SURGICAL TECHNIQUE GUIDE

WITH THE PROXIMAL ULNA PLATE

IJS®-ELBOW

elbow stabilization system

skeletal dynamics®

UNDERSTANDING THE UPPER EXTREMITY

As described by:

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Miami Hand & Upper Extremity Institute

IJS®-ELBOW
elbow stabilization system

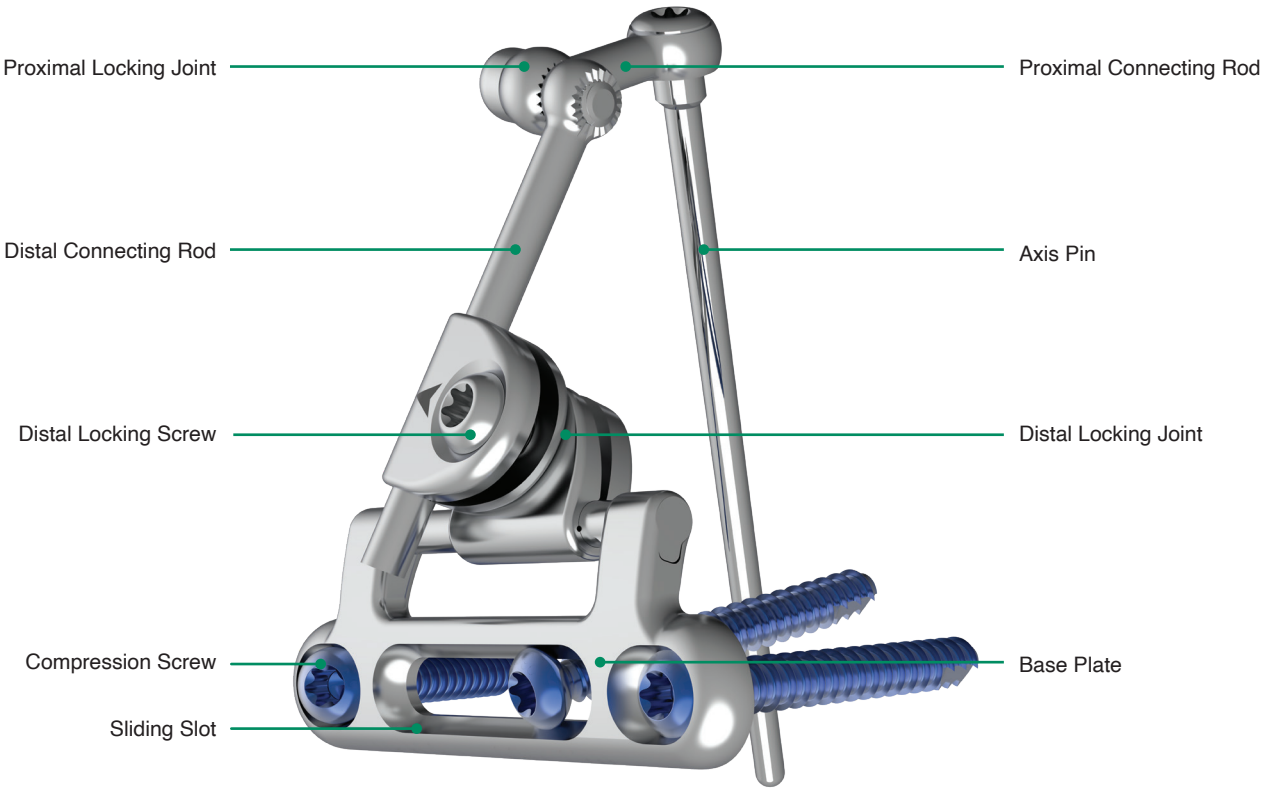
Description

The IJS-E® System is designed to address elbow joint instability procedures through a standard open lateral approach and should only be used by surgeons who have experience with the IJS-E® System.

Each surgeon must evaluate the appropriateness for the use of the IJS-E® System prior to and during these procedures. These guidelines are furnished for information purposes only and are not intended to replace comprehensive training. Prior to use of the IJS-E® System, the surgeon should become familiar with all information contained in this technique guide.

Indications for Use

The Internal Joint Stabilizer - Elbow is intended to provide temporary stabilization of the elbow joint after trauma or chronic elbow dislocation.

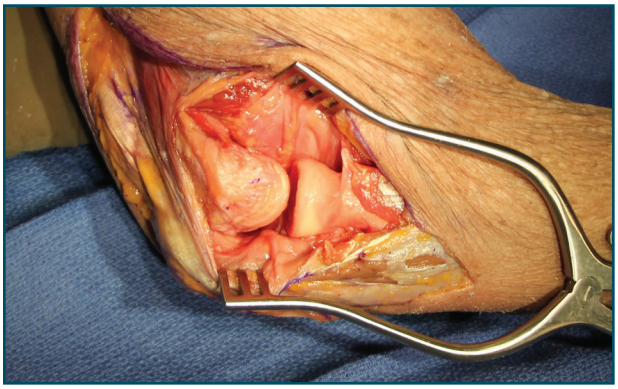


1 SUPERFICIAL EXPOSURE

Make an incision midway between the lateral epicondyle and the olecranon.

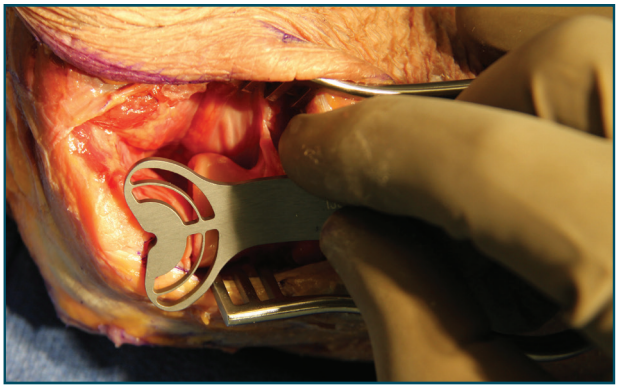
Note:
Place the tourniquet proximal on the arm to allow for free elbow motion.

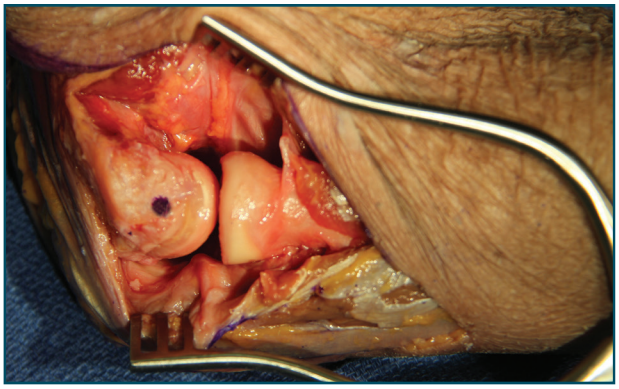
2 DEEP EXPOSURE



Perform a lateral approach to the elbow joint through the surgeon's preferred muscle interval.

CENTER OF ROTATION 3





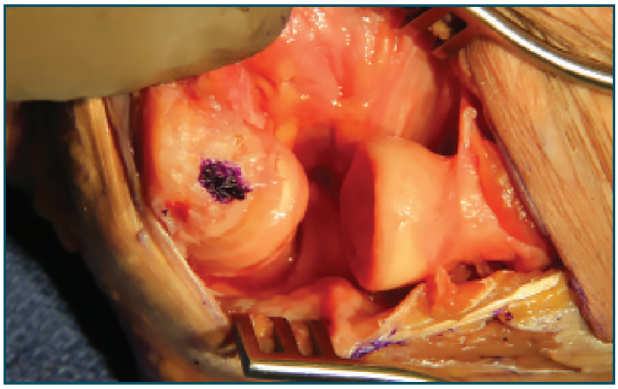
Locate and mark the anatomic center on the lateral capitellum.

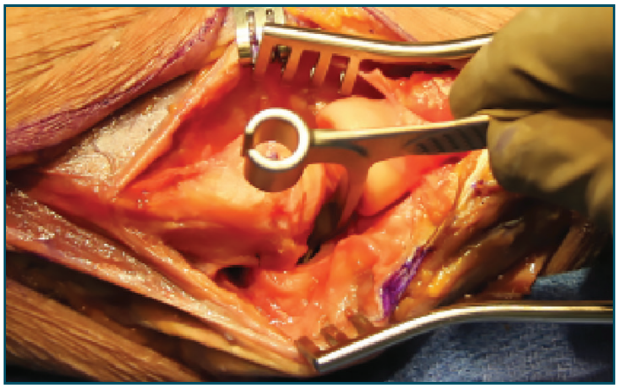
Note:
This is identified as the center of a circle that fits the curvature of the capitellum on the lateral view.

Full visualization of the lateral epicondyle to the capitellum is critical to accurately establish the anatomic center of rotation.

IJS-ELB-ACG: IJS®-E Axis Centering Guide

AXIS GUIDE SIZING 4





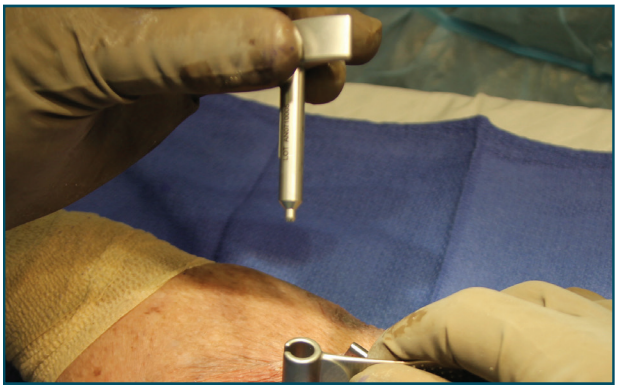
Open the joint by applying a varus stress allowing access to insert the largest sized Axis Guide that is appropriate for the patient.

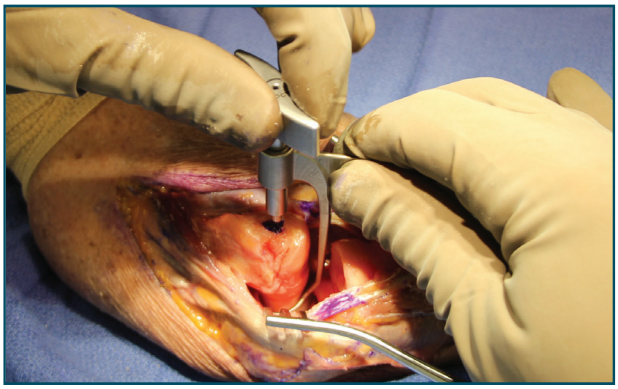
The handle of the Axis Guide should be positioned in-line with the humeral shaft and into the trochlear notch, engaging the medial trochlear expansion.

