stryker

VariAx® 2 Elbow Locking Plate System

Operative technique

VariAx 2 Elbow
Locking Plate System

Contents

This publication sets forth detailed recommended procedures for using Stryker devices and instruments. It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required. A workshop training is recommended prior to performing your first surgery. All non-sterile devices must be cleaned and sterilized before use.

Follow the instructions provided in our reprocessing guide (OT-RG-1). Multi-component instruments must be disassembled for cleaning. Please refer to the corresponding assembly/ disassembly instructions.

Please remember that the compatibility of different product systems has not been tested unless specified otherwise in the product labeling.

See IFU (Instructions for Use)(V15011 and V15013) for a complete list of potential adverse effects, contraindications, warnings and precautions. The surgeon must discuss all relevant risks including the finite lifetime of the device with the patient when necessary.

Introduction

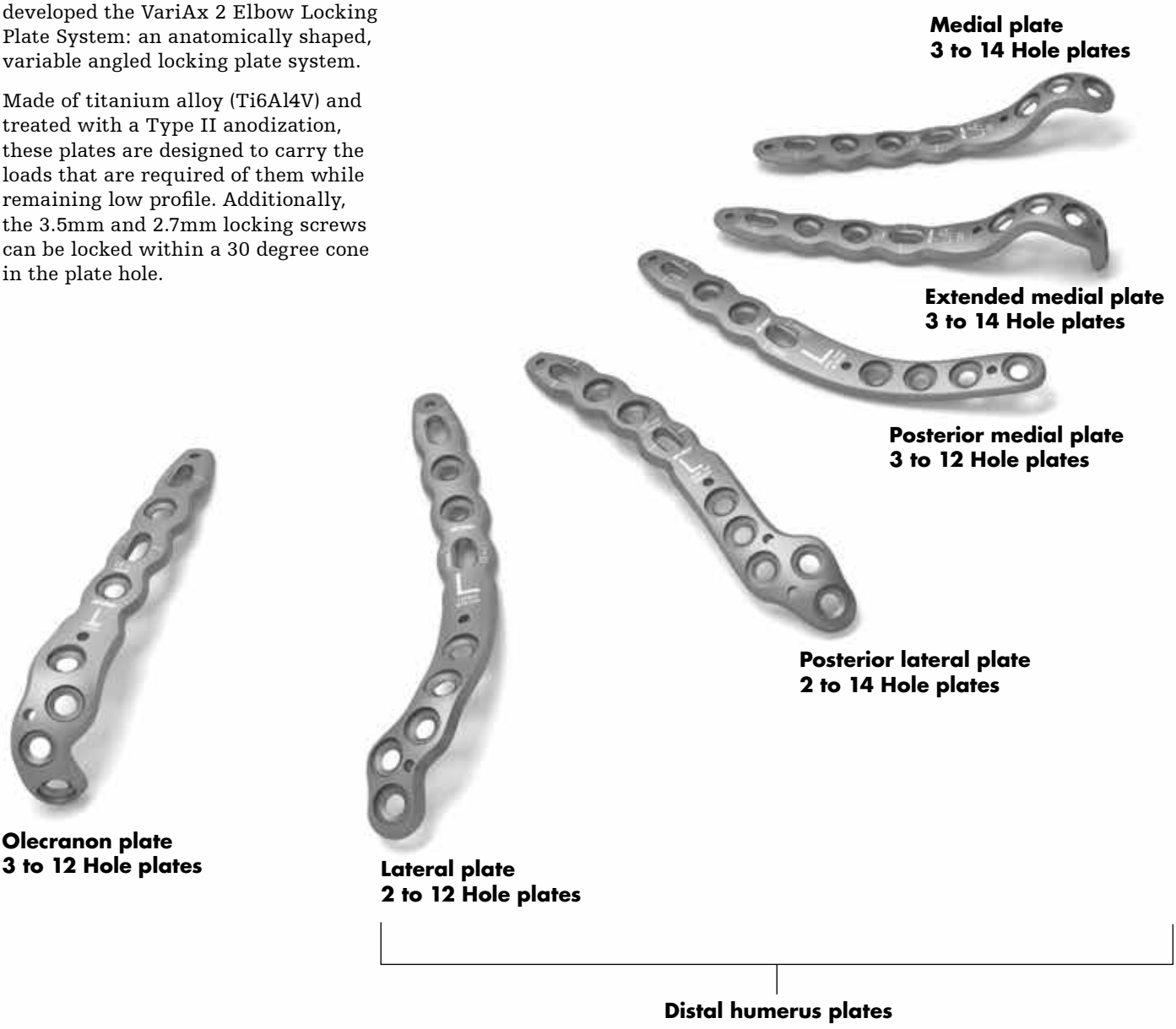
Elbow fractures remain one of the more difficult fractures for orthopaedic surgeons to treat. These fractures are commonly intra-articular and/or involve poor bone quality, and therefore, achieving stability can be problematic. Stable fixation allows early motion which may lead to better functional outcomes. At the same time, the limited soft tissue coverage and the distinct anatomic shape demands implants that can adapt to the anatomy.

With this in mind, Stryker has developed the VariAx 2 Elbow Locking Plate System: an anatomically shaped, variable angled locking plate system.

Made of titanium alloy (Ti6Al4V) and treated with a Type II anodization, these plates are designed to carry the loads that are required of them while remaining low profile. Additionally, the 3.5mm and 2.7mm locking screws can be locked within a 30 degree cone in the plate hole.

Designed with guidance from Professors Emil Schemitsch and Michael McKee from St. Michael's Hospital – University of Toronto along with a number of other international surgeon leaders, the VariAx 2 Locking Plate System is designed to allow surgeons flexibility in choosing which plating approach they wish to use.

The following pages contain a step by step operative technique which illustrate the system.



Indications, precautions & contraindications

Indications

The VariAx 2 Elbow Plating System is intended for fracture fixation of long bones.

The distal humerus plates are indicated for:

- Intra-articular or extraarticular fractures of the distal humerus
- Osteotomies
- Nonunions

The olecranon plates are indicated for:

- Intra-articular or extraarticular fractures of the proximal ulna
- Osteotomies
- Nonunions

Contraindications

The physician's education, training and professional judgment must be relied upon to choose the most appropriate device and treatment. The following contraindications may be of a relative or absolute nature, and must be taken into account by the attending surgeon:

- Any active or suspected latent infection or marked local inflammation in or about the affected area
- Compromised vascularity that would inhibit adequate blood supply to the fracture or the operative site
- Bone stock compromised by disease, infection or prior implantation that can not provide adequate support and/or fixation of the devices
- Material sensitivity, documented or suspected
- Obesity. An overweight or obese patient can produce loads on the implant that can lead to failure of the fixation of the device or to failure of the device itself
- Patients having inadequate tissue coverage over the operative site
- Implant utilization that would interfere with anatomical structures or physiological performance
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care
- Other medical or surgical conditions which would preclude the potential benefit of surgery

Precautions

Stryker systems have not been evaluated for safety and compatibility in MR environment and have not been tested for heating or migration in the MR environment, unless specified otherwise in the product labeling.

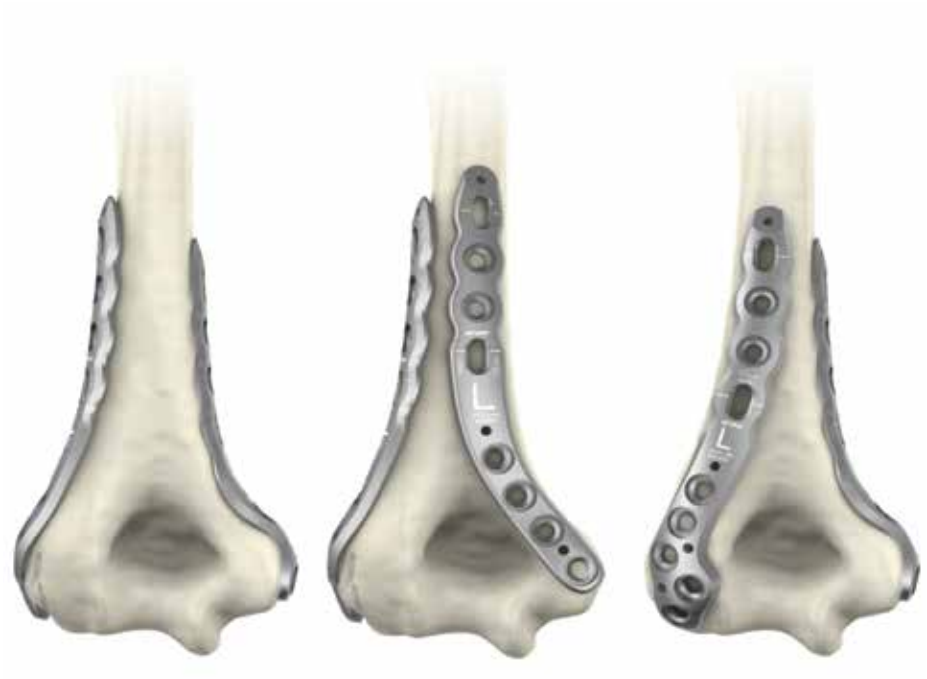
System overview

Patented SmartLock locking technology[1]

The polyaxial locking technology works by using two different grades of titanium. Locking screws are made of titanium alloy (Ti6A14V) which is stronger than the pure titanium plate holes. When a screw is driven into a plate hole, the locking threads on the underside of the screw engage the circular 'lip' in the hole. Unlike monoaxial locking systems, where the screws follow a predetermined path, this technology allows the user to aim and lock the screw within a 30 degree cone.

