NOVEL® SPINAL SPACER SYSTEM
INSTRUCTIONS FOR USE

GENERAL INFORMATION:
The Novel Spinal Spacer System is an intervertebral body fusion device that can also be used as a vertebral replacement device. The implants are a spinal fixation system consisting of various cylindrical shapes (footprints) of varying lengths, widths and heights to accommodate individual patient pathology. System implants are manufactured of surgical grade titanium alloy (ASTM F136) or polyetheretherkeytone, PEEK (ASTM F2026). A radiographic marker made of titanium (ASTM F136) or tantalum (ASTM F560) facilitates visualization. The Novel Spinal System must be used with a supplemental spinal fixation system per the indications for use. When used as an intervertebral body fusion, the Novel Spinal Spacer System is to be used with autogenous bone graft and these patients should have had six months of non-operative treatment. Anterior Disc Prep (ADP) Instruments are provided with the system.

INDICATIONS:
When used as a vertebral body replacement, the Novel 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 Spinal Spacer System is intended for use with supplemental spinal fixation system. Specifically, the Novel Spinal Spacer System is to be used with Alphatec Zodiac® Polyaxial Spinal Fixation System. Furthermore, the Novel Spinal Spacer System is intended for use with allograft.

When used as a lumbar intervertebral body fusion, the Novel Spinal Spacer System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients should have had six months of non-operative treatment. The Novel Spinal Spacer System is to be used with a supplemental fixation system and autogenous bone graft.

When used as a cervical intervertebral body fusion device, the Novel Spinal Spacer System is intended for spinal fusion procedures at one level (C2 to T1) in skeletally mature patients with degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Implants are to be implanted via an open, anterior approach and packed with autogenous bone graft. These patients should have had six months of non-operative treatment. The Novel Spinal Spacer System is to be used with a supplemental fixation system.

CONTRAINDICATIONS:
The Novel 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. Reuse, or multiple use from other systems.

WARNINGS AND PRECAUTIONS:

1. The Novel Spinal Spacer System is an implant device used only to provide internal fixation during the bone fusion process with the assistance of a bone graft (allogenous for vertebral body replacement, autogenous for interbody fusion). A successful result may not be achieved in every instance of use with this device. This fact is especially true in spinal surgery where other patient conditions may compromise the results.
2. The benefit of spinal fusions utilizing any vertebral body replacement or intervertebral body fusion system has not been adequately established in patients with stable spines.
3. Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, compliance of the patient, and other patient conditions which may have an impact on the performance and results 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, dislocation, migration and/or disassembly of the device will occur.
4. ***Implants are a single use device.*** *Under no circumstances should it be reused. While the device may appear to be undamaged, it may have small defects or internal stress patterns, as a result of the prior implantation or removal that could lead to fatigue failure. Additionally, please note that the removed implant has not been designed or validated so as to allow for decontamination of microorganisms. Reuse of this product could lead to cross-infection and/or material degradation as a result of the decontamination process. The company accepts no responsibility for products which have been reused.*
5. Potential risks identified with the use of this device, which may require additional surgery, include device fracture, loss of fixation, non-union, fracture of the vertebra, neurological injury and vascular or visceral injury.
6. Patients who smoke should be advised of the consequences of the fact that an increased incidence of non-union has been reported with patients who smoke.
7. Other significant risks to spinal surgery include alcohol abuse, obesity, and/or patients with poor bone, muscle and/or nerve quality.
8. This device is not intended to be the sole means of spinal support. The Novel Spinal System must be used with additional anterior and or posterior instrumentation to augment stability.
9. Use of this product without a bone graft may 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 may eventually occur.
10. **Instruments provided non-sterile must be cleaned and sterilized before use**. Validated Sterilization cycle parameters are noted in the STERILIZATION/RESTERILIZATION section of this insert.
11. Preoperative and operating procedures, including knowledge of surgical techniques, proper selection and placement of the implant, and good reduction are important considerations in the success of surgery.
12. 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.
13. The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. Metal implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause metal fatigue and consequent breakage, bending, or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

MRI SAFETY INFORMATION:

The Novel Interbody Fusion System has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Novel Interbody Fusion System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

POSSIBLE ADVERSE EFFECTS:

The following complications and adverse reactions have been shown to occur with the use of similar spinal instrumentation. These effects and any other known by the surgeon must be discussed with the patient preoperatively.

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, 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. Bone graft, vertebral body and/or sacral fracture, and/or discontinued growth of fused bone at, above and/or below the surgery level.
6. Non-union and/or pseudoarthrosis.
7. Neurological disorder, pain and/or abnormal sensations caused by improper placement of the device, and/or instruments.
8. Scar tissue formation possibly causing neurological and/or vascular compromise.
9. Bone loss and/or decrease in density due to stress shielding.
10. Subsidence of the device into the vertebral body.
11. Revision surgery.
12. Death.

PREOPERATIVE MANAGEMENT

1. The surgeon should consider for surgery only those patients indicated for the use of the Novel Spinal Spacer System.
2. The surgeon should not consider for surgery those patients contraindicated for the use of the Novel Spinal Spacer System.
3. The surgeon should have a complete understanding of the surgical technique and of the device design rationale, indications, contraindications and applications.
4. The surgeon should have a complete understanding of the function and limitations of each implant and instrument.
5. Careful preoperative planning should include implant strategy and a verification of required inventory for the case.
6. Novel Spinal Spacer System 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.
7. The condition of all implants & instruments should be checked prior to use. Damaged and/or worn implants and instruments should not be used.
8. **Instruments must be cleaned and sterilized prior to use**.

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, especially upon insertion.
3. Careful use of the implants and instruments should be taken. Misuse of the components could cause injury to the patient or operating personnel.
4. Bone graft must be used in conjunction with the Novel Spinal Spacer System to augment stability. Bone graft (allogenous for vertebral body replacement, autogenous for interbody fusion)should be packed inside the device prior to insertion, and around the device after insertion. The graft should extend from the upper vertebra being fused to the lower vertebra being fused.
5. The Novel Spinal Spacer System should be supported by anterior and/or posterior stabilization devices. The Novel Spinal Spacer System is not meant to be the sole support for fusion.

POSTOPERATIVE MANAGEMENT:

Postoperative management by the surgeon, including instruction, warning 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 device. The surgeon should instruct the patient on how to compensate for any loss in range of spinal motion due to bone fusion.
2. The surgeon should instruct the patient regarding 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, vibration motion, fall, jolts or other movements preventing proper healing and/or fusion development.
3. In the case of delayed, mal-, or non-union of bone, the patient must continue to be immobilized in order to prevent bending, dislocation, or breakage of the implant device. Immobilization should continue until a complete bone fusion mass has been developed and confirmed.
4. Postoperative patients should be instructed not to smoke, consume alcohol, or consume non-steroidals and aspirin, as determined by the surgeon. Complete postoperative management to maintain the desired result should also follow implant surgery.
5. Implant devices should be revised or removed immediately if appropriate, upon a case of a non-union, pseudoarthrosis or if the devices have been bent, dislocated or broken.
6. Retrieved implants should be properly disposed of and are not to be reused under any circumstance.

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:

All implants and instruments must be free of packaging material and biocontaminants prior to sterilization. Cleaning, maintenance and mechanical inspection must be performed by hospital personnel trained in the general procedures involving contaminant removal. For complex devices, 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. Assure devices are in the fully extended, open position throughout cleaning. Certain instruments may require dismantling before cleaning. Handle all products with care. Mishandling may lead to damage and possible improper functioning of the device.

Manual Cleaning Steps

Step 1	Rinse devices in deionized (DI) or reverse osmosis (RO) water to remove excess soil.
Step 2	Submerge device in enzyme solution and allow to 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 1 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.

Automatic Washer Cleaning

Step 1	Rinse devices in deionized (DI) or reverse osmosis (RO) water to remove excess soil.
Step 2	Submerge device in enzyme solution and allow to 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:

All implants and instruments are provided non-sterile and must be cleaned and sterilized before use. Implants and instruments should be autoclave sterilized using the following validated cycle parameters. Alphatec products have been validated to achieve sterility using a double layer of single-ply sterilization wrap.

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

UDI Construction

To compile a unique device identifier (UDI) for reusable, reprocessed devices, the device identifier (GTIN) may be ascertained by searching for the part number in the FDA GUDID at https://accessgudid.nlm.nih.gov/. The production identifier(s) (e.g., lot number, serial number) may be found directly marked on the device.

COMPLAINT HANDLING/REPORTING:

All product complaints relating to safety, efficacy or performance of the product should be reported immediately to Alphatec Spine by telephone, email, or letter, per contact information below. 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. You may contact Customer Service directly at: customerservice@atecspine.com.

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

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

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