Note:
There are three sizes of Axis Guides available.

IJS-EAG-XXX: IJS®-E Axis Guide

5 GUIDE WIRE ATTACHMENT



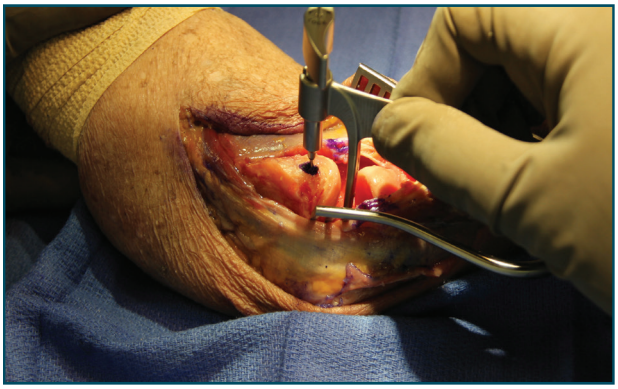


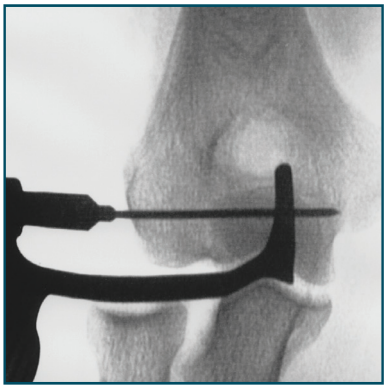
Insert the K-Wire Guide into the Axis Guide so that it is close to the lateral epicondyle without making contact, and then rotate it clockwise to lock it in place.

Caution:
Avoid contacting the lateral epicondyle with the K-Wire Guide as it will prevent the Axis Guide from properly engaging the medial trochlear expansion, causing the assembly to be improperly positioned.

IJS-EAG-KWG: IJS®-E K-wire Guide, 1.5mm

6 GUIDE WIRE INSERTION





Advance the Guide-Wire (1.5mm K-Wire) through the K-wire Guide and into the humerus, stopping short of the medial cortex.

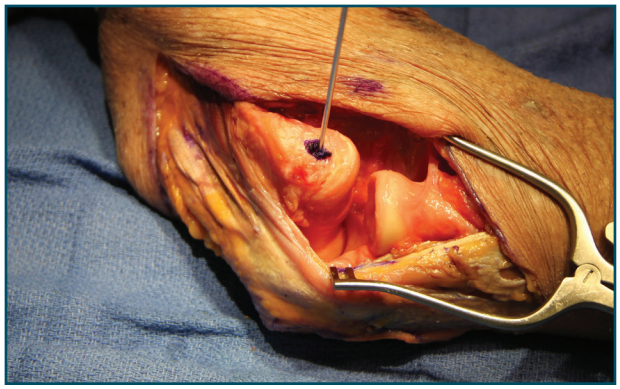
Caution:
DO NOT violate the medial cortex as it may result in ulnar nerve injury.

Note:
The supplied Guide-Wires (1.5mm K-Wire) are specifically designed to provide exact depth readings with the system's Depth Gauge.

KWIR-DES-15127: K-wire, Standard Tip, 1.5mm x 127mm

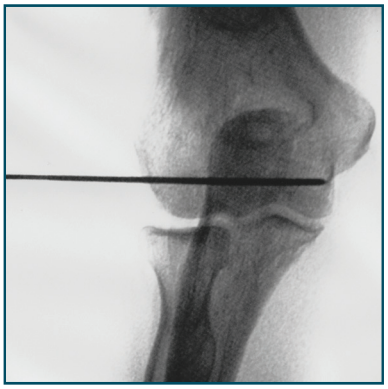
AXIS GUIDE REMOVAL 7

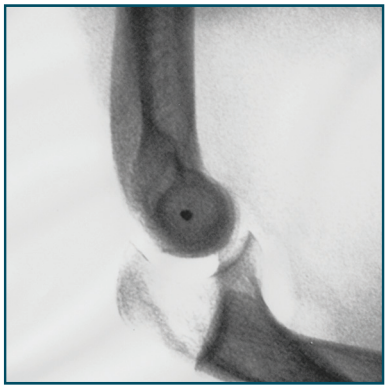
Remove the entire assembly leaving the Guide Wire (1.5mm K-Wire) in place.



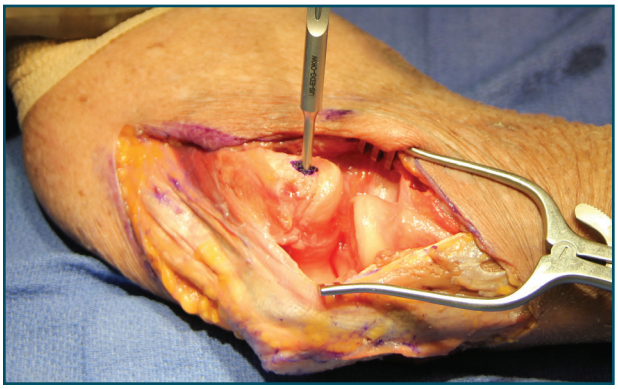
FLUOROSCOPIC CONFIRMATION 8

Confirm that the Guide Wire (1.5mm K-Wire) has been inserted to the correct depth and that the axis of rotation has been properly established using fluoroscopy.





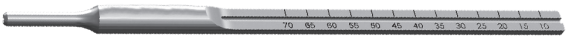
9 AXIS PIN MEASUREMENT



Place the Depth Gauge over the Guide Wire (1.5mm K-Wire) to measure the drilling depth for the proper length of Axis Pin.

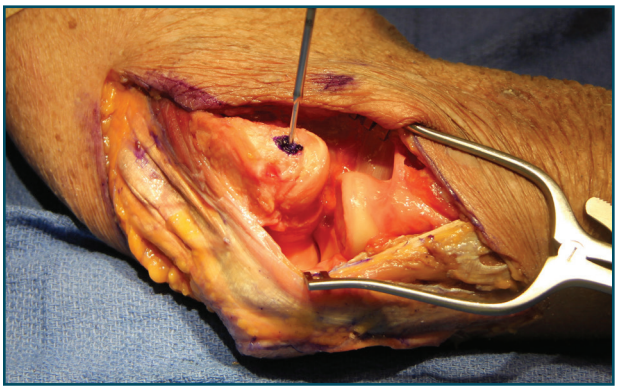
If between sizes, choose a shorter length.

Note:
There are nine lengths of Axis Pin available.



IJS-EDG-OKW: IJS-E Depth Gauge, Over K-Wire

10 AXIS PIN DRILLING



Drill over the Guide Wire (1.5mm K-Wire) to the measured depth using the 2.7mm cannulated IJS-E® Drill.

Remove the Guide Wire (1.5mm K-Wire) after drilling.

Note:
The 2.7mm cannulated IJS-E® Drill has etched depth marks.

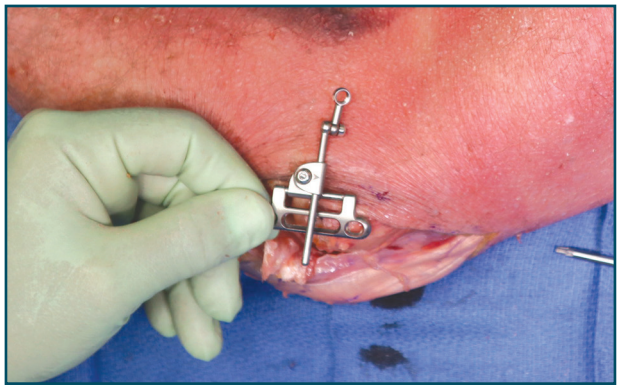
IJS-CDC-2770: IJS-E Drill, Cannulated Distal Cutting, 2.7mm x 70mm

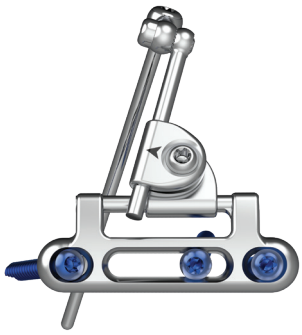
BASE PLATE POSITIONING 11

Position the Base Plate on the proximal aspect of the ulna.

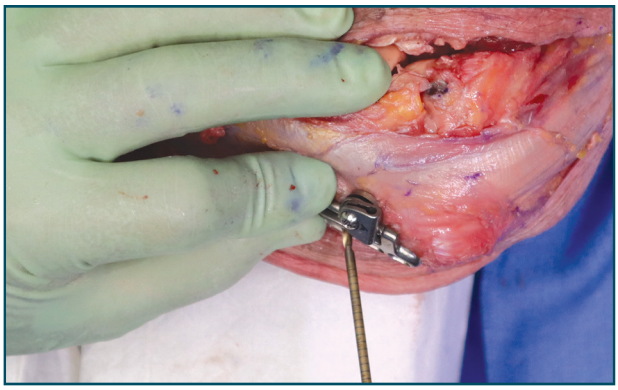
Note:
The use of fluoroscopy will help to position the base plate.

If Proximal Ulna Plate has been applied to the ulna, go to step 15 for IJS-PUP-BPA Base Plate Positioning.





BASE PLATE DRILLING 12



Drill for bicortical fixation through the sliding slot on the Base Plate using the 2.7mm drill bit, aiming towards the coronoid process and away from the radial notch.

Measure using the Depth Gauge for the appropriate length 3.5mm compression screw (Polyaxial Non Locking).

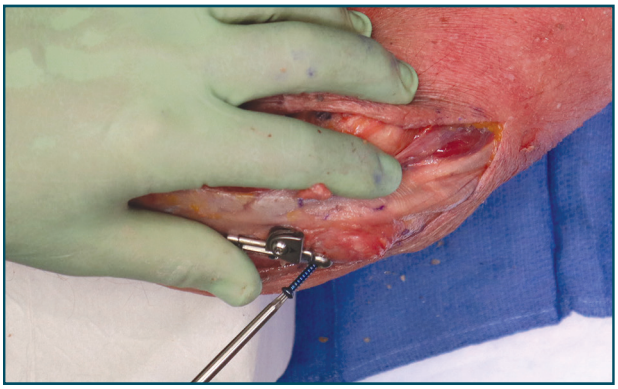
Caution: Avoid drilling into the articular surfaces.

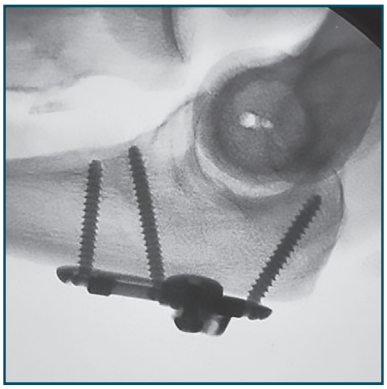
Note: The center-sliding slot of the Base Plate facilitates positioning.

DRLL-SSC-27040: Drill, 2.7mm x 40mm

DPGA-UNV-050: Depth Gauge, Universal, 50mm

13 SCREW INSERTION





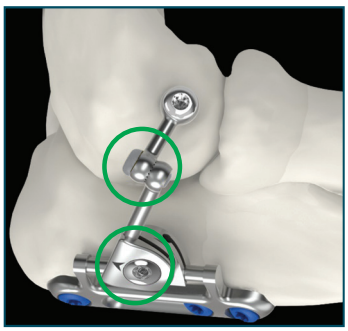
Insert the corresponding 3.5mm compression screw (Polyaxial Non-Locking) using the T-10 Driver.

Repeat step 12 and 13 for the remaining two compression screw holes of the Base Plate.

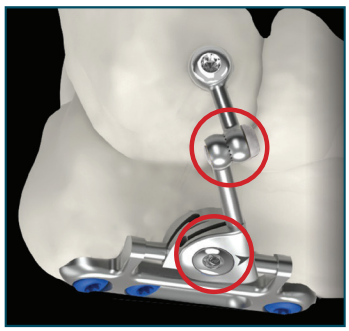
Caution:
Avoid drilling into the articular surfaces.

DRVR-UQC-T10: Driver, Universal QC, T-10

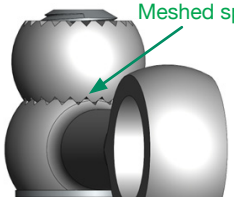
14 CONSTRUCT ALIGNMENT



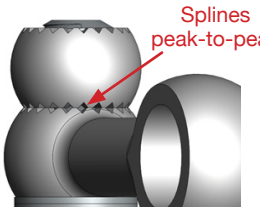
Correct Placement



Incorrect Placement



CORRECT
Splines meshed properly

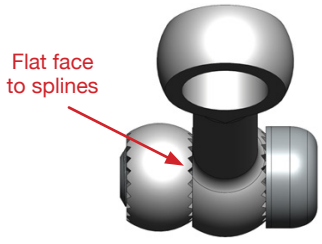


INCORRECT
Splines peak-to-peak

If the head of the Proximal Locking Screw or the arrow of the Distal Locking Joint are NOT pointing proximally:

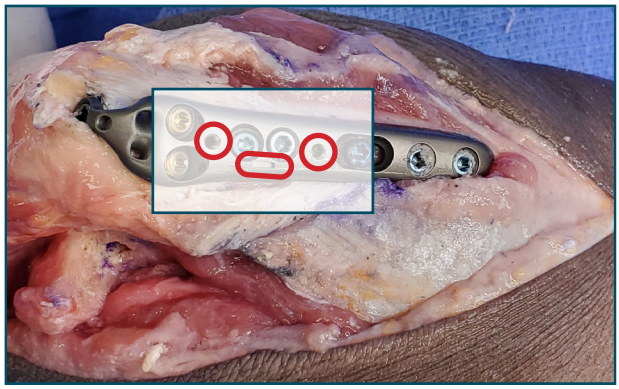
Loosen the Distal Locking Screw and remove the Distal Connecting Rod to flip the Distal Locking Joint 180° so that its arrow is pointing proximal.

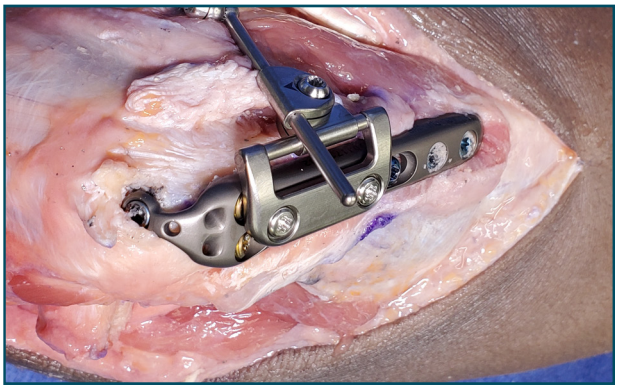
Then reinsert the Distal Connecting Rod back into the Distal Locking Joint with the Proximal Locking Screw also pointing proximal.

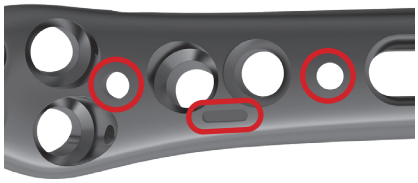


INCORRECT
Incorrect proximal connecting rod orientation

BASE PLATE POSITIONING FOR PROXIMAL ULNA PLATE 15







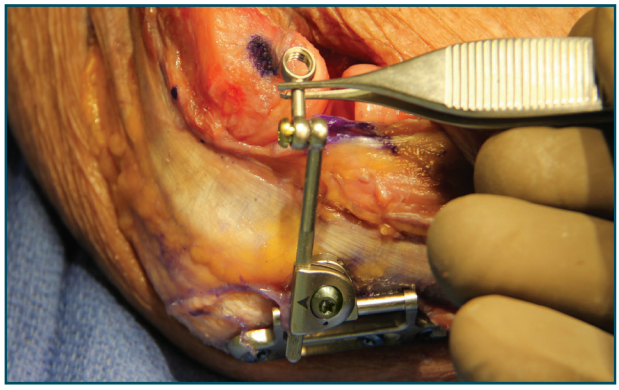
IJS-PUP-SCRW: #4-40 Screws

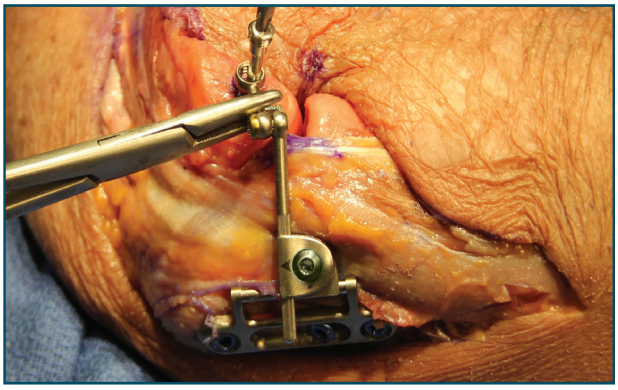
IJS-PUP-BPA: IJS-E Base Plate Assembly, Proximal Ulna Plate

If a Proximal Ulna Plate has been applied to the ulna, position the IJS-PUP-BPA Base Plate into the recess on the plate to align the screw holes. Insert the #4-40 Screws and tighten with the T-10 Driver to secure the IJS Base Plate to the Proximal Ulna Plate.

Note:
Do not fully tighten the #4-40 Screws until both Screws have been introduced into the Base Plate.

INSERTING THE AXIS PIN 16



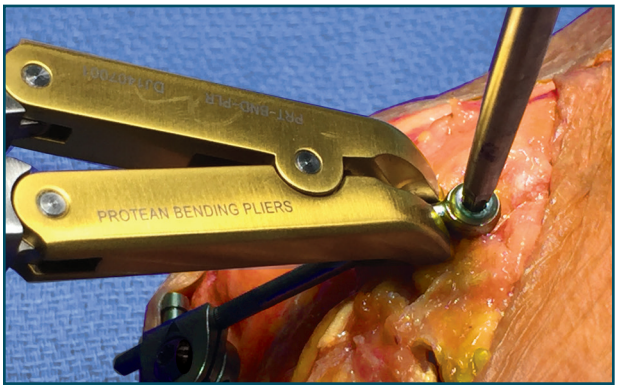


Adjust the Distal Connecting Rod to allow the selected Axis Pin to be inserted through the eyelet of the Proximal Connecting Rod and into the humerus.

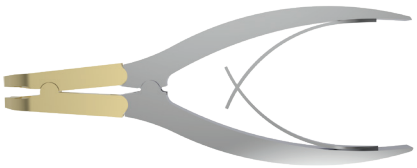
Note:
A needle holder or the PROTEAN® Pliers can be used to hold the Proximal Connecting Rod while inserting the Axis Pin.

IJS-EAP-25XXX: IJS®-E Axis Pin, X.Xmm x XXmm

17 LOCKING THE AXIS PIN

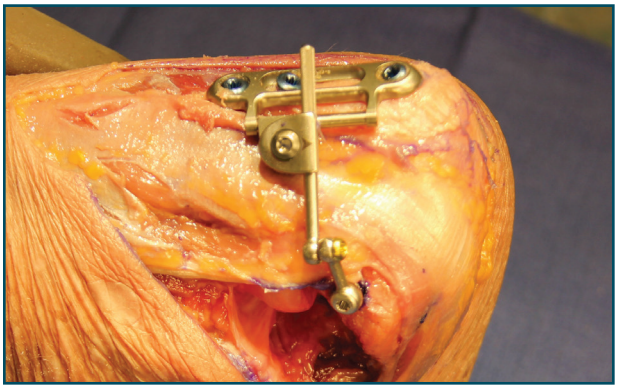


Use the PROTEAN® Pliers to stabilize the Proximal Connecting Rod while fully tightening the Axis Pin using the T-10 Driver.



PRT-BND-PLR: PROTEAN® Plate Bending Pliers

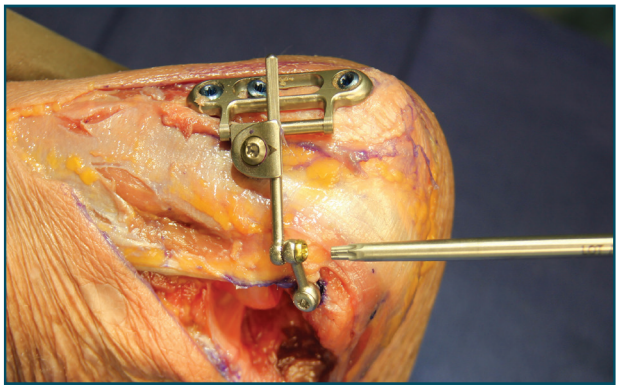
18 ELBOW REDUCTION

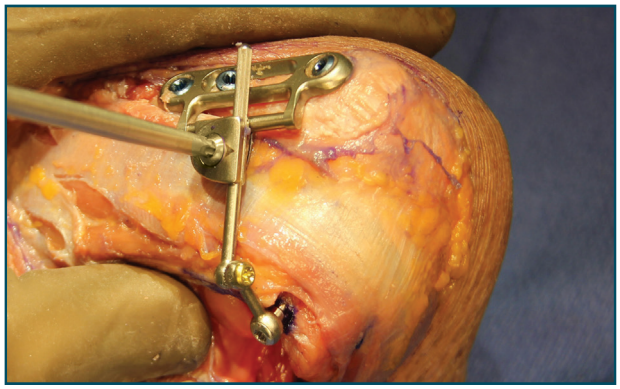


Anatomically reduce the elbow joint.

Note:
Shoulder rotational torque is minimized by placing the patient's hand over their face which also aids in the reduction.

LOCKING THE CONSTRUCT 19





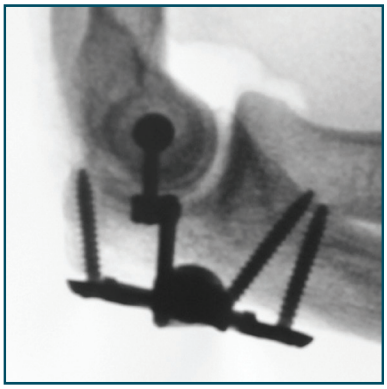
Using the T-10 Driver and the Counter Torque Tool, lock the reduction by first tightening the Proximal Locking Screw and then the Distal Locking Screw.

Warning:
Both the Proximal and Distal Locking Screws must be fully tightened to maintain reduction.

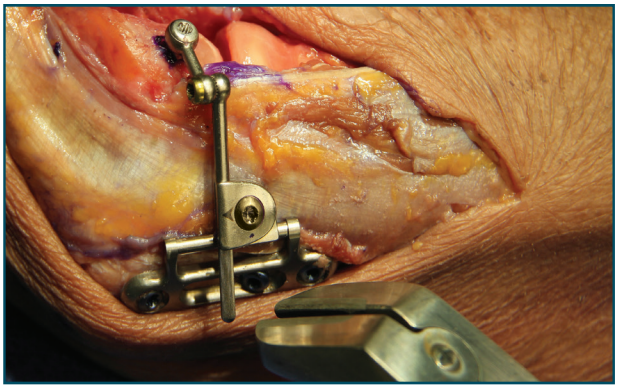
DRVR-UQC-T10: Driver, Universal QC, T-10

FINAL FLUOROSCOPIC CONFIRMATION 20

Confirm that the reduction is maintained through the full ROM using fluoroscopic imaging.



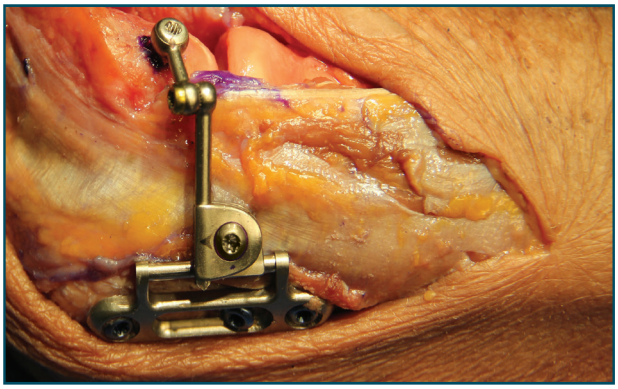
21 TRIMMING THE CONNECTING ROD



Using a pin cutter, remove any excess length from the Distal Connecting Rod that exits the Distal Locking Joint.

Warning:
The Distal Connecting Rod must be trimmed as short as possible where it exits the Distal Locking Joint to minimize the potential for soft tissue irritation.

22 DEEP CLOSURE

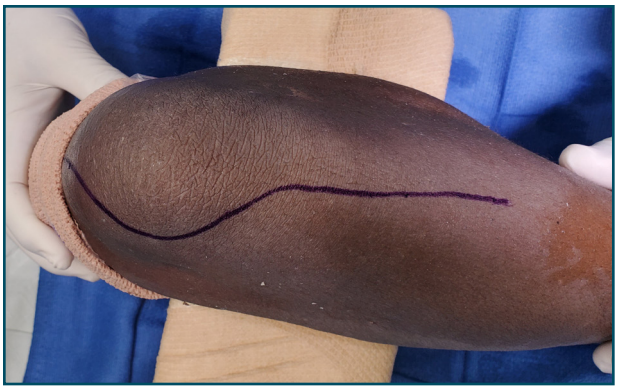


Reattach the origin of the lateral collateral ligament and the origin of the extensor muscle just proximal to the Axis Pin.

CLOSURE 23

Confirm that the reduction is maintained through the full ROM using fluoroscopic imaging.

1 SUPERFICIAL EXPOSURE

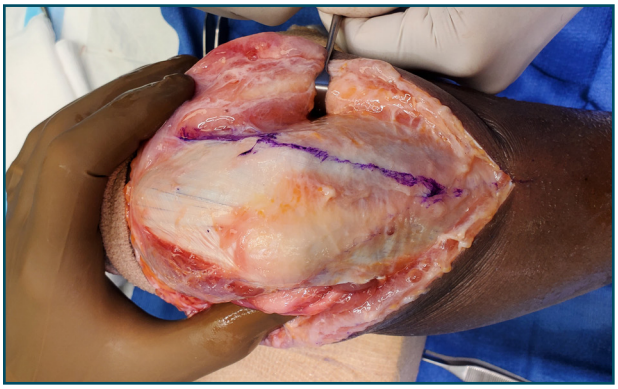


Make a posterior incision.

Note:
Place the tourniquet proximal on the arm to allow for free elbow motion.

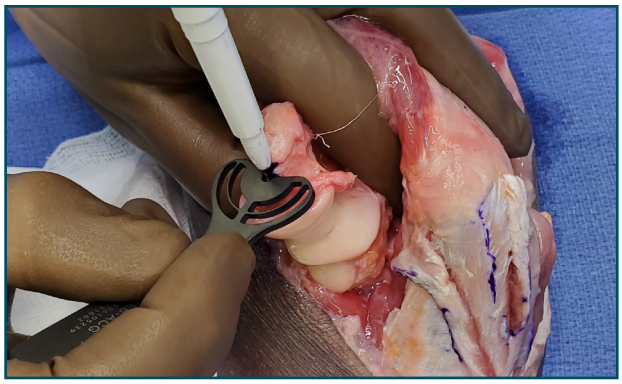
Use caution when identifying the ulnar nerve.

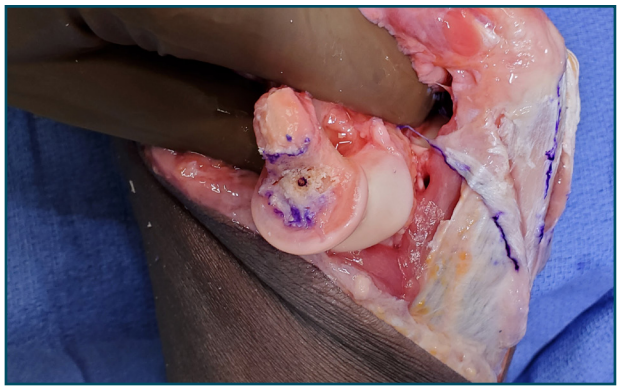
2 DEEP EXPOSURE



Create an incision to expose the lateral epicondyle.

CENTER OF ROTATION 3





Locate and mark the anatomic center on the lateral capitellum.

Note:
This is identified as the center of a circle that fits the curvature of the capitellum on the lateral view.

Full visualization of the lateral epicondyle to the capitellum is critical to accurately establish the anatomic center of rotation.

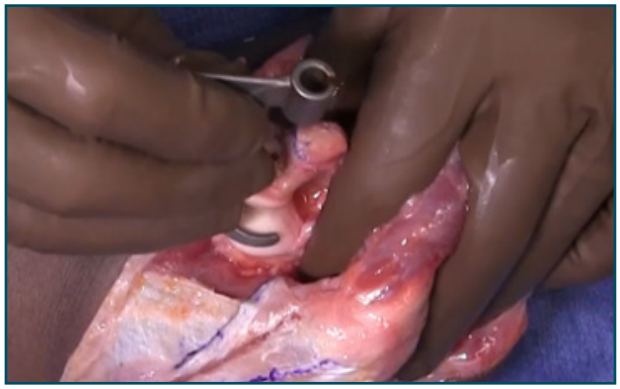
IJS-ELB-ACG: IJS-E Axis Centering Guide

AXIS GUIDE SIZING 4

Open the joint by applying a varus stress allowing access to insert the largest sized axis guide that is appropriate for the patient.

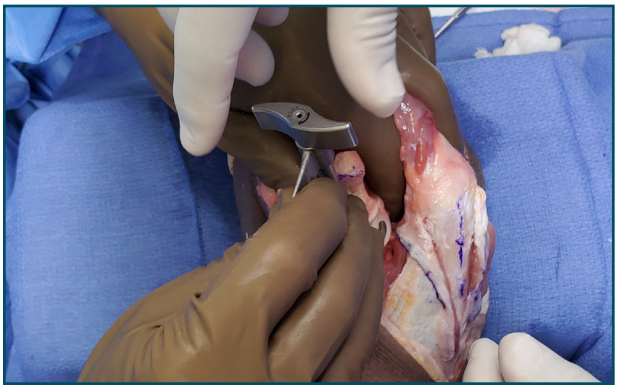
The handle of the Axis Guide should be positioned in-line with the humeral shaft and into the trochlear notch, engaging the medial trochlear expansion.

Note:
There are three sizes of Axis Guides available.



IJS-EAG-XXX: IJS-E Axis Guide

5 GUIDE WIRE ATTACHMENT

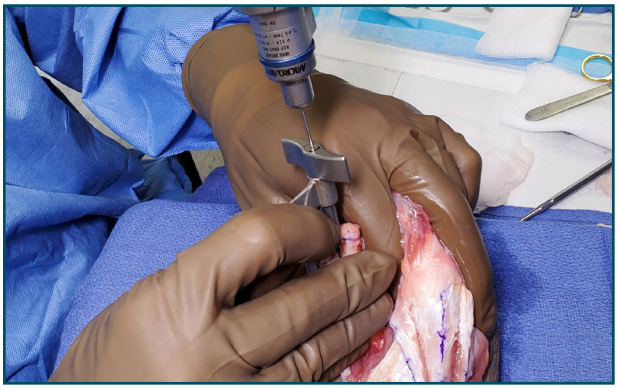


Insert the K-Wire guide into the Axis Guide so that it is close to the lateral epicondyle without making contact, and then rotate it clockwise to lock it in place.

Caution:
Avoid contacting the lateral epicondyle with the K-Wire Guide as it will prevent the Axis Guide from properly engaging the medial trochlear expansion, causing the assembly to be improperly positioned.

IJS-EAG-KWG: IJS-E K-wire Guide, 1.5mm

6 GUIDE WIRE INSERTION



Advance the 1.5mm K-Wire through theK-Wire Guide through the trochlea.