180° or 90° Distal humeral plating

The range of distal humeral plates allows for the option to treat a fracture based on anatomy, surgeon preference, and fracture type.



180º **90º** **90º**

1. The SmartLock Technology is patented by Professor Dietmar Wolter, Hamburg Germany

System overview

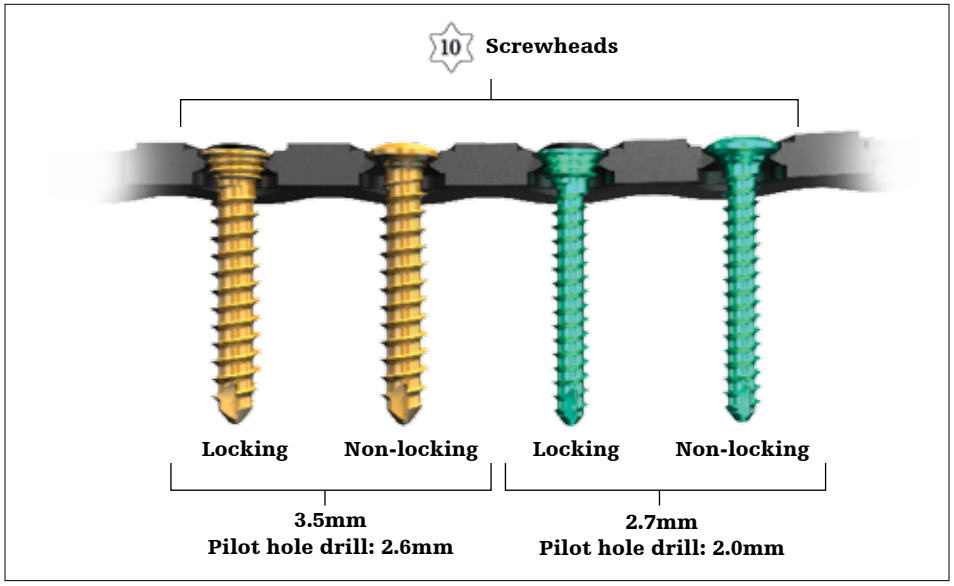
Locking or non-locking screws

The circular holes in the locking plates allow for an option for locking and non-locking screws.

3.5mm or 2.7mm screws

The plates are used with either 3.5mm or 2.7mm screws, giving the choice of screws size based on the anatomy and fracture pattern.

Additionally, all screws in the system are inserted with the same T10 screwdriver for ease-of-use.



Operative technique

Operative technique
Distal humerus

Patient positioning

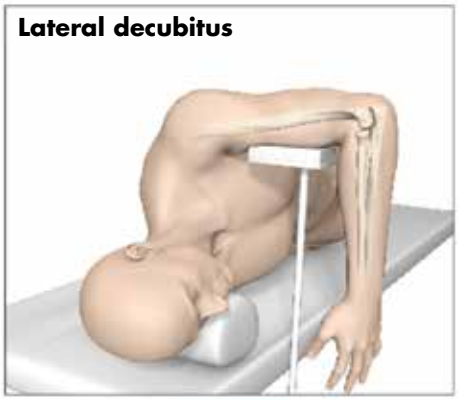
The patient may be positioned in two different ways depending on the clinical condition.

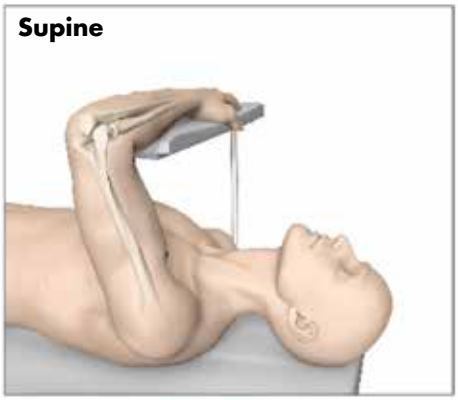
If the injury is isolated:

Lateral Decubitus with a bolster to support the arm.

If poly trauma is present:

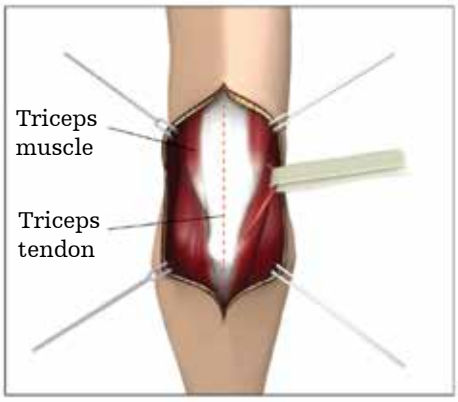
Supine with the arm placed over the chest.

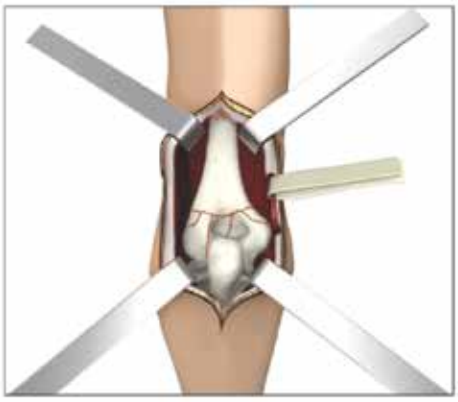




Surgical approach

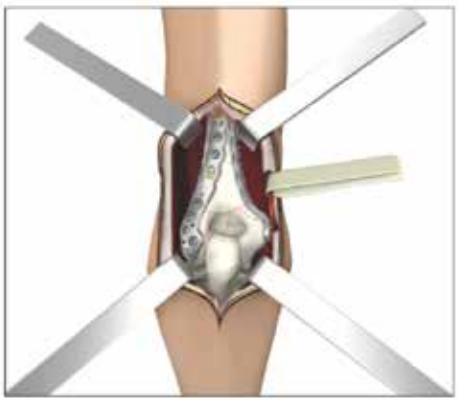
The Posterior Approach is the standard for Distal Humerus fractures. Two common techniques for this approach are the Triceps Splitting and the Olecranon Osteotomy techniques. The former is the preferred technique of the plate designers. The following is an excerpt from an article written by the designers explaining the two techniques. (JBJS Vol 82-A NO. 12 page 1702, December 2000) With either technique, the ulnar nerve should be explored and protected as part of the surgical approach. The radial nerve may require exploration with proximal shaft extension.

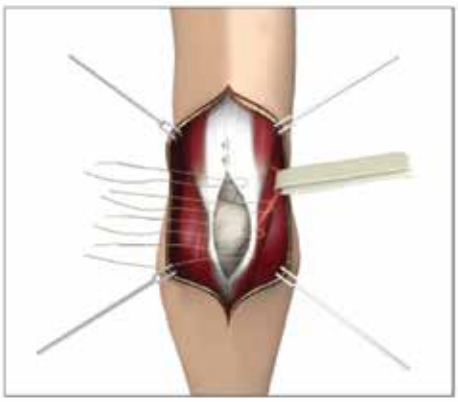




Triceps splitting

A midline incision is made in the triceps aponeurosis from proximally to distally onto the shaft of the ulna. Equal portions of the triceps muscle are reflected medially and laterally with use of sharp dissection to remove the triceps insertion from the olecranon. At the conclusion of the procedure, the triceps insertion is reattached with interrupted, number 2 braided polyester sutures with use of drill-holes through bone in the region of the olecranon.





