ZIMMER BIOMET
Moving You Forward.™

Surgical Technique

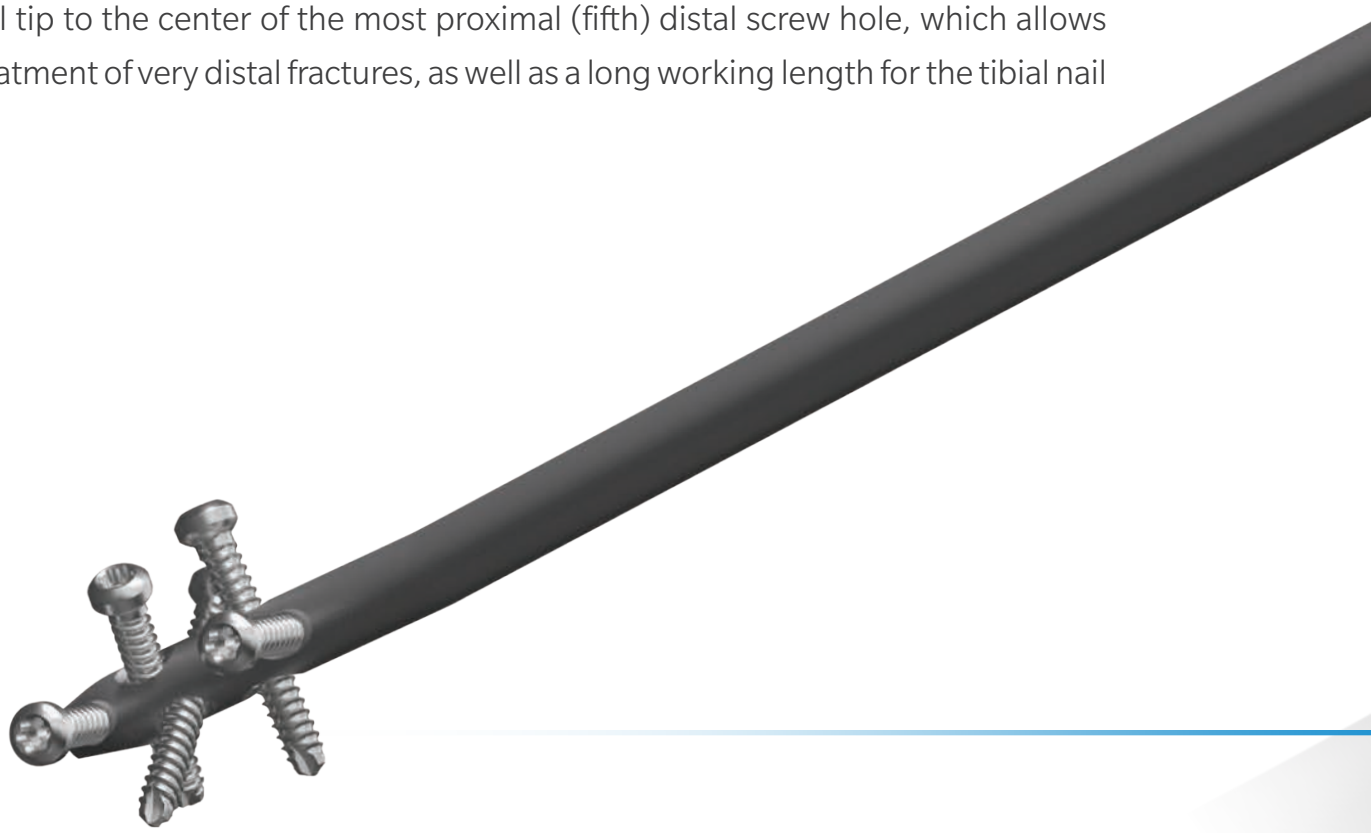
Affixus® Tibial Nail System

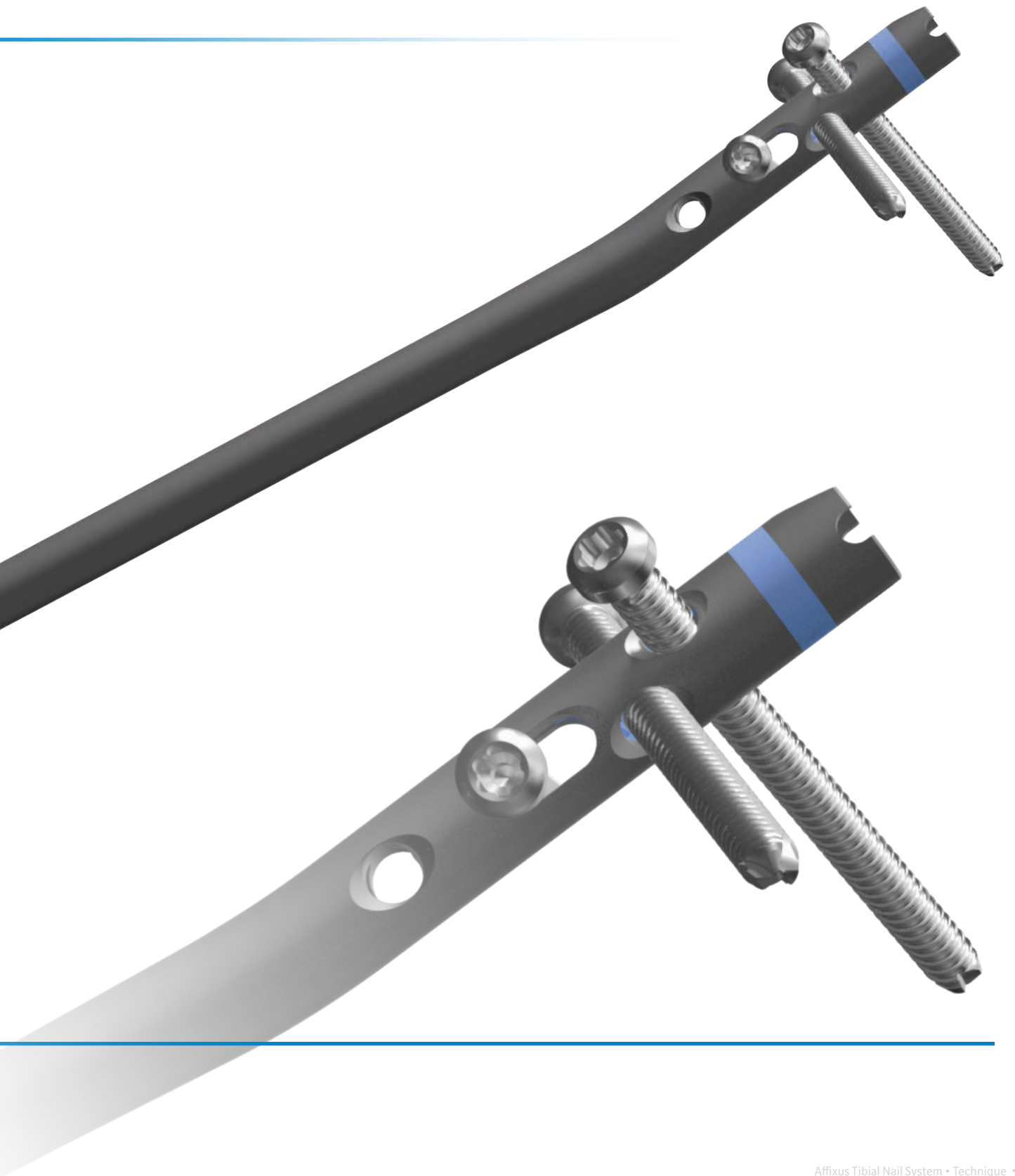
Affixus® Tibial Nail System

Featuring CoreLock™ Technology

› Each nail features CoreLock™ Technology, a preassembled, embedded locking mechanism for locking all proximal oblique screws, which can also be used to internally mechanically compress up to 5mm for a variety of tibial fractures

› Distally, the tibial nail offers an exceptionally low distal aspect of 4.5mm from the center of the most distal screw hole to the nail tip and only 32.5mm from the nail tip to the center of the most proximal (fifth) distal screw hole, which allows treatment of very distal fractures, as well as a long working length for the tibial nail






SUPRA
TIBIA
TOWARDS PATIENT
OBL-P

Table of Contents

Introduction

The Affixus Tibial Nail System is part of a long bone nailing system that offers an implant designed to treat a range of tibial fractures from simple to complex, with versatile locking options. The Affixus platform of instrumentation is designed to provide options and flexibility for many intraoperative approaches while maintaining ease of use and commonality.

The Affixus Tibial Nail System is composedof titanium alloy and features Corelock Technology. Corelock offers a preassembled, embedded locking mechanism for locking all proximal oblique screws. The Corelock locking mechanism can also be used to mechanically compress (internally) up to 5mm for a variety of tibial fractures. Distally, the tibial nail offers an exceptionally low distal aspect of 4.5mm from the center of the most distal screw hole to the tip. Also, the 32.5mm distance from the tip of the nail to the most proximal (fifth) distal screw hole allows for expanded working length for the management of proximal to distal fractures.

The Affixus Tibial nails offer specific anatomical features that aid in insertion, while also offering options to address both proximal and distal fractures. The bullet-style tip and 3º distal bend are designed to aid in ease of insertion of the nail. The oblique orientation of the proximal locking screws, combined with the ability to engage the preassembled locking mechanism, can provide needed proximal stability. The orientation of the distal oblique screws allows for the capture of distal, posterior tibial fractures. The medial anterior descending to posterolateral screw hole is located 20º from the transverse plane and 35º from the sagittal plane. The lateral anterior descending to posteromedial screw hole is located likewise in the transverse plane and sagittal plane.

The Affixus Tibial nails are universal (can be used in left and right limbs) and available in outer diameters of 8mm, 9mm, 10mm, 11mm, 12mm and 13mm for application in a wide variety of patients in lengths of 240mm to 420mm, in10mm increments.

NOTE: Some sizes may require special order.

NOTE: Please refer to the Instructions for Use and the package label for the products to be used with this Surgical Technique.

Indications and Contraindications

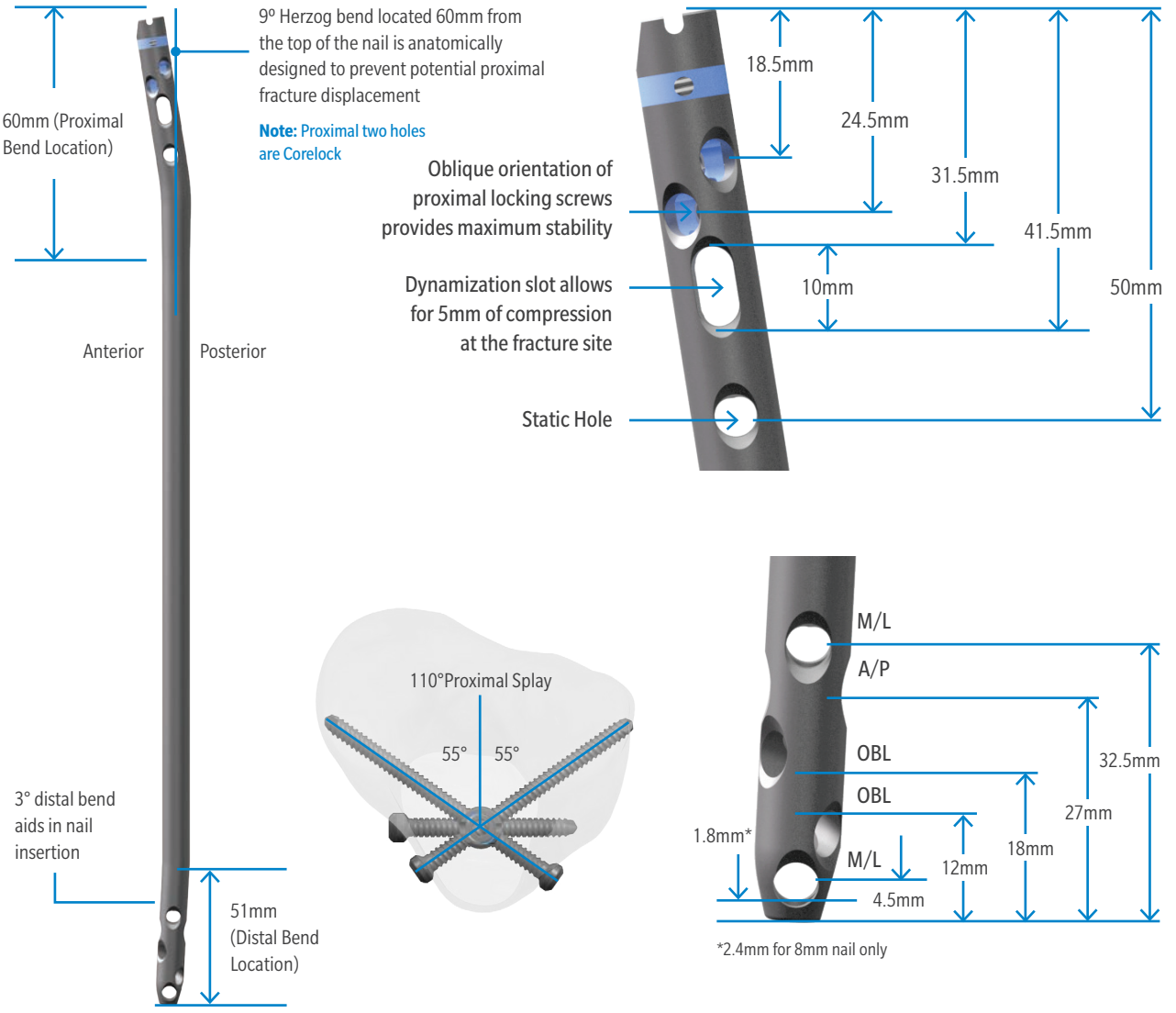
Indications

The Affixus Tibial Nailing System is indicated for temporary stabilization and fixation of tibial fractures and osteotomies including proximal, metaphyseal, and distal shaft fractures, closed fractures, open fractures, pathologic fractures, nonunions, malunions and deformity corrections.

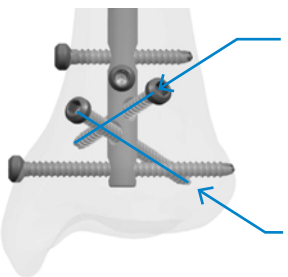
Contraindications

A medullary canal obliterated by a previous fracture or tumor.	Bone shaft having excessive bow or deformity
Lack of bone substance or bone quality, which makes stable seating of the implant impossible	All concomitant diseases that can impair the functioning and the success of the implant
Insufficient blood circulation	Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions
Active Infection	Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation of the device.
Skeletally immature patients	

Features and Benefits

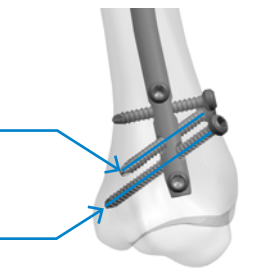


Corelock Technology provides static locking of the two proximal oblique screws. Zimmer Biomet StabiliZe Technology included in all of the remaining seven screw holes, links the nail to interlocking screws to create an advanced construct. This interface helps secure the screw, which aids in controlling rotation, alignment and length.



