GENERAL INFORMATION:
The Spinal Elements Vertebral Body Replacement is a generally box-shaped device that has various holes throughout its geometry. The device is made from polyetheretherketone (PEEK) per ASTM F 2026. All implants are intended for single use only and should not be reused under any circumstances.

INDICATIONS:
The Spinal Elements Vertebral Body Replacement is 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).

This device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the thoracic and/or lumbar spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). The interior of the spacer can be packed with allograft or autograft.

CONTRAINDICATIONS:
1. Patients with probable intolerance to the materials used in the manufacture of this device.
2. Patients with infection, inflammation, fever, tumors, elevated white blood count, obesity, pregnancy, mental illness and other medical conditions which would prohibit beneficial surgical outcome.
3. Patients resistant to following post-operative restrictions on movement especially in athletic and occupational activities.
4. Use with components from other systems.
5. Grossly distorted anatomy caused by congenital abnormalities
6. Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
7. Rapid joint disease, bone absorption, osteopenia. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, and/or the amount of mechanical fixation.
8. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
9. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
10. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
11. Any case not described in the indications for use.
12. Reuse or multiple use.

WARNINGS:
Implants and instruments are provided non-sterile and must be cleaned and sterilized before use. Validated sterilization cycle parameter protocols are noted in the STERILIZATION section of this insert.

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. The Spinal Elements Vertebral Body Replacement system components are temporary implants used for the correction and stabilization of the spine. This system is intended to be used to augment the development of a spinal fusion by providing temporary stabilization. This system is not intended to be the sole means of spinal support. Use of this product 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.

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. 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. The use of allograft material may not give as good a result as pure autograft.

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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. Damaged implants and/or instruments should not be used. Components must be carefully handled and stored in a manner that prevents scratches, damage, and corrosion.
6. The type of implant to be used for the case should be determined prior to beginning the surgery.
7. All parts should be cleaned and sterilized before use.
INTRAOPERATIVE MANAGEMENT
1. Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
2. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
3. Implants should be attached to the corresponding inserter such that they are fully seated on the inserter. Care should be taken not to overtighten the implant to the inserter.
4. 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.
5. Whenever possible or necessary, an imaging system should be utilized to facilitate surgery.
6. Caution should be taken in handling the implants. Damage to the implants may affect their performance.
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.

POSSIBLE ADVERSE EFFECTS
1. Early or late loosening of any or all of the components.
2. Disassembly, bending, and/or breakage of any or all of the components.
3. Foreign body (allergic) reaction to implants.
4. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
5. Infection.
6. Dural tears, persistent CSF leakage, meningitis.
7. Loss of neurological function including paralysis (partial or complete), radiculopathy, and/or the development or continuation of pain, numbness, spasms, or sensory loss.
8. Cauda equina syndrome, neurological deficits, paraplegia, reflex deficits, irritation, and/or muscle loss.
9. Loss of bladder control or other types of urological system compromise.
10. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
11. Fracture, micro-fracture, resorption, damage, or penetration of any spinal bone.
12. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
14. Cessation of any potential growth of the operated portion of the spine.
15. Loss of or increase in spinal mobility or function.
16. Inability to perform the activities of daily living.

CLEANING:
All implants and instruments must be free of packaging material and bio-contaminants prior to sterilization. Cleaning, maintenance and mechanical inspection must be performed by hospital personnel trained in the general procedures involving contaminant removal.

STERILIZATION:
Spinal Elements Vertebral Body Replacement implants and all instruments are provided non-sterile and must be cleaned and sterilized before use. Non-sterile implants and instruments should be autoclave sterilized using the following validated cycle parameters.

<table>
<thead>
<tr>
<th>Method</th>
<th>Cycle Type</th>
<th>Sterilization Temperature</th>
<th>Exposure Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam</td>
<td>Gravity Displacement</td>
<td>270°F (132°C) (minimum)</td>
<td>30 minutes (minimum)</td>
</tr>
<tr>
<td>Steam</td>
<td>Pre-Vacuum</td>
<td>270°F (132°C) (minimum)</td>
<td>5 minutes (minimum)</td>
</tr>
</tbody>
</table>

INFORMATION:

| MAT | Implant material
| QTY | Packaged quantity
| NON-STERILE | Implant/instrument not sterile

For additional information regarding the Spinal Elements Vertebral Body Replacement, please contact Aesculap Implant Systems, Inc. Customer Service at (866) 229-3002.

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