OsteoCentric® Trauma

Femoral Neck Fracture System

Surgical Technique

OsteoCentric TRAUMA

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Intended Use

The OsteoCentric Femoral Neck Fracture System is intended for use in internal fixation of femoral neck fractures of the proximal femur.

Indications for Use

The OsteoCentric Femoral Neck Fracture System is indicated for stable and unstable intertrochanteric and basilar neck fractures in which a stable medial buttress can be reconstructed.

The OsteoCentric Femoral Neck Fracture System is indicated for femoral neck fractures including intracapsular, transcervical, and subcapital 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:

- Allergies and sensitivities to materials in the device
- Active or latent infection
- Obesity
- Pathologic fractures
- Skeletal immaturity
- Osteoporosis or other disease resulting in osteopathology
- Previous implantation
- Tissue viability at or near the operative site
- Compromised blood flow at or near the operative site
- Mental or neuromuscular disorders
- Patient compliance
- Spinal fixation – this device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
- Sepsis
- Malignant primary or metastatic tumors

System Features

The OsteoCentric Femoral Neck Fracture System is designed to provide a bone-implant interface that can resist multi-directional loading encountered in-vivo. This improved interface provides continued immobilization, bone loading, and anatomical reduction in all bone types. The Femoral Neck Fracture System is a product dedicated to the fixation of femoral neck fractures. The design incorporates many innovative features including:

System

- Key-free system
- 316L stainless steel
- Compression Screw for increased compression across fracture

Instrumentation

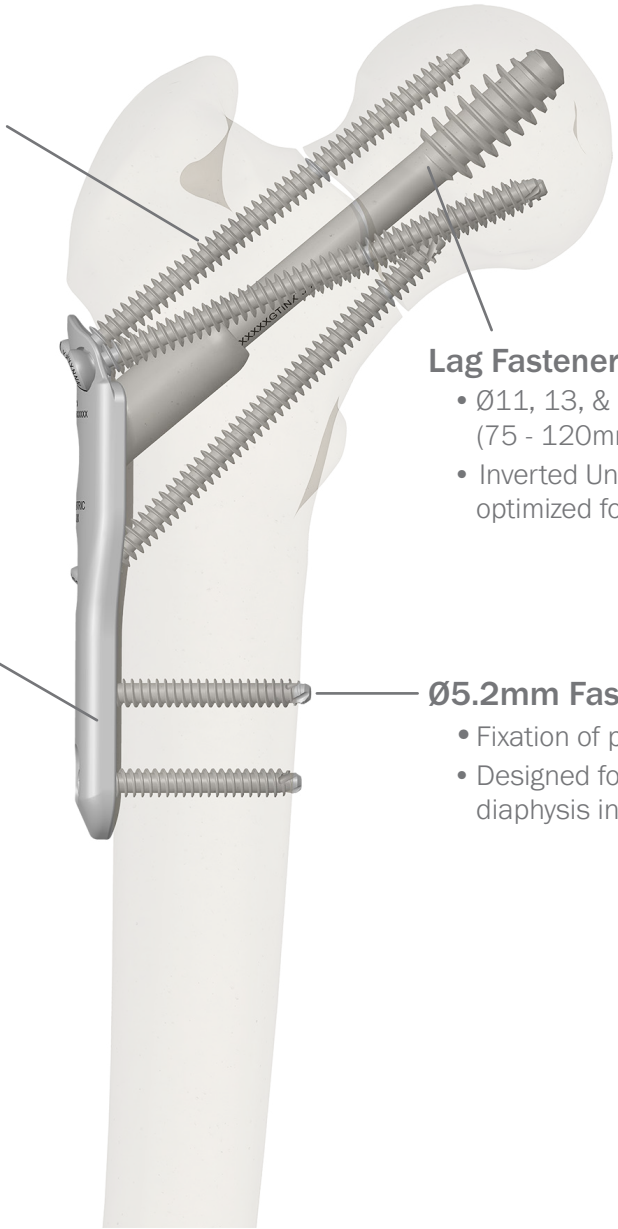
- Plate Guide can be placed & removed with a near-percutaneous incision
- Bone prep minimizes rotational forces on femoral head, with half taps included for dense bone (step tap method)
- Anti-Rotation Sleeve allows for accurate placement of pins into the femoral head to resist rotational forces

Ø6.0mm Fastener

- Provides rotational stability
- Large tooth height for maximum purchase in cancellous bone

Femoral Neck Fixation Plates

- 130° plate barrel angle
- Standard & extended plates (1-4 holes)
- Options for scalable fixation - 3 superior / 1 inferior hole for additional femoral head fixation



Lag Fastener

- Ø11, 13, & 15mm options (75 - 120mm)
- Inverted Unifi*MI* Technology optimized for compressive loads

Ø5.2mm Fastener

- Fixation of plate to femoral shaft
- Designed for femoral diaphysis insertion

The surgeon must select the type and size of implant that best meets the patient's surgical needs. Refer to the Instructions for Use for precautions, warnings, and cleaning instructions. To obtain these materials or more information about products, please contact Customer Service at 1-800-969-0639.

Surgical Technique

Preoperative Preparation & Exposure

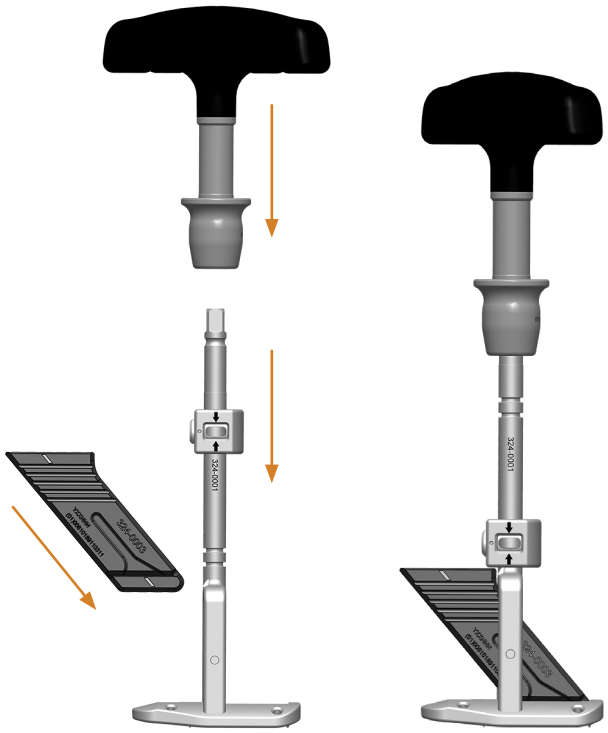
Prior to surgery, ensure the system is complete and appropriate implant sizes are available.

Create an appropriate length incision starting at the lateral aspect of the greater trochanter. This incision will be used for Guide Wire, Lag Fastener, & Plate insertion (Hohmann Retractors recommended).

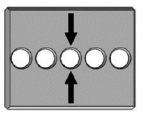
Ensure the fracture is adequately reduced.

Place Guide Wire

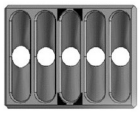
Assemble the targeting construct by connecting the T-Handle (110315) to the Plate Guide (324-0001) & selecting either the Fixed (324-0003) or Adjustable Targeting Insert (324-0004). Targeting Inserts can be locked into position by sliding into the Plate Guide & lowering the Adjustable Depth Stop (324-0011) onto the top of the Insert as shown.



Note: The Fixed Targeting Insert (324-0003) will create the 130° wire angle needed for the Fixation Plate, as well as keep the anterior-posterior alignment fixed. The Adjustable Targeting Insert (324-0004) will create a 130° wire angle while allowing for 9° anterior-posterior angulation if needed.



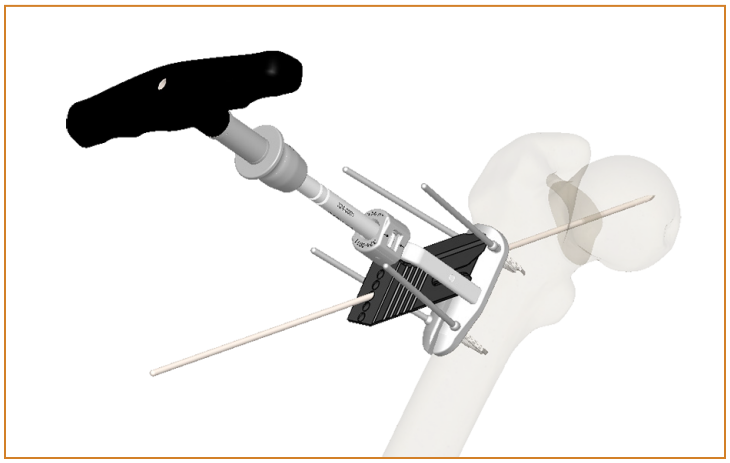
Fixed Targeting Insert



Adjustable Targeting Insert

Place the assembled targeting construct against the lateral side of the femur, ensuring the Plate Guide is aligned with the long axis of the femur. 2.7mm Olive Pins (324-0002) can be used for temporary fixation of the targeting construct. 2.7mm Olive Pins should be inserted in posterior holes first to avoid unintentional anterior rocking of the Plate Guide.

Place the 2.7mm Guide Wire (2004-0023) in the marked center targeting hole with a wire driver, to achieve center-center placement in the femoral head.



Note: If center-center Guide Wire placement in the femoral head is not achieved, Plate Guide removal is not required. Superior and inferior adjustments can be made by removing the Guide Wire and re-inserting in an adjacent targeting hole. If the Fixed Targeting Insert is used, it can be removed and replaced with the Adjustable Targeting Insert for A/P angular adjustments.

