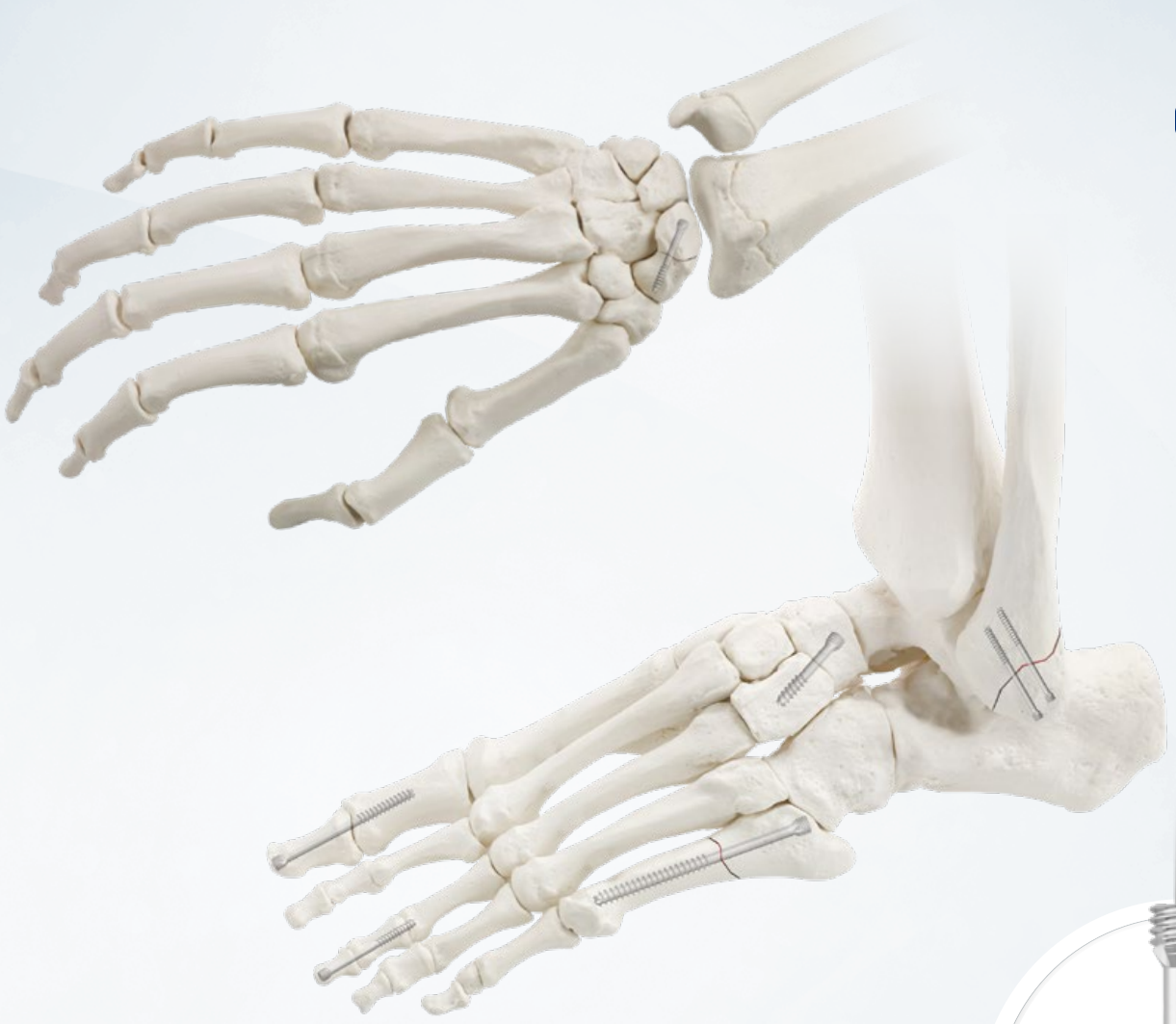

CAPTIVATE®

Headless Compression Screw System
2.5/3.0/4.0mm

SURGICAL TECHNIQUE GUIDE

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SURGICAL TECHNIQUE GUIDE

CAPTIVATE®

Headless Compression Screw System
2.5/3.0/4.0mm

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CAPTIVATE®

Headless Compression Screw System 2.5/3.0/4.0mm

The CAPTIVATE® Headless Compression Screw System offers intraoperative simplicity and versatility with a modular design and streamlined instruments.

The Headless Driver and Compression Sleeve allow surgeon control of reduction and compression.

CAPTIVATE® headless compression screws are used for fracture repair, osteotomy fixation, joint fusion, and reconstruction throughout bony anatomy. The screws can be used independently or in conjunction with plate fixation and are offered in varying lengths and diameters.

Short thread

Long thread

Comprehensive Screw Offering

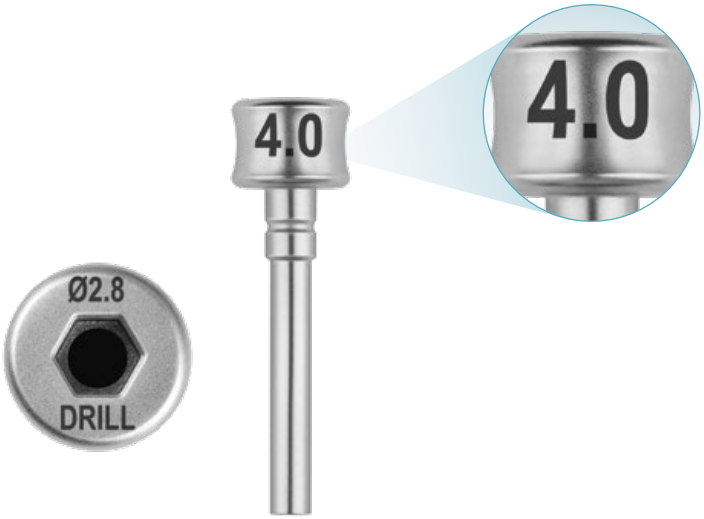
- Designed to optimize purchase for maximum compression and stability
- Short and long thread lengths
- Available in stainless steel or titanium

SCREW OFFERINGS		
Diameter	**Thread Type**	**Lengths**
2.5mm	Short	9-40mm
	Long	17-40mm
3.0mm	Short	10-40mm
	Long	16-40mm
4.0mm	Short	16-60mm
	Long	16-60mm

Short = 20% of length
Long = 40% of length

Easy Identification

- Drill sleeve marked with corresponding drill sizes and screw diameter
- Large font for visibility



Modular by Design

- Independent modules for each diameter provide intraoperative versatility

IMPLANT OVERVIEW

Lag by design

- Chamfered head allows compression before thread engagement

Hexalobe recess

- Optimizes torque transmission

Reverse cutting flutes

- Facilitates screw removal

Self-drilling and self-tapping tips

- Designed for ease of insertion

CAPTIVATE® Headless Driver and Compression Sleeve

- Allows for surgeon-controlled reduction and compression
- Compression sleeve tip ideal for osteoporotic bone

CAPTIVATE® Headless Straight Driver

- Screw head allows compression with straight driver
- Driver aids in intraoperative simplicity

SURGICAL TECHNIQUE

CAPTIVATE®

Headless Compression Screw System 2.5/3.0/4.0mm

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

STEP 1 APPROACH

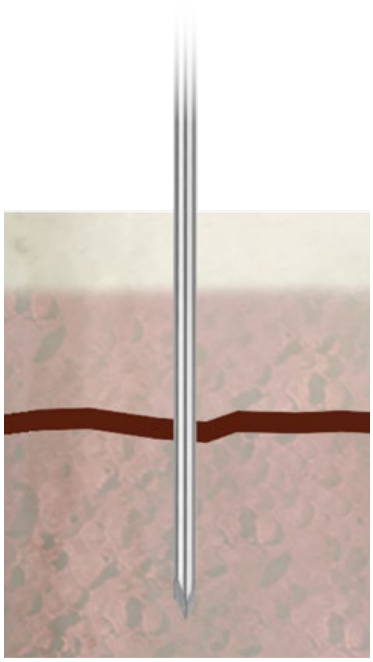
Identify the fracture and create an incision.

STEP 2 GUIDEWIRE INSERTION

Using the **Guidewire Sleeve** for the selected drill, insert the corresponding **Guidewire** to the desired depth.

Confirm the Guidewire position using fluoroscopy.

SCREW DIAMETER	GUIDEWIRE DIAMETER
2.5mm	1.1mm
3.0mm	1.1mm
4.0mm	1.4mm



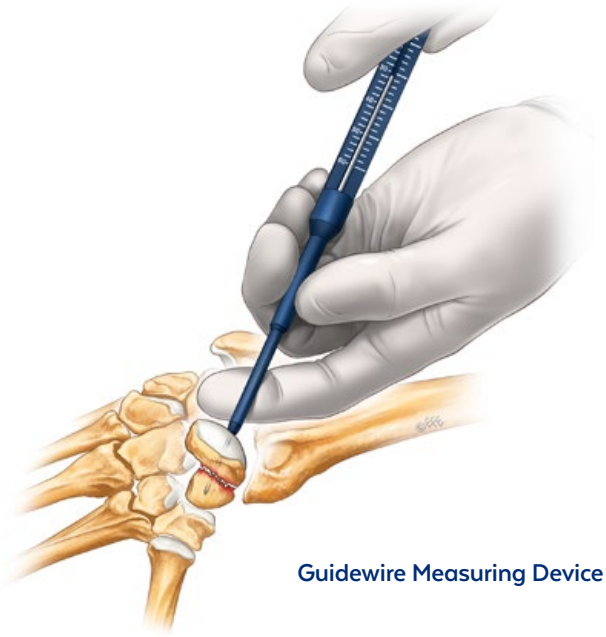
STEP 3 MEASURING SCREW LENGTH

Slide the **Guidewire Measuring Device** over the Guidewire until flush with the bone.

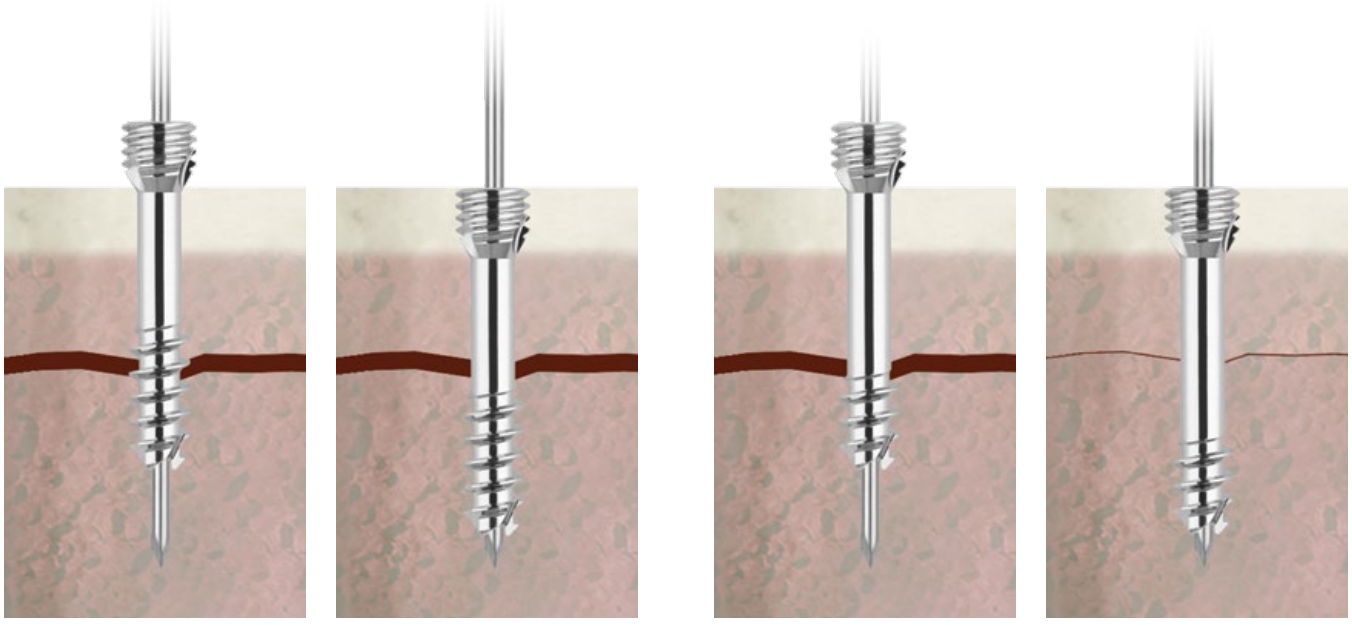
Read the screw length measurement at the end of the Guidewire.

