

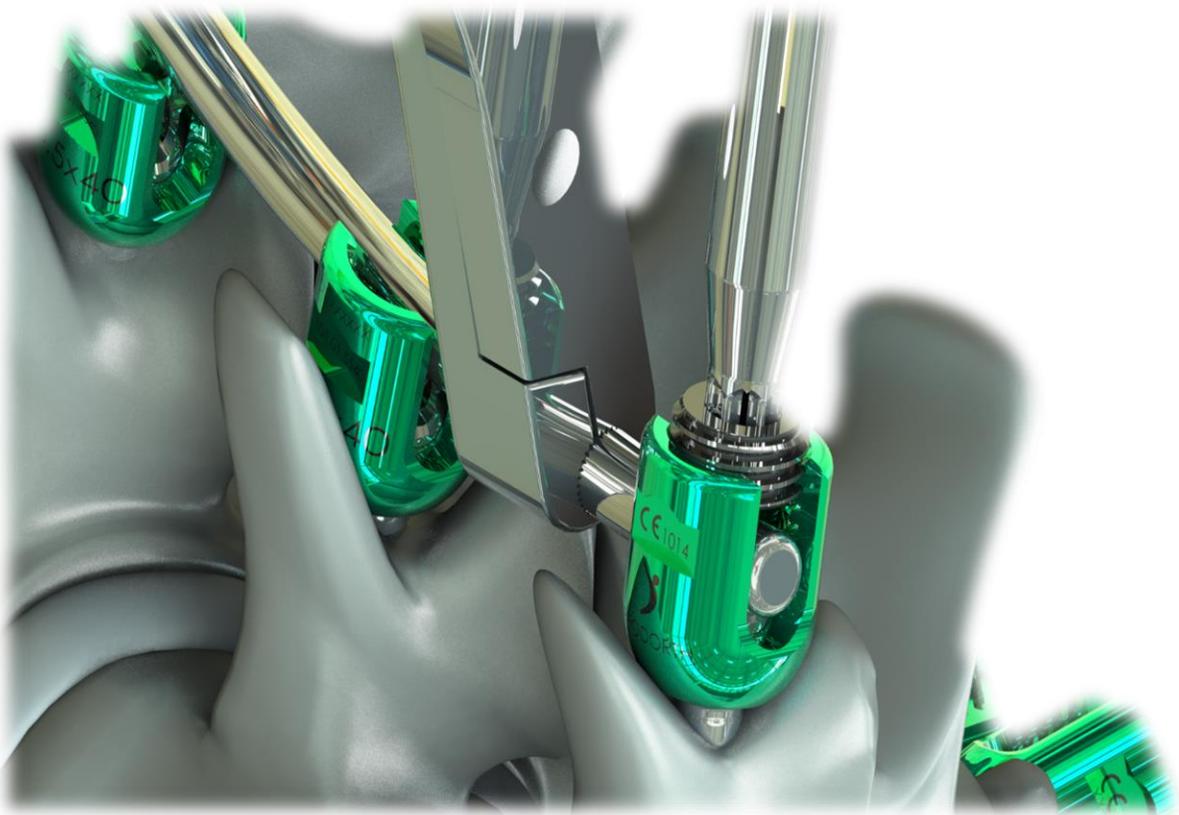


# Surgical Technique Guide

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## Posterior Fixation System

PROXiphias™



## 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 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 Posterior Fixation System* 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 spine.

Posterior Spine System Implants are long-term implants, however they are not able to withstand the forces like healthy bone structures. Spine 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 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:** 37272
- **Product Class:** Annex II of Directive 93/42/EEC) Class IIb
- **Raw Materials:** Ti6Al4V-ELI (ASTM F 136 / ISO 5832-3)
- **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 Posterior Fixation System is 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 Posterior Fixation System is a long-term implant in order to dispose the complaints of the patients which raised because of the pain arising because of any disorders on spine, as well as the herniation at discs, traumas on 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-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.)

**CONTRAINDICATIONS :**

- Infection history; systemic, spine or localized
- Obesity
- Mental diseases
- Alcohol or drug addiction
- Fever or unusual increase in the amount of leukocyte
- Pregnancy
- Allergic reaction against implant materials
- Serious osteoporosis
- 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.
- Pedicular screws with congenital deformity
- Patients who are not obeying precautions or who are not able to.

**SECONDARY AND POSSIBLE SIDE EFFECTS:**

- Bending, loosening or fracture 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
- 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
- Death

**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 Posterior Spine System. 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. In case of using other company's instruments, this might result in galvanic corrosion, incompatibility between the products as well. No component of the Posterior Spine System implants shall be reused.

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

**Types and detailed specifications of Prodorth Posterior Fixation System****Prodorth Polyaxial Screw**

This product is used for dispose 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 by Prodorth retractor. Then the rods are placed through the U-shaped tulips and they are compressed by tightening of the setscrews.

The main purpose of this device is, leading a complete fusion around the entire implants group, and in result obtaining a better health condition with no pain and more relief of the patient.

This product is completely manufactured from Ti6Al4V (ISO 5832-3) material.

**Prodorth Polyaxial Spondylolisthesis Screw**

This product is also used for dispose 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 by Prodorth retractor. Then the rods are placed through the U-shaped tulips and they are compressed by tightening of the setscrews.

The main purpose of this device is, leading a complete fusion around the entire implants group, and in result obtaining a better health condition with no pain and more relief of the patient.

This product is completely manufactured from Ti6Al4V (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 screw and compressed by setscrew and then following parts along them are also placed through the tulip/s of following screw/s therefore a vertical fixation is obtained.

Prodorth Rods are completely manufactured from Ti6Al4V (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 (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 allows positioning at various angles as it needs to be, and can be fixed at that position.

Prodorth Multiaxial Connectors are completely manufactured from Ti6Al4V (ISO 5832-3) material.

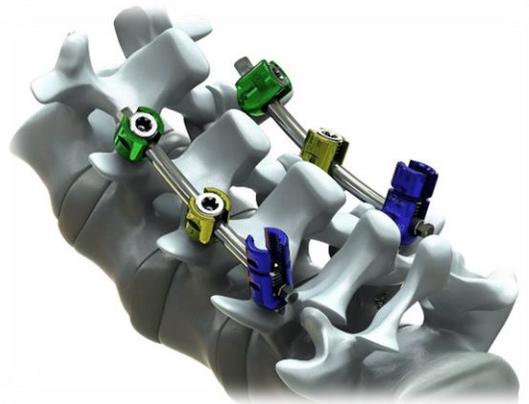
The Prodorth Pedicle screws are offered as color-coded and the table below is representing the meanings of the different colours..

COLOR CODE	SCREW DIAMETER	TAP DIAMETER
Dark Blue	3,5 mm	N/A
Dusty Rose	4,0 mm	4,0 mm
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 head part by milled surface feature.

More reliable tightening with the torque top surface of setscrew. Easy initiative inserting and special design for best holding. Stronger fixation with reverse angled setscrew thread design.