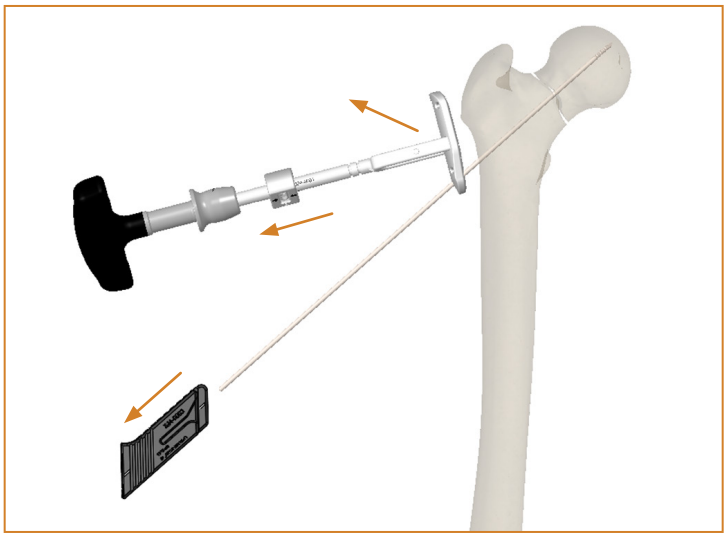
Note: The Plate Guide is a template for the position of the Fixation Plate against the lateral femur. The Plate Guide and Fixation Plate are the same width allowing identical anatomical placement.

Note: The Plate Guide allows for repositioning of the Guide Wire without moving the guide. If the Guide Wire is placed in the central marked hole of the (targeting insert), then the Fixation Plate will sit against the bone in the exact same location as the Plate Guide. If the Wire is moved superior or inferior to an adjacent hole, the final location of the Fixation Plate will move ~4mm per hole accordingly.

Note: Confirm final Femoral Neck Fixation Plate position by removing the Targeting Insert (fixed or adjustable) from the Plate Guide and placing the Fixed Targeting Insert over the updated Guide Wire position in the center targeting hole. If the Olive Pins remain, remove them, then move the Plate Guide so the Targeting Construct re-engages. The Plate Guide now shows the final position of the Fixation Plate.

After the Guide Wire is appropriately positioned in the center of the femoral head, remove the targeting construct in the following order:

- Disengage Adjustable Depth Stop & remove Targeting Insert
- Remove any Olive Pins
- Translate Plate Guide proximally, allowing Wire to pass through Plate Guide slot



Measure Guide Wire

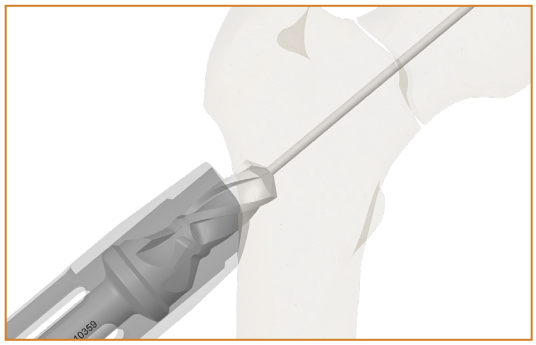
Slide the Guide Wire Depth Gauge (324-0005) over the Guide Wire and advance until resting against the lateral cortex. Note the end of the Guide Wire is read against the markings on the Depth Gauge to determine the appropriate length of Lag Fastener. If the Guide Wire reads between measurements, the smaller of the two sizes should be selected.

Note: Depth gauge subtracts 2mm from wire tip (102mm measures 100mm).

Ream

Place the Reamer Sleeve (324-0006) and the Barrel Reamer (324-0007) over the Guide Wire. Ensure the notched side is positioned distally to allow the sleeve to fully seat.

Under power, advance the Reamer until hitting a hard stop within the Reamer Sleeve. At full depth, the Barrel Reamer indicator will align with a corresponding mark on the Reamer Sleeve.



Warning and Precaution

With any system using guidance wires, special care should be taken to ensure the position of the Guide Wire, using fluoroscopy. Guide Wire placement should be verified periodically especially while using rotating instrumentation.

