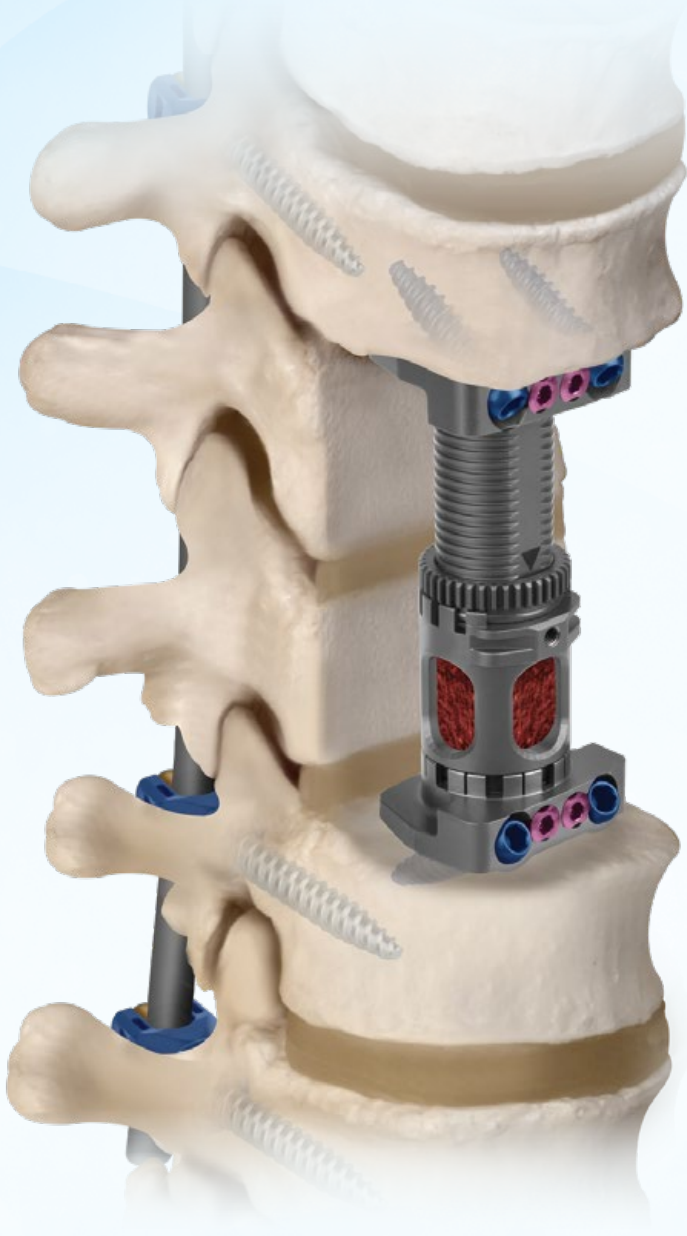




FORTIFY® I

Integrated Corpectomy Spacer System



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

Life moves us 

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

SURGICAL TECHNIQUE GUIDE

FORTIFY® I

Implant Overview	6
Instrument Overview	12
Surgical Technique	
1. Approach/Corpectomy	26
2. Distraction and Implant Sizing	27
3. Core Selection	28
4. Endplate Measurement	28
5. Endplate Selection	29
6. Implant Assembly.....	30
7. Packing Graft Into the Implant.....	31
8. Implant Attachment.....	32
9. Implant Insertion	33
10. Screw Hole Preparation	34
11. Screw Insertion	35
<i>Assembling the Angled Instruments.....</i>	<i>36</i>
12. Positioning the Set Screw.....	40
Final Construct	41
Radiographic Confirmation	42
FORTIFY® I Screw Diagrams	43
Endplate Height Guides.....	48
FORTIFY® I Graft Volumes	55
FORTIFY® I-R Implant Sets.....	58
FORTIFY® I Implant Sets	62
FORTIFY® I Instrument Sets	66
FORTIFY® I Screw Sets.....	70
FORTIFY® I Lateral Screw Set	74
FORTIFY® I Lateral Implant Set	74
FORTIFY® I Lateral Instrument Set	76
Important Information	78

FORTIFY® I

Integrated Corpectomy Spacer System

The FORTIFY® I Corpectomy Spacer System is designed to provide anterior column support and help prevent implant dislodgement. The spacer has integrated titanium plates and screws for additional stabilization between the vertebral bodies and the spacer.

The implants are available in a wide range of footprints, heights, and lordotic/kyphotic angles in PEEK or titanium materials. Maximized expansion ranges and modular endplates allow surgeons to customize each implant to achieve the best possible fit for their patient.

Anterior Column Fixation

Integrated titanium plates and screws designed to help prevent dislodgement, in addition to supplemental fixation

Postoperative Visualization

Radiolucent PEEK implant option gives improved postoperative visualization and a modulus of elasticity closer to bone

Optimized Fit

Maximized expansion ranges and a wide variety of sagittal profiles and footprints for an optimized fit



Anterior Column Fixation

Provides additional stabilization to supplemental fixation

Modular Endplates

Accommodate individual patient anatomy

Continuous Expansion

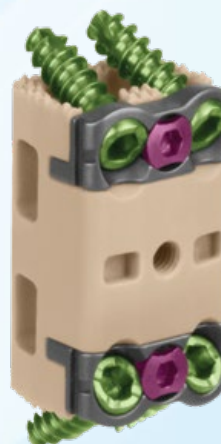
Optimizes fit

Automatic Locking

For height stability

Confident Blocking

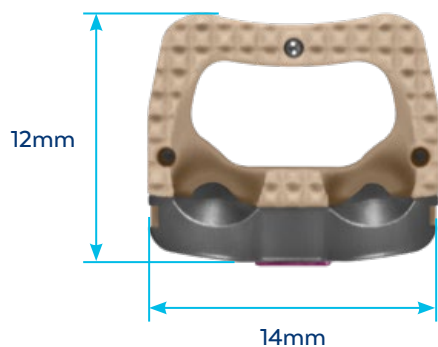
Helps prevent screw backout



IMPLANT OVERVIEW

FORTIFY® I-R Static Implants

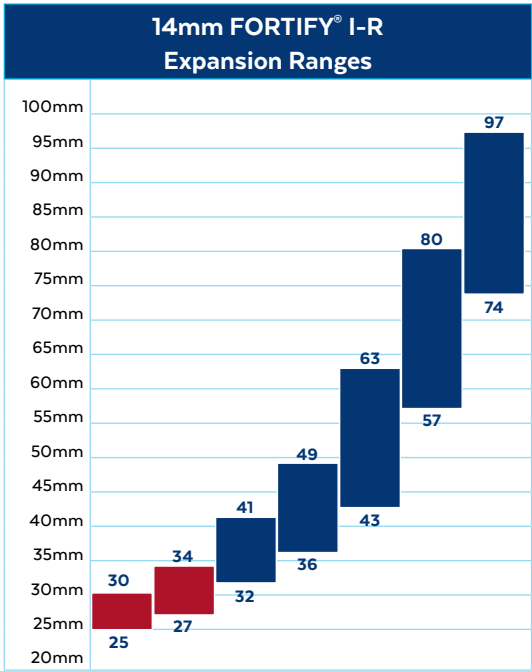
Footprint	Heights	Angles
12x14mm	15-33mm (2mm increments)	0°
		3.5°/3.5°
		0°/7°



14mm FORTIFY® I-R Implants

Core	Heights	Angles
14mm Round	25-98mm*	0°
		3.5°
		7°

* Height range includes FORTIFY® I-R endplates



Red indicates FORTIFY® I-R cores with fixed lower endplates.

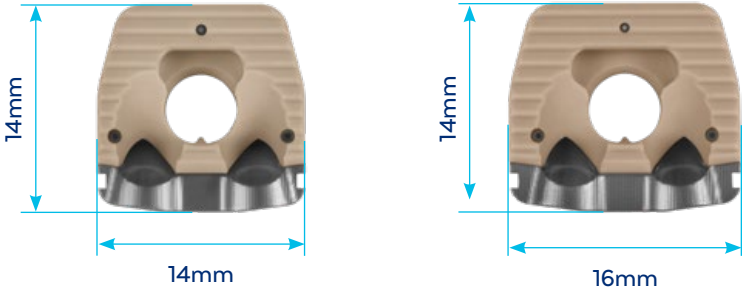
Note: Height ranges in the chart above include a FORTIFY®-R core, an upper endplate, and a lower endplate. Refer to page 48 for additional information.



14mm FORTIFY®-R Core



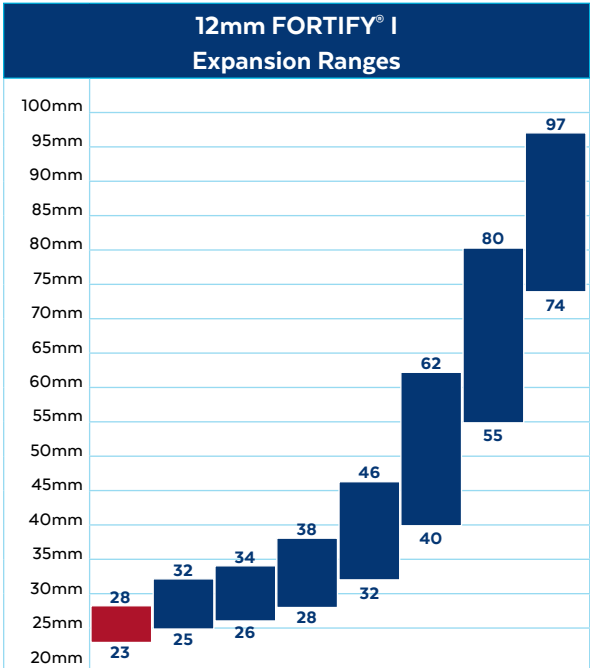
14mm FORTIFY® I-R Core with Fixed Lower Endplate



12mm FORTIFY® I Implants

Core	Heights	Angles
12mm Round	23-97mm*	0°
		3.5°
		7°

* Height range includes FORTIFY® I endplates



Red indicates FORTIFY® I cores with fixed lower endplates.

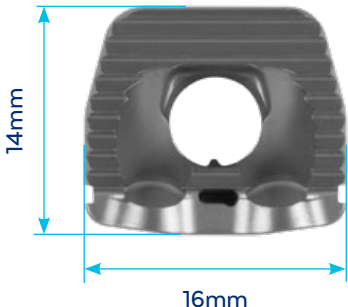
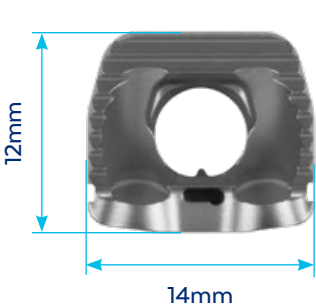
Note: Height ranges in the chart above include a FORTIFY® core, an upper endplate, and a lower endplate. Refer to page 49 for additional information.



12mm FORTIFY® Core



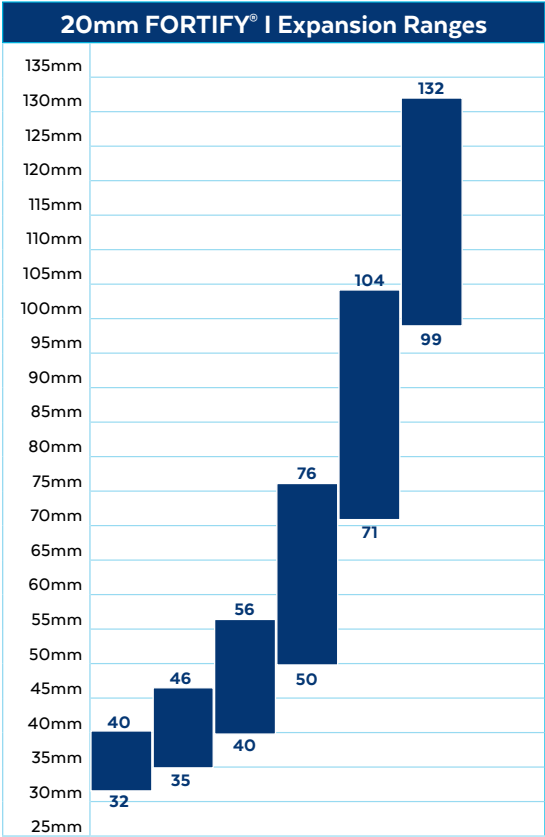
12mm FORTIFY® I Core with Fixed Lower Endplate



20mm FORTIFY® I Implants

Core	Heights	Angles
20mm	32-132mm*	0°
		4°
		8°
		12°
		16°

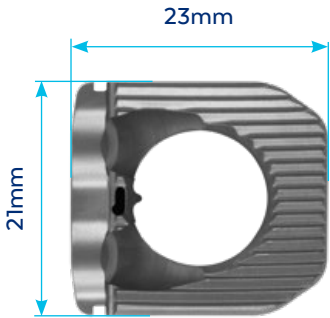
* Height range includes FORTIFY® I endplates



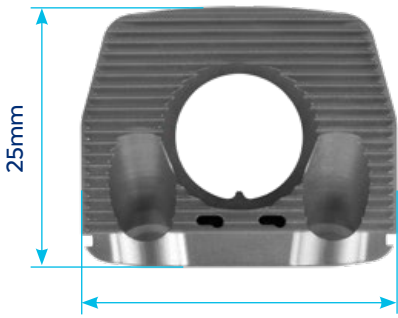
Note: Height ranges in the chart above include a 20mm FORTIFY® core, a FORTIFY® I 21x23mm, 0° upper endplate and a FORTIFY® I 21x23mm, 0° lower endplate. Height and expansion range change depending on the endplate used. Refer to page 50 for additional information.



20mm FORTIFY® Core



Lateral Approach

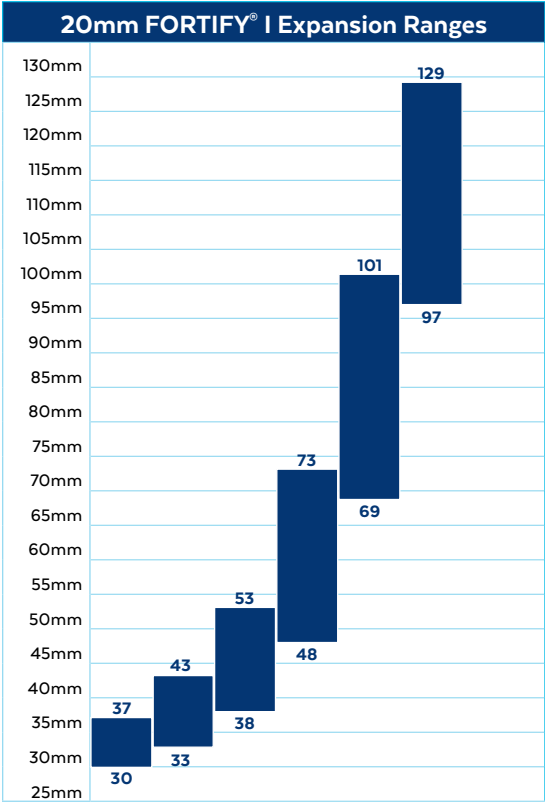


Anterior Approach

20mm FORTIFY® I Lateral Endplates

Core	Heights	Angles
20mm	30-129mm*	0°
		4°
		8°
		12°

* Height range includes FORTIFY® I endplates

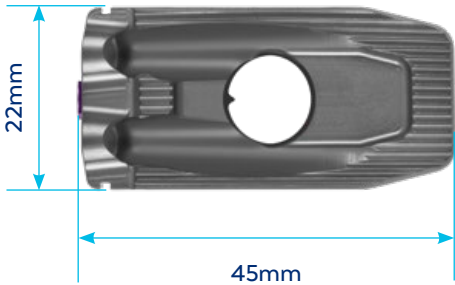
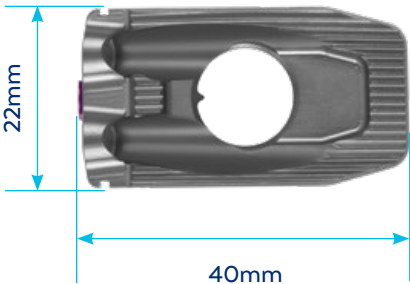


Note: Height ranges in the chart above include a 20mm FORTIFY® core, a FORTIFY® I 22x50mm, 0° upper endplate and a FORTIFY® I 22x50mm, 0° lower endplate. Endplate height and expansion range change depending on the endplate used. Refer to page 51 for additional information.



20mm FORTIFY® Core

FORTIFY® I Lateral Endplates



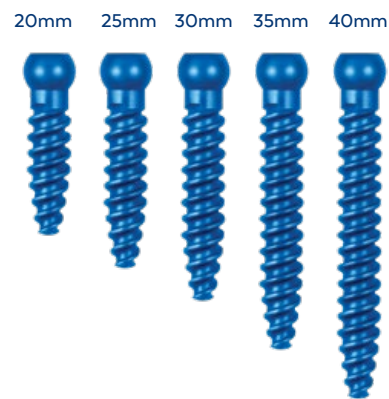
FORTIFY® I Small Screws

- Self-drilling and self-tapping
- 3.6mm and 4.2mm diameter
- Lengths from 12–20mm, in 2mm increments
- Fixed and variable angle ($\pm 4^\circ$)



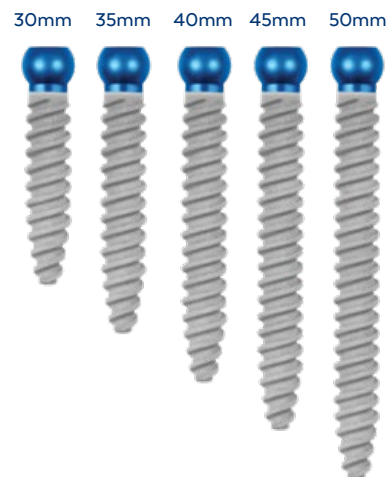
FORTIFY® I Large Screws

- Self-tapping
- 5.5mm diameter
- Lengths 20–40mm, in 5mm increments
- Fixed and variable angle ($\pm 5^\circ$)



FORTIFY® I Lateral Screws

- Hydroxyapatite (HA) coated
- Self-tapping
- 5.5mm diameter
- Lengths 30–50mm, in 5mm increments
- Fixed and variable angle screws (18° – 24°)



INSTRUMENT OVERVIEW

FORTIFY® 12/14mm Instrument Set and FORTIFY® 20mm Instrument Set are needed for this surgery.

ADJUSTABLE TRIALS



Adjustable Trial, Short, 18-36mm 651.030*



Adjustable Trial, Short, 30-63mm 651.031*



Adjustable Trial, Long, 18-36mm 651.130**



Adjustable Trial, Long, 30-63mm 651.131**

* FORTIFY® 12/14mm Instrument Set 951.912

** FORTIFY® 20mm Instrument Set 951.913

ADJUSTABLE TRIALS (CONT'D)



QC Handle, Small, with Cap 650.105* **

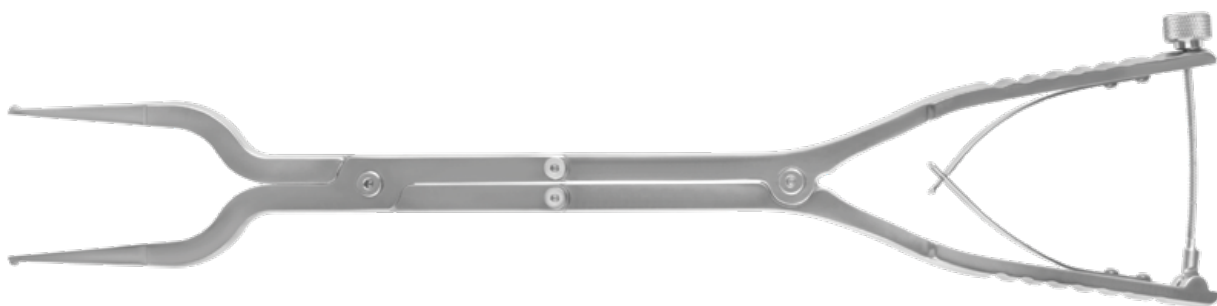


*Adjustable Trial with QC Handle
(Assembled)*

DISTRACTORS



Measuring Distractor, Small 651.035* **



Measuring Distractor, Large 651.036* **

* FORTIFY® 12/14mm Instrument Set 951.912

** FORTIFY® 20mm Instrument Set 951.913

ASSEMBLY TOOLS



Implant Assembly Tool, 12/14mm Core 651.001*



Implant Assembly Tool, 20mm Core 651.101**



10mm Hex Driver 685.155* **



Implant Assembly Tool, 20mm Core 651.101
20mm Support 651.102
10mm Hex Driver 685.155
(Assembled)

* FORTIFY® 12/14mm Instrument Set 951.912

** FORTIFY® 20mm Instrument Set 951.913

GRAFT PACKERS



Graft Packer, 12/14mm Core 651.022*



Graft Packer, 20mm Core 651.122**

INSERTERS



Inserter, Straight, 20mm Core 651.110**



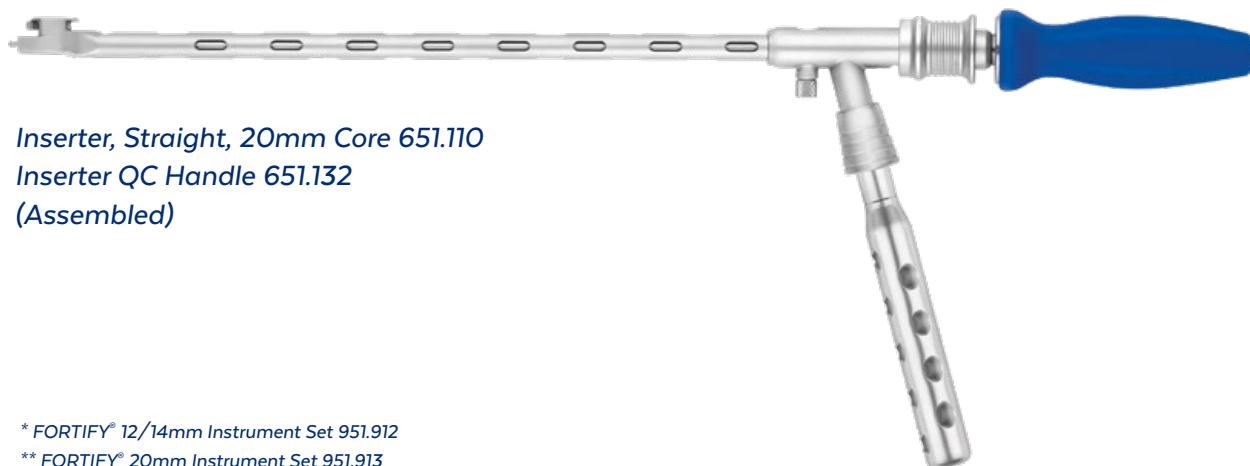
Inserter, Straight,
12/14mm Core 651.010*



Implant Attachment Socket 651.133* **



Inserter QC Handle 651.132* **



*Inserter, Straight, 20mm Core 651.110
Inserter QC Handle 651.132
(Assembled)*

* FORTIFY® 12/14mm Instrument Set 951.912

** FORTIFY® 20mm Instrument Set 951.913

STATIC IMPLANT HOLDERS



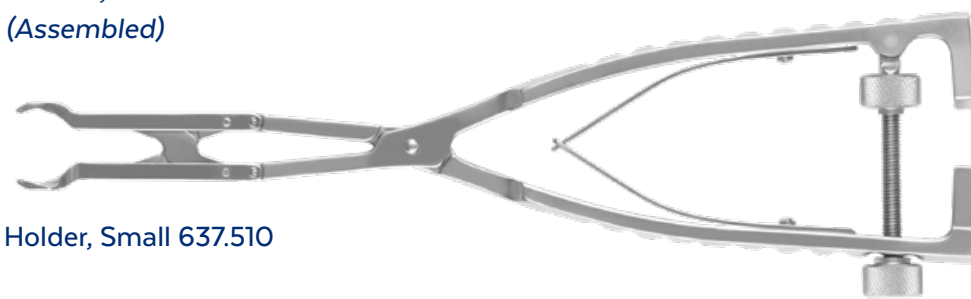
Insertion, Threaded Shaft 637.500



Insertion, Outer Sleeve 637.501



Insertion, Threaded Shaft 637.500
Insertion, Outer Sleeve 637.501
(Assembled)



Holder, Small 637.510

POSITIONERS



Positioner 12/14mm Core 651.011*

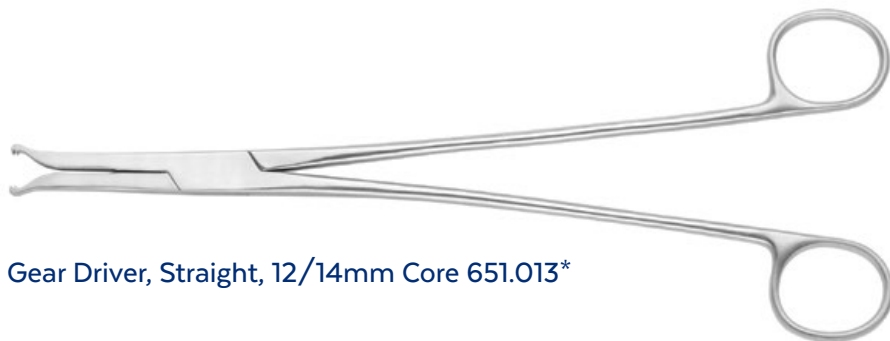


Positioner 20mm Core 651.111**

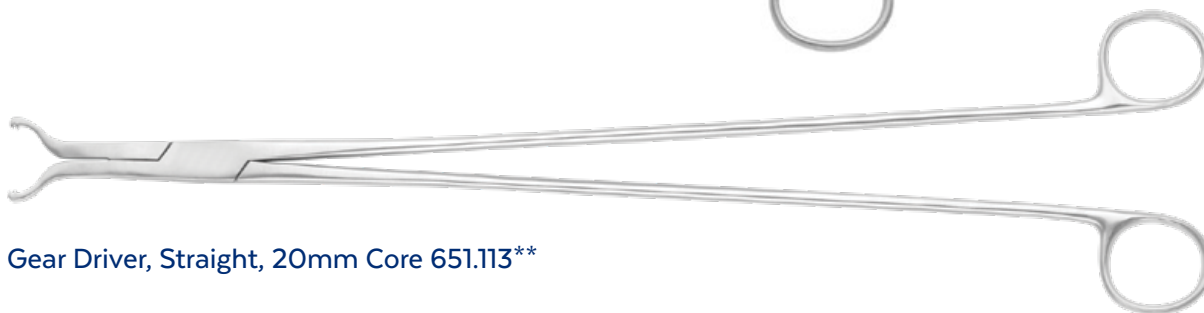
* FORTIFY® 12/14mm Instrument Set 951.912

** FORTIFY® 20mm Instrument Set 951.913

GEAR DRIVERS



Gear Driver, Straight, 12/14mm Core 651.013*



Gear Driver, Straight, 20mm Core 651.113**

TAMPS



Tamp, Straight, 12/14mm Core 651.020*



Tamp, Straight, 20mm Core 651.120**

* FORTIFY® 12/14mm Instrument Set 951.912

** FORTIFY® 20mm Instrument Set 951.913

SMALL TRIALS



Trial Holder, Short 651.023*

	Part Description	Part No.
	Trial Head, 12x14mm - Static*	637.024
	Trial Head, 14x14mm	637.025
	Trial Head, 14x16mm	637.026



Trial Holder, Short (Assembled)

SMALL STRAIGHT INSTRUMENTS



Awl Straight with Self-Centering Sleeve 684.403



Tap, Straight 684.004



Drills, Straight with Self-Centering Sleeve

Length	Part No.
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

* FORTIFY® 12/14mm Instrument Set 951.912

SMALL ANGLED INSTRUMENTS



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 No.	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)



Counter-Torque, Angled Instrument 684.421

SMALL SET SCREW INSTRUMENTS



Set Screw Positioner, 2.0mm Hex, Torque Limiting 650.312



VIP Screwdriver, 2.1mm Hex, QC 671.313

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

LARGE TRIALS



Trial Holder, Long 651.123* **

	Part Description	Part No.
	Trial Head, 21x23mm (lateral approach)	637.125
	Trial Head, 25x30mm (anterior approach)	637.127



Trial Holder, Long (Assembled)

LARGE STRAIGHT INSTRUMENTS



INDEPENDENCE® 3.5mm Hex Straight Shaft 676.502



Self-Centering Straight Instruments with Retracting Front Sleeve



Self-Centering Straight Drill 676.704



Self-Centering Straight Awl 676.706



5.5mm Straight Tap 676.708



INDEPENDENCE® Set Screw Driver, 2.5mm Hex 676.600

* FORTIFY® 12/14mm Instrument Set 951.912

** FORTIFY® 20mm Instrument Set 951.913

LARGE ANGLED INSTRUMENTS



Counter-Torque 676.699



Angled Sleeve 676.700



Shaft 676.701



Nut 676.702



Self-Centering Angled Drill 676.703



5.5mm Angled Tap 676.707



3.5mm Angled Hex Driver, Short 676.710



Angled Driver System with 3.5mm Angled Hex Driver, Short (Assembled)



Self-Centering Bent Awl 676.705



Holder, Large 637.511

LATERAL TRIAL



Trial Holder, Long 651.123

	Part Description	Part No.
	Trial Head, 22mm Lateral	651.128



Trial Holder, Lateral (Assembled)

LATERAL STRAIGHT INSTRUMENTS



Straight Shaft 3.5mm Hex Driver 687.527



Straight Counterbore 687.516



Straight 5.5mm Drill 687.520



Straight Awl 687.524



Straight 5.5mm Tap 687.526



INDEPENDENCE® Set Screw Driver, 2.5mm Hex 676.600

LATERAL ANGLED INSTRUMENTS



Quick-Connect Swivel Handle 687.005



Ratchet Handle 687.105



3.5mm Angled Hex Driver 687.504



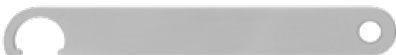
Angled Holder 687.505



Angled Holder Shaft 687.506



Angled Holder Nut 687.507



Spanner Wrench 687.509



Anti-Torque Holder 687.906

LATERAL ANGLED INSTRUMENTS (CONT'D)



Quick-Connect Swivel Handle 687.005
3.5mm Angled Hex Driver 687.504
Anti-Torque Holder 687.906
(Assembled)



Quick-Connect Swivel Handle 687.005
Short 3.5mm Hex Driver Tip 687.026
Angled Holder 687.505
Angled Holder Shaft 687.506
Angled Holder Nut 687.507
Anti-Torque Holder 687.906
(Assembled)



Short 3.5mm Hex Driver Tip 687.026



Short Counterbore Tip 687.514



Short 5.5mm Drill Tip 687.521



Short 5.5mm Tap Tip 687.721



Angled Awl 687.511

SURGICAL TECHNIQUE

FORTIFY® I

Integrated Corpectomy Spacer System

STEP

1

APPROACH/CORPECTOMY

The FORTIFY® I Corpectomy Spacer may be inserted using one of the following approaches: anterior or lateral. For the purpose of this technique guide, an anterior approach is shown. The implant insertion and removal steps are the same for any indicated surgical approach.

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

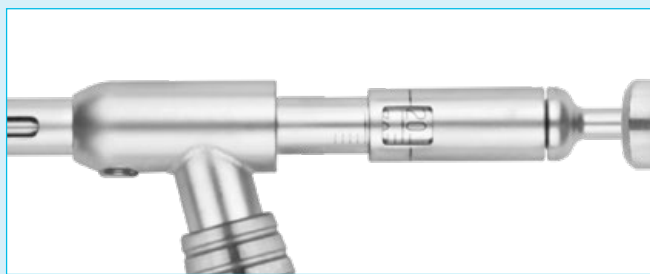
DISTRACTION AND IMPLANT SIZING

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** clockwise. Determine the total implant height required. Remove the trial.

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



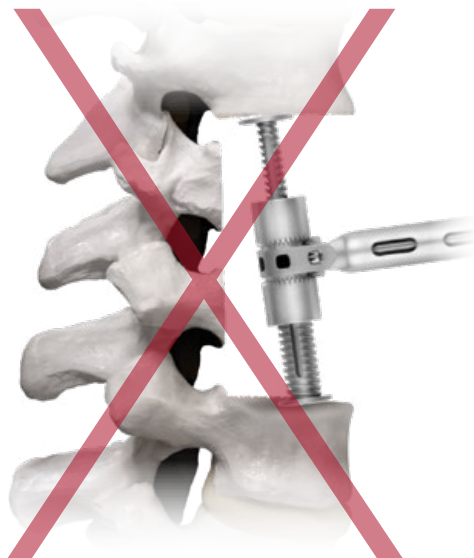
Adjustable Trial at its contracted height



Measured height (mm) is shown through window



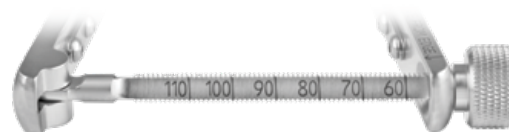
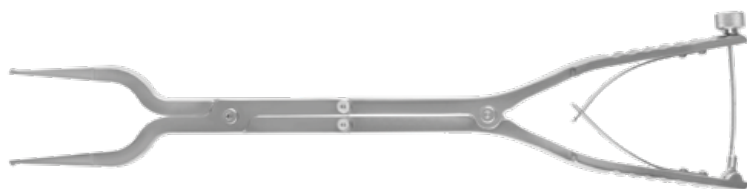
CORRECT



INCORRECT

Sizing defect space using Adjustable Trial

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



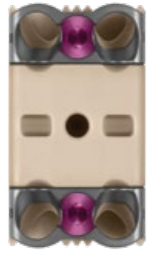
Measuring Distractor

STEP

3

CORE SELECTION

Determine whether a PEEK (FORTIFY® I-R) or titanium (FORTIFY® I) implant is to be used. Select the appropriately sized FORTIFY® Core for implantation. Since all implant expansion ranges overlap, select the implant that best fits into the correctomy space. For example, if a 43mm height is measured, select the 35–48mm core.

	Static	14mm PEEK	12mm Titanium	20mm Titanium
Height Range	15–33mm	Expansion Range 25–97mm	23–97mm	32–132mm Lateral: 30–129mm
				

Note: FORTIFY® I endplates increase the listed height of FORTIFY® core heights. For example, 137.300, FORTIFY® I 12mm Upper Endplate, 12x14mm Footprint, 0°, No Spikes and 137.350 FORTIFY® I 12mm Lower Endplate, 12x14mm Footprint, 0°, No Spikes adds 7mm to the unexpanded height and 9mm to the fully expanded height, respectively of the FORTIFY® 12mm Core, Height 25–37mm for a total FORTIFY® I construct height of 40–62mm. Refer to page 48 for additional information.

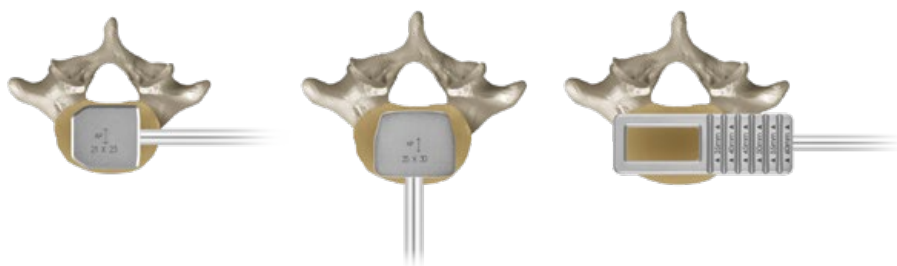
STEP

4

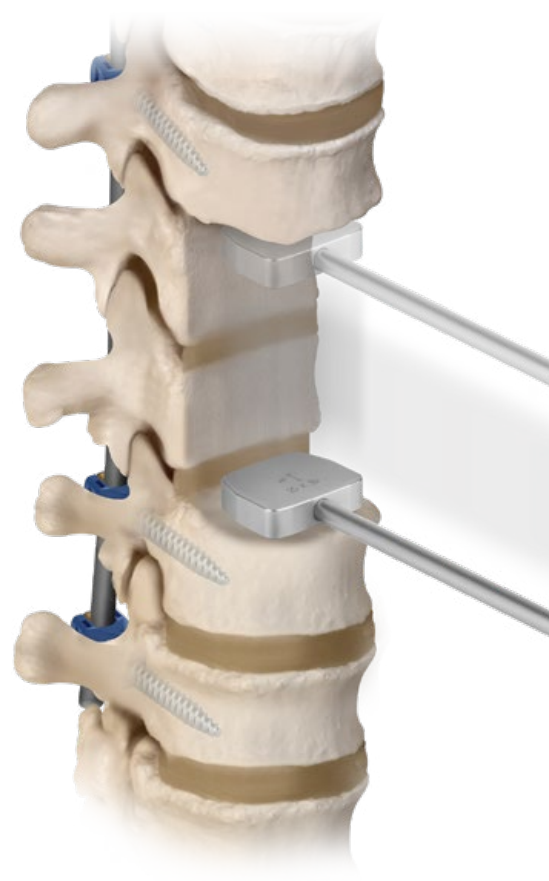
ENDPLATE MEASUREMENT

Assemble the **Trial Head** to the **Trial Holder**. Determine the appropriate footprint of the correctomy space by inserting the trial assembly. Use fluoroscopy to determine the desired sagittal angle of the endplates. Sweep the trial along the defect space to ensure the implant fits the endplates.

