



The Scheker Distal Radio-Ulnar Joint Prosthesis

Technique Guide

www.apτισmedical.com

info@apτισmedical.com

502.523.6738



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GENERAL PRECAUTIONS

All surgical procedures and techniques are the responsibility of the medical professional. The surgeon, based on personal medical training and experience, must evaluate the procedure for appropriateness. No one technique is suitable for all patients.

INDICATIONS FOR USE

Aptis Medical Distal Radio Ulnar Joint implant is intended for replacement of the distal radioulnar joint following ulnar head resection arthroplasty:

Replacement of the distal radio-ulnar head for rheumatoid, degenerative, or post-traumatic arthritis presenting with the following findings:

- Pain and weakness of the wrist joint not improved by non-operative treatment
- Instability of the ulna head with radiographic evidence of dislocation or erosive changes of the distal radio-ulnar joint
- Failed ulna head resection; e.g. Darrach resection
- Primary replacement after fracture of the ulna head or neck.
- Revision following failed ulna head arthroplasty.

CONTRAINDICATIONS

Patients should be made aware of the increased potential for device failure when excessive demands are made upon it. Strenuous loading, excessive mobility, and articular instability all may lead to accelerated wear and eventual failure by loosening, fracture, or dislocation of the device.

Patients should be cautioned to not lift loads of 20 lbs or greater. Doing so may result in device failure.

See product insert for additional information including adverse effects, cautions and warnings.

PATIENT COUNSELING INFORMATION (SEE ALSO WARNINGS)

In addition to the patient related information contained in the Warnings and Adverse Events sections, the following information should be conveyed to the patient:

While the expected life of total joint replacement components is difficult to estimate, it is finite. These components are made of foreign materials, which are placed within the body for the potential restoration of mobility or reduction of pain. However, due to the many biological, mechanical and physiochemical factors which affect these devices, the components cannot be expected to withstand the activity level and loads of normal healthy bone for an unlimited period of time.

Adverse effects of this device may necessitate re-operation, revision, or fusion of the involved joint.

SURGICAL PROCEDURES

A manual is available describing detailed surgical procedures for use of these implant devices. It is the responsibility of the surgeon to be familiar with the procedure before use of these products. In addition, it is the responsibility of the surgeon to be familiar with relevant publications and consult with experienced associates regarding the implant procedures before use.

DISTAL RADIO-ULNAR JOINT PROSTHESIS AND INSTRUMENTATION



The prosthesis consists of a radial plate, an ulnar stem, an Ultra-High-Molecular-Weight Polyethylene (UHMWP) ball, a radial plate cover and two radial plate cover screws or one locking cross pin.

The radial plate replaces the function of the sigmoid notch.

The ulnar stem and ball combination replaces the function of the ulnar head.

The radial plate cover and radial plate cover screws replace the function of the Triangular Fibrocartilage Complex (TFC).



The Instrument Set is set up in an easy to follow manner and contains the following;

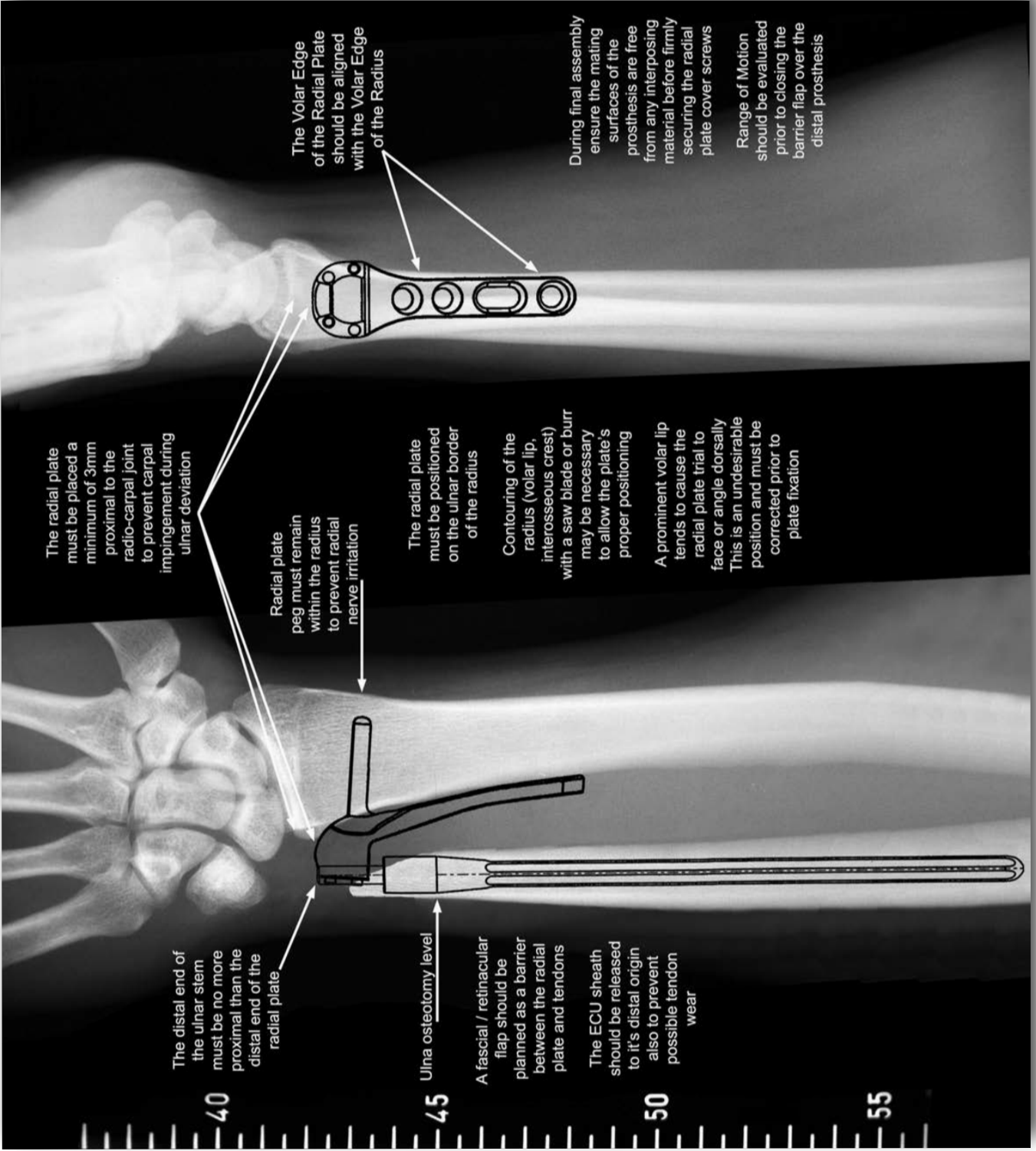
- Three radial plate trials (size 10, size 20, size 30) (two shown)
- One radial peg drill bit
- One 2.5 mm drill guide
- One 2.5 mm drill bit
- One depth gauge for screw length reference
- One quick connect handle for 3.5 mm tap
- One 3.5 mm tap
- One quick connect handle with a 2.5 mm hex driver for 3.5 mm screw
- One ulnar resection level reference guide
- Two guide wires, one blunt, one sharp
- One threaded trial handle / locking screw drill guide
- Four cannulated drill bits (4.0 mm, 4.5 mm, 5.0 mm, 6.0 mm)
- One quick connect extension
- Four reamers (4.0 mm, 4.5 mm, 5.0 mm, 6.0 mm)
- One impactor
- One screw block containing:
 - Forty 3.5 mm cortical or locking screws ranging from 10 mm - 24 mm length
 - Four ulnar resection guide balls (size 10/20 x 2, size 30 x 2)
- One quick connect handle with a 1.5 mm square driver for cover screws / lock pin

TEMPLATING

Templating of preoperative x-rays should be accomplished prior to surgery to determine the correct size and position of prosthesis. The templates display options including three sizes of radial components and sixteen sizes of ulnar stems. When reviewing the templates, the radial plate should be placed no closer than 3 mm proximal to ulnar border of the lunate fossa. This is to prevent possible carpal impingement with the plate. Proximal placement of the plate can vary between the minimum of 3 mm from the lunate fossa up to 2 cm depending on the width of the radius. The contour of the plate generally allows good bone to plate contact but deformities of the radius must be considered. The templates also aid with pre-operative planning if any radial contouring is necessary. On the lateral plane, templates are used to check size and placement of the prosthesis. The chosen size should not protrude into the dorsal or volar planes of the extensors or flexors. The plate should be placed precisely on the ulnar border of the radius. The appropriate ulnar stems are selected by comparing both their diameter and length to the medullary cavity of the ulna. A templating service is offered by Aptis Medical to assist with patient selection, prosthesis selection and prosthesis placement. The service also provides notes intended to assist with each individual case.

