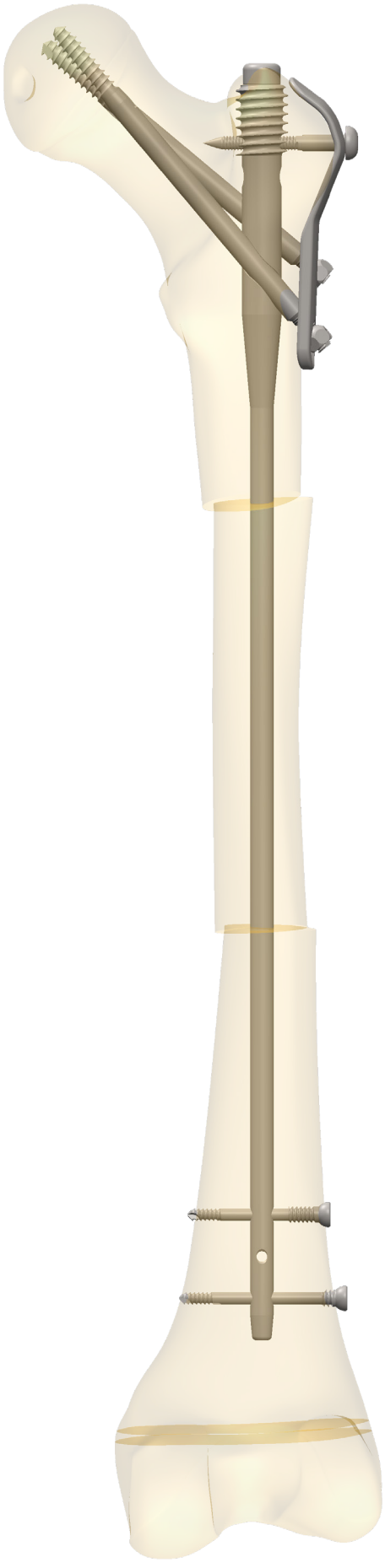
ENOX Nail

The endo-exo medullary system

SURGICAL TECHNIQUE



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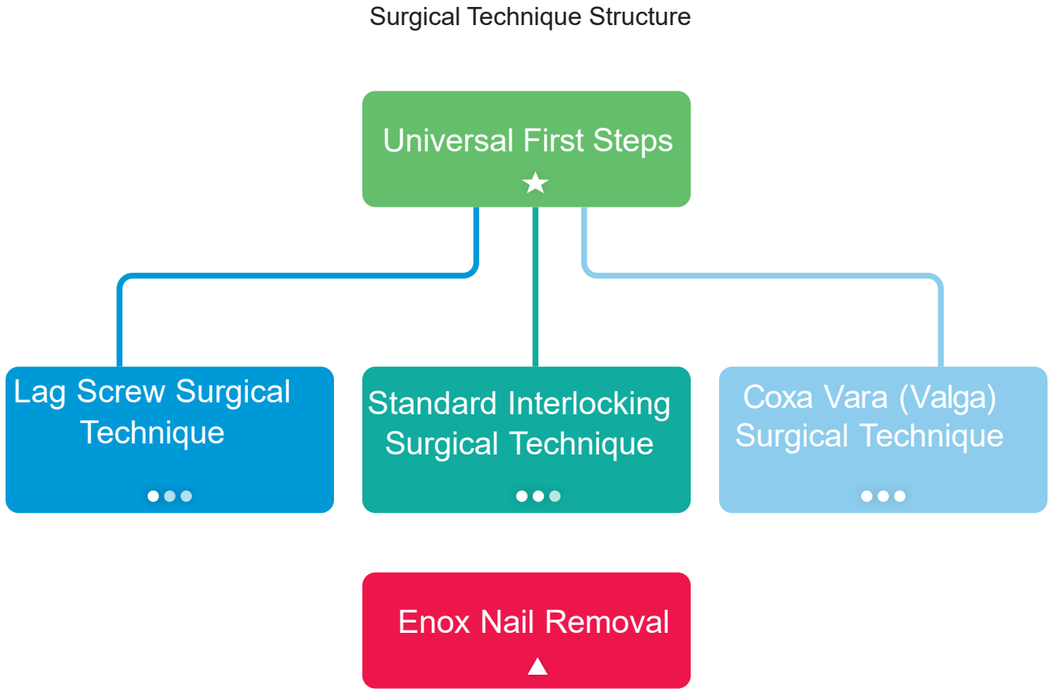


Device Description

The Enox Endo-Exo Medullary System is used for the treatment of fractures or correction of deformities in the femur, tibia and humerus of pediatric patients (child and adolescent).

It is intended as an invasive implantable device for long term implantation within the long bones of the femur, tibia and humerus.

The Enox nail consists of a cannulated straight shaft with a threaded head for proximal fixation into the bone. Distally, the nail's fixation is achieved though interlocking cortical screws or pegs.

In the case of humerus and tibia, where no lag screws are used, additional fixation at the head of the nail may be provided with a transversal cortical screw.

The intramedullary nail is linked to a plate via lag and mechanical screws to create a combined endomedullary/exomedullary osteosynthesis device.

Lag screws are secured to the plate via a hex nut in a semi-spherical seating. The lag screw holes are offset through the nail's axis. This configuration is intended to support the lag screw while maintaining the structural strength of the nail.

This approach aims to create a load sharing system between the nail and plate with the objective of limiting the risk of stress fractures and improving the implant stability.

The plates were designed for two main intended functions: a) provide lateral support to weak lateral cortex of an osteoporotic bone avoiding concentrated stresses at the screw head/bone interface; b) lock the lag screws when treating femoral neck fractures or to lock the k-wires when treating coxa vara or coxa valga using a subtrochanteric osteotomy. The plates are part of the system and are not intended to be used as stand-alone fracture plates.

The system is available is diameters ranging from 4.8 to 8.0mm in 0.8mm increments. Lengths available range from 160 to 320mm.

Distal locking options are a 2.5mm peg for the 4.8mm Nails, a 3.0mm cortical screw for the 5.6mm Nails, and 4.0mm cortical screw for the 6.4mm to 8.0mm Nails.

All implants are manufactured in medical grade Titanium

Intended Use/Purpose

The Enox Endo-Exo Medullary System is indicated as a temporary implant to ensure alignment, stabilization and fixation of pathological long bones that have been surgically prepared (osteotomy) for correction of deformities or fractures caused by trauma or disease.

Indications For Use

The Enox System is used for pediatric patients (child and adolescent) with skeletal dysplasias. It can be used to correct the following conditions:

- Diaphyseal fracture of the femur, tibia and humerus
- Fractures of the femoral neck
- Subtrochanteric, intertrochanteric and combination fractures
- Correction of deformities (OI, Coxa vara, Coxa valga)
- Nonunions and malunions

Intended Users

Note: The device is intended for professional use only.

The intended users for the Enox Endo-Exo Medullary System are orthopedic surgeons.

Contraindications

Do not use in any situation that is not described in the Intended Use section of this insert.

Devices should not be used in patients with:

- Active or suspected latent infection or marked local inflammation in or about the affected area.
- Osteoporosis, insufficient quality or quantity of bone/soft tissue
- Compromised vascularity inhibiting adequate blood supply to the operative site.
- Documented or suspected material sensitivity.
- Sepsis
- Patients with abnormal neurological or mental conditions that compromise their ability to follow a post-operative regimen.
- Other medical or surgical conditions which would preclude the potential benefit of surgery.

Universal First Steps

Step 0 Preoperative Planning

Implant configuration

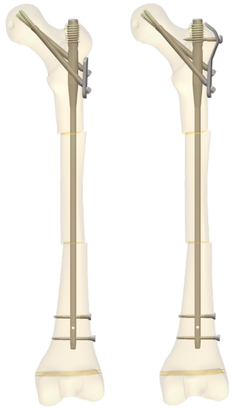
The Enox Nail can be used for 3 surgical techniques in 3 different long bones.

The technique should be chosen following an assessment of the patient's condition.

Lag Screw Surgical Technique

This technique allows the protection of the femoral neck with the use of Lag Screws.

Two choices of plates are offered . The Short Plate has a smaller footprint while the long plate helps to protect the lateral aspect of the greater trochanter

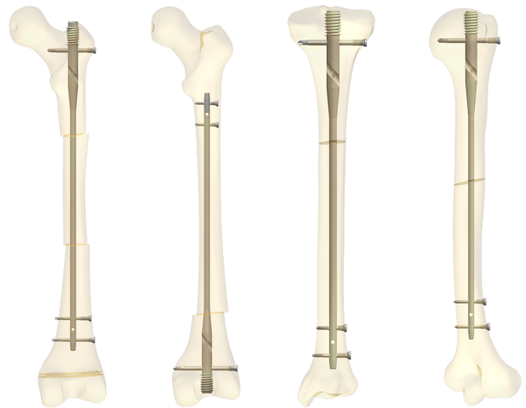


Antegrade Femur:

- Femoral Neck Fixation
- Trochanteric Fractures
- Deformity Correction
- Diaphyseal Fractures

Standard Interlocking Surgical Technique

The Enox Nail can be locked proximally using medial lateral cortical screw and distally using 3 cortical screw (minimum 2), 2 medial-lateral and 1 anterior-posterior.



Antegrade Femur:

- Proximal Fractures
- Diaphyseal Fractures
- Deformity Correction

Retrograde Femur:

- Diaphyseal Fractures
- Distal Fractures
- Deformity Correction

Antegrade Tibia:

- Proximal Fractures
- Diaphyseal Fractures
- Deformity Correction

Antegrade Humerus:

- Proximal Fractures
- Diaphyseal Fractures
- Deformity Correction

Coxa Vara (Valga) Surgical Technique

This technique offers an option for femur with femoral neck too small for the Lag Screw to go through. By using Steinmann Pins, it allows the neck to still be protected. A variety of coxa vara plates are also offered to create the load sharing system.

Antegrade Femur:

- Coxa Vara Correction

Step 1 Nail Selection

The diameter of the nail is selected based on the size of the medullary canal at the isthmus and can be determined preoperatively .

The nail's length can be estimated preoperatively but the final length is determined after osteotomy or fracture reduction.

Antegrade Femur

Using an AP view, the entry point should be at the tip of the greater trochanter. Move the C-arm distally and select the length corresponding to the desired nail insertion depth.

Retrograde Femur

The Nail's head should be fully inserted within the femur and not protrude into the articulation.

Antegrade Tibia

The Nail's head should be fully inserted within the tibia and not protrude into the articulation. The distal segment should extend up to the physeal scar.

Antegrade Humerus

The Nail should extend from the top of the greater tuberosity to the level of the flare created by the medial and lateral ridges.

CAUTION: Select Nail as long as possible so that distal interlocking cortical screws are the furthest away from the fracture/osteotomy site.

CAUTION: The Enox System can only be used for patients weighing 60 kg or less, or as indicated in the following table.

Nail Size	Max. Patient Weight
Ø4.8	40 kg
Ø5.6	40kg
Ø6.4	50kg
Ø7.2 and above	60kg

The Nail available in the implant case Enox are shown in the following table:

Enox Nail

Ø / Shaft	Ø / Head	Ø / Neck	160 mm	180 mm	200 mm	220 mm	240 mm	260 mm	280 mm	300 mm	320 mm
4.8	12.0	9.2	4005148160	4005148180	4005148200	4005148220	4005148240	4005148260	4005148280	4005148300	4005148320
5.6	12.0	9.2	4005156160	4005156180	4005156200	4005156220	4005156240	4005156260	4005156280	4005156300	4005156320
6.4	12.0	9.2	4005164160	4005164180	4005164200	4005164220	4005164240	4005164260	4005164280	4005164300	4005164320
7.2	12.5	9.5	4005172160	4005172180	4005172200	4005172220	4005172240	4005172260	4005172280	4005172300	4005172320
8.0	12.5	9.5	--	--	--	--	--	--	4005108280	4005108300	4005108320

*Special order.

Step 2 Patient Position

Antegrade Femur

Place the patient in a modified supine position, with the affected limb elevated using a folded sheet and the ipsilateral arm secured across the patient's torso. Position the image intensification to allow visualization of the proximal femur in both AP and sagittal views. The affected leg can be adducted 10-15° and the patient's torso can be bent away from the affected leg to facilitate access to the tip of the greater trochanter.

Retrograde Femur/Antegrade Tibia

Place the patient in a supine position on the surgical table with the knee of the affected limb flexed at 90°.

Antegrade Humerus

Place the patient in a semi-reclined (beach chair position) or in a supine position on the surgical table. If the patient is placed in a supine position, extend the ipsilateral shoulder to improve access to the entry point. The head should be tilted to the opposite side (not turned) with the endotracheal tube fixed on the opposite side of the mouth.

Step 3 Entry point/Incision

Antegrade Femur

Through a classic posterolateral approach, the femur is exposed subperiosteally. An entry point through the tip of the greater trochanter is used in adolescents to avoid the piriformis fossa.

Retrograde Femur

The incision is made centered over, but not through, the patellar ligament.

Special care should be taken not to injure the medial and lateral menisci, the articular cartilage or the ACL. The entry point is located in the intercondylar notch, anterior and lateral to the femoral attachment of the posterior cruciate ligament.

Antegrade Tibia

The incision is made centered over, but not through, the patellar ligament. Special care should be taken not to injure the medial and lateral menisci, the articular cartilage or the ACL. The entry point should be in line with the anatomical axis, medial to the lateral tibial eminence or just lateral to the midline.

Antegrade Humerus

A skin incision is made from the AC joint to the beginning of the deltoid fibers splitting the deltoid fibers and underlying supraspinatus tendon. Special care should be taken not to damage the coracoacromial ligament and sub deltoid bursa.

The entry point in the humeral head should be in line with the bicipital groove, which is aligned with the intramedullary canal.

Step 4 Osteotomy

Perform the required osteotomy under image intensification guidance to correct the existing deformities.

NOTE: It is possible to begin the insertion of the Guide Wire (see step 5) before performing the first osteotomy to help determine where they should be done and to help position the Guide Wire as needed.

Step 5 Guide Wire Insertion

For an antegrade femur, the femur is exposed subperiosteally through a classic posterolateral approach. An entry point through the tip of the greater trochanter is used in adolescents to avoid the piriformis fossa.

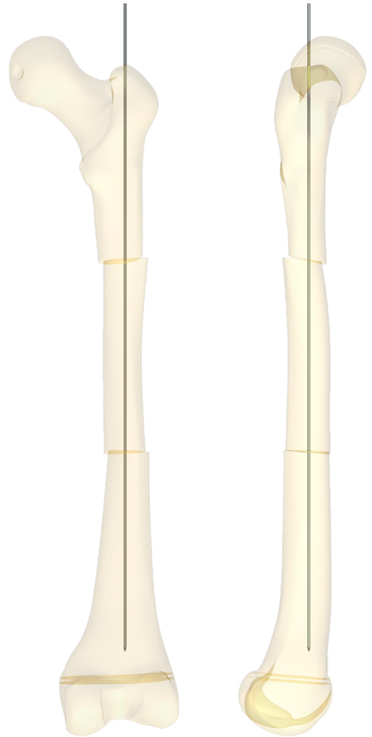
Select the Guide Wire for the Nail size.

Nail size	Guidewire to use
Ø4.8, Ø5.6, Ø6.4	1.6mm
Ø7.2, Ø8.0	2.0mm

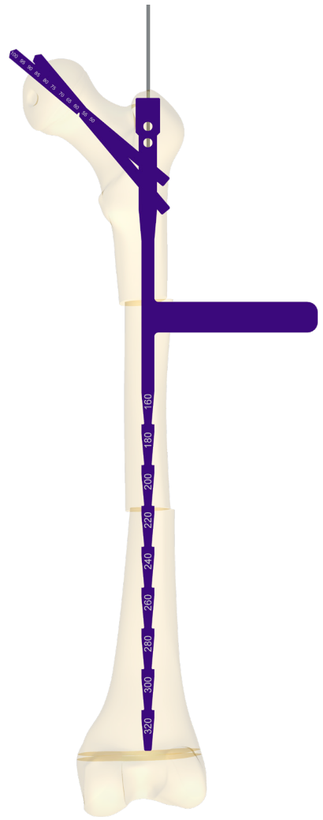
NOTE: All instruments are canulated for a 2.0mm Guide Wire .

