NOVEL® CIS

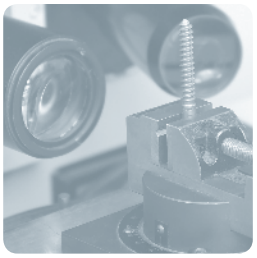
Spinal Spacer System

SURGICAL TECHNIQUE GUIDE

Alphatec Spine®

System Features

- Three footprint options 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



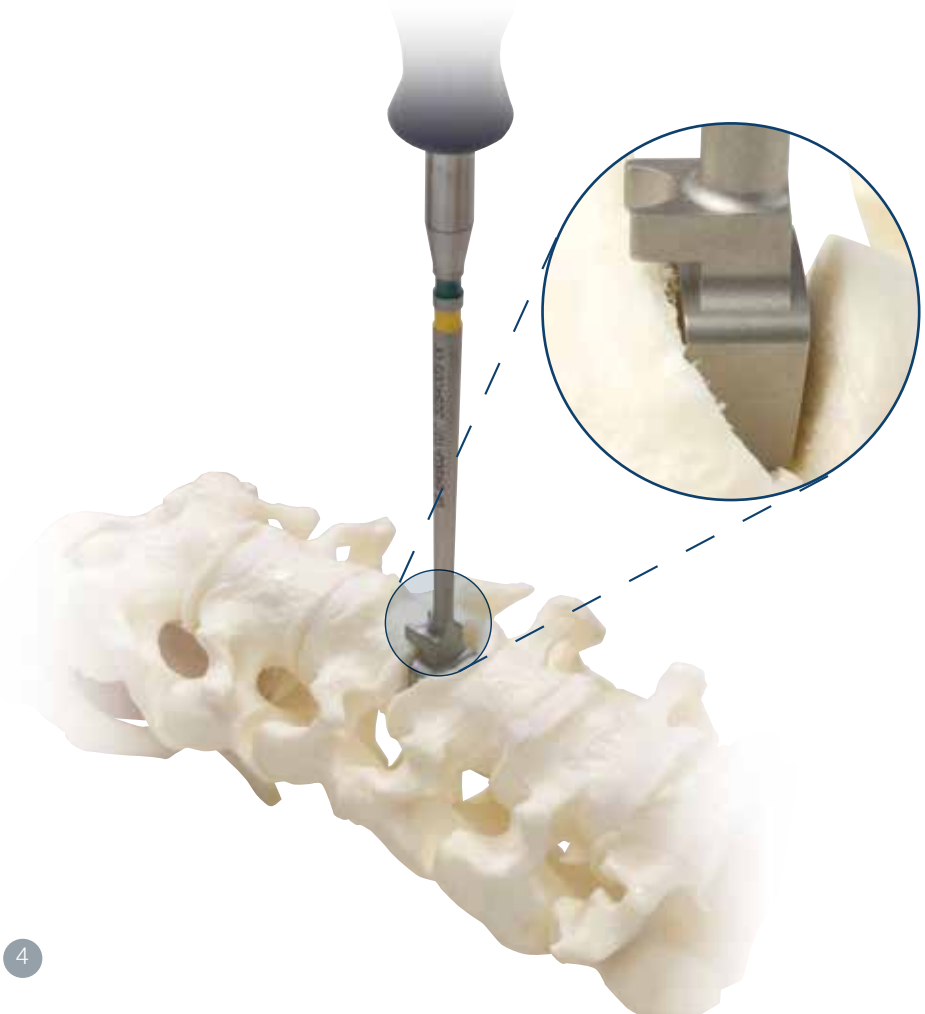
Innovation & Proven Techniques

The Novel Cervical Interbody Spinal 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. 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 Trestle Luxe® or Trestle® Anterior Cervical Plating System with autogenous bone graft. 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 and these patients should have had six months of non-operative treatment.

The Novel Cervical Interbody Spinal Spacer 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



Perform Discectomy

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.

If desired, a rasp and rasping trials (optional) are available to roughen the endplates during preparation of the disc space.

Determine Implant Size

In the newly prepared disc space, insert a trial to confirm the correct disc height. The Novel Cervical implant is available in sizes ranging from 5 - 12mm heights, and three different footprints as specified in the table below. 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. The teeth represent a difference in the trial of 0.5mm on each side (top and bottom), for a total difference of 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.