During the procedure, x-ray or image intensifier views similar to the templated images will confirm accurate placement of the radial plate. A true lateral image should show the plate in a perfectly squared view (not tilted dorsal or volar). If the plate is tilted dorsally it could potentially cause unnecessary wear on the extensors namely the ECU. Dorsal tilt can also allow the plates peg to penetrate the volar surface of the radius which should be avoided. In a true lateral x-ray view with the radial plate trial properly positioned, you should be able to see through the unobstructed holes in the trial plate.

Note: *When imaging during the procedure to assess implant position relative to the anatomy, centralize the area of concern within the image to avoid parabolic distortion.*



The radial plate must be placed a minimum of 3mm proximal to the radio-carpal joint to prevent carpal impingement during ulnar deviation

Radial plate peg must remain within the radius to prevent radial nerve irritation

The Volar Edge of the Radial Plate should be aligned with the Volar Edge of the Radius

During final assembly ensure the mating surfaces of the prosthesis are free from any interposing material before firmly securing the radial plate cover screws

Range of Motion should be evaluated prior to closing the barrier flap over the distal prosthesis

The radial plate must be positioned on the ulnar border of the radius

Contouring of the radius (volar lip, interosseous crest) with a saw blade or burr may be necessary to allow the plate's proper positioning

A prominent volar lip tends to cause the radial plate trial to face or angle dorsally. This is an undesirable position and must be corrected prior to plate fixation

The distal end of the ulnar stem must be no more proximal than the distal end of the radial plate

Ulna osteotomy level

A fascial / retinacular flap should be planned as a barrier between the radial plate and tendons

The ECU sheath should be released to its distal origin also to prevent possible tendon wear

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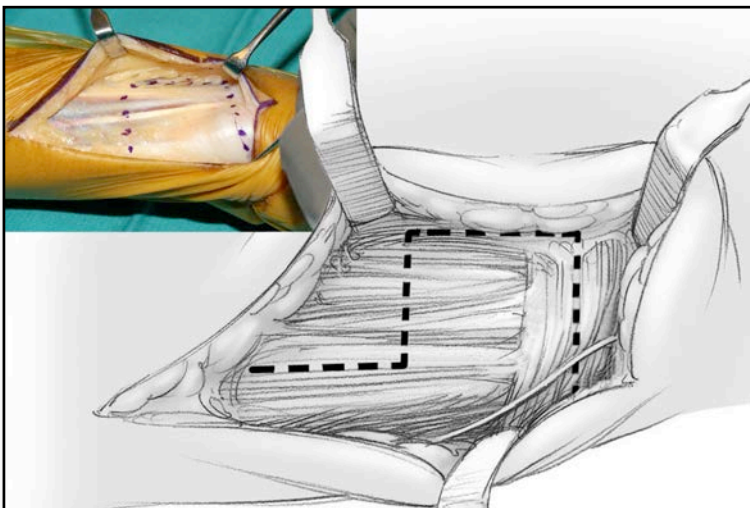
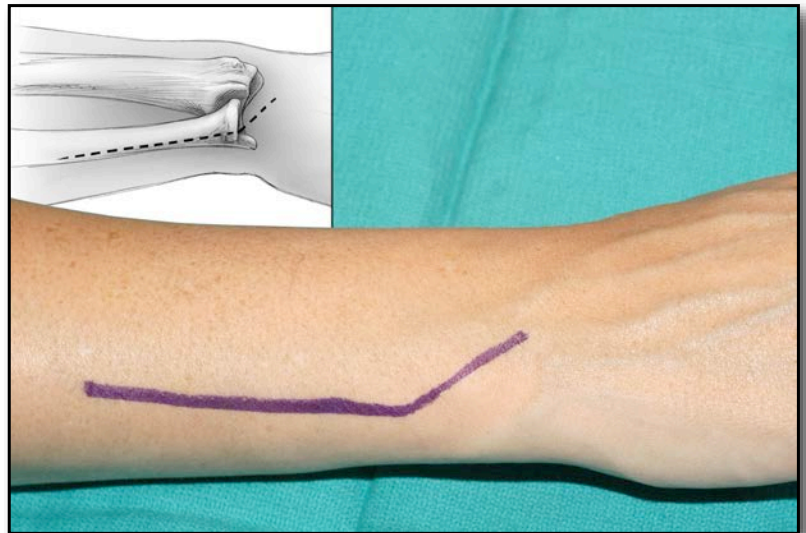
SURGICAL PROCEDURE

Patient Preparation

The procedure is generally accomplished under axillary block and involves standard methods of prepping and draping for the upper extremity. Operative site preparation should be treated the same as any total joint replacement. An adhesive plastic surgical barrier drape is applied to reduce contact between the skin and the implant similar to other total joints such as hip or knees. A tourniquet is always used with a pressure setting of approximately 250 mm Hg (approximately 100 mm Hg above the patient's systolic pressure).

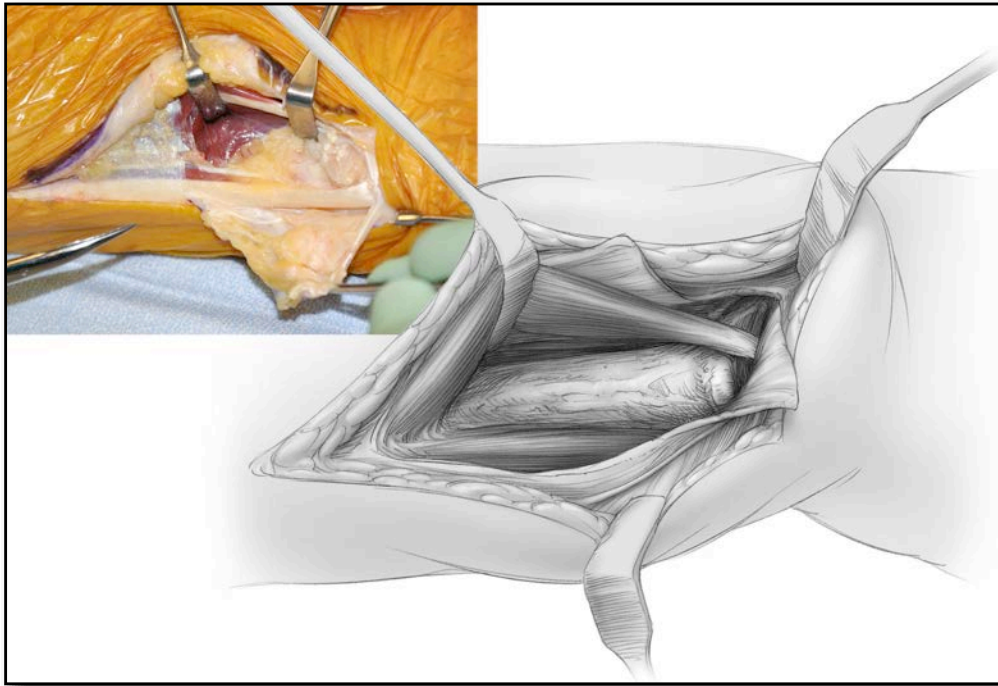
Incision / Dissection

With the forearm in full pronation, a 8-9 cm longitudinal incision is marked splitting the difference between dorsal and lateral along the ulnar border of the distal forearm turning radially at the head of the ulna for an additional 2 cm. The incision should be just radial to the extensor carpi ulnaris (ECU) for added protection of the dorsal sensory branch of the ulnar nerve. If the patient has had prior surgery in the area, the old incision may be incorporated in the exposure.

