stryker

AVS® AS PEEK

Spacer System

Surgical technique guide

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Surgical technique steps

Product catalog

This publication sets forth detailed recommended procedures for using the AVS AS PEEK Spacer. It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required.

Surgical technique

Introduction

This surgical technique guide describes usage of the AVS AS PEEK Spacer as an interbody fusion device (IBD) of the cervical Spine (C2-T1). The AVS AS PEEK Spacers are intended to be used with autogenous bone graft. For usage of the device as a vertebral body replacement in the thoraco-lumbar Spine (T1-L5), please reference the AVS ASL Surgical Technique Guide (Ref #: IBASLST05112).

Exposure

Pre-operative planning
It is important to view pre-operative films so that the placement of the incision is accurate. Surgical approach (left or right sided) is determined according to surgeon preference, patient anatomy, and patient pathology.

Approach
The Reliance C Instruments can be used in either a left or right sided approach to the cervical Spine. Blunt dissection is used to expose the anterior cervical Spine and a self-retaining retractor is used to elevate the longus colli muscles and provide visualization and exposure.

Incision
An incision is made at the desired disc level. If possible, a transverse skin incision parallel to the skin creases of the neck is recommended for cosmetic purposes. Otherwise, a vertical midline incision may be used (See Figure 1).

A K-Wire may be used to confirm that the correct level and midline of the disc have been exposed.

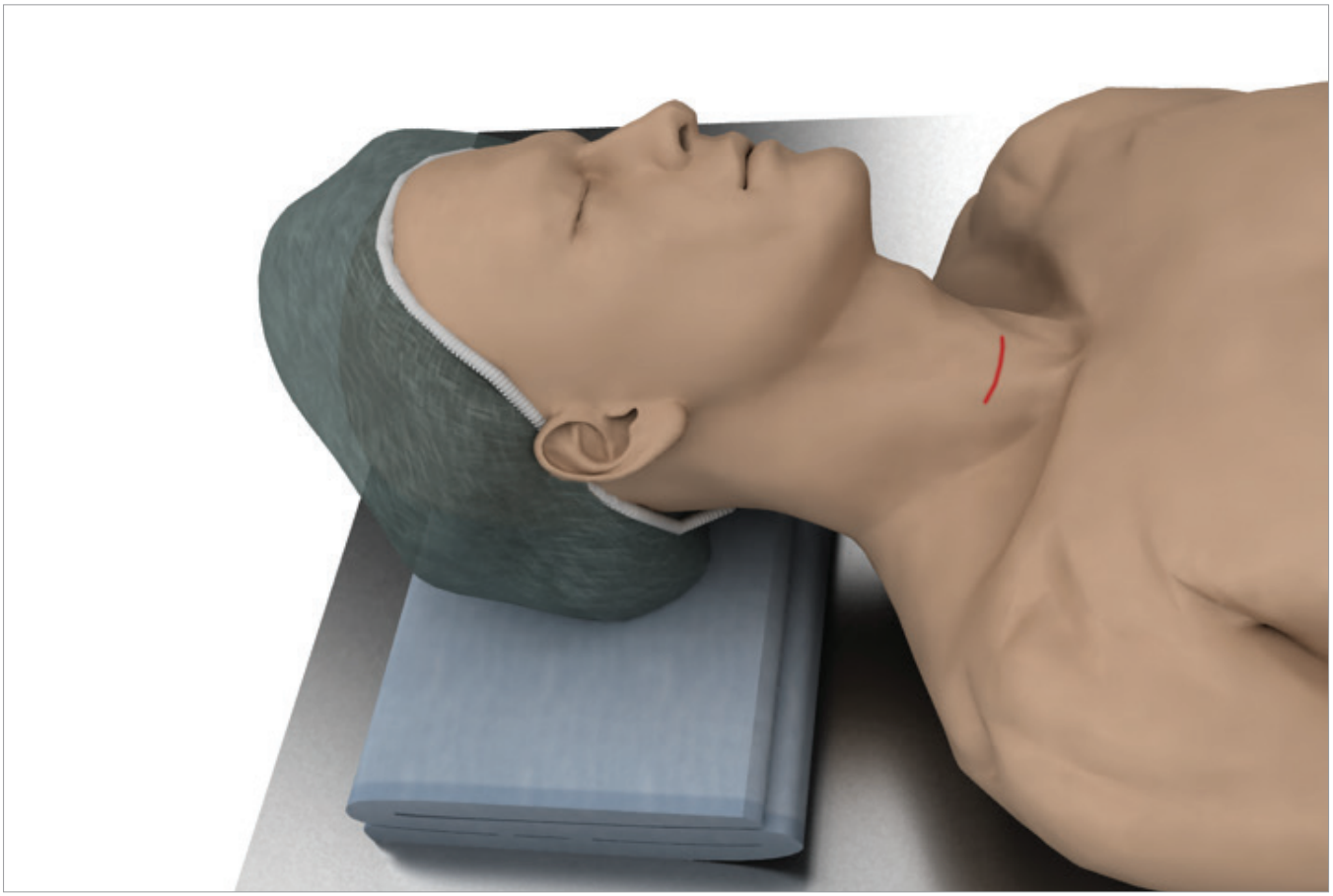


Figure 1
The patient should be positioned in the supine position with the head stabilized in extension and rotated slightly away from the site of the approach. If possible, a transverse incision, parallel to the skin creases in the neck, is recommended.

Step 2

Discectomy

Pre-operative planning
An anterior annulotomy is performed and should be wide enough to allow insertion of the implant (See Figure 2). The AVS AS PEEK Spacer is offered in 14mm and 16mm medial-lateral widths. It is recommended that the appropriate width be selected based on pre-operative measurements.

Using short rongeurs, pituitaries, curettes and/or kerrisons, a discectomy is subsequently performed until an appropriate amount of the disc material has been removed, the posterior longitudinal ligament is exposed, and decompression is achieved.

Distraction may be performed using the Parallel Pin Distractor, which is designed to facilitate both a left and right sided approach thanks to a 360° rotation arm. Curettes are used to elevate additional disc material from the endplates, taking care not to damage the lateral annulus.

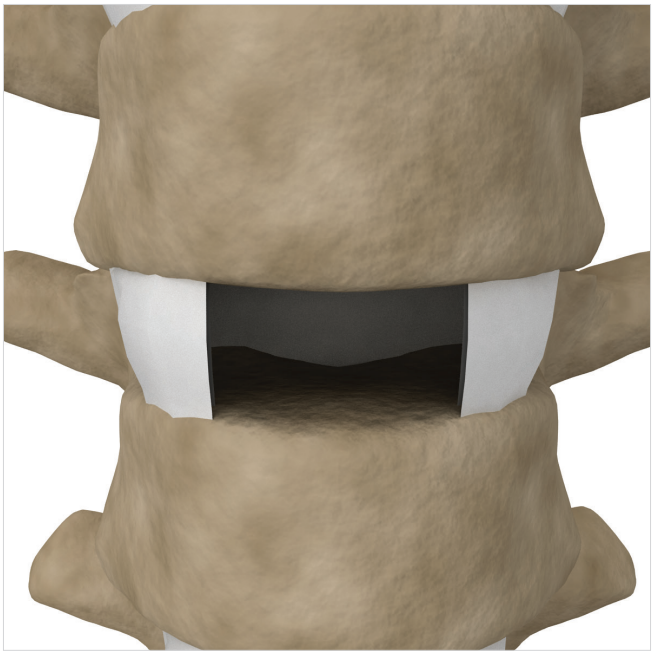


Figure 2

Reliance C Parallel Pin Distractor

Endplate preparation

Straight and angled curettes or rasps should be translated parallel to the endplates until sufficient decortication is achieved (See Figure 3). The curettes can be used to "feel" the endplates and to determine whether soft tissue remains.

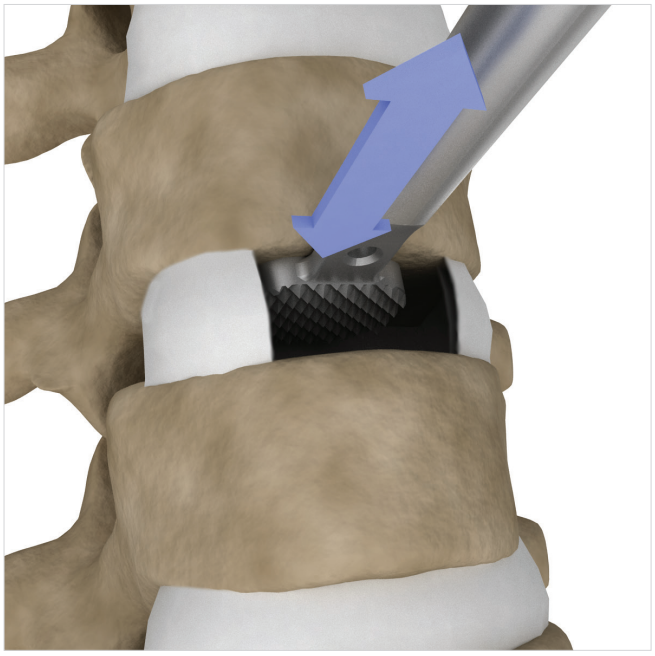


Figure 3

Reliance C Rasp

Step 4

Trialing

It is recommended that preliminary measurements are taken to help determine the appropriate trial size.

A trial is placed in the intra-discal space to determine the appropriate implant size (See Figure 4). Properly sized trials should fit flush within the confines of the anterior cortex, posterior cortex and unconvertebral joints, producing a tight interface with both the superior and inferior endplates. Care should be taken not to use a trial that is too large for the disc space, for this may result in overdistraction. Since the overall shape and height of the AVS AS Trials mimic the profiles of the implants themselves, select the AVS PEEK Spacer based on the trial size.

Note: The AVS AS Trials are only available in 4° of lordosis to help prevent overdistraction of the posterior portion of the vertebral bodies that a parallel trial would cause in patients requiring an implant with 4° of lordosis. If a 0° trial is needed, non footprint-specific 0° trials may be found in the Reliance C Instrumentation tray.

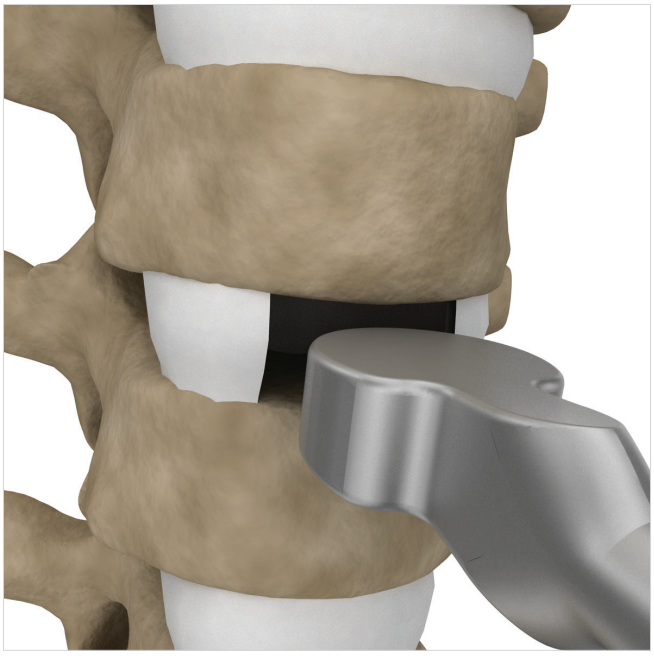


Figure 4

Reliance C Trial

Implant preparation

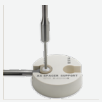
Once the appropriately sized AVS AS PEEK Spacer is identified, it can be assembled to the AVS AS Inserter by positioning the collet tip in the insertion hole with the lever lifted. Subsequent depression of the lever will cause the collet tip to expand, thereby providing a rigid and stable attachment to the spacer.

The AVS AS Graft Support and Graft Compactor have been provided to assist in packing the autogenous bone graft into the graft chamber of the AVS AS PEEK Spacer.

By placing an AVS AS PEEK Spacer assembled to an AVS AS Inserter into the AVS AS Graft Support, the autogenous bone graft material can be packed into the graft chamber using the Graft Compactor.

Note: It is important to regularly lubricate the proximal and distal areas of the AVS AS Inserter with instrument milk (commonly found in hospitals) to prevent the lever and collet tip from binding.

AVS Graft Support
AVS Graft Compactor



AVS AS Inserter

Step 6

Implant insertion and positioning

The AVS AS PEEK Spacer is introduced into the disc space, centered at the midline, and tapped into place (See Figure 5). Axial compression to the AVS AS PEEK Spacer should then be applied.

There are three vertical tantalum markers embedded in the implant to help visually confirm its position under fluoroscopy (See Figure 6).

Note: The anterior markers are 2.5mm long and are located 2mm from the anterior edge.

The posterior marker is 1mm long and is located 1mm from the posterior edge.

