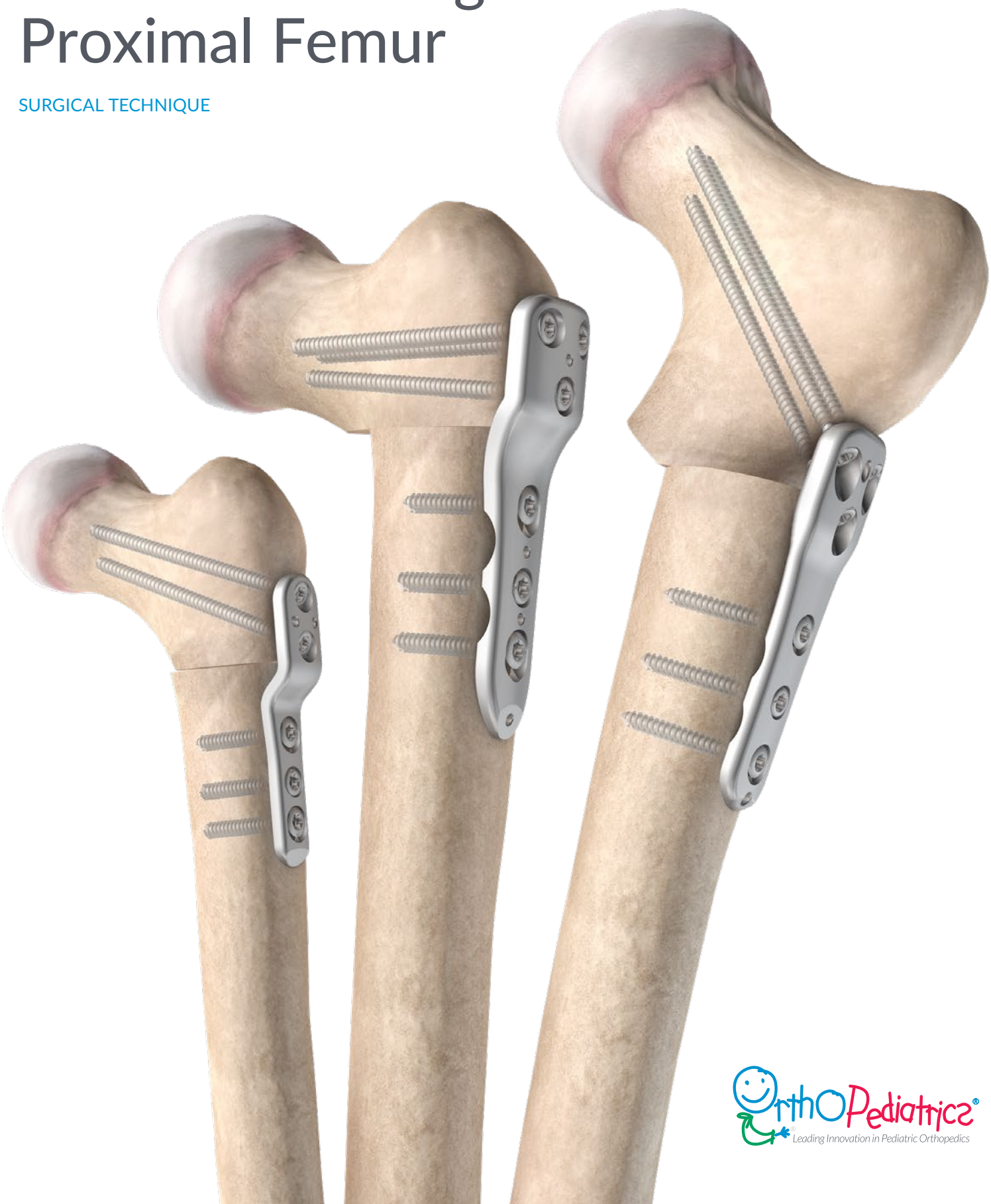
PediLoc® Locking Proximal Femur

SURGICAL TECHNIQUE



OrthoPediatrics®
Leading Innovation in Pediatric Orthopedics

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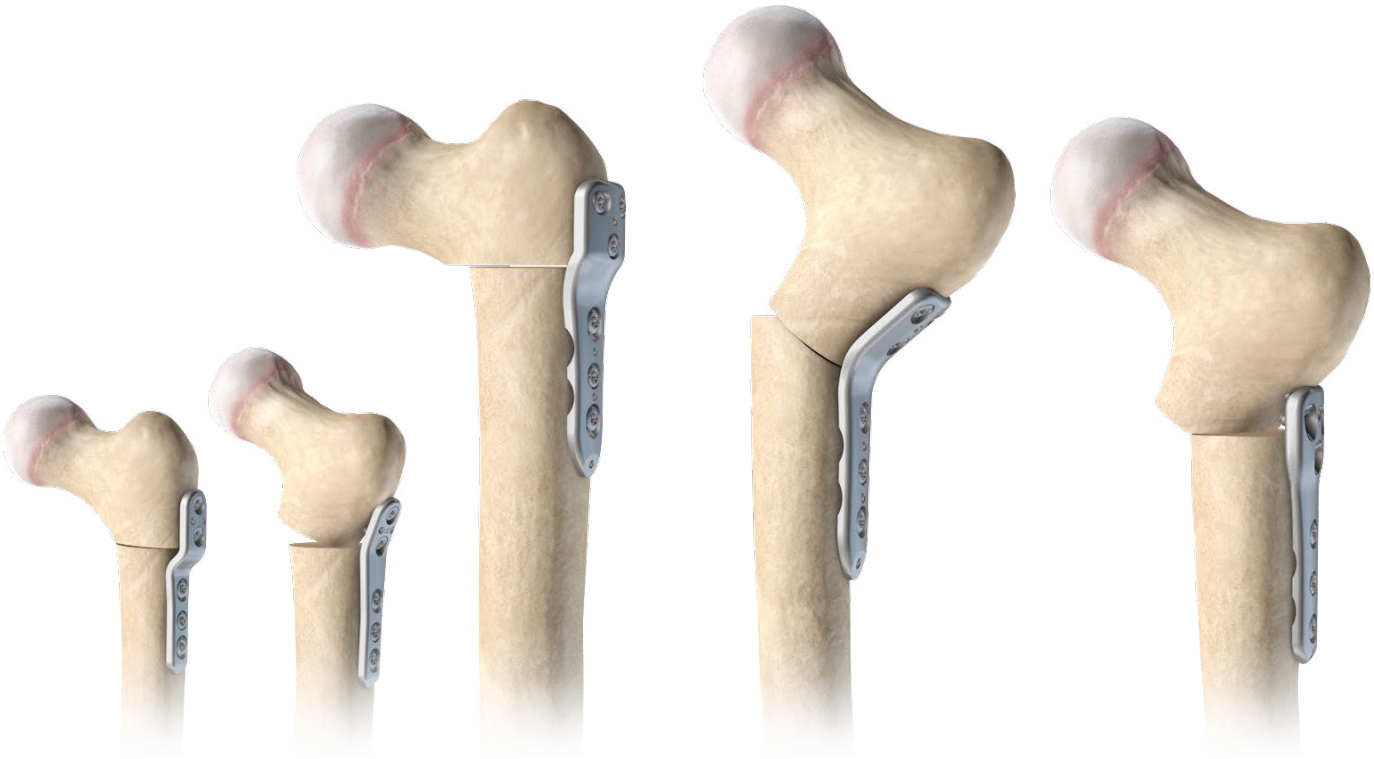
INDICATIONS

The OrthoPediatrics PediLoc® Locking Proximal Femur System is intended for temporary internal fixation and stabilization of long bone fractures and osteotomies, mal-unions and non-unions in pediatric and small stature adults. Specific indications include: intertrochanteric derotation and varus osteotomies, femoral neck and peritrochanteric fractures, and intertrochanteric valgus osteotomies.



SYSTEM OVERVIEW

Infant Plate
3 Hole

3.5mm Plate
90° Offset
3 Hole

4.5mm Plate
90° Offset
3 Hole

SURGICAL TECHNIQUE

Preoperative Planning

The goal of preoperative planning is to approximate the final position of the proximal femur after the deformity correction is performed.

For VARUS corrections, measure the current neck/shaft angle and choose the desired neck/shaft angle. Subtract the desired angle from the current angle, yielding the correction angle. The angle of the plate should be close to that of the desired neck/shaft angle. The correction angle is then added to the angle of the chosen plate to establish the calculated angle.

The calculated angle is the angle at which the initial guide wire should be placed relative to the femoral shaft axis in the AP plane, in order to achieve the desired neck/shaft angle.

NOTE: Determination of the correction and calculated angles forms the plan for the operative procedure. Miscalculating these values may lead to improper implant selection or complications in subsequent steps

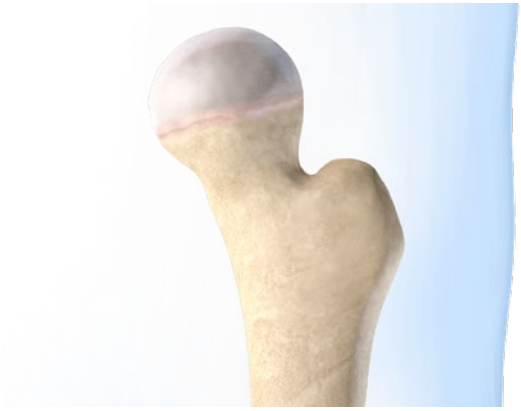


Figure 1: Varus Planning

For VALGUS corrections, measure the current neck/shaft angle and choose the desired neck/shaft angle. Subtract the current angle from the desired angle yielding the correction angle. The angle of the plate should be close to that of the desired neck/shaft angle. The correction angle is then subtracted from the angle of the chosen plate to establish the calculated angle.

The calculated angle is the angle at which the initial guide wire should be placed relative to the femoral shaft axis in the AP plane, in order to achieve the desired neck/shaft angle.