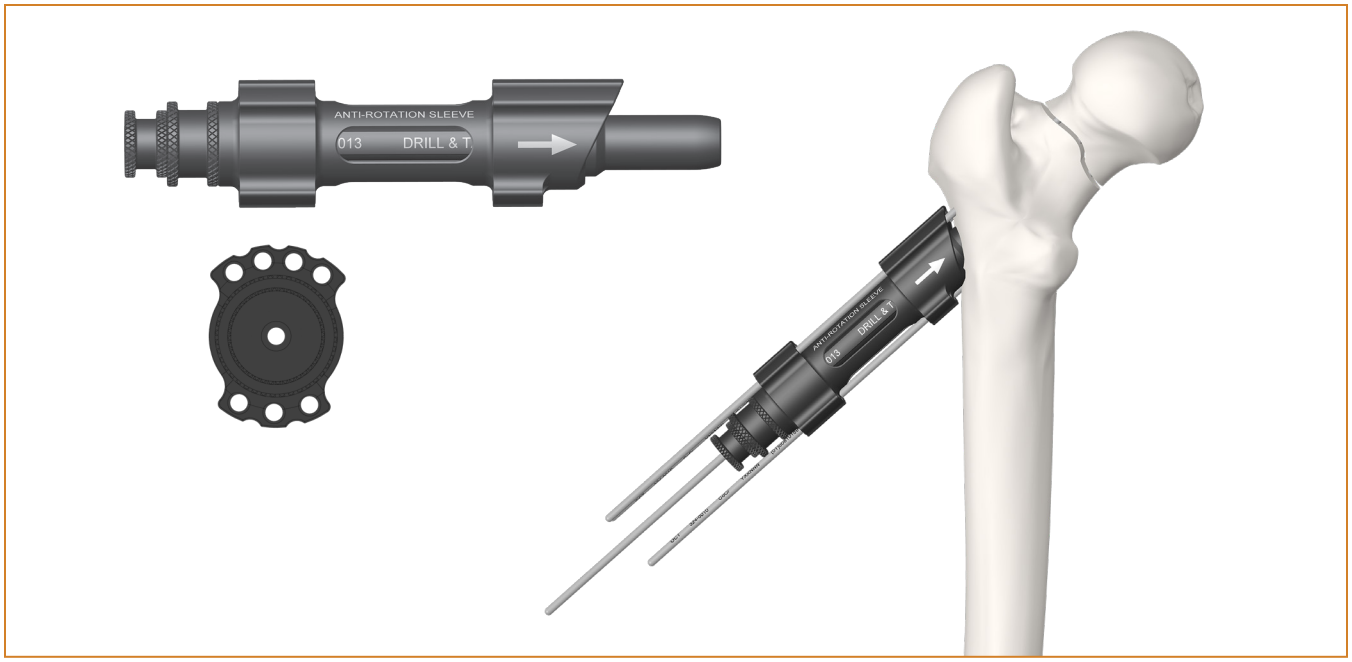
Anti-Rotation Pins

The Anti-Rotation Pins & Sleeve are used to resist rotation of the femoral head during drilling, tapping, & Lag Fastener insertion.

Place the triple sleeve assembly (324-0008, -0009, & -0013) over the Guide Wire until the Drill & Tap Sleeve is fully seated in the reamed barrel path. Orient the Anti-Rotation Sleeve onto the femur as shown.

Place the inferior Anti-Rotation Pin(s) (324-0010) first to maintain proper alignment. Ensure a minimum of one inferior and one superior Anti-Rotation Pin is inserted.

After placing all Anti-Rotation Pins, remove the Insert Centering Sleeve.



Drill Lag Fastener Path

Set the proper drill depth by sliding the Adjustable Depth Stop (324-0011) over the Ø8.2mm Drill Bit (324-0012) until the desired depth is visible in the window. Release the button allowing the Depth Stop to hold the position on the drill bit.

Note: If additional compression utilizing the Compression Screw is desired, a shorter Lag Fastener than what was measured may be used. The drill depth setting must correspond to the original measured depth to ensure the Lag Fastener will be fully inserted into subchondral bone & allow space for compression.

Insert the Ø8.2mm Drill Bit over the Guide Wire and through the Drill & Tap Sleeve. Advance the Drill Bit until the Depth Stop contacts the Drill & Tap Sleeve, indicating that the pilot hole has been drilled to the selected depth. Confirm appropriate drill depth using image intensification. If drill depth is too short, adjust the Adjustable Depth Stop & continue drilling to desired depth for final implant placement.

Remove the Drill Bit, Depth Stop, and Drill & Tap Sleeve. Ensure the Guide Wire stays in place.

Tap Lag Fastener Path

Note: The Lag Fastener cannot be inserted without tapping. Manual tapping the original measured length is required prior to Lag Fastener insertion. Ensure Anti-Rotation Pins remain in place for tapping.

Select Tap / Lag Fastener diameter (Ø11, Ø13, or Ø15mm) based on clinical need & patient anatomy. Slide the Drill & Tap Sleeve over the back end of the Tap (324-0014 to -0019).

Slide the Adjustable Depth Stop over the back end of the Tap until the desired length is visible in the window. Release the button allowing the Depth Stop to hold the position on the Tap.

Note: If additional compression utilizing the Compression Screw is desired, a shorter Lag Fastener may be used. The tap depth setting must correspond to the original measured / drilled depth to ensure the Lag Fastener will be fully inserted into subchondral bone.

Place the Tap construct over the Guide Wire and through the Anti-Rotation Sleeve.

