

Flex-Thread ULNA Intramedullary Nail System

Surgical Technique Guide



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SYSTEM FEATURES

1 Indications for Use

The Flex-Thread Ulna Intramedullary Nail System is intended for use in the fixation of fractures and osteotomies of the ulna.

2 Contraindications

Do not use the Flex-Thread Ulna 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
- · Patients with closed or inadequate medullary canals

3 AO Principles 1, 2

The Flex-Thread Ulna Intramedullary 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



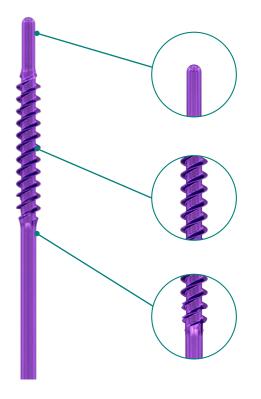
Early and safe mobilization

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

NAIL FEATURES

4 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 proximal ulna as well as provides point-contact fixation within the medullary canal.



Atraumatic Blunt Tip Nose

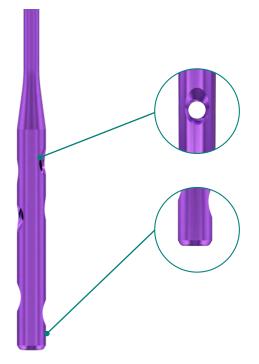
- · Guides Nail Across Fracture Site
- · Minimizes Cortical Disruption

Self-Cutting & Self-Tapping Flutes

- No Tapping Required
- · Decreases Procedure Time

Reverse Cutting Flutes

- · Precision Cut Design
- · Facilitates Nail Removal

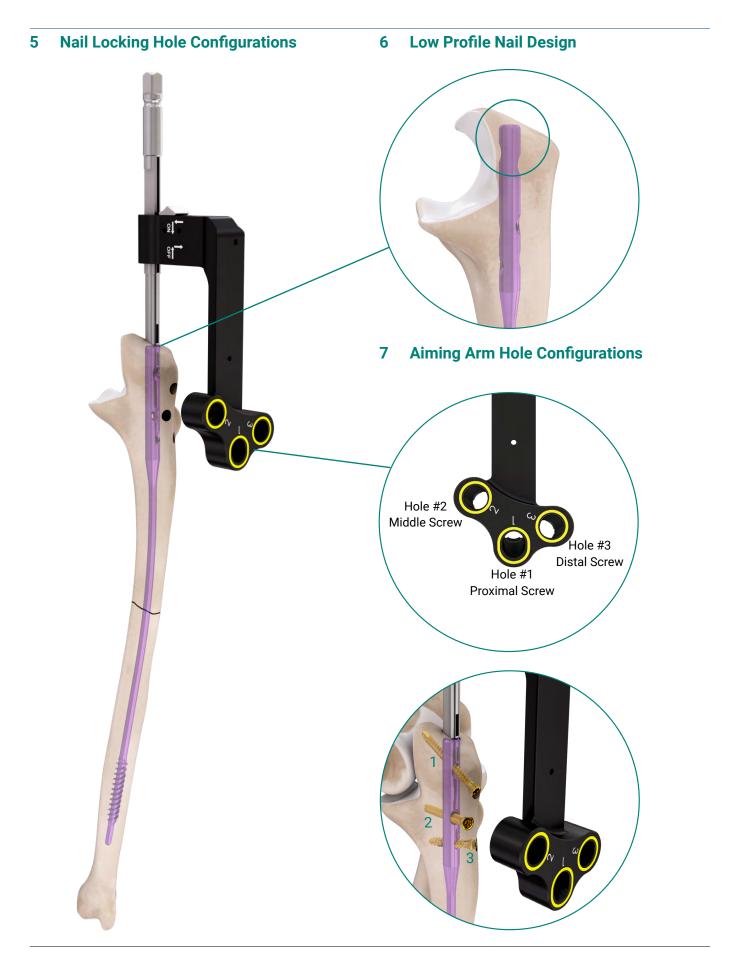


Interlocking Screw Holes

3.5mm ZERO Profile Interlocking Cortex Screws

Low Profile Nail Design

- Anatomic Fit
- · Minimizes Soft Tissue Disruption



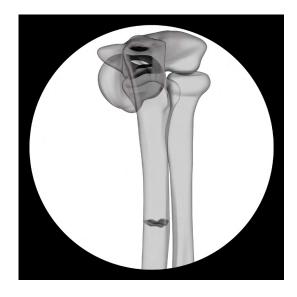
SURGICAL TECHNIQUE

8 Preoperative Planning

Use AP & Lateral radiographs to evaluate the ulna medullary canal geometry.