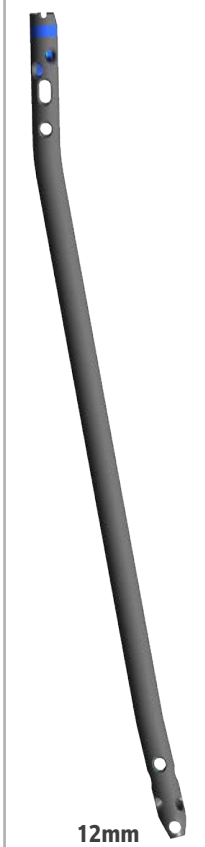
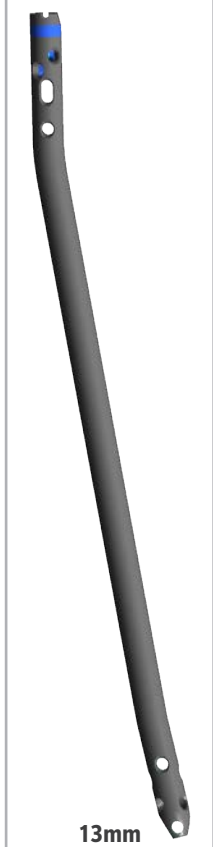
Oblique screw descending from medial anterior to posterolateral at 20° from transverse plane and 35° from sagittal plane, allowing for capture of distal, posterolateral tibial fractures.

Oblique screw descending from lateral anterior to posteromedial at 20° from transverse plane and 35° from sagittal plane, allowing for capture of distal, posteromedial tibial fractures.



Features and Benefits

Proximal Diameter

Ø11mm	Ø11mm	Ø11mm	Ø11mm	Ø12mm	Ø13mm
 8mm	 9mm	 10mm	 11mm	 12mm	 13mm
Ø4mm	Ø5mm	Ø5mm	Ø5mm	Ø5mm	Ø5mm

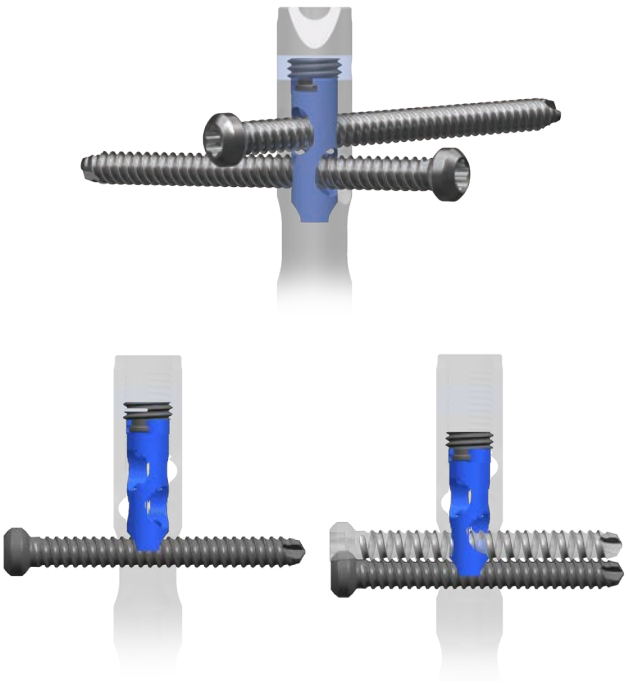
Distal Screw Diameter

Nail Diameters	8mm	9mm	10mm	11mm	12mm	13mm

Proximal Diameters	11mm (for 8mm, 9mm, 10mm, and 11mm nails)
	12mm (12mm nail)
	13mm (13mm nail)

Length Offering
240-420mm (10mm increments)

Features and Benefits



CoreLock™ Technology

Innovation made simple and elegant through deployment of the preassembled, embedded setscrew/locking mechanism

Ability to lock proximal oblique screw to nail via preassembled embedded setscrew/locking mechanism. (Compression needs to occur prior to obliques if both are required)

5mm of internal compression via embedded setscrew/locking mechanism.

Double-Lead Thread Screws

- Composed of Titanium Alloy
- Features a double-lead thread design for quick insertion
- Self-tapping
- Interior of 4mm and 5mm cortical screw head is threaded for secure retention to driver
- Threads are close to screw head and screw tip for better bicortical purchase

Locking Driver or Press-fit driver available for insertion of 4mm or 5mm screw.

Interior of screw head is threaded for retention to locking driver.

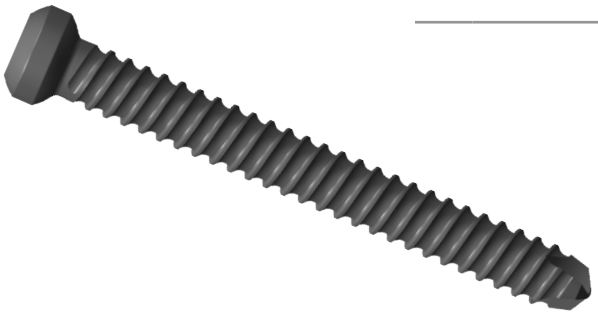
Features and Benefits

4mm Double-Lead Thread Screws

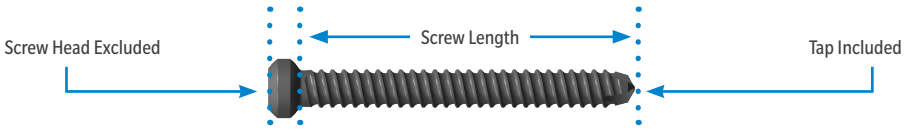
- Used distally for locking 8mm nail only
- 20mm-60mm (Available in 2mm increments)
- 65-90mm lengths (Available in 5mm increments)

5mm Double-Lead Thread Screws

- Utilized for proximal locking all nail sizes
- Used distally for locking 9mm, 10mm, 11mm, 12mm,and 13mm nail sizes
- 20mm - 60mm lengths (Available in 2mm increments)
- 65-120mm lengths (Available in 5mm increments)



Tibia Technique - Measuring 4mm or 5mm Screws



Description	Measurement Options	Tap Length
Screw length measured excludes the screw head and includes the tap length to provide accurate placement of screws.	Screw can be measured using the screw depth gauge or directly off the drill as described in section 14.	**5mm Screw:** 4.5 mm **4mm Screw:** 4.1mm

Features and Benefits - End Cap Details

Locking Driver or Press-fit driver available for end cap insertion

0mm	5mm	10mm
		

End Caps sizes:

11mm, 12mm, and 13mm diameters
(Match the proximal diameter of the tibia nail with the corresponding diameter of the end cap).

Surgical Technique

Pre-operative Planning and Patient Positioning

1. Preoperative Planning

Preoperative planning is recommended before beginning the surgical procedure. An X-Ray Template (XR815407239-3) is available for pre-operative planning. The template allows for determination of the proper nail diameter and length.

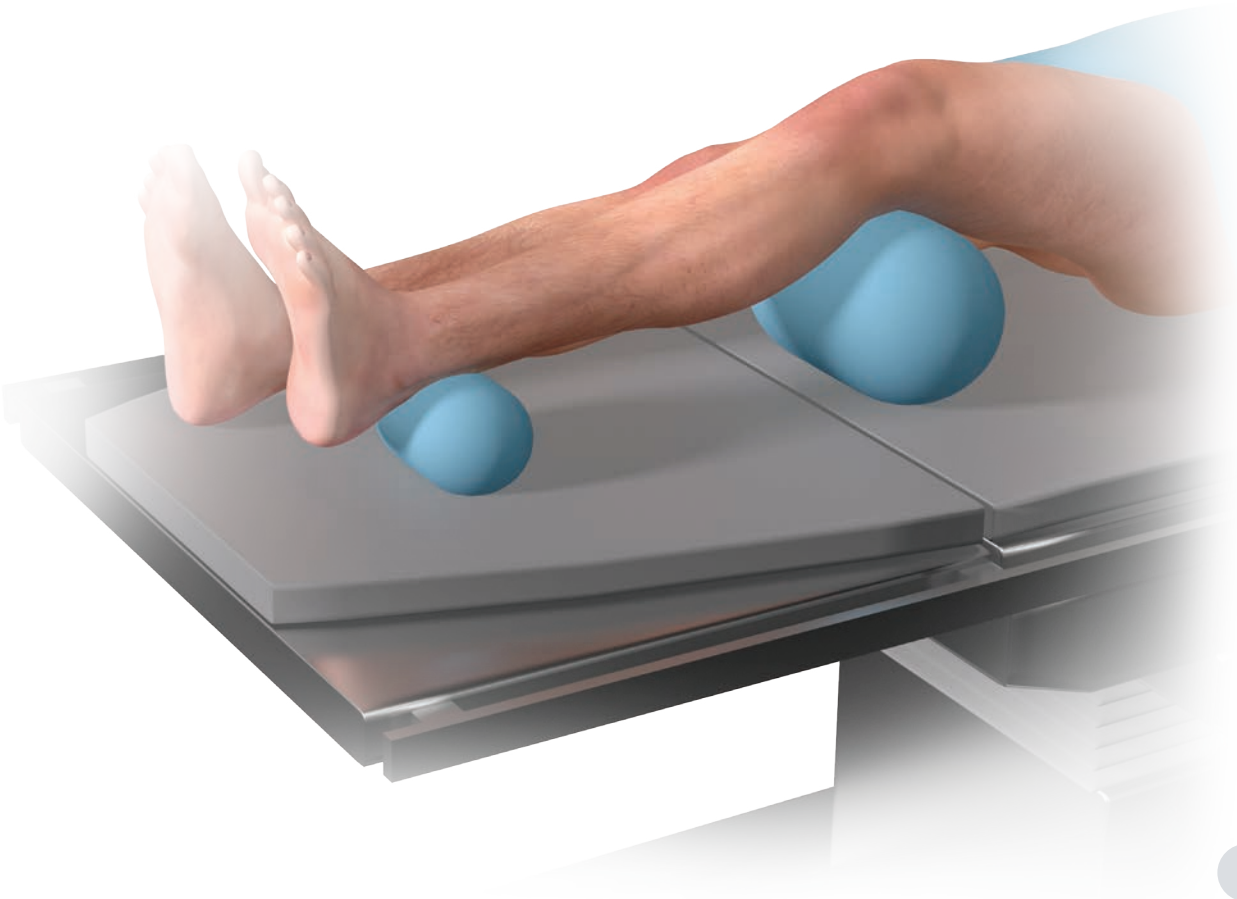
A/P and Lateral x-rays of the injured tibia should be taken preoperatively and evaluated for length, canal size and implant suitability. A/P and Lateral x-rays of the contralateral uninjured tibia can also be taken preoperatively to provide insight into the characteristics of the pre-injured tibia.

2. Patient Positioning

The patient should be positioned in the supine position. The positioning should allow the knee of the injured leg to be placed in at least 10°-20° of flexion. Use e.g. blankets, custom foam devices or sterile bumps to support this position (Figure 1).

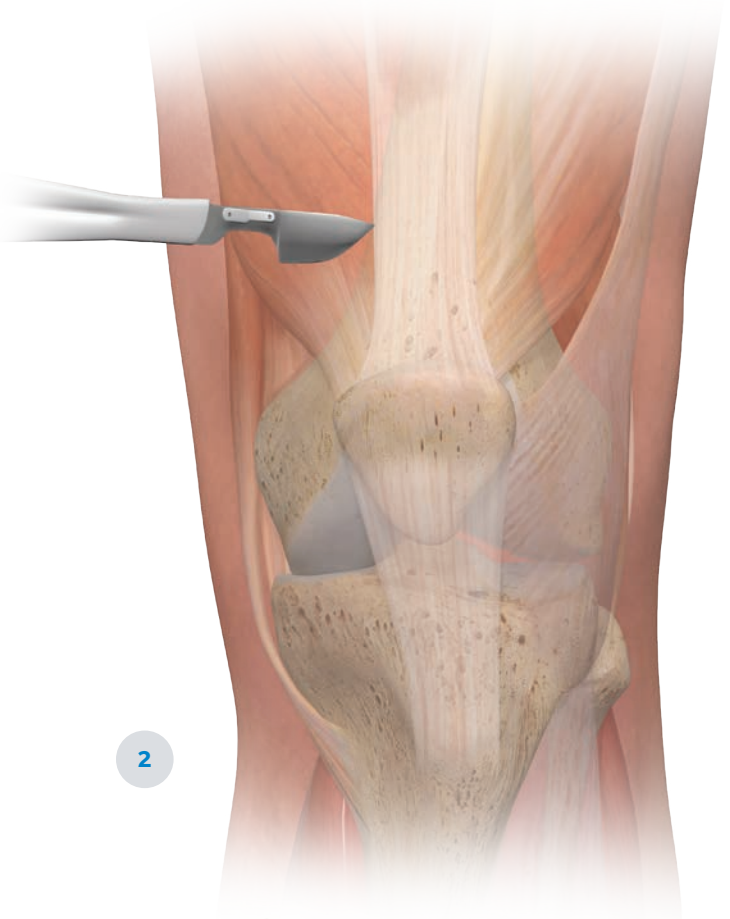
The use of a fracture table can be beneficial to help reduce fractures as well as to facilitate intraoperative imaging with a C-arm. The C-arm should be placed to allow for imaging of the tibia in both planes along the entire length of the bone. Drape the patient appropriately to allow the surgeon to work from the knee to the foot.

Note: Contralateral limb may be prepped into the field and elevated or lowered to allow adequate fluoroscopic imaging if it obstructs the imaging in any manner.

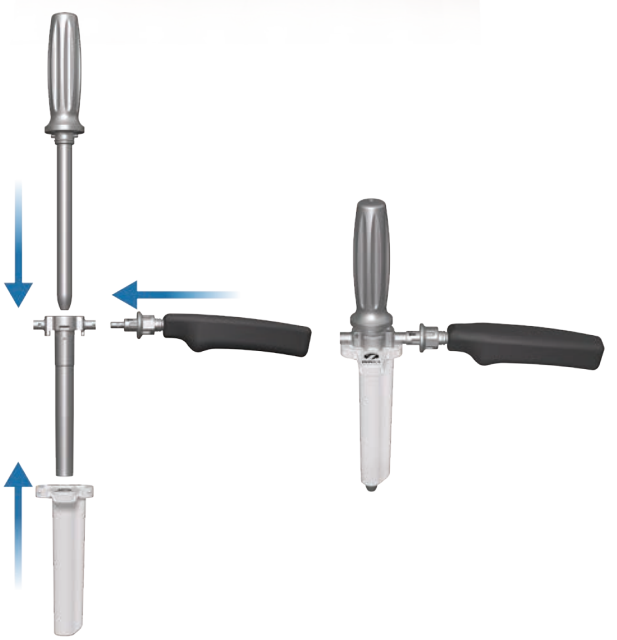


1

Suprapatellar Approach



2



3

3. Reduction

It is critical to achieve anatomic reduction before beginning any of the steps to place the IM Nail. Traction should be used as necessary to help achieve fracture reduction. Several instruments are available to assist in fracture reduction including clamps, ball spike pushers and Steinman pins, femoral distractors or external fixation systems.

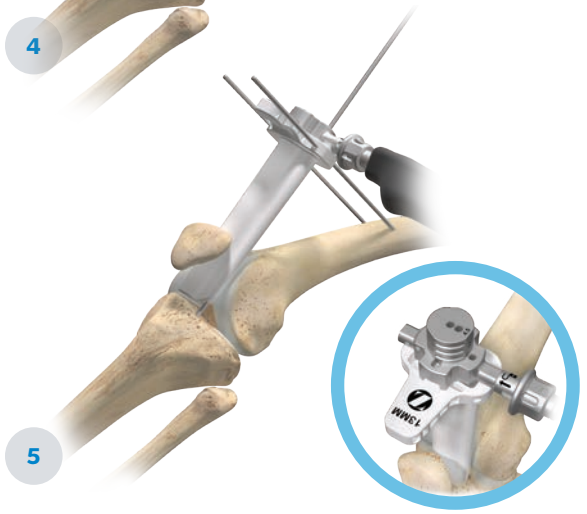
4a. Incision

Make a 3-4mm longitudinal incision 3cm proximal to the superior pole of the patella and carried to the patella. Identify the quadriceps tendon and split it in its mid-substance to the superior pole of the patella (Figure 2).

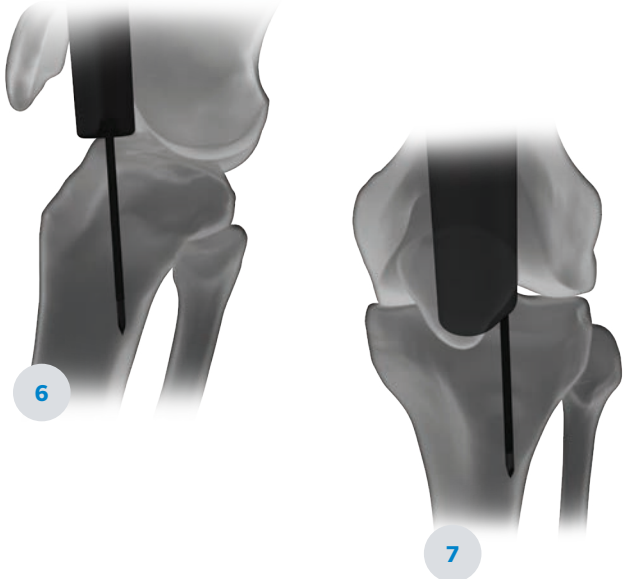
NOTE: Dissection can be utilized to enter the suprapatellar pouch and to mobilize the patella.

Suprapatellar Approach

4



5



6

7

4b. Suprapatellar Entry Point

For 8mm, 9mm, 10mm, and 11mm Tibia Nails, assemble the ENTRY PORTAL TROCAR (211300008), ENTRY PORTAL (211300004), and ENTRY PORTAL SLEEVE (211300007) (Figure 3). Gently advance the assembly into the suprapatellar space until it reaches the desired starting point on the proximal tibia (Figure 4).

NOTE: For 12mm and 13mm Tibia Nails, assemble the Entry Portal Large (211300006), Entry Portal Trocar Large (211300017), and Entry Portal Sleeve Large (211300010) instead.

NOTE: Patients with patella femoral arthritis may require further patellar mobilization and released to further aid in the advancement of the cannula assembly.

Replace the SUPRA ENTRY TROCAR with the SUPRA ENTRY OFFSET TROCAR (211300005) and insert THREADED GUIDE PIN 3.2x444MM (281001175/903003004) through the trocar sleeve to the desired starting point.

NOTE: Use the ENTRY PORTAL OFFSET TROCAR (211300003) for 12 mm or 13 mm nails.

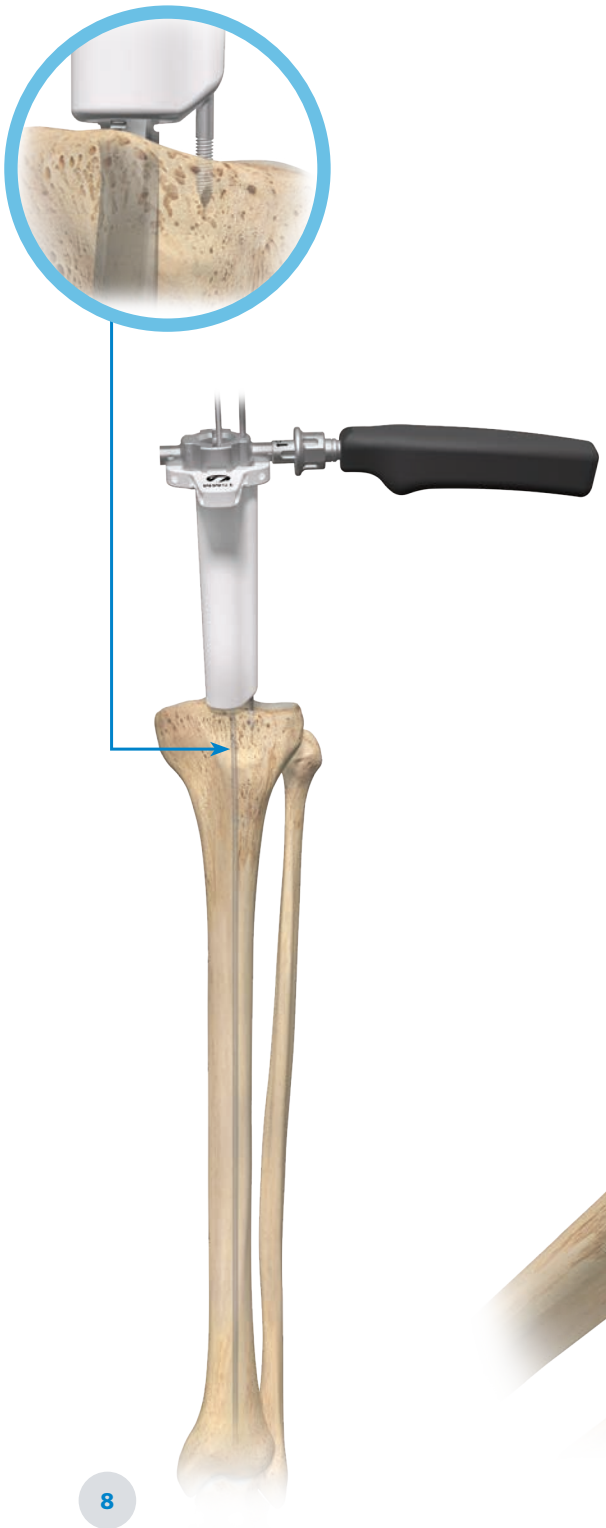
The SUPRA ENTRY OFFSET TROCAR can be used to fine tune the pin placement. To do this, rotate the trocar until the offset hole is aligned with the desired starting point and then advance the pin (Figure 5).

NOTE: Slight flexion and anterior translation of the tibia can assist in aligning the guide wire with the desired starting point.

Advance the guide wire approximately 8-10cm until it is in the intramedullary canal of the tibia (Figure 6).

The guide pin should be parallel to the anterior cortex of the tibial shaft to avoid posterior cortical penetration with the entry reamer (Figure 7).

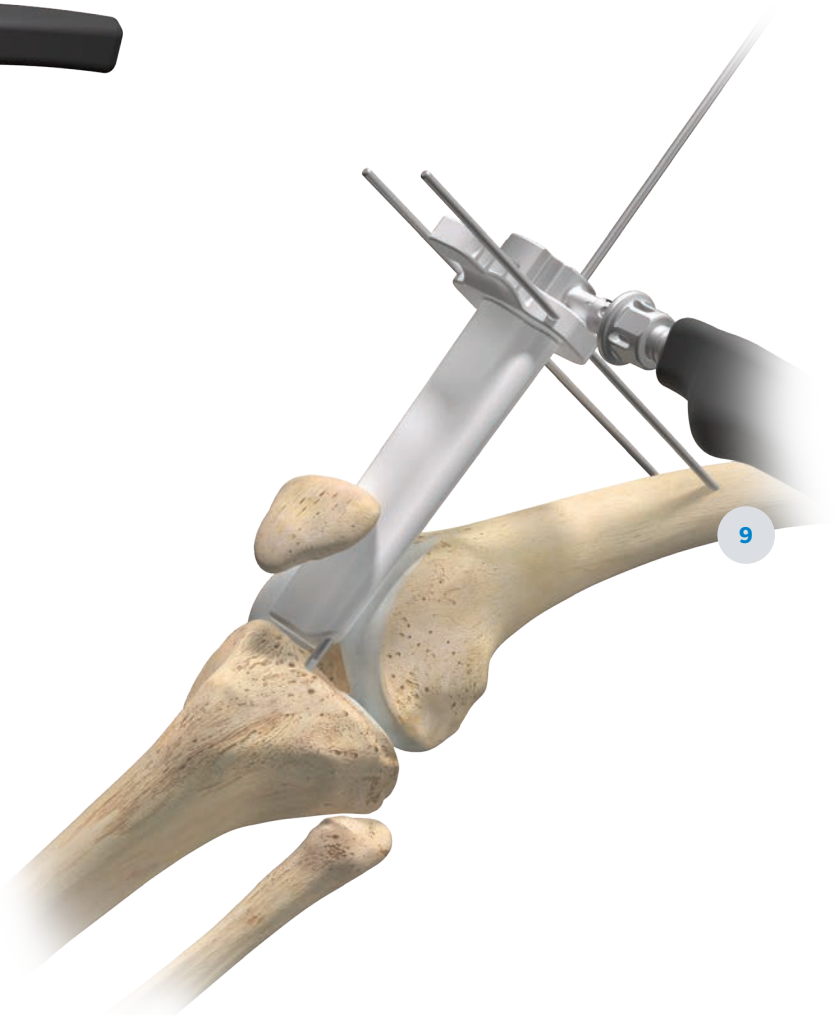
Suprapatellar Approach



5. Opening the Medullary Canal (Suprapatellar Approach)

One SUPRA ENTRY GUIDEWIRE 3.0MM (211300009) may be inserted through the entry sleeve into the proximal tibia to maintain entry portal sleeve position. (Figure 8).

Alternatively, two 3.2MM THREADED GUIDE PIN may be inserted through the sleeve into the femur to maintain sleeve position (Figure 9).



Suprapatellar Approach

10a

Remove the supra offset trocar and place the ENTRY REAMER 12mm (211300012) or TIBIA ENTRY REAMER (211300112) over the guide wire and through the supra entry portal and advance it to the tibia (Figure 10a).

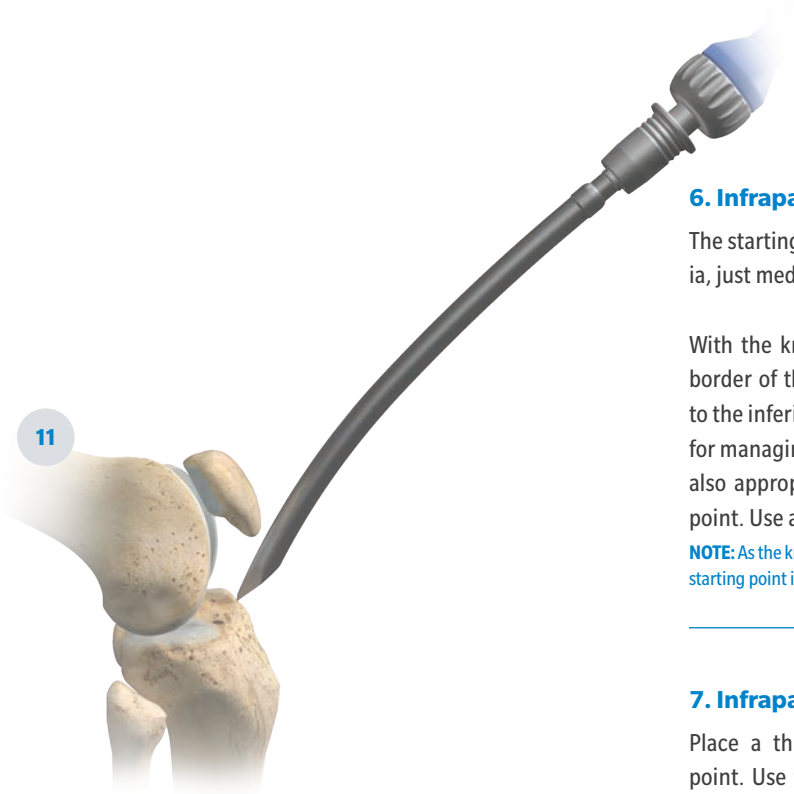
Advance the entry reamer approximately 8 cm, stopping before the reamer reaches to the posterior cortex.

A depth indicator groove on the entry reamer indicates the position of the top of the nail (Figure 10b).

NOTE: For 12mm & 13mm nails, enlarge the entry canal using additional reamers from the reamer caddy.

10b

Infrapatellar Approach



11

6. Infrapatellar Incision

The starting point for the nail is located on the shelf of the tibia, just medial to the Lateral Intracondylar Eminence.

With the knee in flexion, incise the tissue along the medial border of the patellar ligament extending from the joint line to the inferior pole of the patella. There are several techniques for managing the patellar tendon and alternative incisions are also appropriate, as long as they allow for nail entry at this point. Use a retractor if necessary to help manage the tendon.

NOTE: As the knee is in a much less flexed position, the incision is more distal. The starting point in the bone remains the same, regardless of technique.

7. Infrapatellar Entry Point

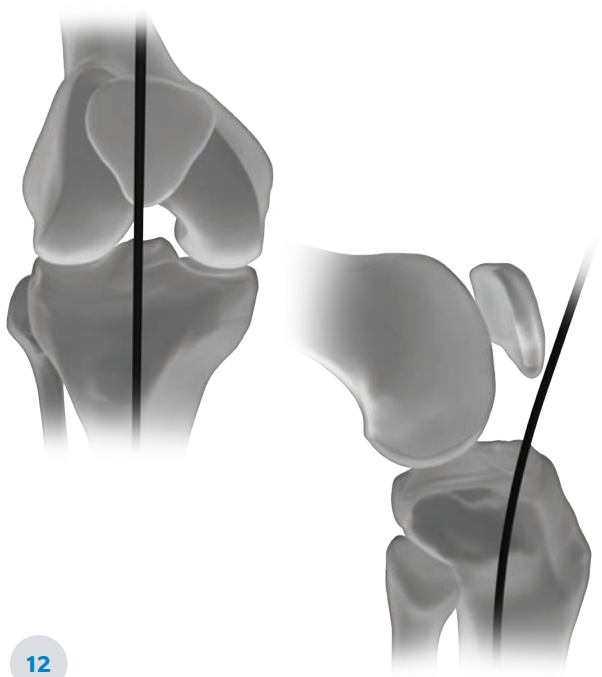
Place a threaded guide pin 3.2x444mm into the starting point. Use the c-arm to visualize the pin's position from a/p and lateral views. The pin should be inserted at the identified point heading slightly posterior into the medullary canal. The ENTRY PORTAL (211300002) and retractors can help protect the surrounding soft tissues during the procedure.

Assemble the ENTRY PORTAL and ENTRY PORTAL OFFSET TROCAR (211300003). Drive the pin through the assembly into the starting point and the center of the medullary canal. Alternatively, the AWL TIBIA, 11mm (211300001) can be used to find the entry point and create the entry portal (Figure 11).

Gently advance the assembly into the infrapatellar space until it reaches the desired starting point on the proximal tibia. Drive the pin through the starting point into the center of the medullary canal.

Radiographic confirmation of this area is essential to prevent damage to the intra-articular structure during portal placement and nail insertion (Figure 12)

NOTE: Patients with patella femoral arthritis may require further patellar mobilization and release to further aid in the advancement of the cannula assembly.



12

Infrapatellar Approach

13

8. Opening the Medullary Canal (Infrapatellar Approach)

Use the ENTRY REAMER 12MM (211300012) or TIBIA ENTRY REAMER (211300112) to prepare the proximal tibia for the proximal portion of the nail.

The groove indicates the final position of the top of the nail (Figure 13). In addition, the C-arm should be used to visualize the depth of the reamer in the proximal tibia. Care should be taken to keep the reamer in line with the shaft of the tibia to avoid reaming through the cortex of the tibia.

