



GLOBUS
MEDICAL



AUTOBAHN™

Trochanteric 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™

Trochanteric Nailing System

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AUTOBAHN™

Trochanteric Nailing System

The AUTOBAHN™ Trochanteric Nailing System is designed to treat a variety of peritrochanteric femur fractures. Streamlined instruments enable system efficiency and optimize surgical workflow.

Dedicated Aiming Guides

- Fewer intraoperative steps
- Key into nail to prevent mismatched angle

Nails

- Accommodate varying patient anatomy with short and long nails
- Offer variety of neck angles for optimal screw placement

Pre-assembled Set Screw

- Improves procedural workflow
- Reduces number of instrument passes



One-Piece Aiming Guide

Prevent mismatched nails

- Unique features on nail correspond to dedicated Aiming Guide for each neck angle

Enhanced visibility

- Allows visualization of the femoral head
- Radiographic markers show nail anteversion alignment



Guided distal locking

- For short nail constructs

Self-retaining drill sleeves

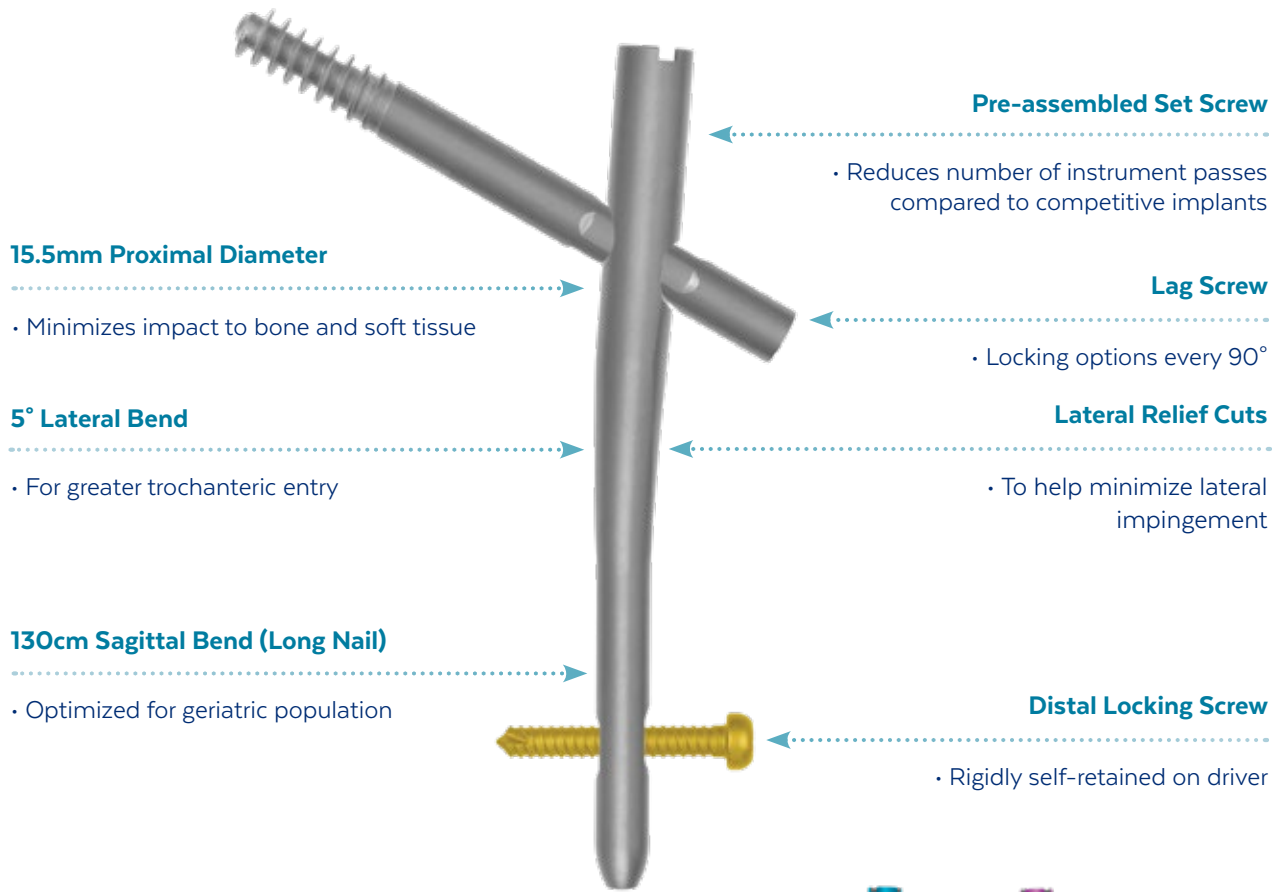
- Easy, automatic sleeve retention
- Locking button prevents drill sleeve advancement

Self-retaining drivers

- Maintain control of screw through soft tissue

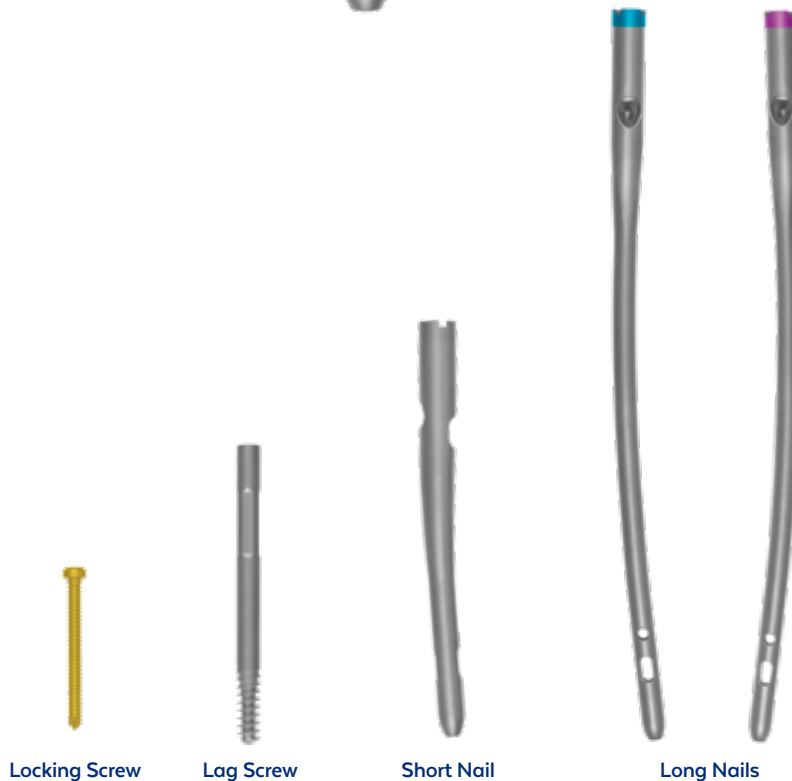


IMPLANT OVERVIEW



Implant Options

- Short and long nails
- 10.5mm Lag Screw
- 5mm Locking Screw



STREAMLINED INSTRUMENTS

Compressor

- Provides tactile feedback for intraoperative reduction



Reaming Module

- Reamer module included in set
- More front cutting reamer options to reduce number of reamer passes compared to competitive systems
- Optimized to help reduce intramedullary pressure



