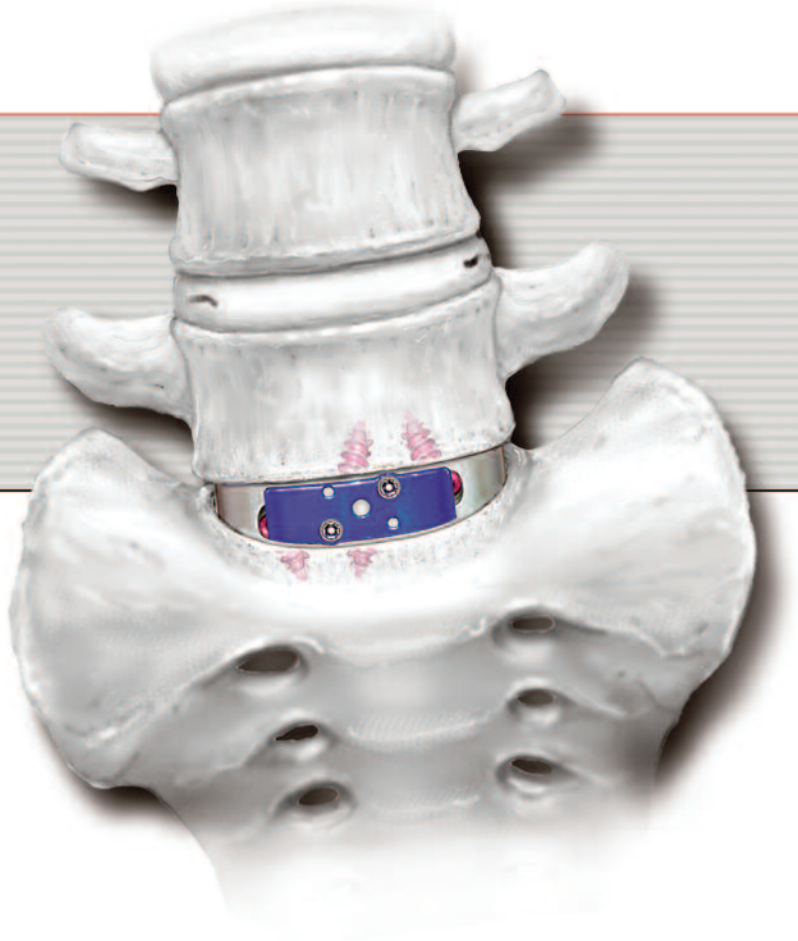
Surgical Technique



PILLAR™ SA

PEEK Spacer System

Jason E. Garber, M.D.
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Las Vegas, Nevada

Draft

BLACKSTONE MEDICAL INC

Breakthrough Thinking®

an Orthofix Company

MICHELSON TECHNOLOGY AT WORK

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Las Vegas, Nevada

PEEK Spacer System

Introduction

An anterior lateral interbody fusion is an operation that is commonly performed to treat lumbar disc herniation and spinal stenosis resulting from degenerative disc disease, spinal instability, and Grade I and II spodylolithesis. Anterior lumbar spacers should:

- Align the spine in an anatomical position
- Maintain graft position
- Increase the likelihood of a fusion
- Allow patients to increase activity in a timely fashion.

The PILLAR SA PEEK Spacer System provides fixation within the intervertebral disc space with Bone Screws and a Cover Plate to prevent screw back-out or hardware failure. The Bone Screws are self-tapping; however, several options for screw placement are available. The trajectory of the Bone Screw placement via the prefixed range of angulations with the PEEK cage enhances purchase in the bone. The Cover Plate shape is low profile and sits flush with the implant to eliminate any bulk near the aorta.

The PILLAR SA PEEK Spacer System is a reliable, adaptable system that can be used to suit surgeon preferences as they repair a wide spectrum of anterior lumbar spinal disorders.

Jason E. Garber, M.D.
Western Regional Center for Brain and Spine Surgery
Nevada Neuro Institute
Las Vegas, Nevada

Pre-Operative

1.

Fig. 1a

Step 1

Preoperative Planning and Patient Positioning

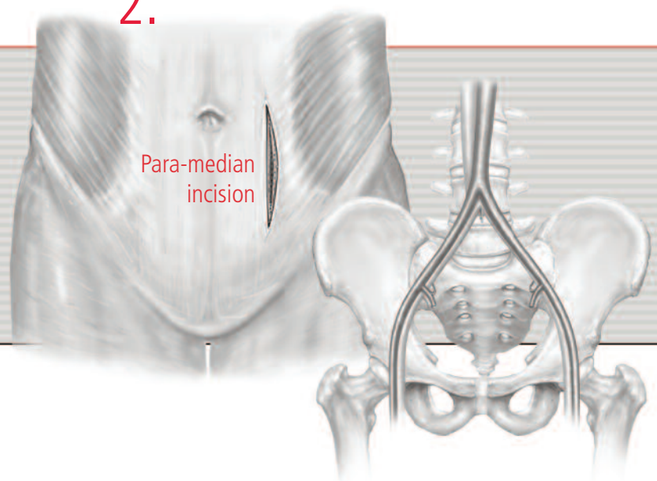
Preoperative planning is critical in the preparation for spinal surgery. A complete radiographic evaluation (AP and lateral films) measuring the vertebral body dimension is recommended for proper diagnosis prior to surgery.

Carefully place the patient in the supine position on the operating table with all bony prominences padded and the lumbar spine in neutral to slight extension following induction of anesthesia. Once the patient is placed on the table, use a lateral C-Arm fluoroscopy to visualize the lumbar spine.

***Note:** At times you may want to break the table in order to gain better access to the level, particularly in treating L5/S1 (Fig. 1a).*
J. Garber, M.D.

Operative

2.

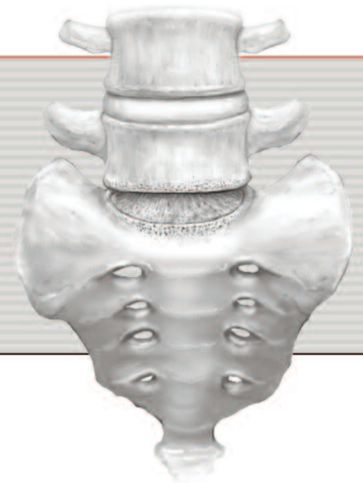


Step 2

Exposure

Adequate visualization of the cephalad and caudal vertebra and disc space is critical. Width of the disc space exposure should be lateral enough for lateral visualization of the sympathetic chains. Use standard radiographic techniques to identify the correct disc level.

3.



Step 3

Discectomy and Disc Space Preparation

Sterilize the implants and instruments as described in the Instructions for Use.

Perform a routine discectomy and remove the disco-cartilageous material.

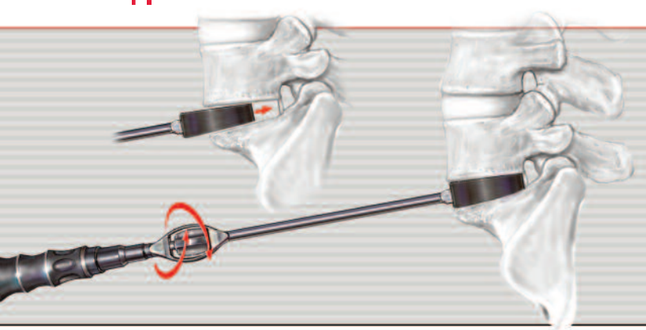
In order to square the end plates to make the PILLAR SA PEEK Spacer insertion more efficient, you may remove any osteophytes using a ½" osteotome and mallet or an osteotome of an appropriate size.

Note: *PILLAR SA PEEK Spacer System does not include rasps, osteotomes, or a mallet.*

Surgical Technique

Operative

4.



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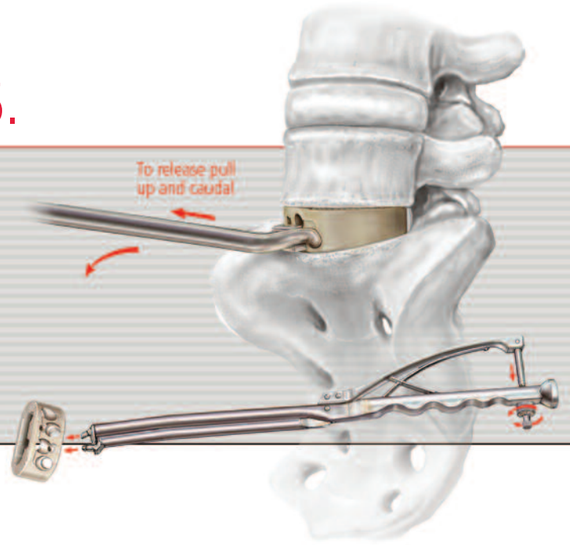

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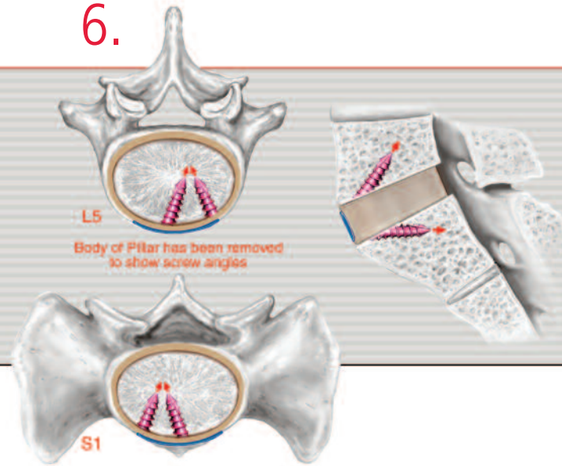
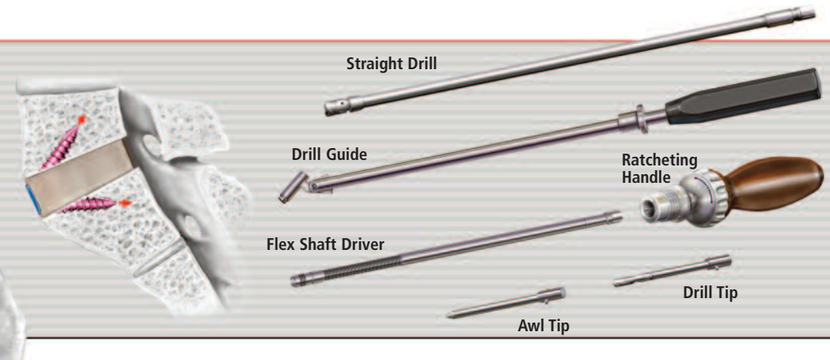




Step 4

Implant Sizing

There are various sizes of the PILLAR™ SA Trials corresponding to the various PILLAR SA implants that are available. (See corresponding Trial sizes on page 13.)

Select appropriate size Trial and attach it to the Trial Insertion Instrument. Turn the center knob clockwise until it stops to secure the Trial to the instrument.

Insert sequential Trial sizes into the prepared disc space until an appropriately tight fit is achieved. Disengage the Trial from the prepared disc space by gently tapping it out using the Integrated Slap Hammer.

Disengage the Trial from the Trial Insertion Instrument by turning the center knob counter-clockwise.

Select the appropriate PILLAR SA implant size according to the Trial.

Step 5

Implant Insertion

Attach the appropriate PILLAR SA implant to the Implant Insertion Instrument through one end hole and the third hole in the implant.

Close the jaws on the Implant Insertion Instrument tips by squeezing the handle. Then turn the knob clockwise to secure the implant onto the instrument.

Implant the PILLAR SA into the prepared space with the Implant Insertion Instrument and tap it into place with a mallet.

To disengage the Implant Insertion Instrument from the implant, turn the knob counter-clockwise and pull the instrument up with a slight turning action.

If the PILLAR SA implant needs to be repositioned in the prepared space, gently tap the implant with the Straight Tamp provided in the Instrument tray.

Step 6

Hole Preparation for Screw Placement

The Bone Screws are self-tapping; however, additional options are provided for placing the starter holes into the cortical bone.

When using the Awl:

1. Use the Awl to create four (4) pilot holes by punching through the cortical shell.

2. For difficult to reach areas, use the Awl Tip and Flex Shaft Driver with the Ratcheting Handle. Attach the Flex Shaft Driver to the Awl Tip. Assemble the Ratcheting Handle to the Flex Shaft Driver. The Handle has the ability to ratchet clockwise, counter-clockwise, or remain stationary in a locked position. These options are indicated on the dial located on the handle. Turn the dial for the option of choice, indicated by laser markings. This assembly must be used in conjunction with the drill guide.

Place either the Awl or the Drill Guide with the Awl Tip through the PILLAR SA implant holes. Punch through the cortical bone to prepare the four (4) Bone Screw holes.

When using the Straight Drill, Drill Guide, and Ratcheting Handle:

1. Attach Straight Drill to the Drill Tip, and attach the Ratcheting Handle to the Straight Drill.

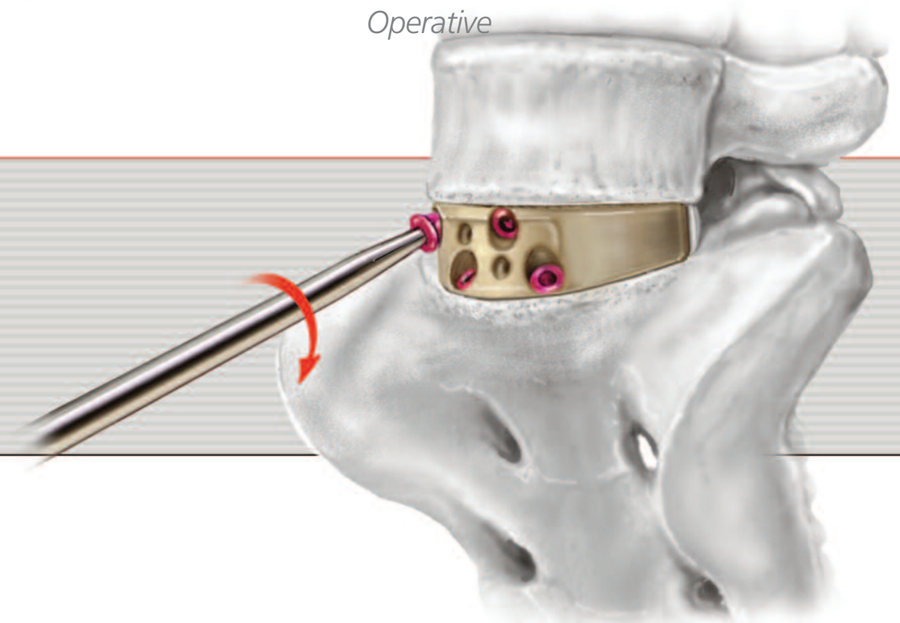
2. For difficult to reach areas, use the Drill Tip and Flex Shaft Driver with the Ratcheting Handle. Assemble the Ratcheting Handle to the Flex Shaft Driver. The Handle has the ability to ratchet clockwise, counter-clockwise, or remain stationary in a locked position. These options are indicated on the dial located on the handle. Turn the dial for the option of choice, indicated by laser markings.

Insert the Drill Guide into the PILLAR SA implant holes. Place the Drill into the Drill Guide. Drill each hole to prepare the four (4) screw holes.

Surgical Technique

Operative

7.



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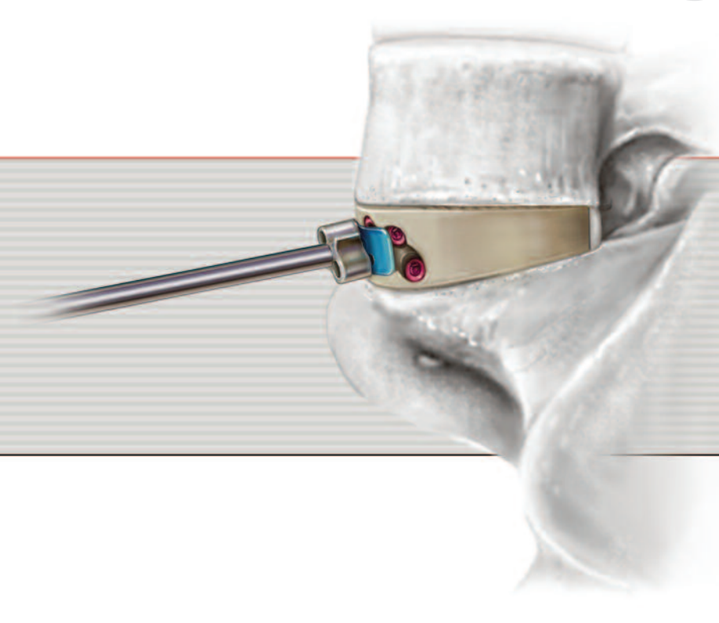

Step 7

Screw Placement

The 5mm self-tapping Bones Screws are available in three lengths (see table). Once the appropriate Bone Screw length is determined, place the four Bone Screws into the PEEK implant by one of the options below.

