

Precision Oblique **ULNAR SHORTENING**

Surgical Technique Manual

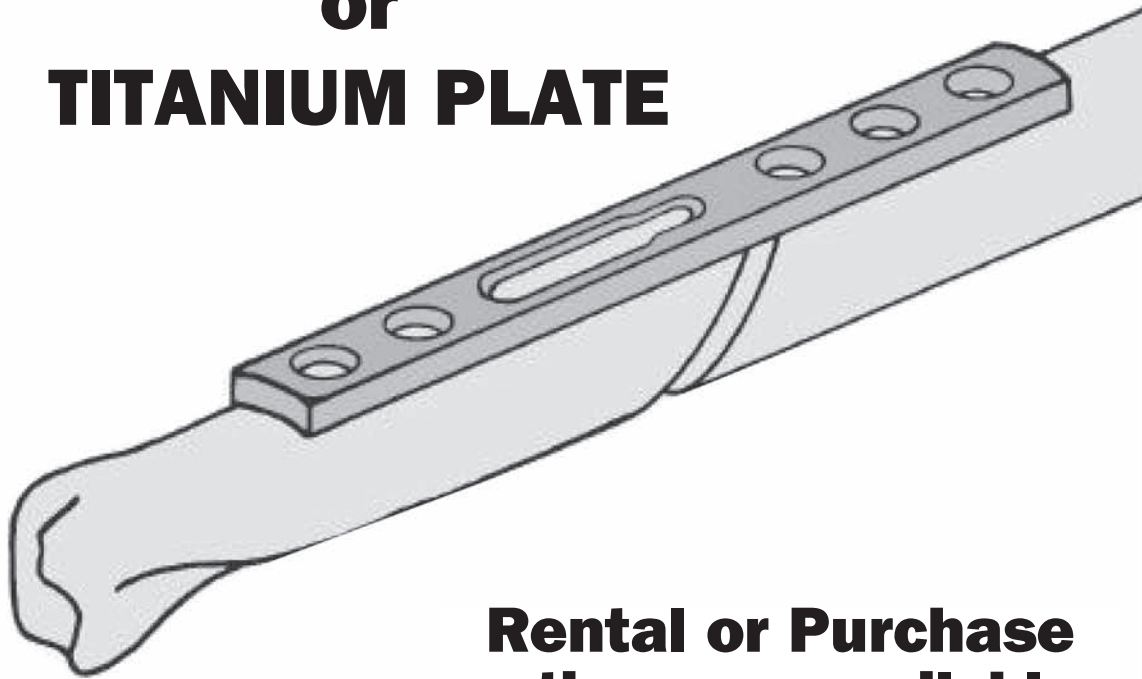
Revised 5/01/05

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STAINLESS STEEL

or

TITANIUM PLATE



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RAYHACK® OSTEOTOMY SYSTEMS

NOTE This updated manual supercedes all previously produced surgical technique manuals.

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**RAYHACK®
OSTEOTOMY
SYSTEMS**

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REFERENCES Rayhack, J.M., Gasser, S., Latta, L., Ouellette, A., Milne, E: *The Precision Oblique Osteotomy for Shortening of the Ulna. The Journal of Hand Surgery*, 18A (5): 908-918, 1993.

DISCLAIMER The RAYHACK® OSTEOTOMY SYSTEMS have been carefully designed to ensure a precision osteotomy when used properly. Failure to carefully follow directions and to use the appropriate equipment in the prescribed manner may result in an unsatisfactory outcome. Creative Medical Designs, Inc. cannot be held responsible for inappropriate use of the RAYHACK® OSTEOTOMY SYSTEMS or for failure to adequately protect soft tissues and surrounding bones at all times, nor for the failure to adequately protect the osteotomy until bone healing has occurred.

STEP

Placement of the Ulnar Saw Guide

The ulna is approached through a 10 cm incision along the medial side of the forearm. The saw guide* must be placed on the subcutaneous border of the ulna. The three counter sunk holes of the saw guide are always placed proximally. The distal end of the saw guide should be approximately 2.0 cm from the end of the ulna. Dorsal or volar placement is not recommended due to the inability of the saw guide to fit between the radius and the ulna, and due to the smaller posterior-anterior thickness of the ulna.

NOTE Some surgeons may prefer to contour the plate to the ulna once it has been exposed and **before** the saw guide is applied. (See Step 5)

REMEMBER to perform this procedure the surgeon will need the following:

- Small Fragment Set
- Mini Fragment Set
- Hall®, Microaire® or Linvatec® sagittal saws (consult www.rayhack.com/instrumentation.htm)
- Specialized Ulnar Bone Stainless Steel or Titanium Plate (Creative M.D. Inc.)
- Specialized Saw Blade (Creative M.D. Inc.)

CAUTION ALL INSTRUMENTS, BONE PLATE, SAW BLADE AND TRAY MUST BE PROPERLY STERILIZED PRIOR TO EACH PROCEDURE. ONLY THE NEW SAW BLADE WITH QUICK COUPLE SAW GRIP IS PACKAGED IN A STERILE POUCH. (CONSULT WWW.RAYHACK.COM/INSTRUMENTATION.HTM)

The distal end of the saw guide should be approximately 2.0 cm from the end of the ulna

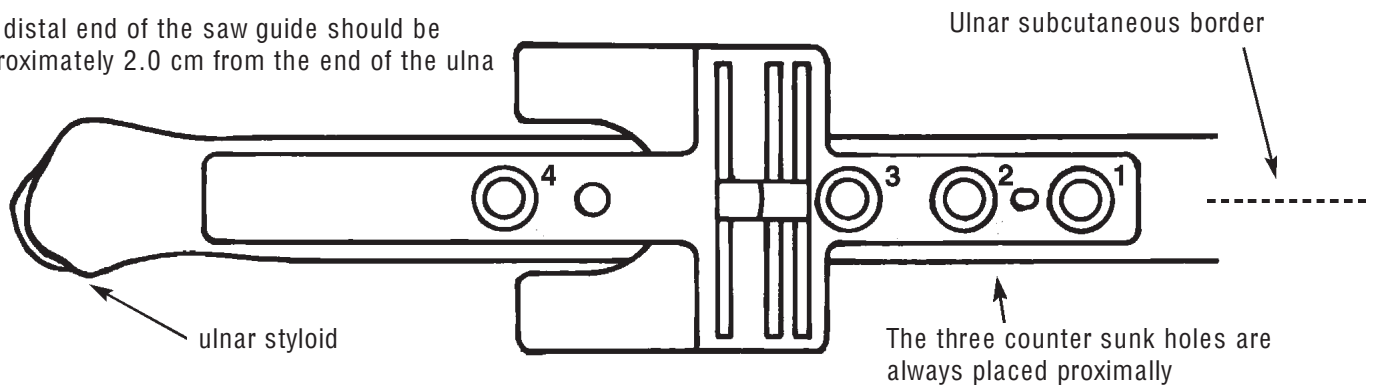


FIG. 1

*Saw Guide U.S. Patents # 5,042,983
5,176,685

STEP 2 Positioning of the Straight Drill Guide

► While manually holding the saw guide centered over the ulna, first drill hole #2 with a 2.5 mm drill bit through the straight drill guide. The proximal portion of the straight drill guide has a small prong proximally and a larger prong distally to allow proper positioning on the saw guide.

NOTE If the surgeon chooses to use the hand held drill guide rather than the straight drill guide, care must be taken to avoid drilling any other hole than screw holes 1 through 4 of the saw guide that corresponds to the holes in the straight drill guide.

► Remove the drill guide and tap the hole with a 3.5 mm tap after measuring the screw depth. Place the appropriate size screw in hole #2.

NOTE Be sure to place the depth gauge into the bottom of the screw hole. This corresponds to the bottom of the bone plate hole as well. **Some surgeons will routinely add 2 mm to their measurement to assure that the far cortex is fully captured by the screw.** (Application of the first screw avoids shifting of the saw guide.) Reapply the drill guide and drill hole #4.

