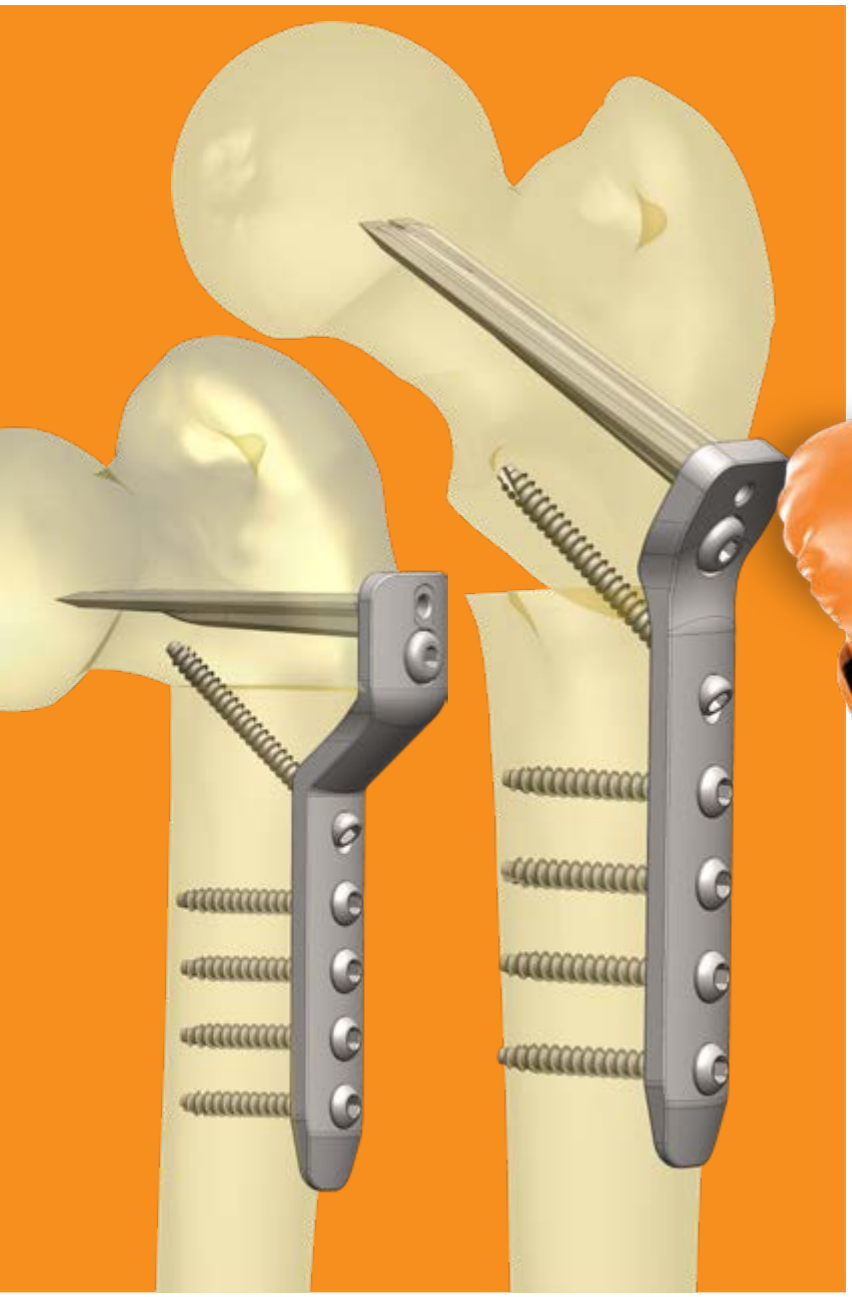
Pega Medical

LolliPOP

The Locking Pediatric Osteotomy Plate system™



A Modular Blade-Plate System for stable fixation of pediatric proximal femoral osteotomies and fractures

SURGICAL TECHNIQUE

The Locking Pediatric Osteotomy Plate (LolliPOP)™ system is a modular hip Blade-Plate system intended for stable fixation of valgus, varus, derotation, flexion and extension, of proximal femoral osteotomies (PFO) and fractures in the pediatric population. PFOs are widely performed reconstructive surgeries in children with hip deformities, such as Coxa Valga, Coxa Vara and other congenital deformities.

The implants are made of medical grade 316L Stainless Steel (as per ASTM F138) and are offered in four families: Infant, Child, Adolescent and HD Adolescent.

Features and Benefits:

- Varus and Valgus Plates range from 90° to 140° of NSA
- Chisel free technique reduces OR time and trauma
- Modularity provides surgical flexibility and reduced inventory
- Intuitive instrumentation for precise control of correction
- Stable in rotation
- Plate design creates biomechanically correct femoral offset

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The Locking Pediatric Osteotomy Plate System (LolliPOP)™

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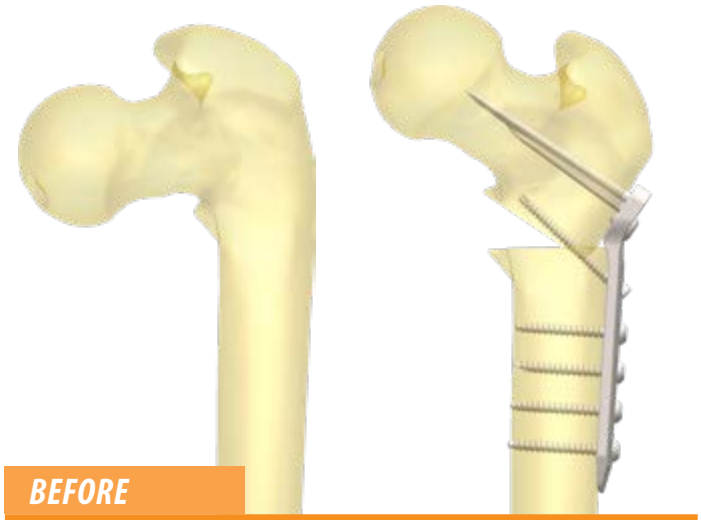
The Locking Pediatric Osteotomy Plate (LolliPOP) system is comprised of a set of Plates, Blades, Connectors, Locking Screws, Polyaxial Compression Screws, and all the instrumentation required for implantation and retrieval of the device.

Indication for Use

The Locking Pediatric Osteotomy Plate (LolliPOP) system is a modular hip Blade-Plate system intended for stable fixation of valgus, varus, derotation, flexion and extension of proximal femoral osteotomies (PFO) in the pediatric (infant, child and adolescent) population. Intended uses include the following:

- Inter and subtrochanteric valgus osteotomies
- Inter and subtrochanteric varus osteotomies
- Inter and subtrochanteric derotation osteotomies
- Inter and subtrochanteric flexion and extension osteotomies
- Inter and subtrochanteric fractures

COXA VALGA CORRECTION



COXA VARA CORRECTION

THE BLADE

The Blade is designed as a single piece construct that is inserted over a Ø2.0mm Guide Wire. The Blade tip is sharp and tapered, as a chisel would be, to facilitate insertion into the bone. The Blade's geometrical construct is intended to promote rigidity in bending. It presents a decreasing thickness, the greater concentration of material being at the level of the connection with the Plate where load is transferred from the neck to the shaft of the proximal femur. The Blade is also designed with a keel which provides rotational stability and additional stiffness to the construct in bending allowing for a slimmer Blade profile.

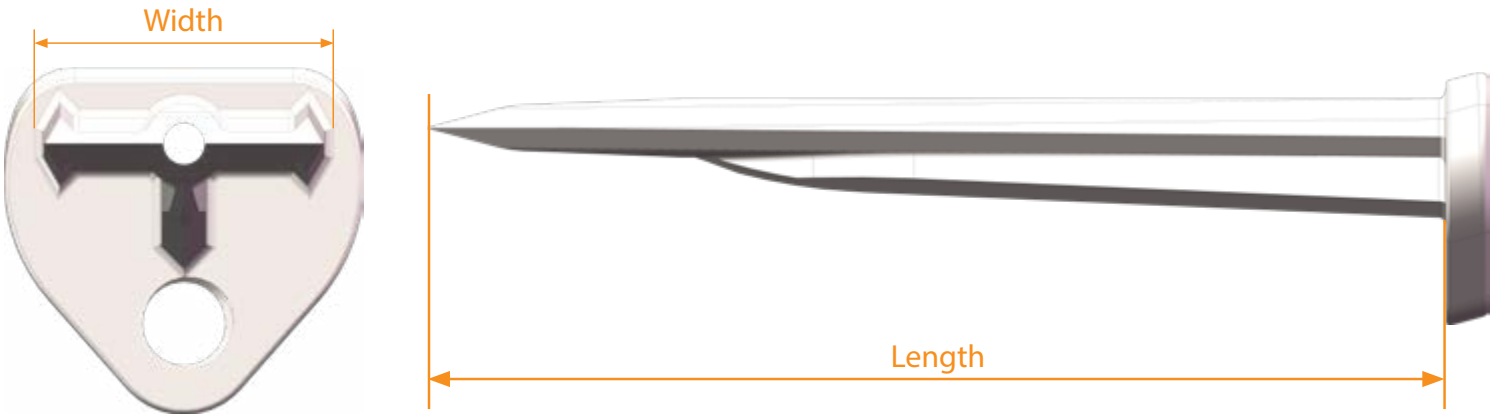


Table 1: Blade components

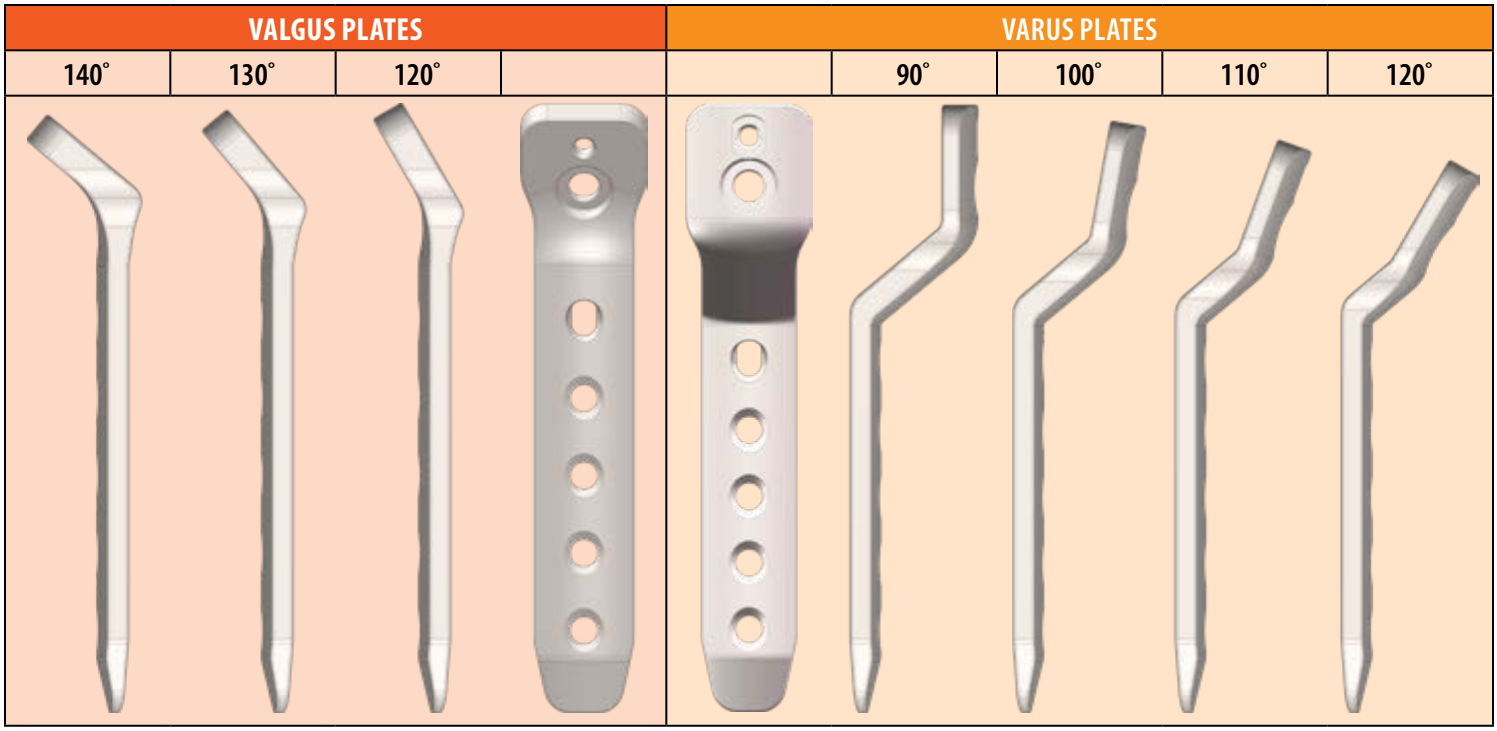
	Blade width (mm)	Blade length (mm)	Catalog #
INFANT (ages 2 to 5)*	8	25	POP-IB-25
		30	POP-IB-30
		35	POP-IB-35
CHILD (ages 6 to 11)*	11	30	POP-CB-30
		35	POP-CB-35
		40	POP-CB-40
		45	POP-CB-45
		50	POP-CB-50
ADOLESCENT & HD ADOLESCENT (ages 12 to 21)*	14	40	POP-AB-40
		45	POP-AB-45
		50	POP-AB-50
		55	POP-AB-55
		60	POP-AB-60
		65	POP-AB-65
		70	POP-AB-70

The Blade is sharp, handle with care in order to avoid harm to the patient or surgical staff.

** Age range provided as reference only.*

THE PLATE

The Plate design classifies the implants into two categories: Valgus and Varus.



All Plate implants present a low profile intended to minimize invasiveness. The medial and lateral offset of the Plates are designed for correct anatomic position of the center of the femoral head in relation to the shaft of the femur and mechanical axis of the lower extremity.

Table 2: Plate components

	Number of screw holes	FINAL NECK SHAFT ANGLE (NSA)						
		VARUS				VALGUS		
		90˚	100˚	110˚	120˚	120˚	130˚	140˚
INFANT *(ages 2 to 5)	3	POP-IVR-090	POP-IVR-100	POP-IVR-110	POP-IVR-120	POP-IVL-120	POP-IVL-130	POP-IVL-140
CHILD *(ages 6 to 11)	4	POP-CVR-090	POP-CVR-100	POP-CVR-110	POP-CVR-120	POP-CVL-120	POP-CVL-130	POP-CVL-140
ADOLESCENT *(ages 12 to 21)	4	POP-AVR-090	POP-AVR-100	POP-AVR-110	POP-AVR-120	POP-AVL-120	POP-AVL-130	POP-AVL-140
HD ADOLESCENT *(ages 12 to 21)	5	POP-HVR-090	POP-HVR-100	POP-HVR-110	POP-HVR-120	POP-HVL-120	POP-HVL-130	POP-HVL-140

** Age range provided as reference only.*

SURGICAL TECHNIQUE OVERVIEW

The following described procedures are applicable to all intended uses of the LolliPOP system including valgus and varus osteotomies. For simplification purposes, the technique has been illustrated with an HD Adolescent Valgus assembly.

