



Percutan[®]

MIS Pedicle Screw System



Advanced Principal Implant System

Contents

Introduction

Key Feature	1-2
Intended Use	3

Surgical Technique

Targeting Needle Insertion	4
Guide Wire Insertion	5
Dilator Insertion	5
Awl Tapping	5
Screw Insertion	6
Rod Length Measurement	7
Rod Insertion (Option I)	7
Rod Insertion (Option II)	8
Rod Insertion (Option III)	9
Set Screw Insertion & Initial Tightening	9
Compression or Distraction	10
Final Tightening	10
Removal	10
Reduction for Spondylolisthesis	10

Implant Ordering Information

Implant	11-12
Instrument	13-14

Percutan[®] MIS Pedicle Screw system

Introduction

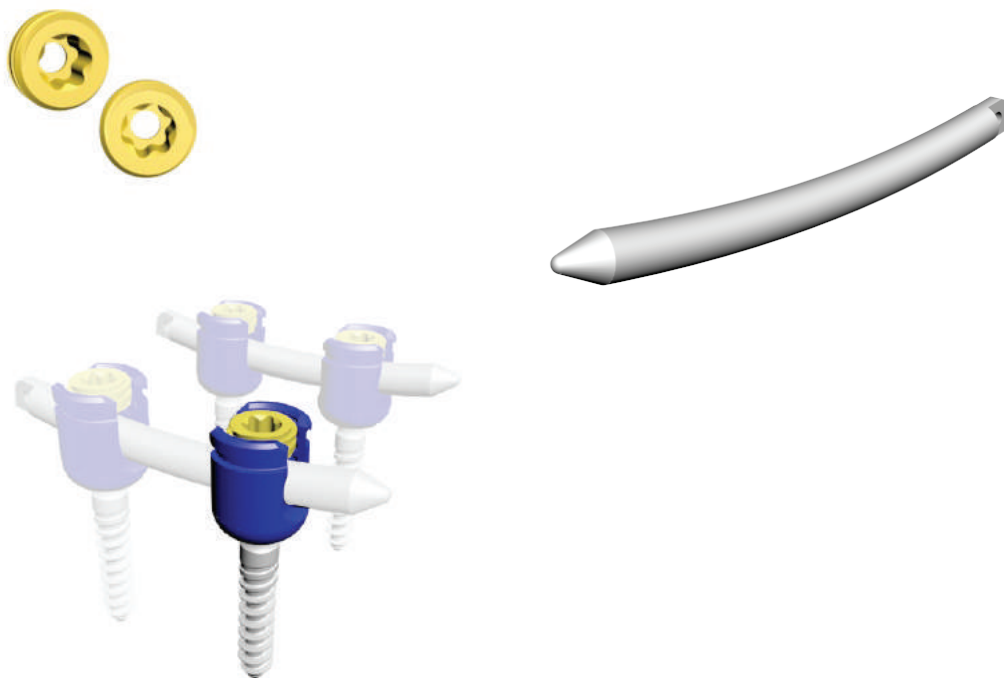
TDM is pleased to introduce the Percutan[®] MIS Pedicle Screw System. This system has designed to offer a new approach to spine fusion for growing minimally invasive fusion market.

The system utilizes a series of cannulated screws, uniquely designed rods and instrumentation intended specifically reduce and complete a stabilization construct through a true soft tissue fascial sparing percutaneous approach.

Key Feature

Implant

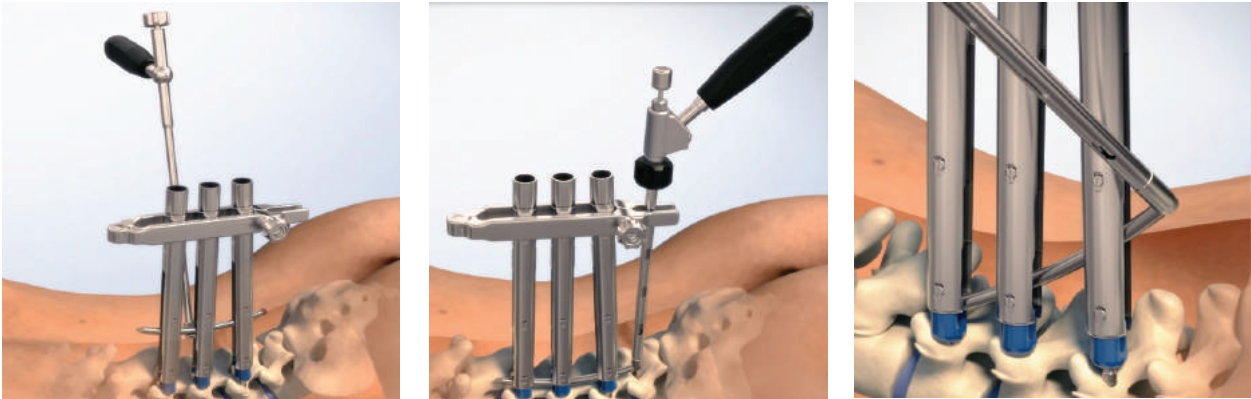
Screw size : 4.5mm to 7.5mm diameters in 25mm -60mm lengths
Low profile , Low volume, and cannulated multi-angle screw
Color-coded
Self tapping
5.5mm Pre-bent Rod (40mm- 90mm)/ Straight rod (from 100mm length)



