ANTHEM®

Ankle Fracture System

SURGICAL TECHNIQUE GUIDE

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

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SURGICAL TECHNIQUE GUIDE

ANTHEM®

Ankle Fracture System

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Ankle Fracture System

The ANTHEM® Ankle Fracture System provides low profile, anatomically contoured plates in a comprehensive set to treat a variety of ankle fractures.

The system features the Posterolateral Distal Fibula Plate and two styles of Lateral Distal Fibula Plates to accommodate surgical preference. One Third Tubular Plates, Hook Plates, Reconstruction Plates, and T-Plates are also included.

A specialized set of instruments facilitates the efficient treatment of ankle fractures. Ankle-specific clamps are provided to help with fracture reduction. Radiolucent retractors and Weitlaners aid in visibility of the fracture site during intraoperative imaging.

Lateral Distal Fibula Plate

Universal Distal Fibula Plate

Posterolateral Distal Fibula Plate

Hook Plate

One Third Tubular Plate

Reconstruction Plate

T-Plate

Anatomic Contour

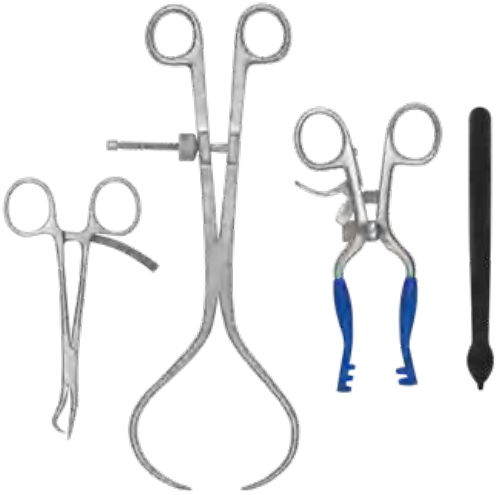
Three types of distal fibula plates are available with contours that match patient anatomy and minimize the need for intraoperative bending.

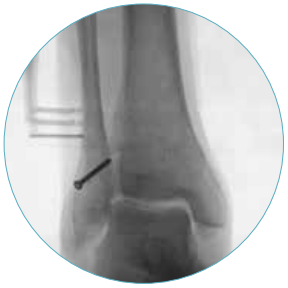
Low Profile Design

Low profile plates are designed for minimal screw prominence to help reduce soft tissue irritation.

Unique Instruments

Clamps designed specifically for ankle anatomy facilitate fracture reduction. Radiolucent Weitlaners and retractors aid in fracture site visibility.





Comprehensive System

A comprehensive selection of implants and instruments are provided to treat a variety of ankle fractures.

IMPLANT OVERVIEW

Lateral Distal Fibula Plate

- Low profile design to minimize soft tissue irritation
- Robust screw cluster of 2.5mm holes allows up to seven points of distal fixation
- Versatile syndesmotic holes accept 3.5mm and 4.0mm screws or suture buttons
- 3 to 15 hole plates (75–228mm) in left and right orientations
- Available in stainless steel and titanium

Universal Distal Fibula Plate

- Accepts 3.5mm or 4.0mm screws throughout entire plate, eliminating the need for multiple drills and drivers
- One plate configuration for left or right fibula
- Versatile syndesmotic holes accept 3.5mm and 4.0mm screws or suture buttons
- 5 to 7 hole plates (101–126mm)
- Available in stainless steel and titanium

Posterolateral Distal Fibula Plate

- Narrow distal profile designed to minimize peroneal irritation
- Scallops for syndesmotic fixation adjacent to the plate
- Versatile syndesmotic holes accept 3.5mm and 4.0mm screws or suture buttons
- 3 to 15 hole plates (70–233mm) in left and right orientations
- Available in stainless steel and titanium

Hook Plate

- Hooks aid in capturing distal fragments
- Low profile design to minimize soft tissue irritation
- Accepts 3.5mm and 4.0mm non-locking and cancellous screws
- Available in stainless steel and titanium

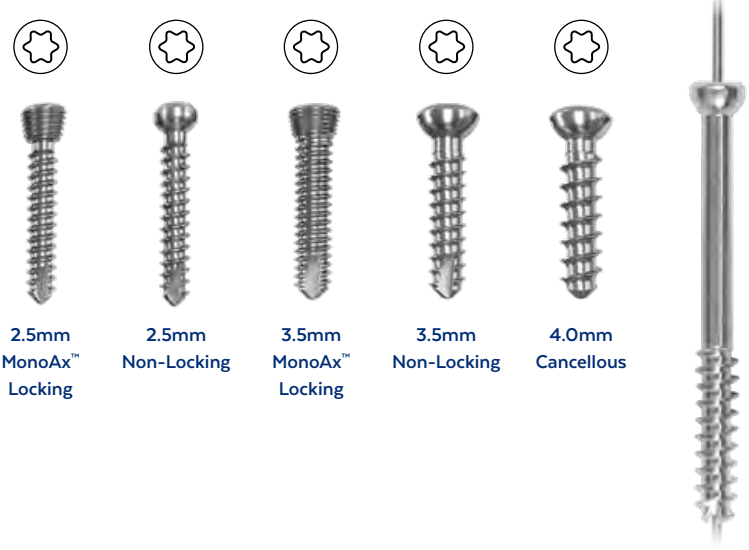
Small Fragment Locking Plates

- One Third Tubular Plates (2 to 12 hole)
- Reconstruction Plates (6 to 10 hole)
- T-Plates (3 head holes with 3 or 5 shaft holes)
- Available in stainless steel and titanium

Screws

Available in stainless steel and titanium

- 2.5mm MonoAx™ Locking (8-30mm)
- 2.5mm Non-Locking (8-30mm)
- 3.5mm MonoAx™ Locking (8-50mm)
- 3.5mm Non-Locking (8-110mm)
- 4.0mm Cancellous (8-50mm)
- 4.0mm Cannulated (20-80mm)

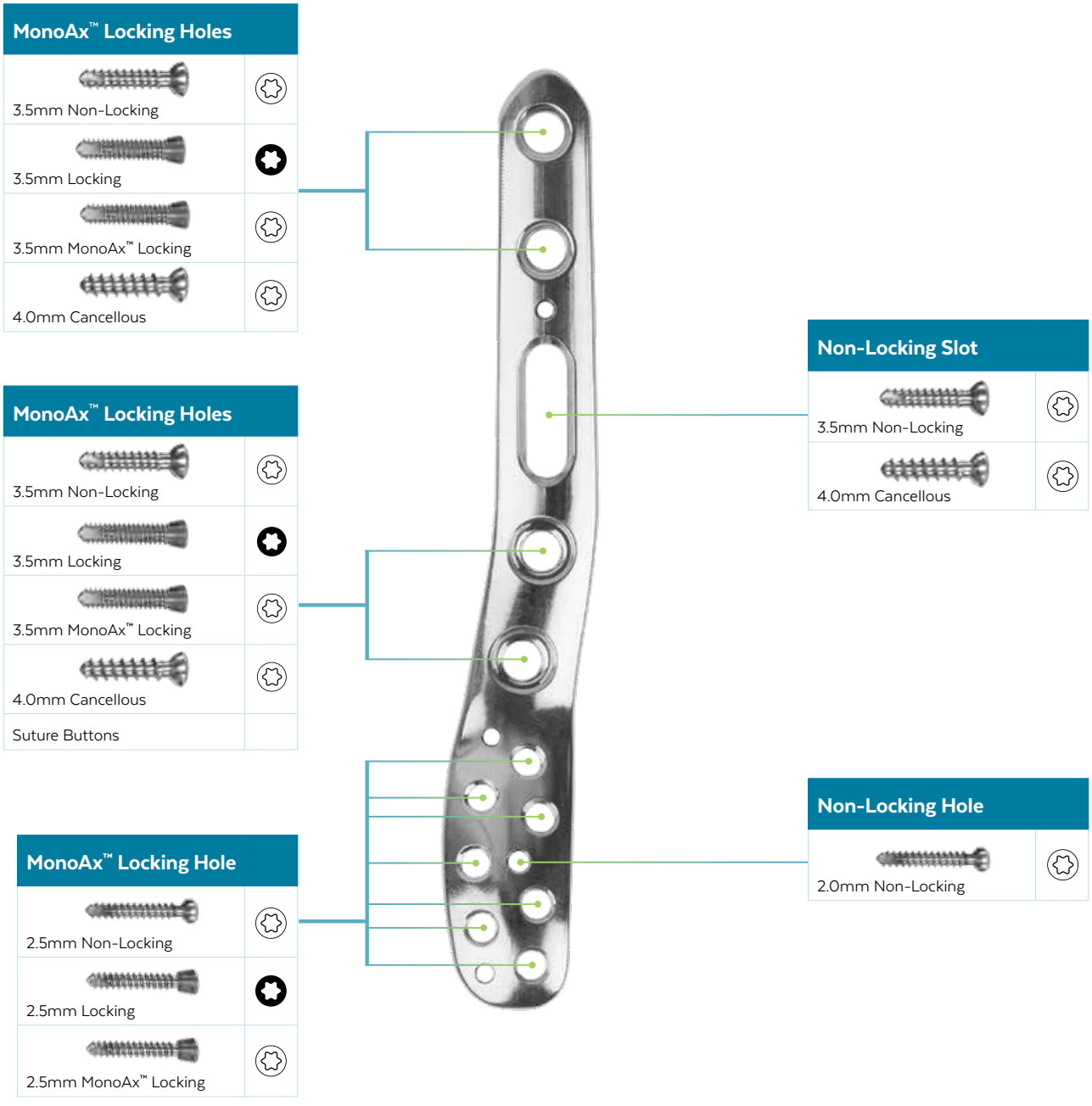


2.5mm MonoAx™ Locking | 2.5mm Non-Locking | 3.5mm MonoAx™ Locking | 3.5mm Non-Locking | 4.0mm Cancellous

4.0mm Cannulated

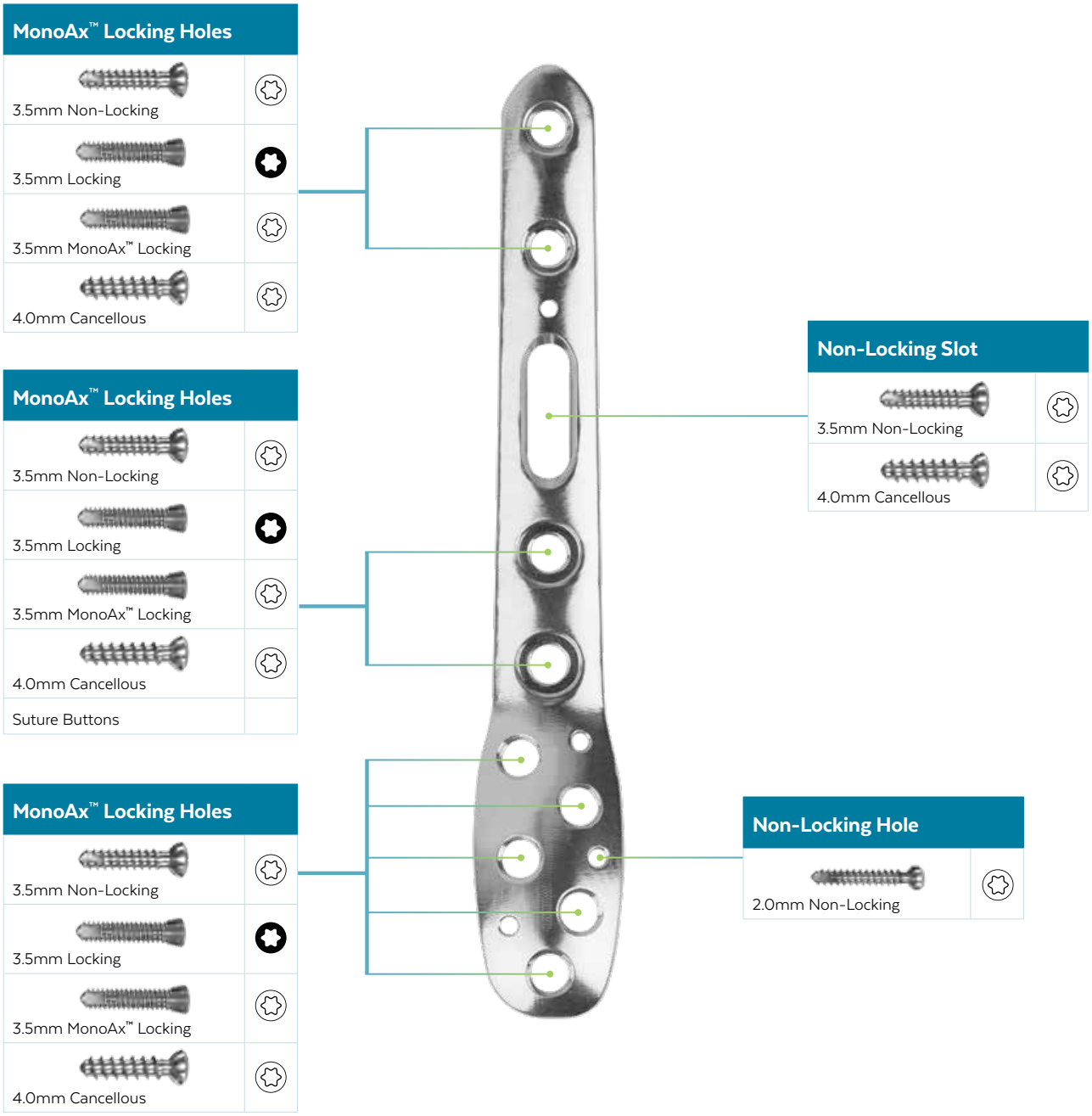
SCREW COMPATIBILITY

Lateral Distal Fibula Plate



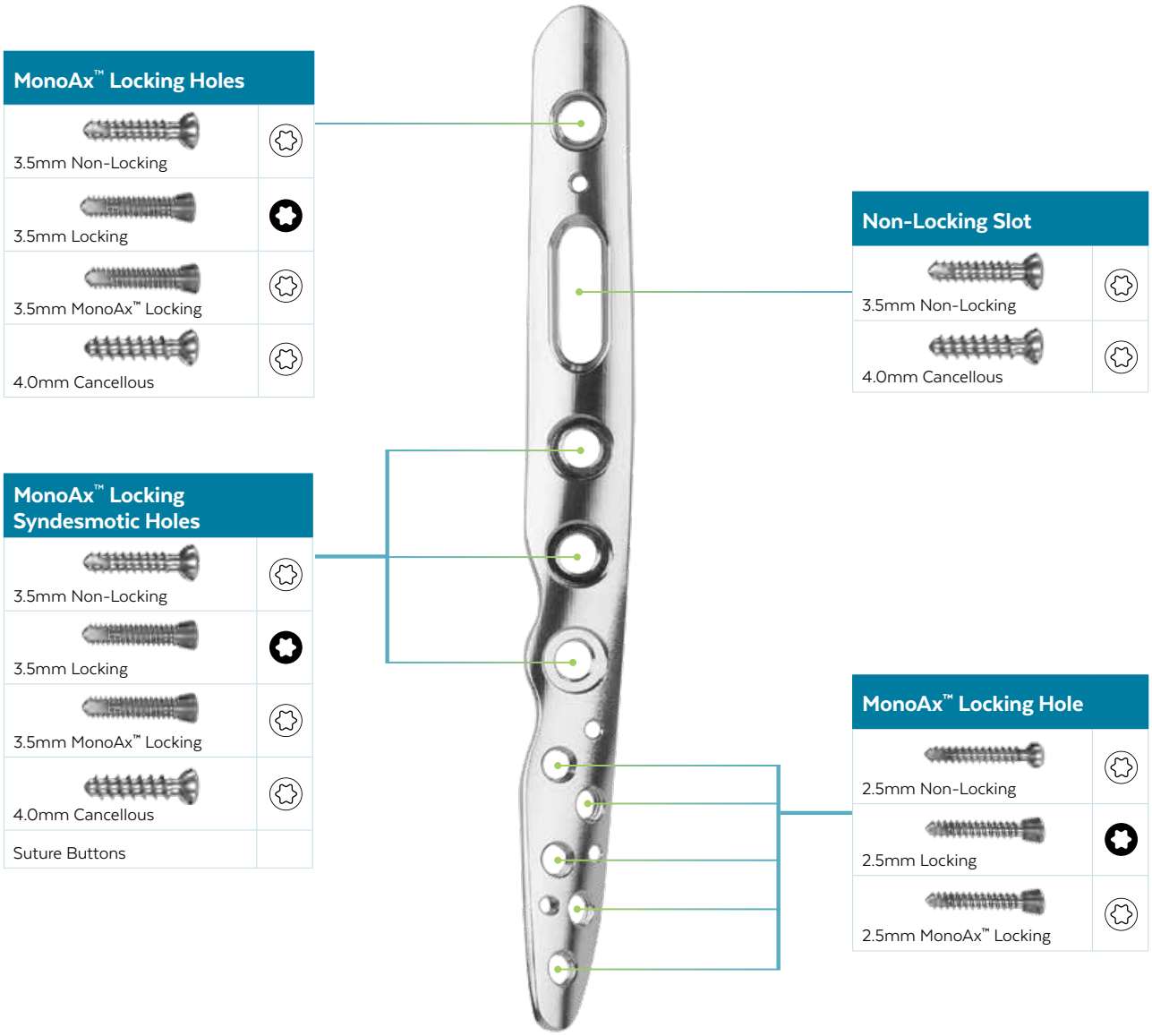
SCREW COMPATIBILITY

Universal Distal Fibula Plate



SCREW COMPATIBILITY

Posterolateral Distal Fibula Plate



SURGICAL TECHNIQUE

ANTHEM®

Distal Fibula Plating

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

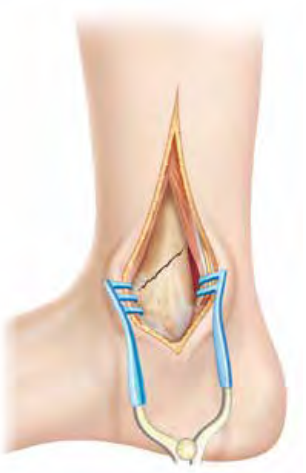
Assess the fracture using preoperative radiographs. Estimate the appropriate length and location of screws for proper plate selection, plate position, and screw placement.

STEP 2 PATIENT POSITIONING

Position the patient supine. If access to the posterior malleolus is necessary, consider a prone position. If necessary, position a sandbag under the buttock and elevate the operative leg with slight flexing of the knee to facilitate neutral ankle position. Examine the fracture.

