PRiMA™

FEMORAL LOCKING PLATE SYSTEM

DISTAL PLATING

Surgical Technique

We **WORK** so they can **PLAY**™

WishBone Medical

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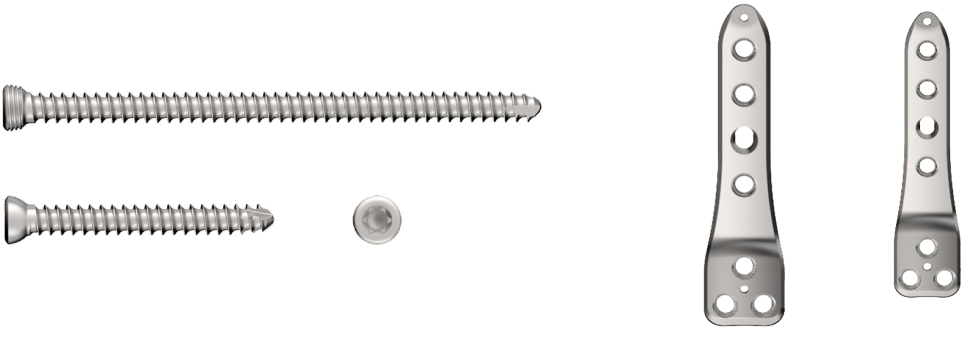
PRIMA™ Distal Femur Locking Plate System

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

The PRIMA Distal Femur Locking Plate Systems offers two plates sizes (3.5mm and 4.5mm) at an 85° angle helping surgeons to avoid the physis during screw insertion. The plates are offered in varying length and screw holes configurations, allowing surgeons to address a wide variety of surgical applications of the distal 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™

DISTAL FEMUR LOCKING PLATE SYSTEM

INSTRUMENT KIT COMPONENTS

3.5mm INSTRUMENT KITS

1. Distal Template Forming Block, 3.5mm
2. Triangular Positioning Plates
   80°/70°/30°, 90°/50°/40°, 100°/60°/20°
3. Distal Wire Guide, 3.5mm
4. Distal Bendable Template, 3.5mm
5. 2.5/3.2mm Double-Ended Drill Guide
6. AO Drill Bit, 2.5mm X 200mm (***x2***)
7. Reduction Sleeve, 2.0mm (***x3***)
8. Threaded Guide Tower, 2.5mm (***x3***)
9. Trocar-Tip Guide Wire, 2.0mm X 230mm (***x4***)
10. Trocar-Tip Guide Wire, 2.0mm X 150mm (***x2***)
11. Small Depth Gauge Assembly
12. Screwdriver, Solid, T15
13. Driver Shaft, AO, Solid, T15

4.5mm INSTRUMENT KITS

1. Distal Template Forming Block, 4.5mm
2. Triangular Positioning Plates
   80°/70°/30°, 90°/50°/40°, 100°/60°/20°
3. Distal Wire Guide, 4.5mm
4. Distal Bendable Template, 4.5mm
5. 2.5/3.2mm Double-Ended Drill Guide
6. AO Drill Bit, 3.2mm X 200mm (***x2***)
7. Reduction Sleeve, 2.5mm (***x3***)
8. Threaded Guide Tower, 3.2mm (***x3***)
9. Trocar-Tip Guide Wire, 2.5mm X 230mm (***x4***)
10. Trocar-Tip Guide Wire, 2.0mm X 150mm (***x2***)
11. Small Depth Gauge Assembly
12. Screwdriver, Solid, T20
13. Driver Shaft, AO, Solid, T20

PRE-OPERATIVE PLANNING

Pre-operative planning is crucial to selecting the appropriate plate that will help achieve the desired correction to the distal femur. Pre-operative x-ray films, CT scans and physical examination can help plan the desired correction.

When performing a distal femoral extension osteotomy in the sagittal plane, clinical examination and lateral x-ray films can be used to determine the degree of knee flexion contracture and/or measurement of the tibio-femoral angle. Segmental analysis of the PDFA (proximal distal femoral angle) and PPTA (posterior proximal tibia angle) can determine the bone versus soft tissue components contributing to the overall flexion (or extension) deformity. Typically, the anterior wedge of bone removed during an extension osteotomy will match the magnitude of flexion contracture.

