

# AUTOBAHN®

Tibial Nailing System



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®**

# Tibial Nailing System

| System Overview                                  | 4  |
|--|----|
| Implant Overview                                 |    |
| Suprapatellar Approach: Surgical Technique       |    |
| 1. Preoperative Planning                         | 8  |
| 2. Patient Positioning                           | 8  |
| 3. Fracture Reduction                            | 9  |
| 4. Determine Length and Diameter                 | 9  |
| 5. Incision and Entry Point                      |    |
| 6. Entry Reaming                                 | 12 |
| 7. Ream Canal                                    | 13 |
| 8. Nail Attachment                               | 13 |
| 9. Nail Insertion                                | 15 |
| 10. Proximal Aiming Guide Assembly               | 16 |
| 11. Compression                                  | 17 |
| 12. Proximal Locking Screw Insertion             | 19 |
| 13. Distal Locking Screw Insertion               | 23 |
| Optional: End Cap Insertion                      | 24 |
| Optional: Nail Removal                           |    |
| Infrapatellar Approach: Surgical Technique       |    |
| 1. Preoperative Planning                         |    |
| 2. Patient Positioning                           |    |
| 3. Fracture Reduction                            | 27 |
| 4. Determine Length and Diameter                 | 27 |
| 5. Incision and Entry Point                      |    |
| 6. Entry Reaming                                 | 29 |
| 7. Ream Canal                                    | 30 |
| 8. Nail Attachment                               | 30 |
| 9. Nail Insertion                                | 32 |
| 10. Proximal Aiming Guide Assembly               | 33 |
| 11. Compression                                  | 34 |
| 12. Proximal Locking Screw Insertion             |    |
| 13. Distal Locking Screw Insertion               | 40 |
| Optional: End Cap Insertion                      | 41 |
| Optional: Nail Removal                           | 42 |
| Instrument Overview                              | 43 |
| AUTOBAHN® Tibial Nailing System Implants         | 57 |
| ANTHEM® Small Fragment Fracture System Module    | 64 |
| CAPTIVATE® 4.0 Headless Compression Screw Module |    |
| AUTOBAHN® Tibial Nailing System Instruments      | 68 |
| Universal Reamer Module                          |    |
| AUTOBAHN® Tibial Nailing System Instruments      |    |
| Important Information                            | 74 |

# **AUTOBAHN®**

# Tibial Nailing System

The AUTOBAHN® Tibial Nailing System is a comprehensive system that incorporates both infrapatellar and suprapatellar approaches in a single tray. The system provides multiple fixation options to address a variety of tibia fractures.

### Threaded Anterior Oblique Locking Holes

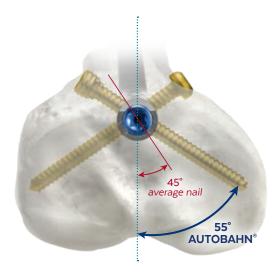
Allow for lagging of anterior fracture fragments





# Unique 55° Proximal Oblique Screws

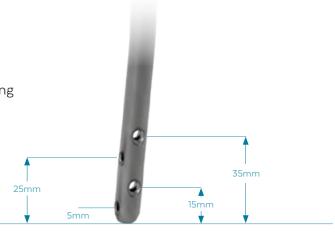
Accommodate the natural anatomy of the tibia to reduce screw prominence around the tibial tuberosity





# Distal Locking Options

- SureStart<sup>™</sup> threaded locking featured in all four distal locking holes allows for optimal fixation in distal patterns
- · Most distal hole is 5mm from the distal end of the nail for extreme nailing cases
- · Most proximal hole is 35mm from the distal end of nail



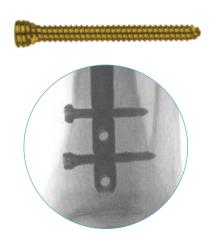
# Suprapatellar Cannula

- One-piece soft Suprapatellar Cannula reduces intraoperative assembly and is designed to protect the articular surface
- · Provides multiple pin anchoring options to the femur and tibia



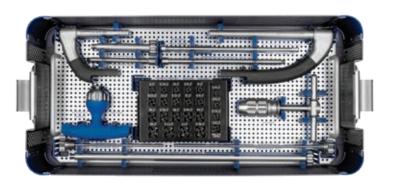
# Headless Locking Screws

Designed to reduce soft tissue irritation



### Comprehensive Instrument Set

Includes instruments for suprapatellar and infrapatellar approaches



# Radiolucent Aiming Guide

· Designed for accuracy and clarity



# Self-Retaining Drill Sleeve

- · Easy, automatic retention during proximal locking screw drilling and insertion
- · Avoids targeter deflection during screw insertion



# Compression Bolt

· Instrument-based compression retains functionality of all holes in the nail



Locking screw in dynamic slot



Locking screw in compression mode

### **IMPLANT** OVERVIEW

#### **Tibial Nail**

- Designed to treat a variety of tibial shaft fractures and help reduce soft tissue irritation
- 10° Herzog Bend
  - Located 67mm from the proximal end of the nail for optimal fit



#### **Locking Screws**

- Headless screws to help reduce tissue irritation
- Standard and headless locking screws
  - 4mm Locking Screws
    - · 8-9mm Nails
    - Compression slot
    - · Static mediolateral
    - · All distal holes
- 5mm Locking Screws
  - · 8-9mm Nails
    - · Proximal oblique holes
    - SureStart<sup>™</sup> Anterior oblique hole
  - · 10-15mm Nails
  - · All locking options
- Partially threaded screws are available for use in non-threaded holes and compression slots



#### **End Caps**

- Compress the most proximal oblique screw to create a fixed angle construct
- Optional cap to prevent tissue ingrowth into the proximal end of the nail



# **SURGICAL** TECHNIQUE

# AUTOBAHN® Tibial Nailing System

# Suprapatellar Approach

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



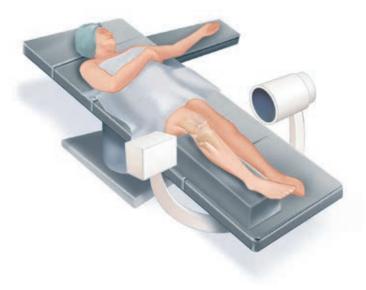
#### PREOPERATIVE PLANNING

Use the nail length and diameter ruler to estimate the appropriate nail needed for the medullary canal. Place the ruler flush against the uninjured tibia. Use the C-arm to confirm nail length and diameter.

# **STEP**

### PATIENT POSITIONING

The patient is placed under anesthesia and positioned supine on a radiolucent table with the operative leg in the semiextended position, which allows for AP and lateral views without moving the operative leg.





Lateral view

AP view

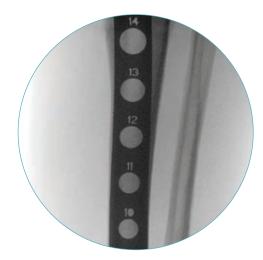
#### FRACTURE REDUCTION **STEP**

Fracture reduction is necessary to re-establish anatomic length, alignment, and rotation of the tibia. Direct reduction instruments and small fragment plates are available to help achieve reduction.



# DETERMINE LENGTH AND DIAMETER

Use the Radiographic Nail Length and Diameter Gauge to determine nail length and diameter. Measure the diameter of the intramedullary canal at the narrowest point. Determine the nail length where the gauge aligns with the physeal scar or the desired nail insertion depth. Length may also be determined by reading the measurement on the K-wire.



Diameter measurement



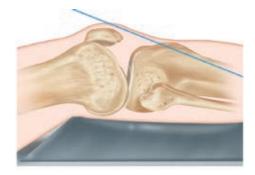
Length measurement

# STEP

# INCISION AND ENTRY POINT

With the knee extended, create a longitudinal incision superior to the patella. Expose the quadriceps tendon by blunt dissection and longitudinally split the tendon at its midline. Ensure that there is enough space for the Suprapatellar Cannula to fit under the patella. The entry point is shown below in different views.







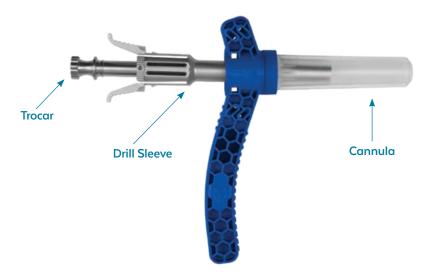
Longitudinal incision

Ventral edge of tibial plateau

Axis of medullary canal

#### **Cannula Assembly**

Connect the Suprapatellar Cannula and Suprapatellar Drill Sleeve, and cut the Suprapatellar Trocar to form the Suprapatellar Cannula assembly.



Suprapatellar Cannula Assembly

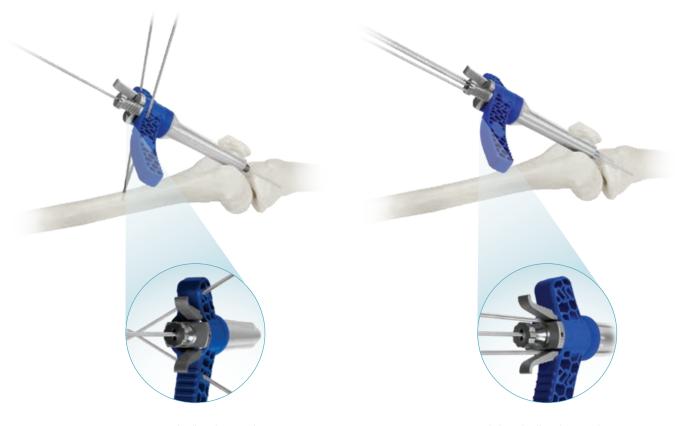
#### **K-Wire Insertion**

Insert the Suprapatellar Cannula assembly into the incision until it reaches the entry point in the proximal tibia.

Insert **3.2x450mm Threaded Tip K-Wires** through the Trocar, manually or under power, into the proximal tibia. Insert K-wires to the desired depth (approximately 8-10cm).



Anchor the Suprapatellar Cannula into the proximal tibia or distal femur using 3.2x450mm Threaded Tip K-Wires. Confirm K-wire position using AP and lateral fluoroscopy.



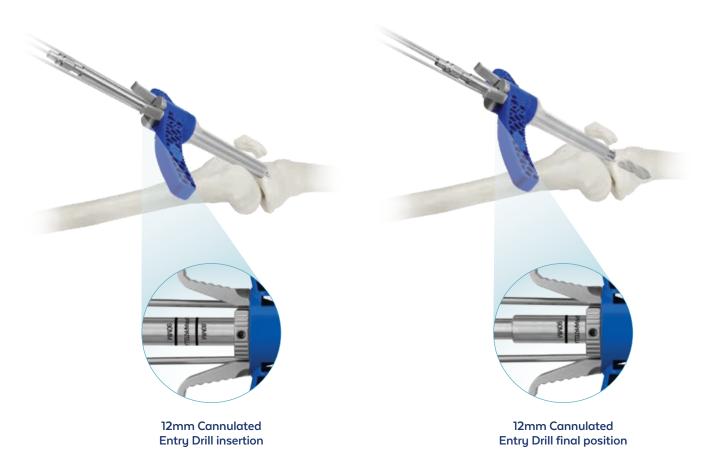
Femoral pin fixation option

Tibial pin fixation option

#### STEP **ENTRY REAMING**

Remove the Suprapatellar Trocar and advance the Cannula and Drill Sleeve to the entry point in the proximal tibia. Using the 12mm Cannulated Entry Drill, drill over the K-wire through the Drill Sleeve until it reaches the entry point in the proximal tibia. Open the medullary canal using the 12mm Cannulated Entry Drill and drill through the Drill Sleeve to the desired depth (approximately 8-10cm). Do not contact the posterior cortex. Note the markings on the drill for suggested depths.