**Polyaxial Screws**  $\varnothing 3,5\text{mm} - \varnothing 8,0\text{mm}$

**Listhesis Polyaxial Screws**  $\varnothing 4,5\text{mm} - \varnothing 7,5\text{mm}$

**Monoaxial Screws**  $\varnothing 4,0\text{mm} - \varnothing 8,0\text{mm}$



**Setscrews** Torx Design



**Transverse Connectors**

( Linear ) 40 / 50 / 60 / 70 / 80 / 90 / 100 mm

**Cervical Transverse Connectors**

( Linear ) 30 / 40 / 50 / 60 mm

**Transverse Connectors**

( Adjustable ) 30-45 / 38-53 / 45-60 / 53-68 / 60-75 mm

**Cervical Transverse Connectors**

( Adjustable ) 20-30 / 30-40 / 40-50 mm

**Bar Type Transverse Connectors**

30-40 / 40-50 / 50-60 mm



**Titanium Rods**

$\varnothing 3,5\text{mm}$  30-200 mm

$\varnothing 5,5\text{mm}$  60-600 mm

$\varnothing 5,6\text{mm}$  100-600 mm

$\varnothing 6,0\text{mm}$  40-600 mm

$\varnothing 6,1\text{mm}$  100-600 mm



**Product List**

Sizes	Polyaxial Screw Code	L. Polyaxial Screw Code	Monoaxial Screw Code	L.Monoaxial Screw Code
Ø 3,5 x 10 mm	101.01.3510	N/A	101.05 3510	N/A
Ø 3,5 x 12 mm	101.01.3512	N/A	101.05 3512	N/A
Ø 3,5 x 14 mm	101.01.3514	N/A	101.05 3514	N/A
Ø 3,5 x 16 mm	101.01.3516	N/A	101.05 3516	N/A
Ø 3,5 x 18 mm	101.01.3518	N/A	101.05 3518	N/A
Ø 3,5 x 20 mm	101.01.3520	N/A	101.05 3520	N/A
Ø 3,5 x 22 mm	101.01.3522	N/A	101.05 3522	N/A
Ø 3,5 x 24 mm	101.01.3524	N/A	101.05 3524	N/A
Ø 3,5 x 26 mm	101.01.3526	N/A	101.05 3526	N/A
Ø 3,5 x 28 mm	101.01.3528	N/A	101.05 3528	N/A
Ø 3,5 x 30 mm	101.01.3530	N/A	101.05 3530	N/A
Ø 3,5 x 32 mm	101.01.3532	N/A	101.05 3532	N/A
Ø 3,5 x 34 mm	101.01.3534	N/A	101.05 3534	N/A
Ø 4,0 x 10 mm	101.01.4010	N/A	101.05 4010	N/A
Ø 4,0 x 12 mm	101.01.4012	N/A	101.05 4012	N/A
Ø 4,0 x 14 mm	101.01.4014	N/A	101.05 4014	N/A
Ø 4,0 x 16 mm	101.01.4016	N/A	101.05 4016	N/A
Ø 4,0 x 18 mm	101.01.4018	N/A	101.05 4018	N/A
Ø 4,0 x 20 mm	101.01.4020	N/A	101.05 4020	N/A
Ø 4,0 x 22 mm	101.01.4022	N/A	101.05 4022	N/A
Ø 4,0 x 24 mm	101.01.4024	N/A	101.05 4024	N/A
Ø 4,0 x 26 mm	101.01.4026	N/A	101.05 4026	N/A
Ø 4,0 x 28 mm	101.01.4028	N/A	101.05 4028	N/A
Ø 4,0 x 30 mm	101.01.4030	N/A	101.05 4030	N/A
Ø 4,0 x 32 mm	101.01.4032	N/A	101.05 4032	N/A
Ø 4,0 x 34 mm	101.01.4034	N/A	101.05 4034	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
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

**Product List**

Sizes	Polyaxial Screw Code	L. Polyaxial Screw Code	Monoaxial Screw Code	L.Monoaxial Screw Code
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
Sizes	P. Cannulated Screw Code	L. P. Cannulated Screw Code	M. Cannulated Screw Code	L.M. Cannulated Screw Code
Ø 5,0 x 30 mm	101.02 5030	101.04 5030	101.07 5030	101.08 5030
Ø 5,0 x 35 mm	101.02 5035	101.04 5035	101.07 5035	101.08 5035
Ø 5,0 x 40 mm	101.02 5040	101.04 5040	101.07 5040	101.08 5040
Ø 5,0 x 45 mm	101.02 5045	101.04 5045	101.07 5045	101.08 5045
Ø 5,0 x 50 mm	101.02 5050	101.04 5050	101.07 5050	101.08 5050
Ø 5,0 x 55 mm	101.02 5055	101.04 5055	101.07 5055	101.08 5055
Ø 5,0 x 60 mm	101.02 5060	101.04 5060	101.07 5060	101.08 5060
Ø 5,5 x 30 mm	101.02 5530	101.04 5530	101.07 5530	101.08 5530
Ø 5,5 x 35 mm	101.02 5535	101.04 5535	101.07 5535	101.08 5535
Ø 5,5 x 40 mm	101.02 5540	101.04 5540	101.07 5540	101.08 5540
Ø 5,5 x 45 mm	101.02 5545	101.04 5545	101.07 5545	101.08 5545
Ø 5,5 x 50 mm	101.02 5550	101.04 5550	101.07 5550	101.08 5550
Ø 5,5 x 55 mm	101.02 5555	101.04 5555	101.07 5555	101.08 5555
Ø 5,5 x 60 mm	101.02 5560	101.04 5560	101.07 5560	101.08 5560
Ø 6,0 x 30 mm	101.02 6030	101.04 6030	101.07 6030	101.08 6030
Ø 6,0 x 35 mm	101.02 6035	101.04 6035	101.07 6035	101.08 6035
Ø 6,0 x 40 mm	101.02 6040	101.04 6040	101.07 6040	101.08 6040
Ø 6,0 x 45 mm	101.02 6045	101.04 6045	101.07 6045	101.08 6045
Ø 6,0 x 50 mm	101.02 6050	101.04 6050	101.07 6050	101.08 6050
Ø 6,0 x 55 mm	101.02 6055	101.04 6055	101.07 6055	101.08 6055
Ø 6,0 x 60 mm	101.02 6060	101.04 6060	101.07 6060	101.08 6060
Ø 6,5 x 30 mm	101.02 6530	101.04 6530	101.07 6530	101.08 6530
Ø 6,5 x 35 mm	101.02 6535	101.04 6535	101.07 6535	101.08 6535
Ø 6,5 x 40 mm	101.02 6540	101.04 6540	101.07 6540	101.08 6540
Ø 6,5 x 45 mm	101.02 6545	101.04 6545	101.07 6545	101.08 6545
Ø 6,5 x 50 mm	101.02 6550	101.04 6550	101.07 6550	101.08 6550
Ø 6,5 x 55 mm	101.02 6555	101.04 6555	101.07 6555	101.08 6555
Ø 6,5 x 60 mm	101.02 6560	101.04 6560	101.07 6560	101.08 6560

