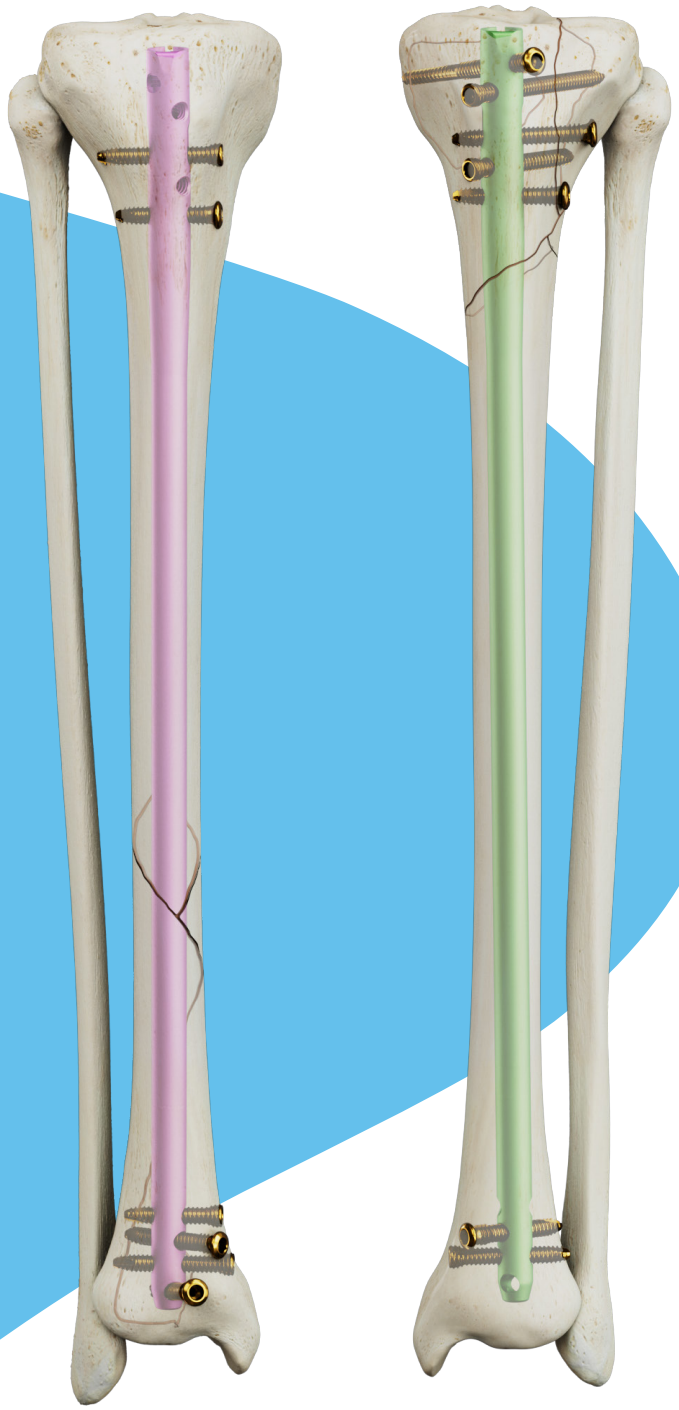
Smith+Nephew

TRIGEN◊ MAX
Tibia Nailing System

Surgical Technique



Introduction

The TRIGEN◊ MAX Tibia Nailing System is a comprehensive approach to the treatment of tibial fractures.

The TRIGEN MAX Tibia Nails are composed of titanium alloy (Ti-6Al-4V). These implants are offered in a variety of diameters (8, 9, 10, 11, 12.5mm) with lengths ranging from 24 to 42cm.

The nails feature threaded screw holes, variable angle screw holes, and multi-planar locking screw configurations designed to facilitate the fixation of complex fractures.

The TRIGEN MAX Tibia Nailing System also offers 4.5mm and 5.0mm Locking Screws and Headless Screws, 5.0mm Lag Screws, a Washer, a Compression Screw, and Nail Caps.

Table of contents

TRIGEN® MAX Tibia Nailing System Overview 2

Surgical Technique 7

1. Patient Positioning 6
2. Preparing the Tibia 8
3. Nail Insertion 12
4. Distal Locking Screw Insertion 14
5. Proximal Locking Screw Insertion 17
6. Shaft Compression 21
7. Implant Removal 22

Optional Implants and Instruments 23

Tips & Tricks 27

Catalog Information 29

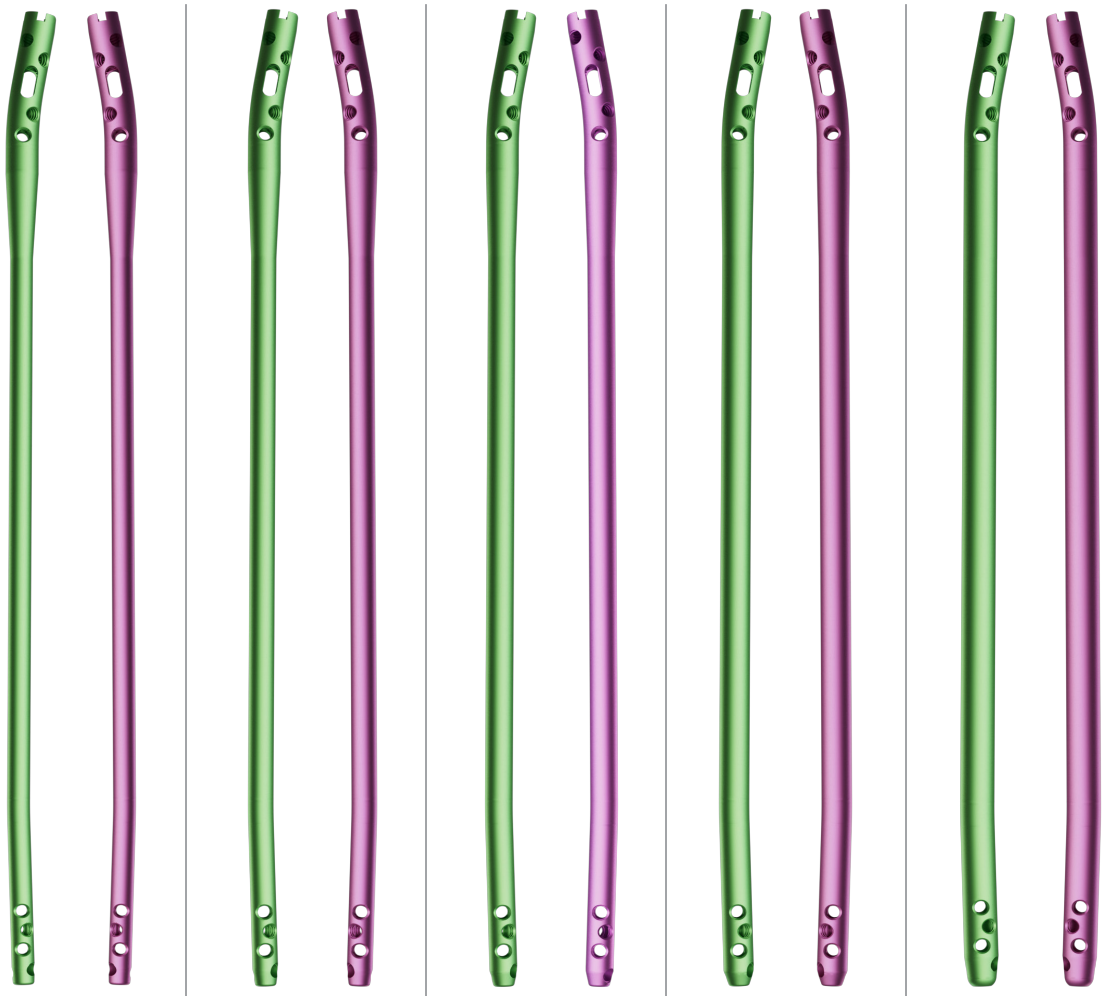
Nota Bene

The following technique is for informational and educational purposes only. It is not intended to serve as medical advice. It is the responsibility of treating physicians to determine and utilize the appropriate products and techniques according to their own clinical judgment for each of their patients. For more information on the product, including its indications for use, contraindications, and product safety information, please refer to the product's label and the Instructions for Use packaged with the product.

Prior to performing this technique, please consult the Instructions for Use documentation provided with each device for additional health and safety information, including indications, contraindications, warnings and precautions.

TRIGEN MAX Tibia Nailing System Overview

Nails

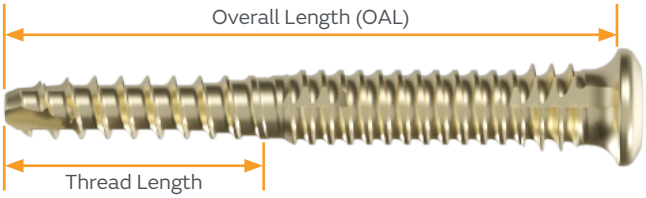


Distal Diameter	**8mm**	**9mm**	**10mm**	**11mm**	**12.5mm**
Proximal Diameter	**12mm**				**12.5mm**
Left/Right Specific	Lime colored nails are Left. Rose colored nails are Right.				
Nail Lengths	24 - 42cm 1cm increments				24 - 42cm 2cm increments
Proximal Screw Options	5.0mm Locking / 5.0mm Headless / 5.0mm Lag				
Distal Screw Options	4.5mm Locking 4.5mm Headless	5.0mm Locking / 5.0mm Headless / 5.0mm Lag			

Screws

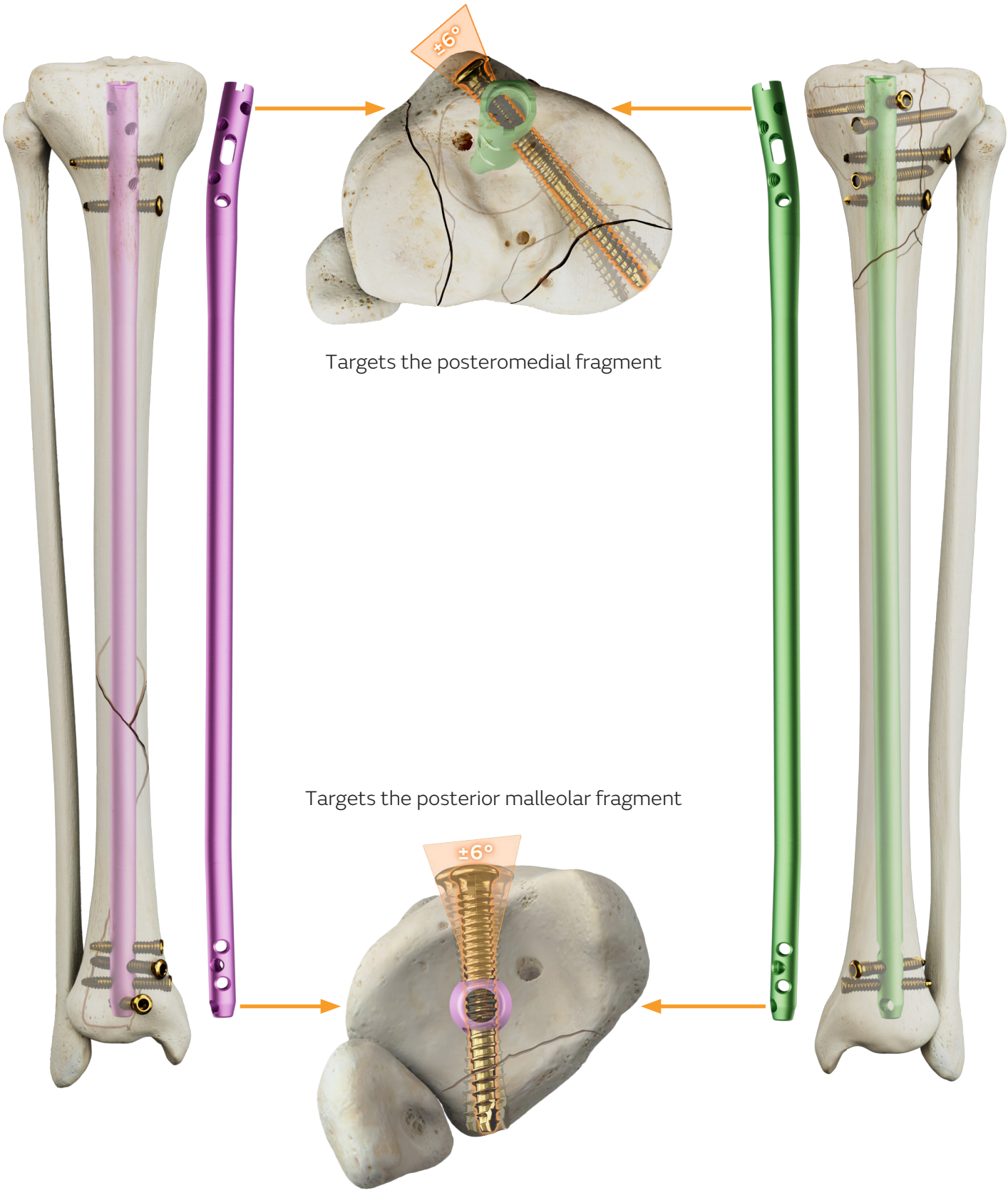
	4.5mm		5.0mm		
	Locking	Headless	Locking	Headless	Lag
					
