OsteoCentric[®]

Small Fragment Set

Technique Guide



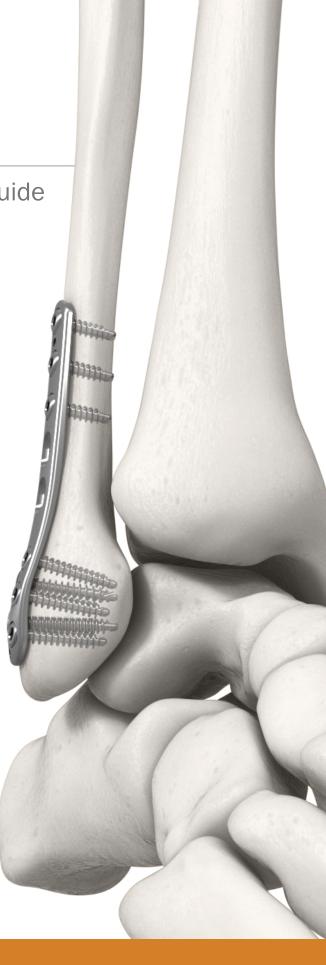


Table of Contents

- UnifiMI® Technology 3
 - Indications for Use 4
 - Contraindications 5
- Compression, 1/3 Tubular, & Reconstruction Plate Technique 5
 - Lateral Distal Fibula Plate Technique 7
 - Lateral Locking Distal Fibula Plate Technique 7
 - Fastener Only Technique 8
 - Long Fastener Technique 8
 - Implants & Instruments List 9
 - 4.0 Super Fasteners & Instruments 11





Mechanical Integration (MI) is a revolutionary new method of instantly securing implants to bone utilizing OsteoCentric's proprietary thread geometry called Unifi*MI* - providing superior primary stability of any implant in normal or compromised bone. 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). Unlike Biological Integration (Osseointegration), the Unifi*MI* connection to bone is instant vs. delayed, removable vs. permanent, mechanical vs. biological.

The screw fasteners in the Small Fragment Set are designed to preserve the integrity of and instantly interlock to the bone with its unique thread geometries. (Figure 1)

Thin Profile, Interlocking Strength

Unifi*MI*'s interlocking threads are designed to increase construct stability while maintaining the benefits of low-profile plates.

Versatile Fixation

The set includes Compression, Reconstruction, 1/3 Tubular, and Distal Fibula plates along with 3.5mm, 3.3mm, and 2.7mm interlocking screw fasteners that work in any plate hole for customized constructs for each patient.

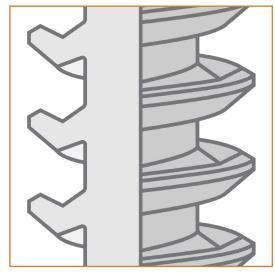
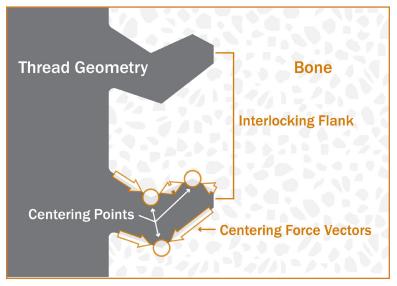


Figure 1



UnifiMI Technology

The unique Unifi*MI* technology provides the benefits of robust fixation and immediate mechanical interlocking with the bone without the need for special techniques or instruments.

The 3.5mm Screw Fastener provides 80° of total angulation proximal-distal and 14° of total angulation axially to allow for variation in the fixation needs. (Figures 2 and 3)

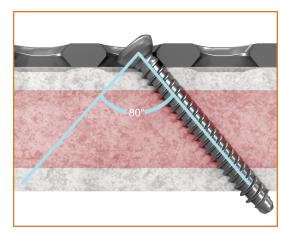
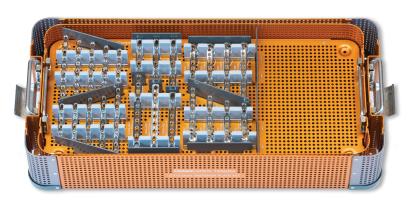


Figure 2





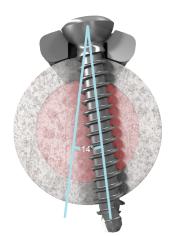


Figure 3

The OsteoCentric Small Fragment set uses all standard instrumentation familiar to orthopedic surgeons. Fasteners and implants are currently available in stainless steel.