Novel Cervical Dimensions

(in millimeters)

Included in set ● Optional ○

Peek		Footprint (depth & width)		
		Small (12x12)	Med (12x14)	Large (14x16)
Height	5	●	●	●
	6	●	●	●
	7	●	●	●
	8	●	●	●
	9	●	●	●
	10	●	●	●
	11	○	○	○
	12	○	○	○

Each spacer offered in 7° lordosis

Choose Implant

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

Place Graft Material

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

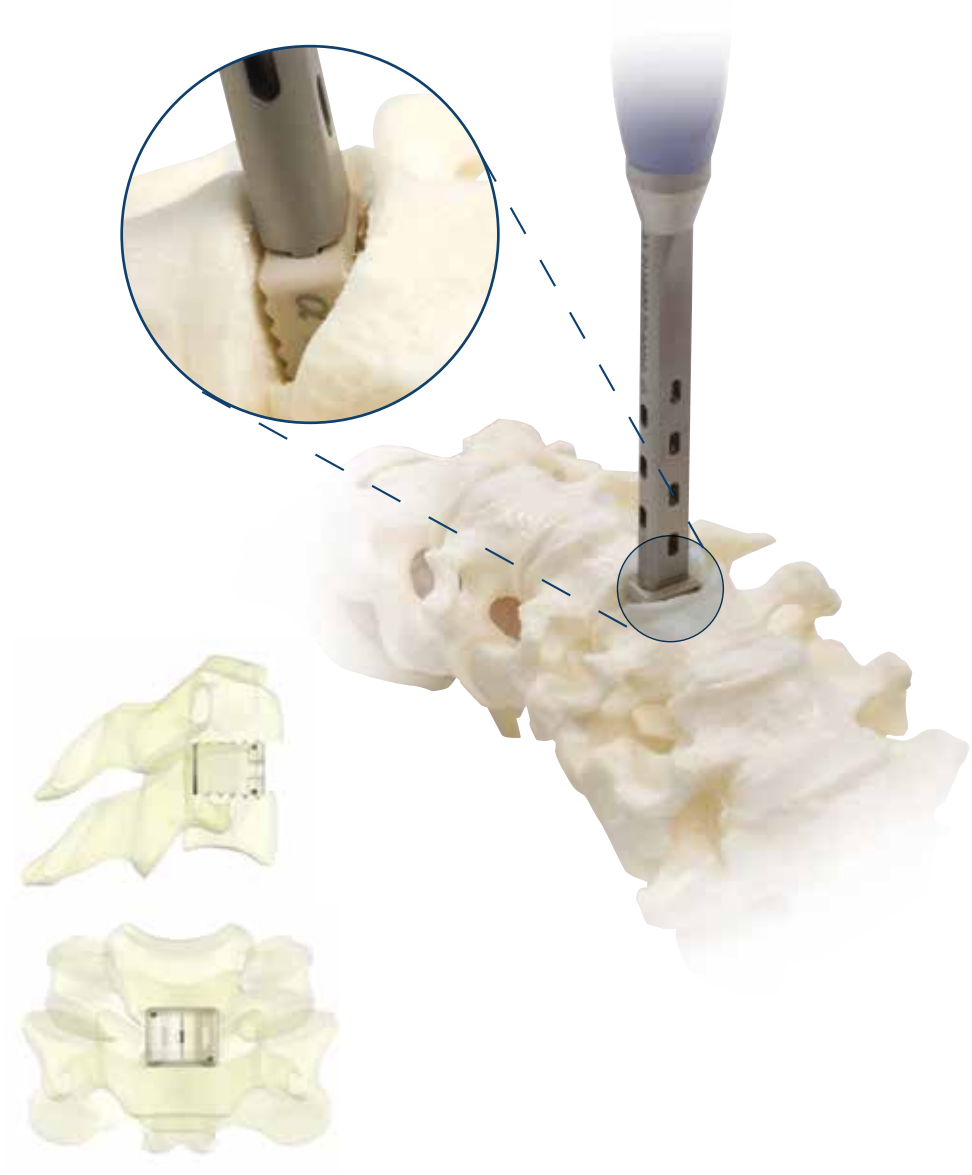
Insert Implant

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

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

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.

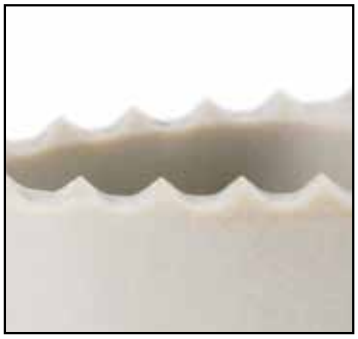
To reassemble, reverse the above procedure. Tighten knurled knob completely prior to loading implant onto inserter.

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

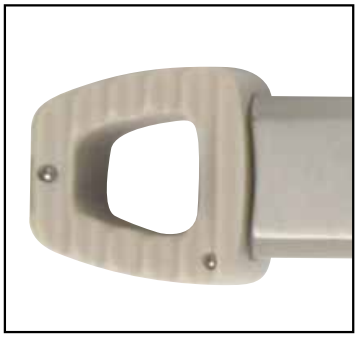
Implant Features

Tantalum radiographic markers ease visual assessment of implant placement.

Tooth pattern is designed to help prevent migration and add stability



Novel inserter provides positive control for surgical approach



Packing Block
64906

Packing Bone Tamp Small/Medium
64906-01

Packing Bone Tamp Large
64906-02

Cervical Inserter
64904-02

Tamp, with Stop
64902-03

Tamp, without Stop
64902-04

Rasp, Small
64901-01

Rasping Trial, Small/Medium
(optional)

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)

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

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

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

Novel Cervical Interbody PEEK Implants

Part Number	Description	Quantity
64763-105	Novel Cervical Spacer, 5mm Small, 7˚ lordotic	2
64763-106	Novel Cervical Spacer, 6mm Small, 7˚ lordotic	2
64763-107	Novel Cervical Spacer, 7mm Small, 7˚ lordotic	2
64763-108	Novel Cervical Spacer, 8mm Small, 7˚ lordotic	2
64763-109	Novel Cervical Spacer, 9mm Small, 7˚ lordotic	2
64763-110	Novel Cervical Spacer, 10mm Small, 7˚ lordotic	2
64763-111	Novel Cervical Spacer, 11mm Small, 7˚ lordotic	Opt
64763-112	Novel Cervical Spacer, 12mm Small, 7˚ lordotic	Opt
64765-105	Novel Cervical Spacer, 5mm Medium, 7˚ lordotic	4
64765-106	Novel Cervical Spacer, 6mm Medium, 7˚ lordotic	4
64765-107	Novel Cervical Spacer, 7mm Medium, 7˚ lordotic	4
64765-108	Novel Cervical Spacer, 8mm Medium, 7˚ lordotic	4
64765-109	Novel Cervical Spacer, 9mm Medium, 7˚ lordotic	2
64765-110	Novel Cervical Spacer, 10mm Medium, 7˚ lordotic	2
64765-111	Novel Cervical Spacer, 11mm Medium, 7˚ lordotic	Opt
64765-112	Novel Cervical Spacer, 12mm Medium, 7˚ lordotic	Opt
64767-105	Novel Cervical Spacer, 5mm Large, 7˚ lordotic	4
64767-106	Novel Cervical Spacer, 6mm Large, 7˚ lordotic	4
64767-107	Novel Cervical Spacer, 7mm Large, 7˚ lordotic	4
64767-108	Novel Cervical Spacer, 8mm Large, 7˚ lordotic	4
64767-109	Novel Cervical Spacer, 9mm Large, 7˚ lordotic	2
64767-110	Novel Cervical Spacer, 10mm Large, 7˚ lordotic	2
64767-111	Novel Cervical Spacer, 11mm Large, 7˚ lordotic	Opt
64767-112	Novel Cervical Spacer, 12mm Large, 7˚ lordotic	Opt

Novel Spinal Spacers - Cervical Interbody Titanium Implants

Part Number	Description	Quantity
64764-105	Novel Cervical Spacer, 5mm Small, 7˚ lordotic	2
64764-106	Novel Cervical Spacer, 6mm Small, 7˚ lordotic	2
64764-107	Novel Cervical Spacer, 7mm Small, 7˚ lordotic	2
64764-108	Novel Cervical Spacer, 8mm Small, 7˚ lordotic	2
64764-109	Novel Cervical Spacer, 9mm Small, 7˚ lordotic	2
64764-110	Novel Cervical Spacer, 10mm Small, 7˚ lordotic	2
64764-111	Novel Cervical Spacer, 11mm Small, 7˚ lordotic	Opt
64764-112	Novel Cervical Spacer, 12mm Small, 7˚ lordotic	Opt
64766-105	Novel Cervical Spacer, 5mm Medium, 7˚ lordotic	4
64766-106	Novel Cervical Spacer, 6mm Medium, 7˚ lordotic	4
64766-107	Novel Cervical Spacer, 7mm Medium, 7˚ lordotic	4
64766-108	Novel Cervical Spacer, 8mm Medium, 7˚ lordotic	4
64766-109	Novel Cervical Spacer, 9mm Medium, 7˚ lordotic	2
64766-110	Novel Cervical Spacer, 10mm Medium, 7˚ lordotic	2
64766-111	Novel Cervical Spacer, 11mm Medium, 7˚ lordotic	Opt
64766-112	Novel Cervical Spacer, 12mm Medium, 7˚ lordotic	Opt
64768-105	Novel Cervical Spacer, 5mm Large, 7˚ lordotic	4
64768-106	Novel Cervical Spacer, 6mm Large, 7˚ lordotic	4
64768-107	Novel Cervical Spacer, 7mm Large, 7˚ lordotic	4
64768-108	Novel Cervical Spacer, 8mm Large, 7˚ lordotic	4
64768-109	Novel Cervical Spacer, 9mm Large, 7˚ lordotic	2
64768-110	Novel Cervical Spacer, 10mm Large, 7˚ lordotic	2
64768-111	Novel Cervical Spacer, 11mm Large, 7˚ lordotic	Opt
64768-112	Novel Cervical Spacer, 12mm Large, 7˚ lordotic	Opt

