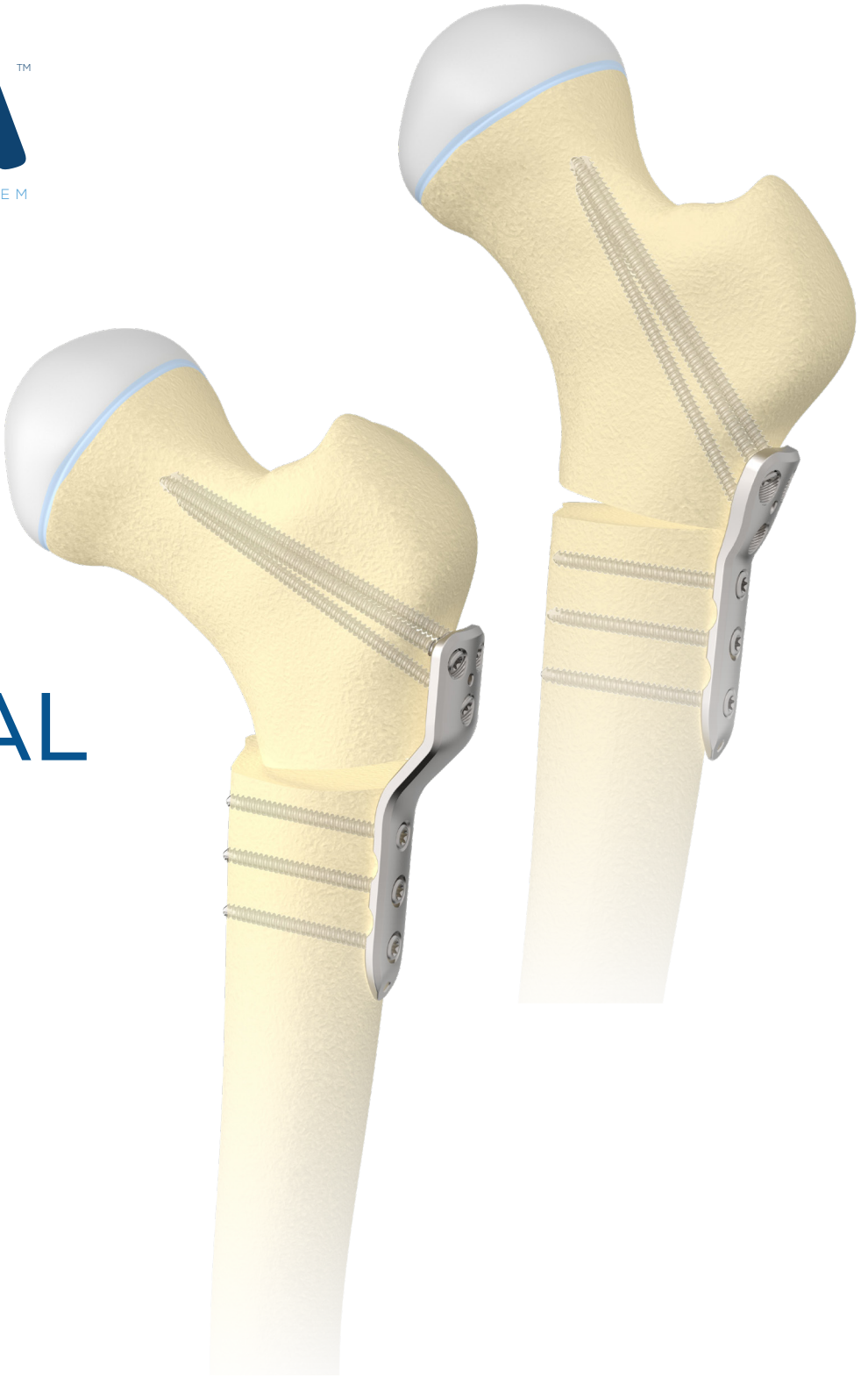
PRiMA™

FEMORAL LOCKING PLATE SYSTEM



PROXIMAL PLATING

Surgical Technique

We **WORK** so they can **PLAY**™

WishBone Medical

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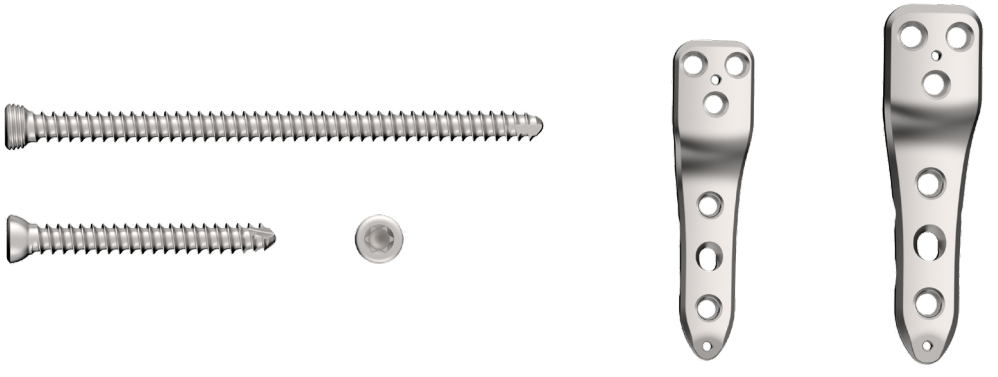
PRIMA™ Proximal Femur Locking Plate System

The PRIMA Proximal Femur Locking Plate System is a complete solution designed to address deformities of the proximal femur as well as aid in trauma reconstruction for the pediatric patient. Surgical interventions include varus osteotomies, valgus osteotomies, rotational corrections, and trauma applications.

The PRIMA Proximal Femur Locking Plate Systems offers two plates sizes (3.5mm and 4.5mm) and five angles (90°, 100°, 110°, 130° and 140°) of varying length and screw holes configurations, allowing surgeons to address a wide variety of surgical applications of the proximal femur in pediatric patients.



3.5mm and 4.5mm bone screws are offered in both locking and non-locking options. Lengths range from 10-70mm.

For product information, including indications, contraindications, warnings, precautions and potential adverse effects, visit www.WishBoneMedical.com.