Screw Lengths	20 - 80mm 2.5mm increments 80 - 110mm 5mm increments	20 - 65mm 2.5mm increments	20 - 80mm 2.5mm increments 80 - 110mm 5mm increments		35 - 80mm 2.5mm increments 80 - 110mm 5mm increments
Drill	4.0mm		4.3mm		4.3mm Step Drill
Driver	4.0mm Hex				

5.0mm Lag Screw

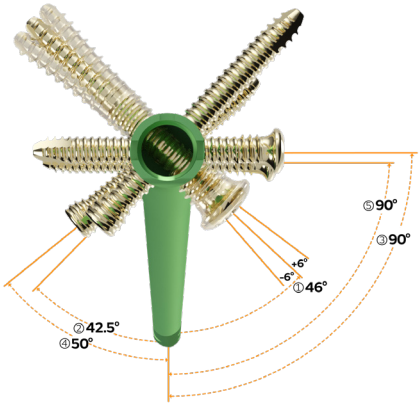


Overall Length (OAL)	35 - 42.5mm 2.5mm increments	45 - 80mm 2.5mm increments	80 - 110mm 5mm increments
Thread Length	18mm	27mm	27mm

Variable Angle Fixation

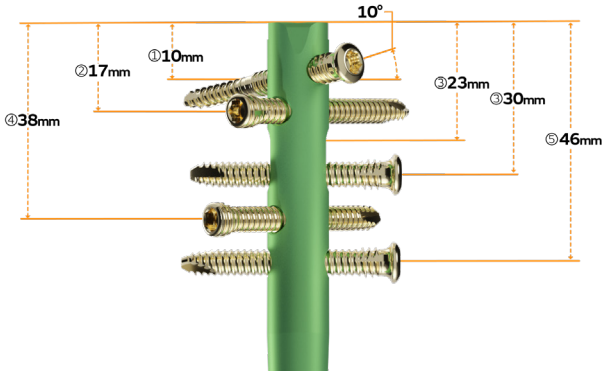


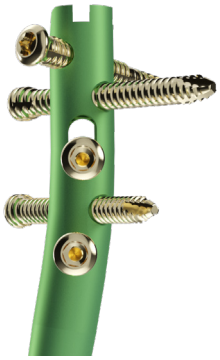
Tibial Nail Specifications

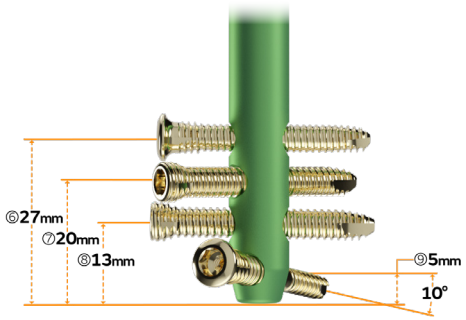


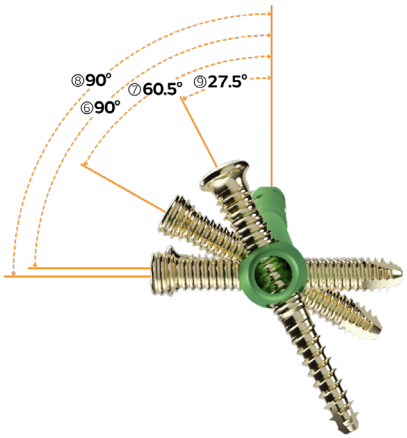
There are five multiplanar screw options in 46mm from the proximal tip of the nail. Designed to treat select tibial plateau fractures, the most proximal screw is angled anterolateral to posteromedial and targets the posteromedial fragment. It is aimed 10° cephalad to caudad to avoid the medial tibial plateau and be more parallel to the joint.

With three screws in the most proximal 30mm, this nail is designed to treat extreme proximal tibia fractures as well.









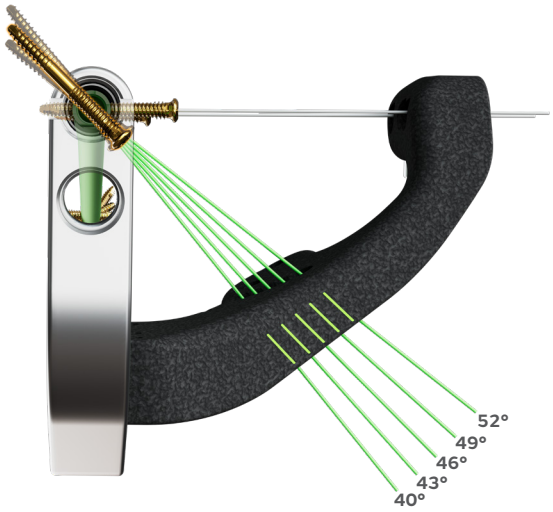
The most distal screw is angled anteromedial to posterolateral, as well as 10° cephalad to caudad.

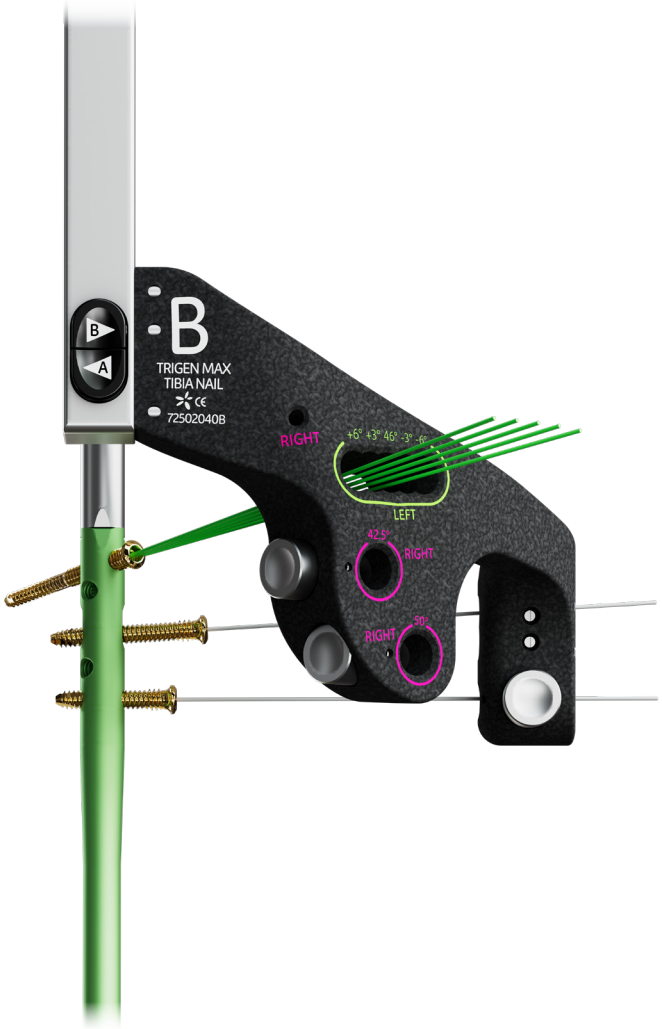
It targets the posterolateral fragment and is designed to avoid the incisura.

There are four screw options in 27mm from the distal tip of the nail, designed to treat extreme distal tibia and select pilon fractures.

Half Drop Specifications

(Example shown is a Left Nail)
4 screws can be inserted using the A Drop on a Left Nail
3 screws can be inserted using the B Drop on a Left Nail
3 screws can be inserted using the A Drop on a Right Nail
4 screws can be inserted using the B Drop on a Right Nail





Surgical Technique

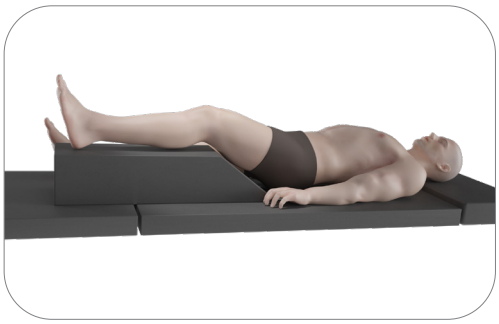


Figure 1.1a

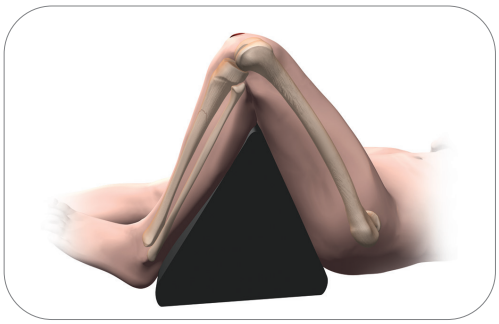


Figure 1.1b

Step 1: Patient Positioning

1.1 Position the patient supine on a radiolucent table with the unaffected limb extended away from the affected limb.

For the semi-extended technique, the operative limb should be in 10–30° of knee flexion (Figure 1.1a).

For the infrapatellar approach, the operative limb should be in 80-90° of knee flexion (Figure 1.1b).

Use a bolster or radiolucent triangle to maintain limb position.

Check for length and rotation by comparison to unaffected limb.

Alternatively, a fracture table may be used with a pin inserted through the calcaneus to place the leg in traction.

A distraction device may also be applied to obtain and/or maintain traction.

1.2 Adjust the C-Arm appropriately to ensure optimal anteroposterior (AP) and lateral visualization of the tibia.

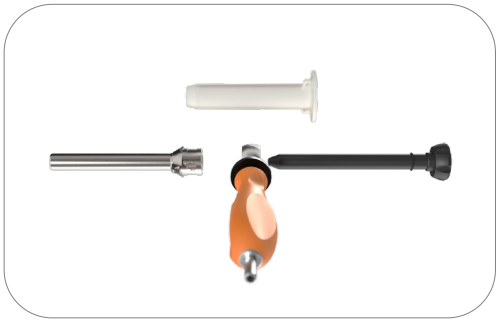


Figure 2.1

Figure 2.2

Figure 2.3

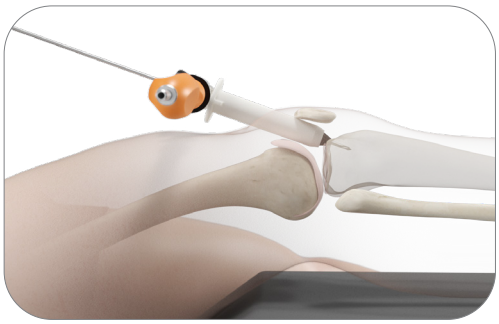


Figure 2.4

Step 2: Preparing the Tibia

2.1 Prepare the Entry Portal Tube

Inspect the Entry Tube to ensure that it is not damaged, bent or chipped. Any flaws in the tube can lead to damage of the surrounding tissues.

For the semi-extended technique, assemble the Semi-Extended Entry Tube (72502031) to the Entry Portal Handle (71674092) by pulling back the black trigger of the Entry Portal Handle. Turn the tube until it clicks into a locked position.

Insert the Semi-Extended Guide Pin Sleeve (72502033) into the Entry Portal Tube until it locks into place.

Optional: Insert the Semi-Extended Entry Portal Tube (72502031) through the Flexible Entry Tube Sleeve (72800122 or 72800123)

For the infrapatellar approach, assemble the Entry Portal Tube (71674060) to the Entry Portal Handle (71674092). Insert the Entry Portal Honeycomb (72502014) into the Entry Portal Tube.

Note: Suction can be applied to the Entry Portal Handle if desired.

2.2 Incision

Make a midline skin incision approximately 3cm in length one to two finger-breaths proximal to the upper pole of the patella. Dissect deeper to include a longitudinal split in the middle of the quadriceps tendon to access the suprapatellar pouch.

Pass the fully assembled entry tube through the skin incision, through the quadriceps tendon split, under the patella in the trochlear groove of the distal femur, until it is sitting on the tibial plateau.

2.3 Locate the Entry Point

Locate the entry point just medial to the lateral tibial eminence in the anteroposterior (AP) view, and in line with the anterior cortex and intramedullary canal in the lateral view.

2.4 Guide Pin Insertion

Insert a 3.2mm Drill Tip Guide Pin (72800133) or 3.2mm Thread Tip Guide Pin (72800132) into a wire driver and insert into the entry point of the tibia..

Note: If the initial Guide Pin's insertion angle or position is suboptimal, replace the Guide Pin Sleeve with the Semi Extended Honeycomb (72502035) and rotate it within the Entry Tube and insert another 3.2mm Guide Pin.

Insert the Guide Pin into the proximal tibia to a depth of 4–6cm. Check the Guide Pin position via radiographic imaging.

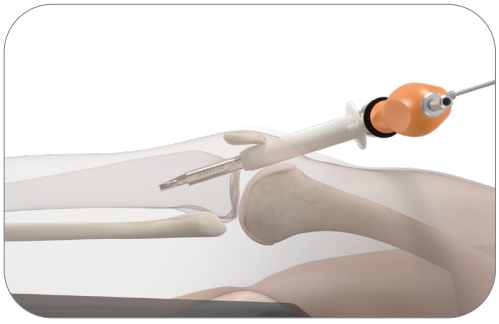


Figure 2.5

Figure 2.6a

Figure2.6b

2.5 Entry Point

After definitive Guide Pin placement, remove the Guide Pin Sleeve while keeping the Entry Tube placed on the tibial plateau.

Attach the 12.5mm Flexible Entry Reamer (72502001) to the surgical power drill and advance over the Guide Pin through the Entry Tube to a depth of 4–6cm.

Alternatively, insert the 11.5mm Rigid Entry Reamer (72502073) into the 12.5mm Channel Reamer (72502088) and attach to the surgical power drill.

With the Entry Tube and Entry Portal Handle in the joint space as described above, advance the Channel Reamer assembly over the Guide Pin through the Entry Tube to a depth of 4–6cm.

Tip: It is helpful to use fluoroscopy to place the Entry Reamer while maintaining alignment and avoiding penetration of the posterior cortex or the soft tissues forcing the entry reamer anterior.

Check position of the entry reamer via radiographic imaging and then remove the Entry Reamer and Guide Pin.

Note: If the Channel Reamer (72502088) was used, detach the 11.5mm Rigid Entry Reamer (72502073) and leave the Channel Reamer in the proximal tibia.

See Tips & Tricks Section on page 27 for alternative methods using Channel Reamer and Cannulated Awl

Note: Figure 2.5 shows the white Flexible Entry Tube Sleeve (72800122) over the Semi-Extended Entry Portal Tube (72502031). There is also a Non-Pinnable Flexible Entry Tube Sleeve (72800123).

The Entry Tube is also pinnable to the femur to help hold it in place if needed.

2.6 Fracture Reduction

Connect the Reducer (72502003) and the Reducer Connector (72502003) so that the words “Slot Orientation” on the connector are in line with the opening at the Reducer’s tip. Then attach it to the T-handle (71674576) (Figure 2.6a).

Place the Reducer through the Entry Tube (if present). It is helpful to direct the Reducer anteriorly on initial insertion to avoid the posterior cortex and assist in directing the 3.0mm X 900mm Ball Tip Guide Rod (72800130) to follow suit in the intramedullary canal. The Reducer can also be placed across the fracture before the Guide Rod (Figure 2.6b).

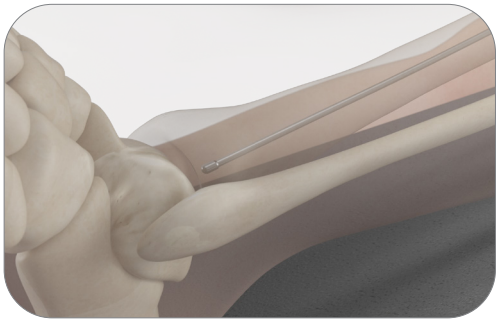


Figure 2.6c

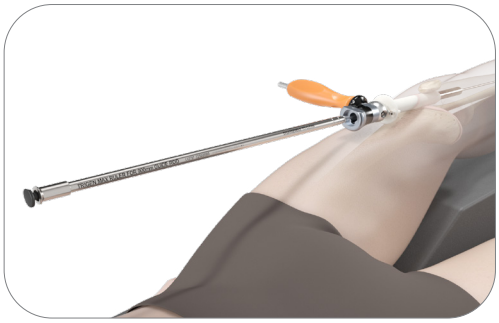


Figure 2.7a

Figure 2.7b

Step 2: Preparing the Tibia *continued*

The Ball Tip Guide Rod typically needs force to place in the intramedullary canal. If additional force is required, open the Gripper (72502006), insert the smooth end of the 3.0mm Ball Tip Guide Rod (72800130) into the front of the Gripper, and close the Gripper. Carefully tapping the Gripper with the Slotted Hammer (71674082) advances the Guide Rod down the tibia.

Direct the Ball Tip Guide Rod past the fracture into the region of the distal epiphyseal scar. Figure 2.6c.

Once the Guide Rod is at the desired depth, detach the Gripper and remove the Reducer from the tibial canal.

Tip: To maintain Guide Rod position within the canal when removing the Reducer, slide the Obturator (72502004) into the T-handle.

After the Reducer has been removed, reconfirm the Guide Rod placement within the distal tibia.

2.7 Determine Nail Length using the Ruler

Slide the Ruler (72502005) over the Guide Rod until the metal tip contacts the proximal tibia. The metal tip of the Ruler denotes the driving end of the nail (Figure 2.7a).

Push down on the top of the Ruler until it contacts the Ball Tip Guide Rod. Ensure that the Ruler is in contact with the Ball Tip Guide Rod. Visually confirm that the end of the Ball Tip Guide Rod is in contact with the end of the Ruler in the window, as shown in Figure 2.7b.

The exposed number at the end of the Ruler is the length of the Guide Rod inside the tibia and hence the corresponding nail length.

Confirm fracture reduction to ensure that the implant length is as intended.

Figure 2.8a

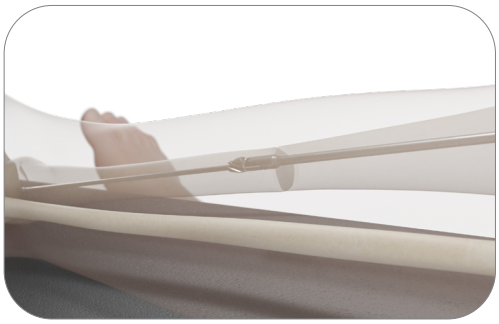


Figure 2.8b

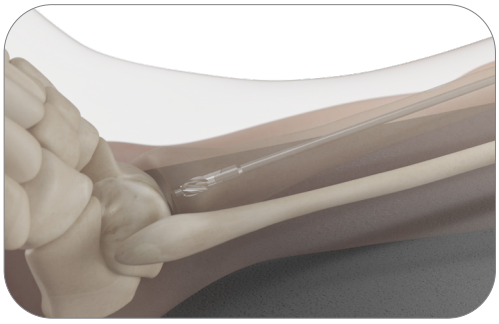
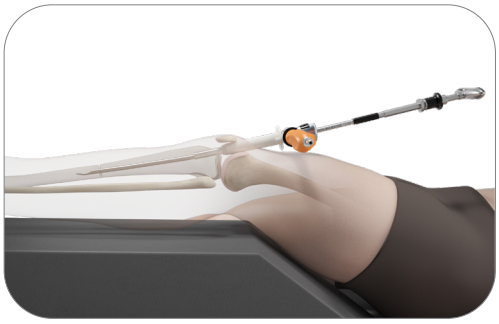


Figure2.8c



Unreamed Nailing

2.8 IM Canal Reaming

Attach the appropriate starting Endcutting Reamer Head size (72502043 through 72502059) to the Flexible Reamer Shaft (72502041) to ream the intramedullary canal. Ream up sequentially in half-millimeter increments to the desired nail diameter.

Note: IM Canal Reaming up to 11.5mm reamer head size can be performed through the 12.5mm Channel Reamer. **See Tips and Tricks section on page 27.**

Note: Orienting the Flexible Reamer Shaft such that the word “Up” is visible will prevent the Reamer Head from falling off during back-table handling (Figure 2.8a).

Tip: Periodically move the reamer back and forth in the canal to clear debris from the cutting flutes.

Verify fracture reduction as the reamer crosses the fracture site (Figure 2.8b)

Continue to confirm Guide Rod placement in the distal tibia throughout reaming (Figure 2.8c).

Tip: To prevent the Guide Rod from being pulled out, insert the Obturator into the back of the IM Reamer when retracting it.

Alternative technique: Unreamed Nailing

The appropriate-diameter implant provides translational fill within the isthmus of the intramedullary canal.

The 8.0mm diameter of the Reducer provides an initial determination of the canal width.

Figure 3.1

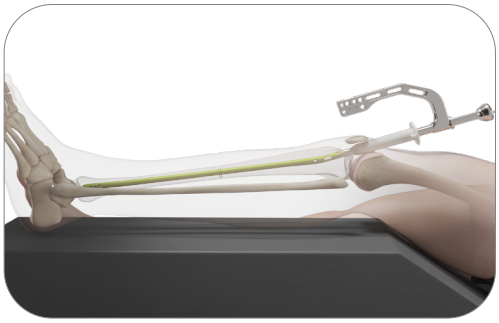


Figure 3.2

Step 3: Nail Insertion

3.1 Nail Assembly

For the semi-extended technique, use the Semi-Extended Guide Bolt (72502037) to attach the Nail to the Semi-Extended Drill Guide (72502036).

For the infrapatellar approach, use the Standard Guide Bolt (72502039) to attach the Nail to the Standard Drill Guide (72502038).

Tighten with the Guide Bolt Wrench (71631140) and T-handle.

Attach the Anterior Drop-Right (72502040A) and Anterior Drop-Left (72502040B) to the Drill Guide.

Note: To verify targeting accuracy, insert a gold 9.0mm Screw Sleeve (72502023) and black 4.3mm Drill Sleeve (72502025) into the Drops and then pass a 4.3mm Long Drill (72800144L) through the assembly and ensure the Drill targets the hole in the Nail (Figure 3.1).

Note: An incorrectly attached nail will not target the hole in the Nail.

3.2 Nail Insertion

Remove the Entry Tube and Channel Reamer if present.

Note: The Flexible Sleeve may be left if desired.

Attach the Medium Cannulated Impactor or Short Cannulated Impactor (72502007 or 72502009) to the Drill Guide.

Orient the Drill Guide assembly in the AP (anteroposterior) position.

Use the Slotted Hammer to tap and advance the nail over the Guide Rod to the desired depth.

Note: If excessive force is required to insert the nail, additional reaming of the intramedullary canal may be required.