Olecranon osteotomy

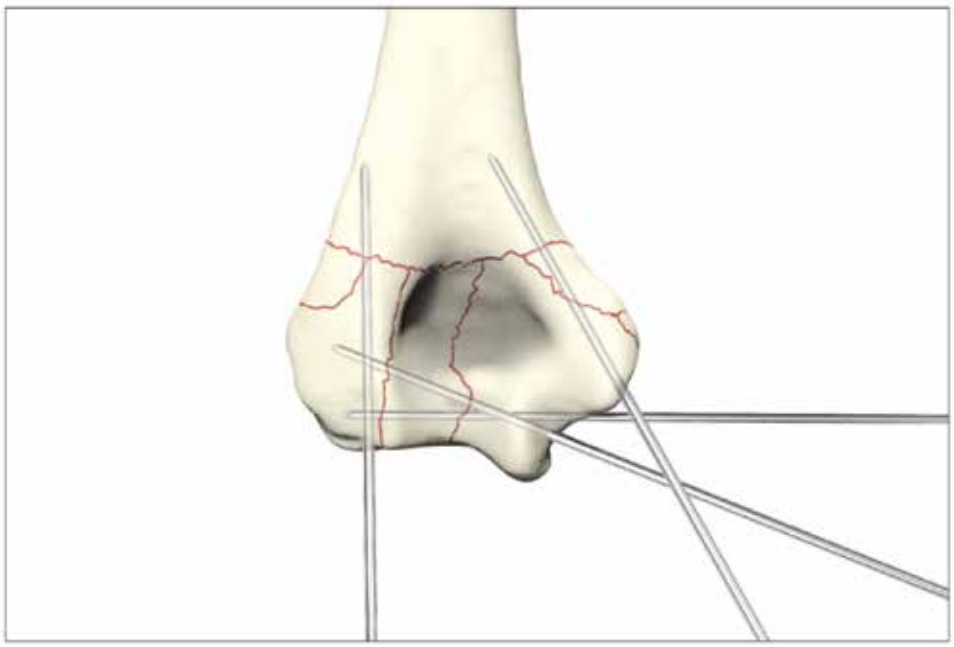
A chevron [apex distal] osteotomy is performed approximately two centimeters from the tip of the olecranon with an oscillating saw, which is meant to exit in the "bare area" of the joint, the midportion of the trochlear fossa or notch where the olecranon is devoid of cartilage. At the conclusion of the procedure, the olecranon is reduced and the fixed with two longitudinal 2.0mm Kirschner wires and an 18 gauge tension-band wire.

Operative technique
Distal humerus

Step 1: Fracture reduction

Fracture reduction is performed in the usual manner. Reduction clamps are provided to facilitate reduction. The fracture is then provisionally stabilized in an anatomic position using k-wires and/or independent interfragmentary screws.

Make sure that these implants do not interfere with the planned trajectory of the screws through the plate or position of the plate on the bone.



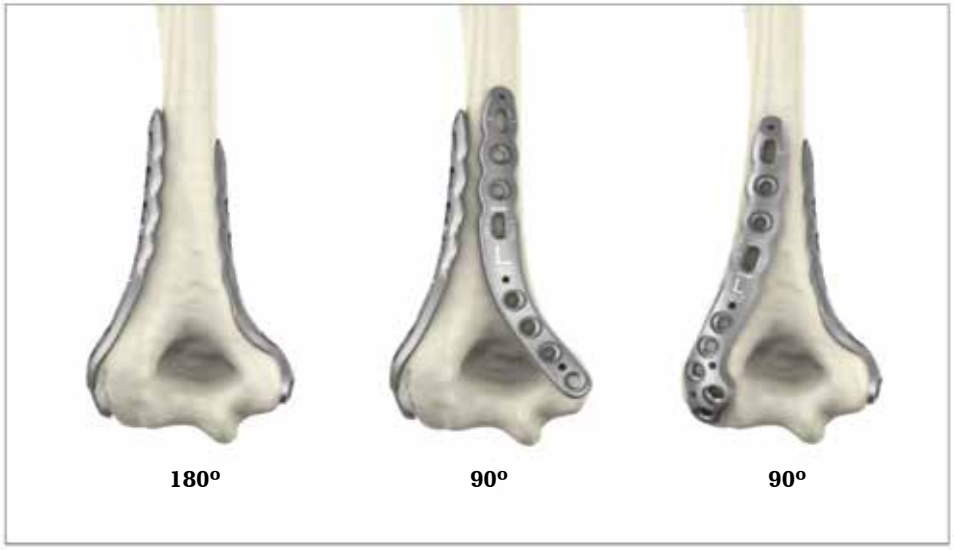
Step 2: Implant choice

Depending on the fracture configuration, the surgeon should choose the clinical method necessary for optimal fracture stability. Double plating may be performed using a 180° construct with a lateral and medial plate. Also, a 90° construct can be created using either a medial and posterior lateral plate or a lateral plate with a posterior medial plate.

Note:
The posterior plates are not designed to be used in tandem.

Screws are available in 2.7mm and 3.5mm diameters as well as locking and non-locking designs. The heads of all screws are 5mm in diameter so that either shaft diameter may be used in any hole of the plate.

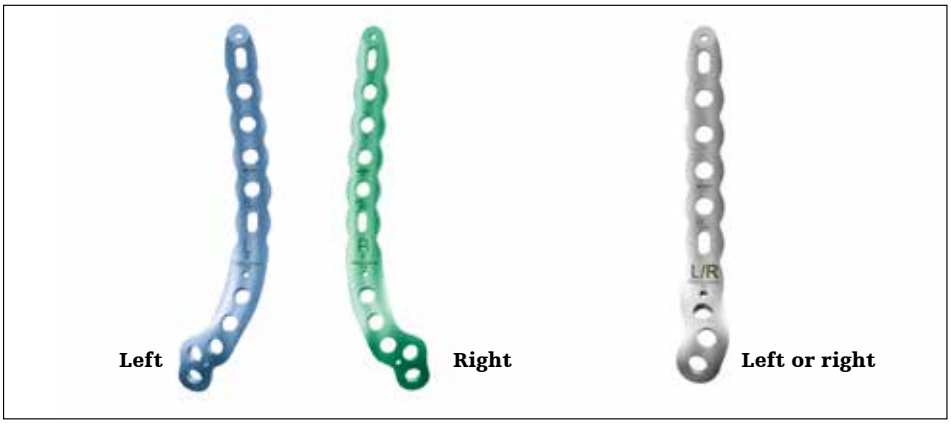
Note:
Locking screws should not be used in the oblong compression/ adaptation holes of the plate.



Operative technique
Distal humerus

Step 2a: Plating trials

Plate Trials are supplied in order to properly determine the correct length of the plate to be implanted. This is especially useful when working with sterile packed plates. Color Coded Trials for each plate design are provided with the exception of the Extended Medial Plate as the Medial Plate has the same length and design proximally.



Examples: **Lateral trials** **Medial trial**

Step 3: Plate positioning

Each plate is anatomically pre-contoured to the specific region of the Distal Humerus. Consideration should be taken for plate positioning.

The ulnar nerve should be identified and protected throughout the procedure.

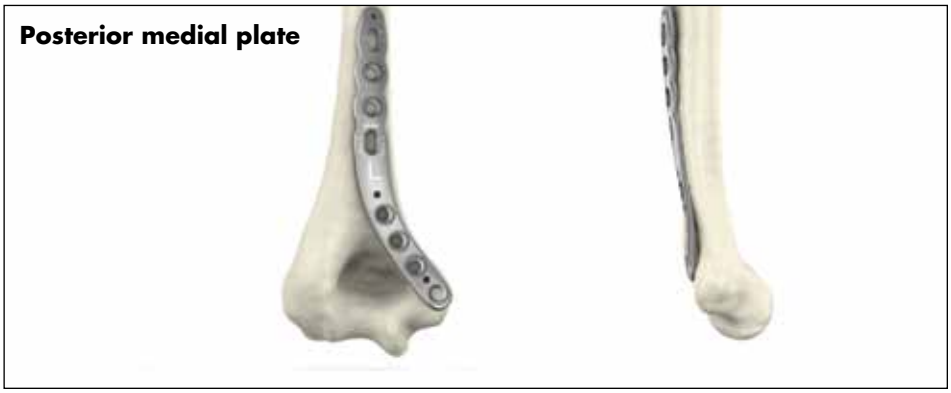
The radial nerve may require exploration with proximal shaft extension.

Medial plates – The Medial Plate comes in two shapes: Standard and Extended. The extended plate is curved around the medial epicondyle in order to place a screw from metaphyseal to diaphyseal in the medial column. Use of this plate requires transposition of the ulnar nerve anteriorly.

The standard plate does not require the transposition of the ulnar nerve. This plate should be positioned distally at the apex of the medial epicondyle.

Plate choice is determined by the fracture location and pattern. Although the distal holes of the medial plates are slightly offset (asymmetric), the plates and hole locations are anatomically correct to either left or right humerii.

Posterior medial plate – The distal portion of the plate should extend to the posterior aspect of the medial epicondyle. It should be placed medial to the olecranon fossa so as not to cause impingement with the olecranon.



Operative technique
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Lateral plate – The distal hole of the lateral plate should sit centrally on the lateral aspect of the distal humerus. Take care not to place the plate too distal as it may impinge on the radial head.

Posterior lateral plate – The distal portion of the plate should be placed lateral to the trochlea on the posterior aspect of the distal humerus. It should also be placed lateral to the olecranon fossa to prevent impingement with the olecranon. Last, it should be placed proximal to the joint surface to prevent impingement with the radial head with the elbow in full extension. This can be checked intra-operatively following provisional plate fixation.

Note:
This operative technique will focus on the placement and fixation of a medial and lateral plate. The posterior plates use the same techniques and instrumentation. When using posterior plates in conjunction with medial or lateral plates, provisionally verify the plate positions so that the plates do not collide along the shaft.

Operative technique

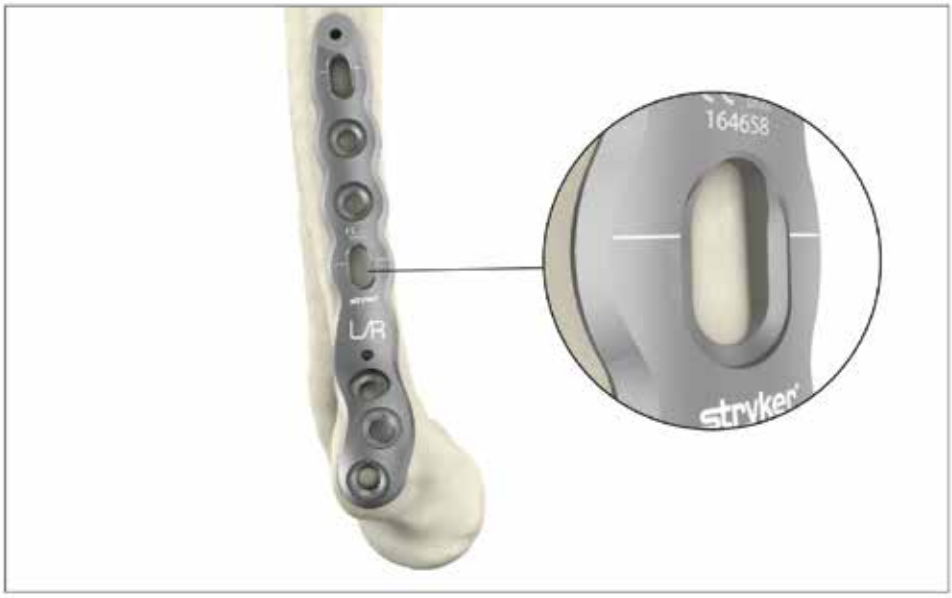
Distal humerus

Step 4: Primary plate fixation – Adaptation/ Compression oblong holes

Each distal humerus plate is designed with oblong holes. These holes can act as an adaptation hole or as a compression hole depending on where the screw is placed in the hole.

The adaptation portion of this hole allows the surgeon to precisely adjust the position of the plate. The adaptation length is approximately 5mm from distal to proximal until the compression mechanism is reached. This point is indicated by a laser marking.

Note:
Locking screws should not be used in the oblong holes of the plate.



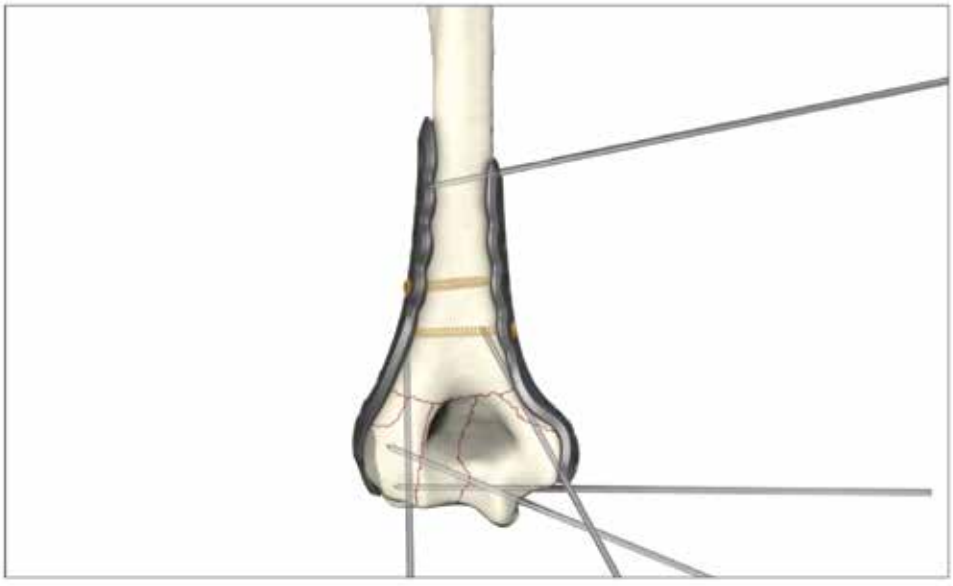
The compression mechanism starts at the proximal end of the hole and provides 1mm of compression.

It is important to note that if the distal oblong hole is to be used as an adaptation hole, it may not be used later as a compression hole since the screw may not be positioned correctly to apply compression.

When using this distal oblong hole in compression mode, a more proximal oblong hole may first be used for adaptation.

Using the appropriate instrumentation, insert a 3.5mm or 2.7mm non-locking screw.

Temporary plate fixation may also be achieved by using a 2.0mm k-wire (390192) in the k-wire holes of the plate.



Operative technique

Distal humerus

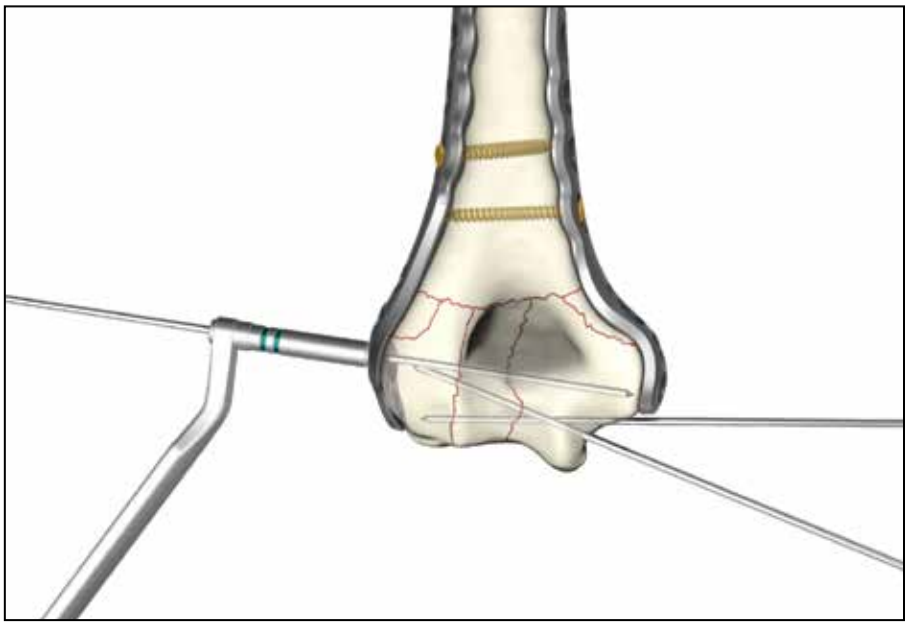
Step 5: Metaphyseal fixation – Optional k-wire placement in the plate holes

Once the plate is in the proper position, metaphyseal fixation may be achieved. Locking or Non-locking Screws may be used depending on the fracture, bone quality, and surgeon preference.

Note:
It is important that any non-locking screws be inserted before any locking screws.

As an option, a 2.0mm k-wire (390192) may be inserted in to a hole to verify the correct angulation of the screw path. Use the appropriate 2.0 drill guide (703883) to ensure the correct angle and centricity of the k-wire hole within the plate.

If 2.7mm screws are subsequently used, pre-drilling is not necessary as the k-wire has created the appropriate 2.0mm pilot hole.



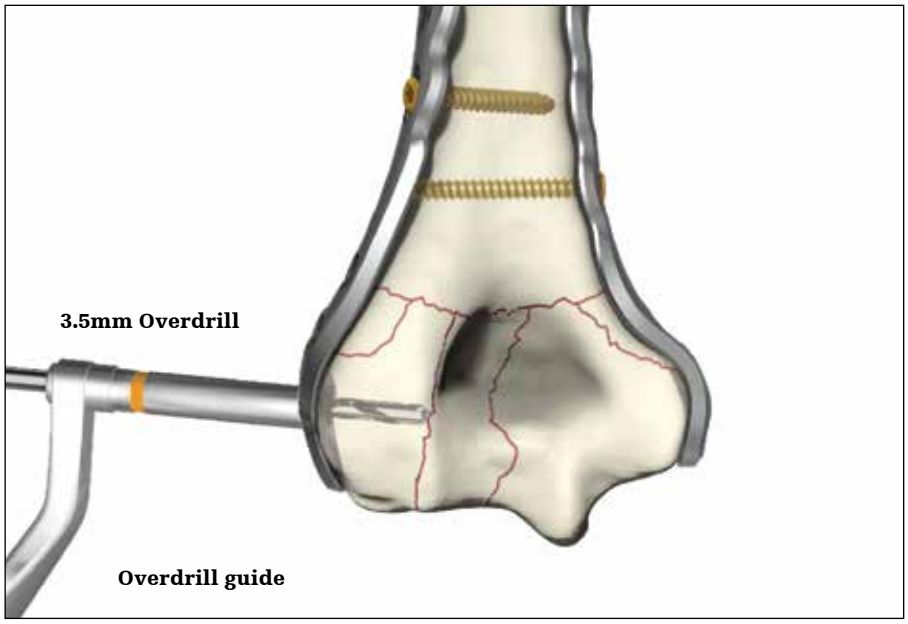
Step 6: Metaphyseal fixation – Lagging techniques

Lagging compression may be helpful to reduce fragments, bring the plate in apposition to the bone, and aid in primary bone healing.

