SURGICAL TECHNIQUE GUIDE

GEMINUS®

VOLAR PLATING SYSTEM

As described by:

Jorge L. Orbay, M.D.

Miami Hand & Upper Extremity Institute

Miami, Florida.

Distributed in the UK by

LEDA

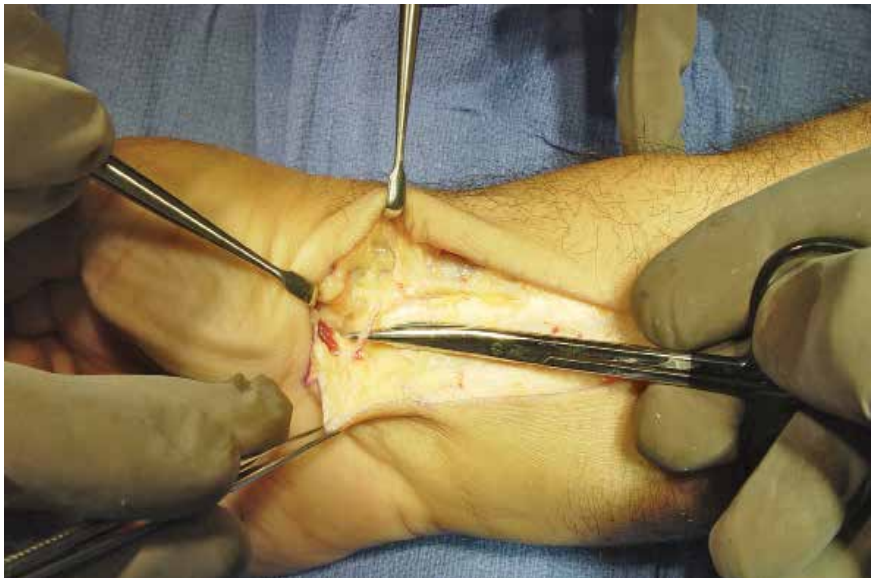
1 EXPOSURE

Make an incision ~ 8cm long over the course of the Flexor Carpi Radialis (FCR) tendon.

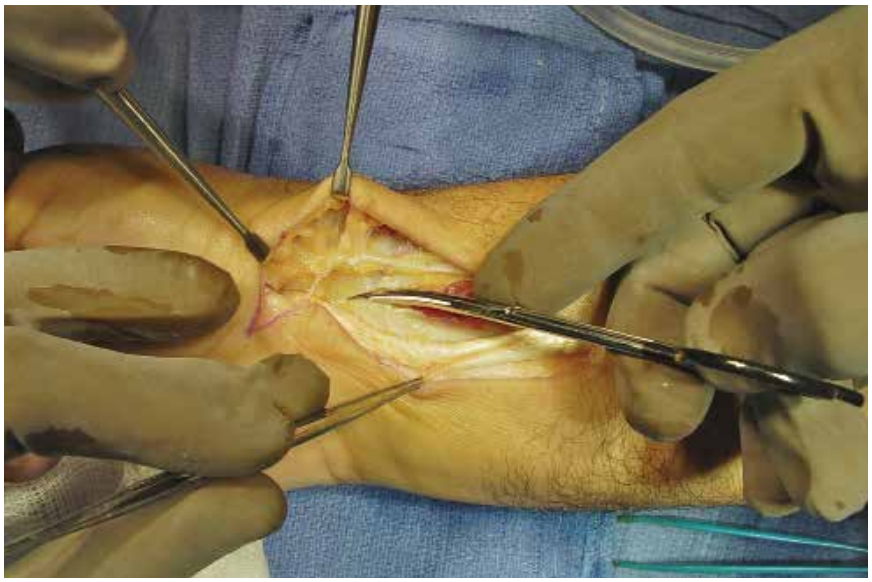
NOTE:
The incision should start distally at the level of the trapezial ridge★, then cross the wrist flexion creases in a zigzag fashion.

2 RELEASE THE FCR TENDON SHEATH

Open the sheath of the FCR tendon and dissect distally past the level of the superficial radial artery.



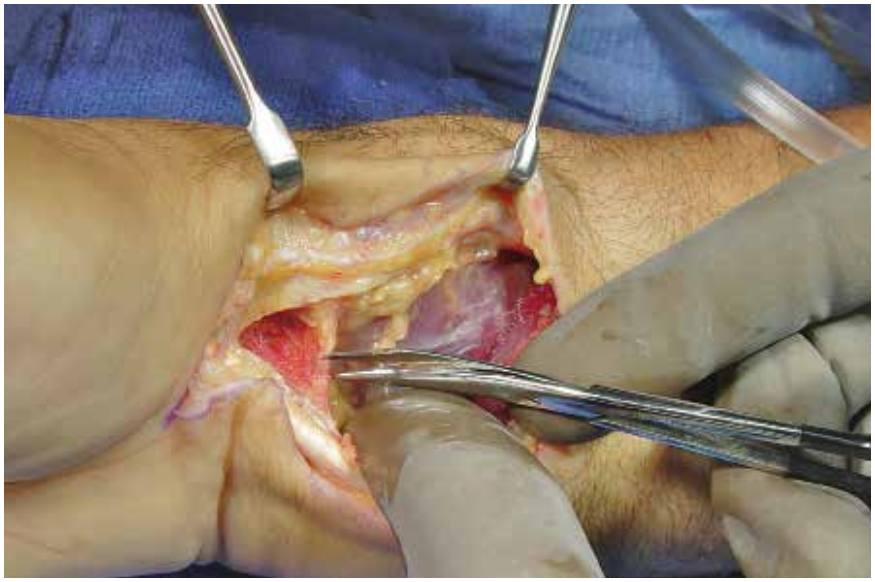
CROSSING THE DEEP FASCIA 3



Retract the FCR tendon ulnarly while protecting the median nerve.

Incise through the floor of the FCR tendon sheath distally to the level of the trapezium.

MID-LEVEL DISSECTION 4



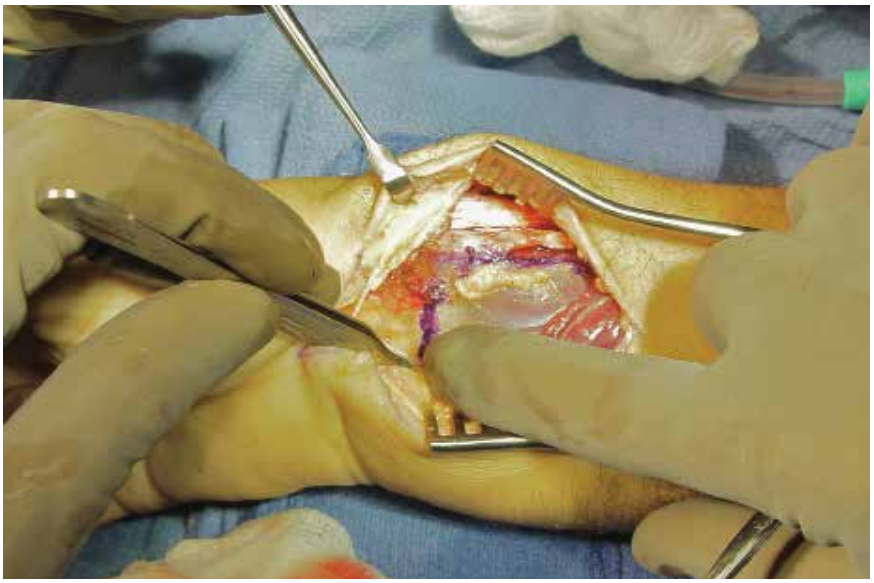
Develop widely the subtendinous space of Parona and expose the Pronator Quadratus (PQ) muscle.

5 IDENTIFYING THE WATERSHED LINE

Identify and mark the location of the **watershed line**; it is best found by palpating for the volar rim of the lunate fossa.

Note:
The Transitional Fibrous Zone (TFZ) is a 1cm wide band of fibrous tissue located between the watershed line and the PQ muscle.

The TFZ must be elevated to properly expose the radius and for proper plate placement.

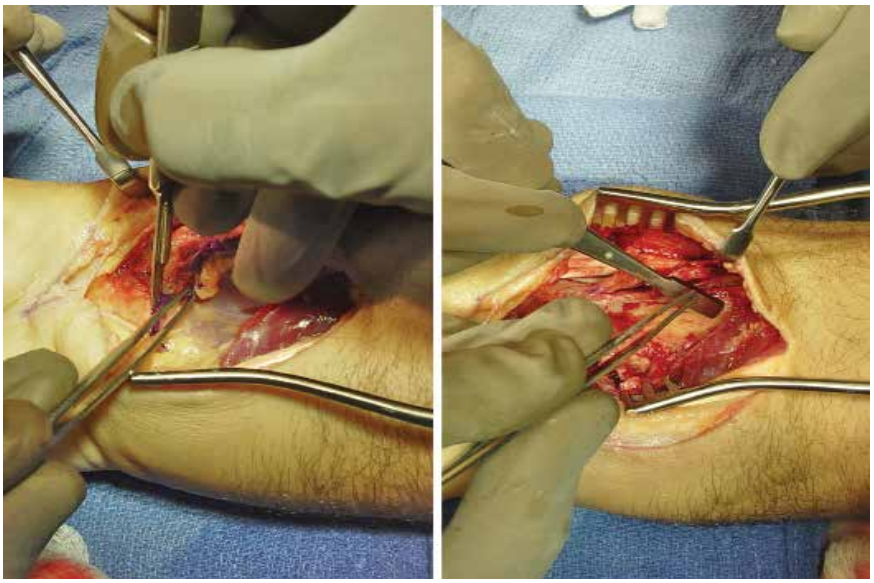


6 ELEVATING THE PQ MUSCLE

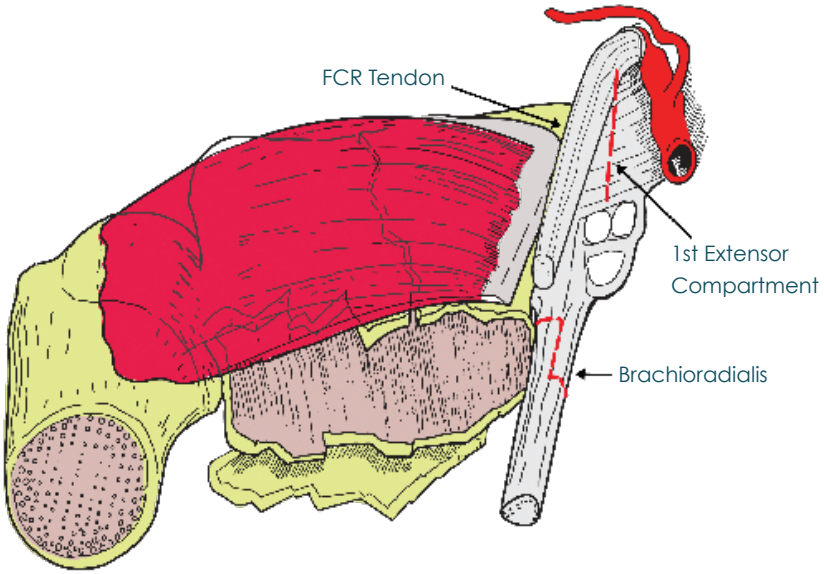
Incise and elevate the TFZ using a scalpel. If necessary, develop as an ulnar based flap.

The PQ muscle is frequently avulsed from its distal attachment to the TFZ. Use a periosteal elevator to lift the PQ muscle from the radius.

Note:
The origin of the Flexor Pollicis Longus (FPL) muscle can be partially released for added exposure.

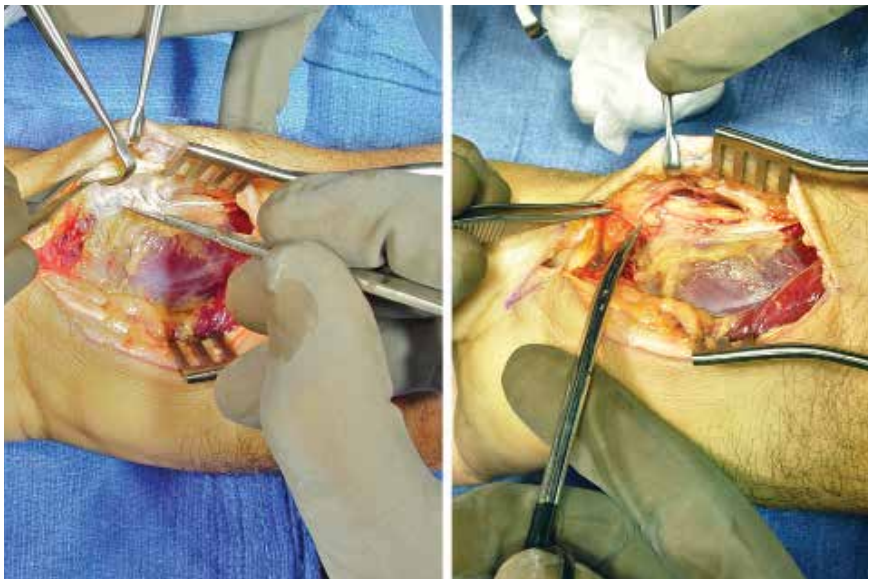


THE RADIAL SEPTUM 7



The radial septum is a complex fascial structure formed by the first extensor compartment, the insertion of the brachioradialis and the distal part of the FCR tendon sheath.