STEP 1

PRE-OPERATIVE PLANNING

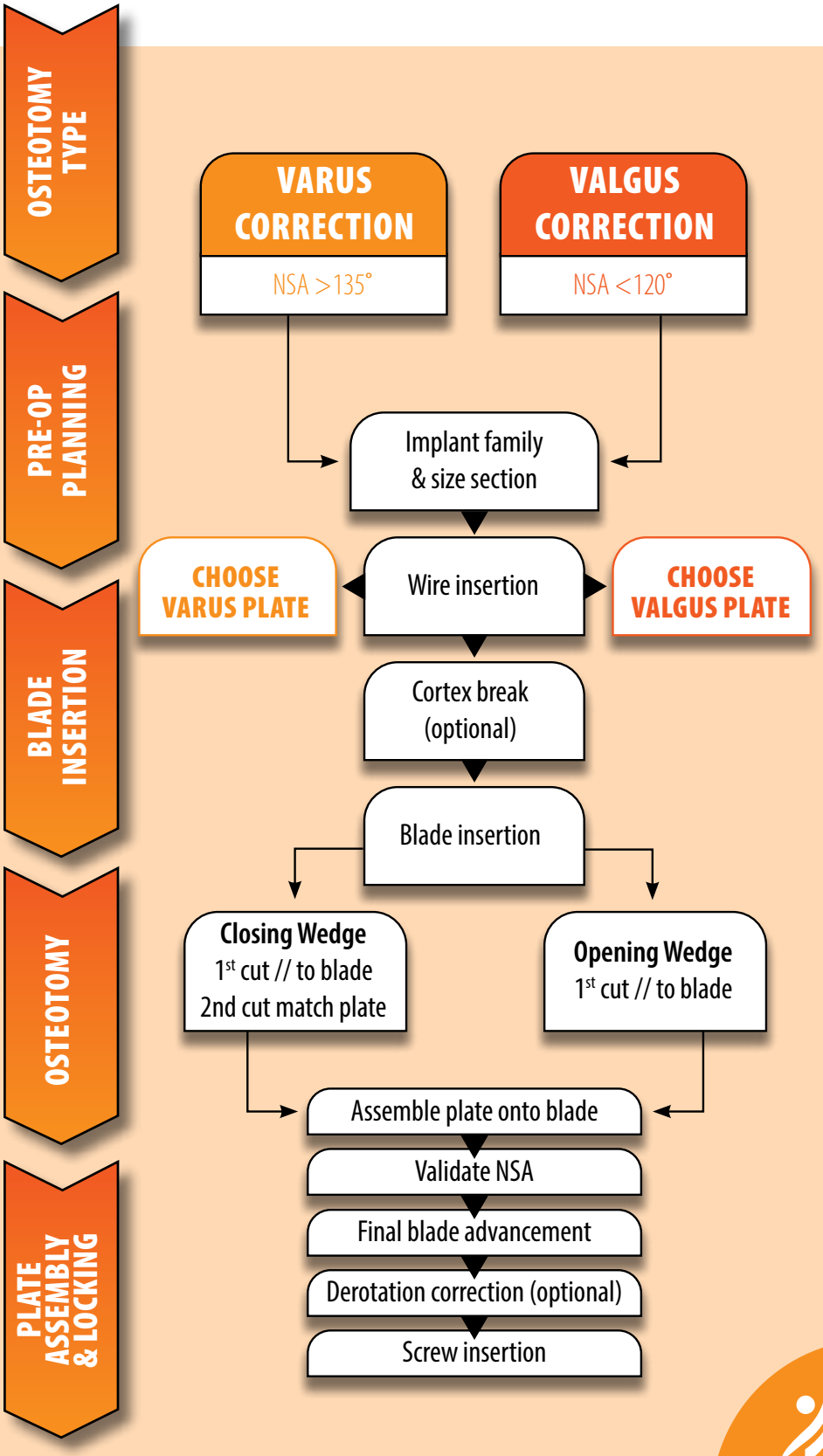
Preoperatively evaluating and planning the surgical procedure aids with implant selection.

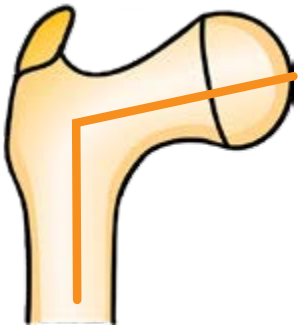
The sizes of the Blade and Plate are based on the age, bone size and bone structure of the patient. It is recommended to select the largest, longest, most stable implant for the patient. Determine the appropriate implant size category:

- Infant (2 to 5 y/o)
- Child (6 to 11 y/o)
- Adolescent (12 to 21 y/o)
- HD Adolescent (12 to 21 y/o)

Select the Blade according to details in Table 1. The length of the Blade can be estimated from X-ray. However, direct validation of the required Blade length after Guide Wire insertion is preferable to ensure the Blade will be 5-10mm short of the capital femoral growth plate in skeletally immature patients.

Select the Plate size from same family as the Blade. Verify the Neck shaft angle (NSA) pre-operatively. Select the Plate's geometry (valgus or varus) according to the final NSA desired and the neck/shaft technique desired.

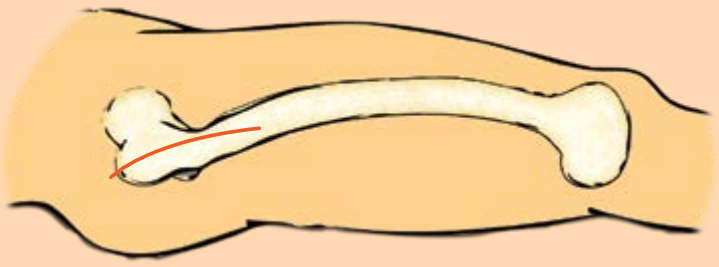


	NSA < 120°			NSA > 135°			
PRE-OPERATIVE NSA							
CORRECTION TYPE	VALGUS OSTEOTOMY			VARUS OSTEOTOMY			
	Opening wedge osteotomy			Closing wedge osteotomy			
PLATE OPTIONS	VALGUS PLATE			VARUS PLATE			
FINAL NSA	140°	130°	120°	90°	100°	110°	120°
							

STEP 2

INCISION/APPROACH

The surgical technique should be performed under image intensification (C-arm) using a radiolucent or fracture table. Position the patient on the radiolucent table in supine, lateral or prone position depending on surgeon preference. The image intensifier should allow visualisation in the AP and lateral views. Perform a straight lateral incision starting at the tip of the greater trochanter to visualize the affected area.



STEP 3

GUIDE WIRE INSERTION (4-5mm distally in the AP view)- FIXED NECK/SHAFT ANGLE TECHNIQUE

Insertion of the Ø2.0mm Guide Wire (POP-GWR120) in the 1-1 position can be done under image intensification by either the Free-Hand Method, or with the guidance of the Positioning Triangles or the Wire Guide.

⚠ **The Guide Wire should not penetrate the physis or the epiphysis of the femoral head.**

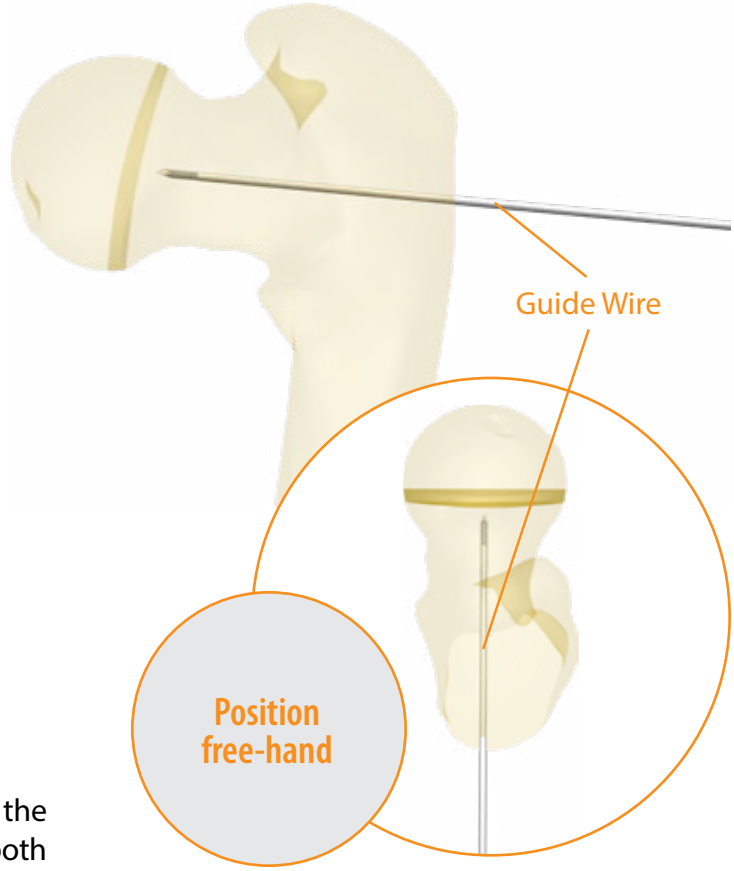
FREE-HAND METHOD

Insert the Guide Wire in the 1-1 position at the base of the greater trochanter and aligned with the femoral neck in both the AP and lateral planes.

Verify that the Guide Wire is centered in the femoral neck in both AP and lateral views.

⚠ **Ensure the Guide Wire has not been bent during insertion as this may lead to inadvertent advancement of the wire during Blade insertion.**

⚠ **To ensure that the Guide Wire is not bent unintentionally during manipulation of the limb, use the Blade Depth Ruler [POP-DPG100] over the wire as protection.**



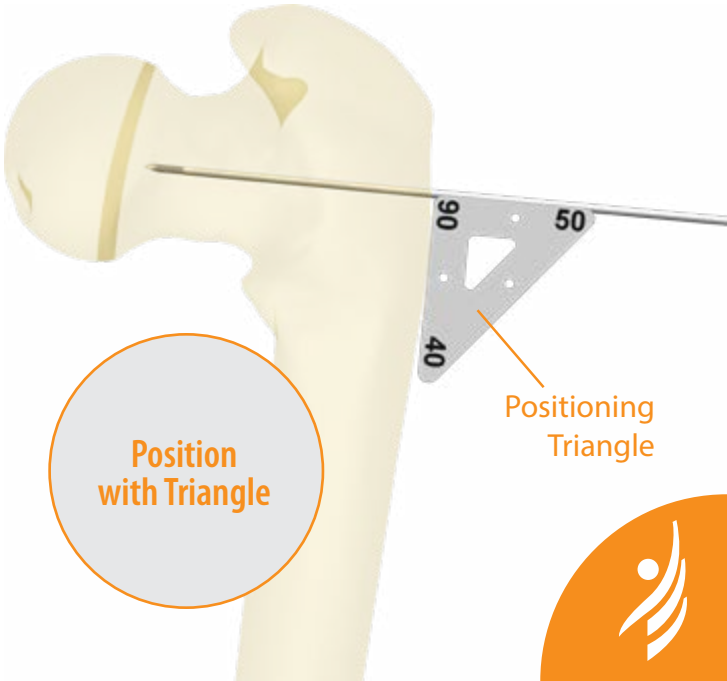
POSITIONING TRIANGLE METHOD

Insert the Guide Wire in the 1-1 position at the base of the greater trochanter and aligned with the femoral neck in both the AP and lateral planes.

Verify that the Guide Wire is be centered in the femoral neck in both AP and lateral views.

POSITIONING TRIANGLES	
CATALOG #	MEASURED ANGLES
POP-TRI100	80-70-30°
POP-TRI101	90-50-40°
POP-TRI102	100-60-20°
POP-TRI103	110-60-10°

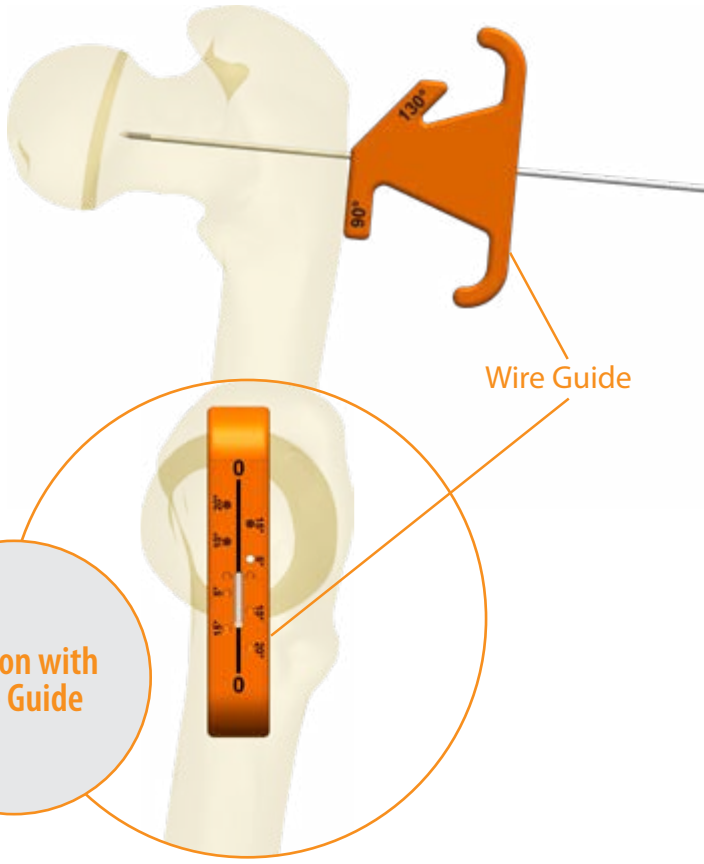
Forceps can be used in the holes of the triangles to hold them up against the cortex inside the incision.



