EXACTECH | SHOULDER

Operative Technique

equinoxe®

Fx Plate

Exactech®

Surgeon focused. Patient driven.™

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INTRODUCTION

The Equinoxe® Shoulder System redefines "anatomical." The primary stem allows independent adjustability of all four anatomic parameters *in situ*. The reverse shoulder is an optimized design that minimizes both scapular notching and torque on the glenoid while seamlessly integrating with the primary stem. The platform fracture stem's offset anterior-lateral fin and asymmetric tuberosity beds define the next generation in complex fracture reconstruction. The Fx Plate provides multiple configurations of blades and screws to address a myriad of classifications of proximal humerus fractures.

Throughout the development process, our team has collaborated on every facet of the Equinoxe Shoulder System including this operative technique. We began the product development process by identifying concerns our team had with the treatment options for complex fractures of the proximal humerus as well as the special surgical challenges that nonunions provide. Our goal was to develop solutions to those concerns, and we believe the Equinoxe Fx Plate helps address the challenges you face in the O.R. every day. In general, we sought the following improvements:

ANATOMIC. REDEFINED.

The contoured plate is asymmetric proximally to align with the bicipital groove and greater tuberosity, and to respect the deltoid insertion. The suture holes are anatomically oriented allowing surgeons to more easily pass the suture after the plate is secured to the bone.

MINIMIZE HUMERAL HEAD COLLAPSE

Unique modular blades can be inserted to further buttress the reconstruction while locking screws diverge to support the humeral head. The large central hole allows for either a 6.5mm locking screw or deployment of bone-void filler after the plate is secured.

FLEXIBILITY

Multiple screw/blade configurations enable a surgeon to treat a spectrum of proximal humeral fractures. Robust instrumentation options are included to address a wide array of surgical technique preferences.

Thank you for considering the Equinoxe Fx Plate. We hope you come to agree, based on your experiences with the Equinoxe in the O.R., that we have accomplished our goals.

Respectfully,

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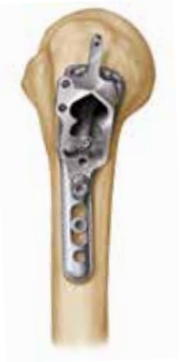
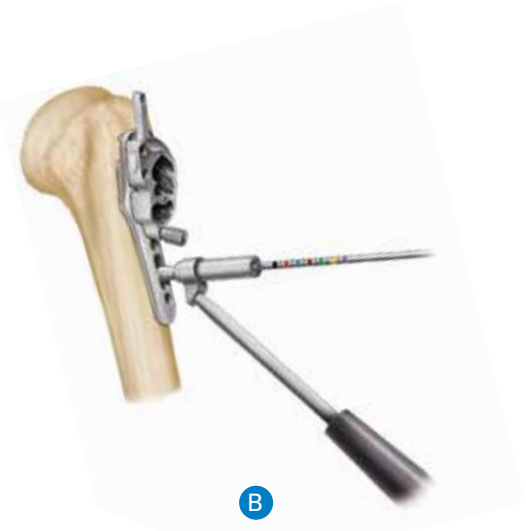
OVERVIEW TECHNIQUE



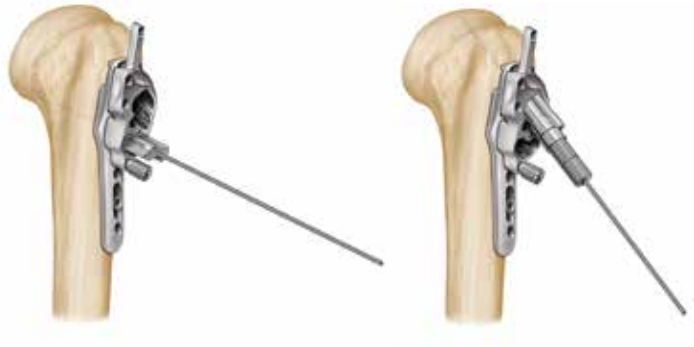
A

Placement of Fx Plate



B

Preparing/Placing Compression Screw



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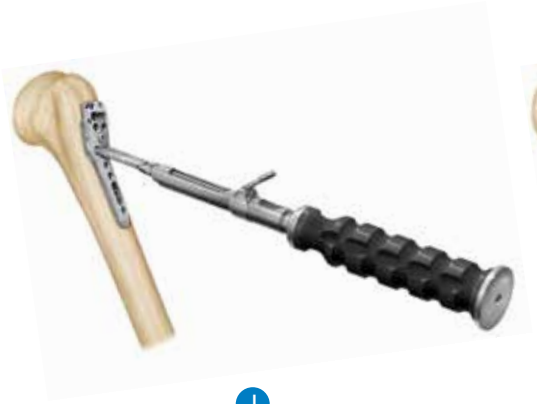

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DETAILED OPERATIVE TECHNIQUE

INDICATIONS

The Equinoxe Proximal Humerus Fracture Plate System is indicated for Open Reduction Internal Fixation (ORIF) procedures of the proximal humerus. The decision to proceed with ORIF should reflect careful consideration of both injury and patient factors. Clinical indications include fractures, fracture dislocations, osteotomies and non-unions of the proximal humerus.

PRE-OPERATIVE PLANNING

After a careful history and physical examination, including identification of the dominant hand and an assessment of activities of daily living, radiographs should be obtained. A standard shoulder trauma series should be obtained, including an AP view, scapular lateral view and an axillary view. A CT scan may provide additional information about involvement of the humeral head and tuberosity displacement. Although not routinely required, reformatted reconstruction views can be obtained to provide additional information about fracture anatomy.

