Paragon 28®

SURGICAL TECHNIQUE GUIDE

Phantom® Fibula Nail System

PHANTOM®
FIBULA NAIL SYSTEM

ACKNOWLEDGMENT:

Paragon 28 would like to thank Charles Moon, MD; Thomas San Giovanni, MD; and Alastair Younger, MD, for their contribution to the development of this system and technique guide.

PRODUCT DESCRIPTION:

The Phantom® Fibula Nail System was designed to provide surgeons a comprehensive intramedullary fibula Nail system. The Phantom® Fibula Nail System offers a variety of implant diameters and lengths to accommodate diverse patient anatomy.[1] There are four different diameter options (Ø2.8 mm, Ø3.4 mm, Ø4.0 mm, and Ø5.5 mm) and three length options (130 mm, 180 mm, 270 mm). A precision guide is provided to help streamline and improve the reproducibility of the initial K-Wire placement. This helps to optimize the start point, which is crucial for successful completion of the operation.[2]

The Phantom® Fibula Nail Outrigger expedites the placement of Threaded Pegs and syndesmotic devices through the Nail and can be used to help control reduction of the fibula to the desired position. The Outrigger is designed to be radiolucent and allow adequate visualization of relevant anatomy during the procedure. An array of instrumentation is provided to help reduce the fibula per surgeon preference. The Phantom® Fibula Nail System includes an internal proximal fixation feature that can be deployed after establishing proper reduction of the fibula and placement of the Nail.

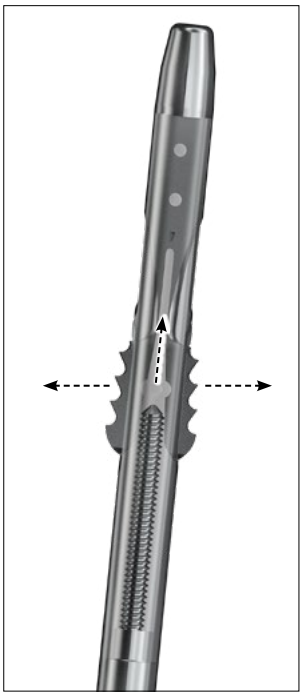
CONTENTS:

IMPLANT OFFERING:

Proximal Fixation Feature

- The "Insertion" or non-deployed state allows for ease of placement of the Nail. Deployment of the proximal fixation feature is performed after fracture reduction and Nail placement to help secure the proximal portion of the Nail and reduce the risk of movement of the Nail in the fibula

Insertion state



Deployed state

Variable Nail Length and Diameters

30/40 mm from base of Nail

Syndesmotic Fixation

- Allows for placement of either rigid or dynamic devices through the Nail and into the tibia to help secure the syndesmosis during healing

Distal Fixation Cluster

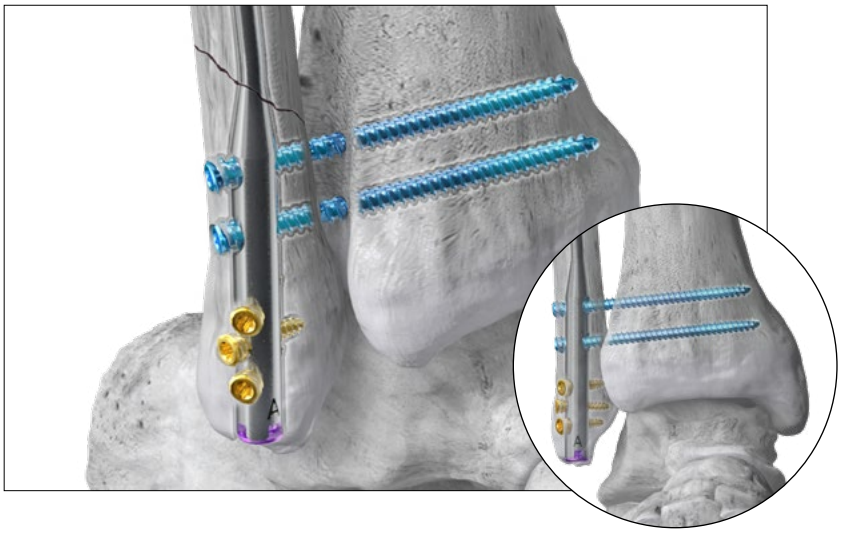
- Allows for placement of Ø2.7 mm Threaded Pegs that interlock with the Nail to secure the distal segment of the fibula with the Nail. These Threaded Pegs are headless to allow for flush placement and to help minimize soft tissue irritation

9 - 19 mm from base of Nail

Nail End Cap

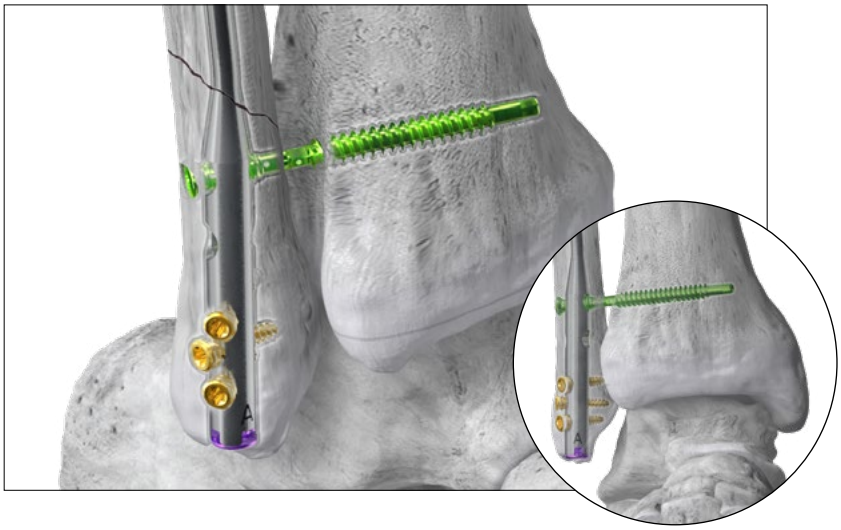
- Offered in 1 mm, 5 mm, 10 mm, and 20 mm length options to be placed in the distal end of the Nail to reduce the possibility of boney ingrowth into the distal end of the Nail. This allows the Nail to be placed at the correct height for the syndesmosis while still engaging the tip of the fibula.

IMPLANT OFFERING SYNDESMOTIC FIXATION:



OPTION 1:

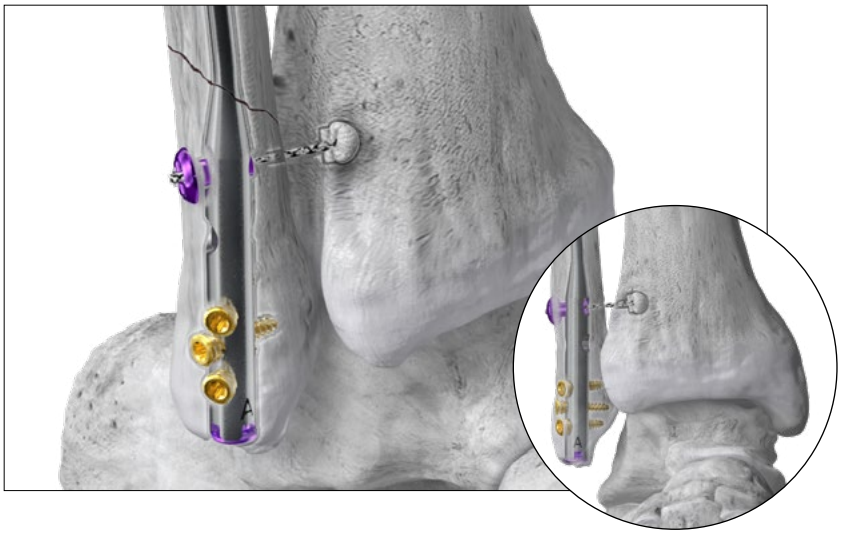
Ø3.5 mm Threaded Pegs Syndesmotic Fixation
- Allows for placement of one or two static Ø3.5 Threaded Peg(s) through the Nail and into the tibia to help secure the syndesmosis during healing using the current technique guide.



OPTION 2:

R3ACT Stabilization System Syndesmotic Fixation
- Allows for placement of a Dynamic Screw through the Nail and into the tibia to help secure the syndesmosis during healing using the R3ACT™ Stabilization System.

- Please refer to the current technique guide for instruction on R3ACT™ placement. Refer to the R3ACT™ Stabilization System Surgical Technique Guide P80-STG-0001 for any additional information about the system.



OPTION 3:

R3FLEX Stabilization System Syndesmotic Fixation
- Allows for placement of a dynamic anchor through the Nail and into the tibia to help secure the syndesmosis during healing using the R3FLEX™ Stabilization System.

- Please refer to this technique for site preparation and refer to the R3FLEX™ Stabilization System Surgical Technique Guide P82-STG-0002 for instructions on dynamic anchor tensioning.

NOTE: All Nail configurations require the use of the Ø2.7 mm Threaded Pegs into the distal cluster of the Nail for correct placement into the fibula. The instructions for use can be found in this current Surgical Technique Guide.

OUTRIGGER FEATURES:

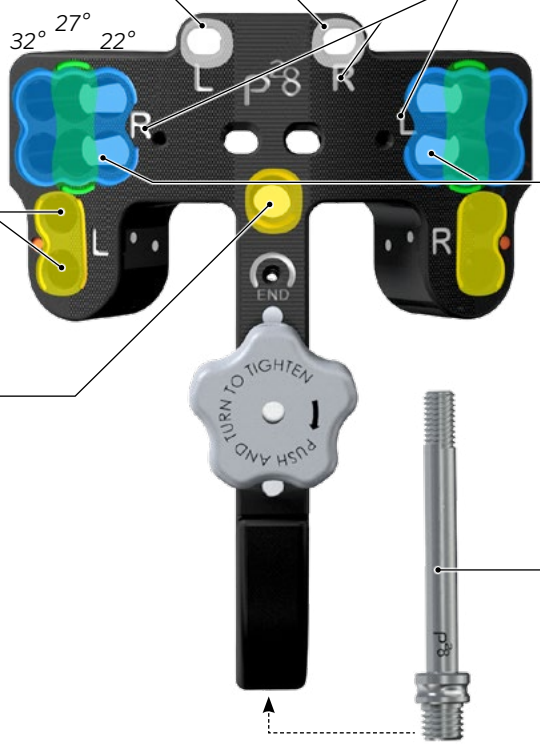
Outrigger Targeter
- Detachable to allow for more ergonomic insertion and additional room for reduction instrumentation, if used

End of Nail Targeting Hole
- Accommodates a Ø1.6 mm wire to help visualize the end of the Nail either visually or under fluoroscopy

Outrigger Knob
- Use to connect the Outrigger Targeter to the Outrigger base. Can be removed after securing the Outrigger Targeter for ease of visualization and manipulation

Outrigger Base
- Ergonomically designed for wide range of patient soft tissue envelopes and Nail placement depths

- Singular mating orientation with the fibula Nail implant for ease of assembly



Temporary reduction targeting hole
- Accommodates K-wire Clamp Sleeve to place a temporary wire into the tibia to maintain appropriate reduction

Laterality indicators
- Guides what holes should be used in the targeter based on operative limb

Ø2.7 mm Threaded Peg

- **Distal Fixation Targeting Holes**
  - Use to guide placement of Ø2.7 mm Threaded Pegs through the Nail and guide wires around the Nail to secure the distal fragment based on limb laterality
- **Center distal fixation targeting hole**
  - Use to guide placement of Ø2.7 mm Threaded Peg through the center of the Nail regardless of limb laterality

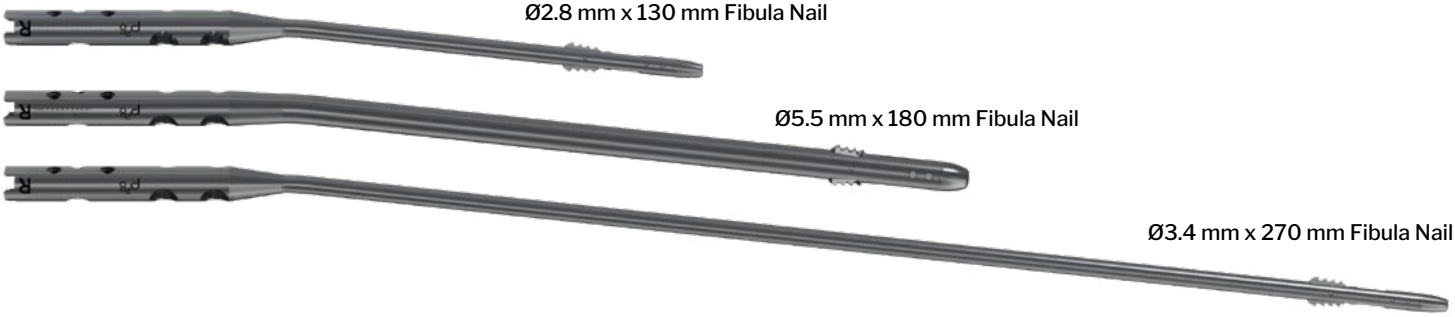
Syndesmotic fixation targeting holes
- Use to guide placement of R3ACT™ Screws, R3FLEX™ Implant, or solid Ø3.5 Threaded Pegs through the Nail and across the syndesmosis

- Blue Holes: accommodate Ø3.5 mm Threaded pegs

- Green Holes: accommodate Ø3.5 mm Threaded Pegs, R3FLEX or R3ACT implants

Outrigger Mounting Bolt
-Secures the Nail to the Outrigger base. Provides threaded interface for insertion/ removal tools

FEATURED IMPLANTS & INSTRUMENTATION:



		Fibula Nail Diameter Options			
		Ø2.8 mm	Ø3.4 mm	Ø4.0 mm	Ø5.5 mm
Fibula Nail Length Options:	130 mm	●	●	●	●
	180 mm	●	●	●	●
	270 mm		●	●	

Nail Template

Curved Reamer Guide

Ø6.8 mm Distal Reamer

		Nail Diameter			
		Ø2.8 mm	Ø3.4 mm	Ø4.0 mm	Ø5.5 mm
Proximal Reamer Diameter:	Ø2.6 mm (Initial)	●	●	●	●
	Ø3.3 mm	●	●	●	●
	Ø3.9 mm		●	●	●
	Ø4.5 mm			●	●
	Ø5.2 mm				●
	Ø6.0 mm				●
	Ø6.5 mm				Optional Over Ream

FEATURED INSTRUMENTATION:

Ø1.6 x 230 mm K-Wire (Entry Wire)


Ø1.6 x 70 mm Olive Wire

Ø2.0 x 150 mm K-Wire (Distal Fixation Wires)

Ø2.3 x 230 mm K-Wire (Tibial Reduction Wire)


Parallel K-Wire Guide/
Soft Tissue Protector

Entry K-Wire Guide


	Distal Threaded Peg	Syndesmotic Threaded Peg	R3ACT™ Stabilization Screw
			
Diameter:	Ø2.7 mm	Ø3.5 mm	Ø4.2 mm
Length:	10 mm - 26 mm *in 2 mm increments*	40 mm - 70 mm *in 2 mm increments*	40 mm - 62.5 mm *in 2.5 mm increments*
Instrument Color:			
Driver:	TX-10 Driver 		
Drill:	Ø2.0 mm 	Ø2.5 mm 	Ø2.8 mm  Ø3.2 mm *14 mm and 17 mm pilot* 
Drill Guide:			
Screw Sleeve:		*22° & 32° Sleeve*  *27° (Center) Sleeve* 	


R3ACT™ Tap

Ø2.7 mm/Ø3.5 mm Countersink


R3FLEX™ Step Drill

FEATURED INSTRUMENTATION:

Targeting Anterior Curved K-Wire Guide

Non-Targeting Posterior Curved K-Wire Guide

K-Wire Clamp Sleeve

Depth Gauge

Ratcheting AO Driver Handle

Torque Limiting Actuation Driver

Bone Hook

Screw Forceps

8 mm Hohmann Retractor

15 mm Hohmann Retractor

Periosteal Elevator

Small Mallet

Impaction Attachment

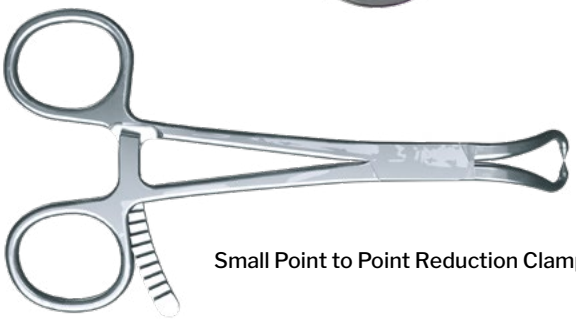
Easy-Out Removal Tool

Removal Hook Body

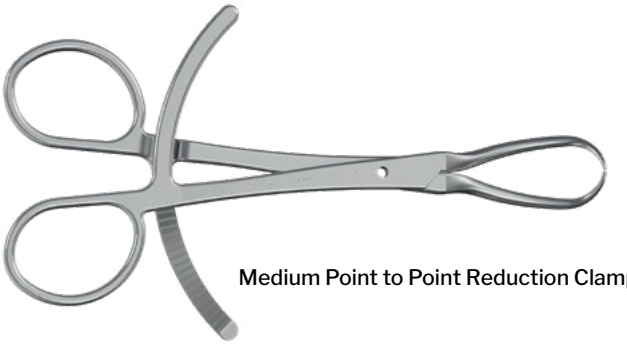
Removal Hook Pin

FEATURED INSTRUMENTATION:

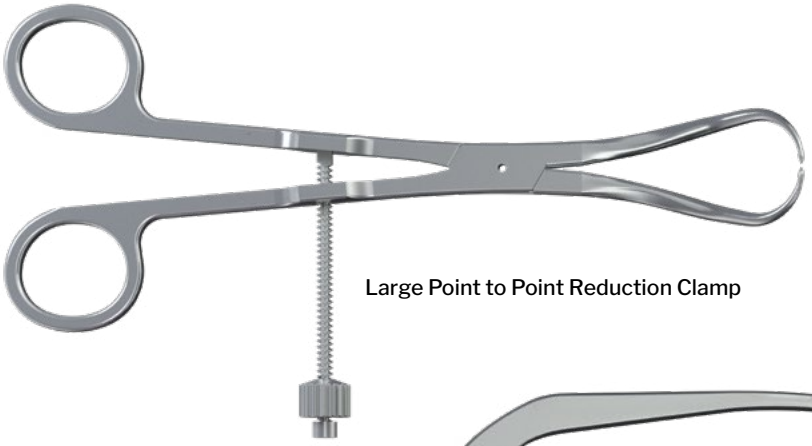
Lobster Claw Forceps



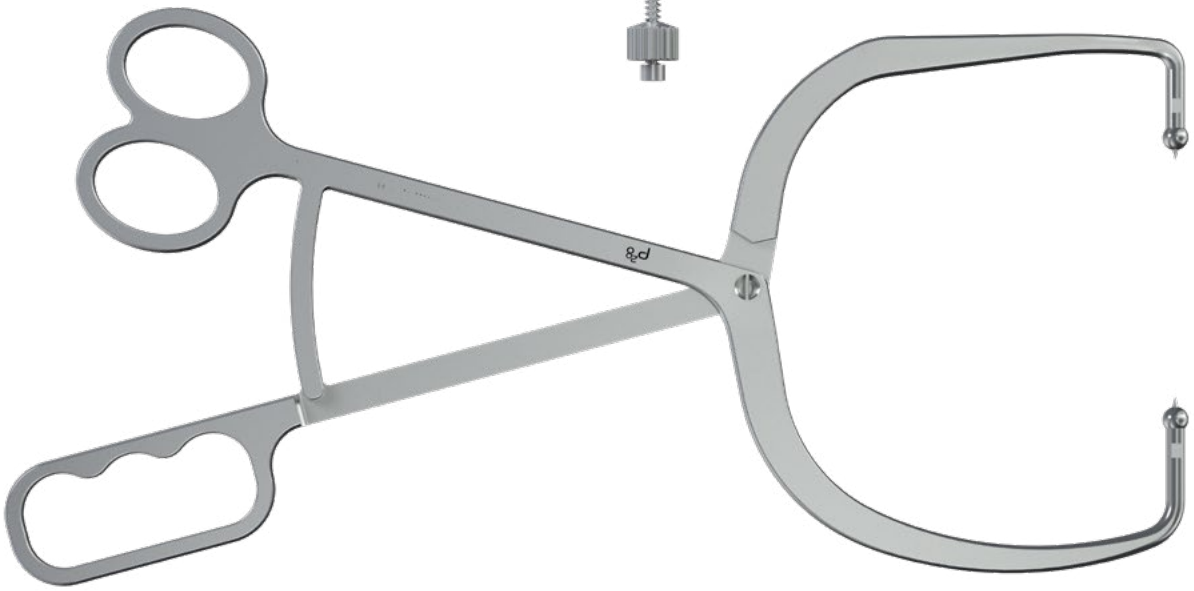
Small Point to Point Reduction Clamp



Medium Point to Point Reduction Clamp



Large Point to Point Reduction Clamp

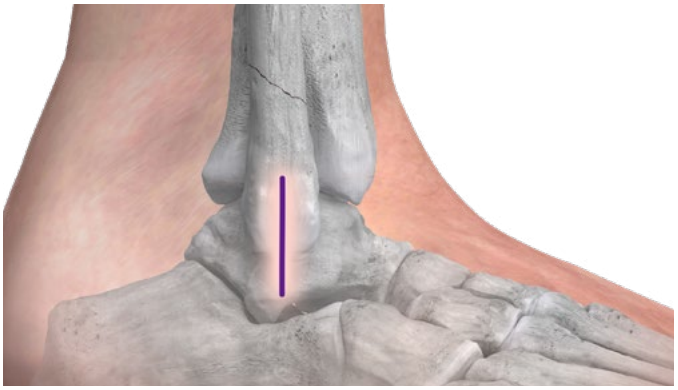


Tenaculum Clamp

INCISION:

Patient positioning is per surgeon preference, and may depend on the pathology and/or previous surgical approaches for a particular patient. Patient positioning options include supine with an ipsilateral bump, lateral decubitus, or prone. The should be internally rotated to allow access to the lateral fibula and allow AP imaging of the ankle.

The leg fracture should be reduced and temporarily stabilized per surgeon preference. Instrumentation is provided to assist in the stabilization of fractures prior to Nail placement.



Make a 1.5-2 cm vertical incision centered over the distal end of the fibula; extending slightly proximal and slightly distal to the tip.

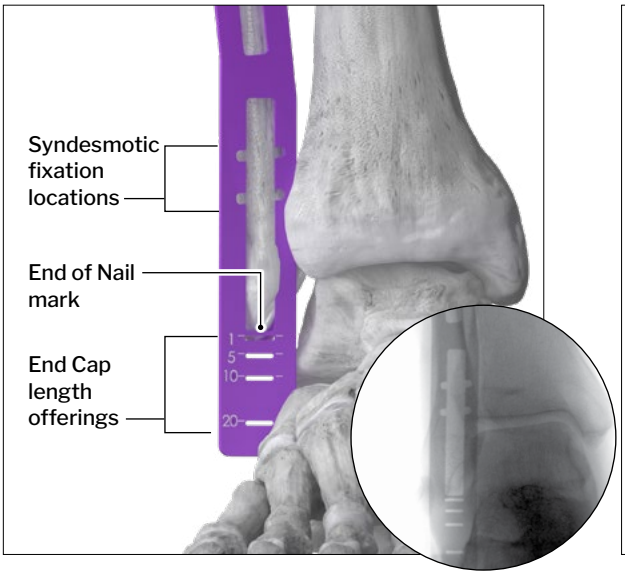
Once past the tip, perform soft tissue dissection per surgeon preference to expose the distal end of the fibula taking care to preserve the peroneal tendons which curve under the tip of the lateral malleolus. Placing the inferior aspect of the entry K-Wire guide directly on bone helps ensure the peroneal tendons are protected.