Take care to select the appropriate diameter and length of nail so adequate fixation can be achieved.





Available Nail Sizes

The following Flex-Thread Ulna sterile-packaged nails are available.

Nails are universal and are not right and left specific.

4.5mm Flex-Thread Ulna Nail		5.5mm Flex-Thread Ulna Nail		6.5mm Flex-Thread Ulna Nail	
Item #	Length (mm)	Item #	Length (mm)	Item #	Length (mm)
FTU 421-S	210	FTU 521-S	210	FTU 621-S	210
FTU 424-S	240	FTU 524-S	240	FTU 624-S	240
FTU 427-S	270	FTU 527-S	270	FTU 627-S	270

9 Patient Positioning

Place the patient in the supine position with radiolucent hand table on affected extremity.

Alternatively, the patient can be placed in the lateral recumbent position using an arm positioning device or a bump.

Using fluoroscopy in both the AP and Lateral planes confirm the presence of intramedullary canal to ensure that the Flex-Thread Ulna nail can be inserted without complication.





10 Surgical Approach

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

A 10-15mm longitudinal incision over the tip of the olecranon is recommended.

A longitudinal incision through the triceps tendon will facilitate the instrumentation.

Starting point should be slightly on the radial side of the ULNA in line with the medullary canal.

Precautions:

Care must be taken to avoid the ulnar nerve and articular surface.





11 Fracture Reduction

Instruments:

8811-1	Bone Reduction Clamps-Small, Pointed
8812-1	Bone Reduction Clamps-Small, Lobster Claw
8813-1	Baby Hohmann Retractor, Narrow

Percutaneously reduce and clamp the fracture with either a small Pointed Bone Reduction Clamp or Small Lobster Claw Bone Reduction Clamp.

Take care to ensure that the clamps do not penetrate or migrate into the intramedullary canal as this will prevent future reaming and nail insertion.

Additionally, consider clamp placement so that they do not interfere with the future Aiming Arm, Provisional K-Wires and/or Drill Sleeves.

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

Baby Hohmann Retractors are included in the instrument set and are recommended to be used to minimize soft tissue disruption.



12 Wire Insertion

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

Insert the 1.6mm x 12" long Trocar Spade Tip Guide Wire and 1.6mm / 6.3mm Soft Tissue Protector Sleeve into the apex of the olecranon with a slight deviation towards the radial side to be in-line with the medullary canal using the k-wire driver.

Using fluoroscopy confirm the wire position is across the fracture/osteotomy and is centrally located in the intramedullary canal in both the posterior to anterior and lateral views.

Technique Tips:

To facilitate proper guide wire positioning it is recommended to use the oscillating feature on the k-wire driver.

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.









13 Opening the Proximal Ulna

Instruments:

8531-1	1.6mm x 12" Trocar / Spade Tip Guide Wire
8532-1	1.6mm / 6.3mm Soft Tissue Protector Sleeve
UBR 067	6.7mm Cannulated Reamer, Calibrated, Rigid

Open the intramedullary canal using the 6.7mm Cannulated Reamer (UBR 067) over the 1.6mm Guide Wire.

Use the 1.6mm / 6.3mm Double Tissue Protector Sleeve to protect the surrounding soft tissues.

Slowly advance the 6.7mm Cannulated Reamer to a minimum depth of 60mm bottoming out the positive stop against the back of the Tissue Protector Sleeve.

Carefully monitor reaming progress radiographically.

Precautions:

The 6.7mm Cannulated Reamer must be used to prepare the proximal ulna for the body of the Flex-Thread Ulna Nail.

Failure to perform this step could result in premature fracture of the bone.

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

All cannulated reamers MUST be reamed over 1.6mm Guide Wire (8531-1).



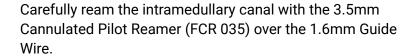




14 Reaming Medullary Canal

Instruments:

8531-1	1.6mm x 12" Trocar / Spade Tip Guide Wire
8532-1	1.6mm / 6.3mm Soft Tissue Protector Sleeve
FCR 035	3.5mm Cannulated Reamer, Calibrated, Rigid
FCR 045	4.5mm Cannulated Reamer, Calibrated, Rigid
FCR 055	5.5mm Cannulated Reamer, Calibrated, Rigid
FRS 135	3.5mm / 4.5mm Soft Tissue Protector Sleeve
	for Cannulated Reamers
FRS 155	5.5mm Soft Tissue Protector Sleeve for
	5.5mm Cannulated Reamers



To protect the soft tissues during guide wire insertion and reaming, use the 1.6mm / 6.3mm Soft Tissue Protector Sleeve with 3.5mm / 4.5mm Soft Tissue Protector Sleeve for Cannulated Reamers.

Ensure all sleeves remain in place and are fully seated on the bone when reaming.

Slowly advance the Cannulated Reamer until the desired cortical interface is achieved. Each cannulated reamer has 210mm, 240mm and 270mm depth markings which correspond to the available nail lengths.

The depth markings can be best visualized using fluoroscopy. The Soft Tissue Protector may need to be pulled back for accurate reading.

Note:

If using the 1.6mm / 6.3mm Soft Tissue Protector Sleeve with the Cannulated Reamers you must subtract 42.5mm from the nail length measurement if reading from the back of the Soft Tissue Protector Sleeve.

In dense bone, allow for bone fragments to clear the flutes by occasionally backing the drill up a few millimeters before re-advancing. Monitor progress radiographically. If hard bone is encountered, the flutes of the reamer may need to be cleared.







If a larger diameter of nail is preferred, continue to sequentially ream the intramedullary canal with the 4.5mm Cannulated Pilot Reamer (FCR 045) or 5.5mm Cannulated Pilot Reamer (FCR 055).

Cannulated Reamer Reference Chart Flex-Thread™ Ulna Nail		
Reamer	Recommended Nail Diameter	
3.5mm (FCR 035)	4.5mm	
4.5mm (FCR 045)	5.5mm	
5.5mm (FCR 055)	6.5mm	

Technique Tip:

All Cannulated Pilot Reamers have depth mark notches which correspond to available nail lengths. This provides a visual reference of where the nail will sit inside of the bone.



15 Nail Assembly

Instruments:

8815-1 Inserter Shaft - Flex-Thread Ulna

8439-1 Inserter Draw Rod

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

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

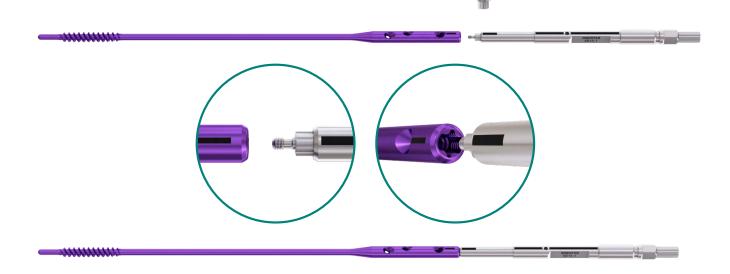
The dark laser etching line on the nail and connecting screw must be aligned with each other.

Technique Tips:

The Inserter Shaft drive tip can only be connected to the nail in one orientation, so the holes of the nail are properly aligned with the Aiming Arm (FUA 100).

The Inserter Draw Rod must engage the nail and then be securely tightened by hand.

Alternatively, it can also be tightened using a T8 driver to prevent the nail from loosening during insertion.



16 Nail Insertion

Instruments:

8815-1	Inserter Shaft - Flex-Thread Ulna
8439-1	Inserter Draw Rod
8437-1	Ratchet Inserter Handle, Blue

Attach the Blue Ratchet Inserter Handle to the square coupling on the back of the Inserter Shaft. Confirm connection is secure.

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 COUNTER-CLOCKWISE prior to nail insertion.

Insert the appropriately sized Flex-Thread Ulna Nail into the proximal ulna by turning the Ratchet Inserter Handle in a clockwise direction.

As the nail is carefully inserted monitor progress using fluoroscopy.

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 ulna.

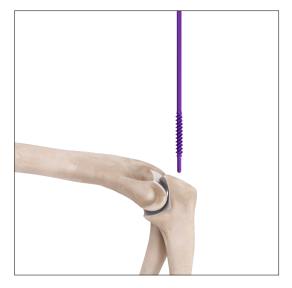
The most proximal hole of the nail (Hole #1) will accept an oblique 3.5mm screw that angles towards the Olecranon Process of the ulna.

Precautions:

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

Do not insert the Flex-Thread Ulna Nail using power.

Only insert the nail using the Blue Ratchet Inserter Handle by hand.





17 Nail Placement and Orientation

If the nail is over-inserted, turn the handle counterclockwise until the proper nail position is achieved.

Confirm the proximal end of the nail is flush or buried inside the ulna using fluoroscopy. After nail has been inserted, the dark laser etching line on the inserter shaft MUST be directly posterior to the subcutaneous border of the ulna.

