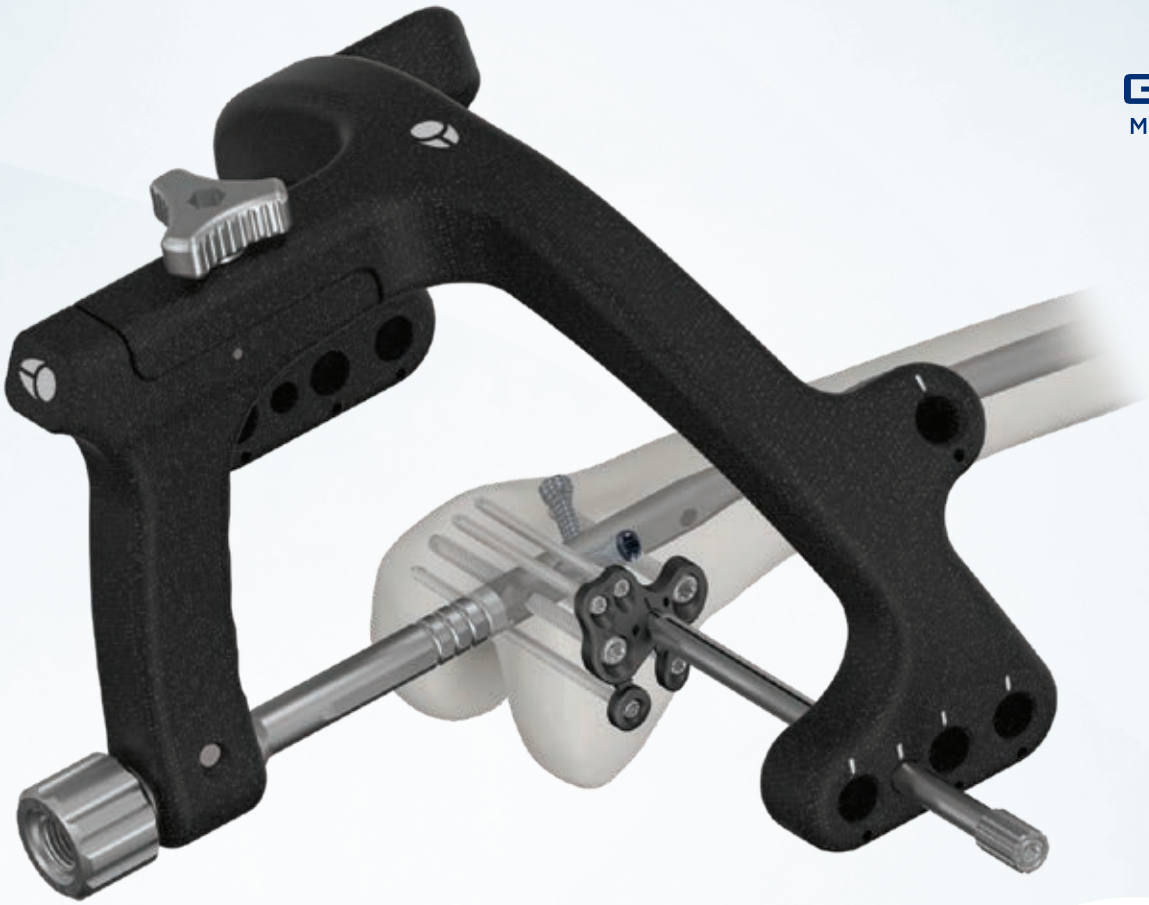

AUTOBAHN® EVO

Retrograde Femoral Nailing System

SURGICAL TECHNIQUE GUIDE

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SURGICAL TECHNIQUE GUIDE

AUTOBAHN® EVO

Retrograde Femoral Nailing System

AUTOBAHN® EVO

Retrograde Femoral Nailing System

AUTOBAHN® EVO Retrograde Nailing offers comprehensive implant and instrument options to address a variety of native and periprosthetic distal femur fractures. The system also features an add-on Locking Washer for added fixation

5° and 10° Entry Options

Allow flexibility and choice of entry point in the presence of a prosthesis

Hybrid Design

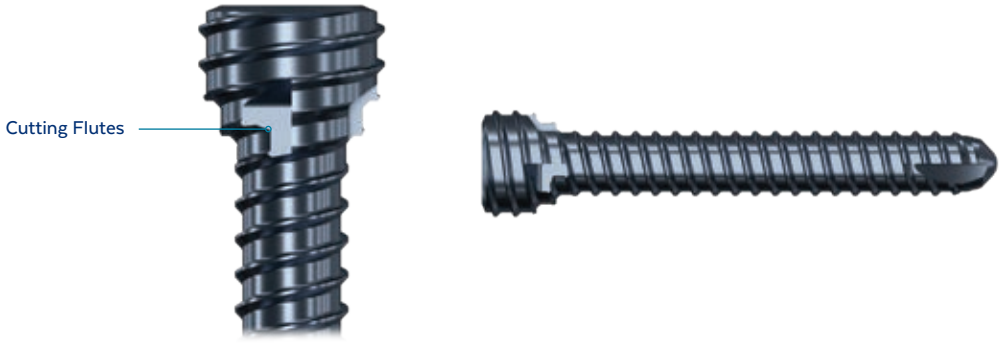
Standard or supracondylar locking configuration

Standard

Supracondylar

Headless Screws

Reduce soft tissue irritation

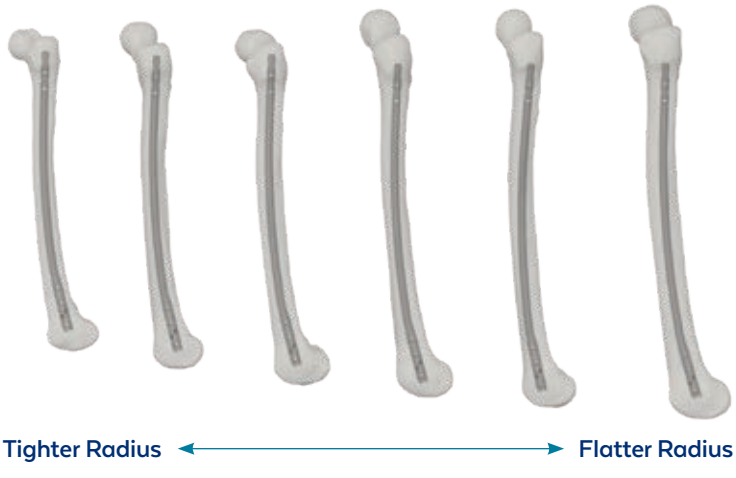


Distal Locking Options

All distal static holes incorporate SureStart® Threaded technology, creating a fixed angle construct

Variable Radius of Curvature

Length-dependent radius designed to fit in varying patient anatomy



Aiming Arm

- Designed for simple and effective targeting
- Allows intraoperative assembly of the Locking Washer

Self-Retaining Sleeves

For convenient one-handed operation

Dedicated Periprosthetic Instruments

Instruments with a smaller diameter facilitate entry wire placement and canal opening in the presence of a knee prosthesis

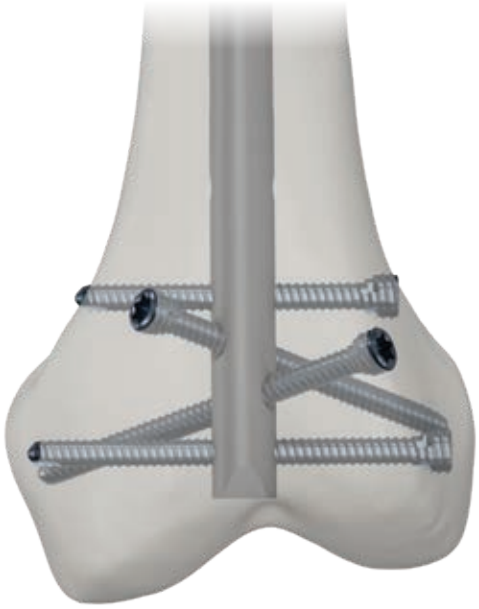
Periprosthetic Wire Guide

Cannulated Opening Drill Bit

IMPLANT OVERVIEW

RETROGRADE NAIL

- Designed to treat a variety of femoral fractures while optimizing anatomic fit
- Diameter: 10-12mm
- Lengths: 320-440mm in 20mm increments
- 11mm and larger nails have flutes
- Distal bend is located 70mm from tip
- Material: Titanium alloy with type II anodization
- Multiplanar oblique screws target the posterior condyles



NAIL LOCKING SCREWS

- Diameter: 5.0mm
- Lengths: 30-55mm in 2.5mm increments and 60-100mm in 5mm increments
- Retained by threaded connection
- T30 drive feature
- Material: Anodized titanium alloy
- Headed and headless locking screws available

Headed Locking Screw

Headless Locking Screw

LOCKING WASHER AND SCREWS

- Locking Washer
  - Styles: 5° and 10°
  - Left and right anatomically contoured
  - Material: Titanium alloy with type II anodization
- Screw Options
  - 5mm Locking Screws (anodized titanium alloy)
  - 5mm Polyaxial Locking Washer Screws (cobalt chrome alloy)
    - 50-100mm in 5mm increments
    - T25 drive feature
  - 3.5mm Polyaxial Locking Screws (cobalt chrome alloy)
    - 36-60mm in 2mm increments
    - 65-95mm in 5mm increments
    - T15 drive feature
- Locking Hole Angulation
  - 5mm Polyaxial Screw angulation ±15°
  - 3.5mm Polyaxial Screw angulation ±20°

Blue areas show polyaxial locking range for 5mm polyaxial screws

Green areas show angulation range of 3.5mm polyaxial locking screws

CONDYLE IMPLANTS

- Condyle Nut Diameter: 14mm
- Condyle Nut Length: 15mm
- Condyle Nut Washer Diameter: 17mm
- 5mm Locking Screw Washer Diameter: 14mm
- Material: Titanium alloy with type II anodization

Condyle Nut

Condyle Nut Washer

5mm Locking Screw

Locking Screw Washer

SURGICAL TECHNIQUE

AUTOBAHN® EVO

Retrograde Femoral Nailing System

Refer to the package insert (also printed in the back of this manual) for important information on indications, device description, contraindications, precautions, warnings, and potential risks associated with this system.

STEP 1 PREOPERATIVE PLANNING

Assess the fracture using preoperative radiographs and/or CT scans.

STEP 2 PATIENT POSITIONING

Position the patient supine on a radiolucent table. Position the injured leg in 30° to 40° of flexion. If necessary, use a leg roll or bump to allow for stabilization of the fracture.

Position the C-arm to facilitate imaging of the proximal and distal femur in AP and lateral views.

AP view

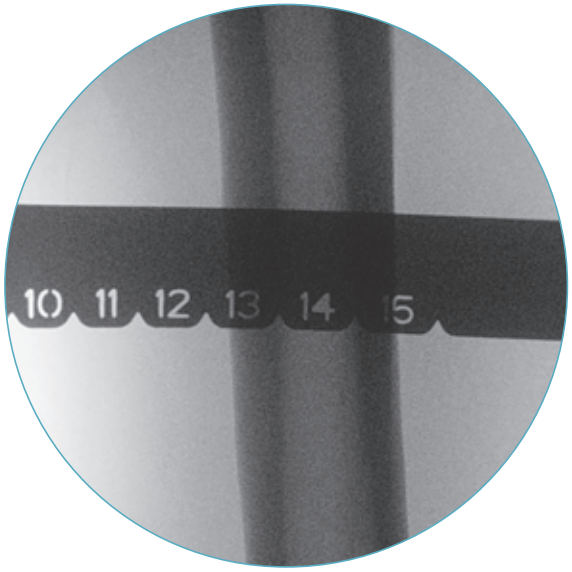
Lateral view

STEP 3 FRACTURE REDUCTION

Anatomic reduction should be performed prior to opening, reaming, and nail insertion.

STEP 4 DETERMINING DIAMETER

Hold the diameter section of the **Nail Length Gauge** over the smallest diameter of the medullary canal at the isthmus. Estimate the nail diameter under fluoroscopy. Alternatively, the contralateral uninjured leg may be used to determine nail diameter. Confirm nail length after reaming.



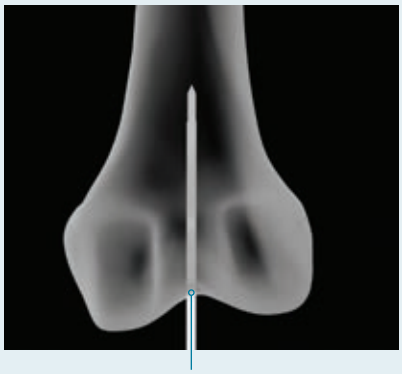
Diameter measurement

IDENTIFY ENTRY POINT

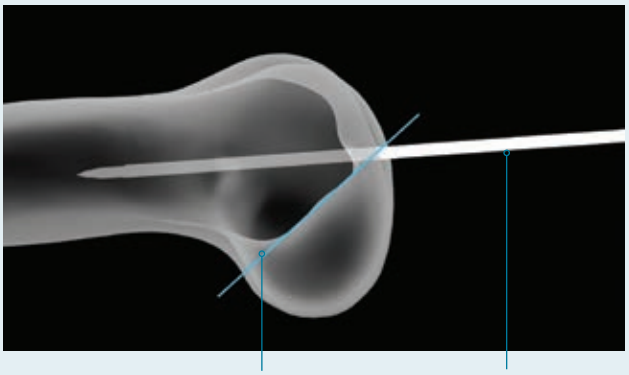
Standard Entry - 5° Nail

Create a longitudinal midline or parapatellar incision in line with the femoral shaft.

The standard entry point for a retrograde nail is located anterolateral to the posterior cruciate ligament, at the top of the intercondylar notch. On lateral fluoroscopy, it is located slightly anterior to Blumensaat's line.



AP view



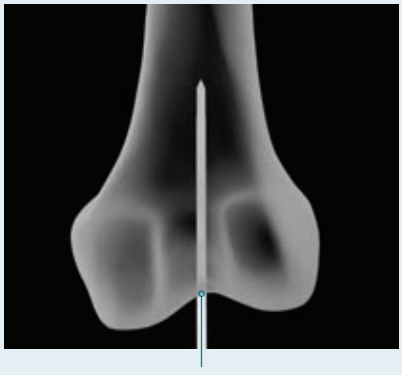
Lateral view

Posterior Entry - 10° Nail

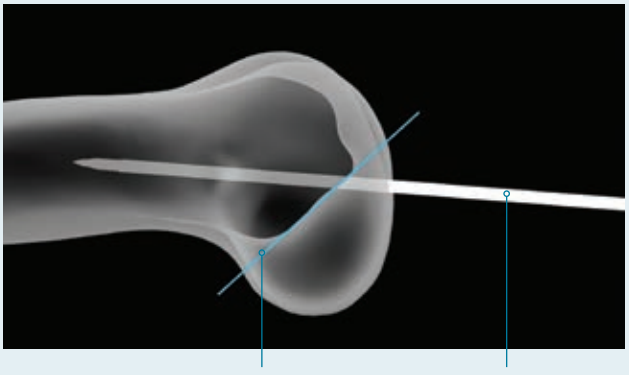
Create a longitudinal midline or parapatellar incision in line with the femoral shaft.

In the presence of an existing knee prosthesis, the entry point for the retrograde nail may be more posterior to accommodate the box of the prosthesis. For this entry point, a retrograde femoral nail with a 10° distal bend is available.

The posterior entry point for a 10° retrograde nail is located slightly anterolateral to the posterior cruciate ligament. On lateral fluoroscopy, it is located slightly posterior to Blumensaat's line.



AP view



Lateral view

STEP 5 INSERTING GUIDEWIRE

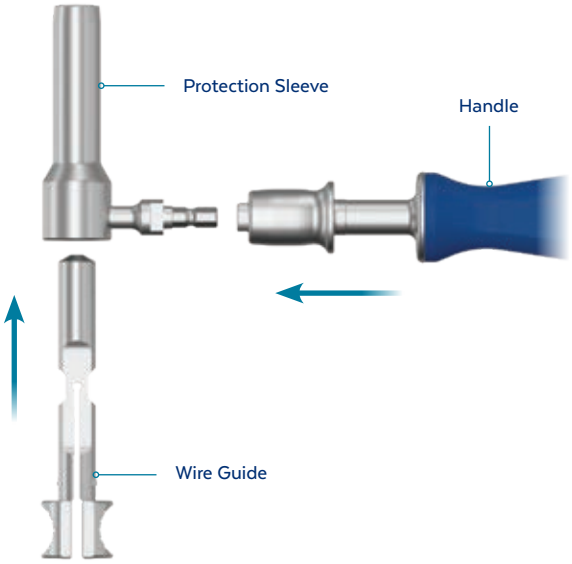
Attach the **Protection Sleeve, 12.8mm** to the **Hall Quick-Connect Handle** and insert the **Multi-Hole Wire Guide, 12.8mm** into the protection sleeve. Alternatively, in the presence of a knee prosthesis, a smaller diameter **Periprosthetic Wire Guide, 11.2mm** may be used.

Insert the protection sleeve assembly into the incision until it reaches bone. Insert the **3.2mm Guidewire** into the selected wire guide and into bone.

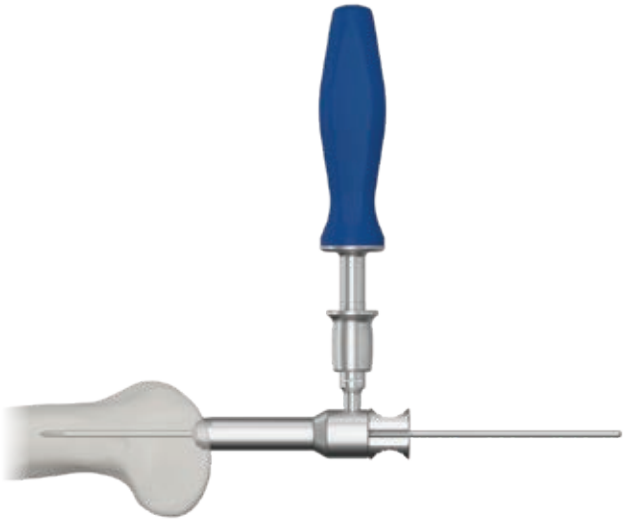
Confirm position on fluoroscopy in both AP and lateral views. Remove the wire guide.

Multi-Hole Wire Guide, 12.8mm

Periprosthetic Wire Guide, 11.2mm



Wire Guide Assembly

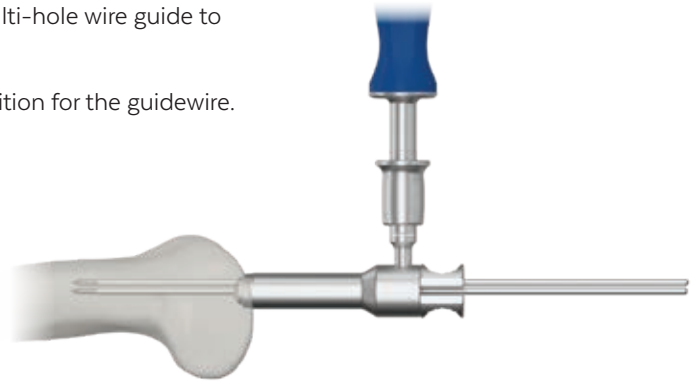


Inserting 3.2mm Guidewire

If desired, an offset guidewire may be inserted through the multi-hole wire guide to achieve a better starting position.

Rotate the wire guide as needed to attain a better starting position for the guidewire.