NOTE: Determination of the correction and calculated angles forms the plan for the operative procedure. Miscalculating these values may lead to improper implant selection or complications in subsequent steps

Figure 2: Valgus Planning

CALCULATED ANGLE

Calculated Angle

- To determine the correction angle, identify current neck shaft angle and desired neck shaft angle
- Subtract current from desired for appropriate correction angle
- Utilizing the appropriate plate angle (90°, 100°, 110°), add correction angle to plate angle obtaining the calculated angle
- The calculated angle will be used to insert the initial guide wire using the adjustable angle wire guide

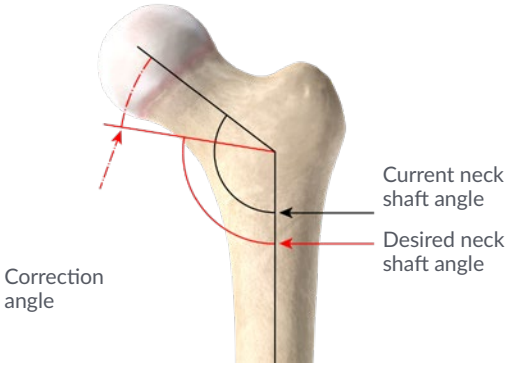


Figure 3

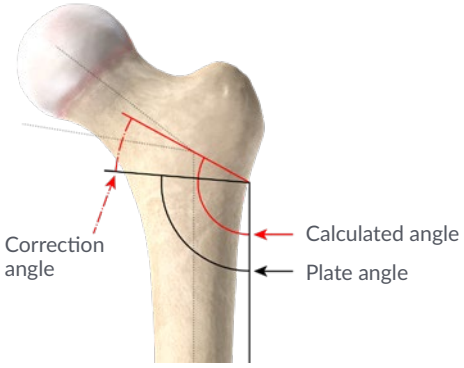
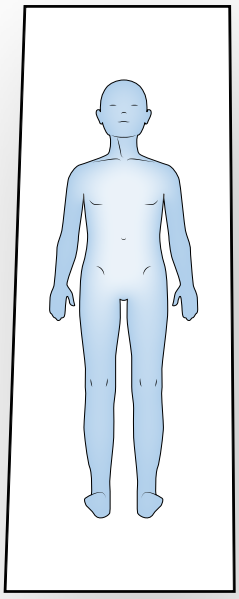


Figure 4

Patient Positioning and Surgical Exposure

Position the patient in either the supine or lateral position according to surgeon preference. If supine, place the operative side as close to the edge of the table as safely as possible to avoid potential interference from the table when instrumenting the proximal femur. A radiolucent table is recommended with the patient in the supine position. Ensure the necessary fluoroscopic views can be obtained prior to draping the patient. Prep and drape the patient in the usual sterile fashion. Expose the proximal femur using a standard lateral approach.

Once patient positioning is complete, continue to one of the following procedures based upon the chosen type of PediLoc® Locking Proximal Femur implant.



INFANT PLATES SURGICAL TECHNIQUE

Place the Initial Guide Wire

Using the calculated angle that was determined preoperatively, place the initial guide wire into the proximal femur. The guide wire should be placed freehand.

NOTE: The initial guide wire corresponds to the "X" screw. As such, the initial guide wire is dependent upon the type of screw—solid or cannulated—that will be used.

- For a solid screw, the initial guide wire is 2.5mm x 200mm.
- For a cannulated screw, the initial guide wire is 1.6mm x 230mm.

NOTE: Infant plates do not use the 2.0mm guide wires at any point in the procedure.

Use fluoroscopy in the AP and lateral planes to confirm proper position of the initial guide wire (Figure 5a). In the lateral plane, optimal position for the guide wire is centered in the femoral neck (Figure 5b). Proper position of the guide wire is critical. Withdraw the wire and adjust the trajectory as needed. Advance the guide wire to within 5mm of the femoral head physis.

CAUTION: Failure to confirm wire position fluoroscopically in both planes may result in screws that violate the femoral neck cortex, cross the physis, or enter the joint space.

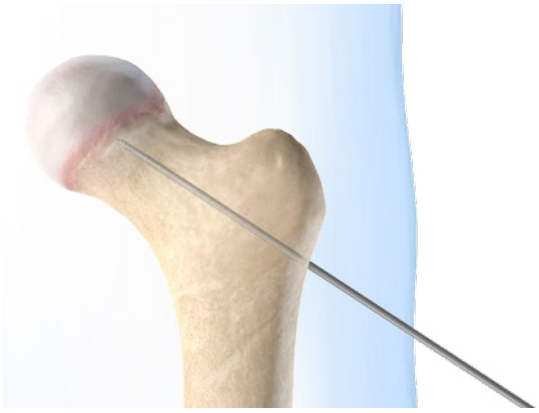


Figure 5a: AP view of initial guide wire placement at calculated angle and within 5mm of physis

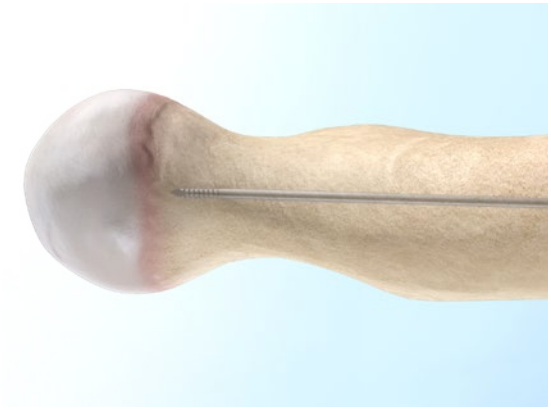


Figure 5b: Lateral view of initial guide wire placement

Place Orienting Guide Wire

While the initial guide wire determines the position of the plate on the proximal femur, the orientation of the plate is established by placing two additional guide wires.

Select the wire guide that corresponds to the size of the initial guide wire used (Figure 6). Pass the appropriate end of the guide over the initial wire and advance to the lateral cortex.

> **NOTE:** The infant wire guides have several markings to ensure the correct size and end are used. Regardless of which guide size or end is used the two additional wires placed to either side of the initial wire will always be 1.6mm x 230mm

	Solid Screws	Cannulated Screws
Initial Wire	2.5mm x 2000mm	1.6mm x 230mm
Wire Guide	Single Stripe	Double Stripe
X and Y Guide Wires	1.6mm x 230mm	1.6mm x 230mm

Rotate the guide about the initial wire, as needed, to set the orientation of the plate—flexion, extension, or neutral (Figure 7). Fix the orientation by placing two 1.6mm x 230mm guide wires through the guide (Figure 8).

> **CAUTION:** Use the wire guide to judge the orientation of the plate. For neutral position—no flexion or extension—the guide should be in line with the axis of the femur in the lateral view.

Perform the Osteotomy

Prior to creating the osteotomy, mark the femur with a line along the axis of the shaft (Figure 9). This line will be used in subsequent steps to judge the relative rotation of the proximal and distal fragments.

Figure 6: Select the appropriate guide and place by noting etched details

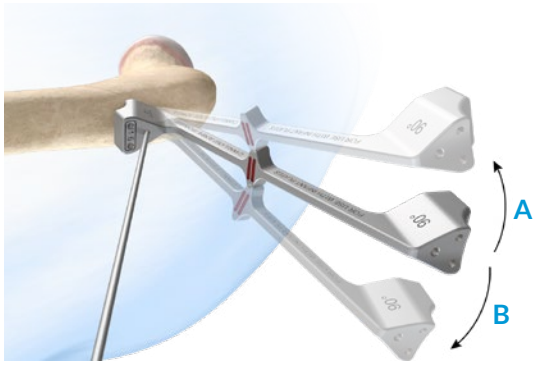


Figure 7: A. Extension B. Flexion

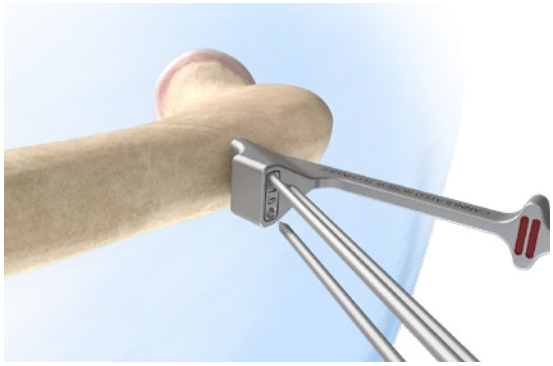


Figure 8: Insert 1.6mm guide wires

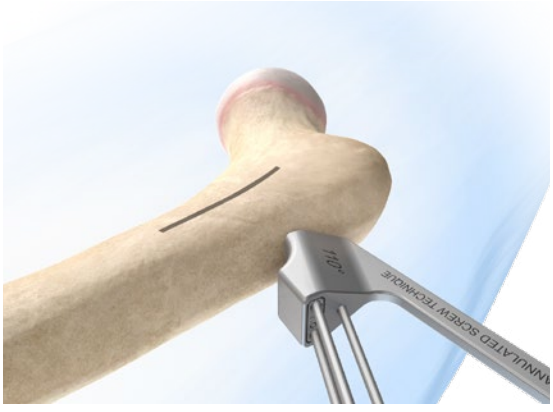


Figure 9: Mark the femur

90° AND 110° INFANT PLATES

For 90° and 110° INFANT PLATES, the direction of the first cut is provided by the wire guide used to place the additional wires. The guide accounts for the plate angle and ensures that the second cut will be transverse to the femoral shaft (Figure 10).

Advance the oscillating saw blade along the under surface of the guide and into the bone. Once the osteotomy is started, the guide can be removed if it obstructs the saw from completing the cut.

With the first cut complete, perform the second cut transverse to the femoral shaft using the same starting point on the lateral cortex (Figure 11).

CAUTION: Using the wrong end of the guide for the first cut will require the second cut to be adjusted (not transverse) in order to achieve a closing wedge osteotomy.

CAUTION: Failure to use the guide to locate the first cut may result in the proximal fragment not fitting within the offset of the plate (if the cut is too distal), or the "Z" screw passing through the osteotomy (if the cut is too proximal).

Once osteotomy is performed, the remainder of the procedure follows a common sequence of steps. Please continue to page 26.

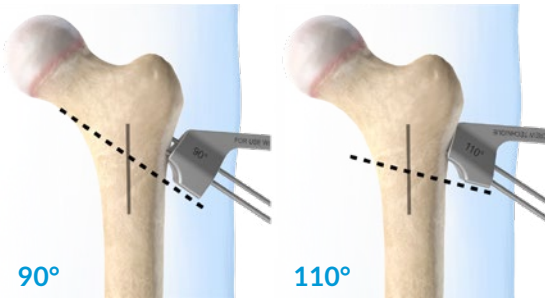


Figure 10: Position guide relative to the angle of the plate

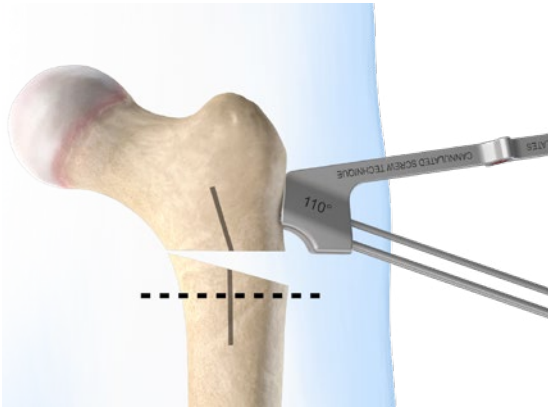


Figure 11: Perform the second cut by advancing the saw so that the cut is transverse to the femoral shaft

130° INFANT PLATE

The 130° INFANT PLATE is designated as a fracture plate. As such, an osteotomy would not be necessary. If needed, it can be used for a valgus osteotomy procedure.

In this case, the osteotomy would be performed with a single cut transverse to the femoral shaft. The position of the cut can be located by placing the lateral edge of the plate head under the two additional wires that flank the initial "X" wire.

Mark the femur along the opposite edge of the plate head (Figure 12). Make a cut transverse to the femoral shaft with an oscillating saw at the level of the marking (Figure 13).

This technique often leads to the lateral cortex corner of the proximal fragment sitting on the cut surface of the femoral shaft. The contact area between the fragments can be increased by removing the lateral cortex corner of either the proximal or distal fragment, if desired.

CAUTION: Do not use either end of the wire guide to locate and orient the osteotomy for the 130° infant plate.

CAUTION: Remove the plate prior to performing the osteotomy to avoid potential damage to the plate from the saw.