PRIMA™

FEMORAL LOCKING PLATE SYSTEM

INSTRUMENT KIT COMPONENTS

3.5mm INSTRUMENT KITS

1. Proximal Template Forming Block, 3.5mm
2. Triangular Positioning Plates
   80°/70°/30°, 90°/50°/40°, 100°/60°/20°
3. Proximal Wire Guide, 3.5mm
4. Slotted Protractor, 2.0mm
5. Proximal Bendable Template, 3.5mm
6. 2.5/3.2mm Double-Ended Drill Guide
7. AO Drill Bit, 2.5mm X 200mm (***x2***)
8. Reduction Sleeve, 2.0mm (***x3***)
9. Threaded Guide Tower, 2.5mm (***x3***)
10. Trocar-Tip Guide Wire, 2.0mm X 230mm (***x5***)
11. Trocar-Tip Guide Wire, 2.0mm X 150mm (***x2***)
12. Small Depth Gauge Assembly
13. Screwdriver, Solid, T15
14. Driver Shaft, AO, Solid, T15

4.5mm INSTRUMENT KITS

1. Proximal Template Forming Block, 4.5mm
2. Triangular Positioning Plates
   80°/70°/30°, 90°/50°/40°, 100°/60°/20°
3. Proximal Wire Guide, 4.5mm
4. Slotted Protractor, 2.0mm
5. Proximal Bendable Template, 4.5mm
6. 2.5/3.2mm Double-Ended Drill Guide
7. AO Drill Bit, 3.2mm X 200mm (***x2***)
8. Reduction Sleeve, 2.5mm (***x3***)
9. Threaded Guide Tower, 3.2mm (***x3***)
10. Trocar-Tip Guide Wire, 2.5mm X 230mm (***x5***)
11. Trocar-Tip Guide Wire, 2.0mm X 150mm (***x2***)
12. Small Depth Gauge Assembly
13. Screwdriver, Solid, T20
14. Driver Shaft, AO, Solid, T20

PRE-OPERATIVE PLANNING

Pre-operative planning is crucial to selecting the appropriate implant that will help achieve the desired correction to the proximal femur. Pre-operative X-ray films should be taken in the A/P view to determine the patient's current neck-shaft angle and to plan the desired neck-shaft angle after deformity correction. If the contralateral femur is also abnormal, consider planning a neck-shaft angle of 130° (normal range is 124-136°).

Varus/Valgus Correction

For a varus or valgus correction, start by measuring the current neck-shaft angle and determine the desired neck-shaft angle. If the desired neck shaft angle (Fig. 1) exactly matches one of the WishBone Proximal Femur plate angles (90°, 100°, 110°, 130°, and 140°), insert the initial guide wire in the center of femoral head in both the A/P and lateral planes, as the plate will allow for desired correction.

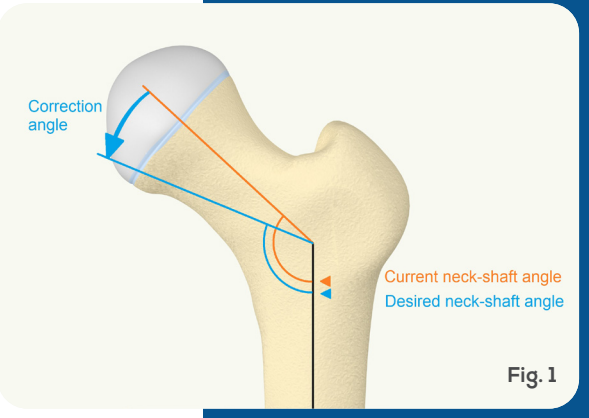


Fig. 1

If the desired neck shaft angle does NOT match the plate angle, the initial guide wire must be inserted off-center in the lateral plane to achieve the desired correction. See example below.

Plate Selection

The plate selected for the procedure should be close to the desired neck-shaft angle.

Example:

Desired neck-shaft angle: 120°

Suggested plate: 110°

Initial Guide Wire Angle

To establish the initial guide wire angle, calculate the angular difference by subtracting the desired neck-shaft angle from the plate intended to be used.

Example:

Suggested plate angle: 110°

Desired neck-shaft angle: 120°

Angular difference: 110°-120 °= -10°

The initial guide wire angle is calculated by adding the angular difference to the current neck-shaft angle.

Example:

Current neck-shaft angle: 145°

Initial guide wire angle: 145°+(-10°) = 135°

To achieve the desired neck-shaft correction angle, the initial guide wire should be inserted at the calculated angle relative to the A/P plane and femoral axis of the femur.

PATIENT POSITIONING & SURGICAL APPROACH

Position the patient in either a supine or lateral position based upon surgeon preference. A radiolucent table is recommended so that fluoroscopy can be used throughout the procedure.

Use a standard lateral subvastus approach to expose the proximal femur.

INITIAL GUIDE WIRE PLACEMENT

INSTRUMENTS

3.5mm Plate
Trocar-Tip Guide Wire, 2.0mm x 150mm (50-900-012015G-X)

4.5mm Plate
Trocar-Tip Guide Wire, 2.0mm x 150mm (50-900-012015G-X)

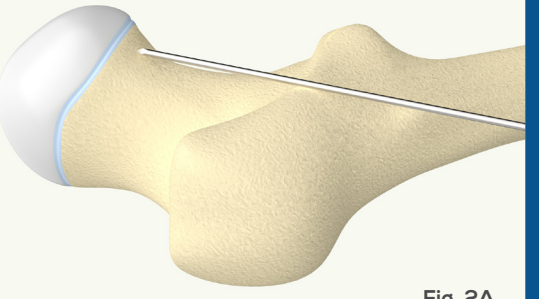


Fig. 2A

Determination of Anteversion

Under lateral fluoroscopy, hold a 2.0mm guide wire on the anterior aspect of the femoral neck so that it is parallel with the central axis of the femoral neck to determine the anteversion (Fig. 2A, 2B).

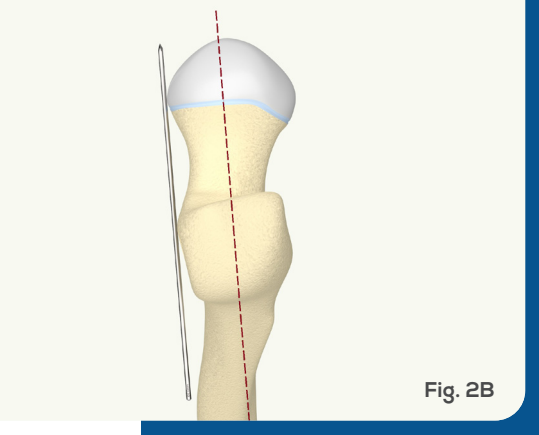


Fig. 2B

INITIAL GUIDE WIRE PLACEMENT, CONT.

Insertion of the Initial Orientation Guide Wire

If the desired neck-shaft angle corresponds to the intended plate to be used, then insert a 2.0mm guide wire toward the center of femoral head in both the A/P and lateral planes as the plate will allow for the desired correction (Fig. 3A, 3B).