Instrument

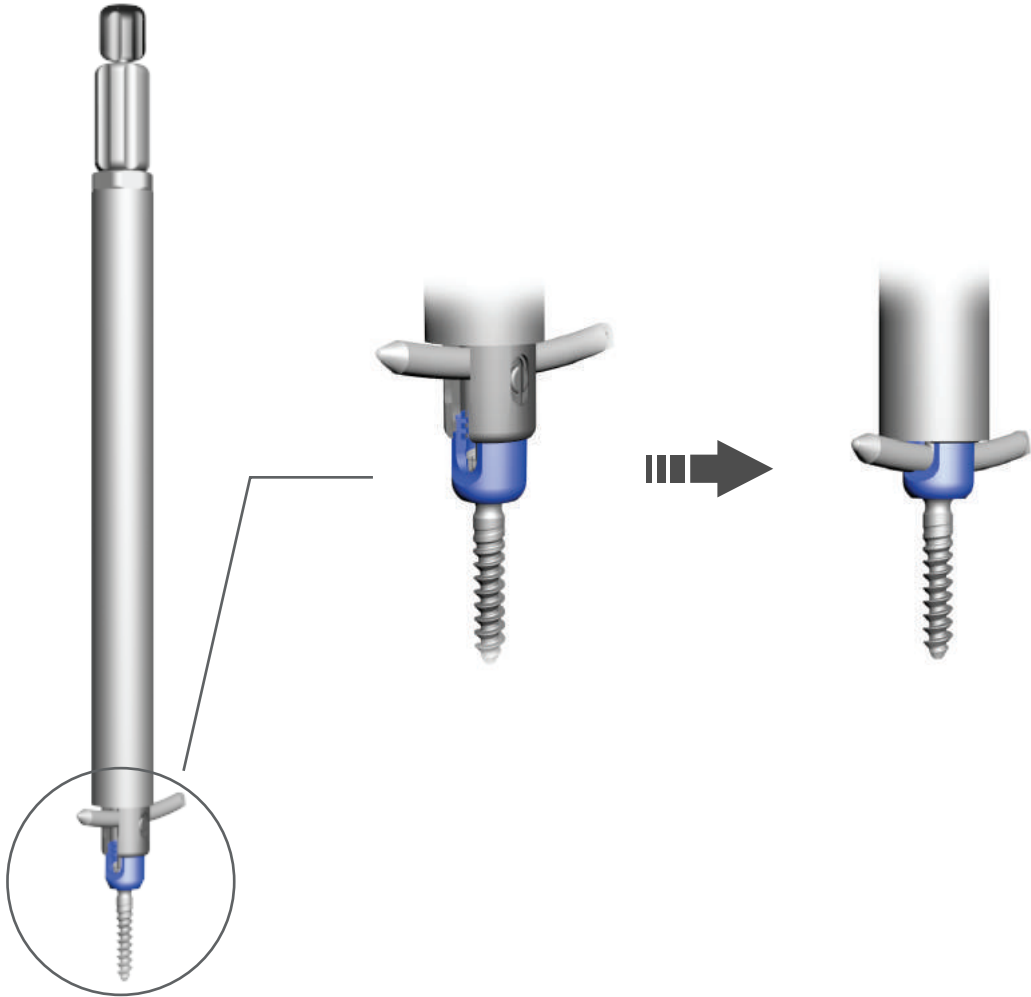
Multiple Rod Inserter Options

Allows percutaneous or mini-open options.



Threaded Rod Reduction

Rod reduction is simple and guided by attaching reduction set screw driver to screw extension.



Intended Use

- Degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies
- Degenerative spondylolisthesis
- Trauma (i.e., fracture or dislocation)
- Spinal stenosis
- Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
- Tumor
- Pseudoarthrosis
- Failed previous fusion

Targeting Needle Insertion

Fluoroscopy in the lateral view is used to confirm the level of surgery, and the cephalad-caudal levels of the respective pedicles are marked on the patient's back with marking pen.

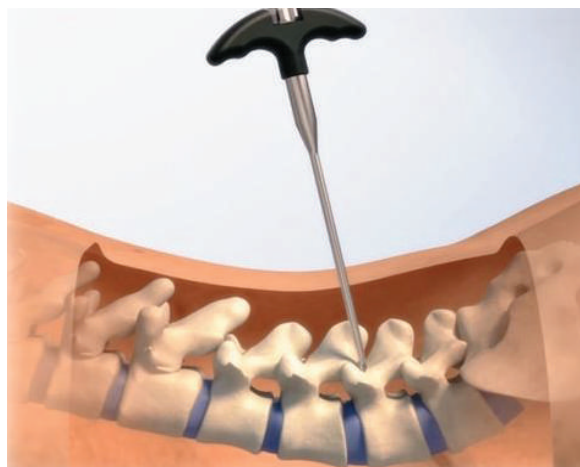
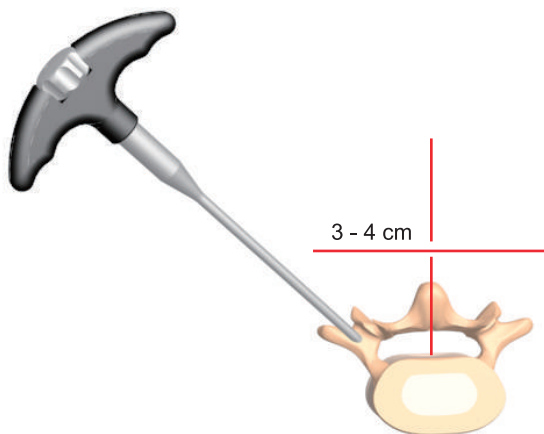
AP fluoroscopic image is used next to confirm both the superior and lateral margins of the pedicle.

