FLEX-THREAD™

# Flex-Thread™ Distal Fibula Intramedullary Nail System

## Surgical Technique Guide

Conventus FLOWER ORTHOPEDICS

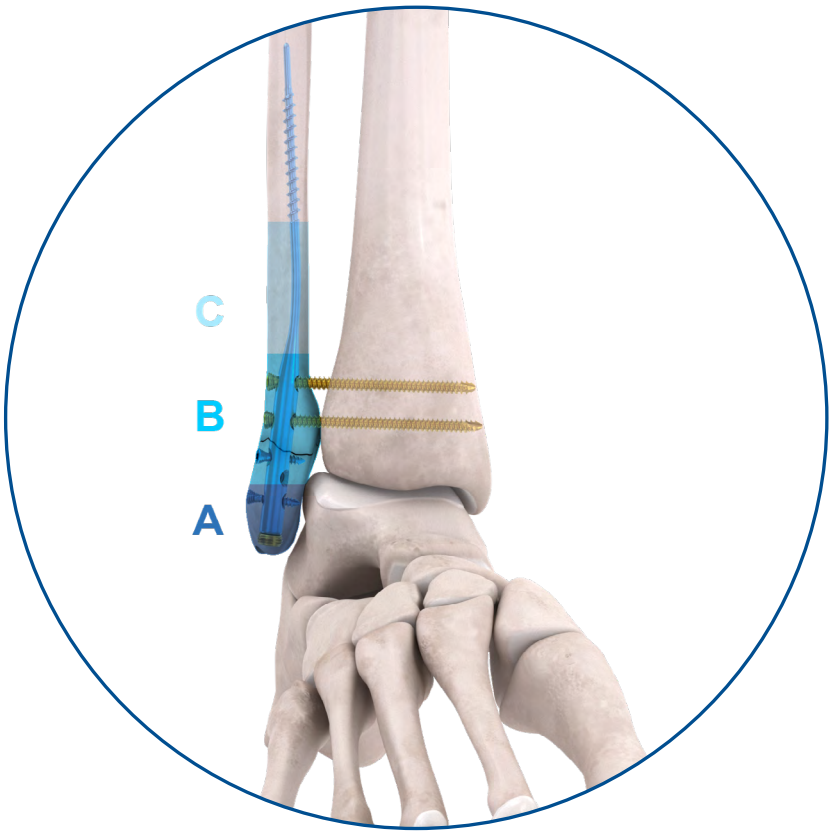
# TABLE OF CONTENTS

# SYSTEM FEATURES

## 1 Intended Use and Contraindications

### 1.1 Intended use

The Flex-Thread™ Distal Fibula Intramedullary Nail System is intended for use in the fixation of fibula fractures and osteotomies.




**Weber Type A** – Refers to an infra-syndesmotic fibular fracture, or a fracture below the syndesmotic ligaments.

**Weber Type B** – Refers to a trans-syndesmotic fibular fracture, or a fracture between the anterior and posterior syndesmotic ligaments.

**Weber Type C** – Refers to a supra-syndesmotic diaphyseal fibular fracture.

### 1.2 Contraindications

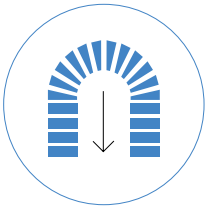
Do not use the Flex-Thread Distal Fibula Intramedullary Nail System in cases of:

- Inadequate bone quantity and/or bone quality
- Foreign body sensitivity to implant material
- Acute localized infections
- Patients with limited blood supply
- Patients who are unwilling or incapable of complying with post-operative care instructions

## 2 AO Principles [1, 2]

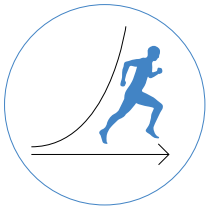
The Flex-Thread Distal Fibula Nail System adheres to the AO Principles of Fracture Management such as:

Fracture reduction to restore anatomical relationships



Fracture fixation providing absolute or relative stability

Preservation of blood supply

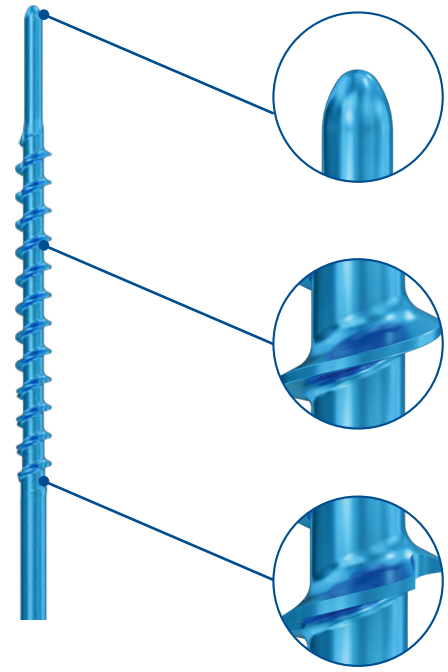


Early and safe mobilization

[1]Muller ME, M Allgower, R Schneider, H Willenegger. Manual of Internal Fixation. 3rd ed. Berlin Heidelberg New York: Springer. 1991
[2]Ruedi TP, RE Buckley, CG Moran. AO Principles of Fracture Management. 2nd ed. Stuttgart, New York: Thieme. 2007

## 3 Nail Design Rationale

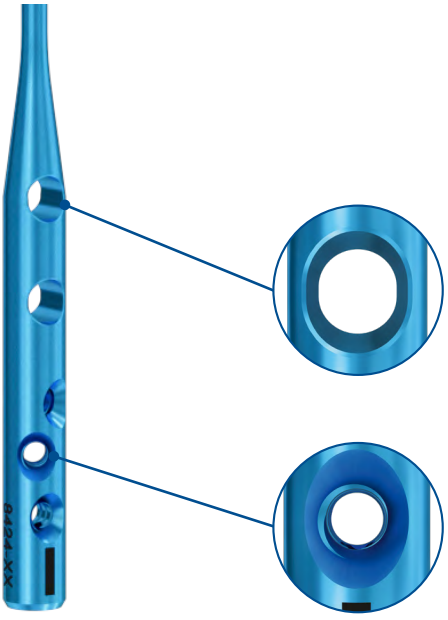
The proprietary Flex-Thread Technology allows the nail to "flex" as it is inserted into the intramedullary canal. This unique flexible design allows for ease of insertion and facilitates the entry point on the distal fibula as well as provides point-contact fixation within the medullary canal.



Atraumatic Blunt Tip Nose:
- Guides Nail Across Fracture Site
- Minimizes Cortical Disruption

Self-Cutting & Self-Tapping Flutes:
- No Tapping Required
- Decreases Procedure Time

Reverse Cutting Flutes:
- Precision Cut Design
- Facilitates Nail Removal



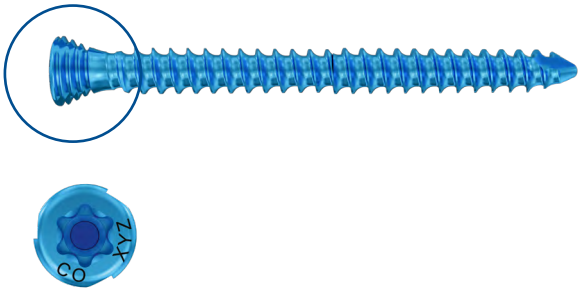
3.8mm Elongated Holes Accept:
- 3.5mm ZERO Profile Interlocking Cortex Screws
- 3.5mm Cortex Screws
- Flexible (Rope) Syndesmotic Fixation Devices

2.7mm Threaded Holes:
- Accept 2.7mm ZERO Profile Interlocking Cortex Screws
- Allow 2.7mm Screws to Lock into Nail
- Provide Improved Fixation

## 4 Screw Design Rationale

### ZERO Profile Interlocking Cortex Screws

- Titanium
- Self-tapping flutes
- ZERO Profile head design minimizes soft tissue irritation
- Threaded head engages cortex for improved fixation
  - 2.7mm screws interdigitate into the nail for improved distal fibula fixation
  - 3.5mm screws available for proximal fibula fixation or syndesmotic fixation



2.7mm Diameter Screws
Light Blue (T8 Driver)
Lengths: 10mm – 30mm (2mm increments)

3.5mm Diameter Screws
Gold (T15 Driver)
Lengths: 10mm – 60mm (2mm increments)
65mm – 70mm (5mm increments)

## 5 End Cap Design Rationale

### 5.1 Threaded End Caps

- Prevent ingrowth of tissue into nail
- Engage distal fibula for additional fixation
- Facilitates nail removal
- Titanium
- T15 Driver (3mm, 5mm, and 10mm)

10mm

5mm

3mm

### 5.2 Low-Profile 1.0mm End Cap

- Prevent ingrowth of tissue into nail
- Facilitates nail removal
- Titanium
- T8 Driver

1mm

## 6 Preoperative Planning

Use AP and Lateral radiographs to evaluate distal fibula canal geometry. Select the appropriate diameter and length of nail.