INSTRUMENTS

3.5mm Plate
Slotted Protractor, 2.0mm (50-100-100000-X)
Trocar-Tip Guide Wire, 2.0mm x 150mm (50-900-012015G-X)

4.5mm Plate
Slotted Protractor, 2.0mm (50-100-100000-X)
Trocar-Tip Guide Wire, 2.0mm x 150mm (50-900-012015G-X)

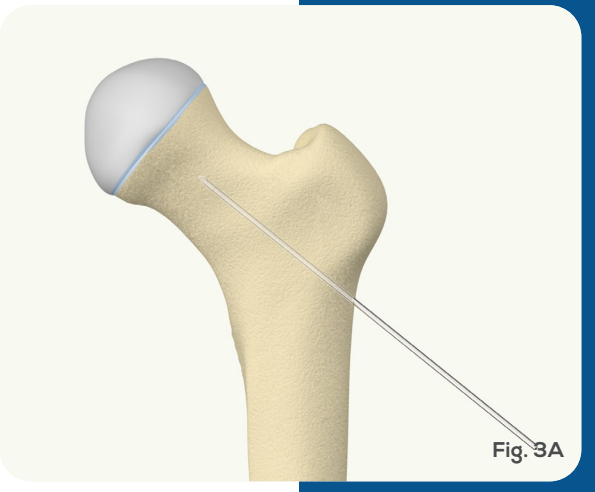


Fig. 3A

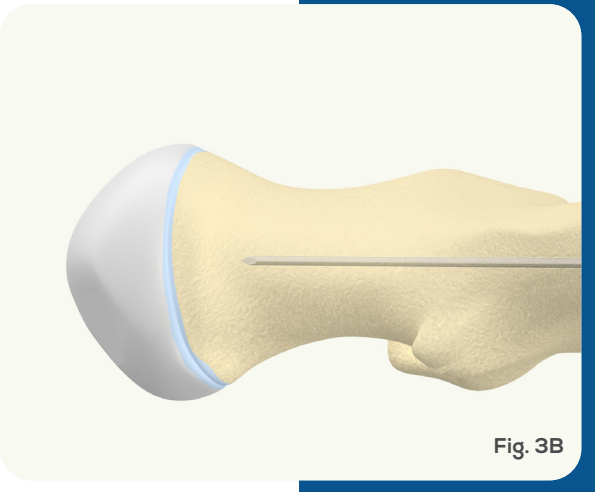


Fig. 3B

If the desired neck shaft angle does NOT match the plate angle, a 2.0mm guide wire should be inserted according to the pre-operative calculated angle. The slotted protractor can be used to guide the insertion angle (Fig. 4). The initial guide wire sets the location and orientation of the plate. The distal stem of the slotted protractor should be touching bone and parallel with the femoral shaft of the femur in the A/P and lateral view. The slotted protractor can be secured to the femoral shaft with a bone clamp or held in place manually.

Under fluoroscopy, insert the orientation guide wire parallel to the anteversion guide wire in the lateral view and advance it up the center of the femoral neck until within approximately 5mm of the femoral head physis. Proper position of the initial orientation guide wire is crucial to an accurate correction. Remove the anteversion guide wire and slotted protractor when satisfactory placement of the initial guide wire has been achieved.

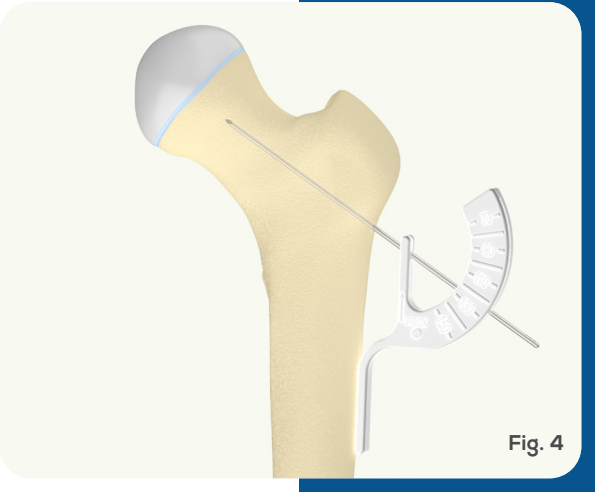


Fig. 4

GUIDE WIRE PLACEMENT FOR THE PROXIMAL SCREWS

INSTRUMENTS

3.5mm Plate
Proximal Wire Guide, 3.5mm (50-113-100000G-X)
Screwdriver, Plastic, Solid, T15 Assembly (SCR-PS15)
Trocar-Tip Guide Wire, 2.0mm x 230mm (50-900-012023G-X)

4.5mm Plate
Proximal Wire Guide, 4.5mm (50-114-100000G-X)
Screwdriver, Plastic, Solid, T20 Assembly (SCR-PS20)
Trocar-Tip Guide Wire, 2.5mm x 230mm (50-900-012523G-X)

Mate the screwdriver to the proximal wire guide by inserting the tip of the screwdriver into the tapered hole on the proximal face of the wire guide (Fig. 5).

Using the screwdriver as a handle, pass the wire guide over the initial guide wire until it abuts the lateral aspect of the proximal femur (Fig. 6).

The initial guide wire sets the location of the plate on the proximal femur; however if flexion or extension is required, the wire guide must be rotated accordingly around the central guide wire before placing the two proximal guide wires. If a neutral plate position is preferred, the wire guide should be in-line with the axis of the femur in the lateral view.

To fix the wire guide in place, pass two guide wires through the proximal holes on the guide. The guide wires should be positioned to within approximately 5mm of the femoral head physis. Placement of the guide wires should be confirmed using fluoroscopy in the A/P and lateral views.

Caution: Failure to confirm satisfactory placement of the initial guide wires with fluoroscopy could lead to screws that penetrate the physis, breach the femoral neck cortex, or cross into the joint space.

Caution: Do not bend the guide wires during insertion through the wire guide as this may result in errored correction or guide wire breakage.

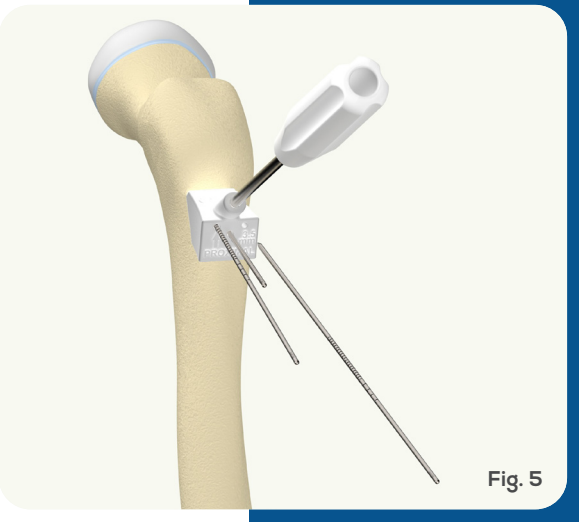


Fig. 5

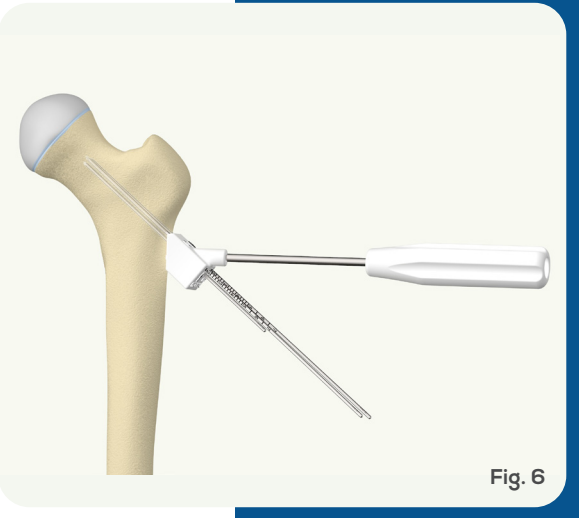


Fig. 6

CREATION OF THE OSTEOTOMY

INSTRUMENTS

3.5mm Plate
Trocar-Tip Guide Wire, 2.0mm x 230mm (50-900-012023G-X)
Triangular Positioning Plate, 80°/70°/30° (50-900-400873G-X)
Triangular Positioning Plate, 90°/50°/40° (50-900-400954G-X)
Triangular Positioning Plate, 100°/60°/20° (50-900-400162G-X)

4.5mm Plate
Trocar-Tip Guide Wire, 2.5mm x 230mm (50-900-012523G-X)
Triangular Positioning Plate, 80°/70°/30° (50-900-400873G-X)
Triangular Positioning Plate, 90°/50°/40° (50-900-400954G-X)
Triangular Positioning Plate, 100°/60°/20° (50-900-400162G-X)

To account for rotational correction, it is recommended prior to making an osteotomy that guide wires are inserted into the femur, or the bone is scored longitudinally to help assess the achieved amount of internal or external correction.

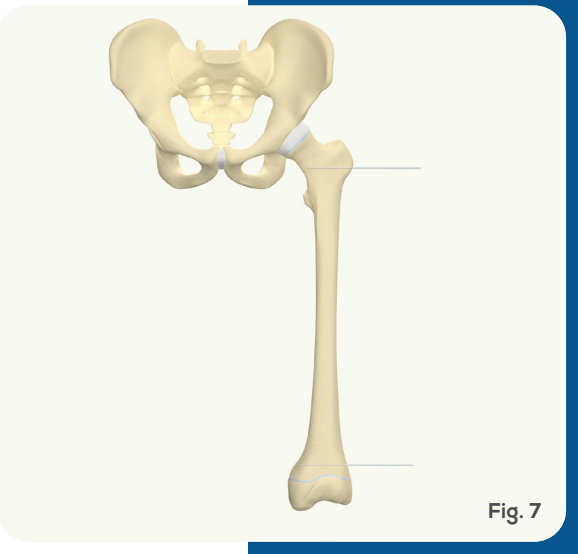


Fig. 7

Option 1 (Guide Wires):

Insert guide wires bicortically into the proximal and distal fragments (Fig. 7). These wires can be used as a guide to control and assess rotational correction. The wire in the proximal fragment should be positioned just proximal to the wire guide so to not interfere with the head of the plate. The wire in the distal fragment can be placed percutaneously and must be distal enough so to not interfere with the shaft of the plate.

Wires may be placed while utilizing true A/P images on fluoroscopy (centered patella for distal marking wire and an orthogonal femoral neck/physis image for the proximal wire). Upon placing the wires parallel to the floor using these images, the wires will be essentially orthogonal to their respective rotational axis. The angle between the wires as viewed axially from the foot should match the preoperative clinical rotational profile and planned rotational correction. After the osteotomy, rotating the femur so the wires are parallel will recreate normal femoral anteversion.

Alternatively, if the wires are not placed orthogonal to the axes, the triangular positioning plates can be used to account for rotational correction. Even if no internal or external rotation is planned, it is recommended to insert the two guide wires to ensure the planned rotational alignment is achieved.

CREATION OF THE OSTEOTOMY

Option 2 (Scoring/Marking the Bone):

Using either a sagittal saw or a marking pen, mark an anterior longitudinal line on the axis of the femur that will extend to both sides of the osteotomy to help judge alignment and rotation of the correction (Fig. 8). The length of the mark should account for any femur shortening planned.

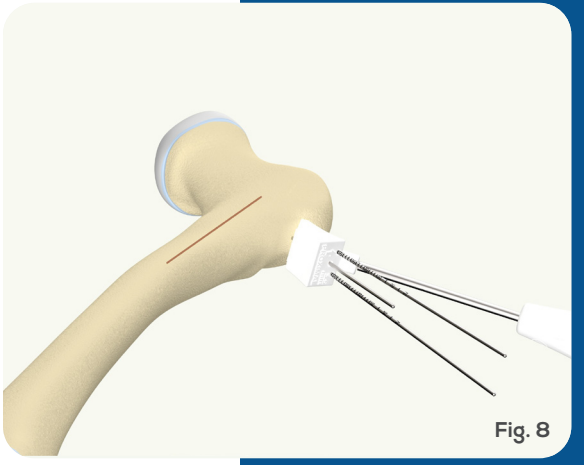


Fig. 8

VARUS CORRECTIONS: 90°, 100°, 110° PLATES

Insertion of the Initial Orientation Guide Wire

Transverse Osteotomy

The starting point for a transverse osteotomy can be referenced off the distal end of the proximal wire guide (Fig. 9). The osteotomy should not be made proximal to the distal edge of the wire guide to ensure all three proximal screws have adequate bone purchase and do not pass through the osteotomy site.

Perform the osteotomy in one perpendicular cut to the shaft of the femur. A single cut osteotomy preserves femoral length at the expense of bone contact at the osteotomy site.

