Inspire®

POROUS PEEK HAFUSE® CERVICAL INTERBODY FUSION SYSTEM

Surgical Technique Guide

CURITEVA®

Table of Contents

Inspire®

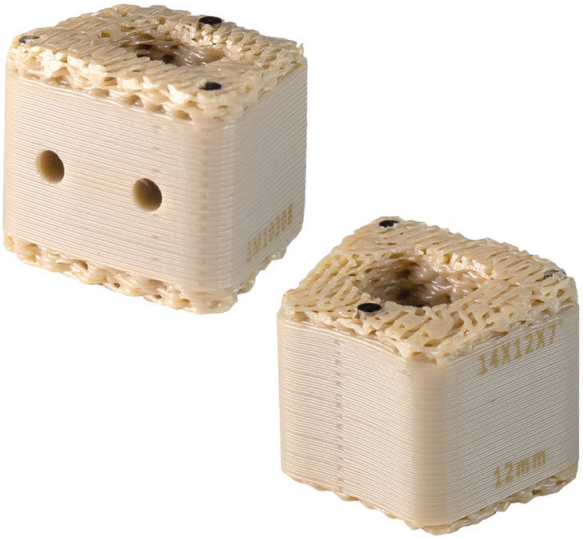
POROUS PEEK HA[FUSE®] CERVICAL INTERBODY FUSION SYSTEM

Disclaimer

The surgical technique shown is for illustrative purposes only. Proper surgical procedure is the responsibility of the medical professional. Please reference the package insert for additional information and system instructions.

Inspire® Porous PEEK HAFUSE®

The Inspire 3D Porous PEEK HAFUSE Cervical Interbody is designed for use in anterior cervical discectomy and fusion procedures in the cervical spine (C2-T1). The implants are manufactured utilizing the Evonik VESTAKEEP® i4 3DF PEEK high-performance polymer on a proprietary, patented Fused Filament Fabrication 3D printer. Application of the patented HAFUSE to this engineered PEEK structure creates a hydrophilic, bioactive, environment for cell attachment, proliferation, and healing. The interbody is available in multiple footprints, with a 7° lordosis to accommodate the patient's anatomy.



PEEK Interbody

Part Number: C234-XXXXYY-7
XXXX - Interbody Footprint, YY - Interbody Height

- Porous PEEK with HAFUSE
- Footprints (mm): 14W x 12D, 16W x 13D and 18W x 14D
- Heights: 6-12mm, offered in 1mm increments
- Lordosis: 7°

Inspire Features

- Excellent fusion visualization
- 100% fully Interconnected porosity with HAFUSE nano texturing on the entire surface of the implant
- Pore size distribution between 100 – 600 microns promoting Osteoconduction*
- Micron-scale surface roughness presents hydrophilic surfaces promoting bone apposition and enhanced Osseointegration*
- Titanium radiopaque markers to optimize visibility and placement
- Large, central graft cavity for packing bone graft
- Simple instrumentation for reliable implant placement

**References available upon request*

Inspire® 3D Porous PEEK with HAFUSE® Technology

Porous PEEK Cervical Interbodies		
Catalog Number	**Description (W x D x H)**	**Graft Volume**
C234-141206-7	14 x 12 x 06mm, 7° Porous PEEK Cervical Interbody	.31cc
C234-141207-7	14 x 12 x 07mm, 7° Porous PEEK Cervical Interbody	.37cc
C234-141208-7	14 x 12 x 08mm, 7° Porous PEEK Cervical Interbody	.43cc
C234-141209-7	14 x 12 x 09mm, 7° Porous PEEK Cervical Interbody	.49cc
C234-141210-7*	14 x 12 x 10mm, 7° Porous PEEK Cervical Interbody	.55cc
C234-141211-7*	14 x 12 x 11mm, 7° Porous PEEK Cervical Interbody	.61cc
C234-141212-7*	14 x 12 x 12mm, 7° Porous PEEK Cervical Interbody	.67cc