Other things to consider during the examination are the length of time since the injury occurred, conditions predisposing the patient to seizure and neurologic and vascular factors.

PATIENT POSITIONING

It is recommended that the patient be placed on an operating table in a supine position. The head of the operating table should be elevated approximately 30 to 60 degrees in a modified beach chair position. It is recommended that the image intensifier is placed above the patient's head to facilitate biplane fluoroscopy. It is critical to ensure that positioning will allow live AP and axillary view images prior to draping. A small bolster should be placed laterally behind the involved shoulder. The patient should be moved to the side of the table so that the upper extremity can be placed in maximum extension without obstruction by the operating table. Alternatively, a Captain's chair or similar positioning device can be used for proper patient positioning. The patient should be secured to the operating table to minimize any changes in position intra-operatively. The entire upper extremity should be prepped and draped to allow complete access to the operative area and full mobility during the procedure. Either a deltopectoral or a superolateral approach may be used depending on the surgeon's preference and clinical parameters.

SURGICAL APPROACH

Deltopectoral Approach

A straight deltopectoral incision is made beginning just lateral to the tip of the coracoid process and extending distally and laterally to the insertion of the deltoid. The subcutaneous tissues are divided and medial and lateral flaps are elevated to expose the deeper muscular layers.

The deltopectoral interval is identified by localization of the cephalic vein. The cephalic vein is usually retracted laterally with the deltoid muscle. In some instances the cephalic vein is more easily retracted medially with the pectoralis major. In either case, care should be taken to preserve the cephalic vein throughout the procedure.

The subdeltoid space is mobilized, as is the pectoralis major. The conjoined tendon muscles are identified and the clavipectoral fascia is divided at the medial edge of the conjoined tendon muscles. The fracture hematoma is usually evident after dividing the clavipectoral fascia. The conjoined tendon muscles and the pectoralis major are retracted medially and the deltoid is retracted laterally. This can be most easily accomplished with the use of a self-retaining type of retractor. Depending on plate length, a portion of the deltoid insertion should be released. After the fracture hematoma has been evacuated, the deeper structures can be visualized. The biceps tendon should be identified as it provides an orientation to the greater and lesser tuberosities. The humeral shaft may be internally or externally rotated to provide access to the greater or lesser tuberosities.

Superolateral Approach

A deltoid splitting approach to the lateral aspect of the proximal humerus can also be used. The skin incision can be either a vertical incision starting at the lateral aspect of the acromion or an elliptical incision that flaps down to expose the deltoid. In either case, the muscle is split longitudinally beginning at the lateral aspect of the acromion. The axillary nerve must be identified and protected as it passes across the split. The nerve creates two soft-tissue windows, one above and one below the nerve, which provide access to the displaced tuberosities and head segments (above) and the humeral shaft (below). The advantage of this approach is improved access to posteriorly displaced greater tuberosity fragments. The disadvantage is potential damage to the axillary nerve and higher risk of heterotopic ossification.

FRACTURE REDUCTION

Once the fracture fragments have been identified, several braided, non-absorbable sutures are passed through the tuberosity-rotator cuff tendon interface and mobilized. Under fluoroscopy, the humeral head segment is elevated and the fracture may be reduced using a broad osteotome. Care is taken to avoid disrupting the medial soft-tissue hinge.

During the fracture reduction, sutures and K-wires can be used to provide provisional stabilization both before applying the plate and during implantation. Care should be taken with placement of K-wires so they will not interfere with the placement of the fracture plate. There are three locations on the plate that will allow a K-wire (0.062 inches) to pass through for provisional fixation.

Depending on the fracture pattern, there are two strategies to consider while implanting the Proximal Humerus Fx Plate: provisionally reducing the fracture with sutures and/or K-wires before applying the Fx Plate or applying the Fx Plate and reducing the fracture to it. Please consider the following pearls:

- As soon as the humerus is exposed, immediately tag the tendon-bone junction of the anterior, superior and posterior cuff with sutures to establish control. Manipulating these sutures can be helpful to reduce the fracture.
- Place sutures between the fragments and reduce them around the humeral head to hold it in place.
- When applying the plate, the **Compression Screw** is usually inserted first, followed by **Proximal Locking Screws, Humeral Blade/Blade Locking Screws** and **Distal Locking Screws**.
- Once the plate is nearly snug to the bone, recheck the plate height and adjust the plate by sliding it along the Compression Screw in the shaft slot. When the proper height is determined, tighten the Compression Screw.
- If applying the plate prior to fracture reduction, the height does not need to be perfect since the Compression Screw slot on the shaft allows for adjustment (±4.8mm).
- While positioning the plate, check the plate height using the **Screw Guide Jig** and identify the trajectory of the lowest screws or blade into the humeral head using the **1.6mm K-Wire Guide**, as this is a critical component of the stability of the fracture construct.
- While reducing the fracture, check the relationships between the humeral head, tuberosities and humeral shaft.

INITIAL PLACEMENT OF Fx PLATE

A fracture plate of appropriate length is selected and the **Targeting Jig** (left or right) is screwed into place on the Fx Plate. The **Targeting Jig Handle** may be used for placing the plate onto the humerus. The plate is applied to the lateral aspect of the humerus and shaft along the bicipital groove. The superior tip of the plate is positioned approximately 12mm distal to the superior greater tuberosity *(Figure 1)*.

Note: *Plate lengths of 80, 115, 150mm are offered.*

A non-locking Compression Screw placed through the slotted hole of the plate should be used to bring the humeral shaft to the plate *(Table 1)*. This will also allow the plate to be adjusted either proximally or distally along the humeral shaft. First the hole is drilled using the **3.3mm Drill Bit**. Once the depth is determined using a **Depth Gauge**, the appropriately sized Compression Screw is then inserted *(Figure 2)*.

TABLE 1 **Compression Screws**

Diameter (mm)	Length (mm)	Color-code
3.8	20	Black
	23	
	26	Orange
	29	
	32	Blue

Figure 1
Placement of Fx Plate

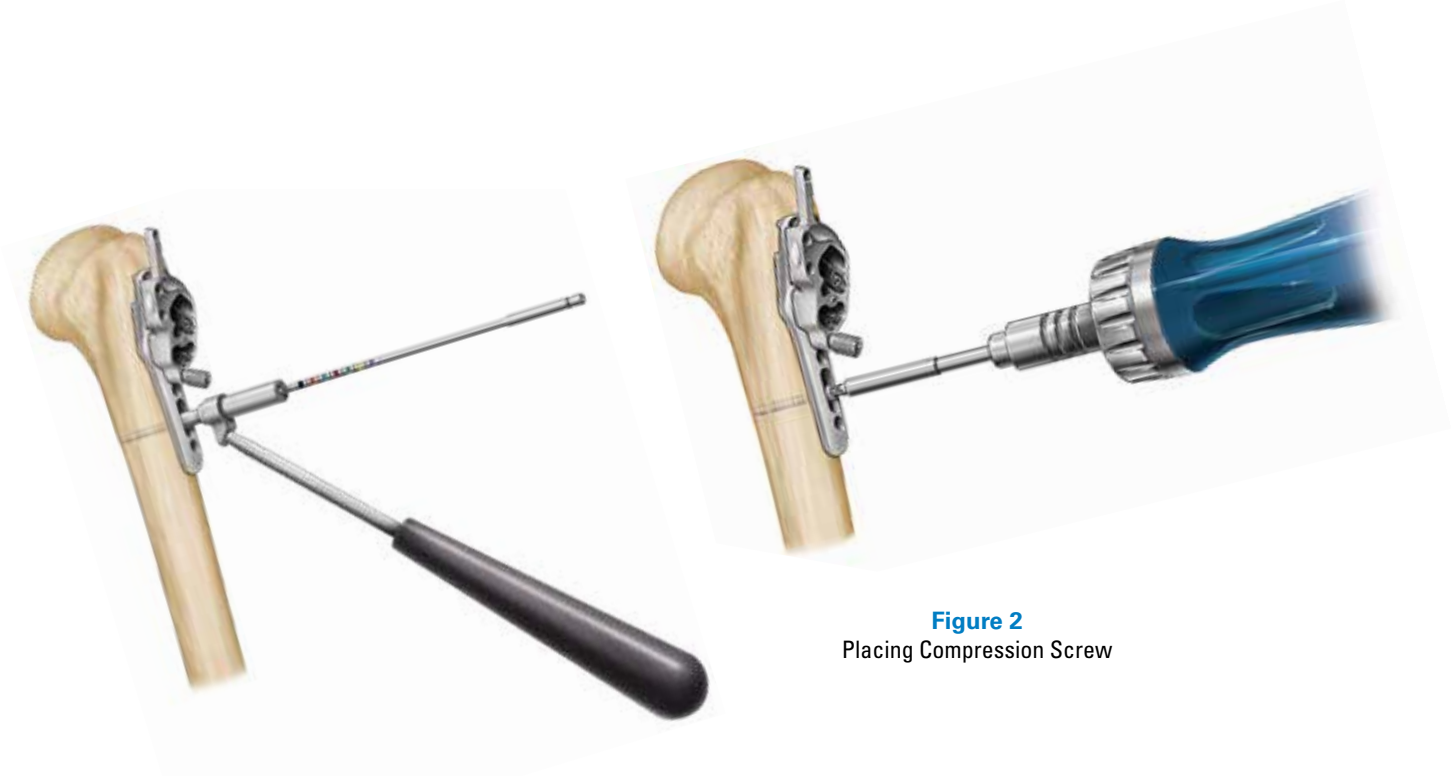


Figure 2
Placing Compression Screw

Figure 3
Setting Plate Height Using Central Hole

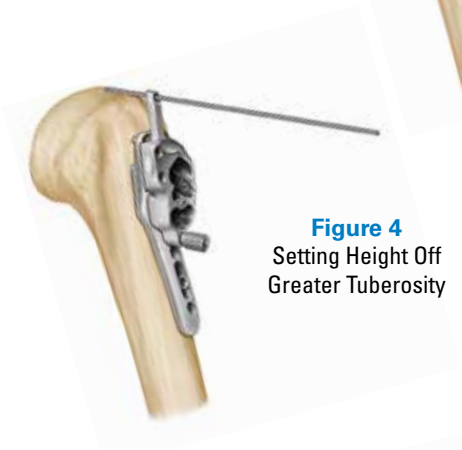


Figure 4
Setting Height Off Greater Tuberosity

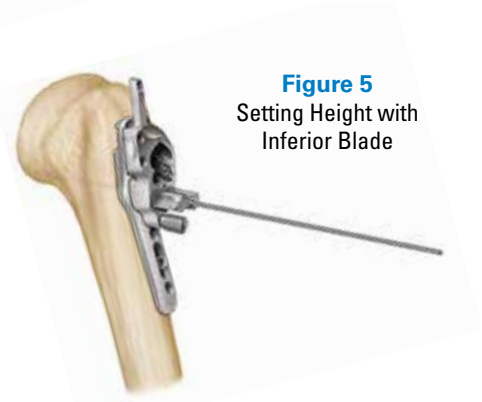


Figure 5
Setting Height with Inferior Blade

SETTING Fx PLATE HEIGHT

There are three options available to set the height of the fracture plate along the humerus.