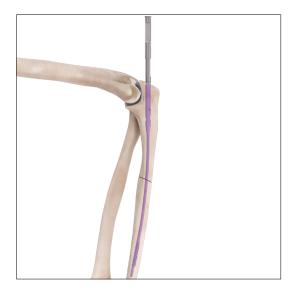
This ensures proper aiming arm attachment and screw targeting.

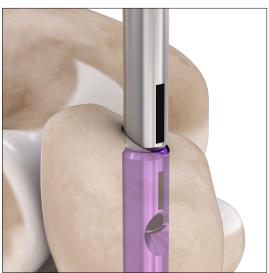
It should be in-plane with the centerline of the ulna.

Technique Tips:

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

One full rotation of the nail will advance the nail approximately 5.5mm.





18 Aiming Arm Attachment

Instruments:

FUA 100 Aiming Arm

8815-1 Inserter Shaft - Flex-Thread Ulna

Once the nail position is confirmed using fluoroscopy, attach the Aiming Arm (FUA 100) to the flat Inserter Shaft (8815-1) by pushing and sliding forward until it clicks into position.

Note:

The aiming arm only attaches to the inserter shaft in ONE position.









19 Provisional Aiming Arm Fixation

Instruments:

FUA 100	Aiming Arm
8535-1	1.6mm / 6.3mm Locking Wire Sleeve
8534-1	6.3mm Screw Sleeve
8117-1	1.6mm x 8", Trocar Tip K-Wire

If desired, the aiming arm can be provisionally pinned to the ulna once the aiming arm has been properly aligned and the nail has been properly oriented.

Insert a 1.6mm x 8", Trocar Tip K-Wire through the 1.6mm / 6.3mm Locking Wire Sleeve and 6.3mm Screw Sleeve.





20 Proximal Interlocking – 3.5mm Screws

Instruments:

8534-1	6.3mm Screw Sleeve
8537-1	2.5mm / 6.3mm Locking Drill Sleeve
8530-1	2.5mm x 257mm Calibrated Drill Bit
8526-1	T15 Screwdriver Shaft, Self-Retaining,
	AO Quick Connect
8548-1	Screwdriver Handle, Black, AO Quick Connect
FUA 100	Aiming Arm

For proximal interlocking screw fixation, insert the 6.3mm Screw Sleeve into the Aiming Arm hole #1.

Next, insert the GOLD 2.5mm Drill Sleeve. Ensure the Drill Sleeve clicks into place and has been fully seated for accurate screw measurement.

Drill with 2.5mm Calibrated Drill Bit that is color coded GOLD 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.

Take care NOT to drill into joint/articular surface.

Remove the inner Drill Sleeve prior to screw insertion.

Next, insert a sterile-packaged 3.5mm ZERO Profile Locking Screw through the 6.3mm Screw Sleeve using the Self-Retaining T15 Screwdriver Shaft and the Small Driver Handle.

Repeat process for Aiming Arm holes #2 and #3 for optimal fixation.

The proximal end of the Flex-Thread Ulna nail will only accept three 3.5mm ZERO Profile Locking Screws.







21 Aiming Arm Removal

Instruments:

FUA 100 Aiming Arm

Verify final nail and screw 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 assembly toward the humerus.

Slide the Aiming Arm off the Inserter Shaft to remove.







22 Optional: End Cap Insertion

Instruments:

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

An optional Nail End Cap can be inserted into the proximal end of the nail to prevent bony ingrowth.

End caps are recommended as they may facilitate nail removal later if necessary.

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.

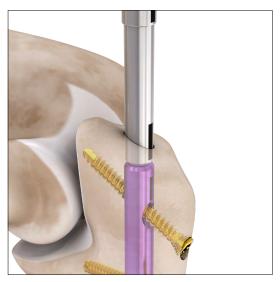
Alternatively, it can be loosened by using the T8 driver.

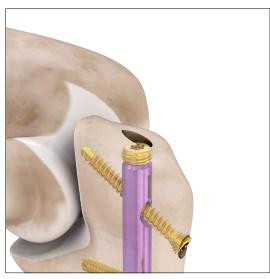
Select the appropriate OPTIONAL Threaded End Cap (3mm, 5mm, or 10mm).

Notes:

There are no 1mm or 3mm etch lines on the Inserter Shaft.

Do not insert Nail End Cap using power.





23 Optional: Implant Removal

Instruments:

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

If present, remove the Threaded/Unthreaded Nail End Cap using either the T15 Screwdriver and Screwdriver Handle for 3mm, 5mm, 10mm and 20mm End Caps. Or, use the T8 Screwdriver and Screwdriver Handle for Unthreaded 1mm End Caps.

