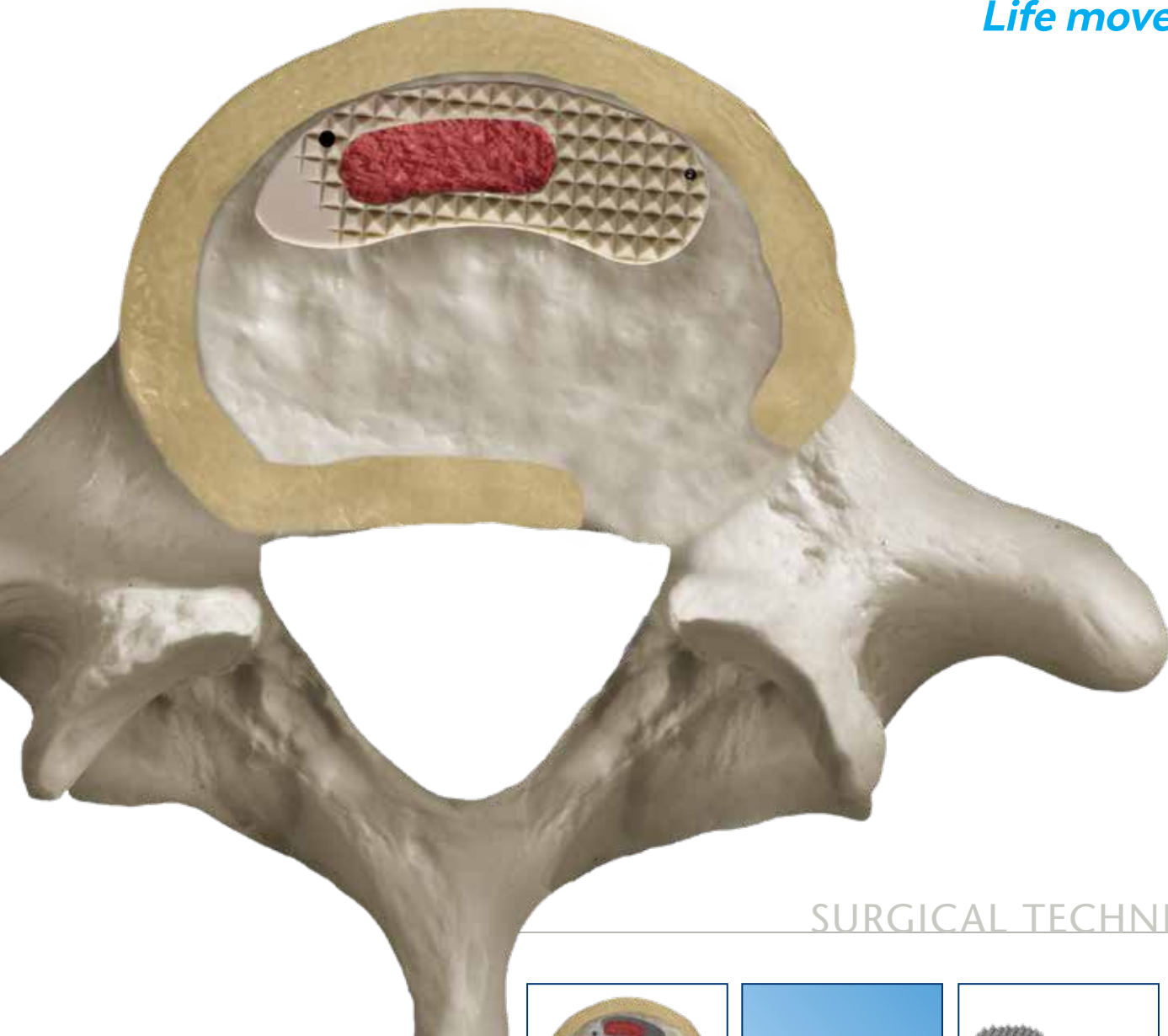




SURGICAL TECHNIQUE



SIGNATURE[®]

TLIF System

A PATRIOT[®] Spacer



Life moves us ➤

At Globus, we move with a sense of urgency to deliver innovations that improve the quality of life for patients with spinal disorders. We are inspired by the needs of these patients and also the needs of the surgeons and health care providers who treat them.

This passion combined with Globus' world class engineering transforms clinical insights into tangible spine care solutions. We are driven to provide the highest quality products to improve

the techniques and outcomes of spine surgery so patients can resume their lives as quickly as possible. We extend our reach beyond our world class implants, instrumentation, and service by partnering with researchers and educators to advance the science and knowledge of spine care.

The energy and enthusiasm each of us bring everyday to Globus is palpable. We are constantly in the pursuit of better patient care and understand that speed is critical because life cannot wait.



GLOBUS
MEDICAL

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SIGNATURE[®]

TLIF System

A PATRIOT[®] Spacer



SIGNATURE[®] is a next generation transforaminal lumbar interbody fusion (TLIF) device for the restoration of segmental sagittal balance that delivers an unprecedented level of surgeon control. SIGNATURE[®] is made from PEEK radiolucent polymer, and is available with a titanium plasma spray (TPS) coating to combine radiolucency with a titanium interface. The all-in-one implant holder allows articulation of the implant in the disc space while maintaining connection throughout insertion. The streamlined system also minimizes the number of instruments passing neural elements compared to a standard TLIF system.

SIGNATURE[®] has been designed for use with Minimally Invasive Surgery (MIS) port and retractor systems. The tapered nose of the implant self-distracts, easing initial insertion. When positioned, the intuitive radiographic markers facilitate proper placement of the device.

SIGNATURE® TLIF SYSTEM

A PATRIOT® SPACER

■ Unprecedented Control

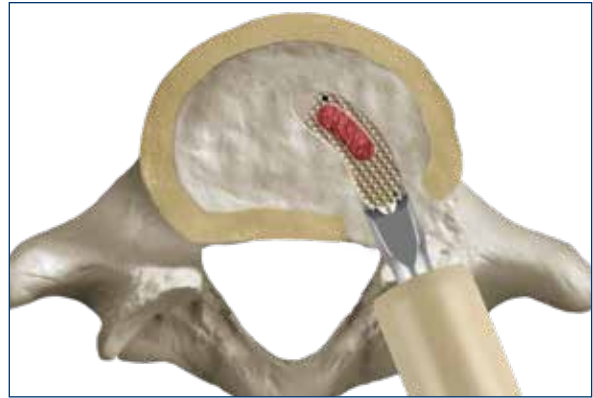
Implant holder allows articulation in the disc space while maintaining connection to the implant throughout insertion

■ Positioning Feedback

Intuitive radiographic targeting provides positioning feedback for proper placement

■ Ease of Insertion

Bulletheaded leading edge self-distracts, easing initial insertion



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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.