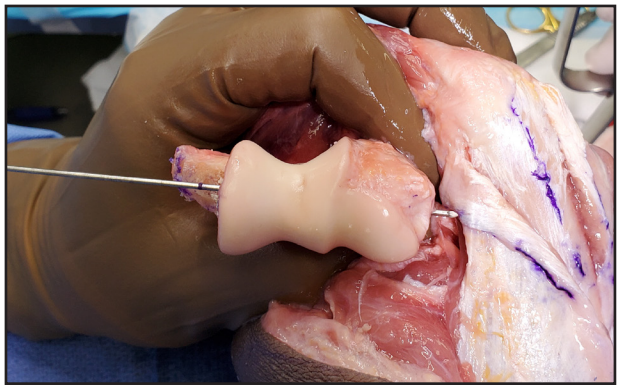
Caution:
Be sure to transpose the ulnar nerve before inserting the K-Wire as it may result in ulnar nerve injury.

Note:
The supplied K-Wires are specifically designed to provide exact depth readings with the system's depth gauge.

KWIR-DES-15127: K-wire, Standard Tip, 1.5mm x 127mm

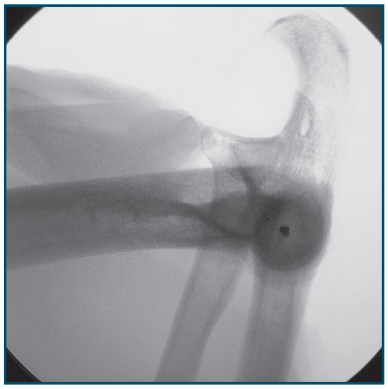
AXIS GUIDE REMOVAL 7

Remove the entire assembly leaving the 1.5mm K-Wire in place.

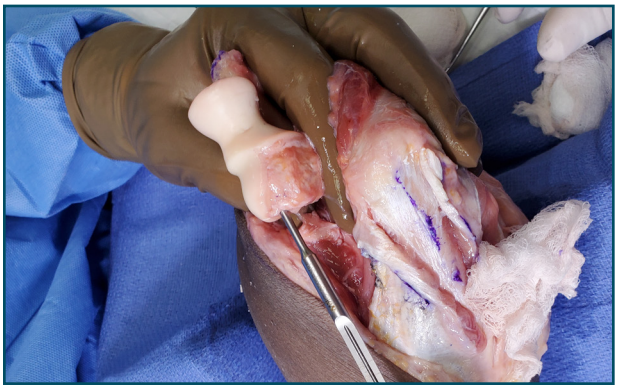


FLUOROSCOPIC CONFIRMATION 8

Confirm that the 1.5mm K-Wire has been inserted to the correct depth and that the axis of rotation has been properly established using fluoroscopy.



9 AXIS PIN MEASUREMENT

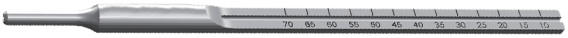


Ensure the end of the K-Wire is located at the exit point on the medial side.

Place the depth gauge over teh 1.5mm K-Wire to measure the drilling depth for the proper length of the Axis Pin.

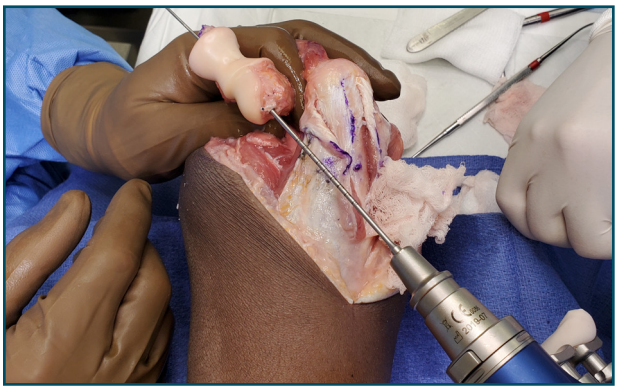
If between sizes, choose the shorter length.

Note:
There are nine lengths of Axis Pin available.



IJS-EDG-OKW: IJS-E Depth Gauge, Over K-wire

10 AXIS PIN DRILLING



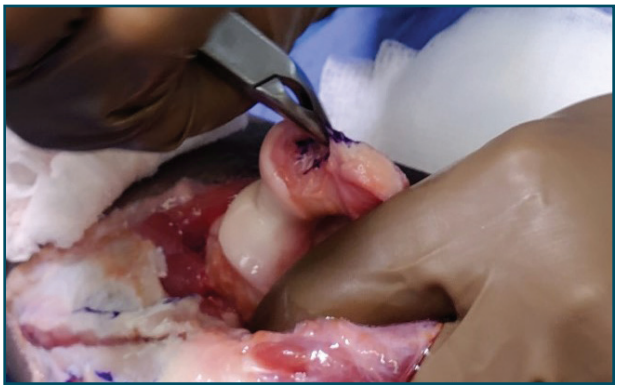
Drill over the 1.5mm K-Wire to the measured depth using the 2.7mm cannulated IJS-E® Drill. Leave the K-Wire in place.

Note:
The 2.7mm cannulated IJS-E® Drill has etched depth marks.

IJS-CDC-2770: IJS-E Drill, Cann Distal Cutting, 2.7mm x 70mm

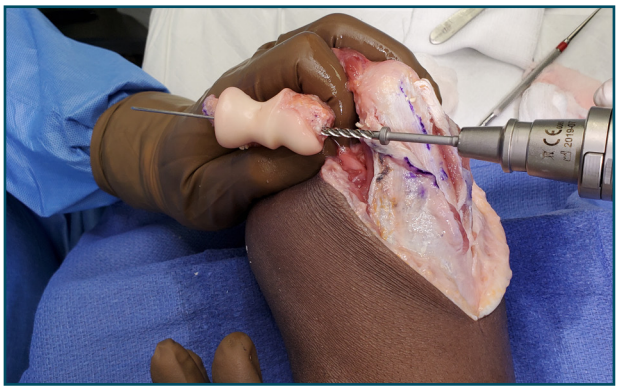
PREPARING THE MEDIAL EPICONDYLE 11

Extend the k-wire through the medial side of the trochlea to prepare for drilling for insertion of the female Axis Pin.



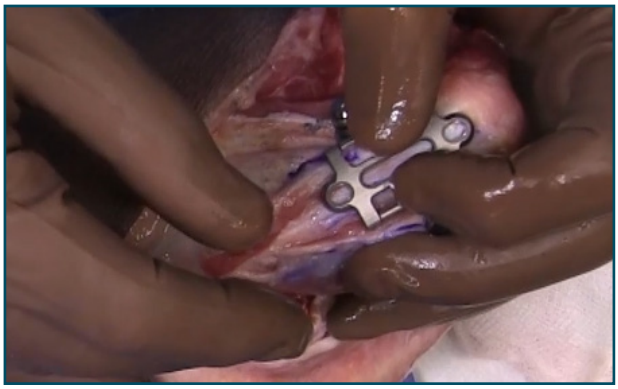
DRILLING FOR FEMALE AXIS PIN 12

Using the Cannulated Stop Drill Bit, drill over the K-Wire to the stop. Remove the drill and K-Wire.



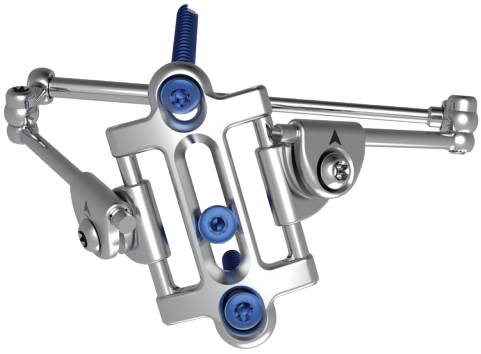
DRLL-CDC-37030: Drill, Cannulated, 3.7mm x 30mm

13 BASE PLATE POSITIONING

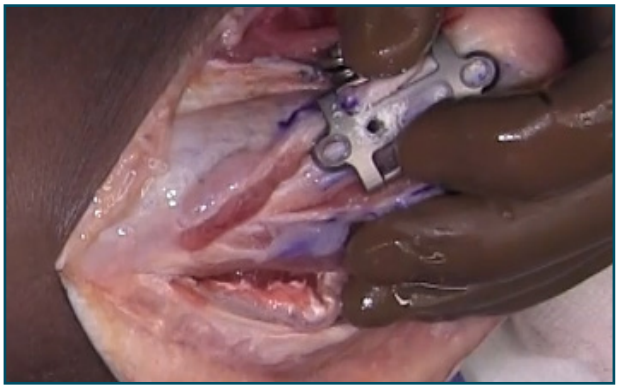


Position the Base Plate on the proximal aspect of the ulna.

Note:
The use of fluoroscopy will help to position the Base Plate.



14 BASE PLATE DRILLING



Drill for bicortical fixation through the sliding slot on the Base Plate using the 2.7mm Drill Bit, aiming towards the coronoid process and away from the radial notch.

Measure using the depth gauge for the appropriate length 3.5mm compression screw (Polyaxial Non-Locking Screw).

Caution:
Avoid drilling into the articular surfaces.

DRLL-SSC-27040: Drill, 2.7mm x 40mm

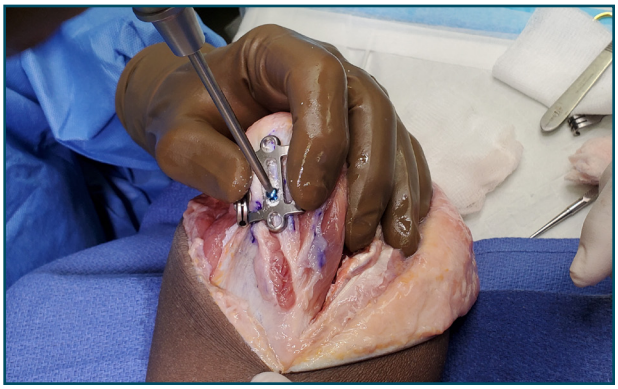
DPGA-UNV-050: Depth Gauge, Universal, 50mm

BASE PLATE ATTACHMENT 15

Insert the 3.5mm compression screw using the T-10 Driver.

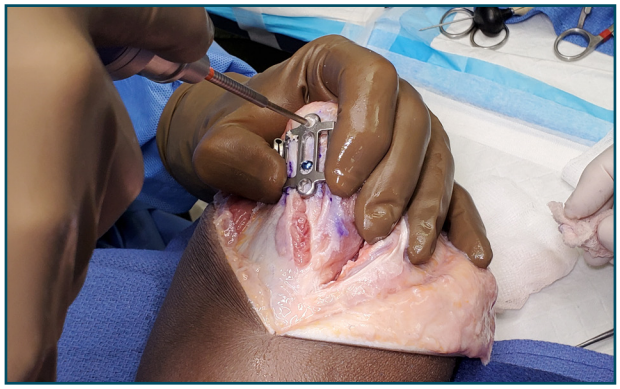
Note:
The center-sliding slot of the Base Plate facilitates positioning.