Once osteotomy is performed, the remainder of the procedure follows a common sequence of steps. Please continue to page 26.

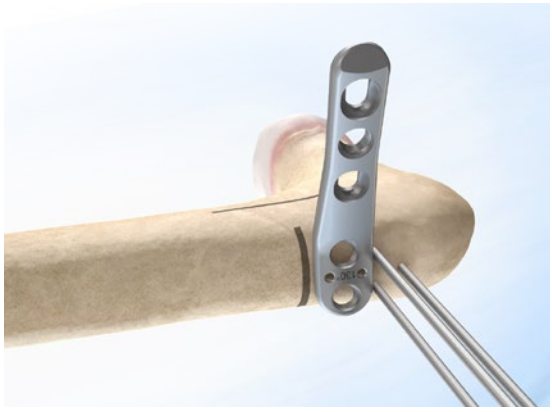


Figure 12: Mark the femur

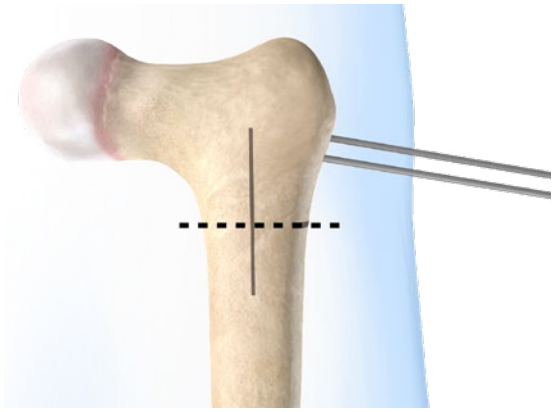


Figure 13: Prepare for first cut

GENERAL PLATES

Surgical Technique

The OrthoPediatrics PediLoc® Locking Proximal Femur System has 90°, 100°, 110°, 120°, 130° and 150° plates offered in two different size ranges: 3.5mm and 4.5mm. The sizes can be identified within the set according to color coding on the instrumentation. 3.5mm instruments are designated with the color BLUE and 4.5mm instruments are designated with the color GREEN.

Furthermore, threaded towers for solid screws have 1 COLOR BAND and threaded towers for cannulated screws have 2 COLOR BANDS.

THE FOLLOWING STEPS DEPICT THE SURGICAL PROCEDURE AS THEY APPLY TO A 4.5mm PLATE.

Place the Initial Guide Wire

Using the calculated angle determined preoperatively, place the initial guide wire into the proximal femur. The guide wire can be approximated freehand or placed with the aid of an angle wire guide.

NOTE: The initial guide wire lies within the triangle created by the "X", "Y", and "Z" screws. As such, when determining the position of the initial guide wire in the AP plane, be aware that the "X" and "Y" screws will be slightly superior to the initial guide wire (Figure 14).

NOTE: For all non-infant plates the initial guide wire is 2.0mm x 150mm.

NOTE: The foot of the angle wire guide—adjustable or fixed—should be placed against the femoral shaft and secured with a bone clamp or held in position (Figure 15). For the adjustable angle guide, pull the knurled knob and rotate the tube to match the calculated angle (Figure 16). Either guide may not contact the lateral cortex of the greater trochanter (Figure 16 and 17). If this is the case, use gentle pressure to advance the guide wire. Excessive pressure may cause the wire to skive.

Figure 14: Distance between guide wires (A) is 4mm for 3.5mm plates and 5mm for 4.5 plates

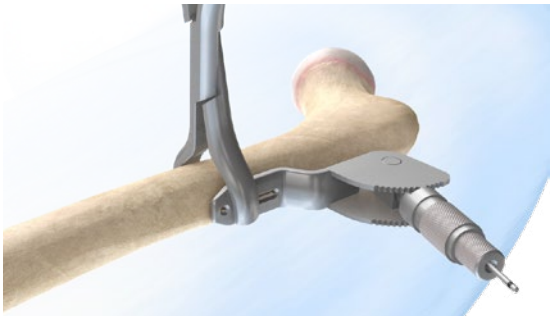


Figure 15: Secure wire guide with bone clamp

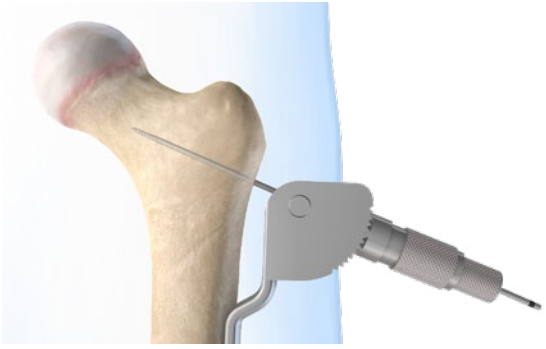


Figure 16: Place initial guide wire using the adjustable angle wire guide if desired

Use fluoroscopy in the AP and lateral planes to confirm proper position of the initial guide wire (Figure 18a). In the lateral plane, optimal position for the guide wire is centered in the femoral neck (Figure 18b). Proper position of the guide wire is critical. Withdraw the wire and adjust the trajectory as needed. Advance the guide wire to within 5mm of the femoral head physis.

CAUTION: Failure to confirm wire position fluoroscopically in both planes may result in screws that violate the femoral neck cortex, cross the physis, or enter the joint space.

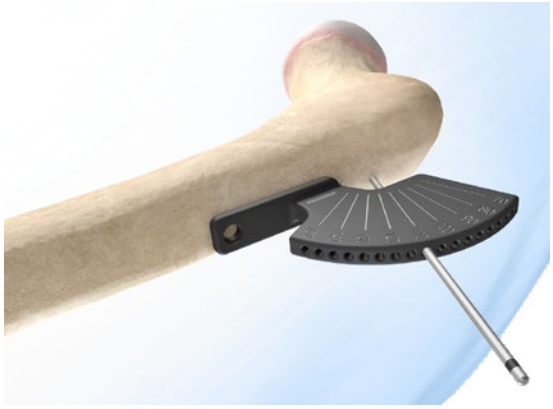


Figure 17: Place initial guide wire using the fixed angle wire guide if desired

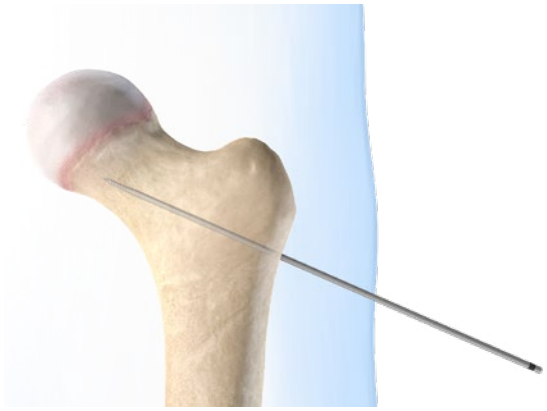


Figure 18a: AP view to confirm placement of initial guide wire

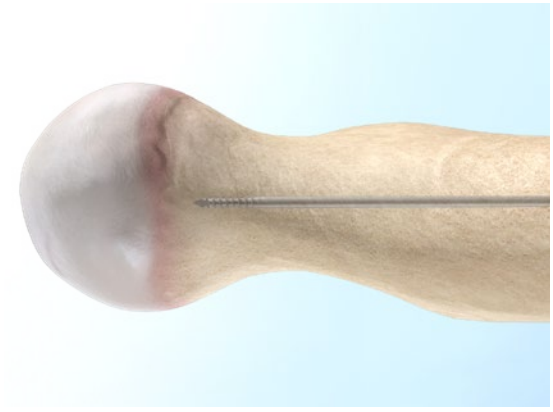


Figure 18b: Confirm placement of initial guide wire

Set the Plate Orientation on the Proximal Femur

While the initial guide wire locates the plate on the proximal femur, the orientation of the plate is established by placing two additional guide wires.

Determine whether solid or cannulated screws will be used and mate the appropriate threaded towers to the applicable wire guide (Figure 19).

NOTE: Take care not to cross-thread the towers onto the wire guide, as this may lead to wire trajectories that do not match that of the plate.

NOTE: Be sure to use the correct combination of wire guide, guide towers, and guide wires. Smaller diameter wires will fit through larger diameter towers, but may lead to difficulty locking the screws to the plate. Furthermore, the guide towers for solid screws and cannulated screws are different lengths. Using the wrong wires and towers may lead to an incorrect screw measurement at a later step.

Pass the guide with towers over the initial wire and advance to the lateral cortex.

Rotate the guide about the initial wire, as needed, to set the orientation of the plate—flexion, extension, or neutral (Figure 20).

	3.5mm Plate		4.5mm Plate	
	Solid Screws	Cannulated Screws	Solid Screws	Cannulated Screws
Initial Wire	2.0mm x 150mm		2.0mm x 150mm	
Wire Guide	Double Blue Band		Double Green Band	
Guide Towers	Single Blue Band	Double Blue Band	Single Green Band	Double Green Band
X and Y Guide Wires	2.5mm x 200mm	1.6mm x 230mm	3.2mm x 200mm	2.0mm x 230mm

Figure 19: Mate the appropriate threaded towers to the wire guide

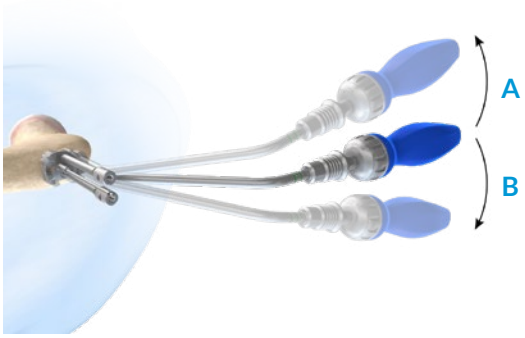


Figure 20: A. Extension B. Flexion

Fix the orientation by placing two guide wires through the “X” and “Y” towers. Wires should be placed to within 5mm of the femoral head physis (Figure 21). Confirm the position of the wires fluoroscopically in the AP and lateral planes (Figure 22).

CAUTION: Use the wire guide to judge the orientation of the plate. For neutral position—no flexion or extension—the guide should be in line with the axis of the femur in the lateral view.

CAUTION: Failure to confirm wire position fluoroscopically in both planes may result in screws that violate the femoral neck cortex, cross the physis, or enter the joint space.

NOTE: The wire guide may not sit flush against lateral cortex.

NOTE: The “Z” wire may be placed at this point. However, it may make removal of the wire guide and creation of the osteotomy difficult in later steps.

CAUTION: In some cases, the actual plate with the towers can be used to place the “X” and “Y” wires. If this is done, the plate must be removed prior to performing the osteotomy to avoid potential damage to the plate from the saw.

Perform the Osteotomy

Prior to creating the osteotomy, mark the femur with a line along the axis of the shaft (Figure 23). This line will used in subsequent steps to judge the relative rotation of the proximal and distal fragments.

