ANTHEM™

Proximal Humerus Fracture System

SURGICAL TECHNIQUE GUIDE

LIFE MOVES US | GLOBUSMEDICAL.COM

GLOBUS MEDICAL

Our mission is to deliver cutting-edge technology, research, and innovative solutions to promote healing in patients with musculoskeletal disorders.

Life Moves Us

SURGICAL TECHNIQUE GUIDE

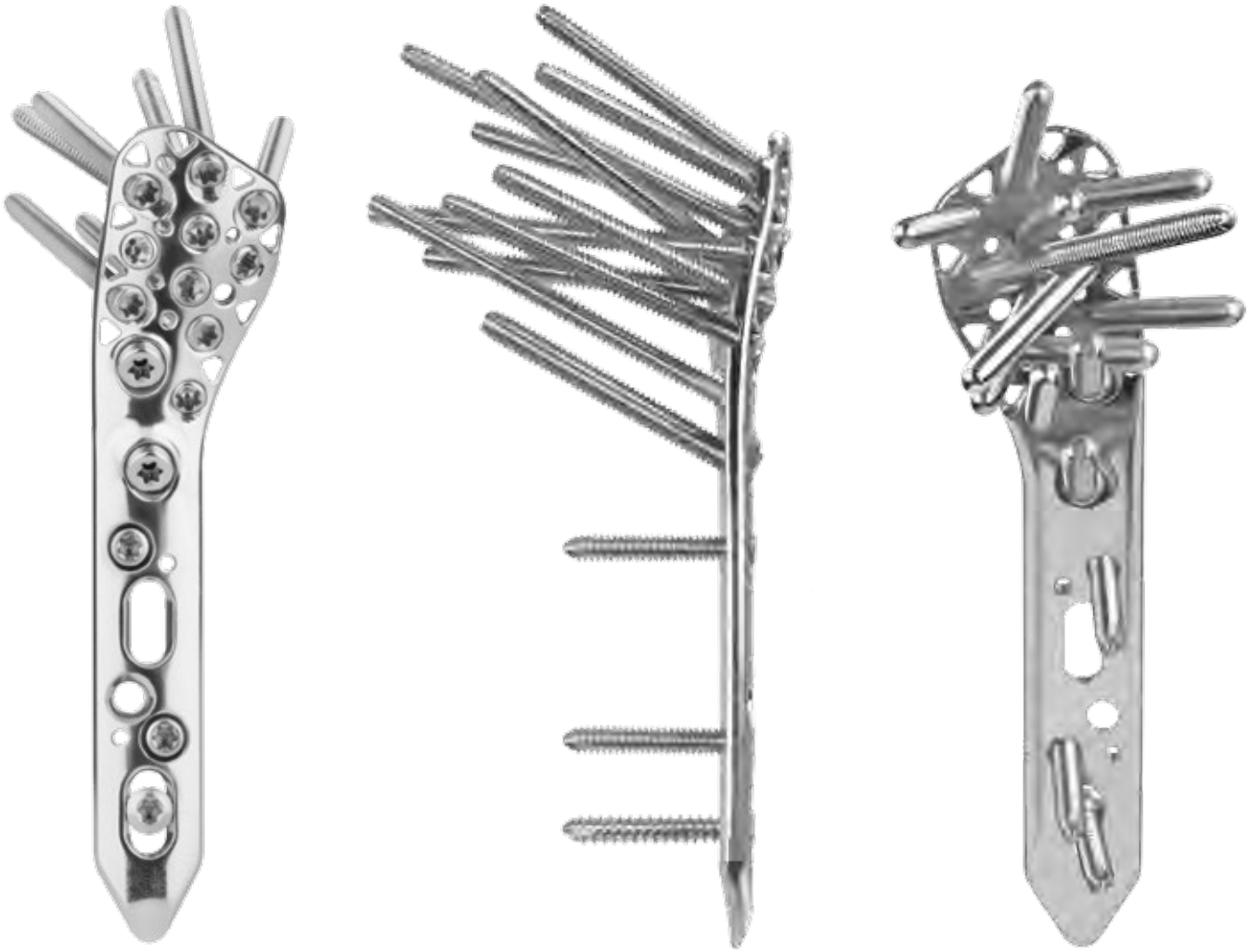
ANTHEM™

Proximal Humerus Fracture System

ANTHEM™

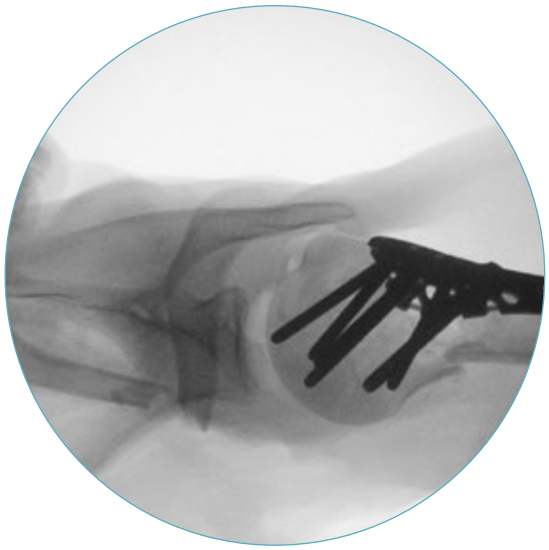
Proximal Humerus Fracture System

The ANTHEM™ Proximal Humerus Fracture System features polyaxial technology to provide intraoperative versatility and address complications commonly associated with proximal humerus fractures.



Anatomic Contour

The plate is contoured to sit low to avoid acromial impingement. Polyaxial locking calcar screws provide ideal bone purchase following optimal plate placement to minimize the risk of varus collapse.

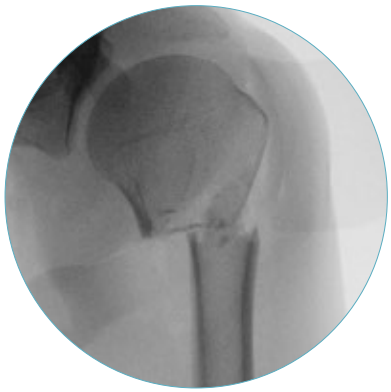


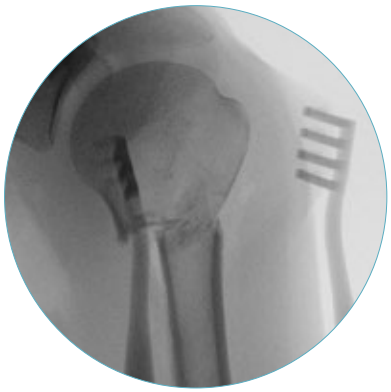
Multiple Calcar Screw Solutions

The system features two polyaxial locking calcar screws that allow for ±20° cone of angulation and one fixed angle calcar screw with an optimized shaft-head inclination angle. Cannulated screws are available to enable higher precision in placement.

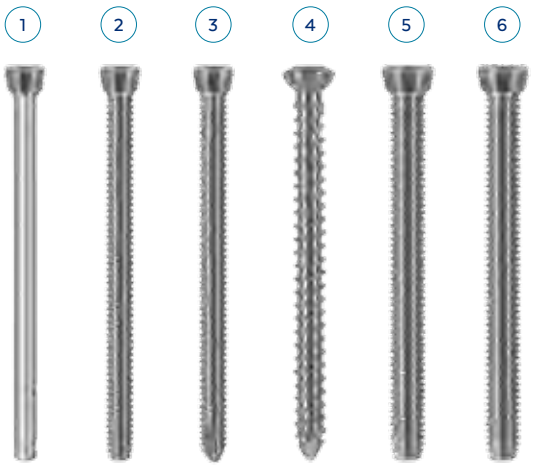
Unique Instruments

Radiolucent retractors aid in visibility of the fracture site.





IMPLANT OVERVIEW



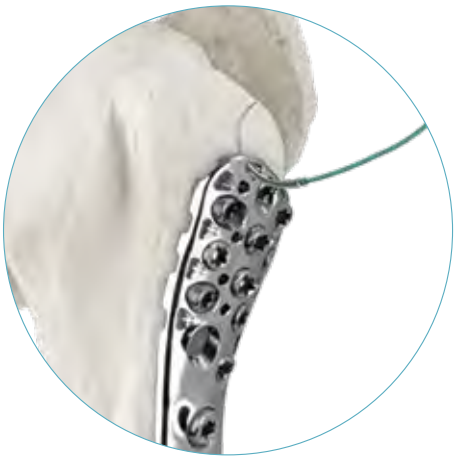
Screw Design

- Locking screws, non-locking screws, and locking pegs
- Polyaxial locking calcar screws
- Cannulated 4.0mm Locking Screws

1. 2.7mm Locking Peg
2. 3.5mm Locking Screw, Blunt Tip
3. 3.5mm Locking Screw, Cutting Flutes
4. 3.5mm Non-Locking Screw
5. 4.0mm Locking Screw
6. 4.0mm Cannulated Locking Screw

Calcar Fixation

- Polyaxial locking screws allow for ±20° cone of angulation
  - Allows for screw removal up to four times
- Two polyaxial calcar screw holes
- One fixed angle calcar screw hole



Suture Fixation

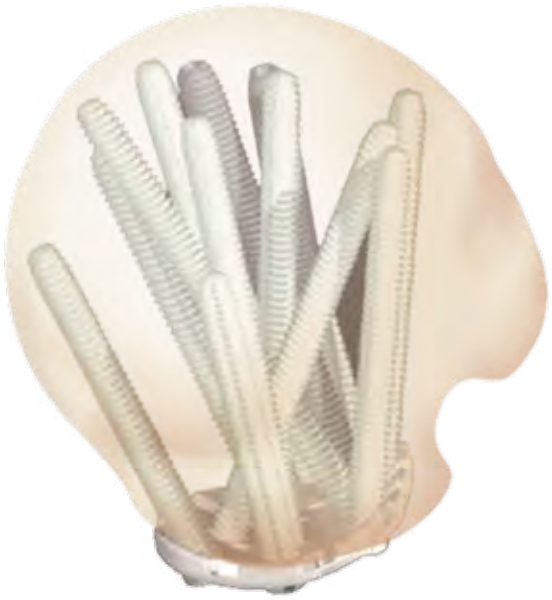
- Unique triangular suture holes for convenient suturing after securing the plate to the bone

