healthy bone structures. Posterior 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. Posterior 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 Fixation System is Titanium alloy (ASTM F 136 / ISO 5832-3)

Current Status of the Device: Device is already CE marked (since 2013) and has been on the market.

Posterior Fixation System GMDN No: : Screws GMDN code 61325, Connectors GMDN code 65114, Hooks GMDN code 65115, Rods GMDN code 65116

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 Fixation System 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 Posterior 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 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 the lumbar discs, and traumas on the 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 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
- Nonunion of the bone
- Trauma (i.e., fracture or dislocation)
- Failed previous fusion

The application area of the Prodorth Posterior Fixation System is in the thoracolumbar and sacral segments.

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

CONTRAINDICATIONS

Prodorth Posterior 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 shortening 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 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 Fixation System implants 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!

TYPES AND DETAILED SPECIFICATIONS OF PRODORTH POSTERIOR FIXATION SYSTEM

Prodorth Polyaxial Screw

This product is used to dispose of disorders on the spine. Prodorth Polyaxial screws work as a complete system with its supplementary elements, rods and connectors, Product is composed of 4 parts; screw, tulip, setscrew and presser, Screw part is placed into pedicles, once the incision is made and the muscles are separated. Then the rods are placed through the U-shaped tulips and they are compressed by tightening the setscrews.
The main purpose of this device is, to lead a complete fusion around the entire implant group, and as a result obtain a better health condition with no pain and more relief for the patient.
This product is completely manufactured from Ti6Al4V-ELI (ISO 5832-3) material.

Prodorth Polyaxial Spondylolisthesis Screw

This product is also used for disposing of the disorders on spine, Prodorth Polyaxial screws work as a complete system with its supplementary elements, rods and connectors. Product is composed of 4 parts; screw, tulip, setscrew and presser. Screw part is placed into pedicles, once the incision is made and the muscles are separated. Then the rods are placed through the U-shaped tulips and they are compressed by tightening the setscrews.
The main purpose of this device is, to lead a complete fusion around the entire implant group, and as a result, obtain a better health condition with no pain and more relief for the patient.
This product is completely manufactured from Ti6Al4V-ELI (ISO 5832-3) material.
Spondylolisthesis screws have a longer tulip, and this is used when the vertebra is over-shifted than its normal position.

Prodorth Rod

Prodorth rods are placed through the tulip part of the screw and compressed by setscrew and then the following parts along them are also placed through the tulip/s of the following screw/s therefore a vertical fixation is obtained.
Prodorth Rods are completely manufactured from Ti6Al4V-ELI (ISO 5832-3) material.

Prodorth Linear Connectors

Linear connectors are attached to rods by their hooks therefore a horizontal fixation is obtained.
This product is completely manufactured from Ti6Al4V-ELI (ISO 5832-3) material.

Prodorth Multiaxial Connectors

Multiaxial connectors are attached to the rods by their hooks therefore a horizontal fixation is obtained. Multiaxial connectors allow positioning at various angles as needed and can be fixed at the required position.
Prodorth Multiaxial Connectors are completely manufactured from Ti6Al4V-ELI (ISO 5832-3) material.
The Prodorth Pedicle screws are offered as color-coded and the table below is representing the meanings of the different colors.

COLOR CODE	SCREW DIAMETER	TAP DIAMETER
Sky Blue	3,5 mm	N/A
Dusty Rose	4,0 mm	N/A
Pink	4,5 mm	4,0 mm
Turquoise	5,0 mm	4,0 mm
Green	5,5 mm	4,0 mm
Sky Blue	6,0 mm	5,0 mm
Blue	6,5 mm	6,0 mm
Magenta	7,0 mm	6,0 mm
Yellow	7,5 mm	6,0 mm
Brown	8,0 mm	6,0 mm

PRODORTH IMPLANTS

- Polyaxial, monoaxial, spondylolisthesis, cannulated types, and various sizes are available
- Stronger connection with the head part by milled surface feature
- More reliable tightening with the torque top surface of the setscrew
- Easy initiative inserting and special design for best holding
- Stronger fixation with reverse angled setscrew thread design

