



Pega Medical

gap nail

The endo-exo medullary system



The first IM nail specifically designed for the treatment of fractures and deformities in patients with small diameter canals.

SURGICAL TECHNIQUE

gap nail

The endo-exo medullary system

The **Gap Nail**, *the endo-exo medullary system*, is used for the treatment of fractures or the correction of deformities in the femur, tibia and humerus of pediatric patients (child and adolescent) ages 2 to 21.

This fixation device consists of an intramedullary nail linked to a plate via Lag and Mechanical Screws creating a combined Endomedullary / Exomedullary osteosynthesis device. This novel approach of osteosynthesis intends to create a load sharing system between the nail and the plate, with the objective of limiting the risk of stress fractures and improving the implant stability in weak bones.

Intended uses:

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

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GAP-ST-EN REV D



Implant Configurations

STANDARD INTERLOCKING SURGICAL TECHNIQUE

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

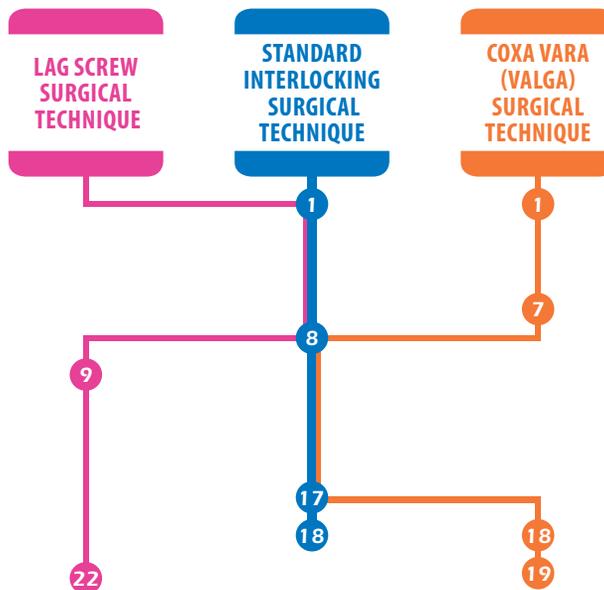
LAG SCREW SURGICAL TECHNIQUE

Antegrade Femur Long & Short Plate



Femoral Neck Fixation
Trochanteric Fractures
Deformity Correction
Diaphyseal Fractures

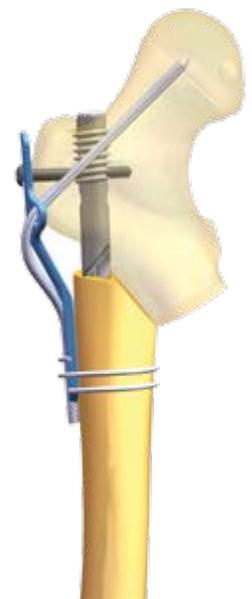
SURGICAL TECHNIQUE STEPS



*You must follow the color steps of each surgical technique. ●●●

COXA VARA (VALGA) SURG. TECH.

Coxa Vara Plate



Coxa Vara Correction

STEP 1

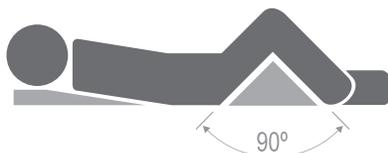
PATIENT POSITIONING

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 C-arm 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.

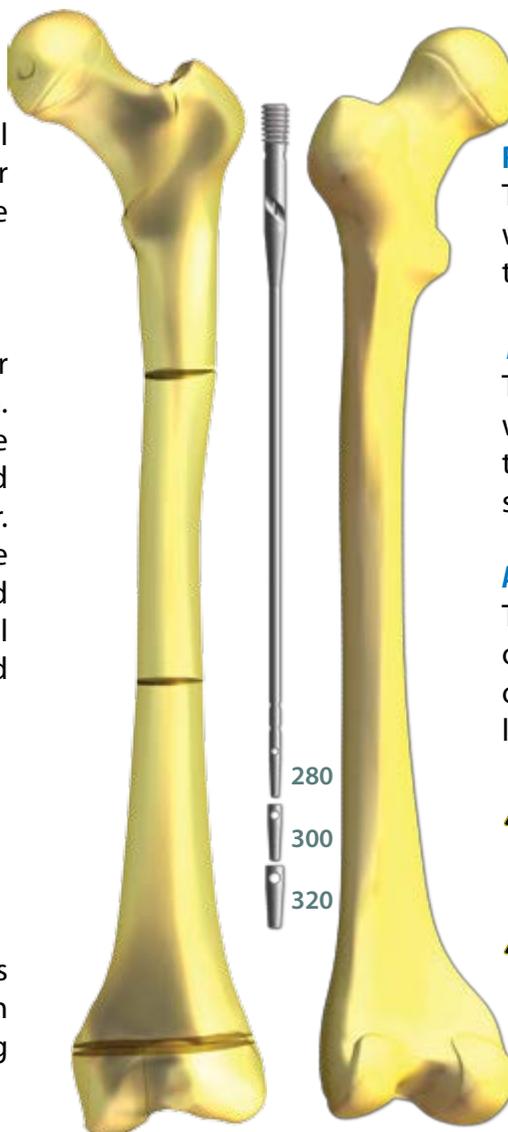
STEP 2

NAIL SELECTION

For Femur, Tibia and Humerus, lateral and AP x-rays are taken. The diameter of the nail is selected based on the size of the medullary canal at the isthmus.

Antegrade Femur

The nail's length is determined after osteotomy or fracture reduction. Position the C-arm in an AP view of the proximal femur; 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. The GAP Nail Template (GAP-TPL100) can also be used to validate the nail's length.



Retrograde Femur

The nail head should be fully inserted within the femur and not protrude in the articulation.

Antegrade Tibia

The nail head should be fully inserted within the tibia and not protrude in the articulation. The distal segment should extend up to the physal 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.

 Nail length selected should be as long as possible with distal interlocking cortical screws away from fracture/osteotomy site.

 The **Gap Implant System** can only be used for patients weighing 60 kg or less or as indicated in the table on page 12.

STEP 3

OSTEOTOMY

If needed, one or several osteotomies can be performed under C-arm guidance to correct the existing deformities.



STEP 4

ENTRY POINT / INCISION

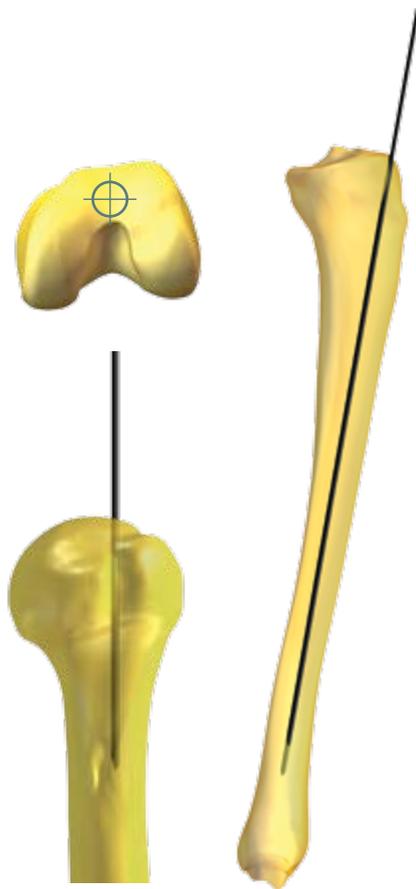
Antegrade Femur

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 5

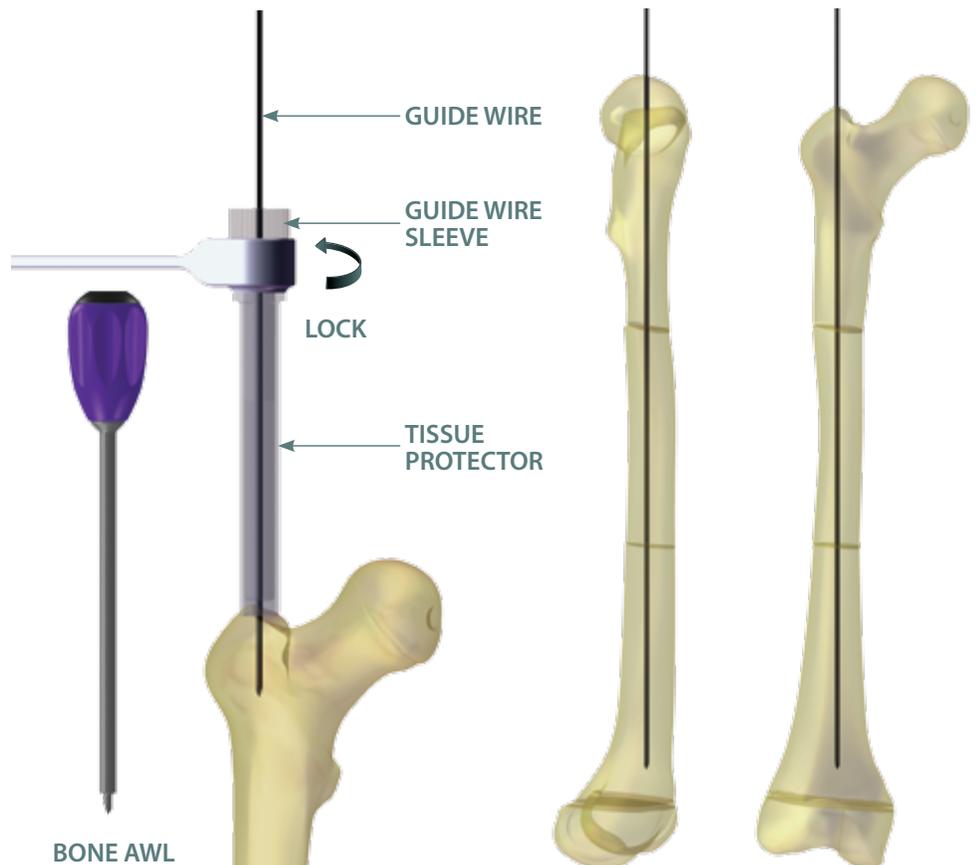
GUIDE WIRE INSERTION

Puncture the cortex using the Bone Awl (GAP-BA W100) or directly with the Guide Wire using the Tissue Protector (GAP-TP116) and adequate Guide Wire Sleeve depending on the nail size.

Nail Size Ø	Guide Wire	Guide Wire Sleeve
4.8 / 5.6 / 6.4	GAP-KWG016 (1.6 mm)	GAP-SGW116
7.2 / 8.0	GAP-KWG020 (2.0 mm)	GAP-SGW120

Insert the Guide Wire into the canal and validate the position under C-arm in both the AP and lateral views prior to reaming.

! If Lag Screws will be used, the Guide Wire should be inline with the femoral neck in the lateral view.





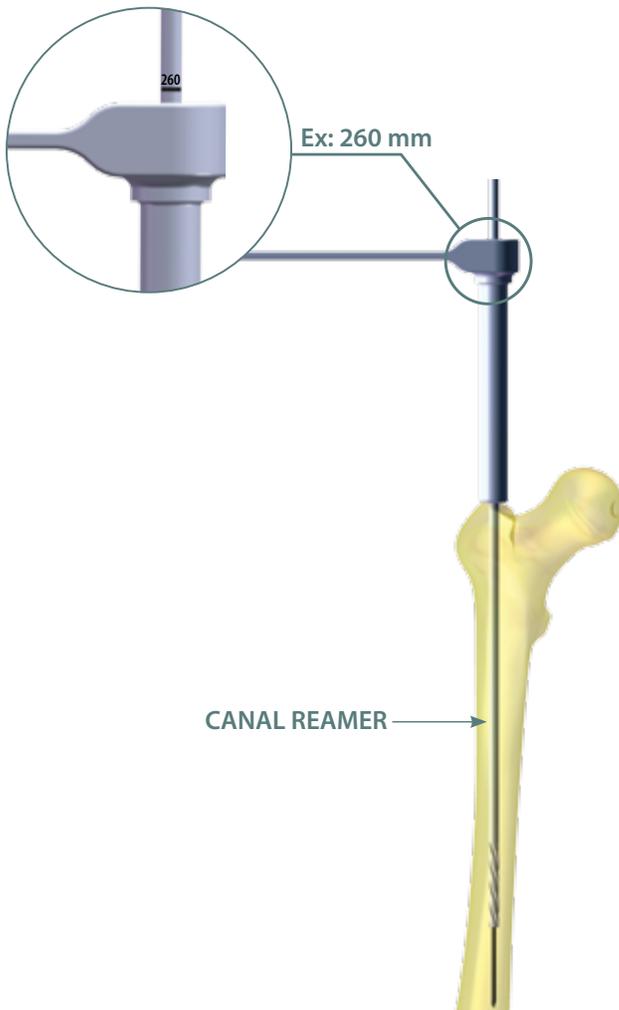
CONICAL REAMING

Select the Conical Reamer corresponding to the selected nail size.

Nail Size Ø	Conical Reamer
4.8 / 5.6 / 6.4	GAP-DTP101
7.2 / 8.0	GAP-DTP052

Ream through the Tissue Protector and over the Guide Wire. Continue reaming until the stopper reaches the edge of the Tissue Protector handle.