WIRE GUIDE METHOD

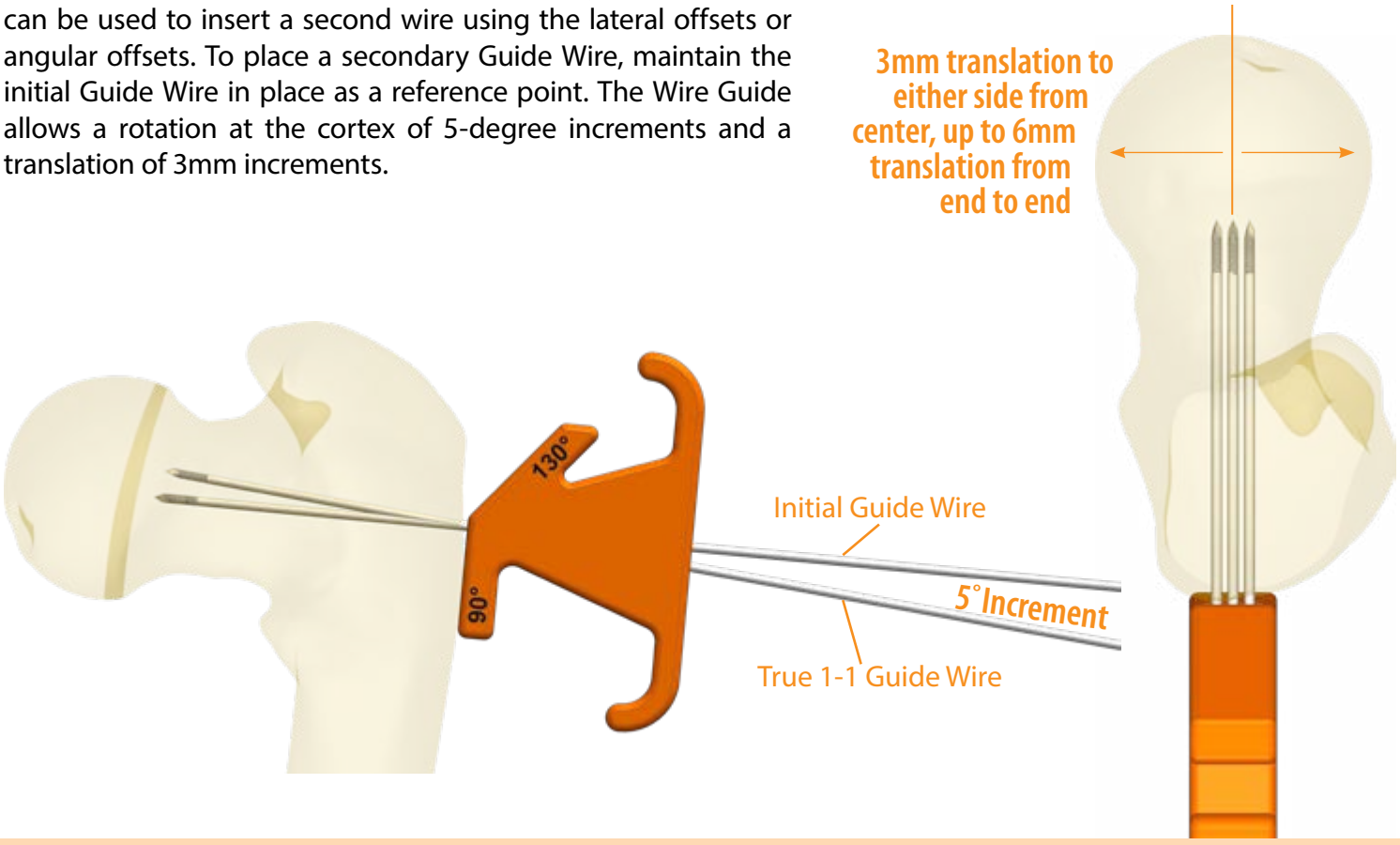
Insert the Guide Wire in the 1-1 position at the base of the greater trochanter and aligned with the femoral neck at the 0-0 position on the Wire Guide [POP-WGD100].

Verify that the Guide Wire is centered in the femoral neck in both AP and lateral views.



⚠ **Ensure that the Guide Wire has not been bent during insertion as this may cause advancement of the wire into the hip joint.**

If the position of the Guide Wire is not satisfactory, the Wire Guide can be used to insert a second wire using the lateral offsets or angular offsets. To place a secondary Guide Wire, maintain the initial Guide Wire in place as a reference point. The Wire Guide allows a rotation at the cortex of 5-degree increments and a translation of 3mm increments.

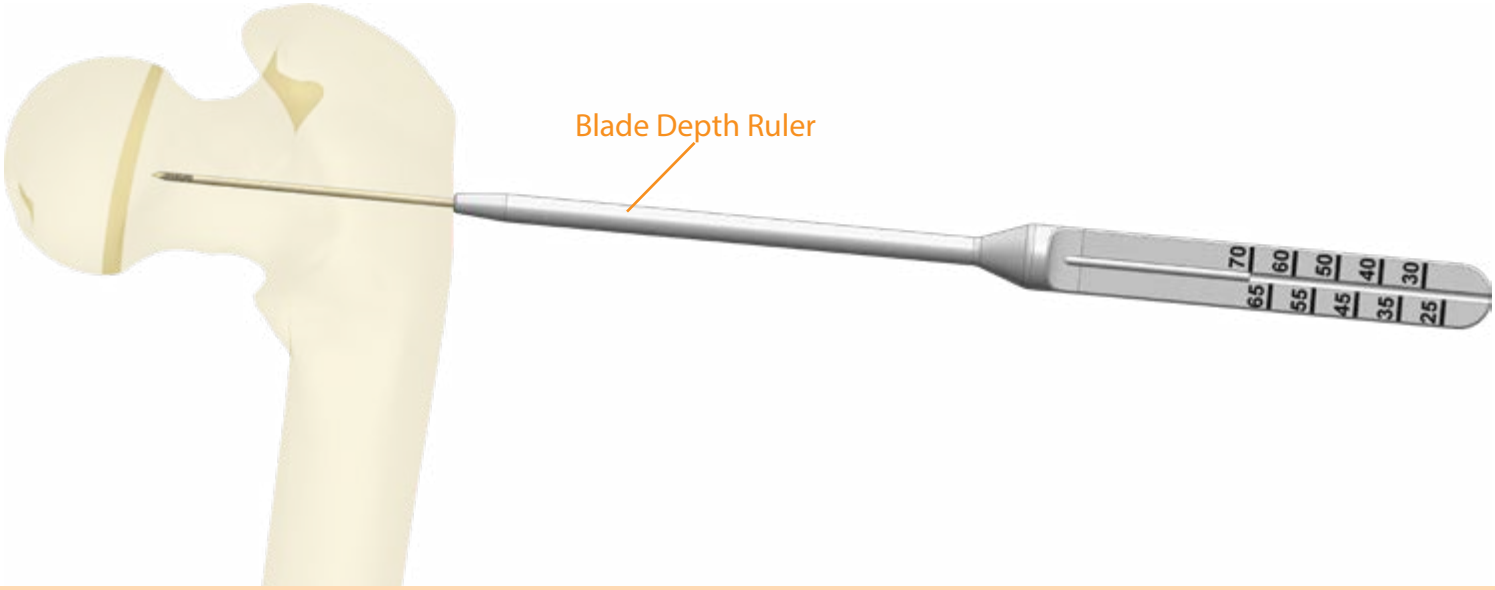


Confirm under C-arm that the position of the true 1-1 Guide Wire is as desired in both A/P and lateral planes, and **remove the initial Guide Wire.**

STEP 4

BLADE LENGTH MEASUREMENT

Measure the Blade length using the Blade Depth Ruler [POP-DPG100] over the Guide Wire.



The end of the Guide Wire allows reading the length of the recommended Blade directly off the Blade Depth Ruler.

If the measurement falls between two sizes, it is recommended to select the shorter size to prevent invasion of the physis.

STEP 5

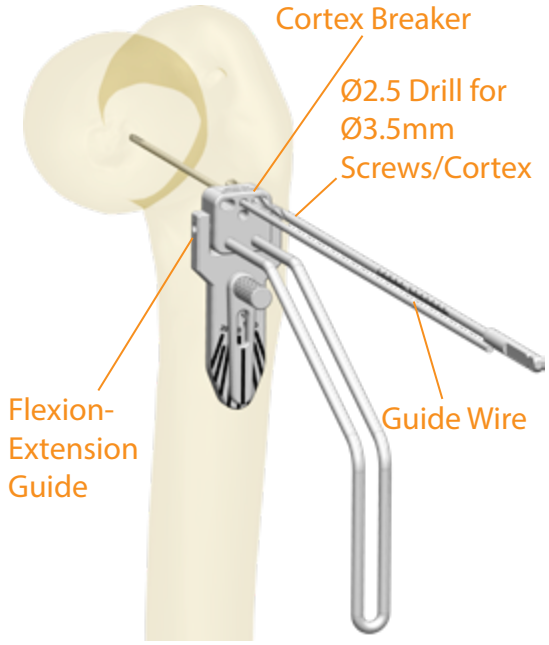
BREAKING THE CORTEX (OPTIONAL)

Use the Cortex Breaker [POP-CBK200] to drill out the cortex, approximately the first 10-15mm of bone, in order to facilitate Blade entry. This step is recommended in adolescent patients and patients with harder bone.

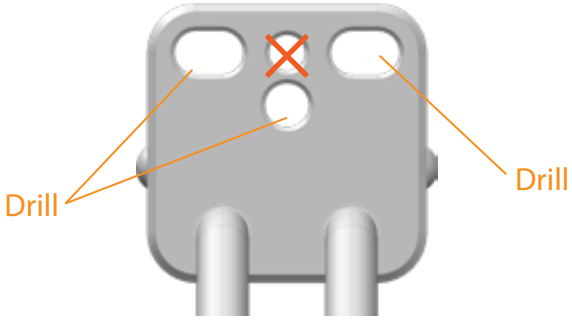
Clip the Flexion-Extension Guide [POP-FXG200] onto the Cortex Breaker.

Slide the Cortex Breaker over the Guide Wire until it lays against the lateral cortex.

Drill all the holes with the Drill marked "Ø2.5 DRILL FOR Ø3.5MM SCREWS/CORTEX" [POP-DCS135]



The Guide Wire is flexible enough to deviate out of the way of the Drill's chuck. Take care not to permanently bend the Guide Wire during this step.



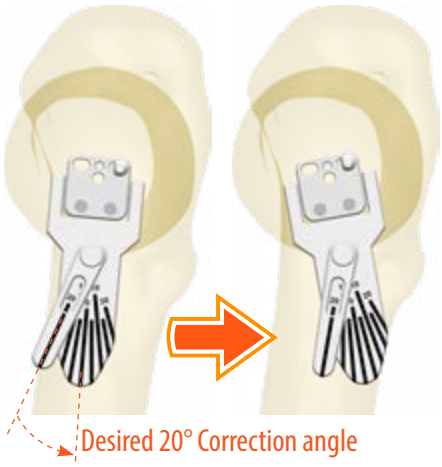
The center hole is for guidance over the Guide Wire, not for drilling. Ensure proper cortex breakage by drilling the whole slot.

The orientation of the Cortex Breaker determines the implant's orientation, and therefore the final flexion angle of the bone.

If no correction is needed, the Flexion-Extension Guide should be aligned with the femoral shaft.

If flexion/extension correction is required, place the dial of the Flexion-Extension Guide to the desired correction angle.

Rotate the Cortex Breaker around the Guide Wire until the dial of the Flexion-Extension Guide is aligned with the femoral shaft.



Drill all the holes with the drill marked "Ø2.5 DRILL FOR Ø3.5MM SCREWS/CORTEX" [POP-DCS135].

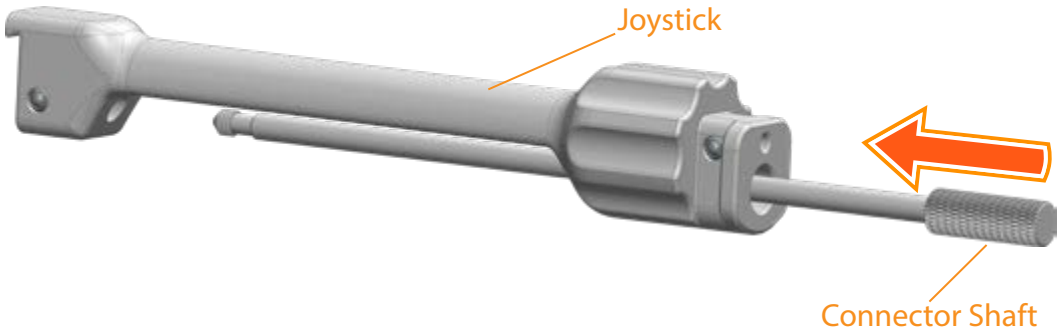
STEP 6

BLADE INSERTION

Select the Joystick and Connector Shaft corresponding to the Blade family in the table.

BLADE FAMILY	JOYSTICK	CONNECTOR SHAFT
Infant	POP-JSK200	POP-SFT200
Child	POP-JSK225	POP-SFT225
Adolescent HD Adolescent	POP-JSK250	POP-SFT250

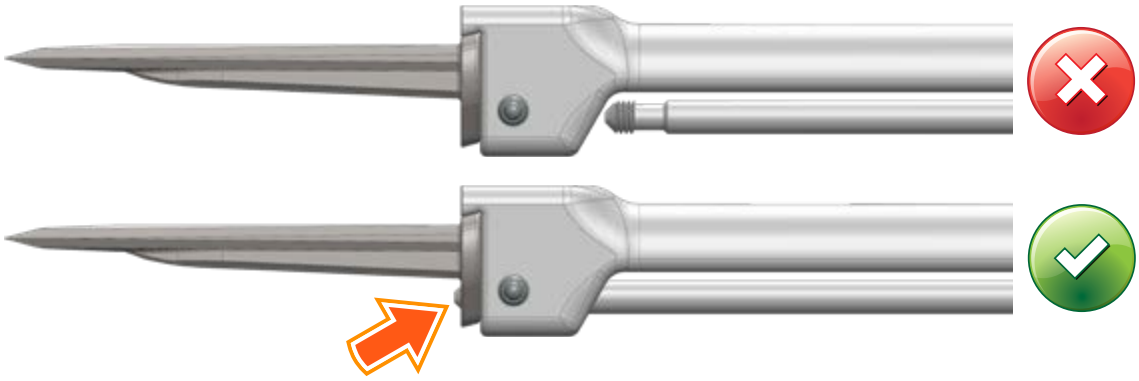
Slide the corresponding Connector Shaft through the Joystick.



Align and hold the Blade onto the Joystick while threading the Connector Shaft into the Blade with a clockwise rotation of the knob.

Always ensure proper contact between the Blade and the Joystick.