When performing a distal femoral osteotomy in the coronal plane (varus or valgus producing), clinical examination and standing full-length AP X-ray films can be used to determine the angle of correction. The angle of correction is calculated based on the angle formed between the mechanical axis of the femur and tibia. Segmental analysis of the mLDFA (mechanical lateral distal femoral angle) and MPTA (medial proximal tibia angle) can determine the respective contributions of the femur and tibia to guide appropriate surgical planning

PATIENT POSITIONING & SURGICAL APPROACH

Position the patient in a supine position with a hip or sacral bump as needed. A radiolucent table is recommended so that fluoroscopy can be used throughout the procedure. Prep and drape the entire affected extremity from the foot to the hip.

Use a standard lateral approach to expose the distal femur, utilizing a longitudinal incision through the iliotibial band and a subvastus approach to the 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)

Locate the Frontal Plane

Optional: Position the leg so that the patella is perfectly anterior and in the midline. Following subperiosteal preparation of the distal femur, place a 2.0mm guide wire extra-periosteally across the front of the femur in the frontal plane (Fig. 1).

The guide wire should be positioned approximately 1cm proximal to the physis and parallel to the joint-line.

Confirm placement of the guide wire with fluoroscopy.

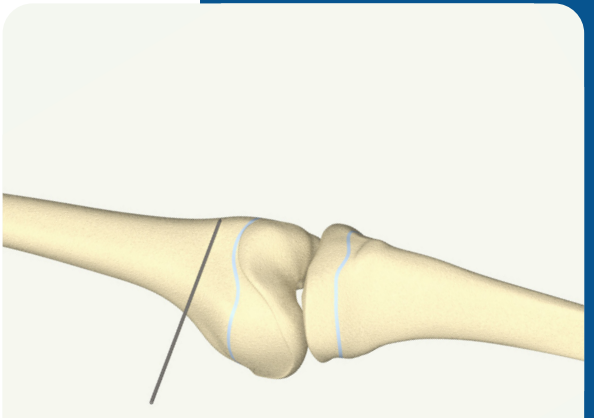


Fig. 1

Insertion of the Initial Orientation Guide Wire

The bendable template can be used to the locate the position of the initial orientation guide wire. Place the distal edge of the bendable template approximalty 2mm proximal to the physis and mark the position of the orientation guide wire (Fig. 2). This will ensure the distal edge of the implant will be just proximal to the physis.

Insert a 2.0mm guide wire parallel to the distal femoral physis. This will be used to orient the location of the plate on the distal femur.

The orientation guide wire should be inserted parallel to the extra-periosteal guide wire and centered in the A/P plane of the femur. This will ensure there is not an unwanted correction angle, while allowing the distal wire guide to be rotated for correction in the sagittal plane and ensuring there will be bone contact for the guide wires that correspond to location of the distal screws.

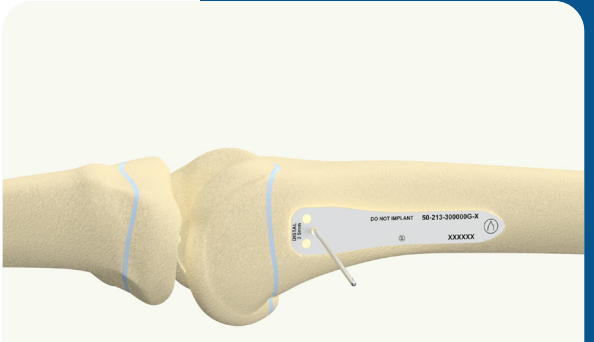


Fig. 2

GUIDE WIRE PLACEMENT FOR THE DISTAL SCREWS

INSTRUMENTS

3.5mm Plate
Trocar-Tip Guide Wire, 2.0mm x 230mm (50-900-012023G-X)
Distal Wire Guide, 3.5mm (50-213-100000G-X)
Screwdriver, Plastic, Solid, T15 Assembly (SCR-PS15)

4.5mm Plate
Trocar-Tip Guide Wire, 2.5mm X 230mm (50-900-012523G-X)
Distal Wire Guide, 4.5mm (50-214-100000G-X)
Screwdriver, Plastic, Solid, T20 Assembly (SCR-PS20)

Mate the screwdriver to the distal wire guide by inserting the tip of the screwdriver into the tapered hole on the distal face of the wire guide (Fig. 3).

Using the screwdriver as a handle, pass the wire guide over the initial orientation guide wire until it abuts the lateral aspect of the distal femur.