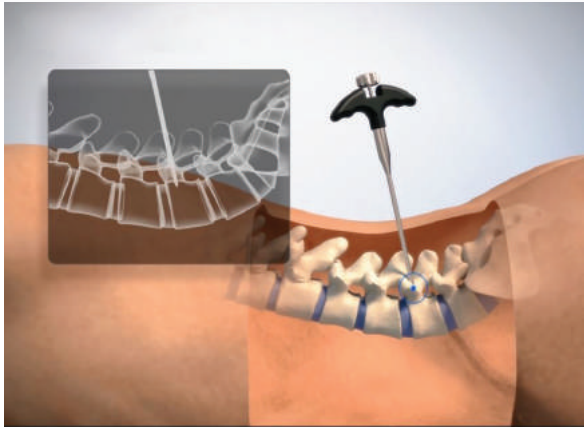
With the minimal angulation of the pedicles in the upper lumbar spine, the intersection of these two lines is the entry point at the skin (usually 3-4cm off midline) to access the pedicle.

A 1cm or 2cm vertical incision is made through the skin and dorsal fascia centered on the location of the pedicle based on fluoroscopy.

A Targeting Needle, a cannulated needle is placed through this stab incision and slowly directed toward the entry point for pedicle.

Using a gentle twisting motion, the targeting needle is slowly advanced through the pedicle and to an appropriate depth in the vertebral body.





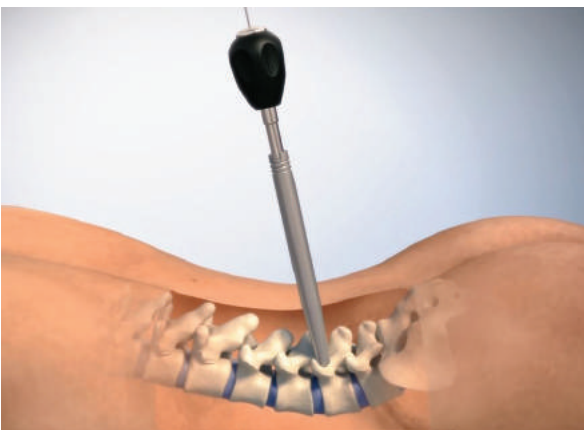
Guide Wire Insertion

A Guide Wire is placed through Targeting Needle into the vertebral body. A lateral fluoroscopic image obtained to confirm that the Guide Wire exists the tip of the Targeting Needle. The K-wire should be placed with care not to penetrate too deeply as the anterior cortex could be perforated and great vessel injury can occur. After the Guide-Wire is placed, the Targeting Needle is removed, without moving the Guide Wire.



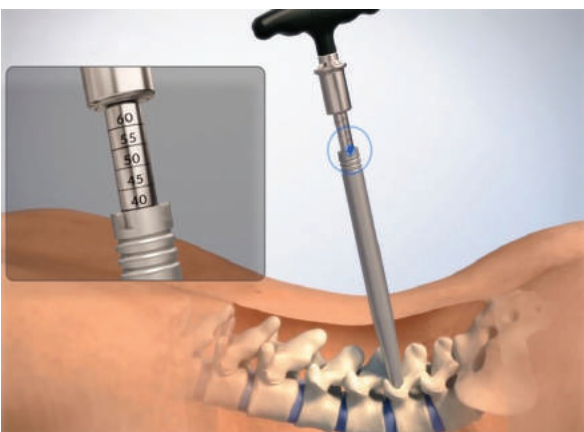
Dilator Insertion

The Dilators are placed over the guide wire to dilate the posterior musculature and soft tissues to provide a space for the insertion of Tap and screw over the K-wire.



Awl Tapping

The Awl is placed over the out Dilator and pilot hole of pedicle is made by Awl and then a Tap of proper size is going through out Dilator and it is tapping to the appropriate depth into vertebral body.