The bevel on the front of the nail marks the connection to the Drill Guide and can be seen in the lateral view to determine proximal insertion depth.

Verify fracture reduction as the nail crosses the fracture site.

Check the final nail position in both the AP and lateral views for correct alignment.

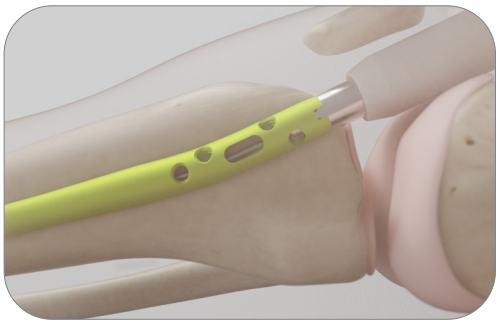


Figure 3.3a

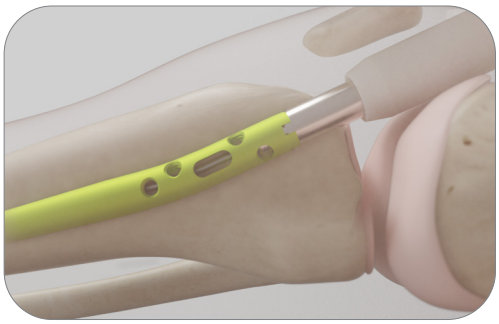


Figure 3.3b

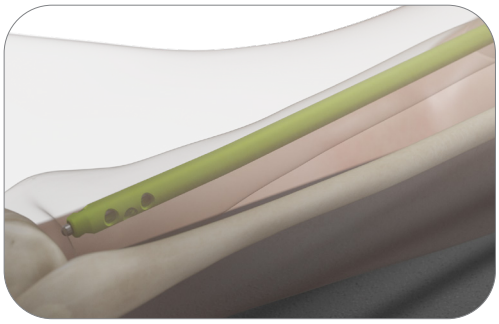


Figure 3.4

3.3 Check Proximal Nail Depth

In the lateral view, confirm nail position by observing the nail/Drill Guide junction. Each circular groove on the Drill Guide's insertion barrel represents a 10mm depth interval.

If compression is desired, insert the nail by the desired amount to be compressed to prevent nail prominence.

Fig 3.3a shows the nail flush. Fig 3.3b shows the nail inserted 7mm deep for 7mm of tibia shaft compression.

3.4 Check Distal Nail Depth

In the anteroposterior (AP) and lateral views, confirm that the nail has been inserted to the desired depth.

Remove the Guide Rod once the nail has been fully seated.

Following nail insertion, confirm that the nail and Drill Guide are securely connected, as hammering can loosen the Guide Bolt.

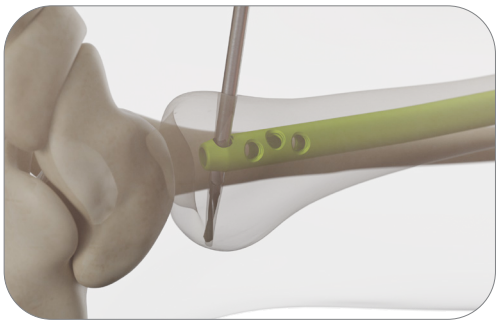


Figure 4.2

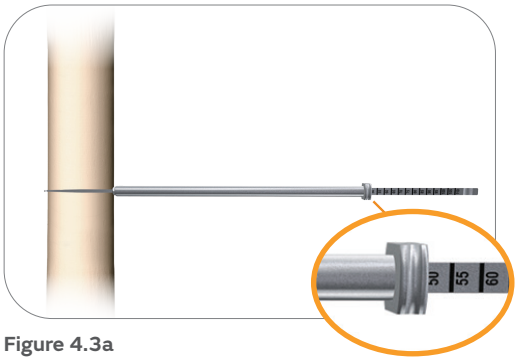


Figure 4.3a

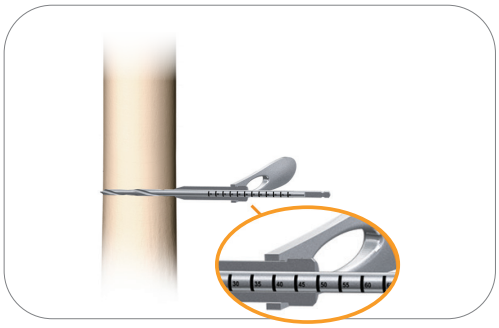


Figure 4.3b

Step 4: Distal Locking Screw Insertion

Note: this surgical technique description will lock the nail distally first, then apply tibia shaft compression, and finally lock the nail proximally.

There are four distal locking screw hole options.

Screw holes 1-3 are statically locked (1 and 3 are M-L).

Screw hole 2 is 30° oblique.

The most distal screw hole is variable angle for posterior malleollar fragment fixation.

4.1 Make a small incision at the radiographically identified site of screw entry and dissect down to bone. Use the "Perfect Circles Technique" radiographically to prepare the bone for screw implantation.

4.2 Attach the appropriate Drill Bit diameter and length and attach to the surgical power drill and drill both cortices.

Note: Distally, there are two methods to determine the desired length of the locking screw.

4.3 The length of the desired locking screw can be determined by

a) Removing the 4.3mm Short Drill (72800144S), and 4.3mm Drill Sleeve (72502025), using the Screw Depth Gauge (72502027) to hook the far cortex, pushing the outer sleeve of the Screw Depth Gauge to bone and reading the markings (Figure 4.3a).

b) Reading the markings on the 4.3mm Short Drill (72800144S) off the Screw Length Sleeve, Short (71674085). (Figure 4.3b)

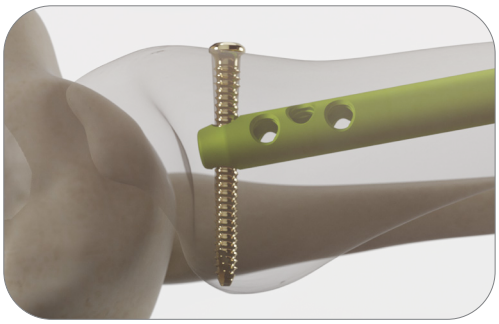


Figure 4.4

4.4 Attach the appropriate diameter and length Locking Screw to the Short or Medium Hexdriver utilizing the Retaining Rod and insert Locking Screw (Figure 4.4).

Note: When securing the screw to the driver, tighten the retaining rod by hand. After screw insertion, if the retaining rod will not release from the screw, use the Retention Release Handle with 2.5mm Hex (72502069). Use this for releasing only, and not for tightening.

Note: If the most distal hole in the nail is going to be used to fix the posterior malleolus, the rotation of the distal tibia must be correct prior to locking the nail proximally.

Note: When particularly hard bone is encountered, the 5.0mm Short Countersink (72502093) may be used after a hole has been drilled. The countersink is suitable for both headed and headless screws. It is advised to confirm hole depth after countersinking.

Note: Only when using 8mm Nails, 4.5mm screws must be used distally. Do not use the 4.3mm Short Drill when drilling for a grey 4.5mm Locking Screw. Its diameter creates too large a hole, and this may compromise locking screw purchase. Use the 4.0mm Short Drill (72800142S).

Interfragmentary Compression using 5.0mm Lag Screws through Variable Angle Distal Screw Hole

The gold colored 5.0mm Lag Screws can be used to compress the posterior malleollar fragment when placed in the most distal Variable Angle Screw Hole.

It is recommended to reduce and clamp the fragment prior to 5.0mm Lag Screw insertion.

Note: Lag Screws do not come in 4.5mm diameter. For 8mm Nails only, 4.5mm Locking or 4.5mm Headless Locking Screws can be used in this Distal Variable Angle Screw Hole.

Insertion of the 5.0mm Lag screws requires the use of the 4.3mm Step Drill (72800145L and 72800145S). Take care to not drill past the far cortex with the Step Drill.

Note: A standard 5.0mm Locking or Headless Screw may be used if bone quality provides insufficient purchase.

Figure 4.5a

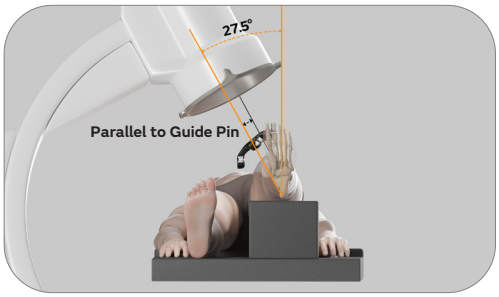


Figure 4.5b

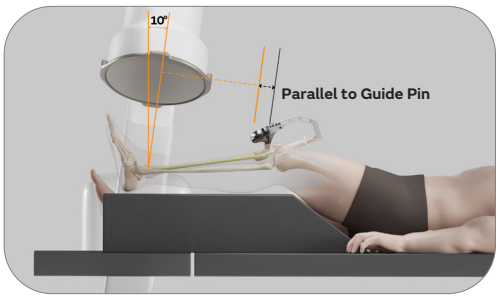


Figure 4.5c

Figure 4.5d

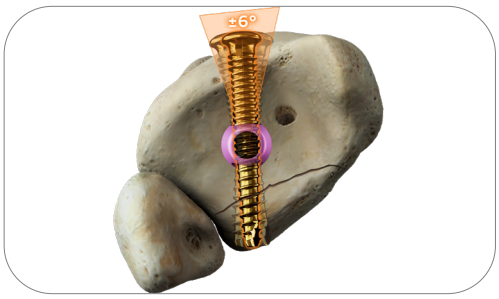


Figure 4.5e

Step 4: Distal Locking Screw Insertion *continued*

4.5 Identify the hole radiographically using the Perfect Circle Technique. Make a small incision at the site of screw entry and dissect down to bone. Radiographically obtain perfect circles and prepare the bone for screw implantation. There is a reference hole in the Half Drop for a 3.2mm Guide Pin to be used to identify the nominal trajectory of the Distal Variable Angle Screw Hole (Figure 4.5a).

To aid in the perfect circle technique for the most distal Variable Angle hole trajectory, place a 3.2mm Guide Pin through the reference hole in the Half Drop corresponding to the side of the nail and align the C-arm in both planes. (Figures 4.5b and 4.5c).

When aligned in both planes, the resulting C-arm image will appear as shown in (Figure 4.5d).

Note: Variable Angle Distal Screw Holes provides a 12°-of-arc targeting, providing fragment specific fixation capacity. Use fluoroscopy to guide fragment specific targeting over this 12° arc (Figure 4.5e).

4.6 Attach the desired length 4.3mm Step Drill (72800145L & 72800145S) to surgical power drill and drill both cortices (Figure 4.6).

Note: Only when using 8mm Nails, 4.5mm screws must be used distally.

Do not use the 4.3mm Short Drill when drilling for a grey 4.5mm Locking Screw. Its diameter creates too large a hole, and this may compromise locking screw purchase. Use the 4.0mm Short Drill (72800142S).