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

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 Unthreaded End

Caps (1mm).

T15 Driver: Removes 3.5mm Screws and Threaded End

Caps (3mm, 5mm, 10mm).

T25 Driver: Removes all Flex-Thread Ulna Nails.

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



PRODUCT INFORMATION

24 Instruments





Ratchet Inserter Handle, Blue 8437-1

Aiming Arm Ulna FUA 100

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

2.5mm / 6.3mm Locking Drill Sleeve 8537-1

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

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

Screwdriver Handle, Black, AO Quick Connect 8548-1



25 Sterile Implants



24

Screws



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

End Caps



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



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



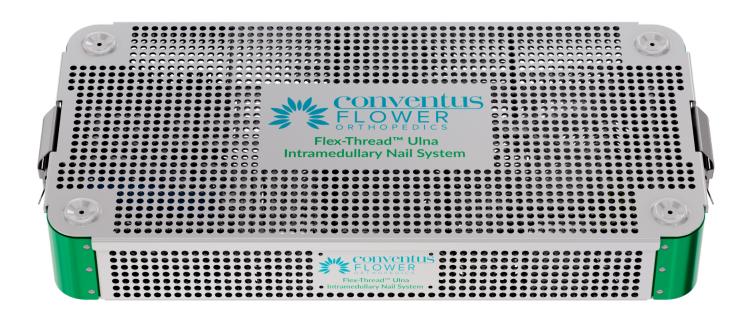
Flex-Thread End Cap, 3mm, T15 8522-3-S

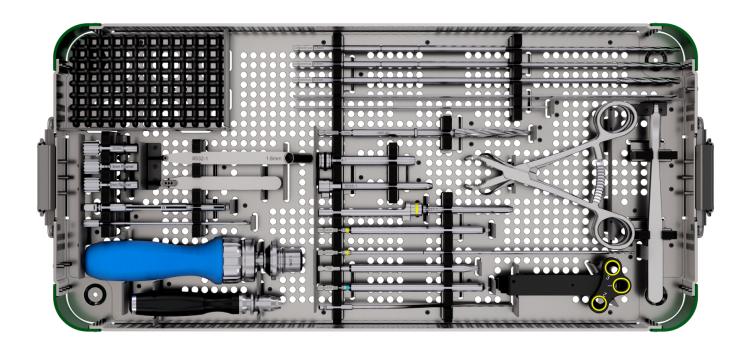


Flex-Thread End Cap, 1mm, T8 8430-1-S

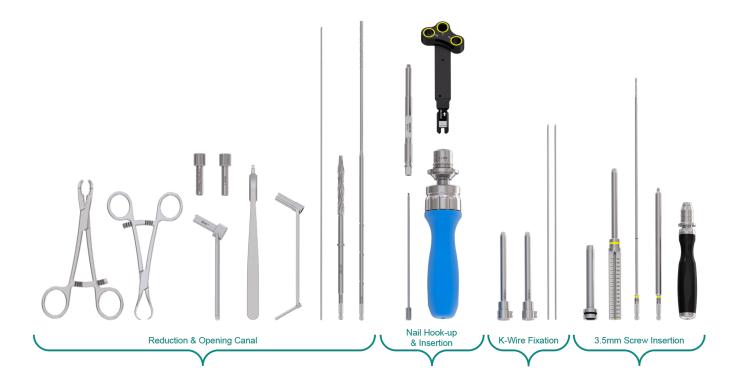
^{*} Available lengths refer to page 28

26 Instrument Tray Layout





27 Surgical Back Table Set Up



IMPLANTS

28 Nails, Screws & End Caps

Flex-Thread ZERO Profile Interlocking Cortex Screws				
Length (mm)	3.5mm			
20	8525-20-S			
22	8525-22-S			
24	8525-24-S			
26	8525-26-S			
28	8525-28-S			
30	8525-30-S			
32	8525-32-S			
34	8525-34-S			
36	8525-36-S			
38	8525-38-S			
40	8525-40-S			
42	8525-42-S			
44	8525-44-S			
46	8525-46-S			
48	8525-48-S			
50	8525-50-S			

Flex-Thread Ulna Nails							
Length (mm)	4.5mm, Gold	5.5mm, Purple	6.5mm, Dark Blue				
210	FTU 421-S	FTU 521-S	FTU 621-S				
240	FTU 424-S	FTU 524-S	FTU 624-S				
270	FTU 427-S	FTU 527-S	FTU 627-S				

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

29 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.

30 Acknowledgements

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

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Robert Tonks, M.D. Scripps Health Sharp HealthCare

31	Notes



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

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