If the measurement is between screw sizes, round down for screw and thread length.

To determine gap closure, select the appropriate screw length.



Guidewire Measuring Device



Incorrect thread length
No compression in fracture gap

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

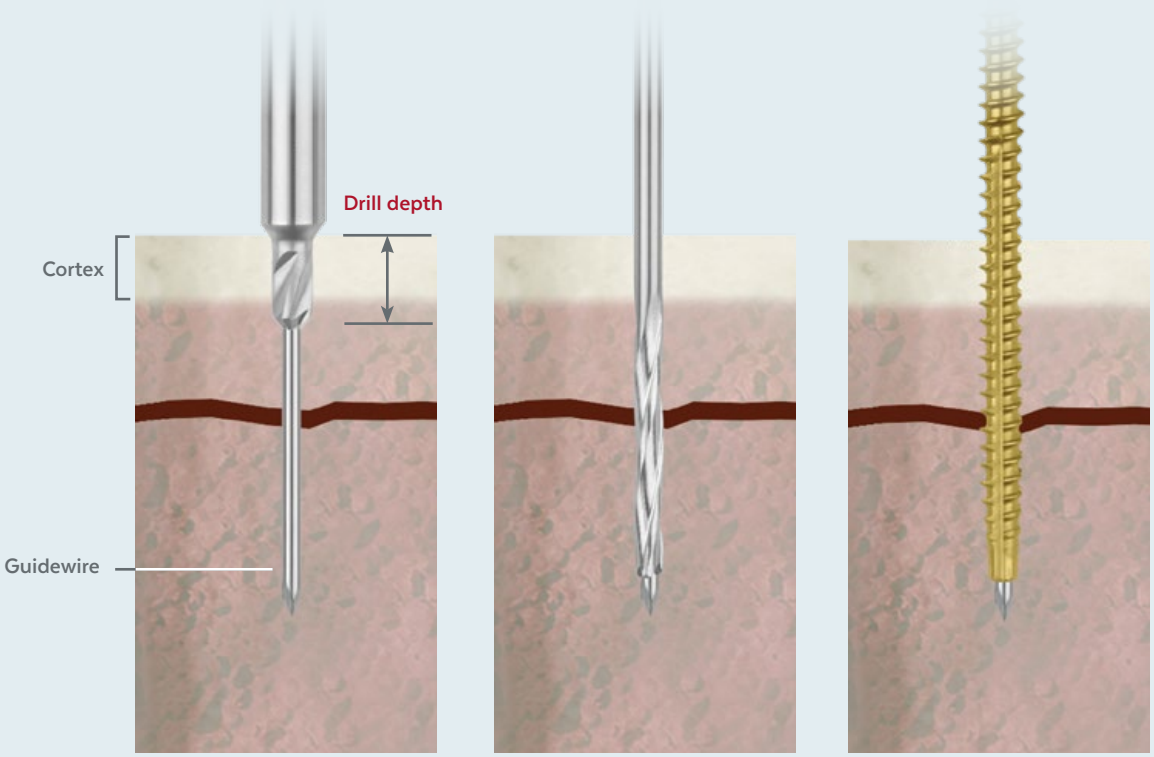
DRILLING AND TAPPING

Select the appropriate size **Near Cortex Drill** and attach to a power drill. Drilling the Near Cortex Drill to the desired depth.

Select the appropriate size **Cancellous Drill**. Using fluoroscopy, drill to the desired screw depth, using incremental markings on the drill as a guide.

Select the appropriate size **Tap**. The screw hole may be tapped prior to insertion if desired.

SCREW DIAMETER	CANCELLOUS DRILL DIAMETER	NEAR CORTEX DRILL DIAMETER
2.5mm	2.0mm	2.5mm
3.0mm	2.2mm	3.0mm
4.0mm	2.8mm	4.0mm



Near Cortex Drill | Cancellous Drill | Tap

ASSEMBLING THE HEADLESS DRIVER AND COMPRESSION SLEEVE

Insert the **Headless Driver** into the **AO Quick Connect Handle**.

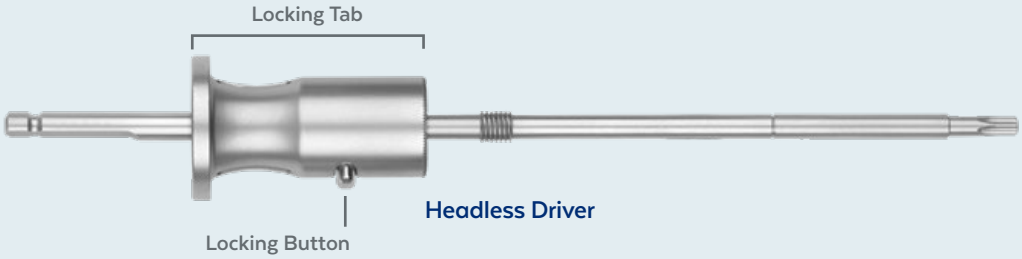
Pull back the locking tab until it clicks.

Rotate the **Compression Sleeve** onto the Headless Driver until it stops.

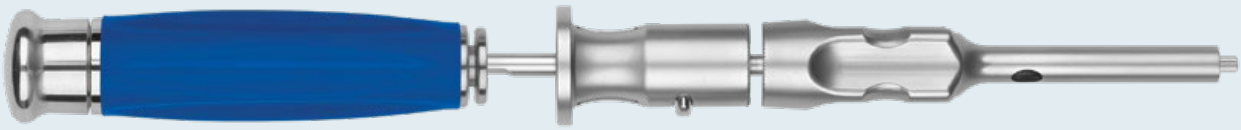
Insert the Headless Driver into the screw and gently thread the Compression Sleeve down onto the screw.

Press the locking button to lock the sleeve prior to compression.

AO Quick Connect Handle



Compression Sleeve



Assembled Headless Driver and Compression Sleeve

DISASSEMBLING THE HEADLESS DRIVER AND COMPRESSION SLEEVE

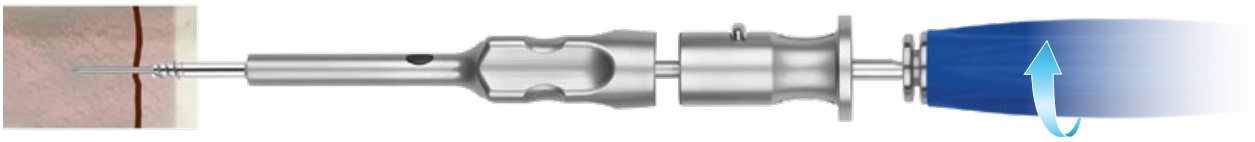
The Headless Driver and Compression Sleeve may be disassembled for cleaning. Refer to the package insert for cleaning and sterilization instructions.

Rotate the Compression Sleeve counterclockwise to remove.

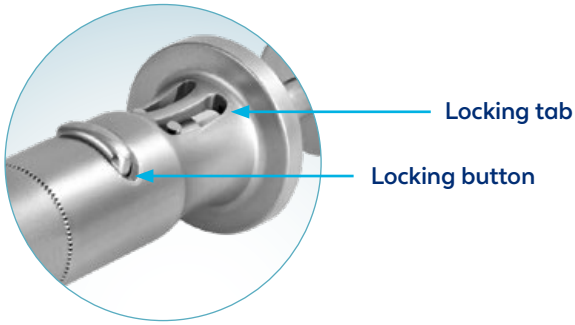
Disconnect the driver from the AO Quick Connect Handle.

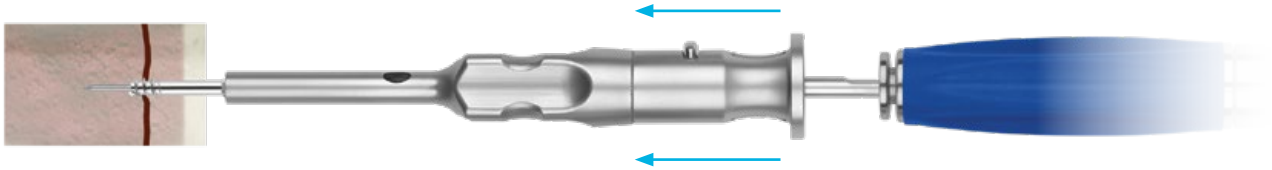
STEP 4 SCREW INSERTION AND COMPRESSION

Using the assembled Headless Driver and Compression Sleeve, rotate the driver clockwise for initial screw insertion.



Engage the locking tab by pressing the locking button.



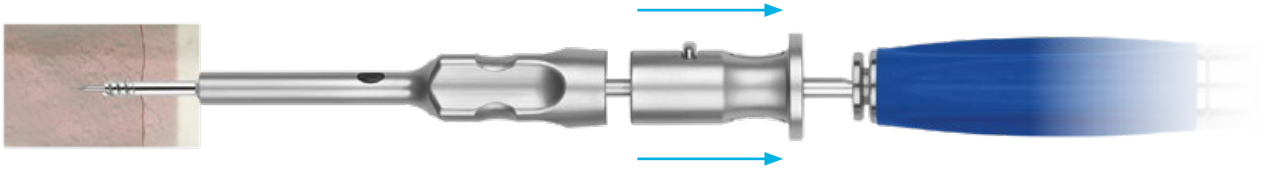


Locking tab engaged

Rotate the driver clockwise to compress and close the fracture gap. Fluoroscopy is required to ensure proper screw trajectory and alignment.

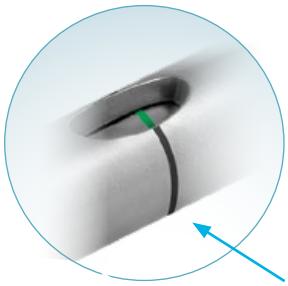
Fracture gap compressed

Unlock the Compression Sleeve by pulling back the locking tab.



Locking tab disengaged

While holding the Compression Sleeve, countersink the screw by rotating the Headless Driver clockwise to the desired depth. When the screw is flush with the bone surface, the green line aligns with the indicator line on the Compression Sleeve. If desired, the screw may be countersunk past the indicator line, up to 2mm, depending on the thickness of the cortex.

