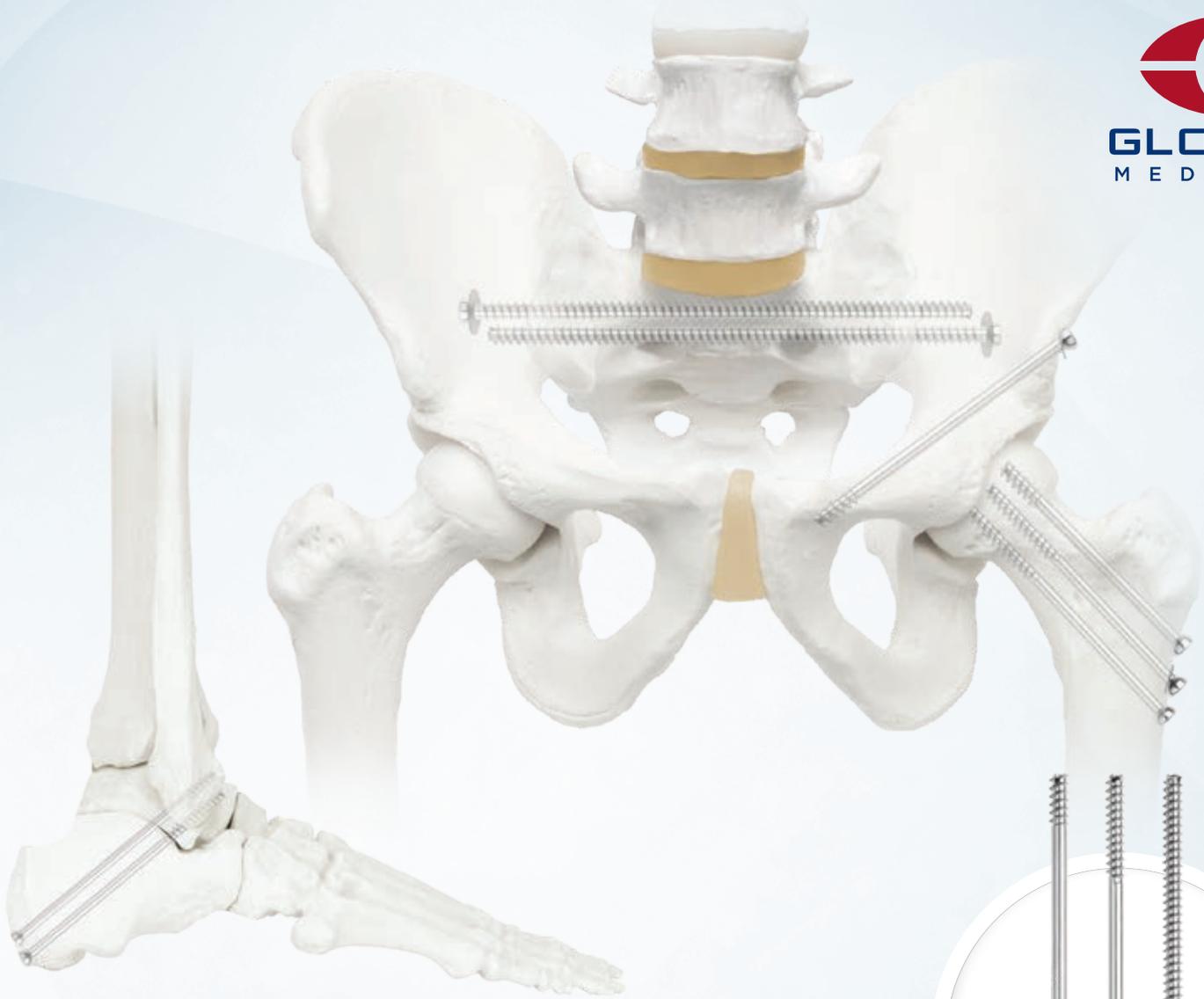




GLOBUS  
MEDICAL



# CAPTIVATE®

6.5/7.5mm 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<sup>®</sup>

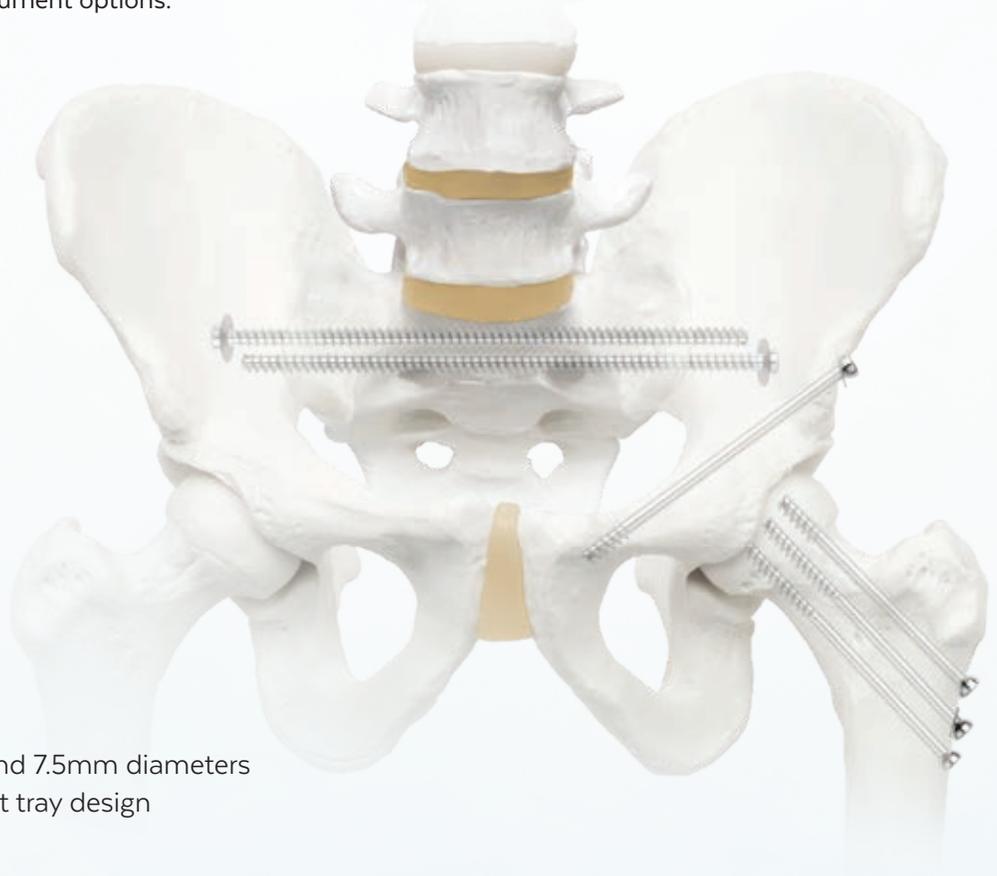
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# CAPTIVATE®

## 6.5/7.5mm Headed Cannulated Screw System

The CAPTIVATE® 6.5/7.5mm Headed Cannulated Screw System delivers intraoperative efficiency without compromising implant and instrument options.