### Available Nail Sizes

3.5mm Flex-Thread Nail

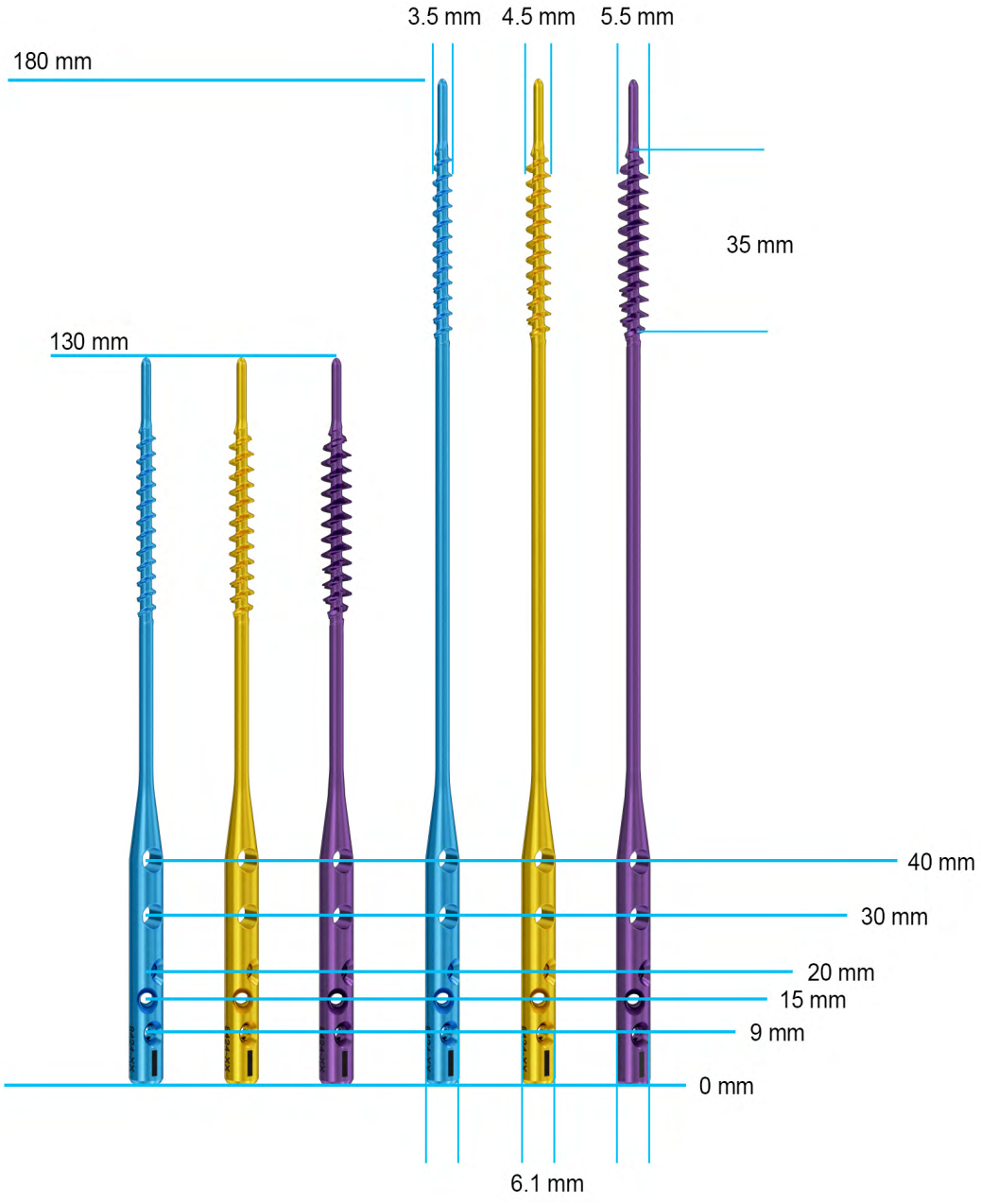
| Item # | Length (mm) |
|---|---|
| 8424-1-S | 130 |
| 8424-3-S | 180 |

4.5mm Flex-Thread Nail

| Item # | Length (mm) |
|---|---|
| 8424-9-S | 130 |
| 8424-11-S | 180 |

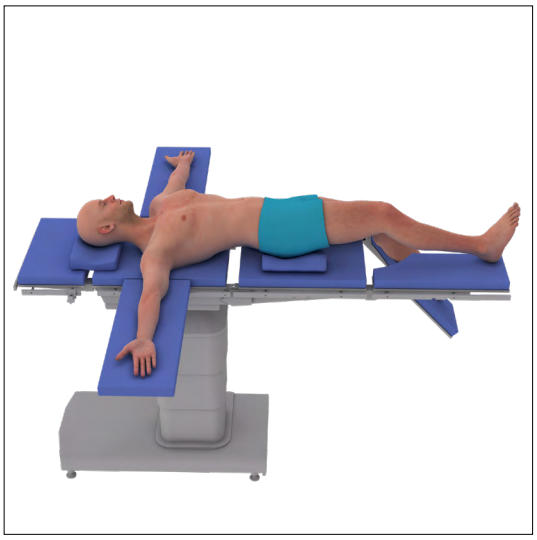
5.5mm Flex-Thread Nail

| Item # | Length (mm) |
|---|---|
| 8424-13-S | 130 |
| 8424-15-S | 180 |



## 7 Patient Positioning

Position the patient supine on a radiolucent table or a flat-top table with a surfboard extension. Place a bump, bean bag, or roll to elevate the ipsilateral hip if desired.



Take care to ensure the needed radiographs are possible through the table in the AP plane. An x-ray of the contralateral leg may also be helpful in order to establish appropriate fibula length and syndesmosis position.

Use AP and Lateral radiographs to evaluate the diameter of the intramedullary canal of the fibula in order to determine the appropriate size (diameter and length) Flex-Thread Distal Fibula Nail.

## 8 Fracture Reduction

**Instruments:**

| | |
|---|---|
| 8553-1 | Bone Reduction Forceps, 5”, Pointed |

Percutaneously reduce the fracture with small pointed bone reduction forceps.

Alternatively, a small incision over the fracture site may be used to facilitate anatomic reduction of the fibula.

**Precautions:**
Take care not to place the reduction clamps in the way of future instrumentation. The clamp handles should be away from the foot to not disturb during the procedure.

Additionally, ensure that the forceps do not obstruct access of future instrumentation to the intermedullary canal.

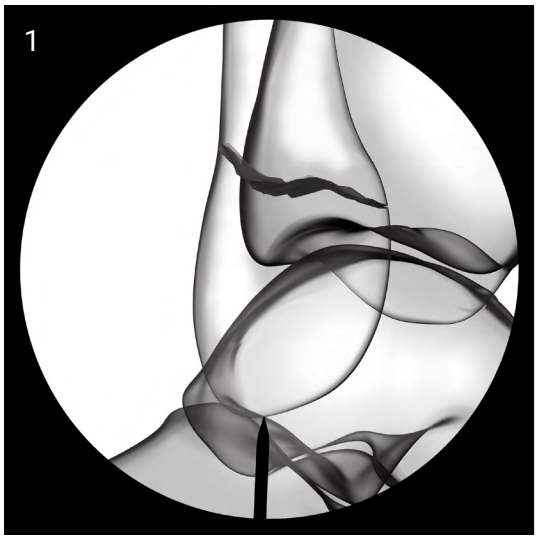
## 9 Starting Point

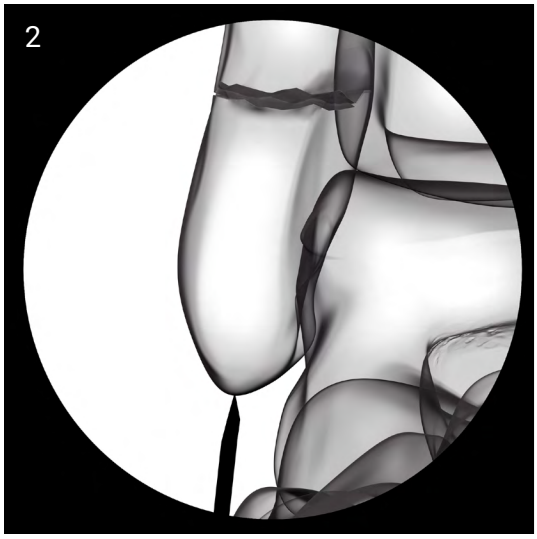
**Instruments:**

| | |
|---|---|
| 8531-1 | 1.6mm x 12” Trocar / Spade Tip Guide Wire |
| 8532-1 | 1.6mm / 6.3mm Soft Tissue Protector Sleeve |
| 8538-1 | 1.6mm K-Wire Offset Sleeve with Handle |

**Optional Instruments:**

| | |
|---|---|
| 8544-1 | 1.6mm K-Wire Offset Insert Sleeve |
| 8527-1 | 6.3mm Cannulated Reamer |
| 8806-1 | Fracture Finger |
| 8808-1 | 1.1mm x 22" Fracture Finger Guide Wire |
| 8548-1 | Screwdriver Handle, Black |




### 9.1 Starting Point Utilizing 1.6mm Guide Wire

Prior to making an incision, a free-hand guide wire and marking pen can be used to mark the skin in order to determine the appropriate trajectory of the initial guide wire.

Confirm the wire position is centrally located in the intramedullary canal in both the AP and lateral views.

Make a small skin incision 1cm distal to the tip of the fibula, down the axis of the fibula.

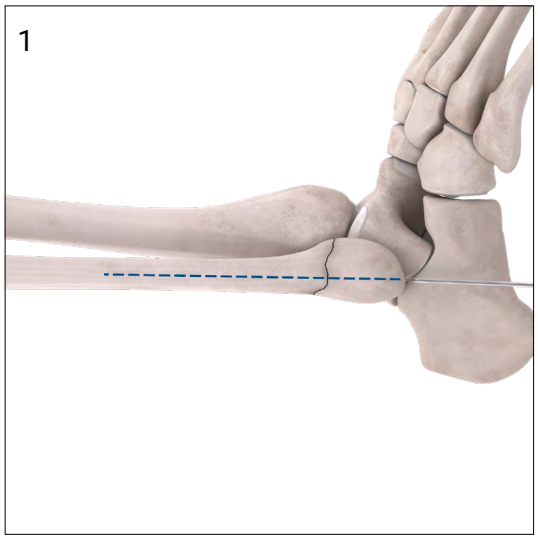
Establish the entry point using the 1.6mm x 12” Trocar / Spade Tip Guide Wire and 1.6mm / 6.3mm Soft Tissue Protector Sleeve. Optionally, the 1.6mm K-Wire Offset Insert Sleeve may be inserted into the 6.3mm end of the Soft Tissue Protector Sleeve to facilitate guide wire insertion if desired.

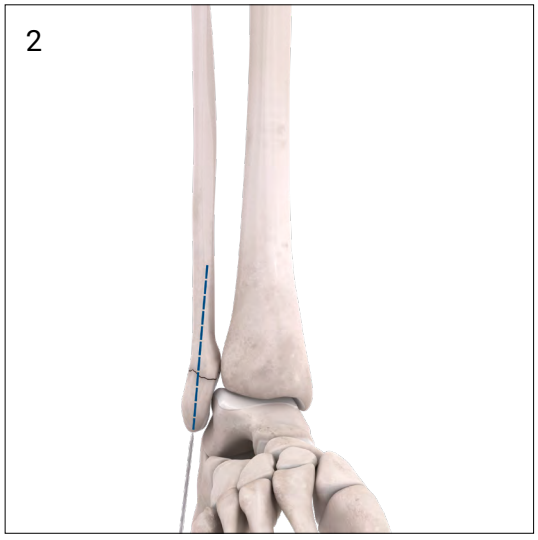
Advance the guide wire 15mm – 20mm into the center of the intramedullary canal and across the fracture site with the wire driver using the oscillating setting. Confirm correct wire position prior to opening the canal.

**Technique Tip:**
If the 1.6mm Guide Wire is difficult to pass across the fracture site, a small lateral incision on the fibula can be made to facilitate wire placement if desired.

**Note:**
Supinating the foot will increase accessibility of the distal fibula.

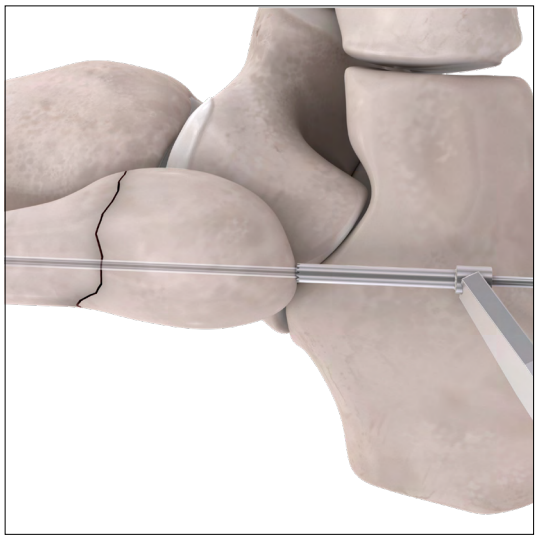
**Precaution:**
Avoid starting too lateral on the distal fibula as it may remove unintended bone from the lateral cortex and/or cause a potential malreduction once nail has been inserted.



**Technique Tip:**

If Guide Wire adjustment is necessary, the 1.6mm K-Wire Offset Sleeve with Handle can be used to insert a second wire that is spaced 2.5mm from the initial Guide Wire.




## Optional Technique:

### 9.2 Starting Point Utilizing Fracture Finger Technique

If the 1.6mm Guide Wire is difficult to pass across the fracture site, the Fracture Finger technique can be used to insert the 1.1mm x 22” Fracture Finger Guide Wire proximally into the fibular canal.

Prior to inserting the Fracture Finger, open the intramedullary canal to a depth of 20mm by slowly advancing the 6.3mm Cannulated Reamer over the 1.6mm x 12” Trocar / Spade Tip Guide Wire.

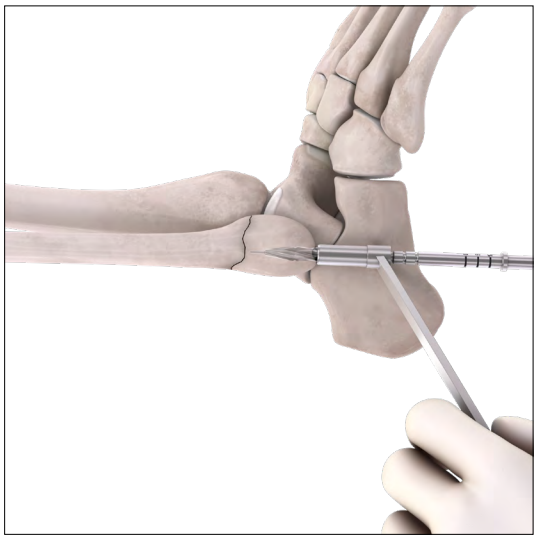
**Technique Tip:**
Half the length of the fluted section of the 6.3mm Cannulated Reamer is approximately 20mm.

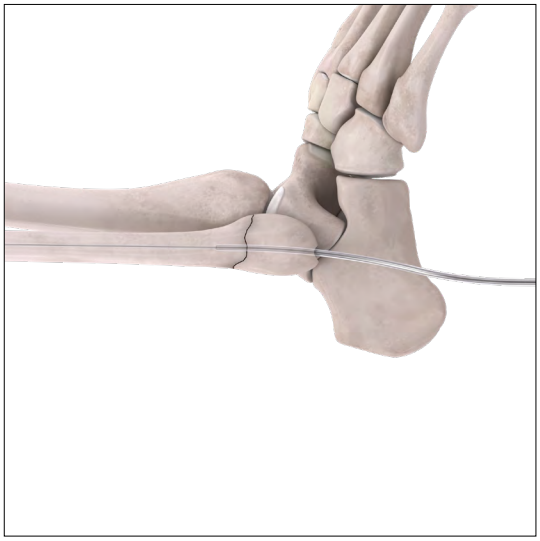
Remove the 1.6mm Guide Wire and 6.3mm Cannulated Reamer.

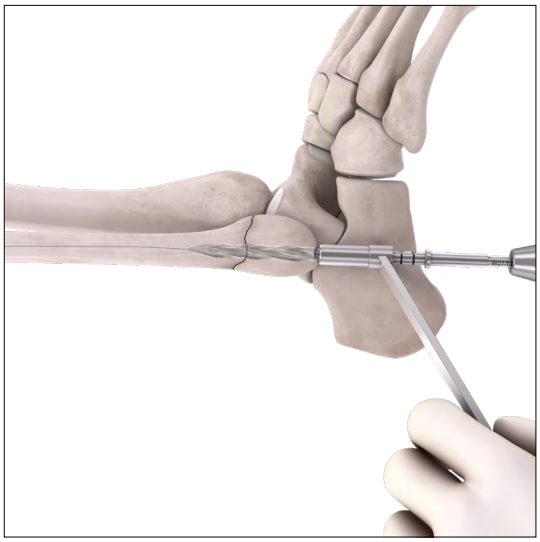
Attach the Screwdriver Handle to the Fracture Finger. Insert the Fracture Finger assembly past the fracture. Direct the tip of the Fracture Finger towards the center of the canal. Insert the 1.1mm x 22” Fracture Finger Guide Wire with the wire driver using the oscillating setting on the k-wire driver. Advance the wire through the hole in the Fracture Finger handle and into the canal.

Remove the Fracture Finger leaving the 1.1mm x 22” Fracture Finger Guide Wire in place.

Confirm correct wire position prior to proceeding to Opening Entry Reaming (Step 10).



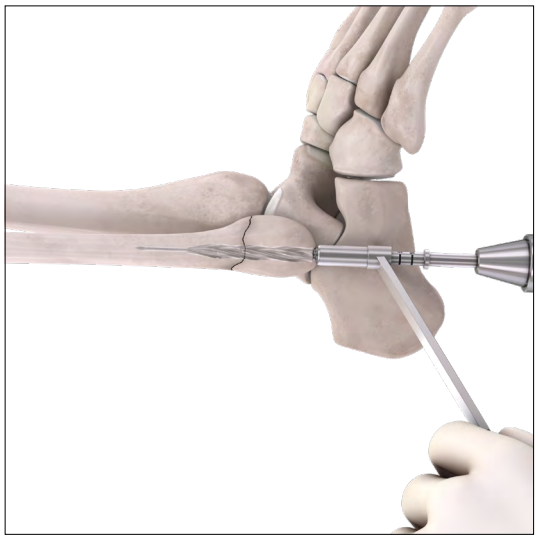




## 10 Opening Entry Reaming

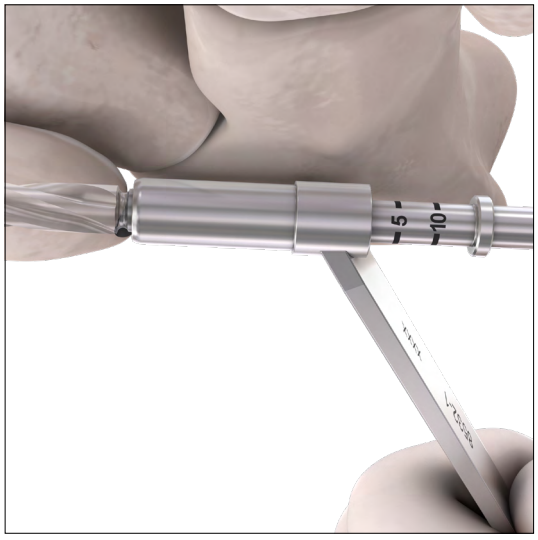
**Instruments:**

| | |
|---|---|
| 8527-1 | 6.3mm Cannulated Reamer |
| 8531-1 | 1.6mm x 12” Trocar / Spade Tip Guide Wire |
| 8532-1 | 1.6mm / 6.3mm Soft Tissue Protector Sleeve |



Open the intramedullary canal using the 6.3mm Cannulated Reamer over the 1.6mm Guide Wire.

The 1.6mm / 6.3mm Soft Tissue Protector Sleeve will protect the surrounding soft tissues.



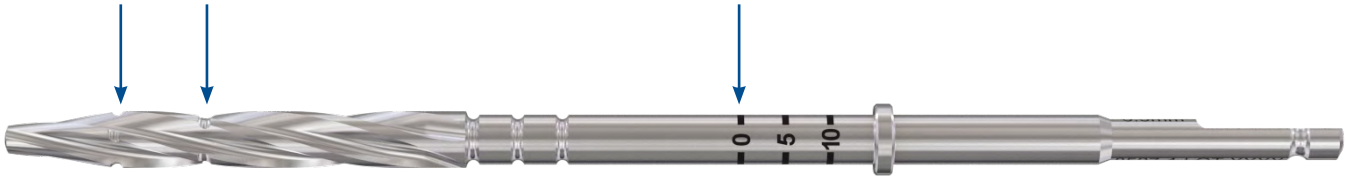

Slowly advance the 6.3mm Cannulated Reamer to a minimum depth of 40mm.

**Technique Tips:**
The depth can be determined by reading the laser markings on the Reamer that align with the back of the Tissue Protector. Alternatively, depth can be determined by using the radiographic notches at the end of the Reamer flutes.

The notches on the flutes indicate where future syndesmotic fixation devices will be implanted if needed clinically.

Flute notches align with the 3.8mm elongated nail holes; notches indicate future syndesmotic fixation placement.

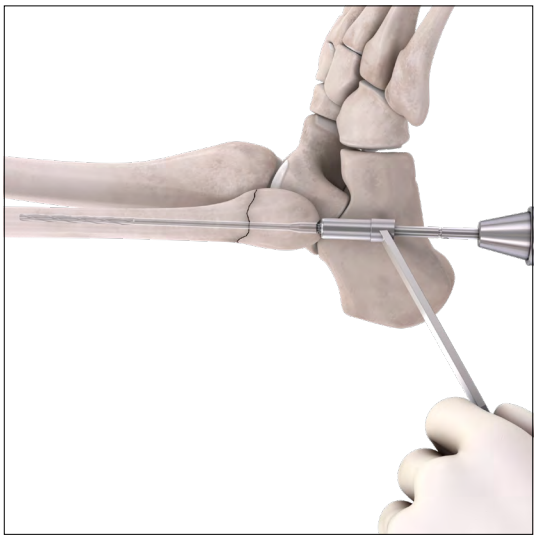
0 indicates minimum depth of 40mm has been reached; 5mm & 10mm markings indicate how far the nail will be buried in the bone.




**Precautions:**
Irrigation during reaming minimizes the potential for thermal necrosis of the bone.

Whenever possible, it may be helpful to over-ream to ensure the nail and syndesmosis fixation devices can be properly positioned.

## 11 Proximal Reaming

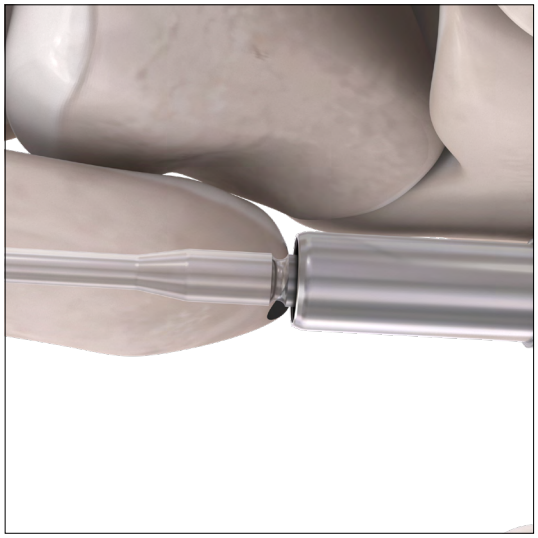


### Instruments:

| | |
|---|---|
| 8528-1-S | 3.2mm Cannulated Reamer |
| 8789-1-S | 4.2mm Cannulated Reamer |
| 8796-1-S | 5.2mm Cannulated Reamer |
| 8531-1 | 1.6mm x 12” Trocar / Spade Tip Guide Wire |
| 8532-1 | 1.6mm / 6.3mm Soft Tissue Protector Sleeve |

### Optional Instruments:

| | |
|---|---|
| 8802-1 | 3.2mm Reamer Sleeve |



Optional Nail Sizing:
Carefully ream the intramedullary canal with the 3.2mm Cannulated Reamer over the 1.6mm Guide Wire. To protect the soft tissues during guide wire insertion and reaming, use the 1.6mm / 6.3mm Soft Tissue Protector Sleeve.

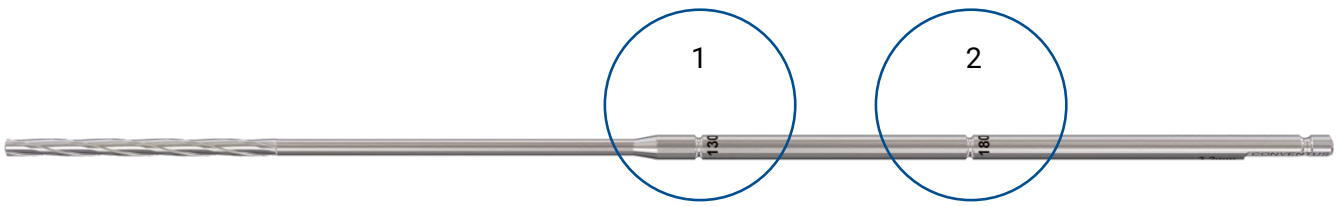
Optionally, the 3.2mm Reamer Sleeve may be inserted into the 1.6mm / 6.3mm Soft Tissue Protector Sleeve to center the 3.2mm Cannulated Reamer.

Slowly advance the Cannulated Reamer to the appropriate depth for the previously selected nail (130mm or 180mm).

In dense bone, allow for bone fragments to clear the flutes by occasionally backing the drill up a few millimeters before readvancing. Monitor progress radiographically using AP and lateral images.

### Technique Tip:

The 3.2mm, 4.2mm and 5.2mm Cannulated Reamers are laser etched and also contain depth mark notches at 130mm (1) and 180mm (2), which corresponds to the nail lengths. This provides a visual reference of where the nail will sit once inside of the bone.



If cortical engagement with the reamer is observed, use the 3.5mm diameter nail. If no cortical engagement is observed, sequentially ream with the 4.2mm Cannulated Reamer. If cortical engagement is observed, use the 4.5mm diameter nail. If no cortical engagement is observed, sequentially ream with the 5.2mm Cannulated Reamer prior to implanting the 5.5mm diameter nail. Monitor progress radiographically using AP and lateral images.

**Precaution:**
Ensure that appropriate reaming has occurred prior to nail insertion. Sequential reaming is recommended for proper canal preparation.

## 12 Nail Assembly

**Instruments:**

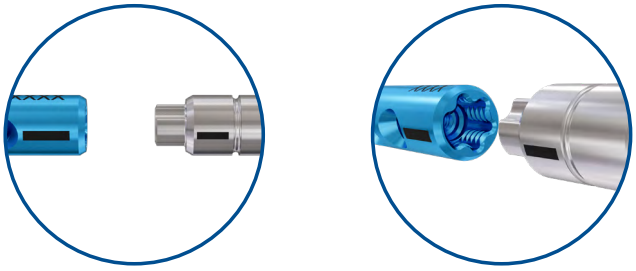
| | |
|---|---|
| 8435-1 | Inserter Shaft |
| 8439-1 | Inserter Draw Rod |

To start the nail assembly, insert the Draw Rod into the Inserter Shaft.

Insert the Draw Rod / Inserter Shaft assembly into the appropriately sized Flex-Thread Nail and turn the knurled end of the Draw Rod clockwise to secure attachment to the Nail.

**Technique Tip:**
The Inserter Shaft tip can only be connected to the nail in one orientation, as indicated by the distal laser line on the nail and the laser line at the tip of the Inserter Shaft.

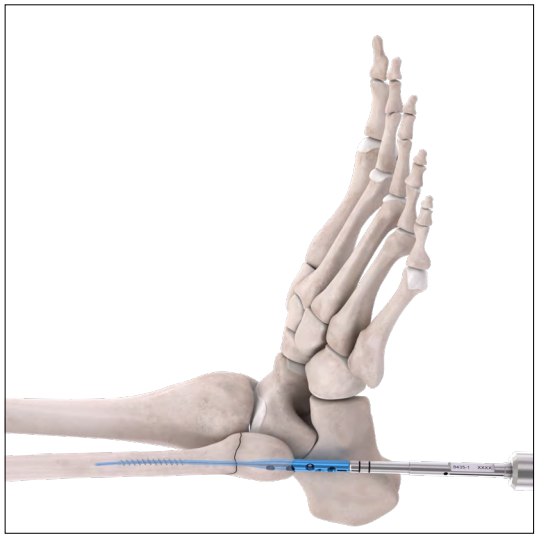
The Inserter Draw Rod must engage the nail and then be securely tightened by hand. Alternatively, it can be tightened by using a T8 driver.



