



SPINE®
CONCEPTS

OLYMPUS MIS

S U R G I C A L T E C H N I Q U E



OLYMPUS MIS

S U R G I C A L T E C H N I Q U E

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System Overview



Introduction

Minimal invasive spine surgery has several advantages over traditional open techniques. Smaller incisions and minimal muscle resection markedly decrease operating time, blood loss and postoperative pain.

The Olympus MIS Polyaxial Pedicle Screw EX System was developed to offer a less invasive surgical option for pedicle screw placement. The system incorporates anatomically driven solutions such as self-tapping cannulated polyaxial screws and pre-lordosed rods. The instrumentation is ergonomically designed to allow for true percutaneous. The Olympus MIS Polyaxial Pedicle Screw EX System offers a simple, precise and highly efficient solution to spinal fixation, instilling confidence in its performance.

Intended use

The Olympus MIS Polyaxial Pedicle Screw EX System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities of the thoracic, lumbar and sacral spine:

- Degenerative disc disease (DDD)
- Spondylolisthesis (Grades 3 and 4)
- Degenerative spondylolisthesis
- Trauma (i.e., fracture or dislocation)
- Spinal stenosis
- Deformities (i.e., scoliosis, kyphosis, and/or lordosis)
- Tumor
- Pseudoarthrosis
- Failed previous fusion
- Revision spine surgery

Preoperative Planning

When using the Olympus MIS Polyaxial Pedicle Screw EX, the patient should be positioned prone on a radiolucent table. Chest rolls may be used, but the knee-to-chest position should be avoided due to the potential risk of spinal cord compression and nerve damage.

Using fluoroscopic imaging, it should be verified that the true views of both anterior-posterior (A/P) and lateral images of the spine (views that adequately delineate pedicle morphology and geometry) are obtainable. Preoperative planning should also be used to help determine a proper entry point and trajectory.

After identifying the pedicle entry point, a targeting needle and a guide should be used to initiate the starting entry point. The targeting needle helps to accurately locate the entry point, while the guide ensures the correct trajectory. Adjustments to the entry angle and the trajectory should be made as often as needed with the assistance of fluoroscopic imaging until the proper position is attained.

Note: This is intended as a guide only. There are multiple techniques for the insertion of pedicle screws and, as with any surgical procedure, a surgeon should be thoroughly trained before proceeding. Your comprehensive training equips you with the necessary skills and knowledge to consider the particular needs of each patient and make the appropriate adjustments when necessary and as required. Please refer to the instructions for use insert for complete system description, indications and warning.

Features and Benefits

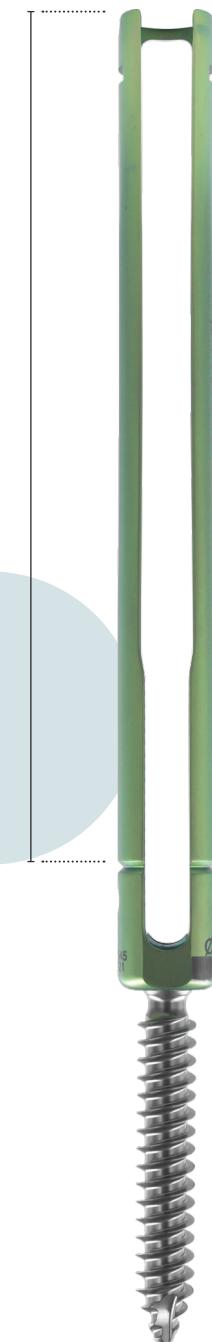
- Ensures proper thread alignment while reducing and locking the rod in one simplified step.
- Minimized muscle disruption.
- Extended screw heads provide a minimized outer diameter to help reduce muscle disruption.
- Friction fit polyaxial screw head.
- The Olympus MIS Screw head is designed to maintain position for rod placement, ensuring stability and accuracy. This feature provides confidence to perform the surgery effectively and efficiently.



OLYMPUS MIS

POLYAXIAL PEDICLE SCREW EX

Specification



150 mm
Extended reach, allowing it to be used in a wide range of patients.

Extended reduction range of 35 mm.



Half Closed Type

Stabilizes rotation and prevents tissue entrapment during placement.



Dual lead Cannulated bone screw

Facilitates smooth penetration, reducing friction.



Self-Tapping

Enhances surgical efficiency through the active tip design.

Operative Technique



Step 1: Pedicle Preparation

Identification

It is recommended that preoperative planning is used to help determine the proper entry point and trajectory, as the starting point is not usually at the point directly over the pedicle.

Identify the operative levels using A/P and lateral fluoroscopy. Plan the entry point to target the pedicle from a transverse trajectory lateral to the facet.

Perform an incision through the skin and fascia, with the typical starting point 3-4cm off the midline. Insert the Targeting Needle to the surface of the pedicle, docking the tip on the bony anatomy of the desired level. Confirm placement with A/P fluoroscopy and make adjustments to the entry angle and trajectory until the proper position is attained.