Lagging through the plate can be performed in the traditional manner using non-locking screws. 3.5mm and 2.7mm drills (703694 for 3.5mm / 703695 for 2.7mm) are provided to create the near cortex gliding hole necessary for lagging.

Note:
The insertion of a metaphyseal locking screw prevents any further movement or reduction of the fragment.

Take care when using the Lag Screw Drill Guide (703686 for 3.5mm/703687 for 2.7mm) for overdrilling through a plate hole as the drill guide's tip or overdrill may damage the plate hole.



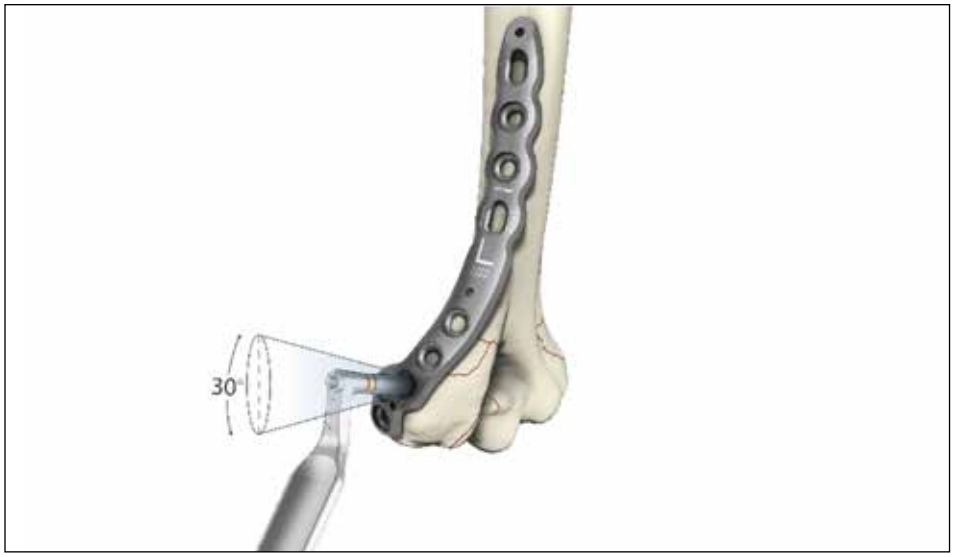
Operative technique
Distal humerus

Step 7: Metaphyseal fixation – Screw pilot hole preparation

Depending on the anatomy and/or fracture pattern, 2.7mm or 3.5mm screws may be implanted. Using the color coded drills and drill guides, the pilot holes are made. The drill guides should be used since they limit the angulation for locking and non-locking screws respectively.

Although the screws are self-tapping, Bone Taps (703898 for 3.5mm / 703899 for 2.7mm) are provided and recommended for use if screw insertion is hindered.

Measurement is obtained by using the standard Depth Gauge (705170) in the usual manner.

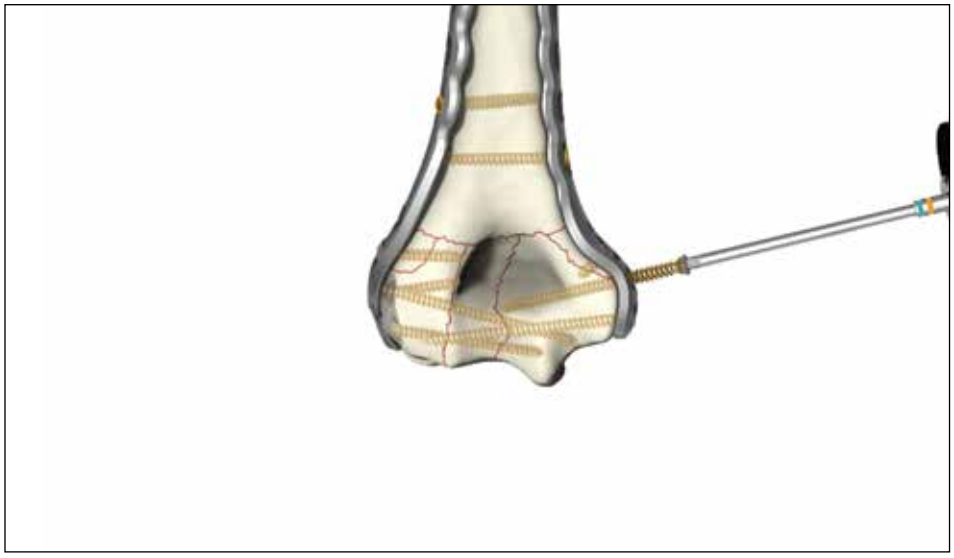


Locking screw angulation

Step 8: Metaphyseal fixation – Screw insertion

Using the Self Retaining Screwdriver (703880) Blade and the appropriate handle, insert the screws until the head is properly seated in the hole. If power insertion is used, it must be used at low speed.

The screws from either side of the humerus should extend past one another but without colliding. This construct provides biomechanically stable fixation.



Operative technique

Distal humerus

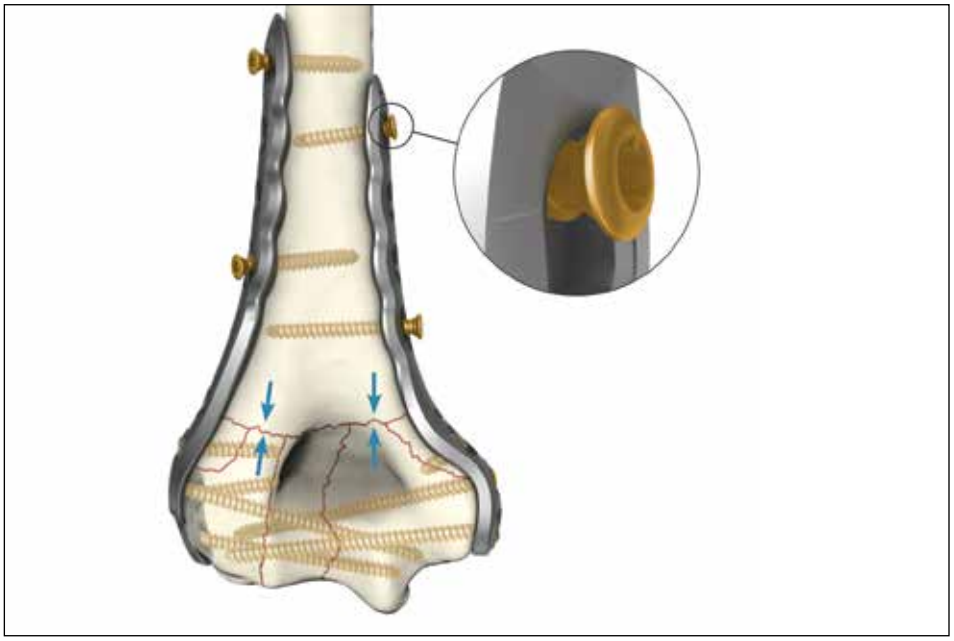
Step 9: Optional Diaphyseal/Metaphyseal compression

Once the metaphyseal portion of the humerus is fixed, a compression hole in the shaft of the plate may be used to compress the diaphysis to the metaphysis if desired. The distal compression hole may be used if it has not already been used as an adaptation hole.

A more proximal oblong hole may be used as well for further compression or if the distal oblong hole has been used as an adaptation hole.

