

FibuNail™

VILEX SMALL BONE NAIL IMPLANT



SURGICAL TECHNIQUE



VILEX

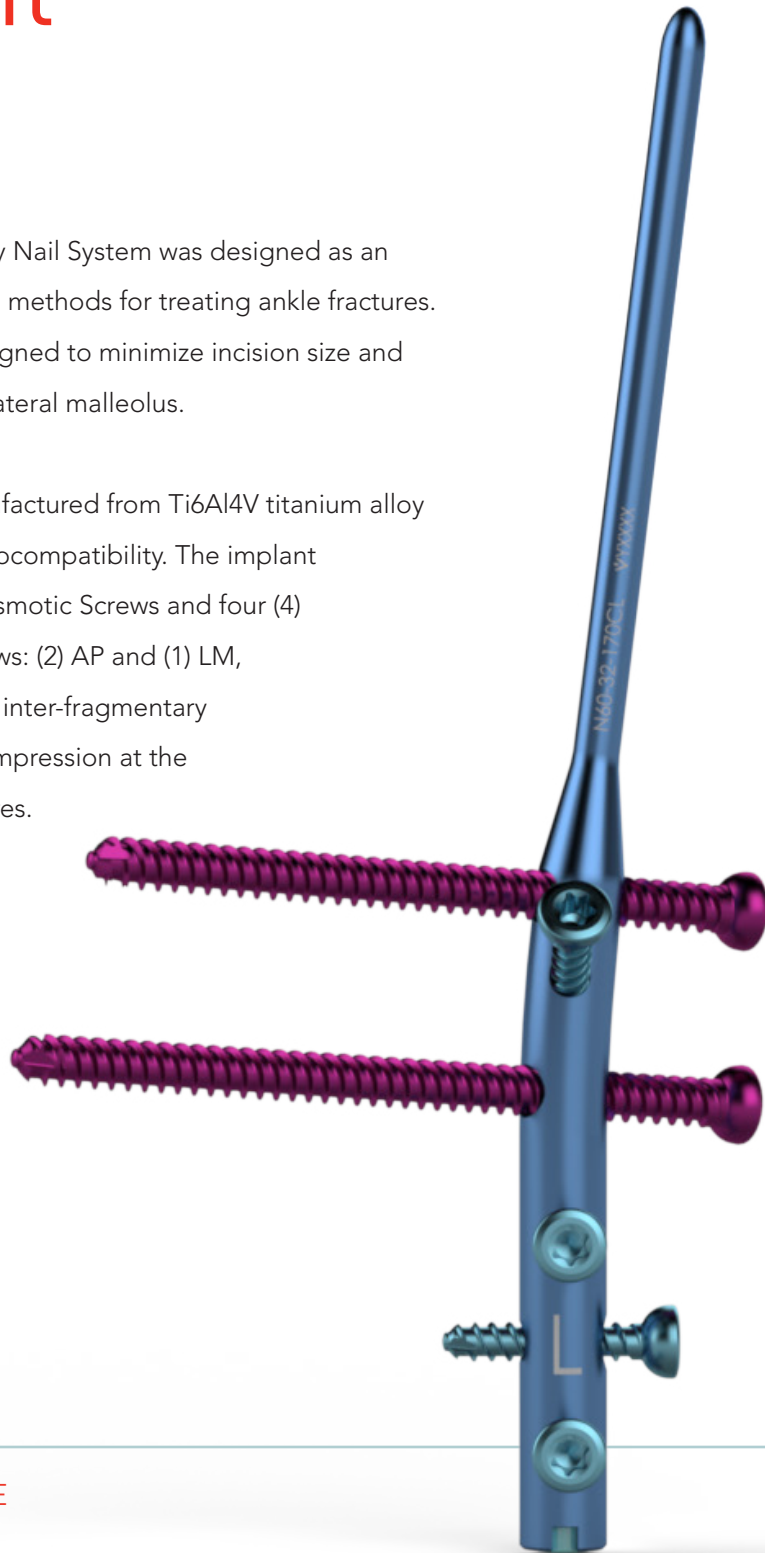


FibuNail™

Design Rationale

The FibuNail™ Intramedullary Nail System was designed as an alternative to traditional ORIF methods for treating ankle fractures. The FibuNail™ system is designed to minimize incision size and soft tissue dissection on the lateral malleolus.

FibuNail™ implants are manufactured from Ti6Al4V titanium alloy for enhanced strength and biocompatibility. The implant accepts two (2) 3.5mm Syndesmotomic Screws and four (4) 2.7mm multiplanar cross screws: (2) AP and (1) LM, and an additional oblique AP inter-fragmentary screw designed to enable compression at the level of many Weber B fractures.



INDICATIONS FOR USE

Fractures and osteotomies of the fibula

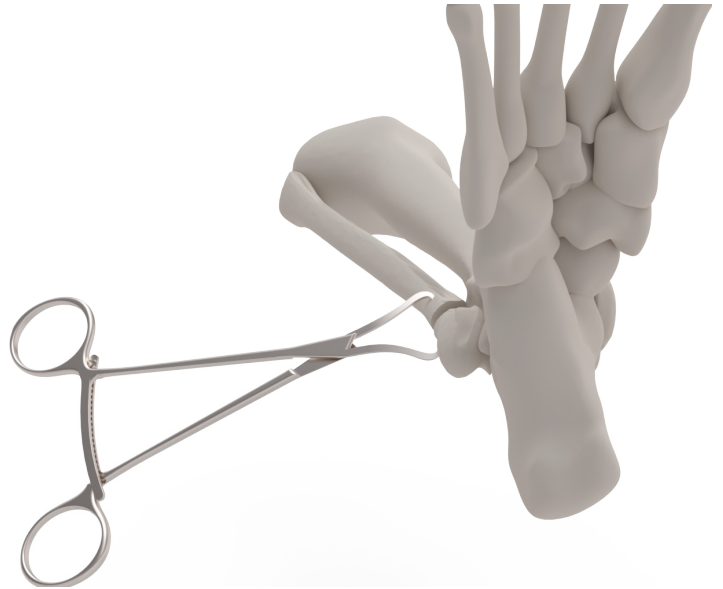
1 Make an incision

Locate the lateral malleolus. Create a 1cm linear incision approximately 1-1.5cm distal to the lateral malleolus. Blunt dissection of the tissues is then performed cautiously to prevent disruption to either the sural nerve or the peroneal tendons.

2 Reduce the fracture

The fibula fracture may be reduced percutaneously with forceps or by using a guide wire as a joystick. A small incision can be created over the fracture site to aid in reduction if necessary.

Keep the reduction clamp in place until the nail has been inserted and the fracture is fixated. A Hintermann distractor and bone reduction forceps are provided to aid in reduction.



3 Place the guide wire

Insert the 1.5mm blunt tip guide wire (K250-15BL) 15-20mm into the medullary canal of the distal fibula with the driver on the oscillate setting. The guide wire should be inserted at the very edge of the distal fibula cartilage. Supinating the foot provides better access to the distal fibula.

To prevent bending the wire, expose no more than 20mm of the wire as you drive it. Use fluoroscopy in both AP and Lateral planes to ensure proper positioning into the center of the fibula. Advance the wire into the fibula after achieving correct wire position.



4 Drill the medullary canal

While holding the reduction and guide wire in place, manually ream the intramedullary canal with the cannulated 6.2mm Distal Reamer (ZF-REAM-DIST) over the 1.5mm guide wire. Attach the reamer to the AO T-Handle for hand reaming. When reaming, use the tissue protector (ZF-D62) to minimize soft tissue irritation and damage.



4 Drill the medullary canal

The 6.2mm Distal Reamer is designed to match the shape of the implant. Ream to the appropriate depth. All of the distal flutes should be engaged in bone. Avoid over-reaming.

Remove the Distal Reamer and attach the cannulated 3.4mm Proximal Reamer (ZF-REAM-PROX) to the T-Handle. It is necessary to determine the length of the nail to be used in order to ream to the proper depth proximally.

Drive the 3.4mm Proximal Reamer over the guide wire and ream proximally.

Use caution during reaming and confirm positioning using bi-planar fluoroscopy to avoid cortical disruption. Reaming may cause disruption of the fracture, or cause additional fracture, if done without caution.

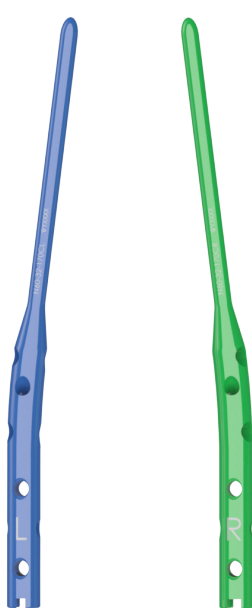


5 Assemble the targeting frame

Assemble the Nail, Targeting Guide Base, AP Arm, and Lateral Arm with the Thumb Screws.