1st EXTENSOR COMPARTMENT 8



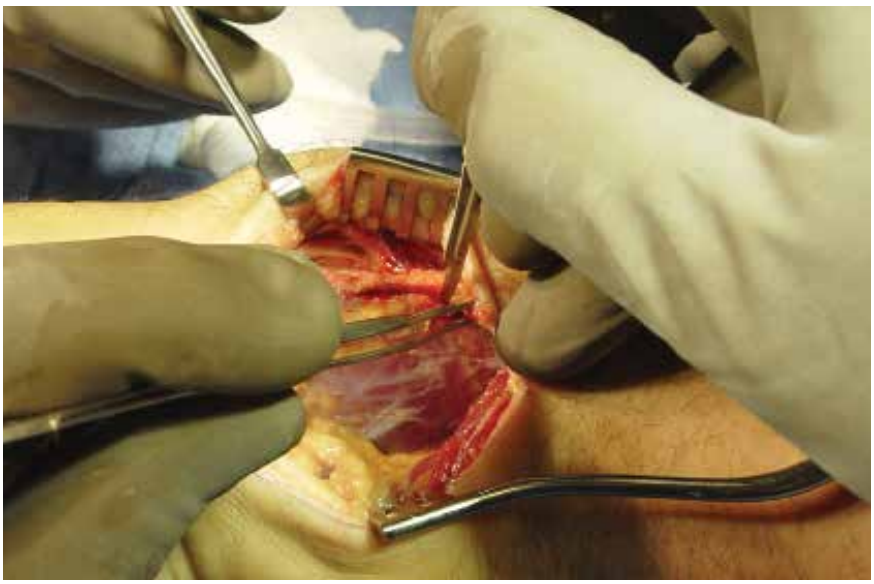
Dissect radially to expose and release the first extensor compartment, then retract the abductor pollicis longus and extensor pollicis brevis tendons.

Note:
Protect the radial artery and sensory nerve.

9 RELEASE OF THE BRACHIORADIALIS

Release the insertion of the brachioradialis using a step cut tenotomy.

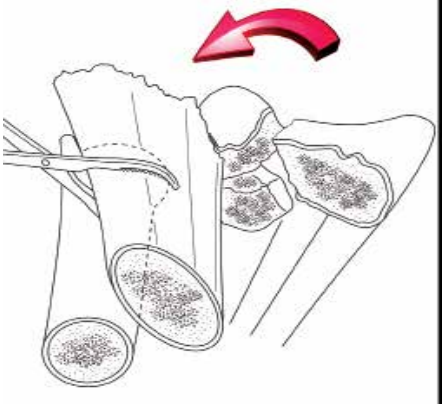
Note:
The brachioradialis is the prime deforming force of the distal radius fracture.



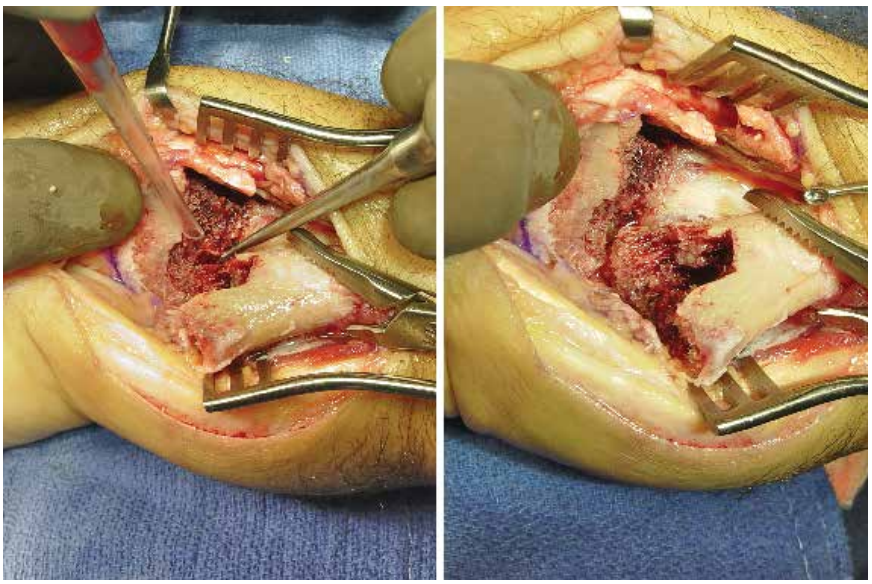
10 INTRA-FOCAL EXPOSURE

Using bone-holding forceps, rotate the proximal fragment into pronation.

Note:
This provides ample exposure of the fracture, allowing for a thorough debridement and provides access to articular fracture fragments.



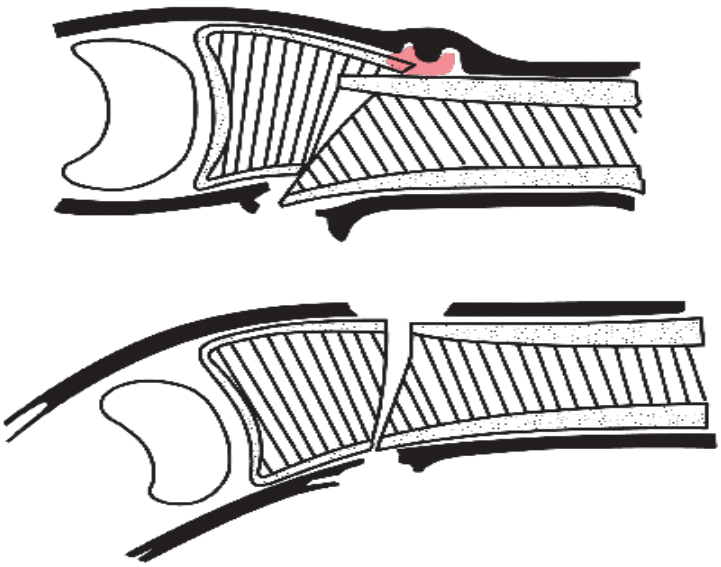
DEBRIDING THE FRACTURE SITE 11



It is necessary to remove clot, fibrous tissue and callus to achieve a proper reduction for complex articular or partially healed fractures.

Note:
Preserve the soft tissue attachments to the medial aspect of the proximal fragment. Here, perforators from the anterior interosseous artery feed the radial shaft.

RELEASING THE DORSAL PERIOSTEUM 12



In some fractures, it may be necessary to release or excise the dorsal periosteum to achieve a proper reduction.

13 INITIAL FRACTURE REDUCTION

Supinate the proximal radius back into place and reduce the volar cortex.

Note:
Providing traction to the hand facilitates in the reduction.

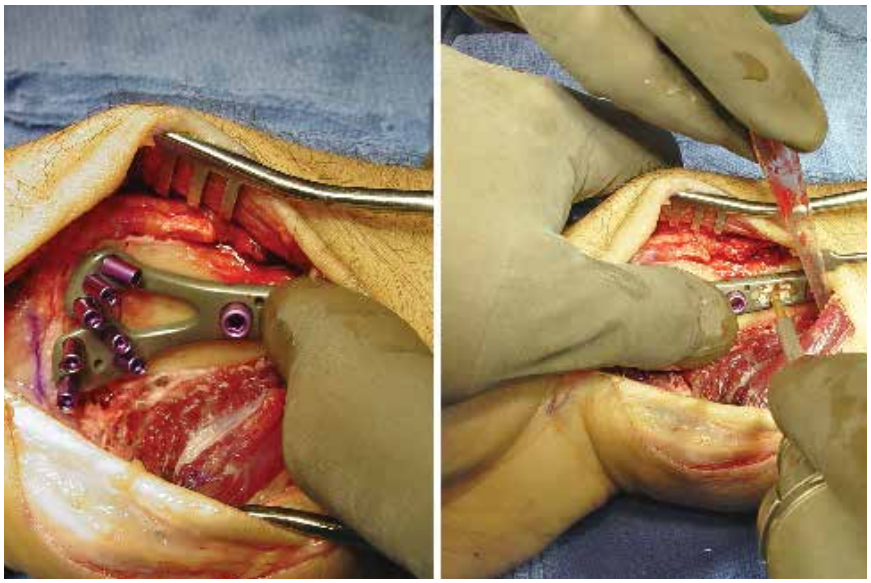
14 PROXIMAL PLATE FIXATION

Position the lunate head of the GEMINUS Plate just proximal to the volar rim of the lunate fossa (watershed line).

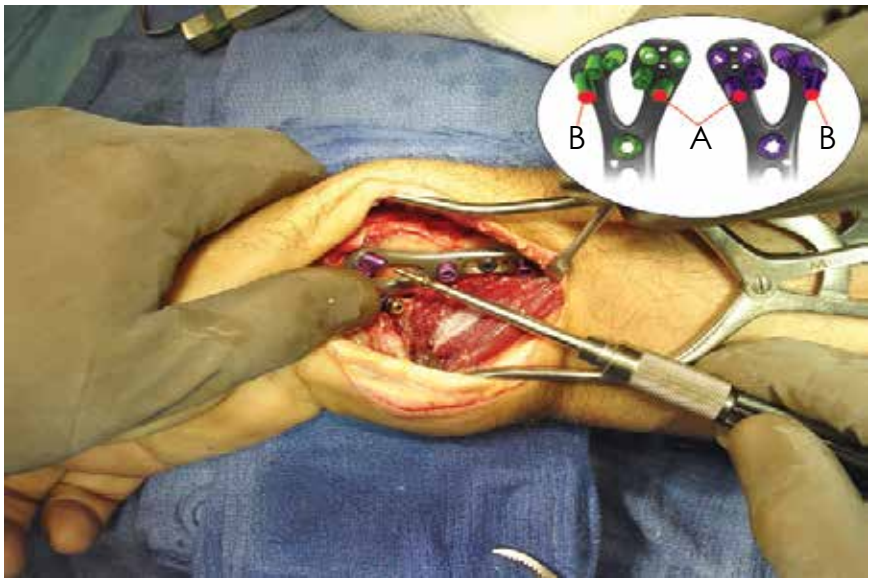
Align the proximal portion of the plate to the radial shaft, then drill through the center of the gliding hole using the 2.5mm bit.

Measure, and then insert a 3.5mm compression screw (Non Locking Cortical Screw).

NOTE:
To avoid contact with flexor tendons, the plate must be applied just proximal to and below the watershed line.



PRE-LOADING K-WIRE A.I.M.ING GUIDES 15



Select two A.I.M.ing Guides and thread them into the pre-loaded drill guides at the proximal ulnar hole (A) of the lunate head, and at the most radial hole (B) of the scaphoid head.

NOTE:
Each A.I.M.ing Guide positions the K-wire in the axis of the corresponding peg.

FINAL FRACTURE REDUCTION 16

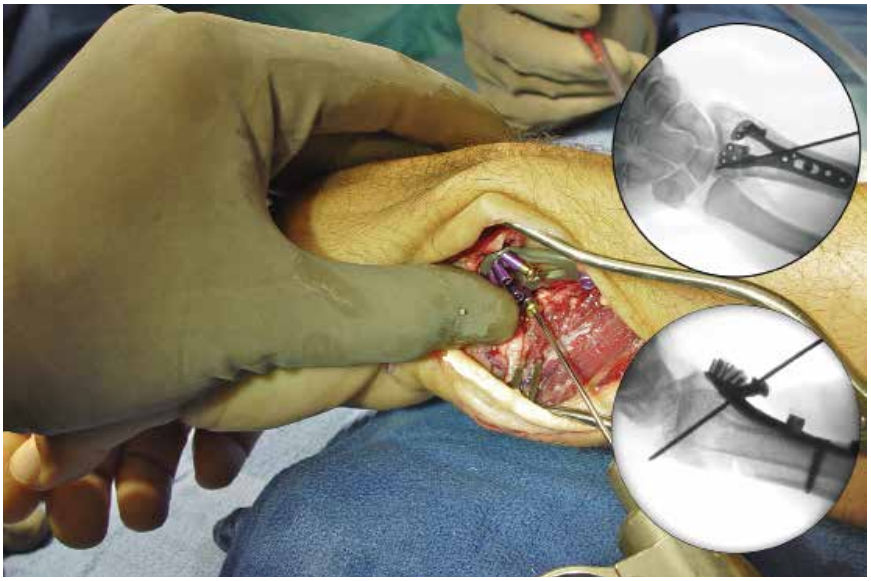
Using the GEMINUS plate as a template, apply longitudinal traction and direct pressure over the dorsal aspect of the radius to reduce the fracture.

It is important that the distal edge of the plate is flush to the surface of the radius.

17 LUNATE FOSSA - PROVISIONAL FIXATION

First, reduce the lunate fossa fragment(s) to the lunate head of the GEMINUS plate using a 1.5mm K-wire through the A.I.M.ing Guide.

Confirm the proper placement of the K-wire at the dorsal ulnar corner using fluoroscopy.

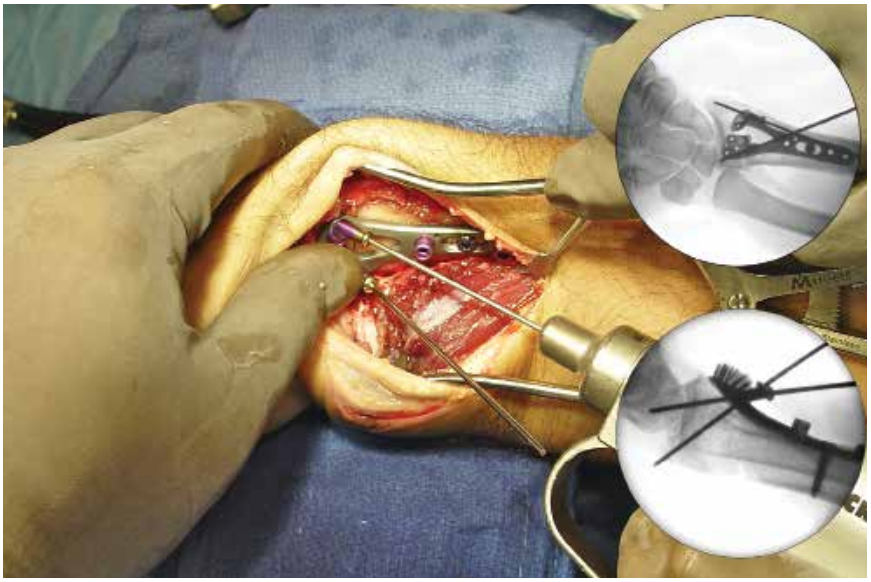


18 SCAPHOID FOSSA - PROVISIONAL FIXATION

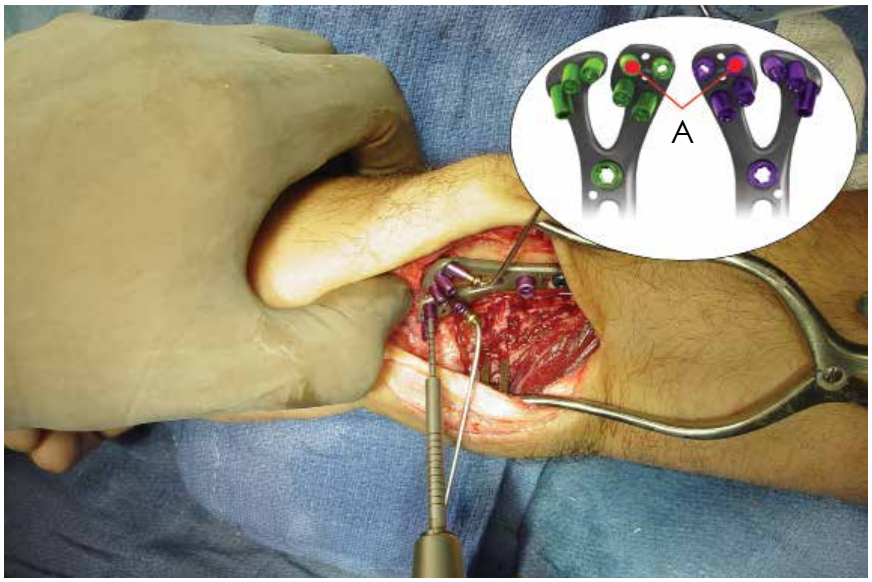
If present, reduce the scaphoid fossa fragment to the already reduced lunate fossa fragment(s).

Confirm final fracture reduction and placement of the K-wires using a 20° elevated lateral fluoroscopic view.

Note:
K-wires also aid in centering the plate to the distal fragments.



PILOT HOLE PREPARATION 19



Bend the K-wires out of the way to facilitate drill insertion.

Using the 2.0mm bit, drill through the pre-loaded drill guide of the medial distal hole of the lunate head (A).

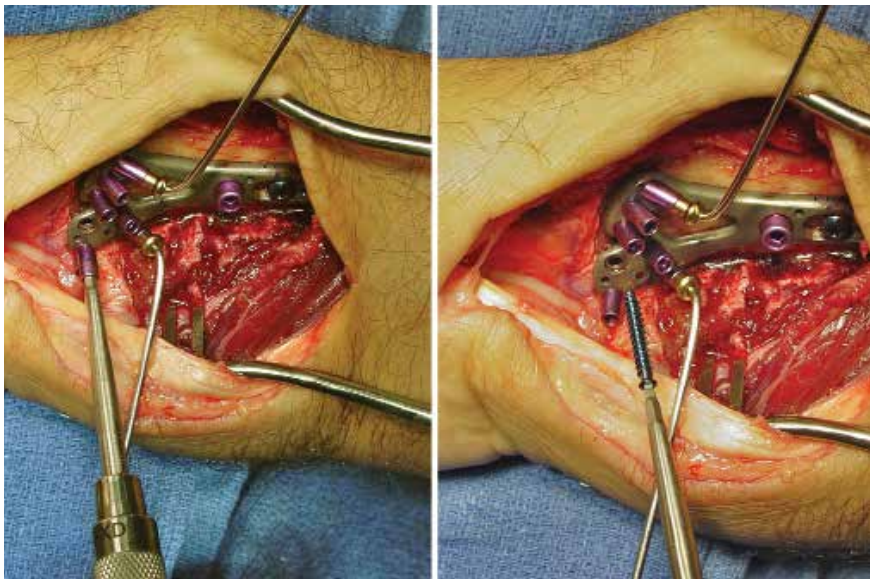
Measure the peg length using the Depth Gauge taking note of the appropriate scale.

Caution:
Prevent excessive peg length as this can potentially cause soft tissue irritation.

NOTE:
Each hole must be prepared sequentially.

The Depth Gauge has a dual scale to reflect measurements either through the pre-loaded drill guides (top scale) or through the GEMINUS plate (bottom scale).

PLATE COMPRESSION 20



Remove the pre-loaded drill guide using the Peg Driver.

Insert a Non Locking Threaded Peg to compress the plate down to the bone.

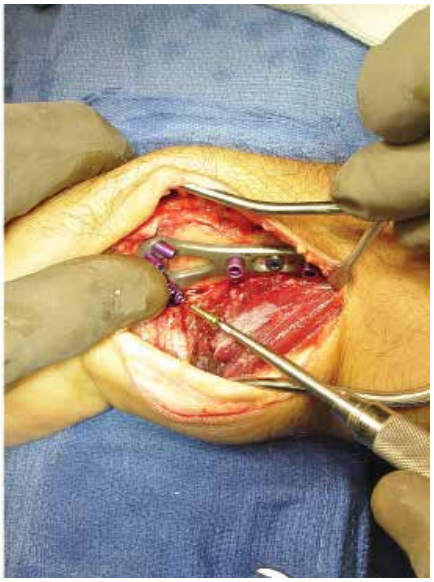
21 PEG PREPARATION

Prepare all remaining available peg holes and insert locking pegs or screws.

Now remove the K-wires and A.I.M.ing guides and complete the holes.

WARNING:
Use only one High Compression Locking Peg or Threaded Non Locking Peg per head.

NOTE:
High Compression Locking Pegs help to reduce and stabilize dorsal fragments.



Smooth Locking Peg

High Compression Locking Peg

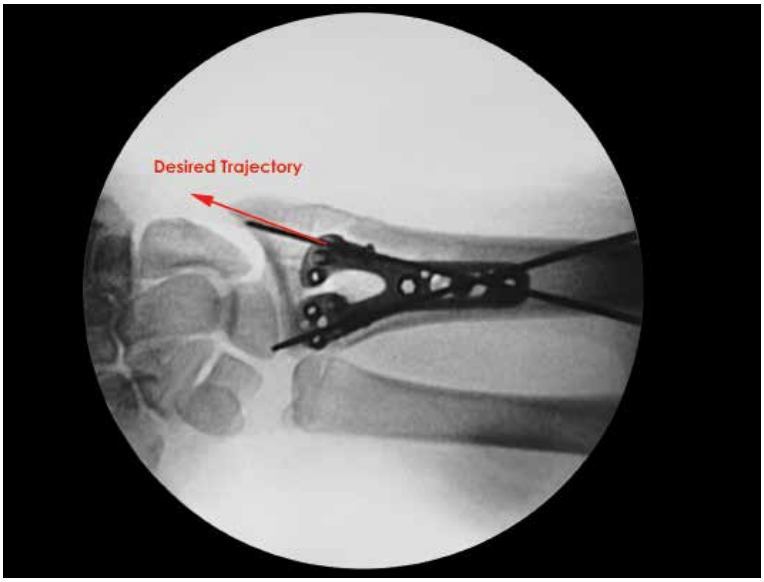
Threaded Locking Peg

22 POLYAXIAL LOCKING SCREW OPTION

In situations where a peg is not optimally positioned, the Polyaxial Locking Screw (PLS) allows you to insert a screw in a desired trajectory different to the one determined by the plate.

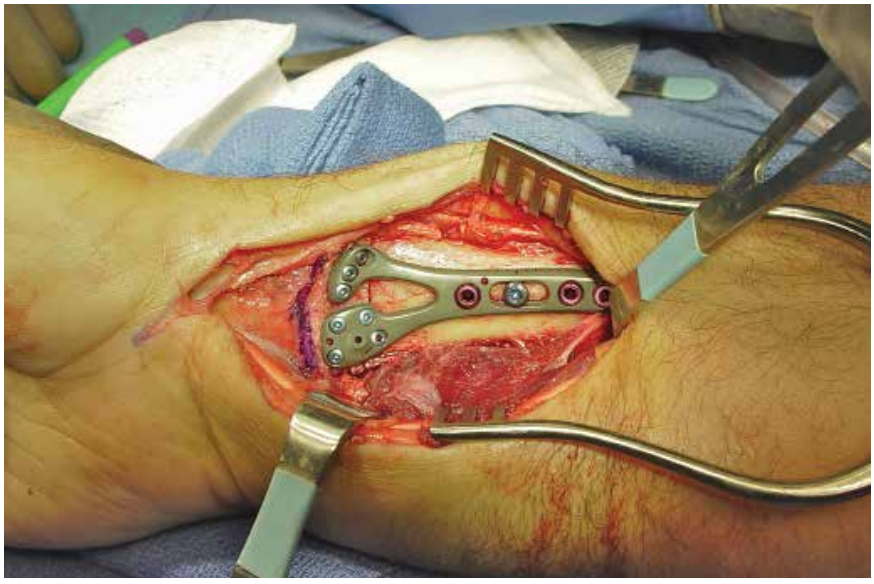
Please refer to the "Polyaxial Locking Screw Surgical Steps" section located at the end of this surgical technique to review the steps and instrumentation.

WARNING:
Do not use a PLS in the most distal hole(s) of the lunate head. Use only one PLS per head.



Polyaxial Locking Screws, Cannulated

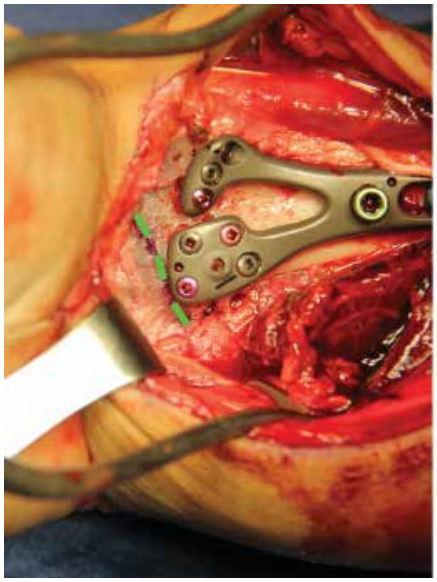
FINAL DISTAL FRAGMENT FIXATION 23



Remove the Threaded Non Locking Peg and replace it with the appropriate length locking peg or screw.

WARNING:
Remove ALL pre-loaded drill guides and A.I.M.ing Guides.

HOOK PLATE EXTENSION OPTION 24



The GEMINUS® Volar Plating System includes a Hook Plate Extension (HPE) to provide increased buttressing support for volar marginal fragments (VMF).

After the fracture has been reduced and fixed with the GEMINUS plate, a remaining VMF may be noted.

Please refer to the "Hook Plate Extension Surgical Steps" section located at the end of this surgical technique to review the steps and instrumentation.

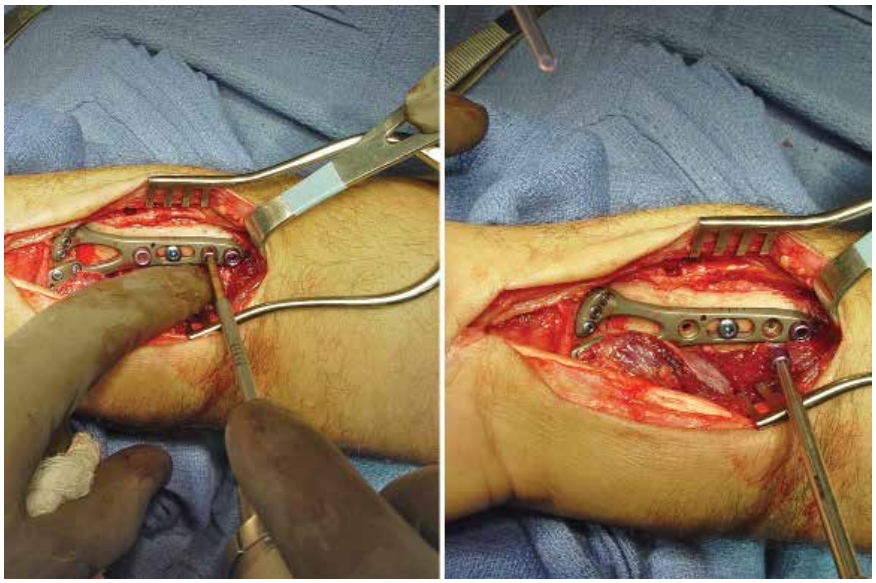
25 PROXIMAL PLATE FIXATION

Drill through the pre-loaded drill guides using the 2.5mm bit.

Measure the screw length using the Depth Gauge taking note of the correct scale.

Remove the pre-loaded drill guide using the T-10 driver and insert the appropriate length 3.5mm Cortical Locking or compression screw (Non Locking Cortical Screw).

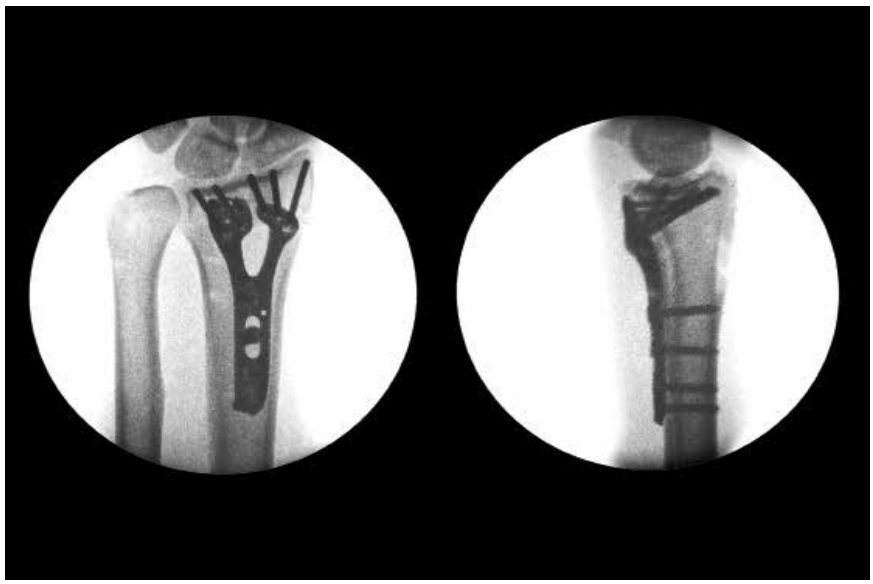
Repeat for all remaining screw holes.



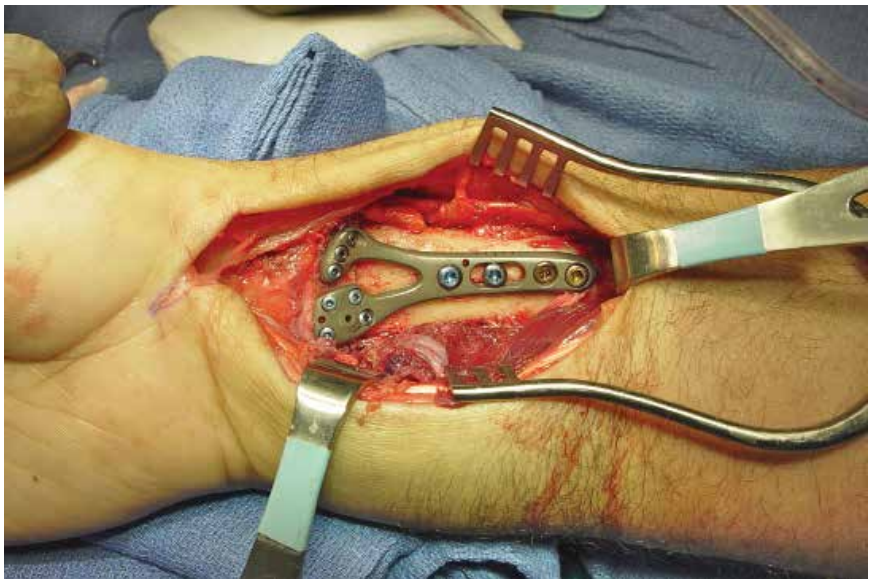
26 FINAL RADIOGRAPHS

Confirm reduction and proper peg placement 2mm proximal to the subchondral plate using a 20°-30° elevated lateral fluoroscopic view.

Also confirm that peg and screw lengths are correct by rotating the wrist under fluoroscopy.



FINAL APPEARANCE 27



Be sure that ALL pegs and screws have been fully tightened prior to wound closure.

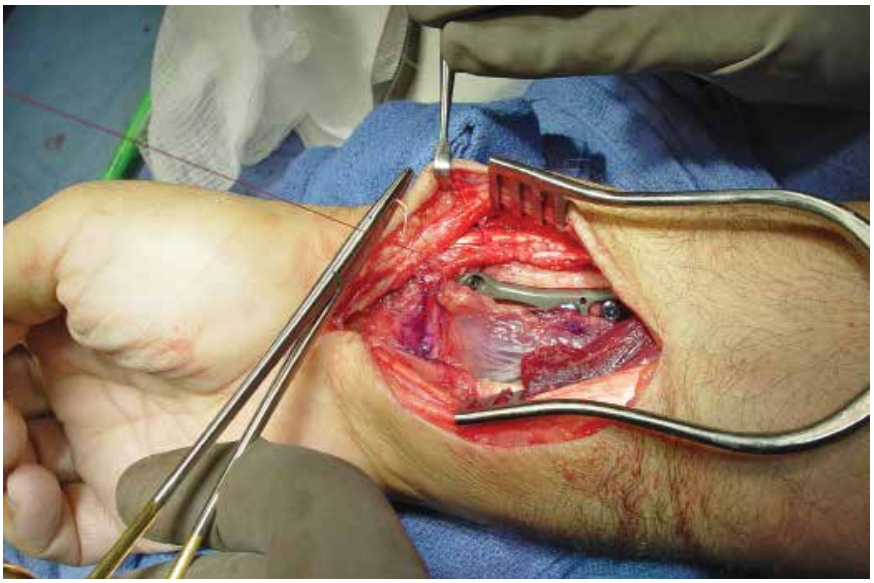
.

BRACHIORADIALIS REPAIR 28

Repair the brachioradialis in a side-to-side fashion to serve as an attachment point for the PQ muscle.

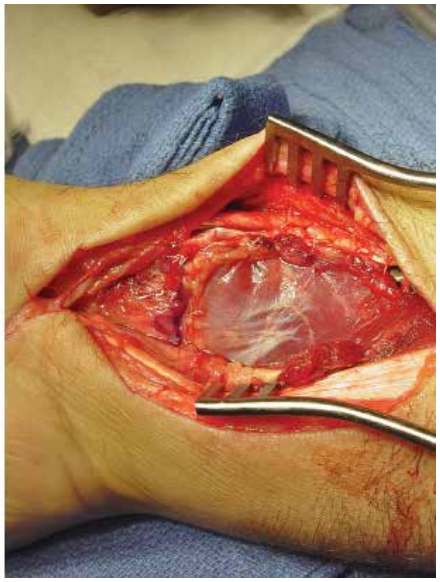
29 TRANSITIONAL FIBROUS ZONE REPAIR

Repair the TFZ in order to cover the distal edge of the GEMINUS plate. This serves to further protect the flexor tendons.

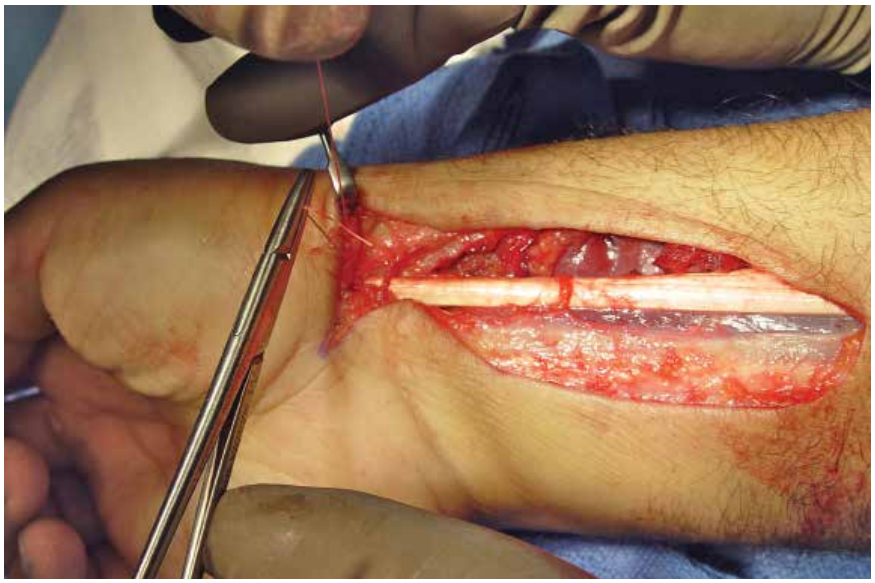


30 PRONATOR QUADRATUS REPAIR

Now suture the PQ muscle to the repaired brachioradialis and TFZ.



FCR TENDON REPOSITIONING 31



Suture the FCR tendon back to its sheath to support the distal pole of the scaphoid.

WOUND CLOSURE 32

Close the incision in your normal fashion.

33 OPTIONAL WASHERS

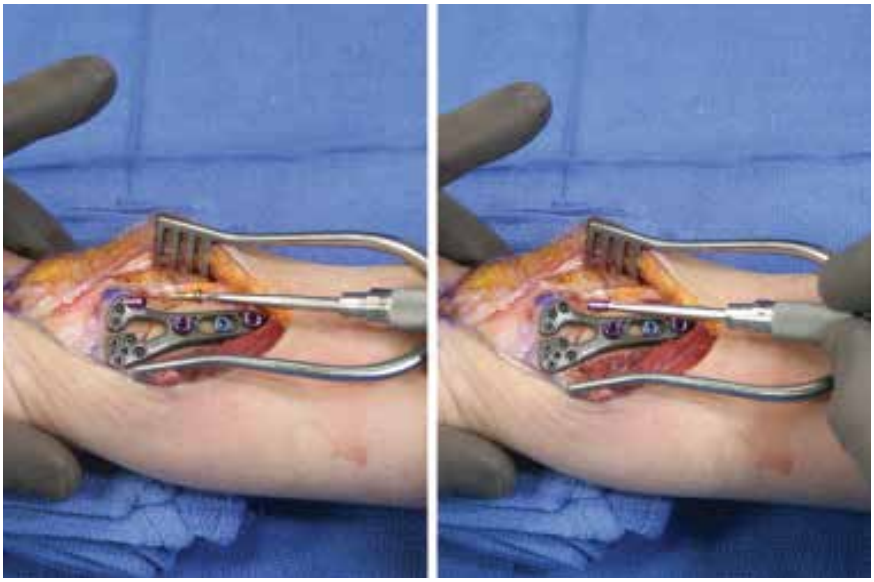
By using a washer, the 2.7mm fully Threaded Non Locking Peg can be used to lag bone fragments when necessary.

Polyaxial Locking Screw (PLS) Surgical Steps

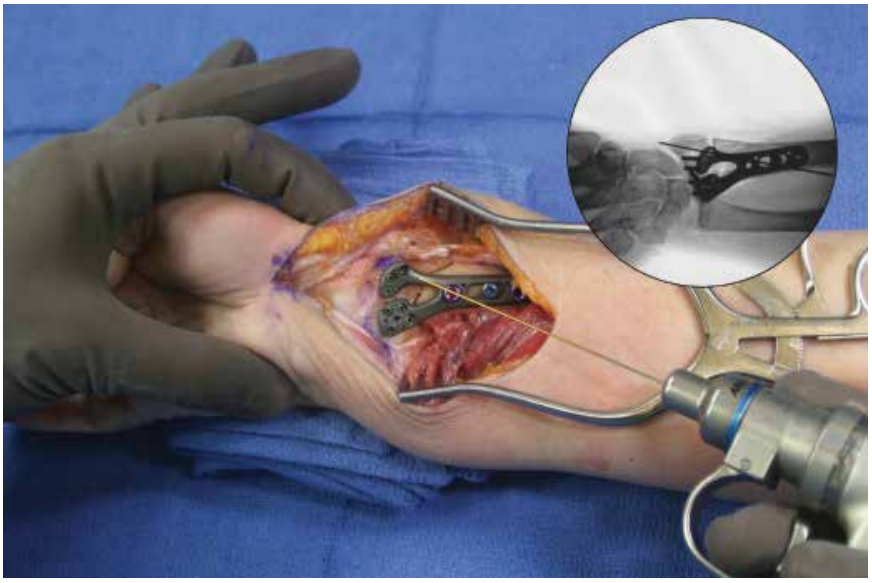
1 PLATE PREPARATION

The PLS is designed to be inserted over a guide wire to assure accuracy.

Remove the respective pre-loaded drill guide from the plate.



ESTABLISHING DESIRED TRAJECTORY 2



Insert the gold end of the .9mm K-wire through the plate in the desired trajectory until the far cortex is reached, then confirm the desired placement using fluoroscopy.

NOTE:
The maximum angulation of the PLS should not exceed 10° from the trajectory of the respective hole.

MEASURING SCREW LENGTH 3

Option 1
Slide the PLS Depth Gauge over the K-wire until flush against the plate to measure screw length.

Option 2
The GEMINUS system's Depth Gauge can also be used; however, the 0.9mm k-wire must first be removed then reinserted and confirmed for proper placement using fluoroscopy.

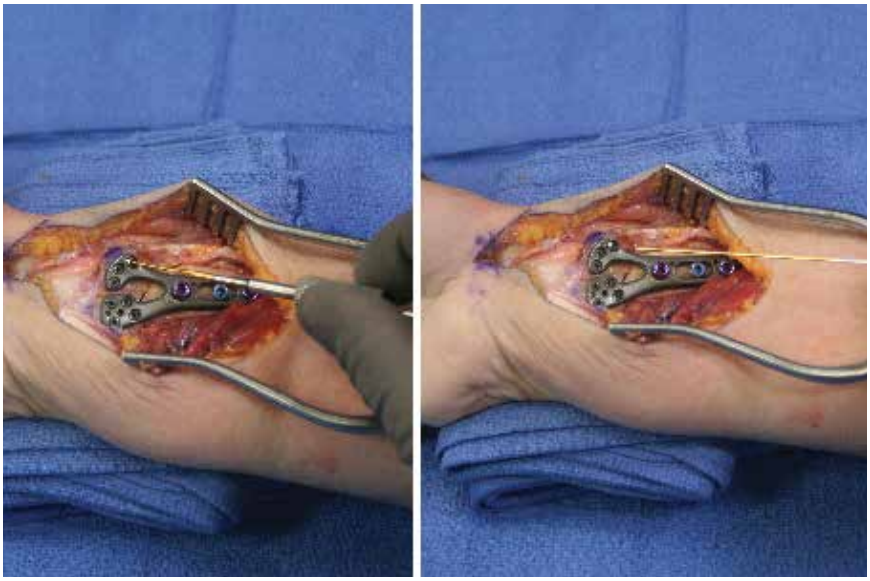
4 PILOT HOLE PREPARATION

Drill over the K-wire using the 2.0mm Cannulated Drill until the far cortex is reached, then remove the Cannulated Drill, leaving the K-wire in place.

