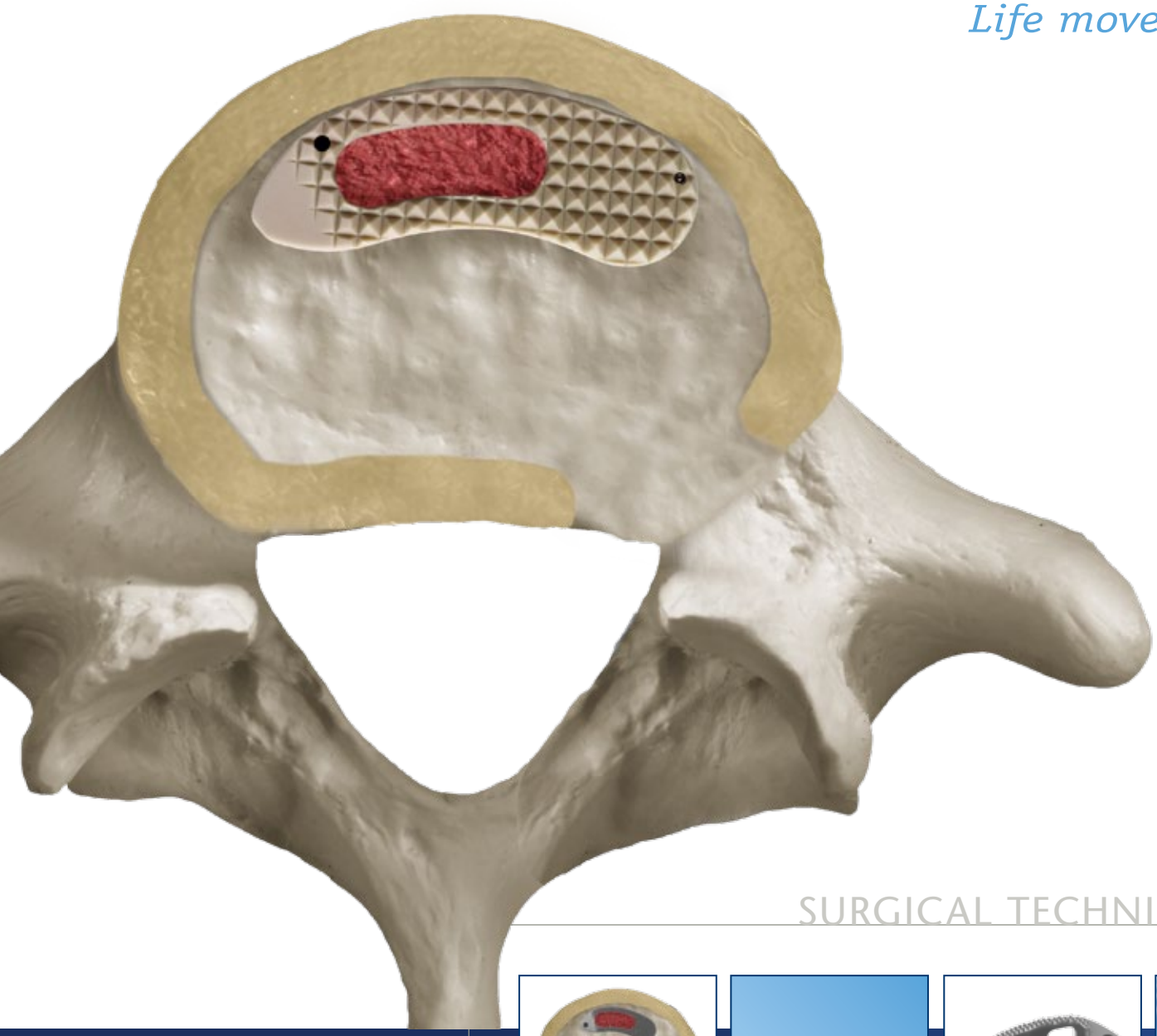
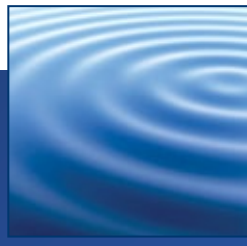
Life moves us



SURGICAL TECHNIQUE



SIGNATURE®

TLIF System

A PATRIOT® Spacer

GLOBUS MEDICAL

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

www.globusmedical.com

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. 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

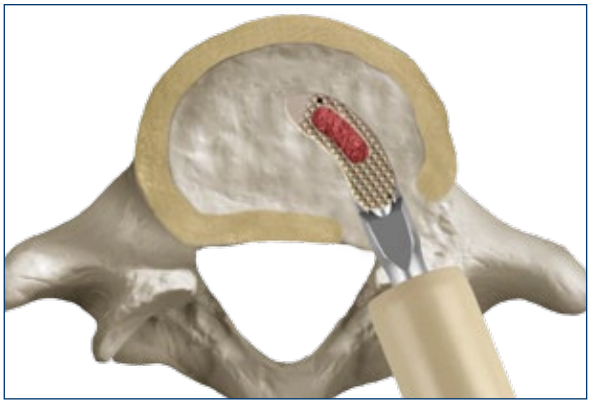
Implant holder allows articulation in the disc space while maintaining connection to the implant throughout insertion

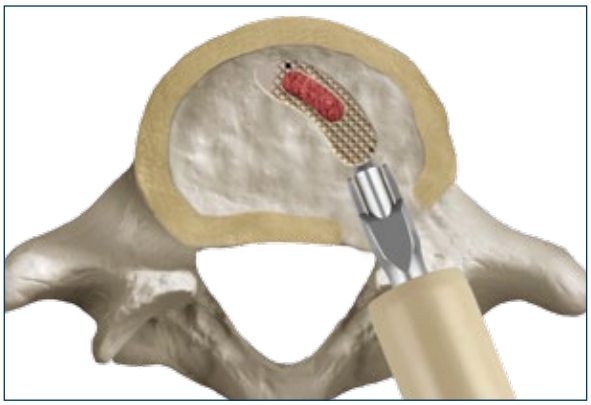
Positioning Feedback

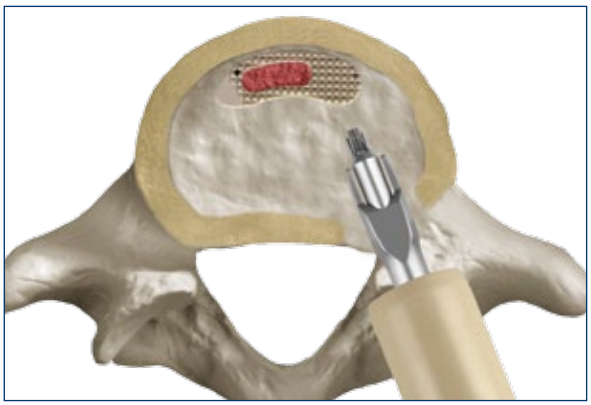
Intuitive radiographic targeting provides positioning feedback for proper placement

