



GLOBUS
MEDICAL



ANTHEM[®]

Clavicle Fracture System



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

Life moves us 

The Surgical Technique shown is for illustrative purposes only. The technique(s) actually employed in each case always depends on the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Additionally, as instruments may occasionally be updated, the instruments depicted in this Surgical Technique may not be exactly the same as the instruments currently available. Please consult with your sales representative or contact Globus directly for more information.

SURGICAL TECHNIQUE GUIDE

ANTHEM[®]

Clavicle Fracture System

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ANTHEM[®]

Clavicle Fracture System

The ANTHEM[®] Clavicle Fracture System provides intraoperative versatility to treat a variety of clavicle fractures. A comprehensive instrument set featuring radiolucent retractors and innovative reduction clamps provides system efficiency and procedural ease. Each ANTHEM[®] Clavicle Plate has a unique research-driven design to anatomically fit where clavicle fractures most commonly occur.



ANTHEM[®] MIDSHAFT42[™] Superior Plate



ANTHEM[®] MIDSHAFT42[™] Anterior Plate



ANTHEM[®] Superior Lateral Plate



ANTHEM[®] Anterior Lateral Plate



ANTHEM[®] Clavicle Hook Plate

RESEARCH-DRIVEN DESIGN

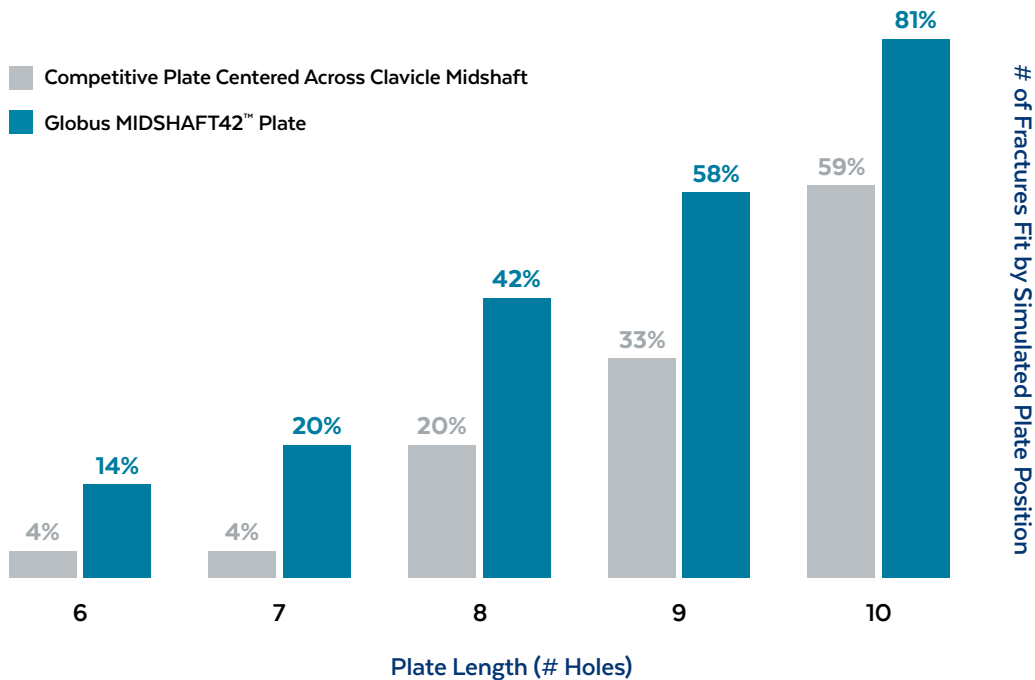
MIDSHAFT42™ PLATES

Fracture zone analysis of 166 operative midshaft clavicle fractures revealed the average fracture is centered at 42% of the clavicle's length from the lateral end, spanning approximately 12%.¹



The MIDSHAFT42™ plates feature a unique, research-driven design engineered to fit the anatomical location where clavicle fractures most commonly occur, with sizes to accommodate common fracture zones.

Ideal Plate Fit Simulated on 166 Clinical Midshaft Fractures



¹ Murthi et al. Where do midshaft clavicle fractures really occur? A novel fracture zone study [abstract]. In: 64th Annual Meeting of the Orthopedic Research Society; 2018 Mar 10-13; New Orleans, LA. Rosemont (IL), #2043.

PLATE CONTOUR

Superior, anterior, and hook plates are offered in two distinct contour options (shallow or deep) to accommodate a range of patient anatomy.



Shallow contour

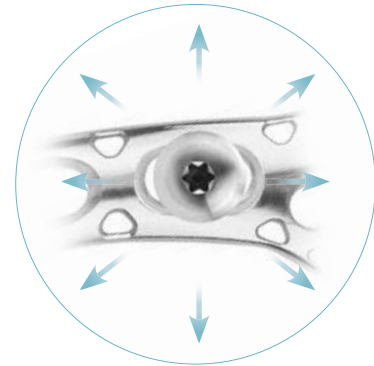


Deep contour

SYSTEM FEATURES

Positioning Slot and Screw

- Allows multidirectional fine-tuning of plate position
- Accepts 2.5mm Positioning Screw, 3.5mm Non-Locking Screw, and 4.0mm Cancellous Screw



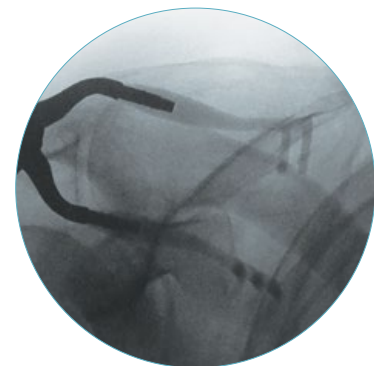
Suture Holes

- Unique triangular suture holes for convenient suturing after securing the plate to bone
- Accept 1.6mm K-wires for provisional fixation



Unique Instruments

- Radiolucent retractors aid in fracture site visibility
- Speed Lock Drill Guides lock to the plate at the nominal screw trajectory



Speed Lock Drill Guide

IMPLANT OVERVIEW

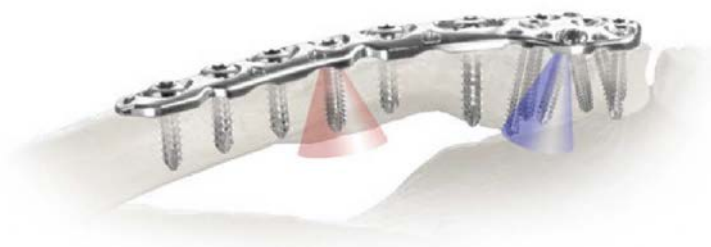
Plate Design

- Optimized contours accommodate clavicle anatomy
- Low profile to minimize soft tissue irritation
- Scalloped undercuts and side cuts to aid in plate bending and evenly distribute loads
- Unique limited contact underside to help support healing of periosteum
- Offered in stainless steel or titanium alloy
- MIDSHAFT42™ plates are designed to fit where midshaft fractures most commonly occur



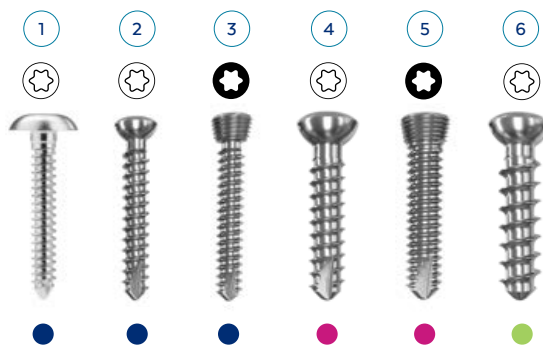
Polyaxial Holes

- Locking screws allow for a $\pm 20^\circ$ cone of angulation
- Allow for screw insertion and removal up to four times
- Seven screws in the lateral extension of the plate form a divergent and convergent pattern to maximize plate fixation



Screw Design

- 1 2.5mm Positioning Screw
- 2 2.5mm Non-Locking Screw
- 3 2.5mm Locking Screw
- 4 3.5mm Non-Locking Screw
- 5 3.5mm Locking Screw
- 6 4.0mm Cancellous Screw



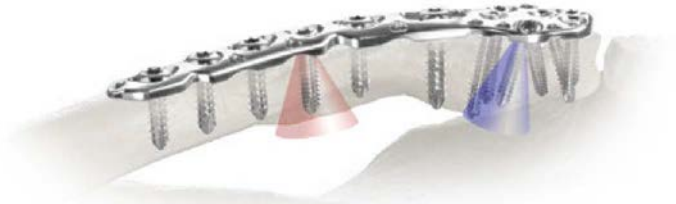
Drills and drill guides are color-coded to screw size

Nominal Polyaxial Screw Trajectories

Locking screws allow for a $\pm 20^\circ$ cone of angulation. Red cones represent 3.5mm screws and purple cones represent 2.5mm screws. Nominal trajectories are shown below.



MDSHAFT42™ Superior Plate



Superior Lateral Plate



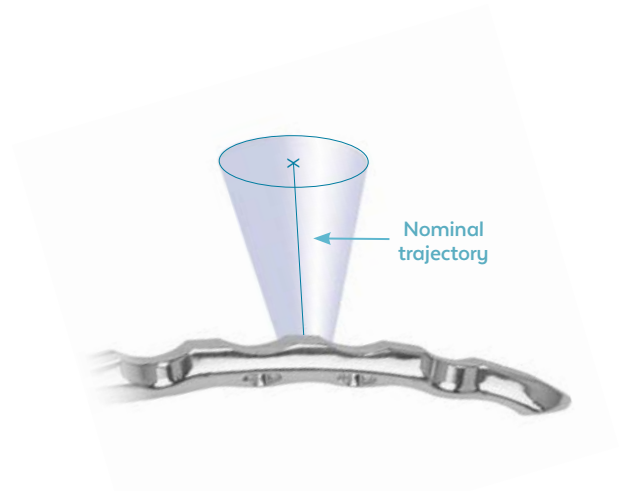
MDSHAFT42™ Anterior Plate



Anterior Lateral Plate



Clavicle Hook Plate



Nominal trajectory is the central axis of the range of polyaxial angulations.

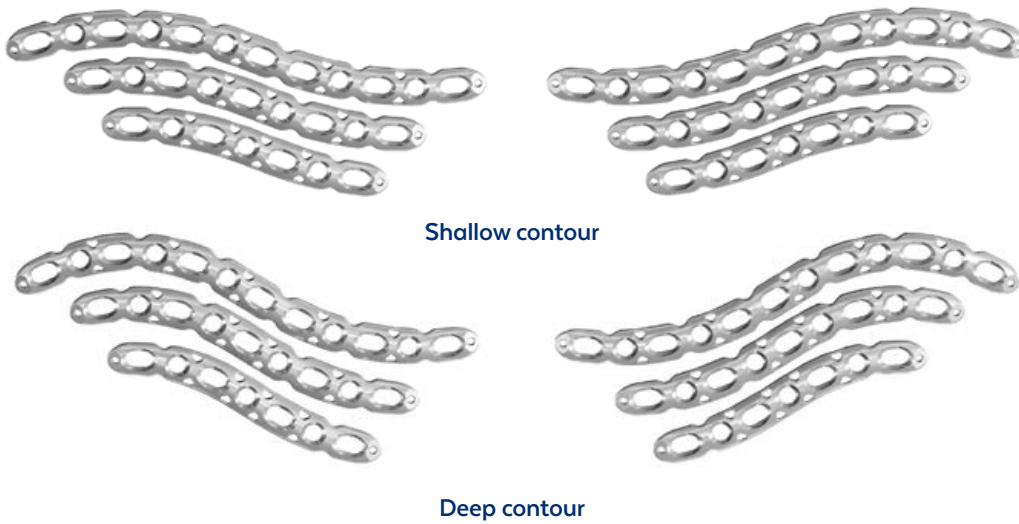
IMPLANT OVERVIEW

ANTHEM® Clavicle Plate Features

- Two contour options (shallow or deep)
- Superior plates offered in left and right orientations

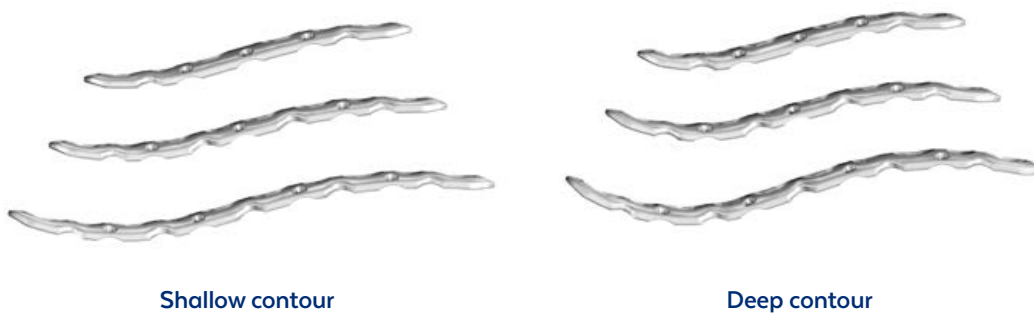
MIDSHAFT42™ Superior Plate

- Plate lengths from 72-125mm (7 to 11 holes)



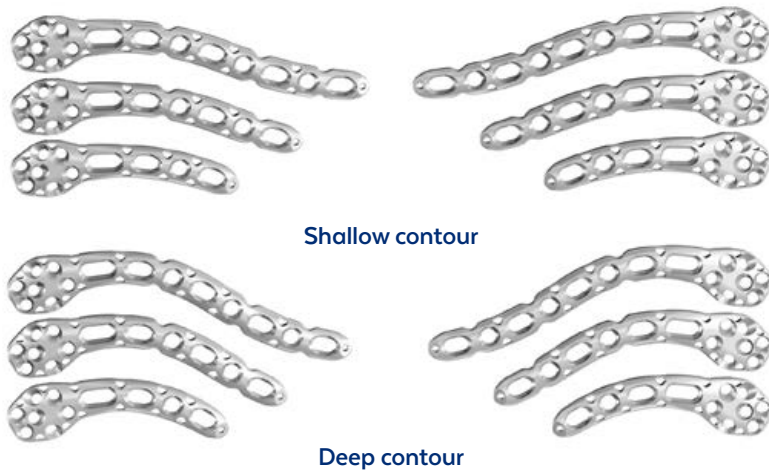
MIDSHAFT42™ Anterior Plate

- Plate lengths from 63-107mm (6 to 10 holes)



Superior Lateral Plate

- Plate lengths from 66-106mm (4 to 8 holes)