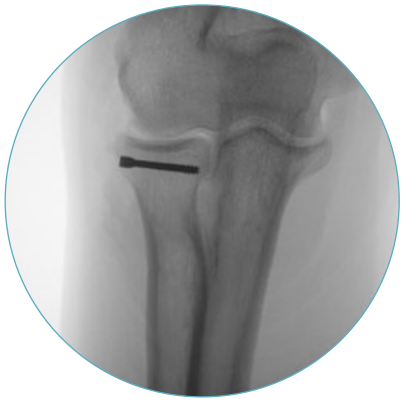


Indicator line

Hold

When satisfactory screw position is achieved, remove both the driver and Guidewire. Remove the Guidewire using the Guidewire Driver. Confirm screw placement with fluoroscopy.

Correct screw placement



AP view of radial head fixation

ALTERNATIVE METHOD FOR SCREW INSERTION WITH GUIDEWIRE

Use the screw forceps to remove the desired screw from the module.

Place the screw over the Guidewire.

Slide the Straight Driver over the Guidewire until the driver tip engages the screw head.

Advance the screw by rotating the driver clockwise.

Continue rotating the driver to countersink the screw until the desired depth is achieved.

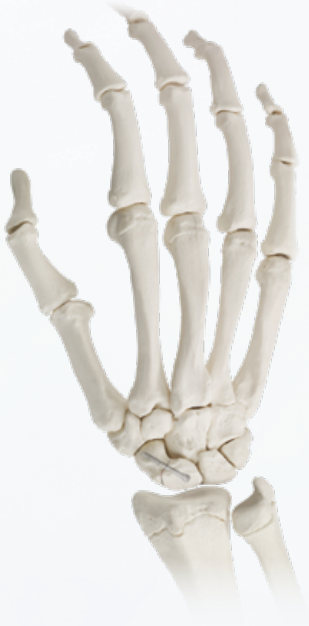
Optional: Screw Removal

Insert the appropriate hexalobular driver into the drive feature of the screw and rotate counterclockwise. Use forceps or other instruments to pull the screw out axially.

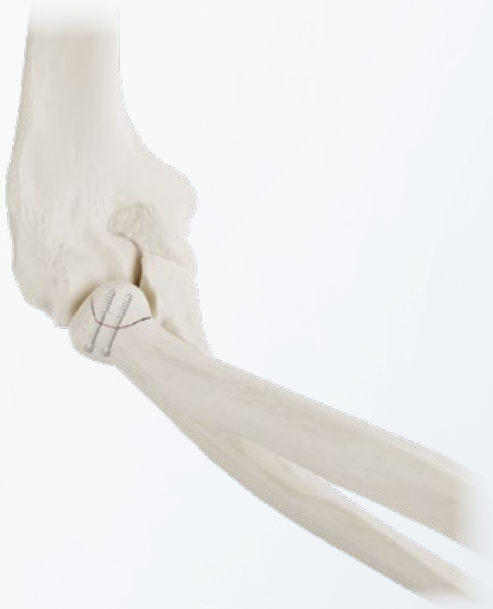
APPLICATIONS

Headless Compression Screws
2.5/3.0/4.0mm

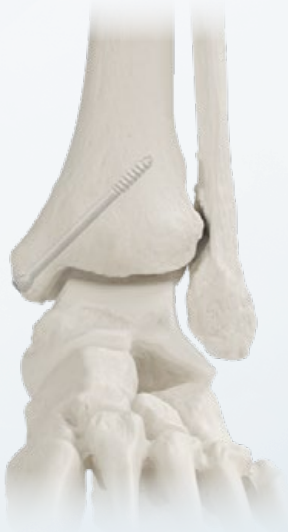
The CAPTIVATE® Headless Compression Screw System is designed for fracture fixation in bony anatomy. Specific applications include the volar approach to scaphoid fixation, dorsal approach to scaphoid fixation, radial head fixation, and medial malleolus fixation. The surgical approach and dissection for each application are shown.



Volar and Dorsal Scaphoid Fixation



Radial Head Fixation



Medial Malleolus Fixation

SURGICAL APPROACH

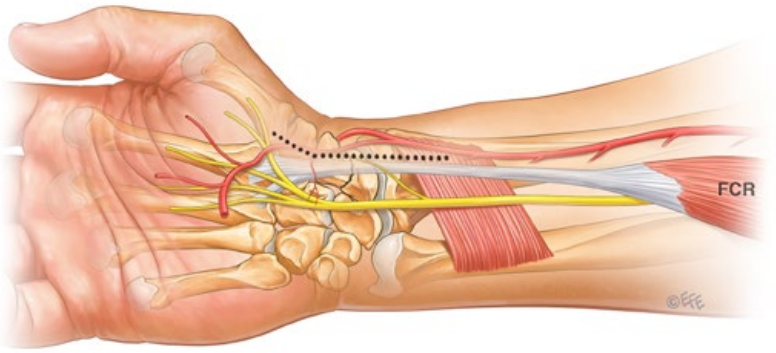
CAPTIVATE®

Headless Screws for Scaphoid Fixation—Volar Approach

The volar approach is preferred for fractures of the distal pole and scaphoid waist. Open exposure of the scaphoid facilitates direct fracture reduction.

STEP 1 SUPERFICIAL DISSECTION

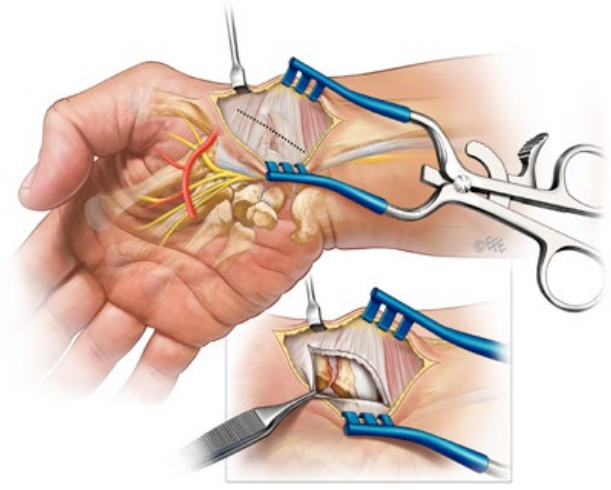
Position the draped limb supine and extend across the hand table. Palpate the distal pole of the scaphoid just distal to the wrist crease. Create an incision longitudinally or obliquely over the distal wrist crease and the distal pole of the scaphoid, radial to the flexor carpi radialis (FCR) tendon.



STEP 2 DEEP DISSECTION

Expose the scaphoid longitudinally along its long axis and raise the full capsular flaps for later closure.

Exposure of the scaphoid may be enhanced by ulnarly deviating the wrist to extend the scaphoid and improve exposure of the scaphoid waist.



If desired, the **Scaphoid Elevator** and **Trapezium Drill** may be used.

STEP 3 GUIDEWIRE PLACEMENT

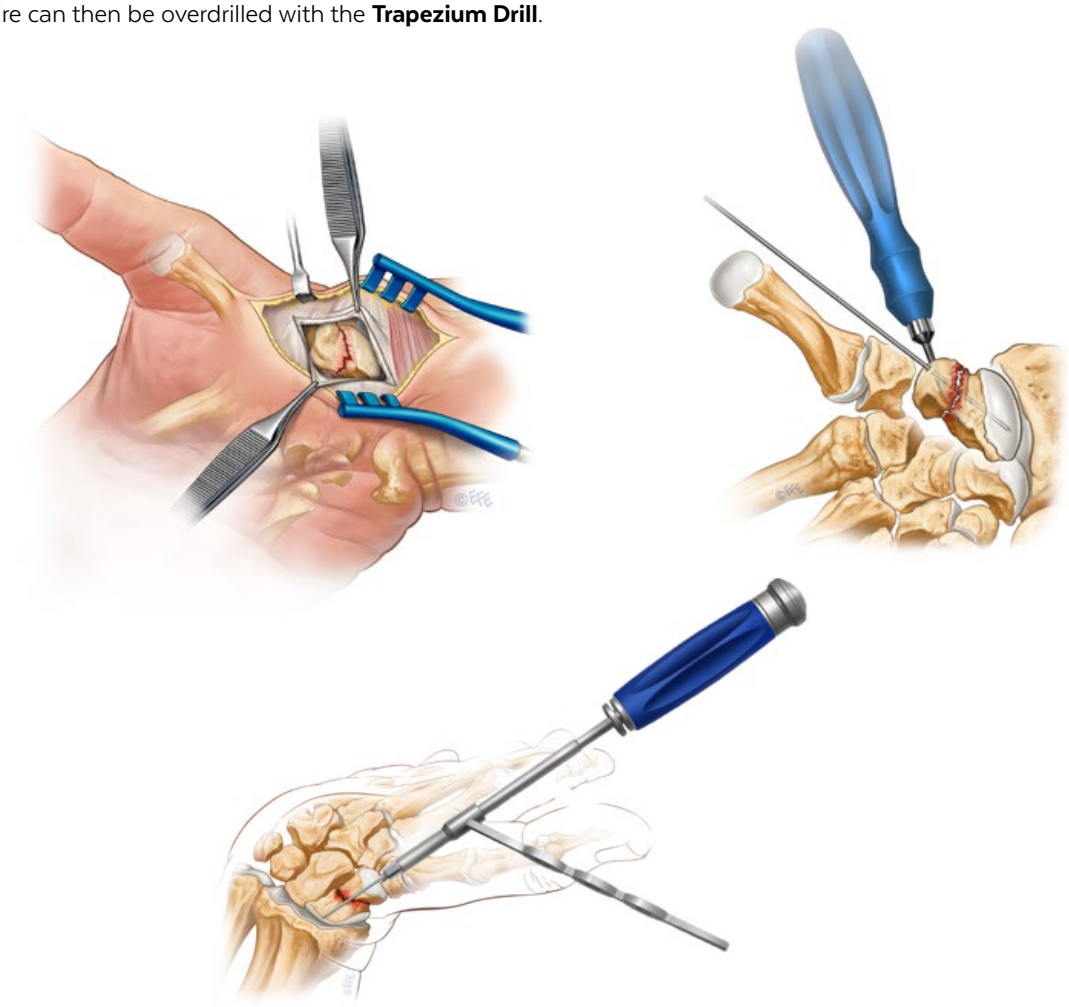
Reduce the fracture and confirm reduction using fluoroscopy.

Place the Guidewire retrograde along the long axis of the scaphoid.

To help with central placement of the Guidewire, place the **Scaphoid Elevator** into the scaphotrapezial joint to move the distal articular surface of the scaphoid.

Alternatively, the Guidewire can be placed through the trapezium and into the scaphoid to achieve central placement.

The Guidewire can then be overdrilled with the **Trapezium Drill**.



Ensure the selected screw is appropriately downsized to be countersunk below the articular surface proximally and distally.

Using fluoroscopy, confirm that central Guidewire placement is in the appropriate position on the anteroposterior, oblique, and lateral images.

STEP 4 SCREW INSERTION

Follow instructions on pages 8-12 for preparation and screw insertion steps.

Refer to page 13 for removal instructions.

