Novel® CIS

Spinal Spacer System

FEATURES

- Three footprint options
- Large area for bone graft
- Large contact area to resist subsidence
- Radiographic markers
- Implants available in PEEK material and Titanium
- Compact and comprehensive instruments

Alphatec Spine®

PREFACE

The Novel® Cervical Interbody Spacer (CIS) 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 the Trestle Luxe® or Trestle® Anterior Cervical Plating System, and with autogenous bone graft. The Novel CIS 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 CIS 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

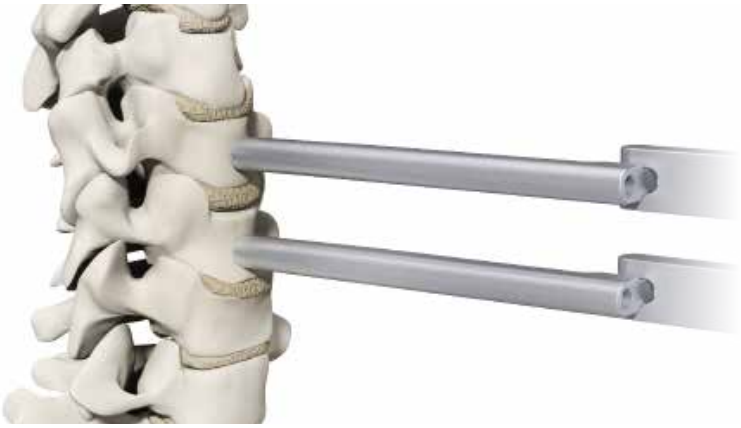
The approach is a standard right anterior pre-sternocleido mastoid approach (Cloward or Smith-Robinsson).

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.

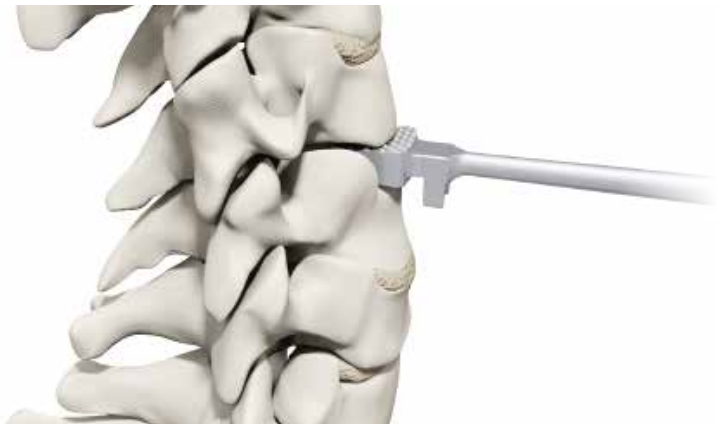
Using commercially available pituitaries, curettes and kerrisons; perform the discectomy at the indicated level. Disc material and cartilage will be removed to expose the posterior longitudinal ligament by the removal of the posterior disc and any osteophytes that may occur.

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.

