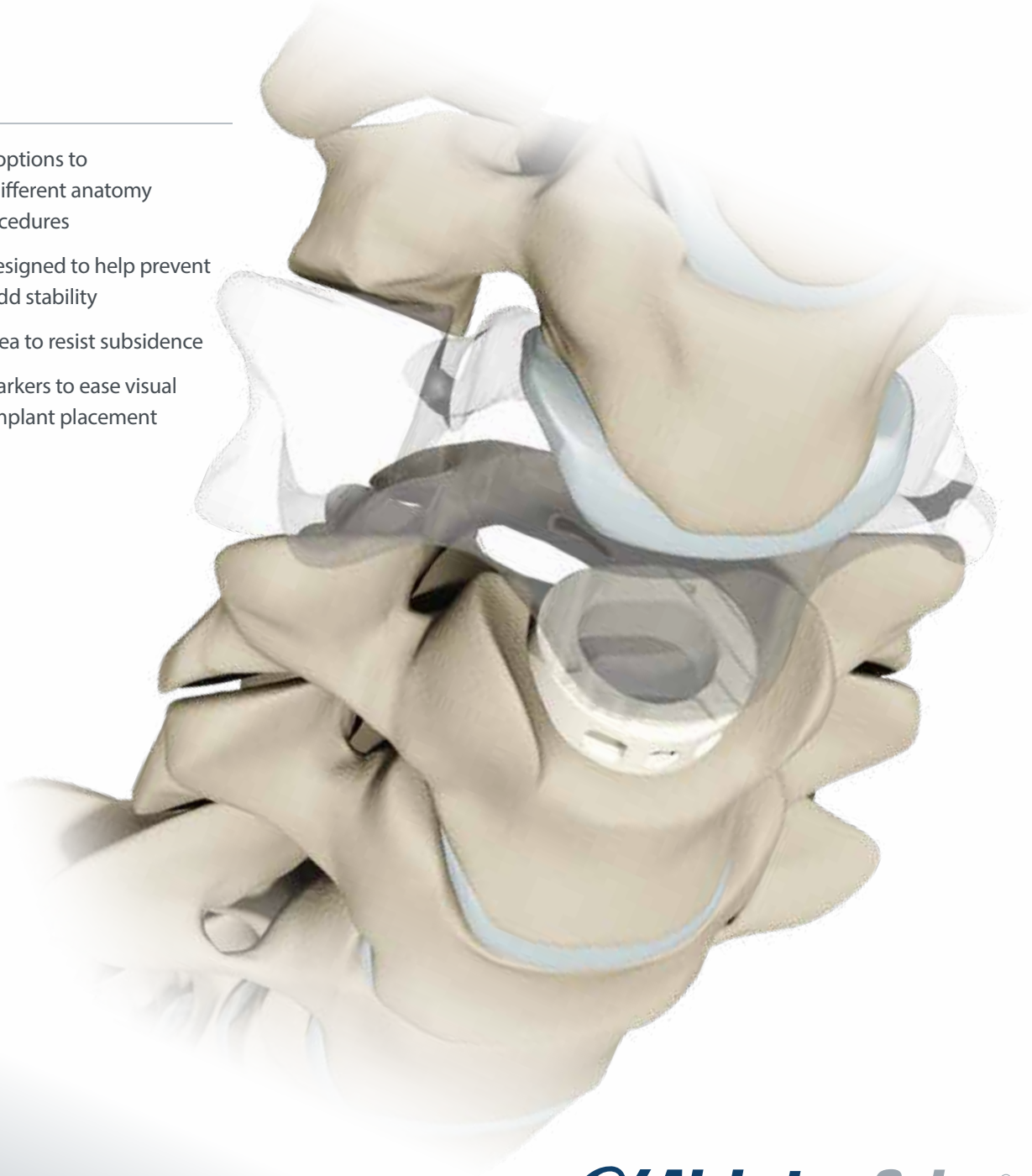
Novel® XS

Spinal Spacer System

FEATURES

- Three footprint options to accommodate different anatomy and surgical procedures
- Tooth pattern designed to help prevent migration and add stability
- Large contact area to resist subsidence
- Radiographic markers to ease visual assessment of implant placement



