Pega Medical

gapnail™

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) with skeletal dysplasias.

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 's stability in weak bones.

Intended uses:

- Correction of deformities (OI, skeletal dysplasia, coxa vara, coxa valga)
- Diaphyseal fractures 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 F

Implant Configurations

STANDARD INTERLOCKING SURGICAL TECHNIQUE

Antegrade Femur

Proximal Fractures
Diaphyseal Fractures
Deformity Correction

Retrograde Femur

Diaphyseal Fractures
Distal Fractures
Deformity Correction

Antegrade Tibia

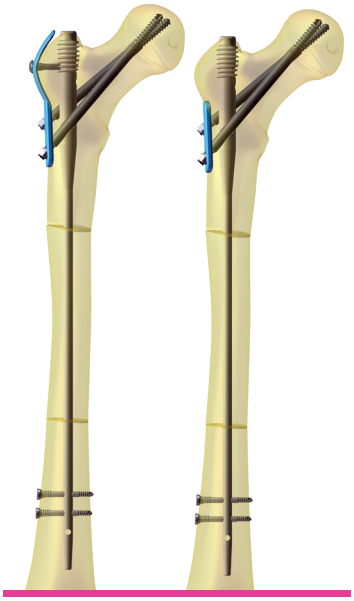
Proximal Fractures
Diaphyseal Fractures
Deformity Correction

Antegrade Humerus

Proximal Fractures
Diaphyseal Fractures
Deformity Correction

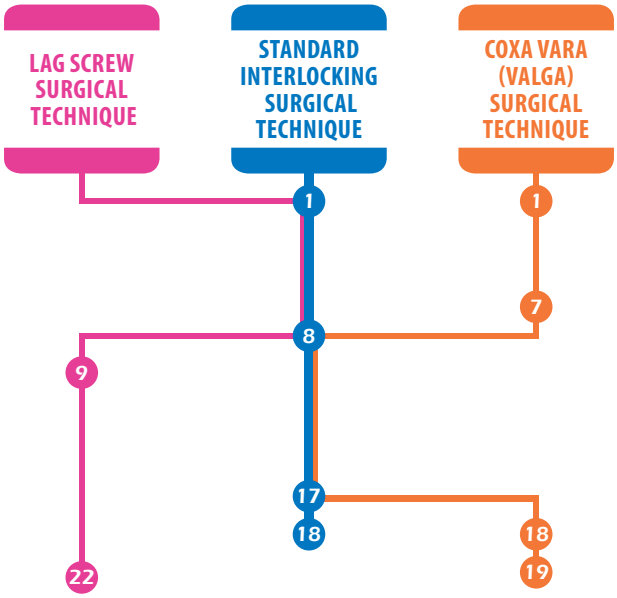
LAG SCREW SURGICAL TECHNIQUE

Antegrade Femur Long & Short Plate



Femoral Neck Fixation
Trochanteric Fractures
Deformity Correction
Diaphyseal Fractures

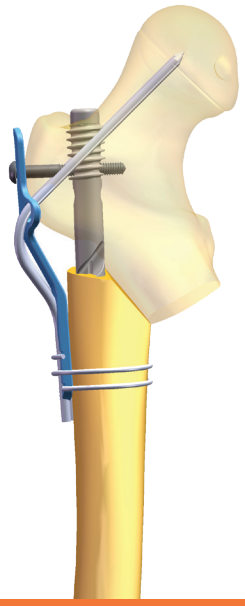
SURGICAL TECHNIQUE STEPS



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

COXA VARA (VALGA) SURG. TECH.

Coxa Vara Plate



Coxa Vara Correction

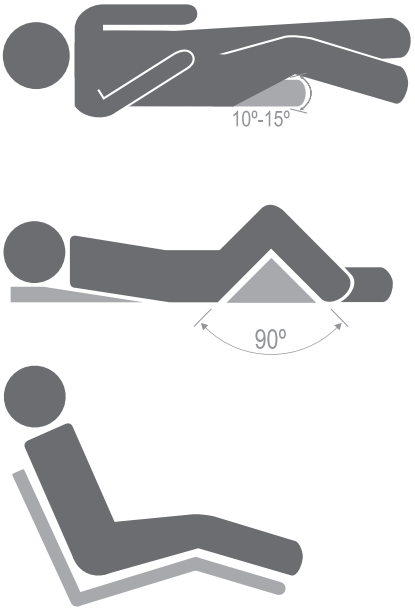
Step 1

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 10-15º 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 90º.

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.

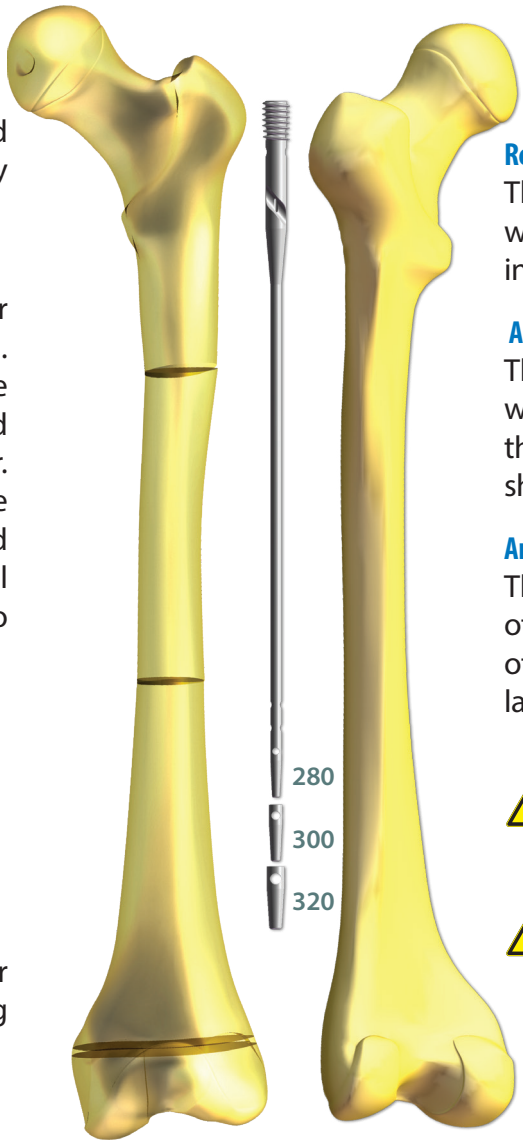
Step 2

NAIL SELECTION

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 be used to validate the nail's length.



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.

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

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

Step 3

OSTEOTOMY

Osteotomies can be performed under C-arm guidance to correct the existing deformities.

STEP 4

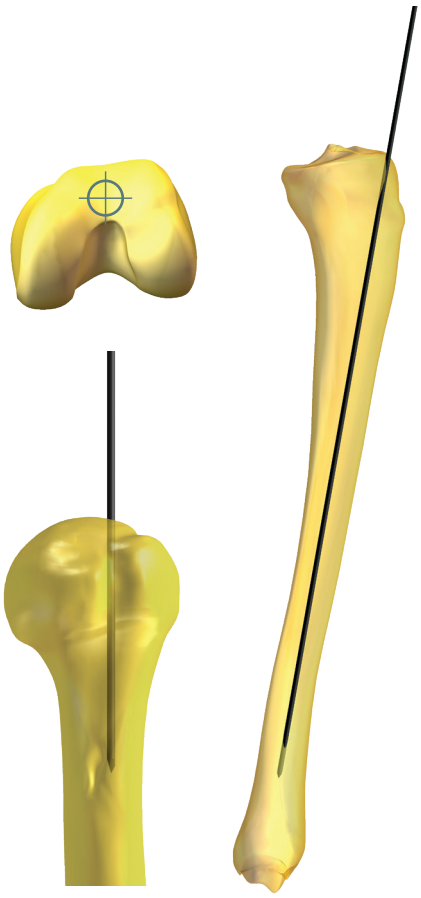
ENTRY POINT / INCISION

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.

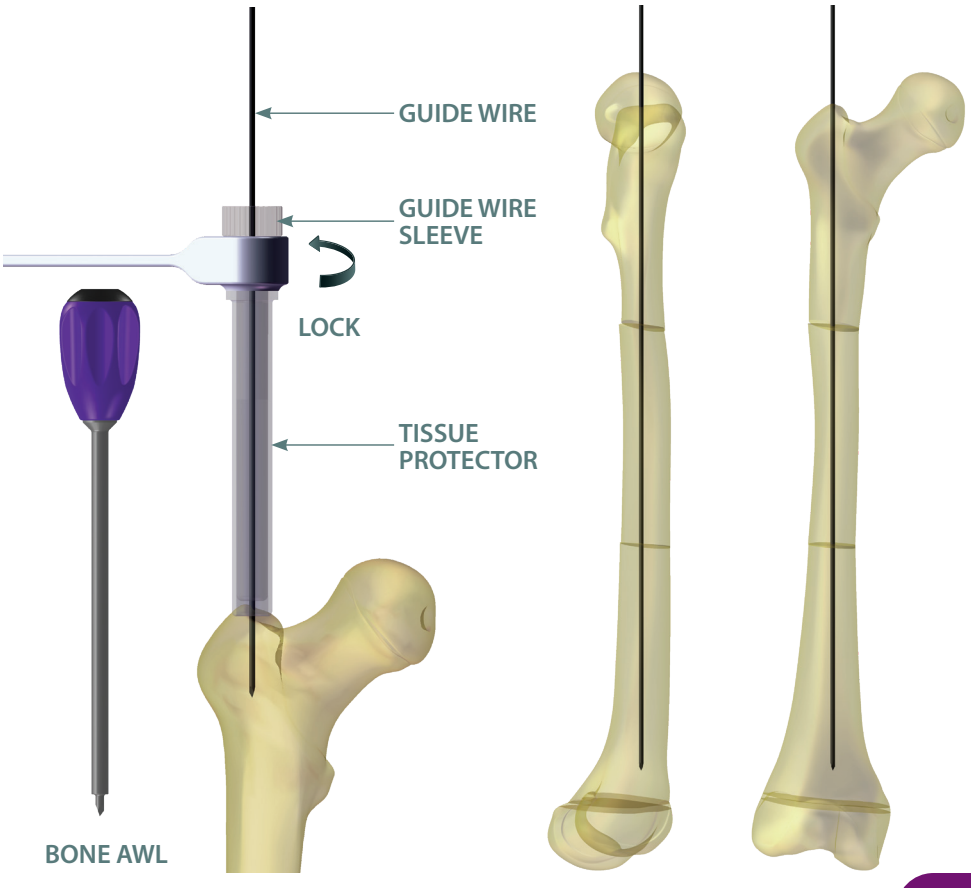
STEP 5

GUIDE WIRE INSERTION

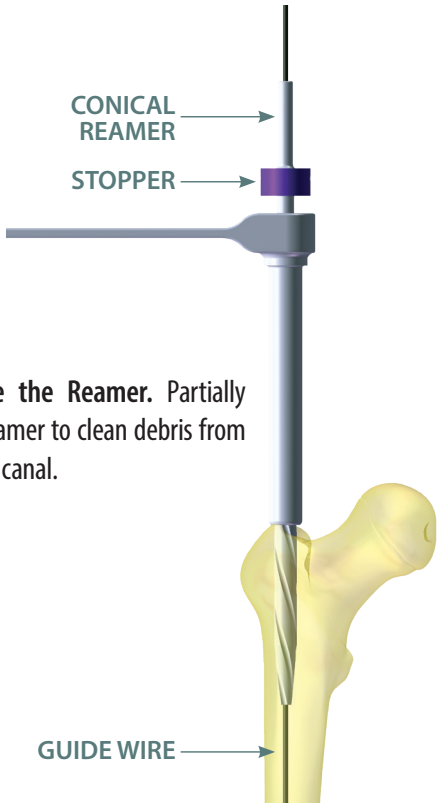
Puncture the cortex using the Bone Awl (GAP-BA W100), or directly with the Guide Wire through the Guide Wire Sleeve corresponding to the selected nail size and the Tissue Protector (GAP-TP116).

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 and validate the position under C-arm in both AP and lateral views prior to reaming.



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



Do not force the Reamer. Partially retract the Reamer to clean debris from the medullary canal.

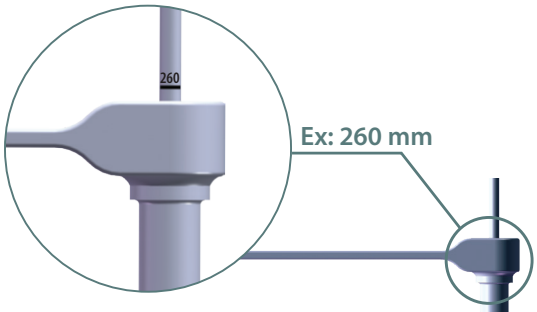
STEP 6

CONICAL REAMING

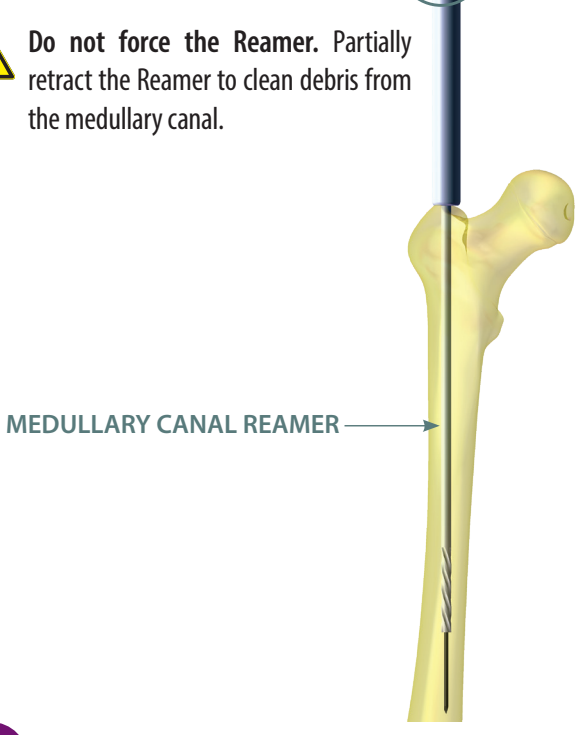
Select the Conical Reamer corresponding to the nail's size.

