

Method: Steam
Cycle: Vacuum
Temperature: 138°C
Exposure Time: 18 min

Remove all packaging material prior to sterilization. Only sterile instruments should be used in surgery. Always immediately re-sterilize all instruments used in surgery.

Routine monitoring per AORN recommended practices for in-hospital sterilization should be followed.

Following are specific warnings, precautions, and adverse effects that should be understood by the surgeon and explained to the patients. These warnings do not include all adverse effects that can occur with surgery in general. General surgical risks should be explained to the patient prior to surgery.

WARNINGS:

Correct selection of the implant is extremely important. Vertebral stabilization success is increased by careful selection of the implant chosen to correct the defect.

If the spinal motion segment is devoid of posterior elements, eg, laminectomy, then supplemental fixation should be provided using pedicle screws.

These warnings do not include all adverse effects that can occur with surgery in general. General surgical risks should be explained to the patients prior to surgery.

PRECAUTIONS

Prior to use, the physician should be trained in the surgical procedure recommended for the use of this device.

The instrumentation is provided NONSTERILE and must be sterilized prior to use.

FIDJI is a single use device and should not be reused. An explanted device should never be reimplanted.

POSSIBLE ADVERSE EFFECTS

- Possible adverse effects associated with general surgery include complications from anesthesia, infection, hematoma and death.
- Possible adverse effects associated with laparoscopic surgery include: organ or bowel injury, peritonitis, incisional herniation, damage to blood vessels, hemorrhage, injury to the nervous system and conversion to open procedures.
- Possible adverse effects associated with gas insufflation include: hypercarbia, gas embolism, retention of gas in the peritoneum, omentum or viscera or lyphocele formation.
- Possible adverse effects associated with spinal surgery include: dural leaks, paralysis (complete or incomplete), sensory loss, loss of bowel and/or bladder control, retrograde ejaculation, failure of the bone to incorporate and scarring of nerve roots.-
Possible adverse effects associated with the FIDJI device may include: fracture of another vertebra during placement, device breakage, device migration, material sensitivity or allergic reaction, spinal cord impingement, bone resorption, loss of disc height, soft tissue damage, damage to large blood vessels and pseudoarthrosis.

Limited Warranty. Abbott Spine products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability of fitness, are hereby disclaimed.

DISTRIBUTED BY:
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For product information or questions pertaining to sales and service, please contact the national distributor in your area.

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FIDJI® Types 1,2,3, and 4

System Contents:

Non-Sterile Instruments - Reusable
Sterile Implants – Single Use Only



Caution: Federal (U.S.A) law restricts this device to sale by or on the order of a physician
Carefully read all instructions and be familiar with the surgical technique(s) prior to use of the device System.
Use universal precautions when handling contaminated or biohazardous components.

DESCRIPTION:

Vertebral Body Replacement (VBR) devices are a surgical repair option in the treatment of trauma, disease, and/or neoplasia of thoracolumbar vertebrae, in whole or in part.

The FIDJI Vertebral Body Replacement Types 1, 2, 3, and 4 devices are hollow blocks that are machined from PEEK OPTIMA® (polyetheretherketone, ASTM F2026); the blocks are tapered to aid in maintaining lordosis of the spine following implantation. The devices have angled teeth on the cephalad and caudal surfaces. The devices include tantalum inserts that serve as a location and orientation markers for radiographs.

INDICATIONS:

FIDJI types 1,2,3, and 4 are vertebral body replacement devices that are intended for use in the thoracic and/or thoracolumbar spine (T1 - L5) to replace a collapsed, damaged or unstable vertebral body resected or excised (i.e., partial or total vertebrectomy procedures) due to tumor or trauma (i.e., fracture).

FIDJI types 1,2,3, and 4 are designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. These devices are intended to be used with bone graft and supplemental fixation, such as the Abbott Spine InCompass System.

CONTRAINDICATIONS:

- 1 - Disease conditions which have been shown to be safely and predictably managed without the use of internal fixation devices are relative contraindications to the use of these devices.
- 2 - Active systemic infection or infection localized to the site of the proposed implantation are contraindications to implantation.

3 - Severe osteoporosis is a relative contraindication because it may prevent adequate fixation of spinal anchors and thus preclude the use of this or any other posterior spinal instrumentation system.

4 - Any entity or condition that totally precludes the possibility of fusion, i.e. cancer, kidney dialysis or osteopenia, is a relative contraindication. Other relative contraindications include obesity, pregnancy, certain degenerative disease, and foreign body sensitivity. In addition, the patient's occupation or activity level or mental capacity may be relative contraindications to this surgery. Specifically, some patients may, because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism or drug abuse, place undue stresses on the implant.

5 - Known patient sensitivity to device materials (PEEK OPTIMA®).

6 - When used without posterior fixation, the device should only be used for Grade 1 or less spondylolisthesis or retrolisthesis.

See also the WARNINGS, PRECAUTIONS AND ADVERSE EFFECTS sections of this insert.

MATERIALS:

The are crafted from PEEK OPTIMA®. As PEEK OPTIMA® is radiolucent, radiographic markers are included in the distal and proximal ends of the PEEK implants. The markers consist of tantalum wires (ASTM F560) that are press-fit into small holes in the implant. Titanium anchors are an optional component of the FIDJI device. To achieve the best results, do not use FIDJI with the components from any other system or company unless otherwise stated in this document. As with other orthopaedic implants, FIDJI should not be reused or reimplanted under any circumstances.

CLEANING:

1. Clean all instruments prior to use, and as soon as possible after use. Do not allow blood and debris to dry on the instruments. If cleaning must be delayed, place instruments in a covered container with appropriate detergent or enzymatic solution to delay drying.
2. Loosen and/or disassemble instruments with removable parts.

3. Manual cleaning is recommended using a neutral pH detergent prepared in accordance with the manufacturers instructions and utilizing a mechanical aid such as a brush. Particular attention should be taken to remove all debris from instruments with cannulations and holes.

4. If ultrasonic cleaners and/or washer decontamination equipment are used, follow equipment manufacturers recommended practices. Abbott Spine recommends performing manual cleaning prior to using automated cleaning equipment. Avoid excessively acidic or alkaline solutions.

INSPECTION

1. Carefully inspect each instrument to ensure all visible blood and soil has been removed.
2. Inspect instruments and instrument cases for damage. Check action of moving parts to ensure proper operation, and ensure disassembled instruments readily assemble with mating components.
3. If damage or wear is noted that may compromise the proper function of the instrument or instrument case, do not use and contact customer service or your Abbott Spine representative for a replacement.
4. If corrosion is noted, do not use and contact customer service or your Abbott Spine representative for a replacement.

STERILIZATION:

The FIDJI implants are gamma sterilized and provided to the end user in sterile packages. There are three layers to the product packaging; the outside carton, the outer blister pack and the inner blister pack. The integrity of the outer blister pack and seal should be verified prior to use; if the packaging is compromised, the implant should be discarded.

Sterility can be verified by the sticker on the bottom of the outer box label. If the sticker is red in color, the product has been properly exposed to gamma sterilization. The inner blister pack is sterile and may be placed directly into the surgical field.

Instruments are supplied visually clean and non-sterile and must be sterilized prior to use. The following sterilization cycle has been validated: