



AUTOBAHN™

Antegrade/Retrograde Femoral Nailing System



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

Life moves us 

The Surgical Technique shown is for illustrative purposes only. The technique(s) actually employed in each case always depends on the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Additionally, as instruments may occasionally be updated, the instruments depicted in this Surgical Technique may not be exactly the same as the instruments currently available. Please consult with your sales representative or contact Globus directly for more information.

SURGICAL TECHNIQUE GUIDE

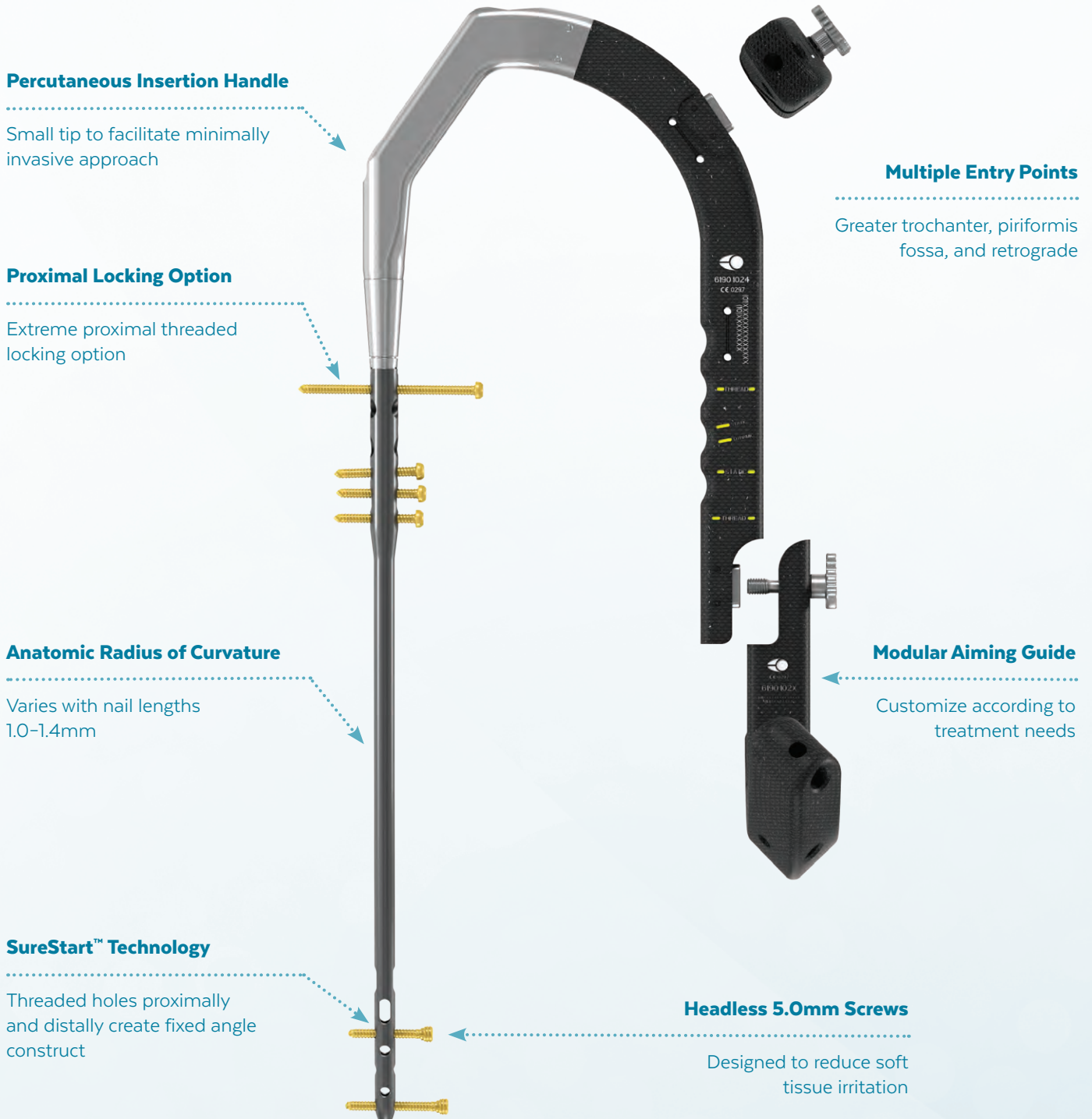
AUTOBAHN™ A/R Femoral Nailing System

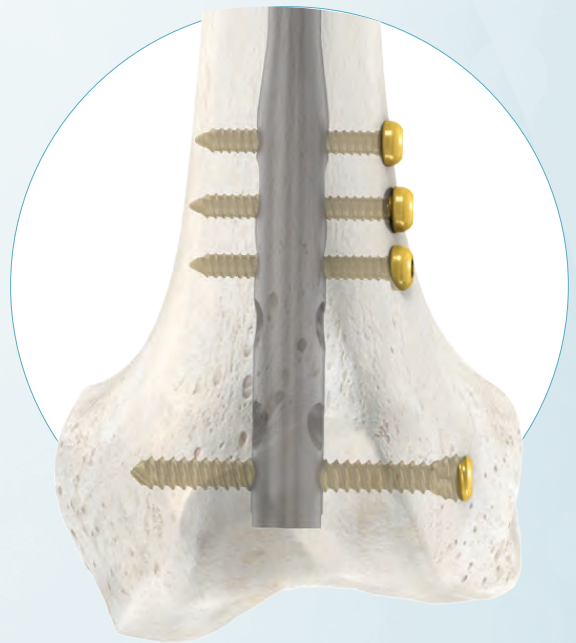
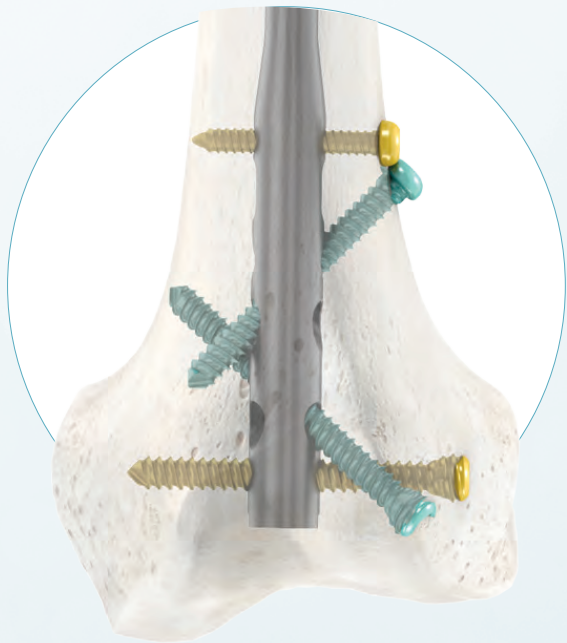
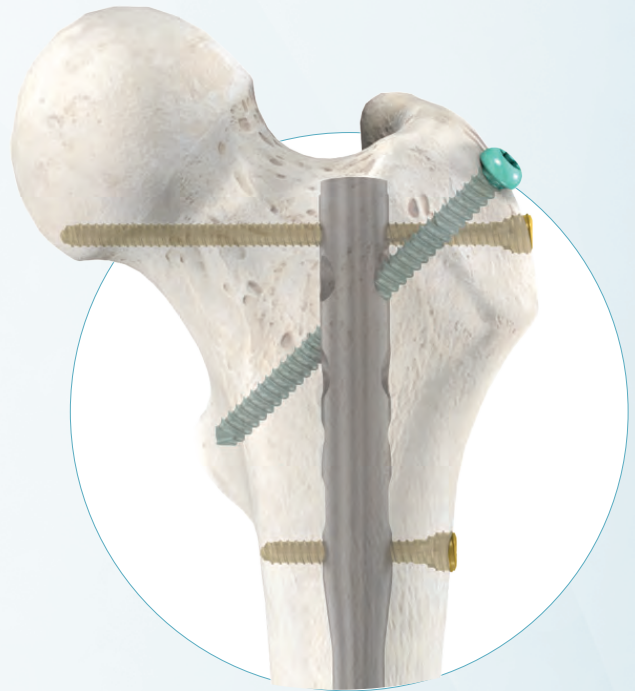
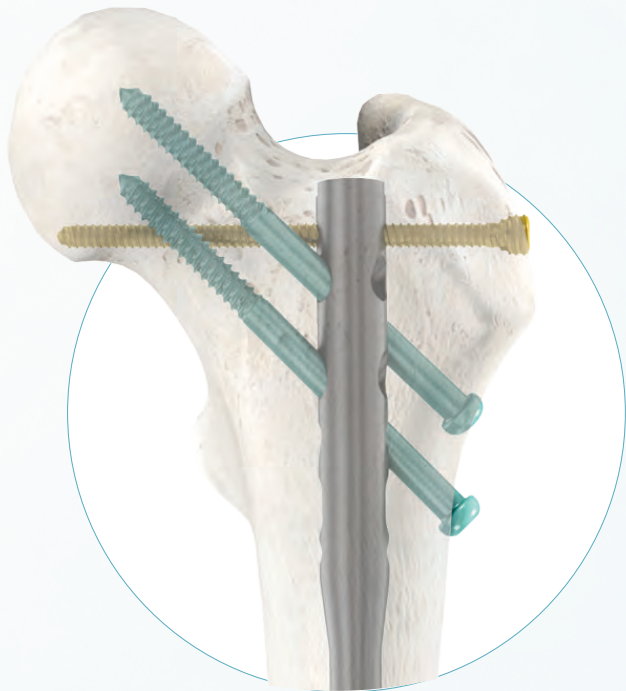
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AUTOBAHN™

Antegrade/Retrograde Femoral Nailing System

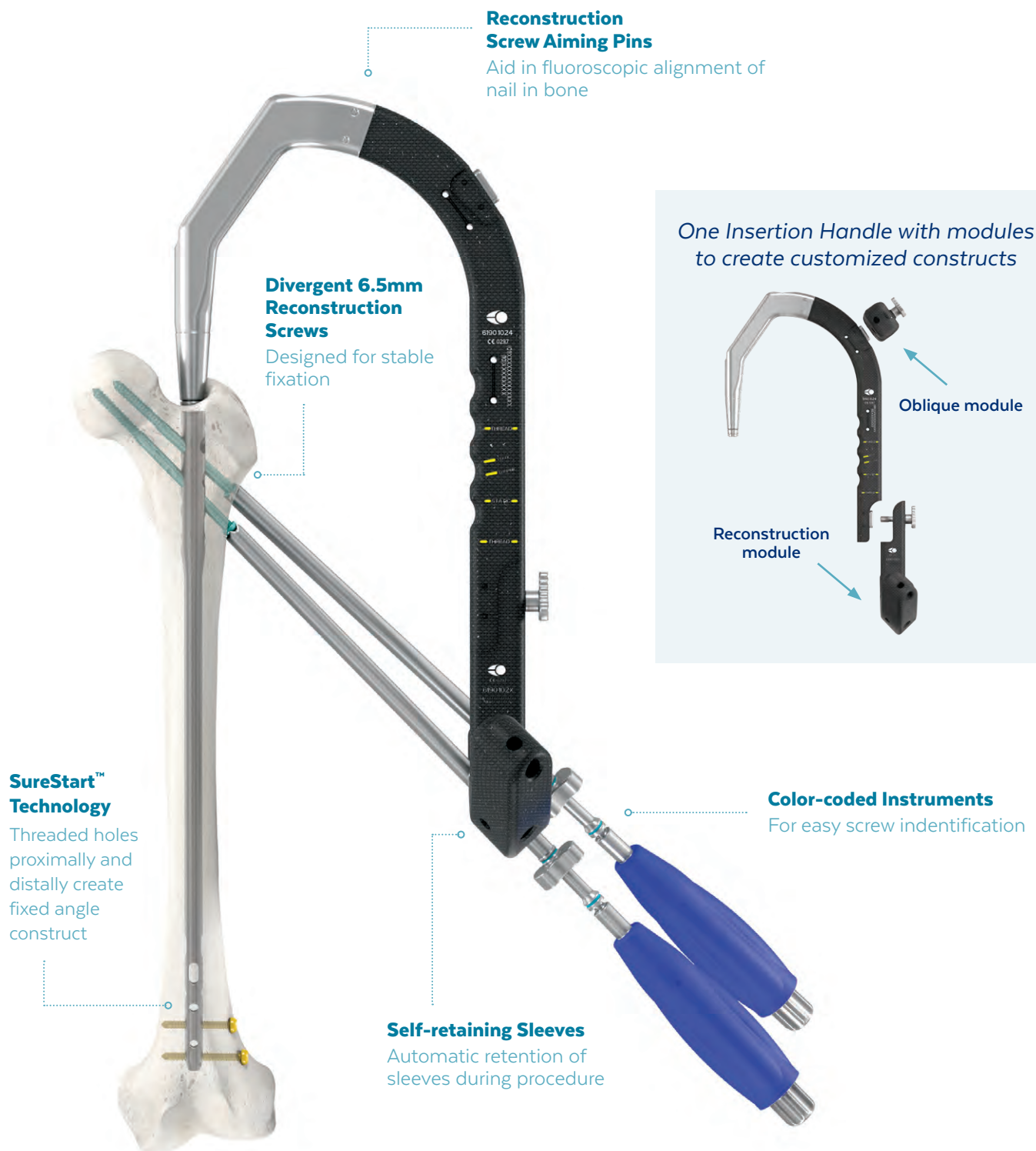
The AUTOBAHN™ Antegrade/Retrograde Femoral Nailing System is a comprehensive system of implants and instruments for the treatment of femoral shaft fractures as well as fractures in the proximal and distal third regions of the femur. The system offers reconstruction screw solutions that target the femoral neck for the antegrade approach and the femoral condyles for the retrograde approach.





