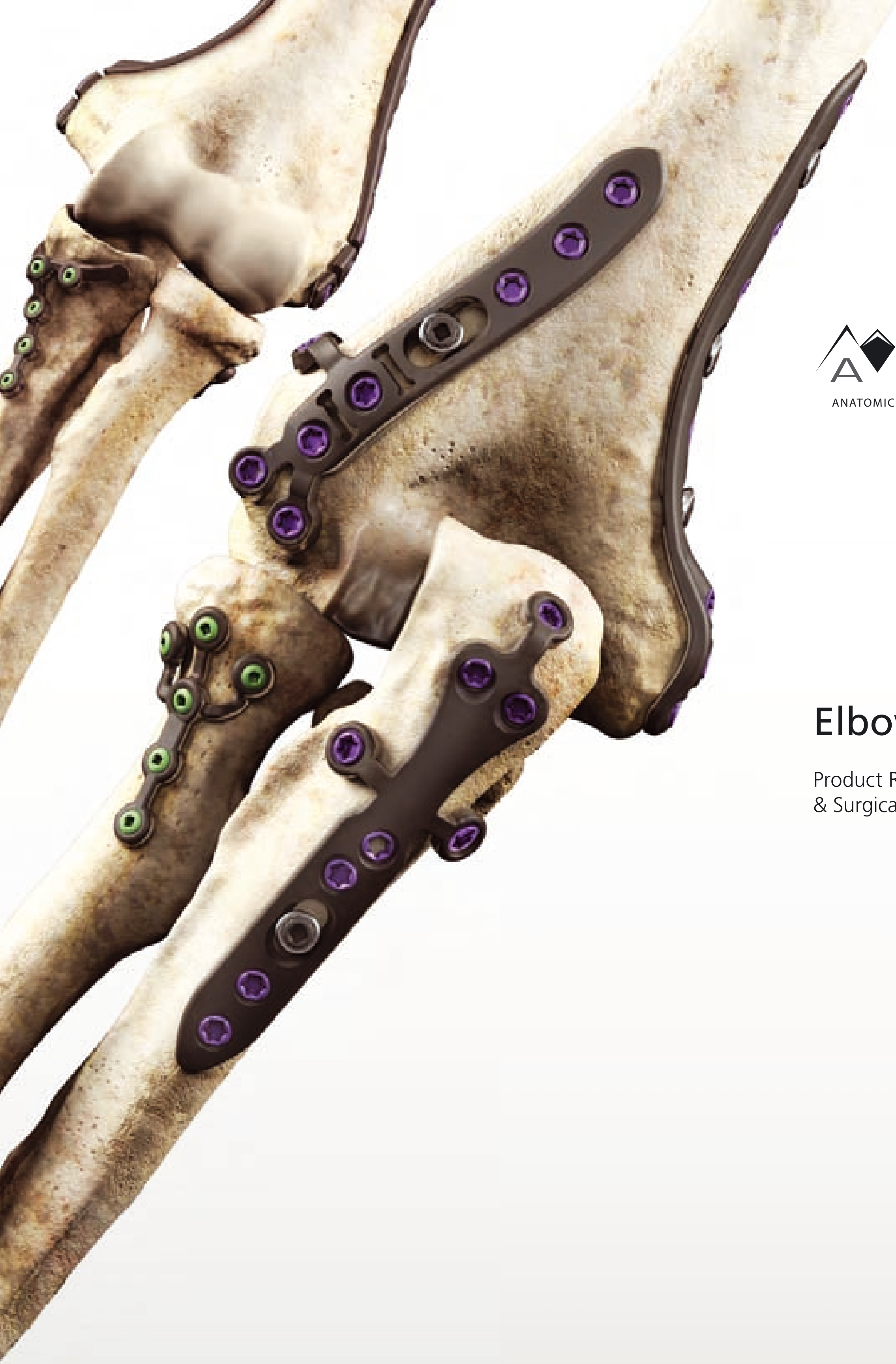

ALPS
ANATOMIC LOCKED PLATING SYSTEM

Elbow Plating System

Product Rationale
& Surgical Technique

DePuy | TRAUMA

DePuy Orthopaedics, Inc.

Contents

Low profile, anatomically contoured elbow plates.

Low profile plate design helps minimize discomfort and soft tissue irritation.

Engineered from TiMAX™ for strength, biocompatibility, a smooth implant surface and enhanced imaging capabilities over stainless steel.

Contoured plates mimic the anatomy of the distal humerus, olecranon, radial head and coronoid.

Available in small and large sizes to best match anatomy.

Bullet tip minimizes soft tissue disruption during insertion.

Low profile F.A.S.T. Guide™ inserts for percutaneous application.

Adapters available for fixed angle K-wire placement for provisional fixation.

The Elbow Plating System features an extensive set of anatomically contoured implants to address a wide array of fractures around the elbow. The anatomic design of each plate matches the natural anatomy of the specificied location. However, in-situ contouring is available for fine adjustment and patient specific customization.

F.A.S.T. Guide™, F.A.S.T. Tabs™ and Provisional Fixation technologies.

F.A.S.T. Guide™ Technology

Pre-loaded and disposable F.A.S.T. Guides facilitate accurate drilling and reduce intraoperative assembly, saving time in the OR.

F.A.S.T. Tabs™ Technology

F.A.S.T. Tab Technology enables in-situ contouring for true plate-to-bone conformity.

Provisional Fixation

Easy K-wire placement through provisional fixation holes for immediate and secure plate positioning.

The Elbow Plating System comes pre-loaded with Fixed Angle Screw Targeting Guides - F.A.S.T. Guides - that direct the trajectory of the drill through the screw hole in the plate. Additionally, F.A.S.T. Tabs technology allows for in-situ contouring for patient specific customization, while provisional fixation holes allow the plate to be securely positioned with K-wires.

Locking, Non-Locking, and Multi-Directional Locking Screw options.

Choose locking, non-locking, or multi-directional locking screws according to need and without compromising plate profile.

Tapered, threaded screws lock into position when tightened to establish a fixed angle construct for improved fixation or when bone quality is poor and optimal screw purchase is required.

Multi-directional locking screws (MDS) allow for up to a 25 degree cone of angulation and lock into the plate by creating their own thread without the risk of cold welding.

Low profile non-locking screws provide the same profile as locking screws.

Slotted holes allow for axial compression.

Particularly helpful in challenging fracture cases, the interlocking screw construct of the Elbow Plates provide you with both versatility and strength. The addition of the MDS screw technology allows you to target and capture fragments for optimum fixation. With the added feature of the low profile non-locking screw, whichever screw option you choose plate profile is maintained for minimum soft tissue disruption.

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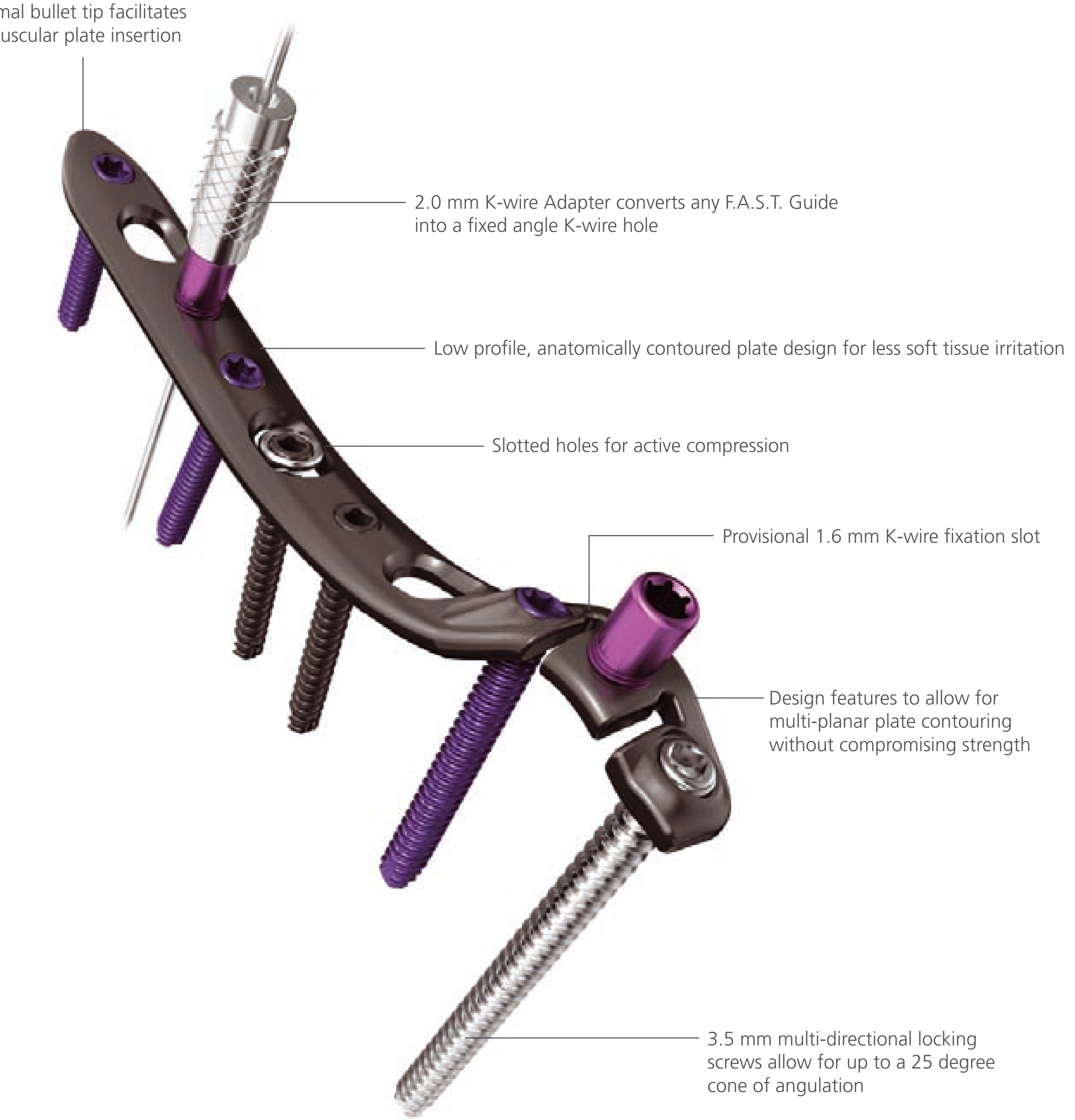
Introduction

The A.L.P.S. Elbow Plating System is a comprehensive system designed to address fractures around the elbow. The system includes eighteen anatomically contoured plates in Medial, Lateral, Posterior Lateral, Olecranon, Radial Head, and Coronoid designs. All plates have TiMAX surface treatment for increased strength compared with stainless steel. F.A.S.T. Guide™ inserts incorporating flexible plating technology have been designed into all implants for fast drilling as well as in-situ contouring to allow for a true anatomic fit.

Note: The pre-assembled F.A.S.T. Guide inserts are NOT to be removed prior to sterilization. They should be removed and discarded only after use.

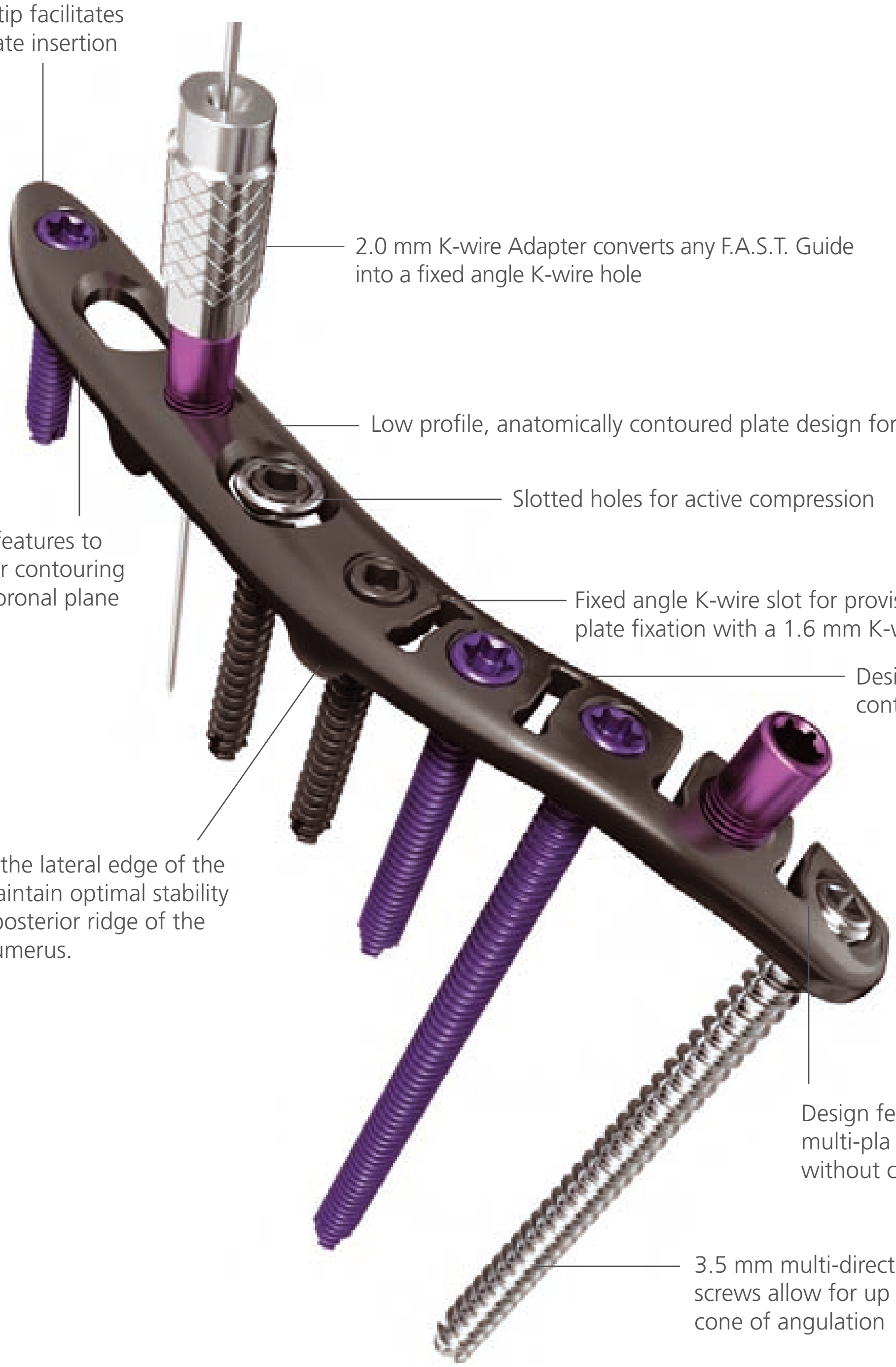
The A.L.P.S Elbow Plating System is intended for fixation of fractures, fusions, osteotomies, and non-unions of the clavicle, humerus, radius, ulna, olecranon, metacarpal, metatarsal, malleolus, tibia and fibula, particularly in osteopenic bone.

Medial Plate



Medial Plate Specifications	Small	Large
Length	80.3 mm	95.3 mm
Width	10.9 mm	10.9 mm
Thickness	2.5 mm	2.5 mm

Lateral Plate



Lateral Plate Specifications	Small	Large
Length	61 mm	82.6 mm
Width	9.7 mm	10.7 mm
Thickness	2.4 mm	2.4 mm

Posterior Lateral Plate

Posterior Lateral Plate Specifications	Small	Large
Length	73.7 mm	91.4 mm
Width	10.7 mm	10.7 mm
Thickness	3.5 mm	3.5 mm

Olecranon Plate

Olecranon Plate Specifications	Small	Large
Length	81 mm	107 mm
Width	10 mm	10 mm
Thickness	2.5 mm	2.5 mm

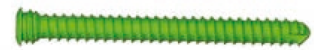
Coronoid and Radius Plates

Coronoid Plate Specifications	
Length	32.7 mm
Width	28 mm
Thickness	1.5 mm

Proximal Radius Plate Specifications	Small	Large
Length	29 mm	36.5 mm
Width	17.5 mm	18 mm
Thickness	1.5 mm	1.5 mm

Screw Specification

2.5 mm Locking Screw (Cat. No. FPXX):

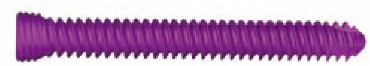


- Self tapping tips to assist with screw insertion
- Square drive to maximize torque delivery
- Triple lead thread on screw head to reduce cross threading
- Tapered threads to reduce screw backout
- Available in lengths of 14 – 40 mm

2.5 mm Non-Locking Screw (Cat. No. SPXX00):

- Self tapping tips to assist with screw insertion
- Square drive to maximize torque delivery
- Available in lengths of 14 – 40 mm

3.5 mm Locking Cortical Screw:



- Larger core diameter and shallower thread pitch for improved bending and shear strength compared to a standard 3.5 mm Cortical Screw
- Self tapping tip minimizes the need for pre-tapping and eases screw insertion
- Tapered screw head helps ensure alignment of the screw head into the plate hole
- Tapered threaded head minimizes screw back-out and construct pullout
- T-15 drive
- Available in lengths of 10 – 70 mm
- Screw (Cat. No. 8161-35-XXX) uses a 2.7 mm Drill Bit (Cat. No. 2141-27-070)

3.5 mm Low Profile Non-Locking Screw:

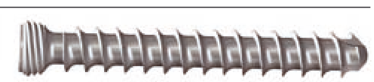
- Low profile head design reduces prominence beyond the plate
- Self tapping tip eases screw insertion
- Square drive to maximize torque delivery
- Type 2 anodized material for increased fatigue strength compared to stainless steel
- Available low profile washer converts screw head to traditional non-locking screw head size for use in active compression holes
- Screw (Cat. No.1312-18-XXX) uses a 2.5 mm Drill Bit (Cat. No. 8290-29-070) and can be installed in any of the threaded holes in the plate
- Available in lengths of 14 – 75 mm

Active Compression Conversion Washer:

- Cobalt chrome washer designed to snap onto the head of low profile 3.5 mm non-locking screw
- Washer converts low profile screw head into a standard profile non locking screw
- Allows for active compression in any of the oblong slots

Note: The washer is for use ONLY with the 3.5 mm Low Profile Non-Locking Screw (Cat. No. 1312-18-XXX).