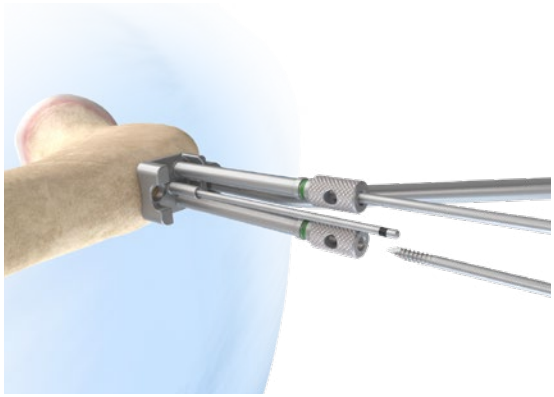


Figure 21: Place the guide wires

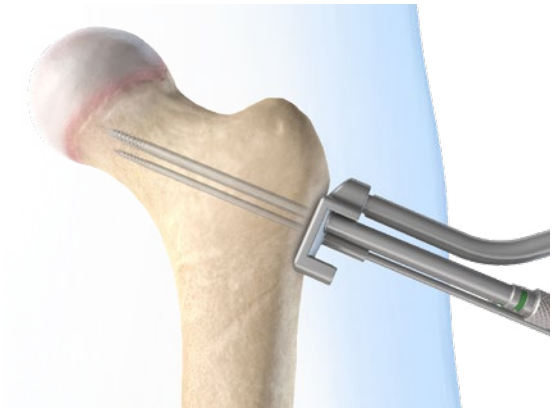


Figure 22: Confirm placement of guide wires

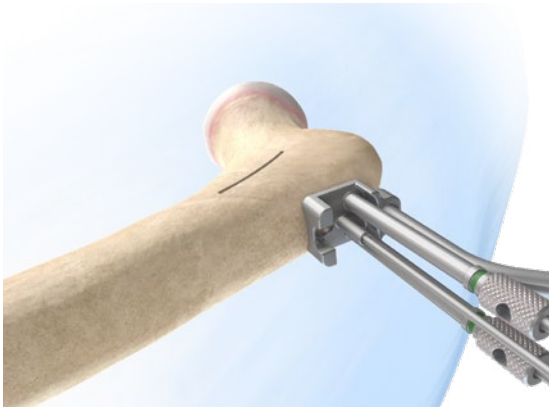


Figure 23: Mark the femur

VARUS CORRECTION - 90°, 100°, 110° and 120° PLATES

If a closing wedge osteotomy with a transverse second cut is desired, the first cut should be made at an angle appropriate for the chosen plate. That angle is determined by subtracting 90° from the plate angle.

For example, for a varus correction with a 120° plate, the first cut should be made 30° (120° minus 90°) down from the initial wire. For a 90° plate, the first cut is parallel to the initial wire.

The starting point for this cut is indicated by the wire guide used to place the "X" and "Y" wires. Mark the location of the osteotomy and remove the guide. For a 90° plate, the cut can be made with the guide in place. Make the first cut at the appropriate angle (Figure 24).

NOTE: The wire guide may not sit flush against lateral cortex.

With the first cut complete, the second cut can be made transverse to the femoral shaft, using the same starting point on the lateral cortex.

CAUTION: Not orienting the first cut at the appropriate angle relative to the "X" and "Y" wires will require the second cut to be adjusted (not transverse) in order to achieve a closing wedge osteotomy.

CAUTION: Failure to use the guide to locate the first cut may result in the proximal fragment not fitting within the offset of the plate (if the cut is too distal), or the "Z" screw passing through the osteotomy (if the cut is too proximal).

NOTE: The closing wedge is one of multiple techniques for performing the osteotomy to achieve the desired correction. Whatever method is employed, the wire guide should be used to locate the start of the osteotomy on the lateral cortex.

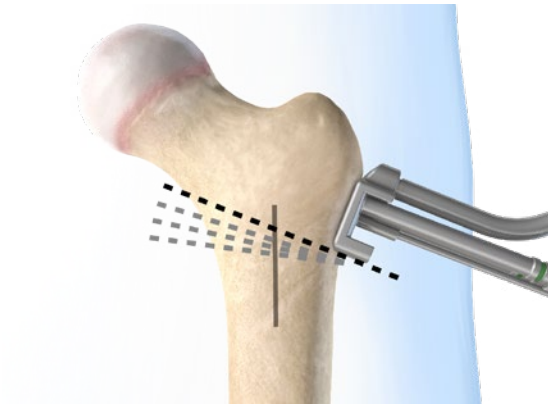


Figure 24: Prepare for first cut

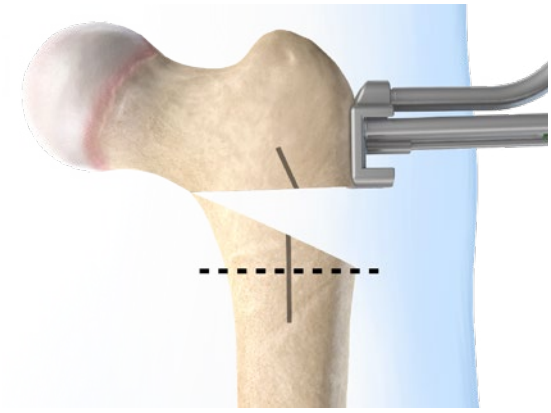


Figure 25: Make the transverse cut

VALGUS CORRECTION - 150° Plate

A valgus osteotomy is typically performed with a single cut transverse to the femoral shaft. The position of the osteotomy can be located using the width of the head of the plate.

Remove the initial guide wire (Figure 26). Place the lateral edge of the plate head under the "X" and "Y" wires, and mark the femur along the opposite edge of the plate head (Figure 27).

Make a cut transverse to the femoral shaft with an oscillating saw at the level of the marking (Figure 28). This technique often leads to the lateral cortex corner of the proximal fragment sitting on the cut surface of the femoral shaft. The contact area between the fragments can be increased by removing the lateral cortex corner of either the proximal or distal fragment, if desired (Figure 29).

CAUTION: Do not use the wire guide to locate and orient the osteotomy for the 150° plate.

CAUTION: Not using the plate head to locate the osteotomy may result in the osteotomy being more proximal or distal than desired.

CAUTION: Failure to remove the initial guide wire may lead to unwanted flexion or extension and push the osteotomy more distal than desired.

CAUTION: Remove the plate prior to performing the osteotomy to avoid potential damage to the plate from the saw.

The 130° plates are designated as fracture plates but can be used for valgus osteotomy procedures, if necessary. The osteotomy would be performed in the same manner as for the 150° plate described above.

Once the osteotomy is performed, the remainder of the procedure follows a common sequence of steps. Please continue to page 26.

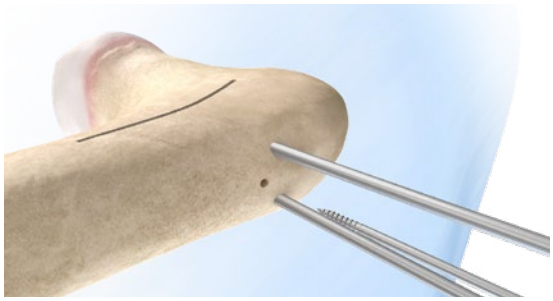


Figure 26: Remove the initial guide wire

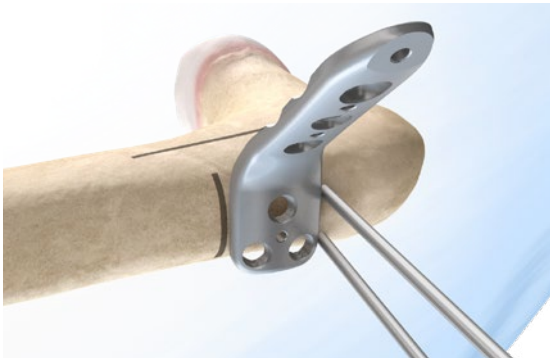


Figure 27: Mark the cut

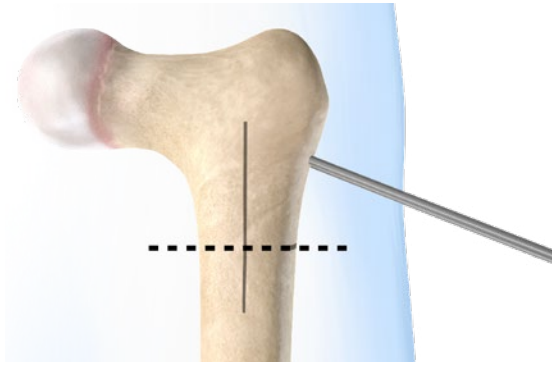


Figure 28: Make the cut

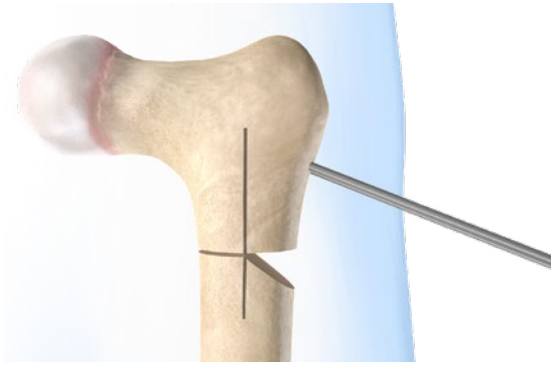


Figure 29: Remove lateral cortex corner, if desired

140° PLATES

Surgical Technique

The OrthoPediatrics PediLoc® Locking Proximal Femur System offers 140° plates in two different size ranges: 3.5mm and 4.5mm. The sizes can be identified within the set according to color coding on the instrumentation. 3.5mm instruments are designated with the color BLUE and 4.5mm instruments are designated with the color GREEN. Furthermore, threaded towers for solid screws have a 1 COLOR BAND and threaded towers for cannulated screws have 2 COLOR BANDS.

THE FOLLOWING STEPS DEPICT THE SURGICAL PROCEDURE AS THEY APPLY TO A 3.5mm 140° PLATE.

Place the Initial Guide Wire

Using the calculated angle determined preoperatively, place the initial guide wire into the proximal femur. The guide wire can be approximated freehand or placed with the aid of an angle wire guide.

NOTE: The initial guide wire lies above the triangle created by the "X", "Y", and "Z" screws. As such, when determining the position of the initial guide wire in the AP plane, be aware that the "X" and "Y" screws will be slightly inferior to the initial guide wire (Figure 30).

NOTE: For all non-infant plates the initial guide wire is 2.0mm x 150mm.

NOTE: The foot of the angle wire guide—adjustable or fixed—should be placed against the femoral shaft and secured with a bone clamp or held in position (Figure 32). For the adjustable angle guide, pull the knurled knob and rotate the tube to match the calculated angle. Either guide may not contact the lateral cortex of the greater trochanter. If this is the case, use gentle pressure to advance the guide wire. Excessive pressure may cause the wire to skive.

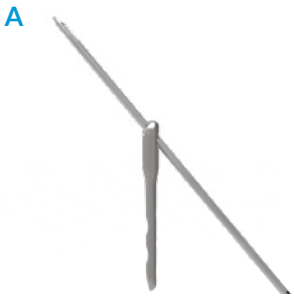


Figure 30: Distance between guide wires (A) is 1.3mm for 3.5mm plates & 3mm for 4.5 plates

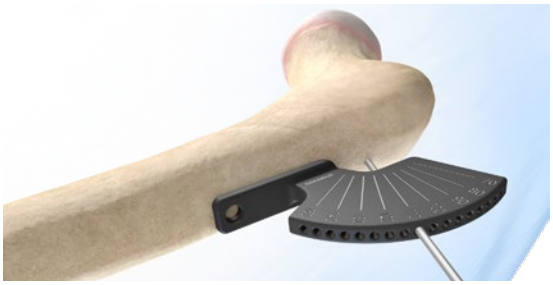


Figure 31: Place the initial guide wire using the fixed angle wire guide, if desired

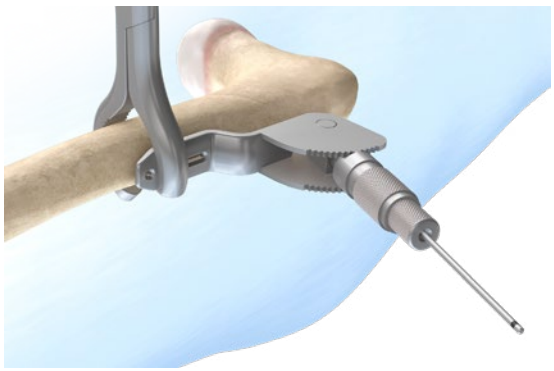


Figure 32: Place the initial guide wire using the adjustable angle wire guide, if desired

Use fluoroscopy in the AP and lateral planes to confirm proper position of the initial guide wire (Figure 33a). In the lateral plane, optimal position for the guide wire is centered in the femoral neck (Figure 33b). Proper position of the guide wire is critical. Withdraw the wire and adjust the trajectory as needed. Advance the guide wire to within 5mm of the femoral head physis.

CAUTION: Failure to confirm wire position fluoroscopically in both planes may result in screws that violate the femoral neck cortex, cross the physis, or enter the joint space.

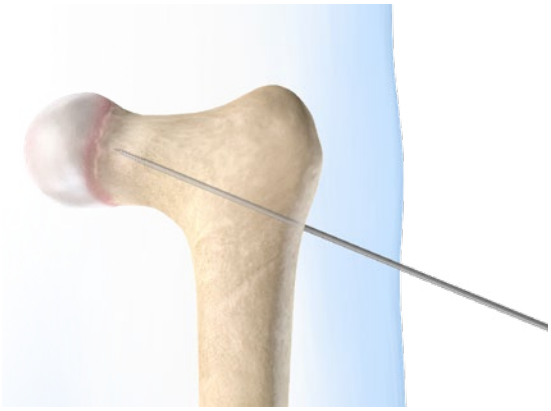


Figure 33a: AP view to confirm placement of the initial guide wire

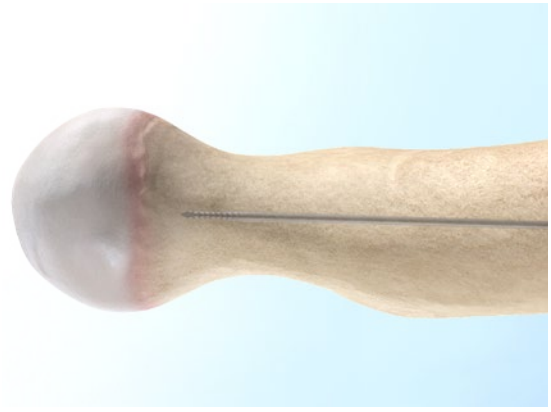


Figure 33b: Confirm placement of the initial guide wire

Set the Plate Orientation on the Proximal Femur

While the initial guide wire locates the plate on the proximal femur, the orientation of the plate is established by placing two additional guide wires.

Determine whether solid or cannulated screws will be used and mate the appropriate threaded towers to the chosen plate (Figure 34).

CAUTION: Failure to confirm wire position fluoroscopically in both planes may result in screws that violate the femoral neck cortex, cross the physis, or enter the joint space.

NOTE: The 140° plates feature a unique screw trajectory compared to other LPF plates. Do not use the available wire guides for placement of the "X" and "Y" wires when using this plate.

NOTE: Be sure to use the correct combination of plate, guide towers, and guide wires. Smaller diameter wires will fit through larger diameter towers, but may lead to difficulty locking the screws to the plate. Furthermore, the guide towers for solid screws and cannulated screws are different lengths. Using the wrong wires and towers may lead to an incorrect screw measurement at a later step.

Figure 34: Mate the appropriate threaded towers to the plate

	3.5mm 140° Plate		4.5mm 140° Plate	
	Solid Screws	Cannulated Screws	Solid Screws	Cannulated Screws
Initial Wire	2.0mm x 150mm		2.0mm x 150mm	
Wire Guide	Use Plate		Use Plate	
Guide Towers	Single Blue Band	Double Blue Band	Single Green Band	Double Green Band
X and Y Guide Wires	2.5mm x 200mm	1.6mm x 230mm	3.2mm x 200mm	2.0mm x 230mm

Pass the plate with towers over the initial wire and advance to the lateral cortex.

Rotate the plate about the initial wire, as needed, to set the orientation of the plate—flexion, extension, or neutral (Figure 35). Fix the orientation by placing two guide wires through the "X" and "Y" towers.

Wires should be placed to within 5mm of the femoral head physis (Figure 36). Confirm the position of the wires fluoroscopically in the AP and lateral planes (Figure 37).

CAUTION: Use the plate to judge the orientation. For neutral position—no flexion or extension—the longitudinal axis of the plate should be in line with the axis of the femur in the lateral view.

CAUTION: Failure to confirm wire position fluoroscopically in both planes may result in screws that violate the femoral neck cortex and/or cross the physis/enter the joint space.

NOTE: The plate may not sit flush against lateral cortex.

NOTE: The "Z" wire may be placed at this point. However, it may make removing the plate and creating the osteotomy difficult in later steps.

CAUTION: The plate must be removed prior to performing the osteotomy to avoid potential damage to the plate from the saw.

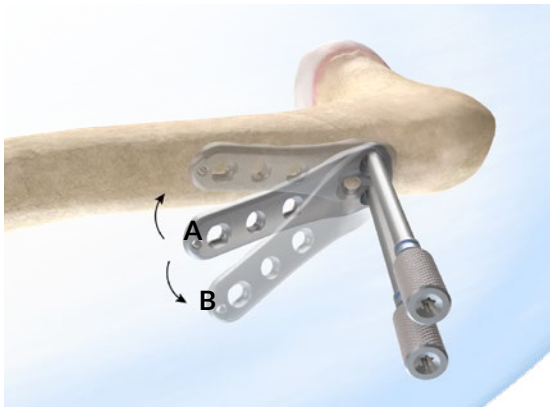


Figure 35: A. Flexion B. Extension

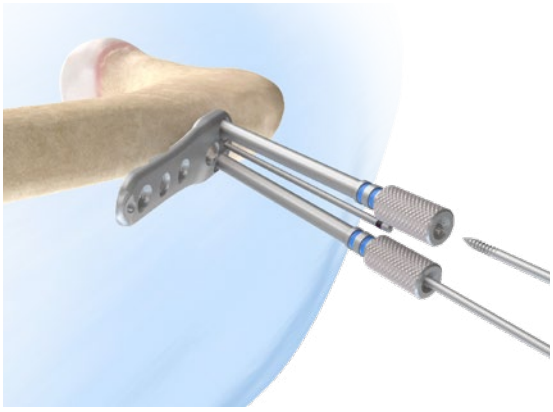


Figure 36: Place the guide wires

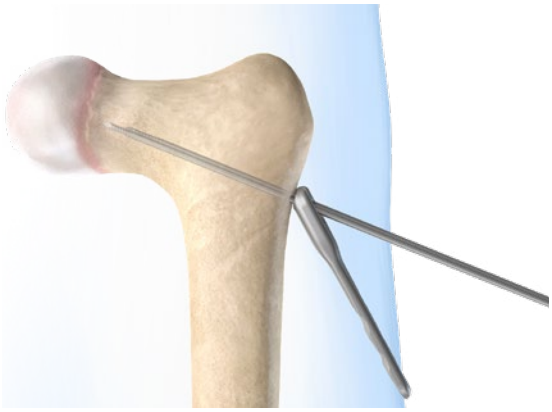


Figure 37: Confirm the placement of the guide wires

Perform the Osteotomy

Prior to creating the osteotomy, mark the femur with a line along the axis of the shaft (Figure 38). This line will be used in subsequent steps to judge the relative rotation of the proximal and distal fragments.

A valgus osteotomy is typically performed with a single cut transverse to the femoral shaft. The position of the osteotomy can be located using the width of the head of the plate.

Place the lateral edge of the plate head under the "X" and "Y" wires and mark the femur along the opposite edge of the plate head (Figure 39). Make a cut transverse to the femoral shaft with an oscillating saw at the level of the marking (Figure 40).

This technique often leads to the lateral cortex corner of the proximal fragment sitting on the cut surface of the femoral shaft. The contact area between the fragments can be increased by removing the lateral cortex corner of either the proximal or distal fragment, if desired (Figure 41).

CAUTION: Do not use a wire guide to locate and orient the osteotomy for the 140° plate.

CAUTION: Not using the plate head to locate the osteotomy may result in the osteotomy being more proximal or distal than desired.

CAUTION: Remove the plate prior to performing the osteotomy to avoid potential damage to the plate from the saw.

Once osteotomy is performed, the remainder of the procedure follows a common sequence of steps. Please continue to page 26.

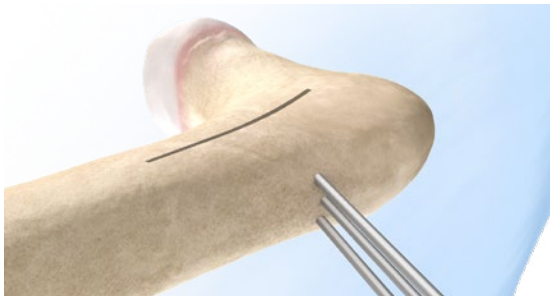


Figure 38: Mark the femur

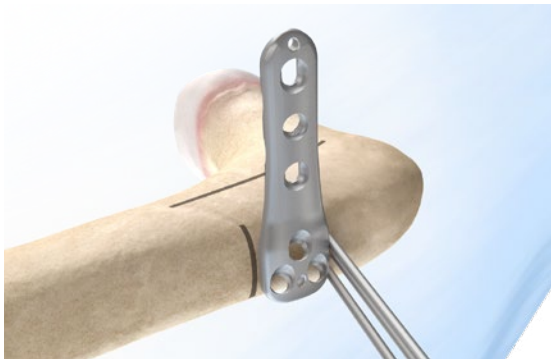


Figure 39: Mark the cut

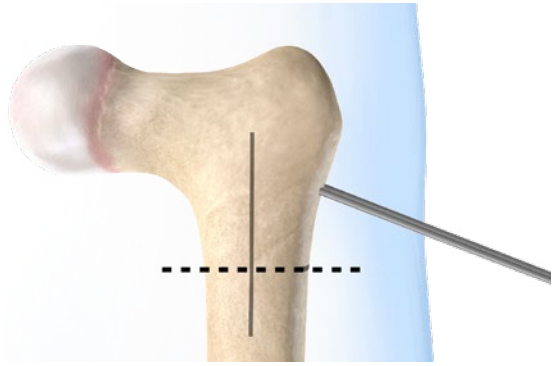


Figure 40: Make the cut

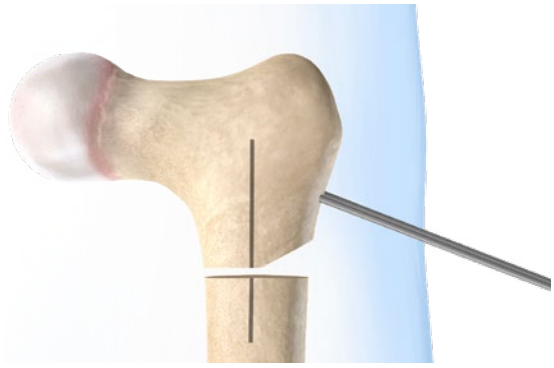


Figure 41: Remove lateral cortex corner, if desired

Secure the Plate to the Proximal Femur

With the osteotomy complete, mate the appropriate threaded towers to the chosen plate and advance the assembly over the guide wires (Figure 42).