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 up to the stopper.



Do not force the Reamer. Partially retract the Reamer to clean debris from the medullary canal.



STEP 7

MEDULLARY CANAL REAMING

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

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's length reaches the top edge of the Tissue Protector handle.

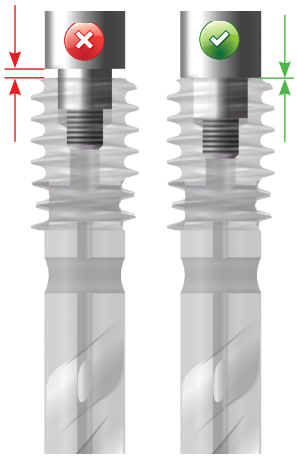
Remove the Tissue Protector once reaming is complete.

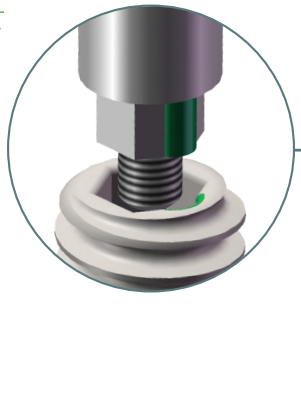
STEP 8

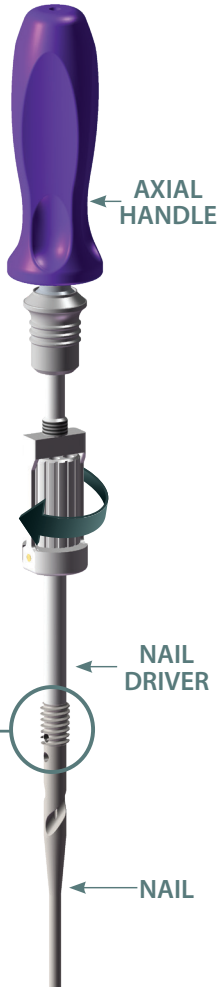
NAIL INSERTION

8.1 Assembly of the Nail onto the Nail Driver
Turn the screw knob until the nail is fully locked on the Nail Driver (GAP-NDR100). There should be no space between the nail head and Nail Driver.

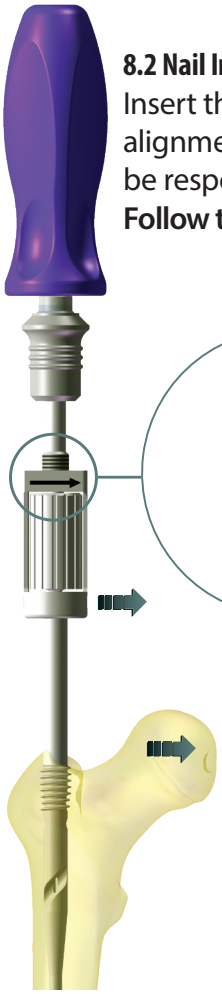
⚠ To assemble, the circular notch on the hexagonal drive of the Nail Driver **must align** with the corresponding notch in the Nail.







8.2 Nail Insertion
Insert the nail over the Guide Wire. Nail alignment with the femoral neck must be respected.
Follow the markings on the Nail Driver.



⚠ **Do not hit the Nail Driver.** The Nail should be inserted with minimal force.

⚠ **Remove the Guide Wire after nail insertion**

STEP 9

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

STEP 9 - Lag Screw Surgical Technique

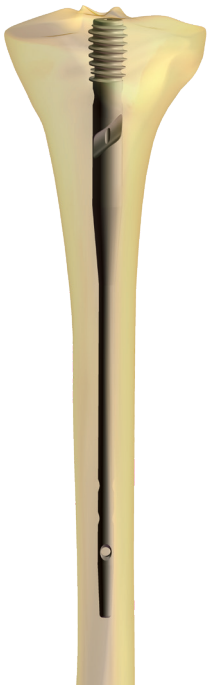
NAIL POSITION, DEPTH AND ALIGNMENT VERIFICATION

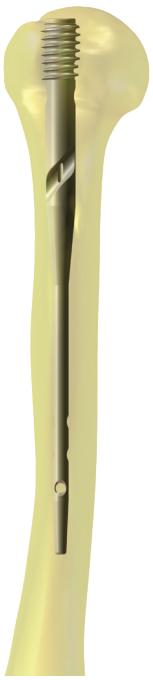
For all configurations, the nail should be centered within the medullary canal and the nail's head should not protrude into the articulation. Angular nail alignment (and thus Cortical Screw orientation) is left to the discretion of the surgeon.

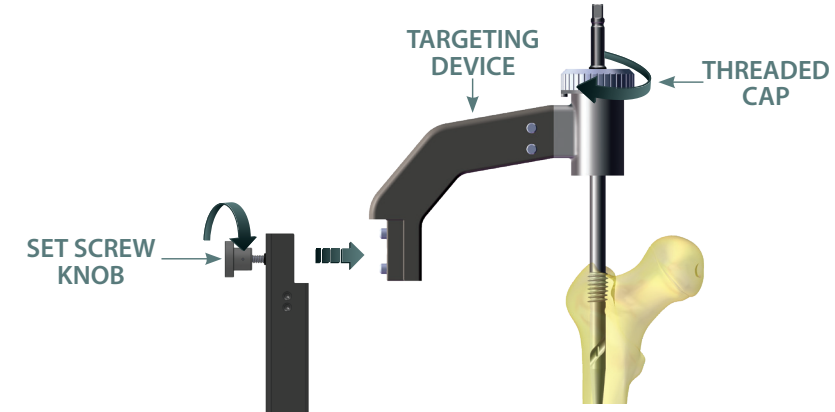
⚠ For Anteversion Correction, the nail's Lag holes must be in line with the femoral neck in the lateral view to provide a proper reference.

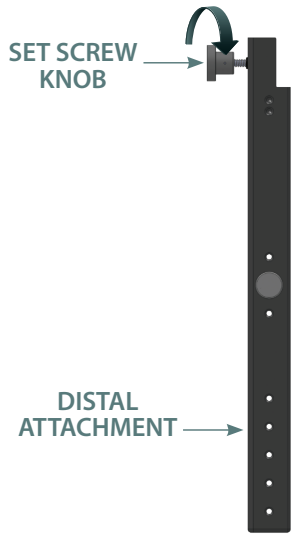

Antegrade Femur


Retrograde Femur


Antegrade Tibia


Antegrade Humerus





STEP 10

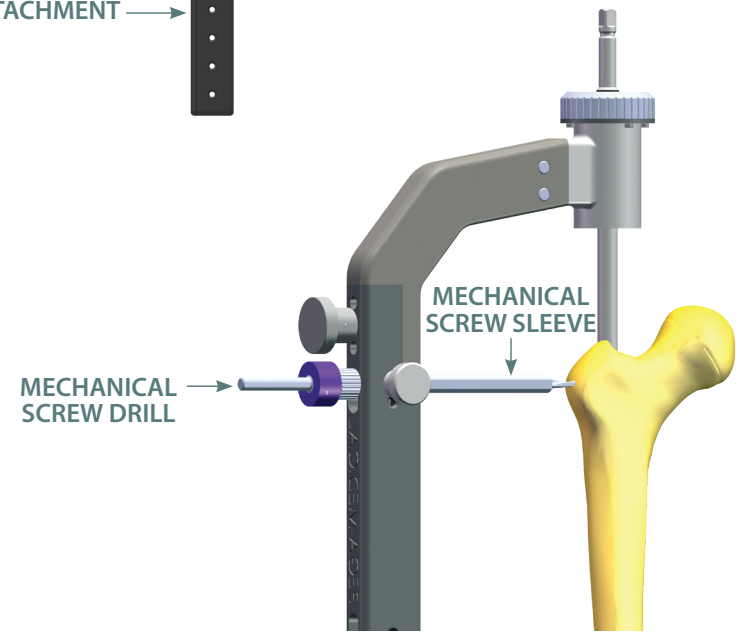
TARGETING DEVICE ASSEMBLY

Slide the Targeting Device (GAP- TGD100) onto the Nail Driver and turn 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

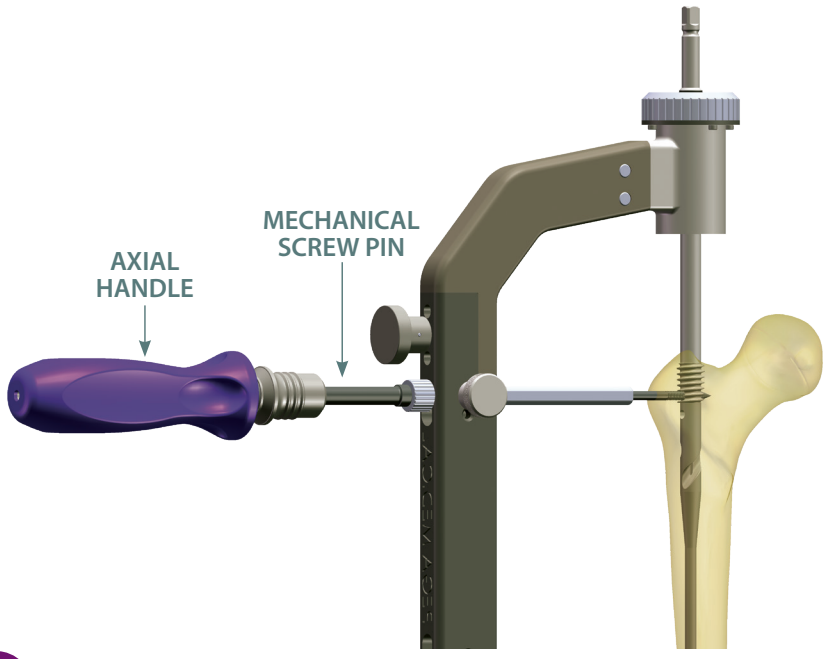
Insert the Mechanical Screw Sleeve (GAP-SMS100) into the proximal hole of the Distal Attachment. Secure by tightening a set-screw. Ream to stopper using the Mechanical Screw Drill (GAP-DMS110).

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).

Insert the pin until it is fully engaged with the nail through the Mechanical Screw Sleeve.

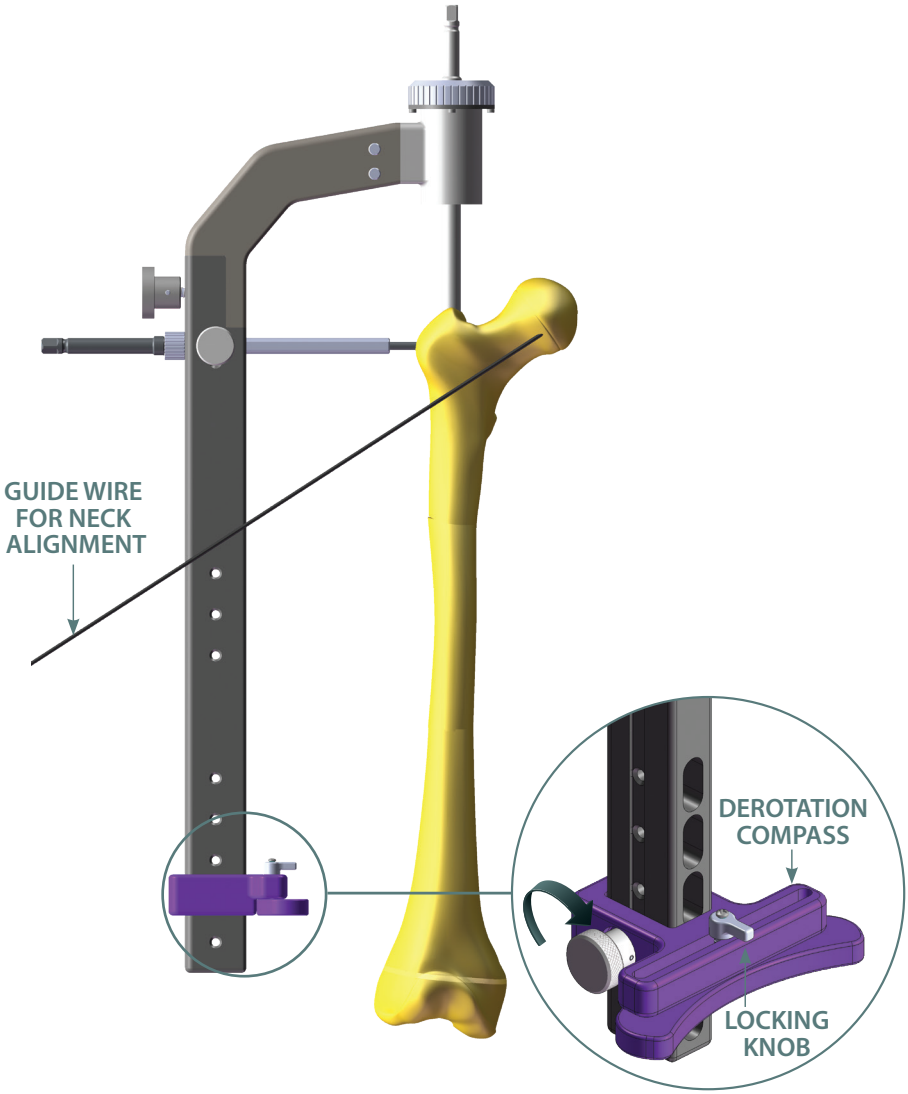


If resistance is felt, retract the pin and clean out the hole. Do not overtighten the Mechanical Screw Pin; this can cause a misalignment between the Distal Attachment and the distal locking holes in the implant.

STEP 13

DEROTATION AND ANTEVERSION CORRECTION (OPTIONAL)

Mount the Derotation Compass (GAP-CMP100) above the level of the distal articulation onto the Distal Attachment using a set-screw.



⚠ 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.