MULTIPLE SOLUTIONS WITH HEADED OR HEADLESS
SCREWS FOR OPTIMIZED FIXATION

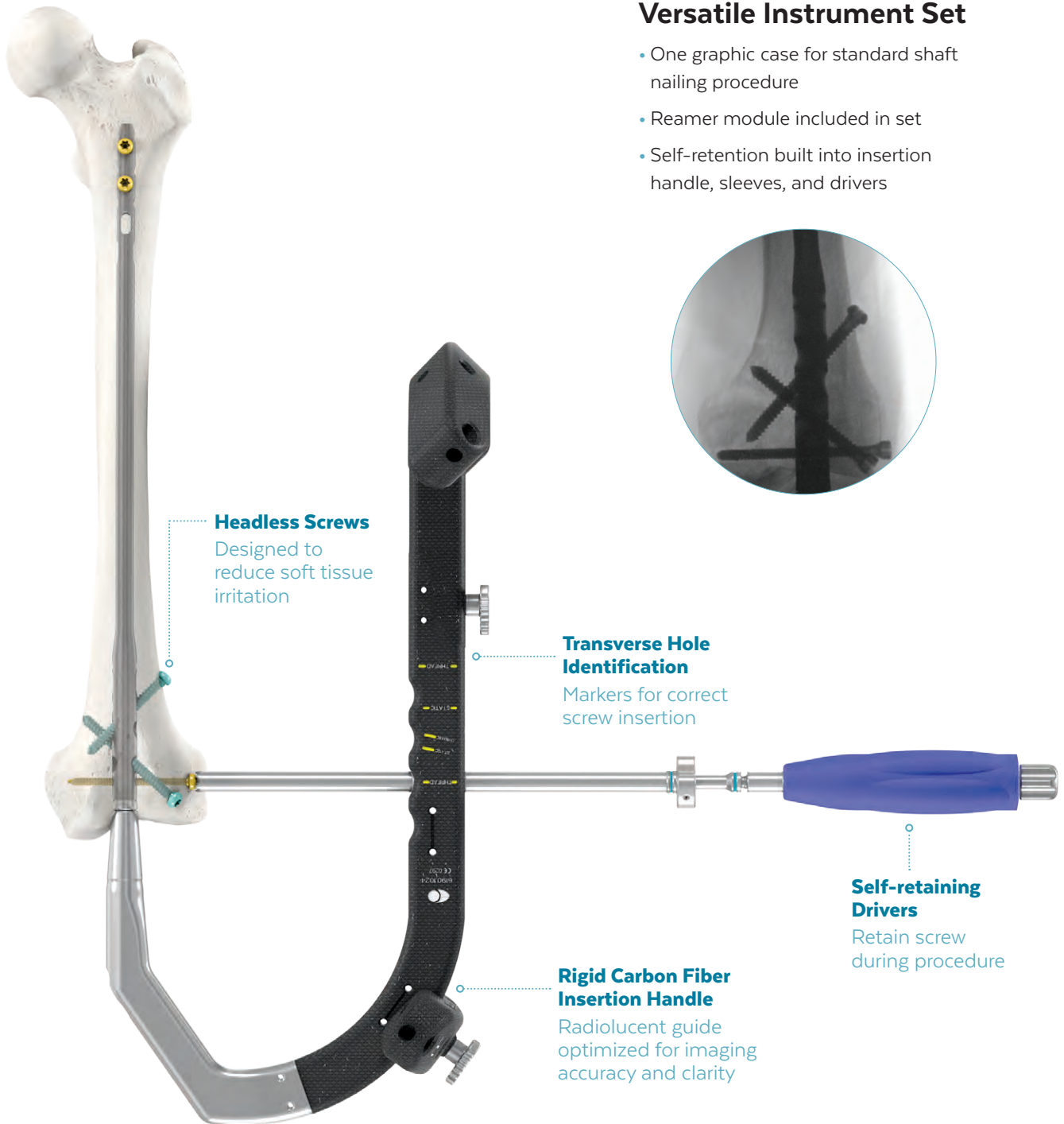
ONE NAIL



MULTIPLE SOLUTIONS

Versatile Instrument Set

- One graphic case for standard shaft nailing procedure
- Reamer module included in set
- Self-retention built into insertion handle, sleeves, and drivers



SURGICAL TECHNIQUE

AUTOBAHN™ Antegrade Nail

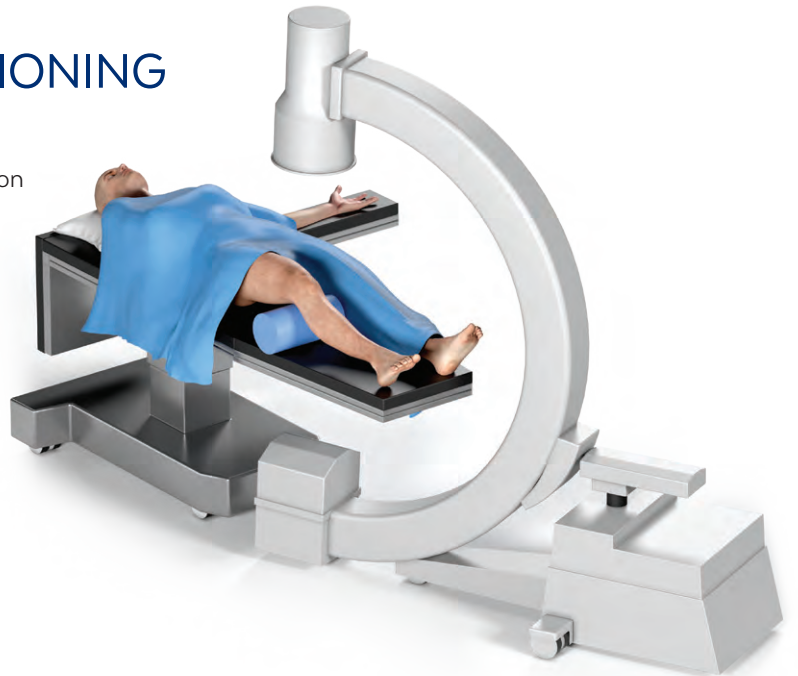
Refer to the package insert (also printed in the back of this manual) for important information on the intended use/indications, device descriptions, contraindications, precautions, warnings, and potential risks associated with this system.

Preoperative Planning

Use X-rays and/or CT images to determine whether an antegrade or retrograde approach is needed based on fracture pattern. Refer to page 33 for the retrograde approach.

STEP 1 PATIENT POSITIONING

Place the patient in a supine or lateral decubitus position on a traction or radiolucent table. Position the C-arm so the proximal and distal ends of the femur can be viewed using AP and lateral fluoroscopy.



STEP 2 FRACTURE REDUCTION

Perform reduction using traction (indirect) or clamp application (direct). If necessary, use a leg roll to allow for reduction and stabilization of the fracture. Confirm reduction using fluoroscopy.

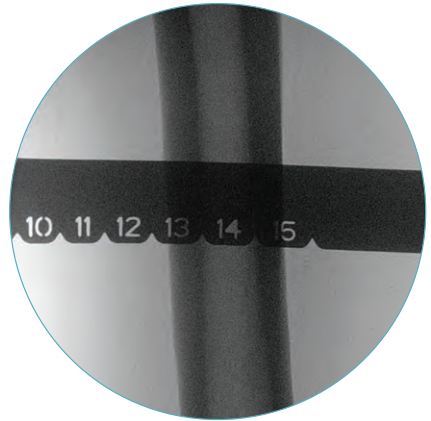
If patient anatomy cannot be restored using traction or manipulation, additional internal or external fixation may be necessary.

STEP

3

DETERMINING NAIL DIAMETER

Using fluoroscopy, measure the diameter of the intramedullary canal at the narrowest part, or the isthmus of the femur with the **Nail Length and Diameter Gauge**. Select the appropriate distal nail diameter. If desired, use the contralateral intact femur to determine the nail diameter.



STEP

4

PROXIMAL EXPOSURE

Identify Nail Entry Point

Determine the desired entry point in the piriformis fossa or greater trochanter.

Greater Trochanter Entry Point

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

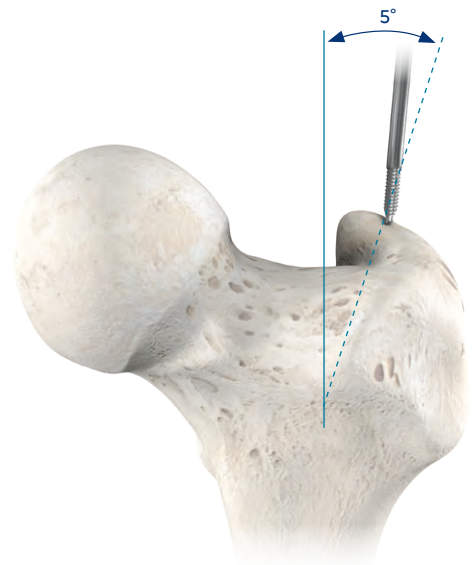
Create an incision at the proximal tip of the trochanter, anterior to the greater trochanter. Separate the muscle fibers.

Under biplanar fluoroscopic guidance, insert the **3.2x450mm Threaded K-wire** through soft tissue until bone is reached. Confirm entry point and trajectory using fluoroscopy. Advance the K-wire to the desired depth in the femur.

Piriformis Fossa Entry Point

The piriformis fossa is medial to the greater trochanter and aligns with the medullary canal in the AP and lateral views. Create an incision proximal to and in line with the piriformis fossa. Separate the muscle fibers.

Under biplanar fluoroscopic guidance, insert the 3.2x450mm Threaded K-wire through soft tissue until bone is reached. Confirm entry point and trajectory using fluoroscopy. Advance the K-wire to the desired depth in the femur.



Greater trochanter entry point
(5° lateral bend)



Piriformis fossa entry point

STEP**5****MEDULLARY CANAL EXPOSURE**

Confirm K-wire position using fluoroscopy in the AP and lateral views. Insert the **Conical Reamer** over the threaded K-wire and through the **Soft Tissue Protection Sleeve**, to open the medullary canal.

Using fluoroscopy, ream to the lesser trochanter. Ensure the reaming path remains in line with the femoral intramedullary canal until reaming is complete. Remove the Conical Reamer and Threaded K-wire while holding tissue sleeve to maintain exposure.



Opening the canal

STEP**6****MEDULLARY CANAL GUIDEWIRE INSERTION**

Confirm fracture reduction using fluoroscopy. Manually insert a **3x1000mm Ball Tip Guidewire** into the center of the intramedullary canal. Using fluoroscopy, confirm the Guidewire is centered and seated in the intercondylar notch. If necessary, the end of the Guidewire may be slightly bent to ease passage across the fracture site. Use caution when bending the Guidewire.

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



**3x1000mm Ball Tip Guidewire
insertion**

STEP

7

DETERMINING NAIL LENGTH

Attach the **Nail Length and Diameter Gauge** to the **Length Gauge Extension**. Slide the Length Gauge Extension over the Ball Tip Guidewire until it rests on bone. Determine nail length by reading the measurement on the Length Gauge at the tip of the Guidewire. Use fluoroscopy to confirm the position of the Length Gauge.



Length Gauge requires the use of 1000mm Guidewire

Measurement 460mm

STEP**8****REAMING THE MEDULLARY CANAL**

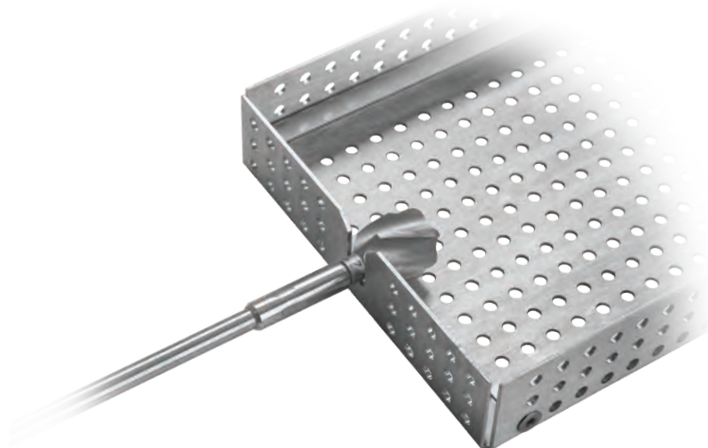
Ensure the Ball Tip Guidewire is inserted into the canal at the desired depth. Confirm fracture reduction using fluoroscopy.

Ream the medullary canal in 0.5mm increments using the **Front Cutting Reamers** and applying steady pressure. Partially retract the reamer to clear debris from the canal while continuing rotation. Using **Piloted Reamers**, ream to 0.5 to 1.5mm greater than the selected nail diameter. After reaming, remove the Piloted Reamers, leaving the Ball Tip Guidewire in place.

If necessary, use the **K-wire Pusher** to ensure the Ball Tip Guidewire is secure during reaming.



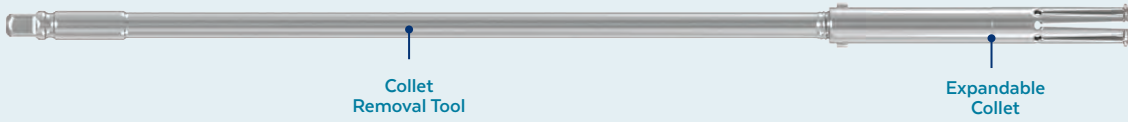
Ream the medullary canal



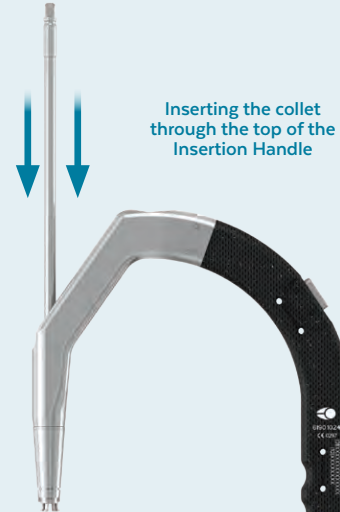
Use the Reaming Module Cover to remove reamer tips

ASSEMBLING INSERTION HANDLE AND ATTACHING NAIL

Attach the Expandable Collet to the Collet Removal Tool.

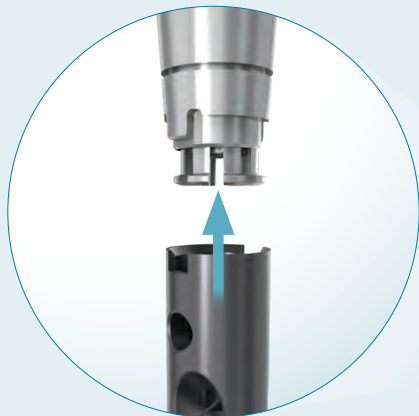


Insert the collet assembly through the top of the Insertion Handle. Align the tabs on the collet with the slots in the inside of the handle. Press the collet into the handle. Once fully seated, the collet should be protruding through the tip of the handle.



Keeping the Collet Removal Tool in place, attach the nail to the Insertion Handle. Align the slots in the nail with the tabs on the Insertion Handle.