### Simple

- One technique for 6.5mm and 7.5mm diameters
- Procedure-based instrument tray design

### Comprehensive

- 16mm and 32mm partially threaded screws
- Fully threaded screws
- 40mm to 180mm lengths (5mm increments) for all screw types
- Non-threaded and threaded 300mm and 450mm guidewire
- Stainless steel and titanium alloy

### Efficient

- Versatile screw modules tailored to meet a variety of surgical demands
- Self-drilling screw design simplifies insertion
- Screw extraction instruments provided in set



## SURGICAL TECHNIQUE

# CAPTIVATE®

## 6.5/7.5mm Headed Cannulated Screw System

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

STEP

1

### GUIDEWIRE INSERTION

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

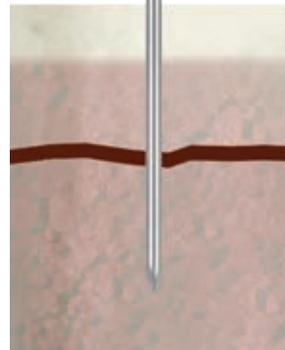
For cannulated screws, insert the appropriate **Guidewire** to the appropriate depth, using fluoroscopy. Remove the drill sleeve and confirm the position of the guidewire using fluoroscopy.

For pre-drilling, proceed to step 2. For screw insertion, proceed to step 3.

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



Identify fracture line



Guidewire insertion

## STEP

## 2

# BONE PREPARATION

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

Measuring must be done before all bone preparation steps.

Slide the **Drill Sleeve** over the guidewire, if applicable, and position on the surface. Attach the corresponding 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 insertion if desired.

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

## STEP

## 3

# SCREW INSERTION

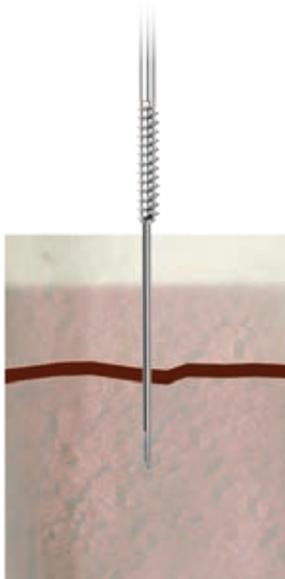
Slide the guide wire **Depth Gauge** over the guide wire until flush with bone. The appropriate screw length is indicated by the guidewire tip along the markings on the gauge.

If using a washer, measure off the bone similarly to measuring with a screw. Add 3.75mm to the measurement to accommodate the portion of the screw outside of the bone.

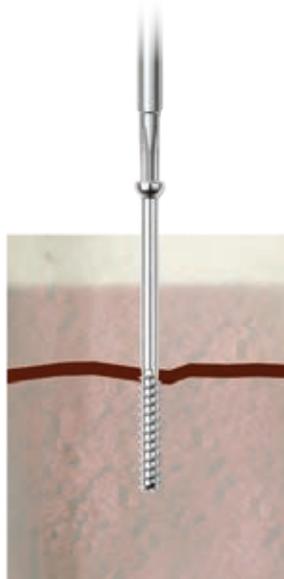
Select the T30 driver and load the selected screw onto the driver.

If desired, a washer may be used with a standard or variable length screw in areas of poor bone quality or thin cortical bone.

Drive the screw over the guidewire, if applicable, and rotate the driver handle clockwise to insert. 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.



Screw guided by  
guidewire



Screw inserted

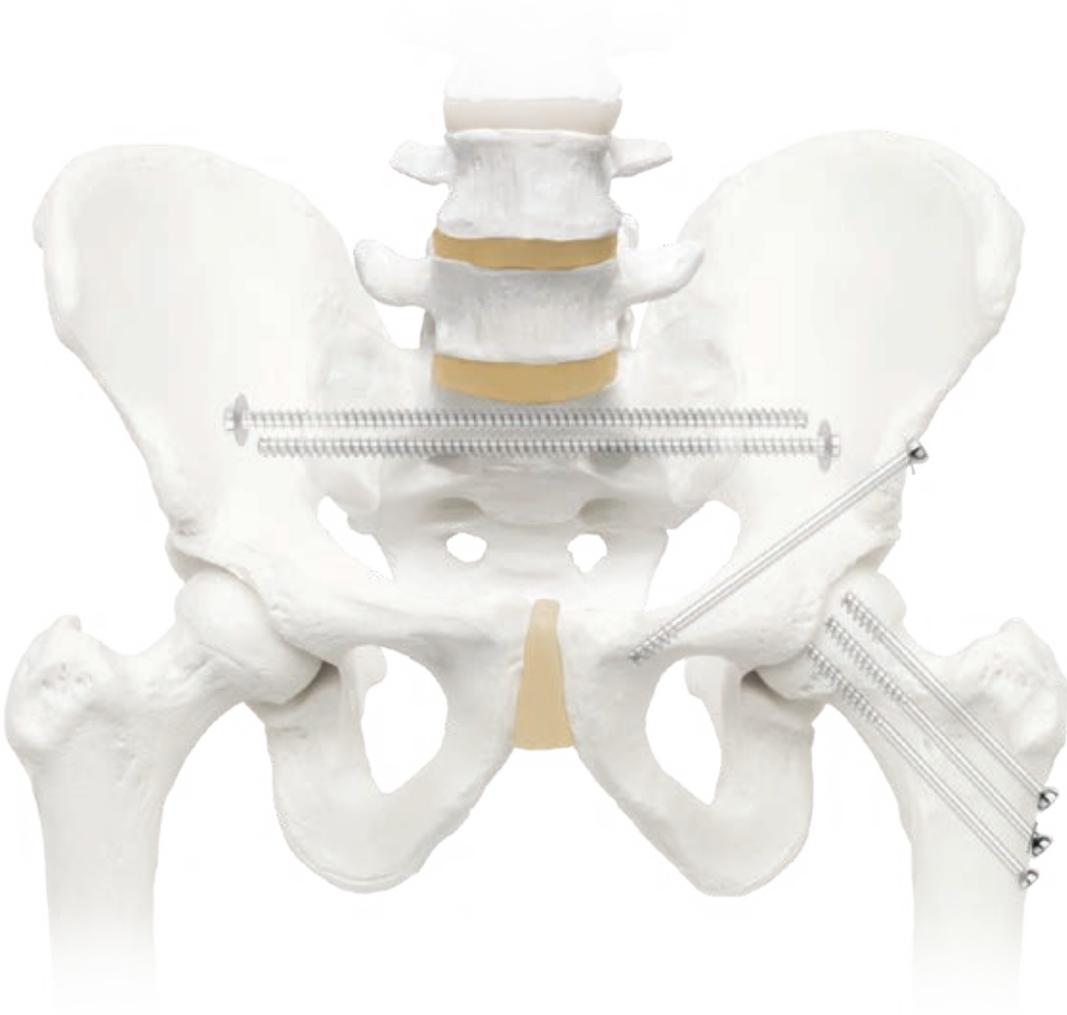


Fracture reduced

## Screw Positioning

When the desired screw position is achieved, remove the guidewire using the Guidewire Driver.

# FINAL POSITION





## OPTIONAL: IMPLANT REMOVAL

Expose the screw head by clearing any bony presence on the screw head. Back out the bone screw as far as possible with the **Solid Screw Driver**. For broken or damaged screws, remove using the **Screw Extractor**. To remove the screw, insert the screw extractor into the screw and rotate counterclockwise.