## 13 Nail Insertion

**Instruments:**

| | |
|---|---|
| 8435-1 | Inserter Shaft |
| 8439-1 | Inserter Draw Rod |
| 8437-1 | Ratchet Inserter Handle, Blue |



Attach the Ratchet Inserter Handle to the square coupling on the back of the Inserter Shaft / Draw Rod / Nail assembly.

Prior to inserting nail, ensure that the Blue Ratchet Inserter Handle is set to forward by turning the silver dial on the blue ratchet driver clockwise prior to nail insertion.

Insert the Flex-Thread Nail assembly into the distal fibula by turning the Ratchet Inserter Handle in a clockwise direction.

**Technique Tips:**

The atraumatic blunt tip nose of the nail will facilitate entry into the intramedullary canal.

Monitor nail insertion progress radiographically to ensure that the nail threads engage the cortical walls of the fibula.

**Precautions:**

If significant resistance is met at any point, stop and remove the nail. A smaller diameter nail may be required.

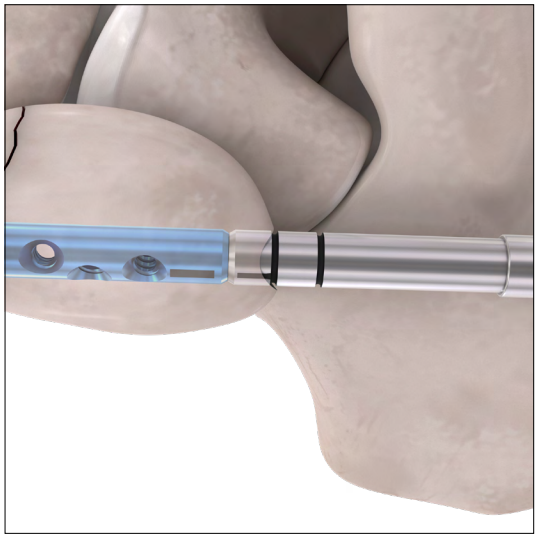
Do not insert the Flex-Thread Nail using power. Only insert the nail using the Ratchet Inserter Handle.

## 14 Confirm Nail Placement and Orientation

The depth of the nail is indicated by 5mm and 10mm graduations on the Inserter Shaft. If the nail is over-inserted, turn the handle counterclockwise until the proper nail position is achieved.

Confirm the distal end of the nail is flush or buried inside the bone. Confirm placement using fluoroscopy.

If syndesmosis fixation is required, note the orientation and placement of the nail. The syndesmosis fixation holes should rest approximately 1cm proximal to the plafond. Additionally, the nail must be rotated using the Ratchet Inserter Handle so the syndesmosis fixation holes are anatomically oriented 30° posterior.



**Technique Tips:**
The Flex-Thread Nail is universal and can be inserted into a Right or Left fibula. The etched laser line on the Inserter Shaft aligns with the two proximal syndesmosis fixation holes. This line can be used as a reference when determining appropriate nail orientation.

After the nail is properly positioned, the Ratchet Inserter Handle should be detached from the Inserter Shaft/Inserter Draw Rod assembly.

## 15 Aiming Arm Attachment

### Instruments:

| | |
|---|---|
| 8433-1 | Aiming Arm |

### Optional Instruments:

| | |
|---|---|
| 8804--1 | 1.6mm K-Wire Stabilization Sleeve |
| 8117-1 | 1.6mm x 8”, Trocar Tip K-Wire |

Once the nail position is confirmed using fluoroscopy, attach the Aiming Arm to the flats of the Inserter Shaft by pushing down and sliding forward until it clicks into position.

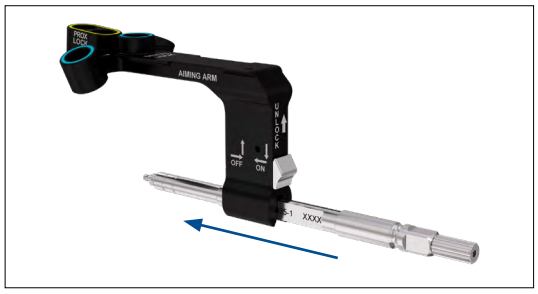
If desired, the Aiming Arm can be provisionally pinned to the fibula using the optional K-Wire Stabilization Sleeve and K-Wires once the syndesmosis holes have been properly aligned.

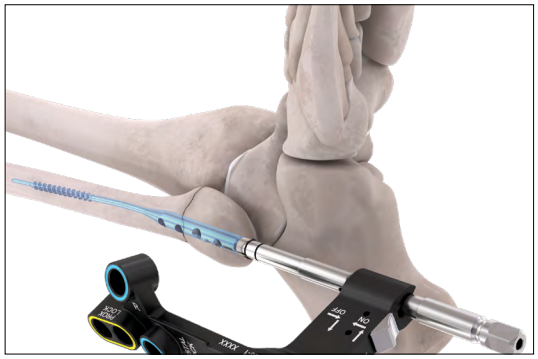
### Note:

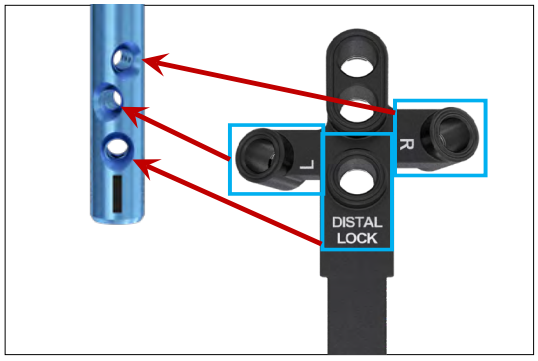
For Distal Locking, the Aiming Arm hole marked:

- "R" for right will target the most proximal 2.7mm threaded screw hole
- "L" for left will target the middle 2.7mm threaded screw hole
- "DISTAL LOCK" will target the most distal 2.7mm threaded screw hole







## 16 Optional: Aiming Arm Provisional Fixation

**Instruments:**

| | |
|---|---|
| 8433-1 | Aiming Arm |
| 8535-1 | 1.6mm / 6.3mm Locking Wire Sleeve |
| 8804--1 | 1.6mm K-Wire Stabilization Sleeve |
| 8117-1 | 1.6mm x 8”, Trocar Tip K-Wire |

Insert the 6.3mm Screw Sleeve into the most "Prox Lock" Aiming Arm hole that is color-coded yellow.

Next, insert the 1.6mm / 6.3mm Locking Wire Sleeve and ensure that the sleeve clicks into place.

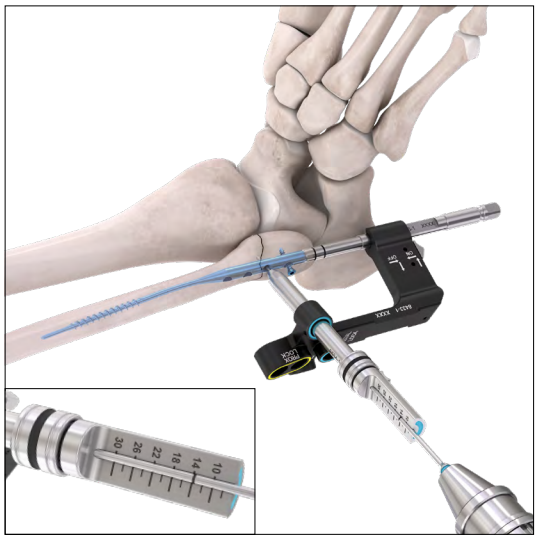
Insert 1.6mm x 8", Trocar Tip K-Wire using k-wire driver and monitor using fluoroscopy.

Alternatively, the additionally available 1.6mm K-Wire Stabilization Sleeve can also be used if a Syndesmosis Screw is desired in the adjacent distal "Prox Lock" aiming arm hole.

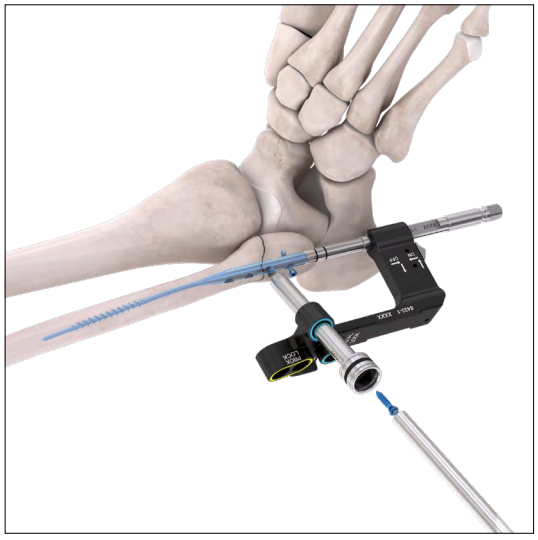
## 17 Distal Interlocking – 2.7mm Screws

### Instruments:

| | |
|---|---|
| 8534-1 | 6.3mm Screw Sleeve |
| 8536-1 | 2.0mm / 6.3mm Locking Drill Sleeve |
| 8529-1-S | 2.0mm x 175mm Calibrated Drill Bit |
| 8524-1-S | T8 Screwdriver Shaft, Self-Retaining |
| 8548-1 | Screwdriver Handle, Black |
| 8433-1 | Aiming Arm |

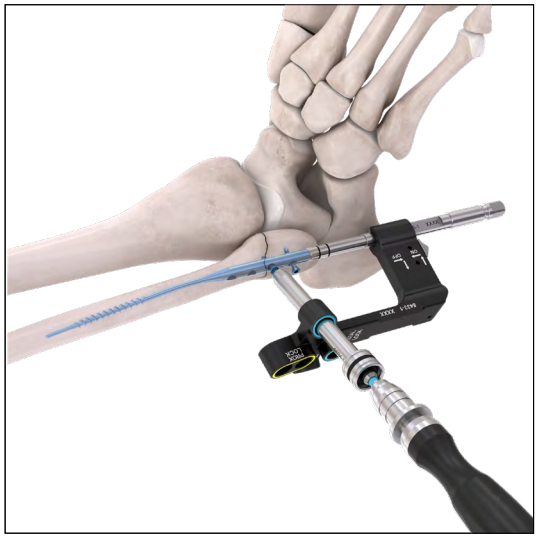


For distal interlocking screw fixation, insert the 6.3mm Screw Sleeve into the Aiming Arm hole that is color-coded blue. Next, insert the 2.0mm / 6.3mm Locking Drill Sleeve. Ensure the Locking Drill Sleeve has been fully seated for accurate measurement. Drill with the 2.0mm Calibrated Drill Bit that is color-coded blue and measure off the back of the sleeve by reading the laser etch line.