SIZE	 Polyaxial Screw Code	 L. Polyaxial Screw Code	 Monoaxial Screw Code	 L. Monoaxial Screw Code
Ø 3,5 x 25 mm	101.01 3525	N/A	101.05 3525	N/A
Ø 3,5 x 30 mm	101.01 3530	N/A	101.05 3530	N/A
Ø 3,5 x 35 mm	101.01 3535	N/A	101.05 3535	N/A
Ø 3,5 x 40 mm	101.01 3540	N/A	101.05 3540	N/A
Ø 3,5 x 45 mm	101.01 3545	N/A	101.05 3545	N/A
Ø 4,0 x 25 mm	101.01 4025	N/A	101.05 4025	N/A
Ø 4,0 x 30 mm	101.01 4030	N/A	101.05 4030	N/A
Ø 4,0 x 35 mm	101.01 4035	N/A	101.05 4035	N/A
Ø 4,0 x 40 mm	101.01 4040	N/A	101.05 4040	N/A
Ø 4,0 x 45 mm	101.01 4045	N/A	101.05 4045	N/A
Ø 4,5 x 25 mm	101.01 4525	101.03 4525	101.05 4525	101.06 4525
Ø 4,5 x 30 mm	101.01 4530	101.03 4530	101.05 4530	101.06 4530
Ø 4,5 x 35 mm	101.01 4535	101.03 4535	101.05 4535	101.06 4535
Ø 4,5 x 40 mm	101.01 4540	101.03 4540	101.05 4540	101.06 4540
Ø 4,5 x 45 mm	101.01 4545	101.03 4545	101.05 4545	101.06 4545
Ø 5,0 x 30 mm	101.01 5030	101.03 5030	101.05 5030	101.06 5030
Ø 5,0 x 35 mm	101.01 5035	101.03 5035	101.05 5035	101.06 5035
Ø 5,0 x 40 mm	101.01 5040	101.03 5040	101.05 5040	101.06 5040
Ø 5,0 x 45 mm	101.01 5045	101.03 5045	101.05 5045	101.06 5045
Ø 5,0 x 50 mm	101.01 5050	101.03 5050	101.05 5050	101.06 5050
Ø 5,0 x 55 mm	101.01 5055	101.03 5055	101.05 5055	101.06 5055
Ø 5,0 x 60 mm	101.01 5060	101.03 5060	101.05 5060	101.06 5060
Ø 5,5 x 30 mm	101.01 5530	101.03 5530	101.05 5530	101.06 5530
Ø 5,5 x 35 mm	101.01 5535	101.03 5535	101.05 5535	101.06 5535
Ø 5,5 x 40 mm	101.01 5540	101.03 5540	101.05 5540	101.06 5540
Ø 5,5 x 45 mm	101.01 5545	101.03 5545	101.05 5545	101.06 5545
Ø 5,5 x 50 mm	101.01 5550	101.03 5550	101.05 5550	101.06 5550
Ø 5,5 x 55 mm	101.01 5555	101.03 5555	101.05 5555	101.06 5555
Ø 5,5 x 60 mm	101.01 5560	101.03 5560	101.05 5560	101.06 5560
Ø 6,0 x 30 mm	101.01 6030	101.03 6030	101.05 6030	101.06 6030
Ø 6,0 x 35 mm	101.01 6035	101.03 6035	101.05 6035	101.06 6035
Ø 6,0 x 40 mm	101.01 6040	101.03 6040	101.05 6040	101.06 6040
Ø 6,0 x 45 mm	101.01 6045	101.03 6045	101.05 6045	101.06 6045
Ø 6,0 x 50 mm	101.01 6050	101.03 6050	101.05 6050	101.06 6050
Ø 6,0 x 55 mm	101.01 6055	101.03 6055	101.05 6055	101.06 6055
Ø 6,0 x 60 mm	101.01 6060	101.03 6060	101.05 6060	101.06 6060

SIZE	 Polyaxial Screw Code	 L. Polyaxial Screw Code	 Monoaxial Screw Code	 L. Monoaxial Screw Code
Ø 6,5 x 30 mm	101.01 6530	101.03 6530	101.05 6530	101.06 6530
Ø 6,5 x 35 mm	101.01 6535	101.03 6535	101.05 6535	101.06 6535
Ø 6,5 x 40 mm	101.01 6540	101.03 6540	101.05 6540	101.06 6540
Ø 6,5 x 45 mm	101.01 6545	101.03 6545	101.05 6545	101.06 6545
Ø 6,5 x 50 mm	101.01 6550	101.03 6550	101.05 6550	101.06 6550
Ø 6,5 x 55 mm	101.01 6555	101.03 6555	101.05 6555	101.06 6555
Ø 6,5 x 60 mm	101.01 6560	101.03 6560	101.05 6560	101.06 6560
Ø 7,0 x 30 mm	101.01 7030	101.03 7030	101.05 7030	101.06 7030
Ø 7,0 x 35 mm	101.01 7035	101.03 7035	101.05 7035	101.06 7035
Ø 7,0 x 40 mm	101.01 7040	101.03 7040	101.05 7040	101.06 7040
Ø 7,0 x 45 mm	101.01 7045	101.03 7045	101.05 7045	101.06 7045
Ø 7,0 x 50 mm	101.01 7050	101.03 7050	101.05 7050	101.06 7050
Ø 7,0 x 55 mm	101.01 7055	101.03 7055	101.05 7055	101.06 7055
Ø 7,0 x 60 mm	101.01 7060	101.03 7060	101.05 7060	101.06 7060
Ø 7,5 x 30 mm	101.01 7530	101.03 7530	101.05 7530	101.06 7530
Ø 7,5 x 35 mm	101.01 7535	101.03 7535	101.05 7535	101.06 7535
Ø 7,5 x 40 mm	101.01 7540	101.03 7540	101.05 7540	101.06 7540
Ø 7,5 x 45 mm	101.01 7545	101.03 7545	101.05 7545	101.06 7545
Ø 7,5 x 50 mm	101.01 7550	101.03 7550	101.05 7550	101.06 7550
Ø 7,5 x 55 mm	101.01 7555	101.03 7555	101.05 7555	101.06 7555
Ø 7,5 x 60 mm	101.01 7560	101.03 7560	101.05 7560	101.06 7560
Ø 7,5 x 65 mm	101.01 7565	101.03 7565	101.05 7565	101.06 7565
Ø 7,5 x 70 mm	101.01 7570	101.03 7570	101.05 7570	101.06 7570
Ø 7,5 x 75 mm	101.01 7575	101.03 7575	101.05 7575	101.06 7575
Ø 7,5 x 80 mm	101.01 7580	101.03 7580	101.05 7580	101.06 7580
Ø 8,0 x 40 mm	101.01 8040	N/A	101.05 8040	N/A
Ø 8,0 x 45 mm	101.01 8045	N/A	101.05 8045	N/A
Ø 8,0 x 50 mm	101.01 8050	N/A	101.05 8050	N/A
Ø 8,0 x 55 mm	101.01 8055	N/A	101.05 8055	N/A
Ø 8,0 x 60 mm	101.01 8060	N/A	101.05 8060	N/A
Ø 8,0 x 70 mm	101.01 8070	N/A	101.05 8070	N/A
Ø 8,0 x 80 mm	101.01 8080	N/A	101.05 8080	N/A
Ø 8,0 x 90 mm	101.01 8090	N/A	101.05 8090	N/A
Ø 8,0 x 100 mm	101.01 80100	N/A	101.05 80100	N/A
Ø 8,0 x 110 mm	101.01 80110	N/A	101.05 80110	N/A
Ø 8,0 x 120 mm	101.01 80120	N/A	101.05 80120	N/A

PROLOBSTER™

Multiaxial Connectors

SIZE	REF.CODE
30 mm - 45 mm	105.01 3045
38 mm - 53 mm	105.01 3853
45 mm - 60 mm	105.01 4560
53 mm - 68 mm	105.01 5368
60 mm - 75 mm	105.01 6075

PROWALRUS™

Laminar Narrow Blade | Laminar Wide Blade | Pedicular

SIZE	REF.CODE
Narrow Blade - Small	151.01 0017N-S
Narrow Blade - Medium	151.01 0017N-M
Narrow Blade - Large	151.01 0017N-L
Wide Blade - Small	151.01 0017W-S
Wide Blade - Medium	151.01 0017W-M
Wide Blade - Large	151.01 0017W-L
Pedicular - Small	151.01 0018-S
Pedicular - Medium	151.01 0018-M
Pedicular - Large	151.01 0018-L

PROLOBSTER-L™

Linear Connectors

SIZE	REF.CODE
40 mm	105.02 0040
50 mm	105.02 0050
60 mm	105.02 0060
70 mm	105.02 0070
80 mm	105.02 0080
90 mm	105.02 0090
100 mm	105.02 0100

PROLOBSTER-B™

Bar Type Multiaxial Connectors

SIZE	REF.CODE
30 mm - 40 mm	105.01 3040
40 mm - 50 mm	105.01 4050
50 mm - 60 mm	105.01 5060

PROKRILL™

Open | Closed

Lateral Connectors

SIZE	REF.CODE
Lateral Connector Short Open	151.01 0009
Lateral Connector Long Open	151.01 0010
Lateral Connector Short Closed	151.01 0013
Lateral Connector Long Closed	151.01 0014

PROSCOBE™

Single | Double | Double-II | Quadruple | T30

Domino Connectors

SIZE	REF.CODE
Domino Connector Single	151.01 0001
Domino Connector Double / II	151.01 0002
Domino Connector Quadruple	151.01 0003
Domino Connector T30	151.01 0005

Titanium Rod

SIZE	REF.CODE
Ø 5,5 x 40 mm	104.01 5540
Ø 5,5 x 50 mm	104.01 5550
Ø 5,5 x 60 mm	104.01 5560
Ø 5,5 x 70 mm	104.01 5570
Ø 5,5 x 80 mm	104.01 5580
Ø 5,5 x 90 mm	104.01 5590
Ø 5,5 x 100 mm	104.01 55100
Ø 5,5 x 110 mm	104.01 55110
Ø 5,5 x 120 mm	104.01 55120
Ø 5,5 x 130 mm	104.01 55130
Ø 5,5 x 140 mm	104.01 55140
Ø 5,5 x 150 mm	104.01 55150
Ø 5,5 x 160 mm	104.01 55160
Ø 5,5 x 170 mm	104.01 55170
Ø 5,5 x 180 mm	104.01 55180
Ø 5,5 x 190 mm	104.01 55190
Ø 5,5 x 200 mm	104.01 55200
Ø 5,5 x 250 mm	104.01 55250
Ø 5,5 x 300 mm	104.01 55300
Ø 5,5 x 350 mm	104.01 55350
Ø 5,5 x 400 mm	104.01 55400
Ø 5,5 x 450 mm	104.01 55450
Ø 5,5 x 500 mm	104.01 55500
Ø 5,5 x 550 mm	104.01 55550
Ø 5,5 x 600 mm	104.01 55600