1. Hex Driver and Ratcheting Handle (straight driver):
Assemble the Ratcheting Handle to the Hex Driver. The Handle has the ability to ratchet clockwise, counter-clockwise, or remain stationary in a locked position. These options are indicated on the dial located on the handle. Turn the dial for the option of choice, indicated by laser markings.
2. U-Joint Driver with Retention and Ratcheting Handle (elbow joint with screw retention):
Assemble the Ratcheting Handle to the U-Joint Driver with Retention. The Handle has the ability to ratchet clockwise, counter-clockwise, or remain stationary in a locked position. These options are indicated on the dial located on the handle. Turn the dial for the option of choice, indicated by laser markings.

Primary Bone Screws
5.0mm X 20mm length*
5.0mm X 25mm length
5.0mm X 30mm length
5.0mm X 35mm length

Rescue Screws
5.5mm X 20mm length*
5.5mm X 25mm length
5.5mm X 30mm length
5.5mm X 35mm length

*20mm by special request

3. U-Joint Driver without Retention and Ratcheting Handle – elbow joint without screw retention
Assemble the Ratcheting Handle to the U-Joint Driver with Retention. The Handle has the ability to ratchet clockwise, counter-clockwise, or remain stationary in a locked position. These options are indicated on the dial located on the handle. Turn the dial for the option of choice, indicated by laser markings.

Screw in the Bone Screws, starting with the two middle Screw holes, turning the Screw clockwise.

Once completed, the position of the Bone Screw heads should be completely recessed within the PILLAR SA PEEK implant.

***Note:** Although typically 25mm or 30mm Bone Screws will be used, to eliminate the possibility of tips touching, do not use two 35mm Bone Screws in the same vertebral body.*

Step 8

Cover Plate Assembly

A Cover Plate Driver is provided to secure the Cover Plate. Engage the Torque Limiting Handle to the Cover Plate Driver by pressing down the mating feature, inserting the Driver, turning slightly, and releasing the mating feature.

The Cover Plates are available in three sizes (see table). Choose the appropriate size Cover Plate corresponding to the width of the implant used.

Cover Plate Sizes
37mm wide Cover Plate
40mm wide Cover Plate
43mm wide Cover Plate

Two options are available for assembling the Cover Plate.

Option 1: Cover Plate Inserter

When using the Cover Plate Inserter, load the selected Cover Plate onto the Cover Plate Inserter. Place the Cover Plate Driver through the top driver guide, advance it to the middle driver guide, and advance it to the bottom driver guide. The guides will line up the Cover Plate Driver with the Cover Plate screws. Turn the Torque Limiting Handle clockwise until it clicks to secure the Cover Plate.

Option 2: Cover Plate Holder

When using the Cover Plate Holder, load the Cover Plate onto the Cover Plate Holder and manually insert the Cover Plate Driver into the Cover Plate screw. Turn the Torque Limiting Handle clockwise until it clicks to secure the Cover Plate.

Surgical Technique

Operative

Removal and Revision

Implant removal and revisions

In the case of implant revision or removal, follow the appropriate steps:

1. Stripped Screw – If it is determined that the Bone Screw assembly is inadequate due to a stripped Bone Screw, the Bone Screw should be removed and exchanged for a self-tapping 5.5mm Rescue Screw.

2. Late Implant Removal or Revision – Caution should be exercised before deciding to reapproach the anterior lumbar spine as adhesions between and around the great vessels make the approach hazardous. Once the PILLAR SA implant is exposed, simply reverse the insertion technique with the same instruments. Do not attempt to remove the construct unless it is completely exposed to avoid inadvertent injury to the great vessels.

a. Remove the Cover Plate with the Cover Plate Holder or Cover Plate Inserter and the Cover Plate Driver.

b. Remove the Bone Screws with the Hex Driver, U-Joint Driver with Retention, or the U-Joint Driver without Retention, and the Ratcheting Handle.

Part Numbers

IMPLANTS & TRIALS

Implants	*Trials*	*Dimensions*	*Implants*	*Trials*	*Dimensions*
Top Tray			*Bottom Tray*		
49-2012	**49-2112**	37mm W x 28mm D x 12.5 mm H, 7°	**49-6012**	**49-6112**	37mm W x 32mm D x 12.5 mm H, 7°
49-2014	**49-2114**	37mm W x 28mm D x 14 mm H, 7°	**49-6014**	**49-6114**	37mm W x 32mm D x 14 mm H, 7°
49-2016	**49-2116**	37mm W x 28mm D x 16 mm H, 7°	**49-6016**	**49-6116**	37mm W x 32mm D x 16 mm H, 7°
49-2018	**49-2118**	37mm W x 28mm D x 18 mm H, 7°	**49-6018**	**49-6118**	37mm W x 32mm D x 18 mm H, 7°
49-2020	**49-2120**	37mm W x 28mm D x 20 mm H, 7°	**49-6020**	**49-6120**	37mm W x 32mm D x 20 mm H, 7°
49-2212	**49-2312**	37mm W x 28mm D x 12.5 mm H, 12°	**49-6212**	**49-6312**	37mm W x 32mm D x 12.5 mm H, 12°
49-2214	**49-2314**	37mm W x 28mm D x 14 mm H, 12°	**49-6214**	**49-6314**	37mm W x 32mm D x 14 mm H, 12°
49-2216	**49-2316**	37mm W x 28mm D x 16 mm H, 12°	**49-6216**	**49-6316**	37mm W x 32mm D x 16 mm H, 12°
49-2218	**49-2318**	37mm W x 28mm D x 18 mm H, 12°	**49-6218**	**49-6318**	37mm W x 32mm D x 18 mm H, 12°
49-2220	**49-2320**	37mm W x 28mm D x 20 mm H, 12°	**49-6220**	**49-6320**	37mm W x 32mm D x 20 mm H, 12°
49-3012	**49-3112**	40mm W x 28mm D x 12.5 mm H, 7°	**49-7012**	**49-7112**	40mm W x 32mm D x 12.5 mm H, 7°
49-3014	**49-3114**	40mm W x 28mm D x 14 mm H, 7°	**49-7014**	**49-7114**	40mm W x 32mm D x 14 mm H, 7°
49-3016	**49-3116**	40mm W x 28mm D x 16 mm H, 7°	**49-7016**	**49-7116**	40mm W x 32mm D x 16 mm H, 7°
49-3018	**49-3118**	40mm W x 28mm D x 18 mm H, 7°	**49-7018**	**49-7118**	40mm W x 32mm D x 18 mm H, 7°
49-3020	**49-3120**	40mm W x 28mm D x 20 mm H, 7°	**49-7020**	**49-7120**	40mm W x 32mm D x 20 mm H, 7°
49-3212	**49-3312**	40mm W x 28mm D x 12.5 mm H, 12°	**49-7212**	**49-7312**	40mm W x 32mm D x 12.5 mm H, 12°
49-3214	**49-3314**	40mm W x 28mm D x 14 mm H, 12°	**49-7214**	**49-7314**	40mm W x 32mm D x 14 mm H, 12°
49-3216	**49-3316**	40mm W x 28mm D x 16 mm H, 12°	**49-7216**	**49-7316**	40mm W x 32mm D x 16 mm H, 12°
49-3218	**49-3318**	40mm W x 28mm D x 18 mm H, 12°	**49-7218**	**49-7318**	40mm W x 32mm D x 18 mm H, 12°
49-3220	**49-3320**	40mm W x 28mm D x 20 mm H, 12°	**49-7220**	**49-7320**	40mm W x 32mm D x 20 mm H, 12°
49-4012	**49-4112**	43mm W x 28mm D x 12.5 mm H, 7°	**49-8012**	**49-8112**	43mm W x 32mm D x 12.5 mm H, 7°
49-4014	**49-4114**	43mm W x 28mm D x 14 mm H, 7°	**49-8014**	**49-8114**	43mm W x 32mm D x 14 mm H, 7°
49-4016	**49-4116**	43mm W x 28mm D x 16 mm H, 7°	**49-8016**	**49-8116**	43mm W x 32mm D x 16 mm H, 7°
49-4018	**49-4118**	43mm W x 28mm D x 18 mm H, 7°	**49-8018**	**49-8118**	43mm W x 32mm D x 18 mm H, 7°
49-4020	**49-4120**	43mm W x 28mm D x 20 mm H, 7°	**49-8020**	**49-8120**	43mm W x 32mm D x 20 mm H, 7°
49-4212	**49-4312**	43mm W x 28mm D x 12.5 mm H, 12°	**49-8212**	**49-8312**	43mm W x 32mm D x 12.5 mm H, 12°
49-4214	**49-4314**	43mm W x 28mm D x 14 mm H, 12°	**49-8214**	**49-8314**	43mm W x 32mm D x 14 mm H, 12°
49-4216	**49-4316**	43mm W x 28mm D x 16 mm H, 12°	**49-8216**	**49-8316**	43mm W x 32mm D x 16 mm H, 12°
49-4218	**49-4318**	43mm W x 28mm D x 18 mm H, 12°	**49-8218**	**49-8318**	43mm W x 32mm D x 18 mm H, 12°
49-4220	**49-4320**	43mm W x 28mm D x 20 mm H, 12°	**49-8220**	**49-8320**	43mm W x 32mm D x 20 mm H, 12°
			49-0010	PILLAR SA Implant - Trial Case Complete	

Bone Screws				*Cover Plates*	
49-5020	5.0 x 20mm Bone Screw	**49-5520**	5.5 x 20mm Bone Screw	**49-0037**	37mm W Cover Plate
49-5025	5.0 x 25mm Bone Screw	**49-5525**	5.5 x 25mm Bone Screw	**49-0040**	40mm W Cover Plate
49-5030	5.0 x 30mm Bone Screw	**49-5530**	5.5 x 30mm Bone Screw	**49-0043**	43mm W Cover Plate
49-5035	5.0 x 35mm Bone Screw	**49-5535**	5.5 x 35mm Bone Screw		

INSTRUMENTS

Top Tray		*Bottom Tray*			
43-0112	Hex Driver	**49-1003**	Drill Guide	**49-1007**	Flex Shaft Driver
49-1017	Cover plate Holder	**49-1010**	Awl Tip	**49-1013**	Ratcheting Handle
49-1000	Implant Insertion Instrument	**49-1009**	Drill Tip	**49-1016**	Torque Limiting Handle
49-1001	Straight Tamp	**49-1008**	Trial Insertion Instrument	**49-1012**	Cover Plate Driver
49-1002	Awl	**49-1004**	Straight Drill	**49-1011**	Cover Plate Inserter
		49-1005	U-Joint Driver with Retention	**49-0020**	PILLAR SA Instrument Case, Complete
		49-1006	U-Joint Driver with Retention		

Items in red available upon request only.

Package Insert

Device System Name:
PILLAR™ SA PEEK Spacer System

DESCRIPTION:
The PILLAR™ SA PEEK Spacer System is comprised of a variety of implants manufactured from PEEK-OPTIMA® LT (Polyetheretherketone), as described by ASTM F-2026, with tantalum markers as described by ASTM F-560. The implants are available in multiple footprint sizes, a variety of heights, and two angles of lordosis: 7° and 12°. The implants incorporate integrated anterior screw holes to allow for medial placement of screws, as well as a titanium plate for securing the screws once in place. The superior and inferior surfaces of the implant have a pattern of ripples that provide increased stability and help prevent movement of the device.

The PILLAR™ SA PEEK Spacer System is provided non-sterile.

INDICATIONS:
When used as an Intervertebral Body Fusion System:

The PILLAR™ SA PEEK Spacer System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels in the lumbar spine (L2-S1). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis at the involved levels. These patients may have had a previous non-fusion surgery at the involved level(s). The PILLAR™ SA PEEK Spacer System is intended for use with autograft.

The PILLAR™ SA PEEK Spacer System is intended for use with the four titanium alloy screws provided with the device. If the physician chooses to use fewer than four of the provided screws, then supplemental internal fixation must be used to augment stability. As an example, the supplemental internal fixation system that may be used is the Blackstone Medical, Inc. Spinal Fixation System (SFS).

Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the PILLAR™ Spacer System.

When used as a Partial Vertebral Body Replacement (VBR) System:

The PILLAR™ SA PEEK Spacer System is indicated for use in the thoracolumbar spine (T1-L5) for partial replacement (i.e. partial vertebrectomy) of a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The PILLAR™ SA PEEK Spacer System is also indicated for treating fractures of the thoracic and lumbar spine.

The PILLAR™ SA PEEK Spacer System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column, even in the absence of fusion for a prolonged period of time. The PILLAR™ SA PEEK Spacer System is intended to be used with autograft or allograft.

The PILLAR™ SA PEEK Spacer System is intended for use with the four titanium alloy screws provided with the device. If the physician chooses to use fewer than four of the provided screws, then supplemental internal fixation must be used to augment stability. As an example, the supplemental internal fixation system that may be used is the Blackstone Medical, Inc. Spinal Fixation System (SFS).

CONTRAINDICATIONS:
The PILLAR™ SA PEEK Spacer System, as with other orthopedic implants, is contraindicated for use in patients:

1.) With active infections in which the use of an implant could preclude adequate and appropriate treatment of the infection, or
2.) Who have had prior fusion at the level to be treated.

Potential Adverse Effects: Potential adverse effects include, but are not limited to:

1.) Failure of the device to provide adequate mechanical stability
2.) Loss of fixation of the implant
3.) Device component failure
4.) Migration or bending of the device
5.) Loss of bony alignment
6.) Non-union
7.) Fracture of bony structures
8.) Resorption without incorporation of any bone graft utilized
9.) Immunogenic response to the implant materials

Note: As with any major surgical procedure, there are risks involved in orthopedic surgery. Infrequent operative and postoperative complications known to occur are: early or late infection, which may result in the need for additional surgeries, damage to blood vessels, spinal cord or peripheral nerves, pulmonary emboli, loss of sensory and/or motor function, impotence, permanent pain and/or deformity. Rarely, some complications may be fatal.

WARNINGS AND PRECAUTIONS:
The surgeon should be aware of the following when using implants:

1.) The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape and design of the implant. The size and shape of the human bones present limiting restrictions of the size and strength of implants. No implant can be expected to withstand the unsupported stresses of full weight bearing.
2.) The correct handling of the implant is extremely important. Implants should not be bent, notched or scratched. These operations can produce defects in surface finish and internal stress concentrations, which may become the focal point for eventual failure of the device.
3.) Single use only. No surgical implants should be reused. Any implant once used should be discarded. Even though the device appears undamaged, it may already have small defects and internal stress patterns that may lead to fatigue failure.
4.) Non-sterile; the PILLAR™ SA PEEK Spacer System implants and instruments are provided non-sterile, and therefore, must be sterilized before each use.
5.) Postoperative care is important. The patient should be instructed in the limitations of the implant and should be cautioned regarding weight bearing and body stress on the device prior to secure bone healing.
6.) Patients with previous surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery.

CLEANING:
All instruments and implants must first be cleaned using established hospital methods before sterilization and introduction into a sterile field. Additionally, all instruments and implants that have been previously taken into a sterile surgical field must first be cleaned using established hospital methods before sterilization and reintroduction into a sterile surgical field. Cleaning can include the use of neutral cleaners followed by a deionized water rinse. All products should be treated with care. Improper use or handling may lead to damage and possible improper functioning of the device.

STERILIZATION:
The PILLAR™ SA PEEK Spacer System components are supplied NON-STERILE. Prior to use, all components should be steam sterilized by the hospital using the recommended cycle:

Method: Steam	Or:	Method: Steam
Cycle: Gravity		Cycle: Prevac
Temperature: 250° F (121° C)		Temperature: 270° F (132° C)
Exposure time: 30 minutes		Exposure time: 8 minutes

PRODUCT COMPLAINTS:
Any Healthcare Professional (e.g., customer or user of this system), who has any complaints, or who has experienced any dissatisfaction with the product quality, identity, durability, reliability, safety, effectiveness, and/or performance, should notify Blackstone Medical, Inc., 1211 Hamburg Turnpike, Suite 300, Wayne, NJ 07470, USA, Telephone: 877-BMI-9494 (877-264-9494), complaints@blackstonemedical.com

FURTHER INFORMATION:
A recommended surgical technique for the use of this system is available upon request from Blackstone Medical, Inc., 90 Brookdale Drive, Springfield, MA 01104, USA, Telephone: 413-731-8711

AUTHORIZED EUROPEAN REPRESENTATIVE:
Medical Device Safety Service (MDSS)
Schiffgraben 41
30175, Hannover
Germany
Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

CE 0086

90-4899B

U.S.A.

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