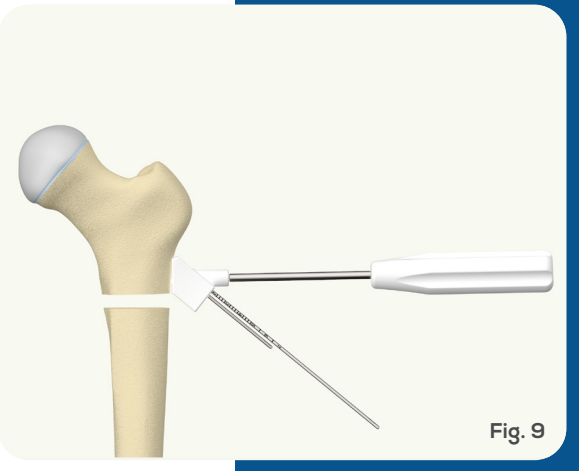


Fig. 9

VARUS CORRECTIONS: 90°, 100°, 110° PLATES

Insertion of the Initial Orientation Guide Wire

Closing Wedge Osteotomy

If a closing wedge osteotomy is planned and the desired neck shaft angle matches the plate angle, the first cut should be parallel to the two proximal guide wires. The starting point for this oblique cut can be referenced off the distal end of the proximal wire guide, and the cut can be made directly off of the wire guide reference face (Fig. 10).

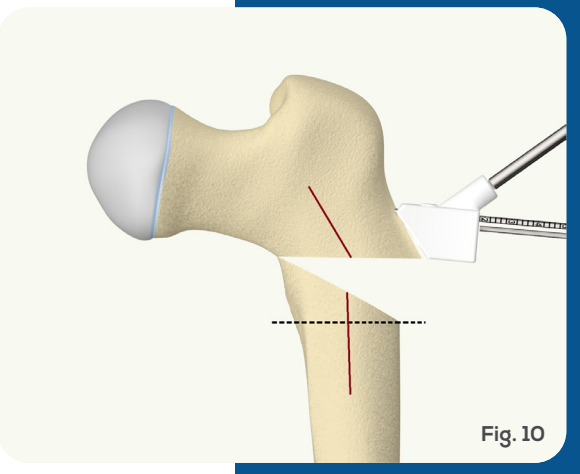


Fig. 10

The osteotomy starting point should not be made proximal to the distal edge of the wire guide to ensure all three proximal screws have adequate bone purchase and do not pass through the osteotomy site.

Following the oblique osteotomy, a second cut can be made transverse to the shaft of the femur, using the same starting point on the lateral cortex.

Note: If the desired neck shaft angle does not match the plate angle, the triangular positioning plates can be used as a reference for the angle of the oblique osteotomy relative to the transverse plane of the femur (Fig. 11).

Oblique Osteotomy Angle =
Current Neck Shaft Angle – Desired Neck Shaft Angle

Caution: Incorrect placement of the initial oblique osteotomy may result in non-conforming plate to bone contact with the proximal fragment, or the most distal proximal screw on the head of the plate may pass through the osteotomy.

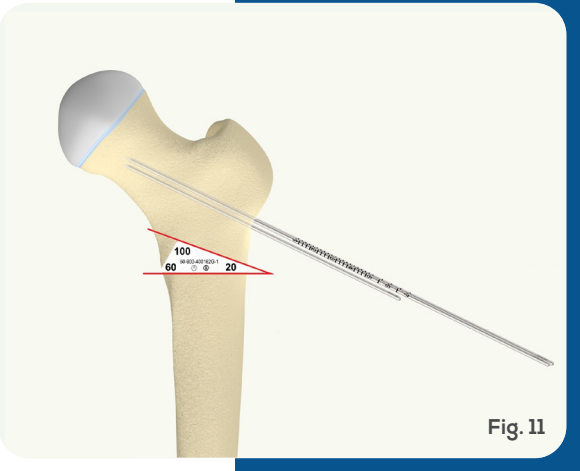


Fig. 11

Note: If there is concern that the initial oblique osteotomy may violate the calcar, a partial closing wedge may be performed. A transverse osteotomy may be made first, followed by an oblique osteotomy started more medial on the proximal fragment to preserve some length while retaining more bone contact than a single cut osteotomy.

VALGUS CORRECTIONS: 130°, 140° PLATES

Insertion of the Initial Orientation Guide Wire

Transverse Osteotomy

The starting point for a transverse osteotomy can be located by using the width of the head of the bendable template. Remove the initial orientation guide wire and place the bendable template head against the two proximal guide wires and mark the femur on the opposite side of the plate (Fig. 12).

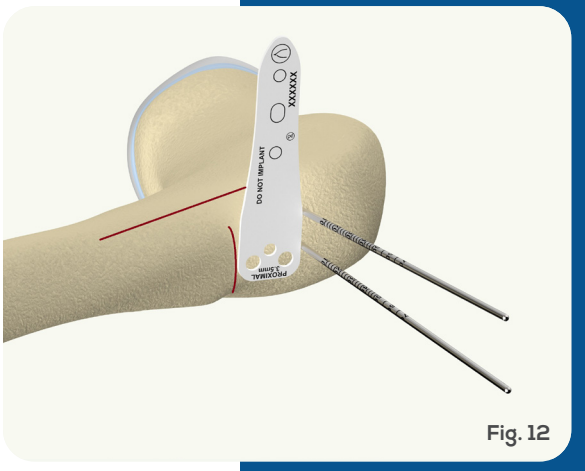


Fig. 12

This will signify the starting location for the transverse osteotomy. The cut should be made perpendicular to the shaft of the femur (Fig 13).

Following the osteotomy, the lateral cortex of the proximal fragment will contact the cut surface of the distal fragment. The contact area between the two fragments can be increased by removing a piece of bone from the lateral cortex of the proximal fragment, at the expense of a few mm of length (Fig. 14).

