

PsOne™

Surgical Technique



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Introduction

The PsOne™ System consists of a set of Pedicle Screws, Rods, Set Screws and instruments. PsOne™ is specially developed for temporary or permanent correction or stabilization of the vertebral column from the thoracic to the sacrum and with the aim of helping consolidation or bone fusion. In combination with a lumbar cage, PsOne™ bears the intervertebral loads and facilitates osteosynthesis.

PsOne™ offers the surgeon a straightforward and safe technique. The set offers Mono Screws, Poly Screws and Reduction Screws.

Indications and Contraindications

Indications

- Degenerative Disc Disease (DDD) with a specific discogenic pain pattern
- Spondylolisthesis
- Instability of the anterior column in association with posterior pathology
- Fractures
- Tumors
- Primary spinal deformities

Contraindications

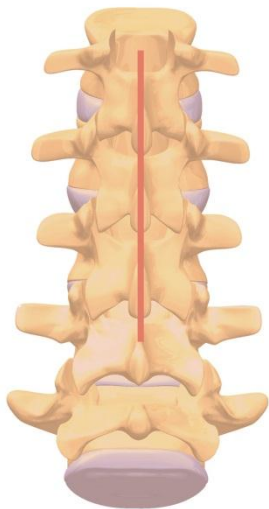
- Insufficient quality or quantity of bone which would inhibit rigid device fixation
- Any abnormality present which affects the normal process of bone remodelling
- Active infection
- Allergy to titanium or its alloys

Preoperative Planning

Use the appropriate imaging techniques to outline the patient's osseous anatomy and to determine the proper size and type of the instrumentation to be used. The PsOne™ System offers a wide range of screw types and sizes. The exact implant and instrument set content is described in the Set Description on page 12 and 13 of this Surgical Technique.

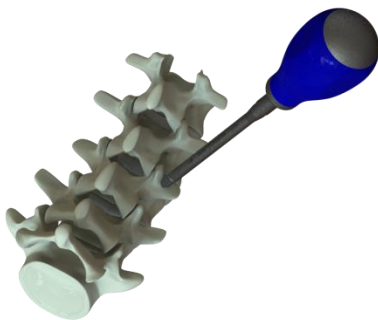
The choice of a particular device must always be carefully weighed against the patients overall evaluation. In case load bearing capacity is not intact, always use the PsOne™ System in combination with a lumbar cage.

Surgical Technique



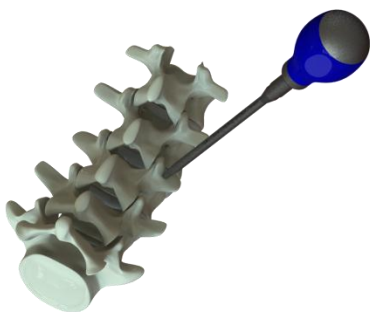
Prepare the patient in prone position (lumbar lordosis must be maintained) and make a midline incision in order to gain access to the level(s) to be treated.

1



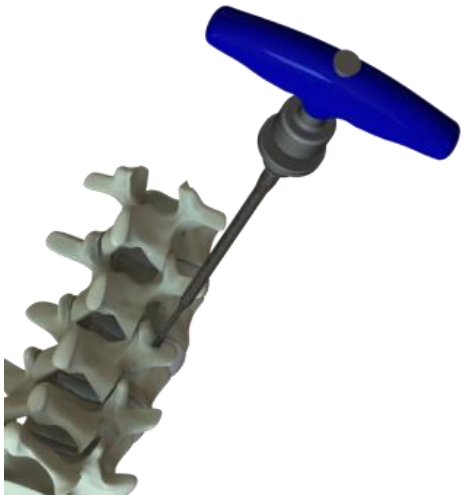
Determine the pedicle canal entry site. Prepare the pedicle canal using the **PsOne™ Pedicle Awl**. Check the position and depth with lateral x-ray/fluoroscopy. Insert the PsOne™ Pedicle Probe and palpate the inner surface of the canal to verify pedicle wall integrity.

2



The **PsOne™ Pedicle Opener** can be used to open up the canal and to compact the bone. Again, insert the PsOne™ Pedicle Probe and palpate the inner surface of the canal to verify pedicle wall integrity.

3



With hard bone quality it is recommended to use the provided **PsOne™ Tap**. Make sure the tap is not inserted deeper than the 'Stop' marking.

4



Decide what Screw type is to be used. The **PsOne™ System** has Mono Screws, Poly Screws and Reduction Screws available. Select the appropriate screw diameter and length. Screws are available in Ø5,5 mm, Ø6,5 mm and Ø7,5 mm and in 30-55 mm length. The colours of the screws indicate the screw diameter.

5

- Blue: Ø5,5 mm
- Grey: Ø6,5 mm
- Gold: Ø7,5 mm

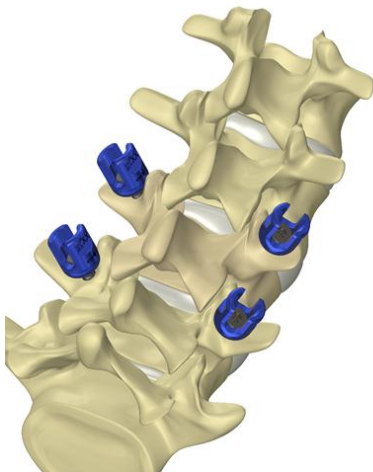


Insert the PsOne™ Screw into the desired pedicle. To do so, hold the free rotating sleeve of the **PsOne™ Screw Driver** with one hand and turn the handle clockwise with the other hand. When a PsOne™ Mono Screw is used, insert the Screw into the desired pedicle until the bottom of the mono screw body contacts the bone surrounding the screw insertion site and the opening in the head allows Rod placement. When a PsOne™ Poly Screw or PsOne™ Reduction Screw is used, advance to a depth where full angulation of the poly axial head is maintained.

6



7 Insert the PsOne™ Screw into the desired pedicle. To do so, hold the free rotating sleeve of the **PsOne™ Screw Driver** with one hand and turn the handle clockwise with the other hand. When a PsOne™ Mono Screw is used, insert the Screw into the desired pedicle until the bottom of the mono screw body contacts the bone surrounding the screw insertion site and the opening in the head allows Rod placement. When a PsOne™ Poly Screw or PsOne™ Reduction Screw is used, advance to a depth where full angulation of the poly axial head is maintained.



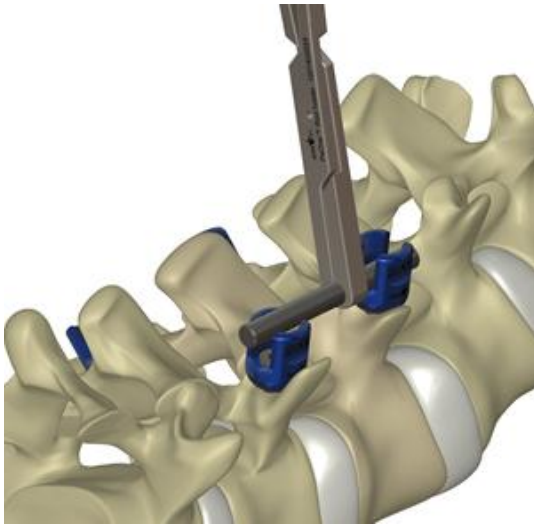
8 To remove the PsOne™ Screw Driver, turn the revolver grip counter clockwise.

Repeat step 6 and 7 until all Screws are placed.



9 Once Screws have been placed, the appropriate Rod length and curve are determined. The Rod should extend approximately 5 mm beyond the most cranial and caudal screws. The PsOne™ System provides pre-cut Ø6,0 mm Rods and a longer Rod that should be cut to the desired length.

Bend the PsOne™ Rod to the desired curve with the **PsOne™ Rod Bender**.