5 SCREW INSERTION

Using the cannulated Initial Driver, insert the appropriate PLS over the guide-wire and into the desired trajectory until the head of the PLS engages the plate.

K-WIRE REMOVAL 6



Remove the Initial Driver and K-wire.

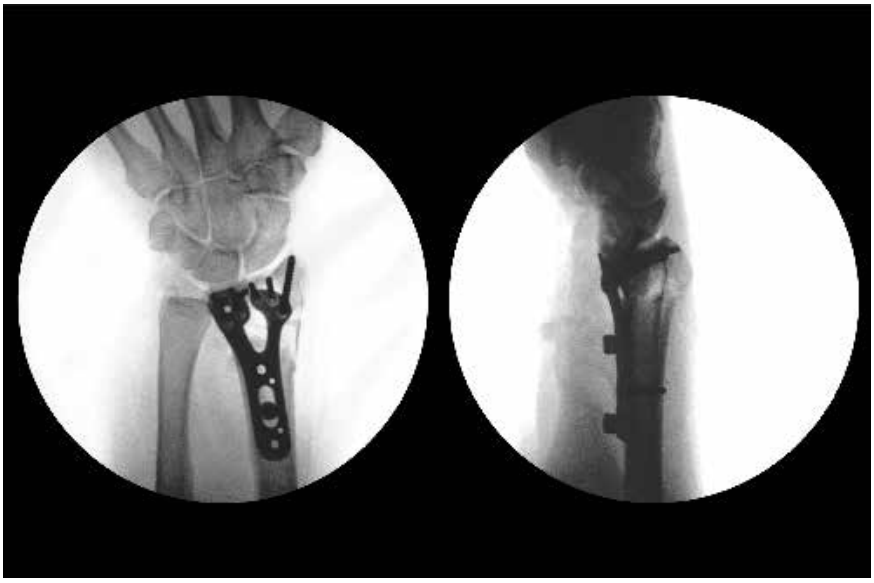
LOCKING THE SCREW 7

Using the stronger non-cannulated PLS Final Driver, be sure to fully seat and lock the PLS into the plate.

8 FINAL RADIOGRAPHS

Confirm the proper placement of the PLS using fluoroscopy.

Refer to Step 27 for final plate fixation and wound closure.

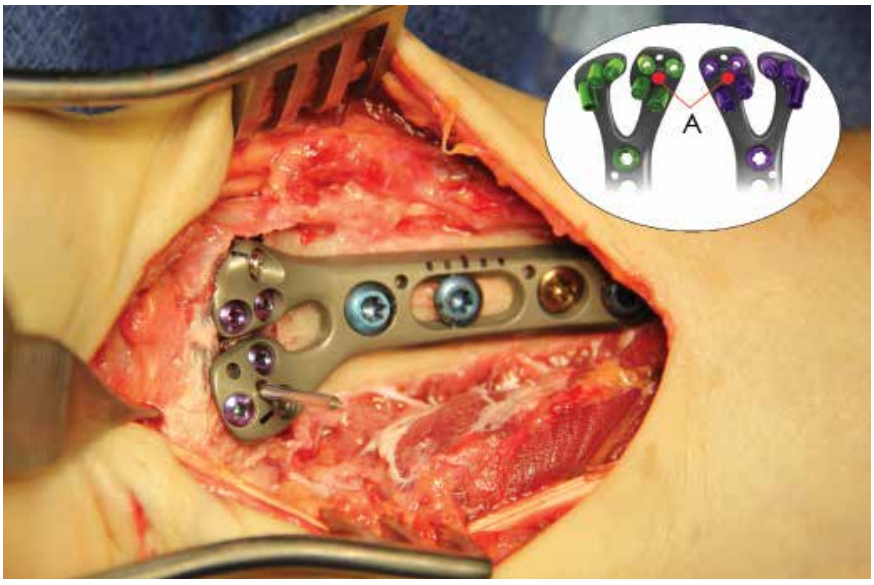


Hook Plate Extension (HPE) Surgical Steps

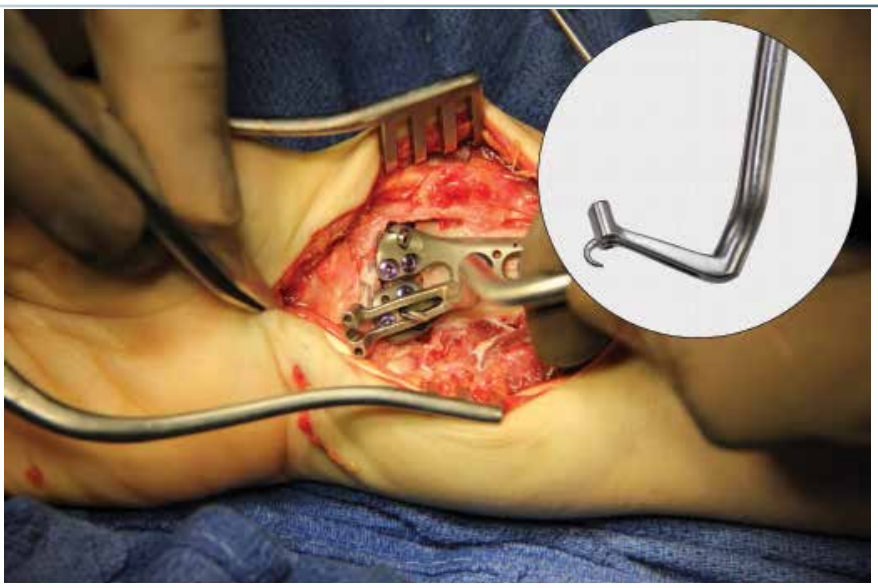
1 GUIDE WIRE PLACEMENT

Advance a 1.5mm K-wire through the central HPE screw hole (A) located on the lunate head of the GEMINUS volar plate.

Cut the K-wire approximately 1cm above the plate. This K-wire helps to position the Reduction Tool when reducing the volar marginal fragment.



REDUCING THE VMF 2

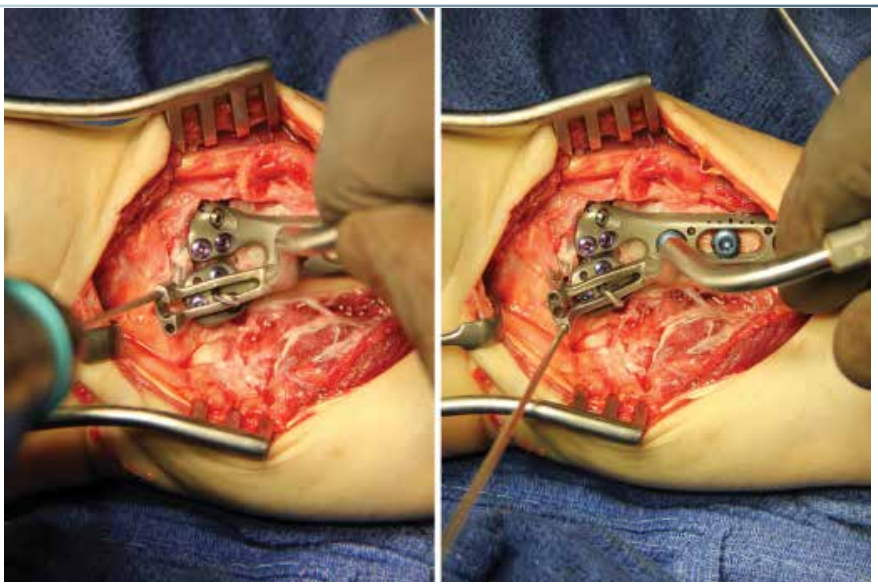


Slide the slot of the Reduction Tool over the K-wire.

Use the hooked tip of the Reduction Tool to reduce the VMF to the plate.

NOTE:
When properly positioned, the base of the Reduction Tool should be flush to the plate with the handle parallel to the radial shaft.

PILOT HOLE PREPARATION 3



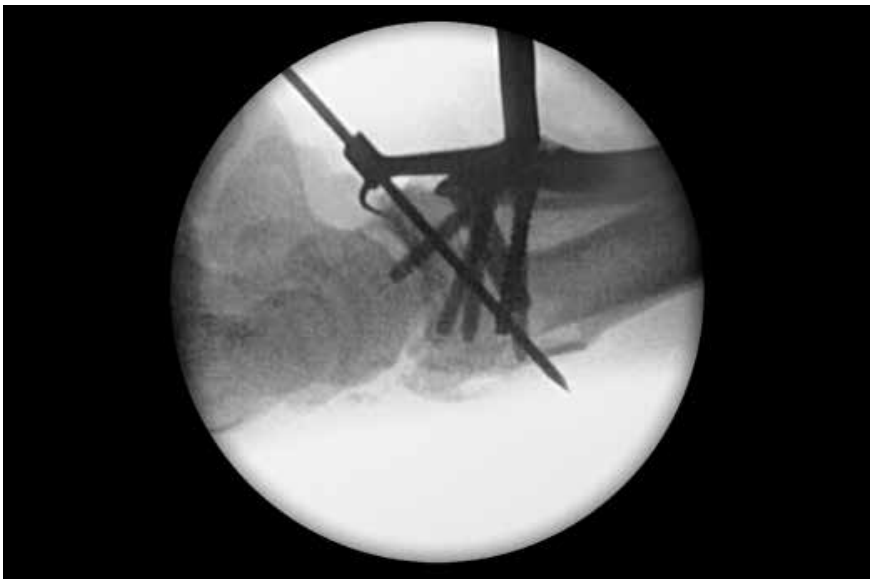
While maintaining the reduction, drill a 1.5mm K-wire through both holes of the Reduction Tool.

Leave the K-wire in place within the second drilled hole.

4 CONFIRMING REDUCTION

Using fluoroscopy, confirm the reduction, and proper placement of the K-wire 1 - 2mm proximal to the subchondral plate.

NOTE:
To avoid contact with flexor tendons, the HPE must be applied proximal to and below the watershed line.



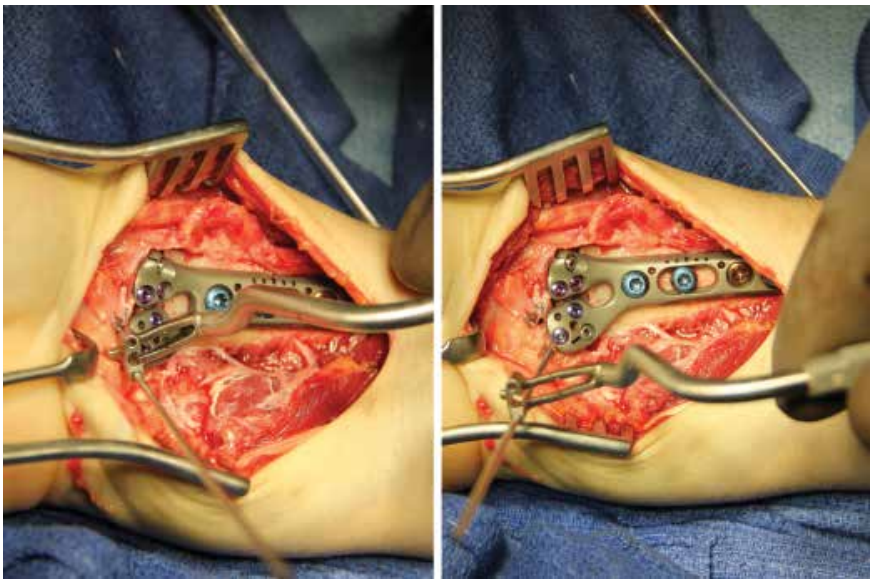
5 REDUCTION TOOL REMOVAL

Remove the cut K-wire from the plate.

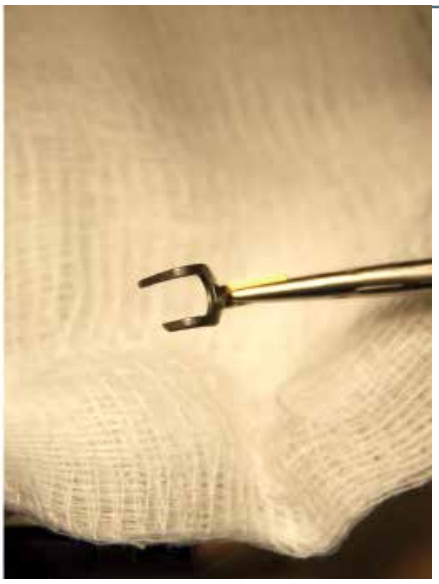
While maintaining the position of the reduced VMF, remove the Reduction Tool by sliding it off of the K-wire.

NOTE:
Take care not to remove the K-wire, as this will allow VMF displacement.

You can mark the pre-drilled hole to ease visualization.



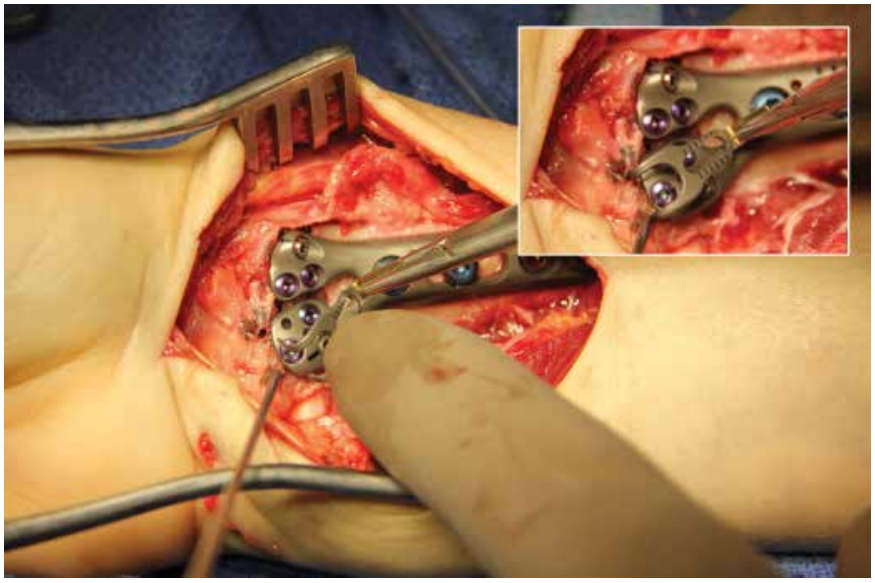
HPE PREPARATION 6



Using a pin cutter, trim the distal half of the HPE leg that corresponds to the remaining K-wire.

NOTE:
Cut the leg at an angle to facilitate insertion.

INITIAL HPE INSERTION 7

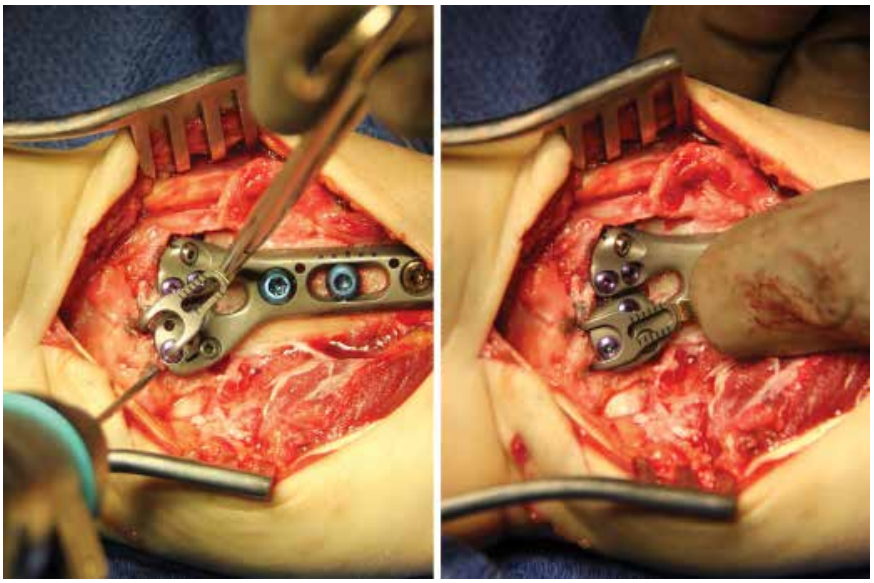


Use a needle holder to grip the HPE by the breakaway handling tab.

Insert the long leg into the first pre-drilled hole of the VMF.

8 FINAL HPE INSERTION

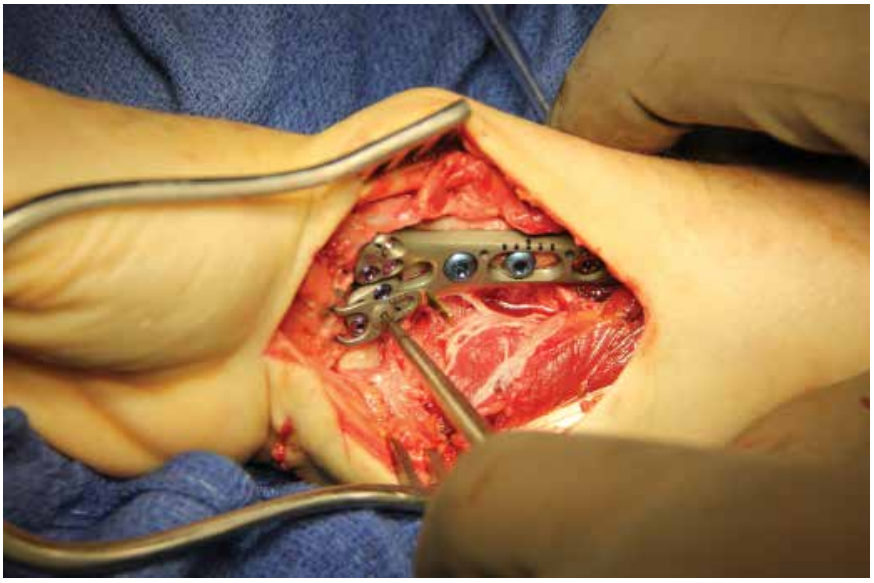
Remove the remaining K-wire, then insert the short leg into the now vacant hole.



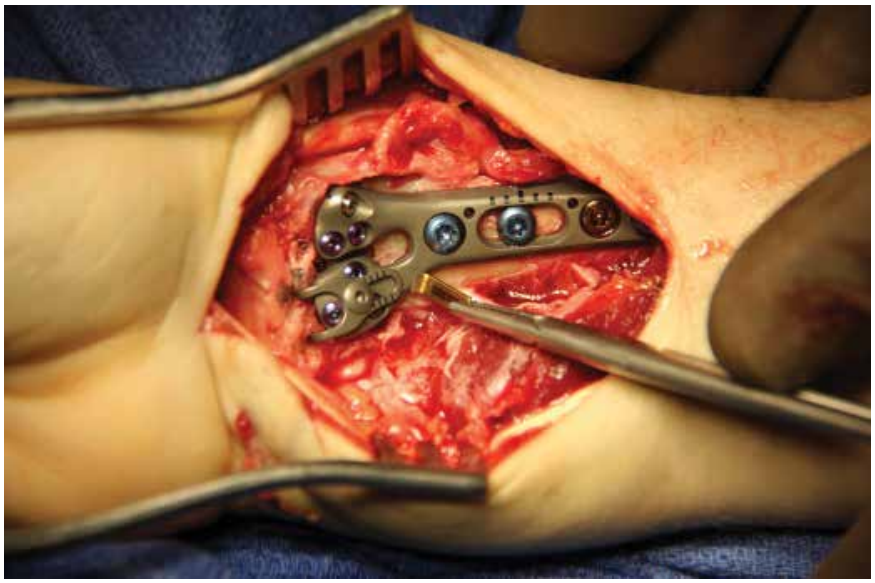
9 LOCKING THE HPE

Lock the HPE to the GEMINUS plate using the Square Tip Driver and an HPE Screw.

NOTE:
Ensure that the HPE Screw is fully tightened to the GEMINUS plate

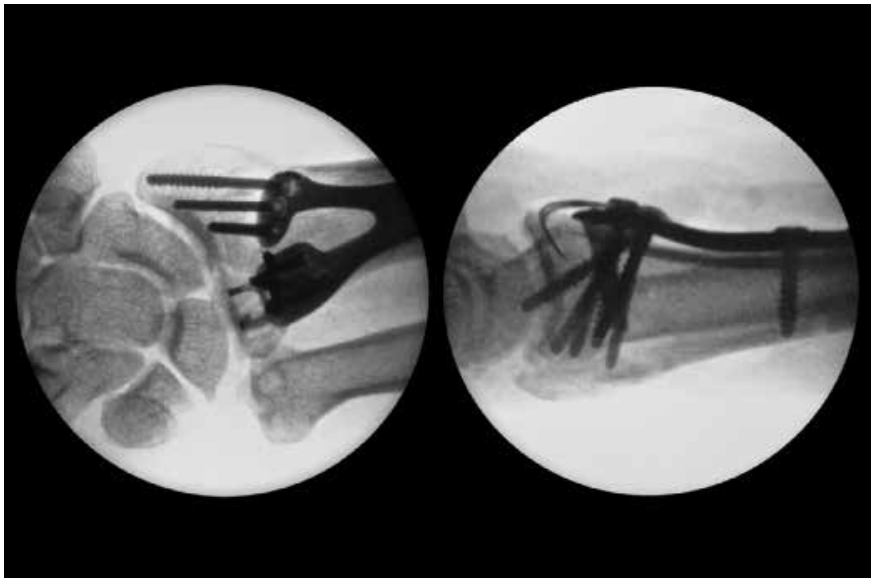


HANDLING TAB REMOVAL 10



Now remove the breakaway handling tab by lowering it toward the radius and separating it from the HPE.

FINAL FLUOROSCOPIC CONFIRMATION 11



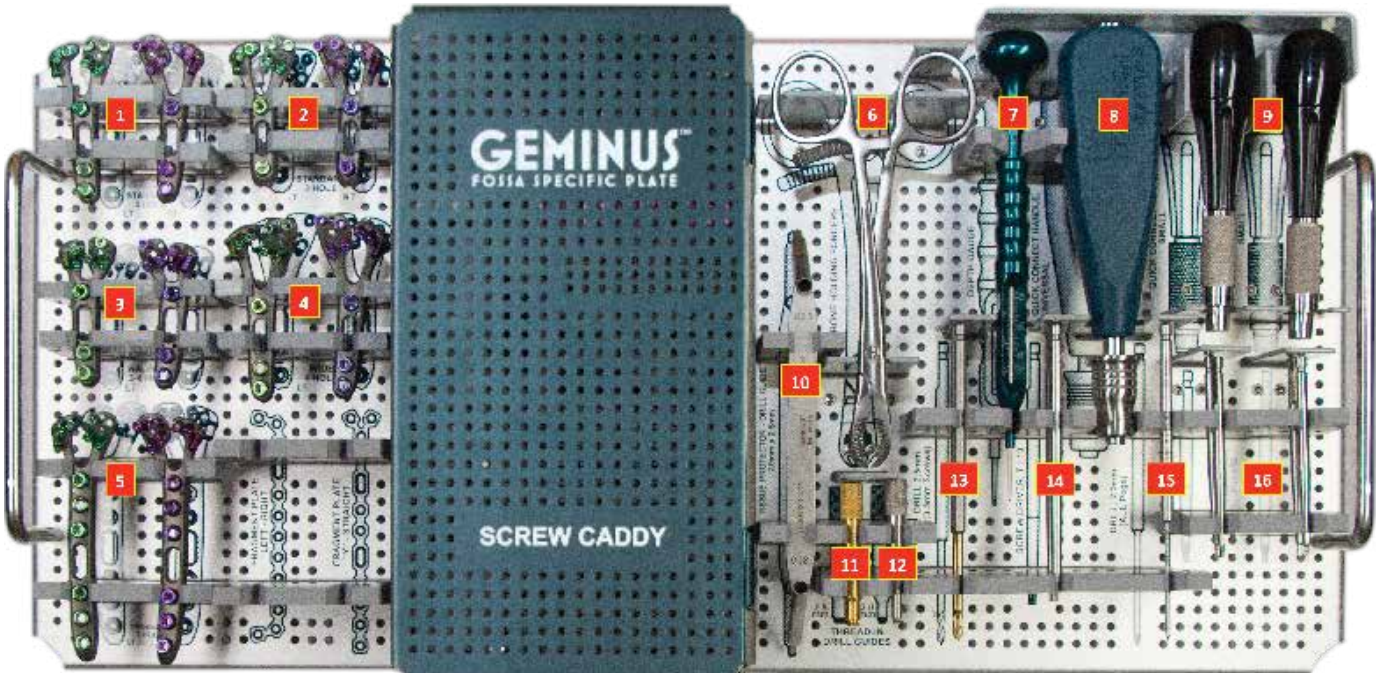
Confirm proper placement of the HPE using fluoroscopy.

It should capture the VMF with its legs positioned just beneath the subchondral bone.

Refer to Step 28 for soft tissue repairs and wound closure.

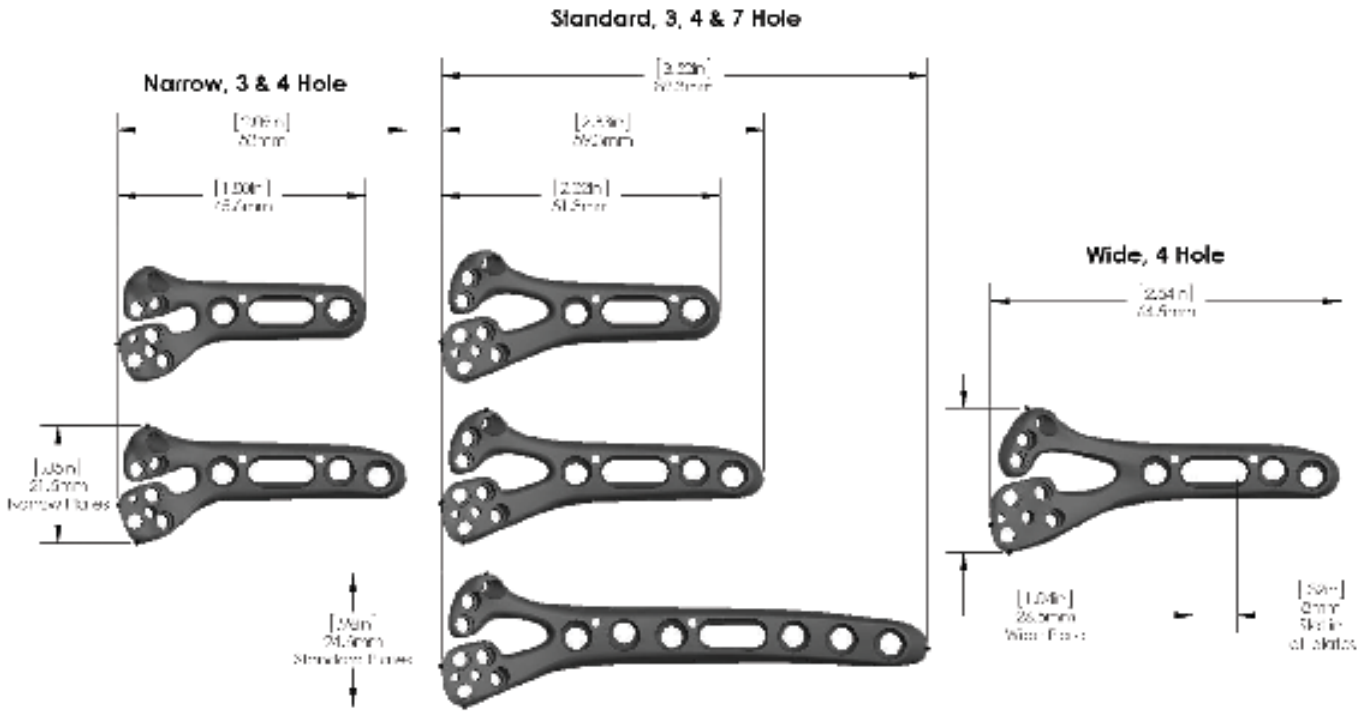
GEMINUS® Volar Distal Radius Plating System - Cat.# GMN-FSP-SYS

INSTRUMENT TRAY (Standard Set Configuration)



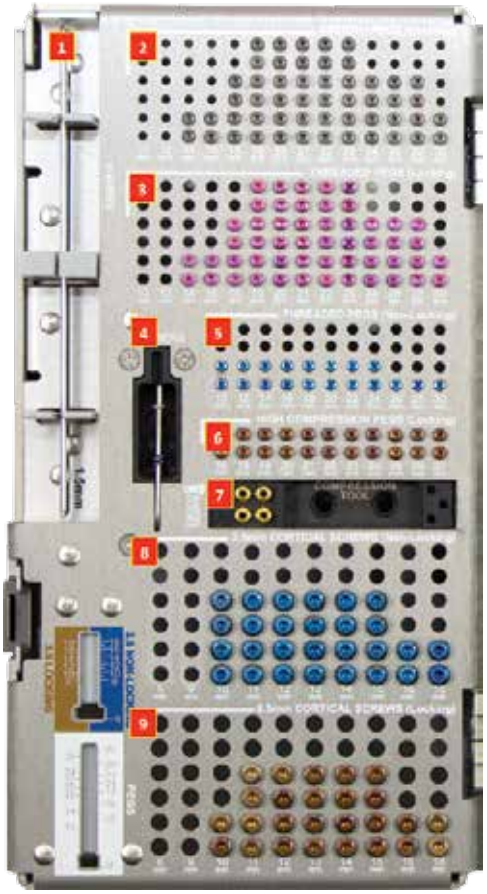
Loc #	Catalog #	Description	Set Qty
1	GMN-LTS-4HL	GEMINUS Plate, Standard, 4 Hole, Left	2
	GMN-RTS-4HL	GEMINUS Plate, Standard, 4 Hole, Right	2
2	GMN-LTS-3HL	GEMINUS Plate, Standard, 3 Hole, Left	1
	GMN-RTS-3HL	GEMINUS Plate, Standard, 3 Hole, Right	1
3	GMN-LTN-3HL	GEMINUS Plate, Narrow, 3 Hole, Left	1
	GMN-RTN-3HL	GEMINUS Plate, Narrow, 3 Hole, Right	1
	GMN-LTN-4HL	GEMINUS Plate, Narrow, 4 Hole, Left	1
	GMN-RTN-4HL	GEMINUS Plate, Narrow, 4 Hole, Right	1
4	GMN-LTW-4HL	GEMINUS Plate, Wide, 4 Hole, Left	1
	GMN-RTW-4HL	GEMINUS Plate, Wide, 4 Hole, Right	1
5	GMN-LTS-7HL	GEMINUS Plate, Standard, 7 Hole, Left	1
	GMN-RTS-7HL	GEMINUS Plate, Standard, 7 Hole, Right	1
6	FRCP-BHM-RTC	Forceps, Bone Holding	1
7	DPGA-SMS-030	Depth Gauge, Standard	1
8	HNDL-UQC-FXD	Handle, Universal Quick Connect	1
9	HNDL-SQC-FXD	Handle, Small Quick Connect	2
10	TPDG-DSD-2025	Tissue Protector / Drill Guide, 2.0mm x 2.5mm	1
11	TPDG-THD-DG25	Thread-in Drill Guide, 2.5mm	1
12	TPDG-THD-DG20	Thread-in Drill Guide, 2.0mm	1
13	DRLL-SSC-25040	Drill, 2.5mm x 40mm	2
14	DRVR-UQC-T10	Driver, T10	2
15	DRLL-SSC-20040	Drill, 2.0mm x 40mm	2
16	DRVR-AOS-S20	Driver, Square Tip 2.0mm	2

GEMINUS PLATES



Single Use Instruments	Catalog Number	Dimensions
	DRLL-SSC-20040	Drill, 2.0mm x 40mm
	DRLL-SSC-25040	Drill, 2.5mm x 40mm
	DRLL-PLS-20	Drill, Cannulated 2.0mm x 40mm
	DRVR-AOS-S20	Driver, Square Tip 2.0mm
	DRVR-UQC-T10	Driver, Quick Connect T10
	GMN-ID-PLS	Initial Driver, PLS
	DRVR-AOS-PLS	Final Driver, PLS
	PDG-AIM-015	A.I.M.ing Guide, 1.5mm
	KWIR-STD-09152	K-Wire, .9mm x 152mm
	KWIR-STD-15127	K-Wire, 1.5mm x 127mm

GEMINUS SCREW CADDY (Standard Set Configuration)



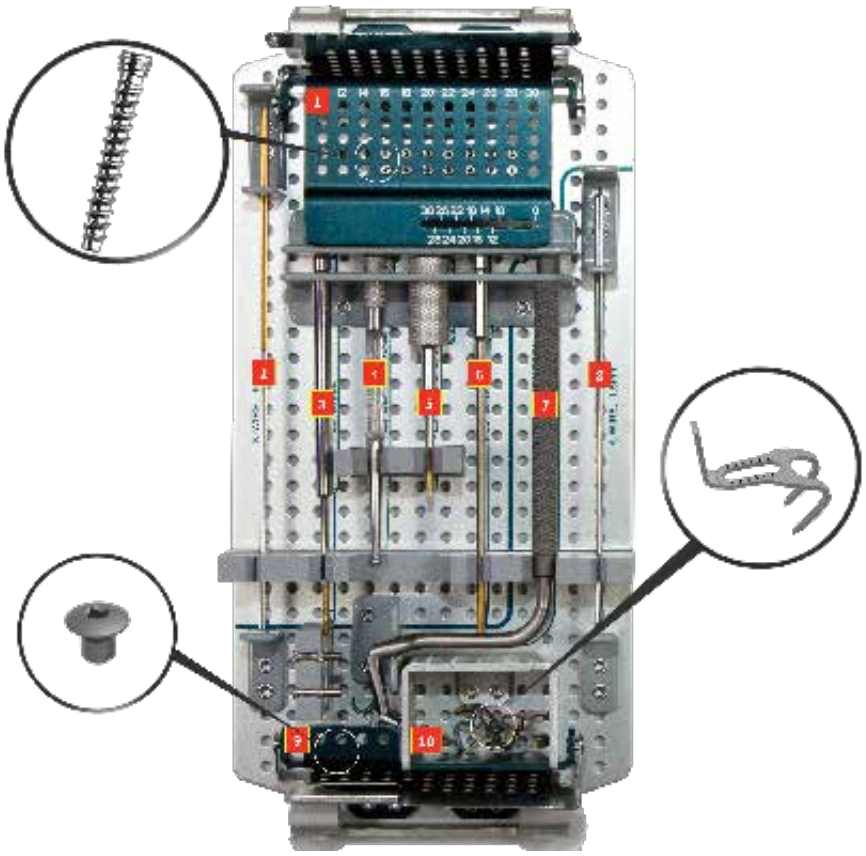
Loc #	Catalog #	Description	Set Qty
1	KWIR-STD-15127	K-Wire, Standard Tip, 1.5mm x 127mm	4
2 	SPLS-20100-TS	Smooth Peg, Locking, 2.0mm x 10mm, Ti	0
	SPLS-20120-TS	Smooth Peg, Locking, 2.0mm x 12mm, Ti	0
	SPLS-20140-TS	Smooth Peg, Locking, 2.0mm x 14mm, Ti	2
	SPLS-20160-TS	Smooth Peg, Locking, 2.0mm x 16mm, Ti	2
	SPLS-20180-TS	Smooth Peg, Locking, 2.0mm x 18mm, Ti	4
	SPLS-20190-TS	Smooth Peg, Locking, 2.0mm x 19mm, Ti	6
	SPLS-20200-TS	Smooth Peg, Locking, 2.0mm x 20mm, Ti	6
	SPLS-20210-TS	Smooth Peg, Locking, 2.0mm x 21mm, Ti	6
	SPLS-20220-TS	Smooth Peg, Locking, 2.0mm x 22mm, Ti	6
	SPLS-20230-TS	Smooth Peg, Locking, 2.0mm x 23mm, Ti	6
	SPLS-20240-TS	Smooth Peg, Locking, 2.0mm x 24mm, Ti	4
	SPLS-20260-TS	Smooth Peg, Locking, 2.0mm x 26mm, Ti	4
	SPLS-20280-TS	Smooth Peg, Locking, 2.0mm x 28mm, Ti	4
	SPLS-20300-TS	Smooth Peg, Locking, 2.0mm x 30mm, Ti	2
3 	TPLS-23100-TS	Threaded Peg, Locking, 2.3mm x 10mm, Ti	0
	TPLS-23120-TS	Threaded Peg, Locking, 2.3mm x 12mm, Ti	0
	TPLS-23140-TS	Threaded Peg, Locking, 2.3mm x 14mm, Ti	2
	TPLS-23160-TS	Threaded Peg, Locking, 2.3mm x 16mm, Ti	2
	TPLS-23180-TS	Threaded Peg, Locking, 2.3mm x 18mm, Ti	4
	TPLS-23190-TS	Threaded Peg, Locking, 2.3mm x 19mm, Ti	6
	TPLS-23200-TS	Threaded Peg, Locking, 2.3mm x 20mm, Ti	6
	TPLS-23210-TS	Threaded Peg, Locking, 2.3mm x 21mm, Ti	6

GEMINUS SCREW CADDY *(continued)* (Standard Set Configuration)

Loc #		Catalog #	Description	Set Qty
3		TPLS-23220-TS	Threaded Peg, Locking, 2.3mm x 22mm, Ti	6
		TPLS-23230-TS	Threaded Peg, Locking, 2.3mm x 23mm, Ti	6
		TPLS-23240-TS	Threaded Peg, Locking, 2.3mm x 24mm, Ti	4
		TPLS-23260-TS	Threaded Peg, Locking, 2.3mm x 26mm, Ti	4
		TPLS-23280-TS	Threaded Peg, Locking, 2.3mm x 28mm, Ti	4
		TPLS-23300-TS	Threaded Peg, Locking, 2.3mm x 30mm, Ti	2
4		WBTN-2750-T	Washer, Button, Inside Ø2.7mm, Outside Ø5.0mm, Ti	2
5		TPNL-27100-TS	Threaded Peg, Non Locking, 2.7mm x 10mm, Ti	2
		TPNL-27120-TS	Threaded Peg, Non Locking, 2.7mm x 12mm, Ti	2
		TPNL-27140-TS	Threaded Peg, Non Locking, 2.7mm x 14mm, Ti	2
		TPNL-27160-TS	Threaded Peg, Non Locking, 2.7mm x 16mm, Ti	2
		TPNL-27180-TS	Threaded Peg, Non Locking, 2.7mm x 18mm, Ti	2
		TPNL-27200-TS	Threaded Peg, Non Locking, 2.7mm x 20mm, Ti	2
		TPNL-27220-TS	Threaded Peg, Non Locking, 2.7mm x 22mm, Ti	2
		TPNL-27240-TS	Threaded Peg, Non Locking, 2.7mm x 24mm, Ti	2
		TPNL-27260-TS	Threaded Peg, Non Locking, 2.7mm x 26mm, Ti	1
		TPNL-27280-TS	Threaded Peg, Non Locking, 2.7mm x 28mm, Ti	1
		TPNL-27300-TS	Threaded Peg, Non Locking, 2.7mm x 30mm, Ti	1
6		HCLP-27160-TS	High Compression Locking Peg, 2.7mm x 16mm, Ti	2
		HCLP-27180-TS	High Compression Locking Peg, 2.7mm x 18mm, Ti	2
		HCLP-27190-TS	High Compression Locking Peg, 2.7mm x 19mm, Ti	2
		HCLP-27200-TS	High Compression Locking Peg, 2.7mm x 20mm, Ti	2
		HCLP-27210-TS	High Compression Locking Peg, 2.7mm x 21mm, Ti	2
		HCLP-27220-TS	High Compression Locking Peg, 2.7mm x 22mm, Ti	2
		HCLP-27230-TS	High Compression Locking Peg, 2.7mm x 23mm, Ti	2
		HCLP-27240-TS	High Compression Locking Peg, 2.7mm x 24mm, Ti	2
		HCLP-27260-TS	High Compression Locking Peg, 2.7mm x 26mm, Ti	2
		HCLP-27280-TS	High Compression Locking Peg, 2.7mm x 28mm, Ti	2
		HCLP-27300-TS	High Compression Locking Peg, 2.7mm x 30mm, Ti	2
7		PDG-AIM-015	AIMing Guides, 1.5mm	4
8		PANL-35080-TS	Screw, Cortical Non Locking, 3.5mm x 8mm, Ti	0
		PANL-35090-TS	Screw, Cortical Non Locking, 3.5mm x 9mm, Ti	0
		PANL-35100-TS	Screw, Cortical Non Locking, 3.5mm x 10mm, Ti	2
		PANL-35110-TS	Screw, Cortical Non Locking, 3.5mm x 11mm, Ti	4
		PANL-35120-TS	Screw, Cortical Non Locking, 3.5mm x 12mm, Ti	4
		PANL-35130-TS	Screw, Cortical Non Locking, 3.5mm x 13mm, Ti	4
		PANL-35140-TS	Screw, Cortical Non Locking, 3.5mm x 14mm, Ti	4
		PANL-35150-TS	Screw, Cortical Non Locking, 3.5mm x 15mm, Ti	4
		PANL-35160-TS	Screw, Cortical Non Locking, 3.5mm x 16mm, Ti	2
		PANL-35180-TS	Screw, Cortical Non Locking, 3.5mm x 18mm, Ti	2
9		COLS-35080-TS	Screw, Cortical Locking, 3.5mm x 8mm, Ti	0
		COLS-35090-TS	Screw, Cortical Locking, 3.5mm x 9mm, Ti	0
		COLS-35100-TS	Screw, Cortical Locking, 3.5mm x 10mm, Ti	2
		COLS-35110-TS	Screw, Cortical Locking, 3.5mm x 11mm, Ti	4
		COLS-35120-TS	Screw, Cortical Locking, 3.5mm x 12mm, Ti	4
		COLS-35130-TS	Screw, Cortical Locking, 3.5mm x 13mm, Ti	4
		COLS-35140-TS	Screw, Cortical Locking, 3.5mm x 14mm, Ti	4
		COLS-35150-TS	Screw, Cortical Locking, 3.5mm x 15mm, Ti	4
		COLS-35160-TS	Screw, Cortical Locking, 3.5mm x 16mm, Ti	2
		COLS-35180-TS	Screw, Cortical Locking, 3.5mm x 18mm, Ti	2

(compression)

PLS and HPE Module (Bottom Base of Tray)



Loc #	Catalog #	Description	Set Qty
1	PALS-25100-CC	Screw, Polyaxial Locking, 2.5mm x 10mm Cannulated, CoCr	0
	PALS-25120-CC	Screw, Polyaxial Locking, 2.5mm x 12mm Cannulated, CoCr	0
	PALS-25140-CC	Screw, Polyaxial Locking, 2.5mm x 14mm Cannulated, CoCr	0
	PALS-25160-CC	Screw, Polyaxial Locking, 2.5mm x 16mm Cannulated, CoCr	2
	PALS-25180-CC	Screw, Polyaxial Locking, 2.5mm x 18mm Cannulated, CoCr	2
	PALS-25200-CC	Screw, Polyaxial Locking, 2.5mm x 20mm Cannulated, CoCr	2
	PALS-25220-CC	Screw, Polyaxial Locking, 2.5mm x 22mm Cannulated, CoCr	2
	PALS-25240-CC	Screw, Polyaxial Locking, 2.5mm x 24mm Cannulated, CoCr	2
	PALS-25260-CC	Screw, Polyaxial Locking, 2.5mm x 26mm Cannulated, CoCr	2
	PALS-25280-CC	Screw, Polyaxial Locking, 2.5mm x 28mm Cannulated, CoCr	2
	PALS-25300-CC	Screw, Polyaxial Locking, 2.5mm x 30mm Cannulated, CoCr	0
2	KWIR-STD-09152	K-Wire, Standard Tip, .9mm x 152mm	4
3	DRLL-PLS-20	Drill, Cannulated, Polyaxial Locking Screw, 2.0mm	2
4	GMN-CDG-PLS	Cannulated Depth Gauge, Polyaxial Locking Screw	1
5	GMN-ID-PLS	Initial Driver, Polyaxial Locking Screw	1
6	DRVR-AOS-PLS	Driver, AO Connection, Polyaxial Locking Screw	2
7	GMN-HP-DG15	GEMINUS Hook Plate, Reduction Tool	1
8	KWIR-STD-15127	K-Wire, Standard Tip, 1.5mm x 127mm	2
9	GMN-HP-SCRW	GEMINUS Hook Plate, Screw	3
10	GMN-HP	GEMINUS Hook Plate	2
	Bottom Tray		
11	GMN-FSP-PLB	GEMINUS Plate Bender	1
12	GMN-FSP-PLH	GEMINUS Plate Holder	1

℞: **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.

Symbols

MATL:	MATERIAL
TI:	TITANIUM ALLOY
SS, SST:	STAINLESS STEEL
CoCr:	COBALT CHROMIUM ALLOY
MADE IN:	MADE IN <<COUNTRY>>
QTY:	QUANTITY


DO NO REUSE (SINGLE USE ONLY)


USE BY (EXPIRATION DATE)

BATCH CODE

STERILIZED USING ETHYLENE OXIDE

STERILIZED USING IRRADIATION

NON STERILE PRODUCT

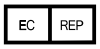
CATALOG NUMBER


CAUTION or ATTENTION,
SEE INSTRUCTIONS FOR USE


CONSULT INSTRUCTIONS FOR USE


MANUFACTURER


TEMPERATURE LIMITATION



AUTHORIZED REPRESENTATIVE IN
THE EUROPEAN COMMUNITY


DO NOT USE IF PACKAGE IS
DAMAGED

Description

The Skeletal Dynamics GEMINUS® Volar Plating System contains bone plates for the repair of distal volar radial fractures. Included in the set are titanium bone screws, fixation pegs, fragment plates, and specialized instrumentation. Also included are a Hook Plate Extension to buttress a volar marginal fragment, and cannulated cobalt chrome polyaxial locking screws for trajectories different than those of the fixed angled bone plates.

The GEMINUS® Volar Plates are available in various sizes and are made of medical grade titanium alloy. Cortical screws affix the plate to the diaphysis and fixed angle pegs are used for distal bone fragments. The system is provided non-sterile and is sterilized in the user facility.

The GEMINUS® Volar Plating System is comprised of:

- Titanium alloy plates, washers and screws
- CoCr Cannulated Polyaxial Locking Screw (PLS)
- Stainless steel K-wires (for provisional fixation; not for implantation)
- System specific instrumentation

Indications

The GEMINUS® Volar Plating System is intended for the fixation of fractures and osteotomies involving the distal radius.

Contraindications

Prior to using the GEMINUS® Volar Plating 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

- All screws must be implanted and fully tightened into the plate to maintain the integrity and strength of the finished construct. If the 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 GEMINUS® Volar Plating System 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 GEMINUS® Volar Plating 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.
- DO NOT open the volar capsule as it may devascularize fracture fragments and destabilize the volar wrist ligaments.
- Use only one 2.7mm Peg (High Compression or Fully Threaded, Non Locking) in each head of the GEMINUS® Volar Plate.
- Use only one 2.5mm PLS in each head of the GEMINUS® Volar Plate.
- DO NOT use the PLS in the most distal hole(s) on the lunate head of the GEMINUS® Volar Plate.

Precautions

- Protect the GEMINUS® Volar Plating System's implantable components against scratching or nicking. Such stress concentration can lead to implant failure.
- Before using the GEMINUS® Volar Plating 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 during provisional fixation of the GEMINUS® Volar Plate.
- DO NOT permanently implant the pre-loaded Drill Guides or A.I.M.ing Guides; they are intended to be removed prior to peg insertion.
- The GEMINUS Volar Plating 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.
- DO NOT use peg/screw lengths that will excessively protrude through the far cortex as it may result in soft tissue irritation.
- The maximum angulation of the PLS should not exceed 10° from the trajectory of the respective hole.
- The Non-locking Threaded Pegs are NOT intended to provide subchondral support. Their use should be limited to capture remote bone fragments where partially or fully threaded pegs cannot be used.
- The Skeletal Dynamics GEMINUS® Volar Plating 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 GEMINUS® Volar Plating 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 surgery: infection, nonunion, persistent pain, stiffness of the fingers, loosening or migration of the implants resulting in mal-alignment.

Directions for Use

The GEMINUS® Volar Plating System should only be used by surgeons who have experience with this system. Each surgeon must evaluate the appropriateness for the use of the GEMINUS® Volar Plating System based on their clinical experiences.

Cleaning

The GEMINUS® Volar Plating 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.
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 Skeletal Dynamics GEMINUS® Volar Plating 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.

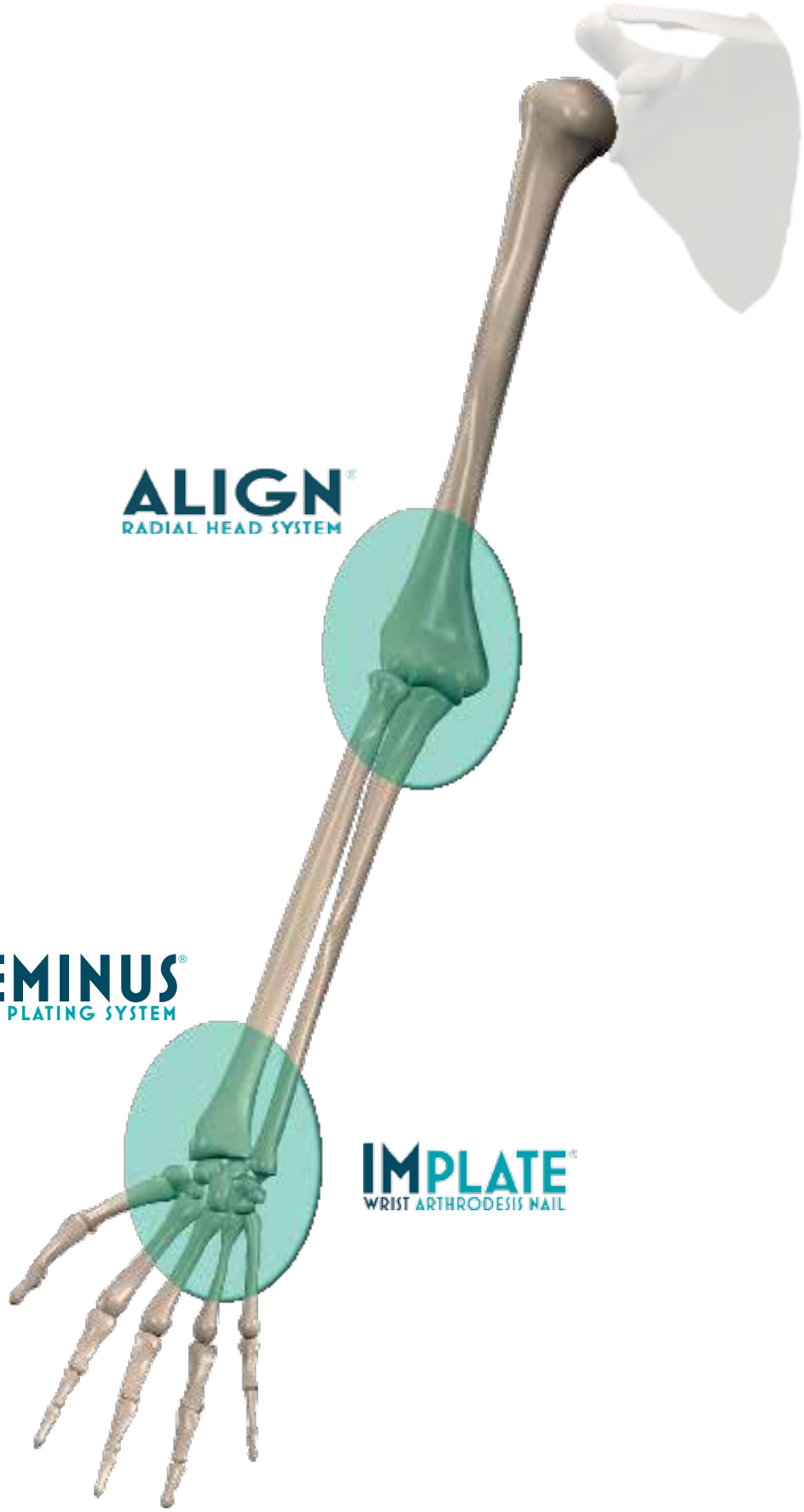
Handling and storage

When not in use, store the clean and disinfected GEMINUS® Volar Plating 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.

NOTES



skeletal® dynamics

DESIGNED AND MANUFACTURED IN THE USA

Distributed in the UK by

LEDA

+44 (0)203 714 2301
sales@ledaortho.com
www.ledaortho.com