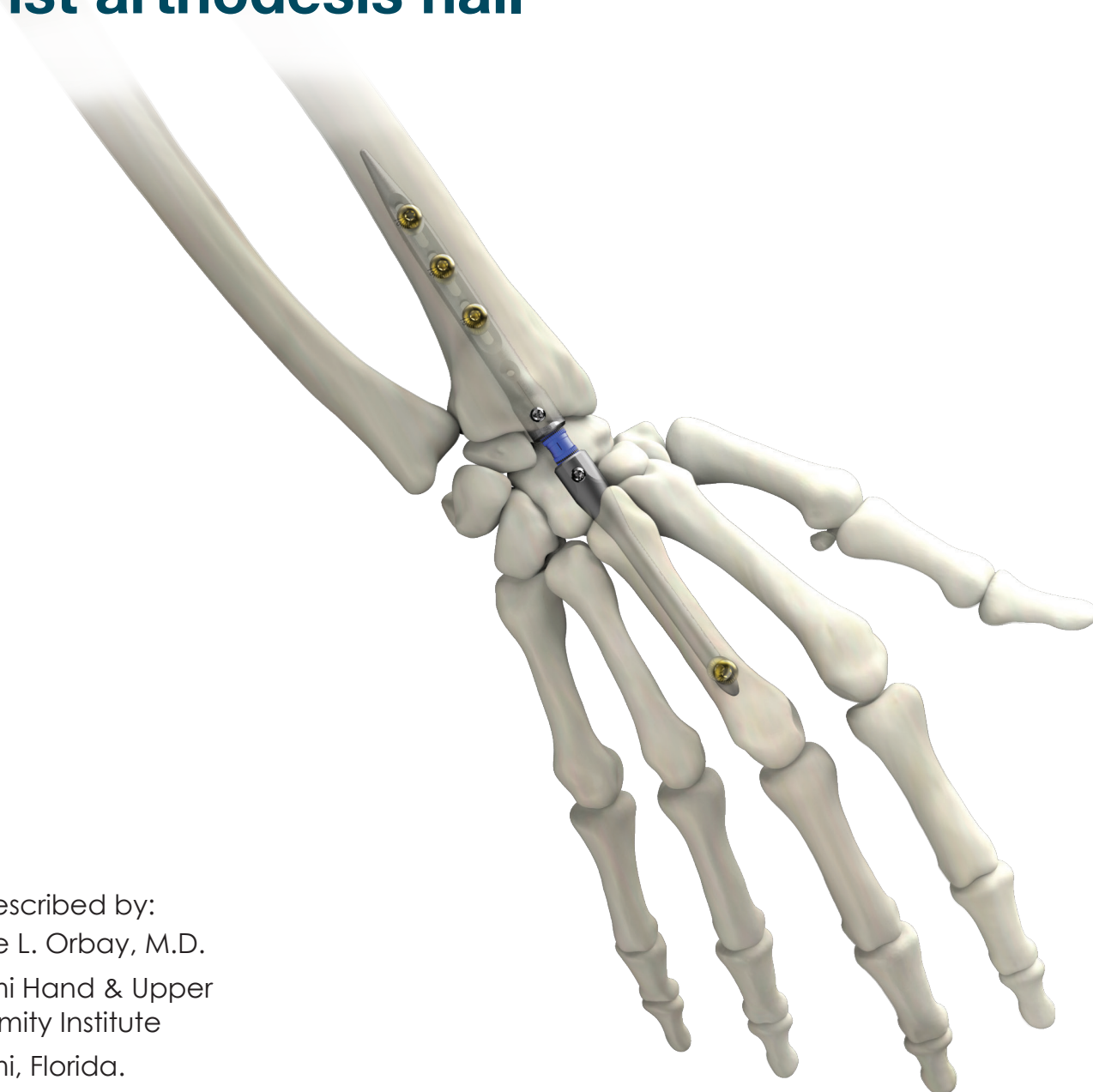


SURGICAL TECHNIQUE GUIDE

IMPLATE[®]

wrist arthodesis nail

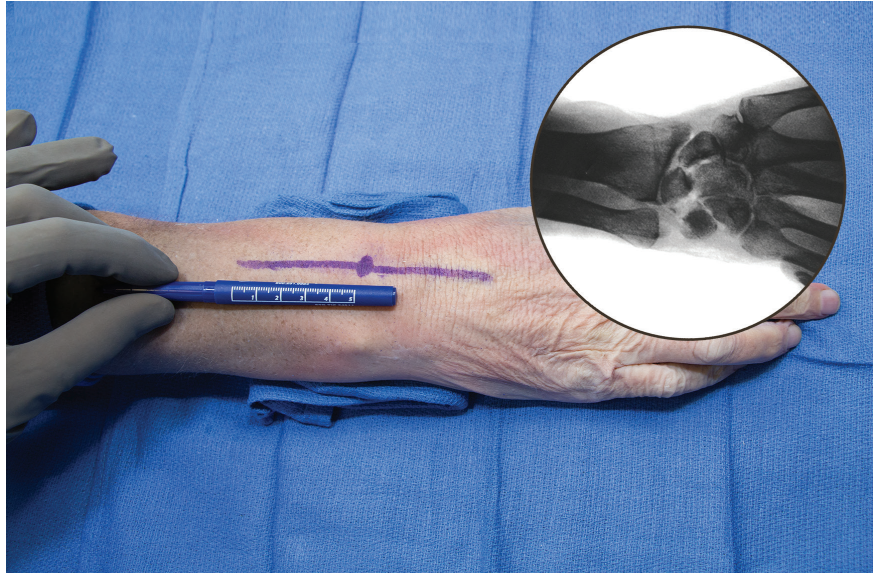


As described by:
Jorge L. Orbay, M.D.
Miami Hand & Upper
Extremity Institute
Miami, Florida.

1

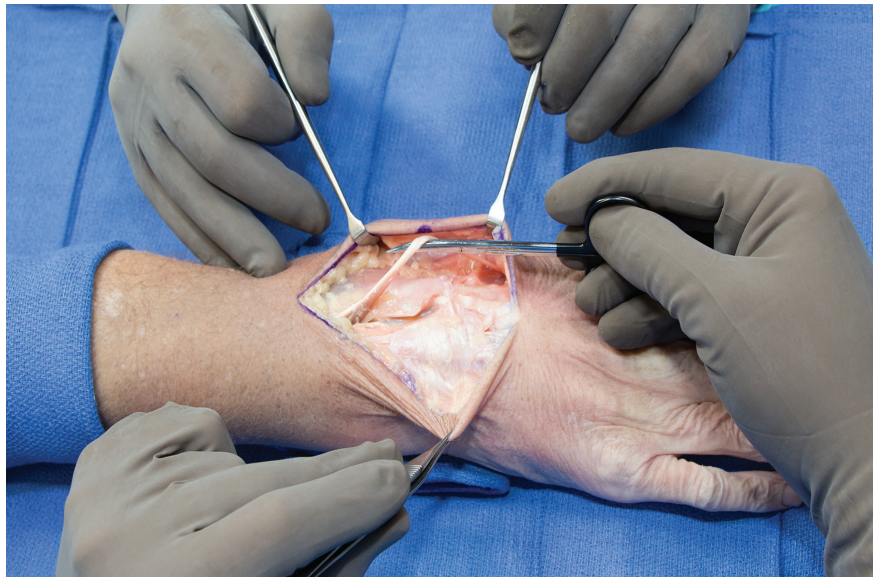
EXPOSURE

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

**2**

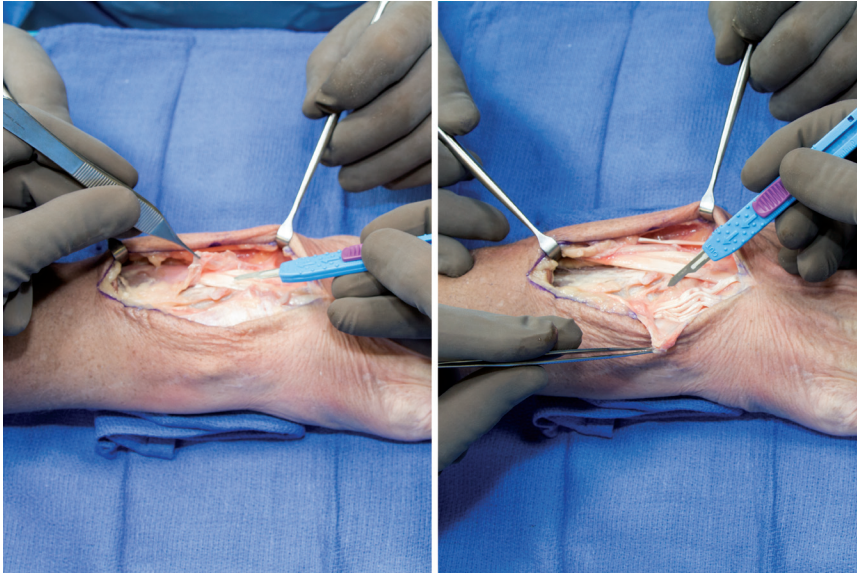
EPL TENDON SHEATH

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



EXTENSOR COMPARTMENTS

3

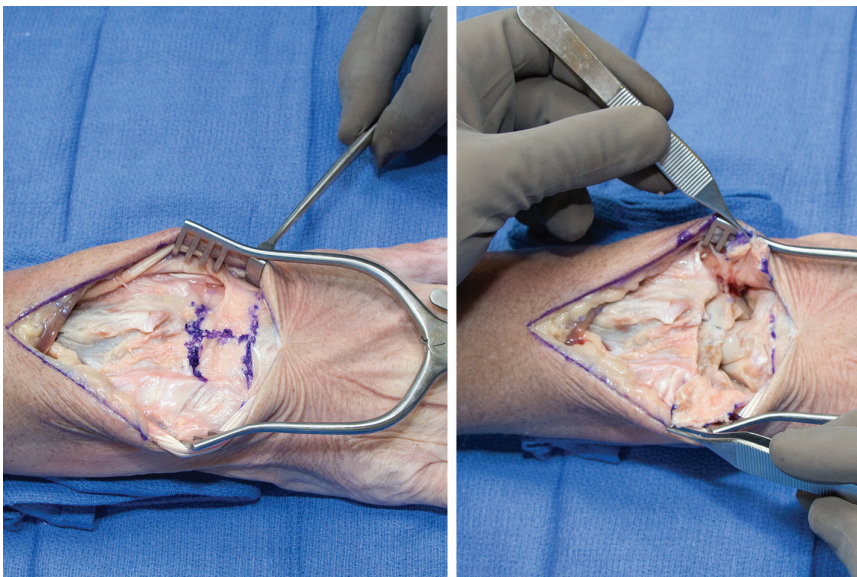


Expose and release the 2nd and 4th extensor compartments.

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.

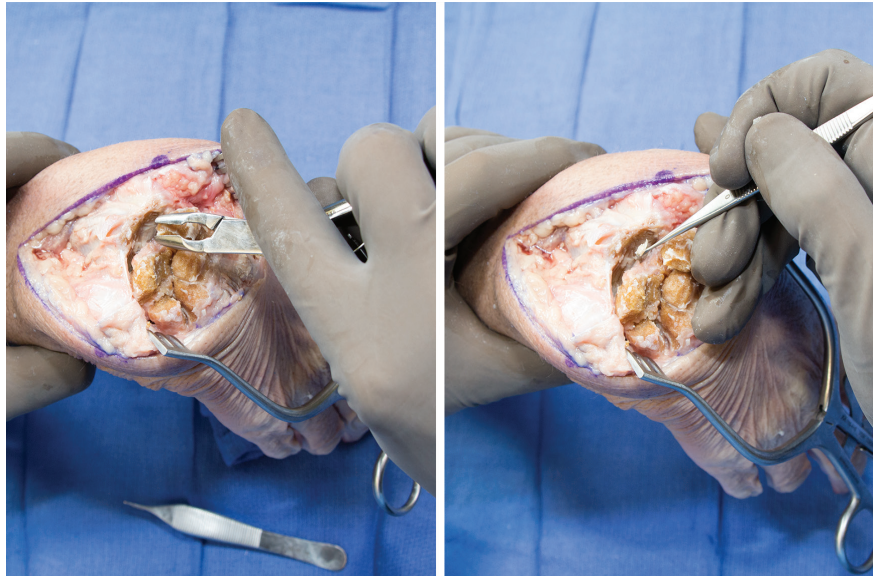
5

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.