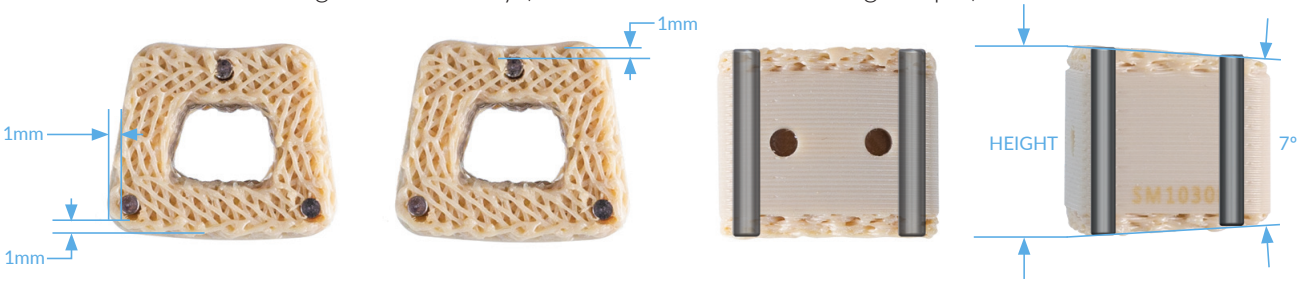
Catalog Number	**Description (W x D x H)**	**Graft Volume**
C234-161306-7*	16 x 13 x 06mm, 7° Porous PEEK Cervical Interbody	.42cc
C234-161307-7*	16 x 13 x 07mm, 7° Porous PEEK Cervical Interbody	.50cc
C234-161308-7*	16 x 13 x 08mm, 7° Porous PEEK Cervical Interbody	.58cc
C234-161309-7*	16 x 13 x 09mm, 7° Porous PEEK Cervical Interbody	.66cc
C234-161310-7*	16 x 13 x 10mm, 7° Porous PEEK Cervical Interbody	.74cc
C234-161311-7*	16 x 13 x 11mm, 7° Porous PEEK Cervical Interbody	.82cc
C234-161312-7*	16 x 13 x 12mm, 7° Porous PEEK Cervical Interbody	.91cc

Catalog Number	**Description (W x D x H)**	**Graft Volume**
C234-181406-7	18 x 14 x 06mm, 7° Porous PEEK Cervical Interbody	.55cc
C234-181407-7	18 x 14 x 07mm, 7° Porous PEEK Cervical Interbody	.66cc
C234-181408-7	18 x 14 x 08mm, 7° Porous PEEK Cervical Interbody	.77cc
C234-181409-7	18 x 14 x 09mm, 7° Porous PEEK Cervical Interbody	.88cc
C234-181410-7*	18 x 14 x 10mm, 7° Porous PEEK Cervical Interbody	.99cc
C234-181411-7*	18 x 14 x 11mm, 7° Porous PEEK Cervical Interbody	1.10cc
C234-181412-7*	18 x 14 x 12mm, 7° Porous PEEK Cervical Interbody	1.21cc

**Available upon request*

Radiographic Markers

- 3 Pins per interbody – 2 anterior, 1 posterior, 1mm diameter
- Pins are 1mm from edges of interbody (measured from external edge of pin)



Instrument Guide

C235-100	Inspire Vise Cervical Inserter

C205-200	Cervical Tamp

C235-300	Graft Packing Block

C235-310	Graft Packer

C205-500	Parallel Rasp

C205-625	5 and 6mm Dual-Headed Trial, 14 x 12mm, Lordotic
C205-626	7 and 8mm Dual-Headed Trial, 14 x 12mm, Lordotic
C205-627	9 and 10mm Dual-Headed Trial, 14 x 12mm, Lordotic
C205-628	11 and 12mm Dual-Headed Trial, 14 x 12mm, Lordotic
C205-645	5 and 6mm Dual-Headed Trial, 18 x 14mm, Lordotic
C205-646	7 and 8mm Dual-Headed Trial, 18 x 14mm, Lordotic
C205-647	9 and 10mm Dual-Headed Trial, 18 x 14mm, Lordotic
C205-648	11 and 12mm Dual-Headed Trial, 18 x 14mm, Lordotic