4 PREPARE ENDPLATE

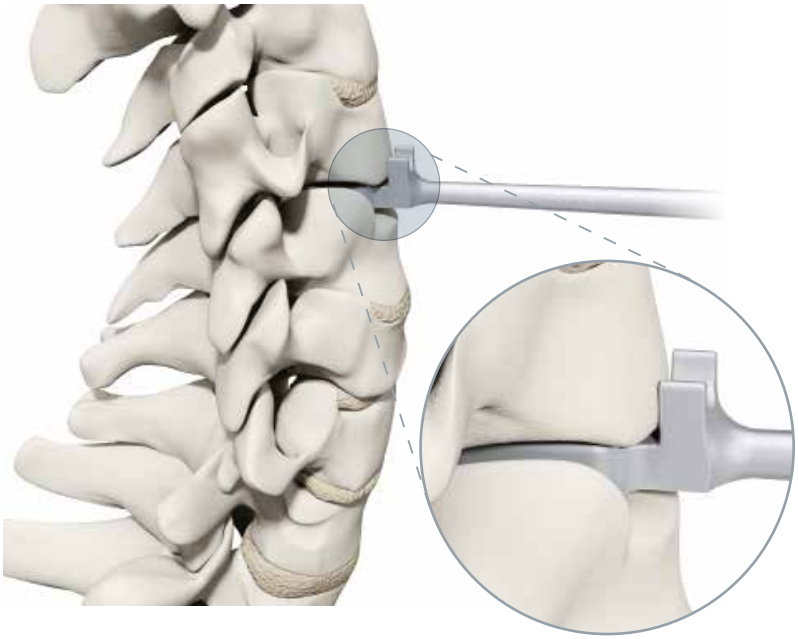
Roughen endplates to bleeding cancellous bone using a rasp and/or rasping trials (optional) which are available to roughen the endplates during preparation of the disc space.



5 DETERMINE IMPLANT SIZE

In the prepared disc space, insert a trial to determine the correct implant size to use. The Novel CIS implant is available in heights ranging from 5 - 12mm, 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 anterior edge of the implant, inclusive of the teeth (ridges). The corresponding trial is sized to match the implant without teeth (undersized 1mm.)



NOTE: The Novel Cervical Trials and Tamp feature a stop located 2mm from the proximal end of the instrument tip and is designed to prevent over insertion into the disc space. The stops are also designed to accommodate Caspar pins, when used.

6 CHOOSE IMPLANT

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

7 PLACE GRAFT MATERIAL

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

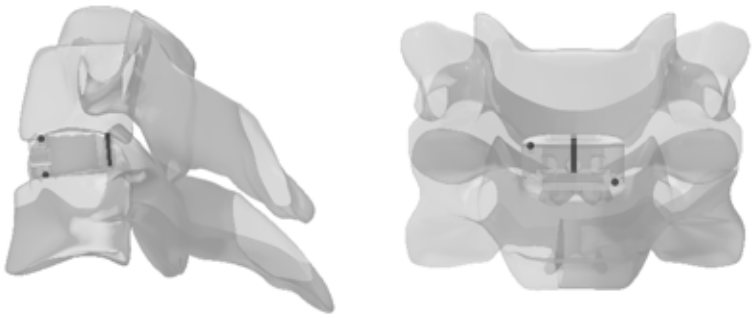
8 INSERT IMPLANT

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

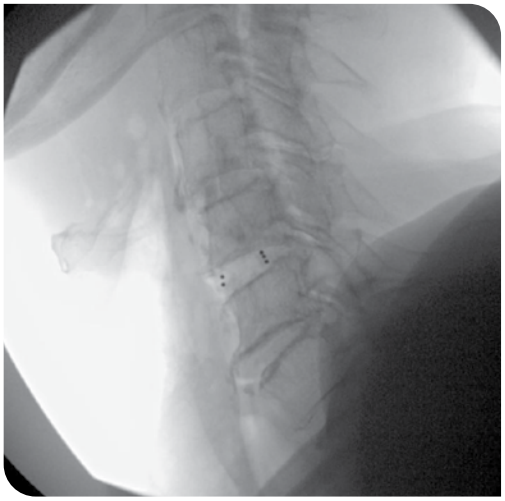
9 VERIFY IMPLANT POSITION

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.

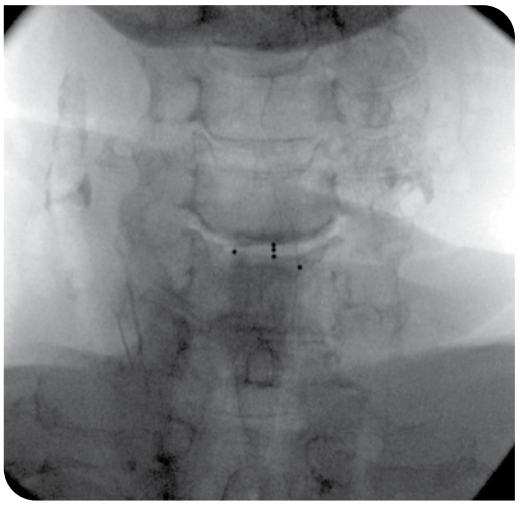
NOTE: Lateral and AP view of spacer properly aligned showing radiographic markers.



