FORTIFY® I-R

Static Corpectomy Spacer System

GLOBUS MEDICAL

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

Life moves us

SURGICAL TECHNIQUE GUIDE

FORTIFY® I-R

FORTIFY® I-R

Static Corpectomy Spacer System

The static FORTIFY® I-R spacer is a corpectomy spacer system designed to provide anterior column support and prevent dislodgement. The PEEK spacer has integrated titanium plates and screws for additional stabilization between the vertebral bodies and the spacer.

The spacer is offered in a wide range of heights and lordotic options and comes preassembled to simplify the procedure.

Postoperative Visualization

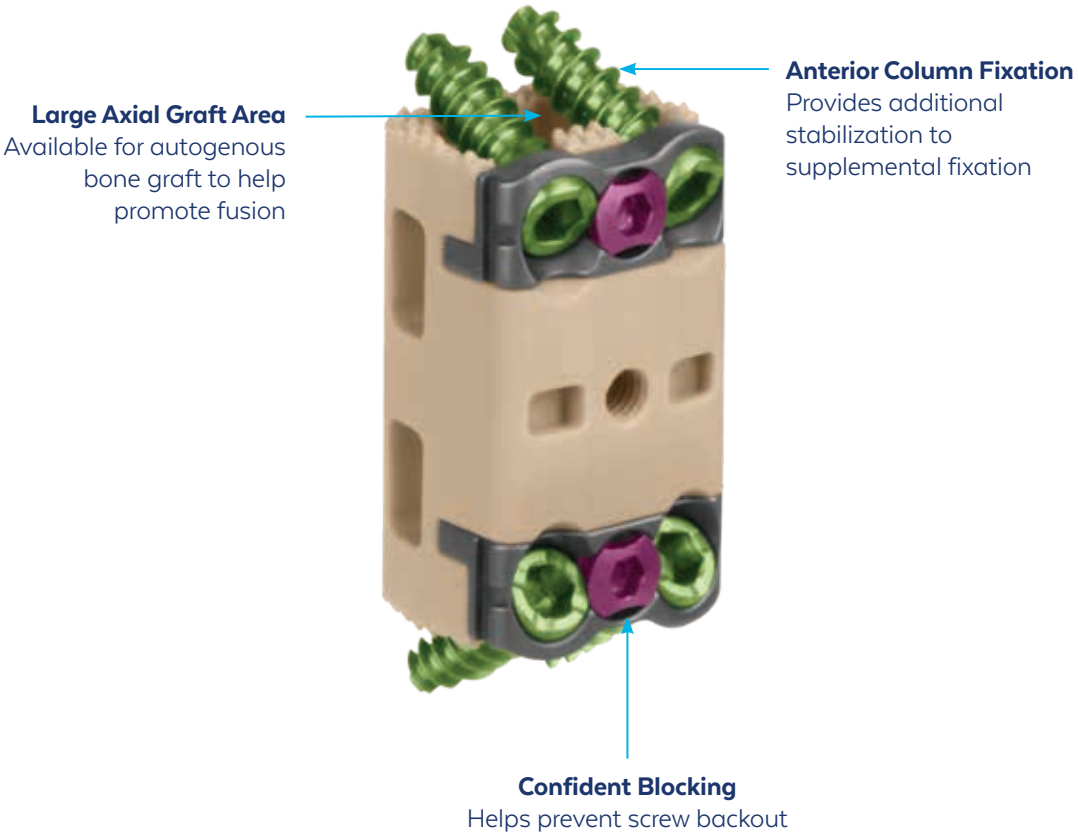
Radiolucent PEEK material gives improved postoperative visualization and a modulus of elasticity closer to bone.

Sagittal Alignment Restoration

A variety of lordotic options are designed to help restore the natural anatomy of the spine.

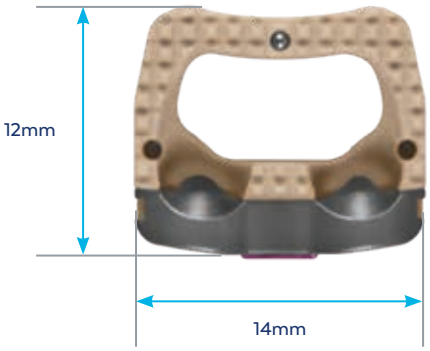
Simple Sizing

The spacer is preassembled and requires no cutting or stacking for proper sizing.



IMPLANT OVERVIEW

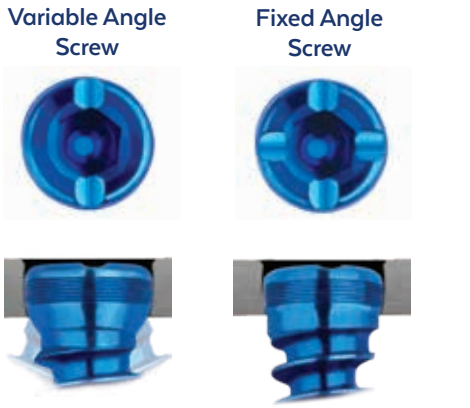
Static Footprint	Heights	Angles
12x14mm	15-33mm (2mm increments)	0°
		3.5°/3.5°
		0°/7°



Note: Radiographic markers are shown on page 23.

FORTIFY® I-R Small Screws

- Self-drilling and self-tapping screws
- 3.6mm and 4.2mm diameter
- Lengths from 12-20mm, in 2mm increments
- Fixed and variable angle screws (±4°)



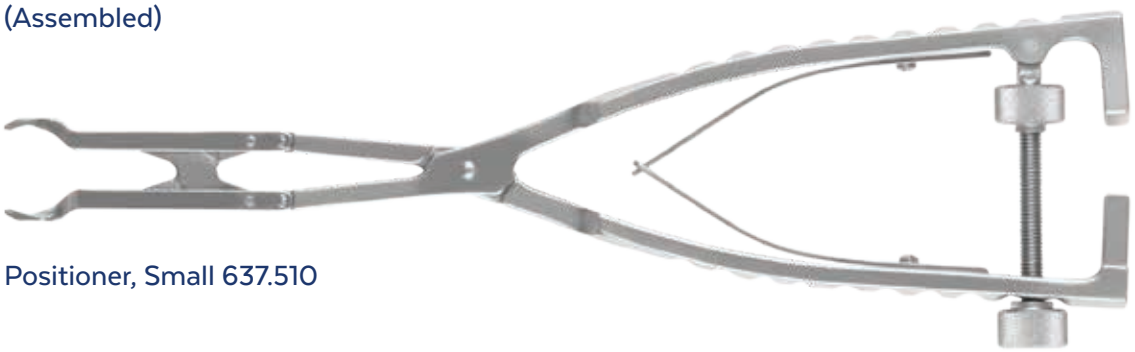
INSTRUMENT OVERVIEW

IMPLANT HOLDERS

Inserter Shaft 637.500

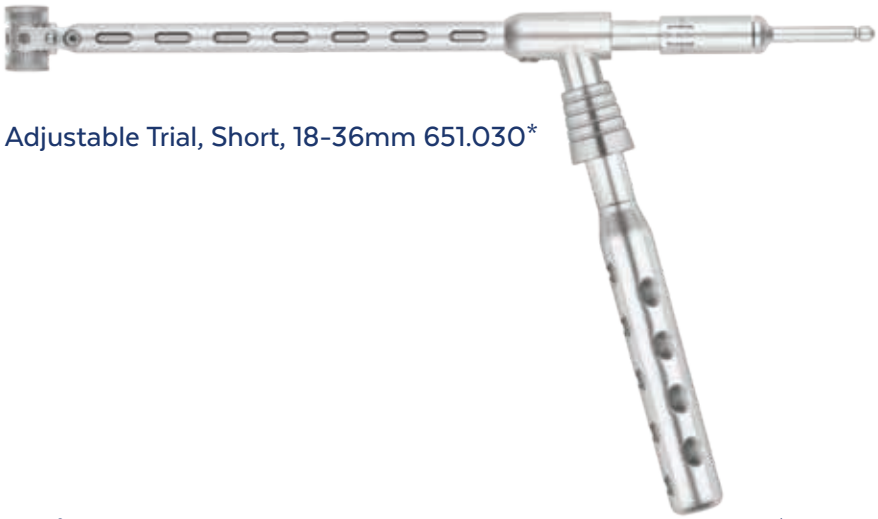
Inserter Sleeve 637.501

Inserter Assembly
Inserter Shaft 637.500
Inserter Sleeve 637.501
(Assembled)



