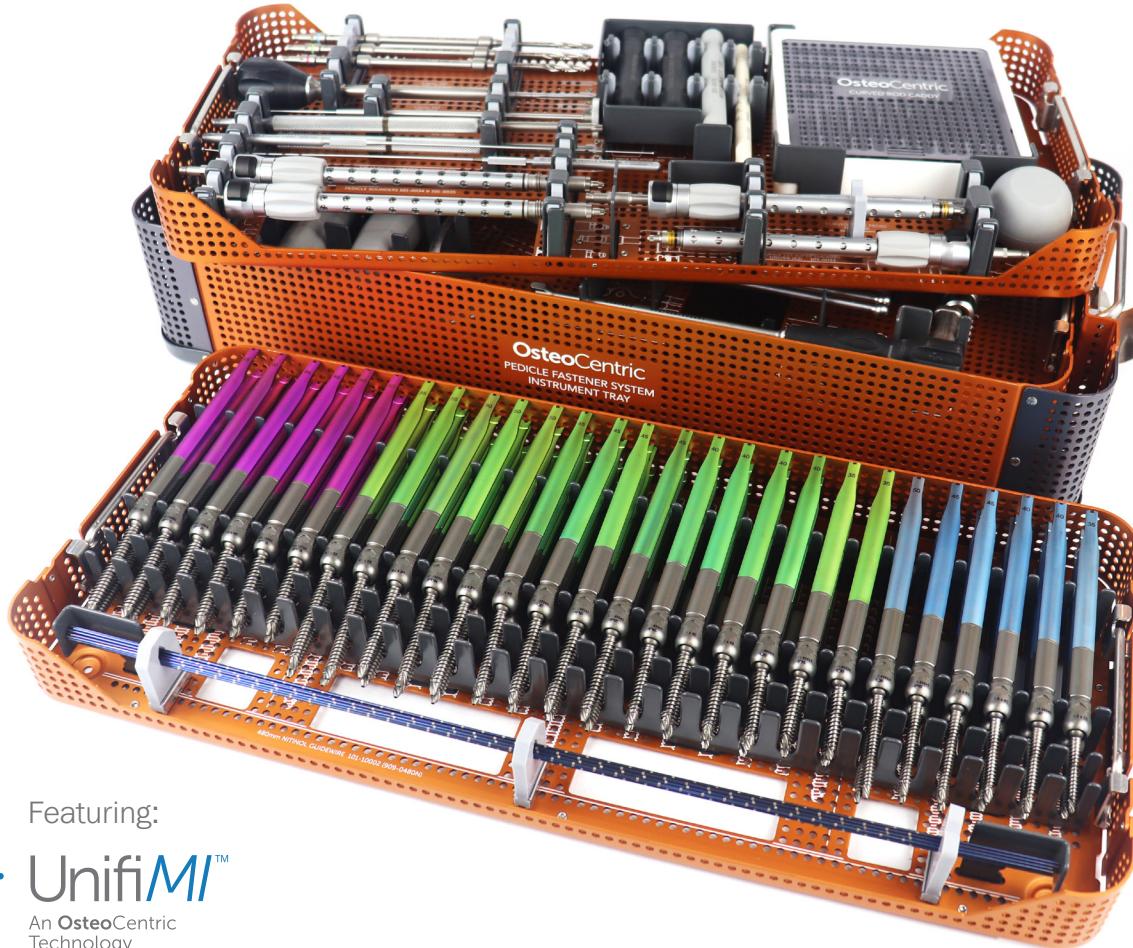


OsteoCentric®

Pedicle Fastener System

Surgical Technique



Featuring:



Mechanical Advantages of UnifiMI® Technology

UnifiMI Technology in a pedicle fastener application allows for an increase in stiffness in all planes including axial, lateral, medial bending, flexion, and extension compared to the standard legacy thread option.¹



OsteoCentric® Pedicle Fastener System

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Mechanical Integration (MI) is a minimally invasive method to instantly secure and stabilize implants to the patient's bone utilizing a proprietary bone preservation technology and unique interlocking thread geometry.

OsteoCentric Fasteners are designed to create a new standard for primary implant stability and expedite robust long-term stability for implants utilizing Osseointegration (OI). UnifiMI, the first Mechanical Integration technology, addresses the problems caused by implant instability across Spine, Sports, Total Joint Reconstruction, Veterinary, Oncology, Extremities, Trauma, SI Fusion, Maxillofacial, Orthodontia, and Dental Implants.



UnifiMI® creates a 58% increase in implant off-axis stability².

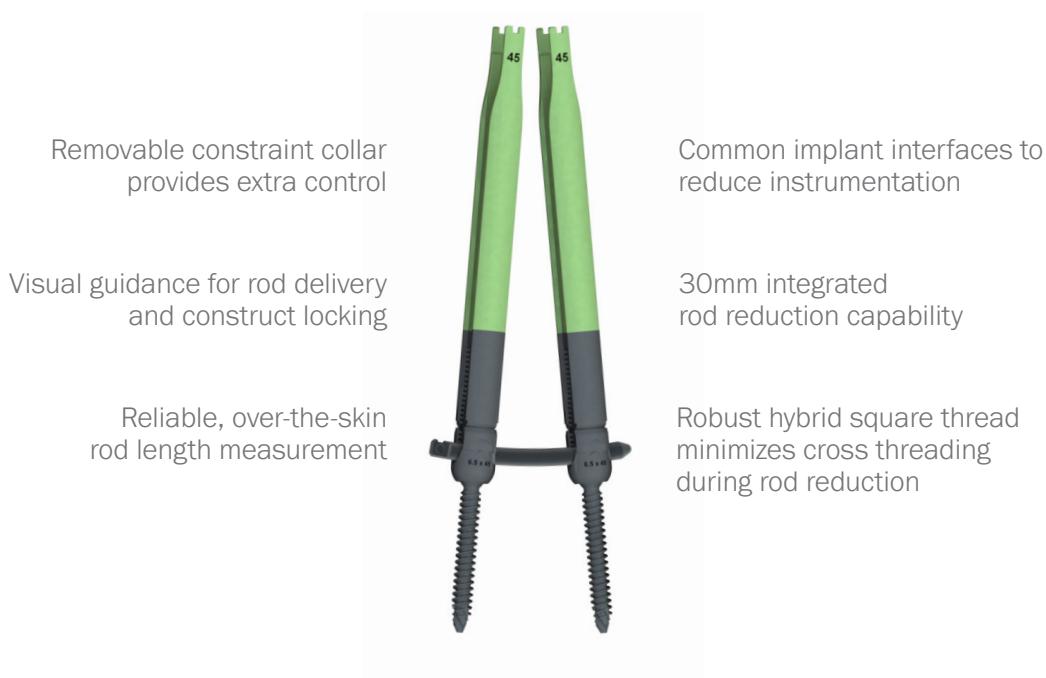


Unique thread geometry instantly and circumferentially interlocks with bone by entrapping and containing bone between the thread form.

This mechanical interlocking creates a structural and functional connection between an implant and bone which performs similar to Biological Integration (Osseointegration).

OsteoCentric Fasteners are designed to create a new standard for primary implant stability and expedite robust long-term stability for implants utilizing Osseointegration (OI).

Design Rationale & System Description



Indications For Use & Materials

The OsteoCentric Pedicle Fastener System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine.

Please see instructions for use for complete system indications for use, description, warnings, and precautions.

Surgical Technique

Pedicle Preparation for MIS Procedures

Targeting Pedicle

Locate pedicle using standard intraoperative techniques under fluoroscopy and create an incision.

Insert the Cannulated Probe assembly through incision and dock the tip on the bony anatomy of the desired level.

Advance the Cannulated Probe to desired depth while ensuring the probe does not breach the pedicle during placement.

Note: Based on surgeon preference, a Jamshidi needle can also be used for targeting.

Guidewire Placement

Remove the inner trocar of the Cannulated Probe by rotating the probe shaft counterclockwise.

Insert the guide wire through the Cannulated Probe and advance to desired depth. Remove the Cannulated probe sleeve from the pedicle.