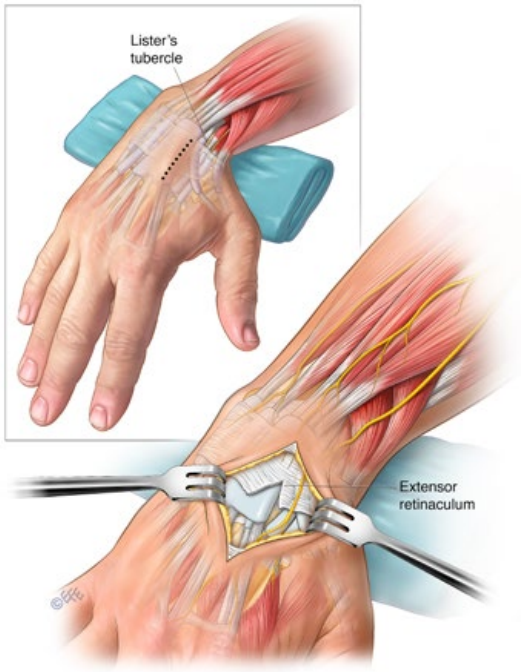
SURGICAL APPROACH

CAPTIVATE®

Headless Screws for Scaphoid Fixation—Dorsal Approach

The dorsal approach is preferred for fractures of the proximal pole and scaphoid waist. Open exposure of the scaphoid can facilitate direct fracture reduction.

STEP 1 SUPERFICIAL DISSECTION



Position the draped limb supine and extend across the hand table with the forearm pronated.

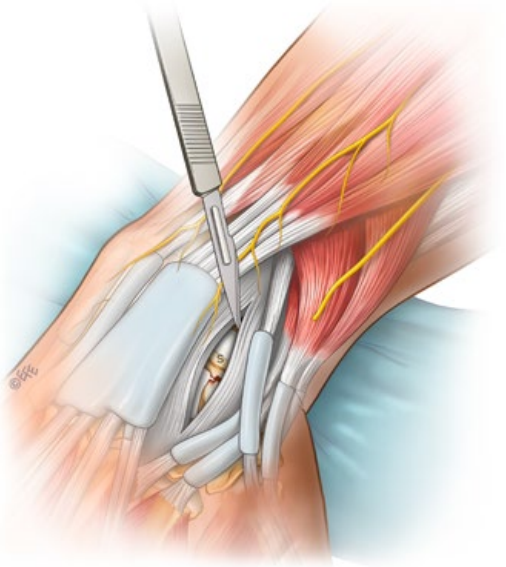
Place the wrist in slight flexion and palpate Lister's Tubercle.

Create a longitudinal or oblique incision just ulnar and distal to Lister's Tubercle.

Identify the extensor tendons exiting the extensor retinaculum.

Release the extensor retinaculum proximally, but not past Lister's Tubercle, to expose the extensor tendons.

STEP 2 DEEP DISSECTION



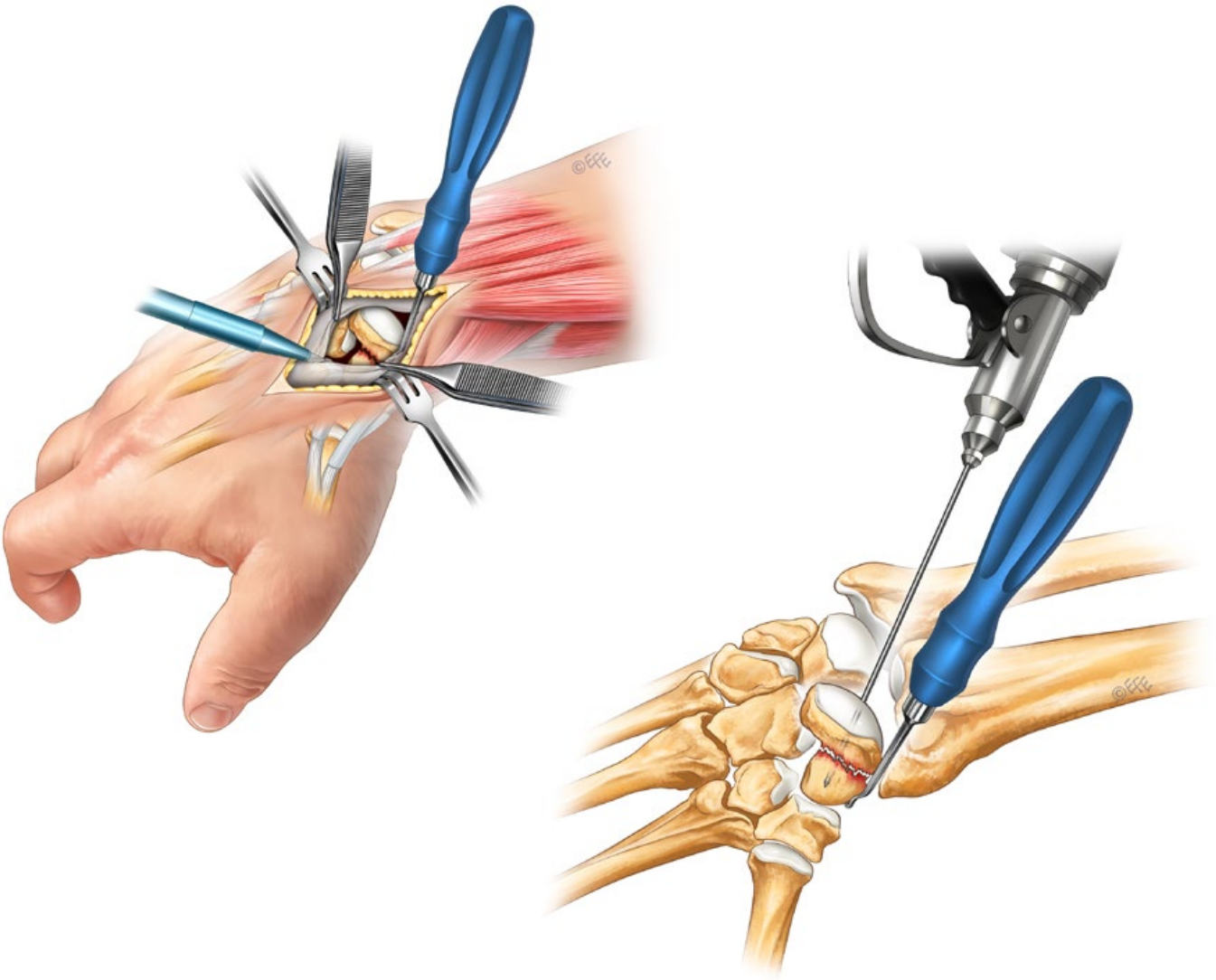
Incise the interval between the third (extensor pollicis longus) and fourth (extensor digitorum comminis) extensor compartment to expose the wrist capsule. Perform a longitudinal arthrotomy and/or a ligament-sparing arthrotomy.

Carefully avoid injury to the scapholunate ligament during wrist arthrotomy.

Ulnar deviation of the wrist results in the extension of the scaphoid which aids in fracture visualization and reduction.

STEP 3 GUIDEWIRE PLACEMENT

With the fracture reduced, place the Guidewire retrograde along the long axis of the scaphoid. If necessary the **Scaphoid Elevator** may be placed into the radio-scaphoid joint to expose the proximal articular surface of the scaphoid.



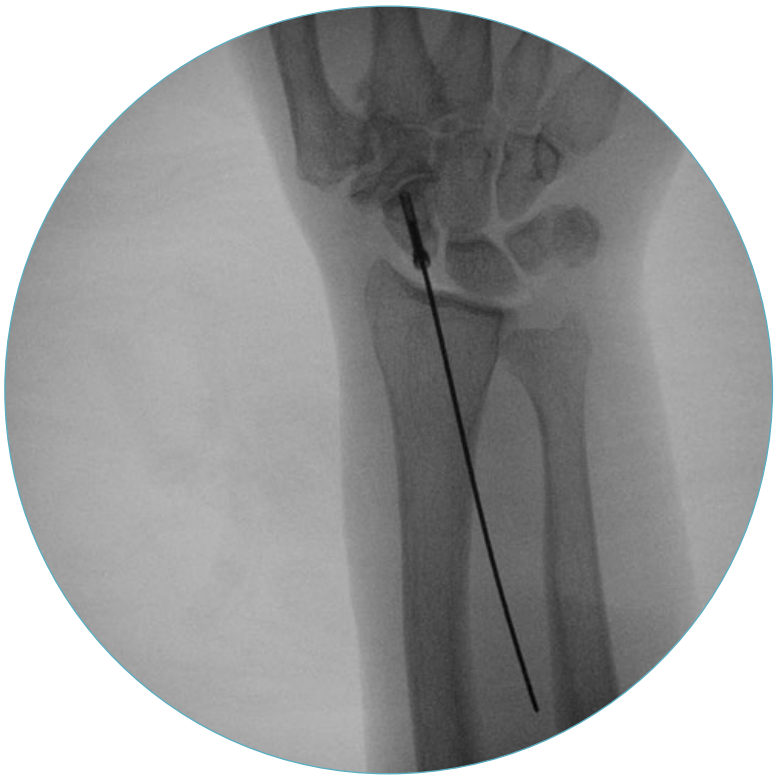
Using fluoroscopy, carefully confirm Guidewire placement is in the appropriate position on the anteroposterior, oblique, and lateral images.

STEP 4 SCREW INSERTION

Follow instructions on pages 8-12 for preparation and screw insertion steps.

Refer to page 13 for removal instructions.

FINAL CONSTRUCT



Scaphoid Fixation—Dorsal approach

SURGICAL APPROACH

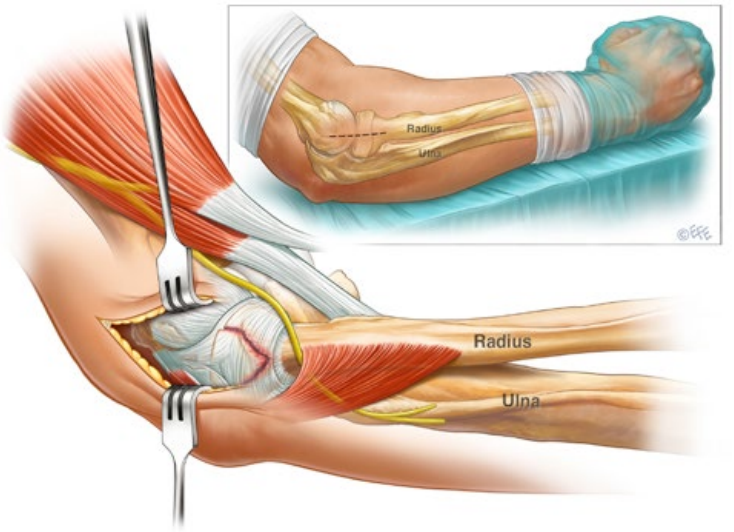
CAPTIVATE®

Headless Screws for Radial Head Fixation

STEP 1 SUPERFICIAL DISSECTION

Use a surgical marker to identify the boundaries of the lateral epicondyle and captiellum of the distal humerus and radial head by palpating the lateral elbow.

Create an incision over the radiocapitellar joint depending on which deep interval is planned.