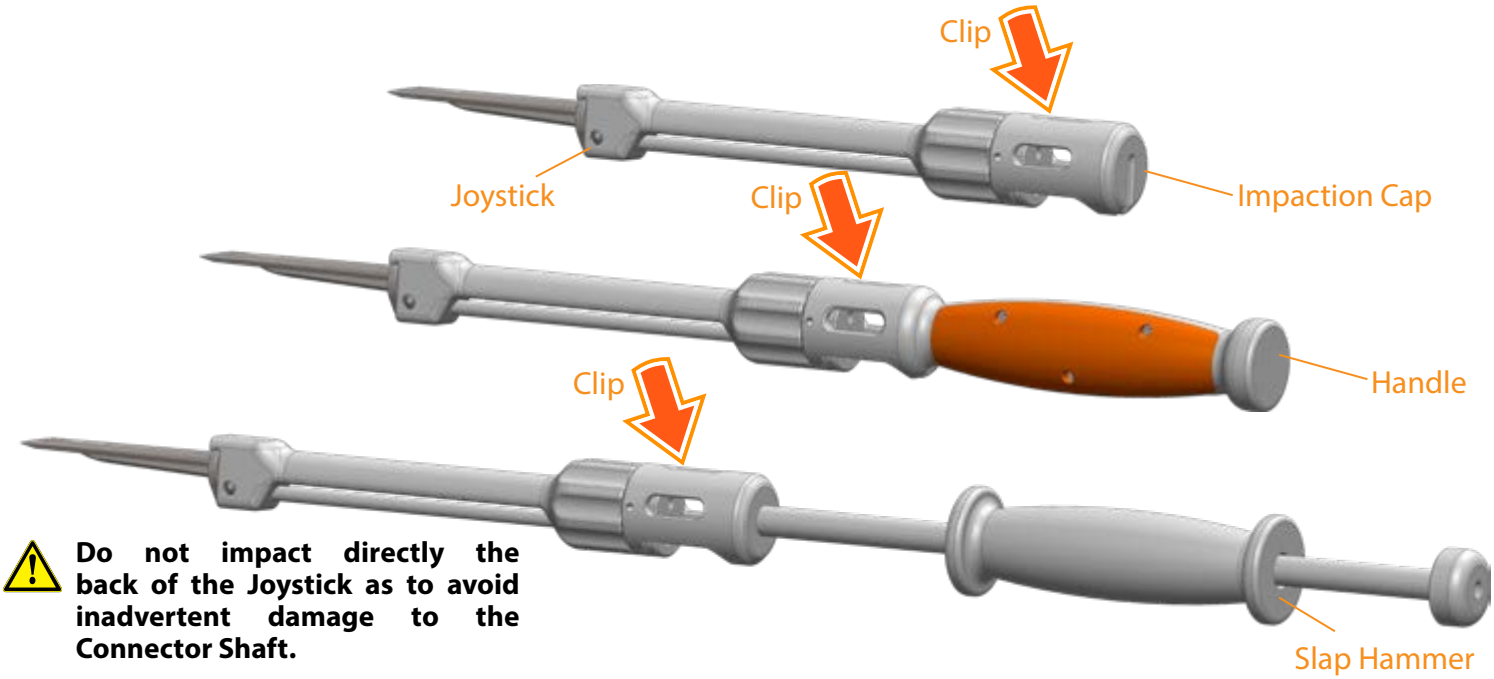
The Connector Shaft tip should be visible through the Blade when fully threaded.



Three options are available for impaction of the Blade into the bone: the Impaction Cap, the Handle or the Slap-Hammer.

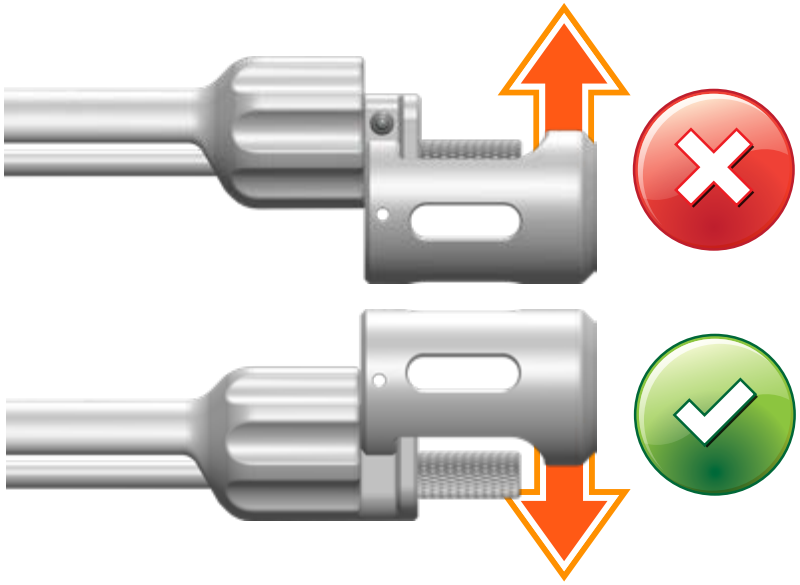
The Impaction Cap and the Handle provide a flat surface at the rear for impacting the Blade into the bone with any standard mallet (not provided) while protecting the connector shaft from unintentional damage. The Slap-Hammer allows impaction of the Blade in the axis of the assembly to avoid bending damage.

Clip the Impaction Cap [POP-CAP100], Handle [POP-HND200] or Slap-Hammer [POP-SLP100] onto the Joystick.

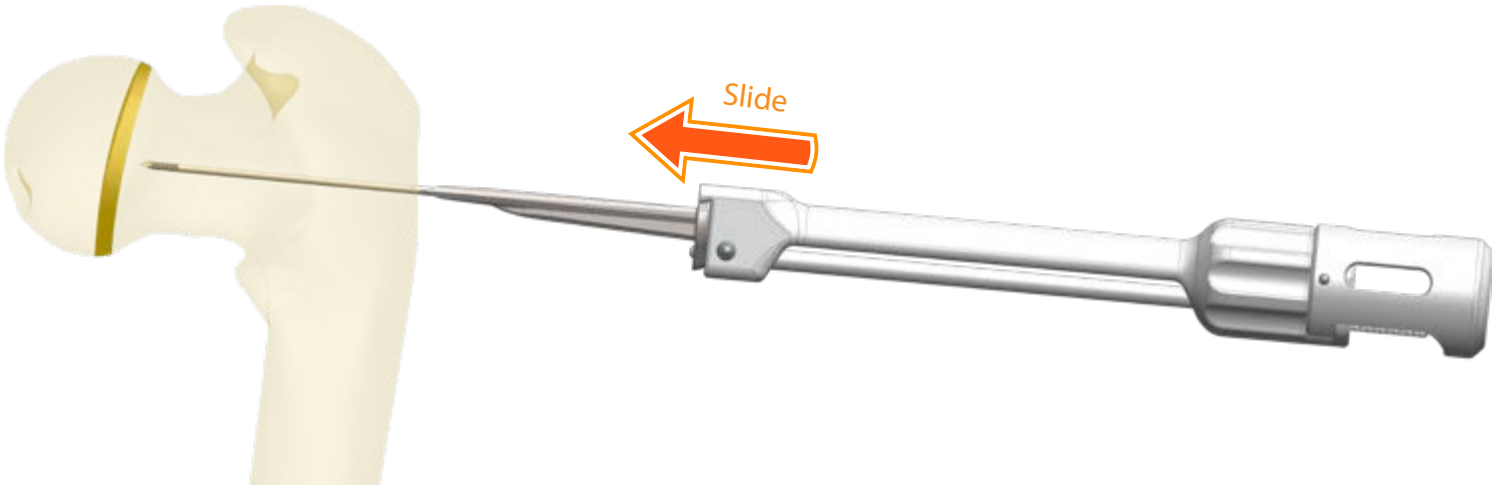


⚠ **Do not impact directly the back of the Joystick as to avoid inadvertent damage to the Connector Shaft.**

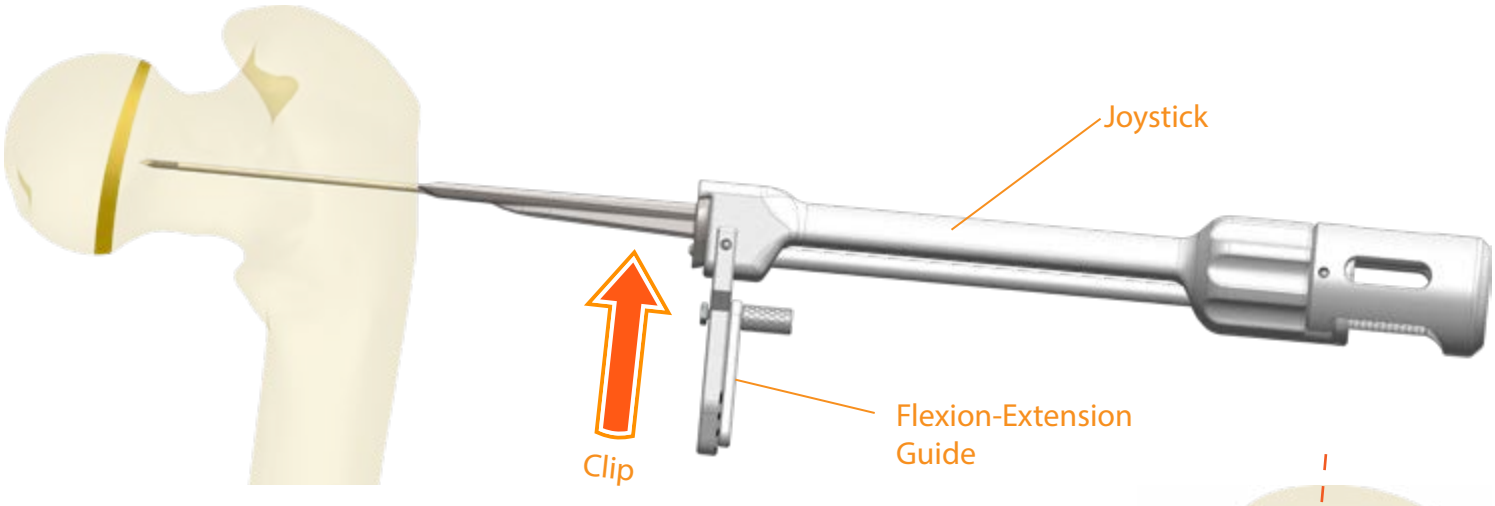
⚠ **Ensure that the Handle, Cap or Slap-Hammer are in the orientation shown for proper assembly/disassembly.**



Slide the Blade and Joystick assembly over the Guide Wire up to the lateral cortex.



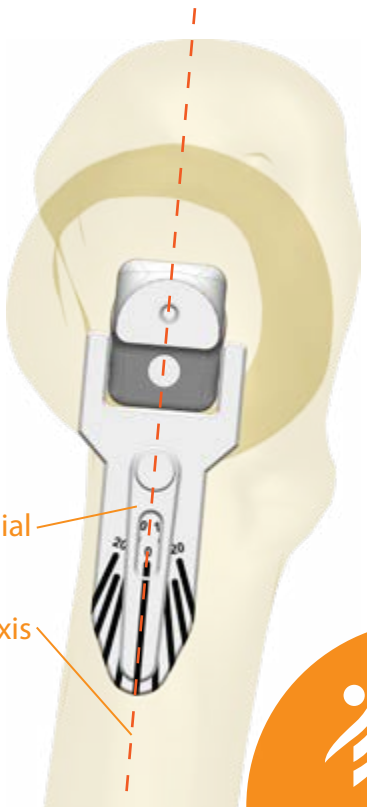
Clip the Flexion-Extension Guide onto the Joystick to confirm the orientation of the Blade before insertion.



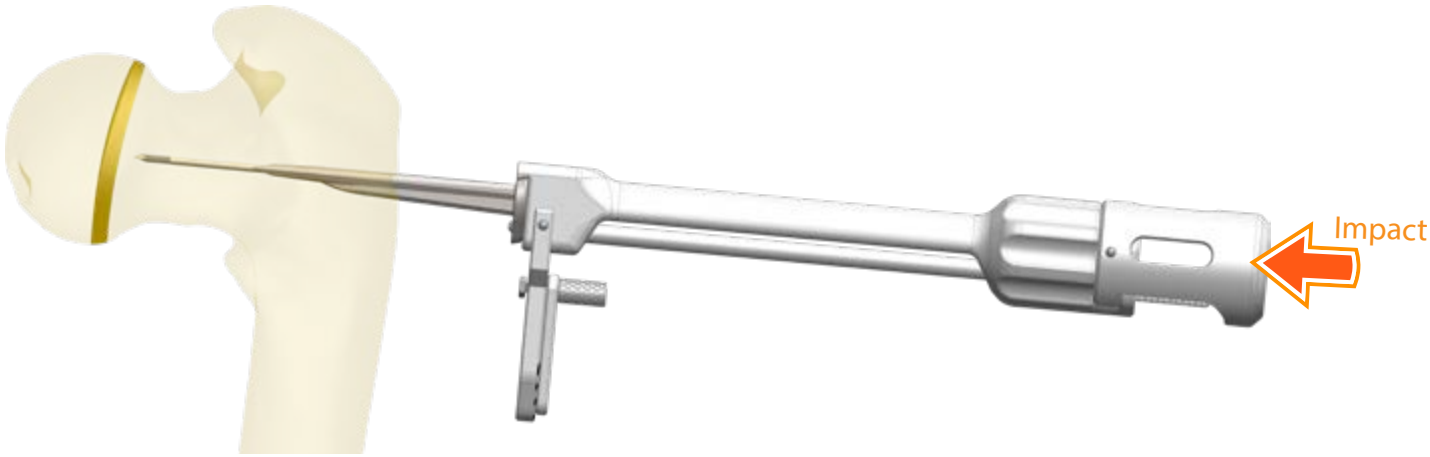
Place the dial of the Flexion-Extension Guide to the desired correction angle, or if previously done to the angle used during cortex breaking.

Drive the Blade by impacting the back end of the Impaction Cap or Handle with a standard mallet (not provided) or directly with the Slap-Hammer.