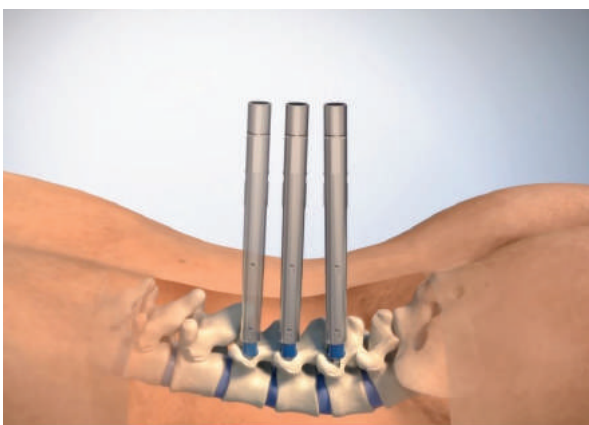


Screw Insertion

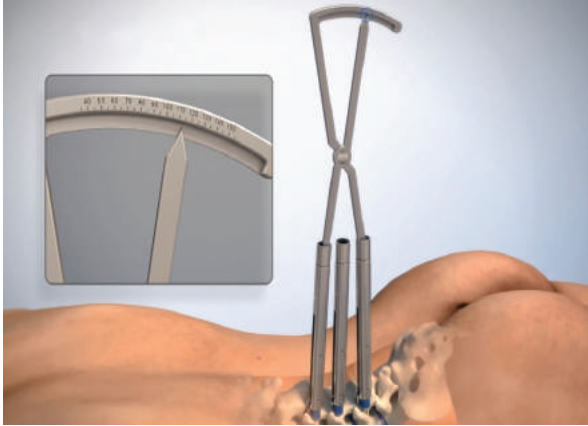
As the following figure, T-handle, Pedicle Screw Driver, Screw Extender and Pedicle Screw are connected and assembled all together.



Assembled Screw Extender with Screw Driver and Pedicle Screw is placed over the Guide Wire and going through the pedicle and to appropriate depth to vertebral body.



The repeatable procedure that pedicle screw is inserted into the vertebral body are applied to the pedicle of other side and upper or lower vertebral body as the following figure.

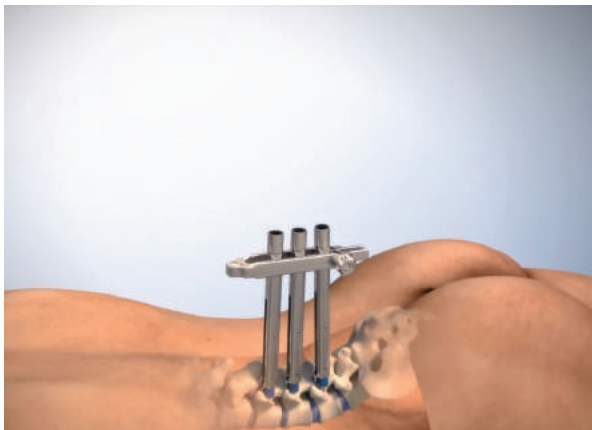


Rod Length Measurement

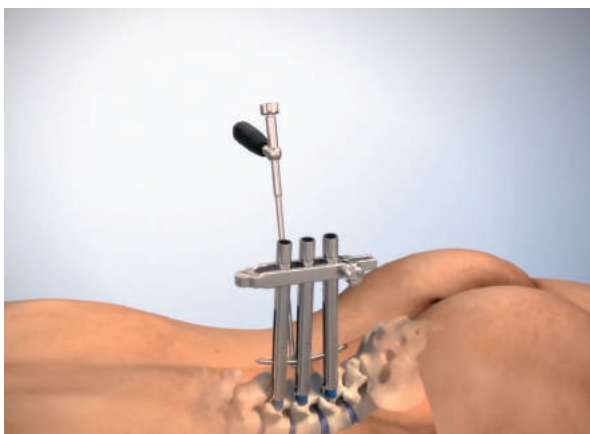
Rod length is measured with Rod Gauge as the following figure.

Rod Gauge is inserted into both proximal end of Screw Extender and distal end of Screw Extender.

The pointer will indicate the appropriate rod length on the Rod Gauge.



Once all the screws are placed, depending on surgeon's preference, the Alignment Tool is assemble on the upper part of Screw Extender, or without attachment of Alignment Tool, it can be inserted rod using Rod Inserter.



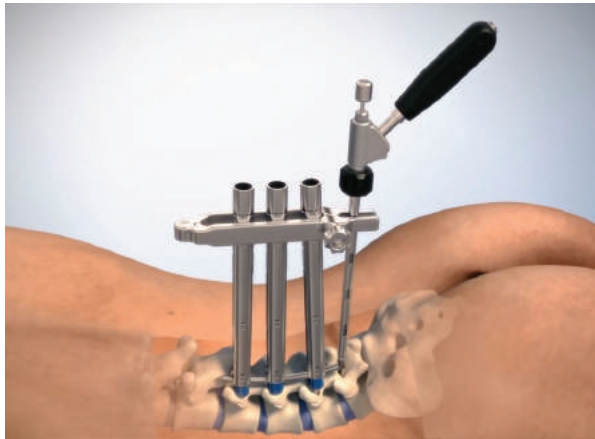
Rod Insertion (Option I) Mini Open Technique

Using the Mini Open Rod Inserter, grasp rod approximately 2 cm from its end.

Push down the rod, guiding it through the Screw Extender and seats firmly into screw heads.