## Product List

Sizes	P. Cannulated Screw Code	L. P. Cannulated Screw Code	M. Cannulated Screw Code	L.M. Cannulated Screw Code
Ø 7,0 x 30 mm	101.02 7030	101.04 7030	101.07 7030	101.08 7030
Ø 7,0 x 35 mm	101.02 7035	101.04 7035	101.07 7035	101.08 7035
Ø 7,0 x 40 mm	101.02 7040	101.04 7040	101.07 7040	101.08 7040
Ø 7,0 x 45 mm	101.02 7045	101.04 7045	101.07 7045	101.08 7045
Ø 7,0 x 50 mm	101.02 7050	101.04 7050	101.07 7050	101.08 7050
Ø 7,0 x 55 mm	101.02 7055	101.04 7055	101.07 7055	101.08 7055
Ø 7,0 x 60 mm	101.02 7060	101.04 7060	101.07 7060	101.08 7060
Ø 7,5 x 30 mm	101.02 7530	101.04 7530	101.07 7530	101.08 7530
Ø 7,5 x 35 mm	101.02 7535	101.04 7535	101.07 7535	101.08 7535
Ø 7,5 x 40 mm	101.02 7540	101.04 7540	101.07 7540	101.08 7540
Ø 7,5 x 45 mm	101.02 7545	101.04 7545	101.07 7545	101.08 7545
Ø 7,5 x 50 mm	101.02 7550	101.04 7550	101.07 7550	101.08 7550
Ø 7,5 x 55 mm	101.02 7555	101.04 7555	101.07 7555	101.08 7555
Ø 7,5 x 60 mm	101.02 7560	101.04 7560	101.07 7560	101.08 7560
Ø 7,5 x 65 mm	101.02 7565	101.04 7565	101.07 7565	101.08 7565
Ø 7,5 x 70 mm	101.02 7570	101.04 7570	101.07 7570	101.08 7570
Ø 7,5 x 75 mm	101.02 7575	101.04 7575	101.07 7575	101.08 7575
Ø 7,5 x 80 mm	101.02 7580	101.04 7580	101.07 7580	101.08 7580

PRODORTH LINEAR TRANSVERSE CONNECTOR - 40mm	105.02 0040	PRODORTH CERVICAL LINEAR TRANSVERSE CONNECTOR - 30mm	105.12 0030
PRODORTH LINEAR TRANSVERSE CONNECTOR - 50mm	105.02 0050	PRODORTH CERVICAL LINEAR TRANSVERSE CONNECTOR - 40mm	105.12 0040
PRODORTH LINEAR TRANSVERSE CONNECTOR - 60mm	105.02 0060	PRODORTH CERVICAL LINEAR TRANSVERSE CONNECTOR - 50mm	105.12 0050
PRODORTH LINEAR TRANSVERSE CONNECTOR - 70mm	105.02 0070	PRODORTH CERVICAL LINEAR TRANSVERSE CONNECTOR - 60mm	105.12 0060
PRODORTH LINEAR TRANSVERSE CONNECTOR - 80mm	105.02 0080	PRODORTH CERVICAL MULTIAXIAL TRANSVERSE CONNECTOR 20mm-30mm	105.11 2030
PRODORTH LINEAR TRANSVERSE CONNECTOR - 90mm	105.02 0090	PRODORTH CERVICAL MULTIAXIAL TRANSVERSE CONNECTOR 30mm-40mm	105.11 3040
PRODORTH LINEAR TRANSVERSE CONNECTOR - 100mm	105.02 0100	PRODORTH CERVICAL MULTIAXIAL TRANSVERSE CONNECTOR 40mm-50mm	105.11 4050
PRODORTH MULTIAXIAL TRANSVERSE CONNECTOR 30mm-45mm	105.01 3045	PRODORTH DOMÍNO CONNECTOR SINGLE	151.01 0001
PRODORTH MULTIAXIAL TRANSVERSE CONNECTOR 38mm-53mm	105.01 3853	PRODORTH DOMÍNO CONNECTOR DOUBLE	151.01 0002
PRODORTH MULTIAXIAL TRANSVERSE CONNECTOR 45mm-60mm	105.01 4560	PRODORTH DOMÍNO CONNECTOR QUADRUPLE	151.01 0003
PRODORTH MULTIAXIAL TRANSVERSE CONNECTOR 53mm-68mm	105.01 5368	PRODORTH DOMÍNO CONNECTOR PRES	151.01 0004
PRODORTH MULTIAXIAL TRANSVERSE CONNECTOR 60mm-75mm	105.01 6075	PRODORTH DOMÍNO CONNECTOR T30	151.01 0005
PRODORTH BAR TYPE MULTIAXIAL TRANSVERSE CONNECTOR 30mm-40mm	105.01 3040	PRODORTH LATERAL CONNECTOR SHORT OPEN	151.01 0009
PRODORTH BAR TYPE MULTIAXIAL TRANSVERSE CONNECTOR 40mm-50mm	105.01 4050	PRODORTH LATERAL CONNECTOR LONG OPEN	151.01 0010
PRODORTH BAR TYPE MULTIAXIAL TRANSVERSE CONNECTOR 50mm-60mm	105.01 5060	PRODORTH LATERAL CONNECTOR SHORT CLOSED	151.01 0013
		PRODORTH LATERAL CONNECTOR LONG CLOSED	151.01 0014
PRODORTH LAMINA HOOK	151.01 0017		
PRODORTH PEDICLE HOOK	151.01 0018		
PRODORTH TRANSVERSE HOOK	151.01 0019		