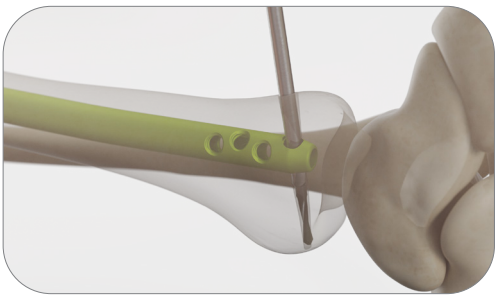
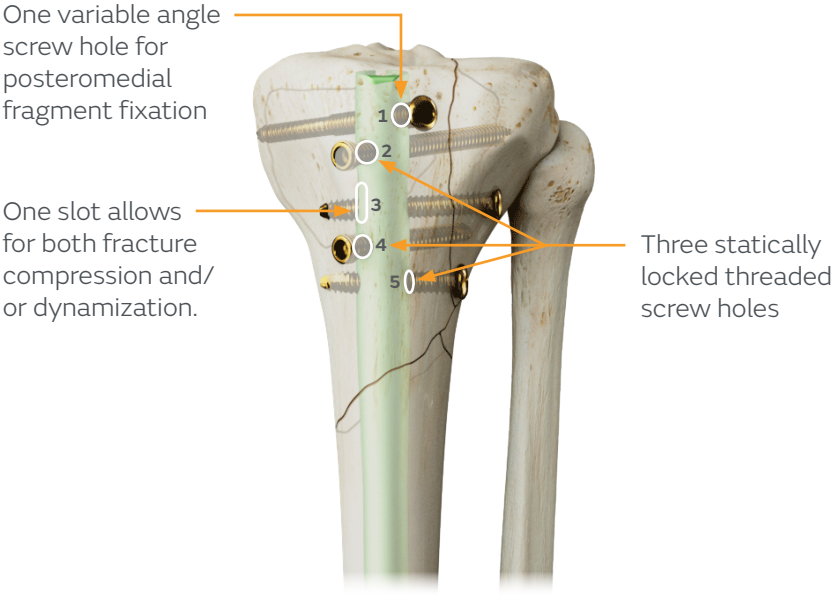


Figure 4.6

Step 5: Proximal Locking Screw Insertion

There are five proximal locking screw hole options



There are Rose, Lime, and White color-coded holes on the Half Drops.

Screws for Left nails are targeted through the Lime holes, and screws for Right nails are targeted through the Rose holes.

White marked holes can be used to target screws for Left and Right nails.

Tip: One or both Half Drops can be attached at a time to the Drill Guide to insert locking screws.

Tip: Half Drops allow the freedom to perform a reduction, place clamps, or place a plate on one side of the proximal tibia while placing locking screws into the other.

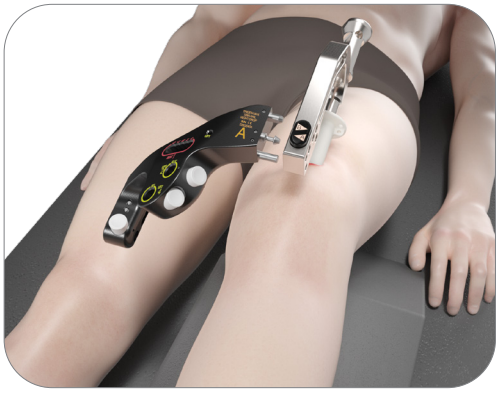


Figure 5.1

Step 5: Proximal Locking Screw Insertion *continued*

5.1 Attach the Anterior Drop-Right (72502040A) and Anterior Drop-Left (72502040B) to the Drill Guide to prepare for proximal screws insertion (Figures 5.1a).

5.2 Assemble and insert the 9.0mm Screw Sleeve (72502023) and Scalpel Handle (72502029) through the self-retaining hole in the Half Drop, and incise the skin (Figures 5.2a and 5.2b).

5.3 Assemble and insert the 4.3mm Drill Sleeve (72502025) and 4.0mm Drill Sleeve Trocar (72502090) down to bone.

Figure 5.2a

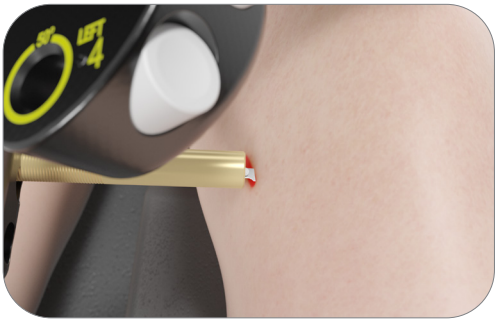


Figure 5.2b

Figure 5.3a

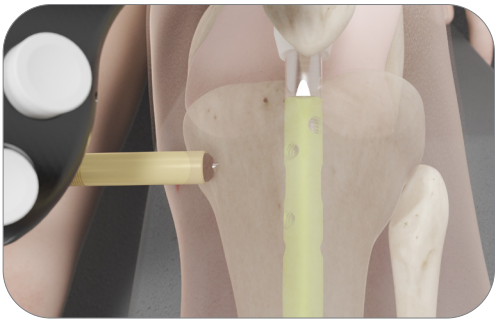


Figure 5.3a

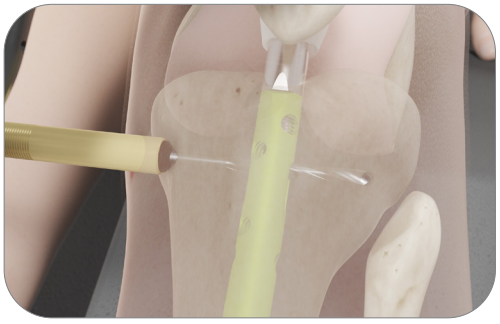


Figure 5.4

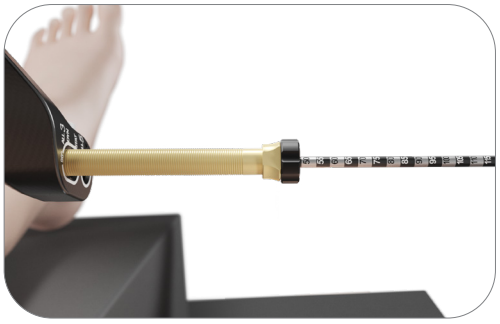


Figure 5.5a

Figure 5.5b

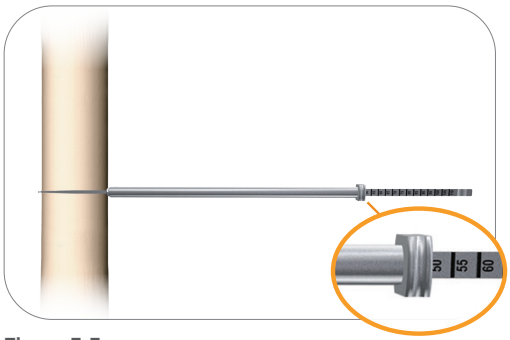


Figure 5.5c

5.4 Remove the Trocar and drill a bicortical path through the nail.

5.5 Determine the length of the locking screw.

Note: Proximally, there are three methods to determine the desired length of the locking screw:

The length of the desired locking screw can be determined by:

a) Reading the markings on the 4.3mm Long Drill (72800144L) off the 4.3mm Drill Sleeve (72502025), (Figure 5.5b). Ensure the Sleeve is on bone.

b) Sliding the 4.3mm Drill Sleeve (72502025) up to the top of the 4.3mm Long Drill (72800144L) and reading the markings on the Sleeve, Figure 5.5c. Ensure the Sleeve is on bone.

c) Removing the 4.3mm Long Drill (72800144L) and 4.3mm Drill Sleeve (72502025), using the Screw Depth Gauge (72502027) to hook the far cortex, pushing the outer sleeve of the Screw Depth Gauge to bone and reading the markings (Figure 5.5a-c).

Note: Screws in the proximal tibia can be prominent in some patients. Headless screws are available to help prevent prominence. Alternatively, Short and Long Countersinks (72502093 and 72502028) are available to countersink headed cortical screws.

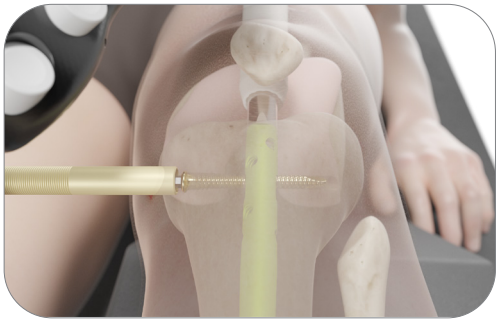


Figure 5.6

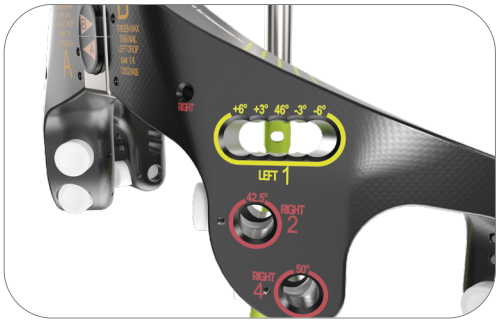


Figure 5.7a

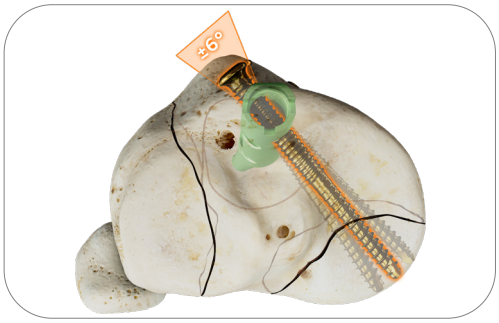


Figure 5.7b

Step 5: Proximal Locking Screw Insertion *continued*

5.6 Attach the appropriate diameter and length Locking Screw to the Medium Hexdriver (72502017) utilizing the Retaining Rod and insert Locking Screw (Figure 5.6).

Interfragmentary Compression using 5.0mm Lag Screws through the most proximal, Variable Angle Screw Hole

5.0mm Lag Screws (gold) are offered for interfragmentary compression. These screws can be used to compress the posteromedial fragment when placed in the most proximal Variable Angle Screw Hole.

It is recommended to reduce and clamp the fragment prior to 5.0mm Lag Screw insertion.

Insertion of the 5.0mm Lag Screws requires the use of the 4.3mm Step Drill (72800145L and 72800145S). Take care to not drill past the far cortex with the Step Drill.

Note: A standard 5.0mm Locking or Headless Screw may be used if bone quality provides insufficient purchase.

5.7 Assemble and insert the 9.0mm Screw Sleeve (72502023) and Scalpel Handle (72502029) through one of the five connected holes in the Half Drop (Fig 5.5), and incise the skin. Follow steps 5.2, 5.3 using a 4.3mm Step Drill (72800145L and 72800145S) and 5.4 (Figure 5.7a).

Note: The most proximal screw is directed towards the posteromedial plateau and can be directed for fragment specific fixation through the proximal Variable Angle Screw Hole (Figure 5.7b).

Note: When securing the screw to the driver, tighten the retaining rod by hand.

Note: After screw insertion, if the retaining rod will not release from the screw, use the Retention Release Handle with 2.5mm Hex (72502069). Use this for releasing only, and not for tightening.

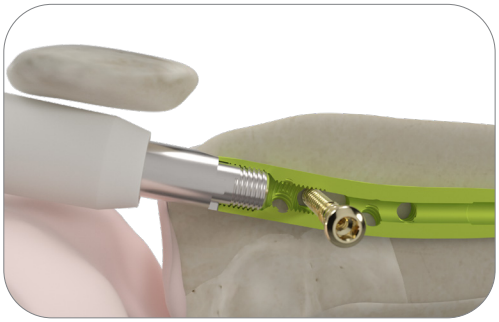


Figure 6

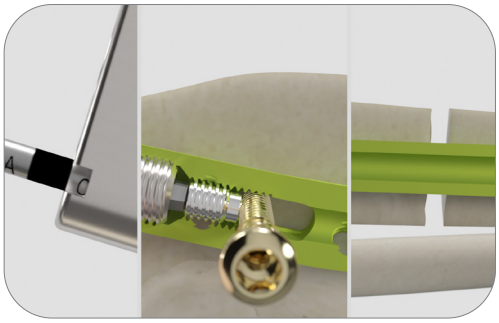


Figure 6.1

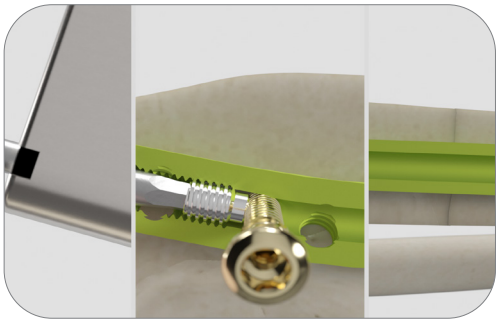


Figure 6.2

Step 6: Tibia Shaft Compression

There are two methods of internal compression. Compress with the Compression Driver (72800121) or with an internal Compression Screw.

Note: When compressing the tibia shaft, sink the nail for the desired amount of compression per Step 3.2 Nail Insertion and insert a 5.0mm Locking Screw through the slot in the nail using the white color-coded hole in the Half Drop per 4.2 Proximal Screw Insertion (Figure 6).

6.1 Attach the Compression Driver (72800121) to the T-Handle and insert the assembly through the Guide Bolt into the top of the nail until it contacts the 5.0mm locking screw in the slot.

6.2 Turn the Compression Driver clockwise to drive the locking screw distally and compress the fracture up to 7mm.

Note: If there are screws in the other proximal holes, the fracture cannot be compressed.

6.3 Once the fracture gap is adequately compressed, lock the nail with up to four additional proximal static screws while the Anterior Drop is still attached to the Drill Guide.

6.4 Screw drilling, measurement and insertion follows the technique described in Step 5 Proximal Locking Screw Insertion.

Alternatively, a Compression Set Screw (72700040) can be inserted with the 3.5mm Tibia Compression Set Screw Hexdriver (72502092) to compress the tibia shaft instead of using the Tibia Compression Driver (72800121) (Figure 6.1).

Confirm the black mark is not visible above the Drill Guide if a screw is to be inserted into the 2nd proximal screw hole, as this ensures the Compression Set Screw does not block the path of the screw (Figure 6.2).

Note: Compression can also be achieved by attaching the Medium Cannulated Impactor (72502007) to the Drill Guide and backslapping with the Slotted Hammer (71674082).

Figure 7.4

Step 7: Implant Removal

Using Tibia Nail Extractor

7.1 Expose the top of the Nail. If a Nail Cap is present, remove it using the Medium Hex Driver and Retention Rod.

Tip: If a hexdriver cannot be inserted into the hex of the Nail Cap, there is a flathead slot on the top surface to help remove it.

Note: If a Compression Set Screw is present and prevents the removal of the transverse screw in the compression slot, release the Set Screw using the 3.5mm Tibia Compression Set Screw Hex driver (72502092) or any 3.5mm Hex driver that will reach down into the nail.

Note: any locking screws more proximal to the Set Screw must be removed to grant access to remove it.

Note: the Set Screw does not need to be fully removed to insert the Tibia Nail Extractor.

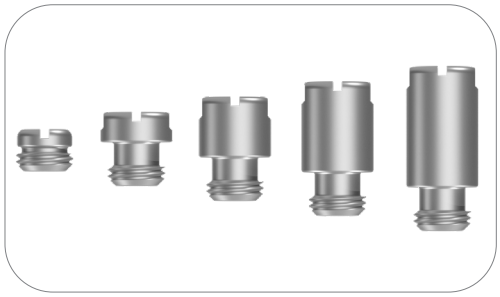
7.2 Insert the Large Cannulated Nail Extractor (72502089) into the top of the Nail and tighten using the Slotted Hammer. Thread the Medium Impactor into the back of the Nail Extractor.

7.3 Remove any remaining Locking Screws. If the Locking Screw is stripped, the Short or Long Cannulated Screw Extractor (72502085 or 72502084) can be used.

7.4 Using the Slotted Hammer and the Medium Impactor, backslap the nail out of the bone.

Optional Implants and Instruments

Nail Caps



Nail Caps

Nail caps of various heights are offered. They can be inserted by using the Medium or Long 4mm Hexdrivers.

Tibial nail caps are designed to provide locking stability to a screw placed in the proximal-most locking screw hole of the nail.

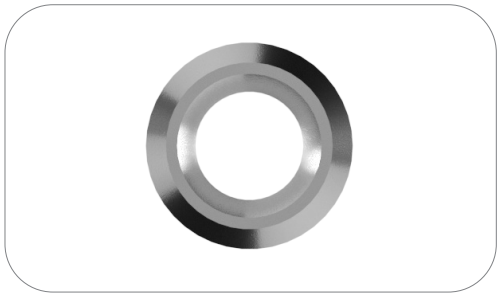
5.0mm Lag Screw

5.0mm Lag Screw

After the 5.0mm Lag Screw is seated in the nail, every subsequent full turn applies 0.1mm of compression across the fracture.

	Screw Length	Drill Bit Size	Hex Size
5.0mm Lag Screw 	35mm-80mm in 2.5mm increments and 80mm-110mm in 5mm increments	4.3mm Step Drill (short or long)	4.0mm Hex (short, medium or long)

13mm Washer



13mm Washer (72600050)

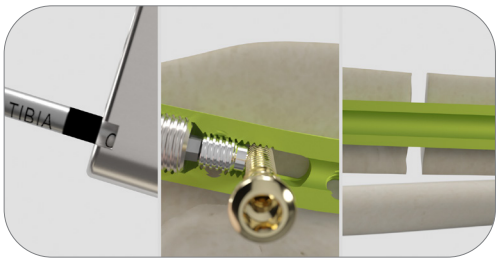
A 13mm Washer designed to be used with either gold 5.0mm Locking Screw or grey 4.5mm Locking Screws is available. When desired, place the Washer on the Screw prior to Screw insertion.

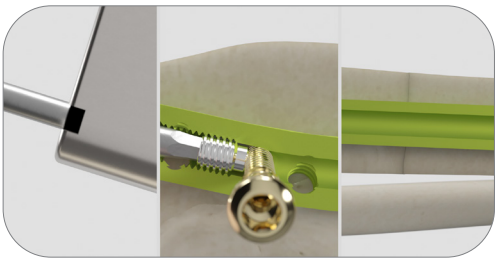
Note: The Washer will not fit through the 9.0mm Gold Sleeve.

Compression Set Screw

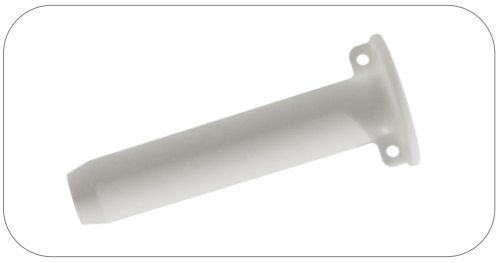
Compression Set Screw

A Compression Set Screw (72700040) with 3.5mm Tibia Compression Set Screw Hexdriver (72502092) can be used to compress the tibia shaft instead of the Tibia Compression Driver (72800121). Confirm the black mark is not visible above the Drill Guide if a screw is to be inserted into the 2nd proximal screw hole, as this ensures the Compression Set Screw does not block the path of the screw.





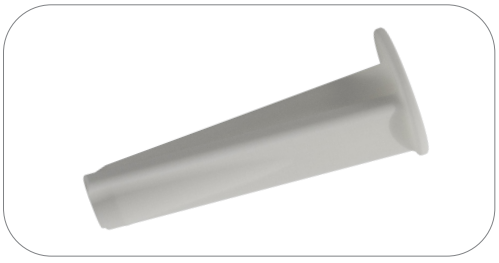
Flexible Entry Tube Sleeve



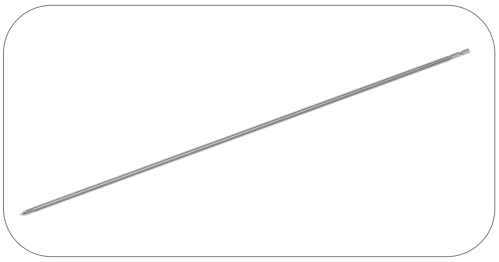
Flexible Entry Tube Sleeve (72800122) and Pinnable Flexible Entry Tube Sleeve (72800123)

Two different flexible protection sleeves are available. Slide over the Semi-Extended Entry Portal Tube (72502031)

Pinnable Flexible Entry Tube Sleeve



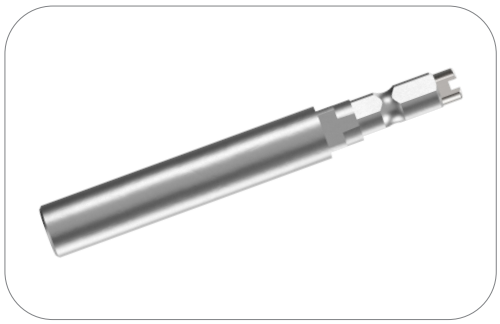
Guide Pin options



Guide Pins

Two different Guide Pin designs are available. Threaded Trocar Tip Guide Pin (72800132) and Drill Tip Guide Pin (72800133)

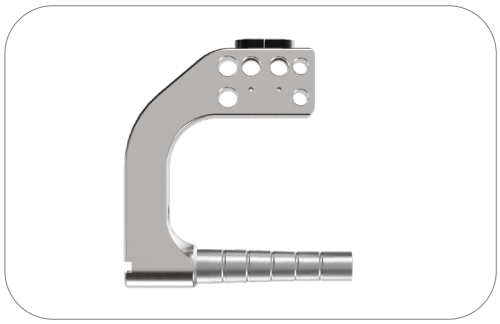
50mm Reamer Extender



50mm Reamer Extender (72502042)

When additional length is needed, the 50mm Reamer Extender (72502042) can be attached to the Flexible Reamer Shaft (72502041)

Standard Drill Guide

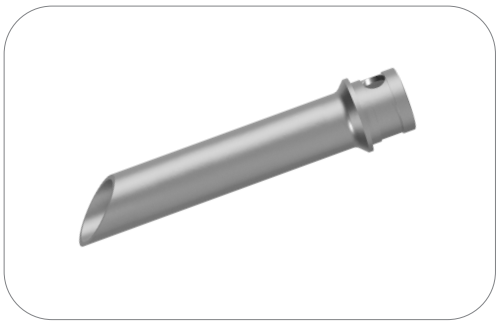


Standard Drill Guide (72502038), Standard Guide Bolt (72502039), Entry Portal Tube (71674060) and Honeycomb (72502014)

The Standard Drill Guide (72502038), Standard Guide Bolt (72502039), Entry Portal Tube (71674060) and Entry Portal Honeycomb (72502014) can be used when an infrapatellar approach is desired.

Standard Guide Bolt

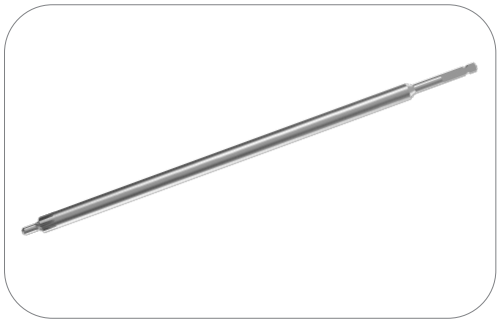
Entry Portal Tube



Entry Portal Honeycomb

Short 5.0mm Countersink

Long 5.0mm Countersink



Hall-Jacobs Screwdriver Handle

Short & Long 5.0mm Countersinks (72502093 and 72502028)

Countersinks are available for when hard/dense bone is encountered. The Long 5.0mm Countersink (72502028) is designed to be used through the gold 9.0mm Screw Sleeve (72502023)

Hall-Jacobs Screwdriver Handle (72502021)

Two driver handle designs are available. A straight screwdriver handle (72502021) and a T-Handle (71674576)

Tips and Tricks

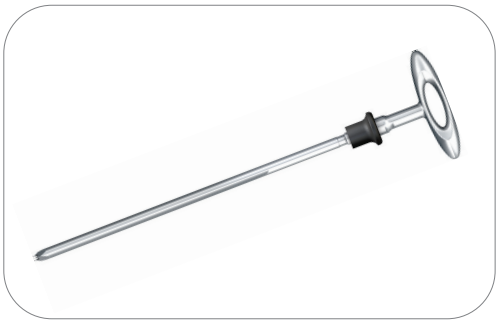


Figure 1

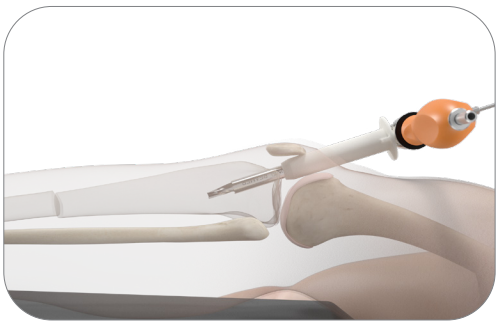


Figure 2

1 Proximal Entry Portal of the Tibia using the Cannulated Awl

The Entry Portal can be created with a Cannulated Awl.