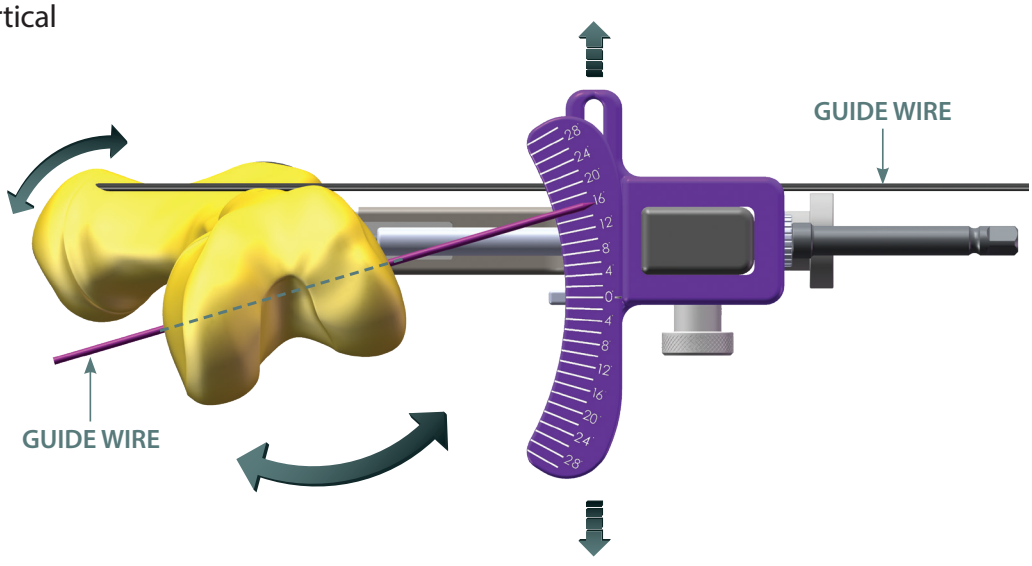
Femoral Neck Reference

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

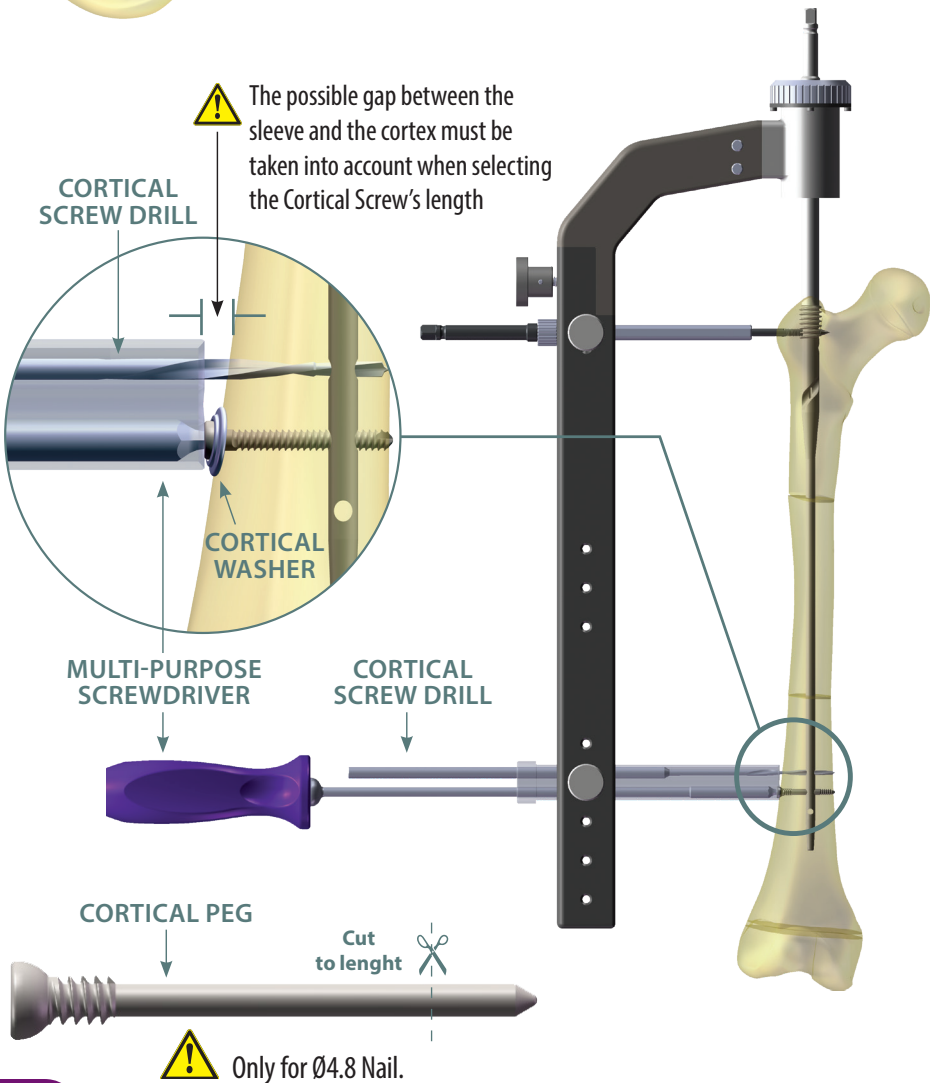
Insert a second Guide Wire, through the distal articulation, parallel to the retrocondylar line.

Slide the compass until the second guide wire alignes with an angular graduation mark, then block the rotation with the locking knob. This reading is 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).



Two screws must be used for distal fixation.



Only for Ø4.8 Nail.

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 position corresponding to the nail's length. Once the sleeve is resting against the cortex, lock it in position using a set-screw.

Nail Size Ø	Screw/Peg Size	Drill's
4.8	2.5	GAP-DCS102 & GAP-DCS102-L
5.6	3.0	GAP-DCS103 & GAP-DCS103-L
6.4 / 7.2 / 8.0	4.0	GAP-DCS104 & GAP-DCS104-L

Flatten the cortex with the Cortical Screw Endmill (GAP-DCE100) to prevent slipping of the cortical drill tip on the curved cortex. Use the shorter Cortical Drill (GAP-DCS102/103/104) to bore a hole up to the far cortex, and note the corresponding Cortical Screw length on the drill.
Maintain the short cortical drill in place and use the longer provided drill (GAP-DCS102-L/103-L/104-L) to make the second hole.

14.3 Cortical Screw Insertion

A minimum of two Cortical Screws must be used for distal fixation of the Nail. It is recommended to keep the short cortical drill in place while inserting the most proximal Cortical Screw first in order to maintain alignment.
Cortical Pegs should be cut to the length noted on the drill with the Lag Thread Cutter (GAP-LGC100) prior to insertion.
Using Multi-Purpose Screwdriver (GAP-TMP100), insert the Cortical Screws (GAP-CS *-**) corresponding to the noted length and nail's 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, retract or remove the Distal Cortical Sleeve because the washer's diameter exceeds the sleeve's internal diameter.

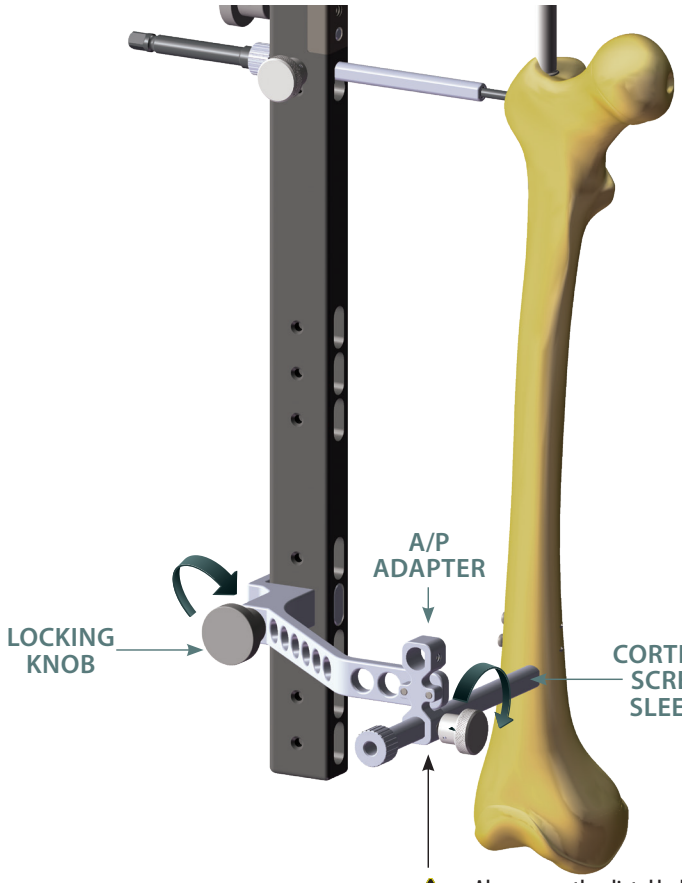
Step 15

A/P FIXATION (OPTIONAL)

Use of an A/P Screw is recommended to improve the rotational stability and the strength of the implant assembly. 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.

Lock the sleeve in its final position. Using the Cortical Screw Drill (see step 14.2), bore a hole to the far cortex and note the corresponding screw length on the drill.

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

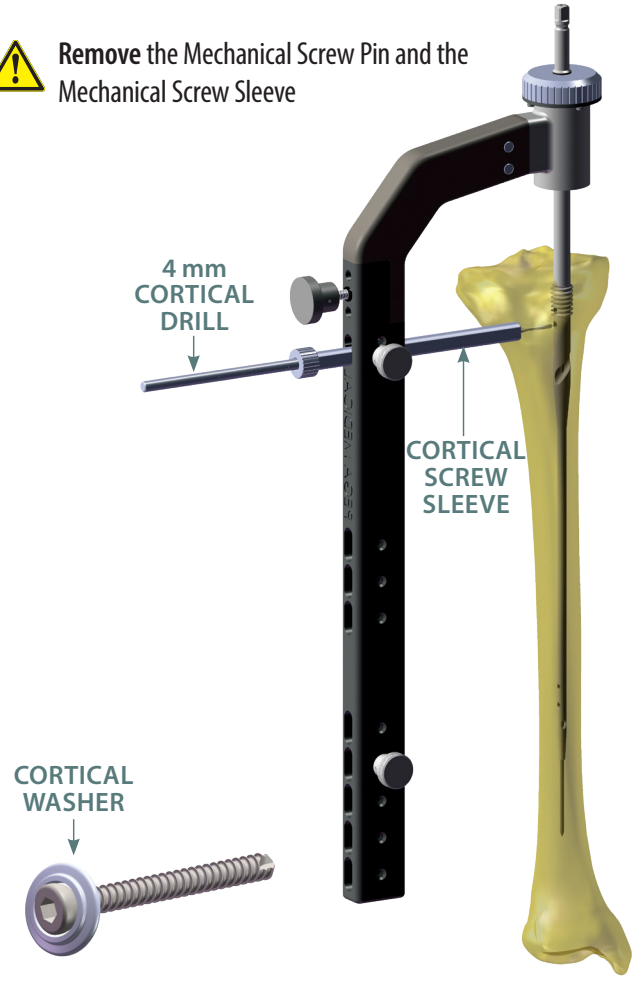
PROXIMAL FIXATION (OPTIONAL)

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

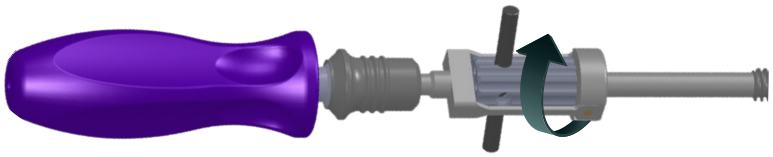
Insert the Cortical Screw Sleeve (GAP-SCS 100) into the Distal Attachment, and make a stab incision to allow insertion of the sleeve up to the cortex. Lock the sleeve in its final position using a set-screw. Using the 4mm Cortical Drill (GAP-DCS 104) drill to the far cortex and note the corresponding 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, remove the sleeve before inserting the washer and screw.

Remove the Mechanical Screw Pin and the Mechanical Screw Sleeve



If the Nail Driver is difficult to remove, insert a pin (¼" or less) through a hole in the Nail Driver knob and rotate counter-clockwise.



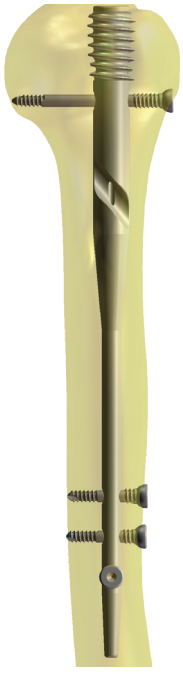
⚠ Impaction of the Nail driver is counter-indicated for removal. Always ensure that the Nail Driver's thread is fully disengaged from the Nail before attempting removal of the instrument.

Antegrade Femur

Antegrade Tibia

gapnail™
The endo-exo medullary system

Retrograde Femur



Antegrade Humerus

STEP 17

INSTRUMENTATION REMOVAL

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

STEP 18

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

NAIL CAP INSERTION

Thread the appropriate Nail Cap (GAP-CP***) using the Multi-Purpose Screwdriver.

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.

STEP 1-8

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

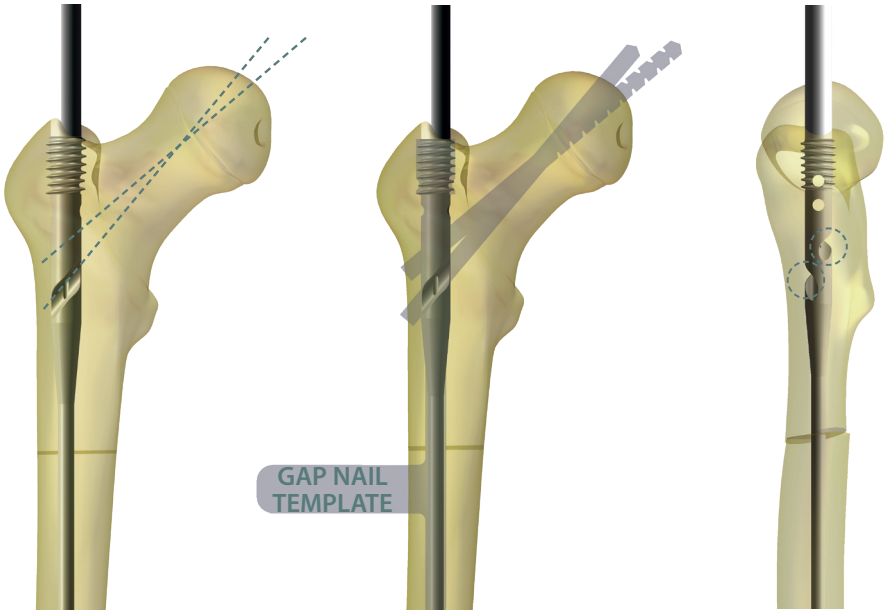
For fractures or osteotomies below the lesser trochanter combined with Lag Screw use, the following limitations should be observed.

