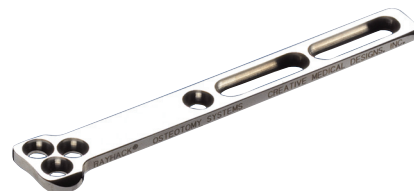


RAYHACK®

Radial Malunion Distraction System

SURGICAL TECHNIQUE



Surgical Technique as described
by John M. Rayhack, MD



WRIGHT.

RAYHACK®

Radial Malunion Distraction System

SURGICAL TECHNIQUE

Indicated for use in severe radial malunions, the RAYHACK® Radial Malunion Distraction System utilizes a multi-plane distractor which controls the distal fragment with the plate already in place. A multi-angled drill guide facilitates correction of pronation or supination deformities, and radial or ulnar translation is easily corrected. The narrow plate width minimizes tendon and soft-tissue irritation. Bone graft may be compressed to secure placement.

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Proper surgical procedures and techniques are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the procedures based on his or her personal medical training and experience. Prior to use of the system, the surgeon should refer to the product package insert for complete warnings, precautions, indications, contraindications and adverse effects. Package inserts are also available by contacting Wright Medical Technology, Inc.

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Appendix 1

22 RAYHACK® Radial Malunion Distraction System Instrumentation

Appendix 2

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The Components

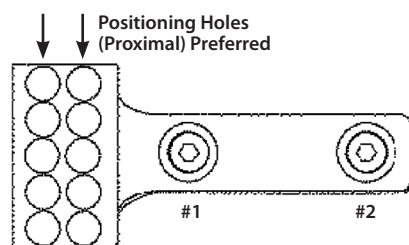


FIGURE 1

Radial Distraction Saw and Drill Guide Base

The saw guide base serves as a template for two holes (#1 and #2) numbered from distal to proximal through which the saw guide, radial distractor and bone plate will be secured to the radius.

Two sets of five transverse “positioning” holes will allow the secure temporary fixation of the multi-angled drill guide to the saw guide base. Proximal (preferred) or distal placement and specific increments of medial or lateral translation can be chosen depending on the position of the distal radial malunion fragment relative to the diaphysis. The distal positioning holes are only used in the rare case of excessive volar tilt of the distal radius in order to avoid drilling the fixation holes into the osteotomy site. | **FIGURE 1**

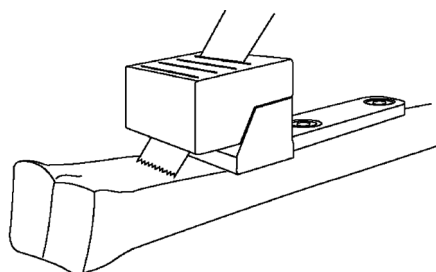


FIGURE 2

The Saw Guide Osteotomy Attachment

The saw guide attachment contains 5 prongs to allow positioning on the saw guide base. Osteotomy angles of 0, 10, 20, and 30 degrees are possible with this attachment. The saw guide attachment can be shifted laterally or medially to permit osteotomies of translated radial malunions. | **FIGURE 2**

Multi-Angled Drill Guide

The multi-angled drill guide allows “fixation” drill holes to be made into the distal radial fragment from +30 degrees proximally to -30 degrees distally at 5 degree increments. These 13 drill holes will permit up to the first 30 degrees of volar or dorsal correction of the articular surface in either volar or dorsal directions. For example: If the radial articular surface is dorsally angulated 20 degrees and 0 degrees of volar tilt is needed upon final correction, the +20 degree holes will be used for drilling the fixation holes with the multi-angled drill guide in the distal radius. In volarly-angulated fracture malunions, the -5 to -30 degree holes will be used. If the radius is too narrow to permit firm placement of these fixation holes, this system will not be suitable for use. | **FIGURE 3**

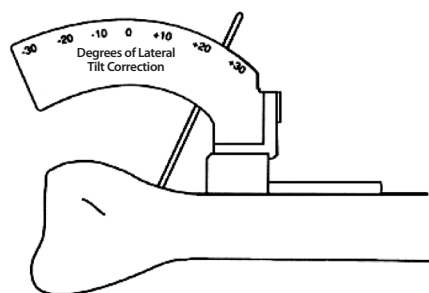


FIGURE 3

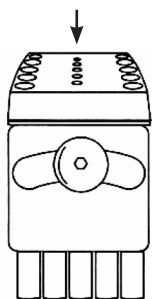


FIGURE 4

.062" K-Wire Holes

Between each set of 2.5mm holes in the drill guide is a corresponding hole for a .062" inch K-wire for all 13 sets of holes in the drill guide. This .062" K-wire will be used to provisionally fix the multi-angled drill guide during drilling of screws #1 and #2. It will also align the distal fragment vertically for application of the fixation screws during placement of the distractor, and help to trim the dorsal cortical fragment to assure a tangential bone surface. | **FIGURE 4**

Supination and Pronation Correction

(Rotation mechanism of the drill guide.)

In rare instances, the distal fragment has healed in a pronated or supinated position. It is possible to correct this rotational deformity through the use of a rotation mechanism, built into the drill guide. The set screw can be loosened (counter-clockwise) by a standard 2.5mm hex screw driver and the guide can be rotated to the side and relocked into position with the set screw. Up to 15 degrees of rotational correction in both directions is possible with this device but it is suggested to make only minimal corrections to avoid overly complicating the procedure. The degrees of angulation are marked on the semi-circular distal portion of the drill guide in 5 degree increments. Usually this will be set at 0 degrees unless modification of angulation is needed. | **FIGURE 5**

EXAMPLE: If the radius is supinated 5 degrees, the guide should be set in a supinated position relative to the proximal portion of the drill guide. The fixation holes are rotated 5 degrees in the coronal plane (a plane running from dorsal to volar and medial to lateral). Once the osteotomy is completed and the distractor is applied, these holes will be vertical and aligned equal distance from the midline, thus correcting the supination abnormality.

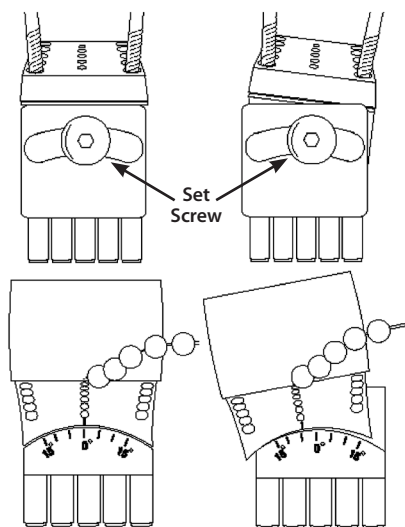


FIGURE 5

Medial and Lateral Translational Deformity

The 5 prongs of the multi-angled drill guide permit medial, lateral, proximal and distal placement of the multi-angled drill guide on the saw guide base. This option is to correct any displacement of the distal radial fragment which may have healed in translated position relative to the shaft. Shift the 5 prongs medially or laterally by one, two, or three holes. This will allow placement of the fixation holes into the distal radial fragment. Each hole that is shifted represents a 4.5mm translation. | **FIGURE 6**

At least two prongs of the multi-angled drill guide must be seated in two of the saw guide base holes. Once the osteotomy is performed, manually shift the fragment in the desired direction relative to the shaft. The multi-plane distractor holes are aligned by inserting the long cortical fixation screws into the distal radial holes. This will correct the original translation. If no translational correction is indicated, all 5 prongs of the drill guide should be seated into the 5 saw guide holes.