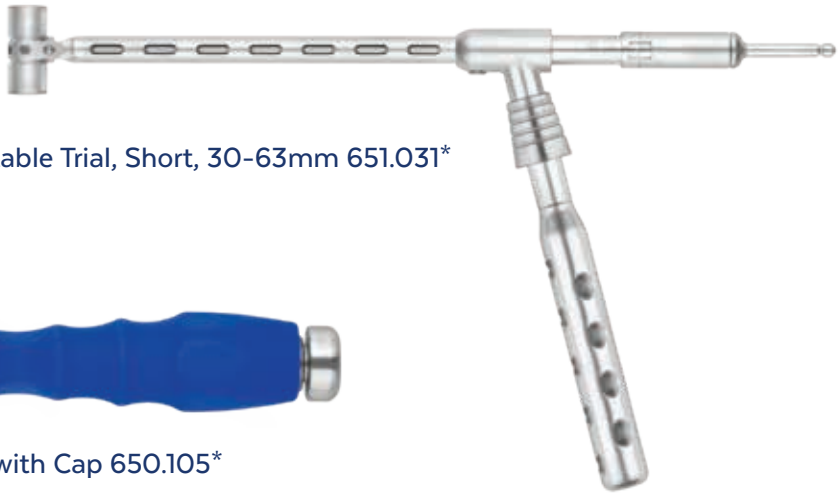
Positioner, Small 637.510

ADJUSTABLE TRIALS



Adjustable Trial, Short, 18-36mm 651.030*

**Instrument located in FORTIFY® 12/14mm Instrument Set 951.912*



Adjustable Trial, Short, 30-63mm 651.031*

QC Handle, Small, with Cap 650.105*

DISTRACTOR

Measuring Distractor, Small 651.035*

TRIALS

Trial Holder, Short 651.023*

	Part Description	Part Number
	Trial Head, 12x14mm	637.024

Trial Head, 12x14mm 637.024
Trial Holder, Short 651.023*
(Assembled)

**Instrument located in FORTIFY® 12/14mm Instrument Set 951.912*

SMALL STRAIGHT INSTRUMENTS

Awl with Self-Centering Sleeve, Straight 684.403

Tap, Straight 684.004

Straight Drill with Self-Centering Sleeve

Length	Part Number
12mm	684.422
14mm	684.424
16mm	684.426
18mm	684.428
20mm	684.430

Screwdriver, 2.5mm Hex, Self-Retaining, with Cap 684.305

SMALL ANGLED INSTRUMENTS

Counter-Torque, Angled Instrument 684.421

Awl with Self-Centering Sleeve, Bent 684.404

Angled Sleeve 684.415

Angled Sleeve with Backing Nut 684.416

Angled Driver Shaft 684.417

	Part Number	Angled Instrument
1	684.419	Angled Tap Tip
2	684.418	Hex Driver Assembly
3	684.418	Hex Driver Assembly
4	684.432	Angled Drill Tip, 12mm
5	684.434	Angled Drill Tip, 14mm
6	684.436	Angled Drill Tip, 16mm
7	684.438	Angled Drill Tip, 18mm
8	684.440	Angled Drill Tip, 20mm

Angled Driver Assembly
Angled Sleeve 684.415, Angled Sleeve with Backing Nut 684.416, Angled Driver Shaft 684.417 (Assembled)

SMALL SET SCREW INSTRUMENTS

Set Screw Positioner, 2.0mm Hex, Torque-Limiting 650.312

Screwdriver, 2.1mm Hex, QC 671.313

GRAFT PACKER

Graft Packer, 12/14mm Core 651.022*

TAMP

Tamp, Straight, 12/14mm Core 651.020*

**Instrument located in FORTIFY® 12/14mm Instrument Set 951.912*

SMALL ADDITIONAL INSTRUMENTS

Quick-Connect Handle, Swivel 636.450

Self-Centering Sleeve – Long 684.402

Self-Centering Sleeve – Short 684.401

Drill Sleeve Adjuster 684.309

SURGICAL TECHNIQUE

FORTIFY® I-R

STEP 1 APPROACH/CORPECTOMY

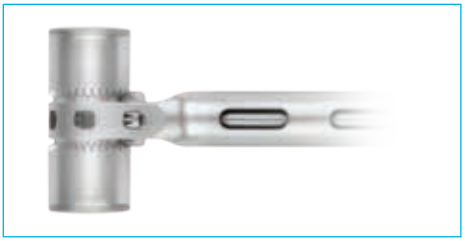
The FORTIFY® I-R Corpectomy Spacer may be inserted using one of the following approaches: anterior, anterolateral, or lateral. For the purposes of this technique guide, an anterior approach is shown. FORTIFY® I-R is intended for use with supplemental fixation. For the purposes of this technique guide, posterior fixation is shown inserted prior to the corpectomy procedure.

Place the patient in the appropriate position for the desired approach. Remove the vertebral body(s) at the desired level(s) to achieve a partial or complete corpectomy. Remove disc material using rongeurs, rasps, curettes, and other suitable preparation instruments.

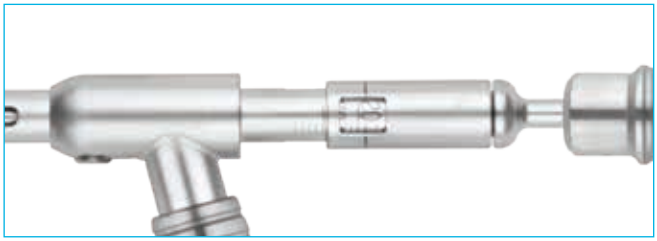
STEP 2 DISTRACTION AND IMPLANT SIZING

Determine the approximate height of the corpectomy space using the **Adjustable Trial***. Insert the trial into the defect space at its contracted height. Expand the trial gradually to the desired height by rotating the **QC Handle, Small, with Cap**.*

Note: Use caution while expanding the Adjustable Trial to avoid excessive distraction and potential damage to the endplates.



Adjustable Trial at its contracted height

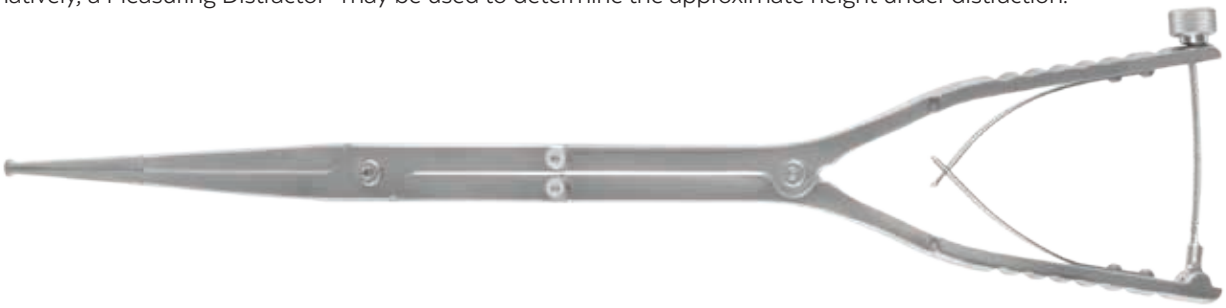


Measured height (mm) is shown through the window

Incorrect

Correct

Alternatively, a Measuring Distractor* may be used to determine the approximate height under distraction.



*Provided in the FORTIFY® 12/14mm Instrument Set 951.912.

STEP 3 ENDPLATE MEASUREMENT

Attach the Trial Head 12x14mm to the Trial Holder, Short.* Sweep the trial along the defect space to ensure the implant fits the endplates. Use fluoroscopy to determine the desired sagittal angle of the endplates.

Endplate measurement using the Trial Holder, Short

STEP 4 PACKING GRAFT INTO THE IMPLANT

Once the proper implant has been selected, the Graft Packer 12/14mm Core* may be used to pack autogeneous graft material or allograft into the implant.

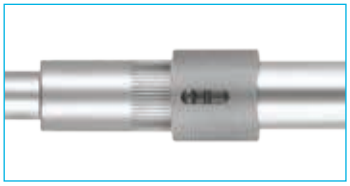
Using the Graft Packer

*Provided in the FORTIFY® 12/14mm Instrument Set 951.912.

STEP 5 IMPLANT ATTACHMENT

Ensure that the Inserter Assembly is in the unlocked position. Thread the implant onto the inserter by rotating the handle clockwise. Lock the inserter by pushing the locking nut forward. The implant is now ready to be inserted.

Inserter Assembly



Unlocked

Locked

STEP 6 IMPLANT INSERTION

Insert the selected implant into the corpectomy space. If needed, the **Tamp, Straight, 12/14mm Core*** may be used for light impaction.

To disengage the implant from the inserter, unlock and rotate the handle counterclockwise.