Be sure that the saw guide remains centered on the ulna. Measure and tap screw hole #4 and apply an appropriate length 3.5 mm screw.

Once the saw guide is firmly attached, drill and tap screws #1 and #3 and apply the appropriately sized screw.

CAUTION Do not overtighten these screws to avoid stripping of the 2.5 mm hexagonal recess in the screw head upon removal. (See Step 4)

NOTE 2.7 mm and 3.5 mm stainless steel or titanium screws, drill bits and taps are **not provided with the rental sets.** Standard operating room equipment including mini fragment and small fragment sets will need to be used in conjunction with the rental equipment. The appropriate saw will also be needed. (See Step 4)

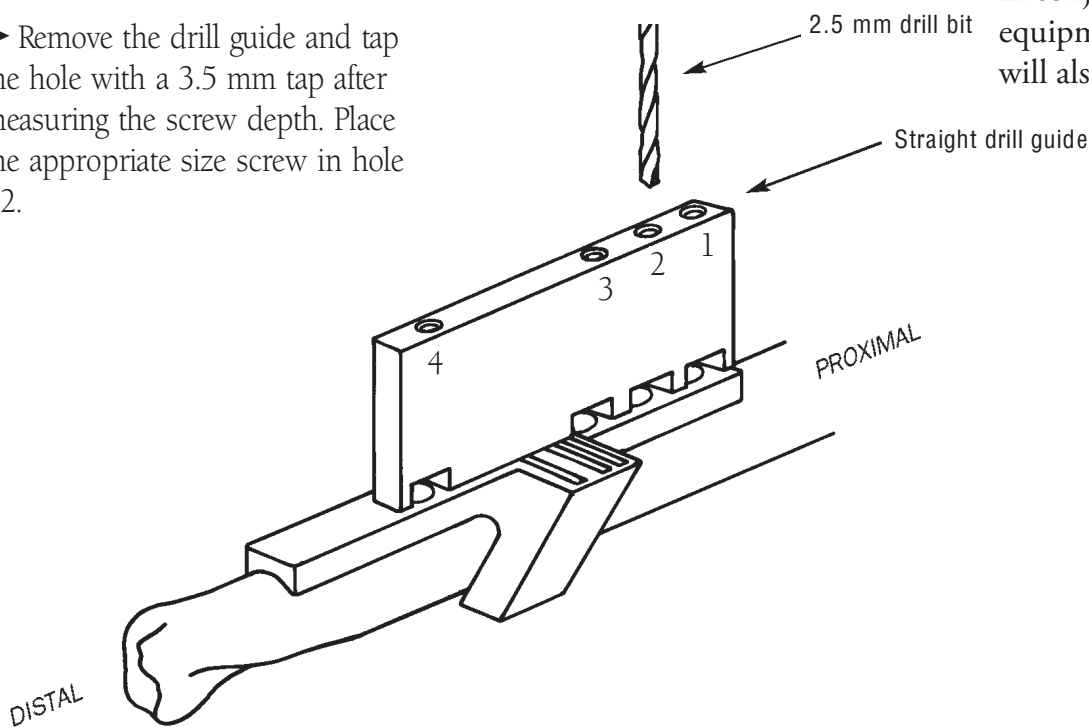


FIG. 2

STEP 3

Width of the Ulnar Osteotomy and Anticipated Linear Shortening

The stated distances between the slots are measured perpendicular to the osteotomy surfaces and represent the actual machined distances in the saw guide. The theoretical linear shortening of the bone; calculated as the hypotenuse of the right triangle is this perpendicular measurement times the square root of 2: (1.414).

Clinical experience has shown that the mathematically possible bone shortening (hypotenuse) is nearly achieved. The surgeon should be aware that due to various clinical factors (amount of plate pre-bending, use of the specified saw blade, degree of linear compression, etc.) the actual amount of bone shortening will be between the stated perpendicular distance between the slots as built into the saw guide and the calculated distance representing the hypotenuse, **but will be fairly close to the hypotenuse in length.**

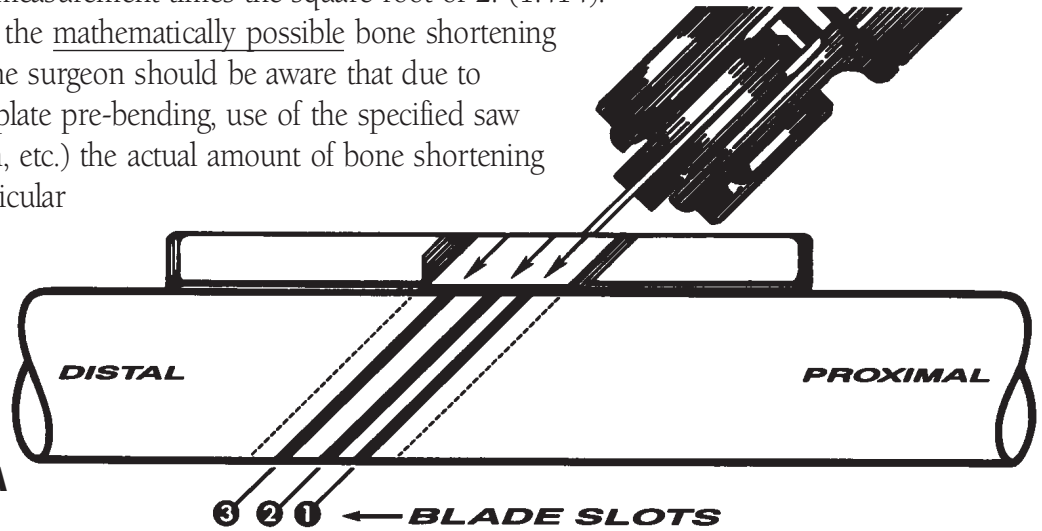


FIG. 3A

OSTEOTOMY WIDTH (Perpendicular to Osteotomy)	HYPOTENUSE (Theoretical Linear Shortening)
Slots 1-2 2.5 mm	3.5 mm
Slots 2-3 3.5 mm	4.9 mm
Slots 1-3 5.25 mm	7.4 mm

