

CAPTIVATE™ SOLA

Headless Compression 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™ SOLA

Headless Compression Screw System

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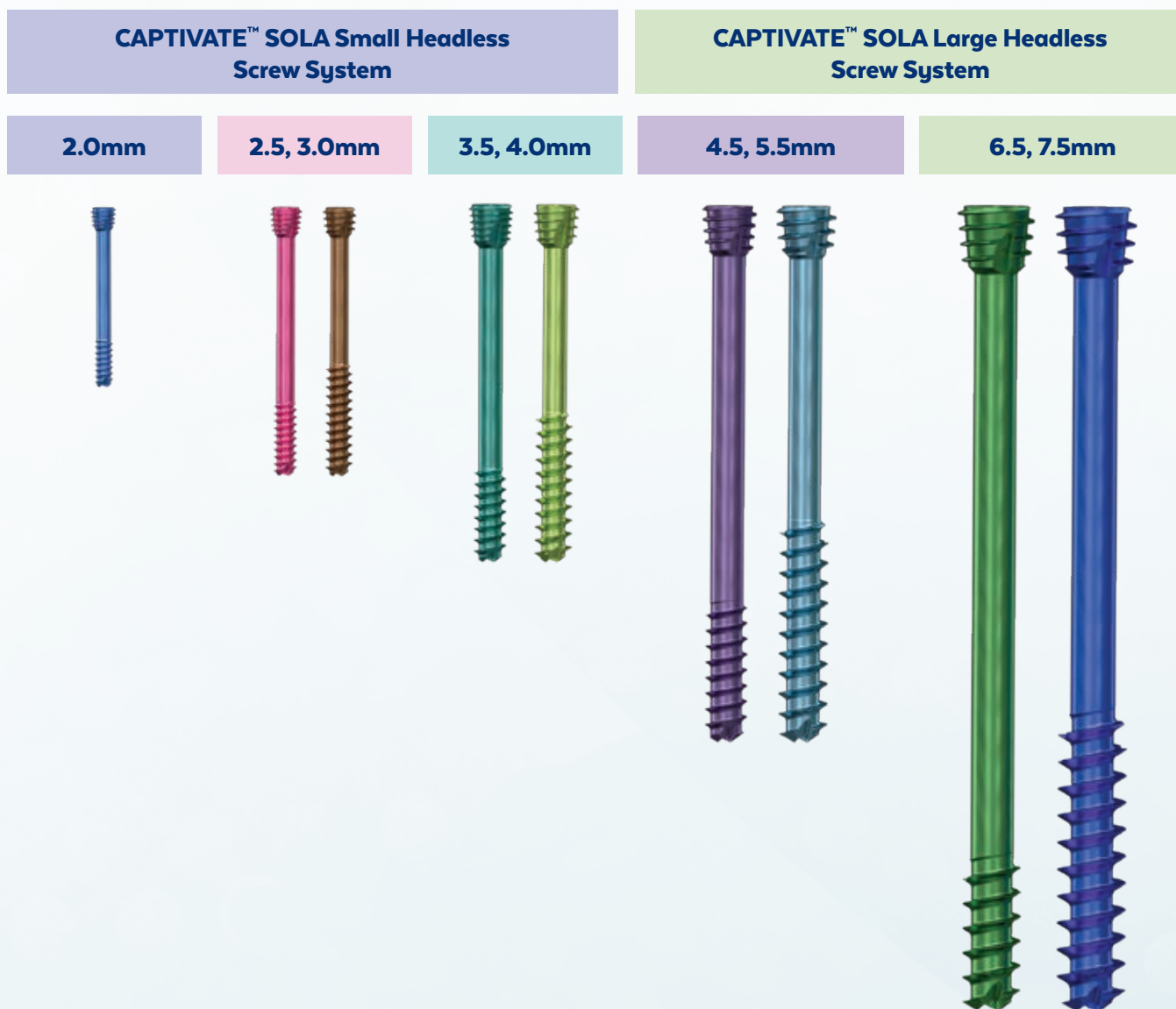
CAPTIVATE™ SOLA

Headless Compression Screw System

The CAPTIVATE™ SOLA Headless Compression Screw System offers a flexible and efficient solution to address fracture repair, bone reconstruction, osteotomy, and arthrodesis procedures through ample implant options and shared instruments for paired screw sizes.

Screw diameters include 2.0, 2.5, 3.0, 3.5, 4.0, 4.5, 5.5, 6.5, and 7.5mm in lengths ranging from 10-140mm. All screws are available in stainless steel and titanium alloy, with options for short and long partial threads.

Small and large modular graphic cases house all nine screw diameters and corresponding instrument modules.



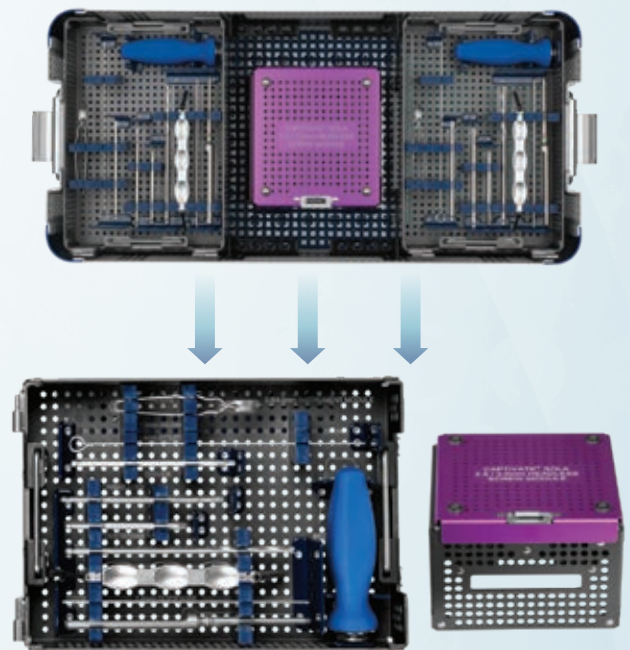
Comprehensive

- Screw sizes include 2.0, 2.5, 3.0, 3.5, 4.0, 4.5, 5.5, 6.5, and 7.5mm
- Broad range of screw lengths from 10-140mm
- Partially threaded screws (short and long thread options)
- Available in stainless steel and titanium alloy



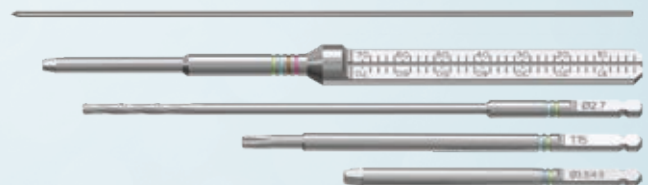
Modular

- Small screw system supports 5 screw diameters (2.0mm and paired 2.5, 3.0mm and 3.5, 4.0mm), along with three corresponding instrument modules
- Large screw system supports four screw diameters, paired 4.5, 5.5mm and 6.5, 7.5mm, along with two corresponding instrument modules
- Instrument module lids allow for independent use of screw modules, increasing system flexibility

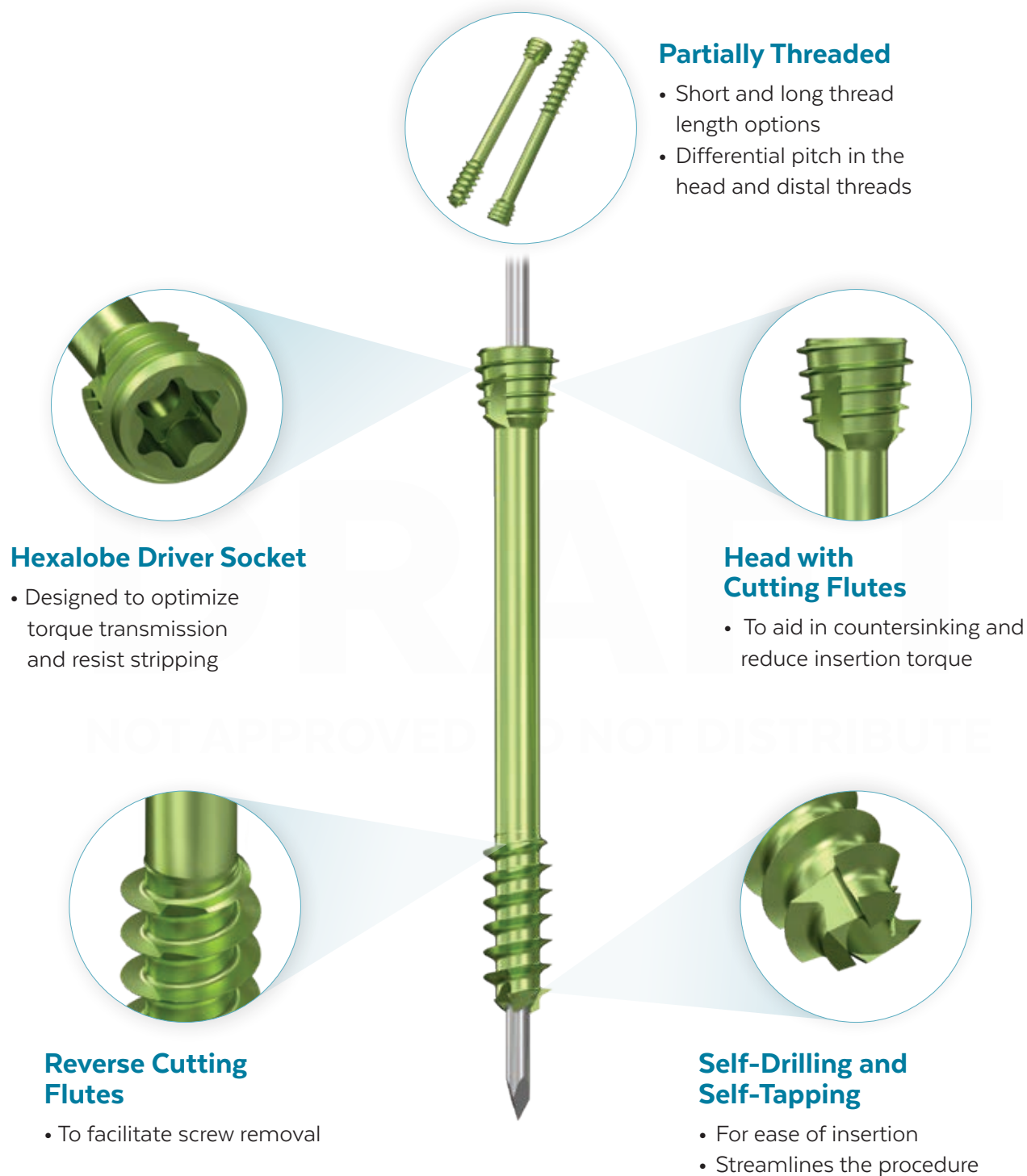


Efficient

- Shared instruments across screw sizes allow for seamless transition between paired screws
- Intuitive graphic case design and color-coded instruments for efficient procedural flow
- Differential pitch in the screw head thread and distal thread, along with self-drilling and self-tapping flutes to streamline insertion