3.5 mm Locking Multi-Directional Screw:

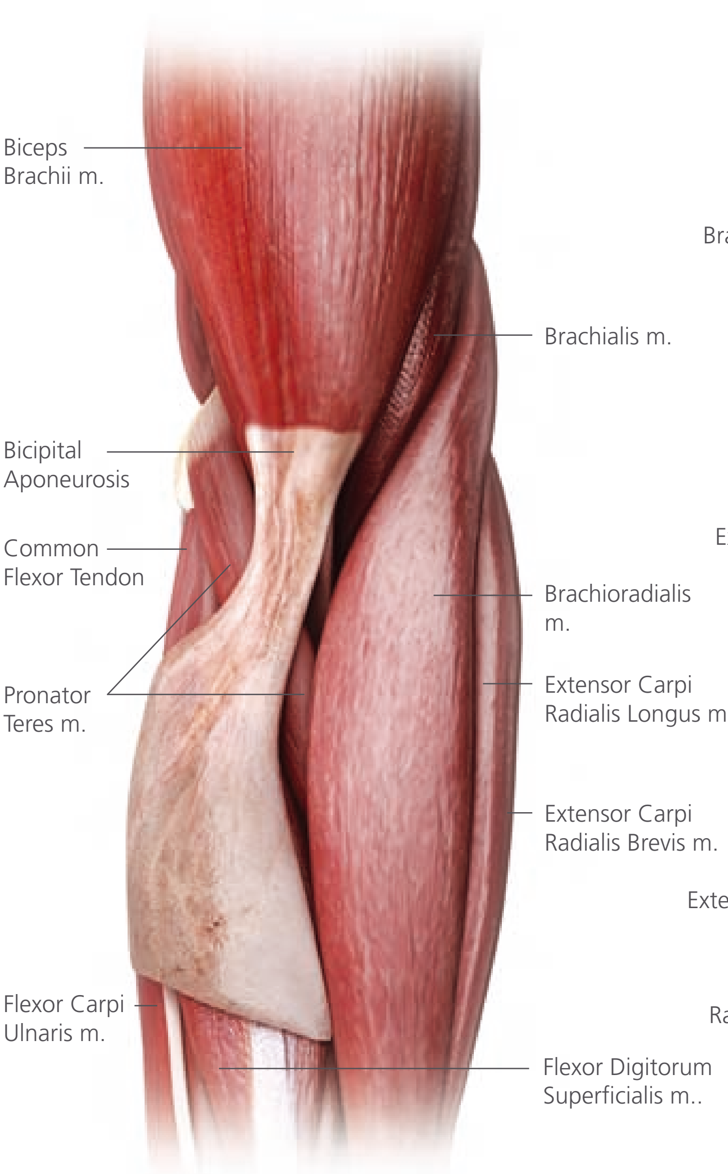


- Cobalt chrome screw with large core diameter
- Multi-Directional capability offers a 25 degree cone of angulation
- Creates own thread in plate to help provide strong and stable construct
- Self tapping tip minimizes the need for pre-tapping and eases screw insertion
- 2.2 mm square drive
- Available in lengths of 20 – 60 mm
- Screw uses the 2.7 mm Drill Bit (Cat. No. 2142-27-070)

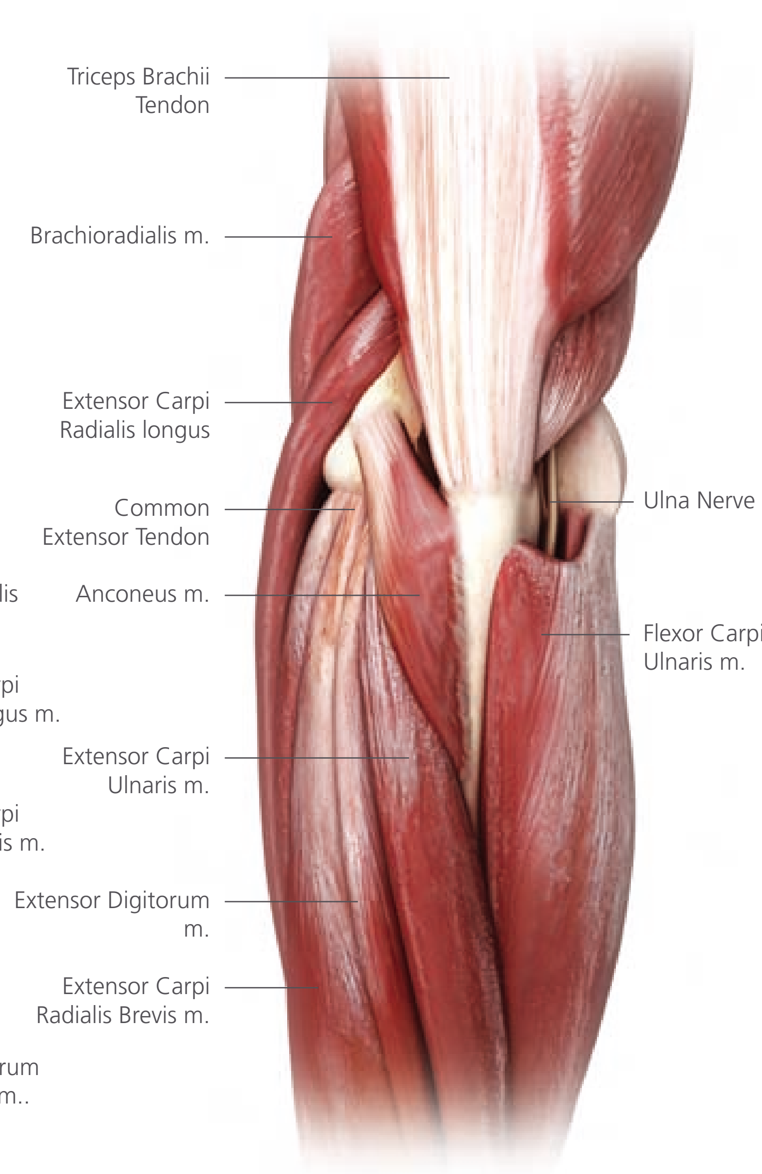
Anatomy

Soft Tissue of the Elbow

Anterior view in extension

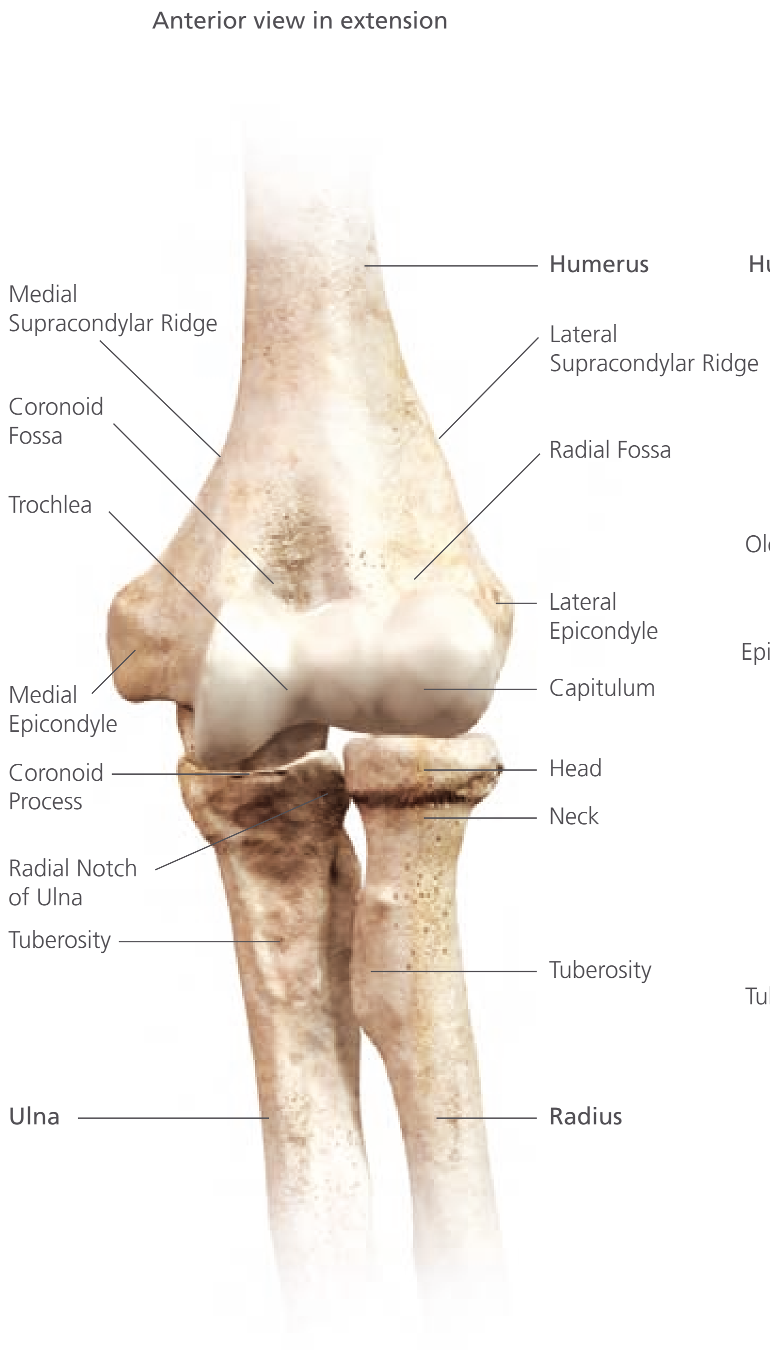


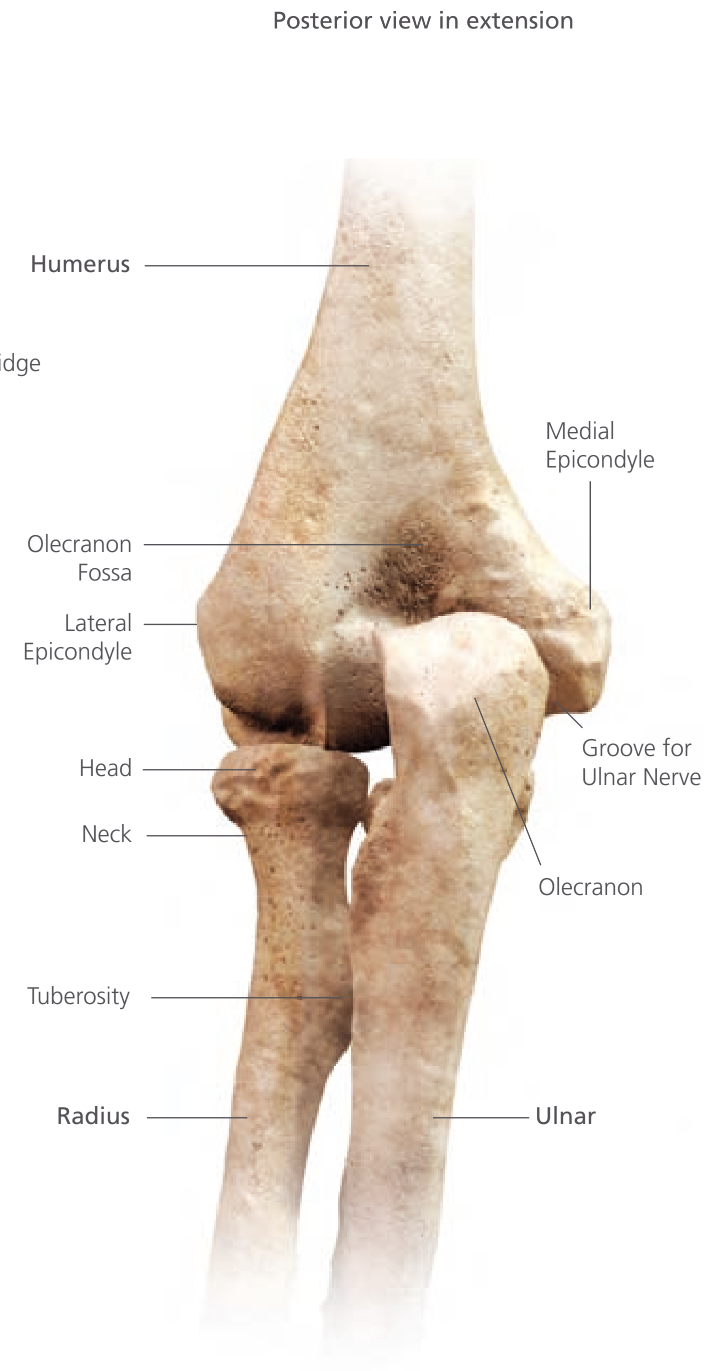
Posterior view in extension



Anatomy

Bones of the Elbow





Patient Position

Figure 1
The supine position with the arm across the chest.

The patient can be placed in either the prone or supine position, depending on surgeon preference.

Supine is the most popular position, with the arm placed across the chest. The surgeon stands on the fractured side of the patient, who is brought to the very edge of the table. Inclining the table 20 to 30 degrees away from the operating surgeon will help keep the arm positioned across the chest (Figure 1).

After sterile preparation and drape, the arm is placed across a small bolster which can help maintain the position and flexion of the proximal forearm. For optimum exposure, the arm should accommodate over 100 degrees of flexion. The operating surgeon stands with sight of the posterior aspect of the elbow and is ready to begin the procedure.

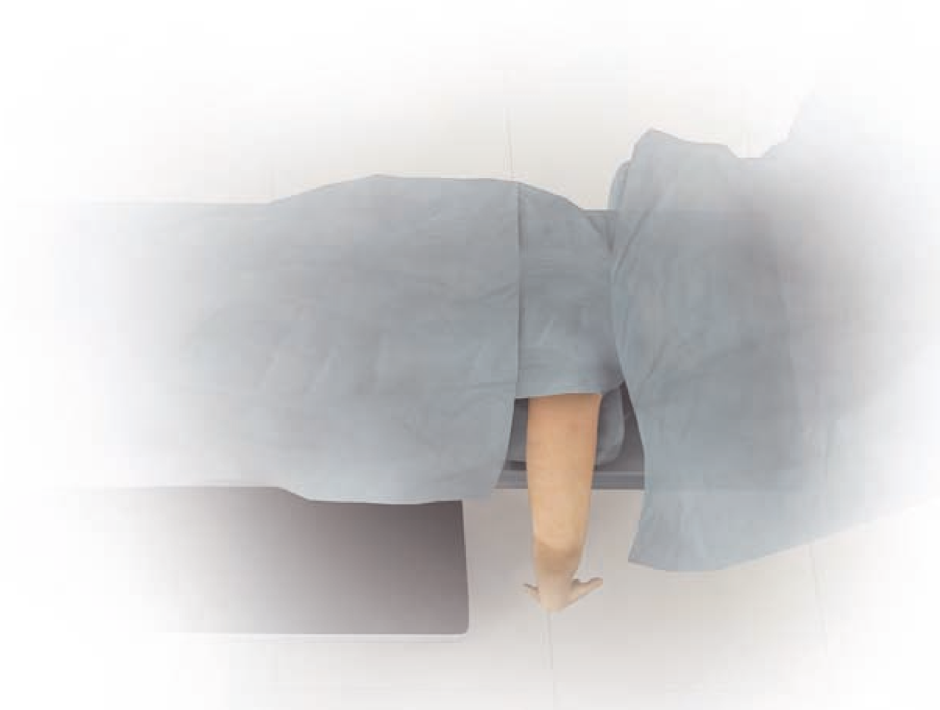


Figure 2
The prone position with the forearm hanging off the side of the operating table.

The prone position can also be used with the forearm hanging off the side of the operative table. This position requires more involvement of the anesthesia team, but for surgeons that are comfortable with this position it can provide good operative exposure (Figure 2).

Exposing the Humerus

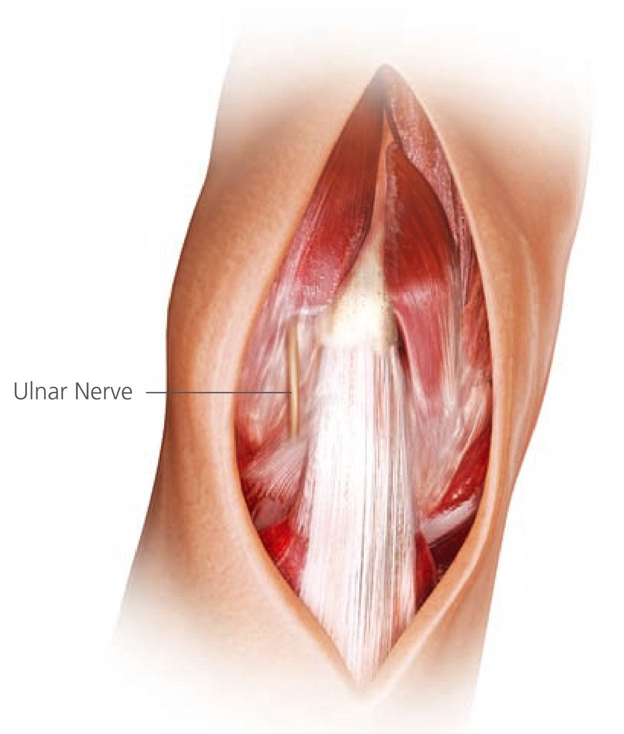
The approach for a distal humerus fracture typically involves a posterior skin incision. The incision should be extended distally, by curving slightly lateral to the tip of the olecranon.

Step 1

The incision will need to extend approximately 15 cm proximal to the tip of the olecranon and approximately 10 cm distal to the tip of the olecranon. The skin is elevated with care to keep the skin flaps as thick as possible (Step 1).

An osteotomy of the olecranon is performed to gain exposure of the distal humerus. This can be a chevron type or straight transverse osteotomy.

