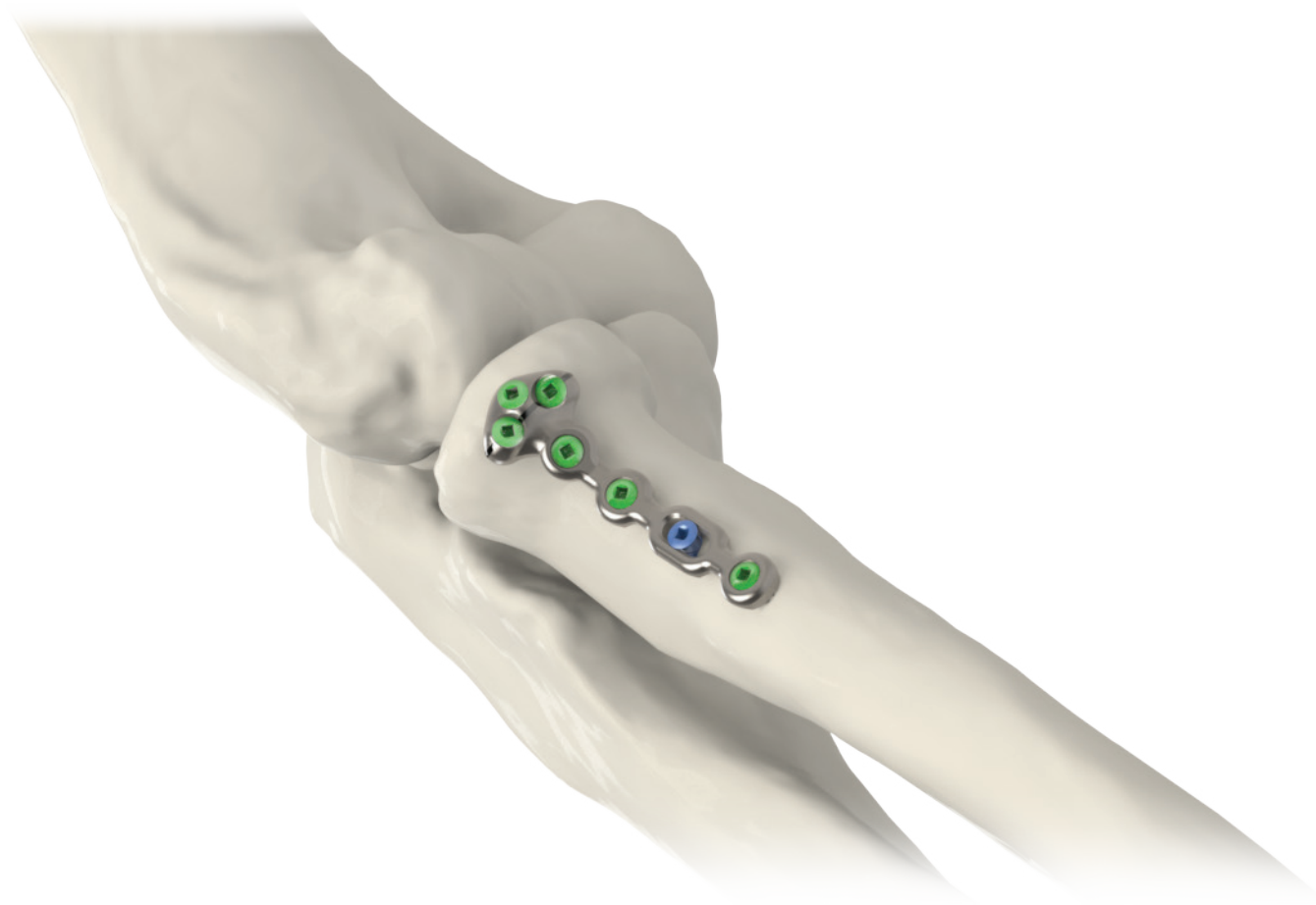


SURGICAL TECHNIQUE GUIDE

PROTEAN[®]

r a d i a l h e a d p l a t e



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

Indications for Use

The PROTEAN[®] Radial Head Plate Module consists of titanium alloy plates (right and left), screws, and specialized instrumentation.

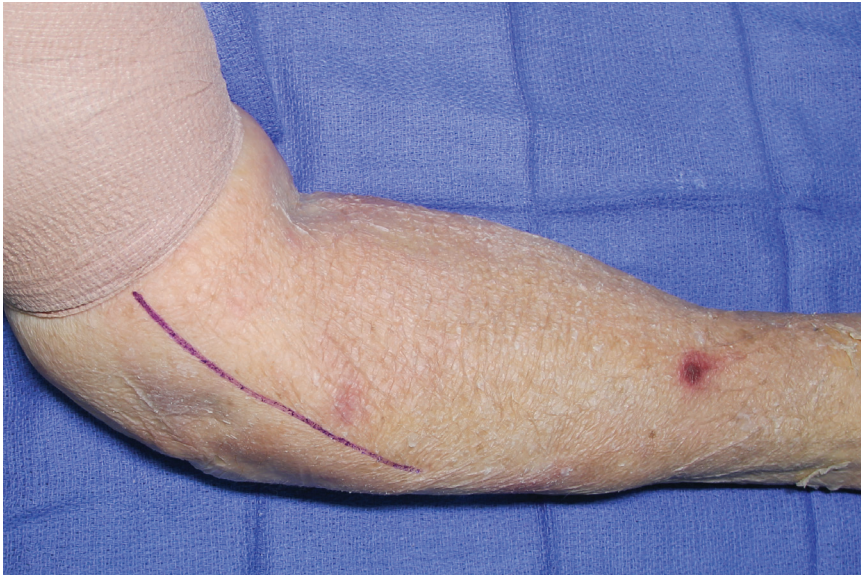
The screws are available in both locking and non-locking configurations and are provided in lengths from 12mm – 40mm, with increments of 2mm.



Please refer to the PROTEAN[®] Radial Head Plate Module Instructions for Use to review the warnings, precautions and contraindications for this system.

ELBOW LANDMARKS

1

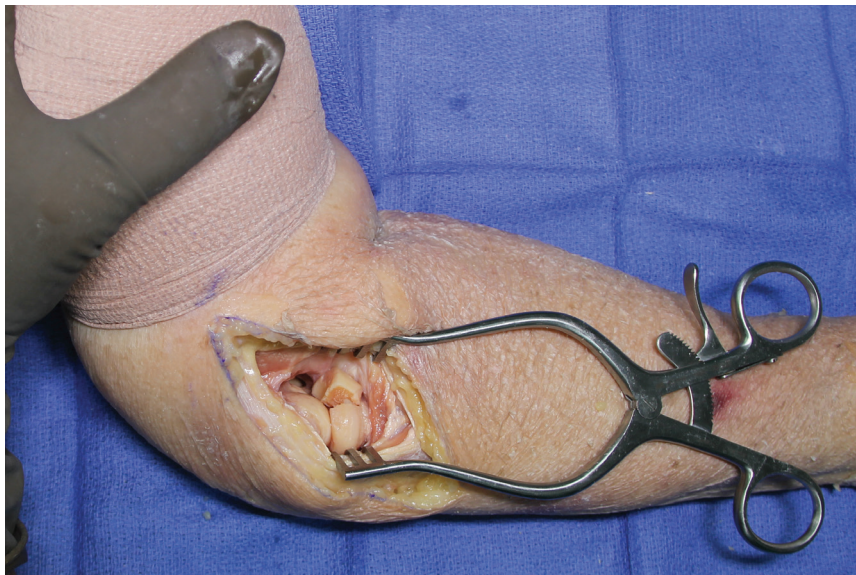


Position the forearm in neutral rotation. With the elbow flexed 90°, palpate and mark the lateral epicondyle.

Make an 8 – 10cm line through the marked point to perform a lateral approach to the elbow through the indicated tissue plane (Kaplan or Kocher).

EXPOSURE

2



Open the joint and gain access to the radial head. Pronate the forearm and limit distal dissection to protect the posterior interosseous branch of the radial nerve.

NOTE:

The posterior interosseous branch of the radial nerve is located 4cm distal to the radiocapitellar joint.

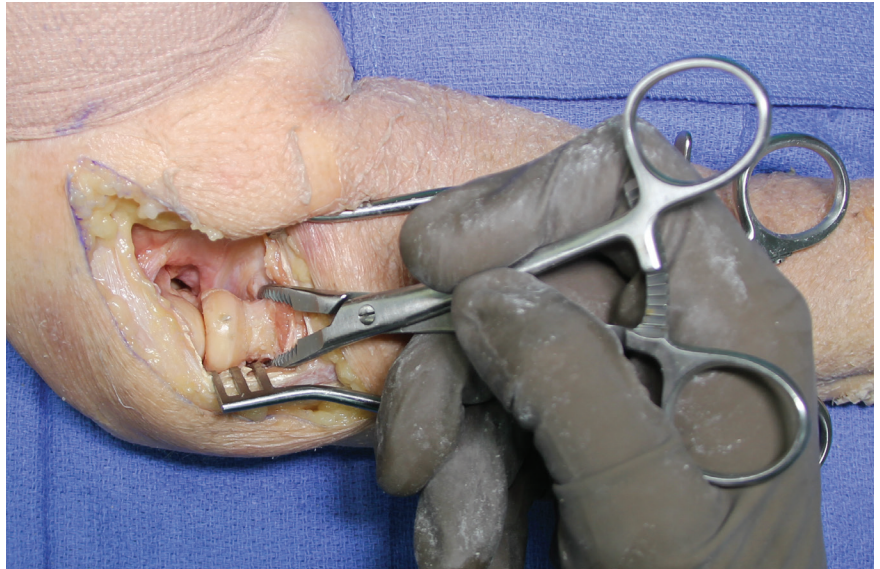
CAUTION:

Limit periosteal stripping to reduce the incidence of avascular necrosis.

3

INITIAL FRACTURE REDUCTION

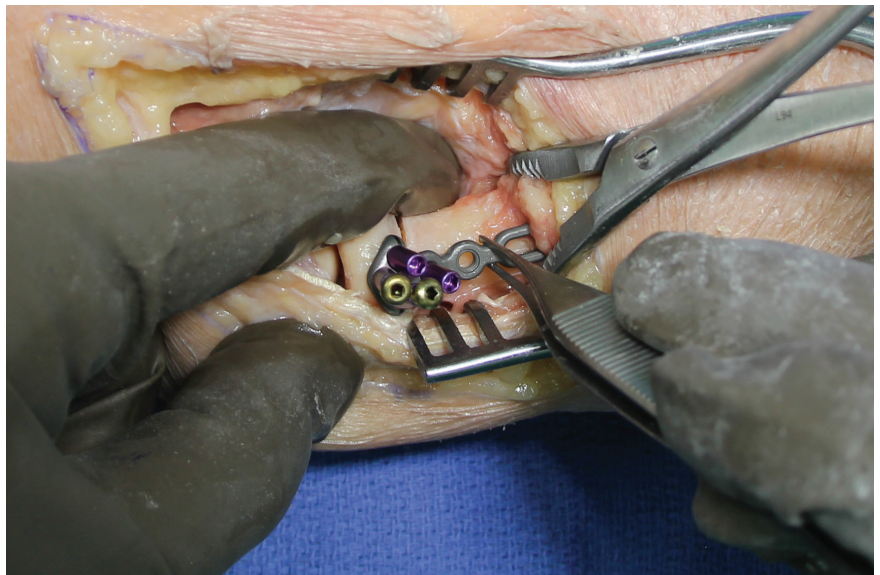
Reduce the fracture.



4

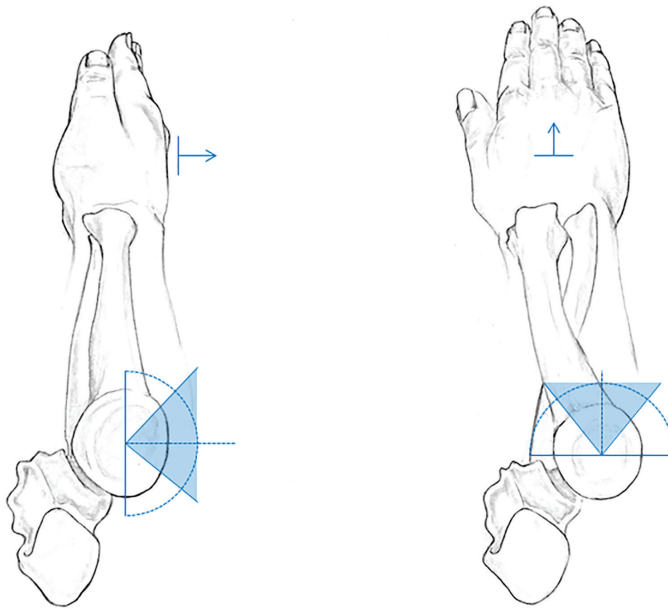
ASSESS PLATE FIT

With the forearm in neutral rotation, maintain radial head reduction and place the plate in the center of the "safe zone" to assess fit.



SAFE ZONE

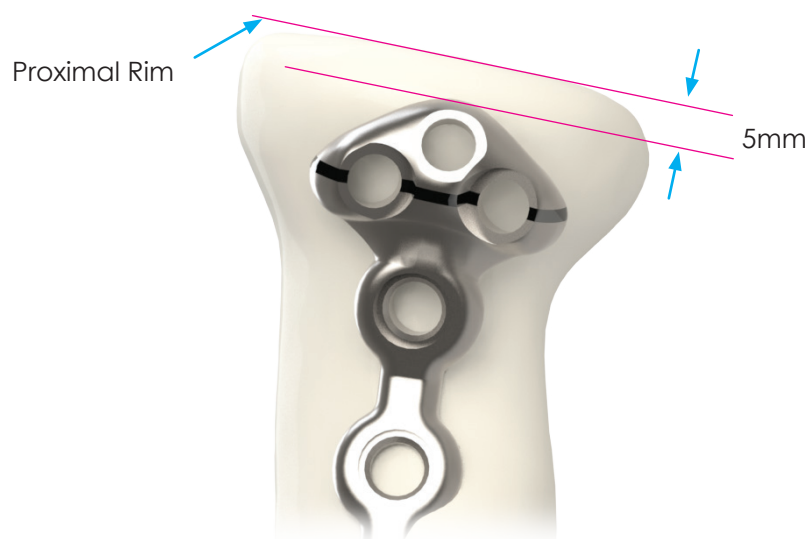
5



The nonarticulating portion is the safe zone for the application of implants to the radial head. It consistently encompasses a 90 degree angle localized by palpation of the radial styloid and Lister's tubercle or approximately perpendicular to the plane of the metacarpals.

ASSESS PLATE FIT

6



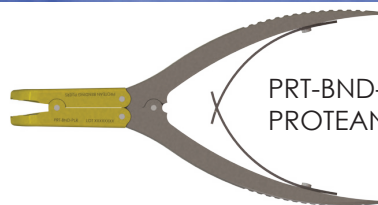
The proximal end of the plate should be 4-5mm distal to the articular margin (proximal rim) of the radial head.

7

PLATE CONTOURING

Contour the plate as needed using the PROTEAN® Bending Pliers. Proper contouring should allow the plate to sit flush on the bone.

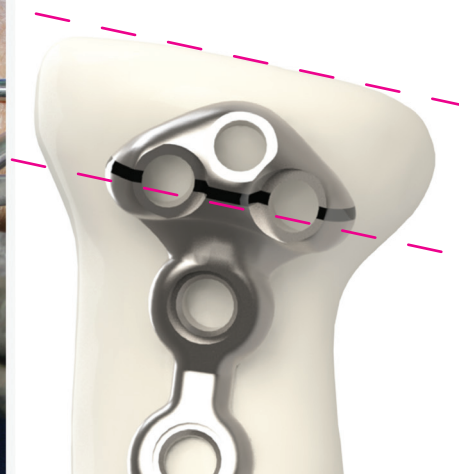
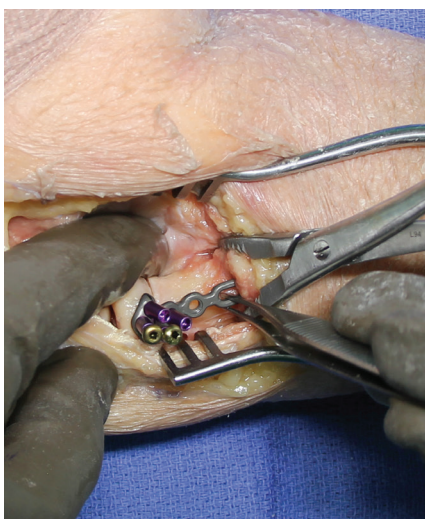
CAUTION:
Excessive contouring may weaken or cause the plate to break.



8

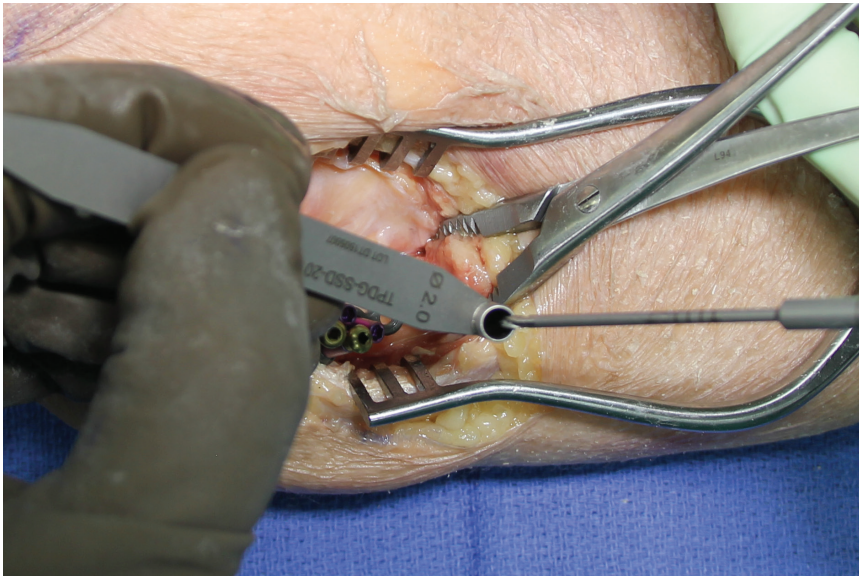
PLATE ALIGNMENT

To ensure proper axial alignment of the plate, align the laser etched mark on the head of the plate parallel to the proximal rim of the radial head.



DISTAL PLATE FIXATION

9



Using the Drill Guide, drill through the center of the gliding hole using the 2.0mm drill bit.

NOTE:

Laser etching on the drill can be used to estimate screw length.



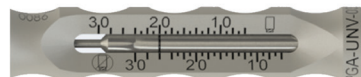
DRLL-SSC-20040 Drill, 2.0mm x 40mm



TPDG-SSD-20
Tissue Protector/Drill Guide,
Single Sided, 2.0mm

SECURE PLATE TO DISTAL FRAGMENT

10



The Depth Gauge has a dual scale to reflect measurements either through the pre-loaded drill guides (top scale) or without pre-loaded drill guides (bottom scale).

Using the depth gauge, measure hole depth and then insert the appropriate length 2.7mm non-locking screw to secure the plate to the distal fragment.

NOTE:

The orientation of the hook on the depth gauge probe corresponds to the flat portion on the depth gauge handle.



DPGA-UNV-030
Depth Gauge, Universal, 30mm



TPNL-27XXX-TS
Threaded Peg, Non-Locking, 2.7mm x XXmm

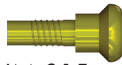
11

LOADING K-WIRE AIMING GUIDES

Using the Driver and Handle, insert an AIMing Guide into the most proximal pre-loaded drill guide (PDG) on the plate. Insert a second AIMing Guide at the most appropriate location to maintain proper reduction.



HNDL-SQC-FXD
Handle, Small QC, Fixed



PDG-AIM-015
AIMing Guides, 1.5mm

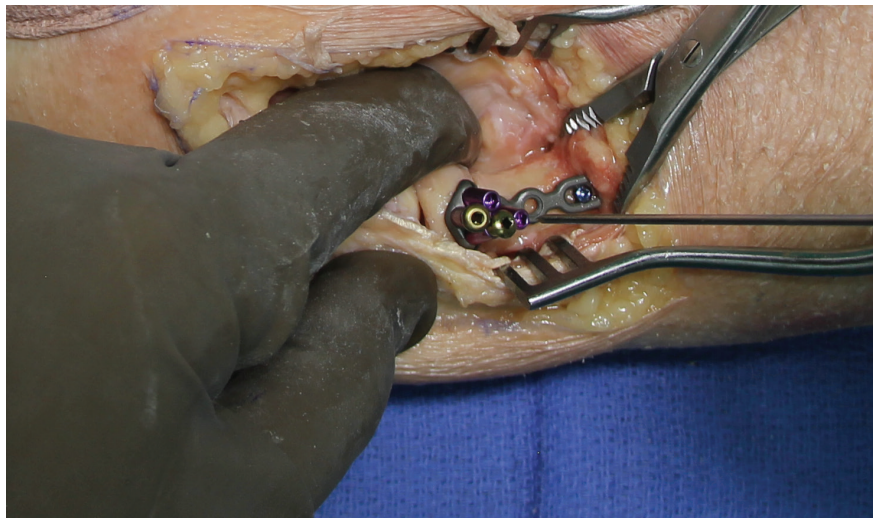


DRVR-AOS-S20
Driver, Peg, Torque Limiting

12

PROVISIONAL FIXATION

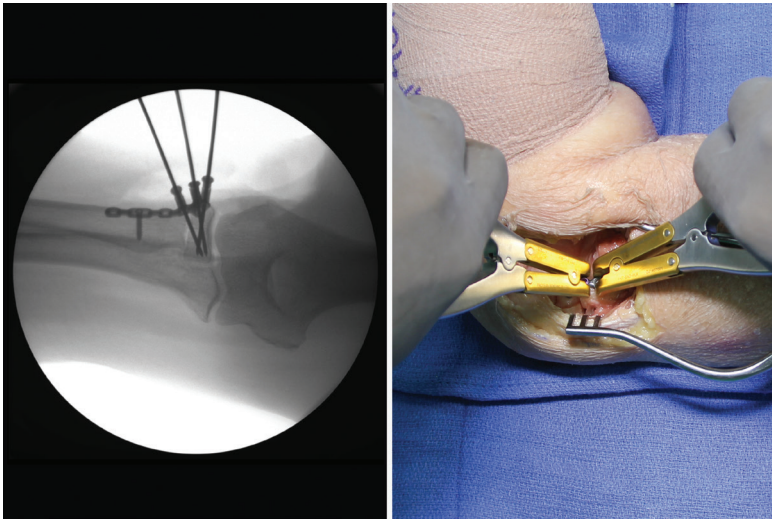
Secure the proximal fragment(s) to the plate using two 1.5mm K-Wires through the AIMing Guide. Additional K-wires may be used to secure remaining fragments.



KWIR-STD-15127
K-Wire, 1.5mm x 127mm

REDUCTION CONFIRMATION

13

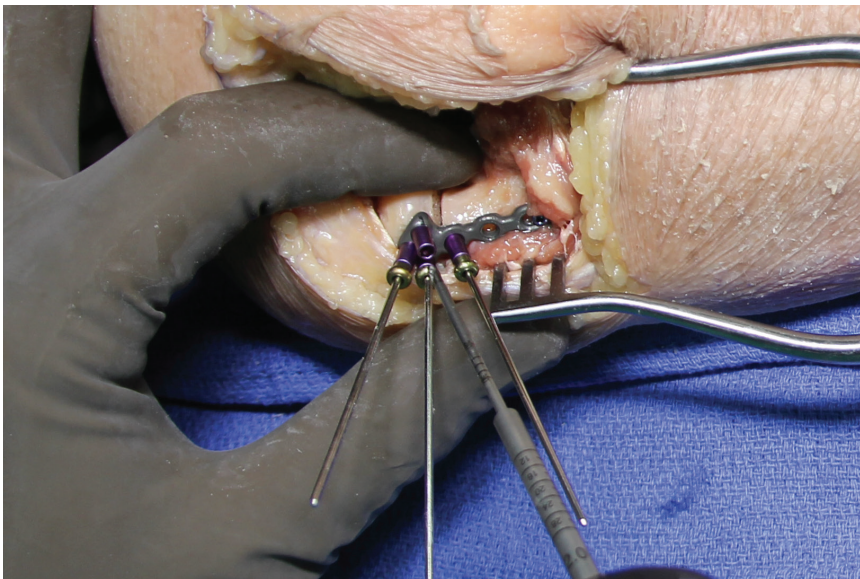


Confirm reduction and proper K-wire placement 2mm distal to the subchondral plate using fluoroscopy.

If additional bending is necessary, use the PROTEAN® Bending Pliers for in situ contouring. Repeat previous step for provisional fixation.

PILOT HOLE PREPARATION

14



Using the 2.0mm Drill, drill through the available PDGs and measure hole depth.

CAUTION:
Be careful not to drill into the proximal radio ulnar joint (PRUJ).

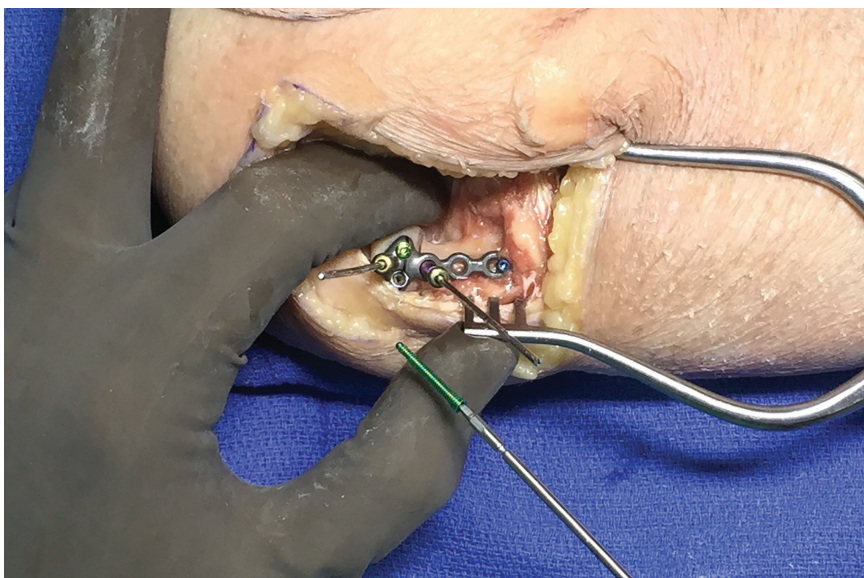
15

PROXIMAL FRAGMENT FIXATION

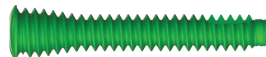
Remove the pre-loaded drill guide using the peg driver. Insert the appropriate length screw. Repeat for the remaining proximal holes not containing K-Wires.

NOTE:

Locking and non-locking screws may be used.



TPNL-27XXX-TS
Threaded Peg, Non-Locking,
2.7mm x XXmm



TPFL-23XXX-TS
Threaded Peg, Fluted, Locking,
2.3mm x XXmm

16

FINAL PROXIMAL FRAGMENT FIXATION

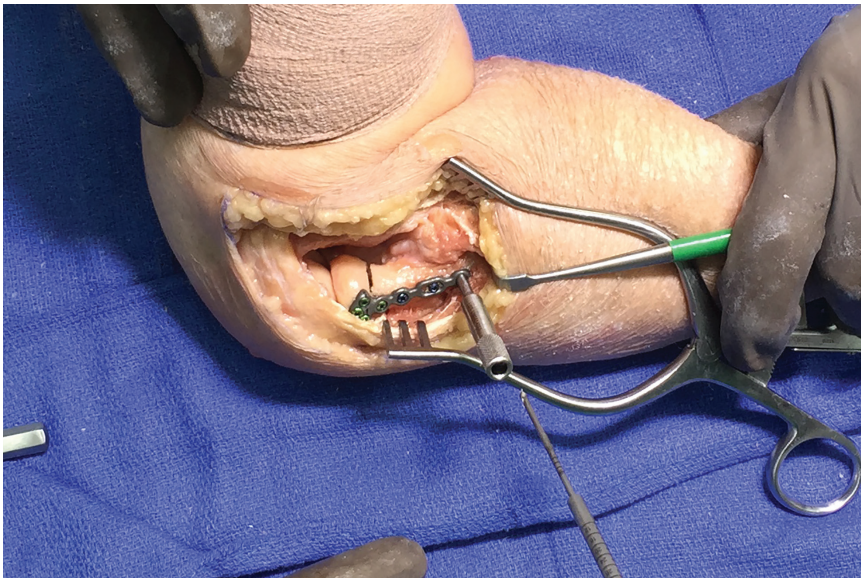
Remove the K-wire and AIMing Guide from the most proximal hole. Drill and measure hole depth. Remove the pre-loaded drill guide and insert an appropriate length 2.3 mm locking screw.

Remove the remaining K-Wires and AIMing Guides. Drill and measure hole depths. Remove the pre-loaded drill guides and insert appropriate length 2.3 mm locking screws.



FINAL DISTAL FRAGMENT FIXATION

17



Using a Drill Guide, drill through the distal shaft holes and approximate hole depth using the measurement marks on the drill. Hole depth can also be measured using the Depth Gauge.

DRILL GUIDE OPTIONS:



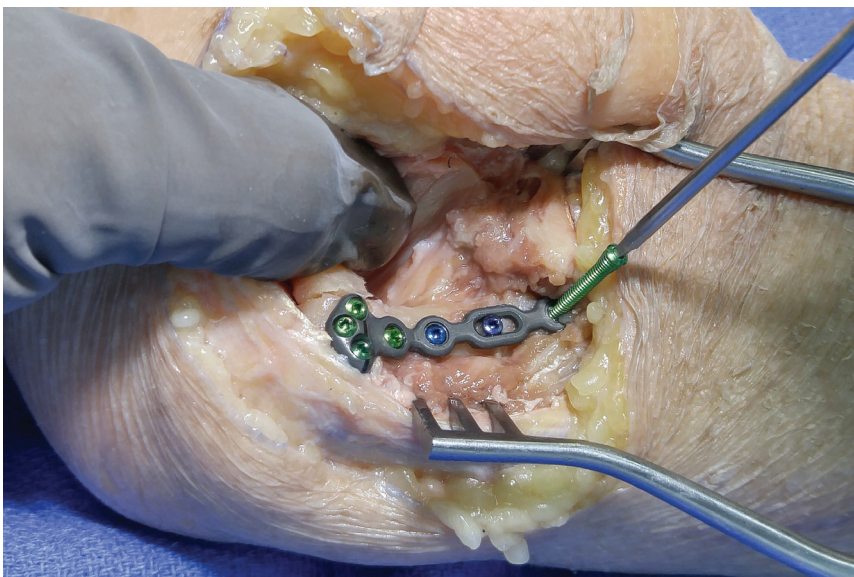
TPDG-THD-DG20
Thread-in Drill Guide, 2.0mm



TPDG-SSD-20
Tissue Protector/Drill Guide, Single-Sided, 2.0mm

INSERT SCREW & CONFIRM PLACEMENT

18



Insert the appropriate length screw (locking or non-locking)

Note:

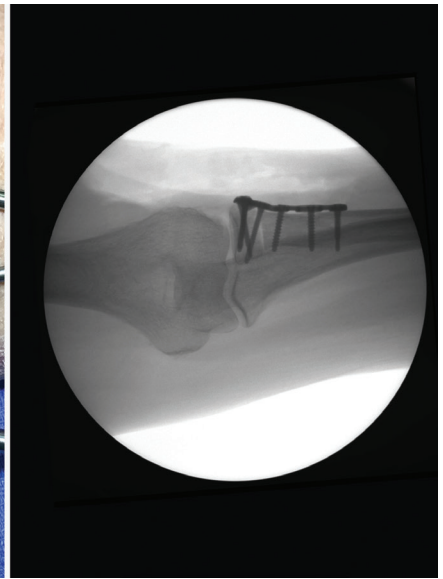
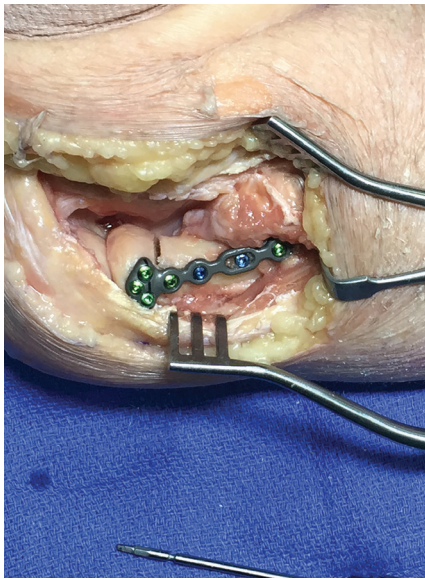
Additional screws can be used adjacent to the plate if necessary for additional fragment reduction.

Confirm proper reduction, screw length and placement using fluoroscopy.

CAUTION:
Confirm no screws violate the proximal radial-ulnar joint space by pronating and supinating the forearm to ensure there is no crepitus.

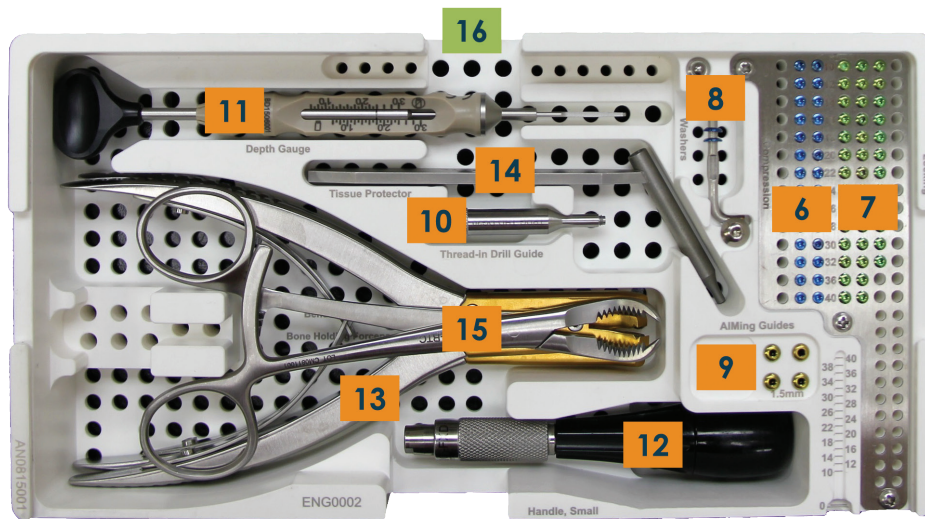
CAUTION:
Confirm that all screws have been fully tightened prior to wound closure.

Close the wound in your normal fashion.



NOTES

INSTRUMENT TRAY (Standard Configuration)



| Loc # | Catalog # | Description |
|-------|----------------|---|
| 1 | PRT-RHP- LT | PROTEAN® Radial Head Plate, Left |
| 2 | PRT-RHP- RT | PROTEAN® Radial Head Plate, Right |
| 3 | KWIR-STD-15127 | K-Wire, 1.5mm x 127mm |
| 4 | DRLL-SSC-20040 | Drill, Solid Side Cutting, 2.0mm x 40mm |
| 5 | DRVR-AOS-S20 | Driver, Peg, Torque Limiting |
| 6 | TPNL-27110-TS | Threaded Peg, Non-Locking, 2.7mm x 10mm, Ti |
| | TPNL-27120-TS | Threaded Peg, Non-Locking, 2.7mm x 12mm, Ti |
| | TPNL-27140-TS | Threaded Peg, Non-Locking, 2.7mm x 14mm, Ti |
| | TPNL-27160-TS | Threaded Peg, Non-Locking, 2.7mm x 16mm, Ti |
| | TPNL-27180-TS | Threaded Peg, Non-Locking, 2.7mm x 18mm, Ti |
| | TPNL-27200-TS | Threaded Peg, Non-Locking, 2.7mm x 20mm, Ti |
| | TPNL-27220-TS | Threaded Peg, Non-Locking, 2.7mm x 22mm, Ti |
| | TPNL-27240-TS | Threaded Peg, Non-Locking, 2.7mm x 24mm, Ti |
| | TPNL-27260-TS | Threaded Peg, Non-Locking, 2.7mm x 26mm, Ti |
| | TPNL-27280-TS | Threaded Peg, Non-Locking, 2.7mm x 28mm, Ti |
| | TPNL-27300-TS | Threaded Peg, Non-Locking, 2.7mm x 30mm, Ti |
| | TPNL-27320-TS | Threaded Peg, Non-Locking, 2.7mm x 32mm, Ti |
| | TPNL-27360-TS | Threaded Peg, Non-Locking, 2.7mm x 36mm, Ti |
| | TPNL-27400-TS | Threaded Peg, Non-Locking, 2.7mm x 40mm, Ti |
| 7 | TPFL-23110-TS | Threaded Peg, Fluted, Locking, 2.3mm x 10mm, Ti |
| | TPFL-23120-TS | Threaded Peg, Fluted, Locking, 2.3mm x 12mm, Ti |
| | TPFL-23140-TS | Threaded Peg, Fluted, Locking, 2.3mm x 14mm, Ti |
| | TPFL-23160-TS | Threaded Peg, Fluted, Locking, 2.3mm x 16mm, Ti |
| | TPFL-23180-TS | Threaded Peg, Fluted, Locking, 2.3mm x 18mm, Ti |
| | TPFL-23200-TS | Threaded Peg, Fluted, Locking, 2.3mm x 20mm, Ti |
| | TPFL-23220-TS | Threaded Peg, Fluted, Locking, 2.3mm x 22mm, Ti |

| Loc # | Catalog # | Description |
|----------------------|---------------|---|
| | TPFL-23200-TS | Threaded Peg, Fluted, Locking, 2.3mm x 20mm, Ti |
| | TPFL-23220-TS | Threaded Peg, Fluted, Locking, 2.3mm x 22mm, Ti |
| | TPFL-23240-TS | Threaded Peg, Fluted, Locking, 2.3mm x 24mm, Ti |
| | TPFL-23260-TS | Threaded Peg, Fluted, Locking, 2.3mm x 26mm, Ti |
| | TPFL-23280-TS | Threaded Peg, Fluted, Locking, 2.3mm x 28mm, Ti |
| | TPFL-23300-TS | Threaded Peg, Fluted, Locking, 2.3mm x 30mm, Ti |
| | TPFL-23320-TS | Threaded Peg, Fluted, Locking, 2.3mm x 32mm, Ti |
| | TPFL-23360-TS | Threaded Peg, Fluted, Locking, 2.3mm x 36mm, Ti |
| | TPFL-23400-TS | Threaded Peg, Fluted, Locking, 2.3mm x 40mm, Ti |
| 8 | WBTN-2750-T | Washer, Button, Inside Ø2.7mm, Outside Ø5.0mm, Ti |
| 9 | PDG-AIM-015 | AlMing Guides, 1.5mm |
| 10 | TPDG-THD-DG20 | Thread-in Drill Guide, 2.0mm |
| 11 | DPGA-UNV-030 | Depth Gauge, Universal, 30mm |
| 12 | HNDL-SQC-FXD | Handle, Small QC, Fixed |
| 13 | PRT-BND-PLR | PROTEAN® Bending Pliers |
| 14 | TPDG-SSD-20 | Tissue Protector / Drill Guide, Single Sided, 2.0mm |
| 15 | FRCP-BHM-RTC | Forceps, Bone Holding Medium, Ratcheting |
| Miscellaneous | | |
| 16 | PRT-MOD | PROTEAN® Module |

NOTES

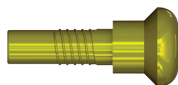
RADIAL HEAD PLATE QUICK REFERENCE CHART



PROTEAN® Radial Head Plate, Left



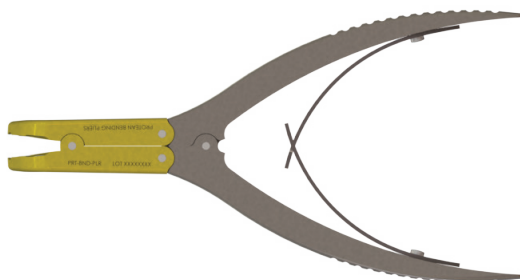
PROTEAN® Radial Head Plate, Right



ALMing Guide, 1.5mm



1.5mm x 127mm K-Wire



PROTEAN® Bending Pliers

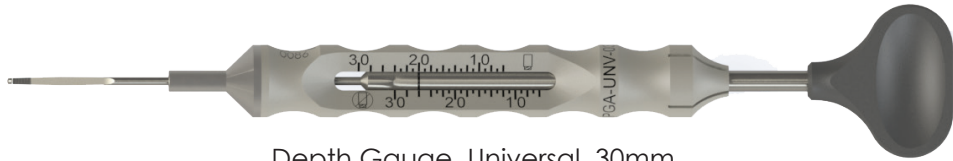


Drill, Solid Side Cutting, 2.0mm x 40mm



Driver, Peg, Torque Limiting

RADIAL HEAD PLATE QUICK REFERENCE CHART (Cont)



Depth Gauge, Universal, 30mm



Threaded Peg, Fluted Locking, 2.3mm x xmm, Ti



Threaded Peg, Non-Locking, 2.7mm x xmm, Ti



Tissue Protector/Drill Guide, Single Sided, 2.0mm



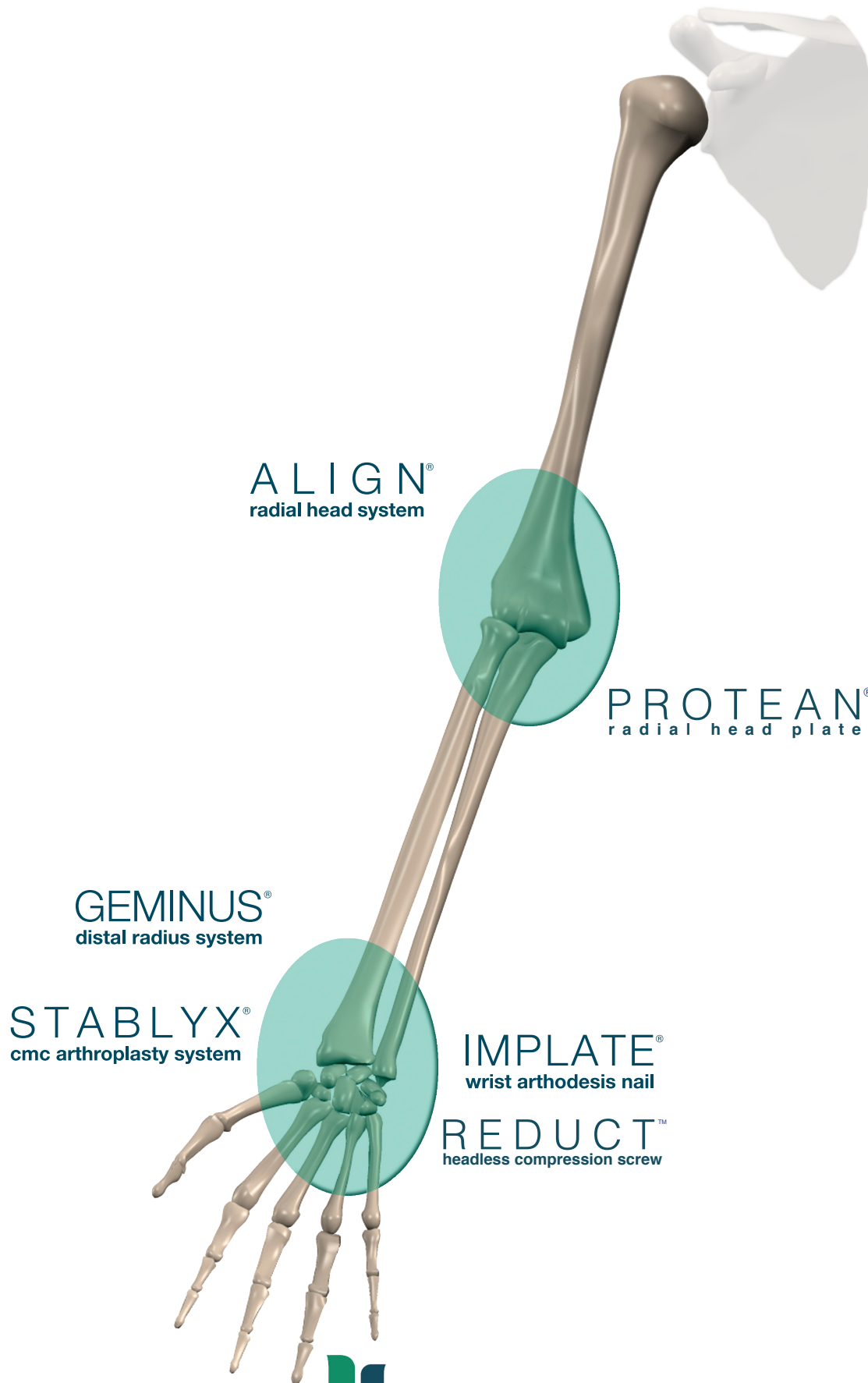
Forceps, Bone Holding Medium, Ratcheting



NOTES







ALIGN[®]
radial head system

PROTEAN[®]
radial head plate

GEMINUS[®]
distal radius system

STABLYX[®]
cmc arthroplasty system

IMPLATE[®]
wrist arthodesis nail

REDUCT[™]
headless compression screw

 **skeletal dynamics**[®]
Innovation Based on Science