IMPLANT OVERVIEW



SYSTEM OVERVIEW

CAPTIVATE™ SOLA Small Headless Screw System (SS & Ti)					
Screw Diameter	2.0mm	2.5mm	3.0mm	3.5mm	4.0mm
Color-Coding	● Blue	● Pink	● Bronze	● Aqua	● Light Green
Screw Lengths (Short Thread)	10-30mm (2mm increments)	10-20mm (1mm increments) 20-40mm (2mm increments)		14-50mm (2mm increments)	14-60mm (2mm increments)
Thread Lengths (Short Thread)	4-8mm*	4-10mm*		4.5-13mm*	5-15mm*
Screw Lengths (Long Thread)	20-30mm (2mm increments)	20-40mm (2mm increments)		24-50mm (2mm increments)	24-60mm (2mm increments)
Thread Lengths (Long Thread)	8-12mm**	8-16mm**		10-20mm**	10-24mm**
Guidewire (Diameter/Length)	0.8/100mm	1.1/150mm		1.4/150mm	
Cannulated Drill Bit (Diameter)	1.6mm	2.0mm		2.7mm	
Cannulated Driver Size	T6	T8		T15	

CAPTIVATE™ SOLA Large Headless Screw System (SS & Ti)				
Screw Diameter	4.5mm	5.5mm	6.5mm	7.5mm
Color-Coding	● Light Purple	● Light Blue	● Green	● Blue
Screw Lengths (Short Thread)	20-50mm (2mm increments) 55-110mm (5mm increments)		30-130mm (5mm increments)	30-140mm (5mm increments)
Thread Lengths (Short Thread)	8-28mm*	8.5-28mm*	16mm	
Screw Lengths (Long Thread)	30-50mm (2mm increments) 55-110mm (5mm increments)		45-130mm (5mm increments)	45-140mm (5mm increments)
Thread Lengths (Long Thread)	12-44mm**	12-44mm**	32mm	
Guidewire (Diameter/Length)	1.6/220mm		2.8/220mm	
Cannulated Drill Bit (Diameter)	3.9mm		5.0mm	
Cannulated Driver Size	T20		T30	

*SHORT THREAD = APPROXIMATELY 25% OF SCREW LENGTH

**LONG THREAD = APPROXIMATELY 40% OF SCREW LENGTH

SYSTEM OVERVIEW

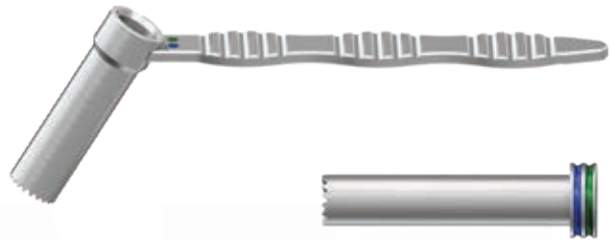
Cobalt Chrome Guidewires

- Higher bending stiffness compared to stainless steel guidewires
- Designed to minimize deflection during wire insertion



Soft Tissue Protectors

- Guidewire sleeves and tissue protectors available in 4.5/5.5mm and 6.5/7.5mm instrument modules
- Designed to protect soft tissue during guidewire placement, drilling, countersinking, and screw insertion



Double Sided Drill Guides

- One instrument to aid in precise guidewire placement and pre-drilling



SURGICAL TECHNIQUE

CAPTIVATE™ SOLA

Headless Compression Screw System

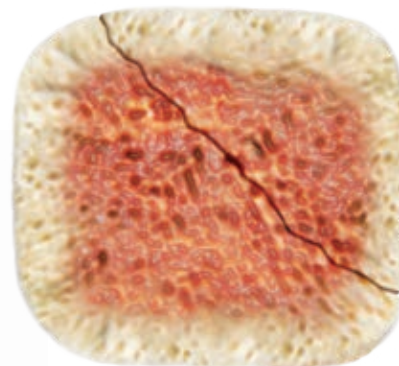
Refer to the package insert (also printed in the back of this manual) for important information on the intended usage/indications, device description, contraindications, precautions, warnings, and potential risks associated with this system.

STEP

1

FRACTURE IDENTIFICATION

Identify the fracture line and make the appropriate minimally invasive incision.



Identifying Fracture Line

STEP

2

GUIDEWIRE INSERTION

Select the appropriate **Guidewire** and **Double Sided Drill Guide** for the chosen screw diameter.

Position the guidewire end of the double sided drill guide as perpendicular as possible to the fracture line. Advance the guidewire through the guidewire end of the double sided drill guide and proceed to the appropriate depth. Confirm position of the guidewire using fluoroscopy.



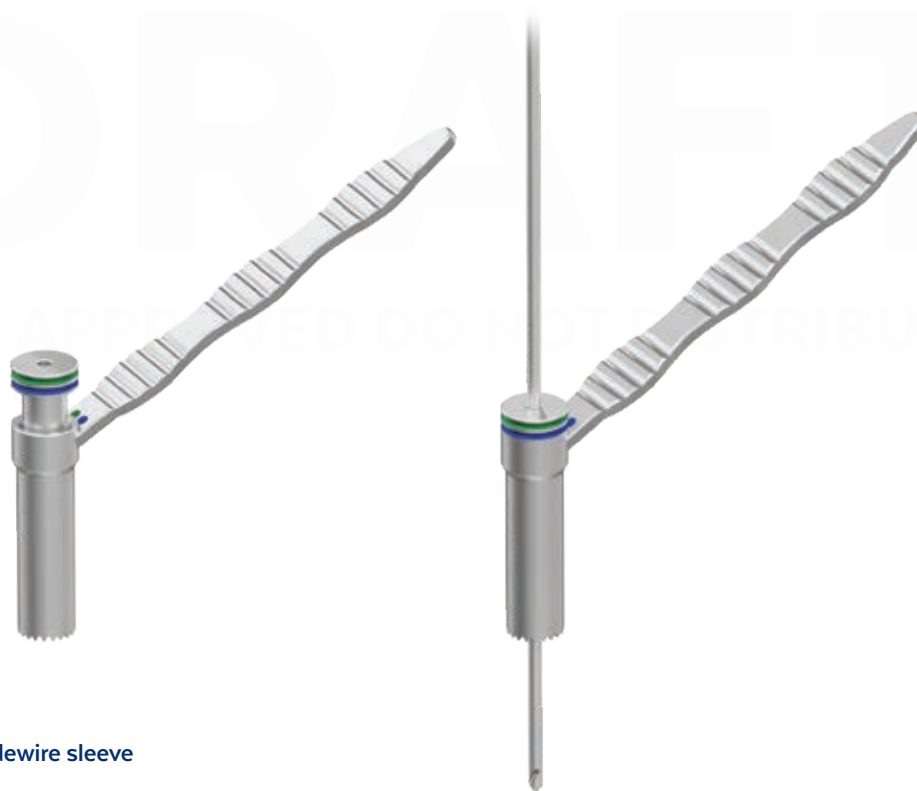
Inserting Guidewire

Optional

Guidewires may be inserted through the **Soft Tissue Protector Sleeve** for 4.5/5.5mm and 6.5/7.5mm screws. Insert the **Guidewire Sleeve** into the sleeve of the tissue protector.

Repeat the same steps for guidewire insertion as previously described with the double sided drill guide. After guidewire placement, the guidewire sleeve may be removed from the sleeve of the tissue protector as all subsequent steps can be performed through the sleeve of the tissue protector alone.

SCREW DIAMETER	GUIDEWIRE (DIAMETER/LENGTH)	SOFT TISSUE PROTECTOR
● 4.5/5.5mm	1.6mm Guidewire/220mm	4.5/5.5mm Tissue Protector & Guidewire Sleeve
● 6.5/7.5mm	2.8mm Guidewire/220mm	6.5/7.5mm Tissue Protector & Guidewire Sleeve

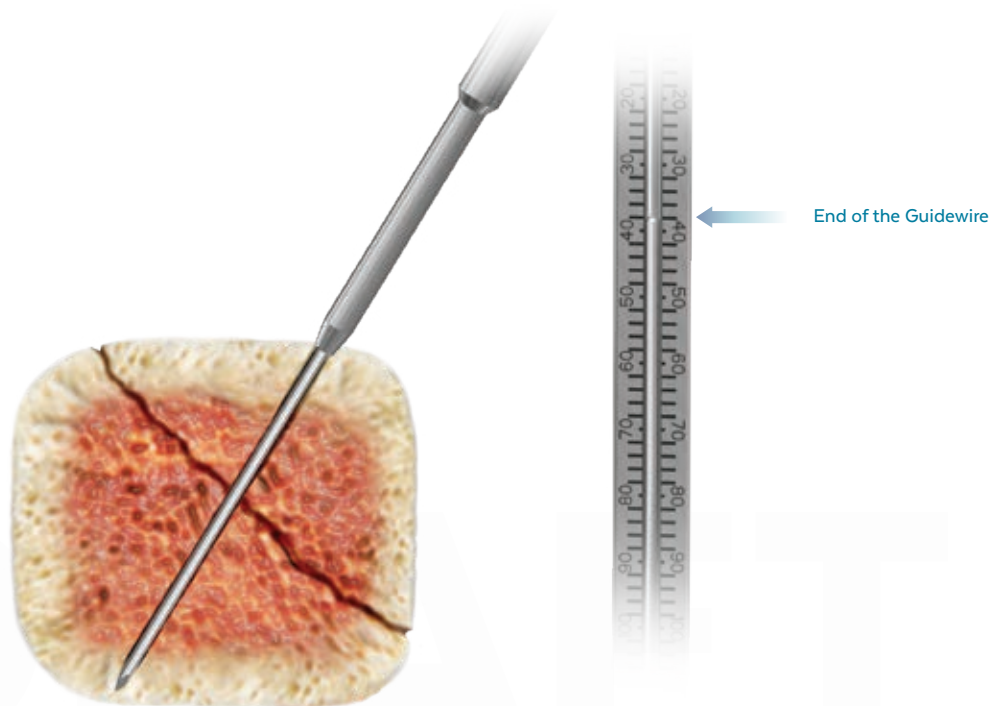


Guidewire sleeve

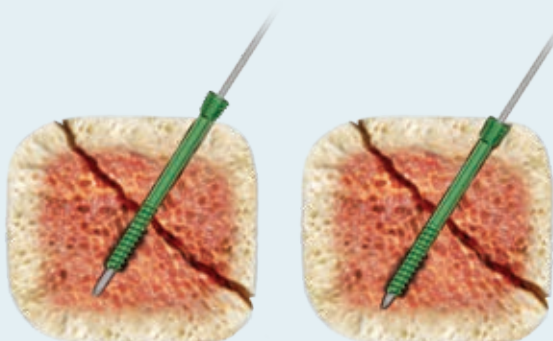
Tissue protector

STEP**3****MEASURING SCREW LENGTH**

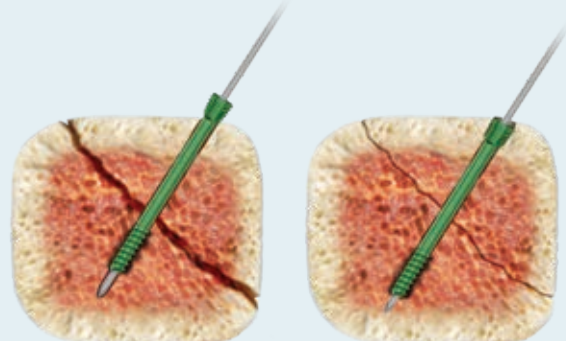
Slide the **Guidewire Measuring Device** over the guidewire until flush with bone. The appropriate screw length is indicated by the end of the guidewire tip along the markings on the gauge. If the measurement is between screw sizes, round down.