Indications For Use

The OsteoCentric Trauma 2.7mm Screw Fastener is intended for fractures and osteotomies of small bones and bone fragments, including the foot, ankle, and hand in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

The OsteoCentric Trauma 3.5mm Screw Fasteners are intended for fixation of fractures, osteotomies and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, tibia, calcaneus, femur and fibula in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by fastener fixation.

The OsteoCentric Trauma Bone Plate and Screw System is intended for fixation of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, tibia, and fibula, including, periarticular and intraarticular fractures.

Contraindications

The physician's education, training, and professional judgment are necessary to determine the appropriate treatment protocol and patient selection. Contraindications may be relative to each patient, and clinicians should always consider all risks and possible reactions when considering the proper treatment protocol. Specific contraindications include:

- Active or latent infection
- · Insufficient quantity or quality of bone/soft tissue
- Material sensitivity If suspected, tests should be performed prior to implantation.
- Sepsis
- Patients who are unwilling or incapable of following postoperative care instructions.
- Spinal fixation This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Compression, 1/3 Tubular, & Reconstruction Plate Technique

Select the type of plate appropriate for the fracture and anatomic area.

If bending is needed, use the Bending Iron L and R or the Bending Iron Reconstruction to customize the plate contour.

Hold the plate to the bone using the Reduction Forceps provided.

Instruments



Bending Iron Left: 110605

Right: 110606



Bending Iron Reconstruction

110610



Reduction Forceps, Points

Narrow: 110630 Broad: 110631



Reduction Forceps, Serrated

110632

Drill for the first screw fastener in the neutral position (*Figure 4*) with the appropriate drill bit for the screw size selected.

Screw Fastener Drill Bit 2.7mm 2.0mm 3.5mm 2.5mm

Measure using the Depth Gauge. (Figure 5)

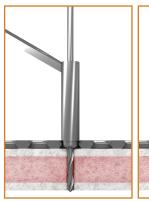




Figure 4

Figure 5

Instruments



Drill Sleeve

3.5mm/2.5mm: 110520 2.7mm/2.0mm: 110521



Universal Drill Sleeve

3.5mm/2.5mm: 110522



Insert Drill Sleeve

3.5mm/2.5mm: 110524



Drill Bit

2.0mm, 100mm: 110007 2.5mm, 110mm: 110013 2.5mm, 145mm: 110014



Depth Gauge

60mm: 110205

- 1. If dense, hard bone is detected, please check to be sure the proper drill bit size has been utilized. If it has, it is recommended to use the appropriately sized tap to prepare the bone for screw insertion.
- 2. Insert the screw fastener using the preferred 2.5mm hex screwdriver.
- 3. Drill for a screw fastener on the opposite side of the fracture. For compression at the fracture with Compression Plates, drill eccentrically (Figure 6) with the drill bit away from the fracture.
- 4. Measure using the Depth Gauge and insert the screw fastener using the preferred 2.5mm hex screwdriver.
- 5. For additional compression at the fracture site, lag screw technique can be used through the plate by overdrilling the near cortex (Figure 7) with the 3.5mm Drill Bit or 2.7mm Drill Bit.
- 6. Insert remaining screw fasteners as appropriate for the fracture.



Figure 6

Figure 7

Instruments

Drill Bit

2.7mm, 100mm: 110016 3.5mm, 110mm: 110028



Lateral Distal Fibula Plate Technique

The Distal Fibula Plate is implanted using the previous techniques. (*Figure 8*) Every screw hole can accept any screw size, however, 2.7mm or 3.3mm Screw Fasteners are often used in the distal cluster with 3.5mm used in the shaft (*Figure 9*).

Screw Fastener	Drill Bit
2.7mm	2.0mm
3.3mm	2.0mm
3.5mm	2.5mm

Lateral Locking Distal Fibula Plate Technique

Leveraging the Unifi*MI* proprietary design, the Locking Distal Fibula Plate allows surgeons to place both locking or non-locking fasteners into the same hole, resulting in lower head prominence (*Figure 10*). Determine the required length of the fastener by using the scale on the 2.0mm calibrated drill guide (*Figure 11*).





Figure 8



Figure 9

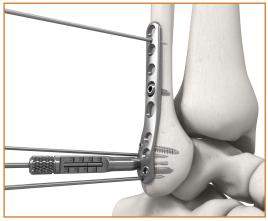


Figure 10



Figure 11

Fastener Only Technique

Screw Fastener implantation uses standard techniques with the appropriate drill bit for the implant chosen.