NOTE: An 18" Guide Wire can also be used (not provided in case) to ensure it protrudes from the power tools. See table above for appropriate diameter.

Insert the wire and validate the position under image intensification in both AP and lateral views prior to reaming. The wire should be in line with the femoral neck in the lateral view.



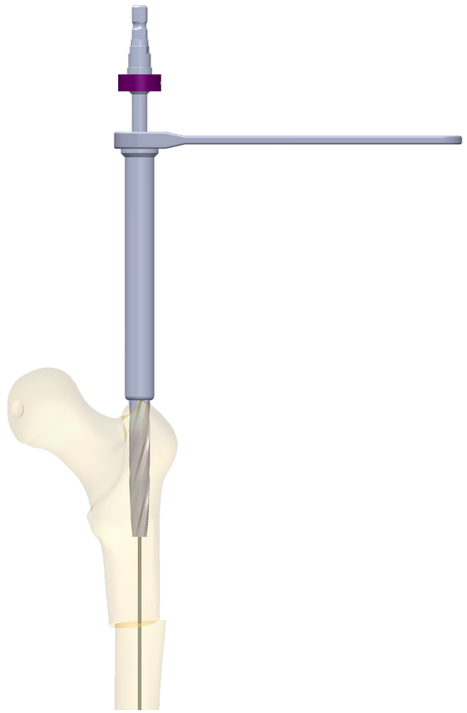
The Enox Nail Template can be used under image intensification to validate the Nail's length, position and depth of insertion. The Nail's head should be fully inserted within the femur and not protrude into the articulation.



CAUTION: Select Nail as long as possible so that distal interlocking Cortical Screws are the furthest away from the fracture/osteotomy site.

Step 6 Conical Reaming

Place the Tissue Protector over the Guide Wire. Using the Conical Reamer, ream through the Tissue Protector and over the wire up to the stopper.



CAUTION: Do not force the reamer. Partially retract it to clean debris from the medullary canal if resistance is felt.

CAUTION: To minimize the risk of overheating, avoid prolonged or excessive reaming in one area, and regularly inspect both the instrument and bone for signs of heat buildup.

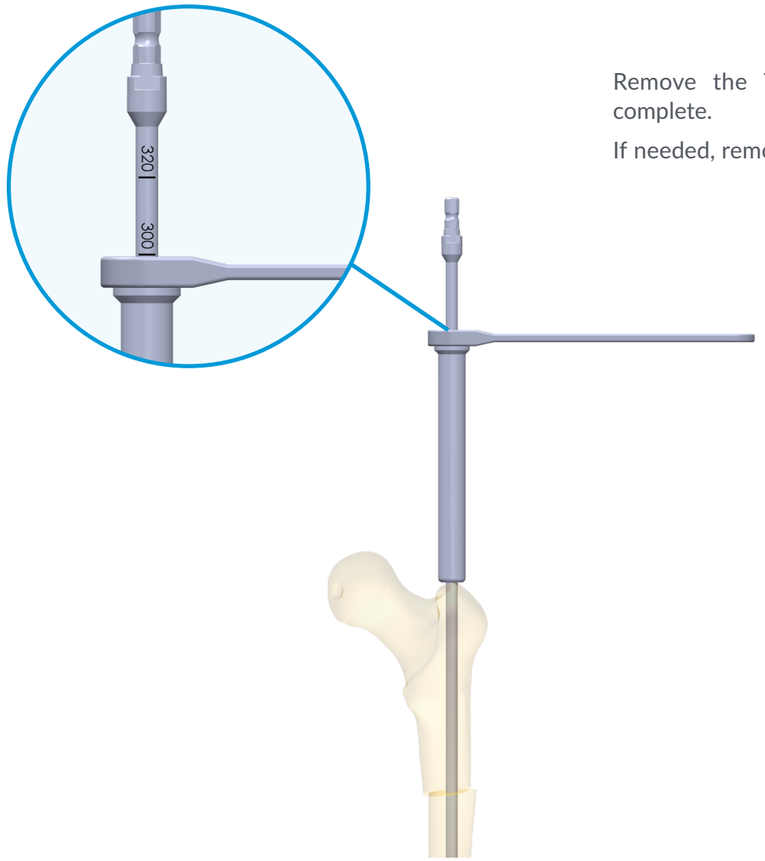
NOTE: The drills and reamers are compatible with powered drills equipped with quickconnect adaptor (A/O and Zimmer-hall).

Step 7 Medullary Canal Reaming

Select the Canal Reamer corresponding to the nail's size.

Nail size	Canal Reamer
Ø4.8	5551751248
Ø5.6	5551751256
Ø6.4	5551751264
Ø7.2	5551751272
Ø8.0	5551751280

Ream through the Tissue Protector and over the Guide Wire. Advance the reamer with steady and moderate pressure.



Ream until the depth marking corresponding to selected Nail's length reaches the top edge of the Tissue Protector handle.

CAUTION: Do not force the reamer. Partially retract it to clean debris from the medullary canal if resistance is felt.

CAUTION: To minimize the risk of overheating, avoid prolonged or excessive reaming in one area, and regularly inspect both the instrument and bone for signs of heat buildup.

Remove the Tissue Protector once reaming is complete.

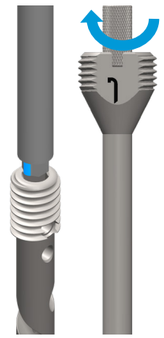
If needed, remove the wire.

Step 8 Nail Insertion

8.1 Nail Driver Assembly

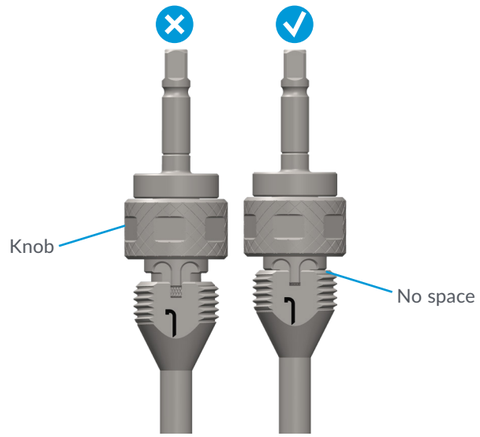
Insert the tip of the Enox Nail Driver in the head of the selected Nail. To assemble, the circular notch on the hexagonal hex of the Nail Driver must align with the corresponding notch in the Nail.

Insert the Enox Nail Driver Screw into the Nail Driver and thread into the Nail until it's finger tight.



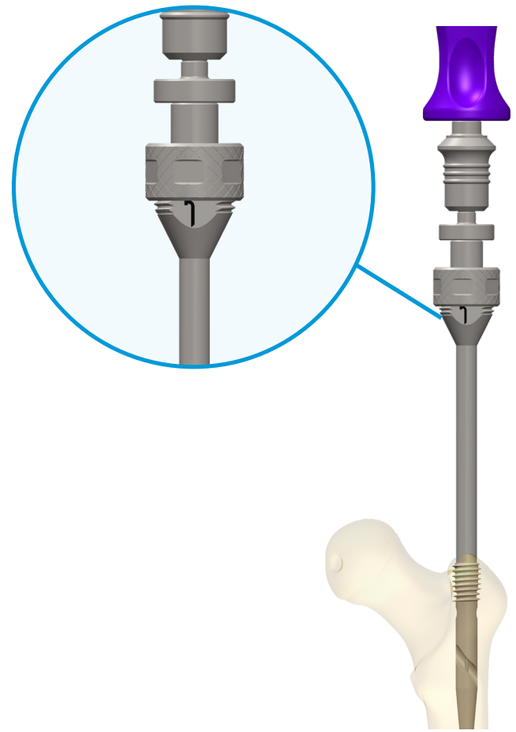
8.2 Nail Driver Adaptor Assembly

Attach the Nail Driver Adaptor onto the Nail Driver. Turn the knob to secure in place. Connect the Axial Handle onto the quick connect of the adaptor.



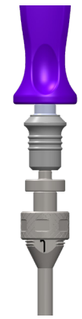
8.3 Nail Insertion

Insert the Nail to its final position. The markings on the Nail Driver indicates the orientation of the Targeting Device.



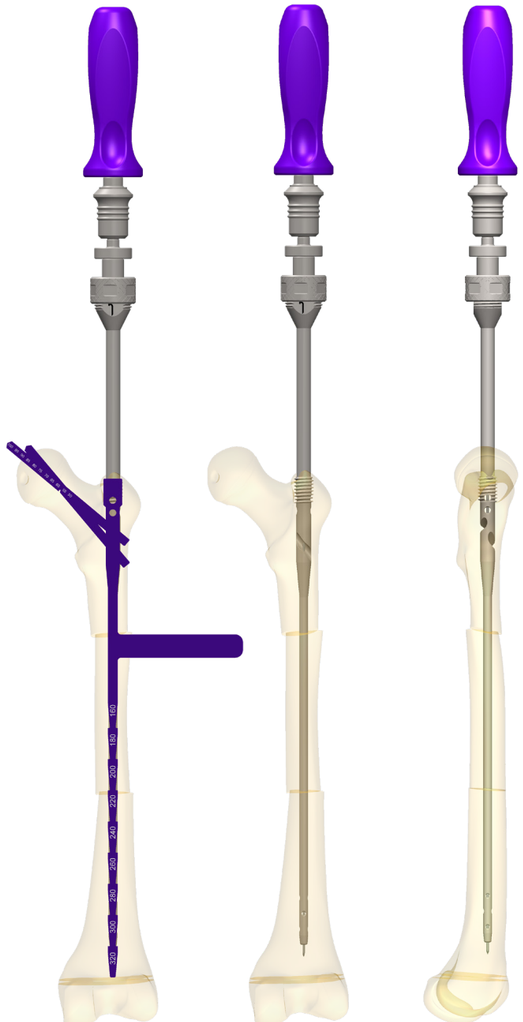
CAUTION: Do not hit the Nail Driver. The Nail should be inserted with minimal force .

CAUTION: The Nail's head should be fully inserted within the bone and not protrude into the articulation.



Step 9 Nail Position Verification

Verify proper alignment of the Nail in both AP and lateral views under image intensification.



In the AP view, verify the Nail's depth and Lag Screw alignment in relation to the neck of the femur. The Enox Nail Template can be used to better approximate the Lag Screws' final position and length.

In the lateral view, verify the centering of the lag holes with the femoral neck; the proximal holes should appear circular in this view. Finally, verify the distal position of the Nail.

CAUTION: The Nail can be inserted further into the bone to better align with the femoral neck if necessary.

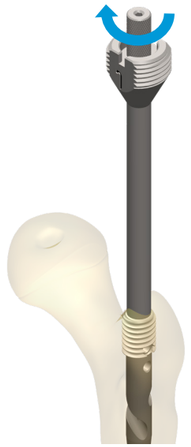
NOTE: Every full revolution of the nail corresponds to 2.4mm of insertion.

When the desired position is attained, remove the handle and the adaptor. Remove the wire (unless removed previously).

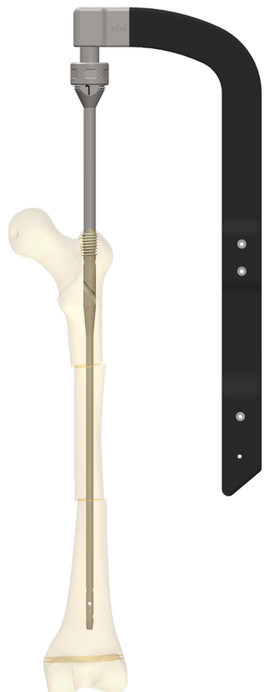
Step 10 Lag Screw Preparation

10.1 Targeting Device Assembly

Ensure the Nail Driver Screw is still secure by retighten the knob of the Nail Driver Screw.



Attach the Targeting Device onto the Nail Driver. Turn the knob to secure in place.

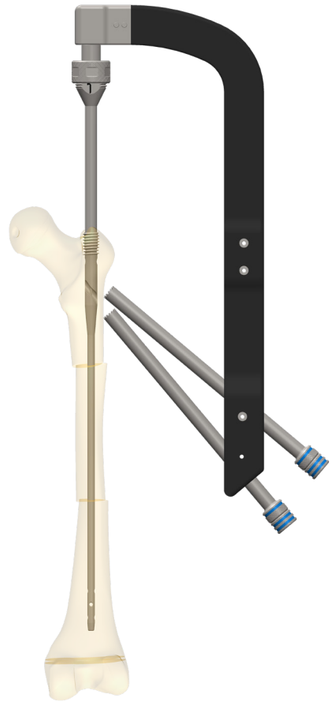


10.2 Lag Screw Preparation

Sleeve Assembly

Insert the Lag Wire Sleeves into each of the Lag Screw Sleeves. Insert the sleeve assemblies in the lag holes (blue) of the Targeting Device. Make stab incisions and push the sleeves up against the cortex.

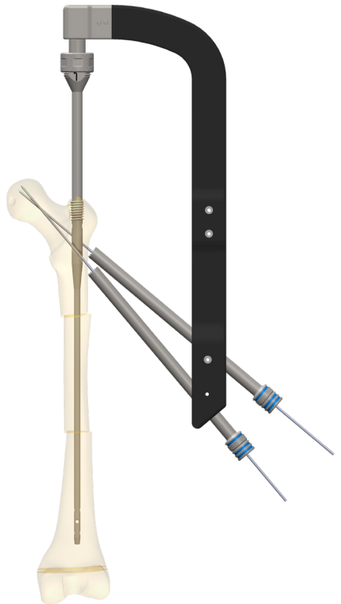
CAUTION: Do not exert forces on the Targeting Device. Such forces may render the targeting inaccurate.

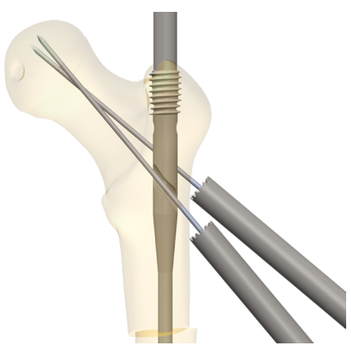


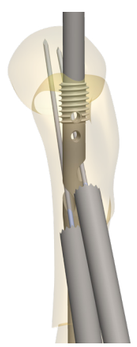
Lag Wire Insertion

Insert the two calibrated 3.2x343 Guide Pin(571674130) through the Lag Wire Sleeves and into the femoral neck. Position at desired depth.

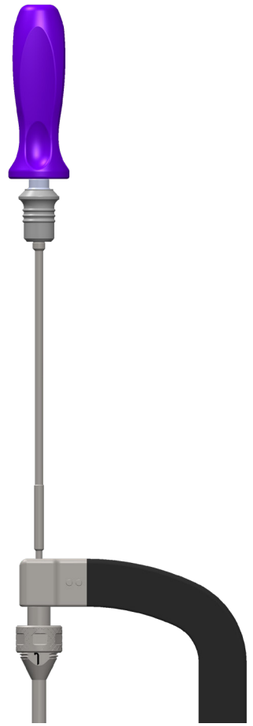
Check the wires placement in both the AP and lateral views. They should be centered within the femoral neck.







CAUTION: While using the Targeting Device, if the connection between it and the Nail becomes loose, use the 2.5mm Hex Screwdriver with handle to retighten them through the hole at the top of the Targeting Device.



10.3 Targeting Device Locking (Optional

Use if there is instability and/or if implanting a Long Plate.