**Provided in the FORTIFY® 12/14mm Instrument Set 951.912.*

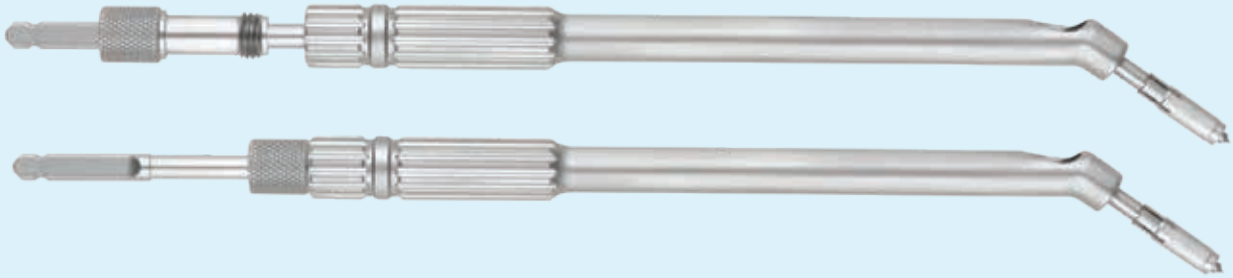
ASSEMBLING THE ANGLED INSTRUMENTS

1. Select the appropriate **Tip** (**Angled Driver, Angled Drill,*** or **Angled Tap***).

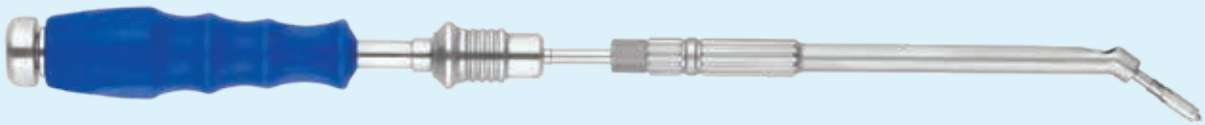
2. Hold the **Angled Driver Body** pointed downward with the cutout facing upward. Insert the selected tip into the cutout on the distal end of the driver body.

3. Insert the **Angled Driver Shaft** into the driver body until the gears on the shaft mesh with the gears on the selected tip.

4. Place the **Backing Nut** over the shaft. Rotate the threads clockwise until the nut sits flush with the driver body.



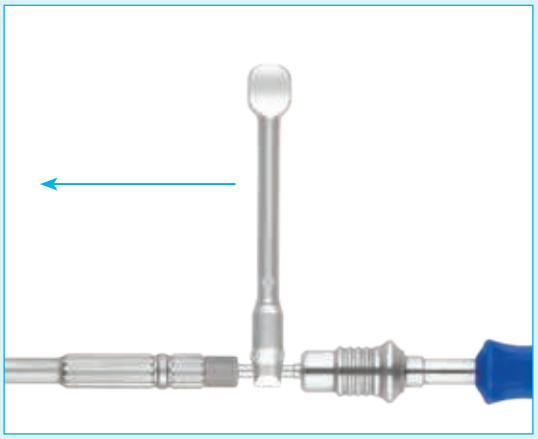
5. Attach a **Quick-Connect Handle, Swivel**. The driver is now ready for use.



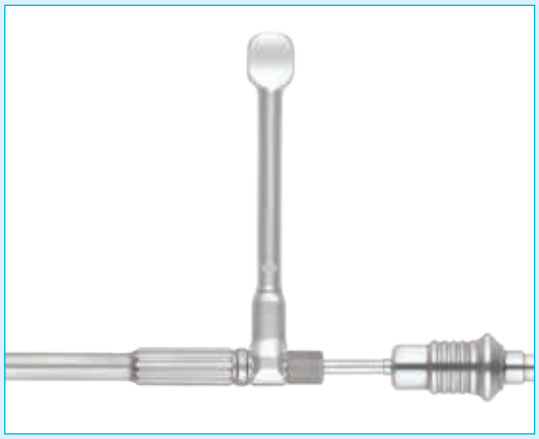
Instrument dimensions are provided on page 25.

6. For additional control of the distal tip, a **Counter-Torque, Angled Instrument** may be attached.

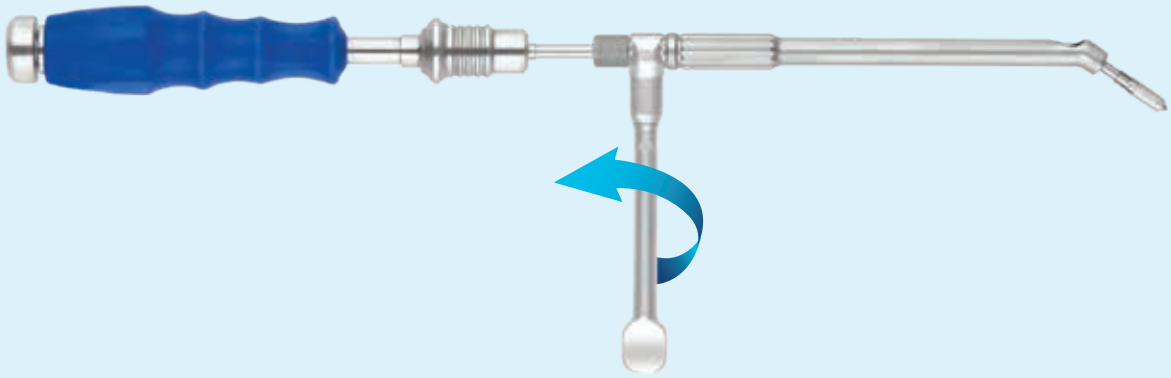
Starting from the top, slide the counter-torque from the smooth portion of the driver body to the knurled portion until fully seated.



Attaching the Counter-Torque



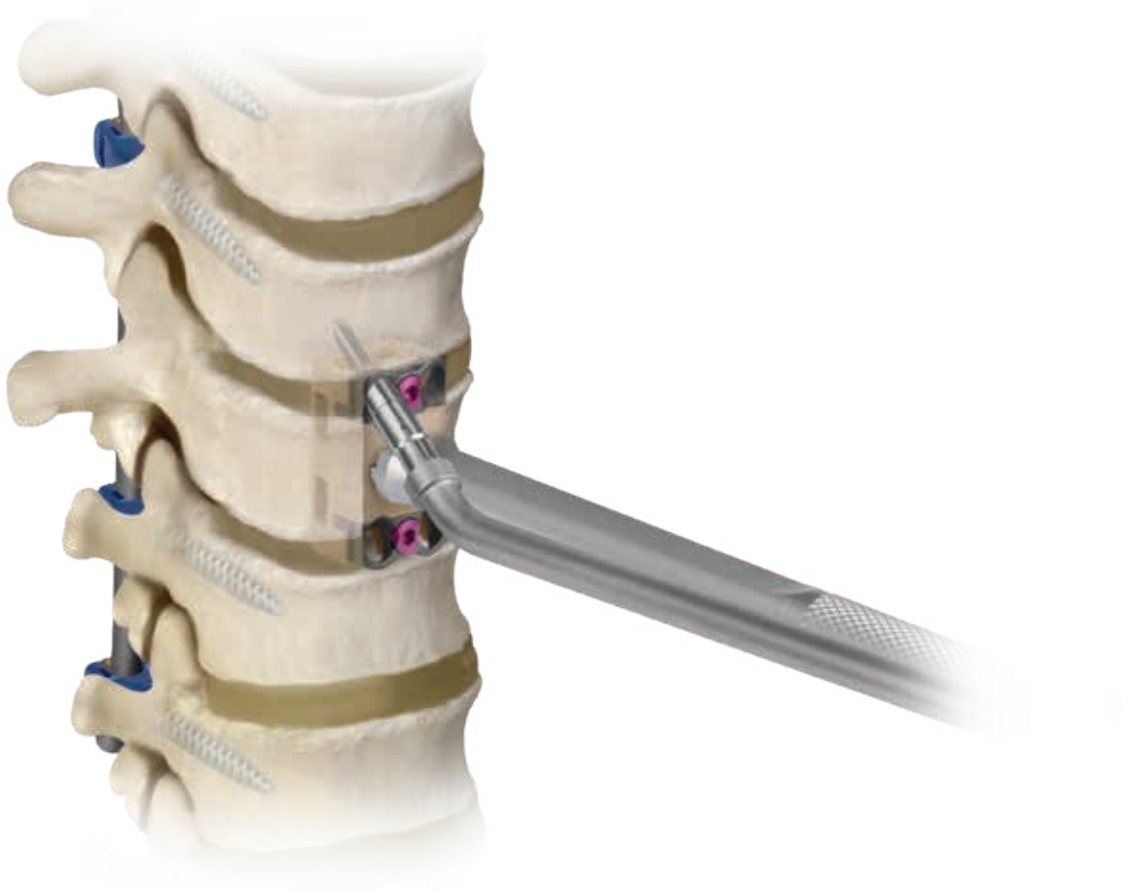
Counter-Torque in final position



7. Rotate the counter-torque clockwise to final tighten.

STEP 7 SCREW HOLE PREPARATION

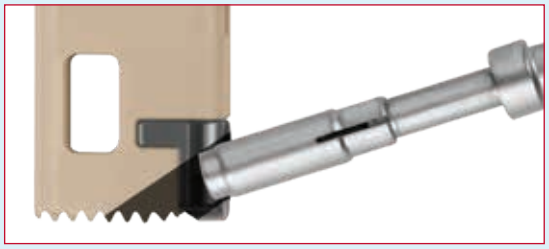
Insert an **Awl with Self-Centering Sleeve** to break the cortex. A self-centering drill and tap may be used to further prepare the screw hole. Depending on the angle and position, a straight or angled instrument may be used.