STEP 2 DEEP DISSECTION

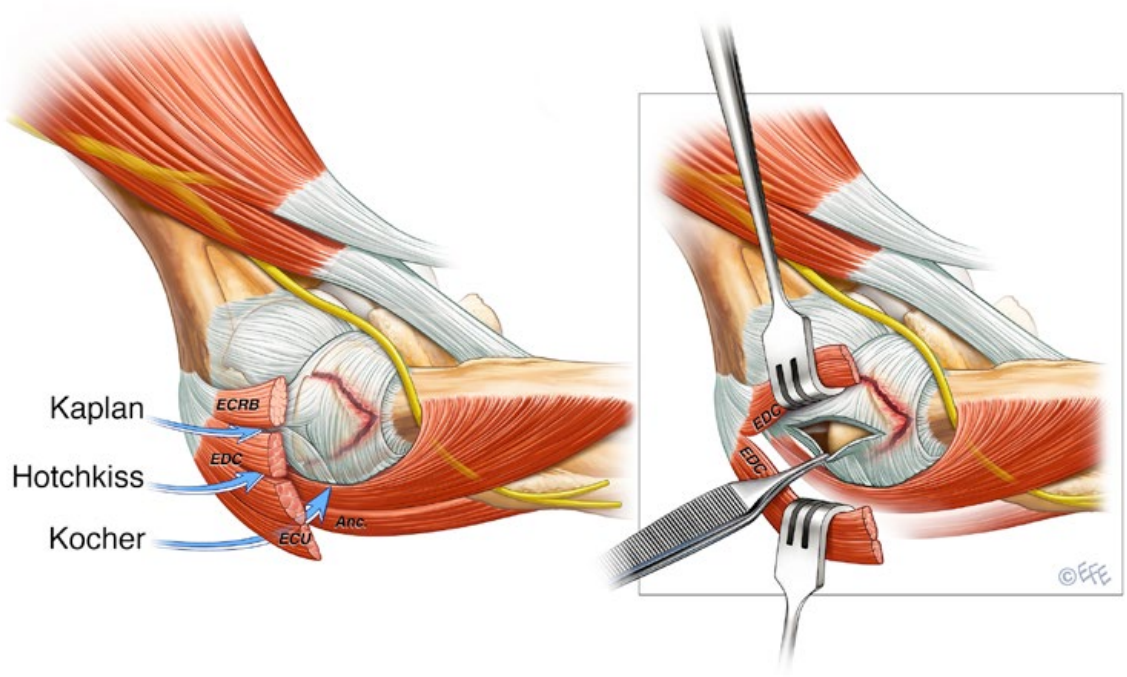
The Kaplan, Hotchkiss, or Kocher interval may be used for radiocapitellar dissection.

- The Kaplan interval is anterior between the extensor digitorum communis (EDC) and extensor carpi radialis brevi tendons (ECRB)
- The Hotchkiss interval is directly through the EDC muscle split
- The Kocher interval is posterior between the ECU and anconeus

The Hotchkiss EDC muscle-splitting approach is recommended for ease of dissection, direct access to the radial head, and avoidance of the lateral collateral ligament complex.

Using the EDC muscle-splitting approach, dissect sharply and directly over the radiocapitellar joint axis until the radiocapitellar joint capsule is identified.

Perform an arthrotomy in line with the EDC muscle split until the radial head and capitellum are exposed and the radiocapitellar joint is entered.



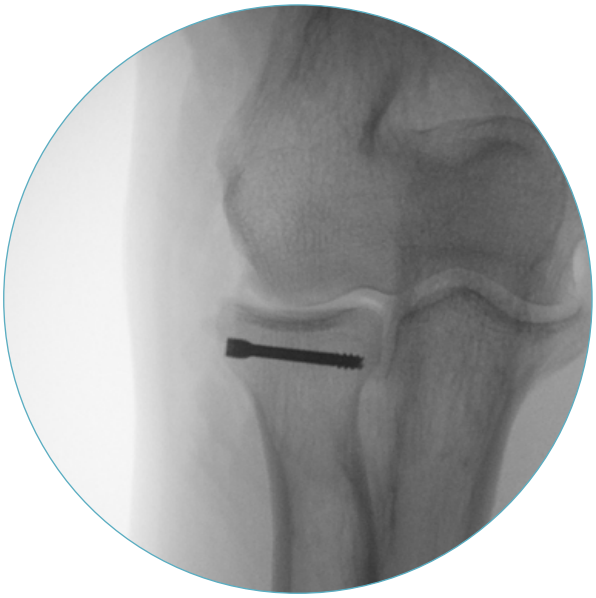
Dissection and arthrotomy should not be taken past the neck of the proximal radius to avoid injury to the posterior interosseous nerve (PIN). The forearm should remain pronated to move the PIN away from the surgical field. Surgical exposure can be increased by elevating the capsule and overlying soft tissue proximally and anteriorly off the supracondylar ridge.

STEP 3 SCREW INSERTION

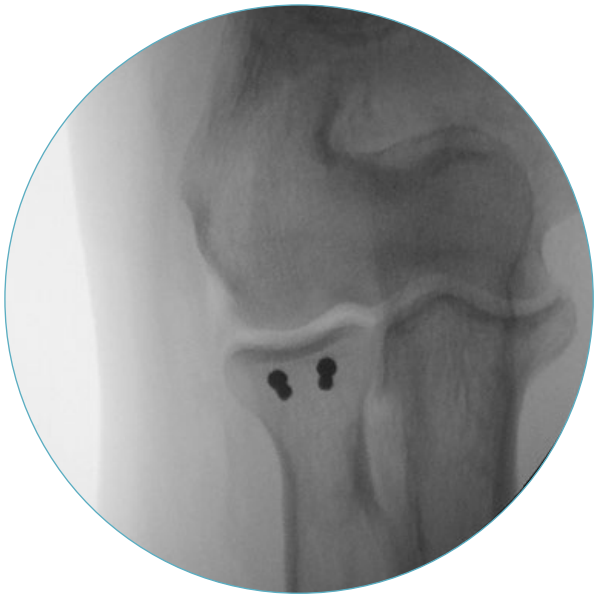
Follow instructions on pages 8-12 for preparation and screw insertion steps.

Refer to page 13 for removal instructions.

FINAL CONSTRUCT



Radial Head Fixation
AP View



Radial Head Fixation
Lateral View

SURGICAL APPROACH

CAPTIVATE®

Headless Screws for Medial Malleolus Fixation

STEP 1 PREOPERATIVE PLANNING

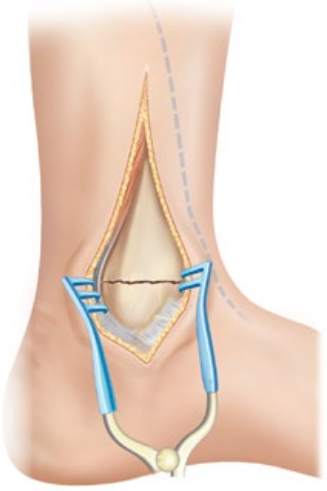
Assess the fracture using preoperative radiographs. Estimate the appropriate length and location of screws for proper screw placement.

STEP 2 PATIENT POSITIONING

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

STEP 3 APPROACH

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

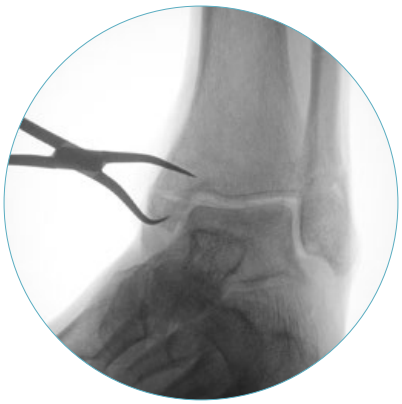


Medial approach

STEP 4 FRACTURE REDUCTION

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

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



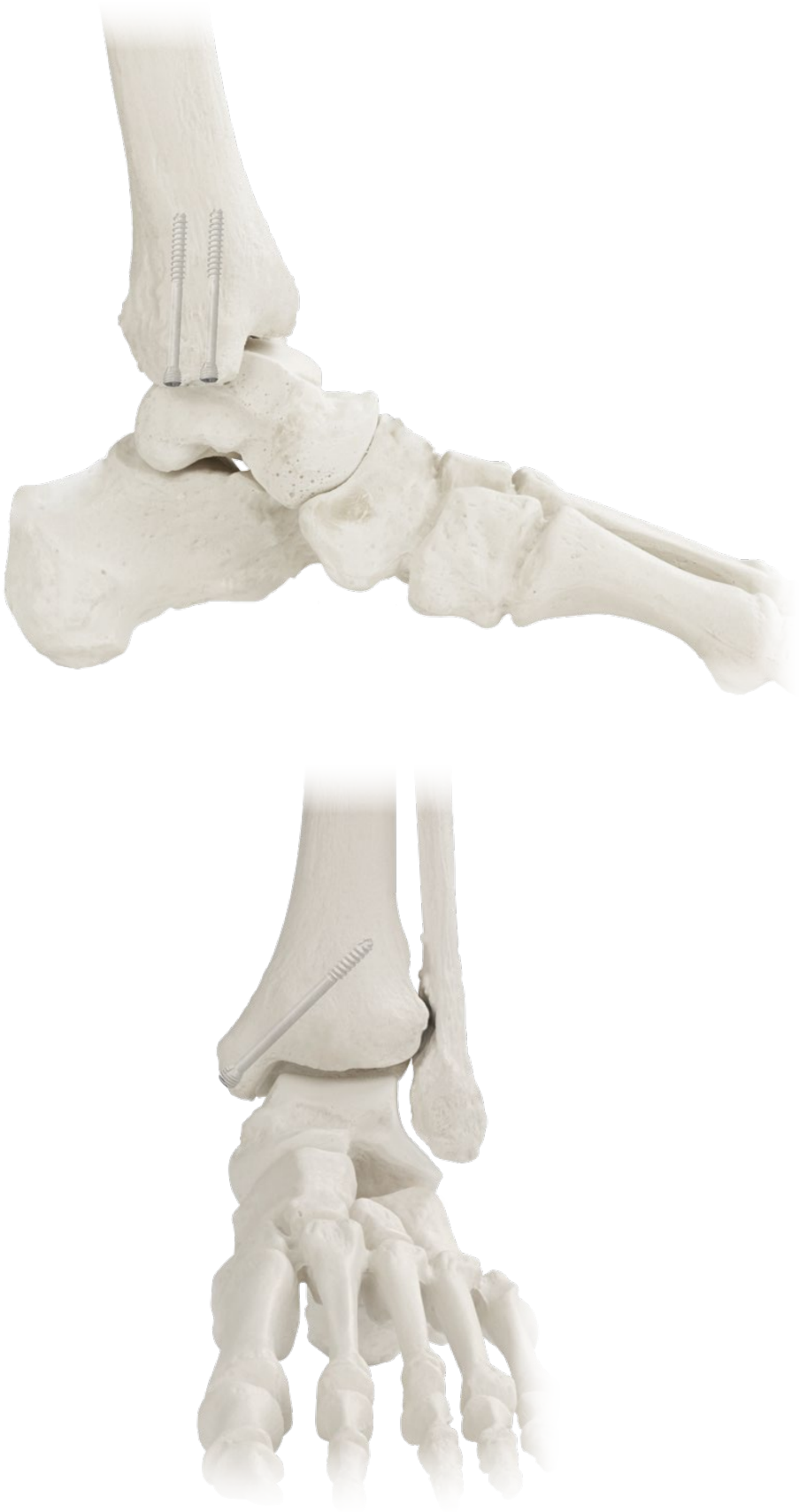
Fracture reduction with the Malleolar Clamp

The Malleolar Clamp is available in the ANTHEM® Ankle Fracture System.

STEP 5 SCREW INSERTION

Follow instructions on pages 8-12 for preparation and screw insertion steps.

Refer to page 13 for removal instructions.