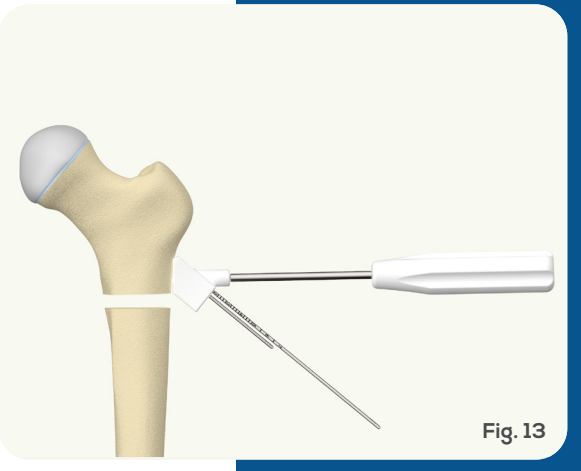


Fig. 13

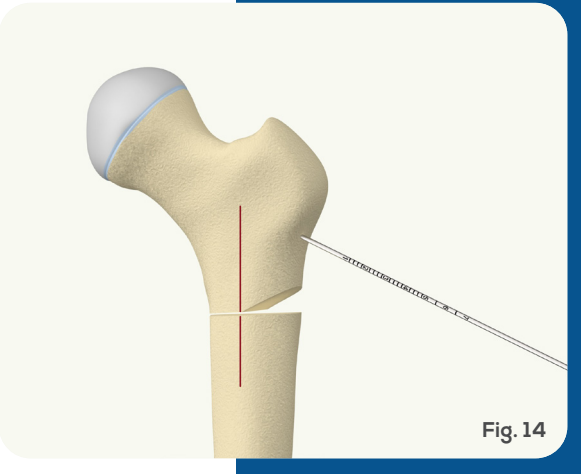


Fig. 14

INTRA-OPERATIVE PLATE TEMPLATING & PLATE SELECTION

INSTRUMENTS

3.5mm Plate
Proximal Bendable Template, 3.5mm (50-113-300000G-X)
Proximal Template Forming Block, 3.5mm (50-113-300002G-X)

4.5mm Plate
Proximal Bendable Template, 4.5mm (50-114-300000G-X)
Proximal Template Forming Block, 4.5mm (50-114-300002G-X)

The proximal femur bendable template can be used in one of two ways to confirm the most optimal Proximal Femur Locking Plate offset or flare.

Option 1: Slide the bendable template over the existing guide wires and form the shape of the plate directly on the bone to determine the desired amount offset (Fig. 15). Remove the bendable template and compare its shape to the proximal template forming block to determine the optimal plate offset.

Option 2: Place the proximal femur bendable template over the post on the proximal template forming block that corresponds to the estimated plate offset to be implanted. Bend the template so to match the forming block (Fig. 16). Next, pass the template over the guide wires to get a visual representation as to how the final implant will contact the bone. If the implant fit is suboptimal, form the bendable template to the other offset offering and retrial its fit on the bone.

Note: The 3.5mm proximal femur bendable template approximates the length of a 3-hole plate. The 4.5mm proximal femur bendable template approximates the length of a 4-hole plate.

Open the selected Proximal Femur Locking Plate implant.

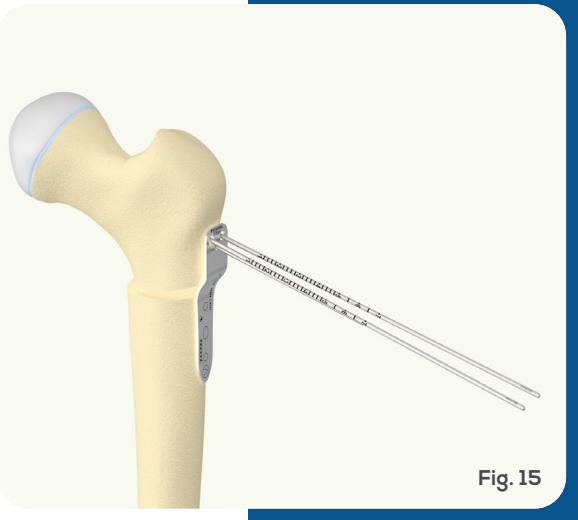


Fig. 15

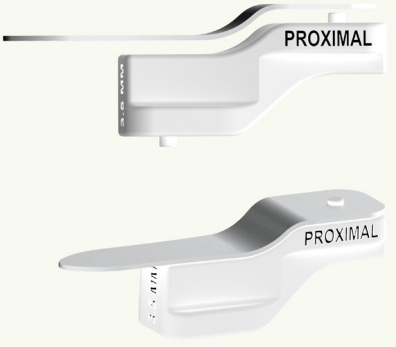


Fig. 16

FIXATION OF THE PROXIMAL FRAGMENT

INSTRUMENTS

3.5mm Plate
Threaded Guide Tower, 2.5mm (50-900-302500G-X)
Reduction Sleeve, 2.0mm (50-900-300020G-X)
Trocar-Tip Guide Wire, 2.0mm x 230mm (50-900-012023G-X)
Driver Shaft, AO, Solid T15 (50-900-201T15G-X)
Screwdriver, Plastic, Solid, T15 Assembly (SCR-PS15)

4.5mm Plate
Threaded Guide Tower, 3.2mm (50-900-303200G-X)
Reduction Sleeve, 2.5mm (50-900-300025G-X)
Trocar-Tip Guide Wire, 2.5mm x 230mm (50-900-012523G-X)
Driver Shaft, AO, Solid T20 (50-900-201T20G-X)
Screwdriver, Plastic, Solid, T20 Assembly (SCR-PS20)

Thread three threaded guide towers to the proximal screw holes on the head of the plate. Next, assemble three reduction sleeves to the threaded guide towers by threading each into the guide towers until the reduction sleeve is flush against the top of the guide tower (Fig 17).

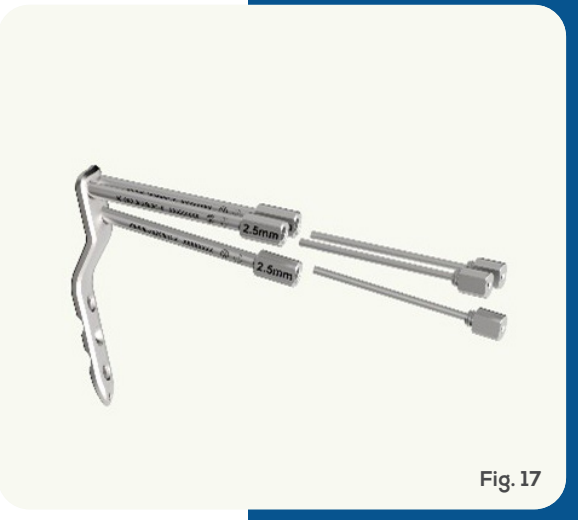


Fig. 17

Caution: Be sure to not cross-thread the guide tower to the plate. This may affect the guide wire trajectory and cause the screws to not lock into the plate.

With the threaded guide towers and reduction sleeve secured to the plate, pass the plate over the three existing guide wires until it abuts the lateral cortex of the femur.

Note: If experiencing difficulty passing the plate over the guide wires, the reduction sleeves can be removed and reattached once the plate is seated.

Note: If the plate does not sit flush with the proximal fragment and is too far off the bone, it may be helpful to remove a small bone wedge from the lateral cortex at the osteotomy site to optimize the position and contact of the plate and the proximal segment (Fig. 18).

