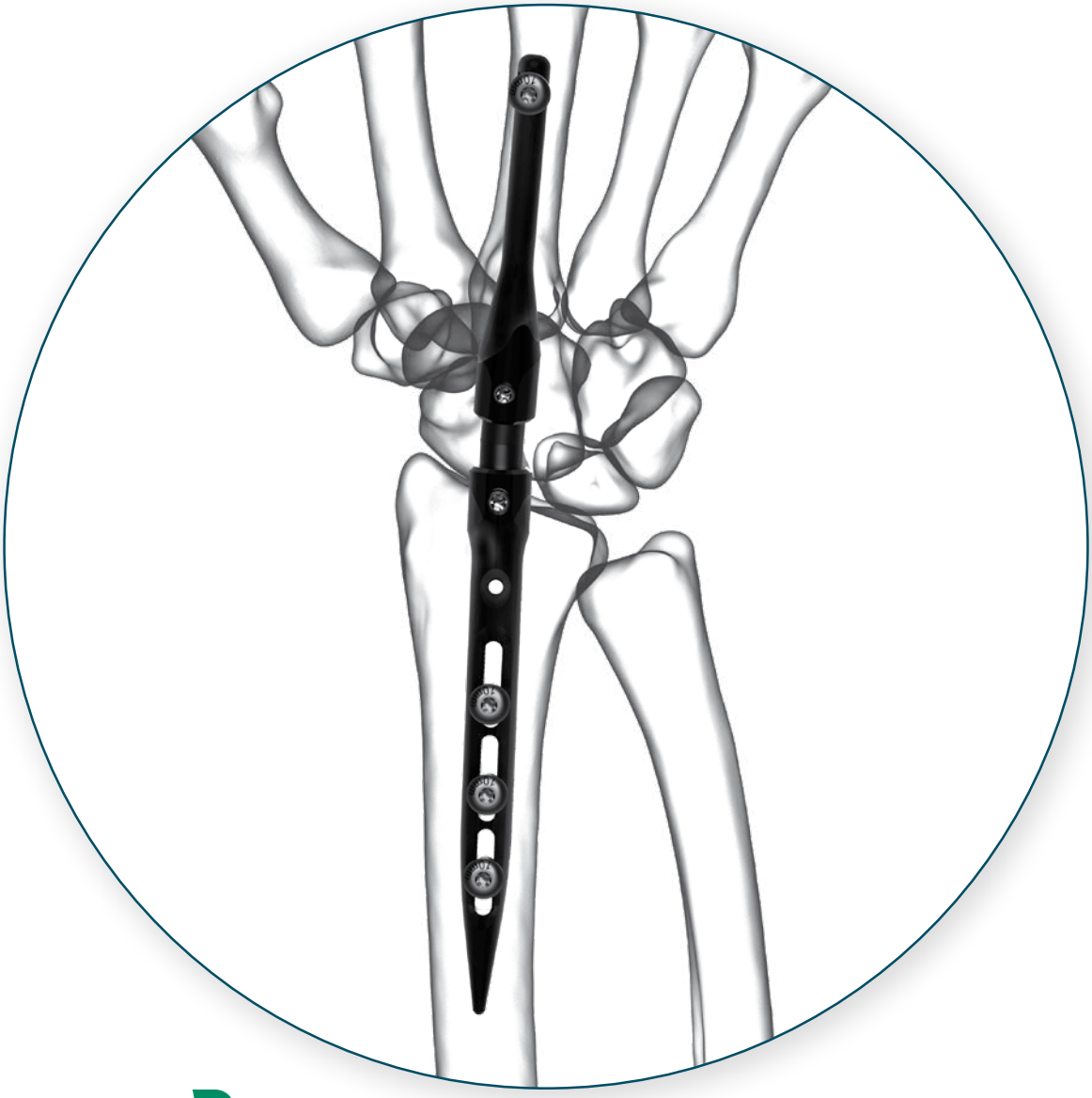
SURGICAL TECHNIQUE GUIDE

IMPLATE®

wrist arthrodesis nail



skeletal dynamics®

UNDERSTANDING THE UPPER EXTREMITY

As described by:
Jorge L. Orbay, M.D.
Miami Hand & Upper Extremity Institute

IMPLATE®
wrist arthrodesis nail

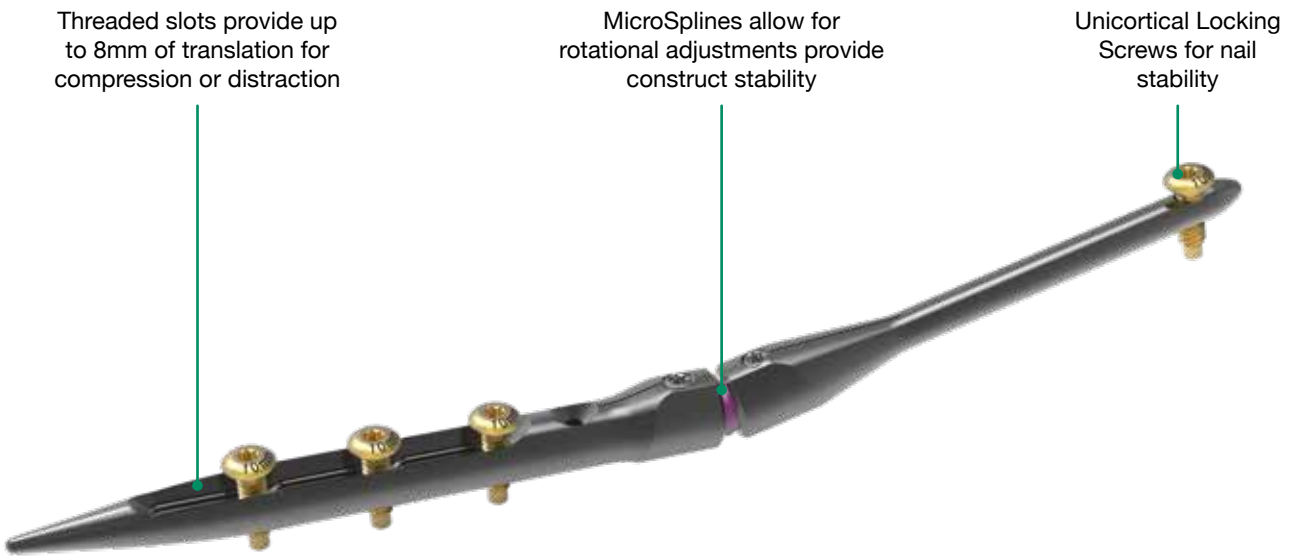
Description

The IMPLATE® WAN System is designed as an intramedullary nailing platform to address wrist arthrodesis procedures utilizing a minimally invasive dorsal approach into the third metacarpal and distal radius by trained physicians. The respective nails are secured within the intramedullary canals by means of Unicortical Bone Screws, and then assembled into a completed construct using a Connector and two Setscrews.

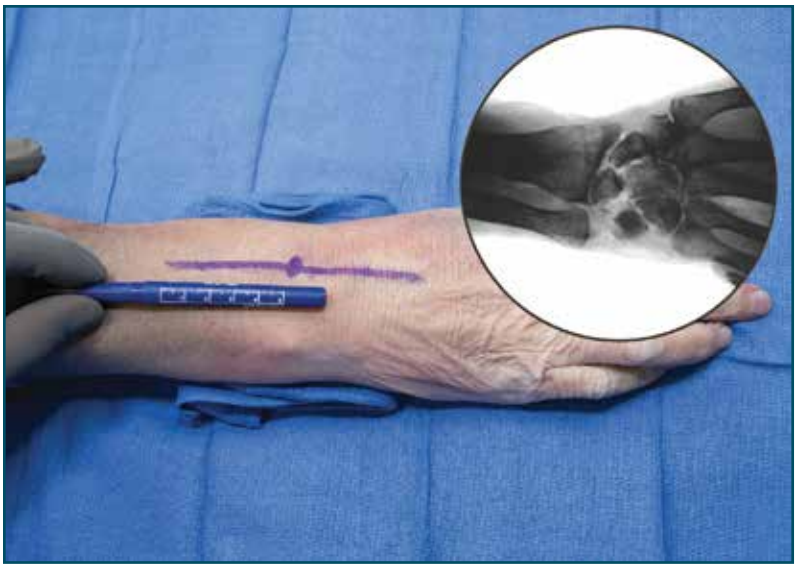
The IMPLATE® WAN System is comprised of:
- Titanium alloy Distal Radius & Metacarpal Intramedullary Nails
- Titanium alloy Connectors in various lengths and angles
- Titanium alloy Unicortical Screws
- Cobalt Chrome Setscrews
- System specific instrumentation

Indications

The IMPLATE® WAN System is intended for wrist arthrodesis. Specific indications include post-traumatic arthritis of the joints of the wrist; rheumatoid wrist deformities requiring restoration; complex carpal instability; post-septic arthritis of the wrist; severe unremitting wrist pain related to motion; brachial plexus nerve palsies; tumor resection; and spastic deformities.