⚠ Do not force the Reamer. Partially retract the Reamer, if needed, to clean debris from the medullary canal.



MEDULLARY CANAL REAMING

Select the Canal Reamer corresponding to the selected nail size. Ream through the Tissue Protector and over the guide wire. Advance the Reamer with steady and moderate pressure.

⚠ Do not force the Reamer. Partially retract the Reamer, if needed, to clean debris from the medullary canal.

Nail Size Ø	Canal Reamer
4.8	GAP-DCA048
5.6	GAP-DCA056
6.4	GAP-DCA064
7.2	GAP-DCA072
8.0	GAP-DCA080

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

⚠ Remove the Tissue Protector once reaming is complete.



STEP 8

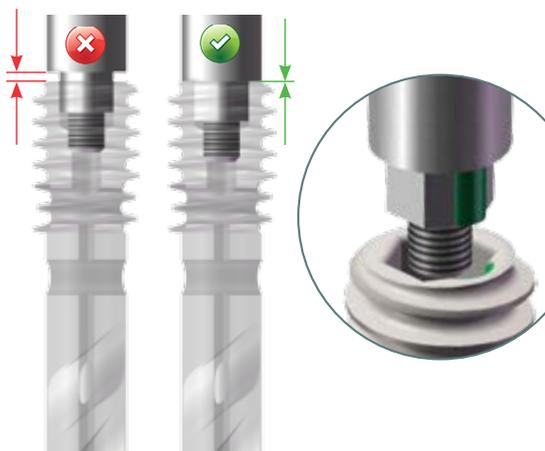


NAIL INSERTION

8.1 Assembly of the Nail onto the Nail Driver

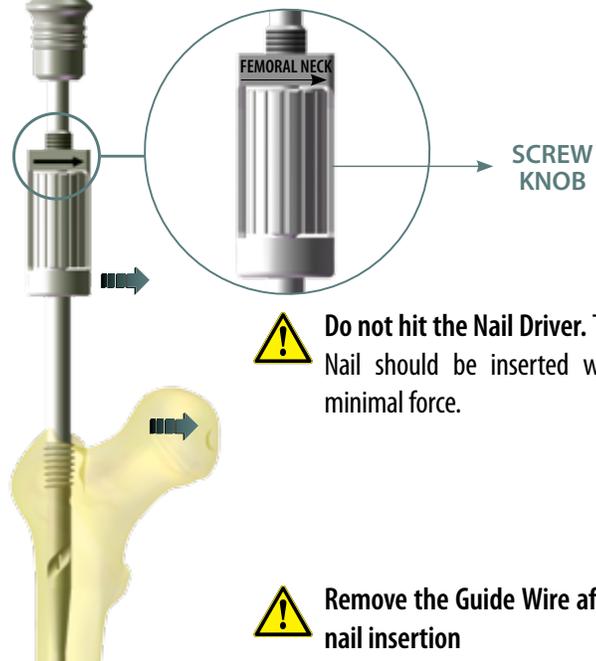
Using the Nail Driver (GAP-NDR100), turn the screw knob until the nail is fully locked on the Nail Driver; there should be no space between the nail head and Nail Driver.

⚠ To assemble, the circular notch on the hexagonal drive of the Nail Driver **must align** with the corresponding notch in the Nail.



8.2 Nail Insertion

Inserted the nail into the prepared canal over the Guide Wire to the desired depth. Nail alignment with femoral neck must be respected. **Follow the markings on the Nail Driver.**



STEP 9



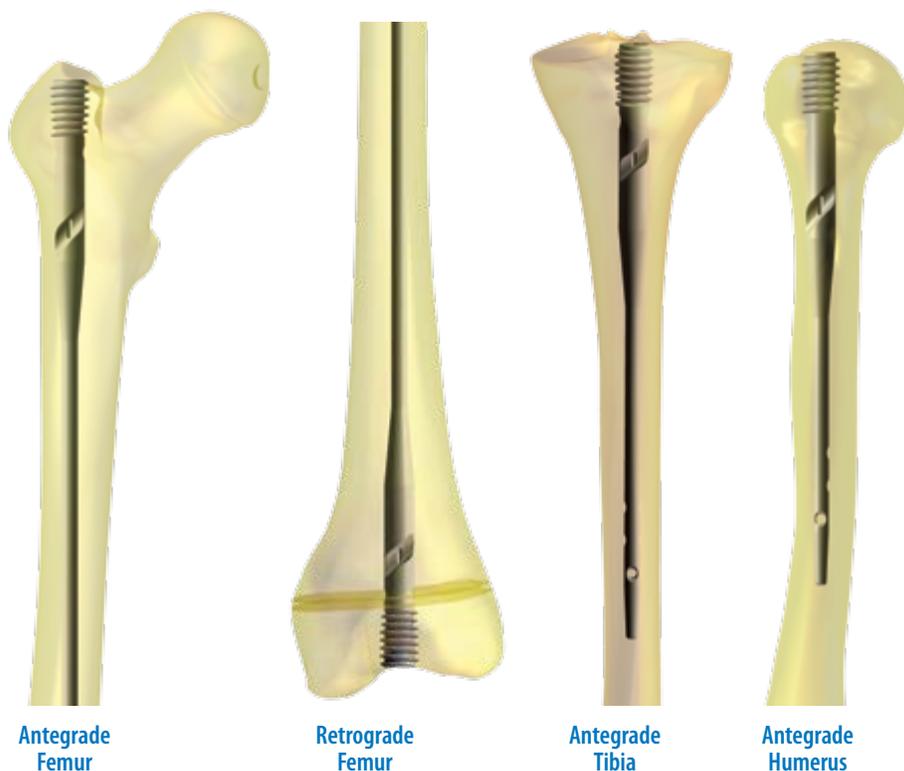
⚠ If Lag Screws are used, skip to page 12:

● **STEP 9 - Lag Screw Surgical Technique**

NAIL POSITION, DEPTH AND ALIGNMENT VERIFICATION

For all configurations, the nail should be centered within the medullary canal and the nail's head should not protrude into the articulation. Angular nail alignment (and thus Cortical Screw orientation) is left to the discretion of the surgeon.

⚠ For Anteversion Correction, the nail's Lag holes must be inline with the femoral neck in the lateral view to provide a proper reference.



STEP 10

TARGETING DEVICE ASSEMBLY

Assemble the Targeting Device (GAP- TGD100) onto the Nail Driver by sliding the assembly onto the Nail Driver and then turning the threaded cap until the assembly is **fully tightened**.

STEP 11

DISTAL ATTACHMENT ASSEMBLY

Mount the Distal Attachment (GAP- DSA150) onto the Targeting Device. Turn the set-screw knob fully to secure.

STEP 12

TARGETING DEVICE LOCKING

12.1 Mechanical Screw Hole Preparation

Insert the Mechanical Screw Sleeve (GAP-SMS100) into the proximal hole of the Distal Attachment. Secure by tightening the set-screw. Ream to stopper using the Mechanical Screw Drill (GAP-DMS110).



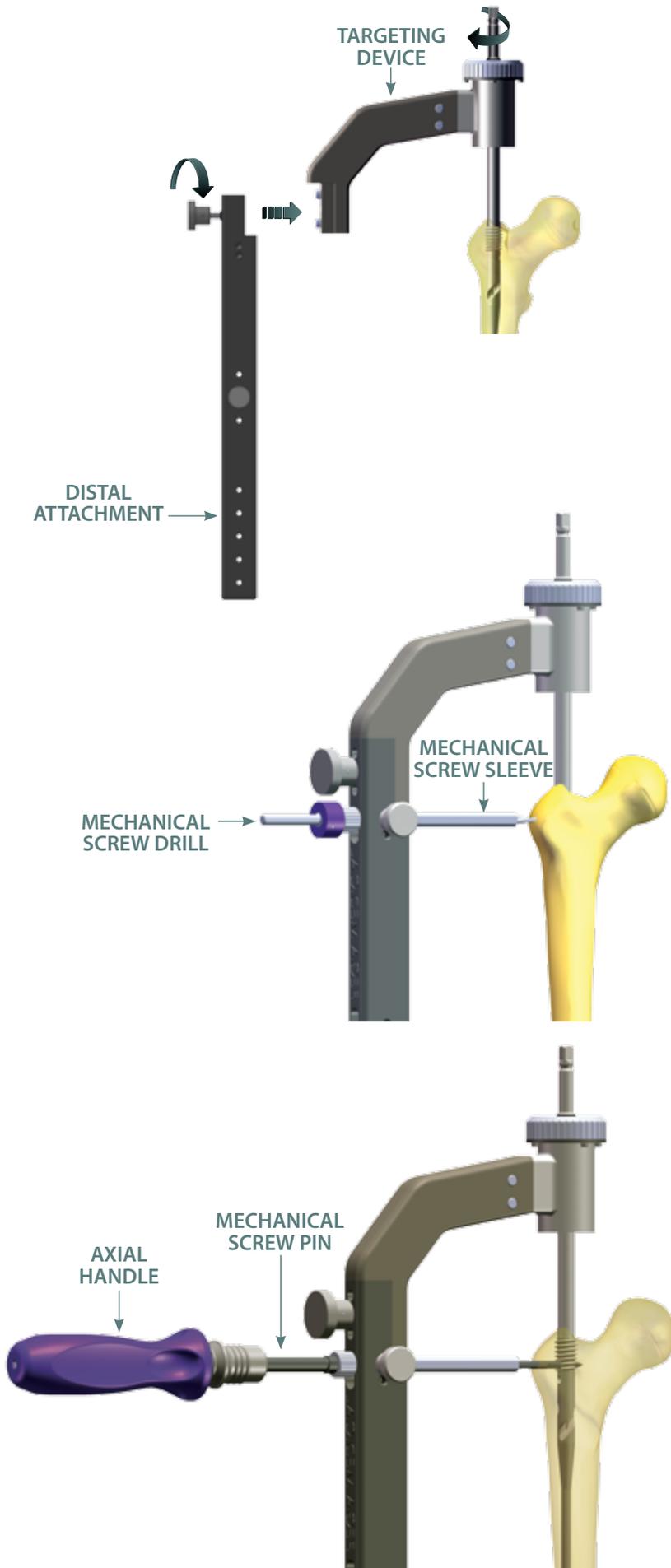
Remove the Mechanical Screw Drill. Leave the Mechanical Screw Sleeve.

12.2 Mechanical Screw Pin Insertion

Mount the Axial Handle (GAP-THA100) onto the Mechanical Screw Pin (GAP-MSP100). Using the Mechanical Screw Sleeve as guidance, insert the pin until it is fully engaged with the nail.



If resistance is felt, retract the pin and clean out the hole. Do not overtighten the Mechanical Screw Pin; this can cause a misalignment between the Distal Attachment and the distal locking holes in the implant.



STEP 13

DEROTATION AND ANTEVERSION CORRECTION (OPTIONAL)

If derotation or anteversion correction is required, mount the Derotation Compass (GAP-CMP100) onto the Distal Attachment using the set-screw. Secure the device above the level of the distal articulation.