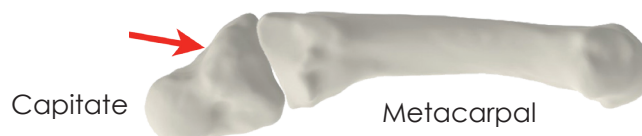
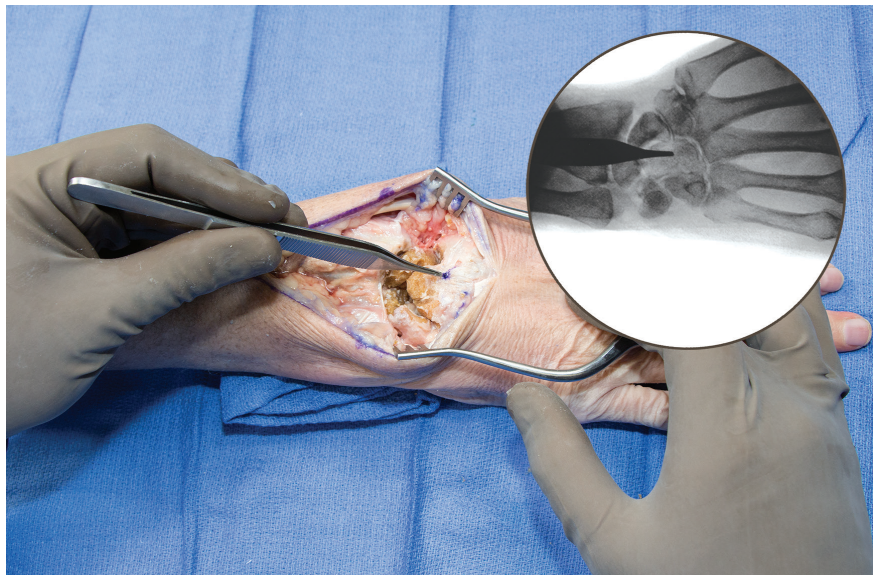
6

METACARPAL NAIL INSERTION POINT

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

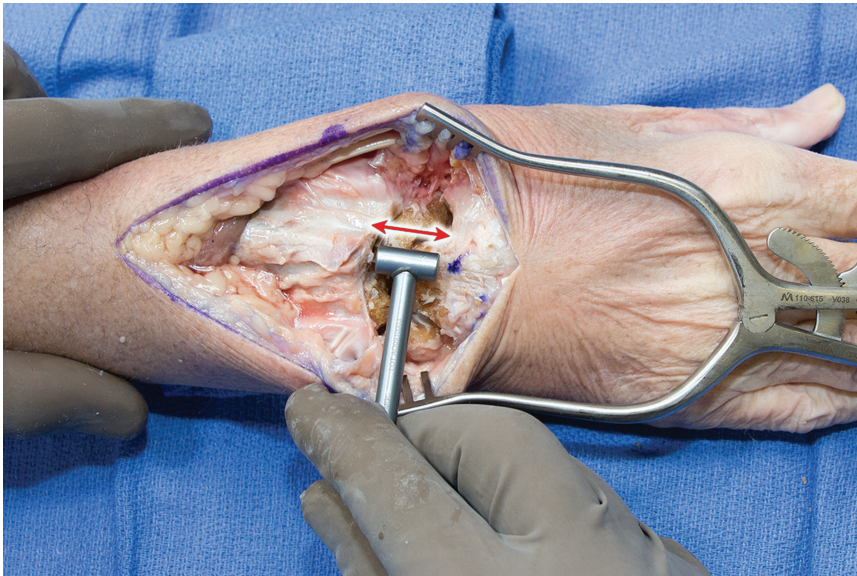
Note:

This location marks the entry point for the Metacarpal Nail.



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.

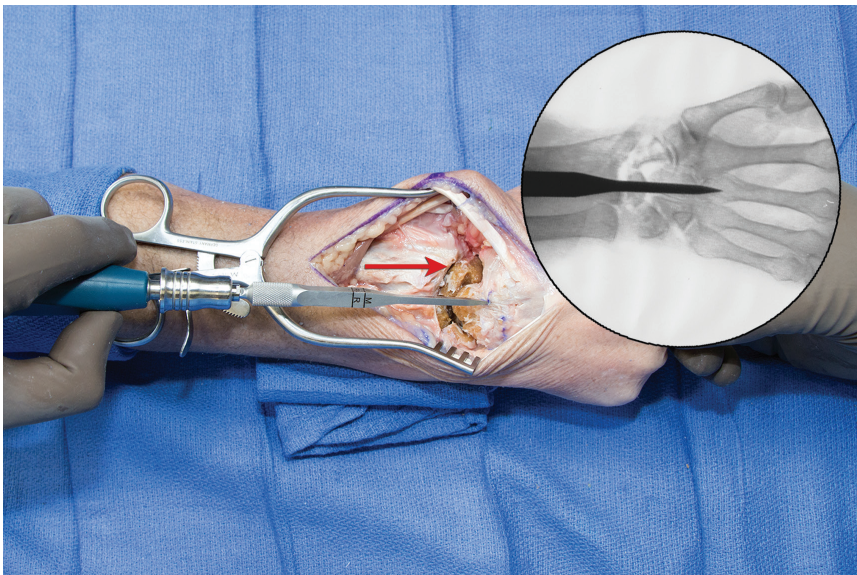
Note:

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.



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:

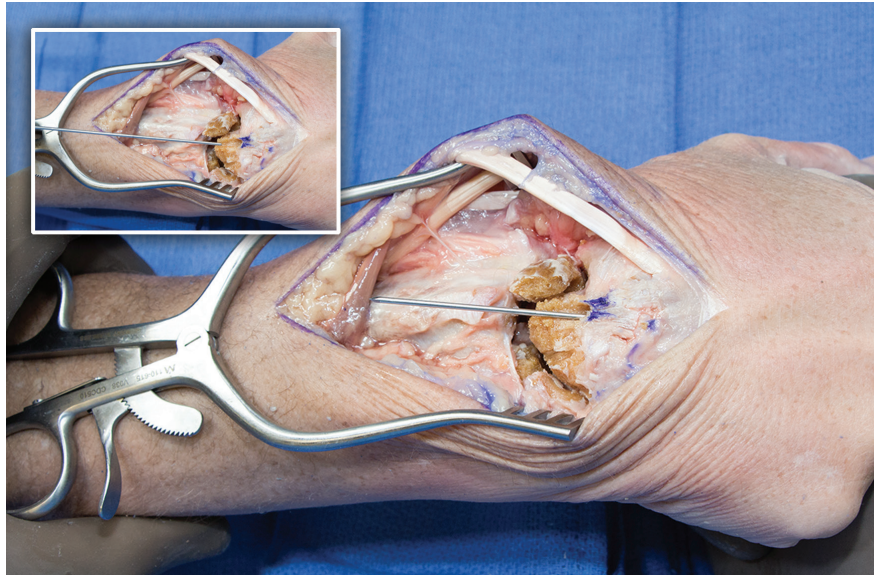
Fluoroscopic imaging is helpful at this step.



9

K-WIRE PLACEMENT

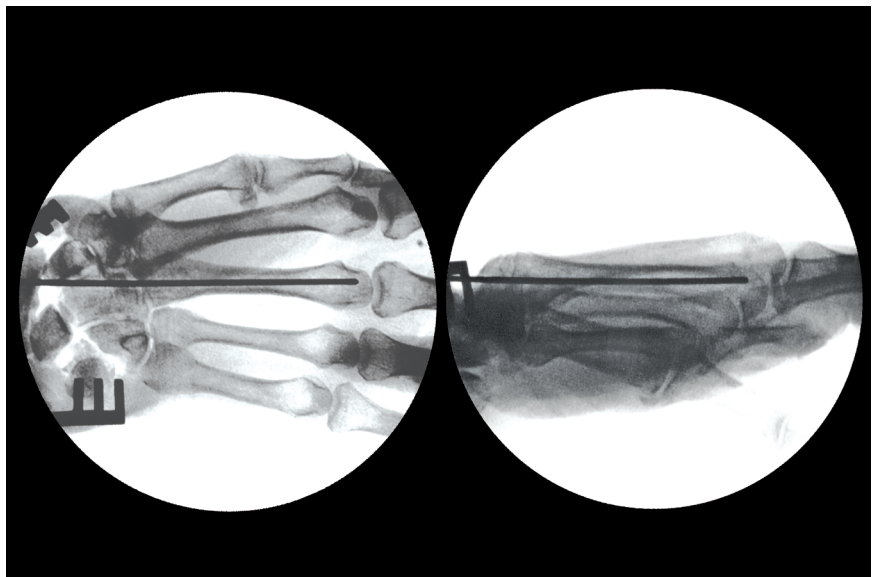
Using a 1.5mm K-wire as a probe, insert the blunt end through the medullary canal to locate the head of the metacarpal.



10

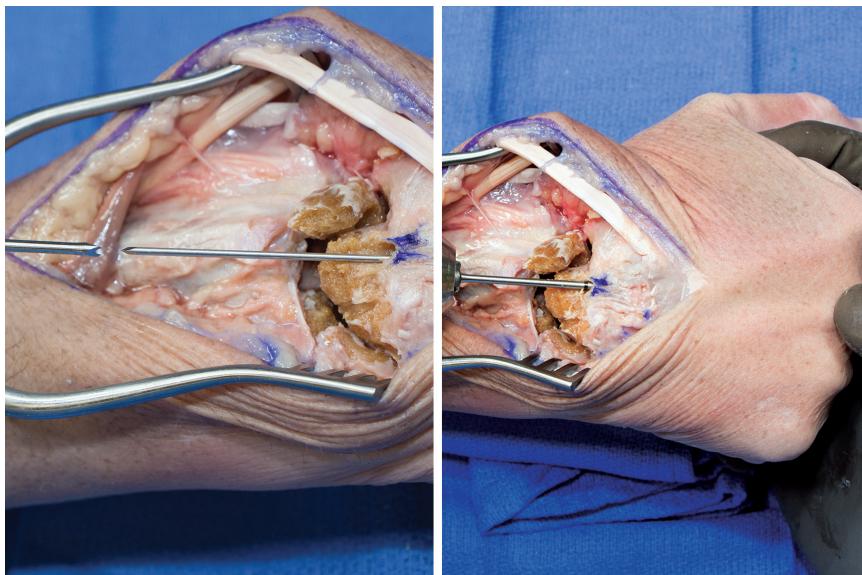
K-WIRE CONFIRMATION

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 (MR)1 to the proper depth.

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

Note:

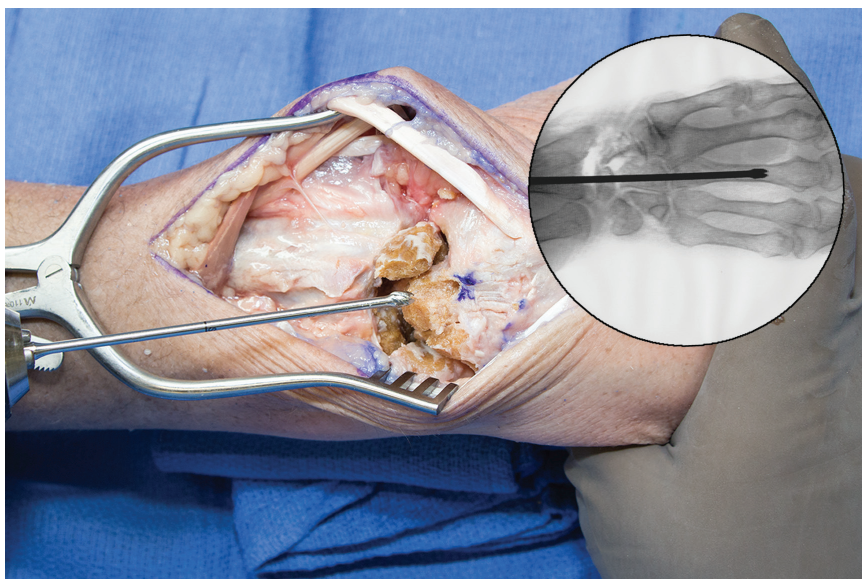
Each Metacarpal Reamer is etched with a "depth mark" to ensure that the proper depth has been achieved.



MR1

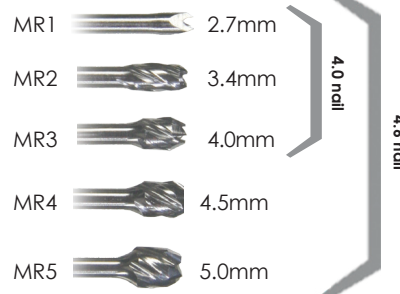
FINAL METACARPAL REAMING

12



The system offers two diameters of Metacarpal Nails; 4.0mm and 4.6mm.

Depending on the diameter of the medullary canal, use MR 3 as the final reamer for the 4.0mm nail or MR 5 as the final reamer for the 4.6mm nail.

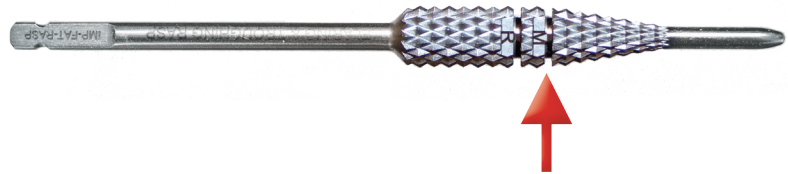
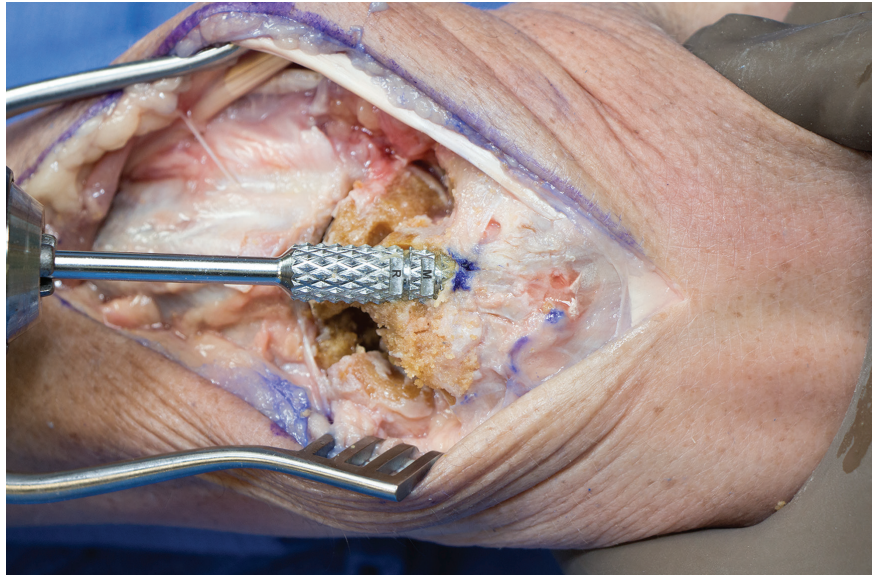


13

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.



14

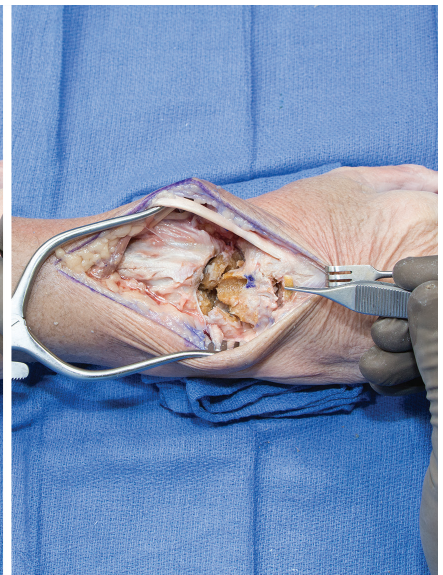
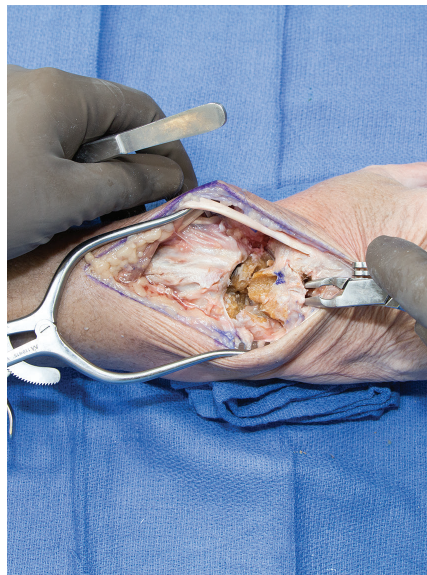
CMC JOINT PREPARATION

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.

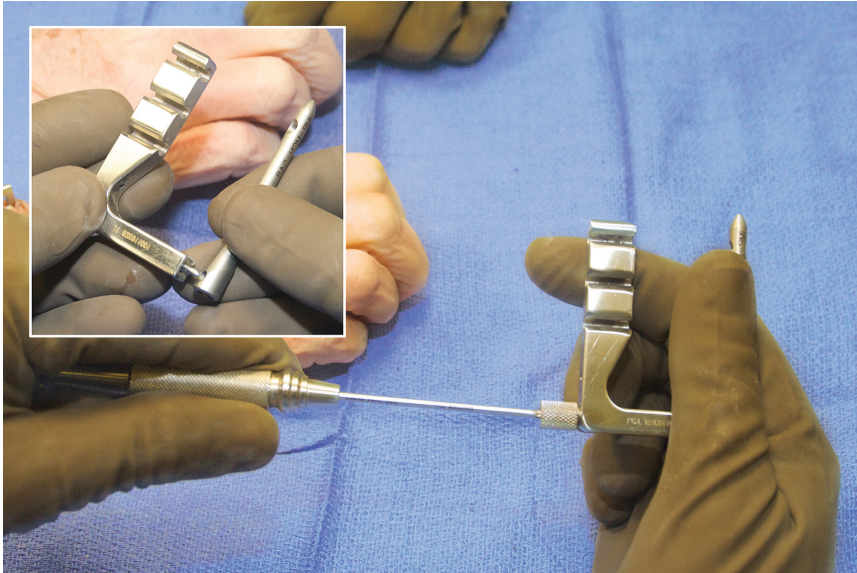
Note:

Ensure bone graft does not enter the medullary canal.



METACARPAL NAIL ASSEMBLY

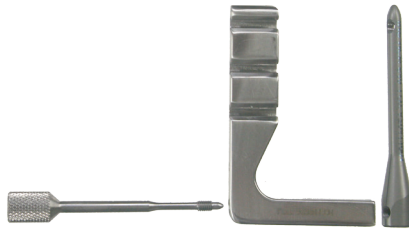
15



Secure the appropriate sized Metacarpal Nail to the Drill Guide using the Lock Screw.

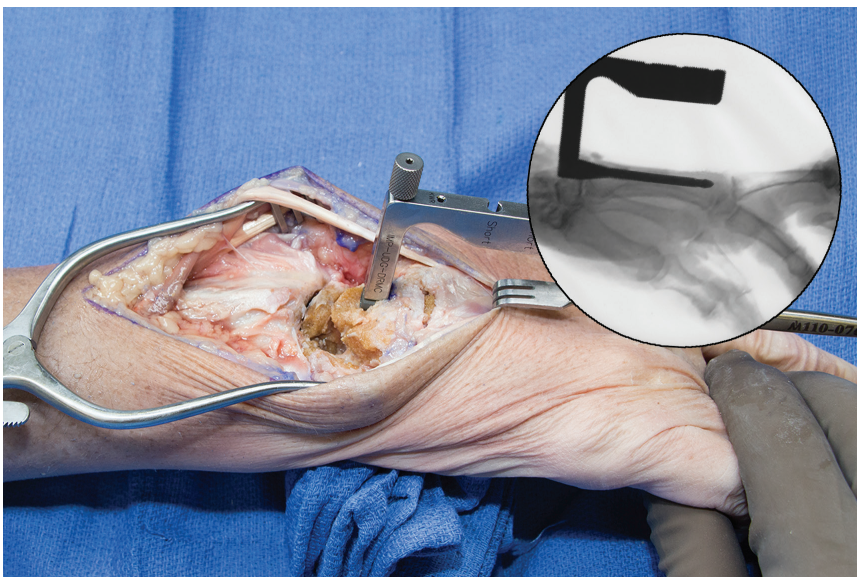
Note:

Be sure to fully tighten the Lock Screw.



METACARPAL NAIL INSERTION

16



Insert the Metacarpal Nail into the medullary canal until the Drill Guide seats flush against the capitate.

17

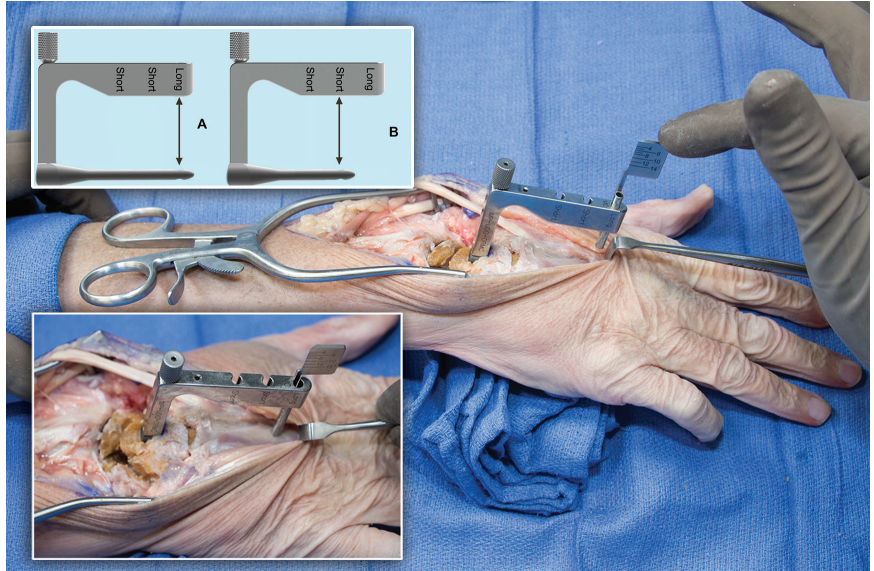
METACARPAL NAIL PREPARATION

Insert the Drill Sleeve through the **distal slot** of the Drill Guide until flush against the bone.

- A. Standard length MC Nail; use the distal slot.
- B. Mini length MC Nail; use the middle slot.

Note:

If necessary, extend the incision distally to allow the Drill Sleeve to contact the bone.



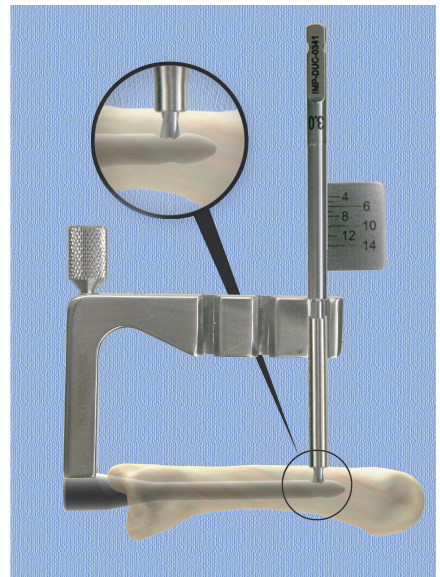
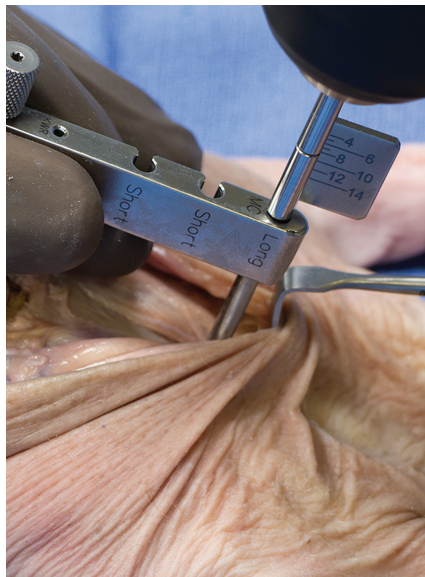
18

METACARPAL NAIL DRILLING

Advance the 3.0mm Unicortical Drill through the near cortex until the mechanical stop of the bit reaches the Drill Guide.