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

Verify proper alignment of the nail in both AP and lateral views under C-aim. 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 should appear circular. Finally, verify the distal position of the implant.

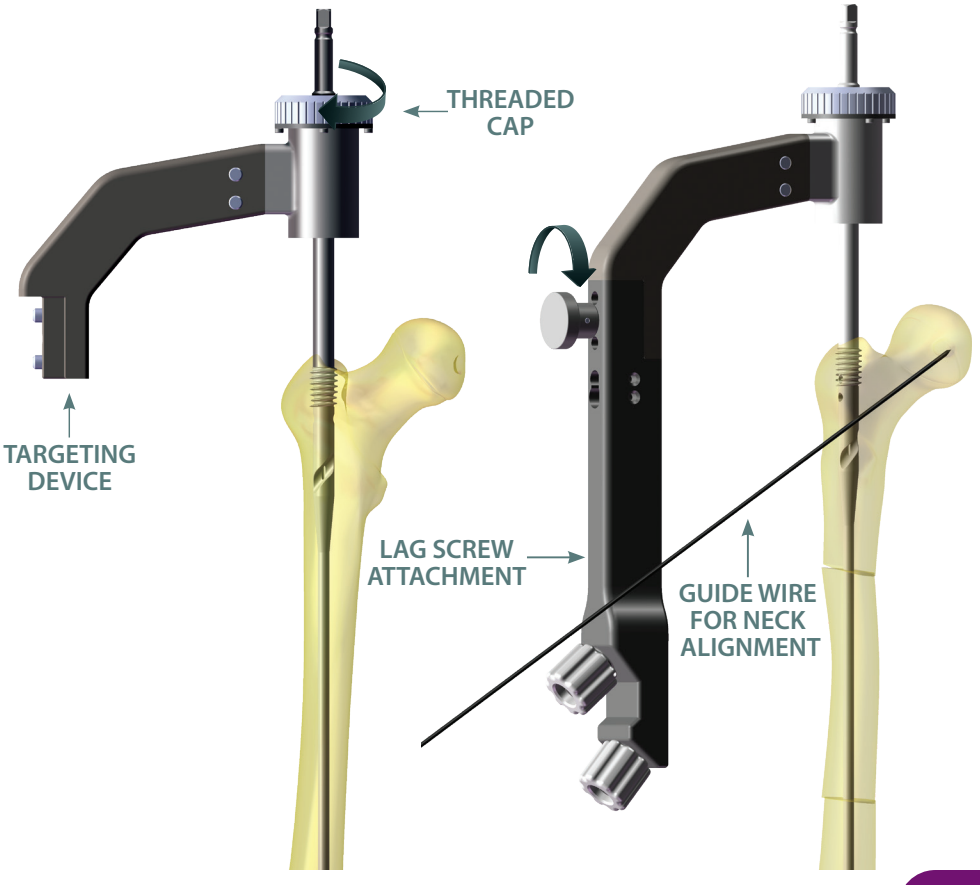


Every full revolution of the nail corresponds to 2.4mm of insertion. When the desired position is attained, **remove** the Axial Handle and the Guide Wire.

STEP 10

TARGETING DEVICE ASSEMBLY

Slide the Targeting Device (GAP-TGD100) onto the Nail Driver and turn 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.

STEP 12

NECK ALIGNMENT AND DEPTH VALIDATION

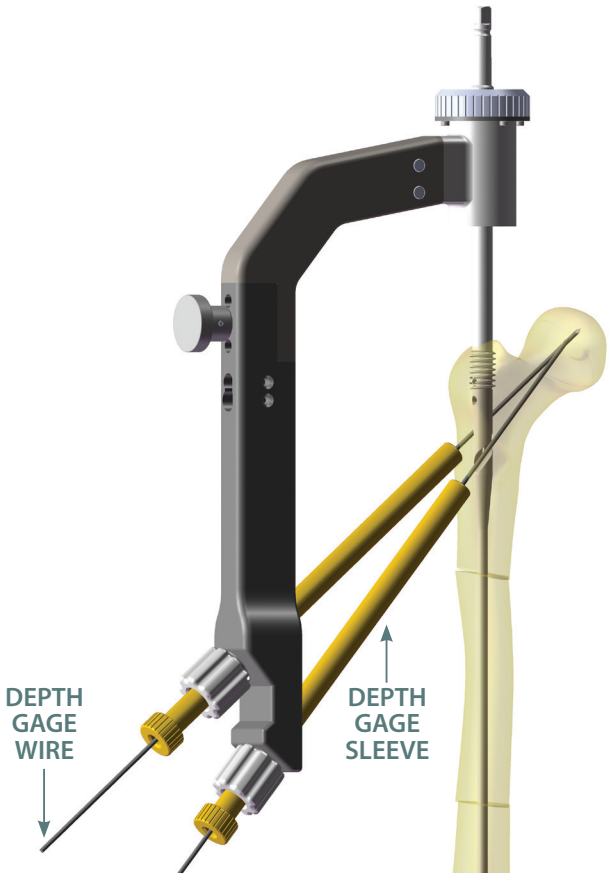
12.1 Cortex Preparation

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

Ream until the stopper of the Lag Endmill (GAP-DLF 155) reaches the sleeve. 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.

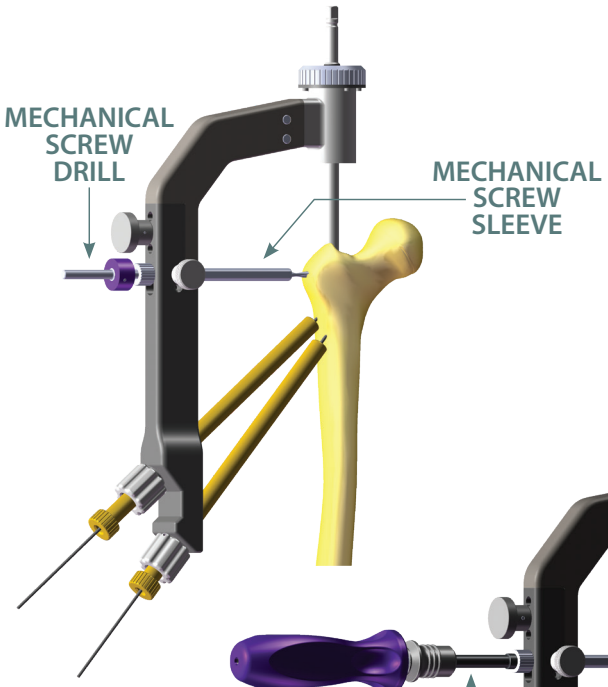
⚠ **If the Nail's position is not adequate,** remove the wires, sleeves, Lag Attachment, Targeting Device and **return to** STEP 9

STEP 13

TARGETING DEVICE LOCKING

13.1 Mechanical Screw Hole Preparation

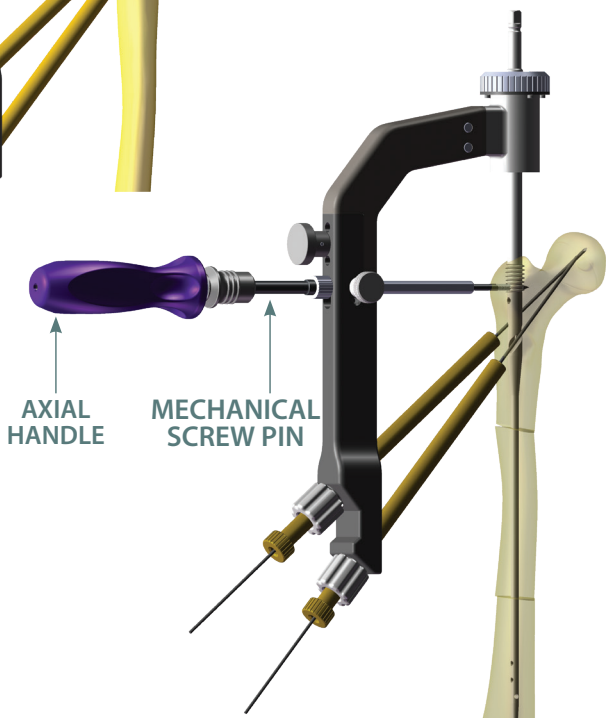
Mount the Mechanical Screw Sleeve (GAP-SMS100) into the proximal hole of the Lag Attachment. Secure by tightening the set-screw. Do not over tighten. Ream to stopper using the Mechanical Screw Drill (GAP-DMS110).



⚠ **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). Insert the pin until it is fully engaged in the nail through the Mechanical Screw Sleeve. 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.**

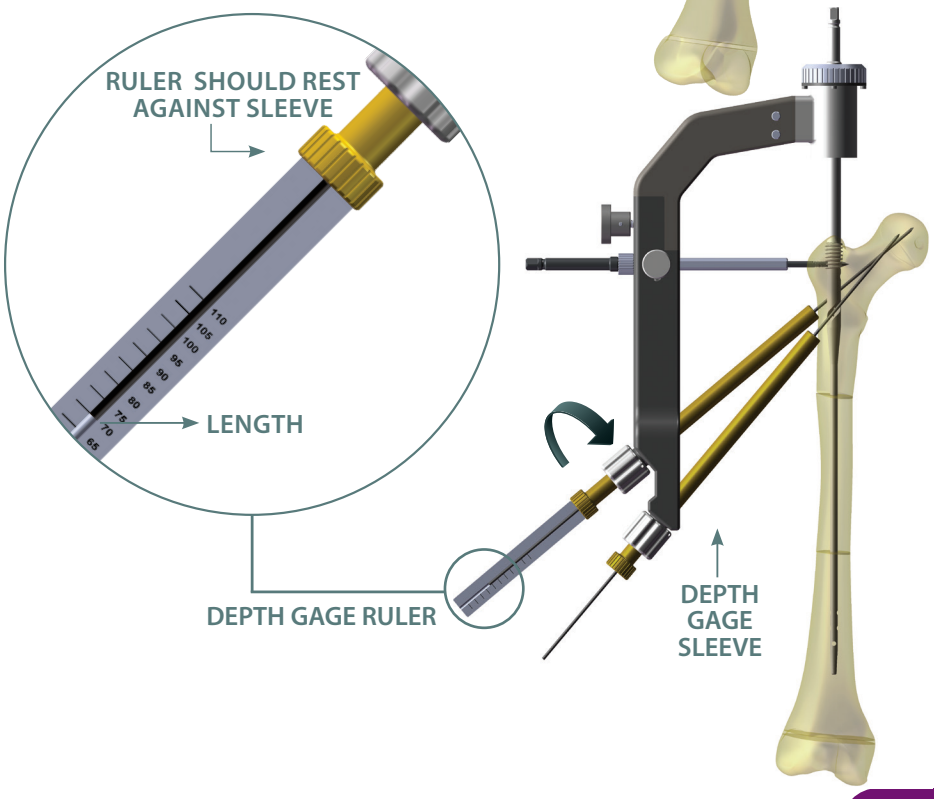
STEP 14

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 shorter 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.



⚠ **Leave** the Depth Gage Wires.

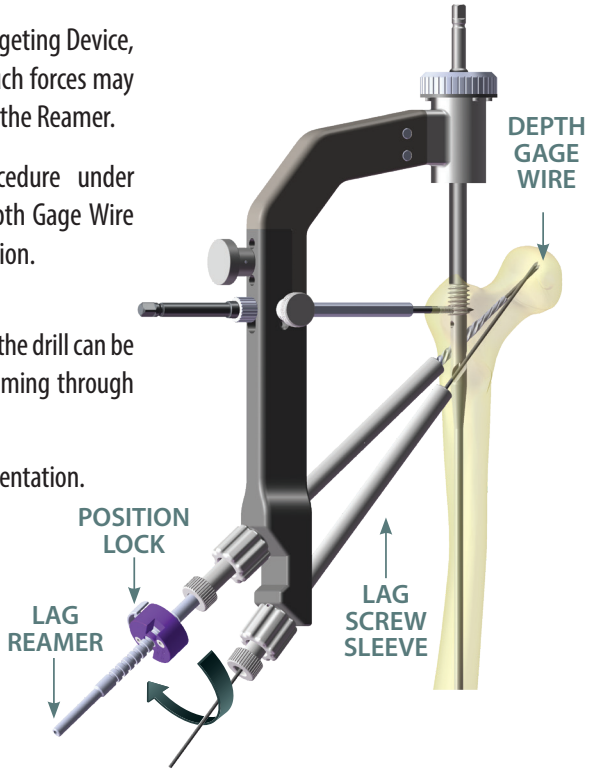
⚠ **Remove** the Depth Gage Ruler and Depth Gage Sleeves once measurements are obtained.

⚠ 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 Gage Wire is not driven into the articulation.

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

⚠ Respect the Position Lock's orientation.



