INTRODUCING

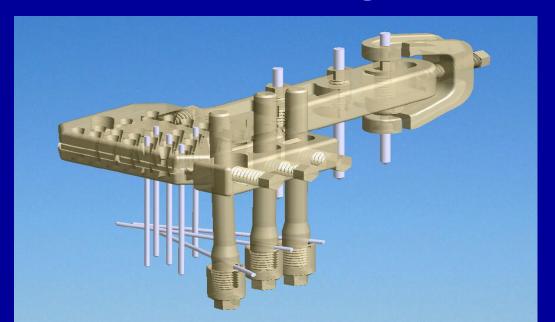


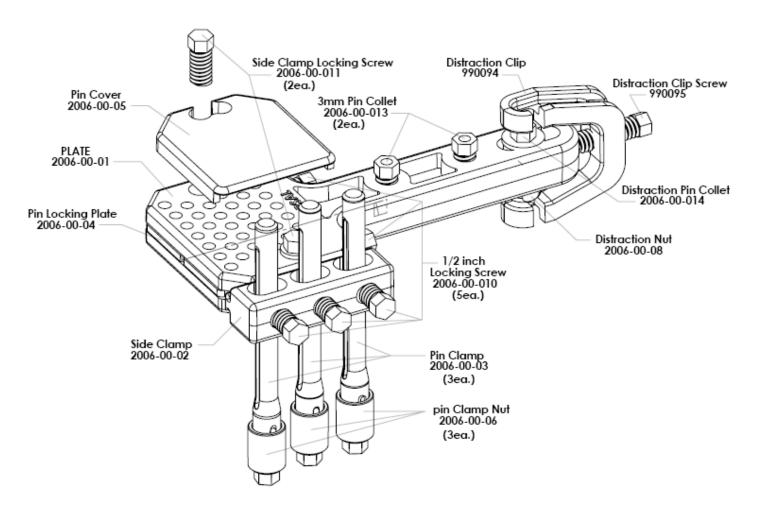
The Non-Bridging eXternal Wrist Fixator System and First Assistant™ Wrist Reduction Device



The NBX Non-Bridging External Fixator

A Non-Bridging External Fixator/Locking Plate capturing a series of .062mm K-wires and 3mm half-pins that are inserted in a multiplanar and multi-directional fashion providing an interlocking matrix securing ALL fracture fragments.

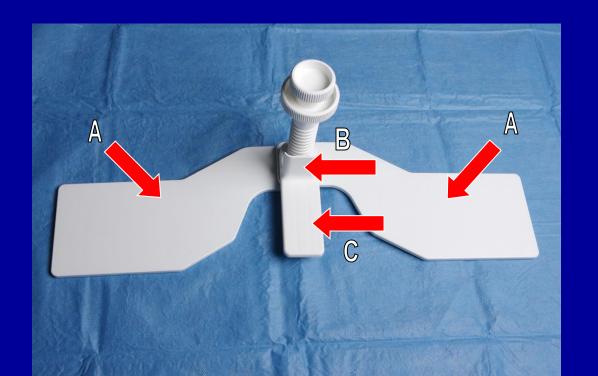




			Checks/Verifications		SHEET of	NuTek Orthopaedics	
			Drafting	Date:	SCALE	TITLE: NBX WRIST FIXATOR SYSTEM	Rev. 0
Α	PRODUCTION RELEASE		Engineering	Date:	UNITS	Material: POLYCARBONATE Finish:	
0	INITIAL RELEASE		Manufacturing	Date:	TOL X.X +/1 X.XX +/01	ASSEMBLY - Reference Only Prawing Number	
Rev	REVISION NUMBER		Quality	Date:	X.XXX +/005	Drawn by: LMM Date: 12-26-06 8006-0	00-00

The First Assistant Wrist Reduction Device

Two radiolucent plastic paddles or arms (A) that articulate at the wrist joint and allow for ulnar deviation and ligamentotaxis of the wrist, coupled with an ulnar buttress post (B) and volar lift arm (C) that helps recreate and maintain anatomic reduction of the wrist fracture.



Patient Positioning

The patient can be positioned one of two ways:

lateral with the operative arm up and extended off the table

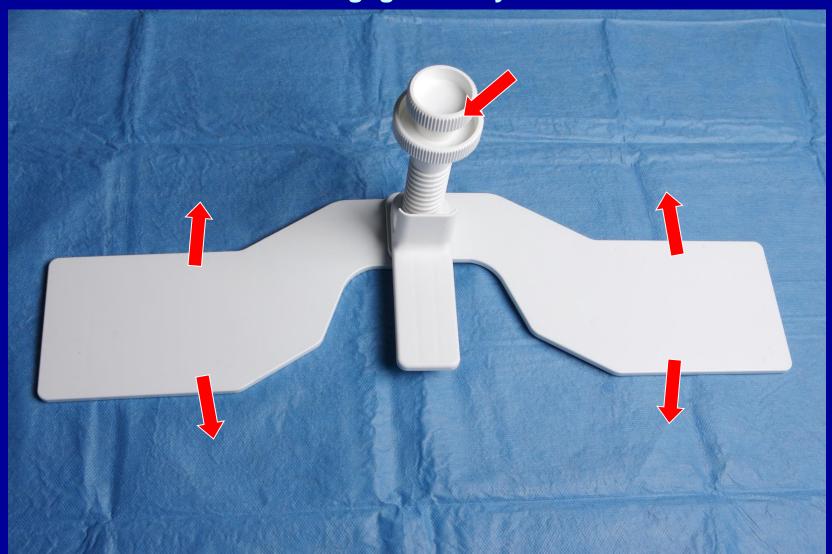
or

in a 'beach chair' position with the operative side and arm at/over the edge of the table

The key is make sure that the forearm is in a neutral position

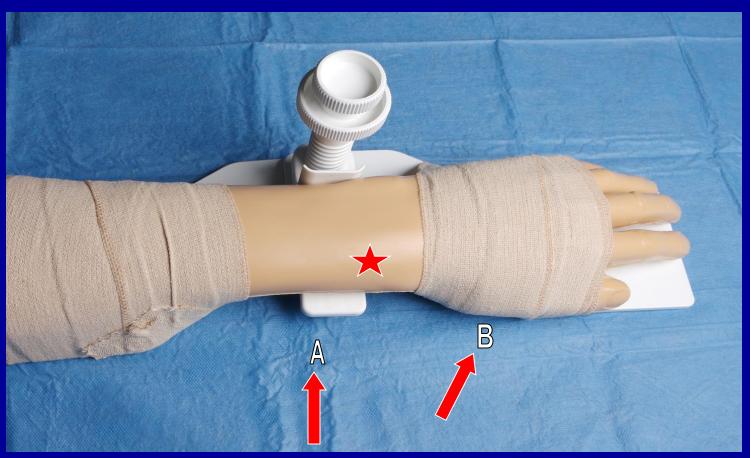
The surgeon can then simply place a sterile drape over the c-arm and use it as the "table" or use a hand table and bring the c-arm in as needed.

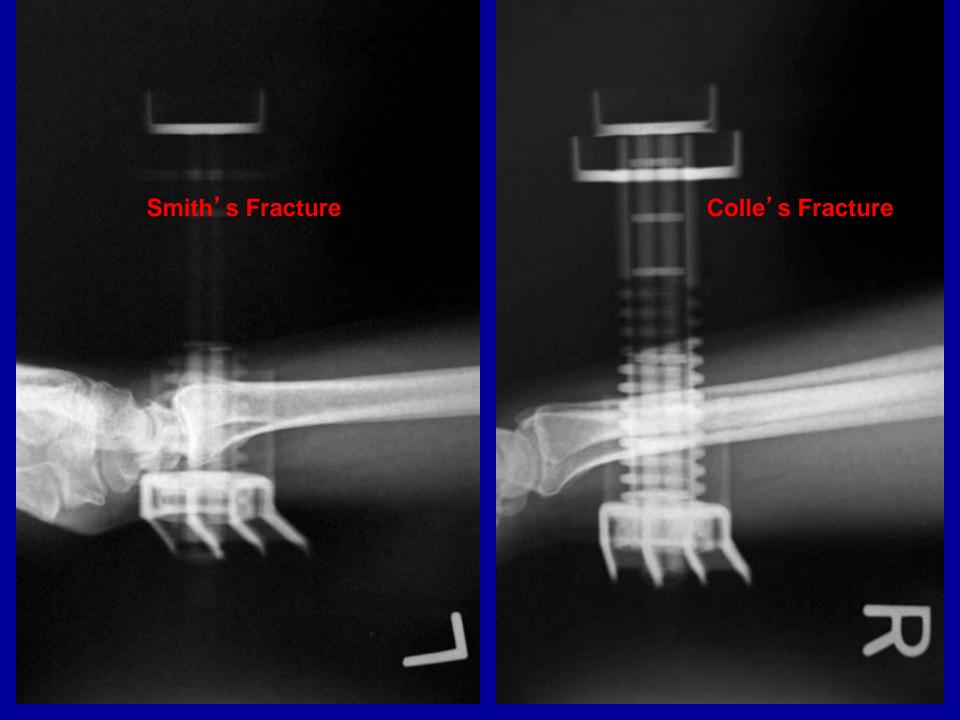
Assemble the First Assistant fracture reduction device by threading the center post through the hinge, leaving the connection loose enough to manipulate both paddles. The teeth on the underside and top side of the paddles should engage loosely.



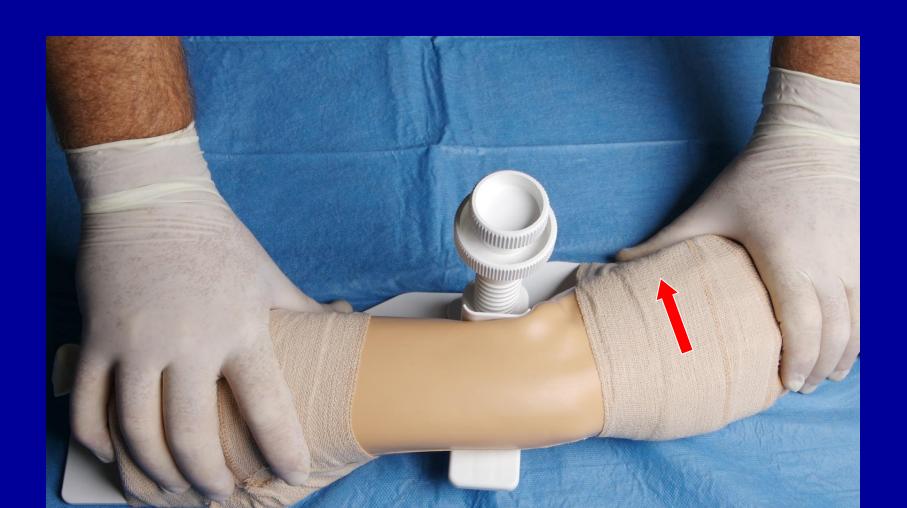
Position the hand on the First Assistant with the radial side away from the center post and lift arm beneath the shaft of the distal radius (A) proximal to the fracture for a Colles Fracture and underneath the fracture for a Smith's fracture.

Secure the forearm and hand to the two arms of the reduction device with Coban, making sure to capture the base of the thumb (B).





Reduce the fracture by ligamentotaxis, pulling the hand into ulnar deviation to re-establish radial height (9mm +/- 2mm) and inclination (22-24 degrees).