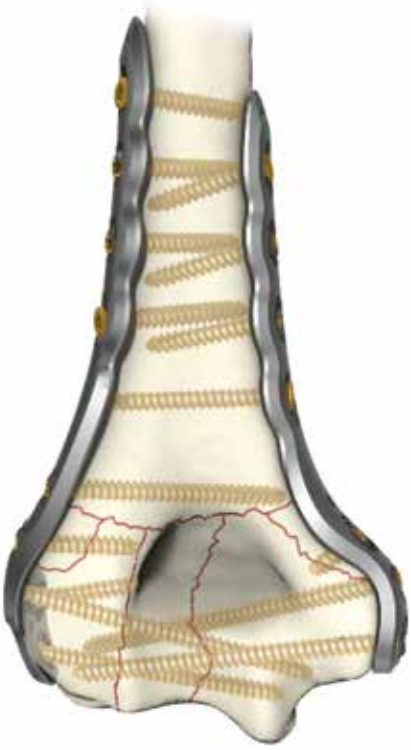
If the distal oblong hole has been used as an adaptation hole for temporary plate fixation, untighten it from the plate to allow compression using a proximal oblong hole. Also, remove any temporary k-wires from the diaphyseal portion of the plate.

Note:
Compression cannot be achieved if any of the circular holes have been fixed proximal to the fracture line. This is also true if the most distal screw (medial column screw) of the extended medial plate crosses proximal to the fracture line.



Step 10: Remaining screw fixation

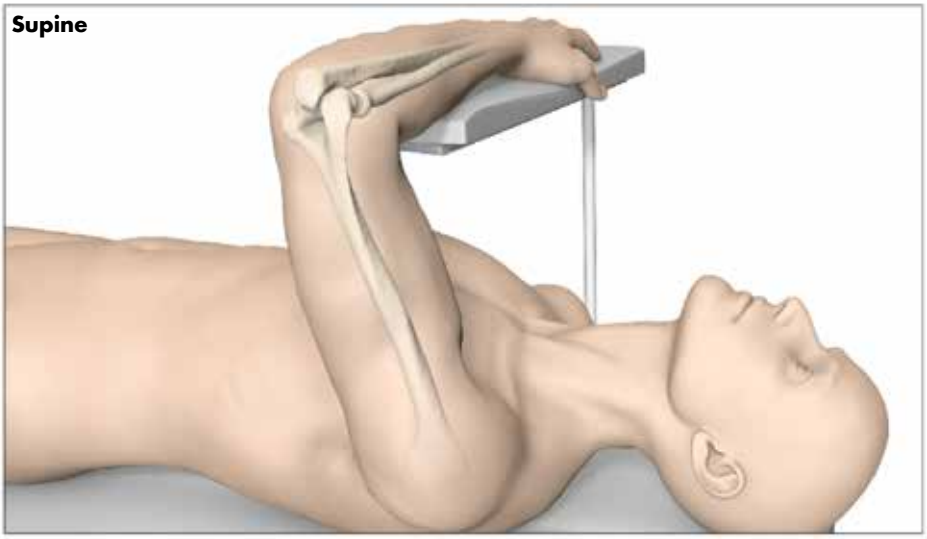
Once the fracture is fixed and any desired compression is performed, the remaining holes are filled with 3.5mm or 2.7mm locking or non-locking screws as per surgeon preference and bone quality. Final radiographs are taken intra-operatively to ensure accurate fracture reduction and screw/plate placement.



Operative technique
Olecranon

Patient positioning

For isolated Olecranon fractures the patient is positioned supine with the arm placed over the chest on a support pad.

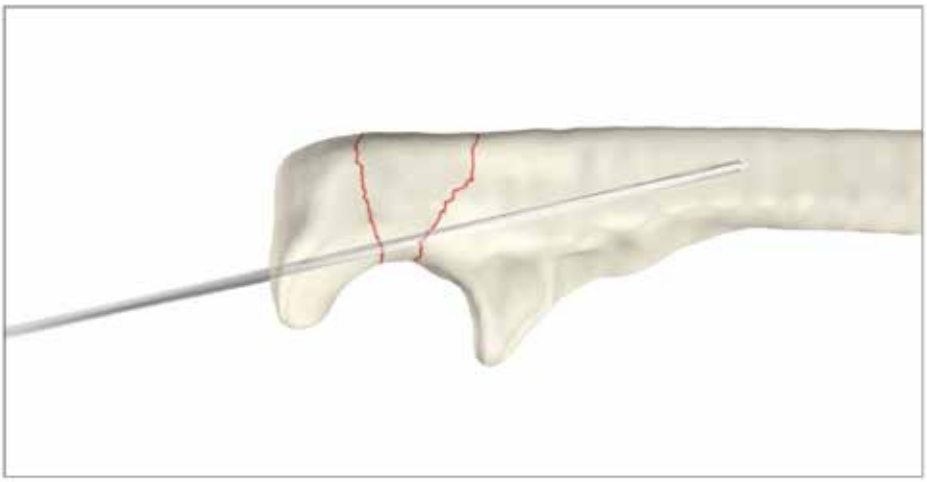


Surgical approach

An incision is made proximal to distal from the humerus supracondylar region posteriorly to approximately 5cm distal to the fracture. Care is taken not to damage the ulnar nerve.

Step 1: Fracture reduction

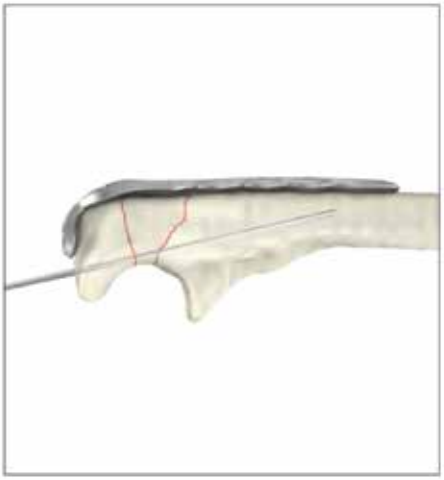
Fracture reduction is performed in the usual manner. Reduction clamps are provided to facilitate reduction. The fracture is then provisionally stabilized in an anatomic position using k-wires.



Step 2: Implant choice

The Olecranon Plates are anatomically contoured specifically for left and right ulnas. The proximal end of the plate is designed to minimize the detachment of the triceps tendon. Screws are available in 2.7mm and 3.5mm diameters as well as locking and non-locking designs. The head of all screws are 5mm in diameter so that either shaft diameter may be used in any hole of the plate.

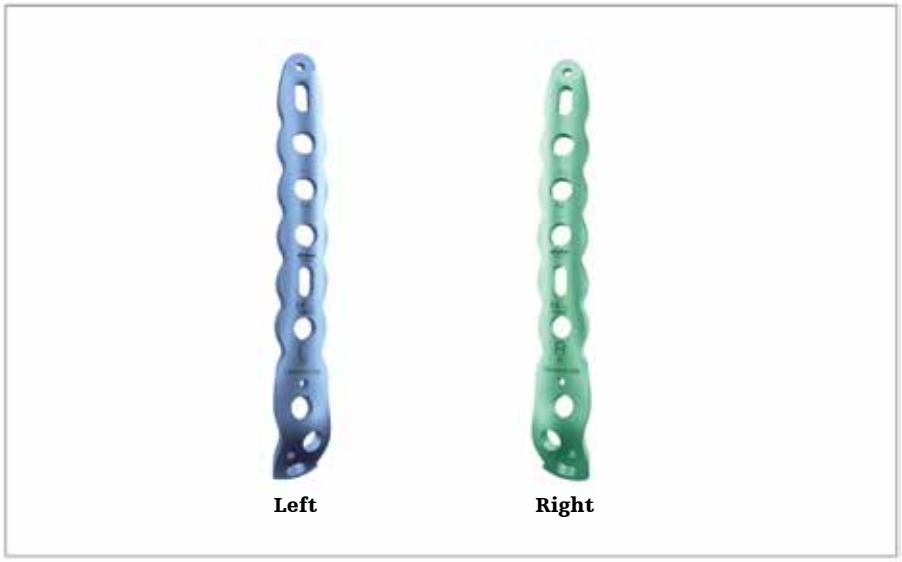
Note:
Locking screws should not be used in the oblong holes of the plate.



Operative technique
Olecranon

Step 2a: Plating trials

Plate Trials are supplied in order to properly determine the correct length of the plate to be implanted. This is especially useful when working with sterile packed plates. Color Coded Trials for Right and Left Olecranon plate designs are provided.