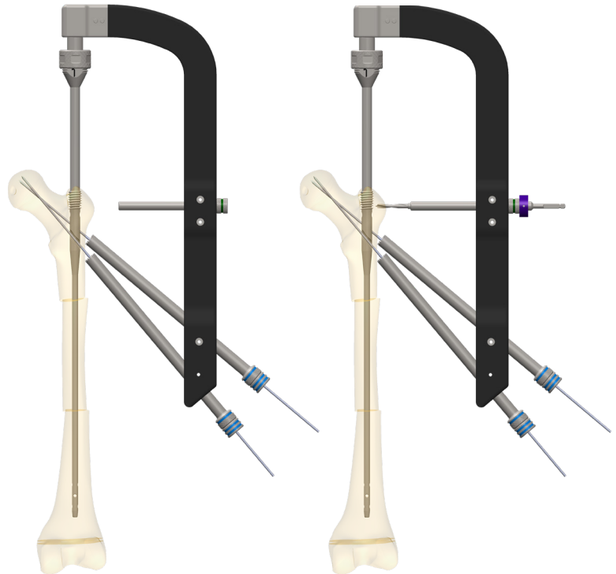
Mechanical Screw Hole Preparation

Mount the Mechanical Screw Sleeve into the mechanical hole (green) of the Targeting Device.

Ream to stopper using the Mechanical Screw Drill.

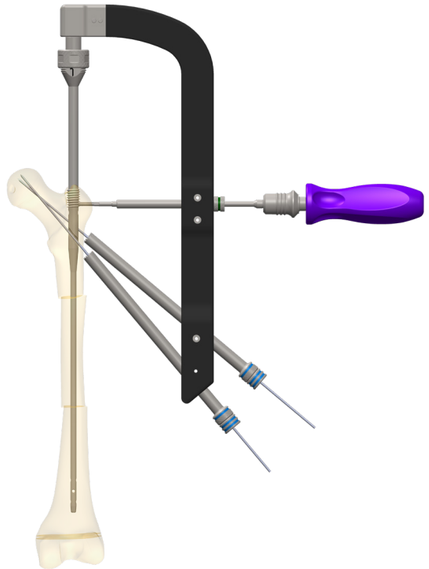
CAUTION: To minimize the risk of overheating, avoid prolonged or excessive reaming in one area, and regularly inspect both the instrument and bone for signs of heat buildup.

Remove the drill. Leave the sleeve in.



Mechanical Screw Pin Insertion

Mount the handle onto the Mechanical Screw Pin. Insert the pin through the sleeve and thread until it is fully engaged in the Nail. If resistance is felt, retract the pin and clean out the hole.



CAUTION: Do not overtighten the pin; this can cause a misalignment between the Targeting Device and the Nail.

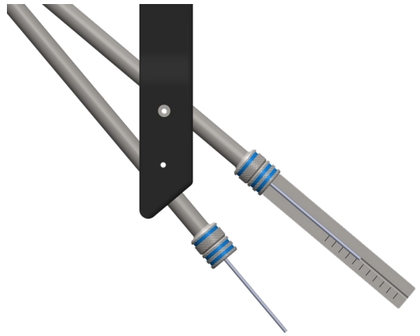
Step 11 Lag Screw Insertion

CAUTION: For fractures or osteotomies below the lesser trochanter combined with the limitation presented in the following table should be observe.

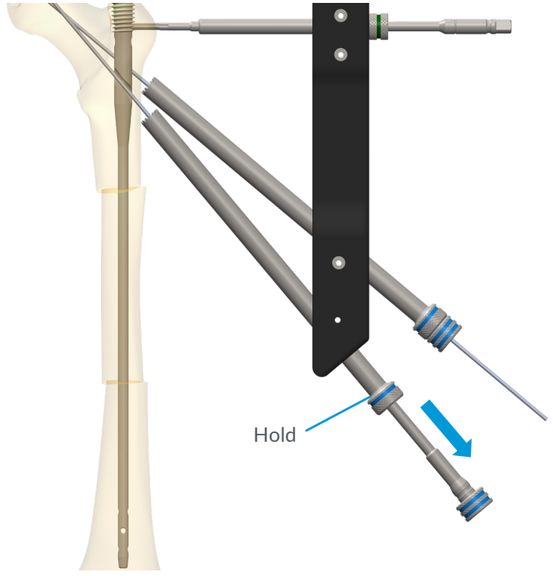
Nail Size	Max. Allowable Lag Screw Length	Max. Patient Weight
Ø4.8	50mm	40 kg
Ø5.6	70mm	40kg
Ø6.4	80mm	50kg
Ø7.2 and above	No limit	60kg

11.1 Lag Screw Length Measurement

Using the Lag Depth Ruler , measure both Lag Screws length. If a measurement is in-between two markings, always select the shorter length.



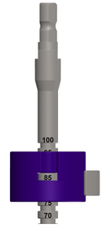
Leave the Lag Wires and the Lag Screw Sleeve in place and remove the Lag Depth Ruler. Holding onto the Lag Screw Sleeves, pull out the Lag Wire Sleeves .



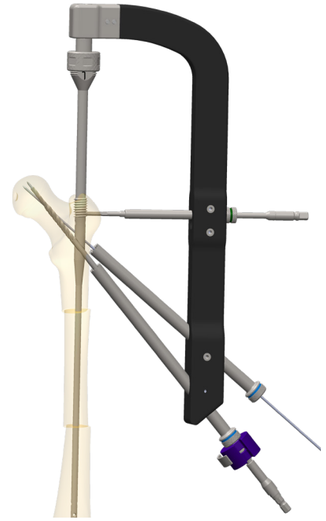
11.2 Lag Hole Reaming

CAUTION: While using the Targeting Device, if the connection between it and the Nail becomes loose, use the 2.5mm Hex Screwdriver with handle to retighten them through the hole at the top of the Targeting Device.

Insert the Position Lock onto the Lag Reamer (through its tip. Using the Position Lock, set the reamer's depth to the desired length.



Ream up to the stopper.



CAUTION: Visualize the reaming procedure under image intensification to ensure that the wires are not driven into the articulation.

CAUTION: Do not exert forces on the Targeting Device or Sleeve. Such forces may prevent accurate targeting resulting in damage to the implant and reamer.

CAUTION: To minimize the risk of overheating, avoid prolonged or excessive reaming in one area, and regularly inspect both the instrument and bone for signs of heat buildup.

NOTE: For the upper lag hole, the reamer can be set to reverse to facilitate reaming through the Nail.

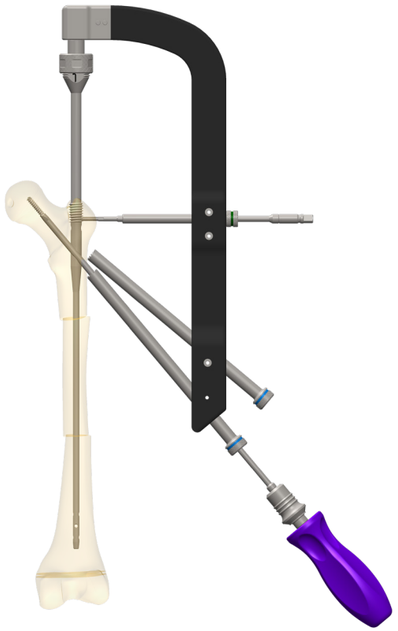
Repeat for the second lag hole.

Remove the Lag Wires.

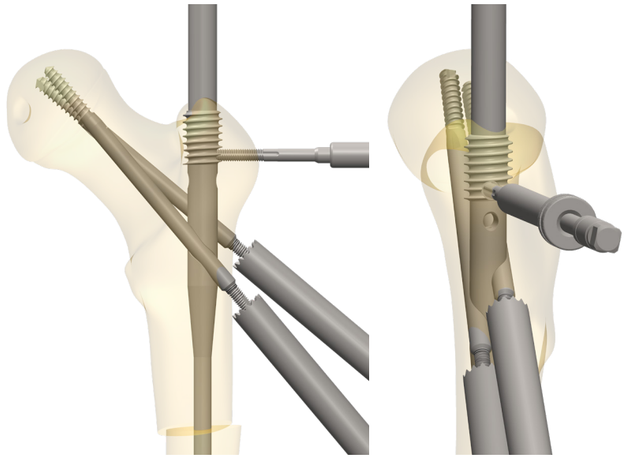
11.3 Lag Screws Insertion

Using the Lag Screwdriver with handle, insert the appropriate Lag Screw through the Lag Screw Sleeve.

Lag Screw	Size (mm)
4005100050	50
4005100055	55
4005100060	60
4005100065	65
4005100070	70
4005100075	75
4005100080	80
4005100085	85
4005100090	90
4005100095	95
4005100100	100



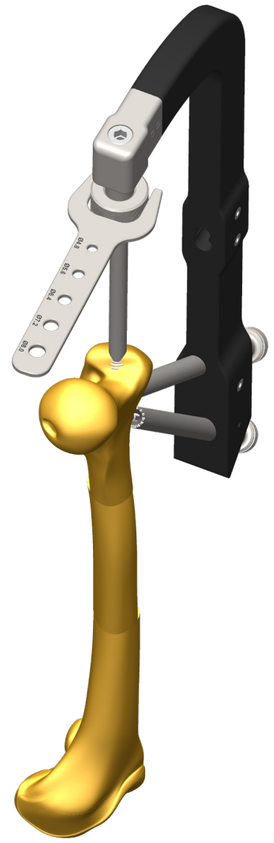
Verify the position of the screws under image intensification in both planes. The screws' shafts should be fully within the cortex leaving only the threaded segment protruding from the lateral cortex.



Step 12 Targeting Device Removal

Remove the Mechanical Screw Pin and Mechanical Screw Sleeve. Untighten the knob of the Targeting Device to detach it from the Nail Driver.

CAUTION: If the knob is hard to untighten, the Multipurpose Wrench can be used.



Unthread the Nail Driver Screw and remove the Nail Driver.

CAUTION: If the Nail Driver Screw cannot be unthreaded by hand, use the Short 2.5mm Hex Screwdriver with handle to unthread it.

Step 13 Distal Locking – Perfect Circle Technique

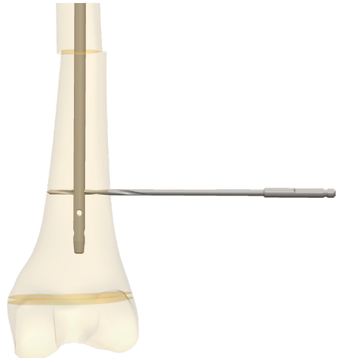
Nail Size	Distal Screw	Cortical Drill
Ø4.8	1035400020-XX (2.5mm)	5551751202
Ø5.6	1035403020-XX (3.0mm)	5551751203
Ø6.4/7.2/8.0	1035404020XX (4.0mm)	5551751204

13.1 Medial-lateral

Using the Cortical Drill associated to the size of the Nail used, use the perfect circle technique to free hand the drilling for the distal Cortical Screws.

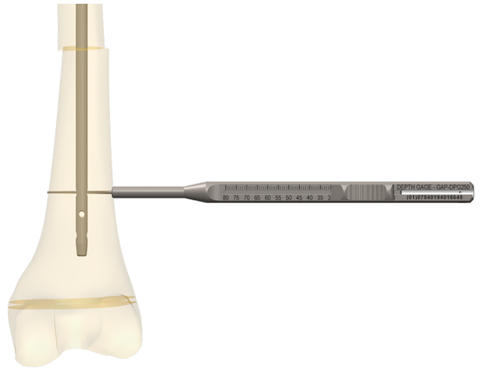
13.2 A/P (optional)

If additional stability is required, a Screw can be added in the A/P orientation. The same drill and free hand perfect circle technique can be used.

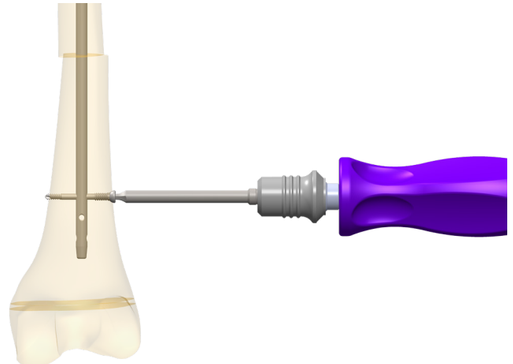


CAUTION: To minimize the risk of overheating, avoid prolonged or excessive drilling in one area, and regularly inspect both the instrument and bone for signs of heat buildup.

Using the Depth Gauge, measure the cortical length for each distal screw. Its diameter depends on the Nail size. See table.



Use the Short 2.5mm Hex Screwdriver with handle to insert the appropriate screw.



CAUTION: A minimum of 2 screws must be used to ensure adequate distal fixation stability.

NOTE: Cortical Washers not provided in case) can be used when dealing with fragile bones to improve distribution of stress onto the cortex.

The washers must be ordered in advance.

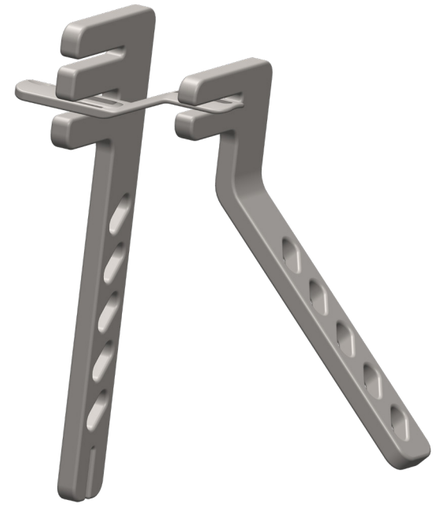
Step 14 Plate Implantation

Two choices of plates are offered. The Short Plate has a smaller footprint while the Long Plate helps to protect the lateral aspect of the greater trochanter.

14.1 Plate Bending (optional)

This step is only performed for the Long Plate.

Using the two Plate Benders, bend the plate to conform to the femur's contour.



CAUTION: The plate should not be excessively or repeatedly bent. It should not be reverse bent in the same location. Use care to ensure that the plate is not scratched or notched during the bending process.

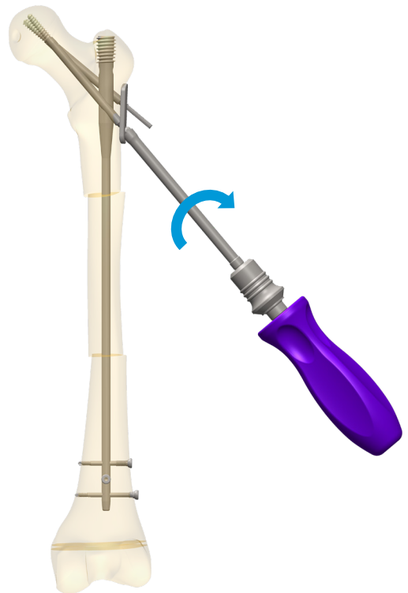
14.2 Plate Insertion

Slide the plate over the Lag Screws' threads.

14.3 Component Insertion

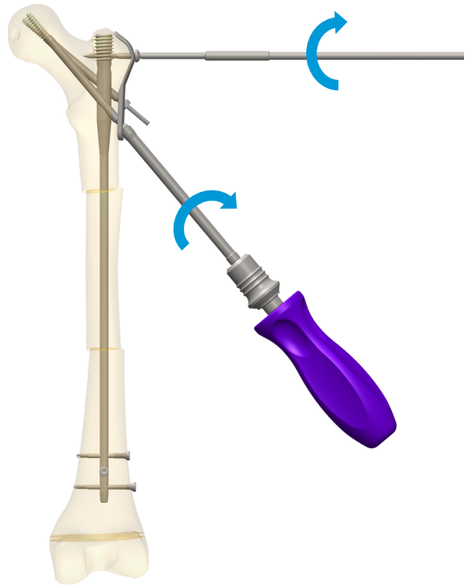
Option A - Using the Short Plate:

Use the Nut Screwdriver with handle and thread the lower Semi-Spherical Nut first followed by the upper.



Option B - Using the Long Plate:

Choose a Mechanical Screw from the two available options. For a smaller femur, use the MS-24 and for a larger femur use the MS-34.