Trial Handle Color	
Parallel	Red
Lordotic	Blue

Trial Ring Color	
5mm	Yellow
6mm	Red
7mm	Green
8mm	Blue
9mm	Orange
10mm	Purple
11mm	Aqua
12mm	Black

Inspire®

Surgical Technique

Step 1: Surgical Approach to the Disc

The patient should be placed in a supine position with the head in slight extension. The cervical spine should be supported to maintain cervical lordosis. Before performing the surgical approach, identify the affected level using fluoroscopy. Utilizing a standard anterior cervical surgical approach, expose the midline of the affected site. **(Figure 1)**

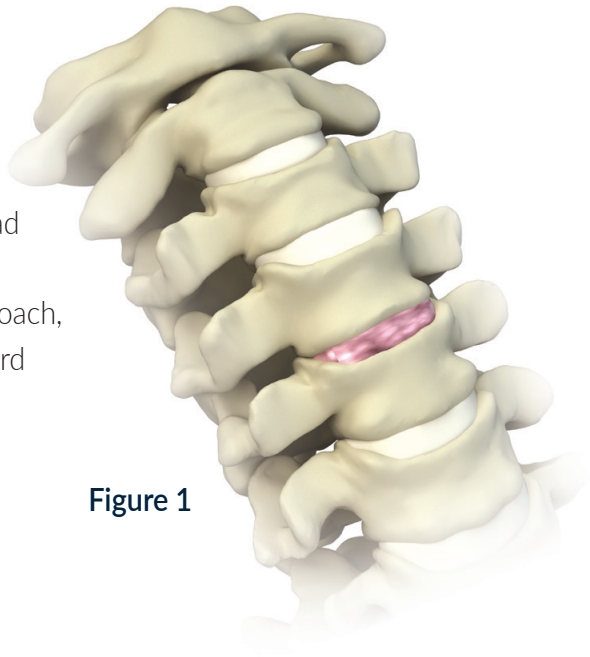


Figure 1

Step 2: Prepare the Endplate

Perform a standard discectomy used with an anterior cervical surgical approach. The Parallel Rasp (C205-500) and/or other endplate preparation instruments are used to remove the cartilaginous layer of the endplates. This will aid in the creation of bleeding bone to promote spinal fusion. **(Figure 2a, 2b)**