# INSTRUMENT OVERVIEW



2.8x300mm Threaded Guidewire, Trocar Tip 6178.0115



2.8x300mm Non-Threaded Guidewire, Drill Tip 6178.0116



2.8x450mm Non-Threaded Guidewire, Drill Tip 6178.0185



2.8x450mm Threaded Guidewire, Trocar Tip 6178.0183



Guide Stick, Short 6178.3302



Guide Stick, Long 6178.3301



QC Handle for Multiple & Parallel Wire Guides 6178.7005



Multiple Wire Guide 6178.0164



Adjustable Parallel Wire Guide  
6178.0165



5.0mm Cannulated Pre-Drill 6178.5350



Cannulated Tap, 6178.5165



Cannulated Countersink, 6178.0117



Cannulated Depth Gauge, 6178.0167



Screw Holding Forceps 6179.2000



Quick-Connect Handle 6178.3000



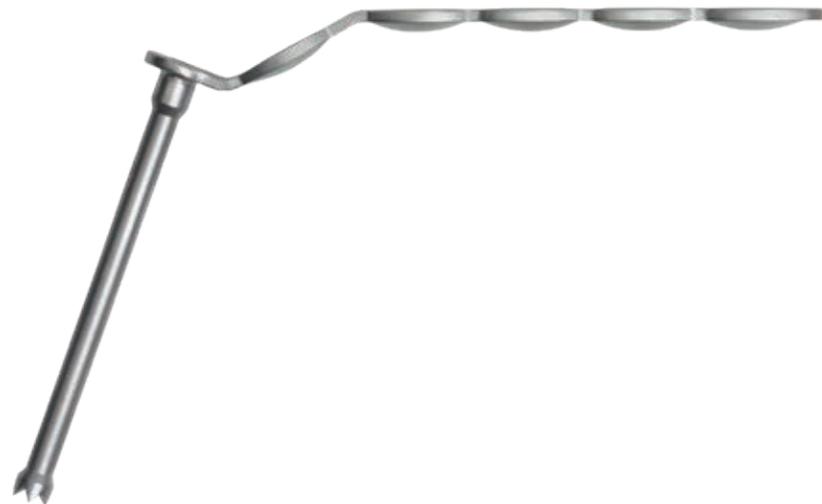
Cannulated Screwdriver 6178.6130



Solid Screwdriver 6178.6430



2.8mm Trocar 6178.0162



2.8mm Guide Wire Sleeve 6178.0163



7.5mm Cannulated Overdrill 6178.5375



Holding Sleeve 6178.0182



Washer Sleeve 6178.0175



Screw Insertion Sleeve 6178.0174



Screw Extractor 6178.0176



Large Quick Coupling 6178.0181



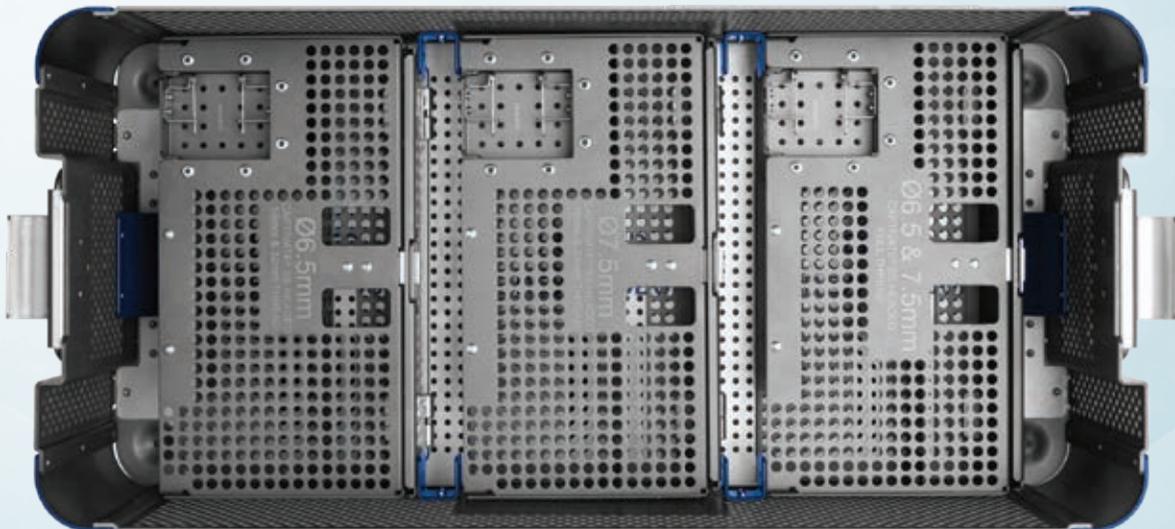
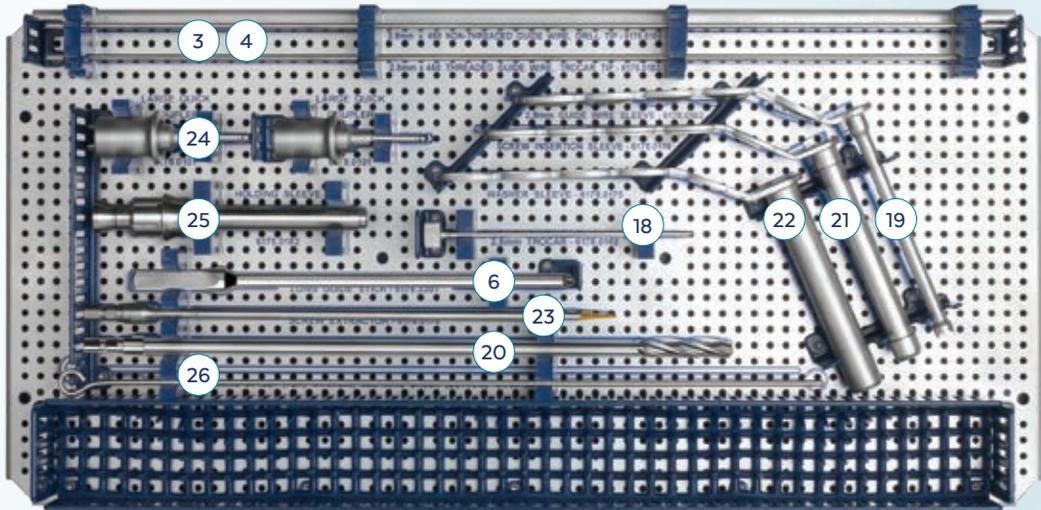
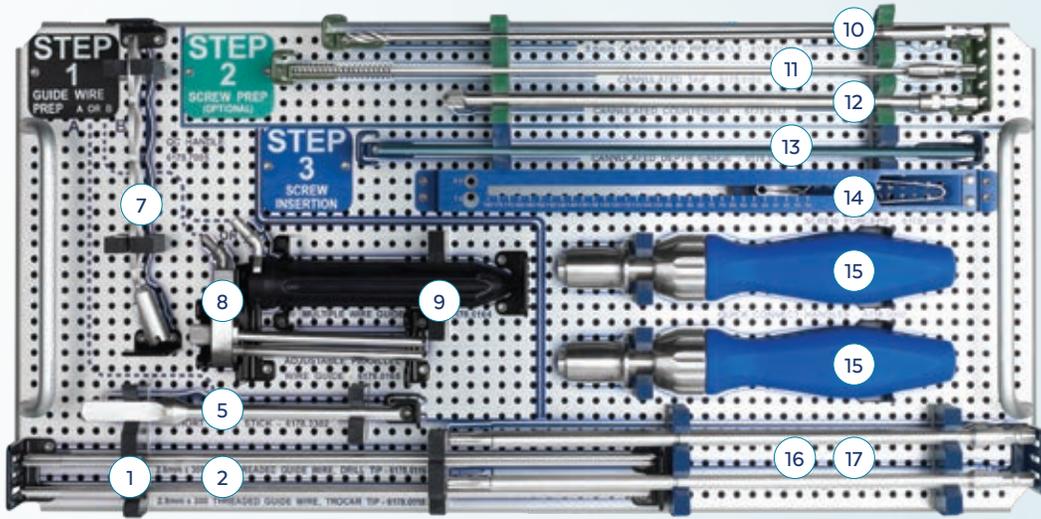
Cleaning Brush 6178.7165