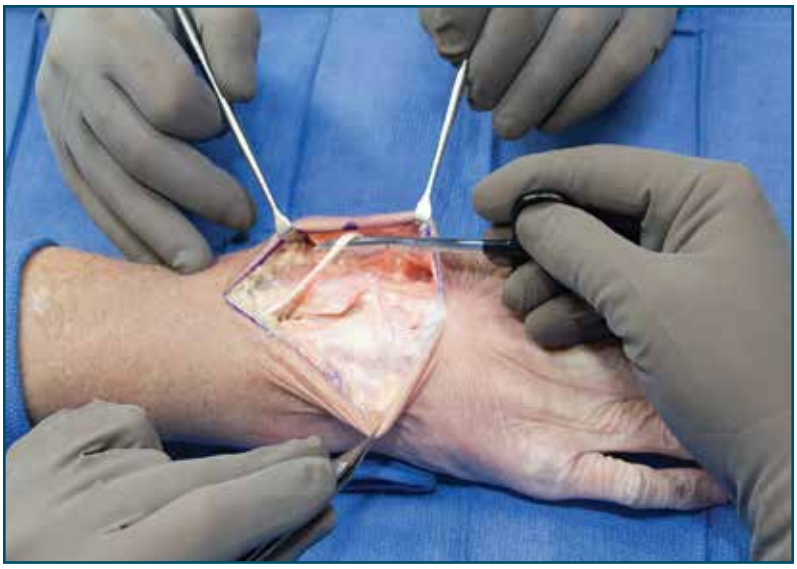


1 EXPOSURE



Make an 8cm - 10cm longitudinal incision centered over Lister's Tubercle to expose the extensor retinaculum.

2 EPL TENDON SHEATH



Open the sheath of the extensor pollicis longus and reflect the tendon radially.

EXTENSOR COMPARTMENTS 3

Expose and release the 2nd and 4th extensor compartments.

If desired, prepare flaps to reconstruct the 4th compartment.

DORSAL CAPSULE 4

Open the dorsal wrist capsule in an "H" fashion.

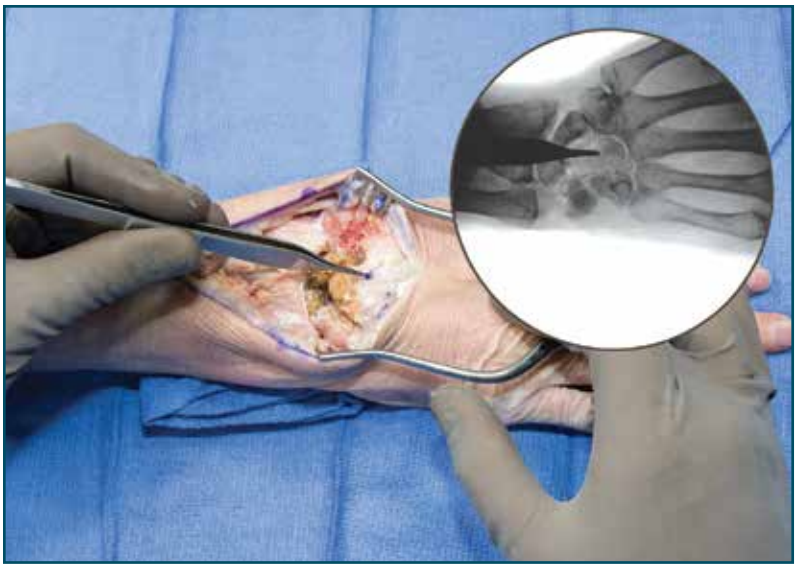
Note:
Once open, reposition the retractors to the plane below the retinacular flaps.

5 DECORTICATION

Position the wrist in flexion allowing access to the radiocarpal and intercarpal joints for complete decortication of the articular surfaces.

Note:
Decortication has been shown to promote the fusion process.

6 METACARPAL NAIL INSERTION POINT



Mark the distal flare on the dorsal surface of the capitate in-line with the 3rd metacarpal.

Note:
This location marks the entry point for the metacarpal nail.

Capitate & Metacarpal

MINIMAL JOINT GAP 7

Using the minimum gap gauge, confirm that there is sufficient spacing between the metacarpal nail insertion point and the dorsal edge of the radius.

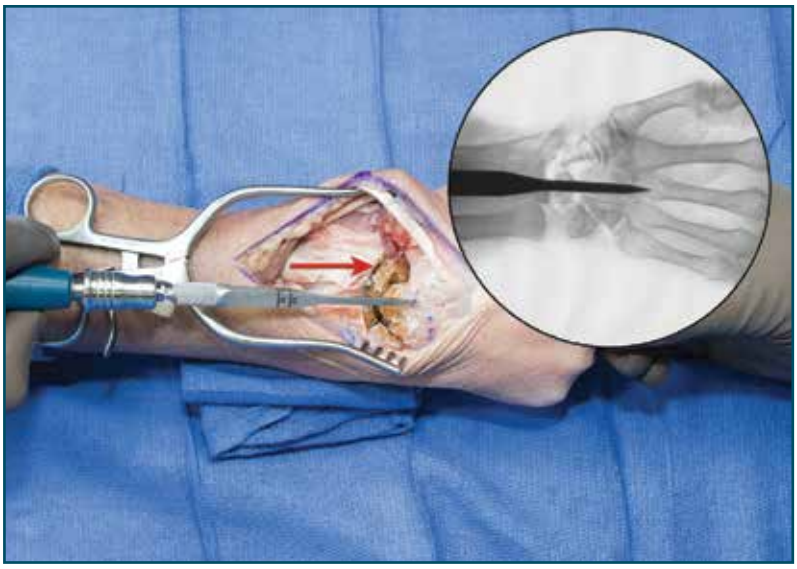
Note:
This gap will ensure that sufficient spacing is available for the shortest connector option. If necessary, extend the spacing by removing bone from the radius.

IMP-WAN-MGG: MPLATE, Minimum Gap Gauge

OPENING THE METACARPAL CANAL 8

Open the medullary canal of the 3rd metacarpal by inserting the AWL through the distal flare of the capitate aimed towards the head.

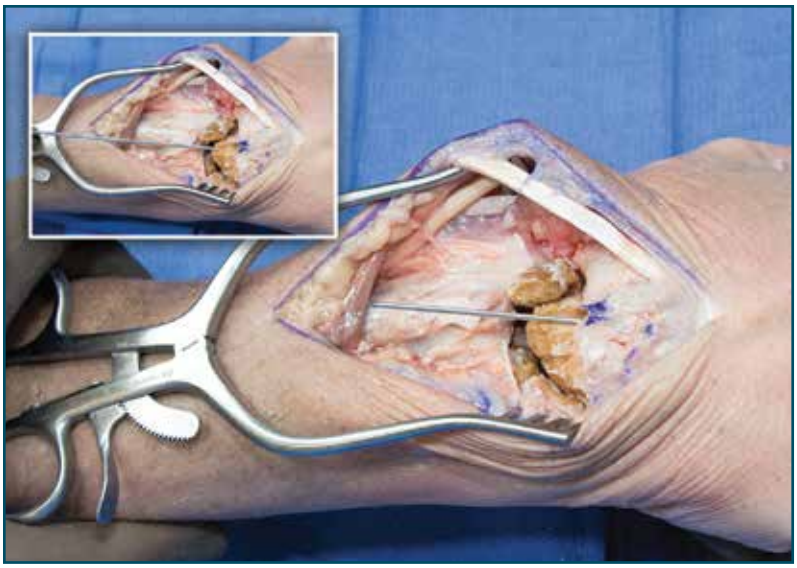
Note:
Fluoroscopic imaging is helpful at this step.



IMP-WAN-AWL: IMPLATE Awl, Wrist Arthrodesis Nails

Capitate & Metacarpal

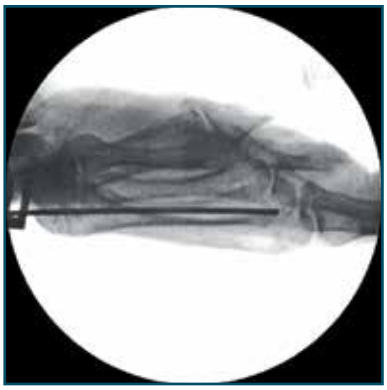
9 K-WIRE PLACEMENT



Using a 1.5mm k-wire as a probe, insert the blunt end through the medullary canal to locate the head of the metacarpal.

KWIR-STD-15127: K-Wire, Standard Tip, 1.6mm x 127mm

10 K-WIRE CONFIRMATION



Fluoroscopic imaging is required to confirm the proper placement of the k-wire.

METACARPAL REAMING 11

Ream over the 1.5mm k-wire using metacarpal reamer to the proper depth.

Remove the k-wire and continue reaming to the proper diameter.