With the Entry Tube and Entry Portal Handle in the joint space as described above, attach the T-Handle (71674576) to the Cannulated Awl (71674000). Insert the 3.2mm T-Handle Trocar (72502013) through the assembled Cannulated Awl and T-Handle to prevent awl slippage and accumulation of cortical bone within the cannulation.

Insert the assembly into the proximal tibia to a depth of 4–6cm.

2 Proximal Entry Portal of the Tibia using the 12.5mm Channel Reamer

The Entry Portal can be created using a Channel Reamer. The outer reamer (Channel) is left in the proximal tibia when removing the inner reamer. IM Reaming through the Channel protects the integrity of the entry portal of the proximal tibia, as well as prevent intraarticular debris from reaming entering into the knee joint.

Insert the 11.5mm Rigid Entry Reamer (72502073) into the 12.5mm Channel Reamer (72502088) and attach to the surgical power drill.

With the Entry Tube and Entry Portal Handle in the joint space as described above, advance the Channel Reamer assembly over the Guide Pin through the Entry Tube to a depth of 4–6cm.

Remove the 11.5mm Rigid Entry Reamer, leaving the 12.5mm Channel Reamer in the proximal tibia. IM canal reaming can be performed up to the 11.5mm Reamer Head size through the 12.5mm Channel Reamer..

Continued on next page

Figure 3a

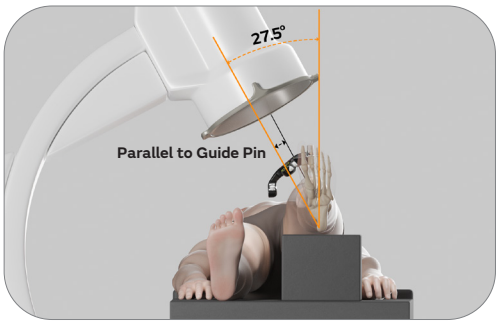


Figure 3b

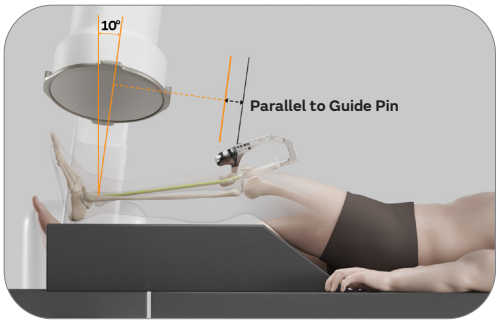


Figure 3c

Figure 3d

3 Identifying the trajectory of the Distal Variable Angle Hole

There is a reference hole in the Half Drop for a 3.2mm Guide Pin to be used to identify the nominal trajectory of the Distal Variable Angle Screw Hole.

To aid in the perfect circle technique for the most distal Variable Angle hole trajectory, place a 3.2mm Guide Pin through the reference hole in the Half Drop corresponding to the side of the nail (see Figure 3a) and align the axis of the C-arm to the Guide Pin while aiming at the distal aspect of the nail (Figures 3b and 3c).

When aligned in both planes, the resulting C-arm image will appear as shown in Figure 3d.

Catalog Information

TRIGEN° MAX Tibia Nails

Cat no	Description
72600824L	8mm X 24cm Left
72600825L	8mm X 25cm Left
72600826L	8mm X 26cm Left
72600827L	8mm X 27cm Left
72600828L	8mm X 28cm Left
72600829L	8mm X 29cm Left
72600830L	8mm X 30cm Left
72600831L	8mm X 31cm Left
72600832L	8mm X 32cm Left
72600833L	8mm X 33cm Left
72600834L	8mm X 34cm Left
72600835L	8mm X 35cm Left
72600836L	8mm X 36cm Left
72600837L	8mm X 37cm Left
72600838L	8mm X 38cm Left
72600839L	8mm X 39cm Left
72600840L	8mm X 40cm Left
72600841L	8mm X 41cm Left
72600842L	8mm X 42cm Left

Cat no	Description
72600824R	8mm X 24cm Right
72600825R	8mm X 25cm Right
72600826R	8mm X 26cm Right
72600827R	8mm X 27cm Right
72600828R	8mm X 28cm Right
72600829R	8mm X 29cm Right
72600830R	8mm X 30cm Right
72600831R	8mm X 31cm Right
72600832R	8mm X 32cm Right
72600833R	8mm X 33cm Right
72600834R	8mm X 34cm Right
72600835R	8mm X 35cm Right
72600836R	8mm X 36cm Right
72600837R	8mm X 37cm Right
72600838R	8mm X 38cm Right
72600839R	8mm X 39cm Right
72600840R	8mm X 40cm Right
72600841R	8mm X 41cm Right
72600842R	8mm X 42cm Right

Cat no	Description
72600924L	9mm X 24cm Left
72600925L	9mm X 25cm Left
72600926L	9mm X 26cm Left
72600927L	9mm X 27cm Left
72600928L	9mm X 28cm Left
72600929L	9mm X 29cm Left
72600930L	9mm X 30cm Left
72600931L	9mm X 31cm Left
72600932L	9mm X 32cm Left
72600933L	9mm X 33cm Left
72600934L	9mm X 34cm Left
72600935L	9mm X 35cm Left
72600936L	9mm X 36cm Left
72600937L	9mm X 37cm Left
72600938L	9mm X 38cm Left
72600939L	9mm X 39cm Left
72600940L	9mm X 40cm Left
72600941L	9mm X 41cm Left
72600942L	9mm X 42cm Left

Cat no	Description
72600924R	9mm X 24cm Right
72600925R	9mm X 25cm Right
72600926R	9mm X 26cm Right
72600927R	9mm X 27cm Right
72600928R	9mm X 28cm Right
72600929R	9mm X 29cm Right
72600930R	9mm X 30cm Right
72600931R	9mm X 31cm Right
72600932R	9mm X 32cm Right
72600933R	9mm X 33cm Right
72600934R	9mm X 34cm Right
72600935R	9mm X 35cm Right
72600936R	9mm X 36cm Right
72600937R	9mm X 37cm Right
72600938R	9mm X 38cm Right
72600939R	9mm X 39cm Right
72600940R	9mm X 40cm Right
72600941R	9mm X 41cm Right
72600942R	9mm X 42cm Right

TRIGEN® MAX Tibia Nails

Cat no	Description
72601024L	10mm X 24cm Left
72601025L	10mm X 25cm Left
72601026L	10mm X 26cm Left
72601027L	10mm X 27cm Left
72601028L	10mm X 28cm Left
72601029L	10mm X 29cm Left
72601030L	10mm X 30cm Left
72601031L	10mm X 31cm Left
72601032L	10mm X 32cm Left
72601033L	10mm X 33cm Left
72601034L	10mm X 34cm Left
72601035L	10mm X 35cm Left
72601036L	10mm X 36cm Left
72601037L	10mm X 37cm Left
72601038L	10mm X 38cm Left
72601039L	10mm X 39cm Left
72601040L	10mm X 40cm Left
72601041L	10mm X 41cm Left
72601042L	10mm X 42cm Left

Cat no	Description
72601024R	10mm X 24cm Right
72601025R	10mm X 25cm Right
72601026R	10mm X 26cm Right
72601027R	10mm X 27cm Right
72601028R	10mm X 28cm Right
72601029R	10mm X 29cm Right
72601030R	10mm X 30cm Right
72601031R	10mm X 31cm Right
72601032R	10mm X 32cm Right
72601033R	10mm X 33cm Right
72601034R	10mm X 34cm Right
72601035R	10mm X 35cm Right
72601036R	10mm X 36cm Right
72601037R	10mm X 37cm Right
72601038R	10mm X 38cm Right
72601039R	10mm X 39cm Right
72601040R	10mm X 40cm Right
72601041R	10mm X 41cm Right
72601042R	10mm X 42cm Right

Cat no	Description
72601124L	11mm X 24cm Left
72601125L	11mm X 25cm Left
72601126L	11mm X 26cm Left
72601127L	11mm X 27cm Left
72601128L	11mm X 28cm Left
72601129L	11mm X 29cm Left
72601130L	11mm X 30cm Left
72601131L	11mm X 31cm Left
72601132L	11mm X 32cm Left
72601133L	11mm X 33cm Left
72601134L	11mm X 34cm Left
72601135L	11mm X 35cm Left
72601136L	11mm X 36cm Left
72601137L	11mm X 37cm Left
72601138L	11mm X 38cm Left
72601139L	11mm X 39cm Left
72601140L	11mm X 40cm Left
72601141L	11mm X 41cm Left
72601142L	11mm X 42cm Left

Cat no	Description
72601124R	11mm X 24cm Right
72601125R	11mm X 25cm Right
72601126R	11mm X 26cm Right
72601127R	11mm X 27cm Right
72601128R	11mm X 28cm Right
72601129R	11mm X 29cm Right
72601130R	11mm X 30cm Right
72601131R	11mm X 31cm Right
72601132R	11mm X 32cm Right
72601133R	11mm X 33cm Right
72601134R	11mm X 34cm Right
72601135R	11mm X 35cm Right
72601136R	11mm X 36cm Right
72601137R	11mm X 37cm Right
72601138R	11mm X 38cm Right
72601139R	11mm X 39cm Right
72601140R	11mm X 40cm Right
72601141R	11mm X 41cm Right
72601142R	11mm X 42cm Right

TRIGEN® MAX Tibia Nails

Cat no	Description
72601224L	12.5mm X 24cm Left
72601226L	12.5mm X 26cm Left
72601228L	12.5mm X 28cm Left
72601230L	12.5mm X 30cm Left
72601232L	12.5mm X 32cm Left
72601234L	12.5mm X 34cm Left
72601236L	12.5mm X 36cm Left
72601238L	12.5mm X 38cm Left
72601240L	12.5mm X 40cm Left
72601242L	12.5mm X 42cm Left

Cat no	Description
72601224R	12.5mm X 24cm Right
72601226R	12.5mm X 26cm Right
72601228R	12.5mm X 28cm Right
72601230R	12.5mm X 30cm Right
72601232R	12.5mm X 32cm Right
72601234R	12.5mm X 34cm Right
72601236R	12.5mm X 36cm Right
72601238R	12.5mm X 38cm Right
72601240R	12.5mm X 40cm Right
72601242R	12.5mm X 42cm Right

TRIGEN MAX Disposables

Cat no	Description
72800142S	TRIGEN MAX 4.0mm Short Drill with AO Quick Connect
72800144S	TRIGEN MAX 4.3mm Short Drill with AO Quick Connect
72800144L	TRIGEN MAX 4.3mm Long Drill with AO Quick Connect
72800130	TRIGEN MAX 3.0mm X 900mm Ball Tipped Guide Rod
72800132	TRIGEN MAX 3.2mm X 360mm Thread Tip Guide Pin
72800133	TRIGEN MAX 3.2mm X 360mm Drill Tip Guide Pin
72502084	TRIGEN MAX Long Cannulated Screw Extractor
72502085	TRIGEN MAX Short Cannulated Screw Extractor
72502089	TRIGEN MAX Large Cannulated Nail Extractor

