

OsteoCentric®

Integrated Locking Proximal Humerus System

Surgical Technique



OsteoCentric®
TECHNOLOGIES

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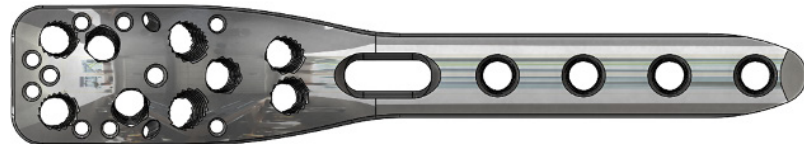
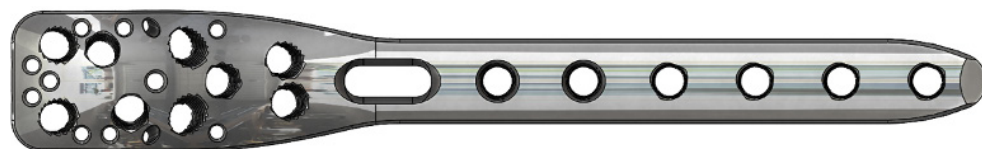


System Overview

The Integrated Locking Proximal Humerus System features a 4.0mm locking fastener which has been specifically designed to address compromised metaphyseal bone and provide increased mechanical integration. The system is designed with recessed suture holes with easy access to pass a suture needle while attaching rotator cuff to plate.

Also, included in this set are anatomically universal plates in various lengths coupled with our clinically proven UnifiMI technology, which has been shown to:

- mechanically integrate with the bone to provide surgeons with instant primary stability
- resist multiplanar and multidirectional loads to create Integrated Fixation
- maintain purchase strength during and after cyclic loading
- reduce toggle and implant displacement



Indications For Use

The OsteoCentric Trauma Bone Plate and Screw System is intended for fixation of fractures, osteotomies, and non-unions of the humerus, including periarticular and intraarticular fractures.

Contraindications

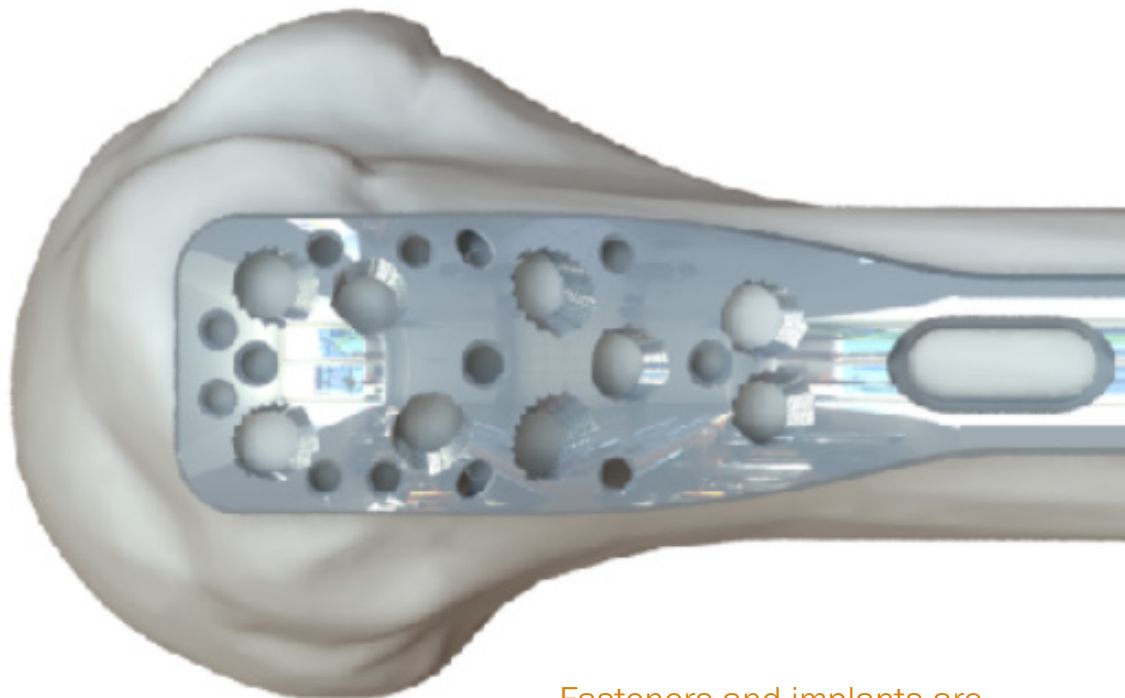
The physician's education, training, and professional judgment are necessary to determine the appropriate treatment protocol and patient selection. Contraindications may be relative to each patient, and clinicians should always consider all risks and possible reactions when considering the proper treatment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

Plate Selection

Choose the plate style that is best suited for the type of fracture. The OsteoCentric plates are anatomically universal. This means the same plate can be used for either the left or right side. The plate system is versatile and can adapt to surgeon preference for initial placement. With any technique, it is recommended to get sufficient anteroposterior, lateral and multiple oblique images to ensure pins and fasteners have not penetrated the humeral head.



Fasteners and implants are currently available in stainless steel.

Surgical Approach

Proper patient positioning and fluoroscopy is critical to ensure the fracture can be adequately visualized. The OsteoCentric system will work in either the deltopectoral and deltoid split approach and is adaptable to surgeon preference and training.

Plate Placement

Place plate 5-8mm distal to the tip of the greater tuberosity and lateral to the bicipital groove. To aid in locking fastener placement, attach the locking screw guide to the plate using the 2.5mm hex driver to advance the set screw.

Insert a 1.6mm k-wire through the most proximal hole in the backpack. The k-wire should rest on top of the humeral head and aims at proximal joint surface. (Figure 1)

Review plate placement in a lateral view and confirm plate rests centered on the lateral greater tuberosity.

Insert a 3.5mm cortical fastener in the oblong hole in the plate and make final plate adjustment before inserting proximal fasteners. (Figure 2)

NOTE: Subacromial impingement may occur if the plate is placed too high.

NOTE: Approach can start with either cortical fastener placement in oblong hole to get plate to bone compression or by placement of a pin proximally to confirm proper plate placement.

For Metaphyseal Fixation

Confirm reduction. With the locking drill guide attached to the plate, assemble the k-wire sleeve, drill sleeve, and screw insertion sleeve (triple sleeve assembly) and place through the backpack in the desired hole. (Figure 3)

If k-wire use is desired for additional reduction, use the 1.6mm k-wire through the k-wire sleeve. Remove the k-wire sleeve and using the 2.8mm calibrated drill bit, drill through the drill sleeve assembly,

OR

Remove the sleeve assembly, insert the coupled threaded drill guide and drill with the 2.8mm calibrated bit. (Figure 4)



Figure 1



Figure 2

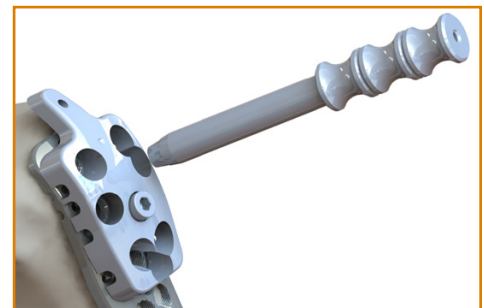


Figure 3

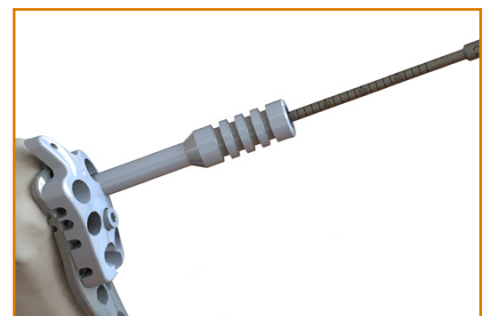


Figure 4

Measure for depth of 4.0mm locking fastener off the 2.8mm calibrated drill bit and drill sleeve assembly or drill off the threaded drill guide. Use the laser markings on the calibrated drill bit to confirm depth. (Figure 5)

Locking screw fasteners may be put in under power using the torque limiting attachment. An audible click will indicate final torque has been achieved (1.5Nm). If use of a compression screw or lag screw is desired in the proximal portion of the plate, a 3.5mm screw fasteners can be used.

Drill with 2.5mm drill bit using the 3.5/2.5mm drill guide. Replace with a 4.0mm locking fastener after reduction is achieved, to avoid fastener head prominence. Ensure to drill with a 2.8 drill bit if replacing with 4.0 locking fastener.

With imaging confirmed, place the remaining locking fasteners in the proximal portion of the plate using the same locking technique. (Figure 6)



Figure 5

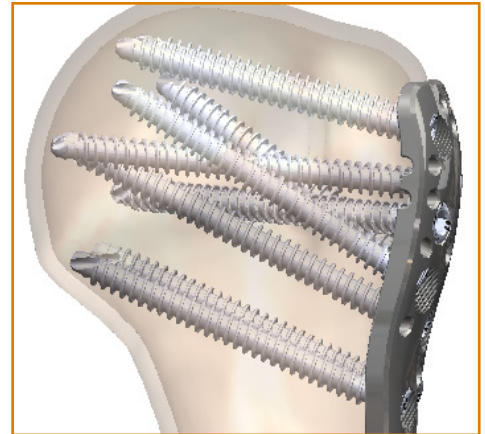


Figure 6

For Diaphyseal Fixation

Using a 2.5mm drill bit, and 3.5/2.5mm Drill Guide, drill for the 3.5mm fastener. Using depth gauge (cat #110205), measure for length of diaphyseal fastener and insert a 3.5mm screw fastener using the 2.5mm hex screwdriver.

Follow 3.5mm fastener technique for remainder of diaphyseal fasteners.

4.0mm locking fasteners may be used in the shaft of the plate. Thread in the threaded drill guide into the threaded shaft hole. Drill with the 2.8mm calibrated drill bit and measure directly off the threaded drill guide and insert 4.0mm locking fastener.

Repeat locking technique as necessary.



Implant List

Part Number	Description	Size (mm)
340-6014	4.0 x 14mm Locking Bone Screw Fastener, ST	14
340-6016	4.0 x 16mm Locking Bone Screw Fastener, ST	16
340-6018	4.0 x 18mm Locking Bone Screw Fastener, ST	18
340-6020	4.0 x 20mm Locking Bone Screw Fastener, ST	20
340-6022	4.0 x 22mm Locking Bone Screw Fastener, ST	22
340-6024	4.0 x 24mm Locking Bone Screw Fastener, ST	24
340-6026	4.0 x 26mm Locking Bone Screw Fastener, ST	26
340-6028	4.0 x 28mm Locking Bone Screw Fastener, ST	28
340-6030	4.0 x 30mm Locking Bone Screw Fastener, ST	30
340-6032	4.0 x 32mm Locking Bone Screw Fastener, ST	32
340-6034	4.0 x 34mm Locking Bone Screw Fastener, ST	34
340-6036	4.0 x 36mm Locking Bone Screw Fastener, ST	36
340-6038	4.0 x 38mm Locking Bone Screw Fastener, ST	38
340-6040	4.0 x 40mm Locking Bone Screw Fastener, ST	40
340-6042	4.0 x 42mm Locking Bone Screw Fastener, ST	42
340-6044	4.0 x 44mm Locking Bone Screw Fastener, ST	44
340-6046	4.0 x 46mm Locking Bone Screw Fastener, ST	46
340-6048	4.0 x 48mm Locking Bone Screw Fastener, ST	48
340-6050	4.0 x 50mm Locking Bone Screw Fastener, ST	50
340-6052	4.0 x 52mm Locking Bone Screw Fastener, ST	52
340-6054	4.0 x 54mm Locking Bone Screw Fastener, ST	54
340-6056	4.0 x 56mm Locking Bone Screw Fastener, ST	56
340-6058	4.0 x 58mm Locking Bone Screw Fastener, ST	58
340-6060	4.0 x 60mm Locking Bone Screw Fastener, ST	60
335-1010	3.5 x 10mm Bone Screw Fastener, ST	10
335-1012	3.5 x 12mm Bone Screw Fastener, ST	12
335-1014	3.5 x 14mm Bone Screw Fastener, ST	14
335-1016	3.5 x 16mm Bone Screw Fastener, ST	16
335-1018	3.5 x 18mm Bone Screw Fastener, ST	18
335-1020	3.5 x 20mm Bone Screw Fastener, ST	20
335-1022	3.5 x 22mm Bone Screw Fastener, ST	22
335-1024	3.5 x 24mm Bone Screw Fastener, ST	24
335-1026	3.5 x 26mm Bone Screw Fastener, ST	26
335-1028	3.5 x 28mm Bone Screw Fastener, ST	28
335-1030	3.5 x 30mm Bone Screw Fastener, ST	30
335-1032	3.5 x 32mm Bone Screw Fastener, ST	32
335-1034	3.5 x 34mm Bone Screw Fastener, ST	34
335-1036	3.5 x 36mm Bone Screw Fastener, ST	36
335-1038	3.5 x 38mm Bone Screw Fastener, ST	38
335-1040	3.5 x 40mm Bone Screw Fastener, ST	40
335-1042	3.5 x 42mm Bone Screw Fastener, ST	42
335-1044	3.5 x 44mm Bone Screw Fastener, ST	44
335-1046	3.5 x 46mm Bone Screw Fastener, ST	46
335-1048	3.5 x 48mm Bone Screw Fastener, ST	48
335-1050	3.5 x 50mm Bone Screw Fastener, ST	50
335-1055	3.5 x 55mm Bone Screw Fastener, ST	55
335-1060	3.5 x 60mm Bone Screw Fastener, ST	60

Integrated Proximal Humerus Plate List

Part Number	Description	Number of Holes
316-03-090	Proximal Humerus Plate, 3 Hole	3
316-05-115	Proximal Humerus Plate, 5 Hole	5
316-07-140	Proximal Humerus Plate, 7 Hole	7

Instrument List

Part Number	Description
120001	K-Wire Sleeve
120002	Drill Sleeve
120003	Screw Insertion Sleeve
120004	Wire Depth Gauge
120005	2.8mm Drill 165mm, Calibrated
120006	Threaded Drill Guide
120007	4.0 x 110mm Standard Tap
120008	Metaphyseal Drill Guide
120009	1.5Nm Torque Limiter
120010	3.5mm Hex Driver
120011	Metaphyseal Drill Guide, Short
130010	1.60, K-wire, Trocar, Smooth, 150mm
110500	Countersink
110302	Silicone Handle,AO QC, 25mm x 135mm
110310	QC T-Handle
110205	Depth Gauge, 60mm
110522	3.5mm/2.5mm Universal Drill Sleeve
110013	2.5mm Drill
110014	2.5 x 145mm Drill
110103	Driver
110028	3.5mm Drill
110444	3.5mm Tap

Note

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