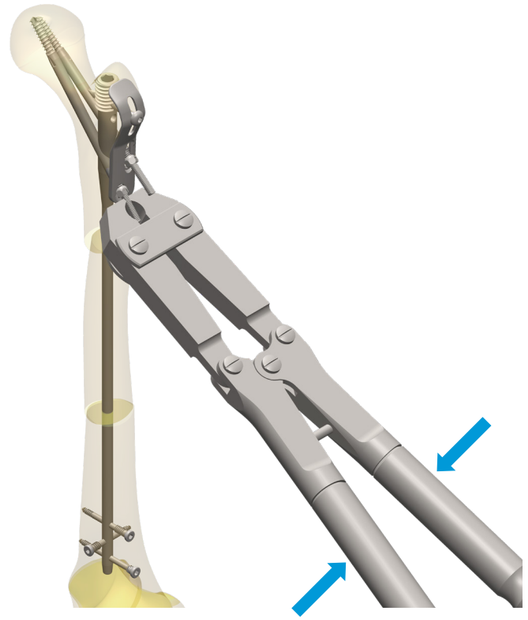
CAUTION: If resistance is felt during insertion, retract the screw and clean out the hole.

Insert the screw using the 2.5mm Hex Screwdriver with handle. Tighten progressively both nut (using the Nut Screwdriver) and the screw, making sure to fully tighten the lower nut first.

Mechanical Screw	Length
1033400024	24mm
1033400034	34mm

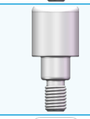
Step 15 Lag Thread Cutting

Cut off the threaded tips of the Lag Screws as close as possible to the nuts using the Lag Thread Cutter.

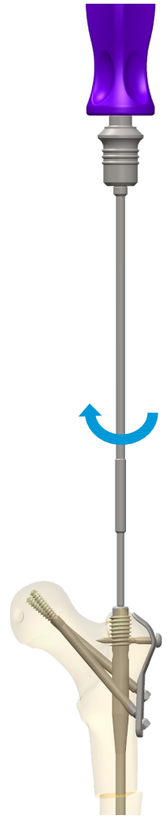


Step 16 Nail Cap Insertion

Select the appropriate Nail Caps to ensure protrusion of the cap from the cortex. Using the 2.5mm Hex Screwdriver with handle, insert the cap into the Nail.

Nail Caps	Height	
1034400115	1.5mm	
103440000	5.0mm	
1034400010	10.0mm	

CAUTION: Not using a cap could result in the accumulation of bone into the hex and cause difficulties during the removal process.



When no femoral neck fixation is required, a standard interlocking procedure can be performed.

Step 4 Osteotomy

Perform the required osteotomy under image intensification guidance to correct the existing deformities.

NOTE: It is possible to begin the insertion of the Guide Wire (see step 5) before performing the first osteotomy to help determine where they should be done and to help position the wire as needed.

Step 5 Guide Wire Insertion

Select the Guide Wire for the Nail size.

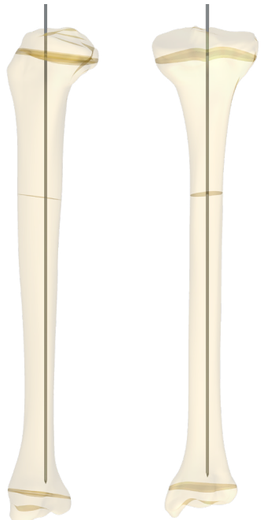
Nail size	Guidewire to use
Ø4.8, Ø5.6, Ø6.4	1.6mm
Ø7.2, Ø8.0	2.0mm

NOTE: All instruments canulated for a 2.0mm Guide Wire .

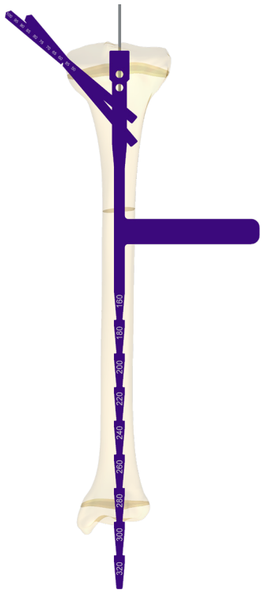
NOTE: An 18" Guide Wire can also be used (not provided in case) to ensure it protrudes from the power tools. See table above for appropriate diameter.

Insert the Guide Wire using the entry point for the specific procedure as presented in step 3 of the Universal First Steps.

Validate the position under image intensification in both AP and lateral views prior to reaming.



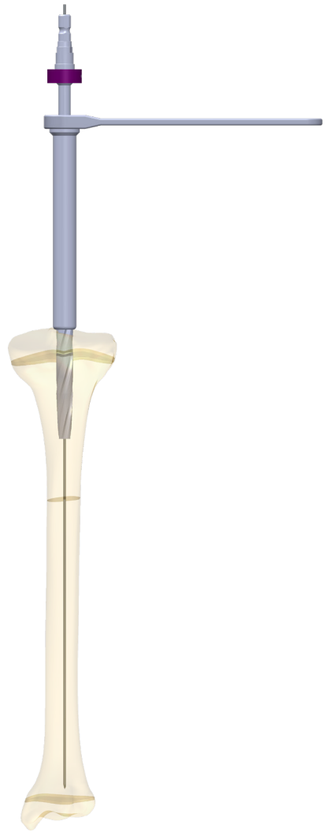
The Enox Nail Template can be used under image intensification to validate the Nail's length.



CAUTION: Select Nail as long as possible so that distal interlocking cortical screws are the furthest away from the fracture/osteotomy site.

Step 6 Conical Reaming

Place the Tissue Protector over the wire. Using the Conical Reamer, ream through the Tissue Protector and over the wire up to the stopper.



CAUTION: Do not force the reamer. Partially retract it to clean debris from the medullary canal if resistance is felt.

CAUTION: To minimize the risk of overheating, avoid prolonged or excessive reaming in one area, and regularly inspect both the instrument and bone for signs of heat buildup.

Step 7 Medullary Canal Reaming

Select the Canal Reamer corresponding to the Nail's size.

Nail size	Canal Reamer
Ø4.8	5551751248
Ø5.6	5551751256
Ø6.4	5551751264
Ø7.2	5551751272
Ø8.0	5551751280

Ream through the Tissue Protector and over the wire. Advance the reamer with steady and moderate pressure. Ream until the depth marking corresponding to selected Nail's length reaches the top edge of the Tissue Protector handle.

CAUTION: Do not force the reamer. Partially retract it to clean debris from the medullary canal if resistance is felt.

CAUTION: To minimize the risk of overheating, avoid prolonged or excessive reaming in one area, and regularly inspect both the instrument and bone for signs of heat buildup.

Remove the Tissue Protector once reaming is complete.

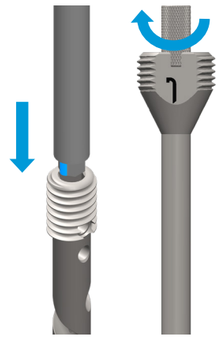
If needed, remove the wire.

Step 8 Nail Insertion

8.1 Nail Driver Assembly

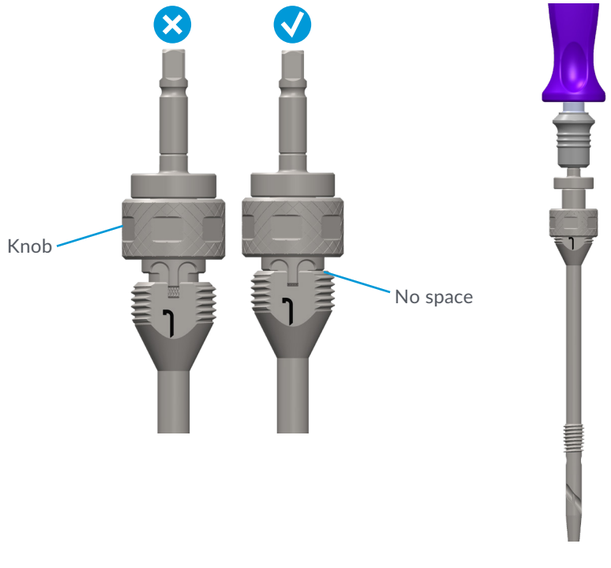
Insert the tip of the Nail Driver in the head of the selected Nail. To assemble, the circular notch on the hexagonal hex of the Nail Driver must align with the corresponding notch in the Nail.

Insert the Nail Driver Screw into the Nail Driver and thread into the Nail until it's finger tight.



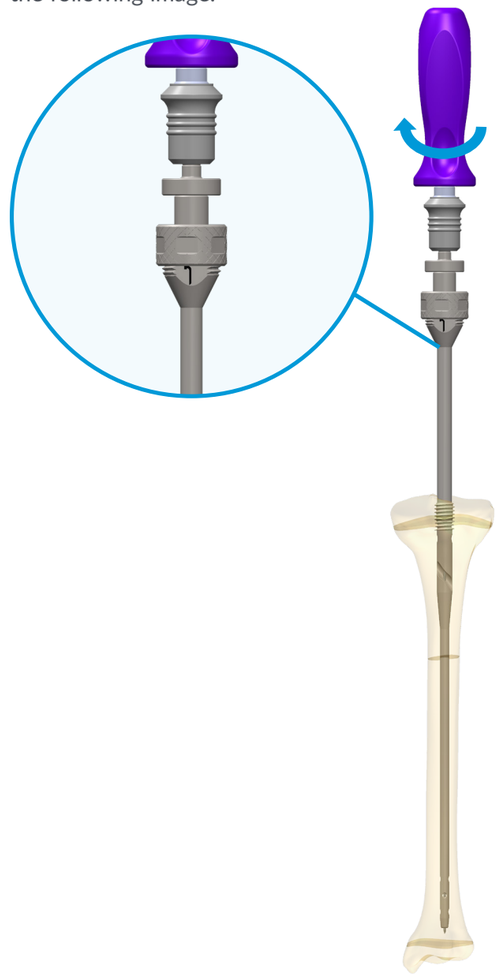
8.2 Nail Driver Adaptor Assembly

Attach the Nail Driver Adaptor onto the Nail Driver. Turn the knob to secure in place. Connect the Axial Handle onto the quick connect of the adaptor.



8.3 Nail Insertion

Insert the Nail. The markings on the Nail Driver indicates the orientation of the Nail as shown in the following image.

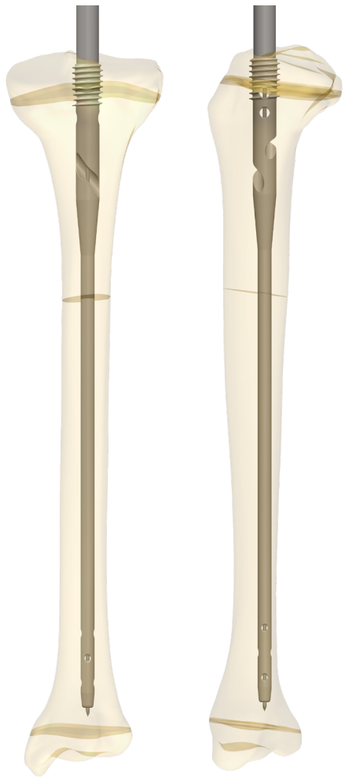


CAUTION: Do not hit the Nail Driver. The Nail should be inserted with minimal force .

CAUTION: The Nail's head should be fully inserted within the bone and not protrude into the articulation.

Step 9 Nail Position Verification

The Nail should be centered within the medullary canal. Angular alignment (and thus Cortical Screw orientation) is left to the discretion of the surgeon.



Verify the proper alignment of the Nail in both AP and lateral views under image intensification.

Verify the depth of the Nail under image intensification. Finally, verify the distal position of the implant.

> **NOTE:** Every full revolution of the nail corresponds to 2.4mm of insertion.

When the desired position is attained, remove the handle and the adaptor. Remove the wire (unless removed previously).

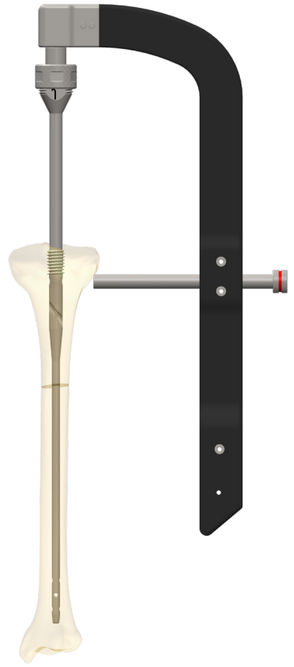
Step 10 Proximal Fixation

10.1 Targeting Device Assembly

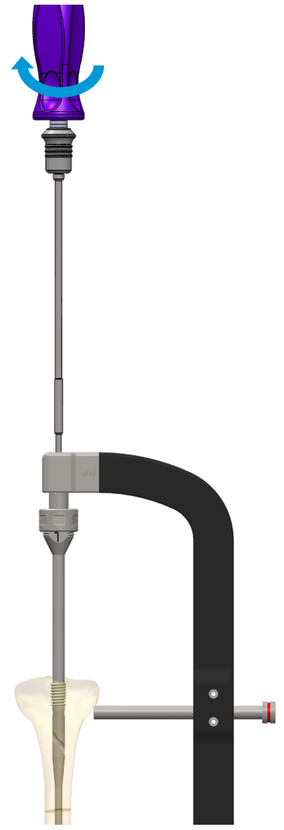
Attach the Targeting Device onto the Nail Driver. Turn the knob to secure in place.

10.2 Proximal Cortical Hole Drilling

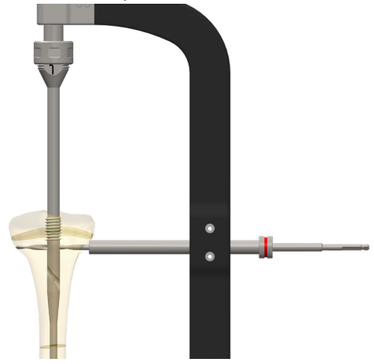
Insert the Cortical Screw Sleeve into the cortical hole (red) of the Targeting Device.



CAUTION: While using the Targeting Device, if the connection between it and the Nail becomes loose, use the 2.5mm Hex Screwdriver with handle to retighten them through the hole at the top of the Targeting Device.



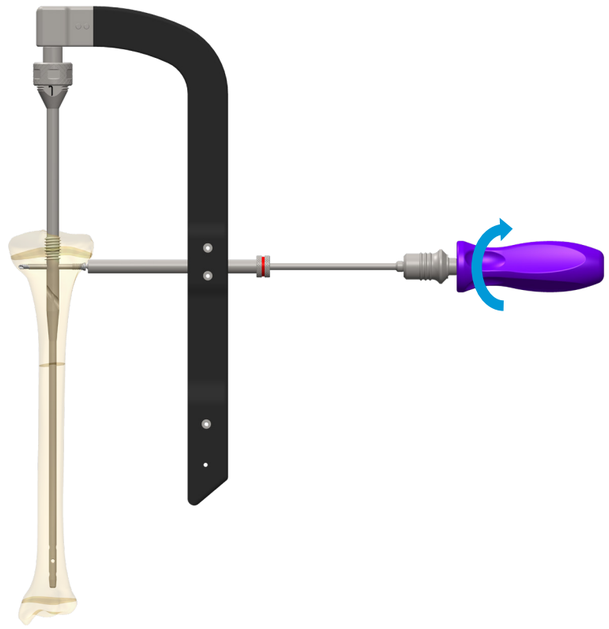
Using the Proximal Cortical Drill, drill through the first cortex up to the second cortex of the bone. Note the depth on the drill.



CAUTION: To minimize the risk of overheating, avoid prolonged or excessive drilling in one area, and regularly inspect both the instrument and bone for signs of heat buildup.

10.3 Proximal Screw Insertion

Select a 4mm Cortical Screw of the appropriate length. Using a 2.5mm Hex Screwdriver with handle, insert the screw through the sleeve and into the bone.

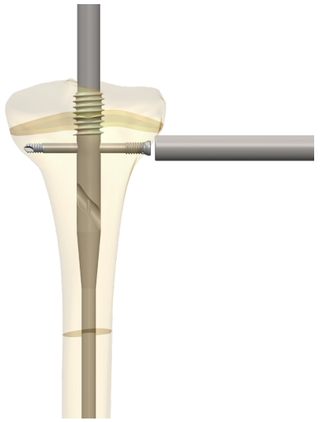


NOTE: A Cortical Washer, not provided in case) can be used when dealing with fragile bones to improve distribution of stress onto the cortex. To do so, remove the sleeve before inserting the washer and screw.