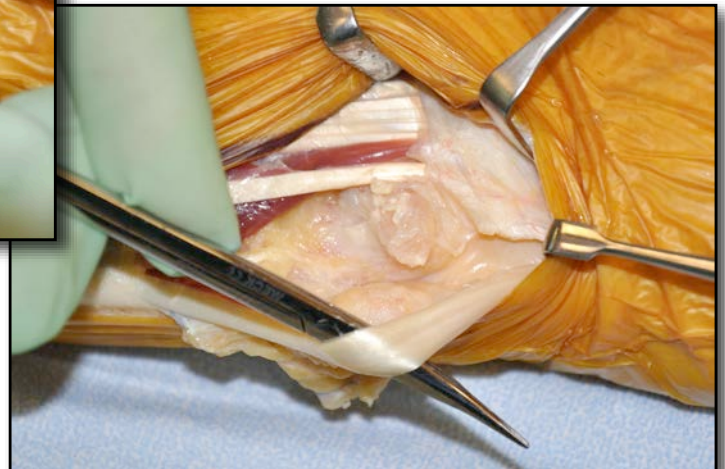


The skin and subcutaneous fat are elevated from the forearm fascia over to the second dorsal compartment. A fascial/retinacular flap based ulnarward and extending radially to the second compartment should be elevated to later provide a barrier between the prosthesis and the ECU tendon. As the flap is reflected ulnarward the dorsal radio-ulnar joint capsule may also be included for additional padding. The ECU is released from the inferior side of the created flap.

With the barrier flap reflected ulnarward, the incision is then carefully deepened approaching the ulna between the ECU and the extensor digiti quinti minimi (EDQ), again taking care to protect the dorsal sensory branch of the ulnar nerve. The EDQ is elevated together with the extensor indicis proprius from the ulna and interosseous membrane.

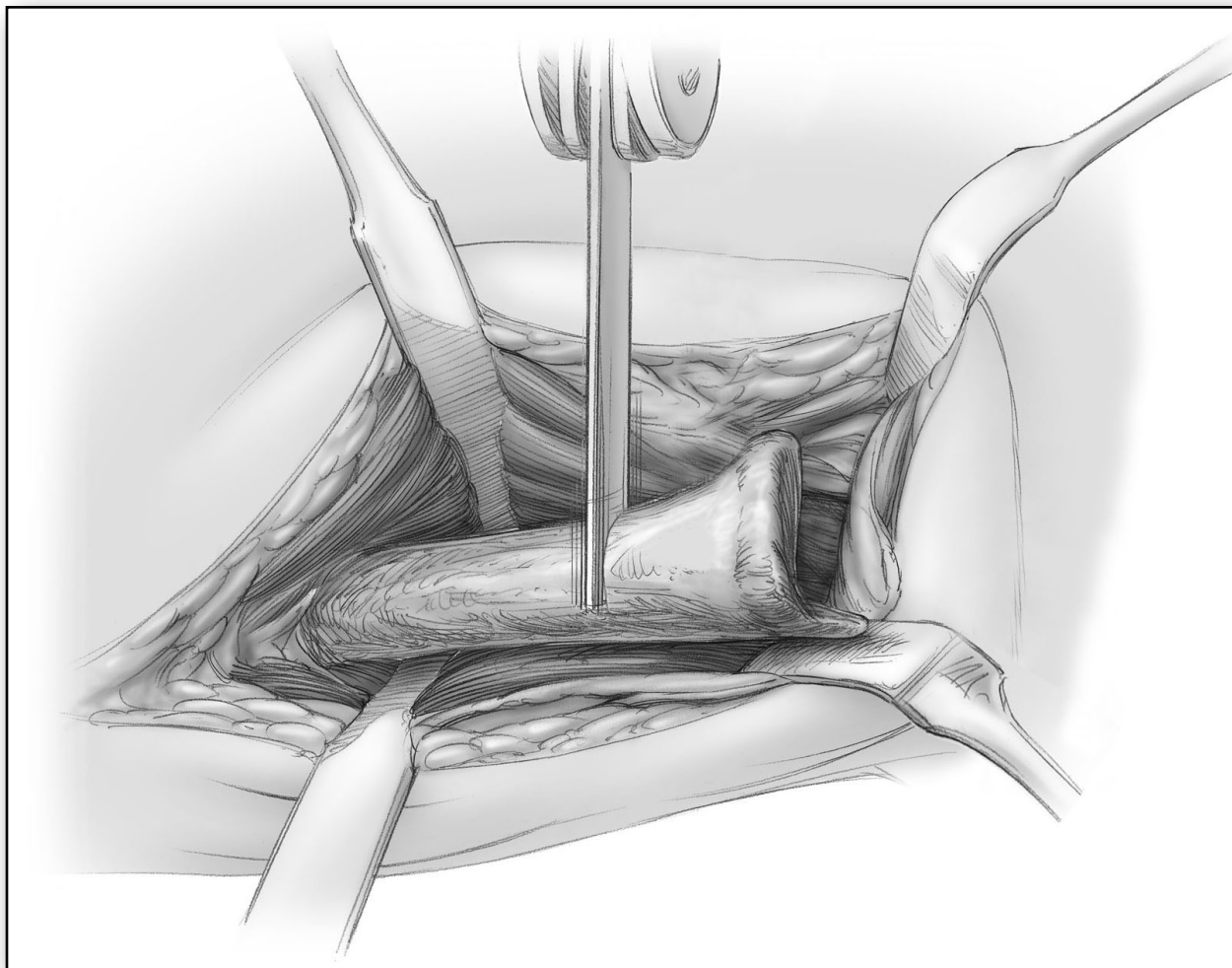


The distal sheath of the elevated ECU is incised to its distal insertion. This eases access and later prevents tethering of the ECU to the distal prosthesis. The extensor digitorum communis (EDC) is also elevated in order to expose the interosseous crest of the radius.



Ulna Head Excision

Good exposure and retraction are paramount for proper visualization and from this point forward an experienced assistant is recommended. Retractors are used to protect soft tissues. The head of the ulna, if present, is excised with an oscillating saw just proximal to the distal radio-ulnar joint at the narrowing or neck of the ulna. The radial attachment of the triangular fibro cartilage if found intact is left undisturbed. This structure can provide a buffering barrier between the prosthesis and the carpal bones. Excising the ulna head allows volar displacement of the shaft of the ulna enabling visualization of the sigmoid notch and the interosseous crest of the radius.