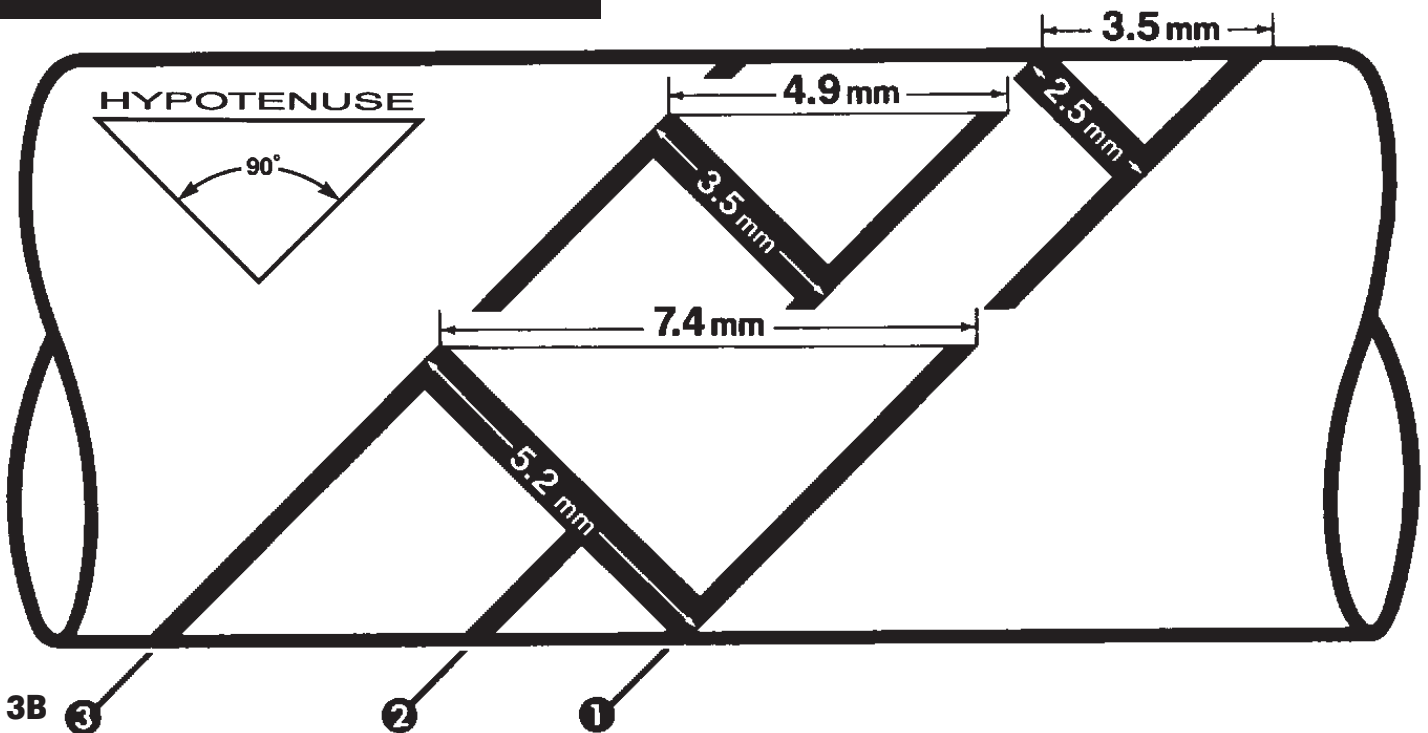


FIG. 3B

STEP

4

Performing the Oblique Ulnar Shortening Osteotomy

The osteotomy is most easily performed by flexing the elbow 110° with the forearm held vertically while aiming the saw blade at a 45° angle toward the ceiling. Once the amount of bone to be removed is determined, the appropriate slots to be used are chosen according to Step 3 on the previous page. For osteotomies greater than 7.4 mm, please see Step 10.

It is imperative for the distal osteotomy cut to be made first, then the proximal. Failure to follow this order may result in non-parallel bone cuts.

CAUTION It is important to protect all soft tissues from the cutting area. Periosteum must be stripped circumferentially at the osteotomy site only. **It is important to irrigate with sterile slush to cool the bone** during the cutting procedures in order to minimize bone necrosis.

NOTE: Only use a HALL®, MICROAIRE® or LINVATEC® sagittal saw with the specialized saw blade

provided in the RAYHACK® OSTEOTOMY SYSTEMS' TRAY.

CAUTION Never pass the saw blade's first marked line:

"ULNAR MAX DEPTH" beyond the top surface of the saw guide. If the ulna is excessively large, pass this saw blade line with utmost care.

NOTE: Consult www.rayhack.com/instrumentation.htm for detailed saw descriptions.

Use of an inappropriate saw blade may damage the saw guide and may result in inaccurate osteotomy cuts.

CAUTION Never pass the saw guide beyond the marked line. Failure to pay strict attention to this detail, may result in soft tissue and bone damage.

Once both osteotomy cuts are made, all screws are removed and placed in the appropriately numbered temporary holding slots in the tray.

CAUTION In removing the ulnar saw guide there may be a great deal of tension on the screws. This is partly increased by the conforming of the straight saw guide to the convex surface of the ulna. **Be sure to carefully apply the screwdriver to avoid stripping of the 2.5 mm hexagonal slot in the screw head, and provide counter pressure to the radial forearm when removing the screw.**

If the screw head socket becomes "stripped" and the saw guide cannot be removed it may be necessary to carefully remove the screw head with Midas Rex instrumentation (Creative Medical Designs, Inc. does not provide this instrumentation).

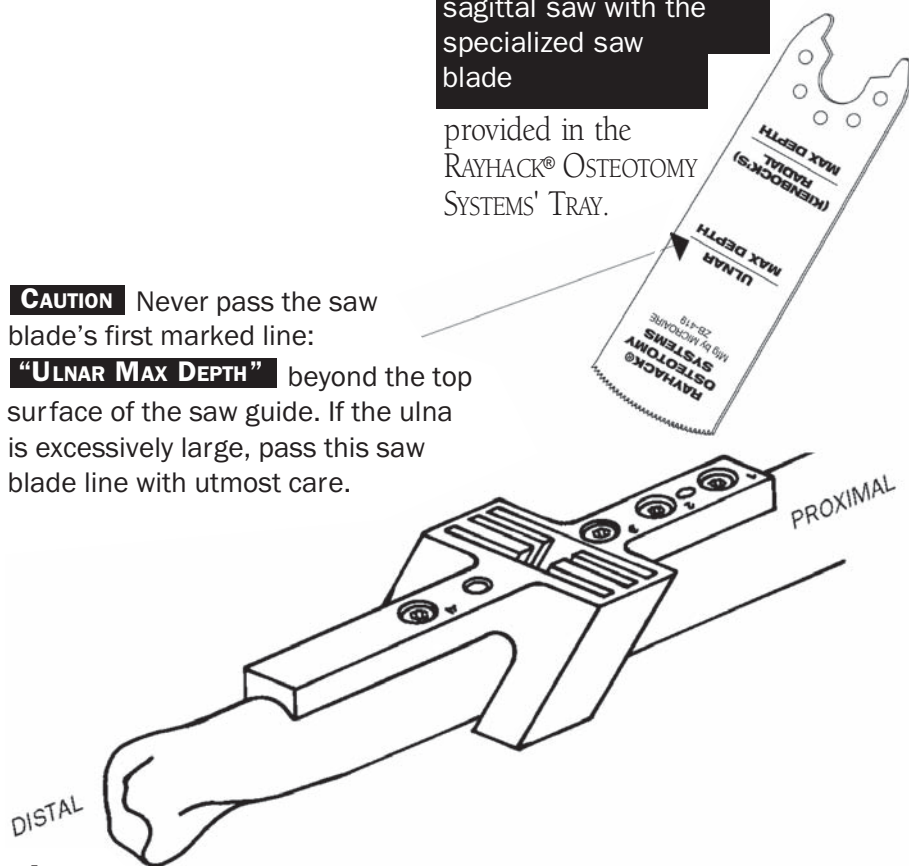


FIG. 4

STEP

5

Ulnar Bone Plate Fixation

► In most cases the ulna will be slightly convex and, the specialized plate (packaged non sterile) should be pre-bent to this shape prior to its application on the ulna. Bending of the plate is facilitated by using the specialized RAYHACK® OSTEOTOMY SYSTEMS' pass through™ plate benders. The unique pass through™ slots in the plate benders will help minimize plate scratching .

NOTE Some surgeons may prefer to contour the plate to the ulna once it has been exposed and before the saw guide is applied. (See Step 1)

► Be sure not to “torque” the plate along its longitudinal axis while applying the pre-bend. The mid portion of the plate should be 1 to 2 mm off of a flat surface once the bending has been accomplished.

► Pre-bending the plate in this manner will help to avoid separation due to a “tension effect” on the osteotomy surfaces which are closest to the interosseous membrane. If this separation is noted during compression of the osteotomy (step 6) the surgeon should consider additional pre-bending of the plate and/or loosening of screw #4.

NOTE The elongated slot in the plate is positioned distally.

► Fix the plate by reapplying screws #1 and #2 respectively taken from the temporary holding slots in the tray.

The ulnar plate is available in stainless steel or titanium. Unless specified otherwise the stainless steel plate will be provided .

NOTE Only use screws made of the same material as the plate.

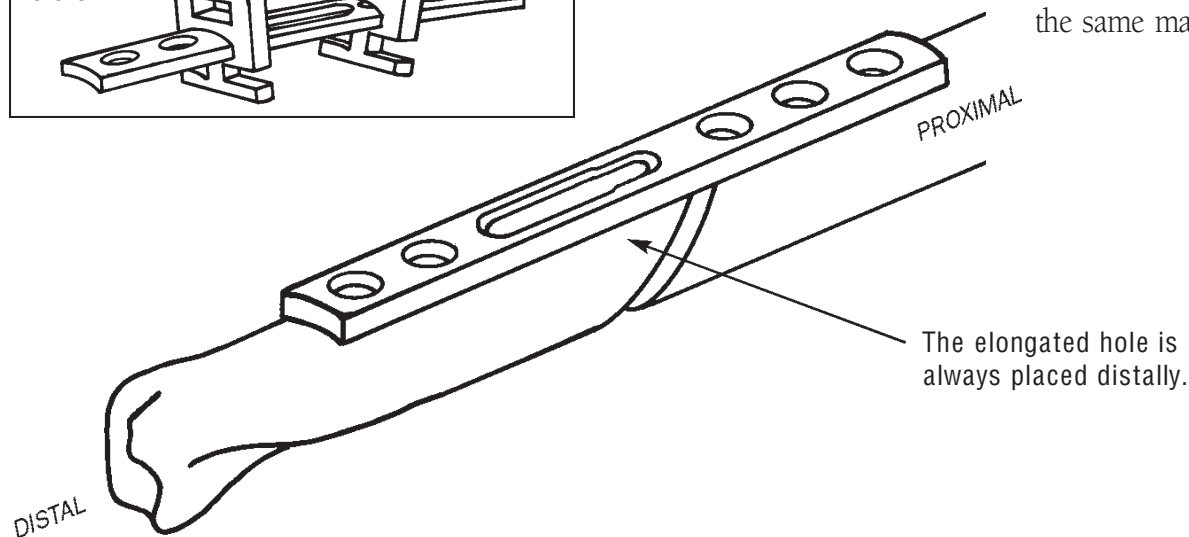
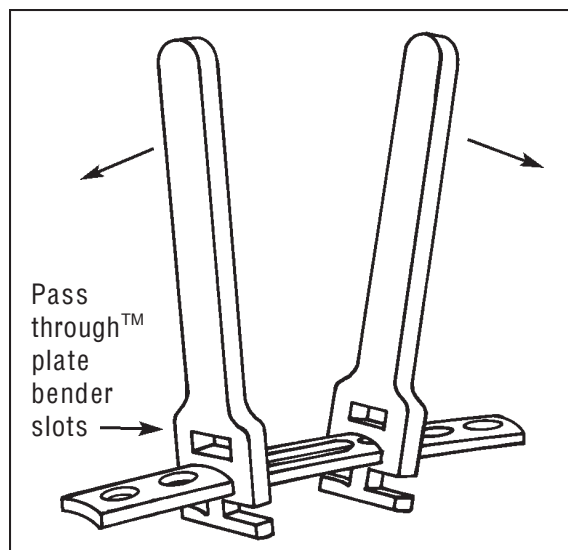


FIG. 5

STEP 6 Application of the Compression-Distraction Device and Compression of the Osteotomy

- Locate the compression-distraction device on the plate over the osteotomy site. Using two additional 3.5 mm cortical screws, fix the compression device through holes #3 and #4 as shown.
- These two additional temporary screws are 4.0 mm longer than the measured length of screws #3 and #4 that were used to hold the saw guide.

NOTE: Make sure that the screw #4 at the distal end of the elongated slot of the plate is slightly loose and is free to move proximally along the slot.

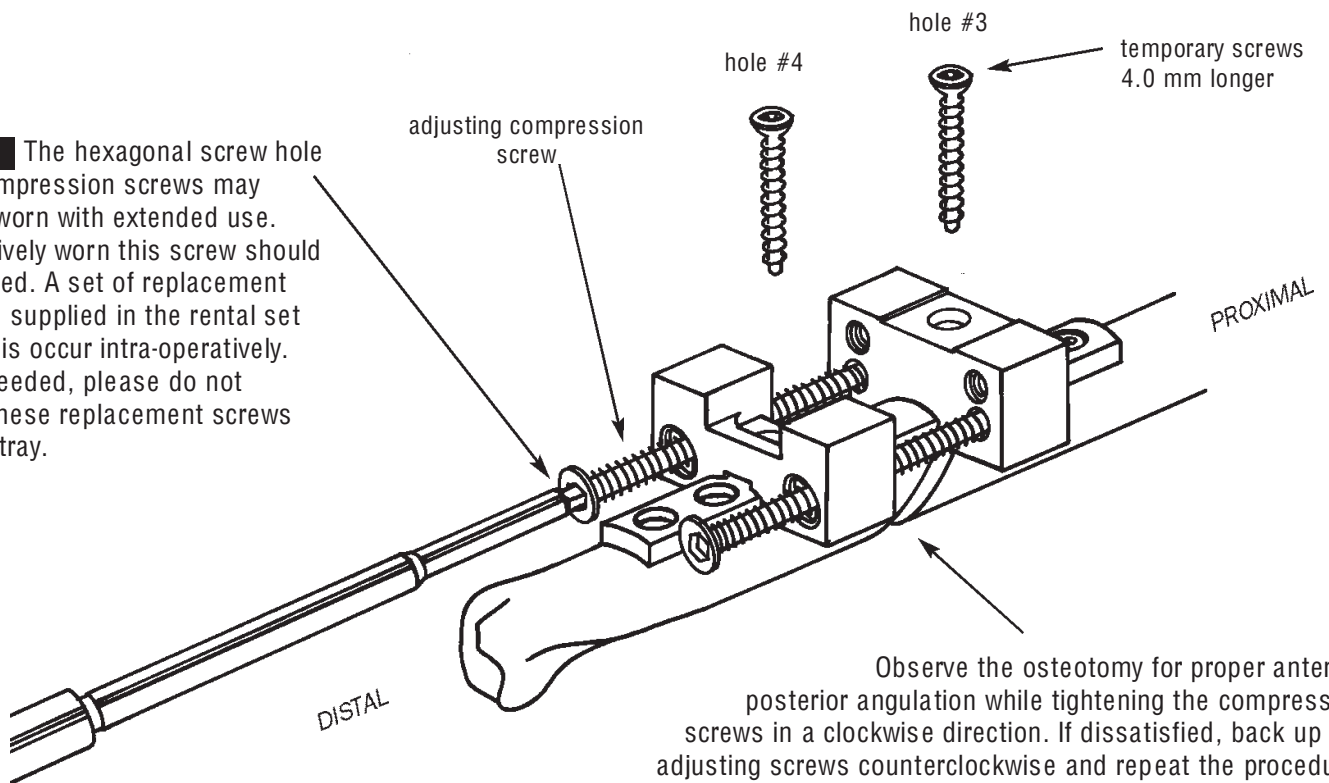
- It may be easier to apply the screw in hole #4 first and then apply screw #3.
- Observe the osteotomy surface while tightening the adjusting screws. Alternate between the two

adjusting screws to provide even compression.

- Once the osteotomy surfaces are visually well approximated on both sides, stop further compression.

CAUTION Over compression will only bend the temporary screws in holes #3 and #4 and will not further compress the osteotomy surfaces.

NOTE The hexagonal screw hole in the compression screws may become worn with extended use. If excessively worn this screw should be replaced. A set of replacement screws is supplied in the rental set should this occur intra-operatively. Unless needed, please do not remove these replacement screws from the tray.



Observe the osteotomy for proper anterior-posterior angulation while tightening the compression screws in a clockwise direction. If dissatisfied, back up the adjusting screws counterclockwise and repeat the procedure. If the osteotomy appears to be separating on the opposite cortex (interosseous surface), loosen the adjusting screws in the compression-distraction device and try loosening cortical screw #4 in the slotted hole and recompress the osteotomy. If this still results in separation of the osteotomy, consider prebending the plate an additional small amount.

FIG. 6 * Compression-Distraction Device
U.S. Patent # 4,929,247

STEP 7

Drilling the 22 Degree Interfragmentary Lag Screw Hole

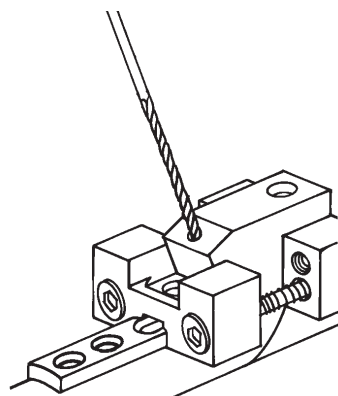
Place the angled drill guide on the fixed proximal block of the compression-distraction device once the osteotomy surface has been compressed. Press the drill guide firmly on to the fixed block to ensure that the guide is in position prior to drilling the interfragmentary screw hole. The angled drill guide should be seated down on the fixed block and manually held firmly in place.