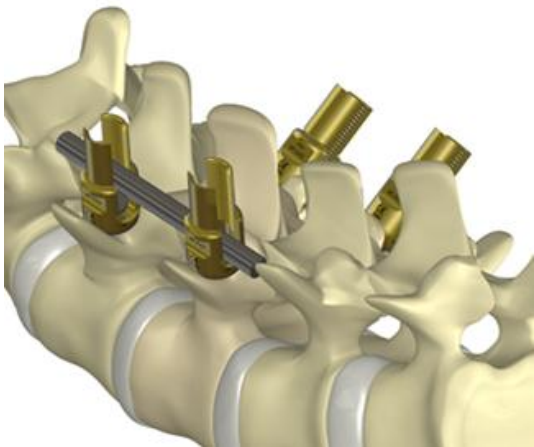
10

Insert the Rod in the Screw heads using the **PsOne™ Rod Holder**. There are several methods to seat the Rod. The method(s) that should be used are depending on the situation and on surgeon's preference.

When a PsOne™ Reduction Screw is used, the reduction tabs in combination with the Set Screw can be used. (10a).

Available instruments to seat the rod:

- PsOne™ Rod Clamp (10b)
- PsOne™ Rod Persuader (10d)
- PsOne™ Rod Fork (10c)
- PsOne™ Pusher (10e)



10a

PsOne™ Reduction Screw

When PsOne™ Reduction Screws are used, the reduction tabs of the screws can be used to seat the Rod. Position the Rod above or inside the reduction tabs of the Reduction head. Continue with step 11 to seat the rod with the PsOne™ Set Screw.

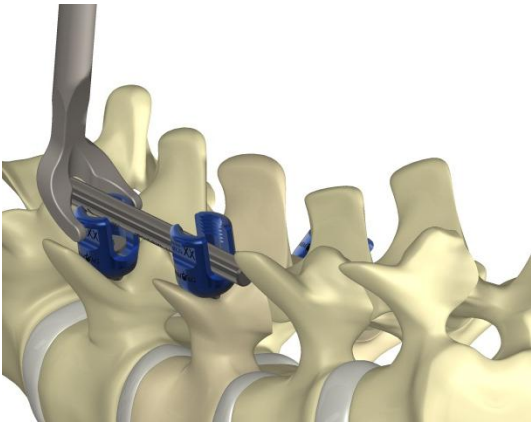


10b

PsOne™ Rod Clamp

Place the Rod in the beak of the PsOne™ Rod Clamp and flip the lever to fasten the Rod. Push the rod into its seat. (In order to release the Rod the lever should be flipped back.)

Continue with step 11.

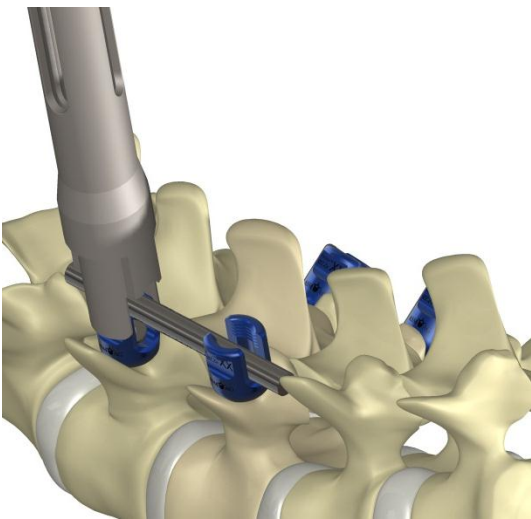


PsOne™ Rod Fork

Place the PsOne™ Rod Fork on top of the Rod with the knobs positioned in the contours of the Screw head. Turn the Rod Fork over the Rod to seat the Rod.

10c

Continue with step 11.

