



INTERBODY FUSION DEVICES

Spinal Elements, Inc. · 3115 Melrose Dr., Suite 200  
Carlsbad, CA 92010 · U.S.A. · 760.607.0121

#### DESCRIPTION:

The Spinal Elements Interbody Fusion Devices are used to provide structural stability and maintain disc space distraction in skeletally mature adults requiring intervertebral body fusion. They are designed to be used in conjunction with supplemental spinal fixation instrumentation.

The series is comprised of cages of various fixed heights and shapes for placement in the cervical or lumbar spine. There are different cages designed for specific regions of the spine and approaches to the spine. Each cage has a hollow center to allow placement of autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft inside of the cage. Ridges on the superior and inferior surfaces of the device help to grip the endplates and prevent expulsion

CAUTION: Federal law (USA) restricts these devices to sale by or on the order of a physician. Implants and disposable instruments single use only.

#### INDICATIONS

The Spinal Elements Cervical Interbody Fusion Devices are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one level or two contiguous levels. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. The Spinal Elements Cervical Interbody Fusion Devices are used to facilitate intervertebral body fusion in the cervical spine at the C3 to C7 disc levels using autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

The Spinal Elements Lumbar Interbody Fusion Devices are indicated for intervertebral body spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level. Spinal Elements Lumbar Interbody Fusion Devices are to be used with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

Warning: An entirely satisfactory result is not always achieved in every surgical case. This particularly applies to spinal surgery, in which numerous external factors may compromise the results. Patients with previous spinal surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery. The risk of device expulsion and migration is higher without the use of supplemental fixation. Never reuse an implant under any circumstances. Even when a removed device appears undamaged, it may contain small defects or residual stresses. These defects and stresses may lead to implant failure. Any retrieved devices should be handled in a manner such that they may not be reused in another surgical procedure.

CONTRAINDICATIONS include, but are not limited to:

- Spondylolisthesis higher than grade I
- Reduced bone density, which does not guarantee a sufficient resting stability (e. g. osteoporosis)
- Fractures
- Tumors
- Scoliosis
- Active infection
- Allergy to tantalum, PEEK, Titanium Alloy (Ti6Al4V ELI)
- Signs of local inflammation
- Fever or leukocytosis
- Morbid obesity
- Pregnancy
- Mental illness

- Suspected or documented allergy or intolerance to composite materials
- Any case not needing a fusion
- Any case not described in the indications
- Any patient unwilling to cooperate with postoperative instructions
- Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery
- These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth
- Spondylolisthesis unable to be reduced to Grade 1
- Any case where the implant components selected for use would be too large or too small to achieve a successful result
- Any case that requires the mixing of metals from two different components or systems
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance
- Prior fusion at the level to be treated
- Any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count

Additional contraindications for the Spinal Elements Interbody Fusion Devices, LLIF include but are not limited to:

- Symptomatic level at L5-S1
- Lumbar deformities with more than 30° of rotation
- Retroperitoneal scarring on both left and right sides (e.g. due to abscess or prior surgery)

- Need for direct nerve decompression through the same approach.

#### PRECAUTIONS:

Intervertebral body fusion should only be undertaken after the surgeon has had hands-on training in these methods of spinal fixation, and has become thoroughly knowledgeable about spinal anatomy and biomechanics. Surgical technique manuals are available for detailed instructions on the correct use of the Spinal Elements Interbody Fusion Devices. The contents of these manuals alone are not adequate for complete instruction in the use of this system. Even for surgeons already experienced in spinal instrumentation and intervertebral body fusion procedures, new skills may be required that are best learned by working with an experienced surgeon or through a course of formal instruction with laboratory training. Lack of experience or expertise with these implants may result in complications. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

#### MAGNETIC RESONANCE ENVIRONMENT

Interbody Fusion Devices have not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

#### POSSIBLE ADVERSE EFFECTS:

Possible adverse events or complications associated with the Spinal Elements Interbody Fusion Devices may include, but are not limited to:

- Bending or fracture of implant. Loosening of the implant.
- Implant material sensitivity, or allergic reaction to a foreign body.
- Infection, early or late.
- Decrease in bone density due to stress shielding.
- Pain, discomfort, or abnormal sensations due to the presence of the device.

- Nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, radicular pain, tethering of nerves in scar tissue, muscle weakness, and paraesthesia.
- Vascular damage could result in catastrophic or fatal bleeding. Malpositioned implants adjacent to large arteries or veins could cause erosion of these vessels and catastrophic bleeding in the later postoperative period.
- Dural tears experienced during surgery could result in need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis.
- Bursitis.
- Paralysis.
- Death.
- Spinal cord impingement or damage.
- Fracture of bony structures.
- Reflex sympathetic dystrophy.
- If a pseudarthrosis occurs coupled with the Spinal Elements Interbody Fusion Devices, a mechanical grinding action could possibly occur which might generate wear debris. Most types of wear debris have shown the potential of initiating local osteolysis in articulating joints.
- Degenerative changes or instability in segments adjacent to fused vertebral levels.