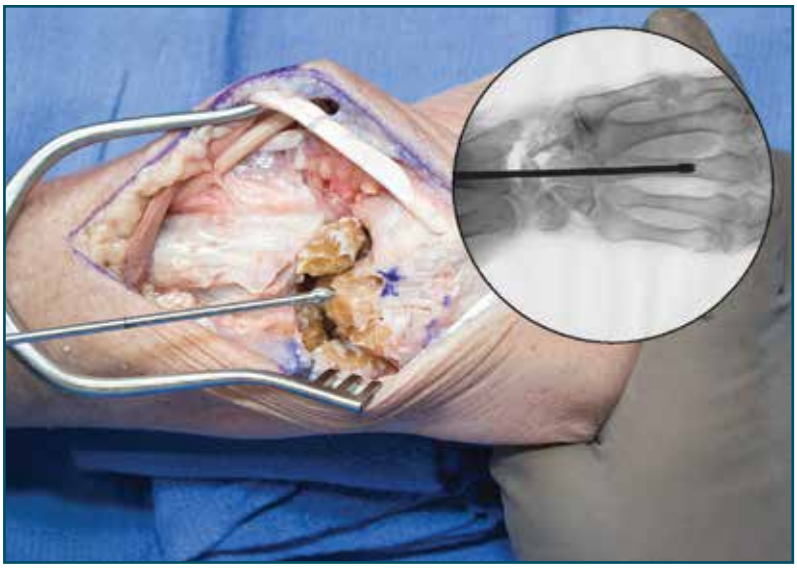
Note:
Each metacarpal reamer is etched with a “depth mark” to ensure that the proper depth has been achieved.

IMP-WAN-MR1: IMPLATE Reamer 1, Metacarpal, 2.7mm x 87mm, Cannulated

FINAL METACARPAL REAMING 12

The system offers two diameters of metacarpal nails; 4.0mm and 4.6mm.

Depending on the diameter of the medullary canal, use MR3 as the final reamer for the 4.0mm nail or MR5 as the final reamer for the 4.6mm nail.



4.0 NAIL

IMP-MCN-S40: Reamer 1, Metacarpal, 2.7mm x 87mm, Cannulated

IMP-MCN-S46: Reamer 2, Metacarpal, 3.4mm x 87mm, Cannulated

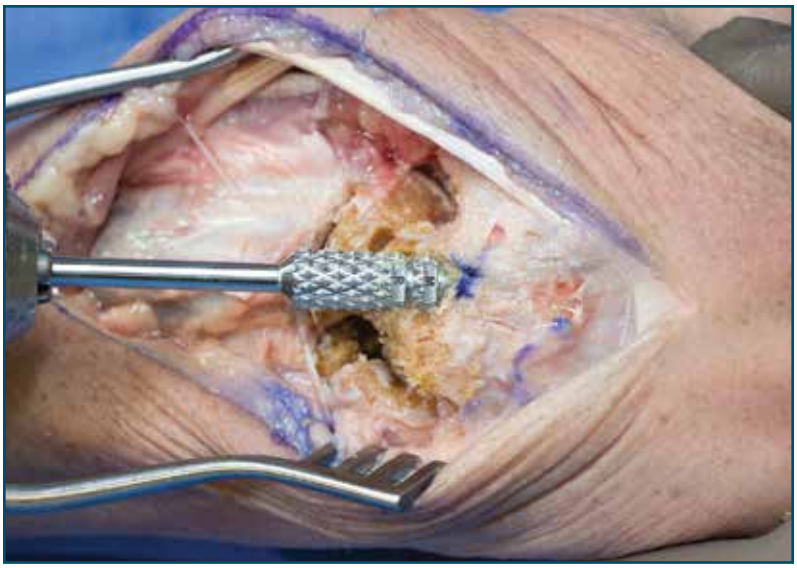
IMP-MCN-S46: Reamer 3, Metacarpal, 4.0mm x 87mm, Cannulated

4.6 NAIL

IMP-MCN-S40: Reamer 4, Metacarpal, 4.5mm x 87mm, Cannulated

IMP-MCN-S46: Reamer 5, Metacarpal, 5.0mm x 87mm, Cannulated

13 FINAL CAPITATE PREPARATION



Insert the flaring-troughing tool into the medullary canal up to the line marked "**M**".

This shapes the opening of the capitate to accept the flared end of the metacarpal nail.

IMP-FAT-RASP: IMPLATE Rasp, Flaring and Troughing

14 CMC JOINT PREPARATION

Gain access to the 3rd CMC joint space for complete decortication of the articular surfaces.

Apply bone graft as needed prior to inserting the metacarpal nail.

Note:
Ensure bone graft does not enter the medullary canal.

METACARPAL NAIL ASSEMBLY 15

Secure the appropriate sized metacarpal nail to the drill guide using the lock screw.

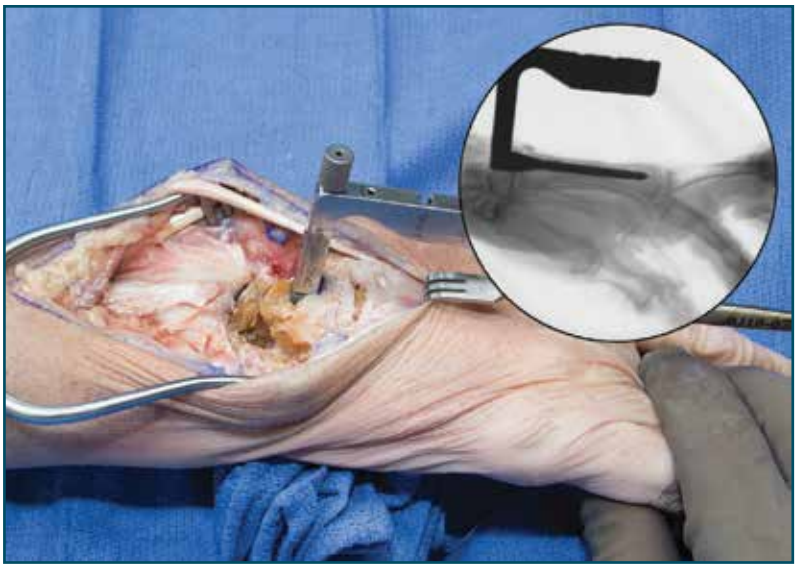
Note:
Be sure to fully tighten the lock screw.

IMP-UDG-DRMC: IMPLATE Uni Drill Guide, DRMC Nails

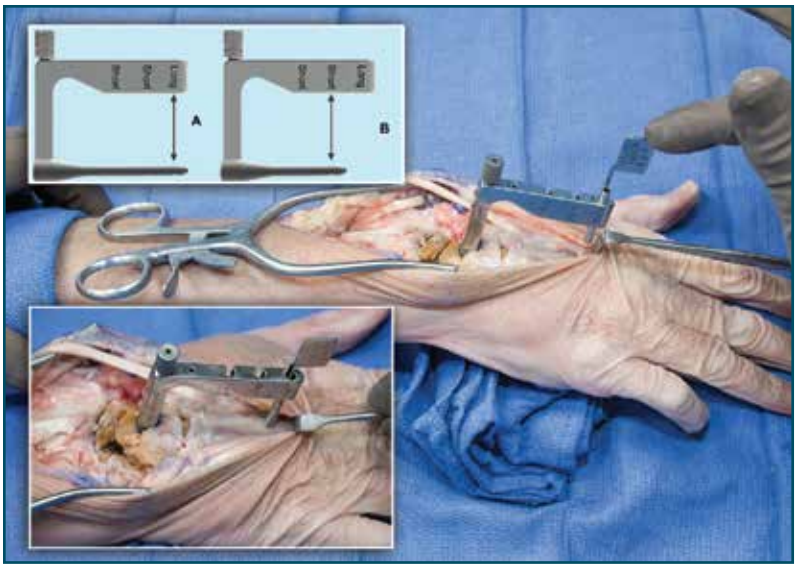
IMP-UDG-LKSC: IMPLATE Lock Screw, Unicort. Drill Guide

METACARPAL NAIL INSERTION 16

Insert the metacarpal nail into the medullary canal until the drill guide seats flush against the capitate.



17 METACARPAL NAIL PREPARATION



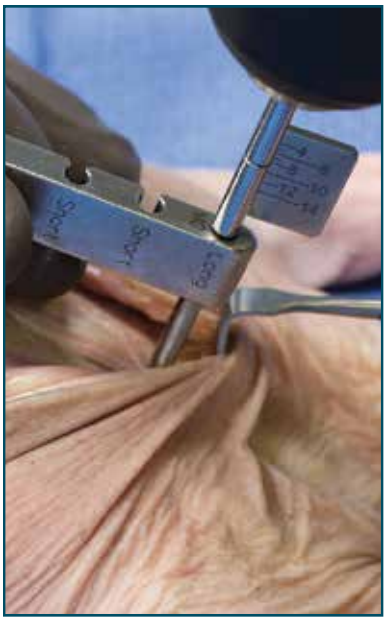
Insert the drill sleeve through the **distal slot** of the drill guide until flush against the bone.

A. standard length metacarpal nail; use the distal slot.
B. Mini length metacarpal nail; use the middle slot.

Note:
If necessary, extend the incision distally to allow the drill sleeve to contact the bone.

MP-UDG-DSLV: IMPLATE Uni Drill Guide, Drill Sleeve

18 METACARPAL NAIL DRILLING



Advance the 3.0mm unicortical drill through the near cortex until the mechanical stop of the bit reaches the drill guide.

Note:
The 3.0mm unicortical drill bit has a mechanical stop that prevents the drill from contacting the metacarpal nail.

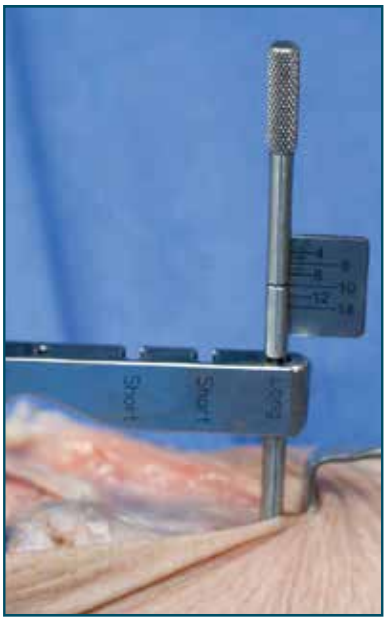
MP-DUC-0341: IMPLATE Drill, Unicortical, 3mm x 41mm

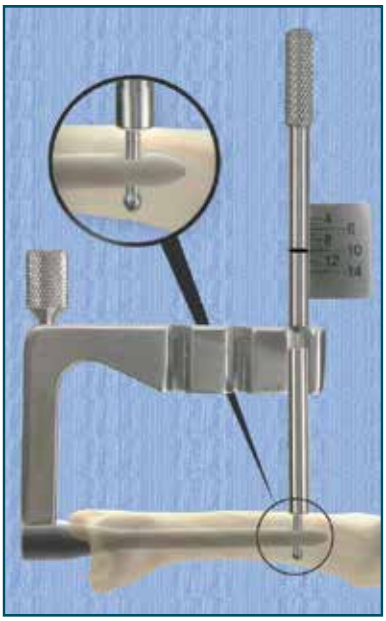
UNICORTICAL SCREW SIZING 19

Insert the depth gauge through the drill sleeve until the far cortex is reached to determine the appropriate screw length.

Note:
The depth gauge is designed to pass through the near cortex and transect the metacarpal nail until the far cortex is reached. This determines the longest possible unicortical screw option.

If between screw lengths, round to the nearest size.



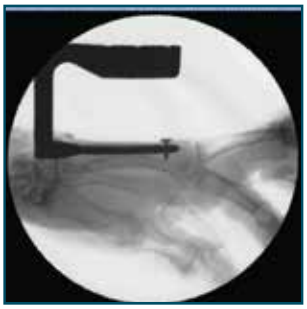


MP-UDG-DGAU: IMPLATE Uni Drill Guide, Depth Gauge

SECURING THE METACARPAL NAIL 20

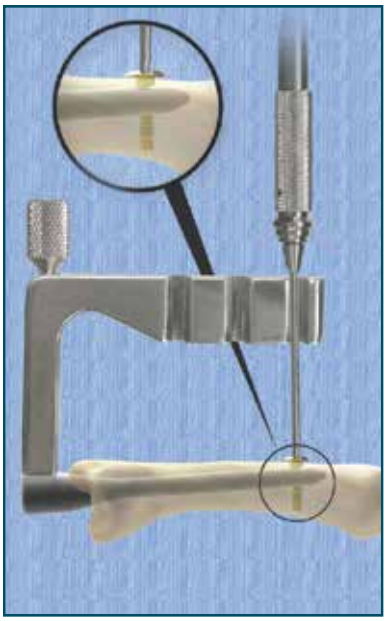
Insert the appropriate length 2.8mm unicortical screw and engage the metacarpal nail.

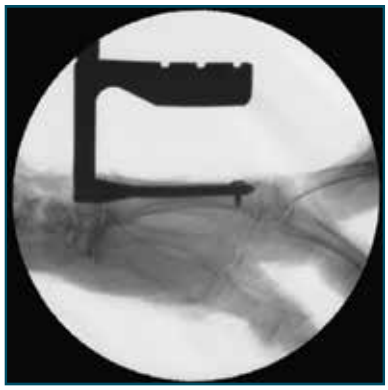
Note:
Lifting the distal tip of the drill guide while advancing the unicortical screw facilitates nail engagement.



HNDL-MQC-FXD: Handle, Mini Quick Connect, Fixed

21 LOCKING THE METACARPAL NAIL

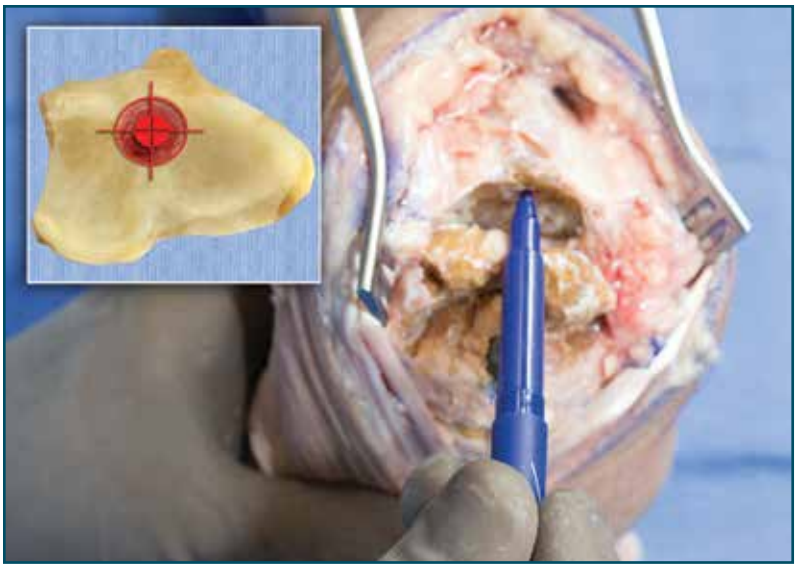




Confirm that the unicortical screw has been fully tightened and that the metacarpal nail is flush to the endosteal surface using fluoroscopic imaging.

After confirmation, remove the drill guide.

22 RADIAL NAIL INSERTION POINT



Flex the hand to fully visualize the distal radius. Mark a point on the ridge between the scapholunate fossae, just below Lister's Tubercle.

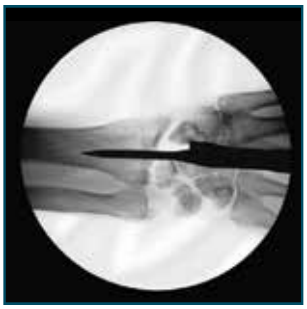
Note:
This location marks the entry point for the radial nail.

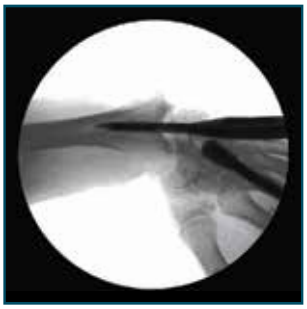
OPENING THE RADIAL CANAL 23

Insert the awl through the previously marked entry point for the distal radius.

Confirm that the proper trajectory has been established using fluoroscopic imaging.

Note:
Adjustments can be made at this time.





NDL-UQC-FXD: Handle, Universal QC, Fixed

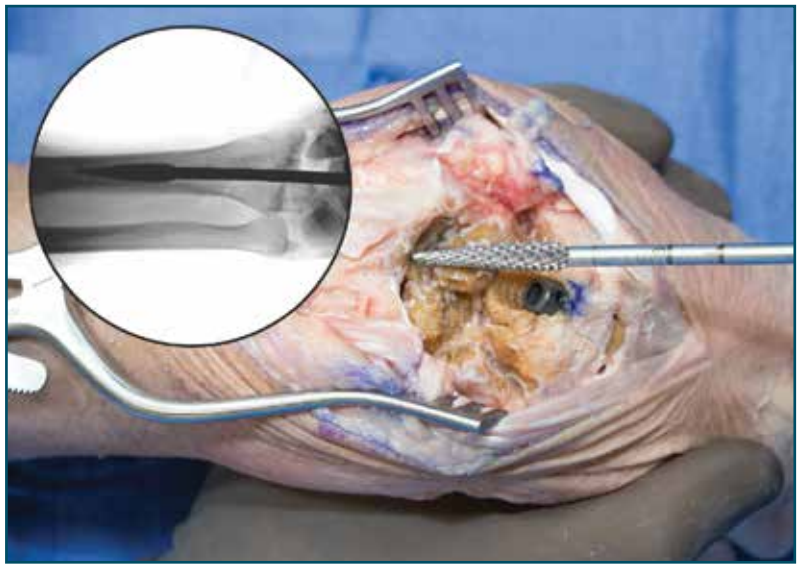
RADIAL RASPING 24

Prepare the medullary canal using the two radial rasps (**RR**).