When measuring screw length using the calibrated drill bit, fluoroscopy is recommended for accurate measurements. Remove the inner Locking Drill Sleeve prior to screw insertion.

Insert a 2.7mm ZERO Profile Interlocking Cortex Screw through the 6.3mm Screw Sleeve using the Self-Retaining T8 Screwdriver Shaft and the Screwdriver Handle. The remaining two Aiming Arm holes color-coded blue can be used for additional 2.7mm ZERO Profile Interlocking Cortex Screw placement.



The 2.7mm ZERO Profile Interlocking Cortex Screws will thread into the nail for improved fixation.

### Precautions:

The Aiming Arm is marked “R” for Right and “L” for Left, however all 3 distal locking holes can be used for maximum fixation on complex fractures or in poor quality bone.

Care should be taken when using the contralateral holes to avoid potential damage to the posterior structures.

The distal nail holes, color-coded blue on the Aiming Arm, only accept 2.7mm ZERO Profile Interlocking Cortex Screws.

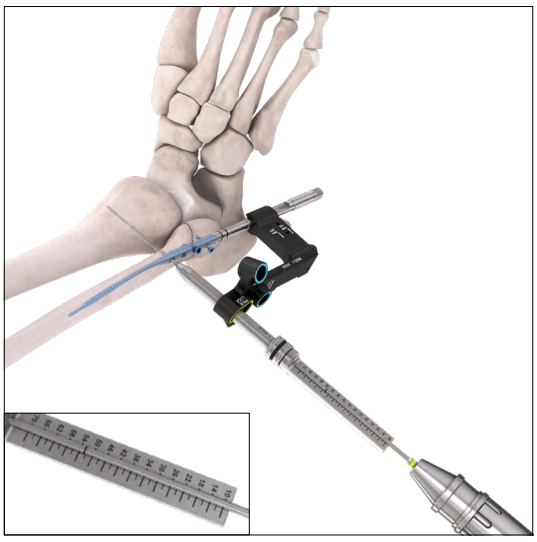
## 18 Proximal Interlocking – 3.5mm Screws or Syndesmotic Devices

The two proximal elongated nail holes accept either 3.5mm ZERO Profile Interlocking Cortex Screws, 3.5mm Cortex Screws or Syndesmotic Fixation Devices. Determine intraoperatively the appropriate fixation for the proximal nail holes.

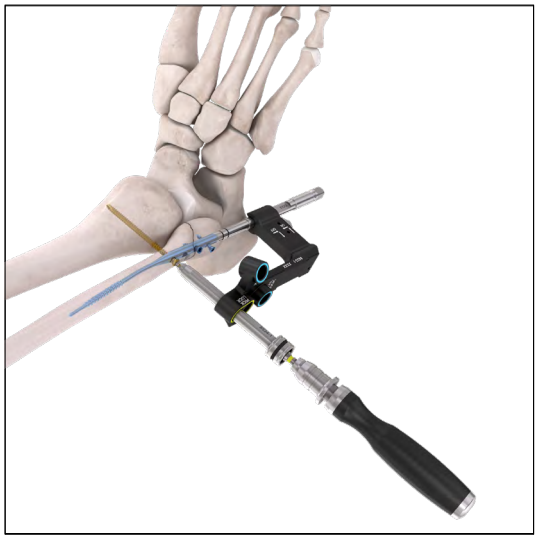
### 18.1 3.5mm Screws

**Instruments:**

| | |
|---|---|
| 8534-1 | 6.3mm Screw Sleeve |
| 8537-1 | 2.5mm / 6.3mm Locking Drill Sleeve |
| 8530-1-S | 2.5mm x 257mm Calibrated Drill Bit |
| 8526-1-S | T15 Screwdriver Shaft, Self-Retaining |
| 8548-1 | Screwdriver Handle, Black |

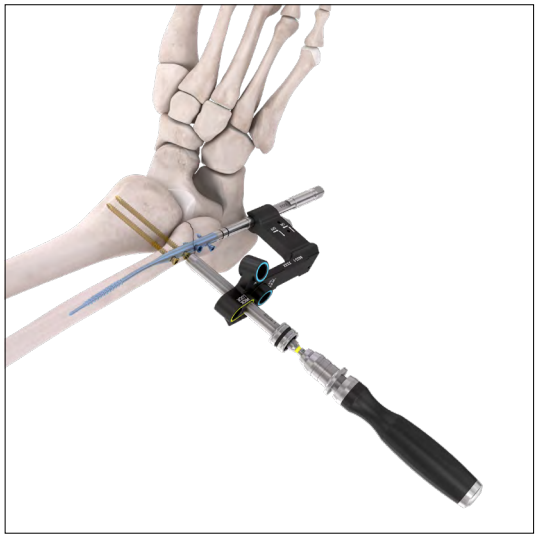


Insert the 6.3mm Screw Sleeve into the “Prox Lock” Aiming Arm hole that is color-coded yellow. Next, insert the 2.5mm / 6.3mm Locking Drill Sleeve. Ensure the Locking Drill Sleeve has been fully inserted for proper measurement. Drill with the 2.5mm Calibrated Drill Bit that is color-coded yellow and measure off the back of the sleeve by reading the laser etch line.



Determine screw length using the drill bit laser markings and read measurement from the back of the Drill Sleeve. Remove the inner Locking Drill Sleeve.

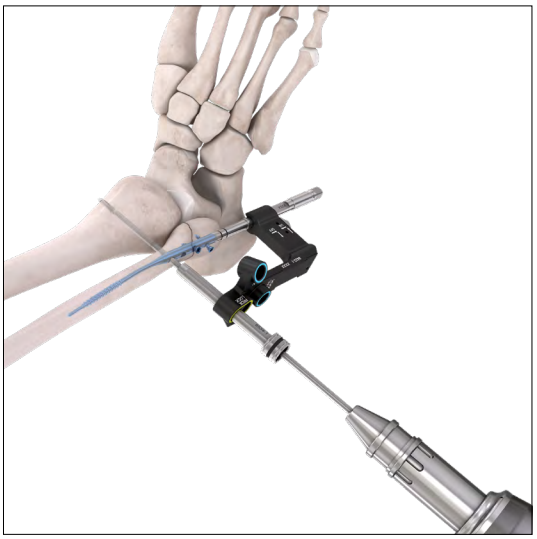
Insert a 3.5mm Cortex Screw or 3.5mm ZERO Profile Interlocking Cortex Screw through the 6.3mm Screw Sleeve using the Self-Retaining T15 Screwdriver Shaft and the Screwdriver Handle. A second 3.5mm Screw can be inserted if desired.



## 18.2 Flexible Syndesmotic Fixation

**Instruments:**

| | |
|---|---|
| 8534-1 | 6.3mm Screw Sleeve |
| 8800-1 | 3.7mm / 6.3mm Locking Drill Sleeve |
| DLF 002 | Constrictor® Rope, 3.7mm Drill Bit |



After reducing the syndesmosis, insert the 6.3mm Screw Sleeve into the "Prox Lock" Aiming Arm hole that is color-coded yellow. Next, insert the 3.7mm / 6.3mm Locking Drill Sleeve.

Drill all four cortices with the 3.7mm Drill Bit from lateral to medial. Advance the drill until the skin is tented on the medial side of the tibia. Make an incision over the tented skin to allow passing pin to exit.

Leave the 3.7mm Drill Bit in place and disconnect the power drill. Remove the 3.7mm / 6.3mm Locking Drill Sleeve and 6.3mm Screw Sleeve.

For flexible syndesmotic fixation using the Constrictor® Rope, refer to the Constrictor® Rope Technique Guide.

**Note:**
The Constrictor® Rope may be inserted/passed through the "Prox Lock" Aiming Arm holes.

It is recommended to remove the Aiming Arm (Step 19) to complete the final placement and tensioning of the Constrictor® Rope.

**Technique Tip:**
It is recommended to use two 3.5mm Cortex Screws (8428-XX-S) through the fibula and tibia for unstable Weber C fractures.