Confirm position and trajectory using fluoroscopy in AP and lateral views. Remove the K-wire and drill.



#### **Ball-Tip K-Wire Insertion**

Manually insert the **3x1000mm Ball-Tip K-Wire** through the Cannula and Drill Sleeve into the center of the canal. Advance the K-wire past the fracture line toward the distal tibia. Using fluoroscopy, confirm that the K-wire is centered.



Ball-Tip K-wire passing fracture line

#### **STEP REAM CANAL**

Confirm cannula position before reaming.

Use fluoroscopy to confirm fracture reduction. Ensure that the 3mm Ball-Tip K-Wire is in the canal at the desired depth.

Through the Suprapatellar Cannula and Suprapatellar Drill Sleeve, use the selected reamer to ream in 0.5mm increments, under power applying steady pressure. Partially retract the reamer to clear debris from the canal while maintaining power. Ream to 0.5-1.5mm greater than the selected nail diameter.

If necessary, the 620mm Flexible Reamer Shaft may be used for the suprapatellar approach for nail lengths over 300mm.

Remove the reamer and the Suprapatellar Drill Sleeve.

Remove the Reamer Shaft, leaving the Ball-Tip K-wire in place for a later step.



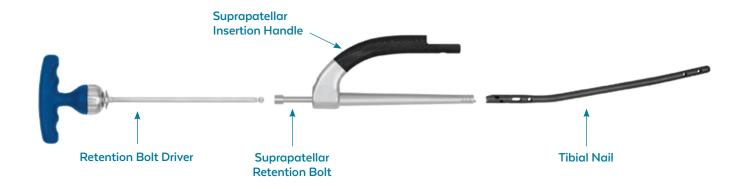
Reamer advancement over Ball-Tip K-wire

# STEP

### **NAIL ATTACHMENT**

Connect the Suprapatellar Insertion Handle and Suprapatellar Retention Bolt to the proximal end of the nail using the Retention Bolt Driver.

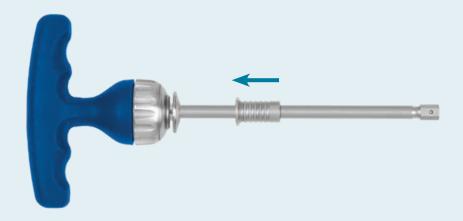
Confirm secure connection of nail to handle.



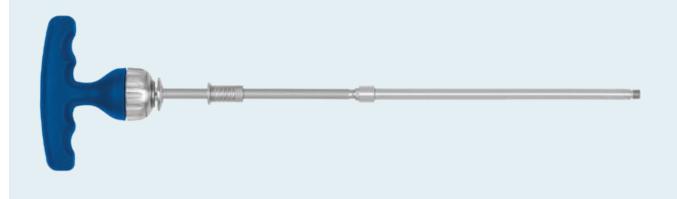
# **O** 8MM SELF-RETAINING DRIVER SHAFT

The 8mm Self-Retaining Driver Shaft may be used instead of the Retention Bolt Driver to connect the Retention Bolt to the nail.

Pull back the retention sleeve on the driver shaft.



Insert the driver shaft into the hex of the Retention Bolt to release retention.



#### **NAIL INSERTION** STEP

Ensure that the Retention Bolt is tightened when inserting the nail.

Insert the nail assembly over the K-wire through the Suprapatellar Cannula until the desired depth is reached. Attach the Impactor to the Suprapatellar Insertion Handle to assist with nail insertion. Impact using the Slotted Mallet. Avoid impacting the carbon fiber portion of the insertion handle directly.

Use fluoroscopy to confirm proximal nail location.

Remove the 3mm Ball-Tip K-Wire.

If fracture compression using the dynamic locking screw slot is desired, the nail must be over-inserted a safe distance from the entry point to accommodate 7mm of maximum compression.



Nail insertion with Impactor



Nail fully seated

# STEP

# PROXIMAL AIMING GUIDE ASSEMBLY

Attach the **Proximal Aiming Guide** to the Suprapatellar Insertion Handle by connecting the location pins onto the Insertion Handle. Ensure that the Aiming Guide is fully seated and secured. Rotate the thumb screw clockwise until the Aiming Guide Insertion Handle assembly is rigid.



Attaching the Proximal Aiming Guide



Fully assembled

#### STEP **COMPRESSION**

To compress the fracture up to 7mm, use the compression slot at the proximal end of the nail. Insert the **Soft Tissue Sleeve**, appropriate drill sleeve, and Trocar into the dynamic position in the Proximal Aiming Guide after locking distally.

Create a stab incision at the intersection of the Soft Tissue Sleeve and skin surface. Advance the Soft Tissue Sleeve until it reaches bone. Drill through both cortices of the bone using the selected drill and drill sleeve. Remove the drill sleeve.

| Drill Size   | Locking Screw Diameter | Where Used  |
|--------------|------------------------|---|
| <b>3.3mm</b> | 4mm                    | <ul><li>8-9mm nails</li><li>Compression slot hole</li><li>Static mediolateral holes</li><li>All distal holes</li></ul>  |
| • 4.2mm      | 5mm                    | <ul> <li>8-9mm nails</li> <li>Proximal oblique holes</li> <li>SureStart™ anterior oblique hole</li> <li>10-15mm nails</li> <li>All locking options</li> </ul> |



Creating a stab incision

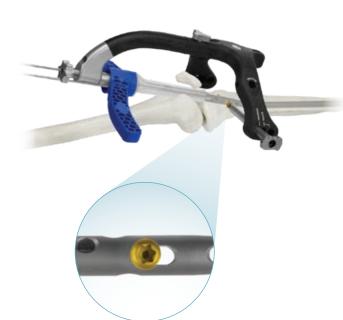


# COMPRESSION (CONT'D)

Insert a locking screw into the dynamic position of the nail through the Soft Tissue Sleeve. Using the **Suprapatellar Compression Bolt**, compress the locking screw in the static position until the desired compression is achieved.

Insert a second proximal locking screw into the most distal static hole of the proximal locking options to lock in the compression. Remove the Compression Bolt before inserting oblique screws.





Locking screw in dynamic slot



Locking screw in compression mode

Alternatively, attach the Impactor and Slap Hammer Shaft to use the backslap technique.

If necessary, over-insert the nail to avoid nail prominence after compression.



Backslap technique



# PROXIMAL LOCKING SCREW INSERTION

#### **Insert Trocar Assembly**

Insert the three-part Trocar assembly (Soft Tissue Sleeve, Drill Sleeve, and Trocar) through the desired proximal hole in the Proximal Aiming Guide.

Ensure that the correct drill sleeve and Trocar combination are chosen for the corresponding nail.

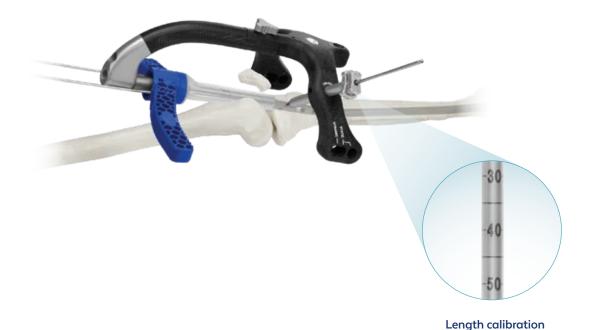


| Drill Size    | Locking Screw Diameter | Nail Details  |
|---------------|------------------------|---|
| <b>3.3</b> mm | 4mm                    | <ul><li>8-9mm nails</li><li>Compression slot hole</li><li>Static mediolateral holes</li><li>All distal holes</li></ul>            |
| • 4.2mm       | 5mm                    | 8-9mm nails     Proximal oblique holes     SureStart <sup>™</sup> anterior oblique hole     10-15mm nails     All locking options |

#### **Drill and Determine Length**

Ensure that the drill sleeve is securely placed. Use the drill corresponding to the screw size as shown in the table above. Drill through both cortices until the tip penetrates the far cortex.

Confirm drill bit position using fluoroscopy. Determine the length from the calibrated drill bit and select the corresponding locking screw. Remove the drill and drill sleeve. Alternatively, the depth gauge may be used to determine screw length.



# PROXIMAL LOCKING SCREW INSERTION (CONT'D)

#### **Insert Locking Screw**

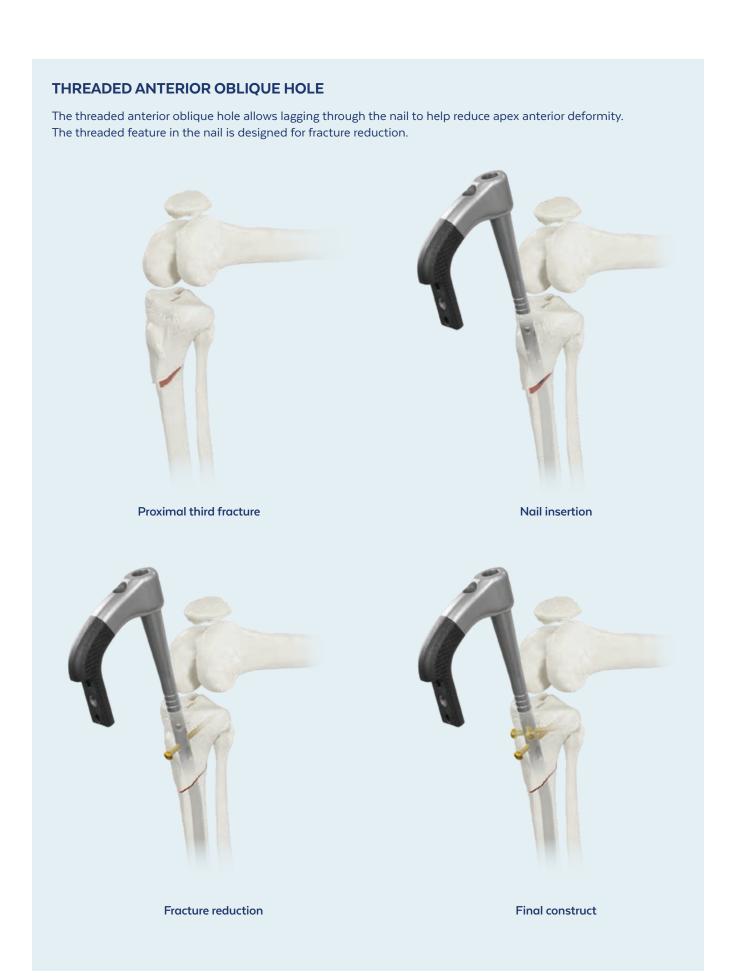
Assemble the Locking Screw Driver by inserting the Retention Rod until it snaps into place.

Select the appropriate locking screw. Using the Retention Rod, secure the locking screw to the Locking Screw Driver. Insert the locking screw through the Soft Tissue Sleeve, manually or under power.

Confirm placement using fluoroscopy.

Repeat steps for additional proximal holes as necessary.





#### **HEADLESS LOCKING SCREWS**

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

Headless screws can be used instead of standard locking screws with any locking options in the AUTOBAHN® Tibial Nailing System. They should only be placed in metaphyseal bone.

#### **Headless Screw Insertion**

Drill and determine length as described in Step 12.

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 tool is available.



**Headless Locking Screw** insertion with driver



**Headless Locking Screw** fully inserted

# DISTAL LOCKING SCREW INSERTION

#### **Alignment**

Use the appropriate locking screws and drill bit for the selected diameter nail.

If using the backslap technique or Compression Bolt, distal locking must be performed before proximal locking.

Using fluoroscopy, confirm fracture reduction prior to distal locking. Align the C-arm with the distal hole until a perfect circle is formed.



#### **Determine Incision Point**

Determine the incision point using fluoroscopy.



#### **Drill and Determine Length**

Insert the appropriate drill tip in the center of the locking hole. Confirm position using fluoroscopy. The drill should almost completely fill the hole. Hold the drill in this position and drill through both cortices.

Remove the drill and insert the Locking Screw Length Gauge through the pre-drilled hole. Rest the gauge on the near cortical wall, extend the tip completely through the tibia, and retract until it reaches the far cortical wall.

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



#### **Insert Locking Screw**

Insert the appropriate length locking screw using the Locking Screw Driver manually or under power. Verify screw length using fluoroscopy. Insert up to four locking screws following the steps above.



# DISTAL LOCKING SCREW INSERTION (CONT'D)

#### **Removing Instruments**

Loosen the Retention Bolt with the Retention Bolt Driver. Remove the Insertion Handle and Aiming Guide assembly together. Detach the Aiming Guide by rotating the thumbwheel counterclockwise.

#### OPTIONAL: END CAP INSERTION

Once the nail is in position, remove the Suprapatellar Insertion Handle by unthreading the Retention Bolt using the Retention Bolt Driver. Alternatively, remove the Retention Bolt, as the Suprapatellar Insertion Handle can be used to align the end cap to the top of the nail.

Optional end caps are available to prevent bony ingrowth or to extend the nail length. The end cap engages the most proximal oblique locking screw to create a fixed-angle construct. Use a 1.8mm K-wire to assist with end cap insertion if desired. Attach the end cap to the Long Locking Screw Driver and insert it into the top of the nail. Confirm nail position using fluoroscopy.



End cap insertion

End cap fully seated

### OPTIONAL: NAIL REMOVAL

Remove the nail through an infrapatellar incision.

Clear the end cap and the locking implants (T30 Driver) of any tissue ingrowth. Remove the end cap using the Long Locking Screw Driver. Remove all locking screws except one proximal locking screw using the Locking Screw Driver.

Before removing the final locking screw, thread the **Extraction Bolt** into the nail and tighten to prevent rotation or displacement of the nail posteriorly below the tibial plateau. Attach the Slap Hammer Shaft to the Extraction Screw. Remove the remaining locking screw using the Locking Screw Driver.

Gently impact to extract the nail using the Slotted Mallet.



End cap removal

**Extraction Bolt insertion** 



Slap Hammer Shaft attachment

Nail removal

# **SURGICAL** TECHNIQUE

# AUTOBAHN® Tibial Nailing System Infrapatellar Approach



#### PREOPERATIVE PLANNING

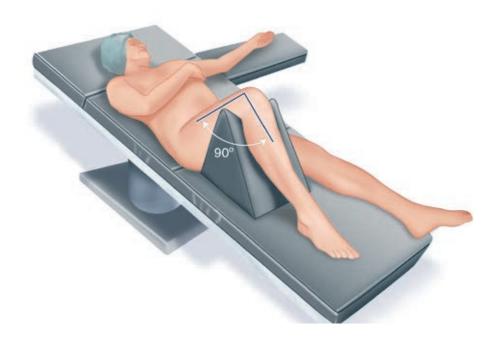
Use the nail length and diameter ruler to estimate the appropriate nail needed for the medullary canal. Place the ruler flush against the uninjured tibia. Use the C-arm to confirm nail length and diameter.

# **STEP**

#### PATIENT POSITIONING

Place the patient under anesthesia and position supine on the radiolucent table with the injured leg flexed at 90°. If necessary, use a bump to allow for fracture reduction and stabilization.

Position the C-arm so the tibia is visualized in the AP and lateral views.



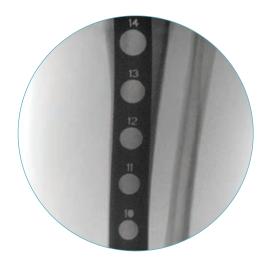
#### FRACTURE REDUCTION **STEP**

Fracture reduction is necessary to re-establish anatomic length, alignment, and rotation of the tibia. Direct reduction instruments and small fragment plates are available to help achieve reduction.



# DETERMINE LENGTH AND DIAMETER

Use the Radiographic Nail Length and Diameter Gauge to determine nail length and diameter. Measure the diameter of the intramedullary canal at the narrowest point. Determine the nail length where the gauge aligns with the physeal scar or the desired nail insertion depth. Length may also be determined by reading the measurement on the K-wire.



Diameter measurement



Length measurement

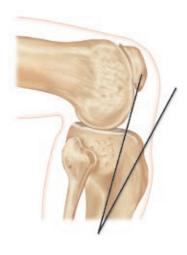
# **STEP**

# INCISION AND ENTRY POINT

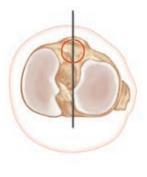
Create an incision in line with the central axis of the tibial canal starting at the inferior pole of the patella and extending to the tibial tuberosity. The entry point is shown below in different views.



Axis of intramedullary canal



Ventral edge of tibial plateau



Intercondylar eminence

#### **K-Wire Insertion**

Insert the 3.2mm Threaded Tip K-Wire, manually or under power, into the proximal tibia to the desired depth (approximately 8-10cm).

Confirm K-wire position using fluoroscopy in AP and lateral views.



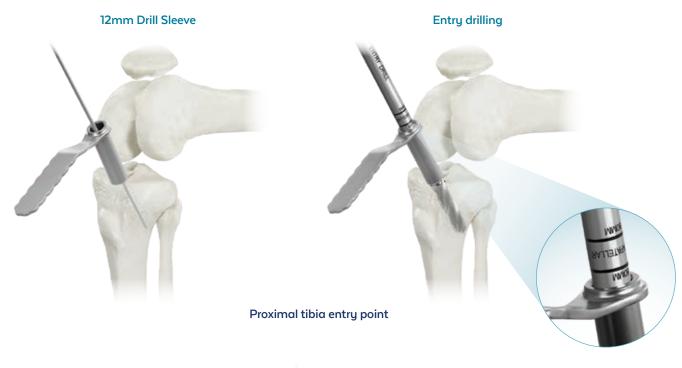
K-wire insertion

#### **ENTRY REAMING STEP**

Place the 12mm Infrapatellar Drill Sleeve over the K-wire until it reaches the entry point in the proximal tibia. Open the proximal tibia using the 12mm Cannulated Entry Drill and drill through the drill sleeve to the desired depth (approximately 8-10cm). Do not contact the posterior cortex. Note the markings on the drill for suggested depths.

Confirm position and trajectory using fluoroscopy in AP and lateral views. Remove the K-wire, drill, and drill sleeve.

Alternatively, place the Cannulated Awl over the K-wire through the 12mm Infrapatellar Drill Sleeve and open the medullary canal. Rotate to advance the awl to the desired depth (approximately 8-10cm). Remove the K-wire, awl, and drill sleeve.



#### **Ball-Tip K-Wire Insertion**

Manually insert the 3x1000mm Ball-Tip K-Wire into the center of the canal. Advance the K-wire past the fracture line toward the distal tibia to desired nail depth. Using fluoroscopy, confirm that the K-wire is centered.



Insert Ball-Tip K-wire

#### **REAM CANAL STEP**

With the selected reamer, ream in 0.5mm increments under power applying steady pressure. Partially retract the reamer to clear debris from the canal while maintaining power. Ream to 0.5-1.5mm greater than the selected nail diameter.

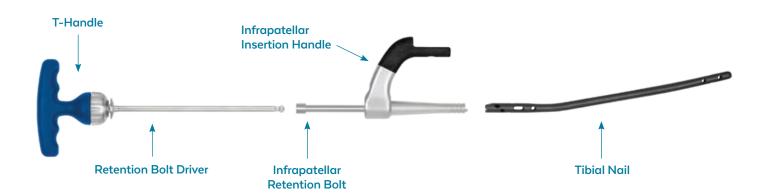
Remove the Reamer Shaft and leave the Ball-Tip K-wire in place for a later step.



# STEP

# **NAIL ATTACHMENT**

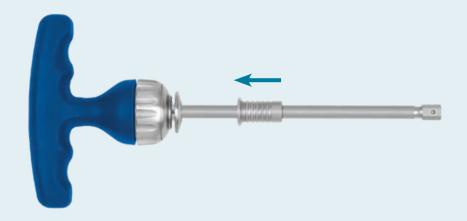
Connect the Infrapatellar Insertion Handle and Tibial Nail Infrapatellar Retention Bolt to the proximal end of the nail using the Retention Bolt Driver.



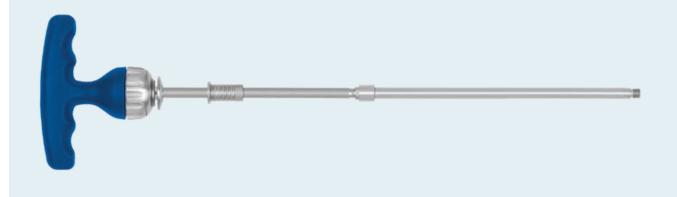
# **O** 8MM SELF-RETAINING DRIVER SHAFT

The 8mm Self-Retaining Driver Shaft may be used instead of the Retention Bolt Driver to connect the Retention Bolt to the nail.

Pull back the retention sleeve on the driver shaft.



Insert the driver shaft into the hex of the Retention Bolt to release retention.



#### **NAIL INSERTION STEP**

Ensure that the Retention Bolt is tightened when inserting the nail.

Insert the nail assembly into the intramedullary canal by rotating and advancing it until it is at or below the tibial opening. Attach the Impactor to the Infrapatellar Insertion Handle. Impact using the Impactor or use the Slap Hammer Shaft with the Slotted Mallet. Avoid impacting the carbon fiber portion of the insertion handle directly.

Use fluoroscopy to confirm proximal nail location.

Remove the 3mm Ball-Tip K-Wire.

If fracture compression using the dynamic locking screw slot is desired, the nail must be over-inserted a safe distance from the entry point to accommodate 7mm of maximum compression.



Nail insertion with Impactor

Nail fully seated

# STEP

# PROXIMAL AIMING GUIDE ASSEMBLY

Attach the Proximal Aiming Guide to the Infrapatellar Insertion Handle by connecting the location pins onto the Insertion Handle. Ensure that the Aiming Guide is fully seated and secured. Rotate the thumb screw clockwise until the Aiming Guide assembly is rigid.



Fully assembled

#### STEP **COMPRESSION**

To compress fractures up to 7mm, use the compression slot at the proximal end of the nail. Insert the Soft Tissue Sleeve, the appropriate drill sleeve, and the Trocar into the dynamic position in the Proximal Aiming Guide after locking distally.

Create a stab incision at the intersection of the Soft Tissue Sleeve and skin surface. Advance the Soft Tissue Sleeve until it reaches bone. Drill through both cortices of the bone using the selected drill and drill sleeve. Remove the drill sleeve.

| Drill Size | Locking Screw Diameter | Nail Details   |
|------------|------------------------|--|
| 9 3.3mm    | 4mm                    | <ul><li>8-9mm nails</li><li>Compression slot</li><li>Static mediolateral</li><li>All distal holes</li></ul>  |
| • 4.2mm    | 5mm                    | <ul> <li>8-9mm Nails</li> <li>Proximal oblique holes</li> <li>SureStart<sup>™</sup> anterior oblique hole</li> <li>10-15mm nails</li> <li>All locking options</li> </ul> |



**Drilling through cortices** 

Insert a locking screw into the dynamic position of the nail through the Soft Tissue Sleeve. Using the Infrapatellar Compression Bolt, compress the locking screw in the static position until the desired compression is achieved.

Insert a second proximal locking screw into the most distal static hole of the proximal locking options to lock in the compression. Remove the Infrapatellar Compression Bolt before inserting oblique screws.

Alternatively, attach the Impactor and Slap Hammer Shaft to use the backslap technique.





Locking screw in dynamic slot



Locking screw in compression mode



Backslap technique



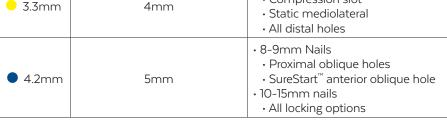
# PROXIMAL LOCKING SCREW INSERTION

#### **Insert Trocar Assembly**

Insert the three-part Trocar assembly (Soft Tissue Sleeve, Drill Sleeve, and Trocar) through the desired proximal hole in the Proximal Aiming Guide.

Ensure that the correct drill sleeve and Trocar combination are chosen for the corresponding nail.

| Drill Size | Locking Screw Diameter | Nail Details  |
|------------|------------------------|---|
| - 3.3mm    | 4mm                    | <ul><li>8-9mm nails</li><li>Compression slot</li><li>Static mediolateral</li><li>All distal holes</li></ul>           |
| • 4.2mm    | 5mm                    | 8-9mm Nails     Proximal oblique holes     SureStart™ anterior oblique hole     10-15mm nails     All locking options |



#### **Drill and Determine Length**

Ensure that the drill sleeve is securely placed. Use the drill corresponding to the screw size as shown in the table above. Drill through both cortices until the tip penetrates the far cortex.

Confirm drill bit position using fluoroscopy. Determine the length from the calibrated drill bit and select the corresponding locking screw. Remove the drill and drill sleeve. Alternatively, the depth gauge may be used to determine screw length.



# **Insert Locking Screw**

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

Select the appropriate locking screw. Using the Retention Rod, secure the locking screw to the Locking Screw Driver. Insert the locking screw through the Soft Tissue Sleeve, manually or under power.

Confirm placement using fluoroscopy.

Repeat steps for additional proximal holes as necessary.





The threaded anterior oblique hole allows lagging through the nail to help reduce apex anterior deformity. The threaded feature in the nail is designed for fracture reduction.



Proximal third fracture



Nail insertion



Fracture reduction



Final construct

### **HEADLESS LOCKING SCREWS**

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

Headless screws can be used instead of standard locking screws with any locking options in the AUTOBAHN® Tibial Nailing System. They should only be placed in metaphyseal bone.

# **Headless Screw Insertion**

Drill and determine length as described in Step 12.

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 tool is available.



**Headless Locking Screw** insertion with driver



**Headless Locking Screw** fully inserted

# DISTAL LOCKING SCREW INSERTION

# **Alignment**

Use the appropriate locking screws and drill bit for the selected diameter nail.

If using the backslap technique or Compression Bolt, distal locking must be performed before proximal locking.

Using fluoroscopy, confirm fracture reduction prior to distal locking. Align the C-arm with the distal hole until a perfect circle is formed.



# **Determine Incision Point**

Determine the incision point using fluoroscopy.



# **Drill and Determine Length**

Insert the appropriate drill tip in the center of the locking hole. Confirm position using fluoroscopy. The drill should almost completely fill the hole. Hold the drill in this position and drill through both cortices.

Remove the drill and insert the Locking Screw Length Gauge through the pre-drilled hole. Rest the gauge on the near cortical wall, extend the tip completely through the tibia, and retract until it reaches the far cortical wall.

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



# **Insert Locking Screw**

Insert the appropriate length locking screw using the Locking Screw Driver manually or under power. Verify screw length using fluoroscopy. Insert up to four locking screws following the steps above.



# **Removing Instruments**

Loosen the Retention Bolt with the Retention Bolt Driver. Remove the Insertion Handle and Aiming Guide assembly together. Detach the Aiming Guide by rotating the thumbwheel counterclockwise.

# **OPTIONAL: END CAP INSERTION**

Once the nail is in position, remove the Insertion Handle by unthreading the Retention Bolt using the Retention Bolt Driver. Alternatively, remove the Retention Bolt as the Infrapatellar Insertion Handle can be used to align the end cap to the top of the nail.

Optional end caps are available to prevent bony ingrowth or to extend the nail length. The end cap engages the most proximal oblique locking screw to create a fixed-angle construct. Use a 1.8mm K-wire to assist with end cap insertion if desired. Attach the end cap to the Long Locking Screw Driver and insert into the top of the nail as desired. Confirm nail position using fluoroscopy.



**End cap insertion** 

End cap fully inserted

# OPTIONAL: NAIL REMOVAL

Remove the nail through an infrapatellar incision.

Clear the end cap and the locking implants (T30 Driver) of any tissue ingrowth. Remove the end cap using the Locking Screw Driver. Remove all locking screws except one proximal locking screw using the Locking Screw Driver.

Before removing the final locking screw, thread the Extraction Bolt into the nail and tighten to prevent rotation or displacement of the nail posteriorly below the tibial plateau. Attach the Slap Hammer Shaft to the Extraction Screw. Remove the remaining locking screw using the Locking Screw Driver.

Gently impact to extract the nail using the Slotted Mallet.



End cap removal



Slap Hammer Shaft attachment

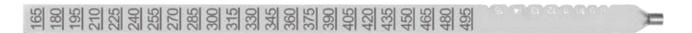
Nail removal

# **INSTRUMENT** OVERVIEW

# **PROXIMAL ENTRY**



Radiographic Length and Diameter Gauge 6183.1002



AUTOBAHN® Tibial Nail Length Gauge 6183.1101



Extension Nail Length Gauge 6176.0011

Threaded Drill Point K-Wire 3.2x450mm 6176.0021





12mm Infrapatellar Drill Sleeve 6183.1005

# PROXIMAL ENTRY (CONT'D)



12mm Cannulated Entry Drill 6183.1006



Suprapatellar Cannula Drill Sleeve 8-11mm 6183.1091



Suprapatellar Trocar 8-11mm 6183.1092

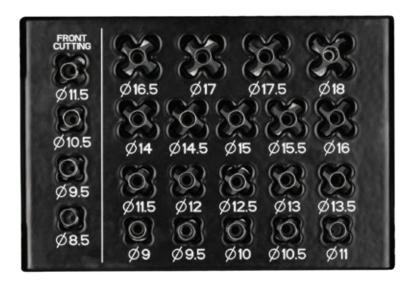


AUTOBAHN® Tibial Nail Suprapatellar Cannula 8-11mm 6183.1096

AUTOBAHN® Tibial Nail Suprapatellar Cannula 8-11mm, without tibial pins 6183.112S

Ball-Tip K-Wire 3.0x1000mm 6176.0022

# **REAMING**



Reamer Head Caddy 9182.0001



Flexible Reamer Shaft, 470mm 6182.0004S



Flexible Reamer Shaft, 620mm 6182.0005S



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

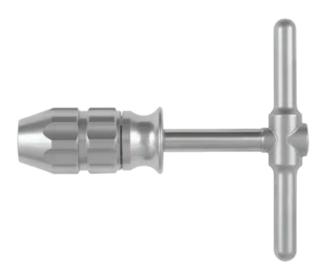


Piloted Reamer Head, 9.0-18mm 6182.1090-.1180

# REAMING (CONT'D)



Reamer Removal Tray 9182.0002



Cannulated T-Handle Jacobs Chuck 6173.9000



Intramedullary Reduction Device 6190.0080

# **REAMING (CONT'D)**



Guide Wire Pusher 6176.0029

Exchange Tube 6183.1043

# **NAIL INSERTION**



AUTOBAHN® Tibial Nail Infrapatellar Handle Assembly 6183.1016



AUTOBAHN® Tibial Nail Infrapatellar Retention Bolt 6183.1018

# NAIL INSERTION (CONT'D)



AUTOBAHN<sup>®</sup> Tibial Nail Suprapatellar Handle Assembly 6183.1015



AUTOBAHN® Tibial Nail Suprapatellar Retention Bolt 6183.1017



8mm T-Handle Ratcheting Driver 6067.0020

# NAIL INSERTION (CONT'D)



Retention Bolt Driver Shaft 6176.0027



8mm Self-Retaining Driver Shaft 6183.1102



Impactor 6183.1020



Slap Hammer Shaft 6183.1094



Slotted Mallet 6176.0020

# LOCKING INSTRUMENTS



AUTOBAHN® Tibial Nail Proximal Aiming Guide 6183.1024



Soft Tissue Drill Sleeve 6183.1054



Drill Sleeve 4.2mm 6183.1083



Trocar 4.2mm 6183.1085



4.2mm Drill, Short 150mm 6183.1030



4.2mm Drill Graduated, Long 330mm 6183.1031

# LOCKING INSTRUMENTS (CONT'D)



Infrapatellar Compression Bolt 6183.1081

# LOCKING INSTRUMENTS (CONT'D) Retention Rod, Locking Screw, Short 6176.0061 Locking Screw Driver, Short 6176.0045 Retention Rod, Locking Screw, Short 6176.0063 T30 Self-Retaining Driver, Long, Tibial Nail 6183.1107 Retention Rod, Locking Screw, Short for Power 6176.0056

Locking Screw Driver, Short for Power 6176.0055

Retention Rod, Locking Screw, Long for Power 6176.0058

# LOCKING INSTRUMENTS (CONT'D)



Length Gauge, Locking Screws 6176.0026



AUTOBAHN® Countersink, Long, 5mm Headless 6183.1104



AUTOBAHN® Countersink, Short, 5mm Headless 6183.1105



AUTOBAHN® Countersink, Long, 4mm Headless 6183.1106



Length Gauge, Distal Screws, Tibial Nail 6183.1108



T30 Self-Retaining Power Driver, Long, Tibial Nail 6183.1109



Hall Quick-Connect Handle 6190.3000

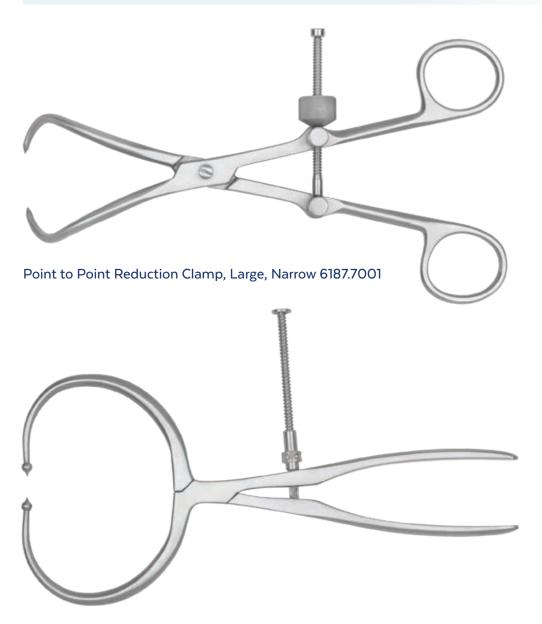


Length Gauge, Locking Screw, Short 6176.0071

# **REMOVAL INSTRUMENTS** Locking Screw Removal Tool 6176.0031 4mm Locking Screw Removal Tool 6183.1103 Punch 6176.0032 Trephine 6176.0048 AUTOBAHN® Tibial Nail Extraction Bolt 6183.1001