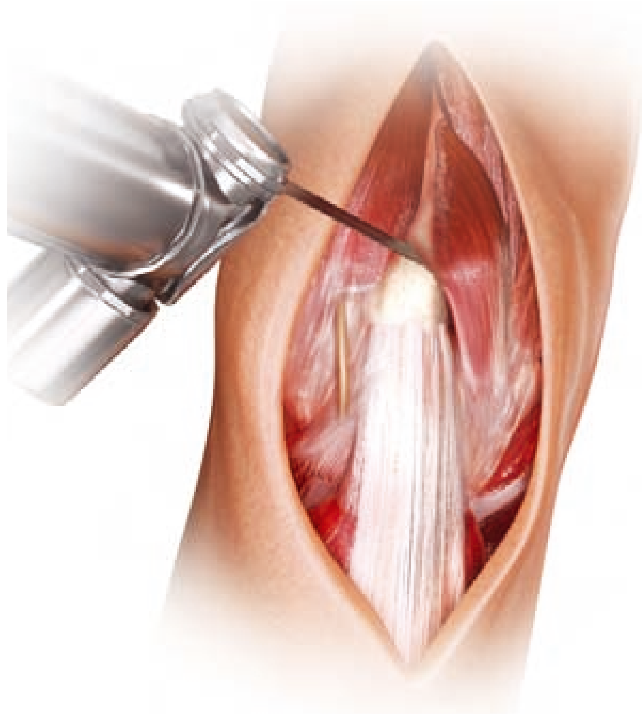
We have decided to use a chevron osteotomy to gain exposure to the distal humerus.



Step 1
Initial incision.

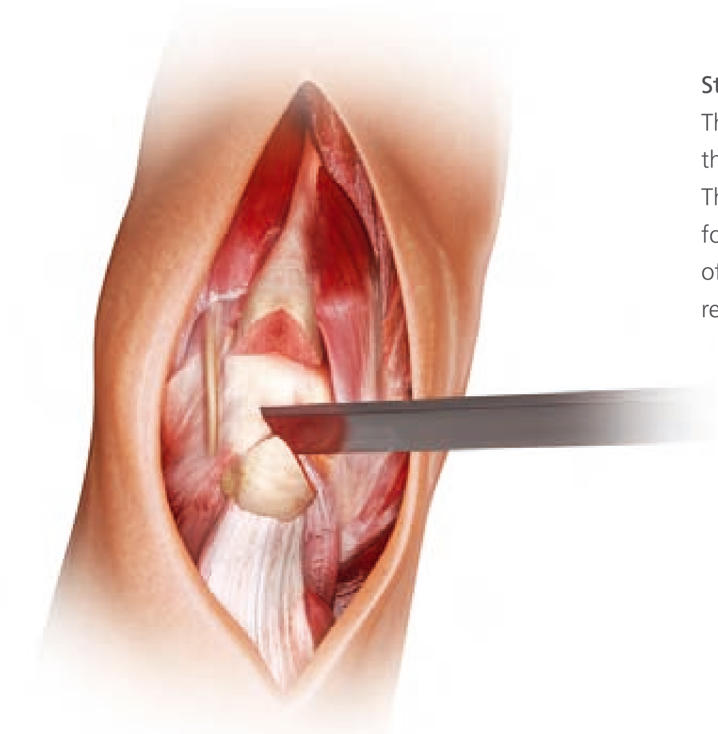
Step 2

Incise the medial and lateral joint capsule to visually identify and mark the central aspect of the greater sigmoid notch. This area is typically devoid of cartilage. The osteotomy can be angled slightly distal to proximal to increase the surface area of the cut. The posterior one-third of the olecranon is cut with a saw (Step 2). Then a flat osteotome is used to drive through the central one-third of the olecranon.

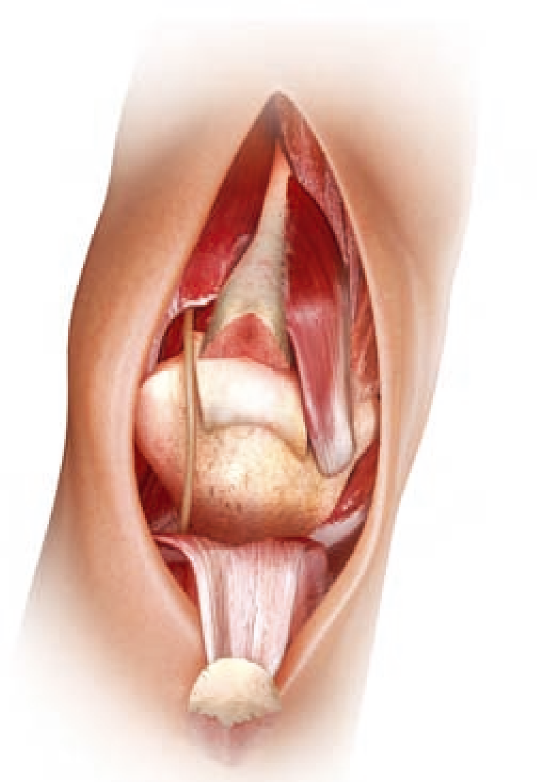


Step 2
The posterior one-third of the olecranon is cut with a saw.

Exposing the Humerus



Step 3
The osteotome is then used as a lever to break off the anterior one-third of the olecranon.



Step 4
Retract the proximal portion of the olecranon posteriorly.

Step 3
The osteotome is then used as a lever to break off the anterior one-third of the olecranon (Step 3). This three-step approach to the osteotomy allows for interdigitation of the rough edges at the end of the procedure, allowing for optimum fragment reduction and fixation.

Step 4
Retract the proximal portion of the olecranon posteriorly. The ulnar nerve will need to be separated from the cubital tunnel and protected for later transposition at the conclusion of the procedure (Step 4).

Note: It is not recommended to use the plating system on the medial side without transposition of the ulnar nerve due to the potential for damage from the close proximity of the instruments.

On the lateral side of the elbow, the anconeus will need to be either transected to retract the proximal fragment or, as a variation, the anconeus can be elevated from distal to proximal and taken as a flap with the osteotomy preserving its vascularity and innervation without transecting it. At the end of the procedure it can be sutured back anatomically.

Once the olecranon fragment is retracted with the triceps, visualization of the distal humerus fracture is obtained.

Humeral Fracture Reduction

The first step to reduction is to identify the major fracture fragments and develop a plan for reassembly of the fracture. Typically, the best approach is to reassemble from distal to proximal reducing the larger fragments first.

When placing K-wires for provisional fixation, care should be taken to place them in the area of the bone that will not interfere with a plate.

If a segment of the distal humerus is missing or comminuted, a bone graft should be positioned to maintain the proper width of the distal humerus.

Step 1
Fragment reconstruction.

Step 1
The most important fragments to assemble accurately are the anterior trochlea and the capitellum. The anterior and medial aspect of the distal humerus is most important for stability whereas fracture fragments off the posterior trochlea and posterior aspect of the capitellum can be sacrificed if significant comminution has taken place (Step 1).

Step 2
Once the distal segment of the humerus containing the articular surface has been reconstructed, this fracture construct can be placed onto the end of the humeral shaft. This can be done by placing 2 mm or 3 mm pins directly through the anterior aspect of the distal humerus down the central aspect of the humeral canal. Often two pins will be needed to cross the fracture site to gain stability and preliminary reduction of the fracture (Step 2).

Step 2
Pin placement.

Humeral Fracture Plate Selection and Screw Placement

Medial column and posterior lateral aspect of the humerus

Figure 1
High transverse non intra-articular fracture.
Medial and Lateral plates.

Figure 2
Low transverse non intra-articular fracture.
Medial and Lateral or Posterior Lateral plates.

If satisfactory reduction of the fracture is achieved, plates can then be positioned either on the medial or lateral columns or on the posterior lateral aspect of the humerus (Figures 1 and 2).

Figure 3

Note: When applying the Medial and Lateral plates, there is an increased chance of hitting screws with the drill bit when drilling towards the side with screws already installed.

Multi-directional screws are available to assist in avoiding other screws that are already installed (Figure 3).

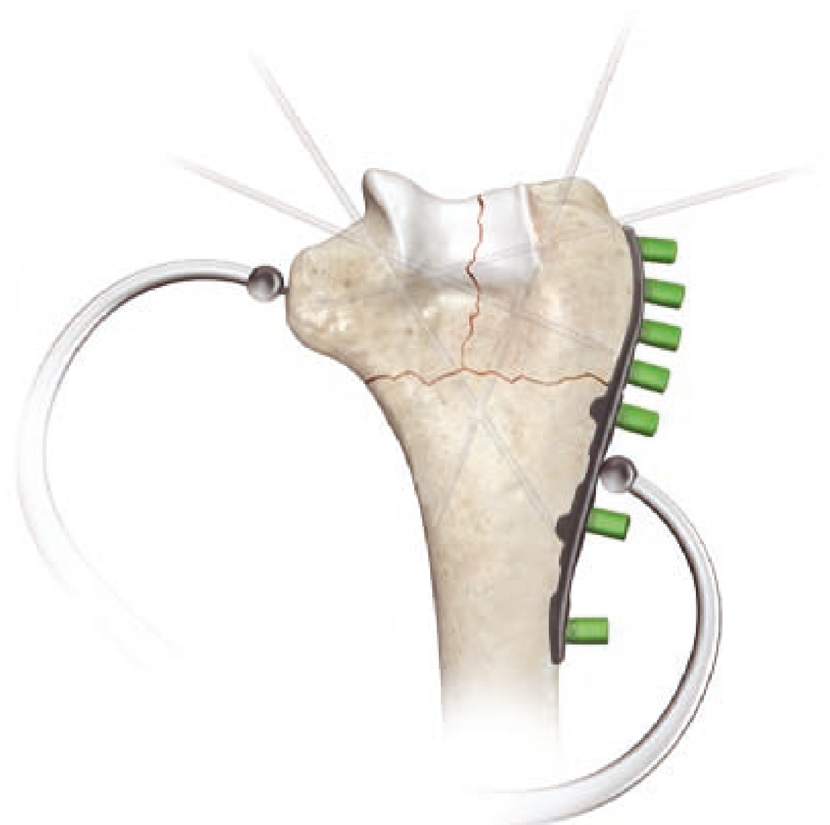
Humeral Fracture Plate Fixation

Determine, and place first, the plate which will gain best initial stability. The placement technique is the same for Medial, Lateral and Posterior Lateral plates. In this technique we have used the Lateral plate as an example.

This less involved fragment can often be reduced better anatomically than the more comminuted side. This allows the more comminuted side to be built off of the more stable side to limit the possibility of non-anatomic angulation.

Step 1

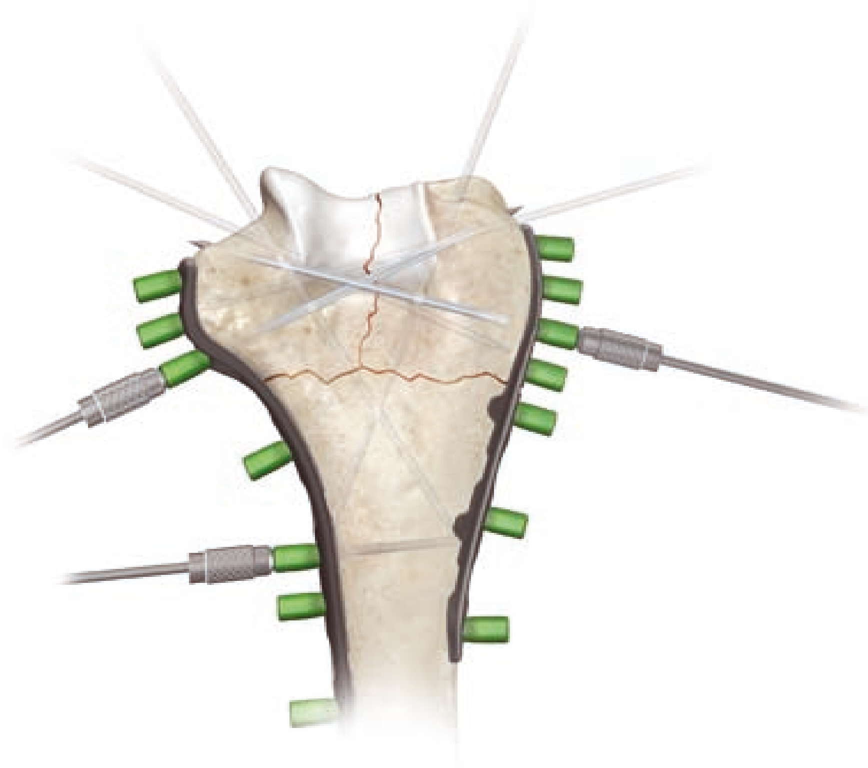
The first plate is placed onto the condyle manually and then one of the large reduction clamps (Cat. Nos.1920 and 13577) can be used to hold this in position (Step 1). Often it is possible to place both column plates in a parallel fashion and use the large fracture reduction clamp to secure both plates at once to the distal humerus.



Step 1
The first plate is held in place with the reduction clamp.

Step 2

Alternatively, the plates can be secured to the bone by using K-wire adapters and inserting fixed angle 2.0 mm K-wires through the F.A.S.T. Guide™ inserts in the proximal and distal segments of the plates (Step 2).



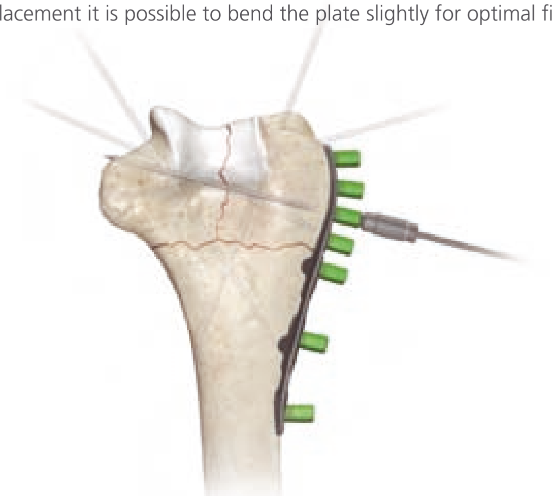
Step 2
Alternatively, a K-wire is inserted through the distal F.A.S.T. Guide.

Humeral Fracture Plate Fixation

Step 3
During placement it is possible to bend the plate slightly for optimal fit.

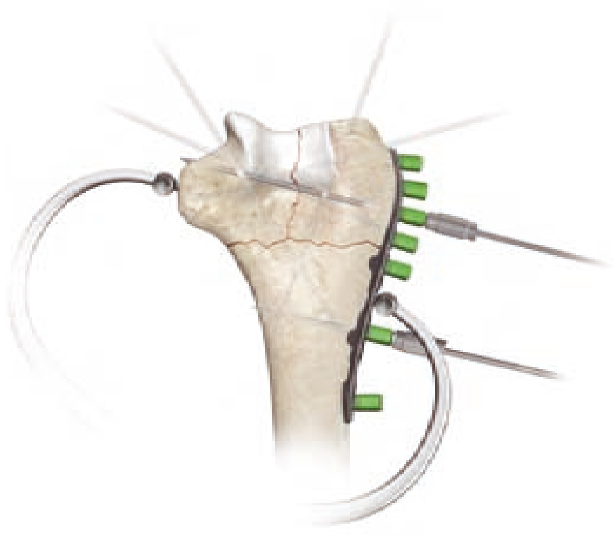
Step 3
During placement it is possible to contour the plate for optimal fit by using the plate benders. The plate can be further contoured if needed in-situ (Step 3).

Note: For further information on plate contouring refer to Appendix A on page 38.



Step 4
Apply plate to bone and insert a K-wire through the distal 3rd position to verify its correct position.

Step 4
Apply the plate to the bone and insert a K-wire through the distal 3rd position and verify that it exits on the opposite condyle (Step 4).



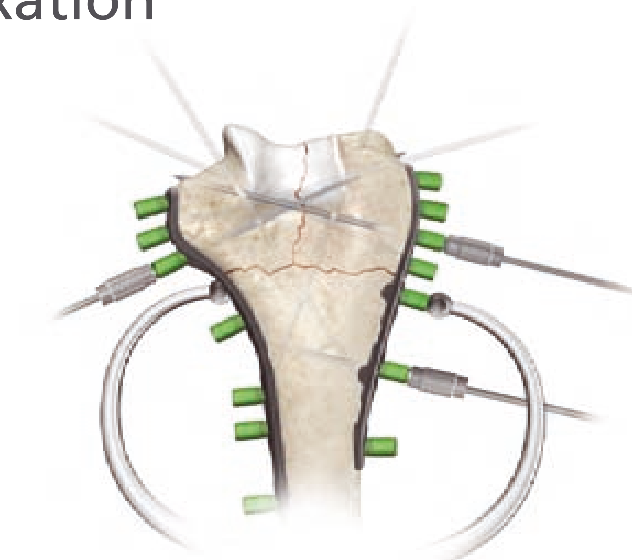
Step 5
Use the clamp to compress the plate to the bone. A 2.0 mm K-wire is inserted through a K-wire adapter in the most proximal hole in the plate.

Step 5
Use the clamp to compress the plate to the bone.

A 2.0 mm K-wire is inserted through a K-wire adapter in a hole proximal to the fracture. This will stabilize the plate to the bone. Once inserted, the distal aspect of the plate can be contoured in-situ for optimal fit (Step 5).

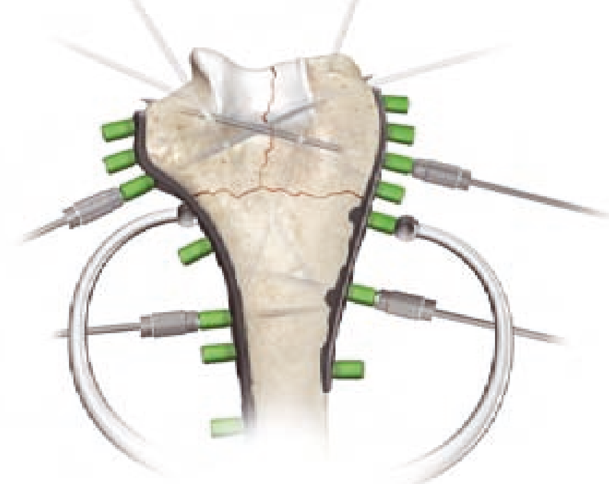
Humeral Fracture Plate Fixation

Step 6
The medial plate is now positioned on the bone. Repeat Step 4 (Step 6).