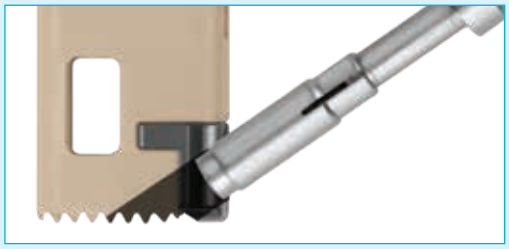
Using the Awl with the Self-Centering Sleeve, Bent

ALIGNING THE SELF-CENTERING SLEEVE

The **Self-Centering Sleeves** ensure proper screw trajectory without the use of a drill guide. The sleeve must be properly engaged with the plate before advancing any screw hole preparation instruments. Proceed to screw insertion prior to preparing the remaining screw hole.



Incorrect



Correct

STEP 8 SCREW INSERTION

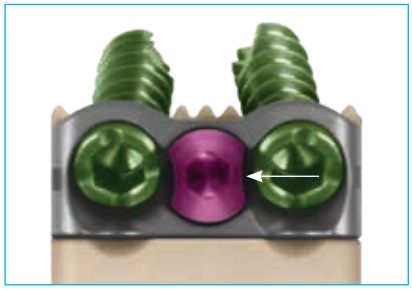
Load the desired screw from the module using the **Angled Driver Assembly** or **Screwdriver, 2.5mm Hex, Self-Retaining, with Cap**. Confirm screw length and diameter using the gauges within the screw module. Insert the screw through the screw hole. As the screw is inserted, the implant lags to the bone. Repeat for the remaining three screw holes.

Screw insertion with the angled driver assembly

STEP 9 SCREW BLOCKING

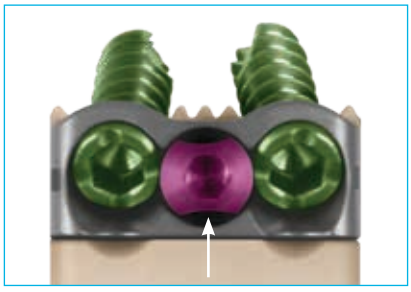
Once the screws are fully seated within the plate, insert the **Set Screw Positioner, 2.0mm Hex, Torque-Limiting** into the blocking set screw and rotate clockwise approximately 90°. The set screw positioner will provide audible, tactile, and visual confirmation that the screw is blocked from backing out. Ensure that both set screws are rotated to the blocked postion.

Initial Position



Cutout on the blocking set screw facing the bone screw

Final Position

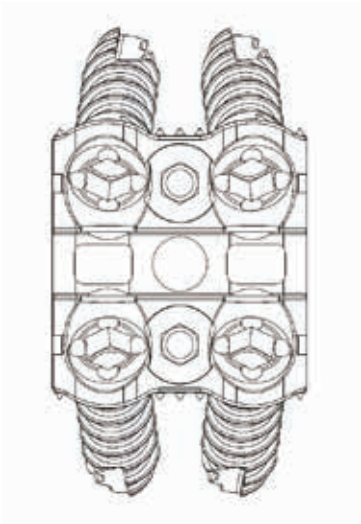
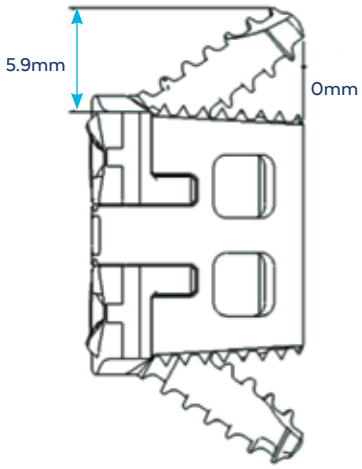
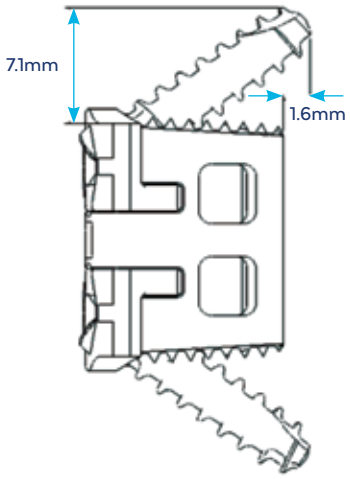
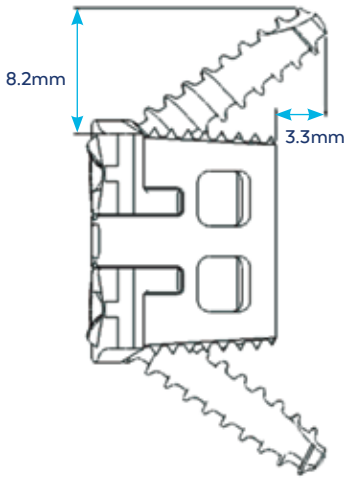
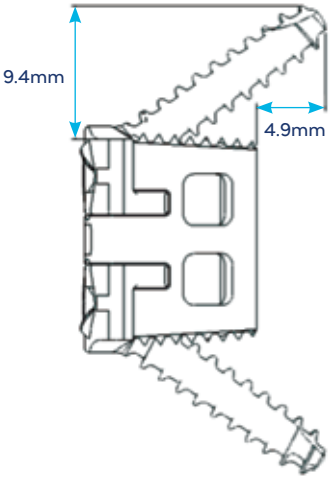
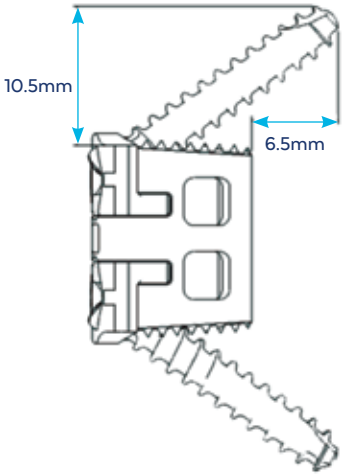


Cutout on the blocking set screw facing away from the bone screw

FINAL CONSTRUCT

RADIOGRAPHIC MARKERS

ADDITIONAL SPECIFICATIONS

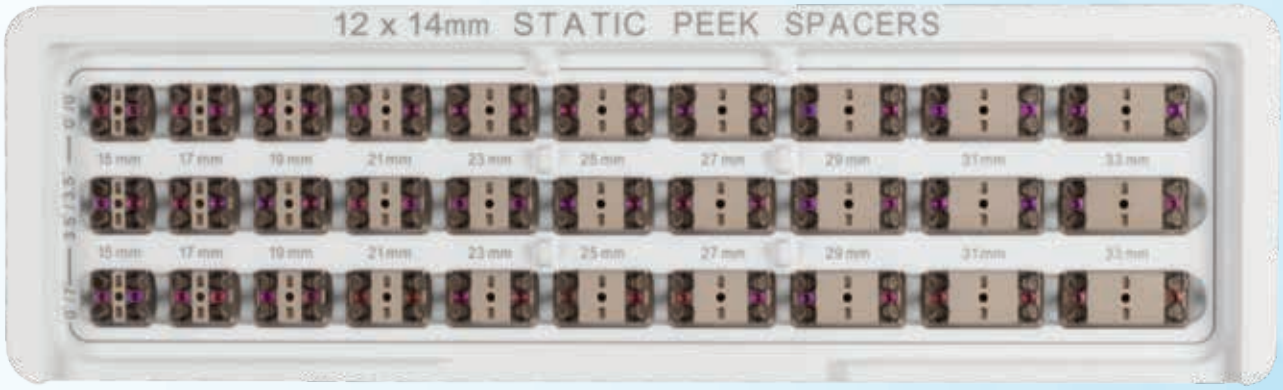
FORTIFY® I-R Static Spacers		
12x14mm	**12mm Screws**	**14mm Screws**
		
16mm Screws	**18mm Screws**	**20mm Screws**
		

Instrument	Diameter (mm)	Depth (mm)	Design
Straight/Bent Awl	2.4	8.6	
Retractable Awl	2.4	8.6	
Straight/Angled Taps	3.5	10.4	
12mm Drill	2.4	8.6	
14mm Drill	2.4	10.6	
16mm Drill	2.4	12.6	
18mm Drill	2.4	14.6	
20mm Drill	2.4	16.6	

FORTIFY® Bone Graft Volumes 12x14mm (cc)			
Height	**0°**	**3.5°-3.5°**	**0°-7°**
15mm	0.69	0.67	0.67
17mm	0.76	0.76	0.75
19mm	0.88	0.88	0.87
21mm	0.98	0.97	0.97
23mm	1.10	1.09	1.09
25mm	1.19	1.18	1.18
27mm	1.31	1.30	1.30
29mm	1.43	1.42	1.42
31mm	1.52	1.51	1.51
33mm	1.61	1.60	1.60