Color-Coded Instruments

- For ease of use in assembling sleeves



SURGICAL TECHNIQUE

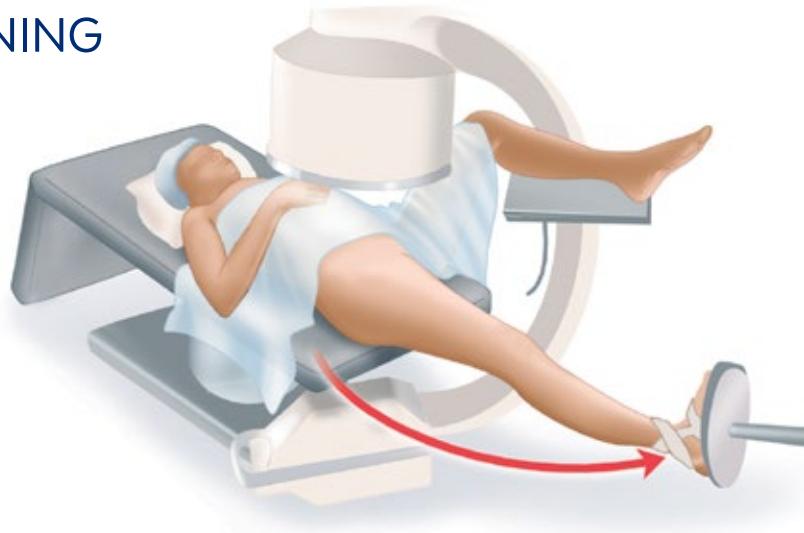
AUTOBAHN™

Trochanteric Nailing System

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

STEP 1 PATIENT POSITIONING

Place the patient in a supine or lateral decubitus position. With the injured leg extended, use fluoroscopy to confirm patient positioning.



STEP 2 FRACTURE REDUCTION

To reduce the fracture, use traction (indirect) or clamp application (direct measure). Confirm reduction using fluoroscopy.

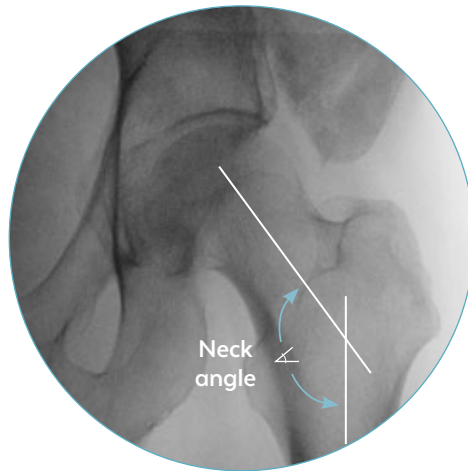


STEP

3

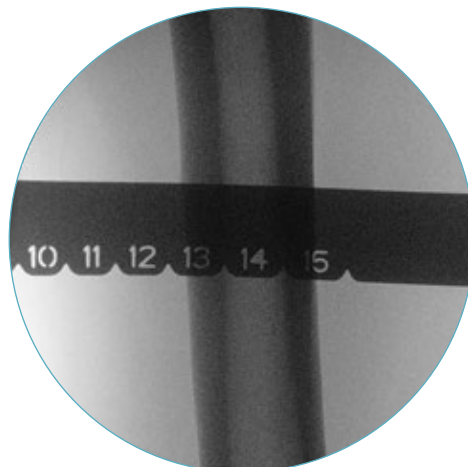
DETERMINING FEMORAL NECK ANGLE

Use fluoroscopy to measure the neck angle and select the appropriate nail. If desired, use the intact femur from the contralateral side to determine neck angle.



Determining Nail Diameter

Under fluoroscopy, use the **Nail Length and Diameter Gauge** to measure the diameter of the intramedullary canal at the isthmus of the femur. The proximal diameter of all AUTOBAHN™ Trochanteric Nails is 15.5mm. Use this measurement to select the appropriate nail shaft diameter. This step may be performed preoperatively.



STEP

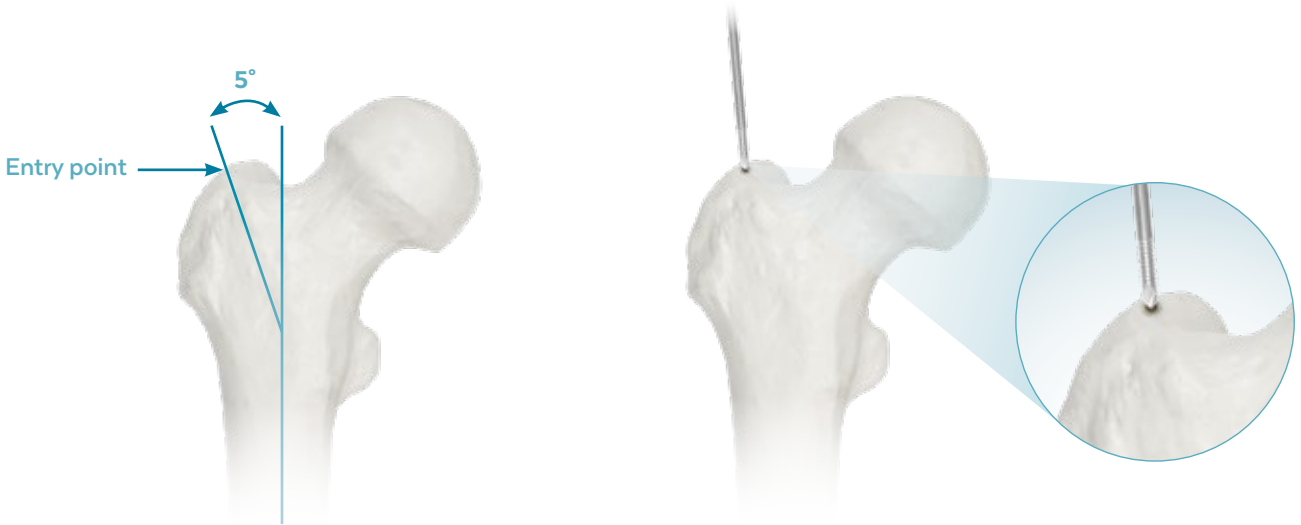
4

PROXIMAL EXPOSURE

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 proximal to the greater trochanter. Separate the muscle fibers. Insert the **3.2x450mm Threaded K-wire** until bone is reached.

Confirm entry point and trajectory using fluoroscopy. Advance the K-wire to the desired depth.



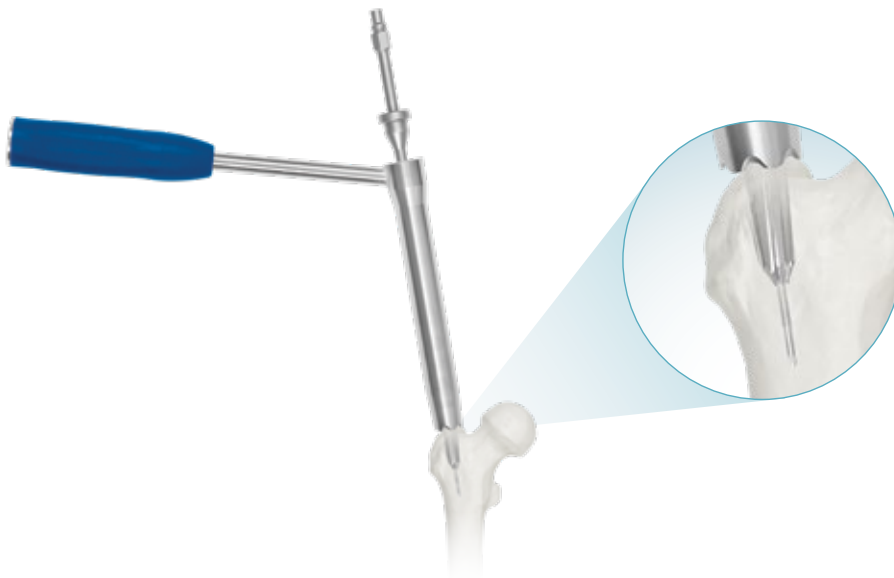
Greater trochanteric entry

STEP

5

MEDULLARY CANAL EXPOSURE

Insert the **Conical Reamer** over the K-wire and through the **Conical Reamer Soft Tissue Protector**. Drill until the Conical Reamer reaches the lesser trochanter manually or using a power drill. Remove the drill, soft tissue protector, and K-wire. Confirm trajectory using fluoroscopy.