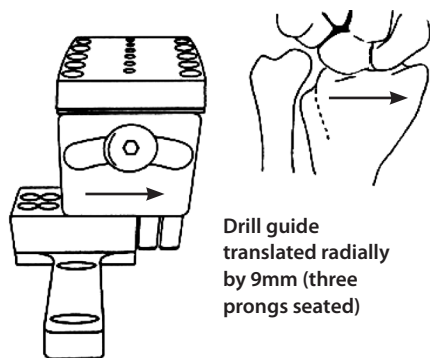


FIGURE 6

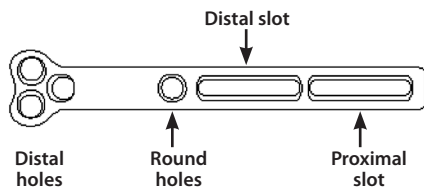


FIGURE 7

Double-Slotted Radial Distraction Plate

The radial distraction plate features a low-profile distal portion with three round screw holes, a round hole in the middle and two slotted holes proximally. It is only available in stainless steel. | **FIGURE 7**

In this procedure the plate is to remain flat and is not to be contoured. The implant provided in the set is shipped non-sterile and must be appropriately sterilized prior to the procedure. This is also true for the tray and all the additional equipment in the set.

The saw blade is packaged in a sterile pouch.

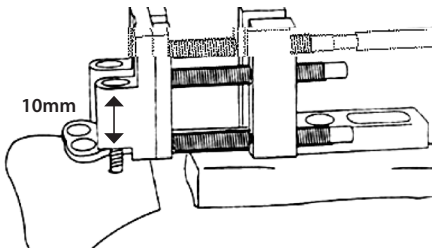


FIGURE 8

RAYHACK® Radial Distractor

The distractor allows the surgeon to gain length and to correct angulatory deformities in both PA and lateral planes. Two 10mm screw columns in the distal aspect of the distractor allow long fixation screws to control the distal fragment. The distractor straddles the plate and uses the same two screw holes for fixation in the radial diaphysis as the previously placed saw guide base. (These screws pass through the distractor, and the slots in the plate permit the plate to move distally during distraction, while the distractor remains in its original position.) Three ball and socket mechanisms permit the concurrent correction of multiple deformities. Radial inclination correction will be accomplished using preferential distraction of the screws on the radial side once the final length is achieved. The same distractor is used for both left and right radii. Compression of the cortical cancellous bone graft is accomplished at the completion of the procedure by one half counter-clockwise turn of all three adjusting screws. | **FIGURE 8**

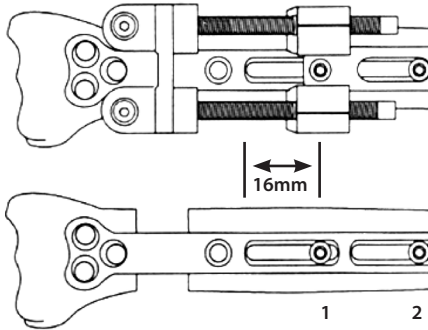


FIGURE 9

How Much Correction is Possible with this System?

In the maximum “safe” distraction of this system, screw #1 will start at the distal end of the middle slot and end in the proximal aspect. This represents approximately 16mm of displacement. In a dorsally angulated radius which has been corrected, this measurement of 16mm represents the distance between the dorsal cortices of the diaphysis and the distal radial fragment. Due to angular correction, the volar cortical distance will be significantly less than 16mm (this assumes a transverse osteotomy). This amount of distraction allows the round hole in the plate to fix to the diaphysis within the recommended limit of this system. In lieu of further distraction the surgeon should consider a concurrent ulnar shortening, after correction of all other parameters has occurred within the safe limit of this system. | **FIGURE 9**

NOTE: Ulnar shortening equipment should be ordered in addition to the radial malunion distraction system.

Additional Equipment Needed to Complete Procedure

A HALL®/LINVATEC, MICROAIRE® mount sagittal saw is required to use the specialized saw blade for the osteotomy.

RAYHACK® Radial Malunion Distraction System

Surgical Technique

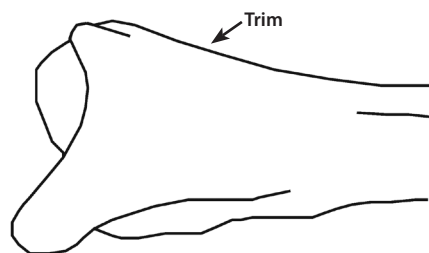


FIGURE 1

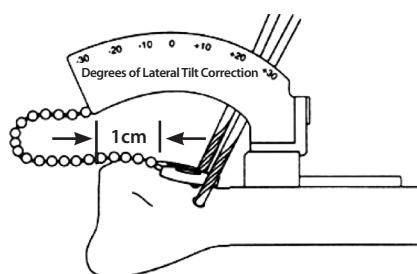


FIGURE 2

STEP 1 - Surgical Approach

A dorsal linear incision (about 13-15cm) is used for the approach. This requires considerable exposure and the EPL and strap muscles will need to be retracted throughout the procedure. Open the capsule of the radial carpal articulation to identify the position and quality of the articular surface. The skin incision should not extend distally past the radial-carpal articulation but should allow this articulation to be examined intraoperatively. The fascia over the strap muscles should be adequately released.

Trimming Lister's Tubercle

Lister's tubercle should be shaved flat. A smooth dorsal surface of the radius is necessary to allow placement of the template and bone plate. This surface is prepared at the beginning of the procedure before preliminary placement of the saw guide and plate template. Failure to shave this area flat may result in a distal plate area which is not flush with the dorsal radius during final screw fixation. This is critical. After the osteotomy is performed, it may be necessary to trim the dorsal aspect of the distal fragment for the plate to lie flat on the radius. Unless this is performed the distal radius may be volarly displaced, thus minimizing bone-plate contact. | **FIGURE 1**

Preliminary Placement of the Saw Guide Base and Multi-Angled Drill Guide

NOTE: This is the most critical step in the entire procedure.

