



INnate™ Surgical Technique Guide

The intramedullary threaded nail for metacarpals
designed by hand surgeons



EXSOMED™
Innovations in Hand Surgery

INDICATIONS FOR USE

The ExsoMed INnate System 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 INnate System is provided sterile. The implant is manufactured from stainless steel and is offered in 3.6mm (recommended for the 4th metacarpal) and 4.5mm diameters. The implants are provided with a separate disposable instrument kit specific to the implant diameter.

DESIGN RATIONALE

The INnate System introduces an intramedullary threaded nail designed specifically for metacarpal fractures to provide surgeons with a reliable solution through a simple approach. The robust length offering with a differential diameter design is intended to accurately fit the intramedullary canal and to create stable fixation and precise reduction for all types of metacarpal fractures.

Multiple lengths for treatment of various shapes and sizes of small bones

- **3.6mm* Diameter:** 25mm, 30mm, 35mm, 40mm, 45mm, 50mm, 55mm Lengths
- **4.5mm Diameter:** 35mm, 40mm, 45mm, 50mm, 55mm, 65mm, 75mm Lengths

Non-compression design avoids shortening in oblique or comminuted fractures

Threads designed for circumferential cortical purchase in the medullary canal

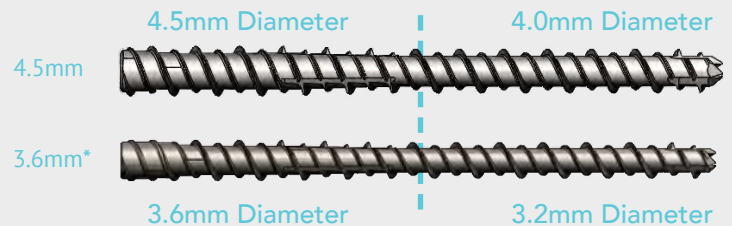
Dual diameter design to allow passage through the isthmus

Fast lead for surgical efficiency



T10 hexalobe to reduce the risk of stripping implant

Cannulated for accurate placement



Smaller diameter leading end design allows passage through isthmus

Anatomic Reduction

- Non-compression implant design allows for precise, anatomic reduction for all metacarpal fracture types, including oblique and comminuted fractures

Stable Fixation

- Various lengths appropriately sized, allow optimal stability and bone purchase for all fracture locations

Less Traumatic

- Cannulated technique with an intramedullary implant designed to minimize soft tissue, cartilage, and vascular damage upon insertion

Early, Active Mobilization

- Large implant diameter with circumferential intramedullary cortical thread engagement is designed to facilitate early, active mobilization post operative protocols for accelerated healing and earlier return to work

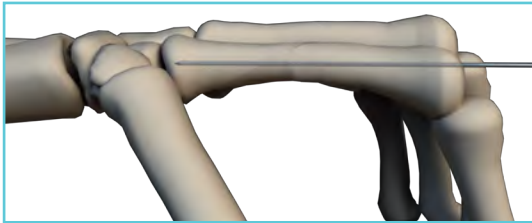
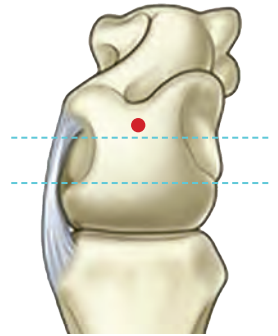
* 3.6mm INnate is recommended for the 4th metacarpal

SURGICAL TECHNIQUE

1 INSERT GUIDE WIRE

Anatomically reduce the fracture fragments.

Insert guide wire percutaneously in a retrograde fashion until the tip of the guide wire is at the proximal cortex.



Note: The guide wire entry point should be in the **dorsal third** of the metacarpal head.

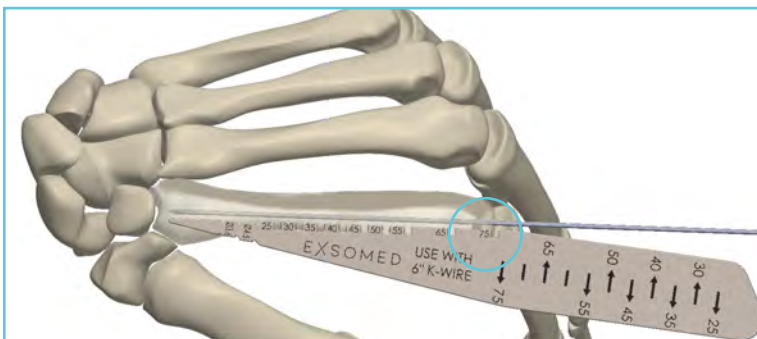
OR Tip: Once the guide wire is in place, make a stab incision at the point of guide wire insertion. This will facilitate the free movement of the drill.

2 MEASURE AND SELECT IMPLANT LENGTH & DIAMETER

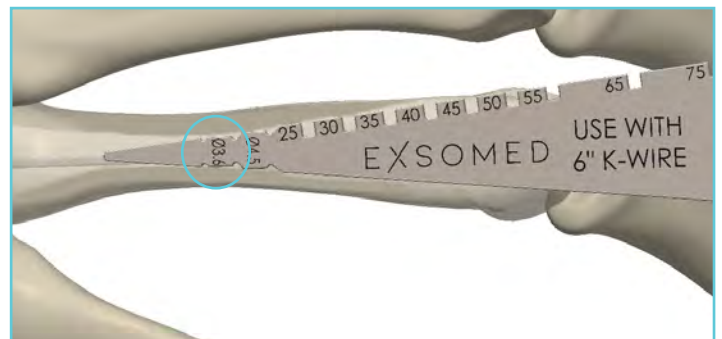
A. The edge of the INnate depth gauge may be used to measure the length of metacarpal directly for determining implant length.

- i. To determine the length of the implant, hold the depth gauge against the dorsum of the hand with the measurement edge aligned with the guide wire
- ii. Under fluoroscopy use the **marked square notches** (e.g. the 9th [last] **square notch** will be for a length of 75mm) along the edge of the depth gauge to select the desired implant length (it may be appropriate to subtract up to 5mm from the depth gauge reading to ensure subflush placement of the implant head)
- iii. The 4.5mm diameter INnate nail is commonly used for most metacarpal fractures, while the 3.6mm diameter INnate implant was purpose built and specifically designed for the narrower isthmus most commonly encountered in the 4th metacarpal. To ensure proper size selection, we recommend measurement with the INnate measurement device enclosed in all instrument kits. To measure, hold the depth gauge against the dorsum of the hand with the edges of the annotated measurement markings aligned with the narrowest part of the intramedullary canal. See example below in image iii., where a 3.6mm diameter implant (highlighted in teal) should be selected over a 4.5mm diameter implant

i and ii.

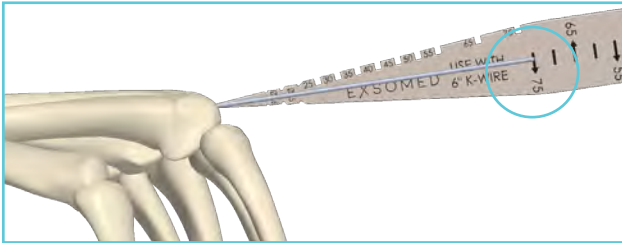


iii.



SURGICAL TECHNIQUE

B. Alternatively, the wider end of the INnate depth gauge may be used to measure the length of metacarpal for determining implant length via the guide wire.



- i. Insert the depth gauge via the stab incision and, under fluoroscopy, confirm the tip of the depth gauge is against the metacarpal head
- ii. Measure the exposed length of the guide wire against the markings to select the appropriate implant length, ensuring that the selected length extends well past the fracture site (e.g. the image to the left will be for a length of 75mm)

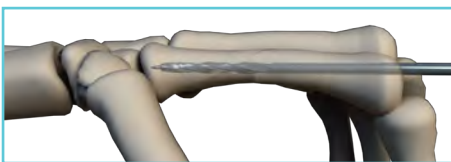
iii. Since the guide wire has been driven to the proximal cortex of the metacarpal, this measurement indicates the length of the metacarpal and not necessarily the desired length of implant (please select implant based on fracture location and note that it may be appropriate to subtract up to 5mm from the depth gauge reading to account for any tissue between the depth gauge and bone, ensuring subflush placement of the implant head)

3 DRILL

Drill by passing the cannulated drill over the guide wire to the desired depth. Depth markings on the drill can be used to monitor drill depth.

OR Tip: Pre-drill the entire length of intended implantation.

Remove the drill carefully while maintaining the guide wire position. Do not remove the guide wire.



OR Tip: Prior to drilling, advance the guide wire into the base of the metacarpal to reduce the chances of dislodging the guide wire when the drill is removed.

4 INSERT IMPLANT AND CONFIRM PLACEMENT

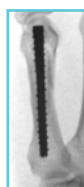
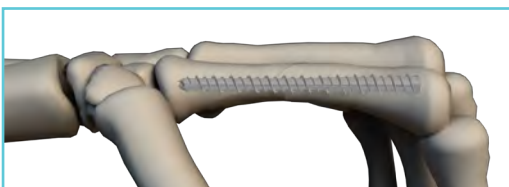
Insert selected implant over the guide wire.



Cannulated T-10 Driver

Advance the implant into the bone to the desired depth. Manually hold reduction as the implant traverses the fracture site and engages the far fragment to prevent gapping at the fracture site.