IMPORTANT Before drilling with the 2.7 mm drill bit the surgeon should visually confirm that the drill bit when placed in the angled drill guide appears to properly transect the osteotomy. If not, the surgeon should consider a "free-hand" drilling of this 2.7 mm first hole.

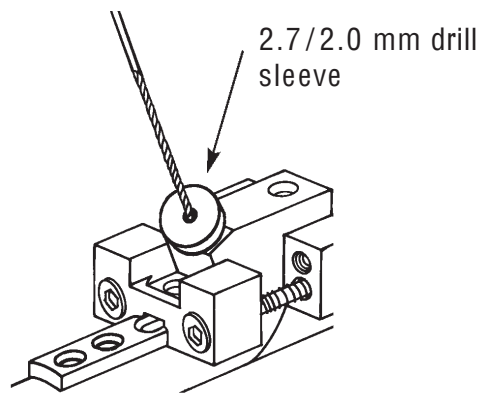
A. Drill the first cortex with a 2.7 mm drill bit.

B. Apply the drill sleeve through the angled drill guide and first cortex, and drill the opposite cortex with the 2.0 mm drill bit in the mini-fragment set. Measure the depth of the hole.

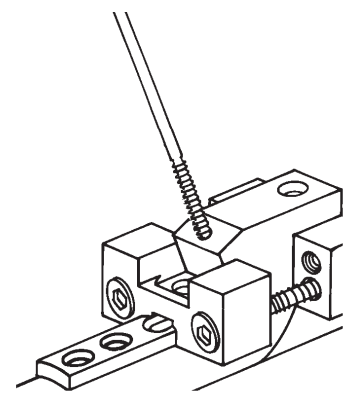
C. Reapply the angled drill guide and tap the far cortex with a 2.7 mm tap—(reapplication of the angled drill guide helps guide the tap to the opposite cortex).



(A) 2.7 mm drill bit



(B) 2.0 mm drill bit



(C) 2.7 mm tap

NOTE If the surgeon feels that the interfragmentary screw will not "capture" enough cortical bone on the tapped (far) side of the hole when the angled drill guide is used, (for example in a very narrow ulna) or that it does not fall within the desired site of the osteotomy, a **free hand** drilling technique may be substituted.

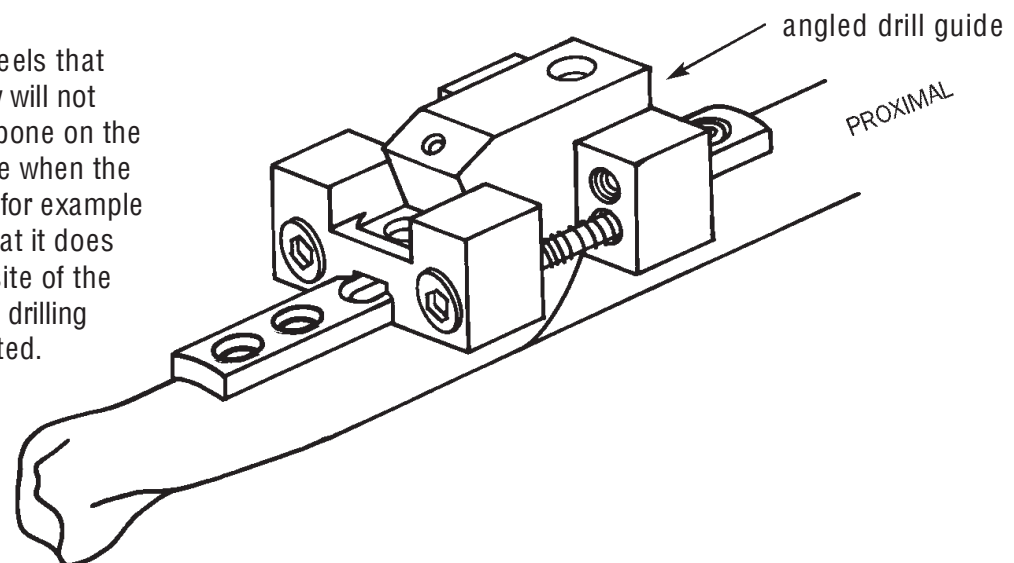


FIG. 7

STEP 8

Oblique 2.7 mm Interfragmentary Lag Screw Application

Insert the appropriately sized 2.7 mm interfragmentary cortical screw from the mini fragment set and gently tighten.

CAUTION Do not over tighten as this may crack the cortical bone.

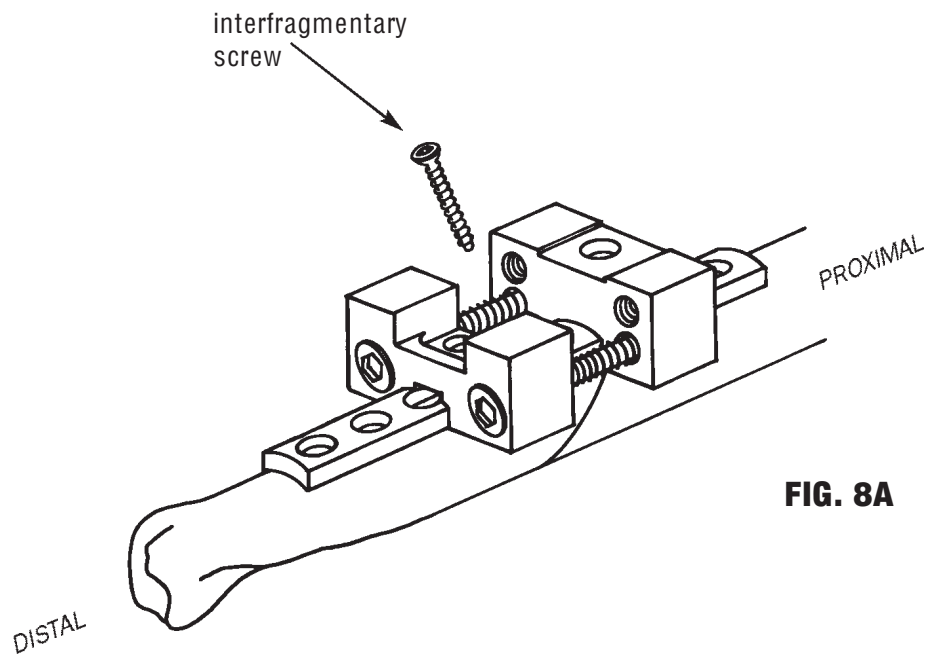


FIG. 8A

Complete the fixation of the plate by drilling the two distal screws (#5 and #6) using the RAYHACK® OSTEOTOMY SYSTEMS' hand-held drill guide. Measure and tap the holes and insert two 3.5 mm cortical bone screws of appropriate size.

NOTE As in the first four screws used to fix the saw guide (step 4) some surgeons elect to add 2 mm to the length of the measured screws to assure screw capture of the far cortex.

NOTE Do not remove or loosen the compression-distraction device until the interfragmentary screw and cortical screws #5 and #6 have been securely tightened.