Note: For multi-level constructs it is recommended to place all guide wires prior to inserting pedicle fasteners.



Tissue Dilation

Place the Dilators over the guide wire from small to large to ensure each Dilator is flush with bone prior to placing the next dilator.

Remove small and large dilators leaving the medium dilator and guide wire; maintain control of the guide wire to prevent it from backing out.



Pedicle Preparation for Open Procedures

Targeting Pedicle

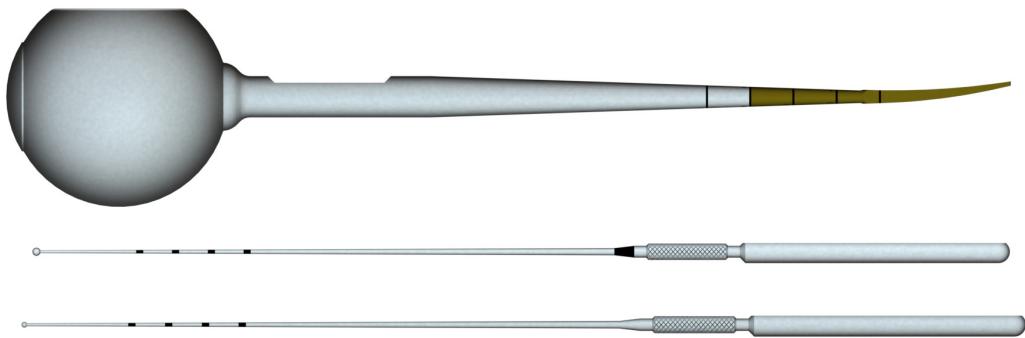
Locate pedicle using standard intraoperative techniques under fluoroscopy and create an incision.

Insert the Curved Lenke Probe through the incision and dock the tip on the bony anatomy of the desired level.

Advance the Curved Lenke Probe to desired depth while ensuring the probe does not breach the pedicle during placement.

Use either the Large or Small Pedicle Sounder to feel for pedicle breaches.

Pedicle sounders (small or large) can be used to confirm the desired length of implant to be implanted.



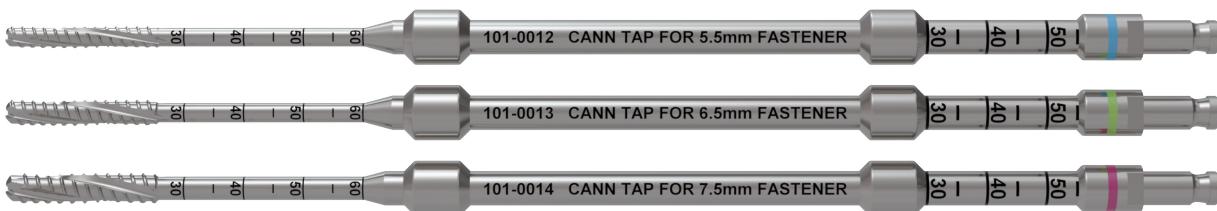
Tapping Pedicle for Open and MIS Procedures (Recommended)

Taps are provided to prepare the bone prior to fastener insertion. They have cutting features which allow for insertion into small pilot holes and are color coded with epoxy rings to match the size of the fastener selected. To provide optimal bone preparation and surgical feel, the taps are designed to cut a preliminary path in the pedicle allowing the fastener to perform the final bone preparation during implant insertion. When necessary or desired, it is acceptable to sequentially tap.

