

Flex-Thread™ Distal Fibula Intramedullary Nail System

Surgical Technique Guide





TABLE OF CONTENTS

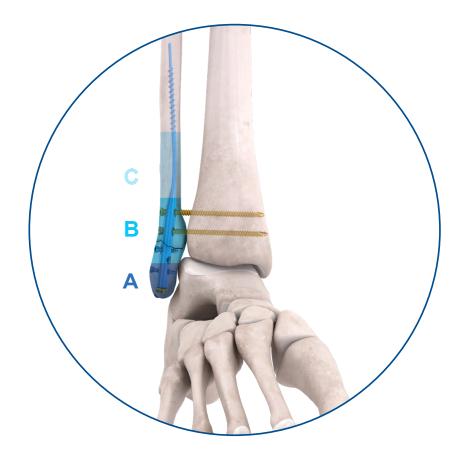
SYSTEM FEATURES	2
1 INTENDED USE AND CONTRAINDICATIONS	2
1.1 INTENDED USE	2
1.2 CONTRAINDICATIONS	2
2 AO PRINCIPLES	3
3 NAIL DESIGN RATIONALE	4
4 SCREW DESIGN RATIONALE	5
5 END CAP DESIGN RATIONALE	5
SURGICAL TECHNIQUE	6
6 PREOPERATIVE PLANNING	6
7 PATIENT POSITIONING	7
8 FRACTURE REDUCTION	8
9 STARTING POINT	9
10 OPENING ENTRY REAMING	13
11 PROXIMAL REAMING	14
12 NAIL ASSEMBLY	16
13 NAIL INSERTION	17
14 CONFIRM NAIL PLACEMENT AND ORIENTATION	18
15 AIMING ARM ATTACHMENT	19
16 OPTIONAL: AIMING ARM PROVISIONAL FIXATION	20
17 DISTAL INTERLOCKING – 2.7MM SCREWS	21
18 PROXIMAL INTERLOCKING – 3.5MM SCREWS OR SYNDESMOTIC DEVICES 18.1 3.5MM SCREWS	22 22
18.2 FLEXIBLE SYNDESMOTIC FIXATION: Constrictor® Rope	23
19 AIMING ARM REMOVAL	24
20 NAIL END CAP INSERTION	24
21 OPTIONAL: IMPLANT REMOVAL	25
PRODUCT INFORMATION	26
22 INSTRUMENTS	26
23 STERILE IMPLANTS	29
24 INSTRUMENT TRAY LAYOUT	31
IMPLANTS	32
25 NAILS, SCREWS & END CAPS	32
APPENDIX	34
26 ADDITIONALLY AVAILABLE IMPLANTS	34
27 CLINICAL REFERENCES	35
28 REFERENCES / DISCLAIMERS	35
29 THANK YOU	35
30 NOTES	36

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

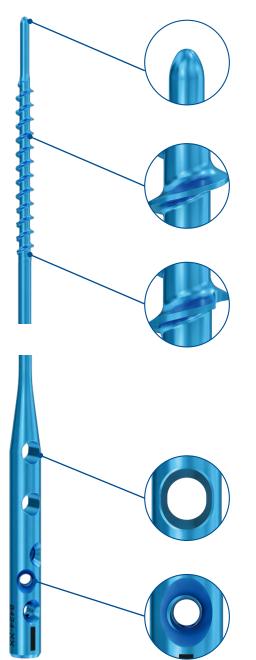


Early and safe mobilization

¹Muller ME, M Allgower, R Schneider, H Willenegger. Manual of Internal Fixation. 3rd ed. Berlin Heidelberg New York: Springer. 1991 ²Ruedi 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



- 3.5mm ZERO Profile Interlocking Cortex Screws
- 3.5mm Cortex Screws
- Flexible (Rope) Syndesmotic Fixation Devices

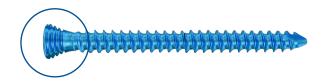
2.7mm Threaded Holes:

- 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)

5.2 Low-Profile 1.0mm End Cap

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









10mm

5mm

3mm

1_mm

SURGICAL TECHNIQUE

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	FI	ex-T	Thread	Nail
0.0111111		CA I	HICAU	INGII