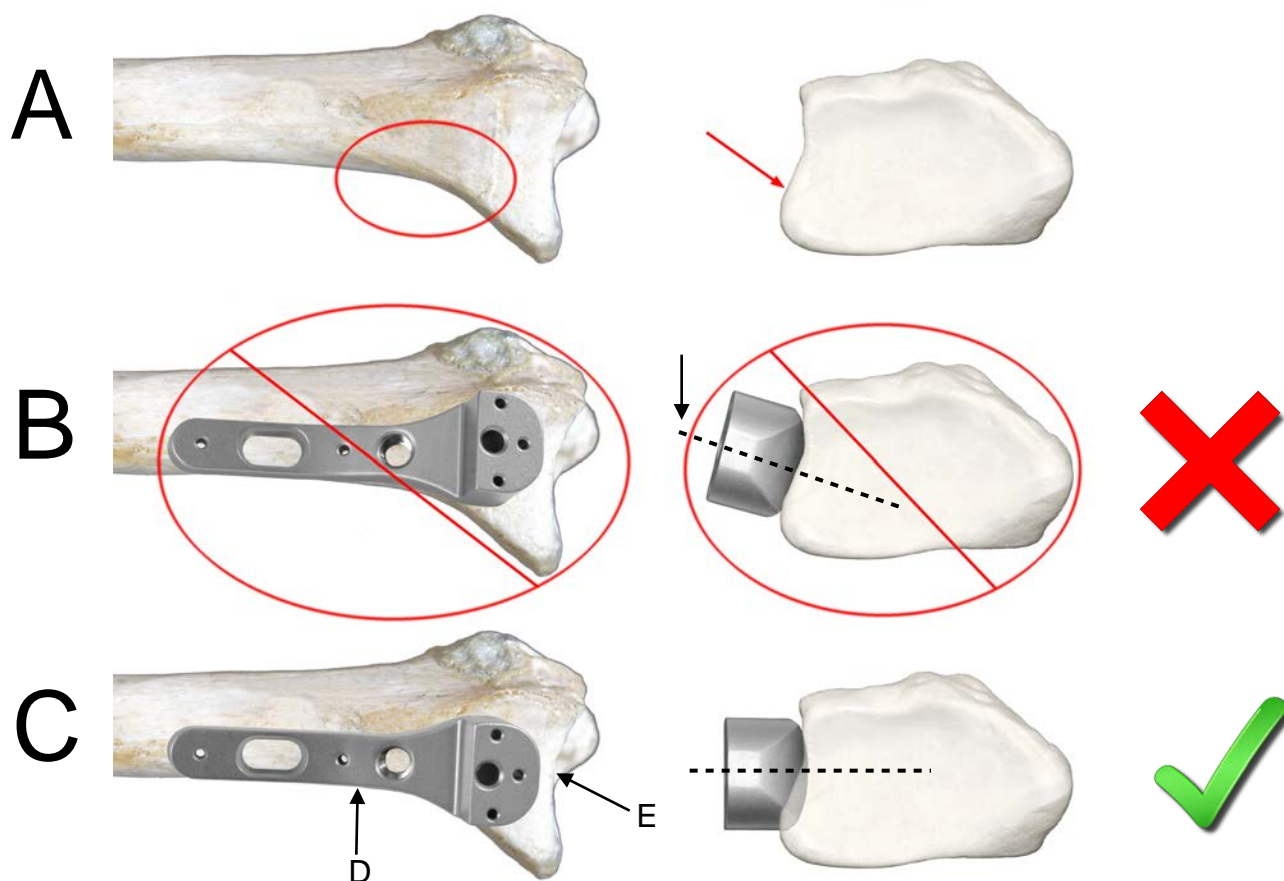


Osteophytes, if present in the area of the Distal Radio-Ulnar Joint, are excised.

The dissection then follows dorsally over the ulna onto the dorsal surface of the interosseous membrane (IOM). The IOM is elevated from the radius along the distal 8-9 cm of the interosseous crest. Forearm rotation should be checked for full pronation and supination. If forearm rotation is lacking due to scarring of the IOM continue to release the IOM as proximal as needed until achieving full motion. The construct of the prosthesis will provide the needed stability.

Radial Plate Trial Positioning

The volar lip of the radius (A) at the sigmoid notch tends to rotate the trial dorsally (B). The volar lip should be reduced by means of a burr or saw blade to allow the trial to face purely ulnarward (C). This is especially critical when using a locking plate as the screw direction is a fixed angle. The radial plate trial is then placed over the interosseous surface of the radius in the area of the sigmoid notch aligning it with the volar edge of the radius. To help ensure the trial is facing the proper direction, the radial peg drill bit can be placed in the large centered distal hole. Once placed in the guide hole, the direction of the bit extended from the plate can be noted and corrected if needed. When the hand is placed flat on the OR table, the bit should be parallel to the table. The pre-contoured design of the plate generally ensures good plate-to-bone contact. If any gross incongruence presents, the radius should be contoured to allow better plate contact. Care should be taken to avoid excising too much cortical bone, weakening the radius. The volar facing edge of the trial should be on the same plane as the volar surface of the radius (D). A minimum of 3 mm must separate the distal end of the trial and the lunate fossa (E) in order to prevent possible carpal impingement. If required, the trial may be positioned more proximally depending on the thickness of the radius but never more than 20 mm proximal to the radial carpal



Using .045" (1.1 mm) k-wires for temporary fixation, the trial's position must be checked with x-ray or an image intensifier. Proper PA and lateral positioning must be confirmed before proceeding.

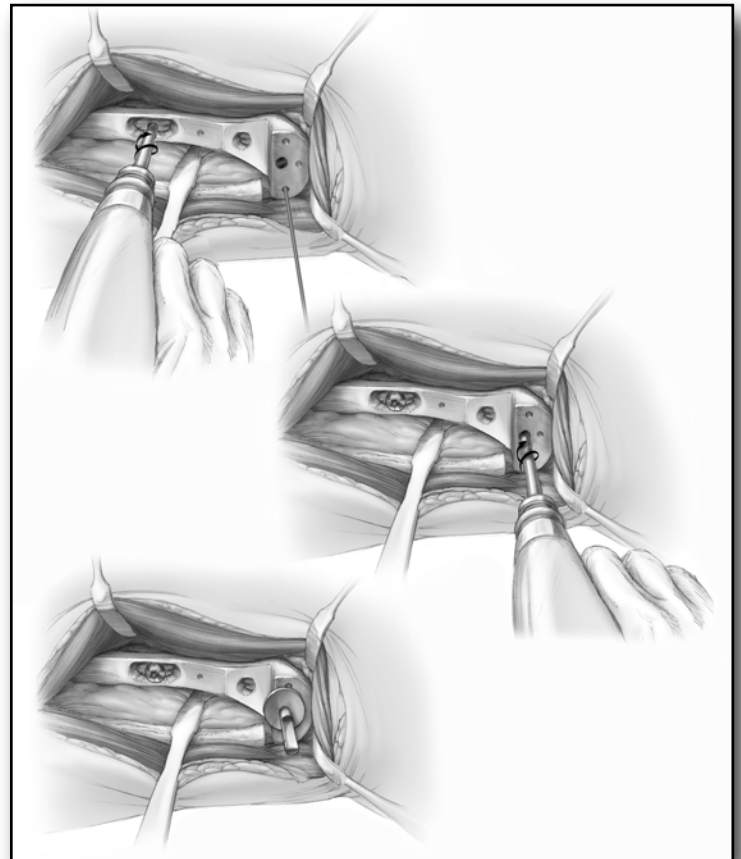
With the forearm and hand positioned flat (palm down) on the operating table, the two k-wires should be parallel to the surface of the table. Also, the radial peg drill bit can be inserted into the distal guide hole of the trial to help visualize the direction the plate is facing. The peg bit should be parallel with the table with the arm in this position.

With a proper lateral x-ray and the trial correctly positioned you should see through the unobstructed holes of the trial.



If adjustments to the position of the trial are necessary, they must be made at this point as the position of the trial directly corresponds to the position of the radial plate part of the prosthesis when implanted.

With the trial k-wired in appropriate position, the locking drill guide is threaded into the size 10 trial and a 2.5 mm hole is drilled transversely through the radius. For the size 20 or 30 trials, the hand held drill guide is used. All drilled holes should be placed centrally through the shaft of the radius avoiding volar or dorsal misdirection. The oval hole allows positioning adjustments for the size 20 and 30 prior to final trial fixation. Screw length is determined using the depth reference guide. A 3.5 mm tap is used to prepare the hole prior to inserting and tightening a 3.5 mm compression screw. Non-self tapping screws protect the tapped thread, allowing screw interchange if the correct length is not initially selected. Excessive screw length must be avoided to prevent radial nerve or soft tissue irritation. With the screw tightened in place the distal k-wire is removed and proper PA and lateral positioning is confirmed prior to continuing. The radial peg drill bit is then inserted through the distal guide hole of the trial, and the hole for the radial peg of the prosthesis is drilled. Care should be taken to avoid passing the bit through the dorsal, volar, or far cortex. Passing the bit or radial plate peg through the far cortex can cause radial nerve scarring.



The radial peg drill bit and screw should be left in place while using x-ray or an image intensifier to confirm PA and lateral positioning. Oblique views of 30° from lateral will assist confirming travel of the radial peg drill bit and the fixation screw. Should either be noted as violating the dorsal or volar cortex, they should be removed and redirected. Also, if multiple drilling attempts are made the radius should be considered weakened and protectively splinted post-operatively. The images of the fixed radial plate trial will mirror that of the radial plate of the prosthesis once it has been placed in position. **Note: mainly on the lateral x-ray view the angle of the x-ray beam relative to the subject can make the plate appear more distal than it actually is as can be seen comparing images between page 12 and page 13.**

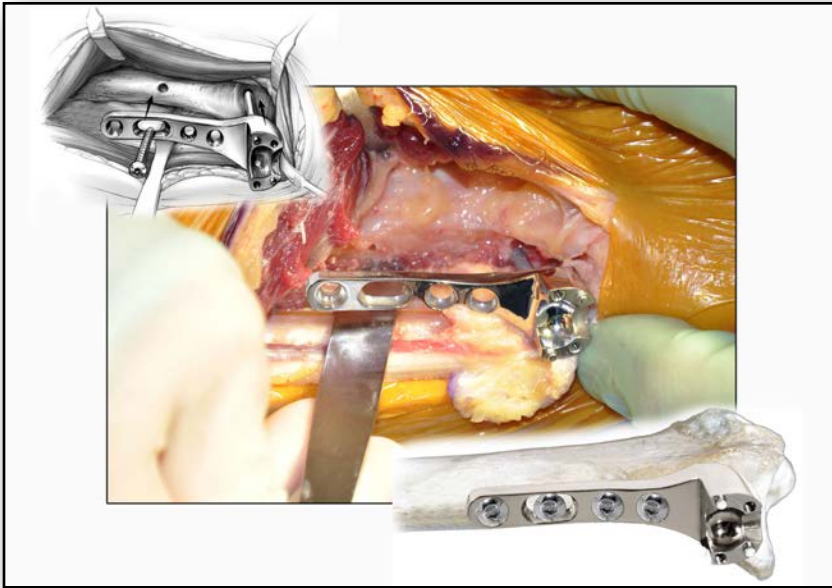


After accepting proper positioning of the radial plate trial, it is removed and the corresponding distal radioulnar joint plate assembly is opened. The assembly contains one radial plate, one UHMWP ball, one radial plate cover and either two radial plate cover screws or a single locking cross pin (depending on the plate selected).

Radial Plate Introduction and Fixation (Compression Plate, Size 20 or 30)

(Replacing the Function of the Sigmoid Notch)

After thorough irrigation, the radial plate is introduced. Soft tissue should be retracted to prevent any from being trapped between the plate and radius. The transverse peg is introduced into the pre-drilled hole. Care should be taken to ensure the peg follows the same path as the former drill bit. If insertion of the peg is difficult, a plastic impactor can be used to protect the plate while gently tapping it into place. Travel of the radial plate's peg should be confirmed prior to completing fixation. Using the appropriate drill guide, the remaining holes are drilled, measured, tapped and the appropriate screws inserted. Depending on the selected radial plate, fixation is completed with 4 or 5 suitably sized 3.5 mm cortical bone screws.



Excessive screw length should be avoided to prevent possible radial nerve scarring or soft tissue irritation. In most cases, a 3.5 mm screw 18 mm in length is recommended for the most distal fixation hole to prevent potential impingement against the transverse peg. Oblique views of 30° from lateral will confirm travel of the radial plate peg and the cortical screws. Should any be noted as violating the volar or dorsal cortex, they should be removed and redirected. The most proximal screw may remain unicortical to help prevent a possible stress riser in smaller bone.



Radial Plate Introduction and Fixation (Locking Plate, Size 10 or 20)

The surgical technique for the locking plate is similar to the non-locking / compression plate with the following provisos during the plate placement. As with the compression plate, ensure that the trial plate is properly aligned on the ulnar border of the radius. The trial cannot be angulated volar or dorsal as this would misdirect the locking screws which are fixed angle. Use an x-ray or image intensifier to confirm on the lateral view of the distal forearm the trial plate's position. The position must allow all drilling and subsequent screws to travel from the ulnar border of the radius to the radial side of the radius with no volar or dorsal misdirection. As in the standard DRUJ procedure, once the trial's position is confirmed, the oval hole of the size 20 trial or the single circular hole in the size 10 trial is drilled, measured, tapped and a compression screw inserted. Next, the hole for the radial peg is drilled using the radial peg drill bit.

The second proviso is an extra step during the permanent plate implantation. After confirming good positioning, the trial is removed and the permanent plate is implanted tightening a compression screw in the prepared hole (fig 1). The next step is to place the locking drill guide in the next distal hole (fig 2), confirm its direction and complete drilling with a 2.5 mm drill bit. The depth of the hole is measured and the hole is tapped using a 3.5 mm tap. A temporary bicortical compression screw is introduced through the locking hole of the plate. The screw is used to draw the radial plate against the radius without damaging the threaded hole. This extra step ensures that the plate is tight against the radius when drilling, tapping and applying the remaining locking screws.

Fig 1



Fig 2



While the two compression screws are holding the plate tight against the radius (fig 3), the remaining threaded locking screw holes are drilled using the locking drill guide. The holes are then measured and tapped. When selecting the correct length locking screw, choose one size (2 mm) less than what is indicated on the reference guide. This adjusts the screw length as the threaded head engages the threaded plate. The appropriate locking screw is then inserted and tightened into the plate.

Fig 3



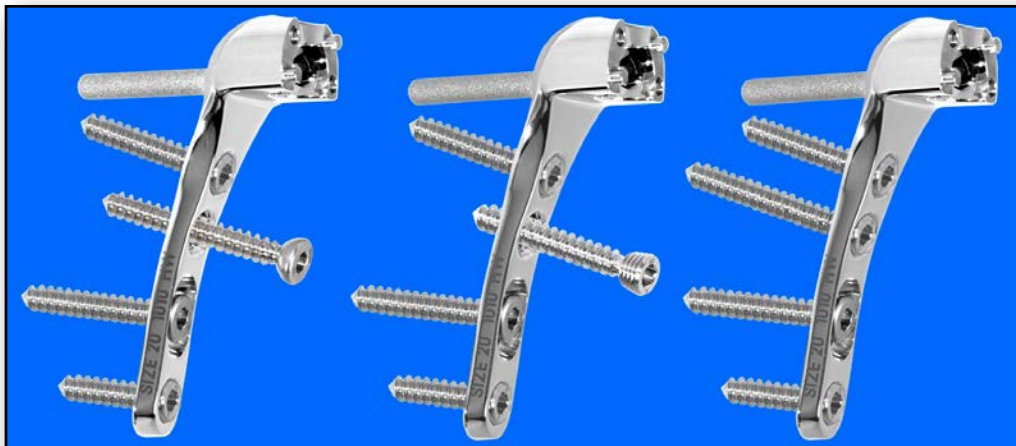
Note: the size 10 locking radial plate has only three locking holes. At this point the most proximal hole is prepared and the appropriate uni-cortical locking screw secured. Next the temporary middle compression screw is removed and replaced with the appropriate length locking screw (2 mm shorter). Finally the temporary distal compression screw is removed and replaced with the appropriate locking screw (fig 4).