The washers must be ordered in advance.

10.4 Position Confirmation

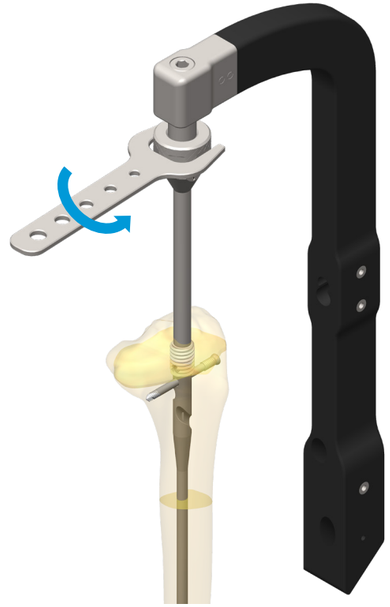
Confirm positioning of the screw under image intensification.



10.5 Targeting Device Removal

Once the screw is in place, remove the sleeve from the Targeting Device. Then, detach the Targeting Device by unthreading the knob.

CAUTION: If the knob is hard to untighten, the Multipurpose Wrench can be used.



Unthread the Nail Driver Screw and remove the Nail Driver.

CAUTION: If the Nail Driver Screw cannot be unthreaded by hand, use the Short 2.5mm Hex Screwdriver with handle to unthread it.

Step 11 Distal Locking – Perfect Circle Technique

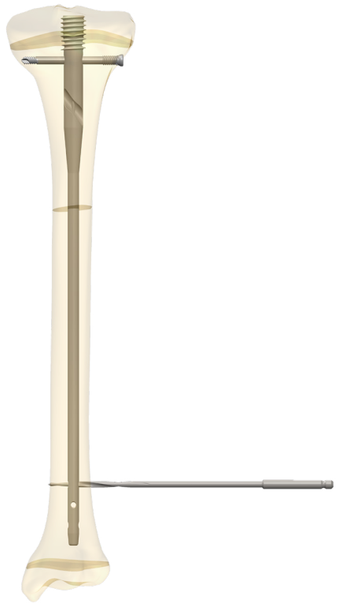
Nail Size	Distal Screw	Cortical Drill
Ø4.8	1035400020-XX (2.5mm)	5551751202
Ø5.6	1035403020-XX (3.0mm)	5551751203
Ø6.4/7.2/8.0	1035404020-XX (4.0mm)	5551751204

11.1 Medial-lateral

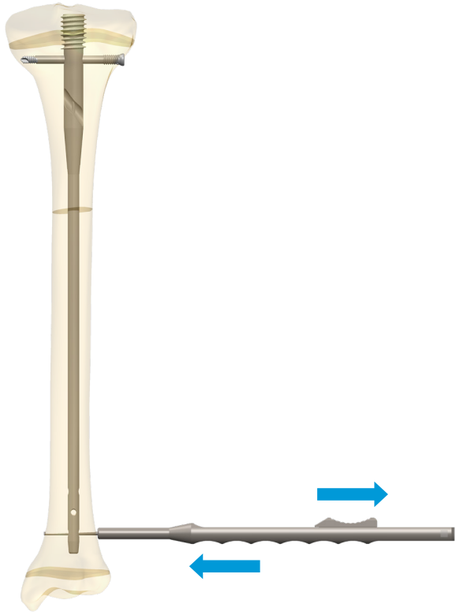
Using the Cortical Drill associated to the size of the Nail used (see table above), use the perfect circle technique to free hand the drilling for the distal Cortical Screws.

11.2 A/P (optional)

If additional stability is required, a screw can be added in the A/P orientation. The same free-hand perfect circle technique can be used.

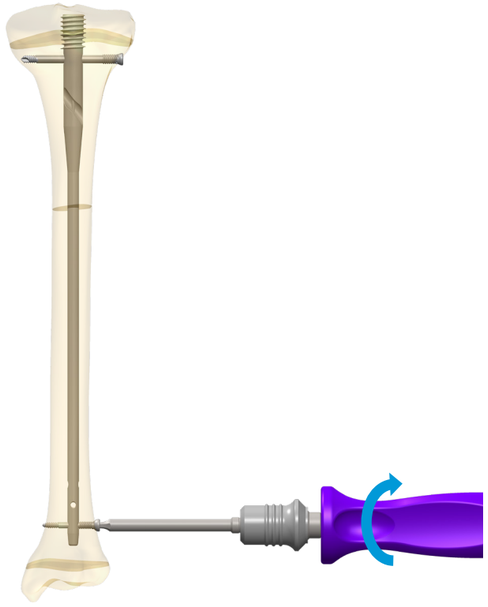


Using the Depth Gauge, measure the cortical length for each distal screws.



The screw's diameter depends on the Nail size. See table on previous page.

Use the Short 2.5mm Hex Screwdriver with handle to insert the chosen Cortical Screws.



CAUTION: A minimum of 2 screws must be used to ensure adequate distal fixation stability.

NOTE: Cortical Washers, not provided in case) can be used when dealing with fragile bones to improve distribution of stress onto the cortex.

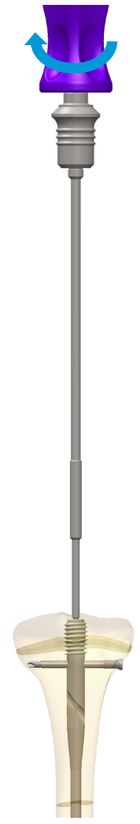
The washers must be ordered in advance.

Step 12 Nail Cap Insertion

Select the appropriate Nail Caps. For an antegrade femur application, the cap should protrude from the cortex. For a humerus, tibia or retrograde femur application, the cap should be flush with the articular cartilage.

Nail Caps	Height	
1034400115	1.5mm	
1034400005	5.0mm	
1034400010	10.0mm	

Using the 2.5mm Hex Screwdriver with handle, insert the cap into the Nail.



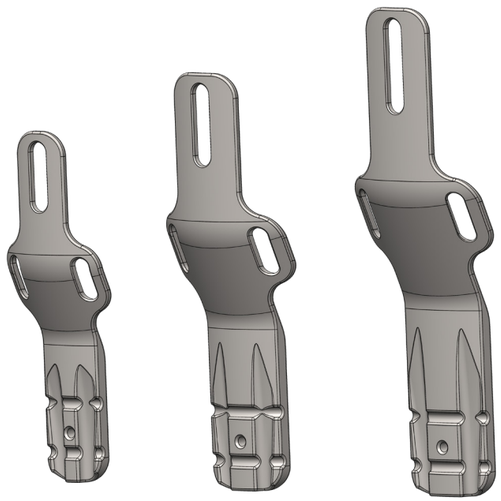
CAUTION: Not using a cap could result in the accumulation of bone into the hex of the Nail and cause difficulties during the removal process.

This technique offers an option for femur with femoral neck too small for the Lag Screw to go through. By using Steinmann Pins, it allows the neck to still be protected. A variety of coxa vara plates are offered to create the load sharing system.

Step 4 Coxa Vara Plate Selection

Preoperative planning is of paramount importance and includes a detailed analysis of the deformity of the proximal femur on both anteroposterior and lateral radiographs (to rule out false coxa vara). Mobility of the hip joint must be checked accurately because the maximum amount of surgical correction depends on the amount of hip adduction preoperatively. The mobility of the hip joint affects the amount of correction required for the head of the femur.

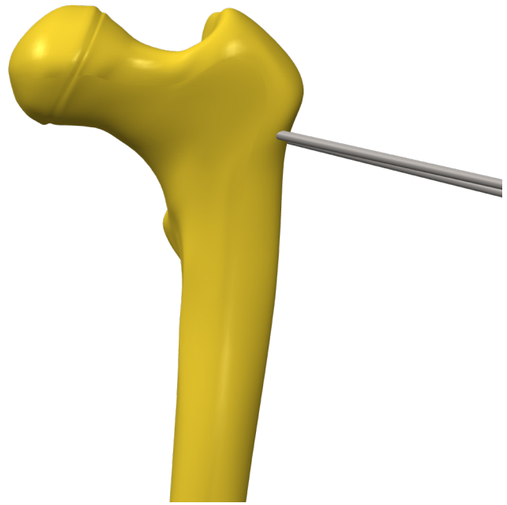
The Coxa Vara Plate comes in three sizes: Small, Medium and Large. Select the plate according to the shape and size of the proximal femur .



Step 5 Steinmann Pins Insertion

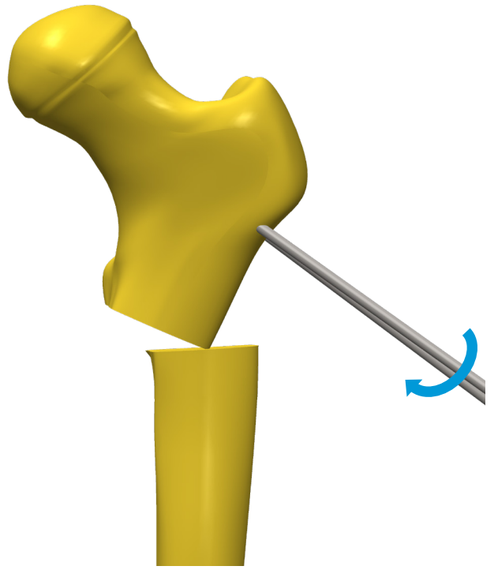
Select the size of the Steinmann Pins 2.4, 2.8 or 3.2 (not provided) according to the size of the bone. Using the chosen plate as a template, place two smooth pins along the femoral neck, across the physis, into the femoral epiphysis.

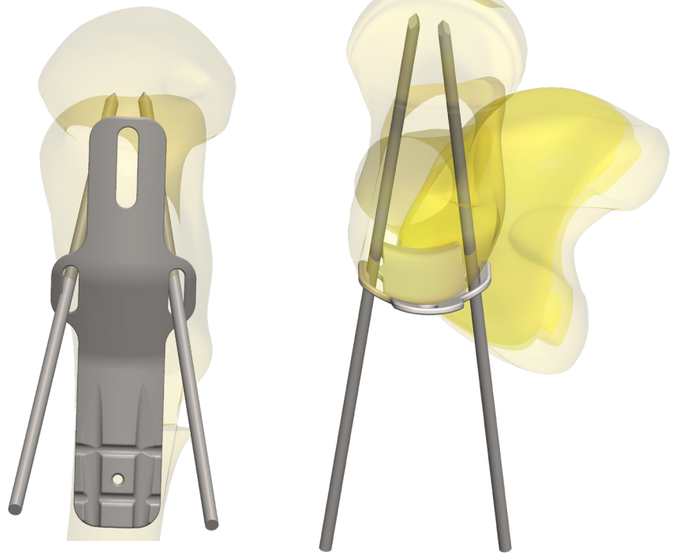
The first pin should be inserted anteriorly on the greater trochanter, posteriorly driven into the head, whereas the second should start posteriorly at the greater trochanter and be driven into the anterior part of the femoral head. This leaves space for the intramedullary Nail in the proximal femoral metaphysis.



Step 6 Osteotomy and Head Positioning

Determine the site of the osteotomy under image intensification. Perform the osteotomy. Then, use the two pins as a “joystick” to allow safe adduction of the proximal fragment without the use of a bone clamp.





Step 7 Guide Wire Insertion

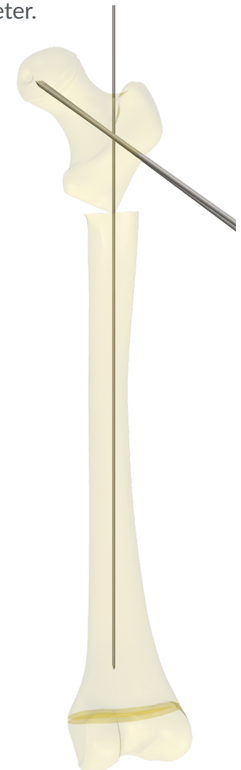
The entry point and the direction of the Guide Wire are crucial to determining the amount of correction. The more distal a hole is, the greater the proximal segment of the femoral head must be rotated to align with the intramedullary canal of the distal segment. This increases the possible angular correction. The final neck/shaft angle (NSA) can be estimated by calculating the angle between the wire and the pins.

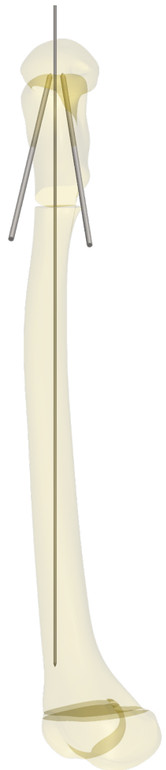
Select the Guide Wire for the Nail size.

Nail size	Guidewire to use
Ø4.8, Ø5.6, Ø6.4	1.6mm
Ø7.2, Ø8.0	2.0mm

NOTE: All instruments are canulated for a 2.0mm Guide Wire.

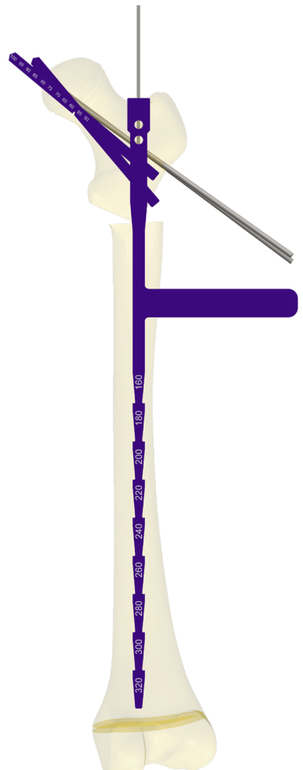
NOTE: An 18" Guide Wire can also be used (not provided in case) to ensure it protrudes from the power tools. See table above for appropriate diameter.





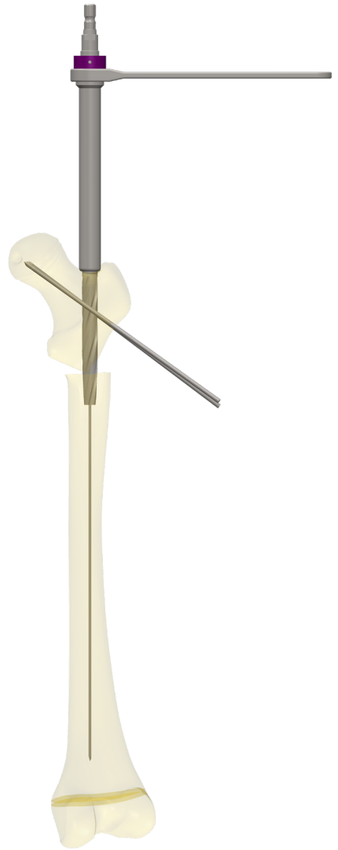
Insert the wire into the canal and validate its final position under image intensification in both the AP and Lateral views prior to reaming.

Once the wire is in place the proper Nail length can be determined. Using image intensification, determine the Nail length required. The Enox Nail Template can also be used to better visualize the Nail length.



Step 8 Conical Reaming

Place the Tissue Protector over the Guide Wire. Using the Conical Reamer, ream through the Tissue Protector and over the wire up to the stopper.



CAUTION: Do not force the reamer. Partially retract it to clean debris from the medullary canal if resistance is felt.

CAUTION: To minimize the risk of overheating, avoid prolonged or excessive reaming in one area, and regularly inspect both the instrument and bone for signs of heat buildup.

Step 9 Medullar Canal Reaming

Select the Canal Reamer corresponding to the Nail's size. Ream through the Tissue Protector and over the wire. Advance the reamer with steady and moderate pressure.

Nail Size	Canal Reamer
Ø4.8	5551751248
Ø5.6	5551751256
Ø6.4	5551751264
Ø7.2	5551751272
Ø8.0	5551751280

Ream until the depth marking corresponding to the length of the Nail reaches the top edge of the Tissue Protector handle.

CAUTION: Do not force the reamer. Partially retract it to clean debris from the medullary canal if resistance is felt.

CAUTION: To minimize the risk of overheating, avoid prolonged or excessive reaming in one area, and regularly inspect both the instrument and bone for signs of heat buildup.

Remove the Tissue Protector once reaming is complete.

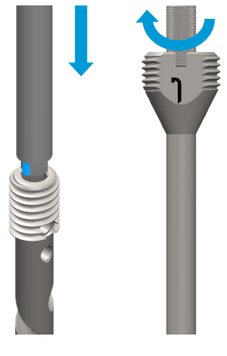
If needed, remove the wire.

Step 10 Nail Insertion

10.1 Nail Driver Assembly

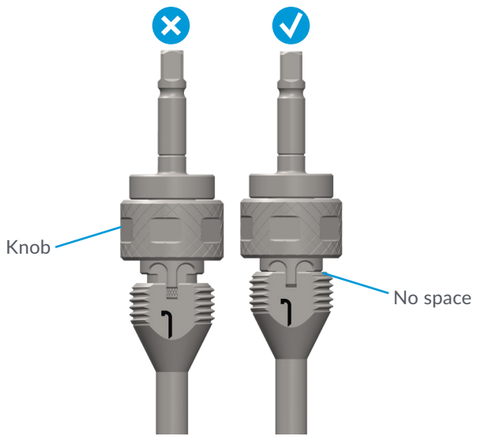
Insert the tip of the Nail Driver in the head of the Nail selected. To assemble, the circular notch on the hexagonal hex of the Nail Driver must align with the corresponding notch in the Nail.

Insert the Nail Driver Screw into the Nail Driver and thread into the Nail until it's finger tight.



8.2 Nail Driver Adaptor Assembly

Attach the Nail Driver Adaptor onto the Nail Driver. Turn the knob to secure in place. Connect the Axial Handle onto the quick connect of the adaptor.



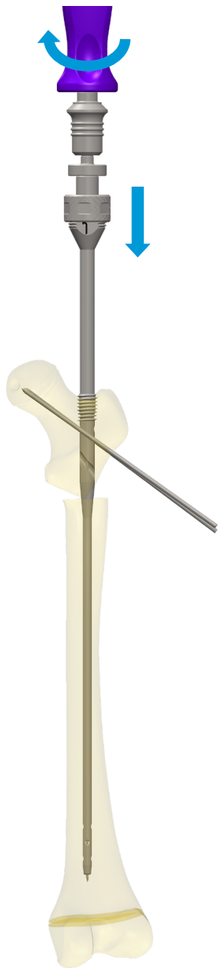
10.3 Nail Insertion

Insert the Nail over the Guide Wire.

In its final position, the markings on the Nail Driver indicates the orientation of the Targeting Device.

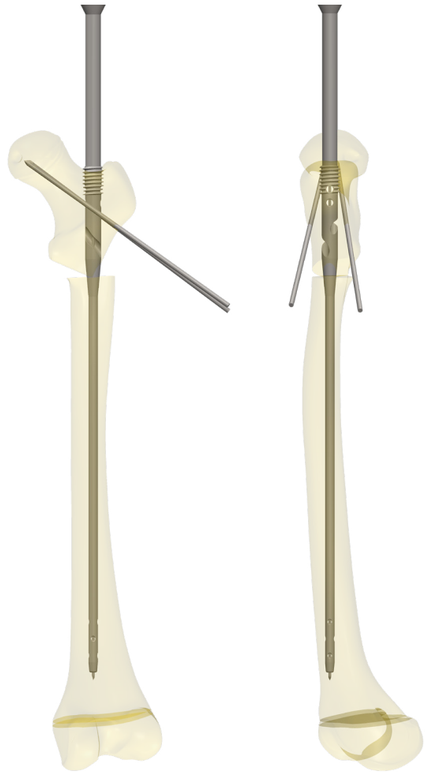
CAUTION: Do not hit the Nail Driver. The Nail should be inserted with minimal force.

CAUTION: The Nail's head should be fully inserted within the bone and not protrude into the articulation.



Step 11 Nail Position Verification

The Nail should be centered within the medullary canal. Verify proper alignment of the nail in both AP and lateral views under image intensification. Verify the depth of the Nail and the distal position of the implant.

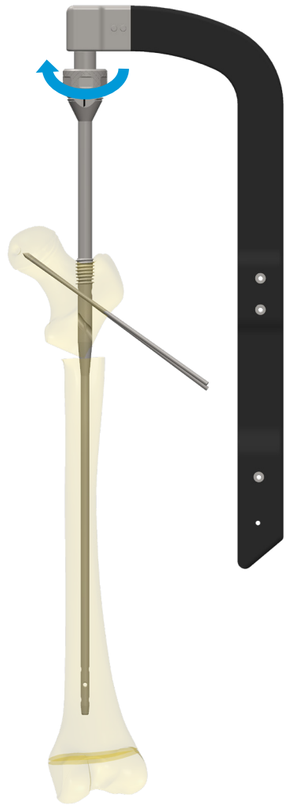


NOTE: Every full revolution of the nail corresponds to 2.4mm of insertion.

When the desired position is attained, remove the handle and the adaptor. Remove the wire (unless removed previously).

Step 12 Targeting Device Assembly

Attach the Targeting Device onto the Nail Driver. Turn the knob to secure in place.



Step 13 Mechanical Screw Hole Preparation

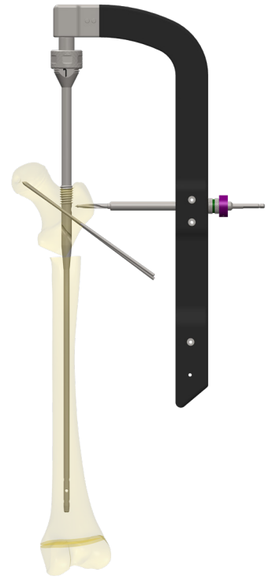
13.1 Mechanical Screw Drilling

While using the Targeting Device, if the connection between it and the Nail becomes loose, use the 2.5mm Hex Screwdriver with handle to retighten them through the hole at the top of the Targeting Device.

CAUTION: While using the Targeting Device, if the connection between it and the Nail becomes loose, use the 2.5mm Hex Screwdriver with handle to retighten them through the hole at the top of the Targeting Device.

Mount the Mechanical Screw Sleeve into the mechanical hole (green) of the Targeting Device.

Drill to the stopper using the Mechanical Screw Drill.

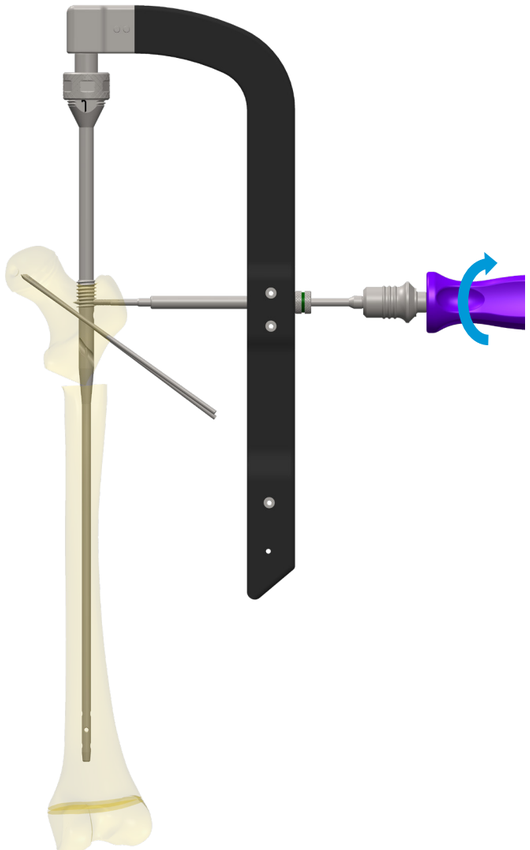


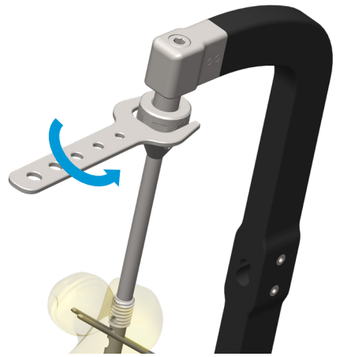
CAUTION: To minimize the risk of overheating, avoid prolonged or excessive drilling in one area, and regularly inspect both the instrument and bone for signs of heat buildup.

Remove the drill. Leave the sleeve.

13.2 Mechanical Screw Pin Insertion

Mount the Axial Handle onto the Mechanical Screw Pin. Insert the pin through the sleeve and thread until it is fully engaged in the Nail. If resistance is felt, retract the pin and clean out the hole.





Unthread the Nail Driver Screw and remove the Nail Driver.

CAUTION: If the Nail Driver Screw cannot be unthreaded by hand, use the Short 2.5mm Hex Screwdriver with handle to unthread it.

13.3 Targeting Device Removal

Unthread the pin from the Nail and remove it. Remove the sleeve. Untighten the knob of the Targeting Device to detach it from the Nail Driver.

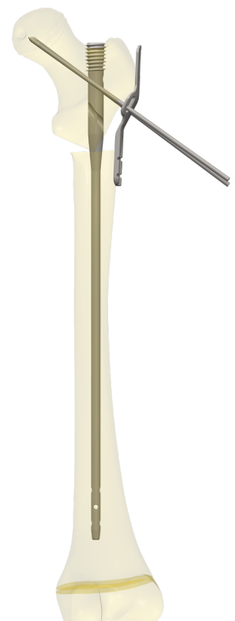
Step 14 Coxa Vara Plate and Wire Locking

14.1 Plate Bending

The plate chosen previously can be bent to better fit the geometry of the bone using the two Plate Benders.

CAUTION: The plate should not be excessively or repeatedly bent. The plate should not be reverse bent in the same location. Use care to ensure that the plate is not scratched or notched during the bending process.

Slide the plate onto the pins up to the bone .



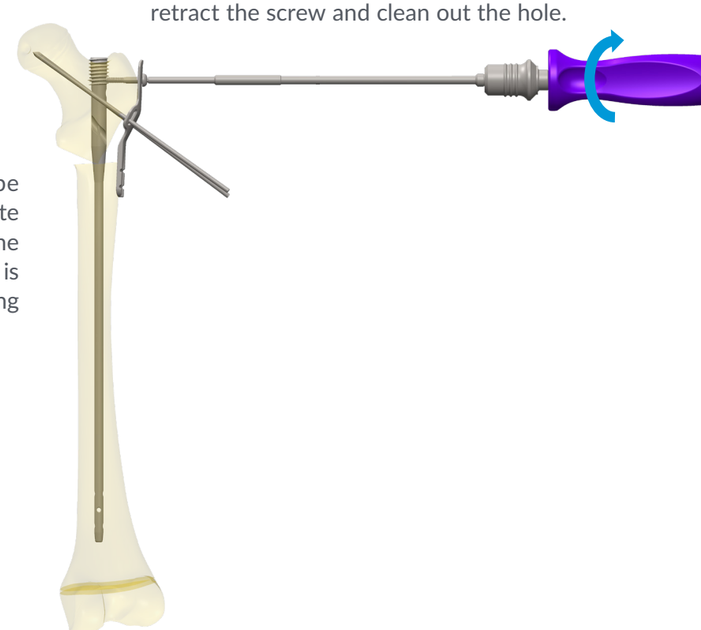
14.2 Mechanical Screw Insertion

Choose a Mechanical Screw; large femurs and/or medially placed Nails will require the longer screw (MS-34), otherwise use MS-24.

Mechanical Screw	Length
1033400024	24mm
1033400034	34mm

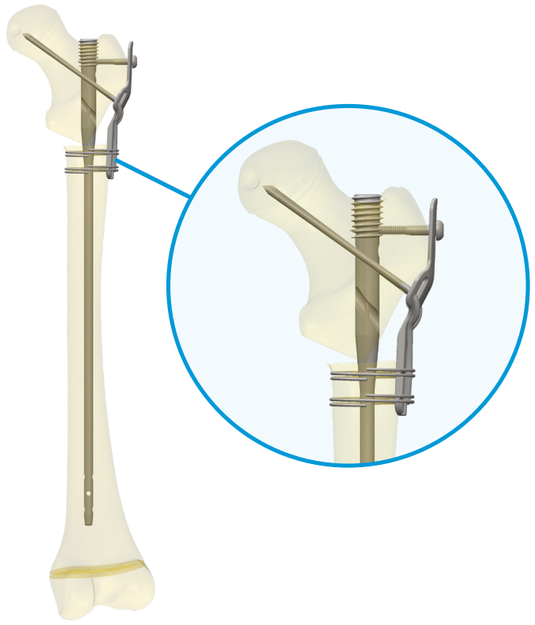
Insert the screw using the 2.5mm Hex Screwdriver with handle.

CAUTION: If resistance is felt during insertion, retract the screw and clean out the hole.



14.3 Wires Locking

Once the screw is in place, bend the pins onto the plate, and secure them to the shaft with cerclage wires (not provided).



Step 15 Distal Locking – Perfect Circle Technique

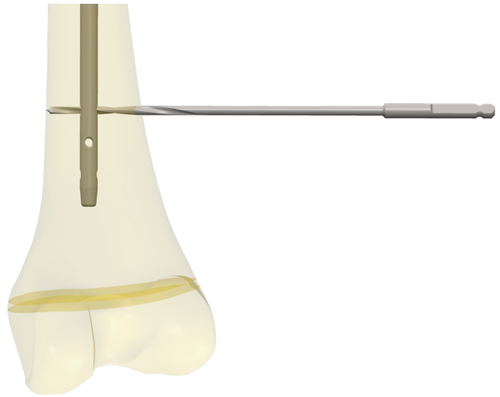
Nail Size	Distal Screw	Cortical Drill
Ø4.8	(2.5mm)	5551751202
Ø5.6	(3.0mm)	5551751203
Ø6.4/7.2/8.0	(4.0mm)	5551751204

15.1 Medial-lateral

Using the Cortical Drill associated to the size of the Nail used (see table above), use the perfect circle technique to free hand the drilling for the distal screws.

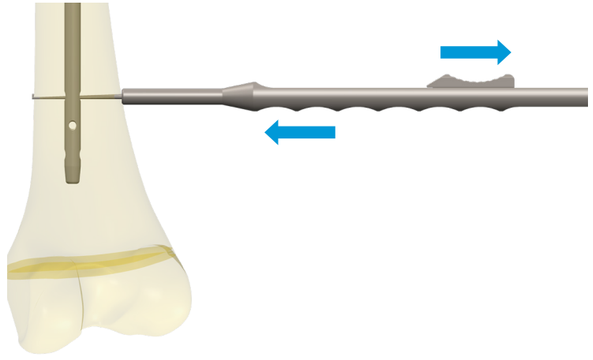
15.2 A/P (optional)

If more rotational stability is required, a screw can be added in the A/P orientation. The same free hand perfect circle technique can be used.

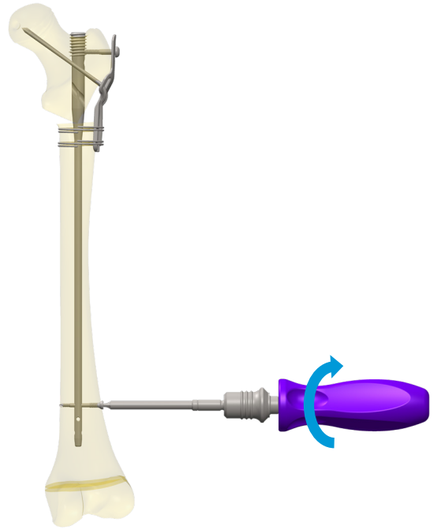


CAUTION: To minimize the risk of overheating, avoid prolonged or excessive drilling in one area, and regularly inspect both the instrument and bone for signs of heat buildup.

Using the Depth Gauge, measure the cortical length for each distal screw. The Cortical Screw diameter depends on the Nail size. See table.



Use the 2.5mm Hex Screwdriver with handle to insert the appropriate screws.



CAUTION: A minimum of 2 screws must be used to ensure adequate distal fixation stability.