Extractor Pin Wrench 6176.0066

# **REDUCTION INSTRUMENTS**



Ball Spike Reduction Clamp, Large 6187.7004



Ball Spike Pusher 6183.1098

# **SMALL FRAGMENT INSTRUMENTS**



T15 Driver, SR, Cannulated, 150mm AO Quick-Connect 6168.5215



Screw Holding Forceps 6179.2000



3.5mm Spring Loaded Soft Tissue Protector 6179.3135



Cannulated Quick-Connect Handle, Internal Coupling 6188.7000



Depth Gauge, 60mm 6179.7020

# **AUTOBAHN®** Tibial Nailing System **IMPLANT SETS**

# 9183.9101

| Part No.   | Description                        | Qty |
|------------|------------------------------------|-----|
| 1183.1025S | AUTOBAHN® Ti Tibial Nail, 10x255mm | 1   |
| 1183.1027S | AUTOBAHN® Ti Tibial Nail, 10x270mm | 1   |
| 1183.1028S | AUTOBAHN® Ti Tibial Nail, 10x285mm | 1   |
| 1183.1030S | AUTOBAHN® Ti Tibial Nail, 10x300mm | 1   |
| 1183.1031S | AUTOBAHN® Ti Tibial Nail, 10x315mm | 2   |
| 1183.1033S | AUTOBAHN® Ti Tibial Nail, 10x330mm | 2   |
| 1183.1034S | AUTOBAHN® Ti Tibial Nail, 10x345mm | 2   |
| 1183.1036S | AUTOBAHN® Ti Tibial Nail, 10x360mm | 2   |
| 1183.1037S | AUTOBAHN® Ti Tibial Nail, 10x375mm | 1   |
| 1183.1039S | AUTOBAHN® Ti Tibial Nail, 10x390mm | 1   |
| 1183.1040S | AUTOBAHN® Ti Tibial Nail, 10x405mm | 1   |

# 9183.9102

| Part No.   | Description                                    | Qty |
|------------|--|-----|
| 1183.1042S | AUTOBAHN® Ti Tibial Nail, 10x420mm             | 1   |
| 1183.1043S | AUTOBAHN® Ti Tibial Nail, 10x435mm             | 1   |
| 1183.1125S | AUTOBAHN® Ti Tibial Nail, 11x255mm             | 1   |
| 1183.1127S | AUTOBAHN® Ti Tibial Nail, 11x270mm             | 1   |
| 1183.11285 | AUTOBAHN <sup>®</sup> Ti Tibial Nail, 11x285mm | 1   |
| 1183.1130S | AUTOBAHN® Ti Tibial Nail, 11x300mm             | 1   |
| 1183.1131S | AUTOBAHN® Ti Tibial Nail, 11x315mm             | 2   |
| 1183.1133S | AUTOBAHN <sup>®</sup> Ti Tibial Nail, 11x330mm | 2   |
| 1183.1134S | AUTOBAHN® Ti Tibial Nail, 11x345mm             | 2   |
| 1183.1136S | AUTOBAHN® Ti Tibial Nail, 11x360mm             | 2   |
| 1183.1137S | AUTOBAHN <sup>®</sup> Ti Tibial Nail, 11x375mm | 1   |

# **AUTOBAHN®** Tibial Nailing System **IMPLANT SETS**

# 9183.9103

| Part No.   | Description                        | Qty |
|------------|------------------------------------|-----|
| 1183.11395 | AUTOBAHN® Ti Tibial Nail, 11x390mm | 1   |
| 1183.1140S | AUTOBAHN® Ti Tibial Nail, 11x405mm | 1   |
| 1183.11425 | AUTOBAHN® Ti Tibial Nail, 11x420mm | 1   |
| 1183.11435 | AUTOBAHN® Ti Tibial Nail, 11x435mm | 1   |
| 1183.1225S | AUTOBAHN® Ti Tibial Nail, 12x255mm | 1   |
| 1183.1227S | AUTOBAHN® Ti Tibial Nail, 12x270mm | 1   |
| 1183.1228S | AUTOBAHN® Ti Tibial Nail, 12x285mm | 1   |
| 1183.1230S | AUTOBAHN® Ti Tibial Nail, 12x300mm | 1   |
| 1183.1231S | AUTOBAHN® Ti Tibial Nail, 12x315mm | 1   |
| 1183.1233S | AUTOBAHN® Ti Tibial Nail, 12x330mm | 1   |
| 1183.1234S | AUTOBAHN® Ti Tibial Nail, 12x345mm | 1   |
| 1183.1236S | AUTOBAHN® Ti Tibial Nail, 12x360mm | 1   |
| 1183.1237S | AUTOBAHN® Ti Tibial Nail, 12x375mm | 1   |
| 1183.1239S | AUTOBAHN® Ti Tibial Nail, 12x390mm | 1   |
| 1183.1240S | AUTOBAHN® Ti Tibial Nail, 12x405mm | 1   |

# 9183.9104

| Part No.   | Description                                    | Qty |
|------------|--|-----|
| 1183.1242S | AUTOBAHN® Ti Tibial Nail, 12x420mm             | 1   |
| 1183.1243S | AUTOBAHN® Ti Tibial Nail, 12x435mm             | 1   |
| 1183.1325S | AUTOBAHN® Ti Tibial Nail, 13x255mm             | 1   |
| 1183.1327S | AUTOBAHN® Ti Tibial Nail, 13x270mm             | 1   |
| 1183.1328S | AUTOBAHN® Ti Tibial Nail, 13x285mm             | 1   |
| 1183.1330S | AUTOBAHN <sup>®</sup> Ti Tibial Nail, 13x300mm | 1   |
| 1183.1331S | AUTOBAHN <sup>®</sup> Ti Tibial Nail, 13x315mm | 1   |
| 1183.1333S | AUTOBAHN® Ti Tibial Nail, 13x330mm             | 1   |
| 1183.1334S | AUTOBAHN° Ti Tibial Nail, 13x345mm             | 1   |
| 1183.1336S | AUTOBAHN <sup>®</sup> Ti Tibial Nail, 13x360mm | 1   |
| 1183.1337S | AUTOBAHN <sup>®</sup> Ti Tibial Nail, 13x375mm | 1   |
| 1183.1339S | AUTOBAHNv Ti Tibial Nail, 13x390mm             | 1   |
| 1183.1340S | AUTOBAHN <sup>®</sup> Ti Tibial Nail, 13x405mm | 1   |
| 1183.1342S | AUTOBAHN® Ti Tibial Nail, 13x420mm             | 1   |
| 1183.1343S | AUTOBAHN <sup>®</sup> Ti Tibial Nail, 13x435mm | 1   |

# **AUTOBAHN®** Tibial Nailing System **IMPLANT SETS**

# 9183.9105

| Part No.   | Description                                   | Qty |
|------------|---|-----|
| 1183.1825S | AUTOBAHN <sup>®</sup> Ti Tibial Nail, 8x255mm | 1   |
| 1183.1827S | AUTOBAHN® Ti Tibial Nail, 8x270mm             | 1   |
| 1183.1828S | AUTOBAHN® Ti Tibial Nail, 8x285mm             | 1   |
| 1183.1830S | AUTOBAHN® Ti Tibial Nail, 8x300mm             | 1   |
| 1183.1831S | AUTOBAHN® Ti Tibial Nail, 8x315mm             | 1   |
| 1183.1833S | AUTOBAHN® Ti Tibial Nail, 8x330mm             | 1   |
| 1183.1834S | AUTOBAHN® Ti Tibial Nail, 8x345mm             | 1   |
| 1183.1836S | AUTOBAHN® Ti Tibial Nail, 8x360mm             | 1   |
| 1183.1837S | AUTOBAHN® Ti Tibial Nail, 8x375mm             | 1   |
| 1183.1839S | AUTOBAHN® Ti Tibial Nail, 8x390mm             | 1   |
| 1183.1840S | AUTOBAHN® Ti Tibial Nail, 8x405mm             | 1   |
| 1183.1842S | AUTOBAHN® Ti Tibial Nail, 8x420mm             | 1   |
| 1183.1843S | AUTOBAHN® Ti Tibial Nail, 8x435mm             | 1   |
| 1183.1925S | AUTOBAHN® Ti Tibial Nail, 9x255mm             | 1   |
| 1183.1927S | AUTOBAHN® Ti Tibial Nail, 9x270mm             | 1   |

# 9183.9106

| Part No.   | Description                                   | Qty |
|------------|---|-----|
| 1183.1928S | AUTOBAHN® Ti Tibial Nail, 9x285mm             | 1   |
| 1183.1930S | AUTOBAHN® Ti Tibial Nail, 9x300mm             | 1   |
| 1183.1931S | AUTOBAHN <sup>®</sup> Ti Tibial Nail, 9x315mm | 1   |
| 1183.1933S | AUTOBAHN° Ti Tibial Nail, 9x330mm             | 1   |
| 1183.1934S | AUTOBAHN° Ti Tibial Nail, 9x345mm             | 1   |
| 1183.1936S | AUTOBAHN <sup>®</sup> Ti Tibial Nail, 9x360mm | 1   |
| 1183.1937S | AUTOBAHN° Ti Tibial Nail, 9x375mm             | 1   |
| 1183.1939S | AUTOBAHN® Ti Tibial Nail, 9x390mm             | 1   |
| 1183.1940S | AUTOBAHN <sup>®</sup> Ti Tibial Nail, 9x405mm | 1   |
| 1183.1942S | AUTOBAHN® Ti Tibial Nail, 9x420mm             | 1   |
| 1183.1943S | AUTOBAHN® Ti Tibial Nail, 9x435mm             | 1   |