The depth marks on the rasps determine the appropriate nail length:

Rasp to **S**; use the short radial nail
Rasp to **L**; use the long radial nail

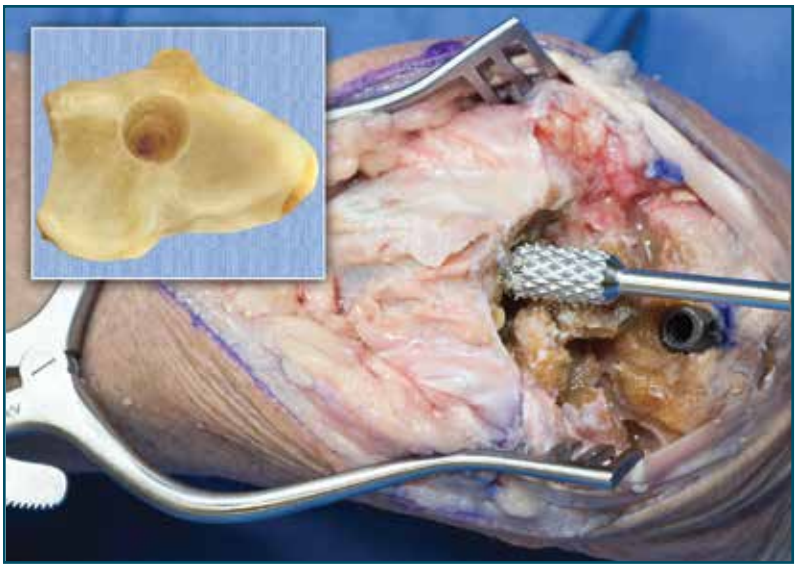
Note:
Fluoroscopic imaging is helpful during this step.



IMP-WAN-RR1: IMPLATE Rasp 1, Distal Radius, 5.5mm x 70mm

IMP-WAN-RR2: IMPLATE Rasp 2, Distal Radius, 7.0mm x 70mm

25 FINAL RADIAL PREPARATION

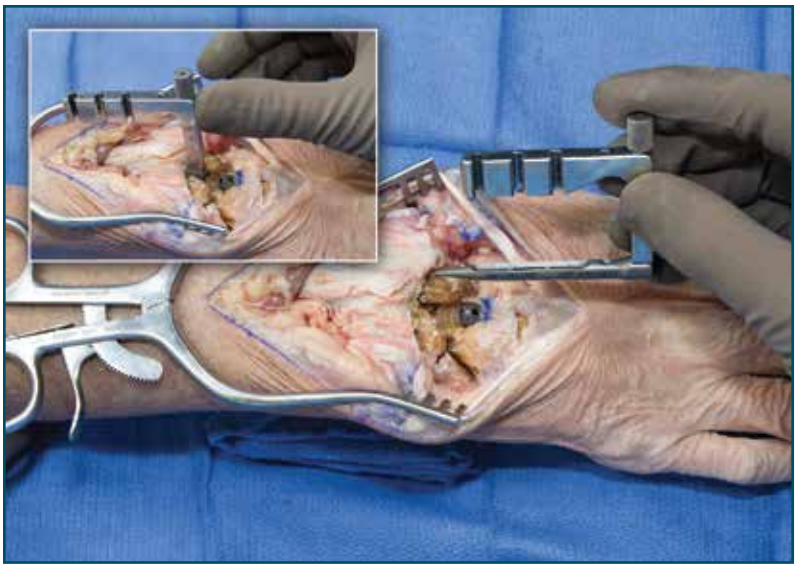


Insert the flaring-troughing tool into the medullary canal up to the line marked "**R**".

This shapes the opening of the canal to accept the flared end of the radial nail.

IMP-FAT-RASP: IMPLATE Rasp, Flaring and Troughing

26 RADIAL NAIL INSERTION



Secure the radial nail to the drill guide using the lock screw.

Insert the radial nail into the medullary canal until the drill guide seats flush against the radius.

Note:
If you do not have sufficient spacing between the two nails, you can remove a small amount of bone from the dorsal edge of the radius, allowing the nail to move proximal.

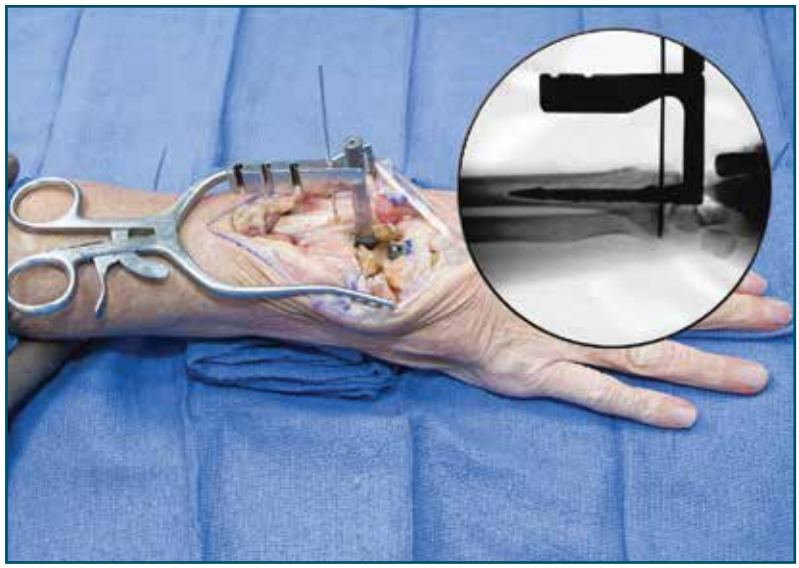
Note:
Be sure to fully tighten the lock screw.

SECURING THE RADIAL NAIL 27

Provisionally secure the radial nail to the radius by inserting a 1.5mm k-wire through the k-wire hole on the drill guide.

Do not bend this k-wire as it will prevent the removal of the drill guide.

Note:
Confirm that the k-wire has transected the nail for bicortical contact using fluoroscopic imaging.



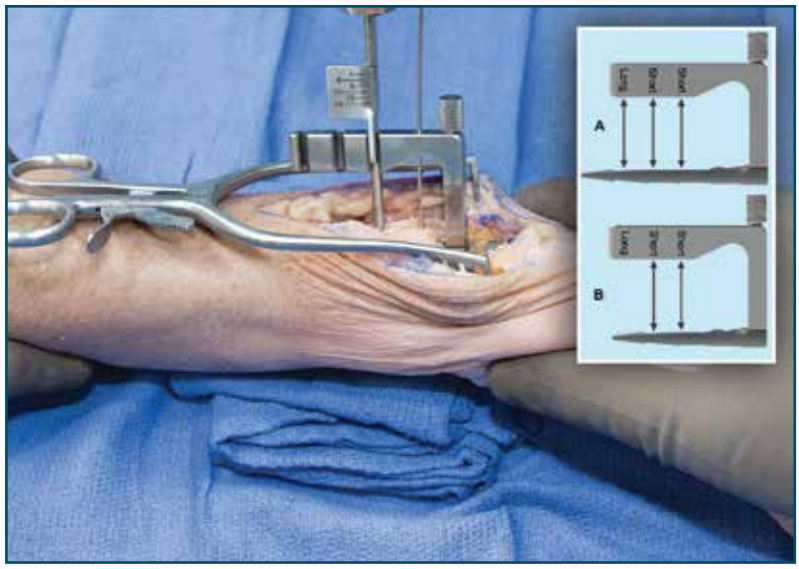
KWIR-STD-15127: K-Wire, Standard Tip, 1.6mm x 127mm

RADIAL NAIL DRILLING 28

Insert the drill sleeve through a slot on the drill guide until flush against the bone:

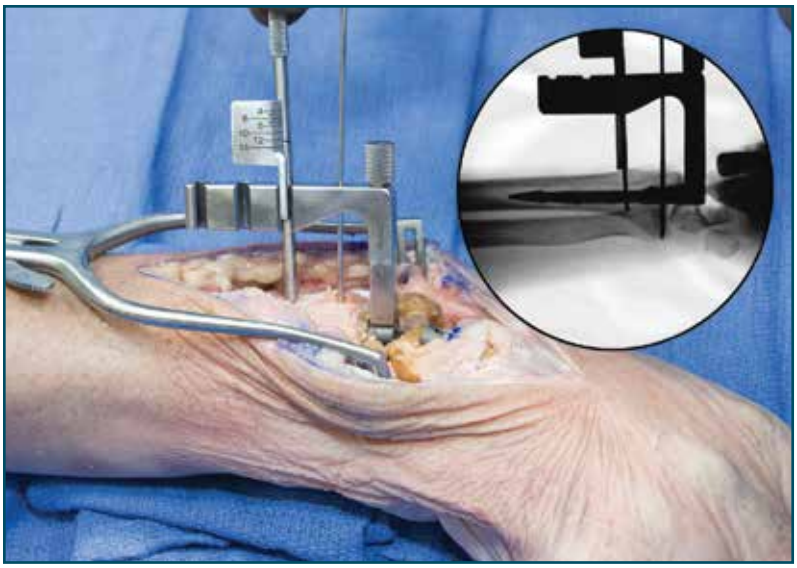
A. Long radial nail; use all three slots
B. Short radial nail; use the middle and distal slots

Advance the 3.0mm drill bit through the near cortex until the mechanical stop of the drill is reached.



