Novel® ALS

Spinal Spacer System

Alphatec Spine®

INTERBODY | Surgical Technique Guide

SYSTEM FEATURES

- Multiple footprint options to accommodate differing patient anatomies
- Large area for bone graft
- Large contact area to resist subsidence
- Radiographic markers to ease visual assessment of implant placement
- Radiolucent PEEK material enhances visualization of fusion process
- Compact and comprehensive instruments simplify the implant process
- Offered as individually packaged sterile product

INNOVATION

The Novel ALIF 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 ALIF Spinal Spacer System is to be used with a supplemental fixation system and autogenous bone graft.

- The Novel Anterior Lumbar Interbody Spinal Spacer System is simple and versatile in its application:
- Three footprint options to accommodate different anatomy and surgical procedures
- Tooth pattern is designed to prevent migration and add stability
- Large contact area to resist subsidence
- Radiographic markers to ease visual assessment of implant placement

CONTENTS

DETERMINE APPROACH

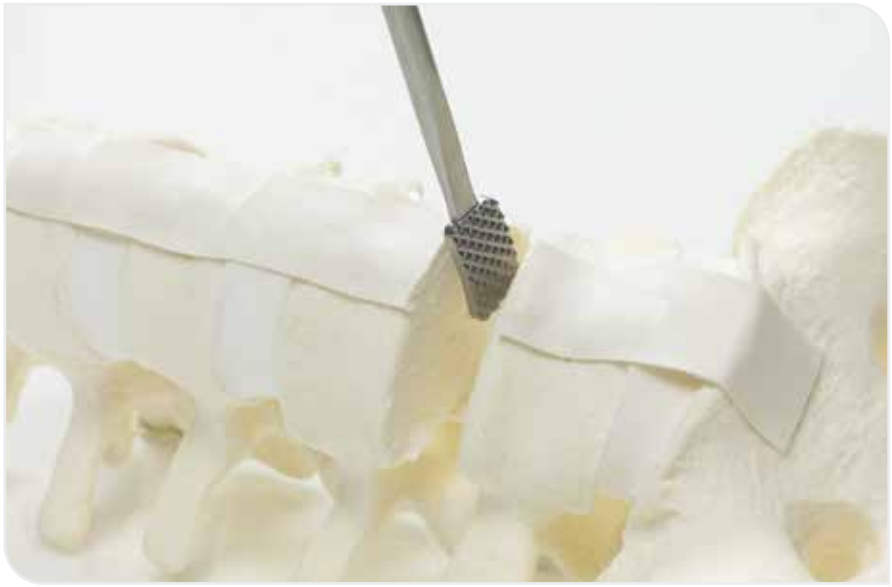
Surgical approach is dependant upon the surgeon's preference of level treated. Universal instrumentation accommodates an anterior or anterolateral (45° offset) approach.

NOTE: Anterolateral approaches preserve anterior longitudinal ligament support and minimize vasculature disruption.

PERFORM DISCECTOMY

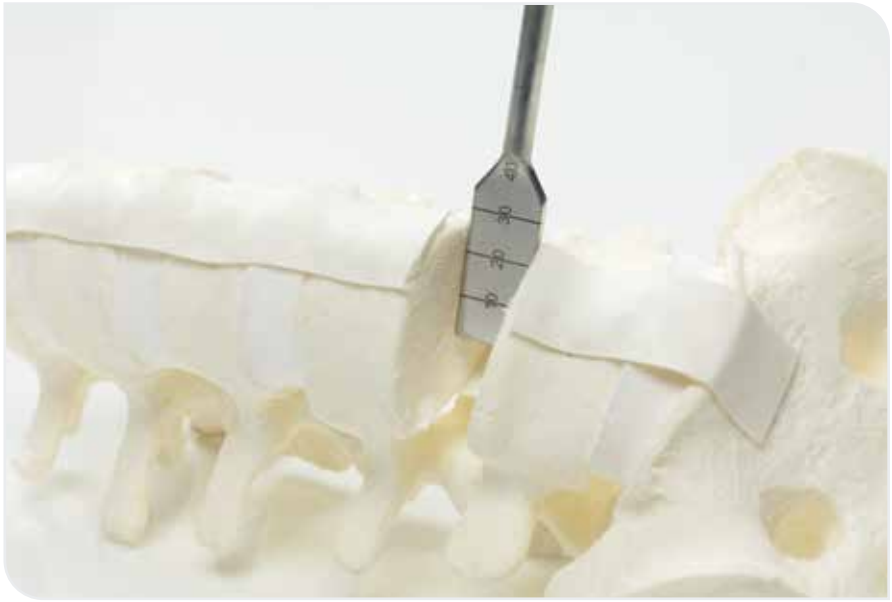
Remove disc material using available pituitaries and currettes. Rasp may be used to remove superficial layers of cartilaginous endplates.