Attach the multi-angled drill guide to the saw guide in the desired two to five holes to correct any translational deformity. If any pronation or supination deformity is present, the drill guide is set to the appropriate degrees of rotational correction. Manually hold the saw guide and attach the multi-angled drill guide on the dorsal radius. | **FIGURE 2**

Before any screw holes are drilled into the radius to fix the saw guide base, open the radial carpal articulation and assure a distance of 1cm from the radial-lunate joint to the template. Insert the two 2.5mm drill bits through the multi-angled drill guide and ensure the drill bits make good contact with the distal radial fragment. Make sure the fixation holes are not placed too far distally. **Apply the template against these drill bits.**

Align the **ulnar** 2.5mm drill bit as far to the ulnar side as possible.

It is recommended that the distal radial articular surface is placed in a **neutral lateral tilt** of the distal radial articular surface. This will leave some margin for any loss of volar tilt correction that occurs in the post-operative period and will diminish the amount of bone trimming necessary on the dorsal radial metaphyseal surface.

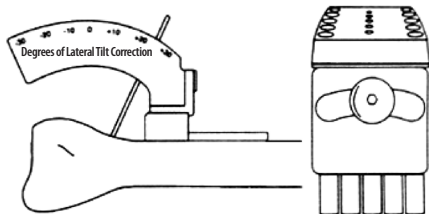


FIGURE 3

STEP 2 - Drilling the .062" K-Wire

Drill a .062" K-wire in the angulated hole corresponding to the same degree of lateral tilt correction* chosen for the 2.5mm fixation holes. Drill through both cortices. This will help to hold the entire apparatus in position until the screws are inserted into the saw guide base. | **FIGURE 3**

*Aim for neutral articular tilt on the lateral projection.

Drilling the Two Saw Guide Base Holes

The proximal screw hole (#2) is drilled through the saw guide using a 2.5mm drill bit and the handheld drill guide. Prior to drilling, ensure the saw guide is positioned properly on the radial shaft. Measure and tap using a 3.5mm tap. Many surgeons will add 2mm to the length of this screw as these screws will ultimately fix the bone plate. Do not be overly concerned about this additional length of screw protruding into the pronator quadratus muscle. This decision is used with discretion. Once the appropriate sized proximal screw is applied, the distal screw hole #1 is drilled, measured, tapped and the screw (also possibly 2mm longer) is applied. | **FIGURE 4**

Over-tightening these screws may strip the hex socket in the screw head upon later screw removal. The same two screw holes that fix the saw guide to the radial diaphysis will ultimately be used to fix the radial distractor and the bone plate to the radius.

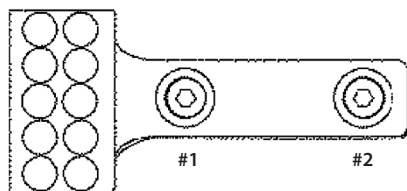


FIGURE 4

Temporarily Remove the .062" K-Wire

Temporarily remove the K-wire to allow unobstructed access to drill the ulnar "fixation" hole through the desired angulation hole.

Drilling the Distal Ulnar Fixation Hole through the Multi-Angled Drill Guide

The drill bit is now drilled into the ulnar side of the distal radial fragment at the chosen degree of angulation. Confirm the drill bit is not "glancing" off the radius. Drill this hole with a 2.5mm drill bit through both cortices. The screw hole has been converged 5 degrees toward the midline in order to avoid interference with the radial cortex, but not enough to converge and hit the opposite fixation screw. Long cortical screws placed through the distractor and into this fixation hole will later press against the ulnar flared portion of the plate and will help "push" the plate distally during the distraction. | **FIGURE 5**

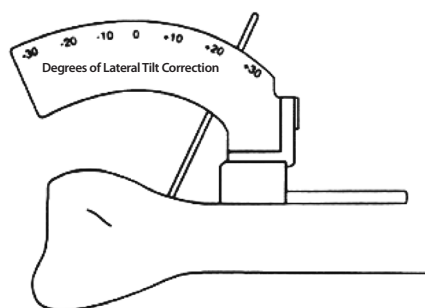


FIGURE 5

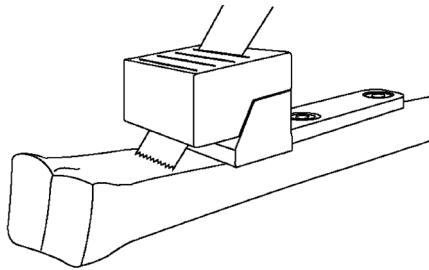


FIGURE 6

STEP 3 - Remove the Drill Guide - X-Ray Confirmation of the Position of the Fixation Screw Hole

Remove the drill guide by gently pulling perpendicular to the axis of the five drill guide holes. Take a postero anterior X-ray with the ulnar fixation hole drilled, the drill guide removed, and the saw-guide base still attached. Confirm the intended location of the fixation hole has been obtained for the plate to be appropriately positioned and not placed too far distally. If there is an error, reposition the saw guide base and re-drill the ulnar 2.5mm hole. This is a critical confirmatory step!

Performing the Osteotomy

Apply the saw guide attachment and choose an osteotomy of 0, 10, 20, or 30 degrees. Use only the saw blade provided as it coordinates with the width of the radius and the saw guide cutting slot. The dimensions of this blade permit use of a HALL®/LINVATEC or MICROAIRE® mount sagittal saws. Use a gentle side-to-side motion and cool with slush saline during this procedure to minimize bone necrosis. Protect the soft tissues on all sides of the radius with a standard retractor to avoid soft tissue damage. | **FIGURE 6**

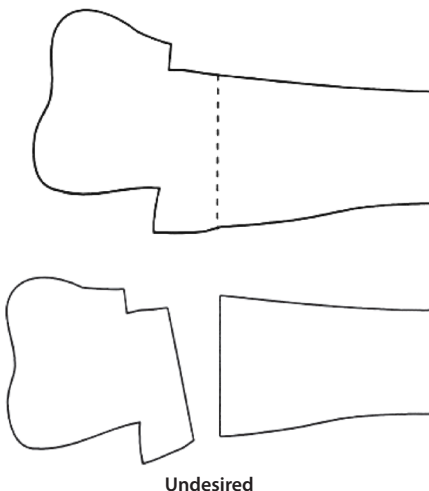


FIGURE 7

The radial osteotomy may be freehanded at any location or angulation desired but must not compromise the angled distal radial “fixation” holes or hole #1 of the saw guide base. Using the 0 degree vertical hole (recommended) will minimize later metaphyseal trimming.

