Novel® CP Spinal Spacer System

INSTRUCTIONS FOR USE - ENGLISH

GENERAL INFORMATION:

The Novel CP Spinal Spacer System is a vertebral body replacement (VBR) device. The implants consist of various shapes (footprints), lengths, widths and heights to accommodate individual patient anatomy. System implants are manufactured from polyetheretherketone, (PEEK Optima LT1 conforming to ASTM F2026) with tantalum marker beads (conforming to ASTM F560) to facilitate radiographic visualization.

INDICATIONS:

The Novel CP Spinal Spacer System is indicated for use in spinal fusion procedures in skeletally mature patients. These patients should have had six months of non-operative treatment. When used as a Vertebral Body Replacement, the Novel CP Spinal Spacer System is indicated to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture), or in cases of partial or complete corpectomy in the cervical, thoracic and lumbar spine (C2 – L5). Novel CP is indicated for use with allograft and requires supplemental spinal fixation. The Novel CP Spinal Spacer System is recommended for use with Alphatec Spine's supplemental fixation systems, such as Trestle Luxe® Anterior Cervical Plating System, Trestle® Anterior Cervical Plating System, Aspida® Anterior Lumbar Plating System, Solanas® Posterior Cervico-Thoracic Instrumentation System, or Zodiac Polyaxial Spinal Fixation System.

CONTRAINDICATIONS:

The Novel CP Spinal Spacer System is contraindicated for:

1. Patients with osteopenia, bone absorption, bone and/or joint disease, deficient soft tissue at the wound site or probable metal and/or coating intolerance.
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. Spinal surgery cases that do not require bone grafting and/or spinal fusion.
4. Patients resistant to following post-operative restrictions on movement especially in athletic and occupational activities.
5. Use with components from other systems.
6. Patients with allergy to PEEK or tantalum.
7. Reuse or multiple uses.

WARNINGS:

1. The implants are provided non-sterile in a caddy that requires steam sterilization prior to use, refer to the *STERILIZATION* section in this IFU.
2. All instruments are provided non-sterile and must be cleaned and sterilized prior to surgery. See *CLEANING* and *STERILIZATION* sections in this IFU.
3. The product implants are single use devices. Do not reuse. While an implant may appear undamaged, it may have small defects or internal stress patterns that could lead to fatigue failure. In addition, the removed implant has not been designed or validated for the decontamination of microorganisms. Reuse of this product could lead to cross-infection and/or material degradation as a result of the decontamination process.
4. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
5. The Novel CP Spinal Spacer System implants are used only to provide internal fixation during the bone fusion process with the assistance of allograft and supplemental fixation. A

successful result may not be achieved in every instance of use with these devices. The benefit of spinal fusions utilizing any vertebral body replacement has not been adequately established in patients with stable spines.

6. Based on fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact the performance of this system. No spinal implant can withstand body loads for an indefinite period of time without the support of bone. In the event that successful fusion is not achieved; bending, breakage, loosening, migration and/or dislocation of the device will occur.
7. Risks identified with the use of these devices, which may require additional surgery, include device component failure, loss of fixation/ stabilization, non-union, vertebral fracture, neurological injury, and/ or vascular or visceral injury.
8. Risk factors that may affect successful surgical outcomes include: Alcohol abuse, obesity, patients with poor bone, muscle and/or nerve quality. Patients who use tobacco or nicotine products should be advised of the consequences that an increased incidence of nonunion has been reported with patients who use tobacco or nicotine products.
9. The System Implants of the Alphatec Spine product lines should not be used with any other company's spinal systems.

PRECAUTIONS:

1. The implantation of the Novel CP Spinal Spacer System Implants should be performed only by experienced spinal surgeons with specific training in the use of this device due to the risk of serious injury to the patient.
2. The Novel CP Spinal Spacer System has not been evaluated for safety and compatibility in the Magnetic Resonance (MR) environment. It has not been tested for heating or migration in the MR environment.
3. Physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may have impact on the performance of the intervertebral body fusion device.
4. Installation and positional adjustment of implants must only be done with special equipment and instruments specific to these devices. They must not be used with other instrumentation unless specifically recommended by Alphatec Spine Inc., because the combination with other instrumentation may be incompatible.

POSSIBLE ADVERSE EFFECTS:

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

1. Initial or delayed loosening, bending, dislocation and/or breakage of device components.
2. Physiological reaction to implant devices due to foreign body intolerance including inflammation, local tissue reaction, seroma, and possible tumor formation.
3. Loss of desired spinal curvature, spinal correction and/or a gain or loss in height.
4. Infection and/or hemorrhaging.
5. Non-union and/or pseudoarthrosis.
6. Neurological disorder, pain and/or abnormal sensations caused by improper placement of the device, and/or instruments.
7. Subsidence of the device into the vertebral body.
8. Revision surgery.
9. Death.

PREOPERATIVE MANAGEMENT:

1. Only patients meeting the criteria listed in the indications for the use section should be selected.

2. Surgeons should have a complete understanding of the surgical technique, system indications, contraindications, warnings and precautions, safety information, as well as functions and limitations of the implants and instruments.
3. Careful preoperative planning should include implant strategy and a verification of required inventory for the case.
4. The condition of all implants & instruments should be checked prior to use. Damaged and/or worn implants and instruments should not be used.

INTRAOPERATIVE MANAGEMENT:

1. The surgical technique manual should be followed carefully.
2. To prevent possible nerve damage and associated disorders, extreme caution should be taken to avoid the spinal cord and nerve roots at all times.
3. Bone graft must be placed in the area to be fused and graft material must extend from the upper to the lower vertebrae being fused.

POSTOPERATIVE MANAGEMENT:

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

1. Patient should be informed and compliant with the purpose and limitations of the implant devices.
2. The surgeon should instruct the patient regarding the amount and time frame after surgery of any weight bearing activity. The increased risk of bending, dislocation, and/or breakage of the implant devices, as well as an undesired surgical result are consequences of any type of early or excessive weight bearing, vibratory motion, falls, jolts or other movements preventing proper healing and/or fusion development.
3. Implant devices should be revised or removed if bent, dislocated or broken.
4. Immobilization should be considered in order to prevent bending, dislocation, or breakage of the implant device in the case of delayed, malunion, or nonunion of bone. Immobilization should continue until a complete bone fusion mass has developed and been confirmed.
5. Postoperative patients should be instructed not to use tobacco or nicotine products, consume alcohol, or use non-steroidal antiinflammatory drugs and aspirin, as determined by the surgeon. Complete postoperative management to maintain the desired result should also follow implant surgery.

INSTRUMENT PREPARATION:

1. Cleaning, inspection, lubrication, and sterilization must be performed by hospital personnel trained in the general procedures involving contaminant removal.
2. Instruments must be cleaned prior to lubrication and sterilization.
3. All instrument hinged, rotating, and articulating parts must be lubricated prior to sterilization with a water soluble and sterilizable lubricant intended for surgical instruments (Hinge-Free® for example).

CLEANING:

Instruments must be cleaned prior to sterilization. Cleaning, maintenance and mechanical inspection must be performed by hospital personnel trained in the general procedures involving contaminant removal. Handle all products with care. Mishandling may lead to damage and possible improper functioning of the device.

Ensure instruments are in the fully extended, open position throughout cleaning. Quick Connect Handles are to be disconnected from the shafted instruments prior to cleaning. Complex instruments, such as those with, cannulas, hinges, retractable features, mated surfaces, and

textured surface finishes, require special attention during cleaning. Manual pre-cleaning of such device features is required before automated cleaning processing.

Manual Cleaning Steps for Instruments

Step 1	Rinse devices in deionized (DI) or reverse osmosis (RO) water to remove excess soil.
Step 2	Submerge device in enzyme solution and soak for 5 minutes.
Step 3	Scrub device using a soft bristled brush until all visible soil has been removed. Use of a syringe or water jet is recommended for hard to reach areas.
Step 4	Rinse devices in lukewarm tap water for a minimum of one minute.
Step 5	Submerge devices in cleaning solution such as CritiKlenz® and sonicate for a minimum of 10 minutes.
Step 6	Thoroughly rinse devices with RO/DI water to remove all detergent residues.
Step 7	Dry devices with a clean soft cloth.

Pre-cleaning for Automatic Washer

Step 1	Rinse devices in deionized (DI) or reverse osmosis (RO) water to remove excess soil.
Step 2	Submerge device in enzyme solution and soak for 5 minutes.
Step 3	Rinse devices in lukewarm tap water to remove detergent residuals.
Step 4	Place devices in fully extended open position into washer and process through a standard washer/disinfector instrument cycle.

Automatic Washer/Disinfector Cycle Steps

Step 1	Pre Wash, cold tap water, 2 minutes.
Step 2	Enzyme wash, hot tap water, 1 minute.
Step 3	Detergent wash, Hot tap water (66 °C/150 °F), 2 minutes.
Step 4	Rinse 2x, hot tap water, 15 seconds.
Step 5	Purified Water rinse, Hot tap water (66 °C/150 °F), 10 seconds.
Step 6	Dry devices with a clean soft cloth. Pressurized air can be used to assist drying.

STERILIZATION / RESTERILIZATION: Non-sterile implants and all instruments must be sterilized using the following validated cycle parameters.

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Pre-Vacuum	132°C (270°F)	4 minutes	45 minutes

COMPLAINT HANDLING/REPORTING:
All product complaints relating to safety, efficacy or performance of the product should be reported immediately to Alphatec Spine by telephone, fax, email or letter. All complaints should be accompanied by name, part number, and lot numbers. The person formulating the complaint should provide their name, address, and as many details as possible. For surgical technique or additional information regarding the Novel Spinal Spacer System, please contact Alphatec Spine, Inc. Customer Service at (800) 922-1356 or (760) 431-9286.

Rx Only	**Caution**: Federal law (USA) restricts these devices to sale by or on the order of a physician

CE This mark applies to all Class I devices

CE 0413 CE0413 applies to all Class IIa and IIb devices

SYMBOLS:

For a listing of Symbols and Explanations, see atecspine.com/eifu

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