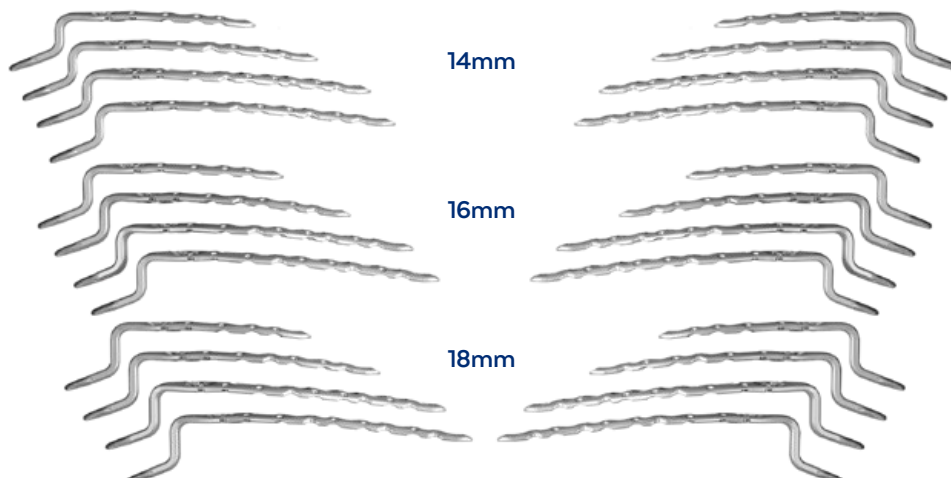
Anterior Lateral Plate

- Plate lengths from 60-103mm (7 to 11 holes)



Clavicle Hook Plate

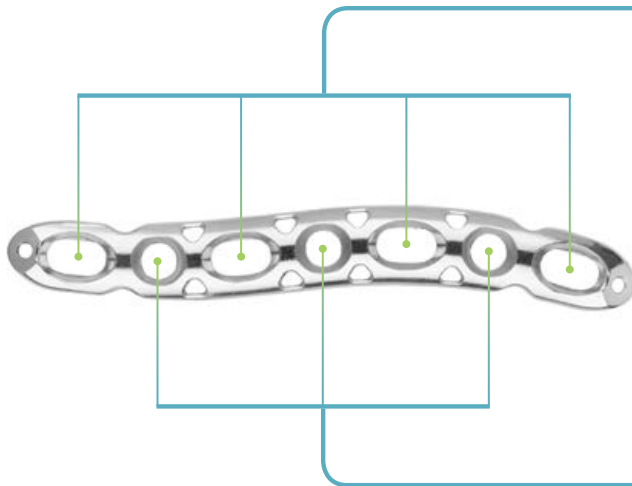
- Plate lengths from 67-106mm (4 to 8 holes)
- Three hook depth options: 14, 16, 18mm
- Hook angulation and tip geometry are designed to minimize soft tissue irritation













SCREW COMPATIBILITY

Screw compatibility is shown for each plate style. If screw-plate locking is desired in a polyaxial hole, only use locking screws. MonoAx® Locking Screws may not be used in a polyaxial hole.

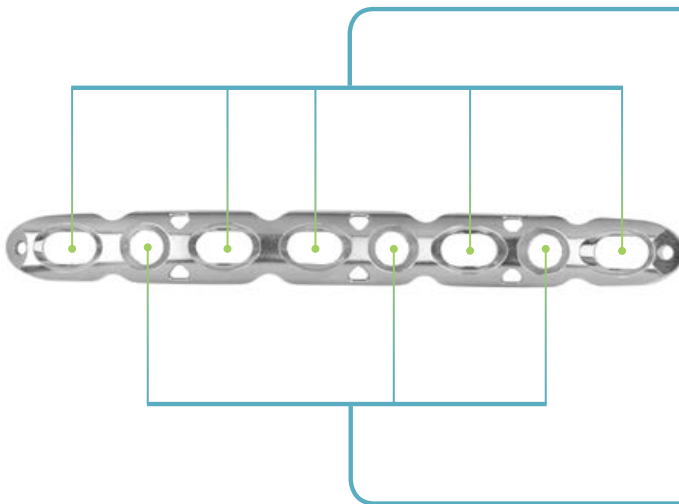
MIDSHAFT42™ Superior Plate













Non-Locking Holes	
 3.5mm Non-Locking	
 4.0mm Cancellous	

Polyaxial Locking Holes	
 3.5mm Locking	
 3.5mm Non-Locking	
 4.0mm Cancellous	

MIDSHAFT42™ Anterior Plate







Non-Locking Holes	
 3.5mm Non-Locking	
 4.0mm Cancellous	







Polyaxial Locking Holes	
 3.5mm Locking	
 3.5mm Non-Locking	
 4.0mm Cancellous	







SCREW COMPATIBILITY





Screw compatibility is shown for each plate style. If screw-plate locking is desired in a polyaxial hole, only use locking screws. MonoAx® Locking Screws may not be used in a polyaxial hole.

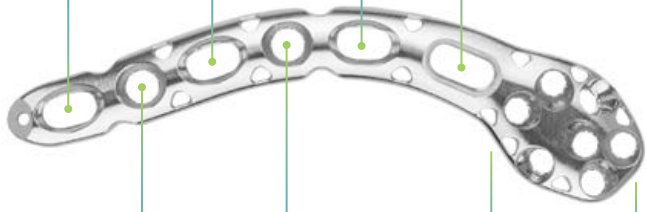
Superior Lateral Plate

Non-Locking Holes	
	
3.5mm Non-Locking	
	
4.0mm Cancellous	





Polyaxial Locking Holes	
	
3.5mm Locking	
	
3.5mm Non-Locking	
	
4.0mm Cancellous	





Positioning Slot	
	
2.5mm Positioning Screw	
	
3.5mm Non-Locking	
	
4.0mm Cancellous	







Polyaxial Locking Holes	
	
2.5mm Locking	
	
2.5mm Non-Locking	




Anterior Lateral Plate

Non-Locking Holes	
	
3.5mm Non-Locking	
	
4.0mm Cancellous	

Polyaxial Locking Holes	
	
2.5mm Locking	
	
2.5mm Non-Locking	

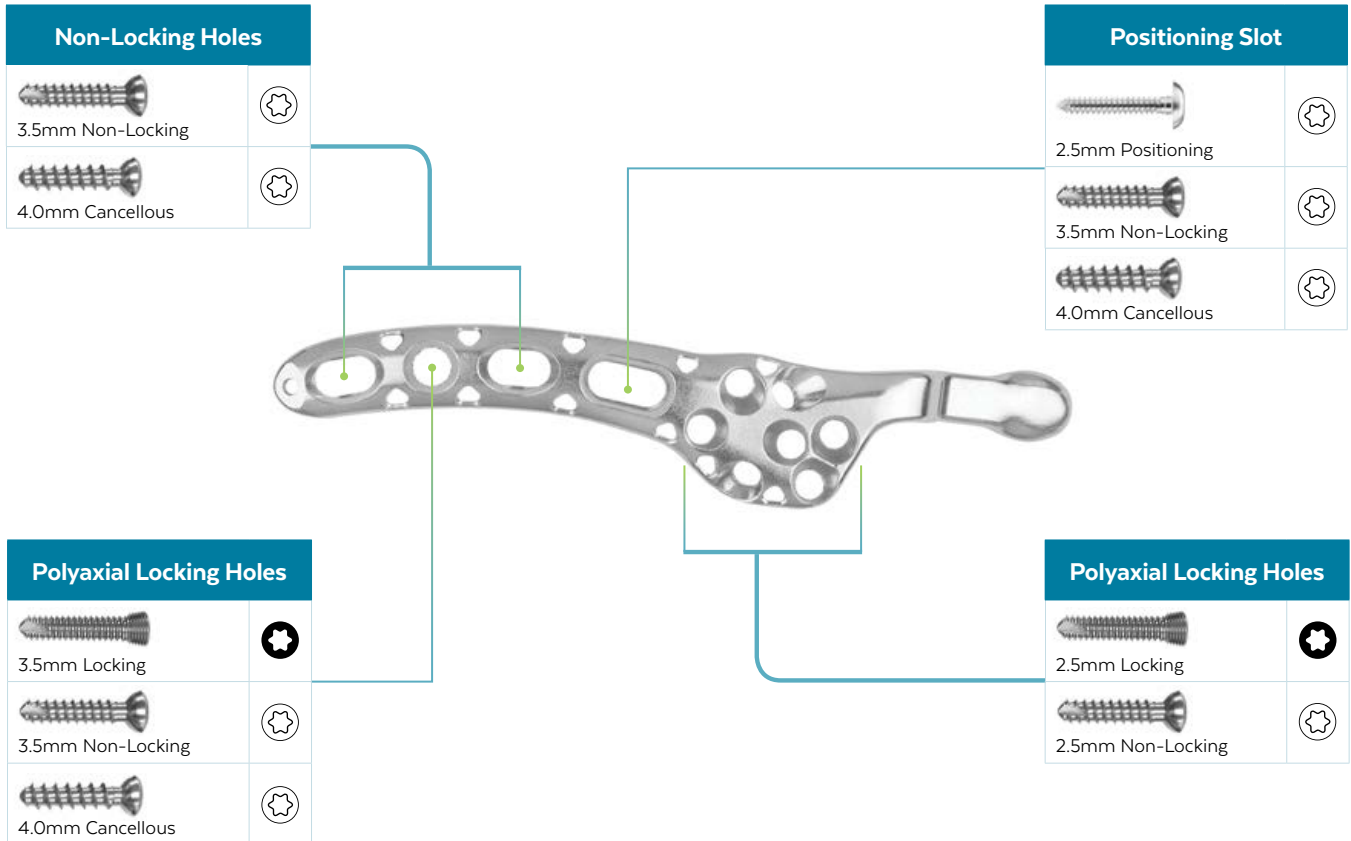
Polyaxial Locking Holes	
	
3.5mm Locking	
	
3.5mm Non-Locking	
	
4.0mm Cancellous	



SCREW COMPATIBILITY

Screw compatibility is shown for each plate style. If screw-plate locking is desired in a polyaxial hole, only use locking screws. MonoAx® Locking Screws may not be used in a polyaxial hole.

Clavicle Hook Plate



SURGICAL TECHNIQUE

ANTHEM[®] Clavicle Fracture System

Refer to the package insert 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 selection of plate type, plate position, and screw placement.

STEP 2 PATIENT POSITIONING

Position the patient in the beach chair or supine position. Using fluoroscopy, examine the fracture. Ensure that the entire clavicle can be fluoroscopically imaged.



To avoid interference from the table during fluoroscopy, place the patient's head in a foam head positioner and tilt the patient's neck 20°. To ensure medial access, position the patient's head looking away from their injured side.



Beach chair position



Intraoperative imaging with
foam head positioner

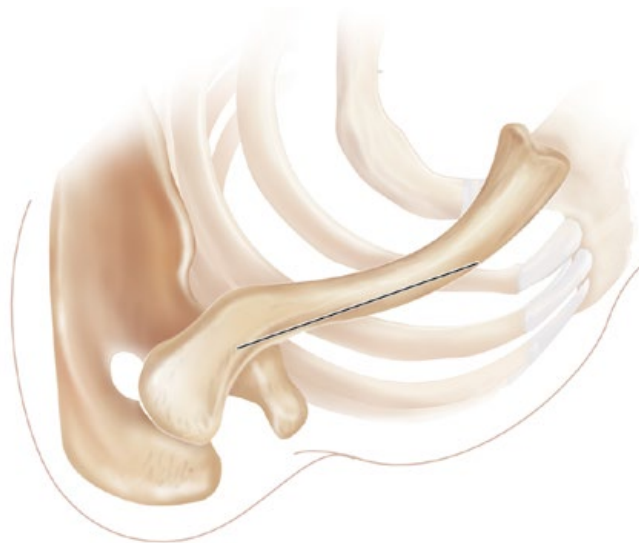


Supine position

Plates may be placed superiorly or anteriorly, based on fracture pattern and surgeon preference.

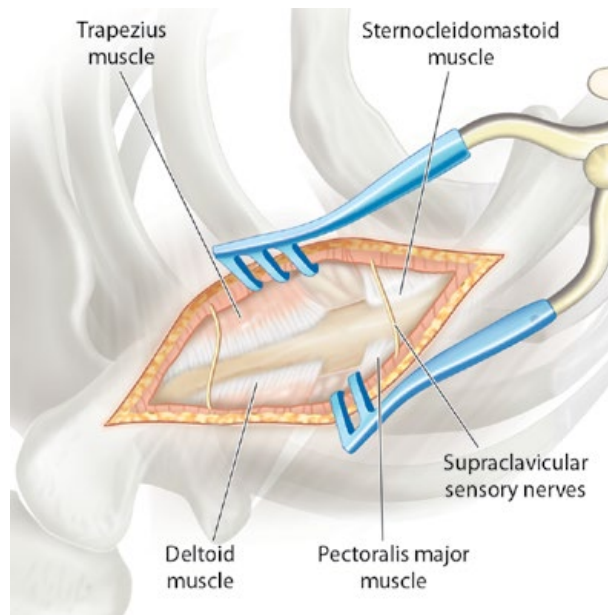
Superior Plate Placement

Create an incision superiorly over the clavicle, centered above the fracture site.



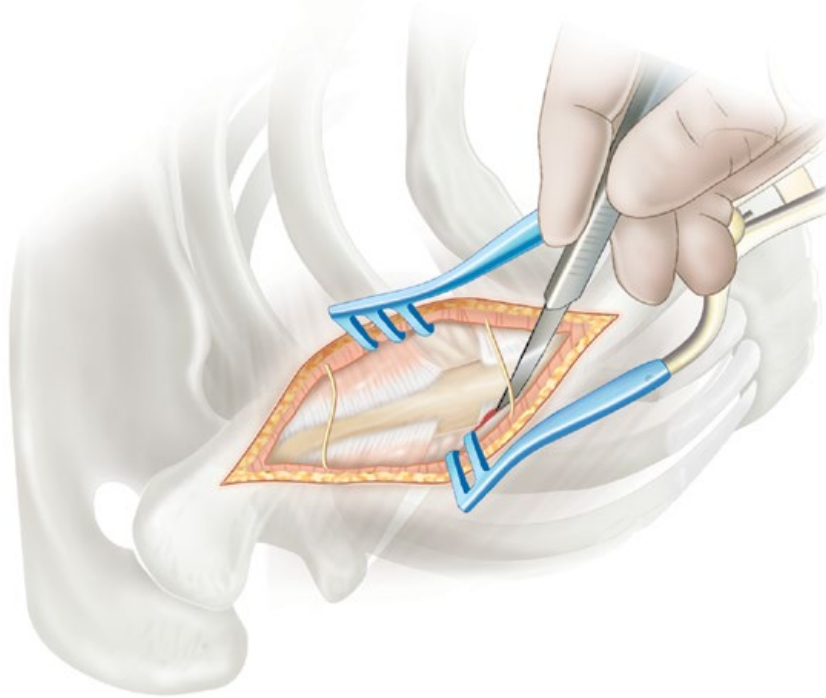
Superior incision

Create subcutaneous flaps anteriorly and posteriorly. At the medial end of the incision, the supraclavicular sensory nerves may be encountered. Identify and protect the nerves.