Additional surgery may be necessary to correct some of these adverse events.

**MATERIAL:** The Spinal Elements Interbody Fusion Devices are made from either PEEK (polyetheretherketone) radiolucent material with embedded tantalum x-ray markers as specified in ASTM F2026 and ASTM F560, respectively or Titanium Alloy (Ti6Al4V ELI) as specified in ASTM F136. No warranties, expressed or implied, are made.

**Packaging:** Packages for each of the components should be intact upon receipt. Damaged packages and products should not be used and should be returned to SPINAL ELEMENTS.

**STERILIZATION:**

Products not clearly marked as sterile should be assumed non-sterile.

**For Sterile Implants and Instruments:**  
Implants and instruments provided sterile will be clearly labeled as such in an unopened sterile package provided by SPINAL ELEMENTS. The contents are sterile unless the package is damaged, opened, or the expiration date on the device label has passed. The integrity of the packaging should be checked to ensure that the sterility of the contents is not compromised. Implants supplied sterilized from SPINAL ELEMENTS must not be re-sterilized.

**For Non-Sterile Implants and Instruments:**  
Implants and instruments used in surgery not clearly labeled as sterile must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization where applicable.

Only sterile products should be placed in the operative field.

**Product Complaints:** Any health care professional (e.g. customer or user) who has experienced dissatisfaction in the services of SPINAL ELEMENTS or who has any complaints about SPINAL ELEMENTS products referring to quality, identity, durability, reliability, safety, effectiveness, and/or performance, should notify this to the sales representative, distributor, or SPINAL ELEMENTS customer service. Further, if any of the devices, instruments or components ever malfunction, (i.e. do not meet any of their performance specifications or otherwise do not perform as intended), or are suspected of doing so, the distributor should be notified immediately.

If any SPINAL ELEMENTS product ever “malfunctions” and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, FAX or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.



3115 Melrose Dr., Suite 200  
Carlsbad, CA 92010 ·  
U.S.A. ·  
760.607.0121

SYMBOL	USED FOR	SYMBOL	USED FOR
	Single Use ONLY		Non-sterile
	Lot Number		Catalog number
	Manufacturer		Quantity
	Instruction for Use <a href="http://Spinalelements.com">Spinalelements.com</a>		Date of Manufacture
	Material		Caution, Consult Accompanying Document

Recommended Sterilization Procedures for Spinal Elements Interbody Fusion Devices Instrumentation and Implants Provided Non-Sterile:

Manufacturer: Spinal Elements  
 Method: Manual Cleaning and Steam  
 SterilizationDevice(s):  
 Trays/Implants/Instruments

Limitations on Reprocessing:	Repeated processing has limited effect on REUSABLE instruments. End of life is normally determined by wear and damage due to use.
------------------------------	--

CLEANING INSTRUCTIONS																									
Point of use:	Use clean flowing water and disposable wipes to remove excess soil. Reprocess instruments as soon as possible to prevent body fluid and tissue from drying on instruments prior to cleaning.																								
Cleaning Agent	Endozime AW Plus is to be prepared as follows: Add ½ ounce of Endozime® AW plus to 1 gallon of warm tap water (17mL/4liter, 27°-44°C)																								
Cleaning - Automated	<p>1) Manually pre-clean the instruments                  (1.1) Immerse and soak for a minimum of 5 minutes in enzymatic detergent at &lt;43°C.                  (1.2) Immerse in enzymatic detergent and clean thoroughly for 14 minutes at &lt;43°C.                  (1.2.1) Scrub all external surfaces with a soft bristle brush until all visible soil has been removed. It is important to make sure that areas of concern with complex or hidden surfaces are effectively cleaned. Use a small diameter brush to clean cannulation holes. Inspect for visible soil on exposed surfaces.                  (1.3) Rinse thoroughly for 2 minutes with warm demineralized water. (Purified water at 27°-44°C)                  (2) Place instruments in an automated washer. Ensure the instruments stay in place and do not touch or overlap so that the design features are accessible for cleaning and do not retain liquid.                  (3) Run the washer per the parameters below:</p> <p>Washer Parameters</p> <table border="1"> <thead> <tr> <th>Cycle</th> <th>Time</th> <th>Parameters</th> <th>Temperature</th> </tr> </thead> <tbody> <tr> <td>Pre-Wash</td> <td>300 seconds</td> <td></td> <td>Cold<sup>1</sup></td> </tr> <tr> <td>Wash 1</td> <td>300 seconds</td> <td>½ Oz Endozime AW Plus per 1 Gallon Tap Water</td> <td>65.5° C</td> </tr> <tr> <td>Wash 2</td> <td>300 seconds</td> <td>½ Oz Endozime AW Plus per 1 Gallon Tap Water</td> <td>65.5° C</td> </tr> <tr> <td>Purified Water Rinse</td> <td>10 seconds</td> <td>Non-Recirculated Purified Water</td> <td>82.2° C<sup>2</sup></td> </tr> <tr> <td>Dry Time</td> <td>7 minutes</td> <td>N/A</td> <td>115.5° C</td> </tr> </tbody> </table> <p><sup>1</sup>Cold tap water line  <sup>2</sup>Purified water tank temperature set at 82.2° C/180° F</p>	Cycle	Time	Parameters	Temperature	Pre-Wash	300 seconds		Cold <sup>1</sup>	Wash 1	300 seconds	½ Oz Endozime AW Plus per 1 Gallon Tap Water	65.5° C	Wash 2	300 seconds	½ Oz Endozime AW Plus per 1 Gallon Tap Water	65.5° C	Purified Water Rinse	10 seconds	Non-Recirculated Purified Water	82.2° C <sup>2</sup>	Dry Time	7 minutes	N/A	115.5° C
Cycle	Time	Parameters	Temperature																						
Pre-Wash	300 seconds		Cold <sup>1</sup>																						
Wash 1	300 seconds	½ Oz Endozime AW Plus per 1 Gallon Tap Water	65.5° C																						
Wash 2	300 seconds	½ Oz Endozime AW Plus per 1 Gallon Tap Water	65.5° C																						
Purified Water Rinse	10 seconds	Non-Recirculated Purified Water	82.2° C <sup>2</sup>																						
Dry Time	7 minutes	N/A	115.5° C																						

Cleaning-Manual	<p>(1) Immerse and soak for a minimum of five (5) minutes in enzymatic detergent at &lt;43°C.</p> <p>(2) Immerse in enzymatic detergent and clean thoroughly for at least 14 minutes at &lt;43°C.</p> <p>(2.1) Scrub all external surfaces with a soft bristle brush until all visible soil has been removed. It is important to make sure that areas of concern with complex or hidden surfaces are effectively cleaned. Use a small diameter brush to clean cannulation holes. Inspect for visible soil on exposed surfaces.</p> <p>(3) Rinse thoroughly for 2 minutes with warm demineralized water. (Purified water at 27°-44°C)</p> <p>(4) Allow instrument to air dry in a clean area. Blow lumens with clean air using filtered air source or syringe.</p>
Maintenance, inspection, and testing;	<p>Carefully inspect each device to ensure that all visible blood and soil have been removed.</p> <p>Inspect lumens to confirm that all foreign material has been removed.</p> <p>Visually inspect for damage and/or wear.</p> <p>Note: If any damage or wear is noted that impairs the function of the instrument, contact your Spinal Elements representative for a replacement.</p>
Packaging:	<p>This set of components may be loaded into a dedicated tray, supplied by the manufacturer, for sterilization. The tray should be wrapped using FDA-cleared sterilization wrap or other FDA-cleared accessory that has been validated to allow sterilant penetration and subsequently maintain sterility.</p>
Sterilization:	<p>Spinal Elements Orca Interbody Fusion Devices should be sterilized utilizing a pre-vacuum steam autoclave for <u>10 minutes</u> at 270°F (132°C).</p> <p>All other Spinal Elements Interbody Fusion Devices should be sterilized utilizing a pre-vacuum steam autoclave for <u>4 minutes</u> at 270°F (132°C).</p> <p>Visually inspect all components for any remaining debris prior to sterilization. The Spinal Elements Interbody Body Fusion system components provided NON-STERILE should be autoclave sterilized using the sterilizer manufacturer's instructions and the institution's procedures for ensuring sterility. The sterilization cycle should occur in a calibrated autoclave.</p> <p>It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications (time and temperature).</p>
Drying:	<p>A minimum drying time of 20 minutes, after sterilization, is recommended.</p> <p>Drying times may vary according to load size and should be increased for large loads.</p> <p>Dry, thoroughly and promptly, after both cleaning and sterilization.</p>
Storage:	<p>Store components in a clean, dry, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and extremes in humidity and temperature.</p>

The instructions provided above have been validated by Spinal Elements as being CAPABLE of preparing a medical device for reuse. It remains the responsibility of the processor to ensure that the reprocessing as actually performed, using equipment, materials, and personnel in the reprocessing facility, achieves the desired result. This normally requires validation and routine monitoring of the process. Any deviation by the re-processor from these instructions should be properly evaluated for effectiveness to avoid potential adverse consequences.