

4. Decontamination / Disinfection

Warning: The decontamination process does not sterilize instruments. Sterilize the instruments prior to use as outlined below.

- Select a proper product for high-level disinfection. Follow the cleaning agent's recommended directions regarding the proper concentration, temperature, contact time and solution re-use. Do not use high acid (pH <4.0) or high alkaline (pH >10) products for disinfection as these may damage the identification markings on the instruments.
- Completely immerse instruments in disinfecting solution - force solution into all areas and cavities. Using a large syringe or pulsating water jet, thoroughly flush all channels, threads and hinged areas with the disinfecting solution to remove debris.

5. Rinsing / Drying

- Thoroughly rinse all instruments with DI or RO water to remove all traces of the disinfecting solution.
- Dry the external surfaces of the instruments using a clean soft, absorbent towel or cloth.

6. Machine Cleaning

The hospital may also use a user qualified automatic machine cleaning cycle for cleaning/disinfection using a proteolytic enzymatic detergent. Follow the pH, concentration, temperature and contact time recommendation of the manufacturer of the detergent. Do not use a high acidic (pH <4.0) or high alkaline (pH >10) detergents.

7. Inspection for Rust

Inspect stainless steel instruments for evidence of "rust" prior to use.

Instruments should be inspected for wear and damage in preparation for the next use. If repair or maintenance of an InterFuse instrument is needed, return the cleaned and disinfected instrument wrapped in adequate packing material in a sturdy box to the address listed below. The InterFuse stainless steel instruments must be completely dry and placed in the InterFuse Instrument Case for storage.

Sterilization prior to use is mandatory. Sterilize the wrapped instruments/accessories using a steam autoclave having a gravity cycle at 121°C (250°F) for 30 minutes with a 30 minute drying cycle. Alternatively, a steam autoclave having a pre-vacuum cycle at 132°C (270°F) for 4 minutes with a 30 minute drying cycle may also be used. The materials used in VTI's instruments (Stainless steel/Ultem/Radel) can withstand a temperature/pressure well over the limits of steam autoclaves.

STORAGE

Sterile packaged implants should be stored at ambient temperatures in a clean dry area that prevents damage to the implant packaging.

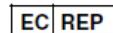
WARRANTY

Vertebral Technologies, Inc. products are guaranteed to be free of defects in workmanship and materials when used properly for its intended purpose. Any product delivered from Vertebral Technologies proving to be defective will be replaced or repaired, at Vertebral Technologies' discretion, at no charge to the customer. These warranties shall not apply to conditions or defects resulting from, but not limited to: negligence, improper use, improper care and handling, improper opening techniques, unauthorized repair work, caustic or abrasive cleaners, or items modified or customized by the customer at the customer's request.

CUSTOMER SERVICE

For further information regarding the InterFuse device or instrument, or for a copy of the InterFuse Surgical Technique Manual, please contact Vertebral Technologies, Inc. or your local InterFuse device distributor.

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SYMBOLS

		 CCYY-MM-DD	Use By		Single Use
	Catalogue number		Sterilized using irradiation		Do not use if package is damaged
	Lot Number		Do not resterilize		Consult instructions for use



## InterFuse® Intervertebral Body Fusion Device

DESCRIPTION

The InterFuse interbody fusion device is designed to stabilize the lumbar spinal column and promote fusion. This modular device incorporates a rail-and-slot design to aid in module insertion and alignment, and to allow the surgeon to tailor the final width of the device to the patient's intervertebral disc space. The InterFuse device is made from radiolucent polyetheretherketone (PEEK) polymer, and each module contains at least one tantalum marker to aid in visualization under x-ray or fluoroscopy. The modules have ridges oriented to resist intradiscal device movement. Each module has a cavity intended for packing of bone graft. The InterFuse device is available in a variety of heights and anterior-posterior (A-P) lengths, and with both parallel and angled endplate contact angles.

INDICATIONS FOR USE

**Caution:** For product sold in the USA Federal Law (USA) restricts this device to sale by or on the order of a physician.

The InterFuse Intervertebral Body Fusion Device is indicated for intervertebral spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one 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 patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The InterFuse device is to be used in patients who have had at least six (6) months of non-operative treatment. These patients may have had a previous non-fusion surgery at the involved spinal level(s). The InterFuse device is indicated for use with autogenous bone graft, and to be used with supplemental internal spinal fixation systems that have been cleared for use by the FDA in the lumbosacral spine (e.g., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems).

CONTRAINDICATIONS

Contraindications for the InterFuse device include, but are not limited to:

- Presence of fever, infection or inflammation (systemic or localized);
- Morbid obesity;
- Pregnancy;
- Mental illness or drug abuse;
- Severe osteopenia (or any other medical or surgical condition) which would preclude potential benefits of implants;
- Suspected or documented allergy or intolerance to metals or polymers (plastics);
- Patients unwilling or unable to follow instructions regarding post-operative care or limitations;
- Diffuse multilevel neoplastic disease such that no adjacent normal segments exist for engagement of instrumentation;
- Any case not listed in the indications.

RELATIVE CONTRAINDICATIONS

- Osteoporosis
- Smoking
- Malnutrition
- Systemic Infection
- Anemia
- Chronic hypoxemia
- Severe cardiopulmonary disease
- Severe depression/psychosocial issues
- Secondary gain issues

## WARNINGS



**The InterFuse device is designed as a permanent implant for single patient use, and must never be reused.** Even though the device may appear undamaged if explanted, it may have developed small defects that may lead to early breakage if re-implanted. The device is supplied STERILE and should not be resterilized.

**The InterFuse device may become loose or break if subjected to increased loading, especially in the condition of delayed union or nonunion.** The implant's longevity can be affected by the patient's weight, activity level, and adherence to load-bearing instructions. Delayed union or nonunion can result in loads on the implant over time that are higher than expected, increasing the risk of implant breakage. The patient should be made aware of the risks of implant failure.

**Correct selection of the implant is extremely important.** A properly sized device will provide the best stability of the spinal column and distribution of the intervertebral load across the vertebral endplates. The strength of even a properly sized device, however, is limited by the size and shape constraints of the intervertebral space, and any such implant cannot be expected to withstand activity levels equal to those placed on normal healthy bone.

These warnings do not include all of the adverse effects which could occur with implantation of the InterFuse device or of any surgery. Patients should be informed of the risks associated with orthopedic surgery, general surgery and the use of general anesthesia prior to surgery. See the PRECAUTIONS and POSSIBLE ADVERSE EFFECTS sections for additional warnings.

## PRECAUTIONS

The implantation of the InterFuse device should be performed only by experienced spinal surgeons with specific training in the use of this device, due to the technically demanding nature of the procedure and the potential for serious injury to the patient.

The InterFuse device is designed to support physiologic loads. Damage to the device from excessive forces or torque from the insertion instruments can cause defects in the device that can lead to misalignment or breakage, and should be avoided. Do not implant any device that has fractured or has visible cracks, surface imperfections or other damage.

The patient should be adequately informed about the advantages, disadvantages, and limitations of the InterFuse device and any supplemental internal fixation devices that may be used. The patient should be encouraged to ambulate as soon as possible following surgery, while limiting lifting and twisting motions and any type of sports activities until the bone is healed. The patient should understand that implants are not as strong as normal healthy bone and could loosen, bend or break if excessive demands are placed on it, especially if the bone has not completely healed. Implants displaced or damaged by improper activities may experience implant migration and subsequent damage to nerves or blood vessels.

The InterFuse device has not been evaluated for safety and compatibility in the MR environment. The Interfuse device has not been tested for heating or migration in the MR environment.

The removal of supplemental fixation following completion of its intended use should be carefully considered by the surgeon. While not removing the supplemental fixation eliminates the risk associated with a second surgery, leaving the implants in place could result in complications that include, but are not limited to:

- risk of additional injury from post-operative trauma;
- bending, loosening, or breakage of the fixation implant;
- possible increased risk of infection;
- pain or discomfort associated with the fixation implant;
- bone loss or reduced bone healing due to stress shielding.

## POSSIBLE ADVERSE EFFECTS

Pre-operatively, the patient should be made aware of the possible adverse effects of orthopedic surgery. Additional surgery may be necessary to correct some of these anticipated events including, but not limited to:

1. Bending or fracture of the implant. Loosening or movement of the implant.
2. Implant material sensitivity, or allergic reaction to a foreign body.
3. Infection, early or late.
4. Decrease in bone density due to stress shielding.
5. Pain, discomfort, or abnormal sensations due to the presence of the device.
6. 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.
7. 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.

8. Dural tears experienced during surgery could result in need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis.
9. Bursitis.
10. Spinal cord impingement or damage.
11. Fracture of bony structures.
12. Reflex sympathetic dystrophy.
13. There is an additional risk if there were to be long term in vivo degradation of the polymer resulting in possible local or systemic adverse reactions from any potential degradation products.
14. If a pseudarthrosis occurs coupled with the InterFuse device, 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.
15. Degenerative changes or instability in segments adjacent to fused vertebral levels.
16. Paralysis.
17. Death.

## DIRECTIONS FOR USE



The InterFuse implant is provided sterile and requires no further preparation before use. The InterFuse implant has been sterilized by Gamma Irradiation.



The InterFuse stainless steel instruments are provided **non-sterile** and must be cleaned and sterilized prior to use according to the procedure outlined in this document.



Before using the InterFuse device for the first time, the surgeon should be thoroughly familiar with the InterFuse Surgical Technique Manual (available at no charge upon request) as well as the functionality and assembly of the device. The content of the manual alone is not adequate for complete instruction in the use of this device, however, and 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.



Pre-operative planning by the surgeon should determine the type of implant required and an adequate supply of the implant sizes should be available prior to surgery, including larger and smaller sizes than those expected to be used. Refer to the Surgical Technique Manual for descriptions and catalog numbers of the InterFuse device and instruments.

## POSTOPERATIVE PATIENT CARE

Postoperative external immobilization (e.g., bracing or casting) is recommended, at the surgeon's discretion. The patient should be encouraged to ambulate as soon as possible following surgery, while limiting lifting and twisting motions and any type of sports activities until the bone is healed.

## INSTRUMENT CLEANING AND STERILIZATION

Before being used for the first time and each use thereafter, the InterFuse instruments must be cleaned and decontaminated. The following procedure is recommended:

### 1. Pre-cleaning / Rinsing

- Keep the instruments moist following use. Remove gross contaminants by rinsing thoroughly with a steady stream of warm (below 43°C / 110°F) water. Give special attention to jaws, hinges, and passages containing spring mechanisms.

### 2. Manual Cleaning

- Hand-wash the devices in a basin filled with a neutral pH (7.0 – 7.8) enzymatic detergent.
- Keep the instruments immersed to prevent aerosolization of microorganisms during brushing and cleaning.
- Use a large syringe or pulsing water-jet to rinse hinged areas and passages containing spring mechanisms.
- Use a nylon bristle brush to clean the devices. Give special attention to channels, cannulations, threads, and hinged areas.
- Inspect to assure all debris has been removed.

### 3. Ultrasonic Cleaning

- Use enzymatic detergents labeled for use in ultrasonic bath.
- Submerge the devices in ultrasonic bath.
- Set and run a cleaning cycle for 10 minutes.
- Remove the devices from ultrasonic bath. Rinse with deionized (DI) or RO water to remove loosened soil and detergent.
- Inspect the devices to assure all soil and detergent is removed.