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

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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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.

**Percutaneous Insertion Handle**
- Small tip to facilitate minimally invasive approach

**Proximal Locking Option**
- Extreme proximal threaded locking option

**Anatomic Radius of Curvature**
- Varies with nail lengths 1.0–1.4mm

**SureStart™ Technology**
- Threaded holes proximally and distally create fixed angle construct

**Multiple Entry Points**
- Greater trochanter, piriformis fossa, and retrograde

**Modular Aiming Guide**
- Customize according to treatment needs

**Headless 5.0mm Screws**
- Designed to reduce soft tissue irritation
MULTIPLE SOLUTIONS WITH HEADED OR HEADLESS SCREWS FOR OPTIMIZED FIXATION
6   AUTOBAHN™ A/R Femoral Nailing System

One Insertion Handle with modules to create customized constructs

Reconstruction Screw Aiming Pins
Aid in fluoroscopic alignment of nail in bone

Divergent 6.5mm Reconstruction Screws
Designed for stable fixation

SureStart™ Technology
Threaded holes proximally and distally create fixed angle construct

Self-retaining Sleeves
Automatic retention of sleeves during procedure

Oblique module
Reconstruction module

Color-coded Instruments
For easy screw indentification
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

Headless Screws
Designed to reduce soft tissue irritation

Transverse Hole Identification
Markers for correct screw insertion

Rigid Carbon Fiber Insertion Handle
Radiolucent guide optimized for imaging accuracy and clarity

Self-retaining Drivers
Retain screw during procedure
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.
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.
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.
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.
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.
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.
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.
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.

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
**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 subcondyral 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.
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.
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.
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 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.
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.

Measurement 460mm

Length Gauge requires the use of 1000mm Guidewire
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.
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.

![Image of Retention Bolt and Retention Bolt Driver]

**Tip:** 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.
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.
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.

**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.

**IMPORTANT**

- B1 intersects B3
- B2 intersects B4
- A2 intersects B2 & B4

These screw trajectories intersect one another and therefore cannot be used together.

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.
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.

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
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.
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.
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
Flexible Reamer Shaft, 470mm, Hall Connection 6182.0004S

Flexible Reamer Shaft, 620mm, Hall Connection 6182.0005S

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

Antegrade/Retrograde Femoral Nail Base Aiming Guide 6190.1024

Slotted Mallet 6176.0020

Expandable Collet Removal Tool 6190.0070

Retention Bolt Driver 6176.0027

Retention Bolt 6190.0002

Expandable Collet 6190.1031
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
Trephine 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

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<thead>
<tr>
<th></th>
<th>Greater Trochanter Nails</th>
<th>Piriformis Fossa/Retrograde Nails</th>
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<tr>
<td>9mm</td>
<td>1190.1916S – 1190.2950S</td>
<td>1190.3916S – 1190.3950S</td>
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<td>1190.1016S – 1190.2050S</td>
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5mm Locking Screws

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6.5mm Locking Screws

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<td>6.5mm fully threaded headed, 70–130mm</td>
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<td>1190.6050S–1190.6140S</td>
<td>6.5mm partially threaded headed, 50–140mm</td>
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<tr>
<td>1190.7050S–1190.7140S</td>
<td>6.5mm fully threaded headless, 50–140mm</td>
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End Caps

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<td>1190.9800S–1190.9820S</td>
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Lateral Washers

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Wires

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<td>6176.0021S</td>
<td>3.2x450mm Threaded K-wire</td>
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<td>6176.0022S</td>
<td>3.0x1000mm Ball Tip Guidewire</td>
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# AUTOBAHN™ Antegrade/Retrograde Femoral Nailing System

## Standard Instrument Set 9190.9100

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<thead>
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<tr>
<td>6190.0023 Conical Reamer</td>
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<td>6190.0024 Soft Tissue Protector, Conical Reamer, Short</td>
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<td>6176.0010 Nail Length Gauge</td>
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<td>6190.0080 Intradmedullary Reduction Tool</td>
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<td>6190.3000 Hall Quick Connect Handle</td>
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<tr>
<td>6183.1104 AUTOBAHN™ Countersink, 5.0mm Headless Screws</td>
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<tr>
<td>9190.1000 Standard Nail Graphic Case</td>
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# AUTOBAHN™ Antegrade/Retrograde Femoral Nailing System

## Recon Instrument Set 9190.9200

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<td>6190.0003</td>
<td>Drill/Driver Guide, 6.5mm Screw</td>
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<td>Wire Guide, 6.5mm Screw</td>
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<td>Tommy Bar</td>
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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 titanium, 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 proximal aspect of the tibial shaft fractures, both post-traumatic and post-surgical 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 fractures, specifically femoral fractures, non-unions, malunions, pseudarthroses, fracture fixation, which may include the following: open and closed femoral fractures, pseudarthrosis 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, comminuted fractures, and simple shaft fractures, proximal metaphyseal, proximal shaft fractures, segmental shaft 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 device.
• 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 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 implantation 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 fracture 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 sterilization 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 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.
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:

<table>
<thead>
<tr>
<th>Method</th>
<th>Cycle Type</th>
<th>Temperature</th>
<th>Exposure Time</th>
<th>Drying Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam</td>
<td>Pre-vacuum</td>
<td>132°C (270°F)</td>
<td>4 Minutes</td>
<td>30 Minutes</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>REF</th>
<th>CATALOGUE NUMBER</th>
<th>STERILE</th>
<th>STERILIZED BY IRRADIATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOT</td>
<td>LOT NUMBER</td>
<td>3 minutes</td>
<td></td>
</tr>
<tr>
<td>CAUTION</td>
<td></td>
<td>MANUFACTURER</td>
<td></td>
</tr>
<tr>
<td>SINGLE USE ONLY</td>
<td></td>
<td>USE BY (YYYY-MM-DD)</td>
<td></td>
</tr>
<tr>
<td>QNTITY</td>
<td></td>
<td>PRESCRIPTION USE ONLY</td>
<td></td>
</tr>
</tbody>
</table>

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