OR Tip: Should excessive resistance be encountered, utilize the self-tapping features of the implant by backing out 1/2 turn and advancing. Repeat as necessary to avoid excessive force upon the driver and implant.



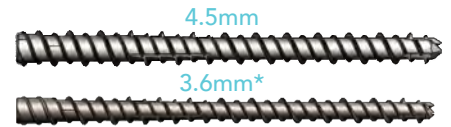
Verify placement and proper reduction with radiographic imaging. The head of the implant should be buried below the articular surface.

Remove the driver and guide wire.

ORDERING INFORMATION

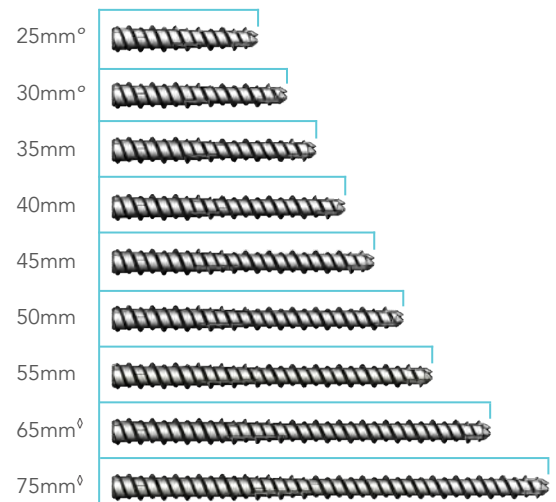
INnate Sterile Implants, 3.6mm*

EXINN923625	INnate Implant, 3.6 x 25mm
EXINN923630	INnate Implant, 3.6 x 30mm
EXINN923635	INnate Implant, 3.6 x 35mm
EXINN923640	INnate Implant, 3.6 x 40mm
EXINN923645	INnate Implant, 3.6 x 45mm
EXINN923650	INnate Implant, 3.6 x 50mm
EXINN923655	INnate Implant, 3.6 x 55mm



INnate Sterile Implants, 4.5mm

EXINN924535	INnate Implant, 4.5 x 35mm
EXINN924540	INnate Implant, 4.5 x 40mm
EXINN924545	INnate Implant, 4.5 x 45mm
EXINN924550	INnate Implant, 4.5 x 50mm
EXINN924555	INnate Implant, 4.5 x 55mm
EXINN924565	INnate Implant, 4.5 x 65mm
EXINN924575	INnate Implant, 4.5 x 75mm



° 25mm and 30mm lengths only available in the 3.6mm diameter
 ◊ 65mm and 75mm lengths only available in the 4.5mm diameter
 * 3.6mm INnate is recommended for the 4th metacarpal

INnate Disposable Instrument Kit

EXINN913600	3.6mm* INnate Instrument Kit	<ul style="list-style-type: none"> 1 .045 Single Trocar Guide Wire 1 .045 Double Trocar Guide Wire 1 Depth Gauge 1 Cannulated Drill, 2.7mm 1 Cannulated Driver, T-10
EXINN914500	4.5mm INnate Instrument Kit	<ul style="list-style-type: none"> 1 .045 Single Trocar Guide Wire 1 .045 Double Trocar Guide Wire 1 Depth Gauge 1 Cannulated Drill, 3.4mm 1 Cannulated Driver, T-10

Cannulated for K-wire placement

Designed for abundant cortical contact, for optimal filling of the intramedullary canal

Hexalobe design for high torque resistance (to ensure implant position remains adjustable in-situ)

Minimized risk of entry point fractures caused by diameter transition, due to midpoint self-tapping features



INnate Disposable Instrument Kit - Sterile Packed



Cannulated T-10 Driver



Cannulated Drill (2.7mm for 3.6mm INnate Instrument Kit and 3.4mm for 4.5 INnate Instrument Kit)



K-wire, 6", Single Trocar, 0.045"



K-wire, 6", Double Trocar, 0.045"



Depth Gauge



ExsoMed
135 Columbia, Suite 201
Aliso Viejo, CA 92656
United States of America
(855) ExsoMed

customer@exsomed.com
www.exsomed.com

ExsoMed and INnate are trademarks of ExsoMed Corporation. These products are covered by one or more issued U.S. and global patents and/or patents pending.

to ExsoMed or its affiliates unless otherwise indicated. This material must not be redistributed, duplicated or disclosed, in whole or in part, without the express written consent of ExsoMed.

© Copyright 2020 ExsoMed Corporation. All rights reserved.

Check product specific instructions for use. For complete product information, including indications, contraindications, warnings, precautions, and potential adverse effects, see the package insert and ExsoMed's website.

This material is intended for health care professionals and the ExsoMed sales force only. Distribution to any other recipient is prohibited. All content herein is protected by copyright, trademarks and other intellectual property rights owned by or licensed