IMPLANT SIZING:

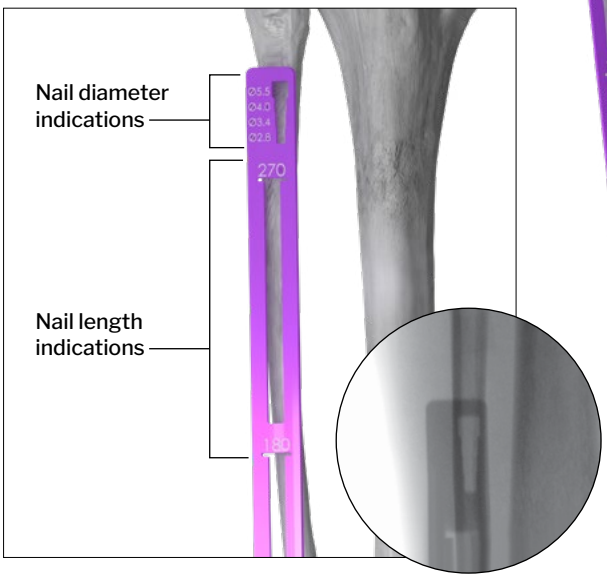
Nail Template

Place the template over the fibula and use fluoroscopy to determine the appropriate width and height of the Nail to accommodate injury and overall canal size.

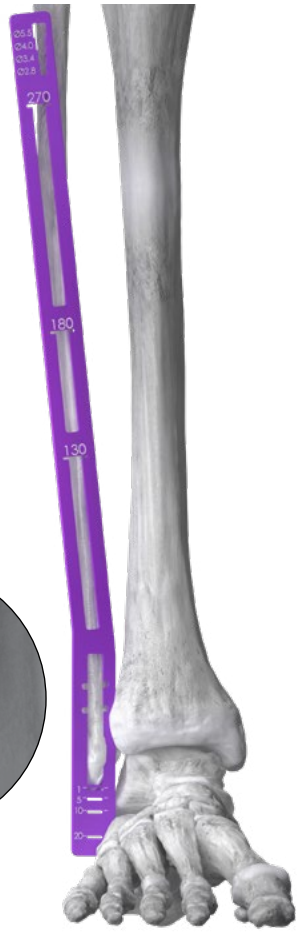
NOTE: Positioning of the template may influence accuracy of the predicted diameters due to the magnification of the fluoroscopy used. The overall shape of the sizer follows the shape of the Nail and the bars represent available Nail lengths.



The distal portion of the template marks the length of available End Caps and marks the location of syndesmotic fixation through the Nail.

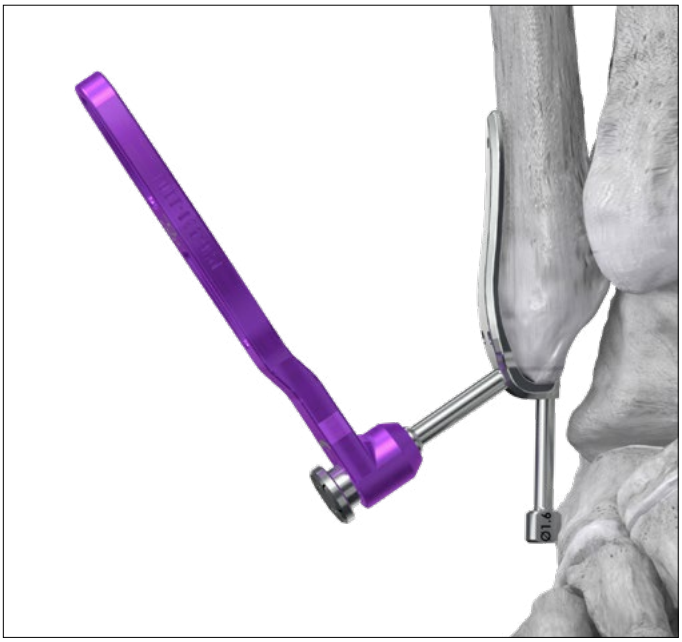


The proximal portion of the template marks the diameters of the available Nail sizes.

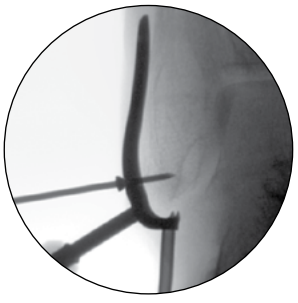


ENTRY WIRE PLACEMENT:

Entry K-Wire Guide

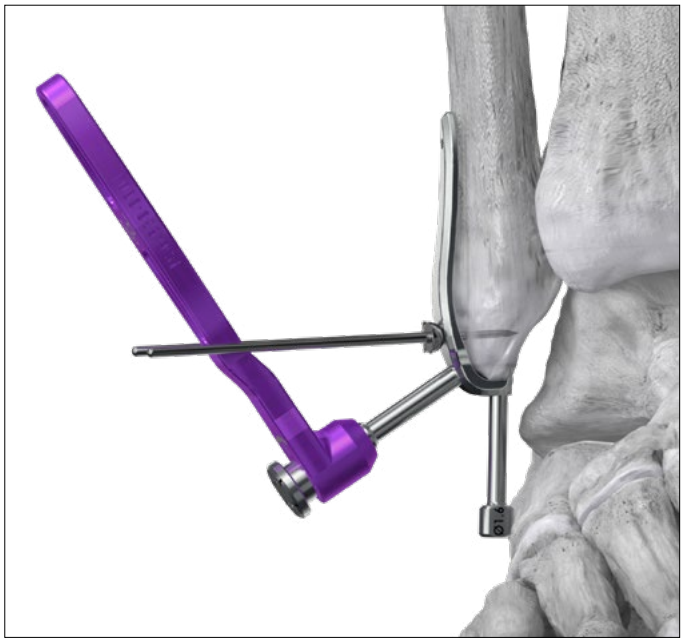


Place the Entry K-wire Guide subcutaneously on the fibula, ensuring contact between the inferior part of the Guide and the distal fibula. On the lateral view, center the tip of the guide superiorly, while aligning the Guide with the long axis of the fibula. On the AP view, confirm the inferior portion of the Guide is abutting the lateral malleolus. The superior portion of the Guide does not need to contact bone. Correct positioning of the entry point is required to help ensure appropriate fracture reduction.

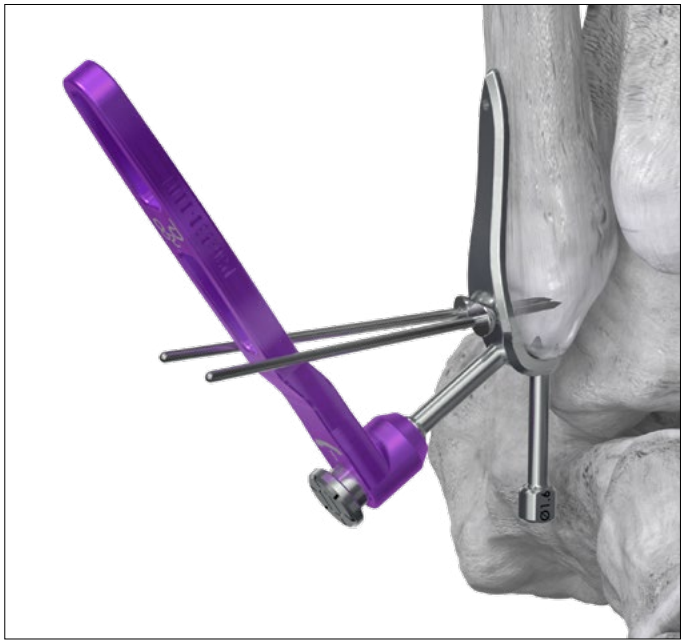


Confirm position and anticipated K-Wire trajectory using fluoroscopy.

If necessary, remove the olives and reposition the guide to the desired position and re-secure with Olive Wires.



After determining the appropriate location of the Entry K-Wire Guide, place two olive wires in the two distal holes of the guide.

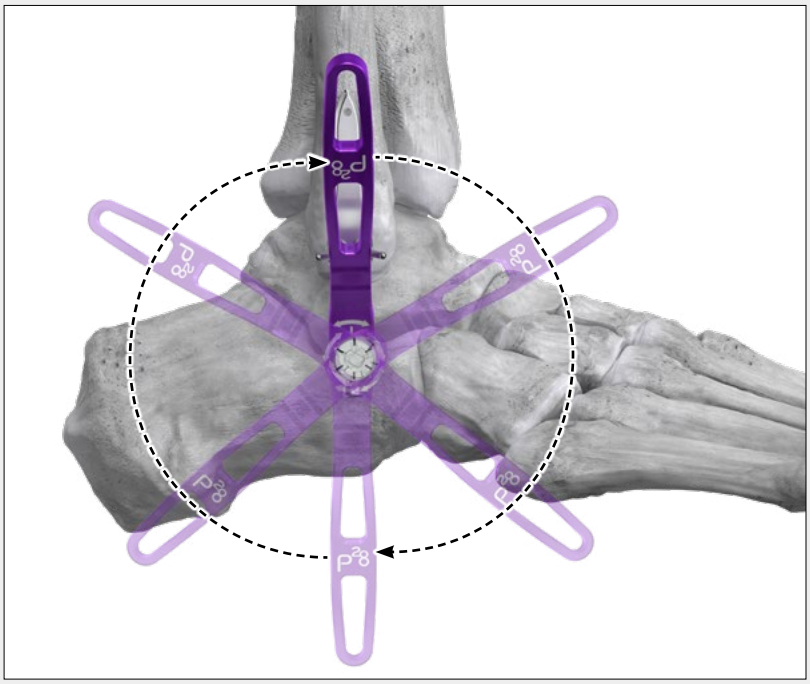


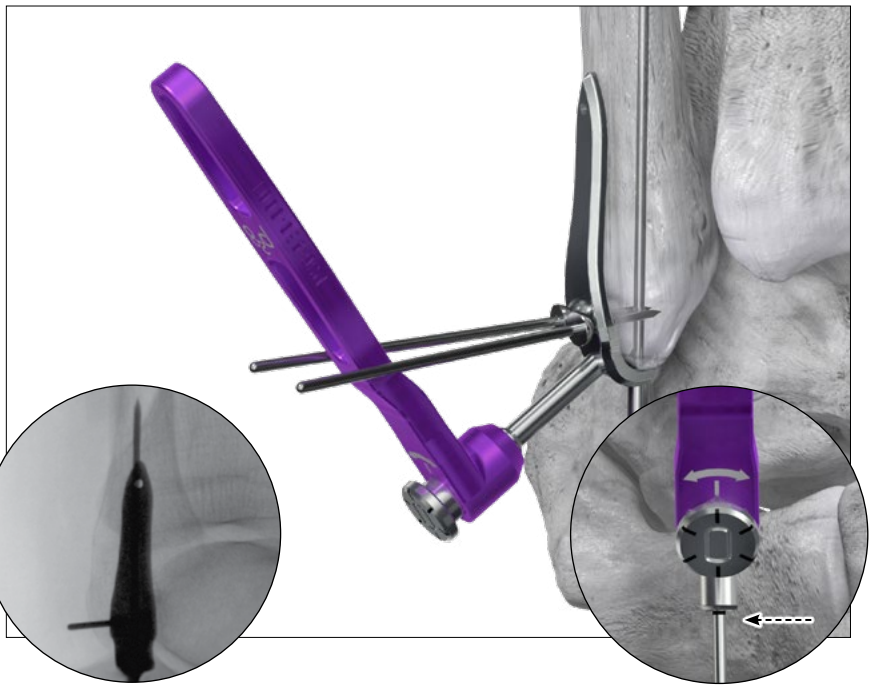
NOTE: Do not place an Olive Wire into the proximal hole near the superior tip of the guide as it will block the path of the entry K-wire.

GUIDE WIRE PLACEMENT:

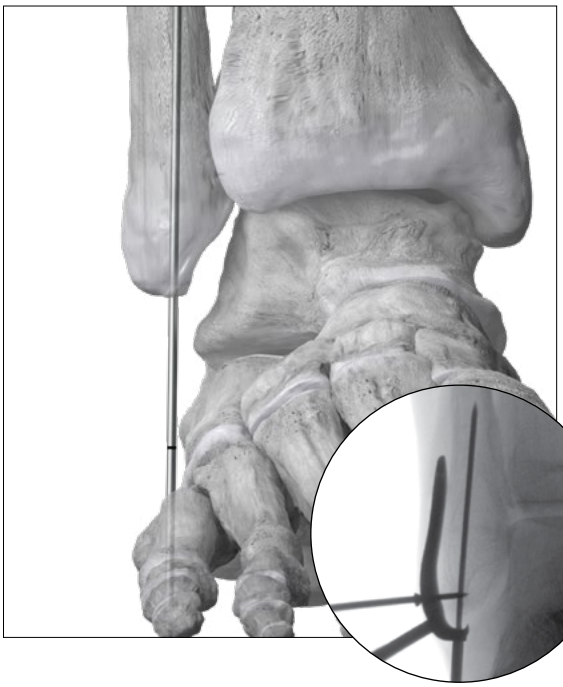
NOTE: The max width of the entry wire guide corresponds to the width of the distal portion of the Nail.

The handle of the wire guide can be pivoted by pulling it away from the patient and moving the handle around to one of the other established positions.





Place the Ø1.6 mm Entry K-Wire through the guide and into the fibula, using fluoroscopy to ensure that the wire does not exit the fibula and has the correct trajectory. The laser mark on the Ø1.6 mm Entry K-wire should be flush with the end of the guide to ensure the minimum length for the distal body of the Nail fits in the fibula.



The Olive Wires and guide can be removed after confirming proper placement of the wire.

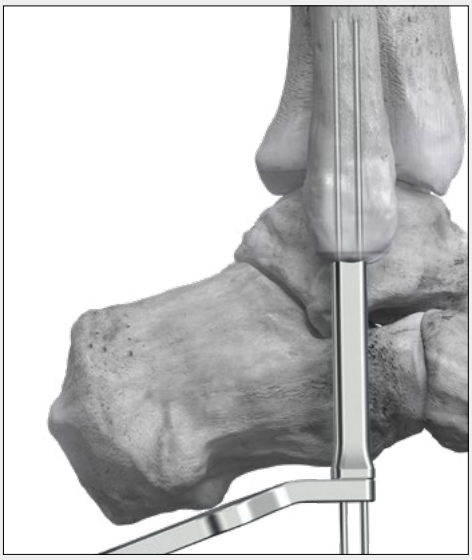
DISTAL REAMING:

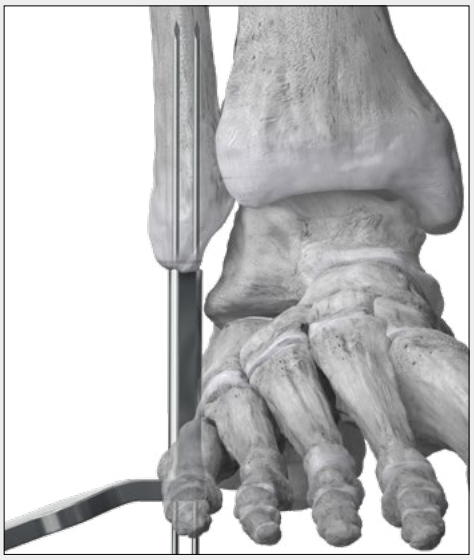
Parallel K-Wire Guide/Soft Tissue Protector

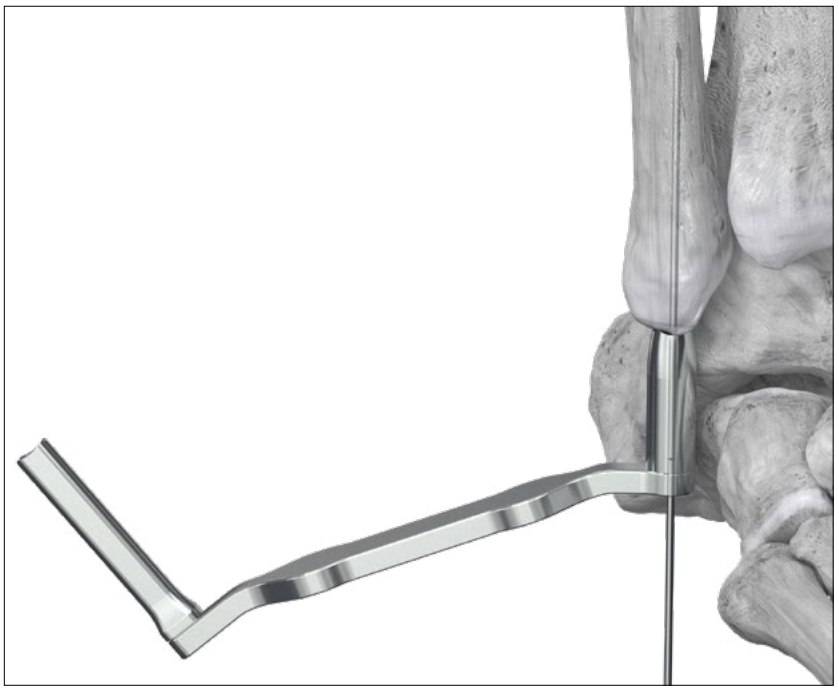
Ø6.8 mm Distal Reamer

NOTE: Laser marks correspond to End Cap lengths when flush with soft tissue protector. Grooves on shaft indicate End Cap lengths under fluoroscopy. Grooves in Reamer flutes indicate syndesmotic hole locations under fluoroscopy.

NOTE: If the trajectory of the wire is correct, but is biased too much in one direction, a parallel wire guide can be used to place a new wire that is offset by 2 or 4 mm based on the hole used.



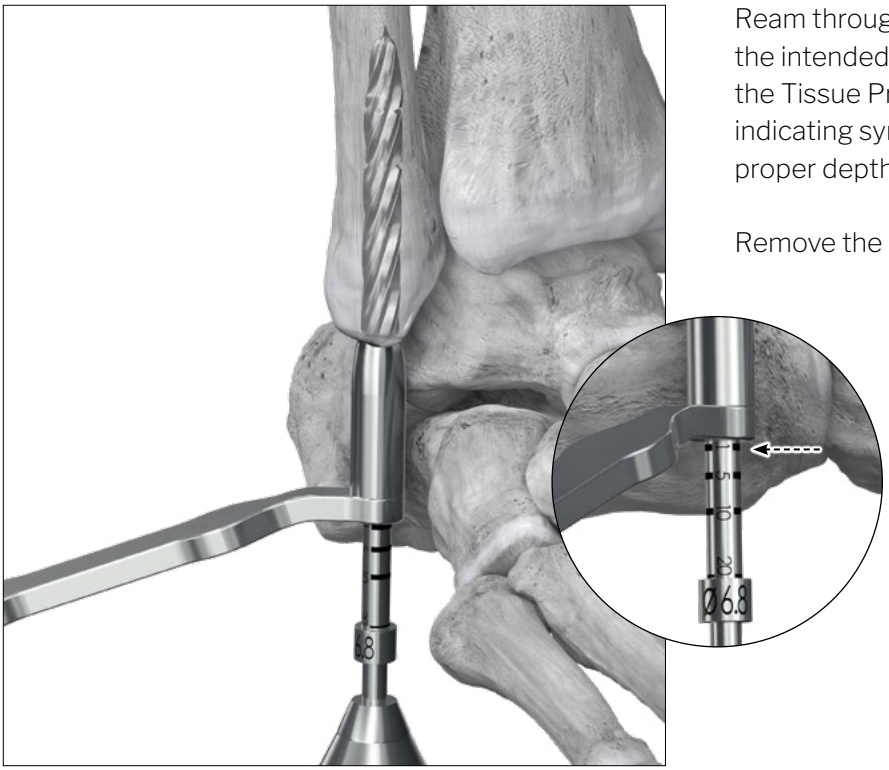




After confirming proper trajectory, slide the Tissue Protector over the wire until touching bone and guide the Ø6.8 mm Distal Reamer over the wire.

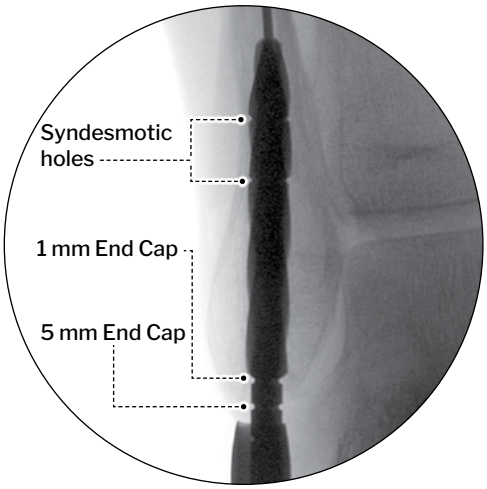
Ensure that the guide is against bone and the peroneal tendons are outside the tissue protector. If necessary, the hindfoot can be slightly inverted/adducted to ream in line and reduce pressure on the guide wire.

DISTAL REAMING:



Ream through the Tissue Protector until the line marking the intended End Cap length on the Reamer is aligned with the Tissue Protector and grooves on the reamer flutes indicating syndesmotic hole position are placed at the proper depth for tibial fixation.

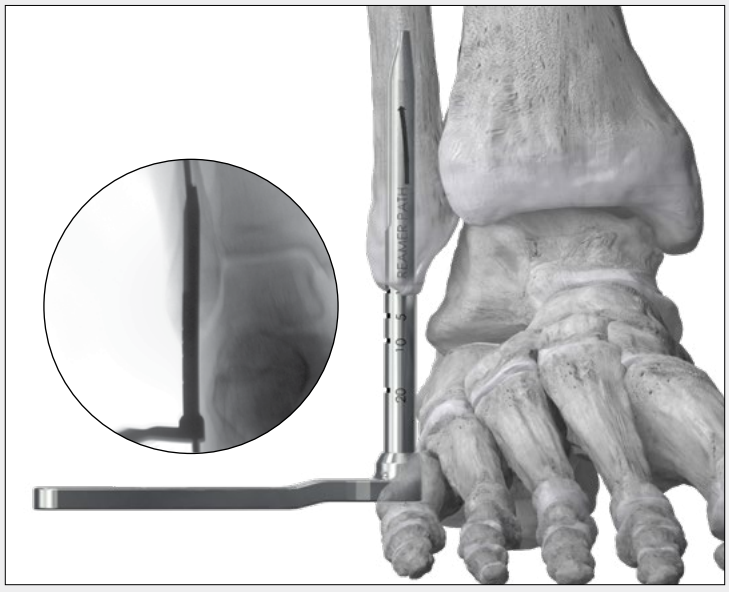
Remove the Tissue Protector, Reamer, and wire.