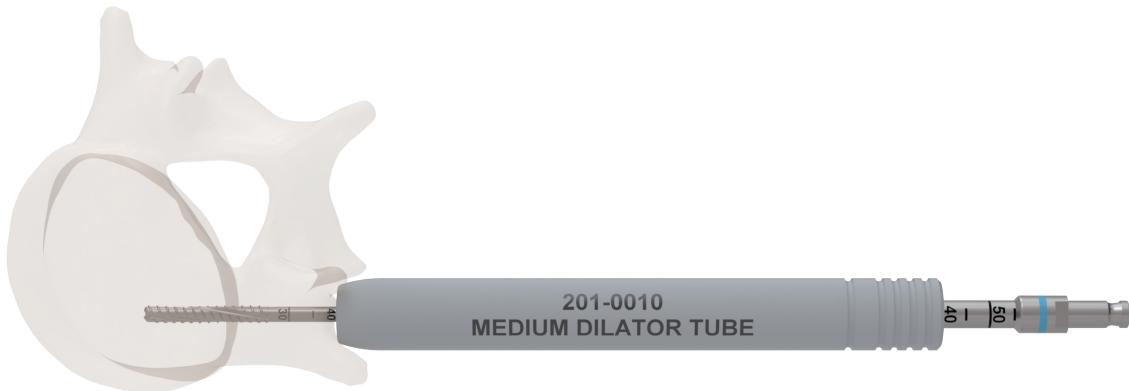
For MIS procedures, advance the appropriate size Cannulated Pedicle Tap over the guide wire and into the pedicle by turning the tap in a clockwise manner.

Note: While tapping, care should be taken to avoid unintentional guide wire advancement.

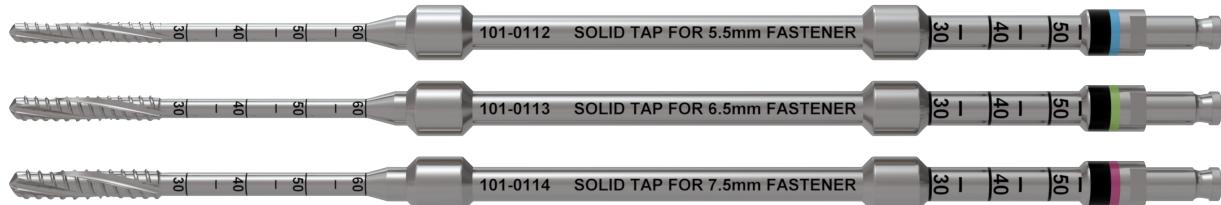
For open procedures, advance the appropriate size Cannulated Pedicle Tap into the pedicle by turning the tap in a clockwise manner.



Note: There are two sections of depth markings. The depth marks near the instrument tip are read off the bone. The depth marks near the handle end are read off the medium dilator as shown below.



Note: Solid Taps are available upon request. Solid taps have a solid black ring next to the epoxy ring to differentiate them from the cannulated taps.



Note: A Power Adapter for use with the taps and drivers is available upon request.



Note: A Ratcheting T-Handle for use with the taps and drivers is available upon request.

Driver Assembly and Fastener Insertion for MIS Procedures



Select the appropriate fastener diameter based on the color of the ring on the tap used in the tapping step. When sequentially tapping, the fastener diameter is indicated by the last tap used.

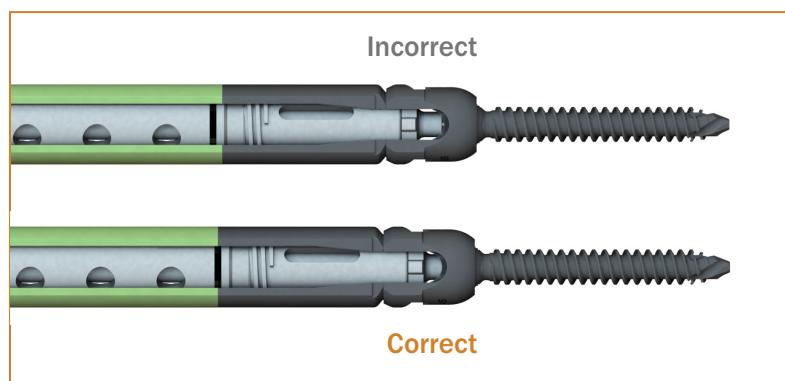
Attach the MIS Locking Driver to the Ratcheting Handle.

Load the appropriate Pedicle fastener onto the MIS Locking Driver by engaging the T25 tip of the driver into the drive feature of the fastener body.

Note: Assembly requires alignment of distal driver with slots in fastener head.

Once the tip is properly seated in the fastener, lower the sleeve of the driver into the threads of the fastener.

Rotate the sleeve clockwise until the fastener is firmly attached (as shown). Slide the locking collar down the sleeve to lock assembly.



Note: Optional Restraint Tube may be used with the fasteners to constrain the tabs as desired. However, when the Restraint Tube is used, the implant construct will NOT fit through the Large Dilator.



Pass the fastener over the guide wire until the tip of the fastener reaches the pedicle entry point. Confirm desired trajectory via fluoroscopy.

Note: Do not advance the fastener into the pedicle until confirming the fastener is aligned with the guide wire. Monitor the tip of the guide wire under fluoroscopy to ensure it does not penetrate the anterior wall of the vertebral body.

Advance the fastener by rotating the Ratcheting Handle clockwise.

Once the fastener is aligned and established in the pedicle, remove the guide wire.

Continue to advance the fastener with fluoroscopic guidance as needed.

Note: Do not hold thumb tab while inserting screw as there is potential for locking sleeve to loosen during insertion.

Driver Assembly and Fastener Insertion for Open Procedures



Select the appropriate fastener diameter based on the color of the ring on the tap used in the tapping step. When sequentially tapping, the fastener diameter is indicated by the last tap used.

Slide the openings of the Tab Removal Tool over the fastener extension and tilt towards the mating tab until the extension breaks away from the fastener.

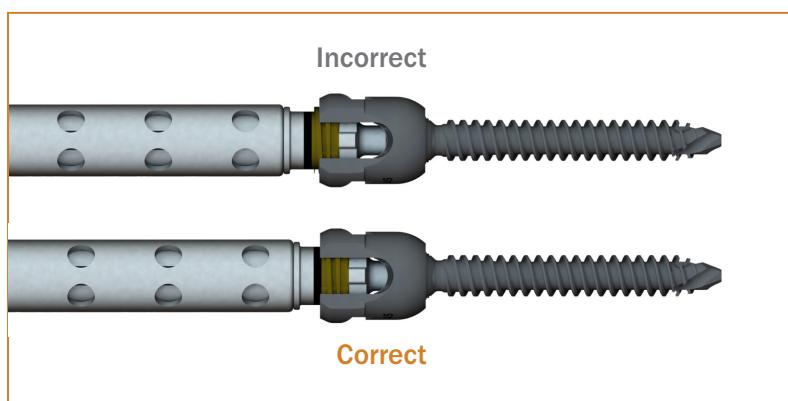
Note: A Tab Breaker Block to assist with Tab Removal is available upon request. Hold the block with one hand and use the Tab Removal tool to remove the tabs with the other hand.

Repeat for all fastener extensions.

Attach the Open Locking Driver to the Ratcheting Handle.

Load the appropriate Pedicle fastener onto the Open Locking Driver by engaging the T25 tip of the driver into the drive feature of the fastener body.

Note: Assembly requires alignment of distal driver with slots in fastener head.



Once the tip is properly seated in the fastener, lower the sleeve of the driver into the threads of the fastener.

Rotate the sleeve clockwise until the fastener is firmly attached (as shown). Slide the locking collar down the sleeve to lock assembly.

Insert the fastener until the tip of the fastener reaches the pedicle entry point and confirm desired trajectory via fluoroscopy.

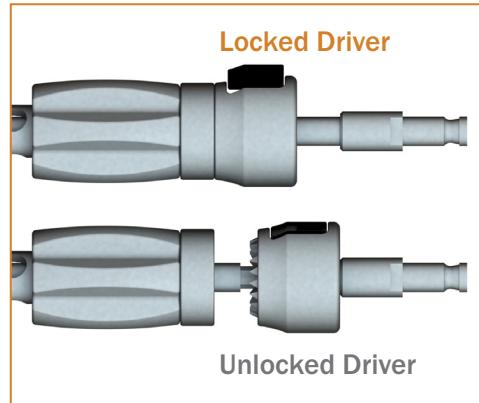
Advance the fastener by rotating the Ratcheting Handle clockwise with fluoroscopic guidance as needed.

Note: Do not hold thumb tab while inserting screw as there is potential for locking sleeve to loosen during insertion.