Dilemma of the Dorsally-Translated Radius Fracture (Lateral Projection)

In cases in which the radius has healed in a dorsally translated position, it is tempting to perform the osteotomy at the site of the original fracture. However, this must allow sufficient space for placement of the 2.5mm “fixation holes” into the distal fragment. If the fracture has occurred in a very distal position, it will be impossible to osteotomize the radius; as there needs to be sufficient area to affix the plate to the distal radius without being placed too far distally. Attempts to make the osteotomy more proximal will leave a “stepped” distal radius which may be unacceptable. Additionally, there may be insufficient space for placement of the fixation screw holes. Under these circumstances, the procedure may not be able to be performed with this system. | **FIGURE 7**

Dilemma of the Distal Radial Non-Union (Non-Translated)

If the radius is fractured at this distal location but not translated as discussed above and healing has not yet occurred, there will be insufficient space for the fixation screws. It is advisable to await fracture healing before a more proximal osteotomy is performed in order to allow for sufficient space for the fixation holes.

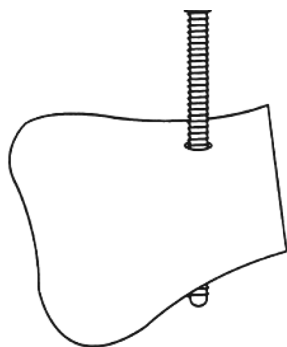


FIGURE 8

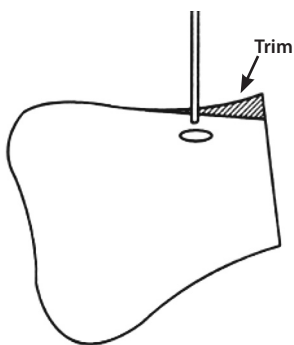


FIGURE 9

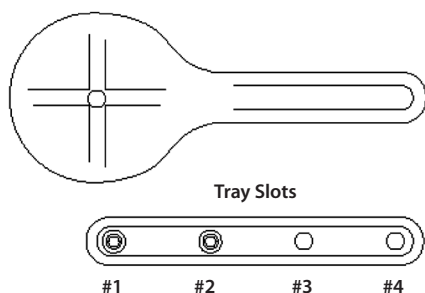


FIGURE 10

STEP 4 - Reapply the Multi-Angled Drill Guide and Replace the .062" K-Wire

After the ulnar 2.5mm drill bit fixation hole is drilled, the .062" K-wire is reinserted through the previously drilled hole in the distal radius. Since the osteotomy has been performed, it will be necessary to hold the radius in its original position during reinsertion. Apply the drill guide to assure placement in the original hole.

Measuring and Tapping the Distal Ulnar Fixation Hole

Measure and record the depth of the ulnar distal "fixation hole." This ulnar hole was drilled at a complex angle and the depth gauge will also be angled into the hole. Hold the K-wire vertically to help align the tap with this hole. Record this length and tap this hole with a 3.5mm tap. | **FIGURE 8**

Trimming the Diaphyseal Fragment

While holding the K-wire vertical, trim any diaphyseal fragment that projects above the plane of the distal radius. This allows the plate to lie flush on the dorsal radial surface. Always trim more rather than less of the triangular fragment. Failure to do so will result in loss of volar tilt correction when the three distal plate screws are finally tightened. If removal of cortical bone down to cancellous bone is necessary for the plate to lie flush with the base at this limited area, it should be performed. This is a non-critical area for stability of the construct once grafting has been performed. | **FIGURE 9**

Removal of the Saw Guide

Carefully remove screws #1 and #2 from the saw guide base and place the screws in the corresponding temporary holding slots in the tray. These screws will be used at the end of the procedure to replace the temporary longer screws in holes #1 and #2 when the distractor is removed.

When removing the screws, be careful not to strip the hex head as this will require a lengthy delay to remove the head with screw removal instrumentation. Ensure no debris is in the screw head hex hole by fully seating the screwdriver and applying counter-traction to the forearm while the screw is turning in a counter-clockwise direction. Stripping of this screw head and its ultimate removal also risks damage to the saw guide base. | **FIGURE 10**

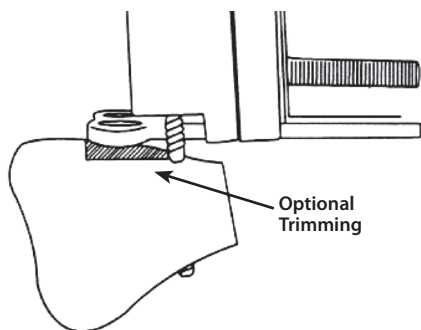


FIGURE 11

STEP 5 - Trimming the Dorsal Radial Metaphysis

It may be necessary to remove the distractor and plate to trim additional bone to avoid any space between the radius and the distractor plate. This is especially apparent if additional volar or dorsal tilt correction is performed using the precision distraction feature. Most of the volar or dorsal correction should be achieved previously by choosing the appropriately angled fixation holes to be drilled through the drill guide. It is important to keep the plate flush against the bone distally where the three cortical screws are applied. Some space between the plate and bone, proximal to the distal three screws, is desirable superior to this distal fragment provided that the distal plate-bone contact area is flush. | **FIGURE 11**

If this space is not adequate and a dorsal diaphyseal “spike” impinges on the plate, the distal fragment may angulate dorsally once the three distal screws are tightened and the desired correction could be lost. Use cancellous bone graft for any bone defects below the plate.

Application of the Plate Over the K-Wire

DO NOT BEND OR CONTOUR THE STAINLESS STEEL PLATE

Place the most proximal of the three distal screw holes of the flared end of the radial distractor plate over the .062” K-wire. With the plate held in place, assure a flush surface with the distal radial fragment. Hold the K-wire vertically and trim additional bone as indicated. | **FIGURE 12**

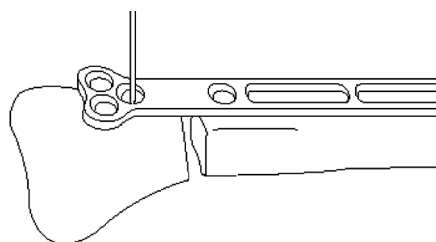


FIGURE 12

Distractor Application

Prior to application, separate the two vertical columns of the distractor by approximately 7mm. Apply the precision distractor over the plate. Longitudinal “ridges” on the under surface of the distractor straddle the radial plate.

Fixation of the Distractor and Plate to the Diaphysis with Temporary Screws that are 4mm Longer

Choose a 2.5mm screw which is 4mm longer than screw #1 and place it through the distractor, the middle plate slot, and then into the most distal radial diaphyseal hole. This holds the plate and the distractor concurrently. This will also be done for screw #2. These two screws (#1 and #2) should not be excessively tightened. | **FIGURE 13**

Screw #1 will pass through the round hole of the distractor and the middle oblong slot in the distractor plate. Screw #2 will be placed through the slot of the distractor and in the distal end of the proximal oblong slot in the plate.