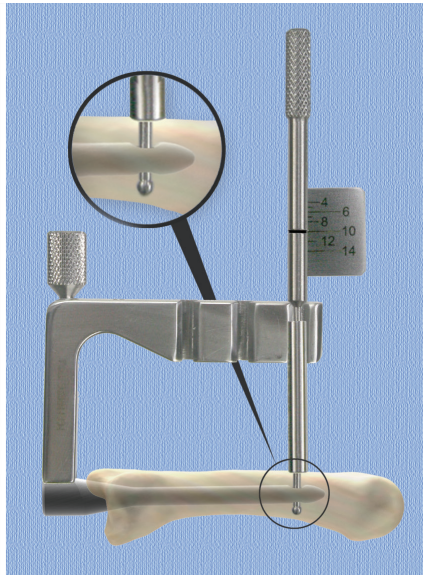
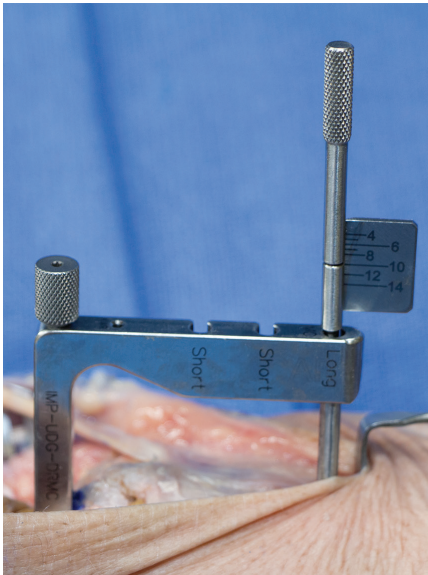
Note:

The 3.0mm Unicortical Drill has a built in mechanical stop that prevents the drill from contacting the Metacarpal Nail.



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:

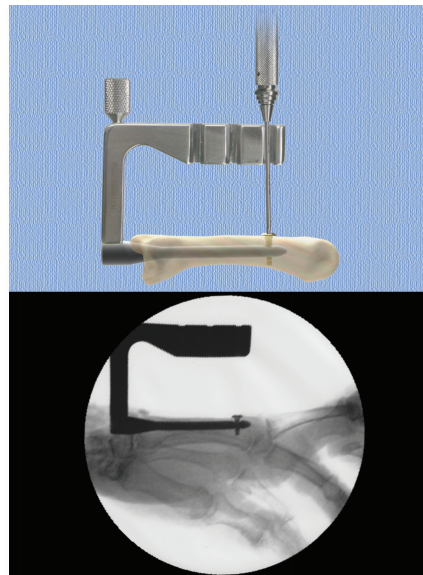
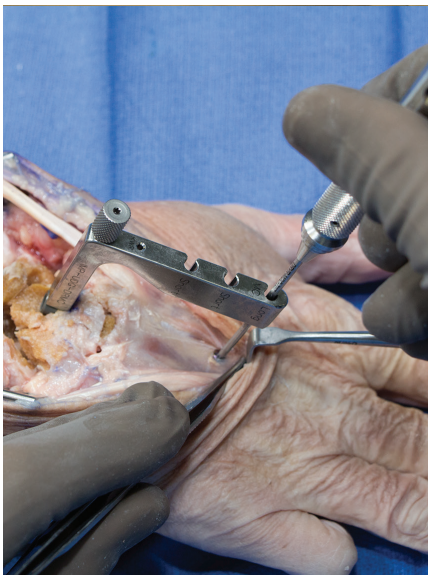
The Depth Gauge is designed to pass through the near cortex and transect the Metacarpal Nail until the far cortex is reached. This determines the longest possible Unicortical Screw option.

If between screw lengths, choose the shorter screw option.



SECURING THE METACARPAL NAIL

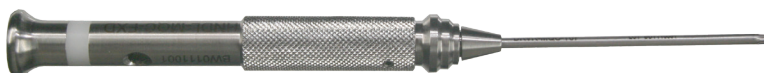
20



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.

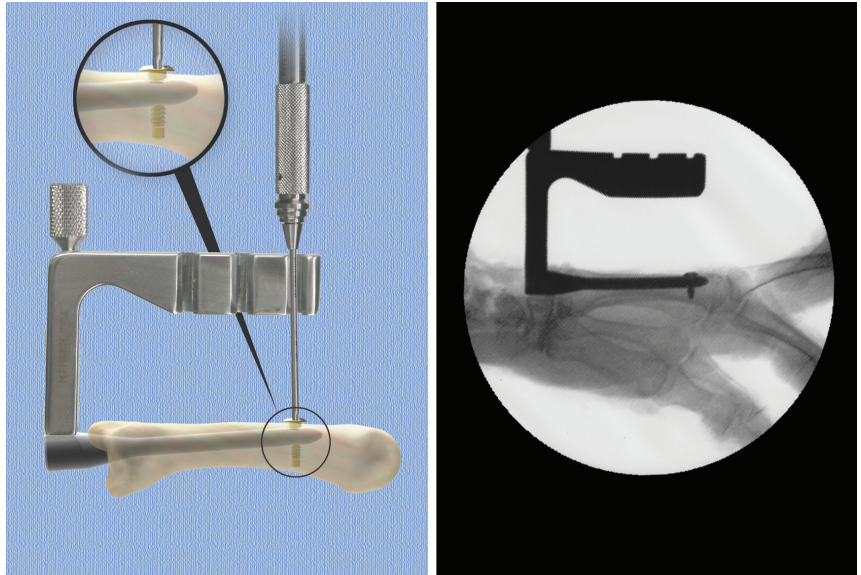


21

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.



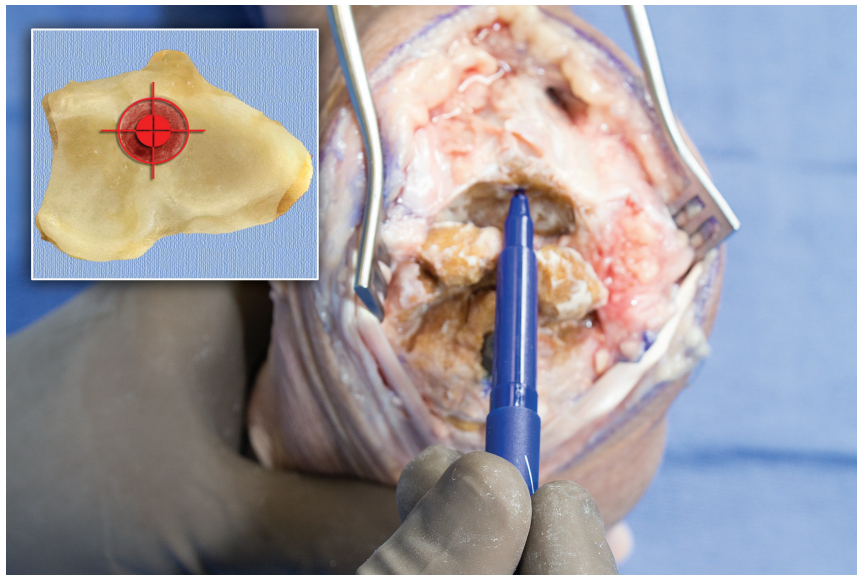
22

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.

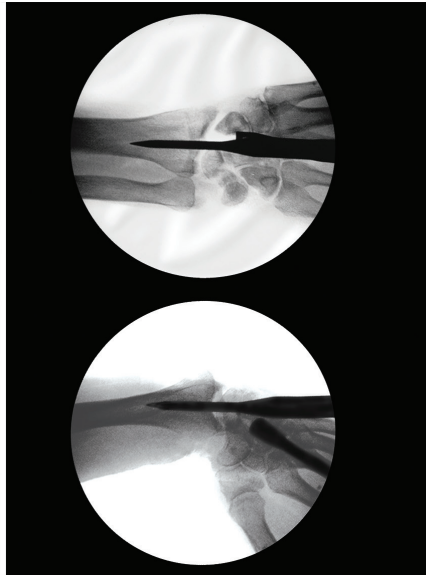
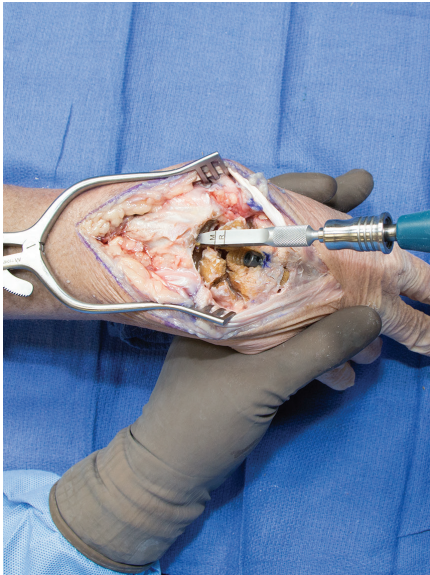
Note:

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.

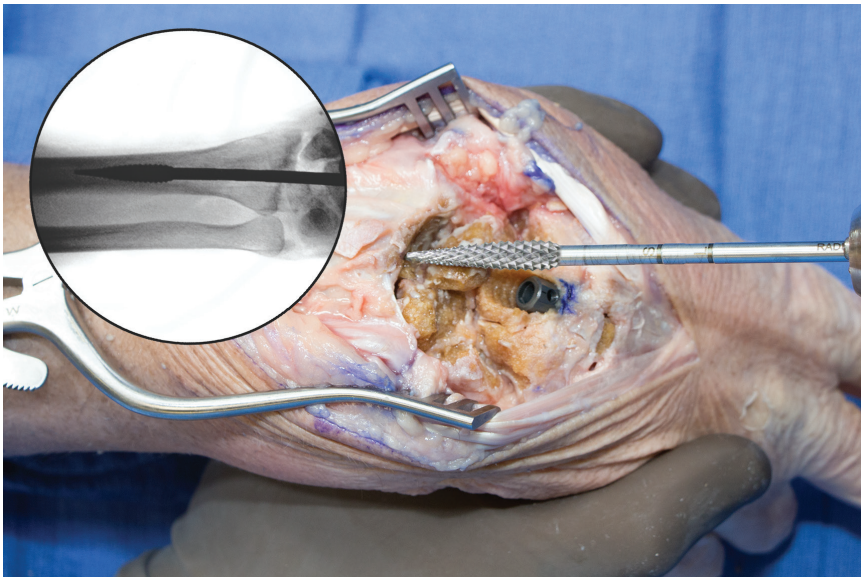
Note:

Adjustments can be made at this time.



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.

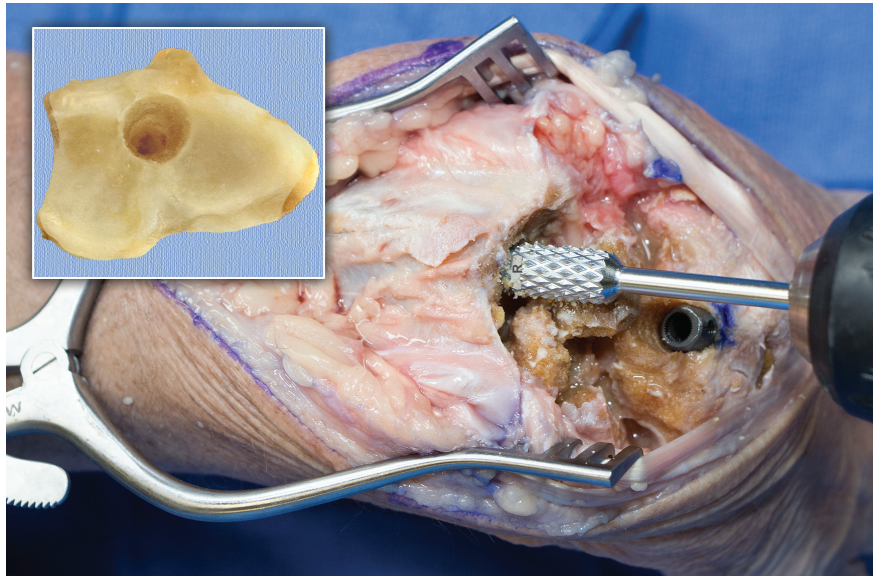


25

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.



26

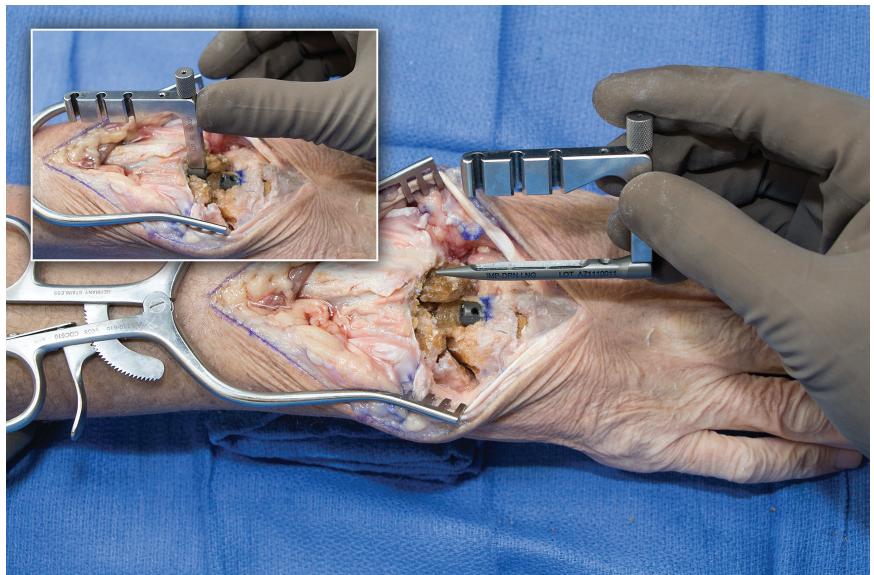
RADIAL NAIL INSERTION

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.

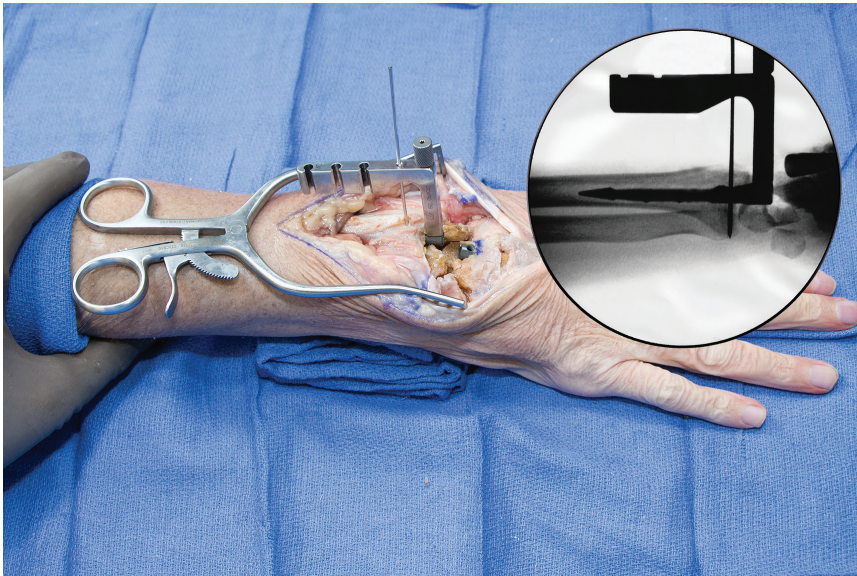
Note:

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.



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.

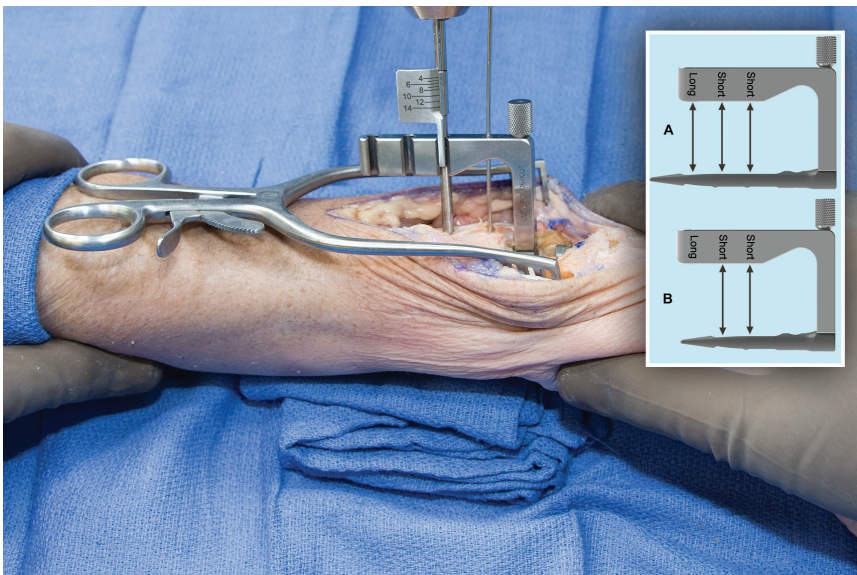
DO NOT bend this K-wire as it will prevent the removal of the Drill Guide.

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



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.



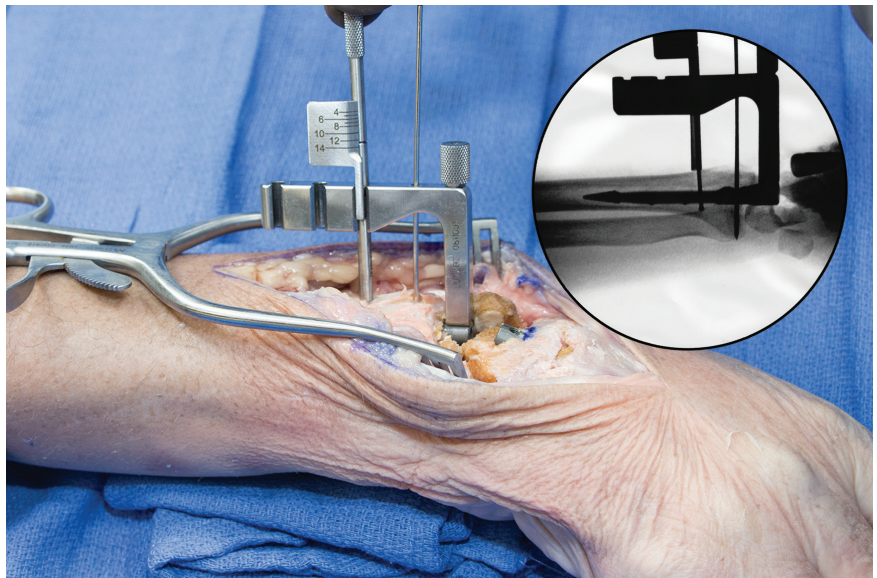
29

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.

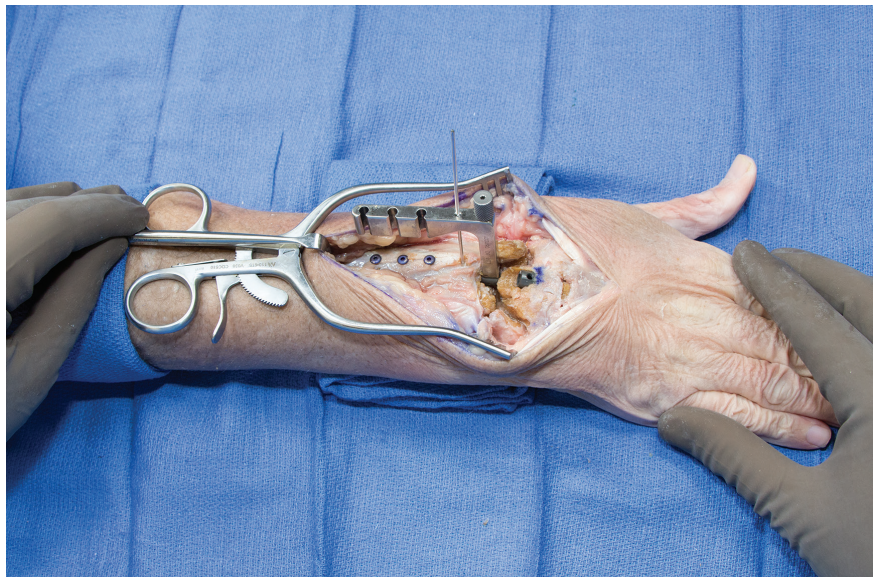


30

FINAL DRILLING AND MEASURING

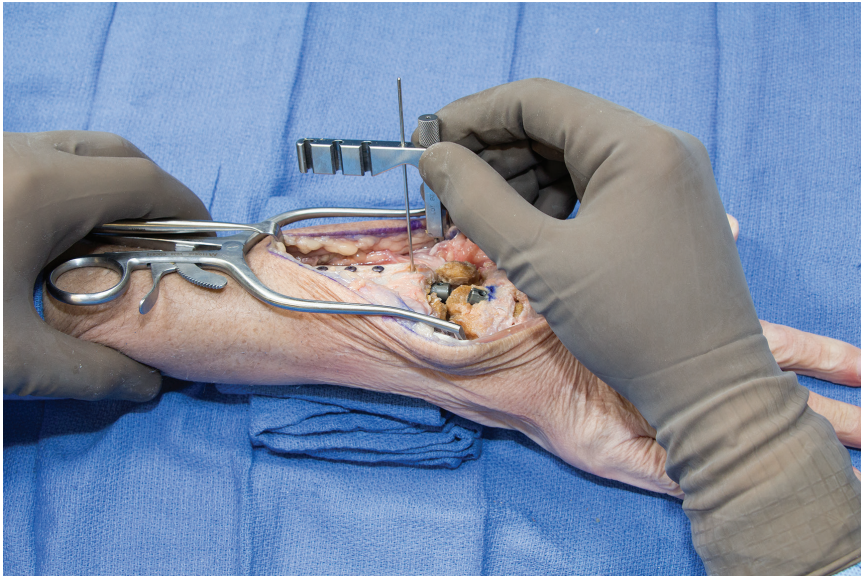
Loosely thread the appropriate length 2.8mm Unicortical Screw to engage the nail.

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



DRILL GUIDE REMOVAL

31

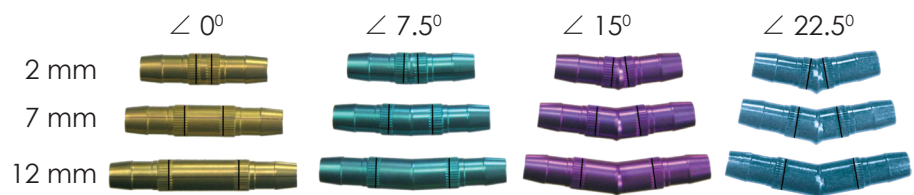


Remove the Drill Guide leaving the K-wire in place.

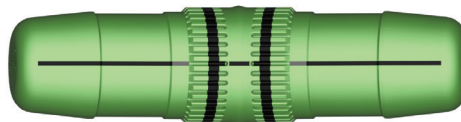
CONNECTOR SELECTION

32

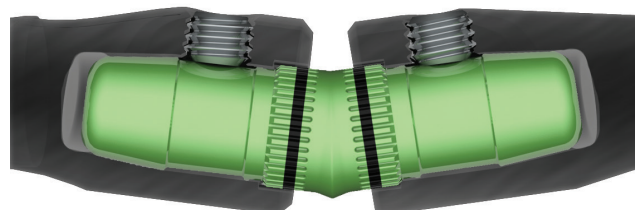
The IMPLATE® System offers connectors in four angle variations and in three lengths. Final Connector length, angle and rotation adjustments can be made prior to locking the construct.



"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.