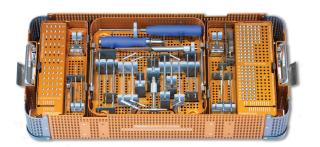
Screw Fastener	Underdrill	Overdrill
2.7mm	2.0mm	2.7mm
3.5mm	2.5mm	3.5mm

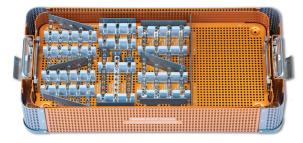
After drilling and before measuring, the Countersink can be used to reduce the profile of the head on the near cortex.

Instruments



• Countersink: 110500





OsteoCentric Trauma Small Fragment Set

Note: If during any fastener insertion technique excessive insertion torque is encountered, it is highly recommended to remove fastener and utilize the correctly sized tap to prepare the bone for fastener insertion.

Long Fastener Technique

Fixation needs may require the use of extra-long fasteners and corresponding instruments. The following are part of the Long Fastener Instrument Set:

Instruments

• Drill Bit

3.5mm Drill Bit 110mm: 110028

2.5mm Drill Bit Calibrated 200mm: 110040

Hex Driver

Long Hex Driver: 110104

Long Hex Driver Fixed 300mm: 110703 2.5mm Hex Driver Sleeve: 110701

• Depth Gauge For Small Frag 150mm: 110206

• 3.5mm Cortical Screw Fastener Tap 200mm: 110454

Screw Fastener Holding Forceps: 1107052.0mm Drill 145mm, Calibrated: 110039

• 2.7mm Cortical Screw Tap 145mm: 110402

• 2.7mm Drill Bit 100mm: 110016



Note: If during any long fastener insertion technique excessive insertion torque is encountered, it is highly recommended to remove fastener and utilize the correctly sized tap to prepare the bone for fastener insertion.

Small Fragment Set Implants

3.5mm Compression Plate

Part #	Holes	Length (mm)
302-564	5	64
302-677	6	77
302-790	7	90
302-8103	8	103
302-9116	9	116
302-10129	10	129



1/3 Tubular Plate With Collar

Part #	Holes	Length (mm)
303-557	5	57
303-669	6	69
303-781	7	81
303-893	8	93
303-10117	10	117



Straight Reconstruction Plate

Part #	Holes	Length (mm)
304-565	5	65
304-678	6	78
304-791	7	91
304-8104	8	104
304-9117	9	117



K-Wires

Part #	Diameter	Length (mm)
130005	1.25mm	150
130010	1.6mm	150
130015	2.0mm	150

2.7mm/3.5mm Lateral Distal Fibula Plate

Part# L	Part# R	Holes	Length (mm)
305-470L	305-470R	4	70
305-580L	305-580R	5	80
305-690L	305-690R	6	90
305-7100L	305-7100R	7	100



2.7mm/3.5mm Locking Lateral Distal Fibula Plate

Part# L	Part# R	Holes	Length (mm)
314-470L	314-470R	4	70
314-580L	314-580R	5	80
314-690L	314-690R	6	90
314-7100L	314-7100R	7	100
314-9120L	314-9120R	9	120
314-11140L	314-11140R	11	140