Measuring device showing
38mm length



Incorrect thread length
No compression in fracture gap



Correct thread length
Compression of fracture gap achieved
with distal threads below gap

STEP

3

MEASURING SCREW LENGTH (CONT'D)

*Note: The direct measuring device for 4.5, 5.5, 6.5, and 7.5mm screws may be inserted through the **4.5/5.5mm Tissue Protector** or **6.5/7.5mm Tissue Protector** to determine screw length*



Measuring device with
tissue protector

STEP

4

PRE-DRILLING (OPTIONAL)

Due to the self-drilling and self-tapping design of the CAPTIVATE™ SOLA screws, pre-drilling is optional. Pilot holes may be pre-drilled for all CAPTIVATE™ screws. Drill to the diameter recommended in the table below. Slide the drill guide end of the double sided drill guide over the guidewire and position on the bone surface. Attach the corresponding drill bit to the desired handle. Insert the **Drill Bit** over the guidewire and pre-drill the near cortex, making sure not to drill beyond the tip of the guidewire.

Use fluoroscopy to ensure that the trajectory is correct and drill to the appropriate length. Back the drill bit out of the bone once the desired depth has been reached without removing the guidewire.



Drilling through double sided drill guide

SCREW DIAMETER	GUIDEWIRE (Diameter/Length)	CANNULATED DRILL BIT Diameter
● 2.0mm	0.8mm/100mm	1.6mm
● 2.5/3.0mm	1.1mm/150mm	2.0mm
● 3.5/4.0mm	1.4mm/150mm	2.7mm
● 4.5/5.5mm	1.6mm/220mm	3.9mm
● 6.5/7.5mm	2.8mm/220mm	5.0mm

Note: The drill bits for 4.5, 5.5, 6.5, and 7.5mm screws may be inserted through the 4.5/5.5mm Tissue Protector or 6.5/7.5mm Tissue Protector for pre-drilling.

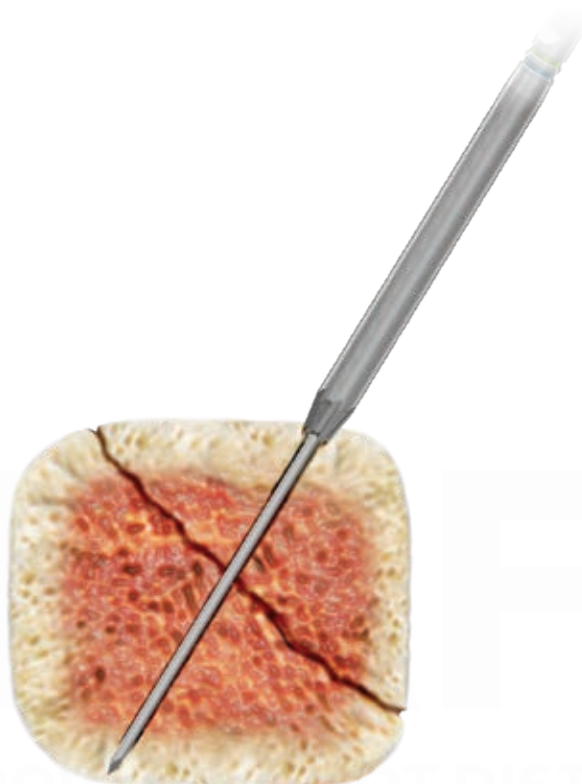


Drilling with tissue protector

STEP**5****COUNTERSINKING THE SCREW HEAD (OPTIONAL)**

Select the correct countersink for the chosen screw diameter.

Attach the countersink to the desired handle. Insert the countersink over the guidewire and advance the countersink into the bone to the desired depth.



Countersinking

Note: The countersinks for 4.5, 5.5, 6.5, and 7.5mm screws may be inserted through the 4.5/5.5mm Tissue Protector or 6.5/7.5mm Tissue Protector for countersinking.



Countersinking with tissue protector

STEP

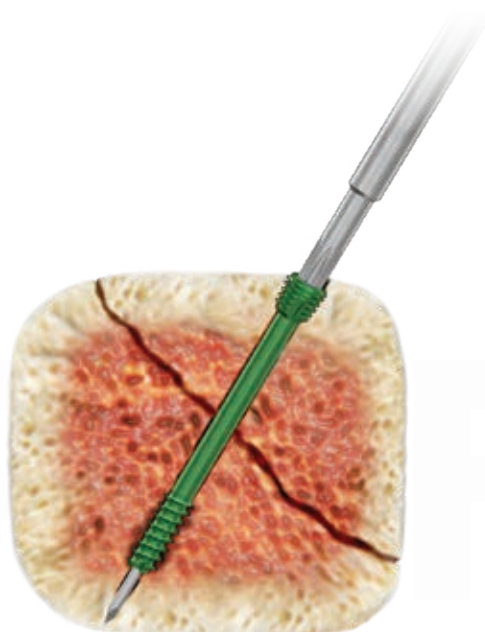
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INSERTING THE SCREW

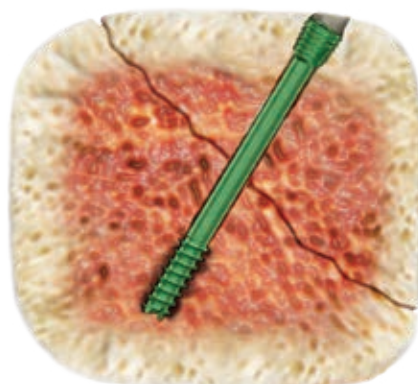
Select a **Driver** that mates with the selected screw size. Load the screw onto the self-retaining driver.

Drive the screw over the guidewire and rotate the driver handle clockwise to insert. Continue to drive until the fracture is reduced and the screw is seated flush or below the surface of the bone. Fluoroscopy is required during this step to ensure proper trajectory and placement.

Once the desired screw position is achieved, remove both the driver and guidewire. Remove the hexalobular driver by pulling out axially away from the screw tip. Remove the guidewire. Final screw positions are shown below.



Inserting screw and reducing fracture



Final position of screw

STEP**6****INSERTING THE SCREW (CONT'D)**

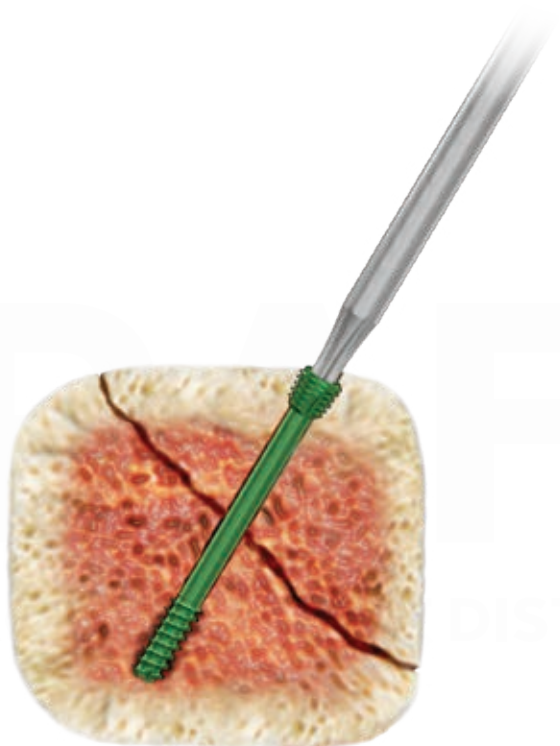
Note: The drivers for 4.5, 5.5, 6.5, and 7.5mm screws may be inserted through the 4.5/5.5mm Tissue Protector or 6.5/7.5mm Tissue Protector for screw insertion.



Inserting screw with
tissue protector

SCREW REMOVAL (OPTIONAL)

Insert the appropriate **Solid Removal Driver** into the drive feature of the screw and rotate counterclockwise. Use forceps or other instruments to pull the screw out axially.



Removal

INSTRUMENT OVERVIEW

2.0mm GUIDEWIRE AND MEASURING INSTRUMENTS



0.8mm Trocar Guidewire, 100mm 6188.1208



- 0.8mm Guidewire Measuring Device, 100mm 6188.8020

2.0mm BONE PREPARATION INSTRUMENTS



- 1.6mm Cannulated Drill Bit, 85mm 6188.5316



- 0.8/1.6mm Double Sided Drill Guide 6188.4020



- 2.0mm Cannulated Countersink 6188.4420



Dental Pick, Curved Tip, Small Handle 6179.7012

2.0mm SCREW INSERTION INSTRUMENTS



Small Handle, Short, AO Quick-Connect 6188.7000



● T6 Driver, Cannulated SR, 90mm, AO Quick-Connect 6188.6406



T6 Removal Driver, Solid 6188.6106



Screw Holding Forceps 6188.2015

2.0mm CLEANING INSTRUMENTS



Cleaning Brush, 1.0mm Cannulation, 170mm 6188.7125



Cleaning Stylet, 0.8mm Cannulation 6188.7225

2.5/3.0mm GUIDEWIRE AND MEASURING INSTRUMENTS



1.1mm Trocar Guidewire, 150mm 6188.1211



1.1mm & 1.4mm Guidewire Measuring Device, 150mm 6188.8025

2.5/3.0mm BONE PREPARATION INSTRUMENTS



2.0mm Cannulated Drill Bit, 140mm 6188.5220



1.1/2.0mm Double Sided Drill Guide 6178.4025



2.5/3.0mm Cannulated Countersink 6188.4425

2.5/3.0mm SCREW INSERTION INSTRUMENTS



Small Handle, Short, AO Quick-Connect 6188.7000



●● T8 Driver, Cannulated, SR, 100mm, AO Quick-Connect 6188.6408



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



Screw Holding Forceps 6179.2000

2.5/3.0mm CLEANING INSTRUMENTS



Cleaning Brush, 1.2mm Cannulation, 170mm 6188.7130



Cleaning Stylet, 1.1mm Cannulation 6188.7230

3.5/4.0mm GUIDEWIRE AND MEASURING INSTRUMENTS



1.4mm Trocar Guidewire, 150mm 6188.1214



●●● 1.1mm & 1.4mm Guidewire Measuring Device, 150mm 6188.8025

3.5/4.0mm BONE PREPARATION INSTRUMENTS



●● 2.7mm Cannulated Drill Bit, 140mm 6188.5327



●● 1.4/2.7mm Double Sided Drill Guide 6178.4035



●● 3.5/4.0mm Cannulated Countersink 6188.4435

3.5/4.0mm SCREW INSERTION INSTRUMENTS



Medium Handle, AO Quick-Connect 6188.7001



T15 Driver, Cannulated, SR, 100mm, AO Quick-Connect 6188.6415



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



Screw Holding Forceps 6179.2000

3.5/4.0mm CLEANING INSTRUMENTS



Cleaning Brush, 1.6mm Cannulation, 185mm 6188.7140



Cleaning Stylet, 1.4mm Cannulation 6188.7240

4.5/5.5mm GUIDEWIRE AND MEASURING INSTRUMENTS



1.6mm Trocar Guidewire, 220mm 6188.1216



1.6 & 2.8mm Guidewire Measuring Device, 220mm 6188.8045



4.5/5.5mm Tissue Protector 6188.9545



4.5/5.5mm Guide Wire Sleeve 6188.7516

4.5/5.5mm BONE PREPARATION INSTRUMENTS



3.9mm Cannulated Drill Bit, 185mm 6188.5330



1.6/3.9mm Double Sided Drill Guide 6188.4045



4.5/5.5mm Cannulated Countersink 6188.4445



Dental Pick, Curved Tip, Small Handle 6179.7012

4.5/5.5mm SCREW INSERTION INSTRUMENTS



Medium Handle, Ratcheting, Cannulated AO Quick-Connect 6179.7013



● T20 Driver, Cannulated, SR, 100mm, AO Quick-Connect 6188.6420



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



2.8mm Drill-Tip Guidewire, 220mm 6188.1228



1.6 & 2.8mm Guidewire Measuring Device, 220mm 6188.8045



6.5/7.5mm Tissue Protector 6188.9565



6.5/7.5mm Guide Wire Sleeve 6188.9028

6.5/7.5mm BONE PREPARATION INSTRUMENTS



5.0mm Cannulated Drill Bit, 222mm 6188.5350



2.8/5.0mm Double Sided Drill Guide 6188.4065



6.5/7.5mm Cannulated Countersink 6188.4465

6.5/7.5mm SCREW INSERTION INSTRUMENTS



Quick-Connect Handle 6178.3000



Large QC Adapter 6178.0181



● T30 Driver, Cannulated, SR, 155mm, Hall Quick-Connect 6188.6430



T30 Removal Driver, Solid 6188.6130



Screw Holding Forceps 6179.2000

6.5/7.5mm CLEANING INSTRUMENTS



3.4mm Cleaning Brush, 230mm 6188.7165



2.8mm Cleaning Stylet, 230mm 6188.7265

CAPTIVATE™ SOLA

Headless Compression Screw System

2.0mm Screw Module 9188.9203 and 9188.9204



2.0mm Short Thread

Screw Length (mm)	Thread Length (mm)	SS Part No.	Ti Part No.	Qty
10	4	4188.2010	3188.2010	2
12	4	4188.2012	3188.2012	2
14	4	4188.2014	3188.2014	2
16	4	4188.2016	3188.2016	2
18	5	4188.2018	3188.2018	2
20	5	4188.2020	3188.2020	2
22	6	4188.2022	3188.2022	2
24	6	4188.2024	3188.2024	2
26	7	4188.2026	3188.2026	2
28	7	4188.2028	3188.2028	2
30	8	4188.2030	3188.2030	2



2.0mm Long Thread

Screw Length (mm)	Thread Length (mm)	SS Part No.	Ti Part No.	Qty
20	8	4188.2120	3188.2120	1
22	9	4188.2122	3188.2122	1
24	10	4188.2124	3188.2124	1
26	10	4188.2126	3188.2126	1
28	11	4188.2128	3188.2128	1
30	12	4188.2130	3188.2130	1

Short Thread = Approximately 25% Total Length or 4mm

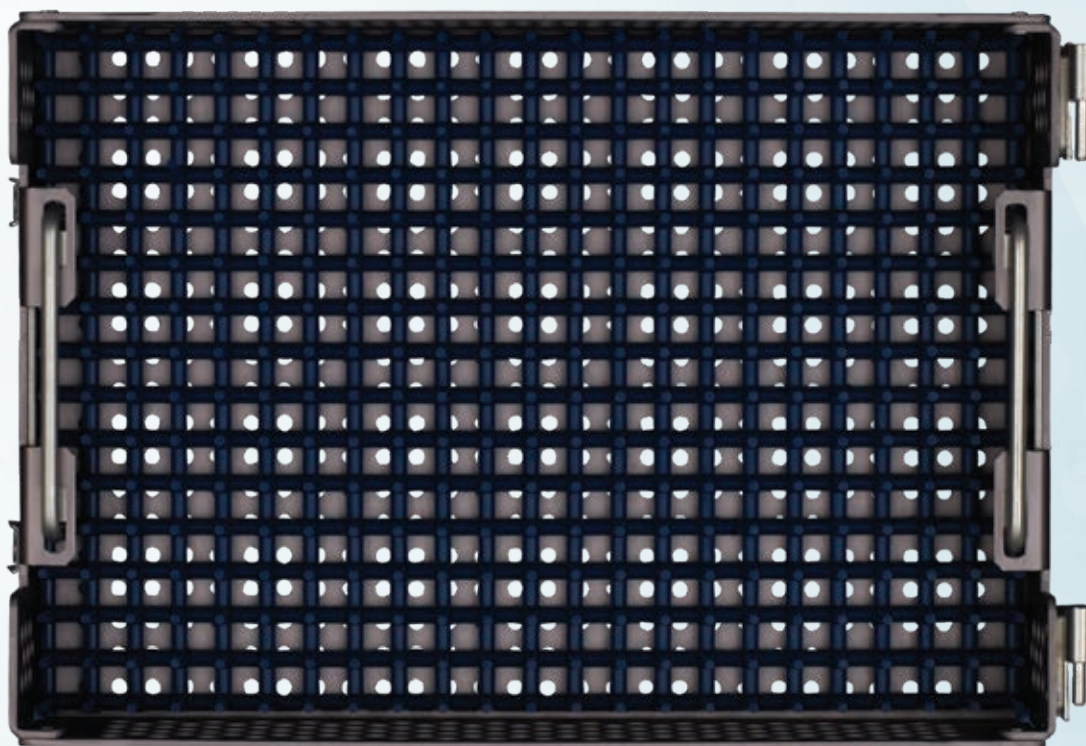
Long Thread = Approximately 40% Total Length

CAPTIVATE™ SOLA

Headless Compression Screw System

Auxiliary Instrument Module 9188.9111

Part No.	Description	Qty
9188.1111	CAPTIVATE™ SOLA Auxiliary Instrument Module	1



CAPTIVATE™ SOLA

Headless Compression Screw System

2.0mm Instrument Module 9188.9205

	Part No.	Description	Qty
1	6188.1208	0.8mm Trocar Guidewire, 100mm	8
2	6188.4020	0.8/1.6mm Double Sided Drill Guide	1
3	6188.8020	0.8mm Guidewire Measuring Device, 100mm	1
4	6188.5316	1.6mm Cannulated Drill Bit, 85mm	2
5	6188.4420	2.0mm Cannulated Countersink	1
6	6188.6406	T6 Driver, Cannulated SR, 90mm, AO Quick-Connect	2
7	6188.7000	Small Handle, Short, AO Quick-Connect	1
8	6179.7012	Dental Pick, Curved Tip, Small Handle	1
9	6188.2015	Screw Holding Forceps	1
	9188.5200	CAPTIVATE™ SOLA 2.0mm Headless Instrument Module Lid	

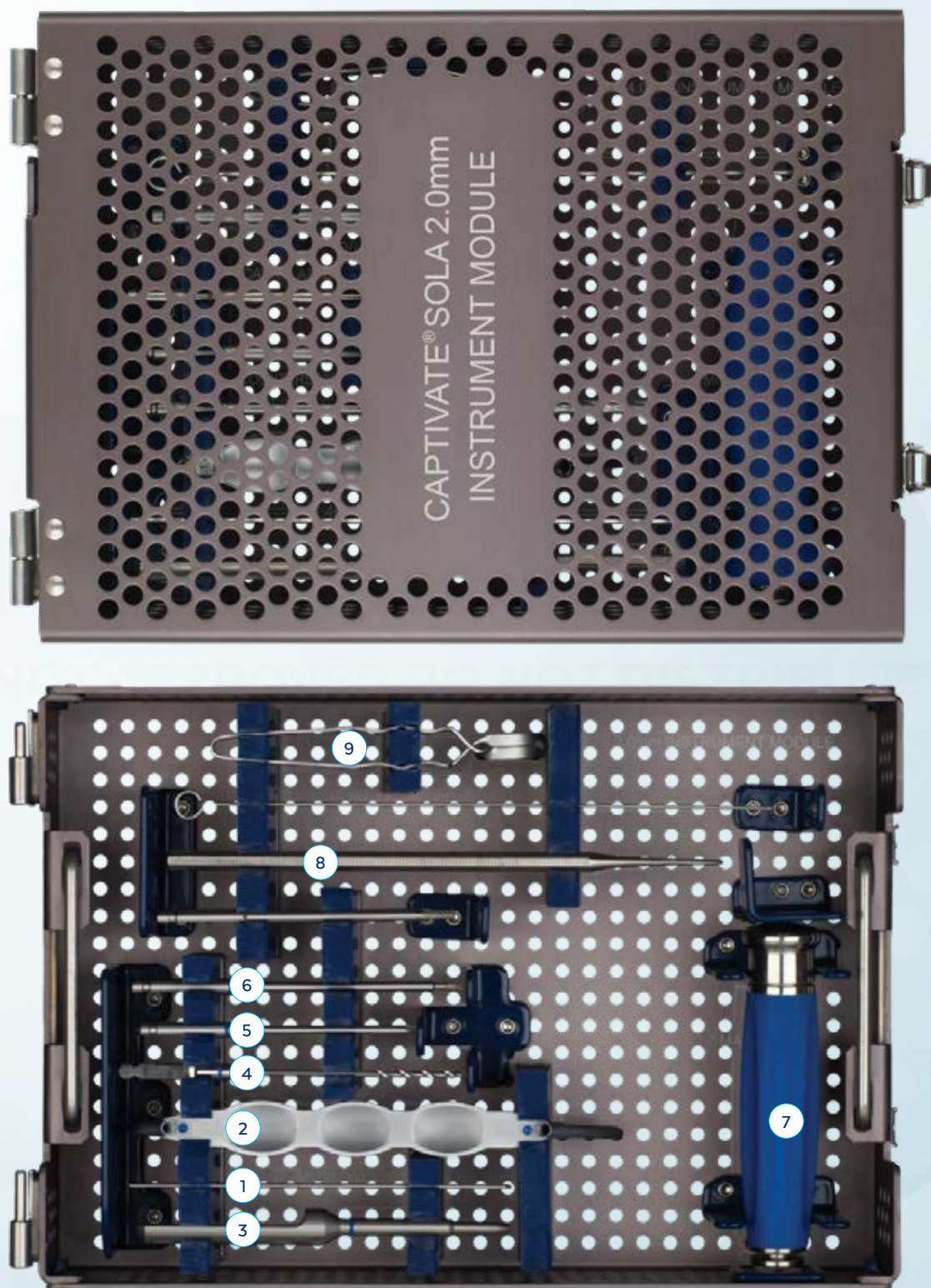
Additionally Available

6188.7125	Cleaning Brush, 1.0mm Cannulation, 170mm	0
6188.7225	Cleaning Stylet, 0.8mm Cannulation	0
6188.6106	T6 Removal Driver, Solid	0

CAPTIVATE™ SOLA

Headless Compression Screw System

2.0mm Instrument Module 9188.9205



CAPTIVATE™ SOLA

Headless Compression Screw System

2.5/3.0mm Screw Module 9188.9253 and 9188.9254



2.5mm Short Thread

Screw Length (mm)	Thread Length (mm)	SS Part No.	Ti Part No.	Qty
10	4	4188.2510	3188.2510	2
12	4	4188.2512	3188.2512	2
14	4	4188.2514	3188.2514	2
16	4	4188.2516	3188.2516	2
18	5	4188.2518	3188.2518	2
20	5	4188.2520	3188.2520	2
22	6	4188.2522	3188.2522	2
24	6	4188.2524	3188.2524	2
26	7	4188.2526	3188.2526	2
28	7	4188.2528	3188.2528	2
30	8	4188.2530	3188.2530	2
32	8	4188.2532	3188.2532	2
34	9	4188.2534	3188.2534	2
36	9	4188.2536	3188.2536	2
38	10	4188.2538	3188.2538	1
40	10	4188.2540	3188.2540	1



2.5mm Long Thread

Screw Length (mm)	Thread Length (mm)	SS Part No.	Ti Part No.	Qty
20	8	4188.2620	3188.2620	1
22	9	4188.2622	3188.2622	1
24	10	4188.2624	3188.2624	1
26	10	4188.2626	3188.2626	1
28	11	4188.2628	3188.2628	1
30	12	4188.2630	3188.2630	1
32	13	4188.2632	3188.2632	1
34	14	4188.2634	3188.2634	1
36	14	4188.2636	3188.2636	1
38	15	4188.2638	3188.2638	1
40	16	4188.2640	3188.2640	1