14.2 Lag Hole Reaming

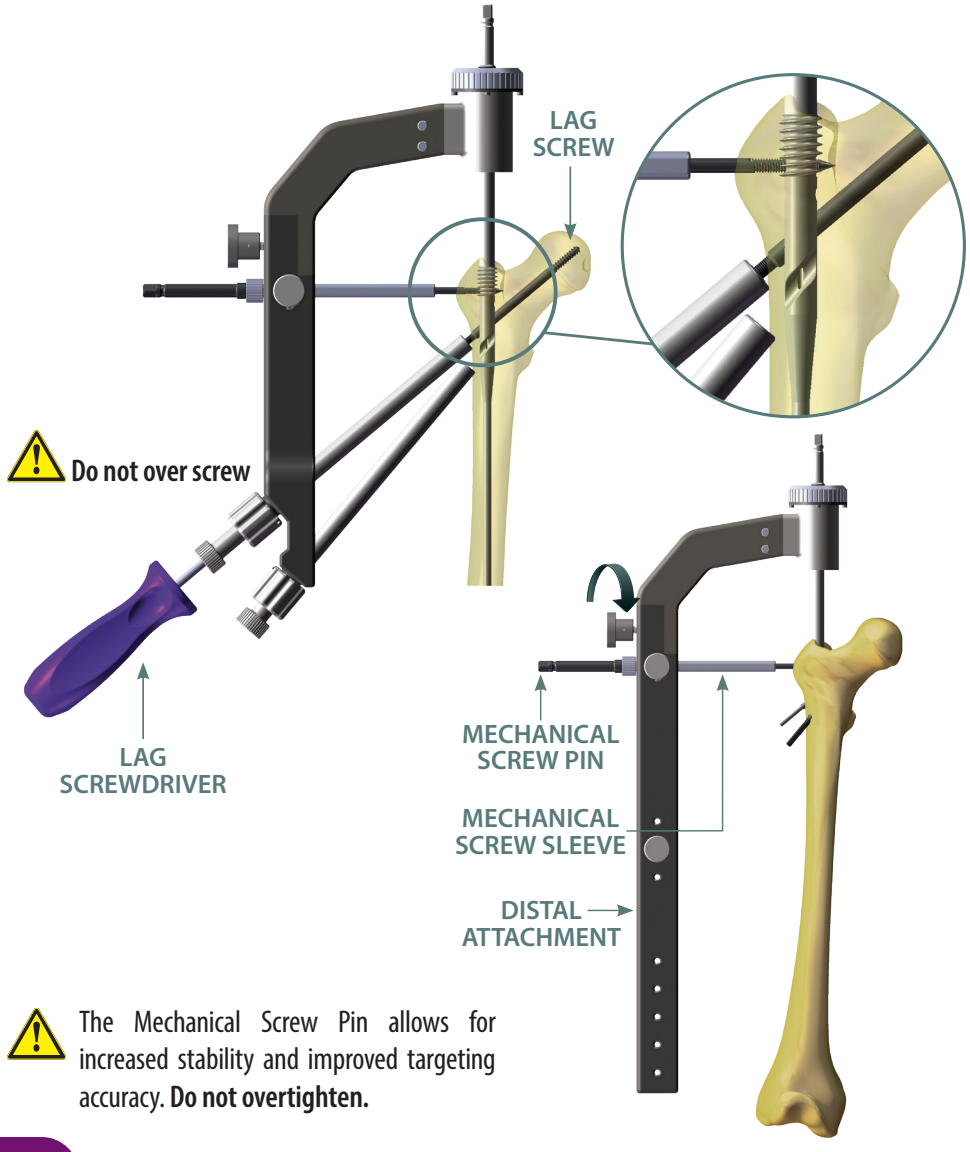
Mount the Lag Screw Sleeve (GAP-SLS155). Using the Position Lock (GAP-LCK080), set the Lag Reamer's (GAP-DLG055) depth to the desired length and ream up to the stopper.

14.3 Lag Screws Insertion

Using the Lag Screwdriver (GAP-TLS100) insert the appropriate Lag Screws (GAP-LG***) through the Lag Screw Sleeve.

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.

⚠ **Remove:**
Mechanical Screw Pin & Lag Screw 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

Mount the Distal Attachment (GAP-DSA 150) onto the Targeting Device and turn the setscrew 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). 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 Ø 4.8 and Ø 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 position corresponding to the cortical screw holes in the Nail. Once the sleeve is resting against the cortex, lock it in position using a set-screw.

Nail Size Ø	Screw Size	Drill (s)
4.8	2.5	GAP-DCS102 & GAP-DCS102-L
5.6	3.0	GAP-DCS103 & GAP-DCS103-L
6.4 / 7.2 / 8.0	4.0	GAP-DCS104 & GAP-DCS104-L

Flatten the cortex with the Cortical Screw Endmill (GAP-DCE100) to prevent slipping of the cortical drill tip on the curved cortex.

Use the shorter Cortical Drill (GAPDCS102/103/104) to bore a hole until the far cortex, and note the corresponding Cortical Screw length on the drill.

Maintain the short cortical drill in place and use the longer provided drill (GAP-DCS102-L/103-L/104-L) to make the second hole.

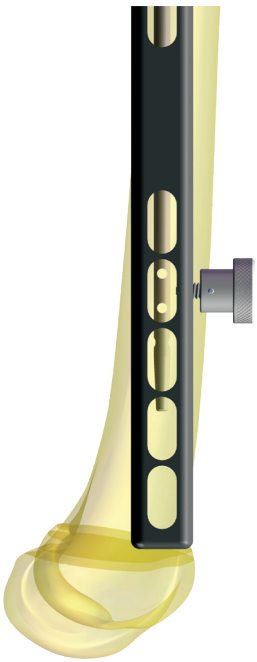
16.3 Cortical Screw Insertion

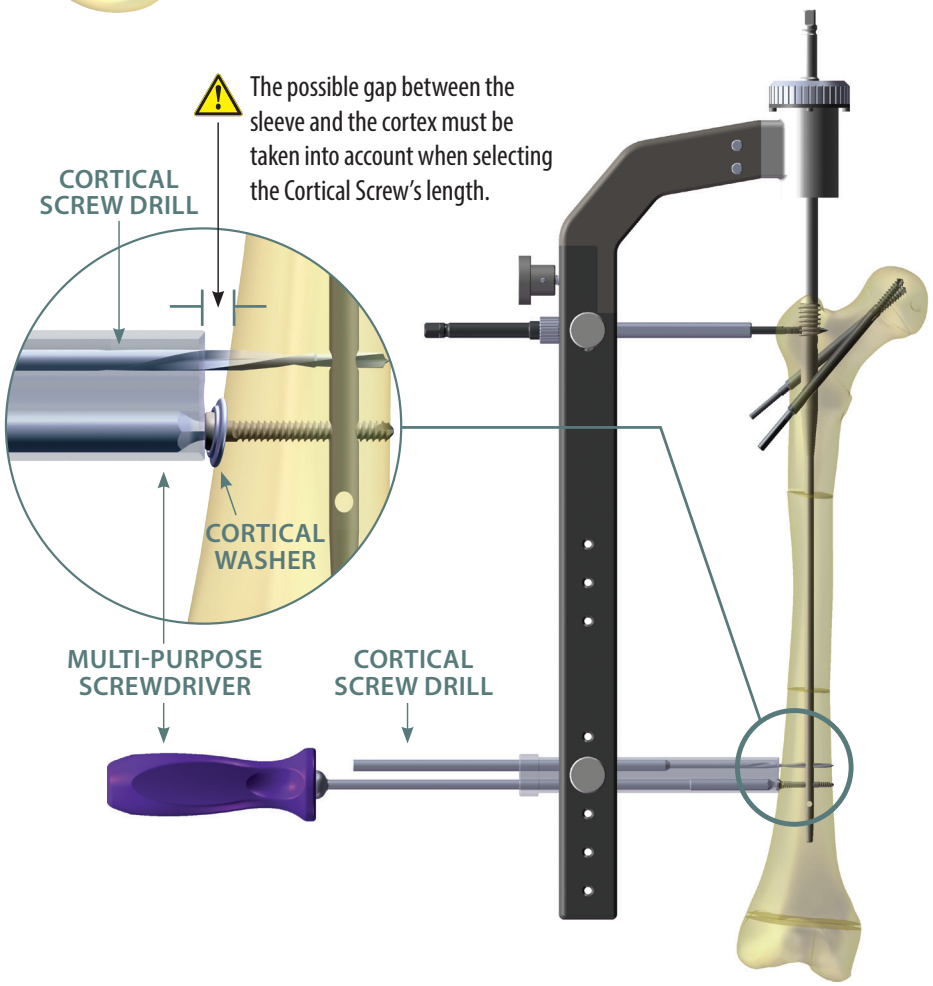
A minimum of two Cortical Screws must be used for distal fixation of the Nail. It is recommended to keep the short cortical drill in place while inserting the most proximal Cortical Screw first in order to maintain alignment.

Cortical Pegs should be cut to the length noted on the drill with the Lag Thread Cutter (GAP-LGC100) prior to insertion.

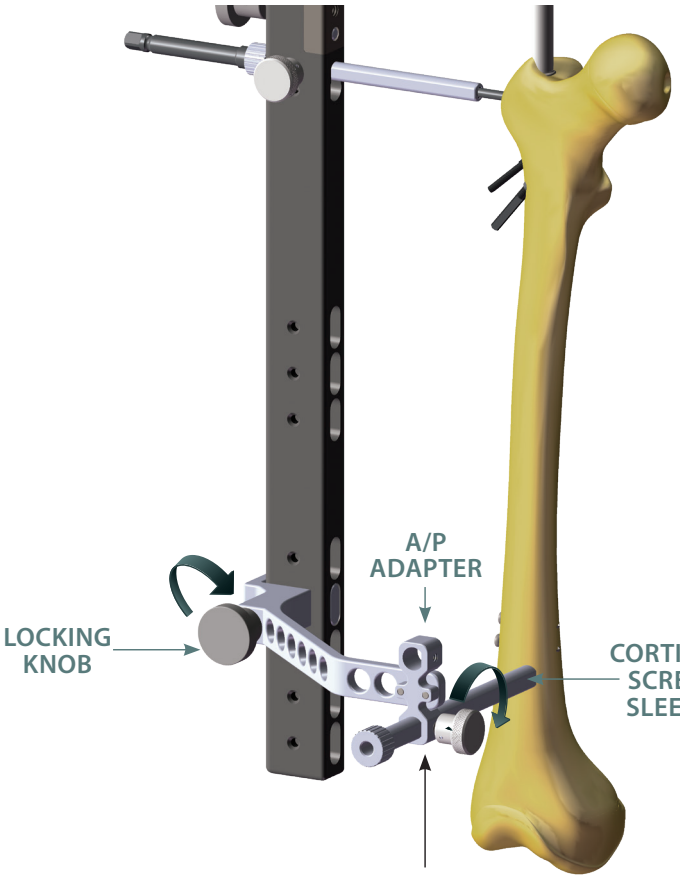
Using Multi-Purpose Screwdriver (GAP-TMP100), insert the Cortical Screws (GAP-CS *-**) corresponding to the noted length and nail's diameter.

A Cortical Washer (GAP-WAS 100) can be used when dealing with fragile bones to improve distribution of stress onto the cortex. To use, retract or remove the Distal Cortical Sleeve because the washer's diameter exceeds the sleeve's internal diameter.





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. Mount the A/P Adapter (GAP-APA100) onto the Distal Attachment using the locking knob. Slide the Cortical Screw Sleeve (GAP-SCS100) into the adapter, make a stab incision, and insert the sleeve up to the cortex. Lock the sleeve in position.

Using the corresponding Cortical Screw Drill (see table in step 16.2), drill through the far cortex, and note the corresponding screw length on the drill.

Finally, insert the Cortical Screw using the Multi-Purpose Screwdriver.

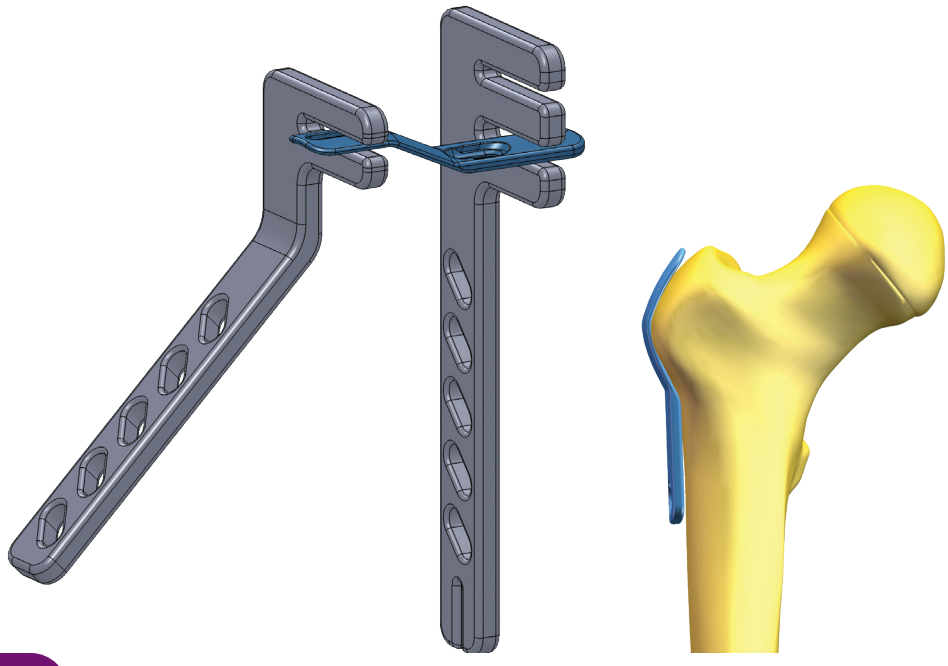
Step 18

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.

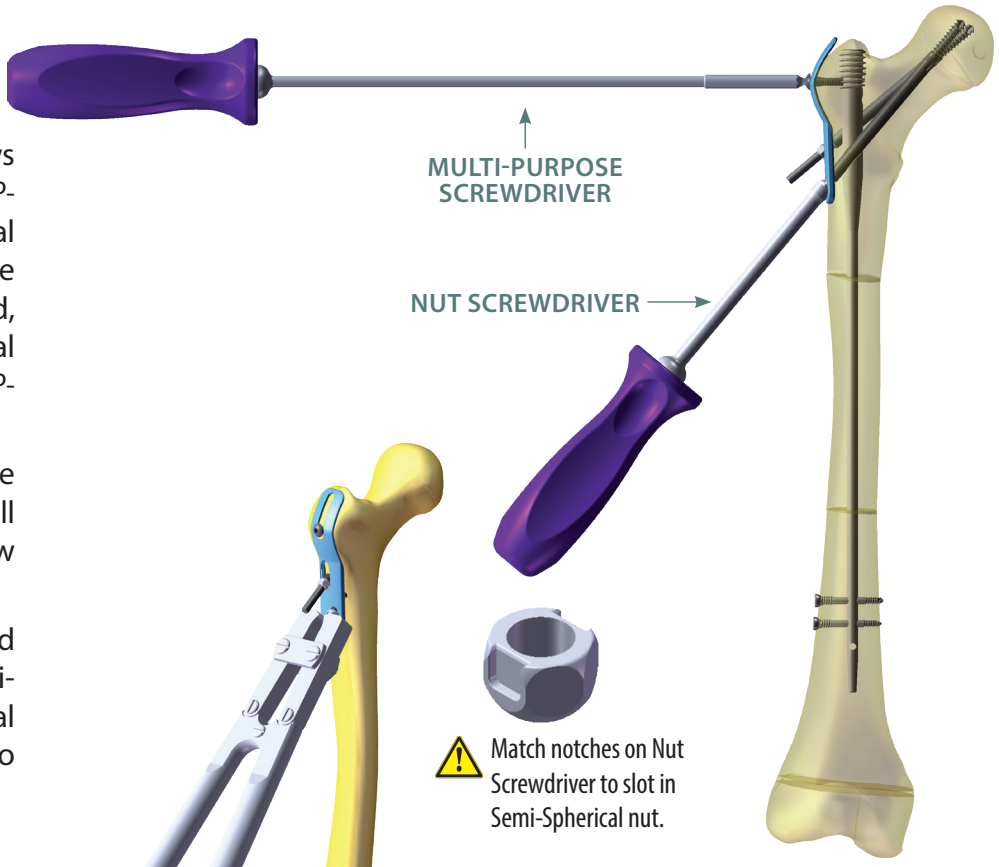
Step 20

PLATE ASSEMBLY

Slide the Plate over the Lag Screws threads. 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.