The nail attaches to the frame in only one orientation and connects to the shaft using the long thumb screw. When assembled properly, the color-coded text will face anterior. Align the pegs into the holes and secure each arm using the short thumb screws.



LEFT = BLUE

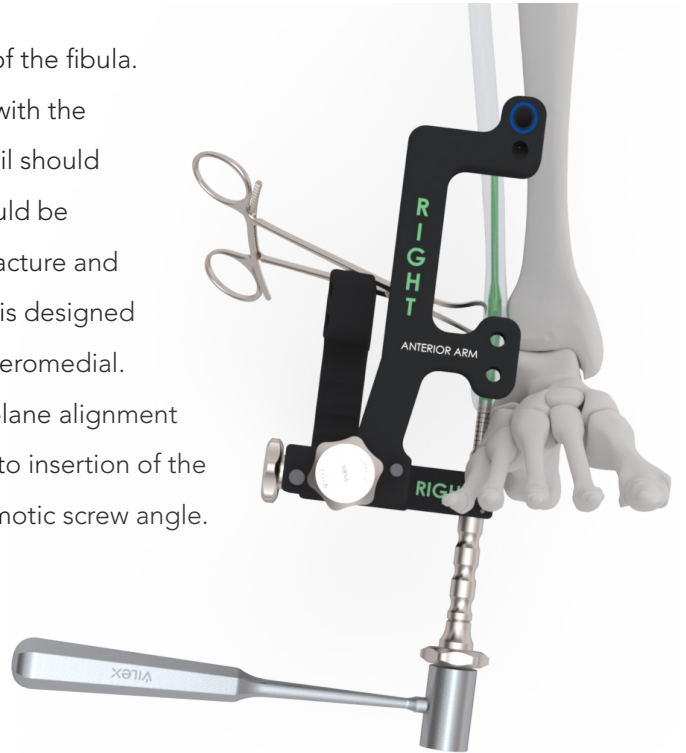
RIGHT = GREEN



6 Insert the nail

Insert the fibula nail into the intramedullary canal of the fibula. If needed, lightly tap the end of the thumb screw with the mallet (ZF-HMMR). The distal-most edge of the nail should be just buried within the distal fibula. The nail should be inserted so that the screw holes line up with the fracture and syndesmotomic screw height. Syndesmotomic targeting is designed for syndesmotomic positioning posteriorlateral to anteromedial. The nail can be rotated slightly to ensure correct plane alignment and should be confirmed under fluoroscopy prior to insertion of the cross screws. Internal rotation reduces the syndesmotomic screw angle.

After the nail is inserted, the distal end of the nail can be located by passing a wire through the wire hole in the Lateral Targeting Arm to confirm positioning in the fibula. Laser markings are provided every 2mm on the insertion shaft to assist in determining depth during insertion.



7

Insert 2.7mm Cross Screws

The first of the four 2.7mm cross screws to be implanted should be the oblique fracture reduction screw. Once this screw has been placed, the reduction clamp should not be needed and can be removed at this stage.

Insert Long Cannula

Insert the long cannula (ZF-CANN) for the 2.7mm cross screws. Cannulas, drill guides, and drills are color coded to match cross screw sizes.

Insert 2.0mm Drill Guide

Insert 2.0mm Drill Guide (ZF-D20) into the cannula. Insert the 2.0mm drill into the drill guide. Make a stab incision for each cross screw. Advance the drill guide against the bone. Ensure that the drill guide is fully seated against the bone to protect the soft tissues during drilling and to ensure correct measurement of screw length.

Advance Drill & Measure

Drill through the far cortex using the 2.0mm drill (ZF-DRILL-20). Use fluoroscopy for confirmation. Screw length can be measured off the drill guide or by using the depth gauge (ZF-DPTH).

Drive 2.7mm Cross Screw

Remove the drill and drill guide. Select the 2.7mm screw and secure it to the self-retaining hexalobe driver. Drive the screws through the cannula using the long T10 hexalobe driver (ZF-T10).