STEP 3 APPROACH

Create a surgical incision over the lateral aspect of the distal fibula in the interval between the sural and superficial peroneal nerves. Avoid disruption of these nerves. Retract and mobilize the peroneal tendons. Verifying the incision allows visualization of the distal fibula and fracture site. Alternatively, a posterolateral approach may be used if access to the posterior malleolus is necessary.



Lateral approach

RADIOLUCENT RETRACTION

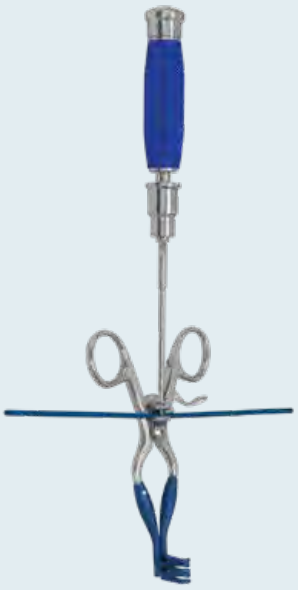
The **Stabilizing Radiolucent Weitlaner** and **Radiolucent Hohmann Retractors** help to improve visibility of the fracture site.

The **Malleable Band** secures the Stabilizing Radiolucent Weitlaner to the patient.

To assemble the Malleable Band, use the **Self-Retaining T8 Driver** to loosen the set screw. Place the Malleable Band in the slot to center and tighten the screw.

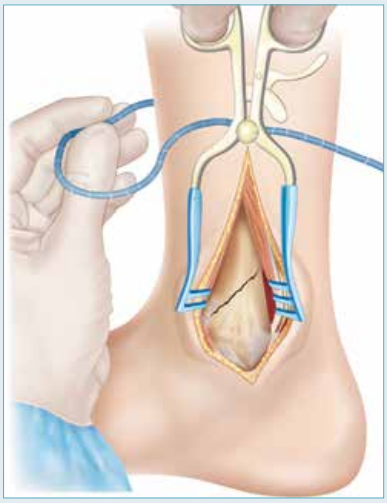
Loosening the set screw

Placing the Malleable Band



Tightening the set screw

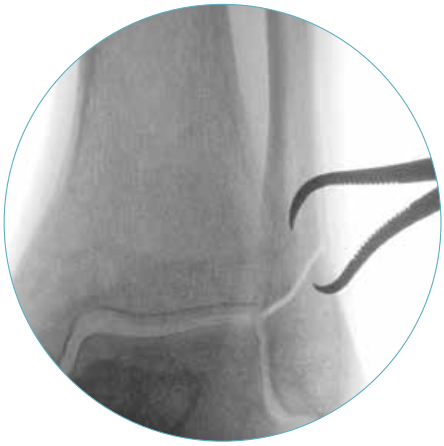
Once assembled, position the Stabilizing Radiolucent Weitlaner and retract the incision. Wrap the band around the patient's lower leg to secure the retractor.



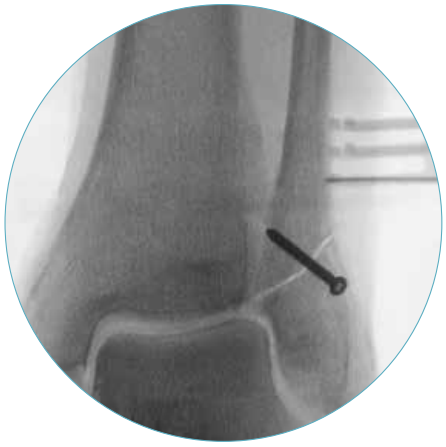
STEP 4 FRACTURE REDUCTION

Reduce the fracture and confirm that fibular length, alignment, and rotation are properly restored. In cases of fibular shortening, distraction may be necessary to regain length.

Once anatomic reduction is achieved, **Point-to-Point Reduction Forceps** and/or K-wires may be used to provisionally hold the reduction. A lag screw may be placed across the fracture site to maintain reduction and fracture compression. Confirm reduction under fluoroscopy.



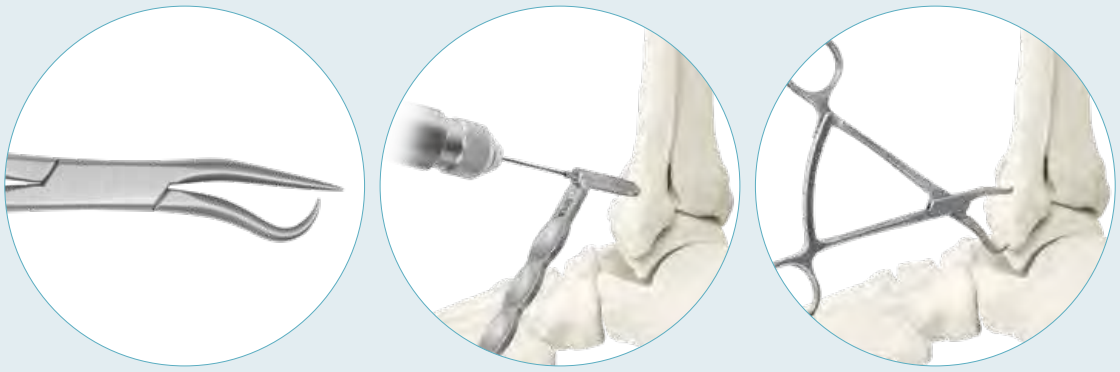
Point-to-Point Reduction Forceps



Lag screw

MALLEOLAR CLAMP

The **Malleolar Clamp** is used to reduce distal fractures. To use the clamp, drill a hole in the distal fibula proximal to the fracture using the **1.8mm Drill Bit**. Place the straight tine of the Malleolar Clamp into the drill hole. Use the curved tine to manipulate and reduce the distal bone fragment.



STEP 5 PLATE SELECTION

Select the distal fibula plate type and length that best accommodates patient anatomy and fracture pattern.

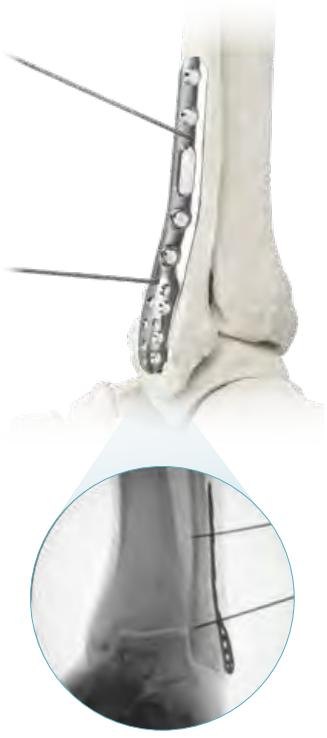
Lateral Distal Fibula Plate
Left or right orientation

Universal Distal Fibula Plate
Single orientation

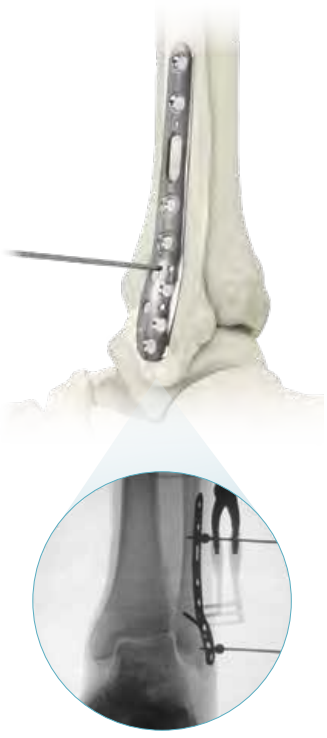
Posterolateral Distal Fibula Plate
Left or right orientation

STEP 6 PLATE PLACEMENT

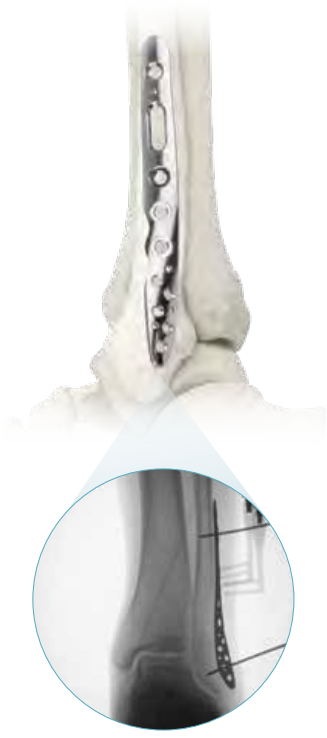
Position the selected plate on the fibula. For optimal placement, position the plate where the implant contour best matches the distal fibula. The plate may be provisionally held using **1.6mm K-wires**, **1.6mm Plate Holding K-wires**, or Point-to-Point Reduction Forceps. The Plate Holding K-wires may be used in K-wire holes or screw holes to provisionally secure the plate to the bone. Confirm plate placement using fluoroscopy and direct visualization.



Lateral Distal Fibula Plate



Universal Distal Fibula Plate

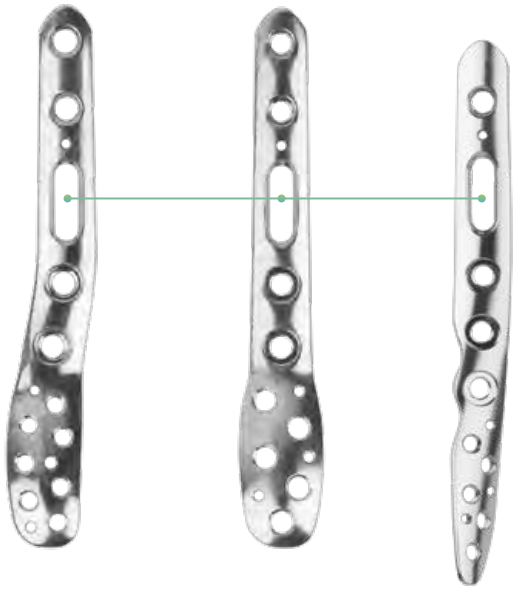


Posterolateral Distal Fibula Plate

STEP 7 SCREW INSERTION

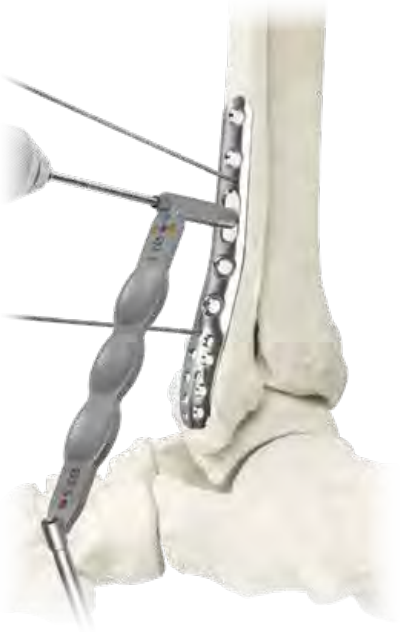
Slot Screw

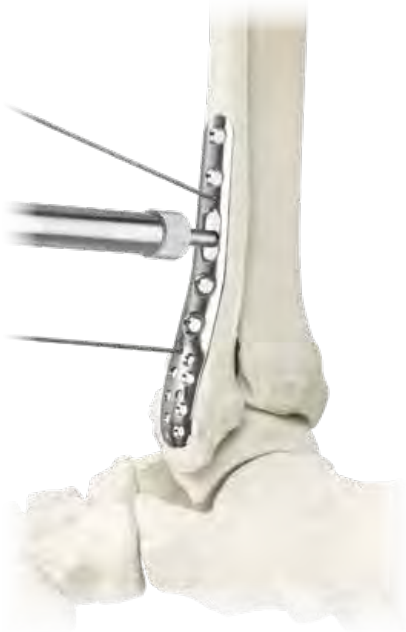
Using the **2.7mm Drill Bit** and the **3.5mm Soft Tissue Protector, Spring Loaded**, drill to the desired depth. Measure screw length using the **Depth Gauge**. Use the **Self-Retaining T15 Driver** or **Screw Holding Forceps** to select the desired screw. Verify screw length and diameter using the gauges within the screw module. Using the T15 Driver and the **Quick Connect Handle**, insert a 3.5mm Non-Locking or a 4.0mm Cancellous Screw into the elongated slot. The slot allows for repositioning of the plate if necessary.

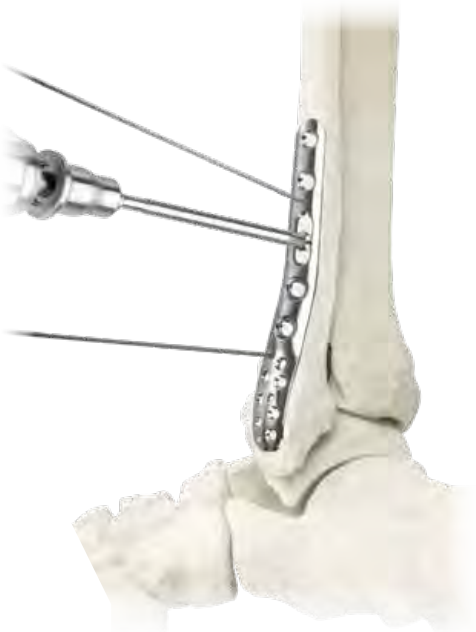


Lateral Distal Fibula Plate | Universal Distal Fibula Plate | Posterolateral Distal Fibula Plate

Non-Locking Slot	
 3.5mm Non-Locking	
 4.0mm Cancellous	







SCREW INSERTION (CONT'D)

COLOR-CODED INSTRUMENTS

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

Color	Screw Diameter	Drill Diameter
Blue	2.5mm	1.8mm
Fuschia	3.5mm	2.7mm
Light Green	4.0mm (Solid)	2.7mm
Gray	4.0mm (Cannulated)	2.85mm

Distal Screws in Lateral and Posterolateral Plates

Determine the appropriate combination of locking, non-locking, and cancellous screws for proper fixation. Insert a minimum of three 2.5mm Locking or Non-Locking Screws in the distal portion of the plate. Ensure screws are placed unicortically to avoid entering the joint space. For the lowest profile construct, use locking screws in each of the distal screw holes.

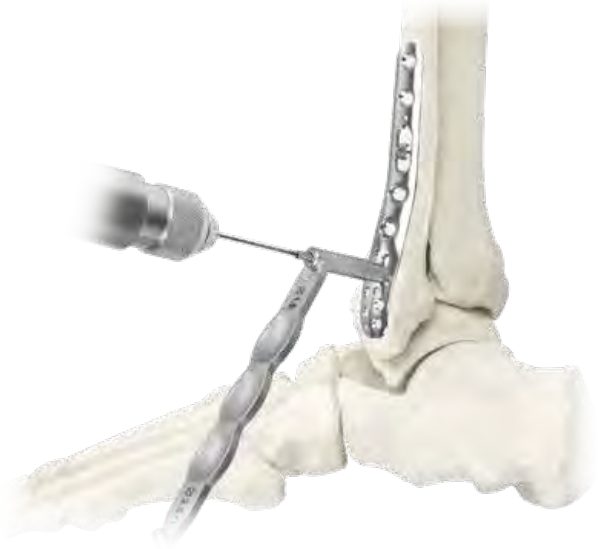
Lateral Distal Fibula Plate

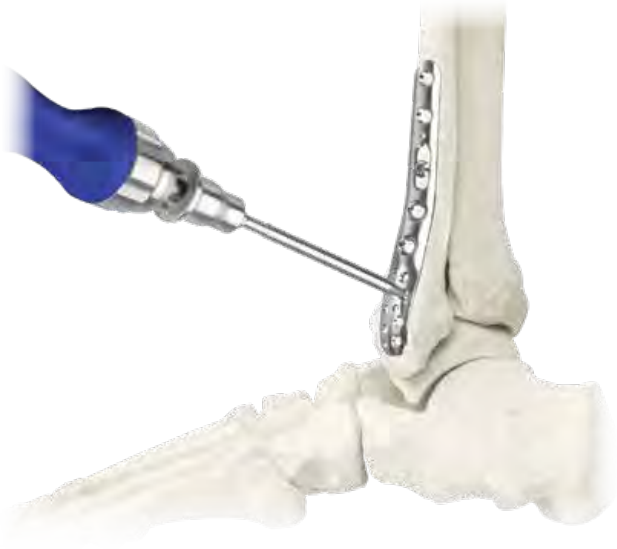
Posterolateral Distal Fibula Plate

MonoAx™ Locking Hole	
 2.5mm Non-Locking	
 2.5mm Locking	
 2.5mm MonoAx™ Locking	

2.5mm Non-Locking Screws

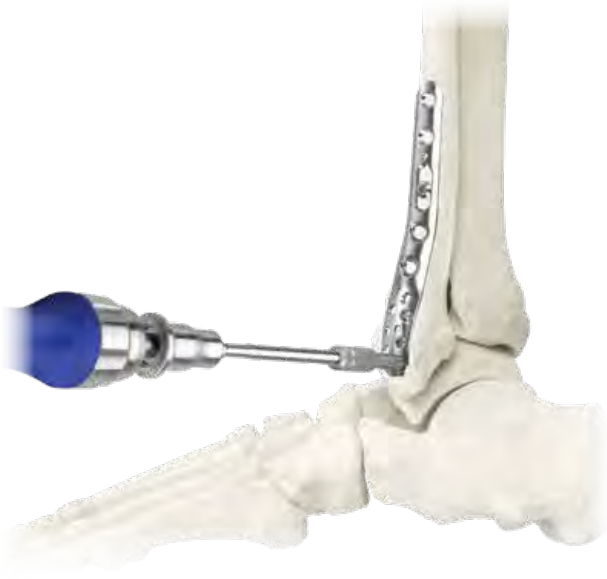
Pre-drill to the desired depth using the **1.8mm Drill Bit** and the **2.5mm Soft Tissue Protector, Spring Loaded**, Measure hole depth using the Depth Gauge. Use the **Self-Retaining T8 Driver** or Screw Holding Forceps to select the desired screw. Verify screw length and diameter using the gauges within the screw module. Insert 2.5mm Non-Locking Screws using the T8 Driver with the Quick Connect Handle.

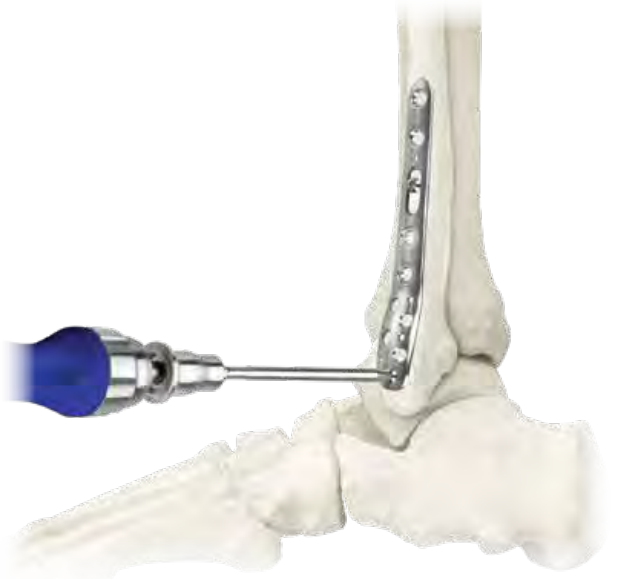




2.5mm Locking Screws

Verify the plate is in secure contact with the bone before placing any locking screws. Thread the **1.8mm Threaded Drill Guide** into the selected screw hole. Pre-drill to the desired depth using the 1.8mm Drill Bit. Remove the drill guide and measure hole depth using the Depth Gauge. 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. Insert 2.5mm Locking Screws using the T8 Driver with the Quick Connect Handle.





Distal Screws in Universal Plate

Insert a minimum of three 3.5mm Locking Screws, 3.5 Non-Locking Screws, or 4.0mm Cancellous Screws in the distal portion of the plate. Ensure screws are placed unicortically to avoid entering the joint space.

Universal Distal Fibula Plate

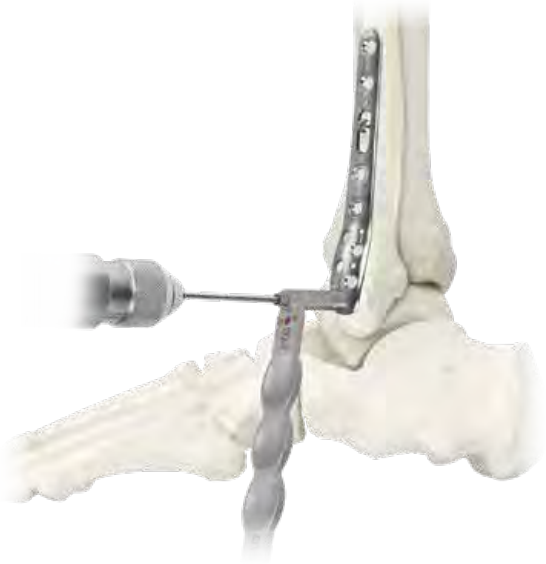
MonoAx™ Locking Holes	
 3.5mm Non-Locking	
 3.5mm Locking	
 4.0mm Cancellous	

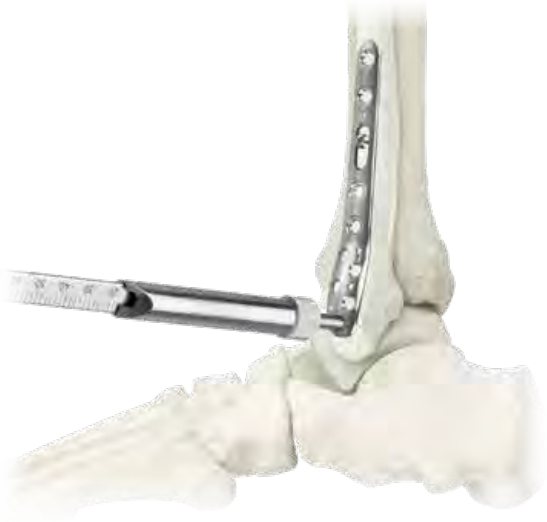
CALIBRATED DRILL BIT

The 2.7mm Calibrated Drill Bit may be used to measure hole depth from the end of the 3.5mm Soft Tissue Protector or the **2.7mm Threaded Drill Guide**. Only depths 20mm or greater may be measured using this drill bit.

3.5mm Non-Locking and 4.0mm Cancellous Screws

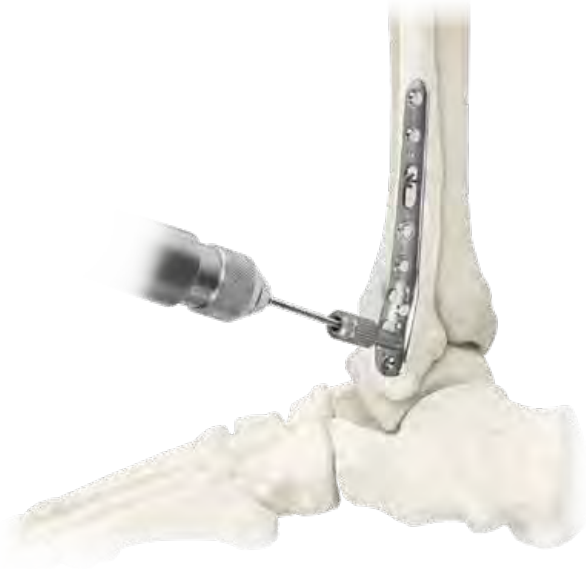
Pre-drill to the desired depth using the 2.7mm Drill Bit and the 3.5mm Soft Tissue Protector, Spring Loaded. Measure hole depth using the Depth Gauge. Use the T15 Driver or Screw Holding Forceps to select the desired screw. Verify screw length and diameter using the gauges within the screw module. Insert 3.5mm Non-Locking or 4.0mm Cancellous Screws using the T15 Driver with the Quick Connect Handle.

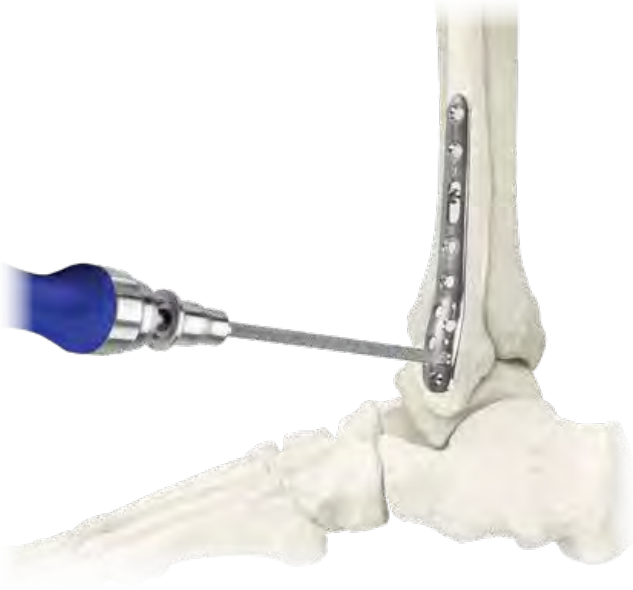




3.5mm Locking Screws

Verify the plate is in secure contact with the bone before placing any locking screws. Thread the 2.7mm Threaded Drill Guide into the selected screw hole. Pre-drill to the desired depth using the 2.7mm Drill Bit. Remove the drill guide and measure hole depth using 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. Insert 3.5mm Locking Screws using the T15 Driver with the Quick Connect Handle.





SCREW INSERTION (CONT'D)

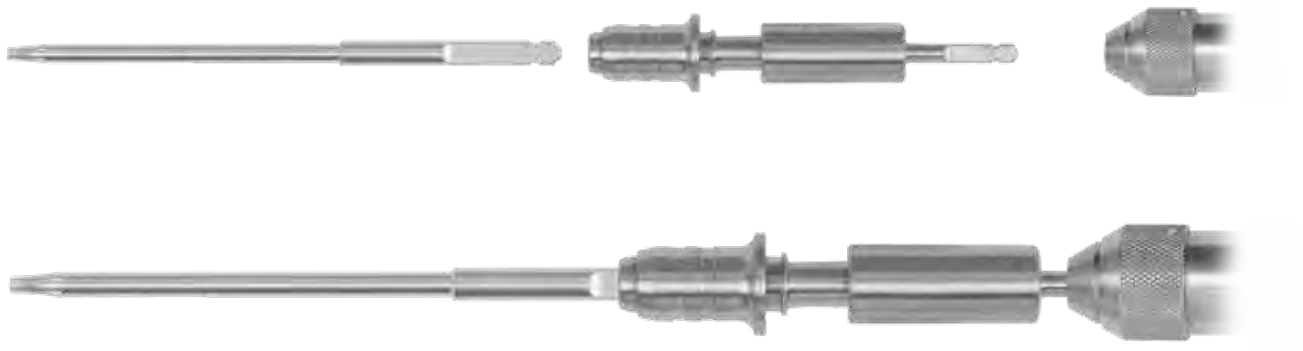
THREADED DRILL GUIDE

The T8 Driver is used to insert and remove the 1.8mm Threaded Drill Guide.

The T15 Driver is used to insert and remove the 2.7mm Threaded Drill Guide.

Optional: Locking Screw Insertion with 0.8Nm Torque Limiter

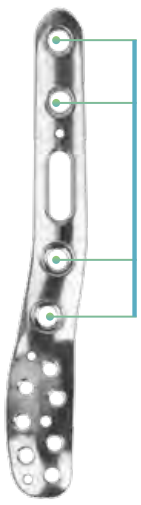
The **0.8Nm Torque Limiter** may be used to insert locking screws under power or in dense bone to help ensure proper tightening torque is not exceeded. Attach the T8 or T15 Driver to the 0.8Nm Torque Limiter under power. Insert the locking screw until the maximum torque has been reached and an audible click is heard. Perform final tightening manually.



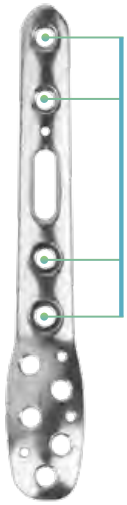
T8 Driver | **0.8Nm Torque Limiting Attachment** | **Drill**

Proximal Shaft Screws

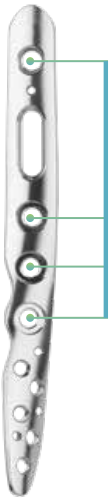
Insert a minimum of three screws above the fracture in the plate shaft. Locking, non-locking, or cancellous screws may be placed in any shaft hole.



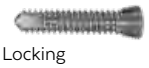
Lateral Distal Fibula Plate



Universal Distal Fibula Plate



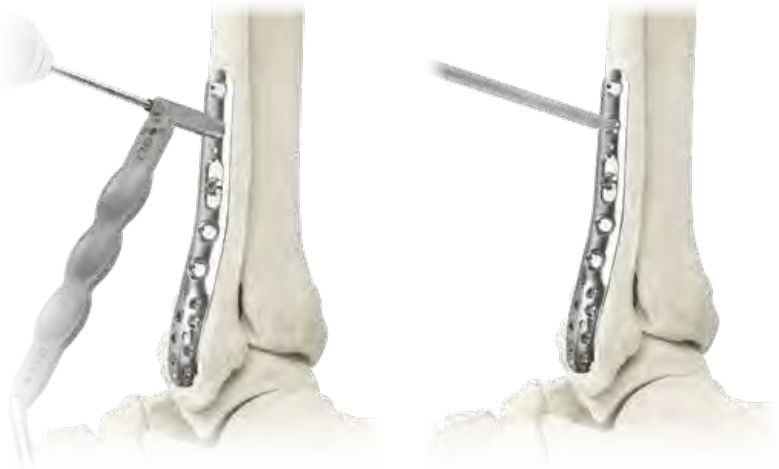
Posterolateral Distal Fibula Plate

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

3.5mm Non-Locking and 4.0mm Cancellous Screws

Pre-drill to the desired depth using the 2.7mm Drill Bit and the 3.5mm Soft Tissue Protector, Spring Loaded. Measure hole depth using the Depth Gauge.

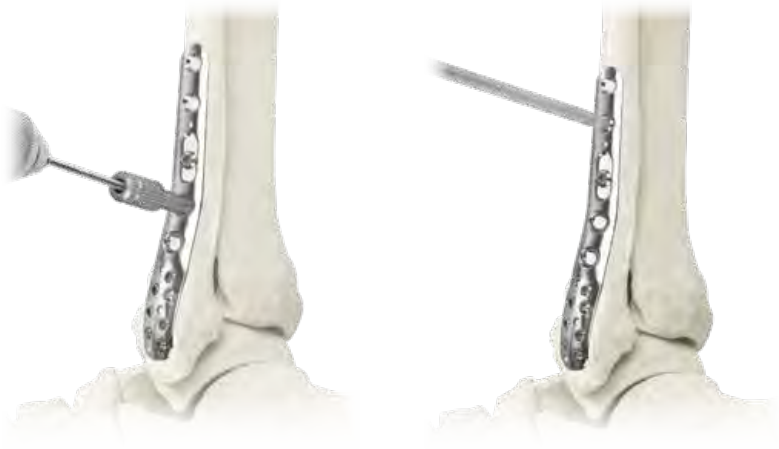
Use the T15 Driver or Screw Holding Forceps to select the desired screw. Verify screw length and diameter using the gauges within the screw module. Insert 3.5mm Non-Locking or 4.0mm Cancellous Screws using the T15 Driver with the Quick Connect Handle.



3.5mm Locking Screws

Verify the plate is in secure contact with the bone before placing any locking screws. Thread the 2.7mm Threaded Drill Guide into the selected screw hole. Pre-drill to the desired depth using the 2.7mm Drill Bit. Remove the drill guide and measure hole depth using the Depth Gauge.

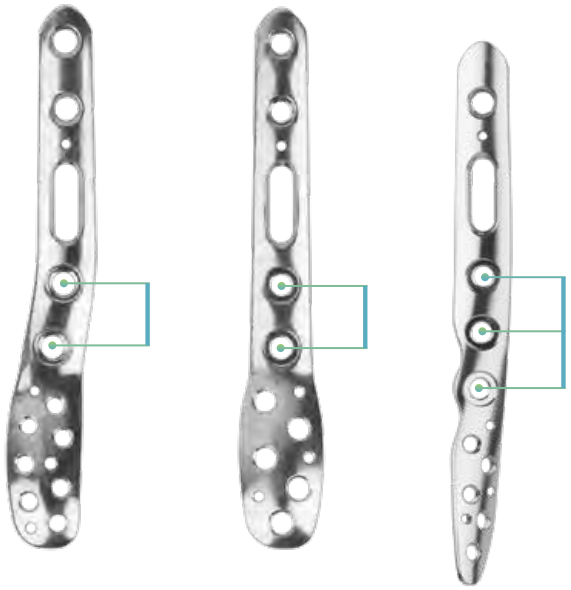
Use the T15 Driver or Screw Holding Forceps to select the desired screw. Verify screw length and diameter using the gauges within the screw module. Insert 3.5mm Locking Screws using the T15 Driver with the Quick Connect Handle.



SCREW INSERTION (CONT'D)

Optional: Syndesmosis Fixation

To asses the integrity of the syndesmosis, perform a stability test such as the Cotton test. If instability is detected, stabilization may be achieved using 3.5mm Non-Locking or 4.0mm Cancellous Screws through any hole on the plate shaft. Syndesmotic screw holes feature a recess that accepts suture buttons.

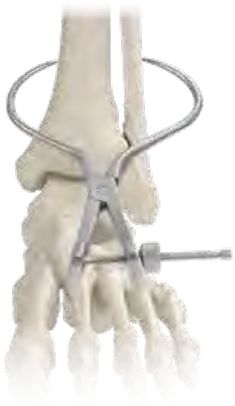


Lateral Distal Fibula Plate | Universal Distal Fibula Plate | Posterolateral Distal Fibula Plate

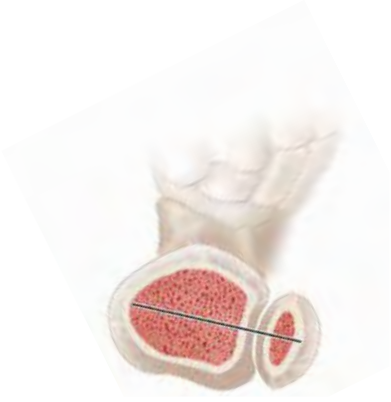
MonoAx™ Locking Holes	
3.5mm Non-Locking	○
3.5mm Locking	●
3.5mm MonoAx™ Locking	○
4.0mm Cancellous	○
Suture Buttons	

Reduction of the syndesmosis can be achieved using the **Syndesmosis Clamp**. Verify reduction using fluoroscopy and confirm the joint is not over compressed. Select the appropriate location for the syndesmotic screws. Screws may be inserted through a syndesmotic screw hole or placed externally to the plate.

Pre-drill using the **2.7mm Calibrated Drill Bit** and the 3.5mm Soft Tissue Protector, Spring Loaded. Ensure the drill is parallel to the tibial plafond and the ankle is in a neutral position. Measure the hole depth using the Depth Gauge. Select and place 3.5mm Non-Locking or 4.0mm Cancellous Screws using the T15 Driver with the Quick Connect Handle.



Syndesmosis Clamp reduction

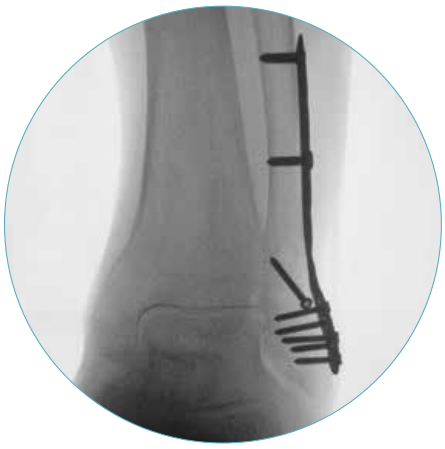


Axial view of syndesmotic screw trajectory

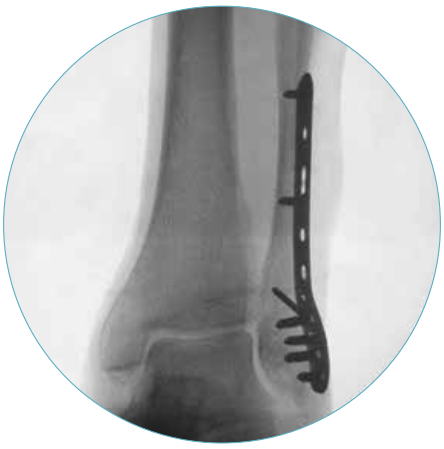
Syndesmotic screws should be placed parallel to the joint and angled posterior to anterior approximately 25-30°.

STEP 8 VERIFY RECONSTRUCTION

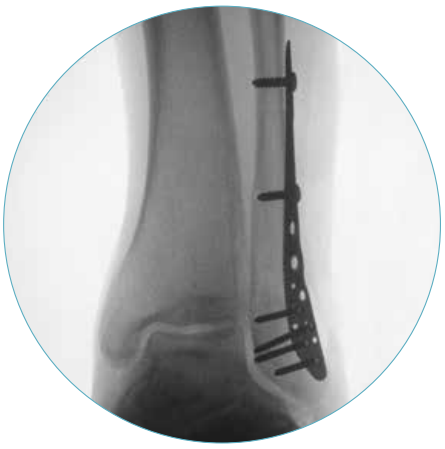
Confirm screw placement, screw trajectories, and joint reconstruction using fluoroscopy.



Lateral Distal Fibula Plate

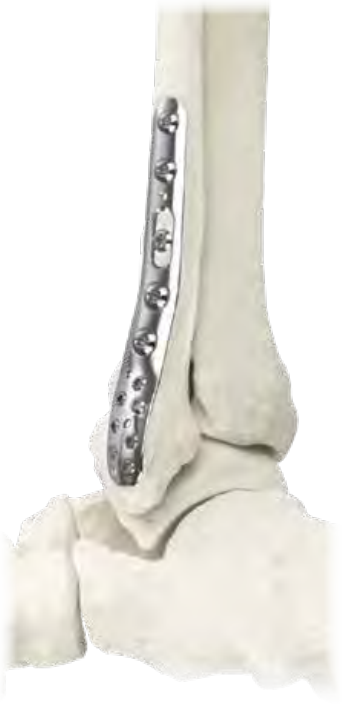


Universal Distal Fibula Plate

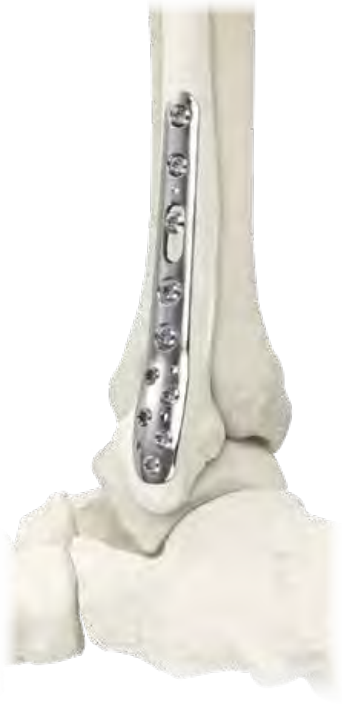


Posterolateral Fibula Plate

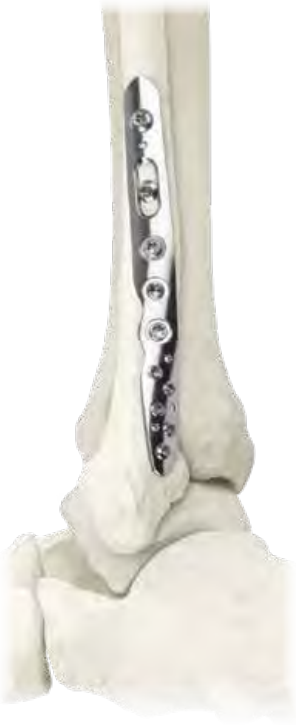
FINAL CONSTRUCT



Lateral Distal Fibula Plate



Universal Distal Fibula Plate



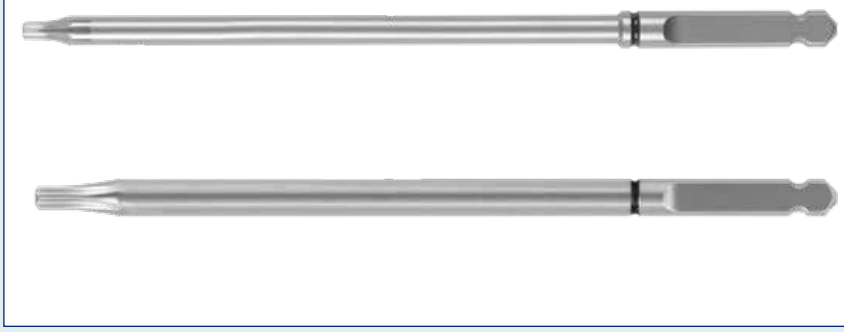
Posterolateral Fibula Plate

OPTIONAL: REMOVAL

Unlock all screws from the plate with a non self-retaining driver but do not remove the locking screws. For 2.5mm screws, use the **Non Self-Retaining T8 Driver**. For 3.5mm and 4.0mm screws, use the **Non Self-Retaining T15 Driver**. This prevents simultaneous rotation of the plate during removal. Remove all locking, non-locking, and cancellous screws using the T8 or T15 Non Self-Retaining Driver. Once all screws are removed, the plate may be removed.

NON SELF-RETAINING DRIVERS

Non Self-Retaining Drivers help to maximize torque applied to the screw head during removal. These drivers are designed to prevent stripping the screw head in challenging clinical scenarios and are color-coded with a black band.



T8 Non Self-Retaining Driver

T15 Non Self-Retaining Driver

ANTHEM®

Hook Plating for Medial Malleolus

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

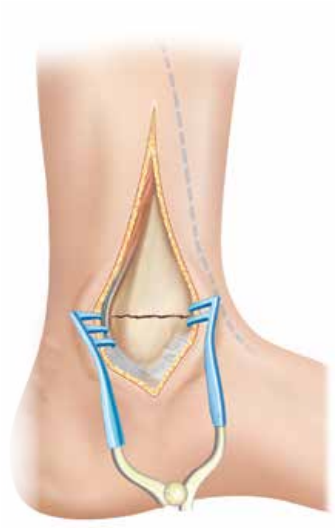
Assess the fracture using preoperative radiographs. Estimate the appropriate length and location of screws for proper plate selection, plate position, and screw placement.

STEP 2 PATIENT POSITIONING

Place the patient supine and externally rotate the operative leg. If access to the posterior malleolus is necessary, consider a prone patient position.

STEP 3 APPROACH

Create a surgical incision beginning approximately 2cm distal to the anterior tip of the medial malleolus and continuing the incision proximally until adequate access to the fracture site is achieved. Carefully retract and mobilize soft tissue structures to gain further exposure.

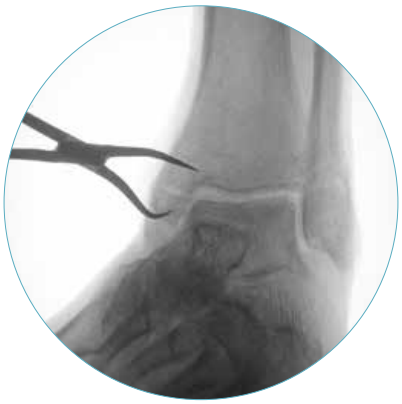


Medial approach

STEP 4 FRACTURE REDUCTION

Reduce the fracture and confirm that length, alignment, and rotation are properly restored. The Malleolar Clamp is available to reduce distal fragments. Confirm reduction using fluoroscopy.

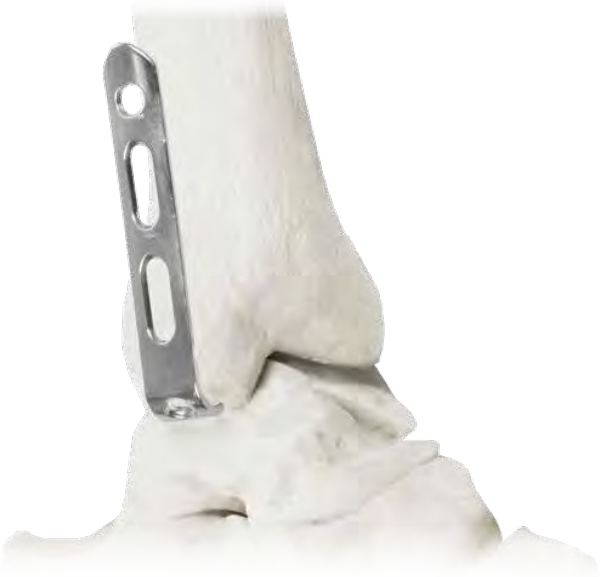
Once reduction is achieved, Point-to-Point Reduction Forceps or K-wires may be used to provisionally hold the bone fragments.



Fracture reduction with Malleolar Clamp

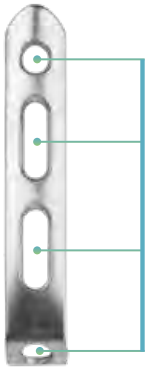
STEP 5 PLATE PLACEMENT

Position the Hook Plate on the tibia, engaging the hooks in the distal fragment. A bone tamp may be used to impact the hooks.



STEP 6 SCREW INSERTION

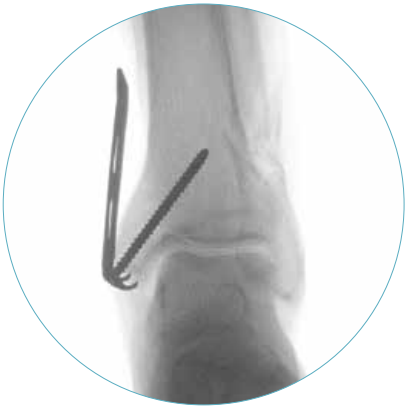
The Hook Plate accepts 3.5mm Non-Locking and 4.0mm Cancellous Screws. The oblong slots may be used for dynamic compression.

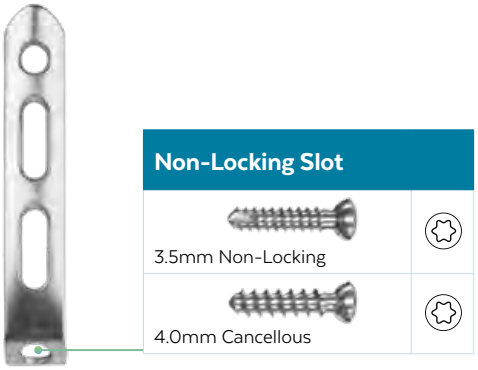


Non-Locking Slot	
3.5mm Non-Locking	
4.0mm Cancellous	

Distal Screw

Pre-drill to the desired depth using the 2.7mm Drill Bit and the 3.5mm Soft Tissue Protector, Spring Loaded. 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. Insert a 3.5mm Non-Locking or a 4.0mm Cancellous Screw using the T15 Driver with the Quick Connect Handle.



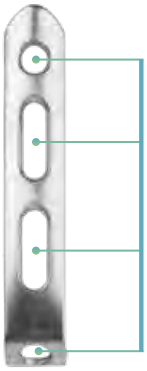


Non-Locking Slot	
3.5mm Non-Locking	
4.0mm Cancellous	

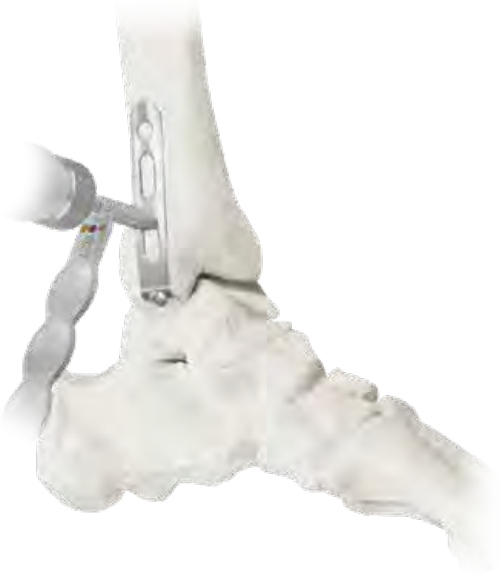
Shaft Screws

Insert screws sequentially along the shaft, moving proximally to help contour the plate. Screws may be placed eccentrically in the slotted holes to provide fracture compression.

Drill to the desired depth using the 2.7mm Drill Bit and the 3.5mm Soft Tissue Protector, Spring Loaded. Measure hole depth using the Depth Gauge. Select and place 3.5mm Non-Locking or 4.0mm Cancellous Screws using the T15 Driver with the Quick Connect Handle.



Non-Locking Slot	
 3.5mm Non-Locking	
 4.0mm Cancellous	



DYNAMIC COMPRESSION

Dynamic compression of the fracture may be achieved by eccentrically placing a non-locking or cancellous screw through a slotted hole. All 2.5mm Non-Locking, 3.5mm Non-Locking, and 4.0mm Cancellous Screws may be used for dynamic compression. If compression is not desired, place the screw in a neutral position.

Place a non-locking or cancellous screw distal to the fracture. Select a slotted hole on the proximal side of the fracture line. Insert the 3.5mm Soft Tissue Protector, Spring Loaded into the oblong hole with no downward pressure. Place the selected Soft Tissue Protector eccentrically in the slotted hole.

Drill to the desired depth with the selected drill. Measure hole depth using the Depth Gauge. Use the T15 Driver or Screw Holding Forceps to select the desired screw. Using the T15 Driver with the Quick Connect Handle, insert the screw into the desired hole. A power drill with a torque limiting adapter may be used to insert the screw under power if desired.

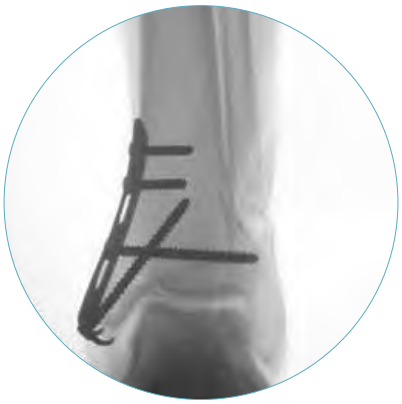
Neutral position

Eccentric position

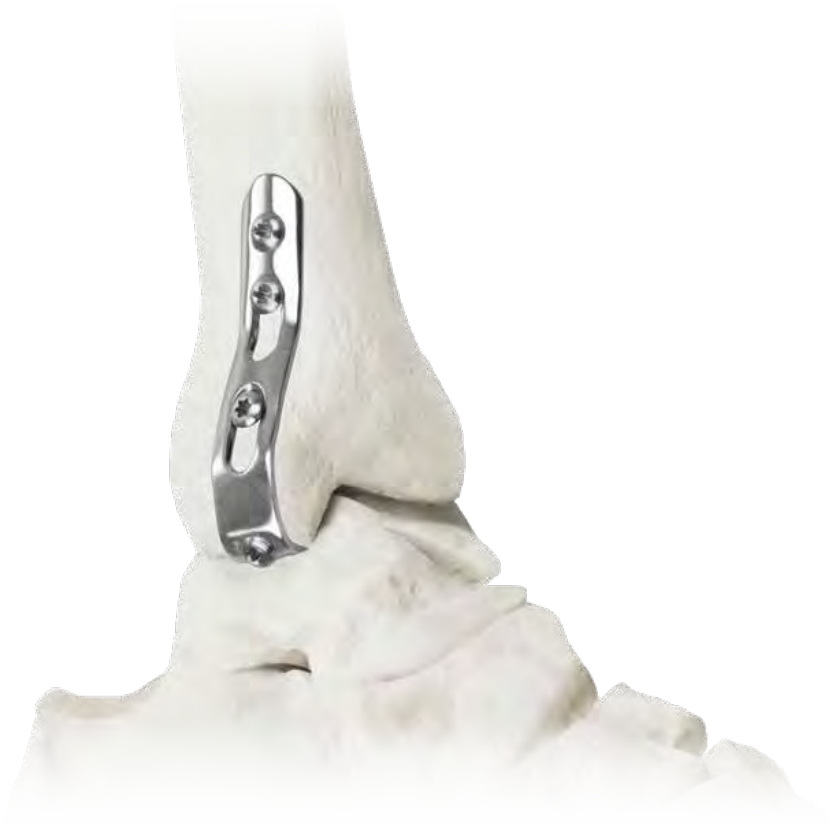
Dynamic compression

STEP 7 VERIFY RECONSTRUCTION

Using fluoroscopy, confirm implant position, screw trajectories, and joint reconstruction.



FINAL CONSTRUCT



OPTIONAL: REMOVAL

Remove all non-locking and cancellous screws using the Non Self-Retaining T15 Driver. Once all screws are removed, the plate may be removed.

SURGICAL TECHNIQUE

CAPTIVATE™

4.0mm Cannulated Screws for Medial Malleolus

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

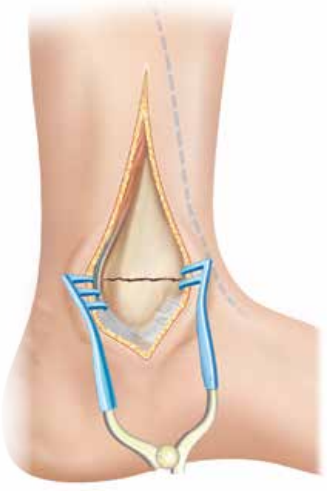
Assess the fracture using preoperative radiographs. Estimate the appropriate length and location of screws for proper screw placement.

STEP 2 PATIENT POSITIONING

Place the patient supine and externally rotate the operative leg. If access to the posterior malleolus is necessary, consider a prone patient position.

STEP 3 APPROACH

Create a surgical incision beginning approximately 2cm distal to the anterior tip of the medial malleolus and continuing the incision proximally until adequate access to the fracture site is achieved. Carefully retract and mobilize soft tissue structures to gain further exposure.

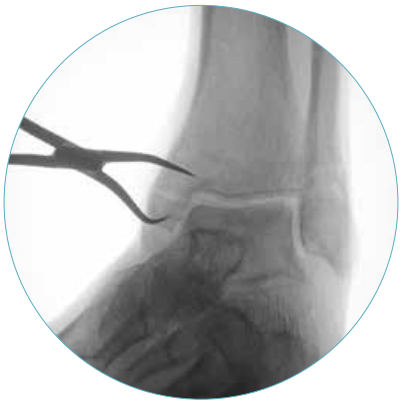


Medial approach

STEP 4 FRACTURE REDUCTION

Reduce the fracture using the Malleolar Clamp and confirm that length, alignment, and rotation are restored. Confirm reduction using fluoroscopy.

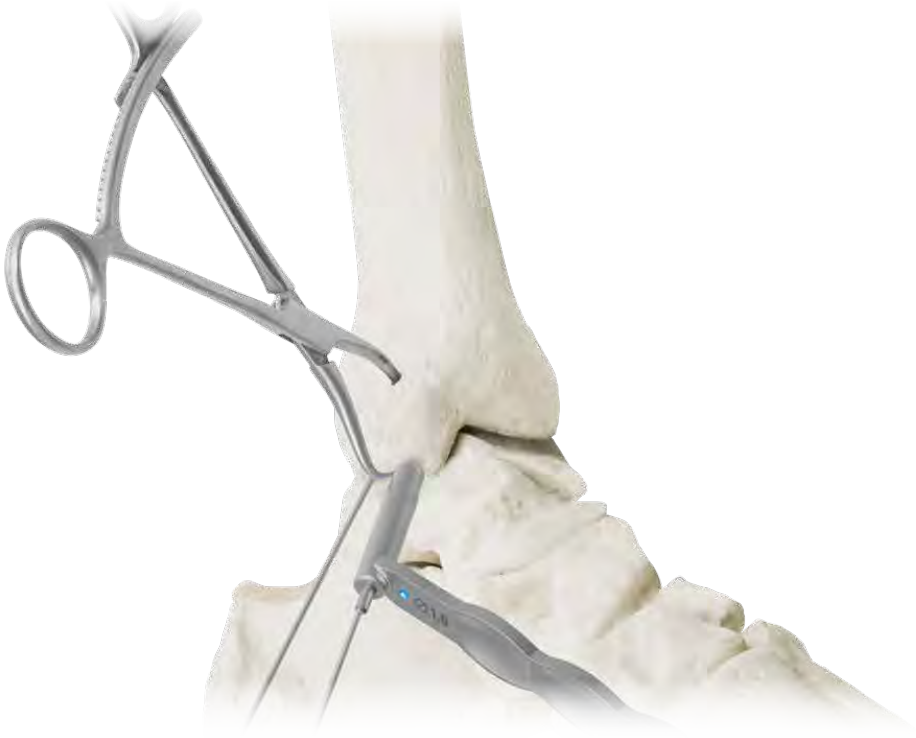
Once reduction is achieved, Point-to-Point Reduction Forceps or K-wires may be used to provisionally hold the bone fragments.



Fracture reduction with the Malleolar Clamp

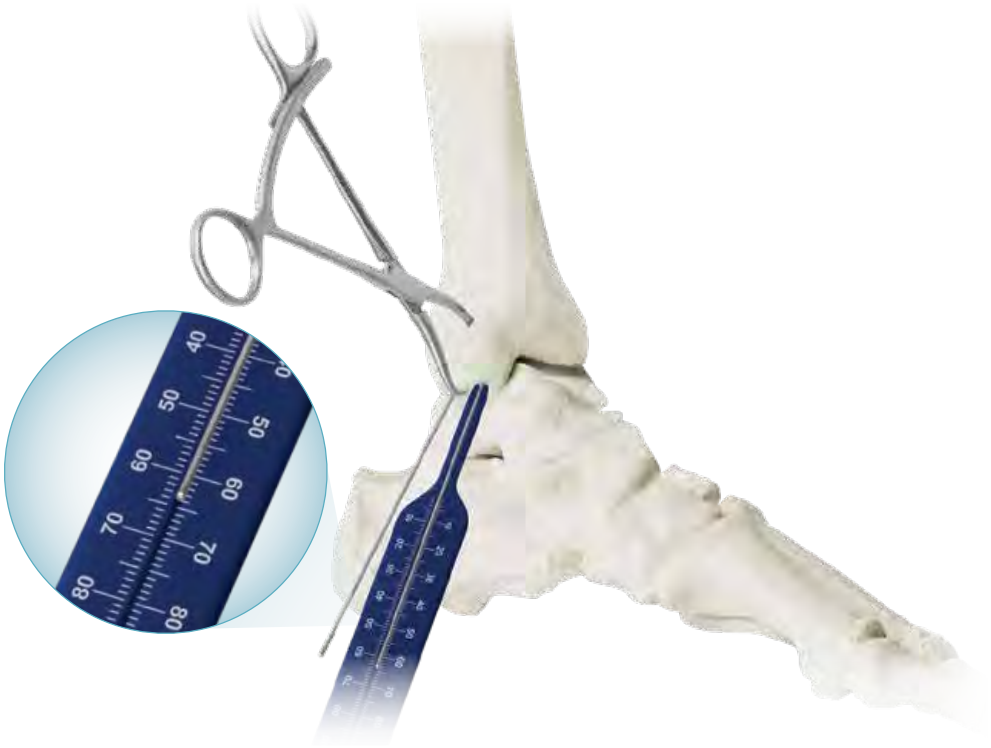
STEP 5 K-WIRE PLACEMENT

Place **1.4mm K-wires** (threaded or non-threaded) perpendicular to the fracture line. Verify that the final K-wire positions represent the desired placement of the cannulated screws.



STEP 6 SCREW LENGTH MEASUREMENT

Slide the **Cannulated Measuring Device** over the K-wire until it reaches bone. Read the length measurement at the end of the K-wire to determine the appropriate screw length.



Optional: Pre-Drilling

CAPTIVATE™ Cannulated Screws are self-drilling and self-tapping; however, pre-drilling of the near cortex may be necessary in patients with dense cortical bone.

Place the 3.5mm Soft Tissue Protector, Spring Loaded over the K-wire. Slide the **2.85mm Cannulated Drill Bit** over the K-wire and through the Spring Loaded Soft Tissue Protector. Drill to the desired depth.

SCREW LENGTH MEASUREMENT (CONT'D)

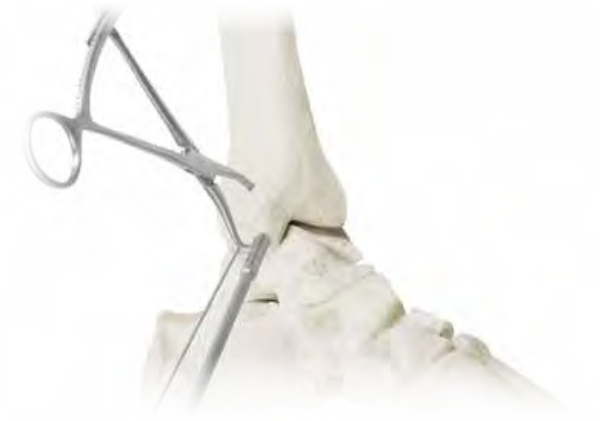
Optional:

A. Countersinking

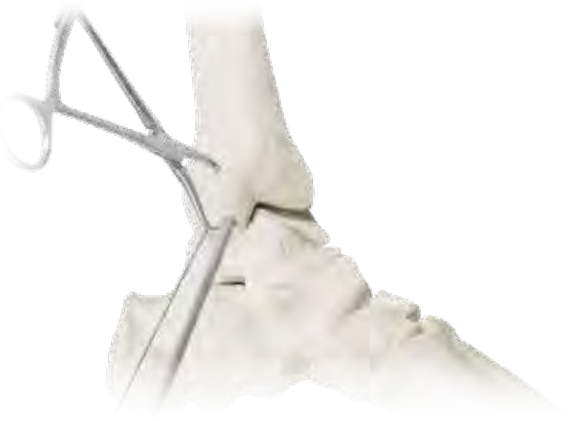
Attach the **Cannulated Countersink** to the Quick Connect Handle and slide over the K-wire. Countersink to the desired depth.

B. Tapping

Attach the **4.0mm Cannulated Tap** to the Quick Connect Handle and slide over the K-wire. Tap to the desired depth.



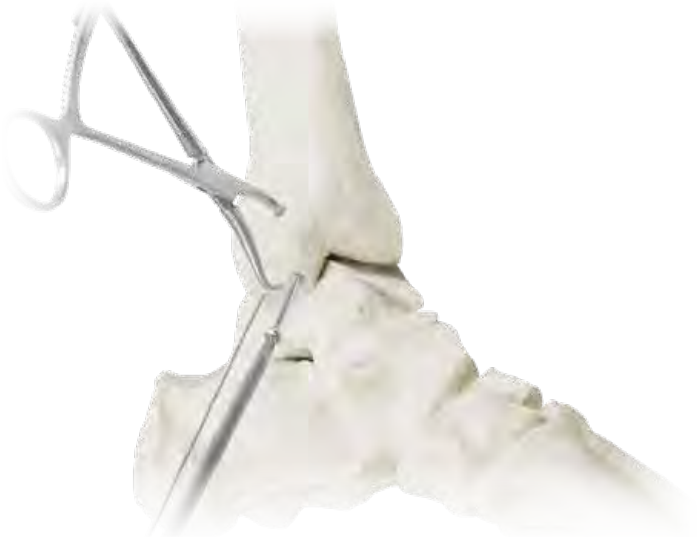
A



B

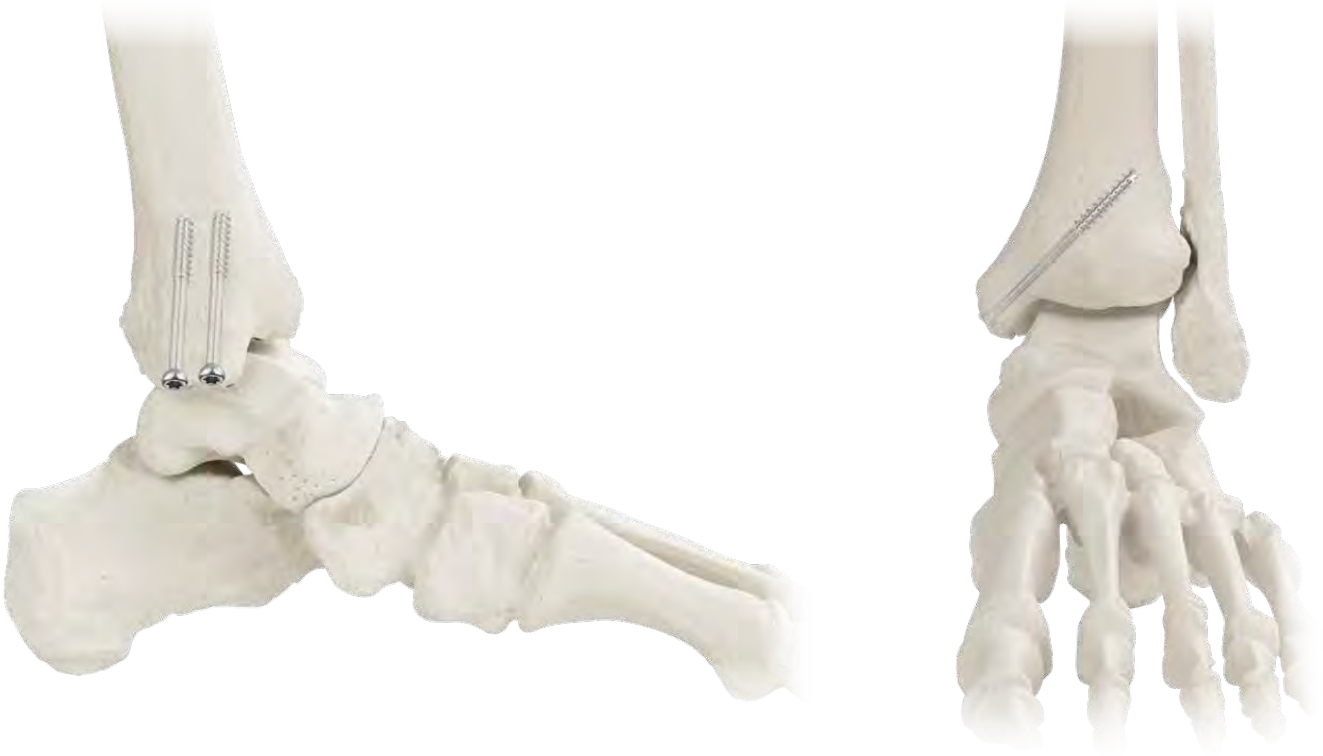
STEP 7 SCREW INSERTION

Select the appropriate screw corresponding to the measured length. If desired, place the **CAPTIVATE™ Washer** on the cannulated screw. Assemble the Quick Connect Handle, the **Self-Retaining Cannulated T15 Driver**, and the cannulated screw. Slide the assembly over the K-wire and insert the screw. Verify that the bone threads of the screw completely pass the fracture line. Remove the K-wire. A second screw may be implanted if additional fixation or rotational stability is desired.



STEP 8 VERIFY RECONSTRUCTION

Using fluoroscopy, confirm screw placement, screw trajectories, and reduction.

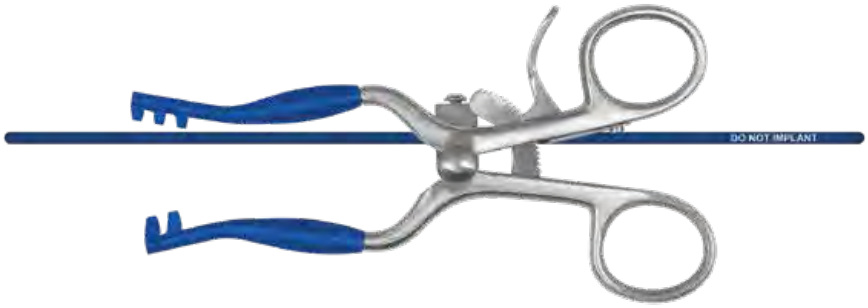


OPTIONAL: REMOVAL

Use the T15 Driver with the Quick Connect Handle to remove all 4.0mm Cannulated Screws.

INSTRUMENT OVERVIEW

RETRACTORS



Stabilizing Radiolucent Weitlaner 2x3, Sharp 6171.0001

Malleable Wire Replacement 6171.7008

Radiolucent Hohmann Retractor, 8mm 6179.7014

Radiolucent Hohmann Retractor, 16mm 6179.7015

Hohmann Retractor, 8mm 6179.7016

Hohmann Retractor, 15mm 6179.7017

ELEVATORS AND CURETTES

Periosteal Elevator, Curved Tip, 6mm 6179.7019

Freer Elevator 6185.0005

Cup Curette 6185.0006

DRILL GUIDES

1.8mm Threaded Drill Guide 6185.3218

2.7mm Threaded Drill Guide 6179.3227

DRILL GUIDES (CONT'D)

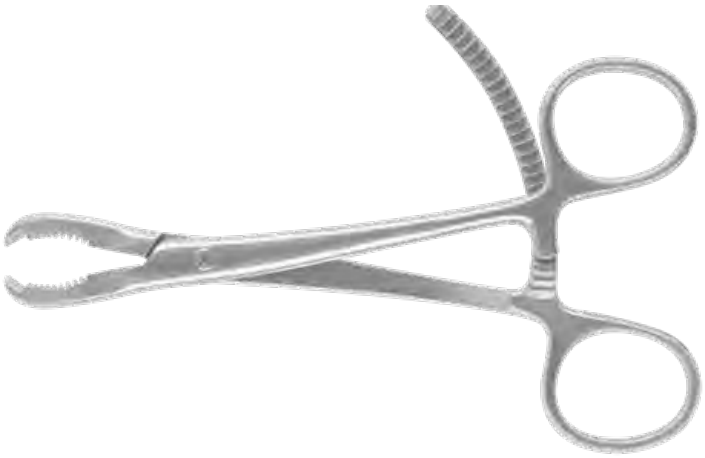
2.5mm Soft Tissue Protector, Spring Loaded 6179.3125

3.5mm Soft Tissue Protector, Spring Loaded 6179.3135

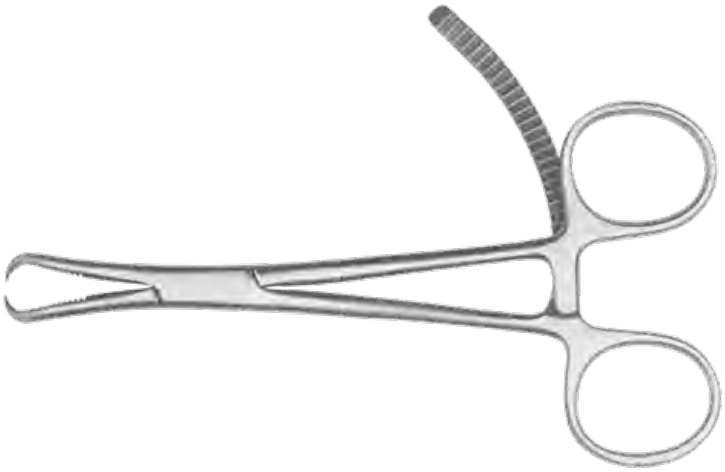
2.5/1.8mm Drill Sleeve 6179.3128

3.5/2.7mm Drill Sleeve 6179.3137

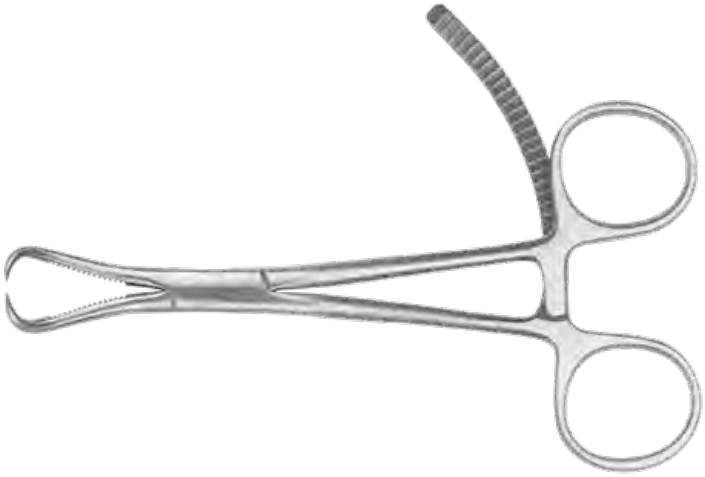
FORCEPS



Lobster Claw Reduction Forceps, Ratcheting 6179.2001

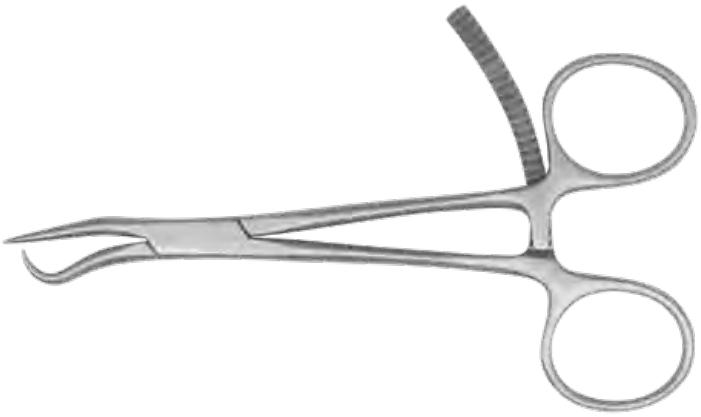


Point-to-Point Reduction Forceps, Narrow, Ratcheting 6179.2003

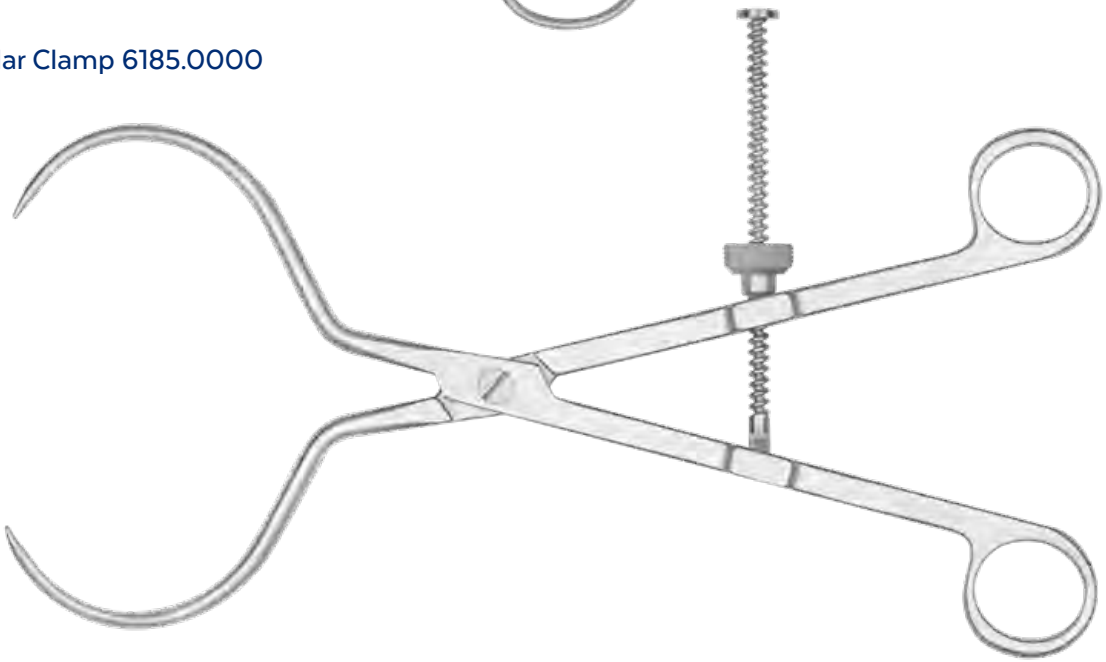


Point-to-Point Reduction Forceps, Wide, Ratcheting 6179.2004

FORCEPS (CONT'D)



Malleolar Clamp 6185.0000



Syndesmosis Clamp, Weber, Spin-down 6185.0002

DEPTH GAUGES

Depth Gauge, 60mm 6179.7020

Depth Gauge, 110mm 6179.7031

DEPTH GAUGES (CONT'D)

Measuring Device, Cannulated 6178.3640

MEDIUM HANDLES

Medium Handle, Ratcheting Cannulated, AO Quick Connect 6179.7013

Medium Handle, Cannulated, AO Quick Connect 6179.7001

DRIVERS

T8 Driver, SR, 60mm, AO Quick Connect 6179.6008

*Items highlighted in grey are additionally available

DRIVERS (CONT'D)

T15 Driver, SR, 100mm, AO Quick Connect 6179.6015

T15 Driver, SR, Cannulated, 150mm, AO Quick Connect 6168.5215

T15 Driver, Non Self-Retaining, 100mm, AO Quick Connect 6179.6115

T8 Driver, Non Self-Retaining, 100mm, AO Quick Connect 6179.6108

DRILLS, TAPS, TORQUE LIMITERS, AND COUNTERSINKS

1.8mm Drill Bit, 137mm, AO Quick Connect 6185.5018

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

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

DRILLS, TAPS, TORQUE LIMITERS, AND COUNTERSINKS (CONT'D)

2.7mm Calibrated Drill Bit, AO Quick Connect 6179.5028

3.5mm Drill Bit, AO Quick Connect 6179.5035

2.85mm Drill Bit, Cannulated, 115mm, AO Quick Connect 6178.5329

4.0mm Tap, Cannulated, AO Quick Connect 6178.5140

Torque Limiting Attachment, 0.8Nm, AO Quick Connect 6185.0008

Countersink, AO Quick Connect 6179.7000

Countersink, Cannulated, AO Quick Connect 6178.7040

DENTAL PICKS

Dental Pick, Curved Tip, Large Handle 6179.7025

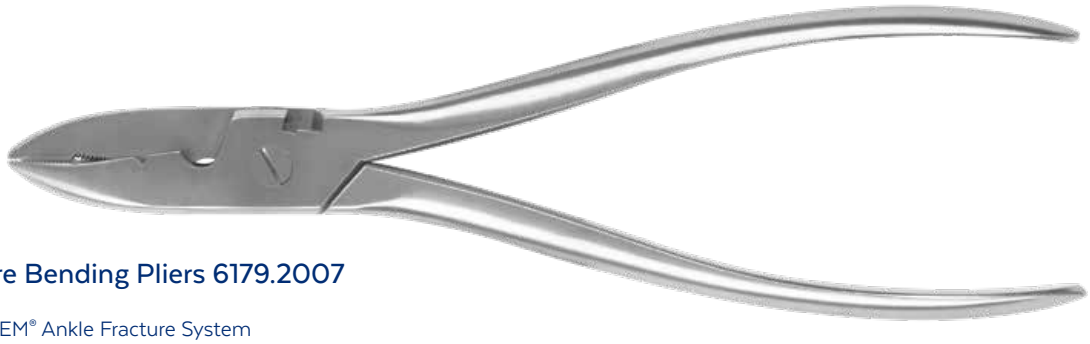
Dental Pick, Curved Tip, Small Handle 6179.7012

PLATE BENDING INSTRUMENTS

Bending Iron 6179.7002

Bending Iron, Inverted 6179.7003

PLIERS



Wire Bending Pliers 6179.2007

K-WIRES

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

2.0mm K-wire, Trocar Tip, 150mm 6179.1120

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

1.4mm K-wire, Threaded Trocar Tip, 150mm 6178.1314

1.4mm K-wire, Trocar Tip, 150mm 6178.1114

ADDITIONAL INSTRUMENTS

Cleaning Brush, 1.4mm Cannulation 6178.7000

Screw Holding Forceps 6179.2000

ANTHEM® SS Ankle Fracture System
IMPLANT SET 9185.9001

Lateral Distal Fibula Plate, SS

Part No.	Description	QTY
2185.2104	4 Hole, 88mm, Right	2
2185.2105	5 Hole, 101mm, Right	2
2185.2107	7 Hole, 126mm, Right	2
2185.2109	9 Hole, 152mm, Right	2
2185.1104	4 Hole, 88mm, Left	2
2185.1105	5 Hole, 101mm, Left	2
2185.1107	7 Hole, 126mm, Left	2
2185.1109	9 Hole, 152mm, Left	2

Posterolateral Distal Fibula Plate, SS

Part No.	Description	QTY
2185.2204	4 Hole, 90mm, Right	2
2185.2205	5 Hole, 106mm, Right	2
2185.2207	7 Hole, 131mm, Right	2
2185.2209	9 Hole, 157mm, Right	2
2185.1204	4 Hole, 90mm, Left	2
2185.1205	5 Hole, 106mm, Left	2
2185.1207	7 Hole, 131mm, Left	2
2185.1209	9 Hole, 157mm, Left	2

Universal Distal Fibula Plate, SS

Part No.	Description	QTY
2185.0405	5 Hole, 101mm	2
2185.0407	7 Hole, 126mm	2

Hook Plate, SS

Part No.	Description	QTY
2185.0304	4 Hole, 66mm	2

One Third Tubular Plate, SS

Part No.	Description	QTY
2179.1302	2 Hole, 24mm	2
2179.1304	4 Hole, 48mm	2
2179.1306	6 Hole, 72mm	2
2179.1307	7 Hole, 84mm	2
2179.1308	8 Hole, 96mm	2
2179.1310	10 Hole, 120mm	2
2179.1312	12 Hole, 144mm	2

T-Plate, 3 Hole Head, SS

Part No.	Description	QTY
2179.0303	3 Hole Shaft, 47mm	2
2179.0305	5 Hole Shaft, 67mm	2

Reconstruction Plate, SS

Part No.	Description	QTY
2179.0006	6 Hole, 70mm	2
2179.0008	8 Hole, 94mm	2
2179.0010	10 Hole, 118mm	2

*Items in gray are additionally available

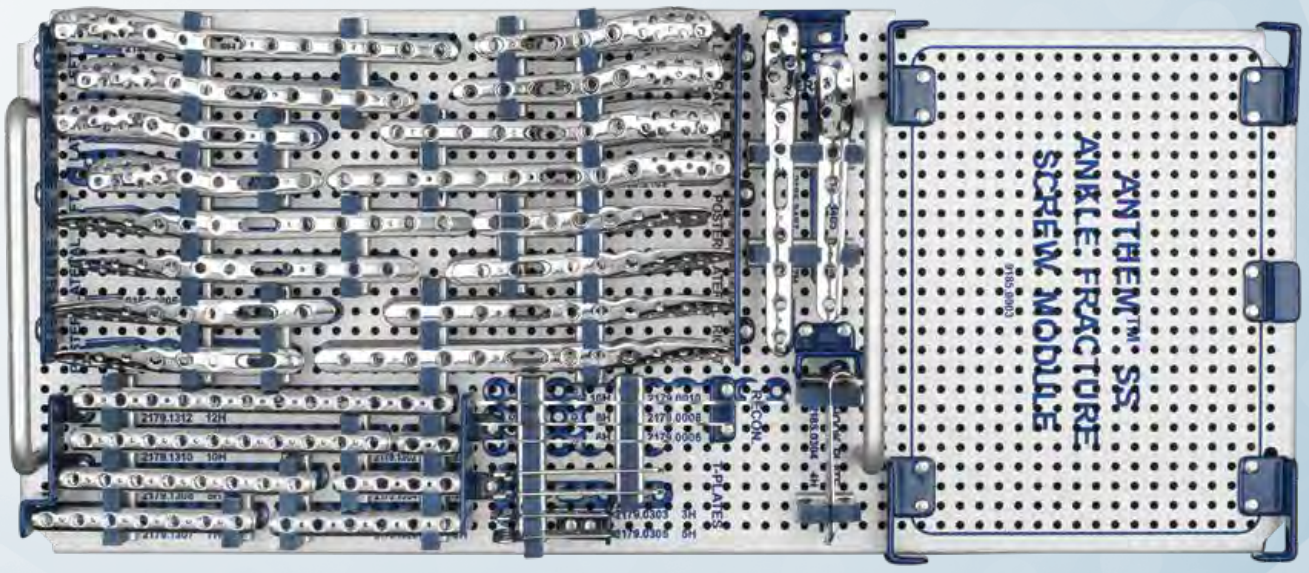
Additionally Available

Lateral Distal Fibula Plate, SS

Part No.	Description	QTY
2185.2103	3 hole, 75mm, Right	
2185.2111	11 Hole, 177mm, Right	
2185.2113	13 Hole, 203mm, Right	
2185.2115	15 Hole, 228mm, Right	
2185.1103	3 Hole, 75mm, Left	
2185.1111	11 Hole, 177mm, Left	
2185.1113	13 Hole, 203mm, Left	
2185.1115	15 Hole, 228mm, Left	

Posterolateral Distal Fibula Plate, SS

Part No.	Description	QTY
2185.2203	3 Hole, 70mm, Right	
2185.2211	11 Hole, 182mm, Right	
2185.2213	13 Hole, 208mm, Right	
2185.2215	15 Hole, 233mm, Right	
2185.1203	3 Hole, 70mm, Left	
2185.1211	11 Hole, 182mm, Left	
2185.1213	13 Hole, 208mm, Left	
2185.1215	15 Hole, 233mm, Left	



**Items in gray are additionally available*

ANTHEM® SS Ankle Fracture System
SCREW MODULE 9185.9003

MonoAx™ Locking Screw, SS

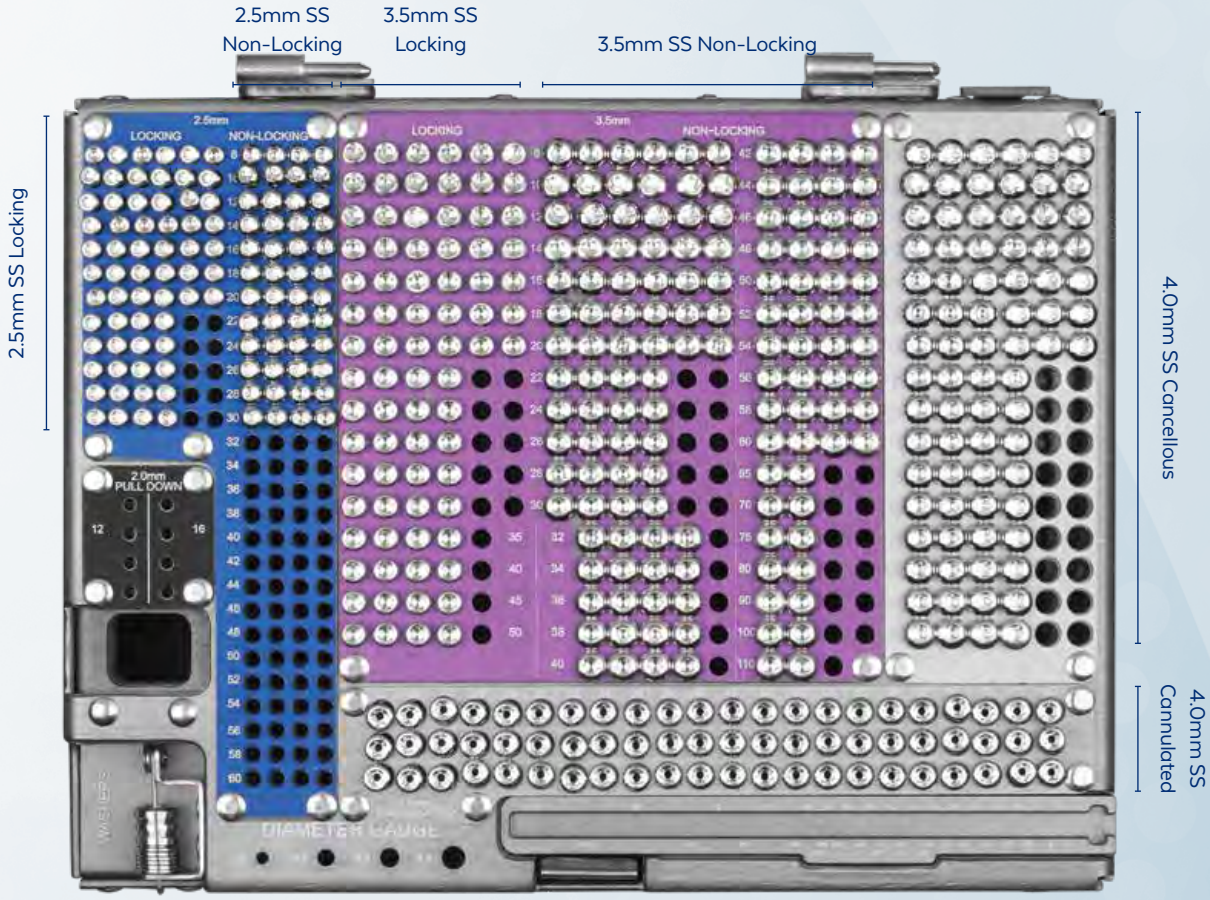
Part No.	Diameter/Length	QTY
2171.5508	2.5x8mm	6
2171.5510	2.5x10mm	6
2171.5512	2.5x12mm	6
2171.5514	2.5x14mm	6
2171.5516	2.5x16mm	6
2171.5518	2.5x18mm	6
2171.5520	2.5x20mm	6
2171.5522	2.5x22mm	4
2171.5524	2.5x24mm	4
2171.5526	2.5x26mm	4
2171.5528	2.5x28mm	4
2171.5530	2.5x30mm	4
2179.5008	3.5x8mm	6
2179.5010	3.5x10mm	6
2179.5012	3.5x12mm	6
2179.5014	3.5x14mm	6
2179.5016	3.5x16mm	6
2179.5018	3.5x18mm	6
2179.5020	3.5x20mm	6
2179.5022	3.5x22mm	4
2179.5024	3.5x24mm	4
2179.5026	3.5x26mm	4
2179.5028	3.5x28mm	4
2179.5030	3.5x30mm	4
2179.5035	3.5x35mm	4
2179.5040	3.5x40mm	4
2179.5045	3.5x45mm	4
2179.5050	3.5x50mm	4

Non-Locking Screw, SS

Part No.	Diameter/Length	QTY
2171.6508	2.5x8mm	4
2171.6510	2.5x10mm	4
2171.6512	2.5x12mm	4
2171.6514	2.5x14mm	4
2171.6516	2.5x16mm	4
2171.6518	2.5x18mm	4
2171.6520	2.5x20mm	4

Non-Locking Screw, SS

Part No.	Diameter/Length	QTY
2171.6522	2.5x22mm	4
2171.6524	2.5x24mm	4
2171.6526	2.5x26mm	4
2171.6528	2.5x28mm	4
2171.6530	2.5x30mm	4
2179.3008	3.5x8mm	6
2179.3010	3.5x10mm	6
2179.3012	3.5x12mm	6
2179.3014	3.5x14mm	6
2179.3016	3.5x16mm	6
2179.3018	3.5x18mm	6
2179.3020	3.5x20mm	6
2179.3022	3.5x22mm	4
2179.3024	3.5x24mm	4
2179.3026	3.5x26mm	4
2179.3028	3.5x28mm	4
2179.3030	3.5x30mm	4
2179.3032	3.5x32mm	4
2179.3034	3.5x34mm	4
2179.3036	3.5x36mm	4
2179.3038	3.5x38mm	4
2179.3040	3.5x40mm	4
2179.3042	3.5x42mm	4
2179.3044	3.5x44mm	4
2179.3046	3.5x46mm	4
2179.3048	3.5x48mm	4
2179.3050	3.5x50mm	4
2179.3052	3.5x52mm	4
2179.3054	3.5x54mm	4
2179.3056	3.5x56mm	4
2179.3058	3.5x58mm	4
2179.3060	3.5x60mm	4
2179.3065	3.5x65mm	2
2179.3070	3.5x70mm	2
2179.3075	3.5x75mm	2
2179.3080	3.5x80mm	2
2179.3090	3.5x90mm	2
2179.3100	3.5x100mm	2
2179.3110	3.5x110mm	2


2.5mm SS
Non-Locking
3.5mm SS
Locking
3.5mm SS Non-Locking
2.5mm SS Locking
4.0mm SS Cancellous
4.0mm SS
Cannulated
2.5mm
LOCKING
NON-LOCKING
3.5mm
LOCKING
NON-LOCKING
2.0mm
PULL DOWN
12
16
DIAMETER GAUGE

ANTHEM® SS Ankle Fracture System
SCREW MODULE 9185.9003 (CONT'D)

Cancellous Screw, Fully Threaded, SS

Part No.	Diameter/Length	QTY
2179.4008	4.0x8mm	6
2179.4010	4.0x10mm	6
2179.4012	4.0x12mm	6
2179.4014	4.0x14mm	6
2179.4016	4.0x16mm	6
2179.4018	4.0x18mm	6
2179.4020	4.0x20mm	6
2179.4022	4.0x22mm	4
2179.4024	4.0x24mm	4
2179.4026	4.0x26mm	4
2179.4028	4.0x28mm	4
2179.4030	4.0x30mm	4
2179.4035	4.0x35mm	4
2179.4040	4.0x40mm	4
2179.4045	4.0x45mm	4
2179.4050	4.0x50mm	4

CAPTIVATE™ Cannulated Screw, Long Thread, SS

Part No.	Diameter/Length	QTY
2178.4420	4.0x20mm	3
2178.4422	4.0x22mm	3
2178.4424	4.0x24mm	3
2178.4426	4.0x26mm	3
2178.4428	4.0x28mm	3
2178.4430	4.0x30mm	3
2178.4432	4.0x32mm	3
2178.4434	4.0x34mm	3
2178.4436	4.0x36mm	3
2178.4438	4.0x38mm	3
2178.4440	4.0x40mm	3
2178.4442	4.0x42mm	3
2178.4444	4.0x44mm	3
2178.4446	4.0x46mm	3
2178.4448	4.0x48mm	3

CAPTIVATE™ Cannulated Screw, Long Thread, SS

Part No.	Diameter/Length	QTY
2178.4450	4.0x50mm	3
2178.4455	4.0x55mm	3
2178.4460	4.0x60mm	3
2178.4465	4.0x65mm	3
2178.4470	4.0x70mm	3
2178.4475	4.0x75mm	3
2178.4480	4.0x80mm	3

Washer, SS

Part No.	Description	QTY
2179.0002	9.0mm	6

CAPTIVATE™ Washer, SS

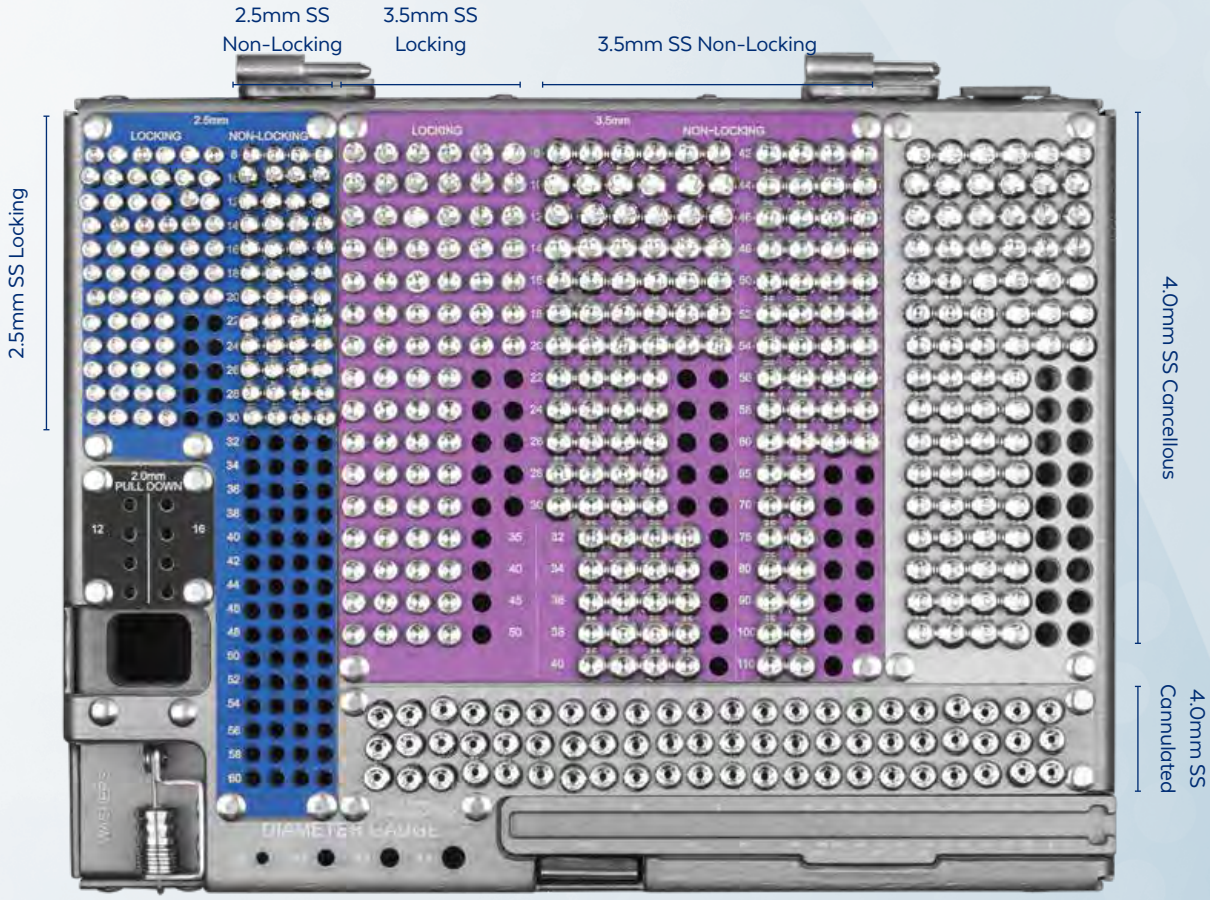
Part No.	Description	QTY
2178.0140	For 4.0mm Cannulated Screw	6

Additionally Available

Non-Locking Screw, SS

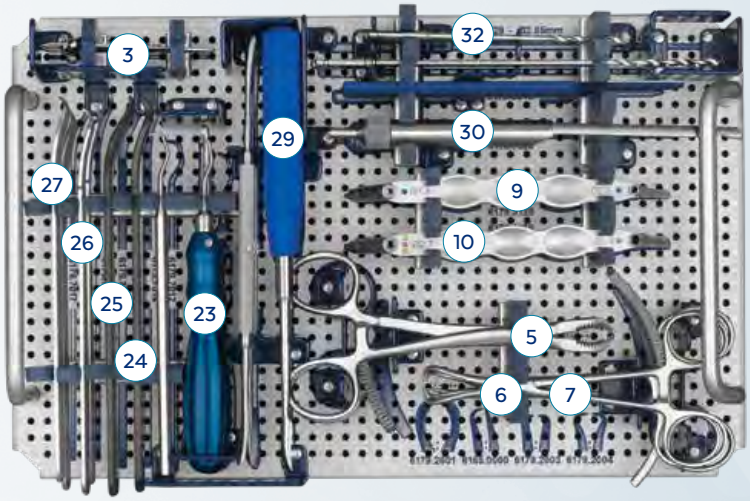
Part No.	Diameter/Length
2171.6532	2.5x32mm
2171.6534	2.5x34mm
2171.6536	2.5x36mm
2171.6538	2.5x38mm
2171.6540	2.5x40mm
2171.6542	2.5x42mm
2171.6544	2.5x44mm
2171.6546	2.5x46mm
2171.6548	2.5x48mm
2171.6550	2.5x50mm
2171.6552	2.5x52mm
2171.6554	2.5x54mm
2171.6556	2.5x56mm
2171.6558	2.5x58mm
2171.6560	2.5x60mm

*Items in gray are additionally available


2.5mm SS
Non-Locking
3.5mm SS
Locking
3.5mm SS Non-Locking
2.5mm SS Locking
4.0mm SS Cancellous
4.0mm SS
Cannulated
2.5mm
LOCKING
NON-LOCKING
3.5mm
LOCKING
NON-LOCKING
2.0mm
PULL DOWN
12
16
DIAMETER GAUGE

ANTHEM® SS Ankle Fracture System
INSTRUMENT SET 9185.9001

	Part No.	Description	QTY
1	6179.1116	1.6mm K-Wire, Trocar Tip, 150mm	10
2	6179.1120	2.0mm K-Wire, Trocar Tip, 150mm	10
3	6179.1216	1.6mm Plate Holding K-wire, Threaded Trocar Tip, 75mm	5
4	6179.2000	Screw Holding Forceps	1
5	6179.2001	Lobster Claw Reduction Forceps, Ratcheting	2
6	6179.2003	Point-to-Point Reduction Forceps, Narrow, Ratcheting	1
7	6179.2004	Point-to-Point Reduction Forceps, Wide, Ratcheting	1
8	6179.2007	Wire Bending Pliers	1
9	6179.3135	3.5mm Soft Tissue Protector, Spring Loaded	1
10	6179.3125	2.5mm Soft Tissue Protector, Spring Loaded	1
11	6179.3227	2.7mm Threaded Drill Guide	4
12	6185.3218	1.8mm Threaded Drill Guide	4
13	6185.5018	1.8mm Drill Bit, 137mm, AO Quick Connect	4
14	6179.5025	2.5mm Drill Bit, 110mm, AO Quick Connect	4
15	6179.5027	2.7mm Drill Bit, 125mm, AO Quick Connect	4
16	6179.5035	3.5mm Drill Bit, 110mm, AO Quick Connect	4
17	6179.6008	T8 Driver, SR, 60mm, AO Quick Connect	4
18	6179.6015	T15 Driver, SR, 100mm, AO Quick Connect	4
19	6179.7000	Countersink, AO Quick Connect	1
20	6179.7013	Medium Handle, Ratcheting, Cannulated, AO Quick Connect	2
21	6179.7002	Bending Iron	1
22	6179.7003	Bending Iron, Inverted	1
23	6179.7025	Dental Pick, Curved Tip, Large Handle	1
24	6179.7014	Radiolucent Hohmann Retractor, 8mm	1
25	6179.7015	Radiolucent Hohmann Retractor, 16mm	1
26	6179.7016	Hohmann Retractor, 8mm	2
27	6179.7017	Hohmann Retractor, 15mm	2
28	6185.0008	Torque Limiting Attachment, 0.8Nm, AO Quick Connect	1
29	6179.7019	Periosteal Elevator, Curved Round Tip, 6mm	1
30	6179.7020	Depth Gauge, 60mm	1
31	6179.7031	Depth Gauge, 110mm	1
32	6178.5329	2.85mm Drill Bit, Cannulated, 115mm, AO Quick Connect	4
33	6178.5140	4.0mm Tap, Cannulated, AO Quick Connect	1
34	6168.5215	T15 Driver, SR, Cannulated, 150mm, AO Quick Connect	2
35	6178.1314	1.4mm K-Wire, Threaded Trocar Tip, 150mm	10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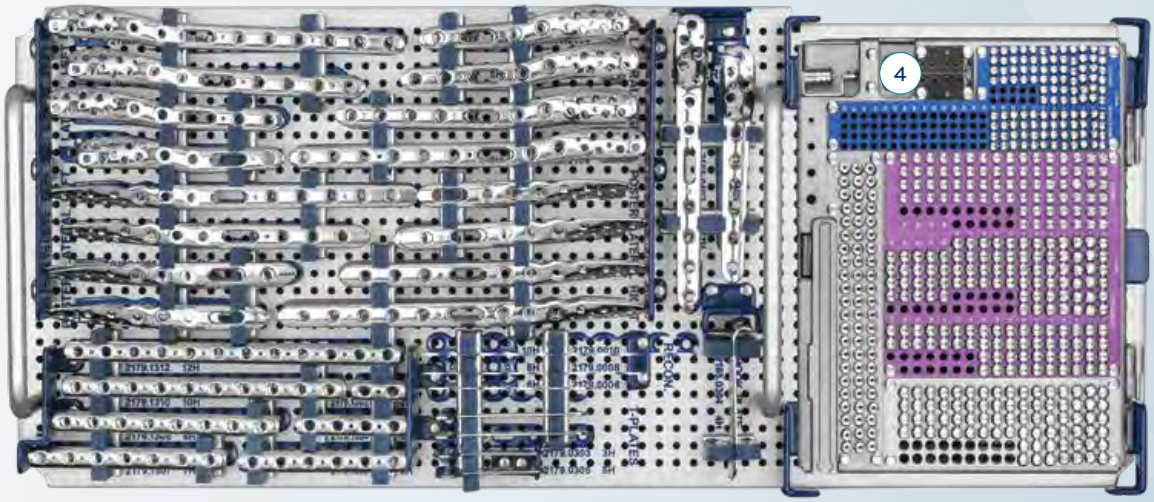
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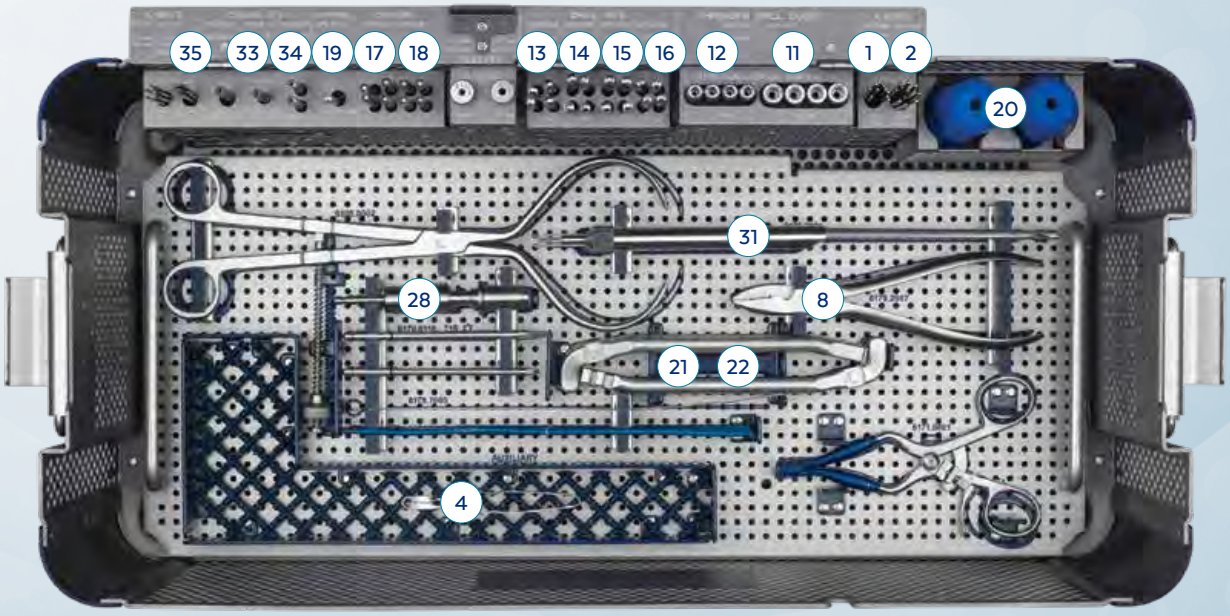
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ANTHEM® SS Ankle Fracture System
INSTRUMENT SET 9185.9001 (CONT'D)

	Part No.	Description	QTY
36	6178.1114	1.4mm K-Wire, Trocar Tip, 150mm	10
37	6178.7040	Countersink, Cannulated, AO Quick Connect	1
38	6178.7000	Cleaning Brush, 1.4mm Cannulation	1
39	6178.3640	Measuring Device, Cannulated	1
40	6185.0000	Malleolar Clamp, Ratcheting	1
41	6185.0002	Syndesmosis Clamp, Weber, Spin-Down	1
42	6185.0005	Freer Elevator	2
43	6185.0006	Cup Curette	1
44	6179.7012	Dental Pick, Curved Tip, Small Handle	1
45	6179.6115	T15 Driver, Non Self-Retaining, 100mm, AO Quick Connect	2
46	6179.6108	T8 Driver, Non Self-Retaining, 100mm, AO Quick Connect	2
47	6179.5028	2.7mm Calibrated Drill Bit, 180mm, AO Quick Connect	2
48	6171.0001	Stabilizing Radiolucent Weitlaner 2x3, 5", Sharp Tip	1
49	6171.7008	Malleable Band	5
50	6179.3137	3.5/2.7mm Drill Sleeve	1
51	6179.3128	2.5/1.8mm Drill Sleeve	1

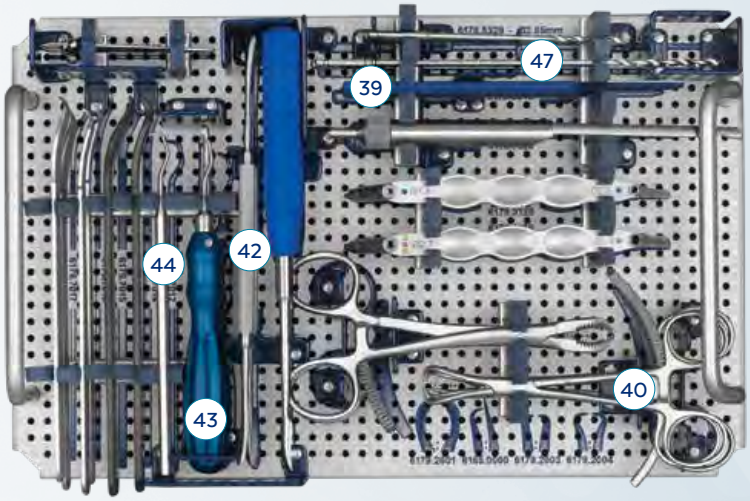
Module/Case

9185.0001	ANTHEM® SS Ankle Fracture System Graphic Case

Additionally Available

6179.7001	Quick Connect Handle, Cannulated, AO Quick Connect

**Items in gray are additionally available*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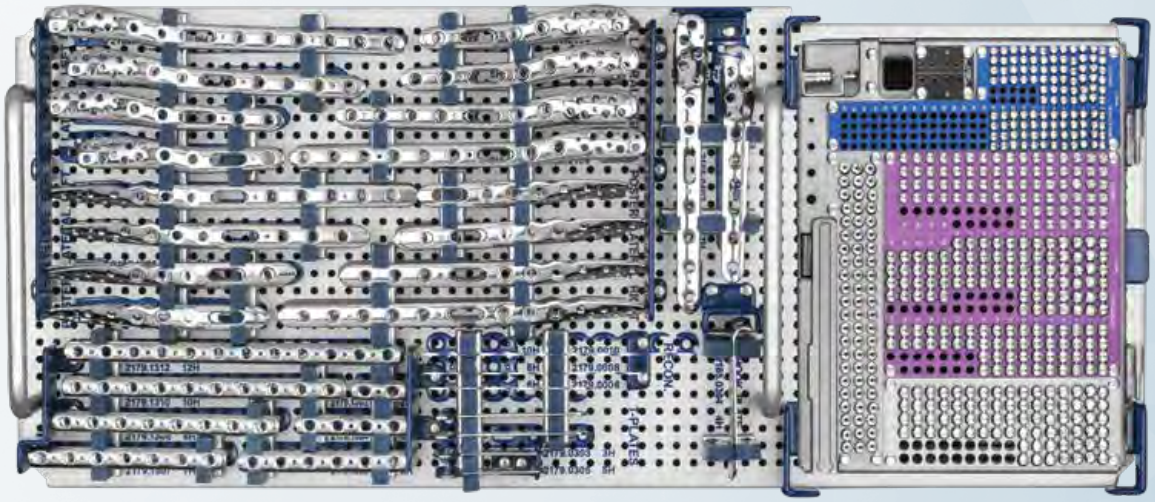