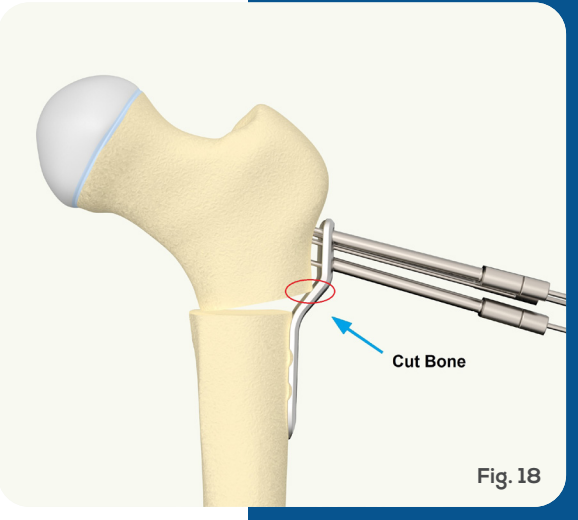


Fig. 18

With the plate properly positioned against the proximal fragment, the orientation guide wire can be removed and a guide wire can be placed into the distal screw hole on the proximal portion of the plate. The guide wire should be inserted to within approximately 5mm of the femoral head physis.

For each screw hole on the head of the plate, remove the guide wire and reduction sleeve. Enlarge the guide wire hole using the provided drill to drill through the guide tower until within approximately 5mm of the femoral head physis (Fig. 19). Confirm the screw length by reading the calibration markings on the end of the drill bit relative to the end of the threaded guide tower.

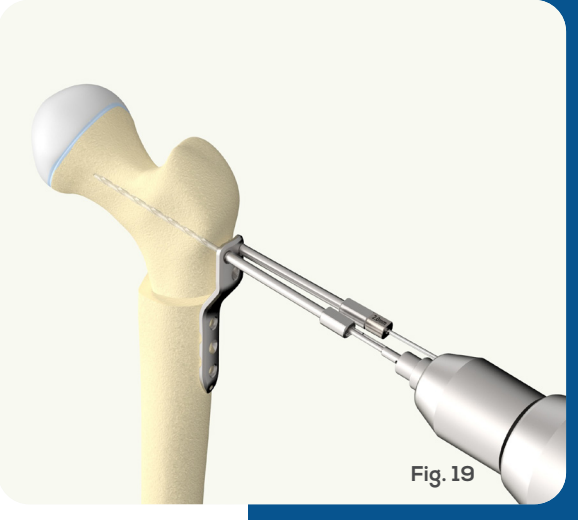


Fig. 19

Remove the drill bit and unthread the guide tower from the plate. Continue to screw insertion.

FIXATION OF THE PROXIMAL FRAGMENT, CONT.

Note: Fixation of the proximal head/neck segment should always be performed with locking screws. The locking screws should be implanted to within approximately 5mm of the femoral head physis.

Locking Screw Insertion by Hand:

Use the appropriate screwdriver to insert the screw by hand until the head is locked to the plate (Fig. 20).

Locking Screw Insertion with Power:

Connect the AO screwdriver to power and drive the screw (under low speed) until just proud of the plate (Fig. 21). Lock the screw to the plate using the manual screwdriver.

Note: Do not fully tighten the screw to the plate under power. Final tightening should always take place by hand.

Caution: Failure to adequately lock a locking screw to the plate may lead to the screw backing out

Repeat the steps described above for the remaining two screw holes on the head of the plate.

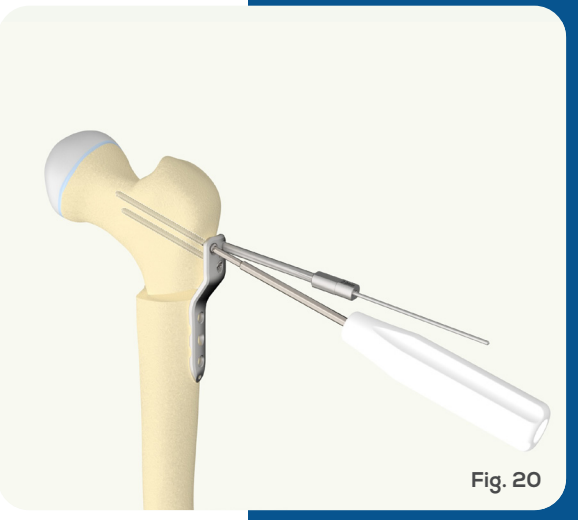


Fig. 20

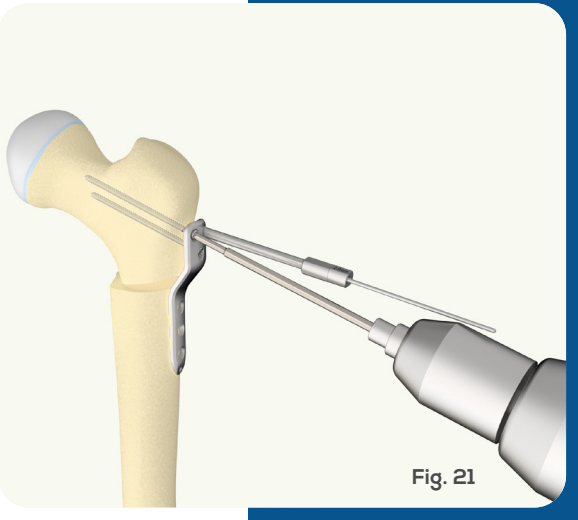


Fig. 21

REDUCTION

INSTRUMENTS

3.5mm Plate
Trocar-Tip Guide Wire, 2.0mm x 150mm (50-90-012015G-X)

4.5mm Plate
Trocar-Tip Guide Wire, 2.0mm x 150mm (50-90-012015G-X)

For optimal fixation, the plate should be parallel with the femoral shaft axis in the A/P and lateral views. Secure the distal fragment to the plate using a bone clamp.

Confirm rotation of the fragments.

Note: If referencing the previously placed rotation marking on the shaft of the femur, use the location of the mark on the distal and proximal fragments to judge relative rotation.

Note: If utilizing the guide wire to assess rotational correction, axial alignment is achieved when the proximal and distal guide wires are parallel to one another.