Ease of Insertion

Bulleted leading edge self-distracts, easing initial insertion



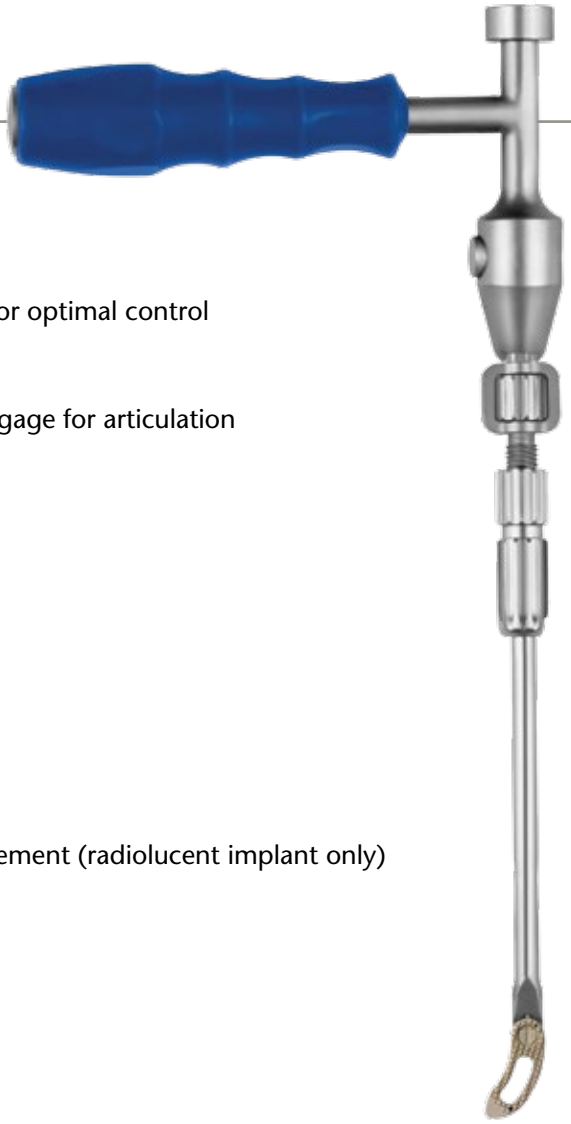




CONTENTS

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



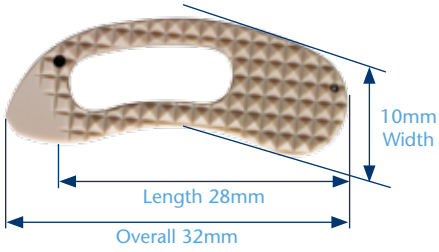
SIGNATURE® Instruments

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

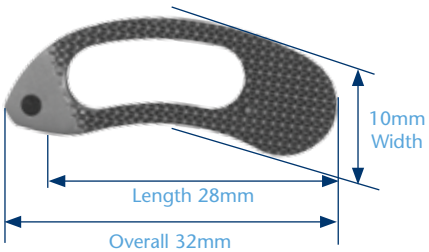
SIGNATURE® Spacer

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

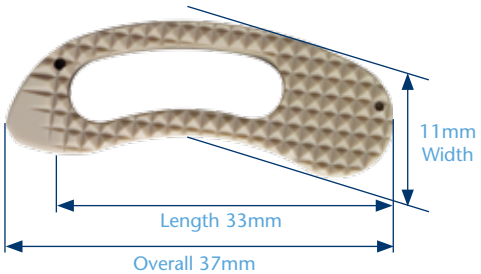
Small PEEK



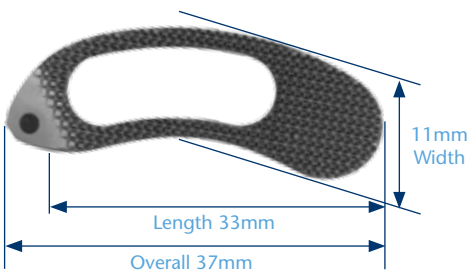
Small Titanium



Large PEEK



Large Titanium



INSTRUMENT OVERVIEW

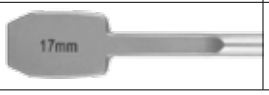
Sizers/Shavers

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

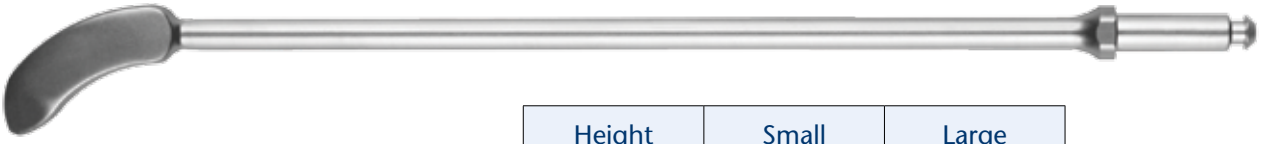
	Height	Part Number
	12mm	668.512
	13mm	668.513
	15mm	668.515
	17mm	668.517

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

Quick Coupling Handle 668.160

L-Handle 679.010

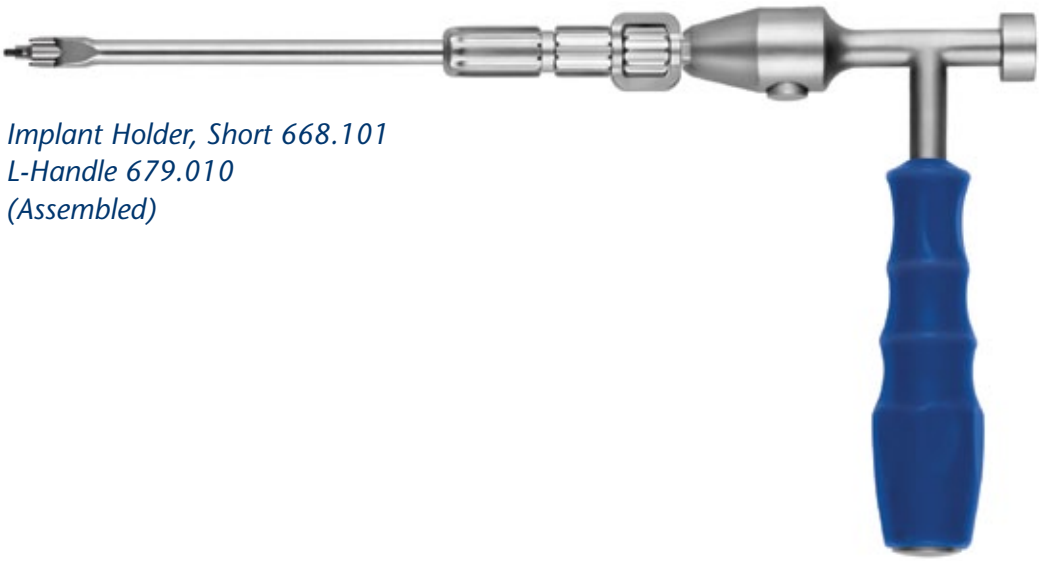
Implant Holder Instruments

Holder 668.150

Implant Holder, Long 668.100

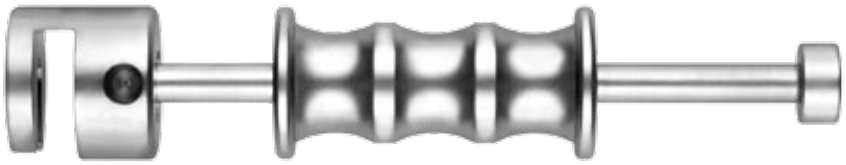
Implant Holder, Short 668.101

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



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

Other Instruments



Slide Hammer, Small 622.410

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]

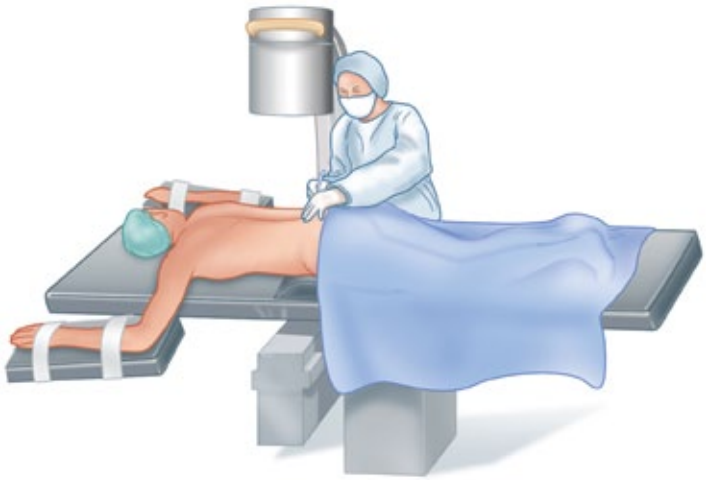
- Reduce soft tissue disruption
- Reduce blood loss
- Reduce scarring
- Reduce postoperative pain
- Shorten hospital stay
- Shorten recovery time

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.

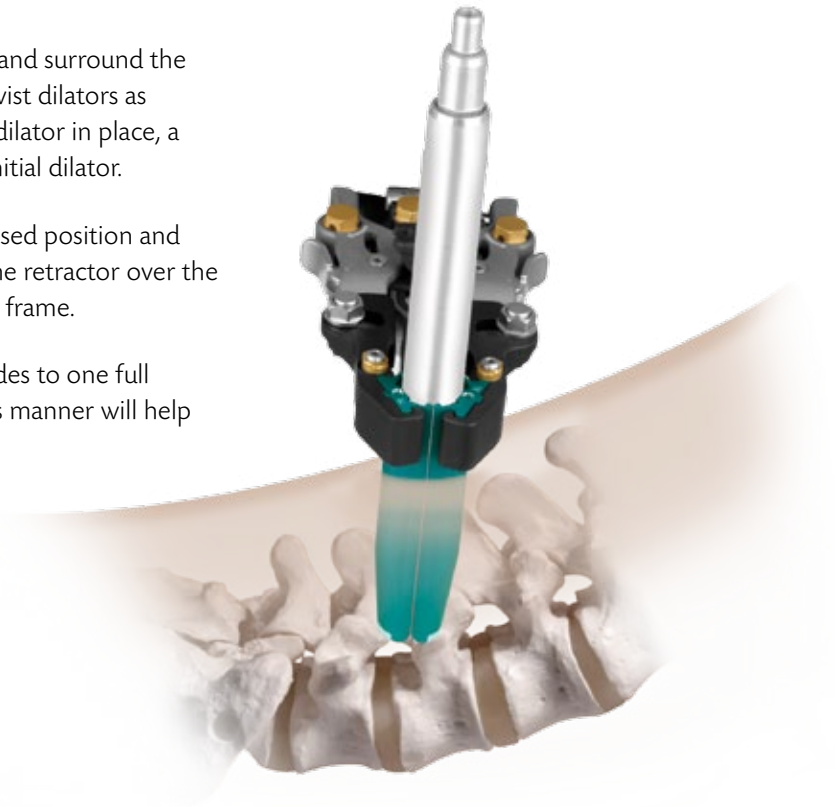


Table Arm Attachment

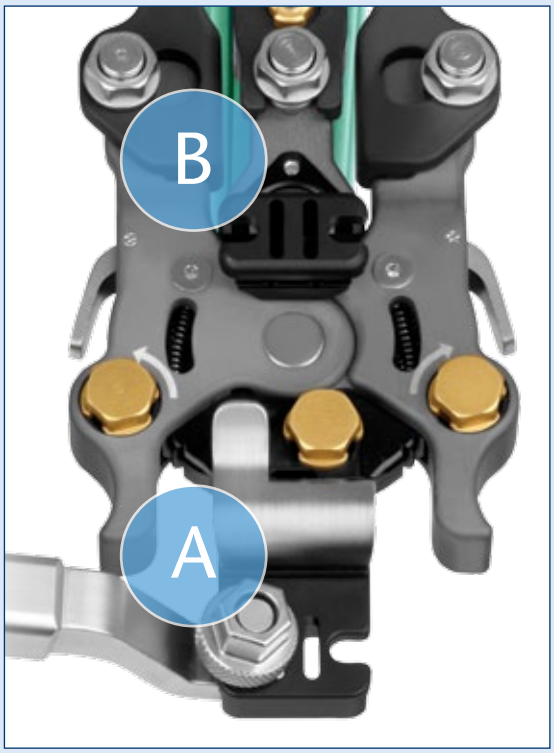
In order to use the MARS™3V Retractor, the Table Arm Assembly must be secured. Attach the table clamp onto the bed rail attachment. Insert the arm assembly into the clamp and secure. The opposite end of the arm assembly is then attached to the Retractor 3 Blade Frame.

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.

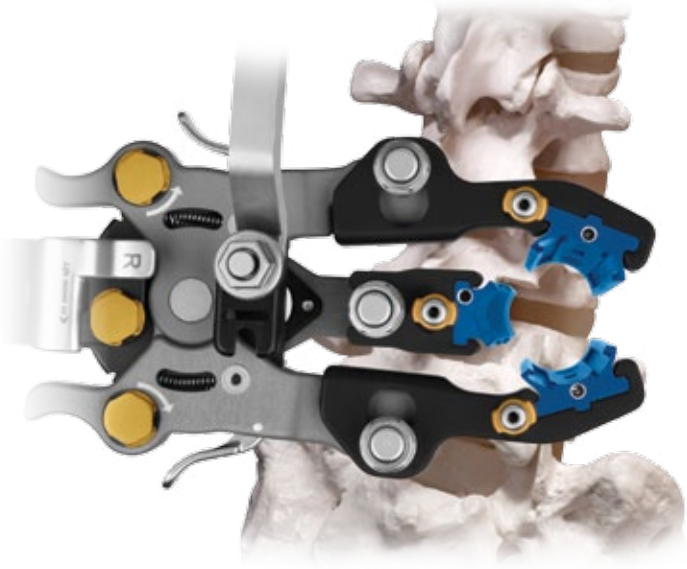
Refer to the LLIF Surgical Technique Guide for additional information (GMTGD32).



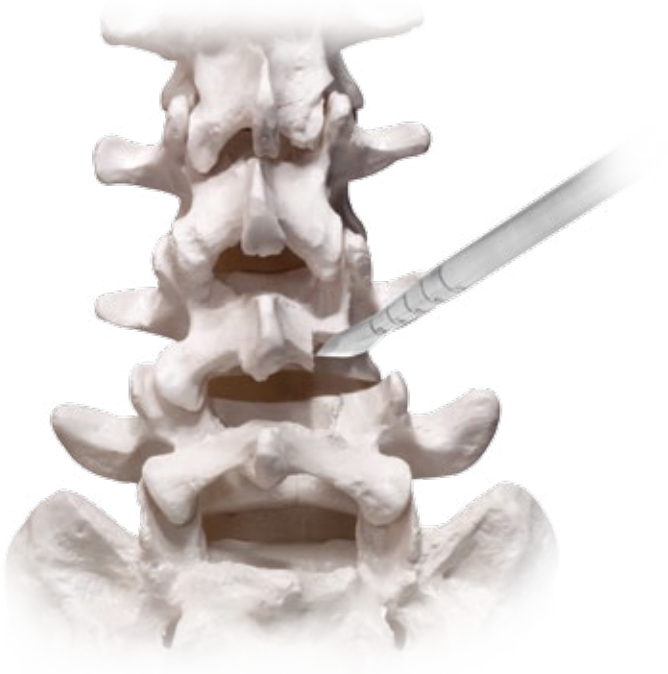
Step 3 Creating Transforaminal Access

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

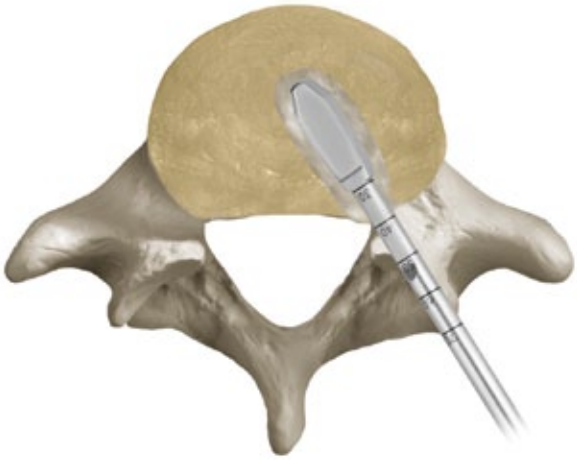


Transforaminal access

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.*

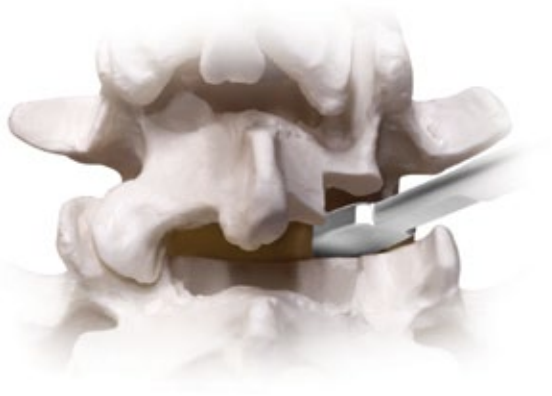


Discectomy using shaver

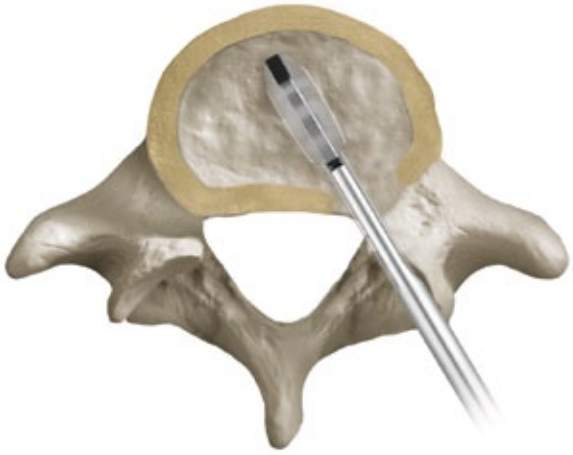
Step 5 Distraction

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.



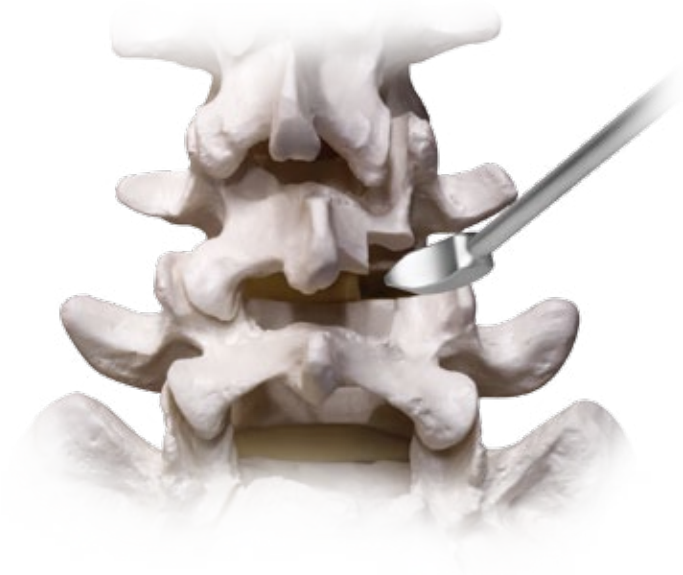
Distraction of disc space using paddle distractor

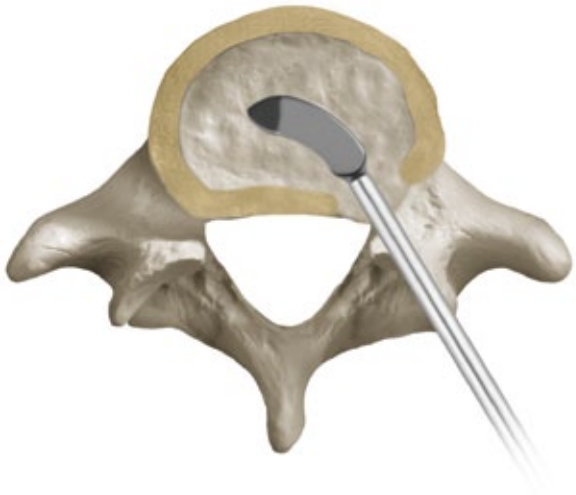


Paddle distractor in disc space

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.



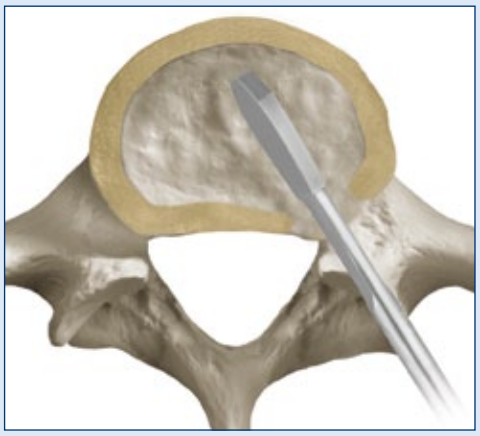


Implant Sizing (cont'd)

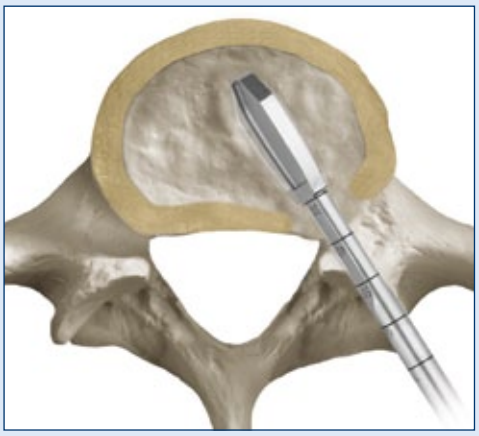
Alternative Sizing

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

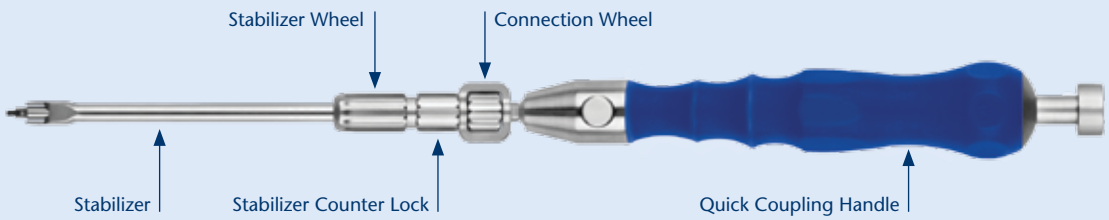


Sizing disc space using sizer/shaver

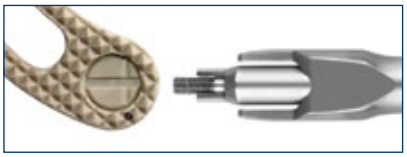
Step 7 Loading the SIGNATURE® Implant

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 **Quick Coupling Handle**. It is then ready for implant attachment.



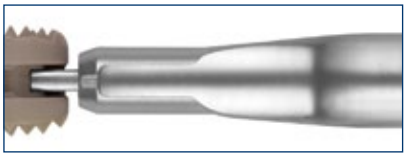
Select the appropriate sized SIGNATURE® TLIF Spacer and fill with autogenous bone graft material. Orient the holder to the implant pivot pin, as shown at right.



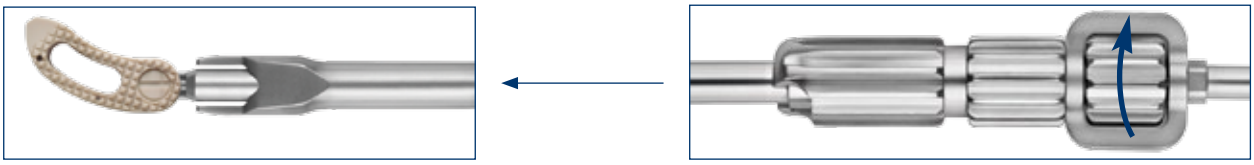
Top view

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.

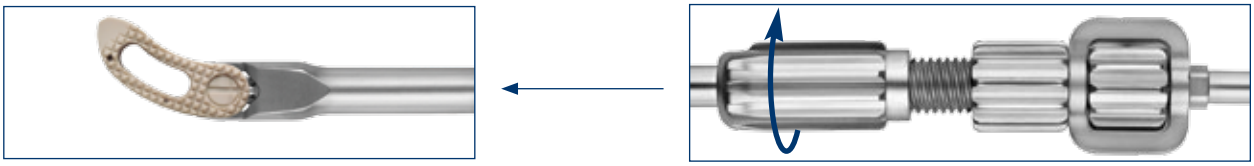


Side view



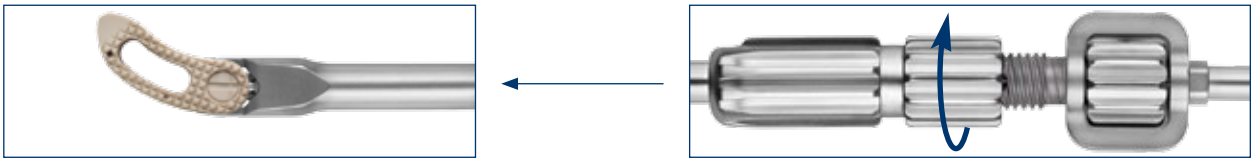
Implant loaded

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.

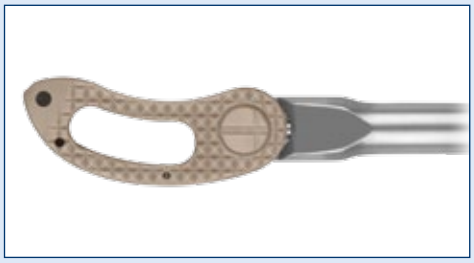


Implant fully locked

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.

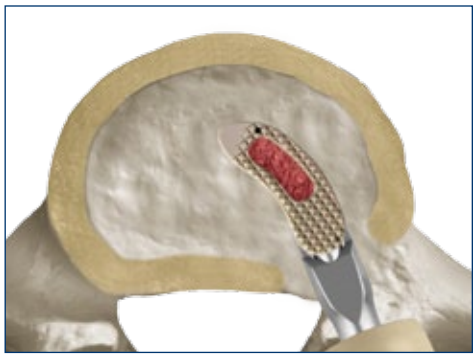


MIS implant fully locked

Step 8 Inserting the Implant

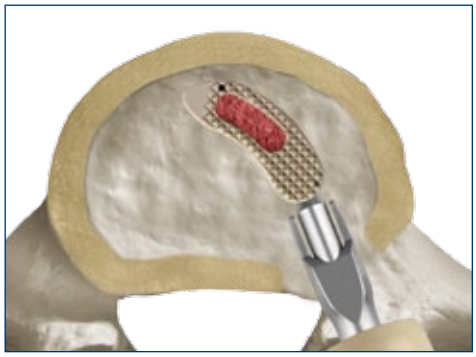
Insert Implant

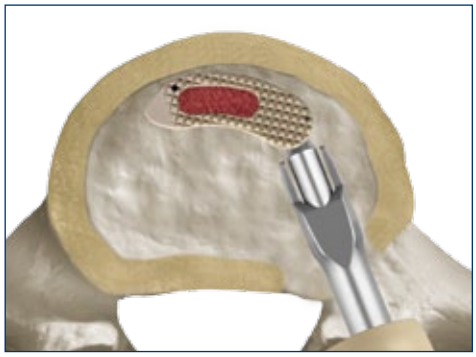
Insert the implant into the disc space with the holder stabilizer engaged.



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.





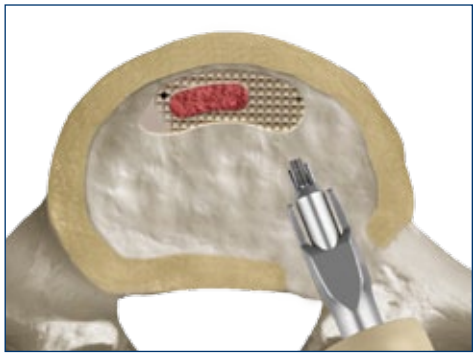
Articulate Implant

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

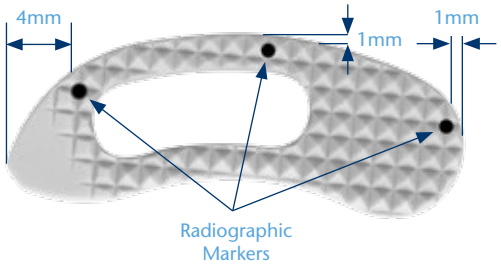
The final position of the implant is shown. Using fluoroscopy, verify the position before disengaging.

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

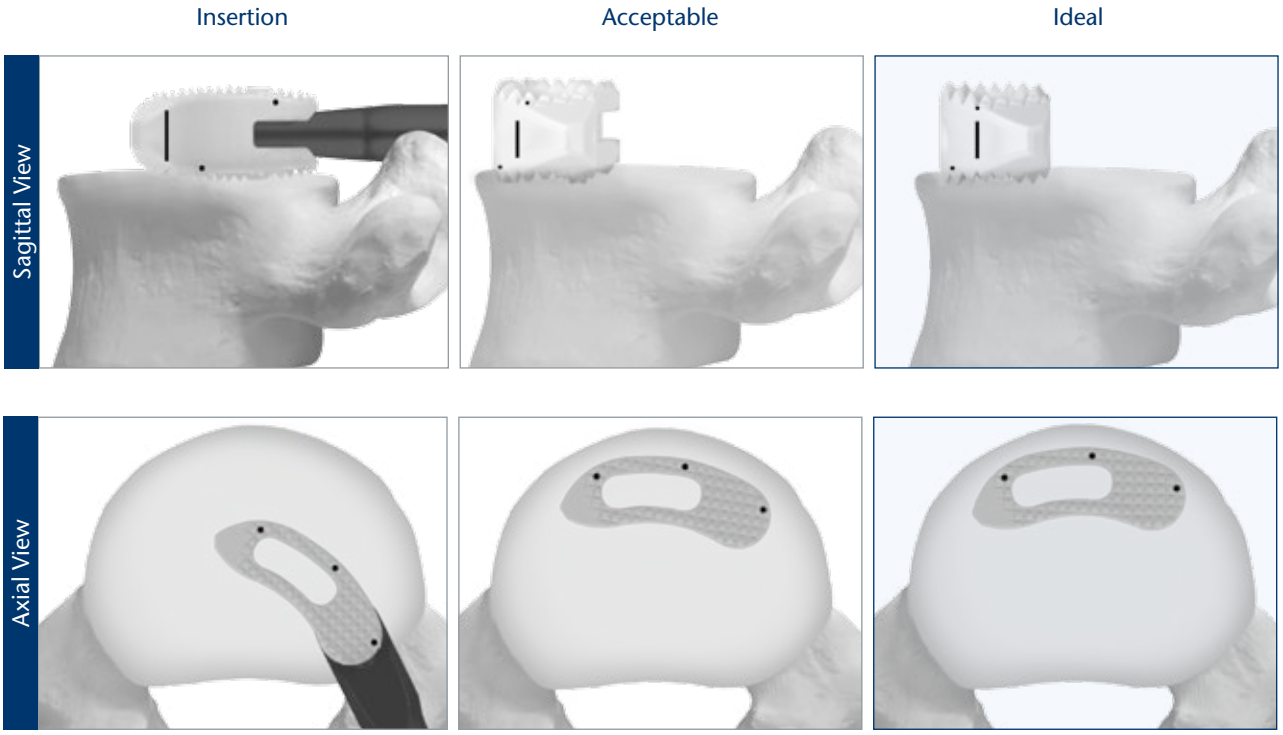


Radiographic Positioning of Radiolucent Implants

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

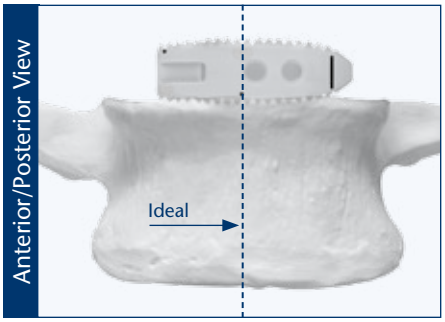


When the marker rod lies between the beads, the implant is in an acceptable position. The ideal position is when the marker is aligned with the posterior marker bead.

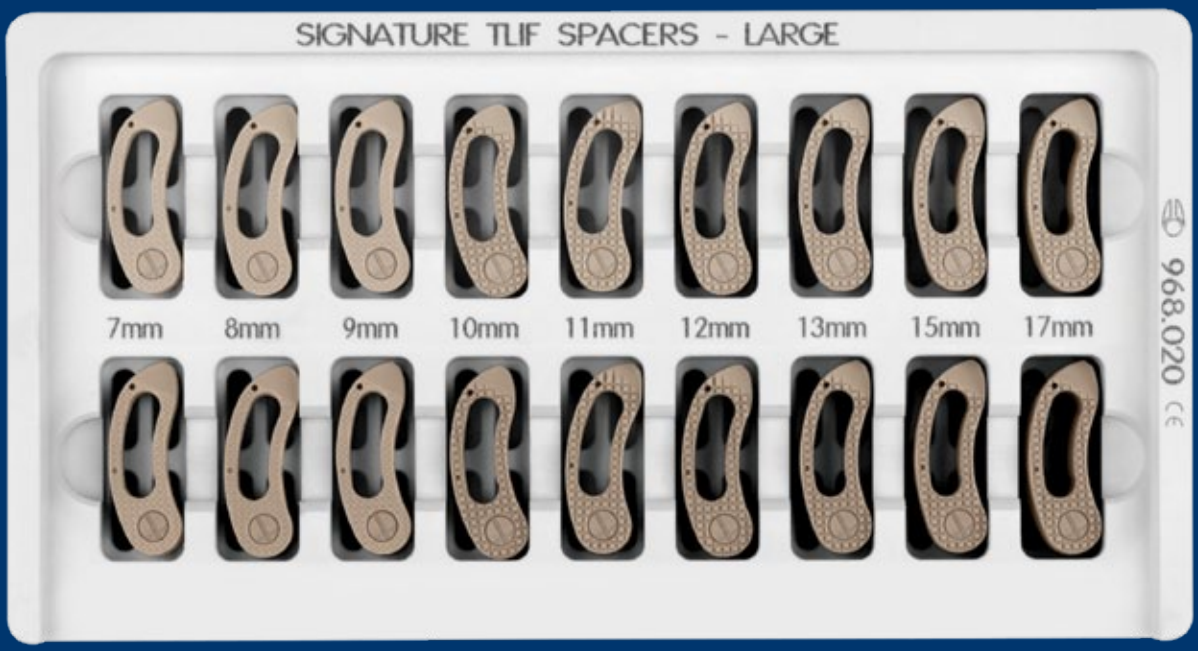


The implant is properly positioned in the anterior portion of the disc space, along the apophyseal ring, as seen above, right.

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	

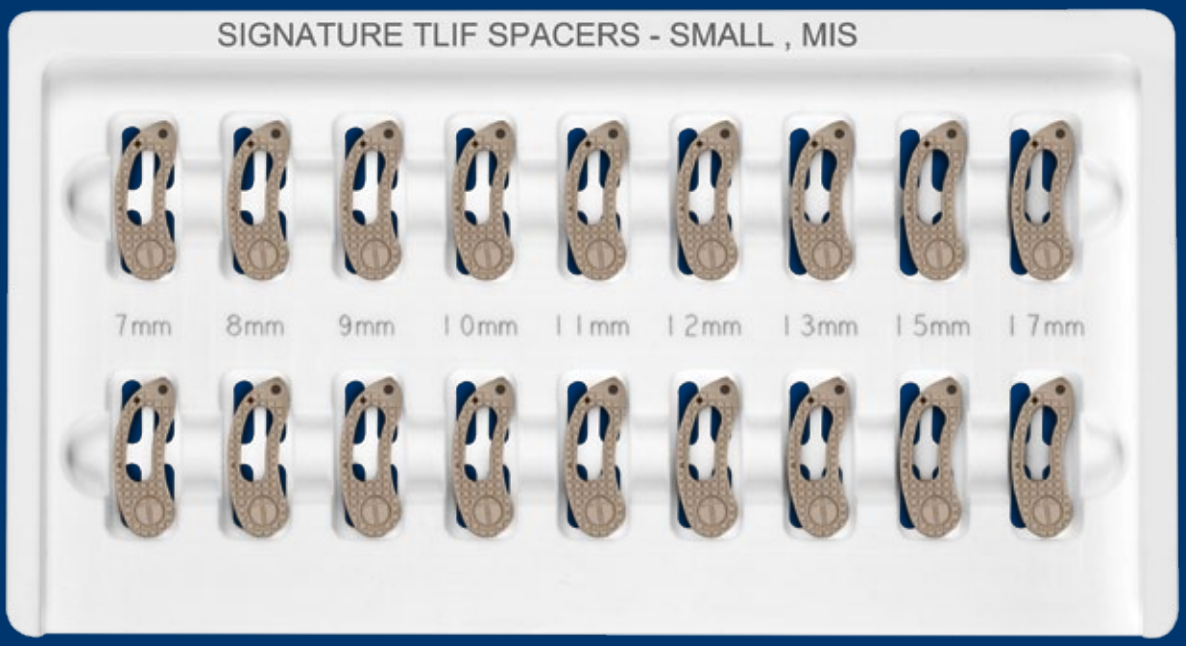
968.903 SIGNATURE® Large Implant Set

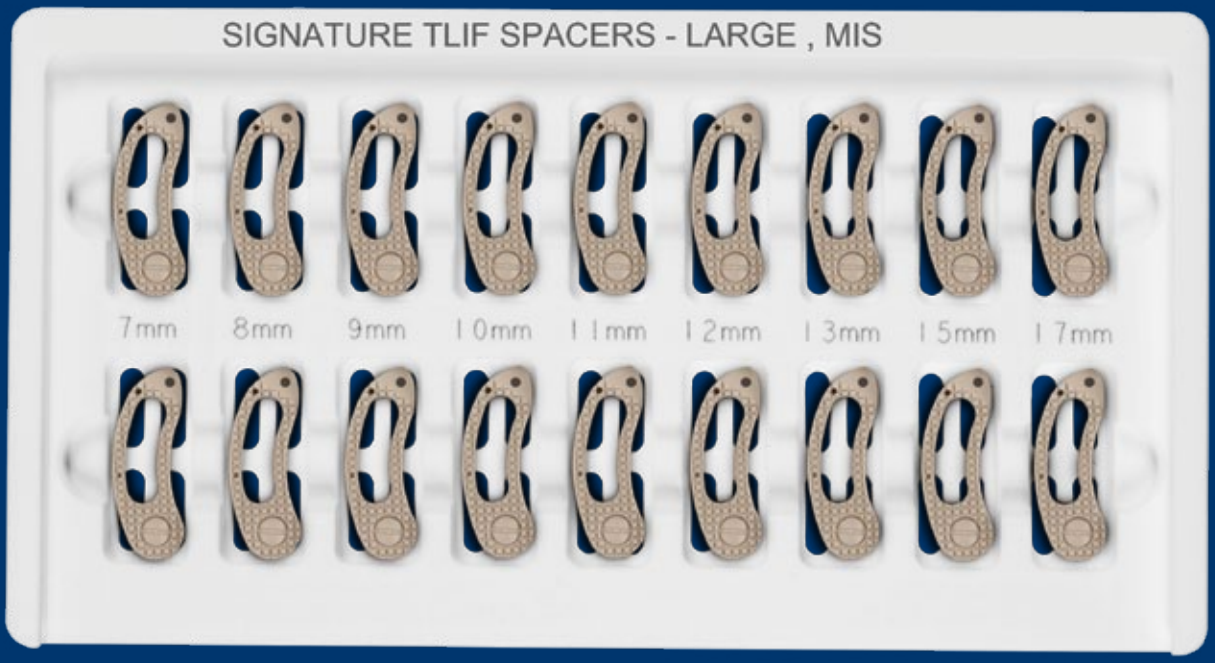
Description		Qty
368.307	SIGNATURE® TLIF Spacer, Large, 7mm	2
368.308	SIGNATURE® TLIF Spacer, Large, 8mm	2
368.309	SIGNATURE® TLIF Spacer, Large, 9mm	2
368.310	SIGNATURE® TLIF Spacer, Large, 10mm	2
368.311	SIGNATURE® TLIF Spacer, Large, 11mm	2
368.312	SIGNATURE® TLIF Spacer, Large, 12mm	2
368.313	SIGNATURE® 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

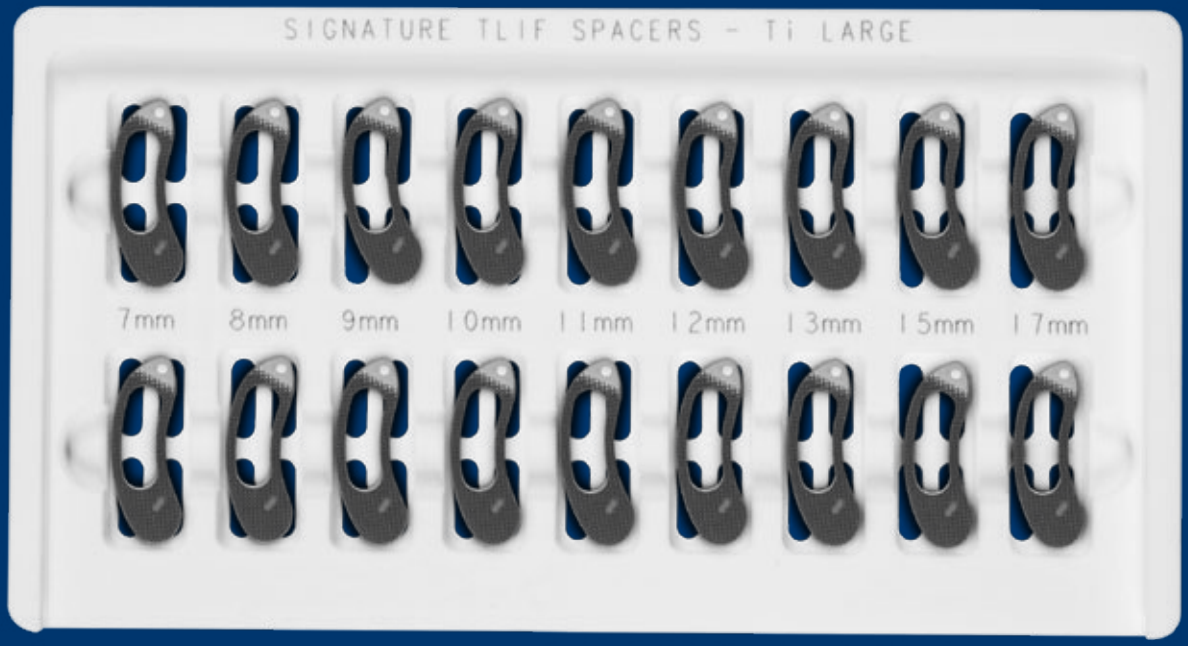
368.234 SIGNATURE® TLIF Spacer, MIS, Small, 14mm

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	

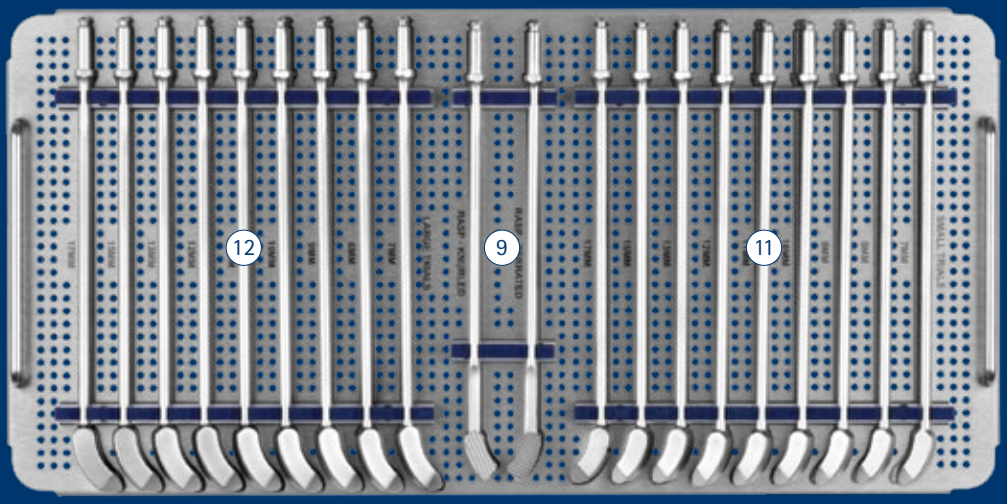
968.910 SIGNATURE® Ti Large Implant Set

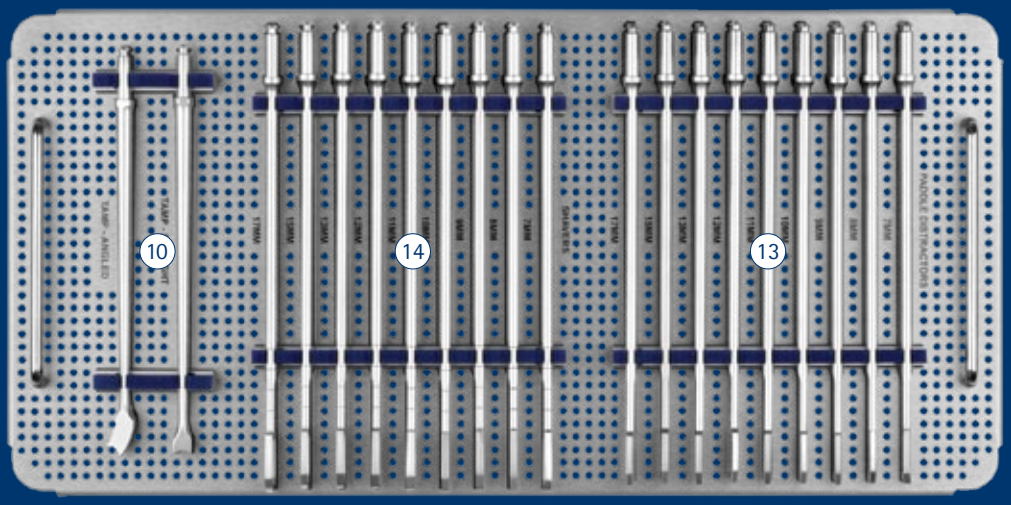
	Description	Qty
168.347	SIGNATURE® TLIF Spacer, Ti Large, 7mm	2
168.348	SIGNATURE® TLIF Spacer, Ti Large, 8mm	2
168.349	SIGNATURE® TLIF Spacer, Ti Large, 9mm	2
168.350	SIGNATURE® TLIF Spacer, Ti Large, 10mm	2
168.351	SIGNATURE® TLIF Spacer, Ti Large, 11mm	2
168.352	SIGNATURE® TLIF Spacer, Ti Large, 12mm	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	

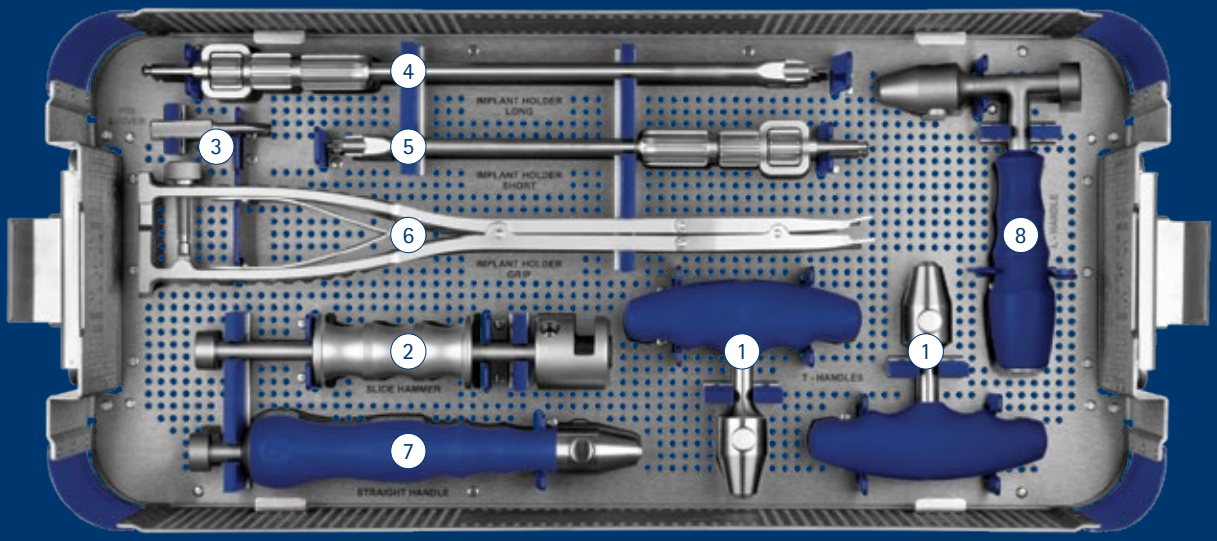
Additionally Available

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® INSTRUMENT SET







SIGNATURE® Instrument Set 968.901

	Instruments		Qty
1	601.800	T-Handle	2
2	622.410	Slide Hammer, Small	1
3	668.050	SIGNATURE® Pin Driver	1
4	668.100	SIGNATURE® Implant Holder, Long	1
5	668.101	SIGNATURE® Implant Holder, Short	1
6	668.150	SIGNATURE® Holder	1
7	668.160	SIGNATURE® Quick Coupling Handle	1
8	679.010	L-Handle	1
9	**Rasps**		
	668.020	SIGNATURE® Rasp, Angled, Serrated	1
	668.021	SIGNATURE® Rasp, Angled, Knurled	1
10	**Tamps**		
	668.040	SIGNATURE® Tamp, Straight	1
	668.041	SIGNATURE® Tamp, Angled	1
11	**Small Trials**		
	668.207	SIGNATURE®, Small, Trial, 7mm	1
	668.208	SIGNATURE®, Small, Trial, 8mm	1
	668.209	SIGNATURE®, Small, Trial, 9mm	1
	668.210	SIGNATURE®, Small, Trial, 10mm	1
	668.211	SIGNATURE®, Small, Trial, 11mm	1
	668.212	SIGNATURE®, Small, Trial, 12mm	1
	668.213	SIGNATURE®, Small, Trial, 13mm	1
	668.215	SIGNATURE®, Small, Trial, 15mm	1
	668.217	SIGNATURE®, Small, Trial, 17mm	1
12	**Large Trials**		
	668.307	SIGNATURE®, Large, Trial, 7mm	1
	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

	Instruments		Qty
12	**Large Trials (cont'd)**		
	668.312	SIGNATURE®, Large, Trial, 12mm	1
	668.313	SIGNATURE®, Large, Trial, 13mm	1
	668.315	SIGNATURE®, Large, Trial, 15mm	1
	668.317	SIGNATURE®, Large, Trial, 17mm	1
13	**Paddle Distractors**		
	668.407	SIGNATURE® Paddle Distractor, 7mm	1
	668.408	SIGNATURE® Paddle Distractor, 8mm	1
	668.409	SIGNATURE® Paddle Distractor, 9mm	1
	668.410	SIGNATURE® Paddle Distractor, 10mm	1
	668.411	SIGNATURE® Paddle Distractor, 11mm	1
	668.412	SIGNATURE® Paddle Distractor, 12mm	1
	668.413	SIGNATURE® Paddle Distractor, 13mm	1
	668.415	SIGNATURE® Paddle Distractor, 15mm	1
	668.417	SIGNATURE® Paddle Distractor, 17mm	1
14	**Sizers/Shavers**		
	668.507	SIGNATURE® Sizer/Shaver, 7mm	1
	668.508	SIGNATURE® Sizer/Shaver, 8mm	1
	668.509	SIGNATURE® Sizer/Shaver, 9mm	1
	668.510	SIGNATURE® Sizer/Shaver, 10mm	1
	668.511	SIGNATURE® Sizer/Shaver, 11mm	1
	668.512	SIGNATURE® Sizer/Shaver, 12mm	1
	668.513	SIGNATURE® Sizer/Shaver, 13mm	1
	668.515	SIGNATURE® Sizer/Shaver, 15mm	1
	668.517	SIGNATURE® Sizer/Shaver, 17mm	1
	968.001	SIGNATURE® Instruments Graphic Case	

IMPORTANT INFORMATION ON THE PATRIOT® LUMBAR SPACER SYSTEM

DESCRIPTION

The PATRIOT® Spacers (CONSTITUTION® PLIF, SIGNATURE® TLIF, CONTINENTAL® ALIF, TransContinental® and TransContinental® M Spacers) are lumbar 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 lumbar spine. The CONSTITUTION® PLIF Spacer is inserted using a posterior approach. The SIGNATURE® TLIF Spacer is inserted using a transforaminal approach. The CONTINENTAL® ALIF Spacer is inserted using an anterior approach. The Transcontinental® and TransContinental® M Spacer are inserted using an anterior or lateral approach. The devices are available in various heights and geometric options to fit the anatomical needs of a wide variety of patients. These spacers are to be filled with autogenous bone graft material. Protrusions on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to resist expulsion.

PATRIOT® Spacers are made from PEEK radiolucent polymer (ASTM F2026) with titanium alloy or tantalum markers (ASTM F560). The SIGNATURE® R Spacer also includes an internal titanium alloy or commercially pure titanium (ASTM F67) component, and the TransContinental® M Spacer also includes 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).

INDICATIONS

PATRIOT® Spacers (CONSTITUTION® PLIF, SIGNATURE® TLIF, CONTINENTAL® ALIF, TransContinental® and TransContinental® M Spacers) are interbody fusion devices intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).

PATRIOT® Spacers are to be filled with autogenous bone graft material. These devices are intended to be used with supplemental 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.

Interbody fusion devices for the treatment of degenerative conditions are designed to withstand both full load bearing and the loads associated with long-term use which could result from the presence of non-union or delayed union.

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.

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.

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 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.

The PATRIOT® Spacers have not been evaluated for safety and compatibility in the MR environment. The PATRIOT® Spacers have not been tested for heating or migration in the MR environment.

Based on fatigue testing results, when using the PATRIOT® Spacers, the surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this 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 demonstrated allergy or foreign body sensitivity to any of the implant materials.
2. Prior fusion at the level(s) to be treated.
3. Severe osteoporosis, which may prevent adequate fixation
4. 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.
5. 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.
6. Any condition not described in the indications for use.

PACKAGING

PATRIOT® Spacers 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 implants from the packaging using aseptic technique.

The instrument sets are provided non-sterile 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

All instruments and implants should be treated with care. Improper use or handling may lead to damage and/or possible malfunction. Instruments should be checked to ensure that they are in working order prior to surgery. All instruments should be inspected prior to use to ensure that there is no unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals, etc. Non-working or damaged instruments should not be used, and should be returned to Globus Medical.

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

PATRIOT® implants are provided sterile or non-sterile. The sterile implants are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of 10^{-6}. The expiration date is provided on the package label. Do not use if expired. These implants are considered sterile unless the packaging has been opened or damaged.

Non-sterile PATRIOT® 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."

The recommended gravity displacement and pre-vacuum sterilization cycles are not considered by the Food and Drug Administration to be standard sterilization cycles. 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 Food and Drug Administration for the selected sterilization cycle specifications (time and temperature).

Implants:
These devices are supplied NONSTERILE. Sterilization is recommended as follows:

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Gravity Displacement (Wrapped)	132°C (270°F)	10 minutes	30 minutes
Steam	Pre-vacuum (Wrapped)	132°C (270°F)	4 minutes	30 minutes

Instruments:
These instruments are supplied NONSTERILE. Sterilization is recommended as follows:

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Gravity Displacement (Wrapped)	132°C (270°F)	25 minutes	30 minutes
Steam	Pre-vacuum (Wrapped)	132°C (270°F)	15 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 autoclave must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

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

REV F

Notes

Notes

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

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

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