Olecranon trials

Step 3: Primary plate fixation

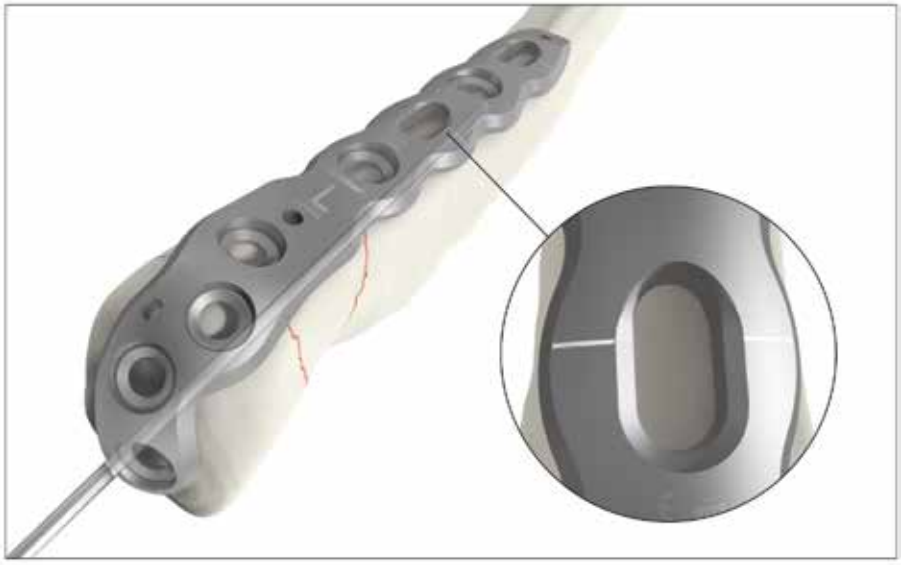
Like the distal humerus plates, the olecranon plate is designed with oblong holes. These holes can act as an adaptation hole or as a compression hole depending on where the screw is placed in the hole.

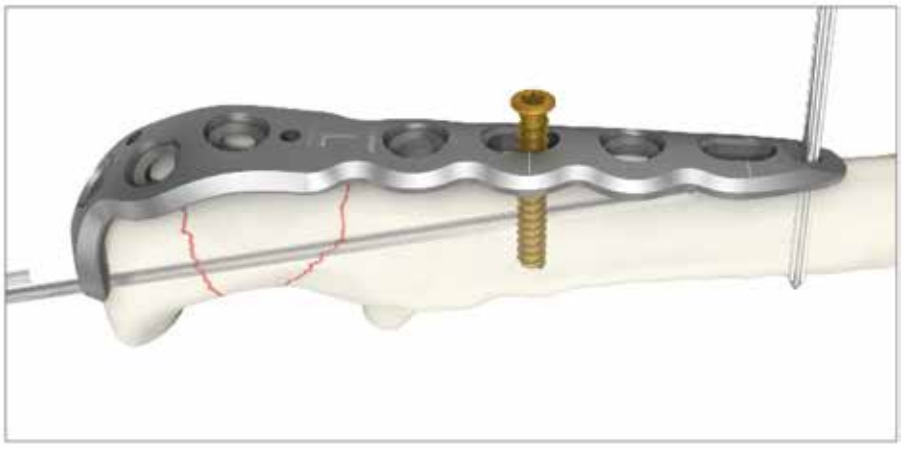
The adaptation length is approximately 5mm from proximal to distal until the compression mechanism is reached.

The compression mechanism starts at the distal end of the hole and provides approximately 1mm of compression.

It is important to note that if an oblong hole is to be used as an adaptation hole, it may not be used later as a compression hole since the screw may not be positioned correctly to apply compression.

When using the proximal oblong hole in compression, a more distal oblong hole may first be used for adaptation. Alternatively, temporary plate fixation may be achieved by using a k-wire in the k-wire holes of the plate.





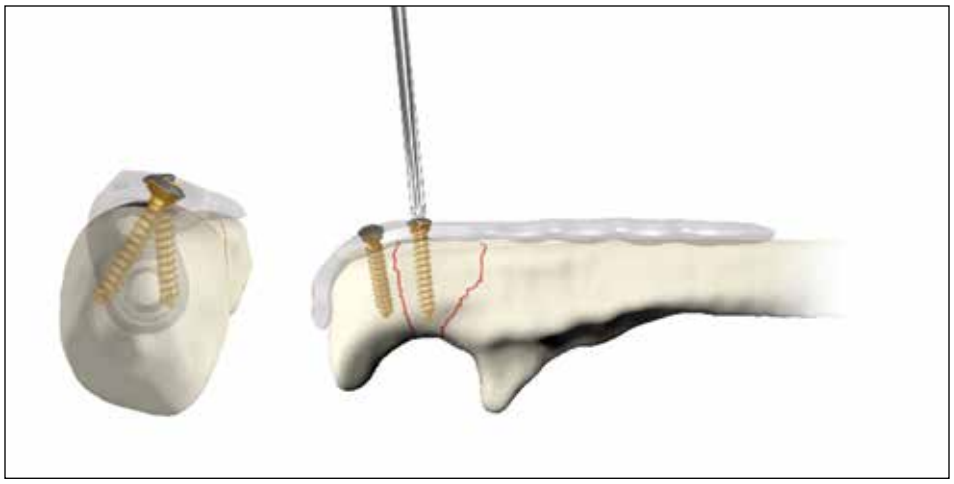
Operative technique

Olecranon

Step 4: Metaphyseal fixation – Proximal posterior screw insertion

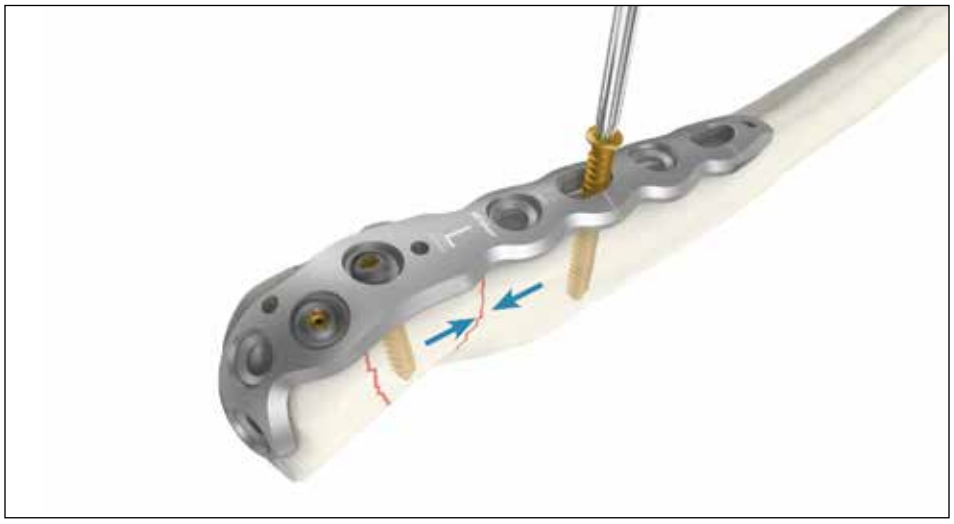
Insert two screws in the posterior aspect of the olecranon in a divergent trajectory. This will enable the subsequent placement of a longer screw to be placed from proximal to distal. Be careful not to penetrate the articular surface of the olecranon.

Although the screws are self-tapping, Bone Taps (703899 for 2.7mm screws / 703898 for 3.5mm screws) are provided and recommended for use if screw insertion in hindered.



Step 5: Diaphyseal/ Metaphyseal compression (optional)

If desired, compression may now be achieved using one of the oblong holes.



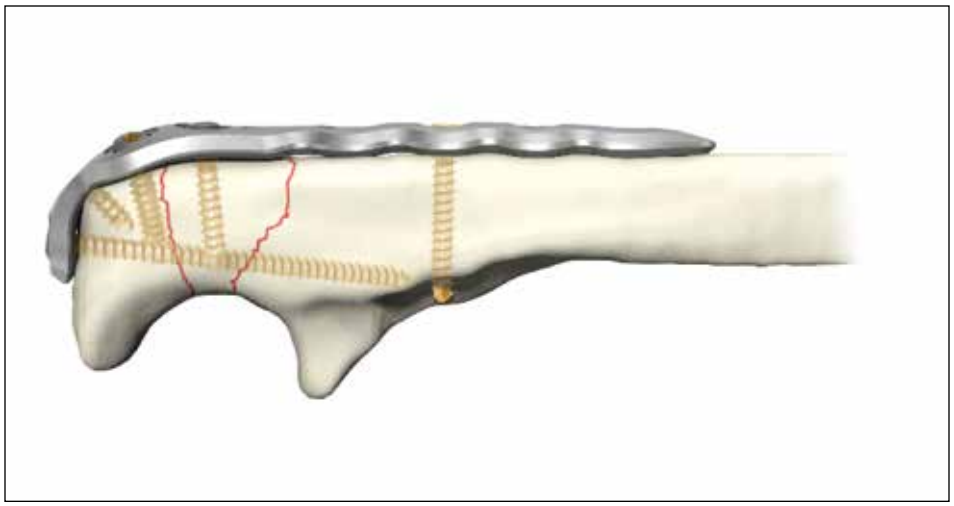
Operative technique
Olecranon

Step 6: Intramedullary fixation – Most proximal screw insertion (home run screw)

Insert the most proximal screw which runs from proximal to distal at the anterior aspect of the ulna past the fracture line and the coronoid process.

If desired, a 2.0mm k-wire (390192) may be placed in the most proximal hole beforehand to show the placement of this screw. 2.0 Drill Guide (703883) to correctly guide the k-wire through the plate hole.