SIZE	REF.CODE
Ø 6,0 x 40 mm	104.01 6040
Ø 6,0 x 50 mm	104.01 6050
Ø 6,0 x 60 mm	104.01 6060
Ø 6,0 x 70 mm	104.01 6070
Ø 6,0 x 80 mm	104.01 6080
Ø 6,0 x 90 mm	104.01 6090
Ø 6,0 x 100 mm	104.01 60100
Ø 6,0 x 110 mm	104.01 60110
Ø 6,0 x 120 mm	104.01 60120
Ø 6,0 x 130 mm	104.01 60130
Ø 6,0 x 140 mm	104.01 60140
Ø 6,0 x 150 mm	104.01 60150
Ø 6,0 x 160 mm	104.01 60160
Ø 6,0 x 170 mm	104.01 60170
Ø 6,0 x 180 mm	104.01 60180
Ø 6,0 x 190 mm	104.01 60190
Ø 6,0 x 200 mm	104.01 60200
Ø 6,0 x 250 mm	104.01 60250
Ø 6,0 x 300 mm	104.01 60300
Ø 6,0 x 350 mm	104.01 60350
Ø 6,0 x 400 mm	104.01 60400
Ø 6,0 x 450 mm	104.01 60450
Ø 6,0 x 500 mm	104.01 60500
Ø 6,0 x 550 mm	104.01 60550
Ø 6,0 x 600 mm	104.01 60600

Curved Rod

SIZE	REF.CODE
Ø 5,5 x 40 mm	104.02 5540
Ø 5,5 x 50 mm	104.02 5550
Ø 5,5 x 60 mm	104.02 5560
Ø 5,5 x 70 mm	104.02 5570
Ø 5,5 x 80 mm	104.02 5580
Ø 5,5 x 90 mm	104.02 5590
Ø 5,5 x 100 mm	104.02 55100
Ø 5,5 x 110 mm	104.02 55110
Ø 5,5 x 120 mm	104.02 55120

Transition Rod

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

PRODORTH POSTERIOR FIXATION 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.

Anti-Torque | PP 100.10.001

Persuader | PP 100.10.002

AWL | PP 100.10.003

Listhesis Head Cutter | PP 100.10.005

Rod Pusher | PP 100.10.006

4-6 Nm Torque Limiting Handle | PP 100.10.007

10-12 Nm Torque Limiting T-handle | PP 100.10.008

T-Handle | PP 100.10.009

Pedicle Probe Curved | PP 100.10.010

Pedicle Probe Straight | PP 100.10.011

Mallet | PP 100.10.012

Polyaxial Screwdriver | PP 100.10.013A

Monoaxial Screwdriver | PP 100.10.013B

Pedicle Screw Setscrew Driver | PP 100.10.014

Transverse Connector Setscrew Driver | PP 100.10.015

Tap 4mm | PP 100.10.016
Tap 5mm | PP 100.10.017
Tap 6mm | PP 100.10.018
*Tap 7mm | PP 100.10.047
*Tap 3mm | PP 100.10.048

Pedicle Screw Pull-out Instrument | PP 100.10.019

Slitted Setscrew Inserter | PP 100.10.020

Pedicle Marker Stop | PP 100.10.021

Pedicle Marker | PP 100.10.022

Feeler Straight | PP 100.10.023

Feeler Curved | PP 100.10.024

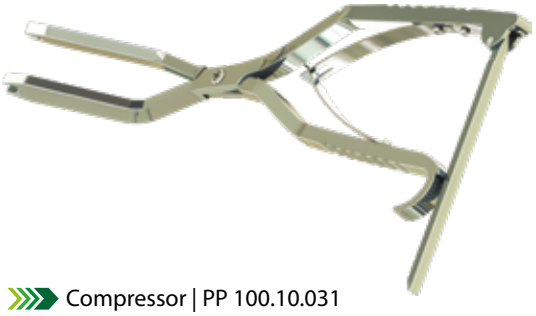
Rocker | PP 100.10.025

In-Situ Bender Left | PP 100.10.026
In-Situ Bender Right | PP 100.10.027

Rod Bender | PP 100.10.028

Rod Holder Forceps | PP 100.10.029

Distractor | PP 100.10.030

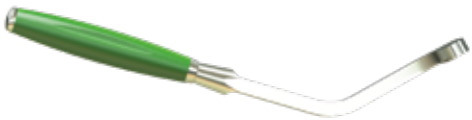


Compressor | PP 100.10.031

Rod Gripper | PP 100.10.032

Rod Holder Strong | PP 100.10.033

Coronal Bender Left (Upon Request) | PP 100.10.038



Coronal Bender Right (Upon Request) | PP 100.10.039

I-Handle Locking (Upon Request) | PP 100.10.042

Ratchet T-Handle (Upon Request) | PP 100.10.043

SURGICAL PROCEDURE

Step 1
Patient Positioning and Exposure

The patient is positioned properly in the prone position. The general essentials of posterior fixation surgery is applied. (Figure 1)

Figure 1

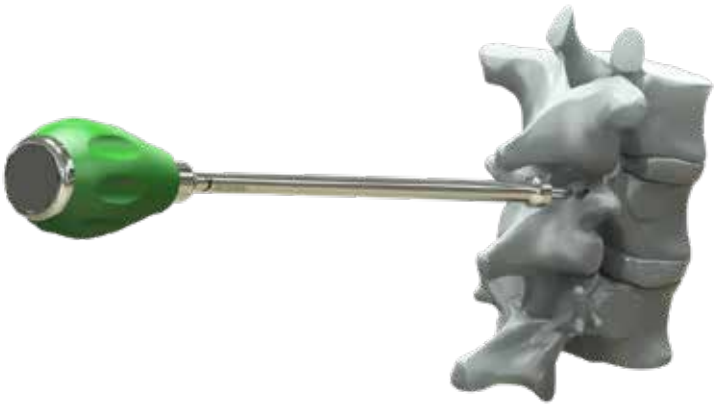


Figure 2

Step 2
Preparation of the Pedicle

Facet joints are cleaned and the inferior facet and the cartilage on the upper facet are removed. Use Awl (PP 100.10.003) to ream the cortical exterior of vertebrae. (Figure 2)

Step 3
Making Interpedicular Path

A Pedicle Probe (PP 100.10.010 / PP 100.10.011) is used for making the intrapedicular path. If you decide to use the curved probe, at first orient the curved part laterally away from the canal.

