Transforaminal Lumbar Interbody Fusion Technique

Acknowledgements
Stryker Spine wishes to thank the following physicians for authoring this surgical technique:

Daryll C. Dykes, MD, PhD
Twin Cities Spine Center
Minneapolis, Minnesota

Frank Feigenbaum, MD
Midwest Neurosurgery Associates, P.A.
Overland Park, Kansas

B. Christoph Meyer, MD
Houston Center for Spinal Reconstruction and Disc Replacement
Houston, Texas

Scott H. Kitchel, MD
Orthopedic Spine Associates
Eugene, Oregon

Amir A. Mehbod, MD
Twin Cities Spine Center
Minneapolis, Minnesota

Eric Truumees, MD
Partner, Michigan Orthopaedic Institute
Attending Spine Surgeon, William Beaumont Hospital
Orthopaedic Director, Gehring Biomechanics Laboratory
Adjunct Faculty, Wayne State University BioEngineering Center
Detroit, MI, USA

Additionally, Stryker Spine wishes to thank the global AVS TL PEEK Spacer System surgeon panel for their dedication to the development of the AVS TL PEEK Spacer System.
# Table Of Contents

## TLIF Surgical Technique

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Exposure</td>
<td>5</td>
</tr>
<tr>
<td>2</td>
<td>Preparation of facet joints</td>
<td>5</td>
</tr>
<tr>
<td>3</td>
<td>TLIF Site preparation</td>
<td>6</td>
</tr>
<tr>
<td>4</td>
<td>Distraction</td>
<td>6</td>
</tr>
<tr>
<td>5</td>
<td>Disectomy and endplate preparation</td>
<td>8</td>
</tr>
<tr>
<td>6</td>
<td>Sizing the disc space</td>
<td>9</td>
</tr>
<tr>
<td>7</td>
<td>AVS TL PEEK Spacer preparation</td>
<td>9</td>
</tr>
<tr>
<td>8</td>
<td>AVS TL PEEK Spacer insertion</td>
<td>9</td>
</tr>
<tr>
<td>9</td>
<td>Placement of bone grafting material</td>
<td>11</td>
</tr>
<tr>
<td>10</td>
<td>Posterior fusion</td>
<td>12</td>
</tr>
<tr>
<td>11</td>
<td>Closure</td>
<td>12</td>
</tr>
</tbody>
</table>

## Implant Reference Numbers

## Instrument Reference Numbers
Transforaminal Lumbar Interbody Fusion Technique

The following technique describes an open TLIF technique. This technique may be applied unilaterally to any lumbar interbody space, based on the pathology being addressed and surgeon preference, and this technique may be performed through an open or minimally invasive approach. In an open or minimally invasive TLIF procedure, the interbody space is generally approached from a posterior approach and an AVS TL implant is inserted into the disc space.

Description

The AVS TL PEEK Spacer System offers implants that are interbody fusion devices intended for use as an aid in spinal fixation. These hollow implants are offered in a variety of lengths, heights and lordotic angles designed to adapt to a variety of patient anatomies. They have serrations on the superior and inferior surfaces designed for multi-directional fixation, ergonomically shaped anterior edges, and flat posterior edges. Radiopaque markers have been embedded within the implants, which are designed to allow for visualization in radiographic images.
Step 1 - Exposure
Open Approach
A TLIF procedure can be performed using a standard open or minimally invasive approach, from the patient’s left or right side. Typically, cage insertion is performed from the symptomatic side in patients with radiculopathy. This technique describes a left-sided approach at L4-L5.

The incision is made over the spinous process of L3 and extends to L5. (Fig. 1) Sharp paraspinal dissection is performed exposing the L3-L4 and L4-L5 facets. Care must be taken to avoid damage to the L3-L4 facet capsules. Unless the surgeon intends to perform concomitant intertransverse fusion, the transverse processes need not be exposed.

Minimally Invasive Approach
The AVS system lends itself to minimally invasive approaches as well. MIS systems rely on proprietary retractor systems and specialized tools, the use of which are best depicted in their individual technique guides. A minimally invasive system which can be used is the Stryker Luxor Retractor System. Please refer to the Luxor surgical technique for additional information on minimally invasive exposure.

NOTE: The remaining steps in the surgical technique are similar in both open and minimally invasive surgical approaches. All images in this technique, however, depict an open approach for image clarity. Please refer to the Luxor surgical technique for additional information on minimally invasive approaches and detailed images.

Step 2 - Preparation of facet joints
Both L4-L5 facet capsules should be removed circumferentially. This is typically accomplished using a cautery device. Bipolar cautery may be useful in achieving hemostasis lateral to the facet joints. The right L4-L5 facet is prepared for fusion by removing the articular cartilage from the facet joint with a burr or other appropriate instrument. (Fig. 2)
**Step 3 - TLIF Site Preparation**

The TLIF site preparation is on the left side. An osteotome may be used to remove the left inferior articular process of L4 with two cuts, a vertical cut just medial to the facet extending superiority to the superior border of the facet and a horizontal cut directed laterally towards the foramen. Once the two cuts are made, the inferior articulating process of L4 may be removed with a kerrison. (Fig. 3) The left lateral edge of the ligamentum flavum is then visualized. A curette may be used to release (but not resect) the ligamentum flavum from the superior lamina of L5, allowing for distraction. The ligamentum flavum should be preserved when possible, but resection of redundant flavum may be necessary in patients with neurologic compression.

**Step 4 - Distraction**

Effective distraction aids in removal of the superior articular process of L5, decompression of the neuroforamen, preparation of the disc space and insertion of the AVS TL PEEK Spacer. This can be accomplished through several techniques: pedicle screw distraction, distraction between boney elements, and/or distraction with a positioning device.

- If pedicle screw distraction is chosen, the screws should be positioned at this time, using standard technique. (Fig. 4) Apply distraction between pedicle screws placed at L4 and L5. (Fig. 5)

- Particularly in patients with less than ideal bone quality, it might be useful to size the interspace with paddle distractors, reamer-distractors, or trials before locking the distraction down through the pedicle screws. Interspace distraction gives an excellent sense of restoration of annular tension and avoids pedicle screw preloading (which may cause post-operative loosening).
Step 4 (Continued)

• Choices for a supplemental spinal fixation system include, but are not limited to, Stryker Spine pedicle screw and rod or plate systems (Xia, Radius, Trio, Mantis, and ES2). Please refer to the surgical techniques of the above mentioned Stryker Spine supplemental fixation systems for additional information on implantation.

• In an open procedure, apply direct distraction between the boney elements of L4 and L5, such as the spinous processes or laminae.

• The patient’s lordosis can be adjusted with a positioning device, such as a Wilson frame (open and minimally invasive procedures).

With sufficient distraction, the L4-L5 foramen will be opened and the entire superior articular process of L5 will be visualized. A small probe may be used to palpate the superior margin of the left L5 pedicle. The superior articular process of L5 should be resected exposing the L4-L5 disc in the L4-L5 foramen. This may be accomplished with an osteotome, rongeur, or other appropriate instrument. Since a consistent leash of veins traverse the foramen over the disc space, the surgeon should be prepared to control bleeding from these veins with bipolar cautery. Hemostasis may be enhanced with topical hemostatic agents and cottonoid pledgets. The exiting L4 nerve root is rostral at this point, under the pars interarticularis, and in many instances is not visible.
Step 5 - Disectomy and Endplate Preparation
Access to the disc space is achieved through an annulotomy, made lateral to the posterior longitudinal ligament. Using a scalpel, vertical cuts should be made parallel to the dura and laterally in the foramen from the endplate of L4 to the endplate of L5. Additional cuts extend horizontally along the endplates of L4 and L5, connecting the vertical cuts. The annulus and any accessible disc material are removed with a pituitary rongeur. (Fig. 6)

Commonly, a large osteophyte will protrude inferiorly off the endplate of L4, and sometimes superiorly off the endplate of L5. Sharp excision of these osteophytes with an osteotome or kerrison punch will provide a larger entry portal if desired.

Throughout the remainder of the procedure, care must be taken to not damage the remaining lateral, anterior or posterior annulus.

A curette or narrow Cobb elevator is used to elevate disc material from the endplates of L4 and L5 on the left lateral side. Next, angled curettes are used to elevate the disc from the endplates of L4 and L5 centrally and on the right side. (Fig. 7) An easily missed portion of the disc lies posteriorly and centrally within the disc space, just ventral to the spinal canal. Special effort should be directed toward removing disc in this zone to provide optimal surface area for interbody fusion. Straight and up biting pituitary rongeurs should be used to remove the disc. Additionally, multiple passes with straight and angled curettes may be necessary to ensure adequate discectomy. Fluoroscopy may help in ensuring clearance of the disc space while limiting the risk of perforating the ventral, lateral or posteromedial annulus.
Step 6 - Sizing the Disc Space
The disc space height is then sized using a series of paddle distractors, reamer-distractors, or trials. The paddle distractor, reamer-distractor, or trial size is serially increased until the appropriate fit within the disc space is achieved. The paddle distractor, reamer-distractor, or trial should fit snugly within the disc space with distraction released, but care must be taken to not oversize the implant. Undersizing may contribute to a loss of lordosis and inadequate stability for fusion, while oversizing may result in difficult insertion of the implant and disruption of the vertebral boney endplate along with autograft.

Step 7 - AVS TL PEEK Spacer Preparation
Identify the appropriate size AVS TL PEEK Spacer and assemble it to either the Straight or Angled, based on surgeon preference. (Fig. 8a & 8b) Inserters for both open and less invasive procedures are available. Pack spacers with autogenous bone graft.

NOTE:
• It is recommended that all inserters are lubricated regularly.

Place the AVS TL implant in the Spacer Support and pack it with autograft using the Graft Compactor. (Fig. 9)

Step 8 - AVS TL Implant Insertion
Carefully insert the AVS TL implant (Fig. 10). The AVS TL implant may then be adjusted to a final position using either the AVS TL Spacer Impactor Straight or AVS TL Impactor Angled, based on surgeon preference. (Fig. 11)
There are three tantalum markers embedded in the implant to help visually confirm its position under fluoroscopy. There is a 5mm marker in the leading edge of the implant. The trailing edge of the implant contains a 2.5mm marker. The anterior midline portion of the implant contains a 1mm marker. (Fig. 12)

In the sagittal plane, the 2.5mm marker and 5mm marker should line up with each other, with the anterior midline marker appearing anterior in the disc space. In the anterior/posterior plane, the anterior midline marker should line up with the midline, and the 5mm and 2.5mm marker should be evenly spaced on either side of the midline marker. The ideal position would have the 2.5mm marker line up with the 5mm marker on a lateral view. (Fig. 13a & 13b)
Use angled osteotomes, curettes and rasps to decorticate the end plates of L4 and L5 dorsal to the AVS TL implant. This will result in the creation of a bleeding surface, which is optimal for fusion once the autograft is placed. (Fig. 14) Remove the pedicle screw distractor.

**Step 9 - Placement of Autogenous Bone Grafting Material**

Autogenous bone grafting material may be placed lateral, ventral and/or dorsal to the implanted AVS TL implant. (Fig. 15).
Step 10 - Posterior Fusion
Since the interbody portion of the procedure is complete, distraction can be released. If pedicle screws were not inserted earlier in the procedure they may now be inserted. Vertical rods connect the screws together and gentle compression should be applied between the L4 and L5 screws bilaterally. This facilitates restoration of segmental lordosis and compression of the AVS TL implant and autogenous bone graft. Apply appropriate final torque tightening to all screws. The remaining autogenous bone graft may be placed in the decorticated right L4-L5 facet to help promote posteriolateral fusion. (Fig. 18) Intraoperative radiographs should be performed to confirm satisfactory position of the AVS TL implant, pedicle screws, and autograft material.

Step 11- Closure
Check the left L4-L5 foramen and TLIF site for any bone fragments or extraneous soft tissue. Once satisfactory decompression of the exiting and traversing nerve roots is confirmed the wound should be closed.