Advance the targeting needle and the guide through the pedicle. Once proper placement is confirmed, remove the inner stylet of the targeting needle.



Figure 1



Figure 2



Figure 3

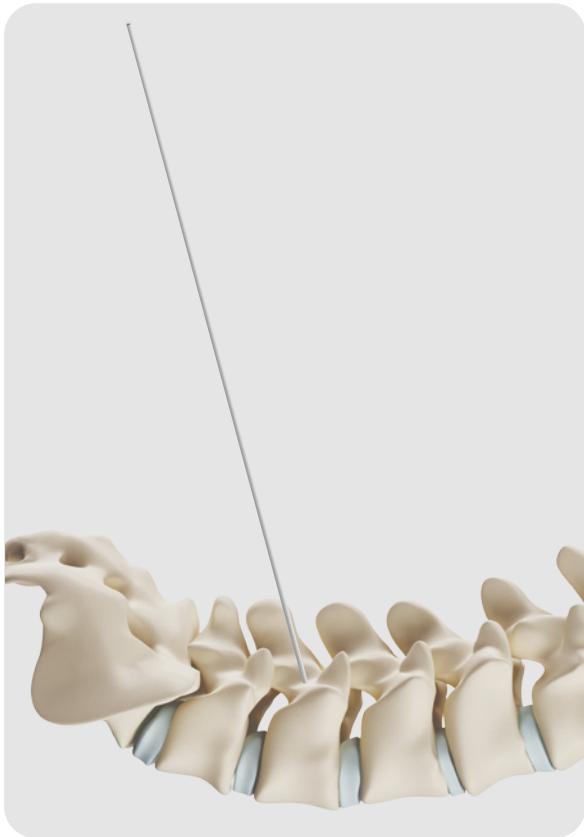


Figure 5

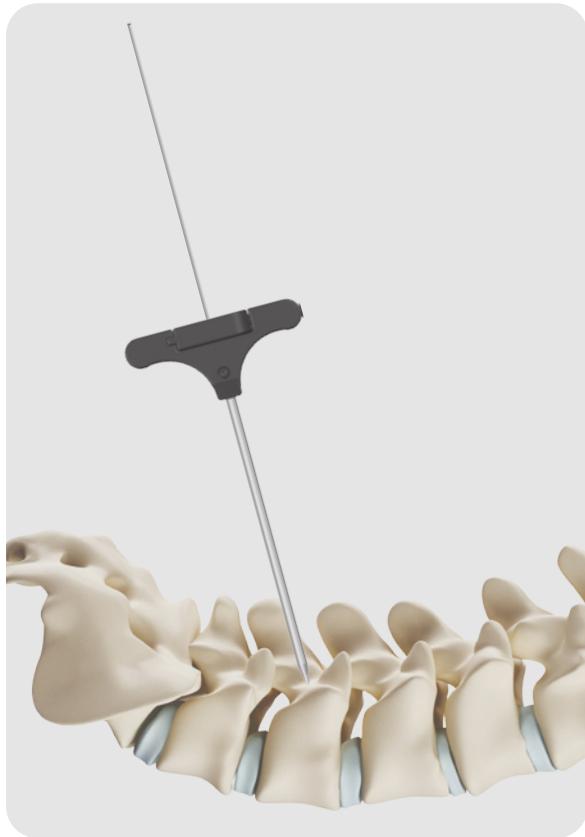


Figure 4

Guidewire Placement

Insert the guidewire through the cannulated target needle and advance the guidewire just past the tip of the Targeting needle. Use caution when advancing the guidewire under fluoroscopy; ensure its location.

Once the guidewire is in place, remove the targeting needle and leave it in place.



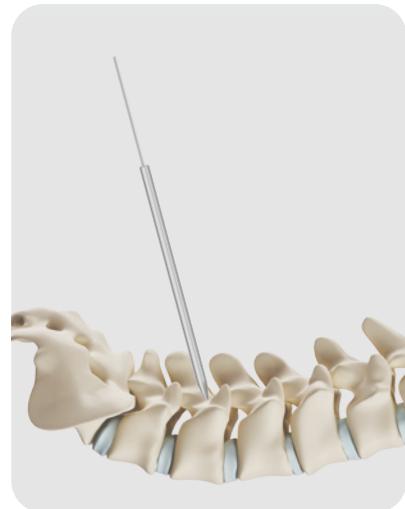


Figure 6

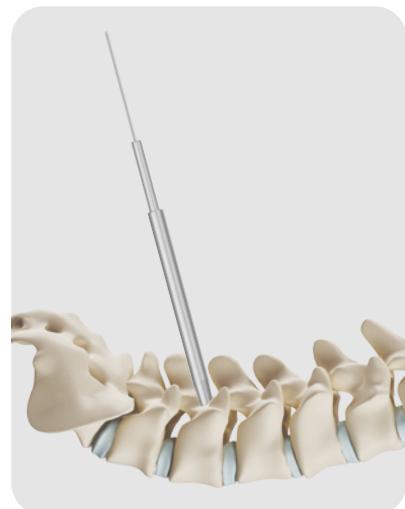


Figure 7

Tissue Dilation

A longitudinal incision approximately 1.5 cm long is made through the skin and fascia. This incision allows for the insertion of the dilators that will be used later in the procedure.

