

# PILLAR® SA

PEEK AND PTC SPACER SYSTEM

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The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Please see Instructions for Use for the complete list of indications, warnings, precautions, potential adverse events, cleaning and sterilization information.

## INTRODUCTION

Anterior lumbar interbody fusion (ALIF) procedures are commonly performed to treat lumbar spine pathology such as disc herniations and spinal stenosis, which may result from degenerative disc disease. Anterior lumbar interbody spacers should:

- Maintain graft position

The PILLAR SA PEEK and PTC Spacer System provides fixation within the intervertebral disc space with Bone Screws and a locking Cover Plate to prevent screw back-out. The Bone Screws are self-tapping; however, several options for screw placement are available. The trajectory of Bone Screw placement within the PILLAR SA PEEK and PTC cage enhances bone purchase. The locking Cover Plate is very low profile and sits flush with the implant. This is very important as such an innovation eliminates any instrumentation bulk adjacent to vital vascular structures.

## PILLAR SA PEEK

- Medially oriented screw holes for easier insertion
- Radiographic tantalum markers assist with accurate implant placement confirmation
- Ovoid shape designed to mimic vertebral anatomic shape for optimal coverage on apophyseal ring



## PILLAR SA PTC

- 3D printed porous titanium endplates are designed to allow the patient bone to grow into the porous plate
- PEEK core to obtain imaging properties while assessing fusion
- Large opening for packing bone grafting material
- Medially oriented screw holes for easier insertion and sound Bone Screw fixation
- Provided sterile
- Ovoid shape designed to mimic vertebral anatomic shape for optimal coverage of apophyseal ring



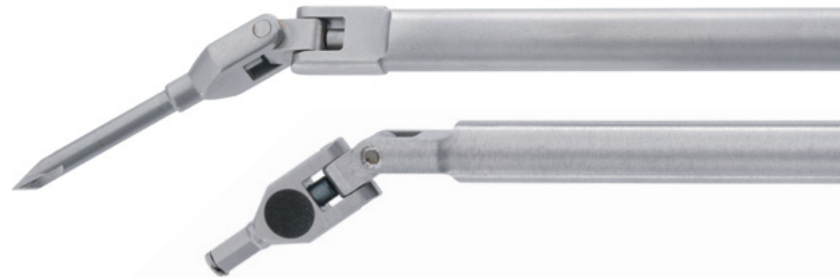
## LOCKING MECHANISM FOR SCREWS

- 1mm Cover Plate sits flush with the cage for a nearly zero profile
- Choices of instruments for easy assembly

## FLEXIBLE INSTRUMENTS

- Multiple choices for difficult surgical apertures
- Multiple instruments provide versatility and physician selectivity

One set of instrumentation can be used with both PILLAR SA PEEK and PTC implants.





**Fig. 1a**

## **1. PREOPERATIVE PLANNING AND PATIENT POSITIONING**

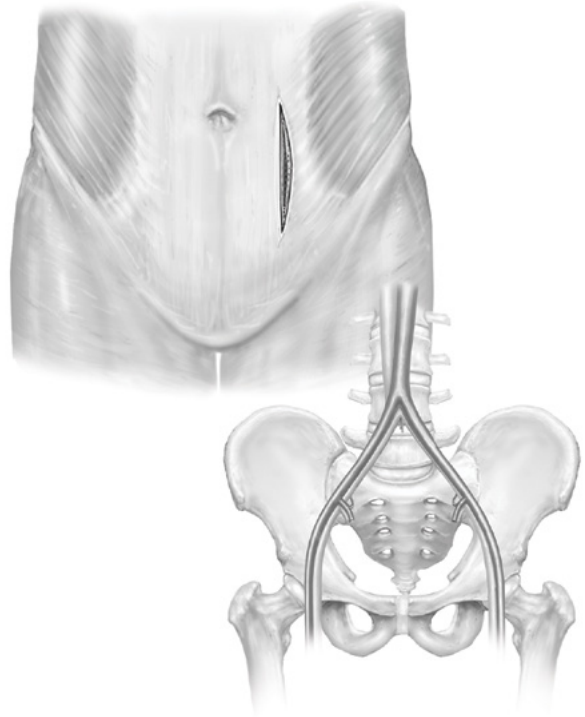
Preoperative planning is critical in the preparation for spinal surgery. A complete radiographic evaluation (A/P and lateral films) measuring the vertebral body dimension is recommended for proper diagnosis prior to surgery.

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**).



Fig. 2a



## 2. PARTIAL VERTEBRAL BODY REPLACEMENT

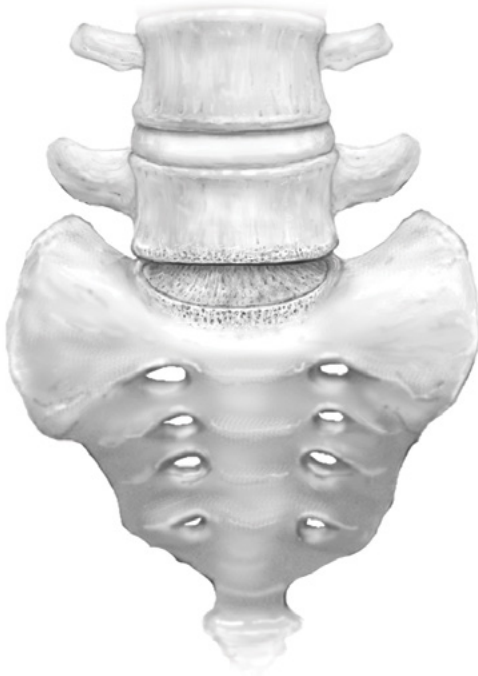
The traumatized or diseased vertebral body is exposed through the appropriate anterior approach. The affected partial vertebral body and disc material is excised and the both superior and inferior surfaces are prepared. (Fig. 2a)

**Note:** For illustration purpose, Intervertebral body technique is presented in this manual. The same steps apply for the partial vertebral body replacement procedure.

## 3. EXPOSURE

The PILLAR SA PEEK and PTC Spacer System instrumentation is designed for use with a direct anterior retro-peritoneal approach.

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.