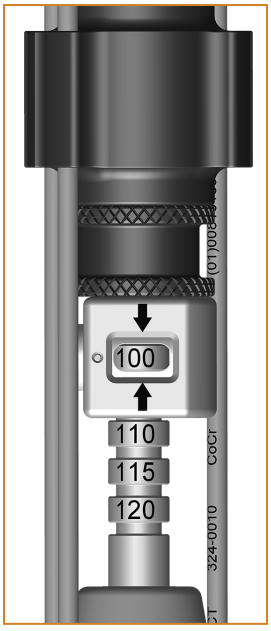
Advance the Tap manually using the T-Handle (110315) until the Depth Stop contacts the top of the Drill & Tap Sleeve, indicating the hole has been tapped to the selected depth. Ensure the Drill & Tap Sleeve is fully seated against the lateral cortex and the depth setting is correct. Use image intensification to confirm appropriate tap depth. If tap depth is too short, adjust the Adjustable Depth Stop & continue tapping the full drilled depth for final implant placement. Ensure pilot hole is drilled to proper depth with 8.2mm Drill Bit.

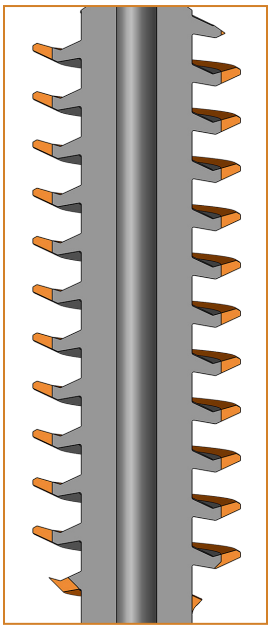
Remove the Tap construct. Ensure the Guide Wire stays in place.

Leave Anti-Rotation Sleeve and Anti-Rotation Pins in place.

Note: Take care to avoid sharp edges of the Tap while loading the Depth Stop and Drill & Tap Sleeve.

Note: If hard bone is anticipated or encountered during tapping, the half-tap of corresponding size (324-0014 to -0016) should be used first to tap the entire thread path (gray profile). The full-height tap still must be inserted to cutting the remaining tooth height (orange profile). This step-tap approach will lower insertion torque in hard bone during tapping & reduce the risk of femoral head/neck rotation.

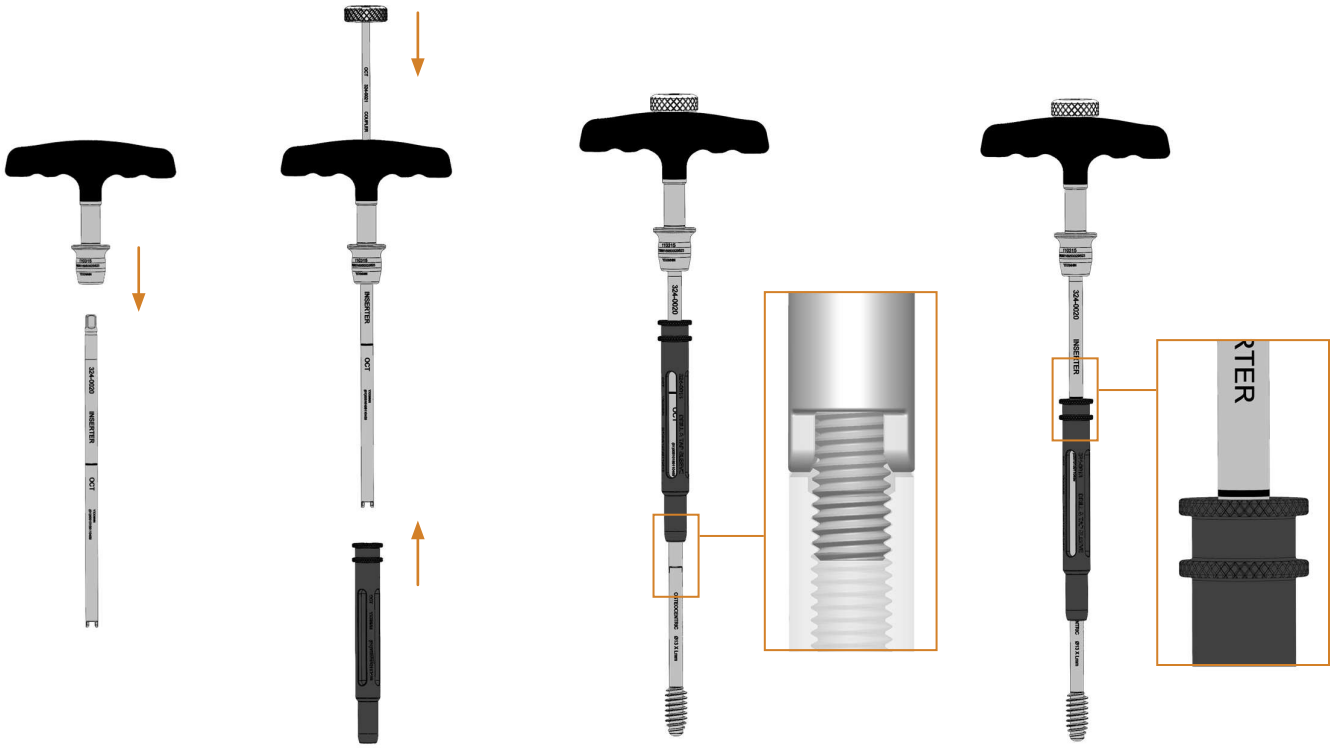




Insert Lag Fastener

Connect the Inserter (324-0020) to the T-Handle. Insert the Coupler (324-0021) through the T-Handle/ Inserter. Slide the Drill & Tap Sleeve onto the Inserter assembly as shown.