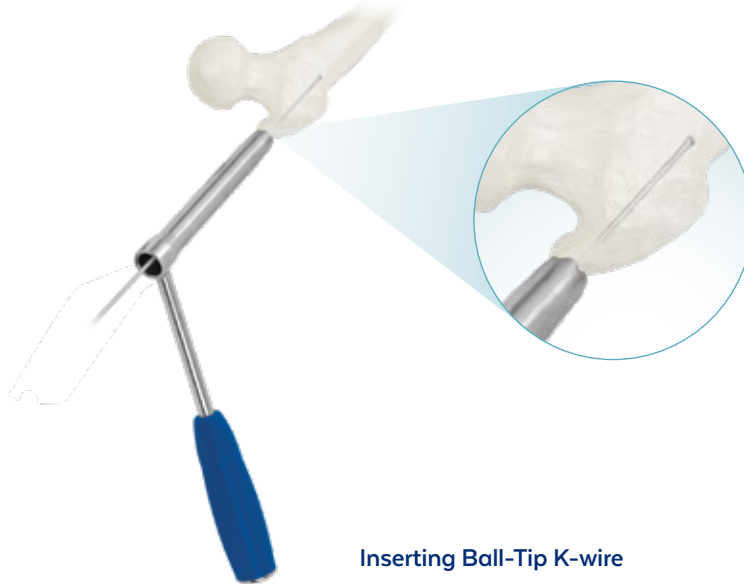


STEP

6

K-WIRE INSERTION FOR MEDULLARY CANAL

Manually insert the **3x1000mm Ball-Tip K-wire** in the center of the medullary canal. Confirm the K-wire is centered. Advance the K-wire to desired nail depth. Confirm K-wire position using fluoroscopy.



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 K-wire until it rests on the greater trochanter. Determine the corresponding nail length by reading the measurement at the end of the K-wire. Confirm the position of the Length Gauge using AP fluoroscopy.



OPTIONAL: REAM MEDULLARY CANAL

Confirm Reduction

Ensure the 3mm Ball-Tip K-wire is in the canal at the desired depth. Confirm fracture reduction using fluoroscopy.



Reaming

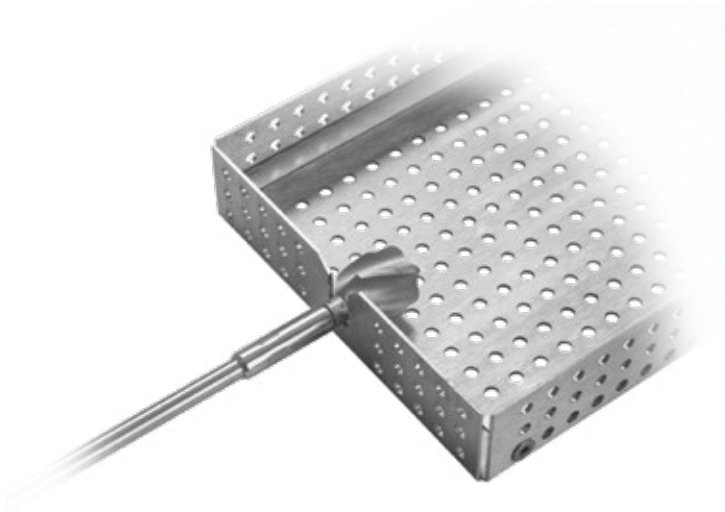
Ream in 0.5mm increments using steady pressure with the **Front Cutting Reamers**. Partially retract the reamer to clear debris from the canal while continuing rotation.

Using **Piloted Reamers**, ream up to 1.5 mm greater than the selected nail diameter. After reaming, remove the Piloted Reamer and leave the Ball-Tip K-wire in place.

If necessary, use the **K-wire Pusher** to hold the guidewire in place when retracting the reamer.



Use the reaming module cover to remove reamer tips.



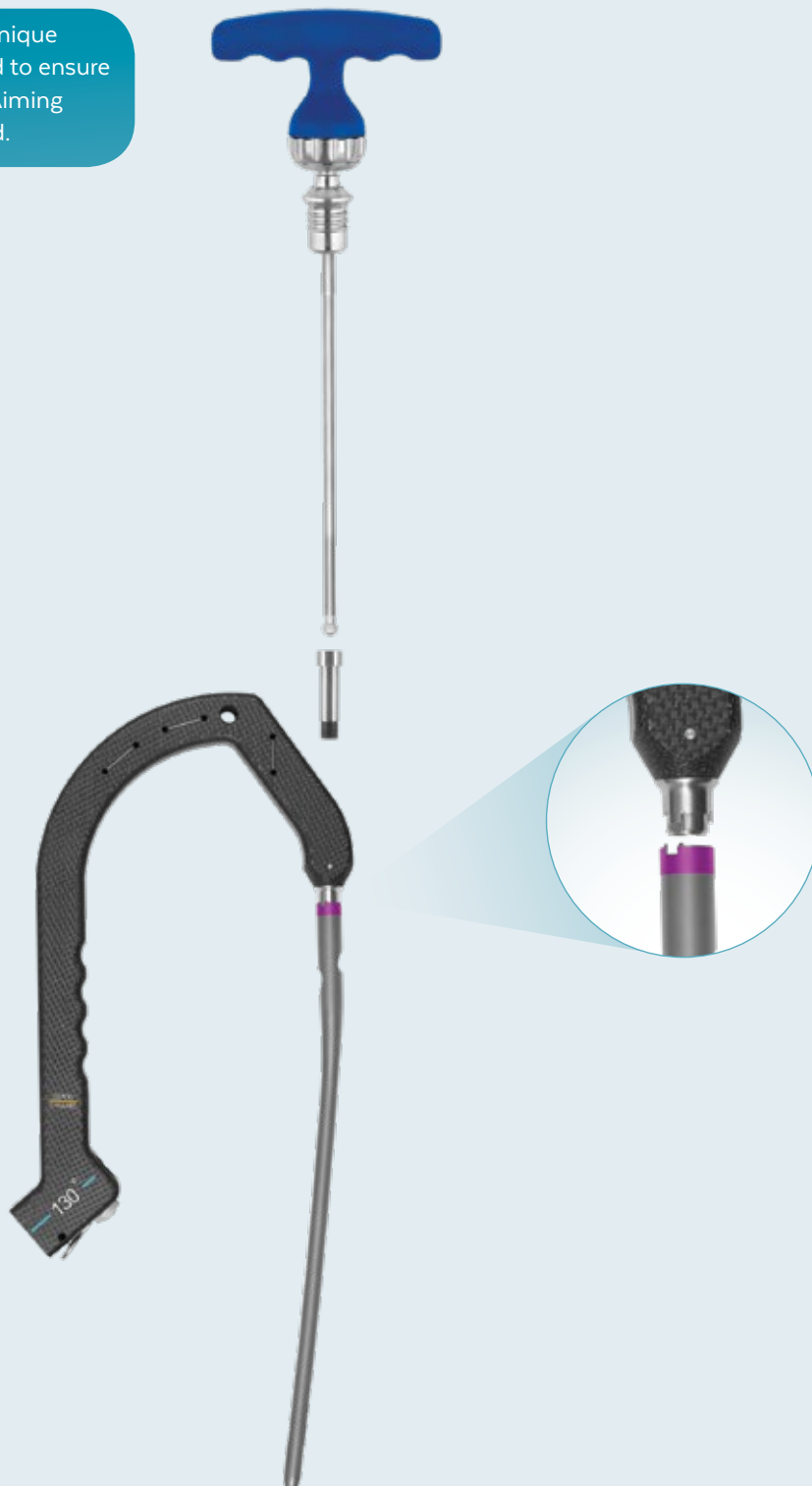
ASSEMBLING THE INSERTION HANDLE TO THE NAIL

Select the **Trochanteric Nail Insertion Handle** that corresponds to the selected nail angle. Insert the **Retention Bolt** into the Insertion Handle.

Attach the corresponding nail to the Insertion Handle using the Retention Bolt. Tighten with the **Retention Bolt Driver**.



Each nail has a unique connection keyed to ensure that the correct Aiming Guide is attached.



STEP**8****NAIL INSERTION**

Insert the nail over the Ball-Tip K-wire into the femur. Confirm fracture reduction using fluoroscopy. Insert the nail as far as possible or until the desired depth is reached.

For long nails, rotate the Insertion Handle anteriorly and advance as far as possible or until the nail reaches the isthmus. Rotate the handle laterally to the desired depth.

Remove the Ball-Tip K-wire.

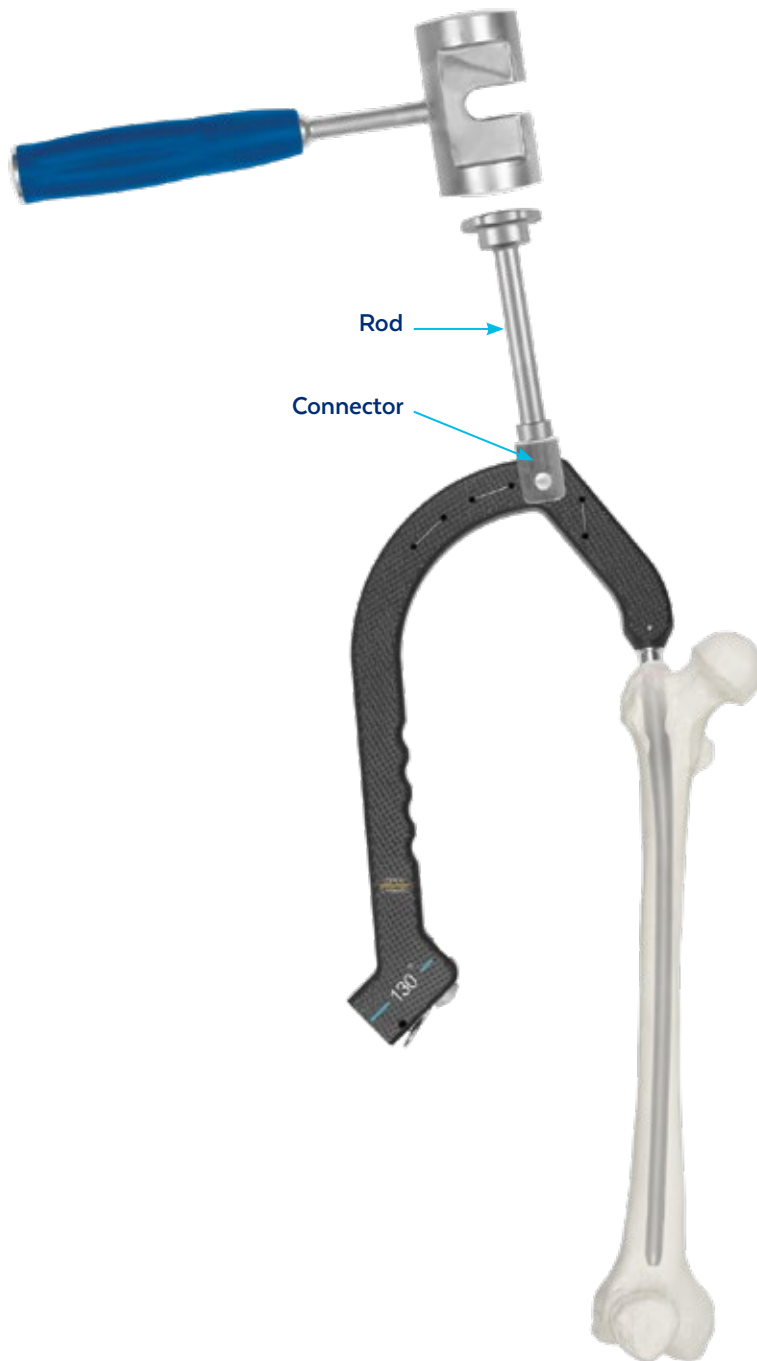


Inserting the nail

Nail Insertion with Impaction

If the nail does not insert easily, select a short or long **Impaction Rod** and thread into the **Impaction Connector**. Connect the Impaction Connector to the Trochanteric Nail Insertion Guide. Apply light taps to the proximal end of the Impaction Rod using the **Slotted Mallet** to slowly advance the nail.

Using fluoroscopy, monitor the nail position during impaction. Remove the Impaction Rod and Impaction Connector when the nail is in the desired position.



STEP

9

VERIFYING NAIL ANTEVERSION

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



ASSEMBLING THE LAG SCREW GUIDE SLEEVE

Ensure correct anteversion of the nail using fluoroscopy and the 3.2mm Threaded K-wire.

Place the color-coded **Lag Screw Drill Guide**, **Lag Screw Wire Guide**, and **Trocar** into the Trochanteric Nail Insertion Handle.

Create an incision and insert the assembly by gently tapping until the tip reaches the cortical wall. Ratchet the Drill Guide to secure it in place.



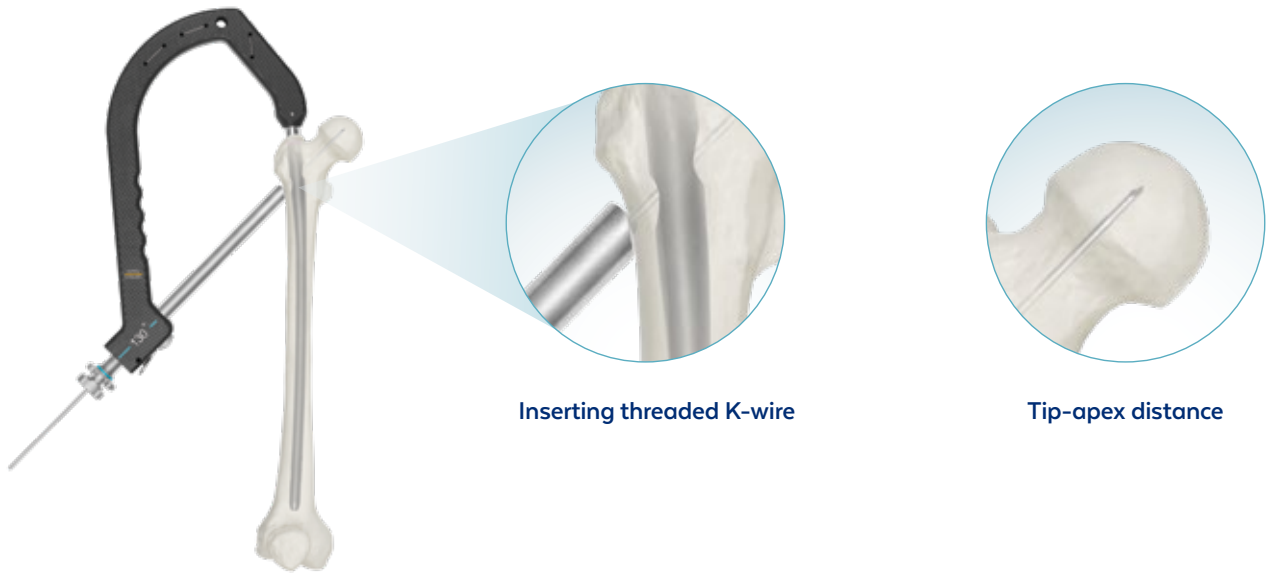
Do not over-ratchet or strike the Lag Screw Drill Guide as this may deform the Insertion Handle.