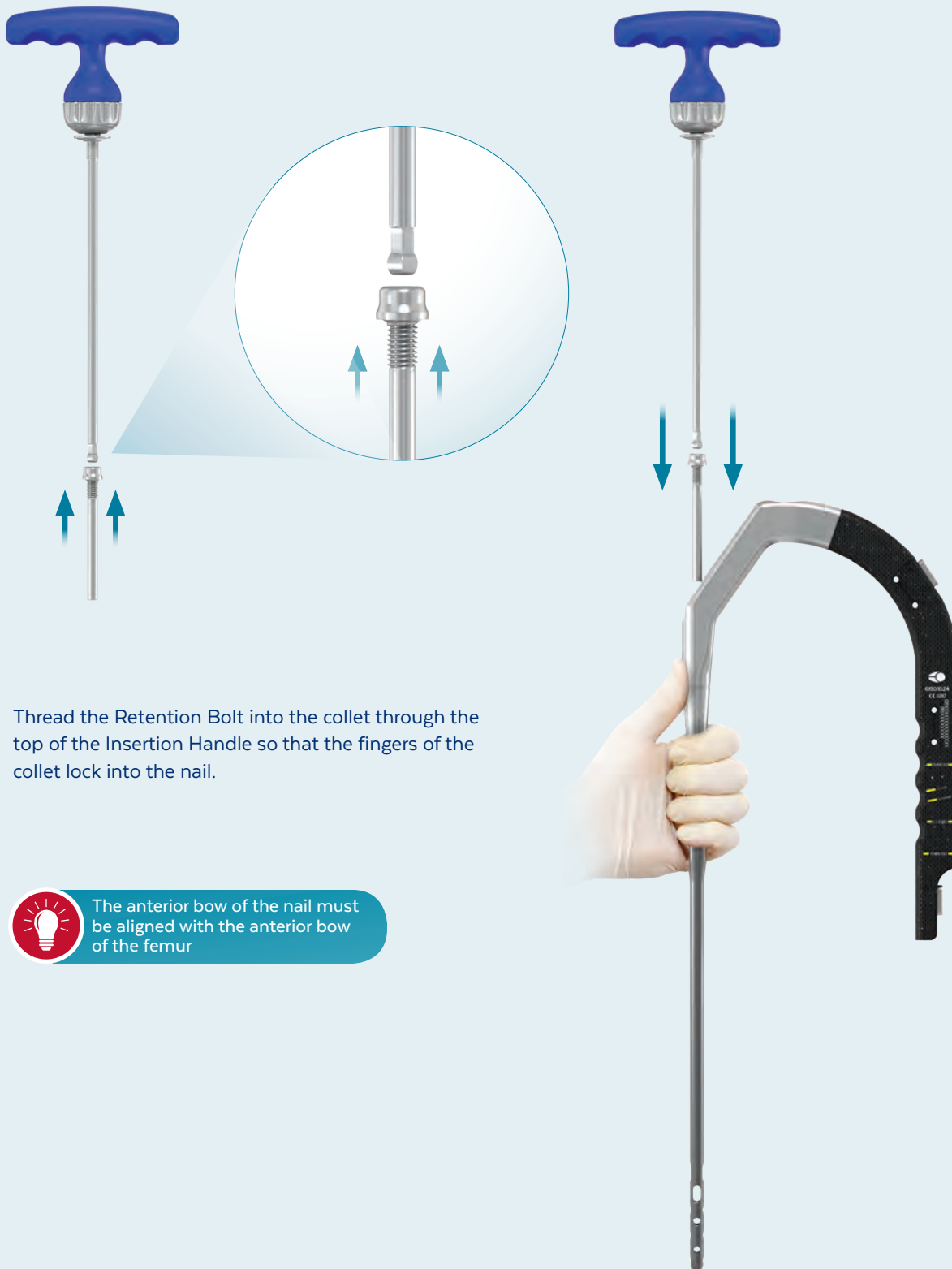
Press the Collet Removal Tool to snap the collet into the top of the nail, so the collet fingers fall into the slot in the nail. Ensure that the collet is secure in the nail. Remove the Collet Removal Tool.



Attaching the nail to the Insertion Handle



Assemble the **Retention Bolt** to the **Retention Bolt Driver** by pressing it on the driver.



Thread the Retention Bolt into the collet through the top of the Insertion Handle so that the fingers of the collet lock into the nail.



The anterior bow of the nail must be aligned with the anterior bow of the femur

STEP**9****FEMORAL NAIL INSERTION**

Insert the nail over the Ball Tip Guidewire into the femoral opening. Manually advance the nail as far as possible and rotate the handle laterally. Monitor nail position using fluoroscopy.

The groove in the aiming guide is 5mm from the top of the nail. It can be used during fluoroscopy to aid in nail placement.



This groove marks 5mm from the top of the nail

If slight impaction is needed to fully seat the nail, thread the **Impaction Rod, Short** into the Insertion Handle. Using the **Slotted Mallet**, slowly advance the nail by applying light taps to the proximal end of the Impaction Rod. **Do not tap the Guidewire or the Insertion Handle.**

Use fluoroscopy to monitor nail position during controlled impaction. Once the nail has crossed the fracture site, remove the Ball Tip Guidewire. When the nail is seated to the desired depth, remove the Impaction Rod.



STEP

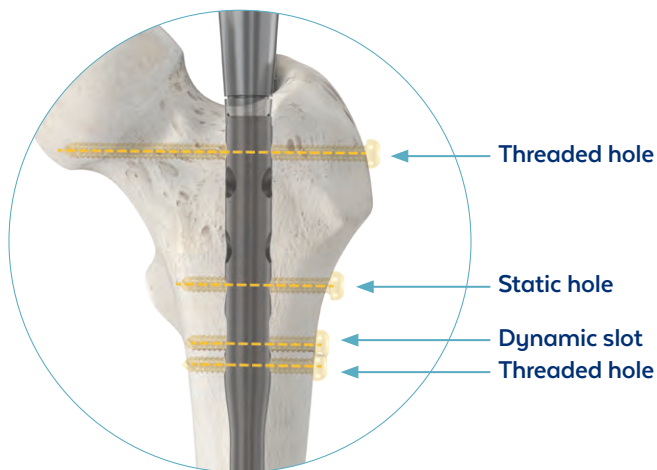
10

PROXIMAL LOCKING SCREW INSERTION

Two types of proximal locking screws may be used, together or individually for fixation. **If inserting 6.5mm screws, they should be inserted first.**

PROXIMAL TRANSVERSE LOCKING SCREW INSERTION

The transverse holes in the nail accept Headed or Headless 5.0mm Locking Screws. Create a fixed angle construct using the threaded holes in the nail.



Place the **Locking Screw Driver Sleeve** and **Trocar** with the yellow color band through the appropriate hole in the Insertion Handle.

Create an incision and insert the Trocar/Sleeve assembly until bone is reached. The assembly engages in the Insertion Handle's self-retention feature for stability. Remove the Trocar when bone is reached and fully seat the sleeve against the bony surface.

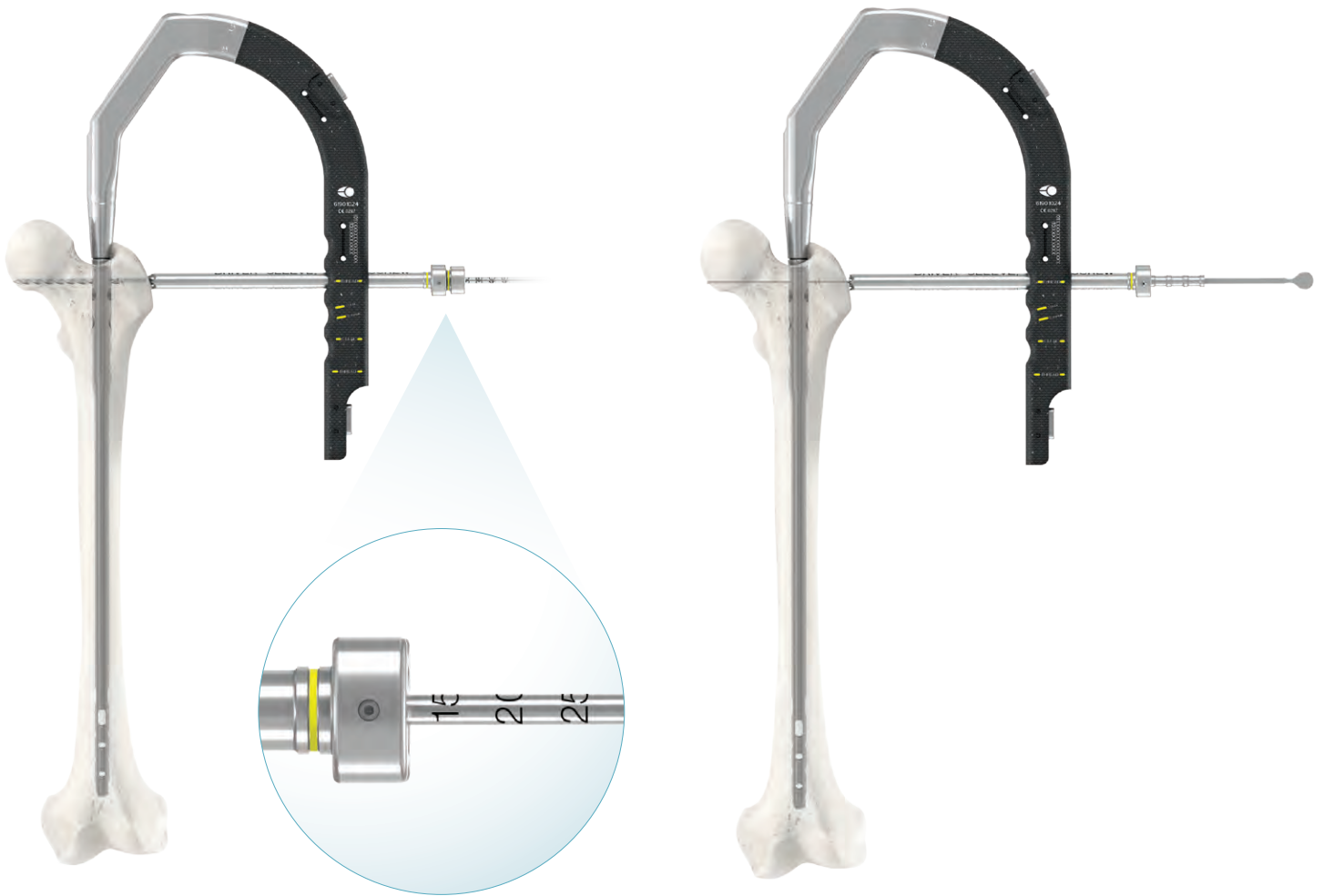
5.0mm Screw Preparation

Insert the Locking Screw Driver Sleeve and appropriate **Graduated 4.2mm Drill** through the drill sleeve. Drill until the far cortical wall is reached.

Measure screw length using the markings on the drill bit or by using the **Locking Screw Length Gauge**.

Remove the drill guide and insert the Locking Screw Length Gauge through the femur. Rest the gauge on the near cortical wall, extend the tip completely through the femur, and retract until it engages the far cortical wall.

Determine the length by reading the measurement on the gauge.



Measurement
115mm

PROXIMAL TRANSVERSE LOCKING SCREW INSERTION (CONT'D)

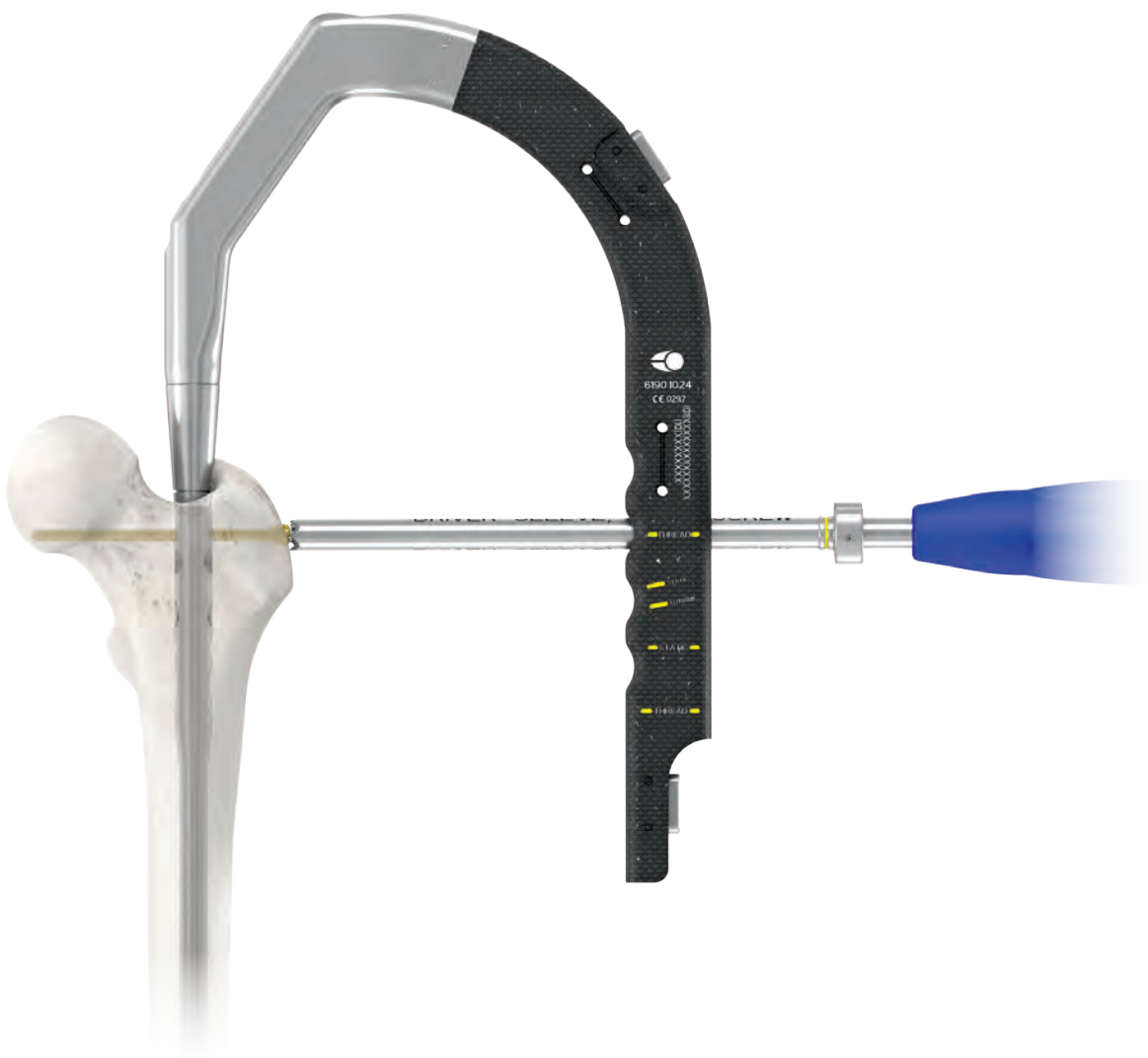
5.0mm Screw Insertion

Assemble the **Locking Screw Driver** by inserting the **Retention Rod** until it snaps into place.