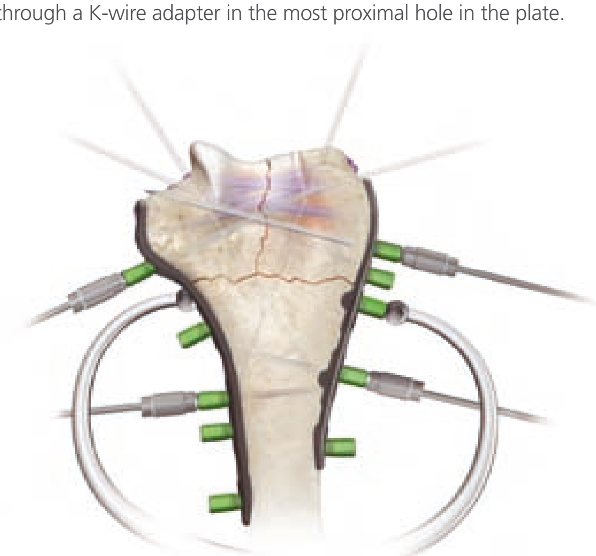
Step 6
Apply the medial plate to bone and insert a K-wire through the distal 3rd position to verify its correct position.

Step 7
Use the clamp to compress the medial plate to the bone, and repeat Step 5 (Step 7).



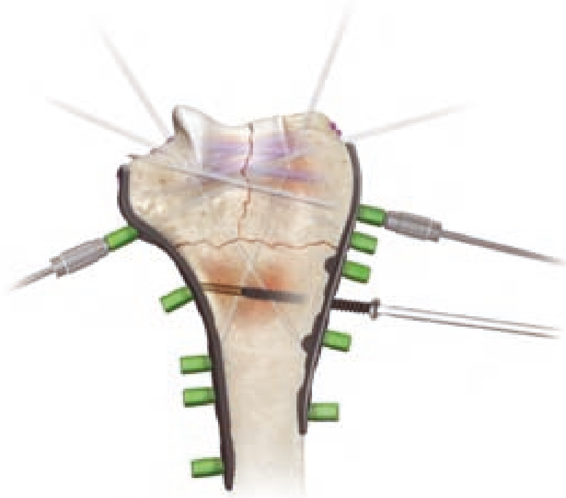
Step 7
Use the clamp to compress the plate to the bone. A 2.0 mm K-wire is inserted through a K-wire adapter in the most proximal hole in the plate.

Step 8
Insert the distal screws to secure the distal fragment. The screw insertion should alternate from one side to the other side.



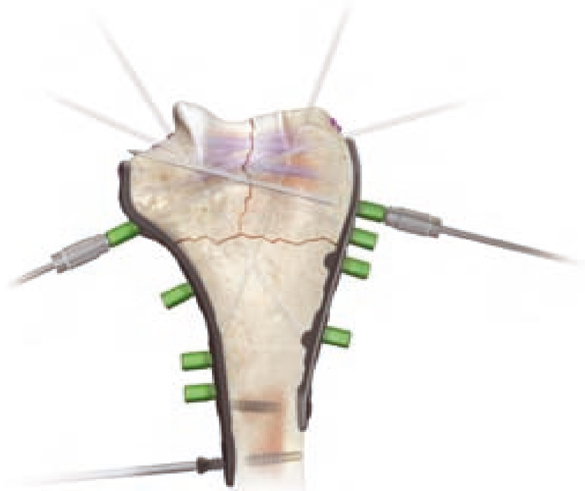
Step 8
Insert the distal screws to secure the distal fragment.
The screw insertion should alternate from one side to the other side.

Humeral Fracture Plate Fixation



Step 9a
If axial compression of the fracture is needed through the plate, the proximal K-wire is removed and a low profile non-locking screw with a washer is inserted in the active compression slot.

Step 9a
If axial compression of the fracture is needed through the plate, the proximal K-wire is removed and a nonlocking screw with a washer is inserted in the active compression slot (Step 9a).



Step 9b
If compression at the fracture site was achieved with a clamp, the proximal screws can be filled with locking or non-locking screws.

Step 9b - Alternative method
If compression at the fracture site was achieved with a clamp, the proximal screws can be filled with locking or non-locking screws (Step 9b).

It is recommended to use a non-locking screw in the most proximal screw holes to facilitate an optimal transition of stress from plate construct to the unplated bone.

See Appendix B on pages 41-44 for screw insertion.

The distal screws should be placed as long as possible, ideally exiting the opposite column. It is not recommended to use short locking screws as the goal is to attempt to incorporate as many fracture fragments as possible reaching the opposite column.

Step 8
Non-locking, locking or multi-directional screws are used to fill the remaining screw holes.

Step 8
Non-Locking, Locking or Multi-Directional Screws can now be used to fill the remaining screw holes (Step 8).

Specific instructions on inserting screws can be found in Appendix B pages 41-44.

Exposing the Radial Head

Step 1
The radial head can be approached from either a direct posterior (Step 1) skin incision in which a flap is raised to expose the radiocapitellar joint area or through a direct lateral approach.

If there is a concurrent coronoid fracture or significant medial instability a single posterior incision is recommended.

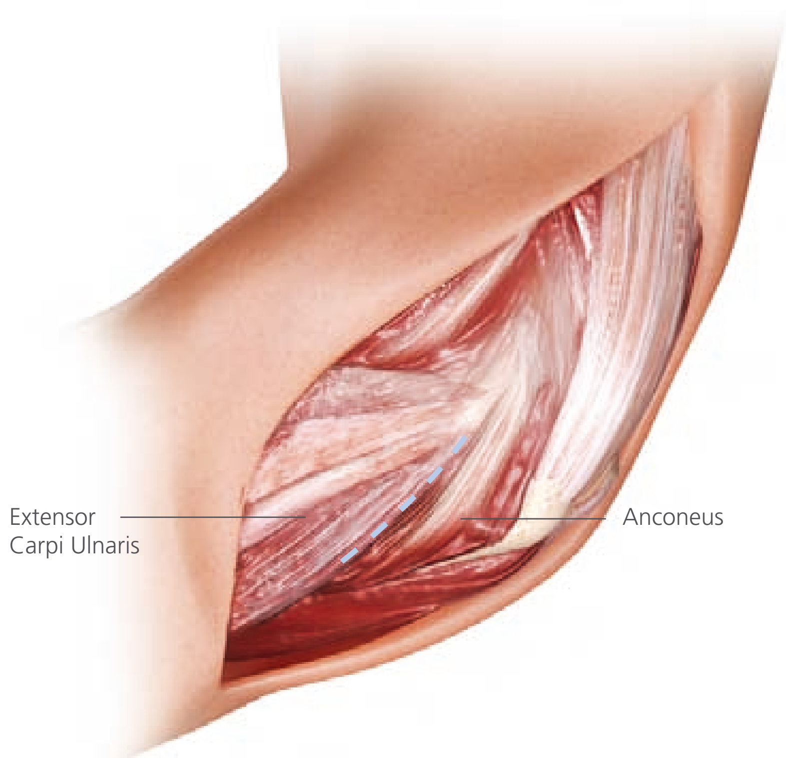
Additionally, a posterior incision is placed through a watershed area between medial and lateral cutaneous nerves and can avoid potential surgical trauma to these sensory nerves.

After the radiocapitellar area is exposed either through a direct lateral or posterior approach, there are two potential avenues of approach to the radial head.

Step 1
Direct posterior approach for radial head exposure.

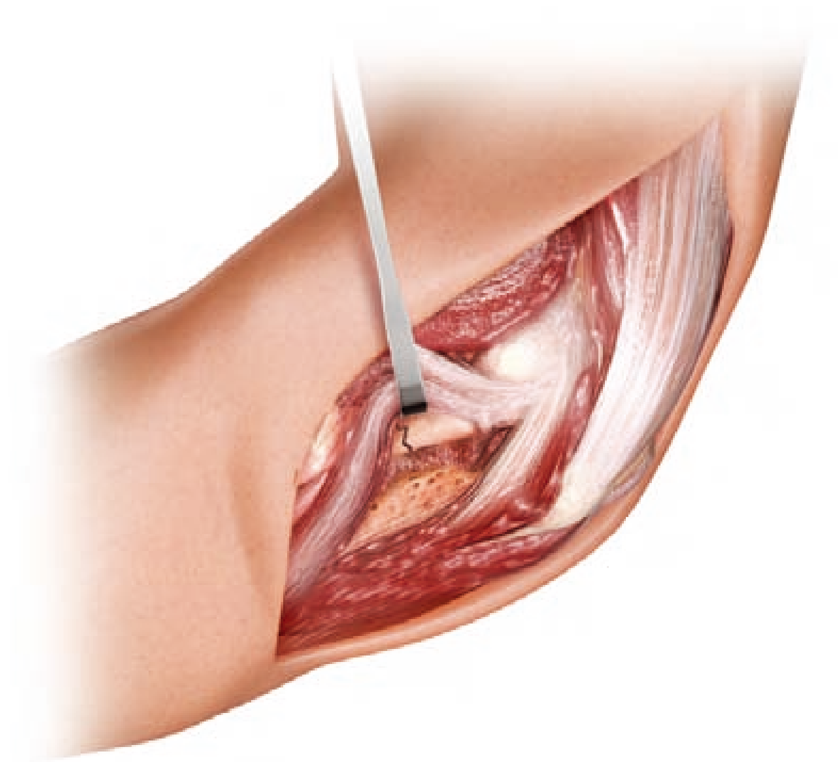
Step 2
The most common approach is the Kocher interval approach which is through the interval between the anconeus and the extensor carpi ulnaris. This is located safely away from the radial nerve and its branches, and it is fairly easy to define (Step 2).

Note: A potential disadvantage is that this interval will put the surgical approach directly over the lateral ulnar collateral ligament which is the main stabilizer of the lateral side of the elbow.



Step 2
The Kocher interval approach, through the interval between the anconeus and the extensor carpi ulnaris.

Exposing the Radial Head



Step 3
Exposure of the radial head fracture.

If the surgical approach is carried straight through the anconeus/extensor carpi ulnaris interval into the joint, the lateral ulnar collateral ligament can be violated. The proper approach using the Kocher interval is to develop the interval between the anconeus and the extensor carpi ulnaris and then elevate anteriorly the extensor carpi ulnaris off of the lateral ulnar collateral ligament until the equator or midpoint of the radiocapitellar joint is exposed. To preserve the integrity of the lateral ulnar collateral ligament complex, the capsule should be incised horizontally at the equator of the radiocapitellar joint. ***Note: If the capsular incision is placed further posterior in the radiocapitellar joint, then potential violation of the lateral ulnar collateral ligament might occur.***

Step 3

Once the radiocapitellar joint has been well exposed and the area of the posterior interosseous nerve protected, adequate exposure of the radial head fracture can be undertaken (Step 3).

If the fracture involves only a wedge of the radial head with the majority of the radial head intact, a buried non-locking screw can be used to reduce and hold the small fragment. In this instance, a non-locking 2.5 mm screw can be used (SPXX000). In many fractures, the fracture occurs at the neck level with additional comminution of the radial head itself. In this situation, the radial neck area is often compressed and this needs to be elevated and fixed.

In addition to the Kocher interval approach, a more direct approach to the radial head that has become recently popular is a direct split of the common extensor tendon directly over the equator of the radiocapitellar joint. This incision is carried directly through the extensor digitorum communis to the level of the radiocapitellar joint capsule, and the capsule at this point of the equator of the radiocapitellar joint is incised to expose the radial head and neck. Fixation of the radial head and neck fracture is commenced as described previously.

Radial Head Fracture Fixation

Step 1
Use the F³® Fragment Plate Holder (Cat. No. 2312-07-012) to position the plate appropriately on the radial head. The plates are designed to be placed in the area of the radial neck that does not impinge on the proximal radioulnar joint and off the articular surface of the radial head. (Step 1).

Step 2
Two sizes of proximal radial plates are available, small and large. Select the most appropriate size to fit the individual. Use the supplied 2.5 plate benders to tailor the fit of the plate to the individual anatomy of the patient (Step 2).

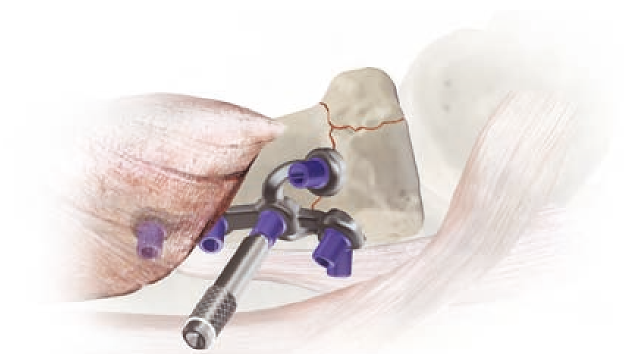
Note: For further information on plate bending refer to Appendix A on page 40.

Note: For small individuals the distal hole of the plate can be broken off to limit the distal exposure needed for plate fixation. It is recommended that a minimum of two screws be placed into the radial shaft.

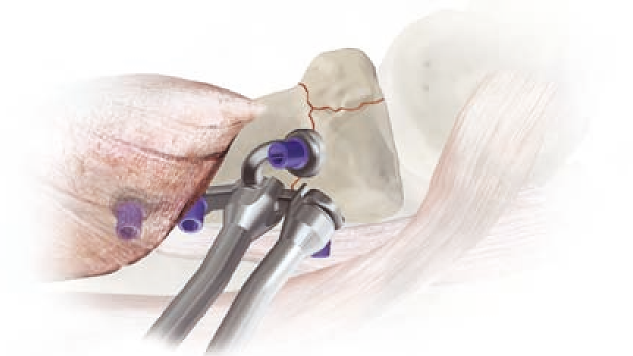
The radial head and neck is then elevated and reduced into its normal position, and the plate is positioned. The first screw can be applied into the shaft region to hold the plate in place. Screw selection will allow for either a non-locking or locking screw to be placed through the plate. The standard locking screw placed through the plate will provide good stability for the fracture construct.

Step 3
Drill through the F.A.S.T. Guide with the 2.0 mm Drill Bit (Cat. No. FDB20) (Step 3).

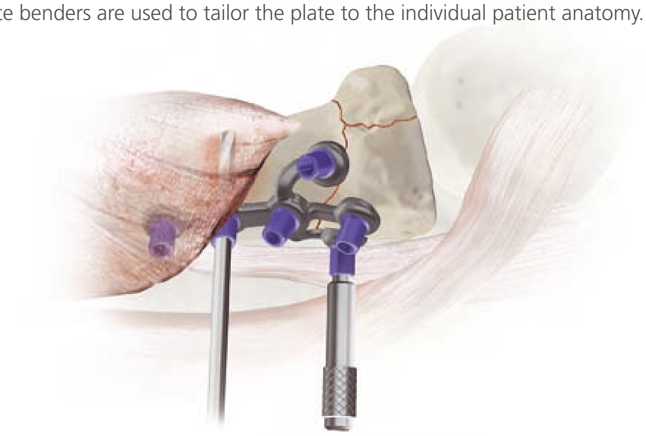
Step 4
Remove the F.A.S.T. Guide with the 1.3 mm Square Driver (Cat. No. 2312-18-012) (Step 4).



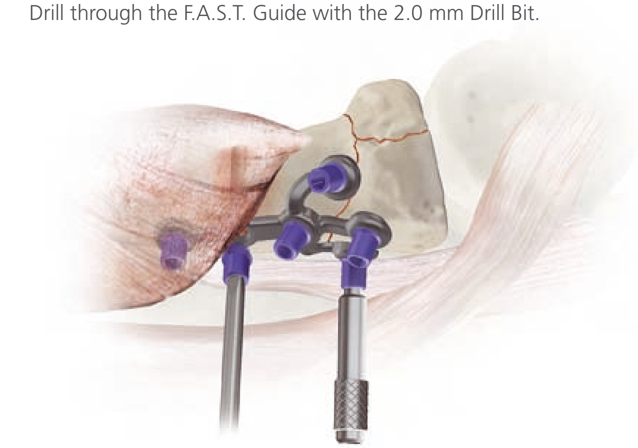
Step 1
The plate is positioned using the F³® Fragment Plate Holder.



Step 2
The plate benders are used to tailor the plate to the individual patient anatomy.



Step 3
Drill through the F.A.S.T. Guide with the 2.0 mm Drill Bit.

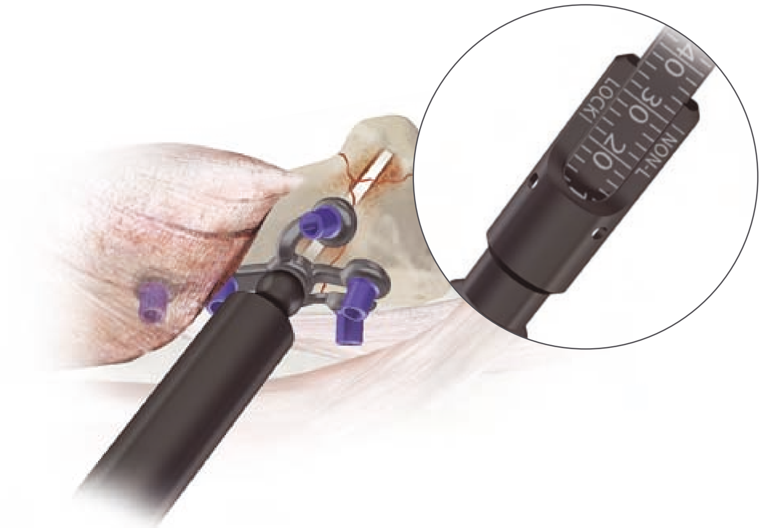


Step 4
Remove the F.A.S.T. Guide with the 1.3 mm Square Driver.