MP-UDG-DSLV: IMPLATE Uni Drill Guide, Drill Sleeve

29 UNICORTICAL SCREW SIZING

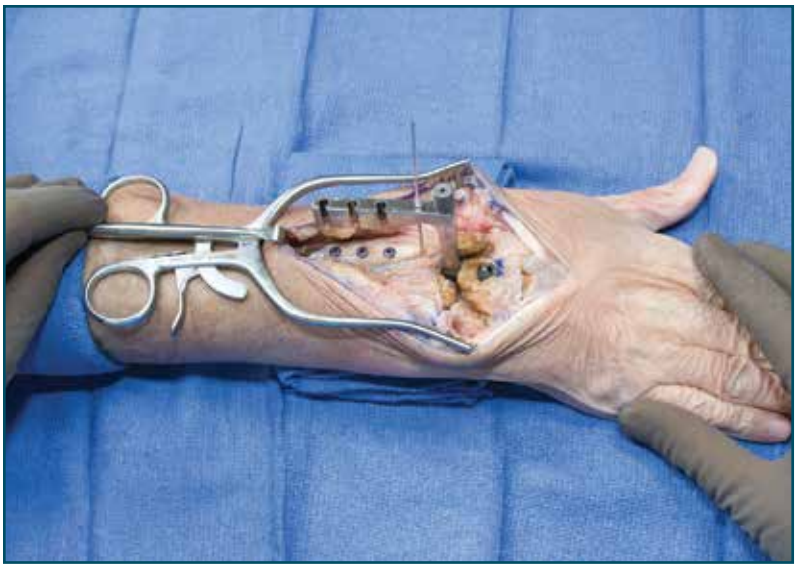


Insert the depth gauge through the drill sleeve until the far cortex is reached to determine the appropriate screw length.

Note:
If between screw lengths, choose the shorter screw option.

IMP-UDG-DGAU: IMPLATE Uni Drill Guide, Depth Gauge

30 FINAL DRILLING AND MEASURING



Loosely thread the appropriate length 2.8mm unicortical screw to engage the nail.

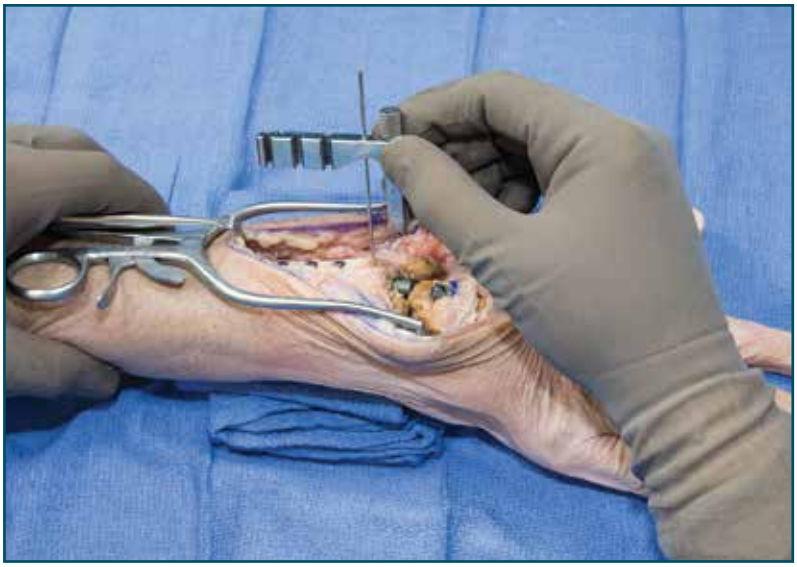
Repeat steps 28 and 29 for the remaining screw hole(s).

DRILL GUIDE REMOVAL 31

Provisionally secure the radial nail to the radius by inserting a 1.5mm k-wire through the k-wire hole on the drill guide.

Do not bend this k-wire as it will prevent the removal of the drill guide.

Note:
Confirm that the k-wire has transected the nail for bicortical contact using fluoroscopic imaging.



CONNECTOR SELECTION 32

The IMPLATE® system offers connectors in four angle variations and in three lengths final connector length, angle and rotation adjustments can be made prior to locking the construct.

"Centering lines" are etched on all connectors in the plane formed by the angle. Insertion depth marks are etched on the splines of the connector to confirm proper seating into the nails. Insertion depth mark will not be visible when properly seated.

IMP-WC-XX00: IMPLATE Connector, Xmm x 0°

IMP-WC-XX15: IMPLATE Connector, Xmm x 15°

IMP-WC-XX07: IMPLATE Connector, Xmm x 7.5°

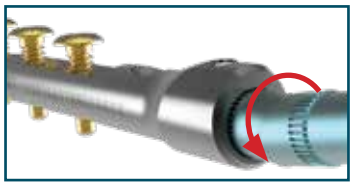
IMP-WC-XX07: IMPLATE Connector, Xmm x 22.5°

33 CONNECTOR ADJUSTMENTS

Length

Select the connector length to allow for full seating of the splines after construct assembly.

Rotation



Rotational adjustments should be made between the connector and the radial nail.

Angulation

Angled connectors allow for adjustments of wrist flexion-extension and radio-ulnar deviation. To adjust the position of the hand in space, rotate the connector until the desired compound angle is obtained. Then engage the splines at both ends.

Extension Radial Deviation Neutral Ulnar Deviation

34 LOADING THE CONNECTOR

Loosely thread the appropriate length 2.8mm unicortical screw to engage the nail.

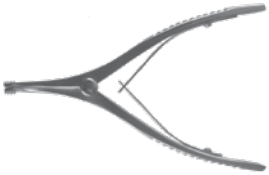
Repeat steps 28 and 29 for the remaining screw hole(s).

FINAL HAND POSITIONING 35

Ensure that the optimal clinical position has been achieved.

Further adjustments can be made at this time.

Note:
A spreader is included in the system to facilitate the removal of the connector.

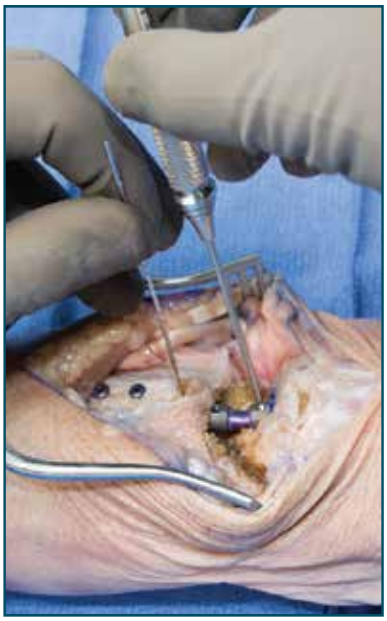


IMP-WAN-SPDR: IMPLATE Spreader, Wrist Arthrodesis Nails

LOCKING THE CONSTRUCT 36

Lock the construct using a set screw in each nail.

Note:
Be sure that the splines are fully engaged at both ends before locking the construct.



HNDL-MQC-FXD: Handle, Mini Quick Connect, Fixed

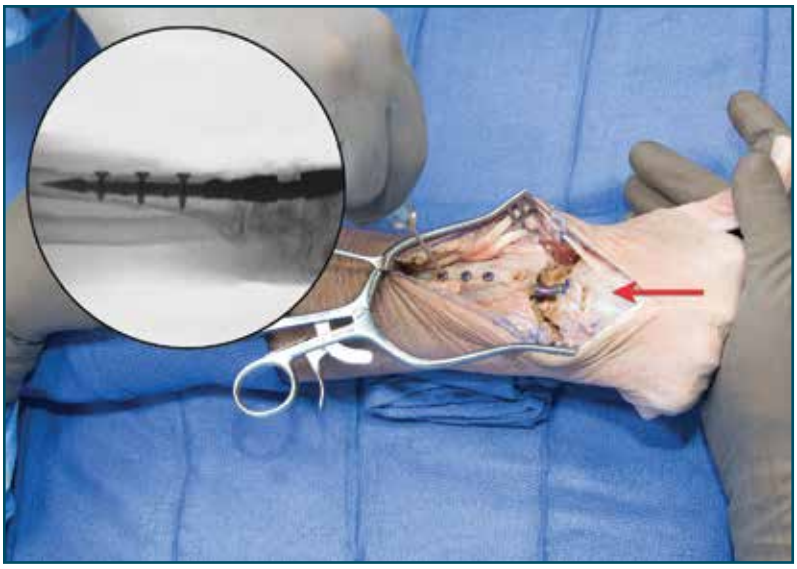
STSC-30020-CS: Set Screw, 3.0mm x 2.0mm, CoCr

37 DISTRACTION - COMPRESSION

Remove the 1.5mm k-wire to allow for distraction or compression of the fusion site.

Apply bone graft as needed.

38 LOCKING THE RADIAL NAIL



After achieving optimal compression or distraction, fully tighten the unicortical screws to lock your position. Each unicortical screw will require subsequent tightening until the radial nail fully compresses to the endosteal surface.

Note:
Fluoroscopic imaging is helpful during this step.