Short Thread = Approximately 25% Total Length or 4mm

Long Thread = Approximately 40% Total Length

CAPTIVATE™ SOLA

Headless Compression Screw System

2.5/3.0mm Screw Module 9188.9253 and 9188.9254



3.0mm Short Thread

Screw Length (mm)	Thread Length (mm)	SS Part No.	Ti Part No.	Qty
10	4	4188.3010	3188.3010	1
12	4	4188.3012	3188.3012	1
14	4	4188.3014	3188.3014	1
16	4	4188.3016	3188.3016	1
18	5	4188.3018	3188.3018	1
20	5	4188.3020	3188.3020	1
22	6	4188.3022	3188.3022	2
24	6	4188.3024	3188.3024	2
26	7	4188.3026	3188.3026	2
28	7	4188.3028	3188.3028	2
30	8	4188.3030	3188.3030	2
32	8	4188.3032	3188.3032	2
34	9	4188.3034	3188.3034	2
36	9	4188.3036	3188.3036	2
38	10	4188.3038	3188.3038	2
40	10	4188.3040	3188.3040	2



3.0mm Long Thread

Screw Length (mm)	Thread Length (mm)	SS Part No.	Ti Part No.	Qty
20	8	4188.3120	3188.3120	1
22	9	4188.3122	3188.3122	1
24	10	4188.3124	3188.3124	1
26	10	4188.3126	3188.3126	1
28	11	4188.3128	3188.3128	1
30	12	4188.3130	3188.3130	1
32	13	4188.3132	3188.3132	1
34	14	4188.3134	3188.3134	1
36	14	4188.3136	3188.3136	1
38	15	4188.3138	3188.3138	1
40	16	4188.3140	3188.3140	1

Short Thread = Approximately 25% Total Length or 4mm

Long Thread = Approximately 40% Total Length

CAPTIVATE™ SOLA

Headless Compression Screw System

2.5/3.0mm Instrument Module 9188.9255

	Part No.	Description	Qty
1	6188.1211	1.1mm Trocar Guidewire, 150mm	8
2	6178.4025	1.1/2.0mm Double Sided Drill Guide	1
3	6188.8025	1.1mm & 1.4mm Guidewire Measuring Device, 150mm	1
4	6188.5220	2.0mm Cannulated Drill Bit, 140mm	2
5	6188.4425	2.5/3.0mm Cannulated Countersink	1
6	6188.7000	Small Handle, Short, AO Quick-Connect	1
7	6188.6408	T8 Driver, Cannulated, SR, 100mm, AO Quick-Connect	2
8	6179.2000	Screw Holding Forceps	1
	9188.5250	CAPTIVATE™ SOLA 2.5/3.0mm Headless Instrument Module Lid	

Additionally Available

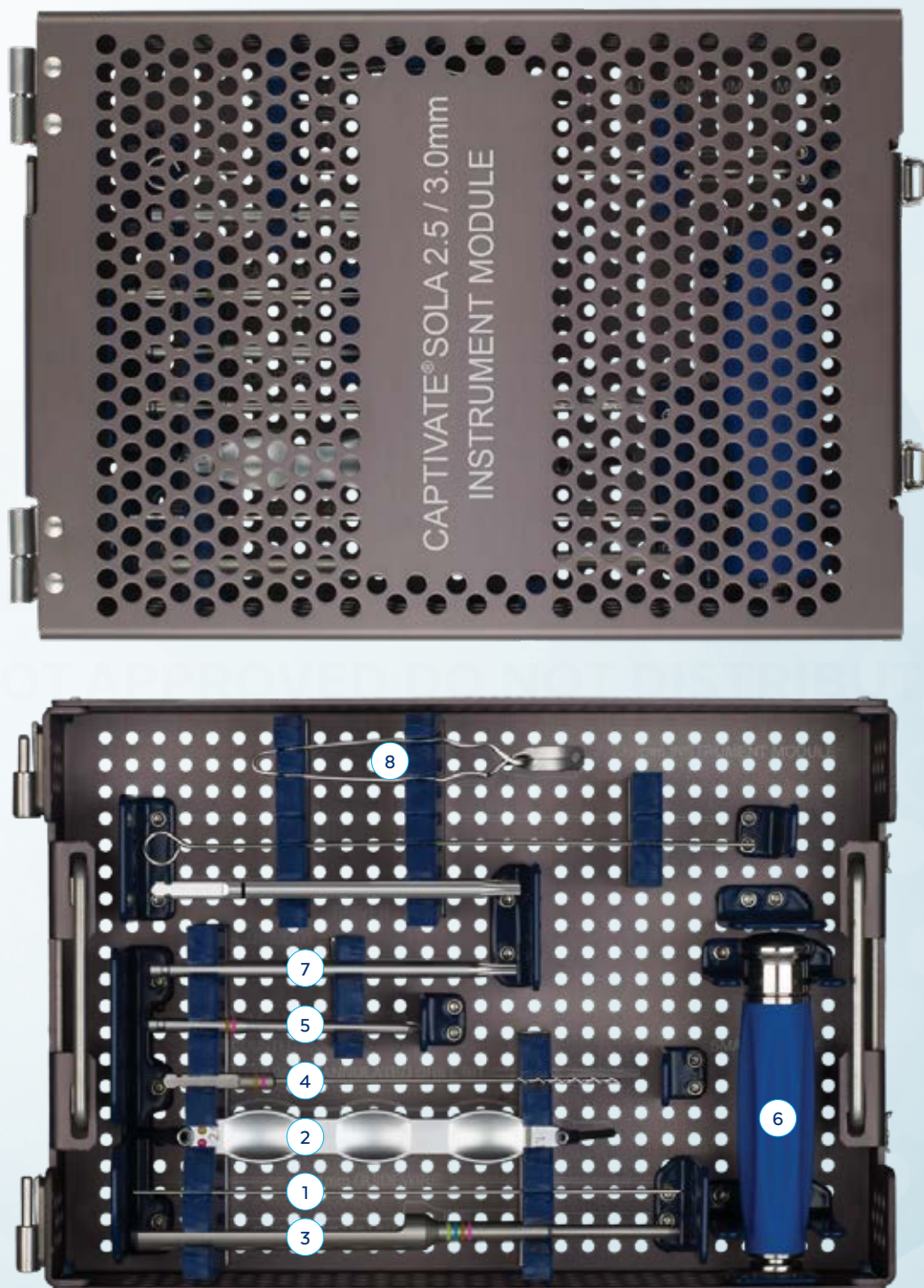
6188.7130	Cleaning Brush, 1.2mm Cannulation, 170mm	0
6188.7230	Cleaning Stylet, 1.1mm Cannulation	0
6179.6108	T8 Driver, Non-Self-Retaining, 100mm, AO Quick-Connect	0

NOT APPROVED DO NOT DISTRIBUTE

CAPTIVATE™ SOLA

Headless Compression Screw System

2.5/3.0mm Instrument Module 9188.9255



CAPTIVATE™ SOLA

Headless Compression Screw System

3.5/4.0mm Screw Module 9188.9353 and 9188.9354



3.5mm Short Thread

Screw Length (mm)	Thread Length (mm)	SS Part No.	Ti Part No.	Qty
14	4.5	4188.3514	3188.3514	0
16	4.5	4188.3516	3188.3516	0
18	5	4188.3518	3188.3518	0
20	5	4188.3520	3188.3520	1
22	6	4188.3522	3188.3522	1
24	6	4188.3524	3188.3524	1
26	7	4188.3526	3188.3526	1
28	7	4188.3528	3188.3528	1
30	8	4188.3530	3188.3530	1
32	8	4188.3532	3188.3532	1
34	9	4188.3534	3188.3534	1
36	9	4188.3536	3188.3536	1
38	10	4188.3538	3188.3538	1
40	10	4188.3540	3188.3540	1
42	11	4188.3542	3188.3542	1
44	11	4188.3544	3188.3544	1
46	12	4188.3546	3188.3546	1
48	12	4188.3548	3188.3548	1
50	13	4188.3550	3188.3550	1



3.5mm Long Thread

Screw Length (mm)	Thread Length (mm)	SS Part No.	Ti Part No.	Qty
24	10	4188.3624	3188.3624	2
26	10	4188.3626	3188.3626	2
28	11	4188.3628	3188.3628	2
30	12	4188.3630	3188.3630	2
32	13	4188.3632	3188.3632	2
34	14	4188.3634	3188.3634	2
36	14	4188.3636	3188.3636	2
38	15	4188.3638	3188.3638	2
40	16	4188.3640	3188.3640	2
42	17	4188.3642	3188.3642	2
44	18	4188.3644	3188.3644	2
46	18	4188.3646	3188.3646	2
48	19	4188.3648	3188.3648	2
50	20	4188.3650	3188.3650	2

Short Thread = Approximately 25% Total Length or 4.5mm

Long Thread = Approximately 40% Total Length

CAPTIVATE™ SOLA

Headless Compression Screw System

3.5/4.0mm Screw Module 9188.9353 and 9188.9354



4.0mm Short Thread

Screw Length (mm)	Thread Length (mm)	SS Part No.	Ti Part No.	Qty
14	5	4188.4014	3188.4014	0
16	5	4188.4016	3188.4016	0
18	5	4188.4018	3188.4018	0
20	5	4188.4020	3188.4020	0
22	6	4188.4022	3188.4022	0
24	6	4188.4024	3188.4024	1
26	7	4188.4026	3188.4026	1
28	7	4188.4028	3188.4028	1
30	8	4188.4030	3188.4030	1
32	8	4188.4032	3188.4032	1
34	9	4188.4034	3188.4034	1
36	9	4188.4036	3188.4036	1
38	10	4188.4038	3188.4038	1
40	10	4188.4040	3188.4040	1
42	11	4188.4042	3188.4042	1
44	11	4188.4044	3188.4044	1
46	12	4188.4046	3188.4046	1
48	12	4188.4048	3188.4048	1
50	13	4188.4050	3188.4050	1
52	13	4188.4052	3188.4052	1
54	14	4188.4054	3188.4054	1
56	14	4188.4056	3188.4056	1
58	15	4188.4058	3188.4058	1
60	15	4188.4060	3188.4060	1



4.0mm Long Thread

Screw Length (mm)	Thread Length (mm)	SS Part No.	Ti Part No.	Qty
24	10	4188.4124	3188.4124	2
26	10	4188.4126	3188.4126	2
28	11	4188.4128	3188.4128	2
30	12	4188.4130	3188.4130	2
32	13	4188.4132	3188.4132	2
34	14	4188.4134	3188.4134	2
36	14	4188.4136	3188.4136	2
38	15	4188.4138	3188.4138	2
40	16	4188.4140	3188.4140	2
42	17	4188.4142	3188.4142	2
44	18	4188.4144	3188.4144	2
46	18	4188.4146	3188.4146	2
48	19	4188.4148	3188.4148	2
50	20	4188.4150	3188.4150	2
52	21	4188.4152	3188.4152	2
54	22	4188.4154	3188.4154	2
56	22	4188.4156	3188.4156	2
58	23	4188.4158	3188.4158	2
60	24	4188.4160	3188.4160	2

Short Thread = Approximately 25% Total Length or 5mm

Long Thread = Approximately 40% Total Length

CAPTIVATE™ SOLA

Headless Compression Screw System

3.5/4.0mm Instrument Module 9188.9355

	Part No.	Description	Qty
1	6188.1214	1.4mm Trocar Guidewire, 150mm	8
2	6178.4035	1.4/2.7mm Double Sided Drill Guide	1
3	6188.8025	1.1mm & 1.4mm Guidewire Measuring Device, 150mm	1
4	6188.5327	2.7mm Cannulated Drill Bit, 140mm	2
5	6188.4435	3.5/4.0mm Cannulated Countersink	1
6	6188.6415	T15 Driver, Cannulated, SR, 100mm, AO Quick-Connect	2
7	6188.7001	Medium Handle, AO Quick-Connect	1
8	6179.2000	Screw Holding Forceps	1
	9188.5350	CAPTIVATE™ SOLA 3.5/4.0mm Headless Instrument Module Lid	

Additionally Available

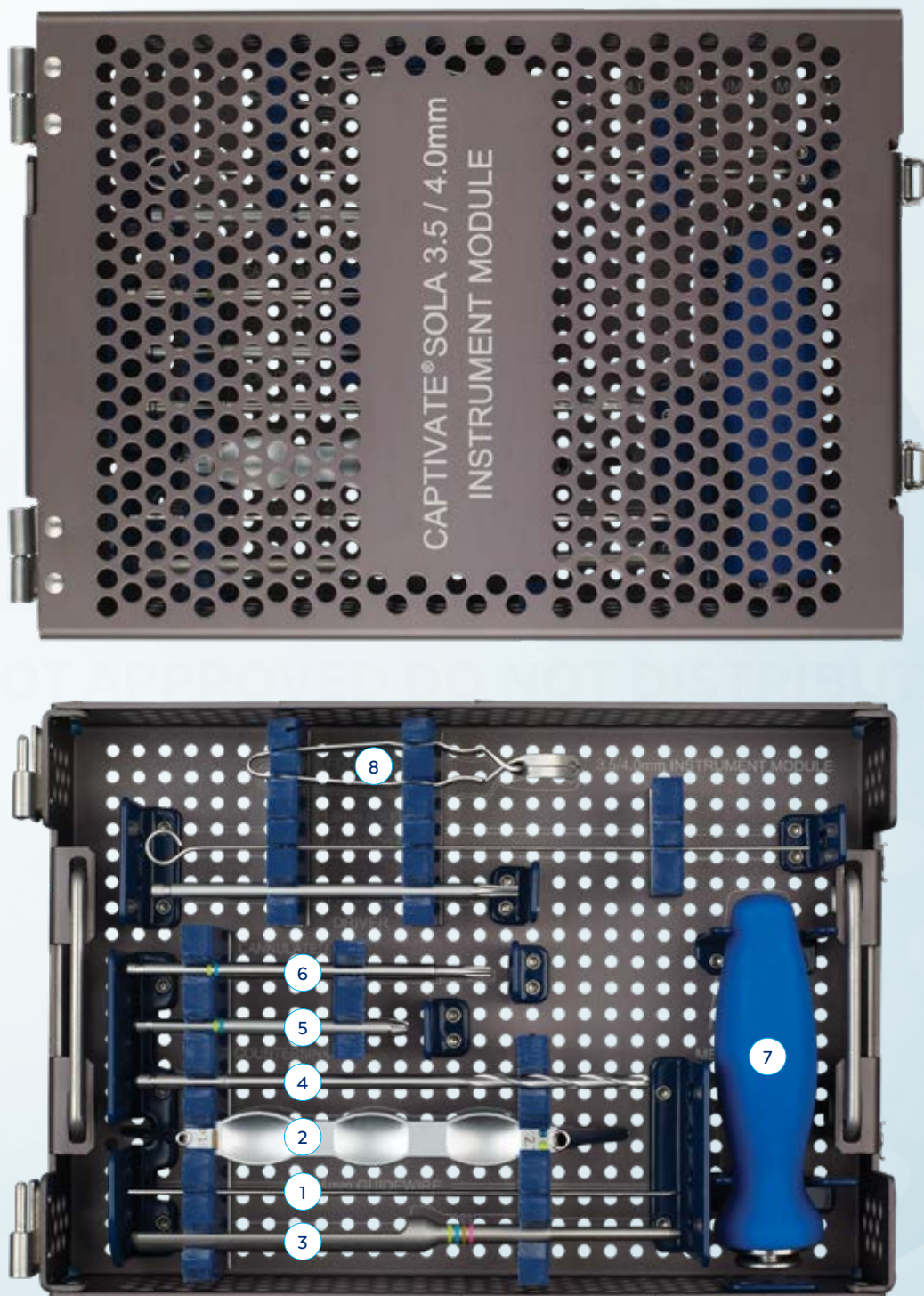
6188.7140	Cleaning Brush, 1.6mm Cannulation, 185mm	0
6188.7240	Cleaning Stylet, 1.4mm Cannulation	0
6179.6115	T15 Driver, Non-Self-Retaining, 100mm AO Quick-Connect	0

NOT APPROVED DO NOT DISTRIBUTE

CAPTIVATE™ SOLA

Headless Compression Screw System

3.5/4.0mm Instrument Module 9188.9355



CAPTIVATE™ SOLA

Headless Compression Screw System

4.5/5.5mm Screw Module 9188.9453 and 9188.9454



4.5mm Short Thread

Screw Length (mm)	Thread Length (mm)	SS Part No.	Ti Part No.	Qty
20	8	4188.4520	3188.4520	1
22	8	4188.4522	3188.4522	1
24	8	4188.4524	3188.4524	2
26	8	4188.4526	3188.4526	2
28	8	4188.4528	3188.4528	2
30	8	4188.4530	3188.4530	2
32	8	4188.4532	3188.4532	2
34	9	4188.4534	3188.4534	2
36	9	4188.4536	3188.4536	2
38	10	4188.4538	3188.4538	2
40	10	4188.4540	3188.4540	2
42	11	4188.4542	3188.4542	2
44	11	4188.4544	3188.4544	2
46	12	4188.4546	3188.4546	2
48	12	4188.4548	3188.4548	2
50	13	4188.4550	3188.4550	2
55	14	4188.4555	3188.4555	2
60	15	4188.4560	3188.4560	2
65	16	4188.4565	3188.4565	2
70	18	4188.4570	3188.4570	2
75	19	4188.4575	3188.4575	2
80	20	4188.4580	3188.4580	2
85	21	4188.4585	3188.4585	2
90	23	4188.4590	3188.4590	2
95	24	4188.4595	3188.4595	2
100	25	4188.4600	3188.4600	2
105	26	4188.4605	3188.4605	0
110	28	4188.4610	3188.4610	0



4.5mm Long Thread

Screw Length (mm)	Thread Length (mm)	SS Part No.	Ti Part No.	Qty
30	12	4188.4730	3188.4730	2
32	13	4188.4732	3188.4732	2
34	14	4188.4734	3188.4734	2
36	14	4188.4736	3188.4736	2
38	15	4188.4738	3188.4738	2
40	16	4188.4740	3188.4740	2
42	17	4188.4742	3188.4742	2
44	18	4188.4744	3188.4744	2
46	18	4188.4746	3188.4746	2
48	19	4188.4748	3188.4748	2
50	20	4188.4750	3188.4750	2
55	22	4188.4755	3188.4755	2
60	24	4188.4760	3188.4760	2
65	26	4188.4765	3188.4765	2
70	28	4188.4770	3188.4770	2
75	30	4188.4775	3188.4775	2
80	32	4188.4780	3188.4780	2
85	34	4188.4785	3188.4785	2
90	36	4188.4790	3188.4790	2
95	38	4188.4795	3188.4795	2
100	40	4188.4800	3188.4800	2
105	42	4188.4805	3188.4805	0
110	44	4188.4810	3188.4810	0

Short Thread = Approximately 25% Total Length or 8mm

Long Thread = Approximately 40% Total Length

CAPTIVATE™ SOLA

Headless Compression Screw System

4.5/5.5mm Screw Module 9188.9453 and 9188.9454



5.5mm Short Thread

Screw Length (mm)	Thread Length (mm)	SS Part No.	Ti Part No.	Qty
20	8.5	4188.5520	3188.5520	0
22	8.5	4188.5522	3188.5522	0
24	8.5	4188.5524	3188.5524	0
26	8.5	4188.5526	3188.5526	0
28	8.5	4188.5528	3188.5528	0
30	8.5	4188.5530	3188.5530	2
32	8.5	4188.5532	3188.5532	2
34	9	4188.5534	3188.5534	2
36	9	4188.5536	3188.5536	2
38	10	4188.5538	3188.5538	2
40	10	4188.5540	3188.5540	2
42	11	4188.5542	3188.5542	2
44	11	4188.5544	3188.5544	2
46	12	4188.5546	3188.5546	2
48	12	4188.5548	3188.5548	2
50	13	4188.5550	3188.5550	2
55	14	4188.5555	3188.5555	2
60	15	4188.5560	3188.5560	2
65	16	4188.5565	3188.5565	2
70	18	4188.5570	3188.5570	2
75	19	4188.5575	3188.5575	2
80	20	4188.5580	3188.5580	2
85	21	4188.5585	3188.5585	1
90	23	4188.5590	3188.5590	1
95	24	4188.5595	3188.5595	1
100	25	4188.5600	3188.5600	1
105	26	4188.5605	3188.5605	0
110	28	4188.5610	3188.5610	0



5.5mm Long Thread

Screw Length (mm)	Thread Length (mm)	SS Part No.	Ti Part No.	Qty
30	12	4188.5730	3188.5730	1
32	13	4188.5732	3188.5732	1
34	14	4188.5734	3188.5734	1
36	14	4188.5736	3188.5736	1
38	15	4188.5738	3188.5738	1
40	16	4188.5740	3188.5740	1
42	17	4188.5742	3188.5742	1
44	18	4188.5744	3188.5744	1
46	18	4188.5746	3188.5746	1
48	19	4188.5748	3188.5748	1
50	20	4188.5750	3188.5750	1
55	22	4188.5755	3188.5755	1
60	24	4188.5760	3188.5760	1
65	26	4188.5765	3188.5765	1
70	28	4188.5770	3188.5770	1
75	30	4188.5775	3188.5775	1
80	32	4188.5780	3188.5780	1
85	34	4188.5785	3188.5785	1
90	36	4188.5790	3188.5790	1
95	38	4188.5795	3188.5795	1
100	40	4188.5800	3188.5800	1
105	42	4188.5805	3188.5805	0
110	44	4188.5810	3188.5810	0

Short Thread = Approximately 25% Total Length or 8.5mm

Long Thread = Approximately 40% Total Length

Items in gray are additionally available.

CAPTIVATE™ SOLA

Headless Compression Screw System

4.5/5.5mm Instrument Module 9188.9455

	Part No.	Description	Qty
1	6188.1216	1.6mm Trocar Guidewire, 220mm	8
2	6188.4045	1.6/3.9mm Double Sided Drill Guide	1
3	6188.8045	1.6 & 2.8mm Guidewire Measuring Device, 220mm	1
4	6188.5330	3.9mm Cannulated Drill Bit, 185mm	2
5	6188.4445	4.5/5.5mm Cannulated Countersink	1
6	6188.6420	T20 Driver, Cannulated, SR, 100mm, AO Quick-Connect	2
7	6179.7013	Medium Handle, Ratcheting, Cannulated AO Quick-Connect	1
8	6179.2000	Screw Holding Forceps	1
9	6188.9545	4.5/5.5mm Tissue Protector	1
10	6188.7516	4.5/5.5mm Guide Wire Sleeve	1
11	6179.7012	Dental Pick, Curved Tip, Small Handle	1
	9188.5450	CAPTIVATE™ SOLA 4.5/5.5mm Headless Instrument Module Lid	

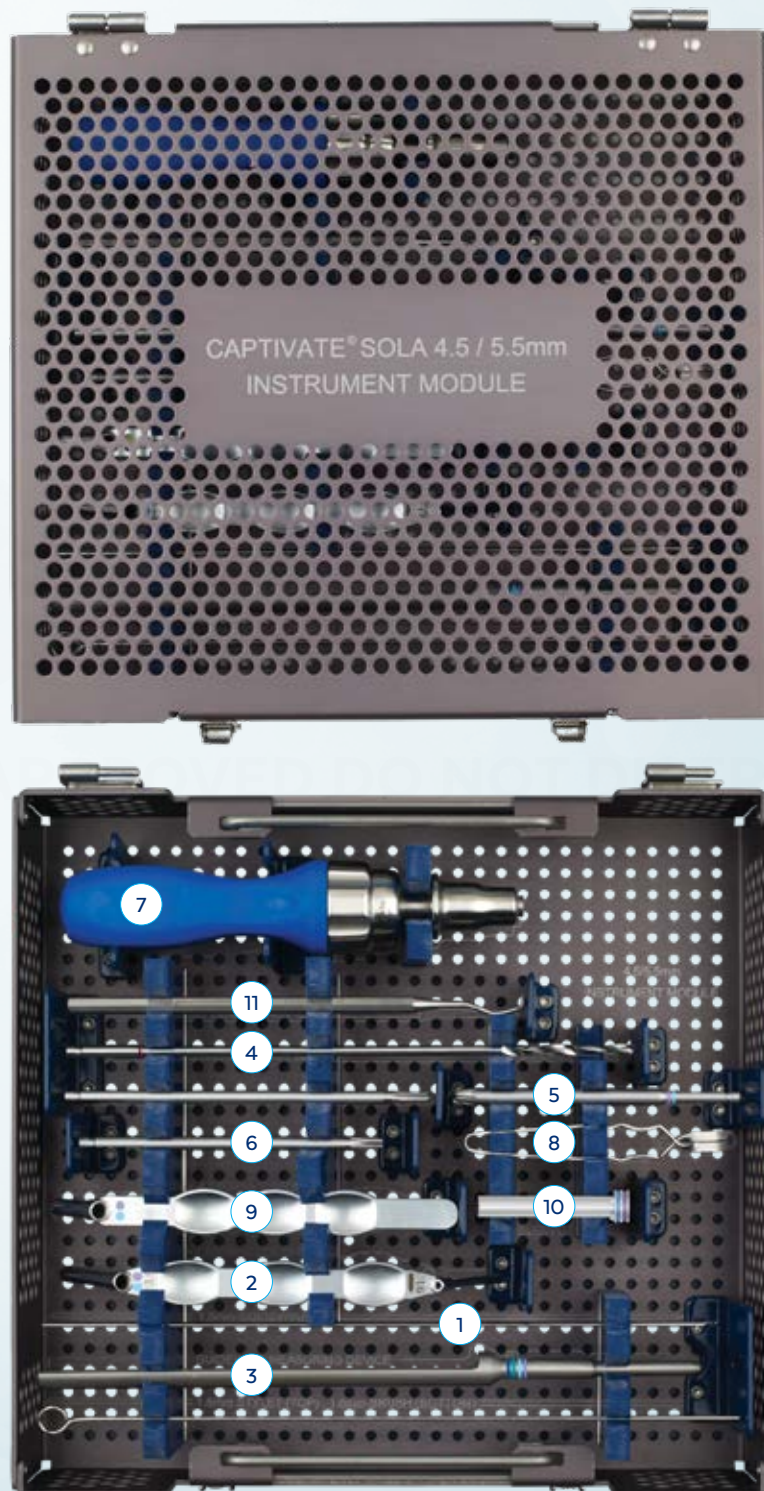
Additionally Available

6178.7145	1.8mm Cleaning Brush	0
6178.7245	1.6mm Cleaning Stylet	0
6178.6120	T20 Driver, Solid	0

CAPTIVATE™ SOLA

Headless Compression Screw System

4.5/5.5mm Instrument Module 9188.9455



CAPTIVATE™ SOLA

Headless Compression Screw System

6.5/7.5mm Screw Module 9188.9653 and 9188.9654



6.5mm Short Thread

Screw Length (mm)	Thread Length (mm)	SS Part No.	Ti Part No.	Qty
30	16	4188.6530	3188.6530	2
35	16	4188.6535	3188.6535	2
40	16	4188.6540	3188.6540	2
45	16	4188.6545	3188.6545	2
50	16	4188.6550	3188.6550	2
55	16	4188.6555	3188.6555	2
60	16	4188.6560	3188.6560	2
65	16	4188.6565	3188.6565	2
70	16	4188.6570	3188.6570	2
75	16	4188.6575	3188.6575	2
80	16	4188.6580	3188.6580	2
85	16	4188.6585	3188.6585	2
90	16	4188.6590	3188.6590	2
95	16	4188.6595	3188.6595	2
100	16	4188.6600	3188.6600	2
105	16	4188.6605	3188.6605	2
110	16	4188.6610	3188.6610	2
115	16	4188.6615	3188.6615	0
120	16	4188.6620	3188.6620	0
125	16	4188.6625	3188.6625	0
130	16	4188.6630	3188.6630	0



6.5mm Long Thread

Screw Length (mm)	Thread Length (mm)	SS Part No.	Ti Part No.	Qty
45	32	4188.6745	3188.6745	2
50	32	4188.6750	3188.6750	2
55	32	4188.6755	3188.6755	2
60	32	4188.6760	3188.6760	2
65	32	4188.6765	3188.6765	2
70	32	4188.6770	3188.6770	2
75	32	4188.6775	3188.6775	2
80	32	4188.6780	3188.6780	2
85	32	4188.6785	3188.6785	2
90	32	4188.6790	3188.6790	2
95	32	4188.6795	3188.6795	2
100	32	4188.6800	3188.6800	2
105	32	4188.6805	3188.6805	2
110	32	4188.6810	3188.6810	2
115	32	4188.6815	3188.6815	0
120	32	4188.6820	3188.6820	0
125	32	4188.6825	3188.6825	0
130	32	4188.6830	3188.6830	0

Short Thread 6.5mm = 16mm

Long Thread 6.5mm = 32mm

CAPTIVATE™ SOLA

Headless Compression Screw System

6.5/7.5mm Screw Module 9188.9653 and 9188.9654



7.5mm Short Thread

Screw Length (mm)	Thread Length (mm)	SS Part No.	Ti Part No.	Qty
30	16	4188.7530	3188.7530	0
35	16	4188.7535	3188.7535	0
40	16	4188.7540	3188.7540	2
45	16	4188.7545	3188.7545	2
50	16	4188.7550	3188.7550	2
55	16	4188.7555	3188.7555	2
60	16	4188.7560	3188.7560	2
65	16	4188.7565	3188.7565	2
70	16	4188.7570	3188.7570	2
75	16	4188.7575	3188.7575	2
80	16	4188.7580	3188.7580	2
85	16	4188.7585	3188.7585	2
90	16	4188.7590	3188.7590	2
95	16	4188.7595	3188.7595	2
100	16	4188.7600	3188.7600	2
105	16	4188.7605	3188.7605	2
110	16	4188.7610	3188.7610	2
115	16	4188.7615	3188.7615	2
120	16	4188.7620	3188.7620	2
125	16	4188.7625	3188.7625	0
130	16	4188.7630	3188.7630	0
135	16	4188.7635	3188.7635	0
140	16	4188.7640	3188.7640	0



7.5mm Long Thread

Screw Length (mm)	Thread Length (mm)	SS Part No.	Ti Part No.	Qty
45	32	4188.7745	3188.7745	1
50	32	4188.7750	3188.7750	1
55	32	4188.7755	3188.7755	1
60	32	4188.7760	3188.7760	1
65	32	4188.7765	3188.7765	1
70	32	4188.7770	3188.7770	1
75	32	4188.7775	3188.7775	1
80	32	4188.7780	3188.7780	1
85	32	4188.7785	3188.7785	1
90	32	4188.7790	3188.7790	1
95	32	4188.7795	3188.7795	1
100	32	4188.7800	3188.7800	1
105	32	4188.7805	3188.7805	1
110	32	4188.7810	3188.7810	1
115	32	4188.7815	3188.7815	1
120	32	4188.7820	3188.7820	1
125	32	4188.7825	3188.7825	0
130	32	4188.7830	3188.7830	0
135	32	4188.7835	3188.7835	0
140	32	4188.7840	3188.7840	0

Short Thread 7.5mm = 16mm

Long Thread 7.5mm = 32mm

CAPTIVATE™ SOLA

Headless Compression Screw System

6.5/7.5mm Instrument Module 9188.9655

	Part No.	Description	Qty
1	6188.1228	2.8mm Drill-Tip Guidewire, 220mm	8
2	6188.4065	2.8/5.0mm Double Sided Drill Guide	1
3	6188.8045	1.6 & 2.8mm Guidewire Measuring Device, 220mm	1
4	6188.5350	5.0mm Cannulated Drill Bit, 222mm	2
5	6188.4465	6.5/7.5mm Cannulated Countersink	1
6	6178.3000	Quick-Connect Handle	1
7	6188.6430	T30 Driver, Cannulated, SR, 155mm, Hall Quick-Connect	2
8	6178.0181	Large QC Adapter	1
9	6188.9565	6.5/7.5mm Tissue Protector	1
10	6188.9028	6.5/7.5mm Guide Wire Sleeve	1
11	6179.2000	Screw Holding Forceps	1
	9188.5650	CAPTIVATE™ SOLA 6.5/7.5mm Headless Instrument Module Lid	