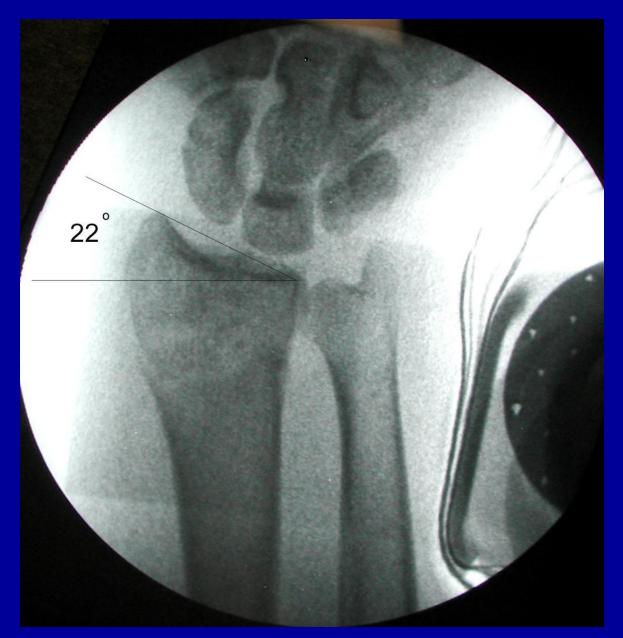
Secure the reduction in ulnar deviation by tightening the TOP knob to lock the arms of the First Assistant in place.



Turn the lower knob on the center post clockwise to elevate the distal end of the radial shaft proximal to the fracture for a Colles fracture, and the distal portion of the radius in a Smith's fracture, to restore volar tilt.

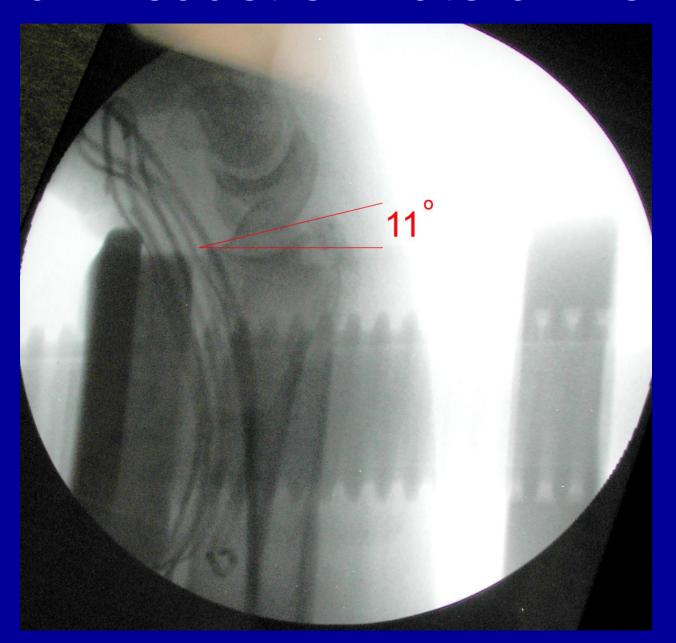


Full Reduction AP View





Full Reduction Lateral View



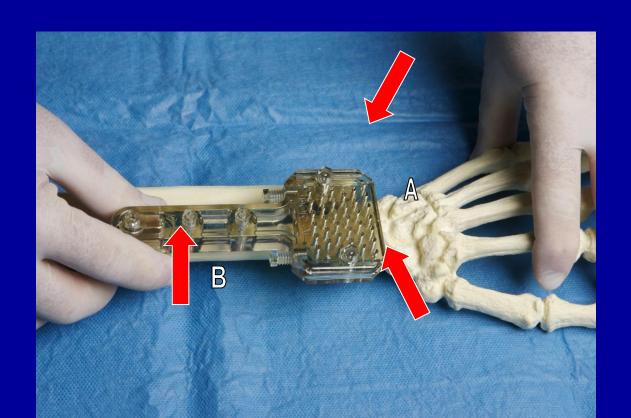


X-Ray Tips

Remember the anatomy and orient the fluoroscopy accordingly:

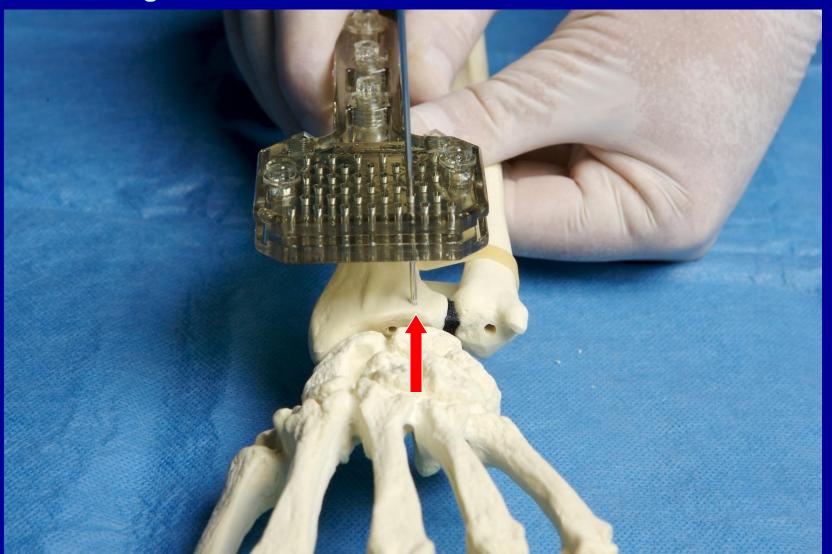
Volar tilt averages 11-12 degrees
Radial inclination averages 22-24 degrees
Radial height averages 9mm +/- 2mm

Position the NBX fixator body over the distal radius to act as a template for the insertion of all K-wires and half-pins, with the distal row of holes over the radial styloid and parallel to the joint covering the fracture site (A), making sure that the proximal arm is centered over the shaft of the radius (B),