The initial orientation guide wire sets the location of the plate on the distal femur. Rotate the wire guide to achieve the desired correction in the sagittal plane. Typically, this is achieved by positioning the screwdriver handle to be parallel with the mechanical axis of the tibia with the leg in maximum passive extension.

Note: Factor in and perform any soft tissue releases before proceeding to the planned correction

With the distal wire guide in the desired position fix it in place by passing two guide wires through the distal holes on the guide (Fig. 4). These guide wires can be place either unicortically or bicortically based on surgeon preference. If passing guide wires bicortically, ensure the physis is not violated.

Caution: Failure to confirm satisfactory placement of the initial guide wires with fluoroscopy could lead to screws that penetrate the physis 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.

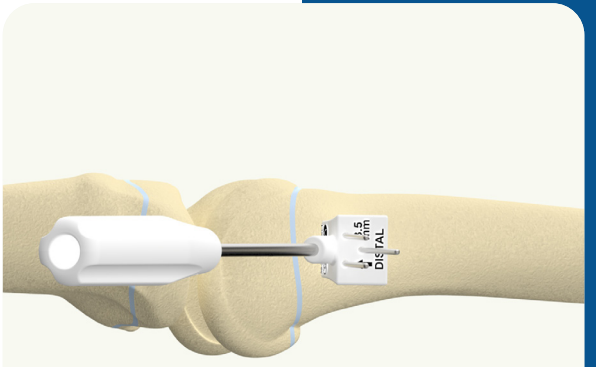


Fig. 3

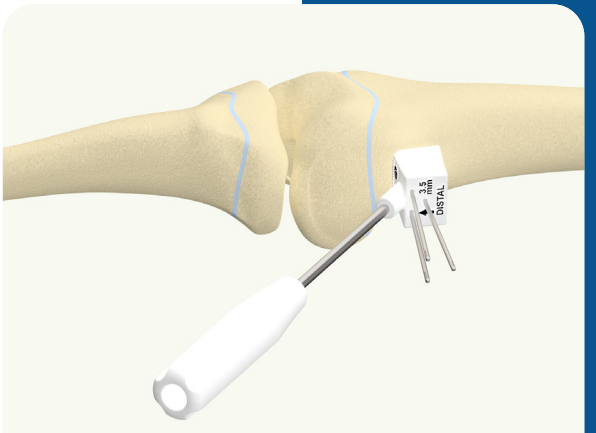


Fig. 4

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 to insert the guide wires into the femur prior to making the osteotomy, or score the bone longitudinally to help assess the achieved amount of internal or external correction.

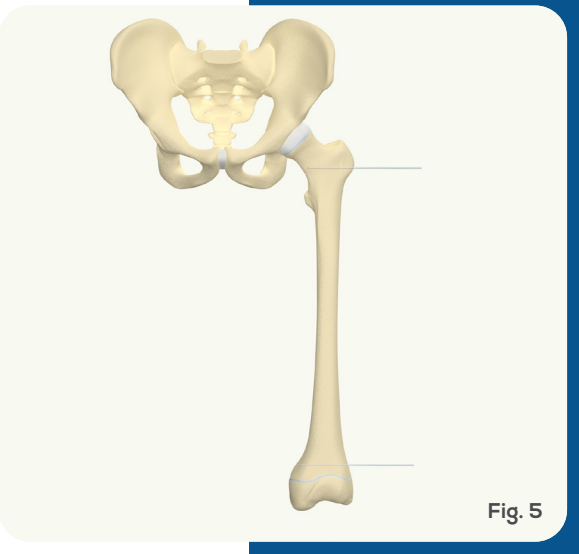


Fig. 5

Option 1 (Guide Wires):

Insert a guide wire into the proximal fragment bicortically. Confirm the proximal femur is in a true A/P view with fluoroscopy and advance the wire parallel to the floor. This wire can be placed percutaneously or within the surgical site. The proximal wire should be positioned proximal enough so to not interfere with the shaft of the final implant.

The orientation guide wire can be used as the reference on the distal fragment to control and assess rotational correction. The angle created between the wires should equal the pre-operative planned rotational correction as measured by prone rotational profile in the physical exam. After osteotomy, rotate the wires to parallel and thereby correct the rotational deformity and create normal anteversion.

Alternatively, 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 a lateral longitudinal line on the axis of the femur that extends to both sides of the osteotomy to help judge alignment and rotation of the correction (Fig. 6). The length of the mark should account for any femur shortening planned.

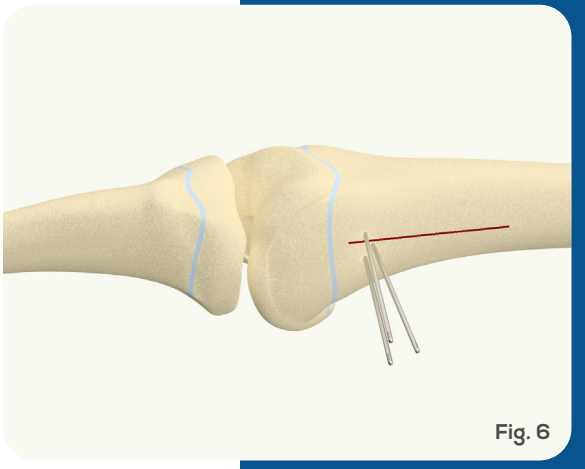


Fig. 6

Extension Osteotomy

The distal osteotomy starting point can be referenced off the proximal edge of the distal wire guide, and the cut can be made directly off of the wire guide reference face (Fig. 7). The distal osteotomy should not be made distal to the proximal edge of the wire guide to ensure all three distal screws have adequate bone purchase and do not pass through the osteotomy site.

Caution: Incorrect placement of the initial osteotomy may result in the most proximal distal screw on the head of the plate passing through the osteotomy site.

The initial distal osteotomy should be parallel to the in-place guide wires and perpendicular to the tibia in maximal extension.

Note: The proximal edge of the distal wire guide is oriented to be parallel to the distal screw guide wires.

The proximal osteotomy starting point is based upon the desired shortening of the limb. The cut should be made perpendicular to the diaphysis of the femur (Fig. 8).

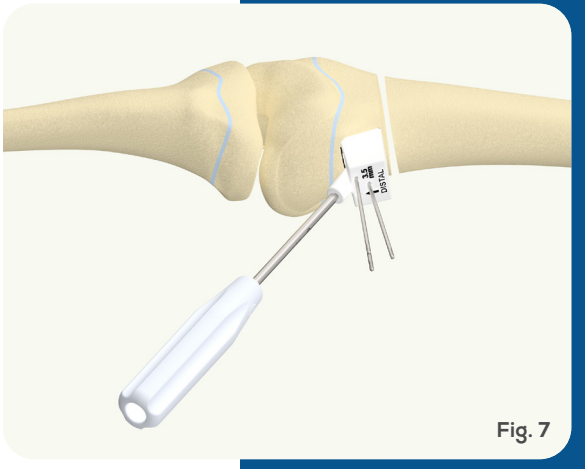


Fig. 7

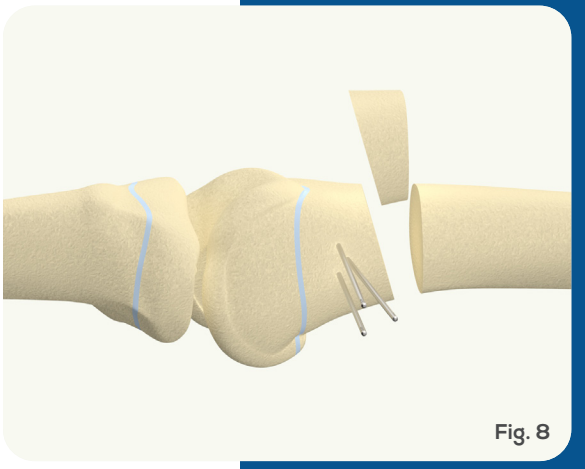


Fig. 8

CREATION OF THE OSTEOTOMY

Closing Wedge Osteotomy

The distal osteotomy starting point can be referenced off the proximal edge of the distal wire guide, and the cut can be made directly off of the wire guide reference face. The distal osteotomy should not be made distal to the proximal edge of the wire guide to ensure all three distal screws have adequate bone purchase and do not pass through the osteotomy site.

Caution: Incorrect placement of the initial osteotomy may result in the most proximal distal screw on the head of the plate passing through the osteotomy site.

The proximal osteotomy should be angled in the coronal plane to account for the desired varus or valgus correction. The triangular positioning plates can be used to approximate the angular correction of the second cut.