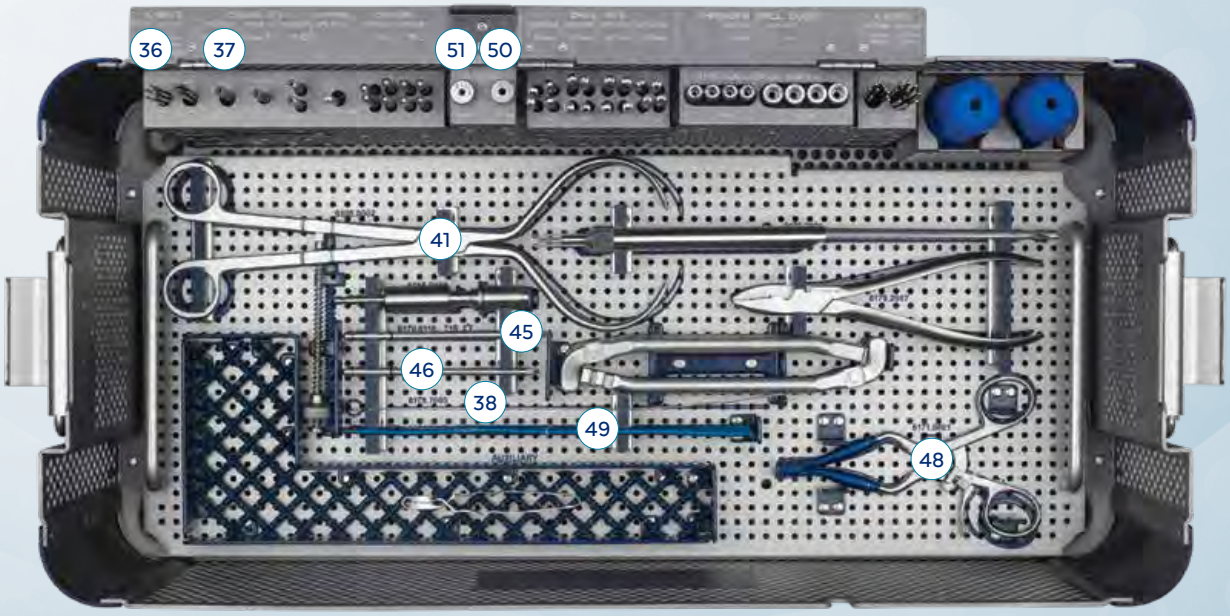
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ANTHEM® Ti Ankle Fracture System
IMPLANT SET 9185.9002

Lateral Distal Fibula Plate, Ti

Part No.	Description	QTY
1185.2104	4 Hole, 88mm, Right	2
1185.2105	5 Hole, 101mm, Right	2
1185.2107	7 Hole, 126mm, Right	2
1185.2109	9 Hole, 152mm, Right	2
1185.1104	4 Hole, 88mm, Left	2
1185.1105	5 Hole, 101mm, Left	2
1185.1107	7 Hole, 126mm, Left	2
1185.1109	9 Hole, 152mm, Left	2

Posterolateral Distal Fibula Plate, Right, Ti

Part No.	Description	QTY
1185.2204	4 Hole, 90mm, Right	2
1185.2205	5 Hole, 106mm, Right	2
1185.2207	7 Hole, 131mm, Right	2
1185.2209	9 Hole, 157mm, Right	2
1185.1204	4 Hole, 90mm, Left	2
1185.1205	5 Hole, 106mm, Left	2
1185.1207	7 Hole, 131mm, Left	2
1185.1209	9 Hole, 157mm, Left	2

Universal Distal Fibula Plate, Ti

Part No.	Description	QTY
1185.0405	5 Hole, 101mm	2
1185.0407	7 Hole, 126mm	2

Hook Plate, Ti

Part No.	Description	QTY
1185.0304	4 Hole, 66mm	2

One Third Tubular Plate, Ti

Part No.	Description	QTY
1179.1302	2 Hole, 24mm	2
1179.1304	4 Hole, 48mm	2
1179.1306	6 Hole, 72mm	2
1179.1307	7 Hole, 84mm	2
1179.1308	8 Hole, 96mm	2
1179.1310	10 Hole, 120mm	2
1179.1312	12 Hole, 144mm	2

T-Plate, 3 Hole Head, Ti

Part No.	Description	QTY
1179.0303	3 Hole Shaft, 47mm	2
1179.0305	5 Hole Shaft, 67mm	2

Reconstruction Plate, Ti

Part No.	Description	QTY
1179.0006	6 Hole, 70mm	2
1179.0008	8 Hole, 94mm	2
1179.0010	10 Hole, 118mm	2

Additionally Available

Lateral Distal Fibula Plate, Ti

Part No.	Description
1185.2103	3 Hole, 75mm, Right
1185.2111	11 Hole, 177mm, Right
1185.2113	13 Hole, 203mm, Right
1185.2115	15 Hole, 228mm, Right
1185.1103	3 Hole, 75mm, Left
1185.1111	11 Hole, 177mm, Left
1185.1113	13 Hole, 203mm, Left
1185.1115	15 Hole, 228mm, Left

Posterolateral Distal Fibula Plate, Ti

Part No.	Description
1185.2203	3 Hole, 70mm, Right
1185.2211	11 Hole, 182mm, Right
1185.2213	13 Hole, 208mm, Right
1185.2215	15 Hole, 233mm, Right
1185.1203	3 Hole, 70mm, Left
1185.1211	11 Hole, 182mm, Left
1185.1213	13 Hole, 208mm, Left
1185.1215	15 Hole, 233mm, Left

**Items in gray are additionally available*

ANTHEM® Ti Ankle Fracture System
SCREW MODULE 9185.9004

Locking Screw, Ti

Part No.	Diameter/Length	QTY
1171.5508	2.5x8mm	6
1171.5510	2.5x10mm	6
1171.5512	2.5x12mm	6
1171.5514	2.5x14mm	6
1171.5516	2.5x16mm	6
1171.5518	2.5x18mm	6
1171.5520	2.5x20mm	6
1171.5522	2.5x22mm	4
1171.5524	2.5x24mm	4
1171.5526	2.5x26mm	4
1171.5528	2.5x28mm	4
1171.5530	2.5x30mm	4
1179.5008	3.5x8mm	6
1179.5010	3.5x10mm	6
1179.5012	3.5x12mm	6
1179.5014	3.5x14mm	6
1179.5016	3.5x16mm	6
1179.5018	3.5x18mm	6
1179.5020	3.5x20mm	6
1179.5022	3.5x22mm	4
1179.5024	3.5x24mm	4
1179.5026	3.5x26mm	4
1179.5028	3.5x28mm	4
1179.5030	3.5x30mm	4
1179.5035	3.5x35mm	4
1179.5040	3.5x40mm	4
1179.5045	3.5x45mm	4
1179.5050	3.5x50mm	4

Non-Locking Screw, Ti

Part No.	Diameter/Length	QTY
1171.6508	2.5x8mm	4
1171.6510	2.5x10mm	4
1171.6512	2.5x12mm	4
1171.6514	2.5x14mm	4
1171.6516	2.5x16mm	4
1171.6518	2.5x18mm	4
1171.6520	2.5x20mm	4
1171.6522	2.5x22mm	4
1171.6524	2.5x24mm	4

Non-Locking Screw, Ti

Part No.	Diameter/Length	QTY
1171.6526	2.5x26mm	4
1171.6528	2.5x28mm	4
1171.6530	2.5x30mm	4
1179.3008	3.5x8mm	6
1179.3010	3.5x10mm	6
1179.3012	3.5x12mm	6
1179.3014	3.5x14mm	6
1179.3016	3.5x16mm	6
1179.3018	3.5x18mm	6
1179.3020	3.5x20mm	6
1179.3022	3.5x22mm	4
1179.3024	3.5x24mm	4
1179.3026	3.5x26mm	4
1179.3028	3.5x28mm	4
1179.3030	3.5x30mm	4
1179.3032	3.5x32mm	4
1179.3034	3.5x34mm	4
1179.3036	3.5x36mm	4
1179.3038	3.5x38mm	4
1179.3040	3.5x40mm	4
1179.3042	3.5x42mm	4
1179.3044	3.5x44mm	4
1179.3046	3.5x46mm	4
1179.3048	3.5x48mm	4
1179.3050	3.5x50mm	4
1179.3052	3.5x52mm	4
1179.3054	3.5x54mm	4
1179.3056	3.5x56mm	4
1179.3058	3.5x58mm	4
1179.3060	3.5x60mm	4
1179.3065	3.5x65mm	2
1179.3070	3.5x70mm	2
1179.3075	3.5x75mm	2
1179.3080	3.5x80mm	2
1179.3090	3.5x90mm	2
1179.3100	3.5x100mm	2
1179.3110	3.5x110mm	2

ANTHEM® Ti Ankle Fracture System
SCREW MODULE 9185.9004 (CONT'D)

Cancellous Screw, Fully Threaded, Ti

Part No.	Diameter/Length	QTY
1179.4008	4.0x8mm	6
1179.4010	4.0x10mm	6
1179.4012	4.0x12mm	6
1179.4014	4.0x14mm	6
1179.4016	4.0x16mm	6
1179.4018	4.0x18mm	6
1179.4020	4.0x20mm	6
1179.4022	4.0x22mm	4
1179.4024	4.0x24mm	4
1179.4026	4.0x26mm	4
1179.4028	4.0x28mm	4
1179.4030	4.0x30mm	4
1179.4035	4.0x35mm	4
1179.4040	4.0x40mm	4
1179.4045	4.0x45mm	4
1179.4050	4.0x50mm	4

CAPTIVATE™ Cannulated Screw, Long Thread, Ti

Part No.	Diameter/Length	QTY
1178.4420	4.0x20mm	3
1178.4422	4.0x22mm	3
1178.4424	4.0x24mm	3
1178.4426	4.0x26mm	3
1178.4428	4.0x28mm	3
1178.4430	4.0x30mm	3
1178.4432	4.0x32mm	3
1178.4434	4.0x34mm	3
1178.4436	4.0x36mm	3
1178.4438	4.0x38mm	3
1178.4440	4.0x40mm	3
1178.4442	4.0x42mm	3
1178.4444	4.0x44mm	3
1178.4446	4.0x46mm	3
1178.4448	4.0x48mm	3
1178.4450	4.0x50mm	3
1178.4455	4.0x55mm	3
1178.4460	4.0x60mm	3
1178.4465	4.0x65mm	3
1178.4470	4.0x70mm	3
1178.4475	4.0x75mm	3
1178.4480	4.0x80mm	3

Washer, Ti

Part No.	Description	QTY
1179.0002	9.0mm	6

CAPTIVATE™ Washer, Ti

Part No.	Description	QTY
1178.0140	For 4.0mm Cannulated Screw	6

Module

9185.0004	ANTHEM® Ti Ankle Fracture System Screw Module

Additionally Available

Non-Locking Screw, Ti

Part No.	Diameter/Length
1171.6532	2.5x32mm
1171.6534	2.5x34mm
1171.6536	2.5x36mm
1171.6538	2.5x38mm
1171.6540	2.5x40mm
1171.6542	2.5x42mm
1171.6544	2.5x44mm
1171.6546	2.5x46mm
1171.6548	2.5x48mm
1171.6550	2.5x50mm
1171.6552	2.5x52mm
1171.6554	2.5x54mm
1171.6556	2.5x56mm
1171.6558	2.5x58mm
1171.6560	2.5x60mm

*Items in gray are additionally available

ANTHEM® Ti Ankle Fracture System
INSTRUMENT SET 9185.9002

Instrument

Part No.	Description	QTY
6179.2000	Screw Holding Forceps	1
6179.2001	Lobster Claw Reduction Forceps, Ratcheting	2
6179.2007	Wire Bending Pliers	1
6179.7000	Countersink, AO Quick Connect	1
6179.7013	Quick Connect Handle, Ratcheting, Cannulated, AO Quick Connect	2
6179.7002	Bending Iron	1
6179.7003	Bending Iron, Inverted	1
6179.7025	Dental Pick, Curved Tip, Large Handle	1
6185.0008	Torque Limiting Attachment, 0.8Nm, AO Quick Connect	1
6179.7019	Periosteal Elevator, Curved Round Tip, 6mm	1
6178.7000	Cleaning Brush, 1.4mm Cannulation	1
6178.3640	Measuring Device, Cannulated	1
6185.0000	Malleolar Clamp, Ratcheting	1
6185.0002	Syndesmosis Clamp, Weber, Spin-Down	1
6185.0005	Freer Elevator	2
6185.0006	Cup Curette	1
6179.7012	Dental Pick, Curved Tip,	1
6171.0001	Stabilizing Radiolucent Weitlaner 2x3, 5", Sharp Tip	1
6171.7008	Malleable Replacement Band Small Handle	5
6178.7040	Countersink, Cannulated, AO Quick Connect	1

K-Wire, Trocar Tip

Part No.	Diameter/Length	QTY
6179.1116	1.6x150mm	10
6179.1120	2.0x150mm	10
6178.1114	1.4x150mm	10

K-Wire, Threaded Trocar Tip

Part No.	Diameter/Length	QTY
6178.1314	1.4x150mm	10

Plate Holding K-Wire, Threaded Trocar Tip

Part No.	Diameter/Length	QTY
6179.1216	1.6x75mm	5

Point-to-Point Reduction Forceps, Ratcheting

Part No.	Description	QTY
6179.2003	Narrow	1
6179.2004	Wide	1

Soft Tissue Protector, Spring Loaded

Part No.	Description	QTY
6179.3135	3.5mm	1
6179.3125	2.5mm	1

Threaded Drill Guide

Part No.	Description	QTY
6179.3227	2.7mm	4
6185.3218	1.8mm	4

Drill Bit, AO Quick Connect

Part No.	Diameter/Length	QTY
6185.5018	1.8x137mm	4
6179.5025	2.5x110mm	4
6179.5027	2.7x125mm	4
6179.5035	3.5x110mm	4

Driver, SR, AO Quick Connect

Part No.	Description	QTY
6179.6008	T8, 60mm	4
6179.6015	T15, 100mm	4

Radiolucent Hohmann Retractor

Part No.	Description	QTY
6179.7014	8mm	1
6179.7015	16mm	1

Hohmann Retractor

Part No.	Description	QTY
6179.7016	8mm	2
6179.7017	15mm	2

ANTHEM® Ti Ankle Fracture System
INSTRUMENT SET 9185.9002 (CONT'D)

Depth Gauge

Part No.	Description	QTY
6179.7020	60mm	1
6179.7031	110mm	1

Drill Bit, Cannulated, AO Quick Connect

Part No.	Diameter/Length	QTY
6178.5329	2.85x190mm	4

Tap, Cannulated, AO Quick Connect

Part No.	Diameter	QTY
6178.5140	4.0mm	1

T15 Driver, SR, Cannulated, AO Quick Connect

Part No.	Length	QTY
6168.5215	150mm	2

Driver, Non Self-Retaining, AO Quick Connect

Part No.	Description	QTY
6179.6115	T15, 100mm	2
6179.6108	T8, 100mm	2

Calibrated Drill Bit, AO Quick Connect

Part No.	Diameter/Length	QTY
6179.5028	2.7x180mm	2

Drill Sleeve

Part No.	Description	QTY
6179.3137	3.5/2.7mm	1
6179.3128	2.5/1.8mm	1

Module/Case

9185.0002	ANTHEM® Ti Ankle Fracture System Graphic Case

Additionally Available

Instrument

Part No.	Description
6179.7001	Quick Connect Handle, Cannulated, AO Quick Connect

**Items in gray are additionally available*

IMPORTANT INFORMATION ON THE 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 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.

IMPORTANT INFORMATION ON THE 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 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 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 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 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 in^2 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			
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	Rx ONLY	PRESCRIPTION USE ONLY

DI201 REV C

IMPORTANT INFORMATION ON CAPTIVATE™ COMPRESSION SCREWS

DESCRIPTION

CAPTIVATE™ Compression Screws consist of bone screws designed to compact juxtaposed bone for reconstruction and enhanced arthrodesis. The implants are available in various diameters and lengths to accommodate patient anatomy, with headless, partially or fully threaded, solid or cannulated, and variable length (VL) options. CAPTIVATE™ implants are manufactured from titanium alloy, cobalt chromium molybdenum alloy, or stainless steel, as specified in ASTM F136, F1295, F1472, F1537 and F138.

INDICATIONS

CAPTIVATE™ Compression Screws are indicated for use in adult and pediatric patients, for fracture repair and fixation, osteotomy, joint fusion, reconstruction and arthrodesis of bones appropriate for the size of the device.

CAPTIVATE™ VL Compression Screws are indicated for use in adult and pediatric patients, for fracture repair and fixation, osteotomy, joint fusion, reconstruction and arthrodesis of the phalanges, metacarpals, carpals, metatarsals, midfoot, hind foot, ankle, fibula, distal tibia, proximal tibia, radius, ulna, humerus, and clavicle

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 compression screw 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. An explanted implant must never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which could lead to breakage

MRI 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.

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.
- 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, intraoperative 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.

Intraoperative

- 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).

Postoperative

- Postoperative 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 postoperative 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 postoperative examinations (e.g., X-ray checks) are advisable.
- The risk of postoperative 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 CAPTIVATE™ COMPRESSION SCREWS

- 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 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 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.

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