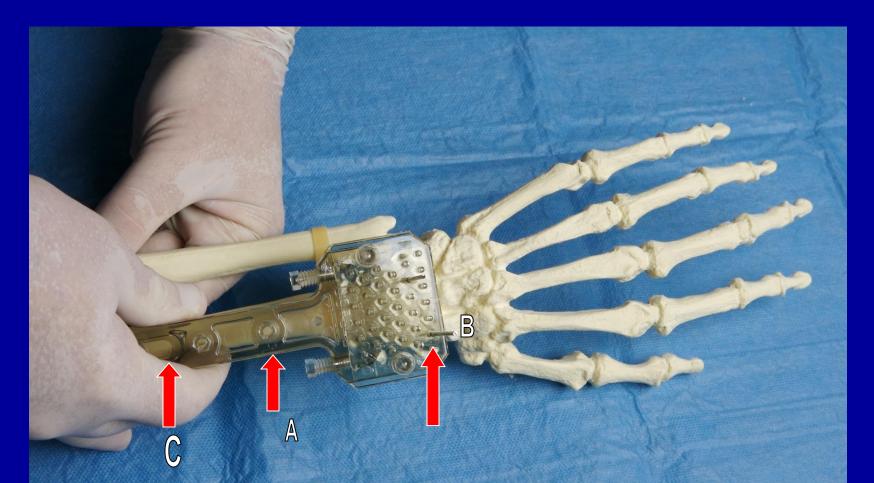
Place the first .062" k-wire into the ulnar side of the distal radius, taking care not to over penetrate the volar cortex.

With the distal row of holes over the radial styloid, this first k-wire will go into either the second or third row of holes.

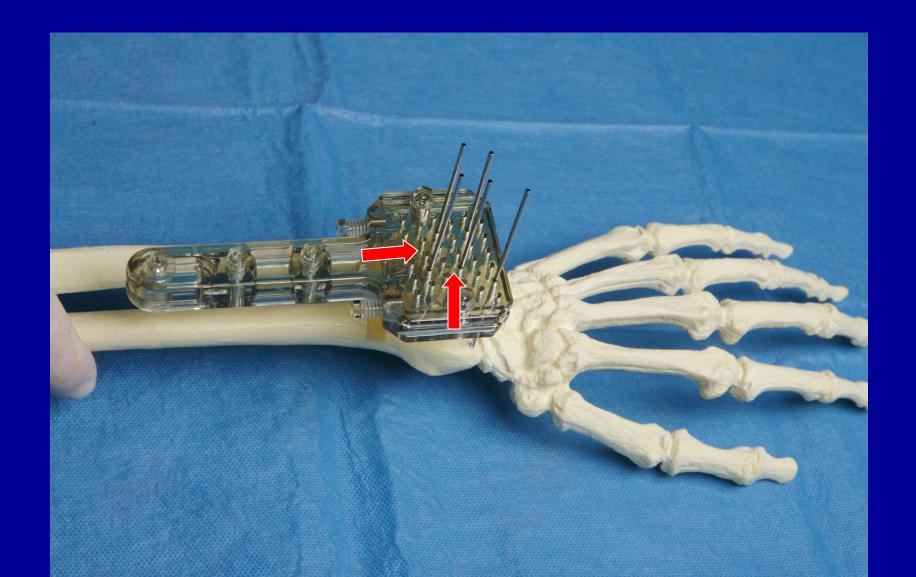


It is critical to ensure that the proximal arm of the fixator is centered over the shaft of the radius (A) before placing the second .062" k-wire into the radial styloid (B).

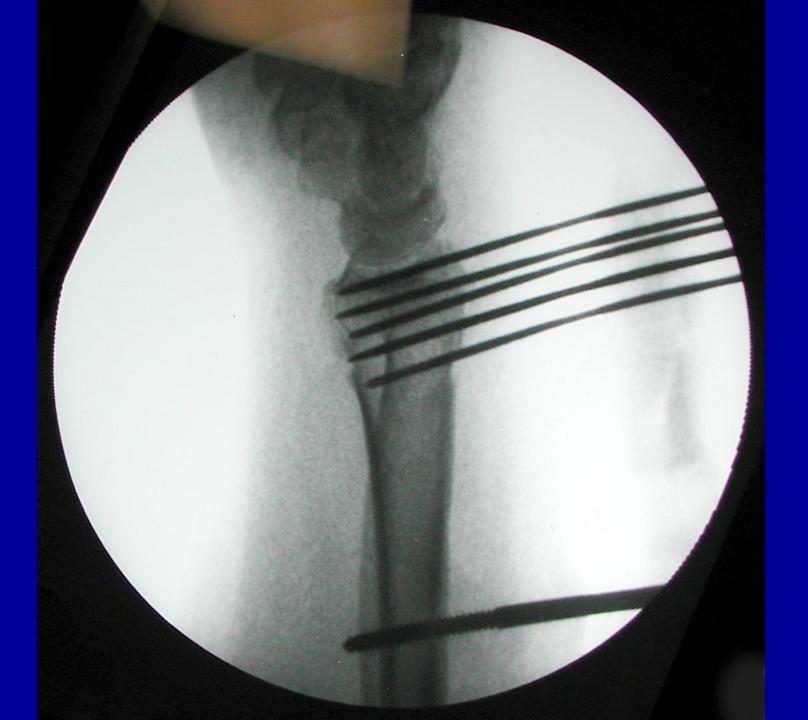
Some surgeons may elect to place the proximal most 3mm halfpin (C) at this point to secure the arm of the fixator to the shaft of the radius, and this is <u>strongly</u> recommended.