Cleaning Stylet 6178.7265

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

Part No.	Description	Qty
1 66178.0115	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 Overdrill	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
6178.7165	Cleaning Brush	1
26 6178.7265	Cleaning Stylet	1
9178.0100	Graphic Case	



# CAPTIVATE® Stainless Steel Headed 6.5mm Partially Threaded Implant Set 9178.9001

Part No.	Description	Qty	Part No.	Description	Qty
2178.6541	6.5x40mm, Cannulated Screw, 16mm, SS	2	2178.6547	6.5x45mm, Cannulated Screw, 32mm, SS	2
2178.6546	6.5x45mm, Cannulated Screw, 16mm, SS	2	2178.6552	6.5x50mm, Cannulated Screw, 32mm, SS	2
2178.6551	6.5x50mm, Cannulated Screw, 16mm, SS	2	2178.6557	6.5x55mm, Cannulated Screw, 32mm, SS	2
2178.6556	6.5x55mm, Cannulated Screw, 16mm, SS	2	2178.6562	6.5x60mm, Cannulated Screw, 32mm, SS	2
2178.6561	6.5x60mm, Cannulated Screw, 16mm, SS	2	2178.6567	6.5x65mm, Cannulated Screw, 32mm, SS	2
2178.6566	6.5x65mm, Cannulated Screw, 16mm, SS	2	2178.6572	6.5x70mm, Cannulated Screw, 32mm, SS	2
2178.6571	6.5x70mm, Cannulated Screw, 16mm, SS	2	2178.6577	6.5x75mm, Cannulated Screw, 32mm, SS	2
2178.6576	6.5x75mm, Cannulated Screw, 16mm, SS	2	2178.6582	6.5x80mm, Cannulated Screw, 32mm, SS	4
2178.6581	6.5x80mm, Cannulated Screw, 16mm, SS	4	2178.6587	6.5x85mm, Cannulated Screw, 32mm, SS	4
2178.6586	6.5x85mm, Cannulated Screw, 16mm, SS	4	2178.6592	6.5x90mm, Cannulated Screw, 32mm, SS	4
2178.6591	6.5x90mm, Cannulated Screw, 16mm, SS	4	2178.6597	6.5x95mm, Cannulated Screw, 32mm, SS	4
2178.6596	6.5x95mm, Cannulated Screw, 16mm, SS	4	2178.6602	6.5x100mm, Cannulated Screw, 32mm, SS	4
2178.6601	6.5x100mm, Cannulated Screw, 16mm, SS	4	2178.6607	6.5x105mm, Cannulated Screw, 32mm, SS	2
2178.6606	6.5x105mm, Cannulated Screw, 16mm, SS	2	2178.6612	6.5x110mm, Cannulated Screw, 32mm, SS	2
2178.6611	6.5x110mm, Cannulated Screw, 16mm, SS	2	2178.6617	6.5x115mm, Cannulated Screw, 32mm, SS	2
2178.6616	6.5x115mm, Cannulated Screw, 16mm, SS	2	2178.6622	6.5x120mm, Cannulated Screw, 32mm, SS	2
2178.6621	6.5x120mm, Cannulated Screw, 16mm, SS	2	2178.6627	6.5x125mm, Cannulated Screw, 32mm, SS	2
2178.6626	6.5x125mm, Cannulated Screw, 16mm, SS	2	2178.0175	CAPTIVATE® 6.5/7.5mm Standard Washer, SS	4
			2178.3175	CAPTIVATE® 6.5/7.5mm Oval Washer, SS	2
			9178.0101	SS Headed 6.5mm Partially Threaded Screw Module	

# CAPTIVATE® Stainless Steel Headed 7.5mm Partially Threaded Implant Set 9178.9002

Part No.	Description	Qty	Part No.	Description	Qty
2178.7541	7.5x40mm, Cannulated Screw, 16mm, SS	2	2178.7547	7.5x45mm, Cannulated Screw, 32mm, SS	2
2178.7546	7.5x45mm, Cannulated Screw, 16mm, SS	2	2178.7552	7.5x50mm, Cannulated Screw, 32mm, SS	2
2178.7551	7.5x50mm, Cannulated Screw, 16mm, SS	2	2178.7557	7.5x55mm, Cannulated Screw, 32mm, SS	2
2178.7556	7.5x55mm, Cannulated Screw, 16mm, SS	2	2178.7562	7.5x60mm, Cannulated Screw, 32mm, SS	2
2178.7561	7.5x60mm, Cannulated Screw, 16mm, SS	2	2178.7567	7.5x65mm, Cannulated Screw, 32mm, SS	2
2178.7566	7.5x65mm, Cannulated Screw, 16mm, SS	2	2178.7572	7.5x70mm, Cannulated Screw, 32mm, SS	2
2178.7571	7.5x70mm, Cannulated Screw, 16mm, SS	2	2178.7577	7.5x75mm, Cannulated Screw, 32mm, SS	2
2178.7576	7.5x75mm, Cannulated Screw, 16mm, SS	2	2178.7582	7.5x80mm, Cannulated Screw, 32mm, SS	4
2178.7581	7.5x80mm, Cannulated Screw, 16mm, SS	4	2178.7587	7.5x85mm, Cannulated Screw, 32mm, SS	4
2178.7586	7.5x85mm, Cannulated Screw, 16mm, SS	4	2178.7592	7.5x90mm, Cannulated Screw, 32mm, SS	4
2178.7591	7.5x90mm, Cannulated Screw, 16mm, SS	4	2178.7597	7.5x95mm, Cannulated Screw, 32mm, SS	4
2178.7596	7.5x95mm, Cannulated Screw, 16mm, SS	4	2178.7602	7.5x100mm, Cannulated Screw, 32mm, SS	4
2178.7601	7.5x100mm, Cannulated Screw, 16mm, SS	4	2178.7607	7.5x105mm, Cannulated Screw, 32mm, SS	2
2178.7606	7.5x105mm, Cannulated Screw, 16mm, SS	2	2178.7612	7.5x110mm, Cannulated Screw, 32mm, SS	2
2178.7611	7.5x110mm, Cannulated Screw, 16mm, SS	2	2178.7617	7.5x115mm, Cannulated Screw, 32mm, SS	2
2178.7616	7.5x115mm, Cannulated Screw, 16mm, SS	2	2178.7622	7.5x120mm, Cannulated Screw, 32mm, SS	2
2178.7621	7.5x120mm, Cannulated Screw, 16mm, SS	2	2178.7627	7.5x125mm, Cannulated Screw, 32mm, SS	2
2178.7626	7.5x125mm, Cannulated Screw, 16mm, SS	2	2178.0175	CAPTIVATE® 6.5/7.5mm Standard Washer, SS	4
			2178.3175	CAPTIVATE® 6.5/7.5mm Oval Washer, SS	2
			9178.0102	SS Headed 7.5mm Partially Threaded Screw Module	