Remove Driver

Once the fastener has reached the desired depth, remove the driver by compressing the button of the locking sleeve and sliding away from the sleeve. Turn the sleeve counterclockwise until it completely disengages from the fastener head.

Repeat previous steps until all fasteners are in place.



Fastener Head Alignment

Use the Head Positioner to achieve desired alignment.

Insert the Head Positioner into the head of the fastener and rotate to desired position.



Rod Selection and Contouring

Determine Rod length by using the Rod Length Template.

Insert each shaft of the Rod Length Template into each of the Fastener Extension Tabs until fully seated in the screw heads.

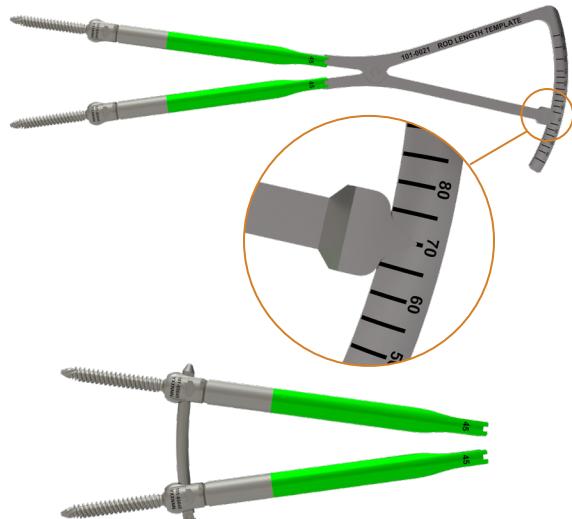
Confirm placement under fluoroscopy.

Note: The indication marks on the Rod Length Template estimate the total rod length required, including the length of the nose and inserter attachment regions. For example, in the images to the right, the Rod Length Template measures a 70mm rod and then a 70mm rod is shown.

Ensure the appropriate contour (small, medium, large) is set on the main cam prior to bending.

Place rod into Rod Bender and squeeze handles to bend rod.

Note: Do not reverse bend rods. Reverse bending may produce internal stresses which may become the focal point for eventual breakage of the construct.



NOTE: OCT Spine does not provide Rod Benders in sets.

Attach Rod to Rod Introducer

Insert the flats of the rod into the opening of the Rod Introducer; orient as shown.

Lock the rod into position by twisting the knob on the proximal end of the Rod Introducer clockwise.

Verify the rod is securely attached to the Rod Introducer prior to the insertion.

Note: The notch of the connection end of the rod must face the handle of the Rod Introducer.



Rod Insertion

Using the Rod Introducer, insert the rounded tip of the rod into each extension.

Slide the rod down the screw extensions until the rod is fully seated in the head of the fasteners.

Utilize fluoroscopy to confirm rod placement and assess rod overhang at each end of the construct prior to removing the Rod Introducer.

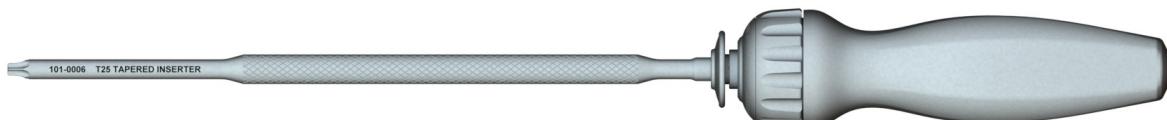
Note: Do not remove Rod Introducer until set screw is placed and tightened.

Set Screw Insertion

Load set screw into the Single Sided Cap Inserter.

Introduce the tip of the inserter into the set screw; a firm push will engage the set screw properly.

Place the set screw into the fastener head and turn clockwise.



Note: A Rescue Sleeve is available upon request to assist in aligning the set screw to the implant after the tabs have been removed. To use, align the rod slot (identified on fluoroscopy and with the laser lines in line with the slot on the top face of the sleeve) with the slot of the tulip and lower onto the top of the tulip.



Compression and Distraction

Ensure fastener has gone through the final locking procedure, and the adjacent fastener has the set screw in place but not fully tightened.

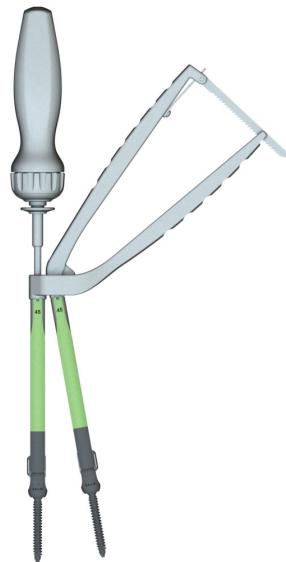
Slide one shaft of the Compressor/Distractor through the locked fastener, and the other shaft through the loose fastener.

Place the Compressor Driver through the hollow of the shaft and fully engage the loose set screw.

Squeeze the handles together until the desired amount of compression/distraction has been achieved. While holding Compression/Distraction load, final tighten the set screw.

Note: The Compressor/Distractor comes equipped with a ratcheting lock at its proximal end as needed.

Note: Compressor and Distractor to be used only when extension tabs on the implant are still intact.



Final Tightening

Assemble T25 drive shaft to the torque limiting handle.

Pull back the plunger and insert the shaft until the “load line” is flush with the plunger, then release.

Lower the Counter Torque over the head of the fastener until seated against the rod.

Insert the T25 Drive Shaft into the Counter Torque.

Note: It is important to ensure that the T25 drive shaft is properly engaged in the Locking Cap prior to final locking. Failing to do so may result in a damaged construct or instrument.

Turn the Torque Limiting Handle clockwise until it “clicks”. The audible and tactile feedback confirms the construct is locked down to its proper specification.

Remove Driver and Counter Torque from the fastener.

Repeat steps for remainder of the construct.

Note: Final locking must be secured using a Torque Limiting Handle of 90 in-lb (10.1 N-m).



Fastener Extension Removal for MIS Procedures

Slide the openings of the Tab Removal Tool over the fastener extension and tilt towards the mating tab until the extension breaks away from the fastener.

Repeat for all fastener extensions.



Pedicle Fastener Removal

Engage the Counter Torque over the fastener head.

Insert the Fastener Driver into the Counter Torque, turn counterclockwise.

Repeat for each set screw.

Remove rods from construct.

If necessary, use the Head Positioner to mobilize the polyaxial fastener head of the implant.

Engage the Fastener Driver T25 Tip into the fastener body socket, turn counterclockwise and remove from the pedicle; repeat for each pedicle fastener.



Contraindications

OsteoCentric Pedicle Fastener System components are contraindicated in the following patient situations:

1. Recent infection (systemic, spinal or localized);
2. Morbid obesity;
3. Mental illness;
4. Drug or alcohol abuse;
5. Fever or leukocytosis;
6. Pregnancy;
7. Metal sensitivity or allergy to implant materials;
8. Severe osteopenia;
9. Presence of congenital abnormalities;
10. Spinal anatomy, tumors or any other complication which prevents secure implantation or decreases the useful life of the device;
11. Any condition where the device will interfere with anatomical structures or physiological performance (including inadequate tissue coverage over the operative site) for pedicle fastener cases;
12. Missing or congenitally deformed pedicles of the fifth lumbar (L5) vertebrae;
13. Patients unable or unwilling to follow postoperative care instructions;
14. Any circumstances not described in the indications for use.