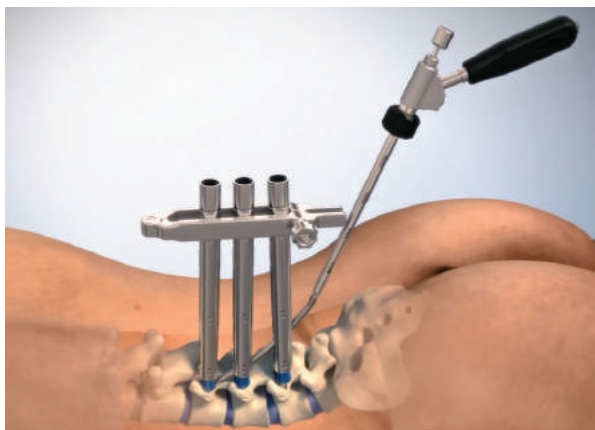
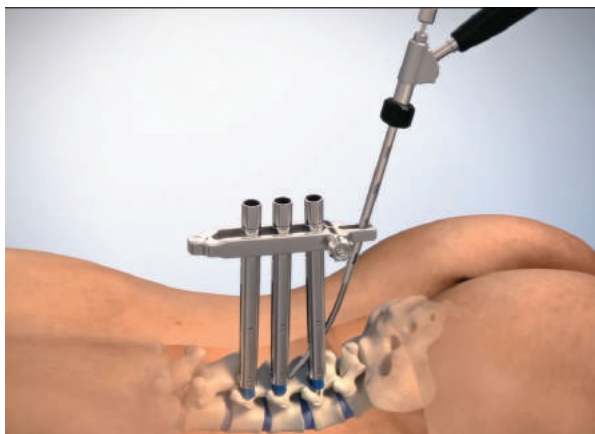
Fluoroscopically confirm rod position.

Manipulate the rod to ensure correct lordotic.

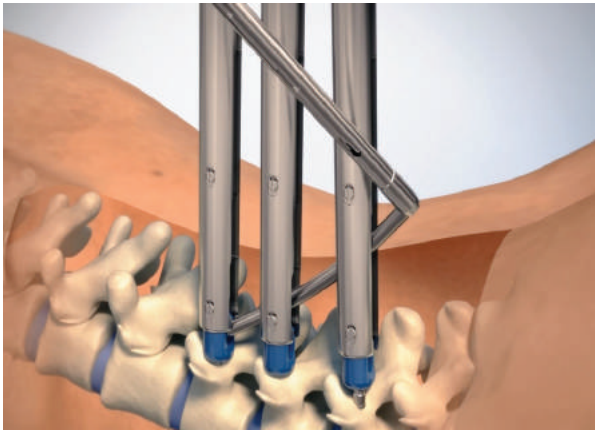


Rod Insertion (Option II) Mini Open Technique

Insert rod into Rod Holder and guiding it Screw Extender and pushing down it to screw head.
And then push it to the proximal Screw Extender.

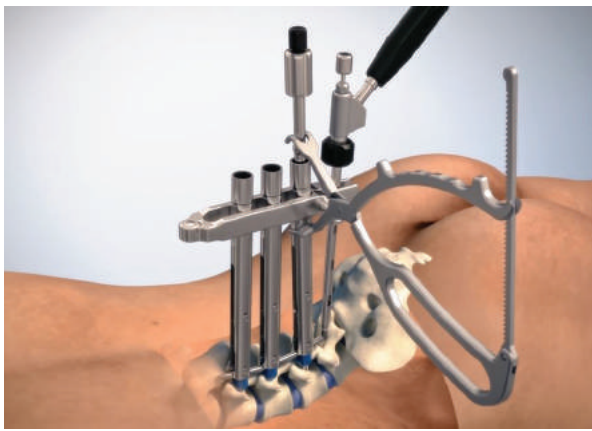


After confirm the rod is in the Screw Extender correctly with Set Screw Starter, turn right the black knob on the Rod Inserter (Percutaneous type).
Push the Rod Inserter slightly and then rod is bent to 90 degree but rod is not released into Rod Inserterh.

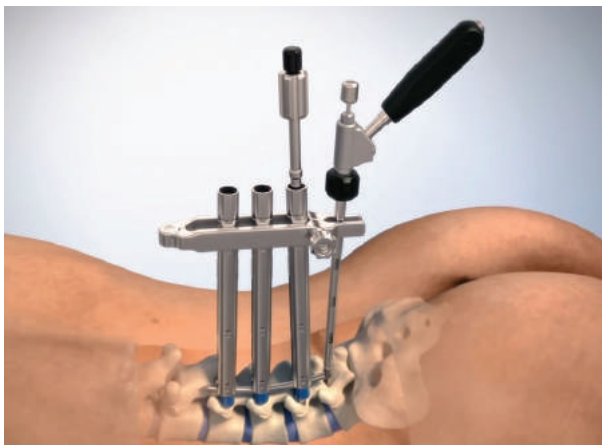


Rod Insertion (Option III) Mini Open Technique

Place the rod into Fixed Angle Rod Inserter and adjust the Screw Extenders in order to slot of Screw Extender are aligned. Insert the rod into the out turned extender sleeve and incision, keeping the shaft of the fixed angle rod inserter lateral to the extender. Guide rod through screw extender while slowly bringing the shaft of the Fixed Angle Rod Inserter parallel to the screw extender fully seated the rod.

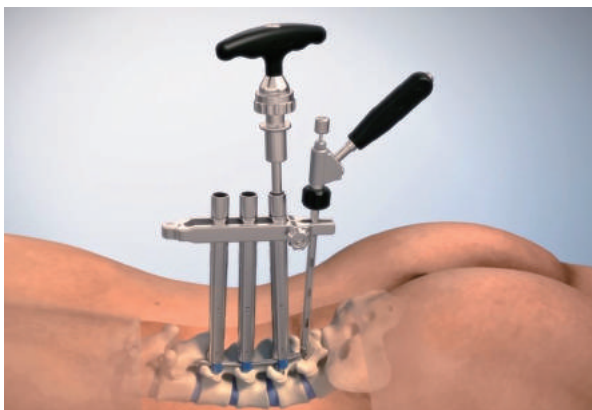


Load the set screw on the Set Screw Driver and lock set screw on the Set Screw Driver with turning right Small Handle on top of Screw Driver. Attach lower part of rod reduction tool to Screw Extender and again attach upper part of rod reduction tool to Set Screw Driver.

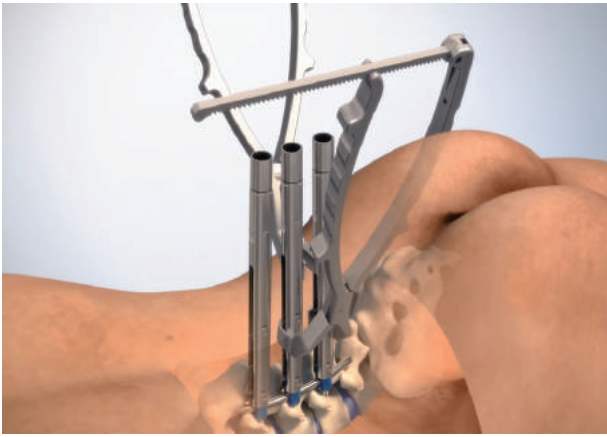


Set Screw Insertion & Initial Tightening

And squeeze rod reduction tool handle until rod is driven into screw head and the instrument final locked position. Turn larger handle to seat set screw into screw head.

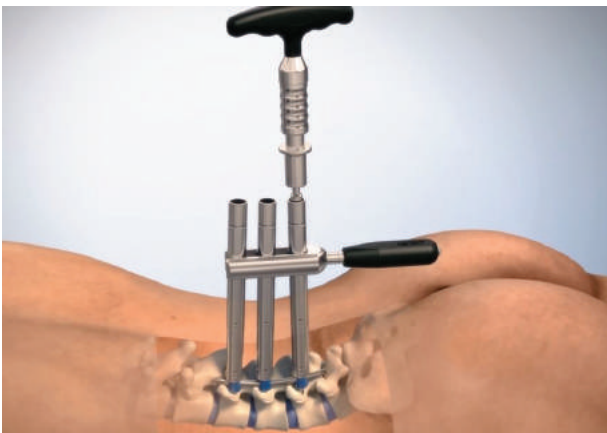


In order to do compression or distraction, set screw is tightened initially. The small handle of Rod Inserter is released and remove Rod Inserter.



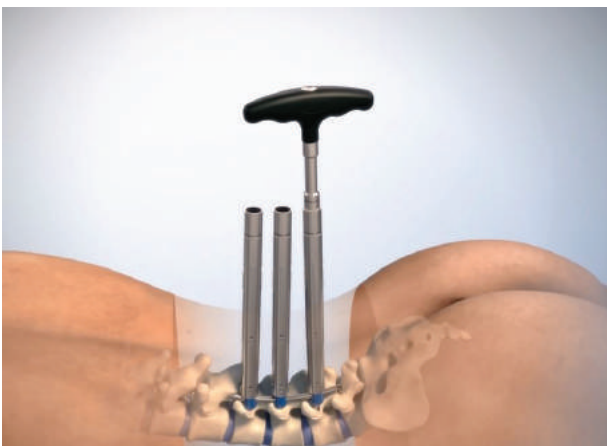
Compression or Distraction

The compression is achieved that compressor is attached to screw extender near the skin.
And attach distractor to upper part of Screw Extender to get leverage function.
Squeeze the handle of compressor for compression.



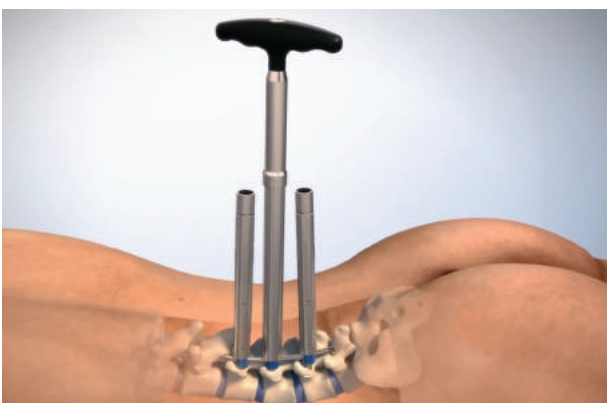
Final Tightening

Using the Torque Handle, tighten set screw firmly.