Fig 4



To complete fixation of the size 20 radial plate the most proximal hole is prepared in the same manner with the exception of remaining uni-cortical. Finally the temporary compression screw is removed and replaced with the appropriate length locking screw (fig 5). All screws should pass no farther than the far cortex of the radius as long screws can become a point of irritation causing nerve scarring. Its recommend the most proximal screw remain uni-cortical to prevent a stress riser.

Fig 5

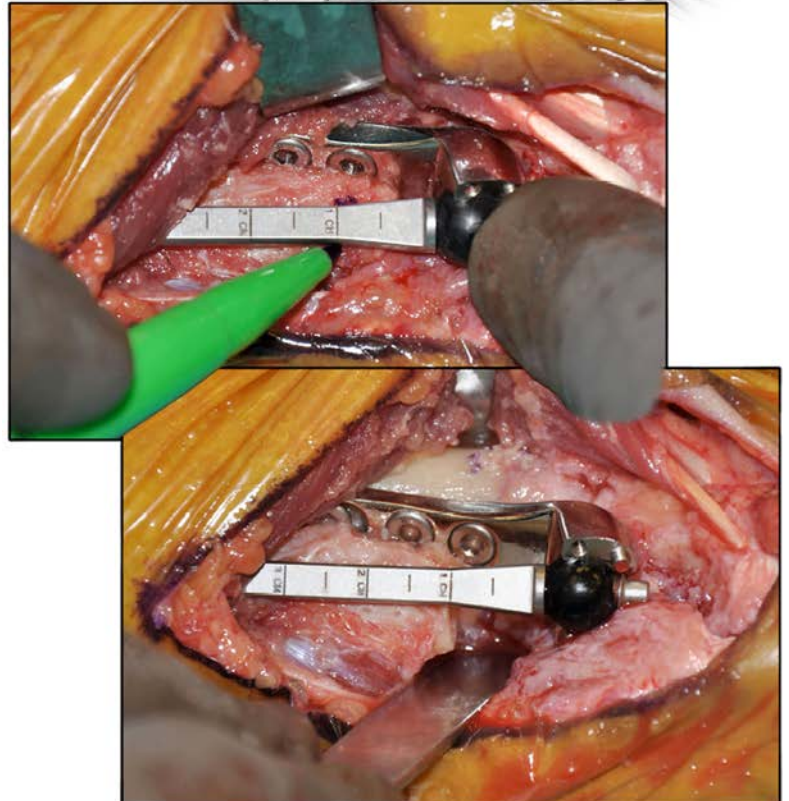
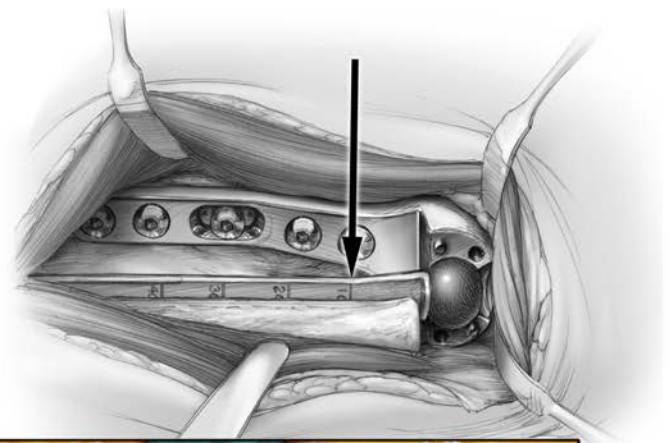


After completing locking plate fixation, the remaining steps of the technique are the same as the compression / non-locking plate.

Distal Ulnar Resection

The ulnar resection reference guide is first mated with a threaded, correspondingly sized interchangeable ball, black for the size 10 and 20 or blue for the size 30 prosthesis. The selected ball must be fully threaded onto the guide prior to use. To determine the final resection level of the ulna, the forearm is first fully pronated before the guide is positioned alongside the ulna and the ball is inserted into the hemi-socket of the fixed radial component. The ulna is juxtaposed along the guide to allow a visual assessment of the amount of ulna shaft to be resected. The guide is marked in 1 cm increments corresponding with the available ulnar stem lengths. The ulna should be marked and resected through good bone stock at the most distal possible option and proper resection level confirmed.

Optional ulnar stems with different extended lengths can be selected when additional distal ulna length has been lost due to injury or previous surgery.



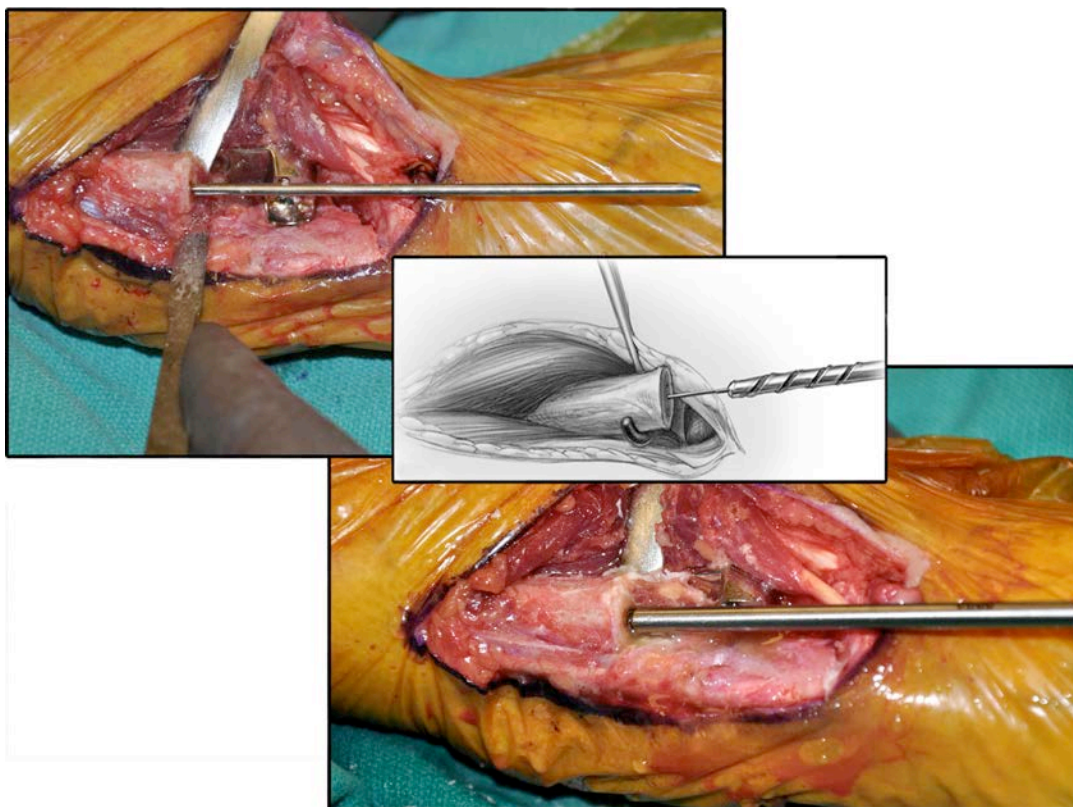
Note: *Marking the resection level with the forearm in full pronation will allow approximately 1 mm of tolerance between the ball and the base of the implanted ulnar stem upon proper completion of the prosthesis.*

For cases with additional ulna loss, the measuring reference guide is marked in increments of 1 cm. Should ulna length fall between the marks, the ulna should be resected to the next closest proximal mark. This length should be determined pre-operatively using a template. The black measure ball for the size 10 and 20. The blue measure ball pictured below for the size 30.