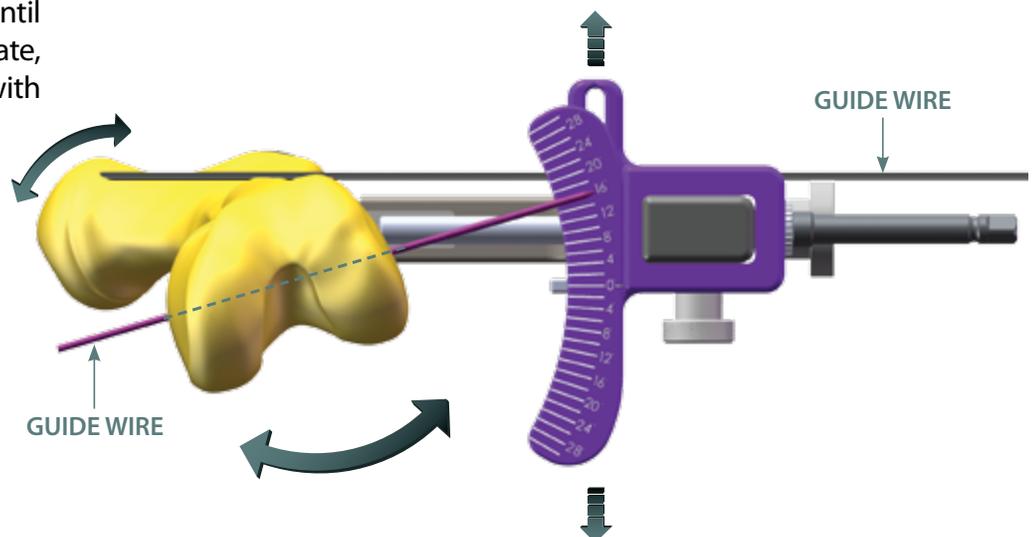
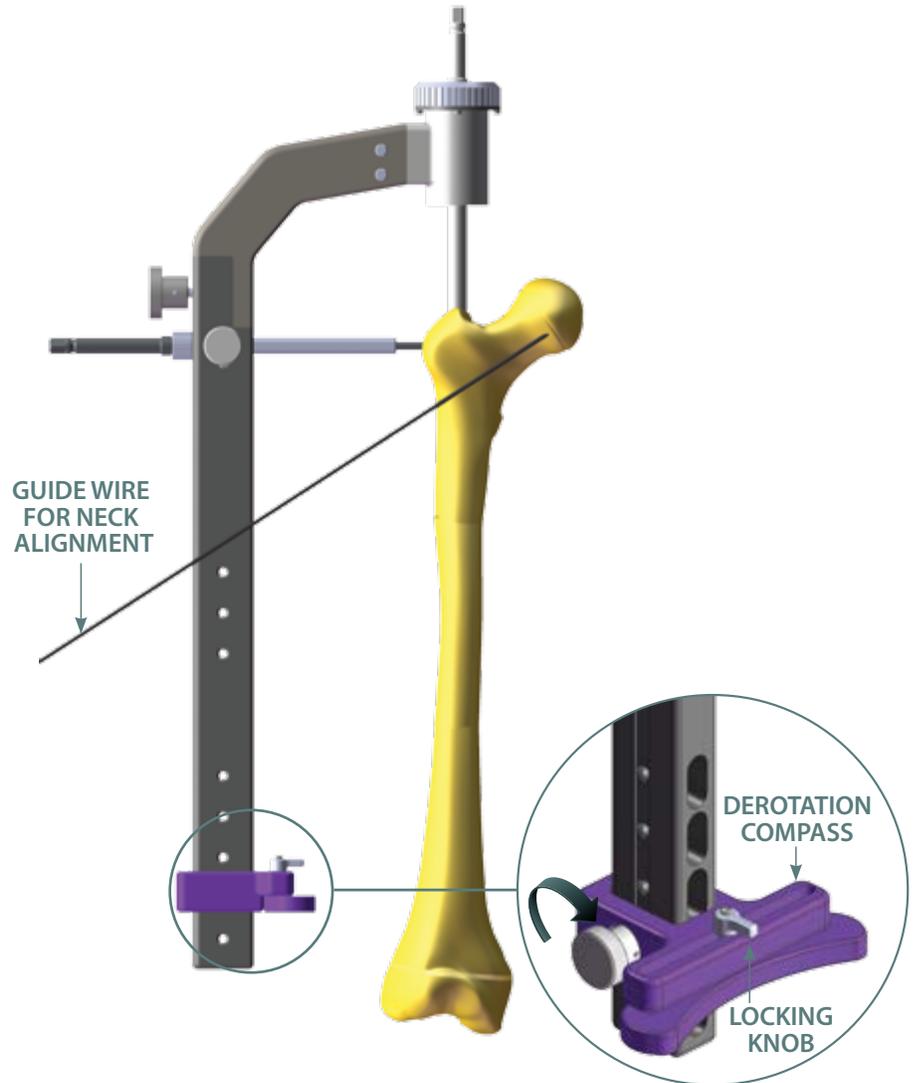
! Do not mount the compass over the distal slot corresponding to the nail size being used since this will prevent the insertion of the Distal Cortical Sleeve.

Femoral Neck Reference

Place a first Guide Wire on the ventral side of the femoral neck under image intensification. The Guide Wire should be parallel to the Distal Attachment.

Insert a second Guide Wire, through the distal articulation, parallel to the retrocondylar line. Slide the compass until the second guide wire aligns with an angular graduation mark, then block the rotation of the compass with the locking knob. This reading will give you the relative angle between the retrocondylar line and the axis of the femoral neck.

Rotate the distal femoral segment until the anteversion angle is adequate, then secure the distal femur with Cortical Screws (see next step).



 For Nails \emptyset 4.8 and \emptyset 5.6, 2 screws must be inserted.

STEP 14

DISTAL FIXATION

14.1 Distal Alignment and Incision

Check the distal alignment using the C-Arm; the holes should appear perfectly circular. Make a stab incision over the proper hole position.

14.2 Distal Screw Hole Preparation

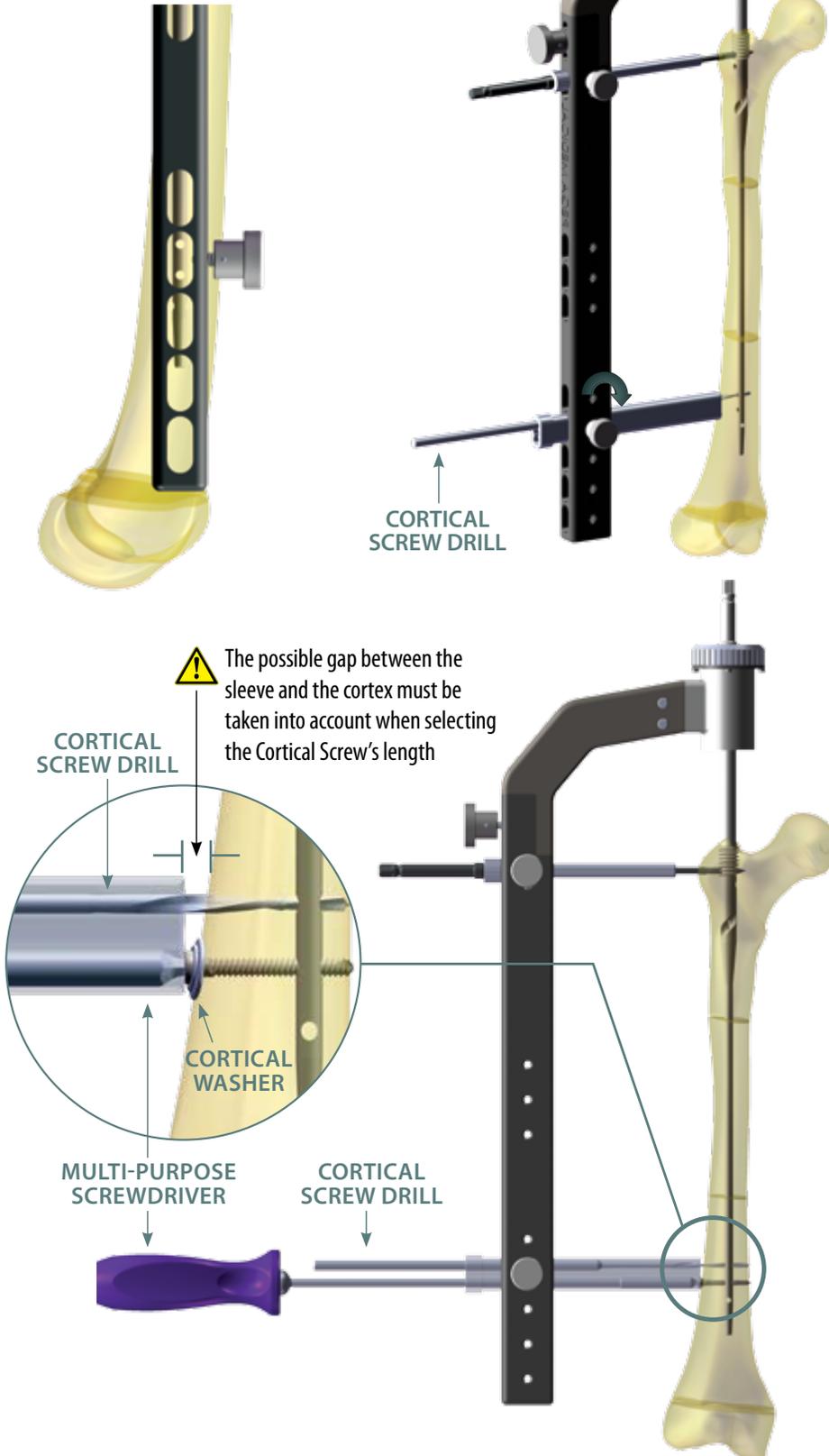
Insert the Distal Cortical Sleeve (GAP-STH100) through the Distal Attachment at the appropriate position corresponding to the nail length. Once the sleeve is resting against the cortex, lock it in position using a set-screw.

Nail Size \emptyset	Screw Size	Drill's	# of Cortical Screw
4.8 / 5.6	3.0	GAP-DCS103 & GAP-DCS103-L	2
6.4 / 7.2 / 8.0	4.0	GAP-DCS104 & GAP-DCS104-L	1 or 2

The Cortical Screw Endmill (GAP-DCE 100) can be used first to flatten the cortex and prevent slipping of the cortical drill tip on the curved cortex. During drilling, check the drill's position under image intensification. After the endmill, use the shorter Cortical Drill (GAP-DCS103/104) to bore a hole until the far cortex, and, note the corresponding Cortical Screw length on the drill. To facilitate the drilling of the second hole and maintain alignment through the nail, leave the short cortical drill in place and use the longer provided drill (GAP-DCS103-L/104-L) to make the second hole.

14.3 Cortical Screw Insertion

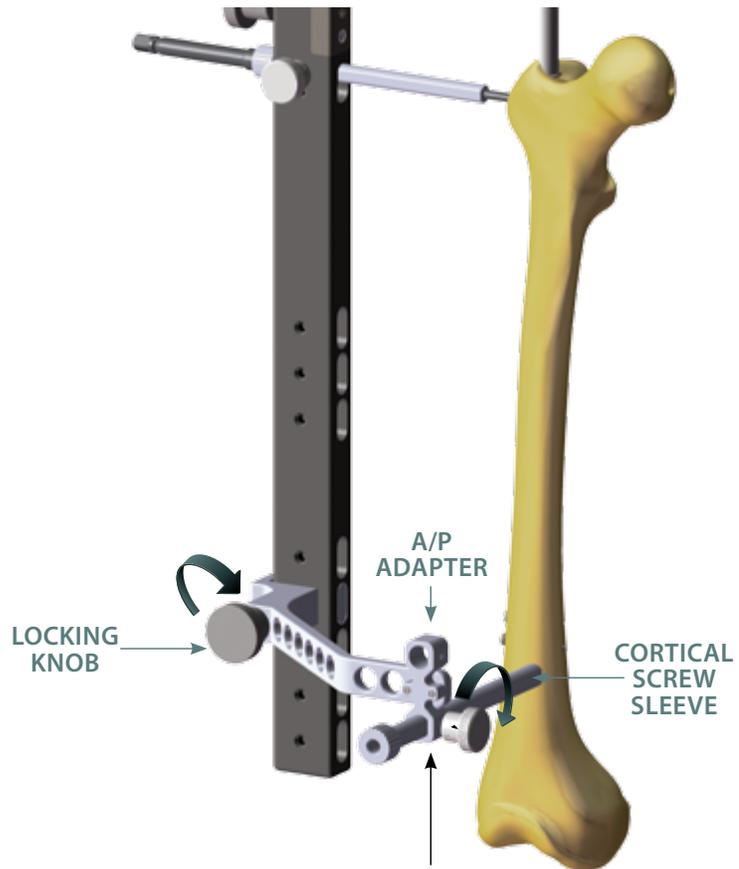
Using the Multi-Purpose Screwdriver (GAP-TMP100), insert the Cortical Screws (GAP-CS*..**) corresponding to noted length and appropriate diameter. A Cortical Washer (GAP-WAS 100) can be used when dealing with fragile bones to improve distribution of stress onto the cortex. To use the washers, retract or remove the Distal Cortical Sleeve because the washer's diameter exceeds the sleeve's internal diameter. It is recommended to keep the **short** cortical drill in place to maintain alignment while inserting the first Cortical Screw.



STEP 15

A/P FIXATION (OPTIONAL)

Use of an A/P Screw is recommended to improve the rotational stability and the strength of the implant assembly. For A/P nail locking, mount the A/P Adapter (GAP-APA100) onto the Distal Attachment using the locking knob. Insert the Cortical Screw Sleeve (GAP-SCS 100) through the A/P Adapter, and, make a stab incision to allow insertion of the sleeve up to the cortex, to then lock the sleeve in its final position. Using the adequate Cortical Screw Drill (see table in step 14.2), bore a hole to the far cortex and note the corresponding screw length on the drill. Finally, insert the Cortical Screw into the bone using the Multi-Purpose Screwdriver.



Always use the distal hole of the A/P Attachment to assemble the Cortical Screw Sleeve.

STEP 16

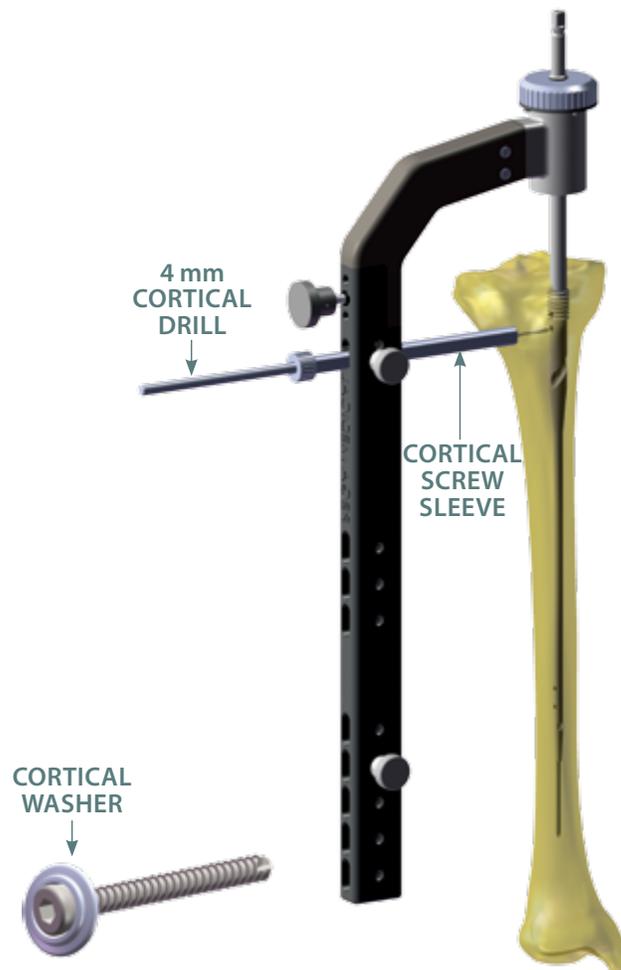
PROXIMAL FIXATION (OPTIONAL)

Use of a proximal Cortical Screw is recommended when additional rotational stability is required.