The Novel CIS System is to be used with a supplemental fixation system, like the Trestle Luxe or Trestle Anterior Cervical Plating Systems, and with autogenous bone graft.



Lateral view



A/P view

10 INSERTER DISASSEMBLY

The 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. Tighten knurled knob completely prior to loading implant onto inserter.

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

11 IMPLANT FEATURES

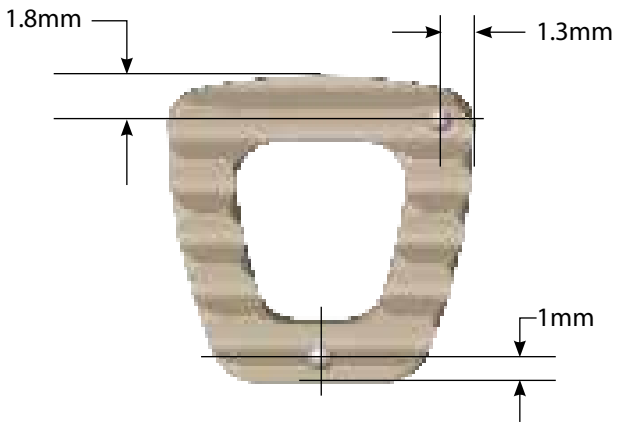
Tantalum radiographic markers ease visual assessment of implant placement and fusion process

Patented tooth pattern prevents migration and adds stability

Novel Inserter provides positive control for surgical approach

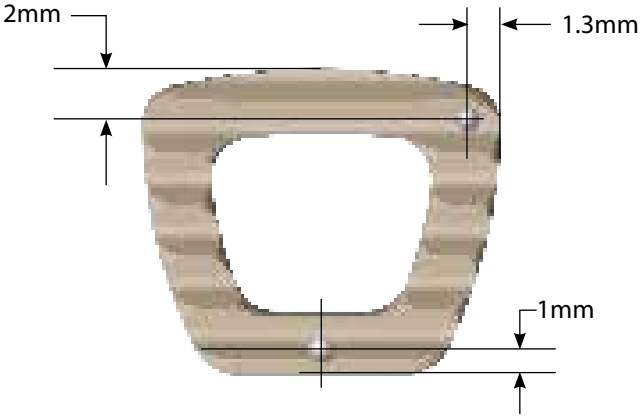
12 RADIOPAQUE MARKER MEASUREMENTS

Novel CIS Small 64763-xxx



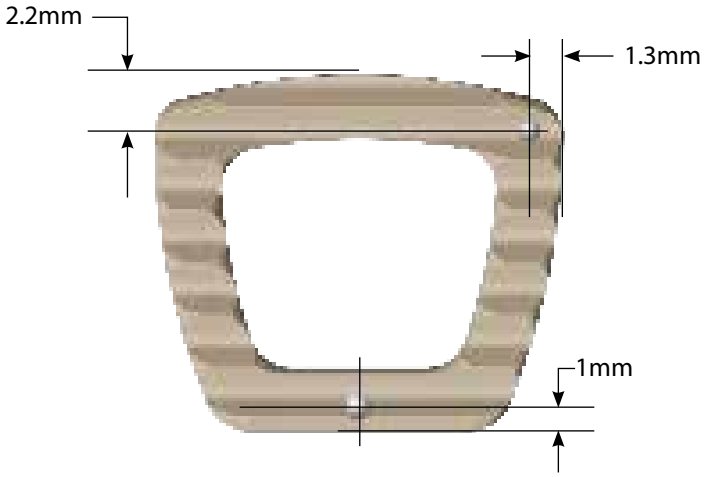
Actual size (12mm x 12mm)