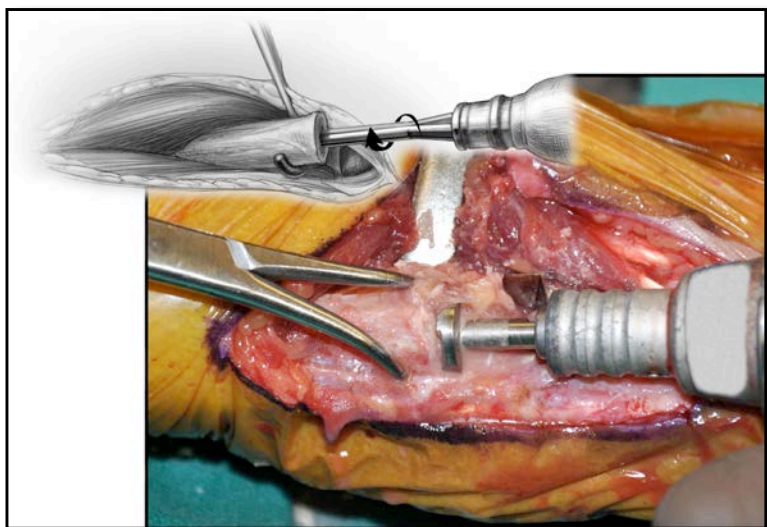


Preparation for the Ulnar Stem

Following appropriate distal ulna resection, a 2 mm or 2.4 mm guide wire is inserted into its medullary canal to act as a centralizing guide. If there is any question as to the travel of the guide wire, it should be confirmed with x-ray or an image intensifier. Next, a predetermined cannulated drill bit (either 4.0, 4.5, 5.0, or 6.0 mm in diameter and marked to a set depth of 11 cm) is inserted over this wire and the medullary canal drilled from the distal end of the ulna. Copious amounts of irrigation should be used to keep the bone and drill bit cool. If significant resistance is met while drilling, the bit should be regularly removed every 5 to 10 seconds, cleaned and cooled until reaching the required depth (11 cm). When the drill bit is removed **it must be ensured that the guide wire is properly repositioned before continuing to drill**. Upon completion of drilling, the bit and guide wire are removed.

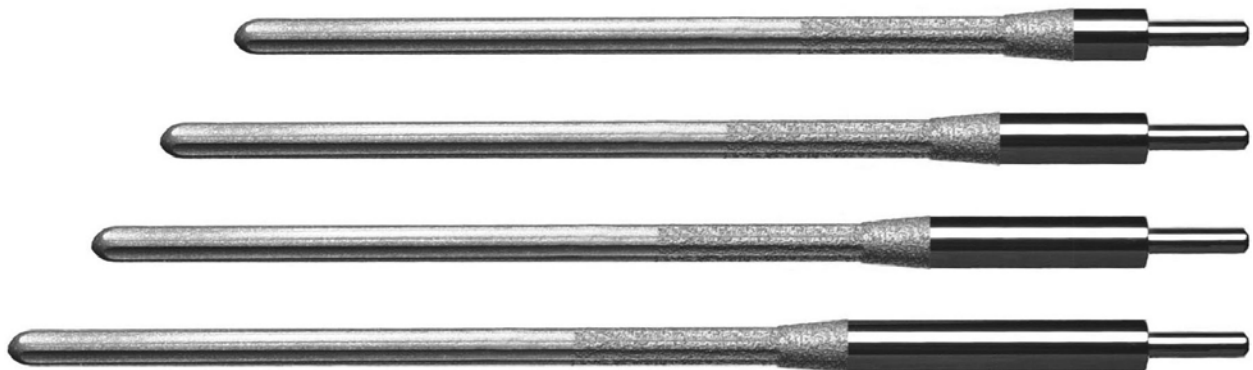


Final ulna preparation requires a medullary finish reamer or broach of an appropriate corresponding size, i.e., 4.0, 4.5, 5.0, or 6.0 mm in diameter. The size of the reamer is selected corresponding to the size of the last cannulated drill bit used. The reamer is inserted into the medullary canal and drilled down until its shoulder comes into contact with the end of the ulna shaft. This is the final step prior to insertion of the ulna stem.



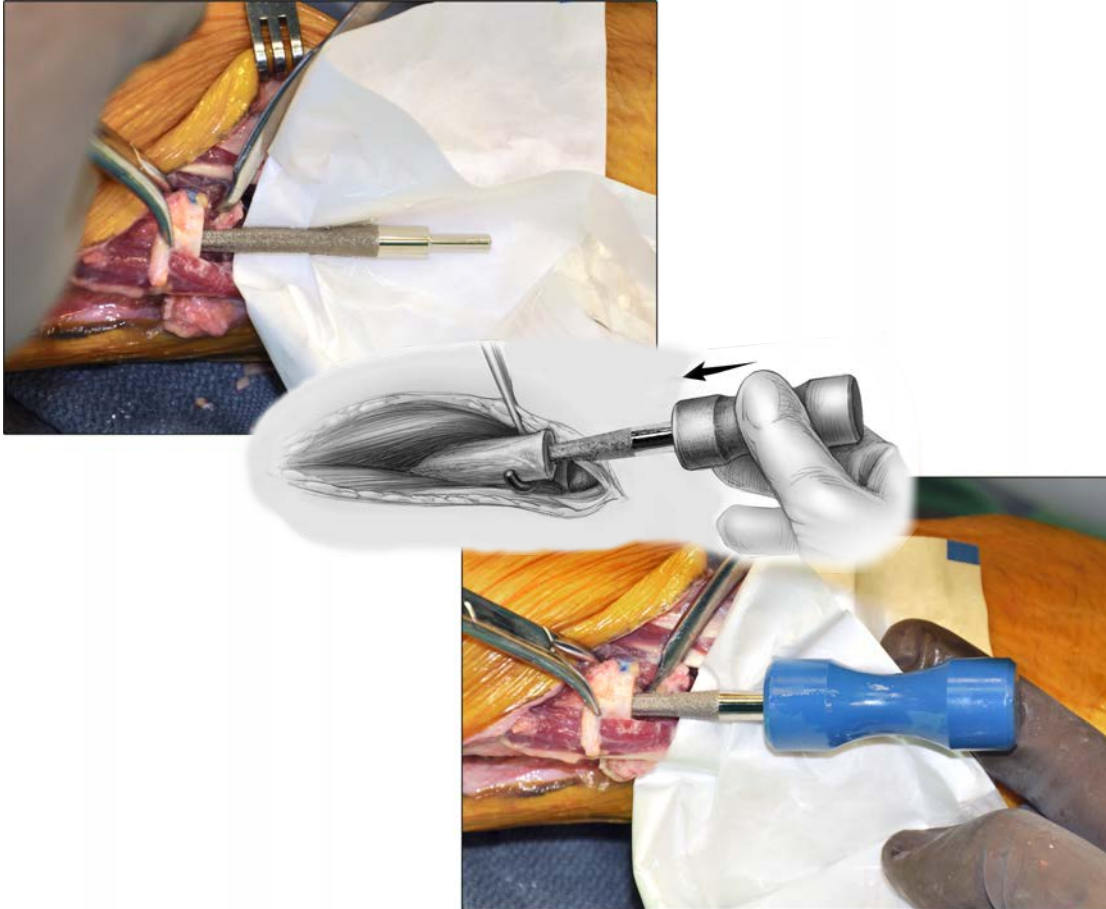
Ulnar Stem Optional Lengths and Diameters

Ulnar Stems	1 cm Extended	2 cm Extended	3 cm Extended	4 cm Extended
4.0 mm Diameter	IS140	IS240	IS340	IS440
4.5 mm Diameter	IS145	IS245	IS345	IS445
5.0 mm Diameter	IS150	IS250	IS350	IS450
6.0 mm Diameter	IS160	IS260	IS360	IS460

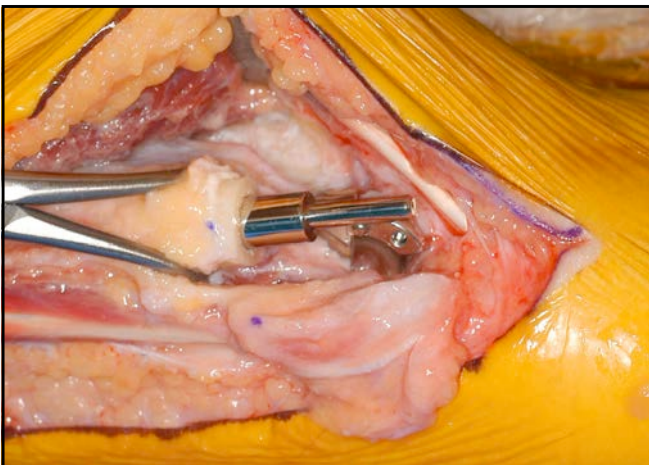


Introduction of the Ulnar Stem

The medullary canal is thoroughly irrigated and the stem of the ulnar component is introduced. We recommend limiting contact with the embedded portion of the stem during insertion. When inserting the stem, resistance is met as the plasma coating engages the interior of the ulna. A plastic impactor is used to protect the distal peg portion of the stem when using a mallet to complete implantation.