After opening reaming, place either an 80cm or 100cm BEAD TIP GUIDEWIRE (211300180 or 211300200) into the medullary canal all the way into the distal tibia.

To aid in manipulation, bend the tip of the guide wire at about a 10-degree angle 5cm from the end.

NOTE: If the guide wire is bent shorter than 5cm from the end of the wire and/or more than 10 degrees it may be difficult to remove from the nail. If the wire becomes lodged inside the nail, utilize the GUIDE WIRE GRIPPER (281001001) and SLOTTED MALLET (211308008) to remove the guide wire from the nail.

Guidewire Insertion

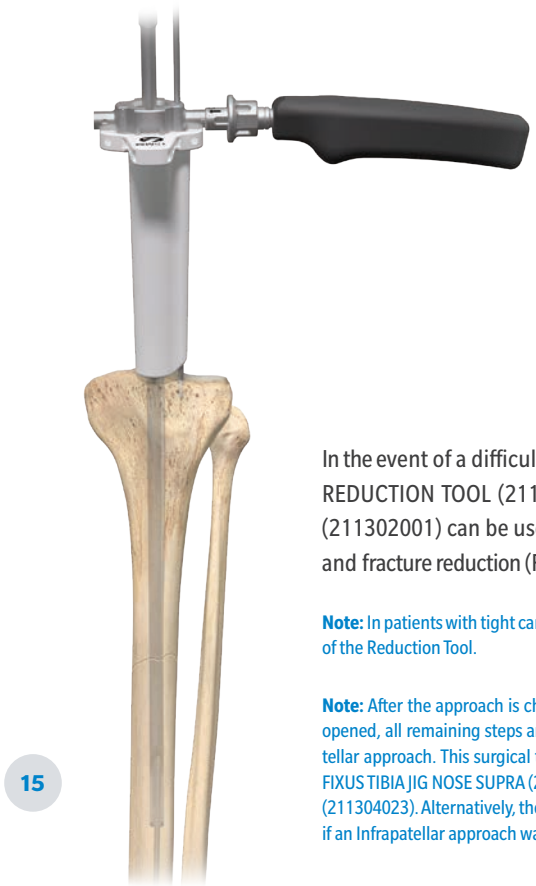
14

9. Guidewire Insertion

Place the BEAD TIP GUIDEWIRE 100cm (211300200) or BEAD TIP GUIDEWIRE 80cm (211300180) into the medullary canal and advanced past the fracture site, into the distal tibia. Confirm the position of the guidewire to be center-center in the AP and lateral views.

To help facilitate the BEAD TIP GUIDEWIRE passage through the fracture site, the PISTOL GRIP WIRE GRIPPER (281001001) may be used (Figure 14).

NOTE: The guide wire may be gently impacted into the distal metaphysis to the level of the physeal scar to prevent accidental removal of the guide wire during reaming. Confirm correct guidewire placement in both AP and lateral views.



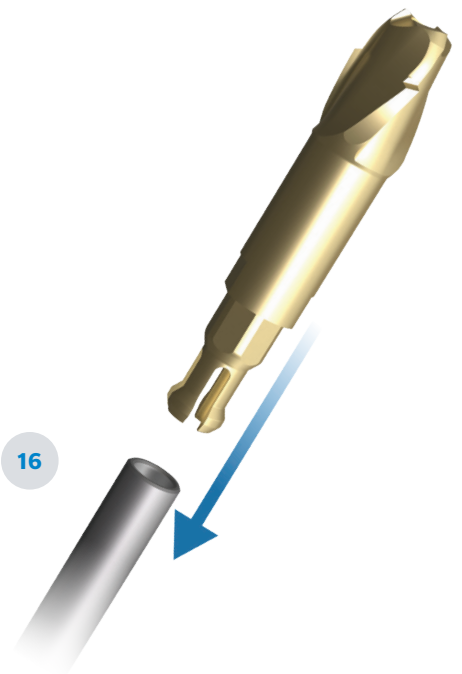
15

In the event of a difficult fracture reduction, the LONG REDUCTION TOOL (211302002) or SHORT REDUCTION TOOL (211302001) can be used to facilitate the guide wire insertion and fracture reduction (Figure 15).

Note: In patients with tight canals, reaming to 9.5mm may help facilitate passage of the Reduction Tool.

Note: After the approach is chosen, entry point is made, and medullary canal is opened, all remaining steps are identical for either the Suprapatellar or Infrapatellar approach. This surgical technique shows the remaining steps with the AFFIXUS TIBIA JIG NOSE SUPRA (211304020) and the AFFIXUS TIBIA JIG BOLT SUPRA (211304023). Alternatively, the AFFIXUS TIBIA JIG NOSE (211304019) may be used if an Infrapatellar approach was selected by the surgeon.

Intramedullary Reaming



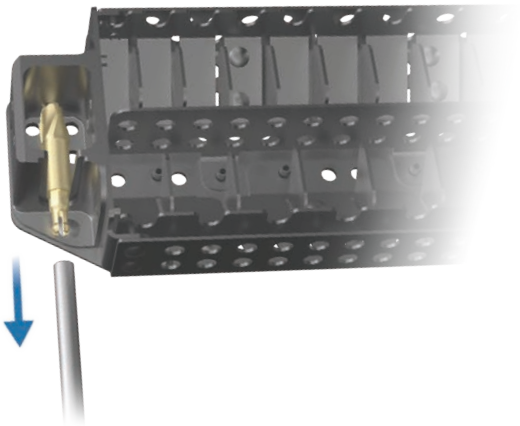
16

Step 10. Intramedullary Reaming

If deemed appropriate, enlarge the medullary canal to the desired diameter using the modular, AFFIXUS PS REAMER HEAD 8.0MM (211300080) to the FLEXIBLE REAMER SHAFT (211300525/ 211300400) (Figure 16)

NOTE: Each AFFIXUS reamer head caddy (120001412) contains modular reamer head diameters from 8mm to 16mm in 0.5mm increments. The removal tool is on the end of the caddy.

NOTE: The 8-12mm diameter Reamer Heads are all forward cutting Reamer Heads to aid in effective reaming of canal.



17

To remove the modular reamer head from the shaft, the AFFIXUS REAMER HEAD CADDY has a small slot in which the non-cutting side of the reamer may be captured (Figure 17).

18

Commence reaming over the Guide Wire 0.5mm increments until the desired diameter has been achieved (Figure 18).

NOTE: The FLEXIBLE REAMER EXTENSION (211300151) may be added to provide additional length to the overall reamer if needed.

During medullary canal reaming, the GUIDEWIRE PUSHER (211300011) can be used to help retain the guidewire during the reamer extraction (Figure 19).

19

The diameter of the selected Affixus Tibial Nail should be 1 - 1.5mm smaller than that of the last reamer used.

NOTE: Since the 3.2mm Bead Tip Guidewire (211300200 sterile) will pass through all AFFIXUS Tibial Nail diameter cannula, an exchange technique is not required.

Nail Selection, Assembly & Insertion

20

Step 11. Determining nail length

Once the tip of the bead tip guidewire reaches the desired depth of nail insertion, slide the NAIL DEPTH GAUGE (211304002) onto the guide wire until resting against the tibial shelf.

Confirm that the tip of the gauge does not fall into the existing tibia entry canal. The nail should be countersunk to prevent impingement (Figure 20).

To obtain the appropriate nail length, read the measurement marked on the laser etch of the guidewire that aligns with the nail depth gauge. The nail length chosen should be at least 1 cm shorter than the measured medullary canal to allow countersinking of the nail (Figure 21).

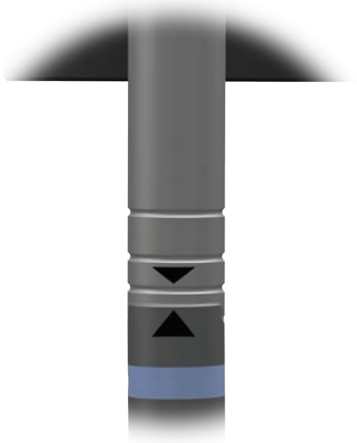
If a nail of the exact measured length is not available, choose the shorter nail option of the closest available length. A direct measurement can also be taken of the uninjured extremity using either radiographs with magnification markers, or directly on the uninjured limb.

NOTE: Alternatively, a second guidewire of equal length may be used to measure the length of the medullary canal. Position the second guide wire at the proximal tip of the shelf of the tibia and measure the difference between the end of the two guidewires.

Nail Selection, Assembly & Insertion

21

Nail Selection, Assembly & Insertion



22

Step 12. Nail Assembly

Align the AFFIXUS TIBIA JIG NOSE SUPRA (211304020) with the proximal aspect of the tibial nail by aligning the arrows on each part. The two tabs on the jig nose should engage with the two slots of the nail and ensure the slope is anterior (Figure 22).

Place the AFFIXUS TIBIA JIG BOLT SUPRA (211304023) into the proximal end of the supra jig nose and proceed to thread into the nail and secure with the JIG BOLT DRIVER (211304000) attached to the AFFIXUS STRAIGHT HANDLE (2RS26-C04-C08) (Figure 23a).

Press the button on the Supra Jig Nose and insert the TIBIA TARGETING GUIDE (211304021) into the supra jig nose. Releasing the button will lock the supra jig nose to the TIBIA TARGETING GUIDE (Figure 23b).

NOTE: To ensure accurate proximal targeting insert the Screw Sheath 5mm (211306018), Drill Sleeve 4.3mm (211306021) and the Interlock Drill Short 4.3mm (211306543 nonsterile or 211306443 sterile) into the appropriate hole in the Tibia Targeting Guide (Figure 23c) to ascertain accuracy.

This single jig allows for placement of 4 proximal interlocking screws, two transverse and two oblique.

23a

Nail Selection, Assembly & Insertion

23b

23c

Nail Selection, Assembly & Insertion

24a

24b

Step 13. Nail Insertion

Insert the tibia nail and jig assembly over the Guide Wire and advance into the medullary canal to the desired depth. Gently manipulate the nail to help avoid penetration of the posterior cortex.

If additional nail depth is needed, attach the AFFIXUS IMPACTION PAD (211304006) to the jig and use the SLOTTED MALLET (211308008) to strike the pad until the nail is at the desired depth (Figure 24a).

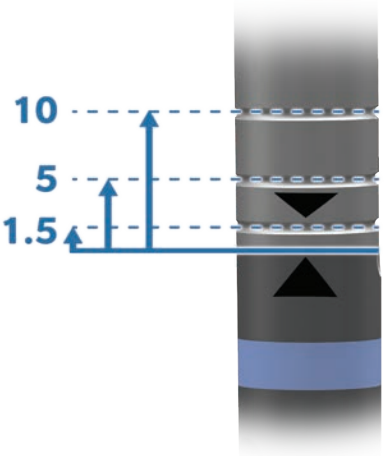
To avoid nail misalignment, do not strike the Tibia Jig Nose directly (Figure 24b).

The fracture should be adequately reduced and out to length during the insertion of the nail and should be monitored with radiographic images.

The guide wire is removed after the nail passes the fracture site.

The nail depth should be well below the chondral surface to minimize irritation to the patellar tendon.

NOTE: When inserting, the nail can be countersunk to the level indicated by the groove on the jig nose (Figure 25).

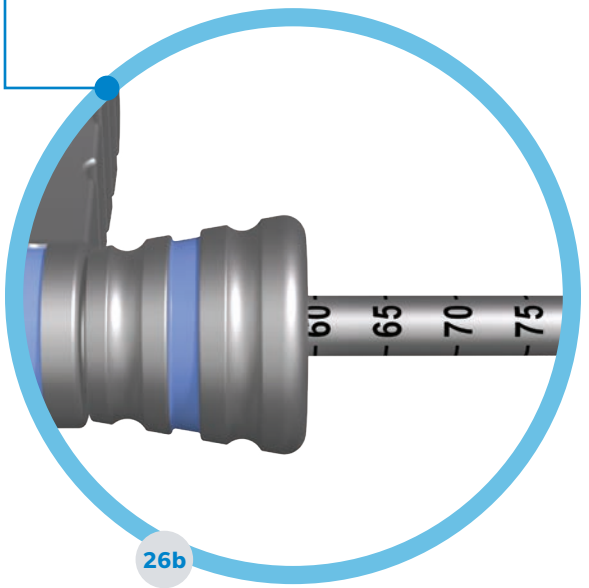


25

Final nail positioning should be checked in both the AP and lateral radiographs to ensure proper alignment.

Proximal Screw Insertion

26a



26b

Step 14. Proximal Locking - Static Screws

Proximal Targeting - Static Locking

Before locking the nail proximally, verify that the Affixus Tibia Jig Bolt Supra is securely tightened and that the Targeting Arm Tibia is properly attached to the nail adapter.

Prior to starting proximal locking ensure that the axis of the tibia, leg length, and rotational alignment are within the desired tolerances.

Assemble the SCREW SHEATH 5MM TIBIA (211306018), drill sleeve 4.3mm tibia (211306021), and if desired, TROCAR 5MM TIBIA (211306027) and insert through the Tibia Targeting Guide Static Hole (Figure 26a).

Make a small incision in order to allow the assembled sleeves to sit on the bone. If used, remove the trocar. Advance assembled sleeves to the near cortex.

Insert the INTERLOCK DRILL SHORT 4.3MM (211306543 / 211306443) through the SCREW SHEATH 5.0MM TIBIA (211306018) and DRILL SLEEVE 4.3MM TIBIA (211306021) to perforate the medial cortex, pass through the nail, and perforate the lateral cortex.

With the sleeve assembly held firmly against the medial cortex, the appropriate screw length is measured off the Interlock Drill bit at the end of the drill sleeve. (Figure 26b)

Alternatively, SCREW DEPTH GAUGE TIBIA (211306037) into the SCREW SHEATH 5.0MM TIBIA (211306018) may be used to determine the appropriate length of the screw.

NOTE: All tibia nail diameters require 5mm diameter proximal screws.

Proximal Screw Insertion

After drilling through both cortices, remove the drill. Insert the hook through the bone to the far cortex. The measurement is taken in a similar way to the calibrated drill markings: the first visible measurement not covered by the tube.

The DRILL SLEEVE (211306021) is removed and the appropriate 5mm screw is inserted through the SCREW SHEATH (211306018. Ensure position of screw with radiographic visualization. Repeat the procedure for the insertion of the second screw.