Removal of the Device (if required)
Either of the two inserters: Spacer MIS Inserter Straight - 48389500, or Spacer MIS Inserter Angled - 48389550 can be used to recover the implant from the disc space. The inserter should be threaded into the implant to remove the spacer from the body.
# AVS TL PEEK Spacer System

## Set Configuration

### AVS TL PEEK Spacers - 25mm Long

<table>
<thead>
<tr>
<th>Reference</th>
<th>Description (height x length x lordosis)</th>
</tr>
</thead>
<tbody>
<tr>
<td>48375070</td>
<td>VERTEBRAL SPACER 7 x 25 x 0°</td>
</tr>
<tr>
<td>48375080</td>
<td>VERTEBRAL SPACER 8 x 25 x 0°</td>
</tr>
<tr>
<td>48375090</td>
<td>VERTEBRAL SPACER 9 x 25 x 0°</td>
</tr>
<tr>
<td>48375100</td>
<td>VERTEBRAL SPACER 10 x 25 x 0°</td>
</tr>
<tr>
<td>48375110</td>
<td>VERTEBRAL SPACER 11 x 25 x 0°</td>
</tr>
<tr>
<td>48375120</td>
<td>VERTEBRAL SPACER 12 x 25 x 0°</td>
</tr>
<tr>
<td>48375130</td>
<td>VERTEBRAL SPACER 13 x 25 x 0°</td>
</tr>
<tr>
<td>48375140</td>
<td>VERTEBRAL SPACER 14 x 25 x 0°</td>
</tr>
<tr>
<td>48375074</td>
<td>VERTEBRAL SPACER 7 x 25 x 4°</td>
</tr>
<tr>
<td>48375084</td>
<td>VERTEBRAL SPACER 8 x 25 x 4°</td>
</tr>
<tr>
<td>48375094</td>
<td>VERTEBRAL SPACER 9 x 25 x 4°</td>
</tr>
<tr>
<td>48375104</td>
<td>VERTEBRAL SPACER 10 x 25 x 4°</td>
</tr>
<tr>
<td>48375114</td>
<td>VERTEBRAL SPACER 11 x 25 x 4°</td>
</tr>
<tr>
<td>48375124</td>
<td>VERTEBRAL SPACER 12 x 25 x 4°</td>
</tr>
<tr>
<td>48375134</td>
<td>VERTEBRAL SPACER 13 x 25 x 4°</td>
</tr>
<tr>
<td>48375144</td>
<td>VERTEBRAL SPACER 14 x 25 x 4°</td>
</tr>
</tbody>
</table>

### AVS TL PEEK Spacers - 30mm Long

<table>
<thead>
<tr>
<th>Reference</th>
<th>Description (height x length x lordosis)</th>
</tr>
</thead>
<tbody>
<tr>
<td>48370090</td>
<td>VERTEBRAL SPACER 9 x 30 x 0°</td>
</tr>
<tr>
<td>48370100</td>
<td>VERTEBRAL SPACER 10 x 30 x 0°</td>
</tr>
<tr>
<td>48370110</td>
<td>VERTEBRAL SPACER 11 x 30 x 0°</td>
</tr>
<tr>
<td>48370120</td>
<td>VERTEBRAL SPACER 12 x 30 x 0°</td>
</tr>
<tr>
<td>48370130</td>
<td>VERTEBRAL SPACER 13 x 30 x 0°</td>
</tr>
<tr>
<td>48370140</td>
<td>VERTEBRAL SPACER 14 x 30 x 0°</td>
</tr>
<tr>
<td>48370150</td>
<td>VERTEBRAL SPACER 15 x 30 x 0°</td>
</tr>
<tr>
<td>48370160</td>
<td>VERTEBRAL SPACER 16 x 30 x 0°</td>
</tr>
<tr>
<td>48370170</td>
<td>VERTEBRAL SPACER 17 x 30 x 0°</td>
</tr>
<tr>
<td>48370180</td>
<td>VERTEBRAL SPACER 18 x 30 x 0°</td>
</tr>
<tr>
<td>48370094</td>
<td>VERTEBRAL SPACER 9 x 30 x 4°</td>
</tr>
<tr>
<td>48370104</td>
<td>VERTEBRAL SPACER 10 x 30 x 4°</td>
</tr>
<tr>
<td>48370114</td>
<td>VERTEBRAL SPACER 11 x 30 x 4°</td>
</tr>
<tr>
<td>48370124</td>
<td>VERTEBRAL SPACER 12 x 30 x 4°</td>
</tr>
<tr>
<td>48370134</td>
<td>VERTEBRAL SPACER 13 x 30 x 4°</td>
</tr>
<tr>
<td>48370144</td>
<td>VERTEBRAL SPACER 14 x 30 x 4°</td>
</tr>
<tr>
<td>48370154</td>
<td>VERTEBRAL SPACER 15 x 30 x 4°</td>
</tr>
<tr>
<td>48370164</td>
<td>VERTEBRAL SPACER 16 x 30 x 4°</td>
</tr>
<tr>
<td>48370174</td>
<td>VERTEBRAL SPACER 17 x 30 x 4°</td>
</tr>
<tr>
<td>48370184</td>
<td>VERTEBRAL SPACER 18 x 30 x 4°</td>
</tr>
<tr>
<td>Reference</td>
<td>Description</td>
</tr>
<tr>
<td>------------</td>
<td>------------------------------------------</td>
</tr>
<tr>
<td>48389500</td>
<td>Spacer MIS inserter straight</td>
</tr>
<tr>
<td>48389550</td>
<td>Spacer MIS inserter angled</td>
</tr>
<tr>
<td>48389200</td>
<td>TL spacer support</td>
</tr>
<tr>
<td>48389250</td>
<td>TL spacer graft compactor</td>
</tr>
<tr>
<td>48389300</td>
<td>TL spacer impactor straight</td>
</tr>
<tr>
<td>48389350</td>
<td>TL spacer impactor angled</td>
</tr>
<tr>
<td>48389407</td>
<td>TL spacer trial 7</td>
</tr>
<tr>
<td>48389408</td>
<td>TL spacer trial 8</td>
</tr>
<tr>
<td>48389409</td>
<td>TL spacer trial 9</td>
</tr>
<tr>
<td>48389410</td>
<td>TL spacer trial 10</td>
</tr>
<tr>
<td>48389411</td>
<td>TL spacer trial 11</td>
</tr>
<tr>
<td>48389412</td>
<td>TL spacer trial 12</td>
</tr>
<tr>
<td>48389413</td>
<td>TL spacer trial 13</td>
</tr>
<tr>
<td>48389414</td>
<td>TL spacer trial 14</td>
</tr>
<tr>
<td>48352015</td>
<td>TL spacer trial 15</td>
</tr>
<tr>
<td>48352016</td>
<td>TL spacer trial 16</td>
</tr>
<tr>
<td>48389417</td>
<td>TL spacer trial 17</td>
</tr>
<tr>
<td>48389418</td>
<td>TL spacer trial 18</td>
</tr>
</tbody>
</table>
IMPORTANT PRODUCT INFORMATION FOR
STRYKER SPINE AVS® TL PEEK SPACERS

DESCRIPTION
The AVS® TL PEEK Spacers are intended for use as an aid in spinal fixation. They are offered in both parallel (0°) and wedge (4°) shapes. The hollow implant has serrations on the top and bottom which are designed to help with fixation. It is offered in two medial/lateral widths, 25 & 30mm, and a variety of heights ranging from 7mm to 18mm.

MATERIAL
All components of all AVS® PEEK Spacers systems are manufactured out of the following materials:
• Implant: Polyetheretherketone (PEEK) (ASTM F2026)
• Radiopaque markers: Tantalum (ASTM F560)

INDICATIONS
The Stryker Spine AVS® TL PEEK Spacers are intervertebral body fusion devices indicated for use with autograft and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft when the subject device is used as an adjunct to fusion in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1.

DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy.

Additionally, the AVS® TL PEEK Spacers can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis.

The AVS® TL Pek Spacers are to be implanted via posterior approach.

The AVS® TL PEEK Spacers are intended to be used with supplemental fixation systems that have been cleared for use in the lumbosacral spine (i.e., posterior pedicle screw and rod systems).

GENERAL CONDITIONS OF USE
The implantation of intervertebral body fusion devices must be performed only by experienced spinal surgeons having undergone the necessary specific training in the use of such systems because this is a technically demanding procedure presenting a risk of serious injury to the patient.

The information contained in the Package Insert is necessary but not sufficient for the use of this device. This information is in no sense intended as a substitute for the professional judgment, skill and experience of the surgeon in careful patient selection, preoperative planning and device selection, knowledge of the anatomy and biomechanics of the spine, understanding of the materials and the mechanical characteristics of the implants used, training and skill in spinal surgery and the use of associated instruments for implantation, securing the patient’s cooperation in following an appropriately defined post-operative management program and conducting scheduled post-operative follow-up examinations.

CAUTION
• Federal (USA) law restricts this device to sale by or on the order of a physician (or properly licensed practitioner) with appropriate training or experience.
• Based on the fatigue testing results, the physician/surgeon must consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the intervertebral body fusion device.
• The implantation of the intervertebral body fusion device must be performed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient.
• Potential risks identified with the use of this intervertebral body fusion device, which may require additional surgery, include: device component fracture, loss of fixation, pseudoarthrosis (i.e. non-union), fracture of the vertebrae, neurological injury, and vascular or visceral injury.
• Specialized instruments are provided by STRYKER Spine and must be used to assure accurate implantation of the intervertebral body fusion device. While rare, intraoperative fracture or breakage of instruments can occur, instruments, which have experienced extensive use or extensive force, are more susceptible to fracture depending on the operative precaution, number of procedures, and disposal attention. Instruments must be examined for wear or damage prior to surgery. Instruments for implantation of the AVS® PEEK Spacers are provided non-sterile and must be sterilized prior to use.
• The components of the system should not be used with components of any other system or manufacturer. Any such use will negate the responsibility of Stryker Spine for the performance of the resulting mixed component implant.
• The AVS® PEEK Spacers have not been evaluated for safety and compatibility in the MR environment. The AVS® PEEK Spacers have not been tested for heating or migration in the MR environment.

INFECTION
Transient bacteremia can occur in daily life. Dental manipulation, endoscopic examination and other minor surgical procedures have been associated with transient bacteremia. To help prevent infection at the implant site, it may be advisable to use antibiotic prophylaxis before and after such procedures.

INSTRUMENTS
Instruments are provided by STRYKER Spine and must be used to assure accurate implantation of the device. While rare, intraoperative fracture or breakage of instruments can occur. Instruments which have experienced extensive use or extensive force are more susceptible to fracture depending on the operative precaution, number of procedures, disposal attention. Instruments must be examined for wear or damage prior to surgery.

REUSE
Never reuse or re-implant surgical implants. These could become contaminated resulting in infection. In addition, even though the device appears undamaged, it may have small defects which could compromise structural integrity reducing its service life and/or leading to patient injury.

Surgeons must verify that the instruments are in good condition and operating order prior to use during surgery.

HANDLING
Correct handling of the implant is extremely important. The operating surgeon must avoid notching or scratching the device.

ALLERGY AND HYPERSENSITIVITY TO FOREIGN BODIES
When hypersensitivity is suspected or proven, it is highly recommended that the tolerance of the skin to the materials that make up the implants be checked before they are implanted.

CONTRA-INDICATIONS
Contraindications may be relative or absolute. The choice of a particular device must be carefully weighed against the patient’s overall evaluation. Circumstances listed below may reduce the chances of a successful outcome:
• The AVS® PEEK Spacers should not be implanted in patients with an active infection at the operative site.
• The AVS® PEEK Spacers are not intended for use except as indicated.
• Marked local inflammation.
• Any abnormality present which affects the normal process of bone remodeling including, but not limited to, severe osteoporosis involving the spine, bone absorption, osteopenia, primary or metastatic tumors involving the spine, active infection at the site or certain metabolic disorders affecting osteogenesis.
• Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care.
• Open wounds.
• Pregnancy.
• Inadequate tissue coverage over the operative site.
• Any neuromuscular deficit which places an unsafe load level on the device during the healing period.
• Obesity. An overweight or obese patient can produce loads on the spinal system which can lead to failure of the fixation of the device or to failure of the device itself. Obesity is defined according to the W.H.O. standards.
The surgical indication and the choice of implants

PRE-OPERATIVE PRECAUTIONS

- Those without a previous surgery.
- Have different clinical outcomes compared to those with a previous surgery.
- May be considered only as a delaying technique or treatment for diseased patients with degenerative disease, elevation of white blood cell count (WBC), or marked left shift in the WBC differential count.
- Prior fusion at the levels to be treated

These contra-indications can be relative or absolute and must be taken into account by the physician when making his decision. The above list is not exhaustive. Surgeons must discuss the relative contraindications with the patients.

INFORMATION FOR PATIENTS

The surgeon must discuss all physical and psychological limitations inherent to the use of the device with the patient. This includes the rehabilitation regimen, physical therapy, and wearing an appropriate orthosis as prescribed by the physician. Particular discussion should be directed to the issues of premature weight bearing, activity levels, and the necessity for periodic medical follow-up.

The surgeon must warn the patient of the surgical risks and make them aware of possible adverse effects.

The surgeon must warn the patient that the device cannot and does not replicate the flexibility, strength, reliability or durability of normal healthy bone, that the implant can break or become damaged as a result of strenuous activity or trauma, and that the device may need to be replaced in the future. If the patient is involved in an occupation or activity which applies inordinate stress upon the implant (e.g., substantial walking, running, lifting, or muscle strain) the surgeon must advise the patient that resultant forces can cause failure of the device. Patients who smoke have been shown to have an increased incidence of nonunions. Surgeries must be made prior to material implantation.

The size and shape of the bone structures determine the size, shape and type of the implants. Once implanted, the implants are subjected to stresses and strains. These repeated stresses on the implants must be taken into consideration by the surgeon at the time of the choice of the implant, during implantation as well as in the post-operative follow-up period. Indeed, the stresses and strains on the implants may cause fatigue, fracture or deformation of the implants, before the bone graft has become completely consolidated. This may result in further side effects or necessitate the early removal of the osteosynthesis device.

INTRA-OPERATIVE PRECAUTIONS

- The insertion of the implants must be carried out using instruments designed and provided for this purpose and in accordance with the specific implantation instructions for each implant. Those detailed instructions are provided in the surgical technique brochure supplied by STRYKER Spine.
- Discard all damaged or mishandled implants.
- Never reuse an implant, even though it may appear undamaged.

PATIENT CARE FOLLOWING TREATMENT

Prior to adequate maturation of the fusion mass, implanted spinal instrumentation may need additional help to accommodate full load bearing. External support may be recommended by the physician from two to four months postoperatively or until x-rays or other procedures confirm adequate maturation of the fusion mass; external immobilization by bracing or casting may be employed. Surgeons must instruct patients regarding appropriate and restricted activities during consolidation and maturation for the fusion mass in order to prevent placing excessive stress on the implants which may lead to fixation or implant failure and accompanying clinical problems. Surgeons must instruct patients to report any unusual changes of the operative site to his/her physician. The physician must closely monitor the patient if a change at the site has been detected.

ADVERSE EFFECTS

Include but are not limited to:

- Late bone fusion or no visible fusion mass and pseudarthrosis;
- While the expected life of spinal implant components is difficult to estimate, it is finite. These components are made of foreign materials which are placed within the body for the potential fusion of the spine and reduction of pain. However, due to the many biological, mechanical and physicochemical factors which affect these devices but cannot be evaluated in vivo, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone;
- Superficial or deep-set infection and inflammatory phenomena;
- Allergic reactions to the implanted materials, although uncommon, can occur;
- Decrease in bone density due to stress shielding;
- Dural leak requiring surgical repair;
- Peripheral neuropathies, nerve damage, heterotopic bone formation and neurovascular compromise, including paralysis, loss of bowel or bladder function, or foot-drop may occur.
- Cessation of growth of the fused portion of the spine;
- Loss of proper spinal curvature, correction, height and/or reduction;
- Delayed Union or Nonunion: Internal fixation appliances are load sharing devices which are used to obtain alignment until normal healing occurs. In the event that healing is delayed, does not occur, or failure to immobilize the delayed/nonunion results, the implant will be subject to excessive and repeated stresses which can eventually cause loosening, bending or fatigue fracture. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. If a nonunion develops or if the implants loosen, bend or break, the device(s) must be revised or removed immediately before serious injury occurs;
- Neurological and dural dura mater lesions from surgical trauma;
- Early loosening may result from inadequate initial fixation, latent infection, premature loading of the device or trauma. Late loosening may result from trauma, infection, biological complications or mechanical problems, with the subsequent possibility of bone erosion, or pain.
- Serious complications may occur with any spinal surgery. These complications include, but are not limited to, genitourinary disorders;
gastrointestinal disorders; vascular disorders, including thrombus; bronchopulmonary disorders, including emboli; bursitis, hemorrhage, myocardial infarction, infection, paralysis or death.

- Inappropriate or improper surgical placement of this device may cause distraction or stress shielding of the graft or fusion mass. This may contribute to failure of an adequate fusion mass to form.
- Intraoperative fissure, fracture, or perforation of the spine can occur due to implantation of the components. Postoperative fracture of bone graft or the intervertebral body above or below the level of surgery can occur due to trauma, the presence of defects, or poor bone stock.

Adverse effects may necessitate reoperation or revision.

The surgeon must warn the patient of these adverse effects as deemed necessary.

REMOVAL
If fusion/bone graft growth occurs, the device will be deeply integrated into the bony tissues. As a result, the AVS® PEEK Spacers are not intended to be removed unless the management of a complication or adverse event requires the removal. Any decision by a physician to remove the device should take into consideration such factors as:

- The risk to the patient of the additional surgical procedure as well as the difficulty of removal.
- Migration of the implant, with subsequent pain and/or neurological, articular or soft tissue lesions
- Pain or abnormal sensations due to the presence of the implants
- Infection or inflammatory reactions
- Reduction in bone density due to the different distribution of mechanical and physiological stresses and strains

PACKAGING
- The implants are single use devices, provided non-sterile, and delivered in individual packages. The typical packaging used is clear plastic tubes and polyethylene bags. The packages must be intact at the time of receipt.
- Implants must be removed entirely from their packaging prior to sterilization.
- The implants may also be supplied as a complete set: implants and instruments are arranged on trays and placed in specially designed storage boxes

FURTHER INFORMATION
A surgical technique brochure is available on request through your STRYKER representative or directly from STRYKER Spine. Users with brochures that are over two years old at the time of surgery are advised to ask for an updated version.

COMPLAINTS
Any health professional having a complaint or grounds for dissatisfaction relating to the identity, quality, durability, reliability, safety, effectiveness or performance of a device should notify STRYKER Spine or its representative. Moreover, if a device has malfunctioned, or is suspected of having malfunctioned, STRYKER Spine or its representative must be advised immediately.

If a STRYKER Spine product has ever worked improperly and could have caused or contributed to the death of or serious injury to a patient, the distributor or STRYKER Spine must be informed as soon as possible by telephone, fax or in writing.

For all complaints, please include the name and reference along with the batch number of the component(s), your name and address and an exhaustive description of the event to help STRYKER Spine understand the causes of the complaint.

For further information regarding services, please contact:

STRYKER Spine
2 Pearl Court, Allendale, NJ 07401-1677 USA
Tel: +1-201-749-8000
A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate the breadth of Stryker product offerings. A surgeon must always refer to the package insert, product label and/or instructions for use before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

Stryker Corporation or its divisions or other corporate affiliated entities own, use or have applied for the following trademarks or service marks: AVS, Stryker. All other trademarks are trademarks of their respective owners or holders.

Not intended for promotional or marketing use outside the United States.

TLAPT-ST-1_Rev7_11833
SC/GS 09/16
Copyright © 2016 Stryker
Printed in USA