# **AUTOBAHN®** Tibial Nailing System IMPLANT SET 9183.9107

| Part No.   | Description  | Qty | Part No.   | Description  | Qty |
|------------|--|-----|------------|--|-----|
| 1183.2025S | Ti Headless Locking Screw, 5x25mm, Fully Threaded      | 2   | 1183.2078S | Ti Headless Locking Screw,<br>5x77.5mm, Fully Threaded | 2   |
| 1183.2028S | Ti Headless Locking Screw, 5x27.5mm, Fully Threaded    | 2   | 1183.2080S | Ti Headless Locking Screw,<br>5x80mm, Fully Threaded   | 2   |
| 1183.2030S | Ti Headless Locking Screw, 5x30mm, Fully Threaded      | 2   | 1183.2083S | Ti Headless Locking Screw,<br>5x82.5mm, Fully Threaded | 2   |
| 1183.2033S | Ti Headless Locking Screw, 5x32.5mm, Fully Threaded    | 2   | 1183.2085S | Ti Headless Locking Screw,<br>5x85mm, Fully Threaded   | 2   |
| 1183.2035S | Ti Headless Locking Screw, 5x35mm, Fully Threaded      | 2   | 1183.2088S | Ti Headless Locking Screw,<br>5x87.5mm, Fully Threaded | 2   |
| 1183.2038S | Ti Headless Locking Screw, 5x37.5mm, Fully Threaded    | 2   | 1183.2090S | Ti Headless Locking Screw,<br>5x90mm, Fully Threaded   | 2   |
| 1183.2040S | Ti Headless Locking Screw, 5x40mm, Fully Threaded      | 2   | 1183.5025S | Ti Locking Screw, 5x25mm,<br>Fully Threaded            | 2   |
| 1183.2043S | Ti Headless Locking Screw, 5x42.5mm, Fully Threaded    | 2   | 1183.5028S | Ti Locking Screw, 5x27.5mm,<br>Fully Threaded          | 2   |
| 1183.2045S | Ti Headless Locking Screw, 5x45mm, Fully Threaded      | 2   | 1183.5030S | Ti Locking Screw, 5x30mm,<br>Fully Threaded            | 2   |
| 1183.2048S | Ti Headless Locking Screw, 5x47.5mm, Fully Threaded    | 2   | 1183.5033S | Ti Locking Screw, 5x32.5mm,<br>Fully Threaded          | 2   |
| 1183.2050S | Ti Headless Locking Screw, 5x50mm, Fully Threaded      | 2   | 1183.5035S | Ti Locking Screw, 5x35mm,<br>Fully Threaded            | 2   |
| 1183.2053S | Ti Headless Locking Screw, 5x52.5mm, Fully Threaded    | 2   | 1183.5038S | Ti Locking Screw, 5x37.5mm,<br>Fully Threaded          | 2   |
| 1183.2055S | Ti Headless Locking Screw,<br>5x55mm, Fully Threaded   | 2   | 1183.5040S | Ti Locking Screw, 5x40mm,<br>Fully Threaded            | 2   |
| 1183.2058S | Ti Headless Locking Screw,<br>5x57.5mm, Fully Threaded | 2   | 1183.5043S | Ti Locking Screw, 5x42.5mm,<br>Fully Threaded          | 2   |
| 1183.2060S | Ti Headless Locking Screw, 5x60mm, Fully Threaded      | 2   | 1183.5045S | Ti Locking Screw, 5x45mm,<br>Fully Threaded            | 2   |
| 1183.2063S | Ti Headless Locking Screw, 5x62.5mm, Fully Threaded    | 2   | 1183.5048S | Ti Locking Screw, 5x47.5mm,<br>Fully Threaded          | 2   |
| 1183.2065S | Ti Headless Locking Screw, 5x65mm, Fully Threaded      | 2   | 1183.5050S | Ti Locking Screw, 5x50mm,<br>Fully Threaded            | 2   |
| 1183.2068S | Ti Headless Locking Screw, 5x67.5mm, Fully Threaded    | 2   | 1183.5053S | Ti Locking Screw, 5x52.5mm,<br>Fully Threaded          | 2   |
| 1183.2070S | Ti Headless Locking Screw, 5x70mm, Fully Threaded      | 2   | 1183.5055S | Ti Locking Screw, 5x55mm,<br>Fully Threaded            | 2   |
| 1183.2073S | Ti Headless Locking Screw, 5x72.5mm, Fully Threaded    | 2   | 1183.5058S | Ti Locking Screw, 5x57.5mm,<br>Fully Threaded          | 2   |
| 1183.2075S | Ti Headless Locking Screw,<br>5x75mm, Fully Threaded   | 2   | 1183.5060S | Ti Locking Screw, 5x60mm,<br>Fully Threaded            | 2   |
|            |  |     |            |  |     |

# AUTOBAHN® Tibial Nailing System IMPLANT SET 9183.9107

| Part No.   | Description                                   | Qty |
|------------|---|-----|
| 1183.5063S | Ti Locking Screw, 5x62.5mm,<br>Fully Threaded | 2   |
| 1183.5065S | Ti Locking Screw, 5x65mm,<br>Fully Threaded   | 2   |
| 1183.5068S | Ti Locking Screw, 5x67.5mm,<br>Fully Threaded | 2   |
| 1183.5070S | Ti Locking Screw, 5x70mm,<br>Fully Threaded   | 2   |
| 1183.5073S | Ti Locking Screw, 5x72.5mm,<br>Fully Threaded | 2   |
| 1183.5075S | Ti Locking Screw, 5x75mm,<br>Fully Threaded   | 2   |
| 1183.5078S | Ti Locking Screw, 5x77.5mm,<br>Fully Threaded | 2   |
| 1183.5080S | Ti Locking Screw, 5x80mm,<br>Fully Threaded   | 2   |
| 1183.5083S | Ti Locking Screw, 5x82.5mm,<br>Fully Threaded | 2   |
| 1183.5085S | Ti Locking Screw, 5x85mm,<br>Fully Threaded   | 2   |
| 1183.5088S | Ti Locking Screw, 5x87.5mm,<br>Fully Threaded | 2   |
| 1183.5090S | Ti Locking Screw, 5x90mm,<br>Fully Threaded   | 2   |

# **AUTOBAHN®** Tibial Nailing System IMPLANT SET 9183.9108

|                   |   | 0.  | 5          |  | 0.  |
|-------------------|---|-----|------------|--|-----|
| Part No.          | Description                                   | Qty | Part No.   | Description  | Qty |
| 1183.4025S        | Ti Locking Screw, 4x25mm, Fully Threaded      | 2   | 1183.4078S | Ti Locking Screw, 4x77.5mm, Fully Threaded             | 2   |
| 1183.4028S        | Ti Locking Screw, 4x27.5mm, Fully Threaded    | 2   | 1183.4080S | Ti Locking Screw, 4x80mm, Fully Threaded               | 2   |
| 1183.4030S        | Ti Locking Screw, 4x30mm,<br>Fully Threaded   | 2   | 1183.4083S | Ti Locking Screw, 4x82.5mm, Fully Threaded             | 2   |
| 1183.4033S        | Ti Locking Screw, 4x32.5mm,<br>Fully Threaded | 2   | 1183.4085S | Ti Locking Screw, 4x85mm,<br>Fully Threaded            | 2   |
| 1183.4035S        | Ti Locking Screw, 4x35mm,<br>Fully Threaded   | 2   | 1183.4088S | Ti Locking Screw, 4x87.5mm,<br>Fully Threaded          | 2   |
| 1183.4038S        | Ti Locking Screw, 4x37.5mm,<br>Fully Threaded | 2   | 1183.4090S | Ti Locking Screw, 4x90mm,<br>Fully Threaded            | 2   |
| 1183.4040S        | Ti Locking Screw, 4x40mm,<br>Fully Threaded   | 2   | 1183.8025S | Ti Headless Locking Screw,<br>4x25mm, Fully Threaded   | 2   |
| 1183.4043S        | Ti Locking Screw, 4x42.5mm,<br>Fully Threaded | 2   | 1183.80285 | Ti Headless Locking Screw,<br>4x27.5mm, Fully Threaded | 2   |
| 1183.4045S        | Ti Locking Screw, 4x45mm,<br>Fully Threaded   | 2   | 1183.8030S | Ti Headless Locking Screw,<br>4x30mm, Fully Threaded   | 2   |
| 1183.4048S        | Ti Locking Screw, 4x47.5mm,<br>Fully Threaded | 2   | 1183.8033S | Ti Headless Locking Screw,<br>4x32.5mm, Fully Threaded | 2   |
| 1183.4050S        | Ti Locking Screw, 4x50mm,<br>Fully Threaded   | 2   | 1183.8035S | Ti Headless Locking Screw,<br>4x35mm, Fully Threaded   | 2   |
| 1183.4053S        | Ti Locking Screw, 4x52.5mm,<br>Fully Threaded | 2   | 1183.8038S | Ti Headless Locking Screw,<br>4x37.5mm, Fully Threaded | 2   |
| 1183.4055S        | Ti Locking Screw, 4x55mm,<br>Fully Threaded   | 2   | 1183.8040S | Ti Headless Locking Screw,<br>4x40mm, Fully Threaded   | 2   |
| 1183.4058S        | Ti Locking Screw, 4x57.5mm,<br>Fully Threaded | 2   | 1183.8043S | Ti Headless Locking Screw,<br>4x42.5mm, Fully Threaded | 2   |
| 1183.4060S        | Ti Locking Screw, 4x60mm,<br>Fully Threaded   | 2   | 1183.8045S | Ti Headless Locking Screw,<br>4x45mm, Fully Threaded   | 2   |
| 1183.4063S        | Ti Locking Screw, 4x62.5mm,<br>Fully Threaded | 2   | 1183.8048S | Ti Headless Locking Screw,<br>4x47.5mm, Fully Threaded | 2   |
| 1183.4065S        | Ti Locking Screw, 4x65mm,<br>Fully Threaded   | 2   | 1183.8050S | Ti Headless Locking Screw,<br>4x50mm, Fully Threaded   | 2   |
| 1183.4068S        | Ti Locking Screw, 4x67.5mm,<br>Fully Threaded | 2   | 1183.8053S | Ti Headless Locking Screw,<br>4x52.5mm, Fully Threaded | 2   |
| 1183.4070S        | Ti Locking Screw, 4x70mm,<br>Fully Threaded   | 2   | 1183.8055S | Ti Headless Locking Screw,<br>4x55mm, Fully Threaded   | 2   |
| 1183.4073S        | Ti Locking Screw, 4x72.5mm,<br>Fully Threaded | 2   | 1183.8058S | Ti Headless Locking Screw,<br>4x57.5mm, Fully Threaded | 2   |
| 1183.4075S        | Ti Locking Screw, 4x75mm, Fully Threaded      | 2   | 1183.8060S | Ti Headless Locking Screw,<br>4x60mm, Fully Threaded   | 2   |
| ALITODALINI® TU . | INCHES CO.                                    |     |            |  |     |

# **AUTOBAHN® Tibial Nailing System** IMPLANT SET 9183.9108

| Part No.   | Description  | Qty |
|------------|--|-----|
| 1183.8063S | Ti Headless Locking Screw,<br>4x62.5mm, Fully Threaded | 2   |
| 1183.8065S | Ti Headless Locking Screw,<br>4x65mm, Fully Threaded   | 2   |
| 1183.8068S | Ti Headless Locking Screw,<br>4x67.5mm, Fully Threaded | 2   |
| 1183.8070S | Ti Headless Locking Screw,<br>4x70mm, Fully Threaded   | 2   |
| 1183.8073S | Ti Headless Locking Screw,<br>4x72.5mm, Fully Threaded | 2   |
| 1183.8075S | Ti Headless Locking Screw,<br>4x75mm, Fully Threaded   | 2   |
| 1183.8078S | Ti Headless Locking Screw,<br>4x77.5mm, Fully Threaded | 2   |
| 1183.8080S | Ti Headless Locking Screw,<br>4x80mm, Fully Threaded   | 2   |
| 1183.8083S | Ti Headless Locking Screw,<br>4x82.5mm, Fully Threaded | 2   |
| 1183.8085S | Ti Headless Locking Screw,<br>4x85mm, Fully Threaded   | 2   |
| 1183.8088S | Ti Headless Locking Screw,<br>4x87.5mm, Fully Threaded | 2   |
| 1183.8090S | Ti Headless Locking Screw,<br>4x90mm, Fully Threaded   | 2   |
| 1183.9010S | AUTOBAHN® Tibial Nail Set Screw,<br>8x18mm             | 2   |
| 1183.9800S | AUTOBAHN® Tibial Nail Ti<br>End Cap                    | 2   |
| 1183.9805S | AUTOBAHN <sup>®</sup> Tibial Nail Ti<br>End Cap, 5mm   | 2   |
| 1183.981OS | AUTOBAHN <sup>®</sup> Tibial Nail Ti<br>End Cap, 10mm  | 2   |