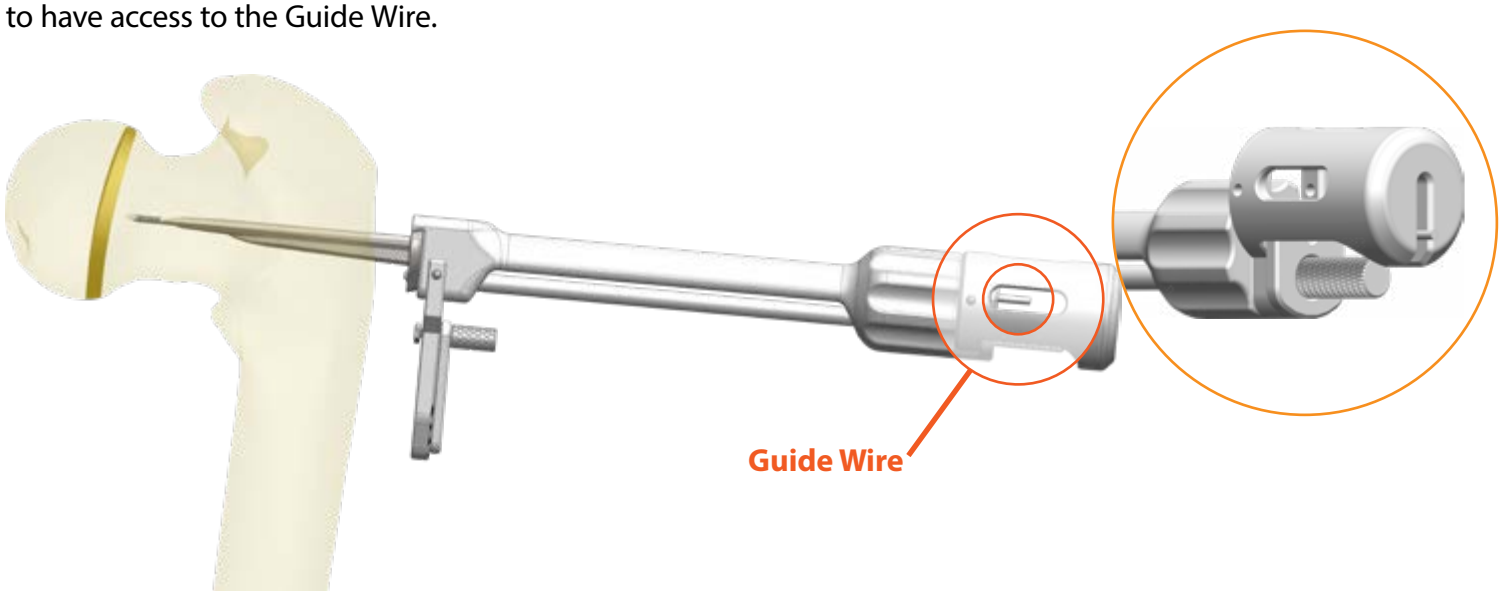
Ensure that the insertion vector remains aligned with the Guide Wire in order to avoid bending or other damage to the Guide Wire.



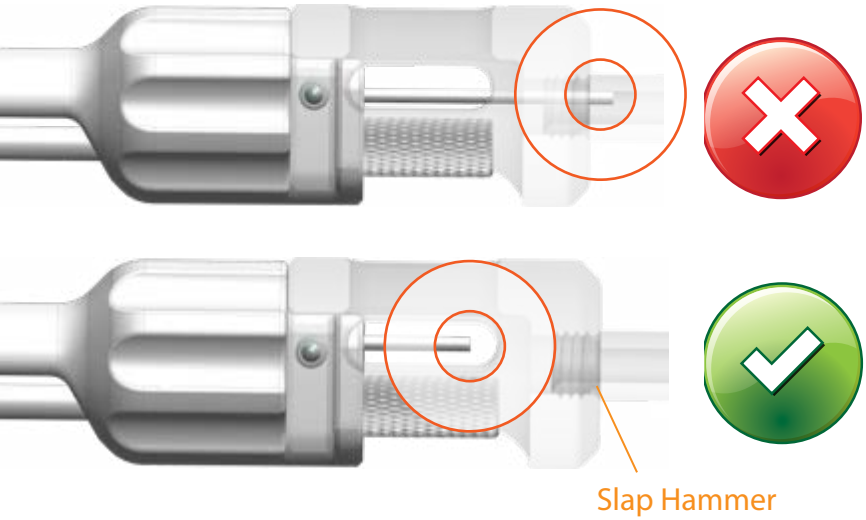
⚠ **Always advance the Blade under fluoroscopy to ensure proper placement and to prevent unintentional Guide Wire advancement.**



When impacting the Blade into the bone, the Guide Wire will become visible through the slot in the Handle or Impaction Cap. At this point, the Guide Wire can be removed if desired; simply unclip the Handle or Impaction Cap to have access to the Guide Wire.



⚠ **The Guide Wire can be removed, if desired, once placement of the Blade is confirmed. However, using the Guide Wire for the next steps will ease alignment of the instruments onto the Blade.**



⚠ **The Slap-Hammer cannot be unclipped from the Joystick when the Guide Wire has advanced into the shaft. The Guide Wire must be removed when the tip is still visible in the window.**

Continue impaction of the Blade until it protrudes 5-10mm from the lateral cortex to ease assembly with the Plate.

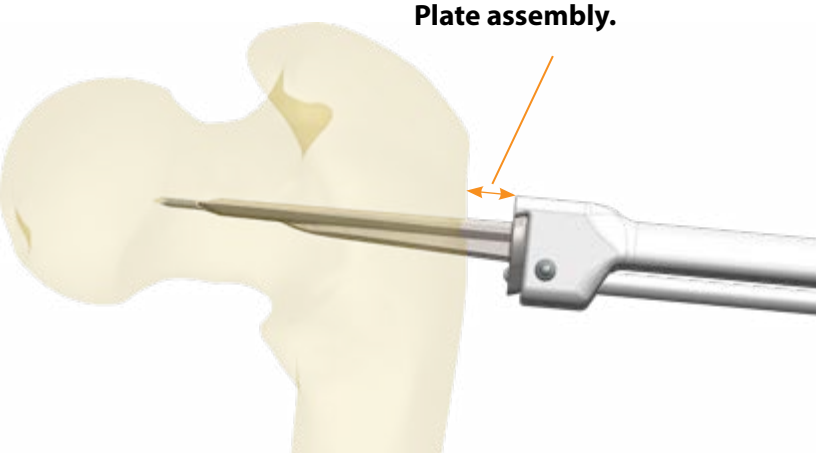
The Flexion-Extension Guide can be unclipped from the Joystick at any time after the blade has started to purchase sufficiently in the bone.

The Blade-Plate assembly will be impacted to its final position against the cortex in STEP 10.

Confirm proper Blade placement under C-arm visualisation before moving on to the next steps.

Remove the Impaction Cap, Handle or Slap-Hammer from the Joystick.

Allow Blade to protrude 10mm from cortex for Plate assembly.



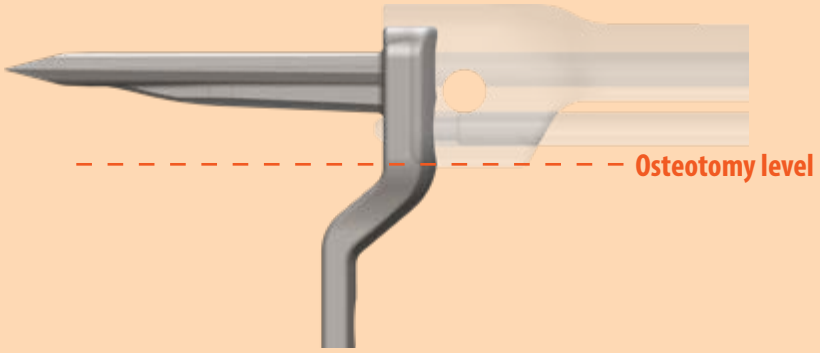
Do not unthread the Connector Shaft; the Joystick should be kept in place for osteotomy preparation and easier manipulation during the next steps.

STEP 7

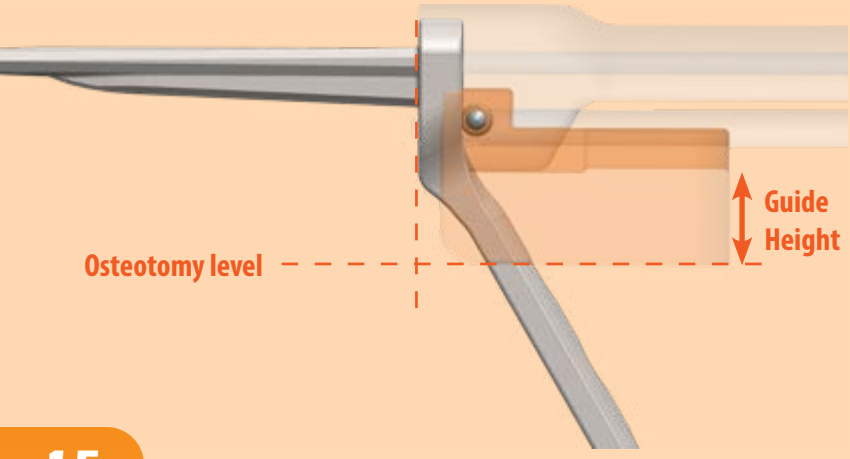
OSTEOTOMY & ANGLE CORRECTION

Before performing the osteotomy, it is recommended to either score the bone or insert two Guide Wires, above and below the osteotomy level in order to retain a rotational reference of the proximal and distal segments of the femur after the osteotomy.

The Joystick's tips have been designed with a square bottom to match the osteotomy level suggested for the **varus Plates**.



When using a **valgus Plate**, the following Osteotomy Guides are provided in the set to optimize osteotomy height.

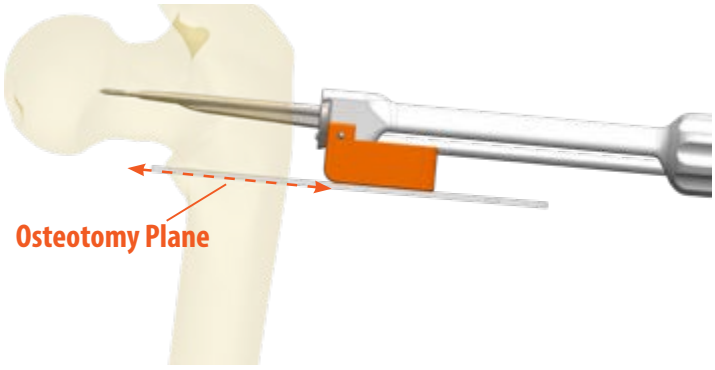


IMPLANT FAMILY	OSTEOTOMY GUIDE FOR VALGUS PLATE	GUIDE HEIGHT (mm)
Infant	POP-OTG200	7
Child	POP-OTG201	9
Adolescent	POP-OTG202	10
HD Adolescent	POP-OTG203	13

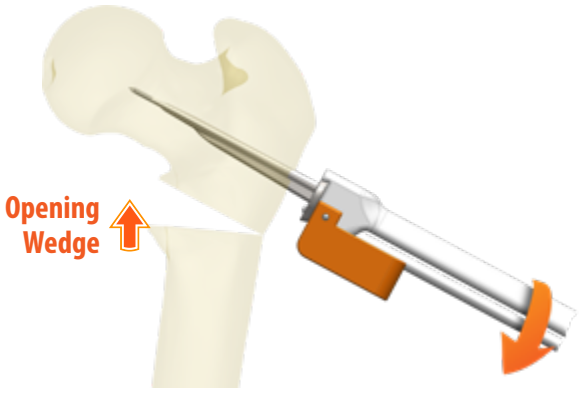
VALGUS CORRECTIONS

Opening Wedge Osteotomy

For Valgus correction of a Coxa Vara, perform the osteotomy cut, parallel to the clipped-on Osteotomy Guide, exercising the proper degree of caution to prevent saw incursion into the femoral neck.



Using the Joystick as a lever, carefully tilt the proximal bone fragment away from the distal femoral bone, to verify the desired position.

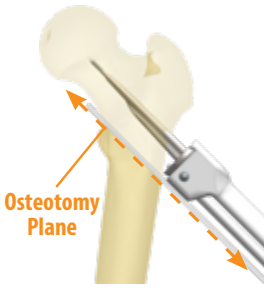


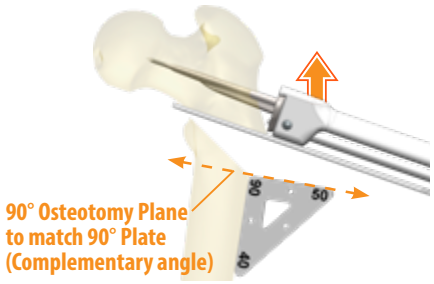
VARUS CORRECTIONS

Closing Wedge Osteotomy

For Varus correction of a Coxa Valga, perform a first osteotomy cut, parallel to the Joystick surface, exercising the proper degree of caution to prevent saw incursion into the femoral neck.

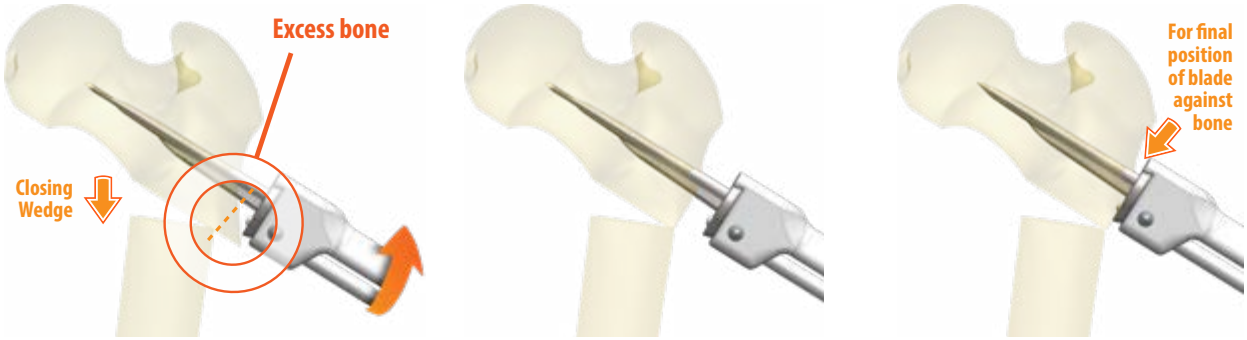
⚠ **Before Proceeding to the secondary osteotomy, it is advisable to place the segments approximately in their final orientations to check the NSA and confirm the angle of the plate desired.**





Using the Joystick as a lever, carefully tilt the proximal bone fragment away for the osteotomy level. Perform a second osteotomy at the same starting point on the lateral cortex, in the angle of the Plate chosen, guided by the Positioning Triangles.

Remove any overlapping or **excess bone** in the area of the Plate's transition.



Using the Joystick as a lever, carefully tilt the proximal bone fragment towards the distal proximal bone, to verify the desired position.

Note: If shortening is necessary, an additional cut can be done to the femoral shaft. The Positioning Triangles can be used to obtain a desired osteotomy surface.