Alphatec Spine®

PREFACE

The Novel® XS Cervical Interbody Spacer System is a cervical intervertebral body fusion device consisting of three footprints and six standard heights to accommodate individual patient pathology using an anterior surgical approach. This system is to be used with supplemental fixation systems like Trestle Luxe® or Trestle® Anterior Cervical Plating System, and with autogenous bone graft. The Novel XS 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 and these patients should have had six months of non-operative treatment.

The Novel XS System is simple and versatile in its application incorporating:

- Three footprint options to accommodate different anatomy and surgical procedures
- Tooth pattern designed to help prevent migration and add stability
- Large contact area to resist subsidence
- Radiographic markers to ease visual assessment of implant placement

CONTENTS

1 SURGICAL APPROACH

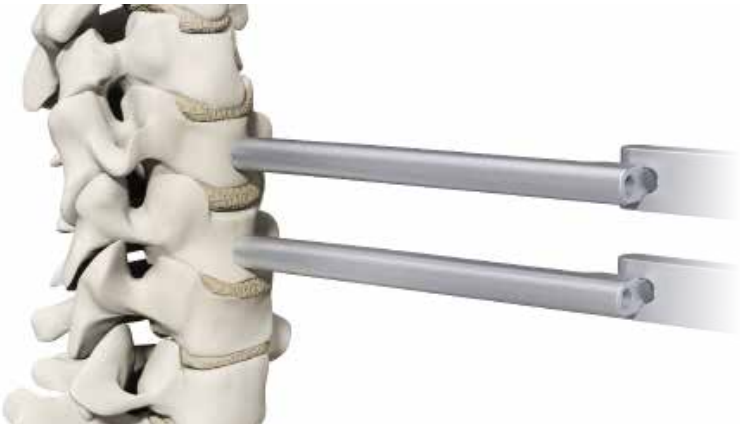
The approach is a standard right anterior pre-sternocleido mastoid approach (Cloward or Smith-Robinsson).

Under image intensifier, determine the correct intervertebral level.

2 DISTRACTION

The use of a Cervical distractor might be useful. First the Cervical distraction pins are positioned using the Screwdriver for Distraction Pin.

The pins should be inserted in the middle of the vertebral bodies above and below the disc space to be treated and parallel to the endplates. All the threads of the pins should be engaged in the vertebral bodies. After removing the screwdriver, the cervical distractor can be slid onto the distraction pins until it reaches the base of the pins (closest to the vertebral body).



3 PERFORM DISCECTOMY

After incision of the anterior longitudinal ligament, the disc is removed using a variety of curettes and rongeurs.

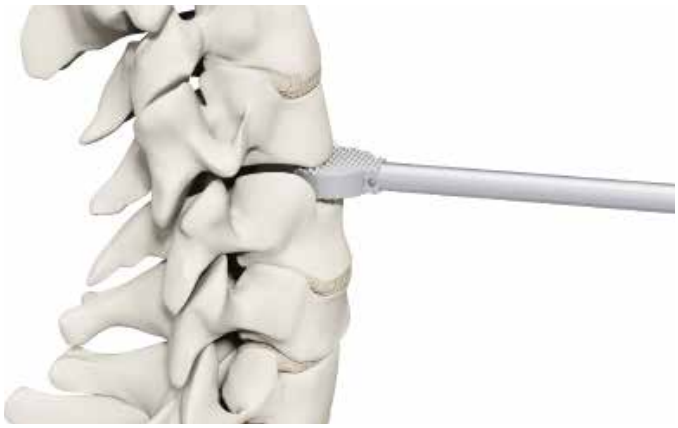
Using commercially available pituitaries, curettes and kerrisons; perform the discectomy at the indicated level. Disc material and cartilage will be removed to expose the posterior longitudinal ligament by the removal of the posterior disc and any osteophytes that may occur.