Warning:
When desired results are achieved, confirm that all screws have been fully tightened.

WOUND CLOSURE 39

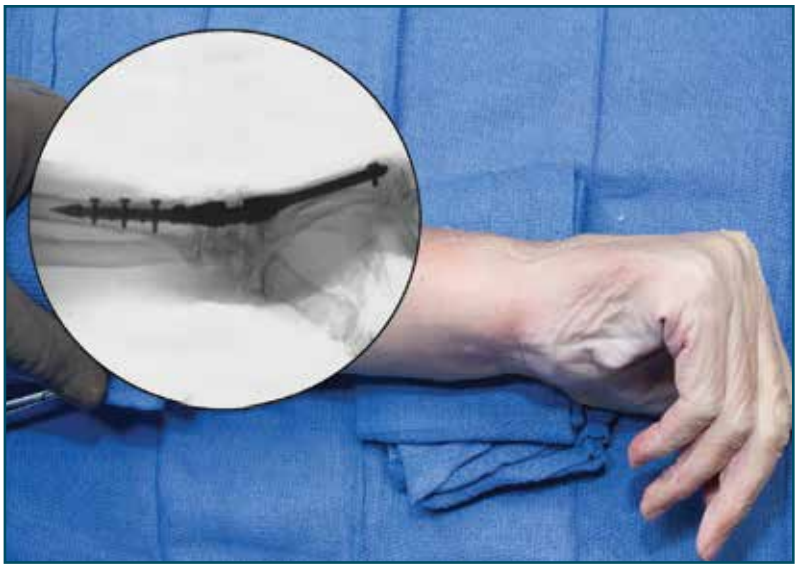
Close the dorsal capsule, then repair the extensor retinaculum as necessary.

Repair the remaining soft tissues as needed, then close the incision.

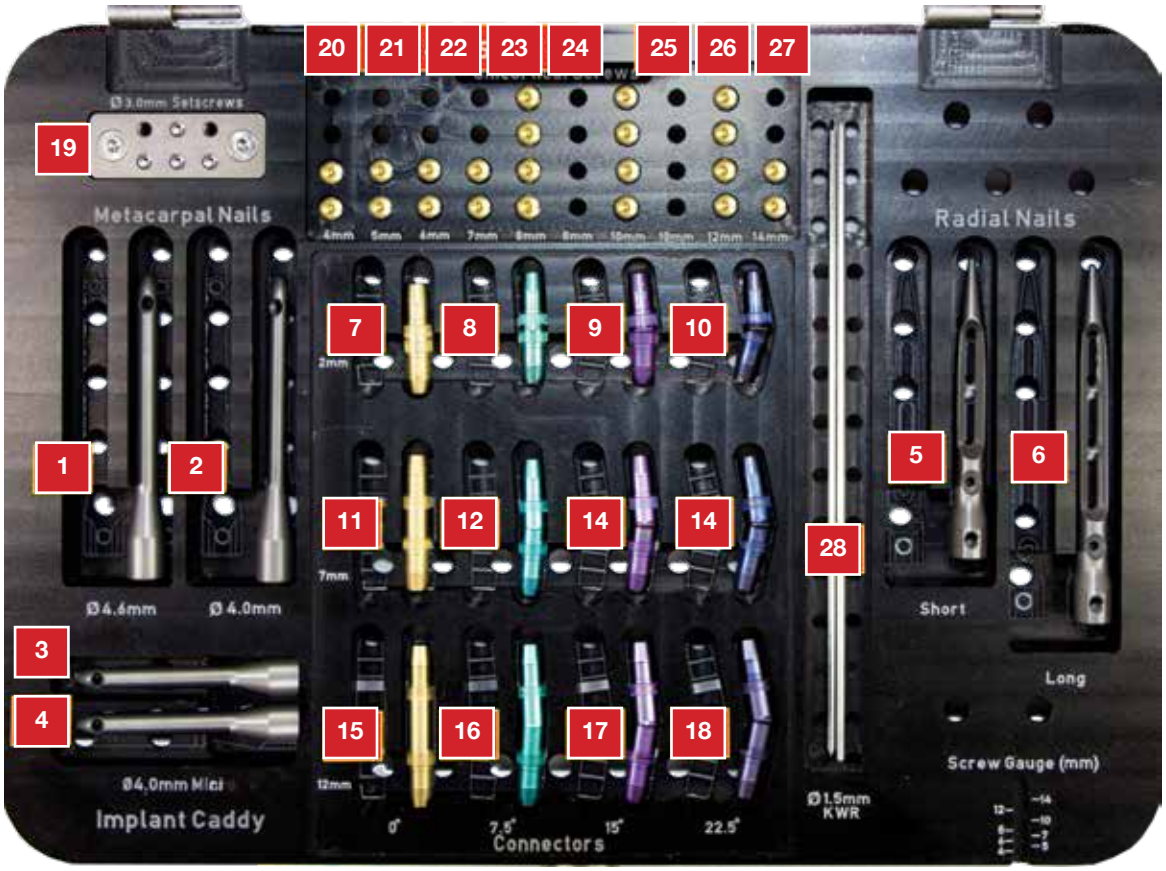
POSTOPERATIVE PROTOCOL 40

Post-operative:
Apply a post operative dressing until the first office visit. Recommend full finger motion as tolerated and non-weight bearing.

First visit (~ 1 week):
Based on clinical judgement, apply a removable orthotic or shortarm cast until fusion occurs.

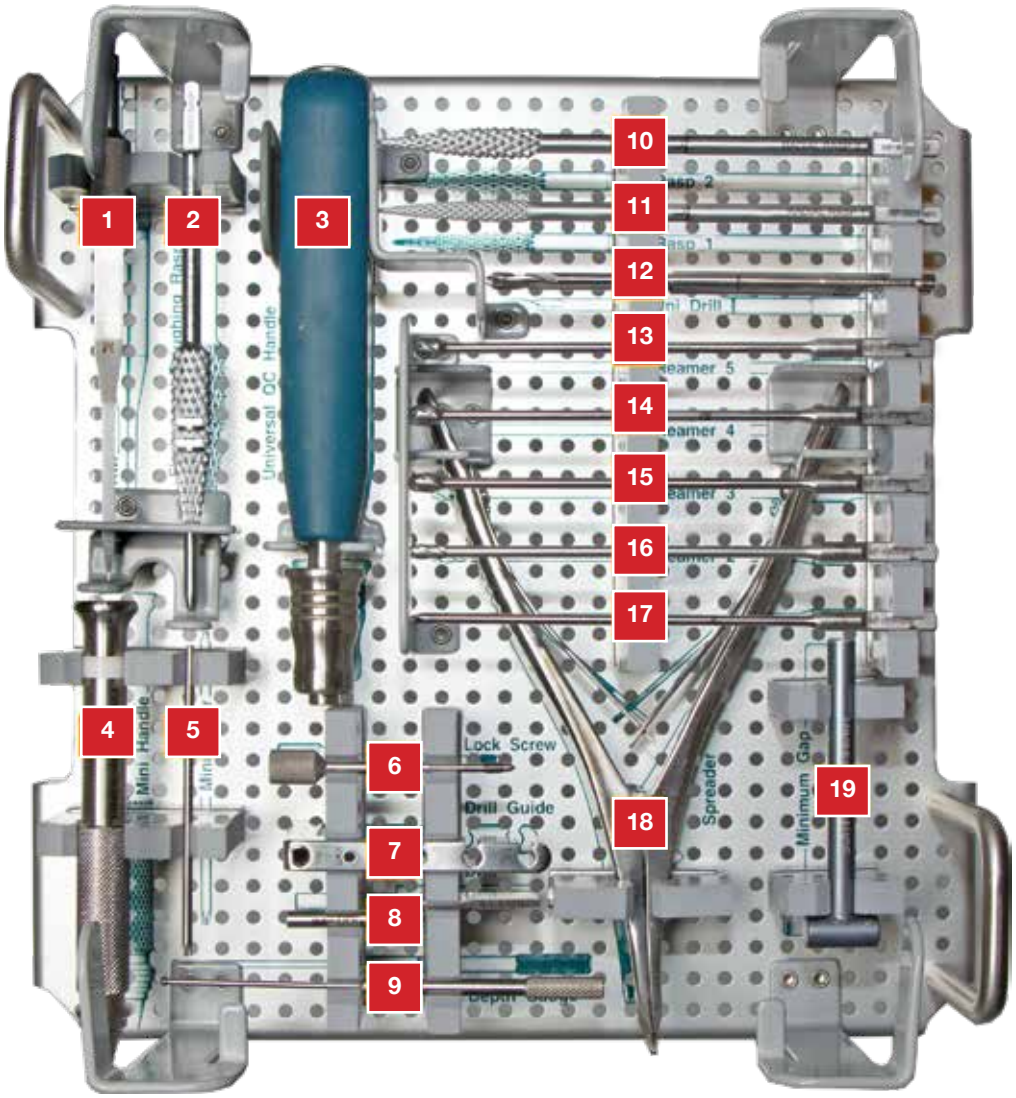


INSTRUMENT TRAY (Standard Configuration)



