

OsteoCentric

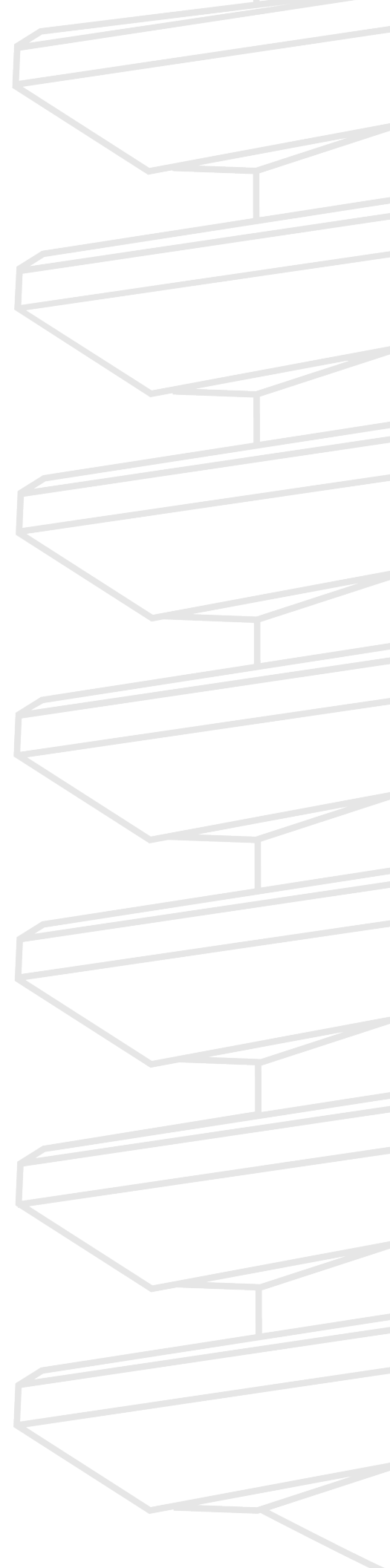
MIS Pedicle Fastener System

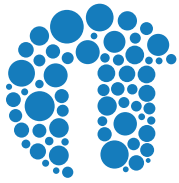
Surgical Technique



Table of Contents

UnifiMI Overview	3
Design Rationale & System Description	4
Indications for Use & Materials	4
Surgical Technique	5
Targeting Pedicle	5
Guide Wire Placement	5
Tissue Dilation	6
Tap Pedicle	6
Driver Assembly & Fastener Insertion	7
Remove Driver	8
Fastener Head Alignment	8
Rod Selection and Contouring	8
Attach Rod to Rod Introducer	9
Rod Insertion	9
Set Screw Insertion	9
Compression and Distraction	10
Final Tightening	10
Fastener Extension Removal	11
Pedicle Fastener Removal	11
Contraindications	11
Instrument List	12
Implant List	13





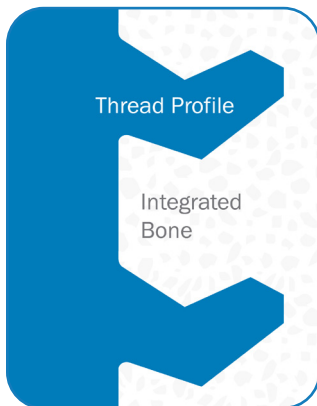
UnifiMI
An **OsteoCentric**
Technology

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 stability.



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



Removable constraint collar provides extra control

Visual guidance for rod delivery and construct locking

Reliable, over-the-skin rod length measurement



Common implant interfaces to reduce instrumentation

30mm integrated rod reduction capability

Robust hybrid square thread minimizes cross threading during rod reduction

Indications For Use & Materials

The OsteoCentric MIS Pedicle Fastener System immobilization 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

TARGETING PEDICLE

Locate pedicle using standard intraoperative techniques under fluoroscopy.

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

Confirm position using A/P and lateral fluoroscopy.

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

Remove the inner trocar of the Cannulated Probe by rotating the impaction cap counterclockwise.

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

GUIDE WIRE PLACEMENT

Insert the guide wire through the Cannulated Probe and advance to desired depth.

Confirm placement with A/P and lateral fluoroscopy, prior to removing the Cannulated Probe.

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.

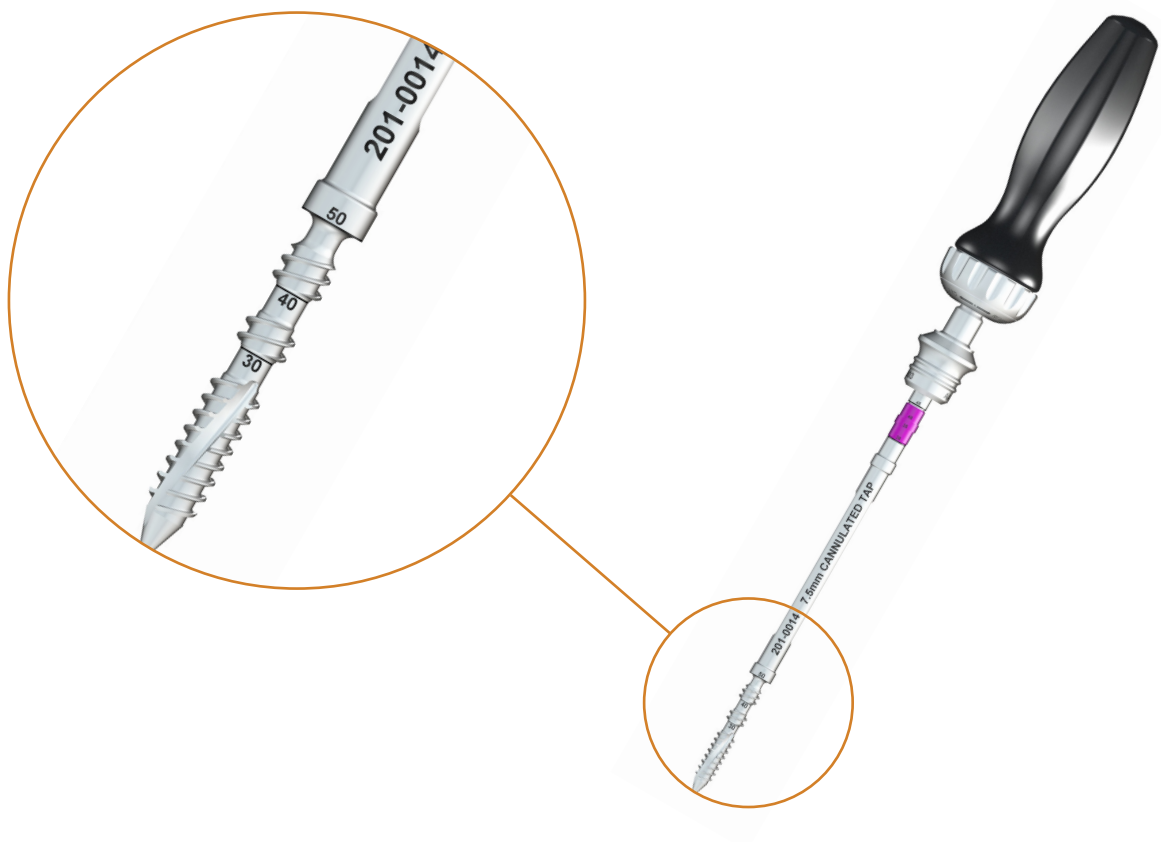
Remove small and large dilators leaving the medium dilator and guide wire; maintain control of the guide wire to prevent it from backing out.



(Optional) TAP PEDICLE

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.



DRIVER ASSEMBLY & FASTENER INSERTION

Attach the Extension Locking Driver to the Ratcheting Handle.

Load the appropriate Pedicle fastener onto the Extension 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 collar may be used with the fasteners to constrain the tabs as desired.

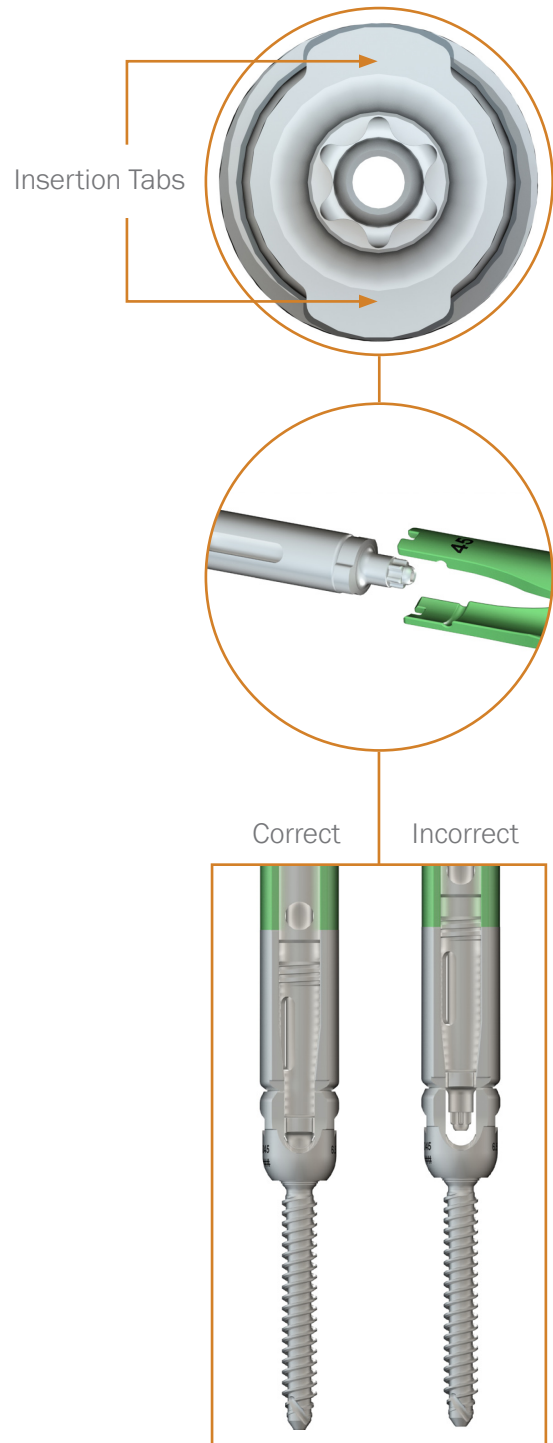
Pass the fastener over the guide wire until the tip of the fastener reaches the pedicle entry point. Confirm desired trajectory via fluoroscopy.

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.



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 counter-clockwise until it completely disengages from the fastener head.

Repeat previous steps to until all fasteners are in place.

Note: Minor height adjustments may be done after fastener implantation by utilizing the Utility Driver with T25 Tip.



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 directly estimate rod length required.

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.



COMPRESSION & 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.



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

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 Spine MIS 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
101-0002	10.1 Nm Torque Limiter Handle
101-0004	Large Head Positioner
101-0016	Bullet Rod Introducer
101-0017	Bullet Rod Introducer Shaft
101-0019	Extension Counter Torque
101-0021	Rod Length Template
101-0022	T25 Driver, Square
101-0023	TAB Removal Tool
101-0024	T25 Driver, Hudson
101-0025	T25 Driver, 1/4 Square
101-0026	Compressor Top Handle
101-0027	Compressor Bottom Handle
101-0028	Distractor Top Handle
101-0029	Distractor Bottom Handle
101-90000	Sterilization Case Lid
101-90005	MIS Instrument Case
101-90009	MIS Instrument Case Upper Tray
101-90010	MIS Instrument Case Lower Tray
101-0001	Utility Screwdriver
101-0032	Straight Ratcheting Handle
101-0003	Short Ratcheting Handle
101-0005	T25 Tapered Tip
101-0006	T25 Hudson Tapered Inserter
101-0007	Cannulated Probe Handle
101-0008	Cannulated Probe Shaft
201-0009	Small Dilator Tube
201-0010	Medium Dilator Tube
201-0011	Large Dilator Tube
101-0012	5.5mm Cannulated Tap
101-0013	6.5mm Cannulated Tap
101-0014	7.5mm Cannulated Tap
101-0030	Restraint Tube
101-0031	MIS T25 Super Locking Driver
101-90000	Sterilization Case Lid
101-90001	Rod Module Lid
101-90004	MIS Implant Case
101-90007	MIS Implant Case Upper Tray
101-90008	MIS Implant Case Lower Tray
101-90002	Guidewire Sterilization Tube
101-90003	Rod Module
909-0480N	480mm Nitinol Guidewire

Implant List

Part#	Description	Length (mm)
101-10001	Set Screw	
101-10035	5.5 Curved Rod	35
101-10040	5.5 Curved Rod	40
101-10045	5.5 Curved Rod	45
101-10050	5.5 Curved Rod	50
101-10055	5.5 Curved Rod	55
101-10060	5.5 Curved Rod	60
101-10065	5.5 Curved Rod	65
101-10070	5.5 Curved Rod	70
101-10075	5.5 Curved Rod	75
101-10080	5.5 Curved Rod	80
101-10090	5.5 Curved Rod	90
101-10100	5.5 Curved Rod	100
101-10110	5.5 Curved Rod	110
101-10120	5.5 Curved Rod	120
101-55035	5.5 Cann Extension Fastener	35
101-55040	5.5 Cann Extension Fastener	40
101-55045	5.5 Cann Extension Fastener	45
101-55050	5.5 Cann Extension Fastener	50
101-65035	6.5 Cann Extension Fastener	35
101-65040	6.5 Cann Extension Fastener	40
101-65045	6.5 Cann Extension Fastener	45
101-65050	6.5 Cann Extension Fastener	50
101-65055	6.5 Cann Extension Fastener	55
101-75030	7.5 Cann Extension Fastener	30
101-75035	7.5 Cann Extension Fastener	35
101-75040	7.5 Cann Extension Fastener	40
101-75045	7.5 Cann Extension Fastener	45

Note

This document is intended exclusively for physicians and is not intended for laypersons. Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice.

All content herein is protected by copyright, trademarks and other intellectual property rights owned by or licensed to OsteoCentric Technologies, Inc. or one of its affiliates and must not be redistributed, duplicated, or disclosed, in whole or in part, without the express written consent of OsteoCentric Technologies, Inc.



75 West 300 N, Suite 150
Logan UT, 84321
Phone: 1-800-969-0639
info@osteocentric.com
osteocentric.com

OsteoCentric Trauma, OsteoCentric SI Fusion, OsteoCentric Extremities, OsteoCentric Spine, OsteoCentric Sports Medicine, OsteoCentric Recon, OsteoCentric Dental, OsteoCentric Oncology, and OsteoCentric Vet are a family of the companies under the OsteoCentric brand and are under common ownership and control within OsteoCentric Technologies.

SP-001-LBL-0004 Rev 03