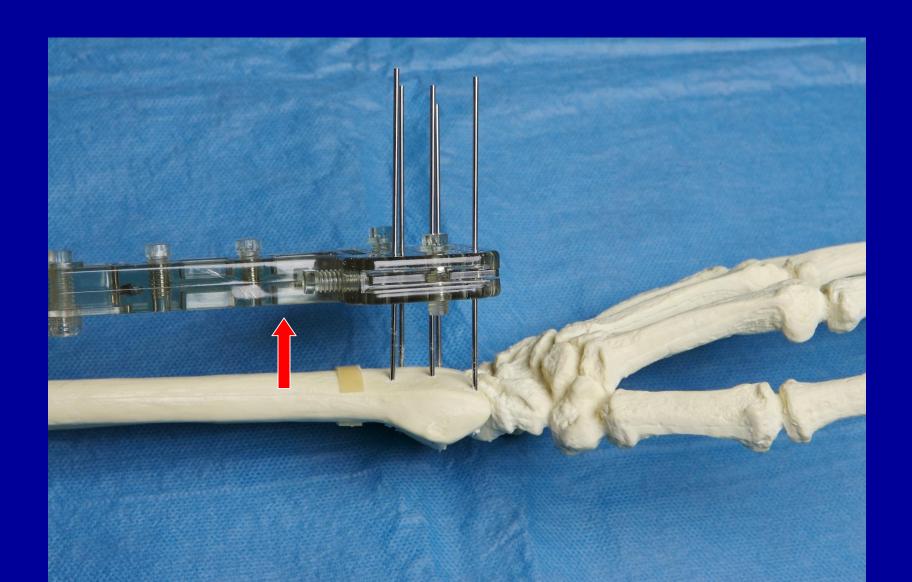
Place additional .062" k-wires into remaining fracture fragments as desired.





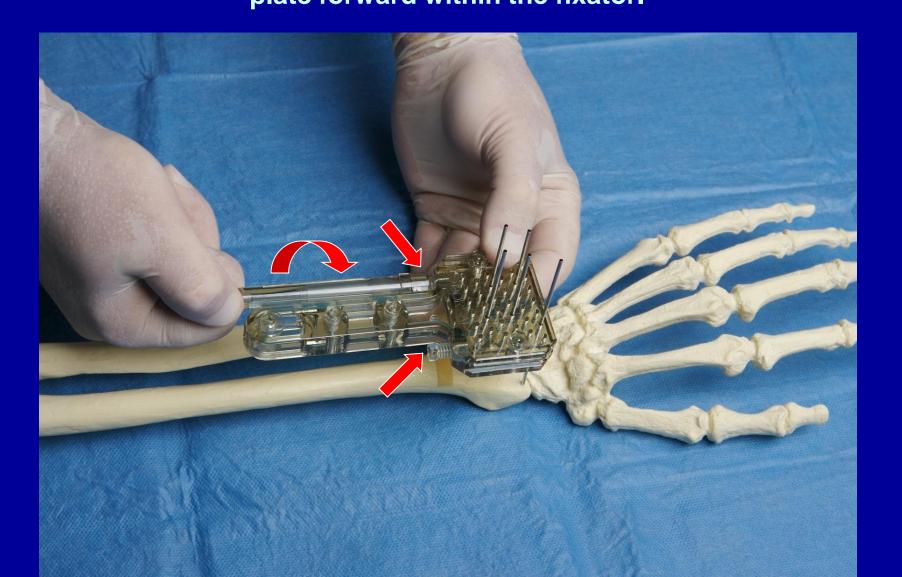


Raise the NBX fixator ½" to ¾" off of the skin to allow clearance for wound and pin site care.



Tighten both locking screws on either side of the fixator body to secure the dorsal pins to the NBX fixator.

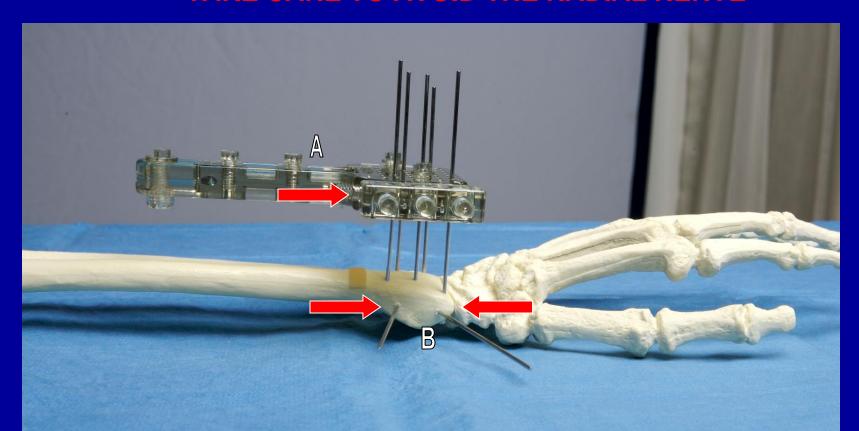
In tightening these 2 screws, the surgeon is pushing the internal plate forward within the fixator.



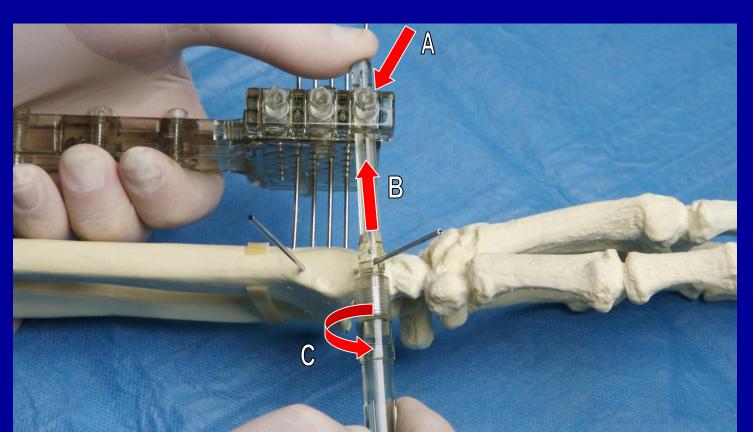
- (A) Slide the side clamp onto the radial side of the NBX fixator.

 The side clamp can be moved proximally or distally before final locking to the fixator once the radial pins are placed and captured by the pin clamps
 - (B) Insert two or three .062" k-wires from radial to ulnar, with the first parallel to the distal articular surface and the others into fracture fragments as desired to interlock with the dorsal pins and secure the fracture in 3 dimensions.