INSTRUMENT OVERVIEW

ELEVATORS

Freer Elevator 6185.0005

Scaphoid Elevator 6188.7002

DENTAL PICK

Dental Pick, Curved Tip, Short Handle 6179.7012

2.5/3.0/4.0mm Soft Tissue Protector 6188.3425

FORCEPS

Screw Holding Forceps 6188.2015
Screw Holding Forceps 6179.2000

GUIDEWIRE MEASURING DEVICE

Guidewire Measuring Device 6188.7025

AO QUICK CONNECT HANDLES

Small Handle, Short, AO Quick Connect 6188.7000

Medium Handle, AO Quick Connect 6188.7001

DRIVERS

2.5mm/3.0mm Headless Driver 6188.6230
4.0mm Headless Driver 6188.6240

2.5mm/3.0mm T8 Driver, Straight, 1.2mm Cannulation, 80mm 6188.6308
4.0mm T15 Driver, Straight, 1.5mm Cannulation, 100mm 6188.6315

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

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

GUIDEWIRES

1.1mm Guidewire, Trocar Tip, 150mm 6188.1111
1.4mm Guidewire, Trocar Tip, 150mm 6188.1114

1.1mm Guidewire, Threaded Trocar Tip, 150mm 6188.1311
1.4mm Guidewire, Threaded Trocar Tip, 150mm 6188.1314

GUIDEWIRE SLEEVES

1.1mm Guidewire Sleeve 6188.3325
1.1mm Guidewire Sleeve 6188.3330
1.4mm Guidewire Sleeve 6188.3340

DRILL SLEEVES

2.0mm Drill Sleeve 6188.3125
2.2mm Drill Sleeve 6188.3130
2.8mm Drill Sleeve 6188.3140

TROCARS

1.1mm Trocar 6188.3730
1.4mm Trocar 6188.3740

TWIST DRILLS

2.0mm Drill Bit, Cannulated 6188.5320
2.2mm Drill Bit, Cannulated 6188.5322
2.8mm Drill Bit, Cannulated 6188.5328

NEAR CORTEX DRILLS

2.5mm Near Cortex Drill Bit 6188.5525
3.0mm Near Cortex Drill Bit 6188.5530
4.0mm Near Cortex Drill Bit 6188.5540

COMPRESSION SLEEVES

2.5mm Compression Sleeve 6188.6725
3.0mm Compression Sleeve 6188.6730
4.0mm Compression Sleeve 6188.6740

CANNULATED TAPS

2.5mm Cannulated Tap 6188.5125
3.0mm Cannulated Tap 6188.5130
4.0mm Cannulated Tap 6188.5140

CLEANING BRUSHES

1.2mm Cleaning Brush 6188.7130
1.4mm Cleaning Brush 6188.7140

CLEANING STYLETS

1.1mm Cleaning Stylet 6188.7230
1.4mm Cleaning Stylet 6188.7240

TRAPEZIUM DRILL

5.1mm Trapezium Drill, 1.2mm Cannulation 6188.5730

TRAPEZIUM DRILL SLEEVE

5.1mm Trapezium Drill Sleeve 6188.3451

CAPTIVATE® 2.5mm Headless Compression Screw Sets
9188.1252 Stainless Steel
9188.1251 Titanium

2.5mm Short Thread

STAINLESS STEEL PART NO.	TITANIUM PART NO.	LENGTH (mm)	QTY
2188.2709	1188.2709	9	2
2188.2710	1188.2710	10	2
2188.2711	1188.2711	11	2
2188.2712	1188.2712	12	2
2188.2713	1188.2713	13	2
2188.2714	1188.2714	14	2
2188.2715	1188.2715	15	2
2188.2716	1188.2716	16	2
2188.2717	1188.2717	17	2
2188.2718	1188.2718	18	2
2188.2719	1188.2719	19	2
2188.2720	1188.2720	20	2
2188.2721	1188.2721	21	2
2188.2722	1188.2722	22	2
2188.2723	1188.2723	23	2
2188.2724	1188.2724	24	2
2188.2725	1188.2725	25	2
2188.2726	1188.2726	26	2
2188.2727	1188.2727	27	2
2188.2728	1188.2728	28	2
2188.2729	1188.2729	29	2
2188.2730	1188.2730	30	2
2188.2732	1188.2732	32	2
2188.2734	1188.2734	34	2
2188.2736	1188.2736	36	2
2188.2738	1188.2738	38	2
2188.2740	1188.2740	40	2

2.5mm Long Thread

STAINLESS STEEL PART NO.	TITANIUM PART NO.	LENGTH (mm)	QTY
2188.2917	1188.2917	17	2
2188.2918	1188.2918	18	2
2188.2919	1188.2919	19	2
2188.2920	1188.2920	20	2
2188.2921	1188.2921	21	2
2188.2922	1188.2922	22	2
2188.2923	1188.2923	23	2
2188.2924	1188.2924	24	2
2188.2925	1188.2925	25	2
2188.2926	1188.2926	26	2
2188.2927	1188.2927	27	2
2188.2928	1188.2928	28	2
2188.2929	1188.2929	29	2
2188.2930	1188.2930	30	2
2188.2932	1188.2932	32	2
2188.2934	1188.2934	34	2
2188.2936	1188.2936	36	2
2188.2938	1188.2938	38	2
2188.2940	1188.2940	40	2


TITANIUM
SHORT THREAD
LONG THREAD
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CAPTIVATE® 3.0mm Headless Compression Screw Sets
9188.1302 Stainless Steel
9188.1301 Titanium

3.0mm Short Thread

STAINLESS STEEL PART NO.	TITANIUM PART NO.	LENGTH (mm)	QTY
2188.3210	1188.3210	10	2
2188.3211	1188.3211	11	2
2188.3212	1188.3212	12	2
2188.3213	1188.3213	13	2
2188.3214	1188.3214	14	2
2188.3215	1188.3215	15	2
2188.3216	1188.3216	16	2
2188.3217	1188.3217	17	2
2188.3218	1188.3218	18	2
2188.3219	1188.3219	19	2
2188.3220	1188.3220	20	2
2188.3221	1188.3221	21	2
2188.3222	1188.3222	22	2
2188.3223	1188.3223	23	2
2188.3224	1188.3224	24	2
2188.3225	1188.3225	25	2
2188.3226	1188.3226	26	2
2188.3227	1188.3227	27	2
2188.3228	1188.3228	28	2
2188.3229	1188.3229	29	2
2188.3230	1188.3230	30	2
2188.3232	1188.3232	32	2
2188.3234	1188.3234	34	2
2188.3236	1188.3236	36	2
2188.3238	1188.3238	38	2
2188.3240	1188.3240	40	2

3.0mm Long Thread

STAINLESS STEEL PART NO.	TITANIUM PART NO.	LENGTH (mm)	QTY
2188.3416	1188.3416	16	2
2188.3417	1188.3417	17	2
2188.3418	1188.3418	18	2
2188.3419	1188.3419	19	2
2188.3420	1188.3420	20	2
2188.3421	1188.3421	21	2
2188.3422	1188.3422	22	2
2188.3423	1188.3423	23	2
2188.3424	1188.3424	24	2
2188.3425	1188.3425	25	2
2188.3426	1188.3426	26	2
2188.3427	1188.3427	27	2
2188.3428	1188.3428	28	2
2188.3429	1188.3429	29	2
2188.3430	1188.3430	30	2
2188.3432	1188.3432	32	2
2188.3434	1188.3434	34	2
2188.3436	1188.3436	36	2
2188.3438	1188.3438	38	2
2188.3440	1188.3440	40	2


TITANIUM
SHORT THREAD
LONG THREAD
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CAPTIVATE® 4.0mm Headless Compression Screw Sets
9188.1402 Stainless Steel
9188.1401 Titanium

4.0mm Short Thread

STAINLESS STEEL PART NO.	TITANIUM PART NO.	LENGTH (mm)	QTY
2188.4216	1188.4216	16	2
2188.4218	1188.4218	18	2
2188.4220	1188.4220	20	2
2188.4222	1188.4222	22	2
2188.4224	1188.4224	24	2
2188.4226	1188.4226	26	2
2188.4228	1188.4228	28	2
2188.4230	1188.4230	30	2
2188.4232	1188.4232	32	2
2188.4234	1188.4234	34	2
2188.4236	1188.4236	36	2
2188.4238	1188.4238	38	2
2188.4240	1188.4240	40	2
2188.4242	1188.4242	42	2
2188.4244	1188.4244	44	2
2188.4246	1188.4246	46	2
2188.4248	1188.4248	48	2
2188.4250	1188.4250	50	2
2188.4252	1188.4252	52	2
2188.4254	1188.4254	54	2
2188.4256	1188.4256	56	2
2188.4258	1188.4258	58	2
2188.4260	1188.4260	60	2

4.0mm Long Thread

STAINLESS STEEL PART NO.	TITANIUM PART NO.	LENGTH (mm)	QTY
2188.4416	1188.4416	16	2
2188.4418	1188.4418	18	2
2188.4420	1188.4420	20	2
2188.4422	1188.4422	22	2
2188.4424	1188.4424	24	2
2188.4426	1188.4426	26	2
2188.4428	1188.4428	28	2
2188.4430	1188.4430	30	2
2188.4432	1188.4432	32	2
2188.4434	1188.4434	34	2
2188.4436	1188.4436	36	2
2188.4438	1188.4438	38	2
2188.4440	1188.4440	40	2
2188.4442	1188.4442	42	2
2188.4444	1188.4444	44	2
2188.4446	1188.4446	46	2
2188.4448	1188.4448	48	2
2188.4450	1188.4450	50	2
2188.4452	1188.4452	52	2
2188.4454	1188.4454	54	2
2188.4456	1188.4456	56	2
2188.4458	1188.4458	58	2
2188.4460	1188.4460	60	2


STAINLESS
SHORT THREAD
LONG THREAD
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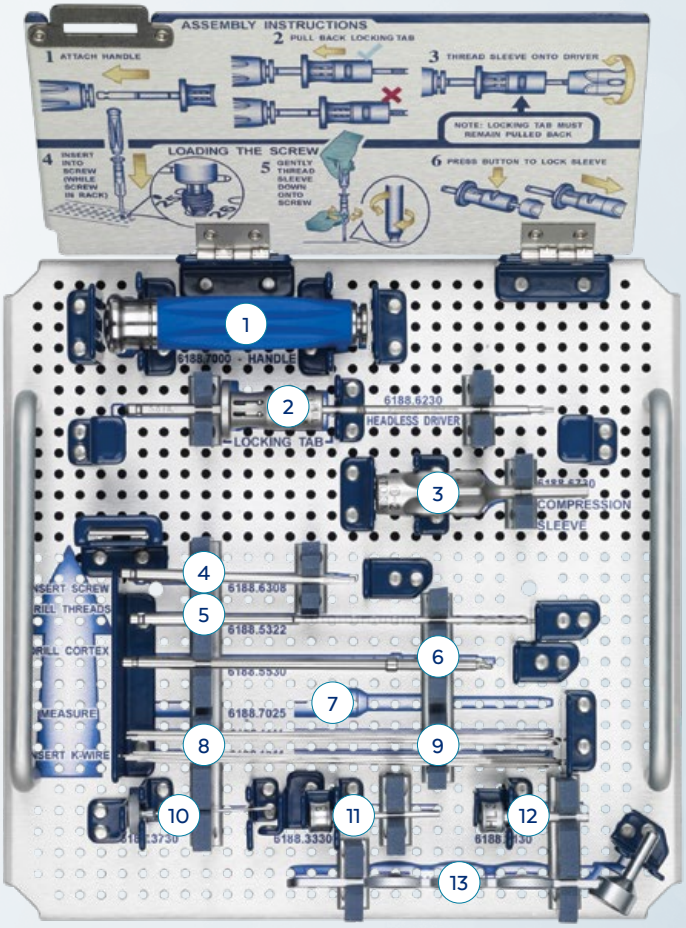
CAPTIVATE® 2.5mm Headless Compression Screw
INSTRUMENT SETS 9188.9251 and 9188.9252

	PART NO.	DESCRIPTION	QTY
1	6188.7000	Small Handle, Short, AO Quick Connect	2
2	6188.6230	2.5mm Headless Driver	2
3	6188.6725	2.5mm Compression Sleeve	2
4	6188.6308	T8 Driver, Cannulated, 100mm, AO Quick Connect	2
5	6188.6230	2.0mm Cannulated Drill Bit	2
6	6188.5525	2.5mm Near Cortex Drill Bit	2
7	6188.7025	Guidewire Measuring Device	1
8	6188.1111	1.1mm Guidewire, Trocar Tip, 150mm	10
9	6188.1311	1.1mm Guidewire, Threaded Trocar Tip, 150mm	10
10	6188.3730	1.1mm Trocar	1
11	6188.3325	1.1mm Guidewire Sleeve	1
12	6188.3125	2.0mm Drill Sleeve	1
13	6188.3425	2.5/3.0/4.0mm Soft Tissue Protector	1
14	6179.7012	Dental Pick, Curved Tip, Short Handle	1
15	6188.5125	2.5mm Cannulated Tap	1
16	6188.7130	1.2mm Cleaning Brush	1
17	6188.7230	1.1mm Cleaning Stylet	1
18	6185.0005	Freer Elevator	1
19	6188.7002	Scaphoid Elevator	1
20	6188.5730	5.1mm Trapezium Drill	1
21	6188.3451	5.1mm Trapezium Drill Sleeve	1
	6179.2015	Screw Holding Forceps	1
	6188.6308	T8 Driver, Non-Self Retaining, 100mm, AO Quick Connect	2
	9188.1252	CAPTIVATE® Headless 2.5mm Screw Module	
	9188.0252	CAPTIVATE® Headless 2.5mm Graphic Case	


ASSEMBLY INSTRUCTIONS
1 ATTACH HANDLE
2 PULL BACK LOCKING TAB
3 THREAD SLEEVE ONTO DRIVER
NOTE: LOCKING TAB MUST REMAIN PULLED BACK
LOADING THE SCREW
4 INSERT INTO SCREW (WHILE SCREW IS RACK)
5 GENTLY THREAD SLEEVE DOWN ONTO SCREW
6 PRESS BUTTON TO LOCK SLEEVE
1
6188.7000 - HANDLE
2
6188.6230
HEADLESS DRIVER
LOCKING TAB
3
COMPRESSION SLEEVE
4
6188.6308
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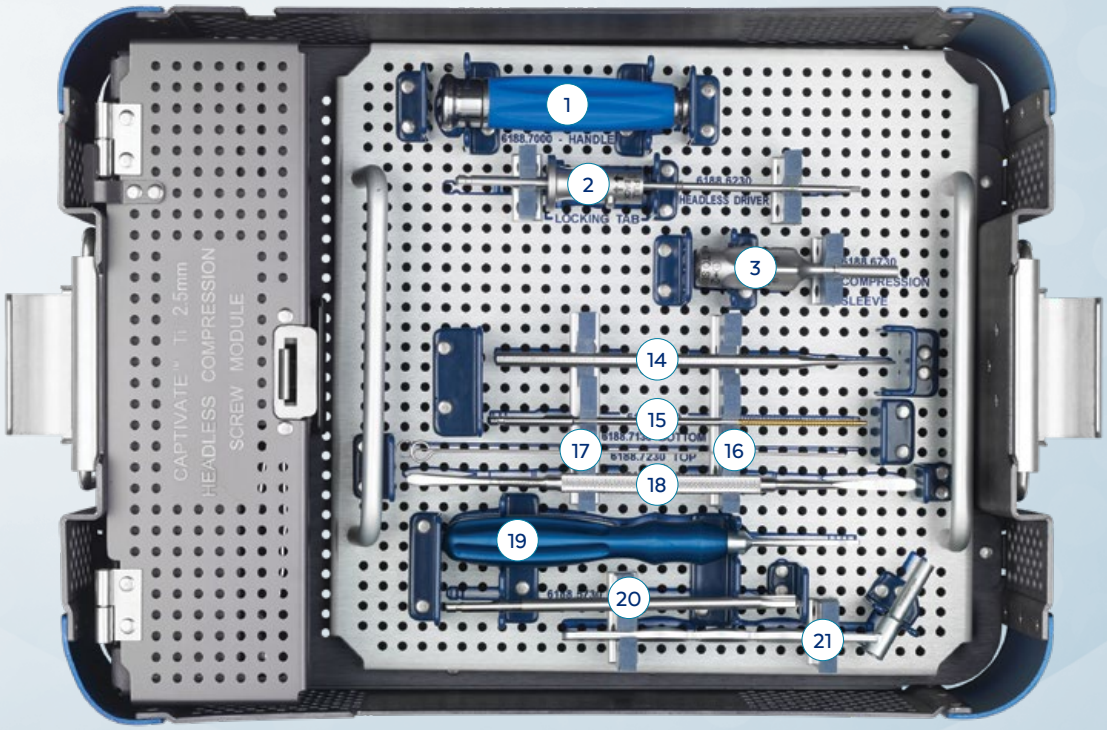
CAPTIVATE™ Ti 2.5mm
HEADLESS COMPRESSION
SCREW MODULE
1
6188.7000 - HANDLE
2
6188.6230
HEADLESS DRIVER
LOCKING TAB
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6188.6730
COMPRESSION SLEEVE
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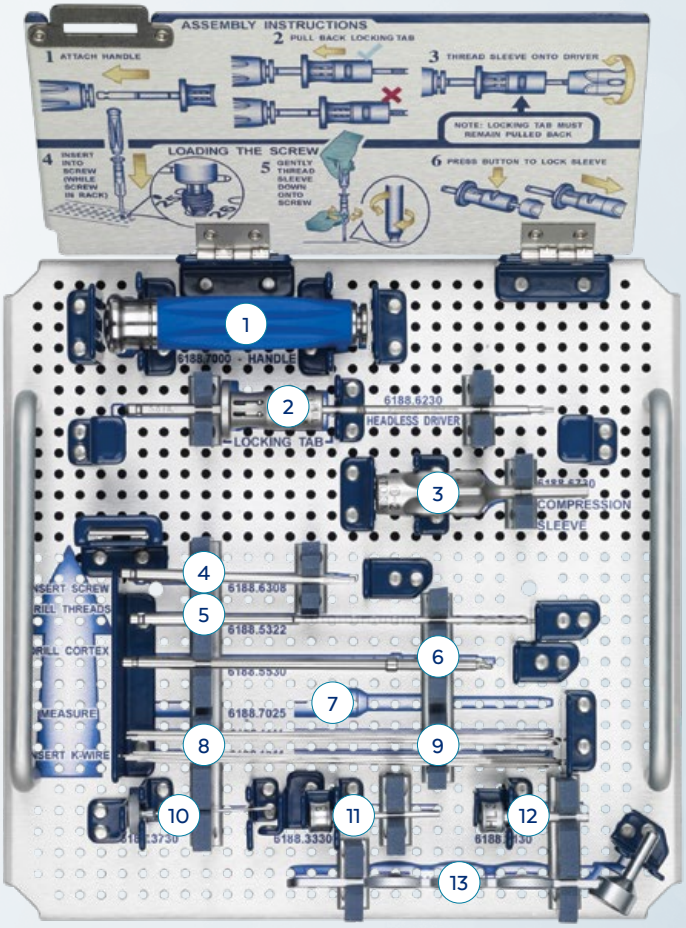
CAPTIVATE® 3.0mm Headless Compression Screw
INSTRUMENT SETS 9188.9301 and 9188.9302

	PART NO.	DESCRIPTION	QTY
1	6188.7000	Small Handle, Short, AO Quick Connect	2
2	6188.6230	3.0mm Headless Driver	2
3	6188.6730	3.0mm Compression Sleeve	2
4	6188.6308	T8 Driver, Cannulated, 100mm, AO Quick Connect	2
5	6188.5322	2.2mm Cannulated Drill Bit	2
6	6188.5530	3.0mm Near Cortex Drill Bit	2
7	6188.7025	Guidewire Measuring Device	1
8	6188.1111	1.1mm Guidewire, Trocar Tip, 150mm	10
9	6188.1311	1.1mm Guidewire, Threaded Trocar Tip, 150mm	10
10	6188.3730	1.1mm Trocar	1
11	6188.3330	1.1mm Guidewire Sleeve	1
12	6188.3130	2.2mm Drill Sleeve	1
13	6188.3425	2.5/3.0/4.0mm Soft Tissue Protector	1
14	6179.7012	Dental Pick, Curved Tip, Short Handle	1
15	6188.5130	3.0mm Cannulated Tap	1
16	6188.7130	1.2mm Cleaning Brush	1
17	6188.7230	1.1mm Cleaning Stylet	1
18	6185.0005	Freer Elevator	1
19	6188.7002	Scaphoid Elevator	1
20	6188.5751	5.1mm Trapezium Drill	1
21	6188.3451	5.1mm Trapezium Drill Sleeve	1
	6179.2015	Screw Holding Forceps	1
	6188.6308	T8 Driver, Non-Self Retaining, 100mm, AO Quick Connect	2
	9188.1301	CAPTIVATE® Headless 3.0mm Screw Module	
	9188.0301	CAPTIVATE® Headless 3.0mm Graphic Case	