Multi-Hole Wire Guide



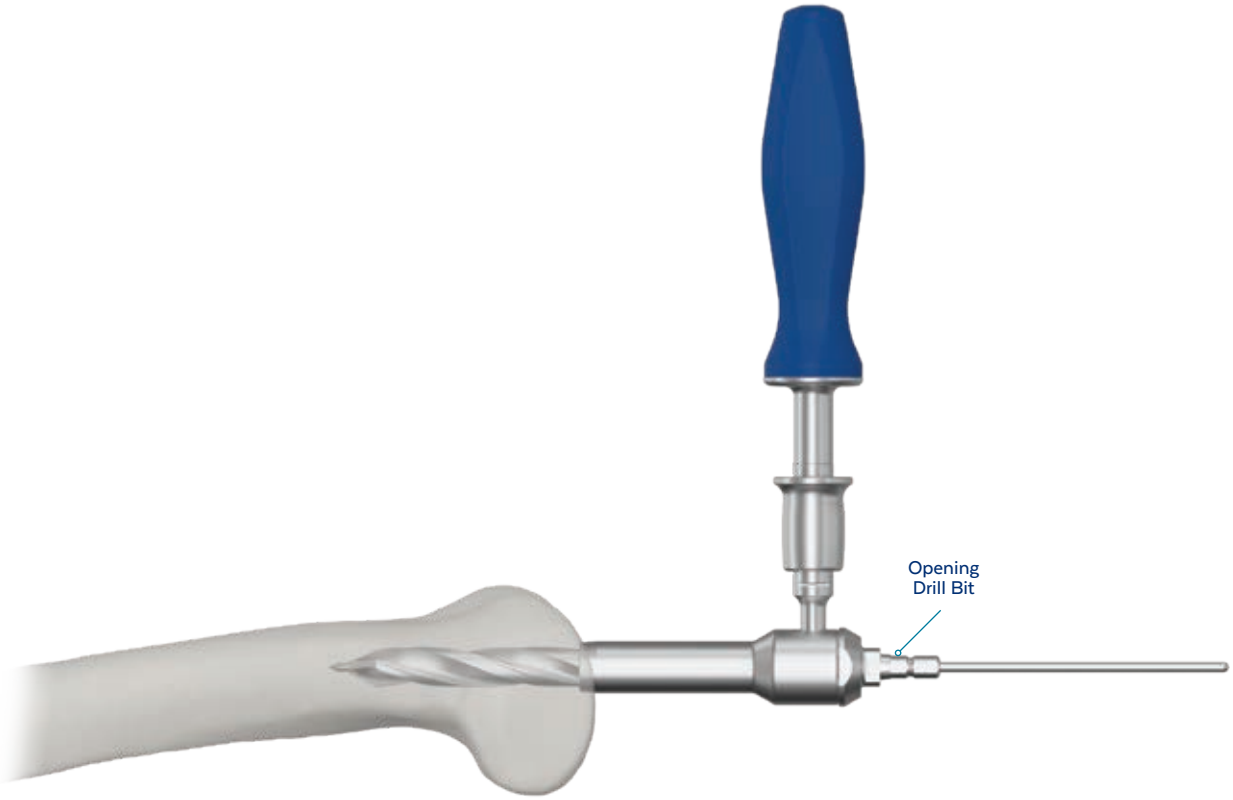
STEP 6 OPENING THE MEDULLARY CANAL

Open the medullary canal using a **Cannulated Opening Drill Bit** placed over the guidewire and into the protection sleeve. Drill to the desired depth. Verify position under fluoroscopy. Remove the drill bit, guidewire, and protection sleeve.

In the presence of an existing knee prosthesis, a smaller 11.2mm diameter cannulated drill bit may be used to provide clearance with the box of the knee prosthesis.

12.8mm Cannulated Opening Drill Bit

11.2mm Cannulated Opening Drill Bit



Opening canal

STEP 7 DETERMINING NAIL LENGTH

Insert the **Ball-Tip Guidewire, 3.0x1000mm** into the medullary canal and past the fracture site. A **T-Handle 3 Jaw Chuck** may be used to grasp the guidewire if necessary.

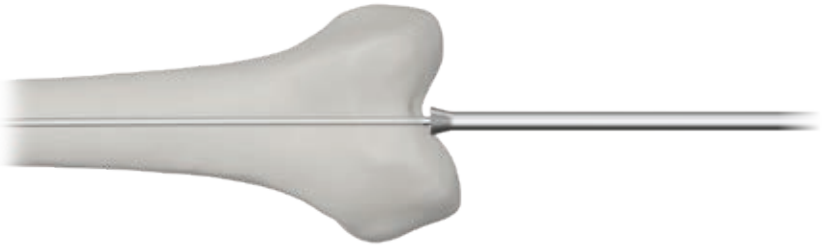
The **Intramedullary Reduction Tool, Hall Connection** may also be used to facilitate passing the guidewire across the fracture site.

Inserting Ball-Tip Guidewire

Ensure the ball-tip guidewire is at the desired proximal location in the medullary canal. Connect the nail length gauge to the **Extension, Nail Length Gauge**.

Pass the length gauge assembly over the ball-tip guidewire to the nail entry point until it rests on bone. Determine nail length directly by reading the measurement on the length gauge at the tip of the guidewire. Use fluoroscopy to confirm the position of the length gauge.

Connecting length gauge instruments



Length gauge extension touching bone

Length Gauge requires the use of the 1000mm Guidewire.

STEP 8 INTRAMEDULLARY REAMING

Ensure the ball-tip guidewire is at the desired depth in the medullary canal. Confirm fracture reduction using fluoroscopy.

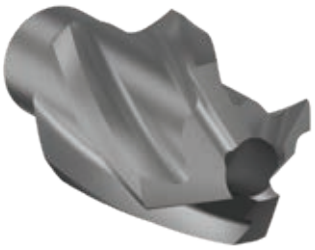
The reamers are modular and may be attached to the **Reamer Shaft**. To attach, insert the reamer shaft into the selected **Reamer Head**.

CAUTION: Ensure the reamer shaft is fully seated into the reamer head prior to insertion over the ball-tip guidewire.

Ream the canal by increasing the reamer size in 0.5mm increments using steady pressure. The **Guidewire Pusher** may be used to ensure the ball-tip guidewire is secure during reaming.

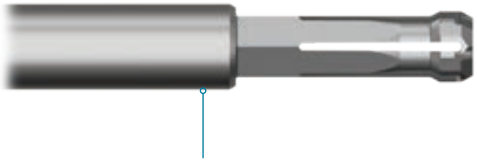
If needed, retract the reamer to clear debris from the canal.

Ream to 1.0-1.5mm greater than the selected nail diameter. Remove the reamer shaft from the intramedullary canal and leave the ball-tip guidewire in place.



Front Cutting

Side Cutting

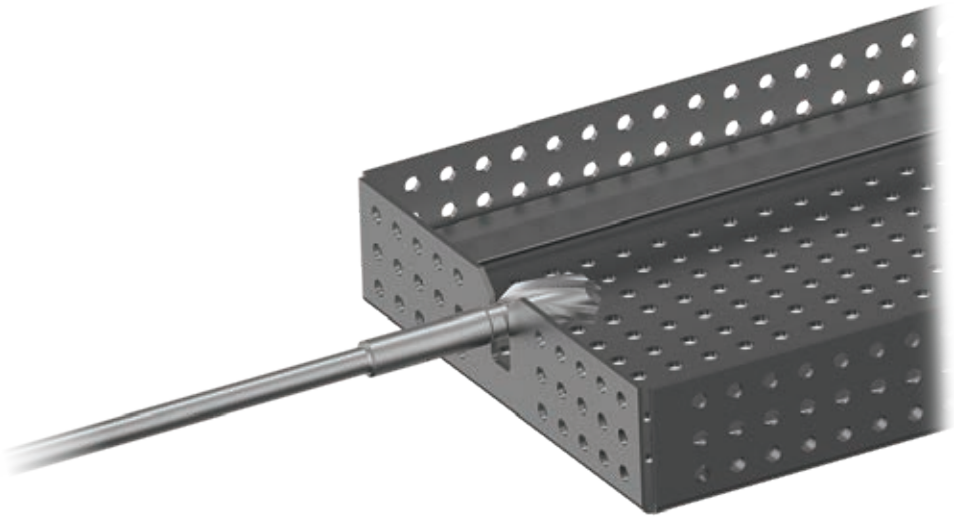


Flexible Reamer Shaft

Reamer Head

Reamer shaft fingers expand within the reamer head to retain it.

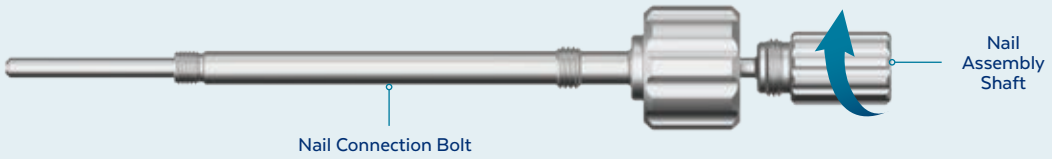
Reamer Shaft engaged with Reamer Head - cross-section view



Use the reamer caddy lid to remove the reamer heads.

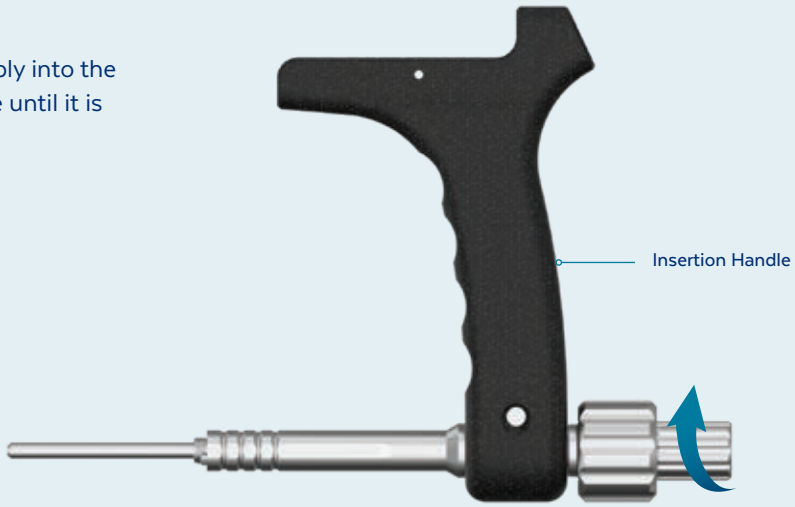
NAIL ASSEMBLY OVERVIEW

Thread the **Nail Assembly Shaft** into the **Nail Connection Bolt**.

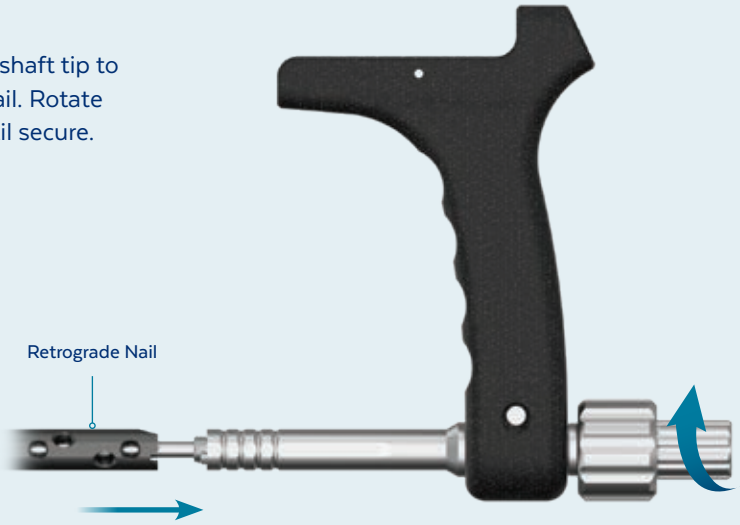


Nail Connection Bolt Assembly

Insert the nail connection bolt assembly into the **Insertion Handle** and rotate clockwise until it is secure and retained.



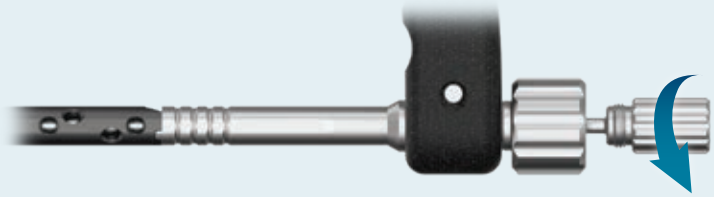
Align the tabs at the insertion handle shaft tip to the notches at the distal end of the nail. Rotate the nail connection bolt clockwise until secure.



Nail Assembly

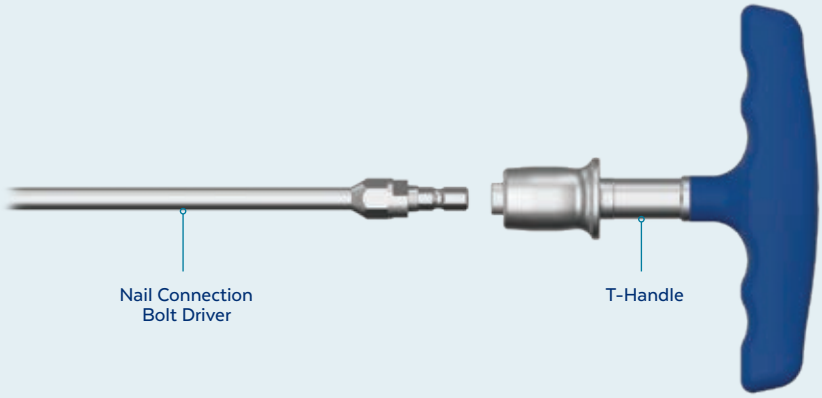
NAIL ASSEMBLY OVERVIEW (CONT'D)

While holding the Nail Connection Bolt, rotate the Nail Assembly Shaft counterclockwise to remove.



Nail Assembly Shaft Removal

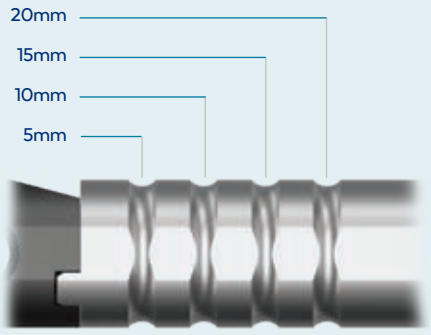
Attach the **Quick-Connect T-Handle** to the **Nail Connection Bolt Driver**.



Insert the nail connection bolt driver into the connection bolt, and rotate the driver clockwise until the connection is rigid.

Final Tighten

The grooves in the insertion handle aid in radiographic visualization of fully seated end caps in 5mm increments.



The anterior bow of the nail should be aligned with the anterior bow of the femur.

STEP 9 NAIL INSERTION

Insert the nail into the medullary canal by passing the nail over the ball-tip guidewire. Light impaction may be applied to the connection bolt using the **Slotted Mallet**.

Do not impact the guidewire or insertion handle. Monitor nail position during insertion using fluoroscopy.

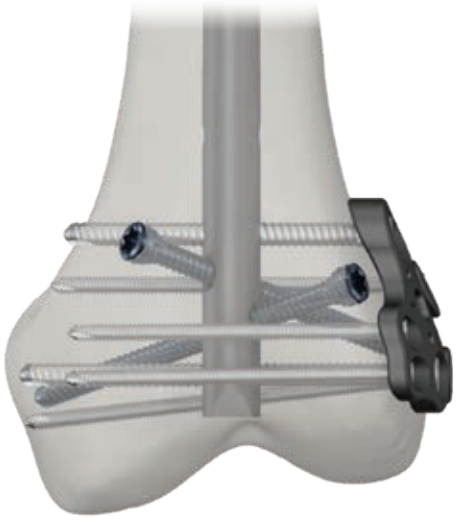
Once the nail has crossed the fracture site, the ball-tip guidewire may be removed.

Inserting Nail

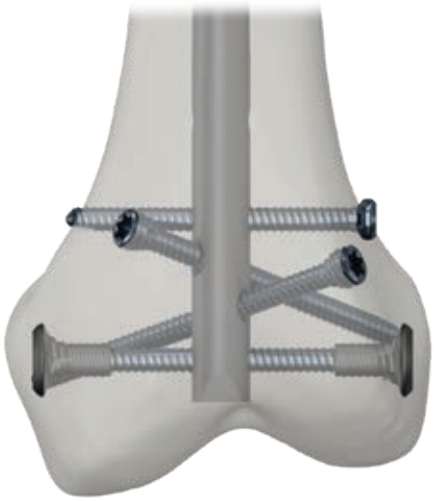
Final Nail Position

STEP 10 LOCKING SCREW INSERTION

Standard Locking Screws



Locking Washer and Screws



Condyle Washer and Screws

Proximal Locking Screws

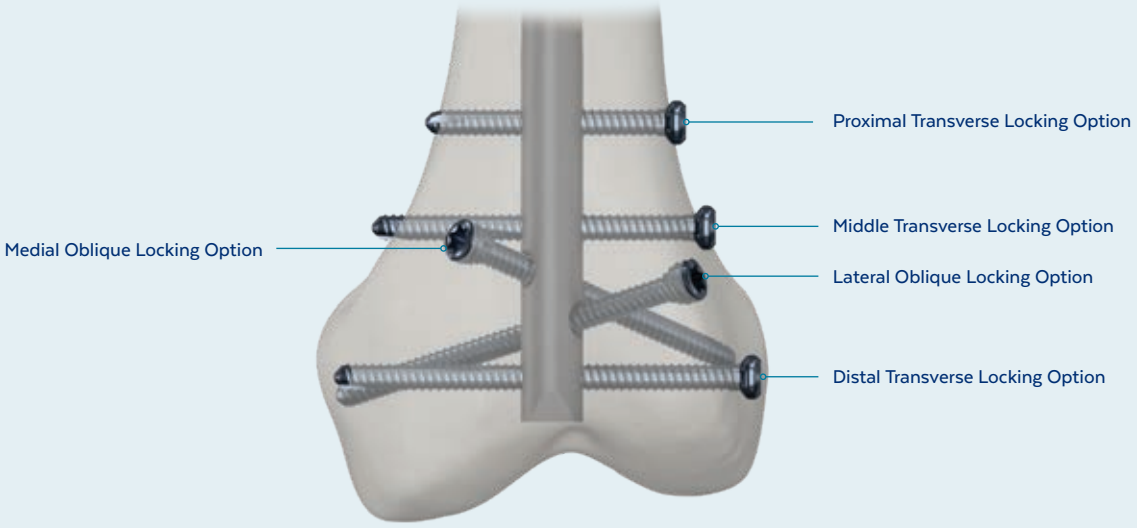
LOCKING SCREW INSERTION (CONT'D)

NAIL LOCKING OPTIONS

Choose the locking option appropriate for the fracture type.

When using SureStart® Threaded holes, tactile feedback may be experienced through the driver as the screw engages the threads in the nail.

None of the 5mm distal interlocking screws intersect with each other. All screws may be used in a single construct.



Distal Locking Options

STANDARD LOCKING SCREWS

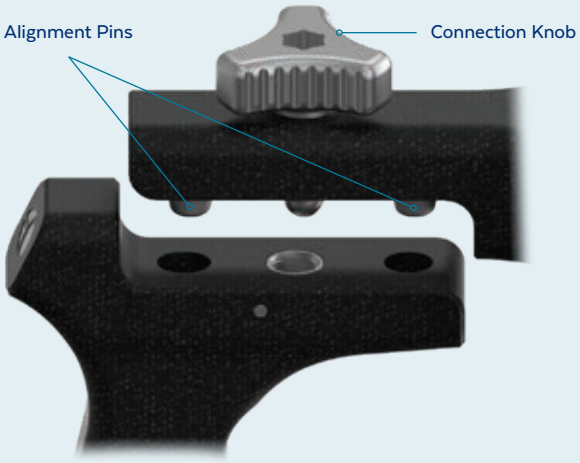
ATTACHING AIMING ARM

AIMING ARM OVERVIEW

The **Aiming Arm** attaches to the insertion handle through two alignment pins and a threaded connection knob.

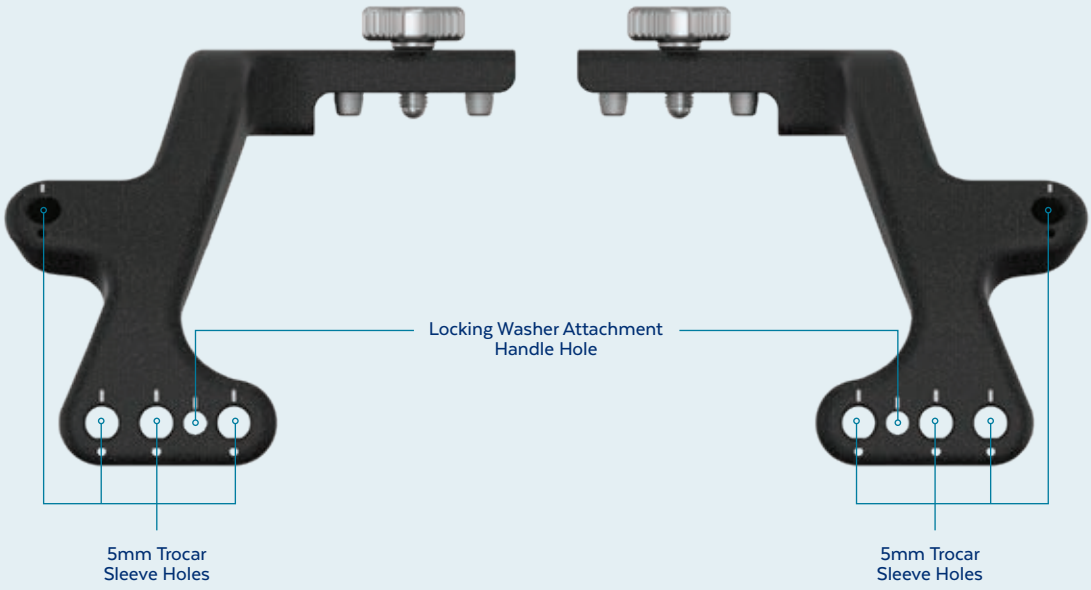
Align the pins on the Aiming Arm with the holes on the Insertion Handle. Rotate the connection knob clockwise to tighten. Ensure the connection knob is threaded down correctly.

Determine which distal and proximal locking holes in the nail will be used for screw placement.



Trocar Sleeve Retention

All holes on the aiming arm facilitate sleeve retention through friction.



INSERTING TROCAR SLEEVES

Insert the 5mm trocar sleeve assembly into the desired 5mm hole in the aiming arm. Refer to Trocar Sleeve Assembly for sleeve assembly and retention instructions. Create a small incision and insert the trocar sleeve assembly into the skin until bone is reached. Rotate the trocar sleeve assembly for retention.

Inserting trocar sleeves

TROCAR SLEEVE ASSEMBLY

The trocar sleeve assembly is designed to facilitate easy insertion and retention.

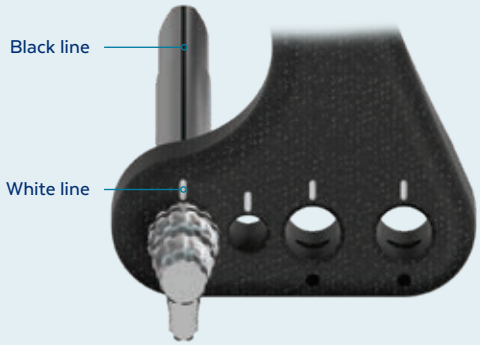
Assemble the 5mm trocar sleeve by inserting the **4.2mm Trocar** into the **4.2mm Drill Sleeve**. Insert the drill sleeve into the **5mm Driver Sleeve** and rotate the drill sleeve clockwise to tighten.

The driver sleeve has cutouts near the distal tip to visualize screw heads under fluoroscopy.

Trocar Sleeve Assembly

All 5mm locking holes through the aiming arm have a friction retention feature. The feature may be engaged by rotating the trocar sleeve assembly.

Insert the sleeve aligning the black line on the sleeve with the white line on the aiming arm near each 5mm hole. Once inserted to the desired depth, rotate the sleeve assembly 90° to engage the retention feature.



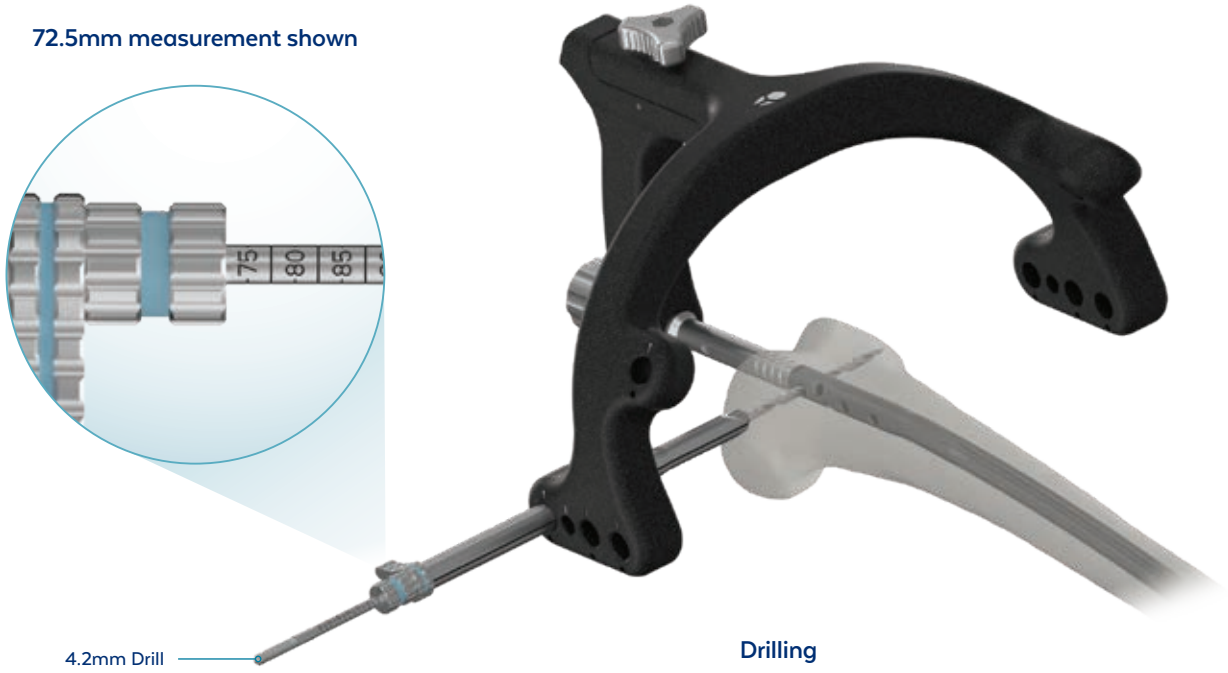
Unlocked

Locked

DRILLING

Remove the trocar. Insert the 4.2mm calibrated drill bit into the drill sleeve and drill to the desired depth. Measure hole depth using the calibrated drill or depth gauge.

Remove the drill bit and drill sleeve.



SCREW LENGTH MEASUREMENT

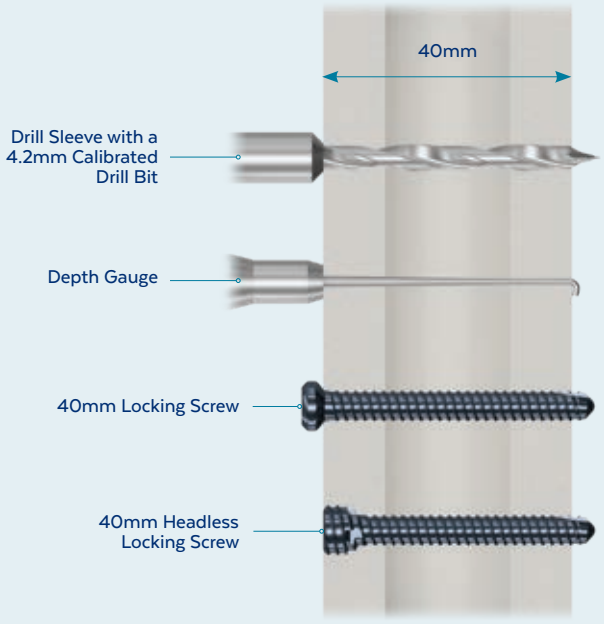
The **4.2mm Calibrated Drill Bit** and **Depth Gauge, 5mm** are used to measure hole depth for 5mm screws.

Depth calibrations are designed to enable 5mm screws to have bi-cortical purchase.

Drill/Depth Gauge Reading - 40mm

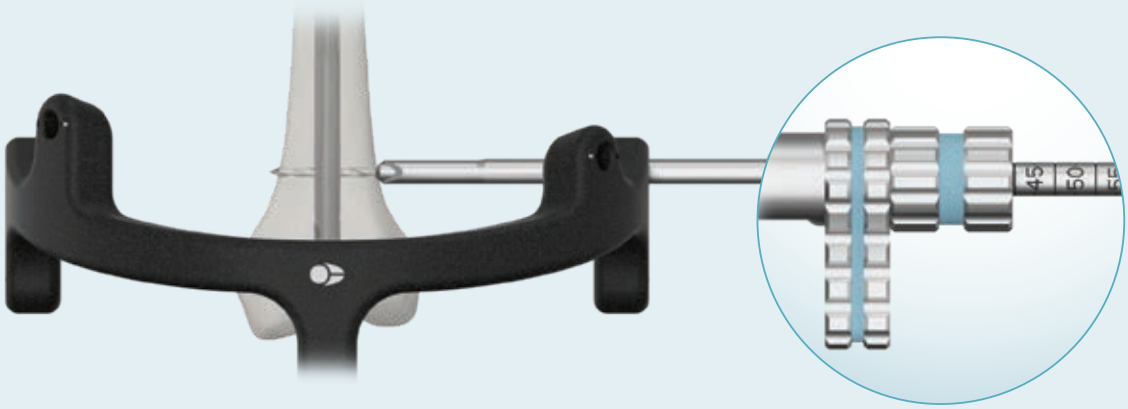
Screw Label - 40mm

Depth reading will result in locking screw having bi-cortical purchase.



SCREW LENGTH MEASUREMENT USING THE CALIBRATED DRILL BIT

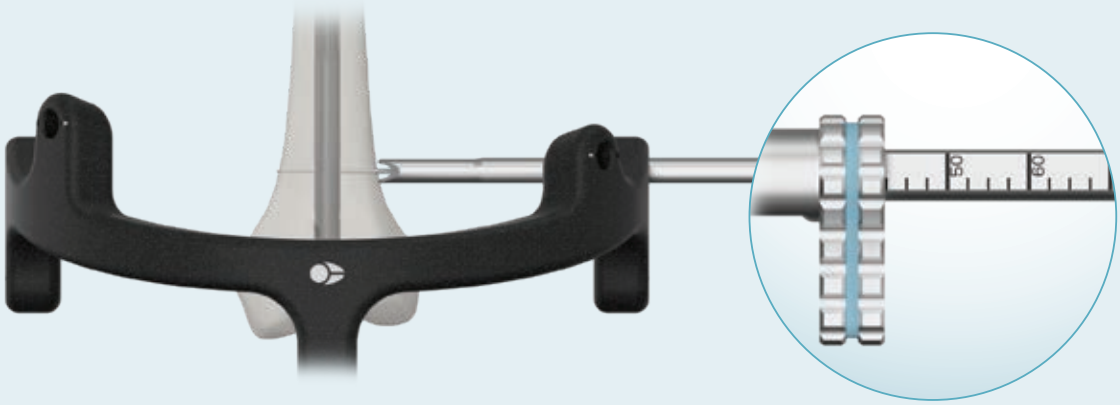
To measure using the calibrated drill, position the tip of the drill bit at the intended final location for the tip of the 5mm locking screw. Determine the measurement directly at the back of the drill sleeve.



42.5mm measurement shown

SCREW LENGTH MEASUREMENT USING THE DEPTH GAUGE

To measure using the depth gauge, remove the drill bit and the drill sleeve. Ensure the driver sleeve is touching bone. Insert the **Depth Gauge, 5mm, Long** stick through the driver sleeve. Extend the tip to the desired position, or through the far cortex, and retract until the hook engages the far cortex. Determine screw length by reading the markings directly at the back of the driver sleeve.



42.5mm measurement shown

INSERTING LOCKING SCREWS

Select the appropriate locking screw. Use the T30 driver to insert the selected 5mm locking screw through the driver sleeve. A retention rod may be used for screw retention as needed.

Confirm screw length using fluoroscopy. Remove the driver and driver sleeve. Repeat steps for additional locking screws as desired.

Inserting locking screw

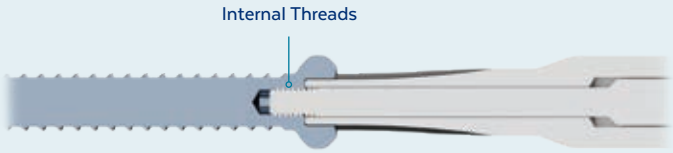
SCREW RETENTION

5mm locking screws and end caps may be retained during insertion.

Insert the **Retention Rod** into the appropriate **T30 Driver**. Rotate the retention rod clockwise to capture the internal screw threads.

After final placement of the screw, remove the T30 driver from the screw or end cap by detaching the power attachment or quick-connect handle, and turning the knob of the retention rod counterclockwise. An **Extraction Pin Wrench** may also be used.

Remove the retention rod and driver.



Cross-section view of retention rod in screw

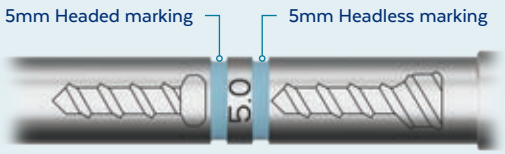
T30 driver and retention rod

DRIVER CALIBRATIONS

All locking screws may be inserted by hand or under power.

Do not final tighten screws under power. Final tightening should be performed by hand using a quick-connect handle. All drivers used through sleeves feature markings that indicate when a screw head is fully seated onto bone.

5mm markings are blue. The 5mm long driver has two markings, one for headed locking screws, and the other for headless locking screws.



Final placement of 5mm Headed Screw shown

INSERTING LOCKING SCREWS (CONT'D)

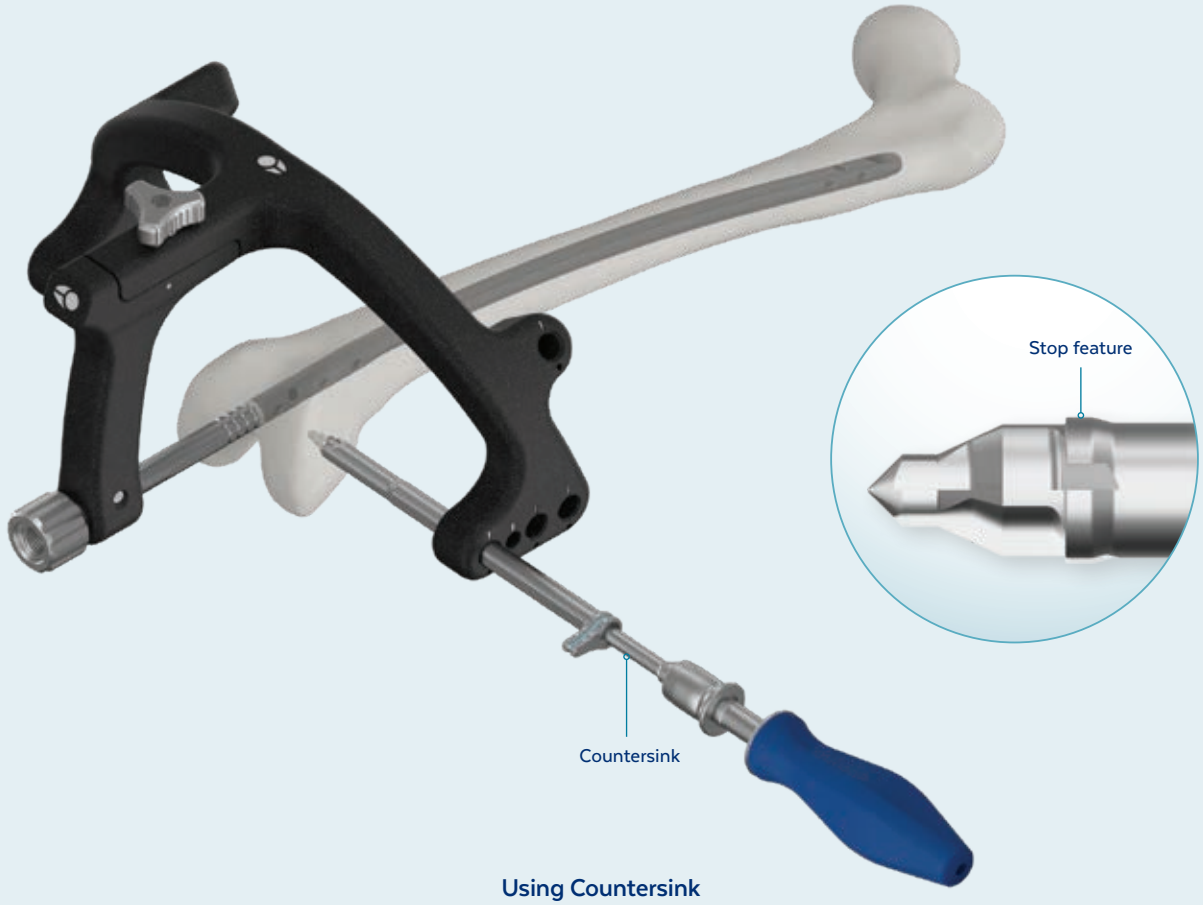
HEADLESS SCREWS

5mm headless screws are available, and may be buried flush or sub-flush to reduce soft-tissue irritation.

A **Countersink** may be used in dense bone to allow easier insertion of the headless screw in the near cortex.

Attach the countersink to a quick-connect handle. Insert the countersink through the 5mm driver sleeve until it reaches cortical bone. Rotate the countersink clockwise until the desired depth is reached.

Note: There is a stop feature on the countersink to prevent over-insertion into the near cortex.



Using Countersink

STANDARD LOCKING
FINAL CONSTRUCT

LOCKING WASHER AND SCREWS

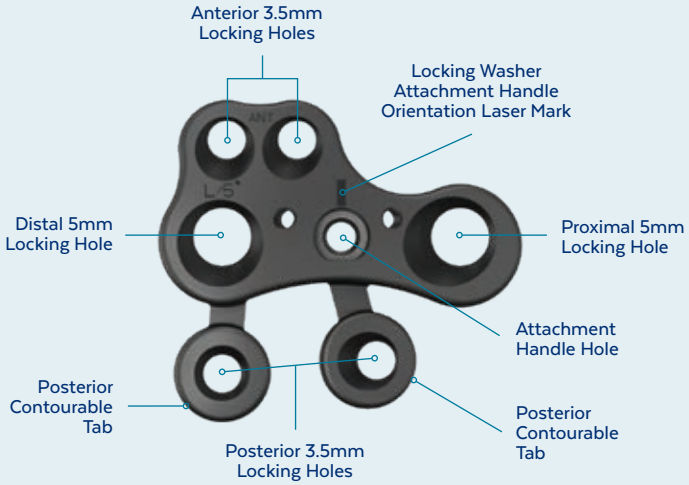
LOCKING WASHER OVERVIEW

The Locking Washer is designed for added distal fixation and lateral buttress of the distal femur. It is a pre-contoured washer with all locking holes, in 3.5mm and 5mm sizes.

The 5° and 10° washers are offered in both left and right orientations.

Both washers are compatible with the 5° and 10° nails. Choose the combination based on nail position and washer fit.

The posterior locking tabs may be contoured to better fit patient anatomy.



Left 5°

Right 5°

Left 10°

Right 10°

LOCKING WASHER OVERVIEW (CONT'D)

SureStart® Threaded Holes

When using SureStart® Threaded holes, tactile feedback may be experienced through the driver as the screw engages the threads in the nail.

Polyaxial Screw Locking

The 5mm holes have a polyaxial cone of ±15°.

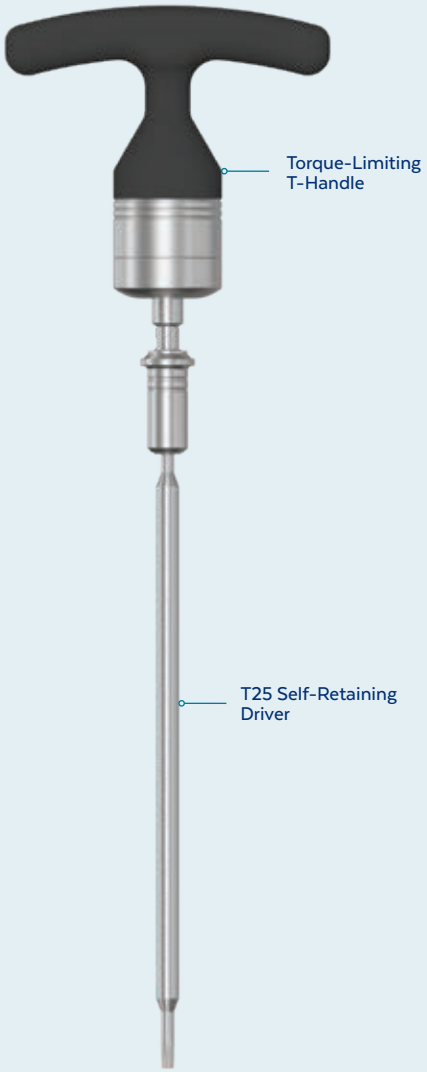
5mm polyaxial screws are designed to lock into the nail and into the locking washer simultaneously.

Do not final tighten under power. Final tightening should be completed by hand with the **T-Handle Large, Small AO QC, Limiting 7Nm**.

Headed Screw Locking

Standard 5mm headed locking screws may also be used with the locking washer using a T30 driver.

5mm standard screws are designed to lock into the nail, but not into the washer.



5mm Headed Locking Screw
Inserting Into Locking Washer

5mm Polyaxial Locking Screw
Inserting Into Locking Washer

LOCKING WASHER OVERVIEW (CONT'D)

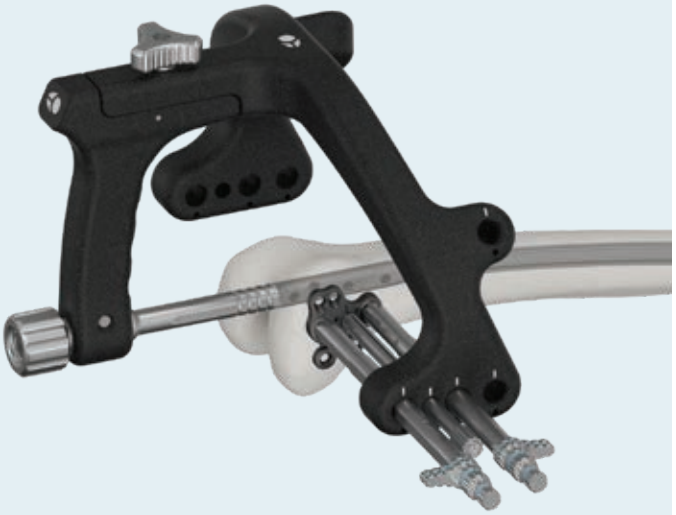
Option 1:

Insert the **Locking Washer Attachment Handle** into the small hole on the aiming arm. Connect the locking washer to the attachment handle. Use the **T25 SR Screwdriver for Power, AO Quick-Connect** to securely attach the handle to the washer by rotating the driver clockwise in the drive recess.

Note: The attachment handle will freely rotate and slide in the aiming arm.

Note: The Locking Washer is designed with an anatomical contour to fit the lateral bony surface of the distal femur.

Locking Washer
Attachment Handle

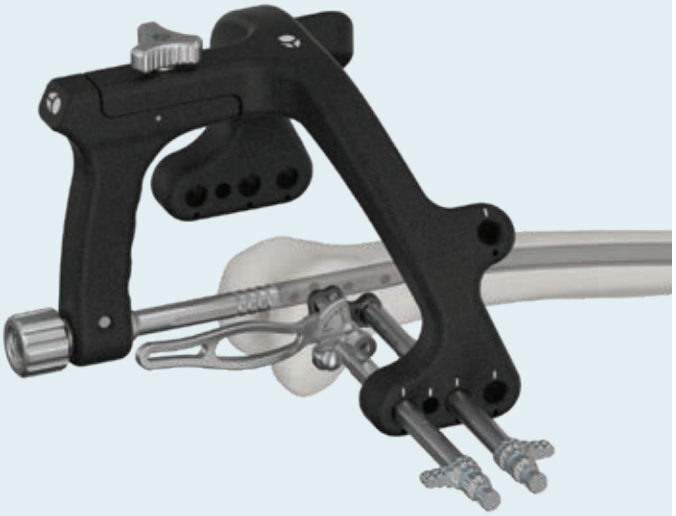


Option 2:

Insert the **Speed Lock Drill Guide, Long** into the anterior-distal-most 3.5mm hole on the locking washer. Engage the lock until the connection to the washer is rigid.

Once assembled and the locking washer is placed on bone, use the 5mm trocar sleeves to align and hold the washer in position.

Speed Lock
Drill Guide



ASSEMBLING LOCKING WASHER

Select the locking washer corresponding to the retrograde nail (5° or 10°). Assemble the selected Locking Washer to the Attachment Handle and Aiming Arm. Refer to *Locking Washer Overview* (page 30) for instructions.

Back Table Assembly

Ensure the attachment handle is correctly oriented by lining up the laser marks

ATTACHING AIMING ARM

Refer to *Aiming Arm Overview* (page 21) for assembly instructions.

Attaching Aiming Arm

DETERMINING WASHER POSITION

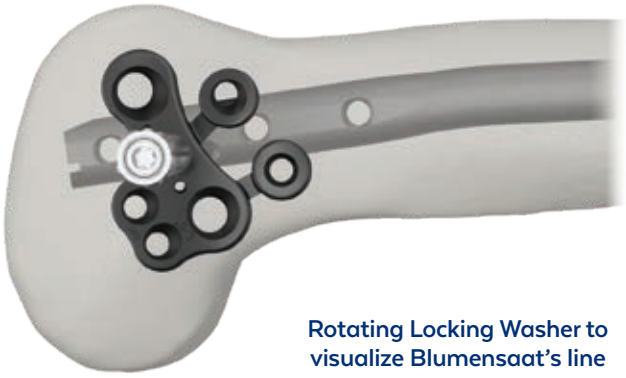
Create a lateral incision, approximately 7-8cm in length. Retract the soft tissue using the **Stabilizing Radiolucent Weitlaner 3x4, 8", Sharp Tip** retractors.

Under lateral fluoroscopy, confirm nail depth in the medullary canal by rotating the locking washer attachment handle to visualize Blumensaat's line.

Slide the Locking Washer toward the lateral cortex using the Locking Washer Attachment Handle. Confirm anatomical fit.

K-wires may be used to provisionally hold the locking washer in place prior to fixation.

Inserting Locking Washer



Rotating Locking Washer to visualize Blumensaat's line

MEDIAL OBLIQUE LOCKING: INSERTING TROCAR SLEEVE ASSEMBLY

Insert the 5mm trocar sleeve assembly into the medial oblique hole in the Aiming Arm. Create a small incision and insert the trocar sleeve assembly into the skin until bone is reached. Rotate the trocar sleeve assembly for retention.

Refer to *Trocar Sleeve Assembly* (page 23) for sleeve assembly and retention instructions.

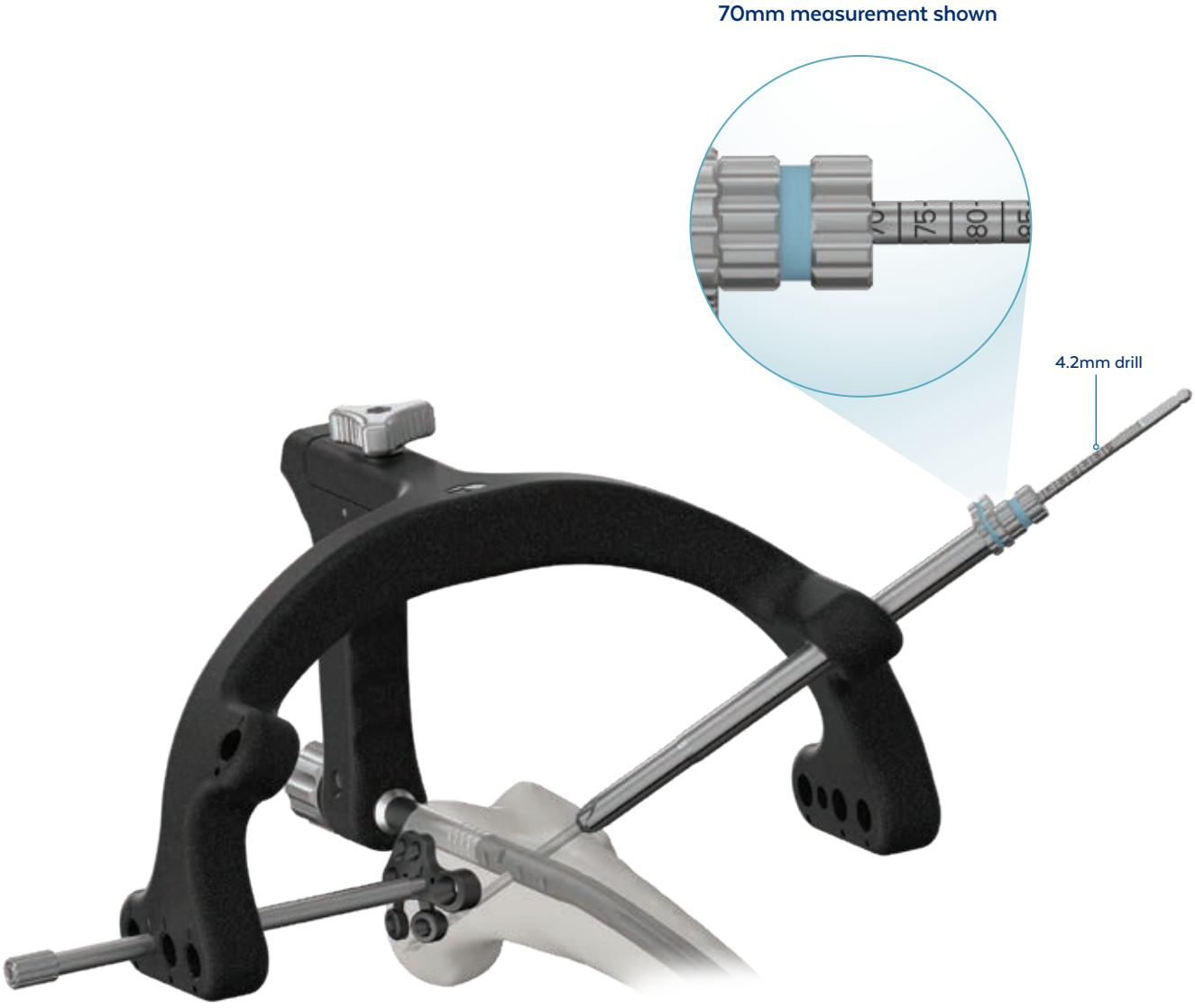
Inserting Trocar Sleeve Assembly

DRILLING MEDIAL OBLIQUE HOLE

Ensure the locking washer is at the desired position on the lateral cortex prior to drilling.

Remove the trocar. Insert the 4.2mm calibrated drill bit into the drill sleeve and drill to the desired depth. Measure hole depth using the calibrated drill or depth gauge. Refer to *Screw Length Measurement Using the Calibrated Drill Bit* (page 25) or *Screw Length Measurement Using the Depth Gauge* (page 25) for instructions.

Remove the drill bit and drill sleeve.



Drilling

INSERTING MEDIAL OBLIQUE LOCKING SCREWS

Select the appropriate 5mm locking screw. Use the T30 driver to insert the selected 5mm locking screw through the driver sleeve. A retention rod may be used for screw retention; refer to *Screw Retention* (page 27) for instructions.

Do not use power for final tightening. Final tightening should be performed manually with a quick-connect handle.

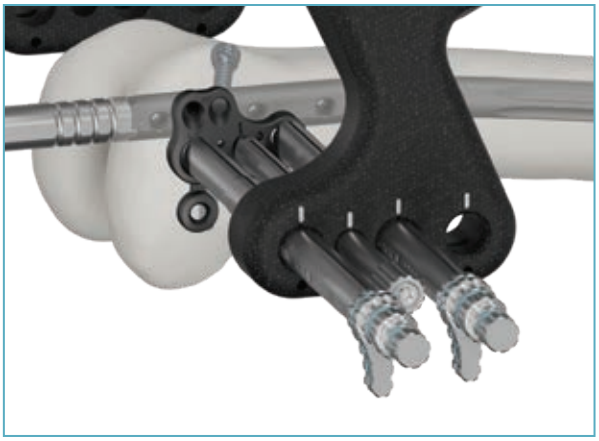
Confirm screw length using fluoroscopy. Remove the driver and driver sleeve.

Inserting Locking Screw

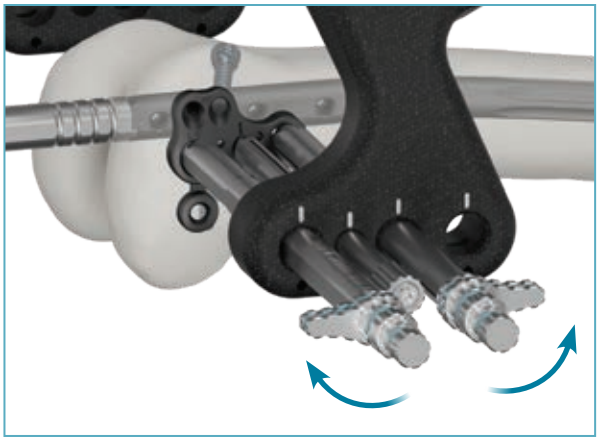
LOCKING WASHER LOCKING: INSERTING TROCAR SLEEVES

Ensure the locking washer is seated on the lateral cortex.

Insert the 5mm trocar sleeves into the two distal-most 5mm lateral holes in the Aiming Arm. Seat the trocar sleeves into the 5mm holes of the locking washer. Rotate each trocar sleeve assembly 90° to secure the sleeves and hold the locking washer against the lateral cortex.



Unlocked



Locked

Inserting Trocar Sleeves

DRILLING DISTAL HOLE

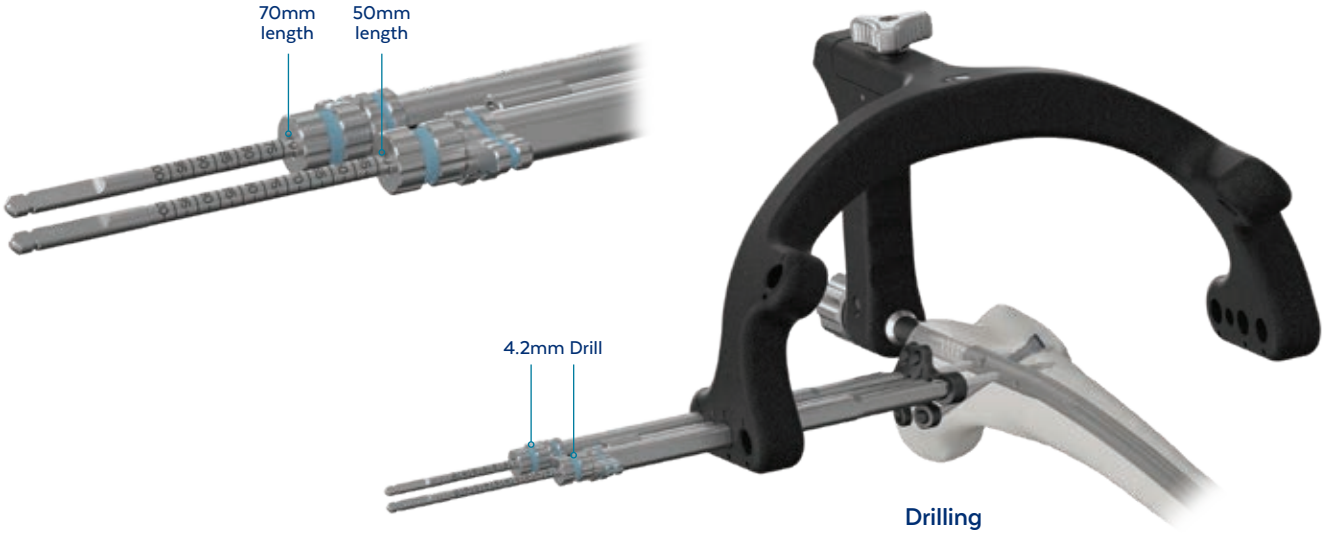
Remove the trocar from the distal trocar sleeve assembly. Verify the drill sleeve is contacting the locking washer.

Insert a 4.2mm calibrated drill bit into the distal drill sleeve and drill to the desired depth. Measure hole depth using the calibrated drill. Refer to *Screw Length Measurement Using the Calibrated Drill Bit* (page 25) for instructions.

DRILLING PROXIMAL HOLE

Remove the trocar from the proximal trocar sleeve assembly. Verify the drill sleeve is contacting the locking washer.

Insert a 4.2mm calibrated drill bit into the proximal drill sleeve and drill to the desired depth. Measure hole depth using the calibrated drill. Refer to *Screw Length Measurement Using the Calibrated Drill Bit* (page 25) for instructions.



Drilling

Alternatively, to measure hole depth, a depth gauge can be used. Refer to *Screw Length Measurement Using the Depth Gauge* (page 25) for instructions.

Do not remove both drill bits to measure simultaneously. Measure hole depth using the depth gauge in sequence with screw insertion.

Using Depth Gauge

INSERTING POLYAXIAL LOCKING WASHER SCREWS

Remove the distal drill bit and drill sleeve. Insert the selected 5mm locking washer screw into the locking washer and nail using the T25 driver. If inserting under power, use the **Torque-Limiting Attachment, 2.5Nm, AO Quick-Connect**. Do not final tighten under power. Verify screw position under fluoroscopy.

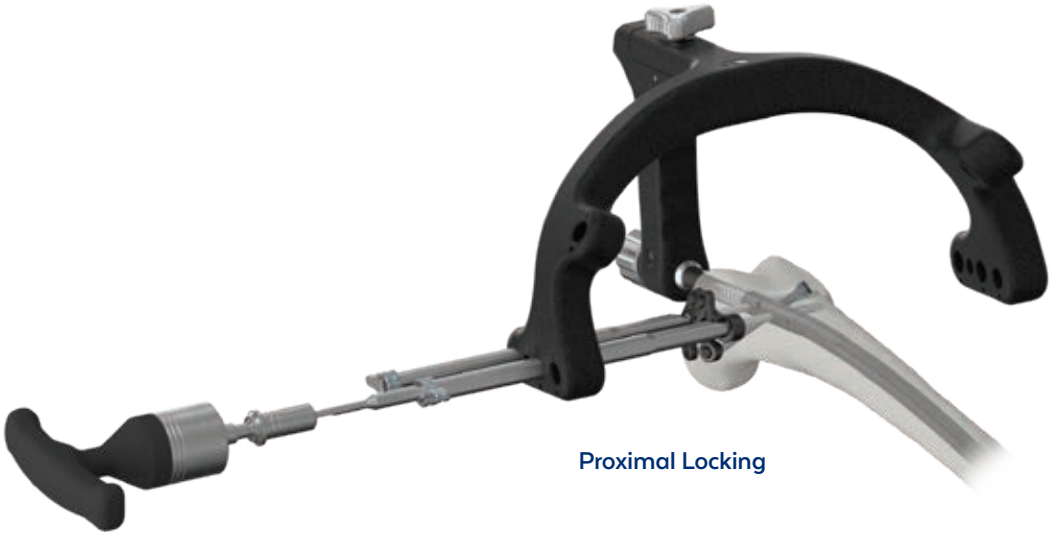
Remove the proximal drill bit and drill sleeve. Insert the selected 5mm locking washer screw into the locking washer and nail using the T25 driver. If inserting under power, use the Torque-Limiting Attachment, 2.5Nm, AO Quick-Connect. Do not final tighten under power. Verify screw position under fluoroscopy.

Remove the Locking Washer Attachment Handle by using the T25 Driver. Insert the driver into the drive recess in the attachment handle and rotate counterclockwise to loosen. Remove the attachment handle. Confirm locking washer fit and position prior to final tightening. Final tighten all 5mm polyaxial screws using the T-Handle Large, Small AO Quick-Connect, Limiting 7Nm.

Confirm screw position and length using fluoroscopy. Remove the driver and driver sleeves.

Alternatively, 5mm headed locking screws may also be used with the locking washer. Use the T30 driver to insert screws.

Distal Locking



Proximal Locking

LATERAL OBLIQUE LOCKING: INSERTING TROCAR SLEEVES

Insert the 5mm trocar sleeve into the lateral oblique hole in the Aiming Arm. Create a small incision and insert the trocar sleeve into the skin until bone is reached. Rotate the trocar sleeve assembly for retention. Refer to *Trocar Sleeve Assembly* (page 23) for sleeve assembly and retention instructions.

Inserting Trocar Sleeves

DRILLING LATERAL OBLIQUE HOLE

Remove the trocar. Insert the 4.2mm calibrated drill bit into the drill sleeve and drill to the desired depth. Measure hole depth using the calibrated drill or depth gauge. Refer to *Screw Length Measurement Using the Calibrated Drill Bit* (page 25) or *Screw Length Measurement Using the Depth Gauge* (page 25) for instructions.

Remove the drill bit and drill sleeve.

72.5mm measurement shown

Drilling

INSERTING LATERAL OBLIQUE LOCKING SCREWS

Select the appropriate 5mm locking screw. Use the T30 driver to insert the selected 5mm locking screw through the driver sleeve. A retention rod may be used for screw retention as needed; refer to *Screw Retention* (page 27) for instructions.

Do not use power for final tightening. Final tightening should be performed manually with a quick-connect handle.

Confirm screw length using fluoroscopy. Remove the driver, driver sleeve, and Aiming Arm.

Inserting Locking Screw

LOCKING WASHER CONTOUR

The posterior 3.5mm holes in the locking washer have tab features that may be contoured. Use the ***In Situ* Bender** to contour the tabs for anatomical fit.

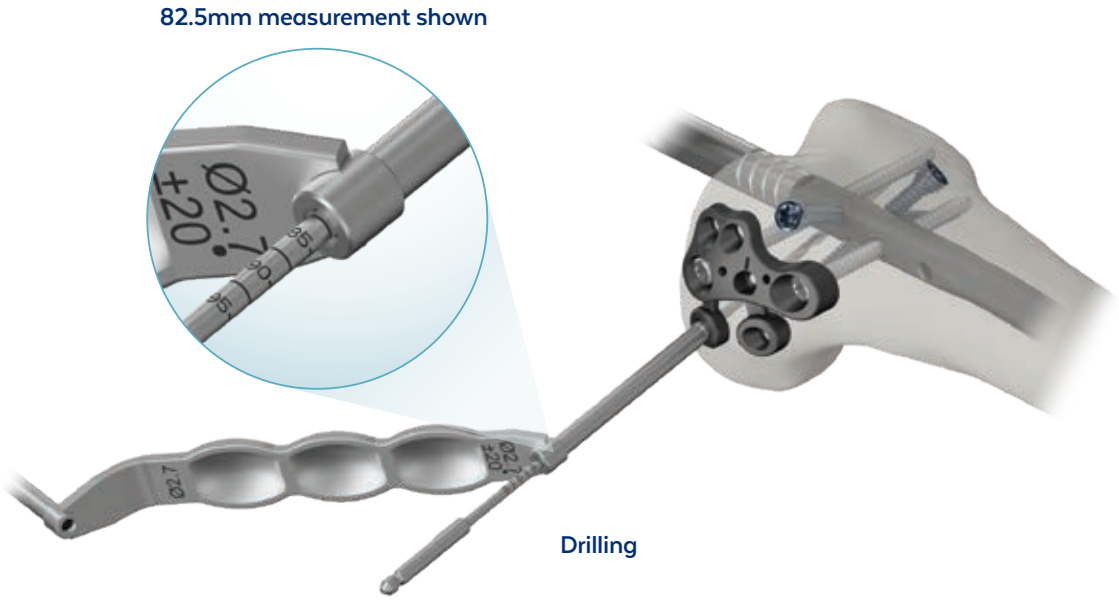
Note: Do not over-contour the tabs as this may cause weakening and breakage of the tab.

Using *In Situ* Bender

DRILLING FOR 3.5mm LOCKING SCREWS

Using the **2.7mm Polyaxial Drill Guide** and **2.7mm Calibrated Drill Bit**, seat the drill guide into the desired 3.5mm hole on the locking washer.

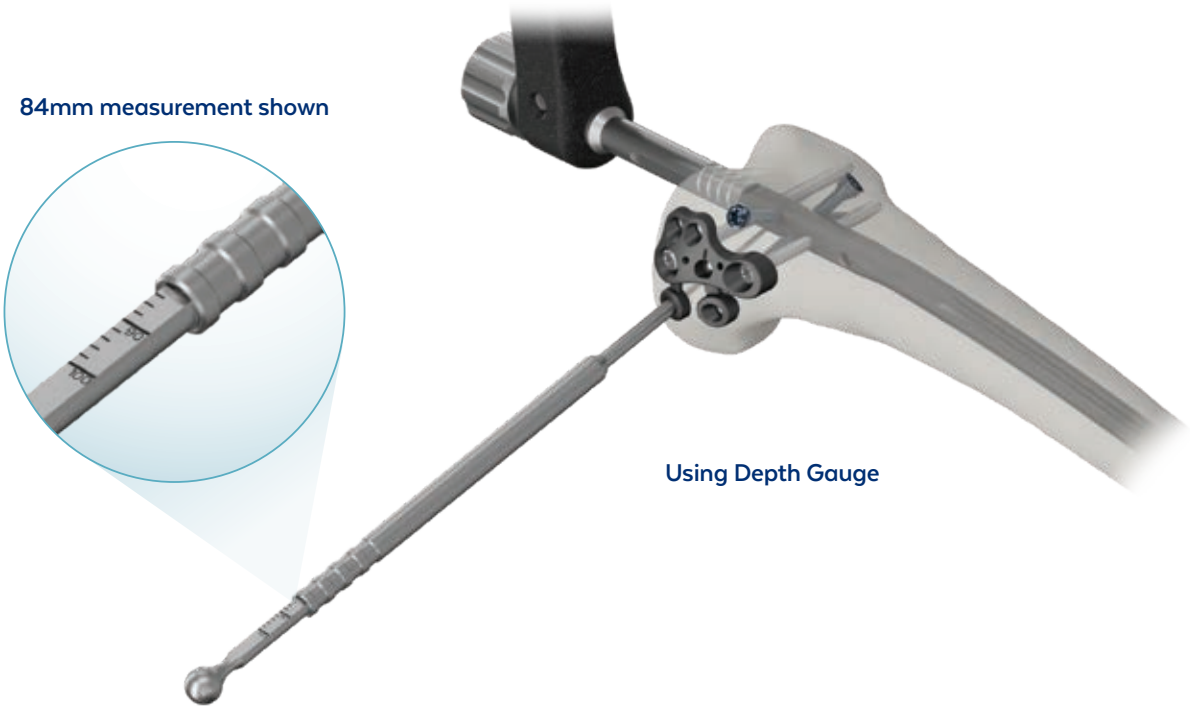
Drill to the desired depth and measure hole depth using the calibrated drill.



Alternatively, to measure hole depth, remove the drill bit and drill guide after drilling.

Insert the **3.5mm Depth Gauge** through the locking washer and drilled hole. Extend the tip completely through the femur and retract until the hook engages the far cortical wall.

Determine the length by reading the measurement directly off the back of the gauge. Remove the depth gauge.



INSERTING 3.5mm LOCKING SCREWS

Insert the selected 3.5mm polyaxial locking screw. Final tighten all 3.5mm locking screws with a **2.5Nm Torque-Limiting Attachment**. Verify screw position under fluoroscopy.

Repeat steps for additional 3.5mm polyaxial locking screws as desired. Ensure that the 3.5mm screws do not interfere with other hardware.

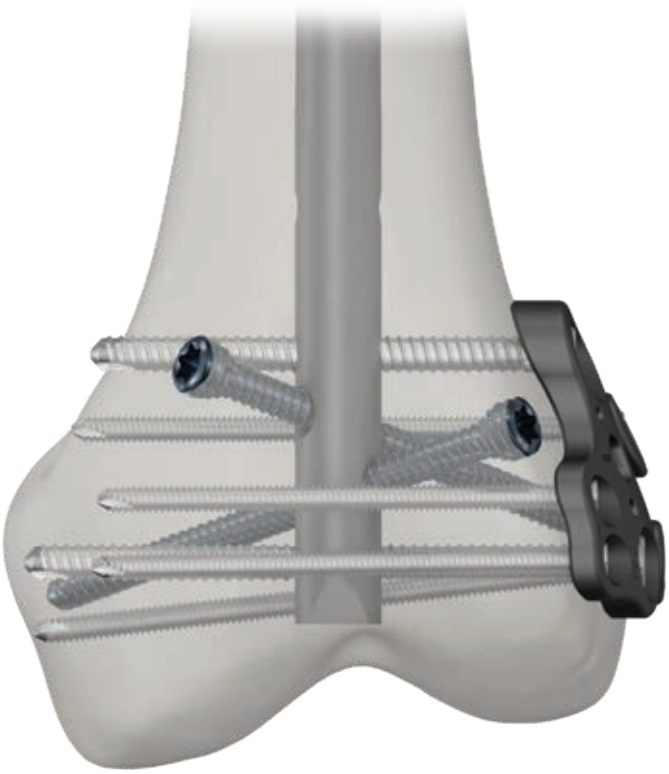
Inserting 3.5mm Locking Screw

Final Construct

Alternatively, 3.5mm non-locking screws can also be used with the 3.5mm holes in the Locking Washer.

Use the T15 driver to insert non-locking screws as desired.

LOCKING WASHER
FINAL CONSTRUCT



CONDYLE WASHER AND SCREWS

CONDYLE LOCKING OVERVIEW

Condyle Nuts and Washers may be used for compression and may only be used with 5mm locking screws placed into lateral-medial holes in the nail.

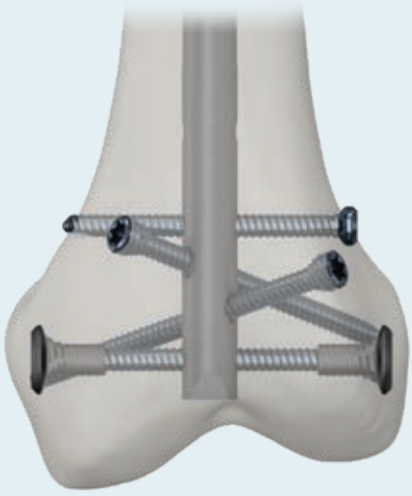
Forceps may be used to provisionally hold the Condyle Nut or Washer prior to screw head engagement on the cortex. The appropriate washer should be positioned over the nut or screw prior to inserting the screw into bone.

CONDYLE IMPLANTS

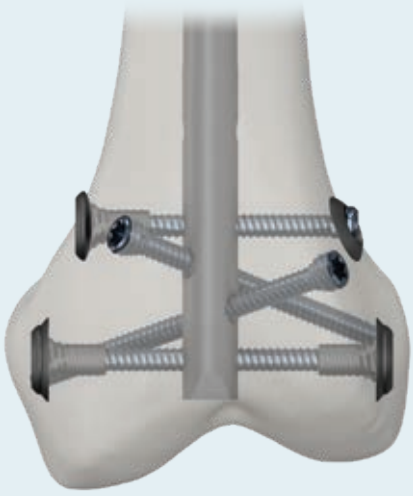
Washer for Screw

Condyle Nut Washer

Condyle Nut



Standard Condyle Nut Construct



Condyle Nut and Washer Construct

ATTACHING AIMING ARM

Refer to *Aiming Arm Overview* (page 21) for assembly instructions.

INSERTING TROCAR SLEEVES

Insert the 5mm trocar sleeve into the desired distal hole in the Aiming Arm. Create a small incision and insert the trocar sleeve into the skin until bone is reached. Rotate the trocar sleeve assembly for retention. Refer to *Trocar Sleeve Assembly* (page 23) for sleeve assembly and retention instructions.

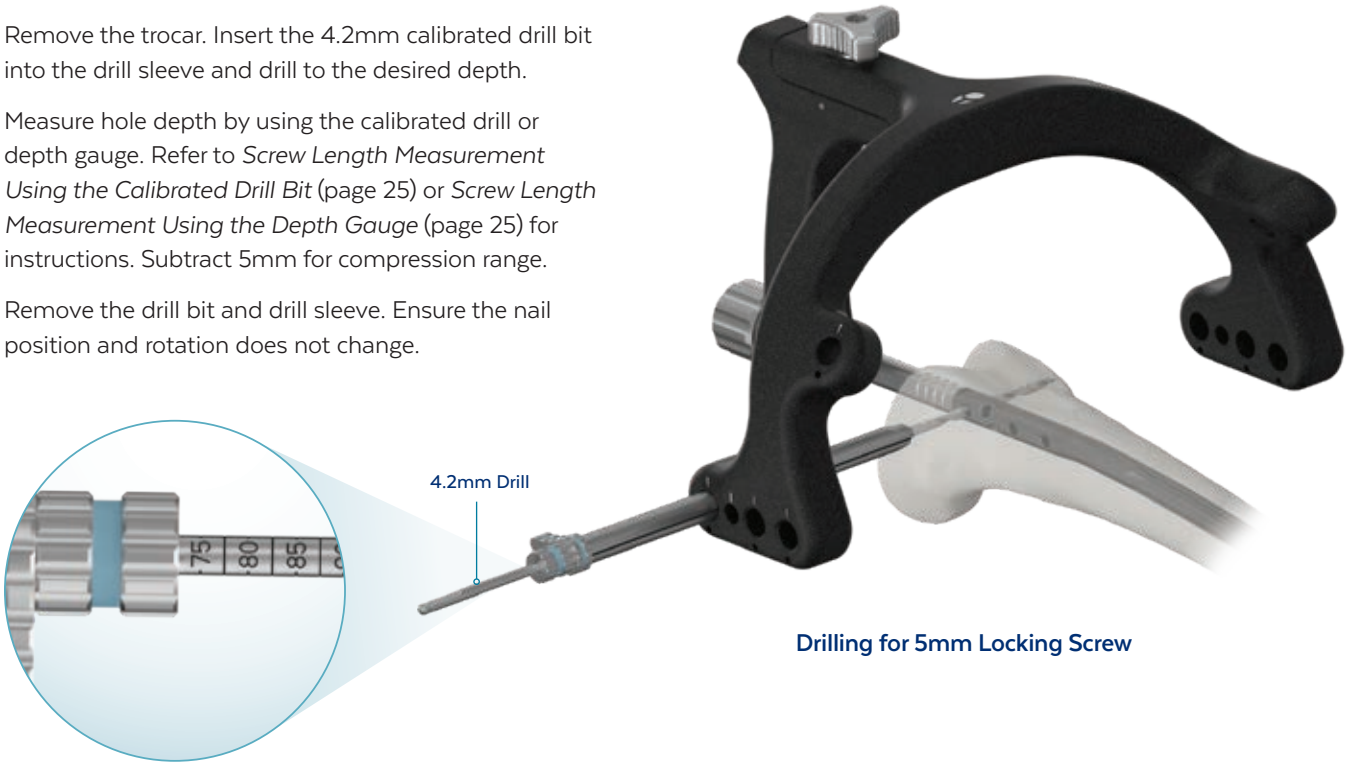
Inserting Trocar Sleeves

DRILLING FOR LOCKING SCREW

Remove the trocar. Insert the 4.2mm calibrated drill bit into the drill sleeve and drill to the desired depth.

Measure hole depth by using the calibrated drill or depth gauge. Refer to *Screw Length Measurement Using the Calibrated Drill Bit* (page 25) or *Screw Length Measurement Using the Depth Gauge* (page 25) for instructions. Subtract 5mm for compression range.

Remove the drill bit and drill sleeve. Ensure the nail position and rotation does not change.



72.5mm measurement shown

Drilling for 5mm Locking Screw

DRILLING FOR CONDYLE NUT

Insert the **6.5mm Drill Bit, Condyle Nut** through the driver sleeve to drill the lateral cortex. Do not over-drill the near cortex as it may affect bone purchase with the condyle nut implant.

Over-Drilling Lateral Cortex

INSERTING SCREW INTO CONDYLE NUT

Pull the driver sleeve away from the cortex and hold the condyle nut over the drilled hole.

Select the appropriate 5mm locking screw. Use the T30 driver to insert the selected 5mm locking screw through the driver sleeve. A retention rod may be used for screw retention as needed; refer to *Screw Retention* (page 27) for instructions.

Do not insert the screw completely and final tighten. Final tightening should be performed once the medial locking side is prepared.

Confirm screw length using fluoroscopy. Remove the driver, driver sleeve, and aiming arm. A washer may be used with the condyle nut or with a 5mm locking screw as needed.

Inserting 5mm Locking Screw through Condyle Nut

MEDIAL LOCKING

From the medial side, insert the 5mm driver sleeve.

Drill the cortex with the 6.5mm drill bit. Remove the drill and driver sleeve.

Inserting Medial Trocar Sleeve

Over-Drilling Medial Cortex

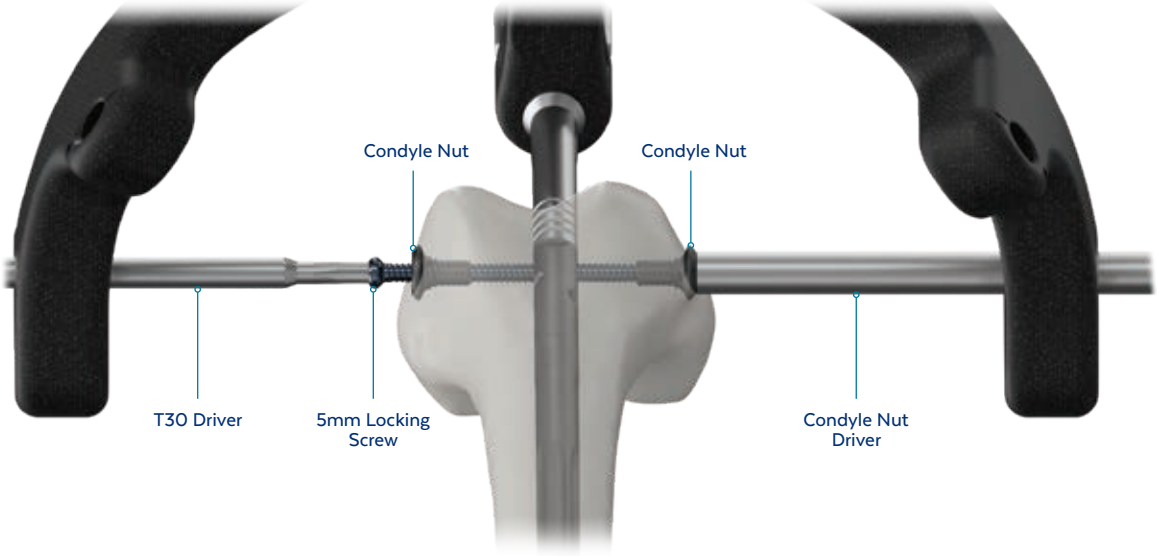
MEDIAL LOCKING (CONT'D)

Hold the Condyle Nut over the drilled hole. Insert the **Condyle Nut Driver** through the aiming arm and engage the Condyle Nut.

Align the Condyle Nut to the screw tip and rotate clockwise until the nut is fully seated. Engage the 5mm screw head on the lateral side with a T30 driver for counter-torque.

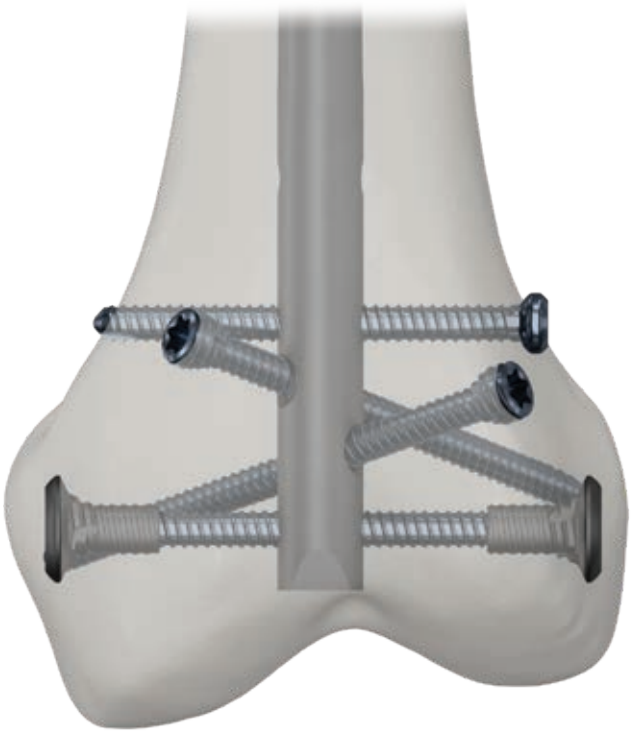
Washers can be used to add cortical contact. Repeat steps for additional locking screws as desired.

Inserting Medial Condyle Nut



Final Tightening with Counter-Torque

CONDYLE WASHER
FINAL CONSTRUCT

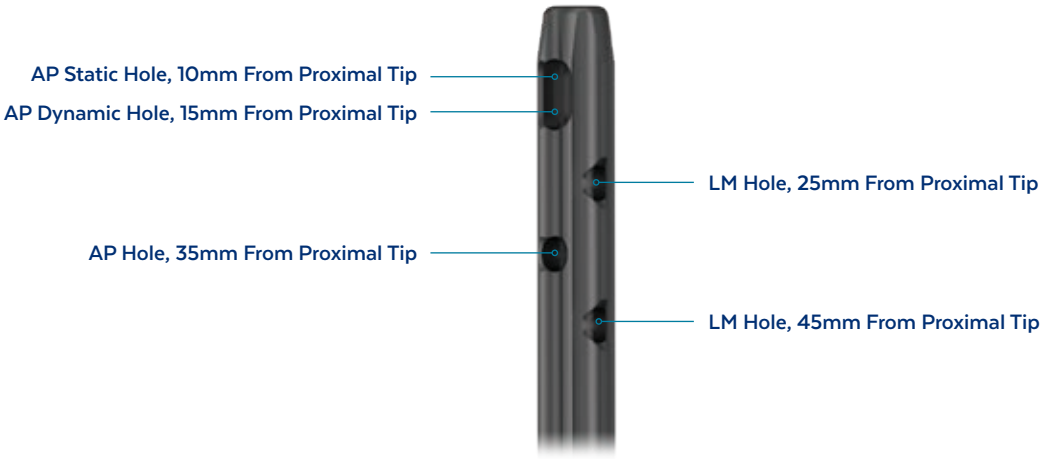


PROXIMAL LOCKING SCREWS

FREEHAND TARGETING

Proximal locking is performed freehand using the perfect circle technique. Verify fracture reduction and alignment on AP and lateral views using fluoroscopy.

Select the desired proximal hole on the nail. Align the C-arm so that the hole is a perfect circle under fluoroscopy. Place a scalpel blade on the skin over the center of the desired hole. Verify position of the blade under fluoroscopy and create a small incision.



Proximal Hole Options

Identifying Incision Point

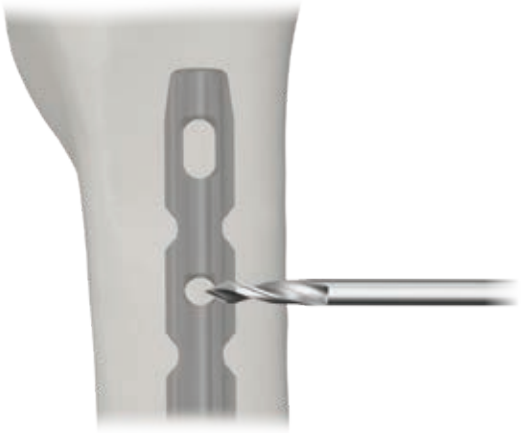
DRILLING AND MEASUREMENT

Insert the 4.2mm drill bit into the incision until bone is reached. Angle the drill bit perpendicular to the nail hole and drill through both cortices. Confirm drill bit position under fluoroscopy.

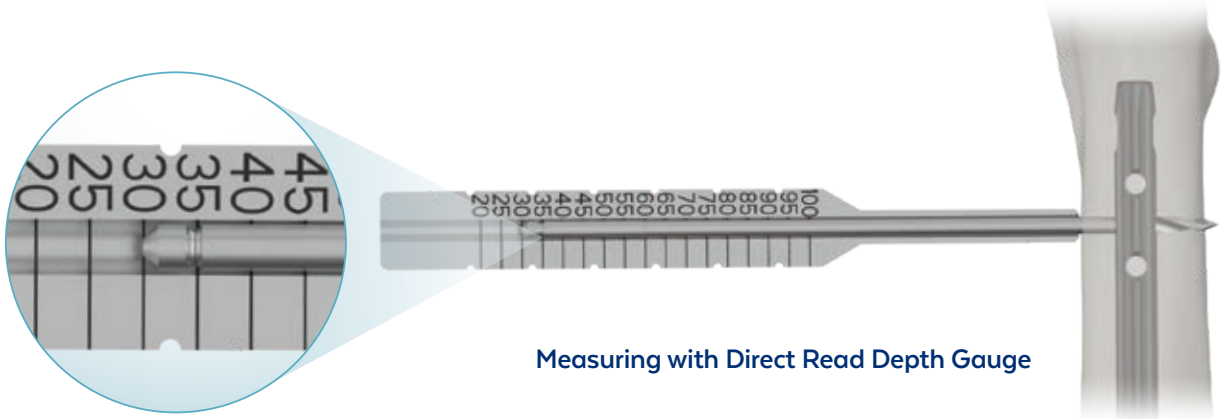
Hole measurement may be performed with the **Direct Read Depth Gauge** or a standard short hook depth gauge.

To use the direct read depth gauge, insert the depth gauge beside the drill bit until bone is reached. Read the measurement directly from the back of the drill bit. Remove the gauge.

Alternatively, to measure hole depth, remove the drill bit. Insert the depth gauge until bone is reached. Extend the hook completely through the femur and retract until the hook engages the far cortical wall. Determine the length by reading the measurement on the gauge. Remove the depth gauge.

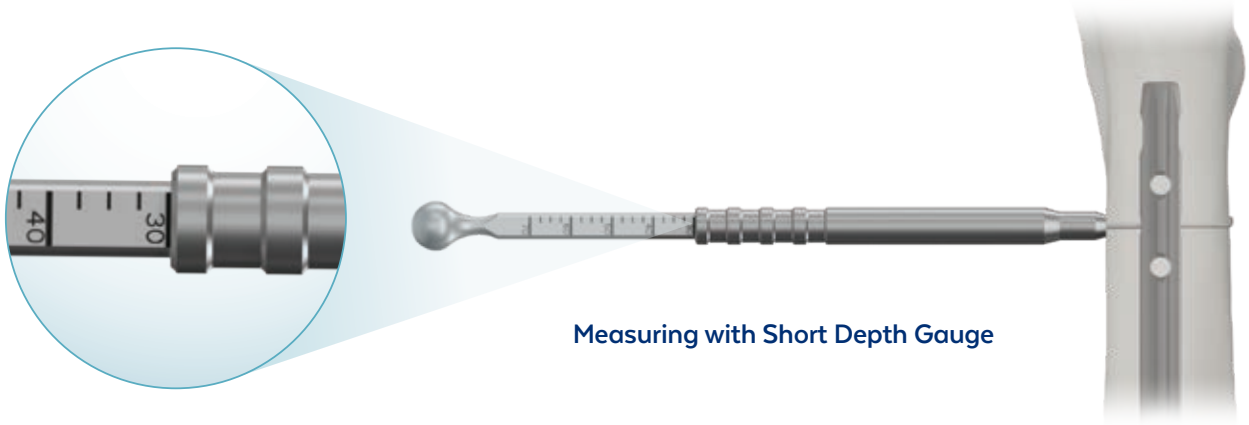


Identifying Drill Start Point



Measuring with Direct Read Depth Gauge

30mm measurement shown



Measuring with Short Depth Gauge

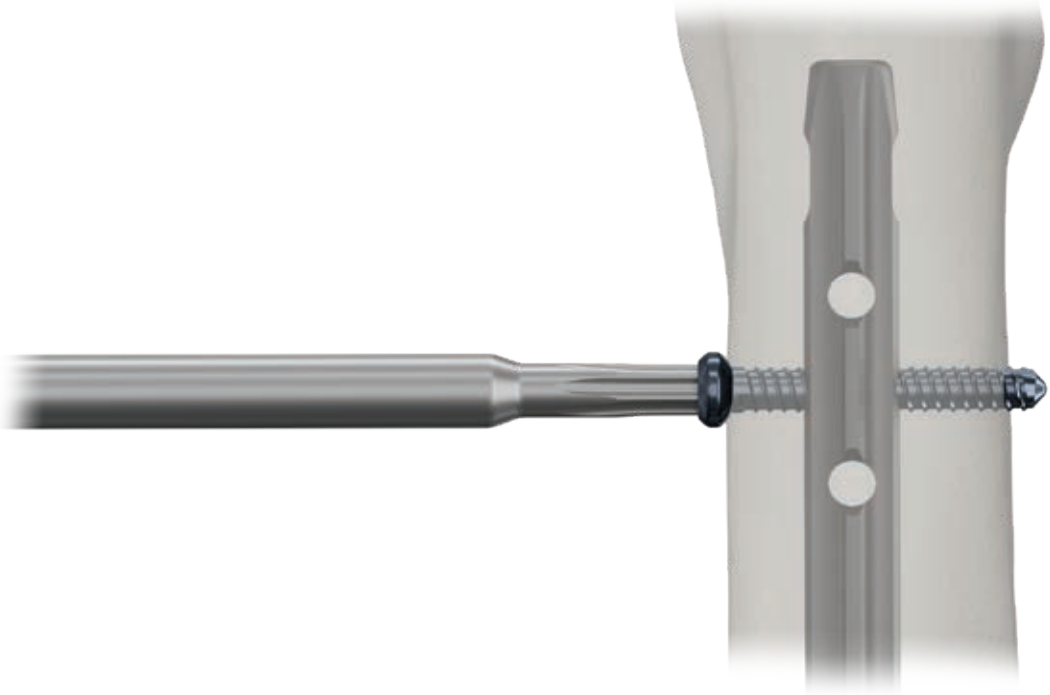
30mm measurement shown

INSERTING LOCKING SCREW

Select the appropriate 5mm locking screw. Use the T30 driver to insert the selected 5mm locking screw through the driver sleeve. A retention rod may be used for screw retention as needed; refer to *Screw Retention* (page 27) for instructions.

Do not use power for final tightening. Final tightening should be performed manually with a quick-connect handle.

Confirm screw length using fluoroscopy. Remove the driver. Repeat steps for additional locking screws.



Inserting Distal Locking Screw

PROXIMAL LOCKING
FINAL CONSTRUCT

OPTIONAL: END CAP INSERTION

The end cap may be used to prevent bony ingrowth covering the distal tip of the nail. End caps may also be used to extend the length of the nail if the nail is overly countersunk.

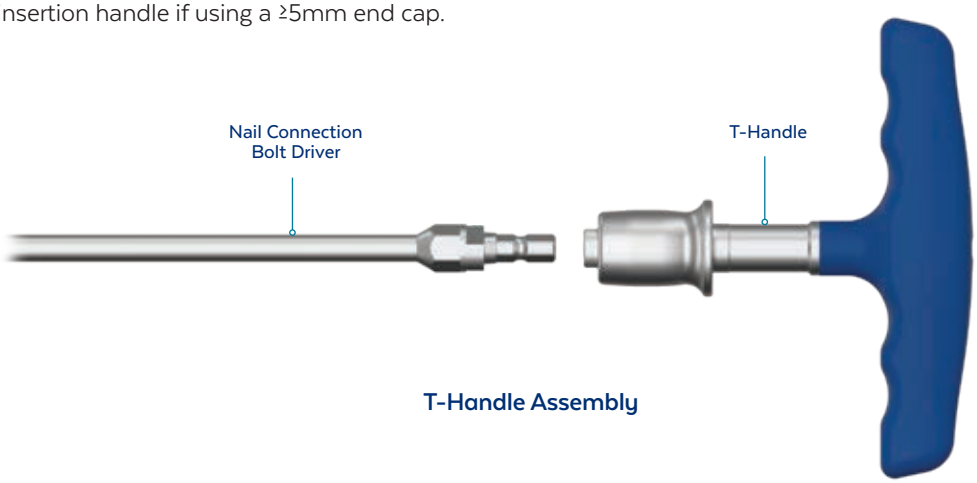
The end cap interfaces with the distal-most 5mm locking screw and creates a fixed angle construct.

Connection Bolt Removal

Attach the nail connection bolt driver to a quick-connect handle, then insert the nail connection bolt driver into the nail connection bolt. Rotate the driver counterclockwise to loosen and remove the bolt.

Keep the insertion handle attached to the nail if using a flush end cap.

Remove the insertion handle if using a ≥5mm end cap.



T-Handle Assembly

End Cap Insertion

A retention rod should be used to retain the end cap onto the T30 driver. Insert the selected end cap into the nail using the T30 driver with a quick-connect handle. Rotate clockwise to tighten. Remove the retention rod and driver.

Confirm position under fluoroscopy.

Inserting End Cap

OPTIONAL: NAIL REMOVAL

If applicable, remove the end cap from the nail with a T30 driver.

Use the appropriate T30 driver to remove the distal locking screws. Engage the screw drive recess and rotate counterclockwise to remove the screws.

Thread the **Nail Extraction Bolt, Retrograde** into the nail with proximal locking screws in place to prevent nail rotation or subsidence.

An extraction pin wrench may be optionally used to tighten the extraction bolt.

Alternatively, the Aiming Arm may be used to remove the distal screws. Attach the Insertion Handle to the nail, and fasten with the Nail Connection Bolt. Attach the Aiming Arm to the Insertion Handle. Target and remove distal screws with the T30 driver through the 5mm driver sleeves. Remove the Aiming Arm and thread the **Backslap Shaft** to the Insertion Handle.

End Cap removal

Distal Screw removal

Extraction Bolt insertion

OPTIONAL: NAIL REMOVAL (CONT'D)

To remove proximal locking screws, use the appropriate T30 driver and engage the screw. Rotate the driver counterclockwise to remove the screw.

Locking Screw removal

Once all screws have been removed, thread the backslap shaft to the nail extraction bolt.

Use the slotted mallet to deliver gentle blows until the nail is fully extracted.

Nail removal

BROKEN NAIL REMOVAL

Thread the nail extraction bolt to the nail, and attach the backslap shaft to the extraction bolt.

Engage each locking screw with a T30 driver and remove. Using the slotted mallet, deliver gentle blows to backslap the nail and remove the distal nail fragment.

Insert the ball-tip guidewire into the cannulation of the proximal nail fragment. Insert the **1.6mm Removal Wire** through the nail cannulation, adjacent to the ball-tip guidewire, until it also extends past the nail fragment.

Attach the T-handle 3 jaw chuck to the ball-tip guidewire and tighten until secure. Use the T-handle to extract the nail fragment.

INSTRUMENT OVERVIEW

NAIL MEASUREMENT

Nail Length Gauge, 6176.0010

Extension Nail Length Gauge, 6176.0011

OPENING

Protection Sleeve 12.8mm, 6257.1017

Multi-Hole Wire Guide, 12.8mm, 6257.1018

Periprosthetic Wire Guide, 11.2mm, 6257.1019

Hall Quick-Connect Handle, 6190.3000

3.2mm Guidewire, Threaded Drill Point, 285mm, 6257.0031*

3.2mm Guidewire, Drill Point, 285mm, 6257.0032*

*Available non-sterile or sterile.
Add "S" to the end of the part number to indicate sterile.

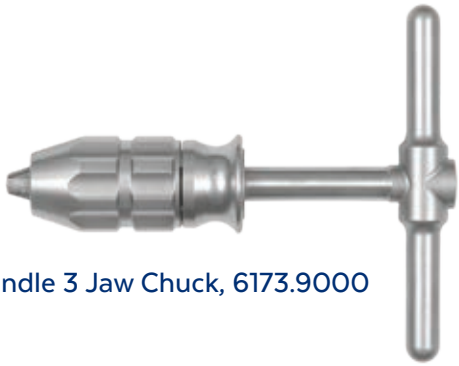
12.8mm Cannulated Opening Drill Bit, 6257.1020

11.2mm Cannulated Opening Drill Bit, 6257.1021

12.8mm Cannulated Opening Drill Bit, Short Flutes, 6257.2020

11.2mm Cannulated Opening Drill Bit, Short Flutes, 6257.2021

Ball-Tip Guidewire 3x1000mm, 6176.0022S



T-Handle 3 Jaw Chuck, 6173.9000

Intramedullary Reduction Tool, Hall Connection, 6257.1062

REAMING

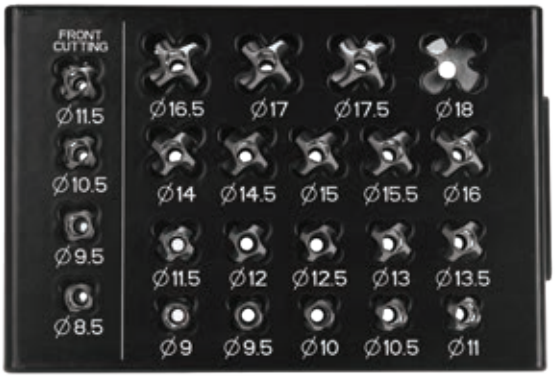
Flexible Reamer Shaft, 470mm, Hall Connection, 6182.0004*

Flexible Reamer Shaft, 620mm, Hall Connection, 6182.0005*

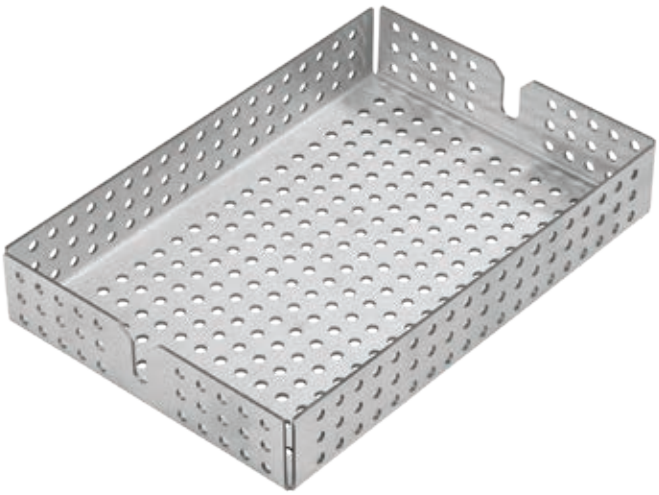
Guidewire Pusher 6176.0029

Front Cutting Reamer Heads, 6182.2085-.2115

Piloted Reamer Heads, 6182.1090-.1180



Reamer Caddy 9182.0001



Reamer Removal Tray 9182.0002

*Available non-sterile or sterile.
Add "S" to the end of the part number to indicate sterile.

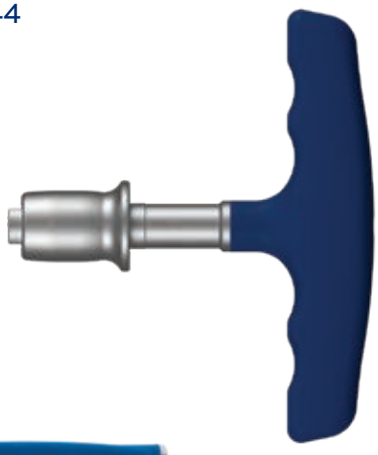
NAIL ASSEMBLY & INSERTION

Insertion Handle,
Retrograde, 6257.1024

Nail Connection Bolt, Retrograde, 6257.1026

Nail Assembly Shaft, 6257.1027

Nail Connection Bolt Driver, Shaft, 6257.1044



Hall Quick-Connect T-Handle, 6257.1058

Slotted Mallet, 6176.0020

5mm TARGETED LOCKING

Aiming Arm, Retrograde, 6257.1040

Driver Sleeve, 5mm, 6257.1029

Drill Sleeve, 4.2mm, 6257.1030

Trocar, 4.2mm, 6257.1031

4.2mm Calibrated Drill Bit, 330mm, 6257.1036*

4.2mm Calibrated Drill Bit, 330mm, Short Flutes, 6257.2036*

Depth Gauge, 5mm, Long, 6257.1050

T30 5mm Screwdriver for Power, Long, 6257.1080

Retention Rod, T30 5mm Screwdriver for Power, Long, 6257.1081

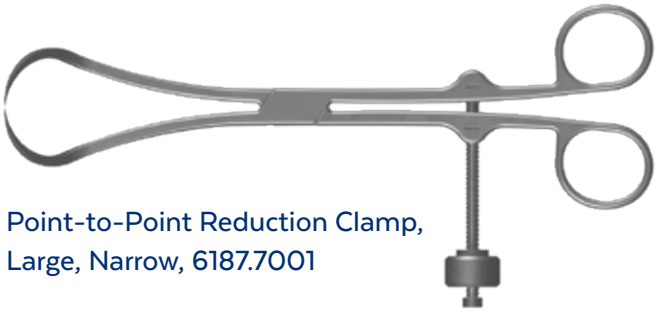
*Available non-sterile or sterile.
Add "S" to the end of the part number to indicate sterile.

LOCKING WASHER

Locking Washer Attachment Handle, 6257.1047

K-Wire, 1.8x150mm, Trocar, 6187.0180

2.7mm Speed Lock Drill Guide, Long, 6171.4227



Point-to-Point Reduction Clamp, Large, Narrow, 6187.7001

Point-to-Point Reduction Forceps, Large, Ratcheting, 6168.2003

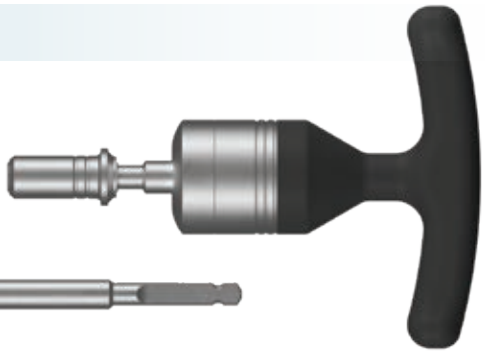
Stabilizing Radiolucent Weitlaner 3x4, 8", Sharp Tip, 6171.0002

T25 SR Screwdriver for Power, Hall Quick-Connect, 6257.1070

Torque-Limiting Attachment, 2.5Nm, AO Quick-Connect, 6187.3801

LOCKING WASHER (CONT'D)

T-Handle Large, Small AO QC, Limiting 7Nm, 6206.2707



In Situ Bender, 6257.1066

2.7mm Polyaxial Drill Guide, 6257.1067

2.7mm Calibrated Drill Bit, 200mm, AO Quick-Connect, 6257.1068

Depth Gauge, 3.5mm, 6257.1071

Driver, T15 SR, 170mm, AO Quick-Connect, 6187.3715

Medium Handle, AO Quick-Connect, 6188.7001

CONDYLE NUT

6.5mm Drill Bit, Condyle Nut, 6257.1035

Condyle Nut Driver, 6257.1065

PROXIMAL LOCKING

4.2mm Drill Bit, 170mm, 6257.1037*

4.2mm Drill Bit, 170mm, Short Flutes, 6257.2036*

Direct Read Depth Gauge, 5mm, 6257.1038

Depth Gauge, 5mm, Short, 6257.1060

T30 Screwdriver for Power, Short, 6257.1063

Retention Rod, T30 Screwdriver for Power, Short, 6257.1064

REMOVAL

Nail Extraction Bolt, Retrograde, 6257.1073

Backslap Shaft, Retrograde, 6257.1028

Locking Screw Removal Tool 6176.0031

Trephine 6190.0048

Extractor Pin Wrench 6176.0066

Punch 6176.0032

Nail Removal Wire 6176.0030S

*Available non-sterile or sterile.
Add "S" to the end of the part number to indicate sterile.

AUTOBAHN® EVO Retrograde Nail
IMPLANTS

Nails

	5°	10°	Description
10mm	6257.5032S – 6257.5044S	6257.6032S – 6257.6044S	20mm increments
11mm	6257.5132S – 6257.5144S	6257.6132S – 6257.6144S	
12mm	6257.5232S – 6257.5244S	6257.6232S – 6257.6244S	

Locking Screws

Part No.	Description
1257.8330* – 1257.8400*	5mm Locking Screws, 30-55mm in 2.5mm increments, 60-100mm in 5mm increments
1257.8530* - 1257.8600*	5mm Headless Locking Screws, 30-55mm in 2.5mm increments, 60-100mm in 5mm increments

End Cap

Part No.	Description
1257.0200*	End Cap, 0mm

Condyle Nut

Part No.	Description
1257.0420	Washer for Nut
1257.0500	Washer for Screw
1257.0510	Condyle Nut

Locking Washer

Part No.	Description
1257.7111	Locking Washer, Left, 5°
1257.7112	Locking Washer, Right, 5°
1257.7211	Locking Washer, Left, 10°
1257.7212	Locking Washer, Right, 10°

Locking Washer Screws

Part No.	Description
7179.5026 – 7179.5095	3.5mm Polyaxial Locking Screws, 26-60mm in 2mm increments, 65-95mm in 5mm increments
7257.7350 – 7257.7400	5mm Polyaxial Locking Screws, 50-100mm in 5mm increments

**Available non-sterile or sterile.*
Add "S" to the end of the part number to indicate sterile.

AUTOBAHN® EVO RETROGRADE NAILING SYSTEM
INSTRUMENT SET I 9257.9201

Part No.	Description	Qty
6173.9000	T-Handle 3 Jaw Chuck	1
6176.0010	Nail Length Gauge	1
6176.0011	Extension, Nail Length Gauge	1
6176.0022S	Ball-Tip Guidewire, 3.0x1000mm	4
6176.0029	Guidewire Pusher	1
6182.0004	Flexible Reamer Shaft, 470mm, Hall Connection	2
6190.3000	Hall Quick-Connect Handle	1
6257.0031	3.2mm Guidewire, Threaded Drill Point, 285mm	4
6257.0032	3.2mm Guidewire, Drill Point, 285mm	4
6257.1017	Protection Sleeve 12.8mm	1
6257.1018	Multi-Hole Wire Guide, Retrograde, 12.8mm	1
6257.1019	Wire Guide, Retrograde, 11.2mm	1
6257.1020	12.8mm Cannulated Opening Drill Bit	1
6257.2020	12.8mm Cannulated Opening Drill Bit, Short Flutes	0
6257.1021	11.2mm Cannulated Opening Drill Bit	1
6257.2021	11.2mm Cannulated Opening Drill Bit, Short Flutes	0
6257.1024	Insertion Handle, Retrograde	1
6257.1026	Nail Connection Bolt, Retrograde	1
6257.1027	Nail Assembly Shaft	1
6257.1028	Backslap Shaft, Retrograde	1
6257.1044	Nail Connection Bolt Driver, Shaft	1
6257.1058	Hall Quick-Connect T-Handle	1
6257.1062	Intramedullary Reduction Tool, Hall Connection	1
6257.1073	Nail Extraction Bolt, Retrograde	1
9257.2001	AUTOBAHN® EVO Retrograde Nail Instrument Set I	

Items in gray are additionally available.

AUTOBAHN® EVO RETROGRADE NAILING SYSTEM
INSTRUMENT SET II 9257.9202

Part No.	Description	Qty
1257.0420	AUTOBAHN® EVO Retrograde Femoral Nail Washer for Nut, Ti	0
1257.0500	AUTOBAHN® EVO Retrograde Femoral Nail Washer for Screw, Ti	0
1257.0510	AUTOBAHN® EVO Retrograde Femoral Nail Condyle Nut, Ti	0
6171.4227	2.7mm Speed Lock Drill Guide	0
6176.0020	Slotted Mallet	1
6176.0031	Locking Screw Removal Tool	0
6176.0032	Punch	0
6176.0048	Trephine	0
6176.0066	Extractor Pin Wrench	1
6257.1029	Driver Sleeve, 5mm	2
6257.1030	Drill Sleeve, 4.2mm	2
6257.1031	Trocar, 4.2mm	2
6257.1035	6.5mm Drill Bit, Condyle Nut	0
6257.2036	4.2mm Calibrated Drill Bit, 330mm, Short Flutes	2
6257.2037	4.2mm Drill Bit, 170mm, Short Flutes	2
6257.1038	Direct Read Depth Gauge, 5mm	1
6257.1040	Aiming Arm, Retrograde	1
6257.1050	Locking Screw Depth Gauge, Long, 5mm	1
6257.1051	Countersink, 5mm Headless Locking Screws	1
6257.1060	Locking Screw Depth Gauge, Short, 5mm	1
6257.1063	Screwdriver for Power, Short	1
6257.1064	Retention Rod, Screwdriver for Power, Short	1
6257.1065	Condyle Nut Driver	0
6257.1080	T30 5mm Screwdriver for Power, Long	2
6257.1081	Retention Rod, T30 5mm Screwdriver for Power, Long	1
9257.2002	AUTOBAHN® EVO Retrograde Nail Instrument Set II	

Items in gray are additionally available.

AUTOBAHN® EVO RETROGRADE NAILING SYSTEM
SCREW SET 9257.9203

Part No.	Description	Qty
1257.8330	AUTOBAHN® EVO Headed Locking Screw, 5x30mm, Ti	3
1257.8333	AUTOBAHN® EVO Headed Locking Screw, 5x32.5mm, Ti	3
1257.8335	AUTOBAHN® EVO Headed Locking Screw, 5x35mm, Ti	3
1257.8338	AUTOBAHN® EVO Headed Locking Screw, 5x37.5mm, Ti	3
1257.8340	AUTOBAHN® EVO Headed Locking Screw, 5x40mm, Ti	3
1257.8343	AUTOBAHN® EVO Headed Locking Screw, 5x42.5mm, Ti	3
1257.8345	AUTOBAHN® EVO Headed Locking Screw, 5x45mm, Ti	3
1257.8348	AUTOBAHN® EVO Headed Locking Screw, 5x47.5mm, Ti	3
1257.8350	AUTOBAHN® EVO Headed Locking Screw, 5x50mm, Ti	3
1257.8353	AUTOBAHN® EVO Headed Locking Screw, 5x52.5mm, Ti	3
1257.8355	AUTOBAHN® EVO Headed Locking Screw, 5x55mm, Ti	3
1257.8360	AUTOBAHN® EVO Headed Locking Screw, 5x60mm, Ti	3
1257.8365	AUTOBAHN® EVO Headed Locking Screw, 5x65mm, Ti	3
1257.8370	AUTOBAHN® EVO Headed Locking Screw, 5x70mm, Ti	3
1257.8375	AUTOBAHN® EVO Headed Locking Screw, 5x75mm, Ti	3
1257.8380	AUTOBAHN® EVO Headed Locking Screw, 5x80mm, Ti	3
1257.8385	AUTOBAHN® EVO Headed Locking Screw, 5x85mm, Ti	3
1257.8390	AUTOBAHN® EVO Headed Locking Screw, 5x90mm, Ti	3
1257.8395	AUTOBAHN® EVO Headed Locking Screw, 5x95mm, Ti	3
1257.8400	AUTOBAHN® EVO Headed Locking Screw, 5x100mm, Ti	3
1257.8530	AUTOBAHN® EVO Headless Locking Screw, 5x30mm, Ti	3
1257.8533	AUTOBAHN® EVO Headless Locking Screw, 5x32.5mm, Ti	3
1257.8535	AUTOBAHN® EVO Headless Locking Screw, 5x35mm, Ti	3
1257.8538	AUTOBAHN® EVO Headless Locking Screw, 5x37.5mm, Ti	3
1257.8540	AUTOBAHN® EVO Headless Locking Screw, 5x40mm, Ti	3
1257.8543	AUTOBAHN® EVO Headless Locking Screw, 5x42.5mm, Ti	3
1257.8545	AUTOBAHN® EVO Headless Locking Screw, 5x45mm, Ti	3
1257.8548	AUTOBAHN® EVO Headless Locking Screw, 5x47.5mm, Ti	3
1257.8550	AUTOBAHN® EVO Headless Locking Screw, 5x50mm, Ti	3
1257.8553	AUTOBAHN® EVO Headless Locking Screw, 5x52.5mm, Ti	3
1257.8555	AUTOBAHN® EVO Headless Locking Screw, 5x55mm, Ti	3
1257.8560	AUTOBAHN® EVO Headless Locking Screw, 5x60mm, Ti	3
1257.8565	AUTOBAHN® EVO Headless Locking Screw, 5x65mm, Ti	3
1257.8570	AUTOBAHN® EVO Headless Locking Screw, 5x70mm, Ti	3
1257.8575	AUTOBAHN® EVO Headless Locking Screw, 5x75mm, Ti	3
1257.8580	AUTOBAHN® EVO Headless Locking Screw, 5x80mm, Ti	3
1257.8585	AUTOBAHN® EVO Headless Locking Screw, 5x85mm, Ti	3
1257.8590	AUTOBAHN® EVO Headless Locking Screw, 5x90mm, Ti	3
1257.8595	AUTOBAHN® EVO Headless Locking Screw, 5x95mm, Ti	3
1257.8600	AUTOBAHN® EVO Headless Locking Screw, 5x100mm, Ti	3
1257.0200	AUTOBAHN® EVO Retrograde Femoral Nail End Cap, 0mm, Ti	1
1257.0205	AUTOBAHN® EVO Retrograde Femoral Nail End Cap, 5mm, Ti	0
1257.0210	AUTOBAHN® EVO Retrograde Femoral Nail End Cap, 10mm, Ti	0
9257.2003	AUTOBAHN® EVO Retrograde Nail Screw Caddy	

Items in gray are additionally available.

AUTOBAHN® EVO RETROGRADE NAILING SYSTEM
LOCKING WASHER SET 9257.9204

Part No.	Description	Qty
1257.7111	AUTOBAHN® EVO Locking Washer, Small, Left, 5°, Ti	1
1257.7112	AUTOBAHN® EVO Locking Washer, Small, Right, 5°, Ti	1
1257.7211	AUTOBAHN® EVO Locking Washer, Small, Left, 10°, Ti	1
1257.7212	AUTOBAHN® EVO Locking Washer, Small, Right, 10°, Ti	1
6168.2003	Point-to-Point Reduction Forceps, Large, Ratcheting	1
6171.0002	Stabilizing Radiolucent Weitlaner 3x4, 8", Sharp Tip	1
6187.0180	K-Wire, 1.8x150mm, Trocar	4
6187.3715	Driver, T15 SR, 170mm, AO Quick-Connect	2
6187.3801	Torque-Limiting Attachment, 2.5Nm, AO Quick-Connect	1
6187.7001	Point-to-Point Reduction Clamp, Large, Narrow	1
6188.7001	Medium Handle, AO Quick-Connect	1
6206.2707	T-Handle Large, Small AO QC, Limiting 7Nm	1
6257.2036	4.2mm Calibrated Drill Bit, 330mm, Short Flutes	0
6257.1047	Locking Washer Attachment Handle	1
6257.1066	*In Situ* Bender	2
6257.1067	2.7mm Polyaxial Drill Guide	1
6257.1068	2.7mm Calibrated Drill Bit, 200mm, AO Quick-Connect	2
6257.1070	T25 SR Screwdriver for Power, AO Quick-Connect	1
6257.1071	Depth Gauge, 3.5mm	1
9257.2004	AUTOBAHN® EVO Locking Washer Set	

Items in gray are additionally available.

AUTOBAHN® EVO RETROGRADE NAILING SYSTEM
LOCKING WASHER SCREW CADDY 9257.9205

Part No.	Description	Qty
1179.3026	ANTHEM® Non-Locking Screw, 3.5x26mm Ti	0
1179.3028	ANTHEM® Non-Locking Screw, 3.5x28mm Ti	0
1179.3030	ANTHEM® Non-Locking Screw, 3.5x30mm Ti	0
1179.3032	ANTHEM® Non-Locking Screw, 3.5x32mm Ti	0
1179.3034	ANTHEM® Non-Locking Screw, 3.5x34mm Ti	0
1179.3036	ANTHEM® Non-Locking Screw, 3.5x36mm Ti	0
1179.3038	ANTHEM® Non-Locking Screw, 3.5x38mm Ti	0
1179.3040	ANTHEM® Non-Locking Screw, 3.5x40mm Ti	0
1179.3042	ANTHEM® Non-Locking Screw, 3.5x42mm Ti	0
1179.3044	ANTHEM® Non-Locking Screw, 3.5x44mm Ti	0
1179.3046	ANTHEM® Non-Locking Screw, 3.5x46mm Ti	0
1179.3048	ANTHEM® Non-Locking Screw, 3.5x48mm Ti	0
1179.3050	ANTHEM® Non-Locking Screw, 3.5x50mm Ti	0
1179.3052	ANTHEM® Non-Locking Screw, 3.5x52mm Ti	0
1179.3054	ANTHEM® Non-Locking Screw, 3.5x54mm Ti	0
1179.3056	ANTHEM® Non-Locking Screw, 3.5x56mm Ti	0
1179.3058	ANTHEM® Non-Locking Screw, 3.5x58mm Ti	0
1179.3060	ANTHEM® Non-Locking Screw, 3.5x60mm Ti	0
1179.3065	ANTHEM® Non-Locking Screw, 3.5x65mm Ti	0
1179.3070	ANTHEM® Non-Locking Screw, 3.5x70mm Ti	0
1179.3075	ANTHEM® Non-Locking Screw, 3.5x75mm Ti	0
1179.3080	ANTHEM® Non-Locking Screw, 3.5x80mm Ti	0
1179.3085	ANTHEM® Non-Locking Screw, 3.5x85mm Ti	0
1179.3090	ANTHEM® Non-Locking Screw, 3.5x90mm Ti	0
1179.3095	ANTHEM® Non-Locking Screw, 3.5x95mm Ti	0
7179.5026	ANTHEM® Locking Screw, 3.5x26mm CoCr	0
7179.5028	ANTHEM® Locking Screw, 3.5x28mm CoCr	0
7179.5030	ANTHEM® Locking Screw, 3.5x30mm CoCr	0
7179.5032	ANTHEM® Locking Screw, 3.5x32mm CoCr	0
7179.5034	ANTHEM® Locking Screw, 3.5x34mm CoCr	0
7179.5036	ANTHEM® Locking Screw, 3.5x36mm CoCr	3
7179.5038	ANTHEM® Locking Screw, 3.5x38mm CoCr	3
7179.5040	ANTHEM® Locking Screw, 3.5x40mm CoCr	3
7179.5042	ANTHEM® Locking Screw, 3.5x42mm CoCr	3
7179.5044	ANTHEM® Locking Screw, 3.5x44mm CoCr	3

Items in gray are additionally available.

AUTOBAHN® EVO RETROGRADE NAILING SYSTEM
LOCKING WASHER SCREW CADDY 9257.9205

Part No.	Description	Qty
7179.5046	ANTHEM® Locking Screw, 3.5x46mm CoCr	3
7179.5048	ANTHEM® Locking Screw, 3.5x48mm CoCr	3
7179.5050	ANTHEM® Locking Screw, 3.5x50mm CoCr	3
7179.5052	ANTHEM® Locking Screw, 3.5x52mm CoCr	3
7179.5054	ANTHEM® Locking Screw, 3.5x54mm CoCr	3
7179.5056	ANTHEM® Locking Screw, 3.5x56mm CoCr	3
7179.5058	ANTHEM® Locking Screw, 3.5x58mm CoCr	3
7179.5060	ANTHEM® Locking Screw, 3.5x60mm CoCr	3
7179.5065	ANTHEM® Locking Screw, 3.5x65mm CoCr	3
7179.5070	ANTHEM® Locking Screw, 3.5x70mm CoCr	3
7179.5075	ANTHEM® Locking Screw, 3.5x75mm CoCr	3
7179.5080	ANTHEM® Locking Screw, 3.5x80mm CoCr	3
7179.5085	ANTHEM® Locking Screw, 3.5x85mm CoCr	3
7179.5090	ANTHEM® Locking Screw, 3.5x90mm CoCr	3
7179.5095	ANTHEM® Locking Screw, 3.5x95mm CoCr	3
7257.7350	AUTOBAHN® EVO Locking Washer Screw, 5x50mm, CoCr	2
7257.7355	AUTOBAHN® EVO Locking Washer Screw, 5x55mm, CoCr	2
7257.7360	AUTOBAHN® EVO Locking Washer Screw, 5x60mm, CoCr	2
7257.7365	AUTOBAHN® EVO Locking Washer Screw, 5x65mm, CoCr	2
7257.7370	AUTOBAHN® EVO Locking Washer Screw, 5x70mm, CoCr	2
7257.7375	AUTOBAHN® EVO Locking Washer Screw, 5x75mm, CoCr	2
7257.7380	AUTOBAHN® EVO Locking Washer Screw, 5x80mm, CoCr	2
7257.7385	AUTOBAHN® EVO Locking Washer Screw, 5x85mm, CoCr	2
7257.7390	AUTOBAHN® EVO Locking Washer Screw, 5x90mm, CoCr	2
7257.7395	AUTOBAHN® EVO Locking Washer Screw, 5x95mm, CoCr	2
7257.7400	AUTOBAHN® EVO Locking Washer Screw, 5x100mm, CoCr	2
9257.2005	AUTOBAHN® EVO Locking Washer Screw Caddy	

Items in gray are additionally available.

AUTOBAHN® EVO RETROGRADE NAILING SYSTEM
5° NAILS 9257.9206

Part No.	Description	Qty
1257.5032S	AUTOBAHN® EVO Retrograde Femoral Nail, 10x320mm, 5°, Ti	1
1257.5034S	AUTOBAHN® EVO Retrograde Femoral Nail, 10x340mm, 5°, Ti	1
1257.5036S	AUTOBAHN® EVO Retrograde Femoral Nail, 10x360mm, 5°, Ti	1
1257.5038S	AUTOBAHN® EVO Retrograde Femoral Nail, 10x380mm, 5°, Ti	1
1257.5040S	AUTOBAHN® EVO Retrograde Femoral Nail, 10x400mm, 5°, Ti	1
1257.5042S	AUTOBAHN® EVO Retrograde Femoral Nail, 10x420mm, 5°, Ti	1
1257.5044S	AUTOBAHN® EVO Retrograde Femoral Nail, 10x440mm, 5°, Ti	1
1257.5132S	AUTOBAHN® EVO Retrograde Femoral Nail, 11x320mm, 5°, Ti	1
1257.5134S	AUTOBAHN® EVO Retrograde Femoral Nail, 11x340mm, 5°, Ti	1
1257.5136S	AUTOBAHN® EVO Retrograde Femoral Nail, 11x360mm, 5°, Ti	1
1257.5138S	AUTOBAHN® EVO Retrograde Femoral Nail, 11x380mm, 5°, Ti	1
1257.5140S	AUTOBAHN® EVO Retrograde Femoral Nail, 11x400mm, 5°, Ti	1
1257.5142S	AUTOBAHN® EVO Retrograde Femoral Nail, 11x420mm, 5°, Ti	1
1257.5144S	AUTOBAHN® EVO Retrograde Femoral Nail, 11x440mm, 5°, Ti	1
1257.5232S	AUTOBAHN® EVO Retrograde Femoral Nail, 12x320mm, 5°, Ti	1
1257.5234S	AUTOBAHN® EVO Retrograde Femoral Nail, 12x340mm, 5°, Ti	1
1257.5236S	AUTOBAHN® EVO Retrograde Femoral Nail, 12x360mm, 5°, Ti	1
1257.5238S	AUTOBAHN® EVO Retrograde Femoral Nail, 12x380mm, 5°, Ti	1
1257.5240S	AUTOBAHN® EVO Retrograde Femoral Nail, 12x400mm, 5°, Ti	1
1257.5242S	AUTOBAHN® EVO Retrograde Femoral Nail, 12x420mm, 5°, Ti	1
1257.5244S	AUTOBAHN® EVO Retrograde Femoral Nail, 12x440mm, 5°, Ti	1
9257.2006	AUTOBAHN® EVO Retrograde Nail Bank, 5°, Soft Case	

AUTOBAHN® EVO RETROGRADE NAILING SYSTEM
10° NAILS 9257.9207

Part No.	Description	Qty
1257.6032S	AUTOBAHN® EVO Retrograde Femoral Nail, 10x320mm, 10°, Ti	1
1257.6034S	AUTOBAHN® EVO Retrograde Femoral Nail, 10x340mm, 10°, Ti	1
1257.6036S	AUTOBAHN® EVO Retrograde Femoral Nail, 10x360mm, 10°, Ti	1
1257.6038S	AUTOBAHN® EVO Retrograde Femoral Nail, 10x380mm, 10°, Ti	1
1257.6040S	AUTOBAHN® EVO Retrograde Femoral Nail, 10x400mm, 10°, Ti	1
1257.6042S	AUTOBAHN® EVO Retrograde Femoral Nail, 10x420mm, 10°, Ti	1
1257.6044S	AUTOBAHN® EVO Retrograde Femoral Nail, 10x440mm, 10°, Ti	1
1257.6132S	AUTOBAHN® EVO Retrograde Femoral Nail, 11x320mm, 10°, Ti	1
1257.6134S	AUTOBAHN® EVO Retrograde Femoral Nail, 11x340mm, 10°, Ti	1
1257.6136S	AUTOBAHN® EVO Retrograde Femoral Nail, 11x360mm, 10°, Ti	1
1257.6138S	AUTOBAHN® EVO Retrograde Femoral Nail, 11x380mm, 10°, Ti	1
1257.6140S	AUTOBAHN® EVO Retrograde Femoral Nail, 11x400mm, 10°, Ti	1
1257.6142S	AUTOBAHN® EVO Retrograde Femoral Nail, 11x420mm, 10°, Ti	1
1257.6144S	AUTOBAHN® EVO Retrograde Femoral Nail, 11x440mm, 10°, Ti	1
1257.6232S	AUTOBAHN® EVO Retrograde Femoral Nail, 12x320mm, 10°, Ti	1
1257.6234S	AUTOBAHN® EVO Retrograde Femoral Nail, 12x340mm, 10°, Ti	1
1257.6236S	AUTOBAHN® EVO Retrograde Femoral Nail, 12x360mm, 10°, Ti	1
1257.6238S	AUTOBAHN® EVO Retrograde Femoral Nail, 12x380mm, 10°, Ti	1
1257.6240S	AUTOBAHN® EVO Retrograde Femoral Nail, 12x400mm, 10°, Ti	1
1257.6242S	AUTOBAHN® EVO Retrograde Femoral Nail, 12x420mm, 10°, Ti	1
1257.6244S	AUTOBAHN® EVO Retrograde Femoral Nail, 12x440mm, 10°, Ti	1
9257.2007	AUTOBAHN® EVO Retrograde Nail Bank, 10°, Soft Case	

AUTOBAHN® EVO RETROGRADE NAILING SYSTEM
STERILE SCREWS 9257.9208

Part No.	Description	Qty
1257.8330S	AUTOBAHN® EVO Headed Locking Screw, 5x30mm, Ti	3
1257.8333S	AUTOBAHN® EVO Headed Locking Screw, 5x32.5mm, Ti	3
1257.8335S	AUTOBAHN® EVO Headed Locking Screw, 5x35mm, Ti	3
1257.8338S	AUTOBAHN® EVO Headed Locking Screw, 5x37.5mm, Ti	3
1257.8340S	AUTOBAHN® EVO Headed Locking Screw, 5x40mm, Ti	3
1257.8343S	AUTOBAHN® EVO Headed Locking Screw, 5x42.5mm, Ti	3
1257.8345S	AUTOBAHN® EVO Headed Locking Screw, 5x45mm, Ti	3
1257.8348S	AUTOBAHN® EVO Headed Locking Screw, 5x47.5mm, Ti	3
1257.8350S	AUTOBAHN® EVO Headed Locking Screw, 5x50mm, Ti	3
1257.8353S	AUTOBAHN® EVO Headed Locking Screw, 5x52.5mm, Ti	3
1257.8355S	AUTOBAHN® EVO Headed Locking Screw, 5x55mm, Ti	3
1257.8360S	AUTOBAHN® EVO Headed Locking Screw, 5x60mm, Ti	3
1257.8365S	AUTOBAHN® EVO Headed Locking Screw, 5x65mm, Ti	3
1257.8370S	AUTOBAHN® EVO Headed Locking Screw, 5x70mm, Ti	3
1257.8375S	AUTOBAHN® EVO Headed Locking Screw, 5x75mm, Ti	3
1257.8380S	AUTOBAHN® EVO Headed Locking Screw, 5x80mm, Ti	3
1257.8385S	AUTOBAHN® EVO Headed Locking Screw, 5x85mm, Ti	3
1257.8390S	AUTOBAHN® EVO Headed Locking Screw, 5x90mm, Ti	3
1257.8395S	AUTOBAHN® EVO Headed Locking Screw, 5x95mm, Ti	3
1257.8400S	AUTOBAHN® EVO Headed Locking Screw, 5x100mm, Ti	3
1257.8530S	AUTOBAHN® EVO Headless Locking Screw, 5x30mm, Ti	3
1257.8533S	AUTOBAHN® EVO Headless Locking Screw, 5x32.5mm, Ti	3
1257.8535S	AUTOBAHN® EVO Headless Locking Screw, 5x35mm, Ti	3
1257.8538S	AUTOBAHN® EVO Headless Locking Screw, 5x37.5mm, Ti	3
1257.8540S	AUTOBAHN® EVO Headless Locking Screw, 5x40mm, Ti	3
1257.8543S	AUTOBAHN® EVO Headless Locking Screw, 5x42.5mm, Ti	3
1257.8545S	AUTOBAHN® EVO Headless Locking Screw, 5x45mm, Ti	3
1257.8548S	AUTOBAHN® EVO Headless Locking Screw, 5x47.5mm, Ti	3
1257.8550S	AUTOBAHN® EVO Headless Locking Screw, 5x50mm, Ti	3
1257.8553S	AUTOBAHN® EVO Headless Locking Screw, 5x52.5mm, Ti	3
1257.8555S	AUTOBAHN® EVO Headless Locking Screw, 5x55mm, Ti	3
1257.8560S	AUTOBAHN® EVO Headless Locking Screw, 5x60mm, Ti	3
1257.8565S	AUTOBAHN® EVO Headless Locking Screw, 5x65mm, Ti	3
1257.8570S	AUTOBAHN® EVO Headless Locking Screw, 5x70mm, Ti	3
1257.8575S	AUTOBAHN® EVO Headless Locking Screw, 5x75mm, Ti	3

AUTOBAHN® EVO RETROGRADE NAILING SYSTEM
STERILE SCREWS 9257.9208

Part No.	Description	Qty
1257.8580S	AUTOBAHN® EVO Headless Locking Screw, 5x80mm, Ti	3
1257.8585S	AUTOBAHN® EVO Headless Locking Screw, 5x85mm, Ti	3
1257.8590S	AUTOBAHN® EVO Headless Locking Screw, 5x90mm, Ti	3
1257.8595S	AUTOBAHN® EVO Headless Locking Screw, 5x95mm, Ti	3
1257.8600S	AUTOBAHN® EVO Headless Locking Screw, 5x100mm, Ti	3
1257.0200S	AUTOBAHN® EVO Retrograde Femoral Nail End Cap, 0mm, Ti	1
1257.0205S	AUTOBAHN® EVO Retrograde Femoral Nail End Cap, 5mm, Ti	0
1257.0210S	AUTOBAHN® EVO Retrograde Femoral Nail End Cap, 10mm, Ti	0
1257.0420S	AUTOBAHN® EVO Retrograde Femoral Nail Washer for Nut, Ti	0
1257.0500S	AUTOBAHN® EVO Retrograde Femoral Nail Washer for Screw, Ti	0
1257.0510S	AUTOBAHN® EVO Retrograde Femoral Nail Condlye Nut, Ti	0
9257.2008	AUTOBAHN® EVO Retrograde Nail Sterile Screws, Soft Case	

Items in gray are additionally available.

IMPORTANT INFORMATION ON ON THE AUTOBAHN® NAILING SYSTEM

DESCRIPTION

The AUTOBAHN® Nailing System is a family of intramedullary nails, screws, and washers designed to be used for internal bone fixation. The implants are available in various lengths and diameters to accommodate a wide range of patient anatomy. The nails are secured with locking screws and all devices are manufactured from titanium alloy, stainless steel, cobalt chromium molybdenum alloy, or titanium molybdenum alloy, and may include radiolucent PEEK polymer inserts.

INDICATIONS

The AUTOBAHN® Tibial Nail is indicated for stabilization of fractures in skeletally mature patients, specifically fractures of the proximal and distal tibia and the tibial shaft, open and closed tibial shaft fractures, certain pre- and postisthmic fractures, non-unions, malunions, pseudarthrosis, corrective osteotomies, prophylactic nailing of impending pathological fractures, tumor resections, simple long bone fractures, severely comminuted, spiral, large oblique and segmental fractures, polytrauma and multiple fractures, reconstruction, following tumor resection and grafting, supracondylar fractures, and bone lengthening and shortening.

The AUTOBAHN® Trochanteric Nail is indicated for treatment of fractures in adults and adolescents (12-21 years of age) in which the growth plates have fused for the following indications: basal neck fractures, fixation of stable and unstable intertrochanteric, pertrochanteric, and subtrochanteric fractures, pathologic fractures (including prophylactic use) in both trochanteric and diaphyseal regions, combinations of pertrochanteric, intertrochanteric, basal neck fractures, long subtrochanteric fractures, tumor resections, fractures resulting from trauma, nonunions, malunions, and revision procedures.

AUTOBAHN® Antegrade/Retrograde Femoral Nails are indicated for long bone fracture fixation in skeletally mature patients, specifically femoral fracture fixation, which may include the following: open and closed femoral fractures, pseudoarthrosis and correction osteotomy, pathologic fractures, impending pathologic fractures, tumor resections, supracondylar fractures, including those with intra-articular extension, ipsilateral hip/shaft fractures, ipsilateral femur/tibia fractures, fractures proximal to a total knee arthroplasty, fractures distal to hip joint, nonunions and malunions, poly trauma patients, fractures in the morbidly obese, fractures involving osteopenic and osteoporotic bone, compound and simple shaft fractures, proximal, metaphyseal, and distal shaft fractures, segmental fractures, closed supracondylar fractures, fractures involving femoral condyles, comminuted fractures, fractures with bone loss, and periprosthetic fractures.

AUTOBAHN® EVO Femoral Nails are indicated for long bone fracture fixation in skeletally mature patients, specifically femoral fracture fixation, which may include the following: open and closed femoral fractures, pseudoarthrosis and correction osteotomy, pathologic fractures, impending pathologic fractures, tumor resections, supracondylar fractures, including those with intra-articular extension, ipsilateral hip/shaft fractures, ipsilateral femur/tibia fractures, fractures proximal to a total knee arthroplasty, fractures distal to hip joint, nonunions and malunions, poly trauma patients, fractures in the morbidly obese, fractures involving osteopenic and osteoporotic bone, compound and simple shaft fractures, proximal, metaphyseal, and distal shaft fractures, segmental fractures, closed supracondylar fractures, fractures involving femoral condyles, comminuted fractures, fractures with bone loss, and periprosthetic fractures. In addition, the AUTOBAHN® EVO Antegrade Nails are intended for use in adolescents (12-21 years) in which the growth plates have fused.

CONTRAINDICATIONS

Use of these implants is contraindicated in patients with the following conditions:

- Any active or suspended latent infection or marked local inflammation, or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials.
- Compromised vascularity that would inhibit adequate blood supply to the fracture or the operative site.
- Bone stock compromised by disease, infection or prior implantation that cannot provide adequate support and/or fixation of the devices.
- A medullary canal obliterated by a previous fracture or tumor.
- Skeletally immature patients.
- Material sensitivity, documented or suspected.
- Patients having inadequate tissue coverage over the operative site.
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care.
- Other medical or surgical conditions which would preclude the potential benefit of surgery.

WARNINGS

The correct implant selection is extremely important. Failure to use the appropriate implant for the fracture condition may accelerate clinical failure. Failure to use the proper component to maintain adequate blood supply and provide rigid fixation may result in loosening, bending, cracking or fracture of the implant and/or bone. The correct implant size for a given patient can be determined by evaluating the patient's height, weight, functional demands and anatomy. Every implant must be used in the correct anatomic location, consistent with accepted standards of internal fixation.

PRECAUTIONS

The implantation of intramedullary nail devices should be performed only by experienced surgeons with specific training in the use of this system because this is a technically demanding procedure presenting a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered when selecting implant size.

Surgical implants must never be reused. An explanted implant must never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which could lead to breakage.

MRI SAFETY INFORMATION

These devices have not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of these devices in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

CAUTIONS

Pre-operative

- Implants are single use only.
- Implants that came in contact with body fluids should never be reused.
- Ensure that all components needed for surgery are available in the surgical suite.
- Inspection is recommended prior to surgery to determine if implants have been damaged during storage.
- While rare, intra-operative fracture or breakage of instruments can occur. Instruments which have experienced excessive use or excessive force are susceptible to fracture. Instruments should be examined for wear or damage prior to surgery.

Intra-operative

- Avoid surface damage of implants.
- Discard all damaged or mishandled implants
- Contouring or bending of an implant should be avoided where possible, because it may reduce its fatigue strength and can cause failure under load.
- Implants are available in different versions, varying for example in length, diameter, material and number of drilled holes. Select the required version carefully.
- During the course of the operation, repeatedly check to ensure that the connection between the implant and the instrument, or between the instruments, is secure.
- Implants which consist of several components must only be used in the prescribed combination (refer to the AUTOBAHN® Surgical Technique Guide).
- After the procedure check the proper positioning of all implants using fluoroscopy.
- Do not use components from this system in conjunction with components from any other manufacturer's system unless otherwise specified (refer to the AUTOBAHN® Surgical Technique Guide).

Post-operative

- Post-operative patient activity: These implants are neither intended to carry the full load of the patient acutely, nor intended to carry a significant portion of the load for extended periods of time. For this reason post-operative instructions and warnings to patients are extremely important. External immobilization (e.g. bracing or casting) may be employed until X-rays or other procedures confirm adequate bone consolidation.
- The injured limb should be kept elevated.
- For stable fracture that are locked statically or dynamically, full weight bearing walking may be started immediately.
- In the event of a delay in bone consolidation, or if such consolidation does not take place, or if explantation is not carried out, complications may occur, for example fracture or loosening of the implant or instability of the implant system. Regular post-operative examinations (e.g., X-ray checks) are advisable.
- If patients cannot follow the recommendations of the physician because of any mental or neuromuscular disorder. For this reason those patients must have additional post-operative follow-up.
- Implant removal should be followed by adequate postoperative management to avoid fracture or refracture of the bone.

Informing the Patient

The implant affects the patient's ability to carry loads and her/his mobility and general living circumstances. The surgeon must counsel each patient individually

IMPORTANT INFORMATION ON ON THE AUTOBAHN® NAILING SYSTEM

on correct behavior and activity after the implantation.

The surgeon must warn patient that the device cannot and does not replicate a normally healthy bone, that the device can break or become damaged as a result of strenuous activity, trauma, malunion or non-union and that the device has a finite expected service life and may need to be removed at some time in the future.

ADVERSE EFFECTS

In many instances, adverse results may be clinically related rather than device related. The following are the most frequent adverse effects involving the use of internal fracture fixation devices:

- Delayed union or non-union of the fracture site.
- These devices can break when subjected to the increased loading associated with delayed unions and/or non-unions. Internal fixation devices are load sharing devices which are intended to hold fracture bone surface in a position to facilitate healing. If healing is delayed or does not occur, the appliance may eventually break due to metal fatigue. Loads on the device produced by load bearing and the patient's activity level will dictate the longevity of the device.
- Conditions attributable to non-union, osteoporosis, osteomalicia, diabetes, inhibited revascularization and poor bone formation can cause loosening, bending, cracking, fracture of the device or premature loss of rigid fixation with the bone.
- Improper alignment can cause a malunion of the bone and/or bending, cracking or even breakage of the device.
- Increased fibrous tissue response around the fracture site due to unstable comminuted fractures.
- Early or late infection, deep or superficial.
- Deep venous thrombosis.
- Avascular necrosis.
- Shortening of the effected bone/fracture site.
- Subclinical nerve damage may possibly occur as a result of the surgical trauma.
- Material sensitivity reactions in patients following surgical implantation have rarely been reported, however their significance awaits further clinical evaluation.
- Fat embolism or adult respiratory distress from reaming the medullary canal.

PACKAGING

These implants and instruments may be supplied pre-packaged and sterile, using gamma irradiation. The integrity of the sterile packaging should be checked to ensure that sterility of the contents is not compromised. Packaging should be carefully checked for completeness and all components should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to Globus Medical. During surgery, after the correct size has been determined, remove the products from the packaging using aseptic technique.

These implants and instruments may also be provided nonsterile and are steam sterilized prior to use, as described in the STERILIZATION section below. Following use or exposure to soil, instruments and instrument trays and cases must be cleaned, as described in the CLEANING section below.

HANDLING

All instruments and implants should be treated with care. Improper use or handling may lead to damage and/or possible malfunction. Instruments should be checked to ensure that they are in working order prior to surgery.

Implants and sterile-packed instruments are single use devices and should not be cleaned. Re-cleaning of single use implants might lead to mechanical failure and/or material degradation. Discard any implants that may have been accidently contaminated.

CLEANING

Instruments should be cleaned separately from instrument trays and cases. Lids should be removed from cases for the cleaning process, if applicable. All instruments that can be disassembled must be disassembled for cleaning. All handles must be detached. Instruments may be reassembled following sterilization. The products should be cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Globus Medical.

Cleaning and disinfecting can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse. Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

The following cleaning methods should be observed when cleaning instruments and instrument trays and cases after use or exposure to soil, and prior to sterilization:

1. Immediately following use, ensure that the instruments are wiped down to remove all visible soil and kept from drying by submerging or covering with a wet towel.
2. Disassemble all instruments that can be disassembled.
3. Rinse the instruments under running tap water to remove all visible soil. Flush the lumens a minimum of 3 times, until the lumens flush clean.
4. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations.
5. Immerse the instruments in the detergent and allow them to soak for a minimum of 2 minutes.
6. Use a soft bristled brush to thoroughly clean the instruments. Use a pipe cleaner for any lumens. Pay close attention to hard to reach areas.
7. Using a sterile syringe, draw up the enzymatic detergent solution. Flush any lumens and hard to reach areas until no soil is seen exiting the area.
8. Remove the instruments from the detergent and rinse them in running warm tap water.
9. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations in an ultrasonic cleaner.
10. Completely immerse the instruments in the ultrasonic cleaner and ensure detergent is in lumens by flushing the lumens. Sonicate for a minimum of 3 minutes.
11. Remove the instruments from the detergent and rinse them in running deionized water or reverse osmosis water for a minimum of 2 minutes.
12. Dry instruments using a clean soft cloth and filtered pressurized air.
13. Visually inspect each instrument for visible soil. If visible soil is present, then repeat cleaning process starting with Step 3.

CONTACT INFORMATION

Globus Medical may be contacted at 1-866-GLOBUS1 (456-2871). A surgical technique manual may be obtained by contacting Globus Medical.

STERILIZATION

These implants and instruments may be available sterile or nonsterile.

Sterile implants are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of 10^{-6}. Sterile products are packaged in a heat sealed Tyvek tray, container/pouch, or pouch/pouch. The expiration date is provided on the package label. These products are considered sterile unless the packaging has been opened or damaged. Sterile implants meet pyrogen limit specifications.

Nonsterile implants and instruments have been validated following ISO 17665-1:2006 Sterilization of health care products – Moist heat to ensure an SAL of 10^{-6}. The use of an FDA-cleared wrap is recommended, per the Association for the Advancement of Medical Instrumentation (AAMI) ST79, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the FDA for the selected sterilization cycle specifications (time and temperature).

When using a rigid sterilization container, the following must be taken into consideration for proper sterilization of Globus devices and loaded graphic cases:

- Recommended sterilization parameters are listed in the table below.
- Only FDA-cleared rigid sterilization containers for use with pre-vacuum steam sterilization may be used.
- When selecting a rigid sterilization container, it must have a minimum filter area of 176 in^2 total, or a minimum of four (4) 7.5in diameter filters.
- No more than one (1) loaded graphic case or its contents can be placed directly into a rigid sterilization container.
- Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.
- The rigid sterilization container manufacturer's instructions for use are to be followed; if questions arise, contact the manufacturer of the specific container for guidance.
- Refer to AAMI ST79 for additional information concerning the use of rigid sterilization containers.

For implants and instruments provided NONSTERILE, sterilization is recommended (wrapped or containerized) as follows:

IMPORTANT INFORMATION ON ON THE AUTOBAHN® NAILING SYSTEM

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Pre-vacuum	132°C (270°F)	4 Minutes	30 Minutes

These parameters are validated to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The sterilizer must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

CAUTION: Federal (USA) Law Restricts this Device to Sale by or on the order of a Physician.

SYMBOL TRANSLATION			
REF	CATALOGUE NUMBER	STERILE R	STERILIZED BY IRRADIATION
LOT	LOT NUMBER	EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
⚠	CAUTION		MANUFACTURER
	SINGLE USE ONLY		USE BY (YYYY-MM-DD)
QTY	QUANTITY	Rx ONLY	PRESCRIPTION USE ONLY

DI203A Rev C

NOTES

NOTES

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GMTGD277
12.22 Rev A