NOTE: Take care not to cross-thread the towers onto the plate as this may lead to wire trajectories that prohibit the screws from locking into the plate.

NOTE: The converging screw design may make passing the plate/tower assembly over the wires difficult. It may be necessary to pass the plate over the corresponding wires and then mate the towers to the plate in situ.

NOTE: Be sure to use the correct combination of plate, guide towers, and guide wires. Smaller diameter wires will fit through larger diameter towers, but may lead to difficulty locking the screws to the plate. Furthermore, the guide towers for solid screws and cannulated screws are different lengths. Using the wrong wires and towers may lead to an incorrect screw measurement at a later step.

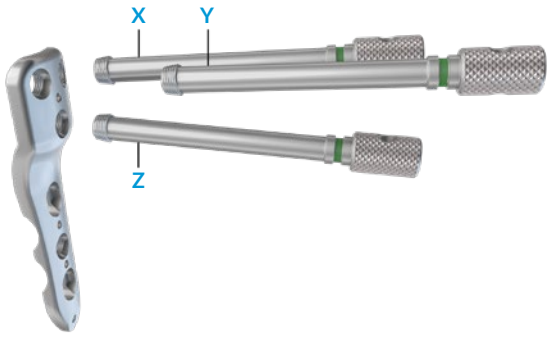


Figure 42: Mate the threaded towers to the plate

	3.5mm Plate (Inc. Infant)		4.5mm Plate	
	Solid Screws	Cannulated Screws	Solid Screws	Cannulated Screws
Guide Towers	Single Blue Band	Double Blue Band	Single Green Band	Double Green Band
Z Guide Wire	Guide Tower On	Guide Tower Off	Guide Tower On	Guide Tower Off

Once the plate is positioned as desired against the proximal fragment, place the guide wire for the “Z” screw (Figure 43). The wire should be placed to within 5mm of the femoral head physis. Confirm the position of the wire fluoroscopically in the AP plane.

CAUTION: Failure to confirm wire position fluoroscopically in the AP plane may result in a screw that violates the femoral neck cortex, cross the physis, or enter the joint space.

NOTE: The plate may not sit flush against the lateral cortex.

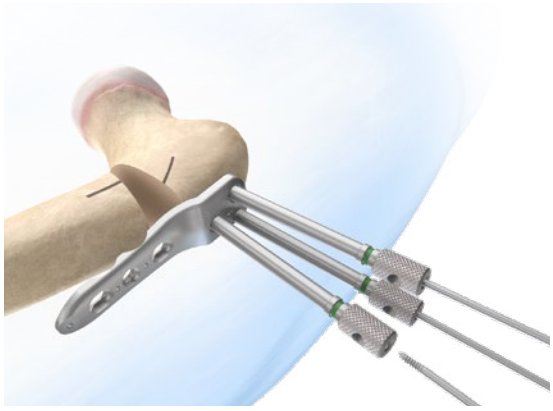


Figure 43: Place guide wire for “Z” screw

LOCKING SOLID SCREW PLACEMENT

Starting with the "X" position, measure the appropriate screw length using the scale on the back of the tower (Figure 44).

NOTE: The measurement for screw length varies between solid and cannulated screws. Be sure to use the correct combination of direct measuring device, tower on/off, and the correct end of the measuring device. Failure to do so may result in an incorrect screw length.

	3.5mm Plate (Inc. Infant)		4.5mm Plate	
	Solid Screws	Cannulated Screws	Solid Screws	Cannulated Screws
Direct Measuring Device	Blue		Green	
Measurement	Guide Tower On	Guide Tower Off	Guide Tower On	Guide Tower Off
End of Measuring Device	Back End	Front End (Nose)	Back End	Front End (Nose)

Remove the tower and guide wire and, if necessary, manually tap the near cortex. Fully insert the chosen screw with the solid driver (Figure 45). Repeat these steps for the "Y" and then "Z" position screws (Figure 46). Complete all steps for a given screw before moving on to the next screw.

CAUTION: In poor quality bone, the trajectory of the screw can be altered if excessive pressure is applied during insertion. This can lead to the screw head not locking into the plate.

CAUTION: Failure to adequately tighten the locking screw into the plate may lead to screw back-out.

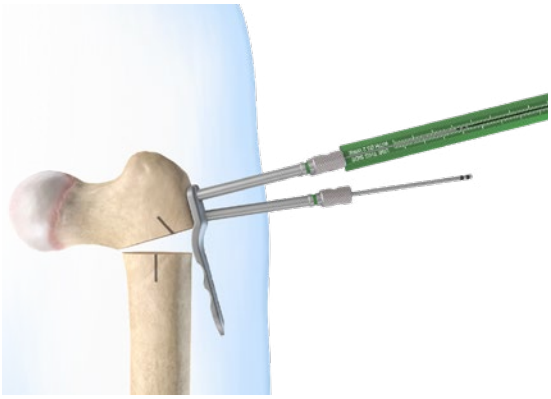


Figure 44: Use the direct measuring device to determine appropriate screw size

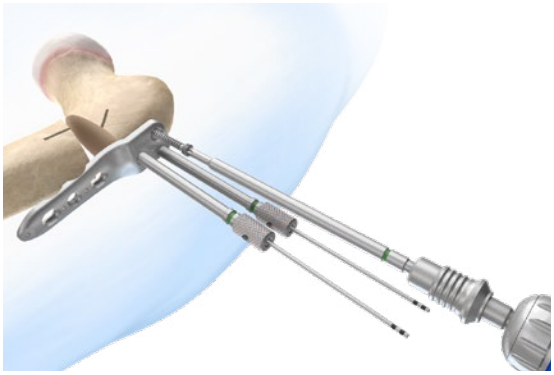


Figure 45: Insert the screw

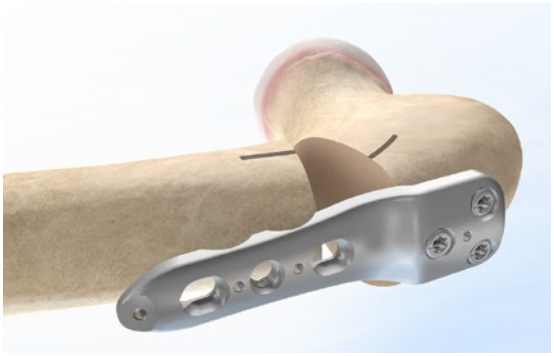


Figure 46: Complete the proximal screw placement

LOCKING CANNULATED SCREW PLACEMENT

Starting with the "X" position, remove the tower and measure for the appropriate screw length (Figure 47).

NOTE: The measurement for screw length varies between solid and cannulated screws. Be sure to use the correct combination of direct measuring device, tower on/off, and the correct end of the measuring device. Failure to do so may result in an incorrect screw length.

	3.5mm Plate (Inc. Infant)		4.5mm Plate	
	Solid Screws	Cannulated Screws	Solid Screws	Cannulated Screws
Direct Measuring Device	Blue		Green	
Measurement	Guide Tower On	Guide Tower Off	Guide Tower On	Guide Tower Off
End of Measuring Device	Back End	Front End (Nose)	Back End	Front End (Nose)

Use the cannulated drill bit to open the near cortex (Figure 48). It is not necessary to drill the full depth of the wire. If necessary, manually tap the near cortex with the cannulated tap. Pass the chosen screw over the wire and insert with the cannulated driver (Figure 49).

CAUTION: If the wire is bent, the cannulated drill and/or driver may advance the wire further or may not pass over the wire at all. If this is the case, mate the corresponding tower to the plate and exchange the wire.

Once the screw is nearly fully seated, remove the guide wire. Final tightening should be performed with a solid (non-cannulated) driver. Repeat these steps for the "Y" and then "Z" position screws (Figure 50). Complete all steps for a given screw before moving on to the next screw.

CAUTION: Failure to adequately tighten the locking screw into the plate may lead to screw back-out.

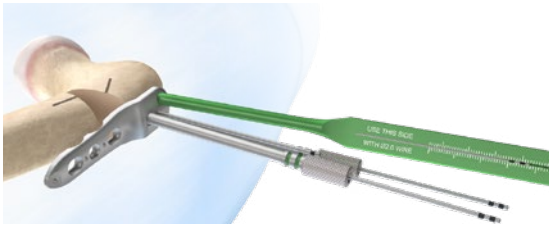


Figure 47: Use the direct measuring device to determine the appropriate screw size

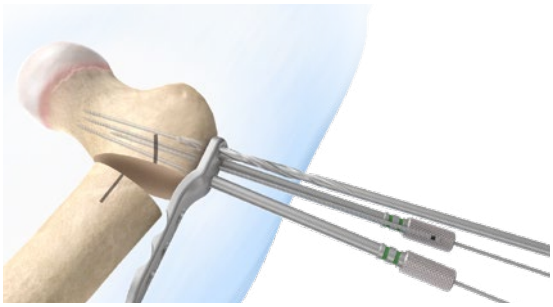


Figure 48: Drill for the screw

Figure 49: Insert the screw

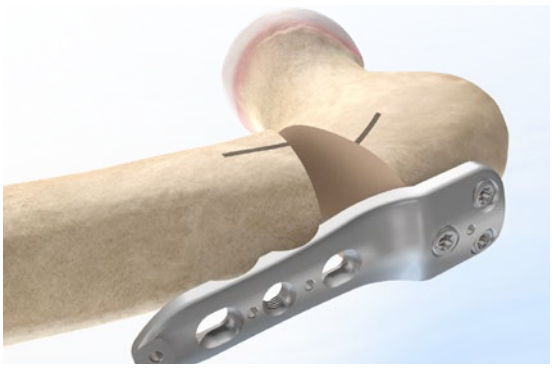


Figure 50: Complete the proximal screw placement

Reduce the Plate to the Femoral Shaft

Using the appropriate bone clamp—infant, small, or large—reduce the plate to the femoral shaft (Figure 51). Optimal fixation is achieved when the plate is aligned with the femoral shaft axis in the AP and lateral planes.

Use the line marked on the femur prior to making the osteotomy as a means of judging the relative rotation of the proximal and distal fragments.

> **NOTE:** When reducing the INFANT plate to the femoral shaft after placing the proximal screws, positioning the bone clamp in the first locking hole will lead to subsequent interference with a compression screw in the first dynamic slot (Figure 52). Compression should be applied through the second dynamic slot to avoid this interference.

