PILLAR® AL

PEEK Spacer System

Anterior Lumbar Interbody Fusion (ALIF) and Partial Vertebral Body Replacement (pVBR)

OPERATIVE TECHNIQUE

ORTHOFIX®

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, and other important medical information.

INTRODUCTION

The availability of multiple sizes and angles of lordosis make the PILLAR AL PEEK Spacer System a versatile solution for varying patient anatomies. The chamfered leading edge makes for smooth insertion while surface teeth provide aggressive anti-migration benefits. Built-in anterior and anterolateral insertion points grant greater flexibility during implantation. Tantalum markers provide clear radiographic identification and the large central opening allows for increased fusion potential.

PILLAR AL IMPLANTS

- Available in three footprints
- Available in 0, 7, and 12 degree lordosis
- True to footprint trials available to ensure precision fit
- Varying implant heights in 2mm increments

Fig. 1

INTERVERTEBRAL BODY FUSION INDICATION

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 of the spinal anomaly 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 lateral C-Arm fluoroscopy to visualize the lumbar spine **(Fig. 1)**.

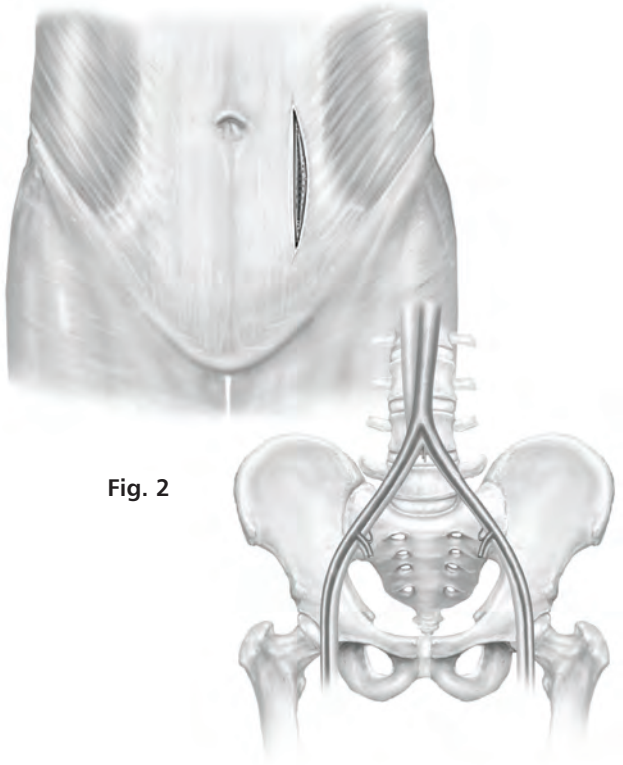

Fig. 2

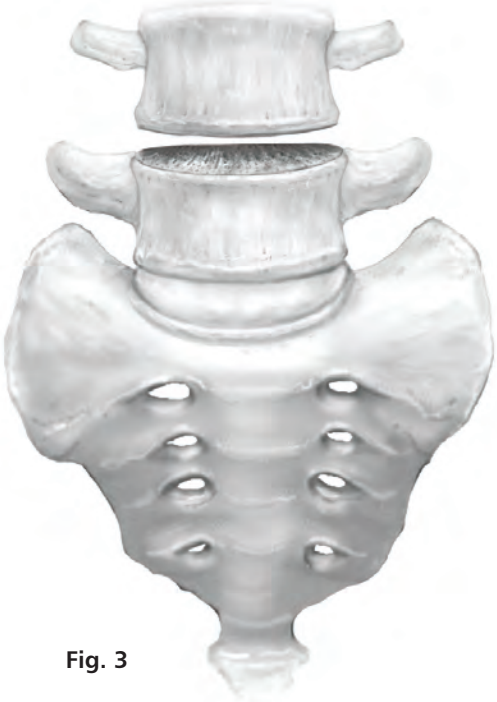

Fig. 3

2. EXPOSURE

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

The PILLAR AL PEEK Spacer System instrumentation is designed for use with a direct anterior retroperitoneal 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 **(Fig. 2)**. Use standard radiographic techniques to identify the correct disc level.