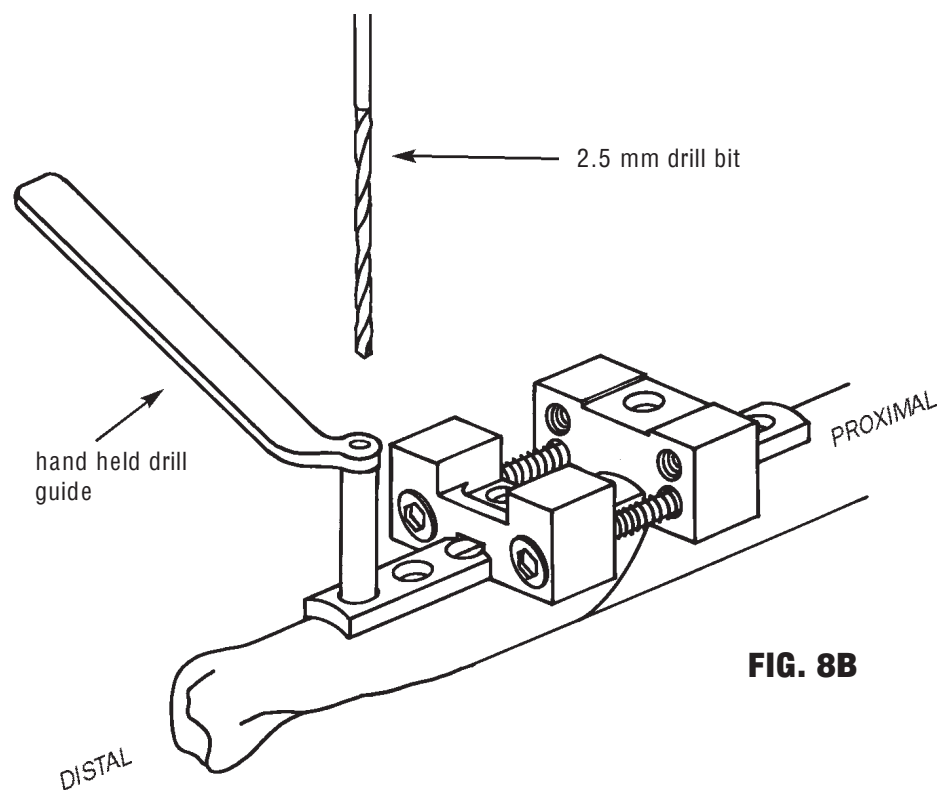


FIG. 8B

STEP

9

Final Fixation of the Osteotomy

Remove the compression-distraction device by loosening the compression screws and then removing temporary screws #3 and #4. Replace the appropriate original cortical screws #3 and #4 from the temporary holding slots in the tray. **DISCARD THE TEMPORARY FIXATION SCREWS** used to hold the compression distraction device.

CAUTION Do not reinsert the temporary fixation screws that were used to hold the compression-distraction device (these temporary screws are 4 mm longer than the measured hole and were used solely to fix the compression-distraction device). Make sure all screws are tight.

CAUTION Do not over-tighten to avoid thread stripping of the tapped bone hole.

NOTE: With the plate slot narrowed at the site of the interfragmentary screw placement, it is not possible to place a 3.5 mm cortical interfragmentary screw without the head protruding above the plate

replace original bone screws

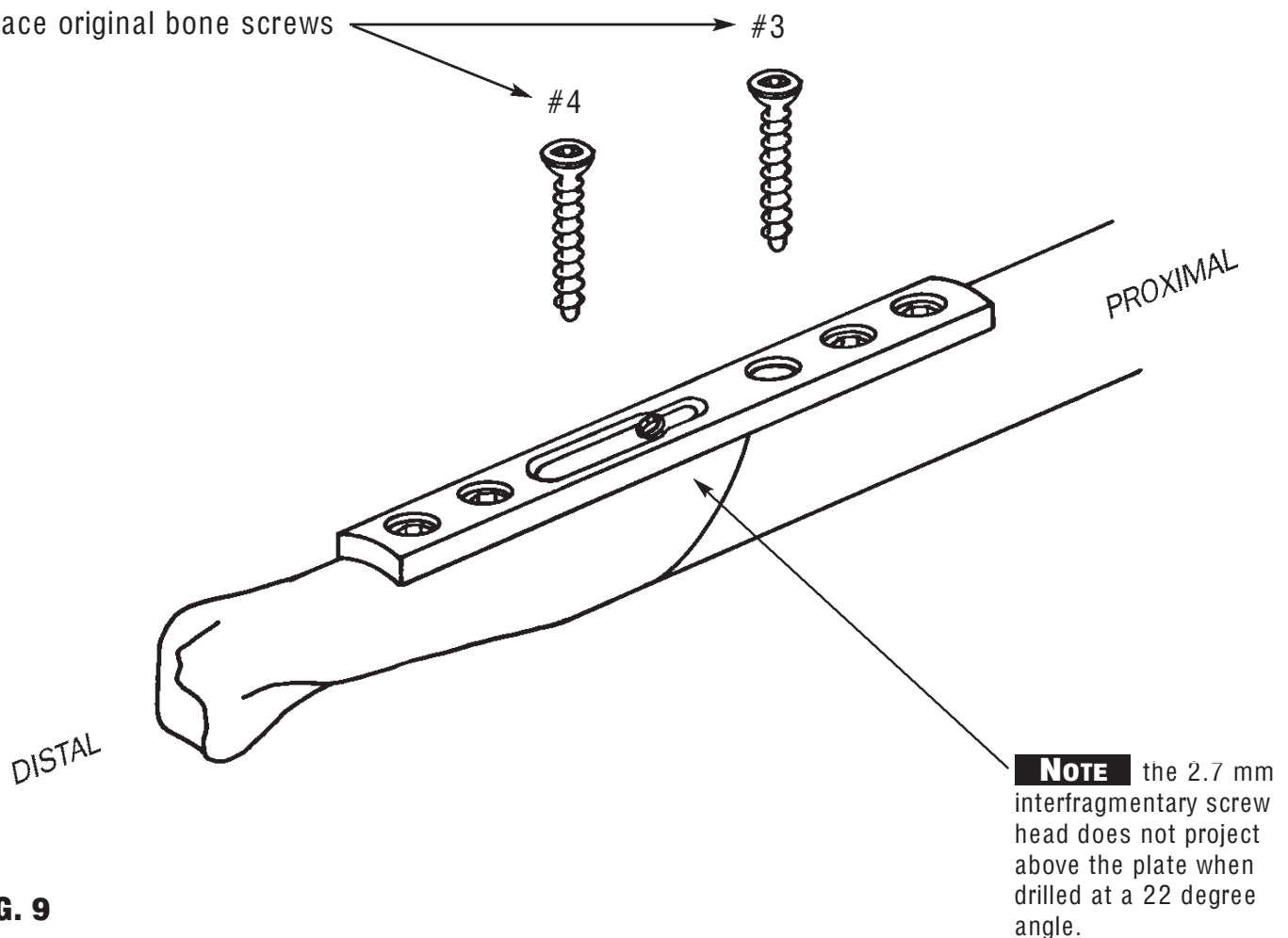


FIG. 9

STEP 10

Osteotomies in excess of 7.4 mm

Occasionally an ulna may be excessively long and require an osteotomy in excess of 7.4 mm. It is possible to use the RAYHACK® OSTEOTOMY SYSTEM to perform this osteotomy. This requires slightly more time and continued strict adherence to specific details. As the osteotomy width becomes larger, the technical demands of approximating the osteotomy may become even greater with the excessive tension exerted by the soft tissues attached to the distal fragment. Use of the compression-distraction device to approximate the osteotomy is particularly helpful in this regard.

It is recommended that any surgeon contemplating such an osteotomy contact Creative Medical Designs, Inc. with any questions or concerns prior to the procedure.

PLEASE NOTE As in the standard osteotomies described in Step 3, there is a difference between the measured perpendicular osteotomy distances and the theoretical linear shortening. **This difference is especially marked in osteotomies greater than 7.4 mm as shown in the chart below.** The stated distances between the slots are measured perpendicular to the osteotomy surfaces and represent the actual machined distances in

the saw guide. The theoretical linear shortening of the bone; calculated as the hypotenuse of the right triangle is this perpendicular measurement times the square root of 2: (1.414). **Clinical experience has**

shown that the amount of bone shortening will be very close (within 1 mm) to the calculated linear shortening (hypotenuse).