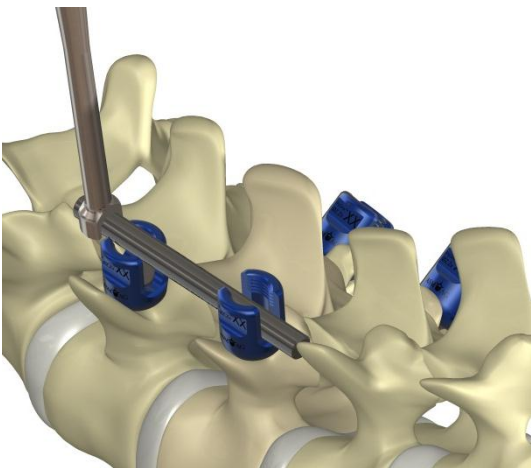


PsOne™ Rod Persuader

Place the PsOne™ Rod Persuader over the Screw head: Hook one side of the Rod Persuader to the Screw head first and tumble the instrument to click onto the other side of the Screw head. Squeeze the handle till the Rod is fully seated.

10d

Continue with step 11 to place the Setscrew through the Rod Persuader.



PsOne™ Pusher

Place the PsOne™ Pusher over the Rod and push it into its seat.

10e

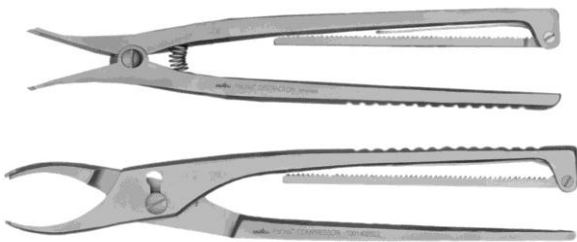
Continue with step 11.



Firmly connect the PsOne™ Set Screw to the **PsOne™ Set Screw Inserter** and insert the Set Screw in the Screw head. To avoid cross-threading during insertion of the Set Screw, first turn counter clockwise, until you feel the thread snapping in the screwhead. Continue turning clockwise.

11

The **PsOne™ Sleeve** can be used together with the Set Screw Inserter to prevent cross threading and to enable wiggling. Place the Sleeve over the head before inserting the Set Screw.



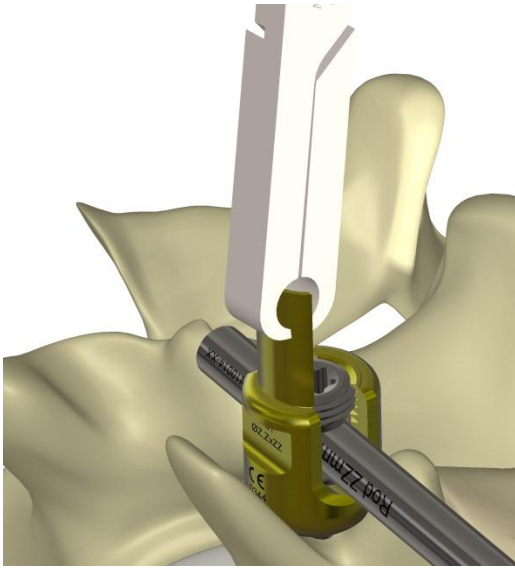
Distraction and compression can be performed with the **PsOne™ Distractor** and the **PsOne™ Compressor**.

12



Position the PsOne™ Anti-Torque Wrench over the head of the Screw to be tightened. Insert the assembled PsOne™ Set Screw Driver with attached PsOne™ Torque Limiter through the cannulated Anti-Torque Wrench into the PsOne™ Set Screw. Tighten the Set Screw until the maximum amount of torque is reached (11,3Nm). Repeat the process until the remaining Set Screws are tightened.

13



After final tightening, when **PsOne™ Reduction Screws** are used, reduction tabs should be removed using pliers.

14



In case Screws have to be removed, the **PsOne™ Pedicle Screw Driver** can be used to untighten the bonescrew.