## 19 Aiming Arm Removal

**Instruments:**

| | |
|---|---|
| 8433-1 | Aiming Arm |

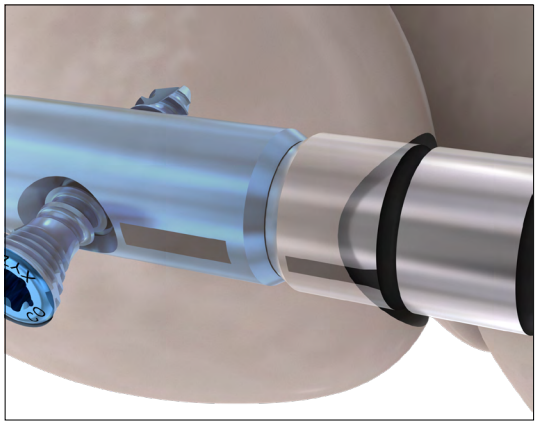
Verify final screw and/or syndesmotic fixation in all planes using fluoroscopy.

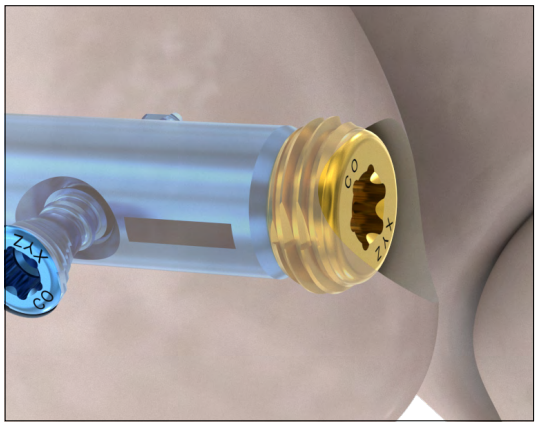
Once verified, the Aiming Arm can be removed.

To remove the Aiming Arm, release the silver thumb lever on the back of the instrument and slide the Aiming Arm distally.

Pull it off of the Inserter Shaft to remove.

## 20 Nail End Cap Insertion





**Instruments:**

| | |
|---|---|
| 8524-1-S | T8 Screwdriver Shaft, Self-Retaining |
| 8526-1-S | T15 Screwdriver Shaft, Self-Retaining |
| 8548-1 | Screwdriver Handle, Black |

An optional Nail End Cap can be inserted into the distal end of the nail to prevent bony ingrowth. End caps are recommended as they may facilitate nail removal later if necessary.

Select the appropriate Threaded End Cap (3mm, 5mm, or 10mm) or Low-Profile 1mm End Cap as indicated by the grooves on the Inserter Shaft. The first etch line is at 5mm and the second etch line is at 10mm.

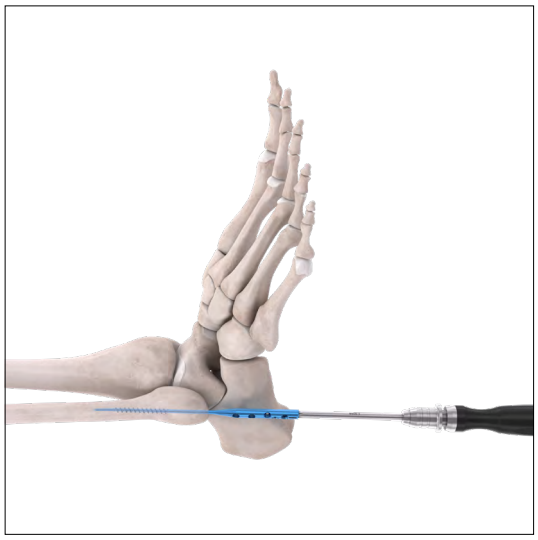
**Note:**
There is NOT a 3mm etch line.

Before inserting the End Cap, detach the Inserter Shaft and Draw Rod from the nail. To detach, turn the knurled end of the Draw Rod counterclockwise to loosen the assembly. Alternatively, it can be loosened by using a T8 driver. Remove the Inserter Shaft and Draw Rod.

Using either the T8 or T15 Screwdriver Shaft connected to the Screwdriver Handle, thread the appropriate End Cap into the distal end of the Nail.

**Precaution:**
Do not insert Nail End Caps using power.Threaded End Caps (3mm, 5mm, 10mm) use the T15 for insertion. The Low-Profile, 1mm End Cap uses the T8.

## 21 Optional: Implant Removal



### Instruments:

| | |
|---|---|
| 8524-1-S | T8 Screwdriver Shaft, Self-Retaining |
| 8526-1-S | T15 Screwdriver Shaft, Self-Retaining |
| 8555-1 | T25 Screwdriver Shaft, Self-Retaining |
| 8548-1 | Screwdriver Handle, Black |

### Optional Instrument:

| | |
|---|---|
| EZO 135 | Removal Tool |

If present, remove the Nail End Cap using the either the T15 Screwdriver and Screwdriver Handle for 3mm, 5mm, 10mm End Caps. Or, use the T8 Screwdriver and Screwdriver Handle for Low-Profile, 1mm End Caps.

Remove all 3.5mm screws using the T15 Screwdriver and Screwdriver Handle and all 2.7mm screws using the T8 Screwdriver and Screwdriver Handle.

If a Constrictor® Rope or other flexible syndesmotic fixation was used, cut the lateral end and remove any button hardware.

Remove the nail by turning counterclockwise with the T25 Screwdriver and Screwdriver Handle.

Confirm all implants have been successfully removed using fluoroscopy.

### Technique Tips:

T8 Driver - Removes 2.7mm Screws and Low-Profile, 1mm End Caps

T15 Driver - Removes 3.5mm Screws and Threaded End Caps (3mm, 5mm, 10mm)

T25 Driver - Removes all Nails

The Screwdriver Handle is universal and will connect to all of the Screwdriver Shafts.

Please refer to the Flex-Thread™ Removal Tool brochure for the EZO 135 product overview, design rationale and surgical technique (FOC 1089).

# PRODUCT INFORMATION

## 22 Instruments

Bone Reduction Forceps, 5”, Pointed
8553-1



1.6mm x 12", Trocar / Spade Tip Guide Wire
8531-1


1.6mm / 6.3mm Soft Tissue Protector Sleeve
8532-1


1.6mm, K-Wire Offset Insert Sleeve
8544-1

1.6mm K-Wire Offset Sleeve with Handle
8538-1



Cannulated Reamers - AO Quick Connect
8528-1-S 3.2mm Cannulated Reamer
8789-1-S 4.2mm Cannulated Reamer
8796-1-S 5.2mm Cannulated Reamer

6.3mm Cannulated Reamer,
AO Quick Connect
8527-1


Inserter Shaft
8435-1

Inserter Draw Rod
8439-1

Ratchet Inserter Handle, Blue
8437-1


Aiming Arm
8433-1


1.6mm / 6.3mm Locking Wire Sleeve
8535-1



1.6mm x 8", Trocar Tip K-Wire
8117-1


6.3mm Screw Sleeve
8534-1

2.0mm / 6.3mm Locking Drill Sleeve
8536-1


2.0mm x 175mm Calibrated Drill Bit,
AO Quick Connect
8529-1-S


T8 Screwdriver Shaft, Self-Retaining,
AO Quick Connect
8524-1-S

Screwdriver Handle, Black,
AO Quick Connect
8548-1

2.5mm / 6.3mm Locking Drill Sleeve
8537-1

2.5mm x 257mm Calibrated Drill Bit,
AO Quick Connect
8530-1-S


T15 Screwdriver Shaft, Self-Retaining,
AO Quick Connect
8526-1-S


3.7mm / 6.3mm Locking Drill Sleeve
8800-1



Constrictor® Rope, 3.7mm Drill Bit
DLF 002


T25 Screwdriver Shaft, Self-Retaining,
AO Quick Connect
8555-1

Fracture Finger
8806-1

1.1mm x 22" Fracture Finger Guide Wire
8808-1


3.2mm Reamer Sleeve
8802-1

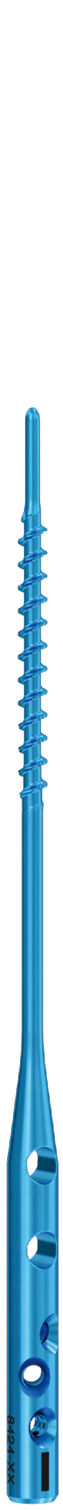
1.6mm K-Wire Stabalization Sleeve
8804-1