Attach the desired Lag Fastener by turning the Coupler until the Lag Fastener is fully seated on the Inserter tabs.

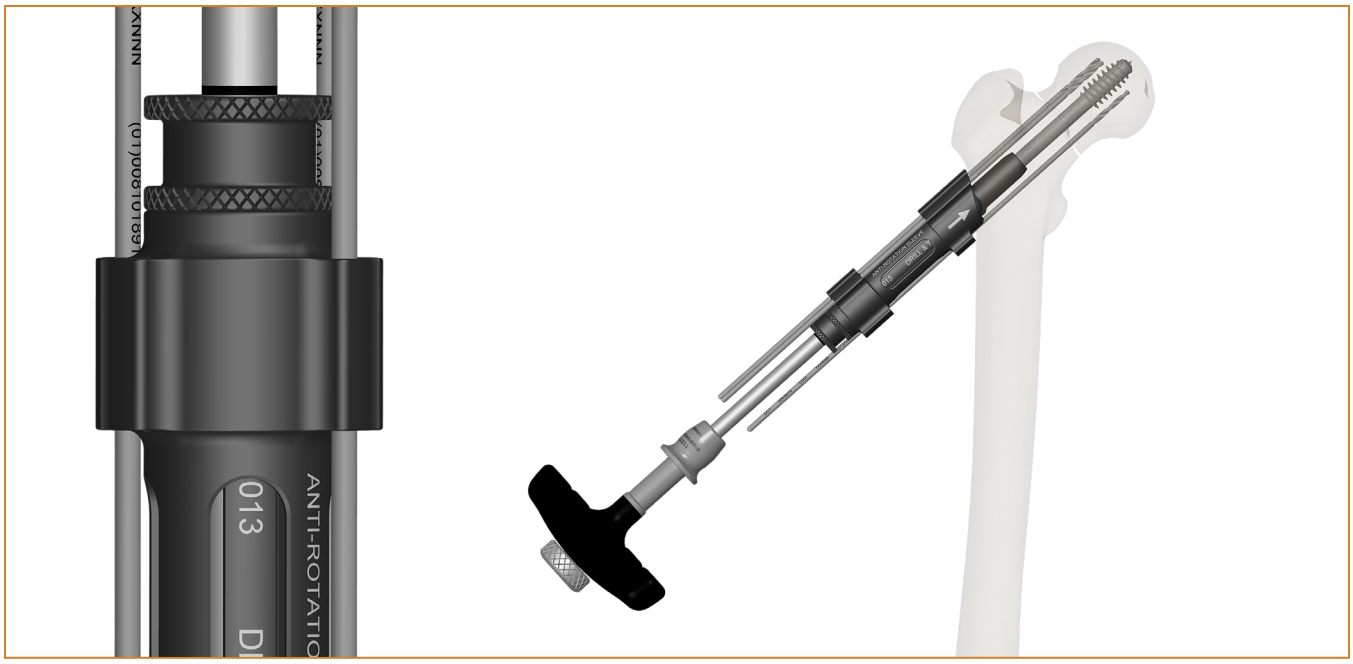


Slide the Lag Fastener onto the Guide Wire and advance into the tapped path.

Advance the Lag Fastener with the T-Handle until the desired depth is achieved. The inserter indicator will align with the end of the Drill & Tap Sleeve when the Lag Fastener is fully inserted. Ensure the Drill & Tap Sleeve is fully inserted.

Note: Insertion of the Lag Fastener should require minimal torque since the path has been tapped. Inserter provides visual indication that Lag Fastener has ben inserted fully (ensure the Drill & Tap Sleeve is fully seated). When the Lag Fastener reaches the end of the tapped path, a sudden increase in torque is expected. The Lag Fastener will not advance beyond the tapped depth.

Note: The Lag Fastener and Fixation Plate are not keyed.



Note: If a Lag Fastener that is shorter than the measured length is used, the calibrated mark on the Inserter will pass below the end of the Drill & Tap Sleeve and will not be visible.

Seat Fixation Plate

Seat the Femoral Neck Fixation Plate fully against the femur. If necessary, use the Impactor (324-0022) & Mallet (324-0023). Impactor consists of Impactor Shaft (324-0022) and Impactor Tip (324-0032).

Ø5.2mm Fasteners & Compression Screw (Optional)

Use the 4.0 / 5.2mm Drill Guide (324-0029) and the 4.0mm x 145mm Drill Bit (324-0034) to drill pilot holes for the Ø5.2mm Fasteners placed in the Fixation Plate Shaft. Use calibrated markings or Large Depth Gauge (110202) to determine fastener length.