NOTE: A Kerrison Rongeur or drill may be used to carry out additional resection.

TIP: The local bone may be saved, decorticated and used as bone graft material.

1 PREPARE ENDPLATE

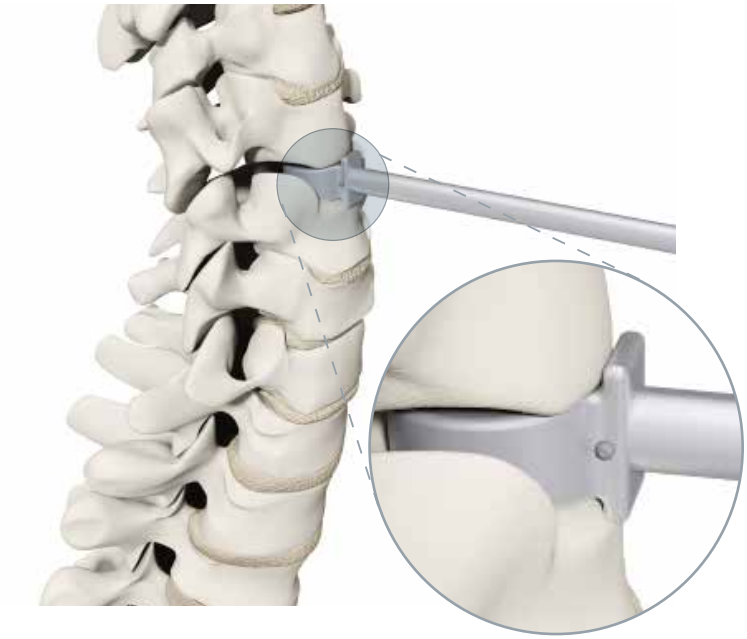
Roughen endplates to bleeding cancellous bone using a rasp and/or rasping trials (optional) which are available to roughen the endplates during preparation of the disc space.



2 DETERMINE IMPLANT SIZE

In the prepared disc space, insert a trial to determine the correct implant size to use. The Novel XS implant is available in heights ranging from 4 - 11mm, and three different footprints. The trials are color coded to differentiate sizes. The appropriate size is determined by selecting the trial that provides the most satisfactory fit in the disc space.

NOTE: The height of the implant is measured on the posterior edge of the implant, inclusive of the teeth (ridges). The corresponding trial is sized to match the implant with teeth line to line.



3 CHOOSE IMPLANT

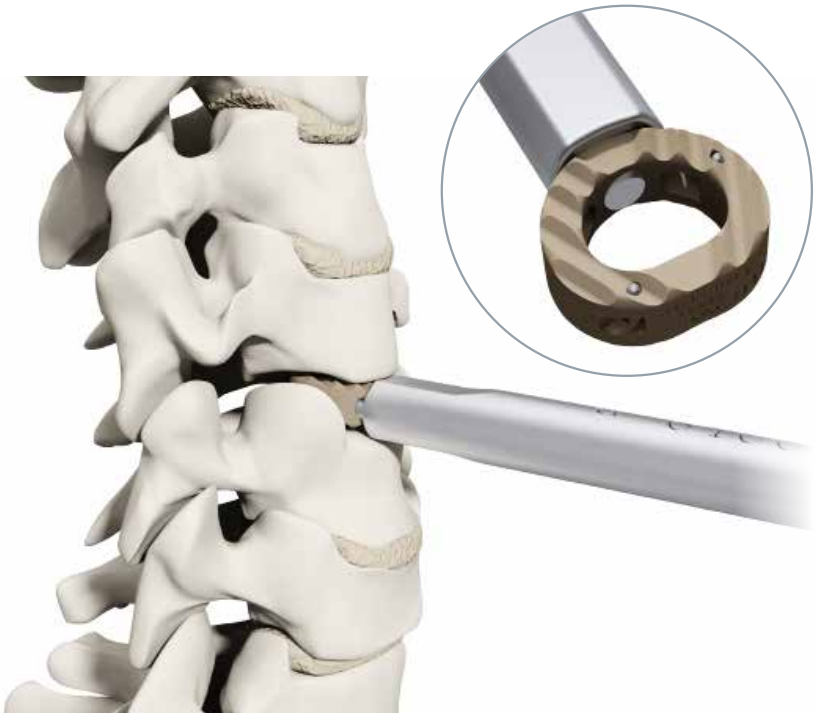
Select the appropriate sized implant. Load implant on the inserter.