# CAPTIVATE<sup>®</sup> Stainless Steel Headed 6.5/7.5mm Fully Threaded Implant Set 9178.9003

Part No.	Description	Qty	Part No.	Description	Qty
2178.6540	6.5x40mm, Cannulated Screw, Full Thread, SS	1	2178.7540	7.5x40mm, Cannulated Screw, Full Thread, SS	1
2178.6545	6.5x45mm, Cannulated Screw, Full Thread, SS	1	2178.7545	7.5x45mm, Cannulated Screw, Full Thread, SS	1
2178.6550	6.5x50mm, Cannulated Screw, Full Thread, SS	1	2178.7550	7.5x50mm, Cannulated Screw, Full Thread, SS	1
2178.6555	6.5x55mm, Cannulated Screw, Full Thread, SS	1	2178.7555	7.5x55mm, Cannulated Screw, Full Thread, SS	1
2178.6560	6.5x60mm, Cannulated Screw, Full Thread, SS	1	2178.7560	7.5x60mm, Cannulated Screw, Full Thread, SS	1
2178.6565	6.5x65mm, Cannulated Screw, Full Thread, SS	1	2178.7565	7.5x65mm, Cannulated Screw, Full Thread, SS	1
2178.6570	6.5x70mm, Cannulated Screw, Full Thread, SS	1	2178.7570	7.5x70mm, Cannulated Screw, Full Thread, SS	1
2178.6575	6.5x75mm, Cannulated Screw, Full Thread, SS	1	2178.7575	7.5x75mm, Cannulated Screw, Full Thread, SS	1
2178.6580	6.5x80mm, Cannulated Screw, Full Thread, SS	1	2178.7580	7.5x80mm, Cannulated Screw, Full Thread, SS	1
2178.6585	6.5x85mm, Cannulated Screw, Full Thread, SS	1	2178.7585	7.5x85mm, Cannulated Screw, Full Thread, SS	1
2178.6590	6.5x90mm, Cannulated Screw, Full Thread, SS	1	2178.7590	7.5x90mm, Cannulated Screw, Full Thread, SS	1
2178.6595	6.5x95mm, Cannulated Screw, Full Thread, SS	1	2178.7595	7.5x95mm, Cannulated Screw, Full Thread, SS	1
2178.6600	6.5x100mm, Cannulated Screw, Full Thread, SS	1	2178.7600	7.5x100mm, Cannulated Screw, Full Thread, SS	1
2178.6605	6.5x105mm, Cannulated Screw, Full Thread, SS	1	2178.7605	7.5x105mm, Cannulated Screw, Full Thread, SS	1
2178.6610	6.5x110mm, Cannulated Screw, Full Thread, SS	1	2178.7610	7.5x110mm, Cannulated Screw, Full Thread, SS	1
2178.6615	6.5x115mm, Cannulated Screw, Full Thread, SS	1	2178.7615	7.5x115mm, Cannulated Screw, Full Thread, SS	1
2178.6620	6.5x120mm, Cannulated Screw, Full Thread, SS	1	2178.7620	7.5x120mm, Cannulated Screw, Full Thread, SS	1
2178.6625	6.5x125mm, Cannulated Screw, Full Thread, SS	1	2178.7625	7.5x125mm, Cannulated Screw, Full Thread, SS	1
			2178.0175	CAPTIVATE <sup>®</sup> 6.5/7.5mm Standard Washer, SS	2
			2178.3175	CAPTIVATE <sup>®</sup> 6.5/7.5mm Oval Washer, SS	2
			9178.0103	SS Headed 6.5/7.5mm Fully Threaded Screw Module	

# CAPTIVATE® Stainless Steel Headed 6.5mm Partially Threaded Long Screw Implant Set 9178.9004

Part No.	Description	Qty	Part No.	Description	Qty
2178.6631	6.5x130mm, Cannulated Screw, 16mm, SS	2	2178.6632	6.5x130mm, Cannulated Screw, 32mm, SS	2
2178.6636	6.5x135mm, Cannulated Screw, 16mm, SS	2	2178.6637	6.5x135mm, Cannulated Screw, 32mm, SS	2
2178.6641	6.5x140mm, Cannulated Screw, 16mm, SS	2	2178.6642	6.5x140mm, Cannulated Screw, 32mm, SS	2
2178.6646	6.5x145mm, Cannulated Screw, 16mm, SS	2	2178.6647	6.5x145mm, Cannulated Screw, 32mm, SS	2
2178.6651	6.5x150mm, Cannulated Screw, 16mm, SS	2	2178.6652	6.5x150mm, Cannulated Screw, 32mm, SS	2
2178.6656	6.5x155mm, Cannulated Screw, 16mm, SS	2	2178.6657	6.5x155mm, Cannulated Screw, 32mm, SS	2
2178.6661	6.5x160mm, Cannulated Screw, 16mm, SS	2	2178.6662	6.5x160mm, Cannulated Screw, 32mm, SS	2
2178.6666	6.5x165mm, Cannulated Screw, 16mm, SS	2	2178.6667	6.5x165mm, Cannulated Screw, 32mm, SS	2
2178.6671	6.5x170mm, Cannulated Screw, 16mm, SS	2	2178.6672	6.5x170mm, Cannulated Screw, 32mm, SS	2
2178.6676	6.5x175mm, Cannulated Screw, 16mm, SS	2	2178.6677	6.5x175mm, Cannulated Screw, 32mm, SS	2
2178.6681	6.5x180mm, Cannulated Screw, 16mm, SS	2	2178.6682	6.5x180mm, Cannulated Screw, 32mm, SS	2
			2178.0175	CAPTIVATE® 6.5/7.5mm Standard Washer, SS	2
			2178.3175	CAPTIVATE® 6.5/7.5mm Oval Washer, SS	2
			9178.0104	SS Headed 6.5mm Partially Threaded Long Screw Module	

# CAPTIVATE® Stainless Steel Headed 7.5mm Partially Threaded Long Screw Implant Set 9178.9005

Part No.	Description	Qty	Part No.	Description	Qty
2178.7631	7.5x130mm, Cannulated Screw, 16mm, SS	2	2178.7632	7.5x130mm, Cannulated Screw, 32mm, SS	2
2178.7636	7.5x135mm, Cannulated Screw, 16mm, SS	2	2178.7637	7.5x135mm, Cannulated Screw, 32mm, SS	2
2178.7641	7.5x140mm, Cannulated Screw, 16mm, SS	2	2178.7642	7.5x140mm, Cannulated Screw, 32mm, SS	2
2178.7646	7.5x145mm, Cannulated Screw, 16mm, SS	2	2178.7647	7.5x145mm, Cannulated Screw, 32mm, SS	2
2178.7651	7.5x150mm, Cannulated Screw, 16mm, SS	2	2178.7652	7.5x150mm, Cannulated Screw, 32mm, SS	2
2178.7656	7.5x155mm, Cannulated Screw, 16mm, SS	2	2178.7657	7.5x155mm, Cannulated Screw, 32mm, SS	2
2178.7661	7.5x160mm, Cannulated Screw, 16mm, SS	2	2178.7662	7.5x160mm, Cannulated Screw, 32mm, SS	2
2178.7666	7.5x165mm, Cannulated Screw, 16mm, SS	2	2178.7667	7.5x165mm, Cannulated Screw, 32mm, SS	2
2178.7671	7.5x170mm, Cannulated Screw, 16mm, SS	2	2178.7672	7.5x170mm, Cannulated Screw, 32mm, SS	2
2178.7676	7.5x175mm, Cannulated Screw, 16mm, SS	2	2178.7677	7.5x175mm, Cannulated Screw, 32mm, SS	2
2178.7681	7.5x180mm, Cannulated Screw, 16mm, SS	2	2178.7682	7.5x180mm, Cannulated Screw, 32mm, SS	2
			2178.0175	CAPTIVATE® 6.5/7.5mm Standard Washer, SS	2
			2178.3175	CAPTIVATE® 6.5/7.5mm Oval Washer, SS	2
			9178.0105	SS Headed 7.5mm Partially Threaded Long Screw Module	

