C-PS PEEK OPTIMA® CERVICAL INTERBODY SPACER

PACKAGE INSERT

RSB SPINE, 2530 Superior Avenue, Suite 703, Cleveland, OH 44114
Phone: 866.241.2104, Fax: 216.241.2820

CAUTION – Federal (or United States) law restricts these devices to sale by or on the order of a physician.

IMPORTANT NOTE TO OPERATING SURGEON

The C-PS is designed to provide biomechanical stabilization as an adjunct to anterior cervical discectomy and must be used with autograft to facilitate fusion. Spinal fixation should only be undertaken after the surgeon has had hands-on training in this method of spinal fixation and has become thoroughly knowledgeable about spinal anatomy and biomechanics. Correct implant size and proper device orientation are critical. A surgical technique is available containing instructions on the important aspects of this surgical procedure.

Preoperative instructions to the patient are essential. The patient should be made aware of the limitations of the implant and potential adverse effects of the surgery. The patient should be instructed to limit postoperative activity, as this will reduce the risk of broken or loose implant components. The patient must be made aware that implant components may break or loosen even though restrictions in activity are followed.

Postoperative evaluation of the fusion and implant status is necessary.

DESCRIPTION

The C-PS is fabricated of PEEK-OPTIMA polyetheretherketone per ASTM F 2026.Various sizes are available to accommodate individual patient anatomy and autograft material size.

STERILIZATION

The C-PS components are supplied clean and not sterile. All implants and instruments must be cleaned and sterilized prior to surgery. AORN recommended practices for in hospital sterilization should be followed and usage of an FDA cleared wrap is recommended.

Sterilization testing of components has shown the following recommendations for sterilization are effective:

Method:	Steam	Method:	Steam
Cycle:	Gravity	Cycle:	Prevacuum
Temperature:	132°C	Temperature:	132°C
Exposure Time:	30 minutes	Exposure Time:	7 minutes
Drying Time:	70 minutes	Drying Time:	60 minutes

INDICATIONS

The C-PS is indicated for intervertebral body fusion of the cervical spine in skeletally mature patients. The device system is designed for use with autograft to facilitate fusion. One device is used per intervertebral space.

The C-PS is intended for use at one level in the cervical spine, from C3 to T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The cervical device is to be used in patients who have had six weeks of non-operative treatment. The C-PS is intended to be used with a supplemental internal fixation system.

CONTRAINDICATIONS

Use of the C-PS and spinal fixation surgery are contraindicated when there was recent or local active infection near or at the site of the proposed implantation. Any conditions that preclude the possibility of fusion are relative contraindications. These include but are not limited to: fever, mental illness, alcoholism or drug abuse, osteoporosis or osteopenia, neurotrophic diseases, obesity, pregnancy, foreign body sensitivity, use with components of other systems, unwillingness to restrict activity, reuse of implantable components, or any use not described under INDICATIONS. See also the WARNINGS, PRECAUTIONS AND POTENTIAL RISKS sections of this insert.

The following are specific warnings, precautions and adverse events that should be understood by the surgeon and explained to the patient. These warnings are specific to internal fixation devices. General surgical risks should be explained to the patient prior to surgery.

WARNINGS

Potential risks identified with the use of this system, which may require additional surgery, include:

device component fracture,
loss of fixation,
non-union,
fracture of the vertebra,
neurologic injury, and
vascular or visceral injury.
See the POTENTIAL RISKS section of the package insert for a complete list of potential risks.

PRECAUTIONS

1. **IMPLANT SELECTION**. The potential for the success of the procedure is increased by selecting the correct size of the implant. These devices are not intended to be used as the sole support for the spine.
2. **DELAYED UNION OR NONUNION**. The System is designed to assist in providing an adequate biomechanical environment for fusion. It is not intended to be and must not be used as the sole support for the spine. If a delayed union or nonunion occurs the implant may fail due to fatigue. Patients should be fully informed of the risk of implant failure.
3. **INSERTION**. The C-PS must fit the cavity prepared in the intervertebral space. Use caution when inserting the device to prevent damage to the due to impaction or bending. Do not use the C-PS to pry apart the vertebrae when attached to any instrument.
4. **PATIENT SELECTION**. Proper patient selection is critical to the success of the procedure. Only patients who satisfy the criteria set forth under the INDICATIONS section of this document AND who do not have any of the conditions set forth under the CONTRAINDICATIONS section of this document should be considered for spinal fixation surgery using the System. In addition, patients who smoke have been shown to have an increased incidence of pseudarthrosis. Based upon the fatigue testing results, the physician/surgeon should consider the level of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.
5. **SINGLE USE ONLY**. These devices are single use only implants and are not to be reused or reimplanted regardless of an apparent undamaged condition.
6. **DEVICE MODIFICATIONS**. Modifications of the components are not recommended. Modifications will compromise mechanical performance and may adversely affect fit and function of the implant.
7. **HANDLING**. Implant components should be handled and stored appropriately to protect them from unintentional damage. The surgeon should avoid introducing notches or scratches into the surfaces as these may induce premature failure of the component.
8. **PATIENT EDUCATION**. Preoperative instructions to the patient are essential. The patient should be made aware of the limitations of the implant and potential risks of the surgery. The patient should be instructed to limit postoperative activity, as this will reduce the risk of deformed, broken or loose implant components. The patient must be made aware that implant components may deform, break or loosen even though restrictions in activity are followed.
9. **POTENTIAL RISKS**
   Potential risks identified with the use of this system, which may require additional surgery, include:

1. Deformation, fracture or loosening of implant component(s).
2. Nonunion or delayed union.
3. Fracture of the vertebra.
4. Neurological, vascular or visceral injury.
5. Allergic reaction to a foreign body.
6. Infection.
7. Decrease in bone density due to stress shielding.
8. Pain, discomfort or abnormal sensations due to the presence of the device.
9. Nerve damage due to surgical trauma.
10. Bursitis.
11. Dural Leak.
12. Paralysis.
13. Death