**Product List**

Sizes	Rod	Sizes	Rod	Sizes	Rod
∅ 3,5 x 30 mm	104.01 3530	∅ 5,6 x 100 mm	104.01 56100	∅ 6,1 x 100 mm	104.01 61100
∅ 3,5 x 40 mm	104.01 3540	∅ 5,6 x 110 mm	104.01 56110	∅ 6,1 x 110 mm	104.01 61110
∅ 3,5 x 50 mm	104.01 3550	∅ 5,6 x 120 mm	104.01 56120	∅ 6,1 x 120 mm	104.01 61120
∅ 3,5 x 60 mm	104.01 3560	∅ 5,6 x 130 mm	104.01 56130	∅ 6,1 x 130 mm	104.01 61130
∅ 3,5 x 70 mm	104.01 3570	∅ 5,6 x 140 mm	104.01 56140	∅ 6,1 x 140 mm	104.01 61140
∅ 3,5 x 80 mm	104.01 3580	∅ 5,6 x 150 mm	104.01 56150	∅ 6,1 x 150 mm	104.01 61150
∅ 3,5 x 90 mm	104.01 3590	∅ 5,6 x 160 mm	104.01 56160	∅ 6,1 x 160 mm	104.01 61160
∅ 3,5 x 100 mm	104.01 35100	∅ 5,6 x 170 mm	104.01 56170	∅ 6,1 x 170 mm	104.01 61170
∅ 3,5 x 110 mm	104.01 35110	∅ 5,6 x 180 mm	104.01 56180	∅ 6,1 x 180 mm	104.01 61180
∅ 3,5 x 120 mm	104.01 35120	∅ 5,6 x 190 mm	104.01 56190	∅ 6,1 x 190 mm	104.01 61190
∅ 3,5 x 130 mm	104.01 35130	∅ 5,6 x 200 mm	104.01 56200	∅ 6,1 x 200 mm	104.01 61200
∅ 3,5 x 140 mm	104.01 35140	∅ 5,6 x 250 mm	104.01 56250	∅ 6,1 x 250 mm	104.01 61250
∅ 3,5 x 150 mm	104.01 35150	∅ 5,6 x 300 mm	104.01 56300	∅ 6,1 x 300 mm	104.01 61300
∅ 3,5 x 160 mm	104.01 35160	∅ 5,6 x 350 mm	104.01 56350	∅ 6,1 x 350 mm	104.01 61350
∅ 3,5 x 170 mm	104.01 35170	∅ 5,6 x 400 mm	104.01 56400	∅ 6,1 x 400 mm	104.01 61400
∅ 3,5 x 180 mm	104.01 35180	∅ 5,6 x 450 mm	104.01 56450	∅ 6,1 x 450 mm	104.01 61450
∅ 3,5 x 190 mm	104.01 35190	∅ 5,6 x 500 mm	104.01 56500	∅ 6,1 x 500 mm	104.01 61500
∅ 3,5 x 200 mm	104.01 35200	∅ 5,6 x 550 mm	104.01 56550	∅ 6,1 x 550 mm	104.01 61550
∅ 5,5 x 40 mm	104.01 5540	∅ 5,6 x 600 mm	104.01 56600	∅ 6,1 x 600 mm	104.01 61600
∅ 5,5 x 50 mm	104.01 5550	∅ 6,0 x 40 mm	104.01 6040		
∅ 5,5 x 60 mm	104.01 5560	∅ 6,0 x 50 mm	104.01 6050	Sizes	Curved Rod
∅ 5,5 x 70 mm	104.01 5570	∅ 6,0 x 60 mm	104.01 6060	∅ 5,5 x 40 mm	104.02 5540
∅ 5,5 x 80 mm	104.01 5580	∅ 6,0 x 70 mm	104.01 6070	∅ 5,5 x 50 mm	104.02 5550
∅ 5,5 x 90 mm	104.01 5590	∅ 6,0 x 80 mm	104.01 6080	∅ 5,5 x 60 mm	104.02 5560
∅ 5,5 x 100 mm	104.01 55100	∅ 6,0 x 90 mm	104.01 6090	∅ 5,5 x 70 mm	104.02 5570
∅ 5,5 x 110 mm	104.01 55110	∅ 6,0 x 100 mm	104.01 60100	∅ 5,5 x 80 mm	104.02 5580
∅ 5,5 x 120 mm	104.01 55120	∅ 6,0 x 110 mm	104.01 60110	∅ 5,5 x 90 mm	104.02 5590
∅ 5,5 x 130 mm	104.01 55130	∅ 6,0 x 120 mm	104.01 60120	∅ 5,5 x 100 mm	104.02 55100
∅ 5,5 x 140 mm	104.01 55140	∅ 6,0 x 130 mm	104.01 60130	∅ 5,5 x 110 mm	104.02 55110
∅ 5,5 x 150 mm	104.01 55150	∅ 6,0 x 140 mm	104.01 60140	∅ 5,5 x 120 mm	104.02 55120
∅ 5,5 x 160 mm	104.01 55160	∅ 6,0 x 150 mm	104.01 60150		
∅ 5,5 x 170 mm	104.01 55170	∅ 6,0 x 160 mm	104.01 60160		
∅ 5,5 x 180 mm	104.01 55180	∅ 6,0 x 170 mm	104.01 60170		
∅ 5,5 x 190 mm	104.01 55190	∅ 6,0 x 180 mm	104.01 60180		
∅ 5,5 x 200 mm	104.01 55200	∅ 6,0 x 190 mm	104.01 60190		
∅ 5,5 x 250 mm	104.01 55250	∅ 6,0 x 200 mm	104.01 60200		
∅ 5,5 x 300 mm	104.01 55300	∅ 6,0 x 250 mm	104.01 60250		
∅ 5,5 x 350 mm	104.01 55350	∅ 6,0 x 300 mm	104.01 60300		
∅ 5,5 x 400 mm	104.01 55400	∅ 6,0 x 350 mm	104.01 60350		
∅ 5,5 x 450 mm	104.01 55450	∅ 6,0 x 400 mm	104.01 60400		
∅ 5,5 x 500 mm	104.01 55500	∅ 6,0 x 450 mm	104.01 60450		
∅ 5,5 x 550 mm	104.01 55550	∅ 6,0 x 500 mm	104.01 60500		
∅ 5,5 x 600 mm	104.01 55600	∅ 6,0 x 550 mm	104.01 60550		
		∅ 6,0 x 600 mm	104.01 60600		

## PRODORTH 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, aluminium, and silicone.



PP 100.10.001 *Anti-Torque*



PP 100.10.002 *Persuader*



PP 100.10.003 *AWL*



PP 100.10.004 *Hex Wrench*



PP 100.10.005 *Head Cutter*



PP 100.10.006 *Rod Pusher*



PP 100.10.008 *10-12 Nm Tork Limiting T Handle*



PP 100.10.007 *4-6 Nm Tork Limiting Handle*



PP 100.10.009 *T Handle Locking 1/4"*



PP 100.10.010 *Bone Probe Curved*



PP 100.10.011 *Bone Probe Straight*



PP 100.10.012 *Mallet*



PP 100.10.013 *Screw Driver 1/4" Adaptor*



PP 100.10.0015 *Transverse Setscrew Driver*



PP 100.10.014 *Setscrew Driver 1/4" Adaptor*



PP 100.10.019 *Screw Driver Pull Out 1/4" Adaptor*



PP 100.10.020 *Setscrew Driver*



PP 100.10.016 *Tap 4mm 1/4" Adaptor*  
PP 100.10.017 *Tap 5mm 1/4" Adaptor*  
PP 100.10.018 *Tap 6mm 1/4" Adaptor*



PP 100.01.023 *Feeler Stright*  
PP 100.01.024 *Feeler Curved*

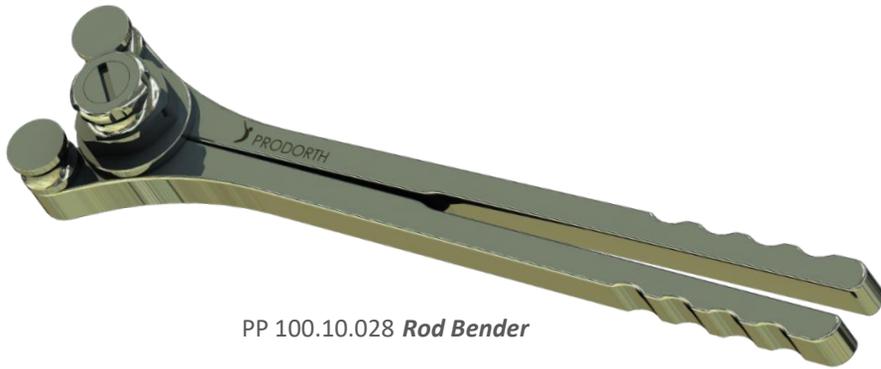


PP 100.10.0021 *Pedicle Marker-1*  
PP 100.10.0022 *Pedicle Marker-2*



PP 100.10.025 *Rocker*

PP 100.10.026 *in-Situ Bender Left*  
PP 100.10.027 *in-Situ Bender Right*



PP 100.10.028 *Rod Bender*



PP 100.10.029 *Rod Holder*



PP 100.10.032 *Rod Gripper*



PP 100.10.030 *Distractor*



PP 100.10.031 *Compressor*



PP 100.10.033 *Strong Rod Holder*

## SURGICAL PROCEDURE

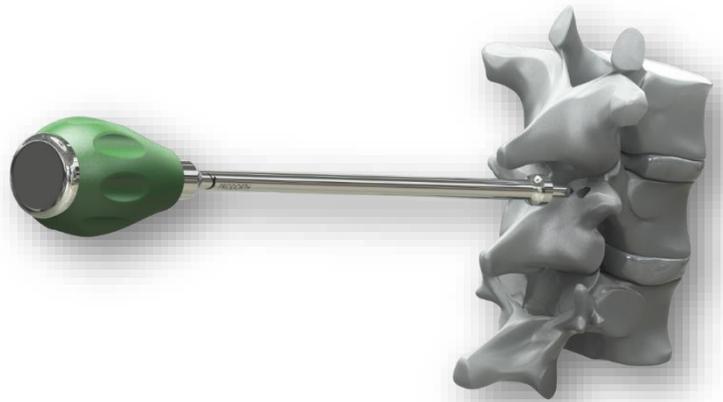
### Step 1

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

### Step 2

#### Preparation of the Pedicle

Facet joints are cleaned and the inferior facet and the cartilage on the upper facet is removed. Find the beginning point of each pedicle screw and at each beginning point use Prodorth AWL or high-speed burr to ream the cortical exterior of vertebrae.