Loc#	Catalog#	Description
1	IMP-MCN-S40	IMPLATE Nail, Metacarpal, Standard, 4.0mm
2	IMP-MCN-S46	IMPLATE Nail, Metacarpal, Standard, 4.6mm
3	IMP-MCN-M40	IMPLATE Nail, Metacarpal, Mini, 4.0mm
4	IMP-MCN-M46	IMPLATE Nail, Metacarpal, Mini, 4.6mm
5	IMP-DRN-SHT	IMPLATE Nail, Distal Radius, Short, Ti
6	IMP-DRN-LNG	IMPLATE Nail, Distal Radius, Long, Ti
7	IMP-WC-0200	IMPLATE Connector, 2mm x 0°
8	IMP-WC-0207	IMPLATE Connector, 2mm x 7.5°
9	IMP-WC-0215	IMPLATE Connector, 2mm x 15°
10	IMP-WC-0222	IMPLATE Connector, 2mm x 22.5°
11	IMP-WC-0700	IMPLATE Connector, 7mm x 0°
12	IMP-WC-0707	IMPLATE Connector, 7mm x 7.5°
13	IMP-WC-0715	IMPLATE Connector, 7mm x 15°
14	IMP-WC-0722	IMPLATE Connector, 7mm x 22.5°
15	IMP-WC-1200	IMPLATE Connector, 12mm x 0°
16	IMP-WC-1207	IMPLATE Connector, 12mm x 7.5°
17	IMP-WC-1215	IMPLATE Connector, 12mm x 15°
18	IMP-WC-1222	IMPLATE Connector, 12mm x 22.5°
19	STSC-30020-CS	Set Screw, 3.0mm x 2.0mm, CoCr
20	UCNL-28040-TS	Unicortical Screw, 2.8mm x 4.0mm, Ti
21	UCNL-28050-TS	Unicortical Screw, 2.8mm x 5.0mm, Ti
22	UCNL-28060-TS	Unicortical Screw, 2.8mm x 6.0mm, Ti
23	UCNL-28070-TS	Unicortical Screw, 2.8mm x 7.0mm, Ti
24	UCNL-28080-TS	Unicortical Screw, 2.8mm x 8.0mm, Ti
25	UCNL-28100-TS	Unicortical Screw, 2.8mm x 10.0mm, Ti
26	UCNL-28120-TS	Unicortical Screw, 2.8mm x 12.0mm, Ti
27	UCNL-28140-TS	Unicortical Screw, 2.8mm x 14.0mm, Ti
28	KWIR-STD-15127: K-Wire, Standard Tip, 1.6mm x 127mm	

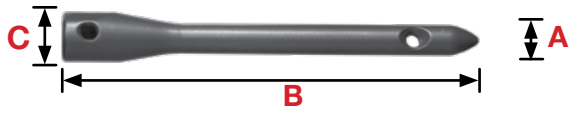
INSTRUMENT TRAY (Standard Configuration)



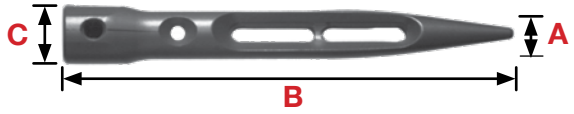
Loc#	Catalog#	Description
1	IMP-WAN-AWL	IMPLATE Awl, Wrist Arthrodesis Nails
2	IMP-FAT-RASP	IMPLATE Rasp, Flaring and Troughing
3	HNDL-UQC-FXD	Handle, Universal QC, Fixed
4	HNDL-MQC-FXD	Handle, Mini Quick Connect, Fixed
5	DRVR-MQC-T07	Driver, Mini QC, T-7
6	IMP-UDG-LKSC	IMPLATE Lock Screw, Unicort. Drill Guide
7	IMP-UDG-DRMC	IMPLATE Uni Drill Guide, DRMC Nails
8	IMP-UDG-DSLV	IMPLATE Uni Drill Guide, Drill Sleeve
9	IMP-UDG-DGAU	IMPLATE Uni Drill Guide, Depth Gauge
10	IMP-WAN-RR2	IMPLATE Rasp 2, Distal Radius, 7.0mm x 70mm
11	IMP-WAN-RR1	IMPLATE Rasp 1, Distal Radius, 5.5mm x 70mm
12	IMP-DUC-0341	IMPLATE Drill, Unicortical, 3mm x 41mm
13	IMP-WAN-MR5	IMPLATE Reamer 5, Metacarpal, 5.0mm x 87mm, Cannulated
14	IMP-WAN-MR4	IMPLATE Reamer 4, Metacarpal, 4.5mm x 87mm, Cannulated
15	IMP-WAN-MR3	IMPLATE Reamer 3, Metacarpal, 4.0mm x 87mm, Cannulated
16	IMP-WAN-MR2	IMPLATE Reamer 2, Metacarpal, 3.4mm x 87mm, Cannulated
17	IMP-WAN-MR1	IMPLATE Reamer 1, Metacarpal, 2.7mm x 87mm, Cannulated
18	IMP-WAN-SPDR	IMPLATE Spreader, Wrist Arthrodesis Nails
19	IMP-WAN-MGG	IMPLATE, Minimum Gap Gauge

IMPLATE® WRIST ARTHRODESIS NAIL

Metacarpal Nails (Ti)

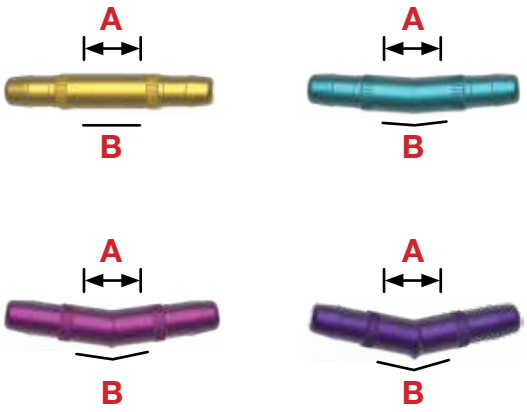


Distal Radius Nails (Ti)



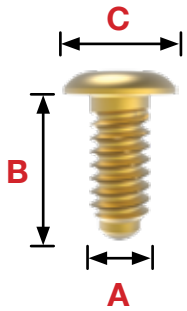
CATALOG#	DIMENSIONS (mm)		
	A	B	C
IMP-MCN-M40	4.0	46	7.6
IMP-MCN-S40	4.0	60	7.6
IMP-MCN-S46	4.6	60	7.6
IMP-MCN-M46	4.6	46	7.6
IMP-DRN-SHT	6.5	59	7.6
IMP-DRN-LNG	6.5	70	7.6

IMPLATE® WRIST ARTHRODESIS CONNECTORS



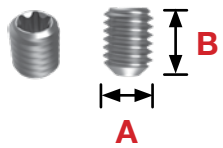
CATALOG#			
	A	B	COLOR
IMP-WC-0200	2mm	0°	Gold
IMP-WC-0700	7mm	0°	Gold
IMP-WC-1200	12mm	0°	Gold
IMP-WC-0207	2mm	7.5°	Teal
IMP-WC-0707	7mm	7.5°	Teal
IMP-WC-1207	12mm	7.5°	Teal
IMP-WC-0215	2mm	15°	Purple
IMP-WC-0715	7mm	15°	Purple
IMP-WC-1215	12mm	15°	Purple
IMP-WC-0222	2mm	22.5°	Blue
IMP-WC-0722	7mm	22.5°	Blue
IMP-WC-1222	12mm	22.5°	Blue

IMPLATE® WRIST ARTHRODESIS UNICORTICAL SCREWS



CATALOG#	DIMENSIONS (mm)		
	A	B	C
UCNL-28040-TS	2.8	4.0	4.0
UCNL-28050-TS	2.8	5.0	4.0
UCNL-28060-TS	2.8	6.0	4.0
UCNL-28070-TS	2.8	7.0	4.0
UCNL-28080-TS	2.8	8.0	4.0
UCNL-28100-TS	2.8	10.0	4.0
UCNL-28120-TS	2.8	12.0	4.0
UCNL-28140-TS	2.8	14.0	4.0

IMPLATE® WRIST ARTHRODESIS SET SCREWS



CATALOG#		
	A	B
STSC-30020-CS	3.0	2.0

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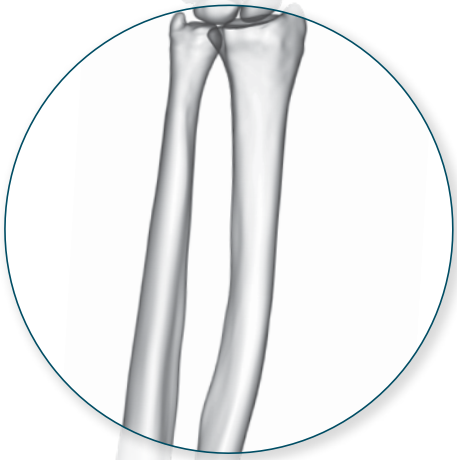
UNDERSTANDING THE UPPER EXTREMITY



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