Note: When the Depth Gauge (110202) tip does not seat into the plate slot completely (rests against the top surface of the plate), 3mm should be subtracted from the measured length.

If dense, hard bone is anticipated or encountered, it is recommended to use the Ø5.2mm Tap (110470) to prepare the bone for fastener insertion.

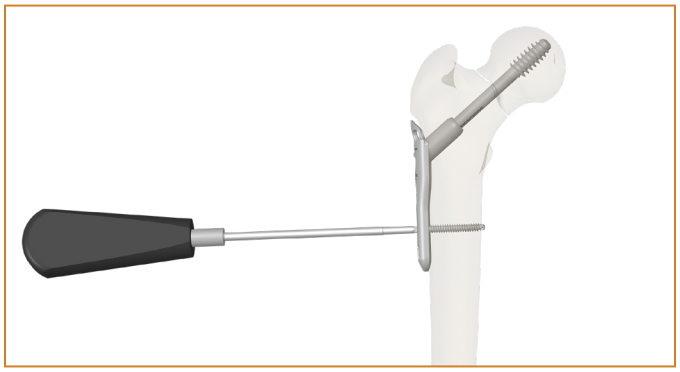
Use a 3.5mm Hex Driver to insert the Ø5.2mm Fastener(s) into the Fixation Plate.

Note: Ø5.2mm fasteners should be placed sequentially from proximal to distal.

If additional compression is desired, use a 3.5mm Hex Driver to insert the Compression Screw (324-60001) which compresses the fracture by threading into the Lag Fastener.

If additional fixation is needed, optional Support Fasteners may be placed across the fracture while the Compression Screw is in place. The Compression Screw may be removed after compression is achieved or left in place.

Note: If additional Ø6.0mm fastener(s) are used, ensure the Compression Screw is fully seated after insertion of Ø6.0mm fasteners.



Ø6.0mm Fasteners

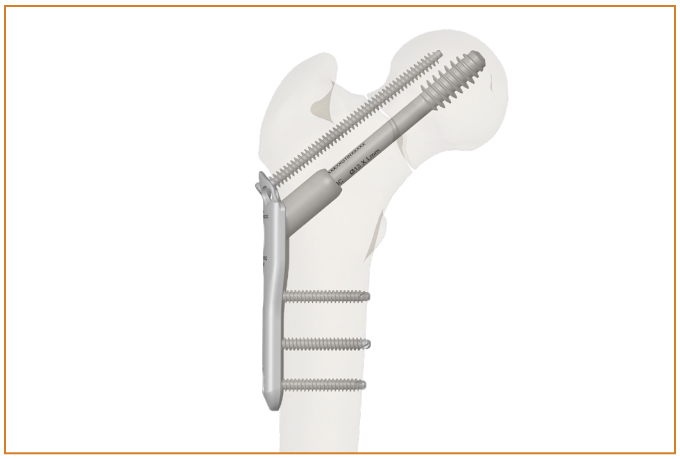
Use of Ø6.0mm Fasteners (360-1XXX) is optional and may be used for additional fixation or rotational control. Ø6.0mm Fasteners may be placed in any of the superior fastener holes on the Extended Femoral Neck Fixation Plate and/or in the first shaft hole of 2, 3 or 4-hole Fixation Plates. Ø6.0mm Fasteners should not be used in the shaft hole of 1-hole Fixation Plates.

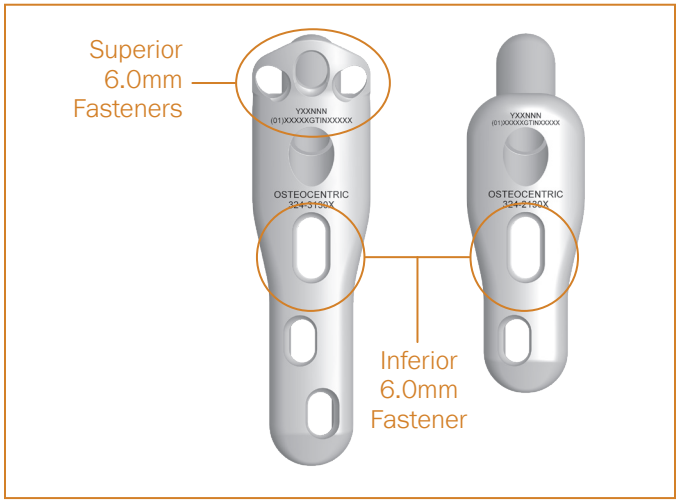
Use the 3.2 / 6.0mm Drill Guide (324-0024) and the 3.2mm x 190mm Drill Bit (324-0025) to drill pilot holes for the Ø6.0mm Fasteners. Use calibrated markings or Large Depth Gauge (110202) to determine fastener length.

If dense, hard bone is anticipated or encountered, it is recommended to use the Ø6.0mm Tap (110475) to prepare the bone for fastener insertion.

Use a 3.5mm Hex Driver to insert the Ø6.0mm fastener(s) into the Fixation Plate.