ASSEMBLY INSTRUCTIONS
1 ATTACH HANDLE
2 PULL BACK LOCKING TAB
3 THREAD SLEEVE ONTO DRIVER
NOTE: LOCKING TAB MUST REMAIN PULLED BACK
LOADING THE SCREW
4 INSERT INTO SCREW (WHILE SCREW IS RACK)
5 GENTLY THREAD SLEEVE DOWN ONTO SCREW
6 PRESS BUTTON TO LOCK SLEEVE
1
6188.7000 - HANDLE
2
6188.6230
HEADLESS DRIVER
LOCKING TAB
3
COMPRESSION SLEEVE
4
6188.6308
5
6188.5322
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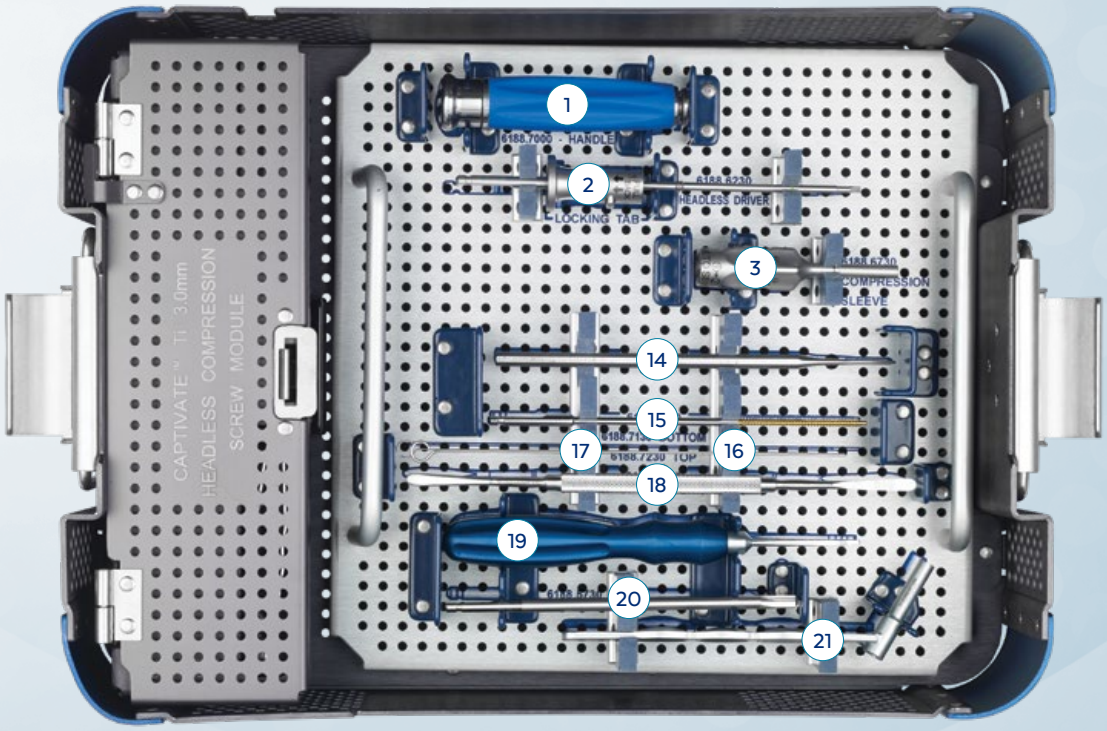
6188.3330


CAPTIVATE™ Ti 3.0mm
HEADLESS COMPRESSION
SCREW MODULE
1
6188.7000 - HANDLE
2
6188.6230
HEADLESS DRIVER
LOCKING TAB
3
6188.6730
COMPRESSION SLEEVE
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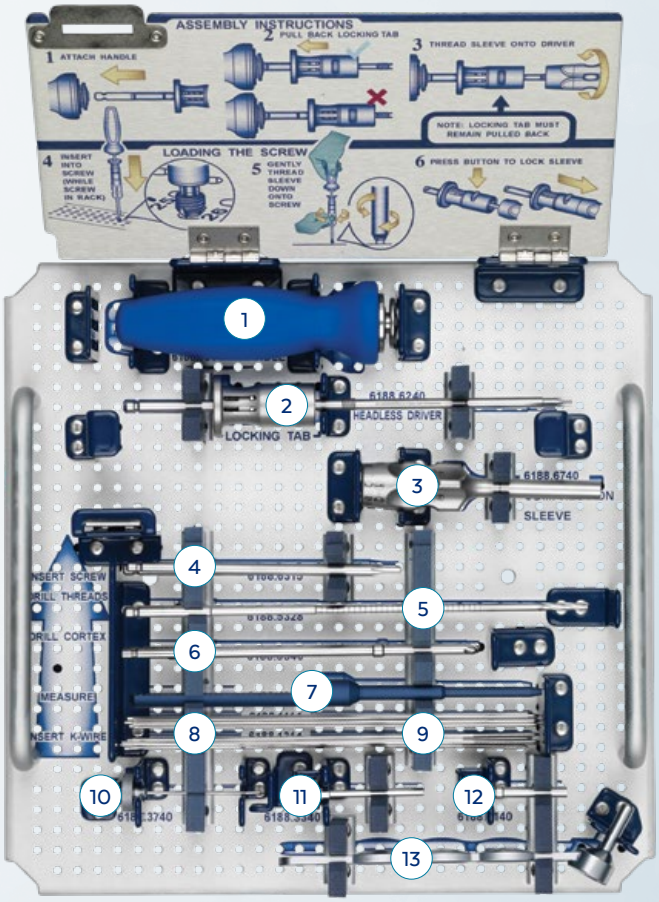
CAPTIVATE® 4.0mm Headless Compression Screw
INSTRUMENT SETS 9188.9401 and 9188.9402

	PART NO.	DESCRIPTION	QTY
1	6188.7001	Medium Handle, AO Quick Connect	2
2	6188.6240	4.0mm Headless Driver	2
3	6188.6740	4.0mm Compression Sleeve	2
4	6188.6315	T15 Driver, Cannulated, 165mm, AO Quick Connect	2
5	6188.5328	2.8mm Cannulated Drill Bit	2
6	6188.5540	4.0mm Near Cortex Drill Bit	2
7	6188.7025	Guidewire Measuring Device	1
8	6188.1114	1.4mm Guidewire, Trocar Tip, 150mm	10
9	6188.1314	1.4mm Guidewire, Threaded Trocar Tip, 150mm	10
10	6188.3740	1.4mm Trocar	1
11	6188.3340	1.4mm Guidewire Sleeve	1
12	6188.3140	2.8mm Drill Sleeve	1
13	6188.3425	2.5/3.0/4.0mm Soft Tissue Protector	1
14	6179.7012	Dental Pick, Curved Tip, Short Handle	1
15	6188.5140	4.0mm Cannulated Tap	1
16	6188.7140	1.5mm Cleaning Brush	1
17	6188.7240	1.4mm Cleaning Stylet	1
18	6185.0005	Freer Elevator	1
	6179.2000	Screw Holding Forceps	1
	9188.1402	CAPTIVATE® Headless 4.0mm Screw Module	
	9188.0402	CAPTIVATE® Headless 4.0mm Graphic Case	


ASSEMBLY INSTRUCTIONS
1 ATTACH HANDLE
2 PULL BACK LOCKING TAB
3 THREAD SLEEVE ONTO DRIVER
NOTE: LOCKING TAB MUST REMAIN PULLED BACK
4 INSERT INTO SCREW (WHILE SCREW IN RACK)
LOADING THE SCREW
5 GENTLY THREAD SLEEVE DOWN ONTO SCREW
6 PRESS BUTTON TO LOCK SLEEVE
1
2
6188.6240
HEADLESS DRIVER
LOCKING TAB
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6188.6740
SLEEVE
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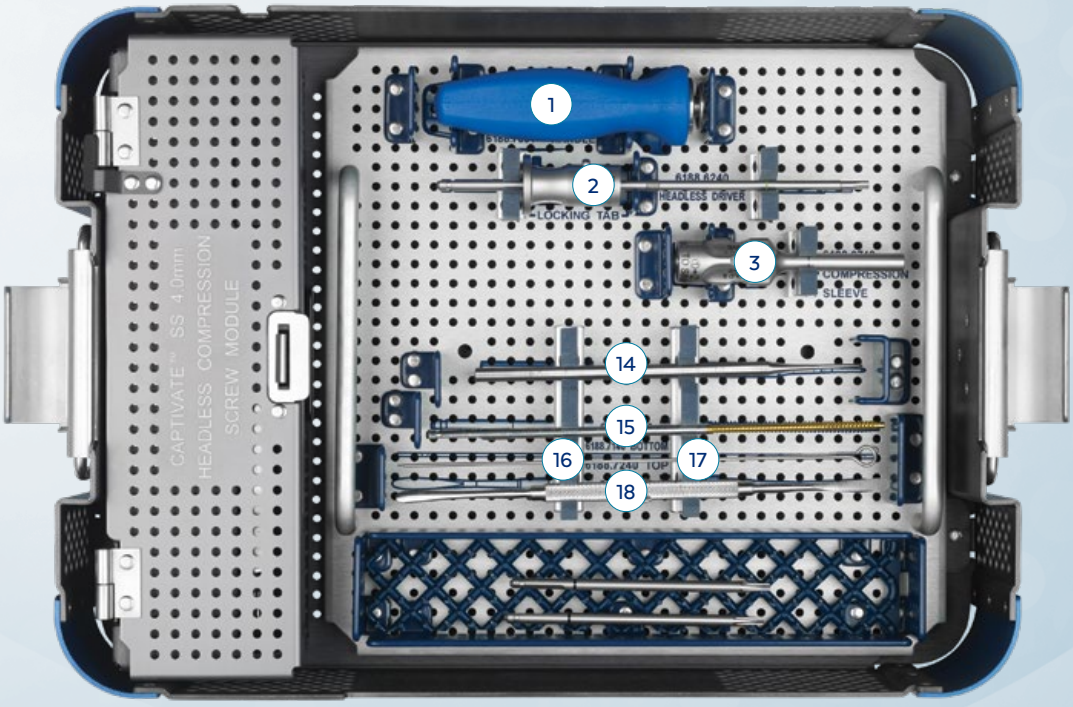
INSERT SCREW
DRILL THREADS
DRILL CORTEX
MEASURE
INSERT K-WIRE


1
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6188.6240
HEADLESS DRIVER
LOCKING TAB
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COMPRESSION SLEEVE
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18
CAPTIVATE™ SS 4.0mm
HEADLESS COMPRESSION
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.

MR SAFETY INFORMATION

These devices have not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of these devices in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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.

Intra-operative

- Avoid surface damage of implants.
- Discard all damaged or mishandled implants
- Contouring or bending of an implant should be avoided where possible, because it may reduce its fatigue strength and can cause failure under load.
- Implants are available in different versions, varying for example in length, diameter, material and number of drilled holes. Select the required version carefully.
- During the course of the operation, repeatedly check to ensure that the connection between the implant and the instrument, or between the instruments, is secure.
- Implants which consist of several components must only be used in the prescribed combination (refer to the 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).

Post-operative

- 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 results of strenuous activity, trauma, mal-union or non-union and that the device has a finite expected service life and may need to be removed at some time in the future.

ADVERSE EFFECTS

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

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

IMPORTANT INFORMATION ON CAPTIVATE® COMPRESSION SCREWS

- Early or late infection, deep or superficial.
- Deep venous thrombosis.
- Avascular necrosis.
- Shortening of the effected bone/fracture site.
- Subclinical nerve damage may possibly occur as a result of the surgical trauma.
- Material sensitivity reactions in patients following surgical implantation have rarely been reported, however their significance awaits further clinical evaluation comminuted fractures.

PACKAGING

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

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

HANDLING

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

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

CLEANING

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

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

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

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

CONTACT INFORMATION

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

STERILIZATION

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

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

Nonsterile implants and instruments have been validated following ANSI/AAMI/ISO 17665-1:2006 Guidelines for Steam Sterility Validation to assure a Sterility Assurance Level (SAL) of 10^{-6}. The use of an FDA-cleared wrap is recommended, per the Association for the Advancement of Medical Instrumentation (AAMI) ST79, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities.* It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the FDA for the selected sterilization cycle specifications (time and temperature).

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

Recommended sterilization parameters are listed in the table below.

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

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

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

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

CAUTION: Federal Law (USA) Restricts this Device to Sale by or on the order of a Physician.

SYMBOL TRANSLATION			
REF	CATALOGUE NUMBER	STERILE R	STERILIZED BY IRRADIATION
LOT	LOT NUMBER	EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
⚠	CAUTION		MANUFACTURER
	SINGLE USE ONLY		USE BY (YYYY-MM-DD)
QTY	QUANTITY		

DI200 REV B

NOTES

NOTES

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

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

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