### Step 3

#### Making interpedicular path

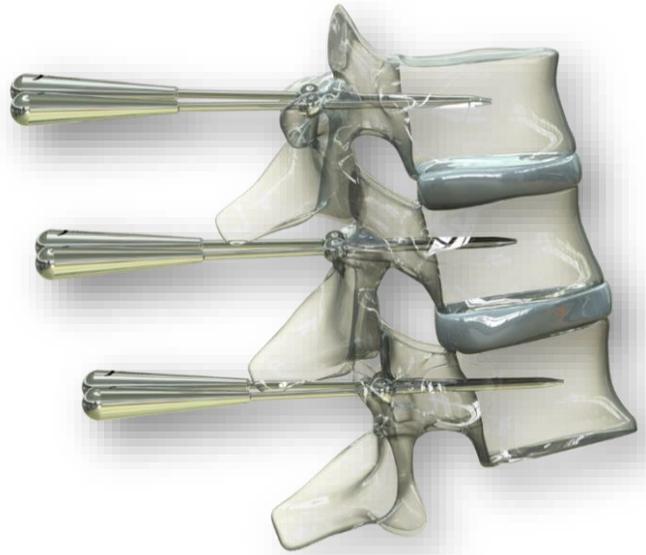
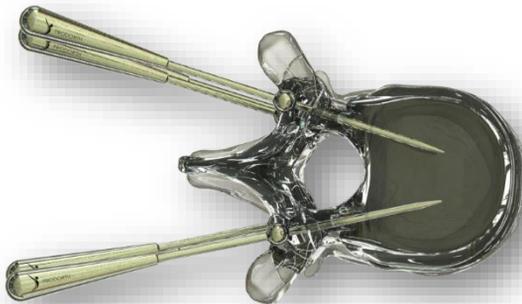
Pedicule probe is used for making the interpedicular path. If you decide to use the curved probe, at first orient the curved part laterally away from the canal.

Push forward the probe through the pedicle and the vertebra up to the desired hole depth.



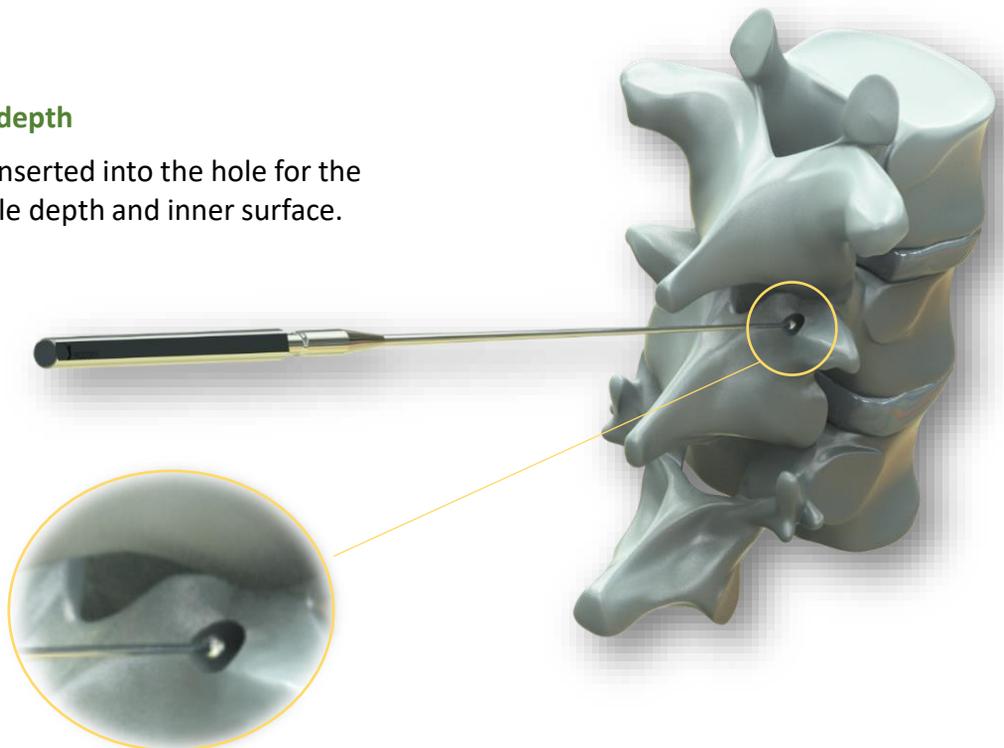
**Step 4**  
**Determination of suitable screw trajectory**

Marker pins may be placed into the hole in order to identify previously how the screw will be advanced. A X-ray view might be helpful for this process.



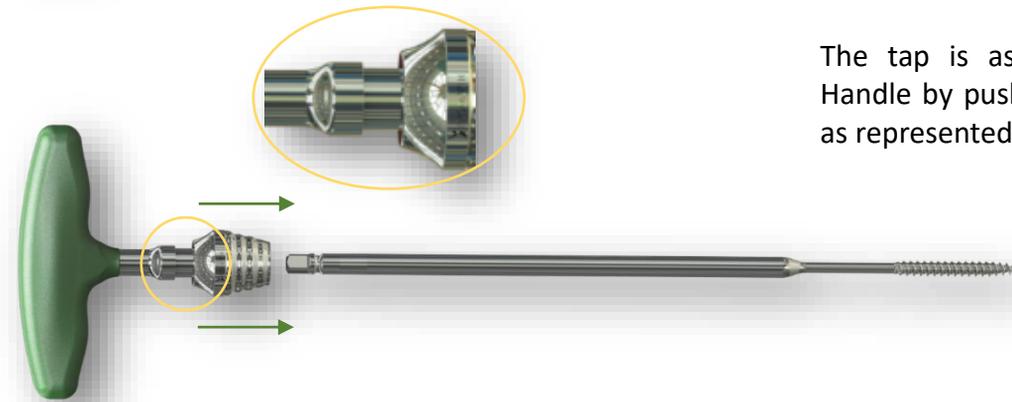
**Step 5**  
**Control of the hole depth**

The feelers may be inserted into the hole for the determination of hole depth and inner surface.



## Step 6 Making the tap into the pedicle

The below picture represents the T-Handle and Tap separately.



