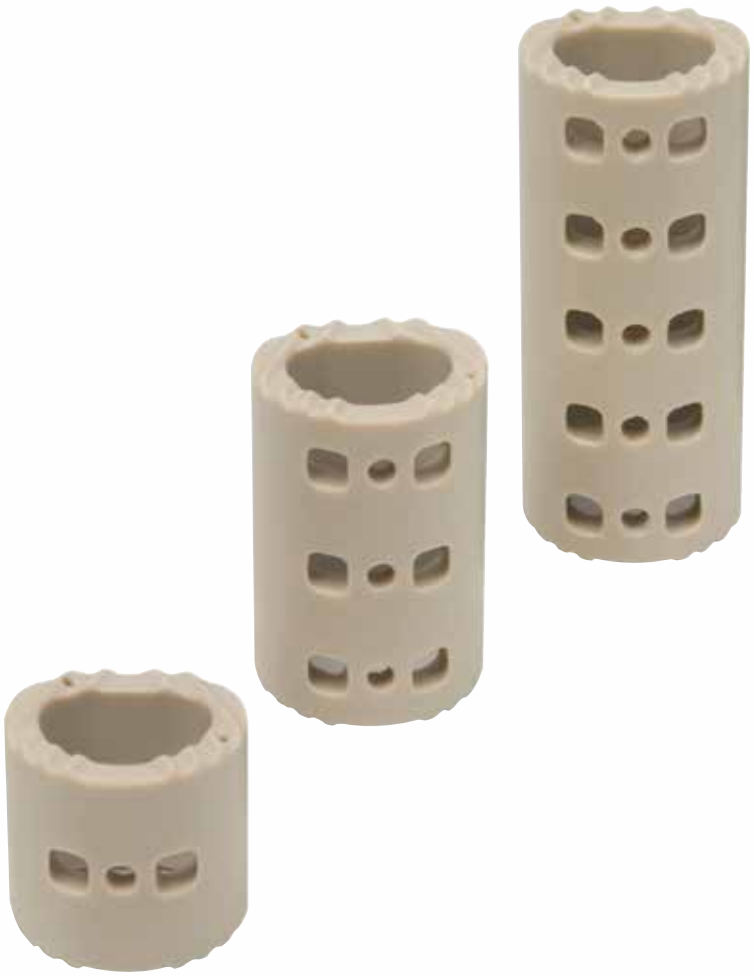
Novel® CP

Spinal Spacer System



Alphatec Spine®

INTERBODY | Surgical Technique Guide

SYSTEM FEATURES

- Small and Medium footprint options to accommodate different anatomy and surgical procedures
- 5° Lordosis
- 10 – 50mm implant sizing in 1mm increments
- Tooth pattern helps prevent migration and adds stability
- Large implant contact area to resist subsidence
- Radiographic markers ease visual assessment of implant placement
- Multiple fenestrations designed to increase bone graft vascularization
- Large area for bone graft placement
- Compact and comprehensive instruments designed to simplify the implant process
- Radiolucent PEEK material enhances visualization of fusion process

INNOVATION & PROVEN TECHNIQUES

As a next step in the evolution of spinal column reconstruction, Alphatec Spine introduces the NOVEL CP Corpectomy Spinal Spacer System:

The NOVEL CP Corpectomy Spinal Spacer System is a vertebral body replacement device consisting of two footprints of varying lengths, widths and heights to accommodate individual patient pathology. The NOVEL Spinal Spacer System is to be used with a supplemental fixation system. Specifically, the NOVEL Spinal Spacer System should be used with the ZODIAC® Polyaxial Spinal Posterior Fixation System and bone graft. The NOVEL CP Corpectomy Spinal Spacer System is intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged or unstable vertebral body due to tumor or trauma (i.e. fracture).

The NOVEL CP Corpectomy Spinal Spacer System is simple and versatile in its application incorporating:

- Small and medium footprint options to accommodate different anatomy and surgical procedures
- 5° Lordosis
- 10 – 50mm implant sizing in 1mm increments
- Tooth pattern helps prevent migration and adds stability
- Large contact area to resist subsidence
- Radiographic markers to ease visual assessment of implant placement
- Multiple fenestrations for increased bone graft vascularization
- Large area for bone graft
- Compact and comprehensive instruments to simplify the implant process

CONTENTS

PERFORM CORPECTOMY

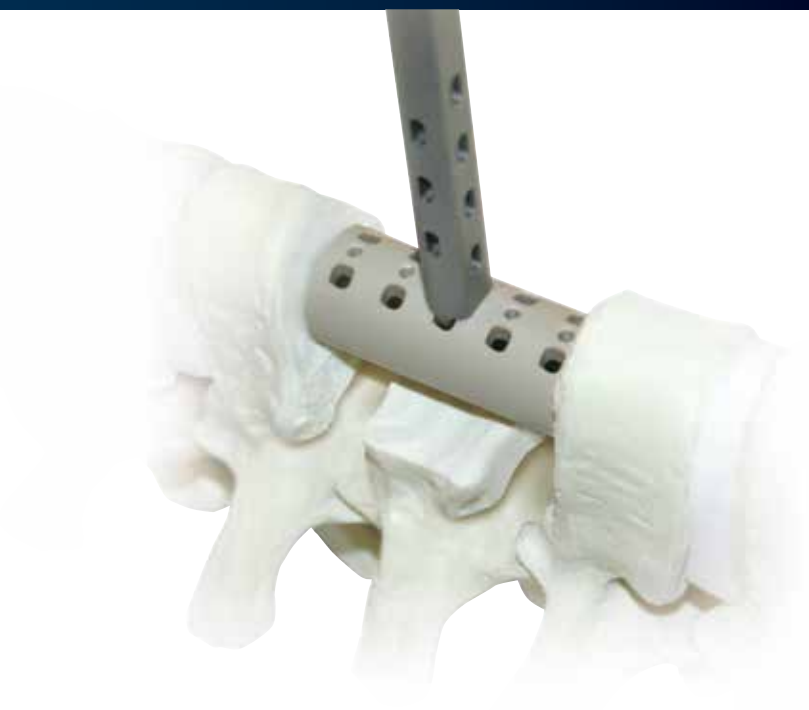
Using commercially available rongeurs, pituitaries, curettes and kerrisons, perform a partial or complete corpectomy at the indicated level, as required. Remove disc material and lightly decorticate the endplates adjacent to the level of the corpectomy. The provided rasp may be used to facilitate decortication of the endplates, if desired. Avoid removal of excessive bony endplate to minimize the risk of implant subsidence.

DETERMINE IMPLANT SIZE

If desired, a commercially available distraction device may be used between the endplates adjacent to the corpectomy site to facilitate restoration of anterior column height. Using the provided caliper, measure the height of the defect in situ from the anterior aspect of the inferior endplate to the anterior aspect of the superior endplate. Account for the size of any distraction device used. Select NOVEL CP implant of desired size.

PLACE GRAFT MATERIAL

Using commercially available forceps and bone tamps, pack the NOVEL CP implant with bone graft prior to insertion. Take care to ensure implant is completely filled with bone graft.



INSERT IMPLANT

Load the implant onto the inserter by engaging the tips of the inserter into the corresponding slots on the implant. Thread the inserter to the implant by rotating the knurled knob of the inner cannula until snug. Avoid overtightening of the implant to the inserter. Insert the implant into the desired position within the corpectomy defect. Use the implant tamp to further manipulate the implant into final position as necessary. The implant inserter may be used to reposition the implant as required.

VERIFY IMPLANT POSITION

Confirm NOVEL CP implant position with AP and lateral fluoroscopy. Use the Implant Tamp to adjust the implant as necessary. Pack additional bone graft material anteriorly. Remove the distraction device if used.

NOVEL CP implant is indicated for use with supplemental anterior, lateral, or posterior fixation, including the Alphatec ZODIAC Polyaxial Spinal Fixation System.

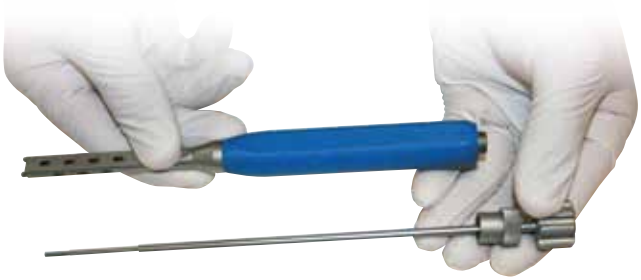
NOTE: Lateral and AP view of spacer in proper alignment showing radiographic markers.

The NOVEL Spinal Spacer System is to be used with a supplemental fixation system, such as the ZODIAC Polyaxial Spinal Fixation System and bone graft.

INSERTER DISASSEMBLY

The CP Inserter is designed for disassembly to facilitate cleaning and sterilization. Remove inner shaft by rotating the knurled knob counter-clockwise until separated from inserter handle. Once separated, remove completely from handle. To reassemble, reverse the above procedure.

NOTE: Take care to avoid tightening both the knurled knob and the thumb nut while loading implant onto inserter.



INSTRUMENTS

CP Caliper

CP Tamp Small: 64902-01

CP Rasp, Small 7°: 64901-01

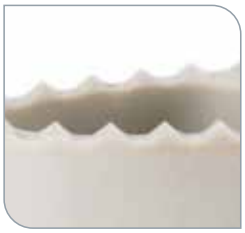
CP Tamp Medium: 64902-02

CP Inserter: 64902-01

IMPLANT FEATURES

Tantalum radiographic markers ease visual assessment of implant placement

Tooth pattern helps prevent migration and adds stability



NOVEL Inserter provides positive control for surgical approach

NOVEL Corpectomy PEEK Implants

Standard

Description	Qty
NOVEL CP Spacer, 10mm Small, 5° Lordotic	1
NOVEL CP Spacer, 12mm Small, 5° Lordotic	1
NOVEL CP Spacer, 14mm Small, 5° Lordotic	1
NOVEL CP Spacer, 16mm Small, 5° Lordotic	1
NOVEL CP Spacer, 18mm Small, 5° Lordotic	1
NOVEL CP Spacer, 20mm Small, 5° Lordotic	1
NOVEL CP Spacer, 22mm Small, 5° Lordotic	1
NOVEL CP Spacer, 24mm Small, 5° Lordotic	1
NOVEL CP Spacer, 26mm Small, 5° Lordotic	1
NOVEL CP Spacer, 28mm Small, 5° Lordotic	1
NOVEL CP Spacer, 30mm Small, 5° Lordotic	1
NOVEL CP Spacer, 32mm Small, 5° Lordotic	1
NOVEL CP Spacer, 34mm Small, 5° Lordotic	1
NOVEL CP Spacer, 36mm Small, 5° Lordotic	1
NOVEL CP Spacer, 38mm Small, 5° Lordotic	1
NOVEL CP Spacer, 40mm Small, 5° Lordotic	1
NOVEL CP Spacer, 42mm Small, 5° Lordotic	1
NOVEL CP Spacer, 44mm Small, 5° Lordotic	1
NOVEL CP Spacer, 46mm Small, 5° Lordotic	1
NOVEL CP Spacer, 48mm Small, 5° Lordotic	1
NOVEL CP Spacer, 50mm Small, 5° Lordotic	1
NOVEL CP Spacer, 10mm Medium, 5° Lordotic	1
NOVEL CP Spacer, 12mm Medium, 5° Lordotic	1
NOVEL CP Spacer, 14mm Medium, 5° Lordotic	1
NOVEL CP Spacer, 16mm Medium, 5° Lordotic	1
NOVEL CP Spacer, 18mm Medium, 5° Lordotic	1
NOVEL CP Spacer, 20mm Medium, 5° Lordotic	1
NOVEL CP Spacer, 22mm Medium, 5° Lordotic	1
NOVEL CP Spacer, 24mm Medium, 5° Lordotic	1
NOVEL CP Spacer, 26mm Medium, 5° Lordotic	1
NOVEL CP Spacer, 28mm Medium, 5° Lordotic	1
NOVEL CP Spacer, 30mm Medium, 5° Lordotic	1
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NOVEL CP Spacer, 40mm Medium, 5° Lordotic	1
NOVEL CP Spacer, 42mm Medium, 5° Lordotic	1
NOVEL CP Spacer, 44mm Medium, 5° Lordotic	1
NOVEL CP Spacer, 46mm Medium, 5° Lordotic	1
NOVEL CP Spacer, 48mm Medium, 5° Lordotic	1
NOVEL CP Spacer, 50mm Medium, 5° Lordotic	1

Optional

Description	Qty
NOVEL CP Spacer, 11mm Small, 5° Lordotic	1
NOVEL CP Spacer, 13mm Small, 5° Lordotic	1
NOVEL CP Spacer, 15mm Small, 5° Lordotic	1
NOVEL CP Spacer, 17mm Small, 5° Lordotic	1
NOVEL CP Spacer, 19mm Small, 5° Lordotic	1
NOVEL CP Spacer, 21mm Small, 5° Lordotic	1
NOVEL CP Spacer, 23mm Small, 5° Lordotic	1
NOVEL CP Spacer, 25mm Small, 5° Lordotic	1
NOVEL CP Spacer, 27mm Small, 5° Lordotic	1
NOVEL CP Spacer, 29mm Small, 5° Lordotic	1
NOVEL CP Spacer, 31mm Small, 5° Lordotic	1
NOVEL CP Spacer, 33mm Small, 5° Lordotic	1
NOVEL CP Spacer, 35mm Small, 5° Lordotic	1
NOVEL CP Spacer, 37mm Small, 5° Lordotic	1
NOVEL CP Spacer, 39mm Small, 5° Lordotic	1
NOVEL CP Spacer, 41mm Small, 5° Lordotic	1
NOVEL CP Spacer, 43mm Small, 5° Lordotic	1
NOVEL CP Spacer, 45mm Small, 5° Lordotic	1
NOVEL CP Spacer, 47mm Small, 5° Lordotic	1
NOVEL CP Spacer, 49mm Small, 5° Lordotic	1
NOVEL CP Spacer, 11mm Medium, 5° Lordotic	1
NOVEL CP Spacer, 13mm Medium, 5° Lordotic	1
NOVEL CP Spacer, 15mm Medium, 5° Lordotic	1
NOVEL CP Spacer, 17mm Medium, 5° Lordotic	1
NOVEL CP Spacer, 19mm Medium, 5° Lordotic	1
NOVEL CP Spacer, 21mm Medium, 5° Lordotic	1
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NOVEL CP Spacer, 39mm Medium, 5° Lordotic	1
NOVEL CP Spacer, 41mm Medium, 5° Lordotic	1
NOVEL CP Spacer, 43mm Medium, 5° Lordotic	1
NOVEL CP Spacer, 45mm Medium, 5° Lordotic	1
NOVEL CP Spacer, 47mm Medium, 5° Lordotic	1
NOVEL CP Spacer, 49mm Medium, 5° Lordotic	1

NOVEL Corpectomy Instruments

Standard

Description	Qty
NOVEL CP Inserter	1
NOVEL CP Rasp, 7° Lordotic	1
NOVEL CP Tamp, Small	1
NOVEL CP Tamp, Medium	1
NOVEL CP Caliper	1

NOVEL® CP SPINAL SPACER SYSTEM
Instructions For Use

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.

Refer to INS-077 for additional information

℞only **Caution: Federal law (USA) restricts these instruments to sale by or on the order of a physician.**

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

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LIT-83241D | 2021/04/20