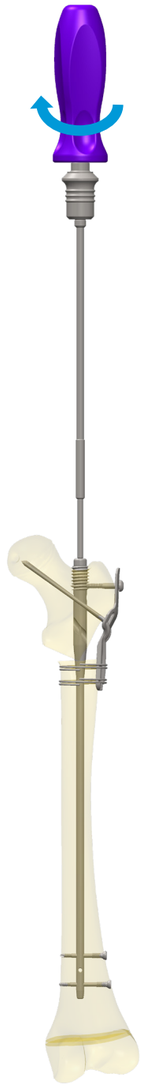
NOTE: Cortical Washers, not provided in case) can be used when dealing with fragile bones to improve distribution of stress onto the cortex.

The washers must be ordered in advance.

Step 16 Nail Cap Insertion

Select the appropriate Nail Caps to ensure protrusion of the cap from the cortex. Using the 2.5mm Hex Screwdriver with handle, insert the cap into the Nail.

Nail Caps	Height	
1034400115	1.5mm	
1034400005	5.0mm	
1034400010	10.0mm	



CAUTION: Not using a cap could result in the accumulation of bone into the hex of the Nail and cause difficulties during the removal process.

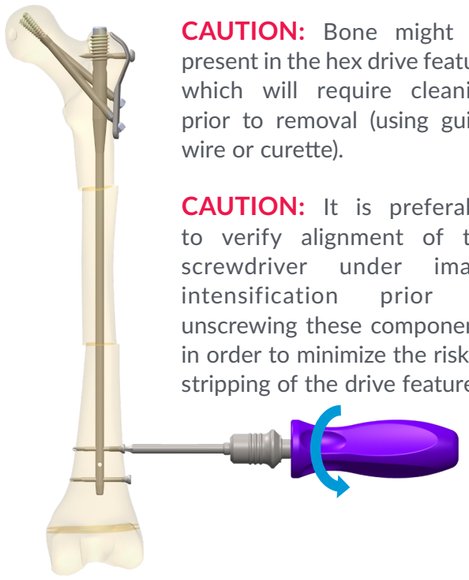
Nail Removal

This surgical technique for removal is based on a Nail configuration with two Lag Screws and a Long Plate (most complex configuration). If Lag Screws were not used, steps 1 through 5 can be skipped.

CAUTION: The implant should be retrieved once the treatment or the revision is completed.

Step 1 Components Removal

Using the Short 2.5mm Hex Screwdriver and Axial Handle, remove the Mechanical Screw, the Cortical Screws and the Nail Cap. The can use for a longer reach if necessary.



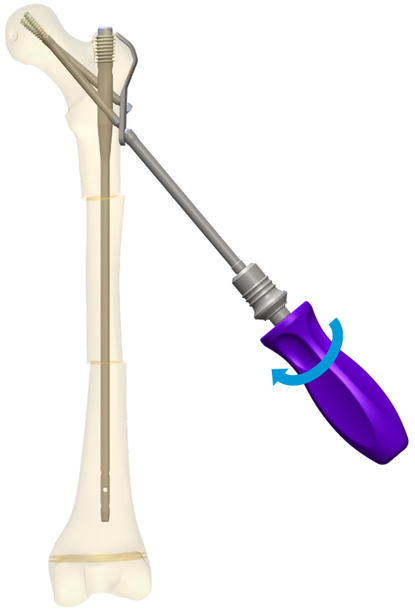
CAUTION: Bone might be present in the hex drive feature which will require cleaning prior to removal (using guide wire or curette).

CAUTION: It is preferable to verify alignment of the screwdriver under image intensification prior to unscrewing these components in order to minimize the risk of stripping of the drive features.

Step 2 Semi-Spherical Nuts Removal

Remove the two Semi-Spherical Nuts from the Lag Screws using the Nut Screwdriver with handle.

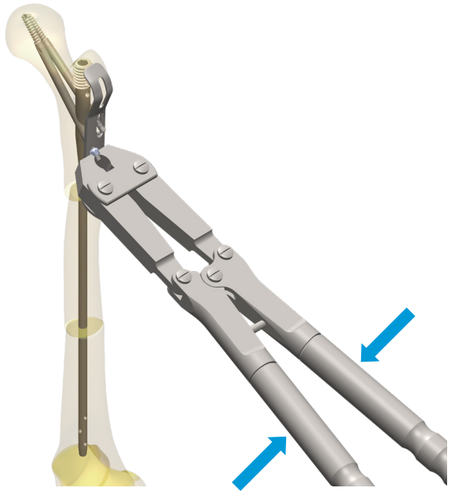
CAUTION: It is possible that, during the initial surgery, cutting the screw's excess thread created a flare which may prevent the nuts from being fully removed. If so, follow step 3.



Step 3 Lag Screws Cutting (Optional

First, unscrew the nut until it is blocked against the flare. Keep rotating the Nut Screwdriver with handle to unscrew the Lag Screw to create a clearance for the Lag Thread Cutter.

Cut the screw in the zone between the nut and the plate, as shown in the images below.



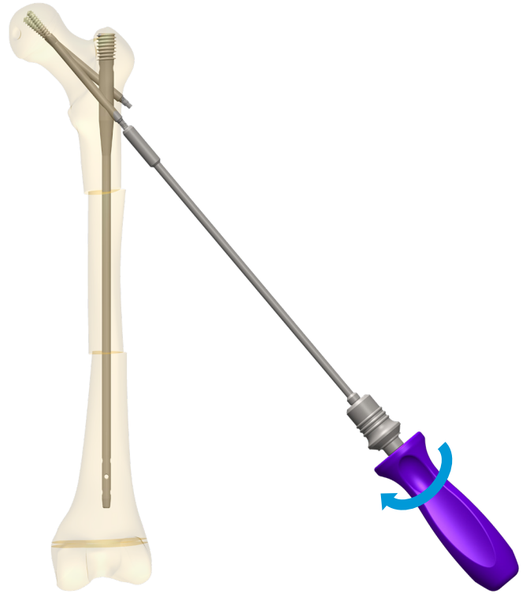
Step 4 Plate Removal

Remove the plate by sliding it along the remaining screw's threads.

Step 5 Lag Screws Removal

5.1 Using Lag Screwdriver

Unscrew both screws using the Lag Screwdriver with handle if enough flat surfaces remain on the protruding tip of the screws.



CAUTION: If the screws were cut to remove the nuts, there might not be enough flat surfaces remaining to use the screwdriver. If so, follow step 5.2.

5.2 Using Pliers (Optional)

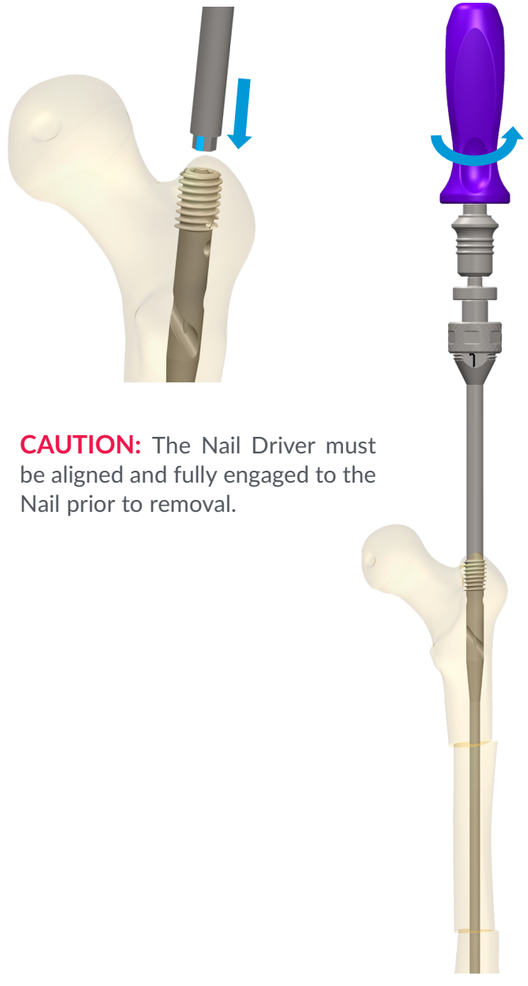
If need be, use pliers (not provided) to remove the rest of the screw. The ability to remove it with pliers depends on bone grip on the screw. Once the length of the thread of the screw is threaded out (about 2 cm) it can be pulled the rest of the way.

Step 6 Nail Removal

Once all interlocking screws have been removed, the Enox Nail can be removed. Two options are available to do so.

Option A - Using the Nail Driver:

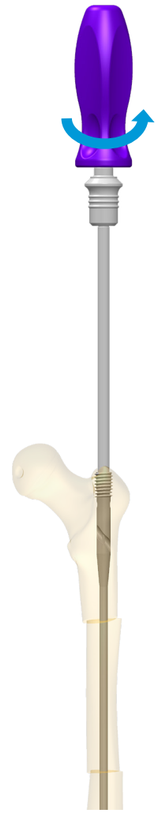
Insert the Nail Driver in the head of the Nail. The orientation of the Nail Driver and the Nail's notch must be respected. Then, thread in the Nail Driver Screw and attach the Nail Driver Adaptor. Attach the handle to the adaptor and unthread the Nail from the bone counterclockwise.



CAUTION: The Nail Driver must be aligned and fully engaged to the Nail prior to removal.

Option B - Using the Rescue Nail Driver:

Insert the Rescue Nail Driver with handle in the hex feature of the Nail and rotate counterclockwise.



CAUTION: The Rescue Nail Driver can only be used for rotation. It will not capture the Nail, nor allow traction to be applied.

Step 7 Implant Measurement

Once the implant is removed, the Multipurpose Wrench can be used to determine the size of implant if the markings are no longer visible.

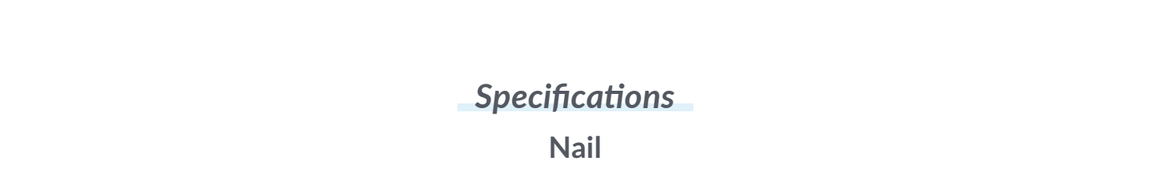
Specifications

Nail

Enox Nail											
Ø / Shaft	**Ø / Head**	**Ø / Neck**	**160 mm**	**180 mm**	**200 mm**	**220 mm**	**240 mm**	**260 mm**	**280 mm**	**300 mm**	**320 mm**
4.8	12.0	9.2	4005148160	4005148180	4005148200	4005148220	4005148240	4005148260	4005148280	4005148300	4005148320
5.6	12.0	9.2	4005156160	4005156180	4005156200	4005156220	4005156240	4005156260	4005156280	4005156300	4005156320
6.4	12.0	9.2	4005164160	4005164180	4005164200	4005164220	4005164240	4005164260	4005164280	4005164300	4005164320
7.2	12.5	9.5	4005172160	4005172180	4005172200	4005172220	4005172240	4005172260	4005172280	4005172300	4005172320
8.0	12.5	9.5	--	--	--	--	--	--	4005108280	4005108300	4005108320

*Special order.

Nail Dimension			
Nail Diameter (mm)	Cannulation (mm)	Distal hole x3	Distal interlocking Screw
Ø4.8	Ø1.7	Ø2.5	1035400020-xx
Ø5.6		Ø3	1035403020-xx
Ø6.4		Ø4	1035404020-xx
Ø7.2	Ø2.1		
Ø8.0			



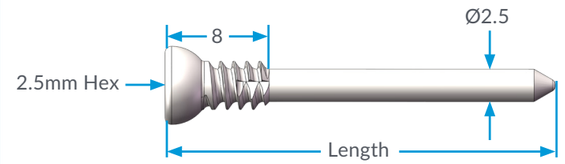
Cortical Screw

Length	2.5mm Cortical Peg	3mm Cortical Screw	4mm Cortical Screw
20mm	1035400020	1035403020	1035404020
25mm	1035400025	1035403025	1035404025
30mm	1035400030	1035403030	1035404030
35mm	1035400035	1035403035	1035404035
40mm	1035400040	1035403040	1035404040
45mm	1035400045	1035403045	1035404045
50mm	1035400050	1035403050	1035404050
55mm	1035400055	1035403055	1035404055
60mm	1035400060*	1035403060	1035404060
65mm	1035400065*	1035403065*	1035404065
70mm	1035400070*	1035403070*	1035404070
75mm	1035400075*	1035403075*	1035404075
80mm	1035400080*	1035403080*	1035404080

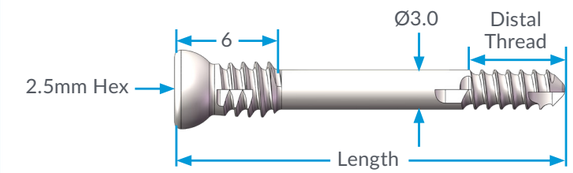
*The following screws are not provided in the case and are available **on order only**:

Cortical Dimensions	
Length	Distal Thread
20mm	8 mm
25mm	
30mm	10 mm
35mm	
40mm	12 mm
45mm	
50mm	
55mm	
60mm	
65mm	
70mm	
75mm	
80mm	

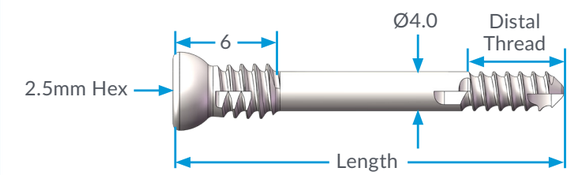
2.5mm Cortical Peg



3mm Cortical Screw

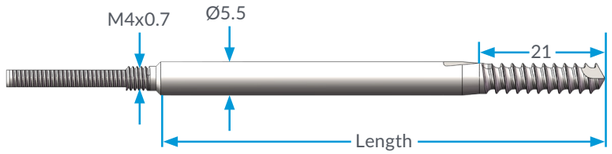


4mm Cortical Screw



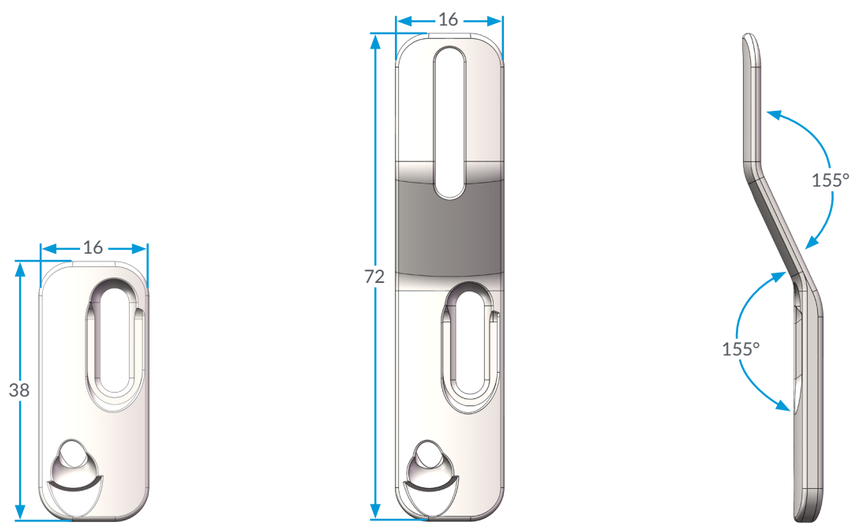
Lag Screw

Length (mm)	Lag Screw
50	4005100050
55	4005100055
60	4005100060
65	4005100065
70	4005100070
75	4005100075
80	4005100080
85	4005100085
90	4005100090
95	4005100095
100	4005100100