Select the appropriate length 5mm Locking Screw. Using a Retention Rod, secure the locking screw to the Locking Screw Driver. Insert the locking screw through the Locking Screw Driver Sleeve until flush with the near lateral cortex. Confirm placement using fluoroscopy.

Disassemble the driver by unthreading the Retention Rod from the screw.

If necessary, use power to drive screws into bone. Do not use power for final screw tightening. Final screw tightening should be done manually. Repeat process for additional proximal transverse locking screws.



USING HEADLESS LOCKING SCREWS

Headless screws are designed to decrease screw head prominence and reduce soft tissue irritation in the proximal and distal femur.

Headless screws can be used in place of standard locking screws with any locking options in the AUTOBAHN™ Antegrade/Retrograde Femoral Nailing System.

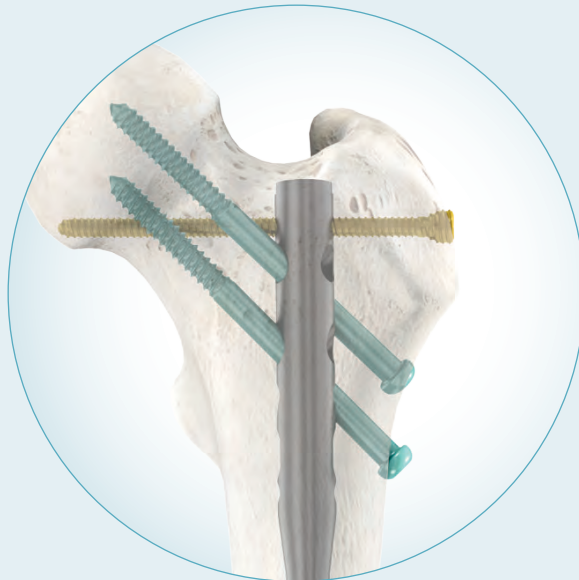
Headless Screw Insertion

Drill and determine length as described in Step 10.

Attach the headless locking screw to the Locking Screw Driver using the self-retaining feature or the threaded capture mechanism.

Using fluoroscopy, insert the headless locking screw until the head of the screw is flush with the bone. Verify screw length using fluoroscopy.

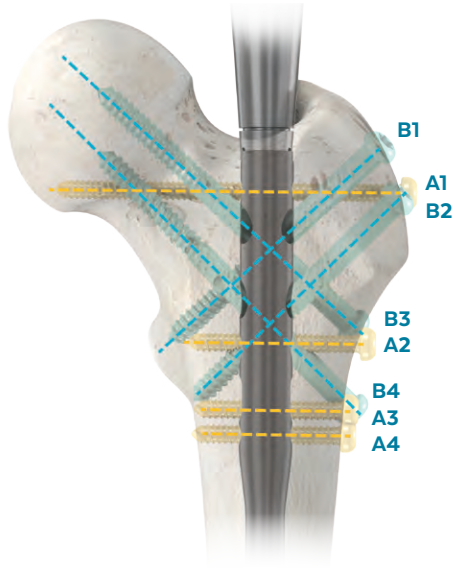
Repeat for additional proximal holes as necessary. A countersink for 6.5mm screws and 5.0mm screws is available if needed to ensure screws fully seat.



Headless Locking Screw
fully inserted

6.5mm SCREW INSERTION

The reconstruction holes in the nail are used with 6.5mm locking screws. Note that not all screw holes can be used at once. When using 6.5mm screws, two screws are recommended.



IMPORTANT
B1 intersects B3
B2 intersects B4
A2 intersects B2 & B4
<i>These screw trajectories intersect one another and cannot be used together.</i>

Attaching the Aiming Modules

Select the appropriate aiming modules for the desired fixation construct.

Use the corresponding aiming modules to insert the 6.5mm locking screws through the nail. Attach the aiming modules to the nail by aligning the tabs and securing with a thumbscrew.

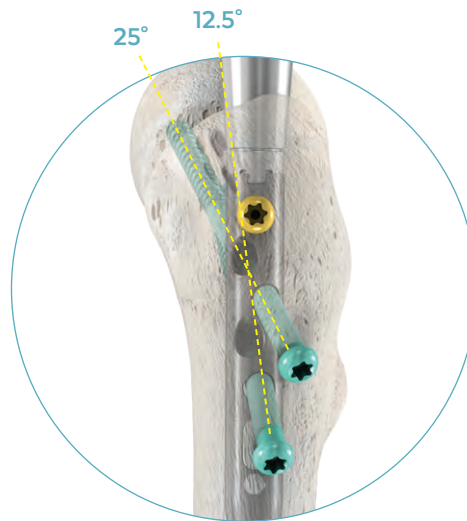


Optional: Verify Nail Anteversion

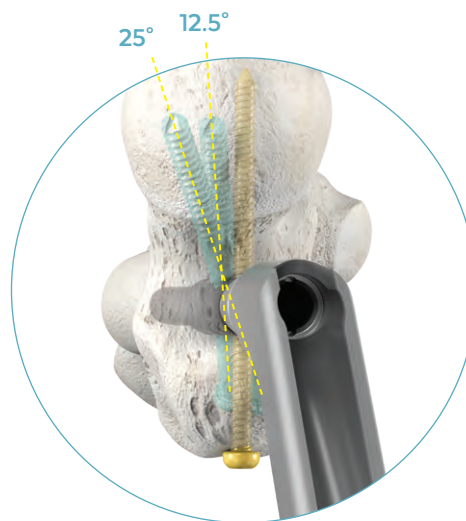
To determine nail anteversion, position the C-arm in a lateral view. To adjust the anteversion, rotate the Antegrade/Retrograde Femoral Nail Insertion Handle so the radiographic marker lines on the sides of the Insertion Handle are parallel to the nail.

The reconstruction screws are anteverted by 12.5° and 25° . Rotate the nail to the desired position of the reconstruction screws in the femoral neck and head.

Ensure correct version of the nail using fluoroscopy. Create an incision and insert the **Driver Sleeve** and **Wire Sleeve for 6.5mm Screws** through the skin, soft tissue, and fascia until the lateral cortex is reached.



Lateral view



Axial view

6.5mm SCREW INSERTION (CONT'D)

K-wire Insertion for 6.5mm Screw

Pass the **3.2mm Threaded K-wire** through the Wire Guide until the lateral cortex is reached. Advance the K-wire across the femoral neck to the desired depth in the subcondylar bone in the femoral head. Verify the K-wire trajectories using fluoroscopy. If necessary, the **Spot-Face Drill for 6.5mm Screws** can be used to create a starting point on the lateral cortex to facilitate K-wire accuracy.

Use the 3.2mm Threaded K-wire and the **Quick Read Length Gauge for 6.5mm Screws** to measure the length of the screw. Remove the Wire Guide and slide the Length Gauge over the threaded K-wire until the stop meets the top of the Driver Guide. Read the screw length where the K-wire stops on the Length Gauge. Remove the threaded K-wire. If necessary, use the **Length Gauge for 6.5mm Screws** to manually measure the length of the screw.

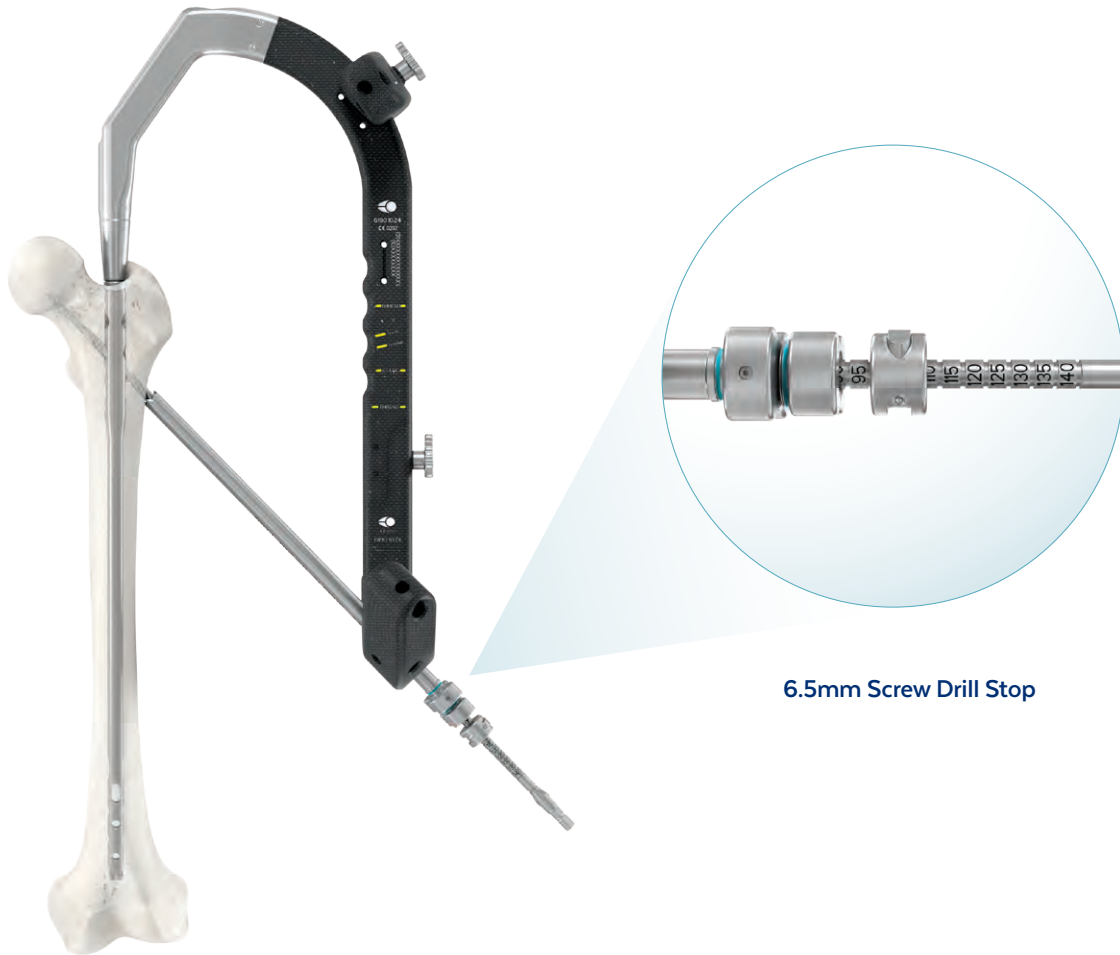


Measurement 105mm

Spot-Face Drill for 6.5mm screws

6.5mm Screw Preparation

For partially threaded 6.5mm screws, slide the **6.5mm Screw Drill Stop** over the **Step Drill** until the desired length is covered. Insert the drill to the appropriate depth. Confirm drill depth using fluoroscopy.



For fully threaded screws, use the **6.5mm Core Drill**. Insert the drill to the appropriate depth. Confirm drill depth using fluoroscopy.

In dense bone, tapping may be necessary prior to screw insertion. Tap to the desired depth with the **T-Handle Chuck** and **6.5mm Screw Tap** through the Drill/Driver Guide.

6.5mm SCREW INSERTION (CONT'D)

6.5mm Screw Insertion

Attach the appropriate length screw to the Locking Screw Driver and Retention Rod as described in proximal transverse locking screw insertion. Insert the screw across the femoral neck into the head. If necessary, a power driver can be used with the **Power Driver Shaft**.



Do not use power for final screw tightening. Perform final screw tightening manually.

Disassemble the driver by unthreading the retention rod from the screw. Use multiple fluoroscopic views to ensure the 6.5mm reconstruction screws are correctly positioned in the femoral neck, greater trochanter, and the femoral head throughout screw insertion. Use AP and lateral fluoroscopy to confirm screw placement.



Headless fully threaded 6.5mm screws are available for use in place of a headed 6.5mm screw

FINAL CONSTRUCTS - ANTEGRADE PIRIFORMIS FOSSA APPROACH



STEP

11

DISTAL LOCKING SCREW INSERTION

Verify fracture reduction and alignment of the nail using fluoroscopy. Align the C-arm with the distal locking hole until a perfect circle is visible. Create an incision in the center of the hole.

Drill using the **Locking Screw Drill** until the far cortical wall is breached.

Slide the **Length Gauge, Quick Read, Locking Screw** onto the drill bit. Read the measurement to determine the corresponding screw length.

Alternatively, insert the Locking Screw Length Gauge through the soft tissue, down to the surface of the femur. Rest the nose of the gauge on the near cortical wall, extend the hook completely through the femur, and retract until it catches on the far cortical wall. Determine length by reading the measurement on the gauge.



Locking Screw Drill

Insert the screw bicortically under power if necessary using Power Driver Shaft. Do not use power for final screw tightening. Perform final screw tightening manually. Verify position with biplanar fluoroscopy.

Disassemble the driver by unthreading the Retention Rod from the screw. Repeat for additional distal locking screws.



STEP

12

INSERTION HANDLE REMOVAL

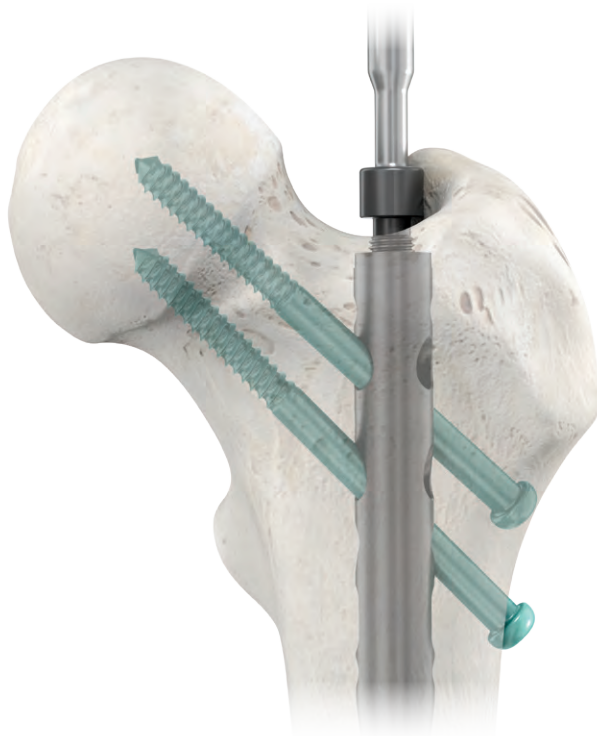
Loosen and remove the Retention Bolt with the Retention Bolt Driver. Rotate slightly to release the Insertion Handle.