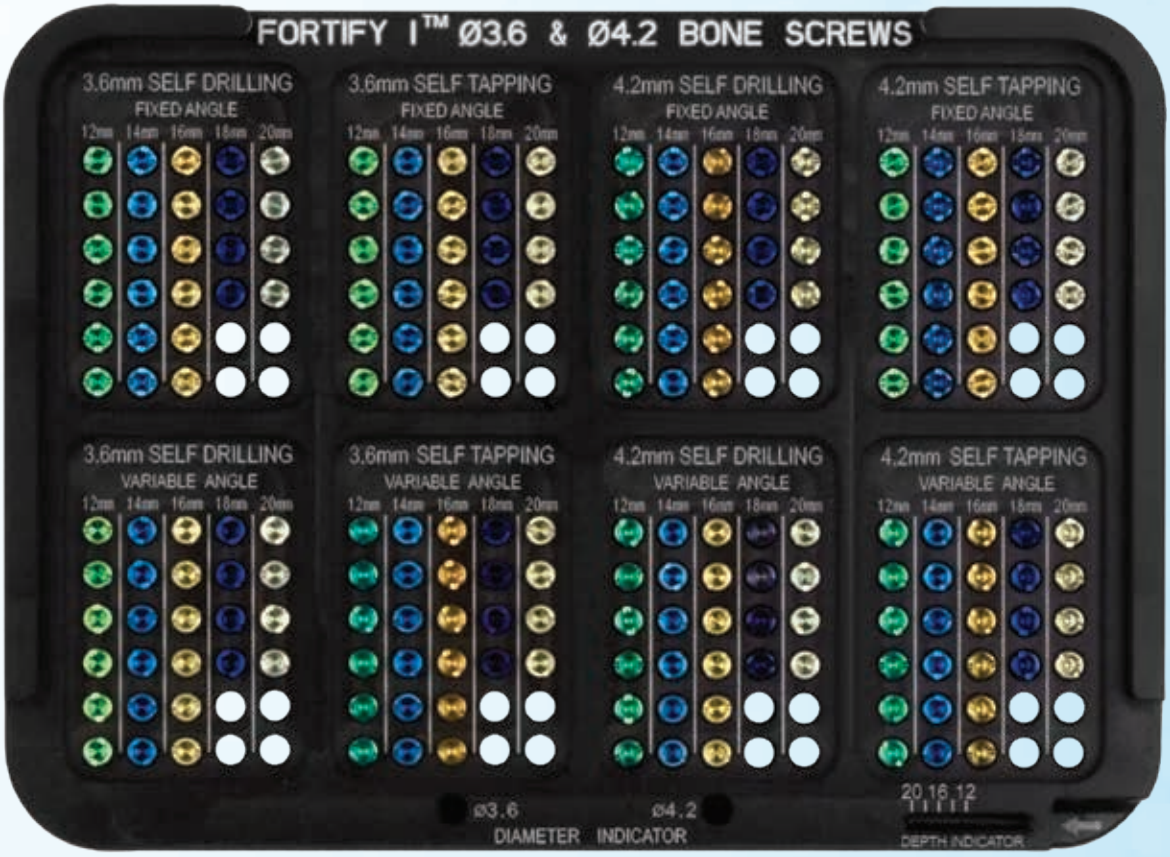
FORTIFY® I-R
STATIC IMPLANT SET 937.901

Part No.	Implant	Qty
337.015	FORTIFY® I-R 12x14mm Static Footprint, 15mm, 0°	1
337.017	FORTIFY® I-R 12x14mm Static Footprint, 17mm, 0°	1
337.019	FORTIFY® I-R 12x14mm Static Footprint, 19mm, 0°	1
337.021	FORTIFY® I-R 12x14mm Static Footprint, 21mm, 0°	1
337.023	FORTIFY® I-R 12x14mm Static Footprint, 23mm, 0°	1
337.025	FORTIFY® I-R 12x14mm Static Footprint, 25mm, 0°	1
337.027	FORTIFY® I-R 12x14mm Static Footprint, 27mm, 0°	1
337.029	FORTIFY® I-R 12x14mm Static Footprint, 29mm, 0°	1
337.031	FORTIFY® I-R 12x14mm Static Footprint, 31mm, 0°	1
337.033	FORTIFY® I-R 12x14mm Static Footprint, 33mm, 0°	1
337.115	FORTIFY® I-R 12x14mm Static Footprint, 15mm, 3.5°-3.5°	1
337.117	FORTIFY® I-R 12x14mm Static Footprint, 17mm, 3.5°-3.5°	1
337.119	FORTIFY® I-R 12x14mm Static Footprint, 19mm, 3.5°-3.5°	1
337.121	FORTIFY® I-R 12x14mm Static Footprint, 21mm, 3.5°-3.5°	1
337.123	FORTIFY® I-R 12x14mm Static Footprint, 23mm, 3.5°-3.5°	1
337.125	FORTIFY® I-R 12x14mm Static Footprint, 25mm, 3.5°-3.5°	1
337.127	FORTIFY® I-R 12x14mm Static Footprint, 27mm, 3.5°-3.5°	1
337.129	FORTIFY® I-R 12x14mm Static Footprint, 29mm, 3.5°-3.5°	1
337.131	FORTIFY® I-R 12x14mm Static Footprint, 31mm, 3.5°-3.5°	1
337.133	FORTIFY® I-R 12x14mm Static Footprint, 33mm, 3.5°-3.5°	1
337.215	FORTIFY® I-R 12x14mm Static Footprint, 15mm, 0°-7°	1
337.217	FORTIFY® I-R 12x14mm Static Footprint, 17mm, 0°-7°	1
337.219	FORTIFY® I-R 12x14mm Static Footprint, 19mm, 0°-7°	1
337.221	FORTIFY® I-R 12x14mm Static Footprint, 21mm, 0°-7°	1
337.223	FORTIFY® I-R 12x14mm Static Footprint, 23mm, 0°-7°	1
337.225	FORTIFY® I-R 12x14mm Static Footprint, 25mm, 0°-7°	1
337.227	FORTIFY® I-R 12x14mm Static Footprint, 27mm, 0°-7°	1
337.229	FORTIFY® I-R 12x14mm Static Footprint, 29mm, 0°-7°	1
337.231	FORTIFY® I-R 12x14mm Static Footprint, 31mm, 0°-7°	1
337.233	FORTIFY® I-R 12x14mm Static Footprint, 33mm, 0°-7°	1
937.001	FORTIFY® I-R 12x14mm Implant Module	


12 x 14mm STATIC PEEK SPACERS
15 mm
17 mm
19 mm
21 mm
23 mm
25 mm
27 mm
29 mm
31 mm
33 mm

FORTIFY® I
SMALL SCREW SET 937.910

Part No.	Implant	Qty
184.012	4.2mm Bone Screw, Variable, Self-Tapping, 12mm	6
184.014	4.2mm Bone Screw, Variable, Self-Tapping, 14mm	6
184.016	4.2mm Bone Screw, Variable, Self-Tapping, 16mm	6
184.018	4.2mm Bone Screw, Variable, Self-Tapping, 18mm	4
184.020	4.2mm Bone Screw, Variable, Self-Tapping, 20mm	4
184.032	4.2mm Bone Screw, Fixed, Self-Tapping, 12mm	6
184.034	4.2mm Bone Screw, Fixed, Self-Tapping, 14mm	6
184.036	4.2mm Bone Screw, Fixed, Self-Tapping, 16mm	6
184.038	4.2mm Bone Screw, Fixed, Self-Tapping, 18mm	4
184.040	4.2mm Bone Screw, Fixed, Self-Tapping, 20mm	4
184.052	4.2mm Bone Screw, Variable, Self-Drilling, 12mm	6
184.054	4.2mm Bone Screw, Variable, Self-Drilling, 14mm	6
184.056	4.2mm Bone Screw, Variable, Self-Drilling, 16mm	6
184.058	4.2mm Bone Screw, Variable, Self-Drilling, 18mm	4
184.060	4.2mm Bone Screw, Variable, Self-Drilling, 20mm	4
184.072	4.2mm Bone Screw, Fixed, Self-Drilling, 12mm	6
184.074	4.2mm Bone Screw, Fixed, Self-Drilling, 14mm	6
184.076	4.2mm Bone Screw, Fixed, Self-Drilling, 16mm	6
184.078	4.2mm Bone Screw, Fixed, Self-Drilling, 18mm	4
184.080	4.2mm Bone Screw, Fixed, Self-Drilling, 20mm	4
184.112	3.6mm Bone Screw, Variable, Self-Tapping, 12mm	6
184.114	3.6mm Bone Screw, Variable, Self-Tapping, 14mm	6
184.116	3.6mm Bone Screw, Variable, Self-Tapping, 16mm	6
184.118	3.6mm Bone Screw, Variable, Self-Tapping, 18mm	4
184.120	3.6mm Bone Screw, Variable, Self-Tapping, 20mm	4
184.132	3.6mm Bone Screw, Fixed, Self-Tapping, 12mm	6
184.134	3.6mm Bone Screw, Fixed, Self-Tapping, 14mm	6
184.136	3.6mm Bone Screw, Fixed, Self-Tapping, 16mm	6
184.138	3.6mm Bone Screw, Fixed, Self-Tapping, 18mm	4
184.140	3.6mm Bone Screw, Fixed, Self-Tapping, 20mm	4
184.152	3.6mm Bone Screw, Variable, Self-Drilling, 12mm	6
184.154	3.6mm Bone Screw, Variable, Self-Drilling, 14mm	6
184.156	3.6mm Bone Screw, Variable, Self-Drilling, 16mm	6
184.158	3.6mm Bone Screw, Variable, Self-Drilling, 18mm	4
184.160	3.6mm Bone Screw, Variable, Self-Drilling, 20mm	4
184.172	3.6mm Bone Screw, Fixed, Self-Drilling, 12mm	6
184.174	3.6mm Bone Screw, Fixed, Self-Drilling, 14mm	6
184.176	3.6mm Bone Screw, Fixed, Self-Drilling, 16mm	6
184.178	3.6mm Bone Screw, Fixed, Self-Drilling, 18mm	4
184.180	3.6mm Bone Screw, Fixed, Self-Drilling, 20mm	4
937.010	FORTIFY® I-R 3.6mm and 4.2mm Screw Module	