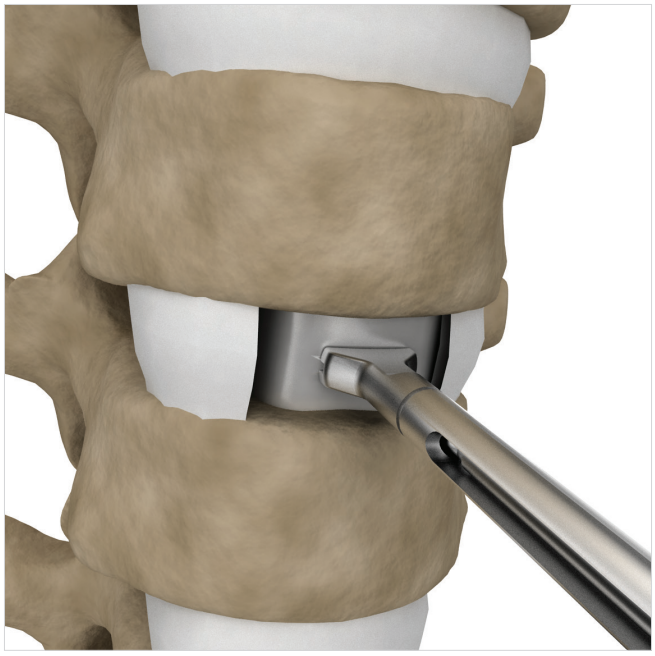


Figure 5

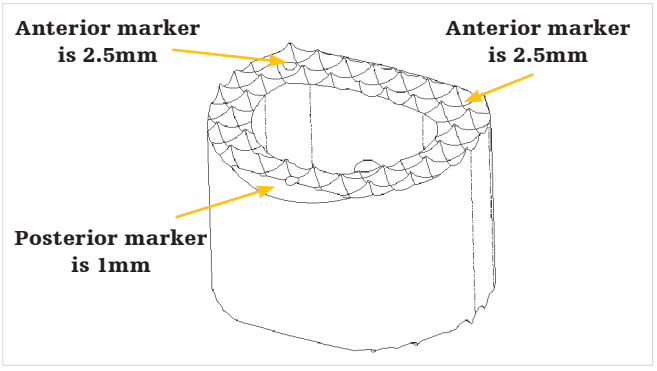


Figure 6

Closure

If necessary, the position of the implant can be adjusted to its final position (See Figure 7) using the AVS AS Impactor.

The application of supplemental fixation, such as Stryker Spine's cervical plate or rod systems (Aviator, Reflex Hybrid, Reflex Zero Profile, DynaTran, or OASYS), is recommended.

The operative site should then be checked for any fragments or extraneous soft tissue. The surgical site may then be closed in the normal fashion.

Implant Removal

To remove the implant, position the collet tip of the AVS AS Inserter in the insertion hole with the lever lifted. Subsequent depression of the lever will cause the collet tip to expand, thereby providing a rigid and stable attachment to the spacer. With the AVS AS Inserter connected to the implant, gently remove the implant from the disc space.

Note: It is recommended that the Parallel Pin Distractor and Pins from the Reliance C instrumentation set be used to distract the disc space before removing the cage.

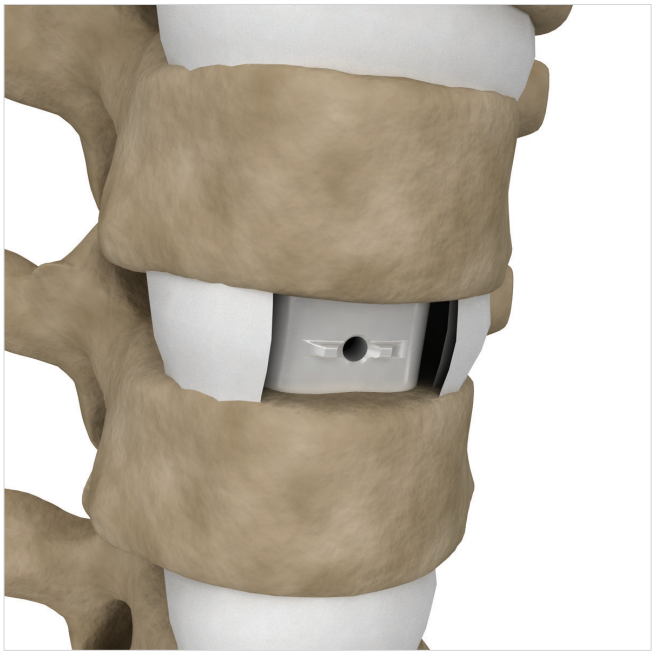


Figure 7

AVS AS Impactor

Product catalog

Catalog #	Description
48322040	AVS AS PEEK Spacer, 12x14mm, 4mm, 0°
48322050	AVS AS PEEK Spacer, 12x14mm, 5mm, 0°
48322060	AVS AS PEEK Spacer, 12x14mm, 6mm, 0°
48322070	AVS AS PEEK Spacer, 12x14mm, 7mm, 0°
48322080	AVS AS PEEK Spacer, 12x14mm, 8mm, 0°
48322090	AVS AS PEEK Spacer, 12x14mm, 9mm, 0°
48322100	AVS AS PEEK Spacer, 12x14mm, 10mm, 0°
48322110	AVS AS PEEK Spacer, 12x14mm, 11mm, 0°
48322120	AVS AS PEEK Spacer, 12x14mm, 12mm, 0°
48322044	AVS AS PEEK Spacer, 12x14mm, 4mm, 4°
48322054	AVS AS PEEK Spacer, 12x14mm, 5mm, 4°
48322064	AVS AS PEEK Spacer, 12x14mm, 6mm, 4°
48322074	AVS AS PEEK Spacer, 12x14mm, 7mm, 4°
48322084	AVS AS PEEK Spacer, 12x14mm, 8mm, 4°
48322094	AVS AS PEEK Spacer, 12x14mm, 9mm, 4°
48322104	AVS AS PEEK Spacer, 12x14mm, 10mm, 4°
48322114	AVS AS PEEK Spacer, 12x14mm, 11mm, 4°
48322124	AVS AS PEEK Spacer, 12x14mm, 12mm, 4°

Catalog #	Description
48324040	AVS AS PEEK Spacer, 14x16mm, 4mm, 0°
48324050	AVS AS PEEK Spacer, 14x16mm, 5mm, 0°
48324060	AVS AS PEEK Spacer, 14x16mm, 6mm, 0°
48324070	AVS AS PEEK Spacer, 14x16mm, 7mm, 0°
48324080	AVS AS PEEK Spacer, 14x16mm, 8mm, 0°
48324090	AVS AS PEEK Spacer, 14x16mm, 9mm, 0°
48324100	AVS AS PEEK Spacer, 14x16mm, 10mm, 0°
48324110	AVS AS PEEK Spacer, 14x16mm, 11mm, 0°
48324120	AVS AS PEEK Spacer, 14x16mm, 12mm, 0°
48324044	AVS AS PEEK Spacer, 14x16mm, 4mm, 4°
48324054	AVS AS PEEK Spacer, 14x16mm, 5mm, 4°
48324064	AVS AS PEEK Spacer, 14x16mm, 6mm, 4°
48324074	AVS AS PEEK Spacer, 14x16mm, 7mm, 4°
48324084	AVS AS PEEK Spacer, 14x16mm, 8mm, 4°
48324094	AVS AS PEEK Spacer, 14x16mm, 9mm, 4°
48324104	AVS AS PEEK Spacer, 14x16mm, 10mm, 4°
48324114	AVS AS PEEK Spacer, 14x16mm, 11mm, 4°
48324124	AVS AS PEEK Spacer, 14x16mm, 12mm, 4°