If desired, 2 rasps are provided to assist in the removal of the superficial layers of the cartilaginous endplates and to further prepare the site.



DETERMINE IMPLANT SIZE

In the newly prepared disc space, a rotating distractor may be used to further prepare the site and determine the appropriate amount of distraction. Additionally, the straight inserter may be used with the provided implant trials.



PLACE GRAFT MATERIAL

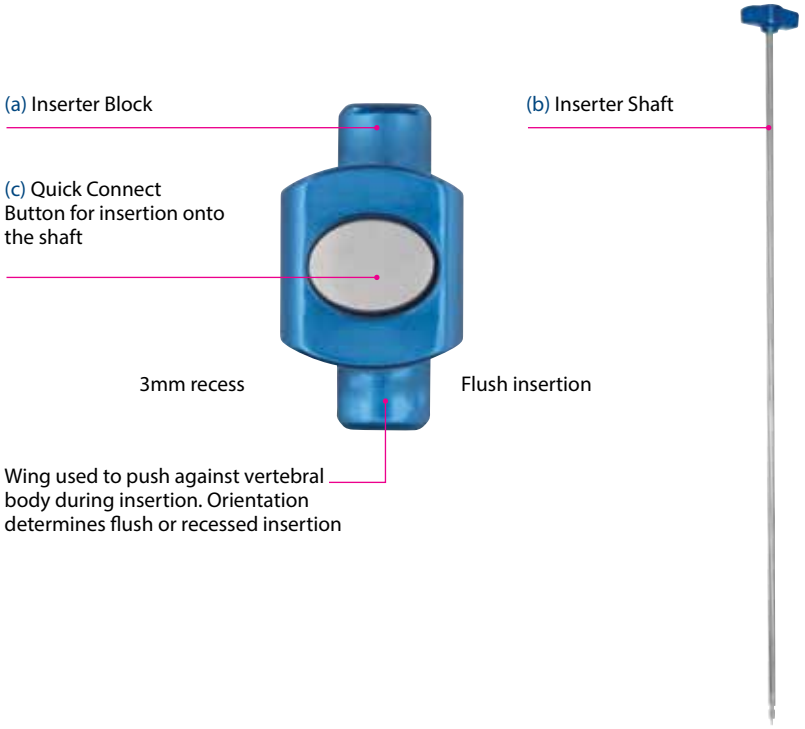
Pack the desired implant with the autogenous bone graft prior to insertion.

LOADING A TRIAL OR IMPLANT

Inserter/Distractor

The inserter/distractor is used to simultaneously distract the vertebral bodies and insert the implant. To load an implant, a distracting block (a) must first be loaded onto the insertion shaft (b). The block is loaded onto the shaft by depressing the spring-loaded button (c) and inserting over the distal end of the shaft.

The blocks incorporate blades that are used to engage the vertebral body during the insertion process and push the inserter out of the wound as the implant is inserted into place. These wings are situated such that the orientation of the block will allow the implant to be inserted flush with the vertebral body, or recessed 3mm.



Inserter/Distractor

The inserter distractor was designed to allow loading of the grafts with no threading. To insert the implant, simply press the threaded end of the implant onto the tip of the shaft. The end of the shaft is tapered to securely fit into the graft.