STEP 8

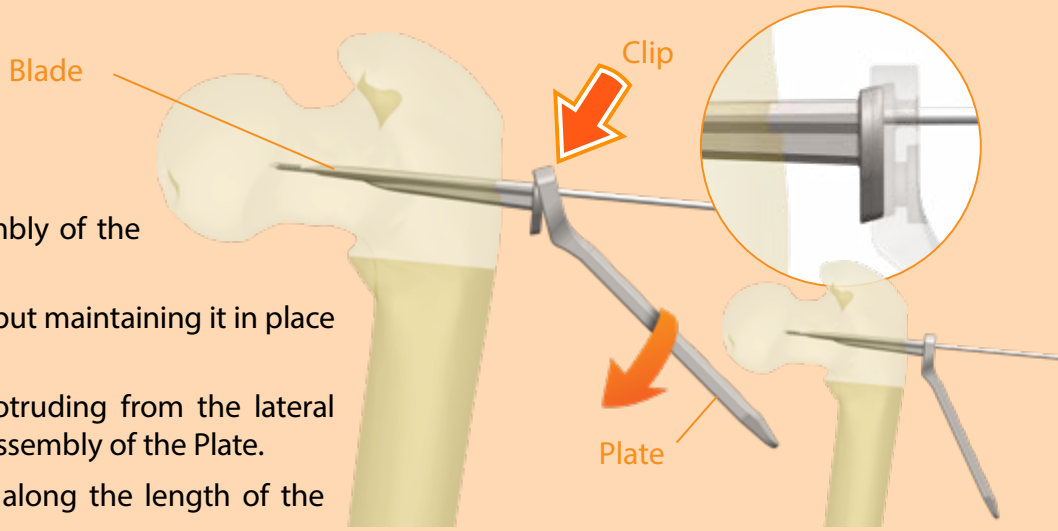


PLATE ASSEMBLY

Remove all instrumentation for assembly of the Plate onto the Blade.

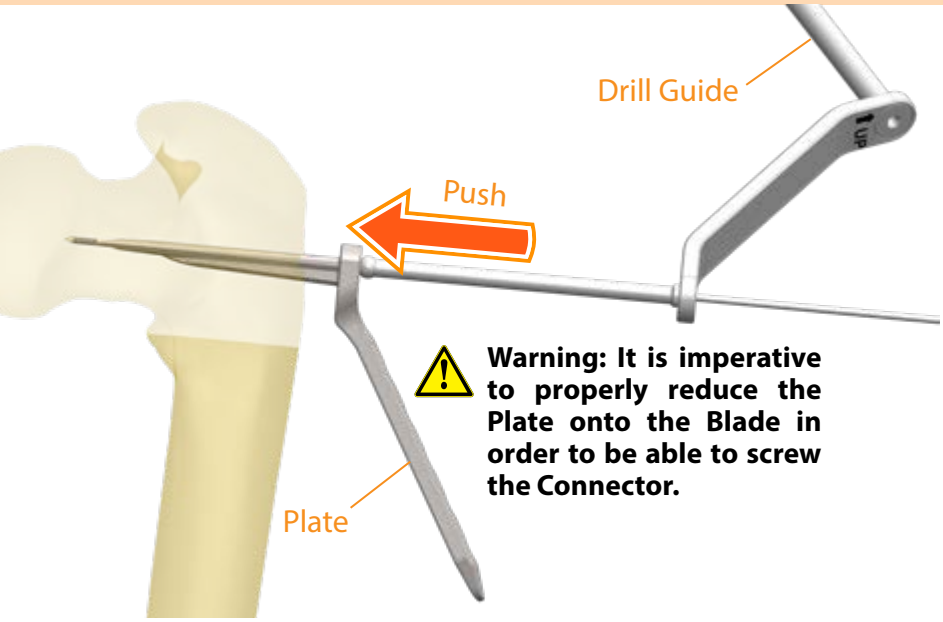
The Guide Wire can also be removed, but maintaining it in place will aid with assembly of the Plate.

The Blade should have been left protruding from the lateral cortex, in the previous steps, to ease assembly of the Plate.

Insert the Plate through the incision along the length of the shaft.

Manually hook the Plate onto the Blade.

Ensure full contact between the Blade and the Plate at the connection section.



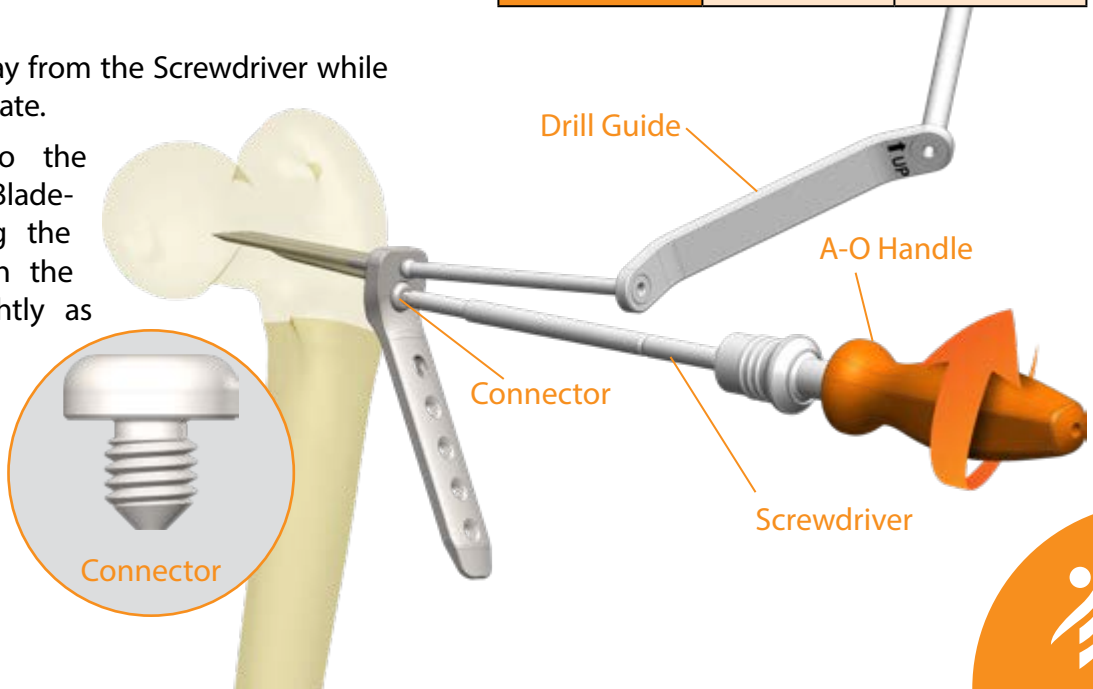
Warning: It is imperative to properly reduce the Plate onto the Blade in order to be able to screw the Connector.

The Drill Guides [POP-OBL200, POP-OBL225, POP-OBL250] can be used, over the Guide Wire if still in place, or directly in the Guide Wire hole of the Plate, to push the Plate against the Blade for maximum contact and ease the threading of the Connector Screw in the next step.

BLADE FAMILY	SCREWDRIVER	CONNECTOR
Infant	GIN-SDR250	POP-M3I
Child	GIN-SDR250	POP-M4C
Adolescent HD Adolescent	GIN-SDR350	POP-M5A

Slightly tilt the Drill Guide away from the Screwdriver while maintaining pressure on the Plate.

Attach the A-O Handle to the Screwdriver and lock the Blade-Plate assembly by threading the Connector clockwise through the Plate into the Blade as tightly as possible.



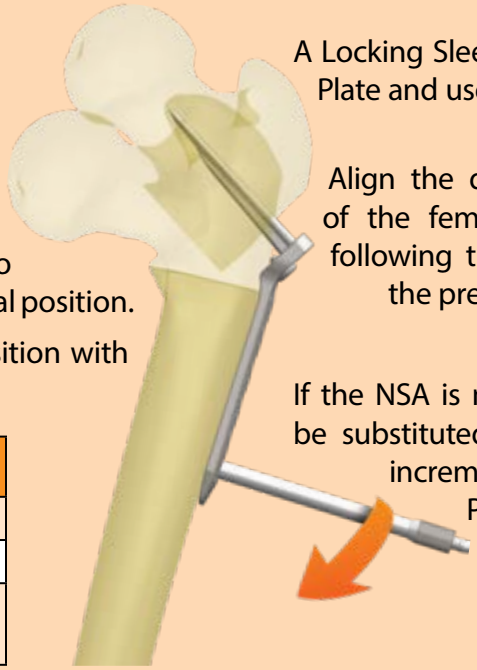
STEP 9

NSA VALIDATION

At this point, it is recommended to validate the NSA using the C-arm before proceeding to impaction of the Blade/Plate assembly into its final position.

Reduce the femoral shaft and maintain the position with the Verbrugge of appropriate size.

BLADE FAMILY	VERBRUGGE	LOCKING SLEEVE
Infant	POP-VBI100	POP-SLV127
Child	POP-VBC125	POP-SLV135
Adolescent HD Adolescent	POP-VBA150	POP-SLV145



A Locking Sleeve can be threaded into the Plate and used to aid manipulation of the implant and proximal femur.

Align the distal and proximal sections of the femur to the initial alignment following the marking on the bone or the previously inserted Guide Wires.

Validate in all required views.

If the NSA is not as desired, the Plate can be substituted to adjust by ±10 degrees increments. However, the type of Plate is not interchangeable; a Varus Plate can not be substituted by a Valgus Plate.

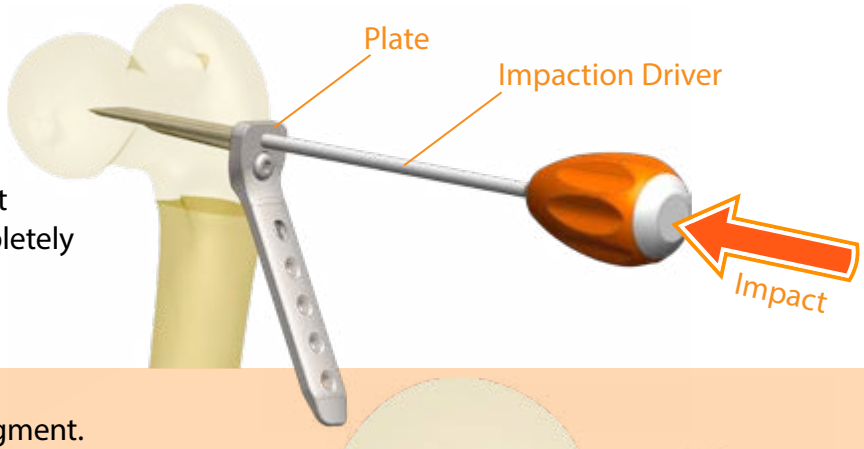
⚠ **Adjusting the osteotomy level might be required when substituting the Plates.**

Substituting the Plates may generate a gap between the fragments when practicing a closing wedge-osteotomy as the second cut corresponds to the plate initially chosen. The wedge of bone removed during the osteotomy can be morselized to fill any gaps caused by a change of Plate angle.

STEP 10

FINAL POSITION OF THE ASSEMBLY

Once the NSA is confirmed, obtain the final position of the implant by impacting directly the back end of the Impaction Driver with a mallet (not provided) until the assembly is resting completely against the lateral cortex.

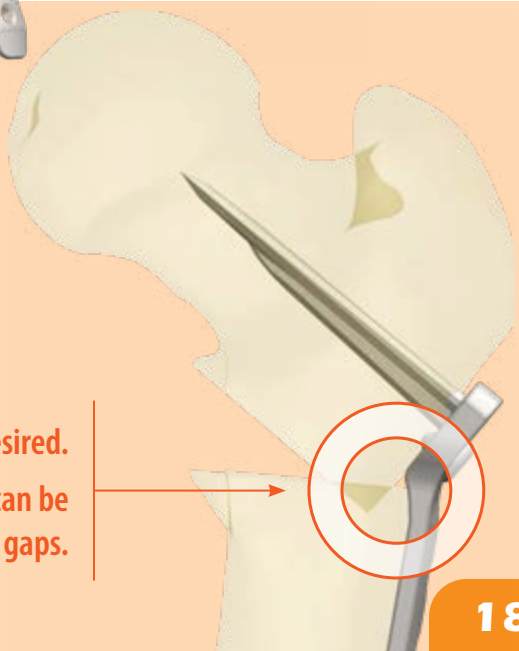


Using the forceps, reduce the proximal femoral fragment.

Align the distal and proximal sections of the femur to the initial alignment following the markings on the bone or the previously inserted Guide Wires.

Ensure contact between the proximal and distal segments. Maintain the position with the Verbrugge of appropriate size.

Validate the final position of the Plate under C-arm.



Adjust the mating surfaces if desired.

The wedges of bone removed during the osteotomy can be morselized to fill any gaps.

Continue to STEP 12 for osteotomy compression screw placement.

If compression is not desired, continue to STEP 13 for locking screw placement and STEP 14 for polyaxial screw placement.

STEP 11 describes the optional process for rotation/derotation correction. When rotation/derotation correction is required, it is recommended to not proceed to compression screw placement. Placing the compression screw first will not allow realignment of the bone segments to the desired correction angle.

STEP 11

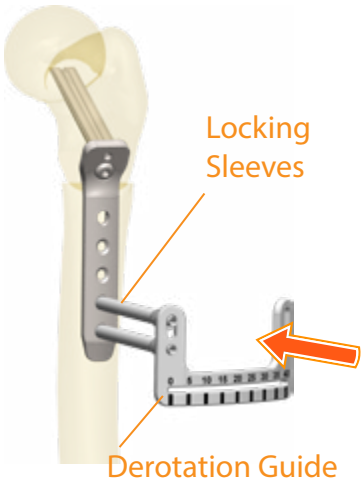
DEROTATION (OPTIONAL)

If compression across the osteotomy is desired, use the Drill Guides according to step 12 after obtaining the desired angle.
Select the Locking Sleeve in the table according to the size of the Plate family:

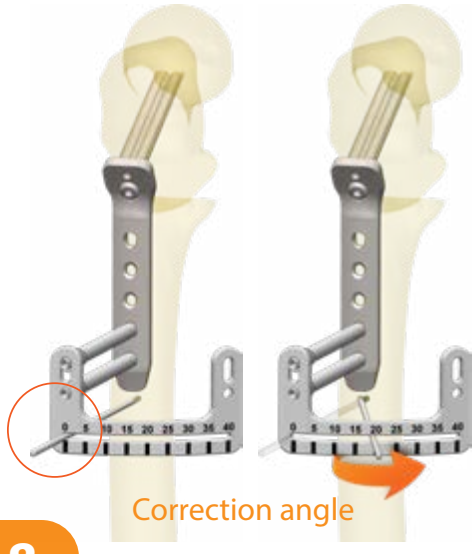
PLATE FAMILY	LOCKING SLEEVE
Infant	POP-SLV127
Child	POP-SLV135
Adolescent HD Adolescent	POP-SLV145

Thread the Locking Sleeves clockwise into the two most distal adjacent holes of the Plate.

Clip the Derotation Guide [POP-DRG100] onto the Locking Sleeves in the appropriate orientation (left or right depending on the correction orientation).



Ensure the distal and proximal sections of the femur are aligned with the marking on the bone or the previously inserted Guide Wires, then clamp the Plate to the bone with the appropriately sized Verbrugge at the level of the most proximal hole.



Insert the provided Ø2.8mm Derotation Pin 10mm into the bone corresponding to the length of the thread of the Guide Wire, at the 0-0 position on the Derotation Guide.

Release the Verbrugge and rotate the distal shaft to the desired correction angle.