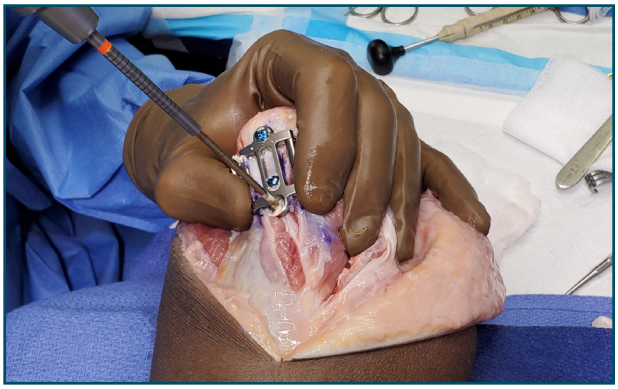
Caution:
Avoid drilling into the articular surface.



DRVR-UQC-T10: Driver, Universal QC, T-10

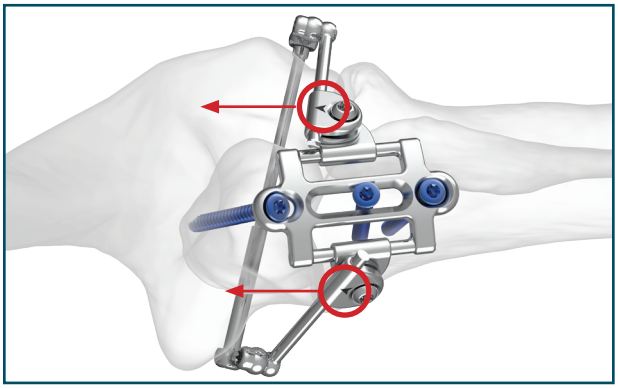
BASE PLATE ATTACHMENT 16





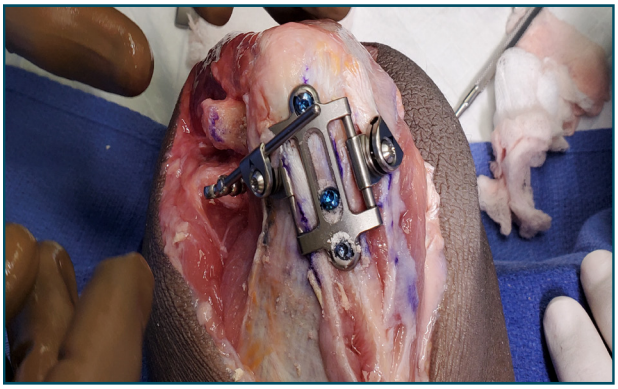
Repeat steps 14 and 15 for the remaining two compression screw holes of the Base Plate.

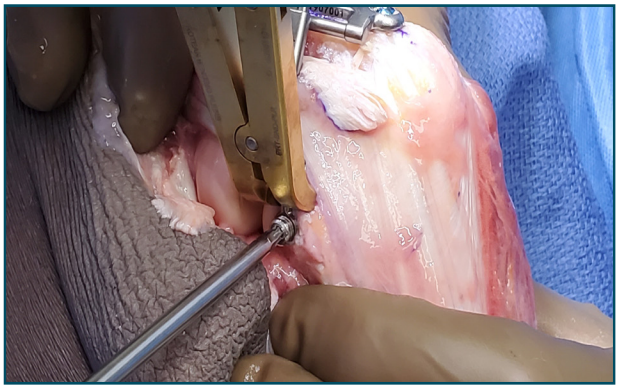
17 CONSTRUCT ASSEMBLY AND ALIGNMENT



Ensure the heads of the Proximal Locking Screws and the arrows of the Distal Locking Joints are directed proximal. If the construct is not positioned correctly, loosen the distal locking screws and remove the Distal Connecting Rods to rotate the Distal Locking Joints 180 degrees so that the arrows are pointing proximally. Then reinsert the Distal Connecting Rods into the Distal Locking Joints with the Proximal Locking Screws also pointing proximal.

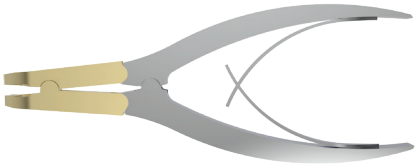
18 LATERAL CONNECTING RODS





Adjust the Distal Connecting Rod on the lateral side to allow the selected Axis Pin to be inserted through the eyelet of the Proximal Connecting Rod and into the humerus.

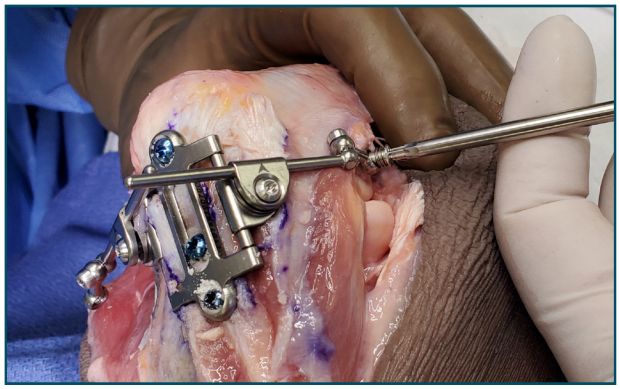
Note:
A needle holder or PROTEAN® pliers can be used to hold the Proximal Connecting Rod while inserting the Axis Pin.



PRT-BND-PLR: PROTEAN Plate Bending Pliers

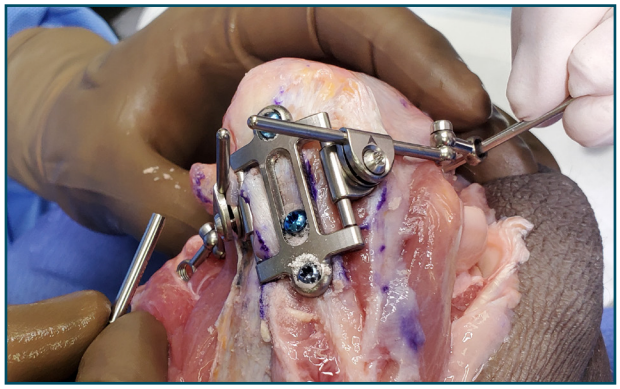
MEDIAL CONNECTING RODS 19

Repeat step 18 for the Medial Connecting Rods.



INSERTING THE AXIS PIN 20

The Male Axis Pin telescopes within the Female Axis Pin through the Proximal Connecting Rod Eyelet on the lateral side and tighten with the T-10 driver. Next, insert the female axis pin through the proximal Next, insert the female axis pin through the Proximal Connecting Rod Eyelet on the medial side and tighten with the T-10 Driver.

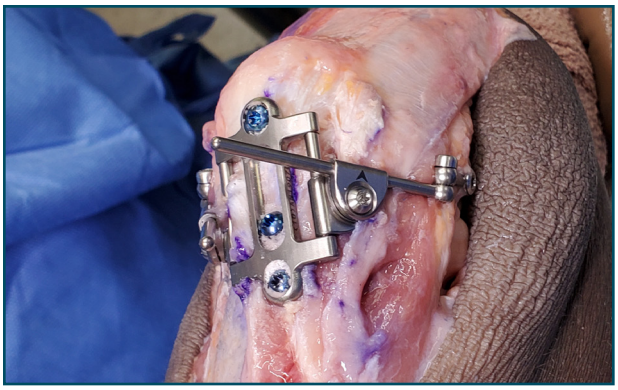


IJS-EAP-F30: IJS-E Axis Pin Female, 30mm

IJS-EAP-25XXX: IJS-E Axis Pin, X.Xmm x XXmm

DRVR-UQC-T10: Driver, Universal QC, T-10

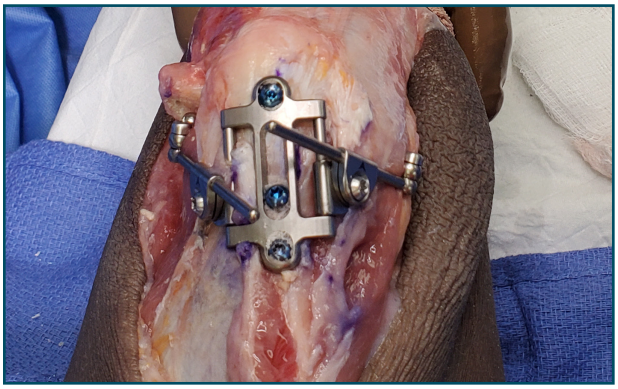
21 ELBOW REDUCTION



Anatomically reduce the elbow joint.

Note:
Shoulder rotational torque is minimized by placing the patient's hand over their face which also aids in the reduction.

22 LOCKING THE CONSTRUCT



Using the T-10 Driver and the Counter Torque Tooll, lock the reduction by first tightening the Proximal Locking Screw, followed by the Distal Locking Screw.

Warning:
Both the Proximal and Distal Locking Screws must be fully tightened to maintain the reduction.

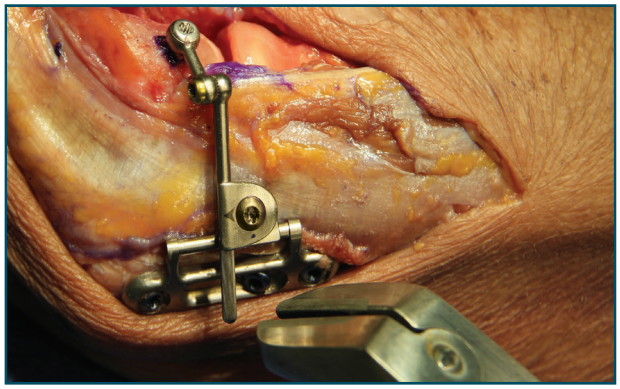
FINAL FLUOROSCOPIC CONFIRMATION 23

Confirm the reduction is maintained through the full range of motion using fluoroscopic imaging.

TRIMMING THE CONNECTING ROD 24

Using a pin cutter, remove any excess length from the Distal Connecting Rod that exits the Distal Locking Joint.

