

# InFrame™ Surgical Technique Guide

The intramedullary micro nail for phalangeal fractures, designed by hand surgeons



E X S O M E D an + acumed company

# 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 2.0mm diameter. The implants are provided sterile packaged while a separate sterile packaged instrument kit provides the tools for implantation.

**Multiple lengths** for treatment of various fracture patterns

• 2.0mm diameter: 12-48mm (2.0mm increments)

Specifically sized for the phalangeal intramedullary (IM) canal to facilitate early, active mobilization post-op protocols for faster return to daily activities

Non-compressive design avoids shortening in oblique or comminuted fractures

Fully threaded design to achieve abundant cortical and cancellous bone purchase in the intramedullary canal

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2.0mm diameter design allows various implantation constructs, providing superior rotational and bending stability, cortical bone purchase, and intramedullary fit

Cannulated for simple and accurate placement

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

### SURGICAL TECHNIQUE

# 1

#### **REDUCE AND INSERT GUIDEWIRE**

Although various constructs are possible (see "additional constructs" section on page 4) to address any phalanx, this surgical technique will focus on creating an "X" construct in the proximal phalanx.

- **a.** Reduce the proximal phalanx fracture under fluoroscopy with a closed reduction technique
- **b.** Insert the dual diameter guidewire percutaneously in an antegrade fashion across the fracture site from the ulnar proximal cortex to the radial distal cortex, as clinical conditions allow
- **c.** Fully advance the guidewire 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 guidewire, always clamp on **only** the larger diameter (figure d). Clamping on the smaller diameter may apply excessive torsional stresses that are applied to the guidewire.

OR Tip: Dorsal and volar placement for the first and second implant, respectively, may facilitate implantation within the narrow IM canal (figure e). 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.





d.

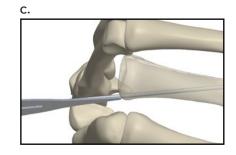


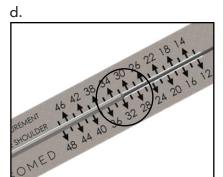


# SURGICAL TECHNIQUE

# 2 MEASURE AND SELECT IMPLANT LENGTH

- a. Verify that the guidewire tip is positioned at the desired final implant tip location
- **b.** Create a dorsal to volar, small stab incision adjacent to the guidewire entry site until the scalpel blade contacts the bone
- **c.** Insert the depth gauge adjacent to the guidewire, via the small stab incision, until the depth gauge tip contacts the bone (confirm under fluoroscopy)
- **d.** Align the guidewire within the center channel of the depth gauge to read the length marking at the diameter transition point of the guidewire (illustrated in the diagram as 32mm) to select the desired implant length



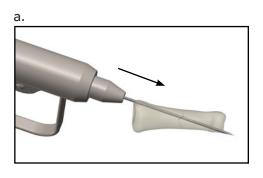


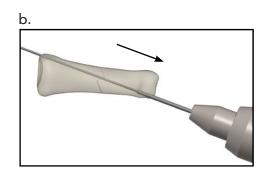
OR Tip: A #15 scalpel is recommended for incision. It may be appropriate to downsize the implant length by 2mm or more from the depth gauge reading to account for any tissue between the depth gauge and bone, as well as for the subosseous placement of the implant. Distal and proximal cortical purchase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

#### INSERT IMPLANT AND CONFIRM PLACEMENT

- **a.** After measurement, clamp the larger diameter of the guidewire to advance it through the bone until enough guidewire is exiting distally so that the larger diameter of the guidewire can be clamped
- **b.** Reposition the wire driver to the opposite side of the phalanx and clamp the larger diameter of the guidewire to distally advance the guidewire so that the smaller diameter spans the fracture site while the larger diameter remains within the distal cortex



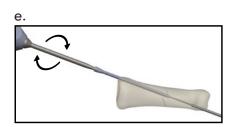


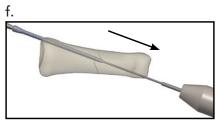
- **c.** Slide the selected implant over the smaller diameter of the guidewire
- **d.** Slide the driver down the guidewire until the driver tip engages the trailing end of the implant



## SURGICAL TECHNIQUE

- e. Advance the implant along the smaller diameter of the guidewire until the fracture site is reached
- f. Advance the larger diameter of the guidewire until it is outside of the intramedullary canal
- g. 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.

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

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

#### 4 INSERT ADDITIONAL IMPLANT

- **a.** Place the second implant by inserting the dual diameter guidewire 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
- **b.** Verify under fluoroscopy that adequate spacing exists between the previously placed implant and newly placed guidewire to avoid implant collision
- c. Repeat steps 2 and 3 to create an "X" construct with the first implant

X pattern



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

OR Tip: Verifying the implant/guidewire 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

- **a.** Based on the fracture pattern and location, other constructs may provide superior rotational and bending stability
- b. Examples include "V," "Y," "Parallel," and "Single" constructs









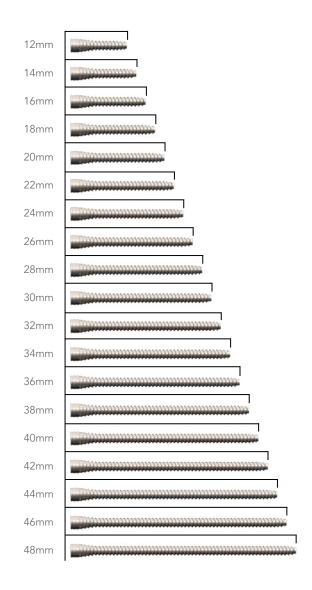
"Single'

## **ORDERING INFORMATION**



## InFrame Sterile Packaged Implants, 2.0mm

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



#### InFrame Sterile Packaged Instrument Kit

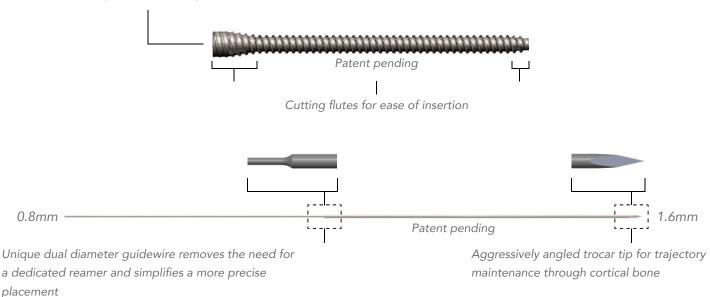
EXINF912000

InFrame Instrument Kit

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

Fully threaded, non-compression design to maintain anatomic length

Cannulated for simple and accurate placement



#### InFrame Sterile Packaged Instrument Kit





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