⚠ Remove the Mechanical Screw Pin and the Mechanical Screw Sleeve

Insert the Cortical Screw Sleeve (GAP-SCS 100) into the Distal Attachment, and, make a stab incision to allow insertion of the sleeve up to the cortex, to then lock the sleeve in its final position using the set-screw. Using the 4mm Cortical Drill (GAP-DCS 104) drill to the far cortex and note the corresponding screw length on the drill. Finally, insert the Cortical Screw into the bone using the Multi-Purpose Screwdriver.

A Cortical Washer (GAP-WAS 100) can be used when dealing with fragile bones to improve distribution of stress onto the cortex. To do so, the sleeve must be retracted from the cortex or removed completely since the washer's diameter exceeds the sleeve's internal diameter.



If the Nail Driver is difficult to remove, insert a pin (1/4" or less) through a hole in the Nail Driver knob and rotate counter-clockwise.



INSTRUMENTATION REMOVAL

- Remove:**
- Cortical Screw Sleeve
 - Distal Attachment.
 - Targeting Device
 - Nail Driver

- If performing Coxa Vara / Coxa Valga correction, return to page 22:**
- STEP 18 - Coxa Vara (Valga) Surgical Tech.

NAIL CAP INSERTION

Using the Multi-Purpose Screwdriver insert the appropriate Nail Cap (GAP-CP***) into the proximal internal thread of the nail.

Nail Caps (Height)	
1.5 mm	GAP-CP015
5.0 mm	GAP-CP050
10.0 mm	GAP-CP100

For Retrograde femur, Antegrade Humerus and Tibia applications, the Nail Cap should be flush with the articular cartilage.

For Proximal Femur applications, the cap should protrude from the cortex.

Antegrade Femur



Antegrade Tibia



gap nail
The endo-exo medullary system



Retrograde Femur



Antegrade Humerus



STEP 1-8

- ⚠ Perform: **STEPS 1 to 8** (page 3)
- **Standard Interlocking Surgical Technique**

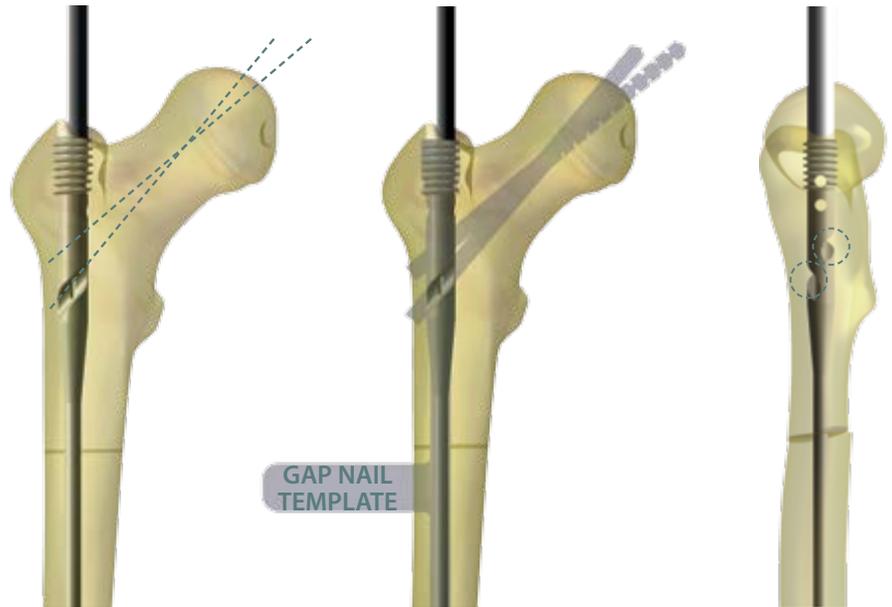
⚠ For fractures or osteotomies below the lesser trochanter combined with Lag Screw use, the following Lag Screw and weight limitations should be observed.

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

STEP 9

NAIL POSITION, DEPTH AND ALIGNMENT VERIFICATION

Using the C-arm, in both the AP and lateral views, verify proper alignment of the nail. In the AP view, verify the nail's depth and consequent Lag Screw alignment. The GAP Nail Template (GAP-TPL100) can be used to better approximate the Lag Screws' final position and length. In the lateral view, verify the centering of the Lag Screw holes with the femoral neck; the proximal holes (Cortical Screw and Mechanical Screw) should appear circular. Finally, verify the distal position of the implant.

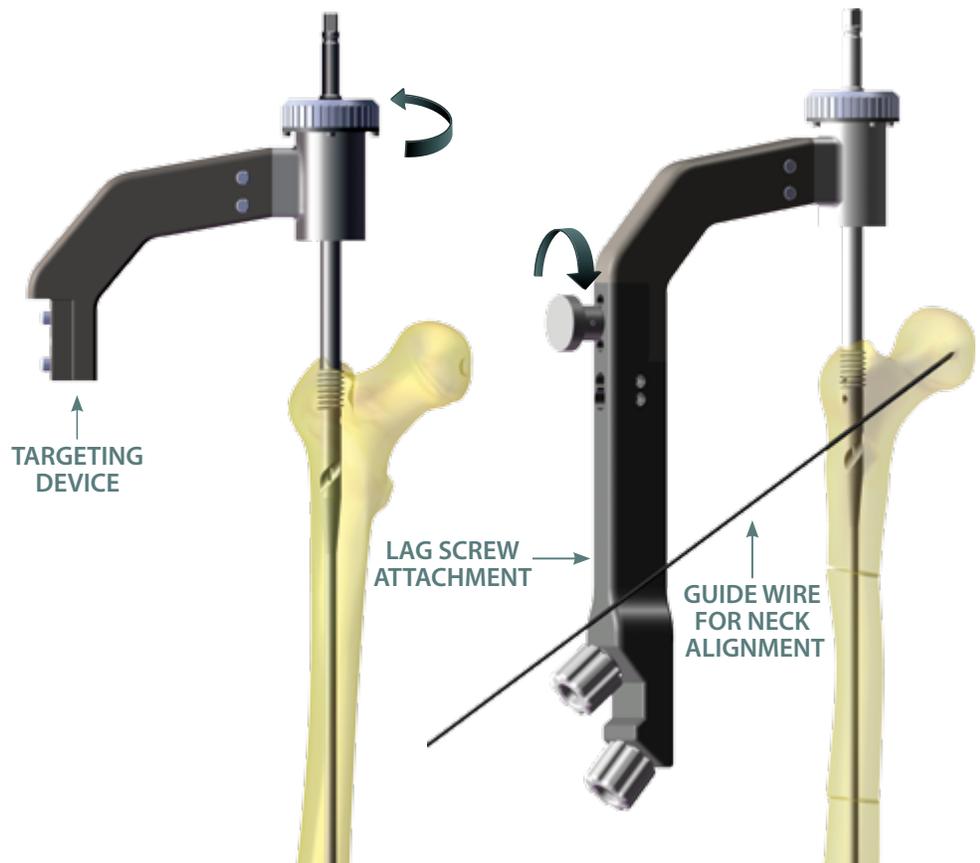


⚠ Every full revolution of the nail corresponds to 2.4mm of insertion. When the desired position is attained, **remove** the Axial Handle and the Guide Wire.

STEP 10

TARGETING DEVICE ASSEMBLY

The Targeting Device (GAP-TGD100) is assembled onto the Nail Driver by sliding the assembly onto the Nail Driver and then turning the threaded cap until the assembly is **fully tightened**.



STEP 11

LAG SCREW ATTACHMENT ASSEMBLY

Mount the Lag Screw Attachment (GAP-LSA 150) onto the Targeting Device. Turn the set-screw knob fully to secure.

Femoral Neck Reference

Place a Guide Wire on the ventral side of the femoral neck under image intensification. The Guide Wire should be parallel to the Lag Attachment.

NECK ALIGNMENT AND DEPTH VALIDATION

12.1 Cortex Preparation

Insert the Lag Screw Sleeve (GAP-SLS155) into the Lag Attachment. Make a stab incision and drive the Sleeve to the bone. Once the sleeve is resting against the cortex, lock it in position using the compression ring.

Using the Lag Endmill (GAP-DLF 155), ream until the stopper reaches the sleeve. This creates a flat surface that allows a more precise insertion of the Depth Gage Wire. Repeat the reaming for the lower Lag Screw hole.



⚠ Do not exert forces on the Lag Attachment or the Targeting Device. Such forces may damage the implant or drills, and render the targeting inaccurate.

⚠ Remove the Lag Screw Sleeve when reaming is complete.

12.2 Depth Gage Wire Insertion

Insert the two Depth Gage Sleeves (GAP-SDG120) through the Lag Attachment, and secure them using the compression rings.

Insert the two Depth Gage Wires (GAP-KDG360, 360 mm long) into the femoral neck and head to the desired depth.

Check the gage wires placement in both the AP and lateral views. Depth Gage Wires should be centered within the femoral neck.



⚠ If the Nail's position is not adequate, remove the wires, sleeves, Lag Attachment, Targeting Device and return to **STEP 9**



STEP 13

TARGETING DEVICE LOCKING

13.1 Mechanical Screw Hole Preparation

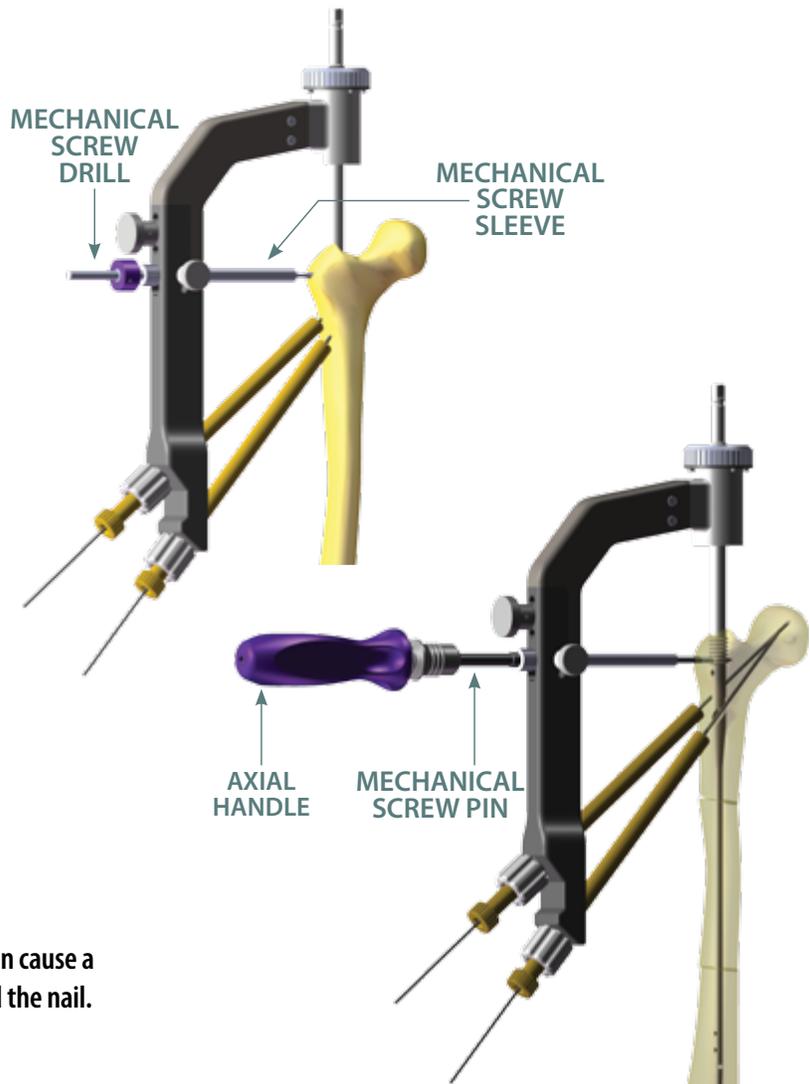
Mount the Mechanical Screw Sleeve (GAP-SMS100) into the proximal hole of the Lag Attachment. Secure by tightening the set-screw. Do not over tighten. Ream to stopper using the Mechanical Screw Drill (GAP-DMS110).

 Remove the Mechanical Screw Drill.
Leave the Mechanical Screw Sleeve.

13.2 Mechanical Screw Pin Insertion

Mount the Axial Handle (GAP-THA100) onto the Mechanical Screw Pin (GAP-MSP100). Using the Mechanical Screw Sleeve as guidance, insert the pin until it is fully engaged in the nail. If resistance is felt, retract the pin and clean out the hole.