FORTIFY I™ Ø3.6 & Ø4.2 BONE SCREWS
3.6mm SELF DRILLING
FIXED ANGLE
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3.6mm SELF TAPPING
FIXED ANGLE
12mm 14mm 16mm 18mm 20mm
4.2mm SELF DRILLING
FIXED ANGLE
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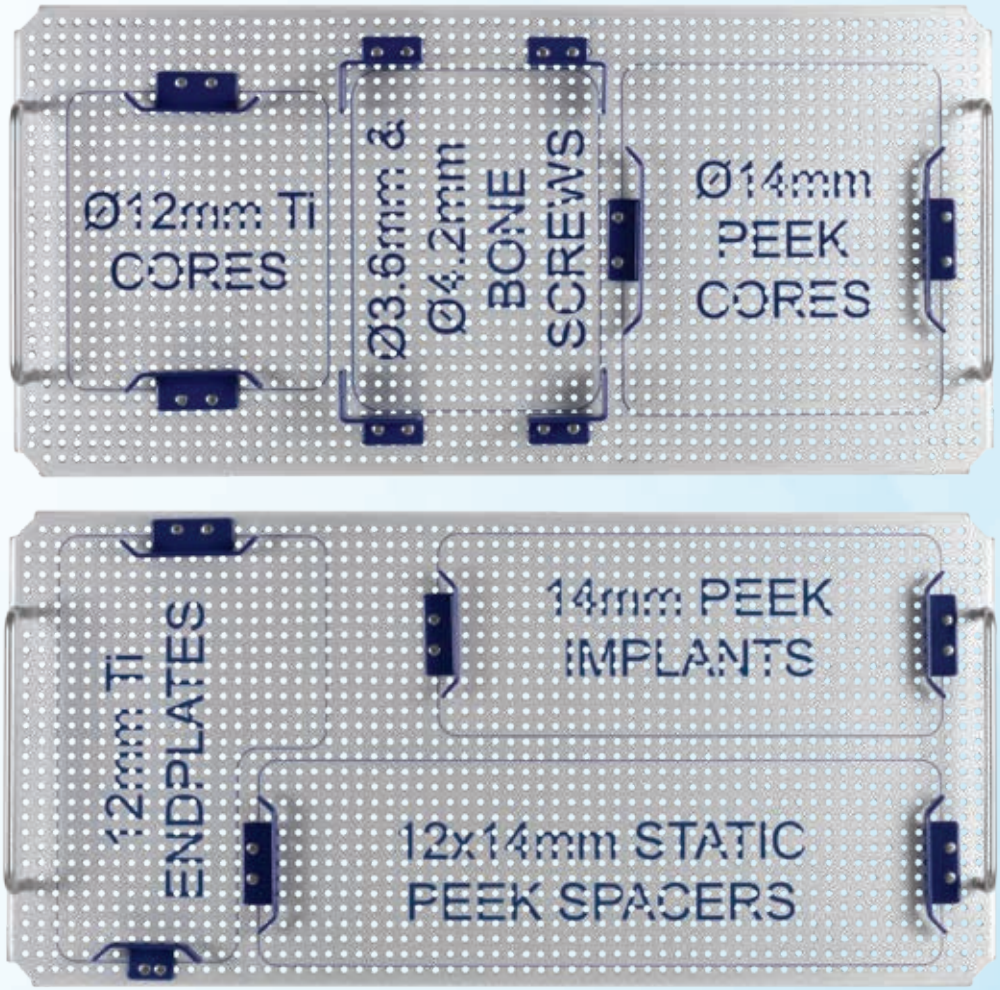
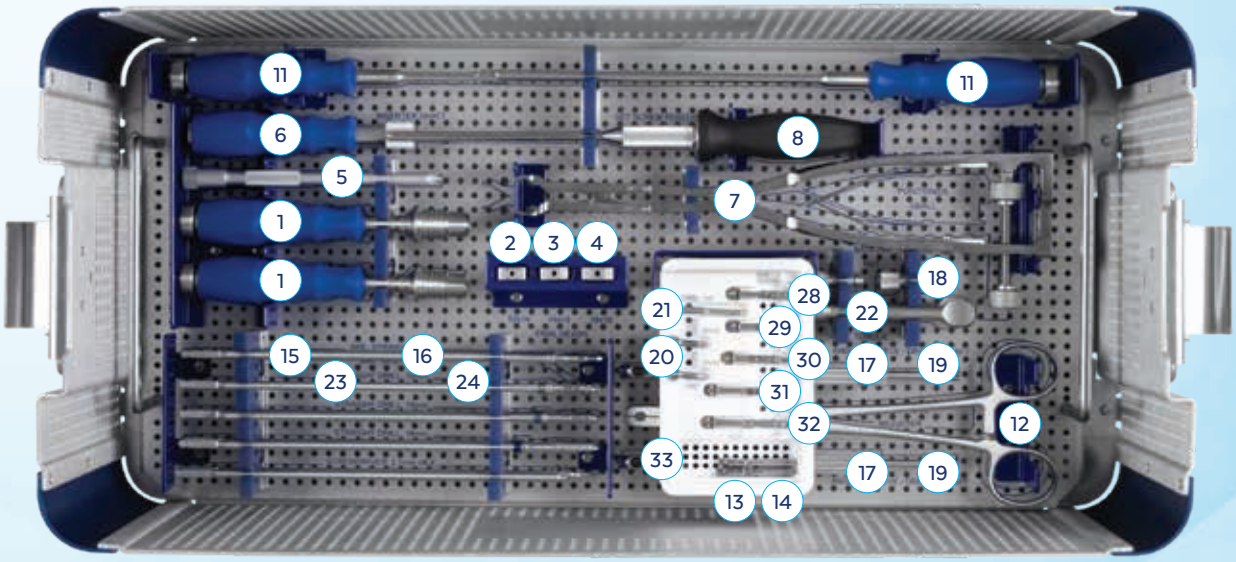
4.2mm SELF TAPPING
FIXED ANGLE
12mm 14mm 16mm 18mm 20mm
3.6mm SELF DRILLING
VARIABLE ANGLE
12mm 14mm 16mm 18mm 20mm
3.6mm SELF TAPPING
VARIABLE ANGLE
12mm 14mm 16mm 18mm 20mm
4.2mm SELF DRILLING
VARIABLE ANGLE
12mm 14mm 16mm 18mm 20mm
4.2mm SELF TAPPING
VARIABLE ANGLE
12mm 14mm 16mm 18mm 20mm
ø3.6
ø4.2
DIAMETER INDICATOR
20 16 12
DEPTH INDICATOR