Note: Measure both superior and inferior endplates as the footprint may be different.



Endplate measurement using Trial Holder



STEP

5

ENDPLATE SELECTION

Static		Heights	Endplates	Footprints	Angles	Screws	
PEEK		15-33mm 2mm incr.		12x14mm	0° 3.5° 7°	Length: 12-20mm Diameter: 3.6mm, 4.2mm Type: Self-Drilling, Self-Tapping Angulation: 35° Fixed, ±4° Variable	
	Core		Heights	Endplates	Footprints		Angles
PEEK		14mm Round	25-97mm		14x14mm 14x16mm		0° 3.5° 7°
	Core		Heights	Endplates	Footprints		Angles
Titanium		12mm Round	23-97mm		12x14mm 14x16mm		0° 3.5° 7°
		20mm Round	32-132mm		Lateral: 21x23mm	0° 4° 8°	
					Anterior: 25x30mm	0° 4° 8° 12° 16°	
		30-129mm		Lateral: 22x40mm 22x45mm 22x50mm	0° 4° 8° 12°		
							
						Length: 30-50mm Diameter: HA Coated 5.5mm Type: Self-Tapping Angulation: 18°-24° Variable	

Choose the appropriate **Implant Assembly Tool**.

Implant Assembly Tool Selection				
Implant to be assembled	14mm FORTIFY® I-R Implant	12mm FORTIFY® I Implant	20mm FORTIFY® I-R Implant	20mm FORTIFY® I Implant
Implant Assembly Tool	651.001	651.001	651.101	
Support Part	651.003	651.002	651.002	

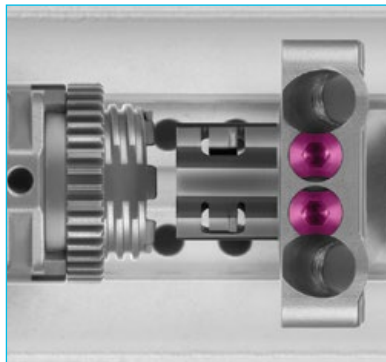
For proper implant assembly, place the assembly tool on a flat surface with the drive screw slide button to the assembler's right, as shown below.



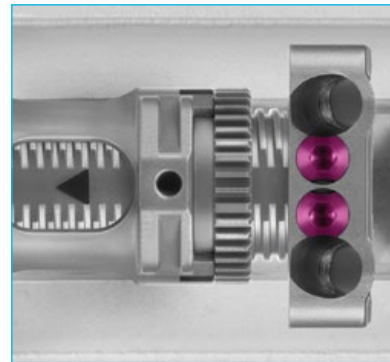
Assembling the Core and Endplates

Select the desired FORTIFY® Core. Select the desired FORTIFY® I Upper and Lower Endplates. When using PEEK, begin with the lower endplate. When using titanium begin with the upper endplate. For the purpose of this technique guide, a titanium implant will be used.

Starting with the upper endplate, align the etched markings on the upper endplate with the gaps of the core. While maintaining alignment, insert the upper endplate into the core. The upper endplate does not have to be fully seated into the core at this time.

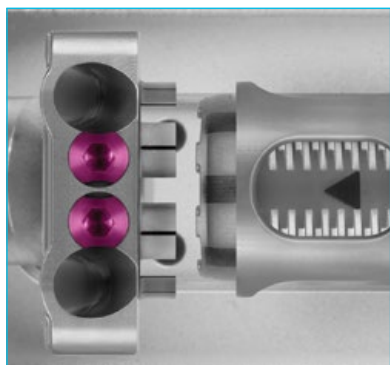


Aligning etchings on upper
endplate to gaps of core

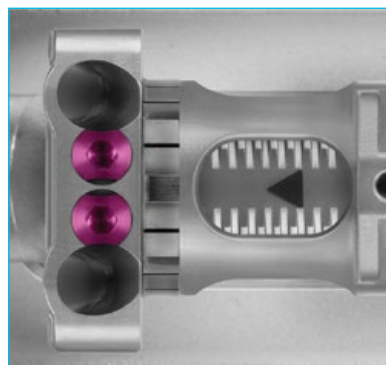


Insertion of core into upper endplate
while maintaining alignment

Align the markings on the core with the gaps between the tabs of the lower endplate. While maintaining alignment, insert the lower endplate onto the core. The lower endplate does not have to be fully seated on the core at this time.



Alignment of etched markings of core to gaps in lower endplate



Insertion of core into lower endplate while maintaining alignment

Note: Ensure the screw holes indicating the endplate angulation are parallel and in line with the implant insertion hole in order to maintain sagittal profile.

STEP

7

PACKING GRAFT MATERIAL

The **Graft Packer** may be used to pack autogeneous graft material or allograft into the implant.



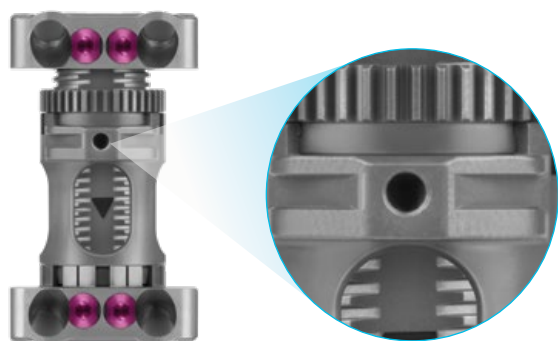
Using Graft Packer

STEP 8 IMPLANT ATTACHMENT

Select the appropriate **Inserter, Straight** for the assembled core size. Attach the **Implant Attachment Socket** to the proximal end of the inserter.



Rotate the socket clockwise, threading the inserter into the implant insertion hole, until finger tight. Once the implant is securely attached to the inserter, remove the socket. Connect the **Inserter QC Handle** by retracting the quick connect shaft and seating it into the proximal end of the inserter. The implant is now ready for insertion.



Implant insertion hole



Implant attached to inserter

STEP**9****IMPLANT INSERTION**

Insert the implant into the corpectomy space. If needed, gently impact on the blue Inserter Handle or the Hex Implant Attachment Socket to seat the implant. Using fluoroscopy to visualize the implant height, expand the implant to the desired height by rotating the inserter handle clockwise. If necessary, contract the implant by rotating the inserter handle counterclockwise. An etched triangle will be visible when the implant is fully expanded.



**Inserting implant into
corpectomy space**



**Implant expanded in
corpectomy space**

To release the implant from the inserter, disconnect the Inserter QC Handle by retracting the quick connect shaft and pulling away from the proximal end of the inserter. Connect the Implant Attachment Socket and rotate it counterclockwise to unthread the inserter from the implant.

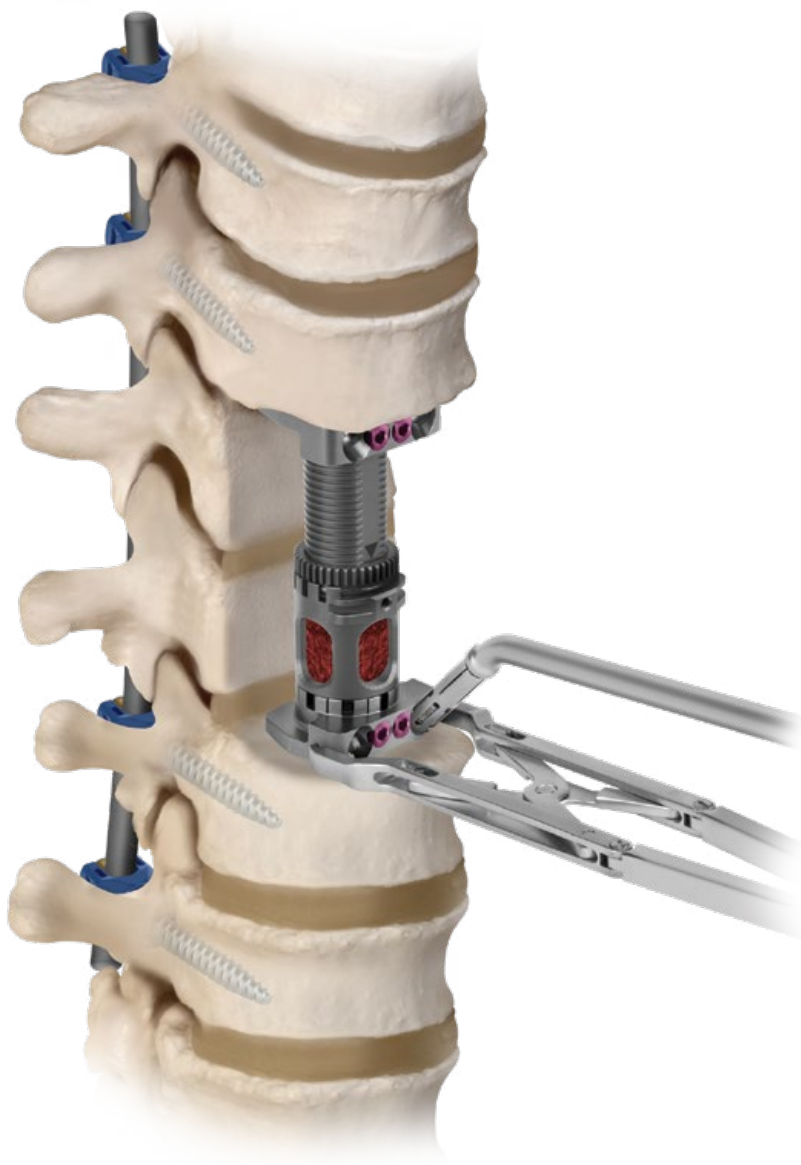
Note: Once the implant is removed from the inserter, the implant is automatically locked. An internal locking mechanism engages when the inserter is disengaged.

STEP 10 SCREW HOLE PREPARATION

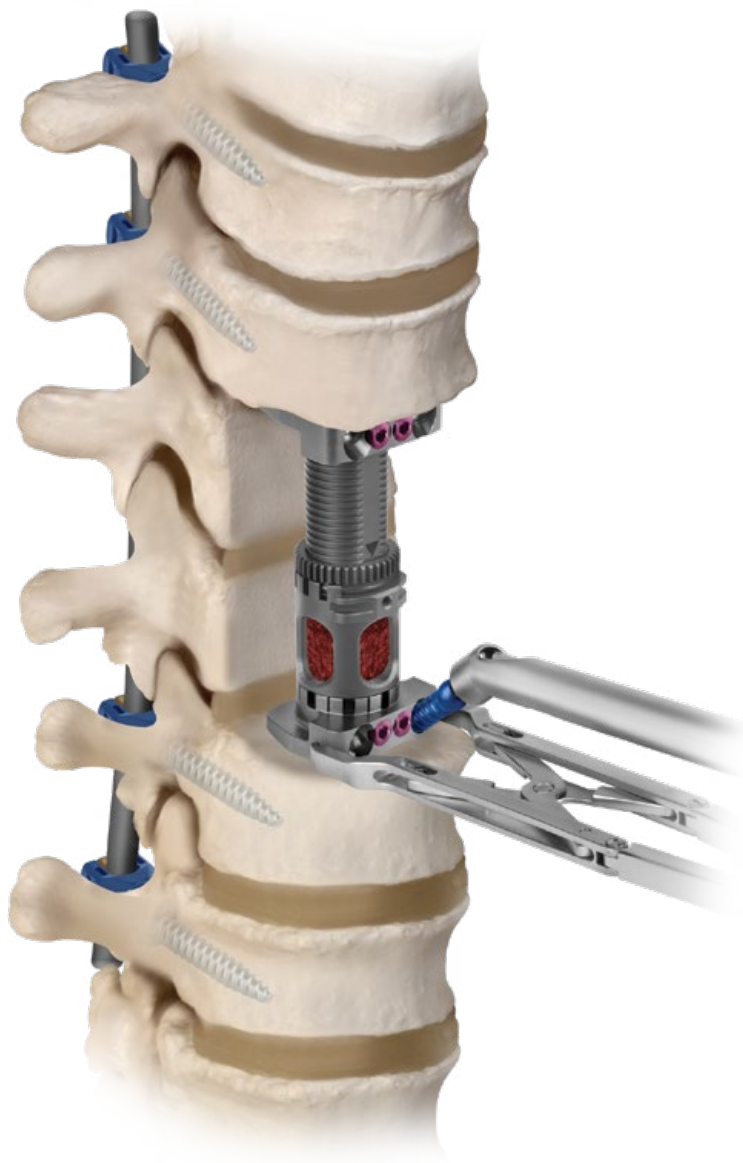
Screw hole preparation is the same for all FORTIFY® I implants. For the purpose of this technique guide, a FORTIFY® I Large implant is shown.

Once the Inserter, Straight has been released, attach the **Holder, Large** to the bottom endplate. Insert the **Awl with Self-Centering Sleeve, Bent** to break the cortex. A **Self-Centering Drill** and **Tap** may be used to further prepare the screw hole.

*Note: The **Holder, Small** is used for FORTIFY® I Small implants.*



Intraoperative fluoroscopy is recommended to ensure that screws are not placed beyond the margins of the vertebral body. Select the appropriate length screw (refer to pages 43–47 for screw length charts). Insert the screw using a straight or angled **Self-Retaining Screwdriver**. Repeat steps 10 and 11 for each screw hole before moving to the next step.



Note: The FORTIFY® I Large angled instruments are preassembled in the set. However, the small and lateral angled instruments require some assembly. Refer to page 36 for FORTIFY® I small angled instrument assembly and page 38 for FORTIFY® I lateral angled instrument assembly.

ASSEMBLING THE ANGLED INSTRUMENTS

The FORTIFY® I Large angled instruments are preassembled in the set. However, small and lateral angled instruments require some assembly.

FORTIFY® I Small/Static

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

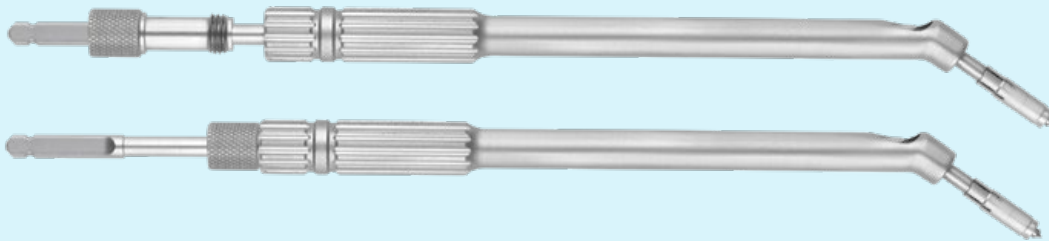
Step 2: Hold the **Angled Sleeve** pointed downward with the cutout facing upward. Insert the selected tip into the cutout on the distal end of the driver sleeve.



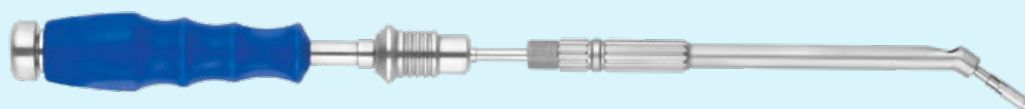
Step 3: Insert the **Angled Driver Shaft** into the driver body until the gears on the shaft mesh with the gears on the selected tip.



Step 4: Place the **Angled Sleeve with Backing Nut** over the shaft. Rotate the threads clockwise until the nut sits flush with the driver sleeve.

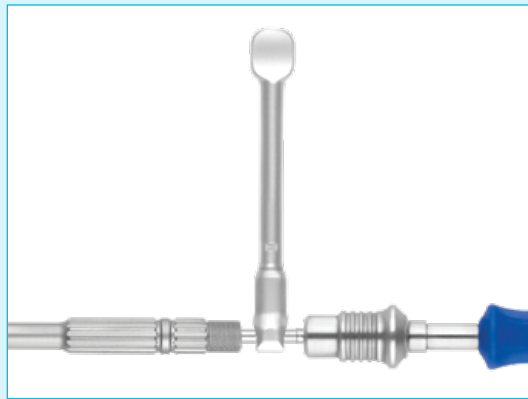


Step 5: Attach the **Quick-Connect Handle, Swivel**. The driver is now ready for use.

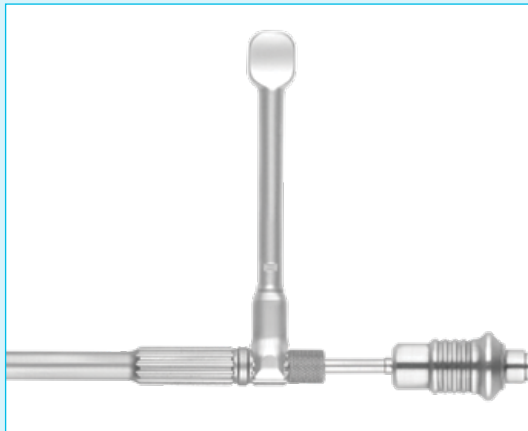


Step 6: For additional control of the distal tip, a **Counter-Torque, Angled Instrument** may be attached.