33

CONNECTOR ADJUSTMENTS

Length

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

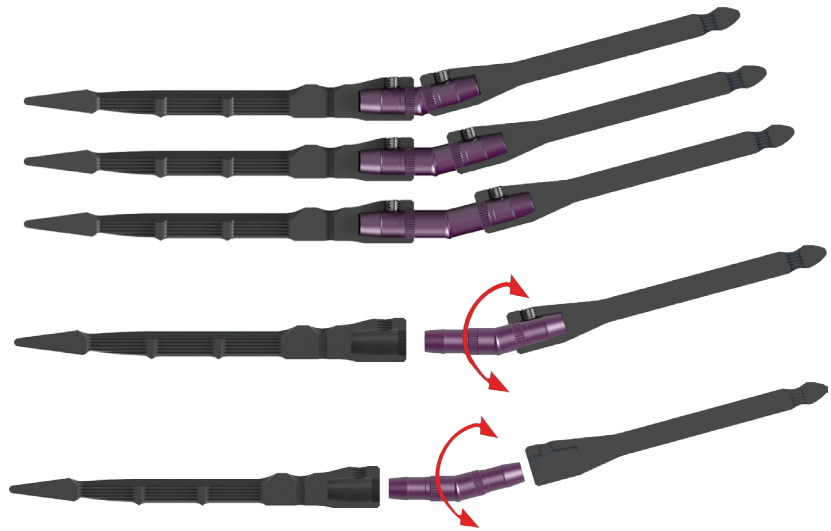
Rotation

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

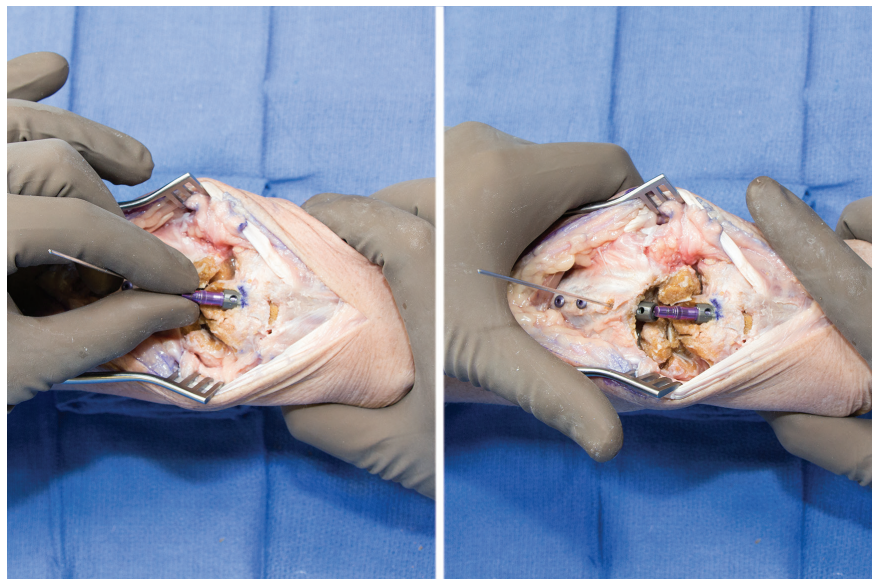
Ulnar Deviation

34

LOADING THE CONNECTOR

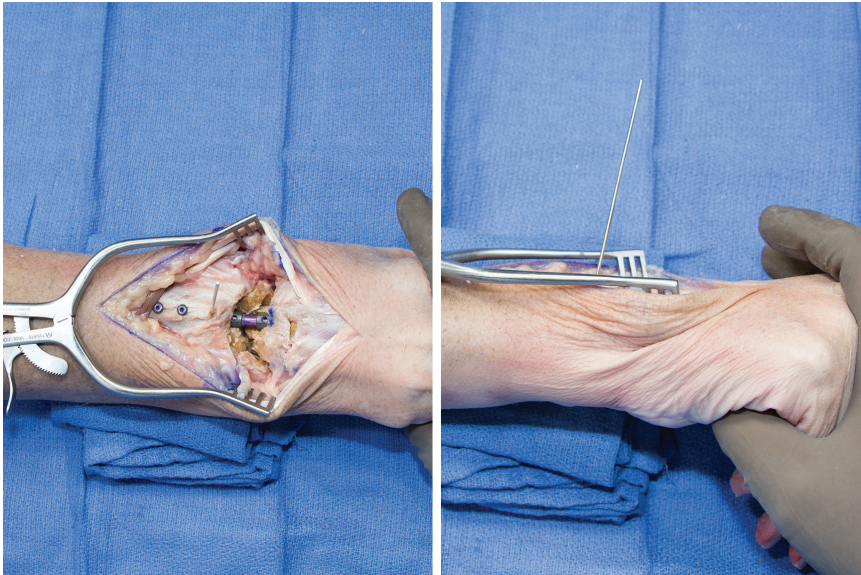
Insert the selected Connector into the Metacarpal Nail until the splines engage taking note of the Connector's orientation.

Then engage the splines of the Connector into the Radial Nail taking note of the hands rotational position.



FINAL HAND POSITIONING

35

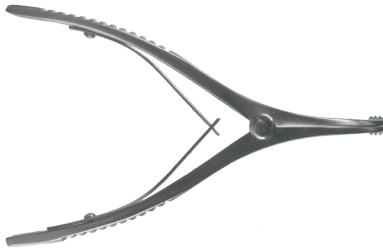


Ensure that the optimal clinical position has been achieved.

Further adjustments can be made at this time.

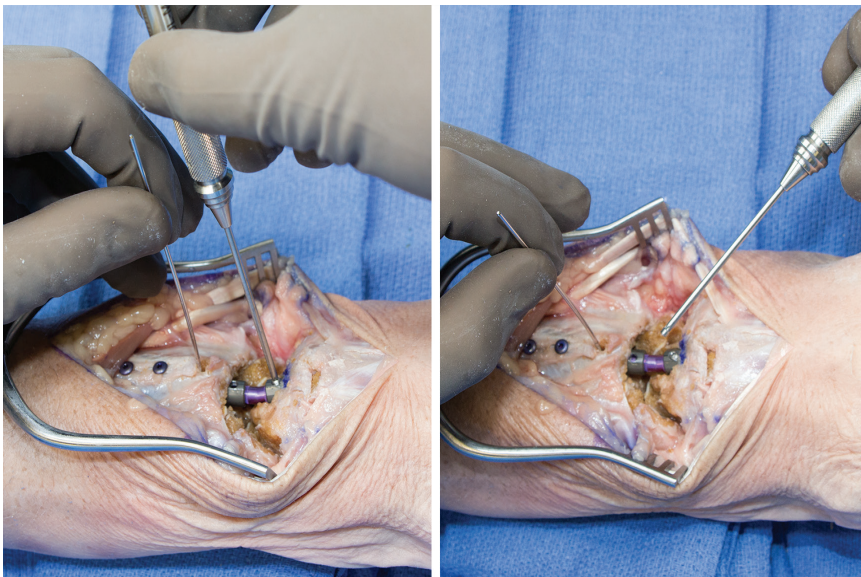
Note:

A Spreader is included in the system to facilitate the removal of the connector.



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.

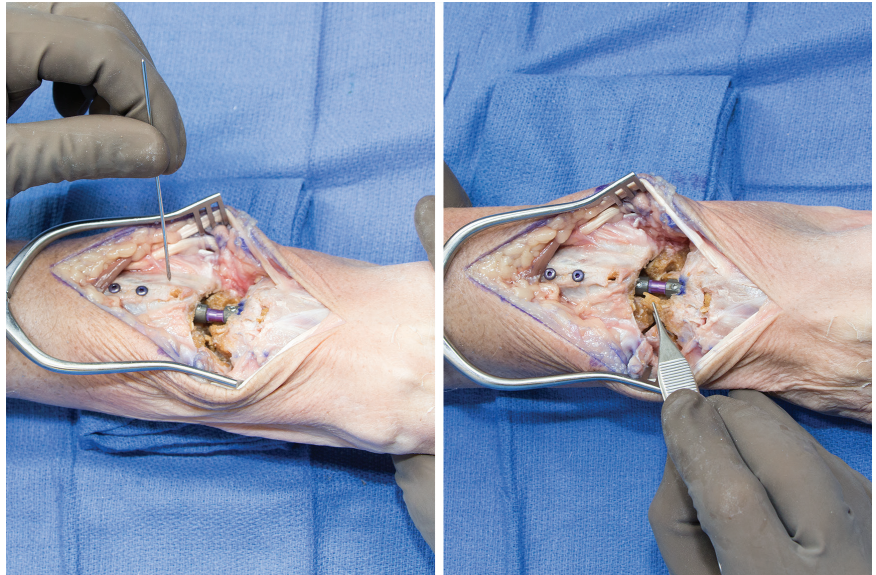


37

DISTRACTION - COMPRESSION

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

Apply bone graft as needed.



38

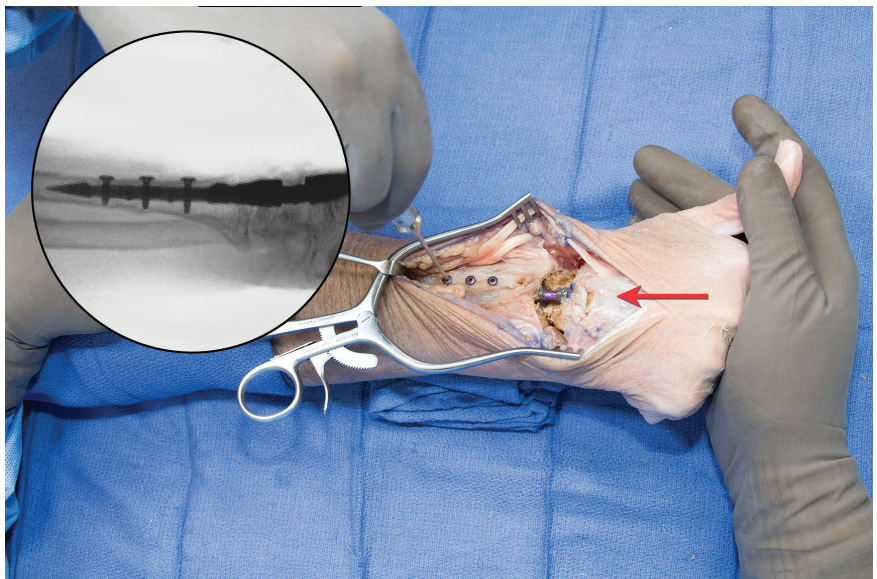
LOCKING THE RADIAL NAIL

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.

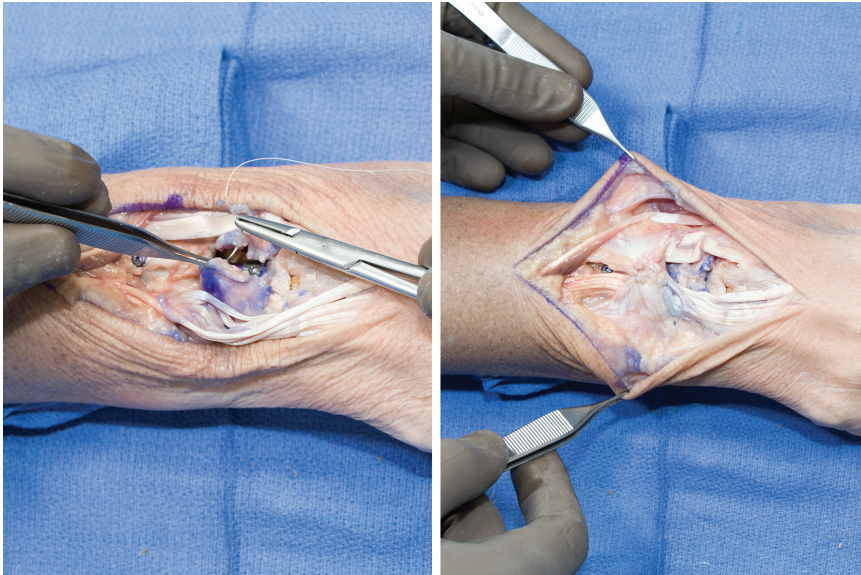
Warning: When desired results are achieved, confirm that **ALL** screws have been fully tightened.

Note:
Fluoroscopic imaging is helpful during this step.



WOUND CLOSURE

39

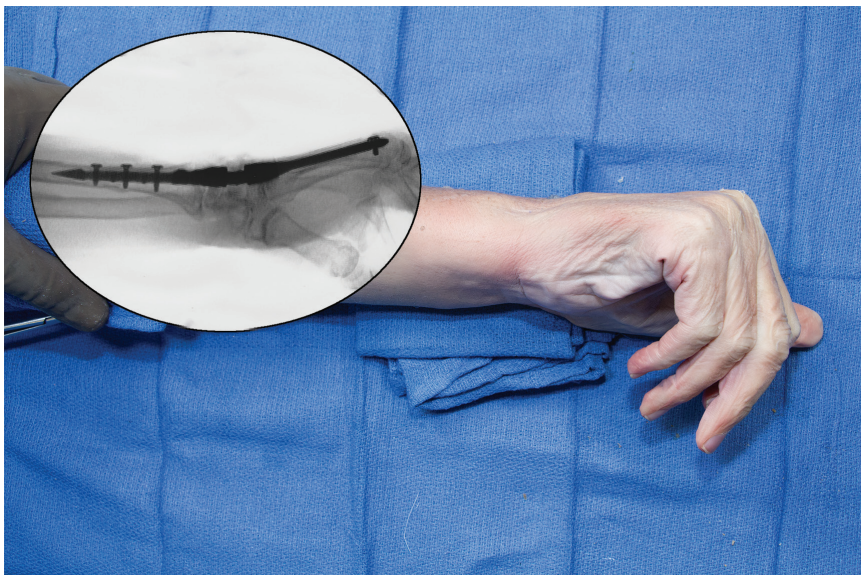


Close the dorsal capsule, then repair the extensor retinaculum as necessary.

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

POSTOPERATIVE PROTOCOL

40



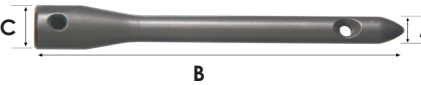
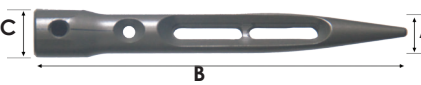
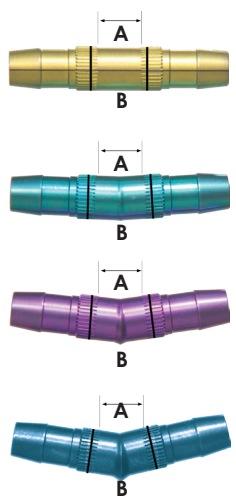
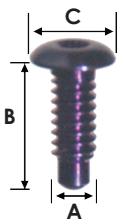

Post-Operative

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

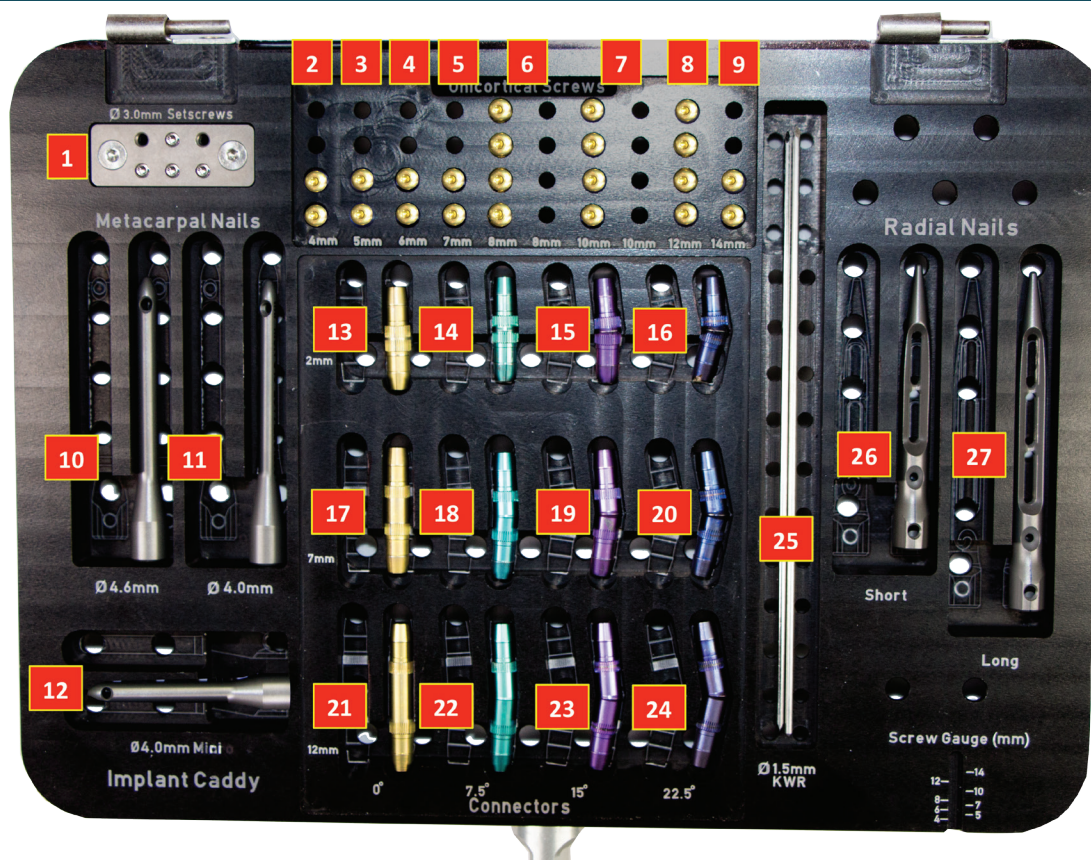
1st Visit (~ 1 Week)

- Based on clinical judgement, apply a removable orthotic or shortarm cast until fusion occurs.

IMPLATE® Wrist Arthrodesis Nail System - Cat.# IMP-WAN-SYS

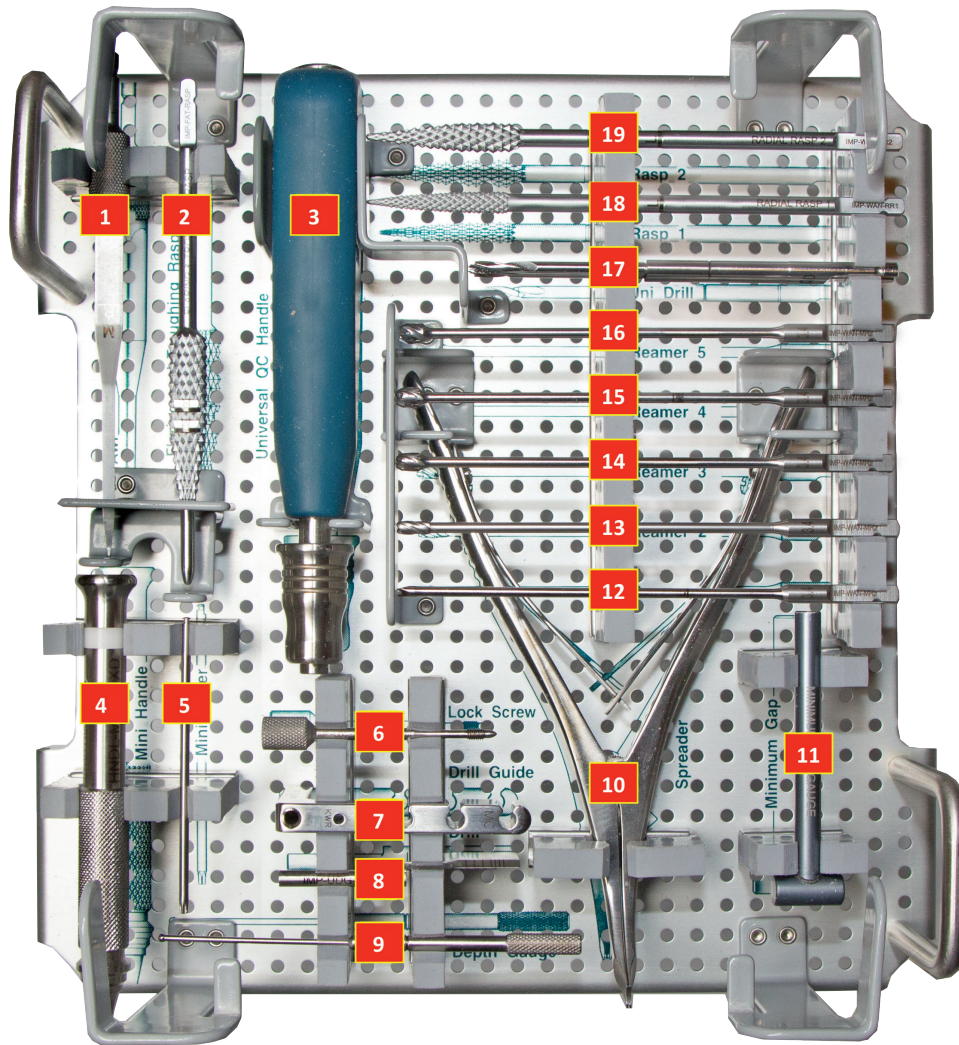
Metacarpal Nails (Ti)		Catalog Number		
	IMP-MCN-M40	A	B	C
	IMP-MCN-S40	4.0mm	46mm	7.6mm
	IMP-MCN-S46	4.0mm	60mm	7.6mm
	IMP-MCN-S46	4.6mm	60mm	7.6mm
Distal Radius Nails (Ti)		Catalog Number		
	IMP-DRN-SHT	A	B	C
	IMP-DRN-LNG	6.5mm	59mm	7.6mm
	IMP-DRN-LNG	6.5mm	70mm	7.6mm
Connectors (Ti)		Catalog Number		
	IMP-WC-0200	A	B	
	IMP-WC-0700	2mm	0°	Gold
	IMP-WC-1200	7mm	0°	Gold
	IMP-WC-0207	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	
Unicortical Screws (Ti)		Catalog Number		
	UCNL-28040-TS	A	B	C
	UCNL-28050-TS	2.8mm	4.0mm	4.0mm
	UCNL-28060-TS	2.8mm	5.0mm	4.0mm
	UCNL-28070-TS	2.8mm	6.0mm	4.0mm
	UCNL-28070-TS	2.8mm	7.0mm	4.0mm
	UCNL-28080-TS	2.8mm	8.0mm	4.0mm
	UCNL-28100-TS	2.8mm	10.0mm	4.0mm
	UCNL-28120-TS	2.8mm	12.0mm	4.0mm
	UCNL-28140-TS	2.8mm	14.0mm	4.0mm
Set Screw (CoCr)		Catalog Number		
	STSC-30020-CS	A	B	
	STSC-30020-CS	3.0mm	2.0mm	
Single Use Instruments		Catalog Number		
IMP-DUC-0341		Unicortical Drill Bit, 3.0mm		
IMP-WAN-MR1		Metacarpal Reamer, 2.7mm		
IMP-WAN-MR2		Metacarpal Reamer, 3.4mm		
IMP-WAN-MR3		Metacarpal Reamer, 4.0mm		
IMP-WAN-MR4		Metacarpal Reamer, 4.5mm		
IMP-WAN-MR5		Metacarpal Reamer, 5.0mm		
DRVR-MQC-T07		Star Driver, T-7		
KWIR-STD-15127		K-wire, 1.5mm (SS)		

IMPLANT CADDY (Standard Set Configuration)



Loc #	Catalog #	Description	Set Qty
1	STSC-30020-CS	Set Screw, 3.0mm x 2.0mm	4
2	UCNL-28040-TS	Unicortical Screw, 2.8mm x 4.0mm	2
3	UCNL-28050-TS	Unicortical Screw, 2.8mm x 5.0mm	2
4	UCNL-28060-TS	Unicortical Screw, 2.8mm x 6.0mm	2
5	UCNL-28070-TS	Unicortical Screw, 2.8mm x 7.0mm	2
6	UCNL-28080-TS	Unicortical Screw, 2.8mm x 8.0mm	4
7	UCNL-28100-TS	Unicortical Screw, 2.8mm x 10.0mm	4
8	UCNL-28120-TS	Unicortical Screw, 2.8mm x 12.0mm	4
9	UCNL-28140-TS	Unicortical Screw, 2.8mm x 14.0mm	2
10	IMP-MCN-S46	Metacarpal Nail, Standard 4.6mm	1
11	IMP-MCN-S40	Metacarpal Nail, Standard 4.0mm	1
12	IMP-MCN-M40	Metacarpal Nail, Mini 4.0mm	1
13	IMP-WC-0200	Connector, 2mm x 0°	1
14	IMP-WC-0207	Connector, 2mm x 7.5°	1
15	IMP-WC-0215	Connector, 2mm x 15°	1
16	IMP-WC-0222	Connector, 2mm x 22.5°	1
17	IMP-WC-0700	Connector, 7mm x 0°	1
18	IMP-WC-0707	Connector, 7mm x 7.5°	1
19	IMP-WC-0715	Connector, 7mm x 15°	1
20	IMP-WC-0722	Connector, 7mm x 22.5°	1
21	IMP-WC-1200	Connector, 12mm x 0°	1
22	IMP-WC-1207	Connector, 12mm x 7.5°	1
23	IMP-WC-1215	Connector, 12mm x 15°	1
24	IMP-WC-1222	Connector, 12mm x 22.5°	1
25	KWIR-STD-15127	K-Wire, 1.5mm x 127mm	2
26	IMP-DRN-SHT	Distal Radius Nail, Short	1
27	IMP-DRN-LNG	Distal Radius Nail, Long	1

IMPLANT TRAY (Standard Set Configuration)
















Loc #	Catalog #	Description	Set Qty
1	IMP-WAN-AWL	Starter Awl	1
2	IMP-FAT-RASP	Flaring - Troughing Rasp	1
3	HNDL-UQC-FXD	Handle, Universal	1
4	HNDL-MQC-FXD	Handle, Mini	1
5	DRVR-MQC-T07	Driver, T-7	2
6	IMP-UDG-LKSC	Lock Screw, Drill Guide	1
7	IMP-UDG-DRMC	Drill Guide	1
8	IMP-UDG-DSLV	Drill Sleeve, Drill Guide	1
9	IMP-UDG-DGAU	Depth Gauge, Drill Guide	1
10	IMP-WAN-SPDR	Spreader	1
11	IMP-WAN-MGG	Minimum Gap Gauge	1
12	IMP-WAN-MR1	Metacarpal Reamer 1, 2.7mm x 87mm	1
13	IMP-WAN-MR2	Metacarpal Reamer 2, 3.4mm x 87mm	1
14	IMP-WAN-MR3	Metacarpal Reamer 3, 4.0mm x 87mm	1
15	IMP-WAN-MR4	Metacarpal Reamer 4, 4.5mm x 87mm	1
16	IMP-WAN-MR5	Metacarpal Reamer 5, 5.0mm x 87mm	1
17	IMP-DUC-0341	Uncortical Drill, 3.0mm x 41mm	1
18	IMP-WAN-RR1	Radial Rasp 1, 5.5mm x 70mm	1
19	IMP-WAN-RR2	Radial Rasp 2, 7.0mm x 70mm	1

R: For use by physicians only. Federal Law restricts this device to sale by or on the order of a physician.

Failure to follow instructions may lead to patient injury.

This package insert is designed to provide Instructions for Use of the IMPLATE Wrist Arthrodesis Nail (WAN) System; it is not a reference to surgical techniques.

SYMBOLS

MATL:	MATERIAL	CoCr:	COBALT CHROMIUM ALLOY
TI:	TITANIUM ALLOY	MADE IN:	MADE IN <<COUNTRY>>
SS, SST:	STAINLESS STEEL	QTY:	QUANTITY
	DO NO REUSE (SINGLE USE ONLY)		CAUTION or ATTENTION, SEE INSTRUCTIONS FOR USE
	USE BY (EXPIRATION DATE)		CONSULT INSTRUCTIONS FOR USE
	BATCH CODE		MANUFACTURER
	STERILIZED USING ETHYLENE OXIDE		TEMPERATURE LIMITATION
	STERILIZED USING IRRADIATION		AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	NON STERILE PRODUCT		DO NOT USE IF PACKAGE IS DAMAGED
	CATALOG NUMBER		

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

Note: All references contained in this document pertaining to Distal Radius Nails, Metacarpal Nails, Connectors, Setscrews, Unicortical Screws and other instrumentation are specific to the IMPLATE WAN System by Skeletal Dynamics.

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.

CONTRAINDICATIONS

Prior to using the IMPLATE® WAN System, ensure that none of the following patient conditions are present: active or latent infection, sepsis, insufficient quantity or quality of bone and/or soft tissue, material sensitivity, or patients who are unwilling or incapable of following post operative care instructions.

WARNINGS

- Every Connector must be secured to the construct using two (2) Setscrews (one at each end for Metacarpal and Distal Radius Nails). If either of the Setscrews are not attached and/or fully tightened, a non-union, delayed union or construct failure may occur.
- All Unicortical Screws must be implanted and fully tightened into the Radial and Metacarpal Nails to maintain the integrity and strength of the finished construct. If the Unicortical Screws are not attached and/or fully tightened, a non-union, delayed union or construct failure may occur.
- The information in this document should be shared with the patient.
- The patient should be informed about the importance of following the post operative rehabilitation prescribed in order to fully understand the possible limitations in activities of daily living. The patient must be warned that failure to follow postoperative care instructions may cause the implant or treatment to fail.
- Potential IMPLATE WAN construct failures such as stress fractures of the bones, loosening of the construct and/or fixation, delayed fusion, non-fusion, or incomplete healing may occur as a result of non compliance to post operative rehabilitation, excessive wrist activities or construct overloading.
- DO NOT reuse any of the IMPLATE WAN System implantable components. Reuse may compromise the structural integrity of the construct and/or lead to failure or infection which may result in patient injury.

PRECAUTIONS

- Protect the IMPLATE WAN System's implantable components against scratching or nicking. Such stress concentration can lead to implant failure.
- Before using the IMPLATE WAN System, inspect all implants and instruments for wear, disfiguration and physical damage. If evidence of wear, disfiguration or physical damage is found, DO NOT use and contact your local Skeletal Dynamics representative or the Skeletal Dynamics Customer Care Department.
- DO NOT permanently implant the Skeletal Dynamics K-Wires; they are intended to be used for provisional fixation of the IMPLATE WAN System construct.
- The IMPLATE WAN System has not been evaluated for safety and compatibility in the MR environment; nor has it been tested for heating or migration in the MR environment.
- The Skeletal Dynamics Wrist Arthrodesis Nail System is to be used only with Skeletal Dynamics instruments, implants and accessories.
- Dispose of contaminated implants and instruments per established facility guidelines and protocols.
- Accuracy of Depth, Gap and Screw Gauges are within + 0.25mm.
- Caution should be taken for interference to pacemakers during electrocautery or by uncertified drills.
- Seek medical help immediately if implant malfunctions.
- To maintain traceability of the IMPLATE WAN System implantable components, you must record each of the respective components LOT numbers into the patient records post implantation.

POTENTIAL ADVERSE EVENTS

The following are potential risks that have been associated with wrist fusion surgery: infection, nonunion, persistent pain, stiffness of the fingers, loosening or migration of the implants resulting in mal-alignment.

DIRECTIONS FOR USE

The IMPLATE WAN System should only be used by surgeons who have experience with this system. Each surgeon must evaluate the appropriateness for the use of the IMPLATE WAN System during wrist arthrodesis procedures based on their experience with the IMPLATE WAN System.

Please refer to the IMPLATE WAN Surgical Technique Guide to review the surgical approach to minimally invasive wrist arthrodesis as described by Jorge L. Orbay, M.D. of the *Miami Hand & Upper Extremity Institute* located in Miami, Florida.

CLEANING

The IMPLATE WAN System instrumentation must be cleaned to achieve sterilization. The recommended manual cleaning instructions are set forth below. Other cleaning methods must be validated by the user.

1. Disassemble instrumentation, if applicable.
2. Rinse components thoroughly under running cool tap water. While rinsing, use a soft bristle brush to loosen and remove as much visible soil as possible from components.
3. Soak components in a neutral enzymatic cleaner for a minimum of ten (10) minutes. Components must be fully immersed in the cleaner. Follow the cleaner manufacturer's instructions for cleaner preparation and exposure time.
4. Thoroughly rinse the components with cool water. While rinsing, use soft bristle brushes, pipettes or a water jet to clean out lumens, holes, and other challenging features.
5. Manually scrub the components thoroughly in newly made, clean, neutral pH enzymatic cleaner using soft bristle brushes or pipettes. All lumens, holes, hinged components, mating surfaces, and crevices, and challenging components should be thoroughly scrubbed. Actuate all moveable features and expose all areas to cleaner and to the brush or pipette.
Note: When scrubbing rasps or planers, a stiff bristle brush will be required.
6. Rinse components thoroughly with deionized or purified water; using pipettes or a water jet to clean out lumens, holes, and other hard to reach or challenging features. Actuate all movable features to fully irrigate all areas.
7. Visually inspect components for soil. Repeat the cleaning procedure until no visible soil remains on the components.
8. Perform a final rinse on the components using deionized water or purified water.
9. Dry the clean components using compressed air or a soft, lint free, clean cloth.

Functional Checks should be performed where possible:

1. Mating devices should be checked for proper assembly.
2. Reusable devices with moving parts should be operated to check correct operation (medical grade lubricant suitable for steam sterilization can be applied as required).
3. Rotating instruments (e.g. drill bits, reamers) should be checked for straightness. This can be achieved by rolling the instrument on a flat surface.

Note: The useful life of these devices is dependent on many factors including, but not limited to the method and duration of each use and the handling of the devices between uses. Routine and careful inspection and functional testing of the device is the best method of determining the serviceable life span for the medical device.

STERILIZATION

The accessories and instruments of the IMPLATE® WAN System is provided non sterile. This system is intended for steam sterilization at the healthcare facility.

1. Place all components and accessories into the designated areas of the sterilization tray
2. Steam sterilization may be accomplished using one of the cycles shown below:

Cycle Type	Temperature	Duration	Drying Time
Pre-Vacuum Autoclave	270°F (132°C)	4 minutes (wrapped)	20 minutes
Gravity Autoclave	270°F (132°C)	15 minutes (wrapped)	20 minutes

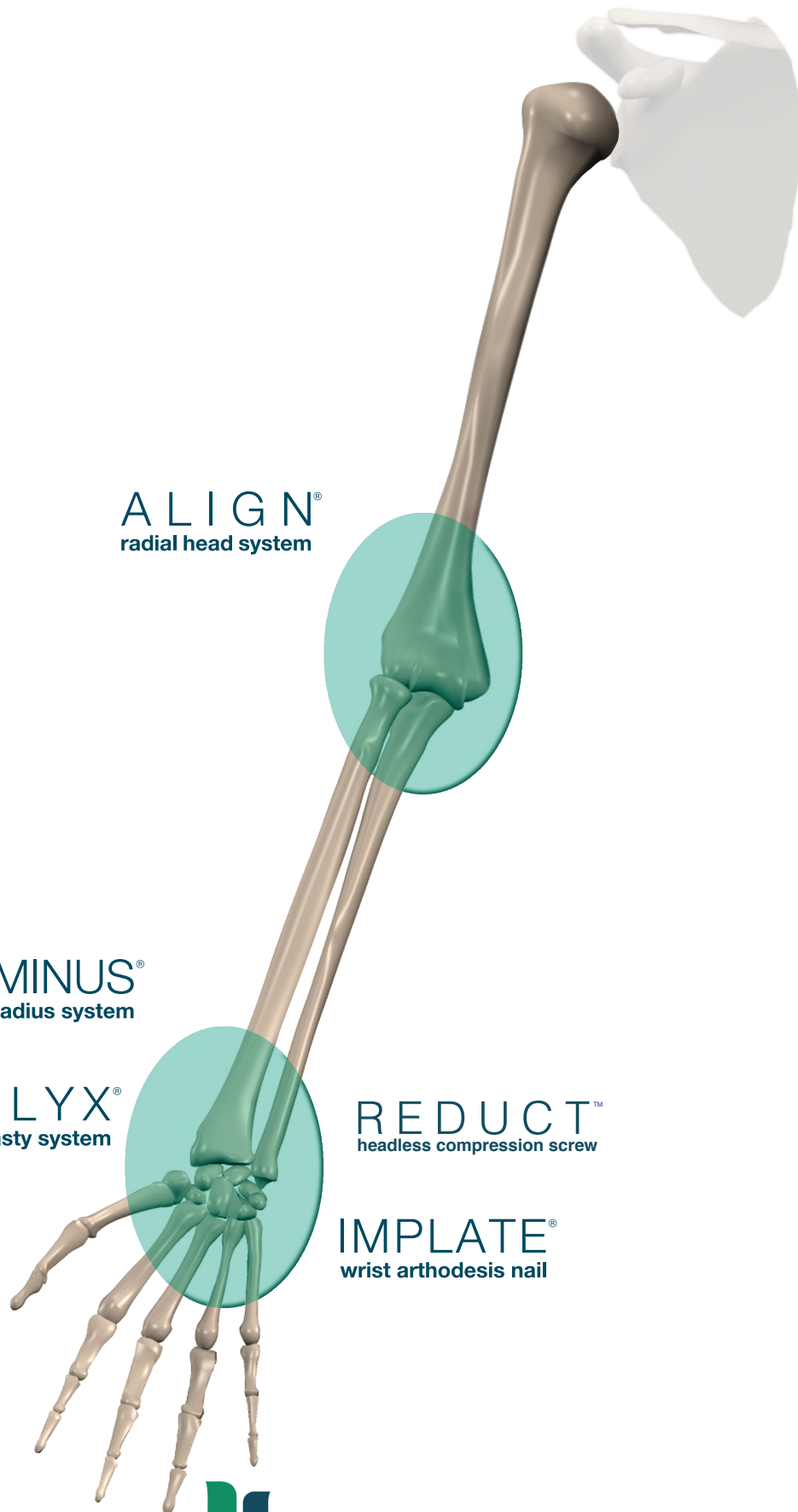
- Follow ANSI/AAMI ST79:2006 - Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
- Flash sterilization is not recommended, but if used, should only be performed according to the requirements of ANSI/AAMI ST79:2006 - Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
- Usage of an FDA approved wrap or sterilization container is required.
- Subsequent instrument sterilization needs to be performed in the tray system provided. For reuse and sterilization, instruments should be arranged within the tray system in the manner supplied by the company.

HANDLING AND STORAGE

When not in use, store the clean and disinfected IMPLATE WAN System within the Sterilization Tray. Prior to use, inspect the instrumentation for serviceability.

DISCLAIMER OF WARRANTY AND LIMITED REMEDIES

Skeletal Dynamics, LLC makes no express or implied warranty, including any implied warranty of merchantability or fitness for a particular purpose, on the product(s) described in this publication. Skeletal Dynamics, LLC shall not be liable under any circumstances for any direct, incidental or consequential damages other than as expressly provided by specific law. No person has authority to bind Skeletal Dynamics, LLC to any representation or warranty except as specifically set forth in this publication. Descriptions or specifications provided by Skeletal Dynamics, LLC in any publication are only included to generally describe the product when manufactured and do not constitute any express warranties.



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radial head system

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headless compression screw

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wrist arthodesis nail

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