Push forward the probe through the pedicle and into the vertebra up to the required hole depth. (Figure 3)

Figure 3

Step 4
Determination of Suitable Screw Trajectory

Marker pins may be placed into the hole in order to identify previously how the screw will be advanced. An X-ray view might be helpful for this process. (Figure 4, Figure 5)

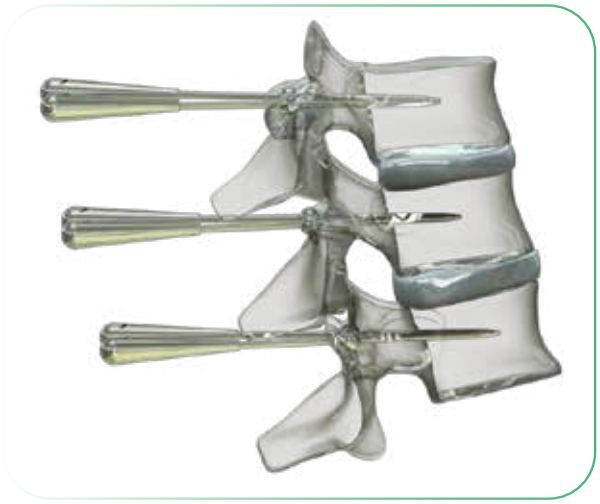


Figure 4

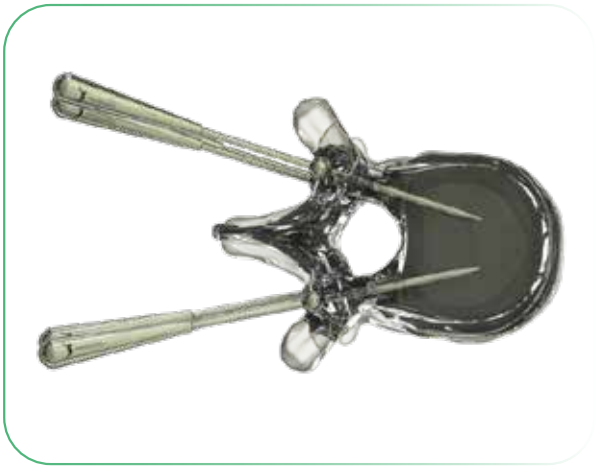


Figure 5

Step 5
Control of the Hole Depth

The feelers may be inserted into the hole for the determination of hole depth and palpate the inner surface to verify pedicle wall integrity. (Figure 6)

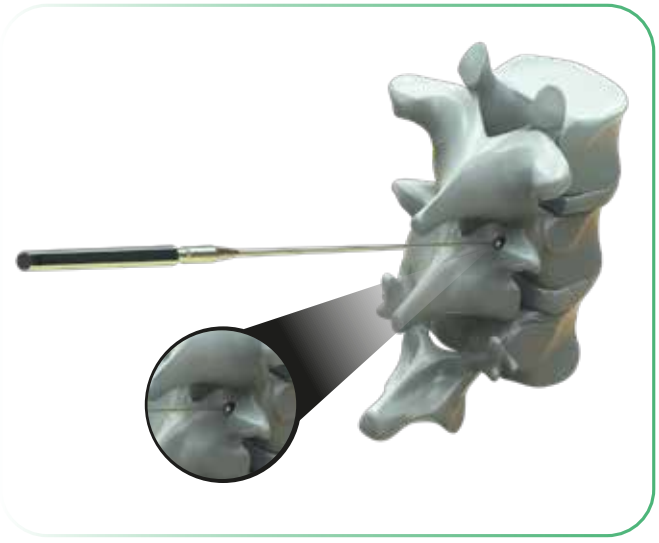


Figure 6

Step 6
Making the Tap Into the Pedicle

T-Handle and Tap are connected by pulling up the latch of the T-handle (Figure 7)

Figure 7

Appropriate screw diameter and length are determined.

The diameter of the selected tap is recommended to be one level smaller than the screw that will be used. For instance, whether a 5,5 mm screw is decided to be introduced 5,0 mm tap should be used. This decision might be different up on the surgeon's opinion and the situation of the patient.

Advance the tap by rotating it clockwise (Figure 8) and after reaching the desired depth, remove the tap by rotating it anticlockwise.

Proper screw length should be selected according to the depth of the tapping hole.