Radial Head Fracture Fixation

Step 5
Measure the drilled hole by taking a direct reading from the NON-L line on the depth gauge (Step 5).

Note: When measuring for a locking screw, the depth gauge is used through the F.A.S.T. Guide and measured off of the LOCK line. When inserting a Non-Locking screw, the F.A.S.T. Guide is removed and the screw is measured off of the NON-L line.



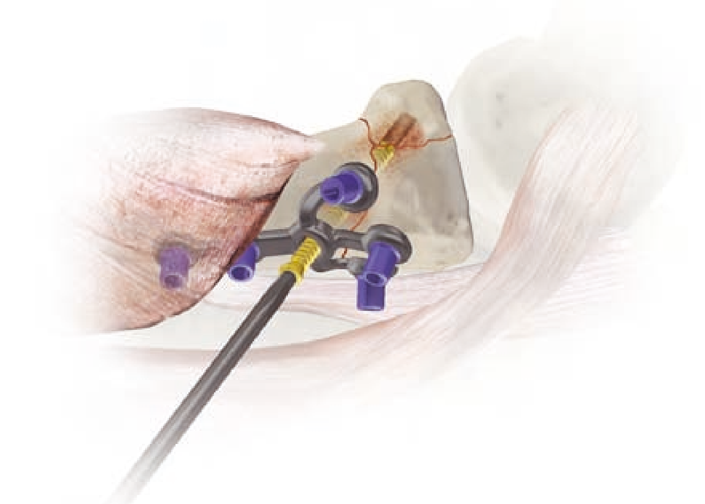
Step 5
Measure the drilled hole by taking a direct reading from the NON-L line on the Depth Gauge.

Step 6
Insert the 2.5 mm Non-Locking Screw with the 1.3 mm Square Driver coupled to the Quick Connect Handle (Cat. No. QCH) (Step 6).

The remaining screws (locking or non-locking) can now be place starting with the radial head region.

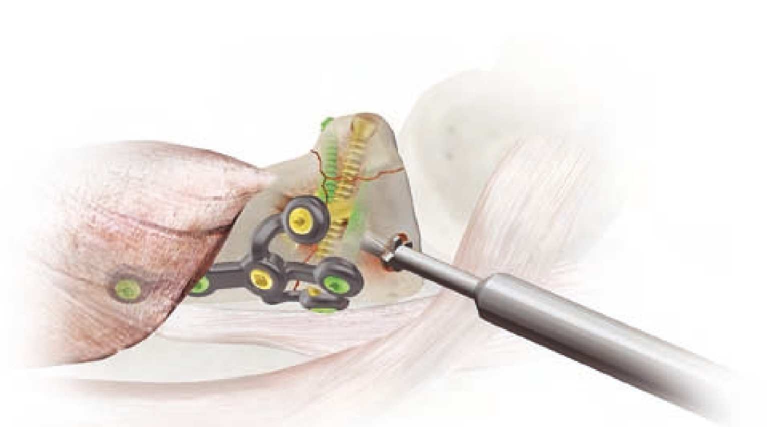
Note: The plate should rest distal to the articular surface of the radial head surface and be positioned by hand in neutral rotation. The nonarticular region of the radial head and neck will now be facing laterally toward the surgeon.

Small wedge fractures of the radial head will need to be fixed with a screw placed outside the plate. These screws should be placed obliquely through the radial head into the distal far cortex in an oblique fashion. It is not uncommon for one or two screws to be placed in this fashion, buried deep to the articular cartilage, for optimal fixation.



Step 6
Insert the 2.5 mm Non-Locking Screw with the 1.3 mm Square Driver coupled to the Quick Connect Handle.

Step 7
The 2.5 mm Counterbore (Cat. No. 2312-18-014) can be used to create a recess where the screw head will sit below the level of the cortex (Step 7).



Step 7
The 2.5 mm Counterbore can be used to create a recess where the screw head will sit below the level of the cortex.

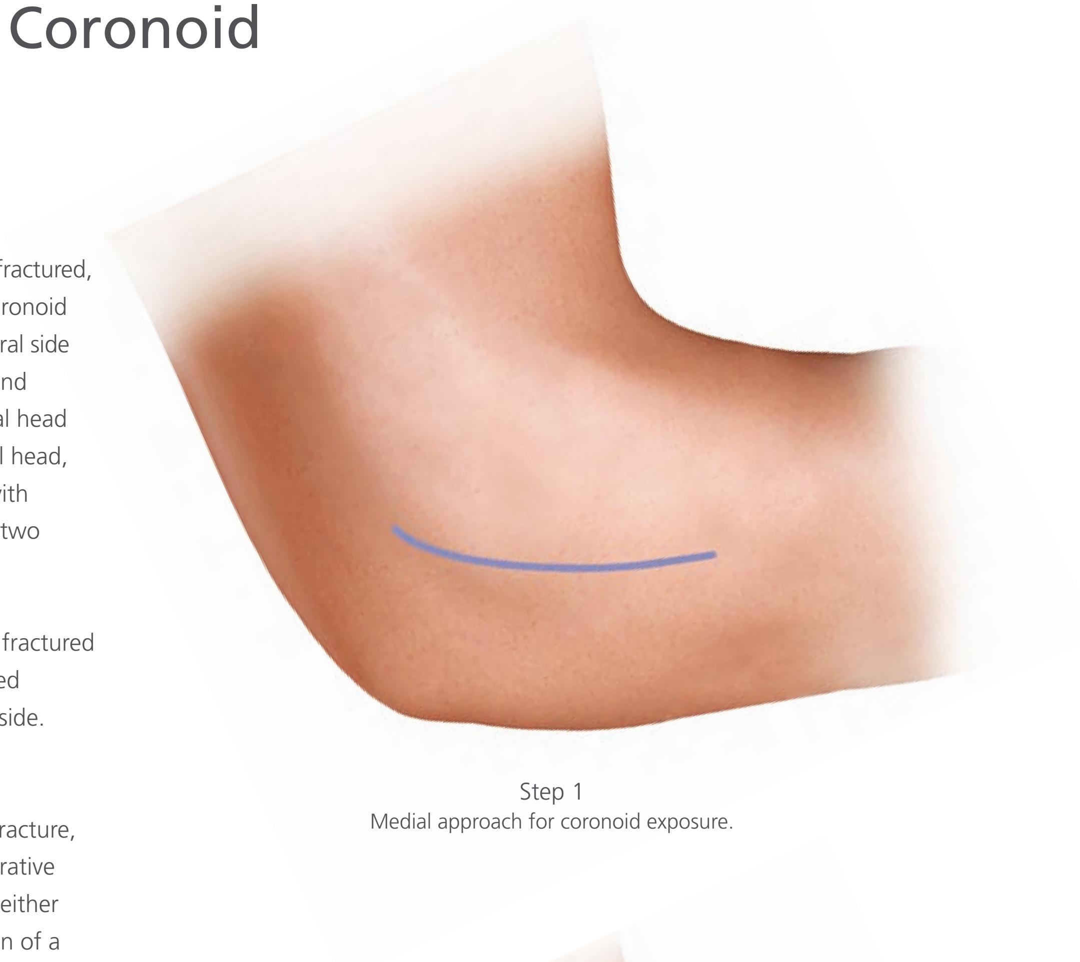
Exposure of the Coronoid

If greater than 15 - 20% of the coronoid is fractured, internal fixation may be considered. The coronoid can potentially be approached from the lateral side if the radial head is significantly fractured and needs to be excised in preparation for radial head replacement. Through the void in the radial head, the coronoid can often be visualized and with posteriorly directed screws, usually at least two in number, the coronoid can be secured.

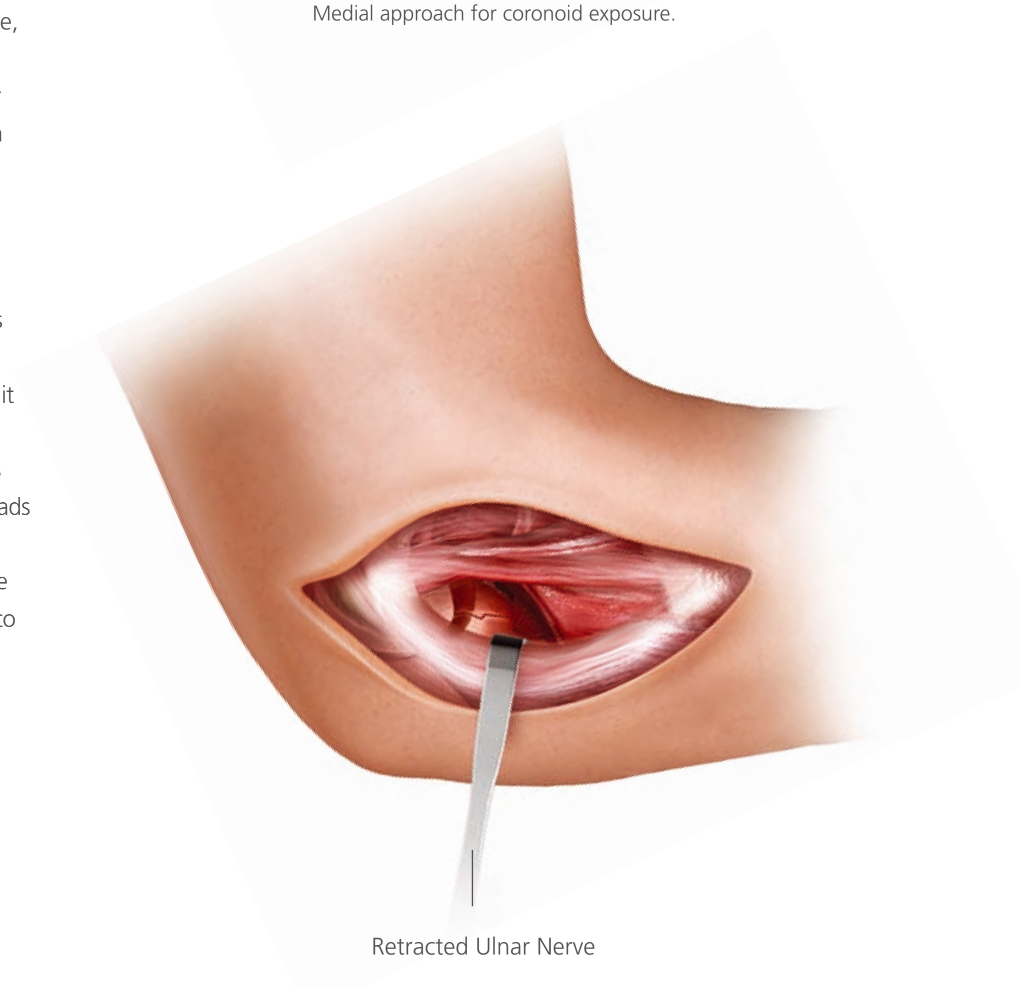
In those cases where the radial head is not fractured or only partially fractured, it is recommended to approach the coronoid from the medial side.

Step 1
In this situation with an isolated coronoid fracture, a medial approach is most efficient for operative exposure. Similar to a radial head fracture, either a direct posterior skin incision with elevation of a medial skin flap or a direct medial approach can be done to expose the coronoid (Step 1).

Step 2
After the skin incision, identify the ulnar nerve. This is then released in situ to help positively identify it throughout the procedure and also to decompress it in case of post-operative swelling. Once the ulnar nerve is decompressed, exposure of the coronoid is achieved through this interval between the two heads of the flexor carpi ulnaris. It is easiest to expose the coronoid by gently elevating the musculature of the flexor pronator group from the ulnar from a distal to proximal direction.

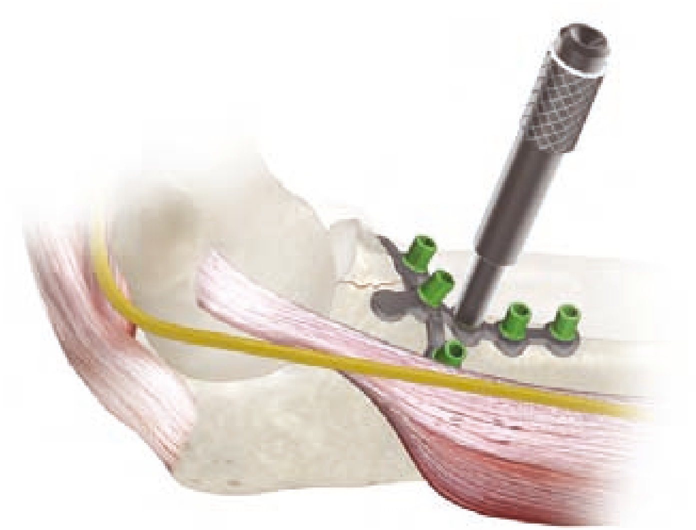


Step 1
Medial approach for coronoid exposure.



Step 2
Gently retract the ulnar nerve posteriorly.

Coronoid Fracture Fixation



Step 1
The plate is positioned using the F³ Fragment Plate Holder.

While doing this it is important to gently retract the ulnar nerve posteriorly (Step 2). As the soft tissue is elevated from the ulnar from a distal to proximal direction, the sublime tubercle can be easily palpated and identified as the insertion site of the medial collateral ligament. The elevation of the flexor pronator group is continued in a distal to proximal direction, elevating the musculature off of the medial collateral ligament, allowing exposure of the capsule of the joint and coronoid. The entire flexor pronator origin does not need to be released for exposure of the coronoid, only a small posterior portion.

The joint capsule which is anterior to the medial collateral ligament can be excised. This will allow for good visualization of the coronoid for accurate reduction and fixation. The medial collateral ligament is preserved and only a small area of the origin of the flexor pronator group needs to be elevated to gain adequate exposure. It should be noted that while elevating the musculature off of the ulnar, care should be made to identify any major branches of the ulnar nerve and protect them during exposure of the coronoid.

With the coronoid exposed, the appropriate plate is selected (right or left). It should be noted that the very medial edge of the ulnar at the sublime tubercle makes a sharp almost 90-degree angle. The plate will be placed at the apex of this significant angle on the ulnar.

Step 1

Use the F³® Fragment Plate Holder (Cat. No. 2312-07-012) to position the plate appropriately on the coronoid fracture (Step 1).

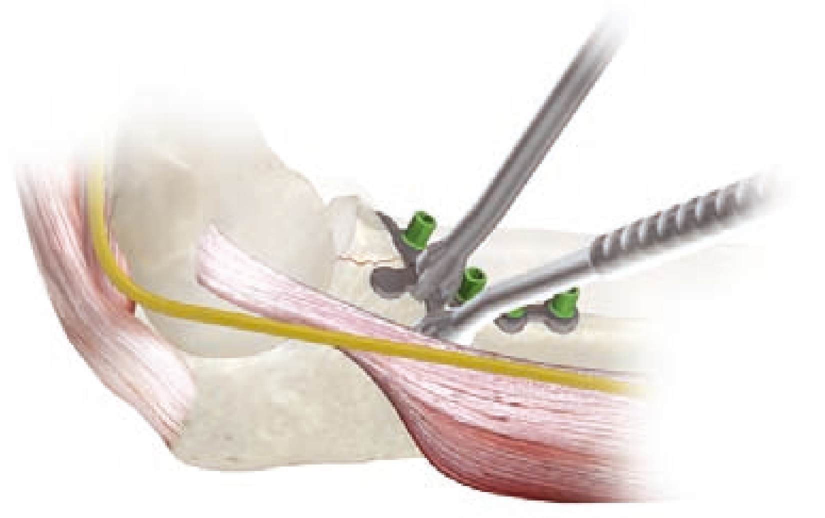
Coronoid Fracture Fixation

Step 2
Due to individual variations in patients, the plate will need to be bent and fine tuned for the individual patient (Step 2).

Note: For further information on plate bending refer to Appendix A on page 40.

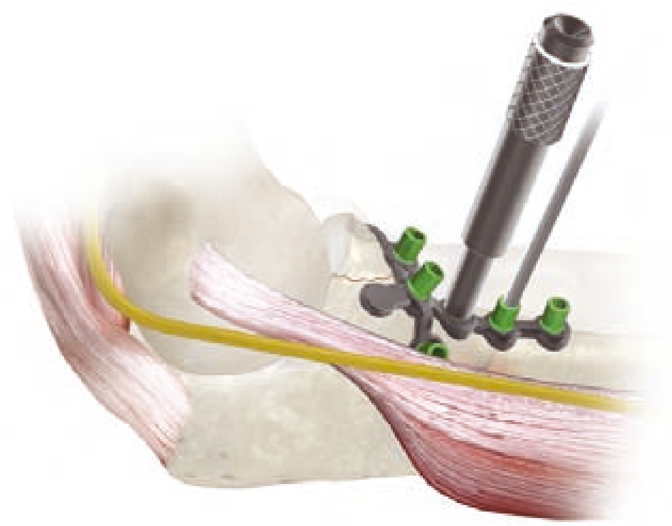
Screw selection will allow for either a 2.5 mm non-locking or locking screw to be placed through the plate. In most situations, the standard locking screw placed through the plate will provide good stability for the fracture construct.

One of the middle screws in the plate can be placed first for preliminary fixation of the implant.



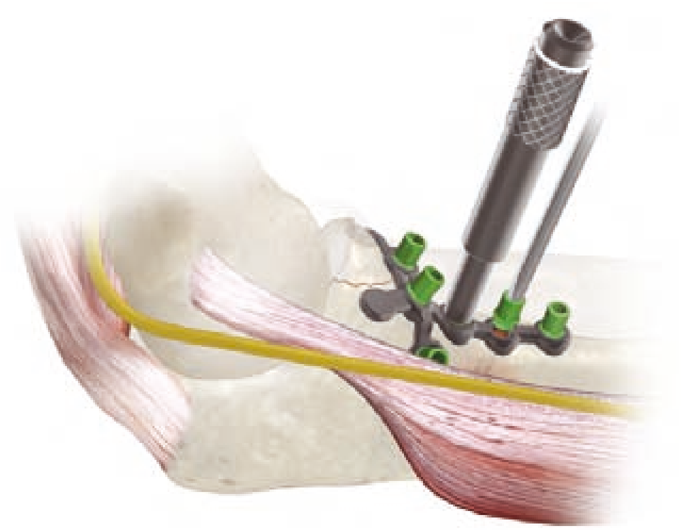
Step 2
The plate is bent and fine tuned for the individual patient.

