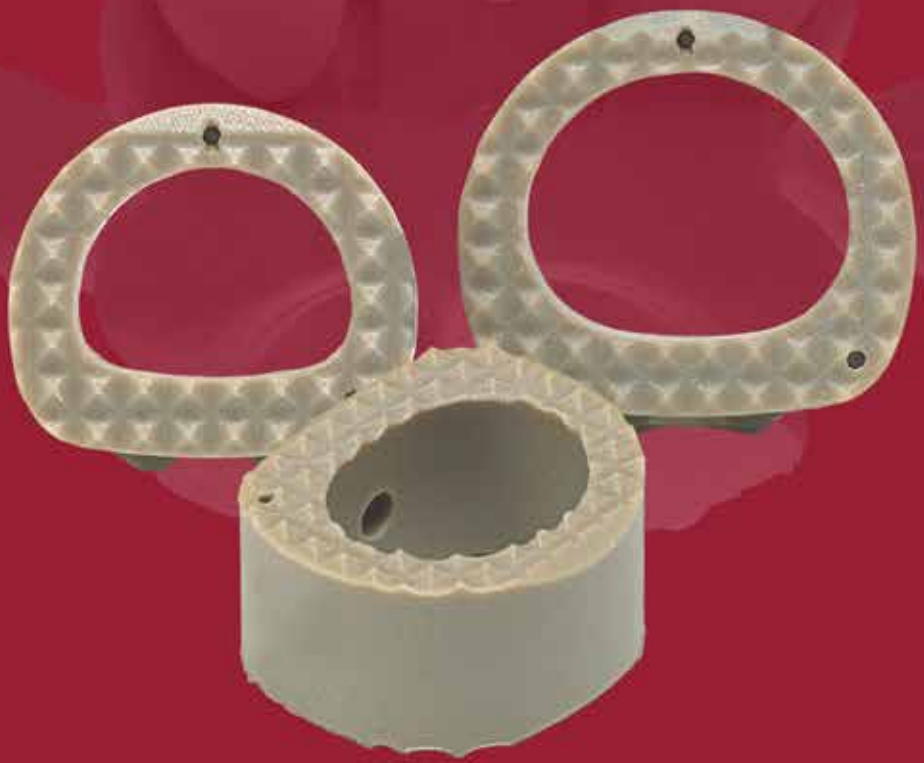
stryker®

Spine

AVS® AS PEEK Spacer
Surgical Technique

- **Comprehensive Sizing**
- **Large Graft Volume**
- **Intuitive Instrumentation**



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).

Step 1: Exposure

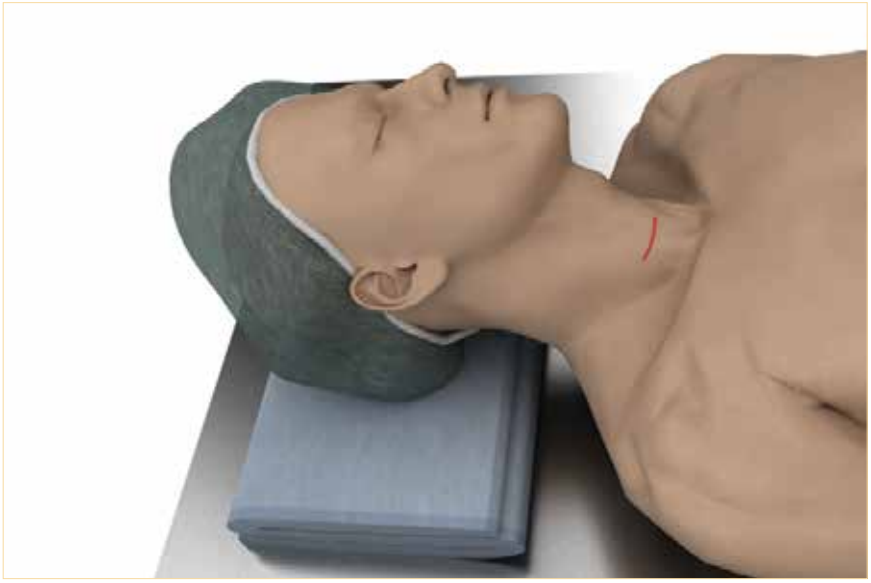


Figure 1 - The patient should be positioned in the supine position with the head stabilized in extension and rotated slightly away from the site of the approach. If possible, a transverse incision, parallel to the skin creases in the neck, is recommended.

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 optimal 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.

Step 2: Discectomy

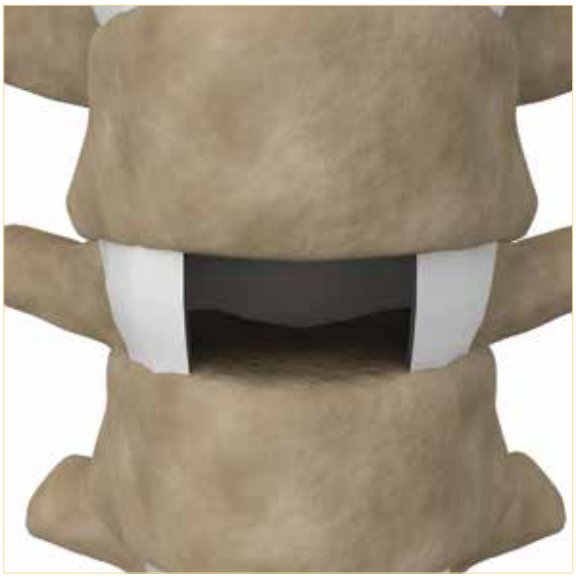


Figure 2

Reliance C Parallel Pin Distractor (48365020)

PRE-OPERATIVE PLANNING

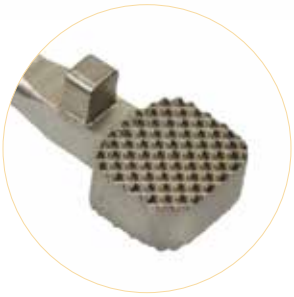
An anterior annulotomy is performed and should be wide enough to allow insertion of the implant (**See Figure 2**). The AVS AS PEEK Spacer is offered in 14mm and 16mm medial-lateral widths. It is recommended that the appropriate width be selected based on pre-operative measurements.

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.

Step 3: Endplate Preparation

Reliance C Rasp
(483652(04-12))



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 ensuring that no soft tissue remains.

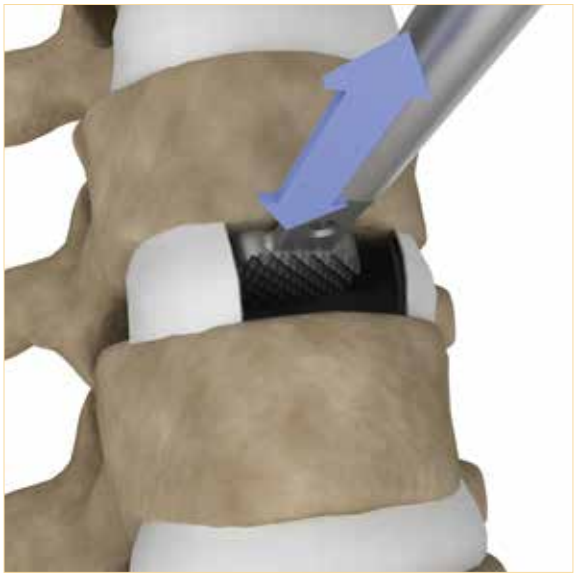


Figure 3

Step 4: Trialing

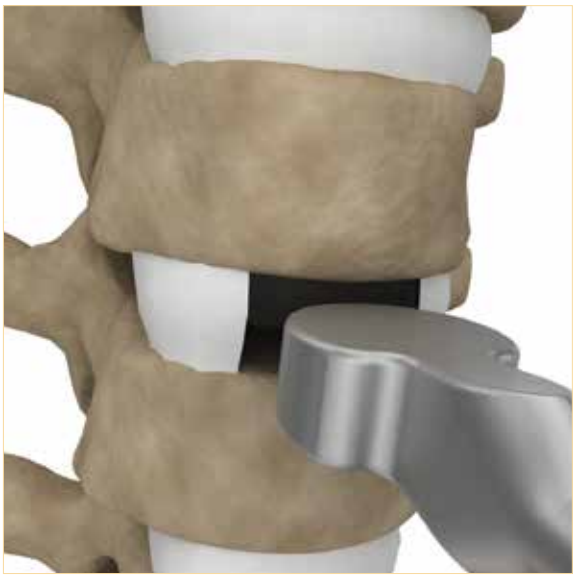


Figure 4

Reliance C Trial
(483653(04-12))

It is recommended that preliminary measurements are taken to 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.

Step 5: Implant Preparation

AVS AS Inserter (48329000)

AVS AS Graft Support (48329100)
AVS AS Graft Compactor (48350923)

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.

Step 6: Implant Insertion and Positioning

Figure 5

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.

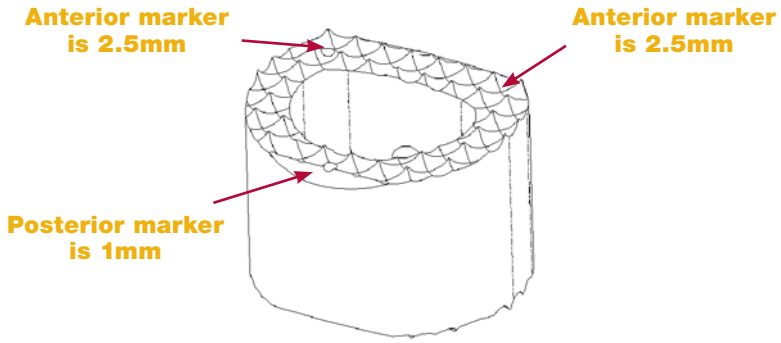


Figure 6

Step 7: Closure

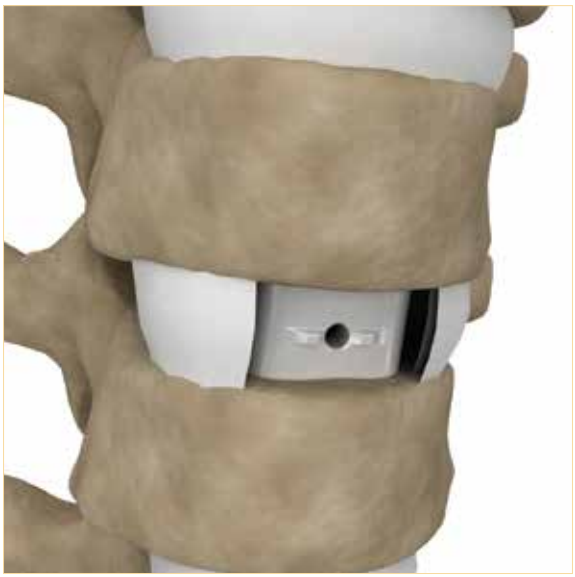


Figure 7

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

AVS AS Impactor (48329050)

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.

AVS AS PEEK Spacer

Implants

Part Number	Description
12 x 14 Footprint	
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°
14 x 16 Footprint	
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

Part Number	Description
48329000	AVS AS Inserter
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
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
48321214	AVS AS PEEK Container

Instruments

Part Number	Description
48360003	Reliance C Container
48360003C	Reliance C Insert
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
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
48365321	Reliance C Curved Tamp
874002	Solis Distraction Pin, 10mm
874009	Solis Distraction Pin, 15mm
874005	Reliance C Pin Driver
874007	Reliance C Pin Guide

Product Information For AVS AS PEEK Spacer

DESCRIPTION

The **Stryker Spine AVS AS PEEK Spacer** is a hollow, ring-shaped PEEK Optima 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 autogenous bone graft. It is intended for use as an interbody fusion device (IBD) of the cervical spine (from C2-C3 to C7-T1).

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 Spacers are 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.

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.

CONTRAINDICATIONS

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 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 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.
- 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.

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.

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 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.
- Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

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.

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

Notes:

Notes:

stryker®

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Stryker Spine
2 Pearl Court
Allendale, NJ 07401-1677 USA
t: 201-760-8000
www.stryker.com

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.

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