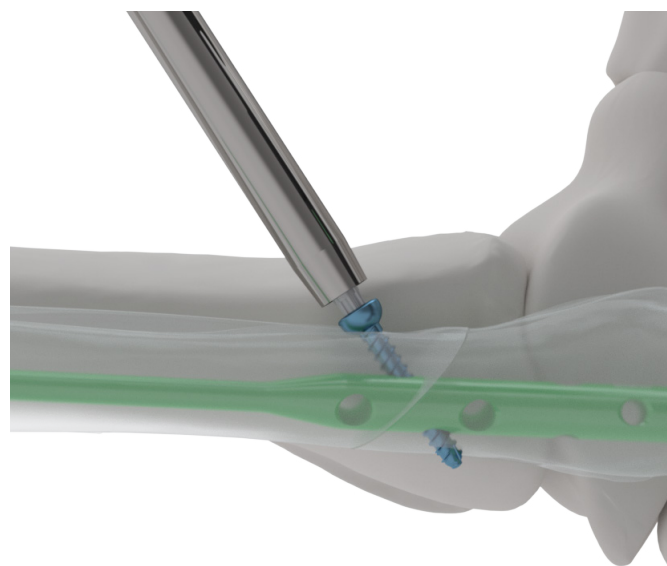


7 Insert 2.7mm Cross Screws

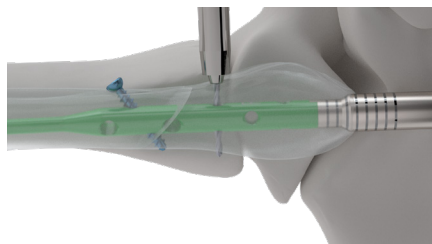
Implant additional 2.7mm Screws

Repeat the previous steps for the remaining distal cross screws.

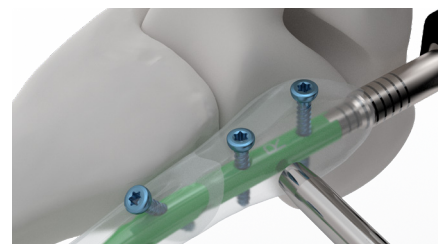
Attach Lateral Targeting Arm for the distal lateral to medial cross screw.



