

Rectangular Corpectomy Cage PACKAGE INSERT

This package insert covers the Rectangular Corpectomy Cage and Manual Surgical Instruments that are used for the implantation of this system. Specific sections for implants and instrumentation highlight important user information for only those devices.

GENERAL INFORMATION

The Rectangular Corpectomy Cage is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The implants have ridges or teeth in both the superior and inferior directions, which resist migration. The implants have cavities to accept packing of autograft and/or allograft. The entire structure is radiolucent so that healing can be assessed by normal radiographic methods. Additionally, radiotherapy can be performed immediately after surgery. The materials used in the implant are listed on the packages. Implants 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. To ensure radiographic visibility for inspecting the implant position, they contain marker pins made of x-ray opaque implant material (Tantalum).

INDICATIONS

The Rectangular Corpectomy Cage is a vertebral body replacement system indicated for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use as a vertebral body replacement in the thoracolumbar spine (from T1 to L5). Rectangular Corpectomy Cage is intended for use with supplemental fixation cleared for use in the thoracolumbar spine and is to be used with autograft and/or allograft.

CONTRAINDICATIONS

- Fractures
- Scoliosis
- Active infection
- Allergy to tantalum, PEEK or Titanium Alloy (Ti6Al4V ELI)
- Bone tumors in the region where the implant would have to be anchored
- Unwillingness or inability of the patient to follow the instructions for postoperative treatment
- Any medical or surgical condition that could preclude the potential success of the implantation
- Pregnancy
- Osteoporosis or similar loss of bone density
- Systemic or metabolic diseases
- Drug abuse or alcoholism
- Generally poor condition of the patient
- Morbid obesity
- Psychosocial issues; inadequate co-operation by the patient
- Fever or leukocytosis
- Any case not needing a fusion
- 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
- 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
- All cases that are not listed under indications

WARNINGS

Implants provided sterile are sterilized through gamma irradiation. Do not re-sterilize implants provided sterile. Devices provided non-sterile must be cleaned and sterilized before use. Implants may be reprocessed prior to use and must be sterilized before use. Validated sterilization cycle parameter protocols are noted in the STERILIZATION section of this insert. Implants that have come in direct contact with a patient or bio-contaminants should be disposed of.

Some instruments may be sharp, depending on their intended use. Care should be taken in handling such instruments to avoid injury to the user or patient.

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating

circumstances may compromise the results. System components are temporary implants used for the correction and stabilization of the spine. Devices are intended to be used to augment the development of a spinal fusion by providing temporary stabilization. Devices are not intended to be the sole means of spinal support. Use of these products without a bone graft or in cases that develop into a non-union will not be successful. No spinal implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device(s) will occur.

Implantation of devices should be performed only by experienced spinal surgeons with specific training in the use of the device. This is a technically demanding procedure presenting a risk of serious injury to the patient.

Preoperative and operating procedures including knowledge of surgical techniques, proper reduction, and proper selection and placement of the implant are important considerations in the successful utilization of this device by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results. The physician should consider the levels of implantation, patient weight, patient activity level, and all other patient conditions that may have an impact on the performance of this device. Patients who smoke have been shown to have an increased incidence of non-union. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spine fusion.

Adequately Instruct the Patient: Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. The patient must be aware of the limitations of the implants. The patient should be encouraged to ambulate to tolerance as soon as possible after surgery and instructed to limit and restrict lifting and twisting motions and any type of sports participation until the bone is healed. The patient should understand that implants are not as strong as normal healthy bone and could loosen, bend and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may experience migration to the devices and damage to nerves or blood vessels.

Implants Can Break When Subjected to The Increased Loading Associated with Delayed Union or Nonunion. Internal fixation appliances are load-sharing devices that are used to obtain an alignment until normal healing occurs. If healing is delayed, or does not occur, the implant may eventually break due to material fatigue. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also contribute to early failure. Patients should be fully informed of the risks of implant failure. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

Physician Note: The physician is the learned intermediary between the company and the patient. The indications, contraindications, warnings, and precautions given in this document must be conveyed to the patient.

PREOPERATIVE MANAGEMENT

1. The surgeon should consider for surgery only those patients indicated for the use of this device.
2. The surgeon should not consider for surgery those patients contraindicated for the use of this device.
3. The surgeon should have a complete understanding of the device's indications, contraindications, and applications.
4. The surgeon should have a complete understanding of the function and limitations of each implant and instrument.
5. Device components should be received and accepted only in packages that have not been damaged or tampered with. Components must be carefully handled and stored in a manner that prevents scratches, damage, and corrosion.
6. All implants and instrument should be inspected for wear and tear prior to use. Devices presenting damage such as cracks, corrosion, bends etc. should not be used. Compromised devices should be segregated and be returned to Spinal Elements.
7. The type of implant to be used for the case should be determined prior to beginning the surgery.
8. All instruments and implants should be processed and sterilized prior to use.

INTRAOPERATIVE MANAGEMENT

1. Caution should be taken in handling the implants. Damage to the implants may affect their performance.
2. Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
3. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
4. Implants should be attached to the corresponding inserter such that they are fully seated on the inserter. Care should be taken not to over-tighten the implant to the inserter.
5. Implants should not be axially rotated with the inserter once they have been implanted. This may lead to damage of the implant and/or the inserter.
6. Whenever possible or necessary, an imaging system should be utilized to facilitate surgery.
7. Implants should not be reused under any circumstances.

POSTOPERATIVE MANAGEMENT

Postoperative management by the surgeon, including instruction and warning to and compliance by the patient, of the following is essential:

1. The patient should have a complete understanding of and compliance with the purpose and limitations of the implant devices.
2. Postoperative patients should be instructed to limit activity as determined by their surgeon.
3. Retrieved implants should be properly disposed of and are not to be reused under any circumstances.
4. Contaminated instruments must be cleaned promptly after use per instructions noted in the Cleaning Instruction section of this insert in order to prevent drying and ensure an effective cleaning.

MAGNETIC RESONANCE ENVIRONMENT

The Rectangular Corpectomy Cage has 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

Potential adverse effects may include, but are not limited to the following:

- 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.
- Death.
- Spinal cord impingement or damage.
- Fracture of bony structures.
- Reflex sympathetic dystrophy.
- If a pseudarthrosis occurs coupled with the Rectangular Corpectomy Cage, 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.

Patients with previous spinal surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery

SINGLE USE

Reuse of a single use device that has come in contact with blood, bone, tissue or other body fluids may lead to patient or user injury. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure, serious injury, transmission of infectious agents and death. All implants are single use.

STERILITY

All devices provided sterile have been gamma irradiation sterilized and are for single use only. Do not re-sterilize sterile devices. All devices provided non-sterile must be sterilized prior to use. Implants and instruments provided sterile will be clearly labeled as such in an unopened sterile package provided by Spinal Elements.

SHELF LIFE

The product expiration date is indicated by the hourglass symbol on the product label. **Caution:** Do not use sterile devices if the packaging providing the sterile barrier has been compromised. 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.

CLEANING AND MAINTENANCE

GENERAL INFORMATION

Spinal Elements' instruments are manufactured from various stainless steels, aluminums, and polymers. All materials used have a history of use in such instruments. All devices provided non-sterile must be cleaned and sterilized prior to use. Do not clean devices provided sterile.

Devices must be free of packaging material prior to cleaning. Cleaning, maintenance and mechanical inspection must be performed by hospital personnel trained in the general procedures involving contaminant removal. Only neutral pH cleaners or detergents labeled for use in cleaning medical devices should be used for cleaning components. Only lubricants that are intended for use on surgical instruments should be used to lubricate instruments. Follow directions from the manufacturer of lubricating and cleaning agents regarding handling, concentration, and use of such agents.

Cleaning instructions are provided in accordance with recognized standards and regulations and are intended to supplement a hospital's existing device cleaning and disinfecting protocol. Contaminated devices should be wiped clean of visible soil at the point of use prior to transfer to a central processing unit for cleaning and sterilization. Contaminated devices must be cleaned promptly after use per the instructions provided in this insert to minimize drying and ensure an effective cleaning.

Spring-Loaded Awls should be disassembled before cleaning by compressing the button and removing the external shaft from the handle. Follow the cleaning instructions listed in the Manual Surgical Instruments section of this insert. Pay special attention to the lumens of the external shafts of disassembled instruments and all guide sleeves.

An instrument lubricant should be applied to the engagement collar of AO Quick Release Handles after cleaning.

An instrument lubricant should be applied to all hinged instruments after cleaning.

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.

Disassemble all components to provide maximum exposure for cleaning.

Cleaning agents with chlorine or chloride as an active ingredient are corrosive to stainless steel and should not be used.

Saline solution has a corrosive effect on stainless steel and should not be used. Use only neutral pH cleaning agents and detergents.

Caution: Automated washer/disinfector systems are not recommended as the sole cleaning method for surgical instruments. Automated cleaning may not be effective. A thorough, manual cleaning process is recommended. An automated system may be used as a follow-up method to manual cleaning.

INSTRUCTIONS

Follow the instructions listed below for manual cleaning prior to sterilization.

1. Disassemble all components before cleaning.
2. Completely submerge instruments in enzyme solution and allow to soak for a minimum of 20 minutes. Use a soft-bristled, nylon brush to gently scrub the device until all visible soil has been removed. Particular attention must be given to crevices, lumens, mated surfaces, connectors and other hard-to-clean areas. Lumens should be cleaned with a long, narrow, and appropriately sized soft-bristled brush (e.g. pipe cleaner brush).
3. Remove the devices from the enzyme solution and rinse in tap water for a minimum of 3 minutes. Thoroughly and aggressively flush lumens, holes and other difficult-to-reach areas.
4. After manual cleaning, and all visible blood, soft tissue, and bone have been removed ultra-sonic cleaning may be used. Place prepared cleaning agents in a sonication unit. Completely submerge device in cleaning solution and sonicate for a minimum of 10 minutes at 45-50kHz.
5. Rinse instrument in purified water for at least 3 minutes or until there is no sign of blood or soil on the device or in the rinse stream. Thoroughly and aggressively flush lumens, holes and other difficult-to-reach areas. Use de-ionized water for final rinse of all components.
6. Repeat the sonication and rinse steps above until all visible contamination has been removed.
7. Thoroughly and promptly, remove excess moisture from the instrument with a clean, absorbent and non-shedding wipe. Allow the tray and components to dry for a minimum of 15 minutes. The tray and components must be thoroughly dry prior to sterilization cycle.

Disinfection is only acceptable as an adjunct to full sterilization for reusable surgical instruments.

Carefully inspect each device to ensure that all visible blood and soil have been removed. Inspect lumens to confirm that all foreign material has been removed.

Visually inspect for damage and/or wear.

STERILIZATION

Rectangular Corpectomy Cage implants are supplied sterile using gamma irradiation.

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

INSTRUCTIONS

Visually inspect all components for any remaining debris prior to sterilization.

The Rectangular Corpectomy Cage 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.

	Method	Cycle Type	Sterilization Temperature	Exposure Time	Dry Time
Wrapped	Steam	Pre-vacuum	270°F (132°C)	4 minutes	20 minutes

Sterilization parameters were validated per ANSI/AAMI/ISO 17665-1: 2006. *Sterilization of Health Care Products – Moist Heat – Part 1 Requirements for the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices* and ANSI-AAM ST 79 - *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*. These parameters were validated to a sterility assurance level (SAL) of 10⁻⁶. 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).

Information

-  REF Catalog Number
-  MAT Material
-  LOT Batch Code
-  QTY Packaged Quantity
-  Manufacturer
-  Date of Manufacture
-  Caution, Consult Accompanying Documents
-  Do Not Re-Use
-  STERILE R Sterilized using irradiation
-  Use-by date
-  NON-STERILE Device Not Sterile
-  Rx Only Prescription Only
-  Instruction for Use are provided electronically at ifu.spinalelements.com

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CAUTION: Federal Law (USA) restricts these devices for sale by or on the order of a physician.