Plate Design

- Low profile to minimize impingement
- Optimally contoured to proximal humerus anatomy, wrapping posteriorly to buttress the greater tuberosity
- Scalloped undercuts to limit periosteal damage and aid in plate bending
- Available in stainless steel and titanium

Screw Trajectories

- Nine fixed angle locking screws in the head of the plate form divergent and convergent patterns to maximize plate fixation



SURGICAL TECHNIQUE

ANTHEM™

Proximal Humerus Fracture System

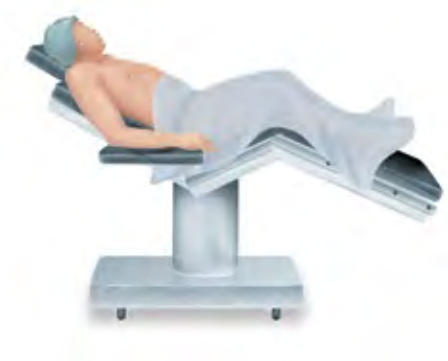
Refer to the package insert (also printed in the back of this manual) for important information on the intended use/ indications, device description, contraindications, precautions, warnings, and potential risks associated with this system.

STEP 1 PREOPERATIVE PLANNING

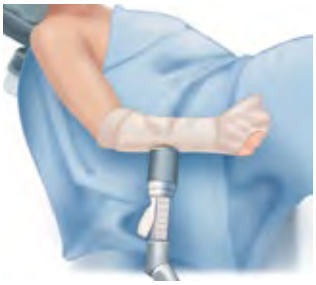
Assess the fracture using preoperative radiographs. Estimate the appropriate length and location of screws to ensure proper plate type, plate position, and screw placement.

STEP 2 PATIENT POSITIONING

The patient is positioned in the beach chair or supine position. For beach chair positioning, an articulating device may be used to position the arm during fixation. A bolster may be used for supine positioning to lift the patient's shoulder. Using fluoroscopy, examine the fracture.



Beach chair positioning

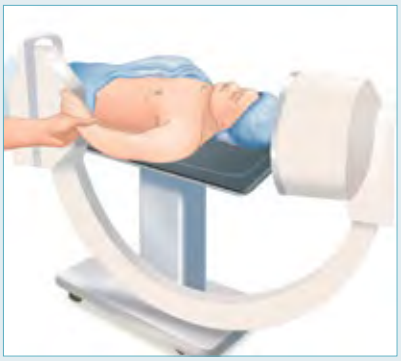


Articulating device

Supine positioning

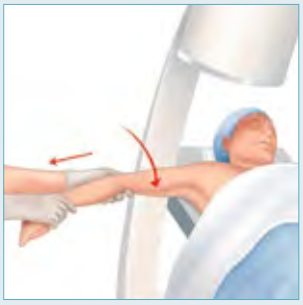
INTRAOPERATIVE IMAGING

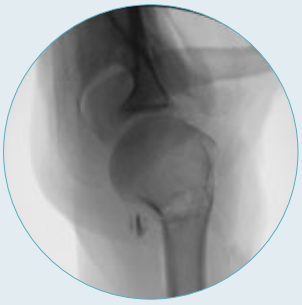
To avoid interference with the C-arm in the supine position, the patient's arm should be positioned at the edge of the table supported on a hand board or Mayo stand to allow for standard axillary imaging. Before prepping and draping, check positioning to verify that intraoperative fluoroscopy can be used to visualize the surgical site. Some suggestions for positioning are shown below.



Velpeau Axillary View

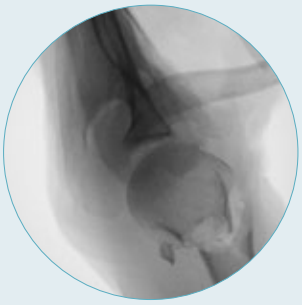
The arm is held in internal rotation and slight longitudinal traction. Gentle traction lateralizes the scapula away from the operating table and the patient's head, allowing an unobstructed image of the proximal humerus and glenoid.





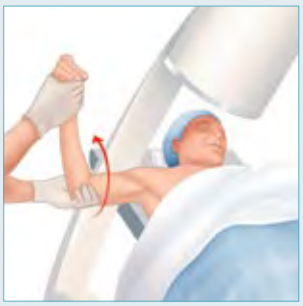
Standard Axillary View

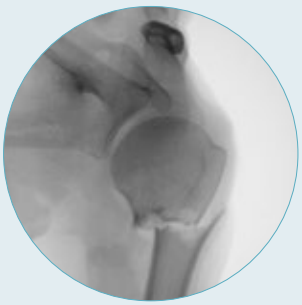
The arm is held in neutral rotation and longitudinal traction. This view shows the position of the lesser tuberosity and the relationship of the humeral head to the glenoid anteroposterior.



AP External Rotation View

The C-arm should be positioned perpendicular to the scapula with the patient's arm in external rotation. This view makes the relationship between the humeral shaft, humeral head, and greater tuberosity apparent.



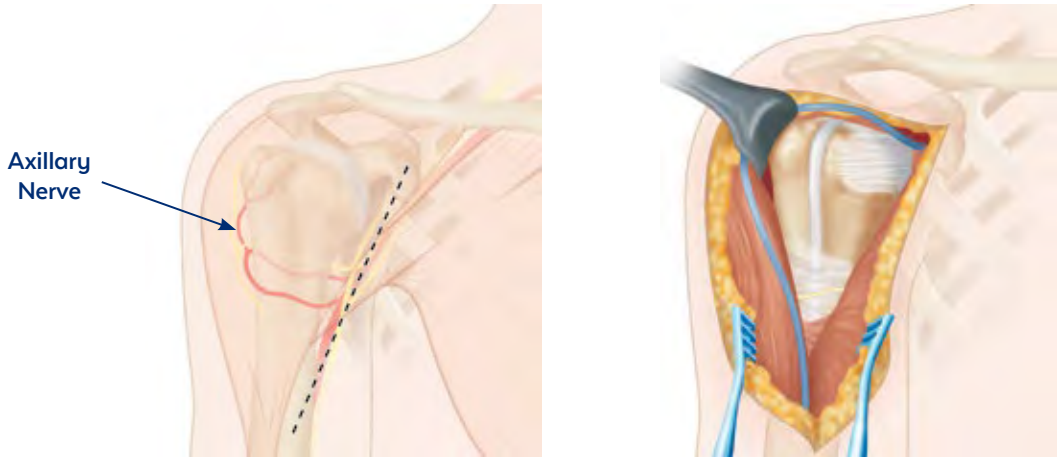


STEP 3 SURGICAL APPROACH

A deltopectoral or a deltoid split approach may be used for the treatment of proximal humerus fractures.

Deltopectoral Approach

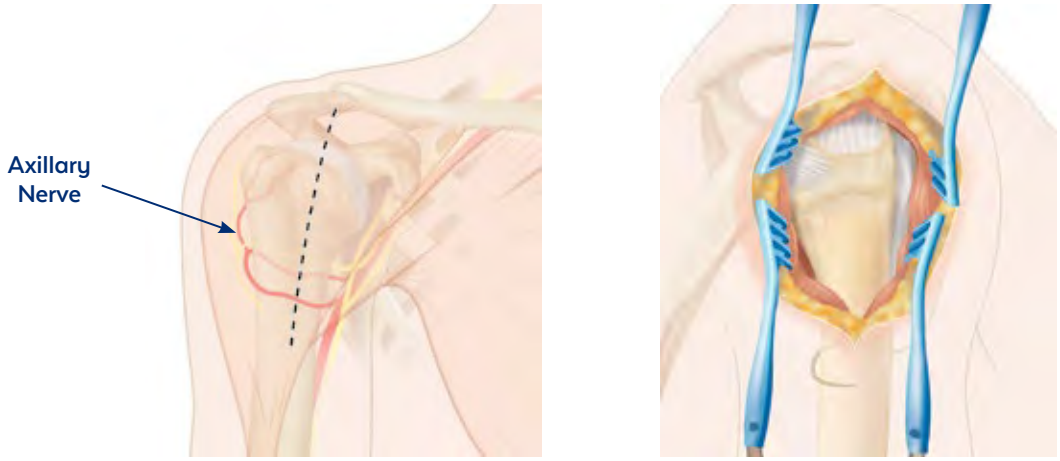
Create an incision starting at the coracoid process extending to the humerus at the level of the deltoid tuberosity. Identify and retract the cephalic vein. Incise the pectoralis fascia lateral to the short head tendon of the biceps brachii muscle, maintaining the coracoacromial ligament proximally and incising the upper border of the pectoralis major muscle insertion by 1-2cm. Avoid damage to the axillary nerve.



Deltopectoral incision and approach

Deltoid Split Approach

Create an incision from the lateral border of the acromion extending distally up to 5cm, parallel to the axis of the humerus. Expose the middle third of the deltoid muscle. Split the deltoid muscle between its fibers. To avoid damage to the axillary nerve, do not split the deltoid muscle more than 5cm distally from its origin.



Deltoid split incision and approach

Placing a suture in the deltoid may help prevent further splitting beyond 5cm.

STEP 4 FRACTURE REDUCTION

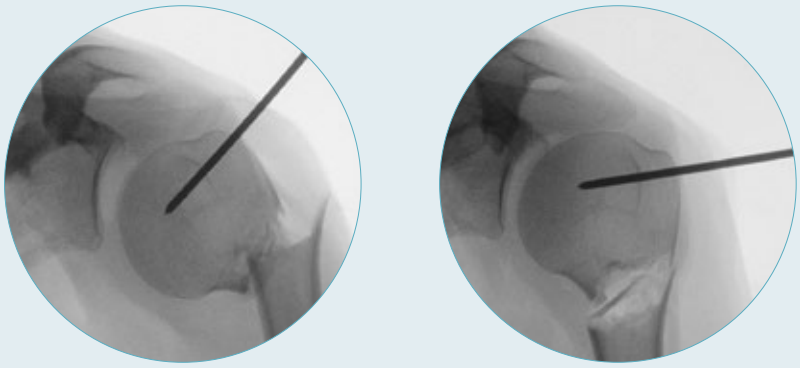
Identify the fracture fragments. If present, evacuate any hematoma.

The fracture may be reduced and provisionally fixed using K-wires, reduction forceps, and/or suture fixation. Reduction instruments should be placed to avoid interference with final plate placement.

Confirm reduction using fluoroscopy. The plate is placed on the greater tuberosity after reduction. Distal extension of the fracture and the use of longer plates may require detachment of the anterior half of the distal deltoid muscle insertion.

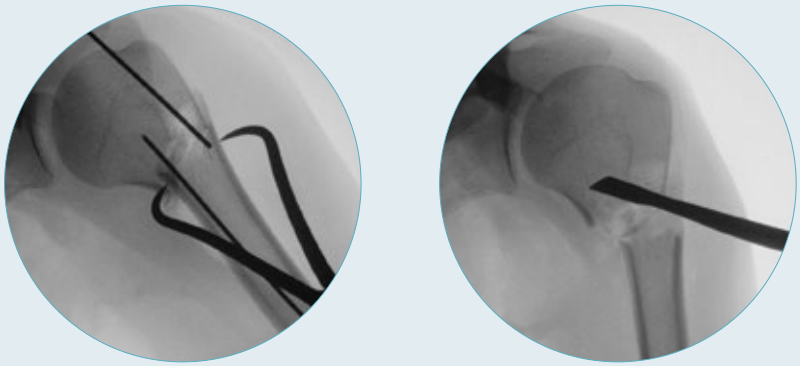
SUGGESTIONS

A K-wire may be placed in the proximal segment to serve as a reduction "joystick."



K-wire used as reduction "joystick"

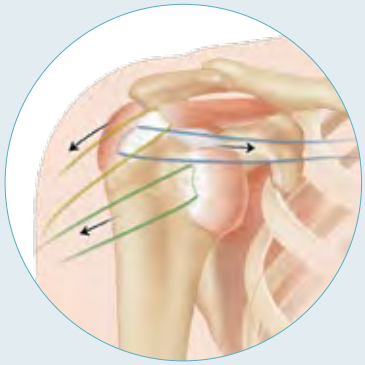
A periosteal elevator may be used to eliminate varus.



Provisional fixation with K-wires

Periosteal elevator to eliminate varus

Sutures in the rotator cuff tendon insertions may be used to aid manipulation and reduction of the fracture. Traction on the sutures helps to achieve reduction. When tied, the sutures bring fragments together for stability.



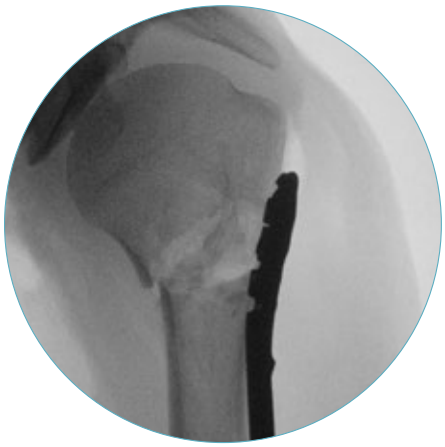
Suture reduction

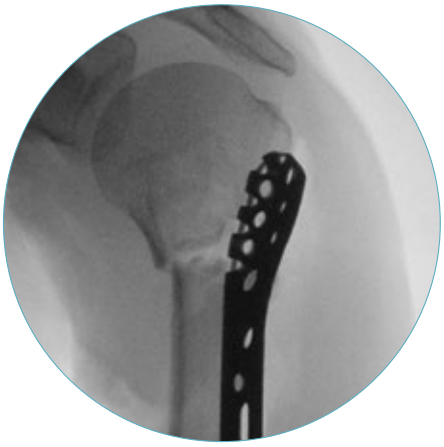
STEP 5 PLATE POSITIONING

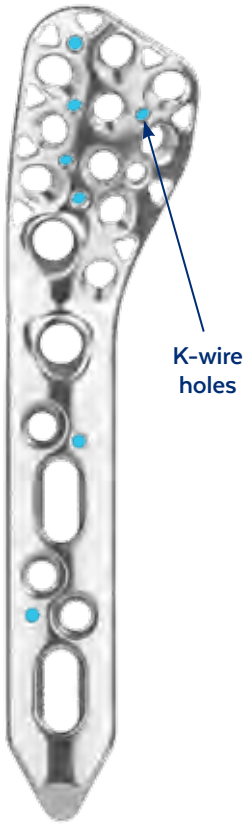
Select the plate size that best accommodates patient anatomy and fracture pattern.

To reduce the risk of subacromial impingement, position the plate at least 3cm distal to the superior border of the greater tuberosity and ensure it does not impinge. The anterior border of the plate should be immediately posterior to the bicipital groove.

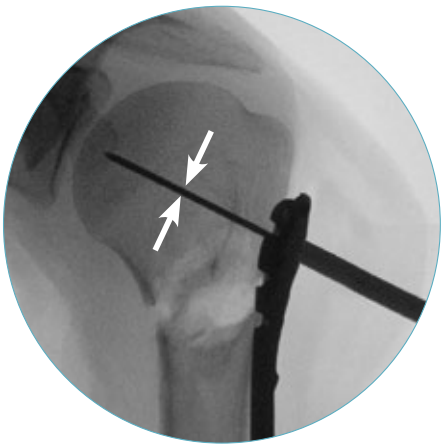
Confirm plate placement using fluoroscopy or palpation of the plate relative to bony structures. The biceps tendon and the ascending branch of the anterior humeral circumflex artery are at risk if the plate is positioned too close to the bicipital groove. K-wires can be used to preliminarily fix the plate to the bone for provisional placement.







For optimal screw placement, place a K-wire through the central hole of the plate. Using AP and axial fluoroscopy, confirm plate position by centering the K-wire in the humeral head.



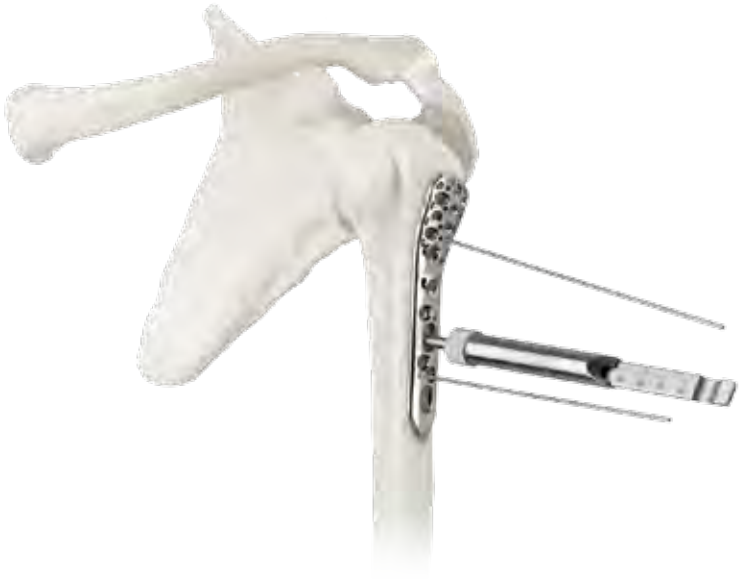
STEP 6 SCREW INSERTION

Plate Shaft Screws

For non-locking screws, use the **2.7mm Drill Bit** and **3.5mm Soft Tissue Protector**.

For locking screws, use the 2.7mm Drill Bit and **2.7mm Threaded Drill Guide**.
Drill the desired screw hole to the appropriate depth.

Measure screw length using the **Depth Gauge**.



SCREW INSERTION (CONT'D)

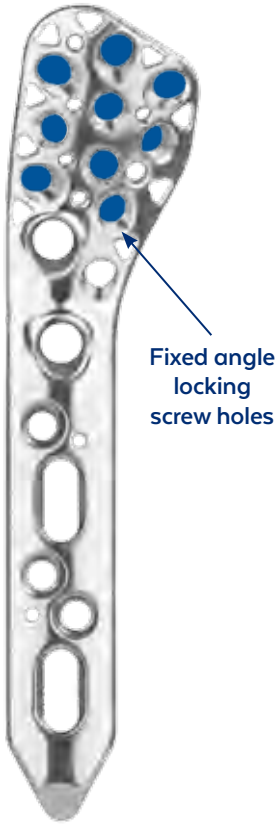
Use the **T15 Driver** or **Screw Holding Forceps** to select the desired screw. Verify screw length and diameter using the gauges within the screw module. Using the T15 Driver, insert the screw into a shaft hole.

Screws may be inserted using the **Quick Connect Handle** or under power. Repeat for all desired shaft holes. Use the elongated slot in the plate for provisional fixation. If necessary, the slot allows for repositioning.

Screw insertion -
Plate Shaft Screw

Plate Head Screws

The **2.7mm Threaded Drill Guide** may be used to facilitate drilling and insertion of proximal locking screws in the head of the plate.

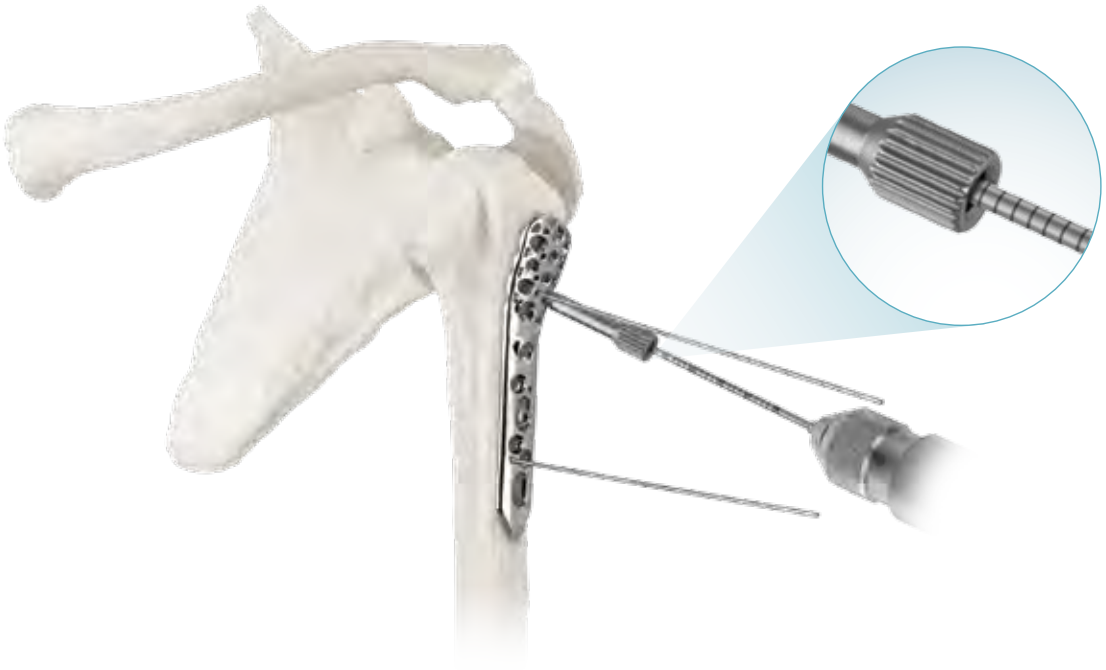


2.7mm Threaded Drill Guide

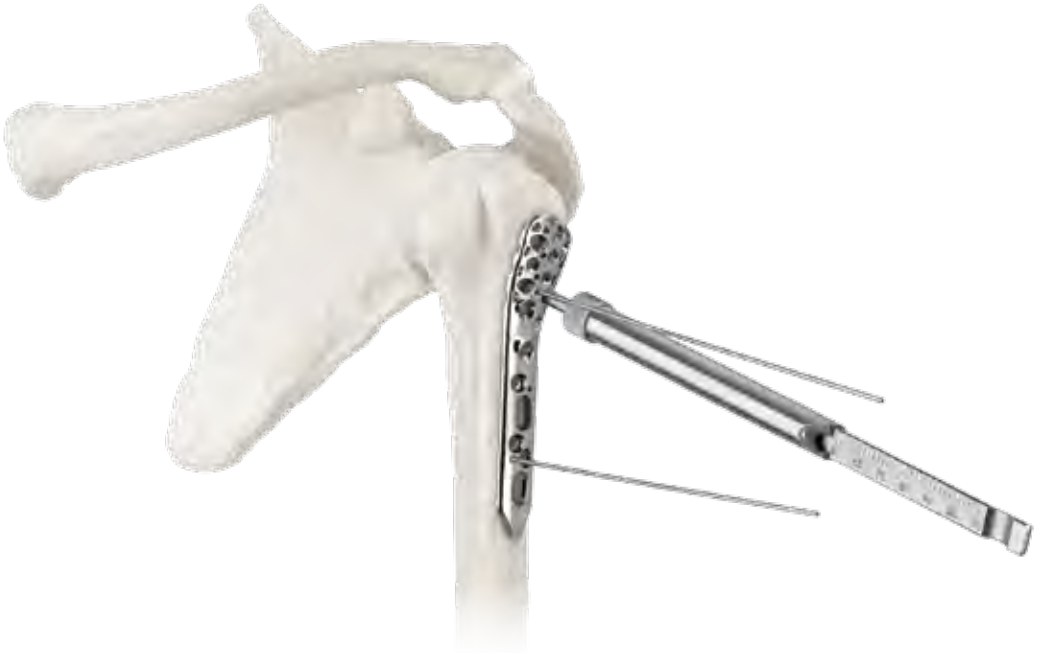
SCREW INSERTION (CONT'D)

Using the 2.7mm Threaded Drill Guide

Secure the 2.7mm Threaded Drill Guide to the plate by threading it into the desired locking screw hole. Insert the 2.7mm Drill Bit into the drill guide and drill the desired screw hole to the appropriate depth.

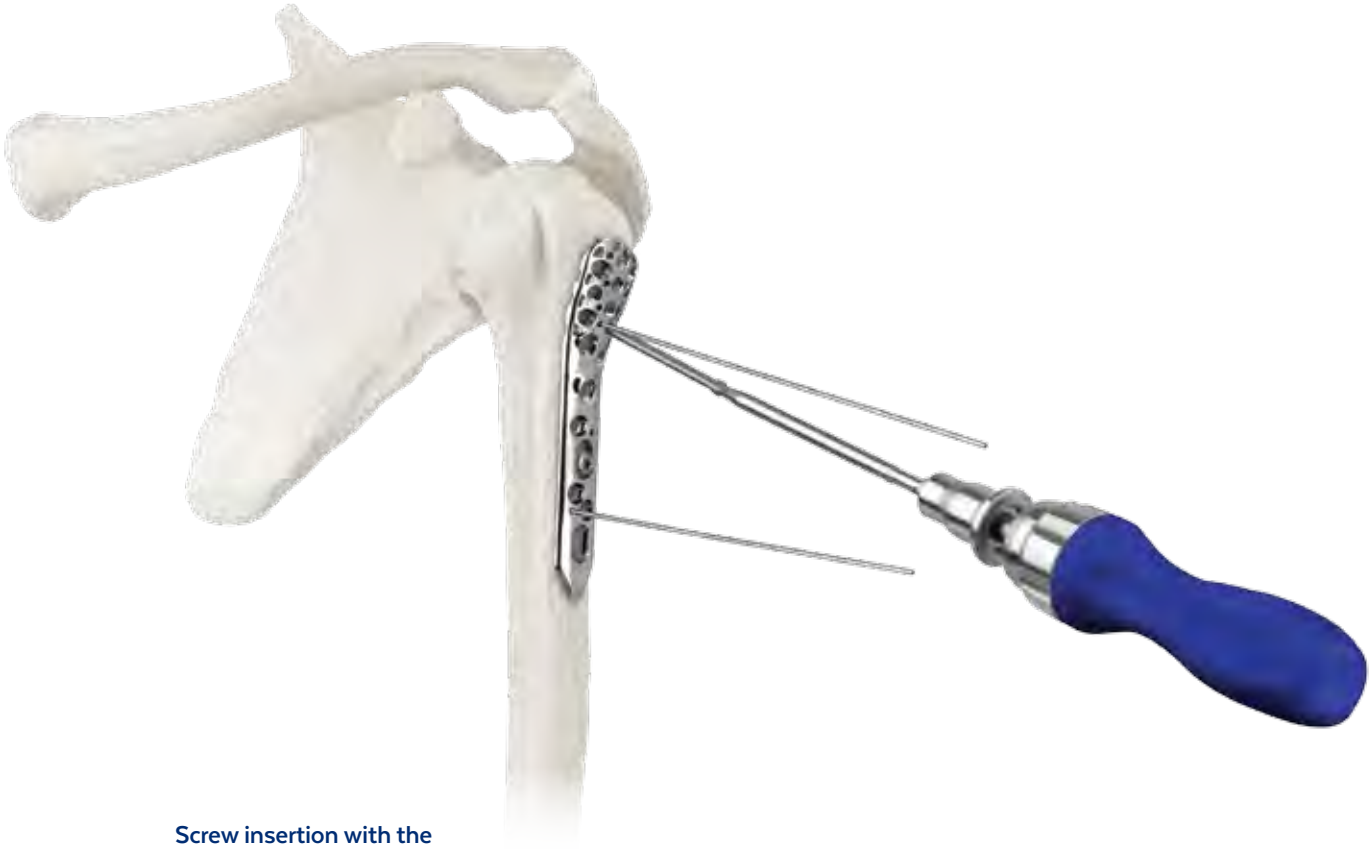


Measure hole depth using the calibrations on the Drill Bit or remove the drill guide and insert the Depth Gauge into the hole.



Use the T15 Driver or Screw Holding Forceps to select the desired screw. Verify screw length and diameter using the gauges within the screw module. Using the T15 Driver, insert the appropriate length screw through the screw hole. Screws may be inserted manually with the Quick Connect Handle or under power. If desired, use the **1.5Nm Torque Limiting Attachment** to ensure adequate final tightening torque.

Place the desired number of screws (typically 5) into the humeral head. The number of screws is determined by the fracture pattern, morphology, and bone quality. In osteoporotic bone, more screws may be required.



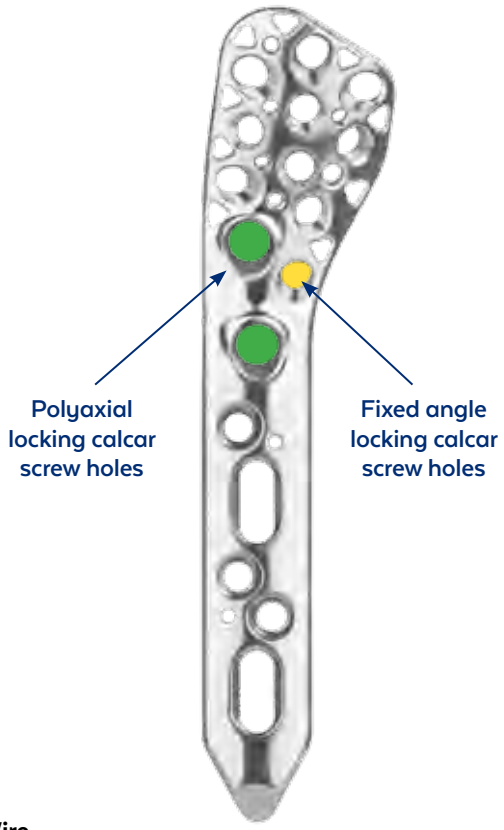
Screw insertion with the 2.7mm Threaded Drill Guide

SCREW INSERTION (CONT'D)

Calcar Screws

The plate accepts two polyaxial locking calcar screws and one fixed angle locking calcar screw. Polyaxial locking holes accept 4.0mm Locking Screws and 4.0mm Cannulated Locking Screws. The fixed angle calcar hole accepts a 3.5mm Locking Screw.

Do not use screw lengths that may penetrate the joint. Screws of appropriate length should stop approximately 5-8mm from the articular surface. If screws are inserted under power, final tightening should be performed manually. Cannulated or non-cannulated screws may be used.



Cannulated Calcar Screws

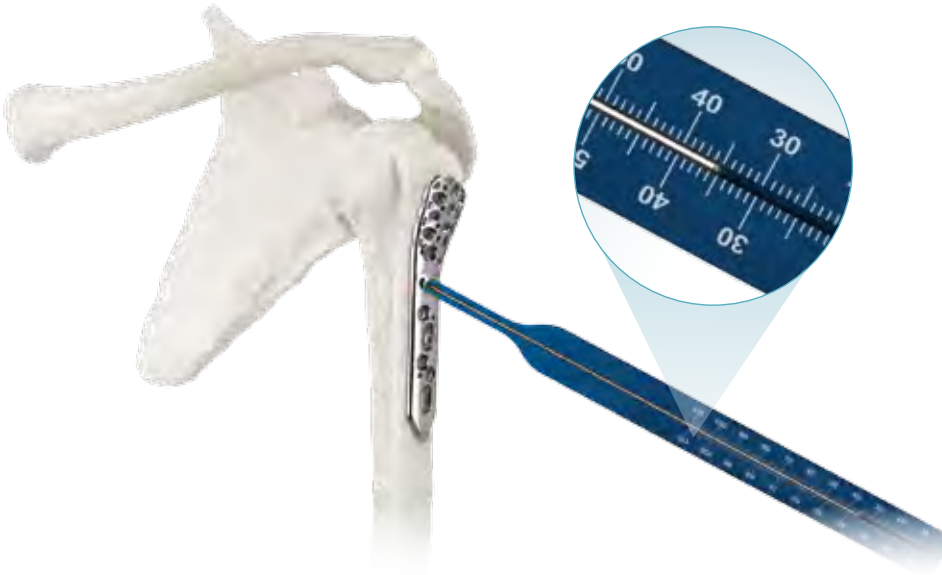
For nominal screw angulation, use the "nominal" side of the **1.6mm K-Wire Polyaxial Guide**. For polyaxial angulation, use the "polyaxial" side of the guide. Insert the **1.6mm K-Wire** through the desired side of the guide. Confirm K-wire position and depth using fluoroscopy.

Nominal trajectory

Polyaxial trajectory

Use the **3.2mm Cannulated Drill Bit** to drill over the K-wire to the desired depth. Confirm drill position and depth using fluoroscopy.

Measure hole depth by inserting the **Direct Measuring Device** over the K-wire and seat flush against the plate.



Use the **Cannulated T15 Driver** or Screw Holding Forceps to select the desired screw. Verify screw length and diameter using gauges within the screw module. Using the driver, insert the screw over the K-wire and through the screw hole. Screws may be inserted using the **2.5Nm Torque Limiting Quick Connect Handle** or under power. If screws are insterted under power, perform final tightening manually.

Screw insertion - Cannulated Calcar Screw

SCREW INSERTION (CONT'D)

Non-Cannulated Calcar Screws

For nominal screw angulation, use the "nominal" side of the **3.2mm Polyaxial Drill Guide**. For polyaxial angulation, use the "polyaxial" side of the drill guide. Insert the **3.2mm Drill Bit** into the desired side of the drill guide and drill the screw hole to the desired depth.

Nominal trajectory

Polyaxial trajectory

Remove the drill guide. Insert the Depth Gauge into the screw hole and measure depth.

Use the T15 Driver or Screw Holding Forceps to select the desired screw. Verify screw length and diameter using the gauges within the screw module. Using the T15 Driver, insert the screw through the screw hole. Screws may be inserted with the 2.5Nm Torque Limiting Quick Connect Handle or under power. If screws are inserted under power, the final tightening should be performed manually.

Screw insertion -
Non-Cannulated Calcar Screw

SCREW INSERTION (CONT'D)

Fixed Angle Calcar Screws

Thread the 2.7mm Threaded Drill Guide into the fixed angle calcar screw hole. Insert the 2.7mm Drill Bit into the drill guide and drill to the desired depth.

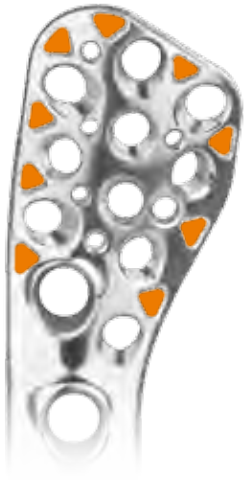
Measure hole depth by the calibrations on the Drill Bit or remove the drill guide and insert the Depth Gauge.

Use the T15 Driver or Screw Holding Forceps to select the desired screw. Verify screw length and diameter using the gauges within the screw module. Using the T15 driver, insert the appropriate length screw through the screw hole. Screws may be inserted with the Quick Connect Handle or manual tightening.

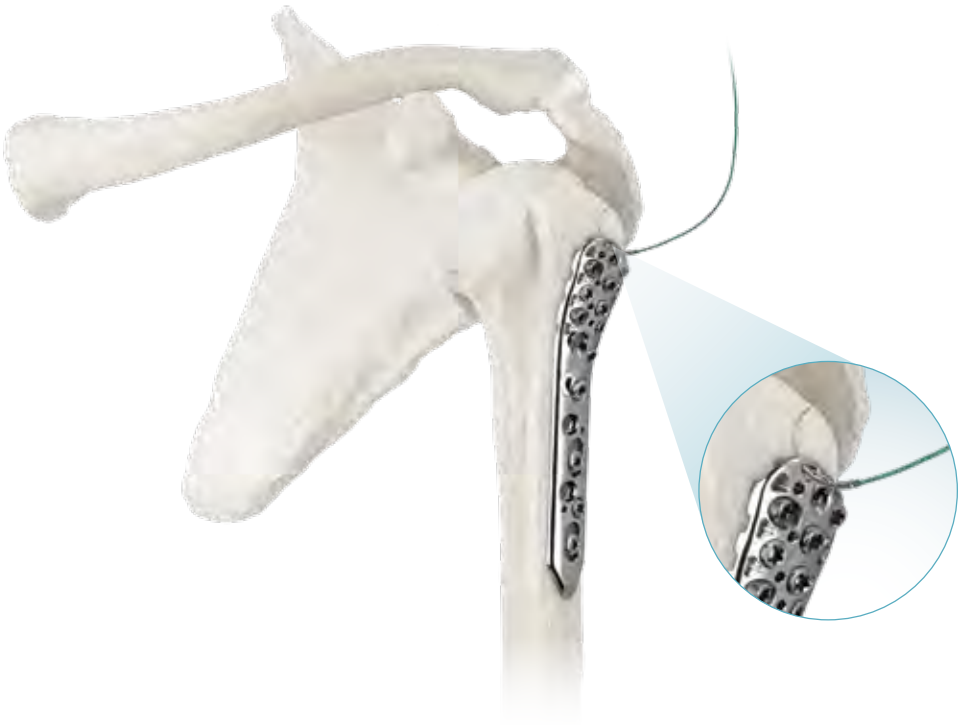
Screw insertion -
Fixed Angle Calcar Screw

STEP 7 SUTURE ATTACHMENT

Sutures may be placed through designated suture holes in the plate.



Suture holes located around the perimeter of the plate



STEP 8 VERIFY PLACEMENT

Using fluoroscopy, direct visualization, and palpation, check for correct reduction and fixation at various arm positions. Ensure that screw tips are not intra-articular. Check plate and screw placement in all planes as angulation and direction may be difficult to visualize.

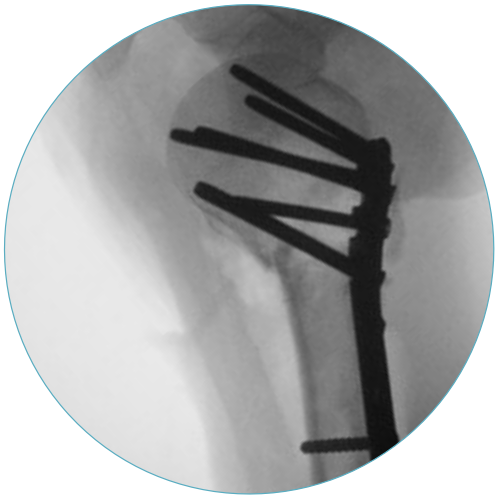


Plate and screw placement

FINAL CONSTRUCT

ANTHEM™ Proximal Humerus Plate

OPTIONAL: REMOVAL

If removal is required, detach the sutures from the construct. Use the T15 Driver to unlock the locking screws from the plate but do not remove. This prevents simultaneous rotation of the plate during removal. Once all locking screws are unlocked, remove all remaining screws from the plate using the T15 Driver. Once all screws are removed, the plate may be removed.

Straight drivers are recommended for removal.

ANTHEM™ SS Proximal Humerus
IMPLANTS 9168.9002

PART NO.	DESCRIPTION	QTY
2168.1088	ANTHEM™ Proximal Humerus Plate, Left, 88mm, SS	2
2168.1103	ANTHEM™ Proximal Humerus Plate, Left, 103mm, SS	2
2168.1135	ANTHEM™ Proximal Humerus Plate, Left, 135mm, SS	1
2168.1165	ANTHEM™ Proximal Humerus Plate, Left, 165mm, SS	1
2168.1195	ANTHEM™ Proximal Humerus Plate, Left, 195mm, SS	1
2168.1225	ANTHEM™ Proximal Humerus Plate, Left, 225mm, SS	1
2168.1255	ANTHEM™ Proximal Humerus Plate, Left, 255mm, SS	1
2168.1285	ANTHEM™ Proximal Humerus Plate, Left, 285mm, SS	1
2168.1315	ANTHEM™ Proximal Humerus Plate, Left, 315mm, SS	1
2168.2088	ANTHEM™ Proximal Humerus Plate, Right, 88mm, SS	2
2168.2103	ANTHEM™ Proximal Humerus Plate, Right, 103mm, SS	2
2168.2135	ANTHEM™ Proximal Humerus Plate, Right, 135mm, SS	1
2168.2165	ANTHEM™ Proximal Humerus Plate, Right, 165mm, SS	1
2168.2195	ANTHEM™ Proximal Humerus Plate, Right, 195mm, SS	1
2168.2225	ANTHEM™ Proximal Humerus Plate, Right, 225mm, SS	1
2168.2255	ANTHEM™ Proximal Humerus Plate, Right, 255mm, SS	1
2168.2285	ANTHEM™ Proximal Humerus Plate, Right, 285mm, SS	1
2168.2315	ANTHEM™ Proximal Humerus Plate, Right, 315mm, SS	1

ANTHEM™ SS Proximal Humerus
IMPLANTS 9168.9002 (cont'd)

PART NO.	DESCRIPTION	QTY
2168.3036	Locking Peg, 2.7x36mm, SS	6
2168.3038	Locking Peg, 2.7x38mm, SS	6
2168.3040	Locking Peg, 2.7x40mm, SS	6
2168.3045	Locking Peg, 2.7x45mm, SS	6
2168.3050	Locking Peg, 2.7x50mm, SS	6
2168.3055	Locking Peg, 2.7x55mm, SS	6
2168.3060	Locking Peg, 2.7x60mm, SS	6
2168.6014	Locking Screw, 3.5x14mm, Blunt Tip, SS	6
2168.6016	Locking Screw, 3.5x16mm, Blunt Tip, SS	6
2168.6018	Locking Screw, 3.5x18mm, Blunt Tip, SS	6
2168.6020	Locking Screw, 3.5x20mm, Blunt Tip, SS	6
2168.6022	Locking Screw, 3.5x22mm, Blunt Tip, SS	6
2168.6024	Locking Screw, 3.5x24mm, Blunt Tip, SS	6
2168.6026	Locking Screw, 3.5x26mm, Blunt Tip, SS	6
2168.6028	Locking Screw, 3.5x28mm, Blunt Tip, SS	6
2168.6030	Locking Screw, 3.5x30mm, Blunt Tip, SS	6
2168.6032	Locking Screw, 3.5x32mm, Blunt Tip, SS	6
2168.6034	Locking Screw, 3.5x34mm, Blunt Tip, SS	6
2168.6036	Locking Screw, 3.5x36mm, Blunt Tip, SS	6
2168.6038	Locking Screw, 3.5x38mm, Blunt Tip, SS	6
2168.6040	Locking Screw, 3.5x40mm, Blunt Tip, SS	6
2168.6045	Locking Screw, 3.5x45mm, Blunt Tip, SS	6
2168.6050	Locking Screw, 3.5x50mm, Blunt Tip, SS	6
2168.6055	Locking Screw, 3.5x55mm, Blunt Tip, SS	6
2168.6060	Locking Screw, 3.5x60mm, Blunt Tip, SS	6
2179.5014	Locking Screw, 3.5x14mm, Cutting Flutes, SS	6
2179.5016	Locking Screw, 3.5x16mm, Cutting Flutes, SS	6
2179.5018	Locking Screw, 3.5x18mm, Cutting Flutes, SS	6
2179.5020	Locking Screw, 3.5x20mm, Cutting Flutes, SS	6
2179.5022	Locking Screw, 3.5x22mm, Cutting Flutes, SS	6
2179.5024	Locking Screw, 3.5x24mm, Cutting Flutes, SS	6
2179.5026	Locking Screw, 3.5x26mm, Cutting Flutes, SS	6
2179.5028	Locking Screw, 3.5x28mm, Cutting Flutes, SS	6
2179.5030	Locking Screw, 3.5x30mm, Cutting Flutes, SS	6
2179.5032	Locking Screw, 3.5x32mm, Cutting Flutes, SS	6
2179.5034	Locking Screw, 3.5x34mm, Cutting Flutes, SS	6
2179.5036	Locking Screw, 3.5x36mm, Cutting Flutes, SS	6

PART NO.	DESCRIPTION	QTY
2179.3014	Non-Locking Screw, 3.5x14mm, SS	6
2179.3016	Non-Locking Screw, 3.5x16mm, SS	6
2179.3018	Non-Locking Screw, 3.5x18mm, SS	6
2179.3020	Non-Locking Screw, 3.5x20mm, SS	6
2179.3022	Non-Locking Screw, 3.5x22mm, SS	6
2179.3024	Non-Locking Screw, 3.5x24mm, SS	6
2179.3026	Non-Locking Screw, 3.5x26mm, SS	6
2179.3028	Non-Locking Screw, 3.5x28mm, SS	6
2179.3030	Non-Locking Screw, 3.5x30mm, SS	6
2179.3032	Non-Locking Screw, 3.5x32mm, SS	6
2179.3034	Non-Locking Screw, 3.5x34mm, SS	6
2179.3036	Non-Locking Screw, 3.5x36mm, SS	6
2179.3038	Non-Locking Screw, 3.5x38mm, SS	6
2179.3040	Non-Locking Screw, 3.5x40mm, SS	6
7168.4020	Locking Screw, 4.0x20mm, CoCr	3
7168.4025	Locking Screw, 4.0x25mm, CoCr	3
7168.4030	Locking Screw, 4.0x30mm, CoCr	3
7168.4035	Locking Screw, 4.0x35mm, CoCr	3
7168.4040	Locking Screw, 4.0x40mm, CoCr	3
7168.4045	Locking Screw, 4.0x45mm, CoCr	3
7168.4050	Locking Screw, 4.0x50mm, CoCr	3
7168.4055	Locking Screw, 4.0x55mm, CoCr	3
7168.4060	Locking Screw, 4.0x60mm, CoCr	3
7168.4065	Locking Screw, 4.0x65mm, CoCr	3
7168.4070	Locking Screw, 4.0x70mm, CoCr	3
7168.5020	Cannulated Locking Screw, 4.0x20mm, CoCr	3
7168.5025	Cannulated Locking Screw, 4.0x25mm, CoCr	3
7168.5030	Cannulated Locking Screw, 4.0x30mm, CoCr	3
7168.5035	Cannulated Locking Screw, 4.0x35mm, CoCr	3
7168.5040	Cannulated Locking Screw, 4.0x40mm, CoCr	3
7168.5045	Cannulated Locking Screw, 4.0x45mm, CoCr	3
7168.5050	Cannulated Locking Screw, 4.0x50mm, CoCr	3
7168.5055	Cannulated Locking Screw, 4.0x55mm, CoCr	3
7168.5060	Cannulated Locking Screw, 4.0x60mm, CoCr	3
7168.5065	Cannulated Locking Screw, 4.0x65mm, CoCr	3
7168.5070	Cannulated Locking Screw, 4.0x70mm, CoCr	3

ANTHEM™ Ti Proximal Humerus
IMPLANTS 9168.9001

PART NO.	DESCRIPTION	QTY
1168.1088	ANTHEM™ Proximal Humerus Plate, Left, 88mm, Ti	2
1168.1103	ANTHEM™ Proximal Humerus Plate, Left, 103mm, Ti	2
1168.1135	ANTHEM™ Proximal Humerus Plate, Left, 135mm, Ti	1
1168.1165	ANTHEM™ Proximal Humerus Plate, Left, 165mm, Ti	1
1168.1195	ANTHEM™ Proximal Humerus Plate, Left, 195mm, Ti	1
1168.1225	ANTHEM™ Proximal Humerus Plate, Left, 225mm, Ti	1
1168.1255	ANTHEM™ Proximal Humerus Plate, Left, 255mm, Ti	1
1168.1285	ANTHEM™ Proximal Humerus Plate, Left, 285mm, Ti	1
1168.1315	ANTHEM™ Proximal Humerus Plate, Left, 315mm, Ti	1
1168.2088	ANTHEM™ Proximal Humerus Plate, Right, 88mm, Ti	2
1168.2103	ANTHEM™ Proximal Humerus Plate, Right, 103mm, Ti	2
1168.2135	ANTHEM™ Proximal Humerus Plate, Right, 135mm, Ti	1
1168.2165	ANTHEM™ Proximal Humerus Plate, Right, 165mm, Ti	1
1168.2195	ANTHEM™ Proximal Humerus Plate, Right, 195mm, Ti	1
1168.2225	ANTHEM™ Proximal Humerus Plate, Right, 225mm, Ti	1
1168.2255	ANTHEM™ Proximal Humerus Plate, Right, 255mm, Ti	1
1168.2285	ANTHEM™ Proximal Humerus Plate, Right, 285mm, Ti	1
1168.2315	ANTHEM™ Proximal Humerus Plate, Right, 315mm, Ti	1

ANTHEM™ Ti Proximal Humerus
IMPLANTS 9168.9001 (cont'd)

PART NO.	DESCRIPTION	QTY
11168.3036	Locking Peg, 2.7x36mm, Ti	6
1168.3038	Locking Peg, 2.7x38mm, Ti	6
1168.3040	Locking Peg, 2.7x40mm, Ti	6
1168.3045	Locking Peg, 2.7x45mm, Ti	6
1168.3050	Locking Peg, 2.7x50mm, Ti	6
1168.3055	Locking Peg, 2.7x55mm, Ti	6
1168.3060	Locking Peg, 2.7x60mm, Ti	6
1168.6014	Locking Screw, 3.5x14mm, Blunt Tip, Ti	6
1168.6016	Locking Screw, 3.5x16mm, Blunt Tip, Ti	6
1168.6018	Locking Screw, 3.5x18mm, Blunt Tip, Ti	6
1168.6020	Locking Screw, 3.5x20mm, Blunt Tip, Ti	6
1168.6022	Locking Screw, 3.5x22mm, Blunt Tip, Ti	6
1168.6024	Locking Screw, 3.5x24mm, Blunt Tip, Ti	6
1168.6026	Locking Screw, 3.5x26mm, Blunt Tip, Ti	6
1168.6028	Locking Screw, 3.5x28mm, Blunt Tip, Ti	6
1168.6030	Locking Screw, 3.5x30mm, Blunt Tip, Ti	6
1168.6032	Locking Screw, 3.5x32mm, Blunt Tip, Ti	6
1168.6034	Locking Screw, 3.5x34mm, Blunt Tip, Ti	6
1168.6036	Locking Screw, 3.5x36mm, Blunt Tip, Ti	6
1168.6038	Locking Screw, 3.5x38mm, Blunt Tip, Ti	6
1168.6040	Locking Screw, 3.5x40mm, Blunt Tip, Ti	6
1168.6045	Locking Screw, 3.5x45mm, Blunt Tip, Ti	6
1168.6050	Locking Screw, 3.5x50mm, Blunt Tip, Ti	6
1168.6055	Locking Screw, 3.5x55mm, Blunt Tip, Ti	6
1168.6060	Locking Screw, 3.5x60mm, Blunt Tip, Ti	6
1179.5014	Locking Screw, 3.5x14mm, Cutting Flutes, Ti	6
1179.5016	Locking Screw, 3.5x16mm, Cutting Flutes, Ti	6
1179.5018	Locking Screw, 3.5x18mm, Cutting Flutes, Ti	6
1179.5020	Locking Screw, 3.5x20mm, Cutting Flutes, Ti	6
1179.5022	Locking Screw, 3.5x22mm, Cutting Flutes, Ti	6
1179.5024	Locking Screw, 3.5x24mm, Cutting Flutes, Ti	6
1179.5026	Locking Screw, 3.5x26mm, Cutting Flutes, Ti	6
1179.5028	Locking Screw, 3.5x28mm, Cutting Flutes, Ti	6
1179.5030	Locking Screw, 3.5x30mm, Cutting Flutes, Ti	6
1179.5032	Locking Screw, 3.5x32mm, Cutting Flutes, Ti	6
1179.5034	Locking Screw, 3.5x34mm, Cutting Flutes, Ti	6
1179.5036	Locking Screw, 3.5x36mm, Cutting Flutes, Ti	6

PART NO.	DESCRIPTION	QTY
1179.3014	Non-Locking Screw, 3.5x14mm, Ti	6
1179.3016	Non-Locking Screw, 3.5x16mm, Ti	6
1179.3018	Non-Locking Screw, 3.5x18mm, Ti	6
1179.3020	Non-Locking Screw, 3.5x20mm, Ti	6
1179.3022	Non-Locking Screw, 3.5x22mm, Ti	6
1179.3024	Non-Locking Screw, 3.5x24mm, Ti	6
1179.3026	Non-Locking Screw, 3.5x26mm, Ti	6
1179.3028	Non-Locking Screw, 3.5x28mm, Ti	6
1179.3030	Non-Locking Screw, 3.5x30mm, Ti	6
1179.3032	Non-Locking Screw, 3.5x32mm, Ti	6
1179.3034	Non-Locking Screw, 3.5x34mm, Ti	6
1179.3036	Non-Locking Screw, 3.5x36mm, Ti	6
1179.3038	Non-Locking Screw, 3.5x38mm, Ti	6
1179.3040	Non-Locking Screw, 3.5x40mm, Ti	6
7168.4020	Locking Screw, 4.0x20mm, CoCr	3
7168.4025	Locking Screw, 4.0x25mm, CoCr	3
7168.4030	Locking Screw, 4.0x30mm, CoCr	3
7168.4035	Locking Screw, 4.0x35mm, CoCr	3
7168.4040	Locking Screw, 4.0x40mm, CoCr	3
7168.4045	Locking Screw, 4.0x45mm, CoCr	3
7168.4050	Locking Screw, 4.0x50mm, CoCr	3
7168.4055	Locking Screw, 4.0x55mm, CoCr	3
7168.4060	Locking Screw, 4.0x60mm, CoCr	3
7168.4065	Locking Screw, 4.0x65mm, CoCr	3
7168.4070	Locking Screw, 4.0x70mm, CoCr	3
7168.5020	Cannulated Locking Screw, 4.0x20mm, CoCr	3
7168.5025	Cannulated Locking Screw, 4.0x25mm, CoCr	3
7168.5030	Cannulated Locking Screw, 4.0x30mm, CoCr	3
7168.5035	Cannulated Locking Screw, 4.0x35mm, CoCr	3
7168.5040	Cannulated Locking Screw, 4.0x40mm, CoCr	3
7168.5045	Cannulated Locking Screw, 4.0x45mm, CoCr	3
7168.5050	Cannulated Locking Screw, 4.0x50mm, CoCr	3
7168.5055	Cannulated Locking Screw, 4.0x55mm, CoCr	3
7168.5060	Cannulated Locking Screw, 4.0x60mm, CoCr	3
7168.5065	Cannulated Locking Screw, 4.0x65mm, CoCr	3
7168.5070	Cannulated Locking Screw, 4.0x70mm, CoCr	3

ANTHEM™ Proximal Humerus
INSTRUMENTS 9168.9001 AND 9168.9002

PART NO.	DESCRIPTION	QTY
6179.5135	3.5mm Tap	1
6179.5027	2.7mm Drill Bit, 125mm, AO Quick Connect	2
6179.5035	3.5mm Drill Bit, 110mm, AO Quick Connect	1
6179.6015	T15 Driver, SR, 100mm, AO Quick Connect	2
6168.5215	T15 Driver, SR, Cannulated, 150mm, AO Quick Connect	2
6179.7000	Countersink	1
6179.3316	1.6mm K-Wire Sleeve Insert	2
6179.3227	2.7mm Threaded Drill Guide	2
6168.7011	Large Torque Limiting Handle, 2.5Nm, Cannulated, AO Quick Connect	1
6179.7013	Medium Handle, Ratcheting, Cannulated, AO Quick Connect	1
6168.7003	Blunt Hohmann Retractor, Radiolucent	2
6168.7002	Browne Deltoid Retractor, Radiolucent	1
6171.0005	Stabilizing Radiolucent Weitlaner, 3x4, 8”, Blunt Tip	1
6168.2002	Self-Retaining Retractor Handle	1
6168.2030	30mm Radiolucent Retractor Blade, Toothed	2
6168.2050	50mm Radiolucent Retractor Blade, Toothed	2
6168.2130	30mm Radiolucent Retractor Blade, Smooth	2
6168.2150	50mm Radiolucent Retractor Blade, Smooth	2
6168.1116	1.6mm K-Wire, Trocar Tip, 229mm	10
6168.1316	1.6mm K-Wire, Threaded Tip, 229mm	10

ANTHEM™ Proximal Humerus
INSTRUMENTS 9168.9001 AND 9168.9002 (cont'd)

PART NO.	DESCRIPTION	QTY
6168.7005	Periosteal Elevator, Straight Square Tip, 13mm	1
6179.7019	Periosteal Elevator, Curved Round Tip, 6mm	1
6168.2003	Point-to-Point Reduction Forceps, Large, Ratcheting	1
6168.2004	Point-to-Point Reduction Forceps, Medium, Ratcheting	1
6168.2005	Verbrugge Clamps, Large	1
6168.2001	Bone Holding Clamp, Large	1
6168.7006	Shoulder Hook	1
6179.7012	Dental Pick, Curved Tip, Small Handle	1
6179.3135	3.5mm Soft Tissue Protector	1
6168.3140	3.2mm Polyaxial Drill Guide	1
6168.3141	1.6mm Polyaxial K-Wire Guide	1
6179.7018	Torque Limiting Attachment, 1.5Nm, AO Quick Connect	1
6168.5332	3.2mm Drill Bit, Cannulated, 175mm, AO Quick Connect	2
6168.5032	3.2mm Drill Bit, 175mm, AO Quick Connect	2
6179.5028	2.7mm Drill Bit, 180mm, AO Quick Connect	2
6168.7010	Cleaning Brush, 1.6mm Cannulation	1
6168.7000	Proximal Humerus Plate Bending Irons	2
6168.7004	Direct Measuring Device	1
6179.7023	Plate Reduction Instrument	1
6179.7031	Depth Gauge, 110mm	1
6179.7020	Depth Gauge, 60mm	1

ADDITIONALLY AVAILABLE

6168.7009	Power Plate Bender

IMPORTANT INFORMATION ON ANTHEM™ FRACTURE SYSTEM

DESCRIPTION

The ANTHEM™ Fracture System is a family of plates and screws designed to be used for internal bone fixation. The implants are available in various sizes and shapes to accommodate patient anatomy, and may be contoured or straight, with locking and non-locking screws. ANTHEM™ implants are manufactured from titanium alloy, cobalt chromium molybdenum alloy, or stainless steel. All implants are for single use only.

INDICATIONS

The ANTHEM™ Fracture System is indicated for fixation of fractures, osteotomies, arthrodesis and reconstruction of bones for the appropriate size of the device to be used in adult patients, including the clavicle, scapula, humerus, radius, ulna, small bones (metacarpals, metatarsals, phalanges), wrist, pelvis, femur, tibia, fibula, ankle, and foot. Small fragment and distal fibula plates may be used in all pediatric subgroups (except neonates) and small stature adults. Distal radius plates may be used in adolescents (12-21 years of age).

WARNINGS

The correct implant selection is extremely important. Failure to use the appropriate implant for the fracture condition may accelerate clinical failure. Failure to use the proper component to maintain adequate blood supply and provide rigid fixation may result in loosening, bending, cracking or fracture of the implant and/or bone. The correct implant size for a given patient can be determined by evaluating the patient's height, weight, functional demands and anatomy. Every implant must be used in the correct anatomic location, consistent with accepted standards of internal fixation.