Novel CIS Medium 64765-xxx



Actual size (14mm x 12mm)

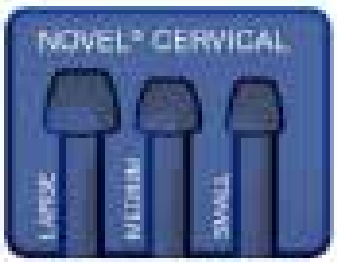
Novel CIS Large 64767-xxx



Actual size (16mm x 14mm)

13 INSTRUMENTS (SKIF-64710-01)

Packing Block
Part# 64906



Packing Bone Tamp Small/Medium Part#
64906-01

Packing Bone Tamp Large
Part# 64906-02

Cervical Inserter
Part #64904-02

Tamp, with Stop
Part# 64902-03

Tamp, without Stop
Part# 64902-04

Rasp, Small
Part# 64901-01

Rasping Trial, Small/Medium (optional)
Part#
64901-105 5mm, 7° Lordotic
64901-106 6mm, 7° Lordotic
64901-107 7mm, 7° Lordotic
64901-108 8mm, 7° Lordotic
64901-109 9mm, 7° Lordotic
64901-110 10mm, 7° Lordotic
64901-111 11mm, 7° Lordotic
64901-112 12mm, 7° Lordotic

Rasping Trial, Large (optional)
Part#
64905-105 5mm, 7° Lordotic
64905-106 6mm, 7° Lordotic
64905-107 7mm, 7° Lordotic
64905-108 8mm, 7° Lordotic
64905-109 9mm, 7° Lordotic
64905-110 10mm, 7° Lordotic
64905-111 11mm, 7° Lordotic
64905-112 12mm, 7° Lordotic

Trial, Small/Medium
Part#
64903-105 5mm, 7° Lordotic
64903-106 6mm, 7° Lordotic
64903-107 7mm, 7° Lordotic
64903-108 8mm, 7° Lordotic
64903-109 9mm, 7° Lordotic
64903-110 10mm, 7° Lordotic
64903-111 11mm, 7° Lordotic
64903-112 12mm, 7° Lordotic

Trial, Large
Part#
64907-105 5mm, 7° Lordotic
64907-106 6mm, 7° Lordotic
64907-107 7mm, 7° Lordotic
64907-108 8mm, 7° Lordotic
64907-109 9mm, 7° Lordotic
64907-110 10mm, 7° Lordotic
64907-111 11mm, 7° Lordotic
64907-112 12mm, 7° Lordotic

14 IMPLANTS (SKIF-64710-02)

SMALL Implant and Instrument Set I.D. 7° Lordotic | CIS

PART #	Small Cervical Spacer 12 x 12 (D x W), 7°	QTY	Bone Graft Vol. (cc)
64763-105	Novel CIS, 5mm Small	2	0.17
64763-106	Novel CIS, 6mm Small	2	0.21
64763-107	Novel CIS, 7mm Small	2	0.25
64763-108	Novel CIS, 8mm Small	2	0.29
64763-109	Novel CIS, 9mm Small	2	0.33
64763-110	Novel CIS, 10mm Small	2	0.36
64763-111	Novel CIS, 11mm Small	OPT	0.40
64763-112	Novel CIS, 12mm Small	OPT	0.44
*Trials 11mm (64903-111) and 12mm (64903-112) optional			