The surgeon should be aware that due to various clinical factors (the amount of plate pre-bending, use of the specified saw blade, degree of linear compression) the actual degree of ulnar shortening will vary slightly but will **closely approach the calculated hypotenuse.**

OSTEOTOMY WIDTH (Perpendicular to Osteotomy)	HYPOTENUSE (Theoretical Linear Shortening)
F: 6.4 mm	6: 9.1 mm
G: 8.3 mm	7: 11.7 mm
H: 10.1 mm	8: 14.2 mm
I: 11.0 mm	9: 15.5 mm
J: 12.8 mm	10: 18.1 mm

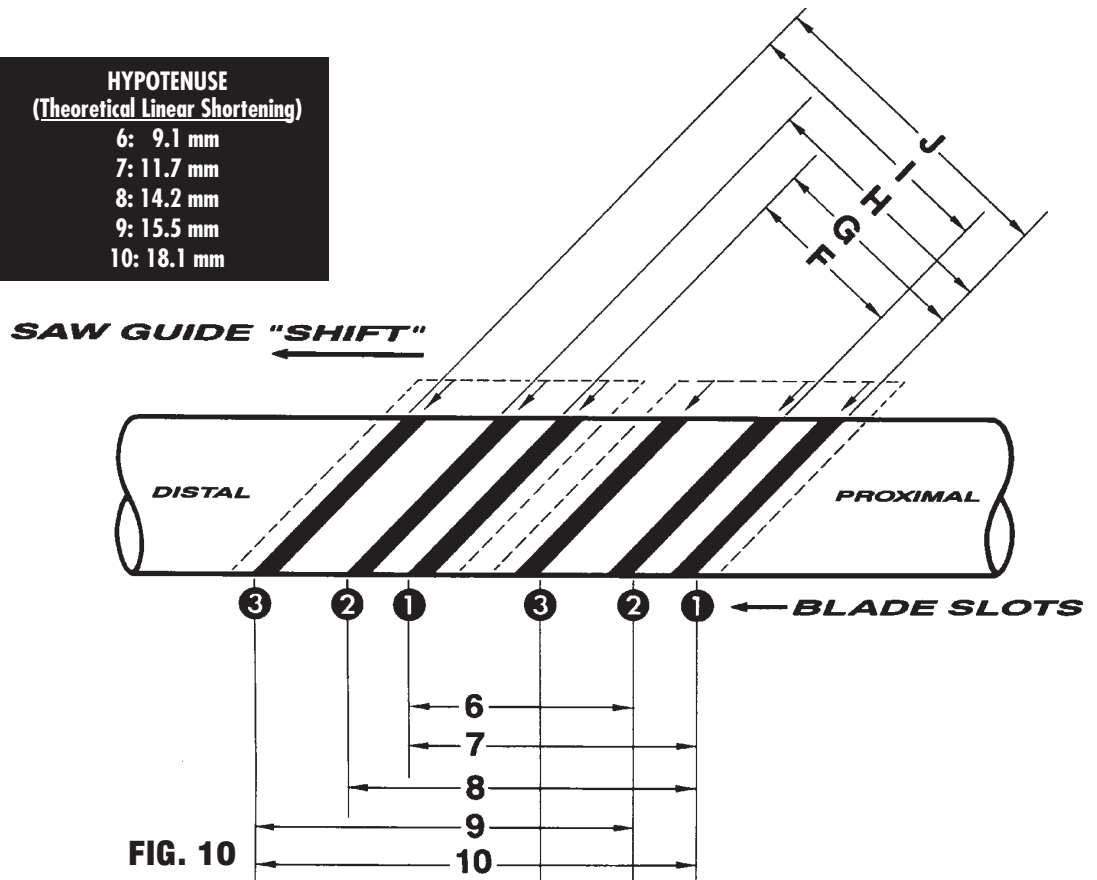


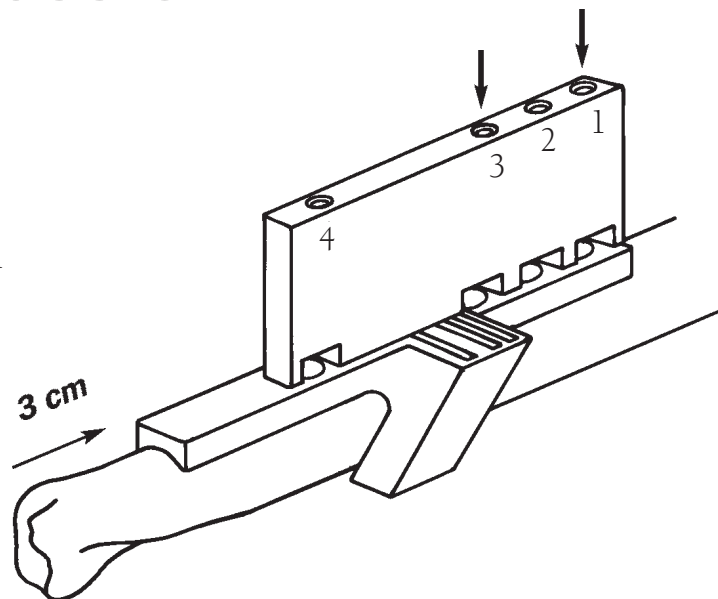
FIG. 10

STEP 10 Osteotomies in excess of 7.4 mm

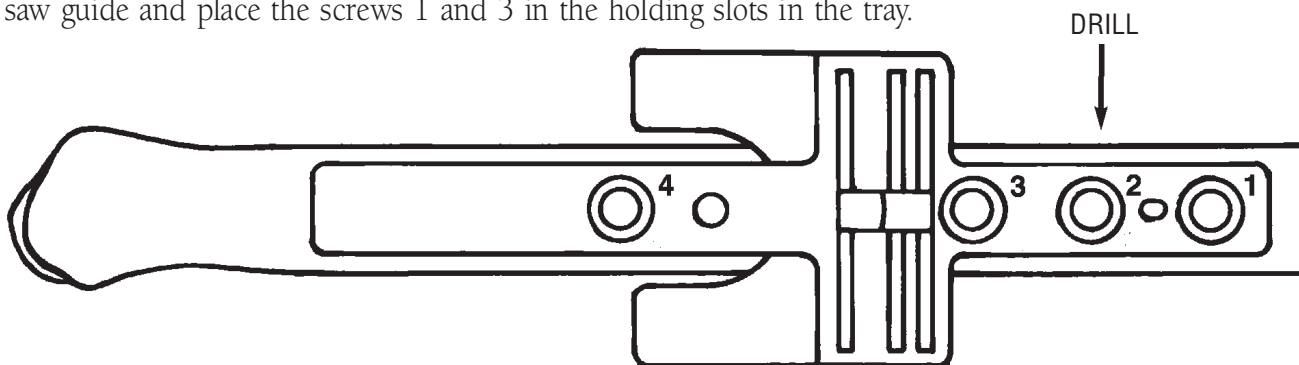
DETAILS

A **APPLY** the saw guide on the ulna about 1cm more proximal than normal to allow for an osteotomy in excess of 7.4 mm

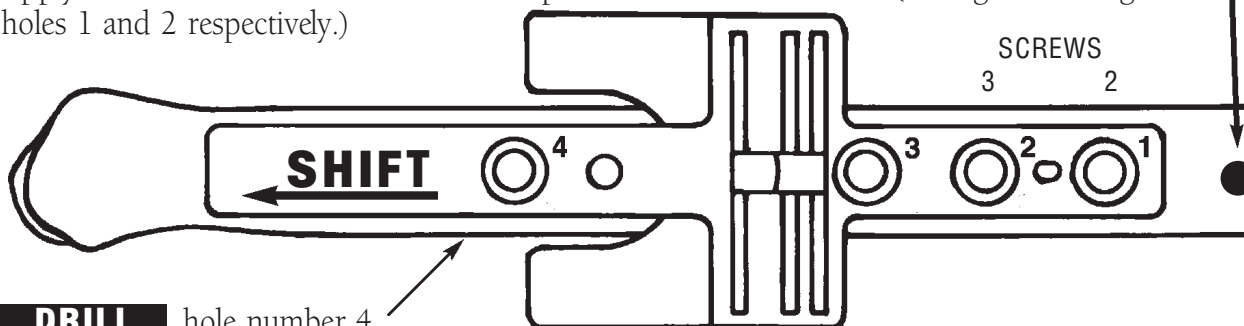
DRILL proximal screw holes number 1, and 3 with the straight drill guide. Measure and tap these screw holes and apply 3.5 mm cortical screws. Apply one screw before drilling the second hole.