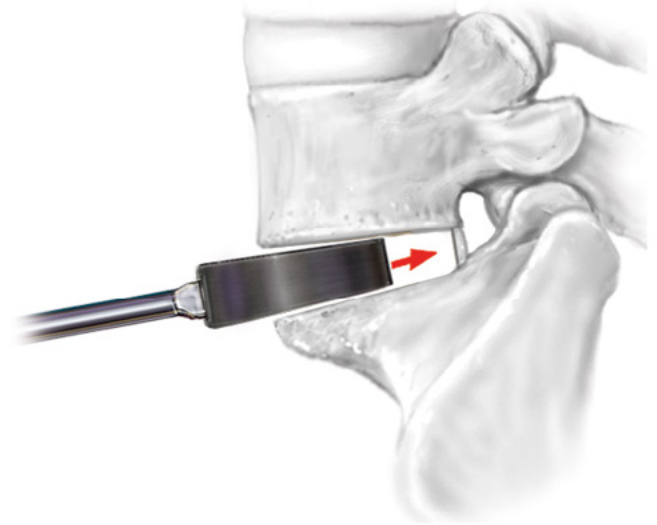


#### 4. DISCECTOMY AND DISC SPACE PREPARATION

Perform a complete anterior lumbar discectomy and remove all residual interbody material.

In order to square off the end plates to make the PILLAR SA PEEK and PTC Spacer insertion more efficient, the surgeon may want to remove any osteophytes using an osteotome of their choice.

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



#### 5. IMPLANT SIZING

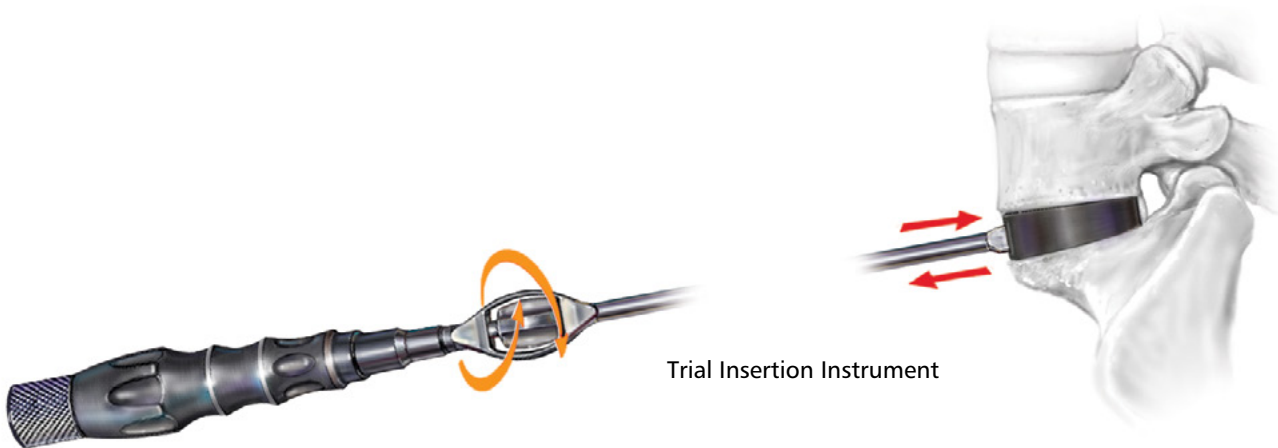
Implant trials are available for intra-operative sizing. Multiple trial sizing options are provided in the PILLAR SA PEEK and PTC Spacer System.

##### Width and Distractor Sizers

**Width Sizers** are provided to predetermine the desired implant width and depth for the disc space. For use after discectomy, slide a Width Sizer's flat face into the disc space until it stops. The correct Width Sizer will be 1-2mm smaller than the vertebrae on each side.

While the **Width Sizer** is inside the disc space, predetermine the desired implant depth by associating the depth indicators to the most anterior portion of the vertebrae. If not visible, use radiography oriented in the most cephalad or caudal direction to see the indicators.

**Distractors/Sizers** are provided to predetermine the desired implant height and confirm the implant depth for the disc space. In collapsed vertebrae, these tools can be used as Distractors by first sliding its flat portion into the disc space until it stops and then slowly rotating the tool



## 5. IMPLANT SIZING (CONT.)

90°. Confirm the desired implant height by trying several sizes and verifying the fit using radiography oriented in the lateral direction. Depth markers will also be visible on this direction to confirm the desired implant depth.

### **Trial Sizing**

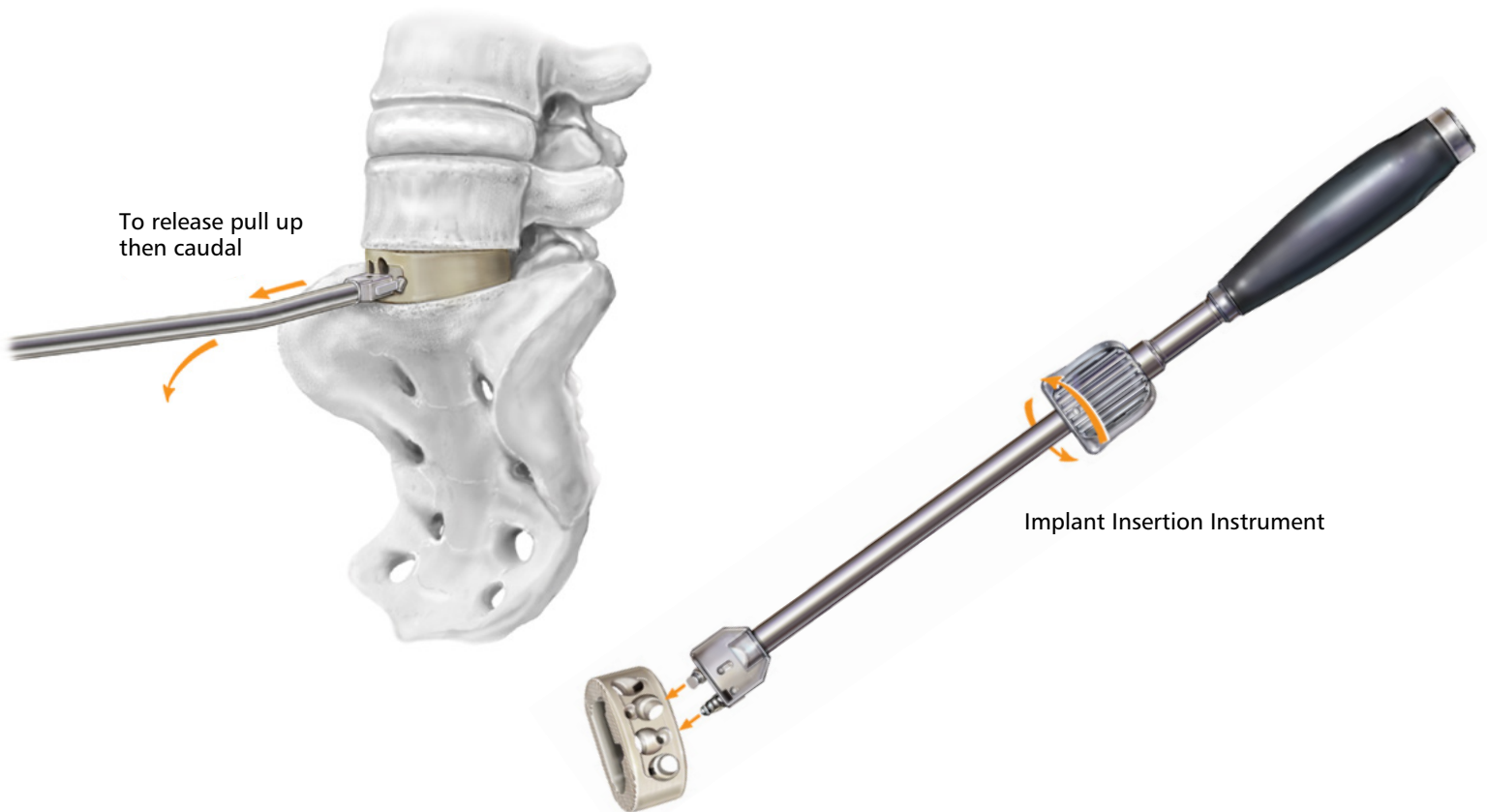
The PILLAR SA **Trials** correspond to the PILLAR SA and PTC implant sizes available.