# CAPTIVATE® Stainless Steel Headed 6.5/7.5mm Fully Threaded Long Screw Implant Set 9178.9006

Part No.	Description	Qty	Part No.	Description	Qty
2178.6630	6.5x130mm, Cannulated Screw, Full Thread, SS	2	2178.7630	7.5x130mm, Cannulated Screw, Full Thread, SS	2
2178.6635	6.5x135mm, Cannulated Screw, Full Thread, SS	2	2178.7635	7.5x135mm, Cannulated Screw, Full Thread, SS	2
2178.6640	6.5x140mm, Cannulated Screw, Full Thread, SS	2	2178.7640	7.5x140mm, Cannulated Screw, Full Thread, SS	2
2178.6645	6.5x145mm, Cannulated Screw, Full Thread, SS	2	2178.7645	7.5x145mm, Cannulated Screw, Full Thread, SS	2
2178.6650	6.5x150mm, Cannulated Screw, Full Thread, SS	2	2178.7650	7.5x150mm, Cannulated Screw, Full Thread, SS	2
2178.6655	6.5x155mm, Cannulated Screw, Full Thread, SS	2	2178.7655	7.5x155mm, Cannulated Screw, Full Thread, SS	2
2178.6660	6.5x160mm, Cannulated Screw, Full Thread, SS	2	2178.7660	7.5x160mm, Cannulated Screw, Full Thread, SS	2
2178.6665	6.5x165mm, Cannulated Screw, Full Thread, SS	2	2178.7665	7.5x165mm, Cannulated Screw, Full Thread, SS	2
2178.6670	6.5x170mm, Cannulated Screw, Full Thread, SS	2	2178.7670	7.5x170mm, Cannulated Screw, Full Thread, SS	2
2178.6675	6.5x175mm, Cannulated Screw, Full Thread, SS	2	2178.7675	7.5x175mm, Cannulated Screw, Full Thread, SS	2
2178.6680	6.5x180mm, Cannulated Screw, Full Thread, SS	2	2178.7680	7.5x180mm, Cannulated Screw, Full Thread, SS	2
			2178.0175	CAPTIVATE® 6.5/7.5mm Standard Washer, SS	2
			2178.3175	CAPTIVATE® 6.5/7.5mm Oval Washer, SS	2
			9178.0106	SS Headed 6.5/7.5mm Fully Threaded Long Screw Module	

# CAPTIVATE® Titanium Headed 6.5mm Partially Threaded Implant Set 9178.9007

Part No.	Description	Qty	Part No.	Description	Qty
1178.6541	6.5x40mm, Cannulated Screw, 16mm, Ti	2	1178.6547	6.5x45mm, Cannulated Screw, 32mm, Ti	2
1178.6546	6.5x45mm, Cannulated Screw, 16mm, Ti	2	1178.6552	6.5x50mm, Cannulated Screw, 32mm, Ti	2
1178.6551	6.5x50mm, Cannulated Screw, 16mm, Ti	2	1178.6557	6.5x55mm, Cannulated Screw, 32mm, Ti	2
1178.6556	6.5x55mm, Cannulated Screw, 16mm, Ti	2	1178.6562	6.5x60mm, Cannulated Screw, 32mm, Ti	2
1178.6561	6.5x60mm, Cannulated Screw, 16mm, Ti	2	1178.6567	6.5x65mm, Cannulated Screw, 32mm, Ti	2
1178.6566	6.5x65mm, Cannulated Screw, 16mm, Ti	2	1178.6572	6.5x70mm, Cannulated Screw, 32mm, Ti	2
1178.6571	6.5x70mm, Cannulated Screw, 16mm, Ti	2	1178.6577	6.5x75mm, Cannulated Screw, 32mm, Ti	2
1178.6576	6.5x75mm, Cannulated Screw, 16mm, Ti	2	1178.6582	6.5x80mm, Cannulated Screw, 32mm, Ti	4
1178.6581	6.5x80mm, Cannulated Screw, 16mm, Ti	4	1178.6587	6.5x85mm, Cannulated Screw, 32mm, Ti	4
1178.6586	6.5x85mm, Cannulated Screw, 16mm, Ti	4	1178.6592	6.5x90mm, Cannulated Screw, 32mm, Ti	4
1178.6591	6.5x90mm, Cannulated Screw, 16mm, Ti	4	1178.6597	6.5x95mm, Cannulated Screw, 32mm, Ti	4
1178.6596	6.5x95mm, Cannulated Screw, 16mm, Ti	4	1178.6602	6.5x100mm, Cannulated Screw, 32mm, Ti	4
1178.6601	6.5x100mm, Cannulated Screw, 16mm, Ti	4	1178.6607	6.5x105mm, Cannulated Screw, 32mm, Ti	2
1178.6606	6.5x105mm, Cannulated Screw, 16mm, Ti	2	1178.6612	6.5x110mm, Cannulated Screw, 32mm, Ti	2
1178.6611	6.5x110mm, Cannulated Screw, 16mm, Ti	2	1178.6617	6.5x115mm, Cannulated Screw, 32mm, Ti	2
1178.6616	6.5x115mm, Cannulated Screw, 16mm, Ti	2	1178.6622	6.5x120mm, Cannulated Screw, 32mm, Ti	2
1178.6621	6.5x120mm, Cannulated Screw, 16mm, Ti	2	1178.6627	6.5x125mm, Cannulated Screw, 32mm, Ti	2
1178.6626	6.5x125mm, Cannulated Screw, 16mm, Ti	2	1178.0175	CAPTIVATE® 6.5/7.5mm Standard Washer, SS	4
			1178.3175	CAPTIVATE® 6.5/7.5mm Oval Washer, SS	2
			9178.0107	Ti Headed 6.5mm Partially Threaded Screw Module	