3. DISCECTOMY AND DISC SPACE PREPERATION

Perform a complete anterior lumbar discectomy and remove all residual interbody material **(Fig. 3)**. In order to square off the end plates to make the PILLAR AL PEEK Spacer insertion more efficient, the surgeon may want to remove any osteophytes using an osteotome of their choice.

Fig. 4a

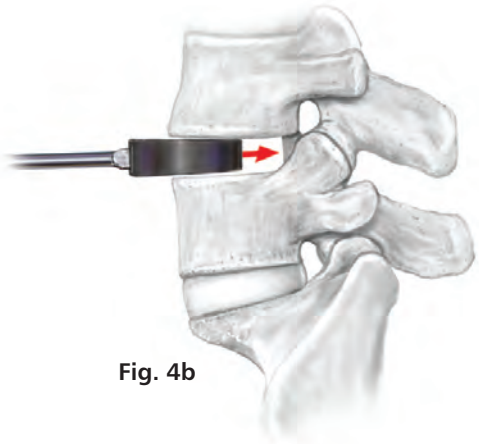

Fig. 4b

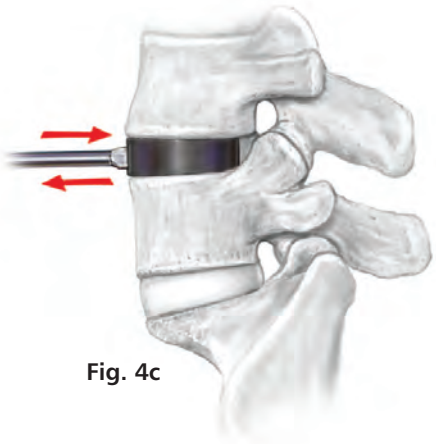

Fig. 4c

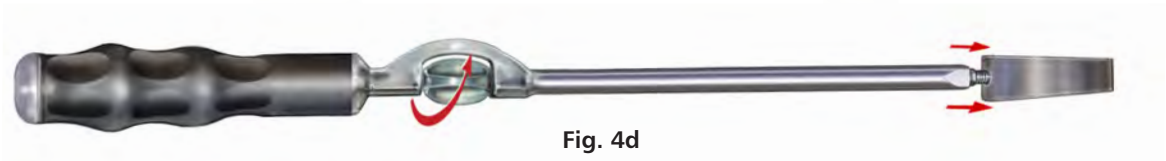

Fig. 4d

4. TRIAL SIZING

The PILLAR AL Trials correspond to the PILLAR AL 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 **(Fig. 4a)**. Insert sequential size trials into the prepared disc space until an appropriately tight fit is achieved and placement is confirmed with a radiograph **(Fig. 4b)**.

When moving the instrument cephalad to caudal, there should be no toggling of the trial within the space with the appropriate size **(Fig. 4c)**. Disengage the Trial from the Trial Insertion Instrument by turning the center knob counter-clockwise **(Fig. 4d)**. Select the size for the PILLAR AL implant according to the appropriate trial size.

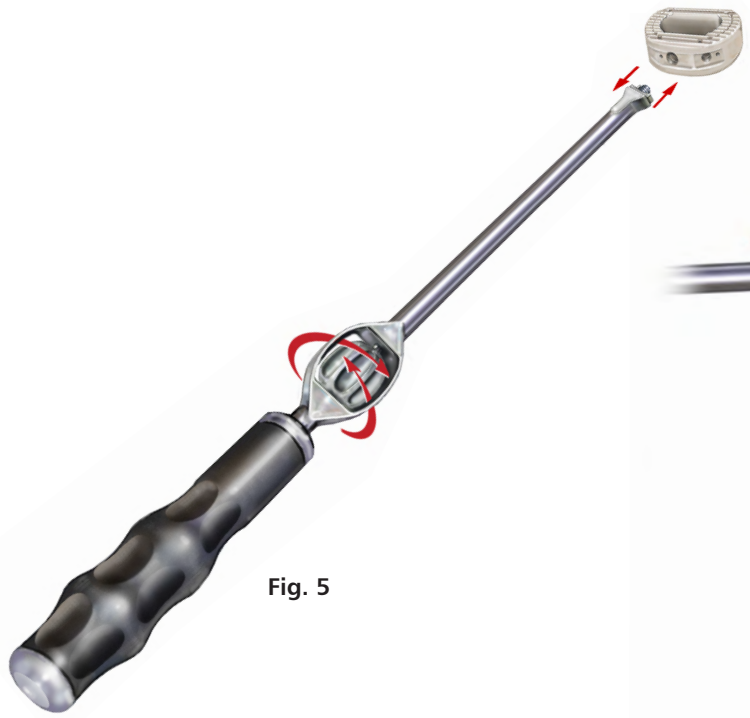

Fig. 5

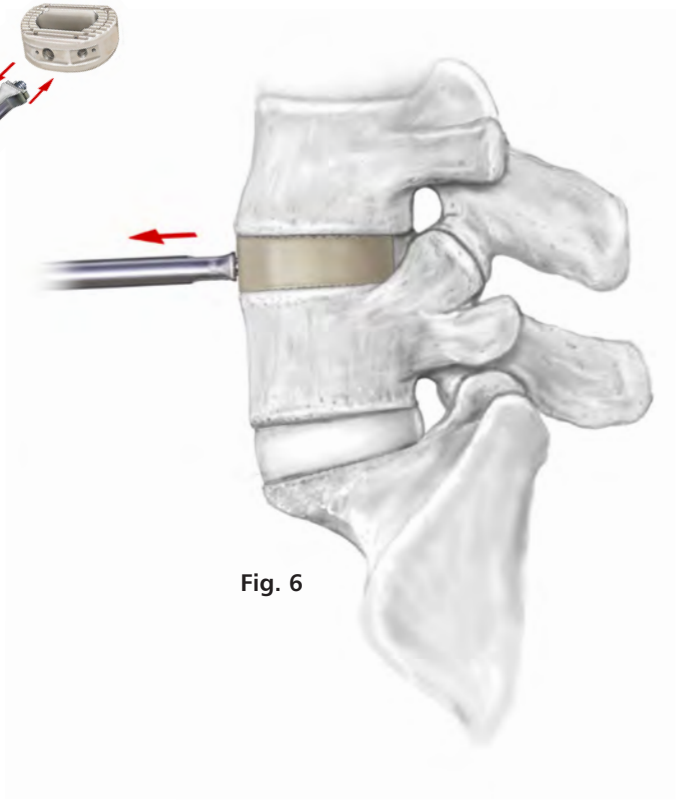

Fig. 6

5. IMPLANT INSERTION

Once the proper implant size has been determined, attach the implant to the inserter and tighten the thumb wheel clockwise **(Fig. 5)**. Autograft may be placed in the window of the implant to help promote fusion. Insert the implant into the disc space. Disengage the implant from the inserter by turning the thumb wheel counter-clockwise. Under guidance of fluoroscopy, the orientation of the implant can be assessed. If repositioning is needed, use the implant tamp.

Secure with some form of supplemental internal fixation. (i.e., Orthofix SFS™ and Firebird® System)

6. IMPLANT REMOVAL AND 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.

If removal of the implant is required, use the implant inserter to re-engage the implant and pull the implant out of the intervertebral space **(Fig. 6)**. If necessary, distract the vertebrae inferior and superior to the implant for removal.

NOTE: Do not attempt to remove the construct unless it is completely exposed to avoid inadvertent injury to the great vessels.

Fig 1b

PARTIAL VBR INDICATION

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 lateral C-Arm fluoroscopy to visualize the lumbar spine **(Fig 1b)**.

Fig 2b

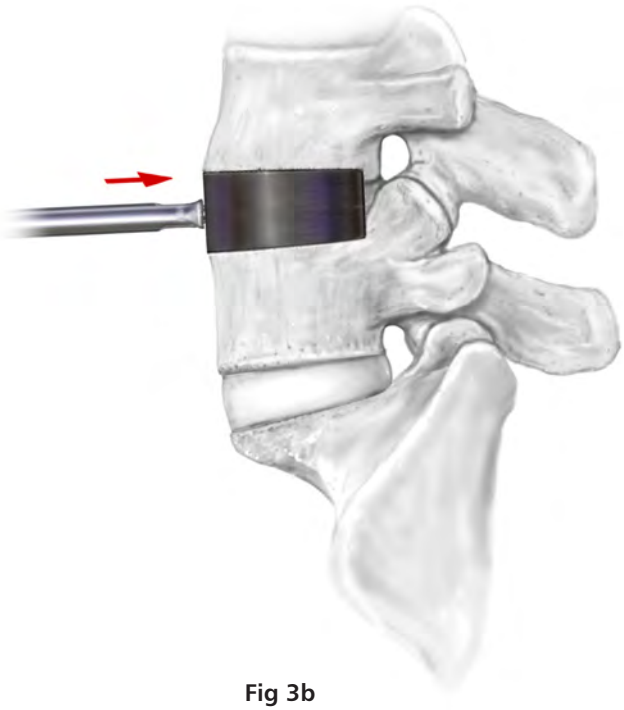

Fig 3b

2. PARTIAL VERTEBRAL BODY REMOVAL

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

3. IMPLANT SIZING

Selection of the proper implant is essential. Attach the trial into the trial inserter and turn thumb wheel clockwise until tight **(Fig 3b)**. Place the trials, in sequential order, into the disc space to determine the proper implant size (height and footprint).

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 AL implant according to the appropriate trial size.

Fig 4b

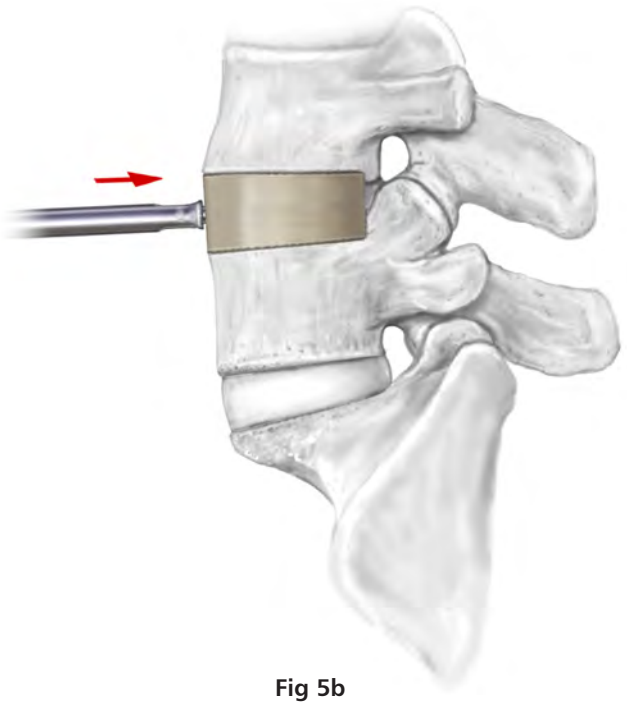

Fig 5b

4. LOADING THE IMPLANT

Once the proper implant size has been determined, attach the implant to the inserter and tighten the thumb wheel clockwise **(Fig 4b)**. Autograft or allograft may be placed in the window of the implant to help promote fusion.

5. IMPLANT INSERTION

Insert the implant into the affected space **(Fig 5b)**. Under guidance of fluoroscopy, the orientation of the implant can be assessed. If repositioning is needed, use the implant tamp.

Secure with some form of supplemental internal fixation. (i.e., Orthofix SFS™ and Firebird® System)

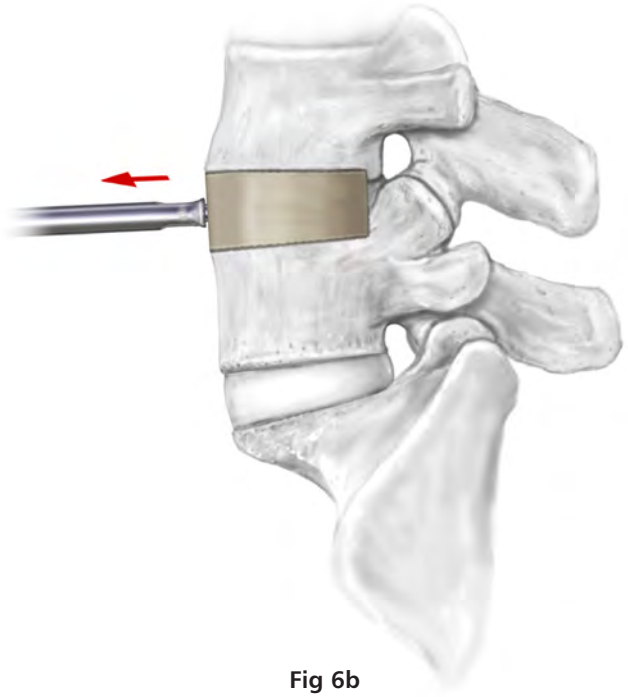

Fig 6b

6. IMPLANT REMOVAL AND REVISION

If removal of the implant is required, use the implant inserter to re-engage the implant and pull the implant out of the affected space. **(Fig 6b)** If necessary, distract inferior and superior to the implant for removal.

Implants and Trials

Implant	Trial	Dimensions	Graft Volumes (cc's)
PILLAR AL 26mm Implants 7°			
48-2108	**48-1208**	26mm W x 20mm D x 8mm H, 7°	1.2
48-2110	**48-1210**	26mm W x 20mm D x 10mm H, 7°	1.5
48-2112	**48-1212**	26mm W x 20mm D x 12mm H, 7°	1.9
48-2114	**48-1214**	26mm W x 20mm D x 14mm H, 7°	2.2
48-2116	**48-1216**	26mm W x 20mm D x 16mm H, 7°	2.5
48-2118	**48-1218**	26mm W x 20mm D x 18mm H, 7°	2.8
48-2120	**48-1220**	26mm W x 20mm D x 20mm H, 7°	3.2

Implant	Trial	Dimensions	Graft Volumes (cc's)
PILLAR AL 30mm Implants Parallel			
48-3008	**48-1408**	30mm W x 24mm D x 8mm H, 0°	2.2
48-3010	**48-1410**	30mm W x 24mm D x 10mm H, 0°	2.7
48-3012	**48-1412**	30mm W x 24mm D x 12mm H, 0°	3.3
48-3014	**48-1414**	30mm W x 24mm D x 14mm H, 0°	3.8
48-3016	**48-1416**	30mm W x 24mm D x 16mm H, 0°	4.4
48-3018	**48-1418**	30mm W x 24mm D x 18mm H, 0°	4.9

Implant	Trial	Dimensions	Graft Volumes (cc's)
PILLAR AL 30mm Implants 7°			
48-3110	**48-1510**	30mm W x 24mm D x 10mm H, 7°	2.3
48-3112	**48-1512**	30mm W x 24mm D x 12mm H, 7°	2.9
48-3114	**48-1514**	30mm W x 24mm D x 14mm H, 7°	3.4
48-3116	**48-1516**	30mm W x 24mm D x 16mm H, 7°	4.0
48-3118	**48-1518**	30mm W x 24mm D x 18mm H, 7°	4.5
48-3120	**48-1520**	30mm W x 24mm D x 20mm H, 7°	5.0
48-3122	**48-1522**	30mm W x 24mm D x 22mm H, 7°	5.6

Implant	Trial	Dimensions	Graft Volumes (cc's)
PILLAR AL 30mm Implants 12°			
48-3212	**48-1612**	30mm W x 24mm D x 12mm H, 12°	2.6
48-3214	**48-1614**	30mm W x 24mm D x 14mm H, 12°	3.1
48-3216	**48-1616**	30mm W x 24mm D x 16mm H, 12°	3.7
48-3218	**48-1618**	30mm W x 24mm D x 18mm H, 12°	4.2
48-3220	**48-1620**	30mm W x 24mm D x 20mm H, 12°	4.8
48-3222	**48-1622**	30mm W x 24mm D x 22mm H, 12°	5.3
48-3224	**48-1624**	30mm W x 24mm D x 24mm H, 12°	5.9

Implant	Trial	Dimensions	Graft Volumes (cc's)
PILLAR AL 34mm Implants 12°			
48-4212	**48-1912**	34mm W x 28mm D x 12mm H, 12°	3.3
48-4214	**48-1914**	34mm W x 28mm D x 14mm H, 12°	4.0
48-4216	**48-1916**	34mm W x 28mm D x 16mm H, 12°	4.8
48-4218	**48-1918**	34mm W x 28mm D x 18mm H, 12°	5.5
48-4220	**48-1920**	34mm W x 28mm D x 20mm H, 12°	6.3
48-4222	**48-1922**	34mm W x 28mm D x 22mm H, 12°	7.0
48-4224	**48-1924**	34mm W x 28mm D x 24mm H, 12°	7.8

Instruments

48-0020	PILLAR AL Instrument Set
48-1005	PILLAR AL Instrument Case
32-2210	10mm ALIF Distractor Bullet
32-2212	12mm ALIF Distractor Bullet
32-2214	14mm ALIF Distractor Bullet
32-2216	16mm ALIF Distractor Bullet
32-2218	18mm ALIF Distractor Bullet
32-2220	20mm ALIF Distractor Bullet
32-2222	22mm ALIF Distractor Bullet
32-2224	24mm ALIF Distractor Bullet
32-1060	ALIF Distractor
32-1061	Distractor Blade Right No Offset
32-1062	Distractor Blade Left No Offset
32-1063	Distractor Blade Right
32-1064	Distractor Blade Left

Other Instruments

32-2050	Distractor/Trial Handle Assembly
48-1002	PILLAR AL Tamp
48-1003	PILLAR AL Bone Packer
32-0021	Anterior Lumbar Discectomy Set
32-1091	Anterior Lumbar Discectomy Case

Top Tray

32-1505	#0 Curette Straight
32-1506	Cobb Elevator, 19mm
46-1011	Ring Curette
46-1012	#4 Curette Straight
46-1013	#2 Curette Straight
46-1100	10" Modular Handle
46-1101	10" Modular Handle Insert

Middle Tray

32-1502	5mm Kerrison Rongeur
32-1503	7mm Kerrison Rongeur
32-1504	8mm Rongeur

Base Tray

46-1401	Large Sypert Rongeur
46-1501	Ferris Smith Rongeur

Description: The PILLAR® Spacer System consists of implants, trials, and instruments.

The PILLAR PEEK Spacer System is comprised of a variety of implants manufactured from PEEK (Polyetheretherketone), as described by ASTM F-2026, with Tantalum markers as described by ASTM F-560. The implants are available in a variety of footprint sizes. Additionally, they are offered in parallel and lordotic profiles in order to restore the natural curvature of the spine. The implants are available in various heights, in either one, or two millimeter increments. The superior and inferior surfaces of the implant have a pattern of ripples to provide increased stability and help prevent anterior/posterior movement of the device.

The PILLAR PEEK Spacer System is intended for intervertebral body fusion or partial vertebral body replacement to aid in the surgical correction and stabilization of the spine.

The PILLAR PEEK Spacer System is not intended to be used as a stand-alone device. The PILLAR PEEK Spacer System must be used with supplemental internal fixation. The PILLAR PEEK Spacer System is provided non-sterile.

Indications: When used as an intervertebral body fusion device, the PILLAR 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 PEEK Spacer System is intended for use with autograft and supplemental internal fixation. As an example, the supplemental internal fixation system that may be used is the Orthofix 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 PEEK Spacer System.

The PILLAR PL PEEK spacer is used singly or in pairs and is implanted using a posterior approach.
The PILLAR TL PEEK spacer is used singly or in pairs and is implanted using a transforaminal approach.
The PILLAR AL PEEK spacer is used singly and is implanted using an anterior approach.
The PILLAR XL PEEK spacer is used singly and is implanted using a lateral approach.

When used as a Partial Vertebral Body Replacement (pVBR) System, the PILLAR 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 PEEK Spacer System is also indicated for treating fractures of the thoracic and lumbar spine.

The PILLAR 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 Partial VBR device is intended to be used with autograft or allograft.

The PILLAR PEEK Spacer System is intended for use with internal fixation. As an example, the supplemental internal fixation system that may be used is the Orthofix, Inc. Spinal Fixation System (SFS).

Contraindications:
The PILLAR 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 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 re-sterilize single-use implants that came in contact with body fluids.

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Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Proper surgical procedure is the responsibility of the medical professional. Operative techniques are furnished as an informative guideline. Each surgeon must evaluate the appropriateness of a technique based on his or her personal medical credentials and experience. Please refer to the "Instructions for Use" supplied with the product for full information on indications for use, contraindications, warnings, precautions, adverse reactions information and sterilization.

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