Select the appropriate Trial by size and lordotic angle, 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 size Trials into the prepared disc space until an appropriately tight fit is achieved and placement is confirmed with a radiograph. Disengage the Trial from the prepared disc space by gently tapping it out using the integrated slap hammer. When moving the instrument cephalad to caudal, there should be no toggling of the Trial within the space with the appropriate size.

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

Select the size for the PILLAR SA PEEK and PTC implant according to the appropriate Trial size.



## 6. IMPLANT INSERTION

Prior to attaching the implant to the instrument, add graft material in the wide central opening. PILLAR SA PEEK and PILLAR SA PTC are indicated for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft material. See graft volume table on pages 12-14.

To attach the PILLAR SA PEEK or PTC implant to the **Implant Insertion Instrument**, align the indicator marked tip to the hole with the indicator mark of the implant. Insert the other tip of the instrument into the third hole of the implant.

Close the jaws on the Implant Insertion Instrument tips by turning the knob clockwise to secure the implant onto the instrument.

Implant the PILLAR SA PEEK or PTC into the prepared interbody space with the Implant Insertion Instrument and tap it into place with a mallet. The PILLAR SA PEEK or PTC should not be counter sunk, but placed flush to the anterior endplates (apophyseal ring).

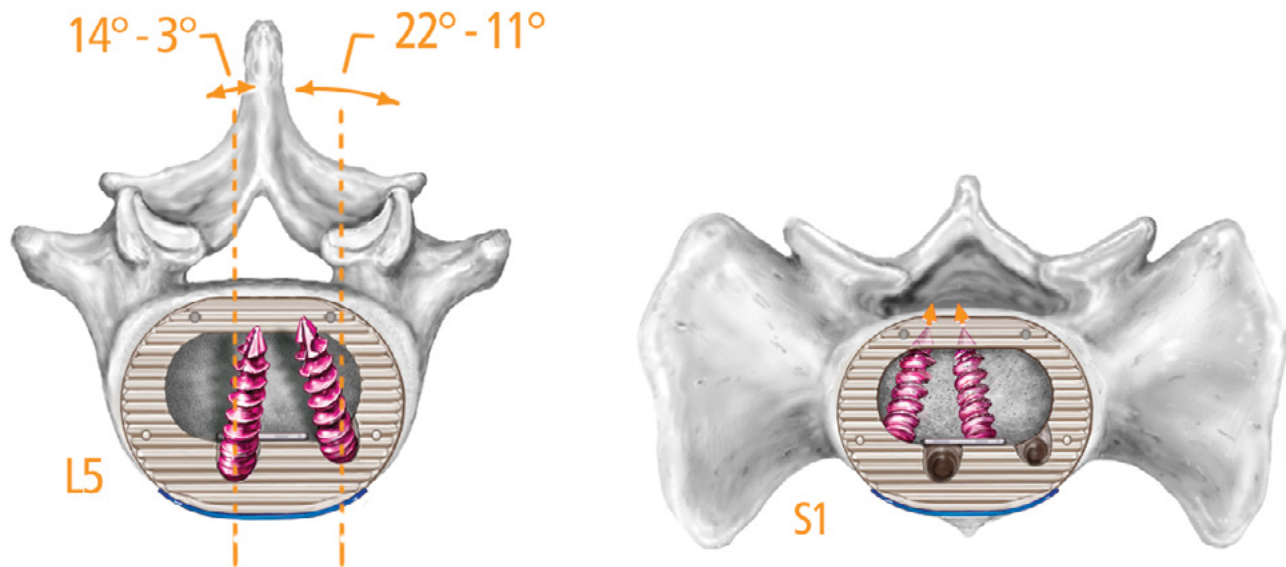
To disengage the Implant Insertion Instrument from the implant, turn the knob counter-clockwise and pull the instrument up and caudal to work with the bend of the instrument. If the PILLAR SA PEEK or PTC implant needs to be positioned further into the prepared space, gently tap the implant with the Straight Tamp provided in the instrument tray.

For PILLAR SA PEEK implant, confirm implant placement radiographically. The posterior tantalum X-ray markers are 2mm away from the center of the pin to the posterior side of the implant. The anterior tantalum X-ray markers are 10mm away from the center of the pin to the anterior side of the implant.

**Note:** PILLAR SA PTC implant does not include tantalum markers, the titanium plates are used to reference implant position.

**Note:** You may need to wiggle the Implant Insertion Instrument once you have loosened the knob in order to disengage the implant from the instrument. If the implant moves while wiggling the instrument, you may not have used a large enough implant for the inner space (i.e. you may have undersized the graft). Consider a larger implant.