OPTIONAL: END CAP INSERTION

Using fluoroscopy, verify the nail is positioned correctly. Select the appropriate end cap. Disconnect Insertion Handle. Attach end cap to a Locking Screw Driver. Insert the end cap through soft tissue and into the top of the nail.

Using fluoroscopy, verify the end cap is positioned properly on top of the nail. Once the end cap is placed, close all wounds and apply the appropriate dressings.



The end cap cannot be used when the most proximal transverse screw hole is used

OPTIONAL: NAIL REMOVAL

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

To remove the reconstruction screws, attach a driver to the screw using the Retention Rod. Rotate the driver counterclockwise until the screw is removed.

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

To remove the distal locking screws, insert the Locking Screw Driver and rotate counterclockwise until removed. If the screw is broken, use the **Extraction Punch** to remove the screw fragments.

Thread the Impaction Rod in the Nail Extraction Bolt and impact with the Slotted Mallet.

Broken Nails

If the nail is broken, remove the proximal fragment and distal locking screws.

Once the reconstruction screws and proximal fragments have been removed, insert the **3.0x1000mm Ball Tip Guidewire** through the nail until the ball end extends past the nail fragment. Insert the **1.6mm Removal Wire** next to the Ball Tip Guidewire until it also extends past the nail fragment.

Attach the **T-Handle Chuck** to the 3.0mm Guidewire and manually tighten. Thread the Long Impaction Rod in the back of the T-Handle Chuck. Using the Slotted Mallet, impact the Impaction Rod until the nail is removed.

SURGICAL TECHNIQUE

AUTOBAHN™ Retrograde Nail

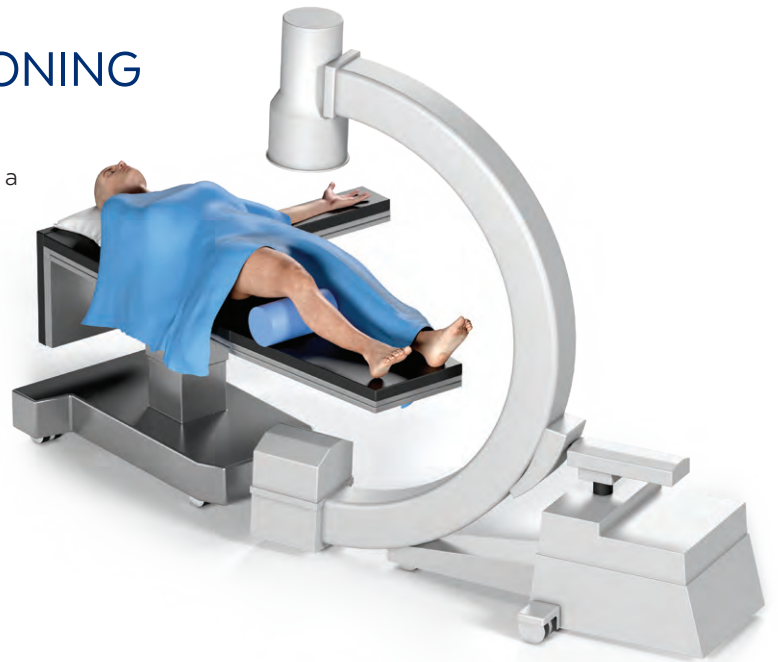
Refer to the package insert (also printed in the back of this manual) for important information on the intended use/indications, device descriptions, contraindications, precautions, warnings, and potential risks associated with this system.

Preoperative Planning

Use X-rays and/or CT images to determine whether an antegrade or retrograde approach is needed based on fracture pattern. Refer to page 8 for the antegrade approach.

STEP 1 PATIENT POSITIONING

Place the patient in a supine or lateral decubitus position on a radiolucent table. Position the C-arm so the proximal and distal ends of the femur can be viewed using AP and lateral fluoroscopy.



STEP 2 FRACTURE REDUCTION

Perform reduction using traction (indirect) or clamp application (direct). If necessary, use a leg roll to allow for reduction and stabilization of the fracture. Confirm reduction using fluoroscopy.

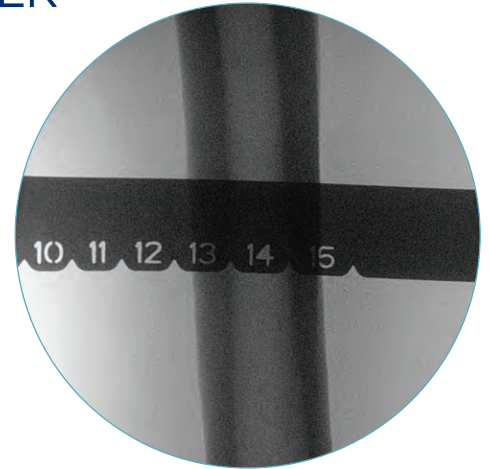
If patient anatomy cannot be restored using traction and/or manipulation, additional internal and/or external fixation may be necessary.

STEP

3

DETERMINING NAIL DIAMETER

Using fluoroscopy, measure the diameter of the intramedullary canal at the narrowest part, or the isthmus of the femur with the Nail Length and Diameter Gauge. Select the appropriate distal nail diameter. If desired, use the contralateral intact femur to determine the nail diameter.



STEP

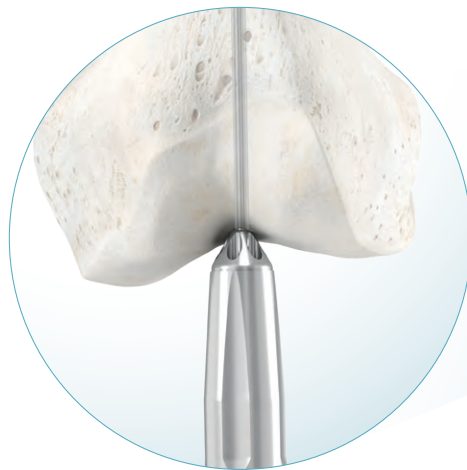
4

INCISION AND ENTRY POINT

To avoid placing the nail too anteriorly, create a midline or medial parapatellar longitudinal incision in line with the medullary canal.

Incise the tendinous structures until the fat pad is exposed. Retract the patellar tendon laterally. Using biplanar fluoroscopy, create an incision and insert the the Soft Tissue Protection Sleeve and the **K-wire Insertion Sleeve** through the intercondylar notch, just above Blumensaat's line. Insert the assembly until it sits on bone.

Insert a Threaded K-wire at the apex of the lateral medullary triangle and in line with the medullary canal. This point is slightly medial to the deepest point of the intercondylar notch. Verify position using fluoroscopy.



K-wire insertion

STEP**5****MEDULLARY CANAL EXPOSURE**

Using fluoroscopy, confirm K-wire position in the AP and lateral views. Remove the K-wire Insertion Sleeve. Insert the Conical Reamer over the threaded K-wire and through the Soft Tissue Protection Sleeve to open the medullary canal.

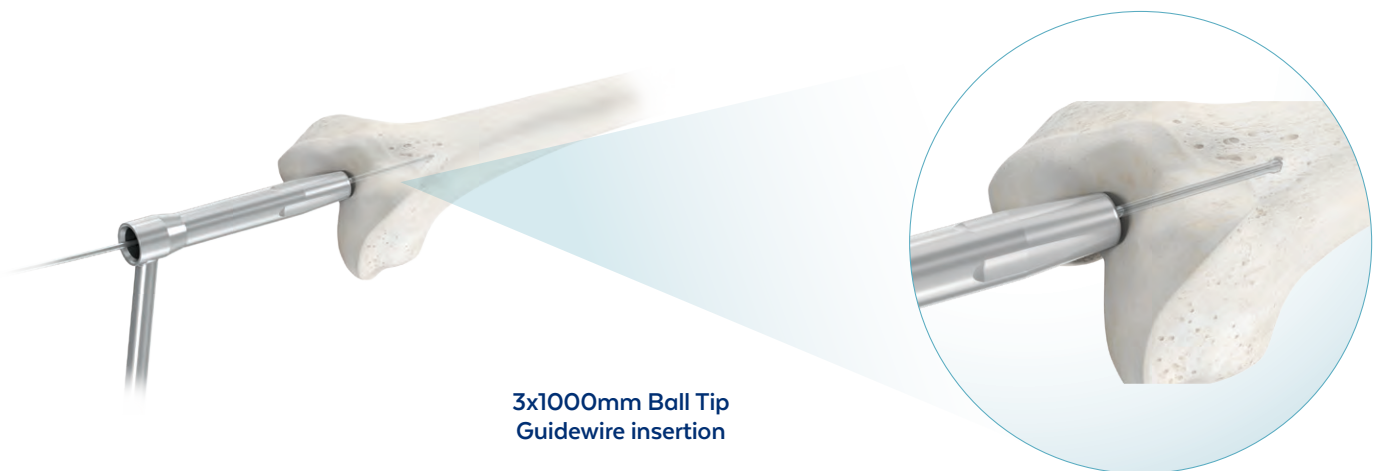
Using fluoroscopy, ream approximately 3–5cm in depth. Ensure that the reaming path is in line with the femoral intramedullary canal until reaming is complete. Remove the Conical Reamer and K-wire to maintain tissue sleeve position.

**STEP****6****MEDULLARY CANAL GUIDEWIRE INSERTION**

Ensure fracture reduction using fluoroscopy. Manually insert a 3x1000mm Ball Tip Guidewire into the center of the intramedullary canal. Using fluoroscopy, confirm the Guidewire is centered and seated in the intercondylar notch.

If necessary, the end of the Guidewire may be slightly bent to simplify passage across the fracture site. Use caution when bending the Guidewire.

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



STEP

7

DETERMINING NAIL LENGTH

Attach the Nail Length and Diameter Gauge to the Length Gauge Extension. Slide the Length Gauge Extension over the Ball Tip Guidewire until it rests on bone. Determine nail length by reading the measurement on the Length Gauge at the tip of the Guidewire. Use fluoroscopy to confirm the position of the Length Gauge.



Length Gauge requires the use of 1000mm Guidewire



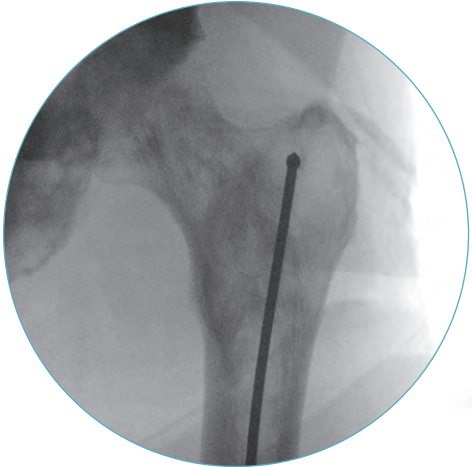
Measurement 460mm

STEP**8****REAMING THE MEDULLARY CANAL**

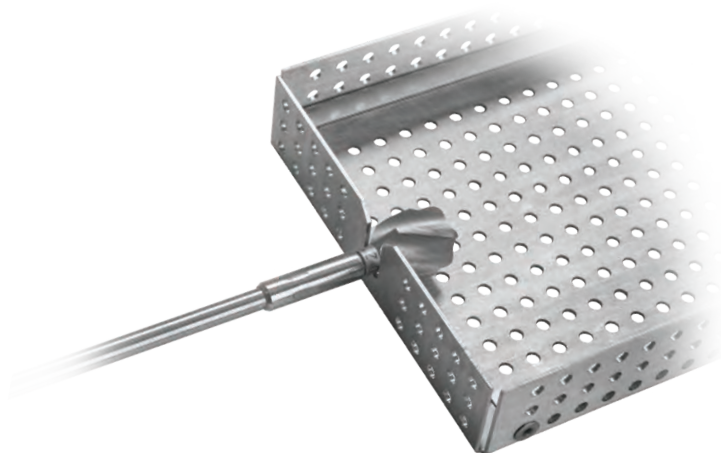
Ensure the Ball Tip Guidewire is inserted into the canal at the desired depth. Confirm fracture reduction using fluoroscopy.

Ream the medullary canal in 0.5mm increments using the **Front Cutting Reamers** and applying steady pressure. Partially retract the reamer to clear debris from the canal while continuing rotation. Using **Piloted Reamers**, ream to 0.5 to 1.5mm greater than the selected nail diameter. After reaming, remove the Piloted Reamers, leaving the Ball Tip Guidewire in place.

If necessary, use the **K-wire Pusher** to ensure the Ball Tip Guidewire is secure during reaming.



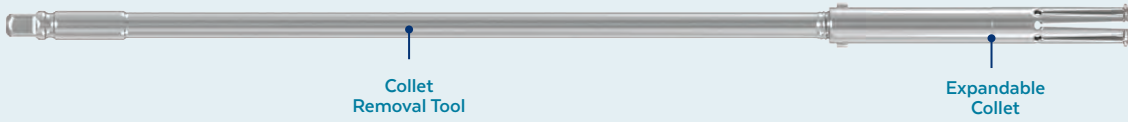
Ream the medullary canal



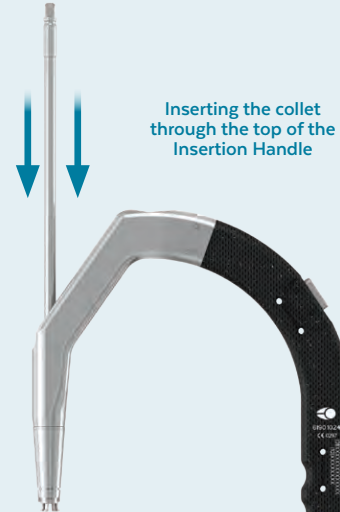
Use the Reaming Module
Cover to remove reamer tips

ASSEMBLING INSERTION HANDLE AND ATTACHING NAIL

Attach the Expandable Collet to the Collet Removal Tool.