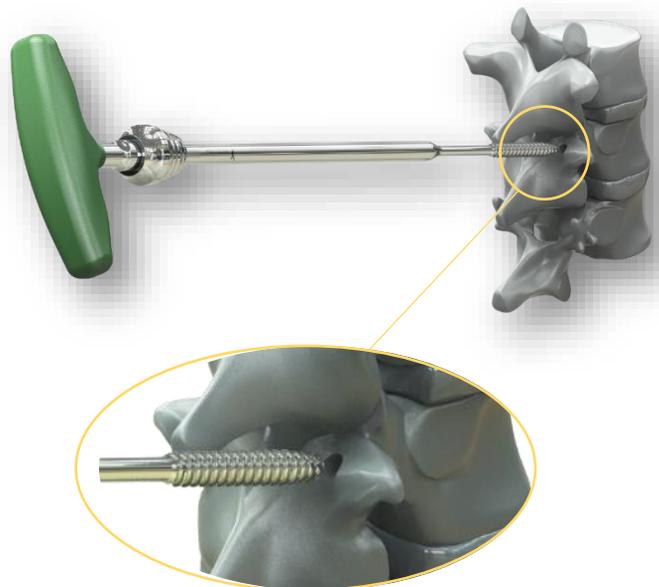
The tap is assembled to the T-Handle by pushing down the circle as represented at the the picture.

Appropriate screw diameter and length are determined.

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

After reaching the desired depth, remove the tap by rotating counterclockwise

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



## Step 7

### Insertion of the Polyaxial Pedicle Screw

Prodorth polyaxial screws are inserted by Prodorth polyaxial screw-driver. All sizes of polyaxial screws, as well as the spondylolisthesis (reduction) screws are inserted with the same driver.

Prodorth screw-driver is connected with T-Handle prior to be engaged with the screw, as it's represented at the below picture. The driver is assembled to the T-Handle by pushing down the circle.



**Connection with T-Handle**

While engaging the the screw to the driver, the silicon T-Handle should be hold constant and the rotatable handle at the middle of the driver will be rotated clockwise and the screw will be engaged in this way.

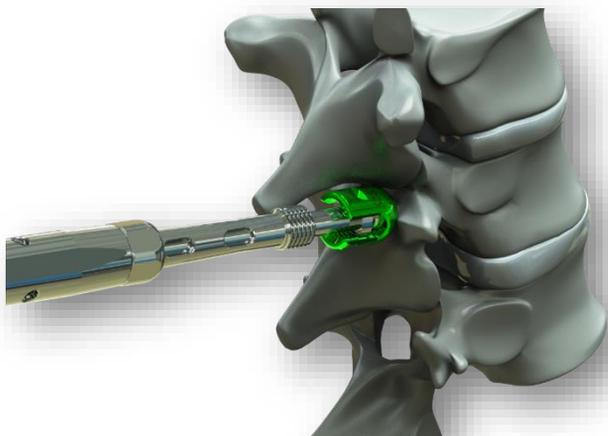


**Warning:** Ensure the driver is completely engaged with the screw before insertion to the pedicle.

### Advancing of the screw

The Polyaxial screw is inserted into the pedicle by holding the middle part of the driver(which is with holes on it) constant and rotating the T-Handle this time.

The screw will be advanced to a position by letting the poly-body is able to move 360° freely.



### Disconnection from screw

In order to remove the driver, this time hold the T-Handle constant and rotate the middle handle of driver counter-clockwise.

This process will be repeated so on until reaching to the desired pedicle screw quantity in the surgery.



### Insertion of the Monoaxial Pedicle Screw

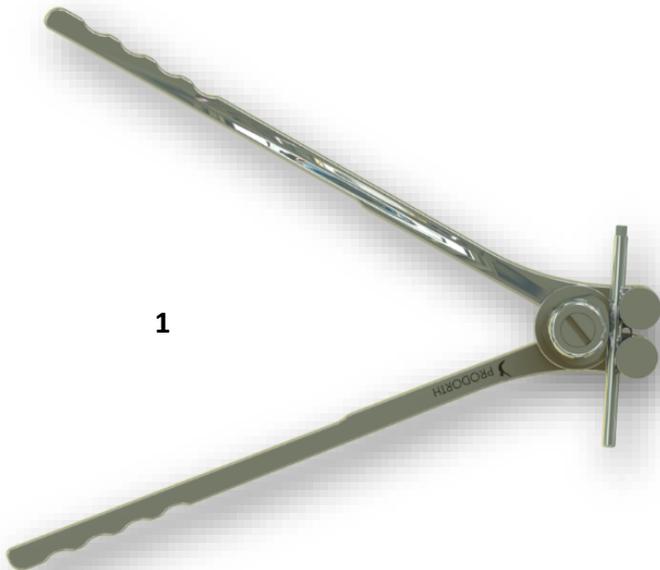
All the process explained for Prodorth polyaxial screws above are also same for Prodorth Monoaxial screws, except the driver selection. Prodorth Monoaxial screw-driver should be used for the insertion of monoaxial screws.

#### Step 8

#### Determination of suitable 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.

1



#### Rod Bending

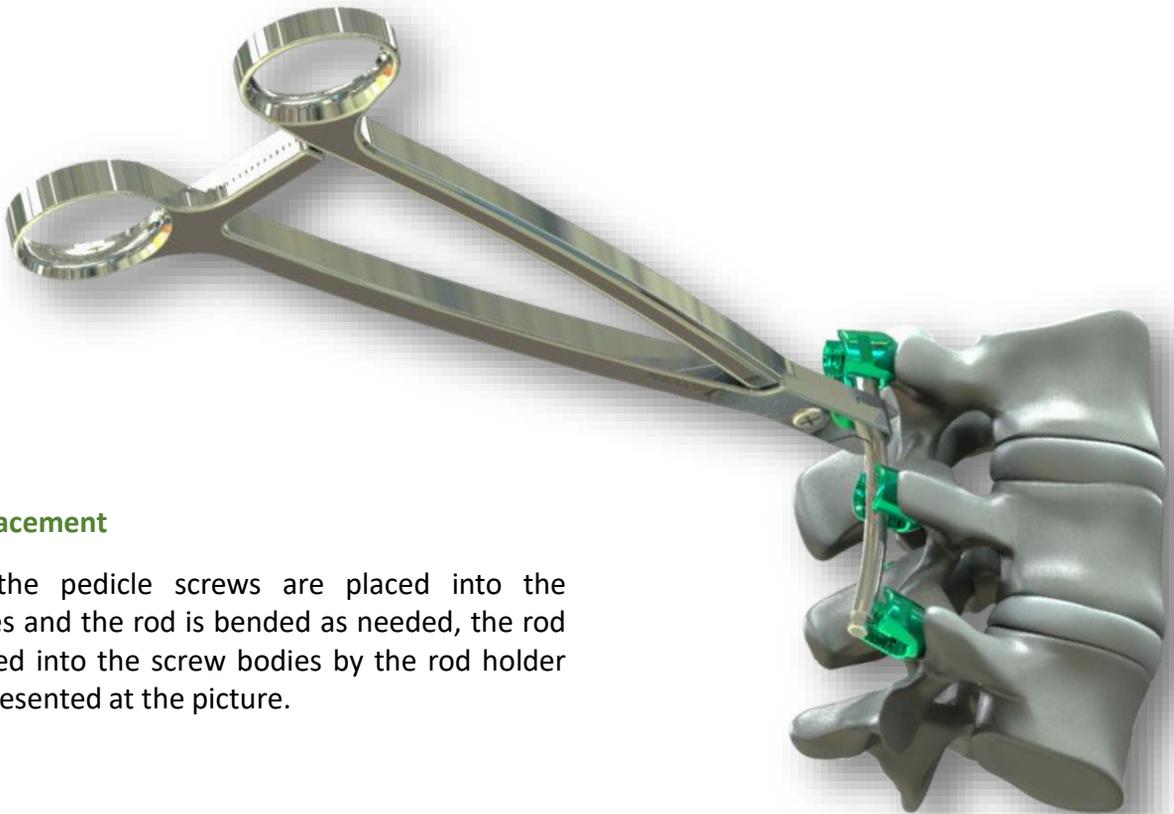
Rod is placed to the screws which are already placed into the pedicles, and the bending amount is determined in order to achieve the necessary sagittal profile.