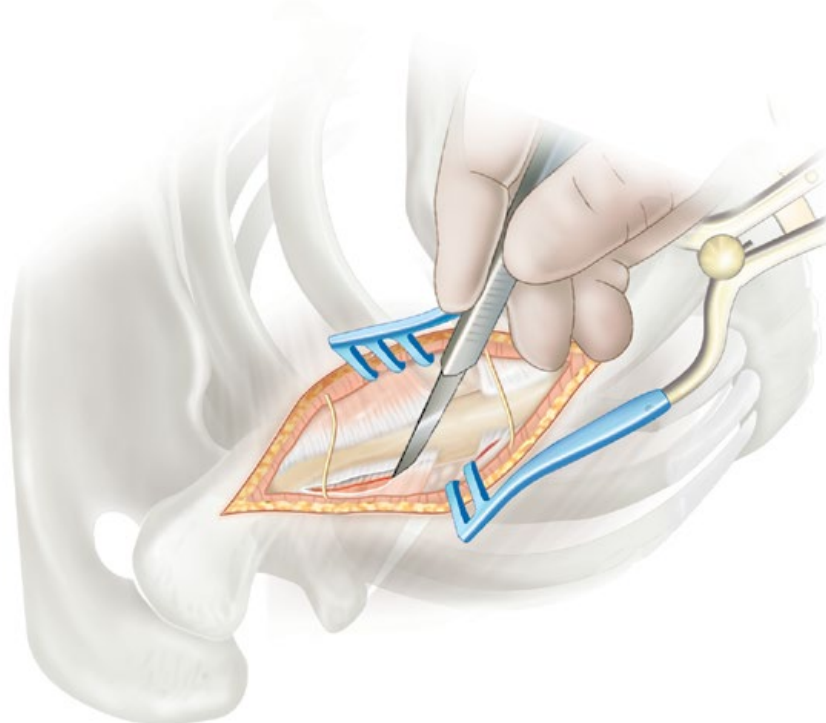
Dissection of subcutaneous flaps

Incise the fascial interval to expose the fracture.



Dissection of clavipectoral fascia

Laterally, the deltoid muscle may be reflected from the distal clavicle anteriorly and posteriorly in a contiguous sheet. Carefully preserve soft tissue attachments of all bone fragments to enable proper bone healing. Comminution of the fracture site is common.

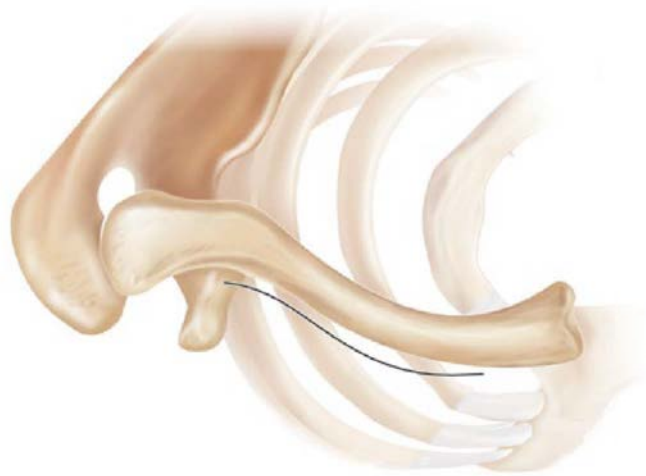


Reflection of deltoid muscle

SURGICAL APPROACH (CONT'D)

Anterior Plate Placement

Create an incision anteriorly, centered above the fracture site.

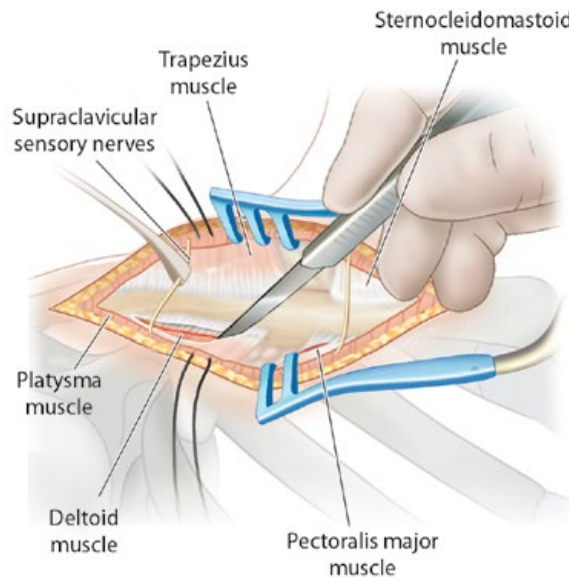


Anterior incision

The fascial interval is incised transversely. Identify the supraclavicular sensory nerves and preserve them. Incise the clavipectoral fascia to expose the underlying clavicle and the attached pectoralis major anteriorly and trapezius posteriorly.

Perform minimal soft tissue dissection of underlying clavipectoral fascia to expose the fracture.

Carefully preserve soft tissue attachments of all bone fragments to enable proper bone healing.



Platysma muscle and clavipectoral fascia incised to expose clavicle

STEP**4****FRACTURE REDUCTION**

The fracture may be reduced and provisionally fixed using reduction forceps, K-wires, interfragmentary screws, plate holding K-wires, or sutures. Restore the length, axis angulation, and rotation of the clavicle. Steps for suture reduction can be seen on pages 20-21.

Confirm reduction using fluoroscopy. Reduction aids should be placed so as not to interfere with final plate placement.

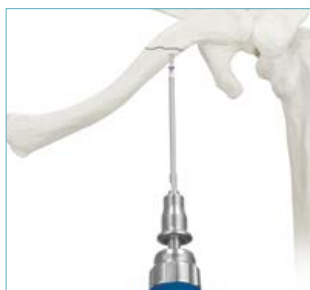
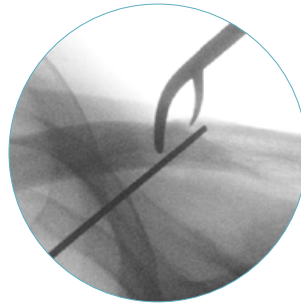
Consider interfragmentary fixation prior to plate placement.



**Point-to-point
reduction forceps**



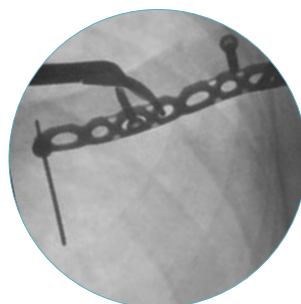
K-wire



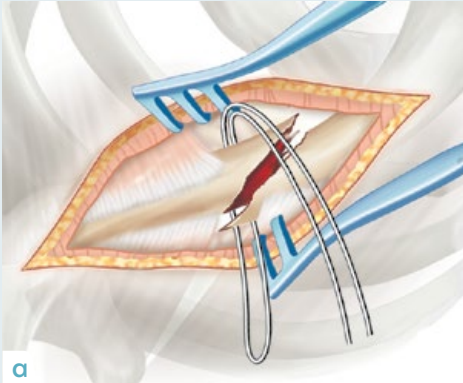
Interfragmentary screw



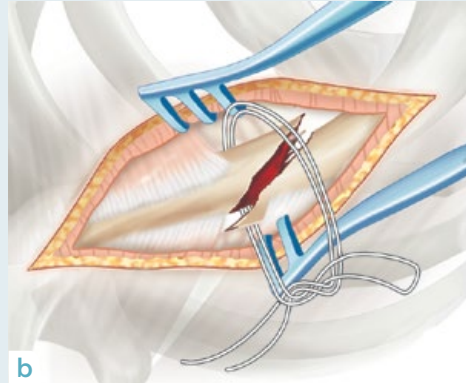
Plate holding K-wire



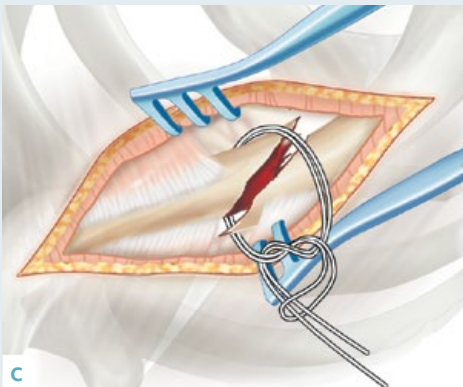
 SUTURE REDUCTION USING CERCLAGE (AROUND BONE)²



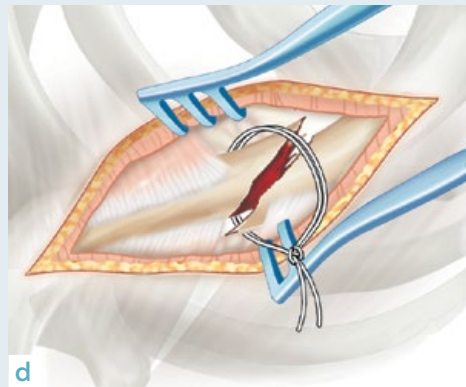
a A doubled-over suture is passed around the tissue.



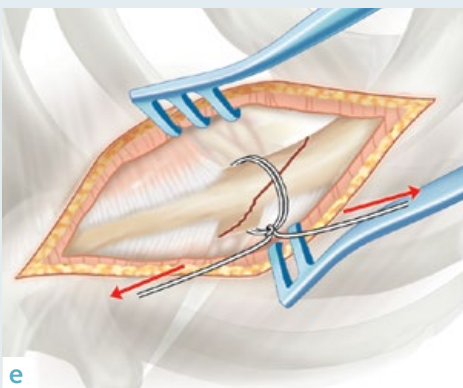
b A single square knot is thrown.



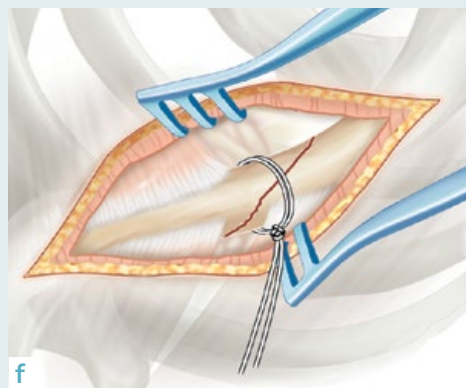
c The two free limbs are passed through the loop.



d The knot is dressed.



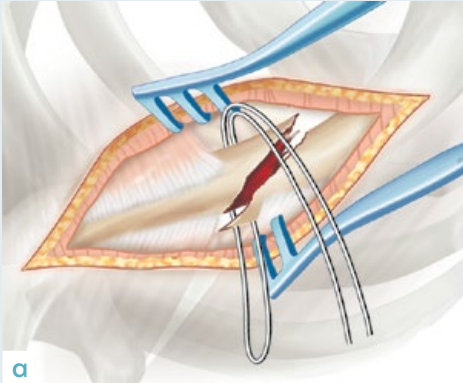
e The knot is slid down by pulling the two free limbs apart. The two limbs can also be pulled back toward the surgeon at once or alternately. A knot pusher can also be used to help the knot down while the limbs are being pulled.



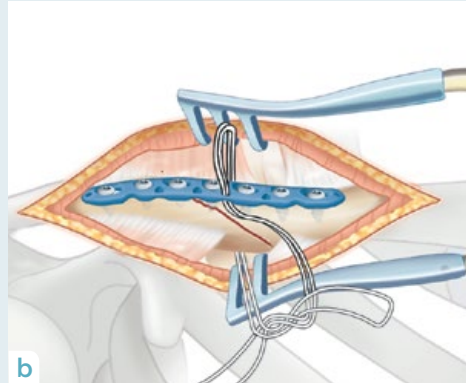
f The tightened knot is secured with three alternating half-hitches or surgeon's knots.

2 Boileau P, et al. 2017. The doubled-suture nice knot. *Orthopedics* Mar 1;40(2):e382-e386.

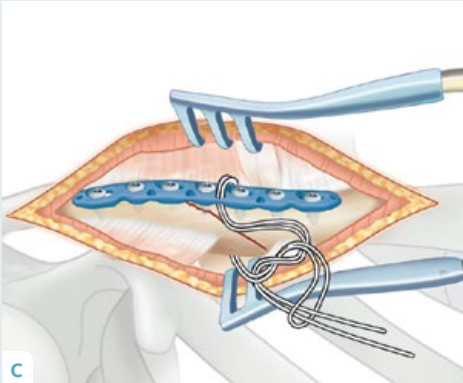
SUTURE REDUCTION USING SUTURE HOLES IN PLATE³



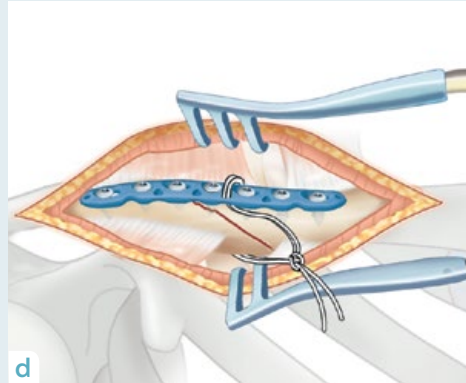
a A doubled-over suture is passed around the tissue.



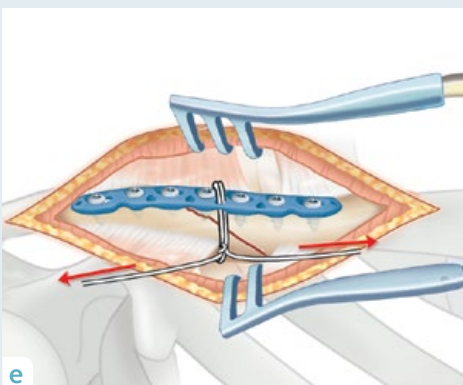
b The suture is passed through the plate, and a square knot is thrown.



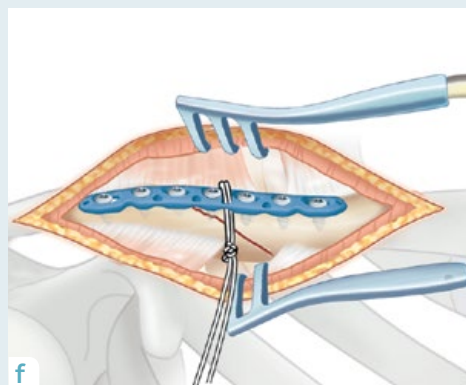
c The two free limbs are passed through the loop.



d The knot is dressed.



e The knot is slid down by pulling the two free limbs apart. The two limbs can also be pulled back toward the surgeon at once or alternately. A knot pusher can also be used to help the knot down while the limbs are being pulled.



f The tightened knot is secured with three alternating half-hitches or surgeon's knots.

STEP**5****PLATE POSITIONING**

Select the plate type and length that best accommodates the patient's anatomy and fracture pattern. Confirm plate placement using fluoroscopy or palpation of its relationship to the bony structures. **K-wires, Plate Holding K-wires, or Reduction Clamps** can be used to preliminarily fix the plate to the bone. K-wires may be inserted through the K-wire holes or suture holes in the plate.



MIDSHAFT42™ Superior Plate



Superior Lateral Plate



MIDSHAFT42™ Anterior Plate



Anterior Lateral Plate



Clavicle Hook Plate

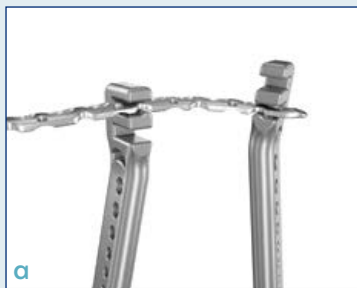
BENDING INSTRUMENTS

Plate bending may be necessary based on patient anatomy. Using **Plate Bending Irons** or the **Clavicle Bending Clamp**, contour the plate as needed. Avoid excessive bending, over-contouring, and bending directly over screw and suture holes which may compromise plate strength and cause breakage.

Clavicle Bending Templates may be used to estimate the necessary contour. Template segments represent average hole spacing and plate width.

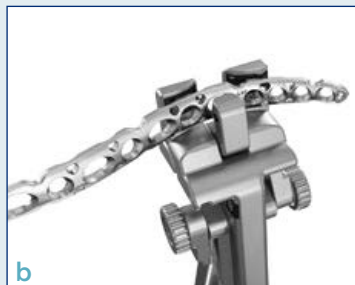


Bending Irons feature multiple slots for out-of-plane and rotational contouring.



Bending irons enable out-of-plane bending using (a) traditional rectangular slots, (b) slots with features to hold plate in place, and (c) using slotted “J” tip of irons.

The **Clavicle Bending Clamp** may be used for plate contouring. Out-of-plane bending is achieved using the proximal or distal jaws of the clamp. In-plane bending at plate side cuts is achieved through bending dies on either side of the clamp.



Bending clamp enables (a and b) out-of-plane bending, and (c) in-plane bending at side cuts of plate

STEP**6****SCREW INSERTION**

Place the desired screws into the clavicle. The number of screws is determined by the fracture pattern, morphology, and bone quality. In osteoporotic bone, more screws may be required. Avoid over-penetration of drills and screws in the clavicle during screw insertion due to the close proximity of the subclavian artery and brachial plexus.

 **2.7mm SPEED LOCK CLAMP**

The 2.7mm Speed Lock Clamp may be used to reduce the plate to bone and drill with the 2.7mm Speed Lock Drill Guide without losing reduction. The clamp must be fully engaged for optimal soft tissue protection.



 **COLOR-CODED INSTRUMENTS**

Drills and drill guides are color-coded to the screw size.

Color	Screw Diameter	Drill Diameter	Lag by Technique Drill Diameter	Drive
Blue	2.5mm Locking, Non-Locking, and Positioning	1.8mm	2.5mm	T8
Fuschia	3.5mm Locking and Non-Locking	2.7mm	3.5mm	T15
Light Green	4.0mm Cancellous	2.7mm	N/A	T15

Positioning Screws



Superior Lateral Plate



Clavicle Hook Plate



2.5mm Positioning Screw ●



3.5mm Non-Locking ●



4.0mm Cancellous ●

For 2.5mm Positioning Screws, use the **1.8mm Drill Bit** and **2.5mm Soft Tissue Protector** to drill a hole through the center of the Positioning Slot.

For 3.5mm Non-Locking Screws and 4.0mm Cancellous Screws, use the **2.7mm Drill Bit** and **3.5mm Soft Tissue Protector** to drill a hole through the center of the Positioning Slot.

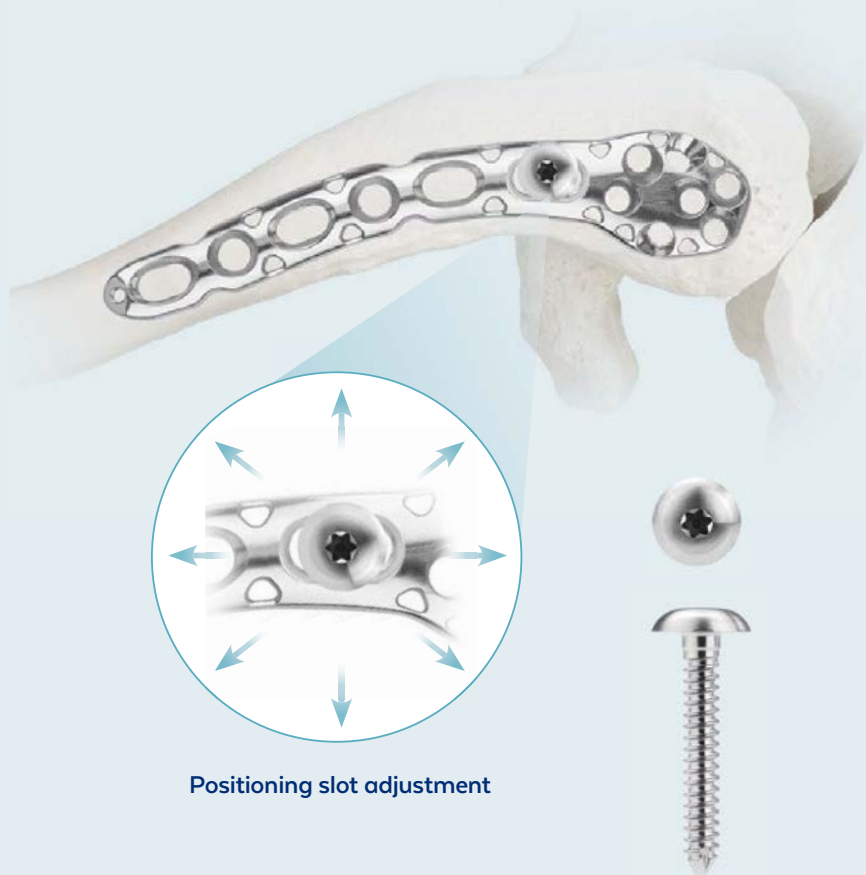


Drilling with Drill Bit and Soft Tissue Protector

POSITIONING SLOT AND SCREW

The Positioning Slot accepts a 2.5mm Positioning Screw, 3.5mm Non-Locking Screw, or 4.0mm Cancellous Screw.

The 2.5mm Positioning Screw allows for intraoperative multidirectional fine-tuning of plate position. The 3.5mm Non-Locking Screw or 4.0mm Cancellous Screw allow medial/lateral adjustment of plate position.



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



Depth gauge measurement

For the 2.5mm Positioning Screw, use the **T8 Driver** or **Screw Holding Forceps** to select the desired screw. For the 3.5mm Non-Locking or 4.0mm Cancellous Screw, use the **T15 Driver** or Screw Holding Forceps.

Verify screw length and diameter using the gauges within the screw module. Using the driver, insert the appropriate length screw through the screw hole.

Screws may be inserted using a **Quick Connect Handle** or under power. If screws are inserted under power, final tightening should be performed manually.

Once the plate is in the desired position, the positioning screw may be tightened against the plate and remain as part of the final construct.



Positioning screw insertion

Non-Locking Screws

2.5mm Non-Locking Screws



Superior Lateral Plate



Clavicle Hook Plate

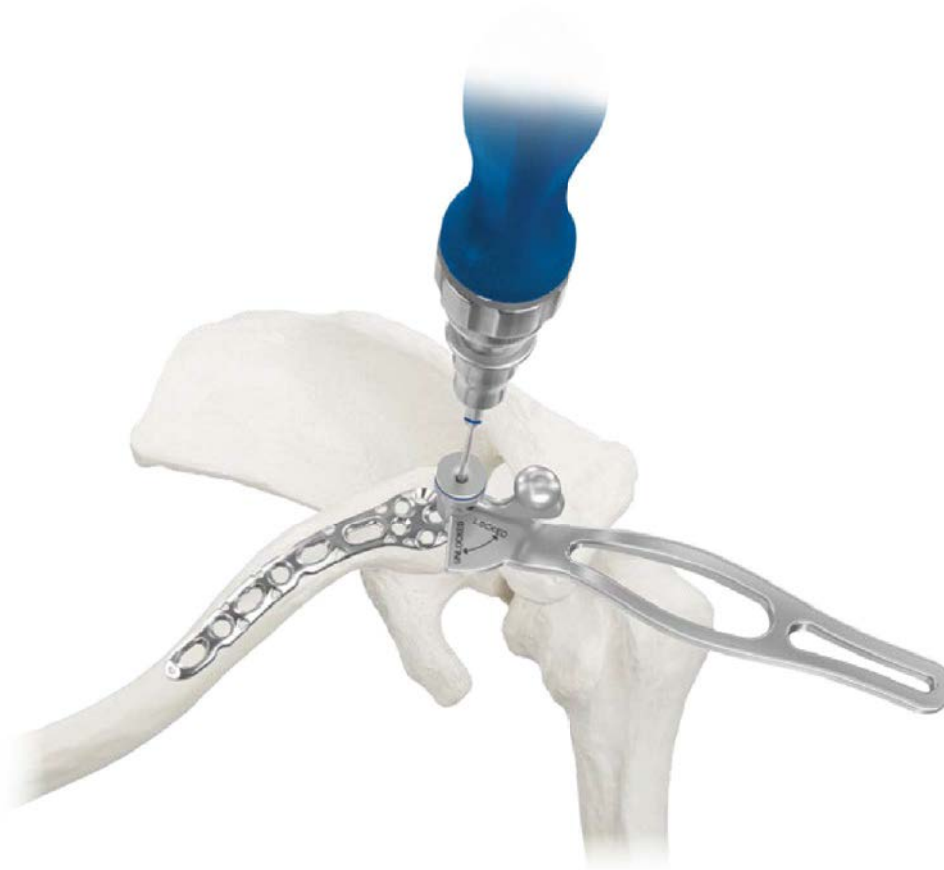


Anterior Lateral Plate



2.5mm Non-Locking ●

Using the 1.8mm Drill Bit and 2.5mm Soft Tissue Protector or **1.8mm Speed Lock Drill Guide**, drill the desired screw hole to the appropriate depth.



Using Speed Lock Drill Guide

Measure screw length using the Depth Gauge.



Depth Gauge measurement

Use the T8 Driver or Screw Holding Forceps to select the desired 2.5mm Non-Locking Screw. Verify screw length and diameter using the gauges within the screw module. Using the driver, insert the appropriate length screw through the screw hole.

Screws may be inserted using a Quick Connect Handle manually or under power. If screws are inserted under power, final tightening should be performed manually.

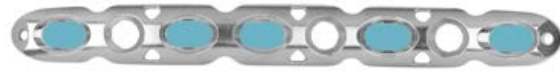


Non-locking screw insertion

3.5mm Non-Locking Screws



Superior Lateral Plate



MIDSHAFT42™ Anterior Plate



MIDSHAFT42™ Superior Plate



Clavicle Hook Plate



Anterior Lateral Plate



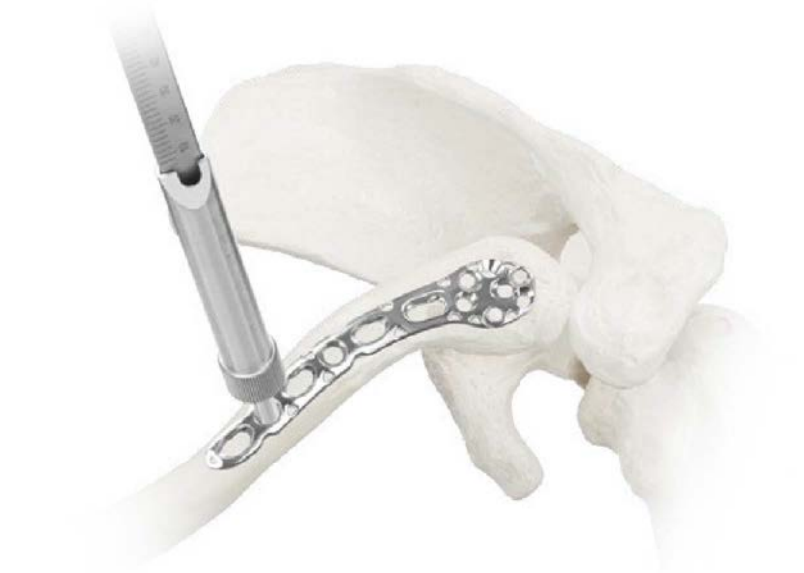
3.5mm Non-Locking ●

Using the 2.7mm Drill Bit and 3.5mm Soft Tissue Protector, drill to the appropriate depth of the desired screw hole.



Drilling with Drill Bit and Soft Tissue Protector

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



Depth Gauge measurement

Use the T15 Driver or Screw Holding Forceps to select the desired 3.5mm Non-Locking Screw. Verify screw length and diameter using the gauges within the screw module. Using the driver, insert the appropriate length screw through the screw hole.

Screws may be inserted using a Quick Connect Handle manually or under power. If screws are inserted under power, final tightening should be performed manually.



Non-locking screw insertion

Polyaxial Locking Screws

2.5mm Polyaxial Locking Screws



Superior Lateral Plate



Clavicle Hook Plate



Anterior Lateral Plate



2.5mm Locking ●

Using the 1.8mm Drill Bit and selected drill guide, drill to the appropriate depth of the desired screw hole.

DRILL GUIDE OPTIONS

1.8mm Speed Lock Drill Guide

This drill guide may be used to drill nominal trajectories. The thumb lock locks the drill guide to the plate at the nominal trajectory.



Speed Lock Drill Guide



Speed Lock Drill Guide
locked in place

DRILL GUIDE OPTIONS (CONT'D)

1.8mm Polyaxial Soft Tissue Protector

This instrument allows for a 40° cone ($\pm 20^\circ$) of angulation on the polyaxial side and nominal trajectory on the nominal side.



The angle should not exceed 20° from the central axis of the screw hole to ensure proper locking.



Polyaxial trajectory



Nominal trajectory

Measure screw length using the Depth Gauge.



Depth Gauge measurement

Use the T8 Driver or Screw Holding Forceps to select the desired screw. Verify screw length and diameter using the gauges within the screw module.

Screws may be inserted using the **1.2Nm Torque Limiting Quick Connect Handle** manually or under power. If screws are inserted under power, perform final tightening manually.



Polyaxial locking screw insertion

3.5mm Polyaxial Locking Screws



Superior Lateral Plate



MIDSHAFT42™ Anterior Plate



MIDSHAFT42™ Superior Plate



Clavicle Hook Plate



Anterior Lateral Plate



3.5mm Locking ●

Use the 2.7mm Drill Bit and selected Drill Guide to drill the desired screw hole to the appropriate depth.

DRILL GUIDE OPTIONS

2.7mm Speed Lock Drill Guide

This drill guide may be used to drill nominal trajectories. The thumb lock locks the drill guide to the plate at the nominal trajectory.



Speed Lock Drill Guide



Speed Lock Drill Guide
locked in place

2.7mm Polyaxial Soft Tissue Protector

This instrument allows for a 40° cone ($\pm 20^\circ$) of angulation on the polyaxial side and nominal trajectory on the nominal side.



The angle should not exceed 20° from the central axis of the screw hole to ensure proper locking.



Polyaxial trajectory



Nominal trajectory

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



Depth Gauge measurement

Use the T15 Driver or Screw Holding Forceps to select the desired screw. Verify screw length and diameter using gauges within the screw module.

Screws may be inserted using the **2.5Nm Torque Limiting Quick Connect Handle** manually or under power. If screws are inserted under power, perform final tightening manually.



Polyaxial locking screw insertion

Cancellous Screws



Superior Lateral Plate



MIDSHAFT42™ Anterior Plate



MIDSHAFT42™ Superior Plate



Clavicle Hook Plate



Anterior Lateral Plate



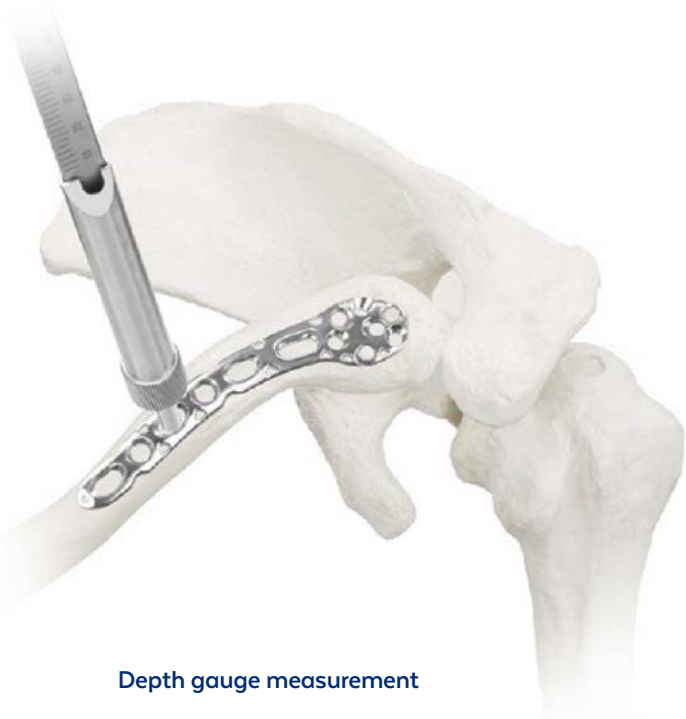
4.0mm Cancellous ●

Use the 2.7mm Drill Bit and 3.5mm Soft Tissue Protector to drill the desired screw hole to the appropriate depth.



Drilling with Drill Bit and Soft Tissue Protector

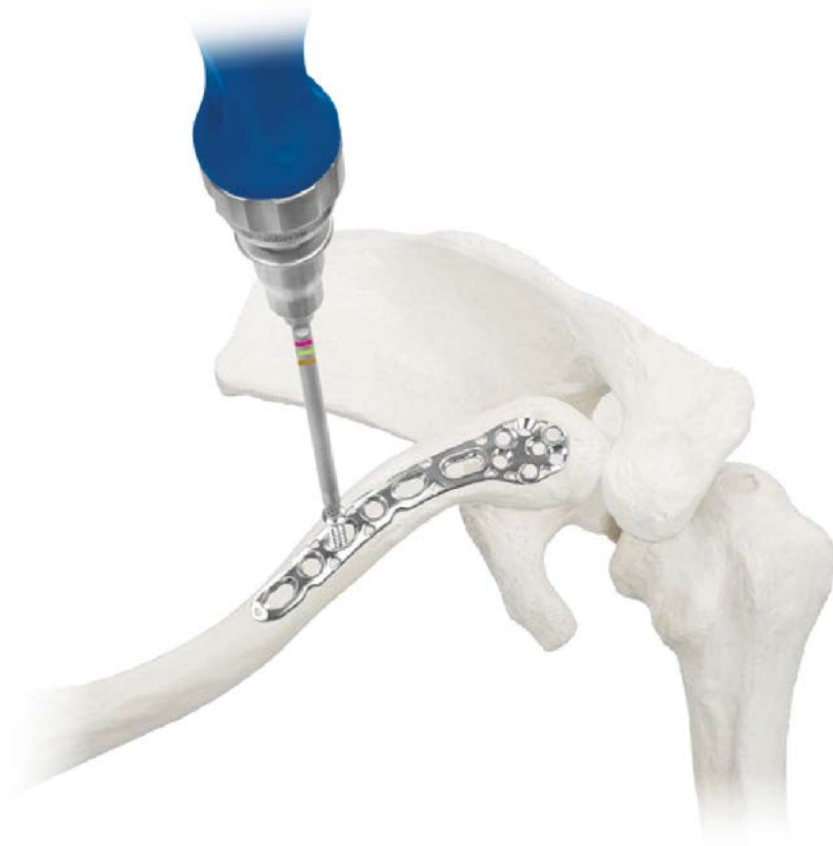
Measure hole depth using the calibrations on the drill bit or remove the drill guide and insert the Depth Gauge.



Depth gauge measurement

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 driver, insert the appropriate length screw through the screw hole.

Screws may be inserted using a Quick Connect Handle manually or inserted under power. If screws are inserted under power, final tightening should be performed manually.

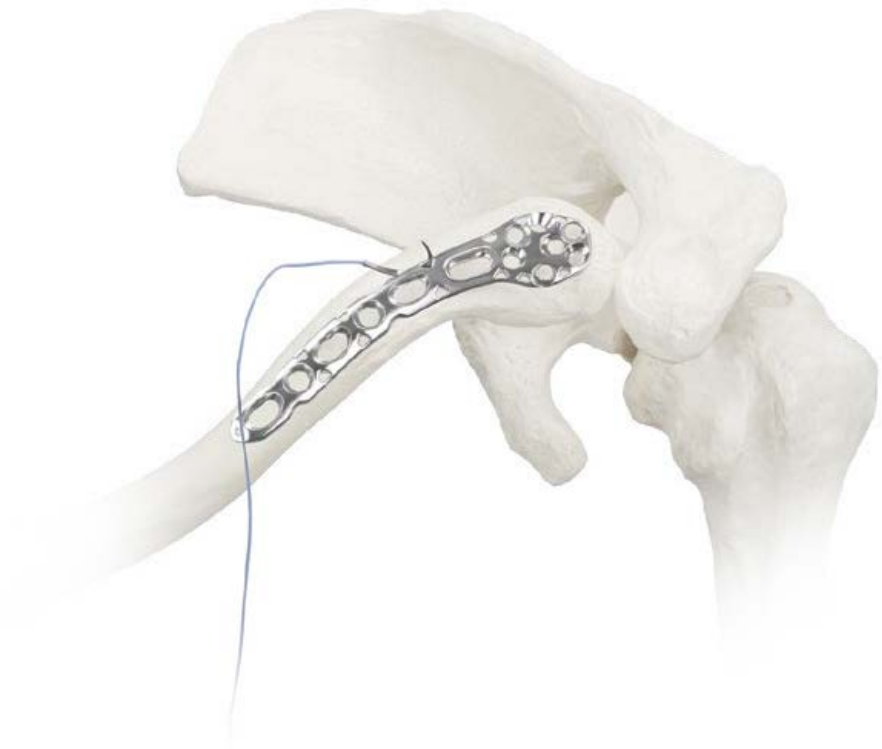


Cancellous screw insertion

STEP 7

SUTURE ATTACHMENT

Sutures may be passed through designated suture holes in the plate. Sutures can be used to augment fracture fixation and for soft tissue repair. Coracoclavicular fractures may be repaired with sutures following application of a hook plate.



Superior Lateral Plate



MIDSHAFT42™ Anterior Plate



MIDSHAFT42™ Superior Plate



Clavicle Hook Plate

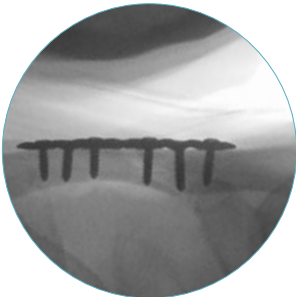


Anterior Lateral Plate

STEP 8

VERIFY PLACEMENT

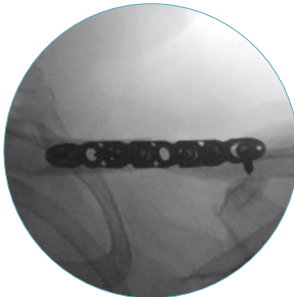
Using fluoroscopy, direct visualization, and palpation, verify correct reduction and fixation. Confirm screw placement in all planes, as angulation and direction may be difficult to visualize.



MIDSHAFT42™ Superior Plate



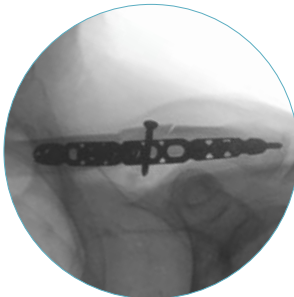
MIDSHAFT42™ Anterior Plate



Superior Lateral Plate



Anterior Lateral Plate



Clavicle Hook Plate



FINAL CONSTRUCTS



MIDSHAFT42™ Superior Plate



Superior Lateral Plate



MIDSHAFT42™ Anterior Plate



Anterior Lateral Plate



Clavicle Hook Plate

OPTIONAL: REMOVAL

For removal, detach the sutures from the construct. Use the T8 Driver for 2.5mm screws or T15 Driver for 3.5mm and 4.0mm screws 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 T8 or T15 Driver. Once all screws are removed, the plate may be removed.



Non Self-Retaining Drivers are recommended for removal.

INSTRUMENT OVERVIEW

RETRACTORS



Stabilizing Radiolucent Weitlaner, 2x3, 5", Sharp Tip 6171.0001



Stabilizing Radiolucent Weitlaner, 3x4, 8", Sharp Tip 6171.0002



Radiolucent Hohmann Retractor, 8mm 6179.7014



Radiolucent Hohmann Retractor, 15mm 6179.7015

RETRACTORS (CONT'D)



Hohmann Retractor, 15mm 6179.7017

REDUCTION INSTRUMENTS



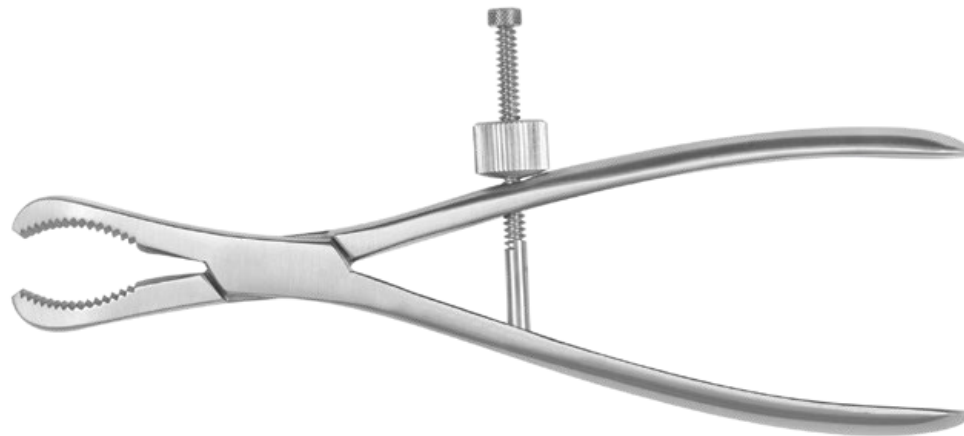
1.6mm K-Wire, Trocar Tip, 150mm 6179.1116



1.6mm K-Wire, Threaded Trocar Tip, 150mm 6171.1316



1.6mm Plate Holding K-Wire, Threaded Trocar Tip, 75mm 6179.1216

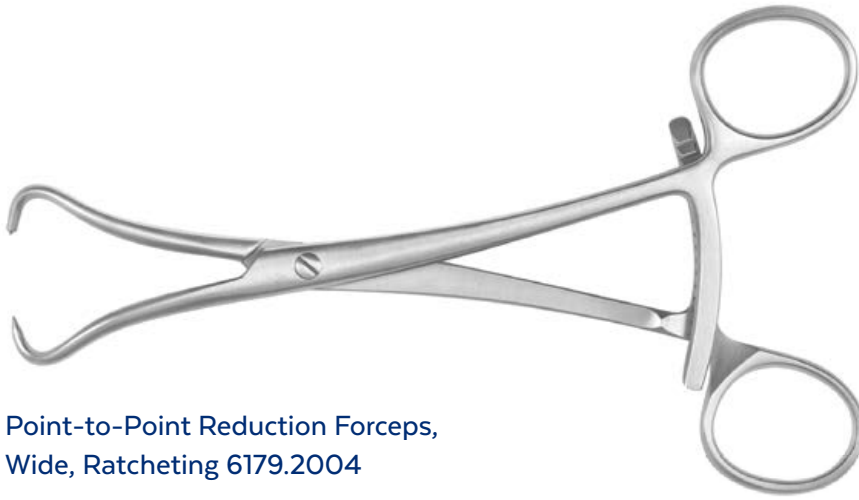


Bone Holding Clamp, Large 6168.2001

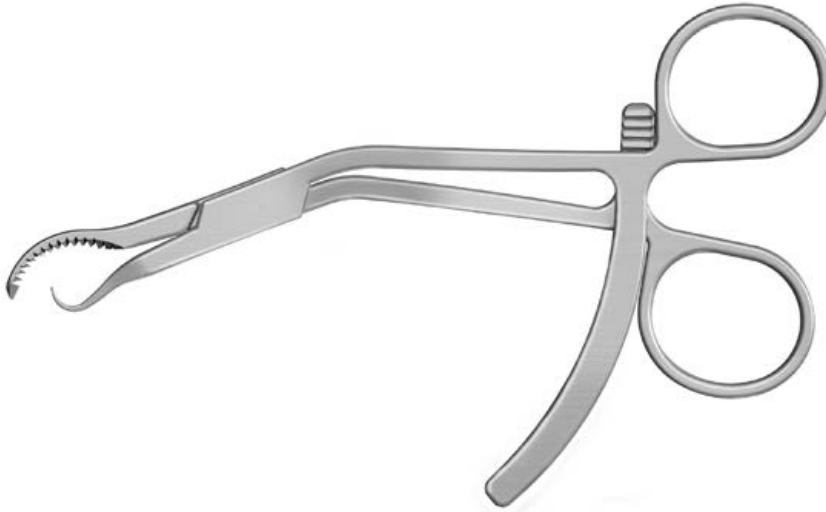


Lobster Claw Reduction Forceps, Ratcheting 6179.2001

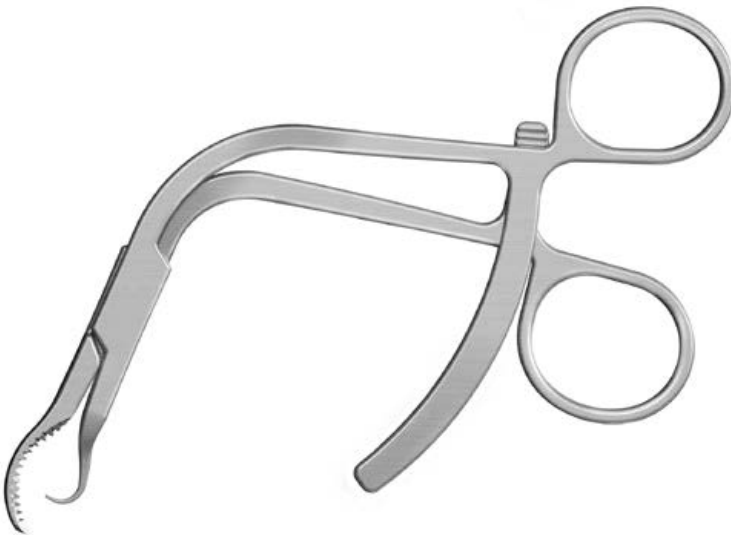
REDUCTION INSTRUMENTS (CONT'D)



Point-to-Point Reduction Forceps,
Wide, Ratcheting 6179.2004



Butterfly Fragment Clamp, Shallow Curve 6186.2001



Butterfly Fragment Clamp, Steep Curve 6186.2003

REDUCTION INSTRUMENTS (CONT'D)



Periosteal Elevator, Curved Round Tip, 6mm 6179.7019



Dental Pick, Large Handle 6179.7025



Periosteal Elevator, Straight Round Tip, 13mm 6186.9005

SCREW PREPARATION INSTRUMENTS



1.6mm K-wire Sleeve Insert 6179.3316



● 2.5mm Soft Tissue Protector 6186.3125



● 3.5mm Soft Tissue Protector 6186.3135



● 1.8mm Polyaxial Soft Tissue Protector 6171.3118



● 2.7mm Polyaxial Soft Tissue Protector 6186.3127

SCREW PREPARATION INSTRUMENTS (CONT'D)



○ 1.8mm Speed Lock Drill Guide 6171.3218



● ● 2.7mm Speed Lock Drill Guide 6171.3227



2.7mm Speed Lock Clamp 6186.3000



● 1.8mm Drill Bit, 100mm, AO Quick Connect 6171.5018



● 1.8mm Drill Bit, 140mm, AO Quick Connect 6179.5018

SCREW PREPARATION INSTRUMENTS (CONT'D)



- 2.5mm Drill Bit, 110mm, AO Quick Connect 6179.5025



- 2.5mm Drill Bit, 180mm, AO Quick Connect 6186.5025



- ● 2.7mm Drill Bit, 125mm, AO Quick Connect 6179.5027



- ● 2.7mm Drill Bit, 180mm, AO Quick Connect 6179.5028



- 3.5mm Drill Bit, 110mm, AO Quick Connect 6179.5035



- 3.5mm Drill Bit, 195mm, AO Quick Connect 6186.5035



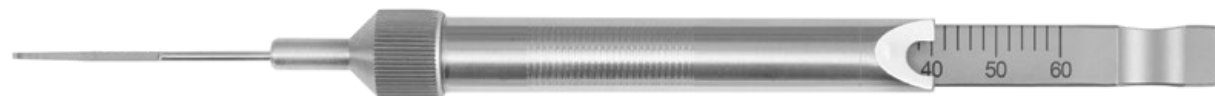
- 2.5mm Tap 6179.5125



- ● 3.5mm Tap 6179.5135



- Countersink 6179.7000



- Depth Gauge, 60mm 6179.7020

SCREW PREPARATION INSTRUMENTS (CONT'D)



Medium Handle, Ratcheting, Cannulated, AO Quick Connect 6179.7013



● Medium Torque Limiting Handle, 1.2Nm, AO Quick Connect 6171.7009



● Large Torque Limiting Handle, 2.5Nm, Cannulated, AO Quick Connect 6168.7011

SCREW INSTRUMENTS



Screw Holding Forceps 6179.2000



● T8 Driver, SR, 100mm, AO Quick Connect 6186.6008



● T8 Driver, SR, 160mm, AO Quick Connect 6186.6108

SCREW INSTRUMENTS (CONT'D)



● ● T15 Driver, SR, 100mm, AO Quick Connect 6186.6015



● ● T15 Driver, SR, 170mm, AO Quick Connect 6186.6115

PLATE BENDING INSTRUMENTS



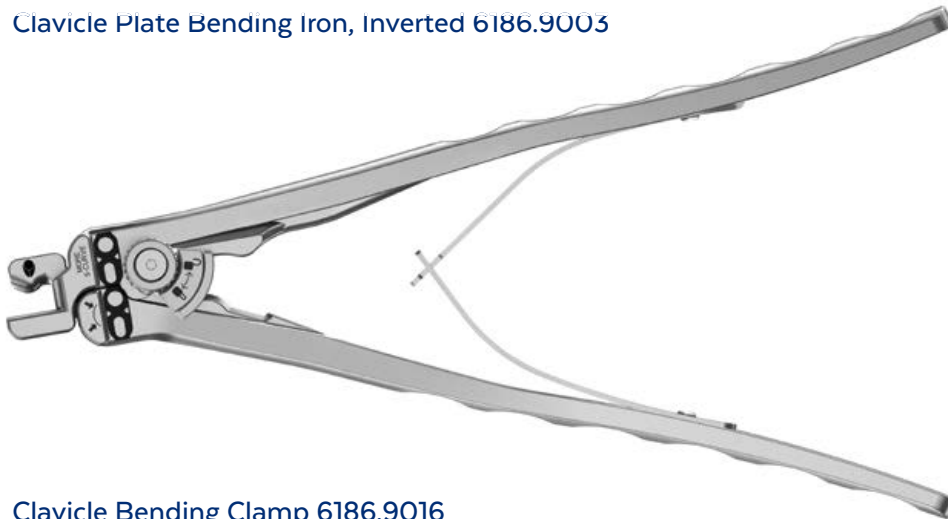
Clavicle Bending Template 6186.7005



Clavicle Plate Bending Iron 6186.9002



Clavicle Plate Bending Iron, Inverted 6186.9003



Clavicle Bending Clamp 6186.9016

ANTHEM[®] SS Clavicle Fracture System

IMPLANTS 9186.9002

PART NO.	DESCRIPTION	QTY
2186.1407	ANTHEM [®] MIDSHAFT42™ Superior Clavicle Plate, Left, Shallow Curve, 7 Holes, 75mm, SS	1
2186.1409	ANTHEM [®] MIDSHAFT42™ Superior Clavicle Plate, Left, Shallow Curve, 9 Holes, 95mm, SS	1
2186.1412	ANTHEM [®] MIDSHAFT42™ Superior Clavicle Plate, Left, Shallow Curve, 12 Holes, 125mm, SS	1
2186.2407	ANTHEM [®] MIDSHAFT42™ Superior Clavicle Plate, Right, Shallow Curve, 7 Holes, 75mm, SS	1
2186.2409	ANTHEM [®] MIDSHAFT42™ Superior Clavicle Plate, Right, Shallow Curve, 9 Holes, 95mm, SS	1
2186.2412	ANTHEM [®] MIDSHAFT42™ Superior Clavicle Plate, Right, Shallow Curve, 12 Holes, 125mm, SS	1
2186.1427	ANTHEM [®] MIDSHAFT42™ Superior Clavicle Plate, Left, Deep Curve, 7 Holes, 72mm, SS	1
2186.1429	ANTHEM [®] MIDSHAFT42™ Superior Clavicle Plate, Left, Deep Curve, 9 Holes, 91mm, SS	1
2186.1432	ANTHEM [®] MIDSHAFT42™ Superior Clavicle Plate, Left, Deep Curve, 12 Holes, 121mm, SS	1
2186.2427	ANTHEM [®] MIDSHAFT42™ Superior Clavicle Plate, Right, Deep Curve, 7 Holes, 72mm, SS	1
2186.2429	ANTHEM [®] MIDSHAFT42™ Superior Clavicle Plate, Right, Deep Curve, 9 Holes, 91mm, SS	1
2186.2432	ANTHEM [®] MIDSHAFT42™ Superior Clavicle Plate, Right, Deep Curve, 12 Holes, 121mm, SS	1
2186.2604	ANTHEM [®] Superior Lateral Clavicle Plate, Right, Shallow Curve, 4 Holes, 67mm, SS	1
2186.2606	ANTHEM [®] Superior Lateral Clavicle Plate, Right, Shallow Curve, 6 Holes, 86mm, SS	1
2186.2608	ANTHEM [®] Superior Lateral Clavicle Plate, Right, Shallow Curve, 8 Holes, 106mm, SS	1
2186.1604	ANTHEM [®] Superior Lateral Clavicle Plate, Left, Shallow Curve, 4 Holes, 67mm, SS	1
2186.1606	ANTHEM [®] Superior Lateral Clavicle Plate, Left, Shallow Curve, 6 Holes, 86mm, SS	1
2186.1608	ANTHEM [®] Superior Lateral Clavicle Plate, Left, Shallow Curve, 8 Holes, 106mm, SS	1
2186.2624	ANTHEM [®] Superior Lateral Clavicle Plate, Right, Deep Curve, 4 Holes, 66mm, SS	1
2186.2626	ANTHEM [®] Superior Lateral Clavicle Plate, Right, Deep Curve, 6 Holes, 83mm, SS	1
2186.2628	ANTHEM [®] Superior Lateral Clavicle Plate, Right, Deep Curve, 8 Holes, 102mm, SS	1
2186.1624	ANTHEM [®] Superior Lateral Clavicle Plate, Left, Deep Curve, 4 Holes, 66mm, SS	1
2186.1626	ANTHEM [®] Superior Lateral Clavicle Plate, Left, Deep Curve, 6 Holes, 83mm, SS	1
2186.1628	ANTHEM [®] Superior Lateral Clavicle Plate, Left, Deep Curve, 8 Holes, 102mm, SS	1
2186.0156	ANTHEM [®] MIDSHAFT42™ Anterior Clavicle Plate, Shallow Curve, 6 Holes, 72mm, SS	1
2186.0158	ANTHEM [®] MIDSHAFT42™ Anterior Clavicle Plate, Shallow Curve, 8 Holes, 87mm, SS	1
2186.0160	ANTHEM [®] MIDSHAFT42™ Anterior Clavicle Plate, Shallow Curve, 10 Holes, 107mm, SS	1
2186.0176	ANTHEM [®] MIDSHAFT42™ Anterior Clavicle Plate, Deep Curve, 6 Holes, 70mm, SS	1
2186.0178	ANTHEM [®] MIDSHAFT42™ Anterior Clavicle Plate, Deep Curve, 8 Holes, 85mm, SS	1
2186.0180	ANTHEM [®] MIDSHAFT42™ Anterior Clavicle Plate, Deep Curve, 10 Holes, 104mm, SS	1
2186.0207	ANTHEM [®] Anterior Lateral Clavicle Plate, Shallow Curve, 7 Holes, 63mm, SS	1
2186.0209	ANTHEM [®] Anterior Lateral Clavicle Plate, Shallow Curve, 9 Holes, 83mm, SS	1
2186.0211	ANTHEM [®] Anterior Lateral Clavicle Plate, Shallow Curve, 11 Holes, 103mm, SS	1
2186.0227	ANTHEM [®] Anterior Lateral Clavicle Plate, Deep Curve, 7 Holes, 60mm, SS	1
2186.0229	ANTHEM [®] Anterior Lateral Clavicle Plate, Deep Curve, 9 Holes, 79mm, SS	1
2186.0231	ANTHEM [®] Anterior Lateral Clavicle Plate, Deep Curve, 11 Holes, 99mm, SS	1

ADDITIONALLY AVAILABLE

2186.0213	ANTHEM [®] Anterior Lateral Clavicle Plate, Shallow Curve, 13 Holes, 122mm, SS
2186.0233	ANTHEM [®] Anterior Lateral Clavicle Plate, Deep Curve, 13 Holes, 119mm, SS

ANTHEM[®] SS Clavicle Fracture System

IMPLANTS 9186.9012

PART NO.	DESCRIPTION	QTY	PART NO.	DESCRIPTION	QTY
7171.5508	Locking Screw, 2.5x8mm, CoCr	4	7179.5012	Locking Screw, 3.5x12mm, CoCr	8
7171.5510	Locking Screw, 2.5x10mm, CoCr	4	7179.5014	Locking Screw, 3.5x14mm, CoCr	8
7171.5512	Locking Screw, 2.5x12mm, CoCr	8	7179.5016	Locking Screw, 3.5x16mm, CoCr	8
7171.5514	Locking Screw, 2.5x14mm, CoCr	8	7179.5018	Locking Screw, 3.5x18mm, CoCr	8
7171.5516	Locking Screw, 2.5x16mm, CoCr	8	7179.5020	Locking Screw, 3.5x20mm, CoCr	4
7171.5518	Locking Screw, 2.5x18mm, CoCr	8	7179.5022	Locking Screw, 3.5x22mm, CoCr	4
7171.5520	Locking Screw, 2.5x20mm, CoCr	4	7179.5024	Locking Screw, 3.5x24mm, CoCr	4
7171.5522	Locking Screw, 2.5x22mm, CoCr	4	7179.5026	Locking Screw, 3.5x26mm, CoCr	4
7171.5524	Locking Screw, 2.5x24mm, CoCr	4	7179.5028	Locking Screw, 3.5x28mm, CoCr	4
7171.5526	Locking Screw, 2.5x26mm, CoCr	4	7179.5030	Locking Screw, 3.5x30mm, CoCr	4
7171.5528	Locking Screw, 2.5x28mm, CoCr	4	2179.3008	Non-Locking Screw, 3.5x8mm, SS	4
7171.5530	Locking Screw, 2.5x30mm, CoCr	4	2179.3010	Non-Locking Screw, 3.5x10mm, SS	4
7171.5532	Locking Screw, 2.5x32mm, CoCr	4	2179.3012	Non-Locking Screw, 3.5x12mm, SS	8
2171.6508	Non-Locking Screw, 2.5x8mm, SS	4	2179.3014	Non-Locking Screw, 3.5x14mm, SS	8
2171.6510	Non-Locking Screw, 2.5x10mm, SS	4	2179.3016	Non-Locking Screw, 3.5x16mm, SS	8
2171.6512	Non-Locking Screw, 2.5x12mm, SS	8	2179.3018	Non-Locking Screw, 3.5x18mm, SS	8
2171.6514	Non-Locking Screw, 2.5x14mm, SS	8	2179.3020	Non-Locking Screw, 3.5x20mm, SS	4
2171.6516	Non-Locking Screw, 2.5x16mm, SS	8	2179.3022	Non-Locking Screw, 3.5x22mm, SS	4
2171.6518	Non-Locking Screw, 2.5x18mm, SS	8	2179.3024	Non-Locking Screw, 3.5x24mm, SS	4
2171.6520	Non-Locking Screw, 2.5x20mm, SS	4	2179.3026	Non-Locking Screw, 3.5x26mm, SS	4
2171.6522	Non-Locking Screw, 2.5x22mm, SS	4	2179.3028	Non-Locking Screw, 3.5x28mm, SS	4
2171.6524	Non-Locking Screw, 2.5x24mm, SS	4	2179.3030	Non-Locking Screw, 3.5x30mm, SS	4
2171.6526	Non-Locking Screw, 2.5x26mm, SS	4	2179.3035	Non-Locking Screw, 3.5x35mm, SS	4
2171.6528	Non-Locking Screw, 2.5x28mm, SS	4	2179.3040	Non-Locking Screw, 3.5x40mm, SS	4
2171.6530	Non-Locking Screw, 2.5x30mm, SS	4	2179.3045	Non-Locking Screw, 3.5x45mm, SS	4
2171.6532	Non-Locking Screw, 2.5x32mm, SS	4	2179.3050	Non-Locking Screw, 3.5x50mm, SS	4
7171.7508	Positioning Screw, 2.5x8mm, CoCr	4	2179.4008	Cancellous Screw, 4.0x8mm, Fully Threaded, SS	4
7171.7510	Positioning Screw, 2.5x10mm, CoCr	4	2179.4010	Cancellous Screw, 4.0x10mm, Fully Threaded, SS	4
7171.7512	Positioning Screw, 2.5x12mm, CoCr	8	2179.4012	Cancellous Screw, 4.0x12mm, Fully Threaded, SS	8
7171.7514	Positioning Screw, 2.5x14mm, CoCr	8	2179.4014	Cancellous Screw, 4.0x14mm, Fully Threaded, SS	8
7171.7516	Positioning Screw, 2.5x16mm, CoCr	8	2179.4016	Cancellous Screw, 4.0x16mm, Fully Threaded, SS	8
7171.7518	Positioning Screw, 2.5x18mm, CoCr	8	2179.4018	Cancellous Screw, 4.0x18mm, Fully Threaded, SS	8
7171.7520	Positioning Screw, 2.5x20mm, CoCr	4	2179.4020	Cancellous Screw, 4.0x20mm, Fully Threaded, SS	4
7171.7522	Positioning Screw, 2.5x22mm, CoCr	4	2179.4022	Cancellous Screw, 4.0x22mm, Fully Threaded, SS	4
7171.7524	Positioning Screw, 2.5x24mm, CoCr	4	2179.4024	Cancellous Screw, 4.0x24mm, Fully Threaded, SS	4
7171.7526	Positioning Screw, 2.5x26mm, CoCr	4	2179.4026	Cancellous Screw, 4.0x26mm, Fully Threaded, SS	4
7171.7528	Positioning Screw, 2.5x28mm, CoCr	4	2179.4028	Cancellous Screw, 4.0x28mm, Fully Threaded, SS	4
7171.7530	Positioning Screw, 2.5x30mm, CoCr	4	2179.4030	Cancellous Screw, 4.0x30mm, Fully Threaded, SS	4
7179.5008	Locking Screw, 3.5x8mm, CoCr	4			
7179.5010	Locking Screw, 3.5x10mm, CoCr	4			

ANTHEM[®] SS Clavicle Fracture System

IMPLANTS 9186.9022

PART NO.	DESCRIPTION	QTY
2186.4404	ANTHEM [®] Clavicle Hook Plate, 14mm Hook, Right, Shallow Curve, 4 Holes, 67mm, SS	1
2186.4406	ANTHEM [®] Clavicle Hook Plate, 14mm Hook, Right, Shallow Curve, 6 Holes, 86mm, SS	1
2186.4408	ANTHEM [®] Clavicle Hook Plate, 14mm Hook, Right, Shallow Curve, 8 Holes, 106mm, SS	1
2186.4428	ANTHEM [®] Clavicle Hook Plate, 14mm Hook, Right, Deep Curve, 8 Holes, 102mm, SS	1
2186.3404	ANTHEM [®] Clavicle Hook Plate, 14mm Hook, Left, Shallow Curve, 4 Holes, 67mm, SS	1
2186.3406	ANTHEM [®] Clavicle Hook Plate, 14mm Hook, Left, Shallow Curve, 6 Holes, 86mm, SS	1
2186.3408	ANTHEM [®] Clavicle Hook Plate, 14mm Hook, Left, Shallow Curve, 8 Holes, 106mm, SS	1
2186.3428	ANTHEM [®] Clavicle Hook Plate, 14mm Hook, Left, Deep Curve, 8 Holes, 102mm, SS	1
2186.4604	ANTHEM [®] Clavicle Hook Plate, 16mm Hook, Right, Shallow Curve, 4 Holes, 67mm, SS	1
2186.4606	ANTHEM [®] Clavicle Hook Plate, 16mm Hook, Right, Shallow Curve, 6 Holes, 86mm, SS	1
2186.4608	ANTHEM [®] Clavicle Hook Plate, 16mm Hook, Right, Shallow Curve, 8 Holes, 106mm, SS	1
2186.4628	ANTHEM [®] Clavicle Hook Plate, 16mm Hook, Right, Deep Curve, 8 Holes, 102mm, SS	1
2186.3604	ANTHEM [®] Clavicle Hook Plate, 16mm Hook, Left, Shallow Curve, 4 Holes, 67mm, SS	1
2186.3606	ANTHEM [®] Clavicle Hook Plate, 16mm Hook, Left, Shallow Curve, 6 Holes, 86mm, SS	1
2186.3608	ANTHEM [®] Clavicle Hook Plate, 16mm Hook, Left, Shallow Curve, 8 Holes, 106mm, SS	1
2186.3628	ANTHEM [®] Clavicle Hook Plate, 16mm Hook, Left, Deep Curve, 8 Holes, 102mm, SS	1
2186.4804	ANTHEM [®] Clavicle Hook Plate, 18mm Hook, Right, Shallow Curve, 4 Holes, 67mm, SS	1
2186.4806	ANTHEM [®] Clavicle Hook Plate, 18mm Hook, Right, Shallow Curve, 6 Holes, 86mm, SS	1
2186.4808	ANTHEM [®] Clavicle Hook Plate, 18mm Hook, Right, Shallow Curve, 8 Holes, 106mm, SS	1
2186.4828	ANTHEM [®] Clavicle Hook Plate, 18mm Hook, Right, Deep Curve, 8 Holes, 102mm, SS	1
2186.3804	ANTHEM [®] Clavicle Hook Plate, 18mm Hook, Left, Shallow Curve, 4 Holes, 67mm, SS	1
2186.3806	ANTHEM [®] Clavicle Hook Plate, 18mm Hook, Left, Shallow Curve, 6 Holes, 86mm, SS	1
2186.3808	ANTHEM [®] Clavicle Hook Plate, 18mm Hook, Left, Shallow Curve, 8 Holes, 106mm, SS	1
2186.3828	ANTHEM [®] Clavicle Hook Plate, 18mm Hook, Left, Deep Curve, 8 Holes, 102mm, SS	1

ANTHEM[®] Ti Clavicle Fracture System

IMPLANTS 9186.9001

PART NO.	DESCRIPTION	QTY
1186.1407	ANTHEM [®] MIDSHAFT42™ Superior Clavicle Plate, Left, Shallow Curve, 7 Holes, 75mm, Ti	1
1186.1409	ANTHEM [®] MIDSHAFT42™ Superior Clavicle Plate, Left, Shallow Curve, 9 Holes, 95mm, Ti	1
1186.1412	ANTHEM [®] MIDSHAFT42™ Superior Clavicle Plate, Left, Shallow Curve, 12 Holes, 125mm, Ti	1
1186.2407	ANTHEM [®] MIDSHAFT42™ Superior Clavicle Plate, Right, Shallow Curve, 7 Holes, 75mm, Ti	1
1186.2409	ANTHEM [®] MIDSHAFT42™ Superior Clavicle Plate, Right, Shallow Curve, 9 Holes, 95mm, Ti	1
1186.2412	ANTHEM [®] MIDSHAFT42™ Superior Clavicle Plate, Right, Shallow Curve, 12 Holes, 125mm, Ti	1
1186.1427	ANTHEM [®] MIDSHAFT42™ Superior Clavicle Plate, Left, Deep Curve, 7 Holes, 72mm, Ti	1
1186.1429	ANTHEM [®] MIDSHAFT42™ Superior Clavicle Plate, Left, Deep Curve, 9 Holes, 91mm, Ti	1
1186.1432	ANTHEM [®] MIDSHAFT42™ Superior Clavicle Plate, Left, Deep Curve, 12 Holes, 121mm, Ti	1
1186.2427	ANTHEM [®] MIDSHAFT42™ Superior Clavicle Plate, Right, Deep Curve, 7 Holes, 72mm, Ti	1
1186.2429	ANTHEM [®] MIDSHAFT42™ Superior Clavicle Plate, Right, Deep Curve, 9 Holes, 91mm, Ti	1
1186.2432	ANTHEM [®] MIDSHAFT42™ Superior Clavicle Plate, Right, Deep Curve, 12 Holes, 121mm, Ti	1
1186.2604	ANTHEM [®] Superior Lateral Clavicle Plate, Right, Shallow Curve, 4 Holes, 67mm, Ti	1
1186.2606	ANTHEM [®] Superior Lateral Clavicle Plate, Right, Shallow Curve, 6 Holes, 86mm, Ti	1
1186.2608	ANTHEM [®] Superior Lateral Clavicle Plate, Right, Shallow Curve, 8 Holes, 106mm, Ti	1
1186.1604	ANTHEM [®] Superior Lateral Clavicle Plate, Left, Shallow Curve, 4 Holes, 67mm, Ti	1
1186.1606	ANTHEM [®] Superior Lateral Clavicle Plate, Left, Shallow Curve, 6 Holes, 86mm, Ti	1
1186.1608	ANTHEM [®] Superior Lateral Clavicle Plate, Left, Shallow Curve, 8 Holes, 106mm, Ti	1
1186.2624	ANTHEM [®] Superior Lateral Clavicle Plate, Right, Deep Curve, 4 Holes, 66mm, Ti	1
1186.2626	ANTHEM [®] Superior Lateral Clavicle Plate, Right, Deep Curve, 6 Holes, 83mm, Ti	1
1186.2628	ANTHEM [®] Superior Lateral Clavicle Plate, Right, Deep Curve, 8 Holes, 102mm, Ti	1
1186.1624	ANTHEM [®] Superior Lateral Clavicle Plate, Left, Deep Curve, 4 Holes, 66mm, Ti	1
1186.1626	ANTHEM [®] Superior Lateral Clavicle Plate, Left, Deep Curve, 6 Holes, 83mm, Ti	1
1186.1628	ANTHEM [®] Superior Lateral Clavicle Plate, Left, Deep Curve, 8 Holes, 102mm, Ti	1
1186.0156	ANTHEM [®] MIDSHAFT42™ Anterior Clavicle Plate, Shallow Curve, 6 Holes, 72mm, Ti	1
1186.0158	ANTHEM [®] MIDSHAFT42™ Anterior Clavicle Plate, Shallow Curve, 8 Holes, 87mm, Ti	1
1186.0160	ANTHEM [®] MIDSHAFT42™ Anterior Clavicle Plate, Shallow Curve, 10 Holes, 107mm, Ti	1
1186.0176	ANTHEM [®] MIDSHAFT42™ Anterior Clavicle Plate, Deep Curve, 6 Holes, 70mm, Ti	1
1186.0178	ANTHEM [®] MIDSHAFT42™ Anterior Clavicle Plate, Deep Curve, 8 Holes, 85mm, Ti	1
1186.0180	ANTHEM [®] MIDSHAFT42™ Anterior Clavicle Plate, Deep Curve, 10 Holes, 104mm, Ti	1
1186.0207	ANTHEM [®] Anterior Lateral Clavicle Plate, Shallow Curve, 7 Holes, 63mm, Ti	1
1186.0209	ANTHEM [®] Anterior Lateral Clavicle Plate, Shallow Curve, 9 Holes, 83mm, Ti	1
1186.0211	ANTHEM [®] Anterior Lateral Clavicle Plate, Shallow Curve, 11 Holes, 103mm, Ti	1
1186.0227	ANTHEM [®] Anterior Lateral Clavicle Plate, Deep Curve, 7 Holes, 60mm, Ti	1
1186.0229	ANTHEM [®] Anterior Lateral Clavicle Plate, Deep Curve, 9 Holes, 79mm, Ti	1
1186.0231	ANTHEM [®] Anterior Lateral Clavicle Plate, Deep Curve, 11 Holes, 99mm, Ti	1

ADDITIONALLY AVAILABLE

1186.0213	ANTHEM [®] Anterior Lateral Clavicle Plate, Shallow Curve, 13 Holes, 122mm, Ti
1186.0233	ANTHEM [®] Anterior Lateral Clavicle Plate, Deep Curve, 13 Holes, 119mm, Ti

ANTHEM[®] Ti Clavicle Fracture System

IMPLANTS 9186.9011

PART NO.	DESCRIPTION	QTY	PART NO.	DESCRIPTION	QTY
7171.5508	Locking Screw, 2.5x8mm, CoCr	4	7179.5012	Locking Screw, 3.5x12mm, CoCr	8
7171.5510	Locking Screw, 2.5x10mm, CoCr	4	7179.5014	Locking Screw, 3.5x14mm, CoCr	8
7171.5512	Locking Screw, 2.5x12mm, CoCr	8	7179.5016	Locking Screw, 3.5x16mm, CoCr	8
7171.5514	Locking Screw, 2.5x14mm, CoCr	8	7179.5018	Locking Screw, 3.5x18mm, CoCr	8
7171.5516	Locking Screw, 2.5x16mm, CoCr	8	7179.5020	Locking Screw, 3.5x20mm, CoCr	4
7171.5518	Locking Screw, 2.5x18mm, CoCr	8	7179.5022	Locking Screw, 3.5x22mm, CoCr	4
7171.5520	Locking Screw, 2.5x20mm, CoCr	4	7179.5024	Locking Screw, 3.5x24mm, CoCr	4
7171.5522	Locking Screw, 2.5x22mm, CoCr	4	7179.5026	Locking Screw, 3.5x26mm, CoCr	4
7171.5524	Locking Screw, 2.5x24mm, CoCr	4	7179.5028	Locking Screw, 3.5x28mm, CoCr	4
7171.5526	Locking Screw, 2.5x26mm, CoCr	4	7179.5030	Locking Screw, 3.5x30mm, CoCr	4
7171.5528	Locking Screw, 2.5x28mm, CoCr	4	1179.3008	Non-Locking Screw, 3.5x8mm, Ti	4
7171.5530	Locking Screw, 2.5x30mm, CoCr	4	1179.3010	Non-Locking Screw, 3.5x10mm, Ti	4
7171.5532	Locking Screw, 2.5x32mm, CoCr	4	1179.3012	Non-Locking Screw, 3.5x12mm, Ti	8
1171.6508	Non-Locking Screw, 2.5x8mm, Ti	4	1179.3014	Non-Locking Screw, 3.5x14mm, Ti	8
1171.6510	Non-Locking Screw, 2.5x10mm, Ti	4	1179.3016	Non-Locking Screw, 3.5x16mm, Ti	8
1171.6512	Non-Locking Screw, 2.5x12mm, Ti	8	1179.3018	Non-Locking Screw, 3.5x18mm, Ti	8
1171.6514	Non-Locking Screw, 2.5x14mm, Ti	8	1179.3020	Non-Locking Screw, 3.5x20mm, Ti	4
1171.6516	Non-Locking Screw, 2.5x16mm, Ti	8	1179.3022	Non-Locking Screw, 3.5x22mm, Ti	4
1171.6518	Non-Locking Screw, 2.5x18mm, Ti	8	1179.3024	Non-Locking Screw, 3.5x24mm, Ti	4
1171.6520	Non-Locking Screw, 2.5x20mm, Ti	4	1179.3026	Non-Locking Screw, 3.5x26mm, Ti	4
1171.6522	Non-Locking Screw, 2.5x22mm, Ti	4	1179.3028	Non-Locking Screw, 3.5x28mm, Ti	4
1171.6524	Non-Locking Screw, 2.5x24mm, Ti	4	1179.3030	Non-Locking Screw, 3.5x30mm, Ti	4
1171.6526	Non-Locking Screw, 2.5x26mm, Ti	4	1179.3035	Non-Locking Screw, 3.5x35mm, Ti	4
1171.6528	Non-Locking Screw, 2.5x28mm, Ti	4	1179.3040	Non-Locking Screw, 3.5x40mm, Ti	4
1171.6530	Non-Locking Screw, 2.5x30mm, Ti	4	1179.3045	Non-Locking Screw, 3.5x45mm, Ti	4
1171.6532	Non-Locking Screw, 2.5x32mm, Ti	4	1179.3050	Non-Locking Screw, 3.5x50mm, Ti	4
7171.7508	Positioning Screw, 2.5x8mm, CoCr	4	1179.4008	Cancellous Screw, 4.0x8mm, Fully Threaded, Ti	4
7171.7510	Positioning Screw, 2.5x10mm, CoCr	4	1179.4010	Cancellous Screw, 4.0x10mm, Fully Threaded, Ti	4
7171.7512	Positioning Screw, 2.5x12mm, CoCr	8	1179.4012	Cancellous Screw, 4.0x12mm, Fully Threaded, Ti	8
7171.7514	Positioning Screw, 2.5x14mm, CoCr	8	1179.4014	Cancellous Screw, 4.0x14mm, Fully Threaded, Ti	8
7171.7516	Positioning Screw, 2.5x16mm, CoCr	8	1179.4016	Cancellous Screw, 4.0x16mm, Fully Threaded, Ti	8
7171.7518	Positioning Screw, 2.5x18mm, CoCr	8	1179.4018	Cancellous Screw, 4.0x18mm, Fully Threaded, Ti	8
7171.7520	Positioning Screw, 2.5x20mm, CoCr	4	1179.4020	Cancellous Screw, 4.0x20mm, Fully Threaded, Ti	4
7171.7522	Positioning Screw, 2.5x22mm, CoCr	4	1179.4022	Cancellous Screw, 4.0x22mm, Fully Threaded, Ti	4
7171.7524	Positioning Screw, 2.5x24mm, CoCr	4	1179.4024	Cancellous Screw, 4.0x24mm, Fully Threaded, Ti	4
7171.7526	Positioning Screw, 2.5x26mm, CoCr	4	1179.4026	Cancellous Screw, 4.0x26mm, Fully Threaded, Ti	4
7171.7528	Positioning Screw, 2.5x28mm, CoCr	4	1179.4028	Cancellous Screw, 4.0x28mm, Fully Threaded, Ti	4
7171.7530	Positioning Screw, 2.5x30mm, CoCr	4	1179.4030	Cancellous Screw, 4.0x30mm, Fully Threaded, Ti	4
7179.5008	Locking Screw, 3.5x8mm, CoCr	4			
7179.5010	Locking Screw, 3.5x10mm, CoCr	4			