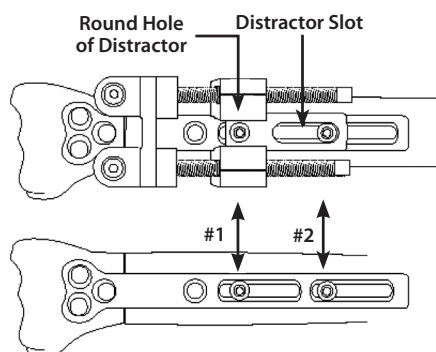


FIGURE 13

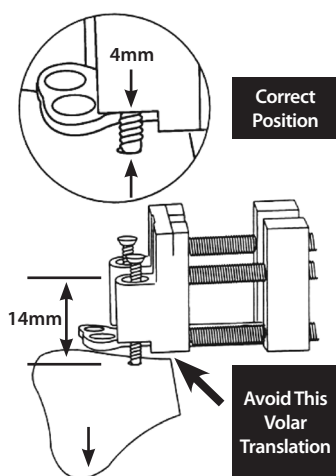


FIGURE 14

STEP 6 - Application of the Long Ulnar Fixation Screw

Place a 3.5mm x 36mm cortical screw, provided in the kit, through the ulnar distal hole of the distractor and into the pre-drilled and tapped ulnar “fixation” hole of the distal radial fragment. The reason for this seemingly excessive length is as follows: the column of the distal portion of the distractor accounts for 10mm of this length and there may be approximately 4mm between the bone and the under surface of this distractor. This is added to the original length of the fixation holes drilled into the distal radial fragment and measured and tapped previously. **Hold the distal fragment against the plate to avoid any volar translation.** Manually line up the ulnar fixation hole with the distractor by looking down the 10mm fixation “column” of the distractor. Hold the .062” K-wire vertically to align the fixation column with the ulnar hole in the distal fragment. Gently distract or compress the adjusting screws to permit the lining up process. If difficulty is still encountered, loosen screws #1 and #2 holding the distractor to the plate and bone to allow more “play” to assist alignment. Once applied, retighten screws #1 and #2. | **FIGURE 14**

Drilling the Radial Fixation Hole

If additional radial inclination on the PA is anticipated in excess of 15 degrees, use a laminar spreader or Freer elevator to gently distract the radial side of the osteotomy before drilling this radial distractor hole. Ensure the drill bit will engage the distal radial fragment.

Place the attached distractor into the radial distractor hole and drill hole with a 2.5mm drill bit. Measure, tap, and insert a 3.5mm screw into this hole. Re-tighten these screws prior to distraction. It is imperative that the distal fragment is held to the plate when applying these screws or the distal fragment will be translated volarly from the plate. Do not over-tighten the fixation screws. The 10mm column length of metal in the distractor keeps the fixation screws vertical and corrects the volar or dorsal tilt from its pre-drilled angular position in the distal radial fragment. Remove the .062” K-wire. | **FIGURE 15**

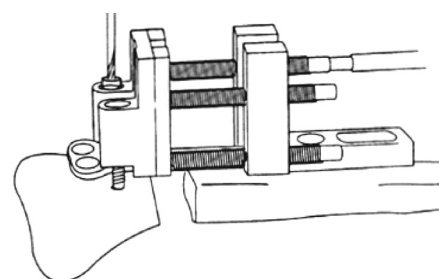


FIGURE 15

Linear Distraction of the Osteotomy

Gently use the screwdriver and gradually distract the three adjusting screws in the compression-distraction device an equal amount. Distract the bottom screw first. **Important: first correct the desired length.** Initially, all screws should be distracted an equal amount. Avoid excessive force as the adjusting screw heads may strip or the cortical bone could break at the point of application of the 3.5mm distraction screws. | **FIGURE 16**

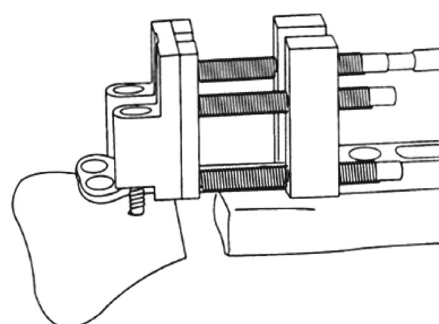


FIGURE 16

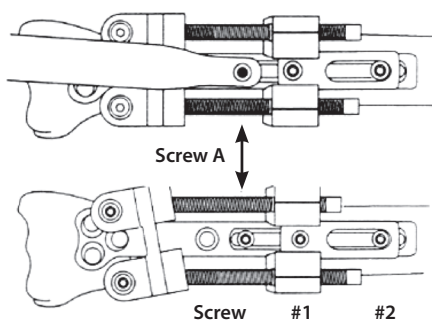


FIGURE 17

STEP 7 - Adding an Additional Bone Screw "A" Proximal to the Round Hole in the Plate

As additional distraction occurs, the distal portion of the middle elongated slot in the plate will appear distal to the round hole in the distractor. Use the handheld drill guide to drill an additional hole through the plate. This will be approximately 8-11mm distal to screw #1. This screw must be kept slightly loose so it is recommended to add 2mm to the depth gauge measurement. This screw will help to avoid separation (dorsally) of the plate from the bone as additional distraction occurs. Screw "A" will not engage the distractor, just the bone plate. **Do not over tighten this screw.** If only minimal distraction occurs in the procedure, there may not be an opportunity to place this screw in the distal portion of the middle slot due to insufficient space distal to screw #1. | **FIGURE 17** At the completion of the distraction of the osteotomy, space may be available to place an additional screw "B" in the distal portion of the proximal slot. Use the handheld drill guide when drilling the hole.

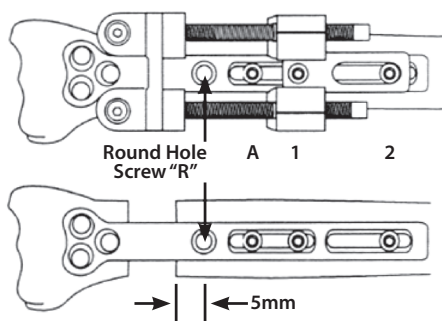


FIGURE 18

Maximal "Safe" Osteotomy Distraction

Eventually, the distraction may reach the point where the round hole (screw "R") in the plate (distal to the long slot) is about 5mm proximal to the proximal radial cut surface. Once this screw is applied, the plate cannot slide proximally. If the round hole is distal to the osteotomy, the only holes fixing the plate are the two slotted holes and proximal plate slippage could occur. It is important to assure the round hole for screw "R" (between the middle slot and the solid portion of the plate) permits secure cortical fixation on the proximal diaphysis. In lieu of further distraction, correct the radial styloid angulation, translation, dorsal or volar tilt, any pronation or supination deformity, and consider a concurrent ulnar shortening procedure. This will minimize tension on the system during excessive distraction and diminish the healing time necessary for incorporation of the bone graft. | **FIGURE 18**

NOTE: Ulnar shortening equipment should be ordered in addition to the Radial Malunion Distraction system.