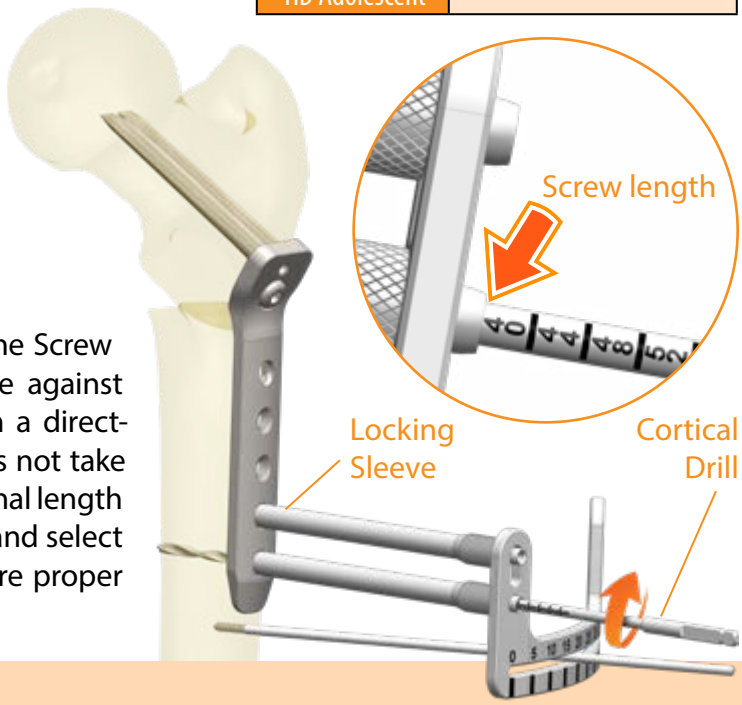
Verify the relative positions of the segments and re-clamp the Plate with the Verbrugge for drilling of the Screw holes.

PLATE FAMILY	VERBRUGGE
Infant	POP-VBI100
Child	POP-VBC125
Adolescent HD Adolescent	POP-VBA150

Select the appropriate Cortical Drill in the table below according to the size of the Plate.

PLATE FAMILY	CORTICAL DRILL
Infant	POP-DCS127
Child	POP-DCS135
Adolescent HD Adolescent	POP-DCS145

Starting with the most distal Locking Sleeve, drill through both cortices and note the depth indicated by the marking on the drill to select the proper Cortical Screw. Once the first hole is drilled, keep the Verbrugge in place, but remove the Derotation Guide, the Ø2.8mm Derotation Pin and the most distal Locking Sleeve.



⚠ **If resistance is felt during drilling, back-out the Cortical Drill and clean out the flutes.**

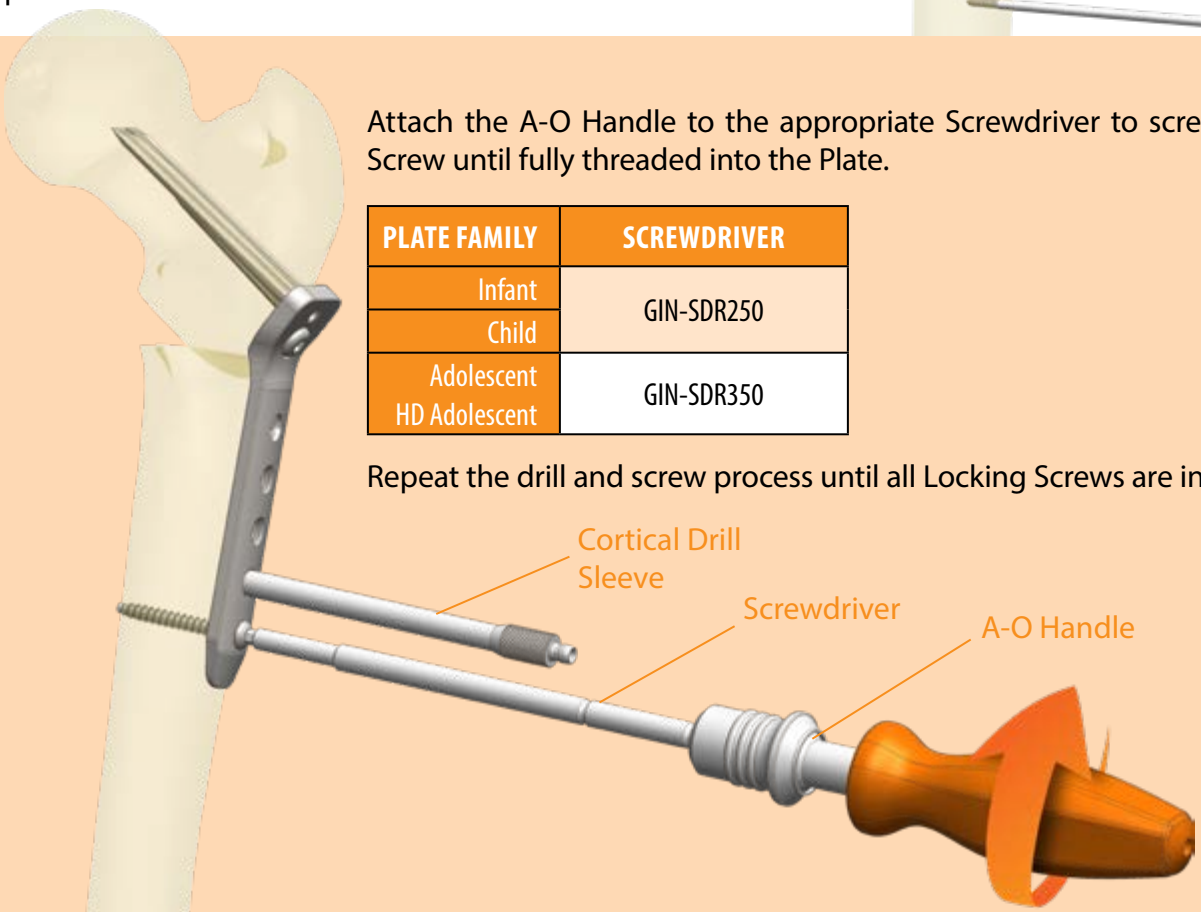
Remove the Locking Sleeve when drilling is complete.

The Screw length required can also be measured with the Screw Depth Gage [GIN-DPG200]. Place the Depth Gage nose against the Plate and use the hook on the far cortex to obtain a direct-measurement of the hole depth. This measurement does not take into account the height of the Screw head. To obtain the final length of Screw required, add 3mm to the direct measurement and select the longest Screw available closest to this value to ensure proper purchase in both cortices.

Attach the A-O Handle to the appropriate Screwdriver to screw in the first Locking Screw until fully threaded into the Plate.

PLATE FAMILY	SCREWDRIVER
Infant Child	GIN-SDR250
Adolescent HD Adolescent	GIN-SDR350

Repeat the drill and screw process until all Locking Screws are inserted.



⚠ **If resistance is felt during threading of the Locking Screws, ensure that bone debris were not introduced into the threads of the Plate, causing the harder advancement of the Screw.**

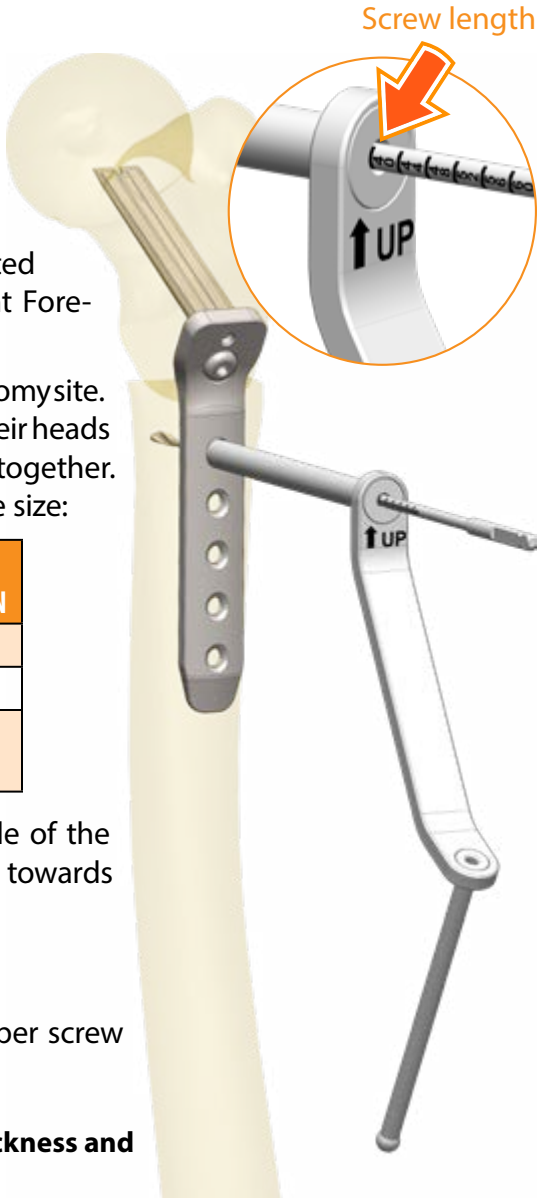
STEP 12

OSTEOTOMY COMPRESSION (OPTIONAL)

When compression of the two segments is desired, the following steps should be completed first using a Polyaxial Compression Screw inserted perpendicular to the shaft (90°position). Alternatively, the Point-to-Point Forceps can be used to compress both segments.

This method can achieve up to **1mm** of compression at the fracture or osteotomy site. As the eccentrically placed Polyaxial Compression Screws are tightened, their heads move down the ramp in the Plate and the bone segments are compressed together. Select the appropriate Drill Guide and Cortical Drill according to the Plate size:

PLATE FAMILY	DRILL GUIDE	CORTICAL DRILL	SCREWDRIVER	POLYAXIAL COMPRESSION
Infant	POP-OBL200	POP-DCS127	GIN-SDR250	Ø2.7mm screw
Child	POP-OBL225	POP-DCS135	GIN-SDR250	Ø3.5mm screw
Adolescent HD Adolescent	POP-OBL250	POP-DCS145	GIN-SDR350	Ø4.5mm screw



Place the compression sleeve of the Drill Guide in the compression hole of the Plate (most proximal hole along the shaft) with the "UP" arrow pointing towards the Blade and proximal femoral head.

⚠ **Verify version before screw insertion.**

Drill through both cortices. Note the depth of drilling to select the proper screw length.

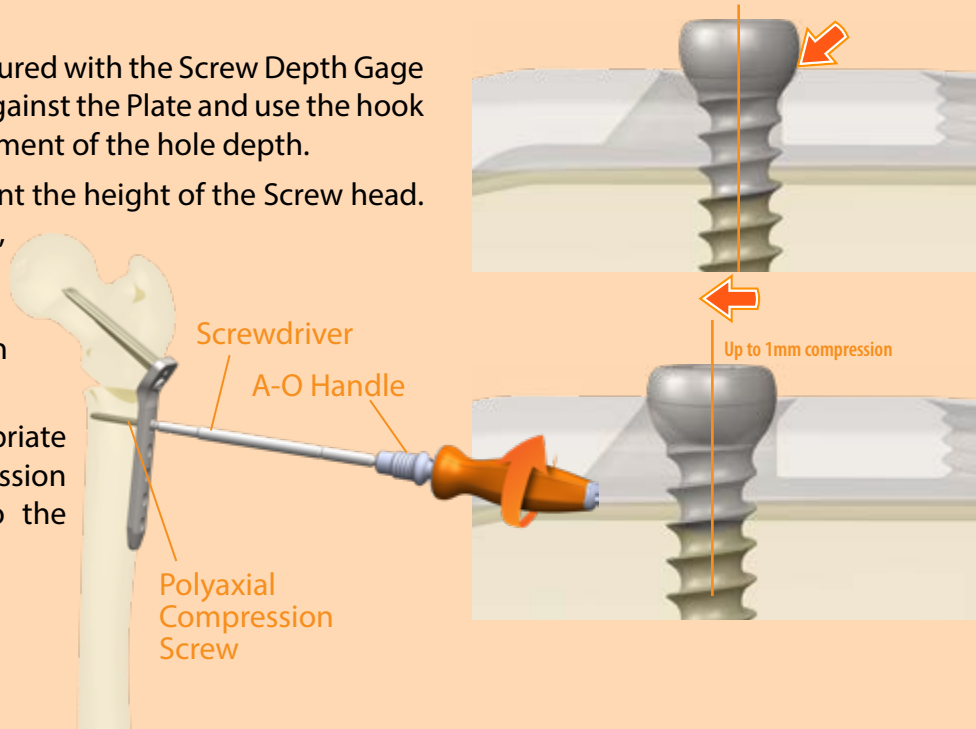
⚠ **The value read on the Cortical Drills takes into account the Plate thickness and height of the Screw head.**

Remove the Drill Guide

The Screw length required can also be-measured with the Screw Depth Gage [GIN-DPG200]. Place the Depth Gage nose against the Plate and use the hook on the far cortex to obtain a direct-measurement of the hole depth.

This measurement does not take into account the height of the Screw head. To obtain the final length of Screw required, add 2-3mm to the direct measurement and select the longest Screw available closest to this value to ensure proper purchase in both cortices.

Attach the A-O Handle to the appropriate Screwdriver, screw in the Polyaxial Compression Screw clockwise until fully threaded into the Bone.



STEP 13

LOCKING SCREW INSERTION

Locking and non-locking screws are available for shaft screw placement.

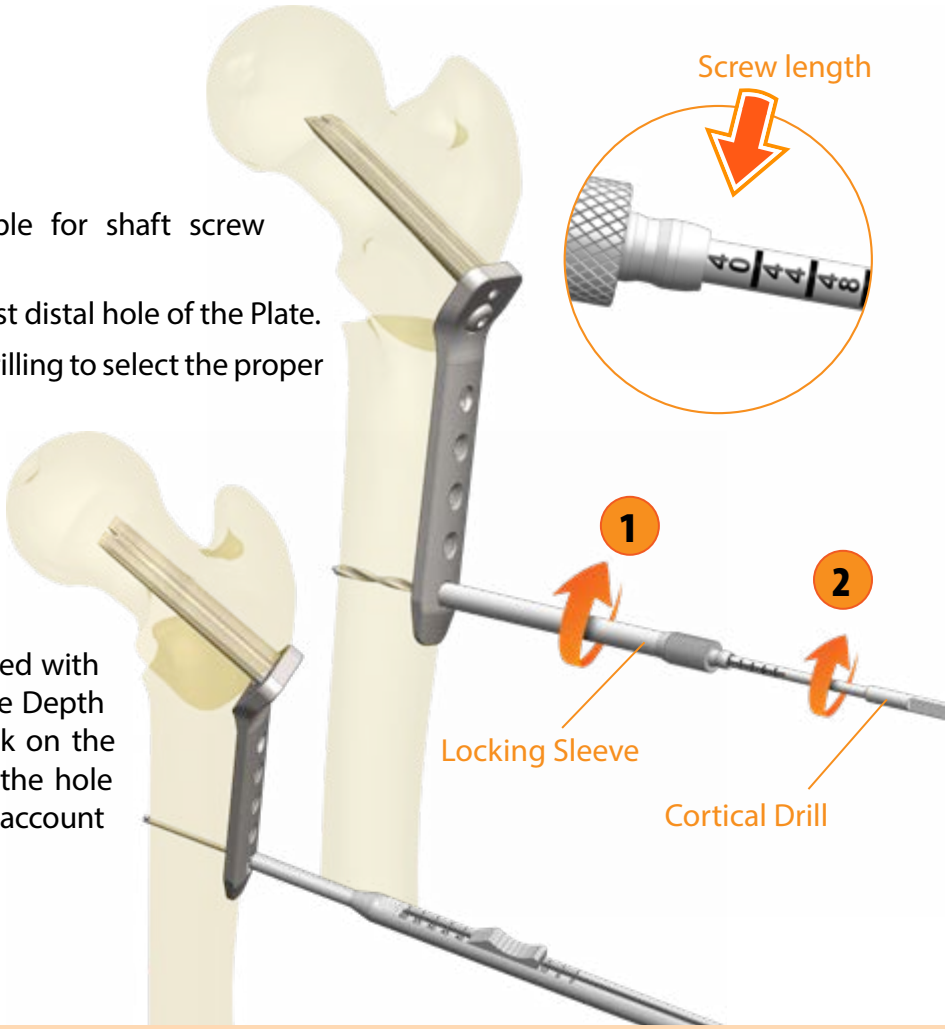
Thread a Locking Sleeve clockwise into the most distal hole of the Plate.

Drill through both cortices. Note the depth of drilling to select the proper screw length.

⚠ The value read on the Cortical Drills takes into account the Plate thickness and height of the Screw head.

Remove the Locking Sleeve.

The Screw length required can also be measured with the Screw Depth Gage [GIN-DPG200]. Place the Depth Gage nose against the Plate and use the hook on the far cortex to obtain a direct-measurement of the hole depth. This measurement does not take into account the height of the Screw head.

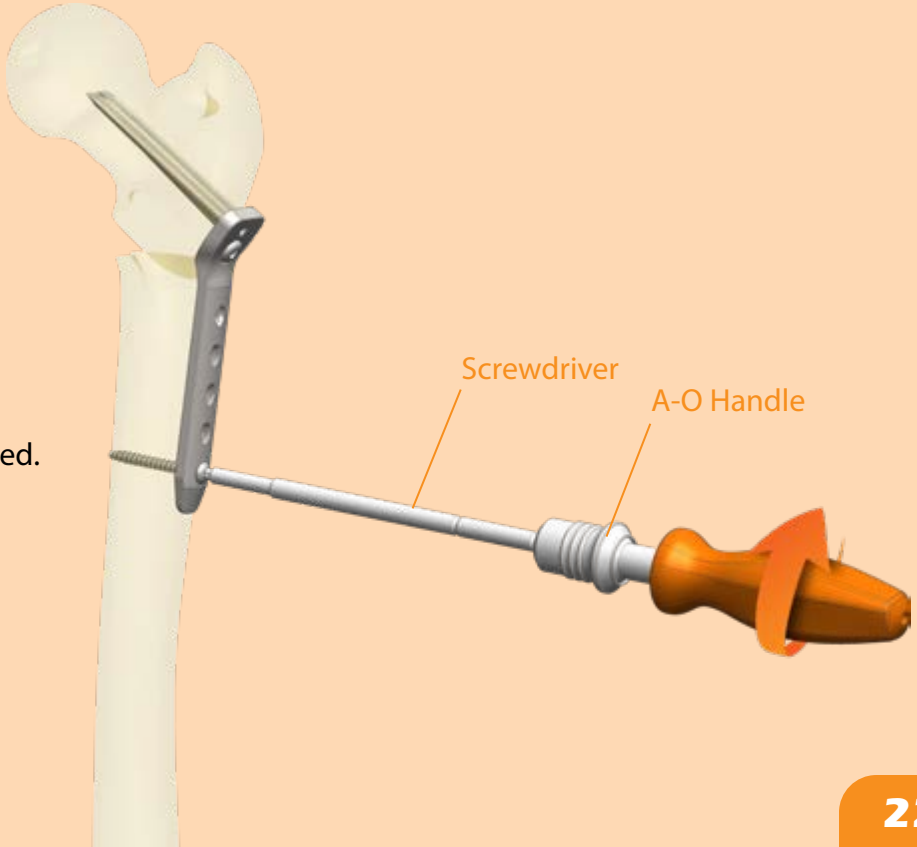


When using the screw depth gage, add 2-3mm to the direct measurement.

Attach the A-O Handle to the appropriate Screwdriver, screw in the first screw clockwise until fully threaded into the Plate.

PLATE FAMILY	SCREWDRIVER
Infant	GIN-SDR250
Child	
Adolescent HD Adolescent	GIN-SDR350

Repeat the process until all screws are inserted.



STEP 14

OBLIQUE SCREW INSERTION

An oblique screw can be inserted in order to cross the osteotomy and fix the two segments together. The Compression Screw should reach the proximal bone segment, but avoid contact with the Blade.

Select the Drill Guide and Cortical Drill according to the Plate family.

PLATE FAMILY	DRILL GUIDE	CORTICAL DRILL
Infant	POP-OBL200	POP-DCS124
Child	POP-OBL225	POP-DCS135
Adolescent HD Adolescent	POP-OBL250	POP-DCS145

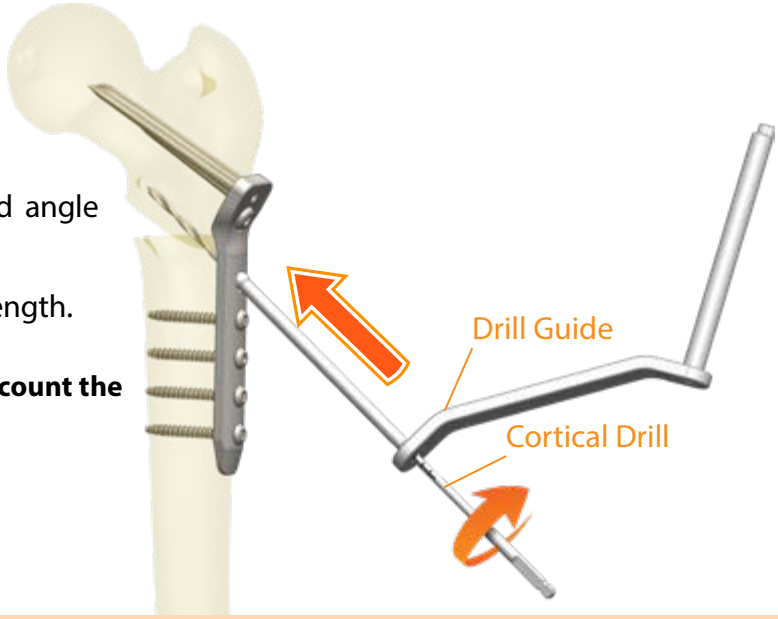
Hold the polyaxial sleeve of the Drill Guide inside the Polaxial Compression Screw hole of the Plate.

Drill a hole using the appropriate Drill in the desired angle though both cortices.

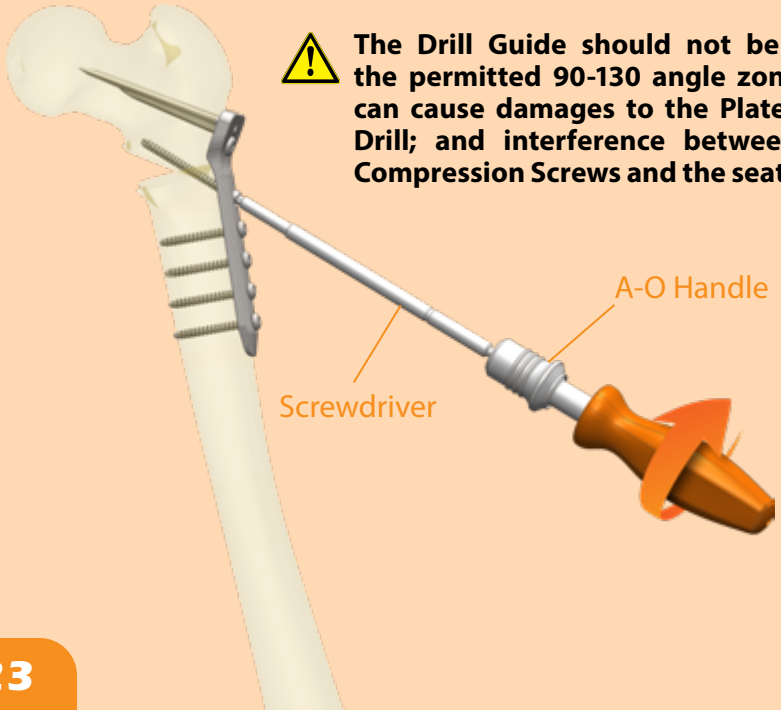
Note the depth of drilling to select the proper Screw length.

⚠ **The value read on the Cortical Drills takes into account the Plate thickness and height of the Screw head.**

Remove the Drill Guide when drilling is complete.



Attach the A-O Handle to the appropriate Screwdriver, screw the Polyaxial Compression Screw until fully threaded ensuring proper compression of the Plate onto the bone.



⚠ **The Drill Guide should not be over-angulated past the permitted 90-130 angle zone. Over-angulation can cause damages to the Plate and the Cortical Drill; and interference between the Polyaxial Compression Screws and the seating in the Plate.**

STEP 15

REMOVAL

There are two options for implant removal once all the Cortical Screws are unscrewed:

- Removing the Blade-Plate-Connector assembly as a one-piece implant **(Recommended)**
- Removing all components individually

Unscrew all the Locking Screws and the Polyaxial Compression Screws using the Screwdriver matching the implant family:

IMPLANT FAMILY	SCREWDRIVER
Infant / Child	GIN-SDR250
Adolescent HD Adolescent	GIN-SDR350

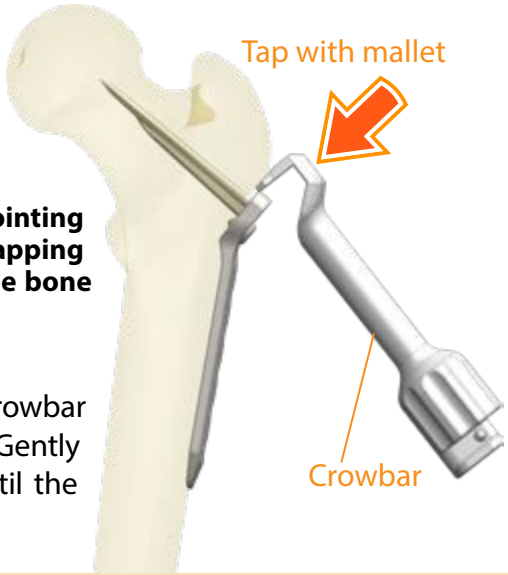
OPTION 1:

The Crowbar can be used to remove the Blade-Plate-connector in one piece.

Select the Crowbar matching the size of the Blade:

BLADE SIZE	CROWBAR
Infant	POP-BAR100
Child	POP-BAR125
Adolescent HD Adolescent	POP-BAR150

⚠ **Ensure that the Crowbar teeth are pointing towards the Blade-Plate when tapping with a mallet to avoid damaging the bone surface.**



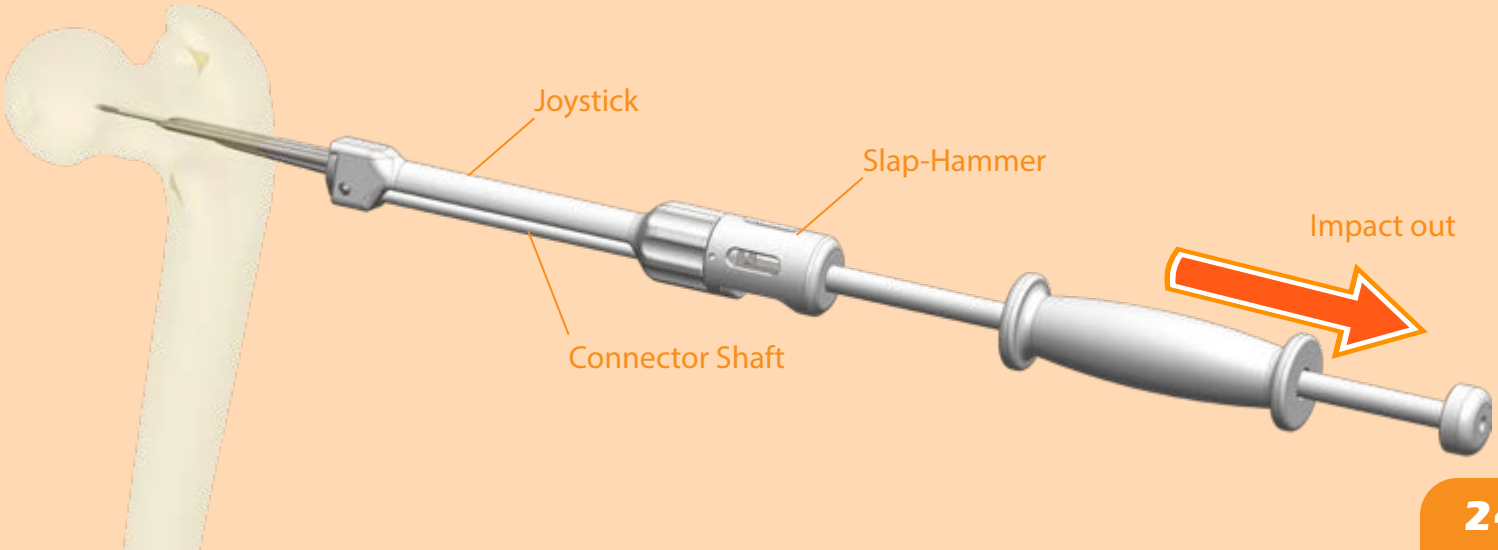
Place the Crowbar over top of the Plate until advancement of the teeth of the Crowbar is not possible anymore because of wedging between the Plate and the Bone. Gently tap the top surface of the Crowbar with a standard mallet (not provided) until the Blade-Plate starts to unwedge from the Bone.

OPTION 2:

Unscrew the connector using the appropriate screwdriver.

Manually unhook the Plate from the Blade.

Attach the Joystick to the Blade using the Connecter Shaft, and use the Slap-Hammer to remove the Blade from the bone.



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