 Do not overtighten the mechanical screw pin ; this can cause a misalignment between the Lag Attachment and the nail.



STEP 14

LAG SCREW INSERTION

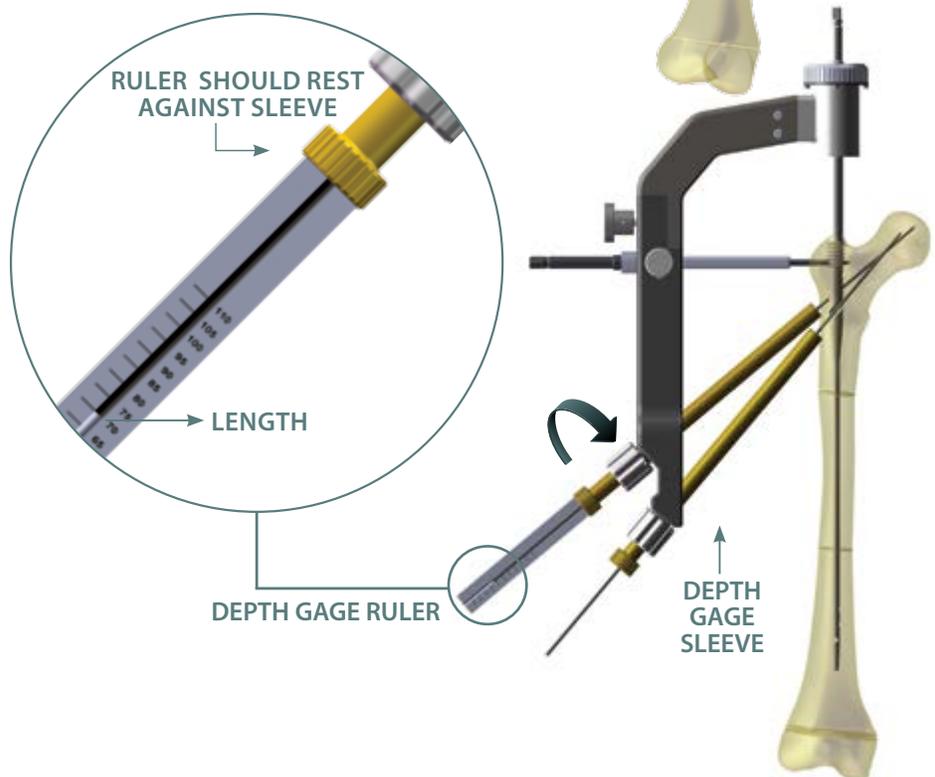
14.1 Lag Screw Length Measurement

Using the Depth Gage Ruler (GAP-DPG120), measure the **Upper** Lag Screw length. If the measurement is in between two markings, always select the smaller length.

Due to the difference in angulation, the Lower Lag Screw will be one size (5 mm) longer than the upper Lag Screw to achieve the same depth in the femoral head.

 Remove the Depth Gage Ruler and Depth Gage Sleeves once measurements are obtained.

 Leave the Depth Gage Wires.



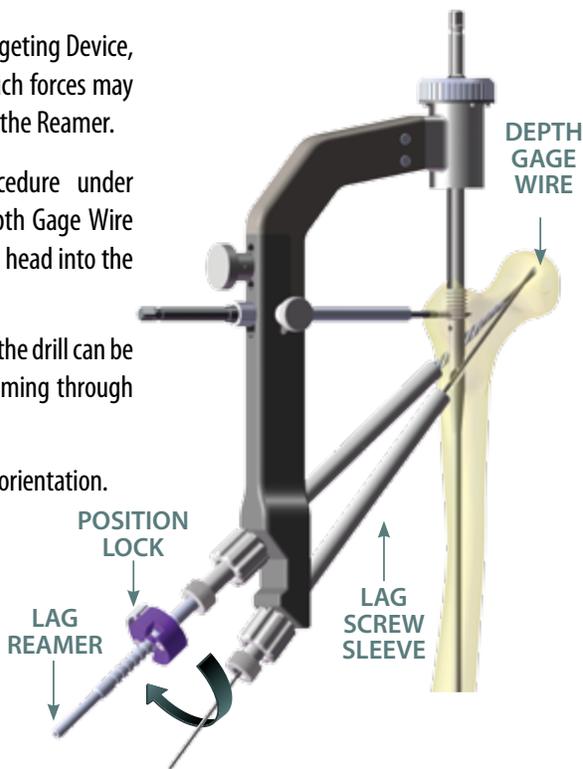
Lag Screw Surgical Technique (Long & Short Plate)

! Do not exert forces on the Targeting Device, Lag Attachment or Sleeve. Such forces may prevent accurate targeting of the Reamer.

! Visualize the reaming procedure under C-Arm to ensure that the Depth Gauge Wire is not driven past the femoral head into the articulation.

! For the upper Lag Screw hole, the drill can be set to reverse to facilitate reaming through the Nail.

! Respect of the Position Lock's orientation.



14.2 Lag Hole Reaming

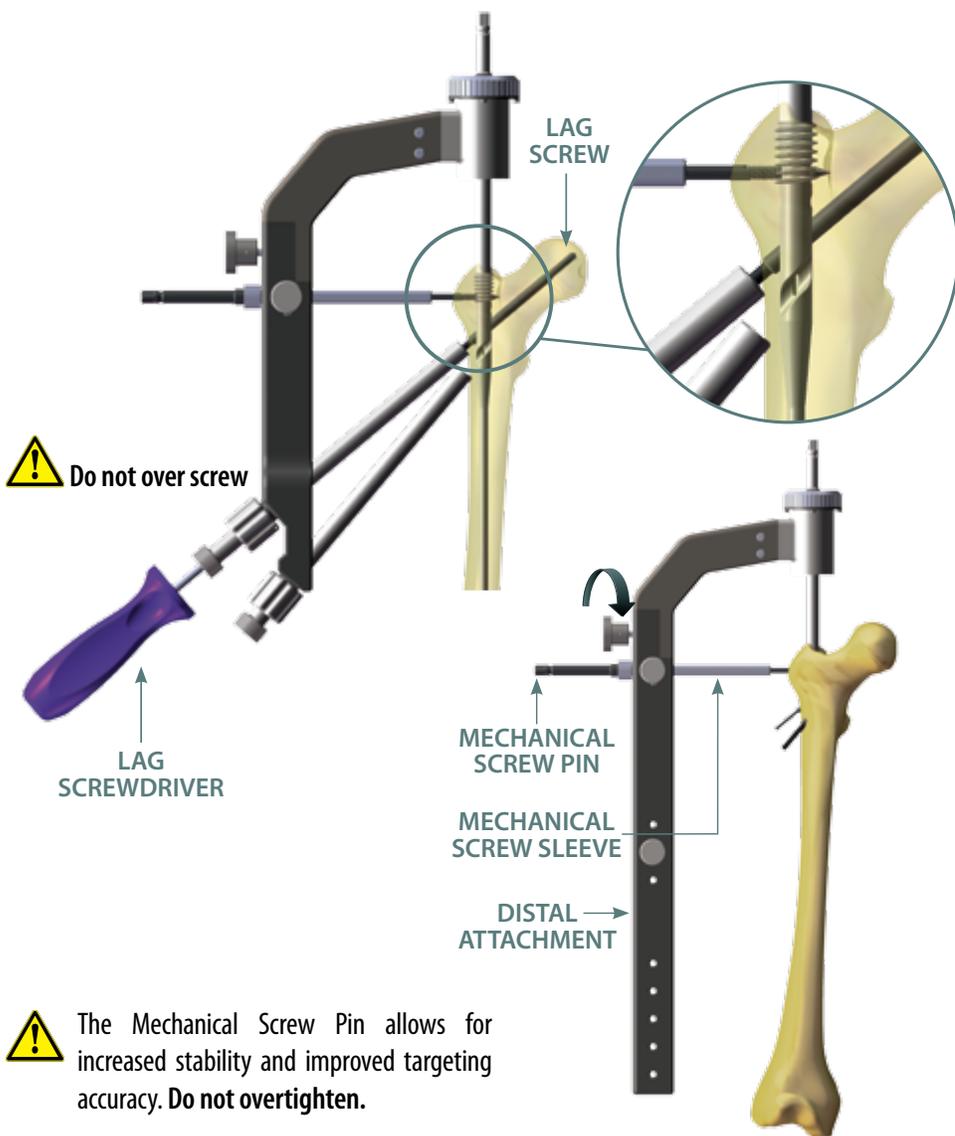
Mount the Lag Screw Sleeve (GAP-SLS155). Using the Position Lock (GAP-LCK080), set the Lag Reamer (GAP-DLG055) depth to the desired length. Ream until stopper reaches the Lag Screw Sleeve.

14.3 Lag Screws Insertion

Using the Lag Screwdriver (GAP-TLS100) insert the appropriate Lag Screws (GAP-LG***). Verify the position of the Lag Screws under image intensification in both planes.

The Lag Screws' shafts should be fully within the cortex leaving only the threaded segment protruding from the lateral cortex.

! Once completed, remove:
Mechanical Screw Pin & Lag Attachment.



! Do not over screw

! The Mechanical Screw Pin allows for increased stability and improved targeting accuracy. Do not overtighten.

STEP 15

DISTAL ATTACHMENT

15.1 Assembly

The Distal Attachment (GAP-DSA 150) is used for distal Cortical Screw preparation and insertion, in both the AP and lateral planes. It can also be used to prepare the proximal cortical and mechanical screw holes. To mount the Distal Attachment onto the Targeting Device, turn the set-screw knob fully.

! The Mechanical Screw Hole should have
● already been prepared at **STEP 13.1**

15.2 Locking

Mount the Axial Handle (GAP-THA100) onto the Mechanical Screw Pin (GAP-MSP100). Using the Mechanical Screw Sleeve as guidance, insert the pin until it is fully engaged in the Nail. If resistance is felt, retract the pin and clean out the hole.

15.3 (optional) Derotation

! For Derotation, see page 8
● **STEP 13 Derotation and Anteversion correction.**



STEP 16

 For Nails \emptyset 4.8 and \emptyset 5.6, 2 screws must be inserted.

DISTAL FIXATION

16.1 Distal Alignment and Incision

Check the distal alignment using a C-arm; the holes should appear perfectly circular. Make a stab incision over the proper hole position.

16.2 Distal Screw Hole Preparation

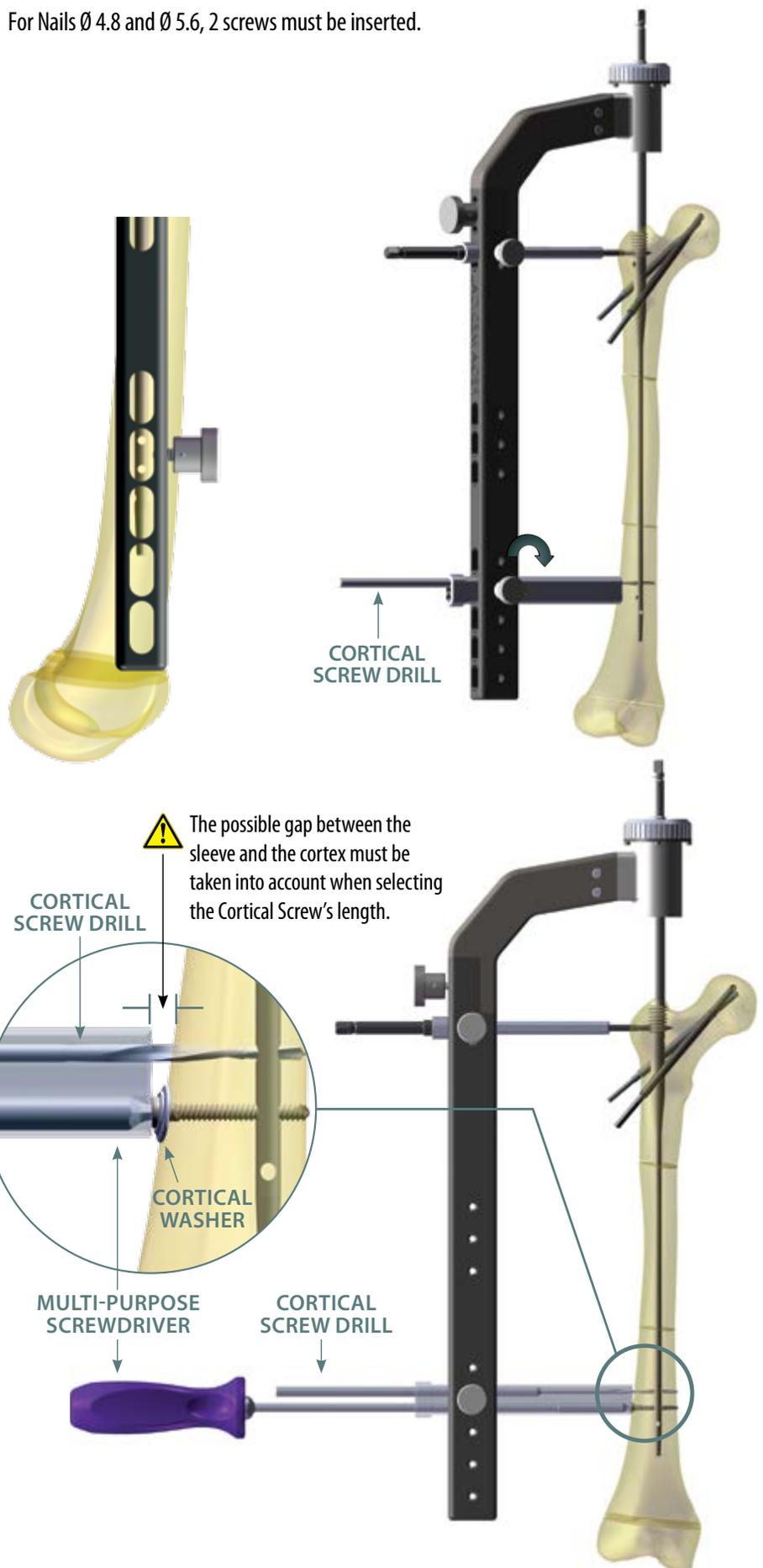
Insert the Distal Cortical Sleeve (GAP-STH100) through the Distal Attachment at the appropriate position corresponding to the cortical screw holes in the selected Nail. Once the sleeve is resting against the cortex, lock it in position using a set-screw.

Nail Size \emptyset	Screw Size	Drill (s)	# of Cortical Screw
4.8 / 5.6	3.0	GAP-DCS103 & GAP-DCS103-L	2
6.4 / 7.2 / 8.0	4.0	GAP-DCS104 & GAP-DCS104-L	1 or 2

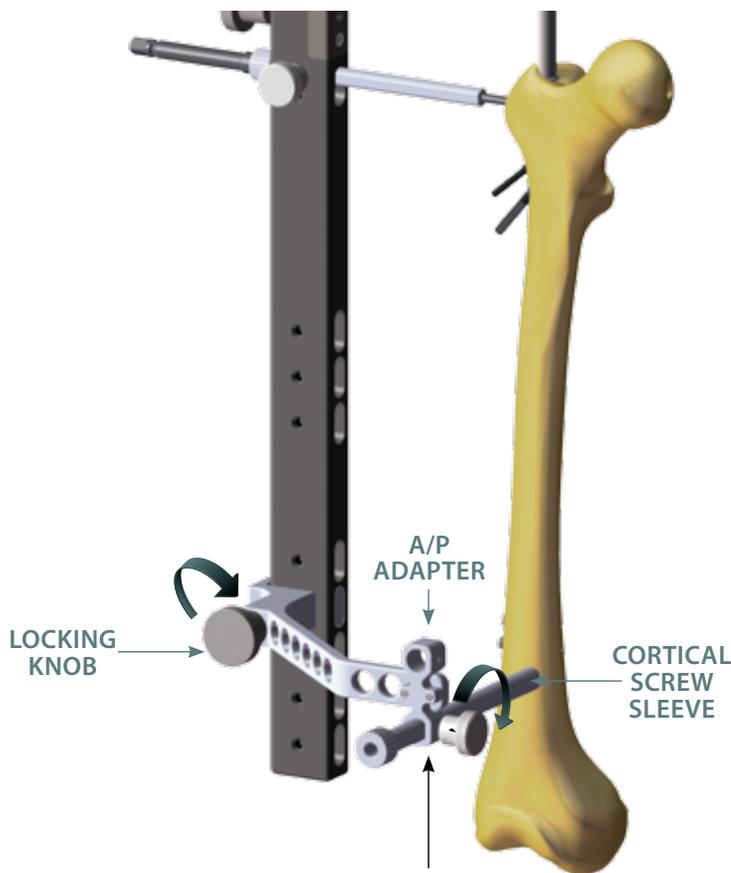
The Cortical Screw Endmill (GAP-DCE 100) can be used first to flatten the cortex and prevent slipping of the cortical drill tip on the curved cortex. During drilling, check the drill's position under image intensification. After the endmill, use the shorter Cortical Drill (GAP-DCS103/104) to bore a hole until the far cortex, and note the corresponding Cortical Screw length on the drill. To facilitate the drilling of the second hole and maintain alignment through the nail, leave the short cortical drill in place and use the longer provided drill (GAP-DCS103-L/104-L) to make the second hole.

16.3 Cortical Screw Insertion

Using the Multi-Purpose Screwdriver (GAP-TMP100), insert the Cortical Screws (GAP-CS *_**) corresponding to noted length and appropriate diameter. A Cortical Washer (GAP-WAS 100) can be used when dealing with fragile bones to improve distribution of stress onto the cortex. To use the washers, retract or remove the Distal Cortical Sleeve because the washer's diameter exceeds the sleeve's internal diameter. It is recommended to keep the **short** cortical drill in place to maintain alignment while inserting the first Cortical Screw.



STEP 17



 Always use distal hole of the A/P Attachment to assemble the Cortical Screw Sleeve.

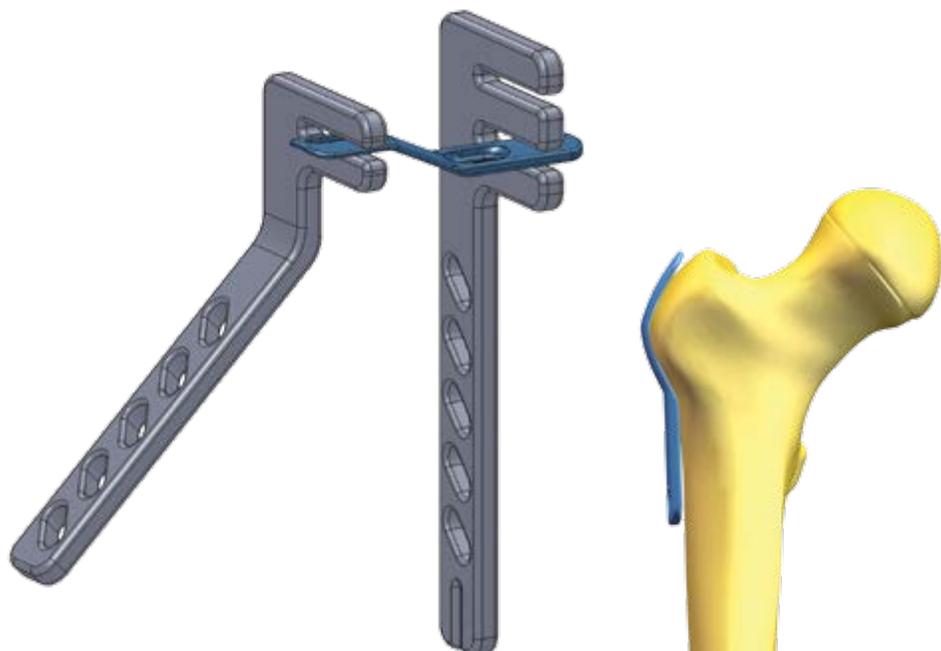
A/P FIXATION (OPTIONAL)

Using an A/P Screw is recommended to improve rotational stability of the implant assembly. For A/P nail locking, mount the A/P Adapter (GAP-APA100) onto the Distal Attachment using the locking knob. Insert the Cortical Screw Sleeve (GAP-SCS 100) into the adapter, and make a stab incision to allow insertion of the sleeve up to the cortex. Lock the sleeve in position. Using the adequate Cortical Screw Drill (see table in step 16.2) drill to the far cortex, and note the corresponding screw length on the drill. Finally, insert the Cortical Screw using the Multi-Purpose Screwdriver.

STEP 18

INSTRUMENTATION REMOVAL

-  **Remove:**
- Mechanical Screw Pin
 - Distal Attachment
 - Targeting Device
 - Nail Driver



STEP 19

LONG PLATE BENDING

This step pertains **only to the Long Plate** (GAP-PLL 100). Using the two Plate Benders (GAP-PLB100, GAP-PLB110), bend the Plate to conform to the femur's geometry.

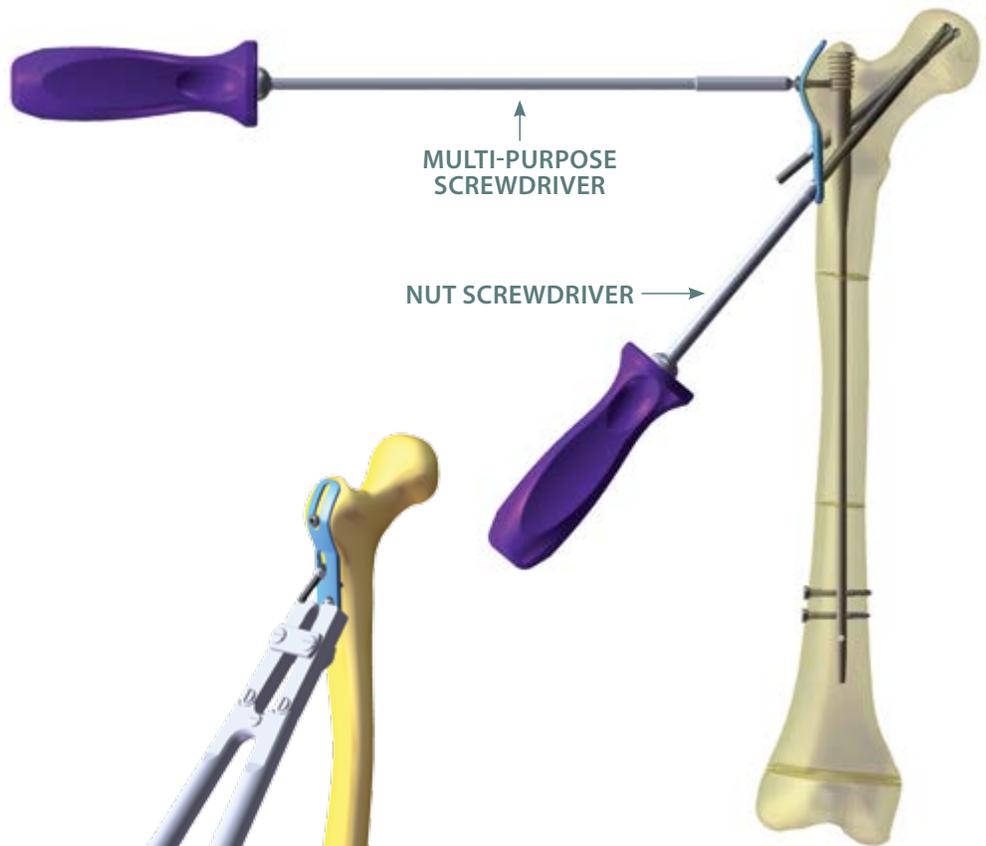
-  The Long Plate should not be excessively or repeatedly bent. The Plate should not be reverse bent in the same location. Use care to ensure that the Plate is not scratched or notched during the bending process.



STEP 20

PLATE ASSEMBLY

Slide the Plate onto the Lag Screws. Using the Nut Screwdriver (GAP-TSN100) thread the lower Semi-Spherical Nut first (GAP-SSN55) followed by the upper. If the Long Plate is being used, do not fully tighten the Semi-Spherical Nuts until the Mechanical Screw (GAP-MS**) is inserted. Select the appropriate Mechanical Screw according to the femur's size and Nail's placement. Large femurs and/or medially placed Nails will require the longer Mechanical Screw (GAP-MS34). Otherwise use GAP-MS24. Insert the Mechanical Screw through the prepared hole. If resistance is felt, retract the screw and clean out the hole. Tighten both Semi-Spherical Nuts and the Mechanical Screw progressively, making sure to **fully tighten the lower Nut first**.



STEP 21

LAG THREAD CUTTING

Cut off the threaded tips of the Lag Screws as close as possible to the surface of the Semi-Spherical Nuts using the Lag Thread Cutter (GAP-LGC100).



STEP 22

NAIL CAP INSERTION

Select the appropriate Nail Cap (GAP-CP***) to ensure protrusion of the Cap from the cortex. Using the Multi-Purpose Screwdriver insert the Nail Cap into the proximal internal thread of the Nail.



Nail Caps (Height)	
1.5 mm	GAP-CP015
5.0 mm	GAP-CP050
10.0 mm	GAP-CP100

Coxa Vara (Valga) Surgical Technique (Coxa Vara Plate)

Based on **Dr. Fassier's** Coxa Vara Technique.
François Fassier, MD, FRCS (C), Montreal, Canada

STEP 1

PREOPERATIVE PLANNING

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.