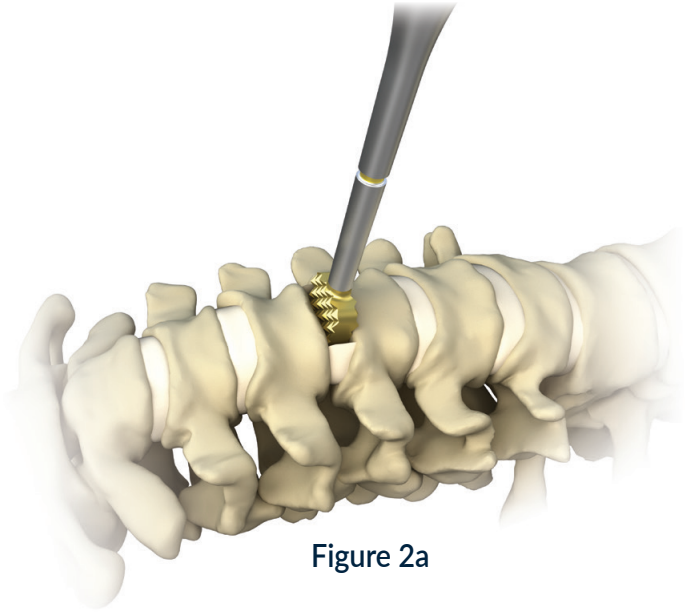


Figure 2a

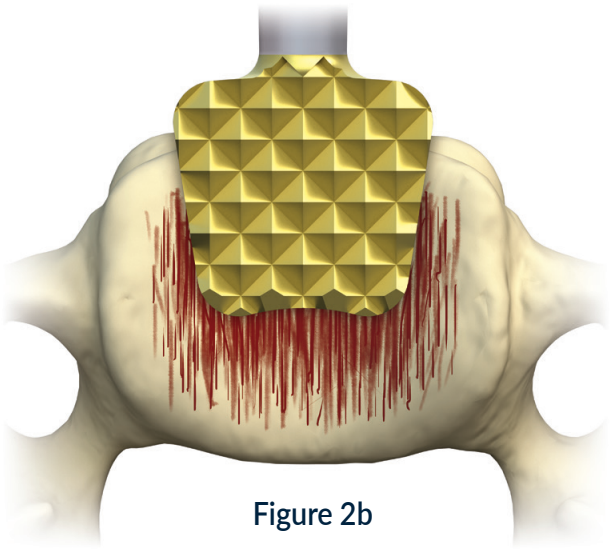


Figure 2b

Step 3: Trial for Implant Size

All sizes of implants are paired with matching Trials for proper implant selection. Select a Trial and sequentially trial until a desired fit within the disc space is achieved. Refer to the ring color on the Trial to select the corresponding implant (refer Instrument Guide). **(Figure 3a, 3b)**

Note: The Trial heights are sized to top of implant surface.

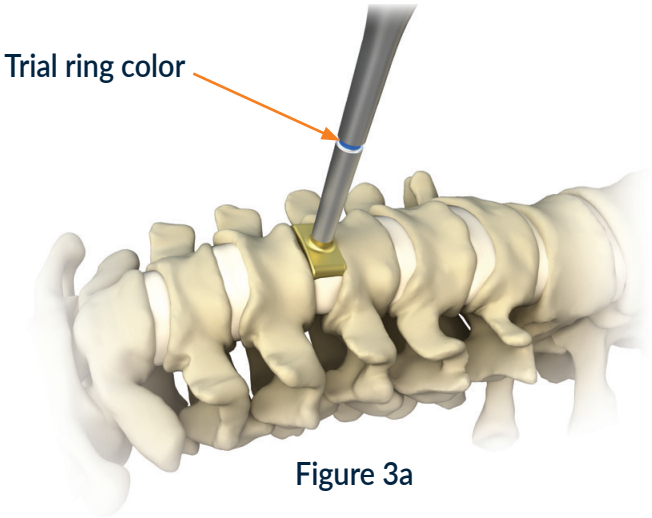


Figure 3a

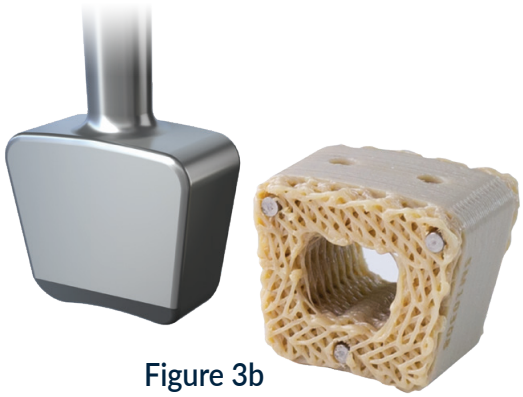


Figure 3b

Step 4: Load the Selected Implant

Insert the two prongs of the Inserter (C235-100-N) into the corresponding holes on the selected interbody device until the face of the instrument is flush with the implant. Then secure the implant to the Inserter by rotating the proximal knob clockwise. **(Figure 4a, 4b)**

