



ANTHEM®

Small Fragment Fracture System



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



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

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ANTHEM®

Small Fragment Fracture System

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ANTHEM®

Small Fragment Fracture System



The ANTHEM® Small Fragment Fracture System offers numerous treatment options for upper and lower extremity trauma. The system features a comprehensive set of implants and instruments designed to improve fracture care.

Multiple plate types are offered with screw lengths up to 100mm. Innovative instruments are designed to improve procedure flow. Radiolucent Hohmann and Weitlaner retractors improve visibility of the fracture site. Versatile bending irons and clamps help to expedite plate contouring.

Comprehensive Plate Offering

The ANTHEM® Small Fragment Fracture System offers 3.5mm Straight Plates, One-Third Tubular Plates, Reconstruction Plates, and T-Plates. All plates are available in stainless steel or titanium alloy.





Versatile Screw Options

Locking, non-locking, and cancellous screws are available in lengths up to 100mm.

Locking and Non-Locking Plates

Locking and non-locking plates are available to accommodate diverse surgical preferences and clinical scenarios.



Improved Procedure Flow

All 3.5mm and 4.0mm screws use the same drill and driver size to reduce intraoperative complexity and improve procedure flow.

Enhanced Bending Instruments

The Universal Bending Clamp provides three mechanisms for in-plane and out-of-plane bending. Bending Irons combine features of standard and reconstruction style irons into one instrument.





Radiolucent Retractors

Radiolucent retractors aid in visibility of the fracture site.



COLOR-CODING

Drill Bits, Taps, and Drill Guides

- Drill bits, taps, and drill guides are color-coded with bands for easy identification of screw and drill diameters
- Instruments with multiple color bands are compatible with multiple diameters

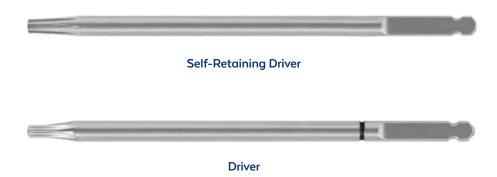
Color	Screw Diameter	Drill Diameter
Blue	2.5mm	1.8mm
Fuschia	3.5mm	2.7mm
Green	4.0mm	2.7mm



Drivers

The color bands indicate driver type.

- No color band: Self-retaining drivers designed to retain screws without a retaining sleeve
- Black color band: Standard drivers designed to seat fully in the screw head to prevent stripping of the screw head in challenging clinical scenarios



IMPLANT OVERVIEW

3.5mm Straight Plates

- Available in 4 to 16 hole configurations (54-190mm)
- Locking and dynamic compression holes
- K-wire holes provide multiple options for provisional fixation
- Low profile design minimizes soft tissue irritation and allows for submuscular implantation
- Non-locking plates available



One-Third Tubular Plates

- Available in 2 to 14 hole configurations (24–168mm)
- Accommodate locking, non-locking, and cancellous screws, and suture buttons up to 6.5mm in diameter
- K-wire holes provide multiple options for provisional fixation
- Non-locking plates available



Reconstruction Plates

- Available in 4 to 16 hole configurations (46-190mm)
- K-wire holes provide multiple options for provisional fixation
- Optimal design for in-plane, out-of-plane, and twist contouring
- Non-locking plates available

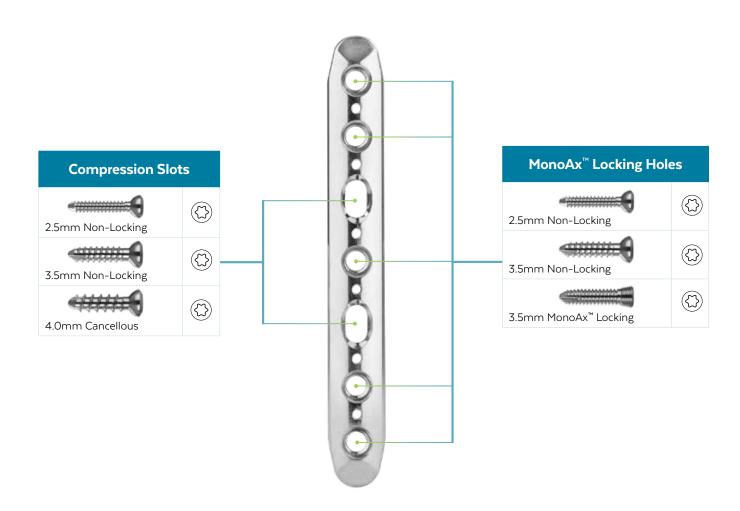


T-Plates

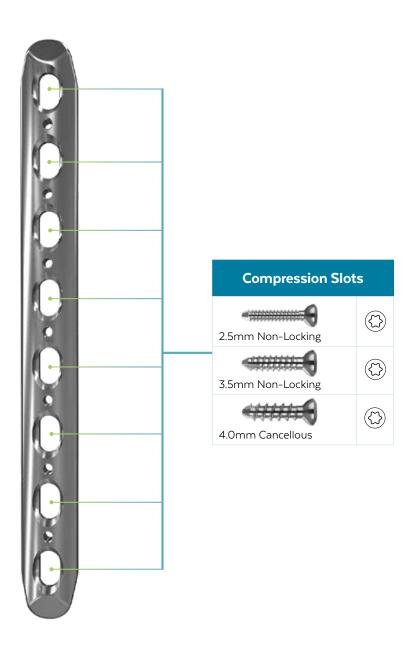
- Available in 3 head hole and 3 or 5 shaft hole configurations (47-67mm)
- Available in 4 head hole and 4 or 6 shaft hole configurations (57-77mm)
- K-wire holes provide multiple options for provisional fixation
- Non-locking plates available



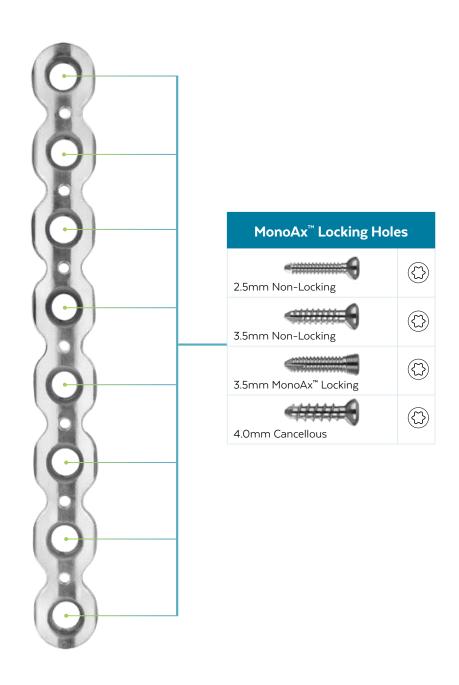
Locking 3.5mm Straight Plate



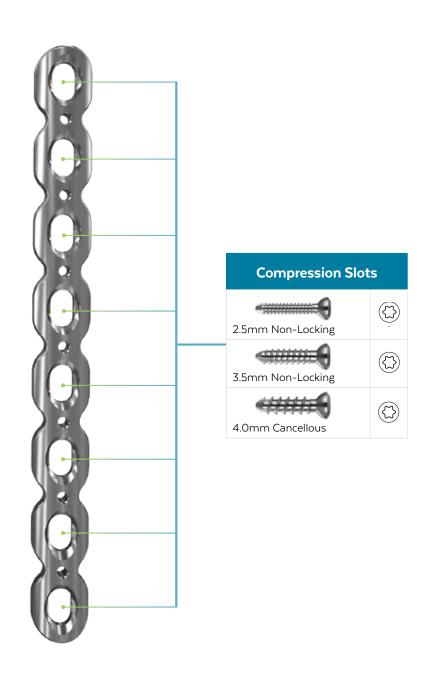
Non-Locking 3.5mm Straight Plate



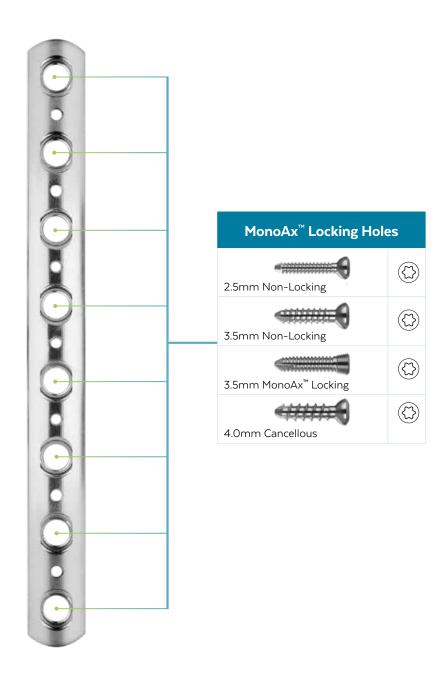
Locking Reconstruction Plate



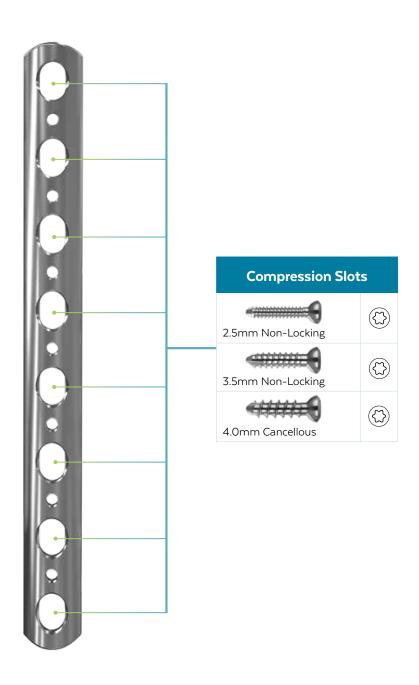
Non-Locking Reconstruction Plate



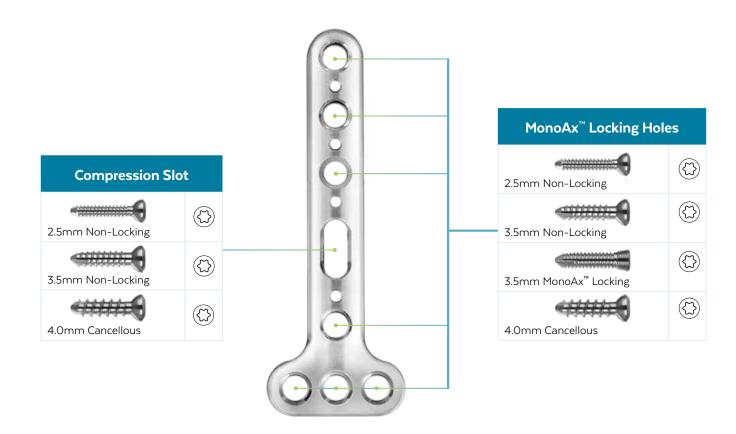
Locking One-Third Tubular Plate



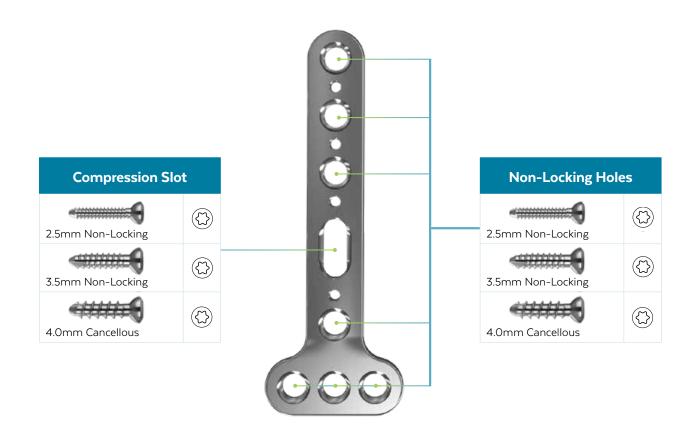
Non-Locking One-Third Tubular Plate



Locking T-Plate



Non-Locking T-Plate



All screws in the ANTHEM® Small Fragment Fracture System use a T15 Driver, and are available in stainless steal or titanium.

2.5mm Non-Locking Screws

- Universally accepted in all plates
- Offered in lengths from 8-70mm





3.5mm Non-Locking Screws

- Universally accepted in all plates
- Offered in lengths from 8-100mm

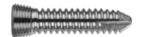




3.5mm MonoAx[™] Locking Screws

- Accepted in all threaded holes
- Offered in lengths from 8-60mm





4.0mm Cancellous Screws

- Fully threaded screws from 8-70mm
- Partially threaded screws from 30-70mm









SURGICAL TECHNIQUE

ANTHEM®

Small Fragment Fracture System

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

STEP

PREOPERATIVE PLANNING

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

STEP

APPROACH AND FRACTURE REDUCTION

Place the patient in the desired operative position. Create an incision to access the fracture site. Reduce the fracture using the appropriate reduction method for the fracture type. Ensure that bone length, alignment, and rotation are properly restored. Joint fractures often require anatomic reduction while functional reduction is usually sufficient for diaphyseal and meta-diaphyseal fractures.

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







Joint fractures typically require anatomic reduction while functional reduction is usually sufficient for diaphyseal and meta-diaphyseal fractures.

APPROACH AND FRACTURE REDUCTION (CONT'D)

Lag Screw Placement

Lag screw fixation may be useful for interfragmentary compression across the fracture prior to plate placement. For successful compression, the screw threads must engage in the far cortex only. If the screw threads engage both cortices, compression is prevented.

2.5mm Non-Locking Lag Screw

With the fracture reduced, drill the near cortex using the 2.5mm Drill Bit and the 2.5mm Spring Loaded Soft Tissue Protector. Insert the 2.5/1.8mm Drill Sleeve into the glide hole. Drill the far cortex using the 1.8mm Drill Bit. Measure hole depth using the Depth Gauge. Select and place the desired 2.5mm Non-Locking Screw using the T15 Driver with the Quick-Connect Handle.

3.5mm Non-Locking Lag Screw

With the fracture reduced, drill the near cortex using the 3.5mm Drill Bit and the 3.5mm Spring Loaded Soft Tissue Protector. Insert the 3.5/2.7mm Drill Sleeve into the glide hole. Drill the far cortex using the 2.7mm Drill Bit. Measure hole depth using the Depth Gauge. Select and place the desired 3.5mm Non-Locking Screw using the T15 Driver with the Quick-Connect Handle.

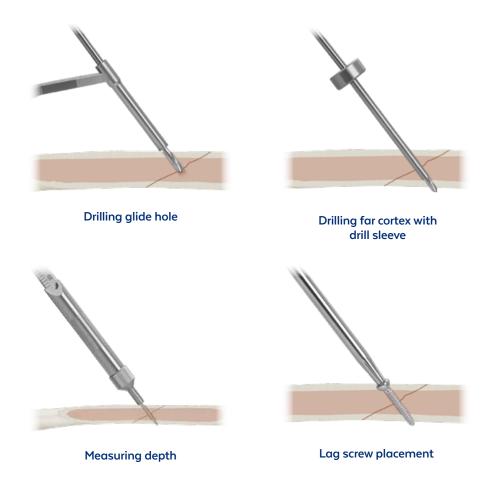




PLATE SELECTION AND CONTOURING

Select the plate that best accommodates patient anatomy and fracture pattern. If needed, contour the selected plate to the bone. Bending Templates are available in 7, 9, and 12 hole lengths to aid in plate contouring.

O USING THE BENDING INSTRUMENTS

Bending Irons feature multiple slots for in-plane bending, out-of-plane bending, and twist contouring. Reconstruction Plates feature cutouts for in-plane bending.







The Universal Bending Clamp provides additional options for plate contouring. Out-of-plane bending is achieved using the jaws of the clamp, while posts on each side of the clamp allow for broad and acute in-plane bending.







PLATE POSITIONING STEP

Position the selected plate on the bone. The plate may be provisionally held with 1.6mm K-Wires, 1.6mm Plate Holding K-Wires, or Point-to-Point Reduction Forceps through K-wire holes. Place K-Wires into K-wire holes or any screw hole for provisional fixation.

The Plate Reduction Instrument may be used to provisionally compress the plate to the bone. Secure the instrument to a power drill using an adapter if needed. Carefully drill the reduction instrument through the screw hole and into the near cortex. Remove the drill. Rotate the thumbwheel clockwise until it contacts the plate. Continue rotating clockwise until the desired reduction is achieved.

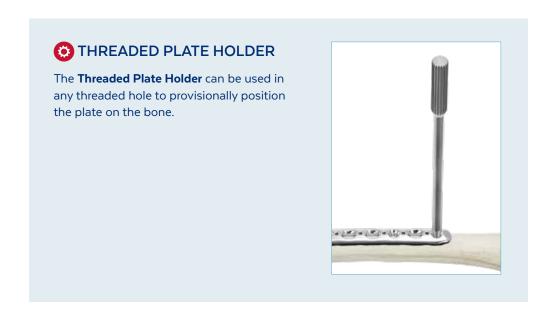
Confirm reduction and plate placement using fluoroscopy.







Compression using Plate Reduction Instrument and Plate Holding K-Wire



SCREW INSERTION STEP

Determine the appropriate screw type (locking, non-locking, or cancellous) and size for fixation. A combination of screw types and diameters may be used. Select the appropriate drill for the selected screw type and diameter. Use the 3.5mm Threaded **Drill Guide** or the Soft Tissue Protector to pre-drill a hole.

2.5mm Non-Locking Screws

All plates accept 2.5mm Non-Locking Screws through any screw hole.

Drill to the desired depth with the 1.8mm Drill Bit and the 2.5mm Spring Loaded Soft Tissue Protector. 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. Using the T15 Driver, insert the screw into the desired hole with the Quick-Connect Handle. A power drill with a Torque-Limiting adapter may be used if desired.



3.5mm Non-Locking and 4.0mm Cancellous Screws

Most plates accept 3.5mm Non-Locking and 4.0mm Cancellous Screws through any screw hole. The exception is the 3.5mm Locking Plate, which does not accept 4.0mm Cancellous Screws in its threaded holes.

Pre-drill to the desired depth using the 2.7mm Drill Bit and the 3.5mm Spring Loaded Soft Tissue Protector. 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. Using the T15 Driver, insert the screw into the desired hole with the Quick-Connect Handle. A power drill with a Torque-Limiting adapter may be used if desired.



SCREW INSERTION (CONT'D)

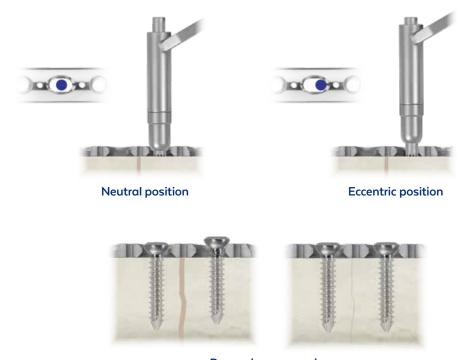


Dynamic Compression

Dynamic compression of the fracture may be achieved by eccentrically placing a non-locking or cancellous screw through a compression slot. 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, drill the hole in a neutral position.

Place the non-locking or cancellous screw on one side of the fracture. Select a compression slot on the opposite side of the fracture line. Insert the 2.5mm or the 3.5mm Soft Tissue Protector into the slot with no downward pressure. Place the Soft Tissue Protector eccentrically in the slot.

Drill to the desired depth. Measure hole depth using the Depth Gauge or 2.7mm Calibrated Drill Bit. Use the T15 Driver or Screw Holding Forceps to select the desired screw. Verify screw length and diameter using the gauges within the screw module. Using the T15 Driver, insert the screw into the desired hole with the Quick-Connect Handle. A power drill with a Torque-Limiting adapter may be used if desired.

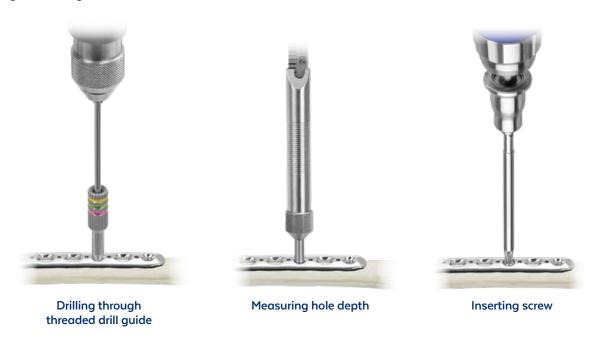


Dynamic compression

3.5mm Locking Screws

Locking screws may be inserted into round holes in the locking plates. Ensure the plate is in final position before placing any locking screws. Thread the **2.7mm Threaded Drill Guide** into the selected screw hole.

Drill to the desired depth through the center of the drill guide so that the hole is perpendicular to the plate using the 2.7mm Drill Bit. Remove the drill guide and measure hole depth using the Depth Gauge. Select and place the corresponding 3.5mm Locking Screw using the T15 Driver and Quick-Connect Handle.





Optional: Locking Screw Insertion with 1.5Nm Torque Limiter

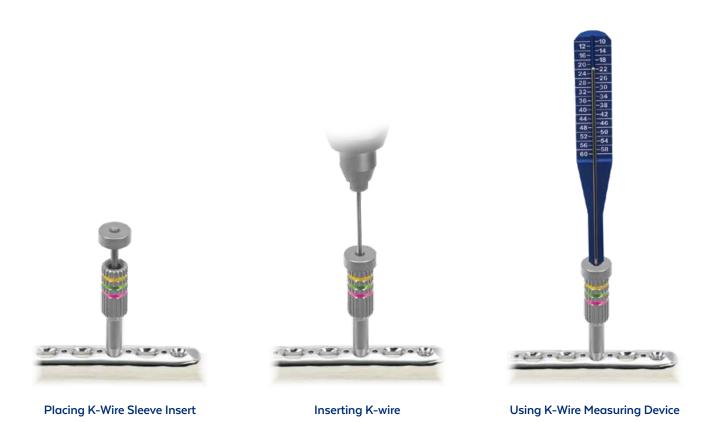
The 1.5Nm Torque Limiter may be used to insert locking screws under power or in dense bone to prevent excessive torque. Attach the T15 Driver to the 1.5Nm Torque Limiter under power. Insert the locking screw until the maximum torque has been reached and an audible click is heard. Perform final tightening manually.

SCREW INSERTION (CONT'D)

Verifying Locking Screw Trajectories

Locking screw trajectories may be verified prior to placing the screws if desired. Place the 1.6mm K-Wire Sleeve Insert into the 2.7mm Threaded Drill Guide. Drive the 1.6mm K-wire through the sleeve to the desired depth and confirm using fluoroscopy. The K-wire indicates the position and trajectory of the locking screw.

To measure depth, slide the K-Wire Measuring Device over the K-wire until it rests on the 1.6mm K-Wire Sleeve Insert. The corresponding screw length is indicated by the end of the K-wire. Remove the measuring device, K-wire, sleeve insert, and drill guide and continue placing locking screws.



VERIFY PLACEMENT STEP

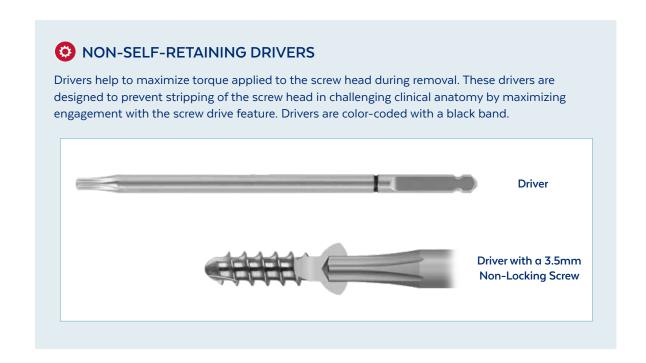
Using fluoroscopy and direct visualization, confirm screw placement, screw trajectories, plate position, and reduction.





OPTIONAL: REMOVAL

Unlock all screws from the plate with the T15 Driver. This prevents simultaneous rotation of the plate during removal. Remove all locking, non-locking, and cancellous screws using the Non-Self-Retaining Driver. Once all screws are removed, the plate may be removed.



INSTRUMENT OVERVIEW

RETRACTORS



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



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

Malleable Wire Replacement 6171.7008



Radiolucent Hohmann Retractor, 8mm 6179.7014



Radiolucent Hohmann Retractor, 16mm 6179.7015

RETRACTORS (CONT'D)



Hohmann Retractor, 8mm 6179.7016

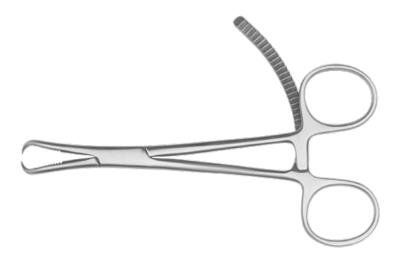


Hohmann Retractor, 15mm 6179.7017

REDUCTION INSTRUMENTS

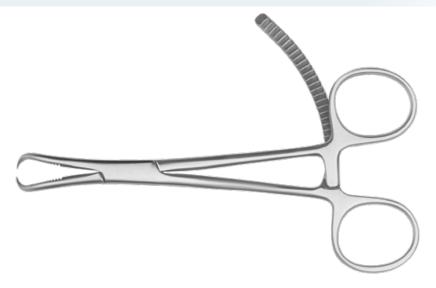


Lobster Claw Reduction Forceps, Ratcheting 6179.2001



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

REDUCTION INSTRUMENTS (CONT'D)



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



Dental Pick, Curved Tip, Large Handle 6179.7025



Verbrugge Clamp 6179.2005

REDUCTION (CONT'D) Plate Reduction Instrument, AO Quick-Connect 6179.7023 DRILLS, TAPS, AND COUNTERSINKS 1.8mm Drill Bit, 140mm, AO Quick-Connect 6179.5018 02.5 2.5mm Drill Bit, 110mm, AO Quick-Connect 6179.5025 The state of the s 2.7mm Drill Bit, 125mm, AO Quick-Connect 6179.5027 2.7mm Calibrated Drill Bit, 180mm, AO Quick-Connect 6179.5028 03.5 3.5mm Drill Bit, 110mm, AO Quick-Connect 6179.5035 2.5mm Non-Locking Tap 6179.5125 3.5mm Non-Locking Tap 6179.5135 Ø4.0mm

DRILLS, TAPS, AND COUNTERSINKS (CONT'D)



Countersink, AO Quick-Connect 6179.7000

DRIVERS AND HANDLES



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



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



T15 Screwdriver, SR 6179.6315



Medium Handle, Cannulated, AO Quick-Connect 6179.7001



Medium Handle, Ratcheting, Cannulated, AO Quick-Connect 6179.7013



Screw Retaining Sleeve 6179.7024

DRIVERS AND HANDLES (CONT'D)



Torque-Limiting Attachment, 1.5Nm, AO Quick-Connect 6179.7018

DRILL GUIDES



2.5mm Soft Tissue Protector, Spring Loaded 6179.3125



3.5mm Soft Tissue Protector, Spring Loaded 6179.3135



2.7mm Threaded Drill Guide 6179.3227



3.5/2.7mm Drill Sleeve 6179.3137





2.5/1.8mm Drill Sleeve 6179.3128

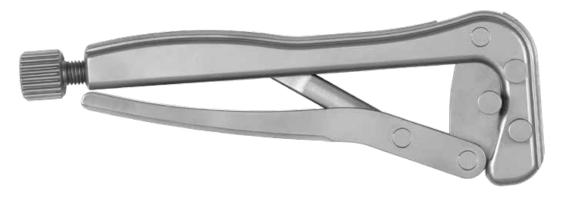
BENDING INSTRUMENTS



Bending Iron 6179.7002



Bending Iron, Inverted 6179.7003



Universal Bending Clamp 6179.7005



Bending Template, 7 hole 6179.7009



Bending Template, 9 hole 6179.7010

BENDING INSTRUMENTS (CONT'D)



Bending Template, 12 hole 6179.7011

DEPTH GAUGE



Depth Gauge, 60mm 6179.7020



Depth Gauge, 110mm 6179.7031



K-Wire Measuring Device 6179.7021

K-WIRES

1.25mm K-Wire, Trocar Tip, 150mm 6179.1113

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

SCREW REMOVAL



Easy-Out Extension Driver, AO Quick-Connect 6179.7026



Rescue Reamer, AO Quick-Connect 6179.7027

ADDITIONAL INSTRUMENTS



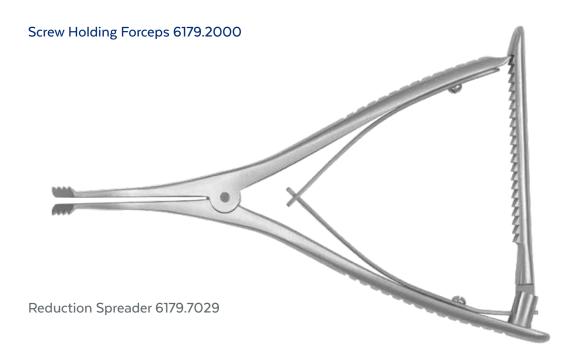
Periosteal Elevator, Curved Round Tip, 6mm 6179.7019

ADDITIONAL INSTRUMENTS (CONT'D)



Threaded Plate Holder 6179.7007





ANTHEM® SS SMALL FRAGMENT FRACTURE SYSTEM **IMPLANT AND INSTRUMENT SET 9179.9001**

ANTHEM® 3.5mm Straight Plate, SS			ANTHEM® 3.5mm Straight Plate, SS	
Part No.	Holes/Length	Qty	Part No.	Hole/Length
2179.3506	6 hole, 75mm	2	2179.3504	4 hole, 54mm
2179.3507	7 hole, 85mm	2	2179.3505	5 hole, 64mm
2179.3509	9 hole, 111mm	2	2179.3508	8 hole, 101mm
2179.3510	10 hole, 122mm	2		
2179.3512	12 hole, 143mm	2		
2179.3514	14 hole, 169mm	2		
2179.3516	16 hole, 190mm	2		
ANTHEM® One-Third Tubular Plate, SS		ANTHEM® One-Third Tubular Plate, SS		
Part No.	Holes/Length	Qty	Part No.	Hole/Length
2179.1305	5 Hole, 60mm	2	2179.1302	2 Hole, 24mm
2179.1306	6 Hole, 72mm	2	2179.1303	3 Hole, 36mm
2179.1307	7 Hole, 84mm	2	2179.1304	4 Hole, 48mm
2179.1308	8 Hole, 96mm	2	2179.1309	9 Hole, 108mm
2179.1310	10 Hole, 120mm	2	2179.1314	14 Hole, 168mm
2179.1312	12 Hole, 144mm	2		
ANTHEM® Reconstruction Plate, SS			ANTHEM® Reconstruction Plate, SS	
Part No.	Holes/Length	Qty	Part No.	Hole/Length
2179.0004	4 Hole, 46mm	2	2179.0005	5 Hole, 58mm
2179.0006	6 Hole, 70mm	2	2179.0007	7 Hole, 82mm
2179.0008	8 Hole, 94mm	2	2179.0009	9 Hole, 106mm
2179.0010	10 Hole, 118mm	2	2179.0016	16 Hole, 190mm
2179.0012	12 Hole, 142mm	2		
2179.0014	14 Hole, 166mm	2		
ANTHEM® T-I	Plate, SS			
Part No.	Holes/Length	Qty		
2179.0303	3 Hole Head, 3 Hole Shaft, 47mm	2		

2

2

2

3 Hole Head, 5 Hole Shaft, 67mm

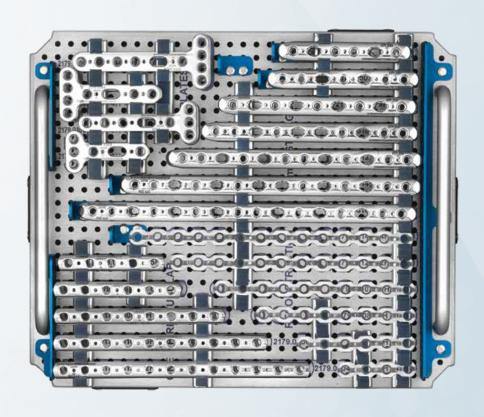
4 Hole Head, 4 Hole Shaft, 57mm

4 Hole Head, 6 Hole Shaft, 77mm

2179.0305

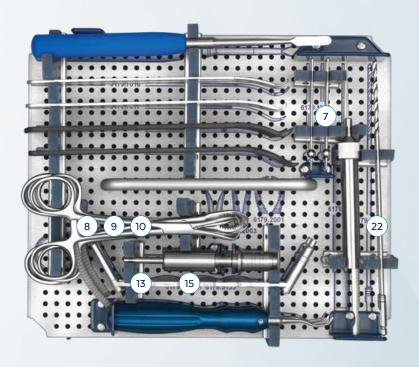
2179.0404

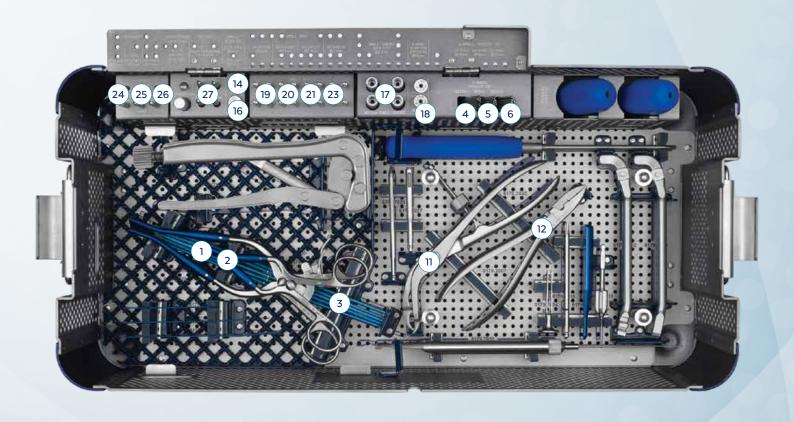
2179.0406



ANTHEM® SS SMALL FRAGMENT FRACTURE SYSTEM IMPLANT AND INSTRUMENT SET 9179.9001 (CONT'D)

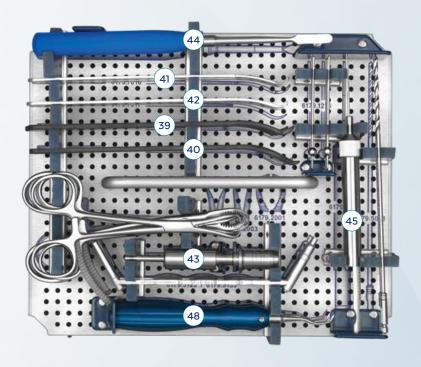
	Part No.	Description	Qty
1	6171.0001	Stabilizing Radiolucent Weitlaner 2x3, 5", Sharp Tip	1
2	6171.0002	Stabilizing Radiolucent Weitlaner 3x4, 8", Sharp Tip	1
3	6171.7008	Malleable Wire Replacement	5
4	6179.1113	1.25mm K-Wire, Trocar Tip, 150mm	10
5	6179.1116	1.6mm K-Wire, Trocar Tip, 150mm	10
6	6179.1120	2.0mm K-Wire, Trocar Tip, 150mm	10
7	6179.1216	1.6mm Plate Holding K-Wire, Threaded Trocar Tip, 75mm	5
8	6179.2001	Lobster Claw Reduction Forceps, Ratcheting	2
9	6179.2003	Point-to-Point Reduction Forceps, Narrow, Ratcheting	1
10	6179.2004	Point-to-Point Reduction Forceps, Wide, Ratcheting	1
1	6179.2005	Verbrugge Clamp	1
12	6179.2007	Wire Bending Pliers	1
13	6179.3125	2.5mm Soft Tissue Protector, Spring Loaded	1
14	6179.3128	2.5mm/1.8mm Drill Sleeve	1
15	6179.3135	3.5mm Soft Tissue Protector, Spring Loaded	1
16	6179.3137	3.5mm/2.7mm Drill Sleeve	1
17	6179.3227	2.7mm Threaded Drill Guide	4
18	6179.3316	1.6mm K-Wire Sleeve Insert	2
19	6179.5018	1.8mm Drill Bit, 140mm, AO Quick-Connect	4
20	6179.5025	2.5mm Drill Bit, 110mm, AO Quick-Connect	4
21	6179.5027	2.7mm Drill Bit, 125mm, AO Quick-Connect	4
22	6179.5028	2.7mm Calibrated Drill Bit, 180mm, AO Quick-Connect	2
23	6179.5035	3.5mm Drill Bit, 110mm, AO Quick-Connect	4
24	6179.5125	2.5mm Non-Locking Tap	1
25	6179.5135	3.5mm Non-Locking Tap	1
26	6179.5140	4.0mm Cancellous Tap	1
27	6179.6015	T15 Driver, SR, 100mm, AO Quick-Connect	4

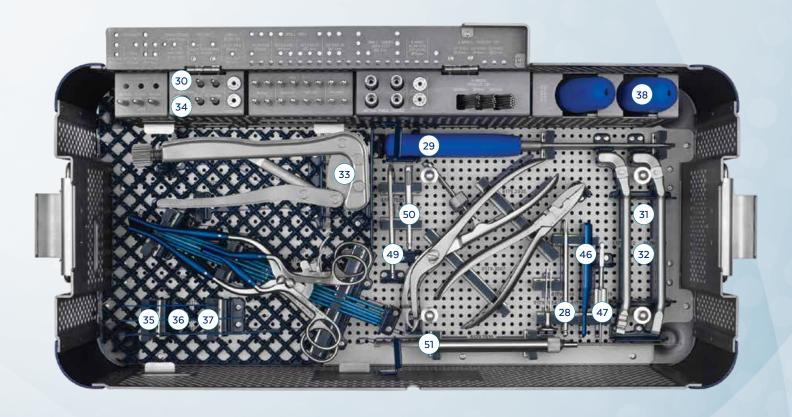




ANTHEM® SS SMALL FRAGMENT FRACTURE SYSTEM IMPLANT AND INSTRUMENT SET 9179.9001 (CONT'D)

	Part No.	Description	Qty
28	6179.6115	T15 Driver, Non-Self-Retaining, 100mm, AO Quick-Connect	2
29	6179.6315	T15 Screwdriver, SR	1
30	6179.7000	Countersink, AO Quick-Connect	1
	6179.7001	Medium Handle, Cannulated, AO Quick-Connect	
31	6179.7002	Bending Iron	1
32	6179.7003	Bending Iron, Inverted	1
33	6179.7005	Universal Bending Clamp	1
34	6179.7007	Threaded Plate Holder	1
35	6179.7009	Bending Template, 7 hole	1
36	6179.7010	Bending Template, 9 hole	1
37	6179.7011	Bending Template, 12 hole	1
38	6179.7013	Medium Handle, Ratcheting, Cannulated, AO Quick-Connect	2
39	6179.7014	Radiolucent Hohmann Retractor, 8mm	2
40	6179.7015	Radiolucent Hohmann Retractor, 16mm	2
41	6179.7016	Hohmann Retractor, 8mm	2
42	6179.7017	Hohmann Retractor, 15mm	2
43	6179.7018	Torque-Limiting Attachment, 1.5Nm, AO Quick-Connect	1
44	6179.7019	Periosteal Elevator, Curved Round Tip, 6mm	1
45	6179.7020	Depth Gauge, 60mm	1
46	6179.7021	K-Wire Measuring Device	1
47	6179.7023	Plate Reduction Instrument, AO Quick-Connect	1
	6179.7024	Screw Retaining Sleeve	1
48	6179.7025	Dental Pick, Curved Tip, Large Handle	2
49	6179.7026	Easy-Out Extraction Driver, AO Quick-Connect	1
50	6179.7027	Rescue Reamer, AO Quick-Connect	1
	6179.7029	Reduction Spreader	
51	6179.7031	Depth Gauge, 110mm	1





ANTHEM® TI SMALL FRAGMENT FRACTURE SYSTEM **IMPLANT AND INSTRUMENT SET 9179.9002**

ANTHEM [*] 3.5m	ım Straight Plate, Ti		ANTHEM® 3.	5mm Straight Plate, Ti
Part No.	Holes/Length	Qty	Part No.	Hole/Length
1179.3505	5 hole, 64mm	2	1179.3504	4 hole, 54mm
1179.3506	6 hole, 75mm	2	1179.3507	7 hole, 85mm
1179.3508	8 hole, 101mm	2	1179.3516	16 hole, 190mm
1179.3509	9 hole, 111mm	2		
1179.3510	10 hole, 122mm	2		
1179.3512	12 hole, 143mm	2		
1179.3514	14 hole, 169mm	2		
ANTHEM® One-	Third Tubular Plate, Ti		ANTHEM® O	ne-Third Tubular Plate, T
Part No.	Holes/Length	Qty	Part No.	Hole/Length
1179.1305	5 Hole, 60mm	2	1179.1302	2 Hole, 24mm
1179.1306	6 Hole, 72mm	2	1179.1303	3 Hole, 36mm
1179.1307	7 Hole, 84mm	2	1179.1304	4 Hole, 48mm
1179.1308	8 Hole, 96mm	2	1179.1309	9 Hole, 108mm
1179.1310	10 Hole, 120mm	2	1179.1314	14 Hole, 168mm
1179.1312	12 Hole, 144mm	2		
ANTHEM [®] Reco	nstruction Plate, Ti		ANTHEM® R	econstruction Plate, Ti
Part No.	Holes/Length	Qty	Part No.	Hole/Length
1179.0004	4 Hole, 46mm	2	1179.0005	5 Hole, 58mm
1179.0006	6 Hole, 70mm	2	1179.0007	7 Hole, 82mm
1179.0008	8 Hole, 94mm	2	1179.0009	9 Hole, 106mm
1179.0010	10 Hole, 118mm	2	1179.0016	16 Hole, 190mm
1179.0012	12 Hole, 142mm	2		
1179.0014	14 Hole, 166mm	2		
ANTHEM [®] T-Pla	ate, Ti			
Part No.	Holes/Length	Qty		
1179.0303	3 Hole Head, 3 Hole Shaft, 47mm	2		
1179.0305	3 Hole Head, 5 Hole Shaft, 67mm	2		

4 Hole Head, 4 Hole Shaft, 57mm

4 Hole Head, 6 Hole Shaft, 77mm

2

2

1179.0404

1179.0406

ANTHEM® TI SMALL FRAGMENT FRACTURE SYSTEM IMPLANT AND INSTRUMENT SET 9179.9002

Part No.	Description	Qty
6171.0001	Stabilizing Radiolucent Weitlaner 2x3, 5", Sharp Tip	1
6171.0002	Stabilizing Radiolucent Weitlaner 3x4, 8", Sharp Tip	1
6171.7008	Malleable Wire Replacement	5
6179.1113	1.25mm K-Wire, Trocar Tip, 150mm	10
6179.1116	1.6mm K-Wire, Trocar Tip, 150mm	10
6179.1120	2.0mm K-Wire, Trocar Tip, 150mm	10
6179.1216	1.6mm Plate Holding K-Wire, Threaded Trocar Tip, 75mm	5
6179.2001	Lobster Claw Reduction Forceps, Ratcheting	2
6179.2003	Point-to-Point Reduction Forceps, Narrow, Ratcheting	1
6179.2004	Point-to-Point Reduction Forceps, Wide, Ratcheting	1
6179.2005	Verbrugge Clamp	1
6179.2007	Wire Bending Pliers	1
6179.3125	2.5mm Soft Tissue Protector, Spring Loaded	1
6179.3128	2.5/1.8mm Drill Sleeve	1
6179.3135	3.5mm Soft Tissue Protector, Spring Loaded	1
6179.3137	3.5/2.7mm Drill Sleeve	1
6179.3227	2.7mm Threaded Drill Guide	4
6179.3316	1.6mm K-Wire Sleeve Insert	2
6179.5018	1.8mm Drill Bit, 140mm, AO Quick-Connect	4
6179.5025	2.5mm Drill Bit, 110mm, AO Quick-Connect	4
6179.5027	2.7mm Drill Bit, 125mm, AO Quick-Connect	4
6179.5028	2.7mm Calibrated Drill Bit, 180mm, AO Quick-Connect	2
6179.5035	3.5mm Drill Bit, 110mm, AO Quick-Connect	4
6179.5125	2.5mm Non-Locking Tap	1
6179.5135	3.5mm Non-Locking Tap	1
6179.5140	4.0mm Cancellous Tap	1
6179.6015	T15 Driver, SR, 100mm, AO Quick-Connect	4

ANTHEM® TI SMALL FRAGMENT FRACTURE SYSTEM IMPLANT AND INSTRUMENT SET 9179.9002 (CONT'D)

Part No.	Description	Qty
6179.6115	T15 Driver, Non-Self-Retaining, 100mm, AO Quick-Connect	2
6179.6315	T15 Screwdriver, SR	1
6179.7000	Countersink, AO Quick-Connect	1
6179.7001	Medium Handle, Cannulated, AO Quick-Connect	
6179.7002	Bending Iron	1
6179.7003	Bending Iron, Inverted	1
6179.7005	Universal Bending Clamp	1
6179.7007	Threaded Plate Holder	1
6179.7009	Bending Template, 7 hole	1
6179.7010	Bending Template, 9 hole	1
6179.7011	Bending Template, 12 hole	1
6179.7013	Medium Handle, Ratcheting, Cannulated, AO Quick-Connect	2
6179.7014	Radiolucent Hohmann Retractor, 8mm	2
6179.7015	Radiolucent Hohmann Retractor, 16mm	2
6179.7016	Hohmann Retractor, 8mm	2
6179.7017	Hohmann Retractor, 15mm	2
6179.7018	Torque-Limiting Attachment, 1.5Nm, AO Quick-Connect	1
6179.7019	Periosteal Elevator, Curved Round Tip, 6mm	1
6179.7020	Depth Gauge, 60mm	1
6179.7021	K-Wire Measuring Device	1
6179.7023	Plate Reduction Instrument, AO Quick-Connect	1
6179.7024	Screw Retaining Sleeve	1
6179.7025	Dental Pick, Curved Tip, Large Handle	2
6179.7026	Easy-Out Extraction Driver, AO Quick-Connect	1
6179.7027	Rescue Reamer, AO Quick-Connect	1
6179.7029	Reduction Spreader	
6179.7031	Depth Gauge, 110mm	1

ANTHEM® SS SMALL FRAGMENT FRACTURE SYSTEM NON-LOCKING IMPLANT SET 9179.9003

ANTHEM® Nor	n-Locking 3.5mm Straight Plate	, SS	ANTHEM® N	on-Locking 3.5mm Straight Plate, SS
Part No.	Holes/Length	Qty	Part No.	Hole/Length
2179.3536	6 hole, 85mm	2	2179.3534	4 hole, 59mm
2179.3537	7 hole, 98mm	2	2179.3535	5 hole, 72mm
2179.3539	9 hole, 124mm	2	2179.3538	8 hole, 111mm
2179.3540	10 hole, 137mm	2		
2179.3542	12 hole, 163mm	2		
2179.3544	14 hole, 189mm	2		
2179.3546	16 hole, 215mm	2		
ANTHEM® Nor	n-Locking One-Third Tubular Pla	te, SS	ANTHEM [®] N	on-Locking One-Third Tubular Plate, S
Part No.	Holes/Length	Qty	Part No.	Hole/Length
2179.1325	5 Hole, 60mm	2	2179.1322	2 Hole, 24mm
2179.1326	6 Hole, 72mm	2	2179.1323	3 Hole, 36mm
2179.1327	7 Hole, 84mm	2	2179.1324	4 Hole, 48mm
2179.1328	8 Hole, 96mm	2	2179.1329	9 Hole, 108mm
2179.1330	10 Hole, 120mm	2	2179.1334	14 Hole, 168mm
2179.1332	12 Hole, 144mm	2		
ANTHEM® Nor	n-Locking Reconstruction Plate,	SS	ANTHEM® N	on-Locking Reconstruction Plate, SS
Part No.	Holes/Length	Qty	Part No.	Hole/Length
2179.0034	4 Hole, 51mm	2	2179.0035	5 Hole, 64mm
2179.0036	6 Hole, 77mm	2	2179.0037	7 Hole, 90mm
2179.0038	8 Hole, 103mm	2	2179.0039	9 Hole, 116mm
2179.0040	10 Hole, 129mm	2	2179.0046	16 Hole, 207mm
2179.0042	12 Hole, 155mm	2		
2179.0044	14 Hole, 181mm	2		
ANTHEM® Nor	n-Locking T-Plate, SS			
Part No.	Holes/Length	Qty		
2179.0313	3 Hole Head, 3 Hole Shaft, 47mm	2		
2179.0315	3 Hole Head, 5 Hole Shaft, 67mm	2		

4 Hole Head, 4 Hole Shaft, 57mm

4 Hole Head, 6 Hole Shaft, 77mm

2

2

2179.0414

2179.0416

^{*} Items listed in gray are additionally available.

ANTHEM® TI SMALL FRAGMENT FRACTURE SYSTEM NON-LOCKING IMPLANT SET 9179.9004

ANTHEM® N	on-Locking 3.5mm Straight Plate	, Ti	ANTHEM® Non-Locking 3.5mm Straight Plate, Ti		
Part No.	Holes/Length	Qty	Part No.	Hole/Length	
1179.3536	6 hole, 85mm	2	1179.3534	4 hole, 59mm	
1179.3537	7 hole, 98mm	2	1179.3535	5 hole, 72mm	
1179.3539	9 hole, 124mm	2	1179.3538	8 hole, 111mm	
1179.3540	10 hole, 137mm	2			
1179.3542	12 hole, 163mm	2			
1179.3544	14 hole, 189mm	2			
1179.3546	16 hole, 215mm	2			
ANTHEM® N	on-Locking One-Third Tubular Pla	nte, Ti	ANTHEM® N	lon-Locking One-Third Tubular Plate,	
Part No.	Holes/Length	Qty	Part No.	Hole/Length	
1179.1325	5 Hole, 60mm	2	1179.1322	2 Hole, 24mm	
1179.1326	6 Hole, 72mm	2	1179.1323	3 Hole, 36mm	
1179.1327	7 Hole, 84mm	2	1179.1324	4 Hole, 48mm	
1179.1328	8 Hole, 96mm	2	1179.1329	9 Hole, 108mm	
1179.1330	10 Hole, 120mm	2	1179.1334	14 Hole, 168mm	
1179.1332	12 Hole, 144mm	2			
ANTHEM® N	on-Locking Reconstruction Plate,	Ti	ANTHEM® N	lon-Locking Reconstruction Plate, Ti	
Part No.	Holes/Length	Qty	Part No.	Hole/Length	
1179.0034	4 Hole, 51mm	2	1179.0035	5 Hole, 64mm	
1179.0036	6 Hole, 77mm	2	1179.0037	7 Hole, 90mm	
1179.0038	8 Hole, 103mm	2	1179.0039	9 Hole, 116mm	
1179.0040	10 Hole, 129mm	2	1179.0046	16 Hole, 207mm	
1179.0042	12 Hole, 155mm	2			
1179.0044	14 Hole, 181mm	2			
ANTHEM® N	on-Locking T-Plate, Ti				
Part No.	Holes/Length	Qty			
1179.0313	3 Hole Head, 3 Hole Shaft, 47mm	2			
1179.0315	3 Hole Head, 5 Hole Shaft, 67mm	2			

4 Hole Head, 4 Hole Shaft, 57mm

4 Hole Head, 6 Hole Shaft, 77mm

2

1179.0414

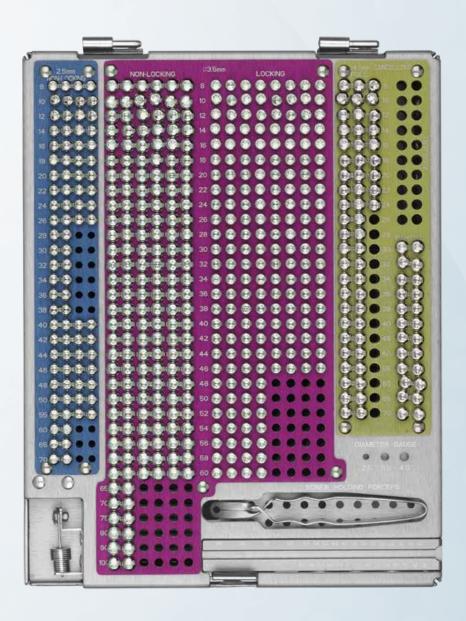
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ANTHEM® SS SMALL FRAGMENT FRACTURE SYSTEM SCREW MODULE SET 9179.9005

Instruments			3.5mm Non-Lo	ocking Screws, SS	
Part No.	Description	Qty	Part No.	Description	Qty
2179.0002	9.0mm Washer, SS	6	2179.3008	3.5x8mm	6
2179.0003	7.0mm Washer, SS	6	2179.3010	3.5x10mm	6
6179.2000	Screw Holding Forceps	1	2179.3012	3.5x12mm	6
			2179.3014	3.5x14mm	6
2.5mm Non-Lo	ocking Screws, SS		2179.3016	3.5x16mm	6
Part No.	Description	Qty	2179.3018	3.5x18mm	6
2179.2508	2.5x8mm	4	2179.3020	3.5x20mm	6
2179.2510	2.5x10mm	4	2179.3022	3.5x22mm	6
2179.2512	2.5x12mm	4	2179.3024	3.5x24mm	6
2179.2514	2.5x14mm	4	2179.3026	3.5x26mm	6
2179.2516	2.5x16mm	4	2179.3028	3.5x28mm	6
2179.2518	2.5x18mm	4	2179.3030	3.5x30mm	6
2179.2520	2.5x20mm	4	2179.3032	3.5x32mm	6
2179.2522	2.5x22mm	4	2179.3034	3.5x34mm	6
2179.2524	2.5x24mm	4	2179.3036	3.5x36mm	6
2179.2526	2.5x26mm	4	2179.3038	3.5x38mm	6
2179.2528	2.5x28mm	2	2179.3040	3.5x40mm	6
2179.2530	2.5x30mm	2	2179.3042	3.5x42mm	6
2179.2532	2.5x32mm	2	2179.3044	3.5x44mm	6
2179.2534	2.5x34mm	2	2179.3046	3.5x46mm	6
2179.2536	2.5x36mm	2	2179.3048	3.5x48mm	6
2179.2538	2.5x38mm	2	2179.3050	3.5x50mm	6
2179.2540	2.5x40mm	4	2179.3052	3.5x52mm	6
2179.2542	2.5x42mm	4	2179.3054	3.5x54mm	6
2179.2544	2.5x44mm	4	2179.3056	3.5x56mm	6
2179.2546	2.5x46mm	4	2179.3058	3.5x58mm	6
2179.2548	2.5x48mm	4	2179.3060	3.5x60mm	6
2179.2550	2.5x50mm	4	2179.3065	3.5x65mm	2
2179.2555	2.5x55mm	4	2179.3070	3.5x70mm	2
2179.2560	2.5x60mm	2	2179.3075	3.5x75mm	2
2179.2565	2.5x65mm	2	2179.3080	3.5x80mm	2
2179.2570	2.5x70mm	2	2179.3090	3.5x90mm	2
			2179.3100	3.5x100mm	2

ANTHEM® SS SMALL FRAGMENT FRACTURE SYSTEM SCREW MODULE SET 9179.9005 (CONT'D)

4.0mm Fully Threaded Cancellous Screws, SS			ews, SS	3.5mm Locking Screws, SS (Cont'd)		
	Part No.	Description	Qty	Part No.	Description	Qty
	2179.4008	4.0x8mm	3	22179.5024	3.5x24mm	8
	2179.4010	4.0x10mm	3	2179.5026	3.5x26mm	8
	2179.4012	4.0x12mm	3	2179.5028	3.5x28mm	8
	2179.4014	4.0x14mm	3	2179.5030	3.5x30mm	8
	2179.4016	4.0x16mm	3	2179.5032	3.5x32mm	8
	2179.4018	4.0x18mm	3	2179.5034	3.5x34mm	8
	2179.4020	4.0x20mm	3	2179.5036	3.5x36mm	8
	2179.4022	4.0x22mm	3	2179.5038	3.5x38mm	8
	2179.4024	4.0x24mm	3	2179.5040	3.5x40mm	8
	2179.4026	4.0x26mm	2	2179.5042	3.5x42mm	8
	2179.4028	4.0x28mm	2	2179.5044	3.5x44mm	8
	2179.4030	4.0x30mm	2	2179.5046	3.5x46mm	8
	2179.4032	4.0x32mm	2	2179.5048	3.5x48mm	4
	2179.4034	4.0x34mm	2	2179.5050	3.5x50mm	4
	2179.4036	4.0x36mm	2	2179.5052	3.5x52mm	4
	2179.4038	4.0x38mm	2	2179.5054	3.5x54mm	4
	2179.4040	4.0x40mm	2	2179.5056	3.5x56mm	4
	2179.4045	4.0x45mm	2	2179.5058	3.5x58mm	4
	2179.4050	4.0x50mm	2	2179.5060	3.5x60mm	4
	2179.4055	4.0x55mm	2			
	2179.4060	4.0x60mm	2	4.0mm Partiall	y Threaded Cancellous	Screws, SS
	2179.4065	4.0x65mm	2	Part No.	Description	Qty
	2179.4070	4.0x70mm	2	2179.8030	4.0x30mm	2
				2179.8032	4.0x32mm	2
	3.5mm Locking	Screws, SS		2179.8034	4.0x34mm	2
	Part No.	Description	Qty	2179.8036	4.0x36mm	2
	2179.5008	3.5x8mm	8	2179.8038	4.0x38mm	2
	2179.5010	3.5x10mm	8	2179.8040	4.0x40mm	2
	2179.5012	3.5x12mm	8	2179.8045	4.0x45mm	2
	2179.5014	3.5x14mm	8	2179.8050	4.0x50mm	2
	2179.5016	3.5x16mm	8	2179.8055	4.0x55mm	2
	2179.5018	3.5x18mm	8	2179.8060	4.0x60mm	2
	2179.5020	3.5x20mm	8	2179.8065	4.0x65mm	2
	2179.5022	3.5x22mm	8	2179.8070	4.0x70mm	2