# **ANTHEM®** Small Fragment Fracture System MODULE 9183.9004

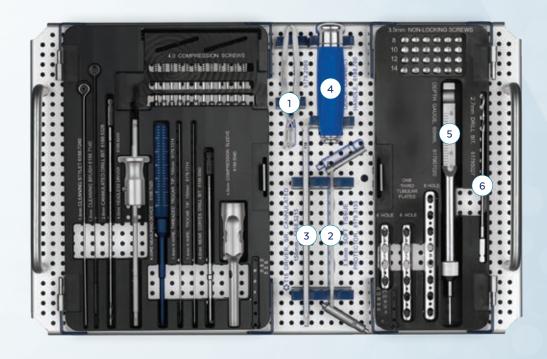
# **Small Fragment Implants**

| Part No.  | Description   | Qty |
|-----------|---|-----|
| 2179.1324 | ANTHEM® SS One Third Tubular Plate, Non-Locking, 4 hole, 48mm | 2   |
| 2179.1326 | ANTHEM® SS One Third Tubular Plate, Non-Locking, 6 hole, 72mm | 2   |
| 2179.1328 | ANTHEM® SS One Third Tubular Plate, Non-Locking, 8 hole, 96mm | 2   |
| 2179.3008 | SS Non-Locking Screw, 3.5x8mm                                 | 4   |
| 2179.3010 | SS Non-Locking Screw, 3.5x10mm                                | 4   |
| 2179.3012 | SS Non-Locking Screw, 3.5x12mm                                | 4   |
| 2179.3014 | SS Non-Locking Screw, 3.5x14mm                                | 4   |

# **Small Fragment Instruments**

| Part | No.       | Description   | Qty |
|------|-----------|---|-----|
| 0    | 6179.2000 | Screw Holding Forceps                                 | 1   |
| 2    | 6179.3135 | 3.5mm Spring Loaded Soft Tissue Protector             | 1   |
| 3    | 6168.5215 | T15 Driver, SR, Cannulated, 150mm, AO Quick-Connect   | 1   |
| 4    | 6188.7000 | Cannulated Quick-Connect Handle, Internal Coupling    | 1   |
| 5    | 6179.7020 | Depth Gauge, 60mm                                     | 1   |
| 6    | 6179.5027 | 2.7mm Drill Bit, 125mm, AO Quick-Connect              | 1   |
|      | 9183.0004 | AUTOBAHN® Tibial Nailing System Small Fragment Module | 1   |

# **ANTHEM®** Small Fragment Fracture System MODULE 9183.9004



# **CAPTIVATE® 4.0mm Compression Screw** MODULE 9183.9005

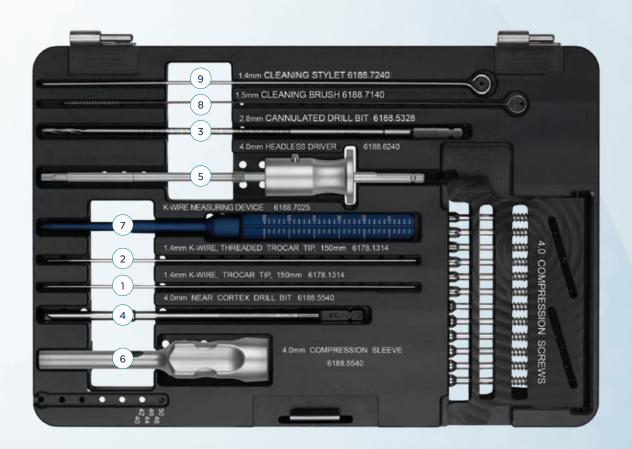
# **CAPTIVATE® 4.0mm Compression Screws**

| Part No.  | Description   | Qty |
|-----------|---|-----|
| 1178.4440 | CAPTIVATE® 4.0x40mm Cannulated Screw, Long Thread, Ti   | 2   |
| 1178.4442 | CAPTIVATE® 4.0x42mm Cannulated Screw, Long Thread, Ti   | 2   |
| 1178.4444 | CAPTIVATE® 4.0x44mm Cannulated Screw, Long Thread, Ti   | 2   |
| 1178.4446 | CAPTIVATE® 4.0x46mm Cannulated Screw, Long Thread, Ti   | 2   |
| 1178.4448 | CAPTIVATE® 4.0x48mm Cannulated Screw, Long Thread, Ti   | 2   |
| 1178.4450 | CAPTIVATE® 4.0x50mm Cannulated Screw, Long Thread, Ti   | 2   |
| 1188.4440 | ${\sf CAPTIVATE}^{\circ} \ {\sf Headless} \ {\sf Compression} \ {\sf Screw}, \ {\sf 4.0x40mm}, \ {\sf Long} \ {\sf Thread}, \ {\sf Ti}$ | 2   |
| 1188.4442 | ${\sf CAPTIVATE}^{\circ}{\sf Headless}{\sf Compression}{\sf Screw},{\sf 4.0x42mm},{\sf Long}{\sf Thread},{\sf Ti}$                      | 2   |
| 1188.4444 | ${\sf CAPTIVATE}^{\circ}\ {\sf Headless}\ {\sf Compression}\ {\sf Screw}, {\sf 4.0x44mm}, {\sf Long}\ {\sf Thread}, {\sf Ti}$           | 2   |
| 1188.4446 | ${\sf CAPTIVATE}^{\circ} \ {\sf Headless} \ {\sf Compression} \ {\sf Screw}, \ {\sf 4.0x46mm}, \ {\sf Long} \ {\sf Thread}, \ {\sf Ti}$ | 2   |
| 1188.4448 | ${\sf CAPTIVATE}^{\circ} \ {\sf Headless} \ {\sf Compression} \ {\sf Screw}, \ {\sf 4.0x48mm}, \ {\sf Long} \ {\sf Thread}, \ {\sf Ti}$ | 2   |
| 1188.4450 | ${\sf CAPTIVATE}^{\circ}\ {\sf Headless}\ {\sf Compression}\ {\sf Screw}, \ {\sf 4.0x50mm}, \ {\sf Long}\ {\sf Thread}, \ {\sf Ti}$     | 2   |

# **CAPTIVATE® 4.0mm Compression Screw Instruments**

|   | Part No.  | Description  | Qty |
|---|-----------|--|-----|
| 0 | 6178.1114 | 1.4mm K-Wire, Trocar Tip, 150mm                          | 5   |
| 2 | 6178.1314 | 1.4mm K-Wire, Threaded Trocar Tip, 150mm                 | 5   |
| 3 | 6188.5328 | 2.8mm Drill Bit, 170mm, 1.5mm Cannulation                | 1   |
| 4 | 6188.5540 | 4.0mm Near Cortex Drill Bit, 1.5mm Cannulation           | 1   |
| 5 | 6188.6240 | 4.0mm Headless Driver                                    | 1   |
| 6 | 6188.6740 | 4.0mm Headless Compression Sleeve                        | 1   |
| 7 | 6188.7025 | 1.5mm K-Wire Measuring Device                            | 1   |
| 8 | 6188.7140 | 1.6mm Cleaning Brush, 185mm                              | 1   |
| 9 | 6188.7240 | 1.4mm Cleaning Stylet, 180mm                             | 1   |
|   | 9183.0005 | AUTOBAHN® Tibial Nailing System Compression Screw Module |     |

# **CAPTIVATE® 4.0mm Compression Screw** MODULE 9183.9005



# **AUTOBAHN®** Tibial Nailing System **INSTRUMENTS 9183.9001**

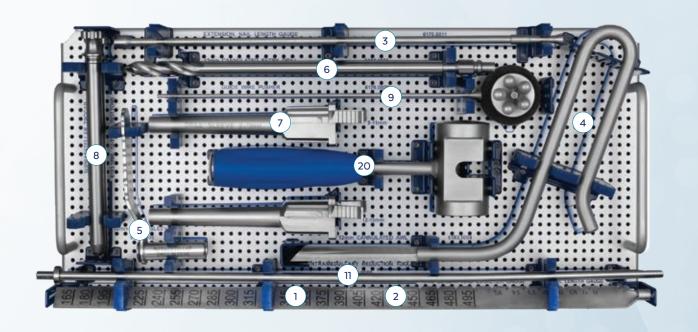
# **Proximal Entry Instruments**

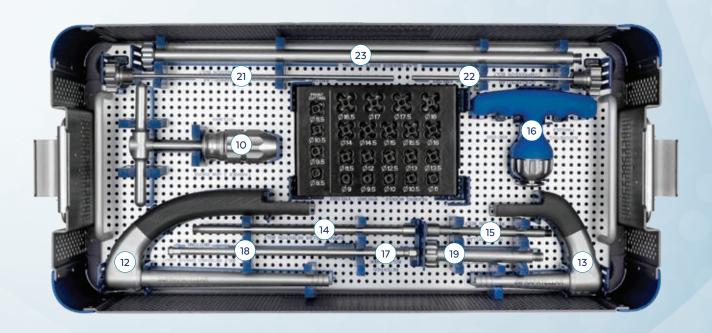
|    | Part No.  | Description                            | Qty |
|----|-----------|--|-----|
| 1  | 6183.1002 | Radiographic Length and Diameter Gauge | 1   |
| 2  | 6183.1101 | AUTOBAHN® Tibial Nail Length Gauge     | 1   |
| 3  | 6176.0011 | Extension Nail Length Gauge            | 1   |
| 4  | 6183.1004 | 12mm Cannulated Awl                    | 1   |
| 5  | 6183.1005 | 12mm Infrapatellar Drill Sleeve        | 1   |
| 6  | 6183.1006 | 12mm Cannulated Entry Drill            | 1   |
| 7  | 6183.1091 | Suprapatellar Drill Sleeve 8-11mm      | 1   |
| 8  | 6183.1092 | Suprapatellar Trocar 8-11mm            | 1   |
| 9  | 6176.0029 | Guide Wire Pusher                      | 1   |
| 10 | 6173.9000 | T-Handle 3 Jaw Chuck                   | 1   |
| 1  | 6190.0080 | Intramedullary Reduction Device        | 1   |

# **Nail Insertion Instruments**

|    | Part No.  | Description  | Qty |
|----|-----------|--|-----|
| 12 | 6183.1015 | AUTOBAHN® Tibial Nail Suprapatellar Handle         | 1   |
| 13 | 6183.1016 | AUTOBAHN® Tibial Nail Infrapatellar Handle         | 1   |
| 14 | 6183.1017 | AUTOBAHN® Tibial Nail Suprapatellar Retention Bolt | 2   |
| 15 | 6183.1018 | AUTOBAHN® Tibial Nail Infrapatellar Retention Bolt | 2   |
| 16 | 6067.0020 | T-Handle, Ratcheting, 1/4" Quick-Connect           | 1   |
| 17 | 6176.0027 | Retention Bolt Driver                              | 1   |
| 18 | 6183.1102 | 8mm Self-Retaining Driver Shaft                    | 1   |
| 19 | 6183.1020 | Impactor   | 1   |
| 20 | 6176.0020 | Slotted Mallet                                     | 1   |
| 21 | 6183.1087 | Suprapatellar Compression Bolt                     | 1   |
| 22 | 6183.1081 | Infrapatellar Compression Bolt                     | 1   |
| 23 | 6183.1094 | Slap Hammer Shaft                                  | 1   |