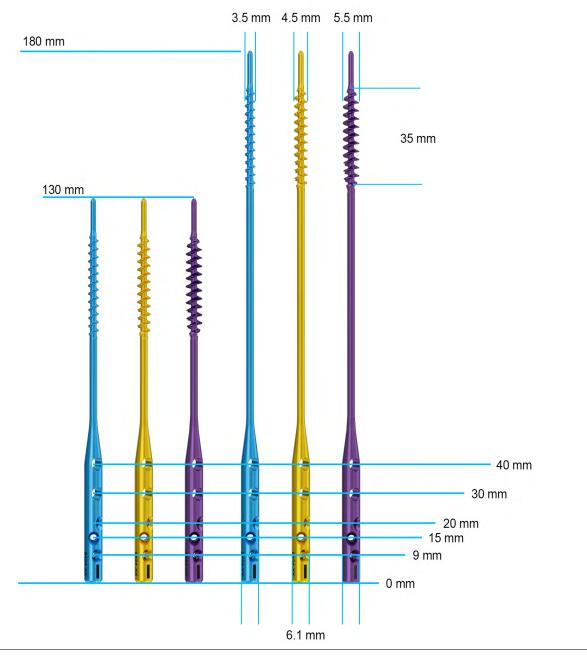
Item #	Length (mm)
8424-1-S	130
8424-3-S	180

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:

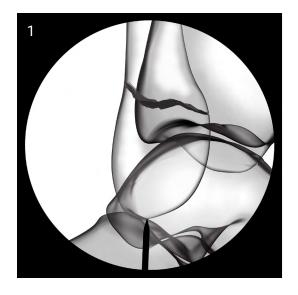


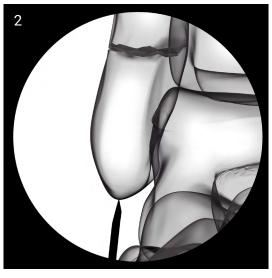
Prior to making an incision, a free-hand guide wire and marking pen can be used to mark the skin in order to determine the appropriate trajectory of the initial guide wire.

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:

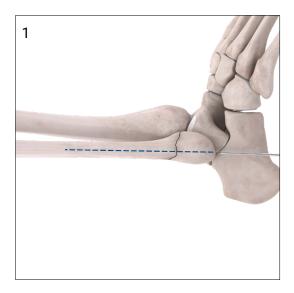
If the 1.6mm Guide Wire is difficult to pass across the fracture site, a small lateral incision on the fibula can be made to facilitate wire placement if desired.

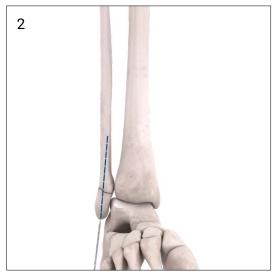
Note:

Supinating the foot will increase accessibility of the distal fibula.

Precaution:

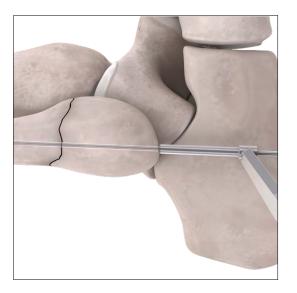
Avoid starting too lateral on the distal fibula as it may remove unintended bone from the lateral cortex and/or cause a potential malreduction once nail has been inserted.





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:

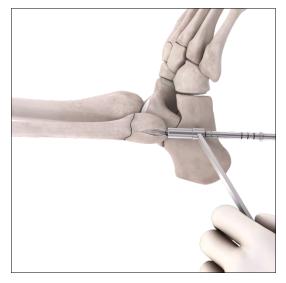
Half the length of the fluted section of the 6.3mm Cannulated Reamer is approximately 20mm.

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.

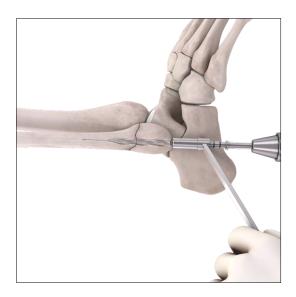
The 1.6mm / 6.3mm Soft Tissue Protector Sleeve will protect the surrounding soft tissues.

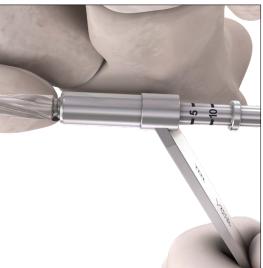
Slowly advance the 6.3mm Cannulated Reamer to a minimum depth of 40mm.

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.