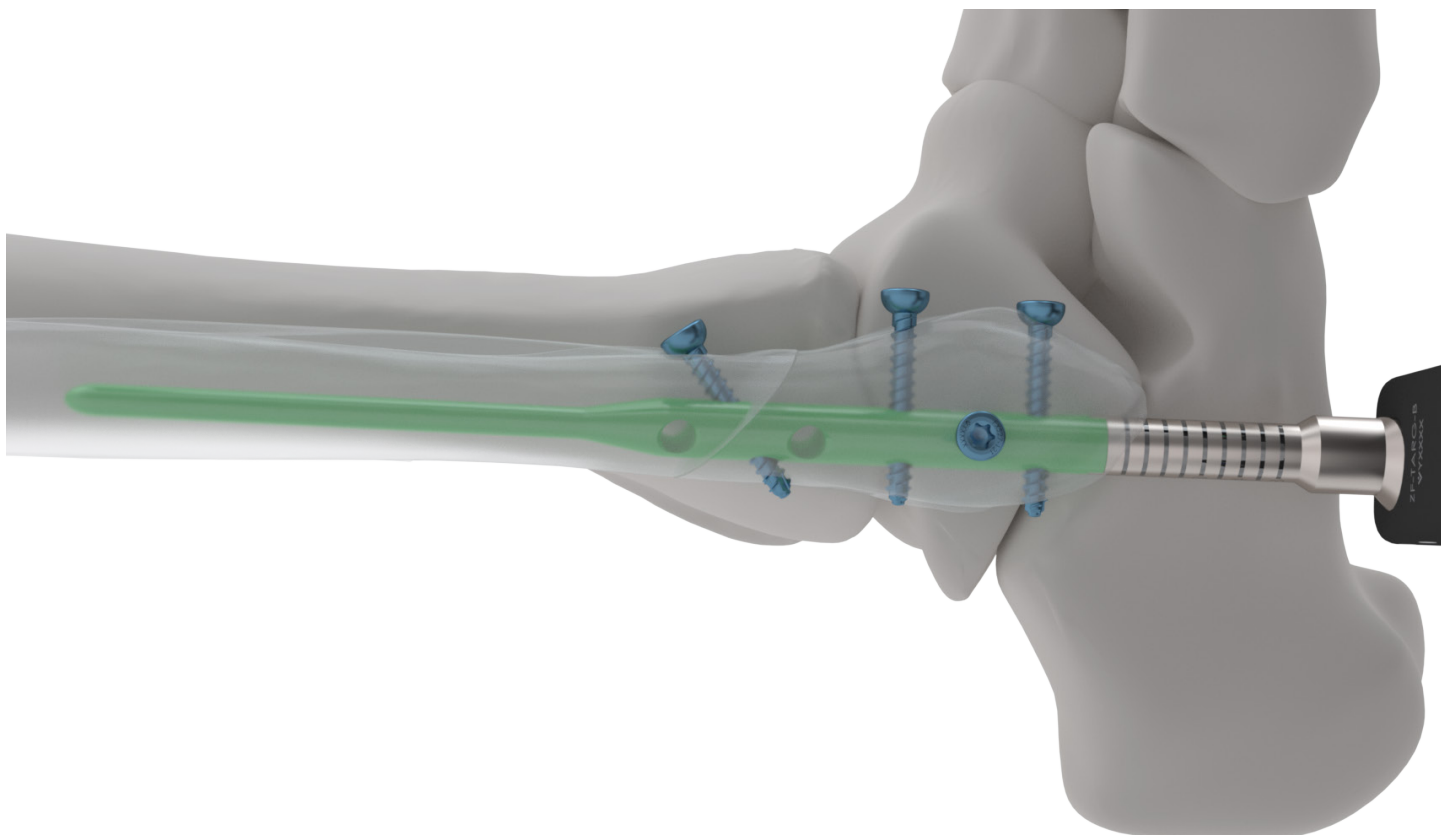
Insert Cannula & Drill Guide



Drill & Measure

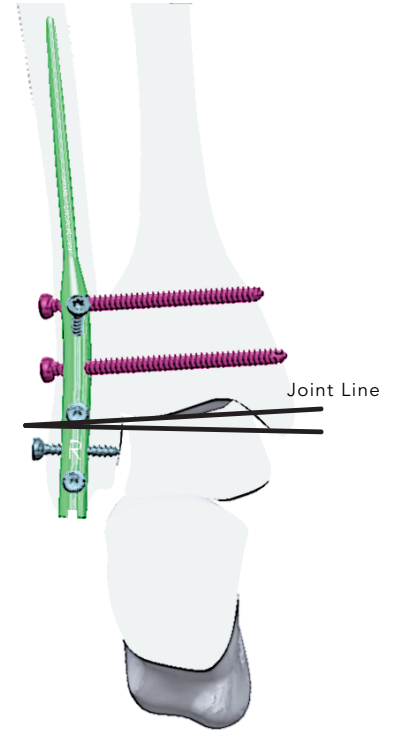
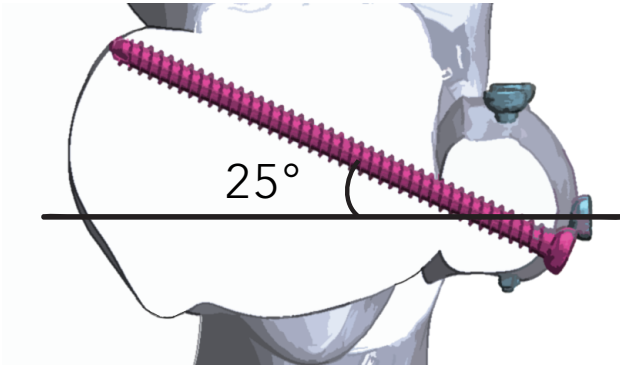


Drive Screws



8 Insert 3.5mm Syndesmotic Screws

Two syndesmotic screws are recommended for syndesmotic fixation. Syndesmotic holes are angulated 25° posteriorlateral to anteromedial. When the nail is positioned properly, syndesmotic screws should be 1-3cm above and parallel with the ankle joint line.



Insert Short Cannula

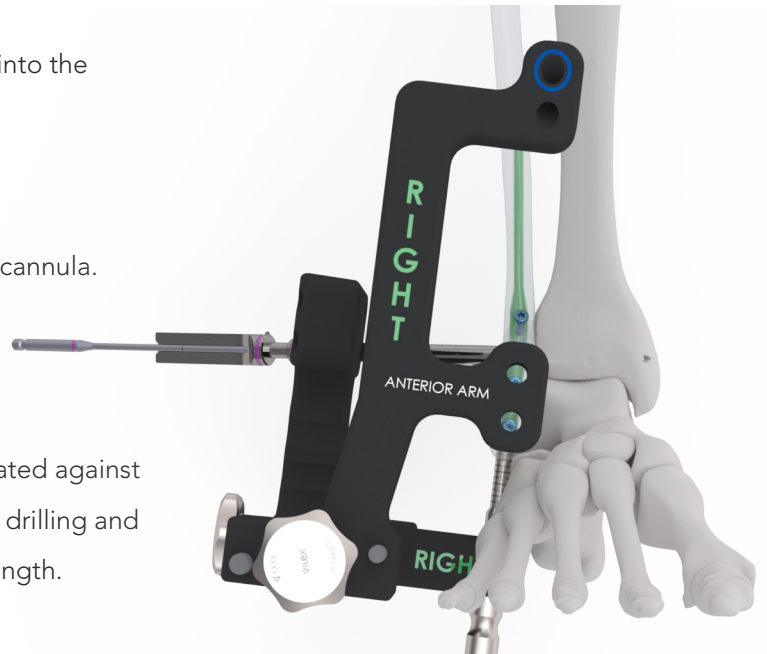
Insert Syndesmotic Cannula (ZF-CANN-S) into the Lateral Arm of the Targeting Guide.