Removal Tool
EZO 135

## 23 Sterile Implants

### Nails

Flex-Thread Distal Fibula Nail, 3.5mm, Titanium



8424-1-S
130mm

8424-3-S
180mm

Flex-Thread Distal Fibula Nail, 4.5mm, Titanium

8424-9-S
130mm

8424-11-S
180mm

Flex-Thread Distal Fibula Nail, 5.5mm, Titanium

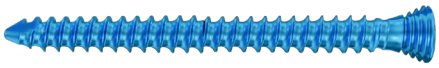
8424-13-S
130mm

8424-15-S
180mm

## Screws

Flex-Thread 3.5mm Cortex Screws, T15
8428-XX-S*

Flex-Thread 3.5mm ZERO Profile Interlocking Cortex Screws, T15
8525-XX-S*



Flex-Thread 2.7mm ZERO Profile Interlocking Cortex Screws, T8
8426-XX-S*

## End Caps

Flex-Thread End Cap, 10mm, T15
8522-2-S

Flex-Thread End Cap, 5mm, T15
8522-1-S

Flex-Thread End Cap, 3mm, T15
8522-3-S

Flex-Thread End Cap, 1mm, T8
8430-1-S

## Flexible Syndesmosis Fixation

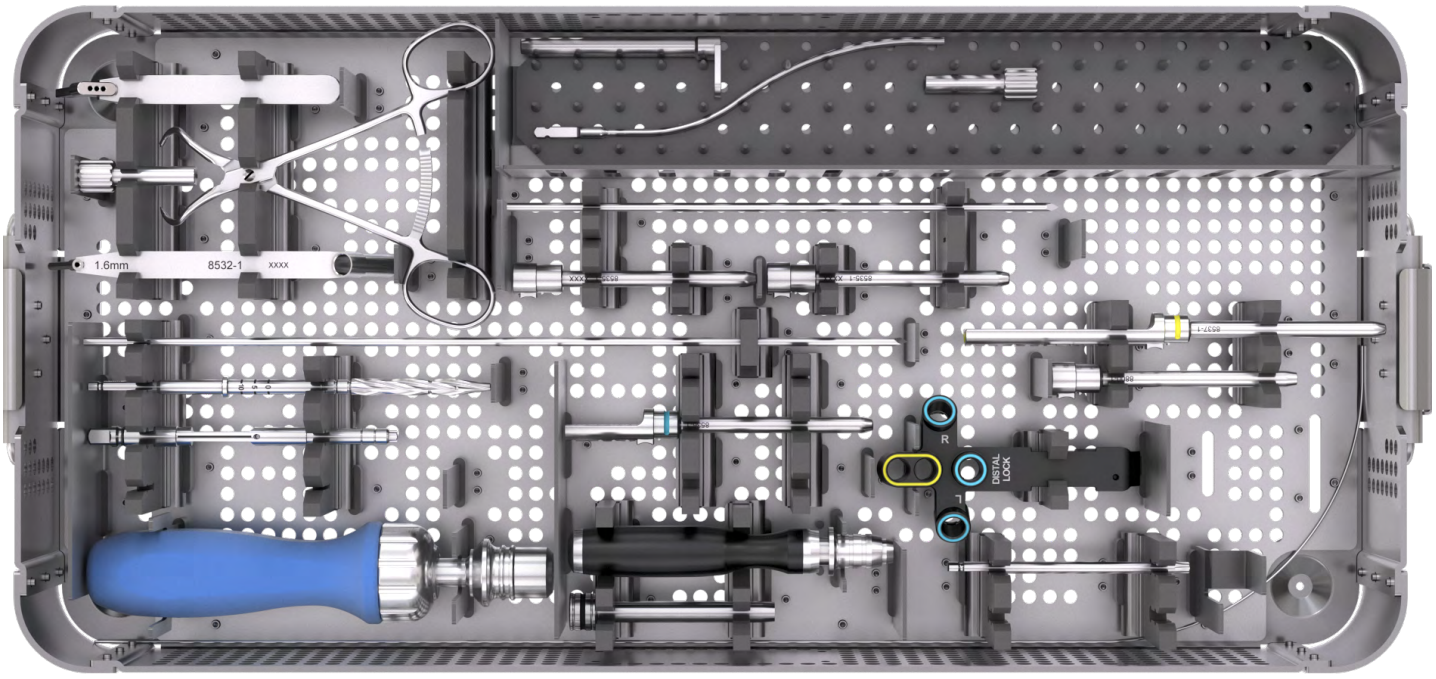
Constrictor® Rope
DLF 002

## FlowerCube™

Flex-Thread Fibula FlowerCube™

* Available lengths refer to page 32

## 24 Instrument Tray Layout

## 25 Nails, Screws & End Caps

### Screws

| | Flex-Thread ZERO Profile Interlocking Cortex Screws | | Flex-Thread Cortex Screws |
|---|---|---|---|
| **Length (mm)** | **2.7mm** | **3.5mm** | **3.5mm** |
| 10 | 8426-10-S | 8525-10-S | 8428-10-S |
| 12 | 8426-12-S | 8525-12-S | 8428-12-S |
| 14 | 8426-14-S | 8525-14-S | 8428-14-S |
| 16 | 8426-16-S | 8525-16-S | 8428-16-S |
| 18 | 8426-18-S | 8525-18-S | 8428-18-S |
| 20 | 8426-20-S | 8525-20-S | 8428-20-S |
| 22 | 8426-22-S | 8525-22-S | 8428-22-S |
| 24 | 8426-24-S | 8525-24-S | 8428-24-S |
| 26 | 8426-26-S | 8525-26-S | 8428-26-S |
| 28 | 8426-28-S | 8525-28-S | 8428-28-S |
| 30 | 8426-30-S | 8525-30-S | 8428-30-S |
| 32 | | 8525-32-S | 8428-32-S |
| 34 | | 8525-34-S | 8428-34-S |
| 36 | | 8525-36-S | 8428-36-S |
| 38 | | 8525-38-S | 8428-38-S |
| 40 | | 8525-40-S | 8428-40-S |
| 42 | | 8525-42-S | 8428-42-S |
| 44 | | 8525-44-S | 8428-44-S |
| 46 | | 8525-46-S | 8428-46-S |
| 48 | | 8525-48-S | 8428-48-S |
| 50 | | 8525-50-S | 8428-50-S |
| 52 | | 8525-52-S | 8428-52-S |
| 54 | | 8525-54-S | 8428-54-S |
| 56 | | 8525-56-S | 8428-56-S |
| 58 | | 8525-58-S | 8428-58-S |
| 60 | | 8525-60-S | 8428-60-S |
| 65 | | 8525-65-S | 8428-65-S |
| 70 | | 8525-70-S | 8428-70-S |

## Nails

| Flex-Thread Nails | | | |
|---|---|---|---|
| **Length (mm)** | **3.5mm** | **4.5mm** | **5.5mm** |
| 130 | 8424-1-S | 8424-9-S | 8424-13-S |
| 180 | 8424-3-S | 8424-11-S | 8424-15-S |

## End Caps

| Flex-Thread End Caps | | |
|---|---|---|
| **Length (mm)** | | |
| 1 | T8 | 8430-1-S |
| 3 | T15 | 8522-3-S |
| 5 | T15 | 8522-1-S |
| 10 | T15 | 8522-2-S |

# APPENDIX

## 26 Additionally Available Implants

### Medium Cannulated FlowerCube
Contains 3.0mm, 3.5mm, 4.0mm & 4.5mm partially threaded cannulated screws, washers, and instrumentation.

### Titanium Cannulated Screws (4.0mm)
CNP 4XX (16mm – 60mm length)
Cannulated Screw, Partially Threaded

### Titanium Cannulated Screws (4.5mm)
CNP 5XX (30mm – 70mm length)
Cannulated Screw, Partially Threaded

### Titanium Washers
OSW 100 - Screw Washer for
3.0mm / 3.5mm / 4.0mm / 4.5mm Screws

### Fibula FlowerCube
Contains straight and anatomic fibula plates, locking and non-locking screws, and instrumentation.

### Straight Locking Fibula Plates

| | | |
|---|---|---|
| DLF 505 | Length: 59mm | 5 Holes |
| DLF 506 | Length: 71mm | 6 Holes |
| DLF 507 | Length: 83mm | 7 Holes |
| DLF 508 | Length: 95mm | 8 Holes |
| DLF 510 | Length: 119mm | 10 Holes |

### Straight Locking Fibula Plates with Syndesmotic Slot

| | | |
|---|---|---|
| DLF 006 | Length: 77mm | 6 Holes |
| DLF 007 | Length: 89mm | 7 Holes |
| DLF 008 | Length: 101mm | 8 Holes |

### Anatomic Distal Fibula Plates

| | | | |
|---|---|---|---|
| DLF 104 | Left | Length: 84.5mm | 4 Holes |
| DLF 204 | Right | Length: 84.5mm | 4 Holes |
| DLF 105 | Left | Length: 96.5mm | 5 Holes |
| DLF 205 | Right | Length: 96.5mm | 5 Holes |
| DLF 107 | Left | Length: 120.5mm | 7 Holes |
| DLF 207 | Right | Length: 120.5mm | 7 Holes |

## 27 Clinical References

Appleton P, McQueen M, Court-Brown C. The fibula nail for treatment of ankle fractures in elderly and high-risk patients. Techniques in Foot & Ankle Surg. 2006;5(3):204-208.

Walton DM, Adams SB, Parekh SG. Intramedullary fixation for fractures of the distal fibula. Foot Ankle Int. 2016;37(1):115-123.

## 28 References / Disclaimers

Testing data on file at Conventus Flower Orthopedics.

This description of technique is provided as an educational tool and clinical aid to assist properly licensed medical professionals in the usage of specific Conventus Orthopaedics and Flower Orthopedics products.

The medical professional must use their professional judgment in making any final determinations in product usage and technique. In doing so, the medical professional should rely on their own training and experience and should conduct a thorough review of pertinent medical literature and the product instructions for use.

Postoperative management is patient-specific and dependent on the treating professional's assessment. Individual results will vary and not all patients will experience the same postoperative activity level or outcomes.

Please also refer to the Flex-Thread reprocessing instructions for cleaning and sterilization information.

## 29 Acknowledgements

We would like to extend our sincere thanks and appreciation to the following surgeons who contributed to the Flex-Thread Distal Fibula Intramedullary Nail System:

**Samuel B. Adams Jr., MD**
Duke Health
Associate Professor of
Orthopaedic Surgery

**Michael Gardner, MD**
Stanford University
Professor of Orthopaedic Surgery

**David N. Garras, MD**
Midwest Orthopaedic Consultants
Foot and Ankle Specialist

## 30 Notes

Conventus Flower Orthopedics
100 Witmer Road, Suite 280
Horsham, PA 19044
T: 877.778.8587

FlowerOrtho.com



**Caution:** Federal law restricts this device to sale by or on the order of a licensed physician.



FOC 1054 Rev E 08/22