1) Using fluoroscopy, the plate height can be determined using the central hole of the plate. A **1.6mm (.062") K-wire** is placed through this hole and should bisect the diameter of the articular surface *(Figure 3)*.

2) The plate height can be determined off the greater tuberosity using a 1.6mm (.062") K-wire through the superior hole of the Targeting Jig *(Figure 4)*.

3) Using the inferior screws/blade location and the 1.6mm K-wire Guide, a 1.6mm (.062") K-wire could be placed along the inferior aspect of the head neck junction to assess the plate height under fluoroscopy *(Figure 5)*.

SCREW AND BLADE PLACEMENT

Once the Fx Plate height has been determined, the surgeon may then prepare the humerus for the placement of Locking Screws and Blades. The Fx Plate provides multiple options for optimal Screw and Blade fixation *(Figure 6)*. The order of placement of these devices is determined intra-operatively.

1) Using only Locking Screws, there are six 3.8mm fixed-angle screw holes and one 6.5mm screw hole available.

2) Using the blade option, the two locations shown can also be used for implanting a Locking Blade with two Blade Locking Screws *(Figure 6a)*.

Note: *A Blade in the superior slot would be useful in a valgus impacted fracture while a Blade in the inferior slot would be useful to keep the humeral head from collapsing into varus.*

Figure 6
Screw/Blade Option
Note: *Place either two Screws or a Blade with two Blade Locking Screws*

Figure 6a
Locking Blade Insertion Points

PREPARING FOR PROXIMAL 3.8MM LOCKING SCREWS

Surgeons can choose to prepare for the 3.8mm Locking Screw with either 2.8mm or 3.3mm instrumentation (i.e. drills and drill guides) based on surgeon preference, bone quality and other relevant factors.

To prepare for the superior and inferior 3.8mm Locking screws, connect the **3.8mm Double Screw Guide** into the Targeting Jig. To prepare for the center 3.8mm Locking Screws, connect the **3.8mm Screw Guide** into the Targeting Jig. Alternatively, the 3.8mm Screw Guides can also be used in any of the superior and inferior screw locations in the Targeting Jig.

Assemble the **2.8mm or 3.3mm Threaded Drill Guide** through the screw guide to lock directly into the plate. A **2.8mm or 3.8mm Drill Bit** is used for preparing the holes for the **3.8mm Locking Screws** *(Figure 7)*.

Prior to drilling for the 3.8mm Locking screw, the screw path trajectory can be verified under fluoroscopy using a 1.6mm K-wire. To assemble the **1.6mm K-wire Insert**, lock the Threaded Drill Guide into the specific hole in the plate and place the 1.6mm K-wire Insert inside the drill guide.

The depth of each hole is determined using the color-coded drill, but they may also be verified with the more traditional **Depth Gauge** *(Figure 8)*.

The 3.8mm Locking Screws are provided in lengths between 20mm and 56mm, in 3mm increments *(Table 2)*.

TABLE 2 **Color-coded 3.8mm Locking Screws**

Diameter (mm)	Length (mm)	Color-code
3.8	20	Black
	23	
	26	Orange
	29	
	32	Blue
	35	
	38	Red
	41	
	44	Green
	47	
	50	Yellow
	53	
	56	Purple

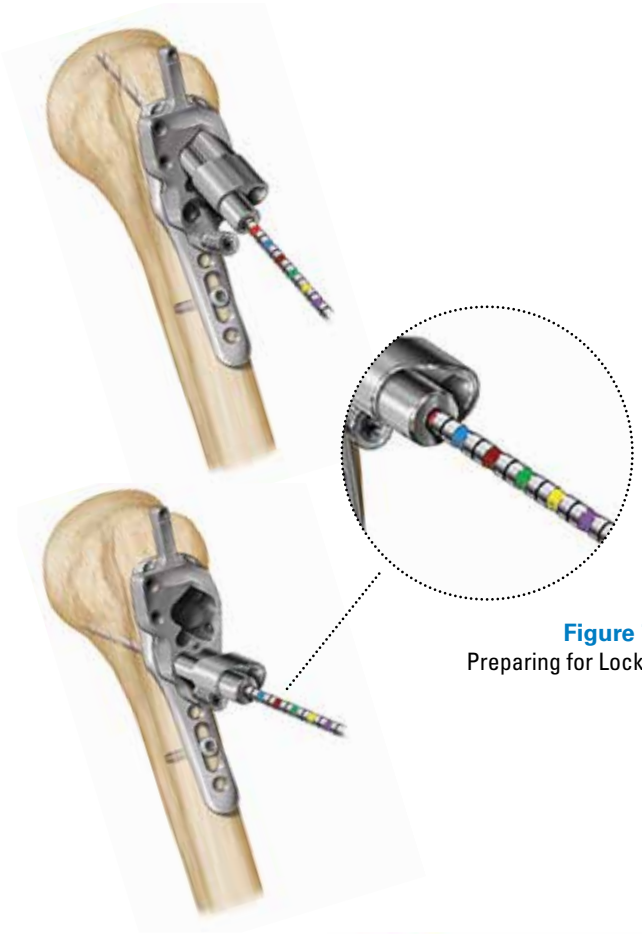


Figure 7
Preparing for Locking Screws

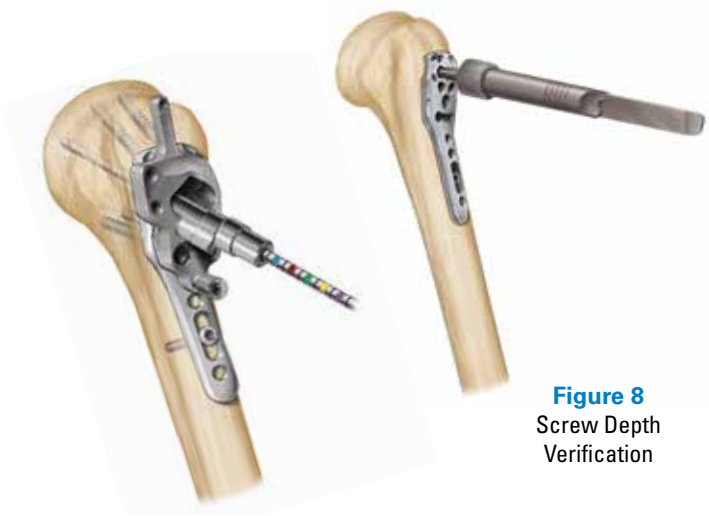


Figure 8
Screw Depth Verification

Figure 9
Placing Locking Screw

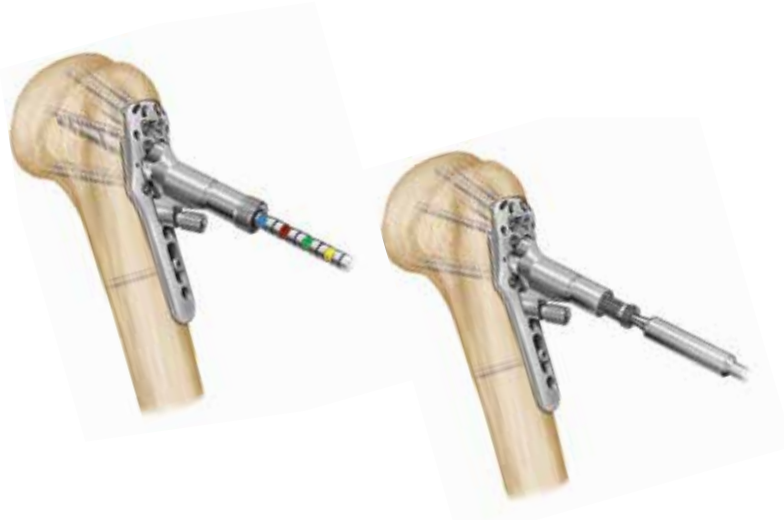


Figure 10
Preparing Central Hole for Locking Screw

Figure 11
Preparing for Locking Blade

The Threaded Drill Guide is removed and the appropriate 3.8mm Locking Screw is inserted. A **Ratcheting Screw Driver** is included in the instrument set to facilitate the placement and tightening of the screws. The **Torque Limiting Adapter** should be used when tightening the screws. The locking depth indicator line on the screw driver will provide visual reference for when the screw is engaging the locking threads in the plate *(Figure 9)*.

The aforementioned steps are then repeated for placing each 3.8mm Locking Screw in the proximal portion of the plate.

PREPARING FOR 6.5MM LOCKING SCREWS

Assemble the **6.5mm Screw Guide** onto the plate for preparation of the **6.5mm Locking Screw**. Place the **6.5mm Threaded Drill Guide** through the 6.5mm Screw Guide to lock directly into the plate. A 6.5mm Drill Bit is used and the depth is determined using the color coded drill or the traditional Depth Gauge *(Figure 10)*.

The 6.5mm Threaded Drill Guide is removed and the appropriately sized 6.5mm Locking Screw is inserted. The locking depth indicator line on the T25 screw driver will provide visual reference for when the screw is engaging the locking threads in the plate.

The 6.5mm Locking Screws are provided in lengths between 32mm and 56mm, in 3mm increments *(Table 3)*.

TABLE 3 Color-coded 6.5mm Locking Screws

Diameter (mm)	Length (mm)	Color-code
6.5	32	Blue
	35	
	38	Red
	41	
	44	Green
	47	
	50	Yellow
	53	
	56	Purple

IMPLANTING LOCKING BLADE

A **Blade Osteotome** is provided to penetrate the outer cortex of the humerus. Assemble the 3.8mm Double Screw Guide into the Targeting Jig. The slot in the 3.8mm Double Screw Guide is used as a guide for the Blade Osteotome for insertion into the humerus. Lasermarked lines are used to determine the Osteotome depth and corresponding blade length. The Blade Osteotome can also be used without the Targeting Jig instrumentation.

***Note**: The Blade Osteotome has lasermarked lines on both sides corresponding to "Jig" or "No Jig" (Figure 11).*

The depth and corresponding blade length can also be determined as if placing a locking screw, using the Drill and Drill Guide as shown in *Figure 6.*

The **Locking Blades** are provided in lengths between 25mm and 55mm, in 5mm increments (*Table 4).*

TABLE 4 Blade Length and Thickness

Thickness (mm)	Length (mm)
2	25
	30
	35
	40
	45
	50
	55

The Locking Blade is attached to the Locking Blade Inserter and then impacted into position *(Figure 12)*. Then insert the two Blade Locking Screws, using the Ratcheting Handle and **Screwdriver** *(Figure 13)*.

Note: *The Blade Locking Screws should be tightened down slowly, alternating between each side. The Torque Limiting Adapter should be used when tightening the screws.*

Note: *In some cases, it may be useful to fill the metaphyseal void with Optecure+ccc, calcium phosphate cement or other void filler. The central hole of the plate allows for the insertion of these FDA-cleared products through a syringe (Figure 14). It is recommended that the bone substitutes be delivered under fluoroscopy to verify that none of the product is leaving the fracture site. If electing to do this, do not insert a 6.5mm Locking Screw (See Figure 10). If a bone-void filler is delivered into the central hole, it is recommended this step be carried out after the insertion of distal Screws or Blade/Blade Locking Screws. The* ***Central Hole Funnel, Graft Impactor*** *and* ***Syringe Attachment*** *are provided to assist in deploying these void fillers.*

PLACING DISTAL LOCKING SCREWS

For appropriate placement of the Distal 3.8mm Locking Screws, screw the Threaded 2.8mm or 3.3mm Drill Guide directly to the plate *(Figure 15)*.

Figure 12
Placing Locking Blade

Figure 13
Placing Blade Locking Screws

Figure 14
Filling Voids with Graft (optional)

Figure 15
Preparing Locking Screws

Figure 16
Placing Locking Screws

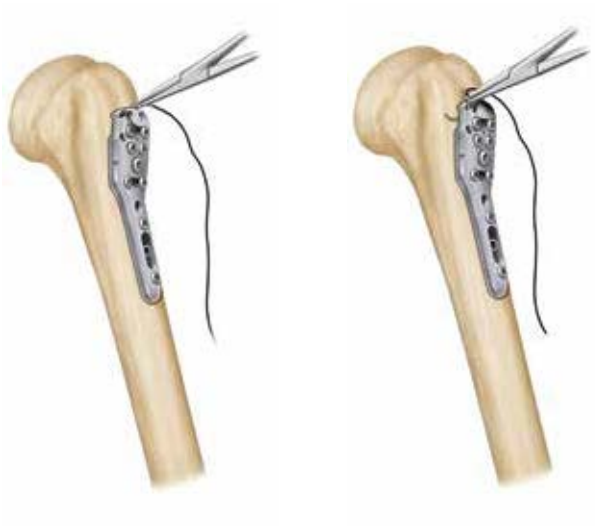


Figure 17
Placing Sutures

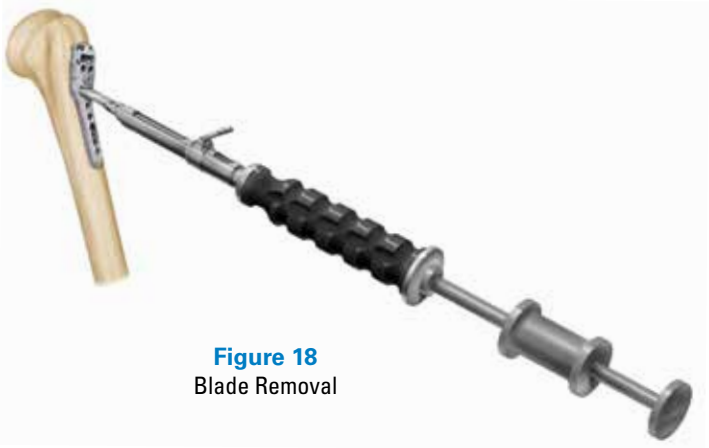


Figure 18
Blade Removal

The 2.8mm or 3.3mm Drill Bit is used and the depth of each hole is determined using the color-coded drill. The Depth Gauge may also be used to accurately verify the screw length. Bicortical fixation is recommended *(Figure 16)*.

APPLYING SUTURES TO Fx PLATE

There are three locations on the plate that will allow sutures to pass through the plate. Heavy braided, non-absorbable sutures are recommended for attaching soft tissue or bony fragments. Sutures may be passed once the plate is fixed to the humerus *(Figure 17)*.

WOUND CLOSURE

The wound is closed in layers over a suction drain with braided non-absorbable sutures to prevent formation of hematoma

POST-OPERATIVE REHABILITATION

Suction drains and antibiotic prophylaxis are maintained for at least 24 hours. Most patients find it more comfortable to sleep with the head of the bed elevated approximately 30 degrees. Shoulder mobilization begins on post-operative day one with passive range of motion allowed to the limits determined at the conclusion of surgical repair. With stable anatomic restoration of the proximal humerus, full range of shoulder motion typically is restored.

Active abduction, forward flexion and rotation are limited until six weeks after surgery when the tuberosities have united. However, active motion at the elbow, wrist and hand is allowed on post-operative day one. Isometric muscle strengthening of the deltoid, biceps and triceps also should be started at this time to avoid pseudosubluxation of the glenohumeral joint. When discharged from the hospital, patients continue their regimen on an outpatient basis.

Patients usually are seen post-operatively at weeks two, four, eight, 12 and 26. Radiographic follow-up includes a shoulder trauma series including scapular AP, scapular lateral and axillary views to assess healing, tuberosity position, fracture settling and the development of osteonecrosis.

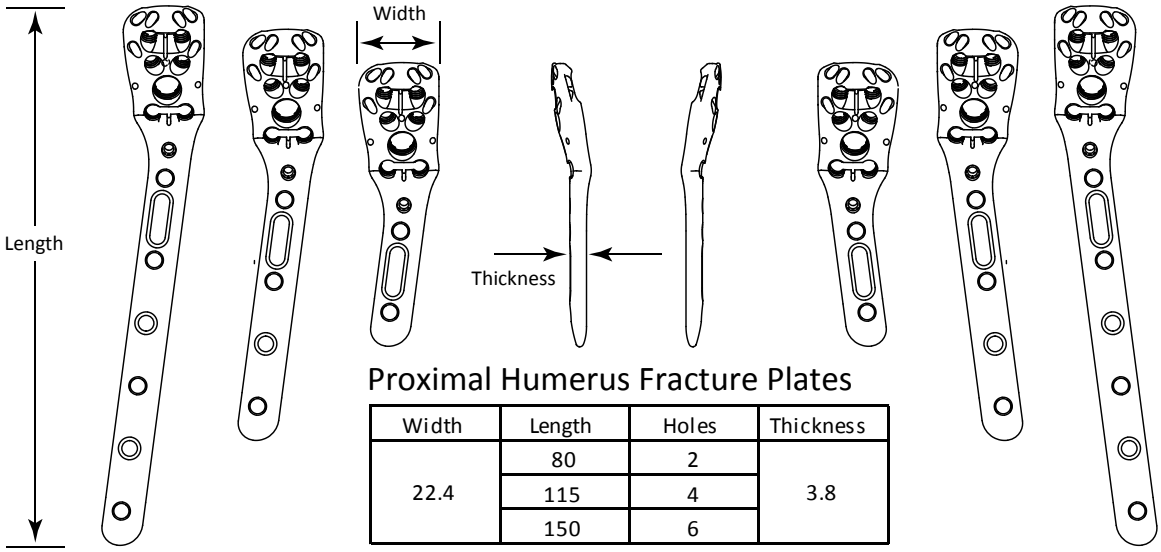
IMPLANT REMOVAL

In the event that the patient must be revised and the implants must be removed, the Ratcheting Handle and Screw Drivers are used. Unlock all of the screws from the plate first before removing them completely from the bone.

To remove the Locking Blade, the screws are removed with the Ratcheting Handle and Screw Driver. The **Blade Inserter** is used to extract the Blade. A slap-hammer may be attached to the Blade Inserter to provide more force if necessary *(Figure 18)*.

SYSTEM SPECIFICATIONS

All dimensions are in millimeters. All implants are 316L stainless steel.

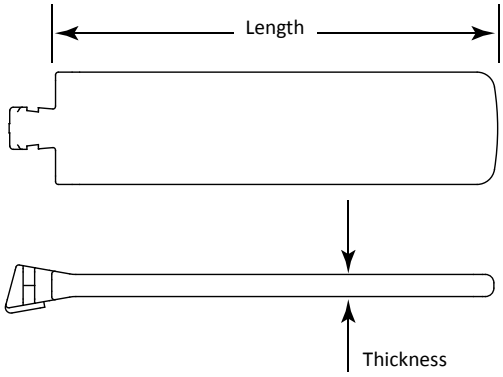


Proximal Humerus Fracture Plates

Width	Length	Holes	Thickness
22.4	80	2	3.8
	115	4	
	150	6	

Humeral Blades

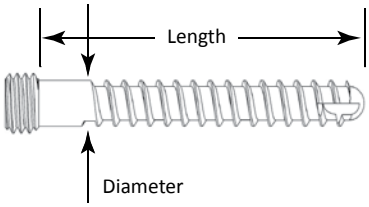
Thickness	Length
2	25
	30
	35
	40
	45
	50
	55



Blade Locking Screw

Locking Screws

Diameter	Length	Color	Diameter	Length	
3.8	20	Black	6.5	32	Blue
	23			35	
	26	Orange		38	Red
	29			41	
	32	Blue		44	Green
	35			47	
	38	Red		50	Yellow
	41			53	
	44	Green		56	Purple
	47				
	50	Yellow			
	53				
	56	Purple			



EQUINOXE IMPLANT SCOPE

Catalog Number	Part Description
Proximal Humerus Fracture Plates	
340-01-01	Fracture Plate, 80mm, Left
340-02-01	Fracture Plate, 80mm, Right
340-01-02	Fracture Plate, 115mm, Left
340-02-02	Fracture Plate, 115mm, Right
340-01-03	Fracture Plate, 150mm, Left
340-02-03	Fracture Plate, 150mm, Right

6.5mm Locking Screws	
340-65-32	6.5mm Locking Screw, 32mm
340-65-35	6.5mm Locking Screw, 35mm
340-65-38	6.5mm Locking Screw, 38mm
340-65-41	6.5mm Locking Screw, 41mm
340-65-44	6.5mm Locking Screw, 44mm
340-65-47	6.5mm Locking Screw, 47mm
340-65-50	6.5mm Locking Screw, 50mm
340-65-53	6.5mm Locking Screw, 53mm
340-65-56	6.5mm Locking Screw, 56mm