Ø6.0mm Fasteners can be used as lag fasteners if desired. Lag by technique is achieved by drilling a glide hole with the 6.0 X 145mm Drill Bit (324-0031).





Implant Removal

If implant removal is required, implants should be removed in reverse order in which they were inserted.

Ø6.0mm Fasteners should be removed using a 3.5mm Hex Driver.

Ø5.2mm Fasteners should be removed using a 3.5mm Hex Driver.

The Compression Screw should be removed using a 3.5mm Hex Driver.

The Femoral Neck Fixation Plate should be removed manually by levering the barrel over the end of the Lag Fastener.

The Lag Fastener can be removed by re-assembling the T-Handle, Inserter, & Coupler. The Coupler should be threaded into the back of the Lag Fastener completely before using the T-Handle to remove the Lag Fastener.

Alternate Technique: The Fixation Plate & Lag Fastener may be removed together if desired (especially longer plates). If this method is employed, the Inserter / Coupler should be placed through the Fixation Plate barrel until seating into the Lag Fastener. The Coupler should be threaded into the Lag Fastener. The T-Handle should be rotated to remove the Lag Fastener.

Implants

Lag Fastener

Length	Ø11mm	Ø13mm	Ø15mm
75mm	324-11075	324-13075	324-15075
80mm	324-11080	324-13080	324-15080
85mm	324-11085	324-13085	324-15085
90mm	324-11090	324-13090	324-15090
95mm	324-11095	324-13095	324-15095
100mm	324-11100	324-13100	324-15100
105mm	324-11105	324-13105	324-15105
110mm	324-11110	324-13110	324-15110
115mm	N/A	324-13115	N/A
120mm	N/A	324-13120	N/A

130° Femoral Neck Fixation Plate

Part #	Holes	Length
324-21301	1	45mm
324-21302	2	66mm
324-21303	3	82mm

130° Extended Femoral Neck Fixation Plate

Part #	Holes	Length
324-31301	1	57mm
324-31302	2	78mm
324-31303	3	94mm
324-31304	4	110mm

Compression Screw

Part #
324-60001

5.2mm Fastener

Part #	Length
352-1028	28mm
352-1030	30mm
352-1032	32mm
352-1034	34mm
352-1036	36mm
352-1038	38mm
352-1040	40mm
352-1042	42mm
352-1044	44mm
352-1046	46mm

6.0mm Fastener

Part #	Length
360-1055	55mm
360-1060	60mm
360-1065	65mm
360-1070	70mm
360-1075	75mm
360-1080	80mm
360-1085	85mm
360-1090	90mm
360-1095	95mm
360-1100	100mm
360-1105	105mm
360-1110	110mm
360-1115	115mm
360-1120	120mm
360-1125	125mm

Instruments

Part #	Description
324-0001	PLATE GUIDE
324-0002	2.7 X 100mm OLIVE PIN SS
324-0003	FIXED TARGETING INSERT
324-0004	ADJUSTABLE TARGETING INSERT
324-0005	GUIDE WIRE DEPTH GAUGE
324-0006	REAMER SLEEVE
324-0007	BARREL REAMER
324-0008	INSERT CENTERING SLEEVE
324-0009	ANTI-ROTATION SLEEVE
324-0010	2.7 X 250mm ANTI-ROTATION PIN
324-0011	ADJUSTABLE DEPTH STOP
324-0012	8.2mm CANNULATED LAG DRILL BIT
324-0013	DRILL & TAP SLEEVE
324-0014	11mm HALF TAP CANNULATED
324-0015	13mm HALF TAP CANNULATED
324-0016	15mm HALF TAP CANNULATED
324-0017	11mm TAP CANNULATED
324-0018	13mm TAP CANNULATED
324-0019	15mm TAP CANNULATED
324-0020	LAG FASTENER INSERTER
324-0021	LAG FASTENER COUPLER
324-0022	IMPACTOR SHAFT
324-0023	MALLET
324-0024	3.2 / 6.0mm DOUBLE DRILL GUIDE
324-0025	3.2 X 190mm DRILL BIT CALIBRATED
324-0029	4.0 / 5.2mm DOUBLE DRILL GUIDE
324-0030	3.5mm HEX DRIVER WITH PADDLE HANDLE
324-0031	6.0 X 165mm DRILL BIT
324-0032	IMPACTOR TIP
324-0033	LARGE AO QC HANDLE
324-0034	4.0 X 145mm DRILL BIT CALIBRATED
110100	3.5mm HEX DRIVER AO QC
110202	LARGE DEPTH GAUGE 125mm
110315	QC T HANDLE QUARTER IN SQUARE
110470	5.2mm FASTENER TAP
110475	6.0mm FASTENER TAP
2004-0023	2.7mm GUIDE WIRE THREADED TROCAR TIP CoCr 300mm

Additional Information

To learn more about the full line of innovative OsteoCentric Technologies surgical solutions, please contact us by calling 1-800-969-0639 or visiting our website at OsteoCentric.com

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Note

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