STEP 10 K-WIRE INSERTION FOR LAG SCREW

Remove the Trocar and pass the 3.2mm Threaded K-wire through the Lag Screw Wire Guide until bone is reached. Advance the K-wire into the femoral head until the desired position is reached.


Optimal K-wire placement into the femoral head should minimize tip-apex distance.



STEP 11 LAG SCREW PREPARATION

Remove the Lag Screw Wire Guide from the Lag Screw Drill Guide and insert the **Lag Screw Length Gauge** over the K-wire. Measurement is prevented if the guide is not removed.

Advance the gauge over the K-wire and insert into the drill guide. The gauge can be used to press the drill guide to the bone if it is not already seated. Determine lag screw length by reading the measurement at the end of the K-wire.

 The Lag Screw Length Gauge is used to measure lag screw length. The drill and lag screws correspond to the tip of the K-wire.



Slide the **Lag Screw Drill Stop** over the **Lag Screw Step Drill** until the desired screw length is visible in the drill stop window. Drill over the K-wire to the appropriate depth on the gauge. Confirm drill depth using fluoroscopy.

If desired, tap the lag screw to the desired depth with the **T-Handle** and **Lag Screw Tap**. In dense bone, tapping may be necessary prior to screw insertion.

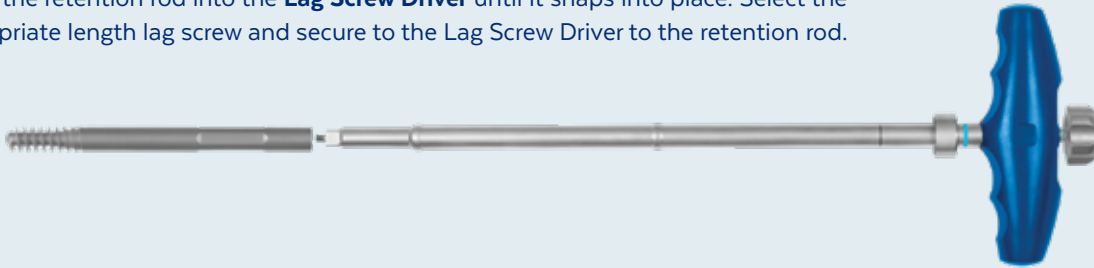


STEP

12

INSERTING THE LAG SCREW

Insert the retention rod into the **Lag Screw Driver** until it snaps into place. Select the appropriate length lag screw and secure to the Lag Screw Driver to the retention rod.



Advance the lag screw and Lag Screw Driver over the K-wire. Confirm placement using fluoroscopy.

When the appropriate depth is reached, ensure the Lag Screw Driver Handle is in line with, or perpendicular to, the Insertion Handle, for locking or controlled collapse.

Interfragmentary Compression

If compression across the fracture(s) is desired, ensure the lag screw is in the correct position and is not in contact with the set screw.

Use the locking feature on the Insertion Handle to prevent the lag screw drill guide from advancing during compression.

Attach the **Compressor** by engaging the end of the Lag Screw Drill Guide and the compression ring on the Lag Screw Driver.

Using fluoroscopy, compress the handles until the desired amount of compression is achieved. Tighten the set screw and remove the Compressor.

Use care to avoid deforming the Insertion Handle as the Compressor is powerful.



The Compressor remains connected to the drill guide and driver while applying compression.



STEP**13****ENGAGING THE SET SCREW**

To lock the construct, insert the **T40 Screw Driver** through the proximal hole on the Insertion Handle. Firmly tighten the set screw against the nail to prevent sliding of the lag screw within the nail.

For controlled collapse, insert the driver through the proximal hole on the Insertion Handle. Lightly tighten the set screw until it engages the nail. Reverse the set screw one quarter turn to allow limited sliding but not rotation of the construct.

Detach the lag screw driver from the lag screw. Remove the K-wire.



Tightening the set screw

Confirm reduction of fracture. Create a stab incision to insert the distal locking screw.

Short Nails

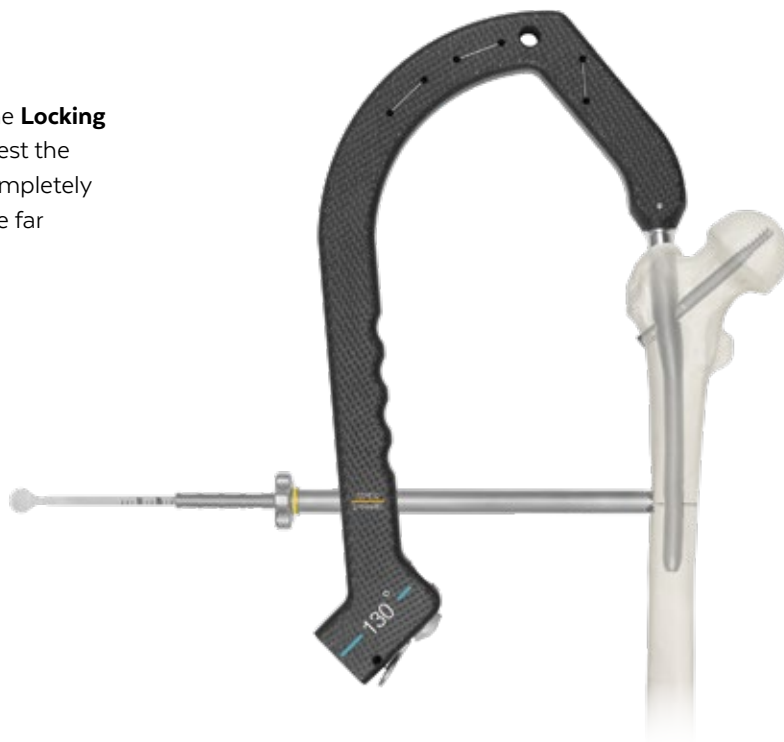
For static locking, use the superior distal locking hole etched “STATIC.” For dynamic compression, use the inferior distal locking hole etched “DYNAMIC.”

Insert the **Distal Locking Screw Driver Guide**, **Distal Locking Drill Guide**, and **Trocar** through the selected distal drill hole. Remove the Trocar when bone is reached. Insert the distal locking drill bit into the drill sleeve. Drill until the far cortical wall is reached.



Alternatively, remove the drill guide and insert the **Locking Screw Length Gauge** through the driver guide. Rest the gauge on the near cortical wall, extend the tip completely through the femur, and retract until it reaches the far cortical wall.

Determine locking screw length by reading the measurement on the gauge.



Using Length Gauge to measure screw length

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 Distal Locking Screw Driver Guide until flush with the near lateral cortex. Confirm placement using fluoroscopy.