PROXIMAL REAMING:

Curved Reamer Guide
- Optional

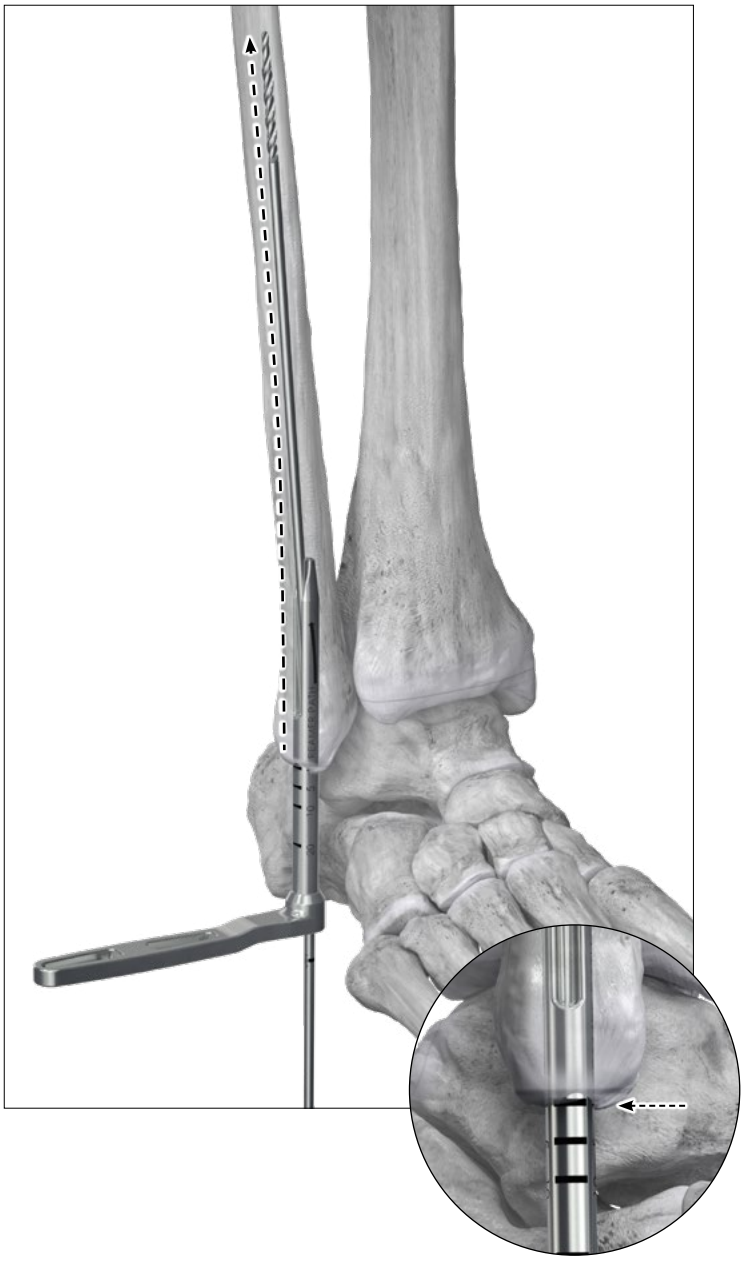
Ø2.6 mm Proximal Reamer

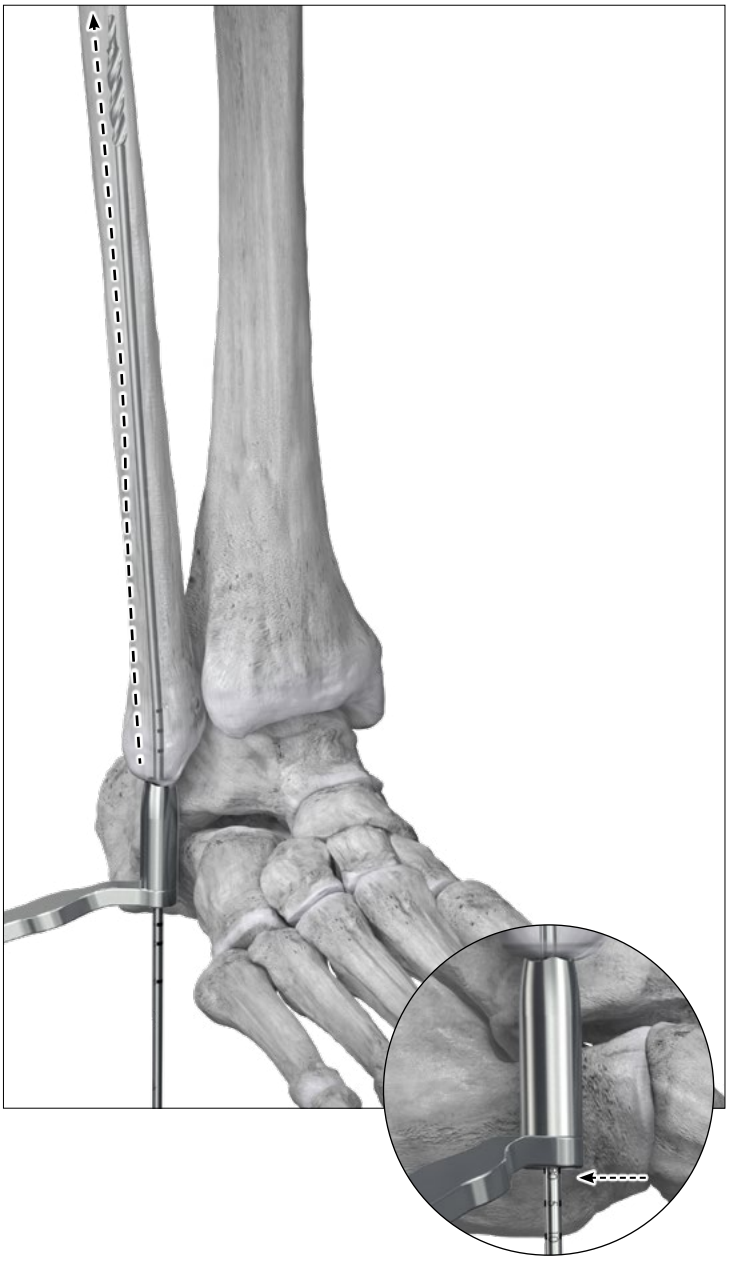


OPTIONAL: CURVED REAMER GUIDE

A Curved Reamer Guide can be used with the initial Ø2.6 mm Proximal Reamer. Be sure to place the guide into the reamed hole in the fibula to the indicated depth for the End Cap to be used. Laser and fluoro marks on the guide correspond to the End Cap offerings. Be sure the handle is facing away from the patient to ensure proper curvature of the proximal reamer.

PROXIMAL REAMING:



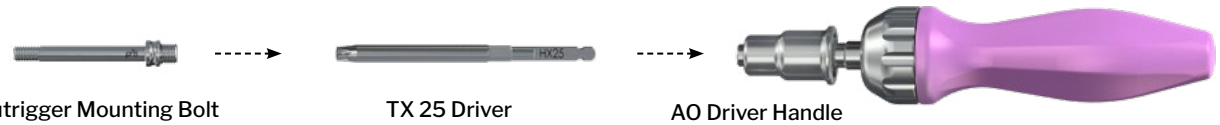


Start with the Ø2.6 mm Proximal Reamer. Ream the fibula under power to the intended height for the Nail to be used. Chatter may be felt early in the first 100 mm of reaming as the Reamer passes through the isthmus of the fibula. For a uniform Nail fit in the intramedullary canal, ensure chatter along full length of selected Nail diameter.

Remove the Curved Reamer Guide and place the soft tissue protector against the bone. Continue reaming at larger diameters until chatter is felt along the length of the fibula for the intended Nail and End Cap length, indicated by the laser marks on the Proximal Reamers. Do not over-ream the fibula.

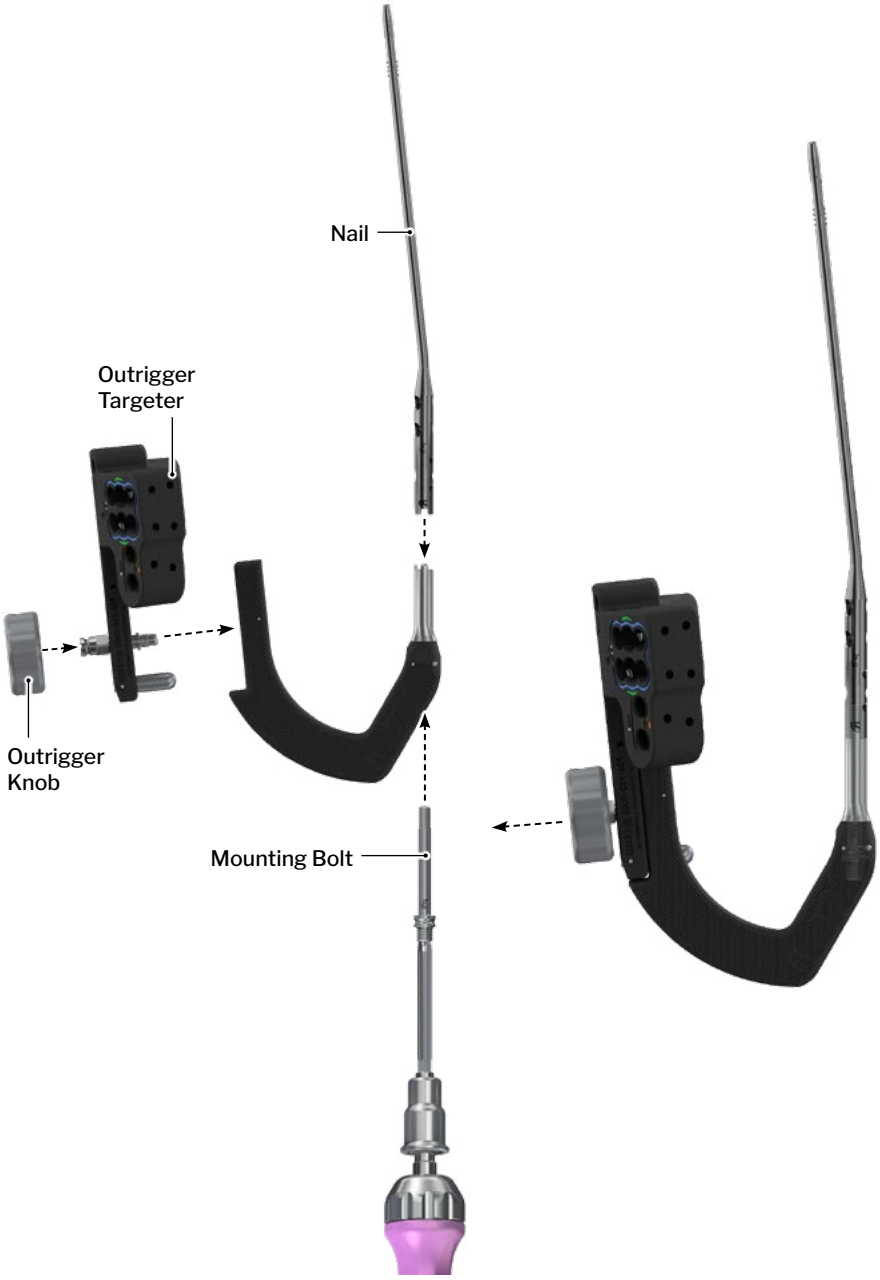
NOTE: Ensure the Reamer is continuously run under power during insertion and removal. Do not stop the Reamer during these steps.

NAIL AND OUTRIGGER ASSEMBLY:

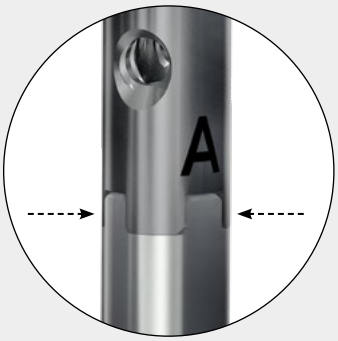


Assemble the appropriate Nail to the Outrigger by placing the Nail on the Outrigger and threading the Mounting Bolt through the Outrigger base into the Nail. Tighten with the provided TX 25 Driver and handle. Attach the Outrigger Targeter to the Outrigger base by pushing in and simultaneously turning the outrigger knob clockwise. The knob can be removed after attaching the base to the targeter for improved fluoroscopic visualization throughout the procedure.

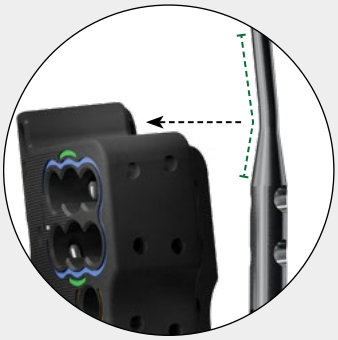
NOTE: The knob self retains after assembly to the targeter and can be removed following tightening.



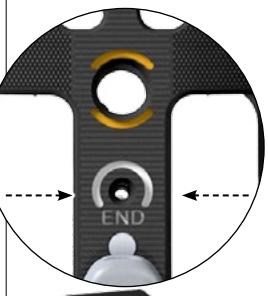
NOTE: The Nail only has one mating orientation with the Outrigger and has a laser mark "A" that should be facing anterior.

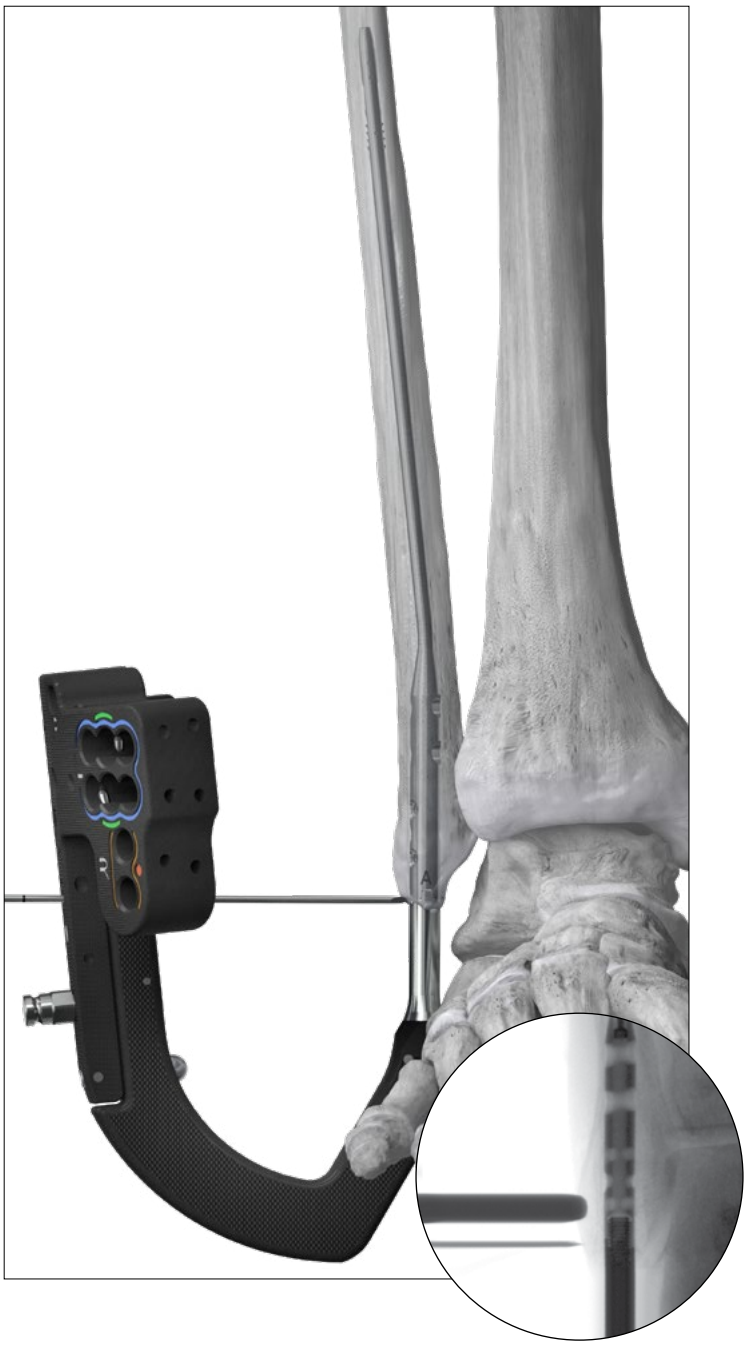


NOTE: Ensure the bend of the Nail is toward the Outrigger.



NAIL PLACEMENT:





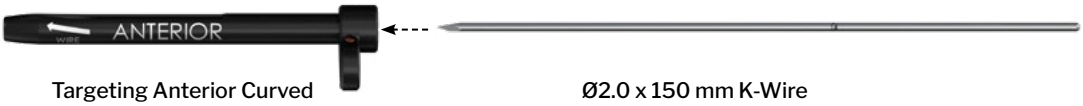
Place the Nail into the fibula and insert to the appropriate depth. Verify the level of syndesmotic hole position with respect to tibial anatomy and ankle joint. The depth of the end of the Nail by placing a Ø1.6 mm K-Wire through the indicated hole in the Outrigger. If the surgeon is having difficulty seating the Nail, thread the Impaction Attachment onto the Mounting Bolt and use the provided Mallet to seat the Nail to the appropriate depth.

If the fracture is reduced, place the Nail such that the Outrigger is centered lateral to the fibula. If the Nail/ Outrigger is being used for fracture reduction, rotate the position of the outrigger slightly from lateral such that fracture reduction will result in a laterally-oriented Outrigger. The final position should allow syndesmotic fixation that follows the transmalleolar axis, the distal fibula matches the lateral wall of the talus, and the syndesmosis devices clear the ankle joint.

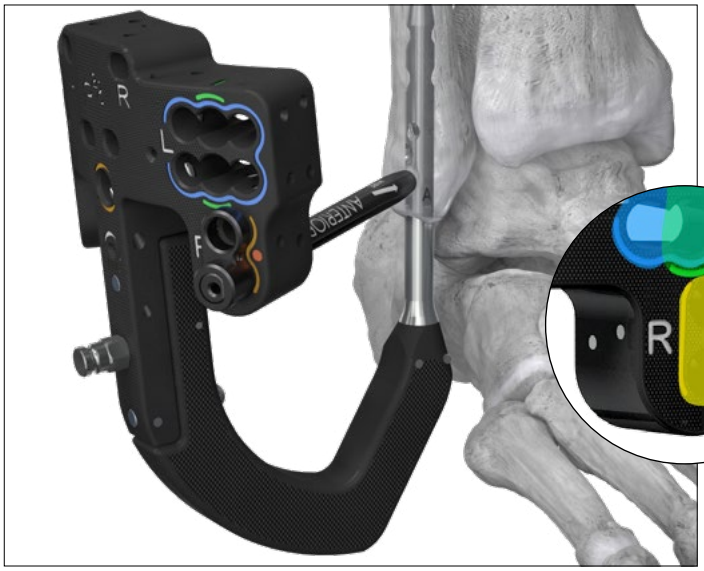
OPTIONAL CURVED WIRE PLACEMENT:

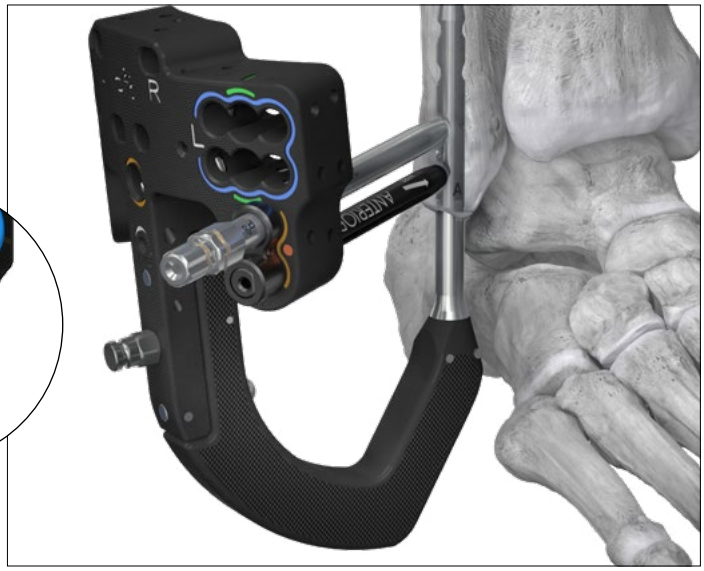
Per surgeon preference, curved wire reduction guides are provided to secure the distal fragment of the fibula to the Outrigger/Nail outside of the Nail body. This allows for deployment of the proximal fixation feature and for fixation devices to be placed through the Nail simultaneous with distraction of the distal segment.

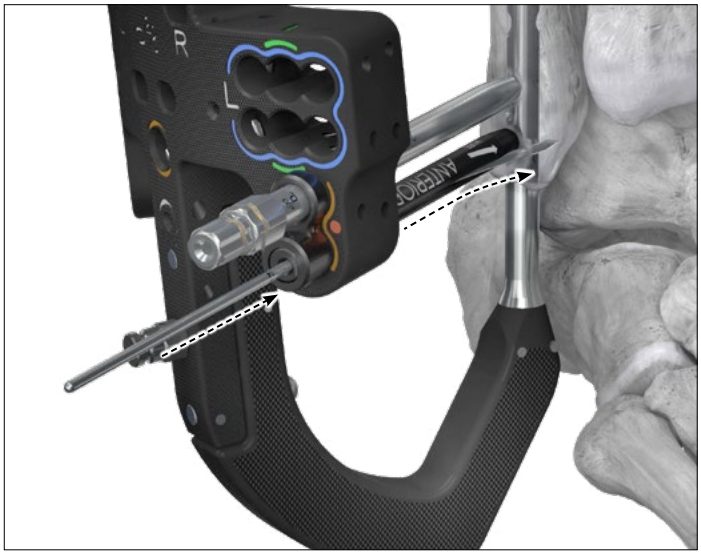
Assemble the Drill Guide by threading the Drill Guide in the Screw Sleeve.



Place the Drill Guide construct and the Targeting Anterior Curved K-Wire Guide in the holes marked for the limb laterality ("R" vs "L") in the Outrigger until it contacts the fibula bone. The Drill Guide construct is required to hold orientation of the Targeting Anterior Curved K-Wire Guide. Ensure the arrow on the guide is pointing anterior and the Orange indicator dots are facing each other.

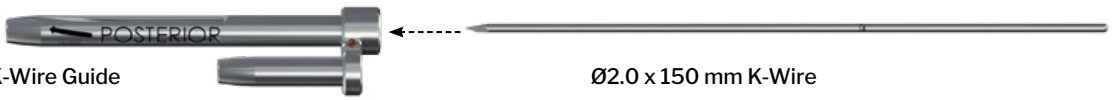






The shape of the Curved Wire Guide body should match the shape of the yellow indicator lines present on the Outrigger Targeter. Place a Ø2.0 mm wire through the Drill Guide construct is required to hold orientation of the Targeting Anterior Curved K-Wire Guide into the anterior portion of the fibula. Ensure the wire does not exit the medial aspect of the fibula by utilizing fluoroscopy. A laser mark on the wire indicates when the wire is placed 14 mm into the fibula.