Insert 2.5mm Drill Guide

Insert 2.5mm Drill Guide (ZF-D25) into the cannula.

Insert the 2.5mm drill into the drill guide.

Make a stab incision for each syndesmotic screw. Advance the drill guide against the bone. Ensure that the drill guide is fully seated against the bone to protect the soft tissues during drilling and to ensure correct measurement of screw length.



Advance Drill & Measure

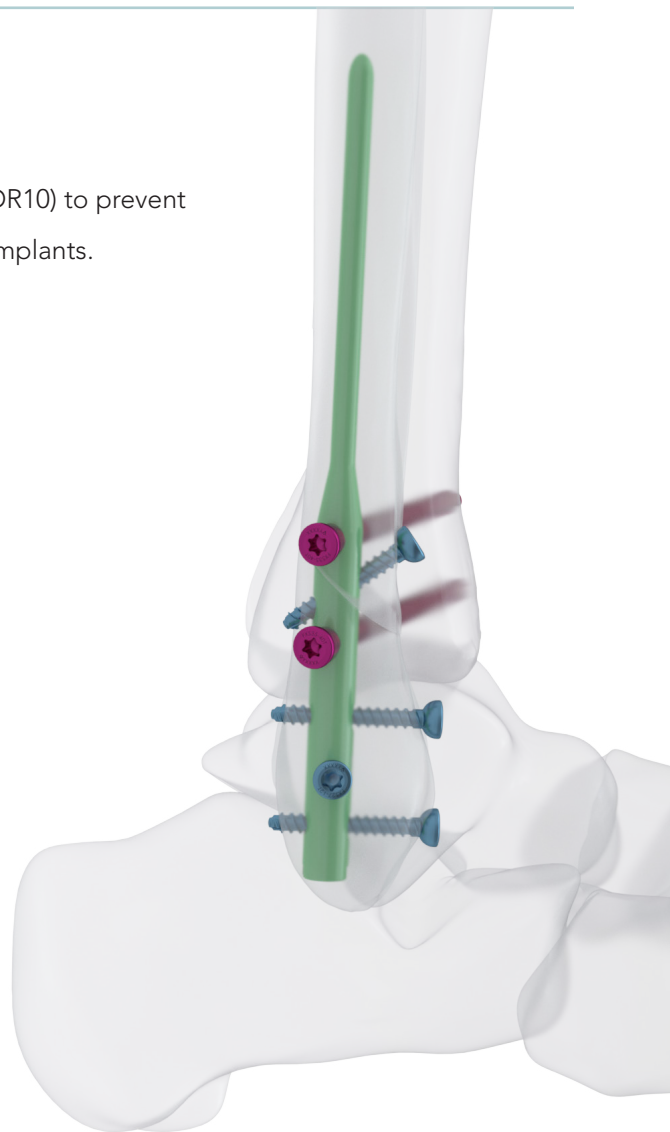
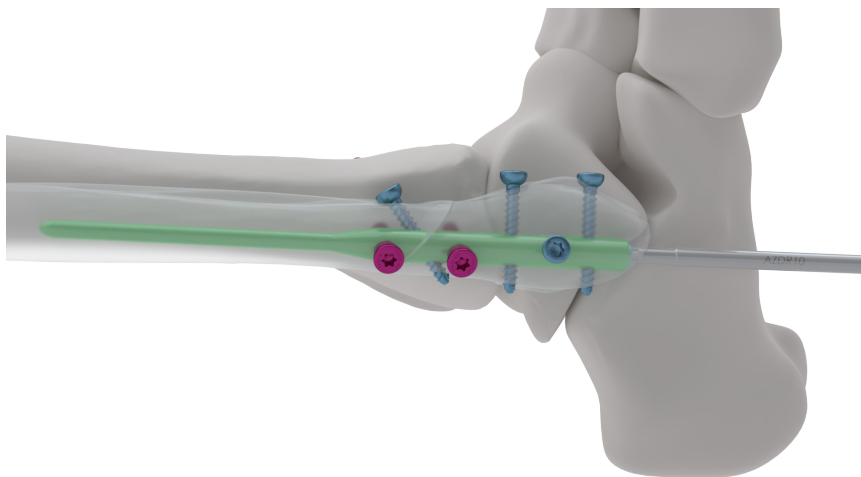
Drill lateral to medial through the nail into the medial cortex of the tibia using the 2.5mm drill (ZF-DRLL-25). Use fluoroscopy for confirmation. Screw length can be measured off the drill guide or by using the depth gauge (ZF-DPTH).