Insert the Mechanical Screw; large femurs and/or medially placed Nails will require the longer Mechanical Screw (GAP-MS34), otherwise use GAP-MS24.

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

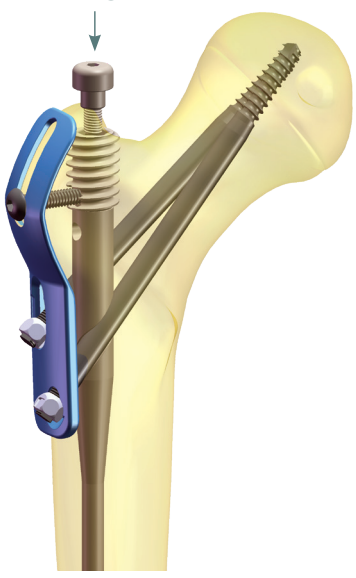
Cut off the threaded tips of the Lag Screws as close as possible to the Semi-Spherical Nuts using the Lag Thread Cutter (GAP-LGC100).

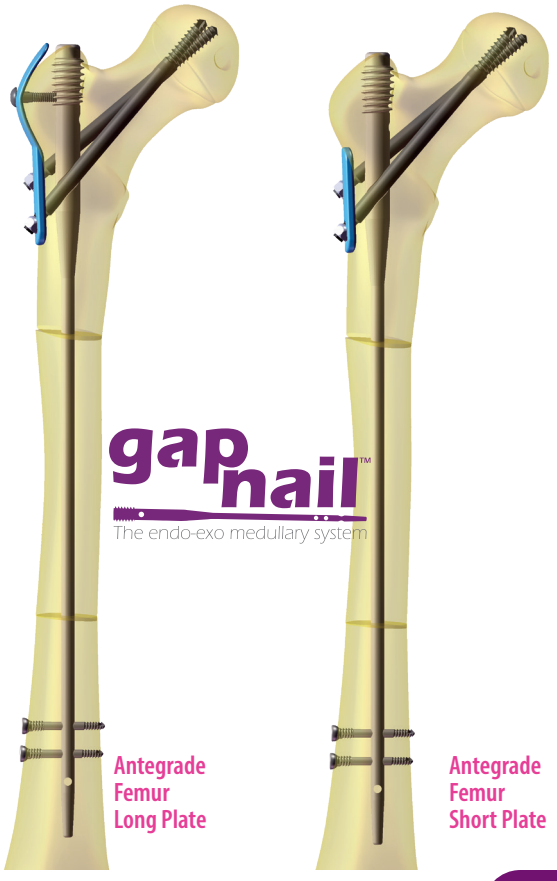
Step 22

NAIL CAP INSERTION

Select the appropriate Nail Cap (GAP-C P***) to ensure protrusion of the Cap from the cortex. Using the Multi-Purpose Screwdriver insert the Nail Cap into the Nail.

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



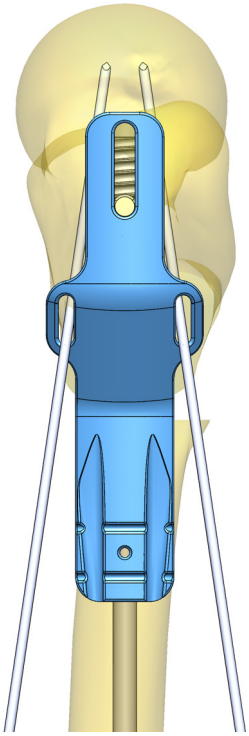


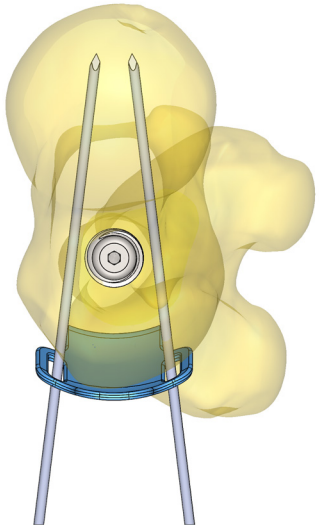
Based on **Dr. Fassier**'s Coxa Vara Technique.
François Fassier, MD, FRCS (C), Montreal, Canada

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.

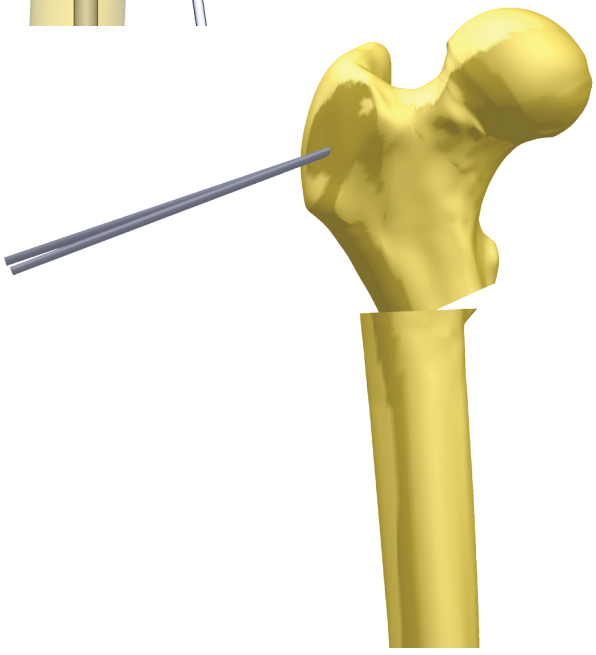




Step 2

K-WIRE INSERTION

Select the size of the Kirshner wire's according to the size of the bone. 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.



Step 3

OSTEOTOMY AND HEAD POSITIONING

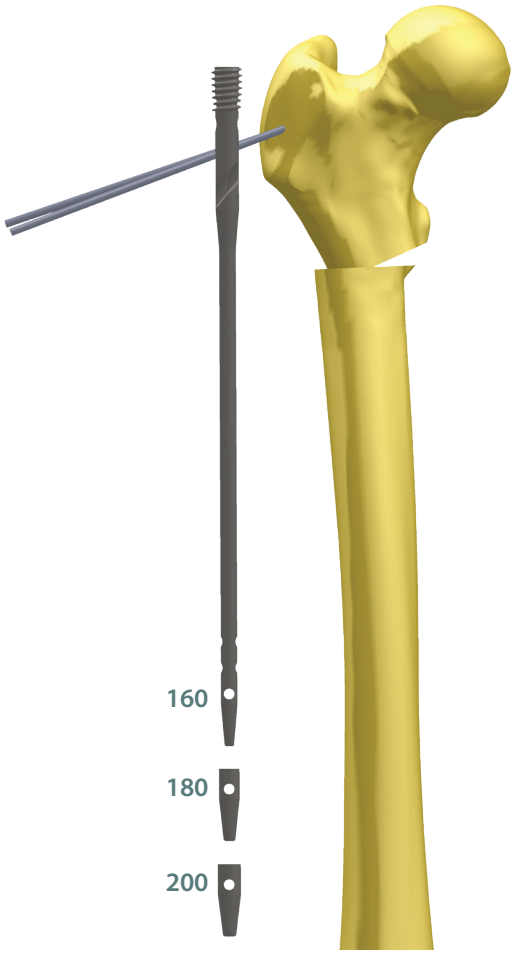
Determine the site of the osteotomy with fluoroscopy. After the osteotomy, use the two Kirshner wires as a "joystick" to allow safe adduction of the proximal fragment without the use of a bone clamp.

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

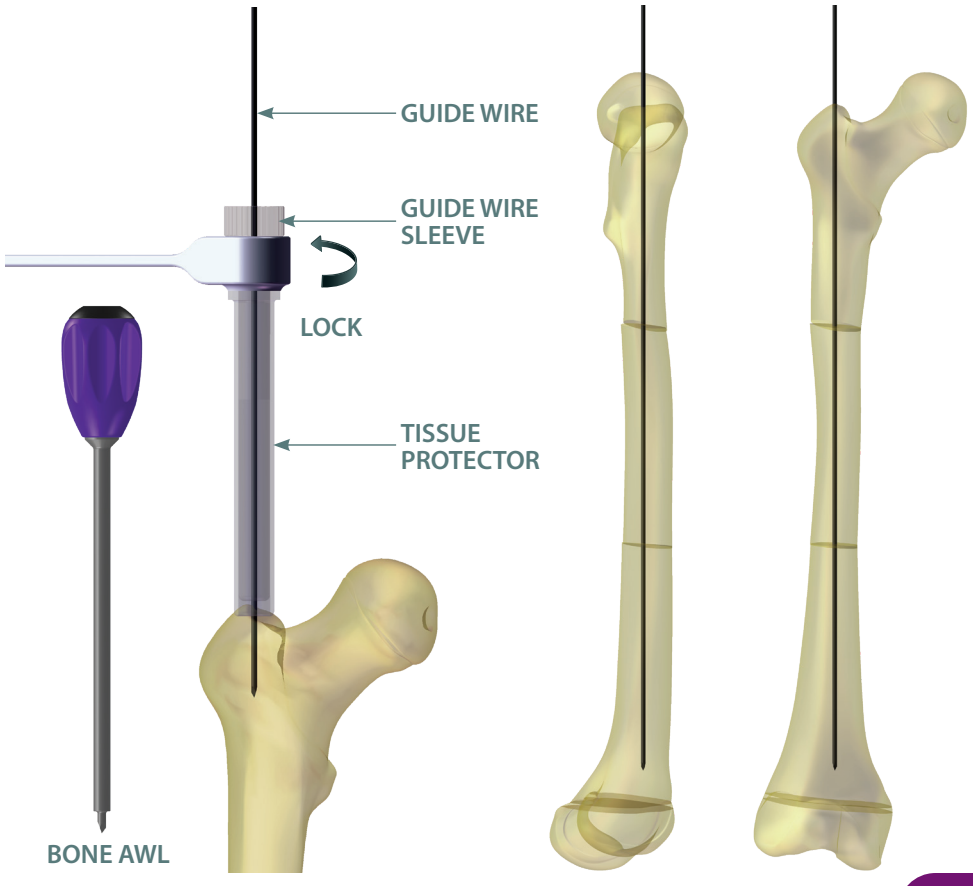
GUIDE WIRE INSERTION

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 increases 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.

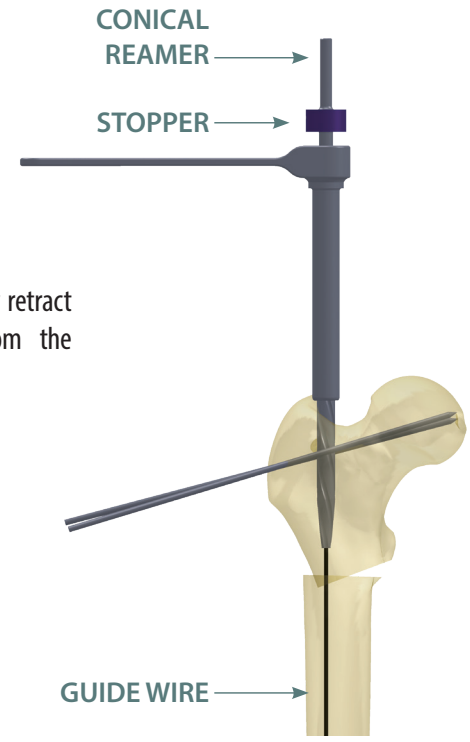
Puncture the cortex using the Bone Awl (GAP-BAW100), or directly with the Guide Wire through the Guide Wire Sleeve, corresponding to the selected nail size, and the Tissue Protector (GAP-TP116).

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



Do not force the Reamer. Partially retract the Reamer to clean debris from the medullary canal.

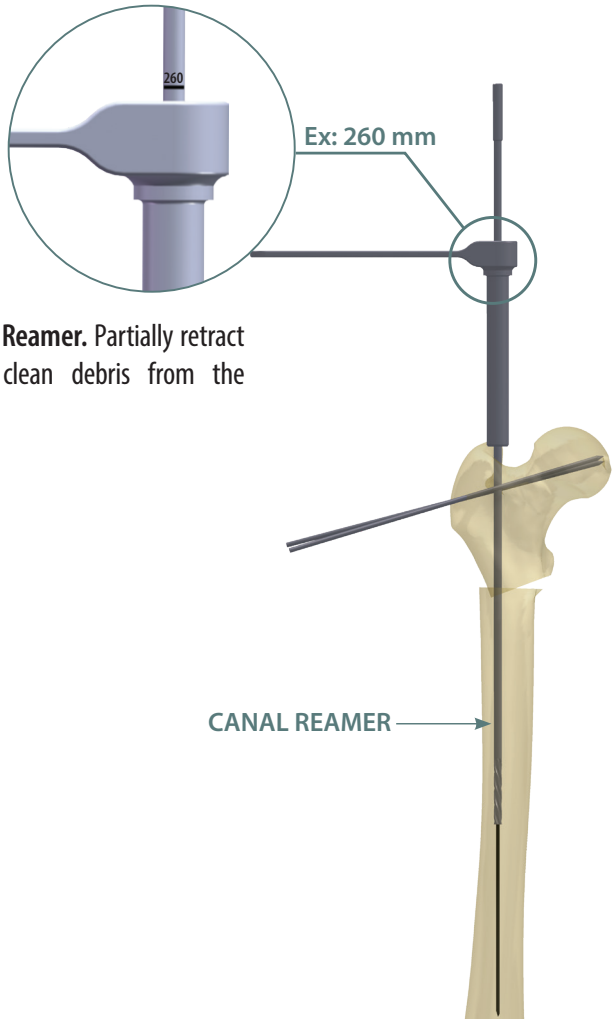
CONICAL REAMING

Select the Conical Reamer corresponding to the 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 up to the stopper.