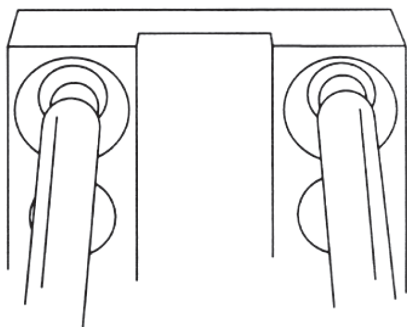


FIGURE 19

STEP 8 - Caution: Binding of the Ball and Socket Mechanism

The ball and socket is designed to assist in placing the distal fragment of the radius in a desired position relative to the diaphysis. There is a limit to the amount of distraction, and concurrent angulation in three planes that this system can tolerate. The linear distraction itself places a considerable amount of tension on the system. Additional angulation of the distal fragment, as seen in the next three steps, by clockwise rotation of the adjusting screw on one side and counter-clockwise rotation of the adjusting screws on the other side will add to the total tension on the system. **Most of the volar and dorsal tilt correction should have been achieved by the use of the appropriate angled holes in the multi-angled drill guide. Do not rely on the distractor to any great extent to control volar and dorsal tilt correction.** Attention to this detail will limit the overall stress on the ball and socket mechanism and perhaps more importantly, obviate the need for additional trimming of the dorsal diaphyseal “lip” to permit the plate to sit flush on the radius. **Avoid excessive stressing of the intended limits of this device. This limit will be perceived in the amount of torque required to tighten the adjusting screws. Damage to the adjusting screws or distractor could prevent use of this equipment in order to complete the procedure.** If excessive resistance is perceived, assure the long fixation screws are not too tight thus preventing manipulation of the distal radial fragment. Consider additional soft tissue release and allow “creep” to occur while the bone graft is procured and then an additional attempt may be made. If it is still too tight to manipulate the distal radial fragment, a concurrent ulnar shortening may be appropriate. Always correct length before attempting angulatory corrections. | **FIGURE 19**

Gaining Radial Length Preferentially

It is possible to angulate the radial side more than the ulnar side by tightening the radial adjusting screw(s) clockwise (lengthening) and slightly turning the ulnar screw(s) counter-clockwise (shortening). The right and left radii will have two adjusting screws (top and bottom) on the ulnar side for the left wrist and on the radial side for the right wrist. Avoid correcting one screw on the double-adjusting screw side more than the other or an unwanted volar or dorsal tilt may occur. However, this may be desired as seen in **FIGURE 22**. With significant radial styloid length adjustment, the distal portion of the plate may approach the radial lunate articulation on the ulnar side. It should not surpass this articulation and can be clinically confirmed by observing the articular surfaces. | **FIGURE 20**

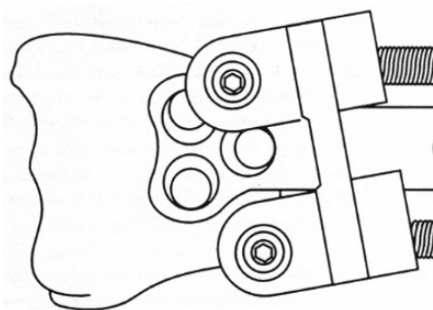


FIGURE 20

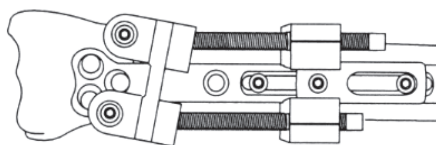


FIGURE 21

STEP 9 - Gaining Ulnar Length Preferentially

It is possible to angulate the ulnar side more than the radial side by turning the ulnar adjusting screw(s) clockwise (lengthening) and slightly turning the radial screw(s) counter-clockwise (shortening). The right and left radii will have the two side-adjusting screws (top and bottom) on the ulnar side for the left wrist and on the radial side for the right wrist. Avoid correcting one screw on the double-adjusting screw side more than the other or an unwanted volar or dorsal tilt may occur. However, this may be desired as seen in the next step below. | **FIGURE 21**

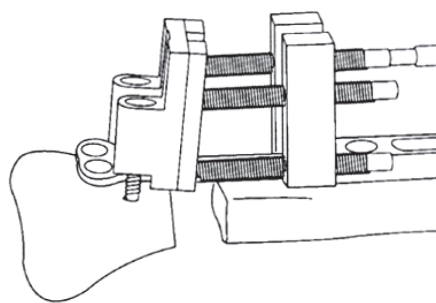


FIGURE 22

Gaining Additional Volar or Dorsal Tilt

It is possible to “fine tune” the correction of volar and dorsal tilt to some degree through the preferential lengthening and shortening of the top and bottom adjusting screws on the same side of the distractor. Most of this correction should have occurred earlier by choosing the appropriately angled-fixation drill holes in the distal radius at the beginning of the procedure (**FIGURE 3**). In the example shown, some dorsal tilt is accomplished by clockwise rotation of the bottom adjusting screw. Additional dorsal correction may be accomplished by clockwise rotation of the bottom adjusting screw or concurrent counter-clockwise rotation of the top two adjusting screws an equal amount. **If additional volar tilt is required, confirm the plate lies flush on the radius distally and the dorsal diaphyseal “lip” is adequately trimmed.** | **FIGURE 22**

Check X-Rays

After distraction and angular corrections are achieved, take X-rays to confirm the position of the distal radial fragment in both PA and Lateral projections. Compare with the scout films of the non-affected extremity to approach an anatomical correction. This may be simplified by image intensification or fluoroscopy as opposed to plain films. The equipment is designed to permit unobstructed view of the distal radial articular surface in both the PA and Lateral projections. The long 3.5mm cortical “fixation” screws in the distal radial fragment (outside the plate in the distractor) are tightened at this point (prior to the X-rays). Tightening the three screws through the plate proximal to the osteotomy (“A”, #1, #2) is also advisable. This will permit an accurate representation of the final bone position before the distal three cortical bone screws and the round hole screw “R” in the plate proximal to the osteotomy are drilled, tapped, and inserted.

If further angular or length correction adjustment is needed, it is imperative to again loosen these screws slightly to permit plate gliding. If the dorsal metaphyseal spike has not been trimmed sufficiently, dorsal angulation may occur as these screws are tightened. If necessary, remove the distractor and perform additional bone trimming of the dorsal-diaphyseal spike (**FIGURE 9**).