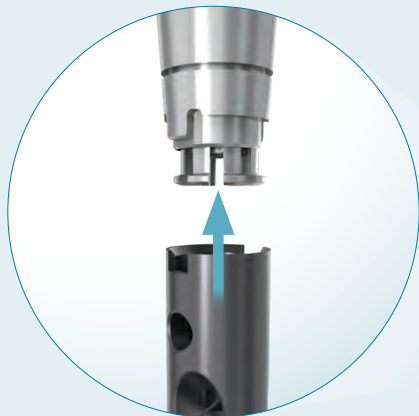


Insert the collet assembly through the top of the Insertion Handle. Align the tabs on the collet with the slots in the inside of the handle. Press the collet into the handle. Once fully seated, the collet should be protruding through the tip of the handle.



Keeping the Collet Removal Tool in place, attach the nail to the Insertion Handle. Align the slots in the nail with the tabs on the Insertion Handle.

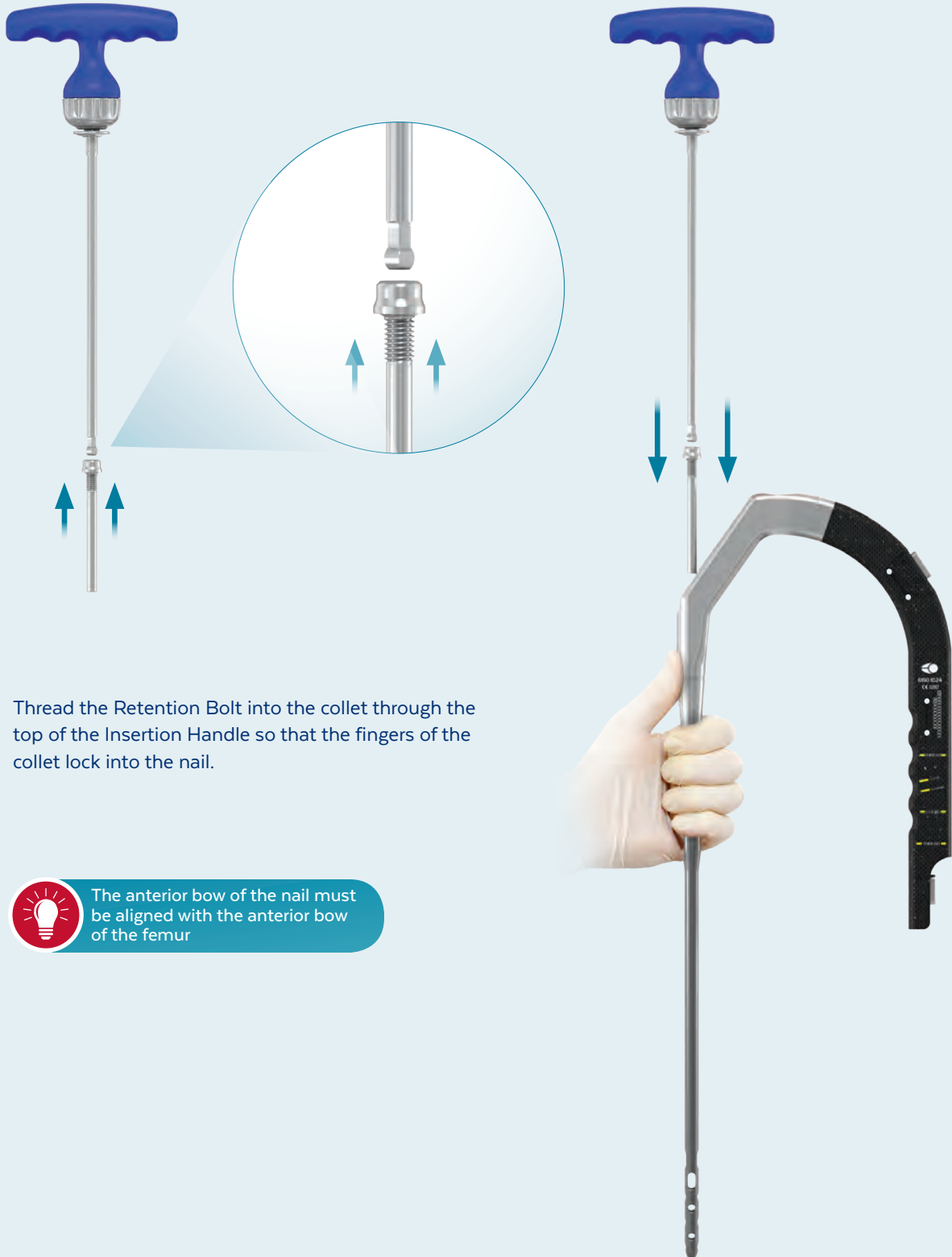
Press the Collet Removal Tool to snap the collet into the top of the nail, so the collet fingers fall into the slot in the nail. Ensure that the collet is secure in the nail. Remove the Collet Removal Tool.



Attaching the nail to the Insertion Handle



Assemble the **Retention Bolt** to the **Retention Bolt Driver** by pressing it on the driver.



Thread the Retention Bolt into the collet through the top of the Insertion Handle so that the fingers of the collet lock into the nail.



The anterior bow of the nail must be aligned with the anterior bow of the femur

STEP**9****FEMORAL NAIL INSERTION**

Insert the nail over the Ball Tip Guidewire into the femoral opening. Manually advance the nail as far as possible and rotate the handle laterally. Monitor nail position using fluoroscopy.

The groove in the aiming guide is 5mm from the top of the nail. It can be used during fluoroscopy to aid in nail placement.



If slight impaction is needed to fully seat the nail, thread the Impaction Rod, Short into the Insertion Handle. Using the Slotted Mallet, slowly advance the nail by applying light taps to the proximal end of the Impaction Rod. **Do not tap the Guidewire or the Insertion Handle.**

Use fluoroscopy to monitor nail position during controlled impaction. Once the nail has crossed the fracture site, remove the Ball Tip Guidewire. When the nail is seated to the desired depth, remove the Impaction Rod.



Two types of distal locking screws may be used, together or individually for fixation. **If inserting 6.5mm screws, they should be inserted first.**

DISTAL TRANSVERSE LOCKING SCREW INSERTION

The transverse holes in the nail accept Headed or Headless 5.0mm Locking Screws. Create a fixed angle construct using the threaded holes in the nail.

Place the **Locking Screw Driver Sleeve** and **Trocar** with the yellow color band through the appropriate hole in the Insertion Handle.

Create an incision and insert the Trocar/Sleeve assembly until bone is reached. The assembly engages in the Insertion Handle's self-retention feature for stability. Remove the Trocar when bone is reached and fully seat the sleeve against the bony surface.



5.0mm Screw Preparation

Insert the Locking Screw Driver Sleeve and appropriate **Graduated 4.2mm Drill** through the drill sleeve. Drill until the far cortical wall is reached.

Measure screw length using the markings on the drill bit or by using the **Locking Screw Length Gauge**.

Remove the drill guide and insert the Locking Screw Length Gauge through the femur. Rest the gauge on the near cortical wall, extend the tip completely through the femur, and retract until it engages the far cortical wall.

Determine the length by reading the measurement on the gauge.



Measurement
115mm

DISTAL TRANSVERSE LOCKING SCREW INSERTION (CONT'D)

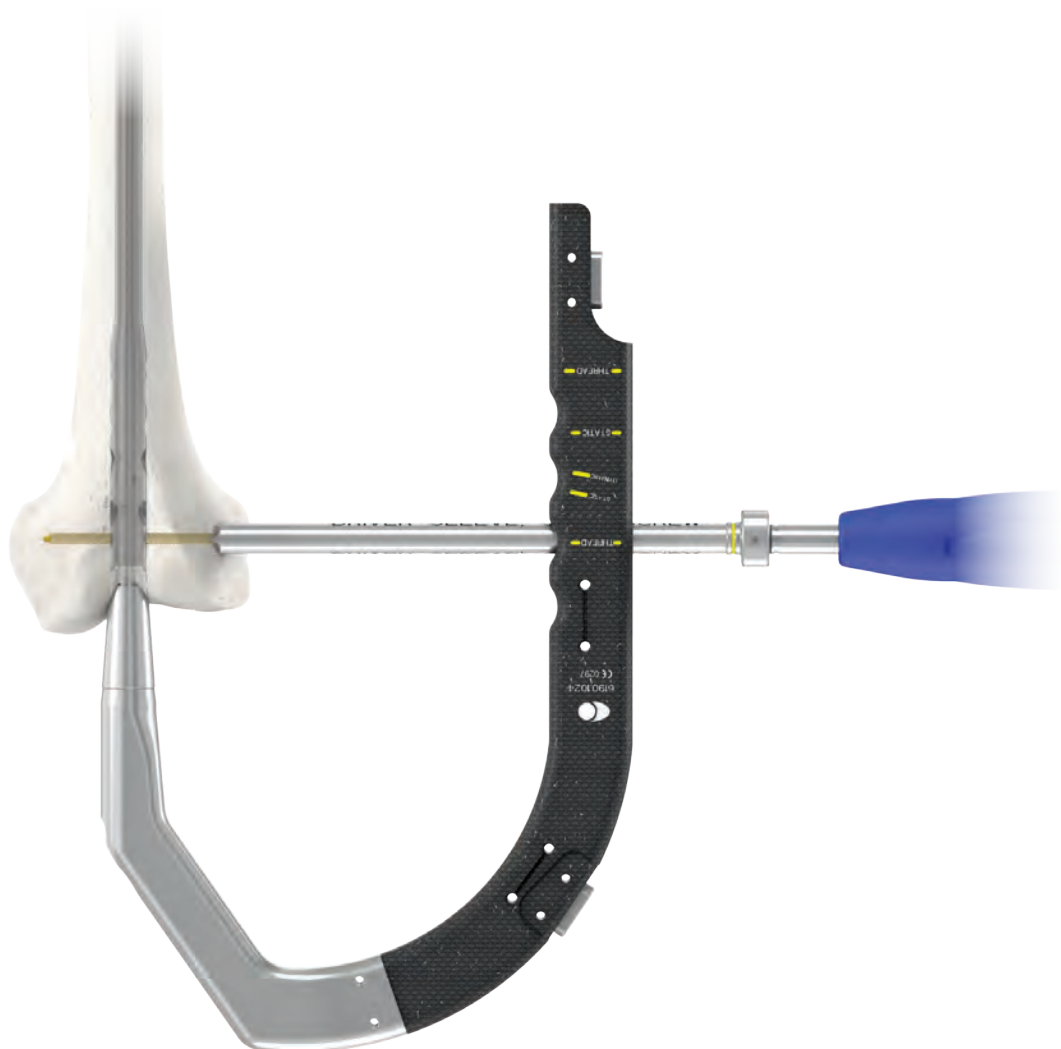
5.0mm Screw Insertion

Assemble the Locking Screw Driver by inserting the Retention Rod until it snaps into place.

Select the appropriate length 5mm Locking Screw. Using a Retention Rod, secure the locking screw to the Locking Screw Driver. Insert the locking screw through the Locking Screw Driver Sleeve until flush with the near lateral cortex. Confirm placement using fluoroscopy.

Disassemble the driver by unthreading the retention rod from the screw.

If necessary, use power to drive screws into bone. Do not use power for final screw tightening. Perform final screw tightening manually. Repeat process for additional distal transverse locking screws.



USING HEADLESS LOCKING SCREWS

Headless screws are designed to decrease screw head prominence and reduce soft tissue irritation in the proximal and distal femur.

Headless screws can be used instead of standard locking screws with any locking options in the AUTOBAHN™ Antegrade/Retrograde Femoral Nailing System.

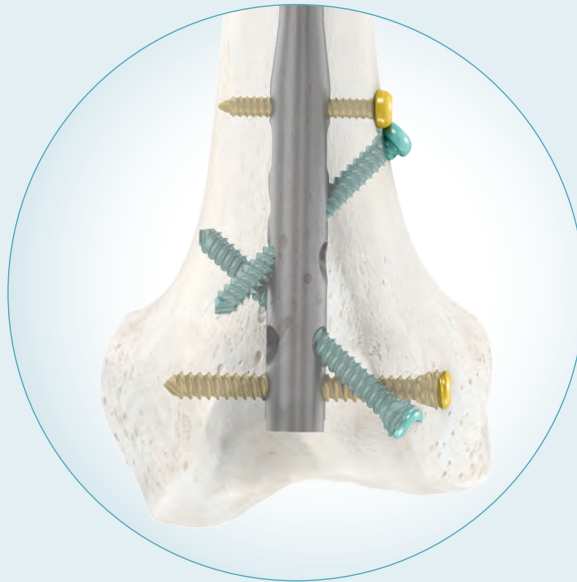
Headless Screw Insertion

Drill and determine length as described in Step 10.

Attach the headless locking screw to the Locking Screw Driver using the self-retaining feature or the threaded capture mechanism.

Using fluoroscopy, insert the headless locking screw until the head of the screw is flush with the bone. Verify screw length using fluoroscopy.

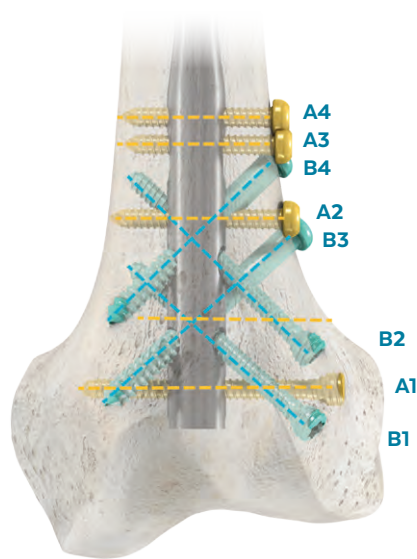
Repeat for additional proximal holes as necessary. A countersink for 6.5mm screws and 5.0mm screws is available if needed to ensure screws fully seat.



Headless Locking Screw
fully inserted

6.5mm SCREW INSERTION

The reconstruction holes in the nail are used with 6.5mm locking screws. Note that not all screw holes can be used at once. When using 6.5mm screws, two screws are recommended.



IMPORTANT
B1 intersects B3
B2 intersects B4
A2 intersects B2 & B4
<i>These screw trajectories intersect one another and therefore cannot be used together</i>

Attaching the Aiming Modules

Select the appropriate aiming modules for the desired fixation construct.