Then the rod is placed to the rod bender and it's contoured as needed. A successfully bended rod should contact with the bottom of each screws' body (tulip).

2

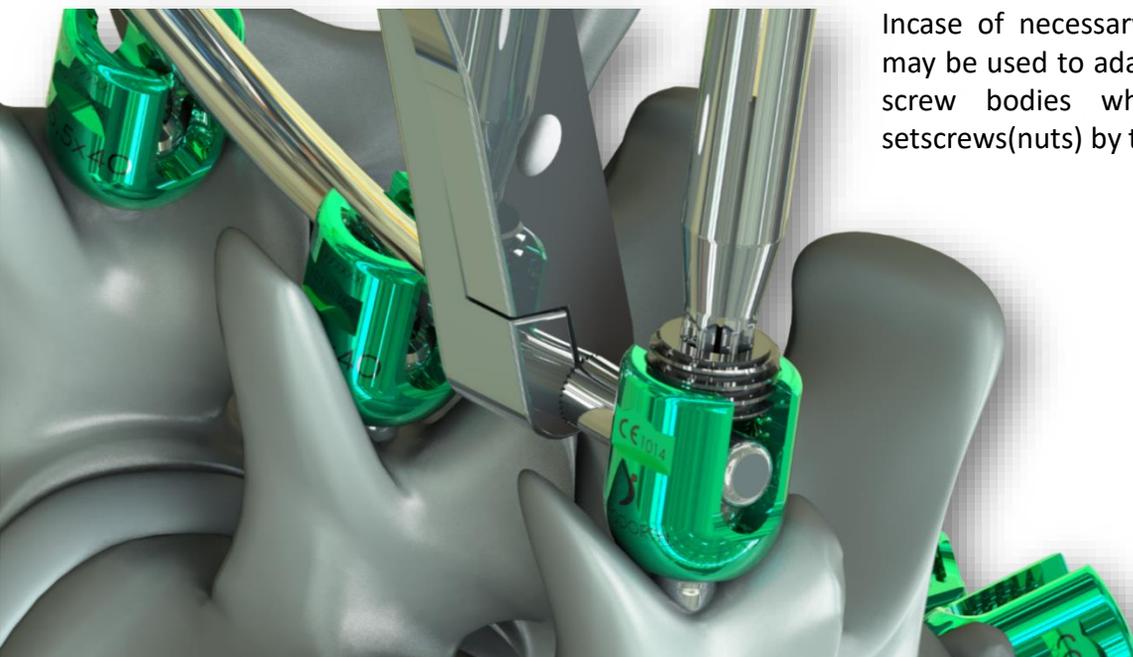


**Note:** You can switch the bending angles by pulling out and rotating the central button of rod bender, thus you can bend the rods through small, medium and large angles.



### Rod Placement

After the pedicle screws are placed into the pedicles and the rod is bended as needed, the rod is placed into the screw bodies by the rod holder as represented at the picture.



In case of necessary, the rod pushers may be used to adapt the rod into the screw bodies while inserting the setscrews(nuts) by the setscrew driver.

## Step 9

### Insertion of Setscrews

The setscrews will be priorly inserted to the the body of screws with the “slitted setscrew-driver”.

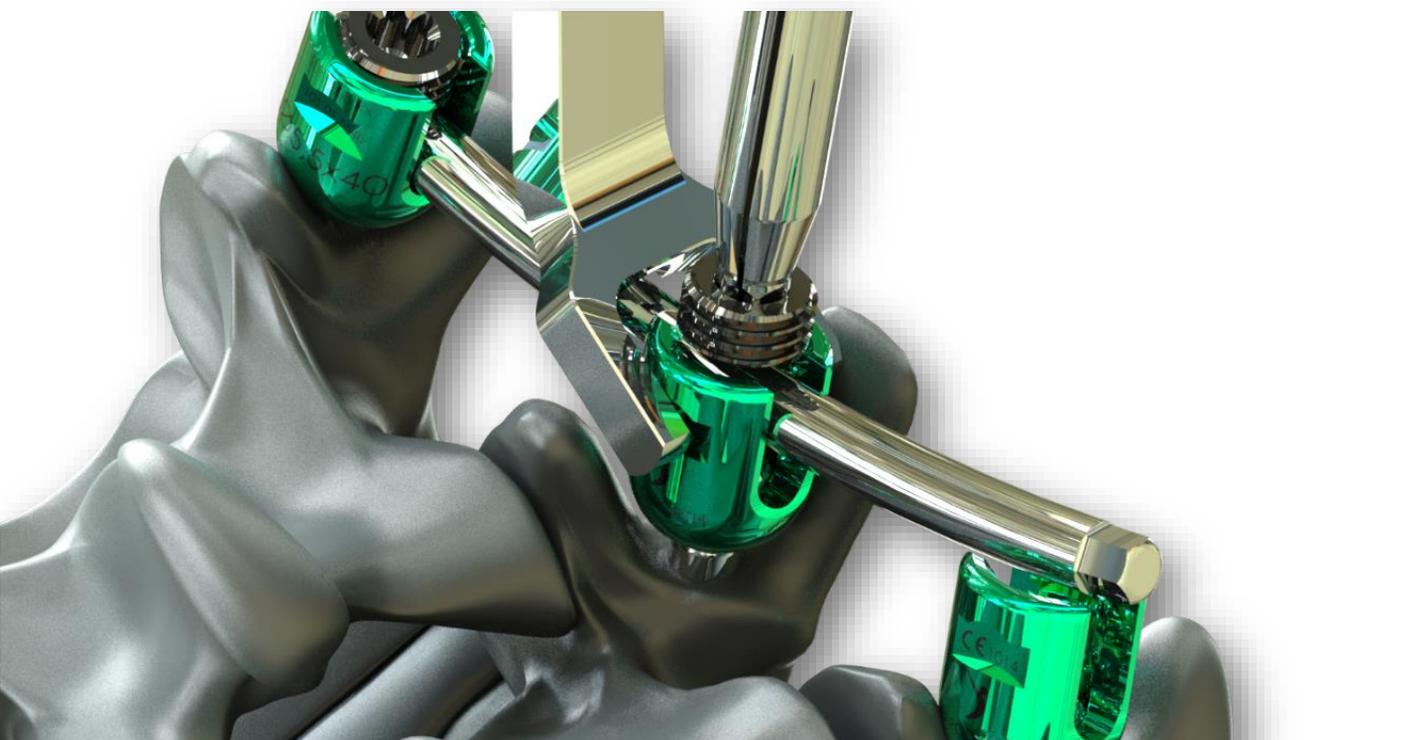
**Warning:** The “Slitted Setscrew-driver” is not an instrument for tightening but only for initial insertion of the setscrews. Since it has a slit on its body, the setscrew can be hold easily and insert smoothly without the risk of dropping the setscrew off.

As its represented at the pictures, the “rocker” instrument is used for a proper insertion of setscrews with the setscrew-driver.

**Warning:** Please pay attention not to place the setscrew to the screws at a cross-threading position. This will result in setscrew squeeze in the screw body and will be very difficult to take it out.

Once you ensure the setscrew is seated properly into the screw’s body, you can go on rotating the setscrew-driver.

**Repeat the process until all setscrews are placed.**

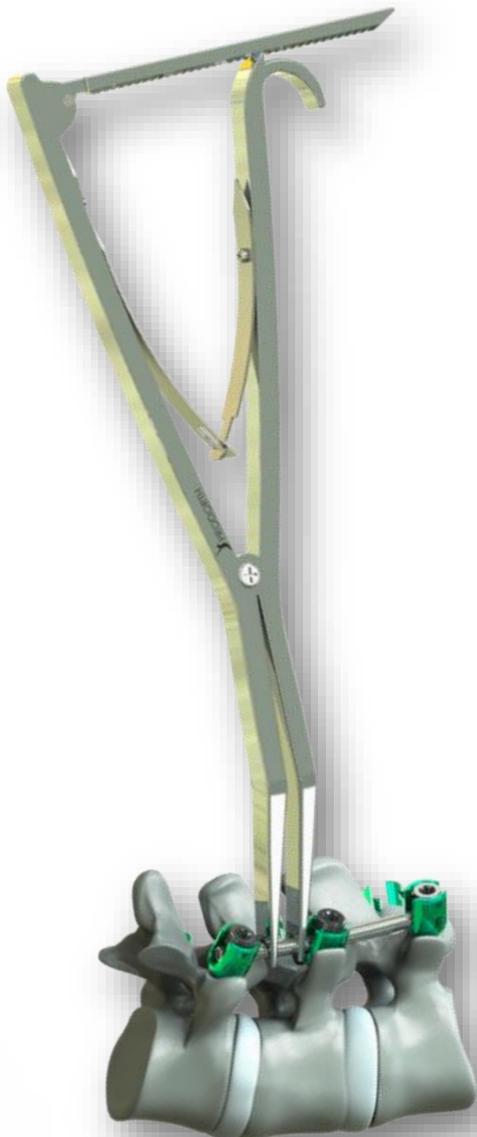
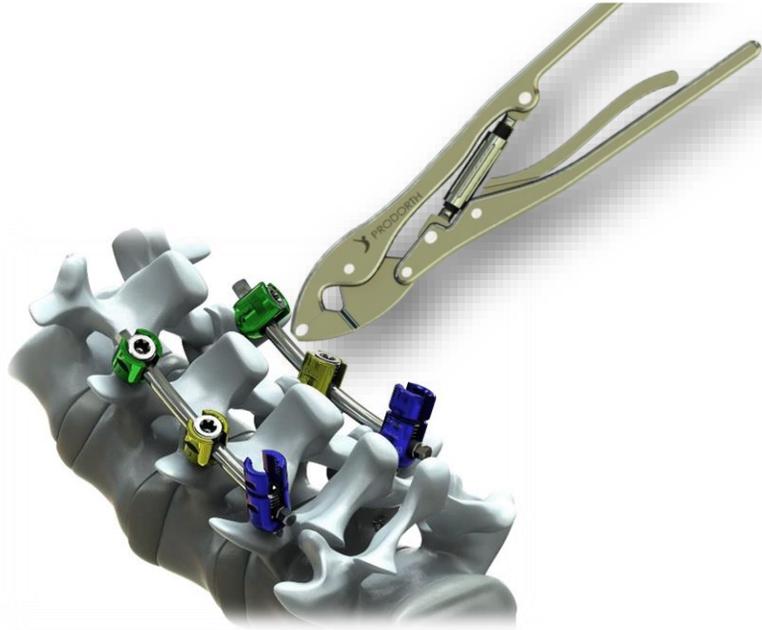


## Step 10

### Positioning of Rods

After all the setscrews are inserted, you can use rod gripper instrument to rotate the rods into lordosis. While the rod is held with Rod Gripper, the setscrew in the superior position is tightened using the Torque T-Handle (10-12 nm). The remaining set screws are left loose to allow for compression and distraction.

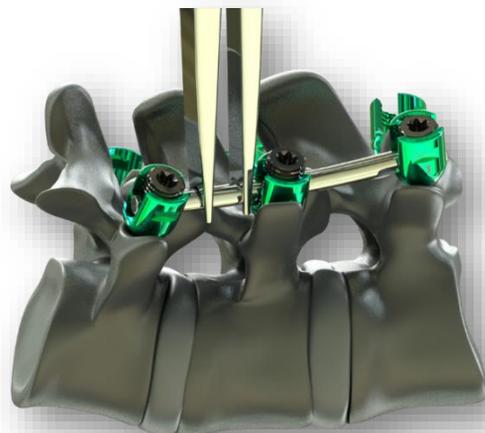
**Note:** The Torque T-Handle (10-12 Nm) is also connected with the setscrew-driver (not the slitted one) by the same process with other T-Handles of Prodorth.



## Step 11

### Distraction –Compression

Tighten the setscrew on one side of the segment and leave the setscrew on the other side as loosed. Compress or distract against the provisionally tightened assembly.





Once reaching the desired amount of correction, you can go further for the final tightening of the setscrews.

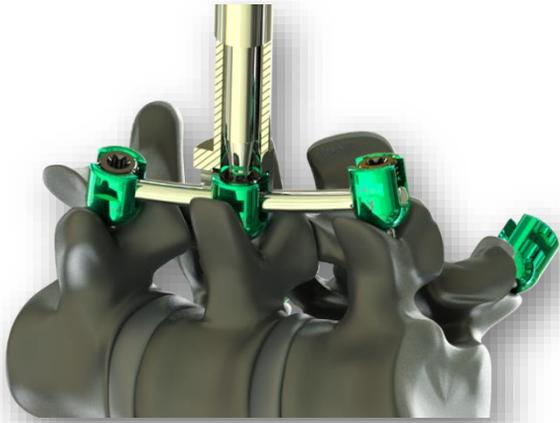


### Step 12

#### Final Tightening of Setscrews

The anti-torque instrument is placed as it's represented at the picture. And then the setscrew driver which is priorly connected to torque T-Handle (10-12 Nm) is inserted through the anti-torque instrument.

Tighten the setscrews until the “click-click” sound is heard from the Torque T-Handle. Repeat the process so on for the each setscrew by using the anti-torque instrument.



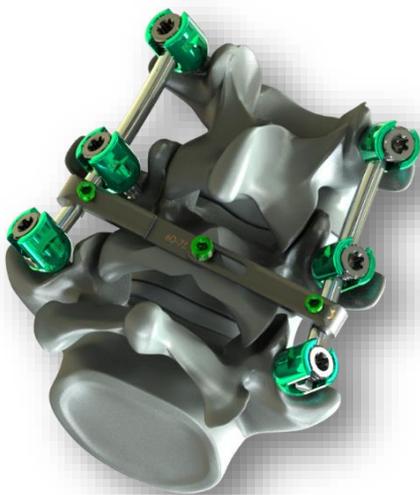
### Step 13

#### Placement of the connectors (If necessary)

Linear or multiaxial connectors may be used incase the surgeon decides it's necessary.

Both of the connectors may be placed between the rods after all above steps are completed and the setscrews on the connectors are tightened with the 4-6 Nm Torque Handle (the spherical shaped) is connected to **connector setscrew-driver** and setscrews are tightened by rotating it clockwise. When the “click-click” sound is heard, this means the tightening is done.

**Note:** The multiaxial connector is not only be used in linear direction, but also it may be positioned at different angles and used in that position.





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See the IFU prior to use for additional information.



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