To prepare a pathway to the pedicle, sequentially use dilators 1, 2, and 3. Once the large dilator is in place, remove the inner dilators and position them over the adjacent guidewire. It is important to leave the large dilator in place to serve as a protective barrier for the soft tissue during the tapping process.

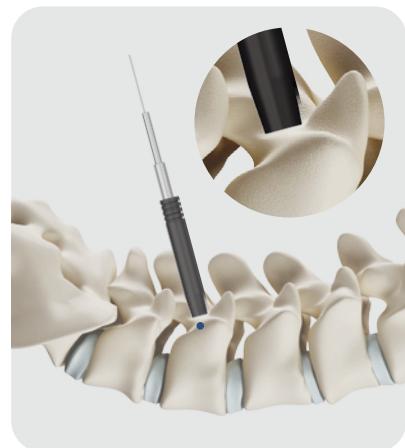


Figure 8

Tapping

Attach the appropriate tap size to the handle. Place the tap over the guidewire and through the large dilator to the surface of the pedicle. The depth markers on the tap shaft where the Tap shaft meets the top of the large dilator are used to monitor insertion. They can also be used to determine screw length. Once desired depth has been achieved remove tap while maintaining control of guidewire.

Caution: Use fluoroscopy to monitor guidewire advancement during tapping.



Figure 9

Operative Technique



Step 2: Screw Insertion

Screw Driver Assembly

Insert the screwdriver with the handle through the blades of The Olympus MIS Polyaxial Pedicle Screw EX with utmost precision, engaging the tip of the screwdriver with hexalobe head of the screw. Rotate the screwdriver knob clockwise to assemble the tip of the screwdriver into the head of the screw. Ensure the screw is firmly attached to the screwdriver.



Screw Implanting

Guide the screwdriver assembly over the guide wire and into the pedicle. Advance the screw to the desired depth and verify placement under fluoroscopy.

After screw placement, remove the screwdriver and the guidewire. Rotate the screwdriver knob in a counterclockwise and gently pull out the screwdriver through the blade of the screw.



Figure 11

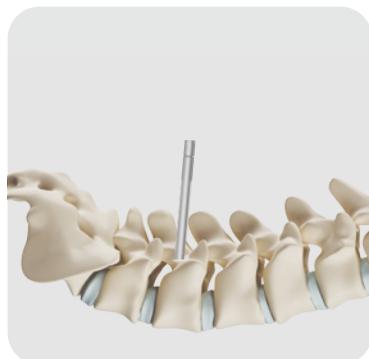


Figure 12



Figure 13

Operative Technique



Step 3: Rod Measurement

Align the screws, and the rod length gauge will allow you to measure the exact length of the rod needed. Assemble the rod length gauge to the proximal end of the screws.

Based on the screw positions, the pointer will indicate the appropriate rod length on the gauge. If the pointer falls between measurements, the measurement should be rounded up to the next rod length. After determining the rod length, remove the rod gauge.

Rod Bending and Guide
The French Rod Bender is allowed to contour the pre-determined rod if necessary.



Figure 14

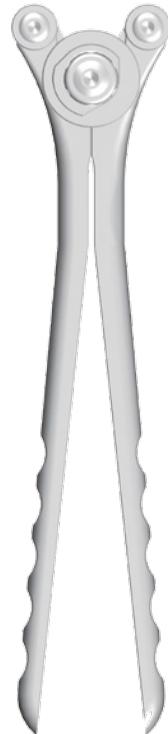


Figure 15

Operative Technique



Step 4: Rod Insertion

Place an appropriate length of the pre-bent rod at the end tip of the rod holder and rotate the handle on the top of the rod holder clockwise.

This will securely lock the rod in the insertion position.

Pass the pre-bent rod through the window of the first screw blade. When the tip of the rod reaches the top of the screw head, advance the rod through the muscle to the top of the next screw and confirm the rod position using fluoroscopy.

At the position of the rod holder for the angle of 90 degrees, pushing downward the rod through the rod holder will be achieved to seat the rod into the pedicle screw heads.