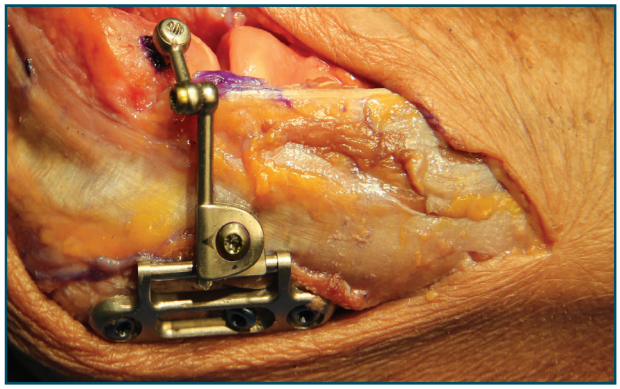
Warning:
The Distal Connecting Rod must be trimmed as short as possible where it exits the Distal Locking Joint to minimize the potential for soft tissue irritation.



25 CLOSURE

Confirm that the reduction is maintained through the full ROM using fluoroscopic imaging.

26 DEEP CLOSURE



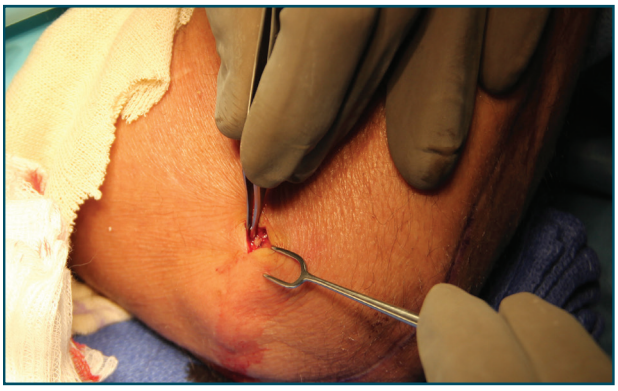
Reattach the origin of the lateral collateral ligament and the origin of the extensor muscle just proximal to the Axis Pin.

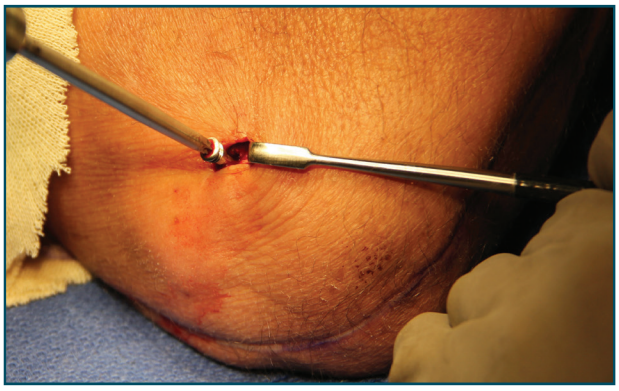
1 LOCATING THE AXIS PIN

Palpate the lateral epicondyle to locate and mark the head of the Axis Pin.

Note:
Use of fluoroscopic imaging will aid in locating the position for each of the construct screws.

2 AXIS PIN REMOVAL





Make a stab incision over the marked area and remove the Axis Pin using the T-10 Driver.

DRVR-UQC-T10: Driver, Universal QC, T-10

LOCATING THE BASE PLATE 3

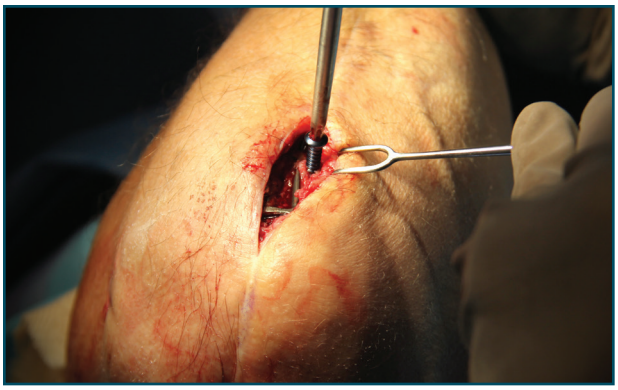
Palpate the posterior surface of the ulna to locate and mark the position of the Base Plate.

Note:
Access can be gained through the previous exposure.

EXPOSING THE BASE PLATE 4

Make an incision to expose the Base Plate.

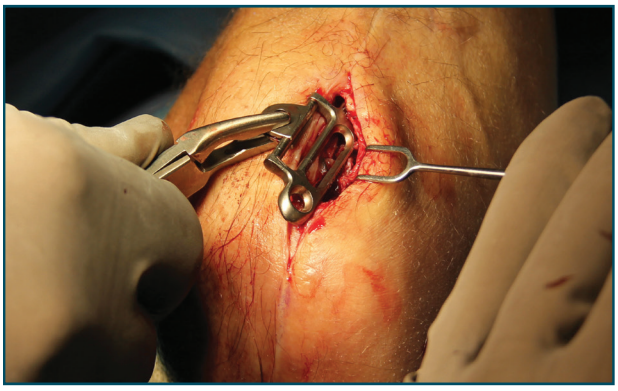
5 SCREW REMOVAL



Using the T-10 Driver, remove the three 3.5mm compression screws (Polyaxial Non-Locking).

If a Proximal Ulna Plate has been applied to the ulna, use the T-10 Driver to remove the two #4-40 Screws.

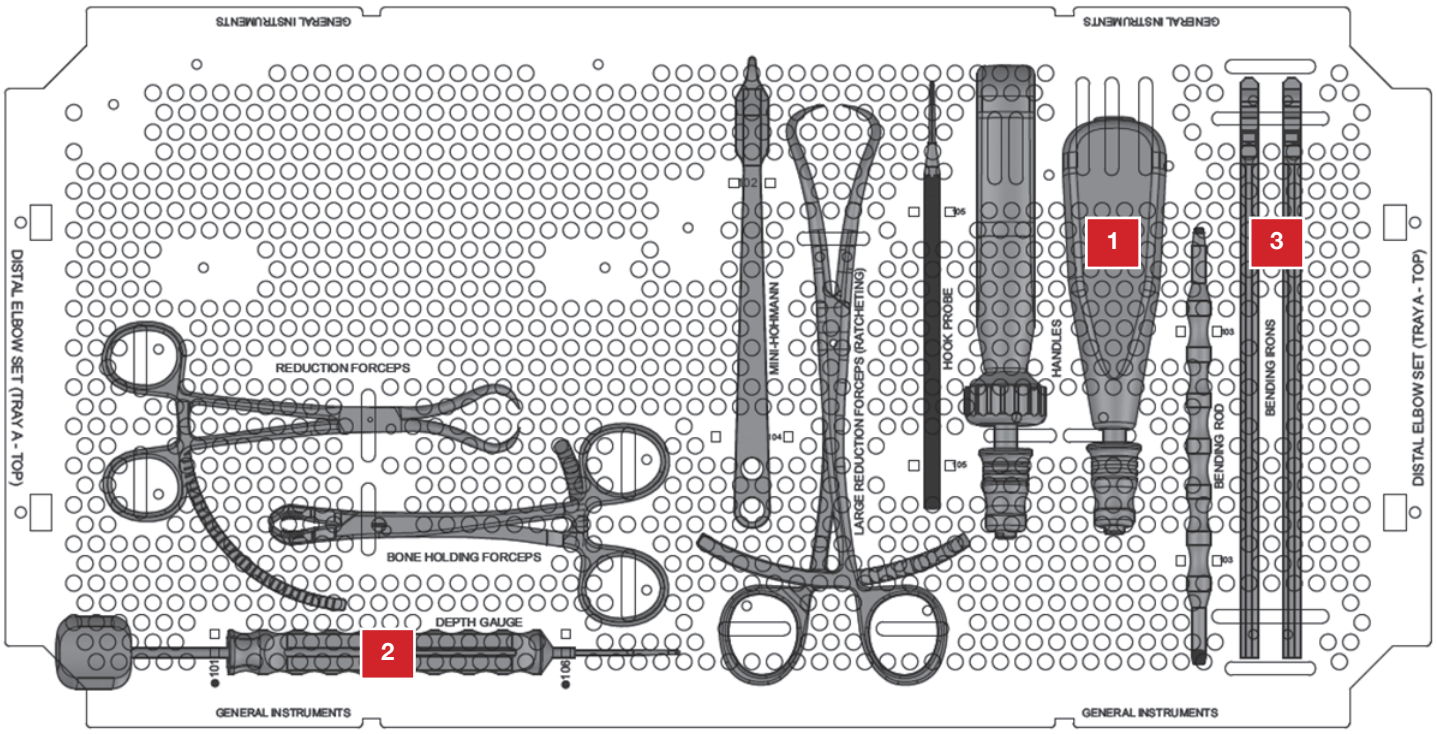
6 CONSTRUCT REMOVAL



Remove the Base Plate construct.

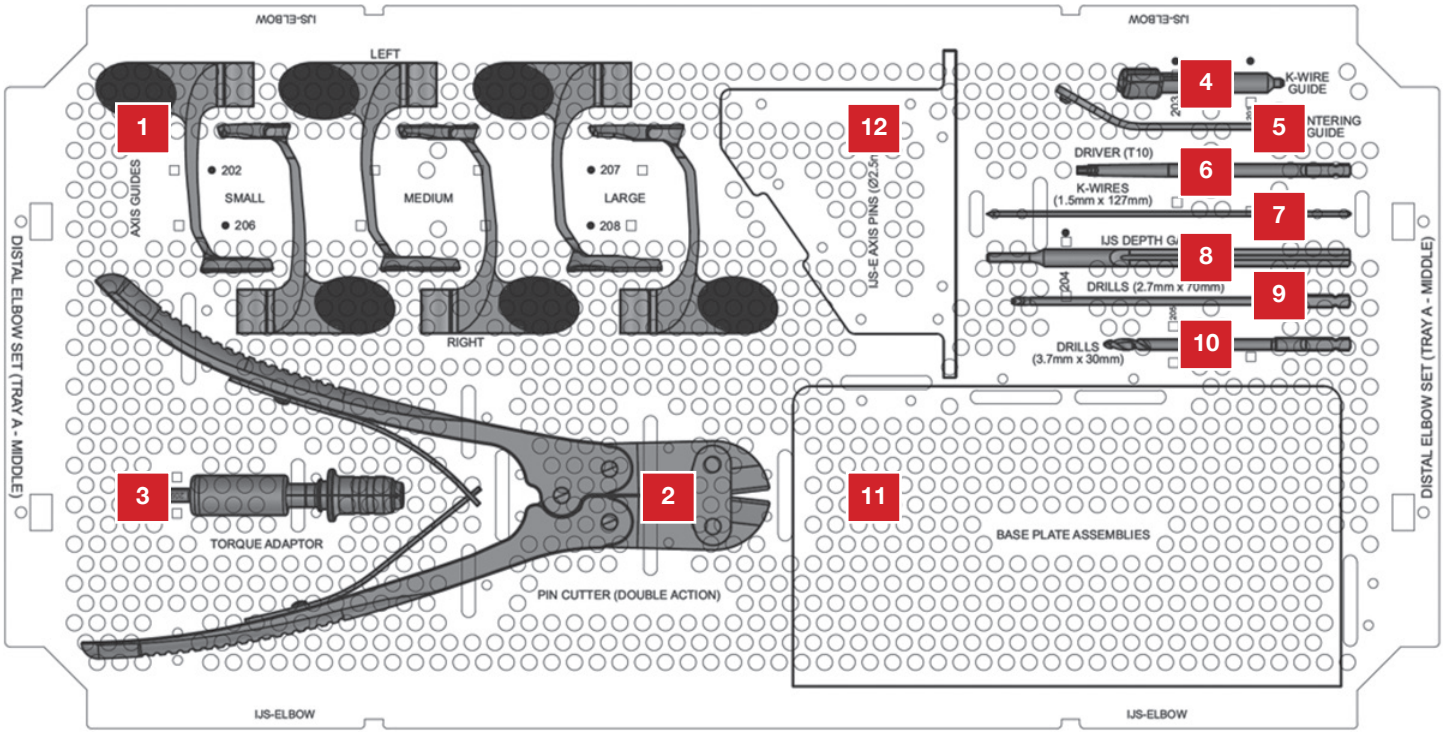
Close both incisions and dress the wound in the usual fashion.

INSTRUMENT TRAY (Standard Configuration)



#	Catalog	Description	#	Catalog	Description
1	HNDL-UQC-FXD	Handle, Quick Connect, Fixed			
2	DPGA-HPS	Depth Gauge, HPS			
3	BND-ROD-DES	Bending Rod, DES			

INSTRUMENT TRAY (Standard Configuration)

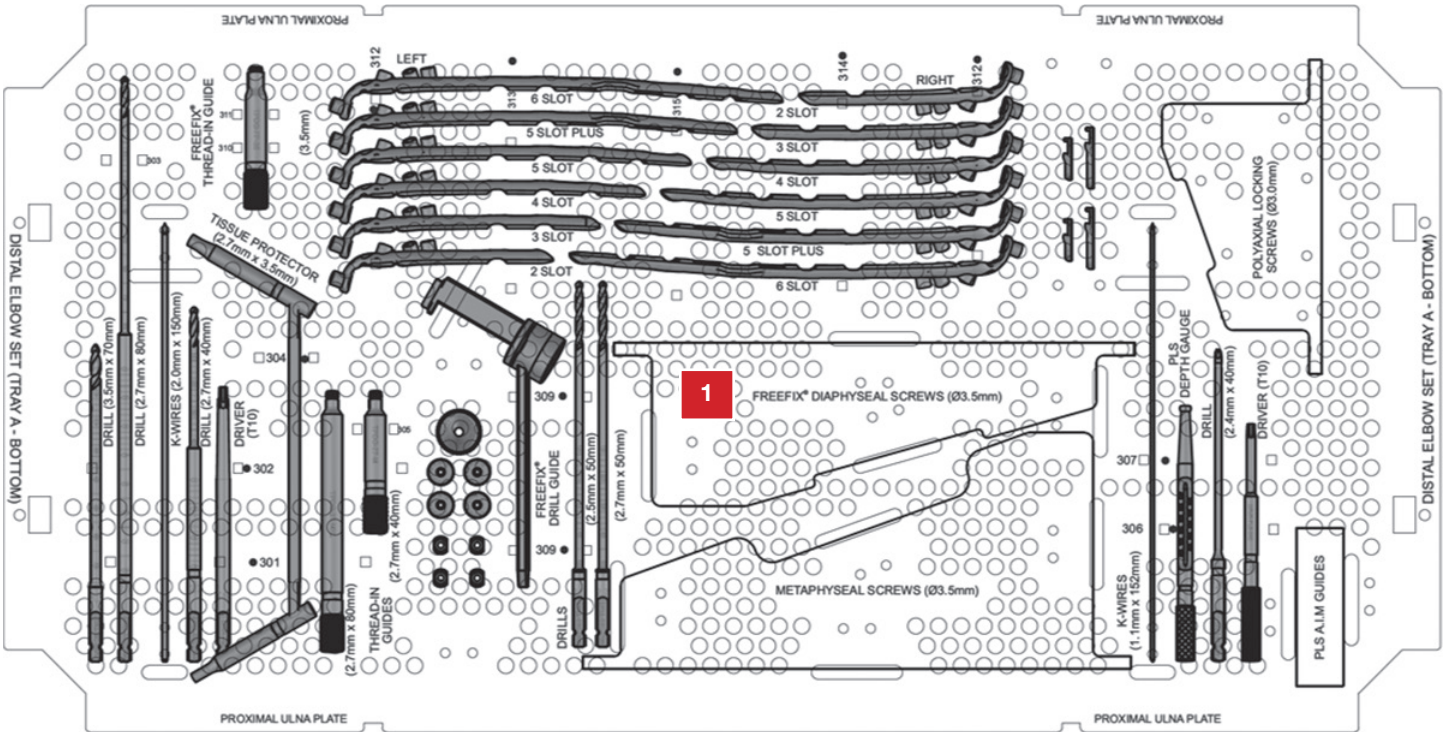


#	Catalog	Description
1	IJS-EAG-SL	IJS-E Axis Trajectory Guide, Rotated, Small, Left
	IJS-EAG-SR	IJS-E Axis Trajectory Guide, Rotated, Small, Right
	IJS-EAG-ML	IJS-E Axis Trajectory Guide, Rotated, Medium, Left
	IJS-EAG-ML	IJS-E Axis Trajectory Guide, Rotated, Medium, Right
	IJS-EAG-LL	IJS-E Axis Trajectory Guide, Rotated, Large, Left
	IJS-EAG-LR	IJS-E Axis Trajectory Guide, Rotated, Large, Right
2	CTP-PI-1123	Cutting Pliers
3	TQA-25	Ao to Ao Torque Adapter, 25 IN-LBS
4	IJS-EAG-KWG	IJS-E K-Wire Guide, 1.5mm
5	IJS-ELB-ACG	IJS-E Axis Centering Guide
6	DRVR-UQC-T10	Driver, Universal Quick Connect, T10
7	KWIR-DES-15127	K-Wire Standard Tip, 1.5mm x 127mm
8	IJS-EDG-OKW	IJS-E Depth Gauge, Over K-Wire
9	IJS-CDC-2770	IJS-E Drill, Cannulated Distal Cutting, 2.7mm x 70mm
10	DRLL-CDC-37030	Drill, Cannulated, 3.7mm x 30mm
11	IJS-ELB-BPA	IJS-E Base Plate Assembly
	IJS-PUP-BPA	IJS-E Base Plate Assembly, Proximal Ulna Plate
	IJS-PUP-SCRW	#4-40 Screws
	IJS-DBL-BPA	Double IJS-E, Assembly

#	Catalog	Description
12	IJS-EAP-25300	IJS-E Axis Pin 2.5mm x 30mm
	IJS-EAP-25350	IJS-E Axis Pin 2.5mm x 35mm
	IJS-EAP-25400	IJS-E Axis Pin 2.5mm x 40mm
	IJS-EAP-25450	IJS-E Axis Pin 2.5mm x 45mm
	IJS-EAP-25500	IJS-E Axis Pin 2.5mm x 50mm
	IJS-EAP-25550	IJS-E Axis Pin 2.5mm x 55mm
	IJS-EAP-25600	IJS-E Axis Pin 2.5mm x 60mm
	IJS-EAP-25650	IJS-E Axis Pin 2.5mm x 65mm
	IJS-EAP-25700	IJS-E Axis Pin 2.5mm x 70mm
	IJS-EAP-F30	IJS-E Axis Pin Female, 30mm

*Not pictured

INSTRUMENT TRAY (Standard Configuration)

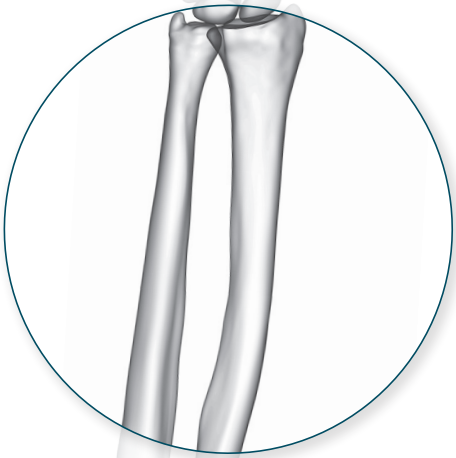


#	Catalog	Description	#	Catalog	Description
1	FFC-35080-TS	Screw, FreeFix Compression, 3.5mm x 08mm, Ti			
	FFC-35100-TS	Screw, FreeFix Compression, 3.5mm x 10mm, Ti			
	FFC-35120-TS	Screw, FreeFix Compression, 3.5mm x 12mm, Ti			
	FFC-35140-TS	Screw, FreeFix Compression, 3.5mm x 14mm, Ti			
	FFC-35160-TS	Screw, FreeFix Compression, 3.5mm x 16mm, Ti			
	FFC-35180-TS	Screw, FreeFix Compression, 3.5mm x 18mm, Ti			
	FFC-35200-TS	Screw, FreeFix Compression, 3.5mm x 20mm, Ti			
	FFC-35220-TS	Screw, FreeFix Compression, 3.5mm x 22mm, Ti			
	FFC-35240-TS	Screw, FreeFix Compression, 3.5mm x 24mm, Ti			
	FFC-35260-TS	Screw, FreeFix Compression, 3.5mm x 26mm, Ti			
	FFC-35280-TS	Screw, FreeFix Compression, 3.5mm x 28mm, Ti			
	FFC-35300-TS	Screw, FreeFix Compression, 3.5mm x 30mm, Ti			
	FFC-35320-TS	Screw, FreeFix Compression, 3.5mm x 32mm, Ti			
	FFC-35340-TS	Screw, FreeFix Compression, 3.5mm x 34mm, Ti			
	FFC-35360-TS	Screw, FreeFix Compression, 3.5mm x 36mm, Ti			
	FFC-35380-TS	Screw, FreeFix Compression, 3.5mm x 38mm, Ti			
	FFC-35400-TS	Screw, FreeFix Compression, 3.5mm x 40mm, Ti			
	FFC-35420-TS	Screw, FreeFix Compression, 3.5mm x 42mm, Ti			
	FFC-35440-TS	Screw, FreeFix Compression, 3.5mm x 44mm, Ti			

*Not pictured

skeletal dynamics®

UNDERSTANDING THE UPPER EXTREMITY



CE 2797
MKT-00455-00
April 2025

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