Use the corresponding aiming modules to insert the 6.5mm locking screws through the nail. Attach the aiming modules to the nail by aligning the tabs and securing with a thumbscrew.



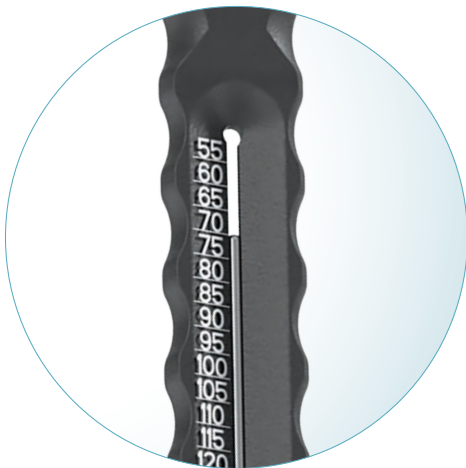
Use the correct side of the aiming module labeled "Retrograde", to aim 6.5mm screws



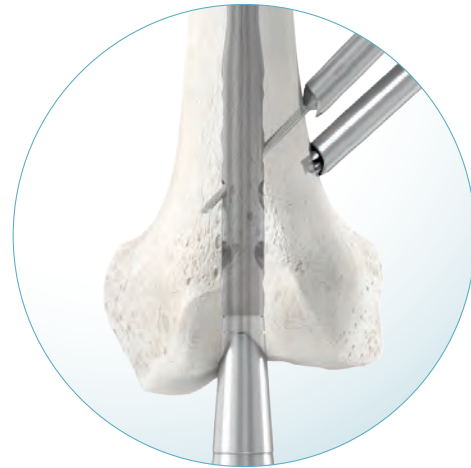
K-wire Insertion for 6.5mm Screw

Pass the 3.2mm Threaded K-wire through the Wire Guide until the lateral cortex is reached. Advance the K-wire across the femoral condyles until the desired depth is reached. Verify the K-wire trajectories using fluoroscopy. If necessary, the Spot-Face Drill for 6.5mm Screws may be used to create a starting point on the lateral cortex to facilitate K-wire accuracy.

Use the 3.2mm Threaded K-wire and the Quick Read Length Gauge for 6.5mm Screws to measure the length of the screw. Remove the Wire Guide and slide the Length Gauge over the threaded K-wire until the stop meets the top of the Driver Guide. Read the screw length where the K-wire stops on the Length Gauge. Remove the threaded K-wire. If necessary, use the Length Gauge for 6.5mm Screws to manually measure the screw length.



Measurement 70mm



Spot-Face Drill for
6.5mm screws

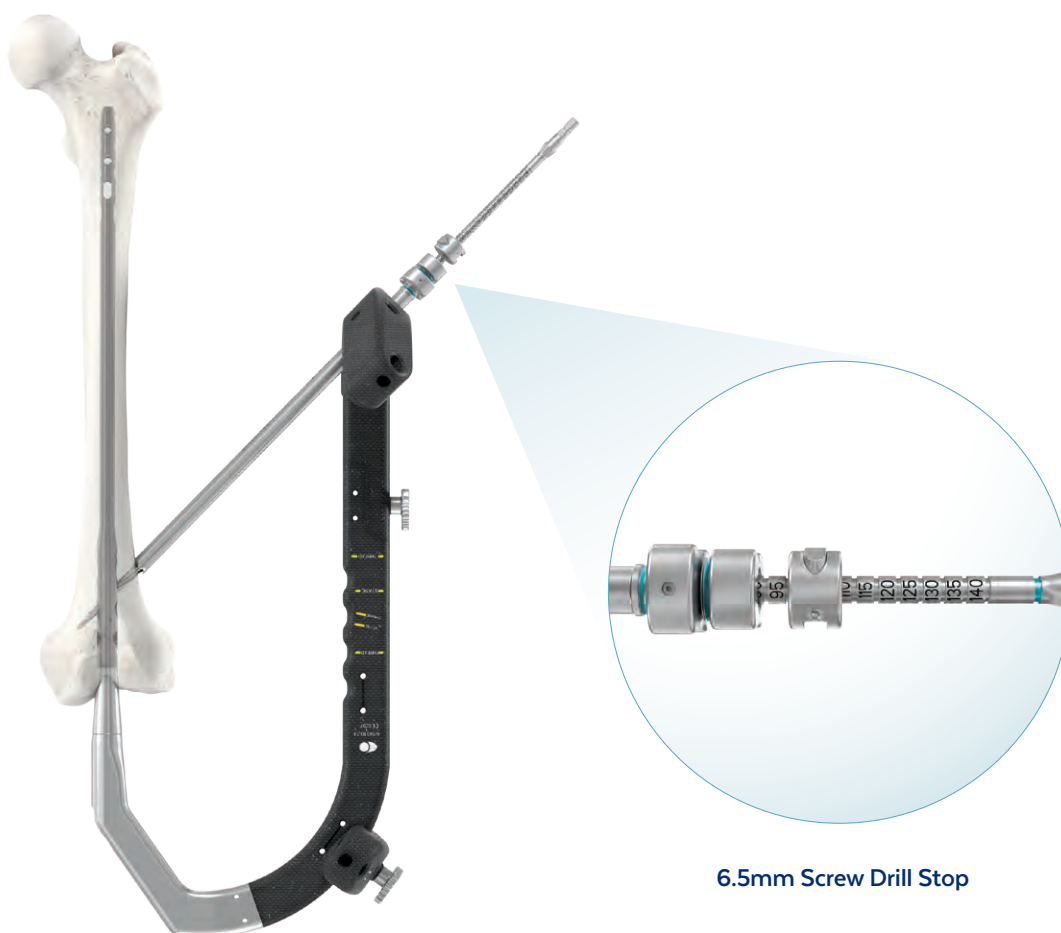
6.5mm SCREW INSERTION (CONT'D)

6.5mm Screw Preparation

For partially threaded 6.5mm screws, slide the 6.5mm Screw Drill Stop over the Step Drill until the desired length is covered. Insert the drill to the appropriate depth. Confirm drill depth using fluoroscopy.

For fully threaded screws, use the 6.5mm Core Drill. Insert the drill to the appropriate length. Confirm drill depth using fluoroscopy.

In dense bone, tapping may be necessary prior to screw insertion. Tap to the desired depth with the T-Handle Chuck and 6.5mm Screw Tap through the Drill/Driver Guide.



6.5mm Screw Drill Stop

For fully threaded screws, use the 6.5mm Core Drill. Insert the drill to the appropriate length. Confirm drill depth using fluoroscopy.

In dense bone, tapping may be necessary prior to screw insertion. Tap to the desired depth with the T-Handle Chuck and 6.5mm Screw Tap through the Drill/Driver Guide.

6.5mm Screw Insertion

Attach the appropriate length screw to the Locking Screw Driver and Retention Rod as described in distal transverse locking screw insertion. Insert the screw across the femoral condyles. If necessary, a power driver can be used with the Power Driver Shaft. Do not use power for final screw tightening. Perform final screw tightening manually.



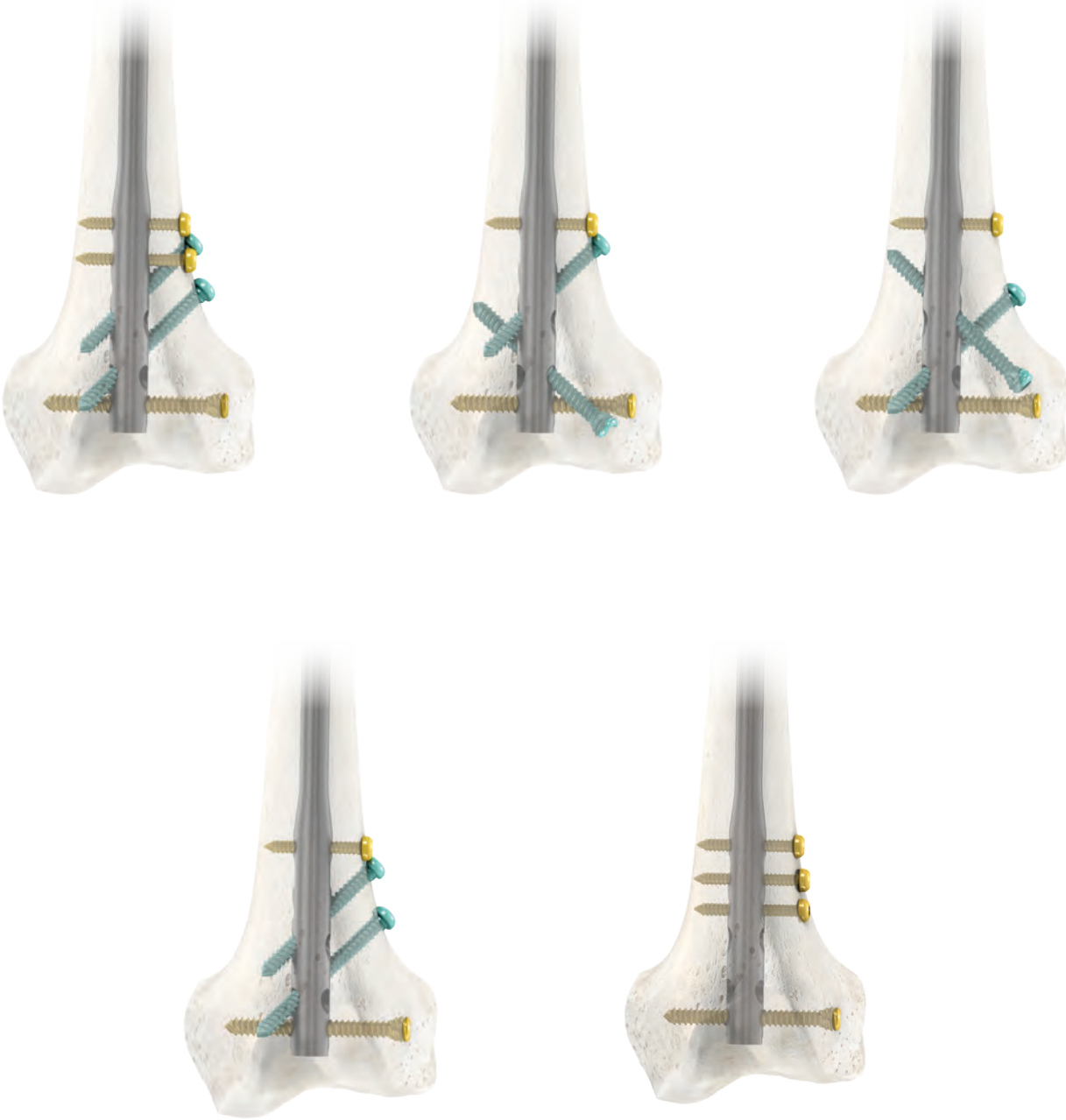
Disassemble the driver by unthreading the Retention Rod from the screw.

Use multiple fluoroscopic views to ensure the 6.5mm reconstruction screws remain in the distal femur throughout screw insertion. Use AP and lateral fluoroscopy to confirm screw placement.



Headless fully threaded 6.5mm screws are available for use in place of a headed 6.5mm screw

FINAL CONSTRUCTS - RETROGRADE APPROACH



STEP

11

PROXIMAL LOCKING SCREW INSERTION

Verify fracture reduction and alignment of the nail using fluoroscopy. Align the C-arm with the proximal locking hole until a perfect circle is visible. Create an incision in the center of the hole.

Drill using the **Locking Screw Drill** until the far cortical wall is breached.

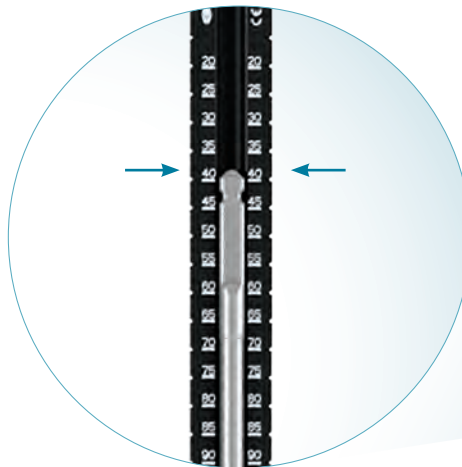
Slide the **Length Gauge, Quick Read, Locking Screw** onto the drill bit. Read the measurement to determine the corresponding screw length.

Alternatively, insert the Locking Screw Length Gauge through the soft tissue down to the surface of the femur. Rest the nose of the gauge on the near cortical wall, extend the hook completely through the femur, and retract until it catches on the far cortical wall. Determine length by reading the measurement on the gauge.



Locking Screw Drill

Measurement
40mm



PROXIMAL LOCKING SCREW INSERTION (CONT'D)

Attach the appropriate length locking screw to the Locking Screw Driver. Do not use power for final screw tightening. Perform final screw tightening manually. Verify position with biplanar fluoroscopy.

Insert the screw bicortically under power if necessary using Power Driver Shaft. Verify position with biplanar fluoroscopy. Repeat for additional proximal locking screws.



STEP

12

INSERTION HANDLE REMOVAL

Loosen and remove the Retention Bolt with the Retention Bolt Driver. Rotate slightly to release the Insertion Handle.



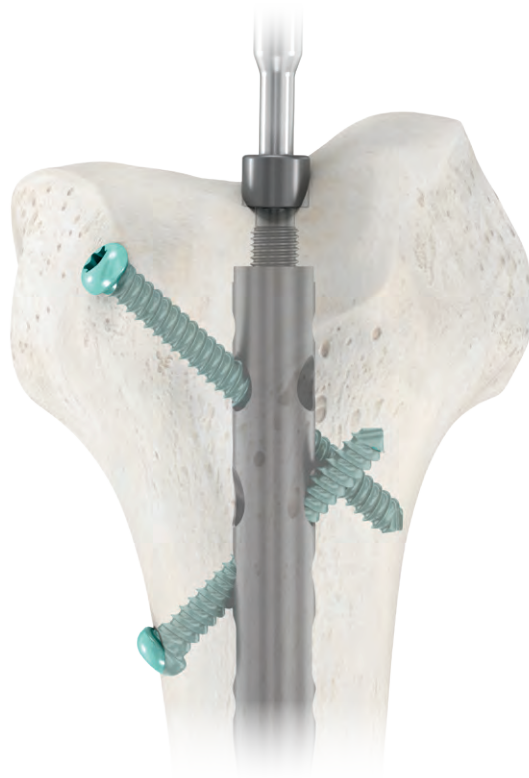
OPTIONAL: END CAP INSERTION

Using fluoroscopy, verify the nail is positioned correctly. Select the appropriate end cap. Attach end cap to a Locking Screw Driver. Insert the end cap into the top of the nail.