MEDIUM Implant and Instrument Set I.D. 7° Lordotic | CIS

PART #	Medium Cervical Spacer 12 x 14 (D x W), 7°	QTY	Bone Graft Vol. (cc)
64765-105	Novel CIS, 5mm Medium	2	0.23
64765-106	Novel CIS, 6mm Medium	2	0.28
64765-107	Novel CIS, 7mm Medium	2	0.33
64765-108	Novel CIS, 8mm Medium	2	0.38
64765-109	Novel CIS, 9mm Medium	2	0.43
64765-110	Novel CIS, 10mm Medium	2	0.48
64765-111	Novel CIS, 11mm Medium	OPT	0.54
64765-112	Novel CIS, 12mm Medium	OPT	0.59
*Trials 11mm (64903-111) and 12mm (64903-112) optional			

LARGE Implant and Instrument Set I.D. 7° Lordotic | CIS

PART #	Large Cervical Spacer 14 x 16 (D x W), 7°	QTY	Bone Graft Vol.(cc)
64767-105	Novel CIS, 5mm Large	2	0.36
64767-106	Novel CIS, 6mm Large	2	0.44
64767-107	Novel CIS, 7mm Large	2	0.53
64767-108	Novel CIS, 8mm Large	2	0.61
64767-109	Novel CIS, 9mm Large	2	0.70
64767-110	Novel CIS, 10mm Large	2	0.78
64767-111	Novel CIS, 11mm Large	OPT	0.86
64767-112	Novel CIS, 12mm Large	OPT	0.95
*Trials 11mm (64907-111) and 12mm (64907-112) optional			

15 TITAMIUM IMPLANTS

SMALL Titanium Implants 7° Lordotic | CIS

PART #	Small Cervical Spacer 12 x 12 (D x W), 7°	QTY
64764-105	Novel CIS, 5mm Small	2
64764-106	Novel CIS, 6mm Small	2
64764-107	Novel CIS, 7mm Small	2
64764-108	Novel CIS, 8mm Small	2
64764-109	Novel CIS, 9mm Small	2
64764-110	Novel CIS, 10mm Small	2
64764-111	Novel CIS, 11mm Small	OPT
64764-112	Novel CIS, 12mm Small	OPT
*Must order titanium implants separately		

MEDIUM Titanium Implants 7° Lordotic | CIS

PART #	Medium Cervical Spacer 12 x 14 (D x W), 7°	QTY
64765-105	Novel CIS, 5mm Medium	2
64765-106	Novel CIS, 6mm Medium	2
64765-107	Novel CIS, 7mm Medium	2
64765-108	Novel CIS, 8mm Medium	2
64765-109	Novel CIS, 9mm Medium	2
64765-110	Novel CIS, 10mm Medium	2
64765-111	Novel CIS, 11mm Medium	OPT
64765-112	Novel CIS, 12mm Medium	OPT
*Must order titanium implants separately		

LARGE Titanium Implants 7° Lordotic | CIS

PART #	Large Cervical Spacer 14 x 16 (D x W), 7°	QTY
64767-105	Novel CIS, 5mm Large	2
64767-106	Novel CIS, 6mm Large	2
64767-107	Novel CIS, 7mm Large	2
64767-108	Novel CIS, 8mm Large	2
64767-109	Novel CIS, 9mm Large	2
64767-110	Novel CIS, 10mm Large	2
64767-111	Novel CIS, 11mm Large	OPT
64767-112	Novel CIS, 12mm Large	OPT
*Must order titanium implants separately		

NOVEL® SPINAL SPACER SYSTEM

GENERAL INFORMATION:
TThe 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 F-136) or polyetheretherkeytone, PEEK (ASTM F-2026). A radiographic marker made of titanium (ASTM F-136) or tantalum (ASTM F-560) facilitates visualization. The NOVEL Spinal System must be used with a supplemental spinal fixation system. Specifically, the Novel Spinal Spacer System should be used with the Alphatec Zodiac® Polyaxial System. The Novel Spinal Spacer System as a cervical intervertebral body fusion device should be used with the Alphatec Trestle® Spinal System. 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.

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. 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 implants and 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.

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. Implants and 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.

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

Excerpt from INS-010

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

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