Step 3
Drill through the F.A.S.T. Guide with the 2.0 mm Drill Bit (Cat. No. FDB20) (Step 3).



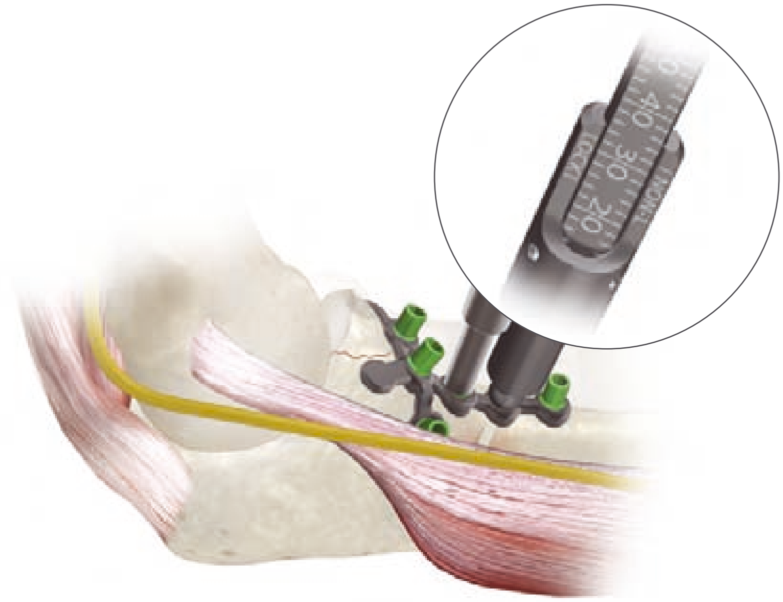
Step 3
Drill through the F.A.S.T. Guide with the 2.0 mm Drill Bit.

Step 4
Remove the F.A.S.T. Guide using the 1.3 mm Square Driver (Cat. No. 2312-18-012) (Step 4).

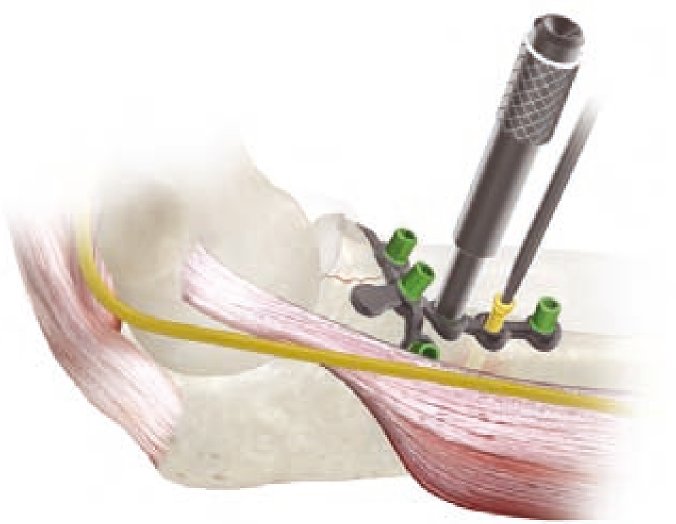


Step 4
Remove the F.A.S.T. Guide using the 1.3 mm Square Driver.

Coronoid Fracture Fixation



Step 6
Measure the drilled hole by taking a direct reading from the NON-L line.



Step 7
Insert the 2.5 mm Non-Locking screw with the 1.3 mm Square Driver coupled to the Quick Connect Handle.

Step 8
All screw holes should be filled to fully anchor the plate for optimal fixation.

Step 6
Measure the drilled hole by taking a direct reading from the NON-L line on the depth gauge (Step 6).

Step 7
Insert the 2.5 mm Non-Locking Screw with the 1.3 mm Square Driver coupled to the Quick Connect Handle (Cat. No. QCH) (Step 7).

Progressive screws are then placed. Locking screws do not require bicortical fixation through the posterior aspect of the ulnar but should be placed deep enough for accurate and stable fixation of the coronoid fracture. It should be noted that the most proximal screw holes in the plate are angled to help avoid intra-articular penetration of screws.

The most lateral tab on the plate should be checked to be sure it is bent down and acting as a buttress on the very lateral aspect of the coronoid. In a similar fashion, it should be checked that the very medial tab is buttressing on the very medial aspect of the coronoid in the area of the sublime tubercle and the medial collateral ligament.

Fluoroscopic views should be taken to be sure there is no penetration of the screws into the joint, and similar to the radial head plate, the plate itself can be shortened by breaking off any unneeded segments of the plate.

Step 8
All screw holes should be filled to fully anchor the plate for optimal fixation (Step 8).

After placement of the plate has been accomplished, the elevated portion of the flexor pronator group is allowed to fall back together. The ulnar nerve is checked to be sure that it is unhindered, and the wound closed in standard fashion.

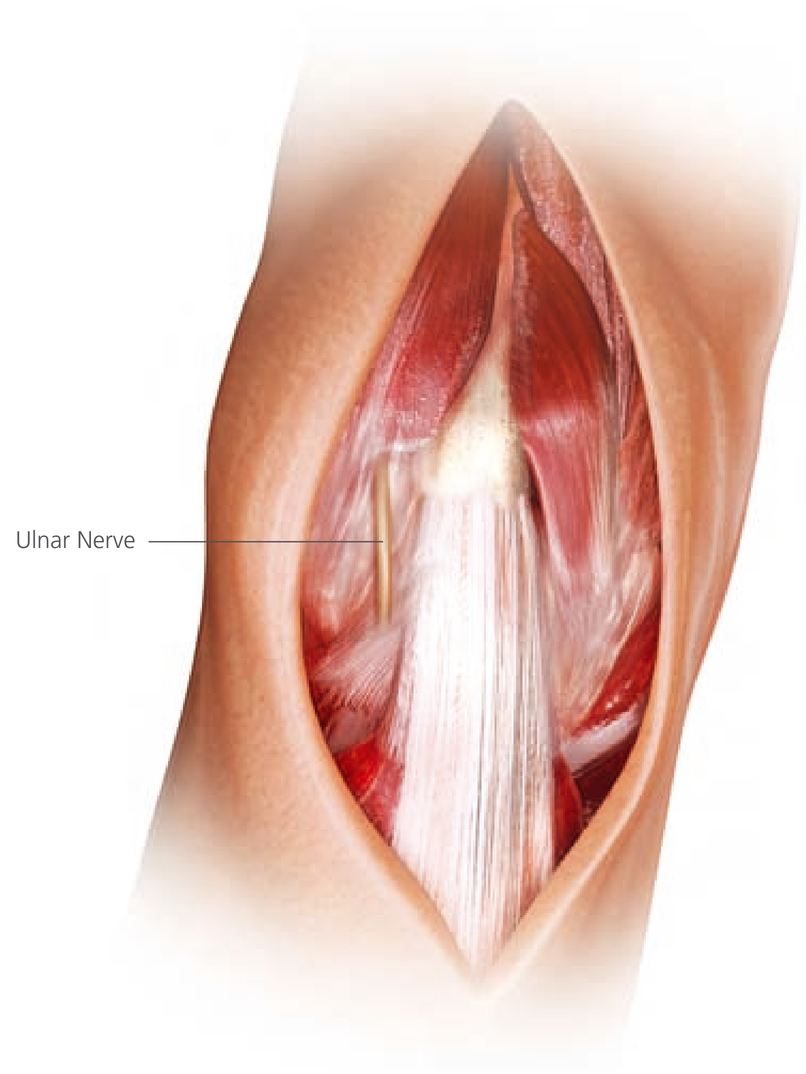
Exposure of the Olecranon

The exposure of an olecranon fracture follows a standard posterior incision. Depending on the surgeon's preference, the incision can be curved slightly laterally or medially over the tip of the olecranon itself. Once the skin incision is made, the fracture site is often quite evident.

Step 1

Elevation of the medial skin flap should be performed to accurately identify the ulnar nerve (Step 1). The ulnar nerve does not need to be necessarily released in situ or transposed but the area of the ulnar nerve should be recognized and protected throughout the procedure.

The olecranon fracture should be opened slightly and irrigated with removal of any loose bone or hematoma. Examination of the articular surface of the humerus can also be done if any question of distal humeral cartilage damage is suspected.



Step 1
Identification of the ulnar nerve.

Olecranon Fracture Fixation

Due to individual variations in patients, the plate will need to be bent and fine tuned for the individual patient. ***Note: For further information on plate bending refer to Appendix A on page 40.***

Reduce the ulnar fracture. A 2 mm pin can be drilled partially into either the medial or lateral aspect of the ulnar, approximately 3 to 4 cm distal to the fracture site. This small hole in the ulnar serves as an area where a prong of the large clamp can grab onto the side of the ulnar.

Step 2
The more proximal prong on the clamp is used over the tip of the olecranon to reduce the fracture in place and a 2 mm pin is placed an oblique fashion across the fracture site.

Step 2
The more proximal prong on the clamp is used over the tip of the olecranon to hold and reduce the fracture in place. Two clamps can be used for reduction as an alternative. While clamps are being held in place, a 2 mm pin can also be placed in an oblique fashion across the fracture site, beginning in an area where the plate would not impinge upon the pin (Step 2).

Step 3
Insert the 3.5 mm locking screw with the T-15 Driver.

Step 3
Insert the twin olecranon 3.5 mm locking screws with the T-15 Driver coupled to the 2.0 Nm Torque-Limiting Screwdriver Handle (Step 3).

Step 4
A low profile 3.5 mm screw with a low profile washer is inserted by hand.

Step 4
If additional compression of the osteotomy site is needed, insert a Non-Locking Screw in the oblong active compression slot (Step 4).

With the twin proximal screws in place, a compression screw can be placed into the oval hole on the distal part of the plate allowing compression at the fracture site. Remove the distal K-wire which was previously inserted in order to achieve compression.

Olecranon Fracture Fixation

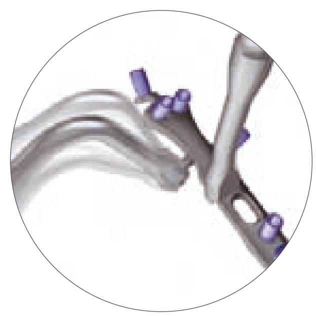
Step 5
If no additional compression is needed, insert a K-wire through the home-run screw to cross the osteotomy site and secure the reduction (Step 5).

Step 5
If no additional compression is needed, insert a K-wire through the home-run screw to cross the osteotomy site and secure the reduction.

Step 6
If step 4 was used instead of 5, then insert the K-wire after the active compression screw is inserted to secure the reduction (Step 6).

Step 6
Insert the K-wire after the active compression screw is inserted to secure the reduction.

Step 7
Fill screws in the shaft and coronoid area (Step 7).



F.A.S.T. Guides can be broken off with the Plate Benders if not necessary.

Step 7
Fill screws in the shaft and coronoid area.

Step 8
Replace the distal K-wire with a screw (Step 8).

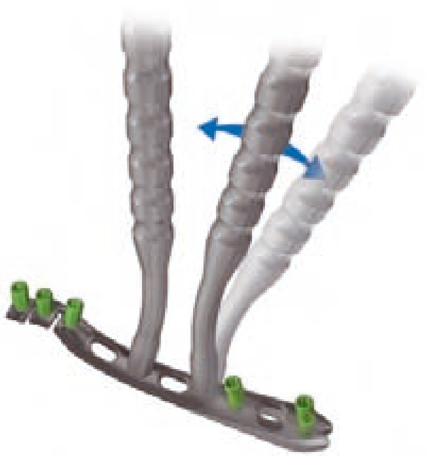
See Appendix B on pages 41-44 for screw insertion.

Step 8
A K-wire can be inserted through a bushing to determine trajectory.

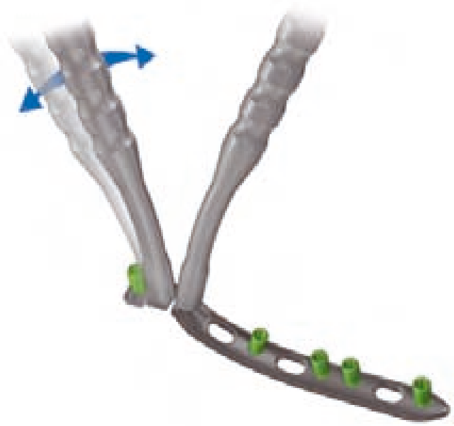
Appendix A Contouring for Medial and Lateral Plates

Note: The benders are not intended to work with the shorter, rounder low profile F.A.S.T. Guide inserts. The benders are to be used only with the tall F.A.S.T. Guide inserts to contour the plate.

Medial / Lateral Plate Benders

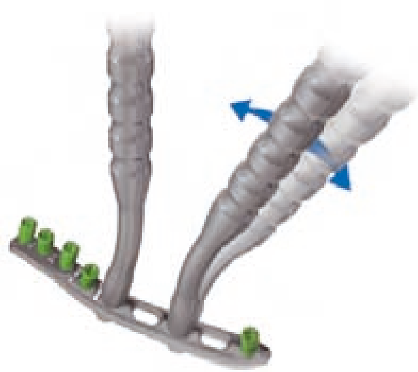


1. Medial plate bent through a slot.



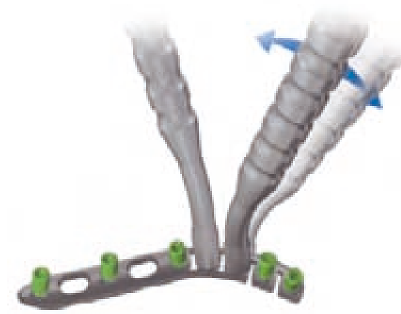
2. Distal end of medial plate bent towards medial condyle.

3. Planar bend at distal end of medial plate.



4. Lateral plate bent through a slot.

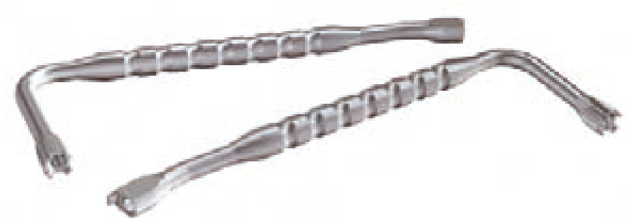
5. Planar bend at distal end of lateral plate.



6. Distal end of lateral plate bent towards lateral condyle.

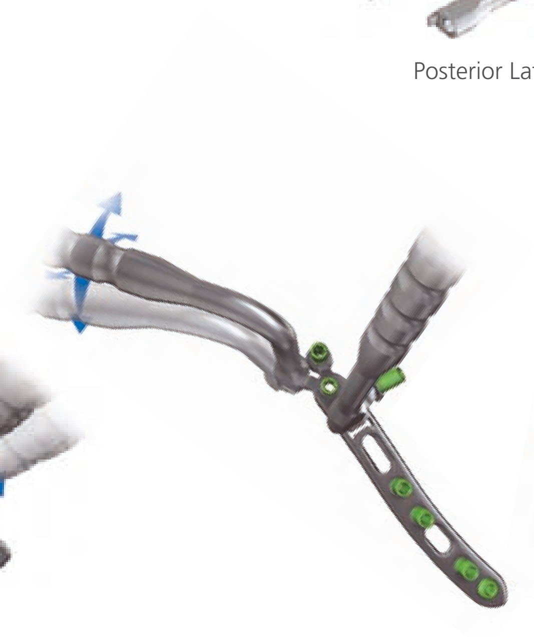
Appendix A Contouring for Posterior Lateral and Olecranon Plates

Note: The benders are not intended to work with the shorter, rounder low profile F.A.S.T. Guide inserts. The benders are to be used only with the tall F.A.S.T. Guide inserts to contour the plate.



Posterior Lateral / Olecranon Plate Benders

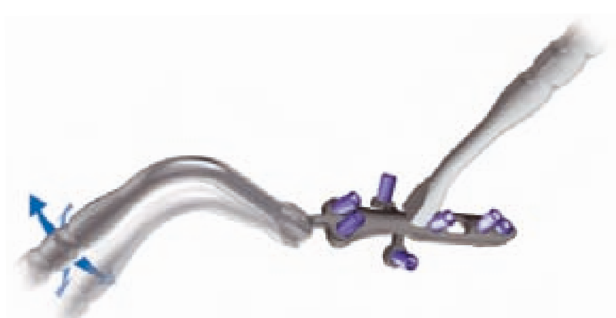
1. Posterior lateral plate bent through a slot.



2. Planar bend applied to posterior lateral plate.

3. Lateral tab of posterior lateral plate bent toward the bone.

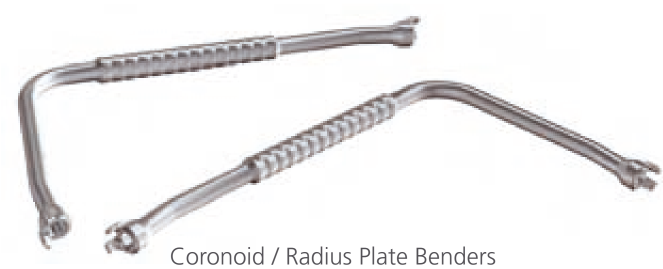
4. Olecranon plate bent through a slot.