Drive 3.5mm Syndesmotic Screw

Remove the drill and drill guide. Select the 3.5mm screw and secure it to the self-retaining hexalobe driver. Drive the screws through the cannula using the long T10 hexalobe driver (ZF-T10).

9 Insert End Cap

Insert the end cap using the short T10 hexalobe driver (AZDR10) to prevent bone in-growth. The end cap is universal for right and left implants.

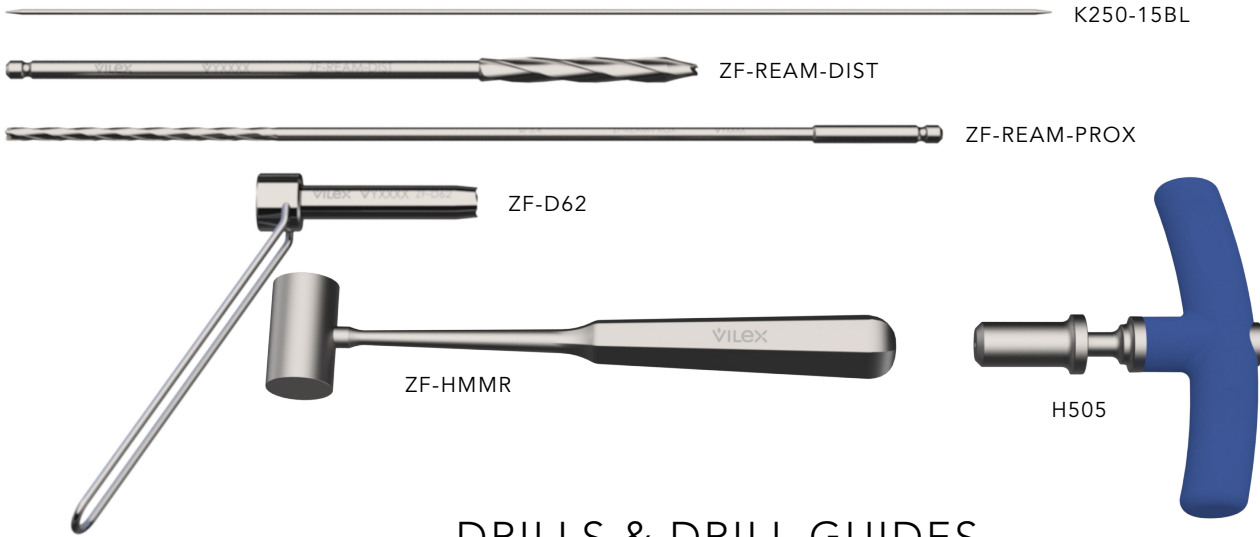


10 Verify Positioning

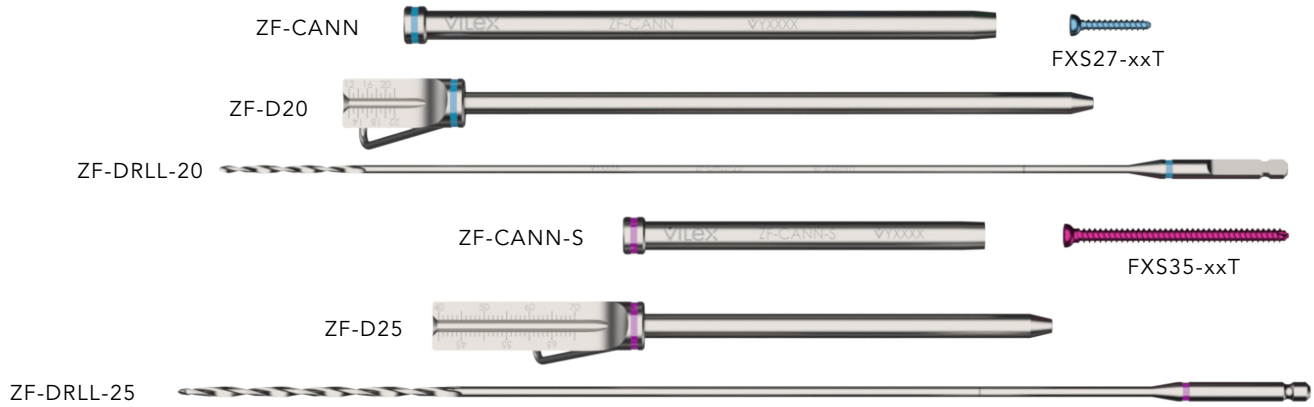
Use bi-planar fluoroscopy (anterior/posterior and medial/lateral) to verify that the implant is fully inserted within the fibula and that the two bone segments are in bone-to-bone contact across the fracture. Close and suture.



REAMERS & NAIL INSERTION



DRILLS & DRILL GUIDES



MEASUREMENT & SCREW INSERTION



Item Listing

VILEX P/N	DESC	CASE QTY	TYPE
N60-32-105CL	Intramedullary Nail, Left Fibula, Titanium, OAL: 105mm	2	Implant
N60-32-105CR	Intramedullary Nail, Right Fibula, Titanium, OAL: 105mm	2	Implant
N60-32-140CL	Intramedullary Nail, Left Fibula, Titanium, OAL: 140mm	2	Implant
N60-32-140CR	Intramedullary Nail, Right Fibula, Titanium, OAL: 140m	2	Implant
N60-32-170CL	Intramedullary Nail, Left Fibula, Titanium, OAL: 170mm	-	Implant
N60-32-170CR	Intramedullary Nail, Right Fibula, Titanium, OAL: 170mm	-	Implant
N60-60-END	End Cap	2	Implant
FXS27-12T	2.7 mm screw x 12mm	4	Implant
FXS27-14T	2.7 mm screw x 14mm	4	Implant
FXS27-16T	2.7 mm screw x 16mm	4	Implant
