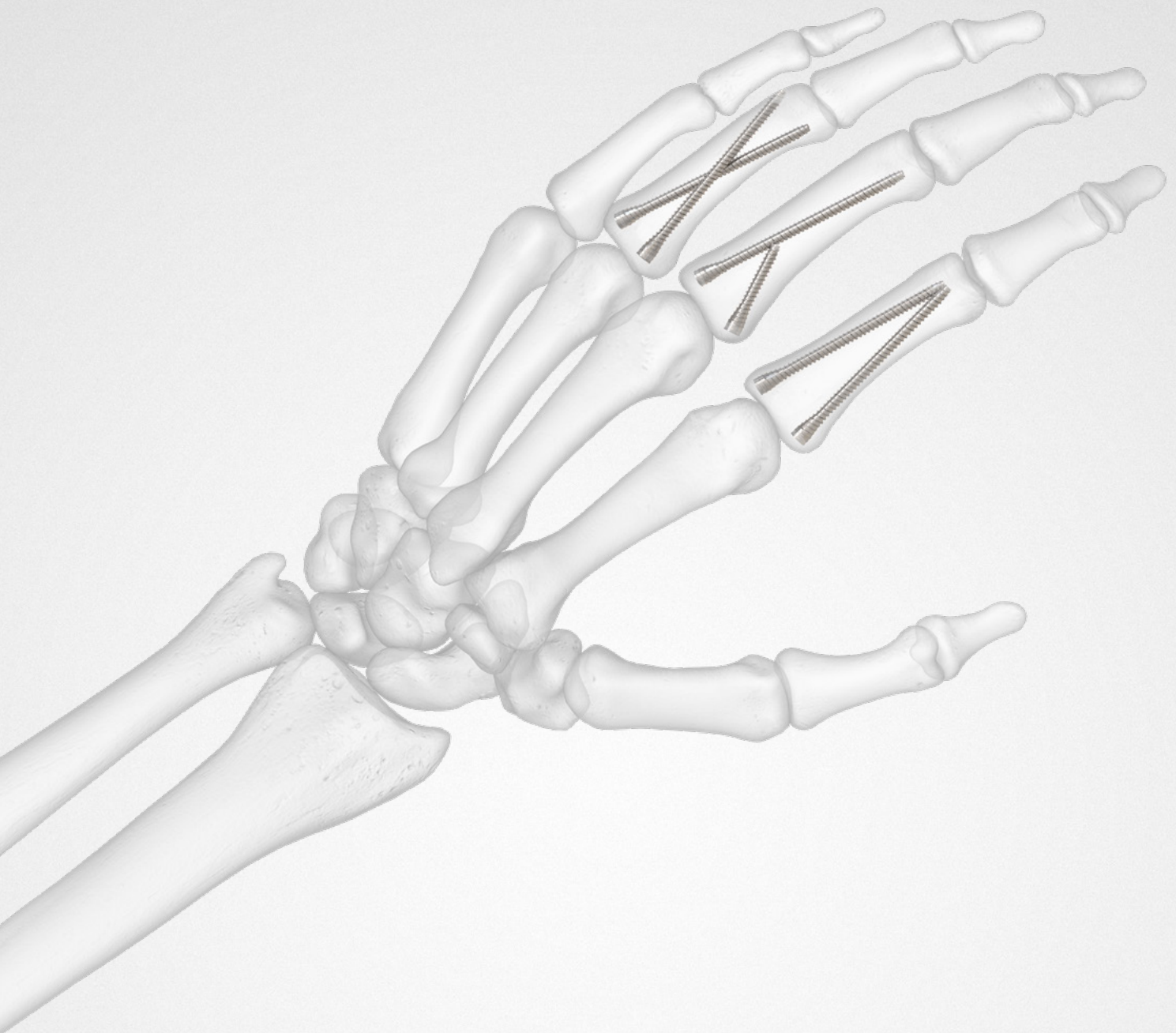


Surgical Technique



Acumed® is a global leader of innovative orthopaedic and medical solutions.



We are dedicated to developing products, service methods, and approaches that improve patient care.



InFrame™ Intramedullary Threaded Micro Nail System

The InFrame Intramedullary Threaded Micro Nail System features a 2.0 mm diameter, stainless steel micro nail with a non-compressive design to achieve various implantation constructs for phalangeal fractures, providing superior rotational and bending stability and intramedullary fixation. The innovative delivery mechanism via the dual diameter guide wire eliminates the need for a dedicated reamer, simplifying a more precise implant placement.

Indications for Use

The ExsoMed InFrame cannulated micro nail is intended for fixation of intra-articular and extra-articular fractures and non-unions of small bones and small bone fragments; arthrodesis of small joints; bunionectomies and osteotomies, including scaphoid and other carpal bones, metacarpals, tarsals, metatarsals, patella, ulnar styloid, capitellum, radial head, and radial styloid.

The implant is manufactured from stainless steel and is offered in a 2.0 mm diameter. They are provided sterile packaged while a separate sterile packaged instrument kit provides the tools for implantation.

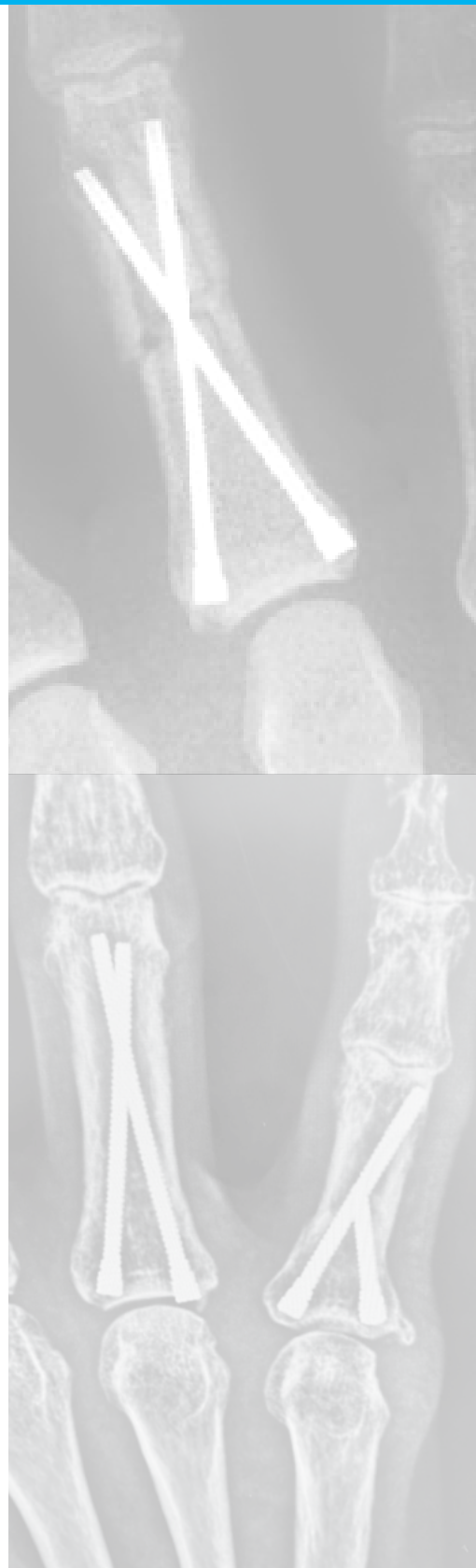
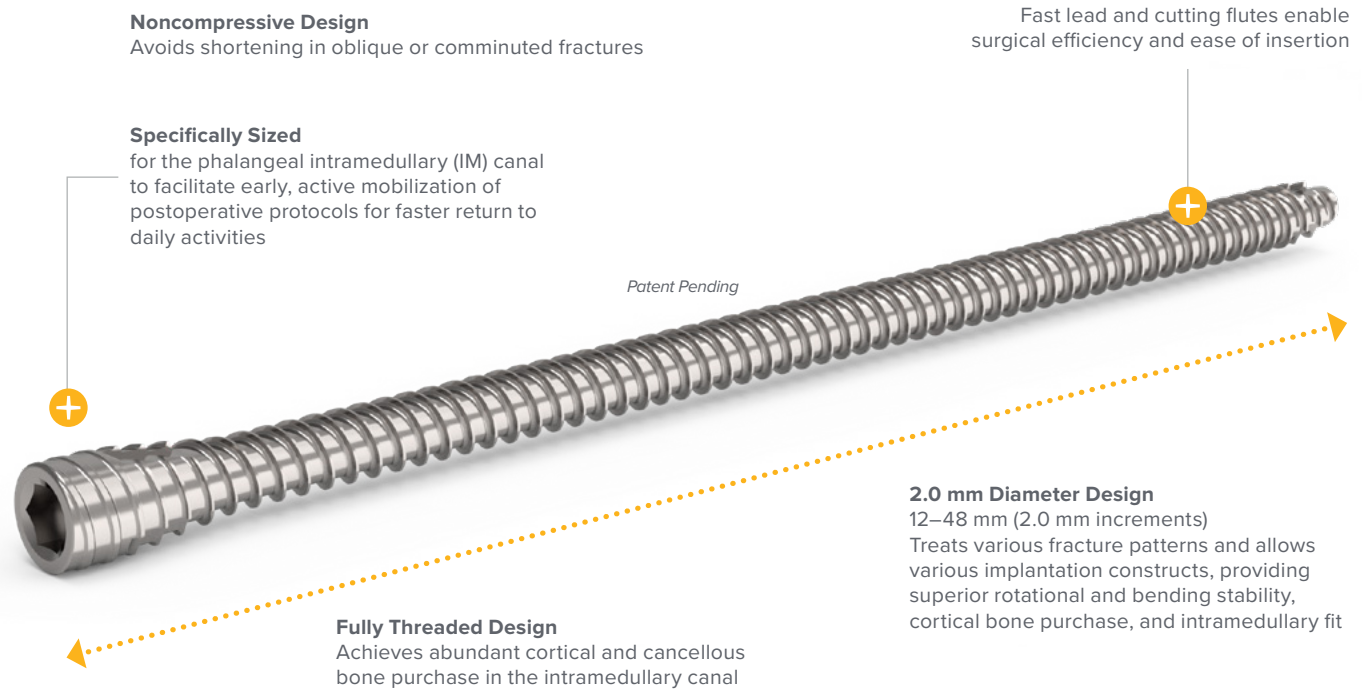


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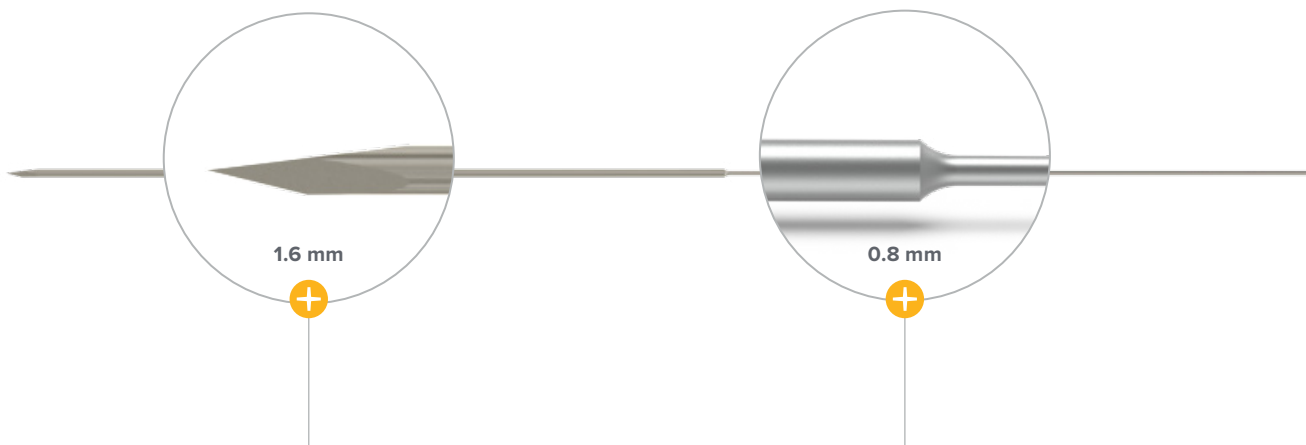
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System Features



Dual Diameter Guide Wire

Innovative delivery mechanism eliminates the need for a dedicated reamer, simplifying a more precise implant placement



Aggressively angled trocar tip for trajectory maintenance through cortical bone

Unique dual diameter guide wire removes the need for a dedicated reamer and simplifies a more precise placement

InFrame Intramedullary Threaded Micro Nail Surgical Technique



Figure 1



Figure 2

1 Reduce and Insert Guide Wire

Reduce the proximal phalanx fracture under fluoroscopy with a closed reduction technique.

Insert the dual diameter guide wire percutaneously in an antegrade fashion across the fracture site from the ulnar proximal cortex to the radial distal cortex, as clinical conditions allow.

Fully advance the guide wire into the proximal phalanx until the trocar tip passes the far side cortical wall and then retract until the trocar tip reaches the desired final implant position.

Note: When advancing or retracting the guide wire, always clamp on only the larger diameter (Figure 1). Clamping on the smaller diameter may apply excessive torsional stresses to the guide wire.

Tip: Dorsal and volar placement for the first and second implant, respectively, may facilitate implantation within the narrow IM canal (Figure 2). Depending on the fracture pattern and clinical assessment, open techniques may be utilized to optimally reduce the fracture. Avoid penetrating the articular surfaces whenever possible.



Figure 3

2 Measure and Select Implant Length

Verify that the guide wire tip is positioned at the desired final implant tip location.

Create a dorsal to volar, small stab incision adjacent to the guide wire entry site until the scalpel blade contacts the bone.

Insert the depth gauge adjacent to the guide wire, via the small stab incision (Figure 3), until the depth gauge tip contacts the bone (confirm under fluoroscopy).

Align the guide wire within the center channel of the depth gauge to read the length marking at the diameter transition point of the guide wire (illustrated in Figure 4 as 32 mm) to select the desired implant length.

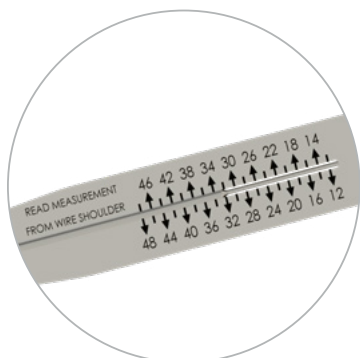


Figure 4

Tip: A #15 scalpel is recommended for incision. It may be appropriate to downsize the implant length by 2 mm or more from the depth gauge reading to account for any tissue between the depth gauge and bone, as well as for the subsosseous placement of the implant. Distal and proximal cortical purchase by the implant is recommended, if possible.

InFrame implants and surgical sets are packaged separately. Surgical sets are compatible with all sizes of InFrame implants offered.

InFrame Intramedullary Threaded Micro Nail Surgical Technique [continued]



Figure 5



Figure 6



Figure 7



Figure 8



Figure 9



Figure 10

3 Insert Implant and Confirm Placement

After measurement, clamp the larger diameter of the guide wire to advance it through the bone until enough guide wire is exiting distally so that the larger diameter of the guide wire can be clamped.

Reposition the wire driver to the opposite side of the phalanx and clamp the larger diameter of the guide wire to distally advance the guide wire so that the smaller diameter spans the fracture site while the larger diameter remains within the distal cortex.

Slide the selected implant over the smaller diameter of the guide wire.

Slide the driver down the guide wire until the driver tip engages the trailing end of the implant.

Advance the implant along the smaller diameter of the guide wire until the fracture site is reached.

Advance the larger diameter of the guide wire until it is outside of the intramedullary canal.

Ensure proper reduction is maintained as the implant engages the distal fragment to prevent distraction at the fracture site.

Note: If excessive resistance is encountered, retract and advance the implant as necessary to avoid applying extreme force upon the driver and implant.

Once the desired implant depth is achieved, verify proper placement and reduction under fluoroscopy and remove the guide wire.

Tip: Both ends of the implant should be buried below the outer surface of the bone.

InFrame Intramedullary Threaded Micro Nail Surgical Technique [continued]



Figure 11

4 Insert Additional Implant

Place the second implant by inserting the dual diameter guide wire from the radial proximal cortex to the ulnar distal cortex, as clinical conditions allow, in a plane volar or dorsal to the first implant to avoid implant collision.

Verify under fluoroscopy that adequate spacing exists between the previously placed implant and newly placed guide wire to avoid implant collision.

Repeat steps 2 and 3 to create an "X" construct with the first implant.

Note: Damage and excessive torque may occur to the threads if the implant/guide wire spacing is not verified. Ensure initial device is fully implanted prior to placing any additional implants.

Tip: Verifying the implant/guide wire spacing will ensure that thread damage does not occur when placing the implant due to intersecting implant trajectories. If continued excessive torque is encountered during the second implant placement, remove the second implant and place a shorter length implant or choose a different trajectory to avoid implant collision.

Additional Constructs

Based on the fracture pattern and location, other constructs may provide superior rotational and bending stability.

Examples include "V," "Y," "Parallel," and "Single" constructs.



Figure 12



Figure 13



Figure 14

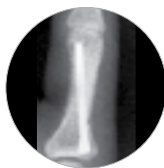


Figure 15

Ordering Information

Sterile Packaged Instrument Kit

InFrame Instrument Kit

- 2 – Dual Diameter Guide Wires, Single Trocar
- 254 mm, 1.6 mm x 0.8 mm Diameter
- 1 – Cannulated 1.6 mm Hex Driver
- 1 – Depth Gauge

EXINF912000



Implants

Sterile Implants, 2.0 mm

InFrame Implant, 2.0 x 12 mm	EXINF922012	
InFrame Implant, 2.0 x 14 mm	EXINF922014	
InFrame Implant, 2.0 x 16 mm	EXINF922016	
InFrame Implant, 2.0 x 18 mm	EXINF922018	
InFrame Implant, 2.0 x 20 mm	EXINF922020	
InFrame Implant, 2.0 x 22 mm	EXINF922022	
InFrame Implant, 2.0 x 24 mm	EXINF922024	
InFrame Implant, 2.0 x 26 mm	EXINF922026	
InFrame Implant, 2.0 x 28 mm	EXINF922028	
InFrame Implant, 2.0 x 30 mm	EXINF922030	
InFrame Implant, 2.0 x 32 mm	EXINF922032	
InFrame Implant, 2.0 x 34 mm	EXINF922034	
InFrame Implant, 2.0 x 36 mm	EXINF922036	
InFrame Implant, 2.0 x 38 mm	EXINF922038	
InFrame Implant, 2.0 x 40 mm	EXINF922040	
InFrame Implant, 2.0 x 42 mm	EXINF922042	
InFrame Implant, 2.0 x 44 mm	EXINF922044	
InFrame Implant, 2.0 x 46 mm	EXINF922046	
InFrame Implant, 2.0 x 48 mm	EXINF922048	



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