Proximal Screw Insertion

26

27

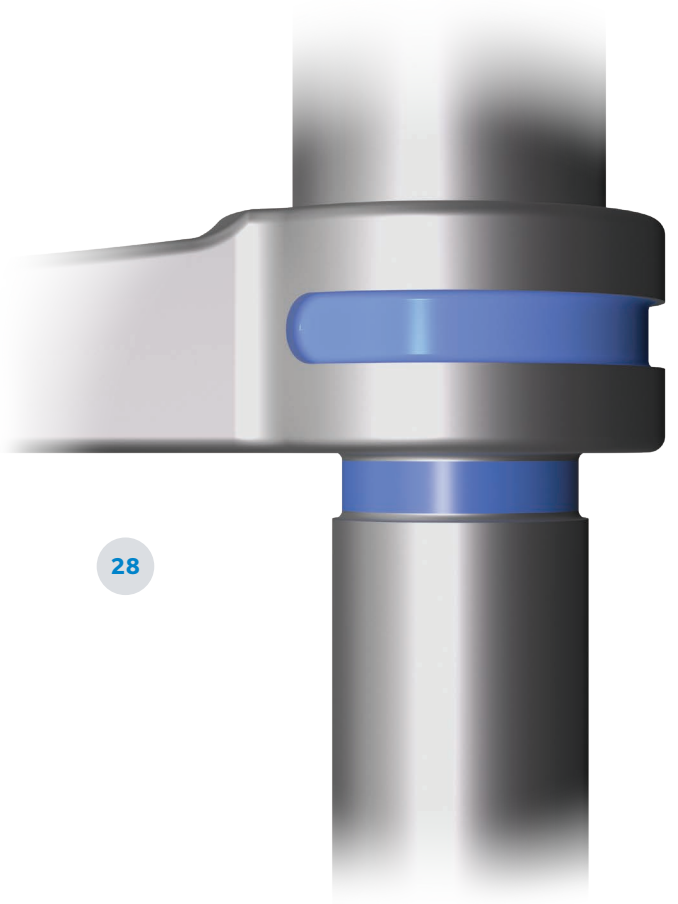
15. Screw Insertion

15a Retaining Screw Assembly:

For proximal screws, after inserting the LOCKING DRIVER SHAFT LONG (211306008) through the locking driver tube long (211306007), attach the LOCKING DRIVER TUBE LONG (211306007) to the AFFIXUS STRAIGHT HANDLE (2RS26-C04-C08) (FIgure 26).

After attaching the Affixus 5mm screw to the LOCKING DRIVER TUBE LONG (211306007), the LOCKING DRIVER TOOL (211306013) is used to tighten the driver to the screw by turning the knob in a clockwise direction (Figure 27).

Proximal Screw Insertion



28

15b. Screw Insertion (Continued)

Press-fit screw Assembly:

For proximal screws, attach the DRIVER BT-25 HEXALOBE SHORT (211306004) to the AFFIXUS STRAIGHT HANDLE (2RS26-C04-C08).

15c. Final Insertion-Proximal Static Locking

During proximal screw insertion the retaining drivers and press-fit drivers include a blue line mark (for tibia) that will indicate when the screw head is fully seated (Figure 28). (Ensure that the screw sheath (211306018) is firmly against the bone).

NOTE: For final tightening of the 5mm screws, the Driver BT-25 Hexalobe Short (211306004) or the Driver BT-25 Hexalobe Distal (211306005) should be used.

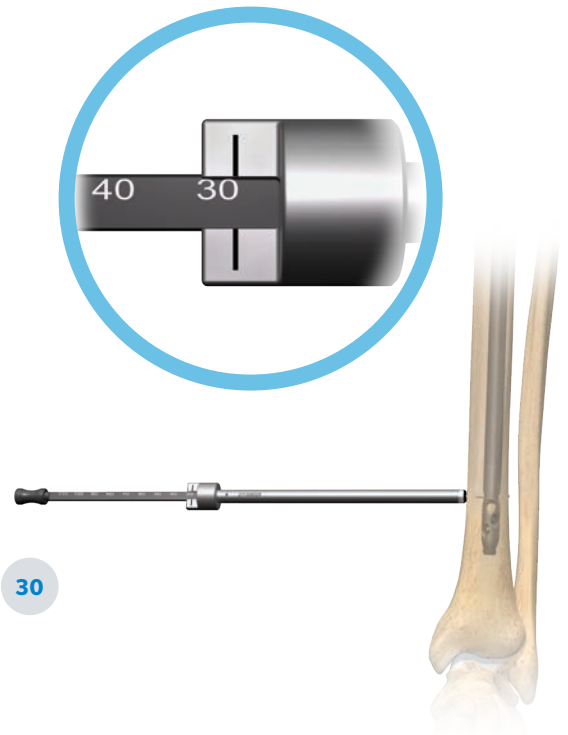
Proximal Screw Insertion

29

15d. Proximal Locking - Static Screws

An additional screw can be inserted in a similar fashion through the distal Static hole of the Tibia Targeting Guide (Figure 29).

Distal Screw Placement



30

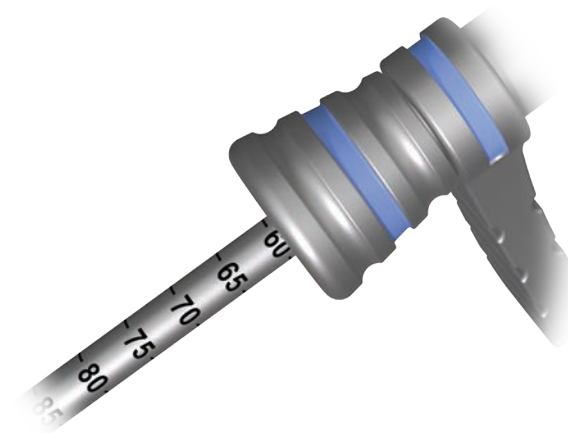
16. Distal Locking

Verify the depth of the nail distally in both A/P and lateral views. The Affixus Tibial Nail may be locked distally with screws in both the sagittal and frontal planes, as well as in descending oblique planes. Distal A/P and oblique locking allows for placement of perpendicular screws and multi-directional screws for a more secure fixation of the distal fragment.

Distal locking may be accomplished using a freehand technique. The image intensifier is aligned with the more distal hole in the nail, such that the hole appears as a perfect circle.

A knife blade is placed on the skin, with the incision point verified on the image intensifier, and a 1cm incision is made over the hole in the nail. The tip of the drill bit appears as a solid circle in the center of the screw hole.

Note: If desired, the Countersink (211306743) may be used for preparation of distal screw placement.



31

Proceed to drill through both cortices with the 4.3MM INTERLOCK DRILL DISTAL (211306043/211306143) and 4.3mm DISTAL DRILL SLEEVE (211306022). The position of the drill bit is confirmed on the image intensifier in both the A/P and Lateral planes, before it is withdrawn. Additional screw holes are drilled in a similar fashion.

Determining the length of the appropriate screw size for distal locking options can be achieved by using the free-hand technique with a SCREW DEPTH GAUGE TUBE (211306029) and a SCREW DEPTH GAUGE HOOK (211306030). After drilling through both cortices, hook the far cortex using the hook instrument (Figure 30).

Alternatively, the measurement is taken by reading the first visible measurement not covered by the tube. Overlay the 4.3mm INTERLOCK DRILL DISTAL with the 4.3MM DISTAL DRILL SLEEVE to read the first visible measurement from the calibrated drill (Figure 31).

NOTE: The 4mm screws are used distally with the 8mm nail only. In this case, use the INTERLOCK DRILL DISTAL 3.3MM (211306032/211306232) with the DRILL SLEEVE 3.3MM DISTAL (211306023).

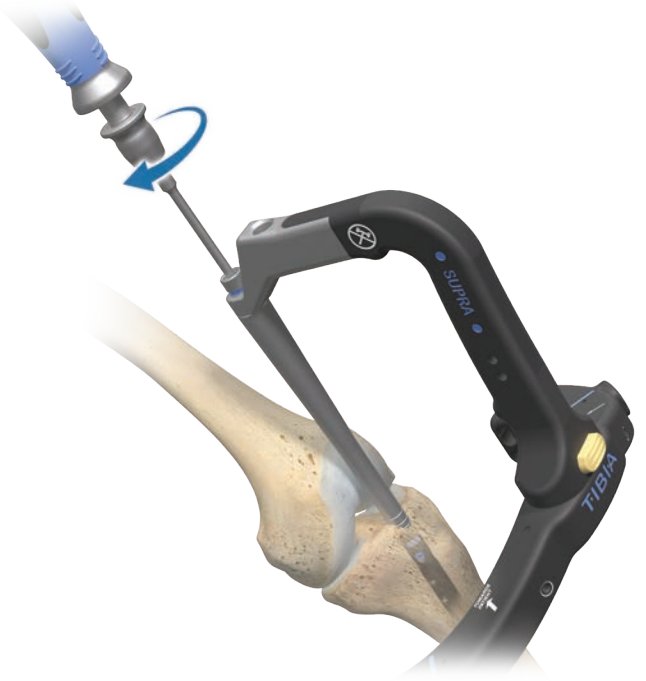
Nail Selection, Assembly & Insertion

16a. Screw Retention – Distal Screws

If using the retaining screw assembly for the distal screws, the LOCKING DRIVER TUBE DISTAL (211306009) and LOCKING DRIVER SHAFT DISTAL (211306010) are used. The LOCKING DRIVER TOOL (211306013) is also used to tighten and loosen the driver to the screw.

If using the press-fit screw assembly for the distal screws, attach the DRIVER BT-25 HEXALOBE DISTAL (211306005) or the DRIVER BT-25 HEXALOBE, SHORT (211306004) for the 4mm or 5mm screws.

Compression Mechanism – CoreLock (Optional)



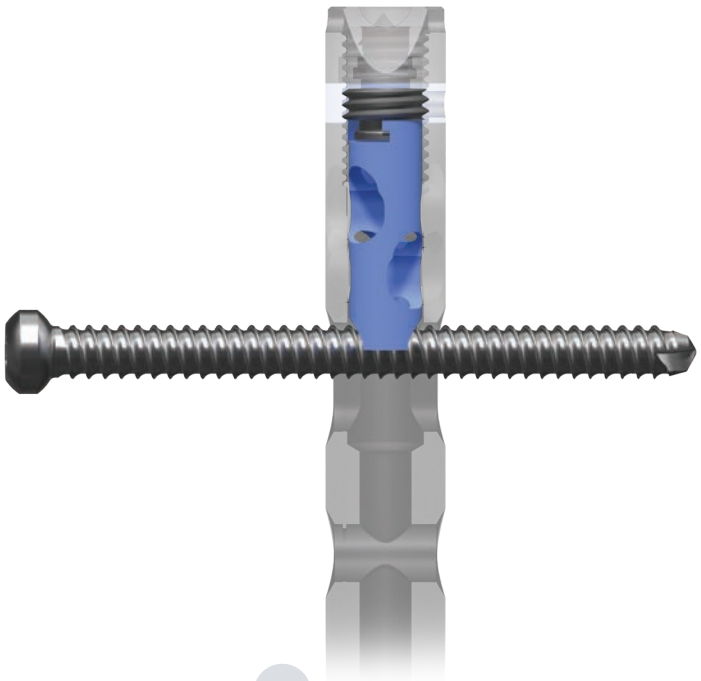
17. Proximal Locking - Compression Mechanism-CoreLock (Optional)

If desired, the Affixus Tibial Nail offers a preassembled, embedded set screw/locking mechanism for the proximal oblique screws, that can provide up to 5mm of internal, mechanical compression.

NOTE: If compression is desired, first ensure distal locking has been completed and a proximal screw has been placed in the dynamic slot.

Attach the RIGID CORELOCK DRIVER HEX 4MM (211304027) to the AFFIXUS TORQUE-LIMITING HANDLE (2TS5-C04-C08) by inserting through the proximal end of either the suprapatellar jig nose or standard jig nose, through the nail until engaged with the CoreLock mechanism, and then turn in a clockwise motion (Figure 31a, 31b).

NOTE: Turn slowly clockwise to tighten until 3-4 clicks are felt from the torque limiting handle.

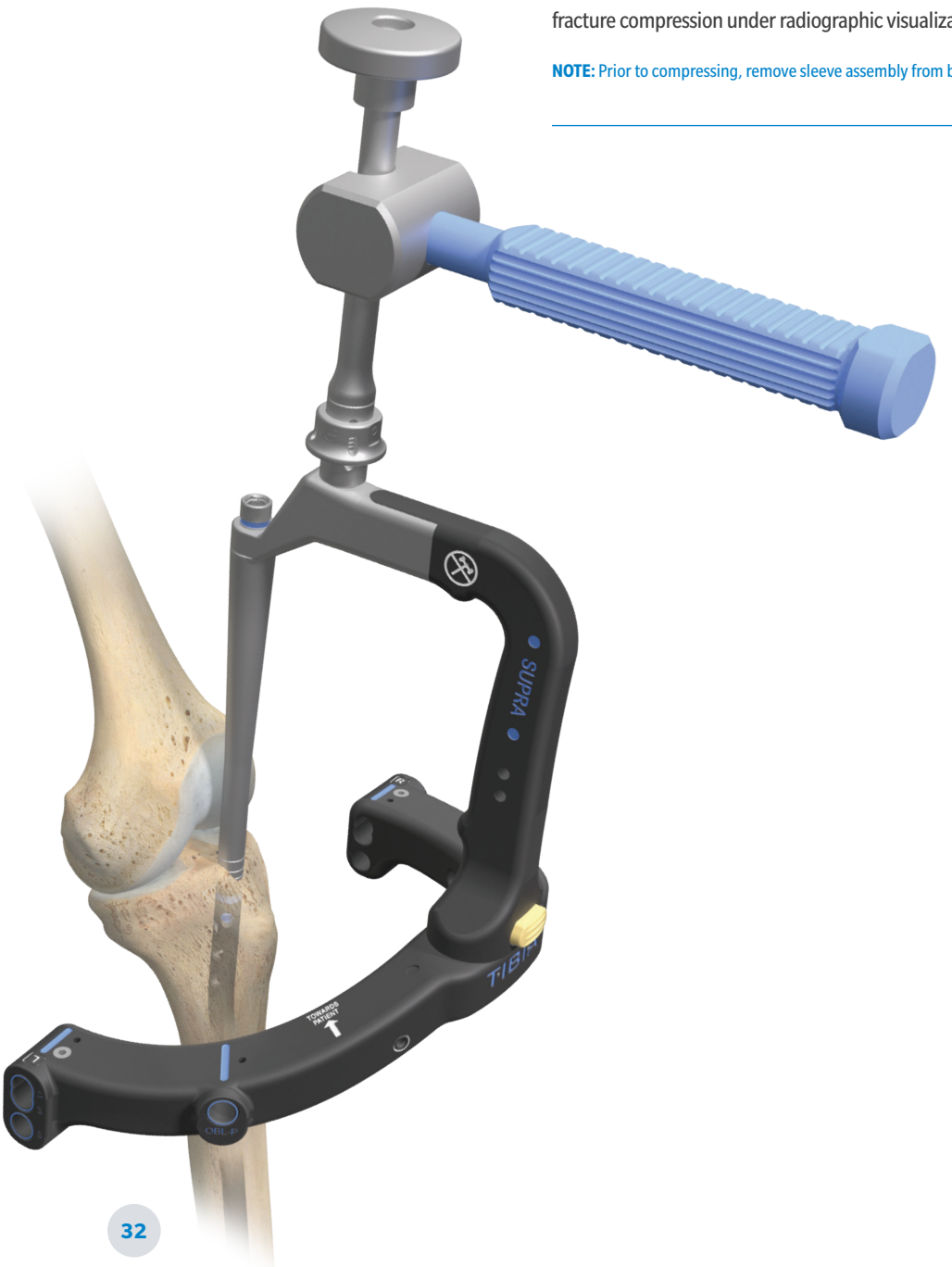


31

Compression Mechanism – CoreLock (Optional)

Alternatively, a backstroke technique can be employed for compression of the fracture. To accomplish manual compression, attach the IMPACTION PAD (211304006) to either of the Jig Noses. Backslap the proximal end of the impaction pad with the SLOTTED MALLET (211308008). Monitor screw position and fracture compression under radiographic visualization (Figure 32).

NOTE: Prior to compressing, remove sleeve assembly from bone



32

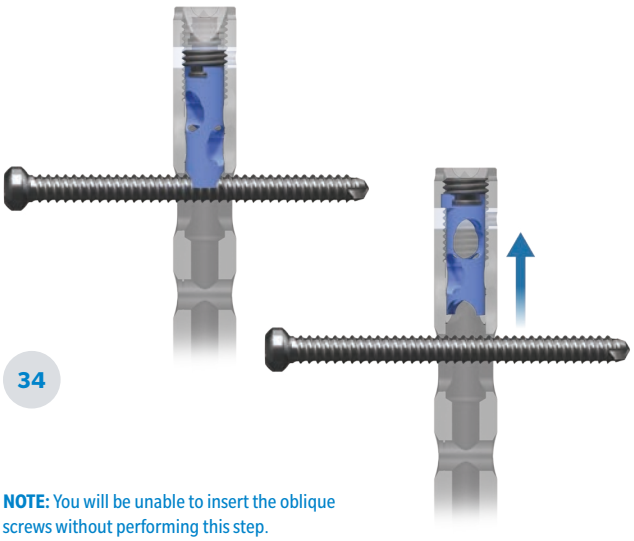
Compression Mechanism – CoreLock (Optional)

17. Compression Mechanism-Corelock (optional) (continued)

After desired compression is achieved, repeat screw insertion through the Distal Static hole letter "S" on the Tibia Targeting Guide to maintain the achieved compression (Figure 33).

33

Compression Mechanism – CoreLock (Optional)



34

NOTE: You will be unable to insert the oblique screws without performing this step.

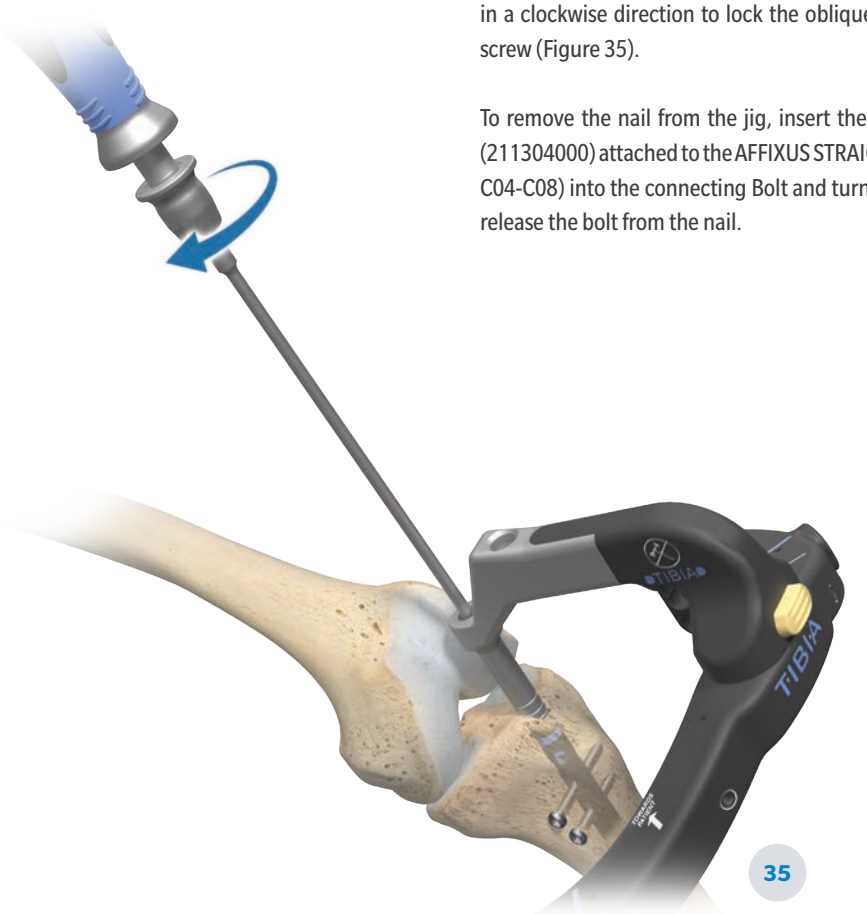
Upon screw insertion into the Distal Static hole, connect the RIGID CORELOCK DRIVER HEX 4mm (211304027) to the AFFIXUS Torque-Limiting Handle and insert through the proximal end of the Jig Nose.

Once the Corelock Driver is engaged with the nail set screw, turn in a counterclockwise direction to reverse the set screw until it stops against the connecting bolt. This step will ensure correct position of the CoreLock for locking the proximal oblique screws, if desired (Figure 34).

Oblique screws can be inserted in the same manner as described earlier. When insertion of the oblique screws is completed, insert the RIGID CORELOCK DRIVER HEX 4mm (211304027) to the AFFIXUS Torque-Limiting Handle and insert through the proximal end of the Jig Nose.

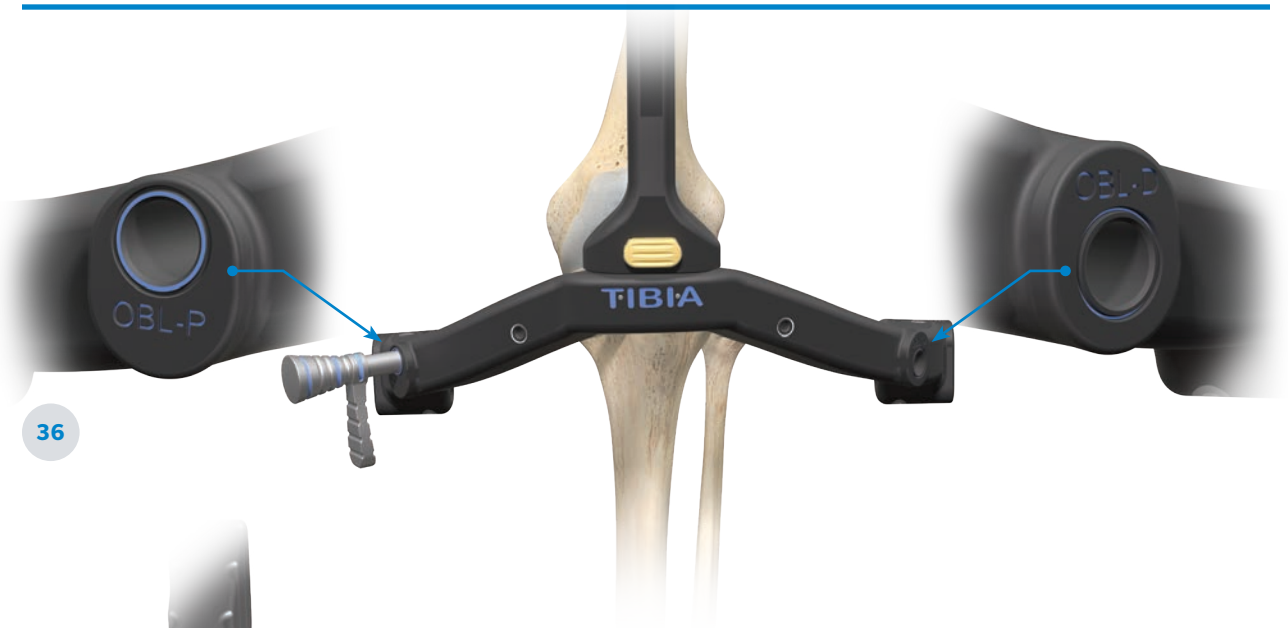
Once the Corelock Driver is engaged with the nail set screw, turn in a clockwise direction to lock the oblique screws with the set screw (Figure 35).

To remove the nail from the jig, insert the Rigid Jig Bolt Driver (211304000) attached to the AFFIXUS STRAIGHT HANDLE (2RS26-C04-C08) into the connecting Bolt and turn counterclockwise to release the bolt from the nail.

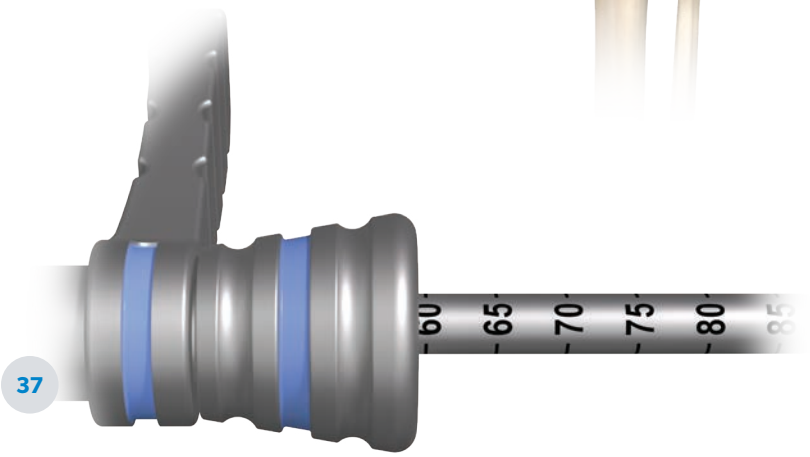


35

Proximal Targeting-Oblique



36



37

18. Proximal Targeting - Oblique

NOTE: If compression is desired, Oblique screw targeting is to be completed after all steps of compression in section 17. Compression Mechanism - Corelock (optional) are finished.

NOTE: If opting to bypass compression using the Corelock meachanism, Oblique screw targeting can begin here.

Assemble the SCREW SHEATH 5MM TIBIA (211306018), DRILL SLEEVE 4.3MM TIBIA (211306021), and if desired, TROCAR 5mm TIBIA (211306027) and insert through the Tibia Targeting Guide marked with "OBL-P" or "OBL-D" (Figure 36). Make a small incision in order to allow the assembled sleeves to sit on the bone. Advance assembled sleeves to the bone and mark the entry point. If used, remove the trocar. Advance assembled sleeves to the near cortex.

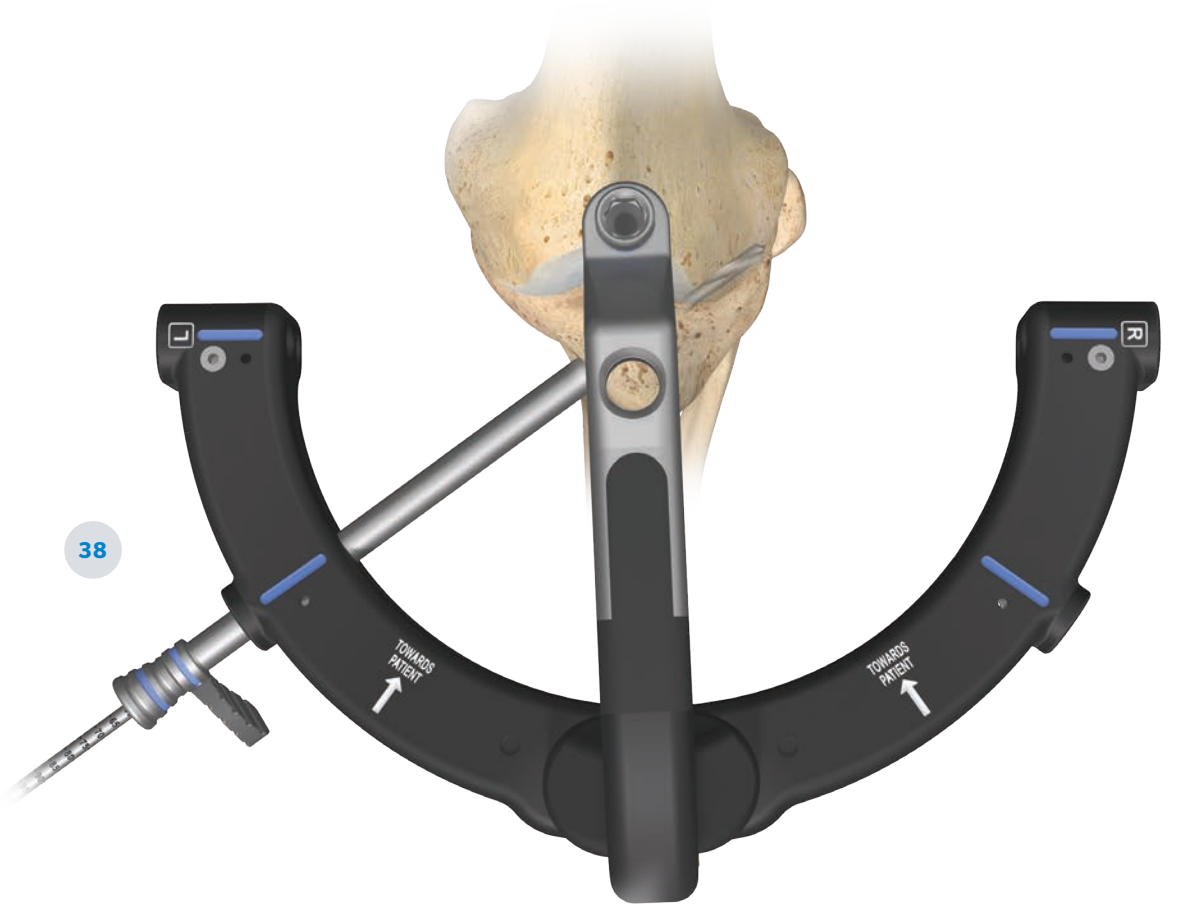
Drive the INTERLOCK DRILL 4.3 (211306443 or 211306543) through the SCREW SHEATH 5MM TIBIA (211306018) and DRILL SLEEVE 4.3MM TIBIA (211306021) to perforate the medial cortex, pass through the nail, and perforate the lateral cortex.

With the sleeve assembly held firmly against the medial cortex, the appropriate screw length is measured off the Interlock Drill bit at the end of the Drill Sleeve (Figure 37).

Alternatively, SCREW DEPTH GAUGE TIBIA (211306037) into the SCREW SHEATH 5.0MM TIBIA (211306018) may be used to determine the appropriate length of the screw.

NOTE: All tibia nail diameters require 5mm diameter proximal screws.

Proximal Targeting-Oblique



18. Proximal Targeting - Oblique (Continued)

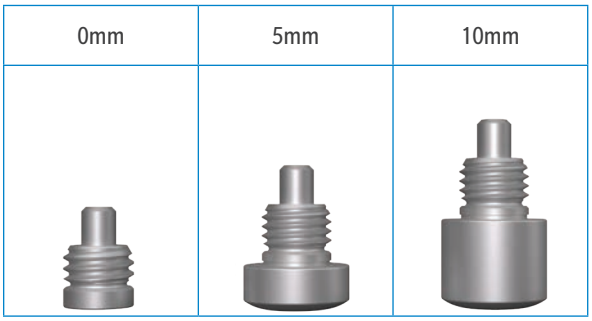
After drilling through both cortices, remove the drill. Insert the hook through the bone to the far cortex. The measurement is taken in a similar way to the calibrated drill markings: the first visible measurement not covered by the tube.

The 5mm Affixus screw is inserted through the Screw Sheath. Ensure position of screw with radiographic visualization. Repeat the procedure for the insertion of the second oblique screw (Figure 38).

To remove the nail from the jig, insert the RIGID JIG BOLT DRIVER (211304000) attached to the AFFIXUS STRAIGHT HANDLE (2RS26-C04-C08) into the connecting Bolt and turn counterclockwise to release the bolt from the nail.

NOTE: Refer to page 35 for the corelock mechanism engaging with the oblique screws.

End Cap Insertion



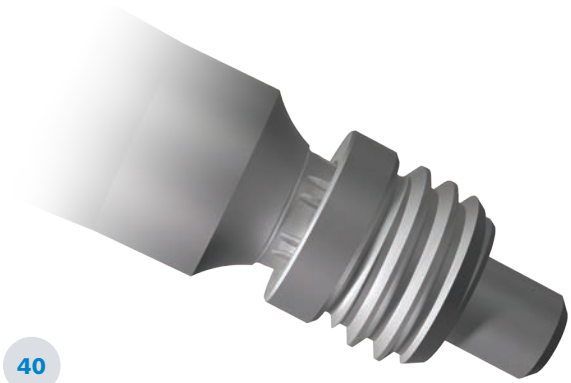
39 **Note:** If using the flush end cap, remove the jig bolt prior to insertion. If using the 5mm or 10mm end caps, then the jig must be removed prior to inserting the end caps.