4 PLACE GRAFT MATERIAL

Using the packing tamps, pack the implant with the autogenous bone graft prior to insertion.

5 INSERT IMPLANT

Using the assembled implant/inserter, insert the implant into the disc space. The implant inserter may be used to reposition the implant as well.

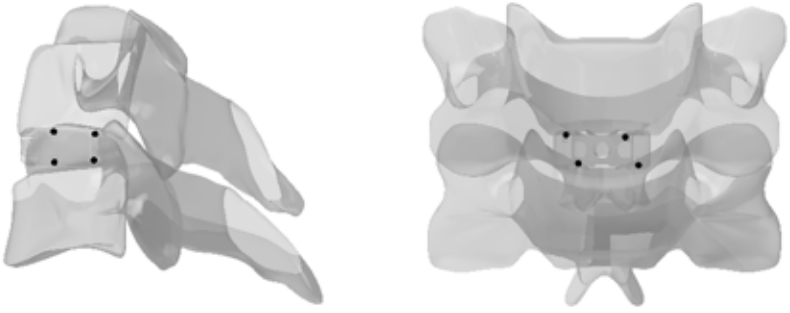


6 VERIFY IMPLANT POSITION

Confirm implant position with AP and lateral fluoroscopy. Use the Implant Tamp provided to manipulate the implant into final position, as necessary. Pack additional autogenous bone grafting material anteriorly. Remove the distraction device if used. An anterior fixation plate (Trestle Luxe or Trestle are recommended) can now be applied for additional fixation.

NOTE: Lateral and AP view of spacer properly aligned showing radiographic markers.

TIP: The Implant Retriever may be used to reposition the implant.



The Novel XS System is to be used wwith a supplemental fixation system. Specifically, the Novel Spinal Spacer System should be used with the Trestle® Anterior Cervical Plating System with autogenous bone graft.

7 INSERTER DISASSEMBLY

The inserter is designed for disassembly to facilitate cleaning and sterilization.

8 IMPLANT FEATURES

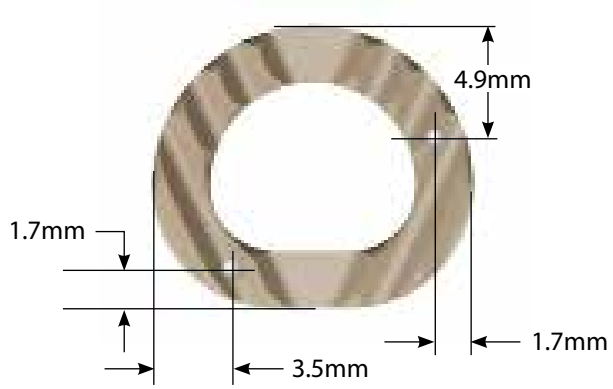
Tantalum radiographic markers ease visual assessment of implant placement and fusion process