OPTIONAL CURVED WIRE PLACEMENT:

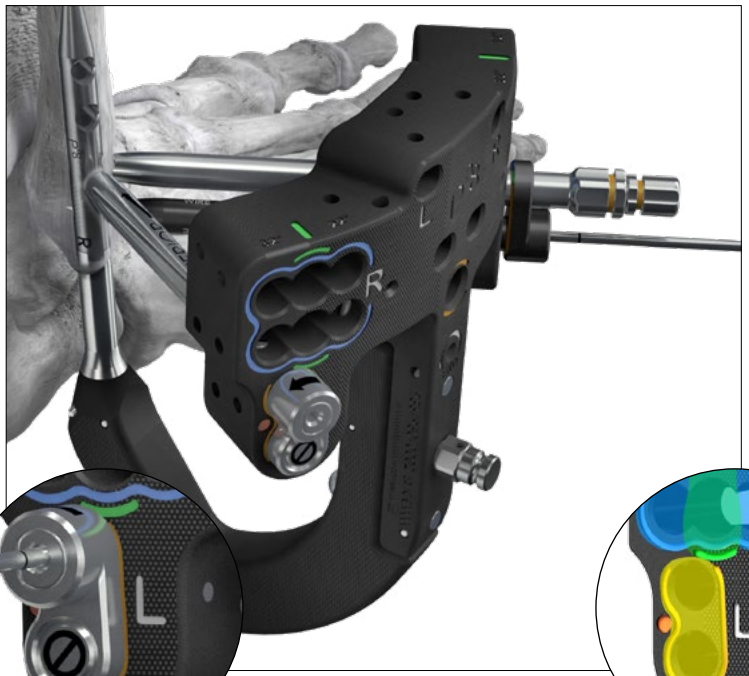


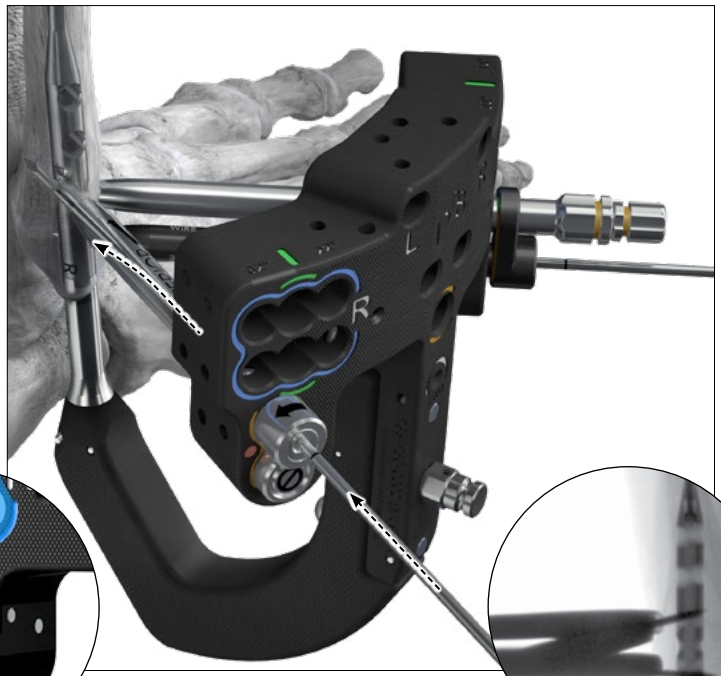
Non-Targeting Posterior Curved K-Wire Guide

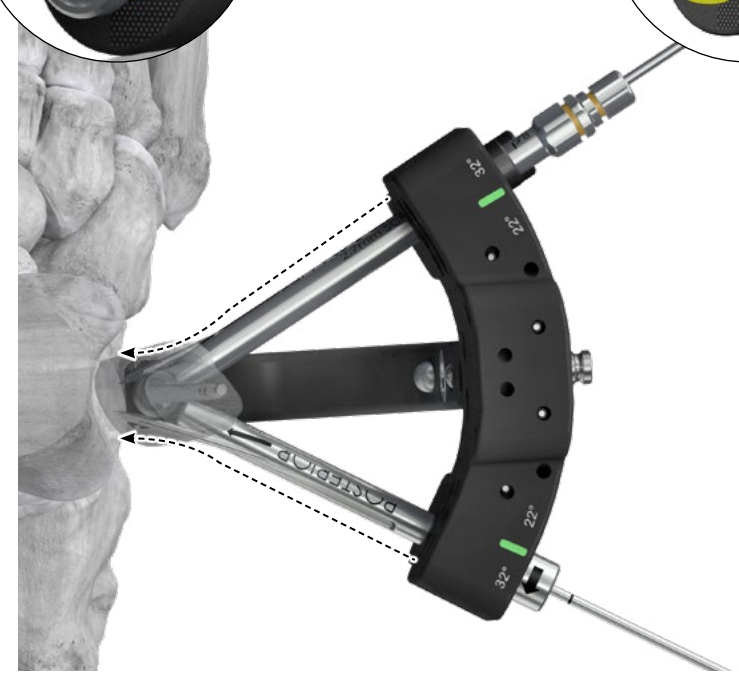
Ø2.0 x 150 mm K-Wire

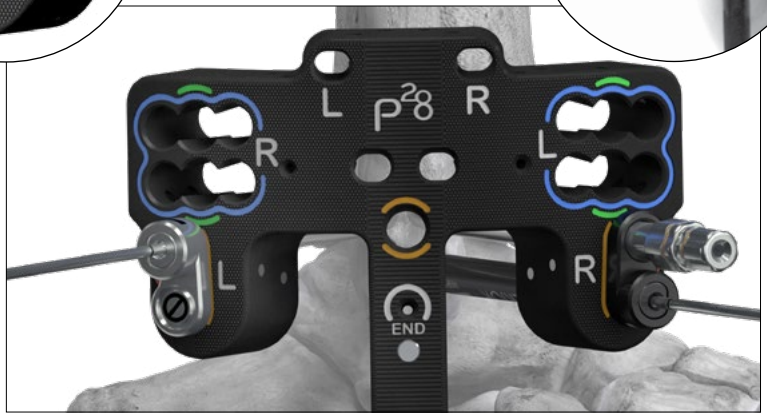
Place the Non-Targeting Posterior Curved K-Wire Guide in the posterior side of the Outrigger until it contacts the fibula bone. Ensure the arrows on the guide are pointing posterior and the Orange indicator dots are facing each other. Assembled Drill Guides are not permitted to be used with the Non-Targeting Posterior Curved K-Wire Guide as they would not target through the Nail if it were used.

NOTE: The silver guide should always be posterior regardless of limb laterality.







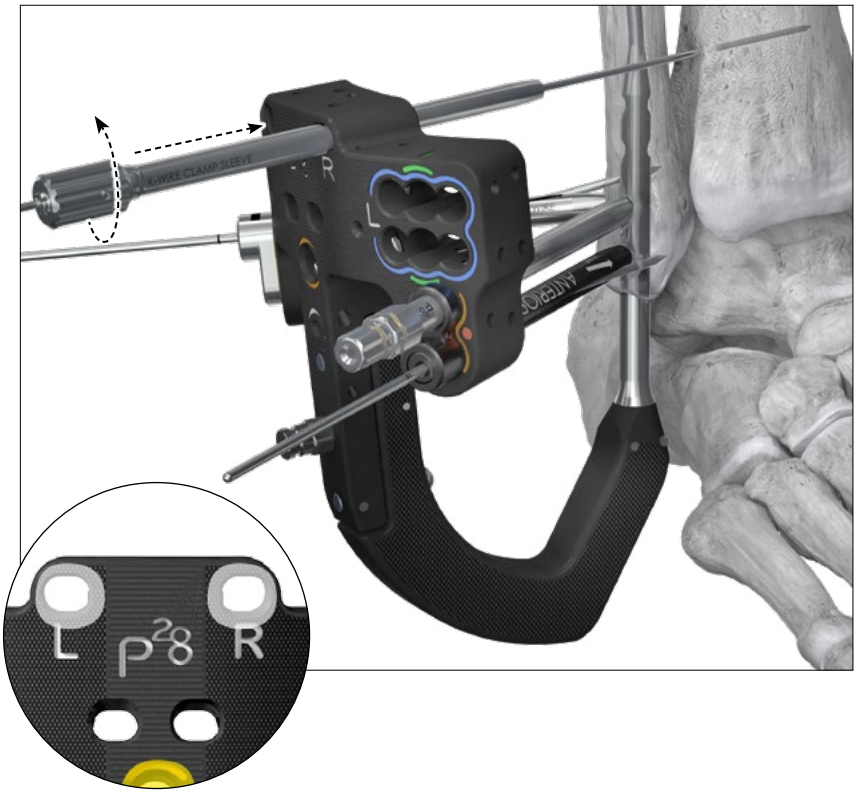


The shape of the Curved Wire Guide body should match the shape of the yellow indicator lines present on the Outrigger Targeter. Place a Ø2.0 mm wire through the Non-Targeting Posterior Curved K-Wire Guide and into the posterior portion of the fibula. Be sure the wire does not exit the medial aspect of the fibula utilizing fluoroscopy. A laser mark on the wire indicates when the wire is placed 14 mm into the fibula.

OPTIONAL REDUCTION WIRE PLACEMENT:

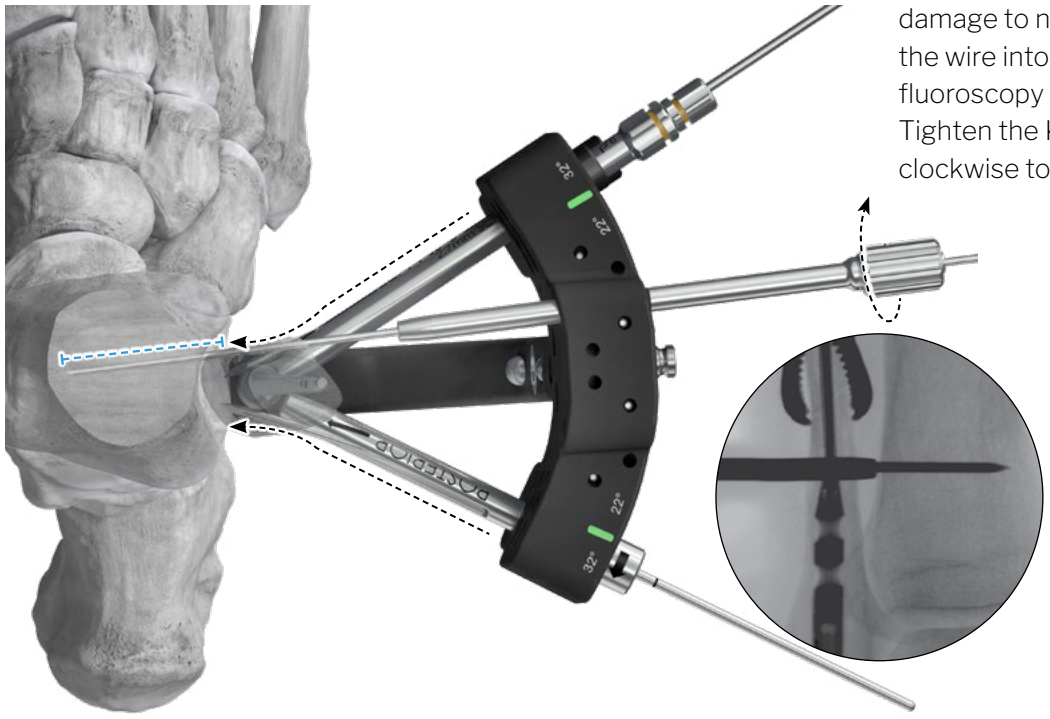
K-Wire Clamp Sleeve

Ø2.3 x 230 mm K-Wire



If not already reduced to the surgeon's satisfaction, the surgeon may use the Nail to gain additional reduction with a combination of gentle traction and rotation of the distal fragment and positioning of the ankle. While maintaining the fracture in a reduced position, place the K-wire Clamp Sleeve in the Outrigger through the hole marking the appropriate laterality.

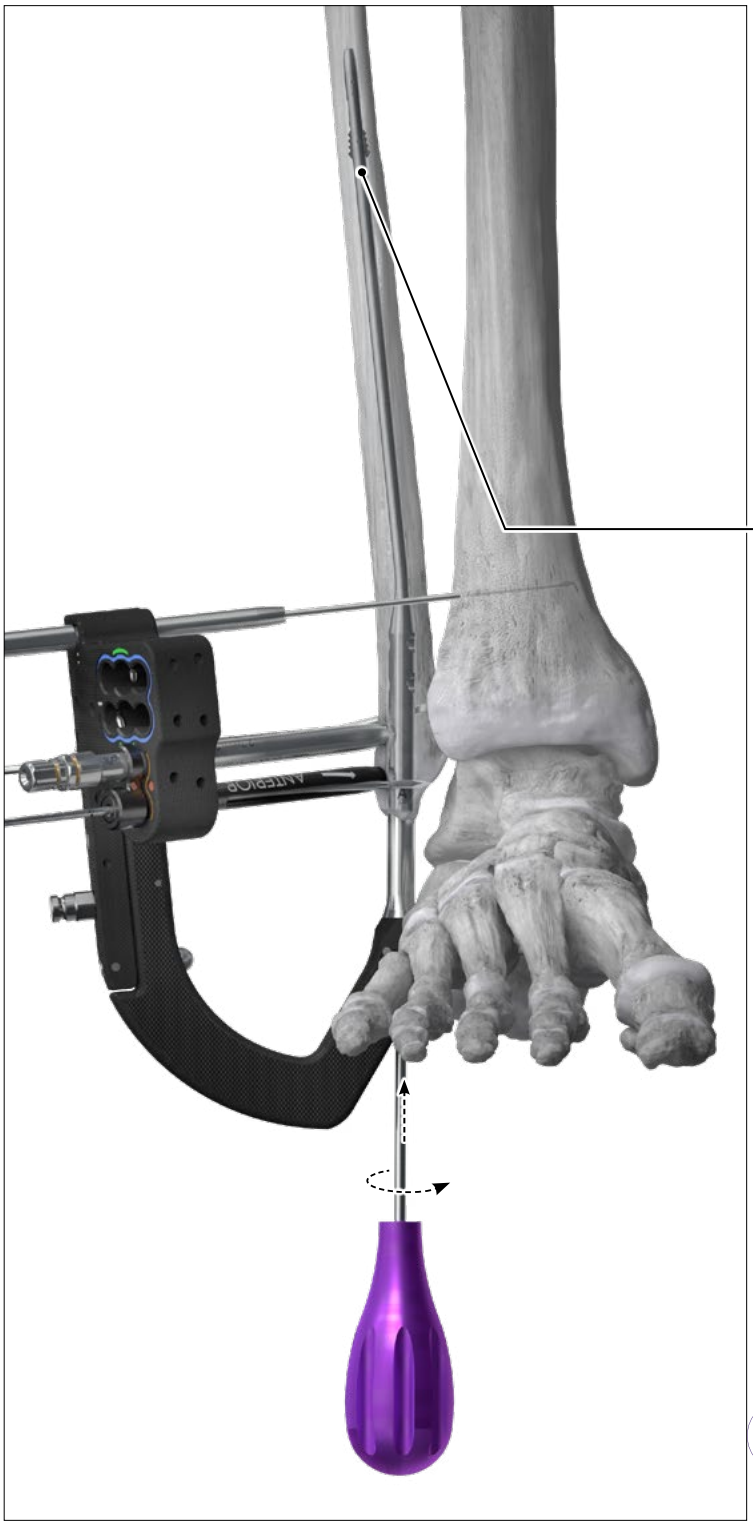
Ensure the knob on the K-Wire Clamp Sleeve is loosened by turning counter-clockwise. The wire should be anterior to the fibula. Make a stab incision where the wire contacts the skin. Ensure the K-wire Clamp Sleeve is touching the tibial bone. Begin by tapping the wire with a mallet until it contacts the tibia to help avoid damage to nearby soft tissues. Finish placing the wire into the tibia under power, utilizing fluoroscopy to confirm appropriate depth. Tighten the K-Wire Clamp Sleeve by turning it clockwise to secure the position of the fibula.



The fibula should now be reduced and provisionally transfixed. The position can be checked with fluoroscopy and if satisfactory, the remaining fixation can be placed.

PROXIMAL FIXATION:

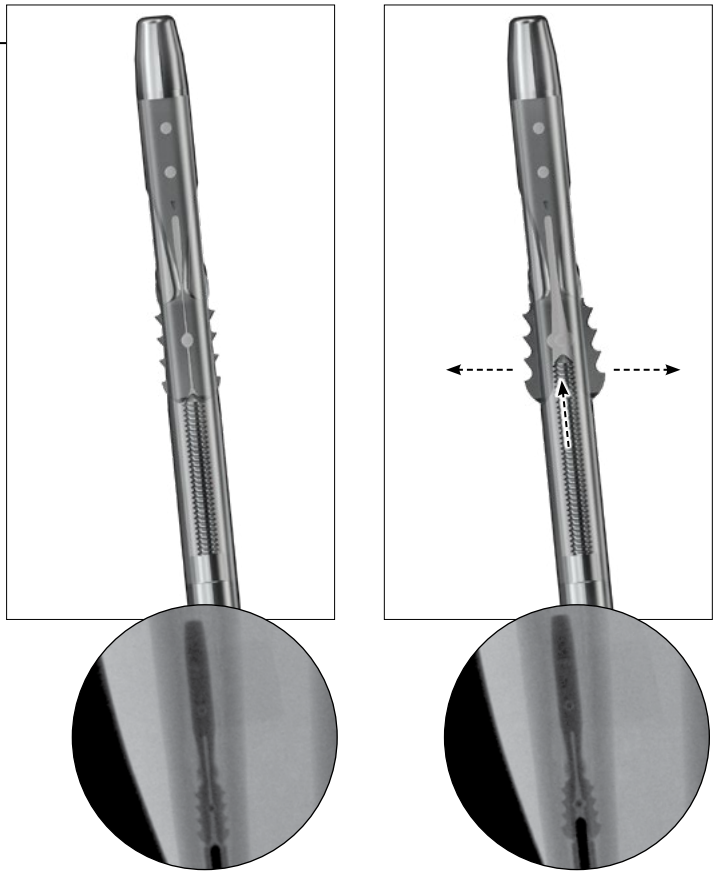
Torque Limiting Actuation Driver



Following confirmation of proper reduction, actuate the proximal fixation feature by inserting the torque-limited Actuation Driver up through the Outrigger Mounting Bolt and into distal end of the Nail until it engages the drive socket of the internal Actuation Screw. While stabilizing the Outrigger assembly with one hand, rotate the actuation Driver clockwise to turn the Screw until the torque limiter slips and an audible “click” is heard. Fluoroscopy may assist in locating the tip of the Actuation Screw to ensure proper expansion of the proximal fixation feature.

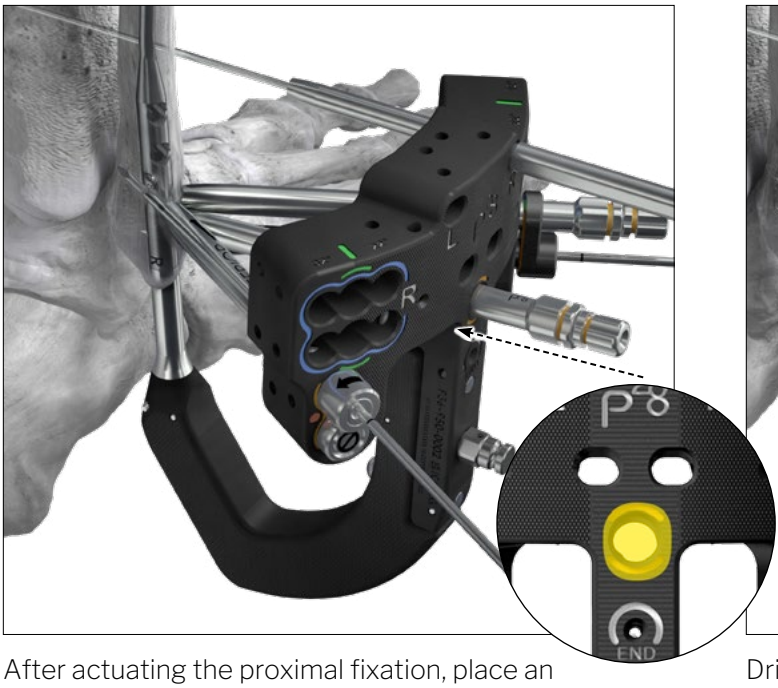
Insertion state

Deployed state

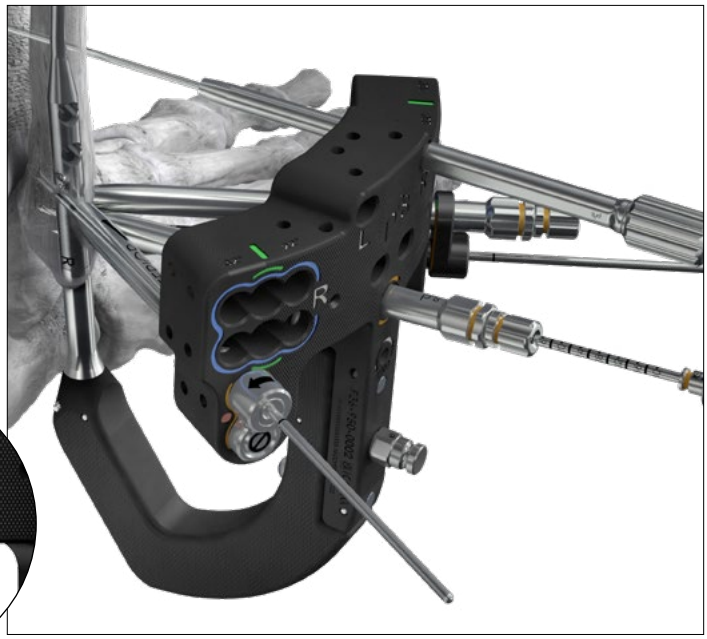


NOTE: To prevent blockage of access to the Actuation Screw, Threaded Pegs may not be targeted through the Nail prior to the proximal fixation step.

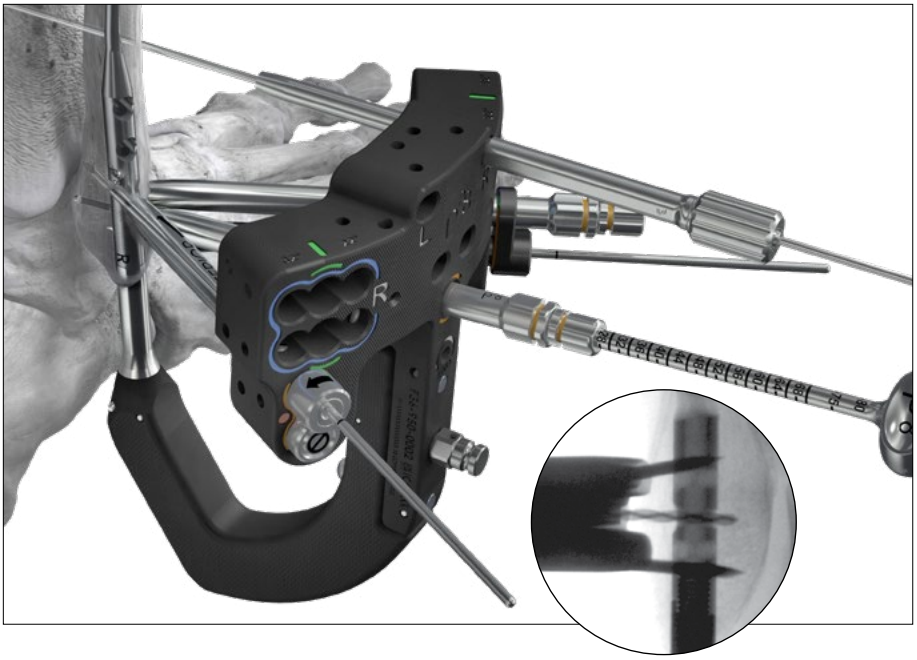
DISTAL FIXATION:

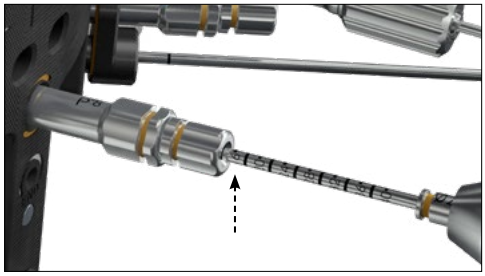


After actuating the proximal fixation, place an assembled Ø2.7 mm Drill Guide in the center hole of the Outrigger Targeter. Make a small incision where the guide contacts the skin and bring the guide down to contact bone.

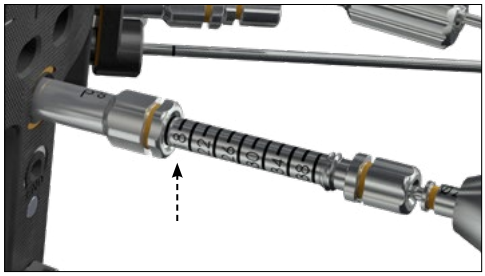


Drill through the guide and through the Nail, ensuring not to violate the joint space, using the provided Ø2.0 mm Drill. Fluoroscopy can be used to confirm unicortical drilling. Length markings on the Drill can be used to determine the Threaded Peg length or the Drill Guide can be unthreaded from the Screw Sleeve and pulled back to the end of the Drill to measure Threaded Peg length. Remove the Drill and Drill Guide after confirming sufficient drilling.