19. End Cap Insertion

If desired, one of four different profile end caps ranging from 0mm to 15mm (5mm increments) can be inserted into the proximal end of the AFFIXUS Tibia Nail to prevent bony in-growth (Figure 39).

When inserting the end cap, attach the LOCKING DRIVER TUBE, END CAP (211306002) and LOCKING DRIVER SHAFT RECON (211306012) to the T-Handle (2RT25-C04-C08) and attach the appropriate end cap to the Locking Driver (Figure 40). The LOCKING DRIVER TOOL (211306013) is used to tighten the driver to the screw by turning the knob in a clockwise direction.

Once the end cap is attached to the driver, turn the T-Handle in a clockwise direction to thread the end cap into the proximal end of the nail (Figure 41).



40

41

Postoperative Care and Implant Removal

20. Postoperative Care

Early range of motion exercises of the knee and ankle are encouraged. Allow toe-touch weight bearing to progress to full weight bearing as fracture callus increases on the x-ray films.

21. Implant Removal

To remove the nail, start by removing the end cap if implanted using the LOCKING DRIVER TUBE, END CAP (211306002) and LOCKING DRIVER SHAFT, RECON (211306012) attached to the AFFIXUS T-Handle (2RT25-C04-C08).

If the corelock mechanism is engaged, release the mechanism prior to screw removal by using the RIGID CORELOCK DRIVER HEX 4MM (211304027) to the AFFIXUS TORQUE-LIMITING HANDLE (2TS5-C04-C08).

Next, remove all but one of the locking screw with the LOCKING DRIVER TUBE DISTAL (211306009) and LOCKING DRIVER SHAFT DISTAL (211306010) attached to the AFFIXUS T-Handle (2RT25-C04-C08) or the DRIVER BT-25 HEXALOBE, SHORT (211306004). It is important to leave one screw in the nail to prevent nail rotation when connecting the nail extractor to the nail.

Alternatively, if all screws have been removed, a 4.3mm Drill Bit (211306543 or 211306143 as applicable) can be placed through any of the removed screw holes.

NOTE: Make sure the final locking screw is removed prior to back slapping the nail out of the tibial canal.

Implant Removal

42

21. Implant Removal (Continued)

Insert a Guide Wire into the end of the nail to help guide the extractor to the proximal portion of the nail. Thread the Extraction Bolt (211308003) or the Affixus Conical Extractor (211308004) to the proximal portion of the nail using the ¾" Hex Driver (14-442066) (Figure 42).

Then thread the Extraction Rod (211308001) on the proximal end of the Extraction Bolt.

Implant Removal

Make sure the final locking screw is removed prior to back slapping the nail out of the femoral canal. Proceed to use the Slotted Mallet (211308008) over the Extraction Rod (211308001) to back slap the nail (Figure 43).

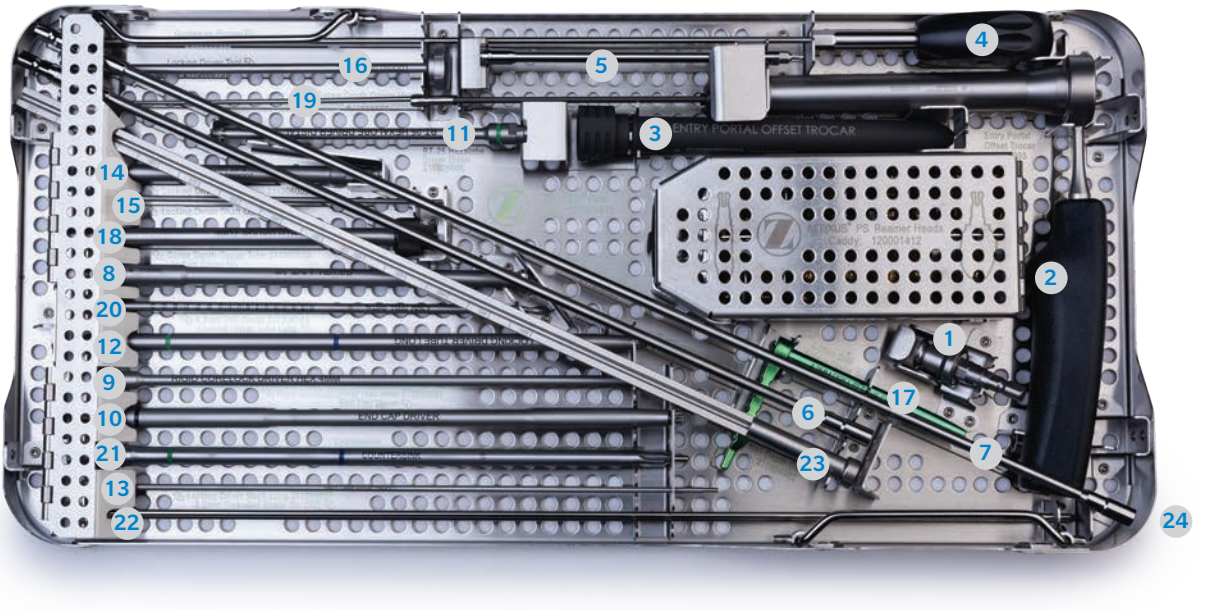
43

System Trays

System Trays - Core Instruments

	Part#	Description
1	27977	STRYKER TO AO ADAPTER
2	211300002	ENTRY PORTAL
3	211300003	ENTRY PORTAL OFFSET TROCAR
4	211300011	GUIDEWIRE PUSHER
5	211300151	FLEXIBLE REAMER EXTENSION
6	211300400	FLEXIBLE REAMER SHAFT 400
7	211300525	FLEXIBLE REAMER SHAFT 525
8	211304000	JIG BOLT DRIVER
9	211304027	RIGID CORELOCK DRIVER HEX 4MM
10	211306002	END CAP DRIVER BT-30 HEXALOBE
11	211306005	DRIVER BT-25 HEXALOBE, DISTAL
12	211306007	LOCKING DRIVER TUBE, LONG

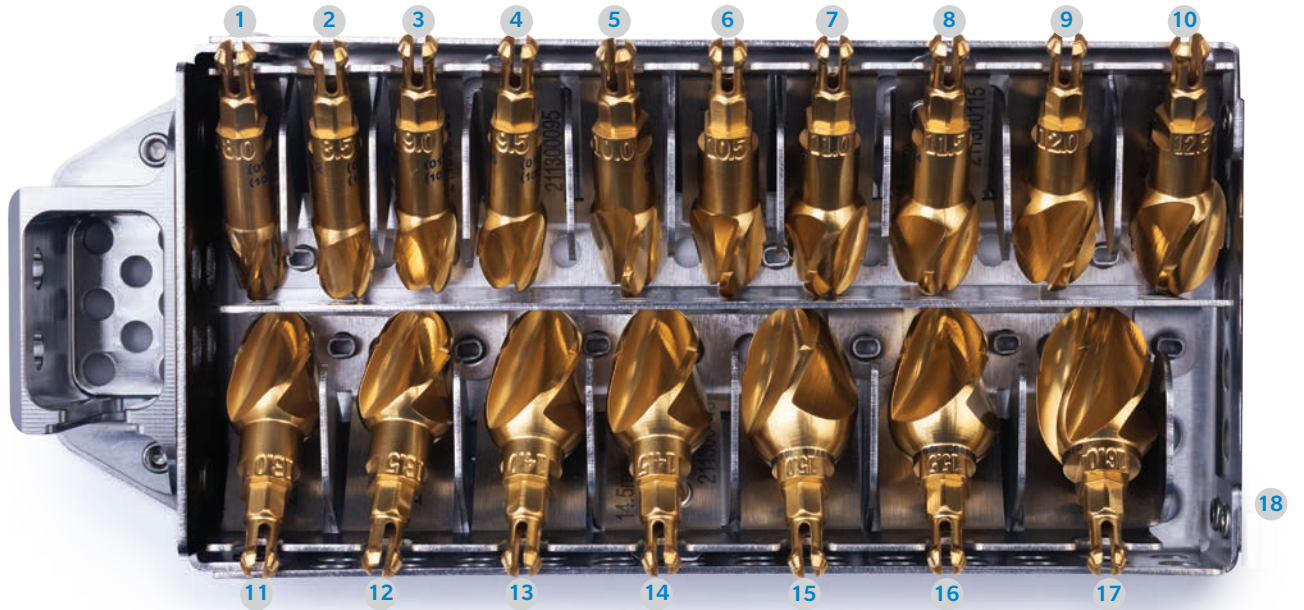
	Part#	Description
13	211306008	LOCKING DRIVER SHAFT, LONG
14	211306009	LOCKING DRIVER TUBE, DISTAL
15	211306010	LOCKING DRIVER SHAFT, DISTAL
16	211306013	LOCKING DRIVER TOOL
17	211306022	DRILL SLEEVE, 4.3MM DISTAL
18	211306029	SCREW DEPTH GAUGE TUBE
19	211306030	SCREW DEPTH GAUGE HOOK
20	211306143	INTERLOCK DRILL DISTAL 4.3MM
21	211306743	COUNTERSINK
22	903003004	THREADED GUIDE PIN 3.2X444
23	211304002	NAIL DEPTH GAUGE
24	120001411	AFFIXUS CORE TRAY



System Trays - Core Instruments

	Part#	Description
1	211300080	Affixus PS Reamer Head 8.0mm
2	211300085	Affixus PS Reamer Head 8.5mm
3	211300090	Affixus PS Reamer Head 9.0mm
4	211300095	Affixus PS Reamer Head 9.5mm
5	211300100	Affixus PS Reamer Head 10.0mm
6	211300105	Affixus PS Reamer Head 10.5mm
7	211300110	Affixus PS Reamer Head 11.0mm
8	211300115	Affixus PS Reamer Head 11.5mm
9	211300120	Affixus PS Reamer Head 12.0mm

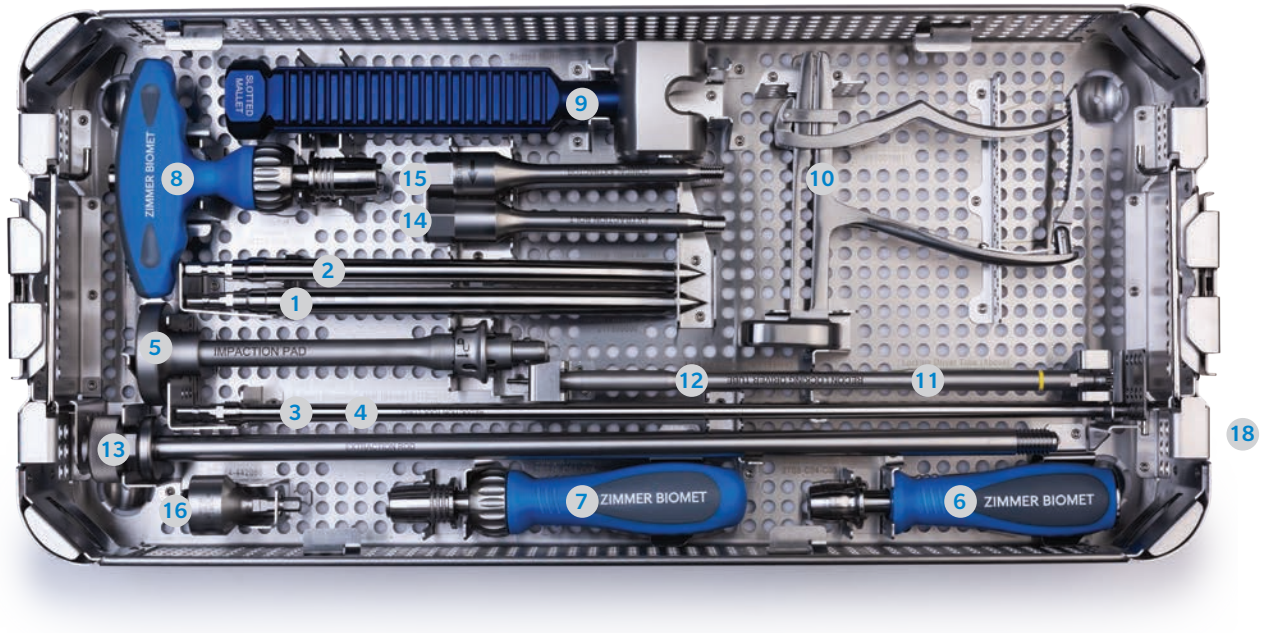
	Part#	Description
10	211300125	Affixus PS Reamer Head 12.5mm
11	211300130	Affixus PS Reamer Head 13.0mm
12	211300135	Affixus PS Reamer Head 13.5mm
13	211300140	Affixus PS Reamer Head 14.0mm
14	211300145	Affixus PS Reamer Head 14.5mm
15	211300150	Affixus PS Reamer Head 15.0mm
16	211300155	Affixus PS Reamer Head 15.5mm
17	211300160	Affixus PS Reamer Head 16.0mm
18	120001412	Affixus Reamer Head Caddy



System Trays - Core Instruments

	Part#	Description
1	211300000	Awl Femoral, 13mm
2	211300001	Awl Tibial, 11mm
3	211302001	Short Reduction Tool
4	211302002	Long Reduction Tool
5	211304006	Impaction Pad
6	2TS5-C04-C08	Torque Square Drive Handle
7	2RS26-C04-C08	AFX Straight Handle, Z/H
8	2RT25-C04-C08	AFX Ratchet T Handle, Z/H
9	211308008	Slotted Mallet

	Part#	Description
10	281001001	Wire Gripper
11	211306011	Locking Driver Tube, Recon
12	211306012	Locking Driver Shaft, Recon
13	211308001	Extraction Rod
14	211308003	Affixus Extraction Bolt
15	211308004	Affixus Conical Extractor
16	14-442066	3/4" Hex Driver
17	110031221	Tray Lid
18	120001410	Affixus Core Base