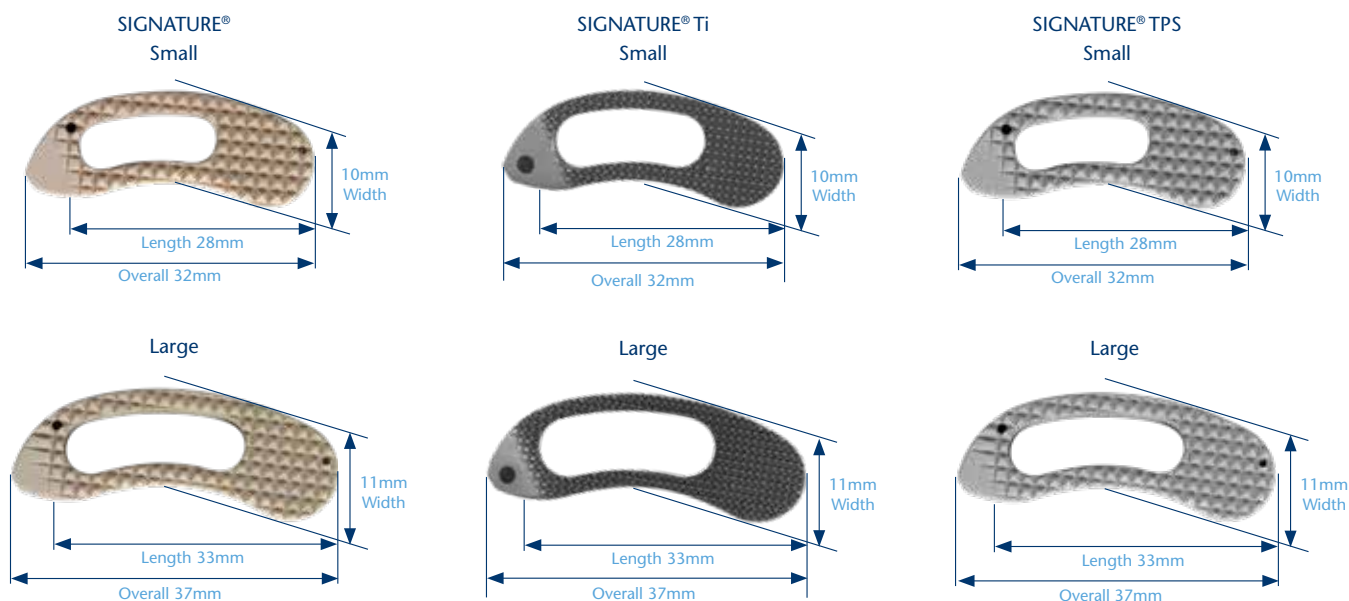
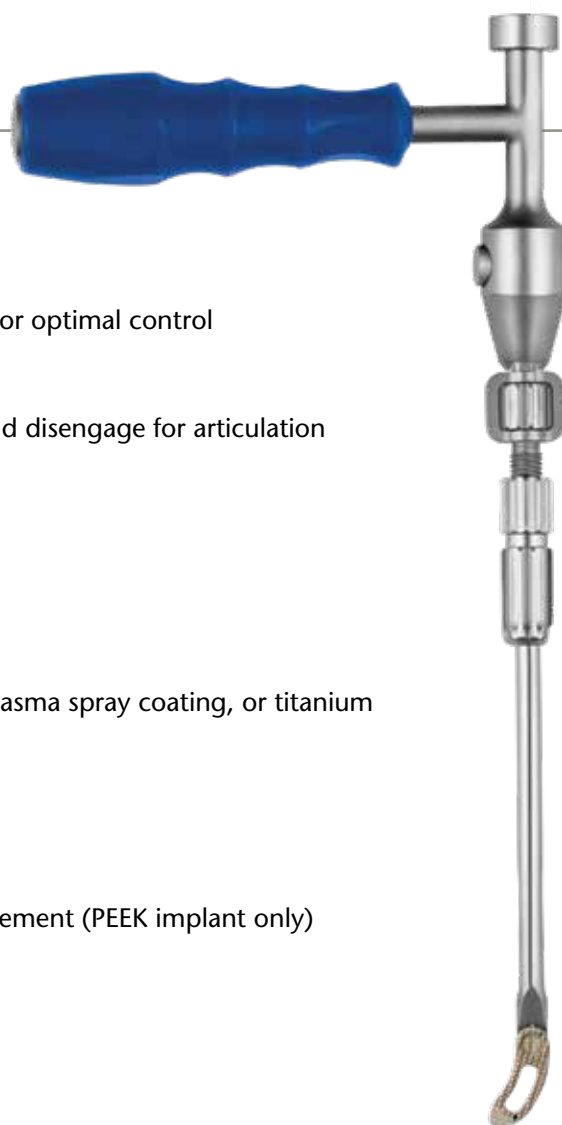
IMPLANT OVERVIEW

SIGNATURE® Instruments

- Implant Holder:
 - Maintains implant connection through final placement for optimal control
 - Provides streamlined profile for MIS approach
 - Uses lateral stabilizers to engage implant for insertion and disengage for articulation
- Paddle distractors, shavers and tamps facilitate discectomy
- Trials and rasps mimic implant geometry

SIGNATURE® Spacers

- Available in PEEK radiolucent polymer, PEEK with titanium plasma spray coating, or titanium
- Integrated pivoting mechanism for controlled articulation
- Designed for MIS application
- Bulleted leading edge self-distracts
- Tantalum radiographic markers indicate proper implant placement (PEEK implant only)
- Two axial footprints: 10x28mm and 11x33mm
- Heights of 7–17mm
- Curved geometry to match vertebral anatomy
- Large axial openings for packing graft material



INSTRUMENT OVERVIEW

Sizers/Shavers



	Height	Part Number
	7mm	668.507
	8mm	668.508
	9mm	668.509
	10mm	668.510
	11mm	668.511

	Height	Part Number
	12mm	668.512
	13mm	668.513
	15mm	668.515
	17mm	668.517

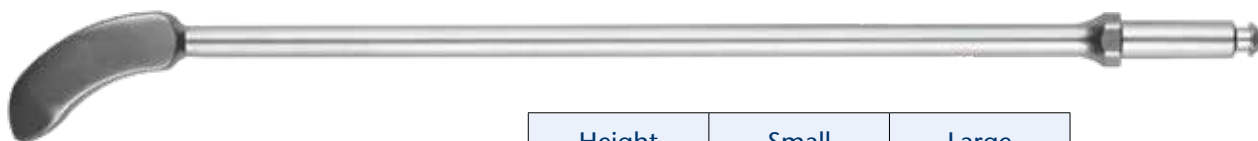
Paddle Distractors



	Height	Part Number
	7mm	668.407
	8mm	668.408
	9mm	668.409
	10mm	668.410
	11mm	668.411

	Height	Part Number
	12mm	668.412
	13mm	668.413
	15mm	668.415
	17mm	668.417

Trials



	Height	Small	Large
	7mm	668.207	668.307
	8mm	668.208	668.308
	9mm	668.209	668.309
	10mm	668.210	668.310
	11mm	668.211	668.311
	12mm	668.212	668.312
	13mm	668.213	668.313
	15mm	668.215	668.315
	17mm	668.217	668.317

Rasps



Rasp, Angled, Serrated 668.020



Rasp, Angled, Knurled 668.021

Tamps



Tamp, Straight 668.040



Tamp, Angled 668.041

Handles



T-Handle 601.800



SIGNATURE® Quick Coupling Handle 668.160



L-Handle 679.010

Implant Holder Instruments



SIGNATURE® Holder 668.150



SIGNATURE® Implant Holder, Long 668.100



SIGNATURE® Implant Holder, Short 668.101

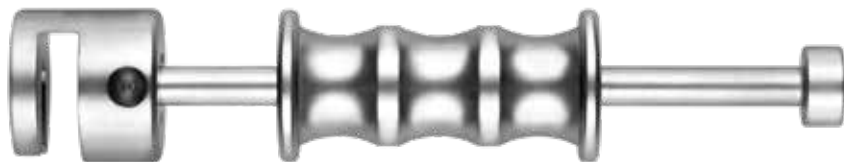


SIGNATURE® Implant Holder, Short 668.101
SIGNATURE® Quick Coupling Handle 668.160
(Assembled)



SIGNATURE® Implant Holder, Short 668.101
L-Handle 679.010
(Assembled)

Other Instruments



Slide Hammer, Small 622.410



SIGNATURE® Pin Driver 668.050

TLIF SURGICAL TECHNIQUE

Minimally Invasive Surgery

Advances in minimally invasive surgery, in particular, implant systems such as SIGNATURE® and retractor systems such as MARS™3V, help to lessen the disruption to the patient's anatomic structures. Without compromising surgical goals, minimally invasive surgery for interbody fusion has been shown to:^{1,2}

- Reduce soft tissue disruption
- Reduce blood loss
- Reduce scarring
- Reduce postoperative pain
- Shorten hospital stay
- Shorten recovery time

Step 1 Transforaminal Approach

Approach

The patient is placed under anesthesia and positioned prone. Lateral C-arm fluoroscopy or other radiographic methods may be utilized throughout the surgery to ensure the correct implant placement.

In addition to the described interbody fusion technique, posterior stabilization, such as REVERE® or REVOLVE®, must be used at the appropriate level(s).