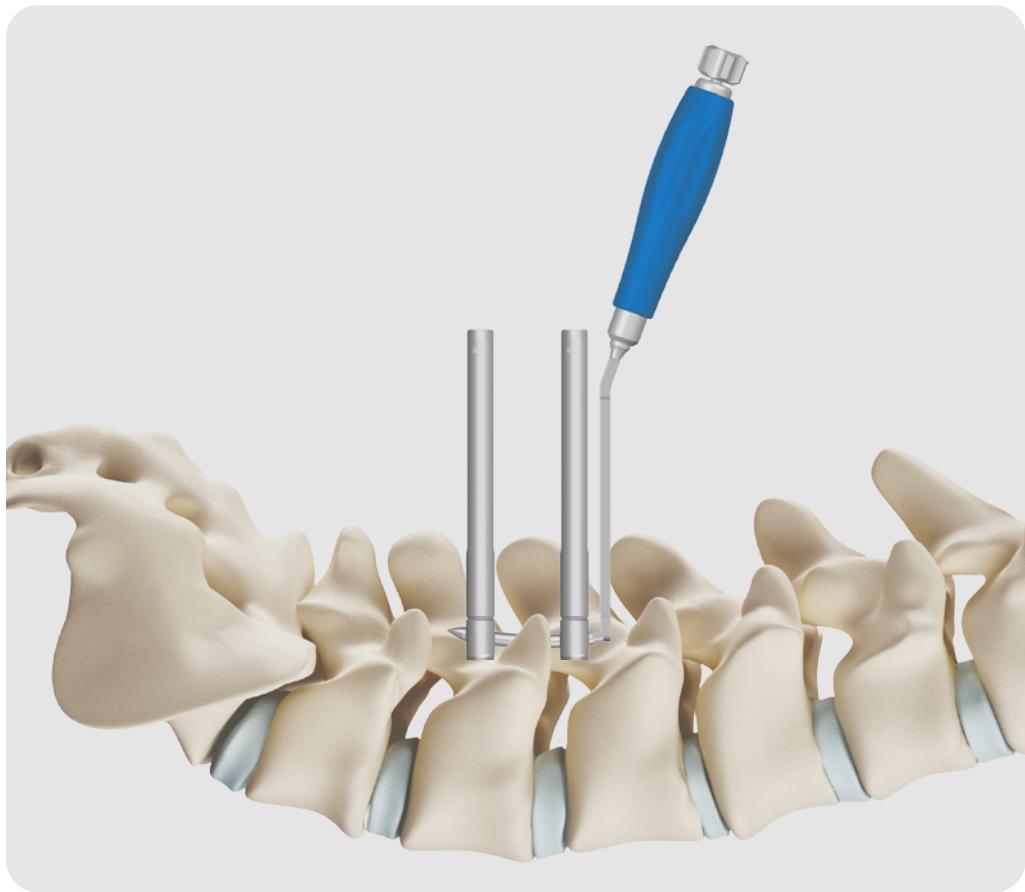


Figure 16

Operative Technique



Step 5: Initial Tightenting

Fixing Sleeve Insertion

After loading the rod into the bottom of the screw head, place a fixing sleeve over one of the blades of the Olympus MIS Polyaxial Cannulated screw. Then, apply another fixing sleeve over a blade of the adjacent Olympus MIS Polyaxial Cannulated screw.

Set Screw Insertion

Load the set screw on the set screw starter, and the set screw is inserted into the each screw head until it is fully seated.