Instrument List

Part#	Description	Set Quantity
101-0002	10.1 Nm Torque Limiter Handle	1
101-0004	Large Head Positioner	1
101-0006	T25 Hudson Tapered Inserter	2
101-0007	Cannulated Probe Handle	1
101-0008	Cannulated Probe Shaft	1
101-0012	Cann Tap for 5.5mm Fastener	1
101-0013	Cann Tap for 6.5mm Fastener	1
101-0014	Cann Tap for 7.5mm Fastener	1
101-0016	Bullet Rod Introducer	2
101-0017	Bullet Rod Introducer Shaft	2
101-0019	Extension Counter Torque	1
101-0021	Rod Length Template	1
101-0022	T25 Driver, Square	1
101-0023	Tab Removal Tool	1
101-0024	T25 Driver, Hudson	1
101-0025	T25 Driver, 1/4 Square	2
101-0026	Compressor Top Handle	1
101-0027	Compressor Bottom Handle	1
101-0028	Distractor Top Handle	1
101-0029	Distractor Bottom Handle	1
101-0030	Restraint Tube	6
101-0031	MIS T25 Super Locking Driver	2
101-0032	Straight Ratcheting Handle	2
101-0033	Open T25 Super Locking Driver	2
101-0034	Small Pedicle Sounder	1
101-0035	Large Pedicle Sounder	1
101-0036	Curved Lenke Probe	1
101-0037	Tab Breaker Block	*
101-0038	Rescue Sleeve	*
101-0040	Small Hudson Ratcheting T-Handle	*
101-0112	Solid Tap for 5.5mm Fastener	*
101-0113	Solid Tap for 6.5mm Fastener	*
101-0114	Solid Tap for 7.5mm Fastener	*
101-90000	Sterilization Case Lid	2
101-90001	Rod Module Lid	1
101-90003	Rod Module	1
101-90004	MIS Implant Case	1
101-90005	MIS Instrument Case	1
101-90007	MIS Implant Case Upper Tray	1
101-90008	MIS Implant Case Lower Tray	1
101-90009	MIS Instrument Case Upper Tray	1
101-90010	MIS Instrument Case Lower Tray	1
104-0006	Small Hudson Power Adapter	*
201-0009	Small Dilator Tube	2
201-0010	Medium Dilator Tube	2
201-0011	Large Dilator Tube	2
909-0480N	480mm Nitinol Guidewire	16

*These instruments are only available upon request and are not present in the system case and tray.

Implant List

Part#	Description	Set Quantity
101-10001	Set Screw	14
101-10035	5.5 x 35mm Curved Rod	2
101-10040	5.5 x 40mm Curved Rod	2
101-10045	5.5 x 45mm Curved Rod	2
101-10050	5.5 x 50mm Curved Rod	2
101-10055	5.5 x 55mm Curved Rod	2
101-10060	5.5 x 60mm Curved Rod	2
101-10065	5.5 x 65mm Curved Rod	2
101-10070	5.5 x 70mm Curved Rod	2
101-10075	5.5 x 75mm Curved Rod	2
101-10080	5.5 x 80mm Curved Rod	2
101-10090	5.5 x 90mm Curved Rod	2
101-10100	5.5 x 100mm Curved Rod	2
101-10110	5.5 x 110mm Curved Rod	2
101-10120	5.5 x 120mm Curved Rod	2
101-55035	5.5 x 35mm Cann Extension Fastener	2
101-55040	5.5 x 40mm Cann Extension Fastener	4
101-55045	5.5 x 45mm Cann Extension Fastener	4
101-55050	5.5 x 50mm Cann Extension Fastener	2
101-65035	6.5 x 35mm Cann Extension Fastener	4
101-65040	6.5 x 40mm Cann Extension Fastener	8
101-65045	6.5 x 45mm Cann Extension Fastener	8
101-65050	6.5 x 50mm Cann Extension Fastener	6
101-65055	6.5 x 55mm Cann Extension Fastener	4
101-75040	7.5 x 40mm Cann Extension Fastener	4
101-75045	7.5 x 45mm Cann Extension Fastener	4
101-75050	7.5 x 50mm Cann Extension Fastener	2
101-75055	7.5 x 55mm Cann Extension Fastener	2



5.5mm



6.5mm



7.5mm

* Approved for additional lengths. Please inquire regarding availability *

Note

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Reference:

1. Nguyen B, Le T, Vo H, Speece B, Webb L. A Novel Method for Evaluating Pedicle Screws Utilizing UnifiMI Thread Technology. Mercer Biomedical Engineering Society. Biomechanical Testing Report.
2. OsteoCentric testing data on file and numbers reflect specific tests in various medium and are not meant to reflect generic claims for improved performance across all clinical applications. Approved conditionally and non-product specific.



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