Patented tooth pattern prevents migration and adds stability

Novel Inserter provides positive control for surgical approach

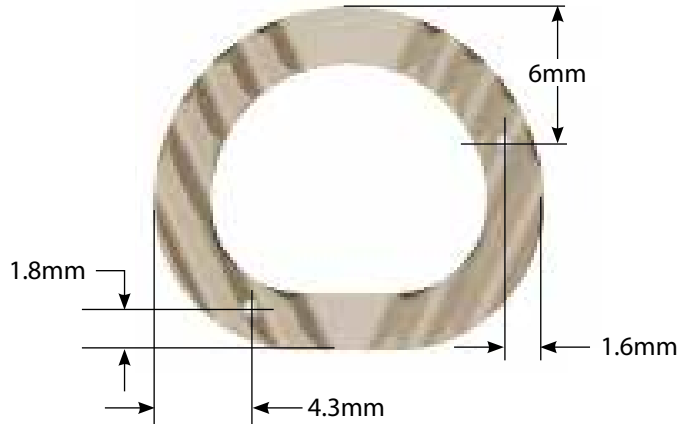
12 RADIOPAQUE MARKER MEASUREMENTS

Novel XS Small 64713-xxx



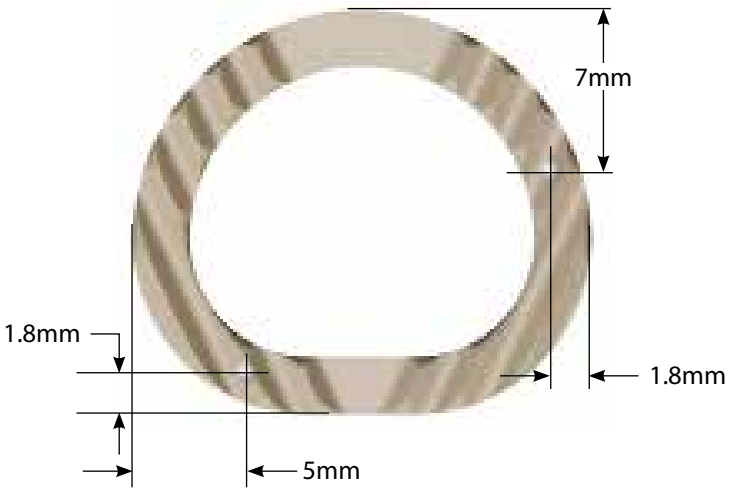
Actual size (14mm x 12mm)

Novel XS Medium 64715-xxx



Actual size (17mm x 15mm)

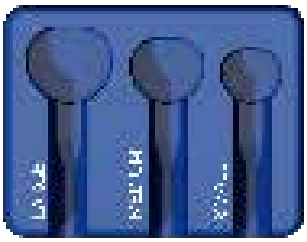
Novel XS Large 64717-xxx



Actual size (20mm x 18mm)

9 INSTRUMENTS

Packing Block
Part# 64096



Packing Bone Tamp Large/Medium
Part# 64097-01

Packing Bone Tamp Small
Part# 64097-02

Novel XS Inserter
Part #64006

Novel XS Inserter
Part #64007

Novel XS Trial, Small
Part#
64793-104 4mm, 0° Lordotic
64793-105 5mm, 0° Lordotic
64793-106 6mm, 0° Lordotic
64793-107 7mm, 0° Lordotic
64793-108 8mm, 0° Lordotic
64793-109 9mm, 0° Lordotic

Novel XS Trial, Medium
Part#
64795-104 4mm, 0° Lordotic
64795-105 5mm, 0° Lordotic
64795-106 6mm, 0° Lordotic
64795-107 7mm, 0° Lordotic
64795-108 8mm, 0° Lordotic
64795-109 9mm, 0° Lordotic

Novel XS Trial, Large
Part#
64797-104 4mm, 0° Lordotic
64797-105 5mm, 0° Lordotic
64797-106 6mm, 0° Lordotic
64797-107 7mm, 0° Lordotic
64797-108 8mm, 0° Lordotic
64797-109 9mm, 0° Lordotic

10 IMPLANTS (SKIF-64711-01)

Small Implant and Instrument Set I.D. 5° Lordotic | XS

PART #	Small XS Cervical Spacer 12 x 14 (DxW), 5°	QTY	Vol.(cc)
64713-104	Novel XS, 4mm Small	2	0.16
64713-105	Novel XS, 5mm Small	2	0.21
64713-106	Novel XS, 6mm Small	2	0.26
64713-107	Novel XS, 7mm Small	2	0.32
64713-108	Novel XS, 8mm Small	2	0.37
64713-109	Novel XS, 9mm Small	2	0.42
64713-110	Novel XS, 10mm Small	OPT	0.44
64713-111	Novel XS, 11mm Small	OPT	0.50
*Non-Lordotic implants (XSNLPK) *10mm Trial (64793-110)			

