



CAPTIVATE[®]

Headed Cannulated Screw System



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

Life moves us 

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

SURGICAL TECHNIQUE GUIDE

CAPTIVATE[®]

Headed Cannulated Screw System

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CAPTIVATE®

Headed Cannulated Screw System

CAPTIVATE® Headed Cannulated Screws deliver intraoperative versatility and efficiency through ample implant options and shared instruments for paired screw sizes.

Each set provides paired screw sizes: 2.5/3.0mm, 3.5/4.0mm, 4.5/5.5mm, and 6.5/7.5mm.

CAPTIVATE® Headed Screws are ideal for treatment of a wide variety of adult and pediatric applications.

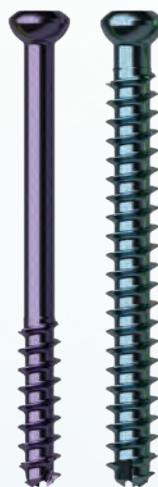
2.5/3.0mm



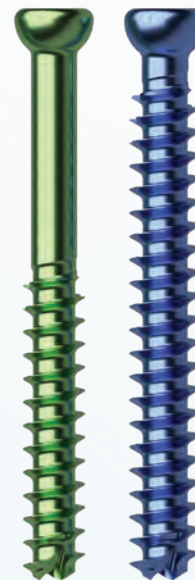
3.5/4.0mm



4.5/5.5mm



6.5/7.5mm



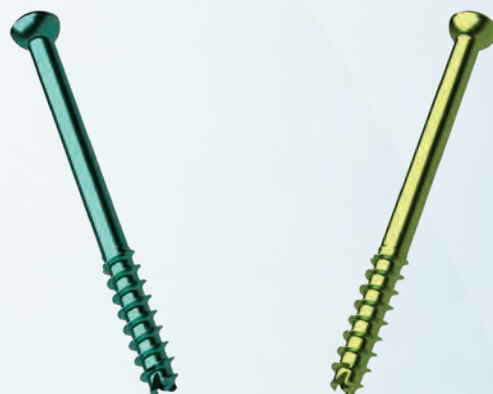
Comprehensive

- Broad range of screw lengths from 8-180mm
- Short, long, partial, and full thread screws
- Available in stainless steel or titanium alloy



Adaptable

- Each set provides paired screw sizes to meet a variety of surgical demands
- Screws are available in 1, 2, and 5mm length increments



Efficient

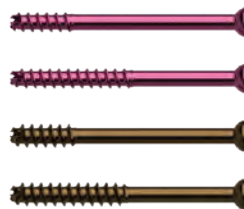
- Standardized instruments allow for seamless transition between paired screw sizes
- Graphic case laid out for efficient procedural flow



IMPLANT OVERVIEW

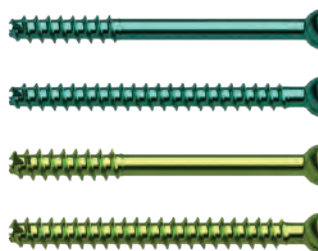
2.5/3.0mm Screws

- Screw lengths from 8-50mm
 - 1mm increments up to 20mm
 - 2mm increments up to 50mm
- Short Thread = 25% of screw length
- Long Thread = 50% of screw length



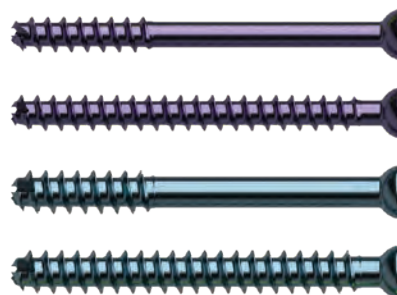
3.5/4.0mm Screws

- Screw lengths from 16-100mm
 - 2mm increments up to 50mm
 - 5mm increments thereafter
- Partial Thread = 33% of screw length
- Full Thread



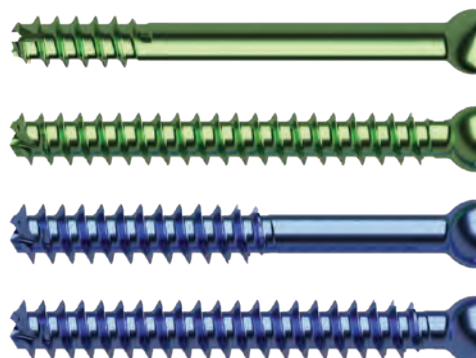
4.5/5.5mm Screws

- Screw lengths from 30-120mm
 - 2mm increments up to 50mm
 - 5mm increments thereafter
- Partial Thread = 33% of screw length
- Full Thread



6.5/7.5mm Screws

- Screw lengths from 40-180mm
 - 5mm increments for all lengths
- 16mm and 32mm Partial Thread
- Full Thread



IMPLANT OVERVIEW



Thread Type

- Short Thread
- Long Thread
- Partial Thread
- Full Thread



Hexalobe Recess

Designed to optimize torque transmission and resist stripping



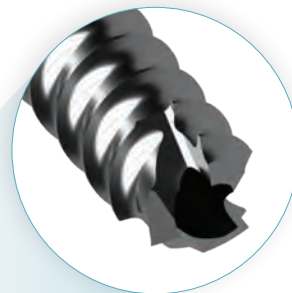
Low-Profile Head

Engineered to minimize soft tissue irritation



Reverse Cutting Flutes

To facilitate screw removal



Self-Drilling and Self-Tapping

For ease of insertion



SURGICAL TECHNIQUE

CAPTIVATE[®] Headed Cannulated Screw System

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

STEP 1 APPROACH AND GUIDEWIRE INSERTION

Identify the fracture line and make the appropriate incision. Determine the guidewire size that corresponds to the selected screw(s), per the table below.

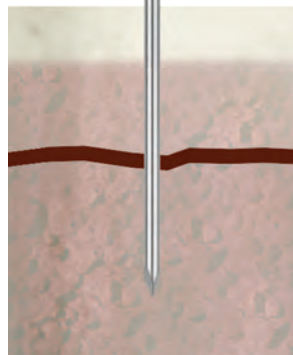
Insert the **Guidewire** to the appropriate depth, using fluoroscopy. Slide the **Soft Tissue Protector** over the Guidewire and position on the surface. Insert the guidewire to the appropriate depth and confirm guidewire positioning using fluoroscopy.

For pre-drilling, proceed to step 3. For screw insertion, proceed to step 4.

Note: The **Parallel Wire Guide** permits fine repositioning for 6.5/7.5mm screws. Ensure screws are positioned at an optimal distance apart for final placement.



Identifying fracture line



Inserting guidewire

SCREW DIAMETER	GUIDEWIRE DIAMETER
● 2.5/3.0mm	1.1mm
● 3.5/4.0mm	1.4mm
● 4.5/5.5mm	1.6mm
● 6.5/7.5mm	2.8mm

STEP

2

MEASURING SCREW LENGTH

Measuring must be completed before all bone preparation steps, except when using a countersink.

Slide the corresponding size **Measuring Device** over the guidewire until flush with the bone.

Screw length is determined by the guidewire tip on the measuring device. If the measurement is between implant sizes, round down.

Note: If using a washer with a 6.5/7.5mm screw, add 3.75mm to the measurement to accommodate the portion of the screw outside of the bone.



Measuring Device showing 30mm length

STEP

3

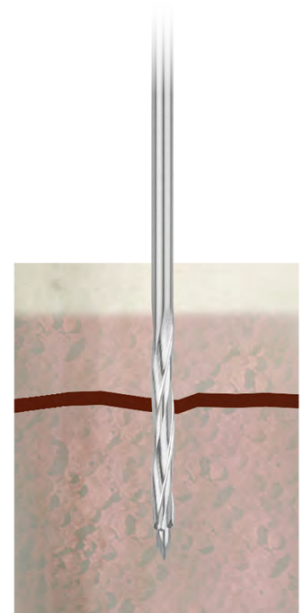
BONE PREPARATION

For self-drilling CAPTIVATE® screws, pre-drilling is optional.

Slide the **Soft Tissue Protector** over the guidewire, if applicable, and position on the surface of the bone. Attach the appropriate drill to the desired handle.

Insert the drill over the guidewire and pre-drill near the cortex. Use fluoroscopy to ensure that the trajectory is correct and drill to the appropriate length. The screw hole may be tapped prior to screw insertion if desired.

Ream to countersink the screw if a lower profile screw is desired. Ensure the countersink does not penetrate the cortex.



Drilling

SCREW DIAMETER	CANNULATED PRE-DRILL	CANNULATED OVER DRILL
● 2.5/3.0mm	2.0mm	-
● 3.5/4.0mm	2.7mm	4.2mm
● 4.5mm	3.2mm	5.7mm
● 5.5mm	3.9mm	5.7mm
● 6.5/7.5mm	5.0mm	7.5mm

STEP

4

SCREW INSERTION

Select the corresponding **Driver** and **Quick-Connect Handle** per the table below and load the selected screw.

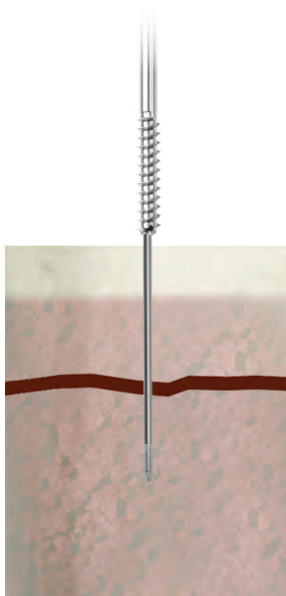
SCREW DIAMETER	DRIVER SIZE
● 2.5/3.0mm	T8
● 3.5/4.0mm	T15
● 4.5/5.5mm	T20
● 6.5/7.5mm	T30

If desired, a washer may be used in areas of poor bone quality or thin cortical bone. Before screw insertion, place the appropriate washer over the guidewire until flush with the bone. See the table below for washer styles and sizes by screw diameter.

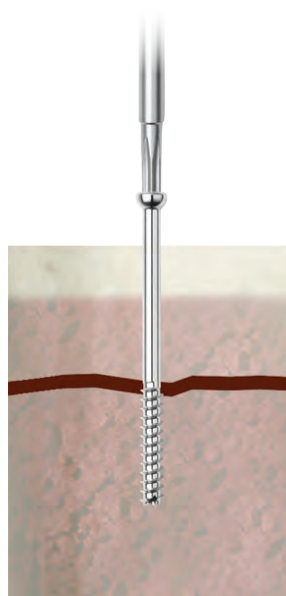
SCREW DIAMETER	WASHER STYLE	WASHER SIZE	WASHER THICKNESS
● 2.5/3.0mm	Round	7.0mm	1.0mm
● 3.5/4.0mm	Round	8.0mm	1.3mm
● 4.5/5.5mm	Round	10.2mm	1.5mm
● 6.5/7.5mm	Round	13.0mm	1.5mm
	Oval	22x13mm	1.5mm

Drive the screw over the guidewire, if applicable, and rotate the handle clockwise to insert the screw to the desired position. Continue to drive until the fracture is reduced. Fluoroscopy is required during this step to ensure proper trajectory and placement.

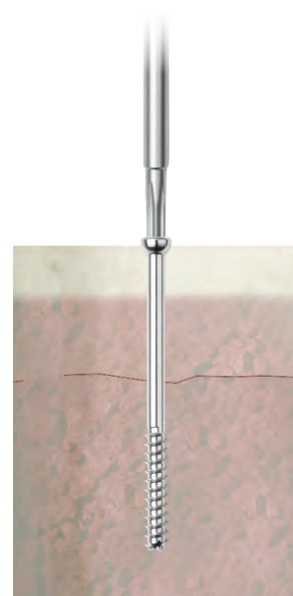
When the desired screw position is achieved, remove both the driver and guidewire. Remove the driver by pulling out axially, away from the screw tip. Remove the guidewire using the guidewire driver.



Guiding screw by guidewire



Inserting screw



Reducing fracture

FINAL POSITION



OPTIONAL: IMPLANT REMOVAL

Expose the head of the screw by removing any bony presence. Engage the screw drive feature with the appropriate **Solid Driver** and rotate counterclockwise to remove the screw. Use screw forceps or other instruments to pull the screw out axially. For broken or damaged 6.5/7.5mm screws, remove using the **6.5/7.5mm Screw Extractor**. To remove the screw, insert the screw extractor into the screw and rotate counterclockwise.

INSTRUMENT OVERVIEW

2.5/3.0mm GUIDEWIRE AND MEASURING INSTRUMENTS



1.1x150mm Trocar Guidewire 6188.1111



1.1x150mm Threaded Trocar Guidewire 6178.1311



● 2.5/3.0mm Measuring Device 6178.3025

2.5/3.0mm BONE PREPARATION INSTRUMENTS



● 2.0 Drill Bit, Cannulated 6178.5325



● 2.0mm Soft Tissue Protector 6178.4025



● 2.5/3.0mm Countersink, Cannulated 6178.8025



● 2.5mm Tap, Cannulated 6178.5225



● 3.0mm Tap, Cannulated 6178.5230

2.5/3.0mm SCREW INSERTION INSTRUMENTS



Quick-Connect Handle, Cannulated 6188.7000



T8 Driver, Solid 6179.6108



T8 Driver, Cannulated 6188.6308



Screw Holding Forceps 6188.2015

2.5/3.0mm CLEANING INSTRUMENTS



1.3mm Cleaning Brush 6188.7130



1.1mm Cleaning Stylet 6178.7225

3.5/4.0mm GUIDEWIRE AND MEASURING INSTRUMENTS



1.4x180mm Trocar Guidewire 6178.1214



1.4x180mm Threaded Trocar Guidewire 6178.1414



●● 3.5/4.0mm Measuring Device 6178.3035

3.5/4.0mm BONE PREPARATION INSTRUMENTS



●● 2.7 Drill Bit, Cannulated 6178.5335



●● 2.7mm Soft Tissue Protector 6178.4035



●● 4.2 Over Drill, Cannulated 6178.5440



●● 4.2 Over Drill Guide 6178.4140



●● 3.5/4.0mm Countersink, Cannulated 6178.8035

3.5/4.0mm BONE PREPARATION INSTRUMENTS



● 3.5mm Tap, Cannulated 6178.5235



● 4.0mm Tap, Cannulated 6178.5240

3.5/4.0mm SCREW INSERTION INSTRUMENTS



Quick-Connect Handle, Cannulated 6188.7001



T15 Driver, Cannulated 6188.6315



T15 Driver, Solid 6179.6115



Screw Holding Forceps 6179.2000

3.5/4.0mm CLEANING INSTRUMENTS



1.8mm Cleaning Brush 6178.7145



1.4mm Cleaning Stylet 6178.7235

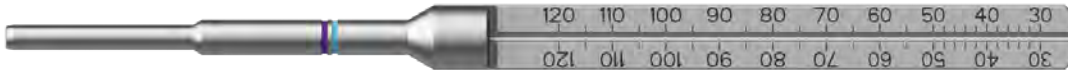
4.5/5.5mm GUIDEWIRE AND MEASURING INSTRUMENTS



1.6x220mm Trocar Guidewire 6178.1216



1.6x220mm Threaded Trocar Guidewire 6178.1416



● 4.5/5.5mm Measuring Device 6178.3045

4.5/5.5mm BONE PREPARATION INSTRUMENTS



● 3.2 Drill Bit, Cannulated 6178.5345



● 3.9 Drill Bit, Cannulated 6178.5355



● 3.2mm Soft Tissue Protector 6178.4045



● 3.9mm Soft Tissue Protector 6178.4055



● 5.7 Over Drill, Cannulated 6178.5455

4.5/5.5mm BONE PREPARATION INSTRUMENTS (CONT'D)



● 5.7 Over Drill Guide 6178.4155



● 4.5/5.5mm Countersink, Cannulated 6178.8045



● 4.5mm Tap, Cannulated 6178.5245



● 5.5mm Tap, Cannulated 6178.5255

4.5/5.5mm SCREW INSERTION INSTRUMENTS



Quick-Connect Handle, Cannulated 6188.7001



T20 Driver, Cannulated 6178.6320



T20 Driver, Solid 6178.6120



Screw Holding Forceps 6179.2000

4.5/5.5mm CLEANING INSTRUMENTS



1.8mm Cleaning Brush 6178.7145



1.6mm Cleaning Stylet 6178.7245

6.5/7.5mm GUIDEWIRE AND MEASURING INSTRUMENTS



2.8x300mm Threaded Trocar Guidewire 6178.0115



2.8x450mm Threaded Trocar Guidewire 6178.0183



2.8x300mm Drill Tip Guidewire 6178.0116



2.8x450mm Drill Tip Guidewire 6178.0185



Guide Stick, Short 6178.3302



Guide Stick, Long 6178.3301



2.8mm Trocar 6178.0162

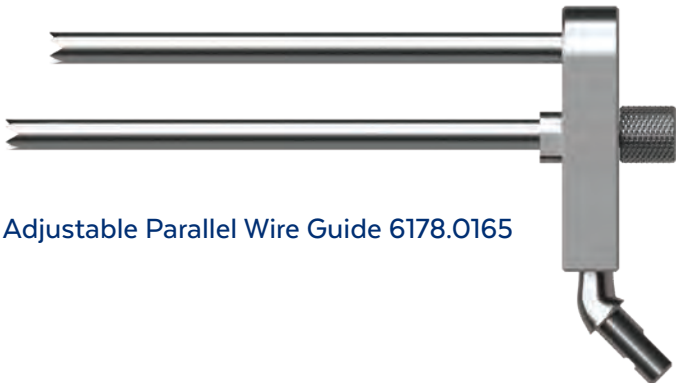
6.5/7.5mm GUIDEWIRE AND MEASURING INSTRUMENTS (CONT'D)



2.8mm Guide Wire Sleeve 6178.0163



Multiple Wire Guide 6178.0164



Adjustable Parallel Wire Guide 6178.0165



QC Handle for Multiple & Parallel Wire Guides 6178.7005



6.5/7.5mm Measuring Device 6178.0167

6.5/7.5mm BONE PREPARATION INSTRUMENTS



5.0 Drill Bit, Cannulated 6178.5350



7.5 Over Drill, Cannulated 6178.5375



6.5/7.5mm Countersink, Cannulated 6178.0117



6.5/7.5mm Tap, Cannulated 6178.5165

6.5/7.5mm SCREW INSERTION INSTRUMENTS



Quick-Connect Handle 6178.3000



Large Quick Coupling 6178.0181



Holding Sleeve 6178.0182

6.5/7.5mm SCREW INSERTION INSTRUMENTS (CONT'D)



T30 Driver, Cannulated 6178.6130



T30 Driver, Solid 6178.6430



Screw Insertion Sleeve 6178.0174



Washer Sleeve 6178.0175

6.5/7.5mm CLEANING INSTRUMENTS



3.4mm Cleaning Brush 6178.7165



2.8mm Cleaning Stylet 6178.7265

6.5/7.5mm REMOVAL INSTRUMENTS



6.5/7.5mm Screw Extractor 6178.0176

CAPTIVATE® 2.5/3.0mm Headed Cannulated Screw System Instrument Set 9178.9101 and 9178.9102

	Part No.	Description	Qty
1	6188.7000	Small Handle, Short, AO Quick-Connect	2
2	6179.6108	T8 Driver, Solid	1
3	6178.8025	2.5/3.0mm Countersink, Cannulated	1
4	6188.6308	T8 Driver, Cannulated	2
5	6188.7130	1.3mm Cleaning Brush	1
6	6178.7225	1.1mm Cleaning Stylet	1
7	6178.4025	2.0mm Soft Tissue Protector	1
8	6178.5325	2.0mm Drill Bit, Cannulated	2
9	6178.3025	2.5/3.0mm Measuring Device	1
10	6178.1311	1.1x150mm Threaded Trocar Guide Wire	10
11	6188.1111	1.1x150mm Trocar Guide Wire	10
	6188.2015	Screw Holding Forceps	1
	9178.2531	2.5/3.0mm Ti Headed Graphic Case	
	9178.2532	2.5/3.0mm SS Headed Graphic Case	

Additionally Available

6178.5225	2.5mm Tap, Cannulated
6178.5230	3.0mm Tap, Cannulated

CAPTIVATE® 2.5/3.0mm Headed Cannulated Screw System Screw Module 9178.9111 and 9178.9112



2.5mm Short Thread

Length	Stainless Steel Part No.	Titanium Part No.	Qty
8mm	-	-	-
9mm	-	-	-
10mm	-	-	-
11mm	-	-	-
12mm	-	-	-
13mm	-	-	-
14mm	-	-	-
15mm	-	-	-
16mm	2178.2716	1178.2716	2
17mm	2178.2717	1178.2717	3
18mm	2178.2718	1178.2718	3
19mm	2178.2719	1178.2719	3
20mm	2178.2720	1178.2720	3
22mm	2178.2722	1178.2722	3
24mm	2178.2724	1178.2724	3
26mm	2178.2726	1178.2726	3
28mm	2178.2728	1178.2728	3
30mm	2178.2730	1178.2730	3
32mm	2178.2732	1178.2732	3
34mm	2178.2734	1178.2734	2
36mm	2178.2736	1178.2736	2
38mm	2178.2738	1178.2738	2
40mm	2178.2740	1178.2740	2



2.5mm Long Thread

Length	Stainless Steel Part No.	Titanium Part No.	Qty
8mm	2178.2908	1178.2908	2
9mm	2178.2909	1178.2909	2
10mm	2178.2910	1178.2910	2
11mm	2178.2911	1178.2911	2
12mm	2178.2912	1178.2912	2
13mm	2178.2913	1178.2913	2
14mm	2178.2914	1178.2914	2
15mm	2178.2915	1178.2915	2
16mm	2178.2916	1178.2916	2
17mm	2178.2917	1178.2917	2
18mm	2178.2918	1178.2918	2
19mm	2178.2919	1178.2919	2
20mm	2178.2920	1178.2920	2
22mm	2178.2922	1178.2922	2
24mm	2178.2924	1178.2924	2
26mm	2178.2926	1178.2926	2
28mm	2178.2928	1178.2928	2
30mm	2178.2930	1178.2930	2
32mm	2178.2932	1178.2932	2
34mm	2178.2934	1178.2934	2
36mm	2178.2936	1178.2936	2
38mm	2178.2938	1178.2938	2
40mm	2178.2940	1178.2940	2

Washers

Part No.	Description	Qty
1178.0025	2.5/3.0mm Washer, Titanium	4
2178.0025	2.5/3.0mm Washer, Stainless Steel	4

CAPTIVATE® 2.5/3.0mm Headed Cannulated Screw System Screw Module 9178.9111 and 9178.9112



3.0mm Short Thread

Length	Stainless Steel Part No.	Titanium Part No.	Qty
8mm	2178.3208	1178.3208	2
9mm	2178.3209	1178.3209	2
10mm	2178.3210	1178.3210	2
11mm	2178.3211	1178.3211	2
12mm	2178.3212	1178.3212	2
13mm	2178.3213	1178.3213	2
14mm	2178.3214	1178.3214	2
15mm	2178.3215	1178.3215	2
16mm	2178.3216	1178.3216	2
17mm	2178.3217	1178.3217	3
18mm	2178.3218	1178.3218	3
19mm	2178.3219	1178.3219	3
20mm	2178.3220	1178.3220	3
22mm	2178.3222	1178.3222	3
24mm	2178.3224	1178.3224	3
26mm	2178.3226	1178.3226	3
28mm	2178.3228	1178.3228	2
30mm	2178.3230	1178.3230	2
32mm	2178.3232	1178.3232	2
34mm	2178.3234	1178.3234	2
36mm	2178.3236	1178.3236	2
38mm	2178.3238	1178.3238	2
40mm	2178.3240	1178.3240	2
42mm	2178.3242	1178.3242	2
44mm	2178.3244	1178.3244	2
46mm	2178.3246	1178.3246	2
48mm	2178.3248	1178.3248	2
50mm	2178.3250	1178.3250	2



3.0mm Long Thread

Length	Stainless Steel Part No.	Titanium Part No.	Qty
8mm	-	-	-
9mm	-	-	-
10mm	-	-	-
11mm	-	-	-
12mm	-	-	-
13mm	-	-	-
14mm	2178.3414	1178.3414	2
15mm	2178.3415	1178.3415	2
16mm	2178.3416	1178.3416	2
17mm	2178.3417	1178.3417	2
18mm	2178.3418	1178.3418	2
19mm	2178.3419	1178.3419	2
20mm	2178.3420	1178.3420	2
22mm	2178.3422	1178.3422	2
24mm	2178.3424	1178.3424	2
26mm	2178.3426	1178.3426	2
28mm	2178.3428	1178.3428	2
30mm	2178.3430	1178.3430	2
32mm	2178.3432	1178.3432	2
34mm	2178.3434	1178.3434	2
36mm	2178.3436	1178.3436	2
38mm	2178.3438	1178.3438	2
40mm	2178.3440	1178.3440	2
42mm	2178.3442	1178.3442	2
44mm	2178.3444	1178.3444	2
46mm	2178.3446	1178.3446	2
48mm	2178.3448	1178.3448	2
50mm	2178.3450	1178.3450	2

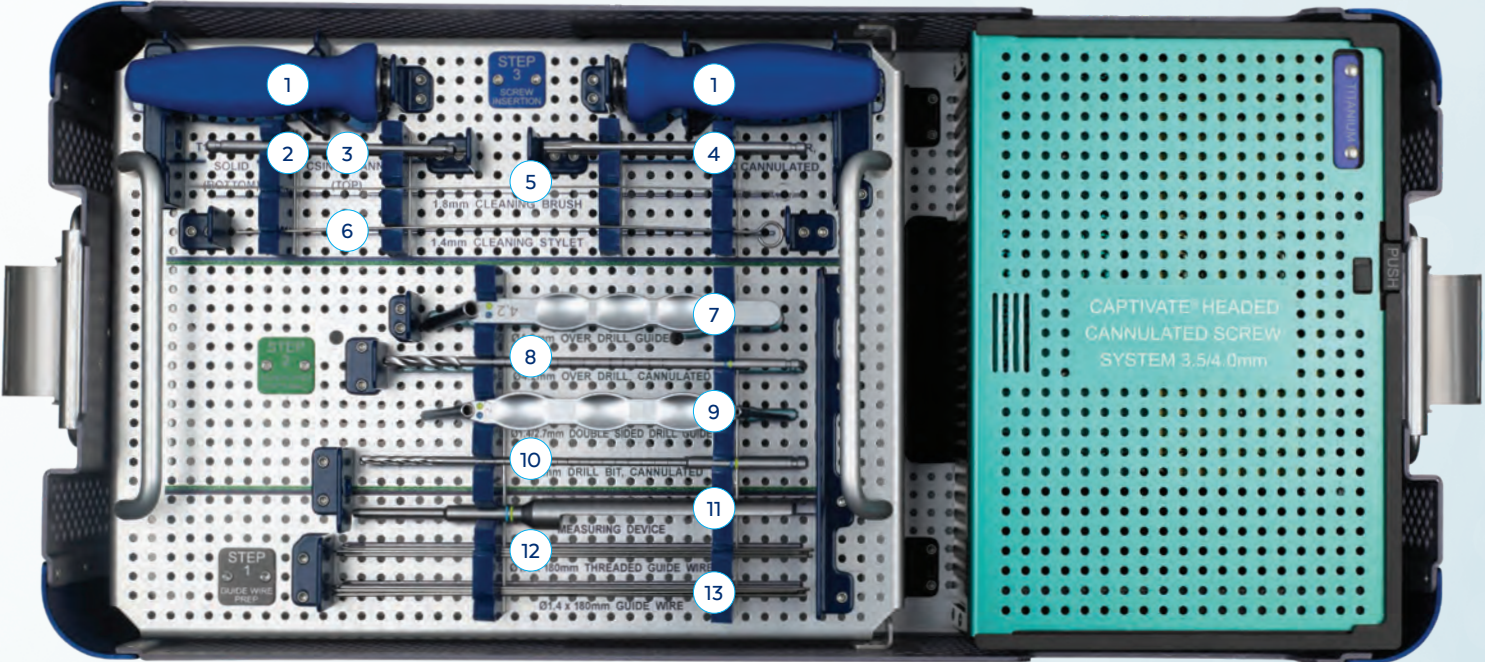
CAPTIVATE® 3.5/4.0mm Headed Cannulated Screw System Instrument Set 9178.9201 and 9178.9202

	Part No.	Description	Qty
1	6188.7001	Quick-Connect Handle, AO	2
2	6179.6115	T15 Driver, Solid	1
3	6178.8035	3.5/4.0mm Countersink, Cannulated	1
4	6188.6315	T15 Driver, Cannulated	2
5	6178.7145	1.8mm Cleaning Brush	1
6	6178.7235	1.4mm Cleaning Stylet	1
7	6178.4140	4.2mm Over Drill Guide	1
8	6178.5440	4.2mm Over Drill, Cannulated	1
9	6178.4035	2.7mm Soft Tissue Protector	1
10	6178.5335	2.7mm Drill Bit, Cannulated	2
11	6178.3035	3.5/4.0mm Measuring Device	1
12	6178.1414	1.4x180mm Threaded Trocar Guide Wire	10
13	6178.1214	1.4x180mm Trocar Guide Wire	10
	6179.2000	Screw Holding Forceps	1
	9178.3541	3.5/4.0mm Ti Headed Graphic Case	
	9178.3542	3.5/4.0mm SS Headed Graphic Case	

Additionally Available

6178.5235	3.5mm Tap, Cannulated
6178.5240	4.0mm Tap, Cannulated

CAPTIVATE[®] 3.5/4.0mm Headed Cannulated Screw System Instrument Set 9178.9201 and 9178.9202



CAPTIVATE® 3.5/4.0mm Headed Cannulated Screw System Screw Module 9178.9211 and 9178.9212



3.5mm Partial Thread

Length	Stainless Steel Part No.	Titanium Part No.	Qty
16mm	2178.3716	1178.3716	2
18mm	2178.3718	1178.3718	2
20mm	2178.3720	1178.3720	2
22mm	2178.3722	1178.3722	2
24mm	2178.3724	1178.3724	2
26mm	2178.3726	1178.3726	2
28mm	2178.3728	1178.3728	2
30mm	2178.3730	1178.3730	2
32mm	2178.3732	1178.3732	2
34mm	2178.3734	1178.3734	2
36mm	2178.3736	1178.3736	3
38mm	2178.3738	1178.3738	3
40mm	2178.3740	1178.3740	3
42mm	2178.3742	1178.3742	3
44mm	2178.3744	1178.3744	3
46mm	2178.3746	1178.3746	3
48mm	2178.3748	1178.3748	3
50mm	2178.3750	1178.3750	3
55mm	2178.3755	1178.3755	3
60mm	2178.3760	1178.3760	2
65mm	2178.3765	1178.3765	2
70mm	2178.3770	1178.3770	2



3.5mm Full Thread

Length	Stainless Steel Part No.	Titanium Part No.	Qty
16mm	2178.3516	1178.3516	2
18mm	2178.3518	1178.3518	2
20mm	2178.3520	1178.3520	2
22mm	2178.3522	1178.3522	2
24mm	2178.3524	1178.3524	2
26mm	2178.3526	1178.3526	2
28mm	2178.3528	1178.3528	2
30mm	2178.3530	1178.3530	2
32mm	2178.3532	1178.3532	2
34mm	2178.3534	1178.3534	2
36mm	2178.3536	1178.3536	2
38mm	2178.3538	1178.3538	2
40mm	2178.3540	1178.3540	2
42mm	2178.3542	1178.3542	2
44mm	2178.3544	1178.3544	2
46mm	2178.3546	1178.3546	2
48mm	2178.3548	1178.3548	2
50mm	2178.3550	1178.3550	2
55mm	2178.3555	1178.3555	2
60mm	2178.3560	1178.3560	2
65mm	2178.3565	1178.3565	2
70mm	2178.3570	1178.3570	2

Washers

Part No.	Description	Qty
1178.0035	3.5/4.0mm Washer, Titanium	4
2178.0035	3.5/4.0mm Washer, Stainless Steel	4

CAPTIVATE® 3.5/4.0mm Headed Cannulated Screw System Screw Module 9178.9211 and 9178.9212



4.0mm Partial Thread

Length	Stainless Steel Part No.	Titanium Part No.	Qty
20mm	2178.4220	1178.4220	2
22mm	2178.4222	1178.4222	2
24mm	2178.4224	1178.4224	2
26mm	2178.4226	1178.4226	2
28mm	2178.4228	1178.4228	2
30mm	2178.4230	1178.4230	2
32mm	2178.4232	1178.4232	2
34mm	2178.4234	1178.4234	3
36mm	2178.4236	1178.4236	3
38mm	2178.4238	1178.4238	3
40mm	2178.4240	1178.4240	3
42mm	2178.4242	1178.4242	3
44mm	2178.4244	1178.4244	3
46mm	2178.4246	1178.4246	3
48mm	2178.4248	1178.4248	3
50mm	2178.4250	1178.4250	2
55mm	2178.4255	1178.4255	2
60mm	2178.4260	1178.4260	2
65mm	2178.4265	1178.4265	2
70mm	2178.4270	1178.4270	2
75mm	2178.4275	1178.4275	2
80mm	2178.4280	1178.4280	2

Additionally Available

85mm	2178.4285	1178.4285
90mm	2178.4290	1178.4290
95mm	2178.4295	1178.4295
100mm	2178.4300	1178.4300



4.0mm Full Thread

Length	Stainless Steel Part No.	Titanium Part No.	Qty
20mm	2178.4020	1178.4020	2
22mm	2178.4022	1178.4022	2
24mm	2178.4024	1178.4024	2
26mm	2178.4026	1178.4026	2
28mm	2178.4028	1178.4028	2
30mm	2178.4030	1178.4030	2
32mm	2178.4032	1178.4032	2
34mm	2178.4034	1178.4034	2
36mm	2178.4036	1178.4036	2
38mm	2178.4038	1178.4038	2
40mm	2178.4040	1178.4040	2
42mm	2178.4042	1178.4042	2
44mm	2178.4044	1178.4044	2
46mm	2178.4046	1178.4046	2
48mm	2178.4048	1178.4048	2
50mm	2178.4050	1178.4050	2
55mm	2178.4055	1178.4055	2
60mm	2178.4060	1178.4060	2
65mm	2178.4065	1178.4065	2
70mm	2178.4070	1178.4070	2
75mm	2178.4075	1178.4075	2
80mm	2178.4080	1178.4080	2

Additionally Available

85mm	2178.4085	1178.4085
90mm	2178.4090	1178.4090
95mm	2178.4095	1178.4095
100mm	2178.4100	1178.4100

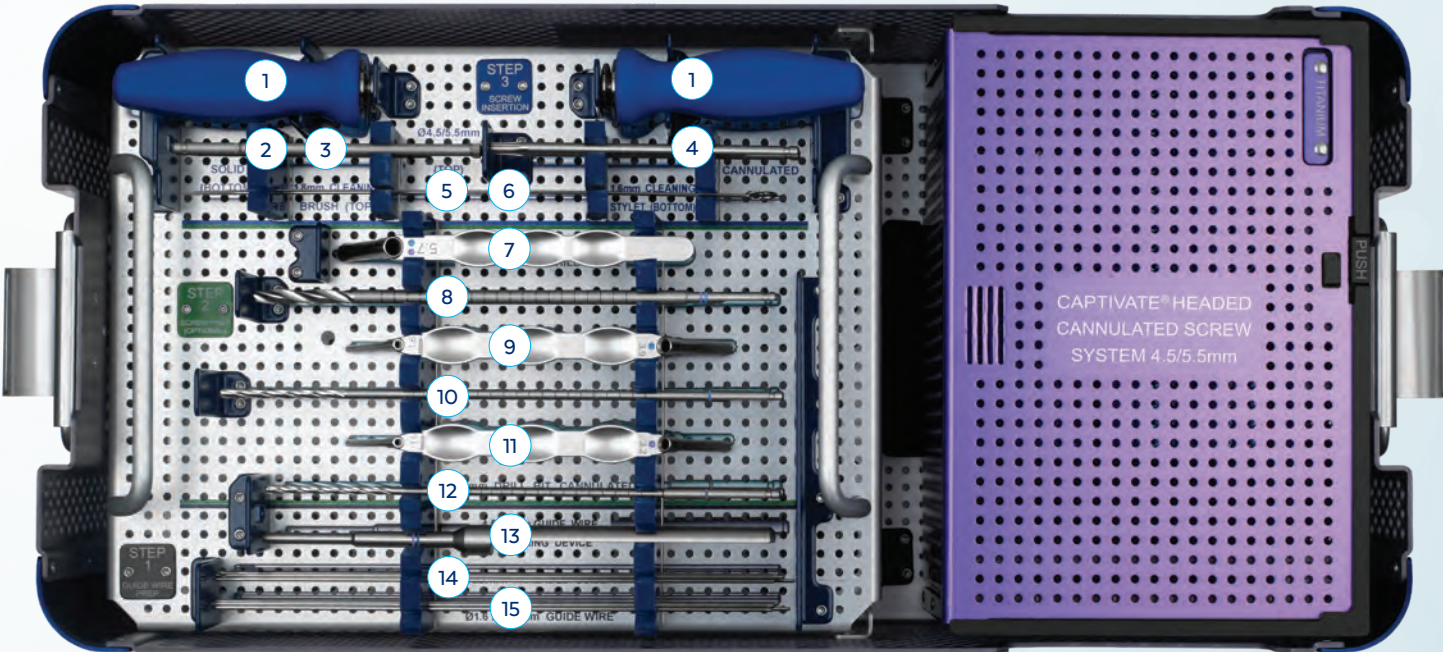
CAPTIVATE® 4.5/5.5mm Headed Cannulated Screw System Instrument Set 9178.9301 and 9178.9302

	Part No.	Description	Qty
1	6188.7001	Quick-Connect Handle, AO	2
2	6179.6120	T20 Driver, Solid	1
3	6178.8045	4.5/5.5mm Countersink, Cannulated	1
4	6188.6320	T20 Driver, Cannulated	2
5	6178.7145	1.8mm Cleaning Brush	1
6	6178.7245	1.6mm Cleaning Stylet	1
7	6178.4155	5.7mm Over Drill Guide	1
8	6178.5455	5.7mm Over Drill, Cannulated	1
9	6178.4055	3.9mm Soft Tissue Protector	1
10	6178.5355	3.9mm Drill Bit, Cannulated	2
11	6178.4045	3.2mm Soft Tissue Protector	1
12	6178.5345	3.2mm Drill Bit, Cannulated	2
13	6178.3045	4.5/5.5 Measuring Device	1
14	6178.1416	1.6x220mm Threaded Trocar Guide Wire	10
15	6178.1216	1.6x220mm Trocar Guide Wire	10
	6179.2000	Screw Holding Forceps	1
	9178.4556	4.5/5.5mm Ti Headed Graphic Case	
	9178.4557	4.5/5.5mm SS Headed Graphic Case	

Additionally Available

6178.5245	4.5mm Tap, Cannulated
6178.5255	5.5mm Tap, Cannulated

CAPTIVATE® 4.5/5.5mm Headed Cannulated Screw System Instrument Set 9178.9301 and 9178.9302



CAPTIVATE® 4.5/5.5mm Headed Cannulated Screw System Screw Module 9178.9311 and 9178.9312



4.5mm Partial Thread

Length	Stainless Steel Part No.	Titanium Part No.	Qty
30mm	2178.4730	1178.4730	2
32mm	2178.4732	1178.4732	2
34mm	2178.4734	1178.4734	2
36mm	2178.4736	1178.4736	2
38mm	2178.4738	1178.4738	2
40mm	2178.4740	1178.4740	2
42mm	2178.4742	1178.4742	2
44mm	2178.4744	1178.4744	2
46mm	2178.4746	1178.4746	2
48mm	2178.4748	1178.4748	2
50mm	2178.4750	1178.4750	2
55mm	2178.4955	1178.4955	2
60mm	2178.4760	1178.4760	2
65mm	2178.4765	1178.4765	2
70mm	2178.4770	1178.4770	2
75mm	2178.4775	1178.4775	2
80mm	2178.4780	1178.4780	2
85mm	2178.4785	1178.4785	2
90mm	2178.4790	1178.4790	2
95mm	2178.4795	1178.4795	2
100mm	2178.4800	1178.4800	2



4.5mm Full Thread

Length	Stainless Steel Part No.	Titanium Part No.	Qty
30mm	2178.4530	1178.4530	2
32mm	2178.4532	1178.4532	2
34mm	2178.4534	1178.4534	2
36mm	2178.4536	1178.4536	2
38mm	2178.4538	1178.4538	2
40mm	2178.4540	1178.4540	2
42mm	2178.4542	1178.4542	2
44mm	2178.4544	1178.4544	2
46mm	2178.4546	1178.4546	2
48mm	2178.4548	1178.4548	2
50mm	2178.4550	1178.4550	2
55mm	2178.4555	1178.4555	2
60mm	2178.4560	1178.4560	2
65mm	2178.4565	1178.4565	2
70mm	2178.4570	1178.4570	2
75mm	2178.4575	1178.4575	2
80mm	2178.4580	1178.4580	2
85mm	2178.4585	1178.4585	2
90mm	2178.4590	1178.4590	2
95mm	2178.4595	1178.4595	2
100mm	2178.4600	1178.4600	2

Washers

Part No.	Description	Qty
1178.0045	4.5/5.5mm Washer, Titanium	4
2178.0045	4.5/5.5mm Washer, Stainless Steel	4

CAPTIVATE® 4.5/5.5mm Headed Cannulated Screw System Screw Module 9178.9311 and 9178.9312



5.5mm Partial Thread

Length	Stainless Steel Part No.	Titanium Part No.	Qty
40mm	2178.5740	1178.5740	2
42mm	2178.5742	1178.5742	2
44mm	2178.5744	1178.5744	2
46mm	2178.5746	1178.5746	2
48mm	2178.5748	1178.5748	2
50mm	2178.5750	1178.5750	2
55mm	2178.5955	1178.5955	2
60mm	2178.5760	1178.5760	2
65mm	2178.5765	1178.5765	2
70mm	2178.5770	1178.5770	2
75mm	2178.5775	1178.5775	2
80mm	2178.5780	1178.5780	2
85mm	2178.5785	1178.5785	2
90mm	2178.5790	1178.5790	2
95mm	2178.5795	1178.5795	2
100mm	2178.5800	1178.5800	2
105mm	2178.5805	1178.5805	2
110mm	2178.5810	1178.5810	2
115mm	2178.5815	1178.5815	2
120mm	2178.5820	1178.5820	2



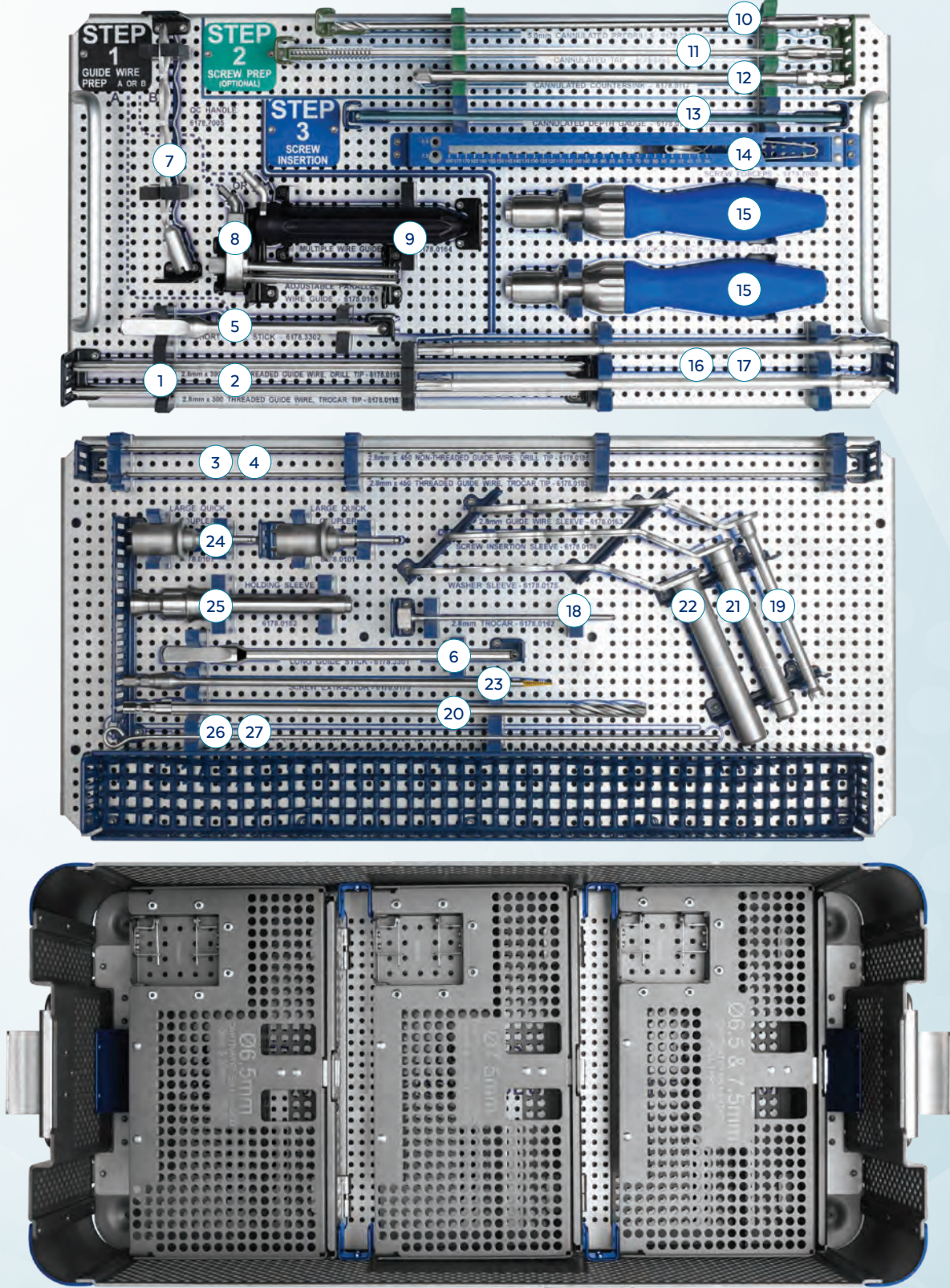
5.5mm Full Thread

Length	Stainless Steel Part No.	Titanium Part No.	Qty
40mm	2178.5540	1178.5540	2
42mm	2178.5542	1178.5542	2
44mm	2178.5544	1178.5544	2
46mm	2178.5546	1178.5546	2
48mm	2178.5548	1178.5548	2
50mm	2178.5550	1178.5550	2
55mm	2178.5555	1178.5555	2
60mm	2178.5560	1178.5560	2
65mm	2178.5565	1178.5565	2
70mm	2178.5570	1178.5570	2
75mm	2178.5575	1178.5575	2
80mm	2178.5580	1178.5580	2
85mm	2178.5585	1178.5585	2
90mm	2178.5590	1178.5590	2
95mm	2178.5595	1178.5595	2
100mm	2178.5600	1178.5600	2
105mm	2178.5605	1178.5605	2
110mm	2178.5610	1178.5610	2
115mm	2178.5615	1178.5615	2
120mm	2178.5620	1178.5620	2

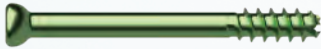
CAPTIVATE® 6.5/7.5mm Headed Cannulated Screw System Instrument Set 9178.9000

	Part No.	Description	Qty
1	6178.0115	2.8x300mm Threaded Guidewire, Trocar Tip	10
2	6178.0116	2.8x300mm Non-Threaded Guidewire, Drill Tip	10
3	6178.0185	2.8x450mm Non-Threaded Guidewire, Drill Tip	3
4	6178.0183	2.8x450mm Threaded Guidewire, Trocar Tip	3
5	6178.3302	Guide Stick, Short	1
6	6178.3301	Guide Stick, Long	1
7	6178.7005	QC Handle for Multiple & Parallel Wire Guides	1
8	6178.0165	Adjustable Parallel Wire Guide	1
9	6178.0164	Multiple Wire Guide	1
10	6178.5350	5.0mm Cannulated Predrill	2
11	6178.5165	Cannulated Tap	1
12	6178.0117	Cannulated Countersink	1
13	6178.0167	Cannulated Depth Gauge	1
14	6179.2000	Screw Holding Forceps	1
15	6178.3000	Quick-Connect Handle	2
16	6178.6130	Cannulated Screwdriver	2
17	6178.6430	Solid Screwdriver	1
18	6178.0162	2.8mm Trocar	1
19	6178.0163	2.8mm Guidewire Sleeve	1
20	6178.5375	7.5mm Cannulated Over Drill	2
21	6178.0174	Screw Insertion Sleeve	1
22	6178.0175	Washer Sleeve	1
23	6178.0176	Screw Extractor	1
24	6178.0181	Large Quick-Coupling	2
25	6178.0182	Holding Sleeve	1
26	6178.7165	Cleaning Brush	1
27	6178.7265	Cleaning Stylet	1
	9178.0100	Graphic Case	

CAPTIVATE® 6.5/7.5mm Headed Cannulated Screw System Instrument Set 9178.9000



CAPTIVATE® 6.5mm Headed Partial Thread Screws Screw Module 9178.9001 and 9178.9007



6.5mm, 16mm Partial Thread



6.5mm, 32mm Partial Thread

Length	Stainless Steel Part No.	Titanium Part No.	Qty	Length	Stainless Steel Part No.	Titanium Part No.	Qty
40mm	2178.6541	1178.6541	2	-	-	-	-
45mm	2178.6546	1178.6546	2	45mm	2178.6547	1178.6547	2
50mm	2178.6551	1178.6551	2	50mm	2178.6552	1178.6552	2
55mm	2178.6556	1178.6556	2	55mm	2178.6557	1178.6557	2
60mm	2178.6561	1178.6561	2	60mm	2178.6562	1178.6562	2
65mm	2178.6566	1178.6566	2	65mm	2178.6567	1178.6567	2
70mm	2178.6571	1178.6571	2	70mm	2178.6572	1178.6572	2
75mm	2178.6576	1178.6576	2	75mm	2178.6577	1178.6577	2
80mm	2178.6581	1178.6581	4	80mm	2178.6582	1178.6582	4
85mm	2178.6586	1178.6586	4	85mm	2178.6587	1178.6587	4
90mm	2178.6591	1178.6591	4	90mm	2178.6592	1178.6592	4
95mm	2178.6596	1178.6596	4	95mm	2178.6597	1178.6597	4
100mm	2178.6601	1178.6601	4	100mm	2178.6602	1178.6602	4
105mm	2178.6606	1178.6606	2	105mm	2178.6607	1178.6607	2
110mm	2178.6611	1178.6611	2	110mm	2178.6612	1178.6612	2
115mm	2178.6616	1178.6616	2	115mm	2178.6617	1178.6617	2
120mm	2178.6621	1178.6621	2	120mm	2178.6622	1178.6622	2
125mm	2178.6626	1178.6626	2	125mm	2178.6627	1178.6627	2

Washers

Part No.	Description	Qty
1178.0175	6.5/7.5mm Standard Washer, Titanium	4
2178.0175	6.5/7.5mm Standard Washer, Stainless Steel	4
1178.3175	6.5/7.5mm Oval Washer, Titanium	2
2178.3175	6.5/7.5mm Oval Washer, Stainless Steel	2

CAPTIVATE® 7.5mm Headed Partial Thread Screws Screw Module 9178.9002 and 9178.9008



7.5mm, 16mm Partial Thread



7.5mm, 32mm Partial Thread

Length	Stainless Steel Part No.	Titanium Part No.	Qty	Length	Stainless Steel Part No.	Titanium Part No.	Qty
40mm	2178.7541	1178.7541	2	-	-	-	-
45mm	2178.7546	1178.7546	2	45mm	2178.7547	1178.7547	2
50mm	2178.7551	1178.7551	2	50mm	2178.7552	1178.7552	2
55mm	2178.7556	1178.7556	2	55mm	2178.7557	1178.7557	2
60mm	2178.7561	1178.7561	2	60mm	2178.7562	1178.7562	2
65mm	2178.7566	1178.7566	2	65mm	2178.7567	1178.7567	2
70mm	2178.7571	1178.7571	2	70mm	2178.7572	1178.7572	2
75mm	2178.7576	1178.7576	2	75mm	2178.7577	1178.7577	2
80mm	2178.7581	1178.7581	4	80mm	2178.7582	1178.7582	4
85mm	2178.7586	1178.7586	4	85mm	2178.7587	1178.7587	4
90mm	2178.7591	1178.7591	4	90mm	2178.7592	1178.7592	4
95mm	2178.7596	1178.7596	4	95mm	2178.7597	1178.7597	4
100mm	2178.7601	1178.7601	4	100mm	2178.7602	1178.7602	4
105mm	2178.7606	1178.7606	2	105mm	2178.7607	1178.7607	2
110mm	2178.7611	1178.7611	2	110mm	2178.7612	1178.7612	2
115mm	2178.7616	1178.7616	2	115mm	2178.7617	1178.7617	2
120mm	2178.7621	1178.7621	2	120mm	2178.7622	1178.7622	2
125mm	2178.7626	1178.7626	2	125mm	2178.7627	1178.7627	2

Washers

Part No.	Description	Qty
1178.0175	6.5/7.5mm Standard Washer, Titanium	4
2178.0175	6.5/7.5mm Standard Washer, Stainless Steel	4
1178.3175	6.5/7.5mm Oval Washer, Titanium	2
2178.3175	6.5/7.5mm Oval Washer, Stainless Steel	2

CAPTIVATE® 6.5/7.5mm Headed Full Thread Screws Screw Module 9178.9003 and 9178.9009



6.5mm, Full Thread



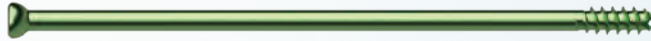
7.5mm, Full Thread

Length	Stainless Steel Part No.	Titanium Part No.	Qty	Length	Stainless Steel Part No.	Titanium Part No.	Qty
40mm	2178.6540	1178.6540	1	40mm	2178.7540	1178.7540	1
45mm	2178.6545	1178.6545	1	45mm	2178.7545	1178.7545	1
50mm	2178.6550	1178.6550	1	50mm	2178.7550	1178.7550	1
55mm	2178.6555	1178.6555	1	55mm	2178.7555	1178.7555	1
60mm	2178.6560	1178.6560	1	60mm	2178.7560	1178.7560	1
65mm	2178.6565	1178.6565	1	65mm	2178.7565	1178.7565	1
70mm	2178.6570	1178.6570	1	70mm	2178.7570	1178.7570	1
75mm	2178.6575	1178.6575	1	75mm	2178.7575	1178.7575	1
80mm	2178.6580	1178.6580	1	80mm	2178.7580	1178.7580	1
85mm	2178.6585	1178.6585	1	85mm	2178.7585	1178.7585	1
90mm	2178.6590	1178.6590	1	90mm	2178.7590	1178.7590	1
95mm	2178.6595	1178.6595	1	95mm	2178.7595	1178.7595	1
100mm	2178.6600	1178.6600	1	100mm	2178.7600	1178.7600	1
105mm	2178.6605	1178.6605	1	105mm	2178.7605	1178.7605	1
110mm	2178.6610	1178.6610	1	110mm	2178.7610	1178.7610	1
115mm	2178.6615	1178.6615	1	115mm	2178.7615	1178.7615	1
120mm	2178.6620	1178.6620	1	120mm	2178.7620	1178.7620	1
125mm	2178.6625	1178.6625	1	125mm	2178.7625	1178.7625	1

Washers

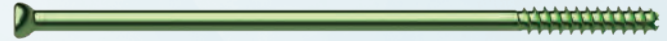
Part No.	Description	Qty
1178.0175	6.5/7.5mm Standard Washer, Titanium	2
2178.0175	6.5/7.5mm Standard Washer, Stainless Steel	2
1178.3175	6.5/7.5mm Oval Washer, Titanium	2
2178.3175	6.5/7.5mm Oval Washer, Stainless Steel	2

CAPTIVATE® 6.5mm Headed Partial Thread Long Screws Screw Module 9178.9004 and 9178.9010



6.5mm, 16mm Partial Thread

Length	Stainless Steel Part No.	Titanium Part No.	Qty
130mm	2178.6631	1178.6631	2
135mm	2178.6636	1178.6636	2
140mm	2178.6641	1178.6641	2
145mm	2178.6646	1178.6646	2
150mm	2178.6651	1178.6651	2
155mm	2178.6656	1178.6656	2
160mm	2178.6661	1178.6661	2
165mm	2178.6666	1178.6666	2
170mm	2178.6671	1178.6671	2
175mm	2178.6676	1178.6676	2
180mm	2178.6681	1178.6681	2



6.5mm, 32mm Partial Thread

Length	Stainless Steel Part No.	Titanium Part No.	Qty
130mm	2178.6632	1178.6632	2
135mm	2178.6637	1178.6637	2
140mm	2178.6642	1178.6642	2
145mm	2178.6647	1178.6647	2
150mm	2178.6652	1178.6652	2
155mm	2178.6657	1178.6657	2
160mm	2178.6662	1178.6662	2
165mm	2178.6667	1178.6667	2
170mm	2178.6672	1178.6672	2
175mm	2178.6677	1178.6677	2
180mm	2178.6682	1178.6682	2

Washers

Part No.	Description	Qty
1178.0175	6.5/7.5mm Standard Washer, Titanium	2
2178.0175	6.5/7.5mm Standard Washer, Stainless Steel	2
1178.3175	6.5/7.5mm Oval Washer, Titanium	2
2178.3175	6.5/7.5mm Oval Washer, Stainless Steel	2

CAPTIVATE® 7.5mm Headed Partial Thread Long Screws Screw Module 9178.9005 and 9178.9011



7.5mm, 16mm Partial Thread

Length	Stainless Steel Part No.	Titanium Part No.	Qty
130mm	2178.7631	1178.7631	2
135mm	2178.7636	1178.7636	2
140mm	2178.7641	1178.7641	2
145mm	2178.7646	1178.7646	2
150mm	2178.7651	1178.7651	2
155mm	2178.7656	1178.7656	2
160mm	2178.7661	1178.7661	2
165mm	2178.7666	1178.7666	2
170mm	2178.7671	1178.7671	2
175mm	2178.7676	1178.7676	2
180mm	2178.7681	1178.7681	2



7.5mm, 32mm Partial Thread

Length	Stainless Steel Part No.	Titanium Part No.	Qty
130mm	2178.7632	1178.7632	2
135mm	2178.7637	1178.7637	2
140mm	2178.7642	1178.7642	2
145mm	2178.7647	1178.7647	2
150mm	2178.7652	1178.7652	2
155mm	2178.7657	1178.7657	2
160mm	2178.7662	1178.7662	2
165mm	2178.7667	1178.7667	2
170mm	2178.7672	1178.7672	2
175mm	2178.7677	1178.7677	2
180mm	2178.7682	1178.7682	2

Washers

Part No.	Description	Qty
1178.0175	6.5/7.5mm Standard Washer, Titanium	2
2178.0175	6.5/7.5mm Standard Washer, Stainless Steel	2
1178.3175	6.5/7.5mm Oval Washer, Titanium	2
2178.3175	6.5/7.5mm Oval Washer, Stainless Steel	2

CAPTIVATE® 6.5/7.5mm

Headed Full Thread Long Screws

Screw Module 9178.9006 and 9178.9012



6.5mm, Full Thread

Length	Stainless Steel Part No.	Titanium Part No.	Qty
130mm	2178.6630	1178.6630	2
135mm	2178.6635	1178.6635	2
140mm	2178.6640	1178.6640	2
145mm	2178.6645	1178.6645	2
150mm	2178.6650	1178.6650	2
155mm	2178.6655	1178.6655	2
160mm	2178.6660	1178.6660	2
165mm	2178.6665	1178.6665	2
170mm	2178.6670	1178.6670	2
175mm	2178.6675	1178.6675	2
175mm	2178.6680	1178.6680	2



7.5mm, Full Thread

Length	Stainless Steel Part No.	Titanium Part No.	Qty
130mm	2178.7630	1178.7630	2
135mm	2178.7635	1178.7635	2
140mm	2178.7640	1178.7640	2
145mm	2178.7645	1178.7645	2
150mm	2178.7650	1178.7650	2
155mm	2178.7655	1178.7655	2
160mm	2178.7660	1178.7660	2
165mm	2178.7665	1178.7665	2
170mm	2178.7670	1178.7670	2
175mm	2178.7675	1178.7675	2
175mm	2178.7680	1178.7680	2

Washers

Part No.	Description	Qty
1178.0175	6.5/7.5mm Standard Washer, Titanium	2
2178.0175	6.5/7.5mm Standard Washer, Stainless Steel	2
1178.3175	6.5/7.5mm Oval Washer, Titanium	2
2178.3175	6.5/7.5mm Oval Washer, Stainless Steel	2

AVAILABLE SETS

2.5mm/3.0mm Headed Screws	
Set No.	Description
9178.9101	CAPTIVATE® Headed Titanium 2.5/3.0mm Instrument Set
9178.9111	CAPTIVATE® Headed Titanium 2.5/3.0mm Screw Module
9178.9102	CAPTIVATE® Headed Stainless Steel 2.5/3.0mm Instrument Set
9178.9112	CAPTIVATE® Headed Stainless Steel 2.5/3.0mm Screw Module

3.5/4.0mm Headed Screws	
Set No.	Description
9178.9201	CAPTIVATE® Headed Titanium 3.5/4.0mm Instrument Set
9178.9211	CAPTIVATE® Headed Titanium 3.5/4.0mm Screw Module
9178.9202	CAPTIVATE® Headed Stainless Steel 3.5/4.0mm Instrument Set
9178.9212	CAPTIVATE® Headed Stainless Steel 3.5/4.0mm Screw Module

4.5/5.5mm Headed Screws	
Set No.	Description
9178.9301	CAPTIVATE® Headed Titanium 4.5/5.5mm Instrument Set
9178.9311	CAPTIVATE® Headed Titanium 4.5/5.5mm Screw Module
9178.9302	CAPTIVATE® Headed Stainless Steel 4.5/5.5mm Instrument Set
9178.9312	CAPTIVATE® Headed Stainless Steel 4.5/5.5mm Screw Module

AVAILABLE SETS

6.5/7.5mm Headed Screws	
Set No.	Description
9178.9000	CAPTIVATE® Headed 6.5/7.5mm Instrument Set
9178.9001	CAPTIVATE® Headed Stainless Steel 6.5mm Partial Thread Screw Module
9178.9002	CAPTIVATE® Headed Stainless Steel 7.5mm Partial Thread Screw Module
9178.9003	CAPTIVATE® Headed Stainless Steel 6.5/7.5mm Full Thread Screw Module
9178.9004	CAPTIVATE® Headed Stainless Steel 6.5mm Partial Thread Long Screw Module
9178.9005	CAPTIVATE® Headed Stainless Steel 7.5mm Partial Thread Long Screw Module
9178.9006	CAPTIVATE® Headed Stainless Steel 6.5/7.5mm Full Thread Long Screw Module
9178.9007	CAPTIVATE® Headed Titanium 6.5mm Partial Thread Screw Module
9178.9008	CAPTIVATE® Headed Titanium 7.5mm Partial Thread Screw Module
9178.9009	CAPTIVATE® Headed Titanium 6.5/7.5mm Full Thread Screw Module
9178.9010	CAPTIVATE® Headed Titanium 6.5mm Partial Thread Long Screw Module
9178.9011	CAPTIVATE® Headed Titanium 7.5mm Partial Thread Long Screw Module
9178.9012	CAPTIVATE® Headed Titanium 6.5/7.5mm Full Thread Long Screw Module

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.

PRECAUTIONS

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

ADVERSE EFFECTS

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

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

IMPORTANT INFORMATION ON CAPTIVATE® COMPRESSION SCREWS

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

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

HANDLING

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

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

CLEANING

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

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

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

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

CONTACT INFORMATION

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

STERILIZATION

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

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

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

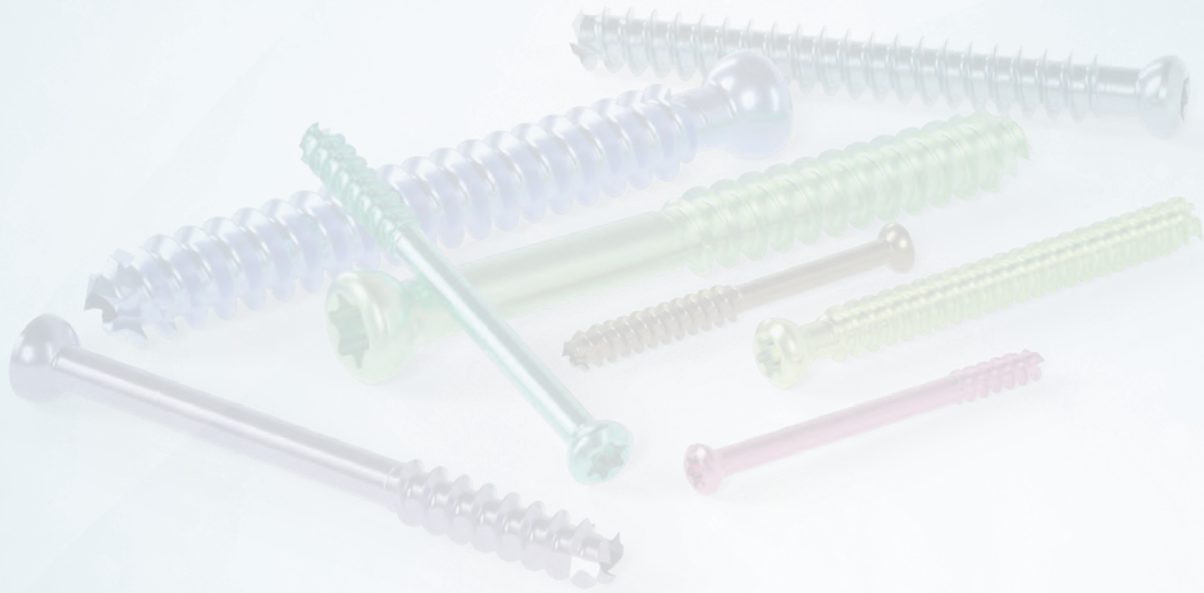
Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Pre-vacuum	132°C (270°F)	4 Minutes	30 Minutes

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 (U.S.A.) Law restricts this Device to Sale by or on the Order of a Physician.

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

DI200A Rev D



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GMTGD273
09.23 Rev B