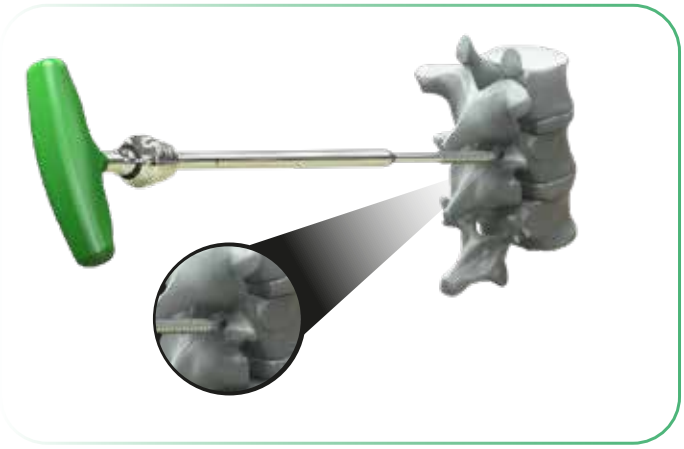


Figure 8

Step 7
Insertion of the Polyaxial Pedicle Screw

Prodorth polyaxial screws are introduced by Prodorth Polyaxial Screwdriver (PP 100.10.013A). All sizes of polyaxial screws, as well as the spondylolisthesis (reduction) screws, are introduced with the same driver.

Prodorth screwdriver is connected with the T-Handle prior to engaging with the screw, as it's represented in the below picture. The driver is connected to the T-Handle by pulling up the latch. (Figure 9)

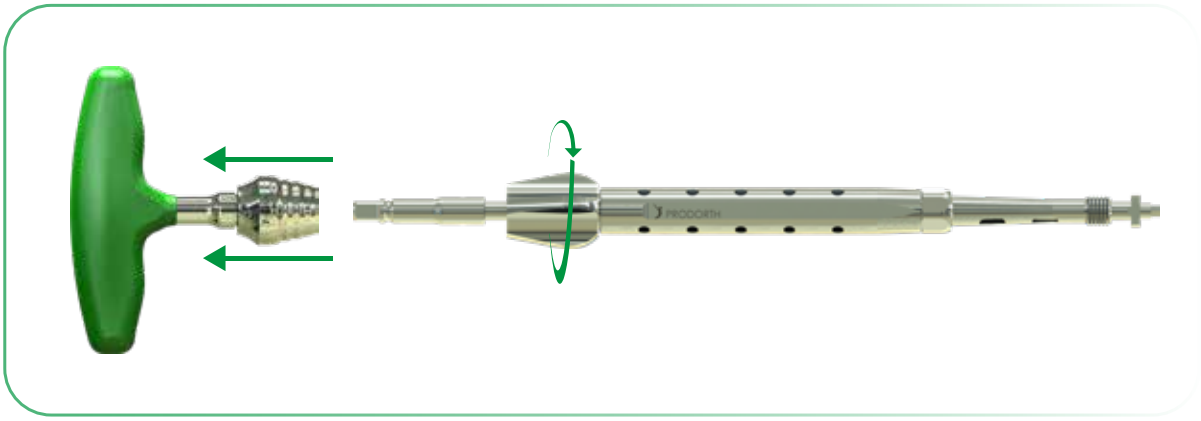


Figure 9

Figure 10

While engaging the screw to the driver, the T-Handle 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. (Figure 10)

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.

Advancing of the Screw

The Polyaxial screw is introduced into the pedicle by holding the middle handle of the driver (that has holes on it) constant and rotating the T-Handle clockwise. The screw should be advanced to a position by letting the poly-body is able to move 360° freely. (Figure 11)

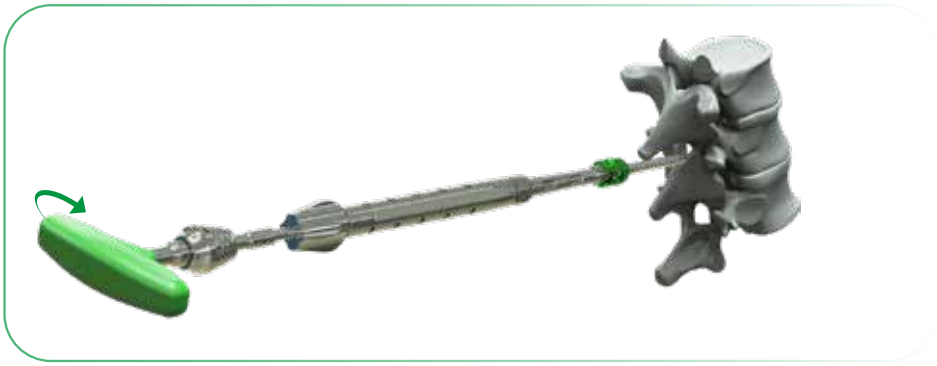


Figure 11

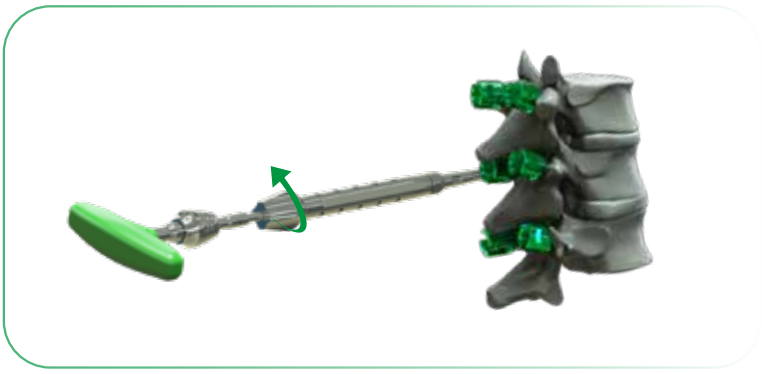


Figure 12

Disconnection from Screw

To disconnect the driver from the screw, hold the T-Handle constant and rotate the middle knob of the driver anticlockwise. (Figure 12)

This process will be repeated so on according to the required quantity of pedicle screws in the surgery.