Depth measured off the Drill

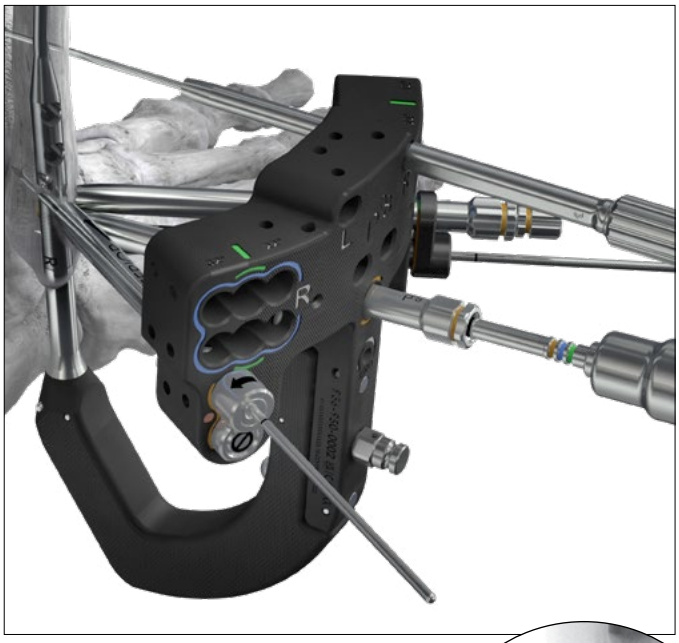


Depth measured off the Drill Guide

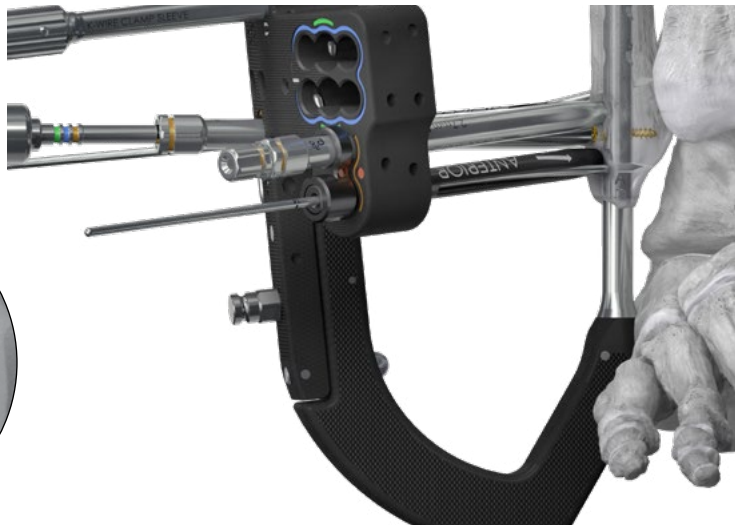
Additionally, a provided probe Depth Gauge can be used to determine Threaded Peg length.

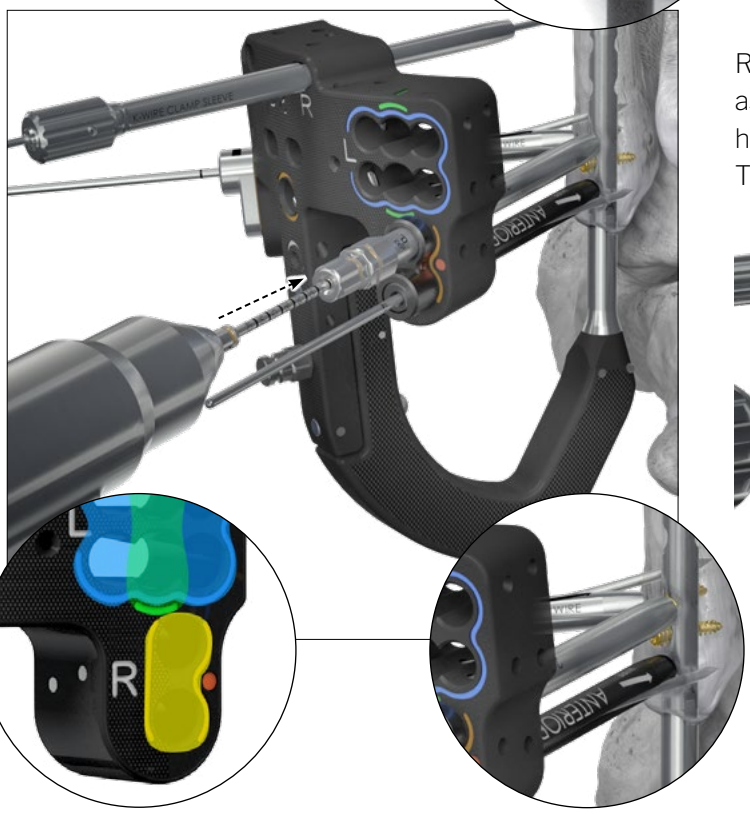
If using the depth gauge and uni-cortically drilling, add 1.0 mm to measured Threaded Peg length.

DISTAL FIXATION:

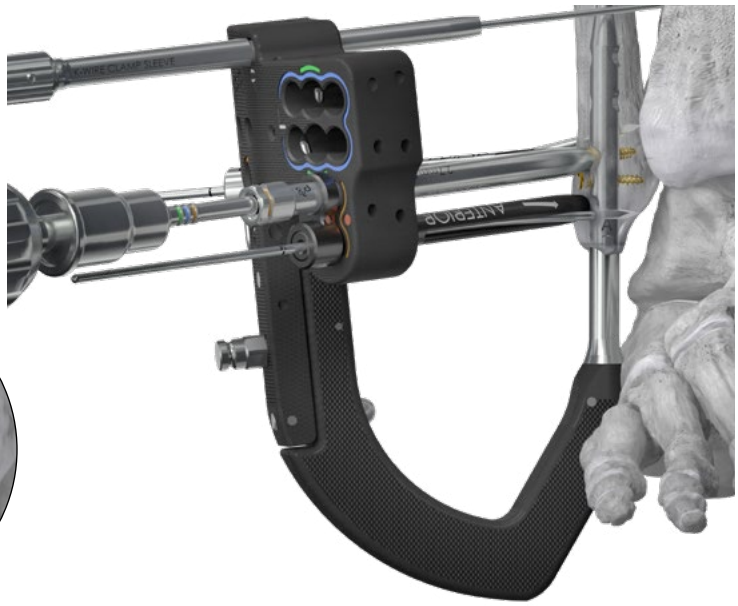


After determining the appropriate length Ø2.7 mm Threaded Peg length, assemble the TX10 Driver to the AO Quick Connect Ratcheting Handle to insert the Threaded Peg through the Ø2.7 mm Screw Sleeve. Ensure the ratcheting collar on the Handle is turned to the fixed or clockwise ratcheting position. With the Screw Sleeve contacting bone, drive the TX-10 Driver until the laser mark indicator line on the Threaded Peg Driver is flush to the back of the Screw Sleeve. Pull back the Screw Sleeve to visually confirm the Threaded Peg is in the desired flush position to the bone.

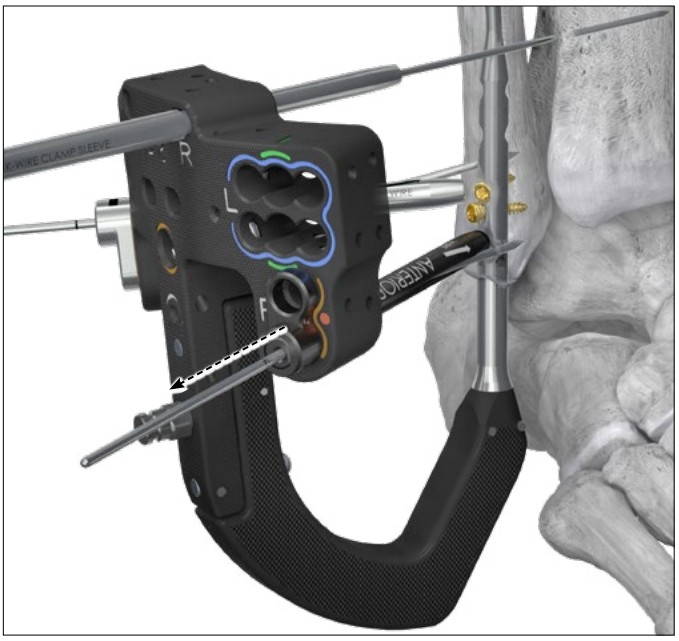




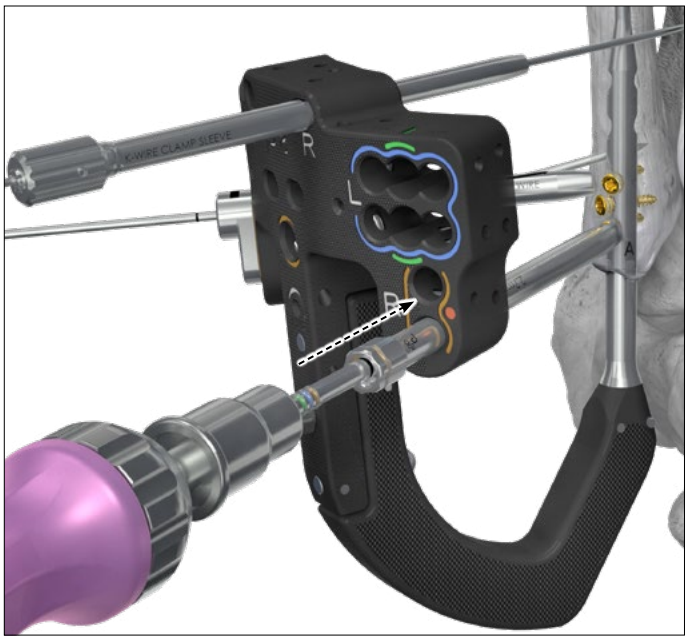
Repeat drilling, measurement, and Threaded Peg placement as described previously for the proximal Threaded Peg hole of the Threaded Peg cluster. Ensure that at least two Threaded Pegs are placed in the distal cluster.



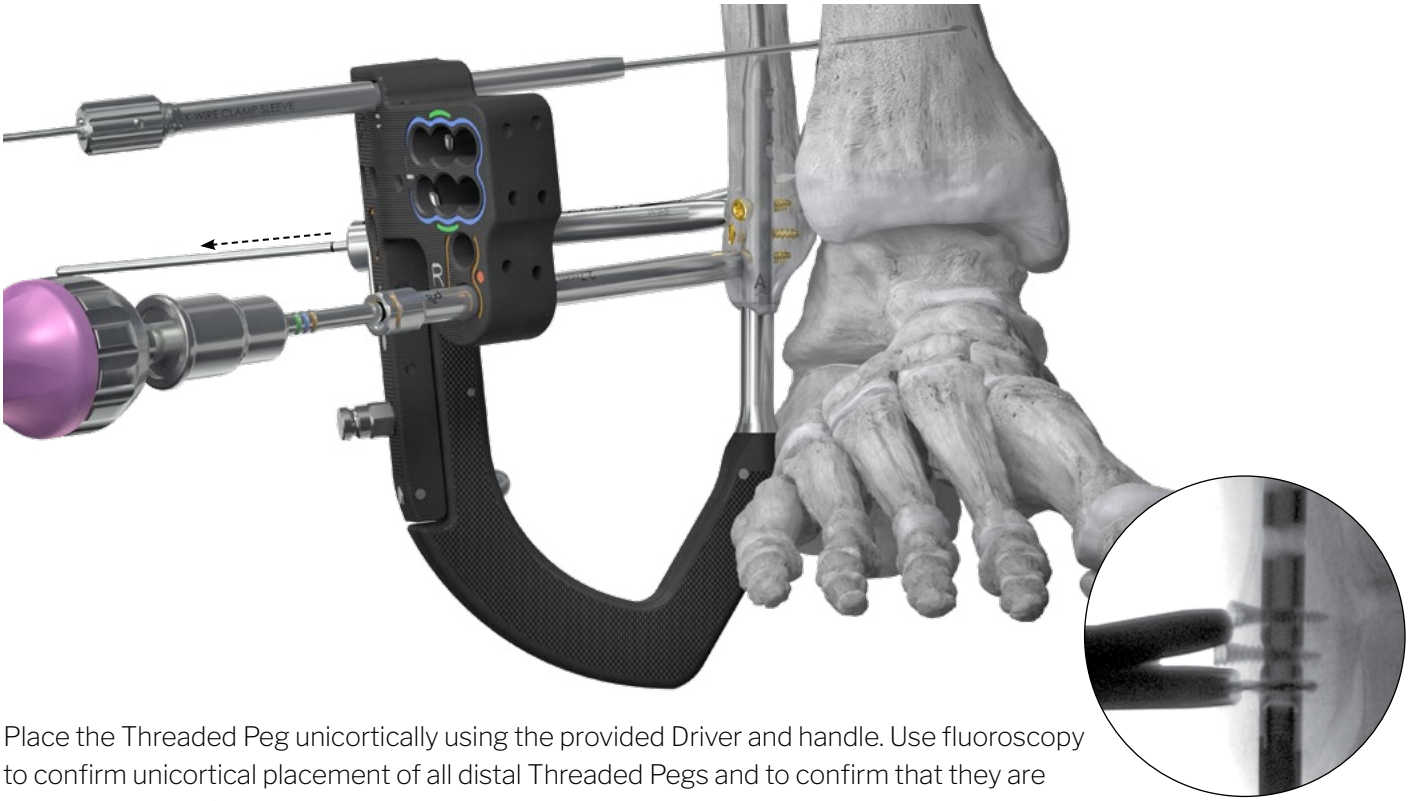
DISTAL FIXATION:



For placement of a third distal Ø2.7 mm Threaded Peg, remove the curved wire in the anterior portion of the fibula.



After removing the Anterior Curved Wire, remove the black Anterior Curved Reduction Sleeve and replace it with a Drill Guide assembly in the final distal hole of the Outrigger Targeter. Repeat unicortical drilling and measurement as described in previous steps.



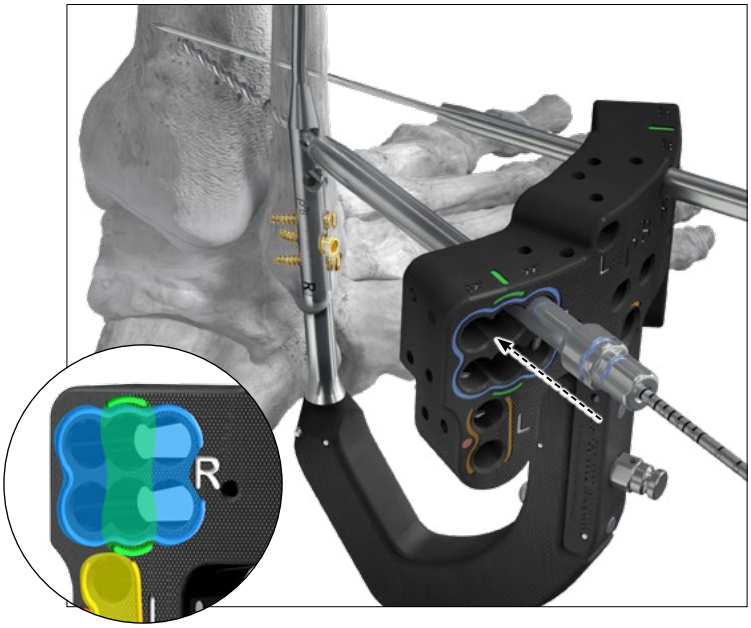
Place the Threaded Peg unicortically using the provided Driver and handle. Use fluoroscopy to confirm unicortical placement of all distal Threaded Pegs and to confirm that they are through the Nail. Continue with either static or dynamic syndesmotic fixation through the Nail. At this time, remove the Posterior Curved Wire and Curved Wire Guide.

OPTION 1: Ø3.5 MM THREADED PEG FIXATION (RIGID FIXATION)

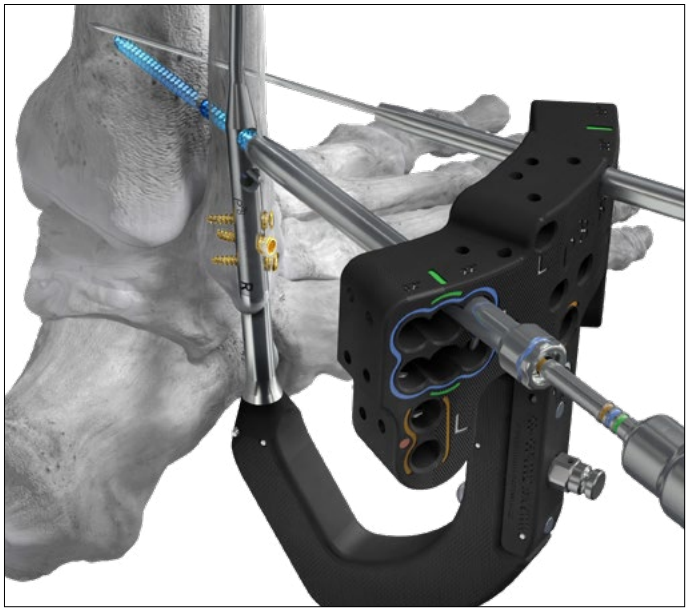
Verify the syndesmosis is reduced and held in a reduced position. For rigid fixation of the syndesmosis with a Ø3.5 mm Threaded Peg, assemble the Drill Guide by placing the Ø2.5 mm Drill Guide in the Ø3.5 mm Screw Sleeve.

Screw Sleeve | Drill Guide | Ø2.5 mm Drill

NOTE: If placing static syndesmotic fixation through the center Outrigger syndesmotic holes, the Ø3.5 mm Center Screw Sleeve must be used in place of the Ø3.5 mm Screw Sleeve.

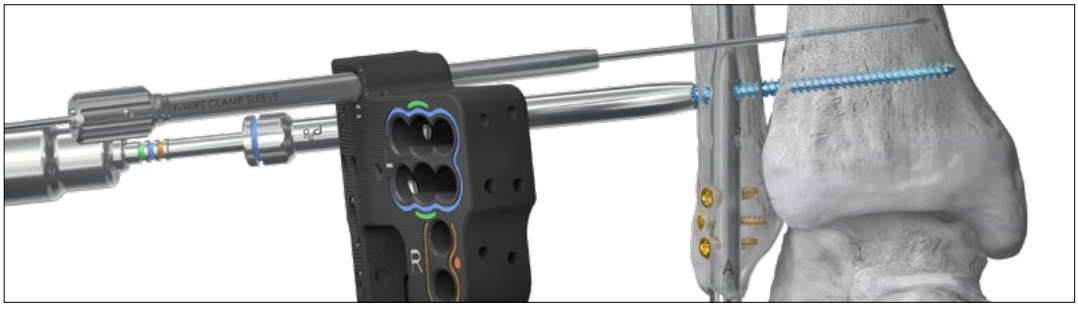


Place an assembled Drill Guide in one of the proximal syndesmotic holes on the Outrigger Targeter based on the desired angle for Threaded Peg placement. Drill to desired Threaded Peg length using the Ø2.5 mm Drill.

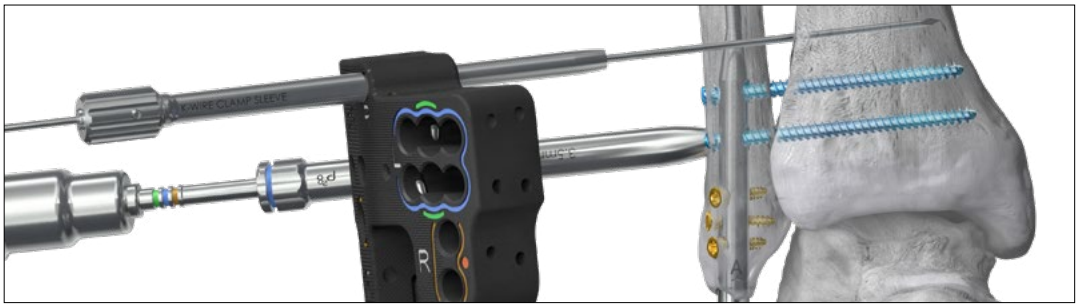


Place the Threaded Peg using the provided TX10 Driver and handle. Use fluoroscopy to confirm appropriate placement and to confirm that it is through the Nail.

Repeat these steps for the distal syndesmotic Threaded Peg hole. Use fluoroscopy to determine appropriate placement and length of the Threaded Pegs.

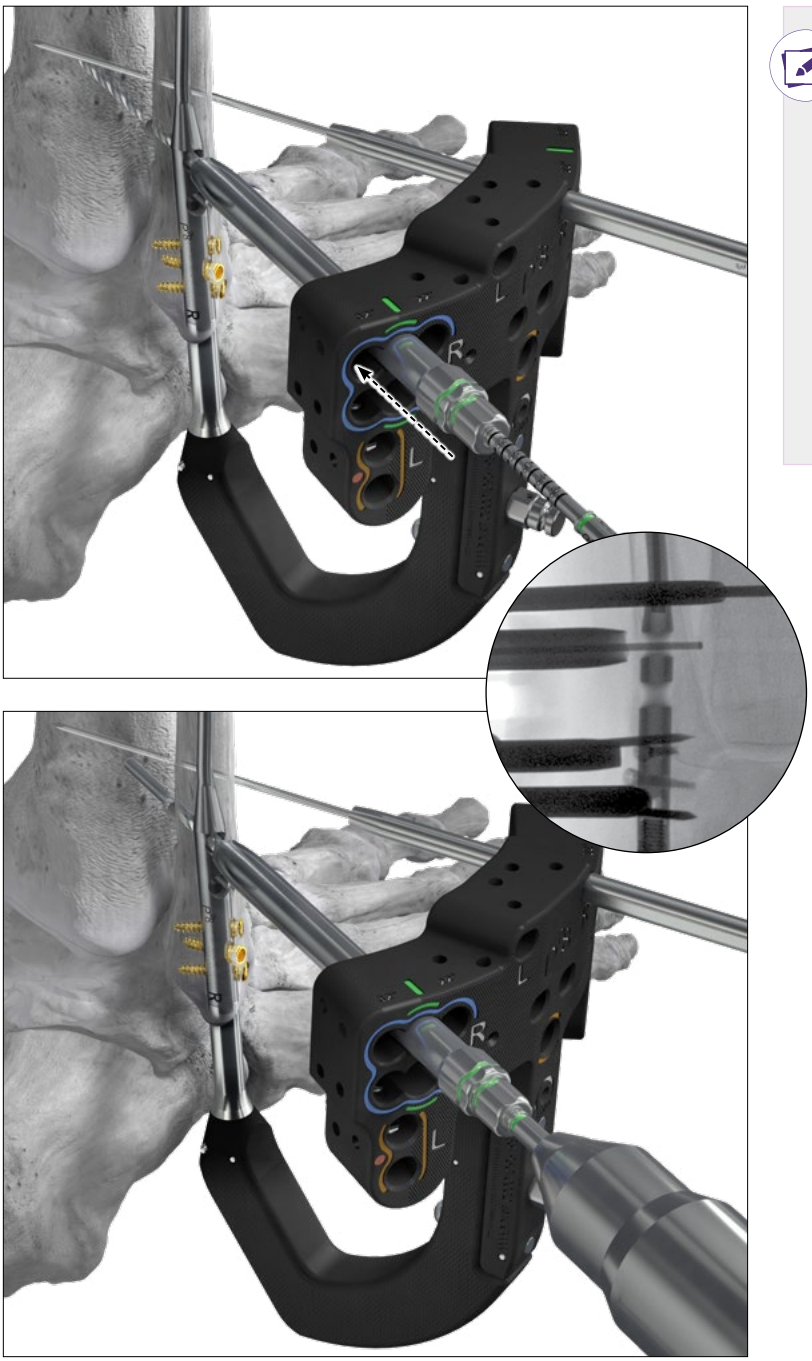


After completion of Threaded Peg placement, remove any remaining curved K-Wires, Curved Reduction Sleeves, and Threaded Peg or Drill Guides.



OPTION 2: R3ACT STABILIZATION SCREW SYSTEM (DYNAMIC)

Verify the syndesmosis is reduced and held in a reduced position. For dynamic fixation of the syndesmosis with a R3ACT Screw, assemble the Drill Guide by placing the Dynamic Drill Guide into the Dynamic Screw Sleeve.



NOTE: The R3ACT Stabilization Screw and associated Sleeves may only be placed in the center, nominal placement angle (27° Posterior to Anterior).