Novel Spinal Spacers - Cervical Interbody Instruments (Standard)

Part Number	Description	Quantity
64906	Novel Cervical Packing Bone Block	1
64906-01	Novel Cervical Packing Bone Tamp Small/Medium	1
64906-02	Novel Cervical Packing Bone Tamp Large	1
64904-02	Novel Cervical Inserter	1
64902-04	Novel Cervical Tamp, without Stop	1
64902-03	Novel Cervical Tamp, with Stop	1
64901-01	Novel Cervical Rasp, Small, 7˚ lordotic	1
64903-105	Novel Cervical Trial, 5mm Small/Medium, 7˚ lordotic	1
64903-106	Novel Cervical Trial, 6mm Small/Medium, 7˚ lordotic	1
64903-107	Novel Cervical Trial, 7mm Small/Medium, 7˚ lordotic	1
64903-108	Novel Cervical Trial, 8mm Small/Medium, 7˚ lordotic	1
64903-109	Novel Cervical Trial, 9mm Small/Medium, 7˚ lordotic	1
64903-110	Novel Cervical Trial, 10mm Small/Medium, 7˚ lordotic	1
64903-111	Novel Cervical Trial, 11mm Small/Medium, 7˚ lordotic	Opt
64903-112	Novel Cervical Trial, 12mm Small/Medium, 7˚ lordotic	Opt
64907-105	Novel Cervical Trial, 5mm Large, 7˚ lordotic	1
64907-106	Novel Cervical Trial, 6mm Large, 7˚ lordotic	1
64907-107	Novel Cervical Trial, 7mm Large, 7˚ lordotic	1
64907-108	Novel Cervical Trial, 8mm Large, 7˚ lordotic	1
64907-109	Novel Cervical Trial, 9mm Large, 7˚ lordotic	1
64907-110	Novel Cervical Trial, 10mm Large, 7˚ lordotic	1
64907-111	Novel Cervical Trial, 11mm Large, 7˚ lordotic	Opt
64907-112	Novel Cervical Trial, 12mm Large, 7˚ lordotic	Opt

Novel Spinal Spacers - Cervical Interbody Instruments (Rasping) - Optional

Part Number	Description	Quantity
64906	Novel Cervical Packing Bone Block	1
64906-01	Novel Cervical Packing Bone Tamp Small/Medium	1
64906-02	Novel Cervical Packing Bone Tamp Large	1
64904-02	Novel Cervical Inserter	1
64902-04	Novel Cervical Tamp, without Stop	1
64902-03	Novel Cervical Tamp, with Stop	1
64901-105	Novel Cervical Rasping Trial, 5mm Small/Medium, 7˚ lordotic	1
64901-106	Novel Cervical Rasping Trial, 6mm Small/Medium, 7˚ lordotic	1
64901-107	Novel Cervical Rasping Trial, 7mm Small/Medium, 7˚ lordotic	1
64901-108	Novel Cervical Rasping Trial, 8mm Small/Medium, 7˚ lordotic	1
64901-109	Novel Cervical Rasping Trial, 9mm Small/Medium, 7˚ lordotic	1
64901-110	Novel Cervical Rasping Trial, 10mm Small/Medium, 7˚ lordotic	1
64901-111	Novel Cervical Rasping Trial, 11mm Small/Medium, 7˚ lordotic	Opt
64901-112	Novel Cervical Rasping Trial, 12mm Small/Medium, 7˚ lordotic	Opt
64905-105	Novel Cervical Rasping Trial, 5mm Large, 7˚ lordotic	1
64905-106	Novel Cervical Rasping Trial, 6mm Large, 7˚ lordotic	1
64905-107	Novel Cervical Rasping Trial, 7mm Large, 7˚ lordotic	1
64905-108	Novel Cervical Rasping Trial, 8mm Large, 7˚ lordotic	1
64905-109	Novel Cervical Rasping Trial, 9mm Large, 7˚ lordotic	1
64905-110	Novel Cervical Rasping Trial, 10mm Large, 7˚ lordotic	1
64905-111	Novel Cervical Rasping Trial, 11mm Large, 7˚ lordotic	Opt
64905-112	Novel Cervical Rasping Trial, 12mm Large, 7˚ lordotic	Opt

IMPLANT PACKAGING INSERT
NOVEL® SPINAL SPACER SYSTEM

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 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.

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.
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.

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.

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.

Excerpt from INS-010H

NOTES