FORTIFY® I
SMALL INSTRUMENT SET 937.907

		Instrument	Qty
1	636.450	Quick-Connect Handle, Swivel	2
2	637.024	Trial Head, 12x14mm	1
3	637.025	Trial Head, 14x14mm	1
4	637.026	Trial Head, 14x16mm	1
5	637.500	Inserter Shaft	1
6	637.501	Inserter Sleeve	1
7	637.510	Positioner, Small	1
8	650.312	Set Screw Positioner, 2.0mm Hex, Torque-Limiting	1
9	671.313	VIP Screwdriver, 2.1mm Hex, QC	1
10	684.004	Tap, Straight	1
11	684.305	Screwdriver, 2.5mm Hex, Self-Retaining, with Cap	2
12	684.309	Drill Sleeve Adjuster	1
13	684.401	Self-Centering Sleeve – Short	2
14	684.402	Self-Centering Sleeve – Long	2
15	684.403	Awl with Self-Centering Sleeve, Straight	1
16	684.404	Awl with Self-Centering Sleeve, Bent	1
17	684.415	Angled Sleeve	2
18	684.416	Angled Sleeve with Backing Nut	2
19	684.417	Angled Driving Shaft	2
20	684.418	Hex Driver Assembly	2
21	684.419	Angled Tap Tip	1
22	684.421	Counter-Torque, Angled Instrument	2
23	684.422	Straight Drill with Self-Centering Sleeve, 12mm	1
24	684.424	Straight Drill with Self-Centering Sleeve, 14mm	1
25	684.426	Straight Drill with Self-Centering Sleeve, 16mm	1
26	684.428	Straight Drill with Self-Centering Sleeve, 18mm	1
27	684.430	Straight Drill with Self-Centering Sleeve, 20mm	1
28	684.432	Angled Drill Tip with Self-Centering Sleeve, 12mm	1
29	684.434	Angled Drill Tip with Self-Centering Sleeve, 14mm	1
30	684.436	Angled Drill Tip with Self-Centering Sleeve, 16mm	1
31	684.438	Angled Drill Tip with Self-Centering Sleeve, 18mm	1
32	684.440	Angled Drill Tip with Self-Centering Sleeve, 20mm	1
33	984.004	COALITION® Module, Angled Instruments	1
	937.101	FORTIFY® I 12/14mm Instrument Graphic Case	


Ø12mm Ti
CORES
Ø3.6mm &
Ø4.2mm
BONE
SCREWS
Ø14mm
PEEK
CORES
12mm Ti
ENDPLATES
14mm PEEK
IMPLANTS
12x14mm STATIC
PEEK SPACERS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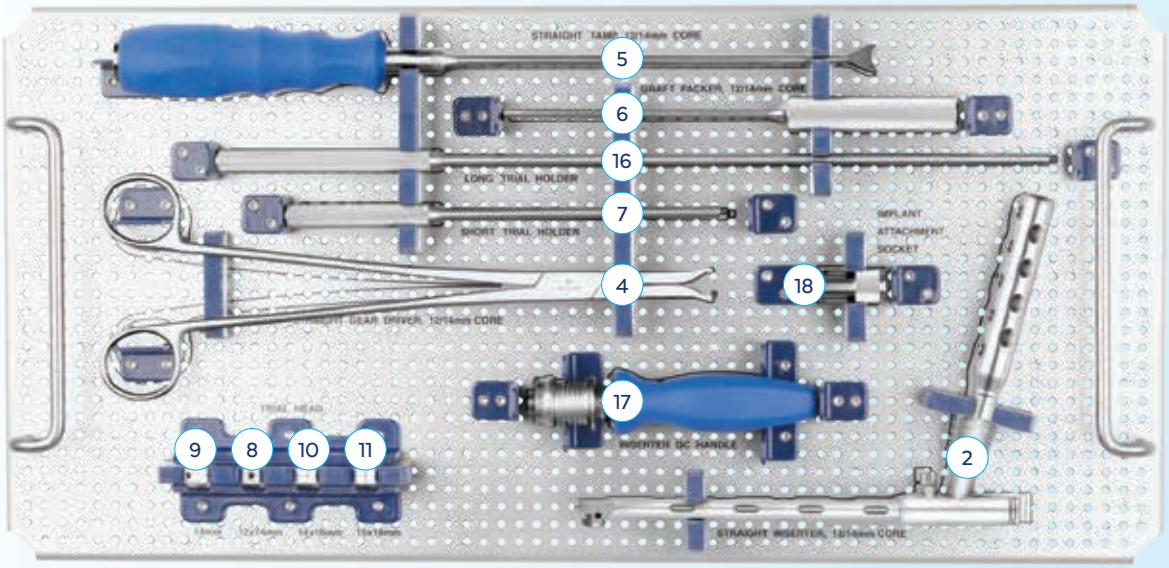
FORTIFY®
12/14mm INSTRUMENT SET 951.9127

	Instrument		Qty
1	651.001	Implant Assembly Tool, 12/14mm Core	1
2	651.010	Inserter, Straight, 12/14mm Core	1
3	651.011	Positioner, 12/14mm Core	1
4	651.013	Gear Driver, Straight, 12/14mm	1
5	651.020	Tamp, Straight, 12/14mm Core	1
6	651.022	Graft Packer, 12/14mm Core	1
7	651.023	Trial Holder, Short	1
8	651.024	Trial Head, 12x14mm	1
9	651.025	Trial Head, 14mm Round	1
10	651.026	Trail Head, 14x16mm	1
11	651.027	Trail Head, 15x18mm	1
12	651.030	Adjustable Trial, Short, 18-36mm	1
13	651.031	Adjustable Trial, Short, 30-63mm	1
14	651.035	Measuring Distractor, Small	1
15	651.036	Measuring Distractor, Large	1
16	651.123	Trial Holder, Long	1
17	651.132	Inserter QC Handle	1
18	651.133	Implant Attachment Socket	1
19	685.155	10mm Hex Driver	1
20	650.105	QC Handle, Small, with Cap	1
	951.101	12/14mm Instruments Graphic Case	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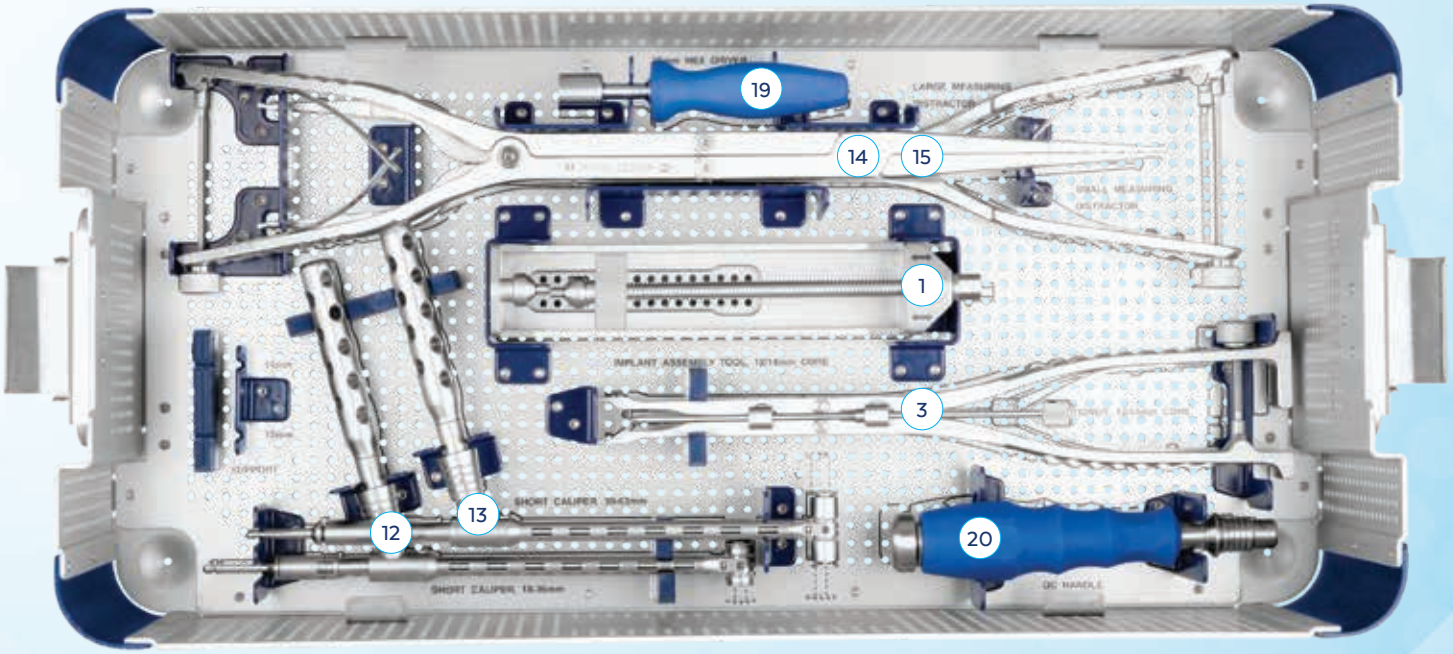
LONG TRIAL HOLDER
SHORT TRIAL HOLDER
IMPLANT ATTACHMENT SOCKET
INSERTER QC HANDLE


19
14
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SHORT CALIPER
QC HANDLE

SETS TO ORDER

Set Number	Description
937.901	FORTIFY® I-R Static Implant Set
937.907	FORTIFY® I Small Instrument Set
937.910	FORTIFY® I Small Screw Set
951.912	FORTIFY® 12/14mm Instrument Set

IMPORTANT INFORMATION ON FORTIFY® CORPECTOMY SPACERS

DESCRIPTION
FORTIFY® and FORTIFY® Integrated Corpectomy Spacers are vertebral body replacement devices used to provide structural stability in skeletally mature individuals following corpectomy or vertebrectomy. The components include a central core and endplates, which are available in a range of sizes and options to accommodate the anatomical needs of a wide variety of patients. The core and endplates can be preoperatively or intraoperatively assembled to best fit individual requirements. Each spacer has an axial hole to allow autograft or allograft to be packed inside the spacer. Protrusions (teeth) on the superior and inferior surfaces grip the endplates of the adjacent vertebrae to resist expulsion. Additional spikes are available on some implants. FORTIFY® Integrated (FORTIFY® I) endplates have an integrated plate to accommodate screws for additional fixation and are assembled to the core. FORTIFY® Variable Angle endplates provide adjustable lordosis/kyphosis.