Inserting distal locking screw

DISTAL LOCKING SCREW INSERTION (CONT'D)

Long Nails

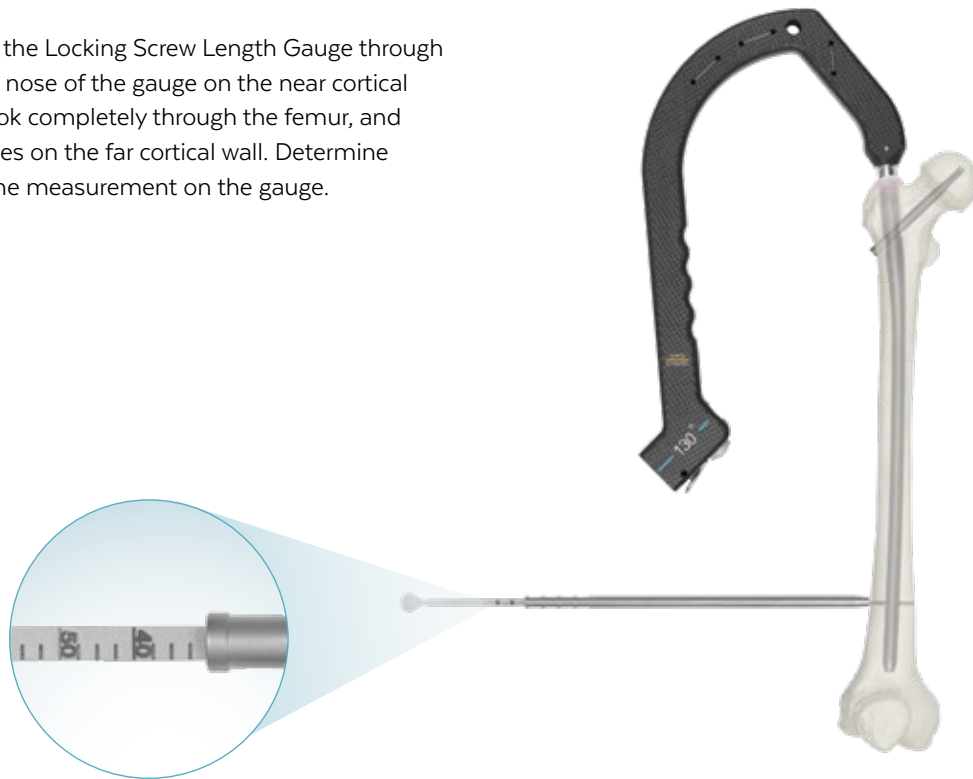
Using fluoroscopy, orient the C-arm for a lateral view of the distal locking holes to achieve a perfect circle. Distal drill holes should be perpendicular to the perfect circle.

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



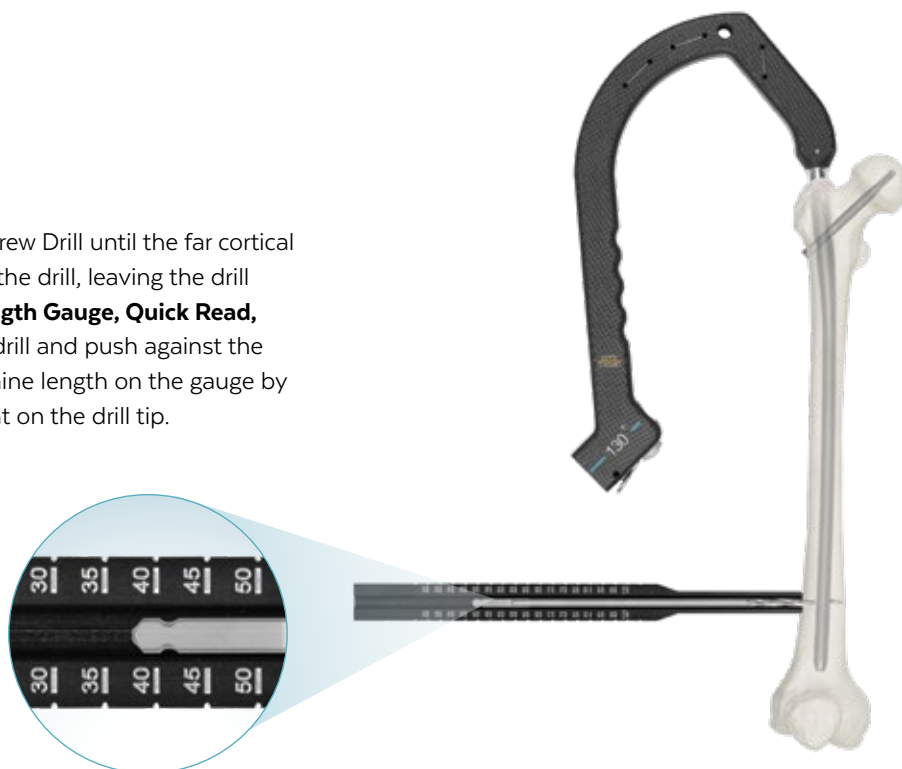
Drilling

Alternatively, insert the Locking Screw Length Gauge through 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.



Measuring using Locking Screw Length Gauge

Drill using the Locking Screw Drill until the far cortical wall is reached. Remove the drill, leaving the drill bit in place. Slide the **Length Gauge, Quick Read, Locking Screw** onto the drill and push against the near cortical wall. Determine length on the gauge by reading the measurement on the drill tip.



Measuring using Length Gauge, Quick Read, Locking Screw

Assemble the Locking Screw Driver by inserting the retention rod until it snaps into place.

Select the appropriate length 5mm Locking Screw. Using the retention rod, secure the locking screw to the Locking Screw Driver. Insert the locking screw through the Distal Locking Screw Driver Guide until flush with the near cortical wall. Confirm placement using fluoroscopy.



Inserting Distal Locking Screw

STEP

15

AIMING GUIDE REMOVAL

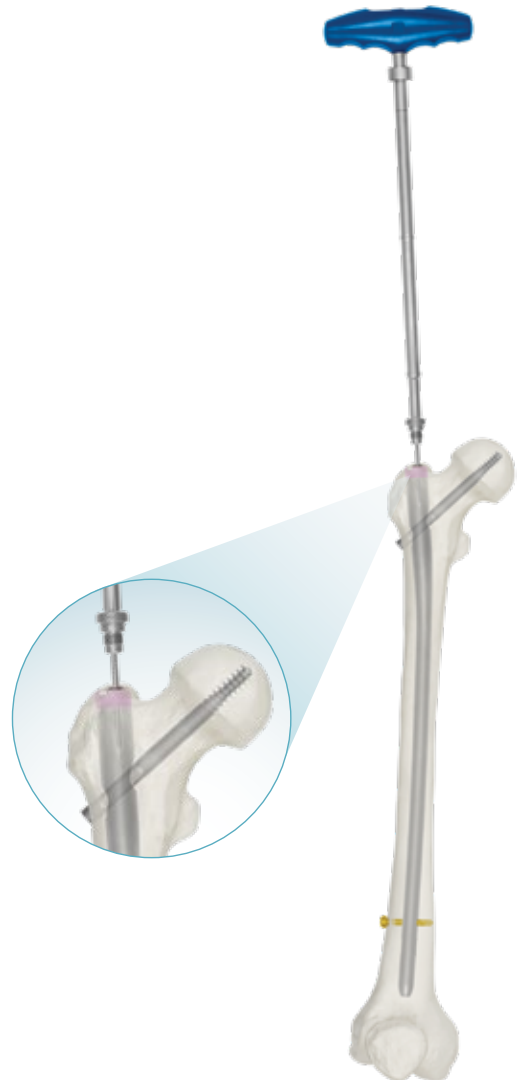
Loosen the retention bolt with the Retention Bolt Driver and remove the Insertion Handle.



OPTIONAL: END CAP INSERTION

An end cap may be used to help prevent bony ingrowth into the nail or to extend the nail length.

Using the Lag Screw Driver, insert the appropriate end cap over the 3.2mm Threaded K-wire to help with alignment.



OPTIONAL: NAIL REMOVAL

Removing Intact Nails

Use the Lag Screw Driver to remove the end cap. Use the T40 Screw Driver to remove the set screw.

To remove the lag screw, attach the Lag Screw Driver using the retention rod. Remove any bony ingrowth and re-engage the driver. Rotate the Lag Screw Driver counterclockwise until the screw is removed.

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

Remove distal locking screws by inserting the **T30 Screw Driver** and rotate counterclockwise until removed. If the screw is broken, use the **Extraction Punch** or Trephine, Locking Screw Removal Tool to remove the screw fragments.

Thread the extraction bolt into the nail and impact upward with the Slotted Mallet. Thread the long impaction rod into the extraction bolt.

Removing Broken Nails

If the nail is broken, remove the proximal nail fragment lag screw and distal locking screws, as described above.