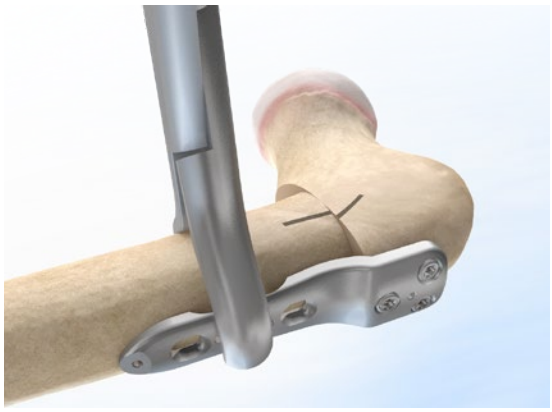


Figure 51: Use a bone clamp to reduce the plate to the femoral shaft

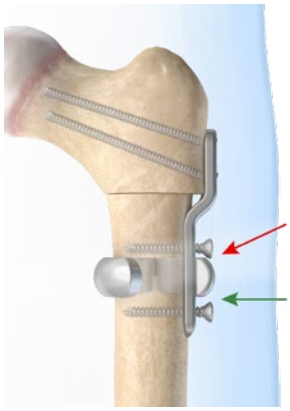


Figure 52: Do not place clamp in top hole

SECURING PLATE TO FEMORAL SHAFT

Distal Fixation

The LPF family of plates features alternating compression slots and locking holes along the plate shaft. If compression is desired, appropriately placed cortical screws must be inserted prior to any locking screws.

Dynamic Compression Screw Placement

Position the appropriate drill bit at the distal end of the compression slot using either the GOLD side of the neutral/load drill guide (Figure 53), or the size-matched side of the double drill guide (not shown).

Drill through both cortices and measure with the appropriate depth gauge (Figure 54).

Insert the chosen screw until the head begins to engage the plate. When engagement begins, simultaneously release some of the pressure exerted by the bone clamp and fully seat the screw into the plate (Figure 55).

With the screw fully seated, the clamp can be removed. If a second compression screw is desired, repeat the steps above. When the head of the second screw begins to engage the plate, loosen the first screw just enough (about ½ turn) to allow the plate to slide further along the femoral shaft. Fully seat the second screw and then re-tighten the first screw.

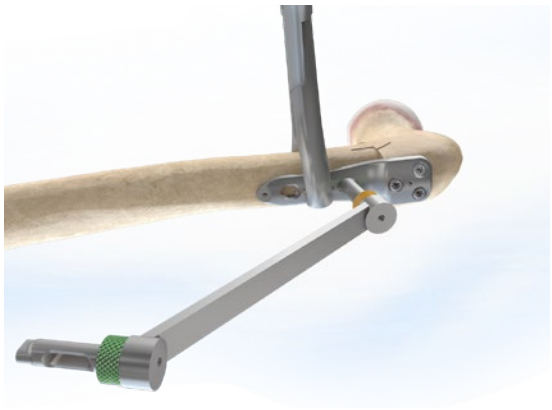


Figure 53: Use the GOLD end of drill guide

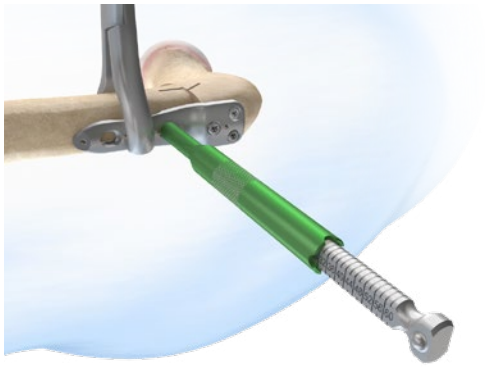


Figure 54: Measure for the screw

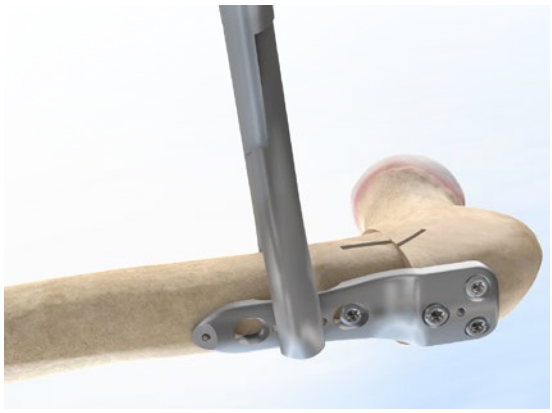


Figure 55: Place the screw

Static Screw Placement

Position the appropriate drill bit at the center or the proximal end of the compression slot using either the GREEN side of the neutral/load drill guide, or the size-matched side of the double drill guide.

Drill through both cortices and measure with the appropriate depth gauge.

Insert the chosen screw until fully seated in the plate. Repeat steps for additional screws, as needed.

Static screws can also be placed through the locking holes. The same procedure is followed, however, the double drill guide must be used, as the oblong ends of the neutral/load drill guide will not fit in the locking holes.

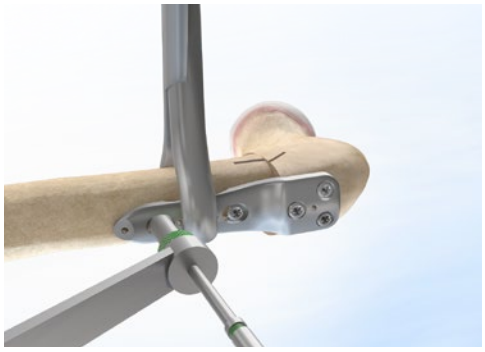


Figure 56a: Position the drill bit with neutral/load drill guide

Figure 56b: Insert the screw

Figure 57a: Position the drill bit with the size matched side of the double drill guide

Figure 57b: Insert the screw

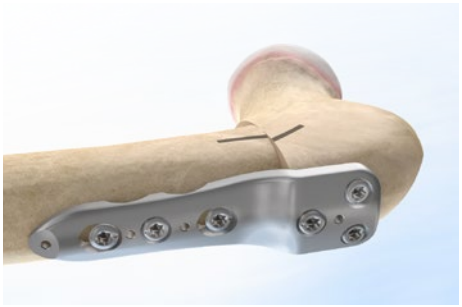


Figure 58: Complete screw insertion

LOCKING SOLID SCREW PLACEMENT

Locking Screw Placement

Mate the appropriate threaded drill guide (tower) to the plate and insert the size-matched calibrated drill bit.

Drill through the near cortex and stop when the far cortex is reached (Figure 59). Note the depth of the drill by reading the calibrations on the back of the tower (Figure 60).

Drill through the far cortex.

Remove the tower. If necessary, manually tap both cortices.

Insert the chosen screw.

Locking screws should be the last screws placed as they create a fixed-angle construct, limiting any potential movement between the plate and the bone.

> **CAUTION:** Failure to adequately tighten locking screws into the plate may lead to screw back-out. Confirm all screws are fully locked prior to closing the incision.

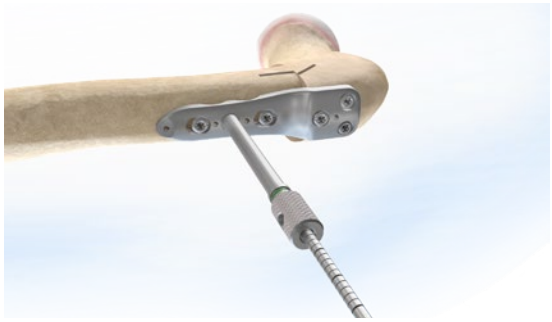


Figure 59: Drill for the screw

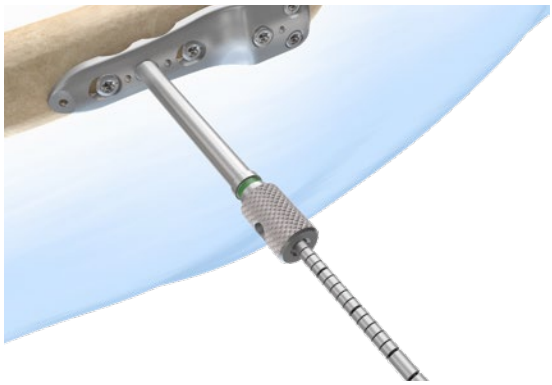


Figure 60: Read the calibrated drill bit to determine screw size

Post-Operative Management

Postoperative management is at the surgeon's discretion. External splinting with a spica cast is advised when using infant plates, owing to the small size of the plate and the likelihood of non-compliance with weight bearing restrictions in this patient population.

IMPLANTS

INFANT PLATES (3.5mm)

Item Number	Angle	Offset (mm)	Holes
00-0907-0103	90°	6	3
00-0907-0143	110°	6	3
00-0907-0183	130°	n/a	3

*special order

3.5mm PLATES

Item Number	Angle	Offset (mm)	Holes
00-0907-1103	90°	6	3
00-0907-1203	90°	12	3
00-0907-1123	100°	6	3
00-0907-1223	100°	12	3
00-0907-1143	110°	6	3
00-0907-1243	110°	12	3
00-0907-1163	120°	6	3
00-0907-1263	120°	12	3
00-0907-2103	130°	n/a	3
00-0907-2104	130°	n/a	4
00-0907-2106	130°	n/a	6
00-0907-2108	130°	n/a	8
00-0907-2110	130°	n/a	10
00-0907-4104	140°	n/a	4
00-0907-3103	150°	n/a	3
00-0907-3105	150°	n/a	5

IMPLANTS

4.5mm PLATES

Item Number	Angle	Offset (mm)	Holes
00-0907-1303	90°	6	3
00-0907-1304	90°	6	4
00-0907-1403	90°	14	3
00-0907-1404	90°	14	4
00-0907-1324	100°	6	4
00-0907-1424	100°	14	4
00-0907-1344	110°	6	4
00-0907-1444	110°	14	4
00-0907-1364	120°	6	4
00-0907-1464	120°	14	4
00-0907-2203	130°	n/a	3
00-0907-2204	130°	n/a	4
00-0907-2206	130°	n/a	6
00-0907-2208	130°	n/a	8
00-0907-2210	130°	n/a	10
00-0907-4204	140°	n/a	4
00-0907-3203	150°	n/a	3
00-0907-3205	150°	n/a	5

IMPLANTS

3.5mm SELF TAPPING CORTICAL SCREW WITH T15 HEXALOBE

Item Number	Size (mm)
00-0903-2510	10
00-0903-2512	12
00-0903-2514	14
00-0903-2516	16
00-0903-2518	18
00-0903-2520	20
00-0903-2522	22
00-0903-2524	24
00-0903-2526	26
00-0903-2528	28
00-0903-2530	30
00-0903-2532	32
00-0903-2534	34
00-0903-2536	36
00-0903-2538	38
00-0903-2540	40
00-0903-2542	42
00-0903-2544	44
00-0903-2546	46
00-0903-2548	48
00-0903-2550	50
00-0903-2555	55
00-0903-2560	60
00-0903-2565	65
00-0903-2570	70