Insertion of the Monoaxial Pedicle Screw

All the processes explained for Prodorth polyaxial screws above are also the same for Prodorth Monoaxial screws, except for the driver selection. Prodorth Monoaxial screwdriver should be used for the introduction of monoaxial screws. (Figure 13)

Figure 13

Step 8
Selection of the Appropriate Size of Rod

After the screws are placed, the suitable rod length should be selected for the concerned area. It's recommended to position the rods tips to be extended around 4 mm out from the first and last screw placed.

Figure 14

Step 9
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 rod bender and it's contoured as required. A properly contoured rod should contact the bottom of each screw's saddle. (Figure14, Figure15)

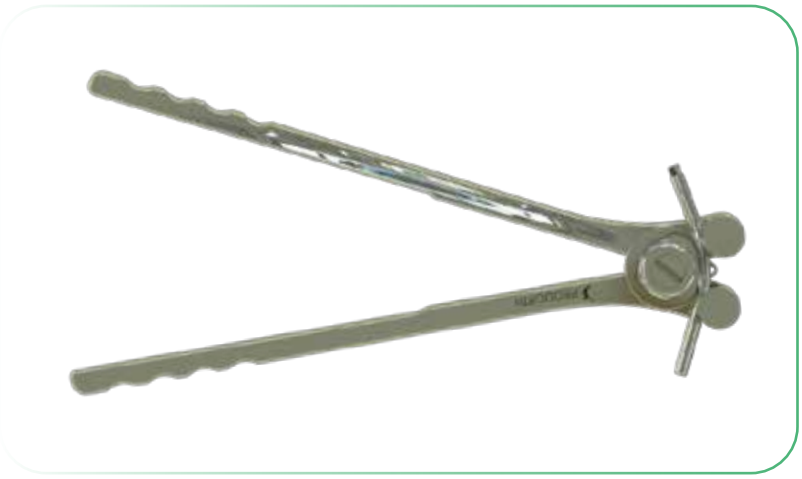
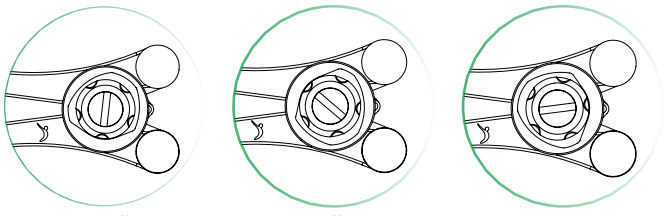


Figure 15

Note: You can switch the bending angles by pulling out and rotating the central wheel of the rod bender, thus you can bend the rods through small, medium, and large angles.



Small Medium Large

Step10
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 Rod Holder Forceps (PP 100.10.029) as represented in Figure 16.

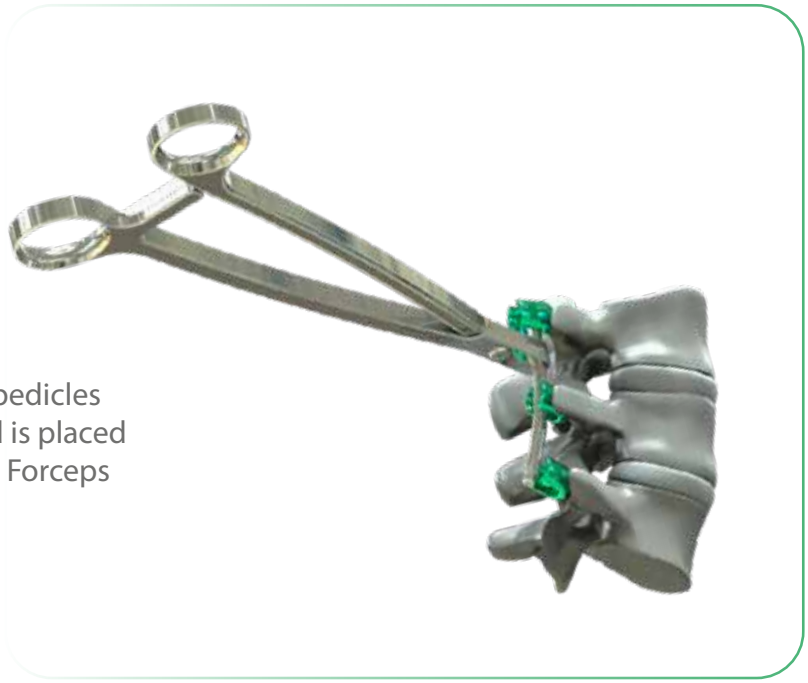


Figure 16

Figure 17

In case of necessity, the Rod Pusher (PP 100.10.006) may be used to settle the rod into the screw saddles while inserting the setscrews(nuts) by the setscrew driver. (Figure 17)

Step 11
Insertion of Setscrews

The setscrews will be priorly introduced into the saddle of screws with "slitted setscrew driver".