Opening Wedge Osteotomy

The distal osteotomy starting point can be referenced off the proximal edge of the distal wire guide, and the cut can be made directly off of the wire guide reference face. The distal osteotomy should not be made distal to the proximal edge of the wire guide to ensure all three distal screws have adequate bone purchase and do not pass through the osteotomy site.

Caution: Incorrect placement of the initial osteotomy may result in the most proximal distal screw on the head of the plate passing through the osteotomy site.

Based on the amount of desired varus/valgus correction determined pre-operatively, make the osteotomy to about within 5-10mm of the opposite cortex. This will help minimize the risk of a cortical hinge fracture. Following the osteotomy, hinge open the fracture and place a bone wedge matching the desired degree of correction.

INTRA-OPERATIVE PLATE TEMPLATING & PLATE SELECTION

INSTRUMENTS

3.5mm Plate
Distal Bendable Template, 3.5mm (50-213-300000G-X)
Distal Template Forming Block, 3.5mm (50-213-300002G-X)

4.5mm Plate
Distal Bendable Template, 4.5mm (50-214-300000G-X)
Distal Template Forming Block, 4.5mm (50-214-300002G-X)

The distal femur bendable template can be used in one of two ways to confirm the most optimal Distal Femur Locking Plate offset and/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 and/or flare (Fig. 9). Remove the bendable template and compare its shape to the distal template forming block to determine the optimal plate offset and/or flare.

Option 2: Place the distal femur bendable template over the post on the distal template forming block that corresponds to the estimated plate offset and/or flare to be implanted. Bend the template so to match the forming block (Fig. 10). 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 and/or flare offerings and retrial its fit on the bone.

Note: The distal femur bendable template approximates the length of a 4-hole plate.

Open the selected Distal Femur Locking Plate implant.

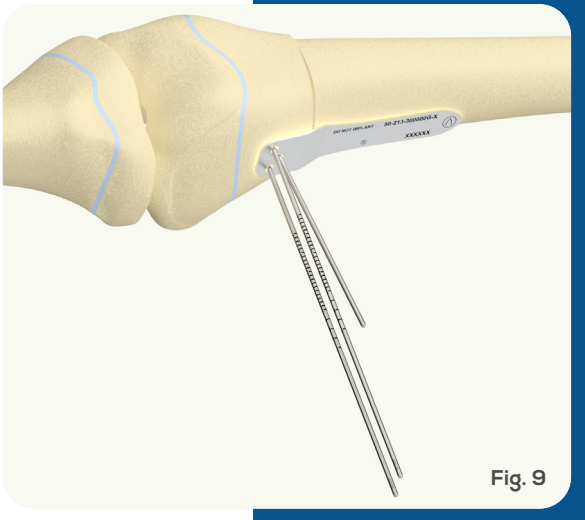


Fig. 9

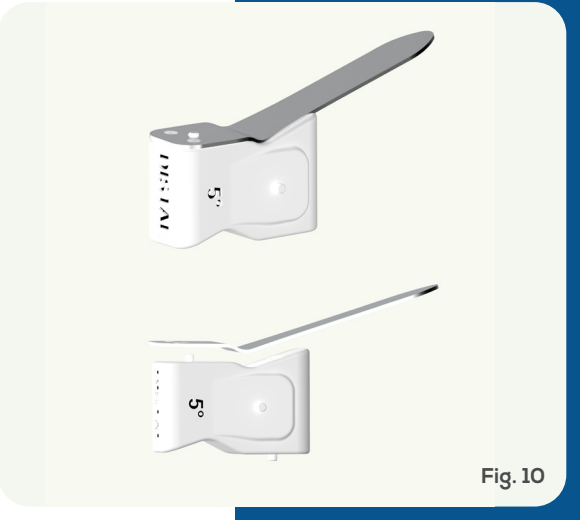


Fig. 10

FIXATION OF THE DISTAL 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)

Remove the initial orientation guide wire, prior to introducing the plate to the femur.

Thread three threaded guide towers to the distal 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.

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 onto the plate.

With the threaded guide towers and reduction sleeve secured to the plate, pass the plate over the two existing guide wires until it abuts the lateral cortex of the femur (Fig. 11).

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

With the plate properly positioned against the distal fragment, a third guide wire can be placed into the proximal screw hole on the distal portion of the plate.

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 (Fig. 12). For unicortical screw insertion, 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. For bicortical screw insertion, reference the screw length with the depth gauge.

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

Note: Fixation of the distal condylar segment should always be performed with locking screws.

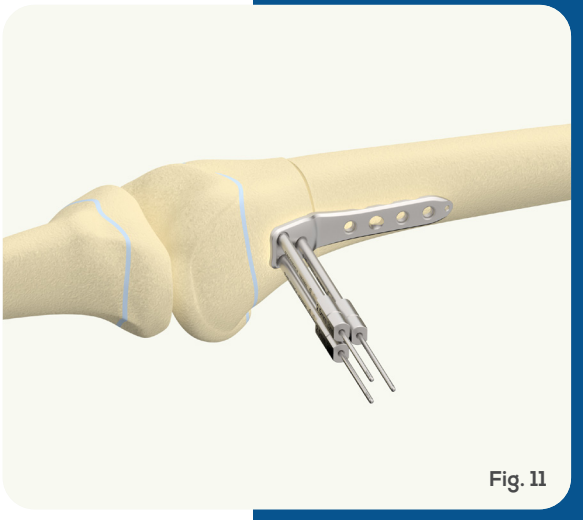


Fig. 11

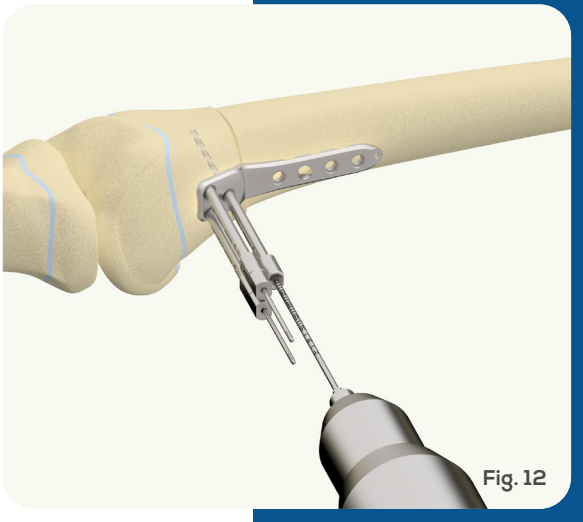


Fig. 12

FIXATION OF THE DISTAL FRAGMENT

Screw Insertion by Hand:
Use the appropriate screwdriver to insert the screw by hand until the head is locked to the plate (Fig. 13).

Screw Insertion with Power:
Connect the AO screwdriver to power and drive the screw (under low speed) until just proud of the plate. 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.

With all three distal screws in place, if rotational correction is going to be judged relative to the proximal guide wire, re-insert the orientation guide wire at this point in the procedure.

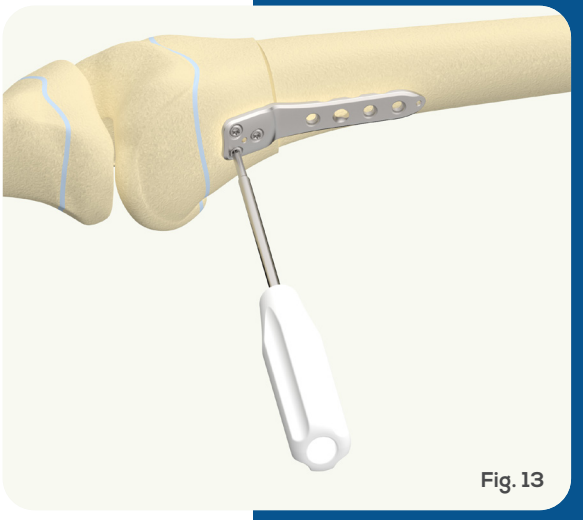


Fig. 13

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)

Reduce the distal and proximal fragments into the desired alignment, derotating the fragments as necessary and secure the proximal fragment to the plate with a bone clamp.

Before inserting screws in the proximal fragment or adjusting internal/external rotation, verify alignment with fluoroscopy. The plate should be positioned parallel to the shaft of the femur in the sagittal plane.

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 initial orientation guide wire is parallel to the bicortical proximal reference guide wire.

PROXIMAL 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)

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 proximal end of the compression slot. Pass the provided drill through the guide and drill through both cortices (Fig. 14).

Use the depth gauge to measure for the screw length (Fig. 15).

Insert a 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.

Compression Hole without Compression

If compression is not desired, place the double-ended drill guide in the center or distal 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 a non-locking screw and use the manual screwdriver to advance the screw until the screw head engages the plate.

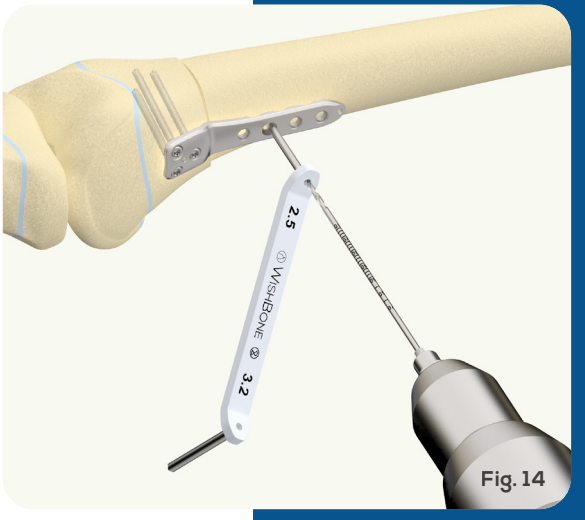


Fig. 14

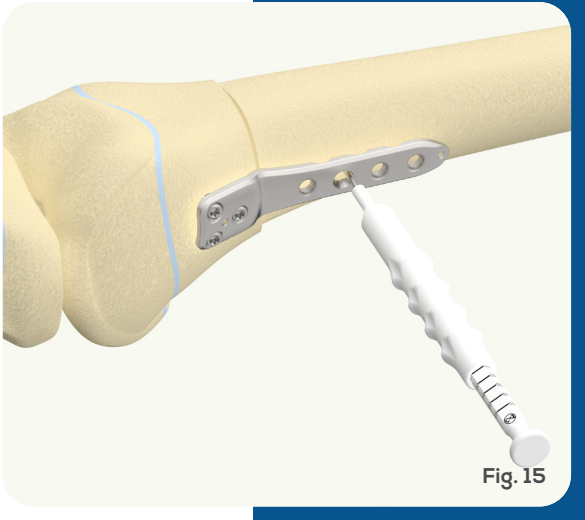


Fig. 15

PROXIMAL SCREW PLACEMENT

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.

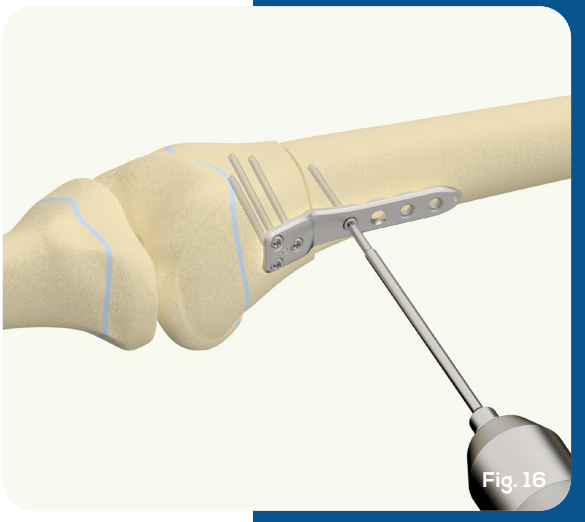


Fig. 16

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.

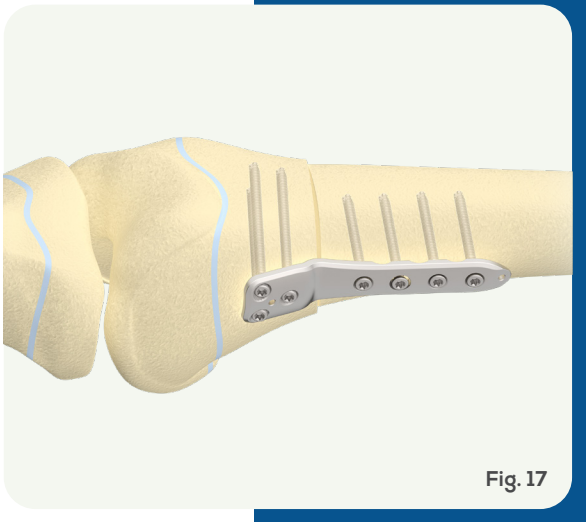


Fig. 17

WishBoneMedical.com
100 Capital Drive
Warsaw, IN 46582
+1-574-306-4006

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

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

We **WORK** so they can **PLAY**.™