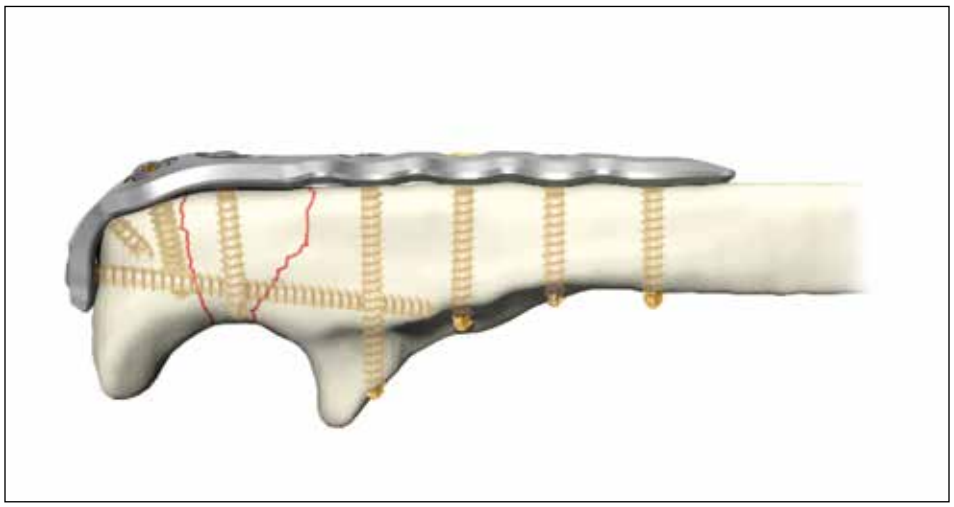
Note:
Any desired metaphyseal diaphyseal compression must be done prior to the insertion of this screw.



Step 7: Diaphyseal fixation – Distal screw fixation

Locking or non-locking screws are placed in the remaining diaphyseal holes.

Final radiographs are taken intraoperatively to ensure accurate fracture reduction and screw/plate placement.



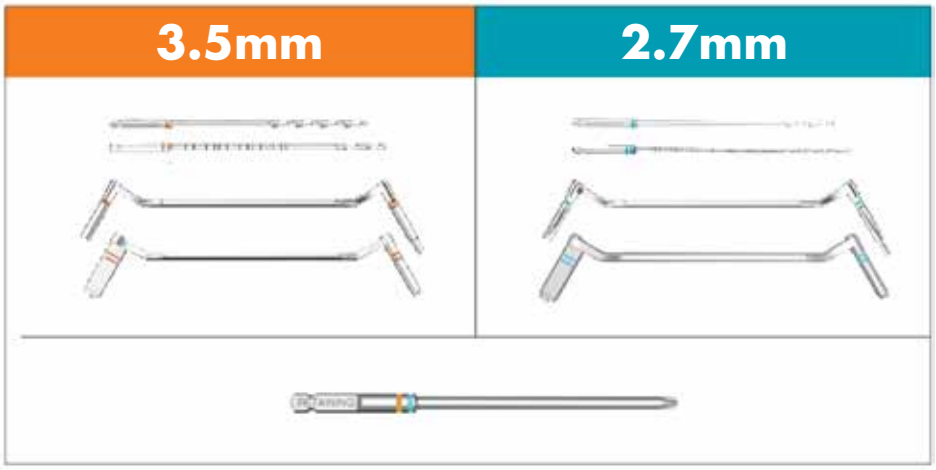
Operative technique
VariAx 2 instrumentation usage

Color coding systems

Color coding of the screws and appropriate instruments helps identify the components during surgery as the color identifies the screw diameter.

All instruments that are color-coded orange are used with the 3.5mm screws, and all of the turquoise blue colored instruments are used with the 2.7mm screws. Additionally, all drills are laser marked with the corresponding drill diameter.

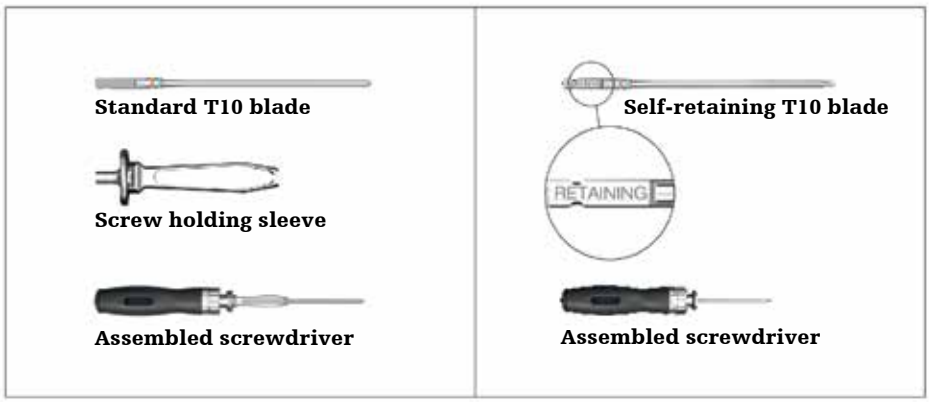
Note:
Always match the color ring marking on the drill bit with the color marking on the drill guide. Additionally, always match the screw anodization color with at least one of the color ring markings.



Screwdriver blade options

The VariAx 2 System has a variety of different blades to choose from. The self–retaining blade (703880) is identified with a symbol and has the word "RETAINING" on the AO coupling interface. Its conical tip helps ensure a friction fit connection with the screw head.

Note:
The self–retaining blade (703880) cannot be used with the screw holding sleeve (703675).



Modular handle

VariAx 2 offers a modular handle system. This is composed of two handle grip sizes (medium and large) that can be interchanged with either a bi-directional ratcheting AO-Coupling insert or a standard AO-Coupling insert.

Both handle sizes are equipped with a spin-cap to allow insertion using a two-finger technique. In order to disengage the insert from the handle, push down on the button on the distal part of the handle and pull the insert away from the handle.

Note:
The inserts must be removed from the handles before cleaning.

The ratcheting insert can work in three modes: clockwise ratcheting, counterclockwise ratcheting or neutral. To switch between the different modes, simply twist the distal part of the insert to the desired driving direction.

Note:
To ensure appropriate ratcheting function, perform appropriate maintenance on the insert by applying medical-grade lubricant oil through the marked cut-outs.

Operative technique
VariAx 2 instrumentation usage

Joystick for plate position & temporary fixation

The Joystick for T10 screw holes (703928) can be used in any circular hole to aid in plate positioning. Additionally, it can also be used to temporarily fix the plate to the bone by inserting a k-wire with a diameter up to 1.6mm through a joystick that is already engaged in the plate hole.

Note:
Do not insert a k-wire through a joystick on the compression side of the fracture if compression is needed.

After inserting the joystick tip in the circular hole, turn the knob on the upper part of the joystick clockwise to fix it in the hole. To remove the joystick, simply remove any k-wire and turn the knob counter–clockwise to disengage the tip from the hole.

Note:
Do not use the engaged joystick to apply bending to the plate as this may damage the plate or joystick.

Taps & countersink

2.7mm and 3.5mm taps (703899 for 2.7mm screws / 703898 for 3.5mm screws) are available in the system. Although all screws are self–tapping, it is recommended to use a tap if excessive resistance is felt during insertion or if the bone is dense.

A countersink (45-80040) is also available for reducing the screw head prominence when the screw is used independently of a plate.

Tap for 3.5mm screws

Countersink

Operative technique
VariAx 2 instrumentation usage

K-wire with stop

The k-wire with Stop (703818) can be used in any screw hole or k-wire hole in order to temporarily fix the plate to the bone.

Depth measurement options

VariAx 2 offers various options to evaluate the screw length. As previously mentioned, all drills are scaled so that the surgeon may evaluate the screw length when using the drill through the dedicated drill guides.

A SpeedGuide is also offered that allows the surgeon to drill and measure the hole depth in one step with a single instrument. For further information on the SpeedGuide, please refer to the SpeedGuide Operative Technique.

Lastly, a standard Depth Gauge (705170) may be used either independently or through a plate hole.

Drill & drill guides

Drill diameter	Drill bit	Drill guide
2.0	703690	703883
2.6	703691	703882

Scaled drill and drill guide

SpeedGuides up to 70mm

Drill diameter	Drill bit	SpeedGuide
2.0	703893	703890
2.6	703895	703889

SpeedGuides

Depth gauge

Operative technique
VariAx 2 instrumentation usage

Plate contouring

All of the plates are pre-contoured to fit to a range of anatomies. Although not usually necessary, the plates may be contoured to adapt to individual patient anatomy. Design requirements are strict when it comes to shaping a plate to the Elbow. For example, the surgeon should avoid sharp bends, reverse bends or bending the device at a screw hole.

Notes

Notes

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Trauma & Extremities

CE 0123

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