DRILL hole number 2 with the straight drill guide. **MEASURE, TAP AND RECORD** the screw length but do **not** apply the screw, instead, place this screw in the holding slot in the tray. Remove the saw guide and place the screws 1 and 3 in the holding slots in the tray.



B **SHIFT** the saw guide one hole distally so that the most proximal screw hole is uncovered. Apply screws number 2 and 3 in their respective holes in the radius. (through the saw guide holes 1 and 2 respectively.)



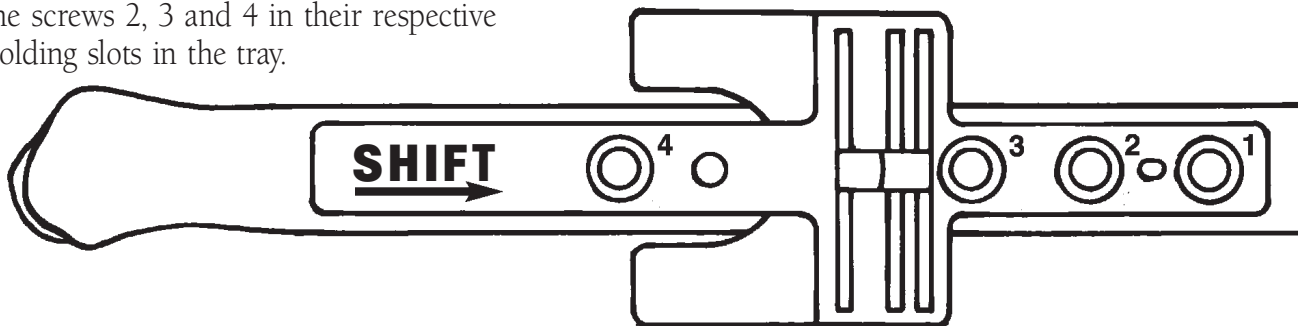
DRILL hole number 4 with the straight drill guide through saw guide hole number 4.

C **CUT** in the saw guide slot chosen for the intended osteotomy according to the chart on page 10; for example, slot number one (the most proximal) for an intended osteotomy of 9.1mm.

STEP 10 Osteotomies in excess of 7.4 mm

DETAILS

- D** **REMOVE** the saw guide and place the screws 2, 3 and 4 in their respective holding slots in the tray.

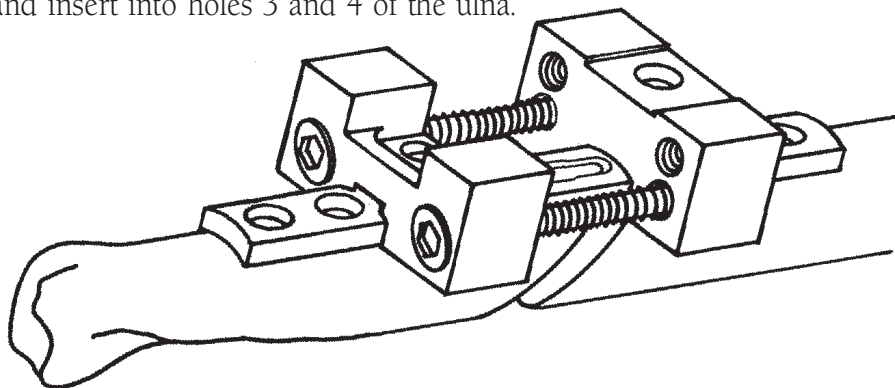


- E** **SHIFT** the saw guide back to its original position. Reapply screws number 1, 2 and 3 through holes 1, 2 and 3 of the saw guide.

PICK the intended slot for the proximal osteotomy saw cut according to the chart. For a 9.1mm osteotomy this would be slot number 2 (Note that cutting through slot number 1 would create an 11.7 mm osteotomy). Prior to performing the osteotomy, place the saw blade down the intended slot and with a ruler measure from the ulnar cut surface to the saw blade. This measurement should approximate the intended length of the osteotomy shortening.

- F** **REMOVE** the saw guide and replace the screws in their respective holding slots in the tray. Remove the intervening bone fragment. Pre-bend the ulnar plate as per the usual routine. Apply the ulnar plate and screws 1 and 2.

- G** **APPLY** the compression device over the plate with screws that are 4 mm longer than original screws 3 and 4 and insert into holes 3 and 4 of the ulna.



NOTE: It may be necessary to grasp the distal ulna with a towel clip to pull it proximally to visualize screw hole number 4 in the distal aspect of the ulnar plate slot. If this is still inaccessible, free hand a parallel screw hole 3 mm proximal to the hole number 4 and use this hole for screw number 4 to compress the osteotomy.

COMPRESS the osteotomy and proceed as per the usual routine for standard ulnar shortening osteotomies.

STEP 11

Intraoperative X-Rays

To visualize the osteotomy surface, it is advisable to obtain two x-rays: one AP forearm in supination or 30 degrees short of full supina-

tion and one PA forearm in pronation. This will usually permit a true frontal and lateral view of the plate and osteotomy. Any

screws deemed to be excessively long or too short may be replaced.

STEP 12

Post Operative Care

Surgeons Please Note

In most cases a volar and dorsal plaster splint can be used to immobilize the forearm until the sutures are removed at two weeks post surgery. Most patients can be placed in a short arm removable thermoplastic splint at this time and

protected until fracture healing has occurred. In those patients who are felt to have reckless tendencies, it is recommended that a sugar tong splint be applied at surgery and a short or long arm cast applied at the two week follow-

up appointment. This can be converted to a thermoplastic splint when the surgeon is convinced that healing is satisfactory.

No activity against resistance is permitted until bone healing has occurred.

WARNING

Plate breakage can occur if the patient remains unprotected prior to bone healing. Immediate unprotected extremity use post surgery is **contraindicated.** In case of delayed union or non-union appropriate corrective measures must be taken by the surgeon to avoid plate breakage and loss of bone fixation.

DELAYED UNION

A delayed union may occur on occasion. As long as no screw "toggle" or "backing out" occurs, the osteotomy will usually heal if

adequately protected. If excessive callus appears or if any longitudinal plate bending occurs, or if screw loosening is noted, the surgeon

should consider additional extended protection of the extremity or surgical intervention with replating and/or bone grafting.

STEP 13

Care and Cleaning of the Instruments

The used saw blade may be manually placed in the saw guide slots in order to remove any bone debris.

Visually inspect these slots to make sure that these slots are completely clean by looking down the slot at a light surface. Clean any bone debris from the other instruments.

ULTRASONIC cleaning is advised to remove any remaining bone debris. Sterilize the tray and instruments.

CAUTION: It is important to clean and thoroughly dry all instruments before replacing in the tray.

Any rust spots that may appear may be lightly buffed using Scotch-Brite™.

The tray cover is locked into position by pushing down on the button located on the cover and pushing this toward the top of the tray.

NOTE: If the adjusting screws are removed from the compression device during cleaning be sure to realign the components properly with screw reinsertion.

DISCARD the used saw blade in an appropriate biohazardous container.

DISCARD the temporary screws used to fix the compression-distraction device through holes #3 and #4.

Scotch-Brite is a registered trademark of the 3M Corporation.

Return of Instruments for Rental Users

Enclose the "RETURNED GOODS STERILIZATION FORM" with the instruments and place a copy in the packing slip envelope and apply to the outside of the express package.

Please return the equipment by Federal Express or other next day carrier immediately following surgery. Please have your office personnel check with your surgical service or hospital shipping and

receiving department to ensure that this important function has been properly performed.

Thank you.



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