Care should be taken not to over insert the selected stem. In all cases the distal end of the stem should be no more proximal than the distal end of the radial plate.

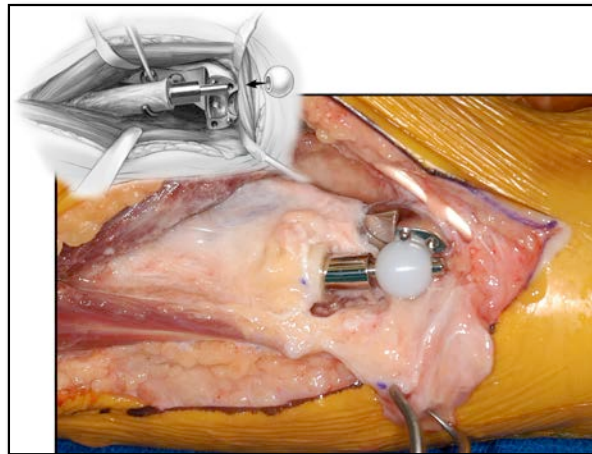


All stems should be impacted until the peg portion of the stem is aligned with the socket of the plate. Extra care should be taken not to over insert the stem. At any time the distal end of the stem should be no more proximal than the distal end of the radial plate. The plasma coating may or may not be fully embedded within the ulna. If the ulna osteotomy level is not ideal, the stem may be left proud of the ulna and not fully embedded. To provide proper support of the ball the distal stem and distal radial plate should be no less than equal.

UHMWP Ball Placement

(Replacing the Function of the Ulna Head)

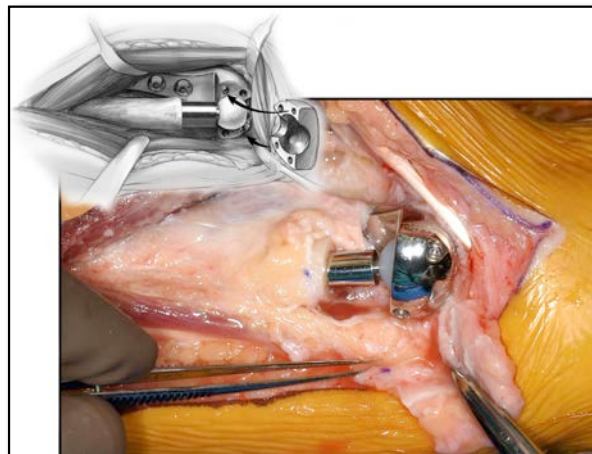
The ultra-high-molecular-weight polyethylene (UHMWP) ball is placed over the distal peg of the ulnar stem. While ensuring the absence of interposing material, the ball and stem are positioned within the hemi-socket of the radial component effectively replacing the two articular surfaces of the DRUJ.



Radial Plate Cover Placement and Fixation Size 20 / Size 30

(Replacing the Stabilizing Characteristics of the TFC)

After ensuring the absence of interposing material, the other half of the radial socket or cover is positioned and secured with either the provided two screws. The screws should be firmly applied (two finger tightening technique) to ensure enclosure of the UHMWP ball. This recreates the stabilizing effects of an intact TFC and completes the prosthesis. The covers of the size 20 and 30 have two pegs for alignment and two screw holes for fixation.

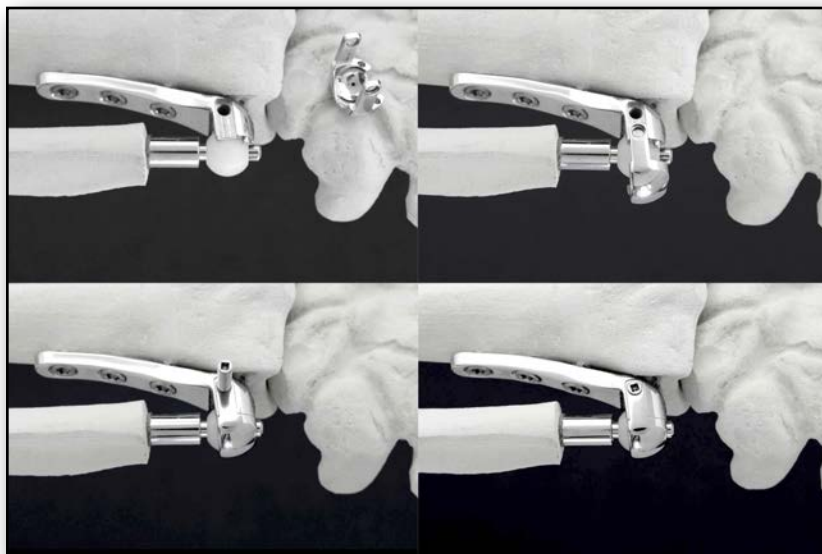


Size 10 Cover Placement

The cover must be fully slid into place prior to inserting and advancing the single locking cross pin. It must be ensured the pin is threading properly and the screwdriver must be in alignment with the pin as it is advanced. If resistance is met, back the pin off and check for interference such as the cover alignment or any interposing material before continuing.

Caution: During final assembly ensure the mating surfaces of the prosthesis are free from interposing material prior to securing the cover. The screws or locking cross pin should be applied firmly using a two finger tightening technique (3.0 to 3.5 lb-in. of force).

AVOID excess force or poor alignment to prevent screw or locking cross pin breakage. **Max** force must remain less than 5 lb-in.



Range of Motion Evaluation

The image intensifier is again used to confirm adequacy of the overall position. The forearm is moved through a full range of prono-supination ensuring free movement. A properly positioned prosthesis should allow a full range of motion. If full range of motion is not realized, notably supination, scaring of the interosseous membrane (IOM) can be the cause and it should be released until the desired motion is obtained.



Closure

After thorough irrigation to remove any bone fragments, bone marrow or debris, the tourniquet is released and complete hemostasis secured. The fascial/retinacular barrier flap is now positioned inferior to the ECU and superior to the distal prosthesis. Closure is achieved by apposing the previously created flaps with 3/0 braided non-absorbing sutures.



Final wound closure follows in a layered fashion. The skin is closed by surgeon's preference. If bleeding is noted, care should be exercised to prevent hematoma. It is recommended that a prophylactic antibiotic be used for a minimum of 5 days.

Post-operative management

A well-padded short arm splint is applied. This splint remains in position for 2 weeks at which time sutures are removed and range of motion exercises are started. Therapy is initiated with active range of motion and weight bearing exercises. Further therapy may or may not be required according to the needs of the patient.



CE 0086

EU Representative:
14-0002 rev. K
Medical Products International
C/O Sigmacon UK Ltd.
Herots Wood, The Common
Stanmore, Middlesex, HA7 3HT
United Kingdom
44 2089 55 7991
Secondary Contact Number + 1 678 787 0126

For more information go to www.apτισmedical.com or e-mail Info@apτισmedical.com

Aptis Medical, LLC
3602 Glenview Avenue, Glenview, KY, 40025 US
P 502.523.6738 or 502.425.8584
F 502.425.7422