# **AUTOBAHN®** Tibial Nailing System **INSTRUMENTS 9183.9001**



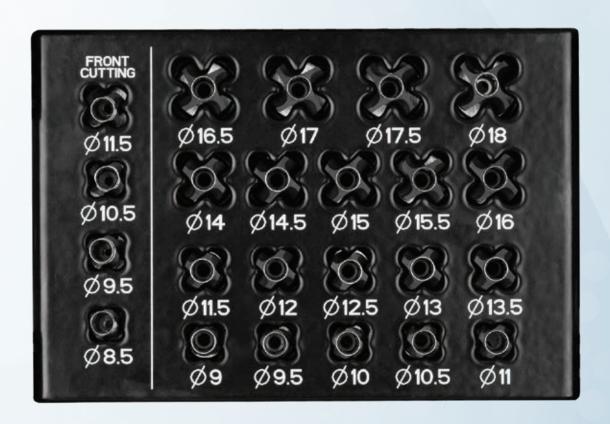


# **UNIVERSAL REAMER** MODULE 9182.9001

# **Reaming Instruments**

| Part No.  | Description                       | Qty |
|-----------|-----------------------------------|-----|
| 6182.2085 | Front Cutting Reamer Head, 8.5mm  | 1   |
| 6182.2095 | Front Cutting Reamer Head, 9.5mm  | 1   |
| 6182.2105 | Front Cutting Reamer Head, 10.5mm | 1   |
| 6182.2115 | Front Cutting Reamer Head, 11.5mm | 1   |
| 6182.1090 | Piloted Reamer Head, 9mm          | 1   |
| 6182.1095 | Piloted Reamer Head, 9.5mm        | 1   |
| 6182.1100 | Piloted Reamer Head, 10mm         | .1  |
| 6182.1105 | Piloted Reamer Head, 10.5mm       | 1   |
| 6182.1110 | Piloted Reamer Head, 11mm         | 1   |
| 6182.1115 | Piloted Reamer Head, 11.5mm       | 1   |
| 6182.1120 | Piloted Reamer Head, 12mm         | 1   |
| 6182.1125 | Piloted Reamer Head, 12.5mm       | 1   |
| 6182.1130 | Piloted Reamer Head, 13mm         | 1   |
| 6182.1135 | Piloted Reamer Head, 13.5mm       | 1   |
| 6182.1140 | Piloted Reamer Head, 14mm         | 1   |
| 6182.1145 | Piloted Reamer Head, 14.5mm       | 1   |
| 6182.1150 | Piloted Reamer Head, 15mm         | 1   |
| 6182.1155 | Piloted Reamer Head, 15.5mm       | 1   |
| 6182.1160 | Piloted Reamer Head, 16mm         | 1   |
| 6182.1165 | Piloted Reamer Head, 16.5mm       | 1   |
| 6182.1170 | Piloted Reamer Head, 17mm         | 1   |
| 6182.1175 | Piloted Reamer Head, 17.5mm       | 1   |
| 6182.1180 | Piloted Reamer Head, 18mm         | 1   |
| 6182.0002 | Reamer Removal Tray               | 1   |

# **UNIVERSAL REAMER** MODULE 9182.9001



# **AUTOBAHN®** Tibial Nailing System **INSTRUMENTS 9183.9002**

# **Locking Instruments**

|    | Part No.  | Description                                      | Qty |
|----|-----------|--|-----|
| 1  | 6183.1024 | AUTOBAHN® Tibial Nail<br>Proximal Aiming Guide   | 1   |
| 2  | 6183.1083 | Drill Sleeve 4.2                                 | 1   |
| 3  | 6183.1084 | Drill Sleeve 3.2                                 | 1   |
| 4  | 6183.1085 | Trocar 4.2                                       | 1   |
| 5  | 6183.1086 | Trocar 3.2                                       | 1   |
| 6  | 6183.1030 | 4.2 Drill Graduated, Long 330mm                  | 2   |
| 7  | 6183.1031 | 4.2 Drill, Short 150mm                           | 2   |
| 8  | 6183.1032 | 3.2 Drill Graduated, Long 330mm                  | 2   |
| 9  | 6183.1033 | 3.2 Drill, Short 150mm                           | 2   |
| 10 | 6176.0045 | Locking Screw Driver, Short                      | 1   |
| 1  | 6183.1107 | Locking Screw Driver, Long                       | 1   |
| 12 | 6183.1054 | Soft Tissue Drill Sleeve                         | 2   |
| 13 | 6176.0026 | Length Gauge, Locking Screws                     | 1   |
| 14 | 6176.0055 | Locking Screw Driver, Short, for Power           | 1   |
| 15 | 6176.0056 | Retention Rod, Locking Screw,<br>Short for Power | 1   |
| 16 | 6183.1109 | Locking Screw Driver, Long, for Power            | 1   |
| 17 | 6176.0058 | Retention Rod, Locking Screw,<br>Long for Power  | 1   |
| 18 | 6176.0061 | Retention Rod, Locking Screw, Short              | 1   |
| 19 | 6176.0063 | Retention Rod, Locking Screw, Long               | 1   |

# **Additionally Available Locking Instruments**

| Part No.  | Description                                |
|-----------|--|
| 6176.0071 | Length Gauge, Locking Screw, Short         |
| 6183.1104 | AUTOBAHN® Countersink, Long, 5mm Headless  |
| 6183.1105 | AUTOBAHN® Countersink, Short, 5mm Headless |
| 6183.1106 | AUTOBAHN® Countersink, Long, 4mm Headless  |
| 6183.1108 | Length Gauge, Distal Screws, Tibial Nail   |
| 6190.3000 | Hall Quick-Connect Handle                  |

# **Reduction Instruments**

|    | Part No.  | Description                                      | Qty |
|----|-----------|--|-----|
| 20 | 6183.1098 | Ball Spike Pusher Reduction Instrument           | 1   |
| 21 | 6187.7001 | Point to Point Reduction Clamp,<br>Large, Narrow | 2   |
| 22 | 6187.7004 | Ball Spike Reduction Clamp, Large                | 1   |

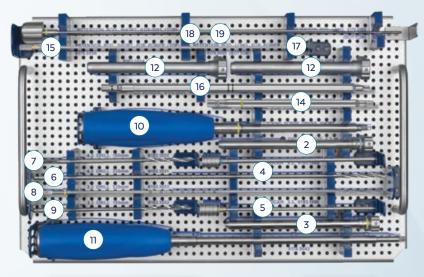
# **Removal Instruments**

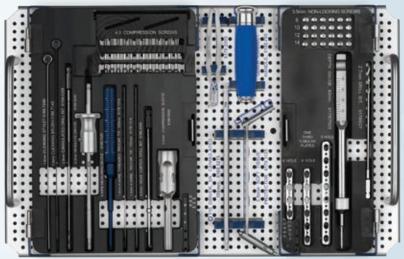
|    | Part No.  | Description                           | Qty |
|----|-----------|---------------------------------------|-----|
| 23 | 6183.1001 | AUTOBAHN® Tibial Nail Extraction Bolt | 1   |
| 24 | 6183.1103 | 4mm Locking Screw Removal Tool        | 1   |
| 25 | 6176.0031 | Locking Screw Removal Tool            | 1   |
| 26 | 6176.0032 | Punch                                 | 1   |
| 27 | 6176.0048 | Trephine                              | 1   |

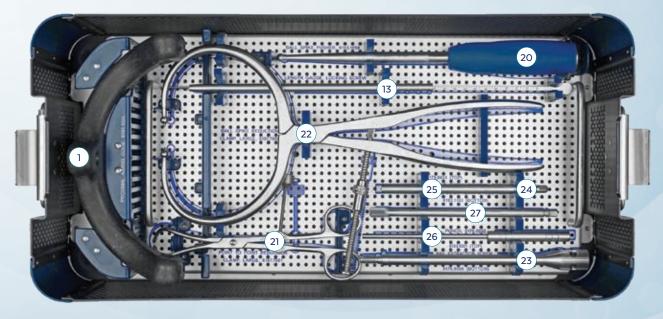
# **Sterile Packed Instruments**

| Part No.   | Description  | Qty |
|------------|--|-----|
| 6716.0021S | 3.2x450mm K-Wires                                  | 6   |
| 6176.0022S | 3.0x1000mm Ball Tip                                | 2   |
| 6183.1096S | Suprapatellar Cannula (8-10mm)                     | 2   |
| 6183.1043S | Exchange Tube                                      | 1   |
| 6182.0001S | Flexible Reamer Shaft, 470mm                       | 2   |
| 6182.0003S | Flexible Reamer Shaft, 620mm                       | 2   |
| 6182.0002S | Reamer Extension                                   | 2   |
| 6183.1112S | Suprapatellar Cannula (8-11mm) without Tibial Pins | 4   |

# **AUTOBAHN®** Tibial Nailing System **INSTRUMENTS 9183.9002**







# 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 preand 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.

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, osteomalicia, diabetes, inhibited revascularization and poor bone formation can cause loosening, bending, cracking, fracture of the device or premature loss of rigid fixation
- 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
- · 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.
- I mplants which consist of several components must only be used in the prescribed combination (refer to the AÛTOBAHN® 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
- 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.

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

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

### CLEANING

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

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

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

- 1. Immediately following use, ensure that the instruments are wiped down to remove all visible soil and kept from drying by submerging or covering with
- 2. Disassemble all instruments that can be disassembled.
- 3. Rinse the instruments under running tap water to remove all visible soil. Flush the lumens a minimum of 3 times, until the lumens flush clean.
- 4. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations.
- 5. Immerse the instruments in the detergent and allow them to soak for a minimum of 2 minutes.
- 6. Use a soft bristled brush to thoroughly clean the instruments. Use a pipe cleaner for any lumens. Pay close attention to hard to reach areas.
- 7. Using a sterile syringe, draw up the enzymatic detergent solution. Flush any lumens and hard to reach areas until no soil is seen exiting the area.
- 8. Remove the instruments from the detergent and rinse them in running warm tap water.
- 9. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations in an ultrasonic cleaner.
- 10. Completely immerse the instruments in the ultrasonic cleaner and ensure detergent is in lumens by flushing the lumens. Sonicate for a minimum of
- 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<sup>-6</sup>. 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

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

# IMPORTANT INFORMATION ON ON THE AUTOBAHN® NAILING SYSTEM

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

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

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

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

|             | SYMBOL TRANSLATION  |           |   |  |
|-------------|---------------------|-----------|---|--|
| REF         | CATALOGUE<br>NUMBER | STERILE R | STERILIZED BY IRRADIATION                           |  |
| LOT         | LOT NUMBER          | EC REP    | AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY |  |
| $\triangle$ | CAUTION             | ***       | MANUFACTURER  |  |
| (2)         | SINGLE USE ONLY     | 23        | USE BY (YYYY-MM-DD)                                 |  |
| QTY         | QUANTITY            | Rx ONLY   | PRESCRIPTION USE ONLY                               |  |

DI203A REV B

| NOTES |  |  |  |
|-------|--|--|--|
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |

| NOTES |  |  |  |
|-------|--|--|--|
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |

| NOTES |  |  |  |
|-------|--|--|--|
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |
|       |  |  |  |





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

Customer Service:

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

©2021 Globus Medical. All rights reserved. Patent www.globusmedical.com/patents. Life moves us is a registered trademark of Globus Medical. Please refer to package insert for description, indications, contraindications, warnings, precautions and other important information.

**( (** 0297

GMTGD198 06.21 Rev C