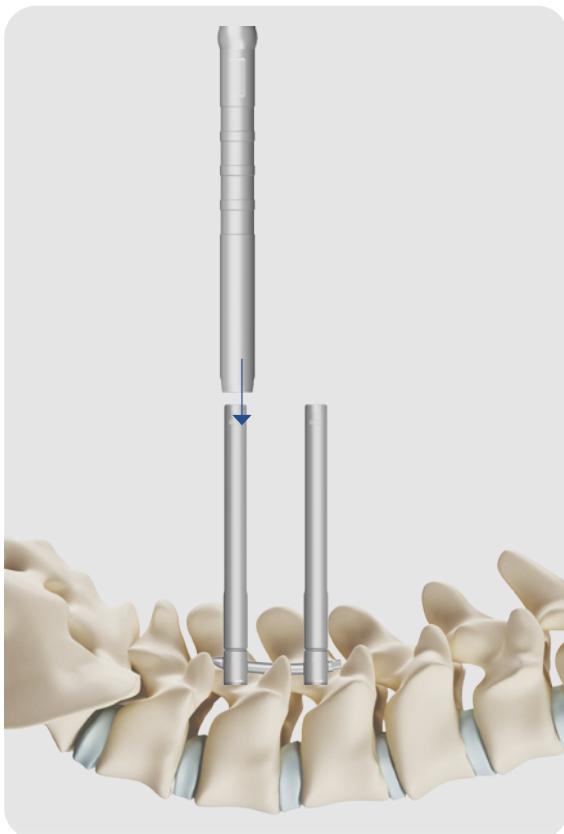


Figure 17

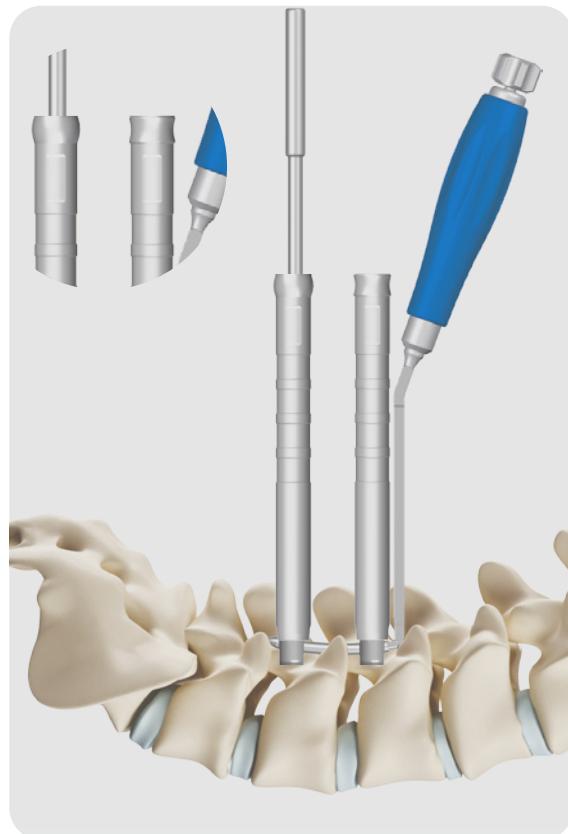


Figure 18

Operative Technique



Step 6: Final Tightening

Fixing Sleeve Insertion

- Fit the torque stabilizer over the exterior of the fixing sleeve, securing it with the screw.
- Next, attach the torque limit handle to the set screw final driver.
- Finally, use the driver to tighten the set screw that is inserted into each screw.

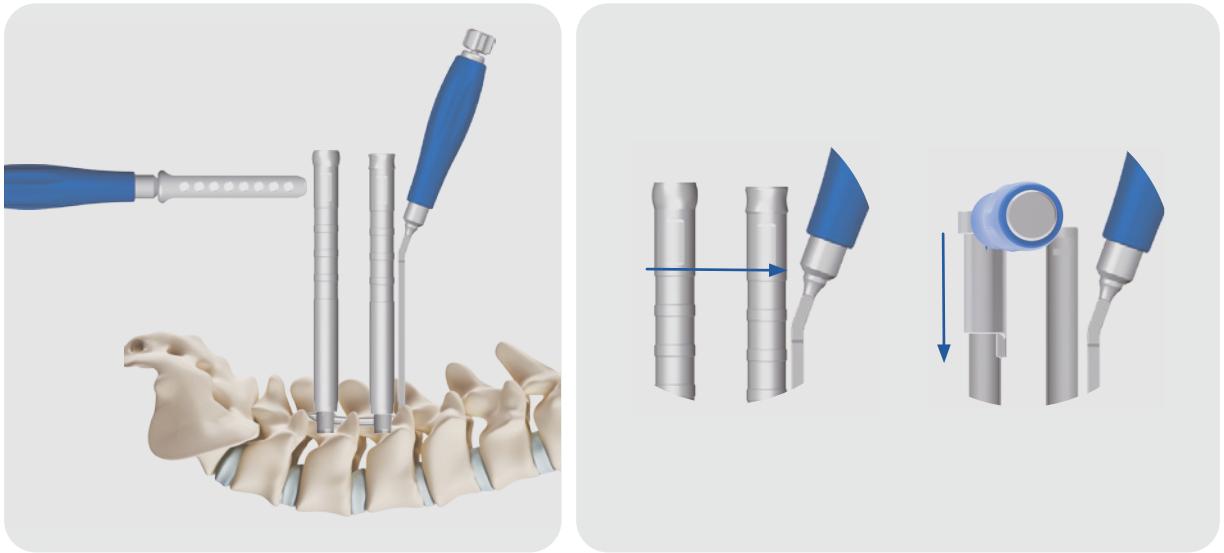


Figure 19



Figure 20

Figure 21

Figure 22

Operative Technique



Step 7: Compression and Distraction

Compression Distraction

The compression-distraction tool will allow you to compress or distract the operable level and maintaining position.