Instruments

Catalog #	Description
48329000	AVS AS Inserter
48329060	AVS AS Spacer Impactor Straight
48329100	AVS AS Graft Support
48350923	AVS AS Graft Compactor
48329050	AVS AS Impactor
48329204	AVS AS Trial, 12 x 4mm
48329205	AVS AS Trial, 12 x 5mm
48329206	AVS AS Trial, 12 x 6mm
48329207	AVS AS Trial, 12 x 7mm
48329208	AVS AS Trial, 12 x 8mm
48329209	AVS AS Trial, 12 x 9mm
48329210	AVS AS Trial, 12 x 10mm

Catalog #	Description
48329211	AVS AS Trial, 12 x 11mm
48329212	AVS AS Trial, 12 x 12mm
48329404	AVS AS Trial, 14 x 4mm
48329405	AVS AS Trial, 14 x 5mm
48329406	AVS AS Trial, 14 x 6mm
48329407	AVS AS Trial, 14 x 7mm
48329408	AVS AS Trial, 14 x 8mm
48329409	AVS AS Trial, 14 x 9mm
48329410	AVS AS Trial, 14 x 10mm
48329411	AVS AS Trial, 14 x 11mm
48329412	AVS AS Trial, 14 x 12mm
48329414	AVS AS PEEK Container

Catalog #	Description
48360003	Reliance C Container
48365000	Reliance C Paddle Distractor
48365020	Reliance C Parallel Pin Distractor
48365110	Reliance C Cobb Spinal Elevator
48365204	Reliance C Double Sided Rasp, 4mm
48365205	Reliance C Double Sided Rasp, 5mm
48365206	Reliance C Double Sided Rasp, 6mm
48365207	Reliance C Double Sided Rasp, 7mm
48365208	Reliance C Double Sided Rasp, 8mm
48365209	Reliance C Double Sided Rasp, 9mm
48365210	Reliance C Double Sided Rasp, 10mm
48365211	Reliance C Double Sided Rasp, 11mm

Catalog #	Description
48365212	Reliance C Double Sided Rasp, 12mm
48365304	Reliance C General Trial, 4mm
48365305	Reliance C General Trial, 5mm
48365306	Reliance C General Trial, 6mm
48365307	Reliance C General Trial, 7mm
48365308	Reliance C General Trial, 8mm
48365309	Reliance C General Trial, 9mm
48365310	Reliance C General Trial, 10mm
48365311	Reliance C General Trial, 11mm
48365312	Reliance C General Trial, 12mm
48365320	Reliance C Flat Tamp

Instructions for use

IFU Reference Number: NORC115M00 Rev 04

Important product information for AVS® AS PEEK Spacer

Non-sterile Product Interbody Application

Description

The Stryker Spine AVS® AS PEEK Spacer is a hollow, ring-shaped PEEK Optima® LT1 cage with three Tantalum marker pins. The cages are offered in a variety of lengths, heights, and lordotic angles to adapt to varying patient anatomies. The hollow, ring-shaped implants have serrations on the top and bottom surfaces of the cage. The hollow space of the implant is intended to hold bone graft material. The use of the AVS® AS PEEK Spacer as an interbody fusion device (IBD) of the cervical Spine (from C2-C3 to C7-T1) is limited to the listed sizes only:

Part number	Size (Height x AP x ML x °)
48322040	4 x 12 x 14mm x 0°
48322050	5 x 12 x 14mm x 0°
48322060	6 x 12 x 14mm x 0°
48322070	7 x 12 x 14mm x 0°
48322080	8 x 12 x 14mm x 0°
48322090	9 x 12 x 14mm x 0°
48322100	10 x 12 x 14mm x 0°
48322110	11 x 12 x 14mm x 0°
48322120	12 x 12 x 14mm x 0°
48322044	4 x 12 x 14mm x 4°
48322054	5 x 12 x 14mm x 4°
48322064	6 x 12 x 14mm x 4°
48322074	7 x 12 x 14mm x 4°
48322084	8 x 12 x 14mm x 4°
48322094	9 x 12 x 14mm x 4°
48322104	10 x 12 x 14mm x 4°
48322114	11 x 12 x 14mm x 4°
48322124	12 x 12 x 14mm x 4°
48324040	4 x 14 x 16mm x 0°
48324050	5 x 14 x 16mm x 0°
48324060	6 x 14 x 16mm x 0°
48324070	7 x 14 x 16mm x 0°
48324080	8 x 14 x 16mm x 0°
48324090	9 x 14 x 16mm x 0°
48324100	10 x 14 x 16mm x 0°
48324110	11 x 14 x 16mm x 0°
48324120	12 x 14 x 16mm x 0°
48324044	4 x 14 x 16mm x 4°
48324054	5 x 14 x 16mm x 4°
48324064	6 x 14 x 16mm x 4°
48324074	7 x 14 x 16mm x 4°
48324084	8 x 14 x 16mm x 4°
48324094	9 x 14 x 16mm x 4°
48324104	10 x 14 x 16mm x 4°
48324114	11 x 14 x 16mm x 4°
48324124	12 x 14 x 16mm x 4°

Indications

The Stryker Spine AVS® AS PEEK Spacers are indicated for use in cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from the C2-C3 disc to the C7-T1 disc. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The AVS® AS PEEK Spacers are to be used with autogenous bone graft and implanted via an open, anterior approach.

The AVS® AS PEEK Spacer is intended to be used with supplemental fixation systems that have been cleared for use in the cervical Spine. This cervical device is to be used in patients who have had six weeks of non-operative treatment.

Vertebral body replacement application

Description

The AVS® AS PEEK Spacer is intended for use as an aid in spinal fixation. It is offered in both parallel (0°) and wedge (4° & 8°) shapes. These shapes are available in a variety of footprint sizes. The hollow, ring shaped implant has serrations on the top and bottom for fixation.

Indications

The Stryker Spine AVS® AS PEEK Spacer is a vertebral body replacement indicated for use in the thoraco-lumbar Spine T1-L5 to replace a collapsed, damaged or unstable vertebral body resected or excised during total and partial vertebrectomy procedures due to tumor or trauma, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. It is recommended to pack bone graft material inside the implant.

The Stryker Spine AVS® AS PEEK Spacer is intended for use with supplemental fixation. The supplemental fixation systems that may be used with the AVS® AS PEEK Spacer include, but are not limited to, Stryker Spine plate or rod systems (XIA, Spiral Radius 90D and Trio).

Material

All components of the system are manufactured out of the following materials:

- Polyetheretherketone (PEEK) (ASTM F2026)
- Tantalum (ASTM F560)

Instructions for use

General conditions of use
Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and limitation of the spinal device. Knowledge of surgical techniques, proper reduction, selection and placement of implants, and pre- and post-operative patient management are other considerations essential to a successful surgical outcome. Consult the medical literature for information regarding proper surgical techniques, precautions, and potential adverse effects associated with spinal fixation surgery.

The implantation of the device 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.

Caution

- Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.
- The implantation of the 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 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.
- Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes as compared to those without a previous surgery.
- The device is designed to be used with a supplemental fixation system.
- The AVS® AS PEEK Spacers have not been evaluated for safety and compatibility in the MR environment. The AVS® AS PEEK Spacers have not been tested for heating or migration in the MR environment.
- Specialized 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, and disposal attention. Instruments must be examined for wear or damage prior to surgery. Instruments for implantation of the AVS® AS PEEK Spacers are provided non-sterile and must be sterilized prior to use.

Contra-indications
Contraindications can 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® AS PEEK Spacer should not be implanted in patients with an active infection at the operative site.
- The AVS® AS 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.
- A condition of senility, mental illness, or substance abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.
- Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests must be made prior to material selection or implantation.
- Other medical or surgical conditions that could preclude the potential benefit of surgery, such as congenital abnormalities, immunosuppressive disease, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or marked left shift in the WBC differential count, must be carefully analyzed before surgery.
- Prior fusion at the levels to be treated.
- Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and/or fixation to the devices.

- Rapid joint disease, bone absorption, osteopenia, osteomalacia, and/or osteoporosis. Osteoporosis or osteopenia are relative contraindications, since this condition may limit the degree of obtainable correction and/or the amount of mechanical fixation.
- Anytime implant utilization would interfere with anatomical structures or physiological performance.

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.

Pre-operative precautions

The surgical indication and the choice of implants must take into account certain important criteria such as:

- Patients involved in an occupation or activity that applies excessive loading upon the implant (e.g., substantial walking, running, lifting, or muscle strain) may be at increased risk for failure of the fusion and/or the device.
- Surgeons must instruct patients in detail about limitations of the implant, including, but not limited to, the impact of excessive loading through patient weight or activity, and be taught to govern their activities accordingly. The procedure will not restore function to the level expected with a normal, healthy Spine, and the patient should not have unrealistic functional expectations.
- A condition of senility, mental illness, chemical dependence or alcoholism. These conditions among others may cause the patients to ignore certain necessary limitations and precautions in the use of the implant, leading to failure and other complications.
- Foreign body sensitivity. Where material sensitivity is suspected appropriate tests should be made prior to material implantation.
- Surgeons must advise such patients who smoke have been shown to have an increased incidence of non-unions. Such patients must be advised of this fact and warned of the potential consequences.
- Care must be taken to protect the components from being marred, nicked, or notched as a result of contact with metal or abrasive objects.
- Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

The choice of implants

The choice of proper shape, size and design of the implant for each patient is crucial to the success of the surgery. The surgeon is responsible for this choice, which depends on each patient.

Patients who are overweight may be responsible for additional stresses and strains on the device which can speed up implant fatigue and/or lead to deformation or failure of the implants.

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 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

The surgeon should warn the patient of all the potential side effects. They 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;

- Peripheral neuropathies, nerve damage, heterotopic bone formation and neurovascular compromise, including paralysis, loss of bowel or bladder function, or foot-drop may occur.
- 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;
- Neurological and spinal dura mater lesions from surgical trauma;
- Dural leak requiring surgical repair;
- 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;
- Pain, discomfort, or abnormal sensations due to the presence of the device;
- 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. 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® AS PEEK Spacer is 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 of 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.

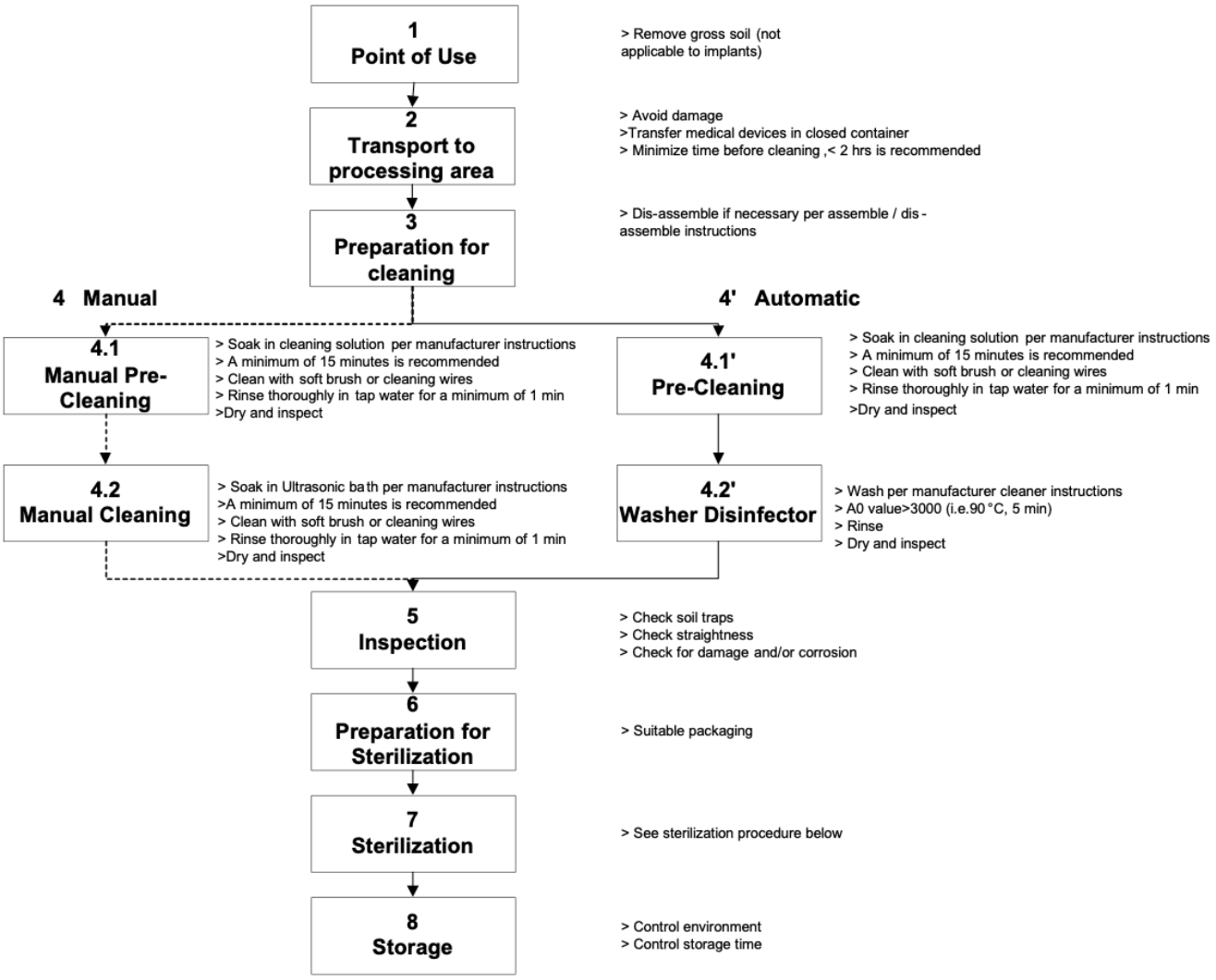
The Spacer Inserter will be used to hold and disengage the device from the vertebrae.

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

Pre-celaing / Cleaning and sterilization procedure recommended for non-sterile medical device

For safety reasons, non-sterile devices must be pre-cleaned, cleaned and sterilized prior to use following the sequence of steps described in the following chart.



Sterilization Procedure Recommended For Non-Sterile Medical Devices Including Implants

Medical Devices should be sterilized in their container by means of moist heat steam sterilization in an autoclave in accordance with standard hospital procedure. The recommended sterilization methods suggested has been validated according to ISO 17655-1 to obtain a Sterility Assurance Level (SAL) of 10-6.

Steam Sterilization with Commercially Available Sterilization Wrap

The following ranges of parameters have been validated on wrapped containers in fully-loaded autoclaves.

Minimal sterilization conditions:

Prevacuum (Porous Load) steam sterilization autoclave:

- Temperature: 132°C (270°F)
- Exposure Time: 4 Minutes
- Dry Time: 45 Minutes

Caution: For products being used in the United States (USA), an FDA cleared sterilization wrap is required to wrap the sterilization containers.

The autoclave must be validated by the hospital and regularly checked to guarantee the recommended sterilization temperature is reached for the entire exposure time.

If after having followed this sterilization method there is still water in the sterilization containers or on/inside the device, the device must be dried and sterilization repeated. Drying times for implants processed in containers and wrapped trays can vary depending upon the type of packaging, type of implants, type of sterilizer, and total load. A minimum dry time of 45 minutes is recommended, but to avoid wet packs, extended dry

times greater than 45 minutes may be needed. See Extended Dry Time Table in the Stryker Spine Instructions for: Cleaning, Sterilization, Inspection, and Maintenance of Non-Sterile Medical Devices NSRDEV_RG. For large loads verification of dry times by the health care provider is recommended.

Caution: Stryker Spine has not validated and does not recommend Flash Sterilization

Steam Sterilization with FDA-Cleared Rigid Containers Option:

In order to ensure proper sterilization of Stryker Spine devices when using the Aesculap SterilContainer (JN series) reusable, rigid sterilization containers, the information below must be followed:

1. Only the following Aesculap reusable rigid container configuration, FDA-cleared, shall be used in a pre-vacuum steam sterilization cycle for use in the USA:

- JN442 – Aesculap SterilContainer, Full Size, 6-inch height, Perforated Bottom
- JK489 – Aesculap SterilContainer, Full Size, 2000 Lid, Aluminum
- US994 – Filter Paper, 7 ½ inches Round, Single Use

2. Aesculap SterilContainer instructions for use must be followed. If questions arise regarding the use of the Aesculap SterilContainer reusable, rigid sterilization container, Stryker Spine recommends contacting Aesculap directly for guidance
3. Sterilization instructions:

a. No more than two (2) individual Stryker Spine tray inserts can be placed directly into the Aesculap SterilContainer (JN Series) reusable, rigid sterilization container (perforated bottom)

b. Stryker Spine devices must be placed in their designated locations within the tray inserts. Stryker Spine's single devices or modules/caddies/racks may be placed into an Aesculap basket (JF223R or similar) which can be loaded into the Aesculap SterilContainer reusable, rigid sterilization containers. NOTE: Devices must be placed such that individual devices are not stacked and remain in an open position to allow uniform exposure to steam.

c. Stryker Spine Container lids must be removed prior to use with the Aesculap reusable, rigid sterilization container

d. Stryker Spine devices were validated under the following USA sterilization parameters for a pre-vacuum, three pulse steam cycle:

- Temperature: 132°C (270°F)
- Exposure Time: 4 minutes
- Cycle Dry Time: 30 minutes

e. Reusable, rigid sterilization containers must not be stacked within the autoclave, as doing so may negatively impact ventilation and sterilization.

Note: Implants may be individually wrapped and sterilized.

Warning:

- Do not use solvents, abrasive cleaners, metal brushes, or abrasive pads. Cleaning agents with aldehydes, bromine, iodine, active chlorine, or chloride as the active ingredient are corrosive to stainless steel are not to be used.

The parameters identified in this document are the minimum for effective cleaning and sterilization of Stryker Spine implants. Stryker Spine does not recommend the use of high pH detergents, however if a detergent with high pH is used Stryker Spine recommends a pH neutralizer to ensure full removal of the high pH solution. In circumstances where sterilization temperature and exposure time required by the hospital is greater than the temperature and time recommended in this document, the effectiveness of the cycle for the purposes of sterilization is assured. However, extended cycle temperature and time may accelerate wear. Implants should be examined for wear or damage prior to use.

For additional information refer to Stryker Spine Instructions for: Cleaning, Sterilization, Inspection, and Maintenance of Non-Sterile Medical Devices NSRDEV_RG.

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.

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

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 give the name and reference along with the batch number of the component(s), your name and address and a complete description of the event to help Stryker Spine understand the causes of the complaint.

For further information or complaints, please contact:

Stryker Spine
2 Pearl Court,
Allendale, NJ 07401-1677 USA
Tel. 201-760-8000
http://www.Stryker.com

Instructions for use

IFU Number: NORCAVSIBD Rev 02

Important product information for Stryker Spine AVS® PEEK Spacers, AVS® AL, AVS® ALign, AVS® ARIA, AVS® Navigator, AVS® PL, AVS® UniLIF™, and AVS® TL | Non-Sterile

Description

AVS® AL (Anterior Large) and AVS® ALign PEEK Spacers

The AVS® AL (Anterior Large) and AVS® ALign PEEK Spacers are intended for use as interbody fusion devices. They are offered in a variety of lengths, heights and lordotic angles. The hollow, ring shaped implant has serrations on the top and bottom for fixation.

AVS® ARIA PEEK Spacers

The AVS® ARIA PEEK Spacers are intended for use as interbody fusion devices. They are offered in a variety of lengths, heights and lordotic angles. The hollow, oblong-shaped implant has serrations on the top and bottom for fixation.

AVS® Navigator PEEK Spacers

The AVS® Navigator PEEK Spacers are intended for use as interbody fusion devices. They are offered in a variety of lengths, heights and lordotic angles. The hollow implant has serrations on the top and bottom for fixation. Radiopaque markers have been embedded within the implant to help allow for visualization in radiographic images.

AVS® Partial Lumbar (PL) and AVS® UniLIF™ PEEK Spacers

The AVS® Partial Lumbar (PL) PEEK Spacers and AVS® UniLIF™ PEEK Spacers are intended for use as an aid in spinal fixation. This hollow, rectangular implant is offered in a variety of lengths, heights and lordotic angles to adapt to a variety of patient anatomies. It has serrations on the superior and inferior surfaces of the implant designed to help with fixation, an ergonomically shaped anterior edge, and a flat posterior edge. Radiopaque markers have been embedded within the implant to help allow for visualization in radiographic images.

AVS® TL PEEK Spacers

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

AVS® AL and AVS® ALign PEEK Spacers

The Stryker Spine AVS® AL and AVS® ALign PEEK Spacers are intervertebral body fusion devices indicated for use with autograft and/or allogenic 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® AL and AVS® ALign PEEK Spacers can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis.

The AVS® AL and AVS® ALign PEEK Spacers are to be implanted via anterior or anterolateral approach.

The AVS® AL and AVS® ALign PEEK Spacers are intended to be used with supplemental fixation systems that have been cleared for use in the lumbosacral spine.

AVS® ARIA PEEK Spacers

The Stryker Spine AVS® ARIA PEEK Spacers are intervertebral body fusion devices indicated for use with autograft and/or allogenic 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® ARIA PEEK Spacers can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis.

The AVS® ARIA PEEK Spacers are intended to be used with supplemental fixation systems that have been cleared for use in the lumbosacral spine.

AVS® Navigator PEEK Spacers

The Stryker Spine AVS® Navigator PEEK Spacers are intervertebral body fusion devices indicated for use with autograft and/or allogenic 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® Navigator PEEK Spacers can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis.

The AVS® Navigator PEEK Spacers are to be implanted via a posterior or posterolateral approach.

The AVS® Navigator PEEK Spacers are intended to be used with supplemental fixation systems that have been cleared for use in the lumbosacral spine.

AVS® PL and AVS® UniLIF PEEK Spacers

The Stryker Spine AVS® PL and AVS® UniLIF™ PEEK Spacers are intervertebral body fusion devices indicated for use with autograft and/or allogenic 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® PL and UniLIF™ PEEK Spacers can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis.

The AVS® PL PEEK Spacers and AVS® UniLIF™ PEEK Spacers are to be implanted via posterior approach.

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

AVS® TL PEEK Spacers

The Stryker Spine AVS® TL PEEK Spacers are intervertebral body fusion devices indicated for use with autograft and/or allogenic 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 Peek 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 spinal 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.
- A condition of senility, mental illness, or substance abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.
- Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests must be made prior to material selection or implantation.
- Other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, 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 advice the patient that resultant forces can cause failure of the device. Patients who smoke have been shown to have an increased incidence of non-unions. Such patients should be advised of this fact and warned of the potential consequences. For diseased patients with degenerative disease, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. In such cases, orthopaedic devices may be considered only as a delaying technique or to provide temporary relief. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

Pre-operative precautions
The surgical indication and the choice of implants must take into account certain important criteria such as:

- Patients involved in an occupation or activity that applies excessive loading upon the implant (e.g., substantial walking, running, lifting, or muscle strain) may be at increased risk for failure of the fusion and/or the device.
- Surgeons must instruct patients in detail about the limitations of the implants, including, but not limited to, the impact of excessive loading through patient weight or activity, and be taught to govern their activities accordingly. The procedure will not restore function to the level expected with a normal, healthy spine, and the patient should not have unrealistic functional expectations.
- A condition of senility, mental illness, chemical dependence or alcoholism. These conditions among others may cause the patients to ignore certain necessary limitations and precautions in the use of the implant, leading to failure and other complications.
- Foreign body sensitivity. Where material sensitivity is suspected appropriate tests should be made prior to material implantation.
- Surgeons must advise patients who smoke have been shown to have an increased incidence of non-unions. Such patients must be advised of this fact and warned of the potential consequences.
- Care must be taken to protect the components from being marred, nicked, or notched as a result of contact with metal or abrasive objects.

The choice of implants
The choice of proper shape, size and design of the implant for each patient is crucial to the success of the surgery. The surgeon is responsible for this choice, which depends on each patient.

Patients who are overweight may add additional stresses and strains on the device which can lead to implant fatigue and/or lead to deformation or failure of the implants.

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 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.

Instructions for use

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 spinal 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.

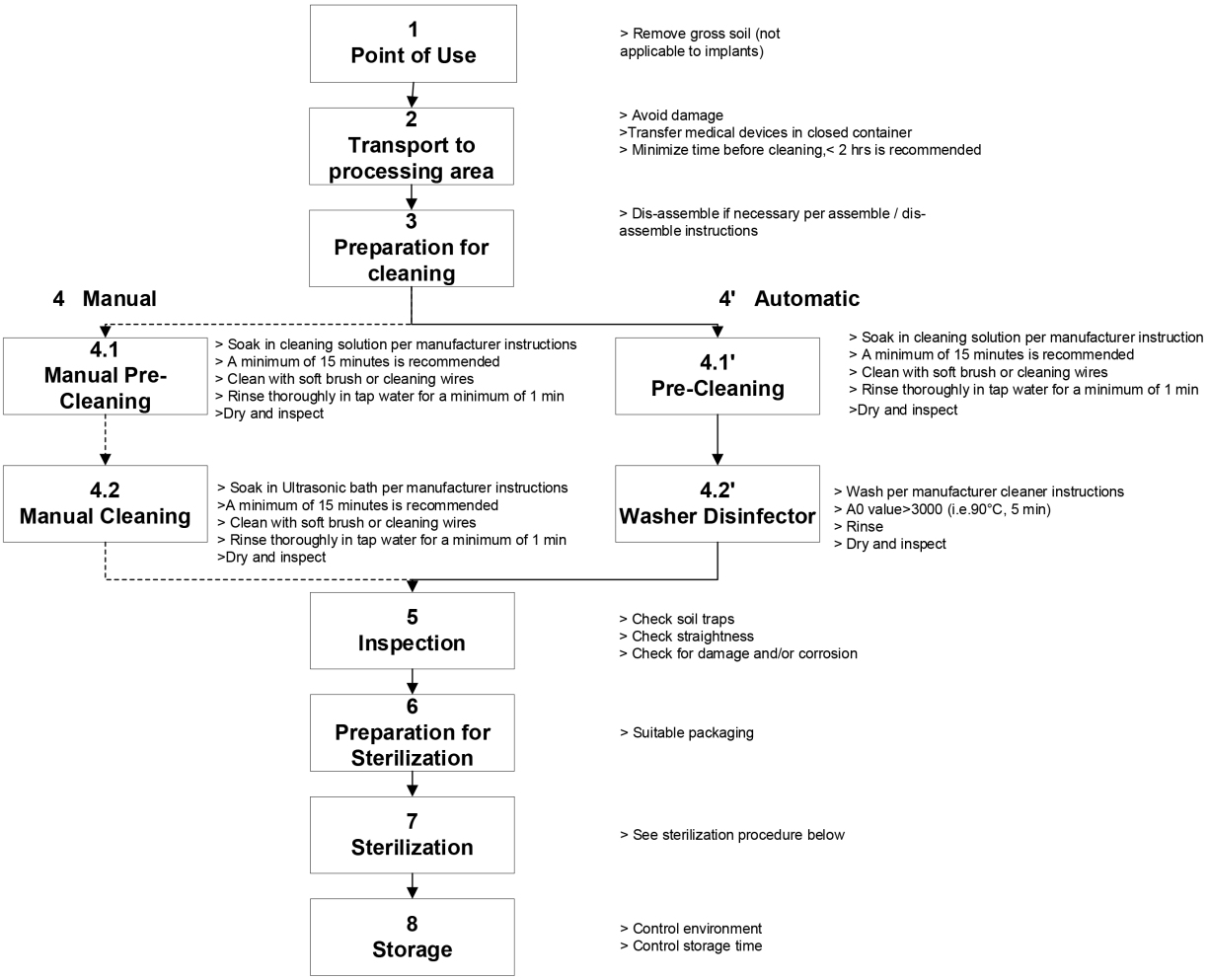
Removal
If fusion / bone graft growth occurs, the device will be deeply integrated into the bony tissues. As a result, the AVS® PEEK Spacers are not intended to be removed unless the management of a complication or adverse event requires the removal. Any decision by a physician to remove the device should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

Pre-cleaning / Cleaning and sterilization procedure for Non-Sterile medical device
For safety reasons, non-sterile devices must be pre-cleaned, cleaned and sterilized prior to use following the sequence of steps described in the following chart.



Sterilization procedure recommended for Non-Sterile medical devices including implants
Medical Devices should be sterilized in their container by means of moist heat steam sterilization in an autoclave in accordance with standard hospital procedure. The recommended sterilization methods suggested has been validated according to ISO 17655-1 to obtain a Sterility Assurance Level (SAL) of 10-6.

Steam Sterilization with Commercially Available Sterilization Wrap

The following ranges of parameters have been validated on wrapped containers in fully-loaded autoclaves.

Minimal sterilization conditions:
Prevacuum (Porous Load) steam sterilization autoclave:

- Temperature: 132°C (270°F)
- Exposure Time: 4 Minutes
- Dry Time: 45 Minutes

Caution: For products being used in the United States (USA), an FDA cleared sterilization wrap is required to wrap the sterilization containers.

The autoclave must be validated by the hospital and regularly checked to guarantee the recommended sterilization temperature is reached for the entire exposure time.

If after having followed this sterilization method there is still water in the sterilization containers or on/inside the device, the device must be dried and sterilization repeated. Drying times for implants processed in containers and wrapped trays can vary depending upon the type of packaging, type of implants, type of sterilizer, and total load. A minimum dry time of 45 minutes is recommended, but to avoid wet packs, extended dry times greater than 45 minutes may be needed. See Extended Dry Time Table in the Stryker Spine Instructions for: Cleaning, Sterilization, Inspection, and Maintenance of Non-Sterile Medical Devices NSRDEV_RG. For large loads verification of dry times by the health care provider is recommended.

Caution: Stryker Spine has not validated and does not recommend Flash Sterilization

Steam Sterilization with FDA-Cleared Rigid Containers Option:

In order to ensure proper sterilization of Stryker Spine devices when using the Aesculap SterilContainer (JN series) reusable, rigid sterilization containers, the information below must be followed:

1. Only the following Aesculap reusable rigid container configuration, FDA-cleared, shall be used in a pre-vacuum steam sterilization cycle for use in the USA:
    - JN442 – Aesculap SterilContainer, Full Size, 6-inch height, Perforated Bottom
    - JK489 – Aesculap SterilContainer, Full Size, 2000 Lid, Aluminum
    - US994 – Filter Paper, 7 ½ inches Round, Single Use
2. Aesculap SterilContainer instructions for use must be followed. If questions arise regarding the use of the Aesculap SterilContainer reusable, rigid sterilization container, Stryker Spine recommends contacting Aesculap directly for guidance
3. Sterilization instructions:
    a. No more than two (2) individual Stryker Spine tray inserts can be placed directly into the Aesculap SterilContainer (JN Series) reusable, rigid sterilization container (perforated bottom)
    b. Stryker Spine devices must be placed in their designated locations within the tray inserts. Stryker Spine's single devices or modules/caddies/racks may be placed into an Aesculap basket (JF223R or similar) which can be loaded into the Aesculap SterilContainer reusable, rigid sterilization containers. **Note:** Devices must be placed such that individual devices are not stacked and remain in an open position to allow uniform exposure to steam.
    c. Stryker Spine Container lids must be removed prior to use with the Aesculap reusable, rigid sterilization container
    d. Stryker Spine devices were validated under the following USA sterilization parameters for a pre-vacuum, three pulse steam cycle:
        - Temperature: 132°C (270°F)
        - Exposure Time: 4 minutes
        - Cycle Dry Time: 30 minutes
    - e. Reusable, rigid sterilization containers must not be stacked within the autoclave, as doing so may negatively impact ventilation and sterilization.

Note: Implants may be individually wrapped and sterilized.

- **Exception:** Stryker Spine AVS ARIA System and AVS AL PEEK Spacer System must not be sterilized using reusable, rigid sterilization containers. These systems shall be sterilized according to the Steam Sterilization with FDA-Cleared/Commercially Available Sterilization Wrap Instructions above.

Refer to Stryker Spine Instructions for: Cleaning, Sterilization, Inspection, and Maintenance of Non-Sterile Medical Devices NSRDEV_RG Appendix 2 Rigid Container Compatibility for Device Sets for the complete list of device sets in scope of rigid container sterilization.

Warning:

- Do not use solvents, abrasive cleaners, metal brushes, or abrasive pads. Cleaning agents with aldehydes, bromine, iodine, active chlorine, or chloride as the active ingredient are corrosive to stainless steel are not to be used.

The parameters identified in this document are the minimum for effective cleaning and sterilization of Stryker Spine implants. Stryker Spine does not recommend the use of high pH detergents, however if a detergent with high pH is used Stryker Spine recommends a pH neutralizer to ensure full removal of the high pH solution. In circumstances where sterilization temperature and exposure time required by the hospital is greater than the temperature and time recommended in this document, the effectiveness of the cycle for the purposes of sterilization is assured. However, extended cycle temperature and time may accelerate wear. Implants should be examined for wear or damage prior to use.

For additional information refer to Stryker Spine Instructions for: Cleaning, Sterilization, Inspection, and Maintenance of Non-Sterile Medical Devices NSRDEV_RG.

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:

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stryker

Spine division

This document is intended solely for the use of healthcare professionals. 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. We do not dispense medical advice and recommend that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate Stryker's products. A surgeon must always refer to the package insert, product label and/ or instructions for use, including the instructions for cleaning and sterilization (if applicable), before using any of Stryker's products. The products depicted are CE marked according to the Medical Device Directive 93/42/EEC or Regulation (EU) 2017/745. 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 representative if you have questions about the availability of Stryker's products in your area.

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