STEP 7



Do not force the Reamer. Partially retract the Reamer to clean debris from the medullary canal.

MEDULLAR CANAL REAMING

Select the Canal Reamer corresponding to the nail's size. Ream through the Tissue Protector and over the Guide Wire. Advance the Reamer with steady and moderate pressure.

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

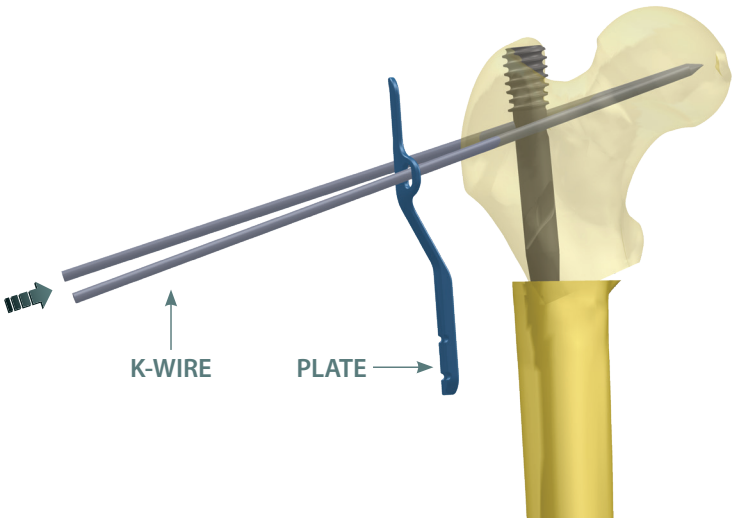
Select the Small, Medium or Large Coxa Vara Plate (GAP-PLC1**) that best fits the bone's size and geometry. The Plate can be bent using the two Plate Benders (GAP-PLB 100, GAP-PLB 110).

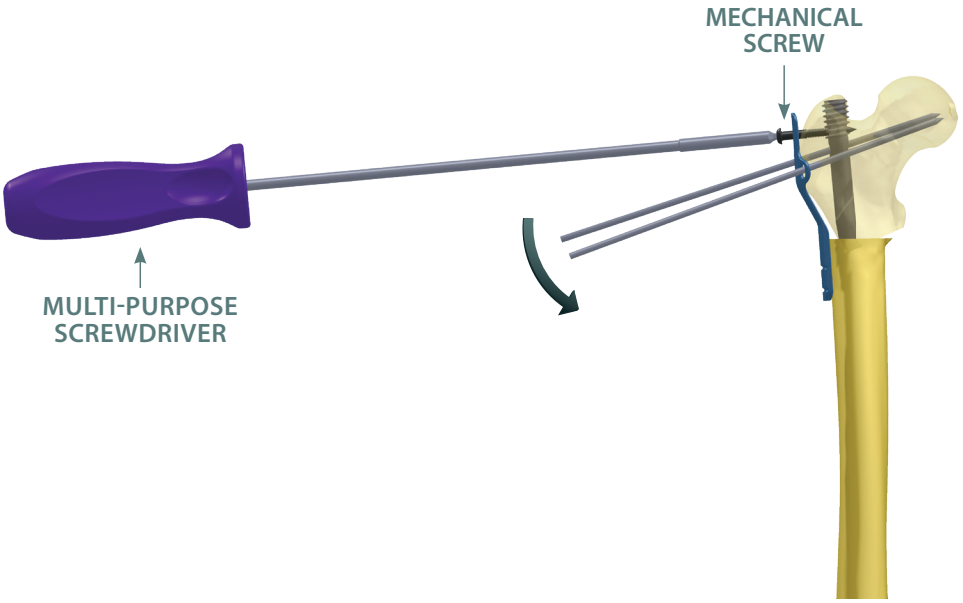
⚠ The Plate should not be excessively or repeatedly bent. The Plate should not be reverse bent in the same location. Use care to ensure that the Plate is not scratched or notched during the bending process.

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

Insert the Mechanical Screw; large femurs and/or medially placed Nails will require the longer Mechanical Screw (GAP-MS34), otherwise use GAP-MS24. 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 secure them to the shaft with cerclage wires.



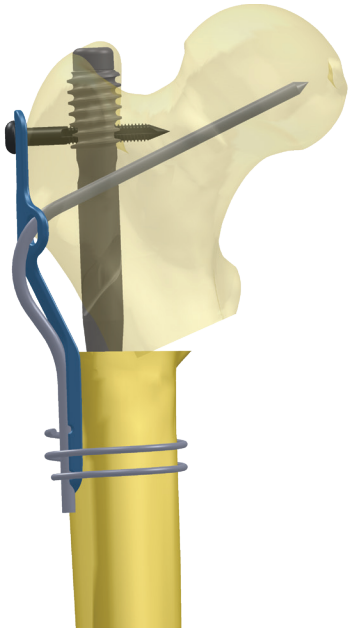


Step 19

NAIL CAP INSERTION

Select the appropriate Nail Cap (GAP-CP***) to ensure that the cap protrudes from the cortex. Using the Multi-Purpose Screwdriver, insert the Nail Cap into the Nail.

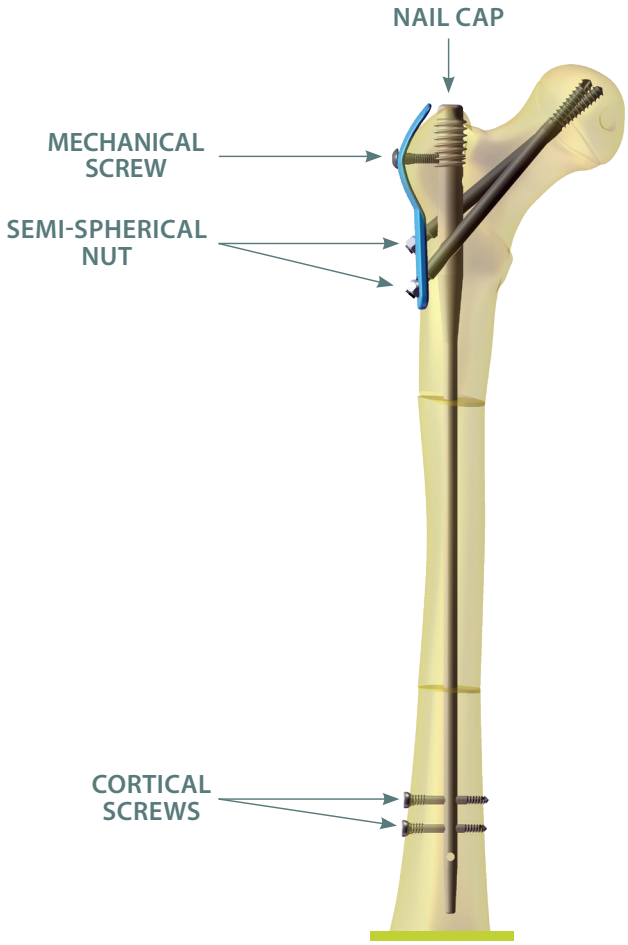
Nail Caps (Height)	
1.5 mm	GAP-CP015
5.0 mm	GAP-CP050
10.0 mm	GAP-CP100



Coxa Vara Plate

gapnail™
The endo-exo medullary system

This surgical technique for removal is based on a GAP Nail configuration with two Lag Screws and a Long Plate (most complex configuration). If Lag Screws were not used, steps 2 through 5 can be skipped.

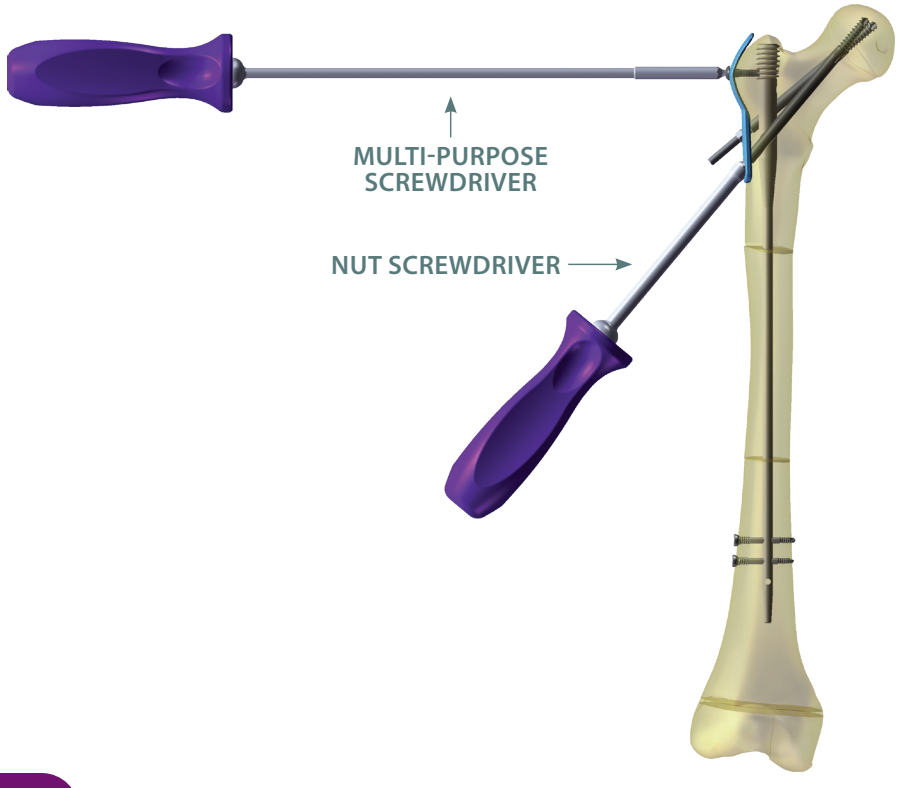


Step 1

The mechanical screw, Cortical screws and Nail Cap can be removed using the Multi-Purpose Screwdriver

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

⚠ It is preferable to verify alignment of the Multi-Purpose Screwdriver using imagery prior to unscrewing these components in order to minimize the risk of stripping of the drive features.



Step 2

Remove the two Semi-Spherical Nuts from the lag screws using the Nut screwdriver.

⚠ It is possible that during the initial surgery, cutting the Lag Screw's excess thread created a flare which may prevent the Semi-Spherical Nut from being fully removed.

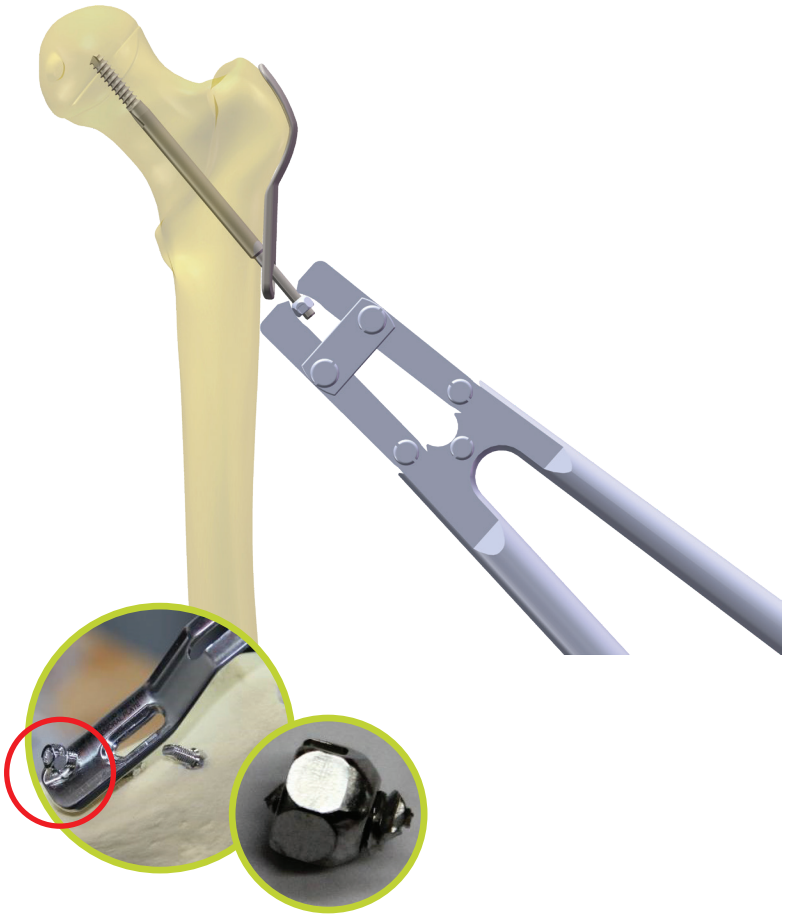
Step 3

If required, cut the tip of the Lag Screw thread with the blocked Semi-Spherical Nut.

First, unscrew the nut until it is blocked against the flare. This creates a clearance of a few threads between the nut and the plate for the lag cutter.

Before cutting, since the Nut is blocked on the Lag Screw's thread, the action of rotating the Nut Screwdriver will unscrew the Lag Screw. Continue unscrewing the lag screw using the Nut Screwdriver to break any contact with the bone.

Once the lag Screw is loosened, cut the screw in the clearance zone between the Semi-spherical nut and the plate, as shown in the images below.