Medium Implant and Instrument Set I.D. 5° Lordotic | XS

PART #	Medium XS Cervical Spacer 15 x 17 (DxW), 5°	QTY	Vol.(cc)
64715-104	Novel XS, 4mm Medium	2	0.30
64715-105	Novel XS, 5mm Medium	2	0.39
64715-106	Novel XS, 6mm Medium	2	0.49
64715-107	Novel XS, 7mm Medium	2	0.59
64715-108	Novel XS, 8mm Medium	2	0.68
64715-109	Novel XS, 9mm Medium	2	0.78
64715-110	Novel XS, 10mm Medium	OPT	0.88
64715-111	Novel XS, 11mm Medium	OPT	0.99
*10mm Trial (64795-110)			

Large Implant and Instrument Set I.D. 5° Lordotic | XS

PART #	Large XS Cervical Spacer 18 x 20 (DxW), 5°	QTY	Vol.(cc)
64717-104	Novel XS, 4mm Large	2	0.49
64717-105	Novel XS, 5mm Large	2	0.64
64717-106	Novel XS, 6mm Large	2	0.79
64717-107	Novel XS, 7mm Large	2	0.94
64717-108	Novel XS, 8mm Large	2	1.10
64717-109	Novel XS, 9mm Large	2	1.25
64717-110	Novel XS, 10mm Large	OPT	1.46
64717-111	Novel XS, 11mm Large	OPT	1.62
*10mm Trial (64797-110)			

10 IMPLANTS (SKIF-64711-03)

Small Implant and Instrument Set I.D. 0º Lordotic | XS

PART #	Small XS Cervical Spacer 12 x 14 (DxW), 0°	QTY	Vol.(cc)
64713-005	Novel XS, 5mm Small	2	0.21
64713-006	Novel XS, 6mm Small	2	0.26
64713-007	Novel XS, 7mm Small	2	0.32
64713-008	Novel XS, 8mm Small	2	0.37
64713-009	Novel XS, 9mm Small	2	0.42

* No 0° Lordotic Trials

Medium Implant and Instrument Set I.D. 0º Lordotic | XS

PART #	Medium XS Cervical Spacer 15 x 17 (DxW), 0°	QTY	Vol.(cc)
64715-005	Novel XS, 5mm Medium	2	0.39
64715-006	Novel XS, 6mm Medium	2	0.49
64715-007	Novel XS, 7mm Medium	2	0.59
64715-008	Novel XS, 8mm Medium	2	0.68
64715-009	Novel XS, 9mm Medium	2	0.78

* No 0° Lordotic Trials

Large Implant and Instrument Set I.D. 0º Lordotic | XS

PART #	Large XS Cervical Spacer 18 x 20 (DxW), 0°	QTY	Vol.(cc)
64717-005	Novel XS, 5mm Large	2	0.64
64717-006	Novel XS, 6mm Large	2	0.79
64717-007	Novel XS, 7mm Large	2	0.94
64717-008	Novel XS, 8mm Large	2	1.10
64717-009	Novel XS, 9mm Large	2	1.25

* No 0° Lordotic Trials

NOVEL® INTERBODY FUSION SYSTEM
IMPLANT PACKAGING INSERT - ENGLISH

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.

Refer to INS-066 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**

Alphatec Spine, Inc.
1950 Camino Vida Roble
Carlsbad, CA 92008 USA
Ph: (760) 431-9286
Ph: (800) 922-1356
Fax: (800) 431-9722
atecspine.com

Alphatec Spine®

CORPORATE HEADQUARTERS
1950 Camino Vida Roble
Carlsbad, California 92008

CUSTOMER SERVICE
Toll Free: 800.922.1356
Local: 760.431.9286
Fax: 800.431.1624

LIT-83200C | 11/10/2021