3.5mm LOCKING CORTICAL SCREW WITH T15 HEXALOBE

Item Number	Size (mm)
00-0903-2610	10
00-0903-2612	12
00-0903-2614	14
00-0903-2616	16
00-0903-2618	18
00-0903-2620	20
00-0903-2622	22
00-0903-2624	24
00-0903-2626	26
00-0903-2628	28
00-0903-2630	30
00-0903-2632	32
00-0903-2634	34
00-0903-2636	36
00-0903-2638	38
00-0903-2640	40
00-0903-2642	42
00-0903-2644	44
00-0903-2646	46
00-0903-2648	48
00-0903-2650	50
00-0903-2655	55
00-0903-2660	60
00-0903-2665	65
00-0903-2670	70

3.5mm CANNULATED SCREW WITH T15 HEXALOBE

Item Number	Size (mm)
00-0907-3730	30
00-0907-3732	32
00-0907-3734	34
00-0907-3736	36
00-0907-3738	38
00-0907-3740	40
00-0907-3745	45
00-0907-3750	50
00-0907-3755	55
00-0907-3760	60
00-0907-3765	65
00-0907-3770	70

IMPLANTS

4.5mm SELF TAPPING CORTICAL SCREW WITH T20 HEXALOBE

Item Number	Size (mm)
00-0907-4510	10
00-0907-4512	12
00-0907-4514	14
00-0907-4516	16
00-0907-4518	18
00-0907-4520	20
00-0907-4522	22
00-0907-4524	24
00-0907-4526	26
00-0907-4528	28
00-0907-4530	30
00-0907-4532	32
00-0907-4534	34
00-0907-4536	36
00-0907-4538	38
00-0907-4540	40
00-0907-4542	42
00-0907-4544	44
00-0907-4546	46
00-0907-4548	48
00-0907-4550	50
00-0907-4555	55
00-0907-4560	60
00-0907-4565	65
00-0907-4570	70
00-0907-4575	75
00-0907-4580	80

4.5mm LOCKING CORTICAL SCREW WITH T20 HEXALOBE

Item Number	Size (mm)
00-0907-4610	10
00-0907-4612	12
00-0907-4614	14
00-0907-4616	16
00-0907-4618	18
00-0907-4620	20
00-0907-4622	22
00-0907-4624	24
00-0907-4626	26
00-0907-4628	28
00-0907-4630	30
00-0907-4632	32
00-0907-4634	34
00-0907-4636	36
00-0907-4638	38
00-0907-4640	40
00-0907-4642	42
00-0907-4644	44
00-0907-4646	46
00-0907-4648	48
00-0907-4650	50
00-0907-4655	55
00-0907-4660	60
00-0907-4665	65
00-0907-4670	70
00-0907-4675	75
00-0907-4680	80

4.5mm CANNULATED SCREW WITH T20 HEXALOBE

Item Number	Size (mm)
00-0907-4730	30
00-0907-4732	32
00-0907-4734	34
00-0907-4736	36
00-0907-4738	38
00-0907-4740	40
00-0907-4745	45
00-0907-4750	50
00-0907-4755	55
00-0907-4760	60
00-0907-4765	65
00-0907-4770	70
00-0907-4775	75
00-0907-4780	80

INSTRUMENTATION

POSITIONING GUIDES

Item Number	Description
01-1200-0014	Precision Wire Guide, 2.0mm
01-0907-0516	1.6mm Monolithic Wire Guide
01-0907-0520	2.0mm Monolithic Wire Guide
01-0907-0525	2.5mm Monolithic Wire Guide
01-0907-0532	3.2mm Monolithic Wire Guide
01-0907-0100	Infant 1.6mm Wire Guide
01-0907-0101	Infant 2.5mm Wire Guide
01-1200-0069	Triangular Positioning Plate 90-40-50°
01-1200-0070	Triangular Positioning Plate 80-70-30°
01-1200-0071	Triangular Positioning Plate 100-60-20°

GUIDES

Item Number	Description
01-0907-0005	1.6mm Threaded Wire Guide
01-0907-0006	2.0mm Threaded Wire Guide
01-1200-0067	2.5mm Threaded Drill Guide
01-1200-0042	3.2mm Threaded Drill Guide
01-1050-0009	2.5/3.5mm Double Drill Guide
01-1200-0056	3.2/4.5mm Double Drill Guide
01-1200-0054	2.5mm Neutral & Load Drill Guide
01-1200-0055	3.2mm Neutral & Load Drill Guide

GUIDE WIRES

Item Number	Description
01-0907-0020	1.6mm x 230mm Guide Wire
01-0907-0021	2.0mm x 230mm Guide Wire
01-0907-0022	2.0mm x 150mm Guide Wire
01-0907-0025	2.5mm x 200mm Guide Wire
01-0907-0026	3.2mm x 200mm Guide Wire

DRILLS

Item Number	Description
01-0907-0009	2.9mm Cannulated Drill Bit
01-0907-0010	3.5mm Cannulated Drill Bit
01-1050-0032	2.5mm Calibrated Drill Bit
01-1200-0041	3.2mm Calibrated Drill Bit
01-1050-0002	2.5mm Drill Bit
01-1200-0051	3.2mm Drill Bit

TAPS

Item Number	Description
01-1050-0006	3.5mm Cortical Tap
01-1200-0052	4.5mm Cortical Tap

MEASURING DEVICES

Item Number	Description
01-0907-0023	3.5mm Direct Measuring Device
01-0907-0024	4.5mm Direct Measuring Device
01-0999-2001	Depth Gauge Scale, 10-100mm
01-1200-0078	3.5mm Depth Gauge Sleeve (Blue)
01-1200-0079	4.5mm Depth Gauge Sleeve (Green)
01-1200-0079	4.5mm Depth Gauge Sleeve (Green), Long

DRIVERS

Item Number	Description
01-0907-0011	T15 Cannulated Drivers
01-0907-0012	T20 Cannulated Drivers
01-0903-0005	T15 Hexalobe Retaining Driver, Short
01-1200-0087	T15 Hexalobe Retaining Driver, Long
01-1200-0088	T20 Hexalobe Retaining Driver, Short
01-1200-0089	T20 Hexalobe Retaining Driver, Long

QUICK CONNECT HANDLES

Item Number	Description
01-0907-0027	Ratcheting Trilobe Handle
01-1030-001	Mini Inline Ratchet

MISCELLANEOUS

Item Number	Description
01-1200-0074	Infant Bone Clamp
01-1200-0057	Small Bone Clamp
01-1200-0058	Large Bone Clamp
01-1200-0062	Bending Iron - Right
01-1200-0064	Bending Iron - Left
01-1030-007	Screw Forceps

IMPORTANT MEDICAL INFORMATION

Contra-Indications

Metallic bone fixation devices should not be used in patients with:

- active infections in or near the fixation site
- a demonstrated sensitivity to metals
- an inability to follow a post-operative regimen

Warnings

- Federal (USA) law restricts this device to sale by or on the order of a physician.
- Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and the limitations of the instrumentation. Pre-operative procedures, knowledge of applicable surgical techniques, good reduction of bone fragments, proper patient selection and correct placement of the implants are all equally important for the successful use of these products.
- The System is not intended to support the patient's weight as excessive loads may cause the device to fail. Weight bearing will depend upon the fracture pattern and stability, patient compliance and other associated injuries. Progression of weight bearing should be at the discretion of the surgeon.
- Use extreme care in the handling and storage of implants and instruments. Cutting, bending or scratching the surface of metal components can significantly reduce the fatigue strength or corrosion resistance of the implant or instrument.
- Repeat use of a surgical implant is strictly forbidden. Each implant used once must be disposed of properly. This is the same even where it appears to be intact. The device may have small faults or internal stresses that if the item is re-used may lead to fatigue failure.
- Mixing of implants from different suppliers is not recommended for reasons of metallurgy, mechanics and design. We decline all responsibility in the case of implants from different sources being mixed..
- United States: The System has not been tested for safety and compatibility with MRI. Risks of heating, migration, or image artifacts may exist. Physician experience should dictate acceptability of the use of MRI.
- Implant Retrieval. The final decision to recover the implant falls to the surgeon. If the patient is suitable, OrthoPediatrics recommends the retrieval of implants as otherwise they may replace the function of the bone and lead to bone reduction and weakening. This is especially important for young and active patients. Routine removal of internal fixation devices after healing may also reduce the occurrence of symptomatic complications of implant breakage, implant loosening or implant related pain.
- Care should be taken not to cut through surgical gloves when handling any sharp-edged surgical instrument and to take into account the risk of infection if a cut appears.

MRI Safety Information

In non-clinical testing the OrthoPediatrics Locking Proximal Femur and Distal Femoral Osteotomy System implants were determined to be MR-Conditional. A patient with this device can be safely scanned immediately after device placement under the following conditions:

Static Magnetic Field

- Static magnetic field of 1.5 Tesla and 3.0 Tesla
- Maximum spatial gradient magnetic field of 2000 Gauss/cm or less
- Maximum whole-body average specific absorption rate (SAR) of 1.0 W/kg or less for 15 minutes of scanning per pulse sequence

MRI-Related Heating

- Based on measurements and calculations of RF heating according to ASTM F2182, the Orthopediatrics implants are expected to produce a maximum temperature rise of 6.1 °C for a whole body SAR of 1.0 W/kg for a 15-minute scan.

Artifact Information

- MR image quality may be compromised if the area of interest is in the same area or relatively close to the position to OrthoPediatrics implants. The maximum artifact beyond the implant was 55 mm for the spin echo sequence and 60 mm for the gradient echo sequence in a 3.0 Tesla MR system (GE Signa HDxt MR System). Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary. The presence of other implants or the health state of the patient may require a modification of the MR conditions.

IMPORTANT MEDICAL INFORMATION

Adverse Effects

The risks associated with this device are the same as with any metallic internal fixation device. These include, but are not limited to the following:

- Delayed or non-union that may lead to breakage of the implant
- Loss of fixation, attributable to non-union, osteoporosis, unstable comminuted fractures
- Bending, fracture, or migration of the implant
- Metal sensitivity, or allergic reaction to a foreign body
- Limb shortening, or decrease in bone density, due to compression of the fracture or bone resorption
- Pain, discomfort, or abnormal sensations due to the presence of the device
- Nerve damage due to surgical trauma
- Necrosis of bone
- Infection, both deep and superficial
- Death
- Vascular disorders including thrombophlebitis, pulmonary embolus, wound hematomas, avascular necrosis

These adverse effects include adverse effects that are important considerations for metallic internal fixation devices. These risks and general surgical risks should be explained to the patient prior to surgery.

Notes

Notes

CAUTION: Federal law restricts this device to sale by or the order of a Physician.

CAUTION: Devices are supplied Non-Sterile. Clean and sterilize before use according to instructions.

CAUTION: Implants components are single-use. Do not reuse.

CAUTION: Only those instruments and implants contained within this system are recommended for use with this technique. Other instruments or implants used in combination or in place of those contained within this system is not recommended.

NOTE: This technique has been provided by one of our medical advisors only as guidance and it is not intended to limit the methods used by trained and experienced surgeons.

This document is intended exclusively for experts in the field, i.e. physicians in particular, and expressly not for the information of laypersons.

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Instructions For Use (IFU), cleaning instructions, and surgical techniques may be obtained by calling OrthoPediatrics® Customer Service at 574-268-6379. Read and understand indications, warnings, and adverse effects explained in IFU's prior to use.

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2850 Frontier Drive | Warsaw, IN 46582
ph: 574.268.6379 or 877.268.6339 | **fax:** 574.268.6302
www.OrthoPediatrics.com