STEP 2

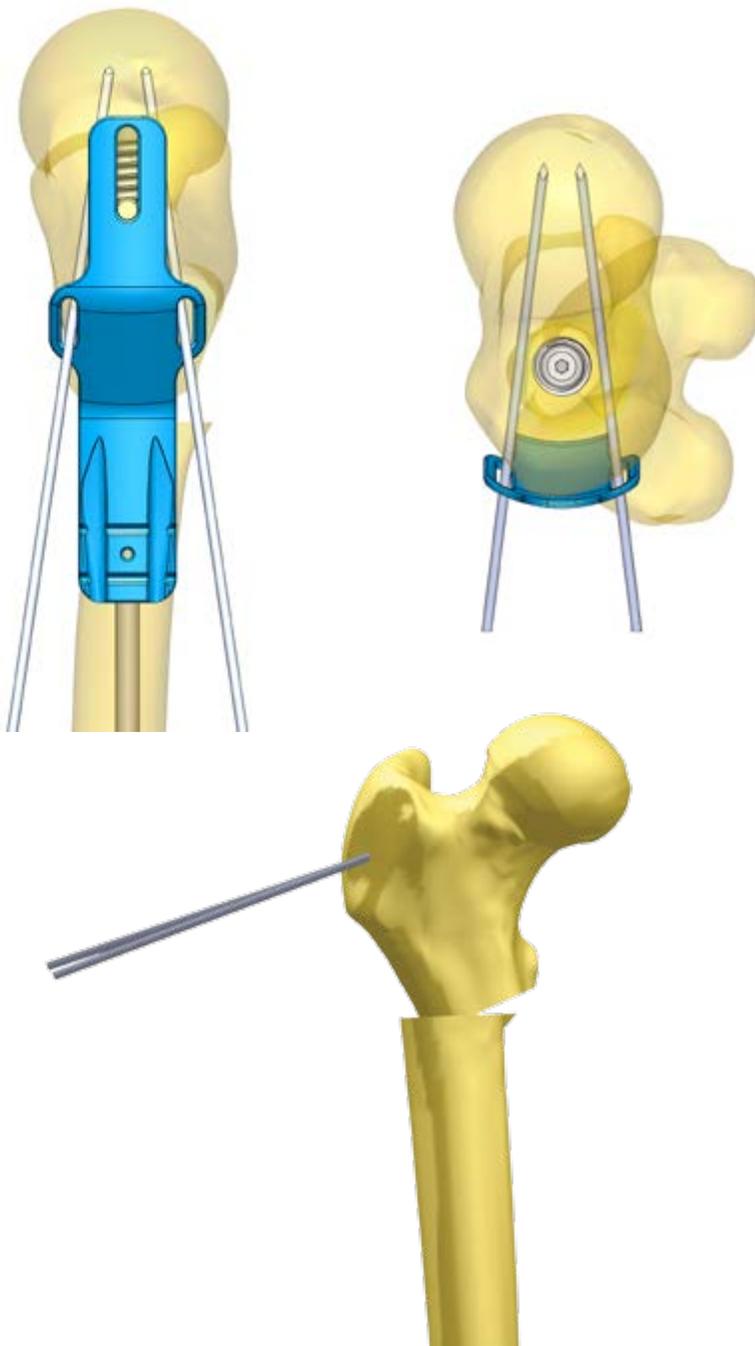
K-WIRE INSERTION

Using the appropriate Coxa Vara Plate (Small, Medium or Large) as a template, place two smooth Kirshner wires along the femoral neck, across the physis, into the femoral epiphysis. The first Kirshner wire 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. Select the size of the Kirshner wire's according to the size of the bone.

STEP 3

OSTEOTOMY AND HEAD POSITIONING

Determine the site of the osteotomy with fluoroscopy. After the osteotomy, use the two Kirshner wires as a "joy stick" allowing safe adduction of the proximal fragment without the use of a bone clamp.



STEP 4

NAIL SELECTION

Using the radiological images, measure the canal diameter at the isthmus. Select the nail diameter accordingly. Determine the nail length after osteotomy. The GAP Nail Template can also be used for the determination of the Nail's length .



STEP 5

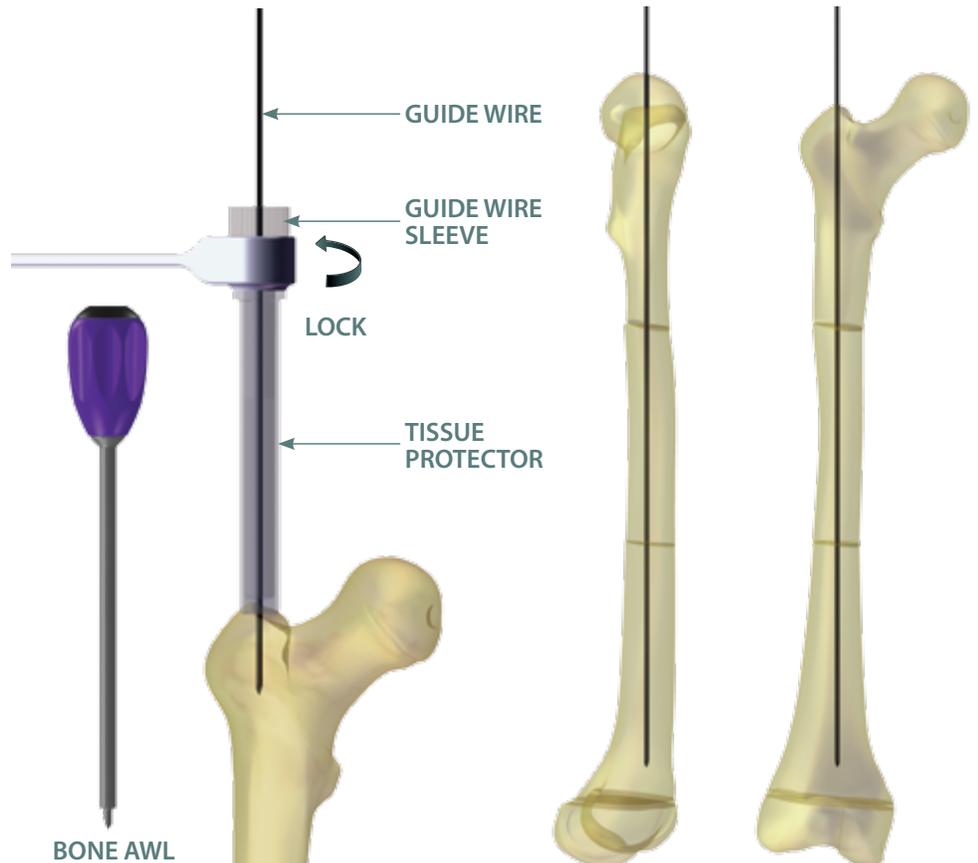
GUIDE WIRE INSERTION

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 increase the possible angular correction. The final neck/shaft angle (NSA) can be estimated by calculating the angle between the Guide Wire and the Kirshner wires.

Puncture the cortex using the Bone Awl (GAP-BAW100) or directly with the Guide Wire through the Guide Wire Sleeve, corresponding to the selected nail size, and the Tissue Protector (GATP116).

Nail Size Ø	Guide Wire	Guide Wire Sleeve
4.8 / 5.6 / 6.4	GAP-KWG016 (1.6 mm)	GAP-SGW116
7.2 / 8.0	GAP-KWG020 (2.0 mm)	GAP-SGW120

Insert the Guide Wire into the canal and validate its final position under C-arm in both the AP and Lateral views prior to reaming.



STEP 6

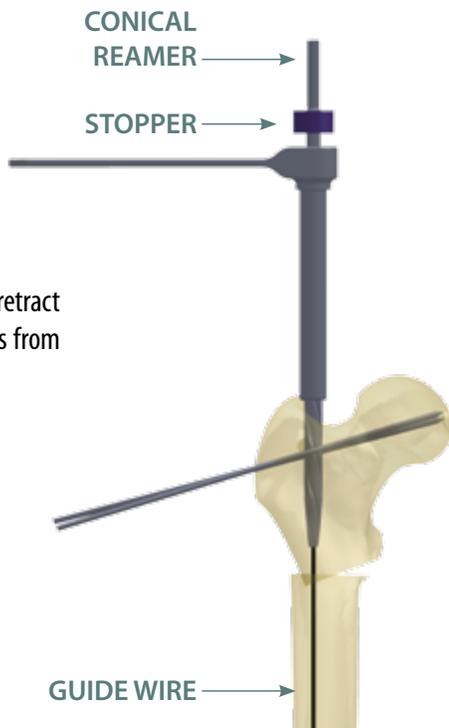
CONICAL REAMING

Select the Conical Reamer corresponding to the chosen Nail's size

Nail Size Ø	Conical Reamer
4.8 / 5.6 / 6.4	GAP-DTP101
7.2 / 8.0	GAP-DTP052

Ream through the Tissue Protector and over the Guide Wire. Continue reaming until the stopper of the Reamer reaches the edge of the Tissue Protector handle.

 **Do not force the Reamer.** Partially retract the Reamer, if needed, to clean debris from the medullary canal.

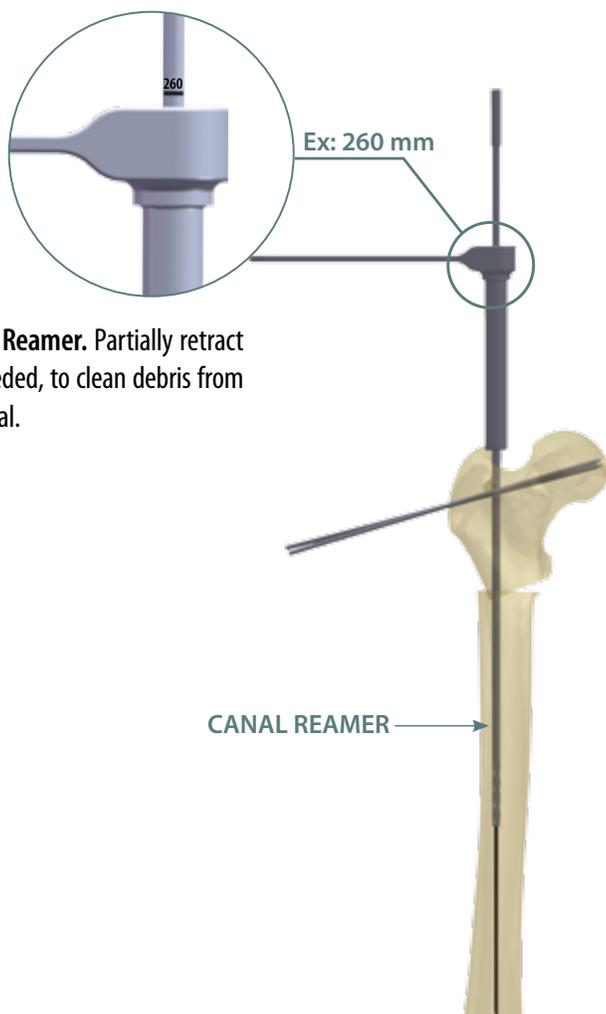


STEP 7

MEDULLAR CANAL REAMING

Select the Canal Reamer corresponding to the selected nail size. Drill through the Tissue Protector and over the Guide Wire. Advance the reamer with steady and moderate pressure.

 **Do not force the Reamer.** Partially retract the Reamer, if needed, to clean debris from the medullary canal.



Nail Size Ø	Canal Reamer
4.8	GAP-DCA048
5.6	GAP-DCA056
6.4	GAP-DCA064
7.2	GAP-DCA072
8.0	GAP-DCA080

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

 **Remove the Tissue Protector** once reaming is complete.

STEP 8-17

 **Perform: STEPS 8 to 17** (page 6)

 **Standard Interlocking Surgical Technique**



STEP 18

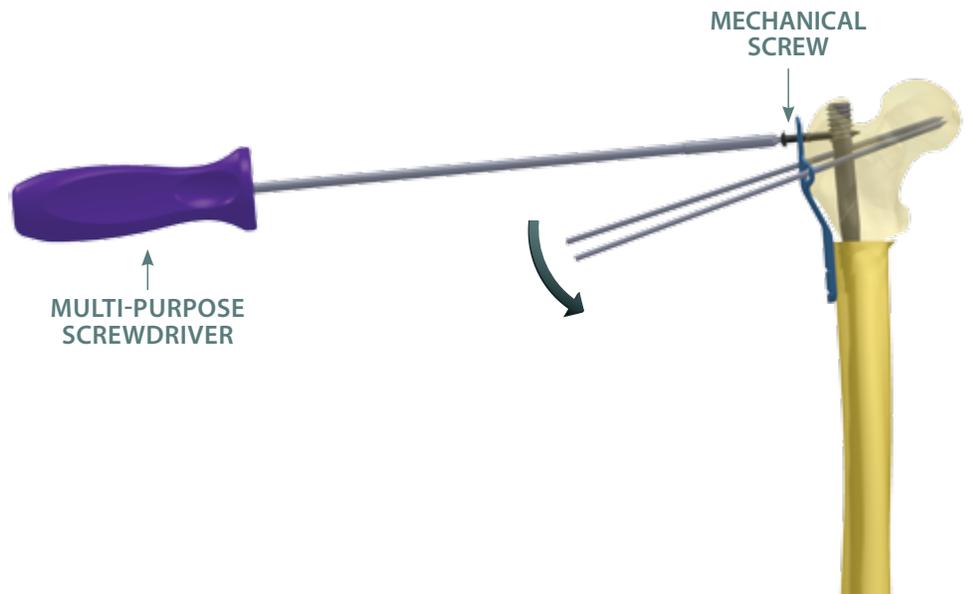
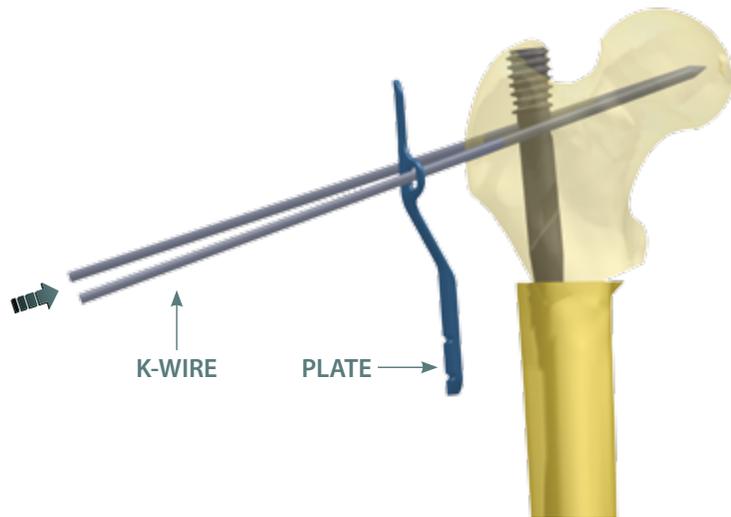
COXA VARA PLATE AND WIRE LOCKING

Select the Small, Medium or Large Coxa Vara Plate (GAP-PLC1**) that best fits the bone's size and geometry. The Plate can be bent using the two Plate Benders (GAP-PLB 100, GAP-PLB 110).