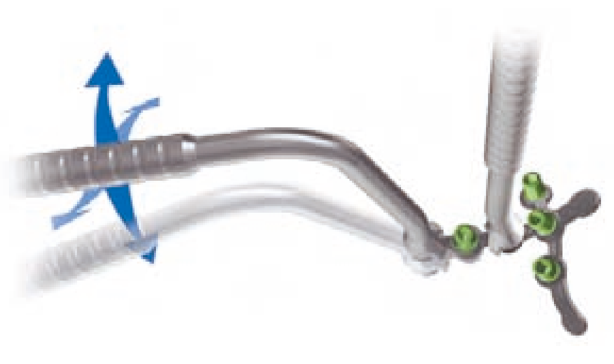
5. Planar bend applied to olecranon plate.

6. If necessary, the benders can be used to break of the arms of the olecranon plate.

Appendix A Contouring for Coronoid and Radius Plates

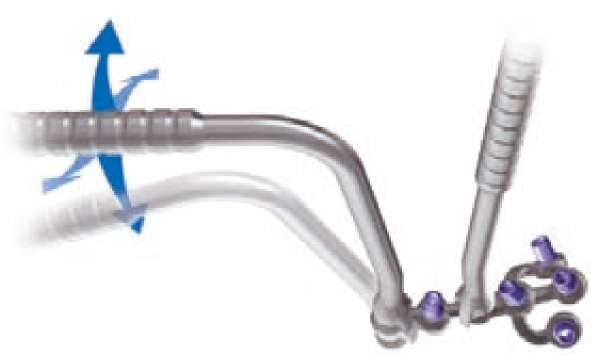


Coronoid / Radius Plate Benders



1. Planar bend applied to coronoid plate.

2. Lateral tab of coronid plate bent toward the bone.



3. Planar bend applied to the shaft of proximal radius plate.

4. Planar bend applied to the arms of proximal radius plate.

Appendix B Non-Locking Screw Insertion

Non-Locking Screw Insertion

Step 1

If Non-Locking Screws are to be used, the F.A.S.T. Guide is removed using the T-15 driver (Cat. No. 2142-15-070) (Step 1).

Step 2

Insert the drill guide into the screw hole and drill through both cortices with the 2.5 mm Drill Bit (Cat. No. 8290-29-070) (Step 2).

Step 3

Measure the drilled hole by taking a direct reading from the NON-L line on the depth gauge (Step 3).

Step 4

The screw is inserted by hand using the black ratchet handle (Cat. No. 8261-66-000) with the 2.2 mm square driver (Cat. No. 8163-01-000) (Step 4).

Step 1
Remove the F.A.S.T. Guide using the T-15 Driver.

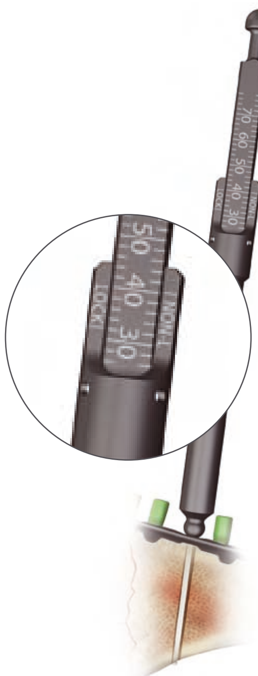
Step 2
Drill through both cortices with the 2.5 mm Drill Bit.

Step 3
Take a direct reading from the NON-L line.

Step 4
Insert by hand using the black ratchet handle with the 2.2 mm Square Driver.

Appendix B Screw Insertion-Active Compression

Step 1
Drill through both cortices with the 2.5 mm Drill Bit.



Step 2
Take a direct reading from the NON-L line.

Step 3
Stab the appropriate 3.5 mm Low Profile Non-Locking screw with the 2.2 mm Square Driver.

Step 4
Insert by hand using the black ratchet handle with the 2.2 mm Square Driver.

Non-locking Screw Insertion (Compression Mode)

If the compression hole is to be used, a non-locking screw must be used in conjunction with a low-profile washer. This will convert the low-profile screw to a standard profile non-locking screw.

Step 1
Insert the drill guide into the screw hole and drill through both cortices with the 2.5 mm drill bit (Cat. No. 8290-29-070). Drill eccentricly in the slot furthest away from the fracture (Step 1).

Step 2
Measure the drilled hole by taking a direct reading from the NON-L line on the depth gauge (Step 2).

Step 3
Stab the appropriate 3.5 mm low profile non-locking screw with the 2.2 mm square driver (Cat. No. 8163-01-000). Once engaged, the screw is placed though the low profile washer (Cat. No. 1312-18-000), which is in the cartridge, and pressure applied until an audible click is heard. Once the assembly is mated correctly, the screw can be advanced into the compression hole of the plate. Slide the screw down the cartridge remove and insert into the active compression slot (Step 3).

Step 4
The screw is inserted by hand using the black ratchet handle (Cat. No. 8261-66-000) with the 2.2 mm square driver (Cat. No. 8163-01-000) (Step 4).

Note: The washer is for use ONLY with the 3.5 mm low profile non-locking screw.

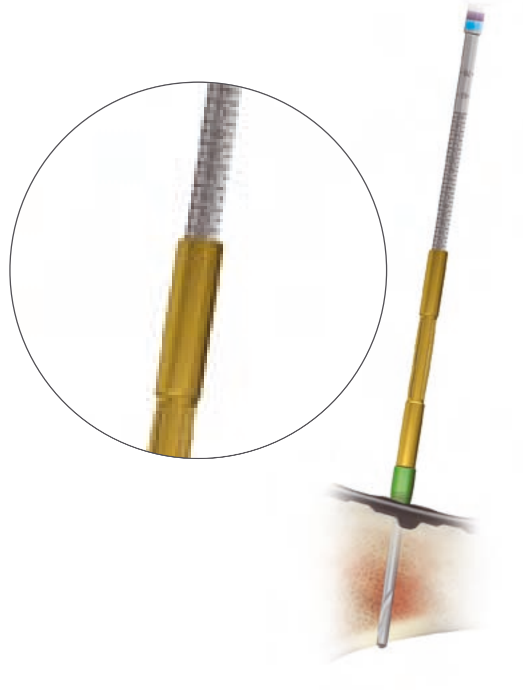
Appendix B **Locking Screw Insertion**

Locking Screw Insertion

Step 1

Slide the Measuring Drill Sleeve (Cat. No. 8163-01-005) onto the 2.7 mm Drill Bit (Cat. No. 2142-27-070). Drill through the F.A.S.T. Guide insert until the far cortex is reached. Slide the Measuring Drill Sleeve onto the top end of the F.A.S.T. Guide insert and read the measurement of the Locking Screw length from the proximal end of the Drill Measuring Sleeve (Step 1).

Note: If a second method of measurement is desired, remove the F.A.S.T. Guide insert, then measure the drilled hole by taking a direct reading from the LOCK line on the Depth Gauge (Step 1).



Step 1
Drill through the F.A.S.T. Guide insert with the 2.7 mm Drill Bit.
Slide the Measuring Drill Sleeve to the top end of the F.A.S.T. Guide insert and read the measurement of the Locking Screw length from the proximal end.

Step 2

Remove the F.A.S.T. Guide using the T-15 driver (2142-15-070) (Step 2).

Step 3

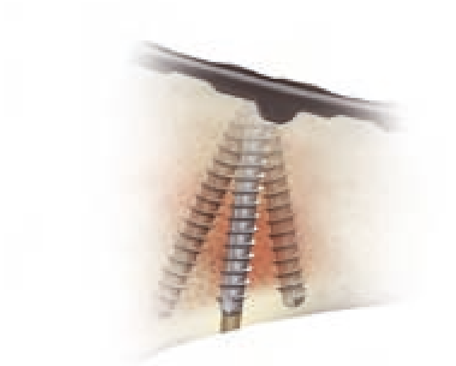
Insert the 3.5 mm locking screw with the T-15 Driver coupled to the 2.0 Nm Torque-Limiting Screwdriver Handle (Step 3).

Once the screw is seated, an audible click will be heard from the driver noting that the screw is fully seated.

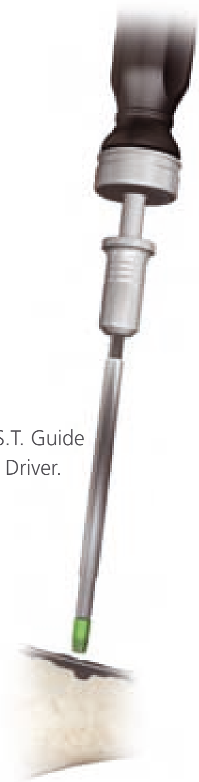
Step 2
Remove the F.A.S.T. Guide using the T-15 Driver.

Step 3
Insert the 3.5 mm Locking Screw with the T-15 Driver coupled to the 2.0 Nm Torque-Limiting Screwdriver Handle.

Appendix B Multi-Directional Screw Insertion (MDS)

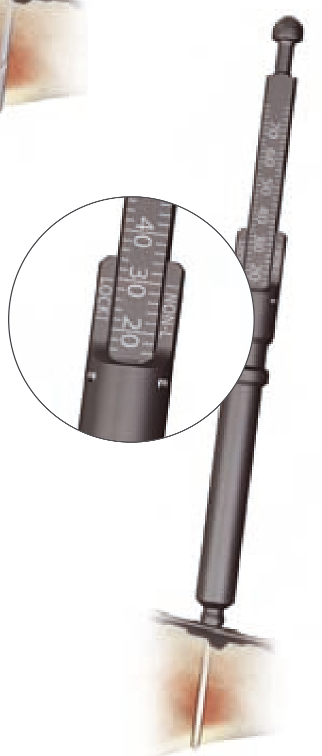


Step 1



Step 2
Remove the F.A.S.T. Guide using the T-15 Driver.

Step 3
Drill using the 2.7 mm Drill Bit through the Drill Guide.



Step 4
Take a direct reading from the L line.

Step 4a
Insert the MDS screw under power using the 2.2 mm Square Driver coupled to the Torque Limiting Power Adapter.

Multi-Directional Screw (MDS) Insertion

Step 1
The MDS screws (Figure 13) are inserted by removing the F.A.S.T. Guide using the T-15 driver (2142-15-070) (Step 1).

Step 2
Drill using the 2.7 mm Drill Bit (Cat. No. 2142-27-070). The drill bit can be angled up to a 25 degree cone of angulation and still have the screw lock into the plate (Step 2).

Step 3
Measure the drilled hole with the Depth Gauge (Cat. No. 2142-35-100) by taking a direct reading from the L line (Step 3).

Step 4
Insert the 3.5 mm MDS screw with the T-15 Driver coupled to the 2.0 Nm Torque-Limiting Screwdriver Handle (Step 4).

Step 4a
Alternatively, the screw can be inserted under power using the 2.2 mm Square Driver (Cat. No. 8163-01-000) coupled to the Torque Limiting Power Adapter (Cat. No. 2312-18-020) (Step 4a).

Once the screw is seated, and audible click will be heard from the driver noting that the screw is fully seated.

Appendix C Screw Removal

Note: Plate screws will often compete for space in a tight area, and the screws can often interdigitate into each other. This is especially relevant with the three distal screws on the Lateral and Medial plates (Step 1).

Therefore it is important to remove the screws in reverse order (last in, first out), to avoid breaking the heads from the screws.

If you don't know the order, the following procedure is recommended (Step 2):

1. Attempt to remove a screw. If it stalls within a turn or two, retighten using the Torque Limiting Power Adapter.

Note: This is very important, as this screw may be interdigitated with another screw, which may cause difficulty during removal. It is critical to retighten the screw prior to moving on to the next screw as described in step 2, otherwise both screws will be difficult to remove.

2. Move on to the next screw and repeat step 1.

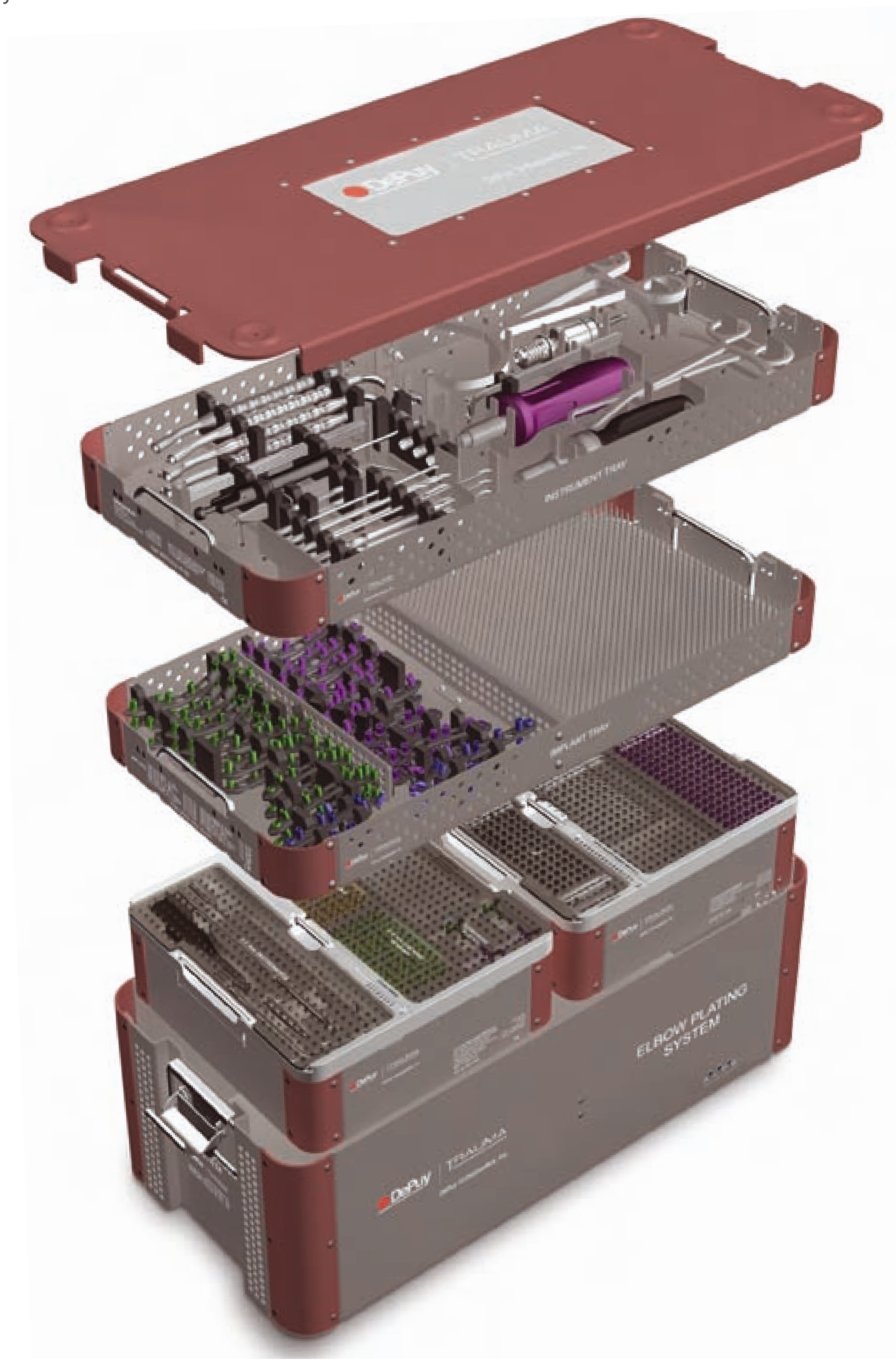
3. Keep moving from one screw to the next until all have been removed.