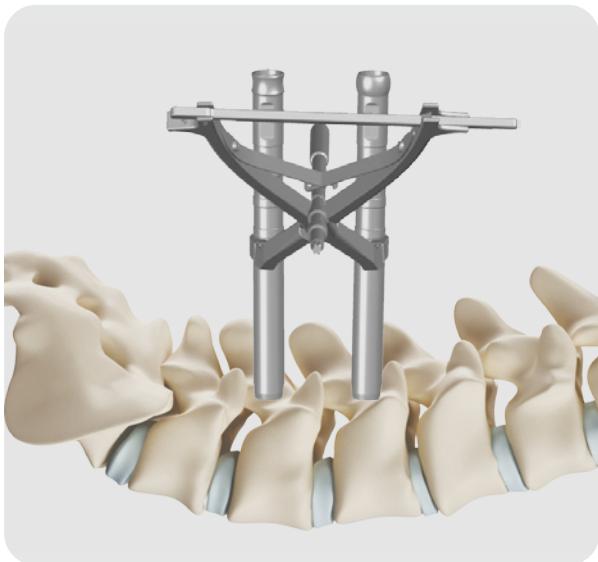


Figure 23



Figure 24

Operative Technique



Step 8: Tap Removal

Fixing Sleeve Insertion

The Olympus MIS Polyaxial Cannulated Screw is designed with break features for easy removal after locking the construct. First, remove the fixing sleeve and rod inserter.

Then, gently position the Olympus Screw Head Positioner on the tap of the Olympus MIS Polyaxial Cannulated Screw after the final tightening has taken place. Ensure the Olympus Screw Head Positioner is firmly seated in the extended tap.

Rock the breaker in a back-and-forth motion until the tabs are away from the screw, and it may be required a repeated procedure a few times to ensure the breakage.



Figure 25

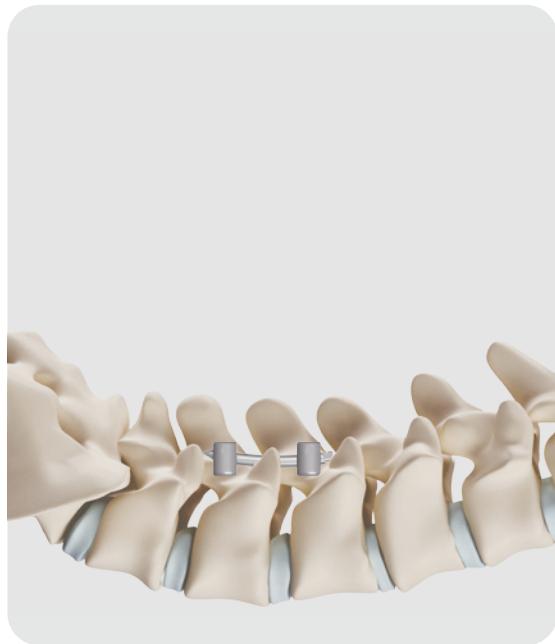
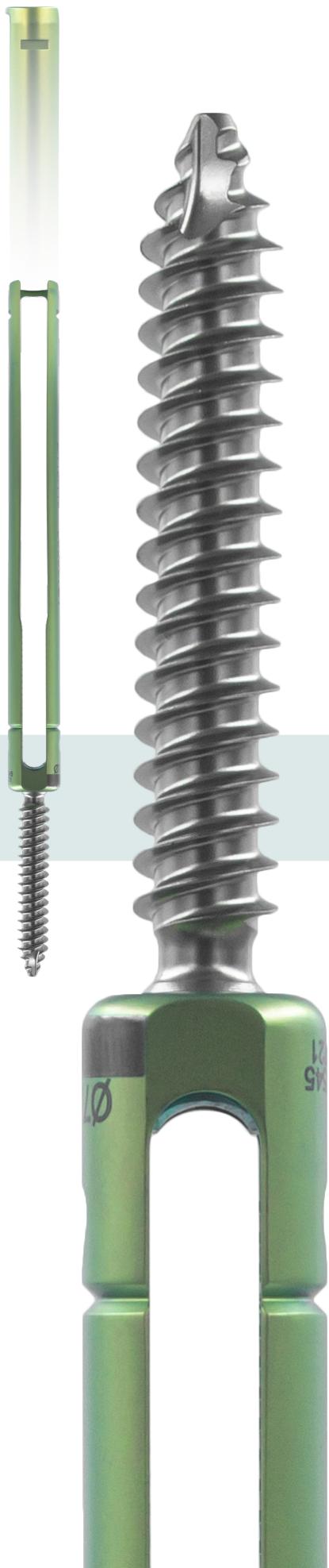


Figure 26



OLYMPUS MIS
SURGICAL TECHNIQUE



IMPLANT

POLYAXIAL PEDICLE SCREW EX

CATALOG NO.	DESCRIPTION	Ø	SIZE
4545-30420	Polyaxial pedicle screw EX		20 mm
4545-30425	Polyaxial pedicle screw EX	Ø 4.5	25 mm
4545-30430	Polyaxial pedicle screw EX		30 mm
4545-30530	Polyaxial pedicle screw EX		30 mm
4545-30535	Polyaxial pedicle screw EX		35 mm
4545-30540	Polyaxial pedicle screw EX		40 mm
4545-30545	Polyaxial pedicle screw EX	Ø 5.5	45 mm
4545-30550	Polyaxial pedicle screw EX		50 mm
4545-30555	Polyaxial pedicle screw EX		55 mm
4545-30560	Polyaxial pedicle screw EX		60 mm
4545-30630	Polyaxial pedicle screw EX		30 mm
4545-30635	Polyaxial pedicle screw EX		35 mm
4545-30640	Polyaxial pedicle screw EX		40 mm
4545-30645	Polyaxial pedicle screw EX		45 mm
4545-30650	Polyaxial pedicle screw EX		50 mm
4545-30655	Polyaxial pedicle screw EX	Ø 6.5	55 mm
4545-30660	Polyaxial pedicle screw EX		60 mm
4545-30665	Polyaxial pedicle screw EX		65 mm
4545-30670	Polyaxial pedicle screw EX		70 mm
4545-30675	Polyaxial pedicle screw EX		75 mm
4545-30680	Polyaxial pedicle screw EX		80 mm
4545-30730	Polyaxial pedicle screw EX		30 mm
4545-30735	Polyaxial pedicle screw EX		35 mm
4545-30740	Polyaxial pedicle screw EX	Ø 7.5	40 mm
4545-30745	Polyaxial pedicle screw EX		45 mm
4545-30750	Polyaxial pedicle screw EX		50 mm
4545-30755	Polyaxial pedicle screw EX		55 mm

POLYAXIAL PEDICLE SCREW EX

CATALOG NO.	DESCRIPTION	\emptyset	SIZE
4545-30760	Polyaxial pedicle screw EX		60mm
4545-30765	Polyaxial pedicle screw EX		65mm
4545-30770	Polyaxial pedicle screw EX	$\emptyset 7.5$	70mm
4545-30775	Polyaxial pedicle screw EX		75mm
4545-30780	Polyaxial pedicle screw EX		80mm
4545-30835	Polyaxial pedicle screw EX		35 mm
4545-30840	Polyaxial pedicle screw EX		40 mm
4545-30845	Polyaxial pedicle screw EX		45 mm
4545-30850	Polyaxial pedicle screw EX		50 mm
4545-30855	Polyaxial pedicle screw EX	$\emptyset 8.5$	55 mm
4545-30860	Polyaxial pedicle screw EX		60 mm
4545-30865	Polyaxial pedicle screw EX		65 mm
4545-30870	Polyaxial pedicle screw EX		70 mm
4545-30875	Polyaxial pedicle screw EX		75 mm
4545-30880	Polyaxial pedicle screw EX		80 mm



SET SCREW

CATALOG NO.	DESCRIPTION
4545-10001	Set screw



ROD CURVED



CATALOG NO.	DESCRIPTION	Ø	SIZE
4545-31040	Rod Curved		40mm
4545-31045	Rod Curved		45mm
4545-31050	Rod Curved		50mm
4545-31055	Rod Curved		55mm
4545-31060	Rod Curved		60mm
4545-31065	Rod Curved		65mm
4545-31070	Rod Curved		70mm
4545-31075	Rod Curved		75mm
4545-31080	Rod Curved		80mm
4545-31085	Rod Curved		85mm
4545-31090	Rod Curved		90mm
4545-31095	Rod Curved		95mm
4545-31100	Rod Curved		100mm
4545-31110	Rod Curved	Ø 5.5	110mm
4545-31120	Rod Curved		120mm
4545-31130	Rod Curved		130mm
4545-31140	Rod Curved		140mm
4545-31150	Rod Curved		150mm
4545-31160	Rod Curved		160mm
4545-31170	Rod Curved		170mm
4545-31180	Rod Curved		180mm
4545-31190	Rod Curved		190mm
4545-31200	Rod Curved		200mm
4545-31250	Rod Curved		250mm
4545-31300	Rod Curved		300mm
4545-31350	Rod Curved		350mm
4545-31400	Rod Curved		400mm

INSTRUMENTS



4901-3019 VP Needle (Diamond ShortTip)
9807-0053 Needle (Diamond Long Tip)



4901-8033 Olympus MIS Guide Wire Tool



4901-0074 Guide Wire 480 mm



4901-8034 Olympus MIS Dilator 1
4901-8035 Olympus MIS Dilator 2
4901-8036 Olympus MIS Dilator 3



4901-8080 Olympus MIS Fixing Sleeve 1
4901-8081 Olympus MIS Fixing Sleeve 2

INSTRUMENTS



4901-8038 Olympus MIS Tap 5.5mm (Cannulated)

4901-8039 Olympus MIS Tap 6.5mm (Cannulated)

4901-8040 Olympus MIS Tap 7.5mm (Cannulated)



4901-8095 Olympus MIS Screw Driver



4901-8024 Olympus MIS Rigid Rod Inserter



4901-8041 Olympus MIS Ring C type



4901-8042 Olympus MIS Closed Ring

INSTRUMENTS



4901-8059 4901-
8060 4901-8097 Set screw Starter
Set screw Starter T-Handle
Set screw Starter T-Handle
Long-Type