3.8mm Locking Screws	
342-38-20	3.8mm Locking Screw, 20mm
342-38-23	3.8mm Locking Screw, 23mm
342-38-26	3.8mm Locking Screw, 26mm
342-38-29	3.8mm Locking Screw, 29mm
342-38-32	3.8mm Locking Screw, 32mm
342-38-35	3.8mm Locking Screw, 35mm
342-38-38	3.8mm Locking Screw, 38mm
342-38-41	3.8mm Locking Screw, 41mm
342-38-44	3.8mm Locking Screw, 44mm
342-38-47	3.8mm Locking Screw, 47mm
342-38-50	3.8mm Locking Screw, 50mm
342-38-53	3.8mm Locking Screw, 53mm
342-38-56	3.8mm Locking Screw, 56mm

EQUINOXE IMPLANT SCOPE

Catalog No.	Part Description
3.8mm Compression Screws	
340-41-20	3.8mm Screw, Compression, 20mm
340-41-23	3.8mm Screw, Compression, 23mm
340-41-26	3.8mm Screw, Compression, 26mm
340-41-29	3.8mm Screw, Compression, 29mm
340-41-32	3.8mm Screw, Compression, 32mm

Locking Humeral Blades	
340-00-25	Humeral Blade, 25mm
340-00-30	Humeral Blade, 30mm
340-00-35	Humeral Blade, 35mm
340-00-40	Humeral Blade, 40mm
340-00-45	Humeral Blade, 45mm
340-00-50	Humeral Blade, 50mm
340-00-55	Humeral Blade, 55mm

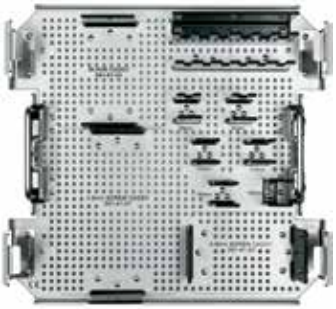
Humeral Blade Locking Screw	
340-00-00	Blade Locking Screw

EQUINOXE Fx PLATE INSTRUMENT LISTING

Catalog No.	Part Description
341-01-00	Torque Limiting Adapter
341-01-01	Targeting Jig Handle
341-15-01	Blade Inserter
341-02-21	Blade Osteotome
341-12-01 341-12-02	Fx Plate Drill Guide Jig, Left Fx Plate Drill Guide Jig, Right
341-12-03 341-12-04	6.5mm Screw Guide, Left 6.5mm Screw Guide, Right
341-01-25	Blade Slap Hammer
341-01-28 341-01-33 341-03-65	2.8mm Drill Bit 3.3mm Drill Bit 6.5mm Drill Bit
341-01-38 341-01-65	T-10 Screw Driver T-25 Screw Driver
341-20-38	T-10 Screw Driver (Fixed Handle)
341-01-40	Screw Depth Gauge (Handle)
341-01-41	Screw Depth Gauge
341-01-70	Central Hole Funnel
341-12-16	K-wire Guide

EQUINOXE INSTRUMENT LISTING

Catalog No.	Part Description	
341-01-71	Syringe Attachment	
341-01-72	Graft Impactor	
341-12-28	Threaded Drill Guide, 2.8mm	
341-12-33	Threaded Drill Guide, 3.3mm	
341-12-65	Threaded Drill Guide, 6.5mm	
341-04-38	Compression Screw Drill Guide	
341-05-38	K-wire Guide Insert, 3.8mm	
341-12-38	3.8mm Screw Guide	
341-12-39	3.8mm Double Screw Guide	
341-07-80	Ratcheting Screw Driver	
341-07-85	Mini AO Handle	
341-35-00	1.6mm x 150mm Kirschner Wire	

Catalog No.	Part Description	
341-41-00	Equinoxe Fracture Implant Tray	
341-41-05	Equinoxe Fracture Plate 3.8mm Screw Caddy	
341-41-02	Equinoxe Fracture Plate 6.5mm Screw Caddy	
341-41-03	Equinoxe Fracture Plate Blade Caddy	

SURGICAL PEARLS

Screws:

- The Shaft 3.8mm Locking Screws are used bi-cortically once the plate is compressed to the shaft.
- The Proximal 3.8 mm and 6.5mm Screws are inserted into the humeral head and are not bi-cortical.
- A soft radius to prevent them from perforating the articulating surface of the humeral head.
- Screws lock to plate via the proximal threaded head.

Blades:

- To guide the osteotome better, it can be helpful to penetrate the cortical bone with a 9mm sagittal saw and/or drill the two holes, as if you were going to use two screws.
- These preparations will allow the osteotome to more readily pass through the cortical bone while preparing the slot for the blade.
- Distal tip has a smooth rounded tip to protect the articular surfaces in the event of head collapse.

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For additional device information, refer to the Exactech Shoulder Proximal Humerus Fracture System–Instructions for Use for a device description, indications, contraindications, precautions and warnings. For further product information, please contact Customer Service, Exactech, Inc., 2320 NW 66th Court, Gainesville, Florida 32653-1630, USA. (352) 377-1140, (800) 392-2832 or FAX (352) 378-2617.

Exactech, as the manufacturer of this device, does not practice medicine, and is not responsible for recommending the appropriate surgical technique for use on a particular patient. These guidelines are intended to be solely informational and each surgeon must evaluate the appropriateness of these guidelines based on his or her personal medical training and experience. Prior to use of this system, the surgeon should refer to the product package insert for comprehensive warnings, precautions, indications for use, contraindications and adverse effects.

 718-05-30 Rev. E 0520

CE 2797 CE Mark is not valid unless there is a CE Mark on the product label.

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