 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 Coxa Vara Plate onto the Kirshner wires up to the bone.

Select the appropriate Mechanical Screw according to the femur's size and Nail's placement. Large femurs and/or medially placed Nails will require the longer Mechanical Screw (GAP-MS34). Otherwise use GAP-MS24. Insert the Mechanical Screw through the prepared hole. If resistance is felt, retract the screw and clean out the hole. Once the Mechanical Screw is in place, bend the Kirshner wires onto the plate, and secured them to the shaft with cerclage wires.

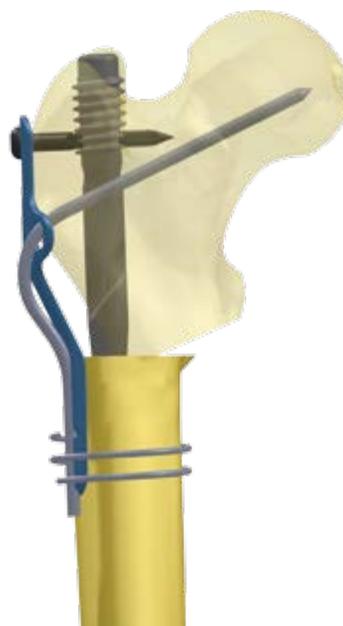


STEP 19

NAIL CAP INSERTION

Select the appropriate Nail Cap (GAP-C P***) to ensure that the cap protrudes from the cortex. Using the Multi-Purpose Screwdriver, insert the Nail Cap into the proximal internal thread of the Nail.

Nail Caps (Height)	
1.5 mm	GAP-CP015
5.0 mm	GAP-CP050
10.0 mm	GAP-CP100



Coxa Vara Plate

Specifications

GAP 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	9.0	GAP-N48-16	GAP-N48-18	GAP-N48-20	GAP-N48-22	GAP-N48-24	GAP-N48-26	GAP-N48-28	GAP-N48-30	GAP-N48-32
5.6	12.0	9.0	GAP-N56-16	GAP-N56-18	GAP-N56-20	GAP-N56-22	GAP-N56-24	GAP-N56-26	GAP-N56-28	GAP-N56-30	GAP-N56-32
6.4	12.0	9.0	GAP-N64-16	GAP-N64-18	GAP-N64-20	GAP-N64-22	GAP-N64-24	GAP-N64-26	GAP-N64-28	GAP-N64-30	GAP-N64-32
7.2	12.5	9.5	GAP-N72-16	GAP-N72-18	GAP-N72-20	GAP-N72-22	GAP-N72-24	GAP-N72-26	GAP-N72-28	GAP-N72-30	GAP-N72-32
8.0	12.5	9.5	--	--	--	--	--	--	GAP-N80-28	GAP-N80-30	GAP-N80-32

GAP 4.8 are Temporarily Unavailable

*Special order.

Lag Screws (L)

50 mm	GAP-LG050
55 mm	GAP-LG055
60 mm	GAP-LG060
65 mm	GAP-LG065
70 mm	GAP-LG070
75 mm	GAP-LG075
80 mm	GAP-LG080
85 mm	GAP-LG085
90 mm	GAP-LG090
95 mm	GAP-LG095
100 mm	GAP-LG100

Mechanical Screws (L)

24 mm	GAP-MS24
34 mm	GAP-MS34

Nail Caps (Height)

1.5 mm	GAP-CP015
5.0 mm	GAP-CP050
10.0 mm	GAP-CP100

Plates

Coxa Vara (Valga) Small	GAP-PLC110
Coxa Vara (Valga) Medium	GAP-PLC120
Coxa Vara (Valga) Large	GAP-PLC130
Long Plate	GAP-PLL100
Short Plate	GAP-PLS100

Components

Semi-Spherical Nut	GAP-SSN55
Cortical Washer	GAP-WAS100

Special Order

Guide Wire 1.6 mm	L = 950 mm	GAP-KWL016
Guide Wire 2.0 mm	L = 950 mm	GAP-KWL020

gap nail
The endo-exo medullary system



Cortical Screws

Ø / L	3.0 mm	4.0 mm
20	GAP-CS3-20	GAP-CS4-20
22	GAP-CS3-22	GAP-CS4-22
24	GAP-CS3-24	GAP-CS4-24
26	GAP-CS3-26	GAP-CS4-26
28	GAP-CS3-28	GAP-CS4-28
30	GAP-CS3-30	GAP-CS4-30
32	GAP-CS3-32	GAP-CS4-32
34	GAP-CS3-34	GAP-CS4-34
36	GAP-CS3-36	GAP-CS4-36
38	GAP-CS3-38	GAP-CS4-38
40	GAP-CS3-40	GAP-CS4-40
45	GAP-CS3-45	GAP-CS4-45
50	GAP-CS3-50	GAP-CS4-50
55	GAP-CS3-55	GAP-CS4-55
60	GAP-CS3-60	GAP-CS4-60
65	GAP-CS3-65	GAP-CS4-65
70	GAP-CS3-70	GAP-CS4-70
75	GAP-CS3-75	GAP-CS4-75
80	GAP-CS3-80	GAP-CS4-80

Misc. Instruments

Tissue Protector	GAP-TP116
Bone Awl	GAP-BAW100
Mechanical Screw Pin	GAP-MSP100
Depth Gage Ruler	GAP-DPG120
Position Lock - Lag Drill	GAP-LCK080
Lag Thread Cutter	GAP-LGC100
Plate Bender "E"	GAP-PLB100
Plate Bender "F"	GAP-PLB110
Gap Nail Template	GAP-TPL100

- Standard Interlocking Surgical Technique
- Lag Screw Surgical Technique
- Coxa Vara (Valga) Surgical Technique



Specifications

Drills And Reamers

Conical Reamer - Ø 4.8 / 5.6 / 6.4	GAP-DTP101
Conical Reamer - Ø 7.2 / 8.0	GAP-DTP052
Canal Reamer - 4.8 mm	GAP-DCA048
Canal Reamer - 5.6 mm	GAP-DCA056
Canal Reamer - 6.4 mm	GAP-DCA064
Canal Reamer - 7.2 mm	GAP-DCA072
Canal Reamer - 8.0 mm	GAP-DCA080
Lag Screw Drill	GAP-DLG055
Lag Endmill	GAP-DLF155
Cortical Screw Drill - 3.0 mm	GAP-DCS103
Cortical Screw Drill - 4.0 mm	GAP-DCS104
Cortical Endmill	GAP-DCE100
Mechanical Screw Drill	GAP-DMS110

Drill Guides and Attachments

Targeting Device	GAP-TGD100
Distal Attachment	GAP-DSA150
Lag Screw Attachment	GAP-LSA150
Ap Adapter	GAP-APA100
Derotation Compass	GAP-CMP100

Guide Wires

Guide Wire 1.6 mm	L = 18"	GAP-KWG016
Guide Wire 2.0 mm	L = 18"	GAP-KWG020
Depth Gage Wire	L = 360 mm	GAP-KDG360

Sleeves

Guide Wire Sleeve - 1.6 mm	GAP-SGW116
Guide Wire Sleeve - 2.0 mm	GAP-SGW120
Lag Screw Sleeve	GAP-SLS155
Depth Gage Sleeve	GAP-SDG120
Cortical Screw Sleeve	GAP-SCS100
Mechanical Screw Sleeve	GAP-SMS100
Distal Cortical Sleeve	GAP-STH100

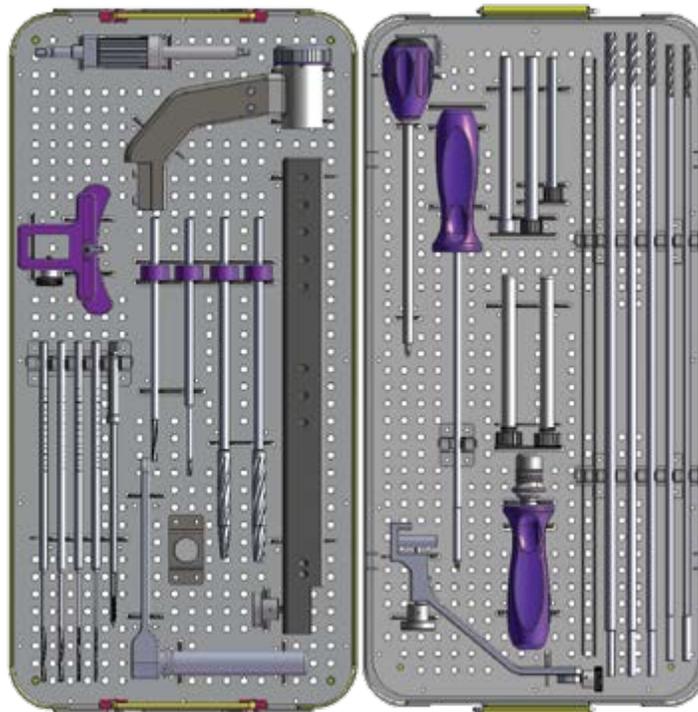
Handles & Drivers

Nail Driver	GAP-NDR100
Multipurpose Screwdriver	GAP-TMP100
Nut Screwdriver	GAP-TSN100
Lag Screw Driver	GAP-TLS100
Axial Handle	GAP-THA100

Cases

Implant Case	●●●	GAP-IMF100
Instrument Main Case	●●●	GAP-INF110
Instrument Lag Case	●	GAP-ILF120

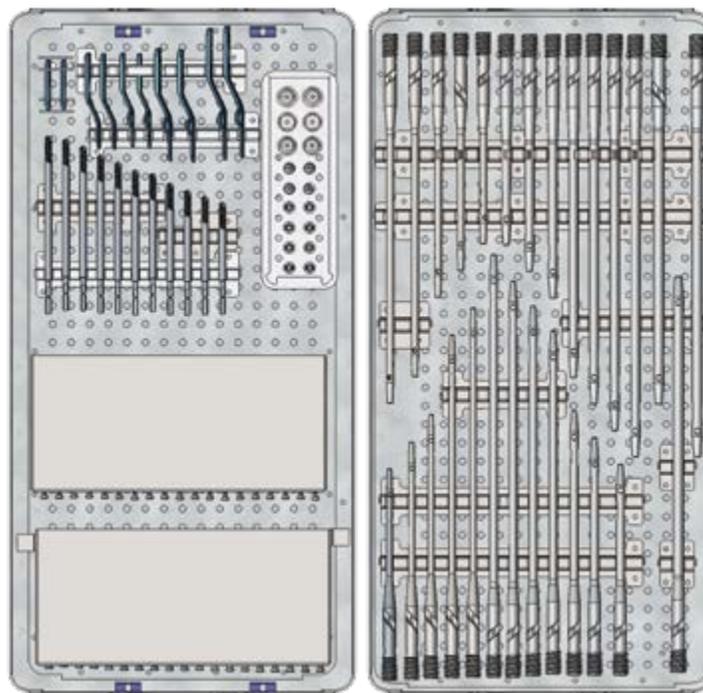
INSTRUMENT MAIN CASE ●●●



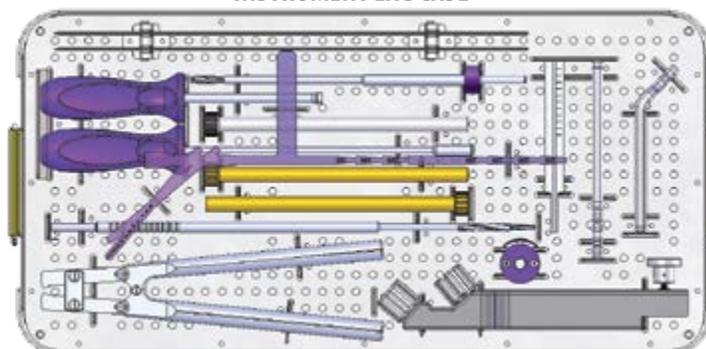
gap
nail
The endo-exo medullary system

- Standard Interlocking Surgical Technique
- Lag Screw Surgical Technique
- Coxa Vara (Valga) Surgical Technique

Top Tray IMPLANT CASE ●●● Lower Tray



INSTRUMENT LAG CASE ●





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