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

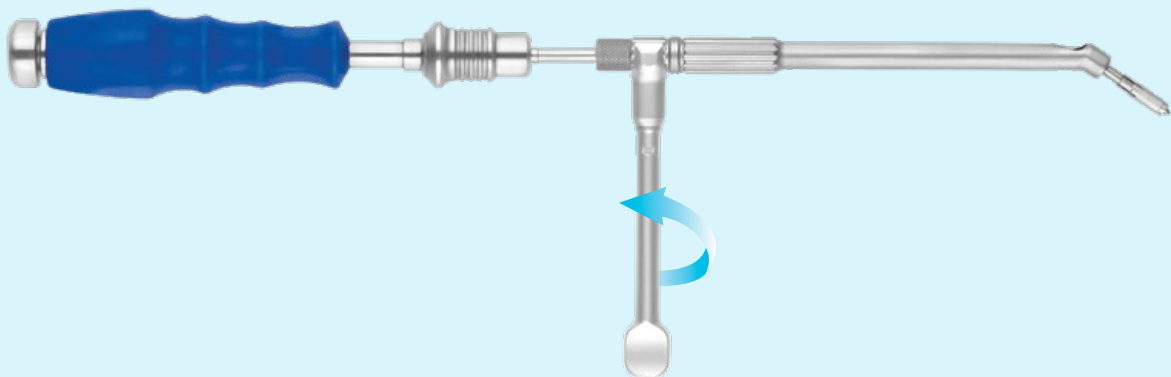


Attaching counter-torque



Counter-torque in final position

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



ASSEMBLING THE ANGLED INSTRUMENTS

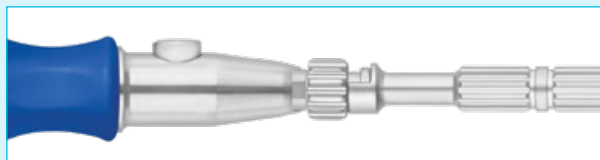
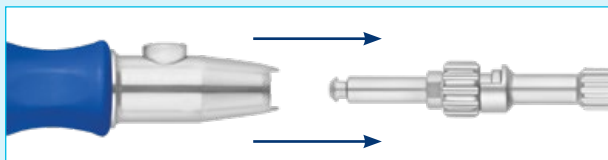
FORTIFY® I Lateral

Angled Driver Assembly Using 3.5mm Angled Hex Driver

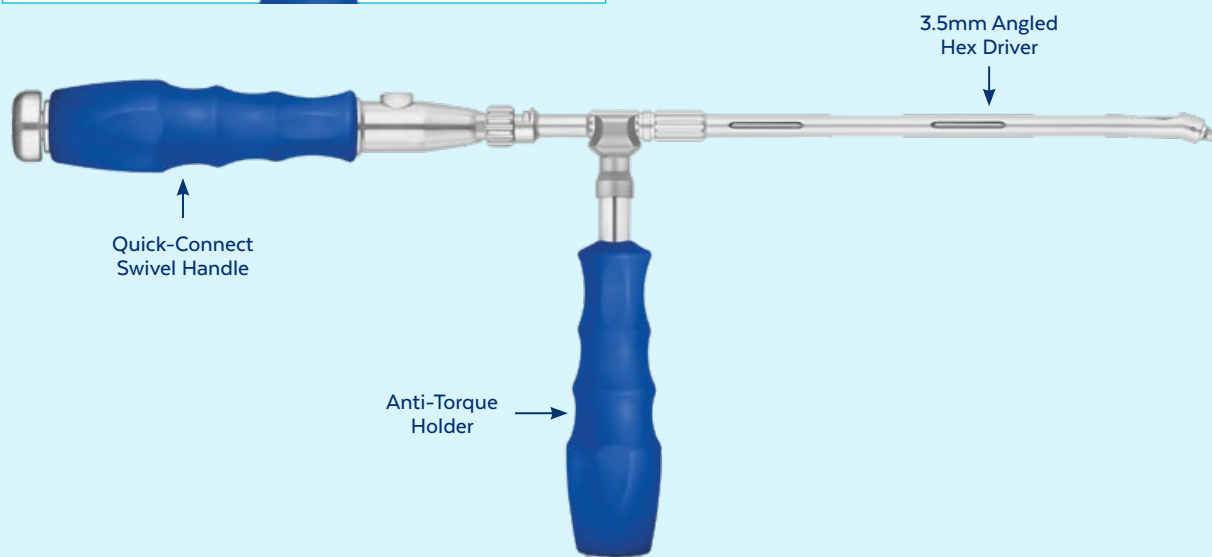
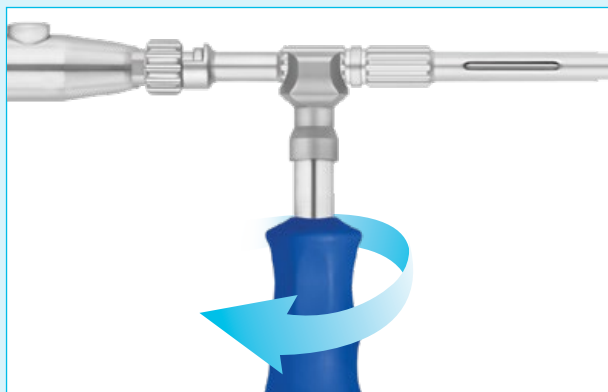
Step 1: Select the **3.5mm Angled Hex Driver**.



Step 2: Connect the **Quick-Connect Swivel Handle** to the hex driver. Slide the **Anti-Torque Holder** from the smooth portion of the hex driver to the knurled portion.



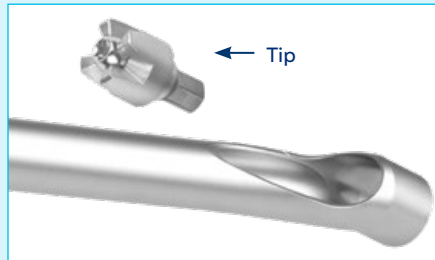
Step 3: Rotate the Anti-Torque Holder clockwise to tighten the swivel handle.



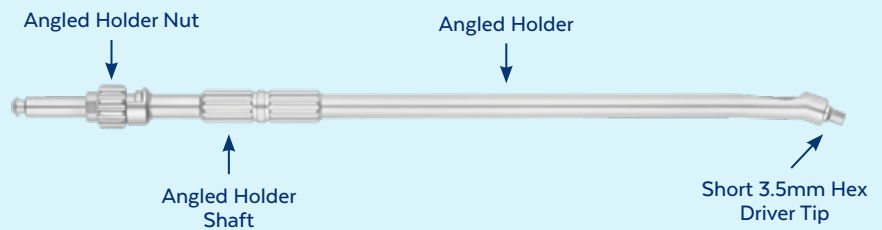
Angled Driver Assembly Using Components

Step 1: Select the appropriate tip.

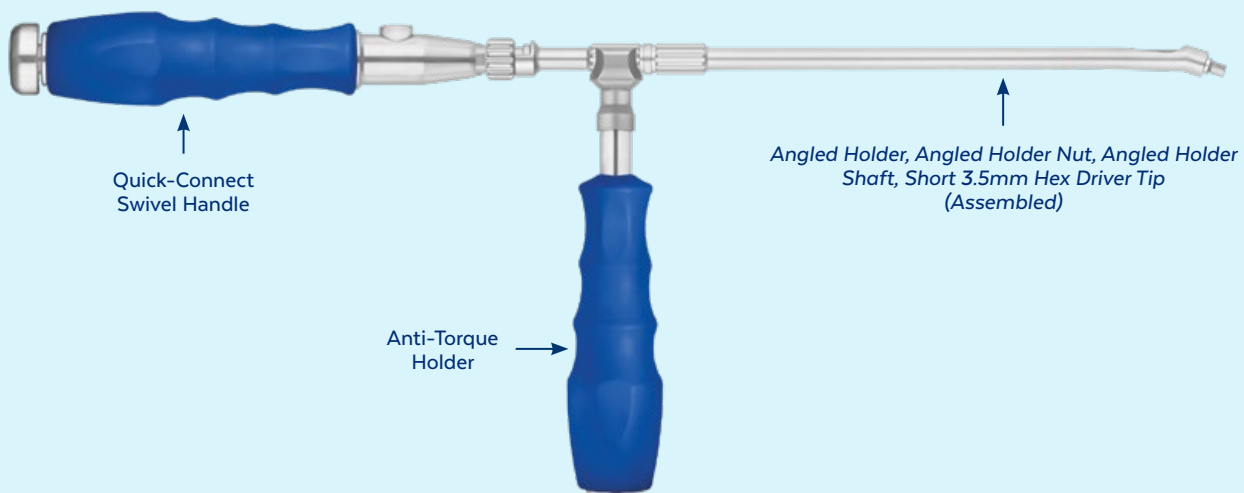
Step 2: Hold the **Angled Holder** pointed downwards with the cutout facing up as shown below. Insert the tip into the distal end of the holder.



Step 3: Place the **Angled Holder Nut** into the notch at the proximal end of the Angled Holder. Insert the **Angled Holder Shaft** through the nut and holder so that the gears of the shaft align with the gears on the tip. Attach the Quick-Connect Swivel Handle to the shaft and rotate the nut counterclockwise until tight. Use the **Spanner Wrench** to tighten the nut.

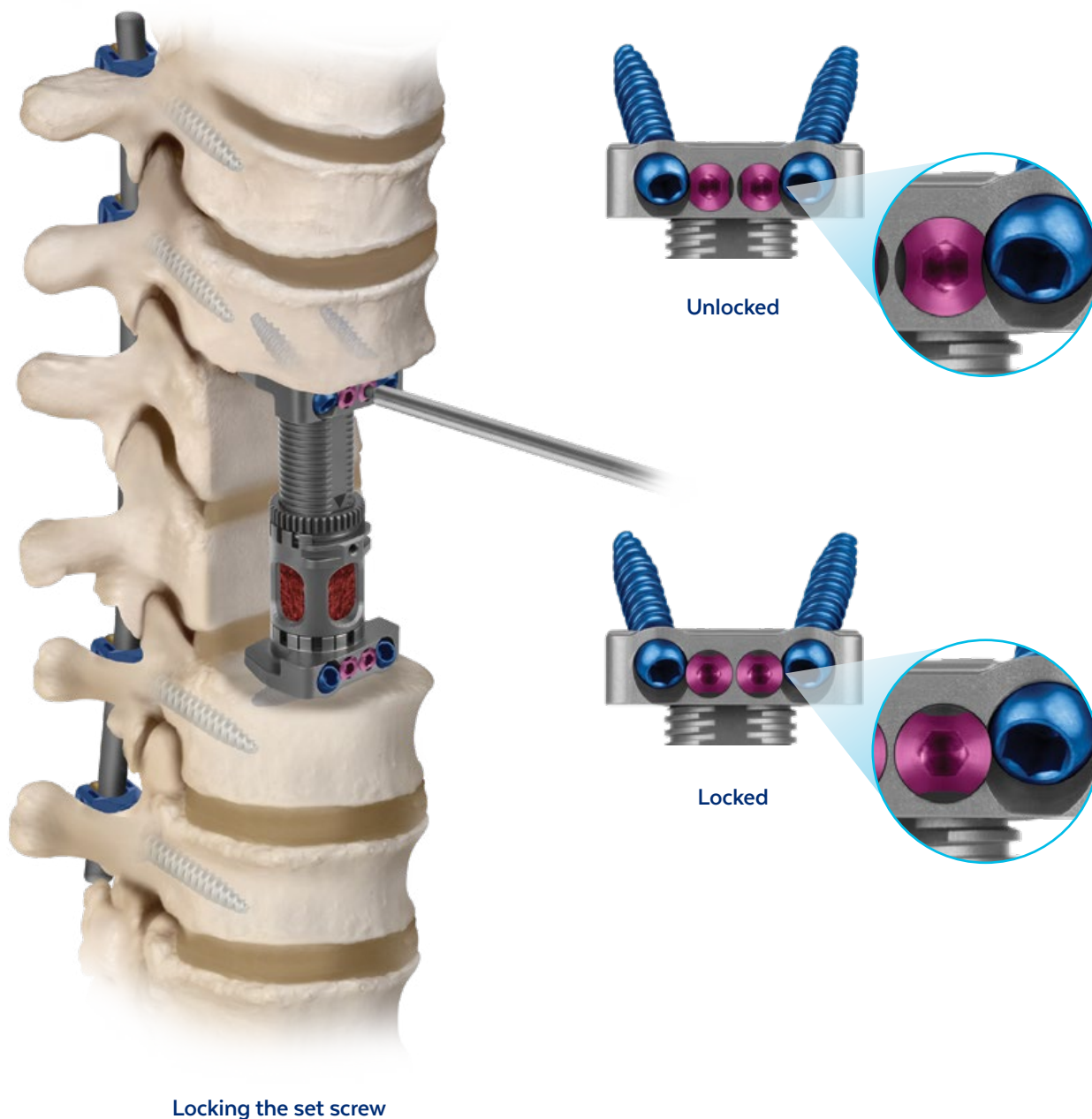


Step 4: Slide the Anti-Torque Holder from the smooth portion of the Angled Holder to the knurled portion. Rotate the Anti-Torque Holder clockwise to tighten the handle.



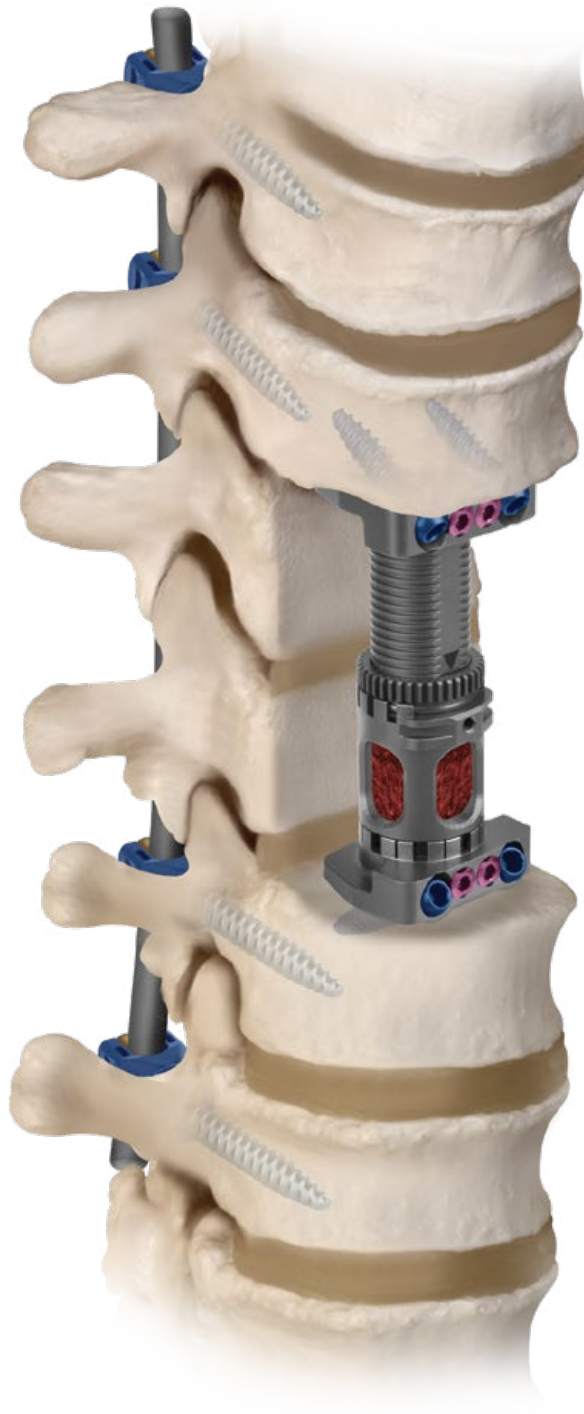
STEP 12 POSITIONING THE SET SCREW

Use a torque-limiting set screw driver to engage the blocking set screws. Rotate the set screws clockwise until the driver clicks twice. The **Set Screw Positioner, 2.0mm Hex, Torque Limiting** should be used for the small and static implants. The **INDEPENDENCE® Set Screw Driver, 2.5mm Hex** should be used for the large and lateral implants.



FINAL CONSTRUCT

FORTIFY® I is intended for use with supplemental fixation, in addition to the FORTIFY® I screws, as shown below.



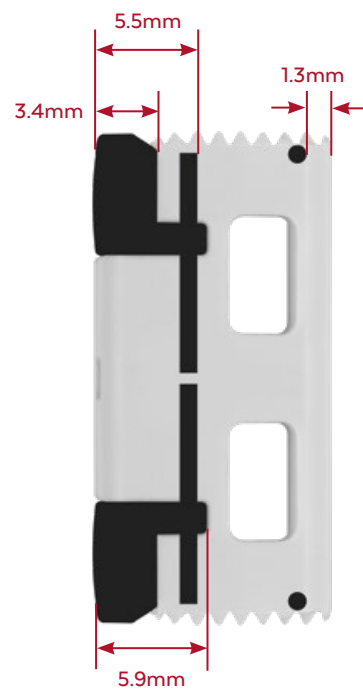
Note: Intraoperative fluoroscopy is recommended when placing fixation screws to ensure that there is no interference with FORTIFY® I screws.

RADIOGRAPHIC CONFIRMATION

The locations of markers and other features are shown below for radiographic visualization.

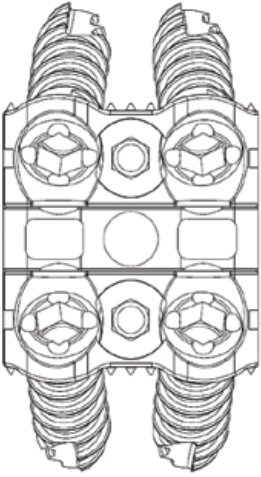
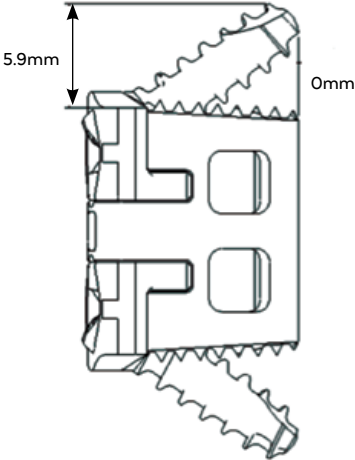
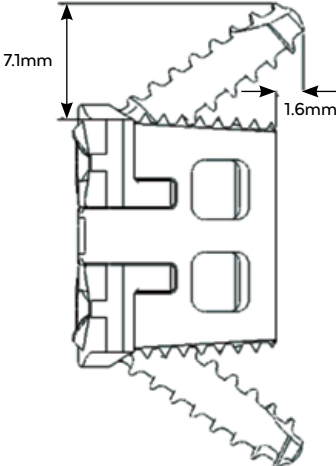
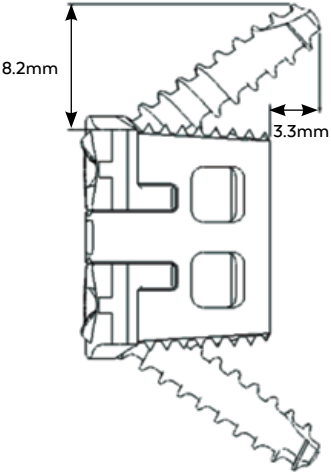
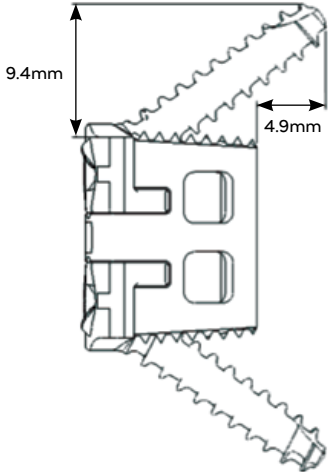
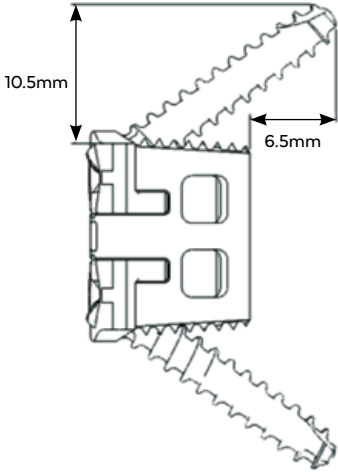


FORTIFY® I-R lateral view



Static FORTIFY® I-R lateral view

FORTIFY® I SCREW DIAGRAMS

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

FORTIFY® I SCREW DIAGRAMS

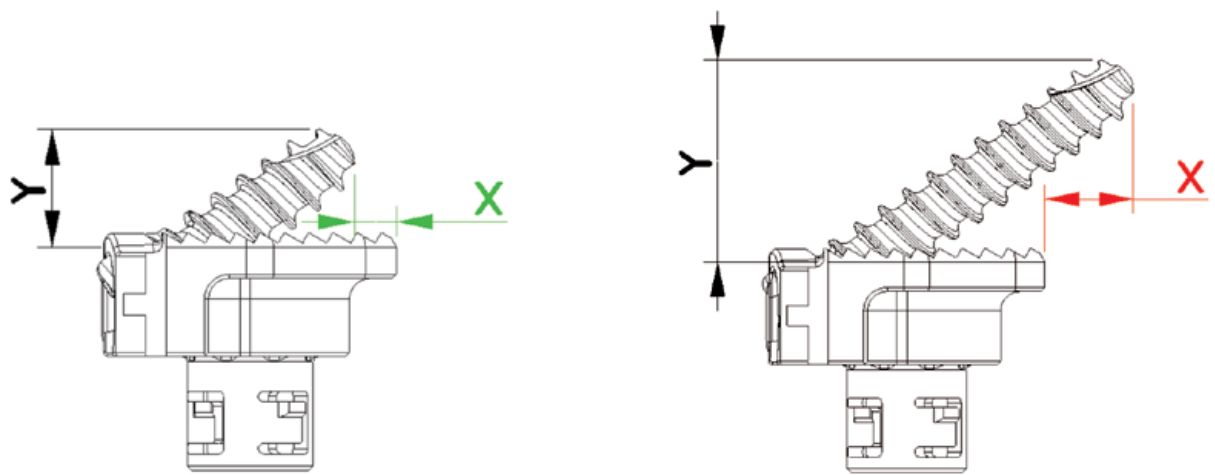
Green Numbers – Indicate the distance from the screw tip to the posterior edge of the endplates

Red Numbers – Indicate the distance the screw tip is past the posterior edge of the endplates

Note: Distance is the same for both upper and lower endplates.

FORTIFY® I-R Small

Footprint	Screw Length	X	Y
14x14mm 14x16mm	12mm	2.0mm	5.9mm
	14mm	0.4mm	7.1mm
	16mm	1.3mm	8.2mm
	18mm	2.9mm	9.4mm
	20mm	4.5mm	10.5mm



FORTIFY® I SCREW DIAGRAMS

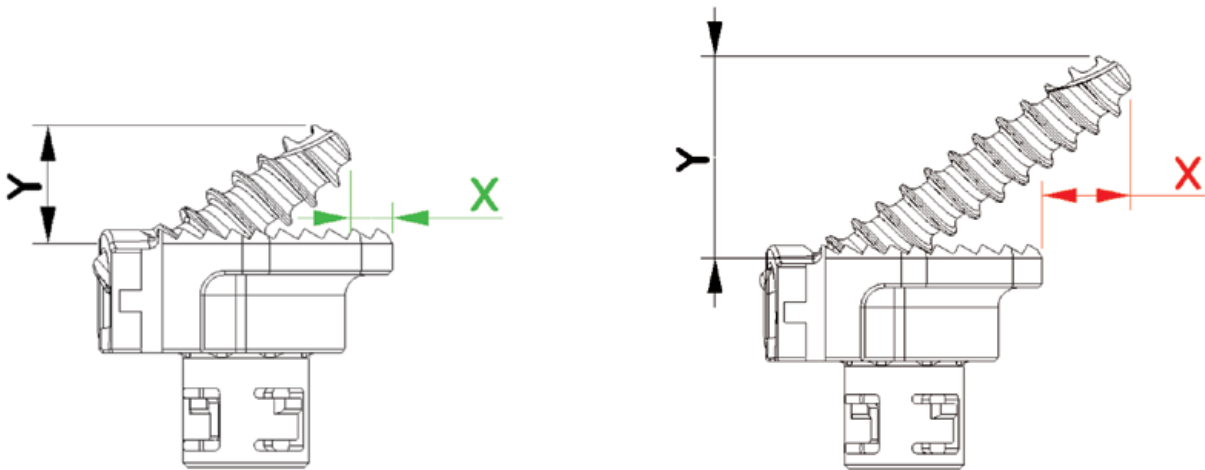
Green Numbers - Indicate the distance from the screw tip to the posterior edge of the endplates

Red Numbers - Indicate the distance the screw tip is past the posterior edge of the endplates

Note: Distance is the same for both upper and lower endplates.

FORTIFY® I Small

Footprint	Screw Length	X	Y
12x14mm	12mm	0.5mm	5.9mm
	14mm	1.1mm	7.1mm
	16mm	2.8mm	8.2mm
	18mm	4.4mm	9.4mm
	20mm	6.0mm	10.5mm
14x16mm	12mm	2.0mm	5.9mm
	14mm	0.4mm	7.1mm
	16mm	1.3mm	8.2mm
	18mm	2.9mm	9.4mm
	20mm	4.5mm	10.5mm



FORTIFY® I SCREW DIAGRAMS

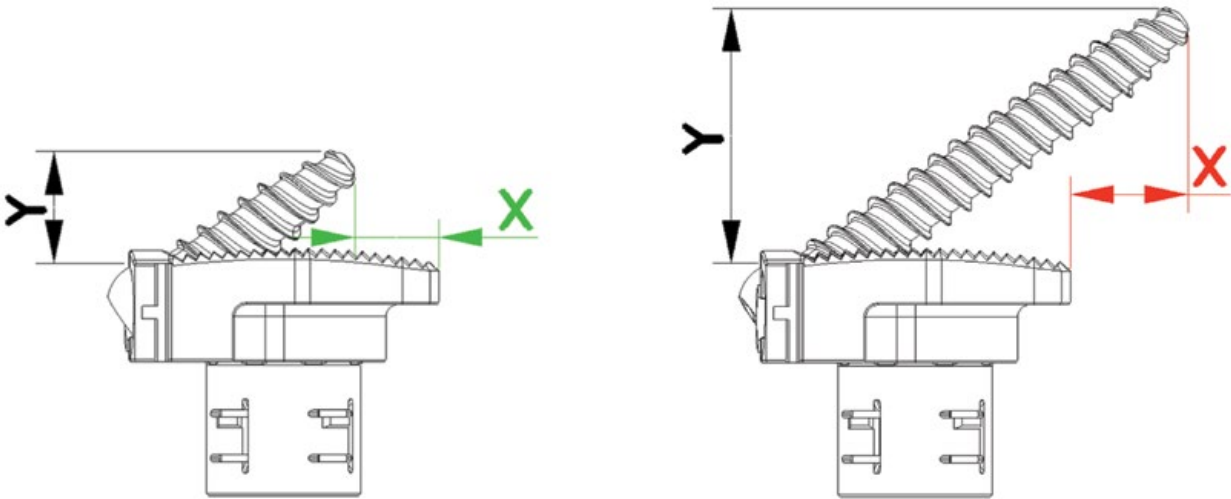
Green Numbers - Indicate the distance from the screw tip to the posterior edge of the endplates

Red Numbers - Indicate the distance the screw tip is past the posterior edge of the endplates

Note: Distance is the same for both upper and lower endplates.

FORTIFY® I Large

Footprint	Screw Length	X	Y
21x23mm	20mm	4.7mm	9mm
	25mm	0.6mm	11.9mm
	30mm	3.5mm	14.8mm
	35mm	7.6mm	17.6mm
	40mm	11.7mm	20.5mm
25x30mm	20mm	6.8mm	9.1mm
	25mm	2.7mm	12mm
	30mm	1.4mm	14.9mm
	35mm	5.4mm	17.7mm
	40mm	9.5mm	20.6mm



FORTIFY® I SCREW DIAGRAMS

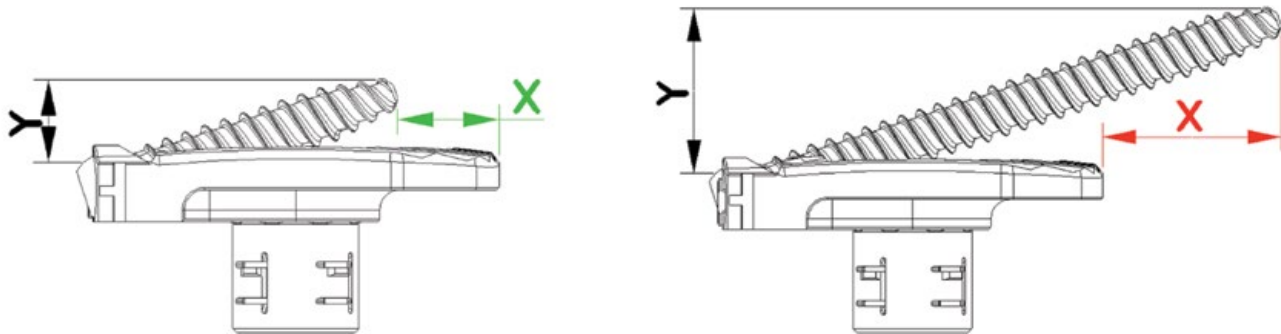
Green Numbers - Indicate the distance from the screw tip to the posterior edge of the endplates

Red Numbers - Indicate the distance the screw tip is past the posterior edge of the endplates

Note: Distance is the same for both upper and lower endplates.

FORTIFY® I Lateral

Footprint	Screw Length	X	Y
22x40mm	30mm	9.8mm	9.1mm
	35mm	5.0mm	10.6mm
	40mm	0.3mm	12mm
	45mm	4.5mm	13.4mm
	50mm	9.3mm	14.9mm
22x45mm	30mm	14.8mm	9.1mm
	35mm	10mm	12mm
	40mm	5.3mm	14.9mm
	45mm	0.5mm	17.7mm
	50mm	4.3mm	20.6mm
22x50mm	30mm	19.8mm	8.2mm
	35mm	15mm	9.8mm
	40mm	10.3mm	11.3mm
	45mm	5.5mm	12.9mm
	50mm	0.7mm	14.4mm



ENDPLATE HEIGHT GUIDES

The tables below list the height ranges for the individual cores. To calculate the assembled implant height range, add the two endplate heights (from the Core Height Table) to the core range (from the Endplate Height Table below). An example is provided below.

14mm PEEK Core Height				
	Part No.	Description	Height Range	Height Range with Endplates
	351.050	FORTIFY®-R 14mm Core, Height 24-32mm	24-32mm	32-41mm
	351.051	FORTIFY®-R 14mm Core, Height 28-40mm	28-40mm	36-49mm
	351.052	FORTIFY®-R 14mm Core, Height 35-54mm	35-54mm	43-63mm
	351.053	FORTIFY®-R 14mm Core, Height 49-71mm	49-71mm	57-80mm
	351.054	FORTIFY®-R 14mm Core, Height 66-88mm	66-88mm	74-97mm

FORTIFY® I-R Small PEEK Endplate Height			
Part No.	Part Description	Add to Starting Height (mm)	Add to Expanded Height (mm)
337.300	FORTIFY® I-R 14mm Upper Endplate, 14x14mm Footprint, 0°, No Spikes	3.5	4
337.301	FORTIFY® I-R 14mm Upper Endplate, 14x14mm Footprint, 3.5°, No Spikes		
337.302	FORTIFY® I-R 14mm Upper Endplate, 14x14mm Footprint, 7°, No Spikes		
337.310	FORTIFY® I-R 14mm Upper Endplate, 14x16mm Footprint, 0°, No Spikes		
337.311	FORTIFY® I-R 14mm Upper Endplate, 14x16mm Footprint, 3.5°, No Spikes		
337.312	FORTIFY® I-R 14mm Upper Endplate, 14x16mm Footprint, 7°, No Spikes	4.5	5
337.350	FORTIFY® I-R 14mm Lower Endplate, 14x14mm Footprint, 0°, No Spikes		
337.351	FORTIFY® I-R 14mm Lower Endplate, 14x14mm Footprint, 3.5°, No Spikes		
337.352	FORTIFY® I-R 14mm Lower Endplate, 14x14mm Footprint, 7°, No Spikes		
337.360	FORTIFY® I-R 14mm Lower Endplate, 14x16mm Footprint, 0°, No Spikes		
337.361	FORTIFY® I-R 14mm Lower Endplate, 14x16mm Footprint, 3.5°, No Spikes		
337.362	FORTIFY® I-R 14mm Lower Endplate, 14x16mm Footprint, 7°, No Spikes		

Example - Calculating Height Range, 14mm PEEK Implant			
Part No.	Part Description	Contracted Height	Expanded Height
351.051	FORTIFY®-R 14mm Core, Height 28-40mm	28mm	40mm
337.301	FORTIFY® I-R 14mm Upper Endplate, 14x14mm Footprint, 3.5°, No Spikes	3.5mm	4mm
337.351	FORTIFY® I-R 14mm Lower Endplate, 14x14mm Footprint, 3.5°, No Spikes	4.5mm	5mm
		Total Contracted Height = 36mm	Total Expanded Height = 49mm

For fixed lower endplates, the height ranges are listed below. No additional height is added.

14mm Fixed Lower Endplate Height			
	Part No.	Description	Height Range*
	337.001	FORTIFY® I-R 14mm Core, Height 25-30mm, 14x14mm Footprint, 0°, No Spikes	25-30mm
	337.002	FORTIFY® I-R 14mm Core, Height 25-30mm, 14x14mm Footprint, 3.5°, No Spikes	25-30mm
	337.003	FORTIFY® I-R 14mm Core, Height 27-34mm, 14x14mm Footprint, 0°, No Spikes	27-34mm
	337.004	FORTIFY® I-R 14mm Core, Height 27-34mm, 14x14mm Footprint, 3.5°, No Spikes	27-34mm

*FORTIFY® I-R Fixed Lower Endplates include Upper Endplate in height range.

ENDPLATE HEIGHT GUIDES

The tables below list the height ranges for the individual cores. To calculate the assembled implant height range, add the two endplate heights (from the Core Height Table) to the core range (from the Endplate Height Table below). An example is provided below.

12mm Titanium Core Height				
	Part No.	Description	Height Range	Height Range with Endplates
	151.050	FORTIFY® 12mm Core, Height 18-23mm	18-23mm	25-32mm
	151.051	FORTIFY® 12mm Core, Height 19-25mm	19-25mm	26-34mm
	151.052	FORTIFY® 12mm Core, Height 21-29mm	21-29mm	28-38mm
	151.053	FORTIFY® 12mm Core, Height 25-37mm	25-37mm	32-46mm
	151.054	FORTIFY® 12mm Core, Height 33-53mm	33-53mm	40-62mm
	151.055	FORTIFY® 12mm Core, Height 48-71mm	48-71mm	55-80mm
	151.056	FORTIFY® 12mm Core, Height 67-88mm	67-88mm	74-97mm

FORTIFY® I Small Titanium Endplate Height			
Part No.	Part Description	Add to Starting Height (mm)	Add to Expanded Height (mm)
137.300	FORTIFY® I 12mm Upper Endplate, 12x14mm Footprint, 0°, No Spikes	3.5	4.5
137.301	FORTIFY® I 12mm Upper Endplate, 12x14mm Footprint, 3.5°, No Spikes		
137.302	FORTIFY® I 12mm Upper Endplate, 12x14mm Footprint, 7°, No Spikes		
137.310	FORTIFY® I 12mm Upper Endplate, 14x16mm Footprint, 0°, No Spikes		
137.311	FORTIFY® I 12mm Upper Endplate, 14x16mm Footprint, 3.5°, No Spikes		
137.312	FORTIFY® I 12mm Upper Endplate, 14x16mm Footprint, 7°, No Spikes		
137.350	FORTIFY® I 12mm Lower Endplate, 12x14mm Footprint, 0°, No Spikes		
137.351	FORTIFY® I 12mm Lower Endplate, 12x14mm Footprint, 3.5°, No Spikes		
137.352	FORTIFY® I 12mm Lower Endplate, 12x14mm Footprint, 7°, No Spikes		
137.360	FORTIFY® I 12mm Lower Endplate, 14x16mm Footprint, 0°, No Spikes		
137.361	FORTIFY® I 12mm Lower Endplate, 14x16mm Footprint, 3.5°, No Spikes		
137.362	FORTIFY® I 12mm Lower Endplate, 14x16mm Footprint, 7°, No Spikes		

Example - Calculating Height Range, 12mm Implant			
Part No.	Part Description	Contracted Height	Expanded Height
151.052	FORTIFY® 12mm Core, Height 21-29mm	21mm	29mm
137.302	FORTIFY® I Upper Endplate, 12x14mm Footprint, 7°, No Spikes	3.5mm	4.5mm
137.352	FORTIFY® I Lower Endplate, 12x14mm Footprint, 7°, No Spikes	3.5mm	4.5mm
		Total Contracted Height = 28mm	Total Expanded Height = 38mm

For fixed lower endplates, the height ranges are listed below. No additional height is added.

12mm Fixed Lower Endplate Height			
	Part No.	Description	Height Range*
	137.001	FORTIFY® I 12mm Core, Height 23-28mm, 12x14mm Footprint, 0°, No Spikes	23-28mm
	137.002	FORTIFY® I 12mm Core, Height 23-28mm, 12x14mm Footprint, 3.5°, No Spikes	23-28mm

*FORTIFY® I Fixed Lower Endplates include Upper Endplate in height range.

ENDPLATE HEIGHT GUIDES

FORTIFY® I Large Titanium Added Endplate Height			
Part No.	Part Description	Add to Starting Height (mm)	Add to Expanded Height (mm)
137.410	FORTIFY® I 20mm Upper Endplate, 21x23mm Footprint, 0°, No Spikes	4.5	6
137.411	FORTIFY® I 20mm Upper Endplate, 21x23mm Footprint, 4°, No Spikes	5.5	6.5
137.412	FORTIFY® I 20mm Upper Endplate, 21x23mm Footprint, 8°, No Spikes	6	7
137.430	FORTIFY® I 20mm Upper Endplate, 25x30mm Footprint, 0°, No Spikes	5	6
137.431	FORTIFY® I 20mm Upper Endplate, 25x30mm Footprint, 4°, No Spikes	5	6
137.432	FORTIFY® I 20mm Upper Endplate, 25x30mm Footprint, 8°, No Spikes	5	6
137.460	FORTIFY® I 20mm Lower Endplate, 21x23mm Footprint, 0°, No Spikes	4.5	5.5
137.461	FORTIFY® I 20mm Lower Endplate, 21x23mm Footprint, 4°, No Spikes	5	6
137.462	FORTIFY® I 20mm Lower Endplate, 21x23mm Footprint, 8°, No Spikes	6	7
137.480	FORTIFY® I 20mm Lower Endplate, 25x30mm Footprint, 0°, No Spikes	5.5	6.5
137.481	FORTIFY® I 20mm Lower Endplate, 25x30mm Footprint, 4°, No Spikes	5.5	6.5
137.482	FORTIFY® I 20mm Lower Endplate, 25x30mm Footprint, 8°, No Spikes	5.5	6.5
137.483	FORTIFY® I 20mm Lower Endplate, 25x30mm Footprint, 12°, No Spikes	5.5	6.5
137.484	FORTIFY® I 20mm Lower Endplate, 25x30mm Footprint, 16°, No Spikes	5.5	6.5

20mm Titanium Core		
	Part No.	Description
	151.150	FORTIFY® 20mm Core, Height 23-28mm
	151.151	FORTIFY® 20mm Core, Height 26-34mm
	151.152	FORTIFY® 20mm Core, Height 31-44mm
	151.153	FORTIFY® 20mm Core, Height 41-64mm
	151.154	FORTIFY® 20mm Core, Height 62-92mm
	151.155	FORTIFY® 20mm Core, Height 90-120mm

FORTIFY® I Large Titanium Added Endplate Height - 21x23mm (LATERAL ONLY)								
Footprint	Upper Endplate	Lower Endplate	Original Core Range (mm)					
			23-28	26-34	31-44	41-64	62-92	90-120
			Core Range with Endplates (mm)					
21x23mm	0°	0°	32-39.5	35-45.5	40-55.5	50-75.5	71-103.5	99-131.5
	0°	4°	32.5-40	35.5-46	40.5-56	50.5-76	71.5-104	99.5-132
	0°	8°	33.5-41	36.5-47	41.5-57	51.5-77	72.5-105	100.5-133
	4°	0°	33-40	36-46	41-56	51-76	72-104	100-132
	4°	4°	33.5-40.5	36.5-46.5	41.5-56.5	51.5-76.5	72.5-104.5	100.5-132.5
	4°	8°	34.5-41.5	37.5-47.5	42.5-57.5	52.5-77.5	73.5-105.5	101.5-133.5
	8°	0°	33.5-40.5	36.5-46.5	41.5-56.5	51.5-76.5	72.5-104.5	100.5-132.5
	8°	4°	34-41	37-47	42-57	52-77	73-105	101-133
	8°	8°	35-42	38-48	43-58	53-78	74-106	102-134

ENDPLATE HEIGHT GUIDES

FORTIFY® I Large Titanium Added Endplate Height - 25x30mm								
Footprint	Upper Endplate	Lower Endplate	Original Core Range (mm)					
			23-28	26-34	31-44	41-64	62-92	90-120
			Core Range with Endplates (mm)					
25x30mm	All	All	33.5-40.5	36.5-46.5	41.5-56.5	51.5-76.5	72.5-104.5	100.5-132.5

Example - Calculating Height Range, 20mm Implant			
Part No.	Part Description	Contracted Height	Expanded Height
151.151	FORTIFY® 20mm Core, Height 26-34mm	26mm	34mm
137.412	FORTIFY® I 20mm Upper Endplate, 21x23mm Footprint, 8°, No Spikes	6mm	7mm
151.462	FORTIFY® I 20mm Lower Endplate, 21x23mm Footprint, 8°, No Spikes	6mm	7mm
		Total Contracted Height = 38mm	Total Expanded Height = 48mm

ENDPLATE HEIGHT GUIDES

FORTIFY® I Lateral Endplate Height			
Part No.	Part Description	Add to Starting Height (mm)	Add to Expanded Height (mm)
137.600	FORTIFY® I 20mm Upper Endplate, 22x40mm Footprint, 0°, No Spikes	3.5	4.5
137.601	FORTIFY® I 20mm Upper Endplate, 22x40mm Footprint, 4°, No Spikes	4	5
137.602	FORTIFY® I 20mm Upper Endplate, 22x40mm Footprint, 8°, No Spikes	5	6
137.603	FORTIFY® I 20mm Upper Endplate, 22x40mm Footprint, 12°, No Spikes	6	7.5
137.610	FORTIFY® I 20mm Upper Endplate, 22x45mm Footprint, 0°, No Spikes	3.5	4.5
137.611	FORTIFY® I 20mm Upper Endplate, 22x45mm Footprint, 4°, No Spikes	4.5	5.5
137.612	FORTIFY® I 20mm Upper Endplate, 22x45mm Footprint, 8°, No Spikes	5.5	6.5
137.613	FORTIFY® I 20mm Upper Endplate, 22x45mm Footprint, 12°, No Spikes	6.5	7.5
137.620	FORTIFY® I 20mm Upper Endplate, 22x50mm Footprint, 0°, No Spikes	3.5	5
137.621	FORTIFY® I 20mm Upper Endplate, 22x50mm Footprint, 4°, No Spikes	4.5	5.5
137.622	FORTIFY® I 20mm Upper Endplate, 22x50mm Footprint, 8°, No Spikes	5.5	6.5
137.623	FORTIFY® I 20mm Upper Endplate, 22x50mm Footprint, 12°, No Spikes	6.5	7.5
137.650	FORTIFY® I 20mm Lower Endplate, 22x40mm Footprint, 0°, No Spikes	3	4
137.651	FORTIFY® I 20mm Lower Endplate, 22x40mm Footprint, 4°, No Spikes	4	5
137.652	FORTIFY® I 20mm Lower Endplate, 22x40mm Footprint, 8°, No Spikes	5	6
137.653	FORTIFY® I 20mm Lower Endplate, 22x40mm Footprint, 12°, No Spikes	6	7
137.660	FORTIFY® I 20mm Lower Endplate, 22x45mm Footprint, 0°, No Spikes	3.5	4.5
137.661	FORTIFY® I 20mm Lower Endplate, 22x45mm Footprint, 4°, No Spikes	4	5
137.662	FORTIFY® I 20mm Lower Endplate, 22x45mm Footprint, 8°, No Spikes	5	6
137.663	FORTIFY® I 20mm Lower Endplate, 22x45mm Footprint, 12°, No Spikes	6	7
137.670	FORTIFY® I 20mm Lower Endplate, 22x50mm Footprint, 0°, No Spikes	3.5	4.5
137.671	FORTIFY® I 20mm Lower Endplate, 22x50mm Footprint, 4°, No Spikes	4.5	5.5
137.672	FORTIFY® I 20mm Lower Endplate, 22x50mm Footprint, 8°, No Spikes	5.5	6.5
137.673	FORTIFY® I 20mm Lower Endplate, 22x50mm Footprint, 12°, No Spikes	6.5	7.5

20mm Titanium Core Height		
	Part No.	Description
	151.150	FORTIFY® 20mm Core, Height 23-28mm
	151.151	FORTIFY® 20mm Core, Height 26-34mm
	151.152	FORTIFY® 20mm Core, Height 31-44mm
	151.153	FORTIFY® 20mm Core, Height 41-64mm
	151.154	FORTIFY® 20mm Core, Height 62-92mm
	151.155	FORTIFY® 20mm Core, Height 90-120mm

ENDPLATE HEIGHT GUIDES

FORTIFY® Lateral Titanium Endplate Height - 22x40mm								
Footprint	Upper Endplate	Lower Endplate	Original Core Range (mm)					
			23-28	26-34	31-44	41-64	62-92	90-120
			Core Range with Endplates (mm)					
22x40mm	0°	0°	29.5-36.5	32.5-42.5	37.5-52.5	47.5-72.5	68.5-100.5	96.5-128.5
	0°	4°	30.5-37.5	33.5-43.5	38.5-53.5	48.5-73.5	69.5-101.5	97.5-129.5
	0°	8°	31.5-38.5	34.5-44.5	39.5-54.5	49.5-74.5	70.5-102.5	98.5-130.5
	0°	12°	32.5-39.5	35.5-45.5	40.5-55.5	50.5-75.5	71.5-103.5	99.5-131.5
	4°	0°	30-37	33-43	38-53	48-73	69-101	97-129
	4°	4°	31-38	34-44	39-54	49-74	70-102	98-130
	4°	8°	32-39	35-45	40-55	50-75	71-103	99-131
	4°	12°	33-40	36-46	41-56	51-76	72-104	100-132
	8°	0°	31-38	34-44	39-54	49-74	70-102	98-130
	8°	4°	32-39	35-45	40-55	50-75	71-103	99-131
	8°	8°	33-40	36-46	41-56	51-76	72-104	100-132
	8°	12°	34-41	37-47	42-57	52-77	73-105	101-133
	12°	0°	32-39.5	35-45.5	40-55.5	50-75.5	71-103.5	99-131.5
	12°	4°	33-40.5	36-46.5	41-56.5	51-76.5	72-104.5	100-132.5
	12°	8°	34-41.5	37-47.5	42-57.5	52-77.5	73-105.5	101-133.5
	12°	12°	35-42.5	38-48.5	43-58.5	53-78.5	74-106.5	102-134.5

FORTIFY® Lateral Titanium Endplate Height - 22x45mm								
Footprint	Upper Endplate	Lower Endplate	Original Core Range (mm)					
			23-28	26-34	31-44	41-64	62-92	90-120
			Core Range with Endplates (mm)					
22x45mm	0°	0°	30-37	33-43	38-53	48-73	69-101	97-129
	0°	4°	30.5-37.5	33.5-43.5	38.5-53.5	48.5-73.5	69.5-101.5	97.5-129.5
	0°	8°	31.5-38.5	34.5-44.5	39.5-54.5	49.5-74.5	70.5-102.5	98.5-130.5
	0°	12°	32.5-39.5	35.5-45.5	40.5-55.5	50.5-75.5	71.5-103.5	99.5-131.5
	4°	0°	31-38	34-44	39-54	49-74	70-102	98-130
	4°	4°	31.5-38.5	34.5-44.5	39.5-54.5	49.5-74.5	70.5-102.5	98.5-130.5
	4°	8°	32.5-39.5	35.5-45.5	40.5-55.5	50.5-75.5	71.5-103.5	99.5-131.5
	4°	12°	33.5-40.5	36.5-46.5	41.5-56.5	51.5-76.5	72.5-104.5	100.5-132.5
	8°	0°	32-39	35-45	40-55	50-75	71-103	99-131
	8°	4°	32.5-39.5	35.5-45.5	40.5-55.5	50.5-75.5	71.5-103.5	99.5-131.5
	8°	8°	33.5-40.5	36.5-46.5	41.5-56.5	51.5-76.5	72.5-104.5	100.5-132.5
	8°	12°	34.5-41.5	37.5-47.5	42.5-57.5	52.5-77.5	73.5-105.5	101.5-133.5
	12°	0°	33-40	36-46	41-56	51-76	72-104	100-132
	12°	4°	33.5-40.5	36.5-46.5	41.5-56.5	51.5-76.5	72.5-104.5	100.5-132.5
	12°	8°	34.5-41.5	37.5-47.5	42.5-57.5	52.5-77.5	73.5-105.5	101.5-133.5
	12°	12°	35.5-42.5	38.5-48.5	43.5-58.5	53.5-78.5	74.5-106.5	102.5-134.5

ENDPLATE HEIGHT GUIDES

FORTIFY® I Lateral Titanium Added Endplate Height – 22x50mm								
Footprint	Upper Endplate	Lower Endplate	Original Core Range (mm)					
			23-28	26-34	31-44	41-64	62-92	90-120
			Core Range with Endplates (mm)					
22x50mm	0°	0°	30-37.5	33-43.5	38-53.5	48-73.5	69-101.5	97-129.5
	0°	4°	31-38.5	34-44.5	39-54.5	49-74.5	70-102.5	98-130.5
	0°	8°	32-39.5	35-45.5	40-55.5	50-75.5	71-103.5	99-131.5
	0°	12°	33-40.5	36-46.5	41-56.5	51-76.5	72-104.5	100-132.5
	4°	0°	31-38	34-44	39-54	49-74	70-102	98-130
	4°	4°	32-39	35-45	40-55	50-75	71-103	99-131
	4°	8°	33-40	36-46	41-56	51-76	72-104	100-132
	4°	12°	34-41	37-47	42-57	52-77	73-105	101-133
	8°	0°	32-39	35-45	40-55	50-75	71-103	99-131
	8°	4°	33-40	36-46	41-56	51-76	72-104	100-132
	8°	8°	34-41	37-47	42-57	52-77	73-105	101-133
	8°	12°	35-42	38-48	43-58	53-78	74-106	102-134
	12°	0°	33-40	36-46	41-56	51-76	72-104	100-132
	12°	4°	34-41	37-47	42-57	52-77	73-105	101-133
	12°	8°	35-42	38-48	43-58	53-78	74-106	102-134
	12°	12°	36-43	39-49	44-59	54-79	75-107	103-135

Example – Calculating Height Range, Lateral Implant			
Part No.	Part Description	Contracted Height	Expanded Height
151.152	FORTIFY® 20mm Core, Height 31-44mm	31mm	44mm
137.623	FORTIFY® I 20mm Upper Endplate, 22x50mm Footprint, 12°, No Spikes	6.5mm	7.5mm
137.673	FORTIFY® I 20mm Lower Endplate, 22x50mm Footprint, 12°, No Spikes	6.5mm	7.5mm
		Total Contracted Height = 44mm	Total Expanded Height = 59mm

FORTIFY® I GRAFT VOLUMES

Graft Volume (cc) for Static FORTIFY® I-R 12x14mm			
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

Each endplate used adds an additional 0.5cc of graft volume to the amount needed for the core.

Graft Volume (cc) for FORTIFY® -R Small PEEK Cores											
Height (mm)	Graft Volume (cc)	Height (mm)	Graft Volume (cc)	Height (mm)	Graft Volume (cc)	Height (mm)	Graft Volume (cc)	Height (mm)	Graft Volume (cc)	Height (mm)	Graft Volume (cc)
15	0.29	30	0.59	45	0.88	60	1.18	75	1.47	90	1.77
16	0.31	31	0.61	46	0.90	61	1.20	76	1.49	91	1.79
17	0.33	32	0.63	47	0.92	62	1.22	77	1.51	92	1.77
18	0.35	33	0.65	48	0.94	63	1.24	78	1.53	93	1.79
19	0.37	34	0.67	49	0.96	64	1.26	79	1.55	-	-
20	0.39	35	0.69	50	0.98	65	1.28	80	1.57	-	-
21	0.41	36	0.71	51	1.00	66	1.30	81	1.59	-	-
22	0.43	37	0.73	52	1.02	67	1.32	82	1.61	-	-
23	0.45	38	0.75	53	1.04	68	1.34	83	1.63	-	-
24	0.47	39	0.77	54	1.06	69	1.35	84	1.65	-	-
25	0.49	40	0.79	55	1.08	70	1.37	85	1.67	-	-
26	0.51	41	0.81	56	1.10	71	1.39	86	1.69	-	-
27	0.53	42	0.82	57	1.12	72	1.41	87	1.71	-	-
28	0.55	43	0.84	58	1.14	73	1.43	88	1.73	-	-
29	0.57	44	0.86	59	1.16	74	1.45	89	1.75	-	-

For fixed lower endplates, 0.5cc of graft volume should be added for the upper endplate only.

Graft Volume (cc) for FORTIFY® I-R Small PEEK Fixed Lower Endplates	
Height (mm)	Graft Volume (cc)
25	0.51
26	0.53
27	0.55
28	0.57
29	0.59
30	0.61
31	0.63
32	0.65
33	0.67
34	0.69

FORTIFY® I GRAFT VOLUMES

Each endplate used adds an additional 0.5cc of graft volume that needs to be added to the amount needed for the core.

Graft Volume (cc) for FORTIFY® Small Titanium Cores											
Height (mm)	Graft Volume (cc)	Height (mm)	Graft Volume (cc)	Height (mm)	Graft Volume (cc)	Height (mm)	Graft Volume (cc)	Height (mm)	Graft Volume (cc)	Height (mm)	Graft Volume (cc)
15	0.37	29	0.71	43	1.06	57	1.40	71	1.75	85	2.09
16	0.39	30	0.74	44	1.08	58	1.43	72	1.77	86	2.12
17	0.42	31	0.76	45	1.11	59	1.45	73	1.80	87	2.14
18	0.44	32	0.79	46	1.13	60	1.48	74	1.82	88	2.17
19	0.47	33	0.81	47	1.16	61	1.50	75	1.85	89	2.19
20	0.49	34	0.84	48	1.18	62	1.53	76	1.87	90	2.22
21	0.52	35	0.86	49	1.21	63	1.55	77	1.90	91	2.24
22	0.54	36	0.89	50	1.23	64	1.58	78	1.92	92	2.27
23	0.57	37	0.91	51	1.26	65	1.60	79	1.95	93	2.29
24	0.59	38	0.94	52	1.28	66	1.63	80	1.97	-	-
25	0.62	39	0.96	53	1.31	67	1.65	81	2.00	-	-
26	0.64	40	0.99	54	1.33	68	1.67	82	2.02	-	-
27	0.67	41	1.01	55	1.35	69	1.70	83	2.04	-	-
28	0.69	42	1.03	56	1.38	70	1.72	84	2.07	-	-

For fixed lower endplates, 0.5cc of graft volume should be added for the upper endplate only.

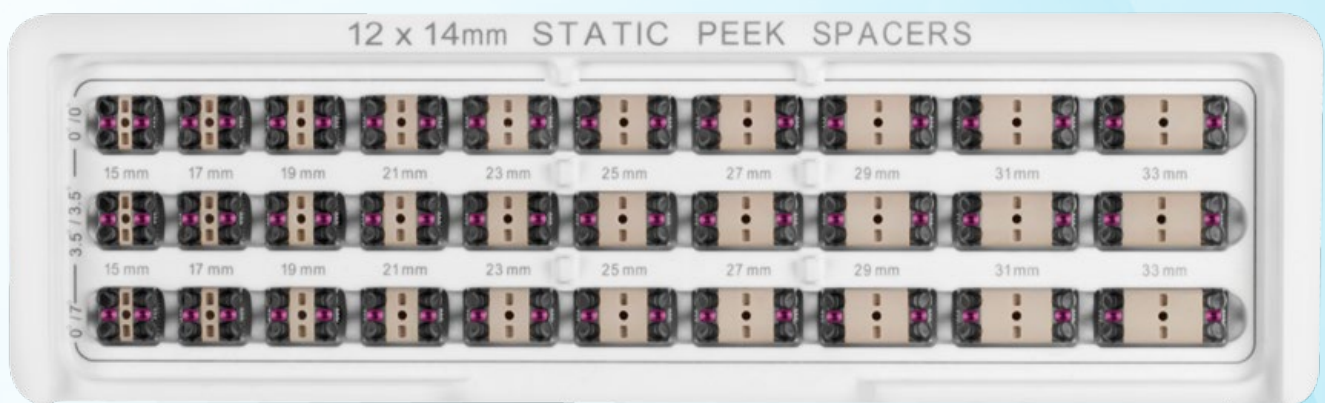
Graft Volume (cc) for FORTIFY® I Small Titanium Fixed Lower Endplates	
Height (mm)	Graft Volume (cc)
23	0.60
24	0.62
25	0.65
26	0.67
27	0.70
28	0.72

FORTIFY® | GRAFT VOLUMES

Graft Volume (cc) for FORTIFY® 20mm Titanium Cores											
Height (mm)	Graft Volume (cc)	Height (mm)	Graft Volume (cc)	Height (mm)	Graft Volume (cc)	Height (mm)	Graft Volume (cc)	Height (mm)	Graft Volume (cc)	Height (mm)	Graft Volume (cc)
23	2.60	44	4.98	65	7.35	86	9.73	107	11.88	128	14.25
24	2.71	45	5.09	66	7.46	87	9.84	108	11.99	129	14.36
25	2.83	46	5.20	67	7.58	88	9.95	109	12.10	130	14.48
26	2.94	47	5.32	68	7.69	89	10.07	110	12.21	131	14.59
27	3.05	48	5.43	69	7.80	90	10.18	111	12.33	132	14.70
28	3.17	49	5.54	70	7.92	91	10.29	112	12.44	133	14.82
29	3.28	50	5.65	71	8.03	92	10.18	113	12.55	134	14.93
30	3.39	51	5.77	72	8.14	93	10.29	114	12.67	135	15.04
31	3.51	52	5.88	73	8.26	94	10.40	115	12.78	-	-
32	3.62	53	5.99	74	8.37	95	10.52	116	12.89	-	-
33	3.73	54	6.11	75	8.48	96	10.63	117	13.01	-	-
34	3.85	55	6.22	76	8.60	97	10.74	118	13.12	-	-
35	3.96	56	6.33	77	8.71	98	10.86	119	13.23	-	-
36	4.07	57	6.45	78	8.82	99	10.97	120	13.35	-	-
37	4.18	58	6.56	79	8.93	100	11.08	121	13.46	-	-
38	4.30	59	6.67	80	9.05	101	11.20	122	13.57	-	-
39	4.41	60	6.79	81	9.16	102	11.31	123	13.68	-	-
40	4.52	61	6.90	82	9.27	103	11.42	124	13.80	-	-
41	4.64	62	7.01	83	9.39	104	11.54	125	13.91	-	-
42	4.75	63	7.13	84	9.50	105	11.65	126	14.02	-	-
43	4.86	64	7.24	85	9.61	106	11.76	127	14.14	-	-

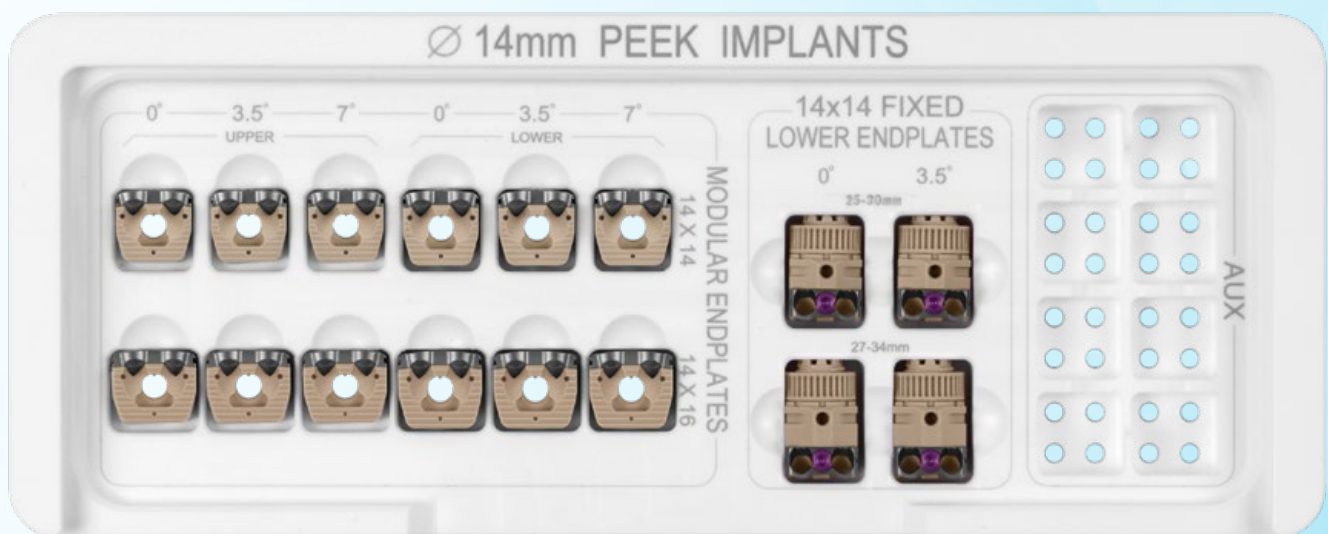
FORTIFY® I-R STATIC IMPLANT SET 937.901

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	



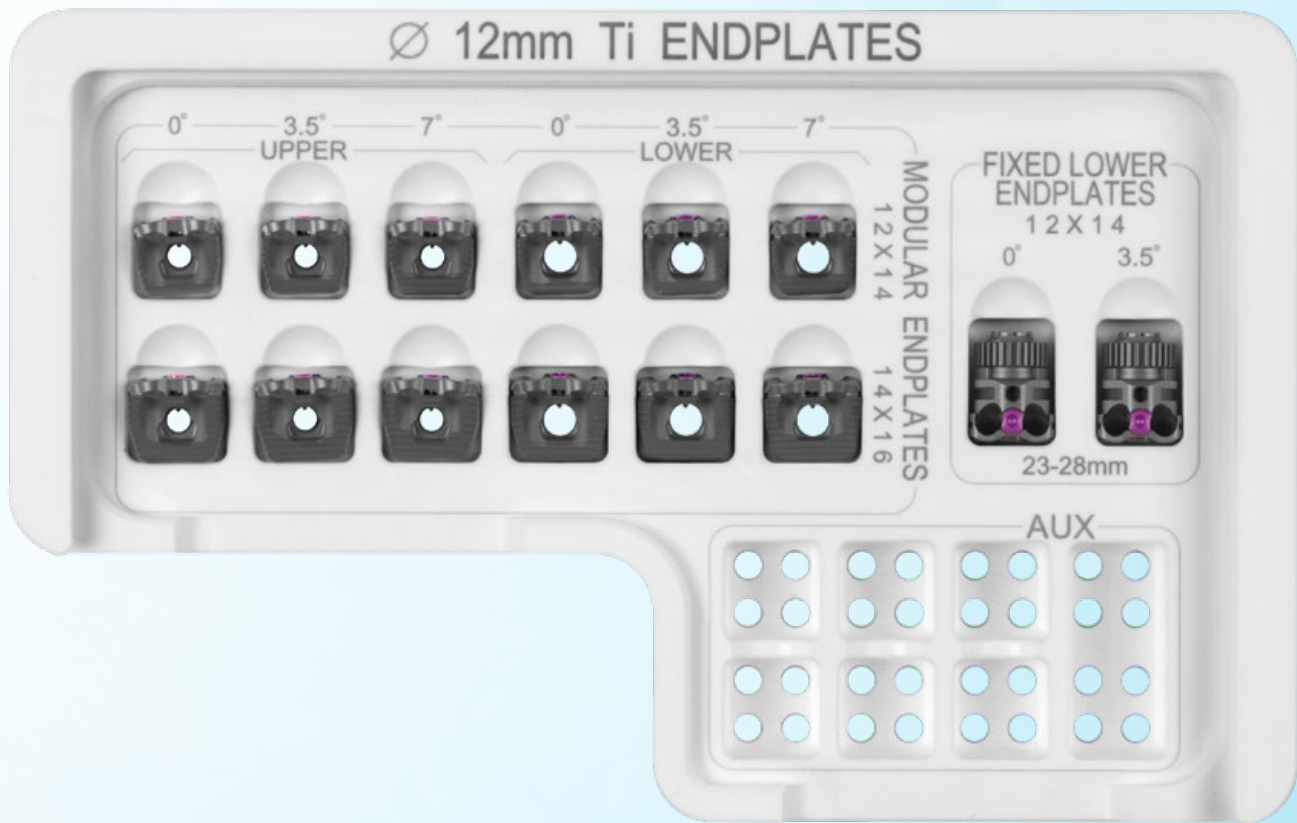
FORTIFY® I-R SMALL IMPLANT SET 937.902

Implant	Qty
337.001 FORTIFY® I-R 14mm Core, Height 25–30mm, 14x14mm Footprint, 0°, No Spikes	1
337.002 FORTIFY® I-R 14mm Core, Height 25–30mm, 14x14mm Footprint, 3.5°, No Spikes	1
337.003 FORTIFY® I-R 14mm Core, Height 27–34mm, 14x14mm Footprint, 0°, No Spikes	1
337.004 FORTIFY® I-R 14mm Core, Height 27–34mm, 14x14mm Footprint, 3.5°, No Spikes	1
337.300 FORTIFY® I-R 14mm Upper Endplate, 14x14mm Footprint, 0°, No Spikes	1
337.301 FORTIFY® I-R 14mm Upper Endplate, 14x14mm Footprint, 3.5°, No Spikes	1
337.302 FORTIFY® I-R 14mm Upper Endplate, 14x14mm Footprint, 7°, No Spikes	1
337.310 FORTIFY® I-R 14mm Upper Endplate, 14x16mm Footprint, 0°, No Spikes	1
337.311 FORTIFY® I-R 14mm Upper Endplate, 14x16mm Footprint, 3.5°, No Spikes	1
337.312 FORTIFY® I-R 14mm Upper Endplate, 14x16mm Footprint, 7°, No Spikes	1
337.350 FORTIFY® I-R 14mm Lower Endplate, 14x14mm Footprint, 0°, No Spikes	1
337.351 FORTIFY® I-R 14mm Lower Endplate, 14x14mm Footprint, 3.5°, No Spikes	1
337.352 FORTIFY® I-R 14mm Lower Endplate, 14x14mm Footprint, 7°, No Spikes	1
337.360 FORTIFY® I-R 14mm Lower Endplate, 14x16mm Footprint, 0°, No Spikes	1
337.361 FORTIFY® I-R 14mm Lower Endplate, 14x16mm Footprint, 3.5°, No Spikes	1
337.362 FORTIFY® I-R 14mm Lower Endplate, 14x16mm Footprint, 7°, No Spikes	1
937.002 FORTIFY® I-R Small Implant Module	



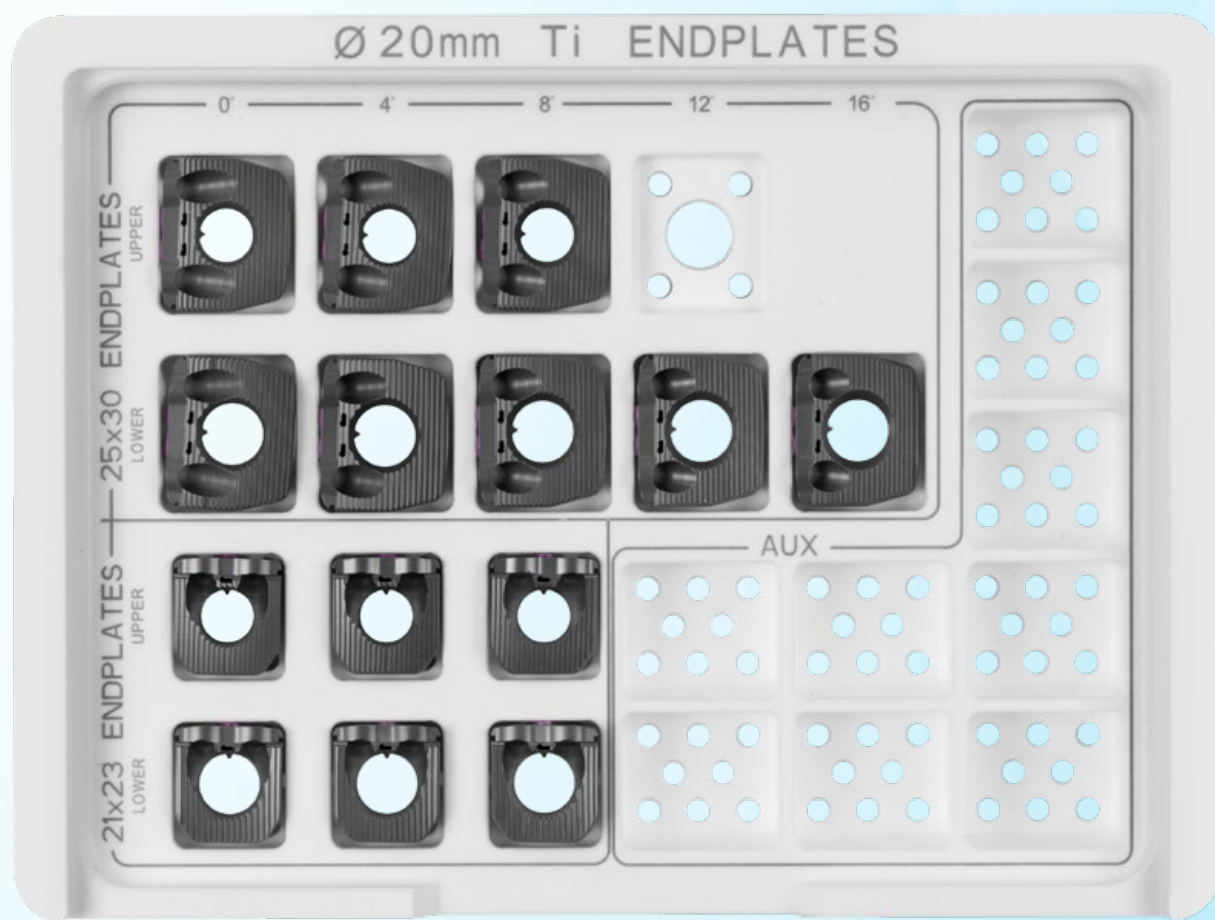
FORTIFY® I SMALL IMPLANT SET 937.903

Implant		Qty
137.001	FORTIFY® I 12mm Core, Height 23–28mm, 12x14mm Footprint, 0°, No Spikes	1
137.002	FORTIFY® I 12mm Core, Height 23–28mm, 12x14mm Footprint, 3.5°, No Spikes	1
137.300	FORTIFY® I 12mm Upper Endplate, 12x14mm Footprint, 0°, No Spikes	1
137.301	FORTIFY® I 12mm Upper Endplate, 12x14mm Footprint, 3.5°, No Spikes	1
137.302	FORTIFY® I 12mm Upper Endplate, 12x14mm Footprint, 7°, No Spikes	1
137.310	FORTIFY® I 12mm Upper Endplate, 14x16mm Footprint, 0°, No Spikes	1
137.311	FORTIFY® I 12mm Upper Endplate, 14x16mm Footprint, 3.5°, No Spikes	1
137.312	FORTIFY® I 12mm Upper Endplate, 14x16mm Footprint, 7°, No Spikes	1
137.350	FORTIFY® I 12mm Lower Endplate, 12x14mm Footprint, 0°, No Spikes	1
137.351	FORTIFY® I 12mm Lower Endplate, 12x14mm Footprint, 3.5°, No Spikes	1
137.352	FORTIFY® I 12mm Lower Endplate, 12x14mm Footprint, 7°, No Spikes	1
137.360	FORTIFY® I 12mm Lower Endplate, 14x16mm Footprint, 0°, No Spikes	1
137.361	FORTIFY® I 12mm Lower Endplate, 14x16mm Footprint, 3.5°, No Spikes	1
137.362	FORTIFY® I 12mm Lower Endplate, 14x16mm Footprint, 7°, No Spikes	1
937.003	FORTIFY® I Small Module	



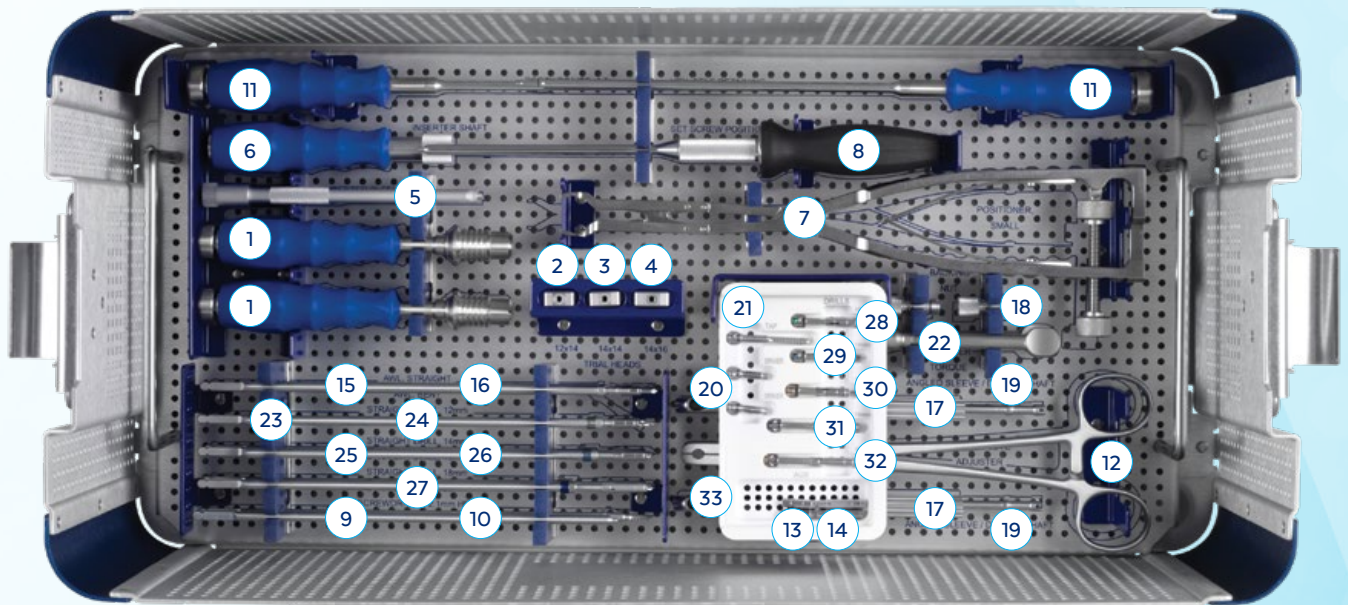
FORTIFY® I LARGE IMPLANT SET 937.905

Implant		Qty
137.410	FORTIFY® I 20mm Upper Endplate, 21x23mm Footprint, 0°, No Spikes	1
137.411	FORTIFY® I 20mm Upper Endplate, 21x23mm Footprint, 4°, No Spikes	1
137.412	FORTIFY® I 20mm Upper Endplate, 21x23mm Footprint, 8°, No Spikes	1
137.430	FORTIFY® I 20mm Upper Endplate, 25x30mm Footprint, 0°, No Spikes	1
137.431	FORTIFY® I 20mm Upper Endplate, 25x30mm Footprint, 4°, No Spikes	1
137.432	FORTIFY® I 20mm Upper Endplate, 25x30mm Footprint, 8°, No Spikes	1
137.460	FORTIFY® I 20mm Lower Endplate, 21x23mm Footprint, 0°, No Spikes	1
137.461	FORTIFY® I 20mm Lower Endplate, 21x23mm Footprint, 4°, No Spikes	1
137.462	FORTIFY® I 20mm Lower Endplate, 21x23mm Footprint, 8°, No Spikes	1
137.480	FORTIFY® I 20mm Lower Endplate, 25x30mm Footprint, 0°, No Spikes	1
137.481	FORTIFY® I 20mm Lower Endplate, 25x30mm Footprint, 4°, No Spikes	1
137.482	FORTIFY® I 20mm Lower Endplate, 25x30mm Footprint, 8°, No Spikes	1
137.483	FORTIFY® I 20mm Lower Endplate, 25x30mm Footprint, 12°, No Spikes	1
137.484	FORTIFY® I 20mm Lower Endplate, 25x30mm Footprint, 16°, No Spikes	1
937.005	FORTIFY® I Large Implant Module	



FORTIFY® I SMALL INSTRUMENT SET 937.907

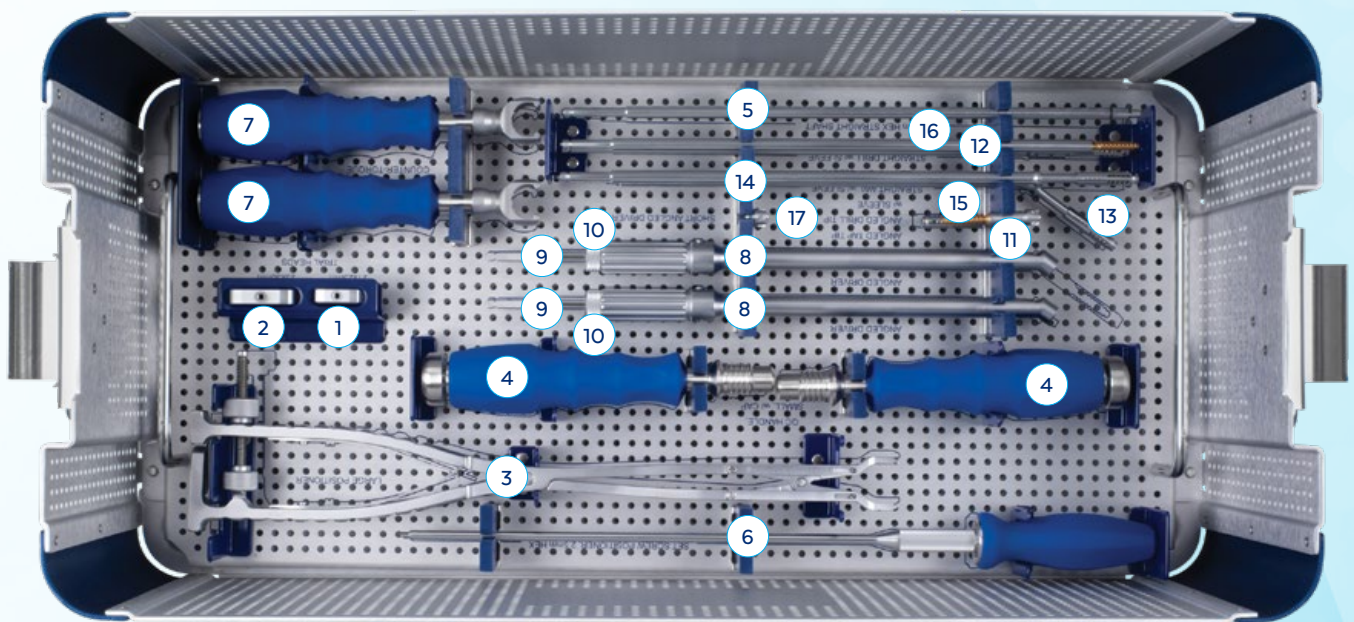
	Instrument	Qty
1	636.450 Quick-Connect Handle, Swivel	2
2	637.024 Trial Head, 12x14mm	1
3	637.025 Trial Head, 14x14mm	1
4	637.026 Trial Head, 14x16mm	1
5	637.500 Inserter Shaft	1
6	637.501 Inserter Sleeve	1
7	637.510 Positioner, Small	1
8	650.312 Set Screw Positioner, 2.0mm Hex, Torque Limiting	1
9	671.313 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 Small Instrument Graphic Case	



FORTIFY® I LARGE

INSTRUMENT SET 937.908

	Instrument		Qty
1	637.125	Trial Head, 21x23mm	1
2	637.127	Trial Head, 25x30mm	1
3	637.511	Holder, Large	1
4	650.105	QC Handle, Small, with Cap	2
5	676.502	INDEPENDENCE® 3.5mm Hex Straight Shaft	1
6	676.600	INDEPENDENCE® Set Screw Driver, 2.5mm Hex	1
7	676.699	Counter-Torque	2
8	676.700	Angled Sleeve	2
9	676.701	Shaft	2
10	676.702	Nut	2
11	676.703	Self-Centering Angled Drill	1
12	676.704	Self-Centering Straight Drill	1
13	676.705	Self-Centering Bent Awl	1
14	676.706	Self-Centering Straight Awl	1
15	676.707	5.5mm Angled Tap	1
16	676.708	5.5mm Straight Tap	1
17	676.710	3.5mm Angled Hex Driver, Short	2
	937.102	FORTIFY® I Large Instrument Graphic Case	



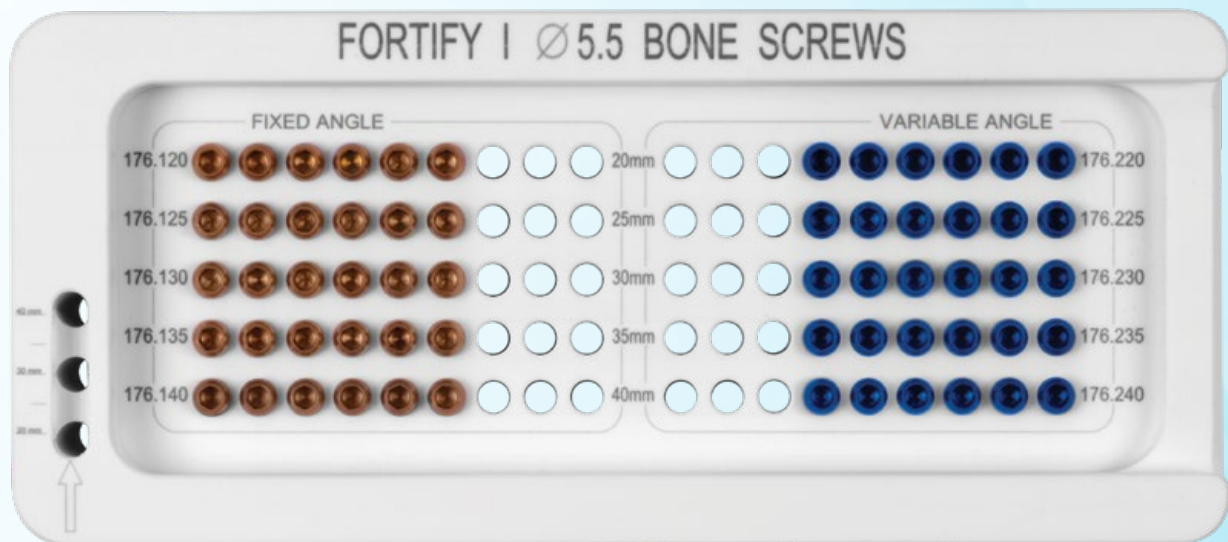
FORTIFY® I SMALL SCREW SET 937.910

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 & 4.2mm Screw Module	



FORTIFY® I LARGE SCREW SET 937.911

Implant		Qty
176.120	Bone Screw, Fixed Angle 5.5mm, 20mm	6
176.125	Bone Screw, Fixed Angle 5.5mm, 25mm	6
176.130	Bone Screw, Fixed Angle 5.5mm, 30mm	6
176.135	Bone Screw, Fixed Angle 5.5mm, 35mm	6
176.140	Bone Screw, Fixed Angle 5.5mm, 40mm	6
176.220	Bone Screw, Variable Angle 5.5mm, 20mm	6
176.225	Bone Screw, Variable Angle 5.5mm, 25mm	6
176.230	Bone Screw, Variable Angle 5.5mm, 30mm	6
176.235	Bone Screw, Variable Angle 5.5mm, 35mm	6
176.240	Bone Screw, Variable Angle 5.5mm, 40mm	6
937.011	FORTIFY® I-R 5.5mm Screw Module	



FORTIFY® I LATERAL SCREW SET 937.912

Implant		Qty
187.230S	5.5mm HA Coated Screw, Variable Angle, 30mm	6
187.235S	5.5mm HA Coated Screw, Variable Angle, 35mm	6
187.240S	5.5mm HA Coated Screw, Variable Angle, 40mm	6
187.245S	5.5mm HA Coated Screw, Variable Angle, 45mm	6
187.250S	5.5mm HA Coated Screw, Variable Angle, 50mm	6
187.255S	5.5mm HA Coated Screw, Variable Angle, 55mm	0
187.260S	5.5mm HA Coated Screw, Variable Angle, 60mm	0
987.003	InterContinental® Screw Bag	

FORTIFY® I LATERAL IMPLANT SET 937.906

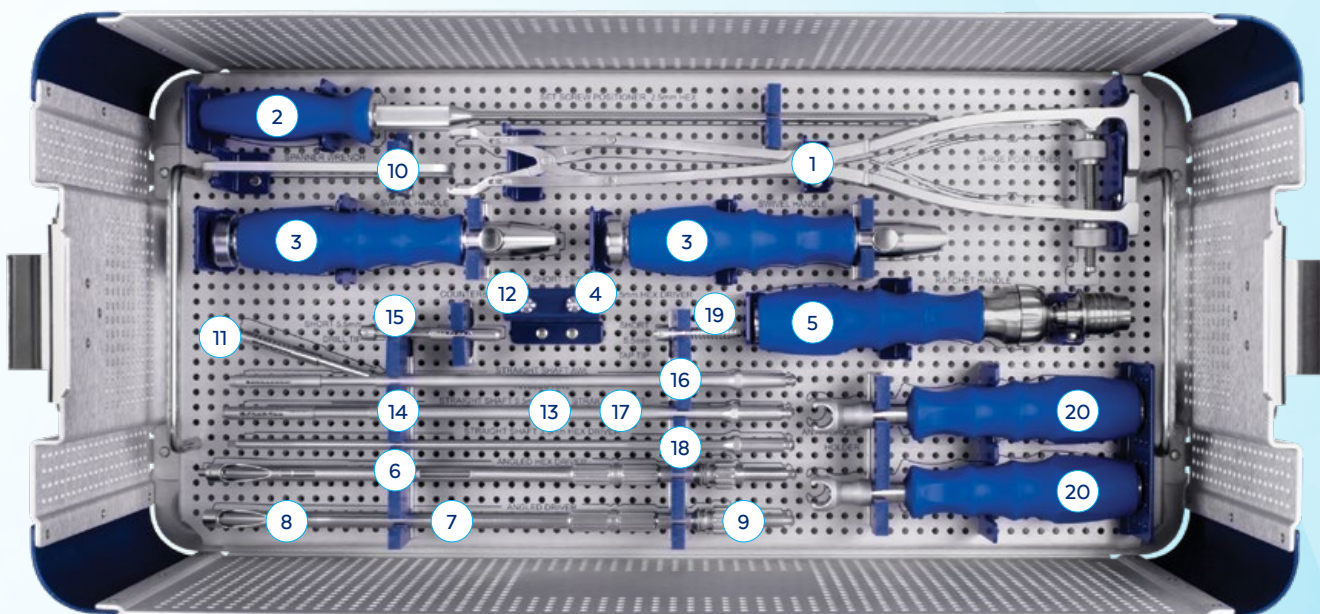
Implant		Qty
137.600	FORTIFY® I 20mm Upper Endplate, 22x40mm Footprint, 0°, No Spikes	1
137.601	FORTIFY® I 20mm Upper Endplate, 22x40mm Footprint, 4°, No Spikes	1
137.602	FORTIFY® I 20mm Upper Endplate, 22x40mm Footprint, 8°, No Spikes	1
137.603	FORTIFY® I 20mm Upper Endplate, 22x40mm Footprint, 12°, No Spikes	1
137.610	FORTIFY® I 20mm Upper Endplate, 22x45mm Footprint, 0°, No Spikes	1
137.611	FORTIFY® I 20mm Upper Endplate, 22x45mm Footprint, 4°, No Spikes	1
137.612	FORTIFY® I 20mm Upper Endplate, 22x45mm Footprint, 8°, No Spikes	1
137.613	FORTIFY® I 20mm Upper Endplate, 22x45mm Footprint, 12°, No Spikes	1
137.620	FORTIFY® I 20mm Upper Endplate, 22x50mm Footprint, 0°, No Spikes	1
137.621	FORTIFY® I 20mm Upper Endplate, 22x50mm Footprint, 4°, No Spikes	1
137.622	FORTIFY® I 20mm Upper Endplate, 22x50mm Footprint, 8°, No Spikes	1
137.623	FORTIFY® I 20mm Upper Endplate, 22x50mm Footprint, 12°, No Spikes	1
137.650	FORTIFY® I 20mm Lower Endplate, 22x40mm Footprint, 0°, No Spikes	1
137.651	FORTIFY® I 20mm Lower Endplate, 22x40mm Footprint, 4°, No Spikes	1
137.652	FORTIFY® I 20mm Lower Endplate, 22x40mm Footprint, 8°, No Spikes	1
137.653	FORTIFY® I 20mm Lower Endplate, 22x40mm Footprint, 12°, No Spikes	1
137.660	FORTIFY® I 20mm Lower Endplate, 22x45mm Footprint, 0°, No Spikes	1
137.661	FORTIFY® I 20mm Lower Endplate, 22x45mm Footprint, 4°, No Spikes	1
137.662	FORTIFY® I 20mm Lower Endplate, 22x45mm Footprint, 8°, No Spikes	1
137.663	FORTIFY® I 20mm Lower Endplate, 22x45mm Footprint, 12°, No Spikes	1
137.670	FORTIFY® I 20mm Lower Endplate, 22x50mm Footprint, 0°, No Spikes	1
137.671	FORTIFY® I 20mm Lower Endplate, 22x50mm Footprint, 4°, No Spikes	1
137.672	FORTIFY® I 20mm Lower Endplate, 22x50mm Footprint, 8°, No Spikes	1
137.673	FORTIFY® I 20mm Lower Endplate, 22x50mm Footprint, 12°, No Spikes	1
937.006	FORTIFY® I Lateral Endplate Module	

*Items in gray are additionally available.



FORTIFY® I LATERAL INSTRUMENT SET 937.909

	Instrument	Qty
1	637.511 Holder, Large	1
2	676.600 INDEPENDENCE® Set Screw Driver, 2.5mm Hex	1
3	687.005 Quick-Connect Swivel Handle	2
4	687.026 InterContinental® Short 3.5mm Hex Driver Tip	1
5	687.105 Ratchet Handle	1
6	687.504 3.5mm Angled Hex Driver	1
7	687.505 InterContinental® Angled Holder	1
8	687.506 InterContinental® Angled Holder – Shaft	1
9	687.507 InterContinental® Angled Holder – Nut	1
10	687.509 Spanner Wrench	1
11	687.511 Angled Awl	1
12	687.514 InterContinental® Short Counterbore Tip	1
13	687.516 InterContinental® Straight Shaft Counterbore	1
14	687.520 InterContinental® Straight Shaft 5.5mm Drill	1
15	687.521 InterContinental® Short 5.5mm Drill Tip	1
16	687.524 InterContinental® Straight Shaft Awl	1
17	687.526 InterContinental® Straight Shaft 5.5mm Tap	1
18	687.527 InterContinental® Straight Shaft 3.5mm Hex Driver	2
19	687.721 InterContinental® Short 5.5mm Tap Tip	1
20	687.906 Anti-Torque Holder	2
	937.103 FORTIFY® I Lateral Instrument Graphic Case	



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.
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

IMPORTANT INFORMATION ON FORTIFY® CORPECTOMY SPACERS

- 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 accidentally 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
Steam	Pre-vacuum	134°C (273°F)	3 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.

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

DI156A REV M



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)

©2021 Globus Medical. All rights reserved. Patent www.globusmedical.com/patents.
Life moves us is a registered trademark of Globus Medical. Please refer to package insert for
description, indications, contraindications, warnings, precautions and other important information.

CE 0297

GMTGD98
05.21 Rev D