Warning: The "Slitted Setscrew Driver" is not an 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.
As represented in Figures 18, Figure 19, the Rocker (PP 100.10.025) instrument can be used for the proper placement of setscrews.

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.

Repeat the process until all setscrews are placed.

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

Figure 18

Figure 19

Step 12
Positioning of Rods

After all the setscrews are placed, you can use the Rod Gripper (PP 100.10.032) to rotate the rods. While the rod is gripped with Rod Gripper, the setscrew in the superior position is tightened using the 10-12 Nm Torque Limiting T-handle (PP 100.10.008). The remaining setscrews are left loose to allow for compression and distraction. (Figure 20)

Note: The 10-12 Nm Torque Limiting T-handle (PP 100.10.008) can be also connected with the Pedicle Screw Setscrew Driver (PP 100.10.014) (non-slitted one) with the same method (pulling up its latch) as other T-Handles of Prodorth.

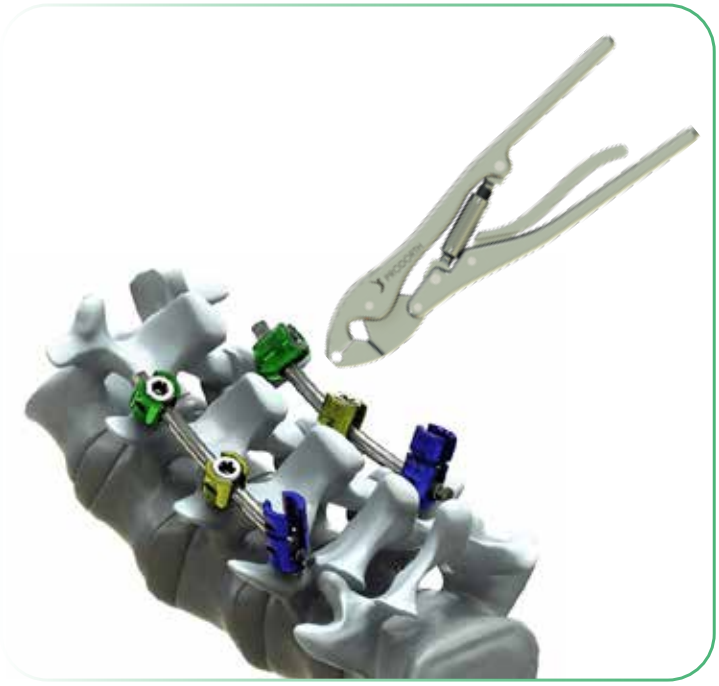


Figure 20

Figure 21

Step 13
Distraction – Compression

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 21, Figure 22, Figure 23)

Figure 22

Once reaching the desired amount of correction, you can go ahead with the final tightening of the setscrews.

Figure 23

Step 14
Final Tightening of Setscrews

The Anti-Torque (PP 100.10.001) is placed as it's represented in Figure 24, Figure 25. Then the Setscrew Driver (PP 100.10.014) (non-slitted one) which is priorly connected to 10-12 Nm Torque Limiting T-handle (PP 100.10.008) is inserted through the Anti-Torque (PP 100.10.001). The torquing process can be done easily in this way.

Figure 24

Figure 25

Tighten the setscrews until the "click-click" sound is heard from the 10-12 Nm Torque Limiting Handle (PP 100.10.008). Repeat the process so on for each setscrew by using the anti-torque instrument. (Figure 26, Figure 27)

Figure 26

Figure 27

Step 15
Placement of the Connectors (If necessary)

Linear or multiaxial connectors may be used up to the surgeon's decision. (Figure 28)

Both of the connectors may be placed between the rods after all the above steps are completed and the setscrews on the connectors are tightened with the 4-6 Nm Torque Limiting Handle (PP 100.10.007) (with the spherical handle) connected to the Transverse Connector Setscrew Driver (PP 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 29)

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

Figure 28

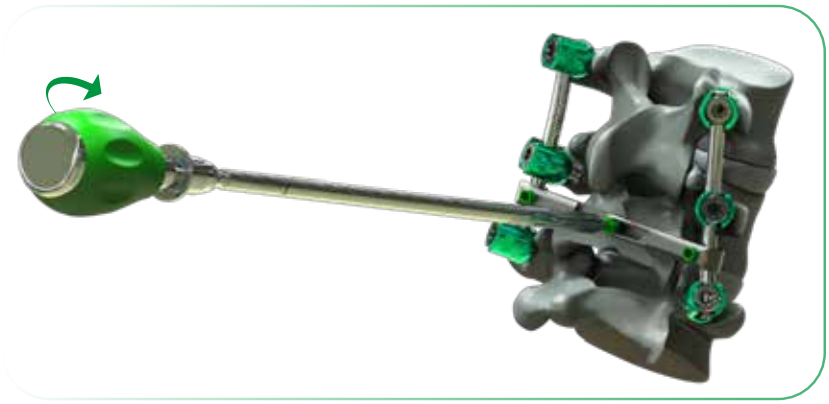


Figure 29

Surgical Technique Guide

Posterior Fixation Systems

PRODORTH

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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