PRECAUTION

The implantation of fixation devices should be performed only by experienced surgeons with specific training in the use of this system because this is a technically demanding procedure presenting a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered when selecting implant size.

Surgical implants must never be reused. Even though the device appears undamaged, it may have small defects and internal stress patterns which could lead to breakage.

MR SAFETY INFORMATION

The ANTHEM™ Fracture implants have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of these devices in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

CONTRAINDICATIONS

Use of these implants is contraindicated in patients in the following cases:

- Any active or suspended 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 cannot provide adequate support and/or fixation of the devices.
- Use of plating on or around growth plates in pediatric patients.
- Material sensitivity, documented or suspected.
- Obesity. An overweight or obese patient can produce loads on the implant that can lead 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.

CAUTIONS

Pre-operative

- These implants are single use only.
- Implants that came in contact with body fluids should never be reused.
- Ensure that all components needed for surgery are available in the surgical suite.
- Inspection is recommended prior to surgery to determine if implants have been damaged during storage.
- While rare, intra-operative fracture or breakage of instruments can occur. Instruments which have experienced excessive use or excessive force are susceptible to fracture. Instruments should be examined for wear or damage prior to surgery.

Intra-operative

- Avoid surface damage of implants.
- Discard all damaged or mishandled implants.
- Contouring or bending of an implant should be avoided where possible, because it may reduce its fatigue strength and can cause failure under load.
- Implants are available in different versions, varying for example in length, diameter, material and number of drilled holes. Select the required version carefully.
- During the course of the operation, repeatedly check to ensure that the connection between the implant and the instrument, or between the instruments, is secure.
- Implants which consist of several components must only be used in the prescribed combination (refer to the ANTHEM™ Surgical Technique Guide).
- After the procedure check the proper positioning of all implants using the image intensifier.
- Do not use components from this system in conjunction with components from any other manufacturer's system unless otherwise specified (refer to the ANTHEM™ Surgical Technique Guide).

Post-operative

- Post-operative patient activity: These implants are neither intended to carry the full load of the patient acutely, nor intended to carry a significant portion of the load for extended periods of time. For this reason post-operative instructions and warnings to patients are extremely important. External immobilization (e.g. bracing or casting) may be employed until X-rays or other procedures confirm adequate bone consolidation.
- The implant is a short-term implant. In the event of a delay in bone consolidation, or if such consolidation does not take place, or if explantation is not carried out, complications may occur, for example fracture or loosening of the implant or instability of the implant system. Regular post-operative examinations (e.g., X-ray checks) are advisable.
- The risk of post-operative complication (e.g. failure of an implant) is higher if patients are obese and/or cannot follow the recommendations of the physician because of any mental or neuromuscular disorder. For this reason those patients must have additional post-operative follow-up.
- Implant removal should be followed by adequate postoperative management to avoid fracture or refracture of the bone.

Informing the Patient

The implant affects the patient's ability to carry loads and her/his mobility and general living circumstances. The surgeon must counsel each patient individually on correct behavior and activity after the implantation.

The surgeon must warn each patient that the device cannot and does not replicate a normally healthy bone, that the device can break or become damaged as a results of strenuous activity, trauma, mal-union or non-union and that the device has a finite expected service life and may need to be removed at some time in the future.

ADVERSE EFFECTS

In many instances, adverse results may be clinically related rather than device related. The following are the most frequent adverse effects involving the use of internal fracture fixation devices:

- Delayed union or non-union of the fracture site.
- These devices can break when subjected to the increased loading associated with delayed unions and/or non-unions. Internal fixation devices are load sharing devices which are intended to hold fracture bone surface in a position to facilitate healing. If healing is delayed or does not occur, the appliance may eventually break due to metal fatigue. Loads on the device produced by load bearing and the patient's activity level will dictate the longevity of the device.
- Conditions attributable to non-union, osteoporosis, osteomalicia, diabetes, inhibited revascularization and poor bone formation can cause loosening, bending, cracking, fracture of the device or premature loss of rigid fixation with the bone.
- Improper alignment can cause a malunion of the bone and/or bending, cracking or even breakage of the device.
- Increased fibrous tissue response around the fracture site due to unstable comminuted fractures.

IMPORTANT INFORMATION ON ANTHEM™ FRACTURE SYSTEM

- Early or late infection, deep or superficial.
- Deep venous thrombosis.
- Avascular necrosis.
- Shortening of the effected bone/fracture site.
- Subclinical nerve damage may possibly occur as a result of the surgical trauma.
- Material sensitivity reactions in patients following surgical implantation have rarely been reported, however their significance awaits further clinical evaluation.

PACKAGING

These implants may be supplied pre-packaged and sterile, using gamma irradiation. The integrity of the sterile packaging should be checked to ensure that sterility of the contents is not compromised. Packaging should be carefully checked for completeness and all components should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to Globus Medical. During surgery, after the correct size has been determined, remove the products from the packaging using aseptic technique.

The instruments are provided nonsterile and are steam sterilized prior to use, as described in the STERILIZATION section below. Following use or exposure to soil, instruments and instrument trays and cases must be cleaned, as described in the CLEANING section below.

HANDLING

All instruments and implants should be treated with care. Improper use or handling may lead to damage and/or possible malfunction. Instruments should be checked to ensure that they are in working order prior to surgery.

Implants are single use devices and should not be cleaned. Re-cleaning of single use implants might lead to mechanical failure and/or material degradation. Discard any implants that may have been accidently contaminated.

CLEANING

Instruments should be cleaned separately from instrument trays and cases. Lids should be removed from cases for the cleaning process, if applicable. All instruments that can be disassembled must be disassembled for cleaning. All handles must be detached. Instruments may be reassembled following sterilization. The products should be cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Globus Medical.

Cleaning and disinfecting can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse. Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

The following cleaning methods should be observed when cleaning instruments after use or exposure to soil, and prior to sterilization:

1. Immediately following use, ensure that the instruments are wiped down to remove all visible soil and kept from drying by submerging or covering with a wet towel.
2. Disassemble all instruments that can be disassembled.
3. Rinse the instruments under running tap water to remove all visible soil. Flush the lumens a minimum of 3 times, until the lumens flush clean.
4. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations.
5. Immerse the instruments in the detergent and allow them to soak for a minimum of 2 minutes.
6. Use a soft bristled brush to thoroughly clean the instruments. Use a pipe cleaner for any lumens. Pay close attention to hard to reach areas.
7. Using a sterile syringe, draw up the enzymatic detergent solution. Flush any lumens and hard to reach areas until no soil is seen exiting the area.
8. Remove the instruments from the detergent and rinse them in running warm tap water.
9. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations in an ultrasonic cleaner.
10. Completely immerse the instruments in the ultrasonic cleaner and ensure detergent is in lumens by flushing the lumens. Sonicate for a minimum of 3 minutes.
11. Remove the instruments from the detergent and rinse them in running deionized water or reverse osmosis water for a minimum of 2 minutes.
12. Dry instruments using a clean soft cloth and filtered pressurized air.
13. Visually inspect each instrument for visible soil. If visible soil is present, then repeat cleaning process starting with Step 3.

CONTACT INFORMATION

Globus Medical may be contacted at 1-866-GLOBUS1 (456-2871). A surgical technique manual may be obtained by contacting Globus Medical.

STERILIZATION

These implants may be available sterile or nonsterile. Instruments are available nonsterile.

Sterile implants are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of 10^{-6}. Sterile products are packaged in a heat sealed, Tyvek pouch. The expiration date is provided in the package label. These products are considered sterile unless the packaging has been opened or damaged. Sterile implants meet pyrogen limit specifications.

Nonsterile implants and instruments have been validated following ANSI/AAMI/ISO 17665-1:2006 Guidelines for Steam Sterility Validation to assure a Sterility Assurance Level (SAL) of 10^{-6}. The use of an FDA-cleared wrap is recommended, per the Association for the Advancement of Medical Instrumentation (AAMI) ST79, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities.* It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the FDA for the selected sterilization cycle specifications (time and temperature).

When using a rigid sterilization container, the following must be taken into consideration for proper sterilization of Globus devices and loaded graphic cases:

- Recommended sterilization parameters are listed in the table below.
- Only FDA-cleared rigid sterilization containers for use with pre-vacuum steam sterilization may be used.
- When selecting a rigid sterilization container, it must have a minimum filter area of 176 in^2 total, or a minimum of four (4) 7.5 in diameter filters.
- No more than one (1) loaded graphic case or its contents can be placed directly into a rigid sterilization container.
- Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.
- The rigid sterilization container manufacturer's instructions for use are to be followed; if questions arise, contact the manufacturer of the specific container for guidance.
- Refer to AAMI ST79 for additional information concerning the use of rigid sterilization containers.

For implants and instruments provided NONSTERILE, sterilization is recommended (wrapped or containerized) as follows:

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Pre-vacuum	132°C (270°F)	4 Minutes	30 Minutes

These parameters are validated to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The sterilizer must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

CAUTION: Federal Law (USA) Restricts this Device to Sale by or on the order of a Physician.

SYMBOL TRANSLATION			
REF	CATALOGUE NUMBER	STERILE R	STERILIZED BY IRRADIATION
LOT	LOT NUMBER	EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
⚠	CAUTION		MANUFACTURER
	SINGLE USE ONLY		USE BY (YYYY-MM-DD)
QTY	QUANTITY		

DI201 REV A

NOTES

NOTES

Globus Medical
Valley Forge Business Center
2560 General Armistead Avenue
Audubon, PA 19403
www.globusmedical.com

Customer Service:
Phone 1-866-GLOBUS1 (or 1-866-456-2871)
Fax 1-866-GLOBUS3 (or 1-866-456-2873)

EC REP: RMS - UK Limited
28 Trinity Road, Nailsea, Somerset, BS48 4NU England

CE 0297

GMTGD182
10.17 Rev B