Using fluoroscopy, verify the end cap is positioned properly on top of the nail. Once the end cap is placed, close all wounds and apply the appropriate dressings.



The end cap cannot be used when the most distal transverse screw hole is used



OPTIONAL: NAIL REMOVAL

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

To remove the reconstruction screws, attach a driver to the screw using the Retention Rod. Rotate the driver counterclockwise until the screw is removed.

Thread the Nail Extraction Bolt in the nail with the proximal screws in place to prevent rotation.

To remove the proximal locking screws, insert the Locking Screw Driver and rotate counterclockwise until removed. If the screw is broken, use the Extraction Punch to remove the screw fragments.

Thread the Impaction Rod in the Nail Extraction Bolt and impact with the Slotted Mallet.

Broken Nails

If the nail is broken, remove the distal fragment and proximal locking screws.

Once the reconstruction screws and distal fragments have been removed, insert the 3.0x1000mm Ball Tip Guidewire through the nail until the ball end extends past the nail fragment. Insert the 1.6mm Removal Wire next to the Ball Tip Guidewire until it also extends past the nail fragment.

Attach the T-Handle Chuck to the 3.0mm Guidewire and manually tighten. Thread the Long Impaction Rod in the back of the T-Handle Chuck. Using the Slotted Mallet, impact the Impaction Rod until the nail is removed.

INSTRUMENT OVERVIEW

PROXIMAL ENTRY



Conical Reamer 6190.0023



Intramedullary Reduction Tool 6190.0080



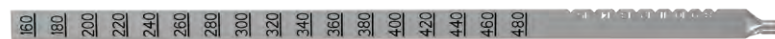
Soft Tissue Protector, Conical Reamer, Long 6190.0025



Soft Tissue Protector, Conical Reamer, Short 6190.0024



Wire Guide, Tissue Protector 6190.1032



Nail Length Gauge 6176.0010

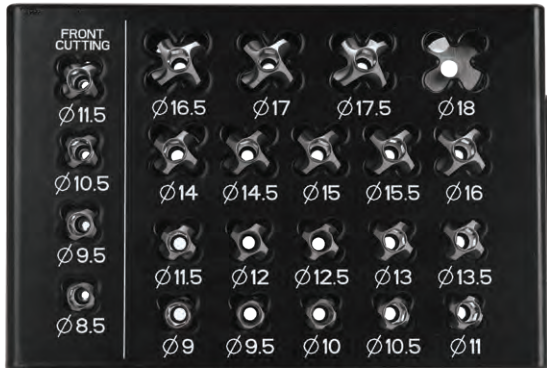


Extension, Nail Length Gauge 6176.0011



Guide Wire Pusher 6176.0029

REAMING



Reamer Head Tray 6176.0049



Reamer Removal Tray 6176.0038



Flexible Reamer Shaft, 470mm 6182.0001



Front Cutting Reamer Heads,
8.5-11.5mm 6182.2085-.2115



Piloted Reamer Head,
9.0-18mm 6182.1090-.1180



Reamer Extension Shaft 6182.0002



Flexible Reamer Shaft, 470mm, Hall Connection 6182.0004S



Flexible Reamer Shaft, 620mm, Hall Connection 6182.0005S

NAIL INSERTION



Retention Bolt 6190.0002



Expandable Collet 6190.1031

Antegrade/Retrograde Femoral Nail Base Aiming Guide 6190.1024



Slotted Mallet 6176.0020



Expandable Collet Removal Tool 6190.0070



Retention Bolt Driver 6176.0027

5.0mm SCREW INSERTION



Driver Sleeve, 5.0mm Screw 6190.0015



Drill Sleeve, 5.0mm Screw 6190.0017



Trocar, 5.0mm Screw 6190.0053



Locking Screw Drill, 170mm 6176.0170S



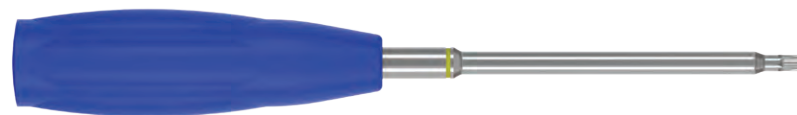
Locking Screw Drill, 350mm 6190.0350S



AUTOBAHN™ Countersink, Long, 5mm Headless 6183.1104



Locking Screw Driver, Long 5.0mm Screw 6176.0042



Locking Screw Driver, Short 5.0mm Screw 6176.0045



Retention Rod, Locking Screw, Short 5.0mm Screw 6176.0061



Retention Rod, Locking Screw, Long 5.0mm Screw 6176.0063

5.0mm SCREW INSERTION (CONT'D)



Length Gauge, Locking Screws 6176.0026



Locking Screw Driver, Short, For Power 5.0mm Screw 6176.0055



Retention Rod, Locking Screw Long, For Power 5.0mm Screw 6176.0058



Locking Screw Driver, Long, For Power 5.0mm Screw 6176.0057



Retention Rod, Locking Screw Short, For Power 5.0mm Screw 6176.0056



Length Gauge, Quick Read, Locking Screw 6176.0069



Hall Quick Connect Handle 6190.3000

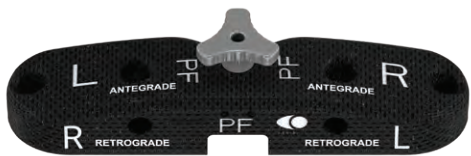
6.5mm SCREW INSERTION



Antegrade/Retrograde Femoral Nail Recon Aiming Module, PF 6190.1026



Antegrade/Retrograde Femoral Nail Recon Aiming Module, GT 6190.1027



Antegrade/Retrograde Femoral Nail Oblique Aiming Module, PF 6190.1028



Antegrade/Retrograde Femoral Nail Oblique Aiming Module, GT 6190.1029



Driver Sleeve, 6.5mm Screw 6190.0003



Drill Sleeve, 6.5mm Screw 6190.0004



K-wire Sleeve, 6.5mm Screw 6190.0051



Step Drill, 6.5mm Screw 6190.0052

6.5mm SCREW INSERTION



Drill Stop, 6.5mm Screw 6190.0006



Locking Screw Driver, 6.5mm Screw 6190.0042



Retention Rod, 6.5mm Locking Screw 6190.0063



Locking Screw Driver, For Power, 6.5mm Screw 6190.0057



Retention Rod, 6.5mm Locking Screw, For Power 6190.0058



Quick Read Length Gauge, 6.5mm Screw 6190.0069



Manual Length Gauge, 6.5mm Screws 6190.0026



AUTOBAHN™ Countersink, 6.5mm Headless Screw 6190.1106

REMOVAL



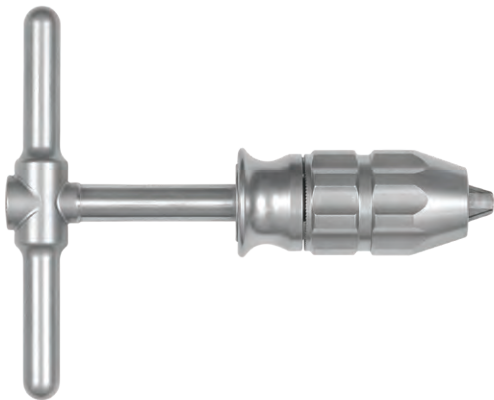
Extractor Pin Wrench 6176.0066



Impaction Rod, Short 6176.0064



Impaction Rod, Long 6176.0016



T-Handle Chuck 6173.9000

Nail Removal Wire 6176.0030S



Locking Screw Removal Tool 6176.0031



Trepine 6190.0048



Punch 6176.0032

K-WIRE



Ball Tip Guidewire 3.0x1000mm 6176.0022



Threaded Drill Point K-wire 3.2x450mm 6176.0021

AUTOBAHN™ Antegrade/Retrograde Femoral Nailing System Implants

Nails 170-480mm

	Greater Trochanter Nails	Piriformis Fossa/Retrograde Nails
9mm	1190.1916S - 1190.2950S	1190.3916S - 1190.3950S
10mm	1190.1016S - 1190.2050S	1190.3016S - 1190.3050S
11mm	1190.1116S - 1190.2150S	1190.3116S - 1190.3150S
12mm	1190.1216S - 1190.2250S	1190.3216S - 1190.3250S
13mm	1190.1316S - 1190.2350S	1190.3316S - 1190.3350S
14mm	1190.1416S - 1190.2450S	1190.3416S - 1190.3450S
15mm	1190.1516S - 1190.2550S	1190.3516S - 1190.3550S

5mm Locking Screws

Part No.	Description
1183.5020S-1183.5090S	5mm fully threaded headed, 20-90mm
1183.2020S-1183.2090S	5mm fully threaded headless, 20-90mm

6.5mm Locking Screws

Part No.	Description
1190.5070S-1190.5130S	6.5mm fully threaded headed, 70-130mm
1190.6050S-1190.6140S	6.5mm partially threaded headed, 50-140mm
1190.7050S-1190.7140S	6.5mm fully threaded headless, 50-140mm

End Caps

Part No.	Description
1190.9800S-1190.9820S	0-20mm

Lateral Washers

Part No.	Description
1190.9000S-1190.9020S	0-20mm

Wires

Part No.	Description
6176.0021S	3.2x450mm Threaded K-wire
6176.0022S	3.0x1000mm Ball Tip Guidewire

AUTOBAHN™ Antegrade/Retrograde Femoral Nailing System Standard Instrument Set 9190.9100

Instruments		QTY
6190.0023	Conical Reamer	1
6190.0024	Soft Tissue Protector, Conical Reamer, Short	1
6190.0025	Soft Tissue Protector, Conical Reamer, Long	1
6176.0029	Guide Wire Pusher	1
6176.0010	Nail Length Gauge	1
6176.0011	Extension, Nail Length Gauge	1
6173.9000	T-Handle Chuck	1
6190.1032	Wire Guide, Insertion	1
6190.0080	Intradmedullary Reduction Tool	1
6190.1024	Antegrade/Retrograde Femoral Nail Base Aiming Guide	1
6190.0053	Trocar, 5.0mm Screw	1
6190.0015	Driver Sleeve, 5.0mm Screw	1
6190.0017	Drill Sleeve, 5.0 Screw	1
6176.0020	Slotted Mallet	1
6190.1031	Expandable Collet	2
6190.0002	Retention Bolt	2
6176.0027	Retention Bolt Driver	1
6176.0064	Impaction Rod, Short	1
6176.0036	Impaction Connector	1
6067.0020	Ratcheting T-Handle	1
6176.0042	Locking Screw Driver, Long 5.0mm Screw	1
6176.0045	Locking Screw Driver, Short 5.0mm screw	1
6176.0061	Retention Rod, Locking Screw, Short 5.0mm Screw	1
6176.0063	Retention Rod, Locking Screw Long 5.0mm Screw	1
6176.0026	Length Gauge, 5.0mm Locking Screw	1
6176.0055	Locking Screw Driver, Short, For Power 5.0mm Screw	1
6176.0057	Locking Screw Driver, Long, For Power 5.0mm Screw	1
6176.0058	Retention Rod, Locking Screw Long, For Power 5.0mm Screw	1
6176.0056	Retention Rod, Locking Screw Short, For Power 5.0mm Screw	1
6190.0070	Expandable Collet Removal Tool	1
6176.0069	Length Gauge, Quick Read, Locking Screw	1
6190.3000	Hall Quick Connect Handle	1
6183.1104	AUTOBAHN™ Countersink, 5.0mm Headless Screws	1
9190.1000	Standard Nail Graphic Case	1

AUTOBAHN™ Antegrade/Retrograde Femoral Nailing System Recon Instrument Set 9190.9200

Instruments		QTY
6190.1026	Antegrade/Retrograde Femoral Nail Recon Aiming Module, PF	1
6190.1028	Antegrade/Retrograde Femoral Nail Oblique Aiming Module, PF	1
6190.0003	Drill/Driver Guide, 6.5mm Screw	2
6190.0004	Wire Guide, 6.5mm Screw	2
6190.0007	Core Drill, 6.5mm Screw	2
6190.0005	Step Drill, 6.5mm Screw	2
6190.0051	Trocar, 6.5mm Screw	2
6190.0006	Drill Stop, 6.5m Screw	2
6190.1027	Antegrade/Retrograde Femoral Nail Recon Aiming Module, GT	1
6190.1029	Antegrade/Retrograde Femoral Nail Oblique Aiming Module, GT	1
6190.0052	6.5mm Screw Tap	1
6190.0042	Locking Screw Driver, 6.5mm Screw	2
6190.0057	Locking Screw Driver, 6.5mm Screw, For Power	2
6190.0058	Retention Rod, 6.5mm Locking Screw, For Power	2
6190.0063	Retention Rod, 6.5mm Locking Screw	2
6190.0069	Length Gauge, 6.5mm Screws	1
6176.0016	Impaction Rod, Long	1
6176.0031	Locking Screw Removal Tool (female easy out)	1
6190.0031	6.5mm Screw Removal Tool	1
6176.0032	Punch	1
6190.0048	Trephine	1
6183.1001	Nail Extraction Screw (male easy out)	1
6176.0066	Tommy Bar	1
6190.3000	Hall Quick Connect Handle	1
6190.0026	Length Gauge, 6.5mm Screw Measurement	1
6190.1106	AUTOBAHN™ Countersink, 6.5mm Headless Screws	1
6190.0008	Spot Face Drill, 6.5mm Screws	1
9190.2000	Recon Nail Graphic Case	1

IMPORTANT INFORMATION ON AUTOBAHN™ NAILING SYSTEM

DESCRIPTION

The AUTOBAHN™ Nailing System is a family of intramedullary nails and screws 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, 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.

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 and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of these devices in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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.

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, osteomalacia, 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.

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.

IMPORTANT INFORMATION ON AUTOBAHN™ NAILING SYSTEM

- 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 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.

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 accidentally 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 tray. 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 in² 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:

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			
	CATALOGUE NUMBER		STERILIZED BY IRRADIATION
	LOT NUMBER		AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	CAUTION		MANUFACTURER
	SINGLE USE ONLY		USE BY (YYYY-MM-DD)
	QUANTITY		PRESCRIPTION USE ONLY

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NOTES



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)

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