Removal

Remove Screw Extender using Screw Holding Extender.



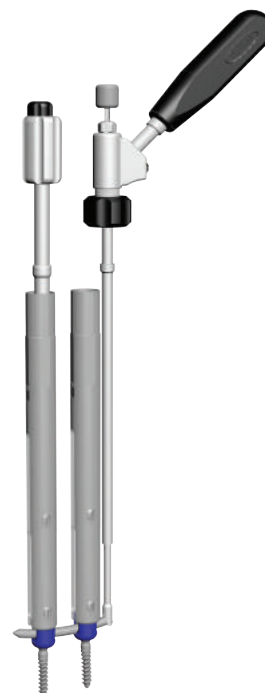
Reduction for Spondylolisthesis

For the reduction, the MIS Reduction Set Screw Driver may be used.
Hold set screw with MIS Reduction Set Screw Driver.
And connect Reduction Wrench on MIS Reduction Set Screw Driver.
Rotate the Reduction Wrench clockwise to achieve the desired reduction.

Implant Ordering Information

MIS Cannulated Polyaxial Screw

Cat No.	Size	Remark
821-34525	4.5mm * 25mm	
821-34530	4.5mm * 30mm	
821-34535	4.5mm * 35mm	
821-34540	4.5mm * 40mm	Option
821-34545	4.5mm * 45mm	Option
821-34550	4.5mm * 50mm	Option
821-34555	4.5mm * 55mm	Option
821-34560	4.5mm * 60mm	Option
821-34565	4.5mm * 65mm	Option
821-34570	4.5mm * 70mm	Option



Cat No.	Size	Remark
821-35025	5.0mm * 25mm	Option
821-35030	5.0mm * 30mm	Option
821-35035	5.0mm * 35mm	Option
821-35040	5.0mm * 40mm	Option
821-35045	5.0mm * 45mm	Option
821-35050	5.0mm * 50mm	Option
821-35055	5.0mm * 55mm	Option
821-35060	5.0mm * 60mm	Option
821-35065	5.0mm * 65mm	Option
821-35070	5.0mm * 70mm	Option

Cat No.	Size	Remark
821-35525	5.5mm * 25mm	Option
821-35530	5.5mm * 30mm	
821-35535	5.5mm * 35mm	
821-35540	5.5mm * 40mm	
821-35545	5.5mm * 45mm	
821-35550	5.5mm * 50mm	
821-35555	5.5mm * 55mm	
821-35560	5.5mm * 60mm	Option
821-35565	5.5mm * 65mm	Option
821-35570	5.5mm * 70mm	Option

Cat No.	Size	Remark
821-36525	6.5mm * 25mm	Option
821-36530	6.5mm * 30mm	
821-36535	6.5mm * 35mm	
821-36540	6.5mm * 40mm	
821-36545	6.5mm * 45mm	
821-36550	6.5mm * 50mm	
821-36555	6.5mm * 55mm	
821-36560	6.5mm * 60mm	Option
821-36565	6.5mm * 65mm	Option
821-36570	6.5mm * 70mm	Option

Cat No.	Size	Remark
821-37525	7.5mm * 25mm	Option
821-37530	7.5mm * 30mm	Option
821-37535	7.5mm * 35mm	
821-37540	7.5mm * 40mm	
821-37545	7.5mm * 45mm	
821-37550	7.5mm * 50mm	
821-37555	7.5mm * 55mm	
821-37560	7.5mm * 60mm	Option
821-37565	7.5mm * 65mm	Option
821-37570	7.5mm * 70mm	Option

Implant Ordering Information

MIS Cannulated Polyaxial Screw

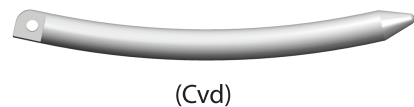
Cat No.	Size	Remark
821-38025	8.0mm * 25mm	Option
821-38030	8.0mm * 30mm	Option
821-38035	8.0mm * 35mm	Option
821-38040	8.0mm * 40mm	Option
821-38045	8.0mm * 45mm	Option
821-38050	8.0mm * 50mm	Option
821-38055	8.0mm * 55mm	Option
821-38060	8.0mm * 60mm	Option
821-38065	8.0mm * 65mm	Option
821-38070	8.0mm * 70mm	Option

Cat No.	Size	Remark
821-38525	8.5mm * 25mm	Option
821-38530	8.5mm * 30mm	Option
821-38535	8.5mm * 35mm	Option
821-38540	8.5mm * 40mm	Option
821-38545	8.5mm * 45mm	Option
821-38550	8.5mm * 50mm	Option
821-38555	8.5mm * 55mm	Option
821-38560	8.5mm * 60mm	Option
821-38565	8.5mm * 65mm	Option
821-38570	8.5mm * 70mm	Option