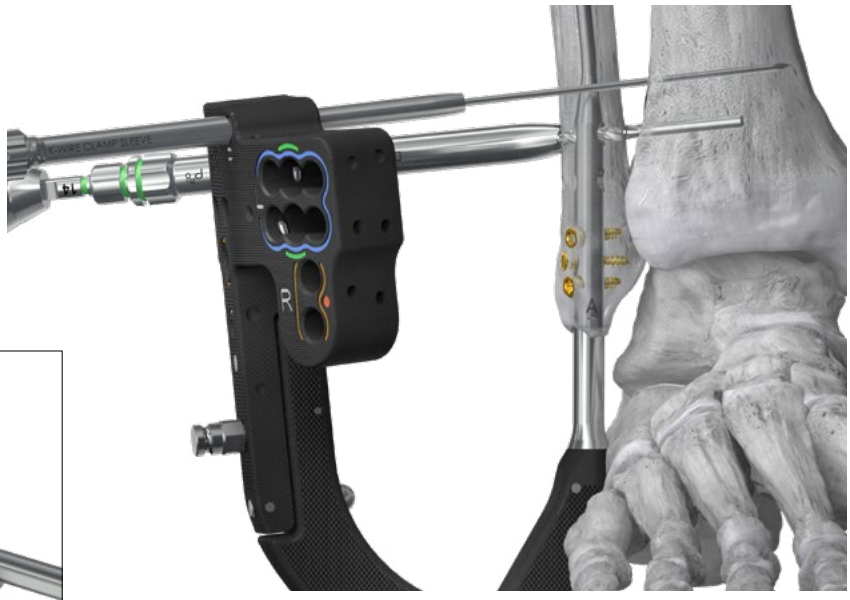
Place an assembled Drill Guide into the center proximal syndesmotic hole on the Outrigger Targeter, denoted with two green marks. Drill across all four cortices of the fibula and tibia with the Ø2.8 mm Drill Bit. It is recommended to drill using fluoroscopy to ensure correct anticipated Screw length. Determine the measurement to the medial tibial far cortex using any of the three previously described measurement techniques.

Using the hook of the Depth Gauge, measure to the tibiofibular clear space to select the R3ACT notch location. Follow the R3ACT technique recommendations for determining the correct notch length based on the measurement.

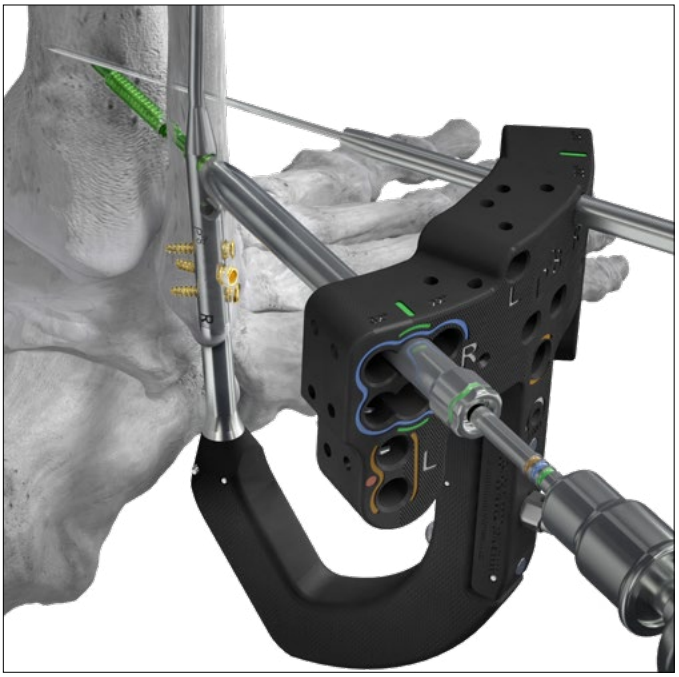
Based on the notch location selected for the R3ACT implant, select the appropriate calibrated Ø3.2 mm R3ACT Pilot Drill. Insert the Drill through the Drill Guide into the Ø2.8 mm Pilot hole and drill until the hard stop of the Ø3.2 mm Drill contacts the Drill Guide. Confirm via fluoroscopy that the flutes of the Ø3.2 mm Drill do not penetrate the tibia.

OPTION 2: R3ACT STABILIZATION SCREW SYSTEM (DYNAMIC)

Drill through just the fibula using the Ø3.2 mm Drill with the Ø2.8 mm pilot based on the notch location of the intended R3ACT device to be used.

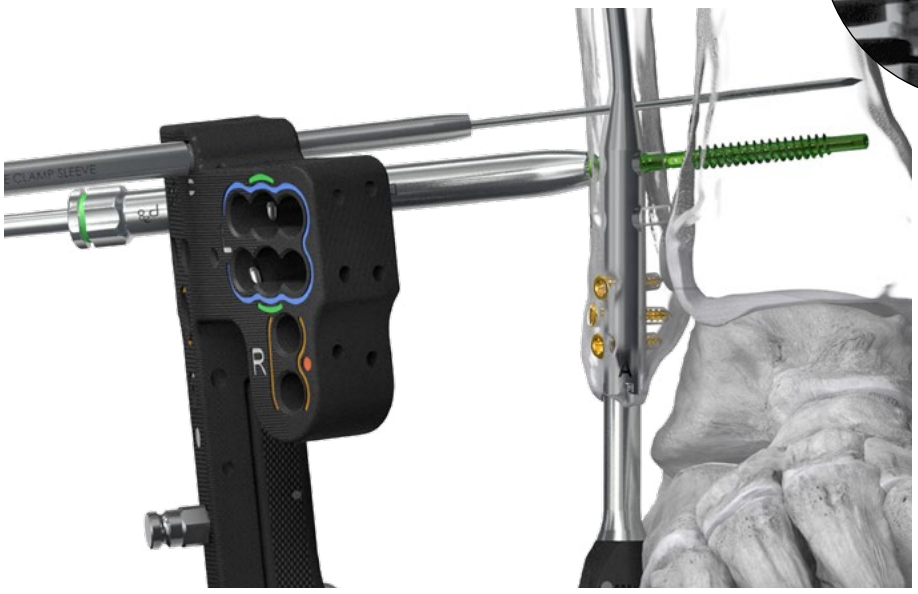


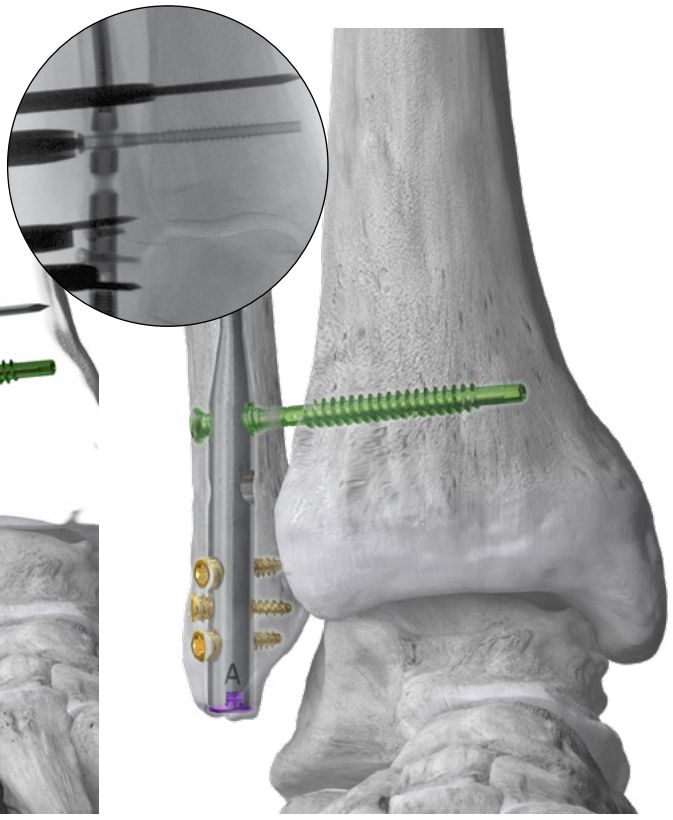
Following drilling, use the provided R3ACT Tap and Handle to fully tap the pre-drilled hole through the fibula and tibia.



After completing the drilling, remove the Drill Guide and place the R3ACT Screw into the Screw Sleeve and advance using the provided Driver and Torque limiting Handle provided in the R3ACT System Instrument tray until the laser mark indicator line is flush to the back of the Screw Sleeve. Use fluoroscopy to confirm the notch in the R3ACT Screw is in the clear space between the tibia and fibula.

Do not use more than one R3ACT Syndesmotic fixation device.



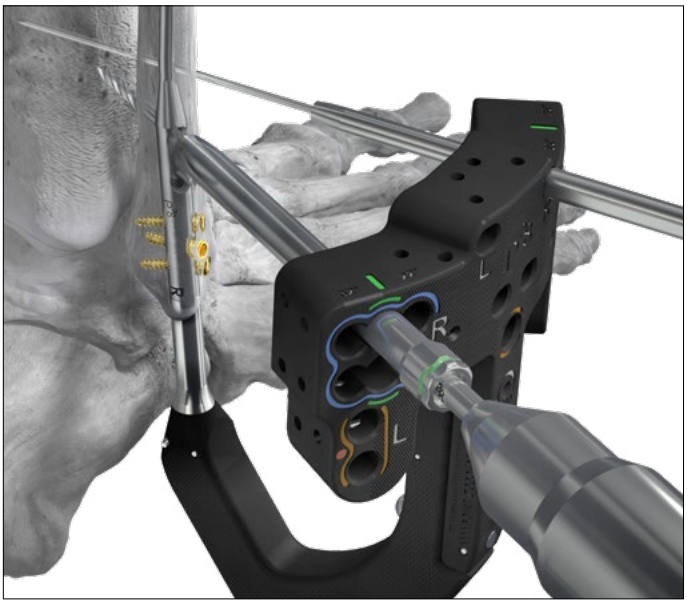


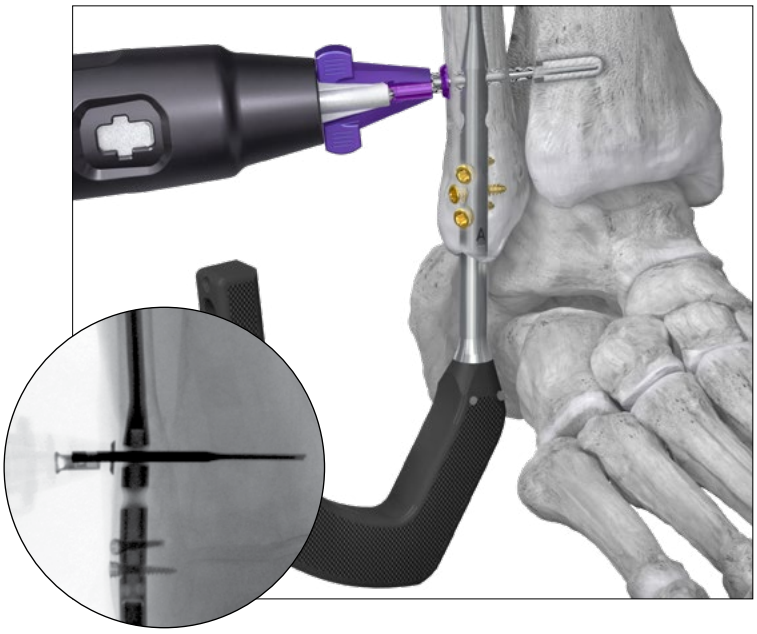
OPTION 3: R3FLEX™ STABILIZATION SYSTEM (DYNAMIC)

Verify the syndesmosis is reduced and held in a reduced position. For dynamic fixation of the syndesmosis with a R3FLEX implant, place the Dynamic Screw Sleeve in the center nominal placement angle.

Dynamic Screw Sleeve

R3FLEX™ Step Drill



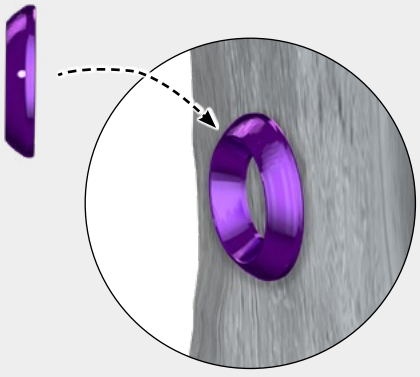


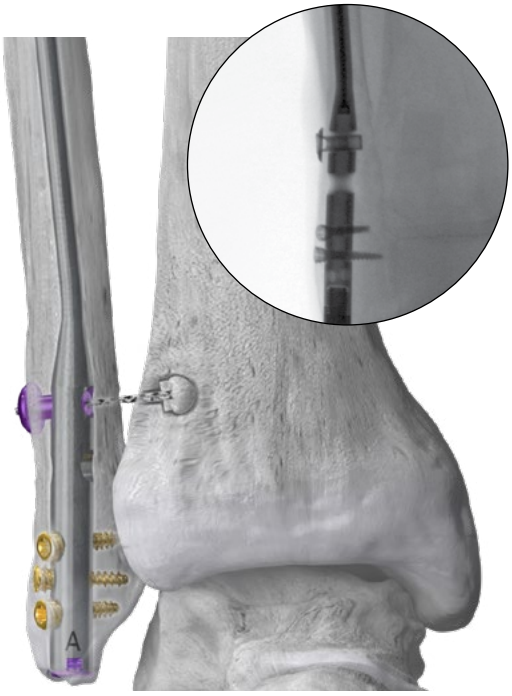
Place the Dynamic Screw Sleeve into the center proximal or distal syndesmotic hole on the Outrigger Targeter, denoted with two green marks. Drill to the hard stop on the R3FLEX Step Drill directly through the Dynamic Screw Sleeve.

Remove the Outrigger Targeter by attaching the knob and turning counter clockwise. After removing the Outrigger Targeter, place the R3FLEX device through the Nail with either a washer or a two hole plate assembled between them.

NOTE: The R3FLEX Implant and associated Sleeve may only be placed in the center, nominal placement angle (27° Posterior to Anterior).

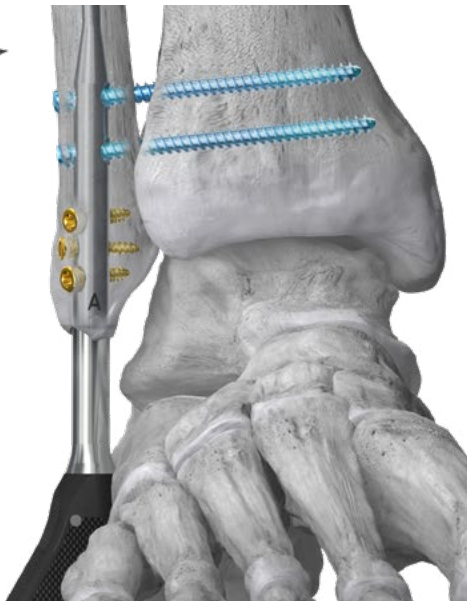
NOTE: The washer is directional and should be placed with the wider, flat side facing toward the surface of the bone.



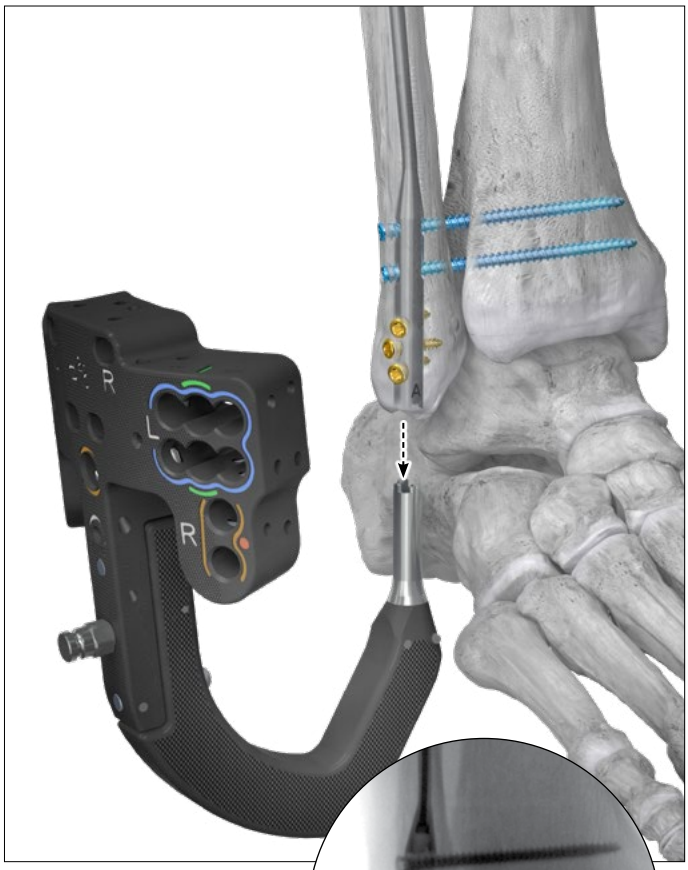


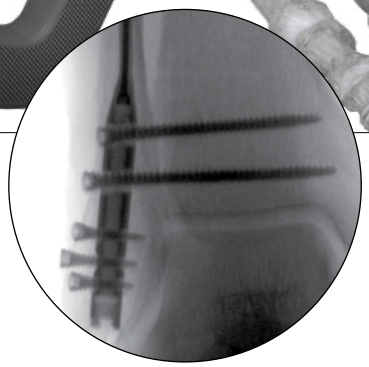
Refer to the R3FLEX Surgical Technique Guide (P82-STG-0002) for information on implantation, tensioning, and securing the implant.

OUTRIGGER REMOVAL:



Loosen the K-wire Clamp Sleeve and remove the Ø2.3 mm K-wire from the bone. Remove the Sleeve from the Outrigger.





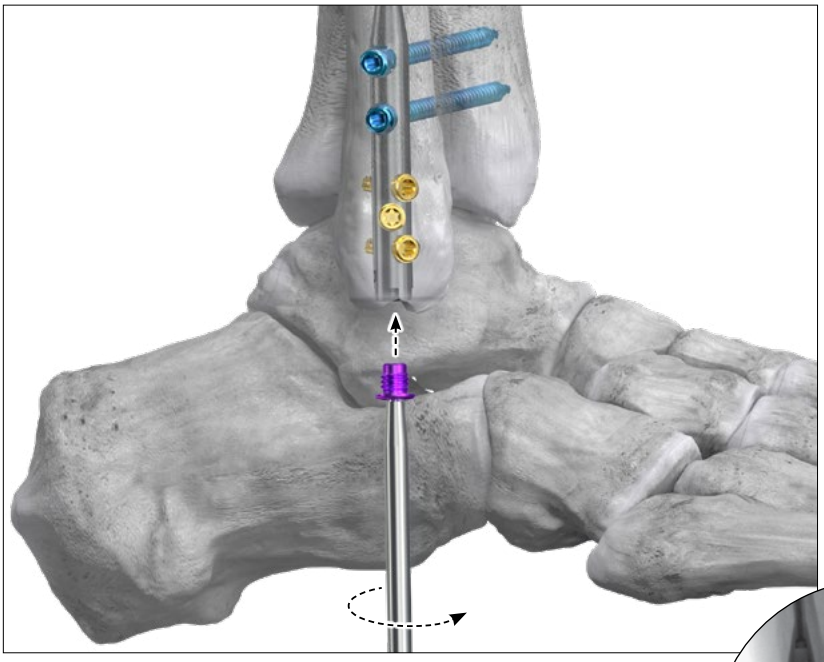
To remove the Outrigger, use the provided TX 25 Driver and handle to loosen and remove the Mounting Bolt. After removing the Mounting Bolt, remove the Outrigger from the Nail.

END CAP PLACEMENT:

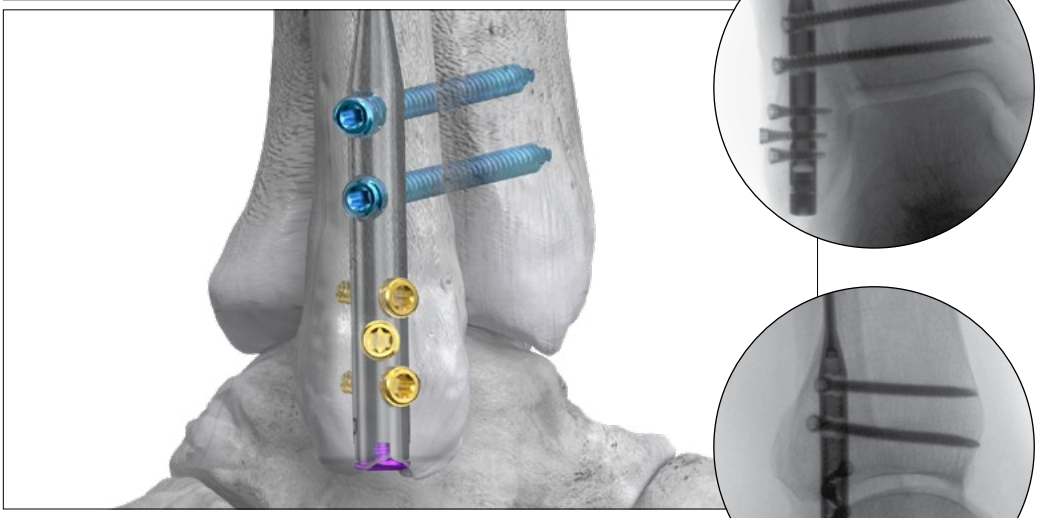
1 mm Nail End Cap

TX 10 Driver

AO Driver Handle

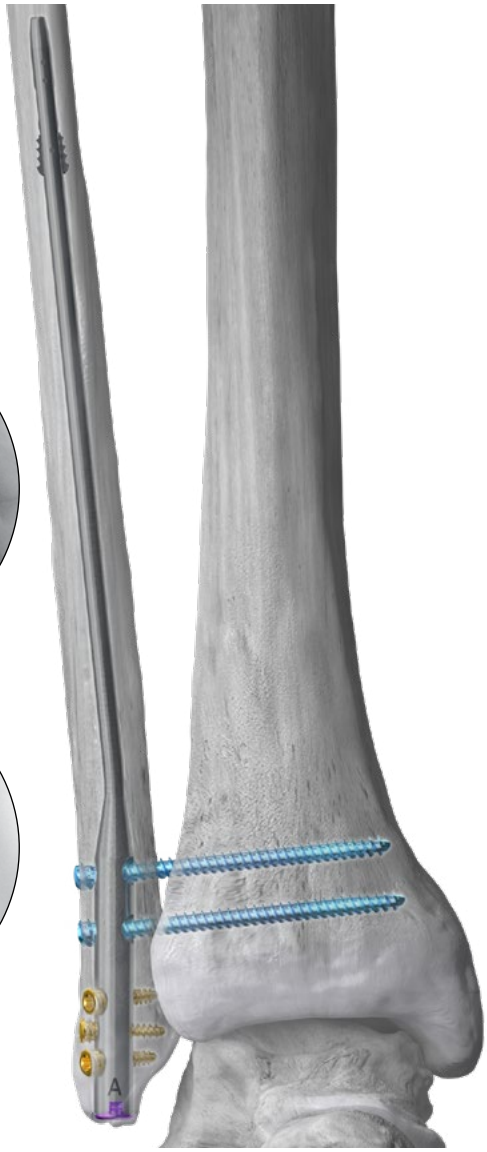


After removing the Outrigger, place the appropriate length End Cap into the distal end of the Nail using the provided TX 10 Driver and handle. The end cap should be at the level of the tip of the fibula.



Use fluoroscopy to confirm appropriate End Cap length and Threaded Peg placement.

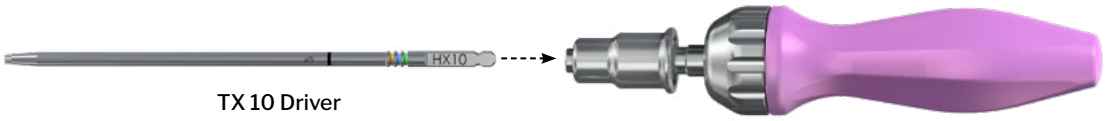
NOTE: The End Cap may not look fully seated on lateral fluoroscopy, but that is due to the cut out in the Nail.



CLOSURE:

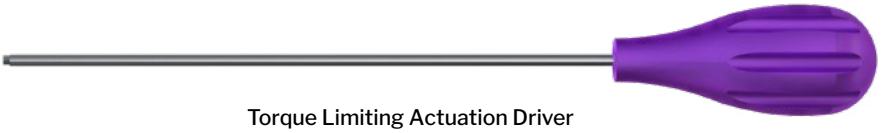
Proceed to incision closure or concomitant procedures at this time.

