PILLAR™ AL

PEEK Spacer System

Anterior Lumbar Interbody Fusion (ALIF)

OPERATIVE TECHNIQUE

MICHELSON TECHNOLOGY AT WORK

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

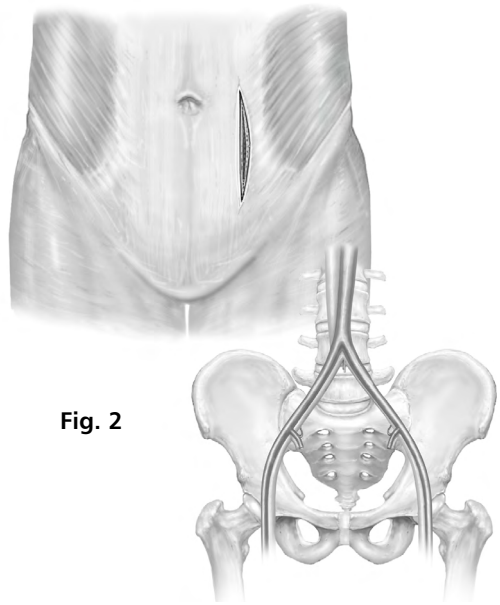

Fig. 2

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) 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**).

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.

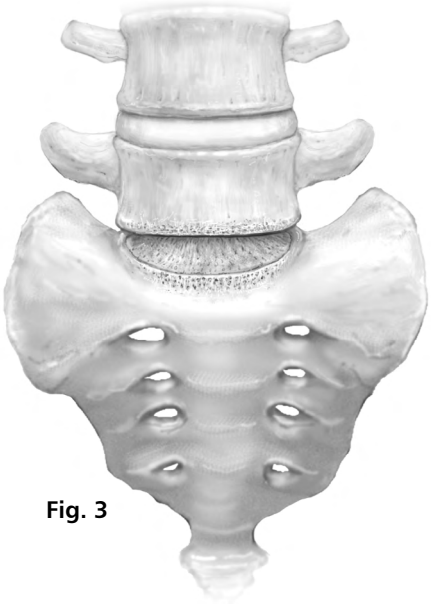

Fig. 3

Fig. 4a

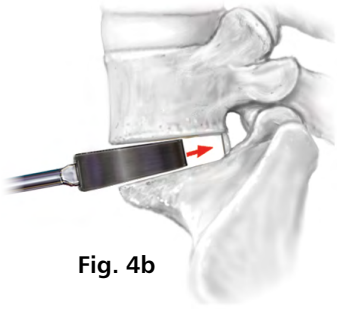

Fig. 4b

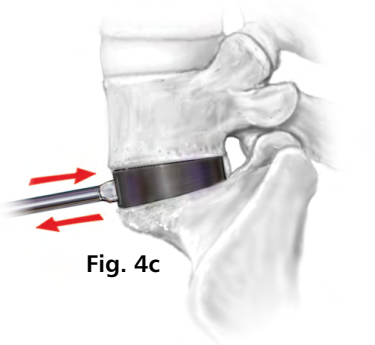

Fig. 4c

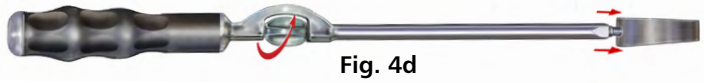

Fig. 4d

3. DISCECTOMY AND DISC SPACE PREPERATION

Perform a complete anterior lumbar discectomy and remove all residual intervertebral disc 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.

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.

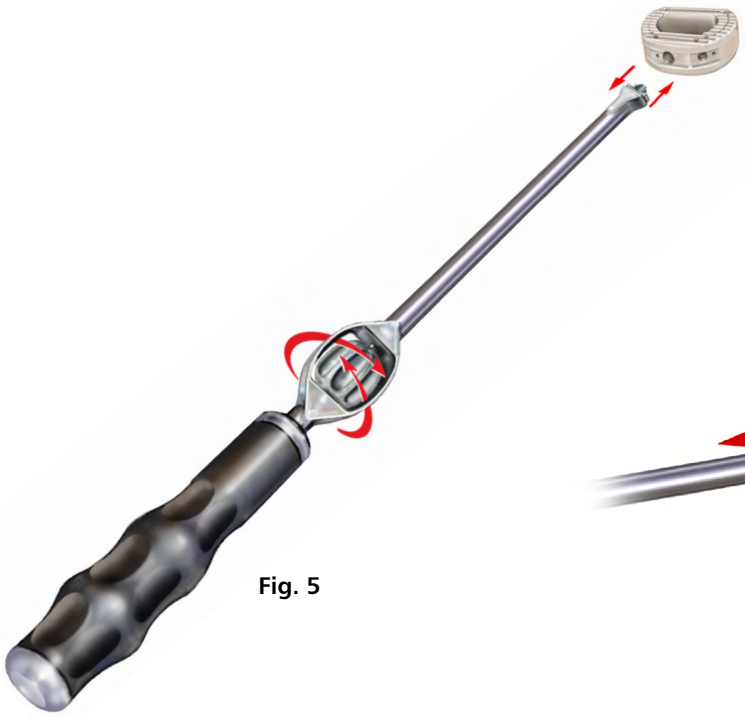

Fig. 5

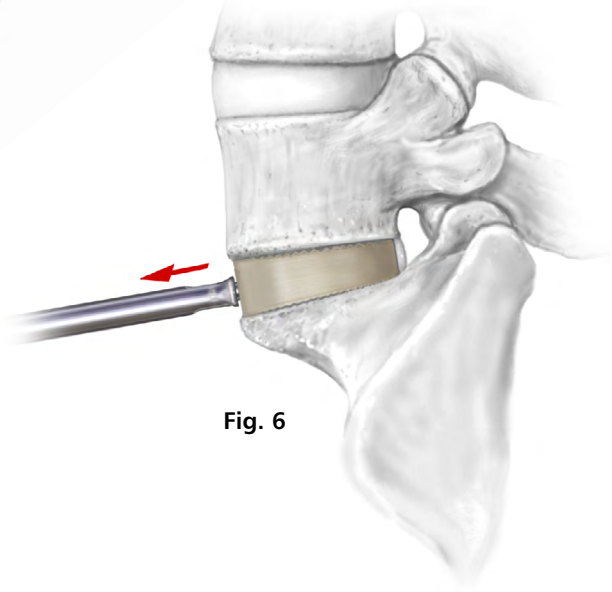

Fig. 6

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 or allogenic bone graft composed of cancellous or corticocancellous bone graft.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

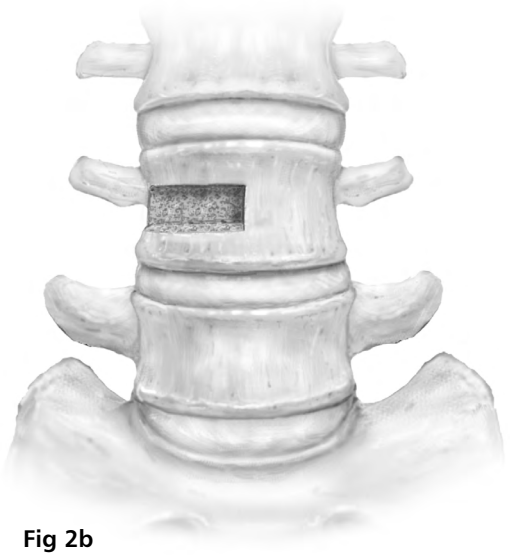

Fig 2b

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)**.

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)**.

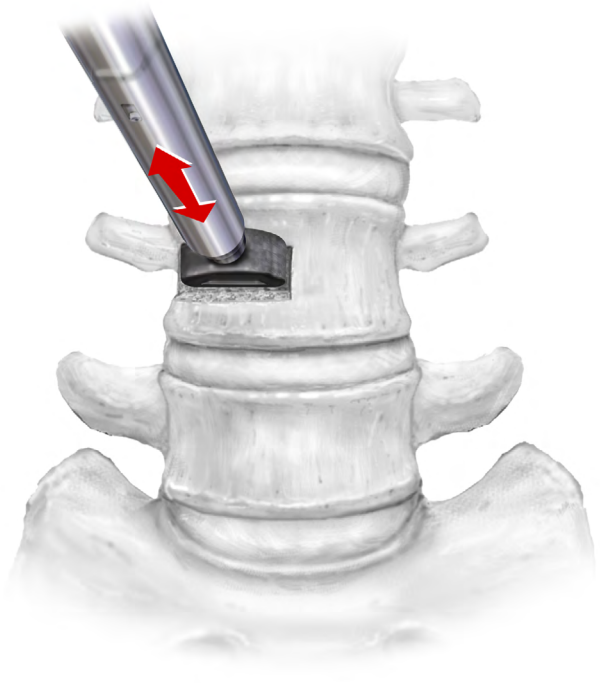

Fig 3b

Fig 4b

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.

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.

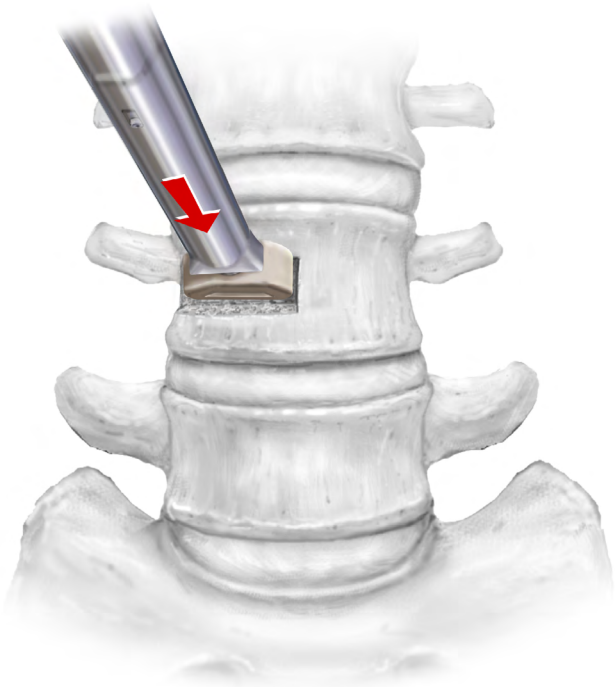

Fig 5b

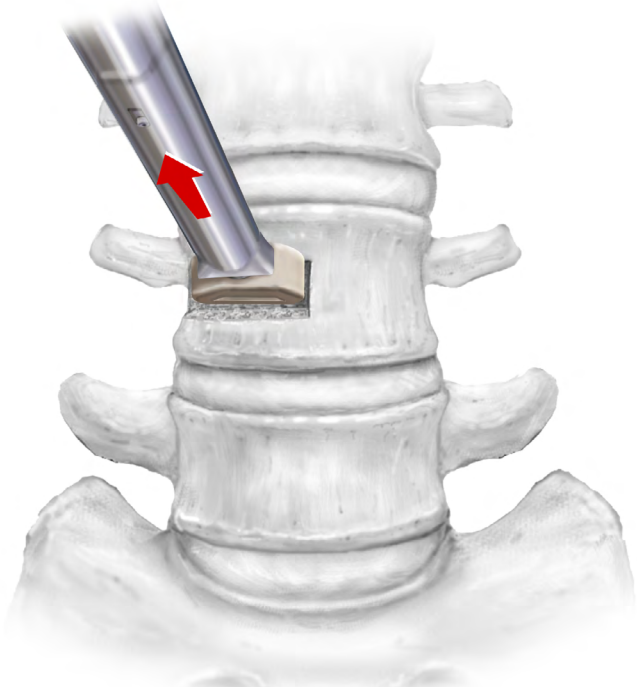

Fig 6b

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)

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 & TRIALS

48-0010	PILLAR AL Trial Implant Set
48-1004	PILLAR AL Trial Implant Case
48-1001	PILLAR AL Implant Inserter
32-2050	Distractor/Trial Handle

Implant	Trial			
48-2108	**48-1208**	AL	26mm x 20mm x 8mm	7º lordotic
48-2110	**48-1210**	AL	26mm x 20mm x 10mm	7º lordotic
48-2112	**48-1212**	AL	26mm x 20mm x 12mm	7º lordotic
48-2114	**48-1214**	AL	26mm x 20mm x 14mm	7º lordotic
48-2116	**48-1216**	AL	26mm x 20mm x 16mm	7º lordotic
48-2118	**48-1218**	AL	26mm x 20mm x 18mm	7º lordotic
48-2120	**48-1220**	AL	26mm x 20mm x 20mm	7º lordotic

Implant	Trial			
48-3008	**48-1408**	AL	30mm x 24mm x 8mm	0º (parallel)
48-3010	**48-1410**	AL	30mm x 24mm x 10mm	0º (parallel)
48-3012	**48-1412**	AL	30mm x 24mm x 12mm	0º (parallel)
48-3014	**48-1414**	AL	30mm x 24mm x 14mm	0º (parallel)
48-3016	**48-1416**	AL	30mm x 24mm x 16mm	0º (parallel)
48-3018	48-1418	AL	30mm x 24mm x 18mm	0º (parallel)

Implant	Trial			
48-3110	**48-1510**	AL	30mm x 24mm x 10mm	7º lordotic
48-3112	**48-1512**	AL	30mm x 24mm x 12mm	7º lordotic
48-3114	**48-1514**	AL	30mm x 24mm x 14mm	7º lordotic
48-3116	**48-1516**	AL	30mm x 24mm x 16mm	7º lordotic
48-3118	**48-1518**	AL	30mm x 24mm x 18mm	7º lordotic
48-3120	**48-1520**	AL	30mm x 24mm x 20mm	7º lordotic
48-3122	**48-1522**	AL	30mm x 24mm x 22mm	7º lordotic

Implant	Trial			
48-3212	**48-1612**	AL	30mm x 24mm x 12mm	12º lordotic
48-3214	**48-1614**	AL	30mm x 24mm x 14mm	12º lordotic
48-3216	**48-1616**	AL	30mm x 24mm x 16mm	12º lordotic
48-3218	**48-1618**	AL	30mm x 24mm x 18mm	12º lordotic
48-3220	**48-1620**	AL	30mm x 24mm x 20mm	12º lordotic
48-3222	**48-1622**	AL	30mm x 24mm x 22mm	12º lordotic
48-3224	**48-1624**	AL	30mm x 24mm x 24mm	12º lordotic
48-4212	**48-1912**	AL	34mm x 28mm x 12mm	12º lordotic
48-4214	**48-1914**	AL	34mm x 28mm x 14mm	12º lordotic
48-4216	**48-1916**	AL	34mm x 28mm x 16mm	12º lordotic
48-4218	**48-1918**	AL	34mm x 28mm x 18mm	12º lordotic
48-4220	**48-1920**	AL	34mm x 28mm x 20mm	12º lordotic
48-4222	**48-1922**	AL	34mm x 28mm x 22mm	12º lordotic
48-4224	**48-1924**	AL	34mm x 28mm x 24mm	12º lordotic

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

Notes

Please visit Orthofix.com/IFU for full information on indications for use, contraindications, warnings, precautions, adverse reactions and sterilization.

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.

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OP-72-9902-US Rev AA
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