15

PsOne™ Surgical Technique Set Description

PsOne™ Implants

PsOne™ Mono Screw	Ø 5,5 mm	length 30 mm	order # MS5530
PsOne™ Mono Screw	Ø 5,5 mm	length 35 mm	order # MS5535
PsOne™ Mono Screw	Ø 5,5 mm	length 40 mm	order # MS5540
PsOne™ Mono Screw	Ø 5,5 mm	length 45 mm	order # MS5545
PsOne™ Mono Screw	Ø 6,5 mm	length 35 mm	order # MS6535
PsOne™ Mono Screw	Ø 6,5 mm	length 40 mm	order # MS6540
PsOne™ Mono Screw	Ø 6,5 mm	length 45 mm	order # MS6545
PsOne™ Mono Screw	Ø 6,5 mm	length 50 mm	order # MS6550
PsOne™ Mono Screw	Ø 6,5 mm	length 55 mm	order # MS6555
PsOne™ Mono Screw	Ø 7,5 mm	length 40 mm	order # MS7540
PsOne™ Mono Screw	Ø 7,5 mm	length 45 mm	order # MS7545
PsOne™ Mono Screw	Ø 7,5 mm	length 50 mm	order # MS7550
PsOne™ Mono Screw	Ø 7,5 mm	length 55 mm	order # MS7555
PsOne™ Poly Screw	Ø 5,5 mm	length 30 mm	order # PS5530
PsOne™ Poly Screw	Ø 5,5 mm	length 35 mm	order # PS5535
PsOne™ Poly Screw	Ø 5,5 mm	length 40 mm	order # PS5540
PsOne™ Poly Screw	Ø 5,5 mm	length 45 mm	order # PS5545
PsOne™ Poly Screw	Ø 6,5 mm	length 35 mm	order # PS6535
PsOne™ Poly Screw	Ø 6,5 mm	length 40 mm	order # PS6540
PsOne™ Poly Screw	Ø 6,5 mm	length 45 mm	order # PS6545
PsOne™ Poly Screw	Ø 6,5 mm	length 50 mm	order # PS6550
PsOne™ Poly Screw	Ø 6,5 mm	length 55 mm	order # PS6555
PsOne™ Poly Screw	Ø 7,5 mm	length 40 mm	order # PS7540
PsOne™ Poly Screw	Ø 7,5 mm	length 45 mm	order # PS7545
PsOne™ Poly Screw	Ø 7,5 mm	length 50 mm	order # PS7550
PsOne™ Poly Screw	Ø 7,5 mm	length 55 mm	order # PS7555
PsOne™ Reduction Screw	Ø 5,5 mm	length 30 mm	order # RS5530
PsOne™ Reduction Screw	Ø 5,5 mm	length 35 mm	order # RS5535
PsOne™ Reduction Screw	Ø 5,5 mm	length 40 mm	order # RS5540
PsOne™ Reduction Screw	Ø 5,5 mm	length 45 mm	order # RS5545
PsOne™ Reduction Screw	Ø 6,5 mm	length 35 mm	order # RS6535
PsOne™ Reduction Screw	Ø 6,5 mm	length 40 mm	order # RS6540
PsOne™ Reduction Screw	Ø 6,5 mm	length 45 mm	order # RS6545
PsOne™ Reduction Screw	Ø 6,5 mm	length 50 mm	order # RS6550
PsOne™ Reduction Screw	Ø 6,5 mm	length 55 mm	order # RS6555
PsOne™ Reduction Screw	Ø 7,5 mm	length 40 mm	order # RS7540
PsOne™ Reduction Screw	Ø 7,5 mm	length 45 mm	order # RS7545
PsOne™ Reduction Screw	Ø 7,5 mm	length 50 mm	order # RS7550
PsOne™ Reduction Screw	Ø 7,5 mm	length 55 mm	order # RS7555

PsOne™ Set Screw

order # S10

PsOne™ Rod	Ø 6,0 mm	length 40 mm	order # R40
PsOne™ Rod	Ø 6,0 mm	length 50 mm	order # R50
PsOne™ Rod	Ø 6,0 mm	length 60 mm	order # R60
PsOne™ Rod	Ø 6,0 mm	length 70 mm	order # R70
PsOne™ Rod	Ø 6,0 mm	length 80 mm	order # R80
PsOne™ Rod	Ø 6,0 mm	length 90 mm	order # R90
PsOne™ Rod	Ø 6,0 mm	length 100 mm	order # R100
PsOne™ Rod	Ø 6,0 mm	length 480 mm	order # R480

PsOne™ Rod Standard Curve	Ø 6,0 mm	length 40 mm	order # R40SC
PsOne™ Rod Standard Curve	Ø 6,0 mm	length 50 mm	order # R50SC
PsOne™ Rod Standard Curve	Ø 6,0 mm	length 60 mm	order # R60SC
PsOne™ Rod Standard Curve	Ø 6,0 mm	length 70 mm	order # R70SC
PsOne™ Rod Standard Curve	Ø 6,0 mm	length 80 mm	order # R80SC
PsOne™ Rod Standard Curve	Ø 6,0 mm	length 90 mm	order # R90SC
PsOne™ Rod Standard Curve	Ø 6,0 mm	length 100 mm	order # R100SC

The PsOne™ Implants are produced out of implant grade titanium alloy (TI6Al4V ELI).

PsOne™ Surgical Technique

PsOne™ Implantation Set Instruments

PsOne™ Set Screw Inserter	1/4 inch	order # 1001402002
PsOne™ Screw Driver	1/4 inch	order # 1001402003
PsOne™ Anti-Torque Wrench		order # 1001402004
PsOne™ Rod Fork		order # 1001402006
PsOne™ Rod Clamp		order # 1001402008
PsOne™ Tap	1/4 inch	order # 1001402009
PsOne™ Removal Tool	1/4 inch	order # 1001402010
PsOne™ Pusher		order # 1001402011
PsOne™ Rod Persuader		order # 1001402012
PsOne™ Pedicle Awl		order # 1001402013
PsOne™ Pedicle Opener		order # 1001402014
PsOne™ Torque Limiter	1/4 inch	order # 1001402015
PsOne™ Pedicle Probe		order # 1001402020
PsOne™ Rod Bender		order # 1001402021
PsOne™ Compressor		order # 1001402022
PsOne™ Distractor		order # 1001402023
PsOne™ Rod Holder		order # 1001402024
PsOne™ Sleeve		order # 1001402027
PsOne™ 1/4" T-Handle with Ratchet	1/4 inch	order # 1001402041
PsOne™ 1/4" Straight Handle 28mm with Ratchet	1/4 inch	order # 1001402044
PsOne™ Set Screw Driver	1/4 inch	order # 1001402140

PsOne™ Trays

PsOne™ Implant Tray	order # 1001401200
PsOne™ Instrument Trays	order # 1001402200

General Information

General Conditions of Use

The device is intended to be used by trained orthopaedic, trauma or general surgeons in an operating room environment.

Reuse

An implant should never be reused. While it may appear undamaged, a used implant may have acquired blemishes or latent compromise of its integrity, which would reduce its service life. It is recommended to verify that the instruments are in good condition and operating order prior to use during surgery.

Magnetic Resonance Imaging

A majority of patients with orthopaedic implants have been imaged with MR without incident. Displacement of these implants is highly unlikely to occur for these are mechanically fixed to the patient's bone structure. However, sufficient currents being induced in the metal by the magnetic and radiofrequency fields can heat a large metallic implant.

It can be assumed that the PsOne™ implants fall in the category of MR conditional, although this is not proven. Therefore it is advised not to use the PsOne™ implants with MR.

Packaging, Cleaning and Sterilisation

PsOne™ Implants are packaged in sealed pouches and are delivered non-sterile. For cleaning and steam sterilisation specifications, please see the IFU.

For further information or remarks, please contact your PsOne™ distributor.

Manufactured by:



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