# CAPTIVATE® Titanium Headed 7.5mm Partially Threaded Implant Set 9178.9008

Part No.	Description	Qty	Part No.	Description	Qty
1178.7541	7.5x40mm, Cannulated Screw, 16mm, Ti	2	1178.7547	7.5x45mm, Cannulated Screw, 32mm, Ti	2
1178.7546	7.5x45mm, Cannulated Screw, 16mm, Ti	2	1178.7552	7.5x50mm, Cannulated Screw, 32mm, Ti	2
1178.7551	7.5x50mm, Cannulated Screw, 16mm, Ti	2	1178.7557	7.5x55mm, Cannulated Screw, 32mm, Ti	2
1178.7556	7.5x55mm, Cannulated Screw, 16mm, Ti	2	1178.7562	7.5x60mm, Cannulated Screw, 32mm, Ti	2
1178.7561	7.5x60mm, Cannulated Screw, 16mm, Ti	2	1178.7567	7.5x65mm, Cannulated Screw, 32mm, Ti	2
1178.7566	7.5x65mm, Cannulated Screw, 16mm, Ti	2	1178.7572	7.5x70mm, Cannulated Screw, 32mm, Ti	2
1178.7571	7.5x70mm, Cannulated Screw, 16mm, Ti	2	1178.7577	7.5x75mm, Cannulated Screw, 32mm, Ti	2
1178.7576	7.5x75mm, Cannulated Screw, 16mm, Ti	2	1178.7582	7.5x80mm, Cannulated Screw, 32mm, Ti	4
1178.7581	7.5x80mm, Cannulated Screw, 16mm, Ti	4	1178.7587	7.5x85mm, Cannulated Screw, 32mm, Ti	4
1178.7586	7.5x85mm, Cannulated Screw, 16mm, Ti	4	1178.7592	7.5x90mm, Cannulated Screw, 32mm, Ti	4
1178.7591	7.5x90mm, Cannulated Screw, 16mm, Ti	4	1178.7597	7.5x95mm, Cannulated Screw, 32mm, Ti	4
1178.7596	7.5x95mm, Cannulated Screw, 16mm, Ti	4	1178.7602	7.5x100mm, Cannulated Screw, 32mm, Ti	4
1178.7601	7.5x100mm, Cannulated Screw, 16mm, Ti	4	1178.7607	7.5x105mm, Cannulated Screw, 32mm, Ti	2
1178.7606	7.5x105mm, Cannulated Screw, 16mm, Ti	2	1178.7612	7.5x110mm, Cannulated Screw, 32mm, Ti	2
1178.7611	7.5x110mm, Cannulated Screw, 16mm, Ti	2	1178.7617	7.5x115mm, Cannulated Screw, 32mm, Ti	2
1178.7616	7.5x115mm, Cannulated Screw, 16mm, Ti	2	1178.7622	7.5x120mm, Cannulated Screw, 32mm, Ti	2
1178.7621	7.5x120mm, Cannulated Screw, 16mm, Ti	2	1178.7627	7.5x125mm, Cannulated Screw, 32mm, Ti	2
1178.7626	7.5x125mm, Cannulated Screw, 16mm, Ti	2	1178.0175	CAPTIVATE® 6.5/7.5mm Standard Washer, SS	4
			1178.3175	CAPTIVATE® 6.5/7.5mm Oval Washer, SS	2
			9178.0108	Ti Headed 7.5mm Partially Threaded Screw Module	

# CAPTIVATE® Titanium Headed 6.5/7.5mm Fully Threaded Implant Set 9178.9009

Part No.	Description	Qty	Part No.	Description	Qty
1178.6540	6.5x40mm, Cannulated Screw, Full Thread, Ti	1	1178.7540	7.5x40mm, Cannulated Screw, Full Thread, Ti	1
1178.6545	6.5x45mm, Cannulated Screw, Full Thread, Ti	1	1178.7545	7.5x45mm, Cannulated Screw, Full Thread, Ti	1
1178.6550	6.5x50mm, Cannulated Screw, Full Thread, Ti	1	1178.7550	7.5x50mm, Cannulated Screw, Full Thread, Ti	1
1178.6555	6.5x55mm, Cannulated Screw, Full Thread, Ti	1	1178.7555	7.5x55mm, Cannulated Screw, Full Thread, Ti	1
1178.6560	6.5x60mm, Cannulated Screw, Full Thread, Ti	1	1178.7560	7.5x60mm, Cannulated Screw, Full Thread, Ti	1
1178.6565	6.5x65mm, Cannulated Screw, Full Thread, Ti	1	1178.7565	7.5x65mm, Cannulated Screw, Full Thread, Ti	1
1178.6570	6.5x70mm, Cannulated Screw, Full Thread, Ti	1	1178.7570	7.5x70mm, Cannulated Screw, Full Thread, Ti	1
1178.6575	6.5x75mm, Cannulated Screw, Full Thread, Ti	1	1178.7575	7.5x75mm, Cannulated Screw, Full Thread, Ti	1
1178.6580	6.5x80mm, Cannulated Screw, Full Thread, Ti	1	1178.7580	7.5x80mm, Cannulated Screw, Full Thread, Ti	1
1178.6585	6.5x85mm, Cannulated Screw, Full Thread, Ti	1	1178.7585	7.5x85mm, Cannulated Screw, Full Thread, Ti	1
1178.6590	6.5x90mm, Cannulated Screw, Full Thread, Ti	1	1178.7590	7.5x90mm, Cannulated Screw, Full Thread, Ti	1
1178.6595	6.5x95mm, Cannulated Screw, Full Thread, Ti	1	1178.7595	7.5x95mm, Cannulated Screw, Full Thread, Ti	1
1178.6600	6.5x100mm, Cannulated Screw, Full Thread, Ti	1	1178.7600	7.5x100mm, Cannulated Screw, Full Thread, Ti	1
1178.6605	6.5x105mm, Cannulated Screw, Full Thread, Ti	1	1178.7605	7.5x105mm, Cannulated Screw, Full Thread, Ti	1
1178.6610	6.5x110mm, Cannulated Screw, Full Thread, Ti	1	1178.7610	7.5x110mm, Cannulated Screw, Full Thread, Ti	1
1178.6615	6.5x115mm, Cannulated Screw, Full Thread, Ti	1	1178.7615	7.5x115mm, Cannulated Screw, Full Thread, Ti	1
1178.6620	6.5x120mm, Cannulated Screw, Full Thread, Ti	1	1178.7620	7.5x120mm, Cannulated Screw, Full Thread, Ti	1
1178.6625	6.5x125mm, Cannulated Screw, Full Thread, Ti	1	1178.7625	7.5x125mm, Cannulated Screw, Full Thread, Ti	1
			1178.0175	CAPTIVATE® 6.5/7.5mm Standard Washer, SS	2
			1178.3175	CAPTIVATE® 6.5/7.5mm Oval Washer, SS	2
			9178.0109	Ti Headed 6.5/7.5mm Fully Threaded Screw Module	