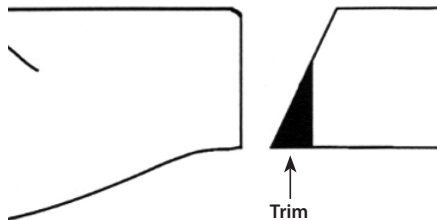


FIGURE 23

STEP 10 - Insertion of the Cortical-Cancellous Bone Graft (and Additional Cancellous Bone Graft)

Cut a tricortical bone graft and make sure it is trimmed and wedged in securely (especially volarly) to assure that no collapse of the distal fragment occurs. This is critical and failure to do so may cause the three distal radial screws to angulate in the holes of the plate due to the small amount of plate-screw contact. Purely cancellous bone graft (without the cortical-cancellous bone graft) is not recommended unless cortical contact is assured on the volar cortex (opposite the plate). Use the thick portion of the iliac crest 2 to 3 inches lateral to the anterior-superior iliac spine for harvesting. Placing the superior crest volarly, the inner and outer iliac tables medially and laterally, and the cancellous cut surfaces proximally and distally, is recommended. **In most instances the cortical-cancellous bone graft may be inserted from the radial side and placed under the plate.** Trim the volar triangular cortical margins to create a more reliable contact surface for insertion of the bone graft. Trimming can also be performed on the distal fragment if necessary to assure vertical surfaces for the bone graft. | **FIGURE 23**

Alternative Bone Grafts: Synthetic bone graft substitutes are not recommended. Composite bone graft substitutes with DBM may be used, but rigid fixation is key.

Minimal Compression of the Bone Graft after Insertion

The two long, distal cortical fixation screws in the compression device are situated proximal to the flare of the radial distraction plate. They effectively push the plate distally with gradual distraction of the adjusting screws. A small amount of compression of the graft can be performed once the graft is inserted. This is accomplished by one half to one full counter-clockwise turn of all three adjusting screws an equal amount.

The plate may need to be tapped proximally due to being “pushed” into a more distal position by the long distal fixation screws during distraction.

Radial Screw Application

Use the 2.5mm drill bit and handheld drill guide to insert the two most distal screws. The intent to **ASSURE DIVERGENCE**. Direct the radial screw 5 degrees radially.

| **FIGURE 24**

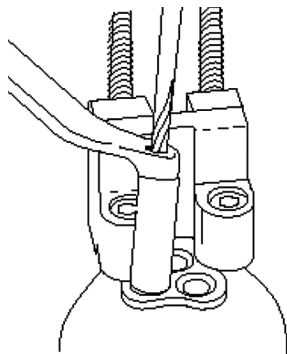


FIGURE 24

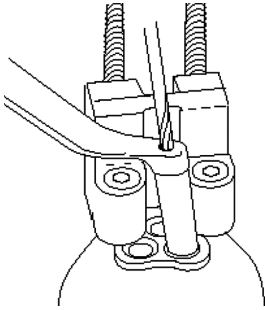


FIGURE 25

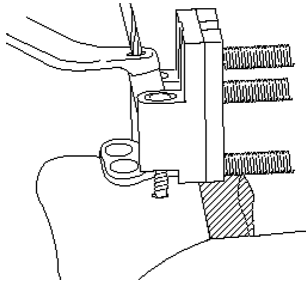


FIGURE 26

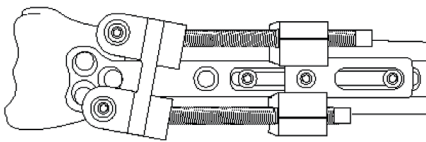


FIGURE 27

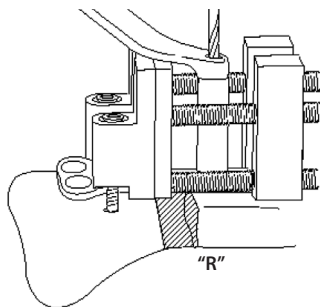


FIGURE 28

STEP 11 - Ulnar Screw Application

Direct the ulnar distal screw ulnarly at 5 degrees.

Ensure the distal radial ulnar and radial carpal joints are free of any screw intrusion. Visualize the radial carpal joint surfaces to assure appropriate screw placement.

| **FIGURE 25**

Proximal Screw Application

The most proximal of these three screws is directed proximally by 5 degrees. Thus, a "tripod fixation" of the distal radius will occur by these distal three screws.

Note excessive angulation (>5 degrees) of the screws could cause the screw heads to become "prominent" and could cause undesired tendon or soft tissue irritation. The plate is designed to fully seat the screw heads to avoid tendon irritation.

With significant angulation of the distal fragment (gaining radial styloid length for example), it may not be possible to apply the third screw (the first screw distal to the osteotomy) until after the radial distractor has been removed. This is due to the fact that the distractor may block access to the bone plate screw hole. It is unlikely that any loss of fixation will occur before the final screw is inserted, however, do not manipulate the radius until the third screw is inserted and all proximal screws through the round hole and two long slots have been inserted. | **FIGURES 26 AND 27**

Round Hole Screw "R" Application

If a satisfactory position has been achieved, the round hole "R" in the plate is now drilled, measured, and tapped. The screw may be 2mm longer than the measurement to assure good bicortical fixation. Avoid undesired angulation of this screw into the osteotomy surface. | **FIGURE 28**

Self-Tapping Screws (Not Recommended)

Preference may be to use self-tapping screws in the three distal plate holes after drilling with the 2.5mm drill bit. Use of self-tapping screws throughout the procedure in which these same self-tapping screws are removed and replaced, may not preserve the integrity of the threaded holes and is not recommended.

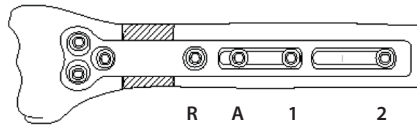


FIGURE 29

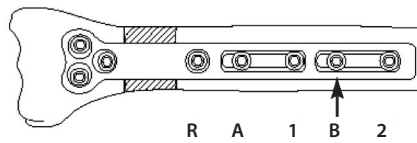


FIGURE 30

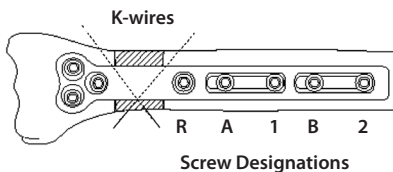


FIGURE 31

STEP 12 - Final Fixation of Screws in the Slotted-Plate/Distractor Removal

Securely tighten screw “R” and screw “A”. Remove the distractor and replace screws #1 and #2 from the temporary holding slots in the tray. Replace these screws in their respective holes through the plate. Discard the temporary longer screws #1 and #2, and the excessively long fixation screws placed in the distractor, into an appropriate biohazardous container. A total of 4 screws are now in the diaphysis fixing the plate: one through the round hole “R”, two in the middle elongated slot (screw #1 and “A”). Screw #1 will now be located in the proximal aspect of the middle slot of the plate, and screw “A” will be in the distal aspect of this middle slot. Screw #2 will now be located in the proximal aspect of the proximal slot of the plate. | **FIGURE 29**

Optional Screw “B” in the Proximal Elongated Slot

There may be room for an additional screw in the distal aspect of the proximal elongated slot distal to screw #2. Application of screw “B” is by surgeon discretion. Use a handheld drill guide to drill this 2.5mm hole. | **FIGURE 30**

Ensure that all screws are securely tightened.