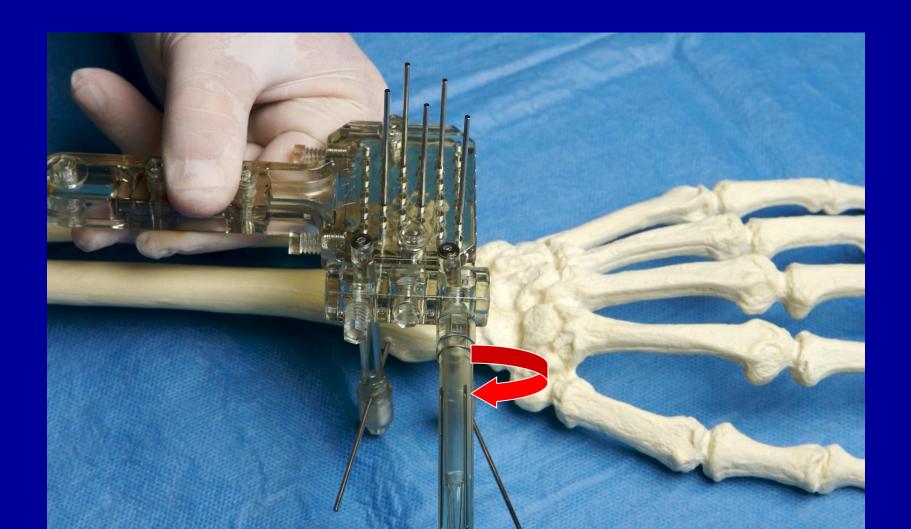
TAKE CARE TO AVOID THE RADIAL NERVE



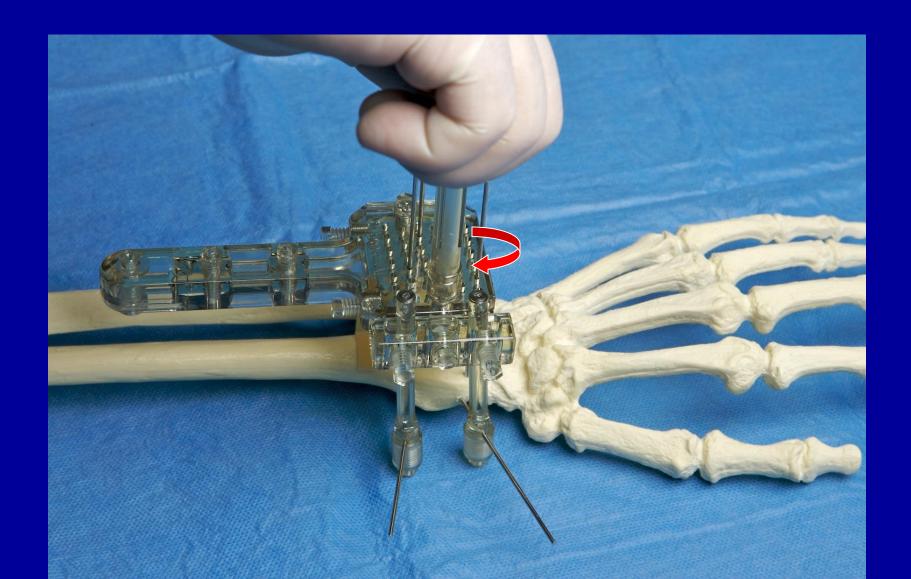
- (A) Loosen each of the appropriate locking screws on the side of the side clamp to allow the pin clamps to slide easily into the side clamp.
 - (B) Slide each pin clamp into the slot on the side clamp from volar to dorsal and drop it down onto the k-wire.
 - (C) Secure each radial k-wire to a pin clamp with the pin clamp nut and wrench, making sure that the shaft of the pin clamp is in either the proximal or distal slot of the side clamp and that the shaft of the pin clamp is not "bent" in any plane.



Secure the pin clamps to the side clamp with the wrench by tightening each locking screw, making sure that the shaft of the pin clamp is in either the proximal or distal portion of the hole in the side clamp and not "bent" in any plane.



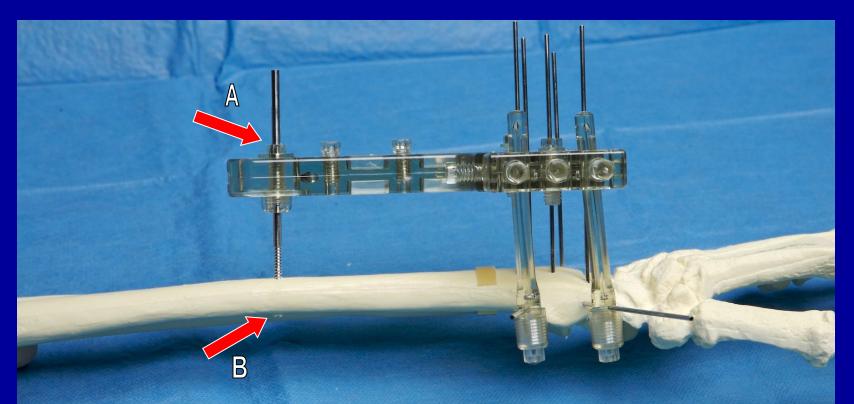
Secure the side clamp to the NBX fixator body by tightening the dorsal locking screw in the radial side.