FORTIFY® and FORTIFY® I Corpectomy Spacers are manufactured from titanium alloy per ASTM F136 and F1295. FORTIFY®-R and FORTIFY® I-R Corpectomy Spacers are manufactured from radiolucent PEEK polymer, with titanium alloy and tantalum components, per ASTM F2026, F136, F1295, and F560. Screws are manufactured from titanium alloy per ASTM F136 and F1295, with or without hydroxyapatite coating per ASTM F1185. FORTIFY® R TPS and FORTIFY® I-R TPS Corpectomy Spacers also have a commercially pure titanium plasma spray coating, as specified in ASTM F67 and F1580.

INDICATIONS
FORTIFY® and FORTIFY® Integrated Corpectomy Spacers are vertebral body replacement devices intended for use in the thoracolumbar spine (T1-L5). FORTIFY® Spacers (titanium) are also intended for use in the cervical spine (C2-T1). All FORTIFY® TPS coated spacers are indicated for the same use as non-coated PEEK versions.

When used in the cervical spine (C2-T1), FORTIFY® devices (titanium) are intended for use in skeletally mature patients to replace a diseased or damaged vertebral body caused by tumor fracture or osteomyelitis, or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in cervical degenerative disorders. These spacers are intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.

When used in the thoracolumbar spine (T1-L5), FORTIFY® and FORTIFY® Integrated devices are intended for use to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). These spacers are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

The interior of the spacers can be packed with autograft or allogenic bone graft comprising cancellous and/or corticocancellous bone graft as an adjunct to fusion.

These devices are intended to be used with FDA-cleared supplemental spinal fixation systems that have been labeled for use in the cervical, thoracic, and/or lumbar spine (i.e., posterior screw and rod systems, anterior plate systems, and anterior screw and rod systems). When used at more than two levels, supplemental fixation should include posterior fixation.

WARNINGS
One of the potential risks identified with this system is death. Other potential risks which may require additional surgery, include:

- device component fracture,
- loss of fixation,
- non-union,
- fracture of the vertebrae,
- neurological injury, and
- vascular or visceral injury.

Certain degenerative diseases or underlying physiological conditions such as diabetes, rheumatoid arthritis, or osteoporosis may alter the healing process, thereby increasing the risk of implant breakage or spinal fracture.

Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without previous surgery.

Components of this system should not be used with components of any other system or manufacturer.

The components of this system are manufactured from PEEK radiolucent polymer, commercially pure titanium, titanium alloy, and tantalum. Mixing of stainless steel implant components with different materials is not recommended for metallurgical, mechanical and functional reasons.

These warnings do not include all adverse effects which could occur with surgery in general, but are important considerations particular to orthopedic implants. General surgical risks should be explained to the patient prior to surgery.

Use this device as supplied and in accordance with the handling and use information provided below.

PRECAUTIONS
The implantation of vertebral body replacement devices should be performed only by experienced spinal 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.

Adequately instruct the patient. Mental or physical impairment which compromises or prevents a patient's ability to comply with necessary limitations or precautions may place that patient at a particular risk during postoperative rehabilitation.

For optimal implant performance, the surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.

MRI SAFETY INFORMATION

Non-clinical testing has demonstrated the FORTIFY® and FORTIFY® Integrated Corpectomy Spacers are MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla and 3.0 Tesla only
- Maximum spatial field gradient of 3,000 gauss/cm (30 T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 1 W/kg

Under the scan conditions defined above, the FORTIFY® and FORTIFY® Integrated Corpectomy Spacers are expected to produce a maximum temperature rise of less than or equal to 3.9°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 35mm from the FORTIFY® and FORTIFY® Integrated Corpectomy Spacers when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.

CONTRAINDICATIONS
Use of these devices is contraindicated in patients with the following conditions:

1. Active systemic infection, infection localized to the site of the proposed implantation, or when the patient has a suspected or documented allergy, foreign body sensitivity, or known intolerance to any of the implant materials.
2. Signs of local inflammation.
3. Prior fusion at the level(s) to be treated.
4. Severe osteoporosis, which may prevent adequate fixation
5. Conditions that may place excessive stresses on bone and implants, such as severe obesity or degenerative diseases, are relative contraindications. The decision whether to use these devices in such conditions must be made by the physician taking into account the risks versus the benefits to the patient.
6. Patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the implant during bony healing and may be at a higher risk of implant failure.
7. Any patient not willing to cooperate with postoperative instructions.
8. Any condition not described in the indications for use.
9. Fever or leukocytosis.
10. Pregnancy.
11. Any other condition that would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevations of the white blood count (WBC), or a marked left shift in the WBC differential count.
12. Any case not needing a fusion.

IMPORTANT INFORMATION ON FORTIFY® CORPECTOMY SPACERS

13. Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery.
14. These devices must not be used for pediatric cases or where the patient still has general skeletal growth.
15. Spondylolisthesis unable to be reduced to Grade 1.
16. Any case where the implant components selected for used would be too large or too small to achieve a successful result.
17. Any case that requires the mixing of metals from two different components or systems.
18. Any patient having inadequate tissue coverage at the operative site or inadequate bone stock or quality.
19. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.

COMPLICATIONS AND POSSIBLE ADVERSE EVENTS
Prior to surgery, patients should be made aware of the following possible adverse effects in addition to the potential need for additional surgery to correct these effects:

- Loosening, bending or breakage of components
- Displacement/migration of device components
- Tissue sensitivity to implant material
- Potential for skin breakdown and/or wound complications
- Non-union or delayed union or mal-union
- Infection
- Nerve damage, including loss of neurological function (sensory and/or motor), paralysis, dysesthesia, hyperesthesia, paresthesia, radiculopathy, reflex deficit, cauda equina syndrome
- Dural tears, cerebral spinal fluid leakage
- Fracture of vertebrae
- Foreign body reaction (allergic) to components or debris
- Vascular or visceral injury
- Change in spinal curvature, loss of correction, height and/or reduction
- Urinary retention or loss of bladder control or other types of disorders of the urogenital system
- Ileus, gastritis, bowel obstruction or other types of gastrointestinal system compromise
- Reproductive system compromise including impotence, sterility, loss of consortium and sexual dysfunction.
- Pain or discomfort
- Bursitis
- Decrease in bone density due to stress shielding
- Loss of bone or fracture of bone above or below the level of surgery
- Bone graft donor site pain, fracture, and/or delayed wound healing
- Restriction of activities
- Lack of effective treatment of symptoms for which surgery was intended
- Need for additional surgical intervention
- Death

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

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

All products should be inspected prior to use to ensure that there is no unacceptable deterioration such as corrosion (i.e. rust, pitting), discoloration, excessive scratches, notches, debris, residue, flaking, wear, cracks, cracked seals, etc. Non-working or damaged instruments should not be used, and should be returned to Globus Medical.

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
All instruments that can be disassembled must be disassembled for cleaning. All handles must be detached. Instruments may be reassembled following sterilization. The instruments 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 of instruments 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 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 and instruments may be available sterile or nonsterile. HA-coated implants are only available sterile.

Sterile implants and instruments are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of 10-6. Sterile products are packaged in a heat sealed, double pouch or container/pouch. The expiration date is provided on the package label. These products are considered sterile unless the packaging has been opened or damaged. Sterile implants and instruments that become nonsterile or have expired packaging are considered nonsterile and may be sterilized according to instructions for nonsterile implants and instruments below, with the exception of HA-coated implants, which cannot be resterilized and should be disposed of according to hospital protocol. Sterile implants meet pyrogen limit specifications.

Nonsterile implants and instruments have been validated to ensure an SAL of 10-6. The use of an FDA-cleared wrap is recommended, per the Association for the Advancement of Medical Instrumentation (AAMI) ST79, Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities. It is the end user's responsibility to use only sterilizers

and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the FDA for the selected sterilization cycle specifications (time and temperature).

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

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

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

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

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

CAUTION: Federal (U.S.A.) Law Restricts this Device to Sale by or on the Order of a Physician.

REF	CATALOGUE NUMBER	STERILE R	STERILIZED BY IRRADIATION
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⚠	CAUTION		MANUFACTURER
	SINGLE USE ONLY		USE BY (YYYY-MM-DD)
QTY	QUANTITY		

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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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