System Trays - Tibia Instruments

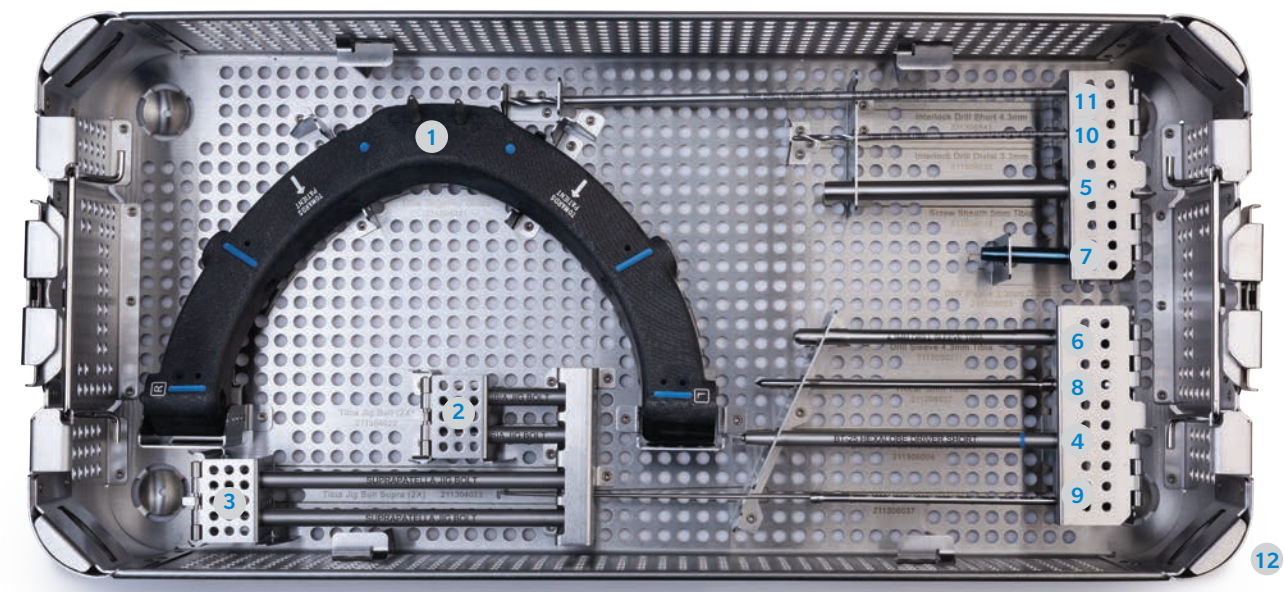
	Part#	Description
1	211300004	Supra Entry Portal
2	211300005	Supra Entry Offset Trocar
3	211300006	Supra Entry Portal Large
4	211300008	Supra Entry Trocar
5	211300009	Supra Entry Guidewire, 3.0mm
6	211300012	Entry Reamer, 12mm

	Part#	Description
7	211300017	Supra Entry Trocar Large
8	211300018	Supra Entry Portal Handle
9	211300112	Tibia Entry Reamer
10	211304019	Affixus Tibia Jig Nose
11	211304020	Affixus Tibia Jig Nose, Supra
12	903003004	Threaded Guide Pin 3.2x444
13	120001413	Affixus Tibia Tray

System Trays - Tibia Instruments

	Part#	Description
1	211304021	Affixus Tibia Targeting Guide
2	211304022	Affixus Tibia Jig Bolt
3	211304023	Affixus Tibia Jig Bolt, Supra
4	211306004	Driver Bt-25 Hexalobe, Short
5	211306018	Screw Sheath, 5.0mm Tibia
6	211306021	Drill Sleeve, 4.3mm Tibia

	Part#	Description
7	211306023	Drill Sleeve, 3.3mm Distal
8	211306027	Trocar, 5.0mm Tibia
9	211306037	Screw Depth Gauge Tibia
10	211306232	Interlock Drill Distal 3.3mm
11	211306543	Interlock Drill Short 4.3mm
12	120001414	Affixus Tibia Base
13	110031221	GTS TRN Connect Lid



Ordering Information

Ordering Information - Disposable Instruments

X-Ray Templates

Part#	Description
XR815407239-3	Affixus Tibia XRay TMP110%

Disposable Instruments

Part#	Description
211300180	Bead Tip Guidewire 80cm St
211300200	Bead Tip Guidewire 100cm St
281001175	Threaded Guide Pin 3.2x444 St
903003004	Threaded Guide Pin 3.2x444
211306043	Interlock Drill Distal 4.3mm St
211306143	Interlock Drill Distal 4.3mm
211306232	Interlock Drill Distal 3.3mm
211306543	Interlock Drill Short 4.3mm
211306743	Countersink

Part#	Description
211306032	Interlock Drill Distal 3.3mm St
211306443	Interlock Drill Short 4.3mm St
211300009	Supra Entry Guidewire 3.0mm
211300007	Entry Portal Sleeve St
211300010	Entry Portal Sleeve Large St

Ordering Information - Implants

Tibia Implants - Nails

Part#	Description
815408240	Affixus Tibia NL 8x240 ST
815408250	Affixus Tibia NL 8x250 ST
815408260	Affixus Tibia NL 8x260 ST
815408270	Affixus Tibia NL 8x270 ST
815408280	Affixus Tibia NL 8x280 ST
815408290	Affixus Tibia NL 8x290 ST
815408300	Affixus Tibia NL 8x300 ST
815408310	Affixus Tibia NL 8x310 ST
815408320	Affixus Tibia NL 8x320 ST
815408330	Affixus Tibia NL 8x330 ST
815408340	Affixus Tibia NL 8x340 ST
815408350	Affixus Tibia NL 8x350 ST
815408360	Affixus Tibia NL 8x360 ST
815408370	Affixus Tibia NL 8x370 ST
815408380	Affixus Tibia NL 8x380 ST
815408390	Affixus Tibia NL 8x390 ST
815408400	Affixus Tibia NL 8x400 ST
815408410	Affixus Tibia NL 8x410 ST
815408420	Affixus Tibia NL 8x420 ST

Tibia Implants - Nails

Part#	Description
815409240	Affixus Tibia NL 9x240 ST
815409250	Affixu Tibia NL 9x250 ST
815409260	Affixus Tibia NL 9x260 ST
815409270	Affixus Tibia NL 9x270 ST
815409280	Affixus Tibia NL 9x280 ST
815409290	Affixus Tibia NL 9x290 ST
815409300	Affixus Tibia NL 9x300 ST
815409310	Affixus Tibia NL 9x310 ST
815409320	Affixus Tibia NL 9x320 ST
815409330	Affixus Tibia NL 9x330 ST
815409340	Affixus Tibia NL 9x340 ST
815409350	Affixus Tibia NL 9x350 ST
815409360	Affixus Tibia NL 9x360 ST
815409370	Affixus Tibia NL 9x370 ST
815409380	Affixus Tibia NL 9x380 ST
815409390	Affixus Tibia NL 9x390 ST
815409400	Affixus Tibia NL 9x400 ST
815409410	Affixus Tibia NL 9x410 ST
815409420	Affixus Tibia NL 9x420 ST
815410240	Affixus Tibia NL 10x240 ST
815410250	Affixus Tibia NL 10x250 ST
815410260	Affixus Tibia NL 10x260 ST
815410270	Affixus Tibia NL 10x270 ST

Ordering Information - Implants

Tibia Implants - Nails

Part#	Description
815410270	Affixus Tibia NL 10x270 ST
815410280	Affixus Tibia NL 10x280 ST
815410290	Affixus Tibia NL 10x290 ST
815410300	Affixus Tibia NL 10x300 ST
815410310	Affixus Tibia NL 10x310 ST
815410320	Affixus Tibia NL 10x320 ST
815410330	Affixus Tibia NL 10x330 ST
815410340	Affixus Tibia NL 10x340 ST
815410350	Affixus Tibia NL 10x350 ST
815410360	Affixus Tibia NL 10x360 ST
815410370	Affixus Tibia NL 10x370 ST
815410380	Affixus Tibia NL 10x380 ST
815410390	Affixus Tibia NL 10x390 ST
815410400	Affixus Tibia NL 10x400 ST

Tibia Implants - Nails

Part#	Description
815410410	Affixus Tibia NL 10x410 ST
815410420	Affixus Tibia NL 10x420 ST
815411240	Affixus Tibia NL 11x240 ST
815411250	Affixus Tibia NL 11x250 ST
815411260	Affixus Tibia NL 11x260 ST
815411270	Affixus Tibia NL 11x270 ST
815411280	Affixus Tibia NL 11x280 ST
815411290	Affixus Tibia NL 11x290 ST
815411300	Affixus Tibia NL 11x300 ST
815411310	Affixus Tibia NL 11x310 ST
815411320	Affixus Tibia NL 11x320 ST
815411330	Affixus Tibia NL 11x330 ST
815411340	Affixus Tibia NL 11x340 ST
815411350	Affixus Tibia NL 11x350 ST
815411360	Affixus Tibia NL 11x360 ST
815411370	Affixus Tibia NL 11x370 ST
815411380	Affixus Tibia NL 11x380 ST
815411390	Affixus Tibia NL 11x390 ST
815411400	Affixus Tibia NL 11x400 ST
815411410	Affixus Tibia NL 11x410 ST
815411420	Affixus Tibia NL 11x420 ST
815412240	Affixus Tibia NL 12x240 ST
815412250	Affixus Tibia NL 12x250 ST
815412260	Affixus Tibia NL 12x260 ST
815412270	Affixus Tibia NL 12x270 ST
815412280	Affixus Tibia NL 12x280 ST
815412290	Affixus Tibia NL 12x290 ST
815412300	Affixus Tibia NL 12x300 ST
815412310	Affixus Tibia NL 12x310 ST
815412320	Affixus Tibia NL 12x320 ST

Ordering Information

Tibia Implants - Nails

Part#	Description
815412330	Affixus Tibia NL 12x330 ST
815412340	Affixus Tibia NL 12x340 ST
815412350	Affixus Tibia NL 12x350 ST
815412360	Affixus Tibia NL 12x360 ST
815412370	Affixus Tibia NL 12x370 ST
815412380	Affixus Tibia NL 12x380 ST
815412390	Affixus Tibia NL 12x390 ST
815412400	Affixus Tibia NL 12x400 ST
815412410	Affixus Tibia NL 12x410 ST
815412420	Affixus Tibia NL 12x420 ST
815413240	Affixus Tibia NL 13x240 ST
815413250	Affixus Tibia NL 13x250 ST
815413260	Affixus Tibia NL 13x260 ST
815413270	Affixus Tibia NL 13x270 ST
815413280	Affixus Tibia NL 13x280 ST
815413290	Affixus Tibia NL 13x290 ST
815413300	Affixus Tibia NL 13x300 ST
815413310	Affixus Tibia NL 13x310 ST
815413320	Affixus Tibia NL 13x320 ST
815413330	Affixus Tibia NL 13x330 ST
815413340	Affixus Tibia NL 13x340 ST
815413350	Affixus Tibia NL 13x350 ST
815413360	Affixus Tibia NL 13x360 ST
815413370	Affixus Tibia NL 13x370 ST
815413380	Affixus Tibia NL 13x380 ST
815413390	Affixus Tibia NL 13x390 ST
815413400	Affixus Tibia NL 13x400 ST
815413410	Affixus Tibia NL 13x410 ST
815413420	Affixus Tibia NL 13x420 ST

4.0mm Cortical Screw

Part#	Description
814540020	Cortical Bone Screw 4x20 ST
814540022	Cortical Bone Screw 4x22 ST
814540024	Cortical Bone Screw 4x24 ST
814540026	Cortical Bone Screw 4x26 ST
814540028	Cortical Bone Screw 4x28 ST
814540030	Cortical Bone Screw 4x30 ST
814540032	Cortical Bone Screw 4x32 ST
814540034	Cortical Bone Screw 4x34 ST
814540036	Cortical Bone Screw 4x36 ST
814540038	Cortical Bone Screw 4x38 ST
814540040	Cortical Bone Screw 4x40 ST
814540042	Cortical Bone Screw 4x42 ST
814540044	Cortical Bone Screw 4x44 ST
814540046	Cortical Bone Screw 4x46 ST
814540048	Cortical Bone Screw 4x48 ST
814540050	Cortical Bone Screw 4x50 ST
814540052	Cortical Bone Screw 4x52 ST
814540054	Cortical Bone Screw 4x54 ST
814540056	Cortical Bone Screw 4x56 ST
814540058	Cortical Bone Screw 4x58 ST
814540060	Cortical Bone Screw 4x60 ST
814540065	Cortical Bone Screw 4x65 ST
814540070	Cortical Bone Screw 4x70 ST
814540075	Cortical Bone Screw 4x75 ST
814540080	Cortical Bone Screw 4x80 ST
814540085	Cortical Bone Screw 4x85 ST
814540090	Cortical Bone Screw 4x90 ST

Ordering Information

5.0mm Cortical Screw

Part#	Description
814650020	Cortical Bone Scr 5.0mm X 20 ST
814650022	Cortical Bone Scr 5.0mm X 22 ST
814650024	Cortical Bone Scr 5.0mm X 24 ST
814650026	Cortical Bone Scr 5.0mm X 26 ST
814650028	Cortical Bone Scr 5.0mm X 28 ST
814650030	Cortical Bone Scr 5.0mm X 30 ST
814650032	Cortical Bone Scr 5.0mm X 32 ST
814650034	Cortical Bone Scr 5.0mm X 34 ST
814650036	Cortical Bone Scr 5.0mm X 36 ST
814650038	Cortical Bone Scr 5.0mm X 38 ST
814650040	Cortical Bone Scr 5.0mm X 40 ST
814650042	Cortical Bone Scr 5.0mm X 42 ST
814650044	Cortical Bone Scr 5.0mm X 44 ST
814650046	Cortical Bone Scr 5.0mm X 46 ST
814650048	Cortical Bone Scr 5.0mm X 48 ST
814650050	Cortical Bone Scr 5.0mm X 50 ST
814650052	Cortical Bone Scr 5.0mm X 52 ST
814650054	Cortical Bone Scr 5.0mm X 54 ST
814650056	Cortical Bone Scr 5.0mm X 56 ST
814650058	Cortical Bone Scr 5.0mm X 58 ST
814650060	Cortical Bone Scr 5.0mm X 60 ST
814650065	Cortical Bone Scr 5.0mm X 65 ST
814650070	Cortical Bone Scr 5.0mm X 70 ST

5.0mm Cortical Screw

Part#	Description
814650075	Cortical Bone Scr 5.0mm X 75 ST
814650080	Cortical Bone Scr 5.0mm X 80 ST
814650085	Cortical Bone Scr 5.0mm x 85 ST
814650090	Cortical Bone Scr 5.0mm x 90 ST
814650095	Cortical Bone Scr 5.0mm x 95 ST
814650100	Cortical Bone Scr 5.0mm x 100 ST
814650105	Cortical Bone Scr 5.0mm x 105 ST
814650110	Cortical Bone Scr 5.0mm x 110 ST
814650115	Cortical Bone Scr 5.0mm x 115 ST
814650120	Cortical Bone Scr 5.0mm x 120 ST

Tibia Implants – End Caps

Part#	Description
814706000	End Cap Flush
814707005	End Cap 11 Prox Dia X 5 ST
814707010	End Cap 11 Prox Dia X 10 ST
814707030	End Cap 12 Prox Dia X 5 ST
814707035	End Cap 12 Prox Dia X 10 ST
814707055	End Cap 13 Prox Dia X 5 ST
814707060	End Cap 13 Prox Dia X 10 ST

Zimmer Biomet does not practice medicine. This technique and post-operative care instructions were developed in conjunction with health care professionals. This document is intended for surgeons and is not intended for laypersons. Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training surgeons have received. As with all surgical procedures, the product/technique used in each case will depend on the surgeon's medical judgment as the best treatment for each patient. Results will vary based on health, weight, activity, and other variables. Not all patients are candidates for this product and/or procedure.

For indications, contraindications, warnings, precautions, potential adverse effects, and patient counseling information, refer to device-specific instructions for use, or contact your local representative; visit zimmerbiomet.com for additional product information. Caution: Federal (USA) law restricts this device to sale by or on the order of a surgeon. Rx only.

ZIMMER BIOMET
Moving You Forward.™

4668.4-US-en-Issue Date 2025-11-07
VV-14944

Legal Distributor
Zimmer Biomet
1800 W. Center Street
Warsaw, IN 46580 USA
Tel: 1-800-348-2759
Fax: 574-372-3968
www.zimmerbiomet.com

Manufacturer
Zimmer Biomet
1800 W. Center Street
Warsaw, IN 46580 USA
Tel: 1-800-348-2759
Fax: 574-372-3968
www.zimmerbiomet.com