Note: Semi-Constrained Bone Screws – 11° variability from midline  
 Constrained Bone Screws and Rescue Bone Screws – 7° variability from midline

## 7. BONE SCREW 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.

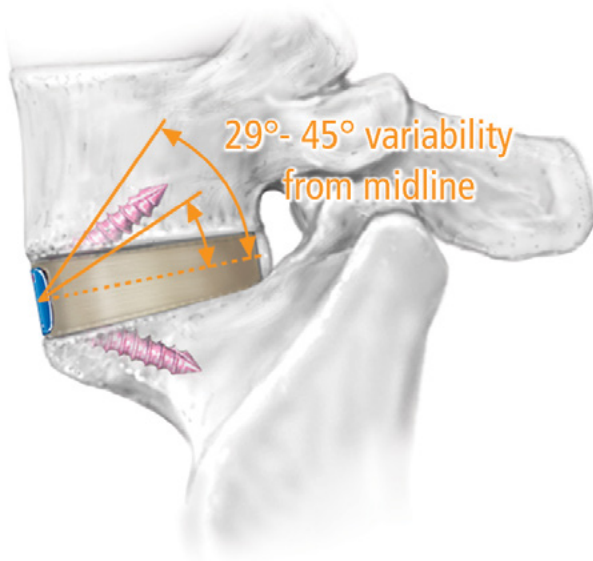
### When using the **Sleeved Awl**:

Fully seat the **Awl** within the Bone Screw hole and punch through the cortical bone.

When using the **Jointed (polyaxial) Awl** and **Drill Guide** for screw trajectory options:

1. Fully seat the Drill Guide within the Bone Screw hole.
2. Fully seat the Jointed Awl within the Drill Guide and punch through the cortical bone.

Depth marks are indicated on the tip of the Awls at **5mm** and **10mm**. The depth of the Sleeved Awl is **10mm**. The depth of the Jointed Awl with the **Drill Guide** is **10mm**. Without the Drill Guide, the depth of the Jointed Awl is **15mm**. Using the Drill Guide, however, will prevent the Awl from possible skidding or slipping.



Note: Semi-Constrained Bone Screws – 16° range of motion  
Constrained Bone Screws and Rescue Bone Screws – 2° range of motion

## 7. BONE SCREW HOLE PREPARATION FOR SCREW PLACEMENT (CONT.)

When using the **Drill**, there are multiple options: a **Straight Shaft** and a **Flex Shaft**. Both work with the **Ratcheting Handle**. When drilling, always use the **Drill Guide** to establish accurate orientation and depth of each pilot hole.

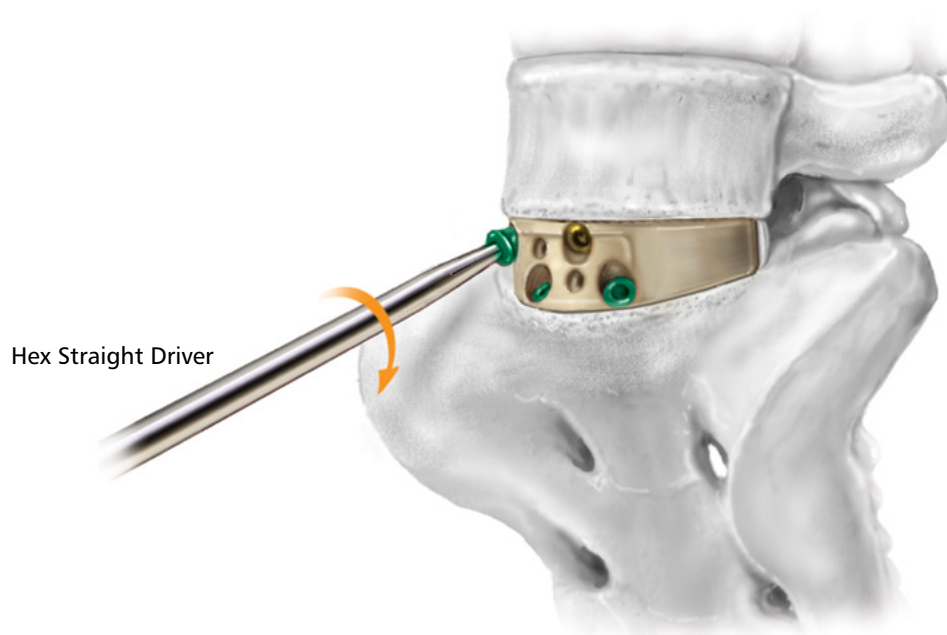
1. Attach the Straight Shaft to the **Drill Tip**, and attach the Ratcheting Handle to the Straight Shaft.
2. For difficult to reach areas, use the Drill Tip and Flex Shaft with the Ratcheting Handle. Assemble the Ratcheting Handle to the Flex Shaft by pushing down the mating instrument into the handle until a click is heard. To release, press the top face of the handle and pull the mating instrument out. 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 PEEK or PTC implant holes. Place the Drill into the Drill Guide. Depth marks are indicated on the Drill Tip at **5mm** and **10mm**. The Drill depth with the Drill Guide is **15mm**. Although not recommended, the depth of the Drill Tip without the Drill Guide is 28mm.

Repeat for preparing the four (4) Bone Screw holes.

**Note:** It is not recommended to drill without the **Drill Guide** but if it is necessary, use extra precaution to avoid creating a pilot hole that is too deep and any potential challenges with removing the instruments from the implant. The depth of the Drill Tip without the Drill Guide is **28mm**.

**Semi Constrained Bone Screws**

5.0mm X 20mm length - Magenta
5.0mm X 25mm length - Green
5.0mm X 30mm length - Gold
5.0mm X 35mm length - Blue

**Constrained Screws** 1/2 black head

5.0mm X 20mm length - Magenta
5.0mm X 25mm length - Green
5.0mm X 30mm length - Gold
5.0mm X 35mm length - Blue

**Rescue Screws** silver head

5.5mm X 20mm length - Magenta
5.5mm X 25mm length - Green
5.5mm X 30mm length - Gold
5.5mm X 35mm length - Blue

## 8. SCREW PLACEMENT

The self-tapping **Semi-Constrained** and **Constrained Bones Screws** are available in four lengths (see table above). Once the appropriate **Bone Screw** length is determined, place the four Bone Screws into the PEEK or PTC implant. Options are listed below.

**1. Hex Straight Driver and Ratcheting Handle:**

Assemble the Ratcheting Handle to the Hex Straight Driver by pushing down the mating instrument into the handle until a loud click is heard. To release press the top face of the handle and pull the mating instrument out. 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 as described above with the Hex Straight 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.

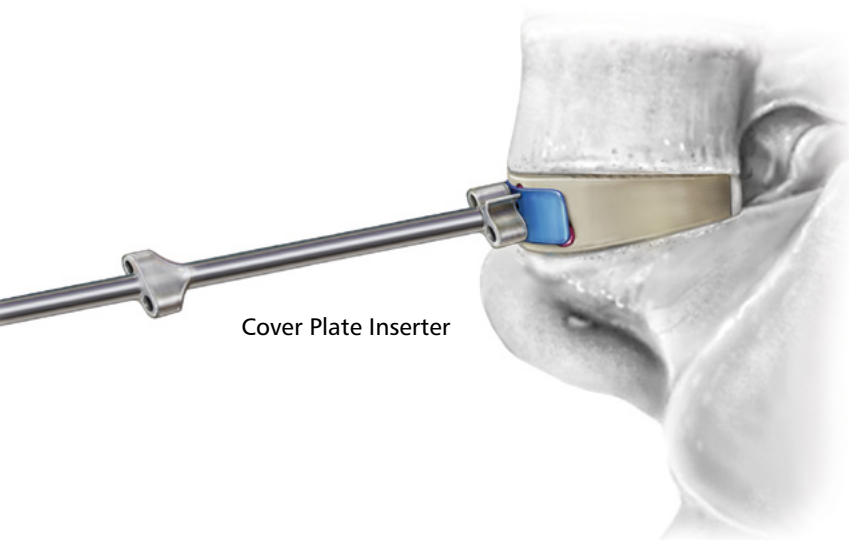
**Note:** A U-Joint Driver without Retention is also provided if screw retention is not desired. To implant the screws, start with the two middle holes to implant in the Bone Screws, turning the Screw clockwise until finger tight.

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

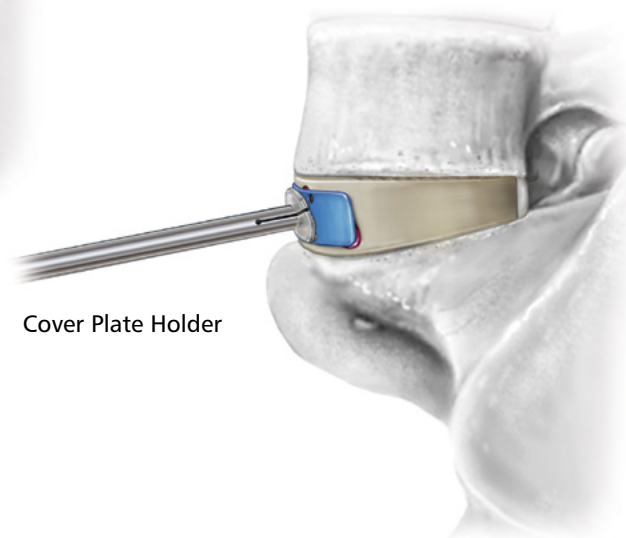
**IMPORTANT:** Four (4) Screws should be used for every stand alone PILLAR SA PEEK and PTC construct or supplemental fixation is required. Verify placement with radiography.

**Note:** Typically 25mm or 30mm Bone Screws will be used. To eliminate the possibility of screw convergence or posterior cortical body breach (ventral to thecal sac), do not use two 35mm Bone Screws in the same vertebral body.

**Note:** You may want to use a double action rongeur to remove anterior osteophytes that might prevent proper screw placement within the PILLAR SA PEEK or PTC implant.



Cover Plate Inserter



Cover Plate Holder

#### Cover Plate Sizes

33mm wide Cover Plate - Magenta
37mm wide Cover Plate - Blue
40mm wide Cover Plate - Green
43mm wide Cover Plate - Gold

## 9. COVER PLATE ASSEMBLY

In order to secure the Bone Screws in place, a **Cover Plate** is provided to prevent bone screw back-out. The Cover Plates are available in four (4) sizes (see table above). The sizes correspond with the widths of the PILLAR SA PEEK and PTC implants.

**Note:** The titanium screws in the locking cover plate engage directly into titanium receptacles in the PILLAR SA PEEK and PTC implant for stronger fixation.

There are two (2) options for securing the Cover Plate over the Bone Screws into the PILLAR SA PEEK and PTC implant.

#### Option 1: Cover Plate Inserter

The guides on the **Cover Plate Inserter** will line up the Cover Plate Driver with the Cover Plate Screws that secure the Cover Plate.

First make sure that the Cover Plate caddy is on a stable, flat surface. Place the end of the Cover Plate Inserter over the Cover Plate and line up the openings over the Cover Plate screw heads. Then gently turn the top knob clock-wise until the Cover Plate is engaged.

**Please note: Do not over-tighten the knob.**

Engage the **Torque Limiting Handle** onto a Cover Plate Driver provided in the set by pressing down the mating feature, inserting the Driver, turning slightly, and releasing the mating feature. Please note that the Cover Plate Driver and the mating feature of the Torque Limiting Handle must line up for proper connection. Both mating features are a specific "D" shape to ensure that no other handle can be used on the Cover Plate Drivers. Using a different handle may strip the small screws of the Cover Plate.

Place the Cover Plate Inserter, loaded with the Cover Plate, over the bone screws on the PILLAR SA PEEK or PTC implant. Holding the Cover Plate Inserter at the top, insert the Cover Plate Driver with the Torque Limiting Handle through the top driver guide, then advance it through the middle guides, and the bottom driver guide. The guides will line up the Cover Plate Driver with the Cover Plate Screws. Turn the Torque Limiting Handle clock-wise until it clicks to secure the Cover Plate. The torque on the Torque Limiting Handle is **2in/lb.**

After locking both screws of the Cover Plate securely, remove the Cover Plate Inserter by turning the top knob counter clock-wise and lifting it off of the Cover Plate.

## 9. COVER PLATE ASSEMBLY (CONT.)

### Option 2: Cover Plate Holder

The **Cover Plate Holder** was designed to allow the surgeon to tilt and rock the instrument when locking the Cover Plate to the **PILLAR SA PEEK and PTC** cage. It provides maximum visibility as well as flexibility. It does not have guides for the Cover Plate Driver.

Before loading the Cover Plate onto the Cover Plate Holder, make sure that the Cover Plate caddy is on a stable, flat surface. Mate the two holes of the Cover Plate to the pins of the Cover Plate Holder and press down.

Engage the Torque Limiting Handle onto a Cover Plate Driver provided in the set by pressing down the mating feature, inserting the Driver, turning slightly, and releasing the mating feature. Please note that the Cover Plate Driver and the mating feature of the Torque Limiting Handle must line up for proper connection. Both mating features are a specific "D" shape to ensure that no other handle can be used on the Cover Plate Drivers. Using a different handle may strip the small screws of the Cover Plate.

Once loaded to the Cover Plate Holder, the Cover Plate will be held securely. Place the Cover Plate attached to the Holder, over the Bone Screws of the PILLAR SA PEEK or PTC cage. Directly engage the Cover Plate Holder with the Torque Limiting Handle to the screws of the Cover Plate. Turn the Torque Limiting Handle clock-wise until it clicks to secure the Cover Plate. The torque on the Torque Limiting Handle is **2in/lb**.

After locking both screws of the Cover Plate securely, remove the Cover Plate Holder from the Cover Plate by tilting the instrument perpendicular to the axis connecting the two screws.

## 10. IMPLANT REMOVAL AND REVISION

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 PEEK or PTC 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 attached to the Torque Limiting Handle.
- b. Remove the Bone Screws with the Hex Driver, U-Joint Driver with Retention, or the U-Joint Driver without Retention with the Ratcheting Handle.

**Note:** On initial implantation of the PILLAR SA PEEK or PTC implant, the surgeon may want to consider placing a protective patch over the surgical interbody site under the great vessels in the event that the site needs to be re-explored. This protective patch may prevent vascular adhesions to the PILLAR SA PEEK or PTC implant or surgical inner space.

**Note:** Also on removal if necessary, you may want to consider a ureteral stenting placed by Urology in order to better identify the ureters and prevent injury in the setting of scar tissue and dissection.

**PILLAR SA PEEK Implants**

Implants	Dimensions	Graft Vol (cc)	Anterior (mm)	Posterior (mm)
<b>Top Tray</b>				
49-9012	33mm W x 28mm D x 12.5mm H, 7°	2.7	12.5	9.4
49-9014	33mm W x 28mm D x 14mm H, 7°	3.1	14.0	11.0
49-9016	33mm W x 28mm D x 16mm H, 7°	3.6	16.0	13.0
49-9018	33mm W x 28mm D x 18mm H, 7°	4.1	18.0	14.9
49-9020	33mm W x 28mm D x 20mm H, 7°	4.6	20.0	16.9
49-9212	33mm W x 28mm D x 12.5mm H, 12°	2.3	12.5	7.2
49-9214	33mm W x 28mm D x 14mm H, 12°	2.7	14.0	8.7
49-9216	33mm W x 28mm D x 16mm H, 12°	3.2	16.0	12.9
49-9218	33mm W x 28mm D x 18mm H, 12°	3.7	18.0	12.7
49-9220	33mm W x 28mm D x 20mm H, 12°	4.2	20.0	16.9
49-2012	37mm W x 28mm D x 12.5mm H, 7°	3.3	12.5	9.4
49-2014	37mm W x 28mm D x 14mm H, 7°	3.7	14.0	10.9
49-2016	37mm W x 28mm D x 16mm H, 7°	4.4	16.0	12.9
49-2018	37mm W x 28mm D x 18mm H, 7°	5.0	18.0	14.9
49-2020	37mm W x 28mm D x 20mm H, 7°	5.6	20.0	16.9
49-2212	37mm W x 28mm D x 12.5mm H, 12°	2.8	12.5	7.2
49-2214	37mm W x 28mm D x 14mm H, 12°	2.3	14.0	8.7
49-2216	37mm W x 28mm D x 16mm H, 12°	4.0	16.0	10.7
49-2218	37mm W x 28mm D x 18mm H, 12°	4.6	18.0	12.7
49-2220	37mm W x 28mm D x 20mm H, 12°	5.2	20.0	14.7
49-3012	40mm W x 28mm D x 12.5mm H, 7°	3.7	12.5	9.4
49-3014	40mm W x 28mm D x 14mm H, 7°	4.2	14.0	10.9
49-3016	40mm W x 28mm D x 16mm H, 7°	5.0	16.0	12.9
49-3018	40mm W x 28mm D x 18mm H, 7°	5.7	18.0	14.9
49-3020	40mm W x 28mm D x 20mm H, 7°	6.4	20.0	16.9
49-3212	40mm W x 28mm D x 12.5mm H, 12°	3.2	12.5	7.2
49-3214	40mm W x 28mm D x 14mm H, 12°	3.7	14.0	8.7
49-3216	40mm W x 28mm D x 16mm H, 12°	4.4	16.0	10.7
49-3218	40mm W x 28mm D x 18mm H, 12°	5.1	18.0	12.7
49-3220	40mm W x 28mm D x 20mm H, 12°	5.9	20.0	14.7
49-4012	43mm W x 28mm D x 12.5mm H, 7°	4.1	12.5	9.4
49-4014	43mm W x 28mm D x 14mm H, 7°	4.7	14.0	10.9
49-4016	43mm W x 28mm D x 16mm H, 7°	5.5	16.0	12.9
49-4018	43mm W x 28mm D x 18mm H, 7°	6.3	18.0	14.9
49-4020	43mm W x 28mm D x 20mm H, 7°	7.1	20.0	16.9
49-4212	43mm W x 28mm D x 12.5mm H, 12°	3.6	12.5	7.2
49-4214	43mm W x 28mm D x 14mm H, 12°	4.2	14.0	8.7
49-4216	43mm W x 28mm D x 16mm H, 12°	5.0	16.0	10.7
49-4218	43mm W x 28mm D x 18mm H, 12°	5.7	18.0	12.7
49-4220	43mm W x 28mm D x 20mm H, 12°	6.5	20.0	14.7

\*Items in blue must be ordered separately

## PILLAR SA PEEK Implants

Implants	Dimensions	Graft Vol (cc)	Anterior (mm)	Posterior (mm)
<b>Bottom Tray</b>				
49-9412	33mm W x 32mm D x 12.5mm H, 7°	3.2	12.5	8.6
49-9414	33mm W x 32mm D x 14mm H, 7°	3.7	14.0	10.1
49-9416	33mm W x 32mm D x 16mm H, 7°	4.3	16.0	12.5
49-9418	33mm W x 32mm D x 18mm H, 7°	5.0	18.0	14.5
49-9420	33mm W x 32mm D x 20mm H, 7°	5.6	20.0	16.5
49-9612	33mm W x 32mm D x 12.5mm H, 12°	2.7	12.5	6.3
49-9614	33mm W x 32mm D x 14mm H, 12°	3.2	14.0	7.9
49-9616	33mm W x 32mm D x 16mm H, 12°	3.9	16.0	9.9
49-9618	33mm W x 32mm D x 18mm H, 12°	4.5	18.0	11.9
49-9620	33mm W x 32mm D x 20mm H, 12°	5.1	20.0	13.9
49-6012	37mm W x 32mm D x 12.5mm H, 7°	4.0	12.5	9.0
49-6014	37mm W x 32mm D x 14mm H, 7°	4.6	14.0	10.5
49-6016	37mm W x 32mm D x 16mm H, 7°	5.4	16.0	12.5
49-6018	37mm W x 32mm D x 18mm H, 7°	6.2	18.0	14.5
49-6020	37mm W x 32mm D x 20mm H, 7°	7.0	20.0	16.5
49-6212	37mm W x 32mm D x 12.5mm H, 12°	3.4	12.5	6.4
49-6214	37mm W x 32mm D x 14mm H, 12°	4.0	14.0	7.9
49-6216	37mm W x 32mm D x 16mm H, 12°	4.8	16.0	9.9
49-6218	37mm W x 32mm D x 18mm H, 12°	5.6	18.0	11.9
49-6220	37mm W x 32mm D x 20mm H, 12°	6.4	20.0	13.9
49-7012	40mm W x 32mm D x 12.5mm H, 7°	4.6	12.5	9.0
49-7014	40mm W x 32mm D x 14mm H, 7°	5.2	14.0	10.5
49-7016	40mm W x 32mm D x 16mm H, 7°	6.1	16.0	12.5
49-7018	40mm W x 32mm D x 18mm H, 7°	7.0	18.0	14.5
49-7020	40mm W x 32mm D x 20mm H, 7°	8.0	20.0	16.5
49-7212	40mm W x 32mm D x 12.5mm H, 12°	3.9	12.5	6.4
49-7214	40mm W x 32mm D x 14mm H, 12°	4.5	14.0	7.9
49-7216	40mm W x 32mm D x 16mm H, 12°	5.4	16.0	9.9
49-7218	40mm W x 32mm D x 18mm H, 12°	6.3	18.0	11.9
49-7220	40mm W x 32mm D x 20mm H, 12°	7.2	20.0	13.9
49-8012	43mm W x 32mm D x 12.5mm H, 7°	5.1	12.5	9.0
49-8014	43mm W x 32mm D x 14mm H, 7°	5.9	14.0	10.5
49-8016	43mm W x 32mm D x 16mm H, 7°	6.9	16.0	12.5
49-8018	43mm W x 32mm D x 18mm H, 7°	7.9	18.0	14.5
49-8020	43mm W x 32mm D x 20mm H, 7°	8.9	20.0	16.5
49-8212	43mm W x 32mm D x 12.5mm H, 12°	4.3	12.5	6.4
49-8214	43mm W x 32mm D x 14mm H, 12°	5.0	14.0	7.9
49-8216	43mm W x 32mm D x 16mm H, 12°	6.0	16.0	9.9
49-8218	43mm W x 32mm D x 18mm H, 12°	7.0	18.0	11.9
49-8220	43mm W x 32mm D x 20mm H, 12°	8.0	20.0	13.9

\*Items in blue must be ordered separately

**PILLAR SA PTC Implants**

Implants	Dimensions	Graft Vol (cc)	Anterior (mm)	Posterior (mm)
39-9012SP	33mm W x 28mm L x 12.5mm H, 7° PTC	2.7	12.5	9.1
39-9014SP	33mm W x 28mm L x 14mm H, 7° PTC	3.0	14.0	10.6
39-9016SP	33mm W x 28mm L x 16mm H, 7° PTC	3.5	16.0	12.6
39-9018SP	33mm W x 28mm L x 18mm H, 7° PTC	4.1	18.0	14.6
39-9212SP	33mm W x 28mm L x 12.5mm H, 12° PTC	2.3	12.5	6.6
39-9214SP	33mm W x 28mm L x 14mm H, 12° PTC	2.7	14.0	8.1
39-9216SP	33mm W x 28mm L x 16mm H, 12° PTC	3.2	16.0	10.1
39-9218SP	33mm W x 28mm L x 18mm H, 12° PTC	3.7	18.0	12.1
39-2012SP	37mm W x 28mm L x 12.5mm H, 7° PTC	3.2	12.5	9.1
39-2014SP	37mm W x 28mm L x 14mm H, 7° PTC	3.7	14.0	10.6
39-2016SP	37mm W x 28mm L x 16mm H, 7° PTC	4.3	16.0	12.6
39-2018SP	37mm W x 28mm L x 18mm H, 7° PTC	5.0	18.0	14.6
39-2212SP	37mm W x 28mm L x 12.5mm H, 12° PTC	2.8	12.5	6.6
39-2214SP	37mm W x 28mm L x 14mm H, 12° PTC	3.3	14.0	8.1
39-2216SP	37mm W x 28mm L x 16mm H, 12° PTC	3.9	16.0	10.1
39-2218SP	37mm W x 28mm L x 18mm H, 12° PTC	4.5	18.0	12.1
39-3012SP	40mm W x 28mm L x 12.5mm H, 7° PTC	3.7	12.5	9.1
39-3014SP	40mm W x 28mm L x 14mm H, 7° PTC	4.2	14.0	10.6
39-3016SP	40mm W x 28mm L x 16mm H, 7° PTC	4.9	16.0	12.6
39-3018SP	40mm W x 28mm L x 18mm H, 7° PTC	5.6	18.0	14.6
39-3212SP	40mm W x 28mm L x 12.5mm H, 12° PTC	3.2	12.5	6.6
39-3214SP	40mm W x 28mm L x 14mm H, 12° PTC	3.7	14.0	8.1
39-3216SP	40mm W x 28mm L x 16mm H, 12° PTC	4.4	16.0	10.1
39-3218SP	40mm W x 28mm L x 18mm H, 12° PTC	5.1	18.0	12.1

\*PILLAR SA PTC is provided sterile



**Semi-Constrained Screws - 5.0mm**

Part #	Description
49-5020	20mm Bone Screw
49-5025	25mm Bone Screw
49-5030	30mm Bone Screw
49-5035	35mm Bone Screw

**Constrained Screws - 5.5mm Shaft/5.0 Body**

Part #	Description
49-5120	20mm Bone Screw
49-5125	25mm Bone Screw
49-5130	30mm Bone Screw
49-5135	35mm Bone Screw

**Rescue Screws - 5.5mm**

Part #	Description
49-5520	20mm Bone Screw
49-5525	5mm Bone Screw
49-5530	30mm Bone Screw
49-5535	35mm Bone Screw

**Cover Plates**

Part #	Description
49-0033	33W Cover Plate
49-0037	37W Cover Plate
49-0040	40W Cover Plate
49-0043	43W Cover Plate

**Description:** The PILLAR SA PEEK Spacer System is comprised of a variety of implants manufactured from PEEK (Polyetheretherketone) as described by ASTM F2026 with tantalum markers as described by ASTM F560. The implants are available in multiple footprints, 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 for Use:** When used as an Intervertebral Body Fusion Device:

The PILLAR SA PEEK Spacer System is indicated for use with bone graft (autograft bone or allogenic bone graft composed of cancellous or corticocancellous bone graft) in patients with degenerative disk disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may have up to Grade I Spondylolisthesis or retrolisthesis at the involved levels. 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 six months of non-operative treatment. Patients with previous non-fusion spinal surgery at the treated level may be treated.

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 fixation must be used to augment stability. As an example, the supplemental fixation system that may be used is the Orthofix Firebird Spinal Fixation System.

The PILLAR SA PEEK Spacer System must be used with autograft or allogenic bone graft composed of cancellous or corticocancellous bone graft.

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

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 fixation must be used to augment stability. As an example, the supplemental fixation that may be used is the Orthofix Firebird Spinal Fixation System.

**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.
2. Who have had prior fusion at the level to be treated.

**Potential Adverse Events:** Potential adverse events 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 human bones present limiting restrictions on the size and strength of implants. No implant can be expected to withstand the unsupported stresses of full weight bearing.
2. 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.
7. Reuse of devices labeled as single-use could result in injury or re-operation due to breakage or infection. Do not attempt to re-sterilize single-use implants that come in contact with body fluids.

**MRI Compatibility Information:** The PILLAR SA PEEK Spacer System has not been evaluated for safety and compatibility in the Magnetic Resonance (MR) environment. This system has not been tested for heating or migration in the MR environment.

**Description:** The PILLAR SA PTC Spacer System is comprised of a variety of implants that have a PEEK core with integrated porous titanium end plates. The implants incorporate integrated anterior screw holes to allow for medial placement of bone screws as well as a titanium plate for securing the bone screws once in place. The implants are designed with a roughened surface on the inferior and superior faces of the implant to provide increased stability and help prevent anterior/posterior movement of the device.

The PILLAR SA PTC Spacer System is intended for intervertebral body fusion to aid in the surgical correction of the spine and is implanted using an anterior approach.

The PILLAR SA PTC spacers are provided sterile. The cover plate, screws and instruments are provided non-sterile and require sterilization prior to use.

The PILLAR SA PTC implants are designed to be used with PILLAR SA PEEK Spacer System instrumentation. The implants are not compatible with components from any other manufacturer's system.

**Indications for Use:** The PILLAR SA PTC 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 PTC Spacer System is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft.

The PILLAR SA PTC Spacer System is intended for use with four of the titanium alloy screws provided with the system. If the physician chooses to use fewer than four of the provided screws then supplemental fixation must be used to augment stability. As an example, a supplemental fixation system that may be used is the Orthofix Firebird® Spinal Fixation System.

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

**Contraindications:** The PILLAR SA PTC Spacer System, as with other orthopedic implants, is contraindicated for use in patients with:

1. Active infections in which the use of an implant could preclude adequate and appropriate treatment of the infection.
2. Rapidly progressive joint disease or bone absorption syndromes such as Paget's disease, osteopenia, osteoporosis, or osteomyelitis which may prevent adequate fixation.
3. Conditions that may place excessive stresses on bone and implants, such as severe obesity, pregnancy or degenerative diseases. The decision to use this system in such conditions must be made by the physician taking into account the risks versus the benefits to the patient.
4. Prior fusion at the level to be treated.
5. Any circumstances not listed under the heading indications.

**Potential Adverse Events:** Potential adverse events 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. In rare instances, 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. No implant can be expected to withstand the unsupported stresses of full weight bearing. The size, shape and condition of the human bones are also contributing factors to the success of the surgery.
2. Do not use damaged implants. 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 may cause internal stress concentrations, which may become the focal point for eventual failure of the device.
3. PILLAR SA PTC spacers are provided STERILE. Do not use if the package is opened or damaged or if the expiration date has passed.
4. DO NOT re-sterilize PILLAR SA PTC spacers as this could result in injury or require reoperation due to breakage.
5. PILLAR SA bone screws and plates are provided non-sterile, and therefore, must be sterilized prior to each use.
6. SINGLE USE ONLY – PILLAR SA PTC Spacer System implants are intended for 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. Reuse could result in injury or require reoperation due to breakage or infection.
7. Non-Sterile; the PILLAR SA PEEK Spacer instruments are provided non-sterile, and therefore, must be thoroughly cleaned and sterilized after each use.
8. 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.
9. Based on the dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact the performance of the intervertebral body fusion device.
10. The implantation of the intervertebral body fusion device should be performed only by experienced spinal surgeons with specific training in the use of this device because it is a technically demanding procedure presenting a risk of serious injury to the patient.
11. Patients with previous surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery.

**MRI Compatibility Information:** The PILLAR SA PTC Spacer System has not been evaluated for safety and compatibility in the Magnetic Resonance (MR) environment. This system has not been tested for heating or migration in the MR environment.



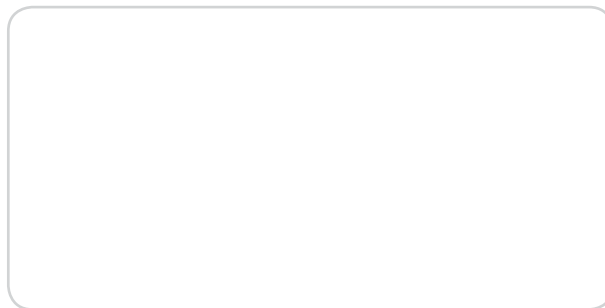
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