IMPLANT REMOVAL:

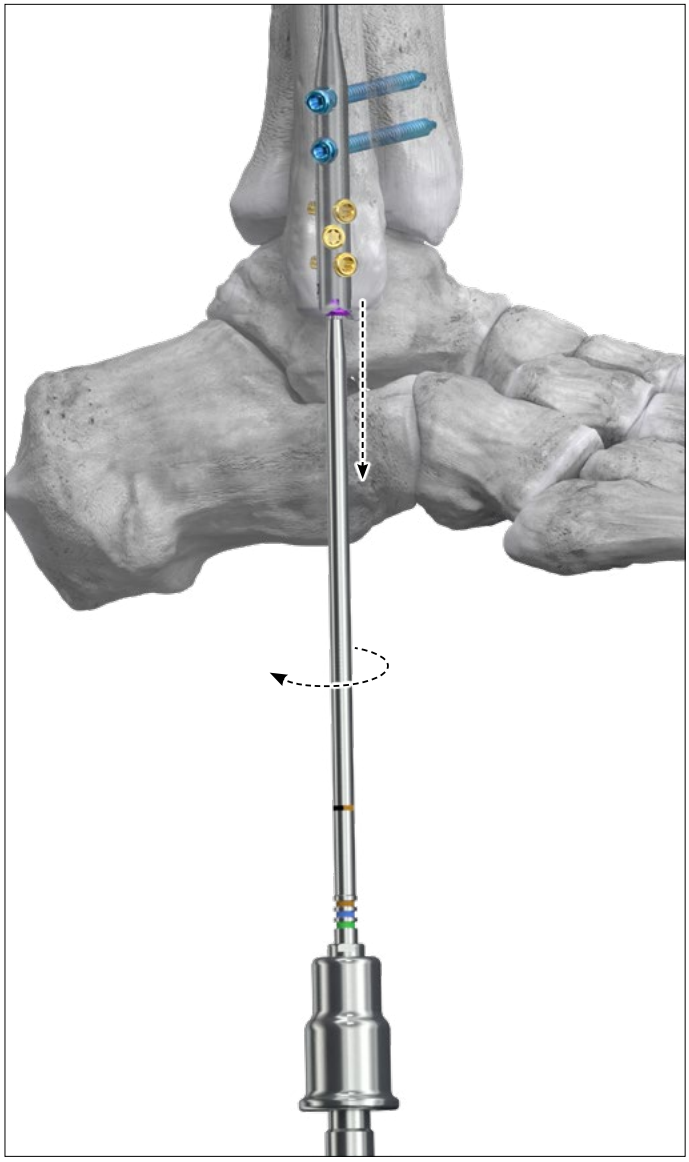


TX 10 Driver

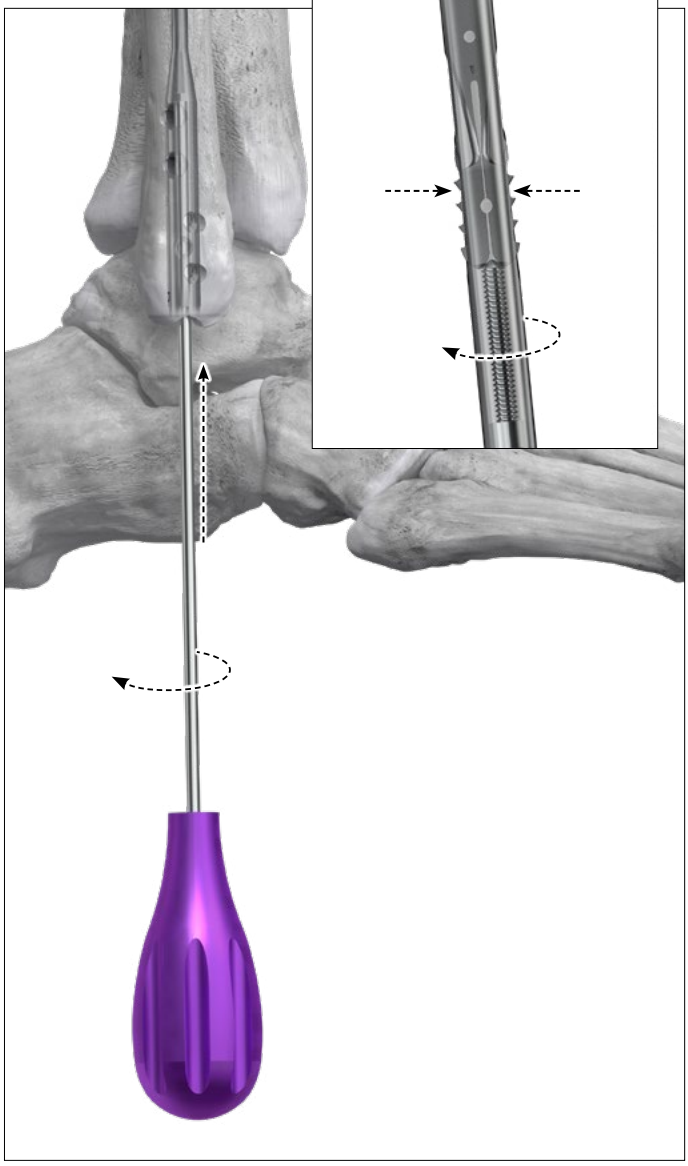
AO Driver Handle



Torque Limiting Actuation Driver



If implanted, locate and remove the End Cap by inserting the TX-10 Driver and rotating counterclockwise. Remove remaining Threaded Pegs in the Nail in the same manner.



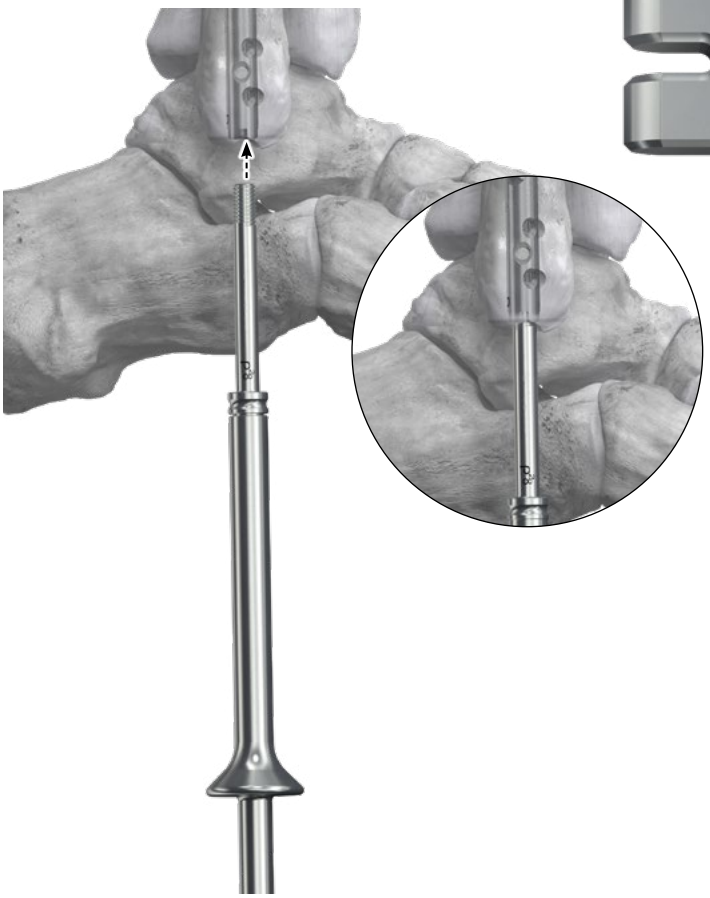
Insert the actuation Driver up through the Nail and turn the Set Screw counterclockwise to allow the proximal fixation to compress into the Nail.

IMPLANT REMOVAL: MOUNTING BOLT

Outrigger Mounting Bolt

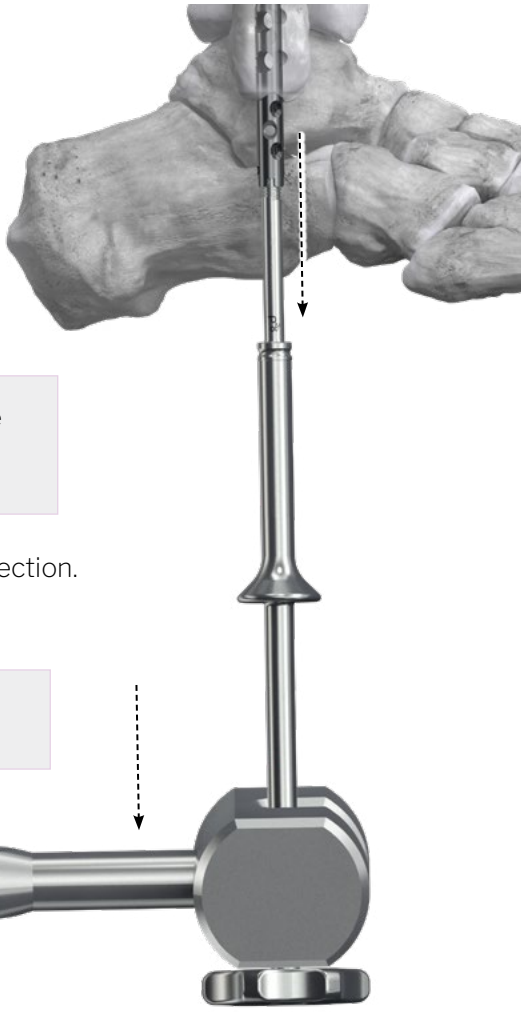
Impaction Attachment

Small Mallet



Thread the Outrigger Mounting Bolt into the end of the Nail until secure. Thread the Slap Hammer into the other end of the Mounting Bolt until secure.

NOTE: If a R3ACT Screw was used and there is difficulty removing, please refer to the R3ACT Surgical Technique Guide (P80-STG-0001) for more instruction on how to remove.

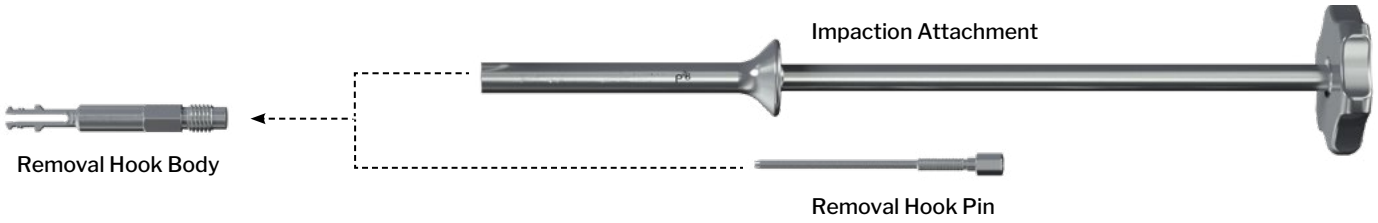


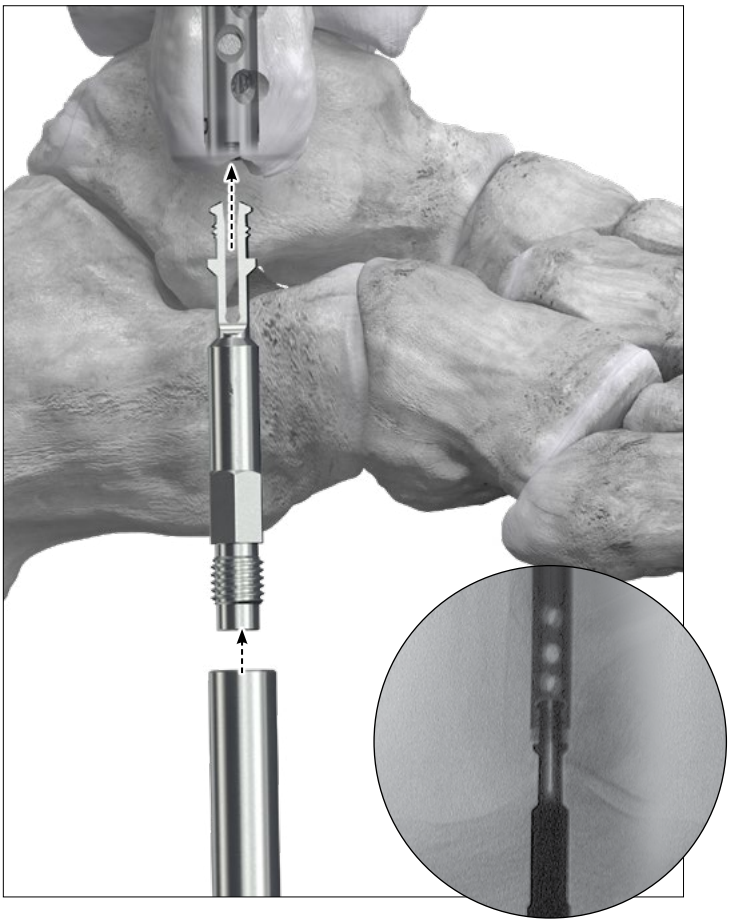
NOTE: If a R3FLEX Implant was used and there is difficulty removing, please refer to the R3FLEX Surgical Technique Guide (P82-STG-0002) for more instruction on how to remove the device.

Use the provided Mallet to strike the Impaction Attachment in an inferior direction. Continue striking until the Nail is removed.

NOTE: If there is difficulty removing the Nail, it may help to impact the Nail a few mm proximally before attempting removal again.

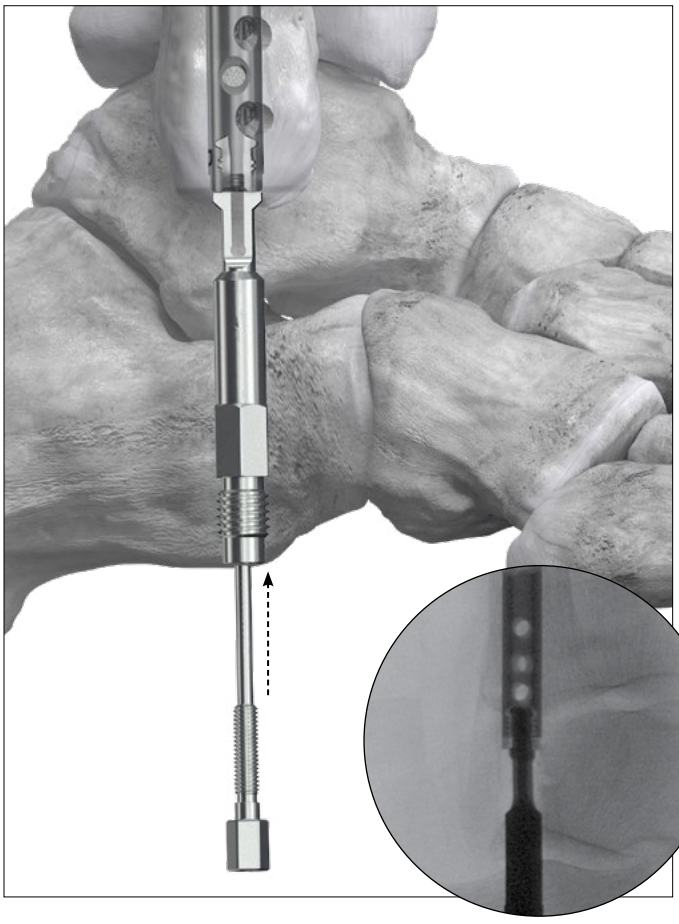
IMPLANT REMOVAL: REMOVAL HOOK





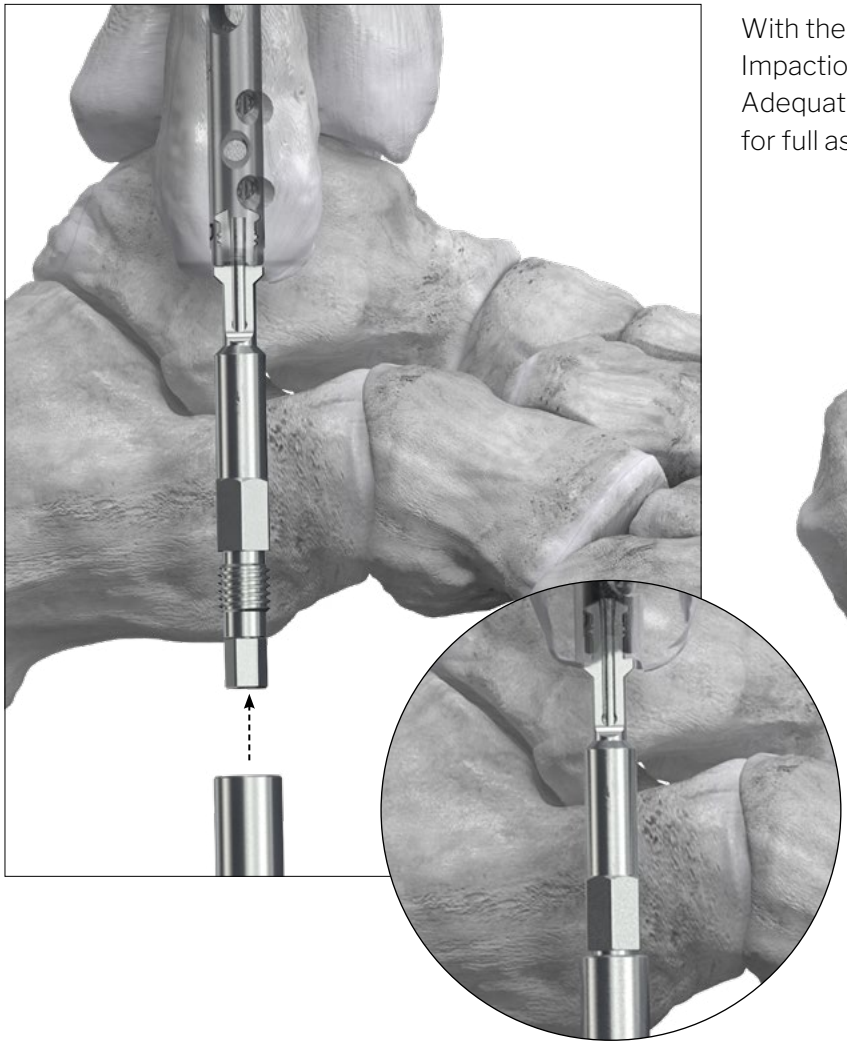
If the surgeon is having difficulty threading the Mounting Bolt into the end of the Nail, a Removal Hook is provided. Thread the Removal Hook Body into the Impaction Attachment and align with the distal end of the Nail. Impact the Removal Hook until it clicks in to the distal end of the Nail.

This can be confirmed under fluoroscopy.

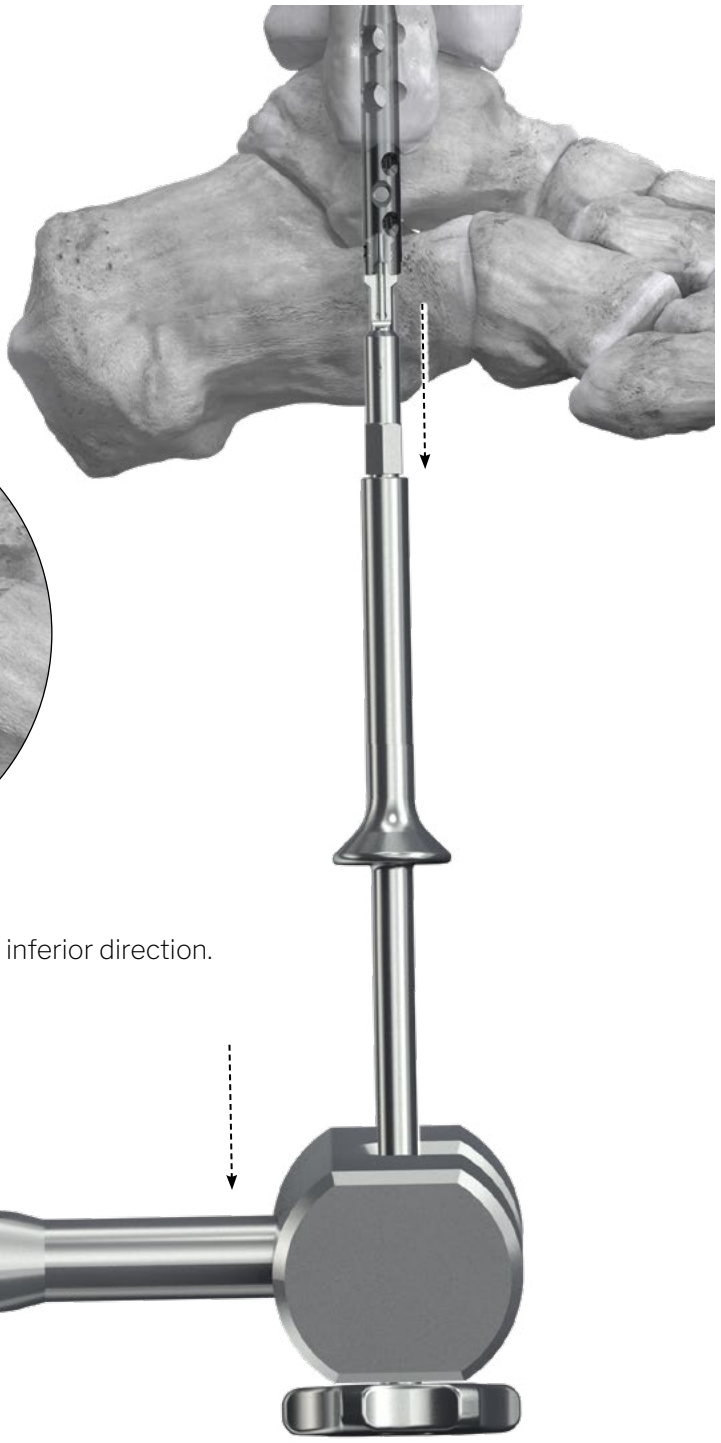


After seating the Removal Hook Body in the Nail, unthread the Impaction Attachment and thread the Removal Hook Pin to the Body. If resistance is met while hand-tightening the TX10 Driver may be used to gently tighten the Removal Hook Pin until it is fully seated and expanded within the distal Nail cavity.

IMPLANT REMOVAL: REMOVAL HOOK



With the Removal Hook Pin inserted, re-thread the Impaction Attachment back on to the Removal Hook Body. Adequate room is provided in the Impaction Attachment for full assembly.



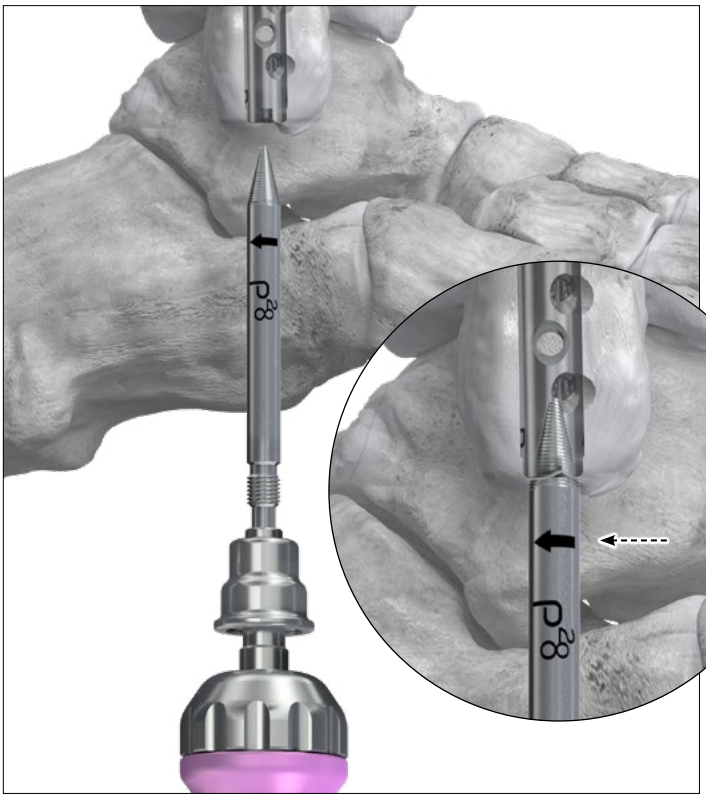
Use the provided Mallet to strike the Impaction Attachment in an inferior direction. Continue striking until the Nail is removed.

IMPLANT REMOVAL: NAIL EASY-OUT

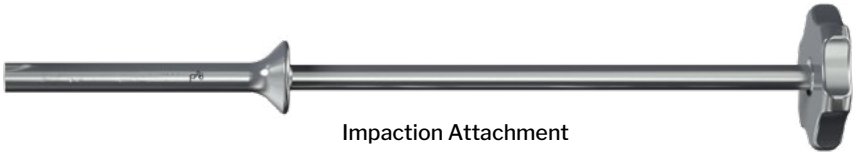
If the surgeon is having difficulty threading the Mounting Bolt into the end of the Nail, an Easy Out Removal Tool is also provided. Connect the Easy Out Removal Tool to the AO Quick Connect Handle.

Easy-Out Removal Tool

AO Driver Handle



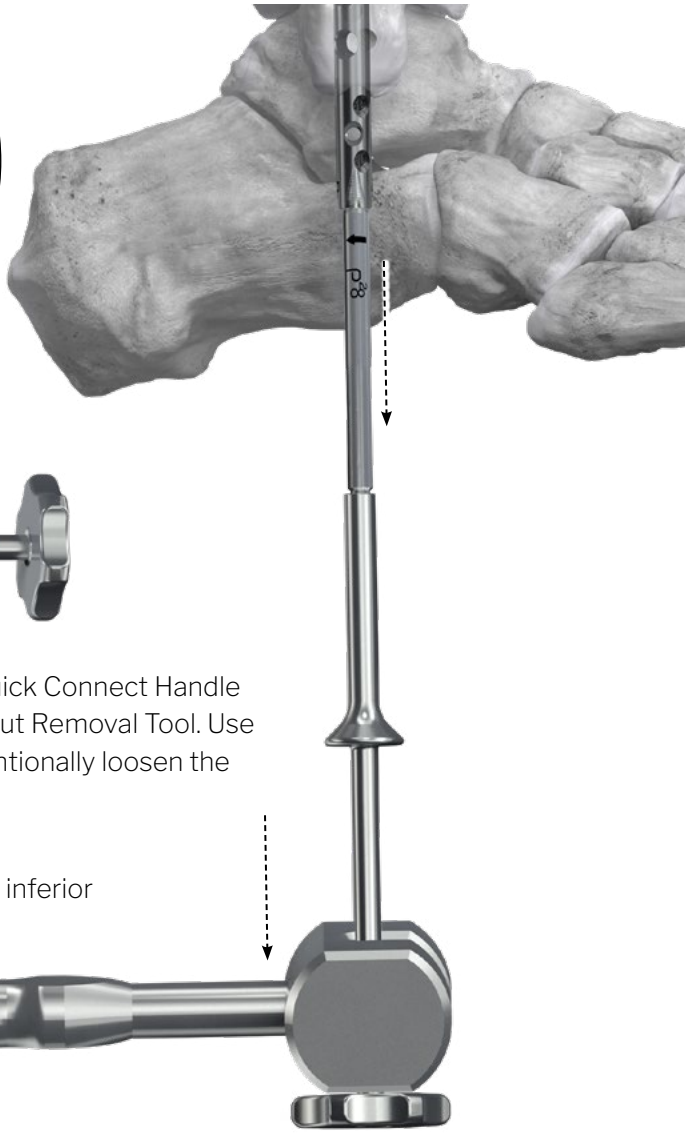
Insert the conical threads of the Easy Out Removal Tool into the distal end of the Nail and gently tamp the back of the AO Quick Connect Handle with the provided Mallet. While maintaining axial pressure against the Nail after tamping, reverse thread the Easy Out Removal Tool counter-clockwise into the Nail a minimum of 1.5 turns or until maximum tightness is achieved. The Easy Out Removal Tool is laser marked with an arrow for rotation direction to tighten.



Impaction Attachment

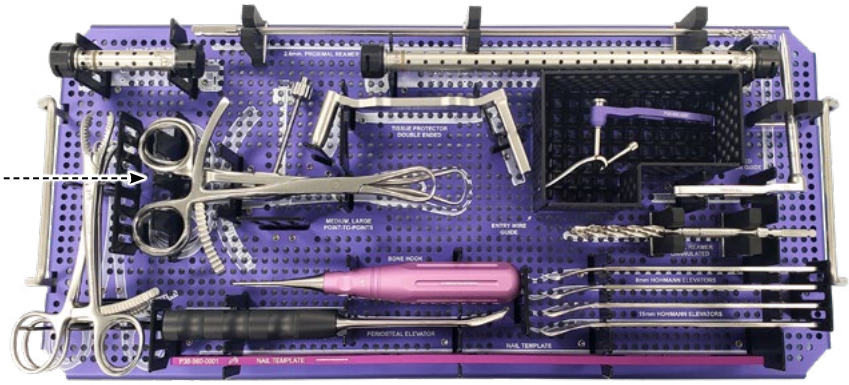
With the removal tool engaged and tightened, remove the AO Quick Connect Handle and thread the Impaction Attachment clockwise onto the Easy Out Removal Tool. Use caution to not overtighten the Impaction Attachment and unintentionally loosen the removal tool.

Use the provided mallet to strike the Impaction Attachment in an inferior direction. Continue striking until the Nail is removed.

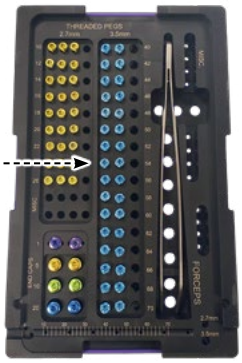


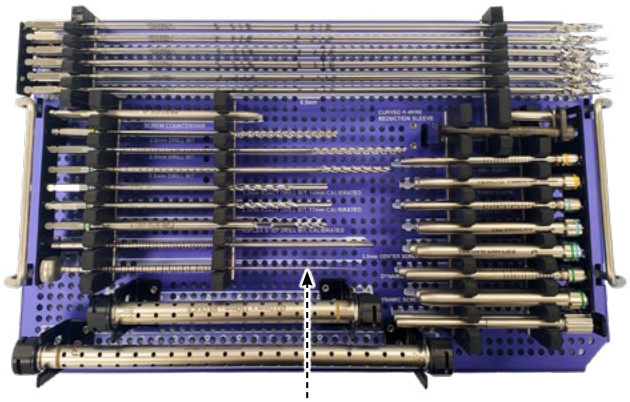
INSTRUMENT CASE:

Fibula Nail Instrument Tray
Reduction Instrumentation, Nail Template, Entry K-Wire Guide, Tissue Protector, Curved Reamer Guide, Distal Reamer, initial Proximal Reamer, Ø1.6 mm K-Wires, and Olive Wires are located within the Tray

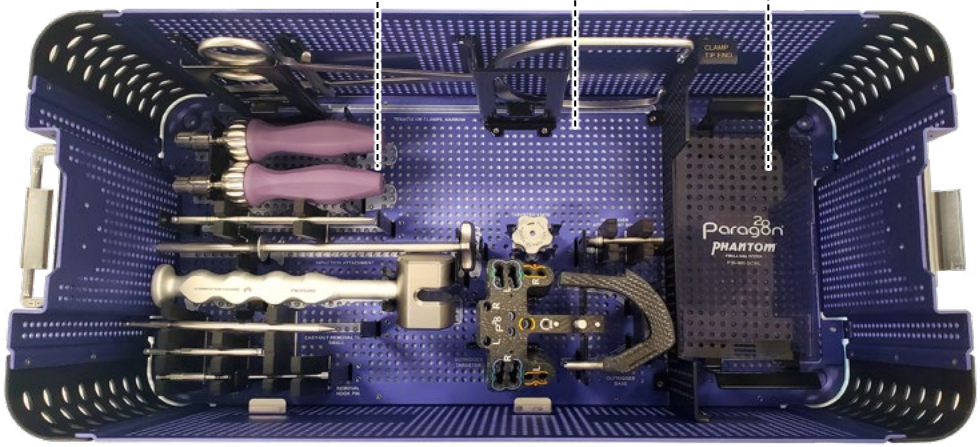


Fibula Nail Threaded Peg Caddy
Ø2.7 mm Threaded Pegs, Ø3.5 mm Threaded Pegs, End Caps, and Forceps are located within the Tray





Fibula Nail Instrument Tray
Screw Sleeves, Drill Guides, Drills, Depth Gauge, Taps, Countersink remaining Proximal Reamers, Curved K-Wire Guides, K-wire Clamp Sleeve, Ø2.0 mm K-Wires, and Ø2.3 mm K-Wires are located within the Tray



Fibula Nail Case Base
Handles, Drivers, Impaction Attachment, Mallet, removal instrumentation, Outrigger components, and Tenaculum are located at the bottom of the Fibular Nail Instrument Case.

INSTRUMENT CASE:

Part #	Description	Quantity	Use
P99-150-0013	Point-to-Point Reduction Forceps, Small, Ratchet	1	Reusable
P99-150-2013	Point-to-Point Reduction Forceps, Medium, Ratchet	1	Reusable
P99-150-0083	Point-to-Point Reduction Forceps, Large, Spin-Down	1	Reusable
P99-150-0017	Lobster Claw Reduction Forceps	1	Reusable
P99-150-1038	Tenaculum Clamps, Narrow	1	Reusable
P99-150-1007	Bone Hook	1	Reusable
P99-150-2104	Periosteal Elevator	1	Reusable
P99-150-0051	Hohmann Elevators, 8 mm, SS	2	Reusable
P99-150-0052	Hohmann Elevators, 15 mm, SS	2	Reusable
P36-912-1623	Ø1.6 mm x 230 mm, Entry Guide wire, Trocar	4	Single-use
P36-912-2015	Ø2.0 mm x 150 mm, Trocar K-Wire	4	Single-use
P99-192-2323	Ø2.3 mm x 230 mm, Trocar K-Wire	4	Single-use
P99-205-1607	Ø1.6 mm x 70 mm, Half Olive Wire, Threaded	4	Single-use
P36-930-0001	Entry Wire Guide	1	Reusable
P36-930-0002	Tissue Protector, Double-Ended	1	Reusable
P36-930-0003	Curved Reamer Guide	1	Reusable
P36-920-6816	Ø6.8 mm Distal Reamer, Cannulated, AO Quick Connect	2	Single-use
P36-915-2632	Ø2.6 mm Proximal Reamer, Solid, AO Quick Connect	2	Single-use
P36-915-3331	Ø3.3 mm Proximal Reamer, Solid, AO Quick Connect	2	Single-use
P36-915-3931	Ø3.9 mm Proximal Reamer, Solid, AO Quick Connect	2	Single-use
P36-915-4531	Ø4.5 mm Proximal Reamer, Solid, AO Quick Connect	2	Single-use
P36-915-5231	Ø5.2 mm Proximal Reamer, Solid, AO Quick Connect	2	Single-use
P36-915-6031	Ø6.0 mm Proximal Reamer, Solid, AO Quick Connect	2	Single-use
P36-915-6531	Ø6.5 mm Proximal Reamer, Solid, AO Quick Connect	2	Single-use
P36-950-0001	Outrigger Base	1	Reusable
P36-950-0002	Outrigger Targeter	1	Reusable
P36-950-0003	Outrigger Attachment Bolt	3	Reusable
P36-950-0004	Targeter Knob	2	Reusable
P36-955-2001	Curved K-Wire Reduction Sleeve, Targeting	1	Reusable
P36-955-2002	Curved K-Wire Reduction Sleeve, Non-Targeting	1	Reusable
P36-955-2003	K-Wire Clamp Sleeve	2	Reusable
P36-955-2701	Ø2.0 mm Drill Guide	2	Reusable
P36-955-2702	Ø2.7 mm Screw Sleeve	2	Reusable
P36-955-3501	Ø2.5 mm Drill Guide	2	Reusable
P36-955-3502	Ø3.5 mm Screw Sleeve	2	Reusable
P36-955-3503	Ø3.5 mm Center Screw Sleeve	2	Reusable
P36-955-4201	Dynamic Drill Guide	2	Reusable

INSTRUMENT CASE:

Part #	Description	Quantity	Use
P36-955-4202	Dynamic Screw Sleeve	2	Reusable
P36-910-2015	Ø2.0 mm Drill Bit, Calibrated, AO Quick Connect	3	Single-use
P36-910-2519	Ø2.5 mm Drill Bit, Calibrated, AO Quick Connect	3	Single-use
P36-910-2818	Ø2.8 mm Drill Bit, Calibrated, AO Quick Connect	3	Single-use
P36-910-3214	Ø3.2 mm R3ACT Drill Bit, 14 mm Calibrated, AO Quick Connect	3	Single-use
P36-910-3217	Ø3.2 mm R3ACT Drill Bit, 17 mm Calibrated, AO Quick Connect	3	Single-use
P36-910-3814	R3FLEX Step Drill Bit, Calibrated, AO Quick Connect	2	Single-use
P36-911-2735	Screw Countersink, AO Quick Connect	2	Single-use
P36-921-4018	Ø4.0 mm Single Lead Tap, AO Quick Connect	2	Single-use
P36-960-0001	Nail Template	1	Reusable
P36-960-0003	Probe Depth Gauge	1	Reusable
P36-940-TT10	T10 Hexalobe Driver, Calibrated, AO Quick Connect	3	Reusable
P36-940-TT25	T25 Hexalobe Driver, AO Quick Connect	2	Reusable
P99-000-AOMN	Medium Ratcheting Handle, Cannulated, AO Quick Connect	2	Reusable
P36-970-0001	Impaction Attachment	1	Reusable
P36-970-0002	Small Mallet	1	Reusable
P36-970-0003	Easy-Out Removal Tool, Small, AO Quick Connect	1	Single-use
P36-970-0006	Removal Hook, Body	1	Reusable
P36-970-0007	Removal Hook, Pin	1	Reusable
P36-913-1623	Ø1.6 mm x 230 mm, Sterilization K-Wire Container	1	Reusable
P36-913-2015	Ø2.0 mm x 150 mm, Sterilization K-Wire Container	1	Reusable
P36-913-2323	Ø2.3 mm x 230 mm, Sterilization K-Wire Container	1	Reusable
P36-913-1670	Ø1.6 mm x 70 mm, Sterilization K-Wire Container	1	Reusable
P31-941-0000	Sterilization K-Wire Container Cap	8	Reusable

STERILE PACKED INSTRUMENTS AND IMPLANTS:

Part #	Description	Quantity	Use
P36-128-130L-S	Ø2.8 mm x 130 mm, Left, Ti, Fibula Nail, Sterile	1	Single-use
P36-128-180L-S	Ø2.8 mm x 180 mm, Left, Ti, Fibula Nail, Sterile	1	Single-use
P36-128-130R-S	Ø2.8 mm x 130 mm, Right, Ti, Fibula Nail, Sterile	1	Single-use
P36-128-180R-S	Ø2.8 mm x 180 mm, Right, Ti, Fibula Nail, Sterile	1	Single-use
P36-134-130L-S	Ø3.4 mm x 130 mm, Left, Ti, Fibula Nail, Sterile	1	Single-use
P36-134-180L-S	Ø3.4 mm x 180 mm, Left, Ti, Fibula Nail, Sterile	1	Single-use
P36-134-270L-S	Ø3.4 mm x 270 mm, Left, Ti, Fibula Nail, Sterile	1	Single-use
P36-134-130R-S	Ø3.4 mm x 130 mm, Right, Ti, Fibula Nail, Sterile	1	Single-use
P36-134-180R-S	Ø3.4 mm x 180 mm, Right, Ti, Fibula Nail, Sterile	1	Single-use
P36-134-270R-S	Ø3.4 mm x 270 mm, Right, Ti, Fibula Nail, Sterile	1	Single-use
P36-140-130L-S	Ø4.0 mm x 130 mm, Left, Ti, Fibula Nail, Sterile	1	Single-use
P36-140-180L-S	Ø4.0 mm x 180 mm, Left, Ti, Fibula Nail, Sterile	1	Single-use
P36-140-270L-S	Ø4.0mm x 270 mm, Left, Ti, Fibula Nail, Sterile	1	Single-use
P36-140-130R-S	Ø4.0 mm x 130 mm, Right, Ti, Fibula Nail, Sterile	1	Single-use
P36-140-180R-S	Ø4.0 mm x 180 mm, Right, Ti, Fibula Nail, Sterile	1	Single-use
P36-140-270R-S	Ø4.0 mm x 270 mm, Right, Ti, Fibula Nail, Sterile	1	Single-use
P36-155-130L-S	Ø5.5 mm x 130 mm, Left, Ti, Fibula Nail, Sterile	1	Single-use
P36-155-180L-S	Ø5.5 mm x 180 mm, Left, Ti, Fibula Nail, Sterile	1	Single-use
P36-155-130R-S	Ø5.5 mm x 130 mm, Right, Ti, Fibula Nail, Sterile	1	Single-use
P36-155-180R-S	Ø5.5 mm x 180 mm, Right, Ti, Fibula Nail, Sterile	1	Single-use
P36-940-0001-S	Actuation Driver, 2.0 mm Hex, Sterile	2	Single-use

THREADED PEG CADDY:

Part #	Description	Quantity	Use
P36-501-2710	Ø2.7 mm x 10 mm, Threaded Peg, Ti	4	Single-use
P36-501-2712	Ø2.7 mm x 12 mm, Threaded Peg, Ti	4	Single-use
P36-501-2714	Ø2.7 mm x 14 mm, Threaded Peg, Ti	4	Single-use
P36-501-2716	Ø2.7 mm x 16 mm, Threaded Peg, Ti	4	Single-use
P36-501-2718	Ø2.7 mm x 18 mm, Threaded Peg, Ti	4	Single-use
P36-501-2720	Ø2.7 mm x 20 mm, Threaded Peg, Ti	4	Single-use
P36-501-2722	Ø2.7 mm x 22 mm, Threaded Peg, Ti	4	Single-use
P36-501-2724	Ø2.7 mm x 24 mm, Threaded Peg, Ti	4	Single-use
P36-501-2726	Ø2.7 mm x 26 mm, Threaded Peg, Ti	4	Single-use
P36-501-3540	Ø3.5 mm x 40 mm, Threaded Peg, Ti	3	Single-use
P36-501-3542	Ø3.5 mm x 42 mm, Threaded Peg, Ti	3	Single-use
P36-501-3544	Ø3.5 mm x 44 mm, Threaded Peg, Ti	3	Single-use
P36-501-3546	Ø3.5 mm x 46 mm, Threaded Peg, Ti	3	Single-use
P36-501-3548	Ø3.5 mm x 48 mm, Threaded Peg, Ti	3	Single-use
P36-501-3550	Ø3.5 mm x 50 mm, Threaded Peg, Ti	3	Single-use
P36-501-3552	Ø3.5 mm x 52 mm, Threaded Peg, Ti	3	Single-use
P36-501-3554	Ø3.5 mm x 54 mm, Threaded Peg, Ti	3	Single-use
P36-501-3556	Ø3.5 mm x 56 mm, Threaded Peg, Ti	3	Single-use
P36-501-3558	Ø3.5 mm x 58 mm, Threaded Peg, Ti	3	Single-use
P36-501-3560	Ø3.5 mm x 60 mm, Threaded Peg, Ti	3	Single-use
P36-501-3562	Ø3.5 mm x 62 mm, Threaded Peg, Ti	3	Single-use
P36-501-3564	Ø3.5 mm x 64 mm, Threaded Peg, Ti	3	Single-use
P36-501-3566	Ø3.5 mm x 66 mm, Threaded Peg, Ti	3	Single-use
P36-501-3568	Ø3.5 mm x 68 mm, Threaded Peg, Ti	3	Single-use
P36-501-3570	Ø3.5 mm x 70 mm, Threaded Peg, Ti	3	Single-use
P36-503-0001	1 mm End Cap, Ti	2	Single-use
P36-503-0005	5 mm End Cap, Ti	2	Single-use
P36-503-0010	10 mm End Cap, Ti	2	Single-use
P36-503-0020	20 mm End Cap, Ti	2	Single-use
P99-150-0001	Screw Forceps	1	Reusable

Indications, Contraindications and Warnings

Refer to www.paragon28.com/ifus for the complete and most current instructions for use document.

INDICATIONS FOR USE (PHANTOM®)

The Phantom® Fibula Nail System is intended for use in the fixation of fibular fractures and osteotomies.

CONTRAINDICATIONS

The Paragon 28® Phantom® Fibula Nail System implants are not designed or sold for any use except as indicated. Use of the Phantom® Fibula Nail System is contraindicated in the following situations:

- Active, suspected or latent infection in the affected area
- Patients who are physiologically or psychologically inadequate
- Corpulence; an overweight or corpulent patient can strain the implant to such a degree that stabilization or implant failure can occur.
- Patients previously sensitized to titanium
- Longitudinal splits, fractures, or deformities
- Insufficient quantity or quality of bone to permit stabilization, conditions that retard healing (not including pathological fractures) and conditions causing poor blood supply.
- Open epiphyseal plates
- In patients where there is a possibility for conservative treatment
- Indications not included in the **INDICATIONS FOR USE**

POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS

In any surgical procedure, the potential for complications and adverse reactions exist. The risks and complications with these implants include:

- Loosening, deformation or fracture of the implant
- Acute post-operative wound infections and late infections with possible sepsis
- Migration, subluxation of the implant with resulting reduction in range of movement
- Fractures resulting from unilateral joint loading
- Thrombosis and embolism
- Wound hematoma and delayed wound healing
- Temporary and protracted functional neurological perturbation
- Tissue reactions as the result of allergy or foreign body reaction to dislodged particles
- Corrosion with localized tissue reaction and pain
- Pain, a feeling of malaise or abnormal sensations due to the implant used
- Bone loss due to stress shielding
- Loss of fixation in bone attributable to nonunion, osteoporosis and/or markedly unstable comminuted fractures
- Nonunion or malunion with rotation or angulation resulting in loss of anatomic positioning
- Irritation of soft tissues, including impingement syndrome

All possible complications listed here are not typical of Paragon 28®, Inc. products but are in principle observed with any implant. Promptly inform Paragon 28®, Inc. as soon as complications occur in connection with the implants or surgical instruments used. In the event of premature failure of an implant in which a causal relationship with its geometry, surface quality or mechanical stability is suspected, please provide Paragon 28®, Inc. with the explant(s) in a cleaned, disinfected and sterile condition. Paragon 28®, Inc. cannot accept any other returns of used implants. The surgeon is held liable for complications associated with inadequate asepsis, inadequate preparation of the osseous implant bed in the case of implants, incorrect indication or surgical technique or incorrect patient information and consequent incorrect patient behavior.

WARNINGS AND PRECAUTIONS

- Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
- Use of an undersized implant in areas of high functional stresses may lead to implant fracture and failure.
- Implants, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
- The implants and guide wires are intended for single use only.
- Instruments, guide wires and Threaded Pegs are to be treated as sharps.
- **Do not use other manufacturer's instruments or implants in conjunction with the Phantom® Fibula Nail System**
- **Do not resterilize the Phantom® Fibula Nail**

MR SAFETY INFORMATION

The Phantom® Fibula Nail System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of the Phantom® Fibula Nail System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

NOTES:

NOTES:

Exclusively foot & ankle

PHANTOM®
FIBULA NAIL SYSTEM

SURGICAL TECHNIQUE GUIDE
Phantom® Fibula Nail System

P36-STG-0001 RevA [2024-09-23]

™Trademarks and ®Registered Marks of Paragon 28®, Inc.
© Copyright 2024 Paragon 28®, Inc. All rights reserved.
Patents: www.paragon28.com/patents

Paragon 28®, Inc.
14445 Grasslands Dr.
Englewood, CO 80112 USA
(855) 786-2828

Endnotes:

1. Internal Data on File (ER-24090401)

2. Internal Data on File (ER-24091101)

Exclusively foot & ankle
Paragon 28®
www.Paragon28.com

Disclaimer:

The purpose of the Phantom® Fibula Nail System Technique Guide is to demonstrate the optionality and functionality of the Phantom® Fibula Nail System implants and instrumentation.

CAUTION: Federal Law (USA) restricts this device to sale and use by, or on the order of, a physician.