FXS27-18T	2.7 mm screw x 18mm	4	Implant
FXS27-20T	2.7 mm screw x 20mm	4	Implant
FXS27-22T	2.7 mm screw x 22mm	4	Implant
FXS27-24T	2.7 mm screw x 24mm	4	Implant
FXS27-26T	2.7 mm screw x 26mm	4	Implant
FXS27-28T	2.7 mm screw x 28mm	4	Implant
FXS35-40T	3.5 mm screw x 40mm	3	Implant
FXS35-45T	3.5 mm screw x 45mm	3	Implant
FXS35-50T	3.5 mm screw x 50mm	3	Implant
FXS35-55T	3.5 mm screw x 55mm	3	Implant
FXS35-60T	3.5 mm screw x 60mm	3	Implant
FXS35-65T	3.5 mm screw x 65mm	3	Implant
FXS35-70T	3.5 mm screw x 70mm	3	Implant

Item Listing

VILEX P/N	DESC	CASE QTY	TYPE
H252	AO Ratchet Handle	1	Instrument
H505	AO T-Handle	1	Instrument
HT202	AO Driver	1	Instrument
AZDR10	T10 Self Retaining Torx Screw Driver	1	Instrument
AZPPFRCP	Bone Reduction Clamp, Point to Point	1	Instrument
ZF-CANN	Screw Targeting Cannula (2.7 screws)	4	Instrument
ZF-CANN-S	Screw Targeting Cannula SHORT (3.5 screws)	2	Instrument
ZF-D20	2.0 Drill Guide For 2.7mm Screw	2	Instrument
ZF-D25	2.5 Drill Guide For 3.5mm Screw	2	Instrument
ZF-D62	Reamer Tissue Protector	1	Instrument
ZF-DPTH	Depth Gauge	1	Instrument
ZF-HINT	Hintermann distractor	1	Instrument
ZF-HMMR	Mallet	1	Instrument
ZF-T10	T10 Self Retaining Torx Screw Driver, Long	2	Instrument
ZF-TARG-A	AP Arm	1	Instrument
ZF-TARG-B	Base	1	Instrument
ZF-TARG-L	Lateral Arm	1	Instrument
ZF-TARG-T	Thumb Screw	3	Instrument
ZF-TARG-TL	Thumb Screw, Long	1	Instrument



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