MIS Rod

Cat No.	Size
821-21040	5.5mm * 40mm (Cvd)
821-21045	5.5mm * 45mm (Cvd)
821-21050	5.5mm * 50mm (Cvd)
821-21055	5.5mm * 55mm (Cvd)
821-21060	5.5mm * 60mm (Cvd)
821-21065	5.5mm * 65mm (Cvd)
821-21070	5.5mm * 70mm (Cvd)
821-21075	5.5mm * 75mm (Cvd)
821-21080	5.5mm * 80mm (Cvd)
821-21090	5.5mm * 90mm (Cvd)

Cat No.	Size
821-21100	5.5mm * 100mm (Str)
821-21110	5.5mm * 110mm (Str)
821-21120	5.5mm * 120mm (Str)
821-21130	5.5mm * 130mm (Str)
821-21140	5.5mm * 140mm (Str)

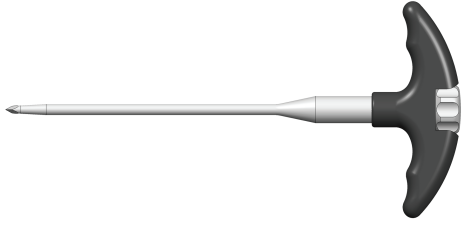








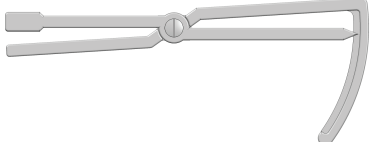









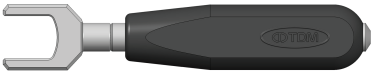
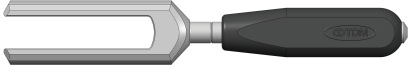
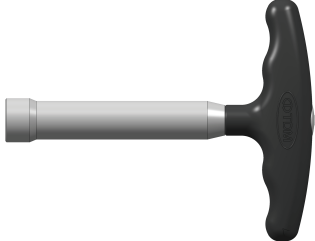



Set Screw

Cat No.	Description
811-00002	Star, Shaped

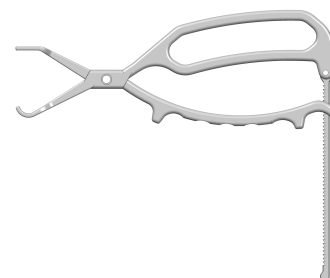
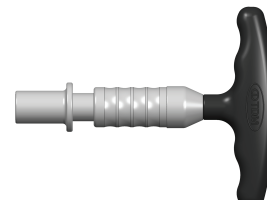
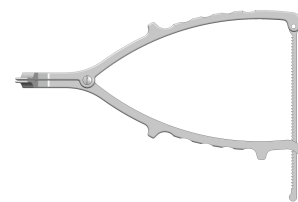


Instrument

Cat No.	Description	
907-20001	MIS Targeting Needle	
907-20002	MIS Guidewire	
907-20003	MIS Guidewire Driver	
907-20004A	MIS Screw Extender Starter	
907-20004B	MIS Screw Extender	
907-20005	MIS Screw Extender Holding Driver	
907-20006	MIS Screw Extender Assemble Handle	
907-20007	MIS Screw Extender Alignment Tool	
907-20008	MIS Cannulated Awl	
907-20009	MIS Rod Gauge	
907-20010	MIS Rod Inserter, Mini Open	
907-20031	MIS Rod Inserter, Fixed Angle	

Cat No.	Description	
907-20011	MIS Rod Inserter	
907-20012	MIS Pedicle Screw Driver	
907-20013	MIS Set Screw Driver Starter	
907-20014	MIS Final Set Screw Driver	
907-20015	MIS Set Screw Driver with Reduction	
907-20016	MIS Torque Wrench (Short)	
907-20017	MIS Torque Wrench (Long)	
907-20018	MIS Reduction Wrench	
907-20019	MIS Dilator (Small)	
907-20020	MIS Dilator (Large)	
901-08001	Holding Forcep	

Cat No.	Description
907-20021	MIS Cannulated Tap (4.5mm)
907-20022	MIS Cannulated Tap (5.5mm)
907-20023	MIS Cannulated Tap (6.5mm)
907-20024	MIS Cannulated Tap (7.5mm)
907-20025	MIS Compressor
907-20026	MIS Distractor
907-10701	French Rod Bender
905-00007	T-Handle, 1/4 Chuck
907-20028	Torque Limit Handle, 1/4 Chuck (12Nm)
907-20029	T-Ratchet handle, 1/4 Chuck
907-20030	MIS Rod Reduction Tool
907-90003	Container for MIS Implants
907-90004	Container for MIS Instruments



No Image



11/2015 150018 REV.0

Sales Office :
104, # 204, Jungang innotceh B/D , 148, Sagimakgo-ro,
Joongwon-gu, Seongnam-si, Kyunggi-do, Korea
Tel. 82-31-732-0631 Fax. 82-31-732-0632

Manufacturer :
#F105-1, #101~104, Sangsan-dong,
333, Cheomdangwagi-ro, Buk-gu, Gwangju-si, Korea
Tel. 82-62-602-7460 Fax. 82-62-602-7461

www.tradimedics.com