K-Wire Fixation of the Bone Graft

Insert K-wires in order to maintain secure fixation of the cortical graft to the diaphysis and distal radial fragment. | **FIGURE 31** (K-wires are not provided by Wright.)

Volar Translation of the Distal Fragment (Possible Advantage)

As viewed on the lateral projection, some volar “translation” or displacement of the distal radial fragment (relative to its anatomic position) will occur in most radial malunions treated with this system. The reason is the plate is straight (and should not be contoured) and the distal radial fragment lies under the plate. Additional trimming of the dorsal radial surface may translate this fragment dorsally relative to the shaft, however, this may weaken the screw contact point for the three distal plate screws. Since the distal fragment is slightly displaced volarly by the straight plate, its original axis may lie below the axis of the diaphysis. The lunate should remain properly aligned with the radial lunate fossa and no clinical deformity should be apparent. There may be less tendency for the extensor tendons to rub on the plate and it is conceivable that this volar displacement may be advantageous.

Additional Cancellous Bone Graft and Wound Closure

Prior to closing, add additional cancellous bone graft around the osteotomy to maximize chances for healing. Any defect between the plate and the bone should also be filled with autogenous cancellous bone graft. It is usually impossible to completely cover the plate with surrounding periosteum and capsule. A small portion of the extensor retinaculum may be used to assist in this partial plate coverage.

STEP 13 - Post-Operative Immobilization

It is recommended that a long-arm, sugar-tong splint be applied at surgery. This should be converted to a long-arm cast for a minimum of 4-6 weeks post surgery or a volar-dorsal plaster splint in trustworthy patients. A short-arm cast may be applied earlier if the surgeon is assured that the patient will be sufficiently cautious to protect the construct until healing occurs. Eventually a thermoplastic splint may replace the short-arm cast until complete healing occurs. No activity against resistance should be allowed until complete osteotomy healing is assured. Patients felt to have reckless tendencies should be additionally protected.

Delayed Unions, Non-Unions, Plate Breakage

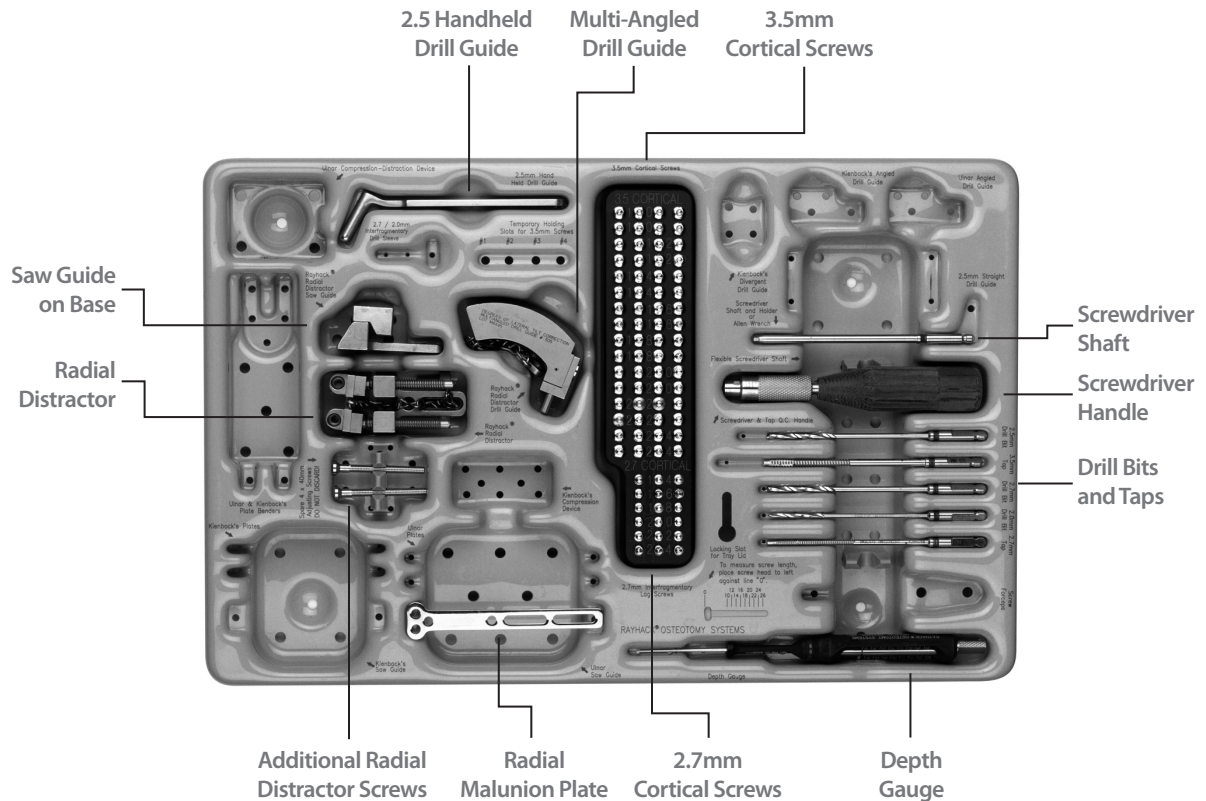
Due to the difficult nature of this procedure, a small percentage of cases may experience delayed unions or non-unions. The addition of abundant cancellous bone graft at the site of the cortical-cancellous bone graft may help to diminish the non-union rate. Delayed unions and non-unions need to be addressed by appropriate immobilization, external stimulation, or additional surgery before loss of bone fixation and/or plate breakage occurs.

Prophylactic Carpal Tunnel and Guyon's Canal Release

Lengthening the radius could precipitate median or ulnar nerve symptoms and surgeons should consider a prophylactic release of the carpal tunnel and Guyon's canal intraoperatively. Post-operative surveillance for these symptoms should be undertaken as well. Signs of soft tissue ischemia or necrosis due to excessive soft tissue stretching should also be closely monitored. Some surgeons may elect a concurrent ulnar shortening rather than to consider any excessive radial lengthening. Patients should be carefully counseled about these and other potential complications of this extremely difficult and often lengthy procedure prior to the surgical procedure.

RAYHACK®

Radial Malunion Distraction Instrumentation



Ordering Information

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