Step 4

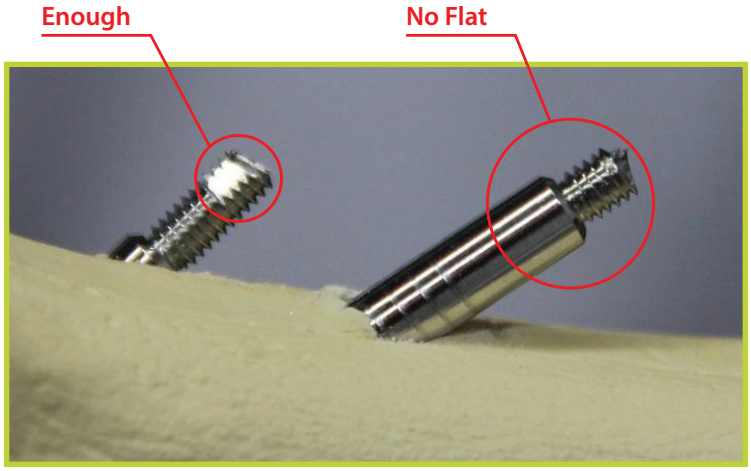
Remove the Long Plate by sliding it along the remaining Lag Screw's threads.

Step 5

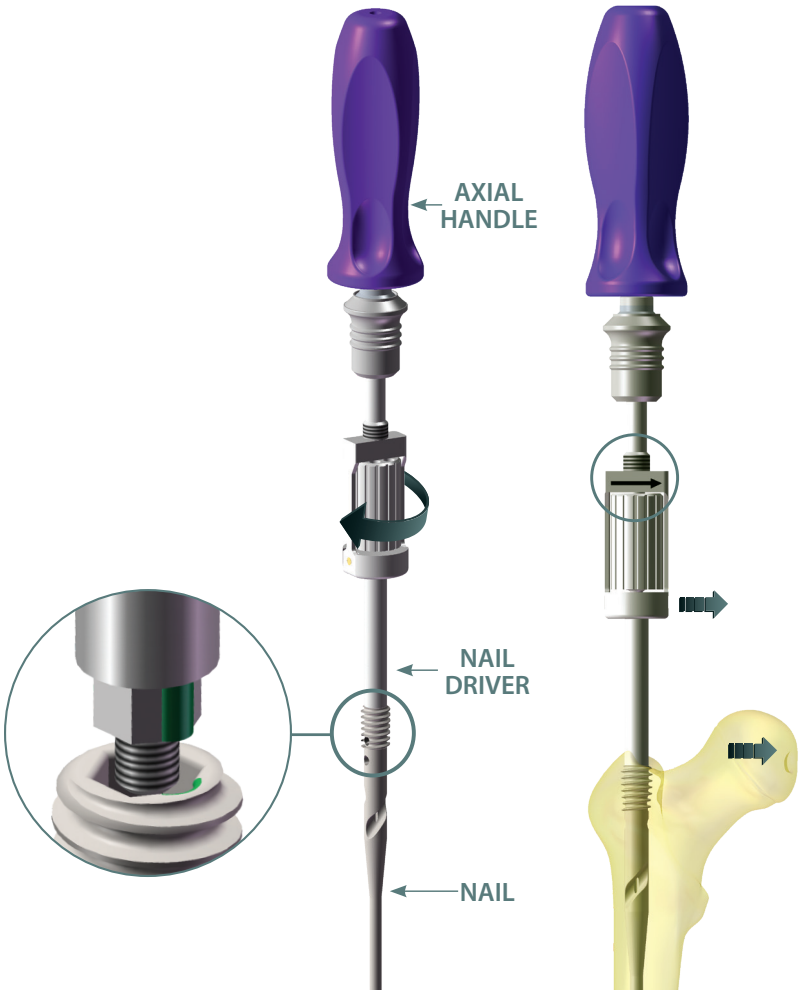
Unscrew both Lag Screws using the Lag Screwdriver if enough flat surfaces remain on the protruding tip of the Lag Screws.

⚠ If the Lag Screws were cut to remove the nuts, there might not be enough flat surfaces remaining to use the Lag Screwdriver.

If need be, use pliers to remove the rest of the Lag Screw. The ability to remove the lag with pliers depends on bone grip on the Lag Screw. Once the length of the thread of the Lag Screw is threaded out (about 2 cm) the screw can be pulled for the rest of the way.

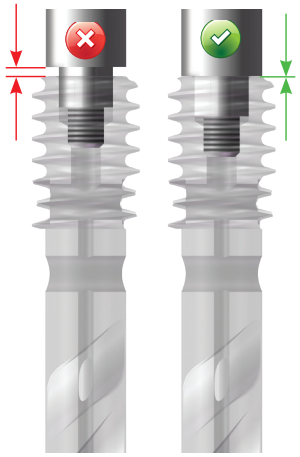


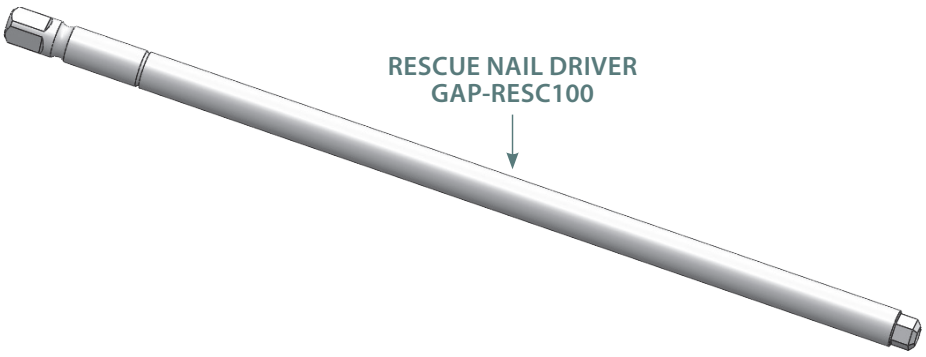
Step 6



Now that all interlocking screws (Cortical and Mechanical) and Lag Screws have been removed, the GAP Nail can be removed using the Nail Driver. Orientation of the Nail Driver notch (highlighted in green on the image below) must be respected. Please refer to Step 8 of the GAP Surgical Technique.

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





Aligning of the Nail Driver notch and Hex with the Nail's internal features might pose some difficulties during surgery; therefore a long cannulated Hex Driver without the notch feature is available in order to aid in removing the GAP Nail.

It is important to note that the Rescue Nail Driver can only be used for rotation. It does not have an internal thread; (unlike the Nail Driver) therefore it will not capture the Nail, nor allow traction to be applied.

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	9.2	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	9.2	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	9.2	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

*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)

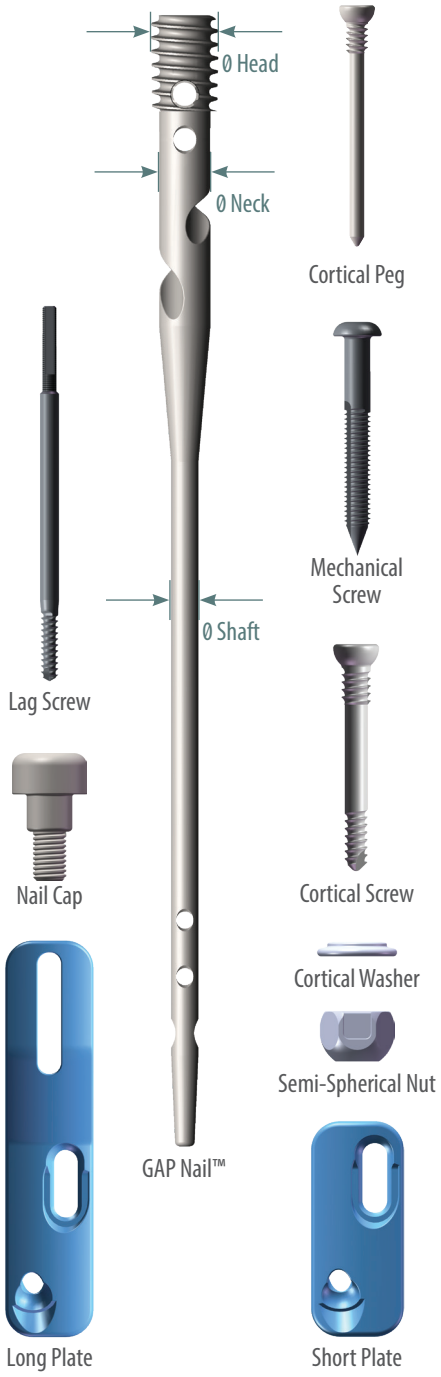
1.5 mm	GAP-CP015
5.0 mm	GAP-CP050
10.0 mm	GAP-CP100

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



Standard Interlocking Surgical Technique

Lag Screw Surgical Technique

Coxa Vara (Valga) Surgical Technique

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

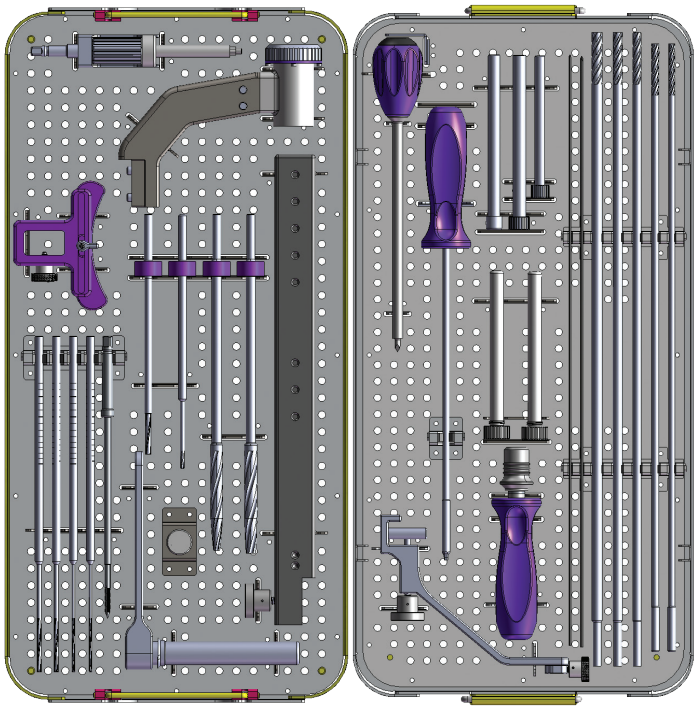
Tissue Protector	GAP-TP116
Bone Awl	GAP-BAW100
Mechanical Screw Pin	GAP-MSP100
Depth Gage Ruler	GAP-DPG120
Position Lock - Lag Drill	GAP-LCK080
Lag Thread Cutter	GAP-LGC100
Plate Bender "E"	GAP-PLB100
Plate Bender "F"	GAP-PLB110
Gap Nail Template	GAP-TPL100

Cortical Peg

Ø / L	Ø 2.5mm
60 mm	GAP-CS2-60

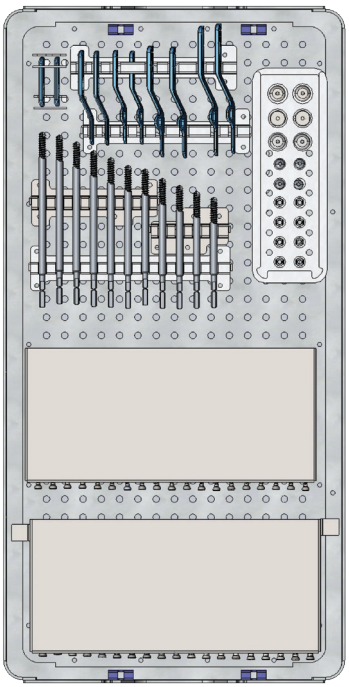
Specifications

INSTRUMENT MAIN CASE

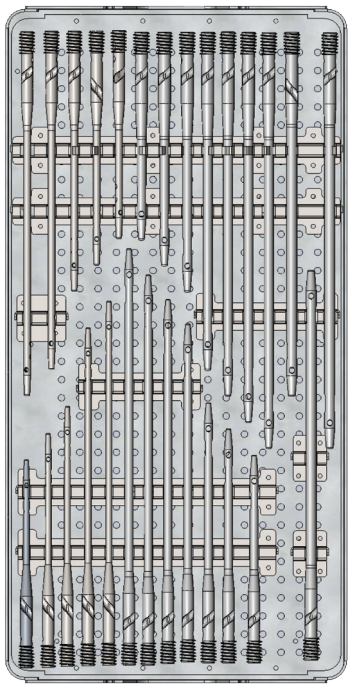


IMPLANT CASE

Top Tray



Lower Tray



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 - 2.0 mm	GAP-DCS102
Cortical Screw Drill - Long - 2.0 mm	GAP-DCS102-L
Cortical Screw Drill - 3.0 mm	GAP-DCS103
Cortical Screw Drill - Long - 3.0 mm	GAP-DCS103-L
Cortical Screw Drill - 4.0 mm	GAP-DCS104
Cortical Screw Drill - Long - 4.0 mm	GAP-DCS104-L
Cortical Endmill	GAP-DCE100
Mechanical Screw Drill	GAP-DMS110

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

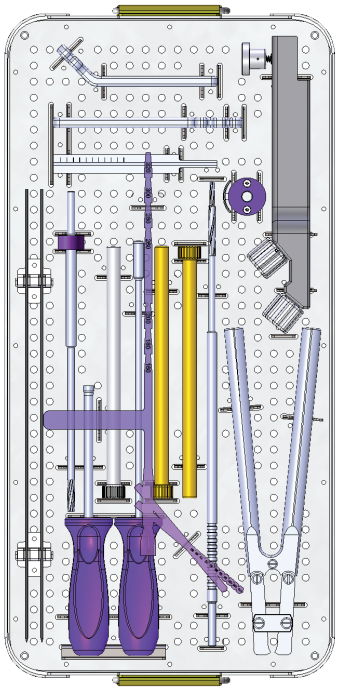
Handles & Drivers	
Nail Driver	GAP-NDR100
Multi-purpose Screwdriver	GAP-TMP100
Nut Screwdriver	GAP-TSN100
Lag Screw Driver	GAP-TLS100
Axial Handle	GAP-THA100

Cases	
Implant Case	GAP-IMF100
Instrument Main Case	GAP-INF110
Instrument Lag Case	GAP-ILF120
Rescue Nail Driver	GAP-RSC100

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" (457mm)	GAP-KWG016
Guide Wire 2.0 mm	L = 18" (457mm)	GAP-KWG020
Depth Gage Wire	L = 360 mm	GAP-KDG360

INSTRUMENT LAG CASE



gapnail™
The endo-exo medullary system

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

Notes

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