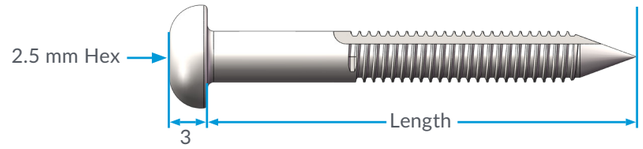
Plate

Type of plate	Catalog#
Short Plate	3072400002
Long Plate	3072400001



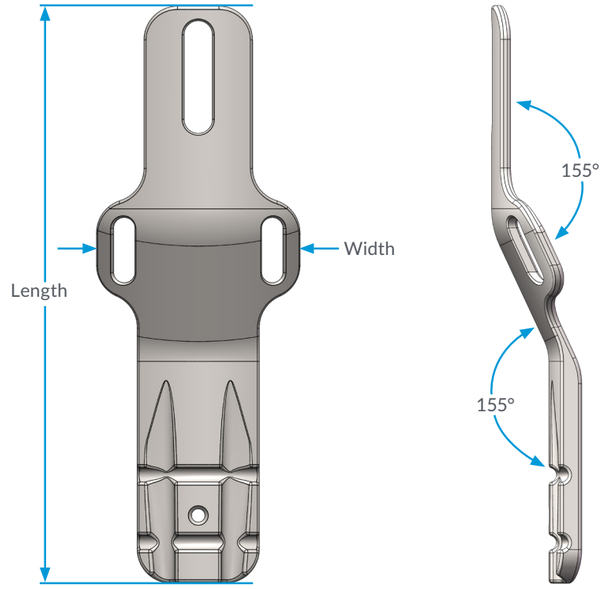
Mechanical Screw

Type of Mechanical Screw	Catalog#	Length (mm)
Short	1033400024	24
Long	1033400034	34



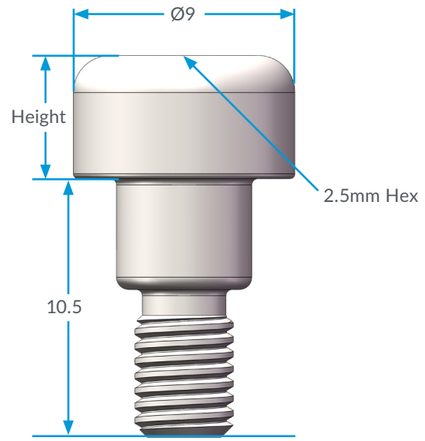
Coxa Vara Plate

Type of Coxa Vara Plate	Catalog#	Length (mm)	Width (mm)
Short Coxa Vara Plate	3071400001	72	24
Medium Coxa Vara Plate	3071400002	85	30
Large Coxa Vara Plate	3071400003	100	32

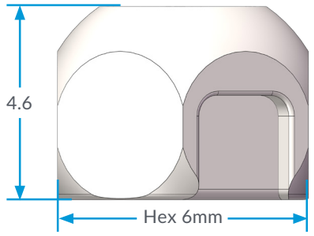


Nail Cap

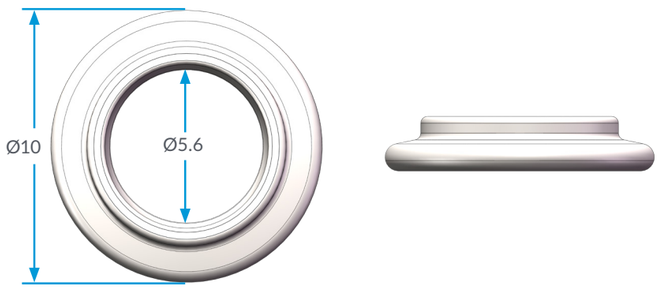
Nail Cap Size	Catalog#	Height (mm)
Short	1034400115	1.5
Regular	1034400005	5
Long	1034400010	10



Semi-Spherical Nut (1035400001)

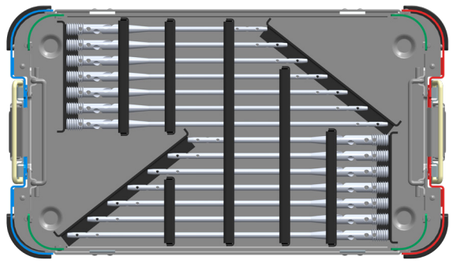


Washer (1035400002) **Not provided in case*

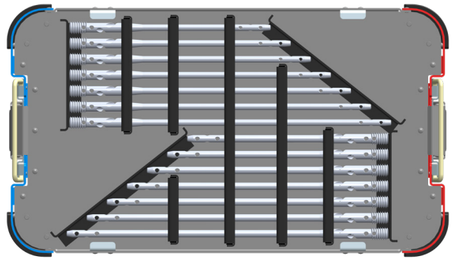


Implant Case – Nail (5551750111)

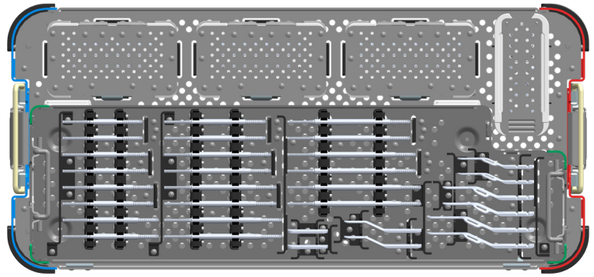
Top Tray



Bottom Tray

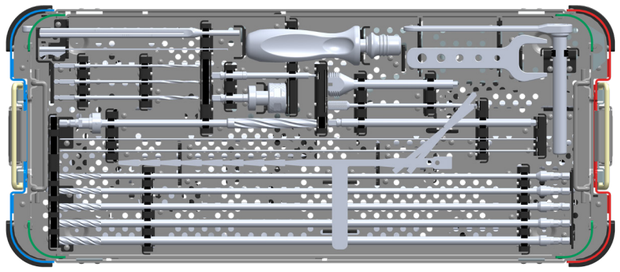


Implant Case – Component (55517501112)

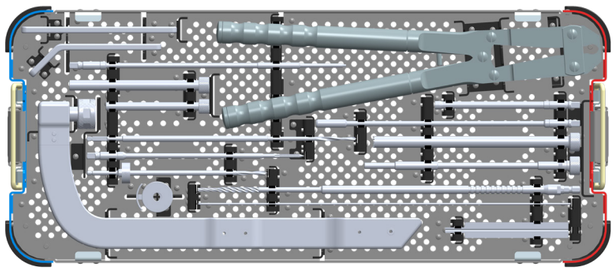


Instrument Case (5551750002)

Top Tray



Bottom Tray



Instruments

Guide Wires

Catalog #	Description
5939999016	Guide Wire - 1.6 mm x 450
5939999020	Guide Wire - 2.0 mm x 450
571674130	Guide Pin 3.2mm x 343mm

Drills and Reamers

Catalog #	Description
5551751002	Conical Reamer
5551751248	Canal Reamer - 4.8 mm
5551751256	Canal Reamer - 5.6 mm
5551751264	Canal Reamer - 6.4 mm
5551751272	Canal Reamer - 7.2 mm
5551751280	Canal Reamer - 8.0 mm
5551751003	Lag Reamer
5551751202	Cortical Screw Drill - 2.5 mm
5551751203	Cortical Screw Drill - 3.0 mm
5551751204	Cortical Screw Drill - 4.0 mm
5551751004	Mechanical Screw Drill
5551751005	Proximal Cortical Screw Drill

Handles and Drivers

Catalog #	Description
5551751006	Short 2.5mm Hex Screwdriver
5551751007	2.5mm Hex Screwdriver
5551751008	Nut Screwdriver Shaft
5551751009	Lag Screwdriver Shaft
5551751010	Rescue Nail Driver
5551751011	Axial Handle

Targeting Device

Catalog #	Description
5551751112	Targeting Device
5551751113	Nail Driver
5551751114	Nail Driver Screw
5551751115	Nail Driver Adaptor

Sleeves

Catalog #	Description
5551751116	Lag Wire Sleeve
5551751117	Lag Screw Sleeve
5551751118	Cortical Screw Sleeve
5551751119	Mechanical Screw Sleeve

Miscellaneous Instruments

Catalog #	Description
5551751120	Tissue Protector
5551751121	Mechanical Screw Pin
5551751122	Lag Depth Ruler
5551751123	Position Lock
5551751124	Lag Thread Cutter
5280122914	Plate bender - V 6mm
5551751125	Enox Nail Template
5551751126	Depth Gage
5551751127	Multipurpose Wrench

Disclosure of Residual Risks

While complications and adverse effects vary depending on the type of orthopedic surgery and while mitigations are implemented to reduce these risks as far as possible, some residual risks, associated with this system, can arise during and following surgery. These residual risks include adverse effects that are important considerations for metallic internal fixation devices. These risks and general surgical risks should be explained to the patient prior to surgery. The residual risks are listed in the sections below for Adverse Effects and Warnings.

Adverse Effects

- Pain, discomfort or abnormal sensations due to the presence of the device.
- Irritation or inflammation of surrounding soft tissue or skin over implant if coverage is insufficient
- Limb shortening or residual deformity with nonunion or malunion
- Bony formation around implant making removal difficult or impossible
- Metal sensibility and/or allergic reaction to a foreign body.
- Possible blood circulation or vessel damage, or avascular necrosis (AVN)
- Nerve damage due to the surgical trauma
- Bone resorption due to stress shielding.
- Postoperative bone fracture and pain.
- Infection, both deep and superficial
- Unrecognized joint penetration
- Inadequate healing

Warnings

- Device breakage or damage can occur when implant is subjected to increased loading associated with delayed union, non-union, or incomplete healing. Proper consolidation should be observed prior to full weight bearing.
- Improper insertion of the device during implantation can increase the possibility of loosening or migration.
- IMD advises against the use of another manufacturer's component with any IMD component. Any such use will negate the responsibility of IMD for the performance of the resulting mix.
- Implants are single use items. Please note that single use devices (SUDs) that come into contact with human blood or tissue should not be reused, reprocessed, or resterilized and should either be returned to the manufacturer or disposed of properly. Reuse of implants may lead to contamination and increase the risk of infection transmission.
- Implants should never be reimplanted. Even if they appear undamaged, the device may have small defects or internal stresses that could lead to implant failure or compromise its performance.
- Correct implant handling is extremely important. Avoid contouring of metallic implants.
- Discard all damaged or mishandled implants, or return them to the manufacturer for proper disposal.
- Selecting the largest diameter implant that is appropriate for the medullary canal of the host bone as well as proper positioning and insertion of the implant are crucial to mitigate the risk of implant failure.
- Failure to use largest possible components or improper positioning/insertion of the device during implantation can increase the possibility of migration, loosening, bending, cracking, or fracture of the device or bone, or both.
- Continuous screening with an image intensifier (fluoroscopy) during guide wire insertion and whenever cannulated instruments are advanced over a guide wire is recommended to prevent unintended guide wire advancement and penetration into the surrounding tissues.
- Plate Bending: The plate should not be excessively or repeatedly bent. The plate should not be reverse bent in the same location. Use care to ensure that plate is not scratched or notched during the bending process.
- Contouring and bending of an implant may reduce its fatigue strength causing failure under load.
- Screws and plates included in the Endo-Exo medullary system can only be used with the Enox Nail. The plates included in the Enox system are not standalone osteosynthesis plates.
- A minimum of two Cortical Screws must be used for distal fixation of the Nail.
- Implant System can only be used for patients weighing 60 kg and under or as indicated in the table below.
- For fractures or osteotomies below the lesser trochanter combined with Lag Screw use, the following Lag Screw and weight limitations should be observed:

Nail Size (Ø)	Max. Allowable Lag Screw Length	Max. Patient Weight
4.8	50 mm	40 Kg
5.6	70 mm	40 Kg
6.4	80 mm	50 Kg
7.2 and above	No Limit	60 Kg

- The patient's mobility should be restricted at the region of the osteotomy or fracture to allow bony union. If a nonunion develops, the implants should be removed. If a solid fusion of bone does not occur, the site should be immobilized until solid bony fusion can be achieved. Failure to immobilize a delayed or nonunion of bone will result in excessive and repeated stresses which are transmitted by the body to any temporary internal fixation device prior to healing of the fracture. Due to normal metal fatigue these stresses can cause eventual bending or breakage of the device.
- Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure. Implant removal should be followed by adequate postoperative management to avoid re-fracture or recurrent deformity.
- Care should be taken not to cut through surgical gloves when handling any sharp-edged implants and instruments, and to take into account the risk of infection if a cut appears.
- Early removal of Implant may cause the risk of re-fracture and the possible complications of an additional operation.
- Pediatric patients with dysplasia should undergo regular follow-up to monitor bone growth closely and ensure it does not result in unprotected bone areas, which could lead to deformation, fracture, or refracture. In such cases, replacing the implant with a larger size is recommended to ensure continued stabilization and support.

The surgeon should be aware, and the patient informed of the following information and limitations:

- Compliance of the patient may affect the results of the fixation
- Patients should be warned to avoid any sudden change in position, strenuous activity, or falls. To achieve a successful union, the patient should not be exposed to mechanical vibrations, whether intrinsic or extrinsic, that may lead to loosening of the device. The patient should be warned of this possibility and instructed to restrict physical activities especially those causing any type of mechanical stress on the area that is being secured by the system. The patient should avoid any type of sport activities or strenuous work during the postoperative or post implant removal healing period.

Complications and/or failure are more likely to occur in

- Physically active patients
- Debilitated patients or patients unable to follow instruction or use weight supporting devices
- Patients that suddenly change position, fall, or are exposed to mechanical vibrations.

MRI Safety Information for the Enox Endo/ Exo Medullary System:

The Enox Endo-Exo Medullary System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Enox Endo-Exo Medullary System in the MR environment is unknown.

Benefits and Performance Characteristics

Please, consult this system's SSCP for the detailed performance characteristics and expected clinical benefits for the devices. The clinical benefits of the instruments are primarily to facilitate appropriate alignment, sizing, implantation and explanation of associated implant.

General Care, Handling and Inspection

Store implants unopened in their respective protective packages until use. Protect the components from contact with objects, which may damage the surface finish. Avoid undue stress or strain when handling or cleaning. Tap water can contain many minerals that may discolor and stain the parts; therefore, it is recommended that deionized water be used for the final rinsing to prevent spotting.

Implant components can be reprocessed by the intended users according to the cleaning and sterilization instructions provided in this document. there is no specific limitation in the number of reprocessing cycles, however each reprocessed implant component must be visually inspected prior to use and dispose of implants that exhibit surface or configuration damage. In case the implant component is reprocessed, the device must be stored and transported in dry conditions.

Cleaning and Sterilization Instructions for Implant Components and Trays

Implants are provided clean but are NON-STERILE when shipped from IMD. The instructions below should be followed for sterilizing items supplied non-sterile. Apply a standard cleaning protocol that is approved by the hospital before implant sterilization. All metallic implants and trays can be steam sterilized following the instructions and parameters listed below:

- Implant components of the ENOX System should be sterilized using sterilization pouches.
- Devices should be dry before packaged for sterilization

Method	Steam
Sterilization type	Prevacuum
Minimal temperature	270°F (132°C)
Minimal cycle time	4 minutes
Minimal drying time	30 minutes

Warning: Do not stack trays during sterilization.

Other sterilization methods and cycles may also be suitable. However, validation of any alternative method using appropriate laboratory techniques is advised.

Cleaning, Sterilization and Re-sterilization Instructions for Instruments

Reusable instruments must be cleaned and sterilized prior to every use. The instrument tray and instruments of the ENOX system should be sterilized wrapped in two layers of 1-ply polypropylene wrap using sequential wrapping techniques.

Please refer to document entitled: "Guidance for Instrument Care" for further information and instructions regarding cleaning, sterilization and re-sterilization of instruments.

Disposal Information

After use, the device is a potential biohazard, since it may be contaminated with blood or other fluids, bone or tissue. Handle and dispose of product in accordance with accepted medical practice and with applicable local, state and national laws and regulations.

Reporting Problems:/ Notice to the User and/or Patient

Intended users and patients should report any suspected serious incident related to the implanted device by informing the manufacturer at info@imd.com.tr or the local IMD distributor, and the competent authority, ministry of health, or delegated agency in the country where the suspected serious incident occurred.

Authorized Representative / Autoriseret repræsentant / Autorisierter Vertreter / Représentant Autorisé / Rappresentante autorizzato / Representante autorizado: