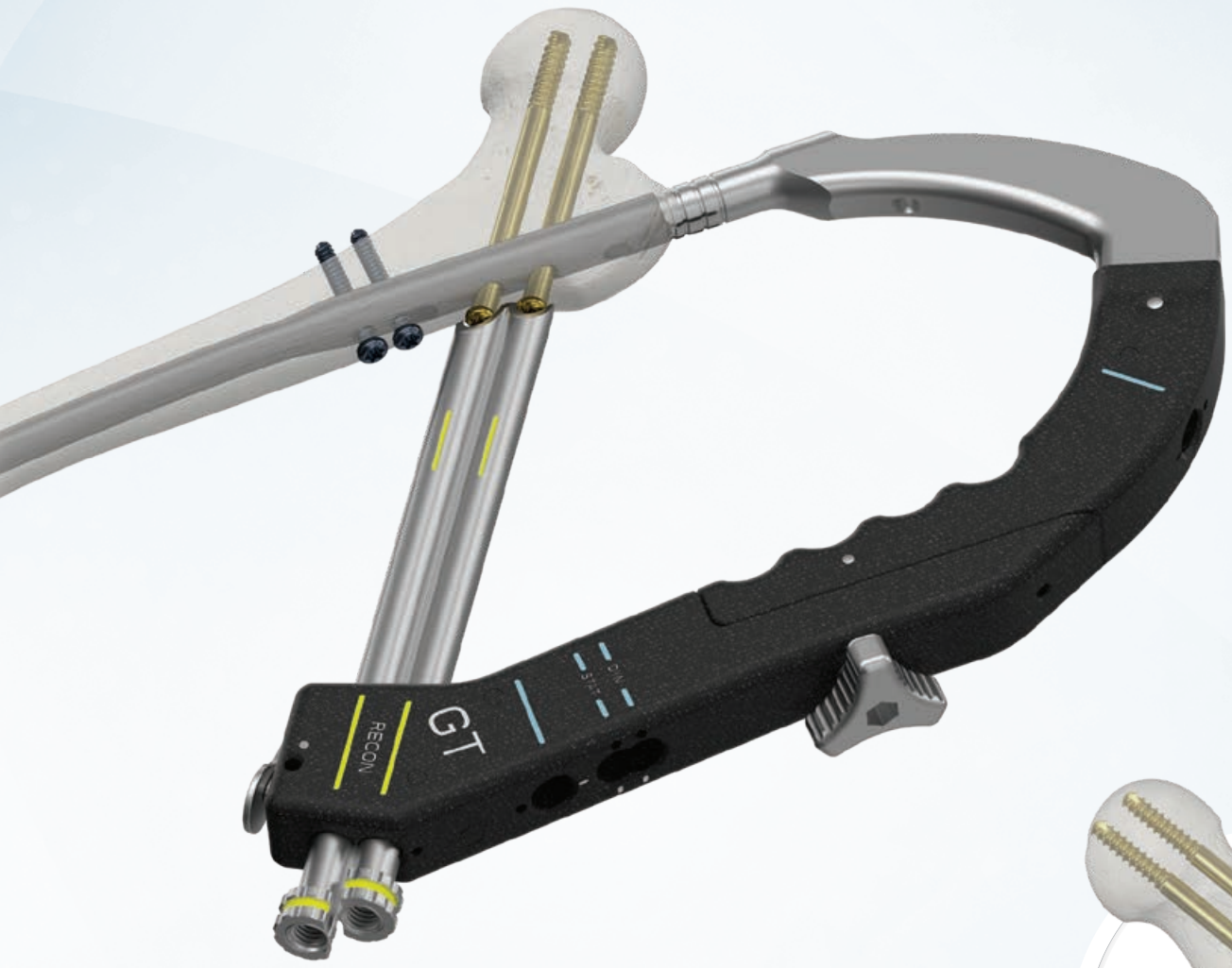



# AUTOBAHN® EVO

## Antegrade Femoral Nailing System

SURGICAL TECHNIQUE GUIDE

GLOBUSMEDICAL.COM | *Life moves us*

GLOBUS MEDICAL

*Our mission is to deliver cutting-edge technology, research, and innovative solutions to promote healing in patients with musculoskeletal disorders.*

***Life moves us***

# SURGICAL TECHNIQUE GUIDE

# AUTOBAHN® EVO

## Antegrade Femoral Nailing System

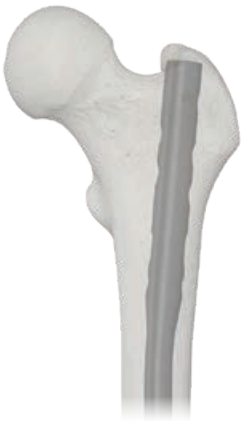
# AUTOBAHN® EVO

## Antegrade Femoral Nailing System

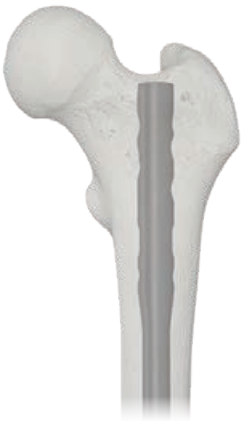
AUTOBAHN® EVO Antegrade Nailing is a system of implants and instruments that facilitates either the greater trochanter (GT) or piriformis fossa (PF) approach.

### GT and PF Options

Allow flexibility and choice of entry point



GT



PF

### Hybrid Design

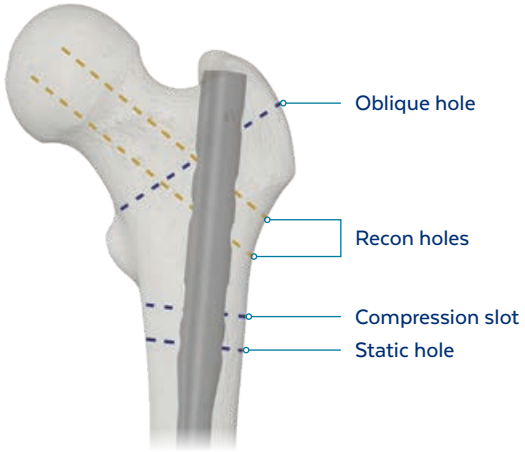
Allows for standard or recon locking configuration

Standard

Recon

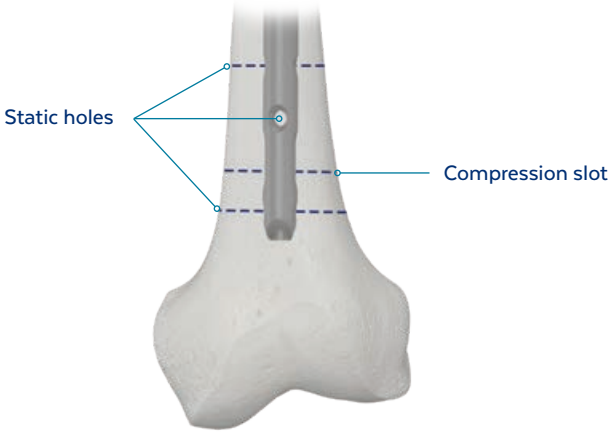
## Proximal Locking Options

- Two parallel recon holes
- One oblique hole
- One compression slot, with 7mm of range
- One static hole



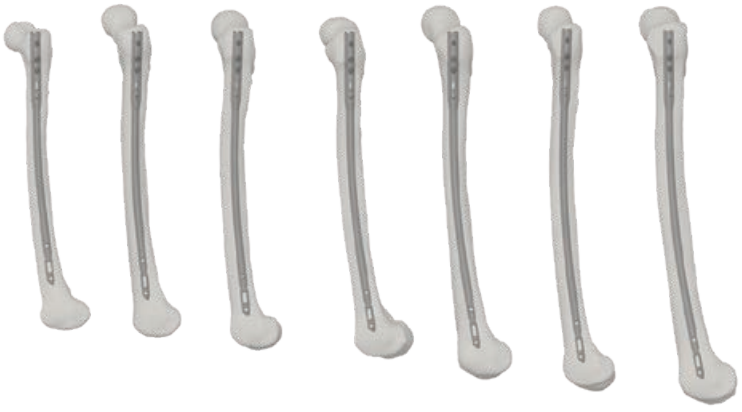

## Distal Locking Options

- All distal static holes incorporate SureStart® threaded technology, creating a fixed angle construct
- Compression slot allows 10mm of compression




## Variable Radius of Curvature

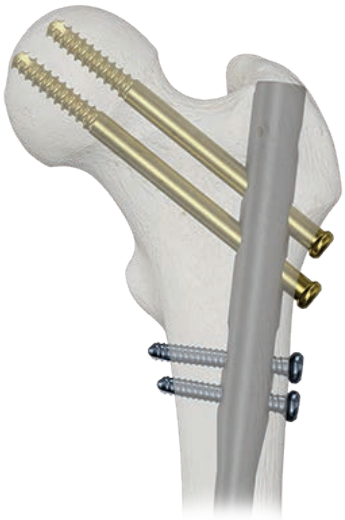
- Length-dependent radius designed to fit in varying patient anatomy



# **IMPLANT** OVERVIEW

## ANTEGRADE NAIL

- Recon neck angle: 127.5°
- GT nail has 5° lateral bend
- Diameter: 10-12mm
- Lengths: 320-440mm in 20mm increments
- 11mm and larger nails have flutes
- Proximal diameter: 13mm
- Material: Titanium alloy with type II anodization



## LOCKING SCREWS

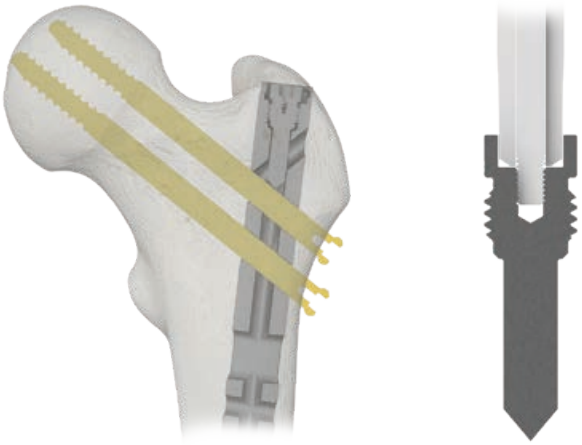
- Diameter: 5.0mm
- Lengths: 30-55mm in 2.5mm increments, 60-70mm in 5mm increments
- Retained by threaded connection
- T30 drive feature
- Material: Anodized titanium alloy

## RECON LOCKING SCREWS

- Diameter: 6.5mm
- Lengths: 70-130mm in 5mm increments
- Thread Length: 25mm
- Retained via threaded connection
- T30 drive feature
- Material: Anodized titanium alloy

## SET SCREW

- Locks the superior recon screw
- Retained by threaded connection
- Material: Titanium alloy with type II anodize



**SURGICAL** TECHNIQUE

# AUTOBAHN® EVO

## Antegrade 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. Estimate the desired entry point at the PF or the GT based on fracture pattern and patient anatomy.

## STEP 2 PATIENT POSITIONING

Position the patient in the lateral decubitus or supine position on a fracture table or a radiolucent table. Position the injured leg in flexion and ensure access to the proximal femur.

The C-arm should be positioned on the contralateral side to allow imaging of the proximal femur in AP and lateral views.

**AP view**

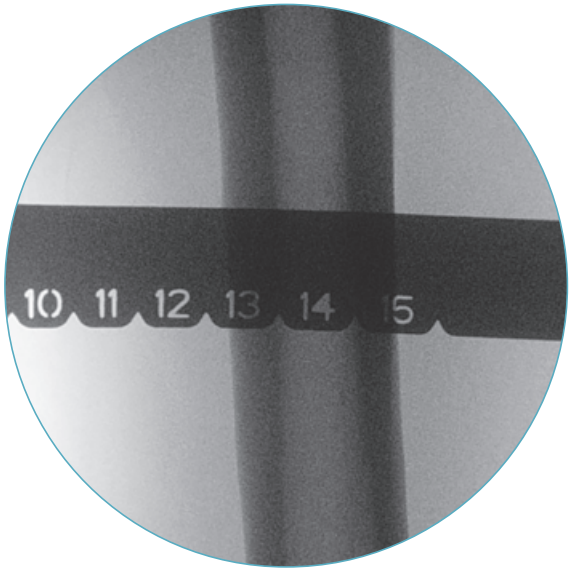
**Lateral view**

## 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. Determine nail length before reaming.




**Diameter measurement**

## IDENTIFY ENTRY POINT

### Greater Trochanter Entry

Locate the tip of the GT using fluoroscopy. In the AP view, the entry point is the tip of the GT. In the lateral view, the entry point is the center of the trochanter in line with the medullary canal.

AP view

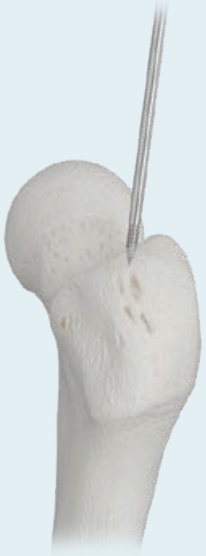
Lateral view

Axial view

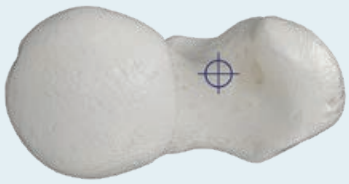
### Piriformis Fossa Entry

The PF is medial to the GT and aligns with the medullary canal in the AP and lateral views.

AP view



Lateral view



Axial view

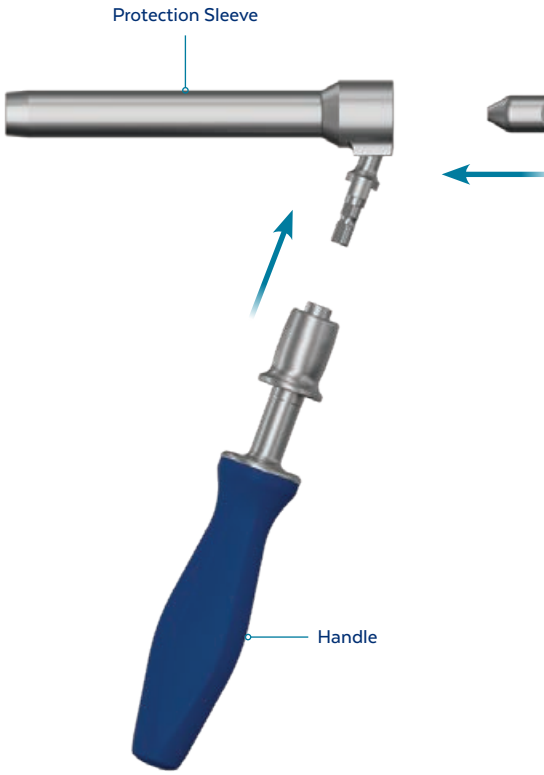
# STEP 5 INSERTING GUIDEWIRE

Create an incision proximal to the desired entry point. Separate the muscle fibers.

Attach the **Protection Sleeve** to the **Hall Quick-Connect Handle** and insert the **Multi-Hole Wire Guide** into the protection sleeve.

Insert the protection sleeve assembly into the incision until it reaches bone at the desired entry point. Insert the **3.2mm Guidewire** into the center hole of the wire guide and into bone.

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

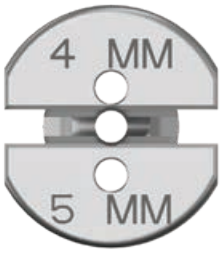



Wire Guide Assembly

Inserting 3.2mm guidewire

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

To rotate the wire guide, push the tabs together, rotate to the desired position, and release.




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 through the protection sleeve. Using fluoroscopy, ream approximately 10cm, or to the lesser trochanter.

Ensure the reaming path remains in line with the femoral intramedullary canal until reaming is complete. Verify depth under fluoroscopy. Remove the drill bit and guidewire while holding the protection sleeve in place to maintain exposure.

**Opening canal**

# OPENING THE MEDULLARY CANAL (CONT'D)

Alternatively, an awl may be used to open the medullary canal.

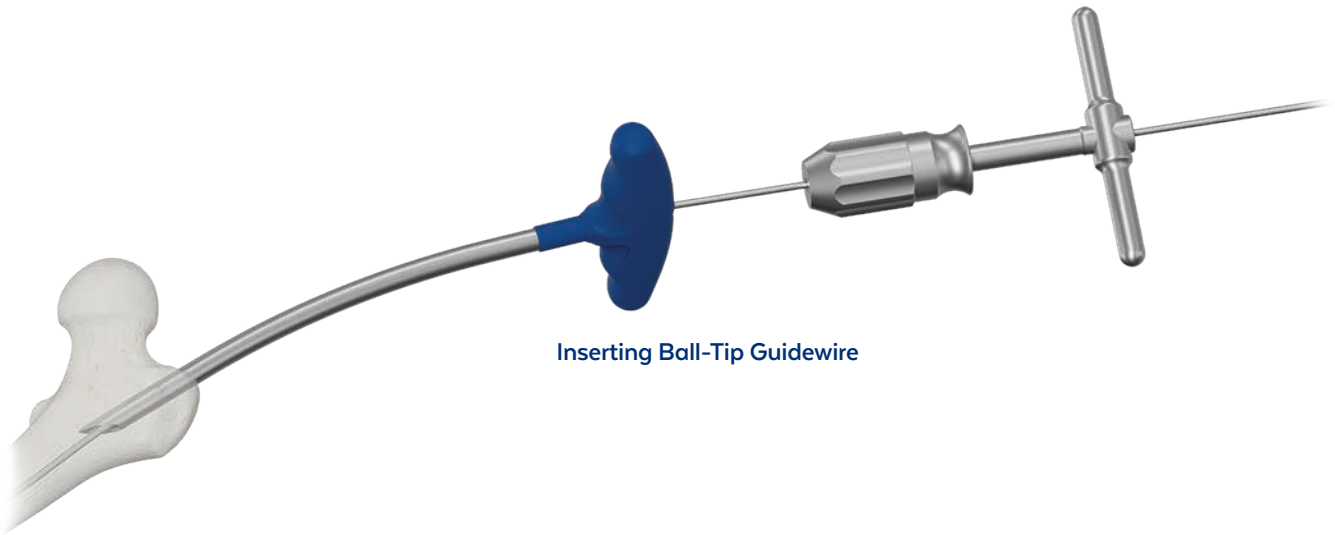
The **9mm Curved Awl** can be used to establish an entry point without the use of a 3.2mm guidewire. Rotate the awl to advance and open the canal. A **Ball-Tip Guidewire, 3x1000mm** can be inserted through the cannulation of the curved awl.

A **T-Handle 3 Jaw Chuck** may be used to grasp the guidewire during insertion.

Verify depth under fluoroscopy. Remove the t-handle and awl and leave the guidewire in place.

Use intramedullary reamers to open the medullary canal to the desired diameter.

Opening canal

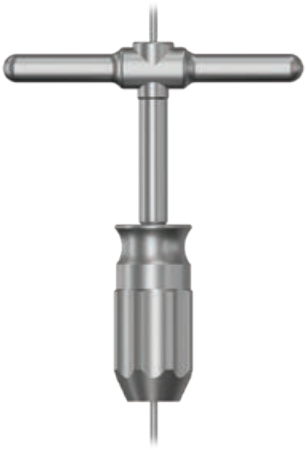


Inserting Ball-Tip Guidewire

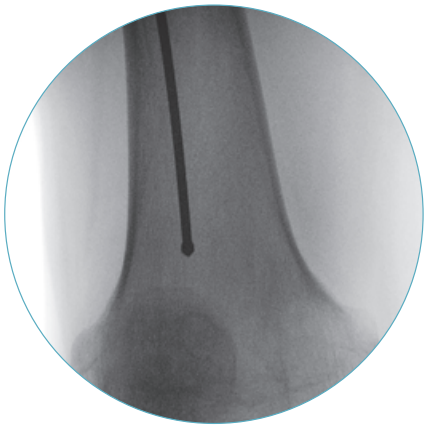
# STEP 7 DETERMINING NAIL LENGTH

Insert the ball-tip guidewire into the medullary canal. A 3 jaw chuck T-handle can be used to grasp the guidewire if necessary.

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



Inserting Ball-Tip Guidewire

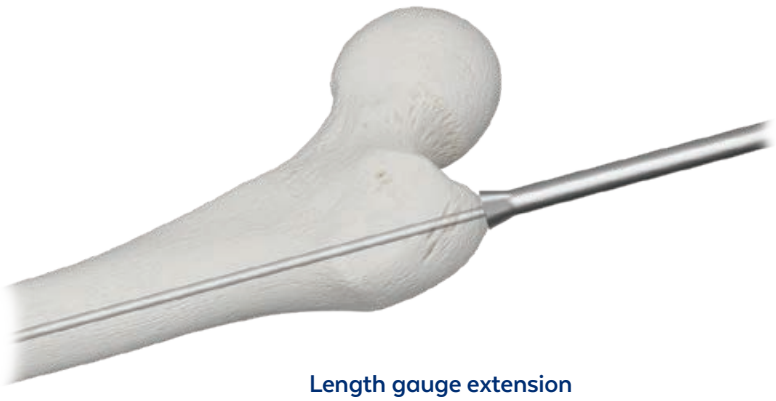


Ball-Tip Guidewire insertion

Ensure the ball-tip wire is at the desired distal 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.

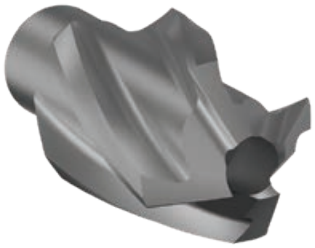
The reamers are modular and can be attached to the **Reamer Shaft**. To attach, insert the reamer shaft into the selected **Reamer Head**.

**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.

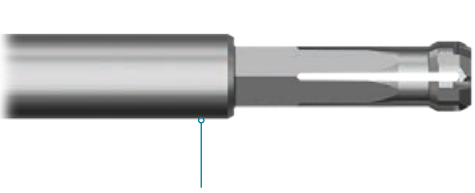
If needed, retract the reamer to clear debris from the canal.

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.



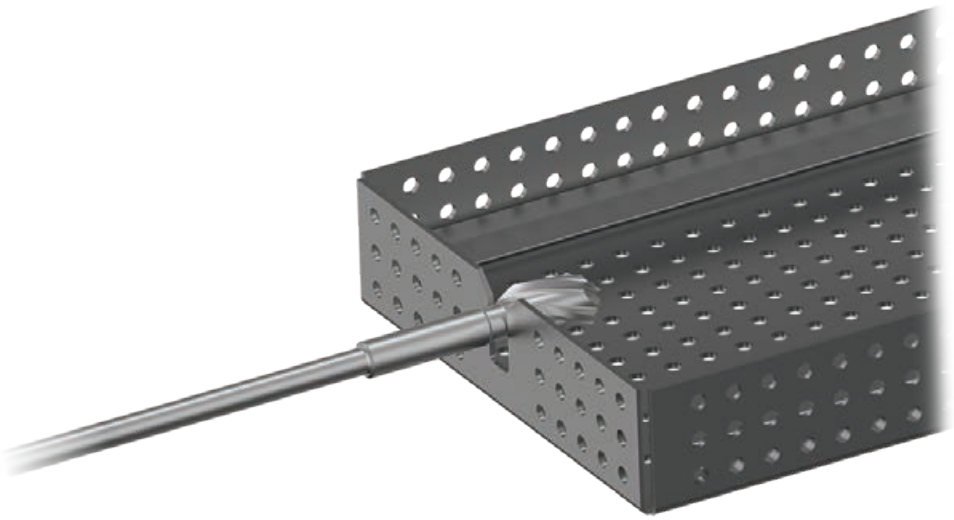
Front Cutting

Side Cutting




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

Reamer Shaft engaged with Reamer Head - cross-section view



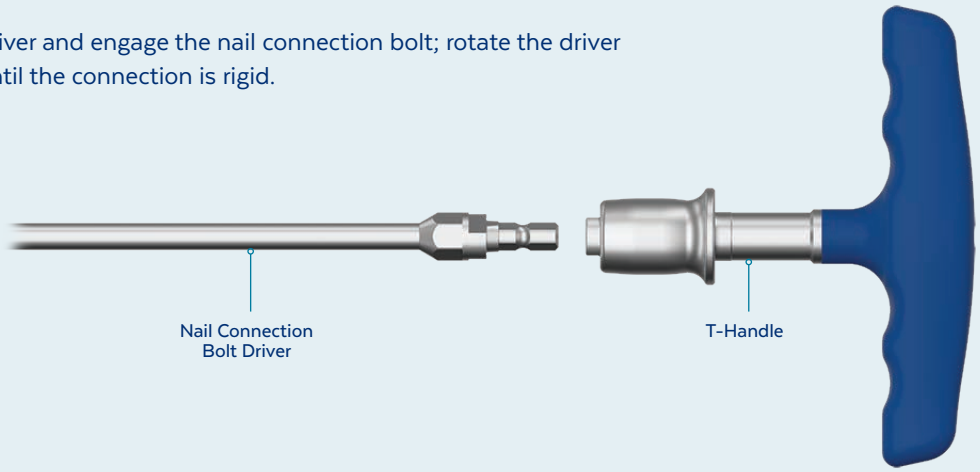
Use the reamer caddy lid to remove the reamer heads.

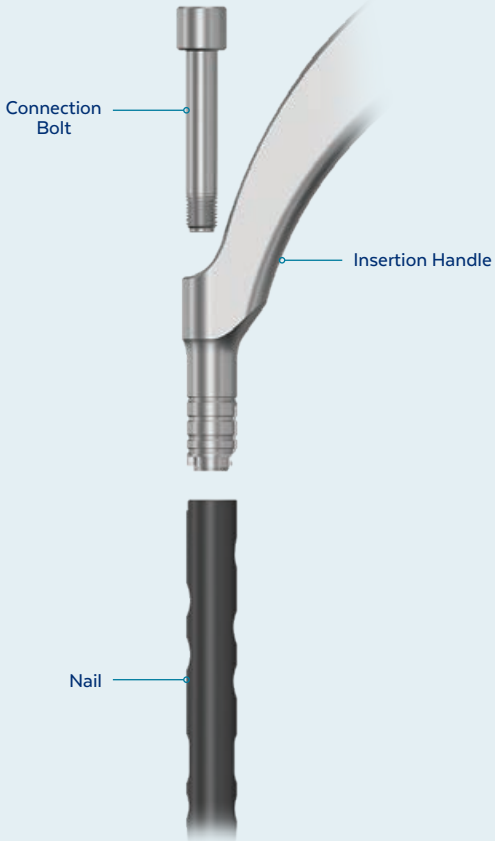
## NAIL ASSEMBLY OVERVIEW

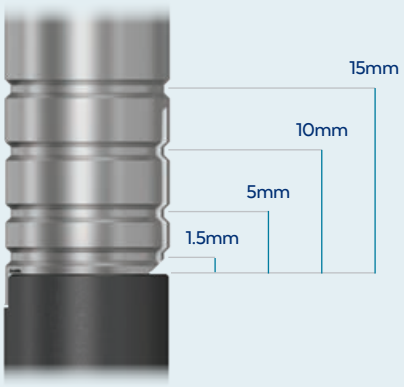
Attach the selected nail to the **Insertion Handle** by aligning the tab at the alignment tip with the notch at the proximal end of the nail.

Insert the **Nail Connection Bolt** into the insertion handle. Attach the **Quick-Connect Handle** to the **Nail Connection Bolt Driver**.

Insert the driver and engage the nail connection bolt; rotate the driver clockwise until the connection is rigid.




The grooves in the insertion handle aid in radiographic visualization of fully seated end cap options.

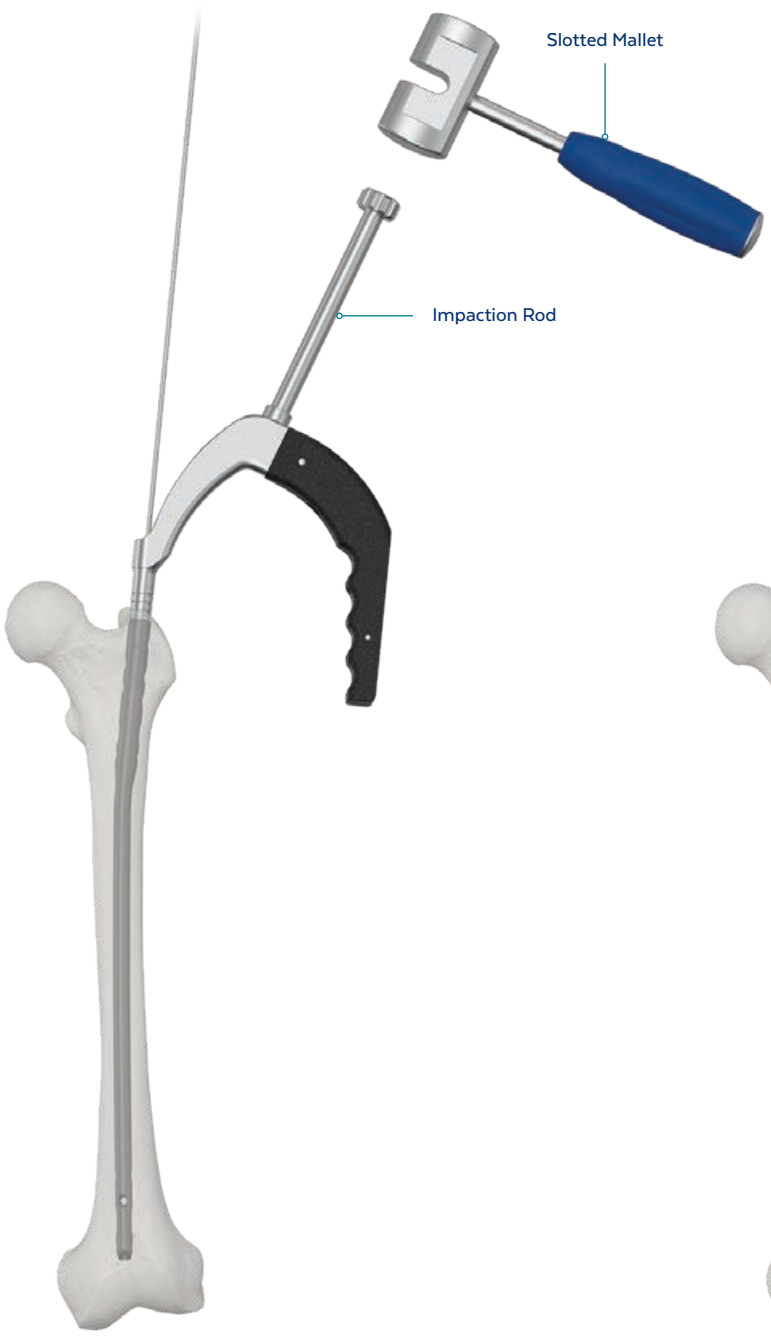
The anterior bow of the nail should be aligned with the anterior bow of the femur.

# STEP 9 NAIL INSERTION

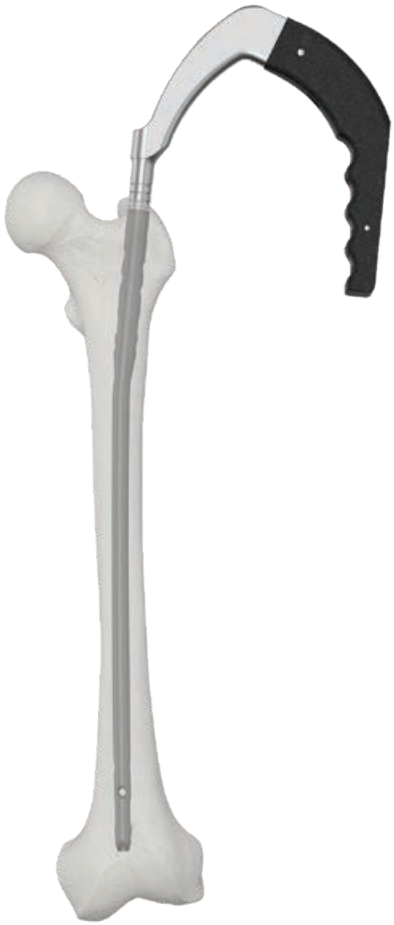
Insert the nail into the medullary canal by passing the nail over the ball-tip guidewire. Light impaction may be applied using the **Impaction Rod** and **Slotted Mallet**.

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. When the nail is seated to the desired depth, remove the impaction rod.



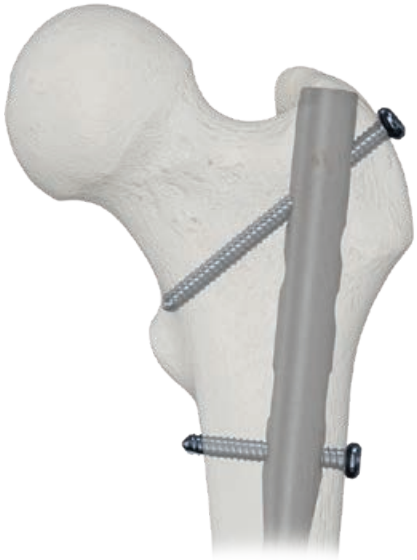

**Inserting nail**



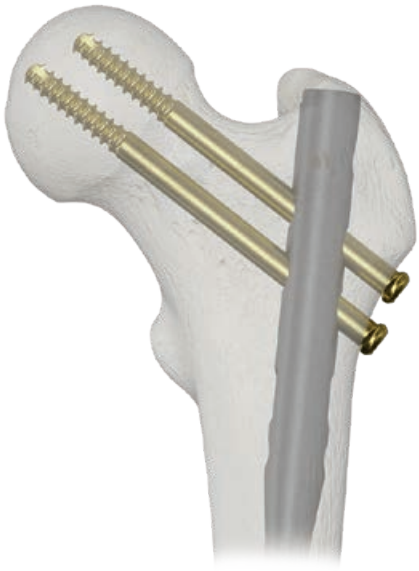
**Nail fully inserted**

# STEP 10 LOCKING SCREW INSERTION

Four locking techniques are available for screw fixation, as shown below. The technique for each locking option is explained in more detail in the following sections. Determine which proximal and distal locking holes in the nail are to be used for screw placement and reference the appropriate section. All screws may be inserted manually or under power.

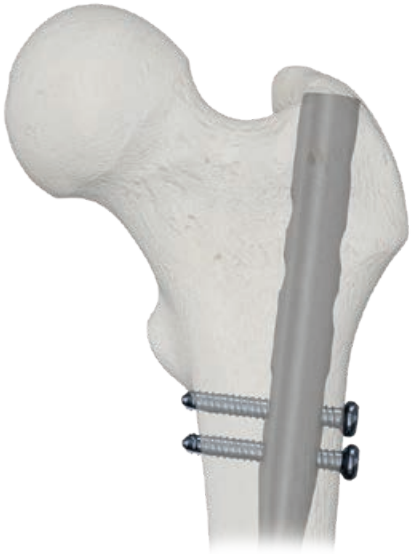


**Standard Locking Screws**



**Recon Locking Screws**

**Distal Locking Screws**



**Compression Locking Screws**

# LOCKING SCREW INSERTION (CONT'D)

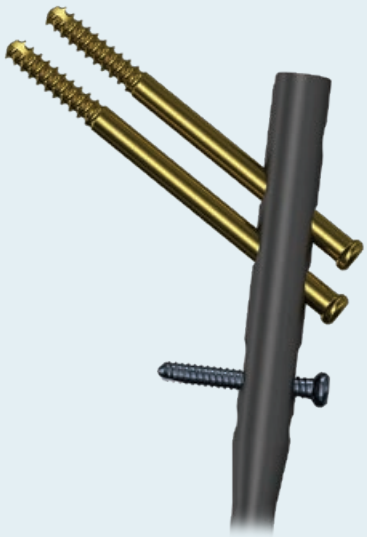
## NAIL LOCKING OPTIONS

Select 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.

The distal-most static screw hole in the proximal section is designed to be inserted at a slight angle of 3°. This prevents screw head interference when achieving compression with a locking screw in the dynamic slot.

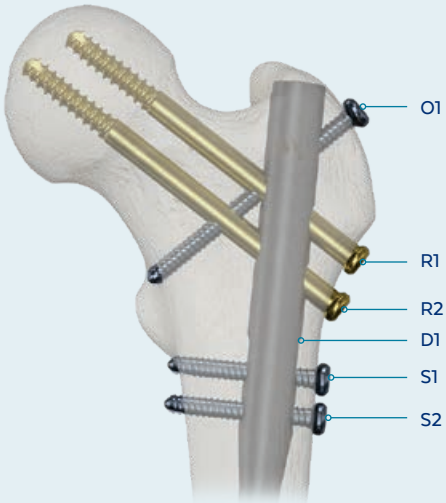
**5mm Oblique Locking**



**Recon Locking**

**CAUTION:** All locking holes cannot be used at once. The most loaded nail can have up to 3 screws proximally. Use care to avoid screw interference.

- R1 and R2 intersect O1
- R2 and D1/S1 screw heads may interfere depending on patient anatomy, screw lengths, and compression achieved using the dynamic slot



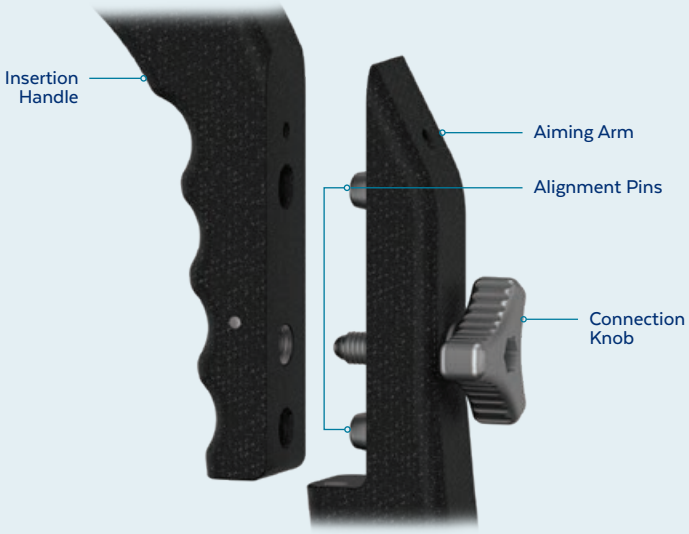
# STANDARD LOCKING SCREWS

## ATTACHING AIMING ARM

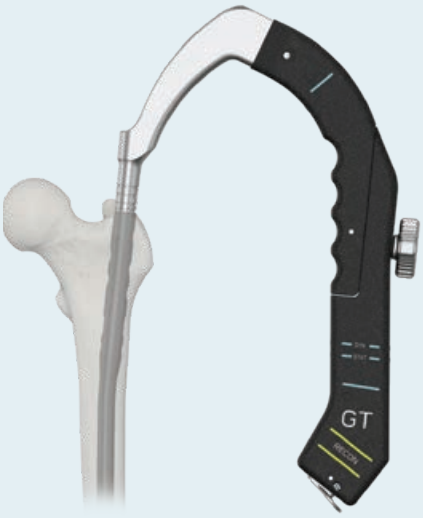
Select the **Aiming Arm** corresponding to the selected nail style (GT or PF). Align and attach the aiming arm to the insertion handle and rotate the connection knob clockwise to tighten.

### AIMING ARM ASSEMBLY

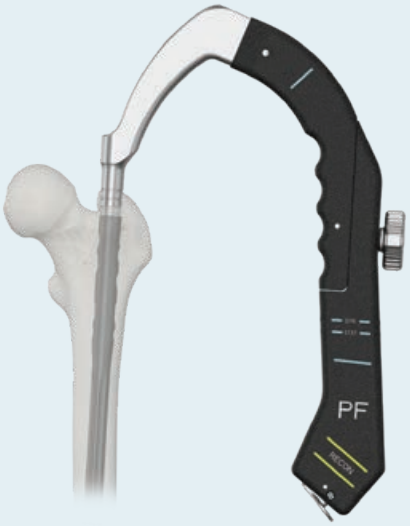
The Aiming Arm attaches to the insertion handle through two alignment pins and a threaded connection knob. Select the aiming arm corresponding to the selected nail style (GT or PF). Align and attach the aiming arm to the insertion handle and rotate the connection knob clockwise to tighten.




If desired, the nail connection bolt driver may be used to securely tighten the aiming arm to the insertion handle. Prior to fixation, determine which proximal and distal locking holes in the nail are to be used for screw placement.




GT Aiming Arm

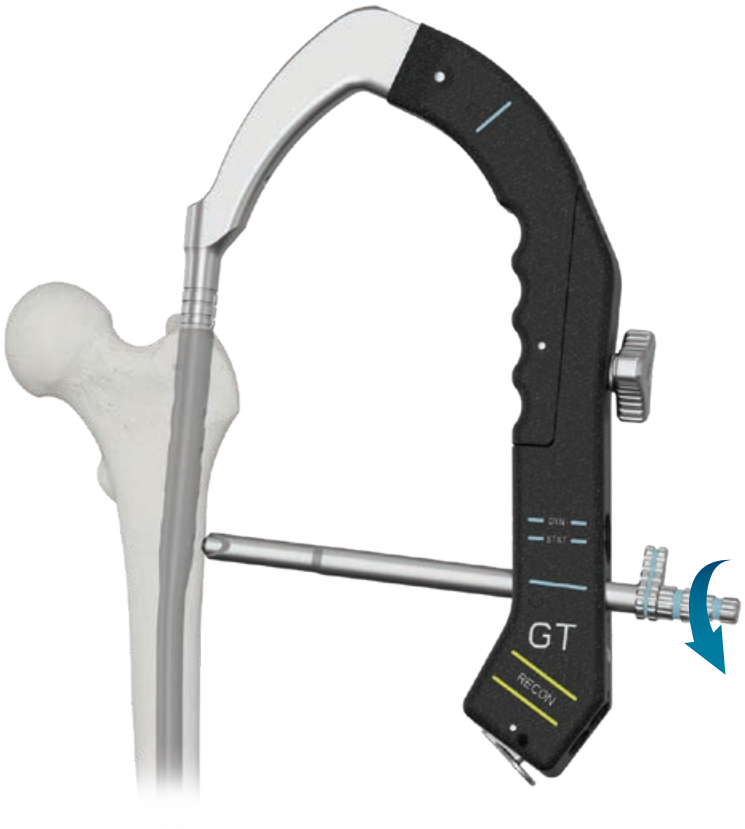



PF Aiming Arm

# INSERTING TROCAR SLEEVES

Insert the 5mm trocar sleeve assembly into the desired 5mm hole in the aiming arm or insertion handle.

Create a small incision and insert the trocar sleeve into the skin until bone is reached. Rotate the trocar sleeve assembly for retention.




**Inserting trocar sleeves**

## 5mm TROCAR SLEEVE ASSEMBLY

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

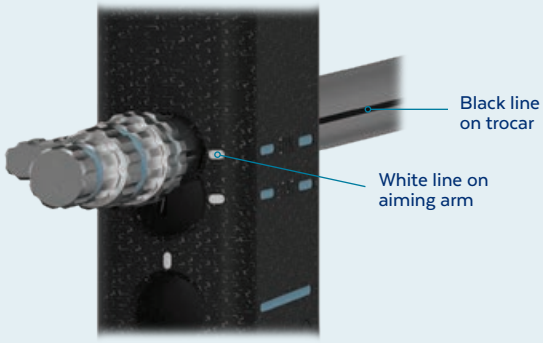
Assemble the 5mm trocar sleeve by inserting the **4.2mm Trocar** into the **4.2mm Drill Sleeve**. Insert the drill sleeve into the **5mm Driver Sleeve** and rotate the drill sleeve clockwise to tighten.

The driver sleeve has cutouts near the distal tip in order to visualize screw heads on fluoroscopy.

## 5mm TROCAR SLEEVE ASSEMBLY (CONT'D)

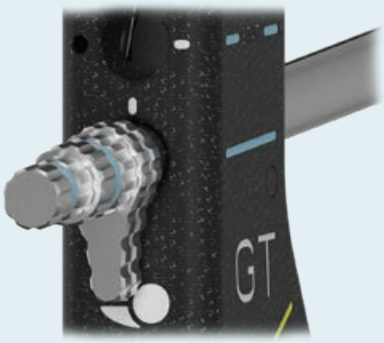
### Rotational Self-Retention

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 as shown below to engage the self-retaining feature for a static or dynamic hole.

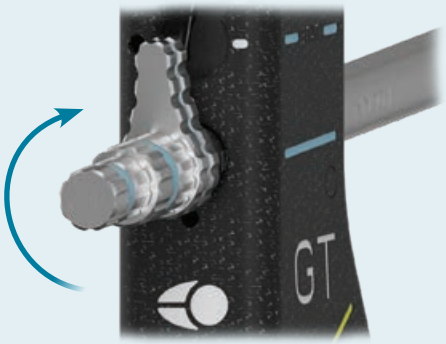



### Static Holes

Rotate the trocar sleeve assembly 180° to allow visualization of the cutout using AP fluoroscopy.



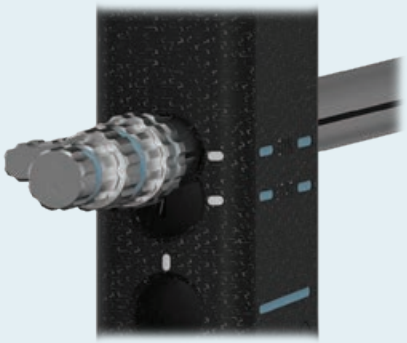

Unlocked



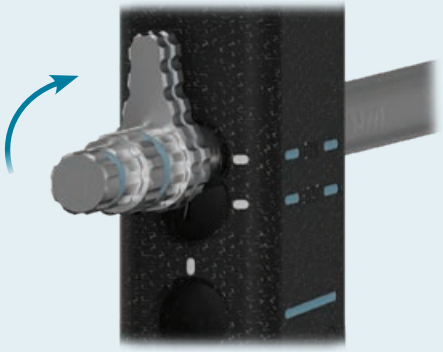

Locked

### Dynamic Slot

Rotate the trocar sleeve assembly 90° to allow visualization of the cutout using AP fluoroscopy.



Unlocked



Locked

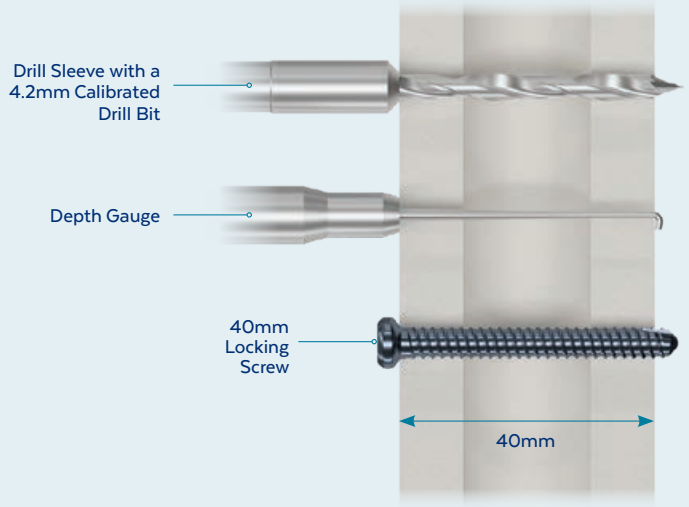
# DRILLING

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

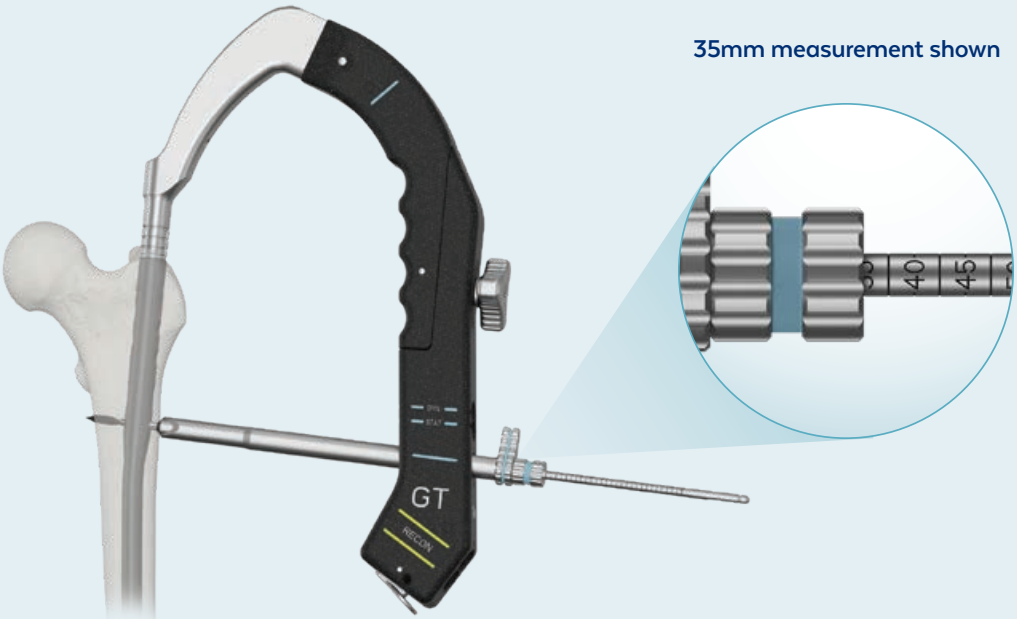
The 4.2mm Calibrated Drill Bit and **Depth Gauge, 5mm** are used to measure hole depth for full thread engagement in the far cortex using 5mm screws.




**40mm depth shown**

## 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.

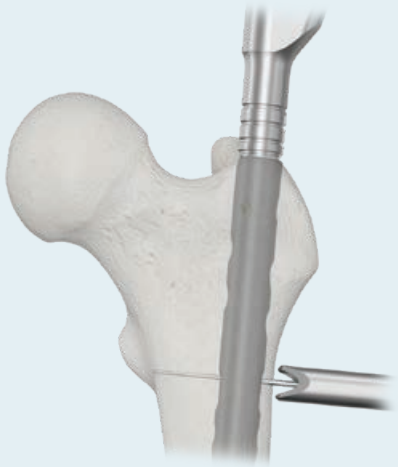



35mm measurement shown

Drilling

## 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 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.



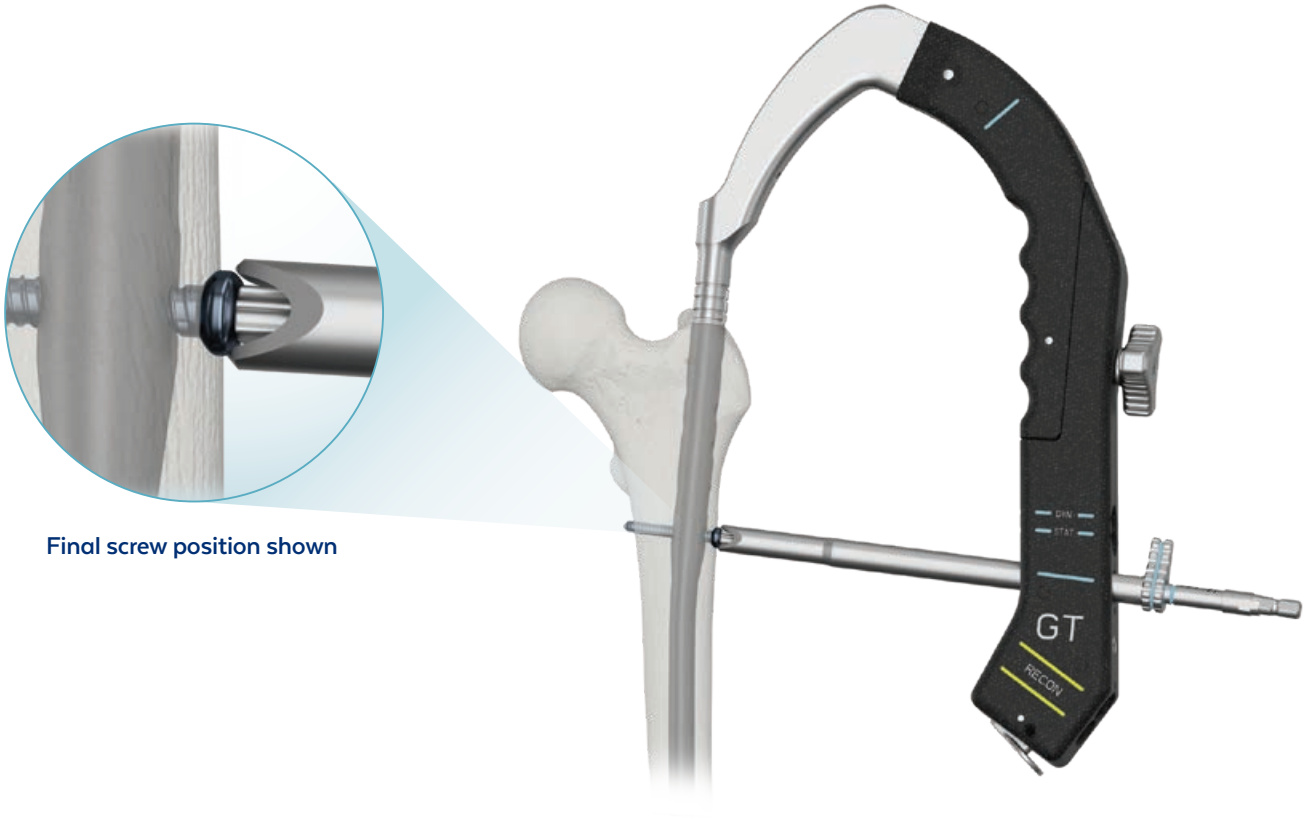
Hooking far cortex with depth gauge


35mm 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.

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




Final screw position shown

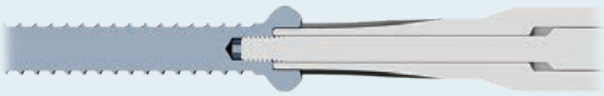
Inserting locking screw

## SCREW RETENTION

All locking screws, end caps, and set screws can be retained during insertion.

Insert the retention rod into the 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 quick-connect handle and rotating the knob of the retention rod counterclockwise. An **Extraction Pin Wrench** may be used.



Cross-section view of Retention Rod in screw

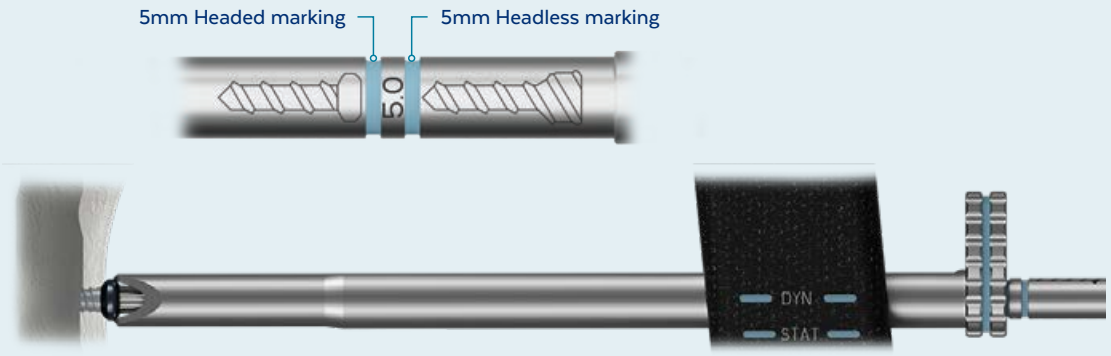
T30 Driver and Retention Rod

## 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 seated onto bone.

**5mm**: Markings are blue. The 5mm long driver has two markings as shown below, one for headed locking screws and the other for headless locking screws.

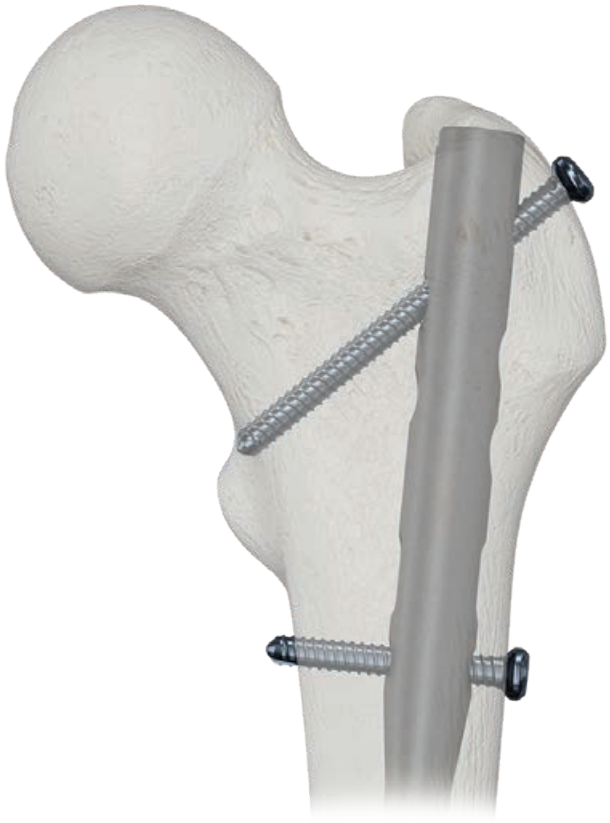



**Final placement of 5mm Headed Screw shown**

**6.5mm**: Markings are yellow.


**Final placement of 6.5mm Recon Screw shown**

# STANDARD LOCKING FINAL CONSTRUCT



# RECON LOCKING SCREWS

## ATTACHING AIMING ARM

Select the Aiming Arm corresponding to the selected nail style (GT or PF). Align and attach the aiming arm to the insertion handle and rotate the connection knob clockwise to tighten.

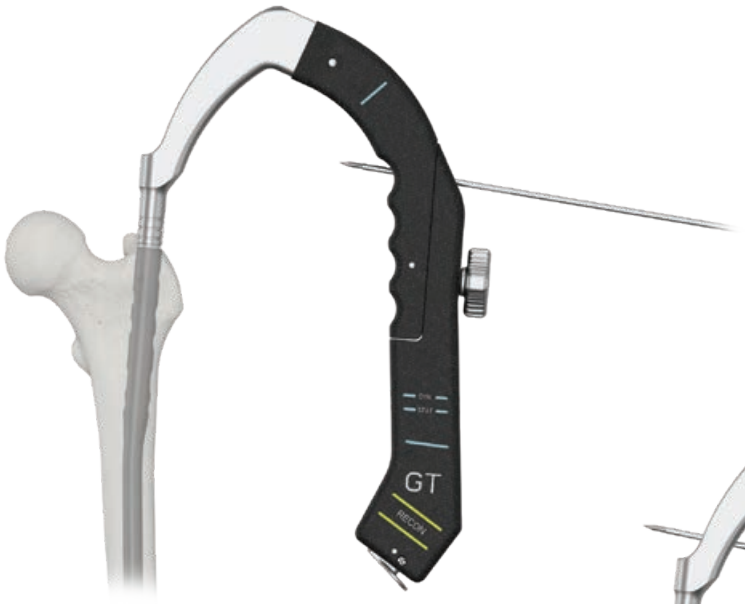
Refer to *Aiming Arm Assembly* (page 19) for assembly instructions.

## CHECKING ANTEVERSION

Insert a guidewire into the anteversion check hole on the aiming arm.

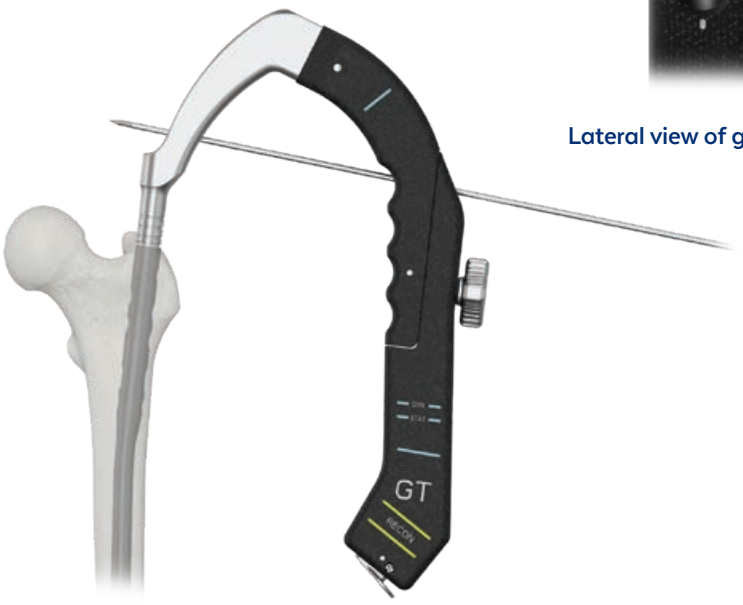
Insert the guidewire through the insertion handle tip. Confirm position using fluoroscopy. Lateral imaging should be in line with the femoral neck.

The guidewire should be located centrally in the lateral view of the femoral neck.




**Insert guidewire through aiming arm**

**Lateral view of guidewire**




**Insert guidewire through insertion handle**

# INSERTING TROCAR SLEEVE(S)

Two single recon trocar sleeves or the dual recon trocar sleeve may be used.

Insert the trocar sleeve(s) into the aiming arm.

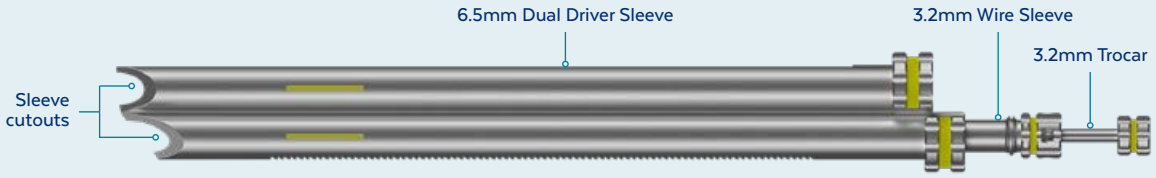
Create a small incision and insert the trocar sleeve(s) into the skin until bone is reached.

Remove the trocar and ensure the trocar sleeve is in contact with bone.


**Inserting dual trocar sleeve(s)**

## 6.5mm DUAL RECON SLEEVE

To assemble the dual recon trocar sleeve, insert the **3.2mm Trocar** into the **3.2mm Wire Sleeve**. Insert the wire sleeve into the inferior hole on the **Dual 6.5mm Driver Sleeve**. Rotate the wire sleeve clockwise to tighten.




### Aiming Arm Retention

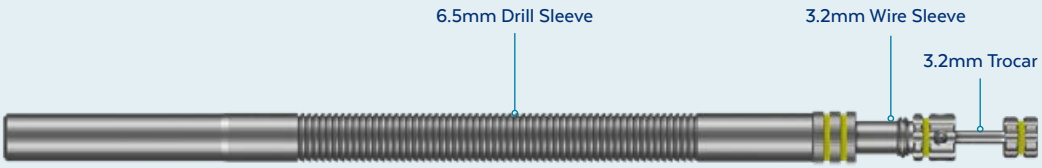
The dual sleeve retains through ratchets in the aiming arm. As the dual sleeve is inserted, it clicks on the ratchet teeth. Correct orientation must be used to engage the ratchet retention.

To remove, press the ratchet paddle to release the sleeve.


**Inserting dual trocar sleeve assembly into aiming arm**

## 6.5mm SINGLE RECON SLEEVE

To assemble a single recon trocar sleeve, insert the 3.2mm trocar into the 3.2mm wire sleeve. Insert the wire sleeve into the **6.5mm Driver Sleeve**. Rotate the wire sleeve clockwise to tighten.




### Aiming Arm Retention

The single sleeve in the inferior recon hole retains through ratchets in the aiming arm. The single sleeve in the superior hole retains with a friction pin. Single sleeves do not need to be rotationally oriented for retention.

To remove, press the ratchet paddle to release the sleeve.


**Inserting single trocar sleeve assemblies into aiming arm**

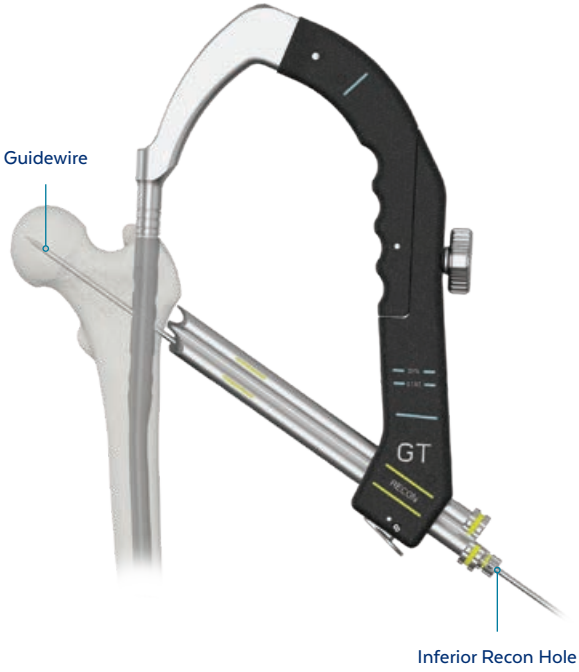
# INSERTING INFERIOR GUIDEWIRE

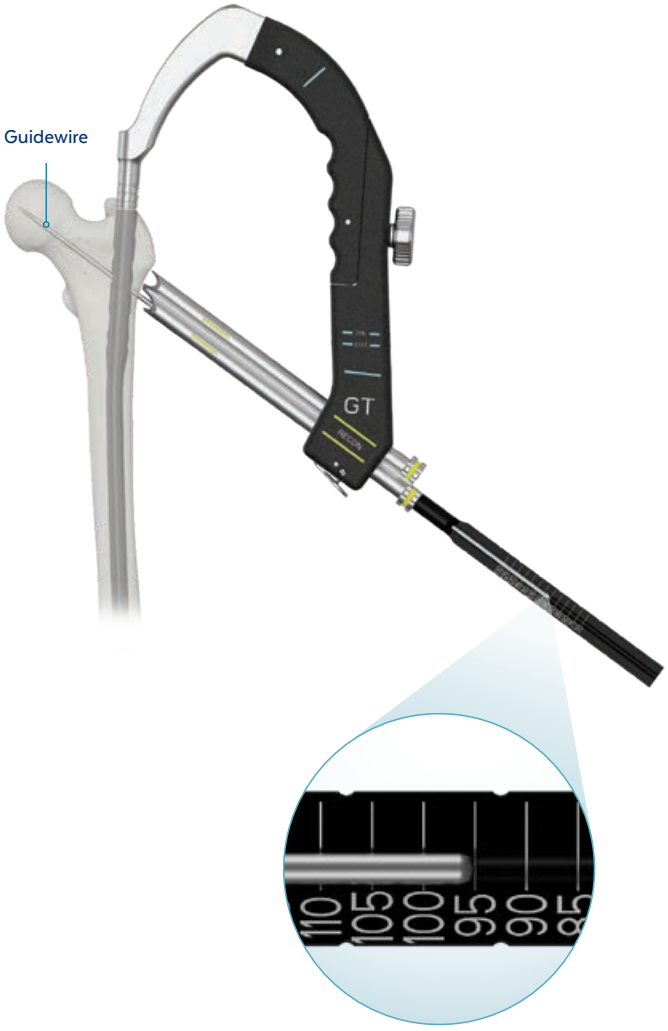
Insert the 400mm 3.2mm guidewire through the inferior hole on the sleeve and into the femoral head.

Verify guidewire position in both AP and lateral views to obtain the desired depth in subchondral bone in the femoral head. The guidewire should be placed slightly proximal to the calcar region in the AP view, and centrally in the lateral view.

Remove the wire sleeve, keeping the guidewire in place. Insert the **Direct Read Depth Gauge, 6.5mm** over the guidewire until it touches the driver sleeve. Read the etching on the gauge at the tip of the guidewire.

Remove the depth gauge.



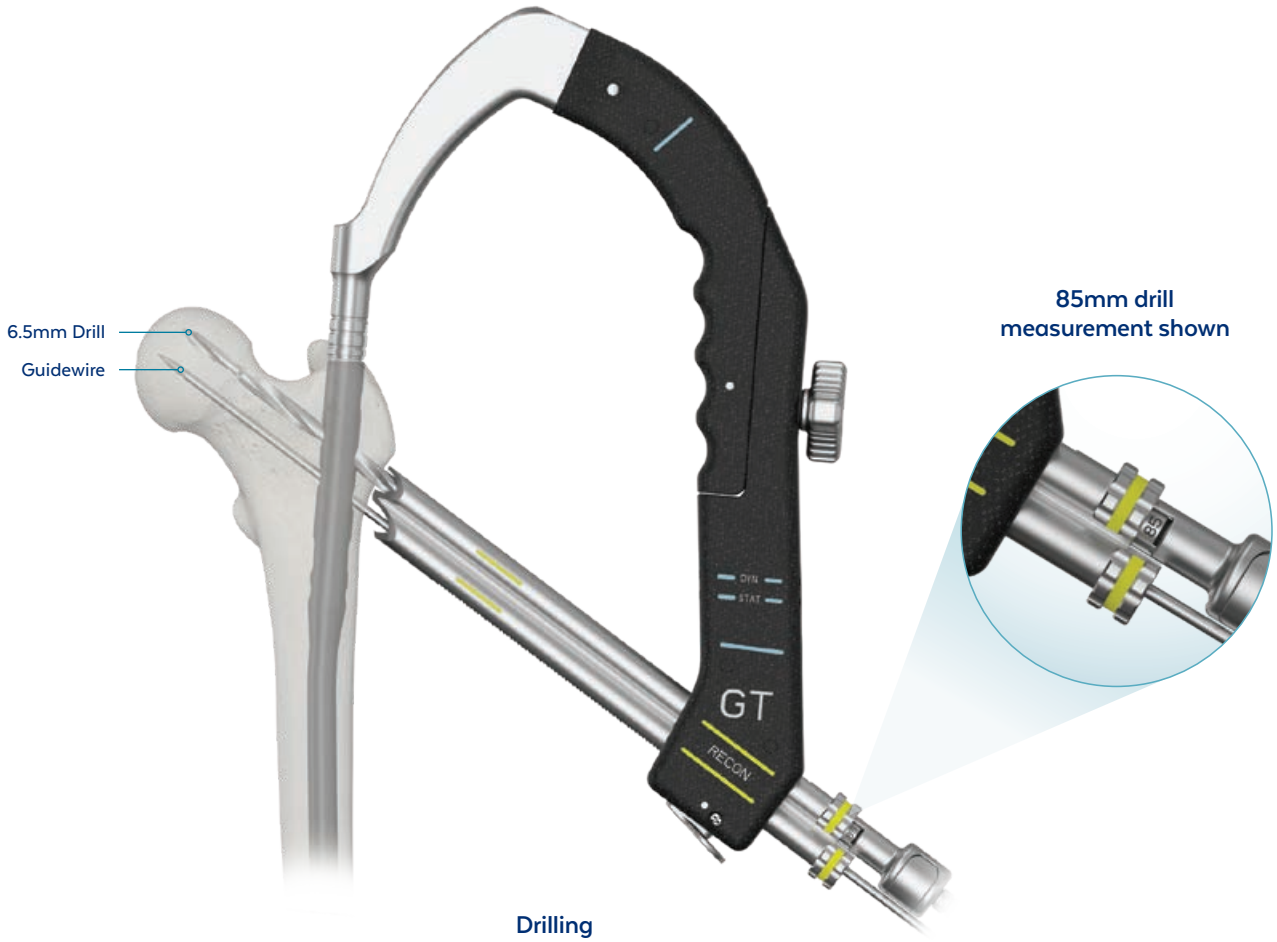



# DRILLING SUPERIOR HOLE

Keep the inferior guidewire in place. Insert the **6.5mm Stepped Drill Bit** into the superior recon hole. Drill until subchondral bone is reached. Verify drill bit position under fluoroscopy. Remove the drill bit.

The **Drill Stop** may be used to limit drilling to a shorter length than the measured length of the inferior guidewire.

If desired, a 3.2x400mm guidewire may be inserted into the superior recon hole and measured prior to drilling.




**Drilling**

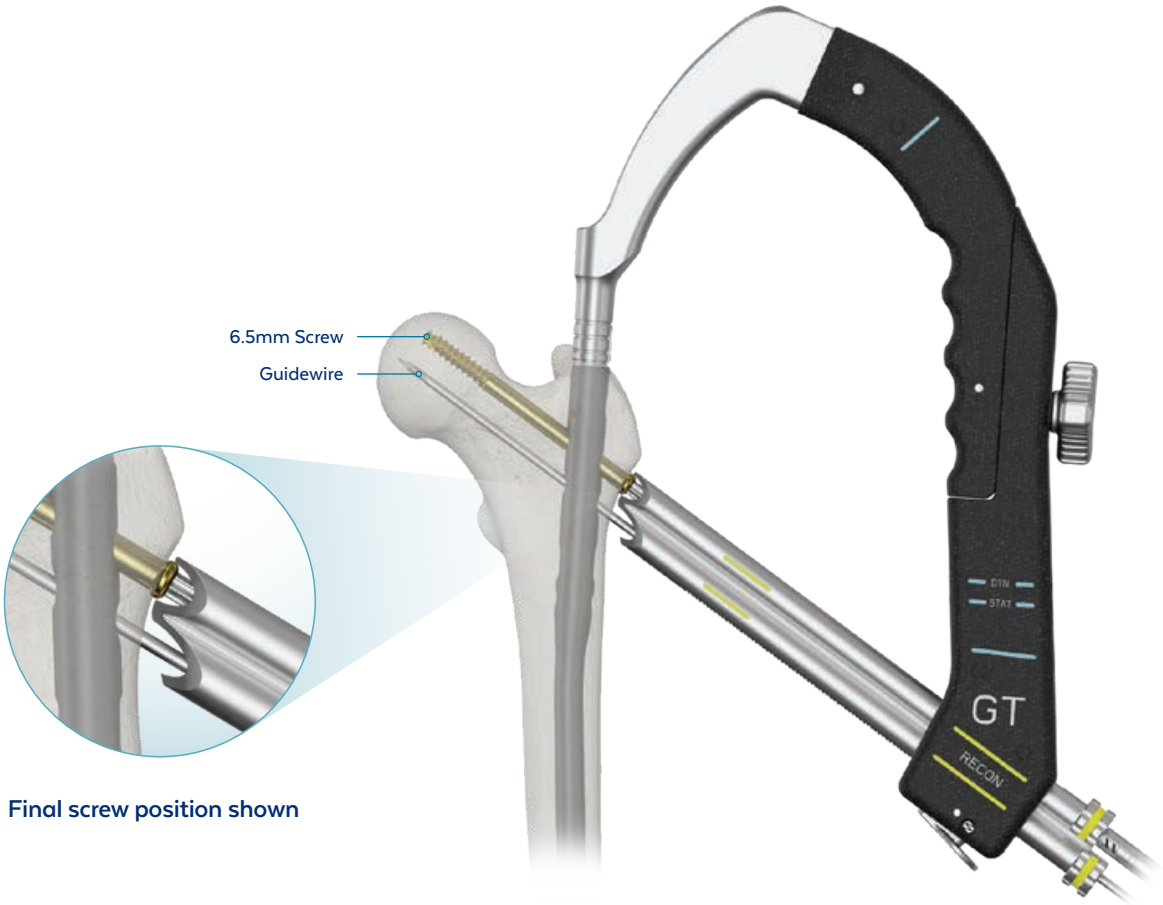
# INSERTING SUPERIOR SCREW

Insert the selected 6.5mm locking screw into the superior recon hole using the T30 driver. The screw is near the intended seating position when the yellow marking on the driver approaches the end of the driver sleeve.

Confirm screw length and position under fluoroscopy. Remove the driver.

A retention rod may be used for screw retention; refer to *Screw Retention* (page 24) for instructions.

In dense bone, a **Tap** may be used prior to screw insertion. Tap to the desired depth using a quick-connect handle.




**Final screw position shown**

**Inserting superior recon screw**

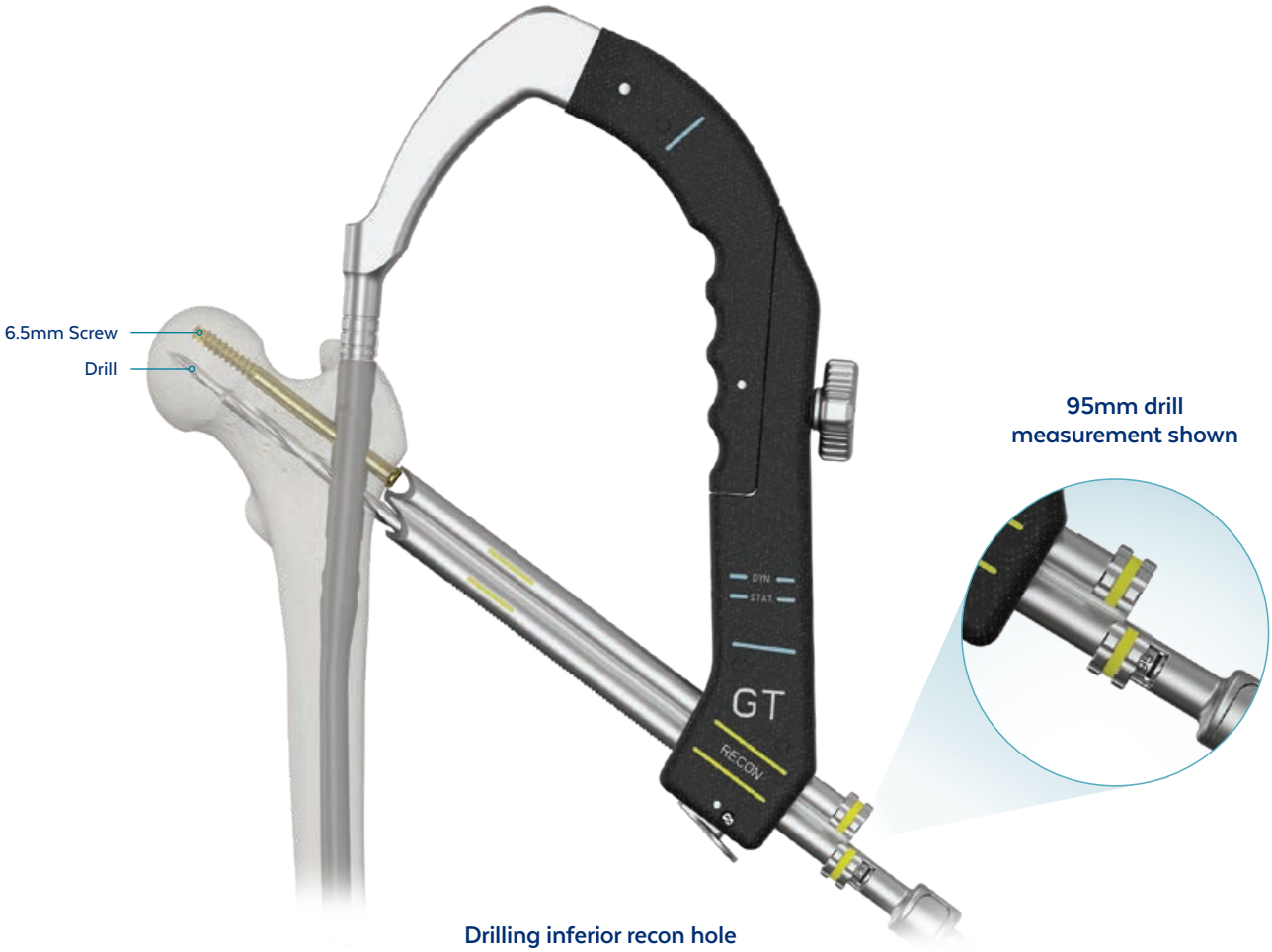
# DRILLING INFERIOR HOLE

Remove the guidewire from the inferior recon hole.

Attach the drill stop to the 6.5mm drill. Verify that the drill stop is seated at the measured length from the previous step.

Insert the 6.5mm drill into the inferior recon hole, and drill until the drill stop reaches the 6.5mm driver sleeve, or until subchondral bone is reached. Verify drill position under fluoroscopy.

Remove the drill bit.




Drilling inferior recon hole

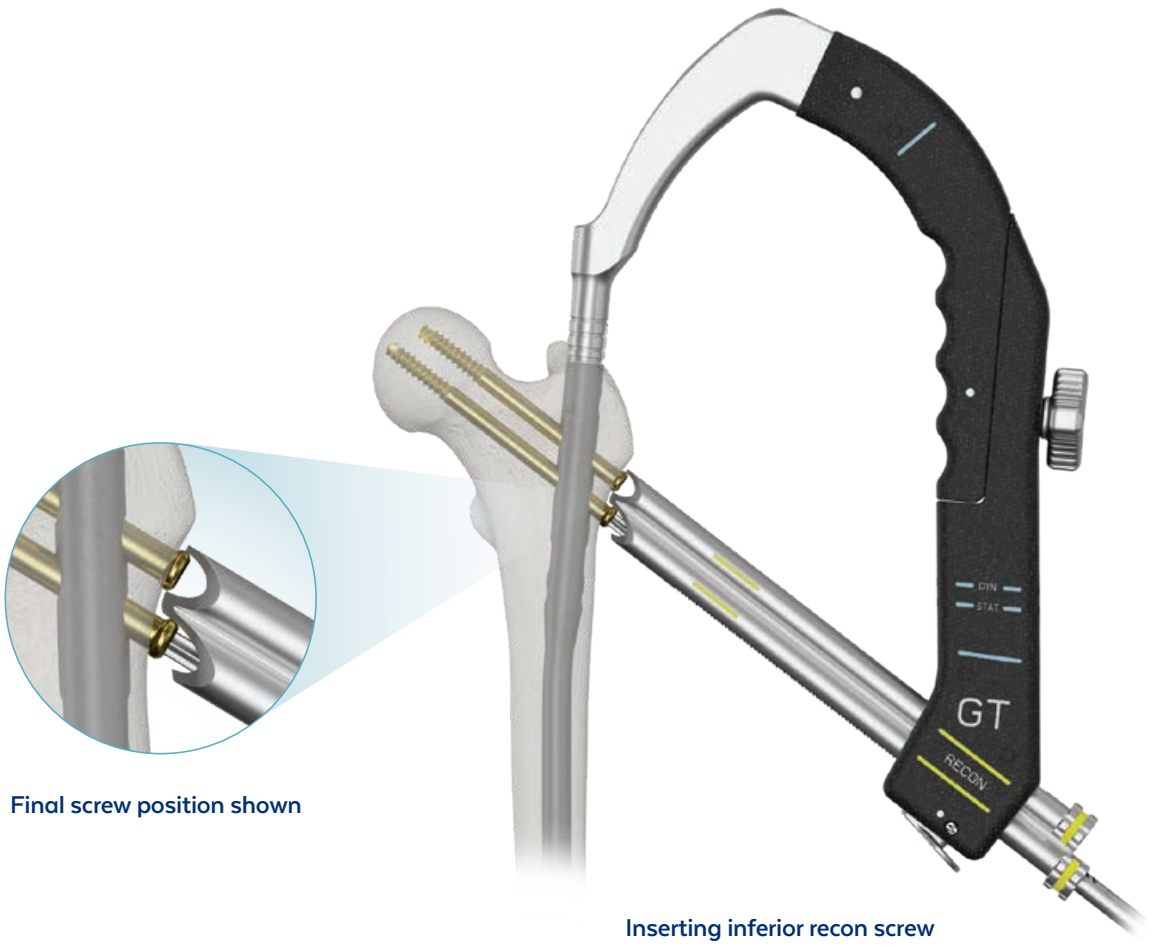
# INSERTING INFERIOR SCREW

Insert the selected 6.5mm locking screw using the T30 driver. The screw is near the intended seating position when the yellow marking on the driver approaches the end of the driver sleeve.

Confirm screw position under fluoroscopy. Remove the driver and driver sleeve(s).

A retention rod may be used for screw retention; refer to *Screw Retention* (page 24) for instructions.

In dense bone, a tap may be used prior to screw insertion. Tap to the desired depth using a quick-connect handle.




**Final screw position shown**

**Inserting inferior recon screw**

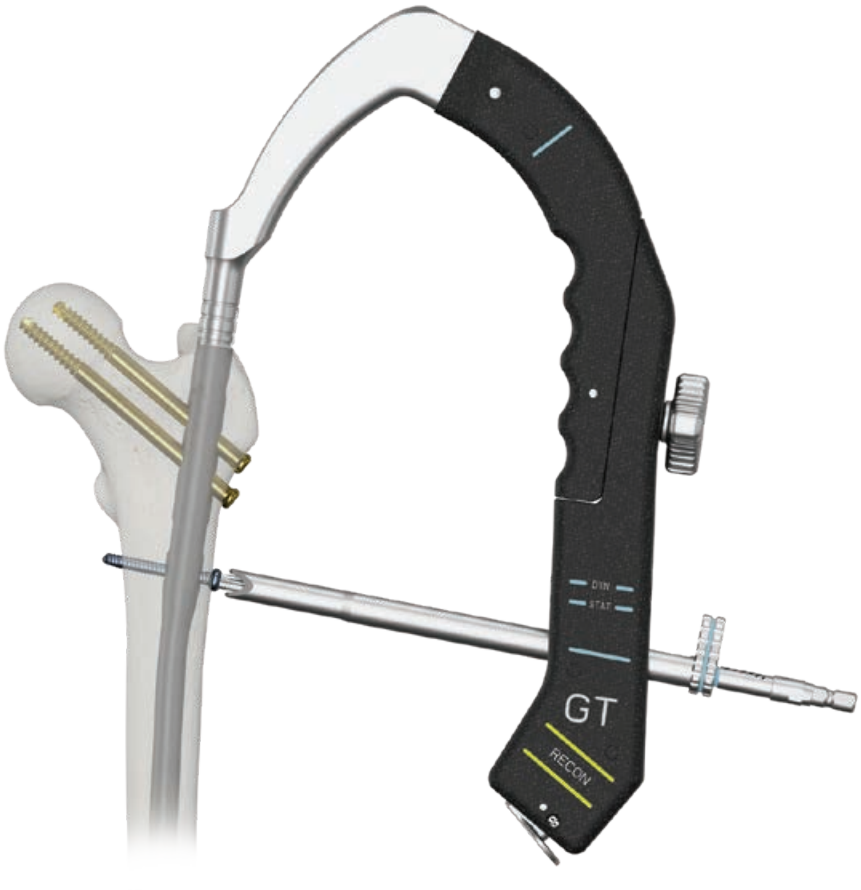
# FLUOROSCOPIC REVIEW

Use multiple fluoroscopic views to ensure the 6.5mm recon screws are correctly positioned in the femoral neck and femoral head.

# OPTIONAL: INSERTING TRANSVERSE STATIC LOCKING SCREW(S)

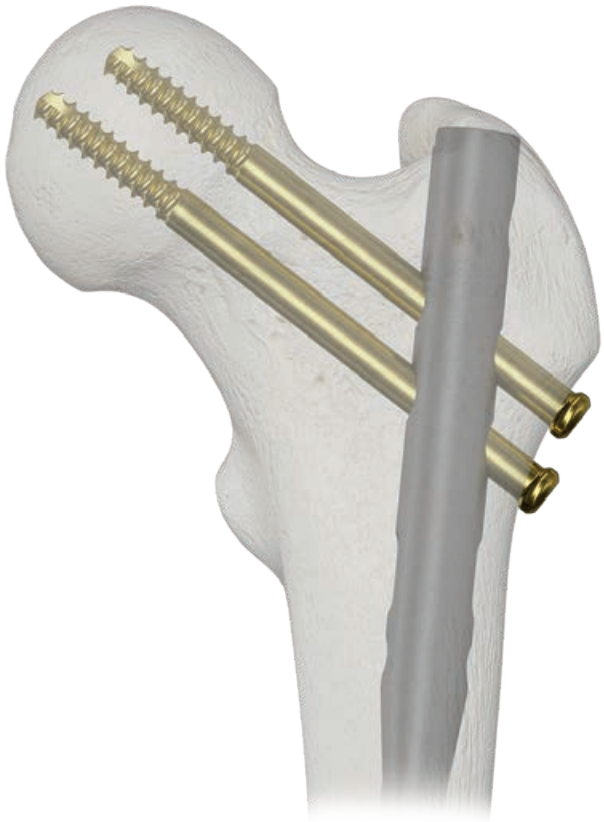
Verify under fluoroscopy to ensure the 5mm trocar sleeves do not interfere with the inferior 6.5mm screw head prior to screw insertion.

Insert 5mm locking screws as needed. Refer to *Standard Locking Screws* (pages 19-26) for instructions.




**Inserting 5mm Locking Screws**

# RECON LOCKING
# FINAL CONSTRUCT

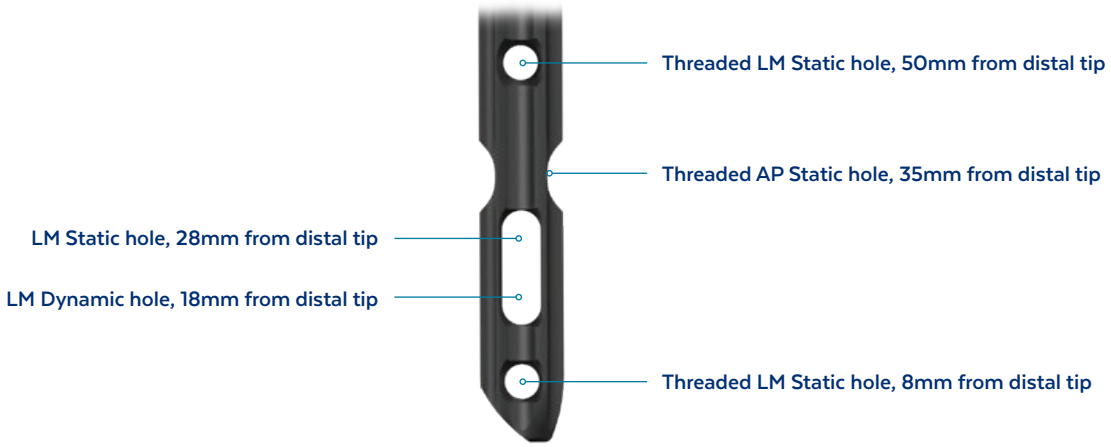


# DISTAL LOCKING SCREWS

## FREEHAND TARGETING

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

Select the desired distal 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.




**Distal hole options**

**Identifying incision location**

# DRILLING AND MEASUREMENT

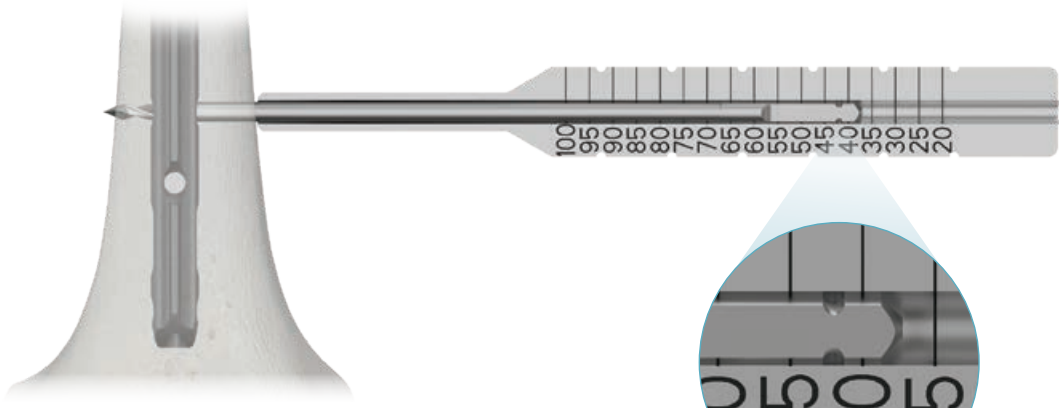
Insert the 4.2mm drill bit into the incision until bone is reached. Angle the drill bit perpendicular to the nail hole and drill through both cortices. Confirm drill bit position under fluoroscopy.

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

To use the direct read depth gauge, insert the depth gauge over the drill bit until bone is reached. Read the marking on the gauge at the back of the drill bit. Remove the gauge.

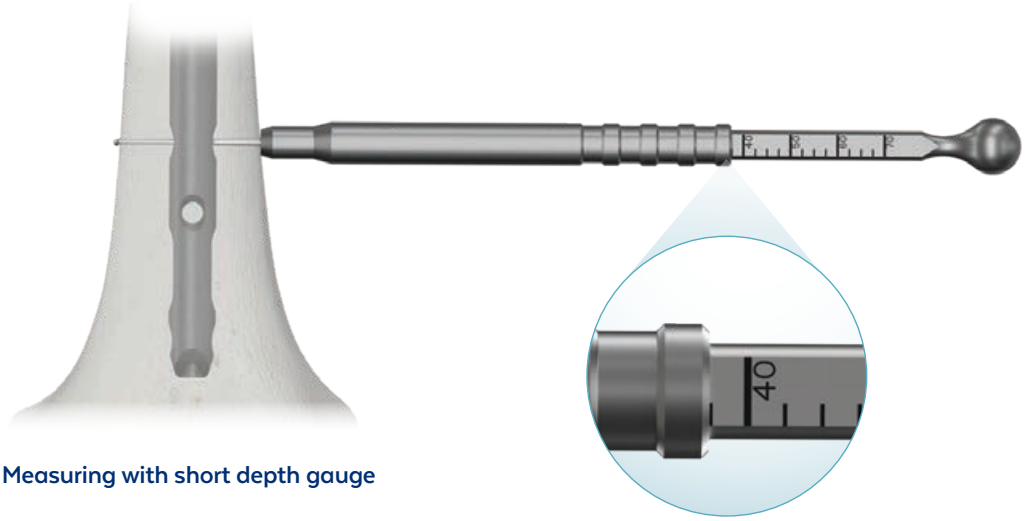
Alternatively, to measure hole depth, remove the drill bit. Insert the depth gauge until bone is reached. Extend the hook completely through the femur and retract until the hook engages the far cortical wall. Determine the length by reading the measurement on the gauge. Remove the depth gauge.

Identifying drill start point




Measuring with direct read depth gauge

37.5mm measurement shown



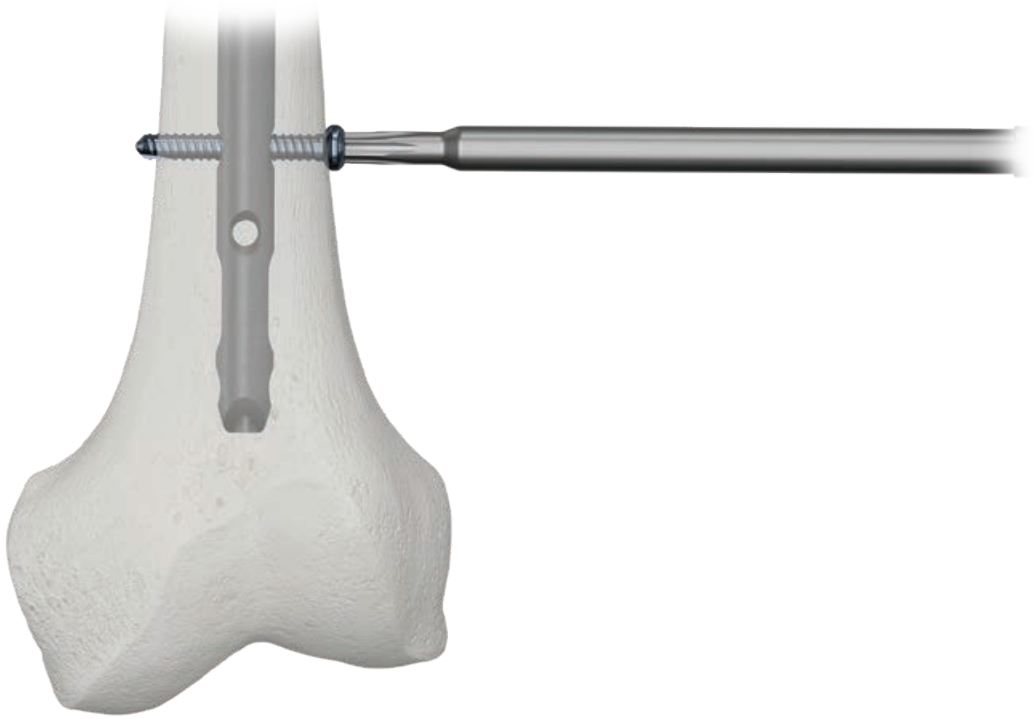

Measuring with short depth gauge

37.5mm measurement shown

# INSERTING DISTAL SCREW

Insert the selected 5mm locking screw using the T30 driver.

Confirm screw length and position under fluoroscopy. Remove the driver. Repeat steps for other locking screws. A retention rod may be used for screw retention; refer to *Screw Retention* (page 24) for instructions.



**Inserting distal locking screw**

# DISTAL LOCKING
# FINAL CONSTRUCT

# COMPRESSION LOCKING SCREWS (Optional)

When using compression, it may be necessary to over-insert the nail to avoid nail prominence after compression.

## DISTAL LOCKING

Distal locking screws must be inserted prior to proximal locking screws. Refer to *Distal Locking Screws* (pages 37-40) for instructions. Insert the desired distal locking screws using the T30 driver.

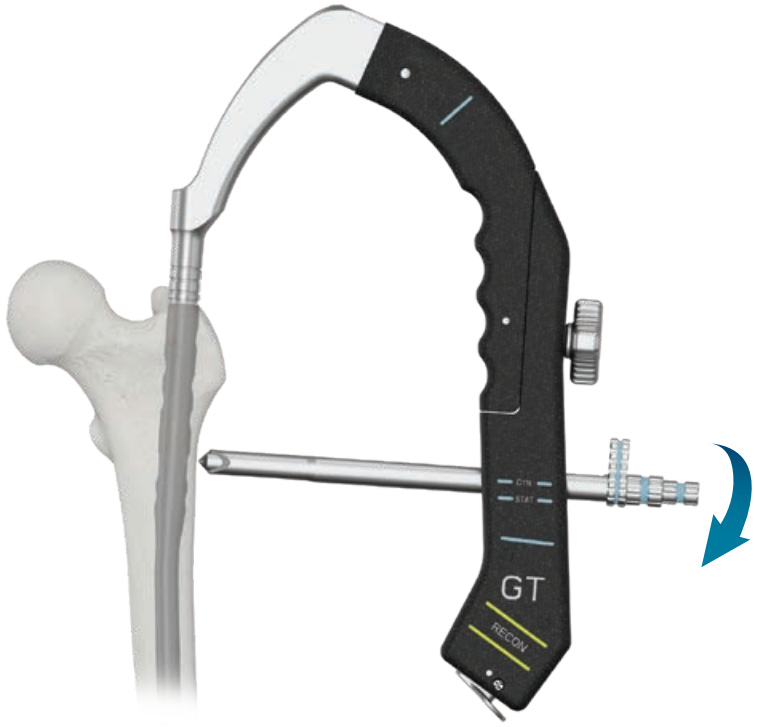
## ATTACHING AIMING ARM

Select the Aiming Arm corresponding to the selected nail style (GT or PF). Align and attach the aiming arm to the insertion handle and rotate the connection knob clockwise to tighten.

Refer to *Aiming Arm Assembly* (page 19) for assembly instructions.

## INSERTING TROCAR SLEEVES

Insert the 5mm trocar sleeve assembly into the dynamic hole position 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.

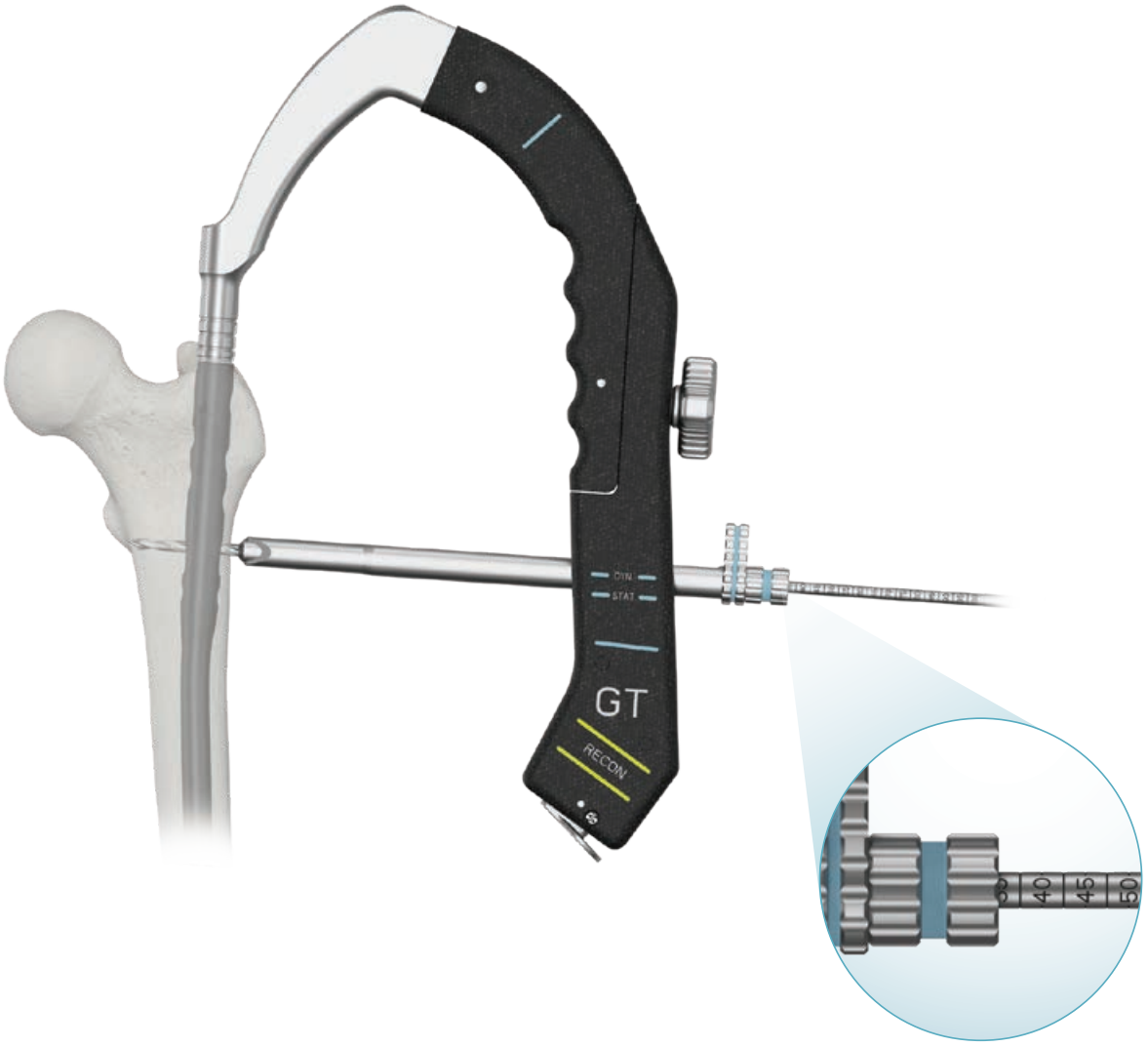



**Inserting trocar sleeves**

# 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 23) or *Screw Length Measurement Using the Depth Gauge* (page 23) for instructions.

Remove the drill bit and drill sleeve.



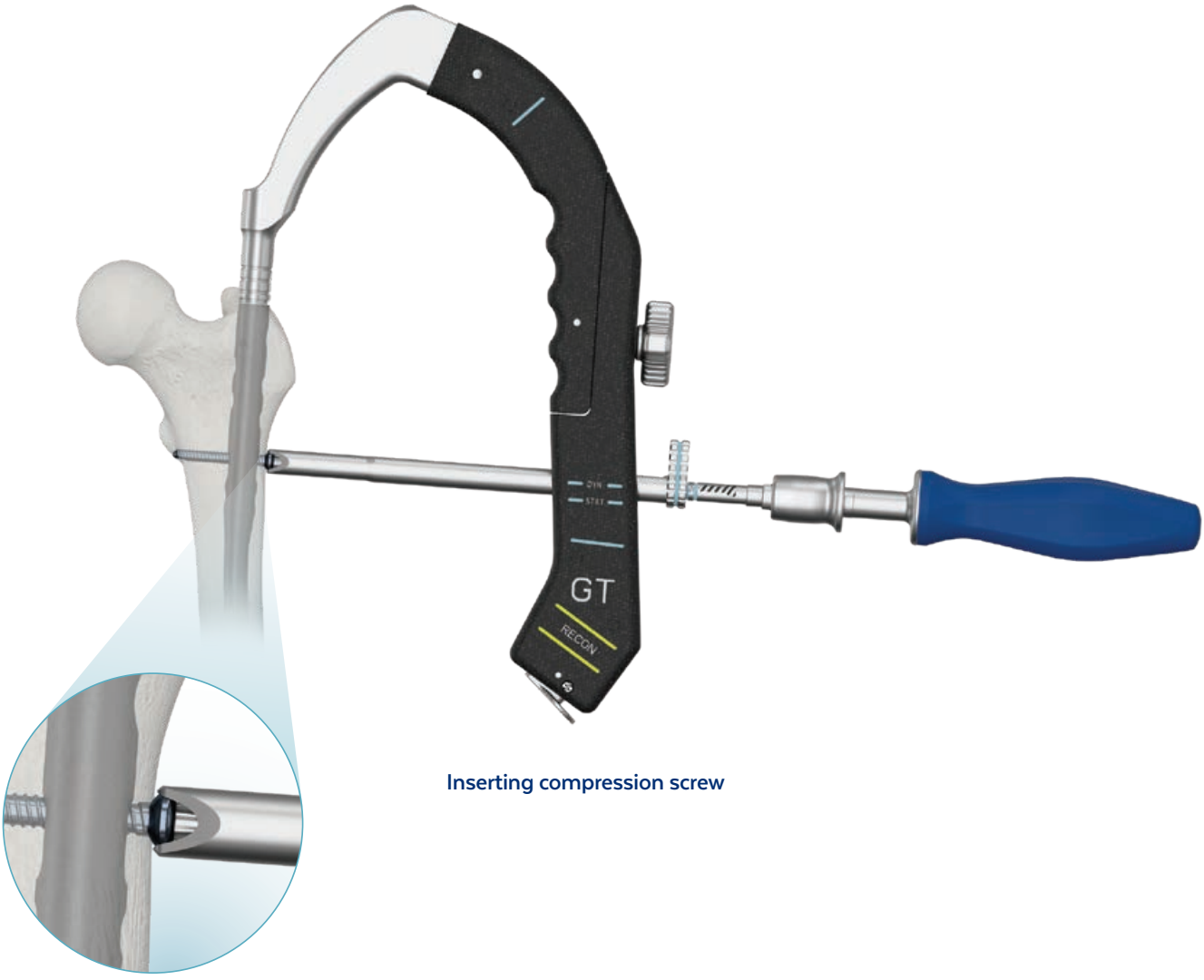

**35mm measurement shown**

# INSERTING COMPRESSION LOCKING SCREW

Insert the selected 5mm locking screw into the nail using the T30 driver with a quick-connect handle. Confirm screw length and position under fluoroscopy. Remove the driver and driver sleeve.

A retention rod may be used for screw retention; refer to *Screw Retention* (page 24) for instructions.

*Note: No other proximal locking screw may be placed prior to applying compression.*

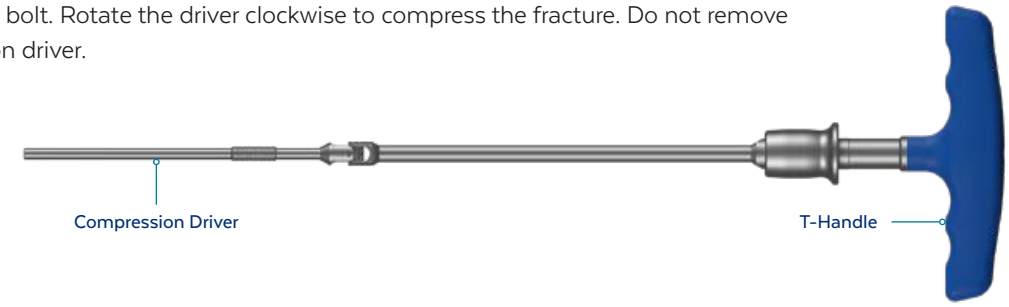


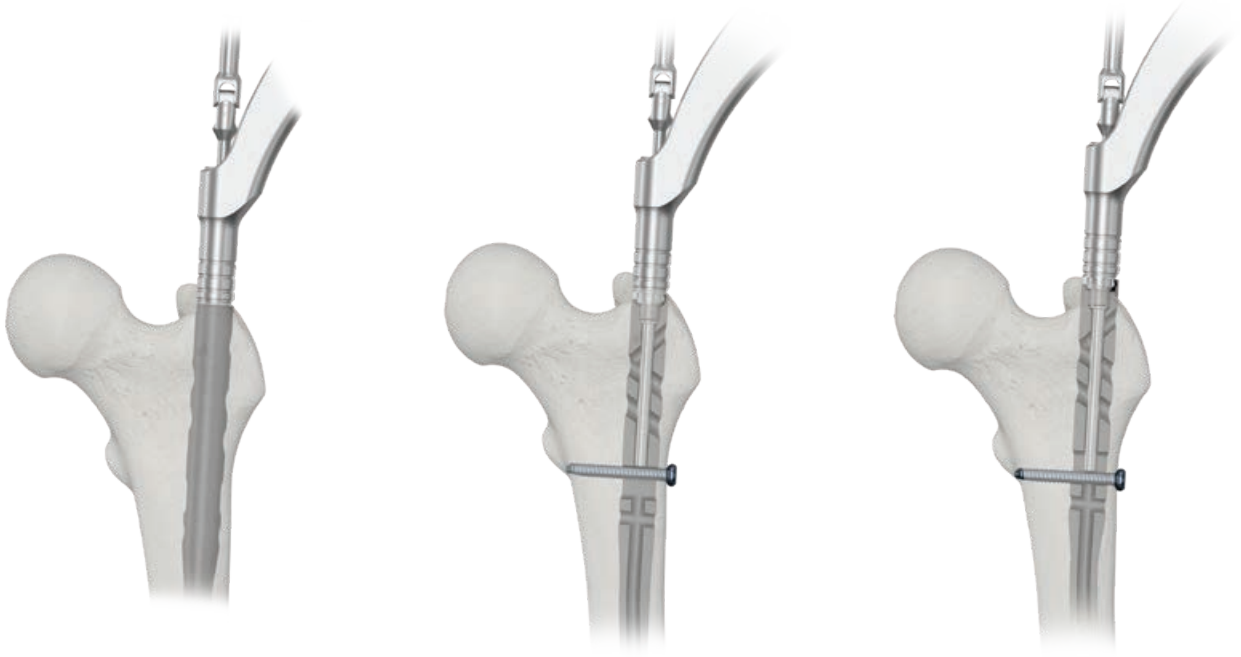

**Inserting compression screw**

**Final screw position shown**

# ACTIVE INTERNAL COMPRESSION

Attach the **Compression Driver** to a quick-connect handle. Insert the compression driver into the Insertion Handle and nail connection bolt. Thread the compression driver into the nail connection bolt. Rotate the driver clockwise to compress the fracture. Do not remove the compression driver.



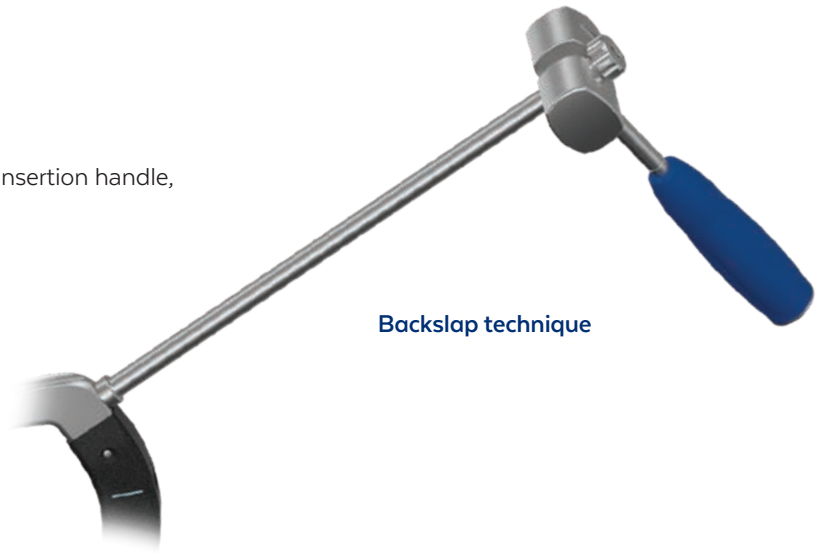
**Inserting compression driver**

**Before compression**

**After compression**

## Backslap Technique

Alternatively, attach the **Backslap Shaft** to the insertion handle, and impact using the slotted mallet.

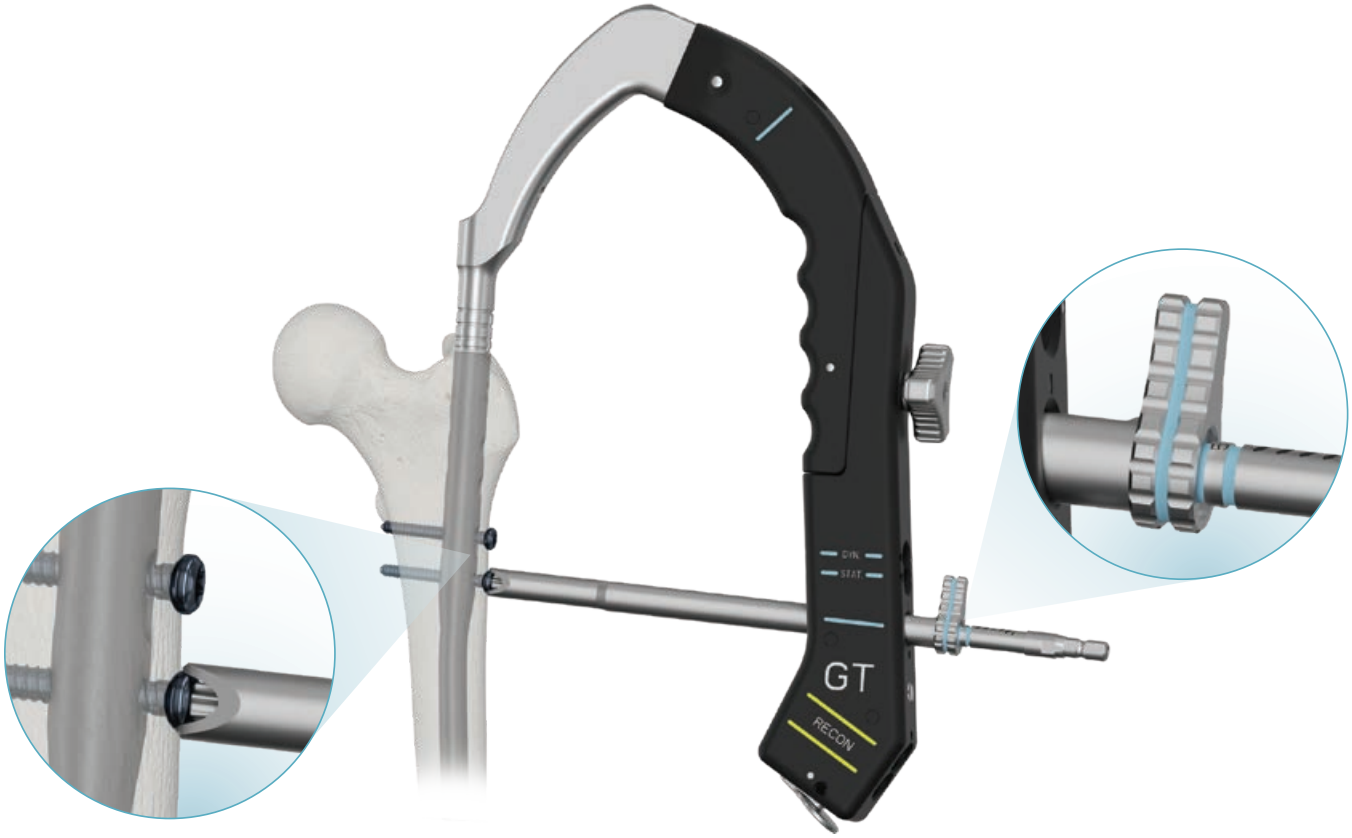


**Backslap technique**

# INSERTING STATIC LOCKING SCREW

When the desired amount of compression is achieved, insert the trocar sleeve assembly into the distal-most static hole on the aiming arm.

Insert the desired 5mm locking screw. Refer to *Standard Locking Screws* (pages 19-26) for instructions. Once the static screw is inserted, the compression driver may be removed.




**Final screw position shown**

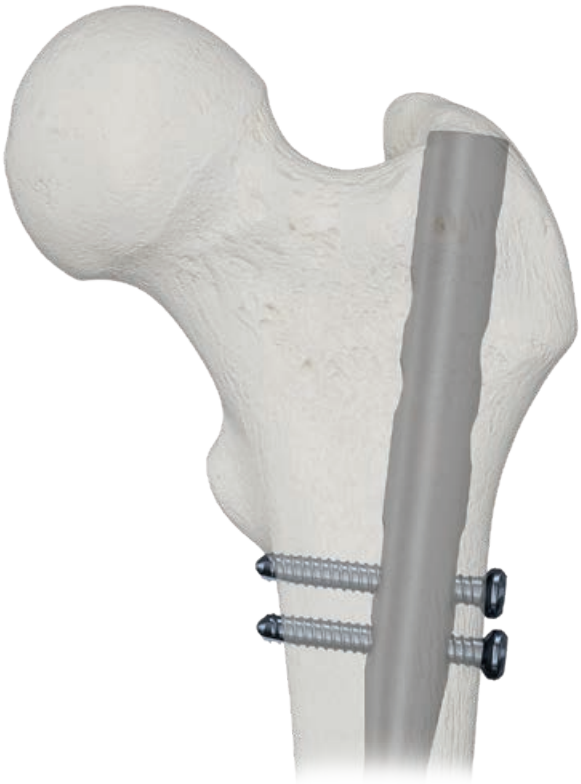
**Inserting static locking screw**

# OPTIONAL: INSERTING RECON SCREWS

If recon screw placement is desired after locking the static screw, verify under fluoroscopy to ensure the 6.5mm trocar sleeve does not interfere with the 5mm locking screw in the compression slot.

Insert 6.5mm locking screws as needed. Refer to the Recon Locking section for instructions.

# COMPRESSION LOCKING FINAL CONSTRUCT



# OPTIONAL: SET SCREW INSERTION

The set screw may be used to lock the superior recon screw, creating a fixed angle construct.

## Connection Bolt Removal

Attach the nail connection bolt driver to the quick-connect handle. Insert the nail connection bolt driver into the insertion handle and engage the nail connection bolt. Rotate the driver counterclockwise to loosen and remove the bolt. Keep the Insertion Handle attached to the nail.

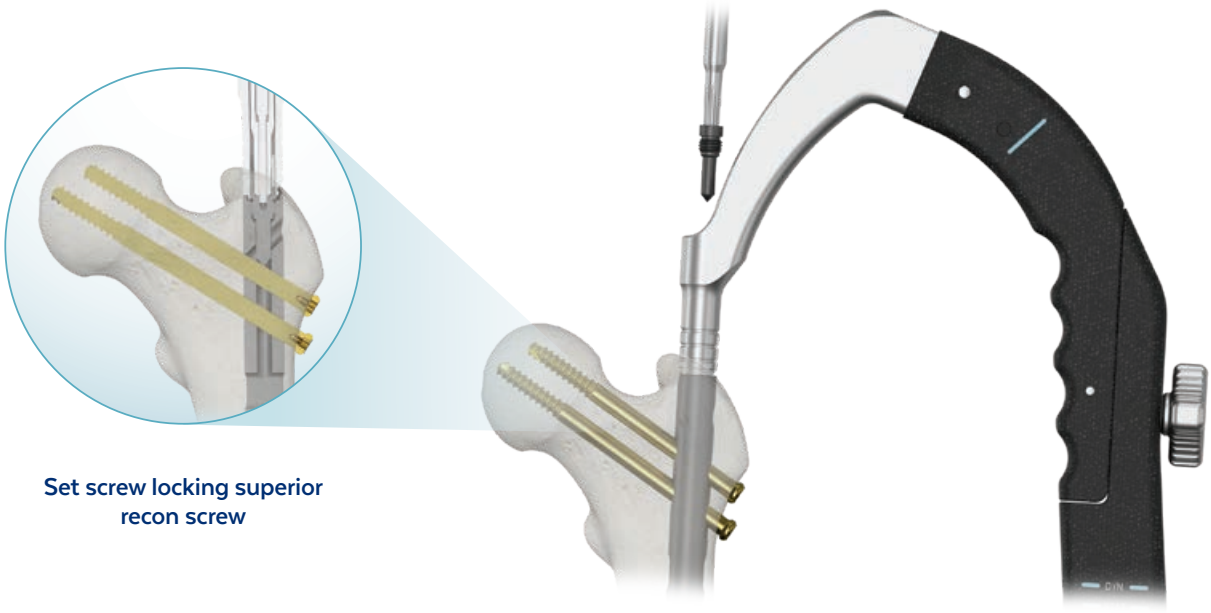
Threaded retention

## Set Screw Insertion

A retention rod should be used to retain the set screw onto the T30 driver; refer to *Screw Retention* (page 24) for instructions. Select the set screw corresponding to the selected nail style (GT or PF).

Insert the selected set screw into the nail using the T30 driver with a quick-connect handle. Rotate clockwise to tighten. Tighten the set screw to lock the superior recon screw. Remove the retention rod and driver.

Confirm position under fluoroscopy. Remove the retention and the driver.



Set screw locking superior recon screw

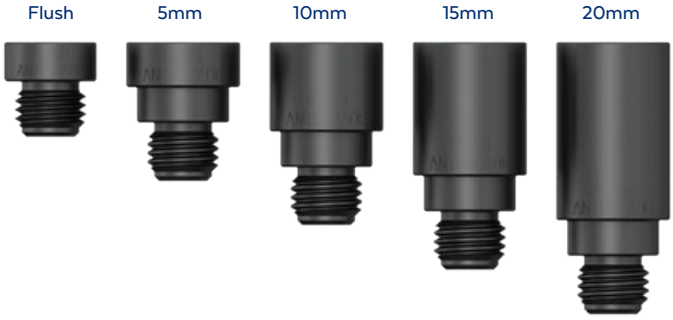
Inserting set screw

# OPTIONAL: END CAP INSERTION

The end cap may be used to prevent bony overgrowth or ingrowth covering the proximal tip of the nail. End caps may also be used to extend the height of the nail, if the nail is overly countersunk.

## Insertion Handle and Connection Bolt Removal

Attach the nail connection bolt driver to a quick-connect handle. Insert the nail connection bolt driver into the insertion handle and engage the nail connection bolt. Rotate the bolt driver counterclockwise to loosen. Remove the bolt and the insertion handle.



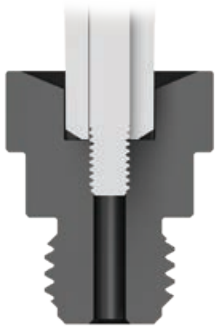

## End Cap Insertion

A retention rod should be used to retain the end cap onto the T30 driver; refer to *Screw Retention* (page 24) for instructions.

Select the desired end cap based on additional length needed.

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.



**Threaded retention**

**Inserting end cap**

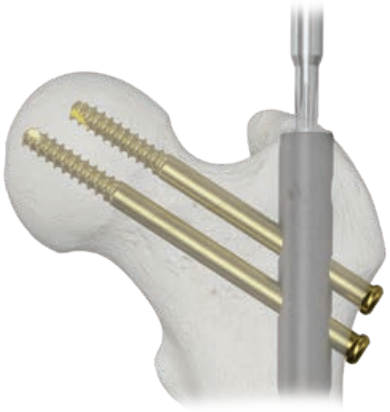
# OPTIONAL: NAIL REMOVAL

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

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

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

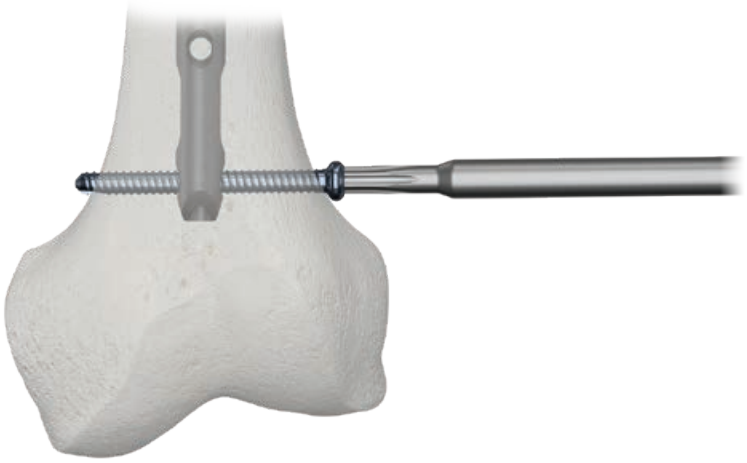
Alternatively, the Aiming Arm may be used to remove proximal screws. Attach the Insertion Handle to the nail, and fasten with the Nail Connection Bolt. Attach the corresponding Aiming Arm to the Insertion Handle. Target and remove proximal screws with the T30 driver through the corresponding driver sleeve. Remove the Aiming Arm and thread the backslap shaft into the Insertion Handle.



End Cap/Set Screw removal

Extraction Bolt insertion

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



Locking Screw removal

# OPTIONAL: NAIL REMOVAL (CONT'D)

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

Use the slotted mallet to fully extract the nail.

**Nail removal**

# BROKEN NAIL REMOVAL

Engage each locking screw with a T30 driver and remove. Thread the nail extraction bolt to the nail, and attach the backslap shaft to the extraction bolt. Using the slotted mallet, deliver gentle blows to backslap the nail and remove the proximal nail fragment.

Insert the ball-tip guidewire into the cannulation of the distal 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 14mm, 6257.1014

Multi-Hole Wire Guide, Antegrade 14mm, 6257.1015

Hall Quick-Connect Handle, 6190.3000



3.2mm Guidewire, Threaded Drill Point, 400mm, 6257.0021*



3.2mm Guidewire, Drill Point, 400mm, 6257.0022*



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



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

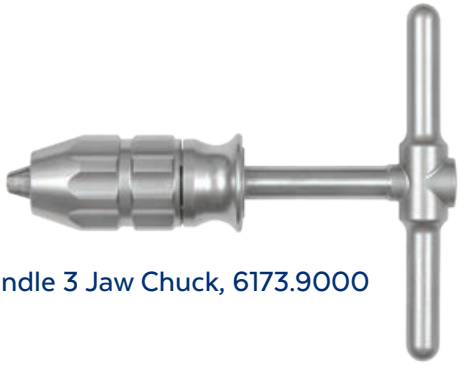
**Available non-sterile or sterile.*
*Add "S" to the end of the part number to indicate sterile.*

## OPENING (CONT'D)

14mm Cannulated Opening Drill Bit, 6257.1043

Awl, 9mm Curved, 6257.1053

Ball-Tip Guidewire 3x1000mm, 6176.0022S



T-Handle 3 Jaw Chuck, 6173.9000

Intramedullary Reduction Tool, Hall Connection, 6257.1062

## REAMING

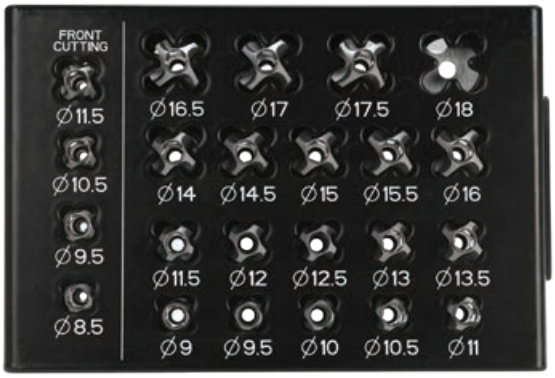
Flexible Reamer Shaft, 470mm, Hall Connection, 6182.0004*

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

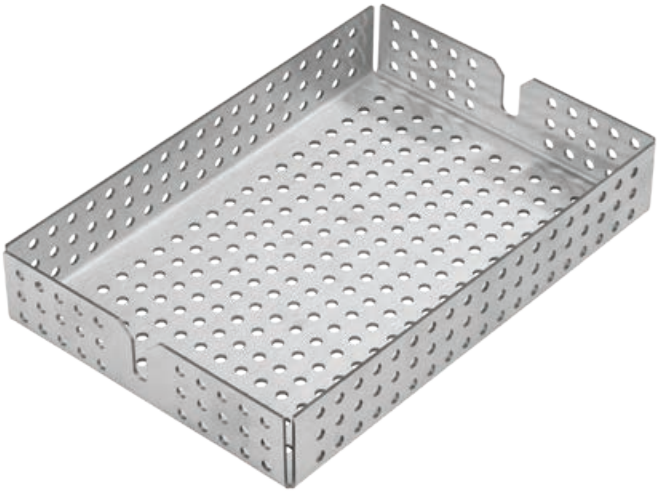
Guidewire Pusher 6176.0029

Front Cutting Reamer Heads, 6182.2085-.2115

Piloted Reamer Heads, 6182.1090-.1180



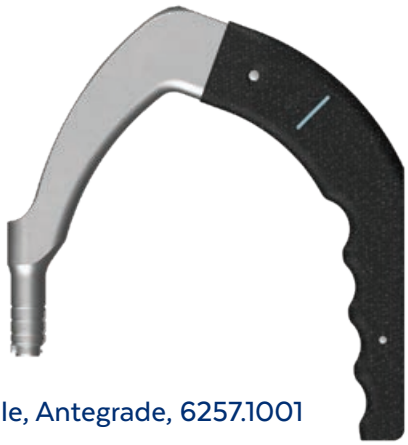

Reamer Caddy 9182.0001



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, Antegrade, 6257.1001

Nail Connection Bolt, Antegrade, 6257.1004

Nail Connection Bolt Driver, Shaft, 6257.1044

Hall Quick-Connect T-Handle, 6257.1058

Impaction Rod, Antegrade, 6257.1046

Slotted Mallet, 6176.0020

## 5mm TARGETED LOCKING


Aiming Arm, Greater Trochanter, 6257.1003


Aiming Arm, Piriformis Fossa, 6257.1056

Driver Sleeve, 5mm, 6257.1029

Drill Sleeve, 4.2mm, 6257.1030

Trocar, 4.2mm, 6257.1031

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.*

## COMPRESSION LOCKING

Compression Driver, 6257.1045

Backslap Shaft, Antegrade, 6257.1069

## 6.5mm RECON LOCKING

Dual Driver Sleeve, 6.5mm, 6257.1055

Driver Sleeve, 6.5mm, 6257.1006

Wire Sleeve, 3.2mm, 6257.1007

Trocar, 3.2mm, 6257.1008

Drill Stop, 6.5mm, 6257.1010


Direct Read Depth Gauge, 6.5mm 6257.1022

6.5mm Stepped Drill Bit, 6257.1009

6.5mm Tap, 6257.1011

T30 6.5mm Screwdriver for Power, Long, 6257.1012

Retention Rod, T30 6.5mm Screwdriver for Power, Long, 6257.1013

## DISTAL LOCKING

4.2mm Drill Bit, 170mm, Short Flutes, 6257.2037*


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, 6183.1001

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 Antegrade Nail
# IMPLANTS

## Nails

| | GT | PF | Description |
|---|---|---|---|
| **10mm** | Left - 1257.3032S-1257.3044S | Left - 1257.1032S-1257.1044S | 20mm increments |
| | Right - 1257.4032S-1257.4044S | Right - 1257.2032S-1257.2044S | |
| **11mm** | Left - 1257.3132S-1257.3144S | Left - 1257.1132S-1257.1144S | |
| | Right - 1257.4132S-1257.4144S | Right - 1257.2132S-1257.2144S | |
| **12mm** | Left - 1257.3232S-1257.3244S | Left - 1257.1232S-1257.1244S | |
| | Right - 1257.4232S-1257.4244S | Right - 1257.2232S-1257.2244S | |

## Locking Screws

| Part No. | Description |
|---|---|
| 1257.8330*-1257.8370* | 5mm Locking Screws - 30-55mm in 2.5mm increments, 60-70mm in 5mm increments |
| 1257.9170*-1257.9230* | 6.5mm Locking Screws - 70-130mm in 5mm increments |

## Set Screws

| Part No. | Description |
|---|---|
| 1257.0301* | Set Screw, PF |
| 1257.0302* | Set Screw, GT |



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

# AUTOBAHN® EVO ANTEGRADE NAILING SYSTEM
## INSTRUMENT SET I 9257.9101

| Part No. | Description | Qty |
|---|---|---|
| 6173.9000 | Universal T-Handle 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 |
| 6183.1001 | Nail Extraction Bolt | 1 |
| 6190.3000 | Hall Quick-Connect Handle | 1 |
| 6257.0021 | 3.2mm Guidewire, Threaded Drill Point, 400mm | 4 |
| 6257.0022 | 3.2mm Guidewire, Drill-Point, 400mm | 4 |
| 6257.0031 | 3.2mm Guidewire, Threaded Drill Point, 285mm | 2 |
| 6257.0032 | 3.2mm Guidewire, Drill-Point, 285mm | 2 |
| 6257.1001 | Insertion Handle, Antegrade | 1 |
| 6257.1004 | Nail Connection Bolt, Antegrade | 2 |
| 6257.1014 | Protection Sleeve 14mm, Opening Reamer | 1 |
| 6257.1015 | Multi-Hole Wire Guide, Antegrade 14mm | 1 |
| 6257.1043 | 14mm Cannulated Opening Drill Bit | 1 |
| 6257.1044 | Nail Connection Bolt Driver, Shaft | 1 |
| 6257.1046 | Impaction Rod, Antegrade | 1 |
| 6257.1053 | Awl, Curved | 0 |
| 6257.1058 | Hall Quick-Connect T-Handle | 1 |
| 6257.1062 | Intramedullary Reduction Tool, Hall Connection | 1 |
| 6257.1069 | Backslap Shaft, Antegrade | 1 |
| | | |
| 9257.1001 | AUTOBAHN® EVO Antegrade Nail Instrument Set I | |

*Items in gray are additionally available.*

# AUTOBAHN® EVO ANTEGRADE NAILING SYSTEM
# INSTRUMENT SET II 9257.9102

| Part No. | Description | Qty |
|---|---|---|
| 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 |
| 6257.1003 | GT Aiming Arm, Antegrade | 1 |
| 6257.1006 | Driver Sleeve, 6.5mm | 2 |
| 6257.1007 | Wire Sleeve, 6.5mm | 2 |
| 6257.1008 | Trocar, 6.5mm | 2 |
| 6257.1009 | 6.5mm Stepped Drill Bit | 1 |
| 6257.1010 | Drill Stop, 6.5mm | 1 |
| 6257.1011 | 6.5mm Tap | 1 |
| 6257.1012 | T30 6.5mm Screwdriver for Power, Long | 2 |
| 6257.1013 | Retention Rod, T30 6.5mm Screwdriver for Power, Long | 1 |
| 6257.1022 | Direct Read Depth Gauge, 6.5mm | 1 |
| 6257.1029 | Driver Sleeve, 5mm | 1 |
| 6257.1030 | Drill Sleeve, 4.2mm | 1 |
| 6257.1031 | Trocar, 4.2mm | 1 |
| 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 |
| 6257.1045 | Compression Driver | 1 |
| 6257.1050 | Locking Screw Depth Gauge, Long, 5mm | 1 |
| 6257.1055 | Dual Driver Sleeve, 6.5mm | 1 |
| 6257.1056 | PF Aiming Arm, Antegrade | 1 |
| 6257.1060 | Locking Screw Depth Gauge, Short, 5mm | 1 |
| 6257.1063 | T30 5mm Screwdriver for Power, Short | 1 |
| 6257.1064 | Retention Rod, T30 5mm Screwdriver for Power, Short | 1 |
| 6257.1080 | T30 5mm Screwdriver for Power, Long | 2 |
| 6257.1081 | Retention Rod, T30 5mm Screwdriver for Power, Long | 1 |
| | | |
| 9257.1002 | AUTOBAHN® EVO Antegrade Nail Instrument Set II | |



*Items in gray are additionally available.*

# AUTOBAHN® EVO ANTEGRADE NAILING SYSTEM
## SCREW SET 9257.9103

| Part No. | Description | Qty |
|---|---|---|
| 1257.8325 | AUTOBAHN® EVO Locking Screw, 5x25mm, Ti | 3 |
| 1257.8328 | AUTOBAHN® EVO Locking Screw, 5x27.5mm, Ti | 3 |
| 1257.8330 | AUTOBAHN® EVO Locking Screw, 5x30mm, Ti | 3 |
| 1257.8333 | AUTOBAHN® EVO Locking Screw, 5x32.5mm, Ti | 3 |
| 1257.8335 | AUTOBAHN® EVO Locking Screw, 5x35mm, Ti | 3 |
| 1257.8338 | AUTOBAHN® EVO Locking Screw, 5x37.5mm, Ti | 3 |
| 1257.8340 | AUTOBAHN® EVO Locking Screw, 5x40mm, Ti | 3 |
| 1257.8343 | AUTOBAHN® EVO Locking Screw, 5x42.5mm, Ti | 3 |
| 1257.8345 | AUTOBAHN® EVO Locking Screw, 5x45mm, Ti | 3 |
| 1257.8348 | AUTOBAHN® EVO Locking Screw, 5x47.5mm, Ti | 3 |
| 1257.8350 | AUTOBAHN® EVO Locking Screw, 5x50mm, Ti | 3 |
| 1257.8353 | AUTOBAHN® EVO Locking Screw, 5x52.5mm, Ti | 3 |
| 1257.8355 | AUTOBAHN® EVO Locking Screw, 5x55mm, Ti | 3 |
| 1257.8360 | AUTOBAHN® EVO Locking Screw, 5x60mm, Ti | 3 |
| 1257.8365 | AUTOBAHN® EVO Locking Screw, 5x65mm, Ti | 3 |
| 1257.8370 | AUTOBAHN® EVO Locking Screw, 5x70mm, Ti | 3 |
| 1257.9170 | AUTOBAHN® EVO Recon Locking Screw, 6.5x70mm, Ti | 2 |
| 1257.9175 | AUTOBAHN® EVO Recon Locking Screw, 6.5x75mm, Ti | 2 |
| 1257.9180 | AUTOBAHN® EVO Recon Locking Screw, 6.5x80mm, Ti | 2 |
| 1257.9185 | AUTOBAHN® EVO Recon Locking Screw, 6.5x85mm, Ti | 3 |
| 1257.9190 | AUTOBAHN® EVO Recon Locking Screw, 6.5x90mm, Ti | 3 |
| 1257.9195 | AUTOBAHN® EVO Recon Locking Screw, 6.5x95mm, Ti | 3 |
| 1257.9200 | AUTOBAHN® EVO Recon Locking Screw, 6.5x100mm, Ti | 3 |
| 1257.9205 | AUTOBAHN® EVO Recon Locking Screw, 6.5x105mm, Ti | 3 |
| 1257.9210 | AUTOBAHN® EVO Recon Locking Screw, 6.5x110mm, Ti | 3 |
| 1257.9215 | AUTOBAHN® EVO Recon Locking Screw, 6.5x115mm, Ti | 2 |
| 1257.9220 | AUTOBAHN® EVO Recon Locking Screw, 6.5x120mm, Ti | 2 |
| 1257.9225 | AUTOBAHN® EVO Recon Locking Screw, 6.5x125mm, Ti | 2 |
| 1257.9230 | AUTOBAHN® EVO Recon Locking Screw, 6.5x130mm, Ti | 2 |
| 1257.0100 | AUTOBAHN® Antegrade Femoral Nail End Cap, 0mm, Ti | 0 |
| 1257.0105 | AUTOBAHN® Antegrade Femoral Nail End Cap, 5mm, Ti | 0 |
| 1257.0110 | AUTOBAHN® Antegrade Femoral Nail End Cap, 10mm, Ti | 0 |
| 1257.0115 | AUTOBAHN® Antegrade Femoral Nail End Cap, 15mm, Ti | 0 |
| 1257.0120 | AUTOBAHN® Antegrade Femoral Nail End Cap, 20mm, Ti | 0 |
| 1257.0301 | AUTOBAHN® EVO Antegrade Set Screw, PF, Ti | 1 |
| 1257.0302 | AUTOBAHN® EVO Antegrade Set Screw, GT, Ti | 1 |
| 9257.1003 | AUTOBAHN® EVO Antegrade Nail Screw Caddy | |

*Items in gray are additionally available.*

# AUTOBAHN® EVO ANTEGRADE NAILING SYSTEM
## NAIL SET LEFT 9257.9104

| Part No. | Description | Qty |
|---|---|---|
| 1257.1032S | AUTOBAHN® EVO Antegrade Femoral Nail, 10x320mm, PF, Left, Ti | 1 |
| 1257.1034S | AUTOBAHN® EVO Antegrade Femoral Nail, 10x340mm, PF, Left, Ti | 1 |
| 1257.1036S | AUTOBAHN® EVO Antegrade Femoral Nail, 10x360mm, PF, Left, Ti | 1 |
| 1257.1038S | AUTOBAHN® EVO Antegrade Femoral Nail, 10x380mm, PF, Left, Ti | 1 |
| 1257.1040S | AUTOBAHN® EVO Antegrade Femoral Nail, 10x400mm, PF, Left, Ti | 1 |
| 1257.1042S | AUTOBAHN® EVO Antegrade Femoral Nail, 10x420mm, PF, Left, Ti | 1 |
| 1257.1044S | AUTOBAHN® EVO Antegrade Femoral Nail, 10x440mm, PF, Left, Ti | 1 |
| 1257.1132S | AUTOBAHN® EVO Antegrade Femoral Nail, 11x320mm, PF, Left, Ti | 1 |
| 1257.1134S | AUTOBAHN® EVO Antegrade Femoral Nail, 11x340mm, PF, Left, Ti | 1 |
| 1257.1136S | AUTOBAHN® EVO Antegrade Femoral Nail, 11x360mm, PF, Left, Ti | 1 |
| 1257.1138S | AUTOBAHN® EVO Antegrade Femoral Nail, 11x380mm, PF, Left, Ti | 1 |
| 1257.1140S | AUTOBAHN® EVO Antegrade Femoral Nail, 11x400mm, PF, Left, Ti | 1 |
| 1257.1142S | AUTOBAHN® EVO Antegrade Femoral Nail, 11x420mm, PF, Left, Ti | 1 |
| 1257.1144S | AUTOBAHN® EVO Antegrade Femoral Nail, 11x440mm, PF, Left, Ti | 1 |
| 1257.1232S | AUTOBAHN® EVO Antegrade Femoral Nail, 12x320mm, PF, Left, Ti | 1 |
| 1257.1234S | AUTOBAHN® EVO Antegrade Femoral Nail, 12x340mm, PF, Left, Ti | 1 |
| 1257.1236S | AUTOBAHN® EVO Antegrade Femoral Nail, 12x360mm, PF, Left, Ti | 1 |
| 1257.1238S | AUTOBAHN® EVO Antegrade Femoral Nail, 12x380mm, PF, Left, Ti | 1 |
| 1257.1240S | AUTOBAHN® EVO Antegrade Femoral Nail, 12x400mm, PF, Left, Ti | 1 |
| 1257.1242S | AUTOBAHN® EVO Antegrade Femoral Nail, 12x420mm, PF, Left, Ti | 1 |
| 1257.1244S | AUTOBAHN® EVO Antegrade Femoral Nail, 12x440mm, PF, Left, Ti | 1 |
| 1257.3032S | AUTOBAHN® EVO Antegrade Femoral Nail, 10x320mm, GT, Left, Ti | 1 |
| 1257.3034S | AUTOBAHN® EVO Antegrade Femoral Nail, 10x340mm, GT, Left, Ti | 1 |
| 1257.3036S | AUTOBAHN® EVO Antegrade Femoral Nail, 10x360mm, GT, Left, Ti | 1 |
| 1257.3038S | AUTOBAHN® EVO Antegrade Femoral Nail, 10x380mm, GT, Left, Ti | 1 |
| 1257.3040S | AUTOBAHN® EVO Antegrade Femoral Nail, 10x400mm, GT, Left, Ti | 1 |
| 1257.3042S | AUTOBAHN® EVO Antegrade Femoral Nail, 10x420mm, GT, Left, Ti | 1 |
| 1257.3044S | AUTOBAHN® EVO Antegrade Femoral Nail, 10x440mm, GT, Left, Ti | 1 |
| 1257.3132S | AUTOBAHN® EVO Antegrade Femoral Nail, 11x320mm, GT, Left, Ti | 1 |
| 1257.3134S | AUTOBAHN® EVO Antegrade Femoral Nail, 11x340mm, GT, Left, Ti | 1 |
| 1257.3136S | AUTOBAHN® EVO Antegrade Femoral Nail, 11x360mm, GT, Left, Ti | 1 |
| 1257.3138S | AUTOBAHN® EVO Antegrade Femoral Nail, 11x380mm, GT, Left, Ti | 1 |
| 1257.3140S | AUTOBAHN® EVO Antegrade Femoral Nail, 11x400mm, GT, Left, Ti | 1 |
| 1257.3142S | AUTOBAHN® EVO Antegrade Femoral Nail, 11x420mm, GT, Left, Ti | 1 |
| 1257.3144S | AUTOBAHN® EVO Antegrade Femoral Nail, 11x440mm, GT, Left, Ti | 1 |
| 1257.3232S | AUTOBAHN® EVO Antegrade Femoral Nail, 12x320mm, GT, Left, Ti | 1 |
| 1257.3234S | AUTOBAHN® EVO Antegrade Femoral Nail, 12x340mm, GT, Left, Ti | 1 |
| 1257.3236S | AUTOBAHN® EVO Antegrade Femoral Nail, 12x360mm, GT, Left, Ti | 1 |
| 1257.3238S | AUTOBAHN® EVO Antegrade Femoral Nail, 12x380mm, GT, Left, Ti | 1 |
| 1257.3240S | AUTOBAHN® EVO Antegrade Femoral Nail, 12x400mm, GT, Left, Ti | 1 |
| 1257.3242S | AUTOBAHN® EVO Antegrade Femoral Nail, 12x420mm, GT, Left, Ti | 1 |
| 1257.3244S | AUTOBAHN® EVO Antegrade Femoral Nail, 12x440mm, GT, Left, Ti | 1 |
| | | |
| 9257.1004 | AUTOBAHN® EVO Antegrade Nail Bank, Left, Soft Case | |

# AUTOBAHN® EVO ANTEGRADE NAILING SYSTEM
## NAIL SET RIGHT 9257.9105

| Part No. | Description | Qty |
|---|---|---|
| 1257.2032S | AUTOBAHN® EVO Antegrade Femoral Nail, 10x320mm, PF, Right, Ti | 1 |
| 1257.2034S | AUTOBAHN® EVO Antegrade Femoral Nail, 10x340mm, PF, Right, Ti | 1 |
| 1257.2036S | AUTOBAHN® EVO Antegrade Femoral Nail, 10x360mm, PF, Right, Ti | 1 |
| 1257.2038S | AUTOBAHN® EVO Antegrade Femoral Nail, 10x380mm, PF, Right, Ti | 1 |
| 1257.2040S | AUTOBAHN® EVO Antegrade Femoral Nail, 10x400mm, PF, Right, Ti | 1 |
| 1257.2042S | AUTOBAHN® EVO Antegrade Femoral Nail, 10x420mm, PF, Right, Ti | 1 |
| 1257.2044S | AUTOBAHN® EVO Antegrade Femoral Nail, 10x440mm, PF, Right, Ti | 1 |
| 1257.2132S | AUTOBAHN® EVO Antegrade Femoral Nail, 11x320mm, PF, Right, Ti | 1 |
| 1257.2134S | AUTOBAHN® EVO Antegrade Femoral Nail, 11x340mm, PF, Right, Ti | 1 |
| 1257.2136S | AUTOBAHN® EVO Antegrade Femoral Nail, 11x360mm, PF, Right, Ti | 1 |
| 1257.2138S | AUTOBAHN® EVO Antegrade Femoral Nail, 11x380mm, PF, Right, Ti | 1 |
| 1257.2140S | AUTOBAHN® EVO Antegrade Femoral Nail, 11x400mm, PF, Right, Ti | 1 |
| 1257.2142S | AUTOBAHN® EVO Antegrade Femoral Nail, 11x420mm, PF, Right, Ti | 1 |
| 1257.2144S | AUTOBAHN® EVO Antegrade Femoral Nail, 11x440mm, PF, Right, Ti | 1 |
| 1257.2232S | AUTOBAHN® EVO Antegrade Femoral Nail, 12x320mm, PF, Right, Ti | 1 |
| 1257.2234S | AUTOBAHN® EVO Antegrade Femoral Nail, 12x340mm, PF, Right, Ti | 1 |
| 1257.2236S | AUTOBAHN® EVO Antegrade Femoral Nail, 12x360mm, PF, Right, Ti | 1 |
| 1257.2238S | AUTOBAHN® EVO Antegrade Femoral Nail, 12x380mm, PF, Right, Ti | 1 |
| 1257.2240S | AUTOBAHN® EVO Antegrade Femoral Nail, 12x400mm, PF, Right, Ti | 1 |
| 1257.2242S | AUTOBAHN® EVO Antegrade Femoral Nail, 12x420mm, PF, Right, Ti | 1 |
| 1257.2244S | AUTOBAHN® EVO Antegrade Femoral Nail, 12x440mm, PF, Right, Ti | 1 |
| 1257.4032S | AUTOBAHN® EVO Antegrade Femoral Nail, 10x320mm, GT, Right, Ti | 1 |
| 1257.4034S | AUTOBAHN® EVO Antegrade Femoral Nail, 10x340mm, GT, Right, Ti | 1 |
| 1257.4036S | AUTOBAHN® EVO Antegrade Femoral Nail, 10x360mm, GT, Right, Ti | 1 |
| 1257.4038S | AUTOBAHN® EVO Antegrade Femoral Nail, 10x380mm, GT, Right, Ti | 1 |
| 1257.4040S | AUTOBAHN® EVO Antegrade Femoral Nail, 10x400mm, GT, Right, Ti | 1 |
| 1257.4042S | AUTOBAHN® EVO Antegrade Femoral Nail, 10x420mm, GT, Right, Ti | 1 |
| 1257.4044S | AUTOBAHN® EVO Antegrade Femoral Nail, 10x440mm, GT, Right, Ti | 1 |
| 1257.4132S | AUTOBAHN® EVO Antegrade Femoral Nail, 11x320mm, GT, Right, Ti | 1 |
| 1257.4134S | AUTOBAHN® EVO Antegrade Femoral Nail, 11x340mm, GT, Right, Ti | 1 |
| 1257.4136S | AUTOBAHN® EVO Antegrade Femoral Nail, 11x360mm, GT, Right, Ti | 1 |
| 1257.4138S | AUTOBAHN® EVO Antegrade Femoral Nail, 11x380mm, GT, Right, Ti | 1 |
| 1257.4140S | AUTOBAHN® EVO Antegrade Femoral Nail, 11x400mm, GT, Right, Ti | 1 |
| 1257.4142S | AUTOBAHN® EVO Antegrade Femoral Nail, 11x420mm, GT, Right, Ti | 1 |
| 1257.4144S | AUTOBAHN® EVO Antegrade Femoral Nail, 11x440mm, GT, Right, Ti | 1 |
| 1257.4232S | AUTOBAHN® EVO Antegrade Femoral Nail, 12x320mm, GT, Right, Ti | 1 |
| 1257.4234S | AUTOBAHN® EVO Antegrade Femoral Nail, 12x340mm, GT, Right, Ti | 1 |
| 1257.4236S | AUTOBAHN® EVO Antegrade Femoral Nail, 12x360mm, GT, Right, Ti | 1 |
| 1257.4238S | AUTOBAHN® EVO Antegrade Femoral Nail, 12x380mm, GT, Right, Ti | 1 |
| 1257.4240S | AUTOBAHN® EVO Antegrade Femoral Nail, 12x400mm, GT, Right, Ti | 1 |
| 1257.4242S | AUTOBAHN® EVO Antegrade Femoral Nail, 12x420mm, GT, Right, Ti | 1 |
| 1257.4244S | AUTOBAHN® EVO Antegrade Femoral Nail, 12x440mm, GT, Right, Ti | 1 |
| | | |
| 9257.1005 | AUTOBAHN® EVO Antegrade Nail Bank, Right, Soft Case | |

# AUTOBAHN® EVO ANTEGRADE NAILING SYSTEM
## STERILE SCREW SET 9257.9106

| Part No. | Description | Qty |
|---|---|---|
| 1257.8325S | AUTOBAHN® EVO Locking Screw, 5x25mm, Ti | 3 |
| 1257.8328S | AUTOBAHN® EVO Locking Screw, 5x27.5mm, Ti | 3 |
| 1257.8330S | AUTOBAHN® EVO Locking Screw, 5x30mm, Ti | 3 |
| 1257.8333S | AUTOBAHN® EVO Locking Screw, 5x32.5mm, Ti | 3 |
| 1257.8335S | AUTOBAHN® EVO Locking Screw, 5x35mm, Ti | 3 |
| 1257.8338S | AUTOBAHN® EVO Locking Screw, 5x37.5mm, Ti | 3 |
| 1257.8340S | AUTOBAHN® EVO Locking Screw, 5x40mm, Ti | 3 |
| 1257.8343S | AUTOBAHN® EVO Locking Screw, 5x42.5mm, Ti | 3 |
| 1257.8345S | AUTOBAHN® EVO Locking Screw, 5x45mm, Ti | 3 |
| 1257.8348S | AUTOBAHN® EVO Locking Screw, 5x47.5mm, Ti | 3 |
| 1257.8350S | AUTOBAHN® EVO Locking Screw, 5x50mm, Ti | 3 |
| 1257.8353S | AUTOBAHN® EVO Locking Screw, 5x52.5mm, Ti | 3 |
| 1257.8355S | AUTOBAHN® EVO Locking Screw, 5x55mm, Ti | 3 |
| 1257.8360S | AUTOBAHN® EVO Locking Screw, 5x60mm, Ti | 3 |
| 1257.8365S | AUTOBAHN® EVO Locking Screw, 5x65mm, Ti | 3 |
| 1257.8370S | AUTOBAHN® EVO Locking Screw, 5x70mm, Ti | 3 |
| 1257.9170S | AUTOBAHN® EVO Recon Locking Screw, 6.5x70mm, Ti | 2 |
| 1257.9175S | AUTOBAHN® EVO Recon Locking Screw, 6.5x75mm, Ti | 2 |
| 1257.9180S | AUTOBAHN® EVO Recon Locking Screw, 6.5x80mm, Ti | 2 |
| 1257.9185S | AUTOBAHN® EVO Recon Locking Screw, 6.5x85mm, Ti | 3 |
| 1257.9190S | AUTOBAHN® EVO Recon Locking Screw, 6.5x90mm, Ti | 3 |
| 1257.9195S | AUTOBAHN® EVO Recon Locking Screw, 6.5x95mm, Ti | 3 |
| 1257.9200S | AUTOBAHN® EVO Recon Locking Screw, 6.5x100mm, Ti | 3 |
| 1257.9205S | AUTOBAHN® EVO Recon Locking Screw, 6.5x105mm, Ti | 3 |
| 1257.9210S | AUTOBAHN® EVO Recon Locking Screw, 6.5x110mm, Ti | 3 |
| 1257.9215S | AUTOBAHN® EVO Recon Locking Screw, 6.5x115mm, Ti | 2 |
| 1257.9220S | AUTOBAHN® EVO Recon Locking Screw, 6.5x120mm, Ti | 2 |
| 1257.9225S | AUTOBAHN® EVO Recon Locking Screw, 6.5x125mm, Ti | 2 |
| 1257.9230S | AUTOBAHN® EVO Recon Locking Screw, 6.5x130mm, Ti | 2 |
| 1257.0100S | AUTOBAHN® Antegrade Femoral Nail End Cap, 0mm, Ti | 0 |
| 1257.0105S | AUTOBAHN® Antegrade Femoral Nail End Cap, 5mm, Ti | 0 |
| 1257.0110S | AUTOBAHN® Antegrade Femoral Nail End Cap, 10mm, Ti | 0 |
| 1257.0115S | AUTOBAHN® Antegrade Femoral Nail End Cap, 15mm, Ti | 0 |
| 1257.0120S | AUTOBAHN® Antegrade Femoral Nail End Cap, 20mm, Ti | 0 |
| 1257.0301S | AUTOBAHN® EVO Antegrade Set Screw, PF, Ti | 1 |
| 1257.0302S | AUTOBAHN® EVO Antegrade Set Screw, GT, Ti | 1 |
| 9257.1006 | AUTOBAHN® EVO Antegrade 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.

# IMPORTANT INFORMATION ON ON THE AUTOBAHN® NAILING SYSTEM

***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 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; or, vacuum sealed Nylon 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 Assurancein 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 theFDA 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.

# IMPORTANT INFORMATION ON ON THE AUTOBAHN® NAILING SYSTEM

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

| 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 D**

Globus Medical
Valley Forge Business Center
2560 General Armistead Avenue
Audubon, PA 19403
www.globusmedical.com

Customer Service:
Phone 1-866-GLOBUS1 (or 1-866-456-2871)
Fax 1-866-GLOBUS3 (or 1-866-456-2873)



GMTGD276
06.23 Rev B