TRIGEN® MAX 4.5mm Locking Screws

Cat no	Description
72700420	4.5mm x 20mm
72700422	4.5mm x 22.5mm
72700425	4.5mm x 25mm
72700427	4.5mm x 27.5mm
72700430	4.5mm x 30mm
72700432	4.5mm x 32.5mm
72700435	4.5mm x 35mm
72700437	4.5mm x 37.5mm
72700440	4.5mm x 40mm (shown)
72700442	4.5mm x 42.5mm
72700445	4.5mm x 45mm
72700447	4.5mm x 47.5mm
72700450	4.5mm x 50mm
72700452	4.5mm x 52.5mm
72700455	4.5mm x 55mm
72700457	4.5mm x 57.5mm
72700460	4.5mm x 60mm
72700462	4.5mm x 62.5mm
72700465	4.5mm x 65mm
72700467	4.5mm x 67.5mm
72700470	4.5mm x 70mm
72700472	4.5mm x 72.5mm
72700475	4.5mm x 75mm
72700477	4.5mm x 77.5mm
72700480	4.5mm x 80mm
72700485	4.5mm x 85mm
72700490	4.5mm x 90mm
72700495	4.5mm x 95mm
72700500	4.5mm x 100mm
72700505	4.5mm x 105mm
72700510	4.5mm x 110mm

TRIGEN MAX 4.5mm Headless Locking Screws

Cat no	Description
72710420	4.5mm x 20mm
72710422	4.5mm x 22.5mm
72710425	4.5mm x 25mm
72710427	4.5mm x 27.5mm
72710430	4.5mm x 30mm
72710432	4.5mm x 32.5mm
72710435	4.5mm x 35mm
72710437	4.5mm x 37.5mm
72710440	4.5mm x 40mm (shown)
72710442	4.5mm x 42.5mm
72710445	4.5mm x 45mm
72710447	4.5mm x 47.5mm
72710450	4.5mm x 50mm
72710452	4.5mm x 52.5mm
72710455	4.5mm x 55mm
72710457	4.5mm x 57.5mm
72710460	4.5mm x 60mm
72710462	4.5mm x 62.5mm
72710465	4.5mm x 65mm

TRIGEN® MAX 5.0mm Locking Screws

Cat no	Description
72700520	5.0mm x 20mm
72700522	5.0mm x 22.5mm
72700525	5.0mm x 25mm
72700527	5.0mm x 27.5mm
72700530	5.0mm x 30mm
72700532	5.0mm x 32.5mm
72700535	5.0mm x 35mm
72700537	5.0mm x 37.5mm
72700540	5.0mm x 40mm (shown)
72700542	5.0mm x 42.5mm
72700545	5.0mm x 45mm
72700547	5.0mm x 47.5mm
72700550	5.0mm x 50mm
72700552	5.0mm x 52.5mm
72700555	5.0mm x 55mm
72700557	5.0mm x 57.5mm
72700560	5.0mm x 60mm
72700562	5.0mm x 62.5mm
72700565	5.0mm x 65mm
72700567	5.0mm x 67.5mm
72700570	5.0mm x 70mm
72700572	5.0mm x 72.5mm
72700575	5.0mm x 75mm
72700577	5.0mm x 77.5mm
72700580	5.0mm x 80mm
72700585	5.0mm x 85mm
72700590	5.0mm x 90mm
72700595	5.0mm x 95mm
72700600	5.0mm x 100mm
72700605	5.0mm x 105mm
72700610	5.0mm x 110mm

TRIGEN MAX 4.5mm Headless Locking Screws

Cat no	Description
72710420	4.5mm x 20mm
72710422	4.5mm x 22.5mm
72710425	4.5mm x 25mm
72710427	4.5mm x 27.5mm
72710430	4.5mm x 30mm
72710432	4.5mm x 32.5mm
72710435	4.5mm x 35mm
72710437	4.5mm x 37.5mm
72710440	4.5mm x 40mm (shown)
72710442	4.5mm x 42.5mm
72710445	4.5mm x 45mm
72710447	4.5mm x 47.5mm
72710450	4.5mm x 50mm
72710452	4.5mm x 52.5mm
72710455	4.5mm x 55mm
72710457	4.5mm x 57.5mm
72710460	4.5mm x 60mm
72710462	4.5mm x 62.5mm
72710465	4.5mm x 65mm

TRIGEN® MAX 5.0mm Lag Screws

Cat no	Description
72720535	5.0mm x 35mm
72720537	5.0mm x 37.5mm
72720540	5.0mm x 40mm (shown)
72720542	5.0mm x 42.5mm
72720545	5.0mm x 45mm
72720547	5.0mm x 47.5mm
72720550	5.0mm x 50mm
72720552	5.0mm x 52.5mm
72720555	5.0mm x 55mm
72720557	5.0mm x 57.5mm
72720560	5.0mm x 60mm
72720562	5.0mm x 62.5mm
72720565	5.0mm x 65mm
72720567	5.0mm x 67.5mm
72720570	5.0mm x 70mm
72720572	5.0mm x 72.5mm
72720575	5.0mm x 75mm
72720577	5.0mm x 77.5mm
72720580	5.0mm x 80mm
72720585	5.0mm x 85mm
72720590	5.0mm x 90mm
72720595	5.0mm x 95mm
72720600	5.0mm x 100mm
72720605	5.0mm x 105mm
72720610	5.0mm x 110mm

TRIGEN MAX Compression Set Screw

Cat no	Description
72700040	TRIGEN MAX Compression Set Screw

TRIGEN MAX Nail Caps

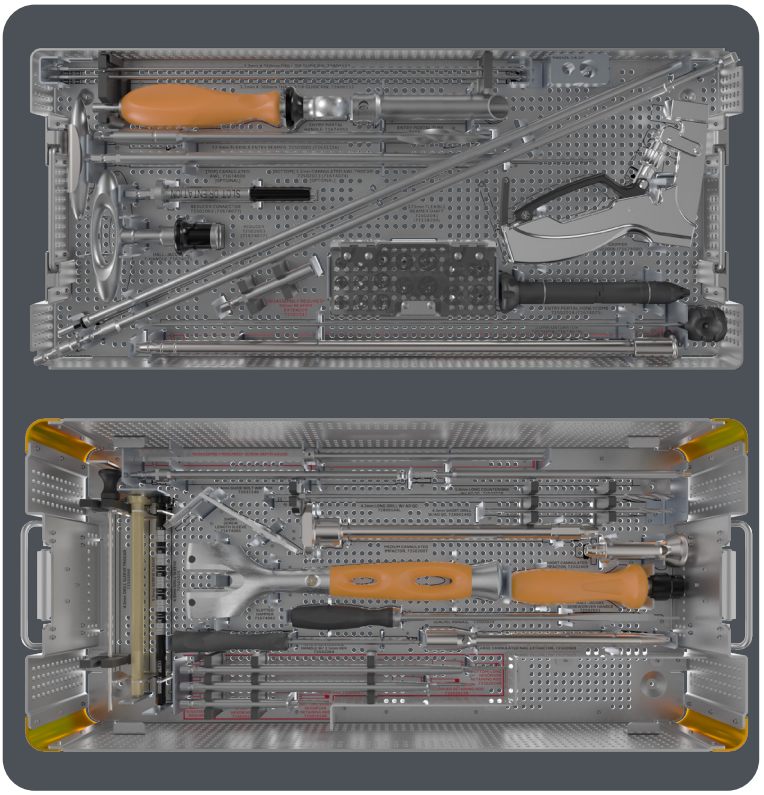
Cat no	Description
72600000	0mm
72600005	5mm
72600010	10mm
72600015	15mm (shown)
72600020	20mm

TRIGEN MAX Washer

Cat no	Description
72600050	TRIGEN MAX 13mm Washer

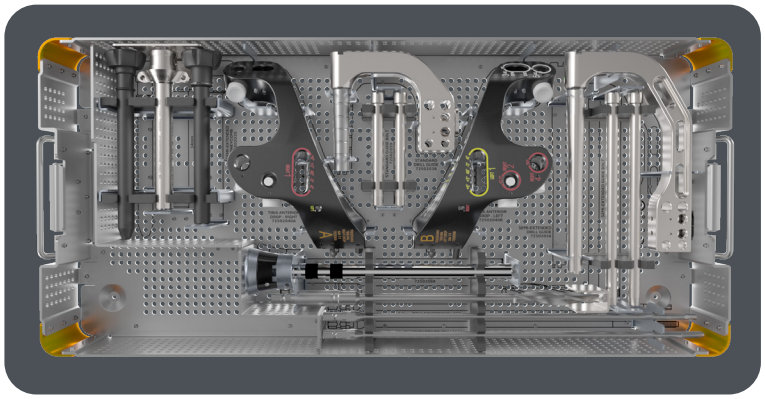
TRIGEN® MAX Base Instrument Tray

Cat no	Description
72501003	TRIGEN MAX Base Instrument Tray
72501009	TRIGEN MAX Tray Lid
72800132	3.2mm x 360mm Thread Tip Guide Pin
72800133	3.2mm x 360mm Drill Tip Guide Pin
72800144L	4.3mm Long Drill w/ AO QC
72800144S	4.3mm Short Drill w/ AO QC
71631140	6.4mm Guide Bolt Wrench
71674000	Cannulated Awl, Optional
72502013	3.2mm Cannulated Awl Trocar, Optional
71674082	Slotted Hammer
71674085	Short Screw Length Sleeve
71674092	Entry Portal Handle
71674060	Entry Portal Tube
72502014	Entry Portal Honeycomb
71674576	Hall-Jacobs T-Handle
72502001	12.5mm Flexible Entry Reamer
72502003	Reducer
72502004	3.0mm Obturator
72502005	Ruler for 900mm Guide Rod
72502006	Gripper
72502007	Medium Cannulated Impactor
72502009	Short Cannulated Impactor
72502021	Hall-Jacobs Screwdriver Handle
72502023	9.0mm Screw Sleeve
72502025	4.3mm Drill Sleeve
72502090	4.0mm Drill Sleeve Trocar
72502027	Screw Depth Gauge
72502028	5.0mm Long Countersink w/ AO QC
72502029	Scalpel Handle
72502041	570mm Flexible Reamer Shaft
72502042	50mm Reamer Extender
72501008	Reamer Head Box
72502043 - 72502059	8.0mm - 16.0mm Endcutting Reamer Head
72502069	Retention Release Handle With 2.5mm Hex
72502089	Large Cannulated Nail Extractor
72502016	4.0mm Long Hexdriver
72502017	4.0mm Medium Hexdriver
72502018	4.0mm Short Hexdriver
72502016R	Long Hexdriver Retaining Rod
72502017R	Medium Hexdriver Retaining Rod
72502018R	Short Hexdriver Retaining Rod



TRIGEN® MAX Tibia Instrument Tray

Cat no	Description
72501004	TRIGEN MAX Tibia Instrument Tray
72501009	TRIGEN MAX Tray Lid
72502031	14mm Semi-Extended Entry Tube
72502033	3.2mm Semi-Extended Guide Pin Sleeve
72502035	Semi-Extended Honeycomb
72502036	Semi-Extended Drill Guide
72502037	Semi-Extended Guide Bolt
72502038	Standard Drill Guide
72502039	Standard Guide Bolt
72502073	11.5mm Rigid Entry Reamer
72502088	12.5mm Channel Reamer
72502092	3.5mm Tibia Compression Set Screw Hexdriver
72800121	Compression Driver
72502040A	Tibia Anterior Drop - Right
72502040B	Tibia Anterior Drop - Left



TRIGEN MAX Disposables

Cat no	Description
72800142S	TRIGEN MAX 4.0mm Short Drill with AO Quick Connect
72800144S	TRIGEN MAX 4.3mm Short Drill With AO Quick Connect
72800144L	TRIGEN MAX 4.3mm Long Drill With AO Quick Connect
72800130	TRIGEN MAX 3.0mm X 900mm Ball Tipped Guide Rod
72800132	TRIGEN MAX 3.2mm X 360mm Thread Tip Guide Pin
72800133	TRIGEN MAX 3.2mm X 360mm Drill Tip Guide Pin
72502084	TRIGEN MAX Long Cannulated Screw Extractor
72502085	TRIGEN MAX Short Cannulated Screw Extractor
72502089	TRIGEN MAX Large Cannulated Nail Extractor
72502089	TRIGEN MAX Large Cannulated Nail Extractor

Notes

Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Smith+Nephew representative or distributor if you have questions about the availability of Smith+Nephew products in your area. For detailed product information, including indications for use, contraindications, precautions and warnings, please consult the product's applicable Instructions for Use (IFU) prior to use.

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