ANTHEM[®] Ti Clavicle Fracture System

IMPLANTS 9186.9021

PART NO.	DESCRIPTION	QTY
1186.4404	ANTHEM [®] Clavicle Hook Plate, 14mm Hook Right, Shallow Curve, 4 Holes, 67mm, Ti	1
1186.4406	ANTHEM [®] Clavicle Hook Plate, 14mm Hook Right, Shallow Curve, 6 Holes, 86mm, Ti	1
1186.4408	ANTHEM [®] Clavicle Hook Plate, 14mm Hook Right, Shallow Curve, 8 Holes, 106mm, Ti	1
1186.4428	ANTHEM [®] Clavicle Hook Plate, 14mm Hook Right, Deep Curve, 8 Holes, 102mm, Ti	1
1186.3404	ANTHEM [®] Clavicle Hook Plate, 14mm Hook Left, Shallow Curve, 4 Holes, 67mm, Ti	1
1186.3406	ANTHEM [®] Clavicle Hook Plate, 14mm Hook Left, Shallow Curve, 6 Holes, 86mm, Ti	1
1186.3408	ANTHEM [®] Clavicle Hook Plate, 14mm Hook Left, Shallow Curve, 8 Holes, 106mm, Ti	1
1186.3428	ANTHEM [®] Clavicle Hook Plate, 14mm Hook Left, Deep Curve, 8 Holes, 102mm, Ti	1
1186.4604	ANTHEM [®] Clavicle Hook Plate, 16mm Hook Right, Shallow Curve, 4 Holes, 67mm, Ti	1
1186.4606	ANTHEM [®] Clavicle Hook Plate, 16mm Hook Right, Shallow Curve, 6 Holes, 86mm, Ti	1
1186.4608	ANTHEM [®] Clavicle Hook Plate, 16mm Hook Right, Shallow Curve, 8 Holes, 106mm, Ti	1
1186.4628	ANTHEM [®] Clavicle Hook Plate, 16mm Hook Right, Deep Curve, 8 Holes, 102mm, Ti	1
1186.3604	ANTHEM [®] Clavicle Hook Plate, 16mm Hook Left, Shallow Curve, 4 Holes, 67mm, Ti	1
1186.3606	ANTHEM [®] Clavicle Hook Plate, 16mm Hook Left, Shallow Curve, 6 Holes, 86mm, Ti	1
1186.3608	ANTHEM [®] Clavicle Hook Plate, 16mm Hook Left, Shallow Curve, 8 Holes, 106mm, Ti	1
1186.3628	ANTHEM [®] Clavicle Hook Plate, 16mm Hook Left, Deep Curve, 8 Holes, 102mm, Ti	1
1186.4804	ANTHEM [®] Clavicle Hook Plate, 18mm Hook Right, Shallow Curve, 4 Holes, 67mm, Ti	1
1186.4806	ANTHEM [®] Clavicle Hook Plate, 18mm Hook Right, Shallow Curve, 6 Holes, 86mm, Ti	1
1186.4808	ANTHEM [®] Clavicle Hook Plate, 18mm Hook Right, Shallow Curve, 8 Holes, 106mm, Ti	1
1186.4828	ANTHEM [®] Clavicle Hook Plate, 18mm Hook Right, Deep Curve, 8 Holes, 102mm, Ti	1
1186.3804	ANTHEM [®] Clavicle Hook Plate, 18mm Hook Left, Shallow Curve, 4 Holes, 67mm, Ti	1
1186.3806	ANTHEM [®] Clavicle Hook Plate, 18mm Hook Left, Shallow Curve, 6 Holes, 86mm, Ti	1
1186.3808	ANTHEM [®] Clavicle Hook Plate, 18mm Hook Left, Shallow Curve, 8 Holes, 106mm, Ti	1
1186.3828	ANTHEM [®] Clavicle Hook Plate, 18mm Hook Left, Deep Curve, 8 Holes, 102mm, Ti	1

ANTHEM[®] Clavicle Fracture System

INSTRUMENTS 9186.9001 & 9186.9002

PART NO.	DESCRIPTION	QTY
6168.2001	Bone Holding Clamp, Large	1
6168.7011	Torque Limiting Handle, 2.5Nm, AO Quick Connect	1
6171.0001	Stabilizing Radiolucent Weitlaners, 2x3, 6", Sharp Tip	1
6171.0002	Radiolucent Weitlaners, 3x4, 8", Sharp Tip	1
6171.1316	1.6mm K-Wire, Threaded Trocar Tip, 150mm	10
6171.3118	1.8mm Polyaxial Soft Tissue Protector	1
6171.3218	1.8mm Speed Lock Drill Guide	1
6171.5018	1.8mm Drill Bit, 100mm, AO Quick Connect	2
6171.7009	Torque Limiting Handle, 1.2Nm, AO Quick Connect	1
6179.1116	1.6mm K-Wire, Trocar Tip, 150mm	10
6179.1216	1.6mm Plate Holding K-Wire, Threaded Trocar Tip, 75mm	5
6179.2000	Screw Holding Forceps	1
6179.2001	Lobster Claw Reduction Forceps, Ratcheting	2
6179.2004	Point-to-Point Reduction Forceps, Wide, Ratcheting	3
6171.3227	2.7mm Speed Lock Drill Guide	1
6179.3316	1.6mm K-Wire Sleeve Insert	2
6179.5018	1.8mm Drill Bit, 140mm, AO Quick Connect	2
6179.5025	2.5mm Drill Bit, 110mm, AO Quick Connect	2
6179.5027	2.7mm Drill Bit, 125mm, AO Quick Connect	2
6179.5028	2.7mm Drill Bit, 180mm, AO Quick Connect	2
6179.5035	3.5mm Drill Bit, 110mm, AO Quick Connect	2
6179.5125	2.5mm Tap	1
6179.5135	3.5mm Tap	1
6179.7000	Countersink	1
6179.7013	Ratcheting Handle	2

PART NO.	DESCRIPTION	QTY
6179.7014	Radiolucent Hohmann Retractor, 8mm	2
6179.7015	Radiolucent Hohmann Retractor, 15mm	2
6179.7017	Hohmann Retractor, 15mm	1
6179.7019	Periosteal Elevator, Curved Round Tip, 6mm	1
6179.7020	Depth Gauge, 60mm	1
6179.7025	Dental Pick, Large Handle	1
6186.2001	Butterfly Fragment Clamp, Shallow Curve	1
6186.2003	Butterfly Fragment Clamp, Steep Curve	1
6186.3000	2.7mm Speed Lock Clamp	1
6186.3125	2.5mm Soft Tissue Protector	1
6186.3127	2.7mm Polyaxial Soft Tissue Protector	1
6186.3135	3.5mm Soft Tissue Protector	1
6186.3504	Targeting Guide, Superior Lateral Clavicle Plate, Left	1
6186.3505	Targeting Guide, Superior Lateral Clavicle Plate, Right	1
6186.5025	2.5mm Drill Bit, 180mm, AO Quick Connect	2
6186.5035	3.5mm Drill Bit, 195mm, AO Quick Connect	2
6186.6008	T8 Driver, SR, 100mm, AO Quick Connect	2
6186.6015	T15 Driver, SR, 100mm, AO Quick Connect	2
6186.6108	T8 Driver, SR, 160mm, AO Quick Connect	2
6186.6115	T15 Driver, SR, 170mm, AO Quick Connect	2
6186.7005	Clavicle Bending Template	5
6186.9002	Plate Bending Iron, Clavicle	1
6186.9003	Plate Bending Iron, Clavicle, Inverted	1
6186.9005	Periosteal Elevator, Straight Round Tip, 13mm	1
6186.9016	Clavicle Plate Bending Clamp	1
6186.3518	Targeting Guide Drill Sleeve	2

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, titanium alloy, cobalt chromium molybdenum alloy, or stainless steel, as specified in ASTM F67, F136, F1295, F1472, F1537, F2229, F138 and F139. 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. The clavicle hook plate may be used for dislocations of the acromioclavicular joint. Mini fragment plates are also indicated for fixation of fractures of the acetabulum, patella, and bone fragments, replantation, malunions and nonunions, and for non-load bearing stabilization and reduction of long bone fragments.

Small fragment, mini fragment, proximal tibia, clavicle and distal fibula plates may be used in all pediatric subgroups (except neonates) and small stature adults. Distal radius and mini fragment plates may be used in adolescents (12-21 years of age). Plating may be used in patients with osteopenic bone.

CONTRAINDICATIONS

Use of these implants is contraindicated in patients with the following conditions:

- 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.

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.

PRECAUTIONS

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

These devices have not been evaluated for safety and compatibility in the MR environment. It has 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.

CAUTIONS

Pre-operative

- These implants are for 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 result 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, osteomalacia, 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.

IMPORTANT INFORMATION ON ANTHEM® FRACTURE SYSTEM

- Improper alignment can cause a mal-union 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.
- 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 accidentally 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 and instrument trays and cases 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 Enzo® (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 Enzo® (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 to ensure an 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 in² total, or a minimum of four (4) 7.5in 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:

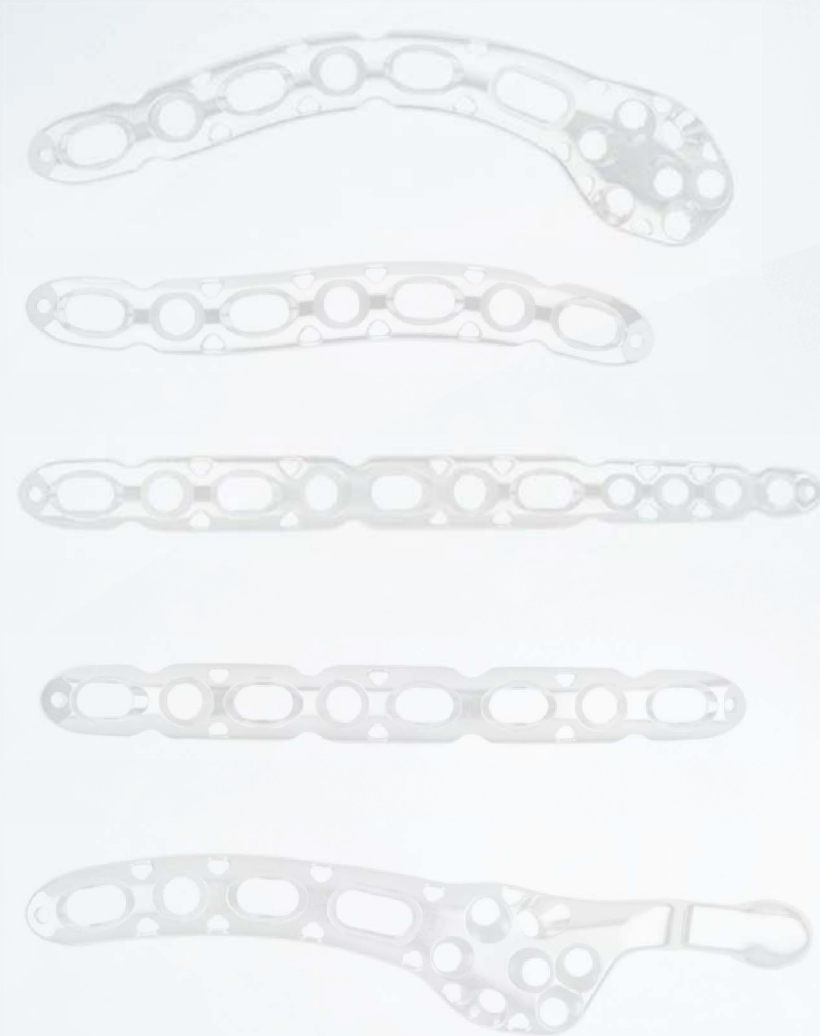
Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Pre-vacuum	132°C (270°F)	4 Minutes	30 Minutes

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			
	CATALOGUE NUMBER		STERILIZED BY IRRADIATION
	LOT NUMBER		AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	CAUTION		MANUFACTURER
	SINGLE USE ONLY		USE BY (YYYY-MM-DD)
	QUANTITY		PRESCRIPTION USE ONLY

DI201 REV D



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)

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