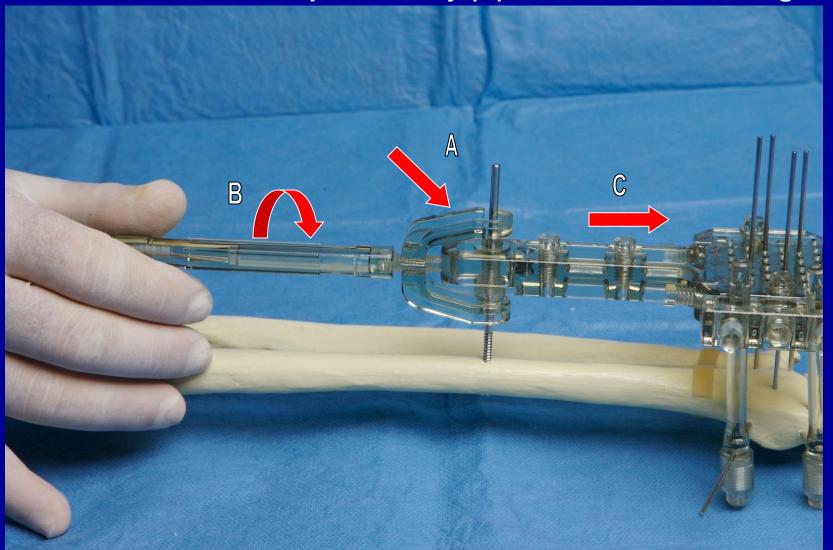
Remove the foam piece holding the proximal collet in place and insert the proximal 3mm half-pin into the distraction pin collet, with the pin collet in the distal end of the slot (A) to allow for final distraction of the fracture, and through the radial shaft taking care not to over penetrate the volar cortex (B).

DO NOT USE POWER UNTIL THE THREADED PORTION OF THE HALF-PIN IS FULLY THROUGH THE COLLET AND ON BONE AS IT MAY CATCH ON THE COLLET

(A small stab incision is normally made and blunt dissection with a small clamp down to bone for all 3mm hal-pins to protect neuro-vascular structures, with a suture on either side of each pin.)

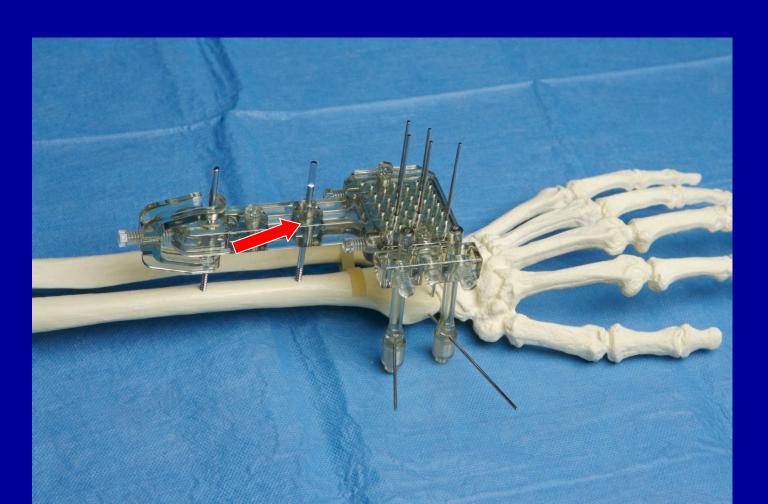


Apply the distraction device to the proximal 3mm half-pin, with both arms around the pin above and below the arm of the fixator and distraction screw at the distal end of the fixator (A). Turn the distraction screw clockwise (B) to force the fixator body and secured fracture complex distally (C) to restore normal length.

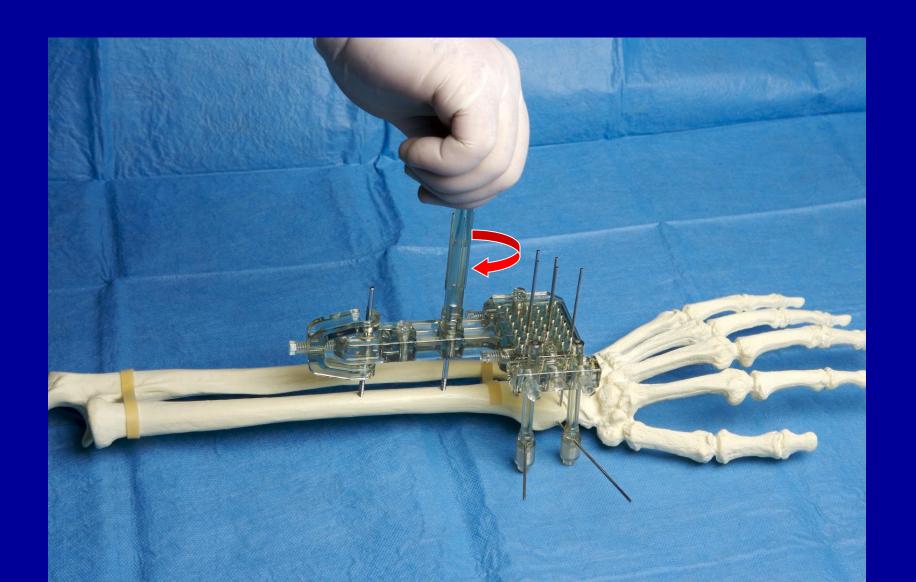


With the final distraction held in place by the distraction device, insert a second 3mm half-pin into the distal radius through one of the two remaining holes on the shaft of the NBX fixator arm.

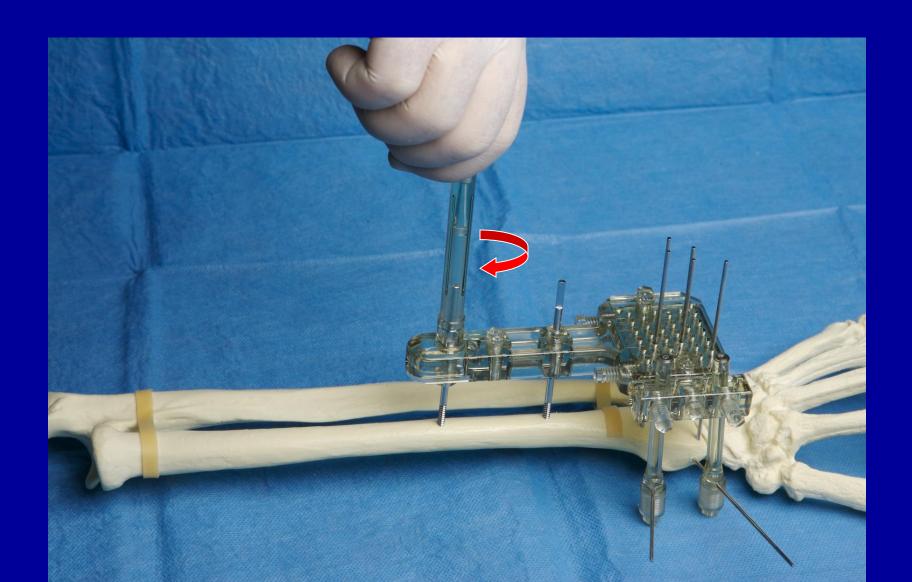
DO NOT USE POWER UNTIL THE THREADED PORTION OF THE HALF-PIN IS FULLY THROUGH THE COLLET AND ON BONE AS IT MAY CATCH ON THE COLLET



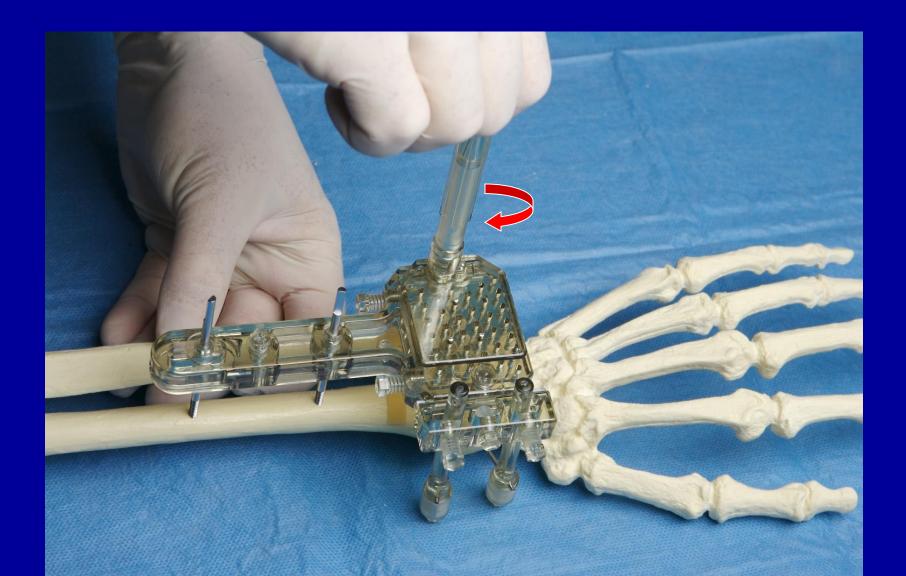
Tighten the pin collet for the distal 3mm half-pin clockwise to secure the distraction.



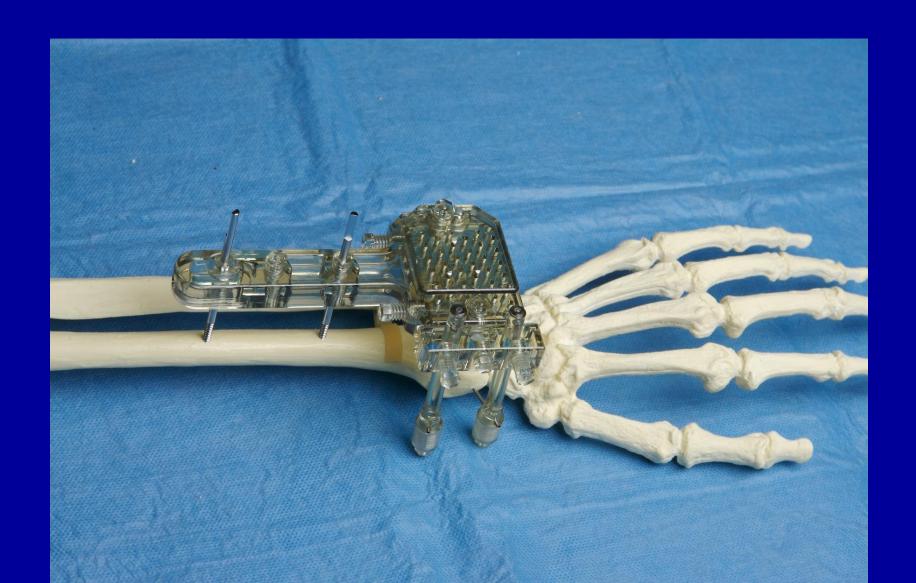
Remove the distraction device and secure the proximal 3mm halfpin by tightening the pin collet clockwise.



Cut the radial k-wires and apply pin covers, then cut the dorsal pins and secure the pin cover by tightening the locking screw on the ulnar dorsal side of the NBX fixator.



Installation of the NBX fixator is complete.



Prior to waking the patient up, and after removing the arm from the First Assistant, the surgeon MUST place the wrist through a full range of motion:

Volar and dorsal felxion Radial and Ulnar Deviation Pronation and Supination

Have the surgeon save and print copies like the 2 below to show to the patient in Recovery to "implant" the idea that they can move their hand, fingers and wrist!



By placing the hand, wrist and fingers through the entire range of motion, the surgeon will free up any extensor tendons that may have been "speared" by a K-wire. The fibers of the tendons run longitudinally and the range of motion creates a split in line with the fibers that allows full range of motion and heals following removal of the NBX fixator.

In well over 140 cases done to date, there has not been a single report of tendon rupture or tenosynovitis.



Post-Operative Care

- Normal closure and dressing will usually consist of a stitch on either side of the proximal half-pins and sterile dressing wrapped under the fixator around all pins and K-wires, with cast padding wrapped around the arm, finally covered with an Ace bandage.
- Patient is advised to move the fingers and wrist as tolerated.
- The first post-operative visit usually occurs from 3 to 5 days after surgery, at which time the above dressing and stitches are removed.
- Patient is instructed in pin tract cleaning and care (from soap and water to peroxide, etc., based on surgeon preference) and is informed they can shower with the device and resume activities of daily living, with NO heavy lifting or undue stress to be placed on the wrist.
- Depending on radiographic evidence of healing, the NBX fixator is removed from 6-8 weeks after surgery.