Once removed, insert the 3.0x1000mm Ball-Tip K-wire through the nail until the ball end protrudes past the nail fragment. Insert the **Nail Removal Wire** next to the Ball-Tip K-wire until it also protrudes past the nail fragment.

Attach the **T-Handle Chuck** to the 3.0mm K-wire and 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 6176.0023



Soft Tissue Protector,
Conical Reamer 6176.0024



Guide Wire Pusher 6176.0029

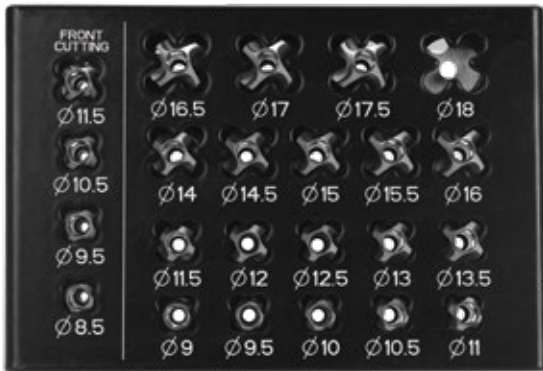


Nail Length and Diameter Gauge 6176.0010



Extension, Nail Length Gauge 6176.0011

REAMING



Reamer Head Tray 6176.0049



Flexible Reamer Shaft, 470mm 6182.0001



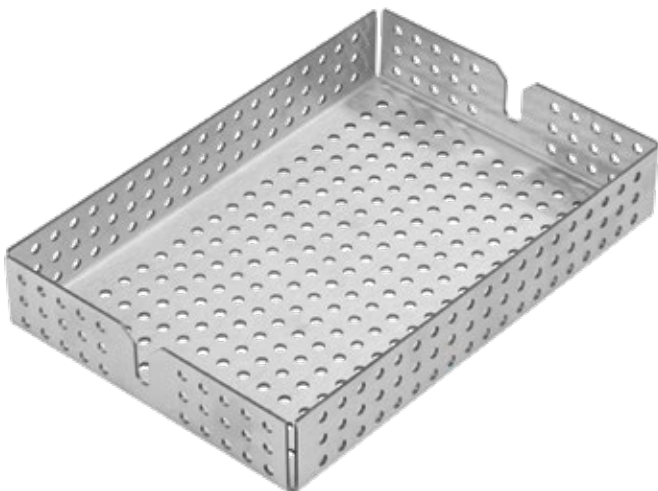
Front Cutting Reamer Heads,
8.5-11.5mm 6182.2085-.2115



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



Reamer Extension Shaft 6182.0002



Reamer Removal Tray 6176.0038

NAIL INSERTION



AUTOBAHN™ Trochanteric Nail Aiming Guide 6176.0125, .0130



Retention Bolt 6176.0002



Retention Bolt Driver 6176.0027



Slotted Mallet 6176.0020

LAG SCREW INSERTION



Drill Guide, Lag Screw 6176.0003



Wire Guide, Lag Screw 6176.0004



Trocar, Lag Screw 6176.0051



Step Drill, Lag Screw, 10mm 6176.0005



Lag Screw Tap 6176.0052

LAG SCREW INSERTION (CONT'D)



Drill Stop, Lag Screw 6176.0007



Length Gauge, Lag Screw 6176.0037



Compressor 6176.0035



Screw Driver, T40, Straight, 6176.0044



Screw Driver, T40, Hinged, 6176.0065



Lag Screw Driver 6176.0012



Retention Rod, Lag Screw Driver 6176.0043

DISTAL LOCKING INSERTION



Driver Guide, Distal Locking 6176.0017



Locking Screw Driver, Long 6176.0062



Locking Screw Driver, Short 6176.0060



Retention Rod, Locking Screw, Short 6176.0061



Retention Rod, Locking Screw, Long 6176.0063



Drill Guide, Distal Locking 6176.0041

DISTAL LOCKING INSERTION (CONT'D)



Length Gauge, Locking Screws 6176.0026



Length Gauge, Quick Read, Locking Screw 6176.0069



Locking Screw Driver, Short, For Power 6176.0055



Locking Screw Driver, Long, For Power 6176.0057



Retention Rod, Locking Screw, Long, For Power 6176.0058



Retention Rod, Locking Screw, Short, For Power 6176.0056



Distal Locking Trocar, 6176.0053

DISTAL LOCKING INSERTION (CONT'D)



Distal Locking Drill, 170mm 6176.0170



Distal Locking Drill, 295mm 6176.0270

REMOVAL



Extractor Pin Wrench 6176.0066



Impaction Rod, Short 6176.0064



Impaction Rod 6176.0016



Impaction Connector 6176.0036



Nail Removal Wire 6176.0030

REMOVAL (CONT'D)



Locking Screw Removal Tool 6176.0031



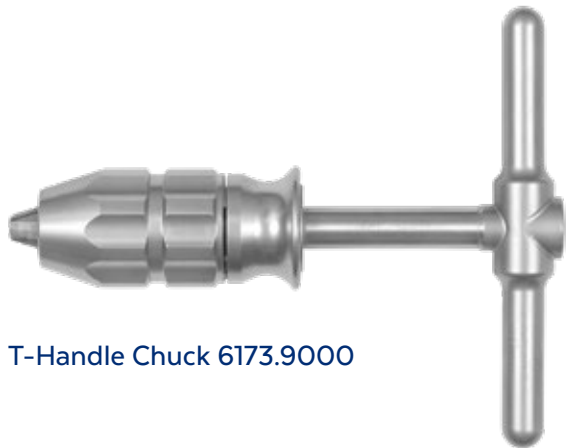
Punch 6176.0032



Trepine 6176.0048



Nail Extraction Bolt 6176.0034



T-Handle Chuck 6173.9000

K-WIRE



Ball-Tip K-wire 3.0x1000mm 6176.0022



Threaded Drill Point K-wire 3.2x450mm 6176.0021

AUTOBAHN™ Trochanteric Nail IMPLANTS

Nails 170-480mm

	125°	130°
9mm	1176.3917S - 1176.4948S	1176.5917S - 1176.6948S
10mm	1176.3017S - 1176.4048S	1176.5017S - 1176.6048S
11mm	1176.3117S - 1176.4148S	1176.5117S - 1176.6148S
12mm	1176.3232S - 1176.4248S	1176.5232S - 1176.6248S
13mm	1176.3317S - 1176.4348S	1176.3517S - 1176.6348S
14mm	1176.3417S - 1176.4448S	1176.5417S - 1176.6448S
15mm	1176.3517S - 1176.4548S	1176.5517S - 1176.6548S

11mm Lag Screws

PART NO.	DESCRIPTION
1176.0070S - 1173.0130S	70-130mm

5mm Locking Screws

PART NO.	DESCRIPTION
1183.5023S - 1183.5110S	22.5-110mm

End Caps

PART NO.	DESCRIPTION
1176.9000S - 1176.9020S	0-20mm

K-wires

PART NO.	DESCRIPTION
6176.0021S	3.2x450mm Threaded
6176.0022S	3.0x1000mm Ball Tip