2.7mm Screw Fastener Self-Tapping

10mm - 32mm, 2mm increments 327-10xx

2.7mm Long Screw Fastener Self-Tapping

34mm - 50mm, 2mm increments 50mm -110mm, 5mm increments 327-1xxx

3.3mm Screw Fastener Self-Tapping

12mm - 22mm, 2mm increments 333-10xx

3.3mm Locking Screw Fastener Self-Tapping

12mm - 22mm, 2mm increments 333-60xx

3.5mm Screw Fastener Self-Tapping

10mm - 50mm, 2mm increments 335-10xx

3.5mm Long Screw Fastener Self-Tapping

52mm - 88mm, 2mm increments 90mm - 130mm, 5 mm increments 335-1090-1130

7mm Washer 300-0701

9mm Washer 300-0901



Full Instrument List

Part #	Description	Part #	Description
110007	2.0mm Drill Bit 100mm	110625	Periosteal Elevator 6mm Width
110013	2.5mm Drill Bit 110mm	110630	Reduction Forceps Narrow
110014	2.5mm Drill Bit 145mm	110631	Reduction Forceps Broad
110016	2.7mm Drill Bit 100mm	110632	Reduction Forceps Serrated
110028	3.5mm Drill Bit 110mm	110701	2.5mm Hex Driver Sleeve
110040	2.5mm Drill Bit Calibrated 200mm	110702	2.0mm Threaded Drill Guide Calibrated
110045	2.0mm Drill Bit Calibrated 110mm	110703	Long Hex Driver Fixed 300mm
110103	2.5mm Hex Driver QC Shaft 110mm	110705	Screw Fastener Holding Forceps
110104	Long Hex Driver	130005	1.25mm X 150mm K-Wire Smooth
110205	Depth Gauge for Small Frag 60mm	130010	1.6mm X 150mm K-Wire Smooth
110206	Depth Gauge For Small Frag 150mm	130015	2.0mm X 150mm K-Wire Smooth
110302	AO QC Handle	A2200	Small Fragment Fastener Set Outer Case
110310	QC T-Handle	A2200-01	Lid
110422	2.7mm Screw Fastener Tap 110mm	A2200-02	Small Fragment Set Instrument Tray Upper
110424	3.5mm Screw Fastener Tap 110mm	A2200-03	Small Fragment Set Instrument Tray Lower
110444	3.5mm Screw Fastener Tap 135mm	A2200-04	3.5mm Small Fragment Fastener Caddy
110454	3.5mm Cortical Screw Fastener Tap	A2200-06	2.7/3.3mm Small Fragment Fastener Caddy
	200mm	A2200-07	2.7/3.3/3.3mm Locking Fastener Caddy
110500	3.5mm Countersink	A2300	Small Fragment Plate Set Outer Case
110520	3.5mm/2.5mm Drill Sleeve	A2300-01	Small Fragment Plate Set Instrument Tray
110521	2.7mm/2.0mm Drill Sleeve	A2300-02	Small Fragment Plate Set Implant Tray
110522	3.5mm/2.5mm Universal Drill Sleeve	A2300-03	Locking LDFP and Instrument Tray
110524	3.5mm/2.5mm Insert Drill Sleeve	A2300-04	Locking LDFP 9 Hole, 11 Hole Plate Tray
110535	2.0mm Threaded Drill Guide Calibrated	A2400	Long Fastener Outer Tray
110600	Sharp Hook	A2400-02	Long 3.5mm Fastener Caddy
110605	Bending Iron	A2400-03	Long Fastener Instrument Tray
110606	Bending Iron	A2400-01	Long 2.7mm Fastener Caddy
110610	Bending Iron Reconstruction	110039	2.0mm Drill 145mm, Calibrated
110620	Hohmann Retractor 8mm Width	110402	2.7mm Cortical Screw Tap 145mm
110621	Hohmann Retractor 15mm Width	110016	2.7mm Drill Bit 100mm

4.0mm Super Fasteners

or radicinors	
Description	Length
4.0 Bone Screw Super Fastener ST	12mm
4.0 Bone Screw Super Fastener ST	14mm
4.0 Bone Screw Super Fastener ST	16mm
4.0 Bone Screw Super Fastener ST	18mm
4.0 Bone Screw Super Fastener ST	20mm
4.0 Bone Screw Super Fastener ST	22mm
4.0 Bone Screw Super Fastener ST	24mm
4.0 Bone Screw Super Fastener ST	26mm
4.0 Bone Screw Super Fastener ST	28mm
4.0 Bone Screw Super Fastener ST	30mm
4.0 Bone Screw Super Fastener ST	32mm
4.0 Bone Screw Super Fastener ST	34mm
4.0 Bone Screw Super Fastener ST	36mm
4.0 Bone Screw Super Fastener ST	38mm
4.0 Bone Screw Super Fastener ST	40mm
4.0 Bone Screw Super Fastener ST	42mm
4.0 Bone Screw Super Fastener ST	44mm
	46mm
	48mm
	50mm
	52mm
	54mm
	56mm
	58mm
	60mm
	62mm
	64mm
	66mm
	68mm
	70mm
	72mm
	74mm
	76mm
	78mm
	80mm
	85mm
4.0 Bone Screw Super Fastener ST	90mm
	A.O Bone Screw Super Fastener ST 4.O Bone Screw Super Fastener ST

4.0 Super Fastener Instruments

Part Number	Description	Quantity
321-0001	4.0mm 2.5mm Drill Sleeve	1
321-0003	4.0mm Drill 110mm	2
321-0004	4.0mm Drill 200mm Calibrated	2
321-0005	Depth Gauge	1
321-0006	4.0 SF Bone Screw Tap, 145mm	1
110500	3.5mm Countersink	1
110702	2.5mm Hex Driver with Silicone Handle	1
110103	2.5mm Hex Driver w/ AO Adapter	1
110104	Long Hex Driver	1
110310	QC T-Handle	1
110013	2.5mm Drill Bit 110mm	2
110040	2.5mm Drill Bit 200mm	2
110205	Depth Gauge, 60mm	1
321-90001	4.0 Super Fastener Tray Outer	1
321-90002	4.0 Super Fastener Tray Caddy	1
321-90003	4.0 Super Fastener Tray Lid	1

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