4901-8061 Set screw Screw Final Driver



4901-8079
4901-8092 Olympus MIS Compressor &
Distractor
Olympus MIS Compressor & Dis-
tractor Bar



4901-8044 Olympus MIS Torque Stabilizer



4901-8031 Olympus MIS Screw Head Positio-
ner

INSTRUMENTS



4901-8058

Poly Axial Bone Screw Driver
I-handle



4901-8103
4901-8104

Olympus MIS Ratcheting I-Handle
Olympus MIS Ratcheting T-Handle



9807-0052

Torque Limit Handle



4901-8051

Olympus MIS French Rod Bender



9807-0038

Cannulated Awl

INSTRUMENTS



4901-8108 Counter Torque
4901-8082 Counter Torque (Half Closed)



4901-8046 Rod Holder Forceps type



4901-8025 Olympus MIS Persuader
4901-8065 Olympus MIS Persuader
(Half Closed)



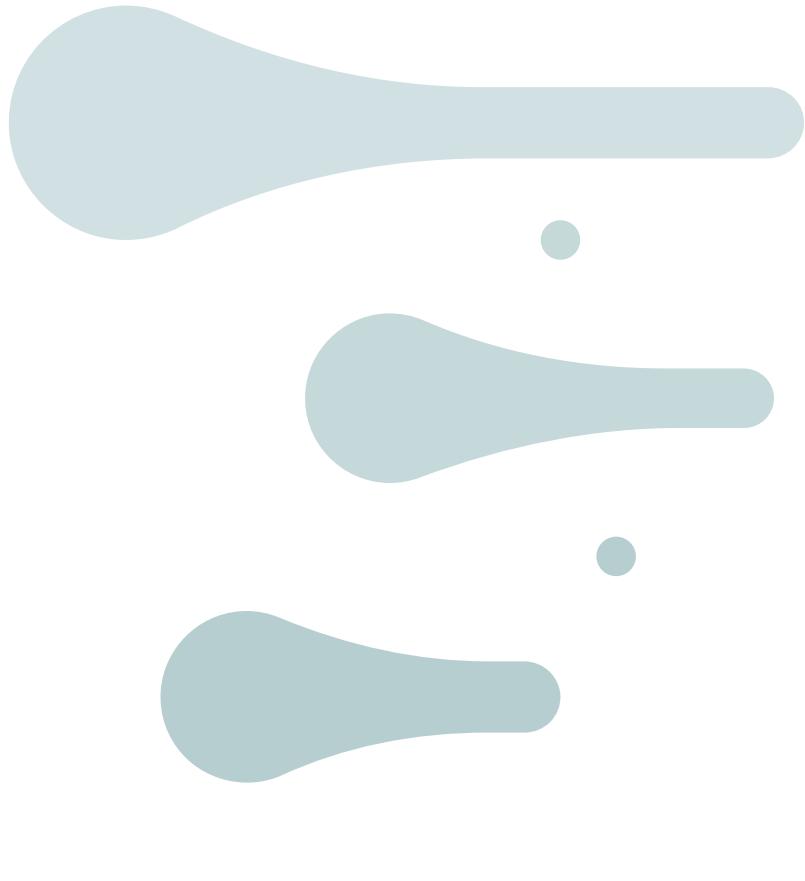
4901-8107 Olympus MIS Rod Length Gauge



4901-8101 Olympus MIS Tab Breaker
4901-8111 Olympus MIS Ring Cutter

Warning and Cautions

1. The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.
2. Thorough knowledge of spinal anatomy, biomechanics, surgical techniques, proper reduction, selection, and placement of implants, and pre- and post-operative patient management is essential to a successful surgical outcome.
3. Appropriate selection, placement, and fixation of the spinal system components are critical factors that affect the spine fixation system's safety, effectiveness, and service life. As in the case of all prosthetic implants, the durability of these components is affected by numerous biological, biomechanics and other extrinsic factors, which limit their safety, effectiveness and service life. Accordingly, strict adherence to the indications, contraindications, cautions, and warnings for this product is essential to maximize the performance potentially (Note: While proper implant selection can minimize risks, the size and shape of human bones present limitations on the size, shape, and strength of the implants).
4. Experience with spinal fusion procedures and spinal fixation is required, and hands-on training in the use of this device with a proper surgical technique manual or operational literature is necessary.
5. The product must be used only for patients who meet the criteria described in the above indications.
6. The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.
7. Olympus MIS Spinal Fixation Systems have not been evaluated for safety and compatibility in the MR environment, and they have not been tested for heating, migration, or image artifacts in the MR environment. The safety of Olympus MIS Spinal Fixation Systems in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.
8. The Spine Fixation System is not for sale to a physician but to a surgeon.



OLYMPUS MIS

S U R G I C A L T E C H N I Q U E



SPINE®

C O N C E P T S



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