Inserter configured with Novel implant

Standard Inserter

The standard inserter was designed to thread onto the novel PEEK ALIF implant or titanium trial. To insert, place the device onto the end of the inserter, and rotate the knurled knob clockwise to ensure a secure fit.

Inserter configured with AlphaGRAFT implant

Standard Inserter

DISTRACT AND INSERT IMPLANT

Select the appropriate sized implant, load the inserter and place into proper position to engage. The implant inserter may be used to reposition implant as well.

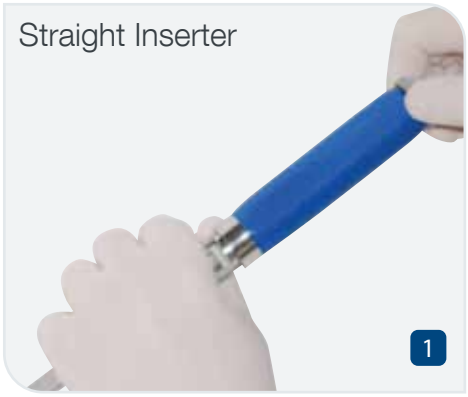
VERIFY IMPLANT POSITION

Confirm implant position with AP and lateral fluoroscopy. Use the Implant Tamps provided to manipulate the implant into final position. Pack additional autogenous bone grafting material anteriorly. Remove the distraction device by pulling away from the inserted implant.

INSERTER DISASSEMBLY

Both inserters may be disassembled to facilitate cleaning and sterilization. Instructions to disassemble are provided for below.

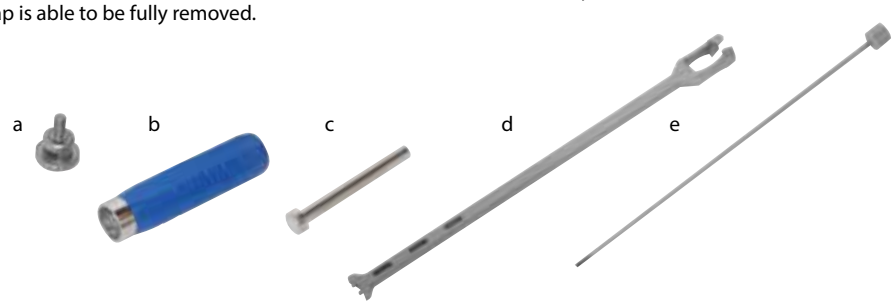
Straight Inserter



Rotate the knurled knob (a) on the proximal end of the instrument counter clockwise until the end cap is able to be fully removed.

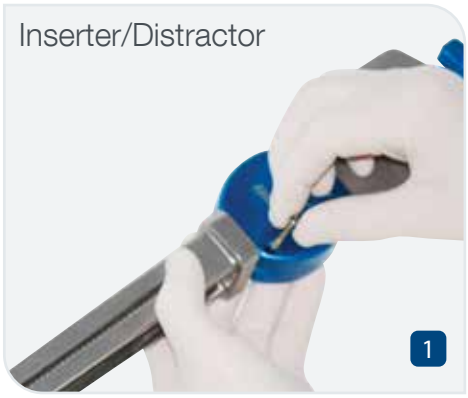
Remove the handle (b) by sliding away from the inserter body.

The inner handle shaft (c) may be removed by pushing down and twisting to disengage it, and then pulled out of the inserter body (d). The remaining inner shaft may be removed by pulling it away from the inserter shaft body (e) until fully disengaged.

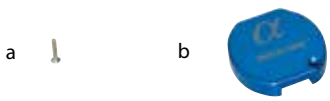


To re-assemble, reverse the above directions, taking care to ensure the knurled knob is firmly tightened after assembly.

Inserter/Distractor



Loosen the two screws (a) on both sides of the anodized cover plates (b) using a standard 5/64" allen wrench (not standard in set). After removing both screws, both sides of the anodized cover plates may be removed by simply pulling apart.



The inner shaft (c) may be removed by pulling away from the inserter assembly.

Two spring loaded pawls may be manually held out of the way to facilitate removal of the shaft from the inserter body (d).

To re-assemble, reverse the above directions, ensuring that both retaining screws are securely tightened.

IMPLANTS

Offered in small, medium and large footprints, and in lordotic angles of 7 and 12°.
Heights range from 8-18mm, in 2mm increments.

Small
26W x 23D

Medium
32W x 26D

Large
36W x 30D

7° Lordotic Angle

12° Lordotic Angle

IMPLANT FEATURES

Tantalum radiographic markers ease visual assessment of implant placement

Tooth pattern is designed to prevent migration and add stability

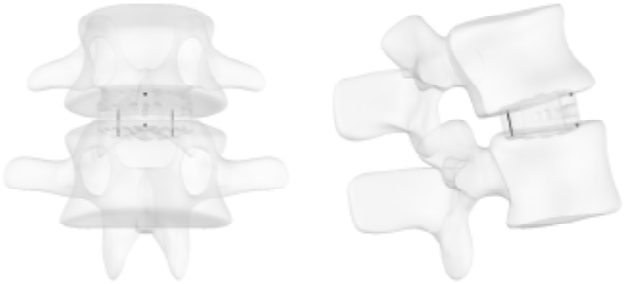


Image showing A/P and Lateral images of radiographic markers

Full set of trials included for all footprint options

INSTRUMENTS

The Universal ALIF instruments are intended to support both the Novel ALIF and AlphaGRAFT®. Interbody devices. The instrument set includes two rasps (single and double sided), 2 impact tamps, and 1 positioning instrument. Rotating distractors with 2 quick connect T-Handles come in heights ranging from 8-20mm to support endplate preparation and implant insertion

There are 2 inserters available to support both the Novel ALIF as well as AlphaGRAFT biologic Interbody products. A standard, straight inserter is provided that will allow simple insertion of the implant after necessary preparation and distraction has occurred. In addition, a new inserter/ distractor is available for both the Novel ALIF and AlphaGRAFT devices that will provide for controlled distraction and insertion of the implant in one step.

NOVEL® INTERBODY FUSION SYSTEM

GENERAL INFORMATION:
The Novel Interbody Fusion System is an intervertebral body fusion 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 polyetheretherketone (PEEK conforming to ASTM F-2026). Radiographic markers made of tantalum (ASTM F-560) facilitate visualization. The Novel Interbody Fusion System must be used with supplemental spinal fixation. The Novel Interbody Fusion System is to be used with autogenous bone graft and these patients should have had six months of non-operative treatment.

INDICATIONS:
When used as an Intervertebral Body Fusion device, the Novel Interbody Fusion system is indicated for interbody fusion procedures and is indicated for use 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. Patients should have received 6 months of non-operative treatment prior to treatment with the device. The device is intended to be used with supplemental fixation. These DDD patients may also have up to a Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). It is indicated to be used with autograft bone.

CONTRAINDICATIONS:
The Novel Interbody Fusion 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 non-Alphatec Spine source products.
6. Reuse or multiple use.

WARNINGS AND PRECAUTIONS:
1. The Novel Interbody Fusion System is an implant device used only to provide internal fixation during the bone fusion process with the assistance of a autogenous bone graft. 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 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, and/or disassembly of the device will occur.
4. This product is 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. The instruments are provided non-sterile and 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.
14. The implants are provided sterile unless package is opened or damaged. Do not use if package is opened or damaged.
15. The implants are for single use and must not be re-sterilized.
16. Do not use implants after the expiration date indicated on the label.

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 Interbody Fusion System.

2. The surgeon should not consider for surgery those patients contraindicated for the use of the Novel Interbody Fusion 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 Interbody Fusion System device components should be received and accepted only in packages that have not been damaged or tampered with.
7. Components must be carefully handled and stored in a manner that prevents scratches, damage, and corrosion.
8. The condition of all implants & instruments should be checked prior to use.
9. 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, 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. Autogenous bone graft must be used in conjunction with the Novel Interbody Fusion System to augment stability. Bone graft 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 Interbody Fusion System should be supported by anterior and/ or posterior stabilization devices. The Novel Interbody Fusion 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.

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

Excerpt from INS-066

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

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