Step 1

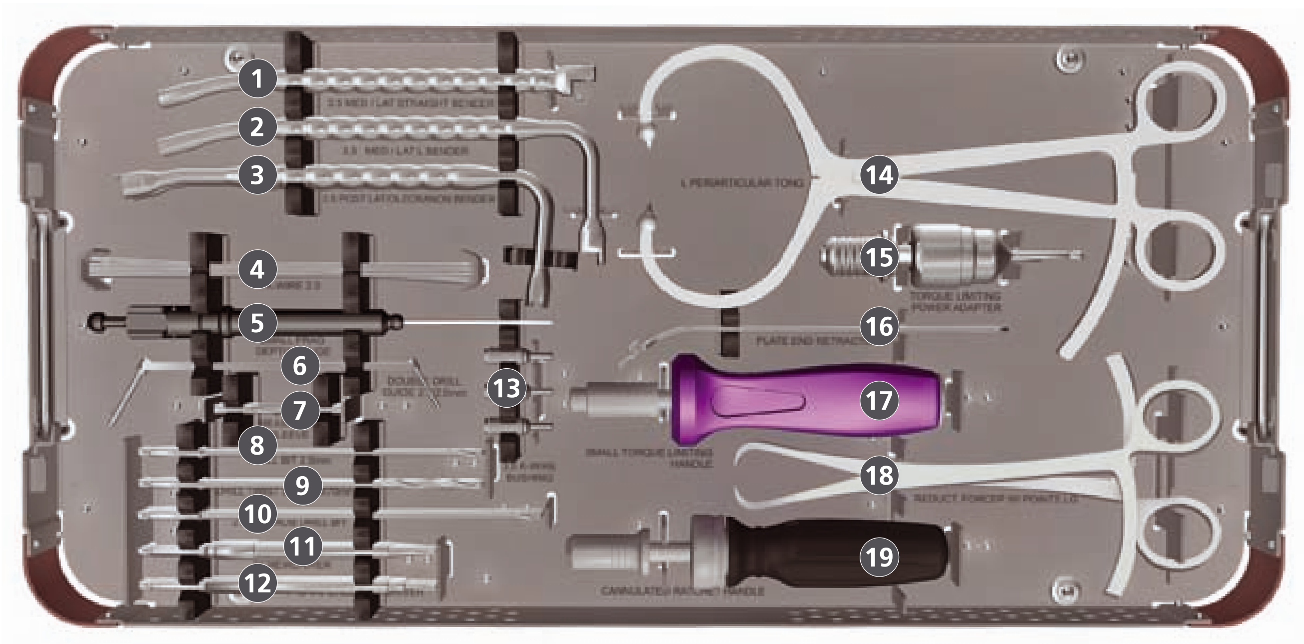
Step 2

Instrument Trays

The Elbow Plating System



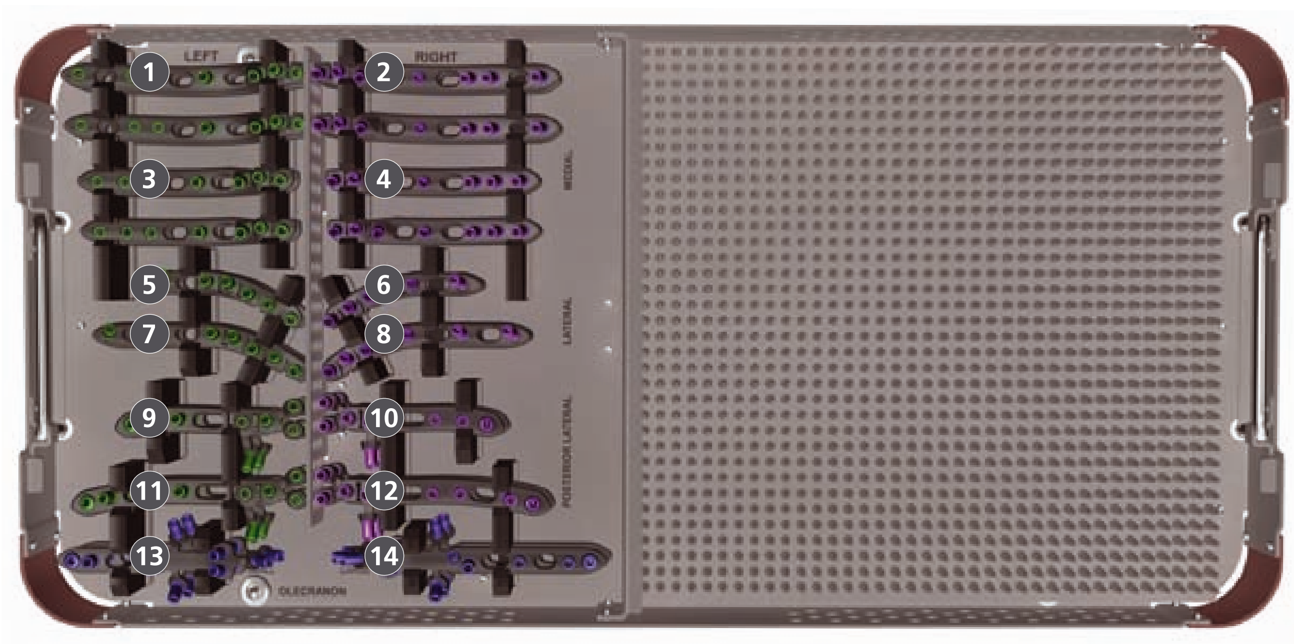
Instrument Trays



Instrument Tray

1. 2312-18-003 3.5 Medial/Lateral Straight Bender
2. 2312-18-004 3.5 Medial/Lateral L Bender
3. 2312-18-008 (2) 3.5 Post. Lateral/Olecranon Bender
4. 14179-6 (12) 2.0 mm K-wire
5. 2142-35-100 Small Frag Depth Gauge
6. 9399-99-435 Double Drill Guide 2.7/2.0mm
7. 8163-01-005 (2) Drill Measuring Sleeve
8. 8290-29-070 (2) Drill Bit 2.5 mm
9. 8290-32-070 (2) Drill Twist Scp 3.5 x 70 mm
10. 2142-27-070 (3) 2.7 mm Calibrated Drill Bit
11. 8163-01-000 (2) 2.2 mm Square Screwdriver
12. 2142-15-070 (2) T-15 Tapered Driver
13. 2312-18-007 (3) 2.0 mm K-wire Adapter
14. 1920 L Periarticular Tong
15. 2312-18-020 2.0 mm Torque Limiting Power Adapter
16. 2142-13-567 Plate End Retractor
17. 2141-18-001 Small Torque Limiting Handle
18. 13577 (2) Reduction Forcep W/Points Lg
19. 8261-66-000 Cannulated Ratchet Handle

Instrument Trays



Implant Tray

Medial Plates

1.	1312-18-703 (4)	10 Hole - Left
2.	1312-18-701 (4)	10 Hole - Right
3.	1312-18-702 (4)	9 Hole - Left
4.	1312-18-700 (4)	9 Hole - Right

Lateral Plates

5.	1312-18-202 (2)	7 Hole - Left
6.	1312-18-200 (2)	7 Hole - Right
7.	1312-18-203 (2)	9 Hole - Left
8.	1312-18-201 (2)	9 Hole - Right

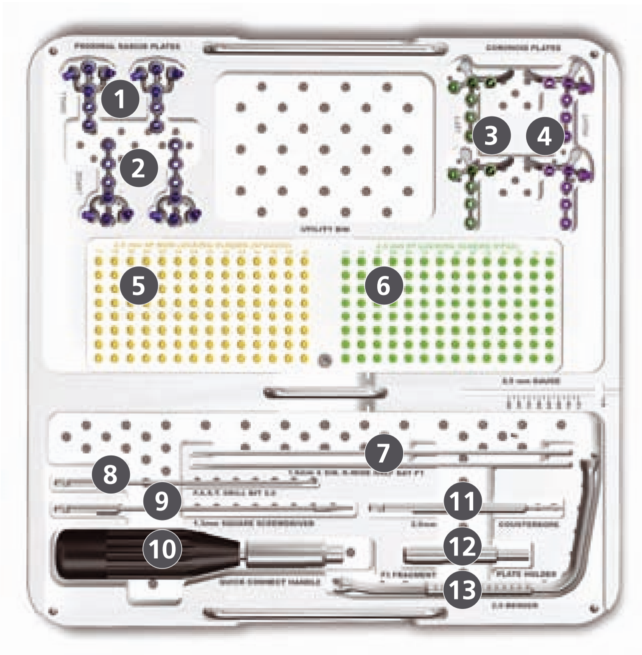
Posterior Lateral Plates

9.	1312-18-302 (2)	9 Hole - Left
10.	1312-18-300 (2)	9 Hole - Right
11.	1312-18-303 (2)	11 Hole - Left
12.	1312-18-301 (2)	11 Hole - Right

Olecranon Plates

13.	1312-18-600 (2)	10 Hole - Small
14.	1312-18-601 (2)	13 Hole - Large

Instrument Trays



2.5 mm Implant Module

Proximal Radius Plates

1.	1312-18-400 (2)	Small
2.	1312-18-401 (2)	Large

Coronoid Plates

3.	1312-18-501 (2)	Left
4.	1312-18-500 (2)	Right

5. 2.5 mm SP Non-locking Screw

SP14000	Peg Screw 2.5 x 14 mm
SP16000	Peg Screw 2.5 x 16 mm
SP18000	Peg Screw 2.5 x 18 mm
SP20000	Peg Screw 2.5 x 20 mm
SP22000	Peg Screw 2.5 x 22 mm
SP24000	Peg Screw 2.5 x 24 mm
SP26000	Peg Screw 2.5 x 26 mm
SP28000	Peg Screw 2.5 x 28 mm
SP30000	Peg Screw 2.5 x 30 mm
SP32000	Peg Screw 2.5 x 32 mm
SP34000	Peg Screw 2.5 x 34 mm
SP36000	Peg Screw 2.5 x 36 mm
SP38000	Peg Screw 2.5 x 38 mm
SP40000	Peg Screw 2.5 x 40 mm

6. 2.5 FP Locking Screw

FP14	Peg Full Thread 2.5 x 14 mm
FP16	Peg Full Thread 2.5 x 16 mm
FP18	Peg Full Thread 2.5 x 18 mm
FP20	Peg Full Thread 2.5 x 20 mm
FP22	Peg Full Thread 2.5 x 22 mm
FP24	Peg Full Thread 2.5 x 24 mm
FP26	Peg Full Thread 2.5 x 26 mm
FP28	Peg Full Thread 2.5 x 28 mm
FP30	Peg Full Thread 2.5 x 30 mm
FP32	Peg Full Thread 2.5 x 32 mm
FP34	Peg Full Thread 2.5 x 34 mm
FP36	Peg Full Thread 2.5 x 36 mm
FP38	Peg Full Thread 2.5 x 38 mm
FP40	Peg Full Thread 2.5 x 40 mm

7.	14425-6 (12)	1.6 mm x 6 in. K-wire Half Bay PT
8.	FDB 2.0 (2)	F.A.S.T. Drill Bit 2.0
9.	2312-18-012 (2)	1.3 mm Square Screwdriver
10.	QCH	Quick Connect Handle
11.	2312-18-014	2.5 mm Counterbore
12.	2312-07-012	F3 Fragment Plate Holder
13.	2312-18-005	2.5 mm Bender

Instrument Trays

3.5 mm Screw Module

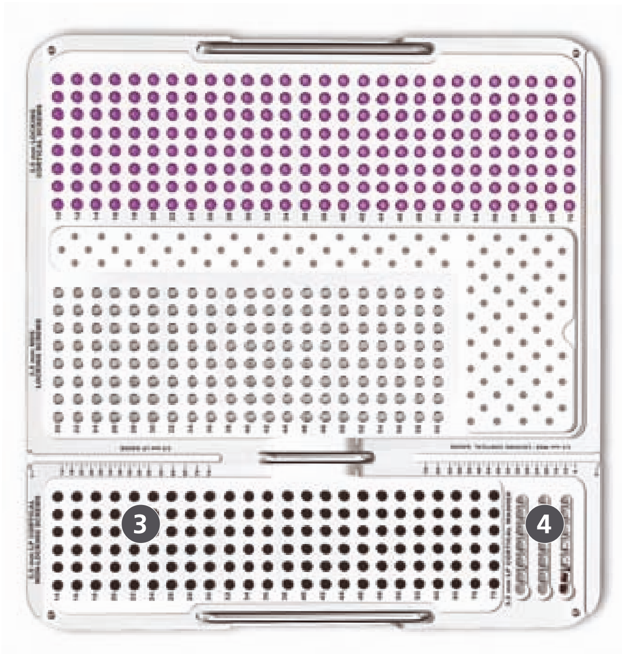
1. 3.5 mm Locking Cortical Screw

8161-35-010	3.5 mm Cortical Locking Screw 10 mm
8161-35-012	3.5 mm Cortical Locking Screw 12 mm
8161-35-014	3.5 mm Cortical Locking Screw 14 mm
8161-35-016	3.5 mm Cortical Locking Screw 16 mm
8161-35-018	3.5 mm Cortical Locking Screw 18 mm
8161-35-020	3.5 mm Cortical Locking Screw 20 mm
8161-35-022	3.5 mm Cortical Locking Screw 22 mm
8161-35-024	3.5 mm Cortical Locking Screw 24 mm
8161-35-026	3.5 mm Cortical Locking Screw 26 mm
8161-35-028	3.5 mm Cortical Locking Screw 28 mm
8161-35-030	3.5 mm Cortical Locking Screw 30 mm
8161-35-032	3.5 mm Cortical Locking Screw 32 mm
8161-35-034	3.5 mm Cortical Locking Screw 34 mm
8161-35-036	3.5 mm Cortical Locking Screw 36 mm
8161-35-038	3.5 mm Cortical Locking Screw 38 mm
8161-35-040	3.5 mm Cortical Locking Screw 40 mm
8161-35-042	3.5 mm Cortical Locking Screw 42 mm
8161-35-044	3.5 mm Cortical Locking Screw 44 mm
8161-35-046	3.5 mm Cortical Locking Screw 46 mm
8161-35-048	3.5 mm Cortical Locking Screw 48 mm
8161-35-050	3.5 mm Cortical Locking Screw 50 mm
8161-35-052	3.5 mm Cortical Locking Screw 52 mm
8161-35-054	3.5 mm Cortical Locking Screw 54 mm
8161-35-056	3.5 mm Cortical Locking Screw 56 mm
8161-35-058	3.5 mm Cortical Locking Screw 58 mm
8161-35-060	3.5 mm Cortical Locking Screw 60 mm
8161-35-065	3.5 mm Cortical Locking Screw 65 mm
8161-35-070	3.5 mm Cortical Locking Screw 70 mm

2. Multi-Directional Screw

8163-35-020	3.5 mm Multi-Directional Screw 20 mm
8163-35-022	3.5 mm Multi-Directional Screw 22 mm
8163-35-024	3.5 mm Multi-Directional Screw 24 mm
8163-35-026	3.5 mm Multi-Directional Screw 26 mm
8163-35-028	3.5 mm Multi-Directional Screw 28 mm
8163-35-030	3.5 mm Multi-Directional Screw 30 mm
8163-35-032	3.5 mm Multi-Directional Screw 32 mm
8163-35-034	3.5 mm Multi-Directional Screw 34 mm
8163-35-036	3.5 mm Multi-Directional Screw 36 mm
8163-35-038	3.5 mm Multi-Directional Screw 38 mm
8163-35-040	3.5 mm Multi-Directional Screw 40 mm
8163-35-042	3.5 mm Multi-Directional Screw 42 mm
8163-35-044	3.5 mm Multi-Directional Screw 44 mm
8163-35-046	3.5 mm Multi-Directional Screw 46 mm
8163-35-048	3.5 mm Multi-Directional Screw 48 mm
8163-35-050	3.5 mm Multi-Directional Screw 50 mm
8163-35-052	3.5 mm Multi-Directional Screw 52 mm
8163-35-054	3.5 mm Multi-Directional Screw 54 mm
8163-35-056	3.5 mm Multi-Directional Screw 56 mm
8163-35-058	3.5 mm Multi-Directional Screw 58 mm
8163-35-060	3.5 mm Multi-Directional Screw 60 mm

Instrument Trays



3.5 mm Screw Module (continued)

3. 3.5 mm Low Profile Cortical Screw

1312-18-014	3.5 mm Low Profile Cortical 14 mm
1312-18-016	3.5 mm Low Profile Cortical 16 mm
1312-18-018	3.5 mm Low Profile Cortical 18 mm
1312-18-020	3.5 mm Low Profile Cortical 20 mm
1312-18-022	3.5 mm Low Profile Cortical 22 mm
1312-18-024	3.5 mm Low Profile Cortical 24 mm
1312-18-026	3.5 mm Low Profile Cortical 26 mm
1312-18-028	3.5 mm Low Profile Cortical 28 mm
1312-18-030	3.5 mm Low Profile Cortical 30 mm
1312-18-032	3.5 mm Low Profile Cortical 32 mm
1312-18-034	3.5 mm Low Profile Cortical 34 mm
1312-18-036	3.5 mm Low Profile Cortical 36 mm
1312-18-038	3.5 mm Low Profile Cortical 38 mm
1312-18-040	3.5 mm Low Profile Cortical 40 mm
1312-18-042	3.5 mm Low Profile Cortical 42 mm
1312-18-044	3.5 mm Low Profile Cortical 44 mm
1312-18-046	3.5 mm Low Profile Cortical 46 mm
1312-18-048	3.5 mm Low Profile Cortical 48 mm
1312-18-050	3.5 mm Low ProFile Cortical 50 mm
1312-18-055	3.5 mm Low Profile Cortical 55 mm
1312-18-060	3.5 mm Low Profile Cortical 60 mm
1312-18-065	3.5 mm Low Profile Cortical 65 mm
1312-18-070	3.5 mm Low Profile Cortical 70 mm
1312-18-075	3.5 mm Low Profile Cortical 75 mm

4. Low Profile Cortical Washer

1312-18-000	3.5 mm Low Profile Cortical Washer

Notes

Notes

Notes

Orthopaedic Screws, Plates, Intramedullary Nails, Compression Hip Screws, Pins and Wires

Important: This Essential Product Information does not include all of the information necessary for selection and use of a device. Please see full labeling for all necessary information.

Indications: The use of metallic surgical appliances provides the orthopaedic surgeon a means of bone fixation and helps generally in the management of fractures and reconstructive surgeries. These implants are intended as a guide to normal healing, and are NOT intended to replace normal body structure or bear the weight of the body in the presence of incomplete bone healing. Delayed unions or nonunions in the presence of load bearing or weight bearing might eventually cause the implant to break due to metal fatigue. All metal surgical implants are subjected to repeated stress in use, which can result in metal fatigue.

Contraindications: Screws, plates, intramedullary nails, compression hip screws, pins and wires are contraindicated in: active infection, conditions which tend to retard healing such as blood supply limitations, previous infections, insufficient quantity or quality of bone to permit stabilization of the fracture complex, conditions that restrict the patient's ability or willingness to follow postoperative instructions during the healing process, foreign body sensitivity, and cases where the implant(s) would cross open epiphyseal plates in skeletally immature patients.

Additional Contraindication for Orthopaedic Screws and Plates only: Cases with malignant primary or metastatic tumors which preclude adequate bone support or screw fixations, unless supplemental fixation or stabilization methods are utilized.

Additional Contraindication for Retrograde Femoral Nailing: A history of septic arthritis of the knee and knee extension contracture with inability to attain at least 45° of flexion.

Additional Contraindications for Compression Hip Screws only: Inadequate implant support due to the lack of medial buttress.

Warnings and Precautions: Bone screws and pins are intended for partial weight bearing and non-weight bearing applications. These components cannot be expected to withstand the unsupported stresses of full weight bearing.

Adverse Events: The following are the most frequent adverse events after fixation with orthopaedic screws, plates, intramedullary nails, compression hip screws, pins and wires: loosening, bending, cracking or fracture of the components or loss of fixation in bone attributable to nonunion, osteoporosis, markedly unstable comminuted fractures; loss of anatomic position with nonunion or malunion with rotation or angulation; infection and allergies and adverse reactions to the device material. Surgeons should take care when targeting and drilling for the proximal screws in any tibial nail with oblique proximal screws. Care should be taken as the drill bit is advanced to penetrate the far cortex. Advancing the drill bit too far in this area may cause injury to the deep peroneal nerve. Fluoroscopy should be used to verify correct positioning of the drill bit.

Additional Adverse Events for Compression Hip Screw only: Screw cutout of the femoral head (usually associated with osteoporotic bone).

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