DISTAL SCREW PLACEMENT

INSTRUMENTS

3.5mm Plate
AO Drill Bit, 2.5mm x 200mm (50-900-102520G-X)
2.5/3.2 Double-Ended Drill Guide (50-900-312532G-X)
Small Depth Gauge Assembly (10-1000-SML-DPA)
Threaded Guide Tower, 2.5mm (50-900-302500G-X)
Screwdriver, Plastic, Solid, T15 Assembly (SCR-PS15)
Driver Shaft, AO, Solid, T15 (50-900-201T15G-X)

4.5mm Plate
AO Drill Bit, 3.2mm x 200mm (50-900-103220G-X)
2.5/3.2 Double-Ended Drill Guide (50-900-312532G-X)
Small Depth Gauge Assembly (10-1000-SML-DPA)
Threaded Guide Tower, 3.2mm (50-900-303200G-X)
Screwdriver, Plastic, Solid, T20 Assembly (SCR-PS20)
Driver Shaft, AO, Solid, T20 (50-900-201T20G-X)

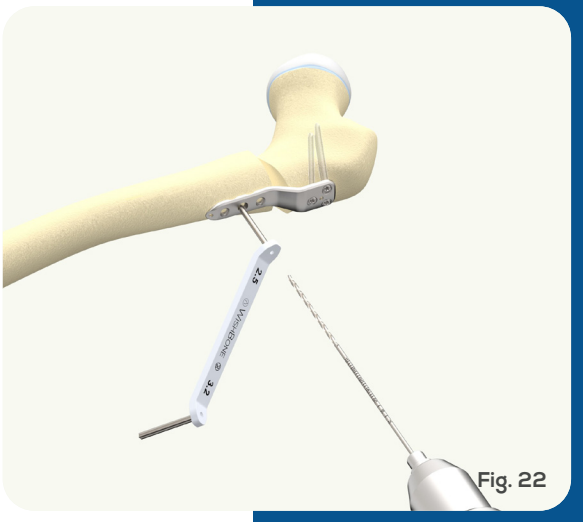


Fig. 22

Locking or non-locking screws can be used on the shaft of the plate. If compression is required, a non-locking screw should always be placed before any locking screws are inserted.

Compression Hole with Compression

To obtain compression, place the double-ended drill guide in the most distal end of the compression slot (Fig. 22). Pass the provided drill through the guide and drill through both cortices (Fig. 23).

Use the depth gauge to measure for the screw length (Fig. 24).

Insert the non-locking screw and use the manual screwdriver to advance the screw until the screw head begins to engage the plate. When engagement starts to occur, unlock the bone clamp to allow for compression and complete screw insertion manually.

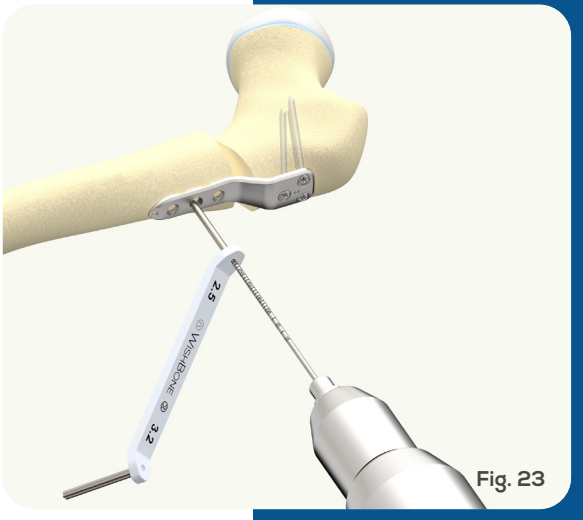


Fig. 23

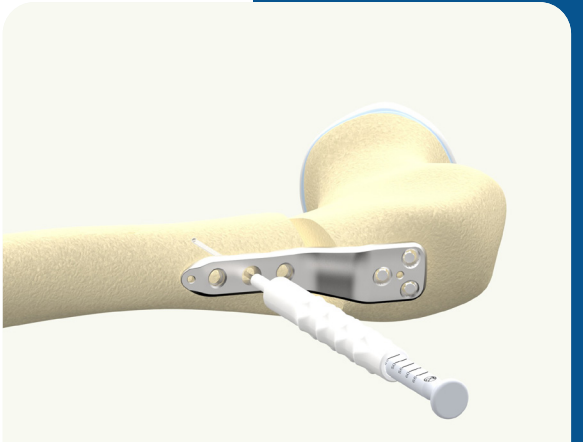


Fig. 24

DISTAL SCREW PLACEMENT, CONT.

Compression Hole without Compression

If compression is not desired, place the double-ended drill guide in the center or proximal end the compression slot. Pass the provided drill through the guide and drill through both cortices.

Use the depth gauge to measure for the screw length.

Insert the non-locking screw and use the manual screwdriver to advance the screw until the screw head engages the plate.

Locking Holes with Locking Screws

Assemble the threaded guide tower to the plate and use the drill to drill through both cortices.

Confirm the screw length by reading the calibration markings on the end of the drill bit relative to the end of the threaded guide tower or remove the threaded guide tower and use the depth gauge to measure for the screw length.

Insert the locking screw and use the manual screwdriver to advance the screw until the screw head is locked to the plate.

Locking Holes with Non-Locking Screws

If a non-locking screw is desired, place the double-ended drill guide in the center of the screw hole. Pass the provided drill through the guide and drill through both cortices.

Use the depth gauge to measure for the screw length.

Insert the non-locking screw and use the manual screwdriver to advance the screw until the screw head engages the plate.

Repeat the steps described above for the remaining shaft holes. If using guide wires to assess rotational correction both the proximal and orientation wire can be removed. A final fluoroscopic image can be taken to confirm the desired correction has been achieved and the plate and screws are in the proper position (Fig. 25).

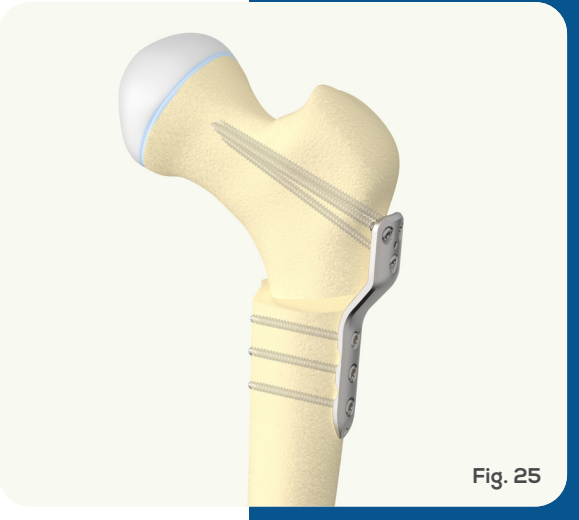


Fig. 25

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Caution: Federal law restricts this device to sale by or on the order of a physician.

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