ANTHEM® TI SMALL FRAGMENT FRACTURE SYSTEM SCREW MODULE SET 9179.9006

Instruments			3.5mm Non-Lo	cking Screws, Ti	
Part No.	Description	Qty	Part No.	Description	Qty
1179.0002	9.0mm Washer, Ti	6	1179.3008	3.5x8mm	6
1179.0003	7.0mm Washer, Ti	6	1179.3010	3.5x10mm	6
6179.2000	Screw Holding Forceps	1	1179.3012	3.5x12mm	6
			1179.3014	3.5x14mm	6
2.5mm Non-Lo	cking Screws, Ti		1179.3016	3.5x16mm	6
Part No.	Description	Qty	1179.3018	3.5x18mm	6
1179.2508	2.5x8mm	4	1179.3020	3.5x20mm	6
1179.2510	2.5x10mm	4	1179.3022	3.5 x22mm	6
1179.2512	2.5x12mm	4	1179.3024	3.5x24mm	6
1179.2514	2.5x14mm	4	1179.3026	3.5x26mm	6
1179.2516	2.5x16mm	4	1179.3028	3.5x28mm	6
1179.2518	2.5x18mm	4	1179.3030	3.5x30mm	6
1179.2520	2.5x20mm	4	1179.3032	3.5x32mm	6
1179.2522	2.5x22mm	4	1179.3034	3.5x34mm	6
1179.2524	2.5x24mm	4	1179.3036	3.5x36mm	6
1179.2526	2.5x26mm	4	1179.3038	3.5x38mm	6
1179.2528	2.5x28mm	2	1179.3040	3.5x40mm	6
1179.2530	2.5x30mm	2	1179.3042	3.5x42mm	6
1179.2532	2.5x32mm	2	1179.3044	3.5x44mm	6
1179.2534	2.5x34mm	2	1179.3046	3.5x46mm	6
1179.2536	2.5x36mm	2	1179.3048	3.5x48mm	6
1179.2538	2.5x38mm	2	1179.3050	3.5x50mm	6
1179.2540	2.5x40mm	4	1179.3052	3.5x52mm	6
1179.2542	2.5x42mm	4	1179.3054	3.5x54mm	6
1179.2544	2.5x44mm	4	1179.3056	3.5x56mm	6
1179.2546	2.5x46mm	4	1179.3058	3.5x58mm	6
1179.2548	2.5x48mm	4	1179.3060	3.5x60mm	6
1179.2550	2.5x50mm	4	1179.3065	3.5x65mm	2
1179.2555	2.5x55mm	4	1179.3070	3.5x70mm	2
1179.2560	2.5x60mm	2	1179.3075	3.5x75mm	2
1179.2565	2.5x65mm	2	1179.3080	3.5x80mm	2
1179.2570	2.5x70mm	2	1179.3090	3.5x90mm	2
			1179.3100	3.5x100mm	2

ANTHEM® TI SMALL FRAGMENT FRACTURE SYSTEM SCREW MODULE SET 9179.9006

4.0mm Fully Threaded Cancellous Screws, Ti		3.5mm Lockin	3.5mm Locking Screws, Ti (Cont'd)		
Part No.	Description	Qty	Part No.	Description	Qty
1179.4008	4.0x8mm	3	1179.5024	3.5x24mm	8
1179.4010	4.0x10mm	3	1179.5026	3.5x26mm	8
1179.4012	4.0x12mm	3	1179.5028	3.5x28mm	8
1179.4014	4.0x14mm	3	1179.5030	3.5x30mm	8
1179.4016	4.0x16mm	3	1179.5032	3.5x32mm	8
1179.4018	4.0x18mm	3	1179.5034	3.5x34mm	8
1179.4020	4.0x20mm	3	1179.5036	3.5x36mm	8
1179.4022	4.0x22mm	3	1179.5038	3.5x38mm	8
1179.4024	4.0x24mm	3	1179.5040	3.5x40mm	8
1179.4026	4.0x26mm	2	1179.5042	3.5x42mm	8
1179.4028	4.0x28mm	2	1179.5044	3.5x44mm	8
1179.4030	4.0x30mm	2	1179.5046	3.5x46mm	8
1179.4032	4.0x32mm	2	1179.5048	3.5x48mm	4
1179.4034	4.0x34mm	2	1179.5050	3.5x50mm	4
1179.4036	4.0x36mm	2	1179.5052	3.5x52mm	4
1179.4038	4.0x38mm	2	1179.5054	3.5x54mm	4
1179.4040	4.0x40mm	2	1179.5056	3.5x56mm	4
1179.4045	4.0x45mm	2	1179.5058	3.5x58mm	4
1179.4050	4.0x50mm	2	1179.5060	3.5x60mm	4
1179.4055	4.0x55mm	2			
1179.4060	4.0x60mm	2	4.0mm Partia	lly Threaded Cancellou	s Screws, Ti
1179.4065	4.0x65mm	2	Part No.	Description	Qty
1179.4070	4.0x70mm	2	1179.8030	4.0x30mm	2
			1179.8032	4.0x32mm	2
3.5mm Lockin	g Screws, Ti		1179.8034	4.0x34mm	2
Part No.	Description	Qty	1179.8036	4.0x36mm	2
1179.5008	3.5x8mm	8	1179.8038	4.0x38mm	2
1179.5010	3.5x10mm	8	1179.8040	4.0x40mm	2
1179.5012	3.5x12mm	8	1179.8045	4.0x45mm	2
1179.5014	3.5x14mm	8	1179.8050	4.0x50mm	2
1179.5016	3.5x16mm	8	1179.8055	4.0x55mm	2
1179.5018	3.5x18mm	8	1179.8060	4.0x60mm	2
1179.5020	3.5x20mm	8	1179.8065	4.0x65mm	2
1179.5022	3.5x22mm	8	1179.8070	4.0x70mm	2

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 nonunion, and for non-load bearing stabilization and reduction of long bone fragments. Metaphyseal plates are indicated for non-load bearing stabilization and reduction of long bone fragments, and for fixation of bones including the radius and ulna.

Small fragment, mini fragment, proximal tibia, clavicle, metaphyseal, and distal fibula plates may be used in all pediatric subgroups (except neonates) and small stature adults. Distal radius, distal tibia, metaphyseal, 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
- Compromised vascularity that would inhibit adequate blood supply to the
- 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.

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
- 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
- During the course of the operation, repeatedly check to ensure that the connection between the implant and the instrument, or between the
- 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 postoperative 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.

IMPORTANT INFORMATION ON THE ANTHEM® FRACTURE SYSTEM

- 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 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.

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.

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
- 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 or in a container/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

- Recommended sterilization parameters are listed in the table below.
- Only FDA-cleared rigid sterilization containers for use with pre-vacuum steam sterilization may be used.
- When selecting a rigid sterilization container, it must have a minimum filter area of 176 in² total, or a minimum of four (4) 7.5in diameter filters
- No more than one (1) loaded graphic case or its contents can be placed directly into a rigid sterilization container.
- Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.
- The rigid sterilization container manufacturer's instructions for use are to be followed; if questions arise, contact the manufacturer of the specific container for guidance.
- Refer to AAMI ST79 for additional information concerning the use of rigid sterilization containers.

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

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

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

IMPORTANT INFORMATION ON THE ANTHEM® FRACTURE SYSTEM

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			
\triangle	CAUTION	***	MANUFACTURER			
8	SINGLE USE ONLY	Σ	USE BY (YYYY-MM-DD)			
QTY	QUANTITY	Rx only	PRESCRIPTION USE ONLY			

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NOTES						





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

Customer Service:

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

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