AUTOBAHN™ Trochanteric Nail

Short Nail

INSTRUMENTS 9176.0048

PART NO.	DESCRIPTION	QTY
6176.0023	Conical Reamer	1
6176.0024	Soft Tissue Protector, Conical Reamer	1
6176.0002	Retention Bolt	2
6176.0027	Retention Bolt Driver	1
6176.0020	Slotted Mallet	1
6176.0003	Drill Guide, Lag Screw	1
6176.0004	Wire Guide, Lag Screw	1
6176.0051	Trocar, Lag Screw	1
6176.0005	Step Drill, Lag Screw, 10mm	1
6176.0007	Drill Stop, Lag Screw	1
6176.0037	Length Gauge, Lag Screw	1
6176.0035	Compressor	1
6176.0012	Lag Screw Driver	1
6176.0043	Retention Rod, Lag Screw Driver	1
6176.0017	Driver Guide, Distal Locking	1
6176.0042	Locking Screw Driver, Long	1
6176.0045	Locking Screw Driver, Short	1
6176.0061	Retention Rod, Locking Screw, Short	1
6176.0063	Retention Rod, Locking Screw, Long	1
6176.0041	Drill guide, Distal locking	1
6176.0065	Screw Driver, T40, Hinged	1
6176.0044	Screw Driver, T40, Straight	1
6176.0064	Impaction Rod, Short	1
6176.0036	Impaction Connector	1
6176.0048	Graphic Case	

AUTOBAHN™ Trochanteric Nail

Long Nail and Auxillary

INSTRUMENTS 9176.0049

PART NO.	DESCRIPTION	QTY
6176.0029	Guide Wire Pusher	1
6176.0010	Nail Length Gauge	1
6176.0011	Extension, Nail Length Gauge	1
9182.0001	Reamer Head Tray	1
9182.0002	Reamer Removal tray	1
6176.0052	Lag Screw Tap	1
6176.0026	Length Gauge, Locking Screws	1
6176.0055	Locking Screw Driver, Short, For Power	1
6176.0057	Locking Screw Driver, Long, For Power	1
6176.0058	Retention Rod, Locking Screw, Long, For Power	1
6176.0056	Retention Rod, Locking Screw, Short, For Power	1
6176.0016	Impaction Rod, Long	1
6176.0031	Locking Screw Removal Tool	1
6176.0032	Punch	1
6176.0048	Trephine	1
6176.0034	Nail Extraction Bolt	1
6173.9000	T-Handle Chuck	1
6176.0069	Length Gauge, Quick Read, Locking Screw	1
9176.0049	Graphic Case	

Reamer Module

PART NO.	DESCRIPTION	PART NO.	DESCRIPTION
6182.2085	Front Cutting Reamer Head, 8.5mm	6182.1130	Piloted Reamer Head, 13mm
6182.2095	Front Cutting Reamer Head, 9.5mm	6182.1135	Piloted Reamer Head, 13.5mm
6182.2105	Front Cutting Reamer Head, 10.5mm	6182.1140	Piloted Reamer Head, 14mm
6182.2115	Front Cutting Reamer Head, 11.5mm	6182.1145	Piloted Reamer Head, 14.5mm
6182.1090	Piloted Reamer Head, 9.0mm	6182.1150	Piloted Reamer Head, 15mm
6182.1095	Piloted Reamer Head, 9.5mm	6182.1155	Piloted Reamer Head, 15.5mm
6182.1100	Piloted Reamer Head, 10mm	6182.1160	Piloted Reamer Head, 16mm
6182.1105	Piloted Reamer Head, 10.5mm	6182.1165	Piloted Reamer Head, 16.5mm
6182.1110	Piloted Reamer Head, 11mm	6182.1170	Piloted Reamer Head, 17mm
6182.1115	Piloted Reamer Head, 11.5mm	6182.1175	Piloted Reamer Head, 17.5mm
6182.1120	Piloted Reamer Head, 12mm	6182.1180	Piloted Reamer Head, 18mm
6182.1125	Piloted Reamer Head, 12.5mm		

IMPORTANT INFORMATION ON ON THE 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.

IMPORTANT INFORMATION ON ON THE AUTOBAHN™ NAILING SYSTEM

- Do not use components from this system in conjunction with components from any other manufacturer's system unless otherwise specified (refer to the AUTOBAHN™ Surgical Technique Guide).

Post-operative

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

Informing the Patient

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

IMPORTANT INFORMATION ON ON THE AUTOBAHN™ NAILING SYSTEM











- 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:

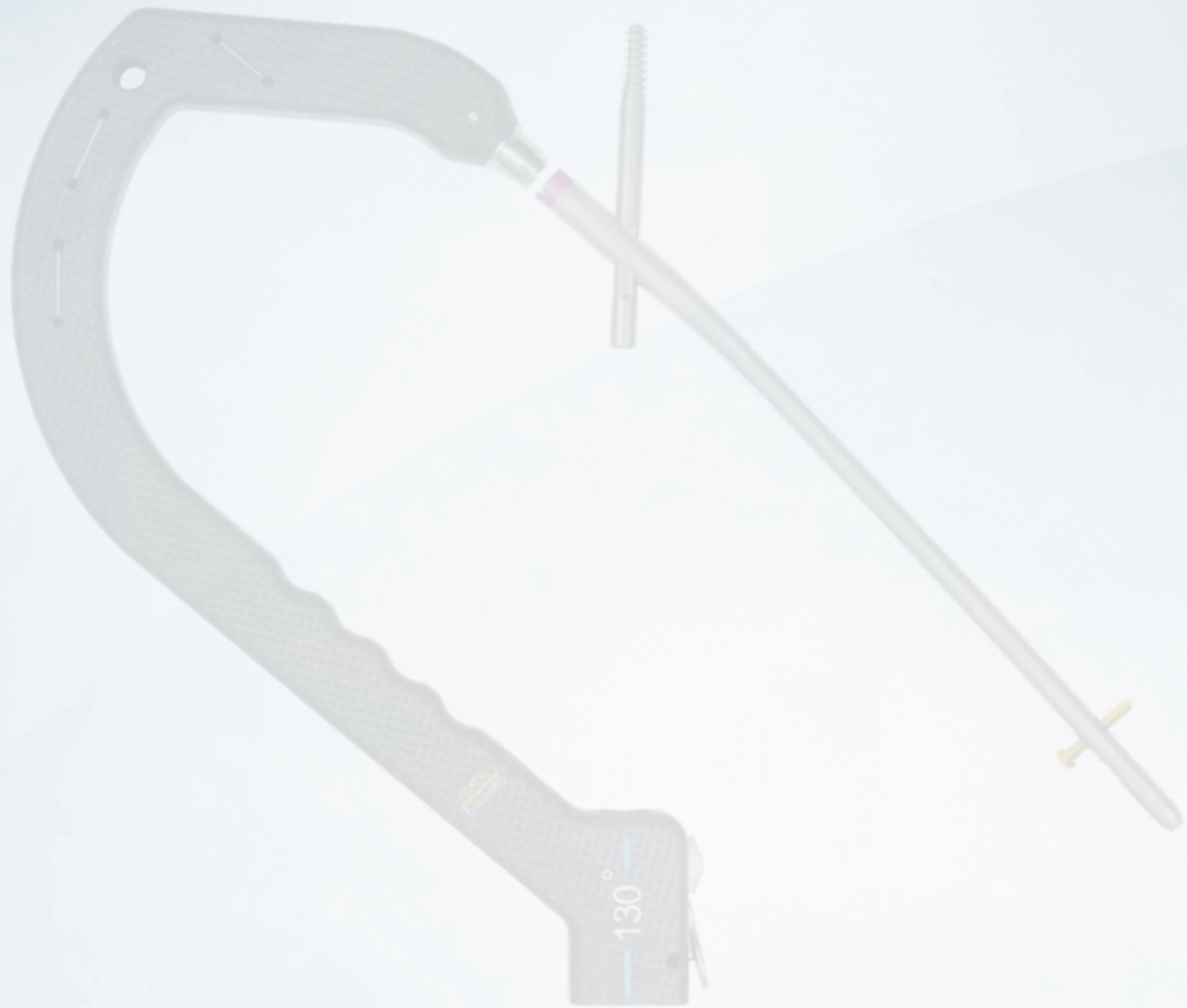
Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Pre-vacuum	132°C (270°F)	4 Minutes	30 Minutes

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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