The incision can be made 4–4.5cm lateral to the midline and the trajectory should be in line with the disc. Finger dissect between the multifidus and longissimus muscles until the facet joint is palpable.

¹ Peng C.W., Yue W.M., et al. Clinical and Radiological Outcomes of Minimally Invasive Versus Open Transforaminal Lumbar Interbody Fusion. SPINE 34: 1385-9, 2009.

² Kim KT, Lee SH, et al. The Quantitative Analysis of Tissue Injury Markers After Mini-Open Lumbar Fusion. SPINE 6: 712-716, 2006.

Step 2 Using the Retractor

MARS™3V dilators may be used to retract soft tissue and surround the facet. Keep downward pressure on the dilators and twist dilators as needed when approaching the facet. With the initial dilator in place, a series of cannulas are progressively passed over the initial dilator.

Ensure that the MARS™3V Retractor is in the fully closed position and the blades are securely attached to the frame. Slide the retractor over the cannulas and apply gentle downward pressure on the frame.

Before removing the cannulas, articulate all three blades to one full turn of the silver knobs. Articulating the blades in this manner will help prevent tissue creep as the cannulas are removed.

Once the retractor has been securely positioned and the Articulating Arm Assembly tightened, remove the cannulas.

Use AP fluoroscopy to verify the positioning.

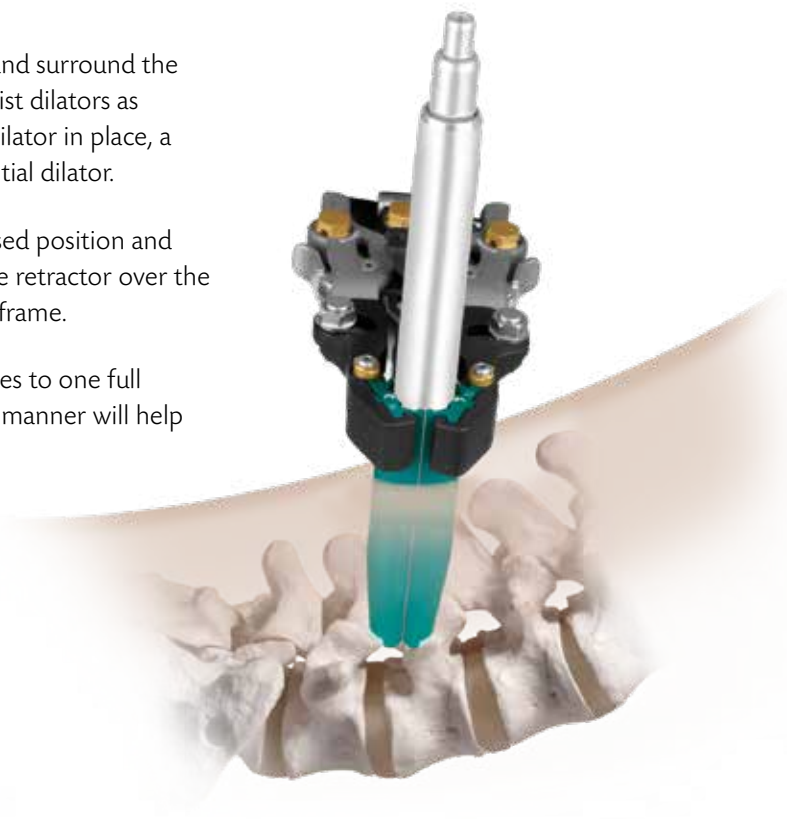


Table Arm Attachment

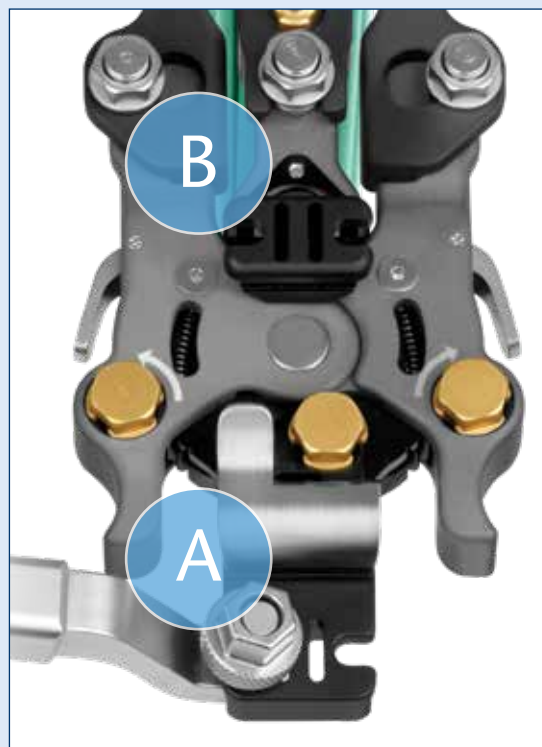
In order to use the MARS™3V Retractor, the Table Arm Assembly must be secured. Attach the table clamp onto the bed rail attachment. Insert the arm assembly into the clamp and secure. The opposite end of the arm assembly is then attached to the Retractor 3 Blade Frame.

There are two options for attachment positions on the retractor, as shown at right.

Attaching the arm assembly to point A maintains retractor position relative to the posterior blade position and translates the cephalad and caudad blades laterally when the retractor is opened.

Attaching the arm assembly to point B maintains the retractor position relative to the cephalad and caudad blade position, and translates the posterior blade medially.

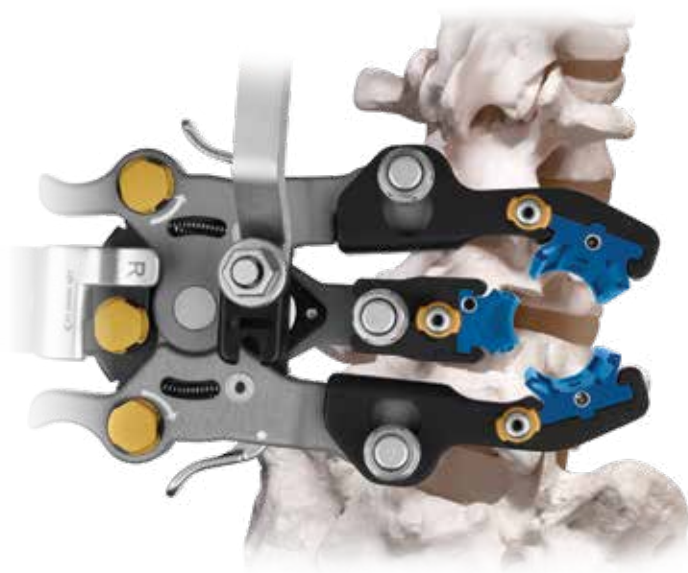
Refer to the LLIF Surgical Technique Guide for additional information (GMTGD32).



Step 3 Creating Transforaminal Access

Use an osteotome* to remove the inferior facet of the cephalad vertebrae and the superior facet of the caudal vertebrae at the appropriate level(s). This creates a working transforaminal access window to the disc.

**Available in the Posterior Disc Prep Instruments Set II.*



Approach using MARS™3V
Retractor System



Transforaminal access

Step 4 Discectomy/Endplate Preparation

Remove disc material using Rongeurs*, Curettes, **SIGNATURE® Rasp, Angled** and other suitable instruments. The **SIGNATURE® Sizer/Shaver** may be used to remove superficial layers of the cartilaginous endplates. Insert the smallest shaver into the disc space for further disc removal and endplate preparation, moving to larger shavers as needed. Careful disc removal and endplate preparation maximizes the potential for a successful fusion.

**Available in the Posterior Disc Prep Instrument Set I and II.*



Discectomy using shaver

Step 5 Distraction

Distraction of the disc space aids in visualization, as well as decompression and restoration of disc height. Assemble the desired **SIGNATURE® Paddle Distractor** onto the **T-Handle**. Insert within the disc space. In order to achieve adequate distraction, rotate the distractor until the desired height is reached.

Alternatively, shavers may be used for distraction. Use caution while using shavers to avoid damage to the endplate.



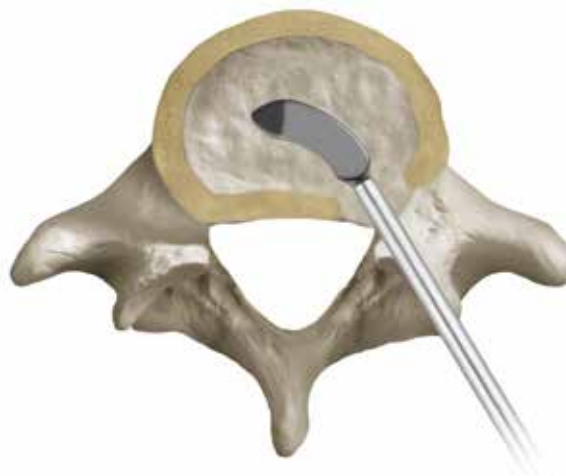
Distraction of disc space using
paddle distractor



Paddle distractor in disc space

Step 6 Implant Sizing

Assemble the desired **SIGNATURE® Trial** onto the T-Handle. Insert into the disc space, using gentle impaction if needed. Determine which trial best fits the prepared disc space. A secure fit is desirable in order to maintain disc height and stabilize the segment, and may be confirmed using fluoroscopy and tactile feel.



Implant Sizing (cont'd)

Alternative Sizing

Alternatively, Paddle Distractors and Sizer/Shavers may be used to size the disc space. Insert and rotate to determine the appropriate implant height.

Note: Use caution while using shavers or paddle distractors for sizing to avoid damage to the endplates.



Sizing disc space using paddle distractor



Sizing disc space using sizer/shaver

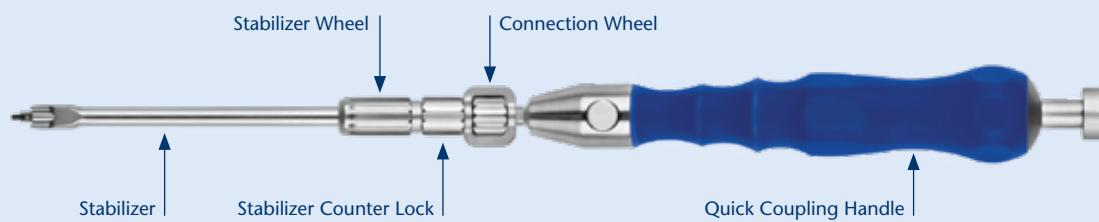
Step

7

Loading the SIGNATURE® Implant

Assembling the Implant Holder Assembly

The streamlined **SIGNATURE® Implant Holder** is designed to maintain control of the implant throughout insertion. Select a holder length, short or long, and attach to either the **L-Handle** or the **SIGNATURE® Quick Coupling Handle**. It is then ready for implant attachment.



Select the appropriate sized SIGNATURE® TLIF Spacer and fill with autogenous bone graft material. Orient the holder to the implant pivot pin, as shown at right.

Insert the holder into the pivot pin slot in the implant, as shown right.

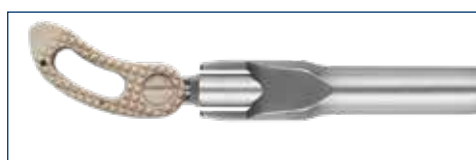
Rotate the connection wheel clockwise to begin loading the implant. Rotate until a snug fit is achieved.



Top view



Side view



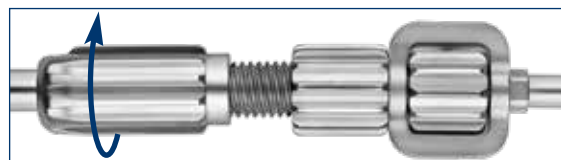
Implant loaded



Rotate the stabilizer wheel clockwise to advance the stabilizer for a rigid connection.



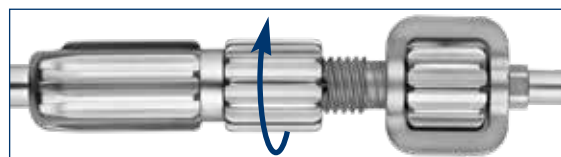
Rigid connection



Rotate the stabilizer counter lock clockwise until flush with the stabilizer lock.



Implant fully locked



Additional Implant Offering

SIGNATURE® MIS and Ti implants are additionally available and can be distinguished from the standard SIGNATURE® implant by the presence of circle etched at the tip of the implant nose.

The SIGNATURE® MIS and Ti implants have a profile that is aligned with the holder as compared to the standard SIGNATURE® implant, and may ease insertion through a port or MIS retractor.

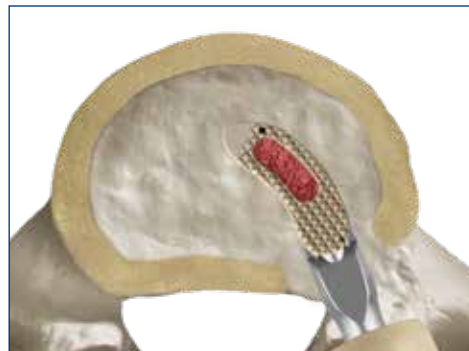


MIS implant fully locked

Step 8 Inserting the Implant

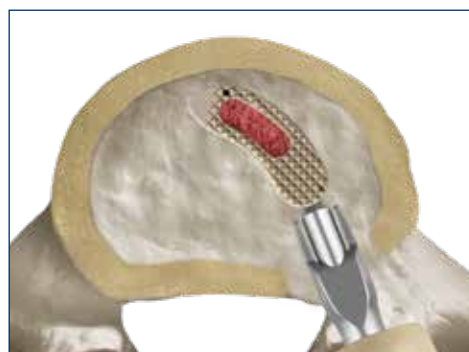
Insert Implant

Insert the implant into the disc space with the holder stabilizer engaged.



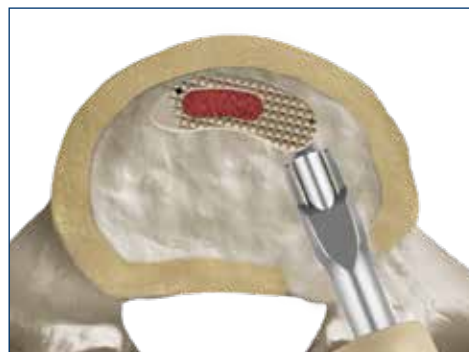
Disengage Stabilizers

When the implant crosses the vertebral midline (radiographic markers will indicate implant position), disengage the stabilizer by first rotating the stabilizer counter lock counterclockwise, then the stabilizer wheel counterclockwise, as seen below.



Articulate Implant

Once the stabilizer is disengaged, the implant is articulated further into the disc space, along the apophyseal ring. Impact the implant into the disc space as needed.



Disengage Implant

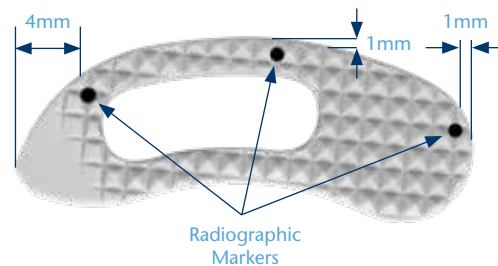
The final position of the implant is shown. Using fluoroscopy, verify the position before disengaging.

Release the implant from the holder by rotating the connection wheel counterclockwise.

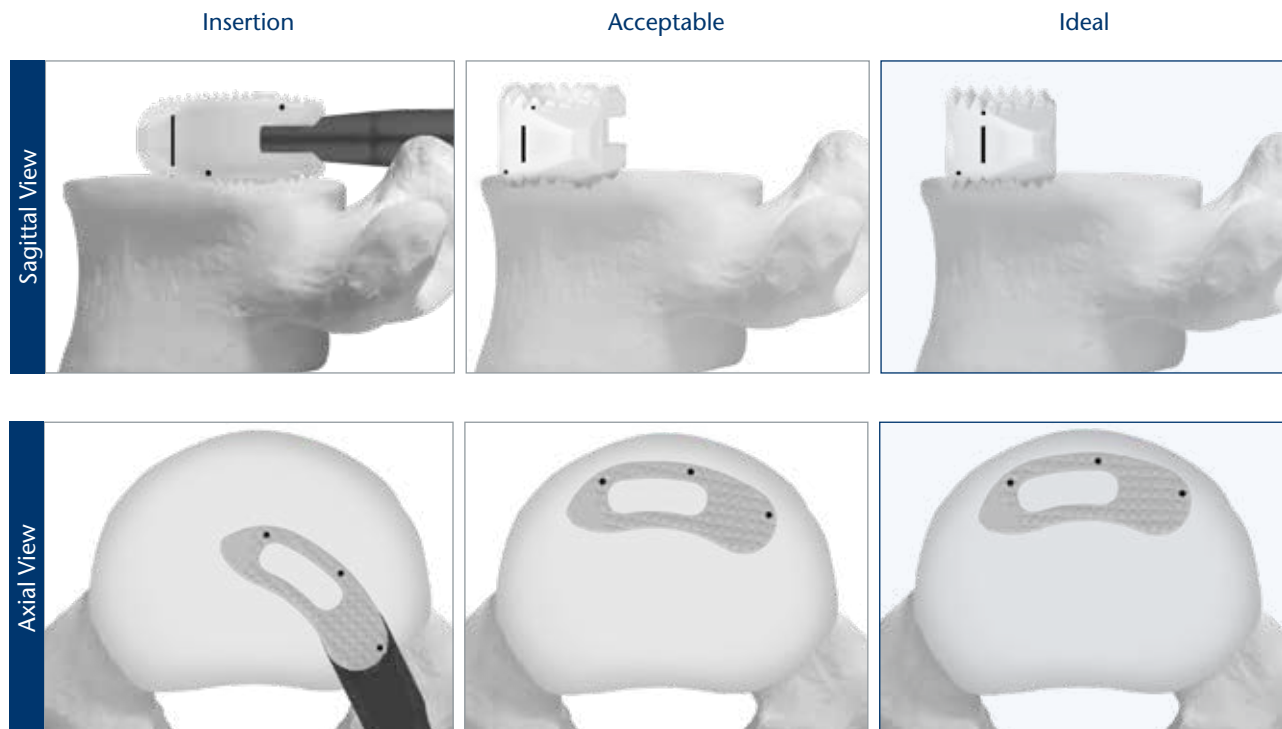


Radiographic Positioning of Radiolucent Implants

While advancing a radiolucent implant into the final position, radiographic markers indicate the implant position.

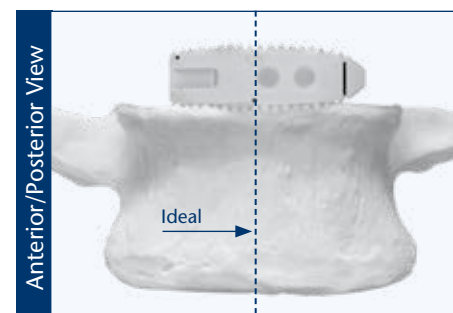


When the marker rod lies between the beads, the implant is in an acceptable position. The ideal position is when the marker is aligned with the posterior marker bead.



The implant is properly positioned in the anterior portion of the disc space, along the apophyseal ring, as seen above, right.

When in the ideal position, the medial marker bead should be aligned with the midline.



SIGNATURE® IMPLANT SETS



SIGNATURE® Implant Sets

968.902 SIGNATURE® Small Implant Set

Description	Qty
368.207 SIGNATURE® TLIF Spacer, Small, 7mm	2
368.208 SIGNATURE® TLIF Spacer, Small, 8mm	2
368.209 SIGNATURE® TLIF Spacer, Small, 9mm	2
368.210 SIGNATURE® TLIF Spacer, Small, 10mm	2
368.211 SIGNATURE® TLIF Spacer, Small, 11mm	2
368.212 SIGNATURE® TLIF Spacer, Small, 12mm	2
368.213 SIGNATURE® TLIF Spacer, Small, 13mm	2
368.215 SIGNATURE® TLIF Spacer, Small, 15mm	2
368.217 SIGNATURE® TLIF Spacer, Small, 17mm	2
968.010 SIGNATURE® Implant Module, Small	



968.903 SIGNATURE® Large Implant Set

Description	Qty
368.307 SIGNATURE® TLIF Spacer, Large, 7mm	2
368.308 SIGNATURE® TLIF Spacer, Large, 8mm	2
368.309 SIGNATURE® TLIF Spacer, Large, 9mm	2
368.310 SIGNATURE® TLIF Spacer, Large, 10mm	2
368.311 SIGNATURE® TLIF Spacer, Large, 11mm	2
368.312 SIGNATURE® TLIF Spacer, Large, 12mm	2
368.313 SIGNATURE® TLIF Spacer, Large, 13mm	2
368.315 SIGNATURE® TLIF Spacer, Large, 15mm	2
368.317 SIGNATURE® TLIF Spacer, Large, 17mm	2
968.020 SIGNATURE® Implant Module, Large	



Additionally Available

368.214 SIGNATURE® TLIF Spacer, Small, 14mm
368.216 SIGNATURE® TLIF Spacer, Small, 16mm
368.314 SIGNATURE® TLIF Spacer, Large, 14mm
368.316 SIGNATURE® TLIF Spacer, Large, 16mm

SIGNATURE® MIS IMPLANT SETS



SIGNATURE® MIS Implant Sets

968.905 SIGNATURE® Small, MIS Implant Set

Description	Qty
368.227 SIGNATURE® TLIF Spacer, MIS, Small, 7mm	2
368.228 SIGNATURE® TLIF Spacer, MIS, Small, 8mm	2
368.229 SIGNATURE® TLIF Spacer, MIS, Small, 9mm	2
368.230 SIGNATURE® TLIF Spacer, MIS, Small, 10mm	2
368.231 SIGNATURE® TLIF Spacer, MIS, Small, 11mm	2
368.232 SIGNATURE® TLIF Spacer, MIS, Small, 12mm	2
368.233 SIGNATURE® TLIF Spacer, MIS, Small, 13mm	2
368.235 SIGNATURE® TLIF Spacer, MIS, Small, 15mm	2
368.237 SIGNATURE® TLIF Spacer, MIS, Small, 17mm	2
968.040 SIGNATURE® Implant Module, Small, MIS	



968.906 SIGNATURE® Large, MIS Implant Set

Description	Qty
368.327 SIGNATURE® TLIF Spacer, MIS, Large, 7mm	2
368.328 SIGNATURE® TLIF Spacer, MIS, Large, 8mm	2
368.329 SIGNATURE® TLIF Spacer, MIS, Large, 9mm	2
368.330 SIGNATURE® TLIF Spacer, MIS, Large, 10mm	2
368.331 SIGNATURE® TLIF Spacer, MIS, Large, 11mm	2
368.332 SIGNATURE® TLIF Spacer, MIS, Large, 12mm	2
368.333 SIGNATURE® TLIF Spacer, MIS, Large, 13mm	2
368.335 SIGNATURE® TLIF Spacer, MIS, Large, 15mm	2
368.337 SIGNATURE® TLIF Spacer, MIS, Large, 17mm	2
968.050 SIGNATURE® Implant Module, Large, MIS	



Additionally Available

368.234 SIGNATURE® TLIF Spacer, MIS, Small, 14mm
368.236 SIGNATURE® TLIF Spacer, MIS, Small, 16mm
368.334 SIGNATURE® TLIF Spacer, MIS, Large, 14mm
368.336 SIGNATURE® TLIF Spacer, MIS, Large, 16mm

SIGNATURE® TITANIUM IMPLANT SETS



SIGNATURE® Titanium Implant Sets

968.909 SIGNATURE® Ti Small Implant Set

Description	Qty
168.247 SIGNATURE® TLIF Spacer, Ti Small, 7mm	2
168.248 SIGNATURE® TLIF Spacer, Ti Small, 8mm	2
168.249 SIGNATURE® TLIF Spacer, Ti Small, 9mm	2
168.250 SIGNATURE® TLIF Spacer, Ti Small, 10mm	2
168.251 SIGNATURE® TLIF Spacer, Ti Small, 11mm	2
168.252 SIGNATURE® TLIF Spacer, Ti Small, 12mm	2
168.253 SIGNATURE® TLIF Spacer, Ti Small, 13mm	2
168.255 SIGNATURE® TLIF Spacer, Ti Small, 15mm	2
168.257 SIGNATURE® TLIF Spacer, Ti Small, 17mm	2
968.080 SIGNATURE® Implant Module, Ti Small	



968.910 SIGNATURE® Ti Large Implant Set

Description	Qty
168.347 SIGNATURE® TLIF Spacer, Ti Large, 7mm	2
168.348 SIGNATURE® TLIF Spacer, Ti Large, 8mm	2
168.349 SIGNATURE® TLIF Spacer, Ti Large, 9mm	2
168.350 SIGNATURE® TLIF Spacer, Ti Large, 10mm	2
168.351 SIGNATURE® TLIF Spacer, Ti Large, 11mm	2
168.352 SIGNATURE® TLIF Spacer, Ti Large, 12mm	2
168.353 SIGNATURE® TLIF Spacer, Ti Large, 13mm	2
168.355 SIGNATURE® TLIF Spacer, Ti Large, 15mm	2
168.357 SIGNATURE® TLIF Spacer, Ti Large, 17mm	2
968.090 SIGNATURE® Implant Module, Ti Large	



Additionally Available

168.254 SIGNATURE® TLIF Spacer, Ti Small, 14mm
168.256 SIGNATURE® TLIF Spacer, Ti Small, 16mm
168.354 SIGNATURE® TLIF Spacer, Ti Large, 14mm
168.356 SIGNATURE® TLIF Spacer, Ti Large, 16mm

SIGNATURE® TPS IMPLANT SET



SIGNATURE® TPS Implant Sets

968.952 SIGNATURE® TPS Small Implant Set

Description		Qty
368.207CS	SIGNATURE® TLIF TPS Spacer, Small, 7mm	2
368.208CS	SIGNATURE® TLIF TPS Spacer, Small, 8mm	2
368.209CS	SIGNATURE® TLIF TPS Spacer, Small, 9mm	2
368.210CS	SIGNATURE® TLIF TPS Spacer, Small, 10mm	2
368.211CS	SIGNATURE® TLIF TPS Spacer, Small, 11mm	2
368.212CS	SIGNATURE® TLIF TPS Spacer, Small, 12mm	2
368.213CS	SIGNATURE® TLIF TPS Spacer, Small, 13mm	2
368.214CS	SIGNATURE® TLIF TPS Spacer, Small, 14mm	
368.215CS	SIGNATURE® TLIF TPS Spacer, Small, 15mm	2
368.217CS	SIGNATURE® TLIF TPS Spacer, Small, 17mm	2
968.003	Soft Case, PATRIOT®, SIGNATURE®-TPS (32 Box)	

968.953 SIGNATURE® TPS Large, Implant Set

Description		Qty
368.307CS	SIGNATURE® TLIF TPS Spacer, Large, 7mm	2
368.308CS	SIGNATURE® TLIF TPS Spacer, Large, 8mm	2
368.309CS	SIGNATURE® TLIF TPS Spacer, Large, 9mm	2
368.310CS	SIGNATURE® TLIF TPS Spacer, Large, 10mm	2
368.311CS	SIGNATURE® TLIF TPS Spacer, Large, 11mm	2
368.312CS	SIGNATURE® TLIF TPS Spacer, Large, 12mm	2
368.313CS	SIGNATURE® TLIF TPS Spacer, Large, 13mm	2
368.314CS	SIGNATURE® TLIF TPS Spacer, Large, 14mm	
368.315CS	SIGNATURE® TLIF TPS Spacer, Large, 15mm	2
368.317CS	SIGNATURE® TLIF TPS Spacer, Large, 17mm	2
968.003	Soft Case, PATRIOT®, SIGNATURE®-TPS (32 Box)	

Sterile packaged.

Items highlighted in gray are additionally available.

SIGNATURE® TPS MIS IMPLANT SET



SIGNATURE® TPS MIS Implant Sets

968.954 SIGNATURE® TPS Small, MIS Implant Set

Description		Qty
368.227CS	SIGNATURE® TLIF TPS Spacer, MIS, Small, 7mm	2
368.228CS	SIGNATURE® TLIF TPS Spacer, MIS, Small, 8mm	2
368.229CS	SIGNATURE® TLIF TPS Spacer, MIS, Small, 9mm	2
368.230CS	SIGNATURE® TLIF TPS Spacer, MIS, Small, 10mm	2
368.231CS	SIGNATURE® TLIF TPS Spacer, MIS, Small, 11mm	2
368.232CS	SIGNATURE® TLIF TPS Spacer, MIS, Small, 12mm	2
368.233CS	SIGNATURE® TLIF TPS Spacer, MIS, Small, 13mm	2
368.235CS	SIGNATURE® TLIF TPS Spacer, MIS, Small, 15mm	2
368.237CS	SIGNATURE® TLIF TPS Spacer, MIS, Small, 17mm	2
968.003	Soft Case, PATRIOT®, SIGNATURE®-TPS (32 Box)	2

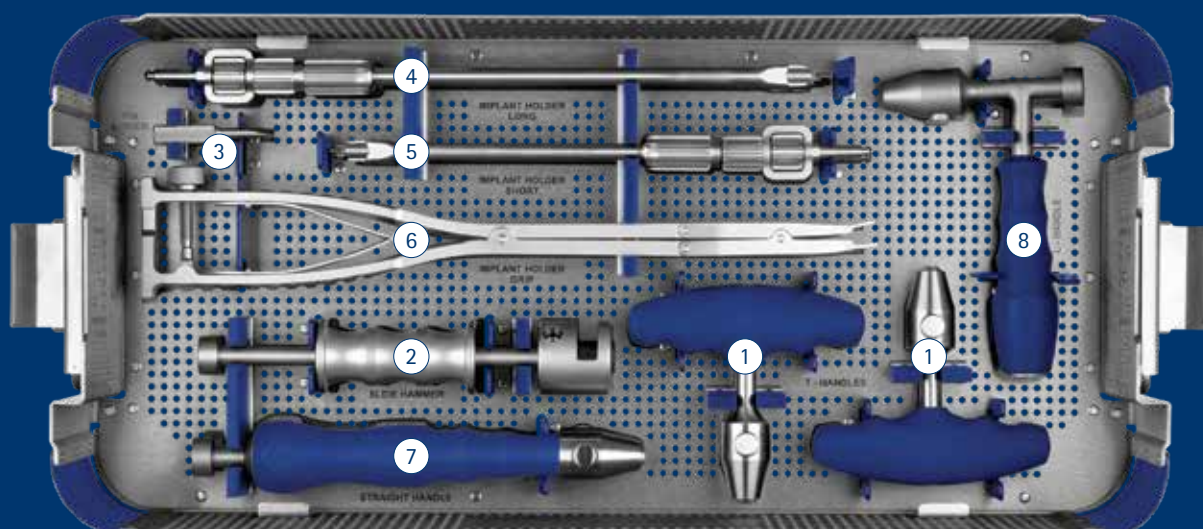
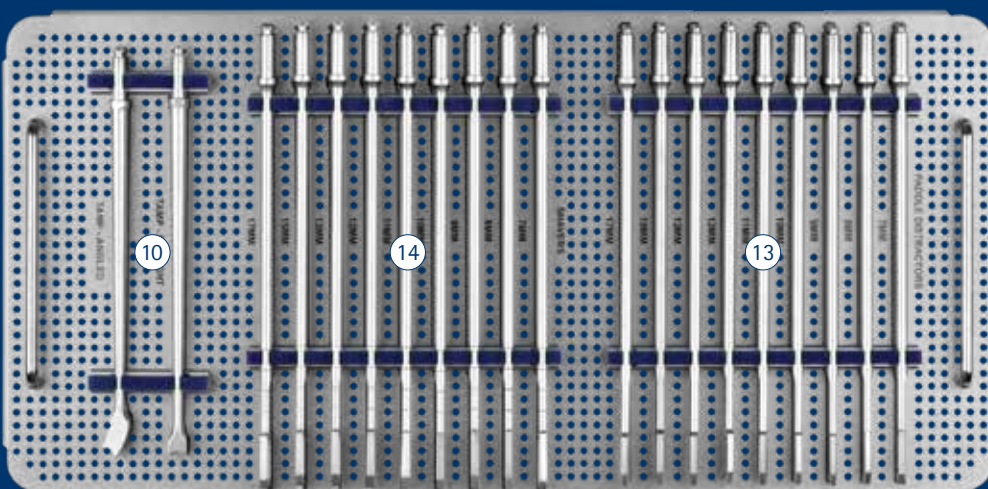
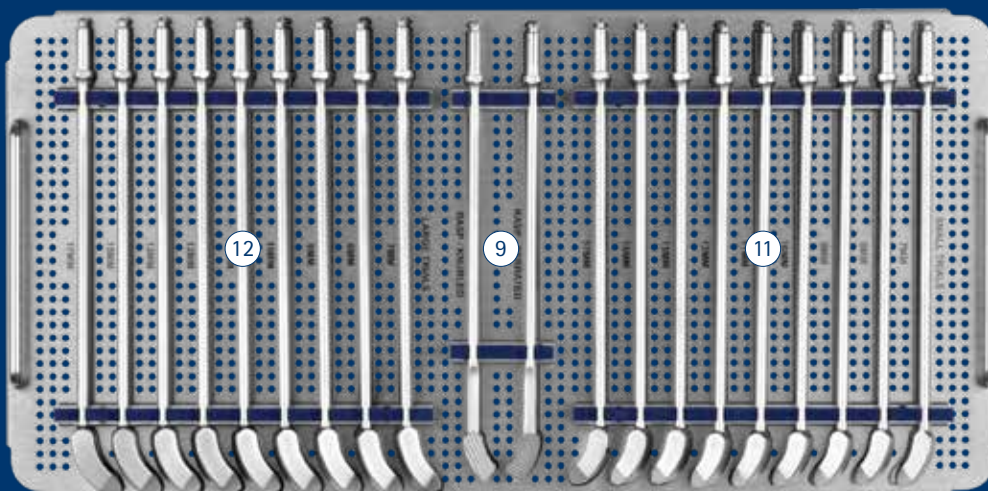
968.955 SIGNATURE® TPS Large, MIS Implant Set

Description		Qty
368.327CS	SIGNATURE® TLIF TPS Spacer, MIS, Large, 7mm	2
368.328CS	SIGNATURE® TLIF TPS Spacer, MIS, Large, 8mm	2
368.329CS	SIGNATURE® TLIF TPS Spacer, MIS, Large, 9mm	2
368.330CS	SIGNATURE® TLIF TPS Spacer, MIS, Large, 10mm	2
368.331CS	SIGNATURE® TLIF TPS Spacer, MIS, Large, 11mm	2
368.332CS	SIGNATURE® TLIF TPS Spacer, MIS, Large, 12mm	2
368.333CS	SIGNATURE® TLIF TPS Spacer, MIS, Large, 13mm	2
368.335CS	SIGNATURE® TLIF TPS Spacer, MIS, Large, 15mm	2
368.337CS	SIGNATURE® TLIF TPS Spacer, MIS, Large, 17mm	2
968.003	Soft Case, PATRIOT®, SIGNATURE®-TPS (32 Box)	

Sterile packaged.

Items highlighted in gray are additionally available.

SIGNATURE® INSTRUMENT SET



SIGNATURE® Instrument Set 968.901

Instruments	Qty	Instruments	Qty
1 601.800 T-Handle	2	12 Large Trials (cont'd)	
2 622.410 Slide Hammer, Small	1	668.312 SIGNATURE®, Large, Trial, 12mm	1
3 668.050 SIGNATURE® Pin Driver	1	668.313 SIGNATURE®, Large, Trial, 13mm	1
4 668.100 SIGNATURE® Implant Holder, Long	1	668.315 SIGNATURE®, Large, Trial, 15mm	1
5 668.101 SIGNATURE® Implant Holder, Short	1	668.317 SIGNATURE®, Large, Trial, 17mm	1
6 668.150 SIGNATURE® Holder	1	13 Paddle Distractors	
7 668.160 SIGNATURE® Quick Coupling Handle	1	668.407 SIGNATURE® Paddle Distractor, 7mm	1
8 679.010 L-Handle	1	668.408 SIGNATURE® Paddle Distractor, 8mm	1
9 Rasps		668.409 SIGNATURE® Paddle Distractor, 9mm	1
668.020 SIGNATURE® Rasp, Angled, Serrated	1	668.410 SIGNATURE® Paddle Distractor, 10mm	1
668.021 SIGNATURE® Rasp, Angled, Knurled	1	668.411 SIGNATURE® Paddle Distractor, 11mm	1
10 Tamps		668.412 SIGNATURE® Paddle Distractor, 12mm	1
668.040 SIGNATURE® Tamp, Straight	1	668.413 SIGNATURE® Paddle Distractor, 13mm	1
668.041 SIGNATURE® Tamp, Angled	1	668.415 SIGNATURE® Paddle Distractor, 15mm	1
11 Small Trials		668.417 SIGNATURE® Paddle Distractor, 17mm	1
668.207 SIGNATURE®, Small, Trial, 7mm	1	14 Sizers/Shavers	
668.208 SIGNATURE®, Small, Trial, 8mm	1	668.507 SIGNATURE® Sizer/Shaver, 7mm	1
668.209 SIGNATURE®, Small, Trial, 9mm	1	668.508 SIGNATURE® Sizer/Shaver, 8mm	1
668.210 SIGNATURE®, Small, Trial, 10mm	1	668.509 SIGNATURE® Sizer/Shaver, 9mm	1
668.211 SIGNATURE®, Small, Trial, 11mm	1	668.510 SIGNATURE® Sizer/Shaver, 10mm	1
668.212 SIGNATURE®, Small, Trial, 12mm	1	668.511 SIGNATURE® Sizer/Shaver, 11mm	1
668.213 SIGNATURE®, Small, Trial, 13mm	1	668.512 SIGNATURE® Sizer/Shaver, 12mm	1
668.215 SIGNATURE®, Small, Trial, 15mm	1	668.513 SIGNATURE® Sizer/Shaver, 13mm	1
668.217 SIGNATURE®, Small, Trial, 17mm	1	668.515 SIGNATURE® Sizer/Shaver, 15mm	1
12 Large Trials		668.517 SIGNATURE® Sizer/Shaver, 17mm	1
668.307 SIGNATURE®, Large, Trial, 7mm	1	968.001 SIGNATURE® Instruments Graphic Case	
668.308 SIGNATURE®, Large, Trial, 8mm	1		
668.309 SIGNATURE®, Large, Trial, 9mm	1		
668.310 SIGNATURE®, Large, Trial, 10mm	1		
668.311 SIGNATURE®, Large, Trial, 11mm	1		

IMPORTANT INFORMATION ON THE PATRIOT® LUMBAR SPACER SYSTEM

DESCRIPTION

PATRIOT® Spacers (including CONSTITUTION®, SIGNATURE®, CONTINENTAL®, TransContinental®, and TransContinental® M) are thoracolumbar interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. Each of the PATRIOT® spacers provides a different shape to accommodate various surgical approaches to the spine. CONSTITUTION® PLIF Spacers are inserted using a posterior or transforaminal approach. SIGNATURE® TLIF Spacers are inserted using a transforaminal or lateral approach. CONTINENTAL® ALIF Spacers are inserted using an anterior, anterolateral, or lateral approach. TransContinental® and TransContinental® M Spacers are inserted using an anterior, anterolateral, or lateral approach. All approaches may be used in the lumbar spine; only anterior, anterolateral, or lateral approaches may be used in the thoracic spine. The devices are available in various heights and geometric options to fit the anatomical needs of a wide variety of patients. Protrusions on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to resist expulsion. Each spacer has an axial hole to allow grafting material to be packed inside the spacer.

PATRIOT® Spacers are made from radiolucent PEEK polymer (ASTM F2026) with titanium alloy or tantalum markers (ASTM F560). SIGNATURE® R Spacers also include an internal titanium alloy or commercially pure titanium (ASTM F67) component, and TransContinental® M Spacers also include an integrated titanium alloy nut. The SIGNATURE® Ti Spacer is made from titanium alloy or commercially pure titanium. The titanium alloy is TAV (ASTM F136) or TAN (ASTM F1295). PATRIOT® TPS Spacers also have a commercially pure titanium plasma spray coating, as specified in ASTM F67 and F1580.

INDICATIONS

PATRIOT® Spacers (including CONSTITUTION®, SIGNATURE®, CONTINENTAL®, TransContinental®, and TransContinental® M) are interbody fusion devices indicated at one or more levels of the thoracic spine (T1-T12), thoracolumbar junction (T12-L1), or lumbosacral spine (L1-S1) as adjunct to fusion in patients with the following indications: degenerative disc disease (DDD), disc herniation (with myelopathy and/or radiculopathy), spondylolisthesis, deformity (degenerative scoliosis or kyphosis), spinal stenosis, and failed previous fusion (pseudarthrosis). DDD is defined as discogenic back pain with degeneration of the disc as confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. PATRIOT® Spacers are to be filled with autograft bone and/or allogenic bone graft composed of cancellous, and/or corticocancellous bone. These devices are intended to be used with supplemental fixation systems that have been cleared for use in the thoracolumbosacral spine (e.g., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). Hyperlordotic interbody devices ($\geq 20^\circ$ lordosis) must be used with at least anterior supplemental fixation. All PATRIOT® TPS coated spacers are indicated for the same use as non-coated PEEK versions.

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 involved 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 radiolucent PEEK 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 that 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 intervertebral fusion 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 may appear 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



The PATRIOT® 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 PATRIOT® Spacers are expected to produce a maximum temperature rise of less than or equal to 3.9°C after 15 minutes of continuous scanning.

The image artifact caused by the device is not expected to extend beyond 35mm from the device 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 risk 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 use 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

IMPORTANT INFORMATION ON THE PATRIOT® LUMBAR SPACER SYSTEM

- 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 Enzo® (or a similar enzymatic detergent) per manufacturer's recommendations.
5. Immerse the instruments in the detergent and allow them to soak for a minimum of 2 minutes.
6. Use a soft bristled brush to thoroughly clean the instruments. Use a pipe cleaner for any lumens. Pay close attention to hard to reach areas.
7. Using a sterile syringe, draw up the enzymatic detergent solution. Flush any lumens and hard to reach areas until no soil is seen exiting the area.
8. Remove the instruments from the detergent and rinse them in running warm tap water.
9. Prepare Enzo® (or a similar enzymatic detergent) per manufacturer's recommendations in an ultrasonic cleaner.
10. Completely immerse the instruments in the ultrasonic cleaner and ensure detergent is in lumens by flushing the lumens. Sonicate for a minimum of 3 minutes.

11. Remove the instruments from the detergent and rinse them in running deionized water or reverse osmosis water for a minimum of 2 minutes.
12. Dry instruments using a clean soft cloth and filtered pressurized air.
13. Visually inspect each instrument for visible soil. If visible soil is present, then repeat cleaning process starting with Step 3.

CONTACT INFORMATION

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

STERILIZATION

These implants and instruments may be available sterile or nonsterile.

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 in 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. 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:

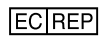
- Recommended sterilization parameters are listed in the table below.
- Only FDA-cleared rigid sterilization containers for use with pre-vacuum steam sterilization may be used.
- When selecting a rigid sterilization container, it must have a minimum filter area of 176 in² total, or a minimum of four (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.

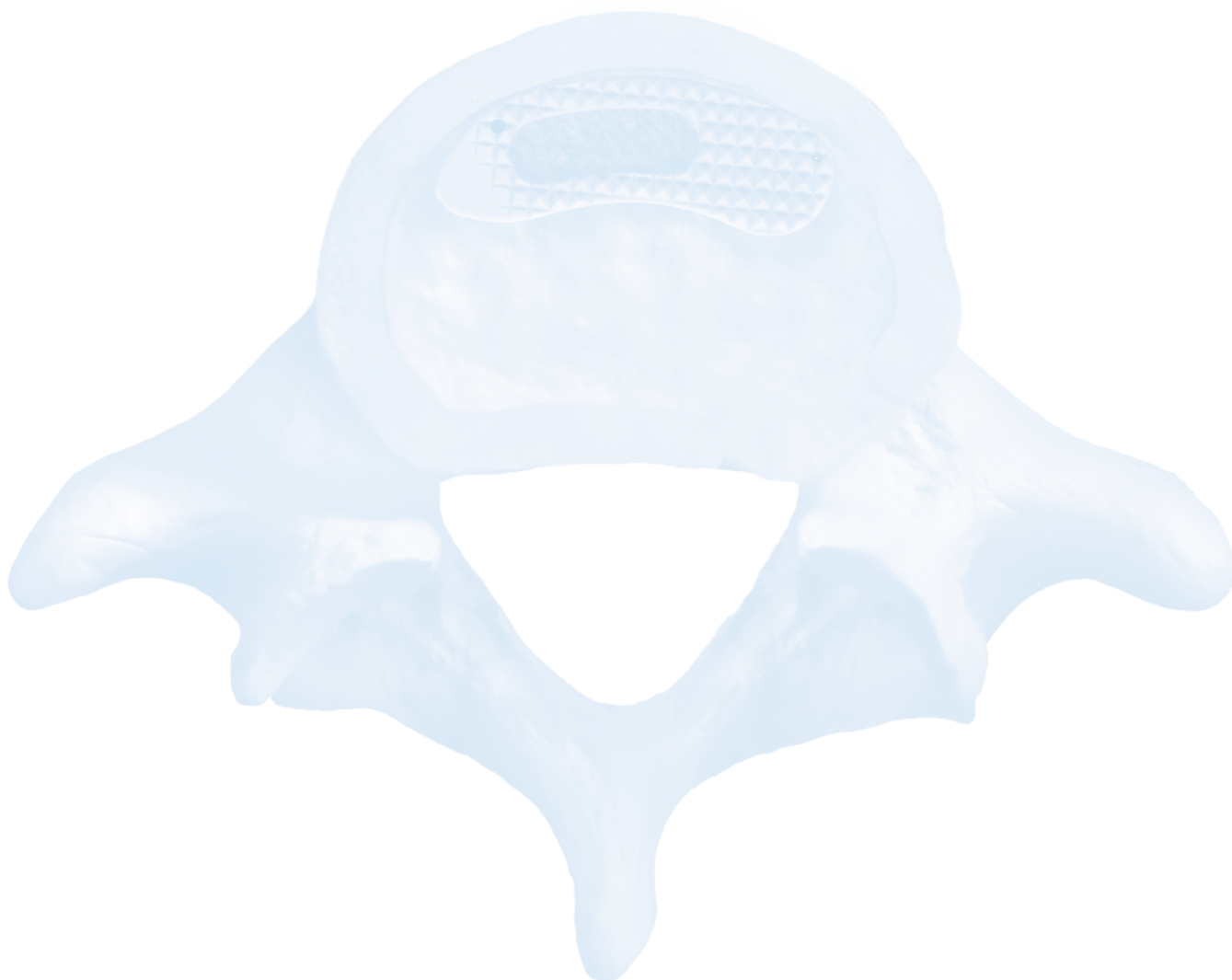
CAUTION: Federal (U.S.A.) Law Restricts this Device to Sale by or on the Order of a Physician.

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

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This image shows a single sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.

This image shows a single sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.



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