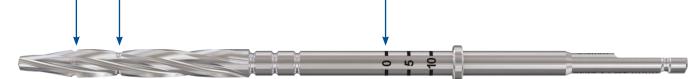
The notches on the flutes indicate where future syndesmotic fixation devices will be implanted if needed clinically.





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
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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).

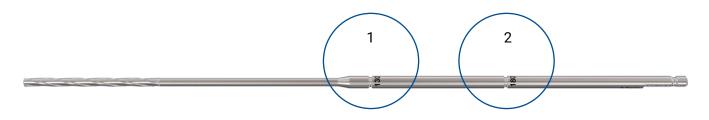
In dense bone, allow for bone fragments to clear the flutes by occasionally backing the drill up a few millimeters before readvancing. Monitor progress radiographically using AP and lateral images.

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 Shaft8439-1 Inserter Draw Rod

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

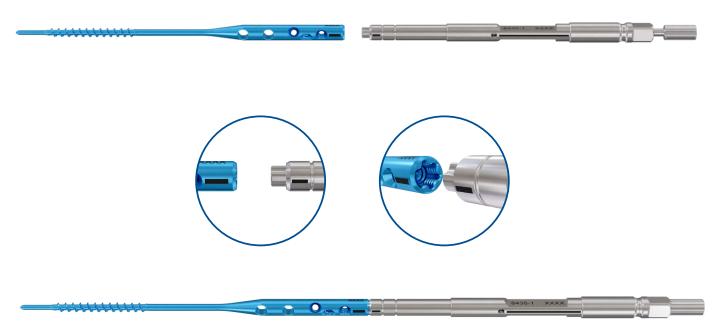
Insert the Draw Rod / Inserter Shaft assembly into the appropriately sized Flex-Thread Nail and turn the knurled end of the Draw Rod clockwise to secure attachment to the Nail.

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.

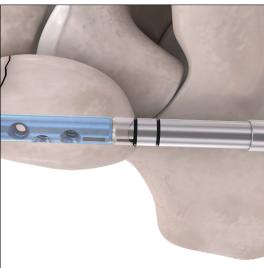
If syndesmosis fixation is required, note the orientation and placement of the nail. The syndesmosis fixation holes should rest approximately 1cm proximal to the plafond. Additionally, the nail must be rotated using the Ratchet Inserter Handle so the syndesmosis fixation holes are anatomically oriented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

1.6mm K-Wire Stabilization Sleeve1.6mm 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:

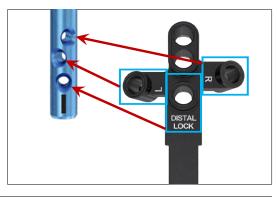
- "R" for right will target the most proximal 2.7mm threaded screw hole
- "L" for left will target the middle 2.7mm threaded screw hole
- "DISTAL LOCK" will target the most distal 2.7mm threaded screw hole











16 Optional: Aiming Arm Provisional Fixation

Instruments:

8433-1	Aiming Arm
8535-1	1.6mm / 6.3mm Locking Wire Sleeve
88041	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
8800-1
DLF 002
6.3mm Screw Sleeve
3.7mm / 6.3mm Locking Drill Sleeve
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.

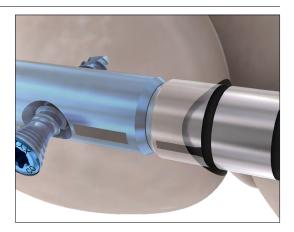
Select the appropriate Threaded End Cap (3mm, 5mm, or 10mm) or Low-Profile 1mm End Cap as indicated by the grooves on the Inserter Shaft. The first etch line is at 5mm and the second etch line is at 10mm.

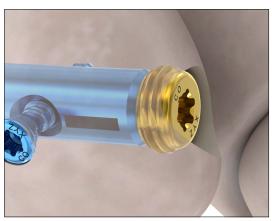
Note:

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 T

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-ThreadTM 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-S8789-1-S4.2mm Cannulated Reamer8796-1-S5.2mm 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



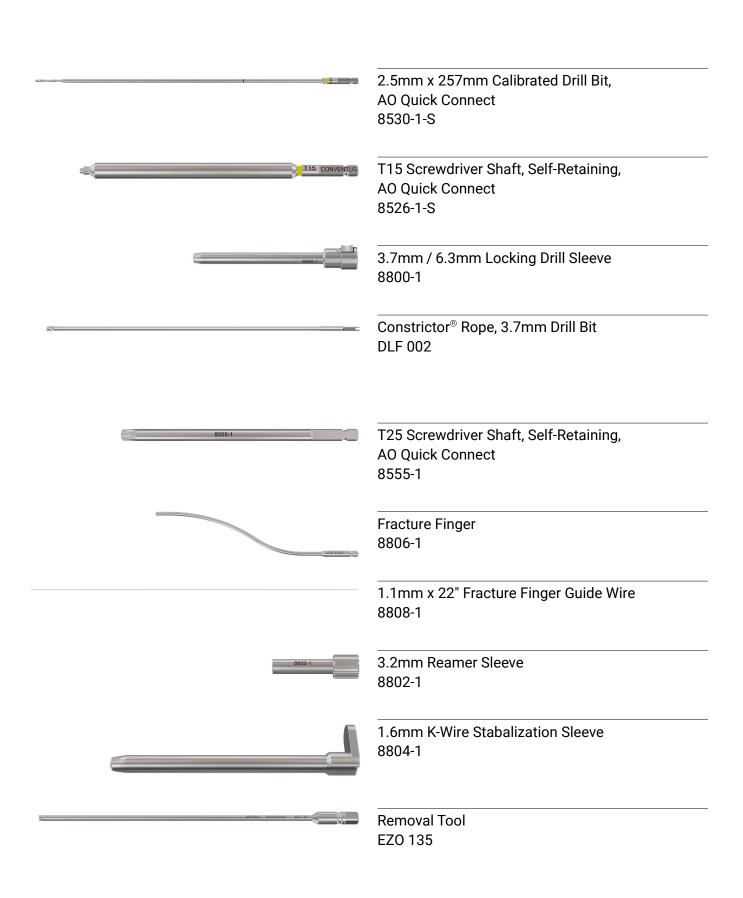
T8 Screwdriver Shaft, Self-Retaining, AO Quick Connect 8524-1-S



Screwdriver Handle, Black, AO Quick Connect 8548-1



2.5mm / 6.3mm Locking Drill Sleeve 8537-1



23 **Sterile Implants Nails** Flex-Thread Distal Fibula Nail, Flex-Thread Distal Fibula Nail, Flex-Thread Distal Fibula Nail, 5.5mm, Titanium 3.5mm, Titanium 4.5mm, Titanium

8424-13-S

130mm

8424-15-S

180mm

8424-11-S

180mm

8424-9-S

130mm

8424-1-S

130mm

8424-3-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





Constrictor® Rope DLF 002

FlowerCubeTM

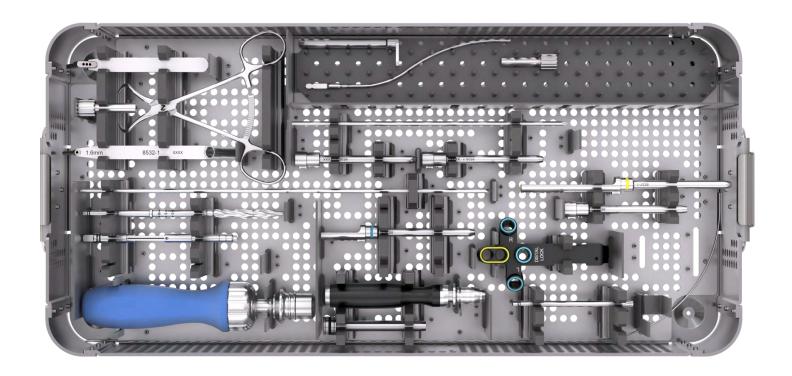


Flex-Thread Fibula FlowerCube™

^{*} Available lengths refer to page 32

24 Instrument Tray Layout





IMPLANTS

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 Orthopaedics 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, MDMidwest Orthopaedic Consultants
Foot and Ankle Specialist

30	Notes



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FlowerOrtho.com

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FOC 1054 Rev E 08/22

Proprietary & Confidential - Page 39 of 40 - Uncontrolled if Printed

FOC 1054 Flex-Thread Surgical Technique Guide (DOC-304) Ver. 4

Approved By:

(CO-227) Updating the Flex-Thread Fibula STG and Usage Form

Description

Updated logo and fixed typos for both documents. Removing the reduction device and addressing complaint 2022-13 for the STG.

Justification

Implementing new updated documents and addressing complaint.

Assigned To:	Initiated By:	Priority:	Impact:
Kediley Peralta	Kediley Peralta	Medium	Major

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