# CAPTIVATE® Titanium Headed 6.5mm Partially Threaded Long Screw Implant Set 9178.9010

Part No.	Description	Qty	Part No.	Description	Qty
1178.6631	6.5x130mm, Cannulated Screw, 16mm, Ti	2	1178.6632	6.5x130mm, Cannulated Screw, 32mm, Ti	2
1178.6636	6.5x135mm, Cannulated Screw, 16mm, Ti	2	1178.6637	6.5x135mm, Cannulated Screw, 32mm, Ti	2
1178.6641	6.5x140mm, Cannulated Screw, 16mm, Ti	2	1178.6642	6.5x140mm, Cannulated Screw, 32mm, Ti	2
1178.6646	6.5x145mm, Cannulated Screw, 16mm, Ti	2	1178.6647	6.5x145mm, Cannulated Screw, 32mm, Ti	2
1178.6651	6.5x150mm, Cannulated Screw, 16mm, Ti	2	1178.6652	6.5x150mm, Cannulated Screw, 32mm, Ti	2
1178.6656	6.5x155mm, Cannulated Screw, 16mm, Ti	2	1178.6657	6.5x155mm, Cannulated Screw, 32mm, Ti	2
1178.6661	6.5x160mm, Cannulated Screw, 16mm, Ti	2	1178.6662	6.5x160mm, Cannulated Screw, 32mm, Ti	2
1178.6666	6.5x165mm, Cannulated Screw, 16mm, Ti	2	1178.6667	6.5x165mm, Cannulated Screw, 32mm, Ti	2
1178.6671	6.5x170mm, Cannulated Screw, 16mm, Ti	2	1178.6672	6.5x170mm, Cannulated Screw, 32mm, Ti	2
1178.6676	6.5x175mm, Cannulated Screw, 16mm, Ti	2	1178.6677	6.5x175mm, Cannulated Screw, 32mm, Ti	2
1178.6681	6.5x180mm, Cannulated Screw, 16mm, Ti	2	1178.6682	6.5x180mm, Cannulated Screw, 32mm, Ti	2
			1178.0175	CAPTIVATE® 6.5/7.5mm Standard Washer, SS	2
			1178.3175	CAPTIVATE® 6.5/7.5mm Oval Washer, SS	2
			9178.0110	Ti Headed 6.5mm Partially Threaded Long Screw Module	

# CAPTIVATE® Titanium Headed 7.5mm Partially Threaded Long Screw Implant Set 9178.9011

Part No.	Description	Qty	Part No.	Description	Qty
1178.7631	7.5x130mm, Cannulated Screw, 16mm, Ti	2	1178.7632	7.5x130mm, Cannulated Screw, 32mm, Ti	2
1178.7636	7.5x135mm, Cannulated Screw, 16mm, Ti	2	1178.7637	7.5x135mm, Cannulated Screw, 32mm, Ti	2
1178.7641	7.5x140mm, Cannulated Screw, 16mm, Ti	2	1178.7642	7.5x140mm, Cannulated Screw, 32mm, Ti	2
1178.7646	7.5x145mm, Cannulated Screw, 16mm, Ti	2	1178.7647	7.5x145mm, Cannulated Screw, 32mm, Ti	2
1178.7651	7.5x150mm, Cannulated Screw, 16mm, Ti	2	1178.7652	7.5x150mm, Cannulated Screw, 32mm, Ti	2
1178.7656	7.5x155mm, Cannulated Screw, 16mm, Ti	2	1178.7657	7.5x155mm, Cannulated Screw, 32mm, Ti	2
1178.7661	7.5x160mm, Cannulated Screw, 16mm, Ti	2	1178.7662	7.5x160mm, Cannulated Screw, 32mm, Ti	2
1178.7666	7.5x165mm, Cannulated Screw, 16mm, Ti	2	1178.7667	7.5x165mm, Cannulated Screw, 32mm, Ti	2
1178.7671	7.5x170mm, Cannulated Screw, 16mm, Ti	2	1178.7672	7.5x170mm, Cannulated Screw, 32mm, Ti	2
1178.7676	7.5x175mm, Cannulated Screw, 16mm, Ti	2	1178.7677	7.5x175mm, Cannulated Screw, 32mm, Ti	2
1178.7681	7.5x180mm, Cannulated Screw, 16mm, Ti	2	1178.7682	7.5x180mm, Cannulated Screw, 32mm, Ti	2
			1178.0175	CAPTIVATE® 6.5/7.5mm Standard Washer, SS	2
			1178.3175	CAPTIVATE® 6.5/7.5mm Oval Washer, SS	2
			9178.0111	Ti Headed 7.5mm Partially Threaded Long Screw Module	

# CAPTIVATE® Titanium Headed 6.5/7.5mm Fully Threaded Long Screw Implant Set 9178.9012

Part No.	Description	Qty	Part No.	Description	Qty
1178.6630	6.5x130mm, Cannulated Screw, Full Thread, Ti	2	1178.7630	7.5x130mm, Cannulated Screw, Full Thread, Ti	2
1178.6635	6.5x135mm, Cannulated Screw, Full Thread, Ti	2	1178.7635	7.5x135mm, Cannulated Screw, Full Thread, Ti	2
1178.6640	6.5x140mm, Cannulated Screw, Full Thread, Ti	2	1178.7640	7.5x140mm, Cannulated Screw, Full Thread, Ti	2
1178.6645	6.5x145mm, Cannulated Screw, Full Thread, Ti	2	1178.7645	7.5x145mm, Cannulated Screw, Full Thread, Ti	2
1178.6650	6.5x150mm, Cannulated Screw, Full Thread, Ti	2	1178.7650	7.5x150mm, Cannulated Screw, Full Thread, Ti	2
1178.6655	6.5x155mm, Cannulated Screw, Full Thread, Ti	2	1178.7655	7.5x155mm, Cannulated Screw, Full Thread, Ti	2
1178.6660	6.5x160mm, Cannulated Screw, Full Thread, Ti	2	1178.7660	7.5x160mm, Cannulated Screw, Full Thread, Ti	2
1178.6665	6.5x165mm, Cannulated Screw, Full Thread, Ti	2	1178.7665	7.5x165mm, Cannulated Screw, Full Thread, Ti	2
1178.6670	6.5x170mm, Cannulated Screw, Full Thread, Ti	2	1178.7670	7.5x170mm, Cannulated Screw, Full Thread, Ti	2
1178.6675	6.5x175mm, Cannulated Screw, Full Thread, Ti	2	1178.7675	7.5x175mm, Cannulated Screw, Full Thread, Ti	2
1178.6680	6.5x180mm, Cannulated Screw, Full Thread, Ti	2	1178.7680	7.5x180mm, Cannulated Screw, Full Thread, Ti	2
			1178.0175	CAPTIVATE® 6.5/7.5mm Standard Washer, SS	2
			1178.3175	CAPTIVATE® 6.5/7.5mm Oval Washer, SS	2
			9178.0112	Ti Headed 6.5/7.5mm Fully Threaded 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.
- Subclinal 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

## IMPORTANT INFORMATION ON CAPTIVATE® COMPRESSION SCREWS

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<sup>®</sup> (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<sup>®</sup> (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<sup>-6</sup>. 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<sup>-6</sup>. The use of an FDA-cleared wrap

is recommended, per the Association for the Advancement of Medical Instrumentation (AAMI) ST79, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the FDA for the selected sterilization cycle specifications (time and temperature).

When using a rigid sterilization container, the following must be taken into consideration for proper sterilization of Globus devices and loaded graphic cases:

Recommended sterilization parameters are listed in the table below.

- Only FDA-cleared rigid sterilization containers for use with pre-vacuum steam sterilization may be used.
- When selecting a rigid sterilization container, it must have a minimum filter area of 176 in<sup>2</sup> total, or a minimum of four (4) 7.5in diameter filters.
- No more than one (1) loaded graphic case or its contents can be placed directly into a rigid sterilization container.
- Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.
- The rigid sterilization container manufacturer's instructions for use are to be followed; if questions arise, contact the manufacturer of the specific container for guidance.
- Refer to AAMI ST79 for additional information concerning the use of rigid sterilization containers.

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

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

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

**CAUTION:** Federal (USA) 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		

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