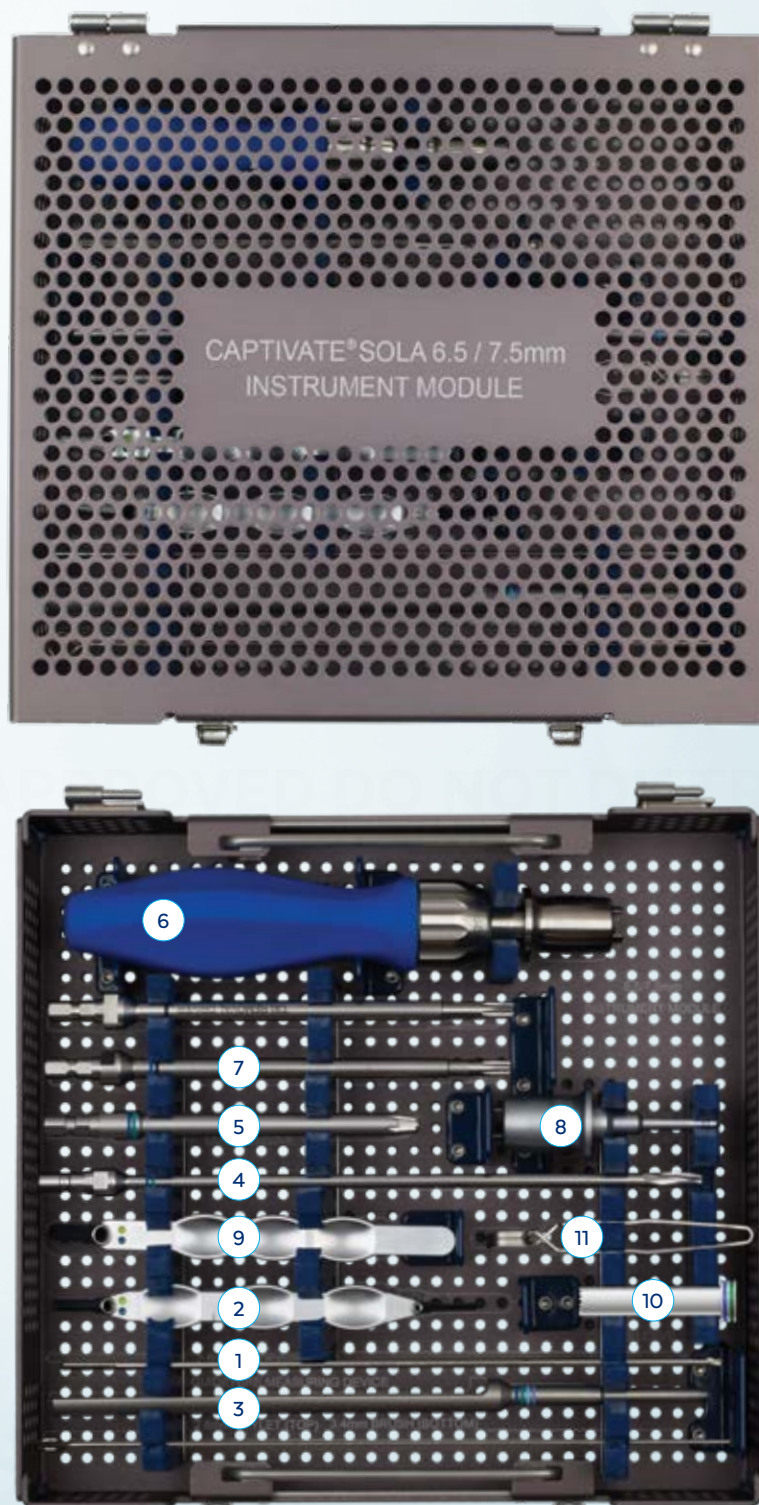
Additionally Available

6188.7165	3.4mm Cleaning Brush, 230mm	0
6188.7265	2.8mm Cleaning Stylet, 230mm	0
6188.6130	T30 Removal Driver, Solid	0

CAPTIVATE™ SOLA

Headless Compression Screw System

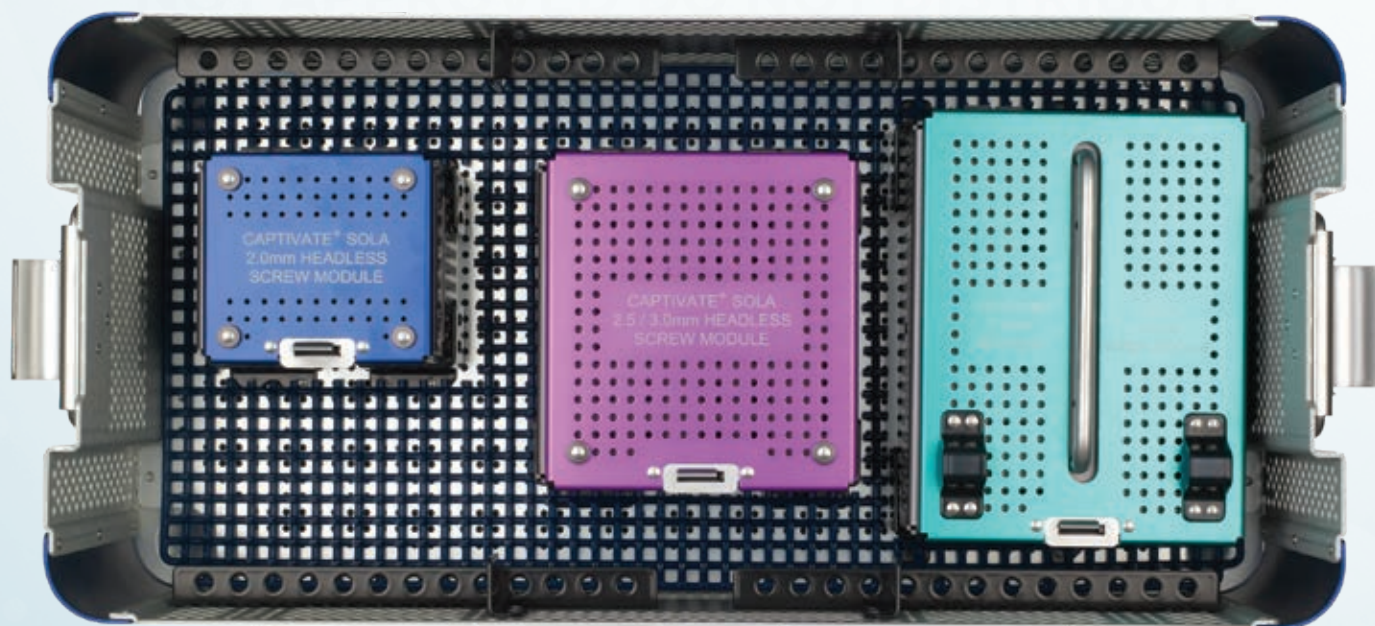
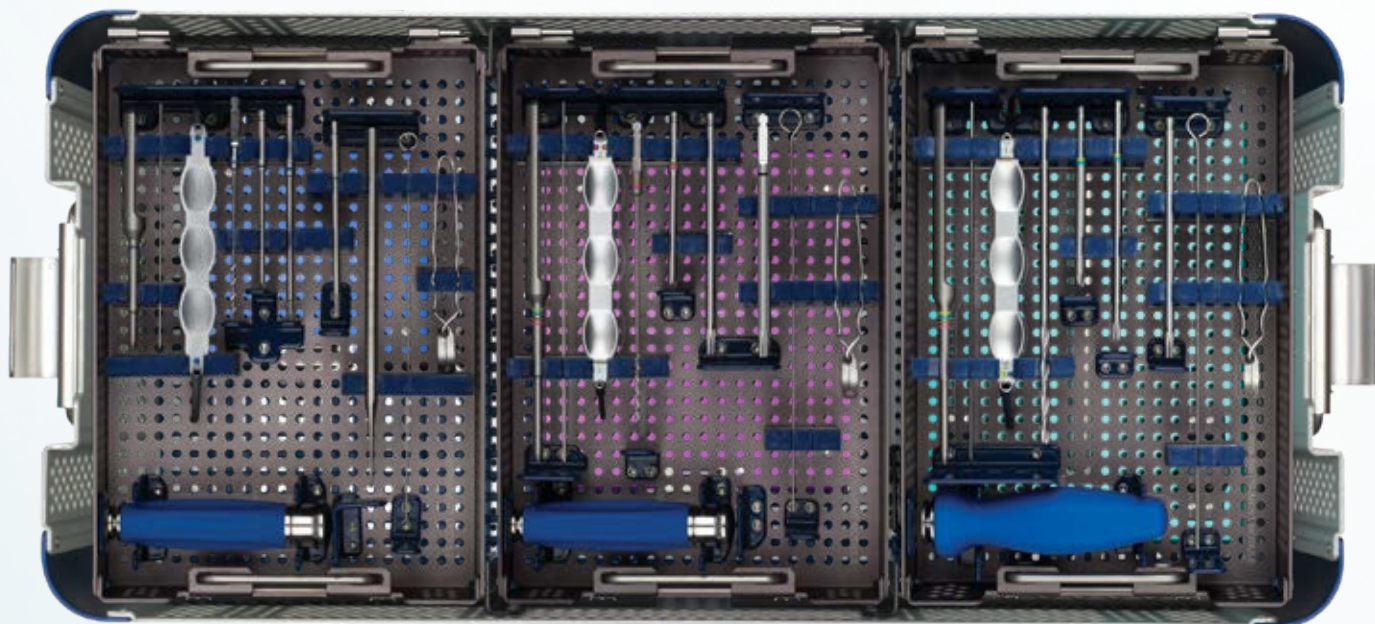
6.5/7.5mm Instrument Module 9188.9655



CAPTIVATE™ SOLA

Small Headless Screw System Layout

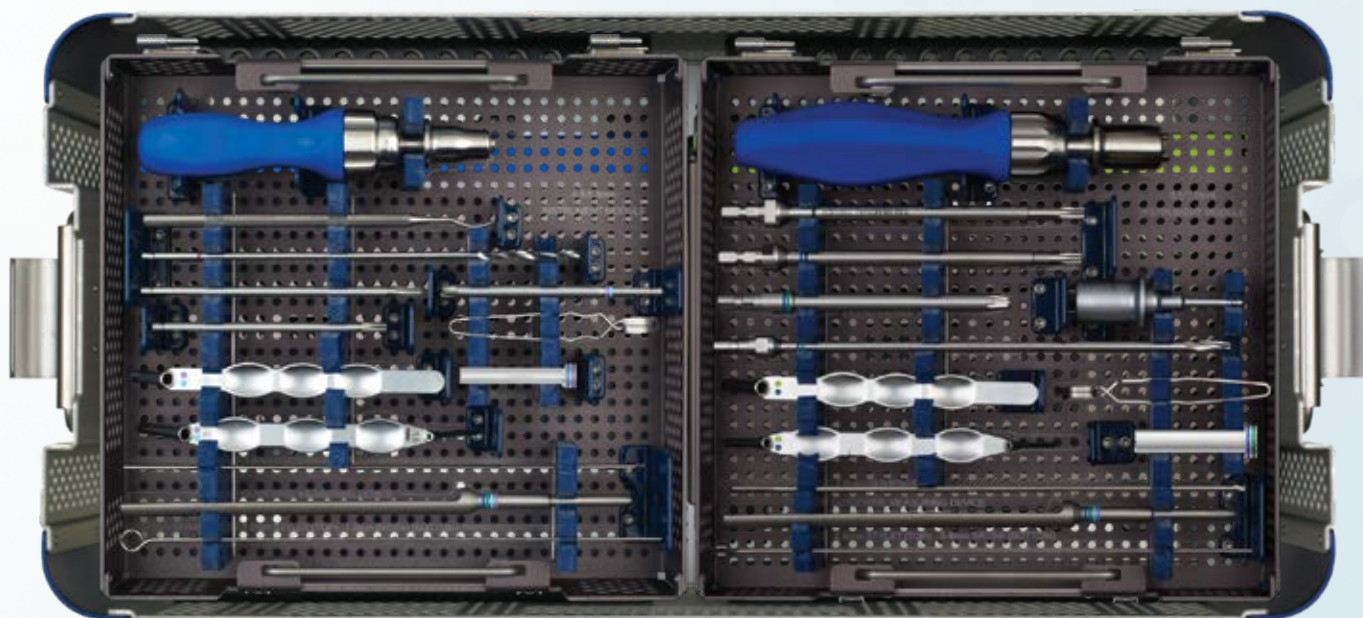
Layout with Carrying Case 9188.9210 and 9188.9220



CAPTIVATE™ SOLA

Large Headless Screw System Layout

Layout with Carrying Case 9188.9310 and 9188.9320



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.

IMPORTANT INFORMATION ON CAPTIVATE™ COMPRESSION SCREWS

- Subclinical nerve damage may possibly occur as a result of the surgical trauma.
- Material sensitivity reactions in patients following surgical implantation have rarely been reported, however their significance awaits further clinical evaluation.

PACKAGING

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

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

HANDLING

All instruments and implants should be treated with care. Improper use or 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



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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