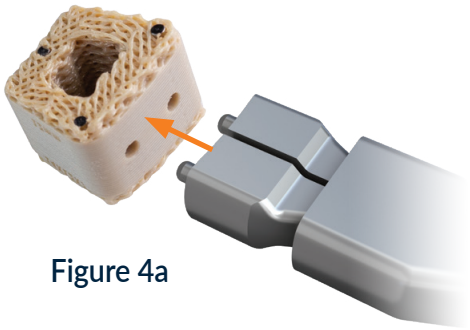


Figure 4a

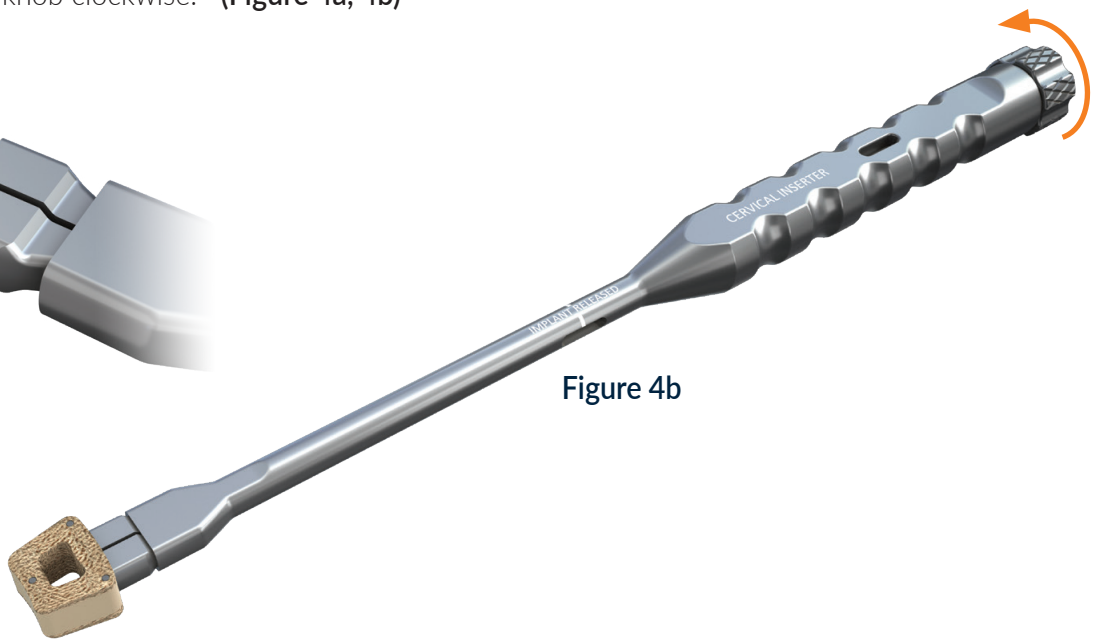


Figure 4b

Step 5: Pack the Implant with Grafting Material

Place the interbody into the appropriate window of the Graft Packing Block (C235-300). Firmly pack autograft and/or allograft material into the graft area of the interbody using the Graft Packer (C235-310). To ensure optimal contact with endplates, pack the interbody until the graft material overflows from the graft area. **(Figure 5)**

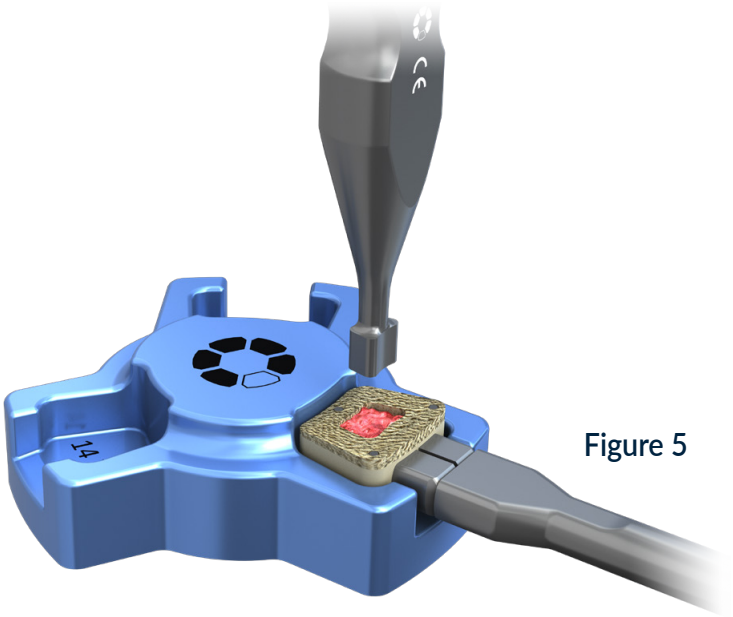


Figure 5

Step 6: Insert Implant

Insert the implant gently into the disc space towards its final position. Once inserted to the proper depth, release the Inserter from the implant by rotating the proximal knob counterclockwise. **(Figure 6a, 6b)**

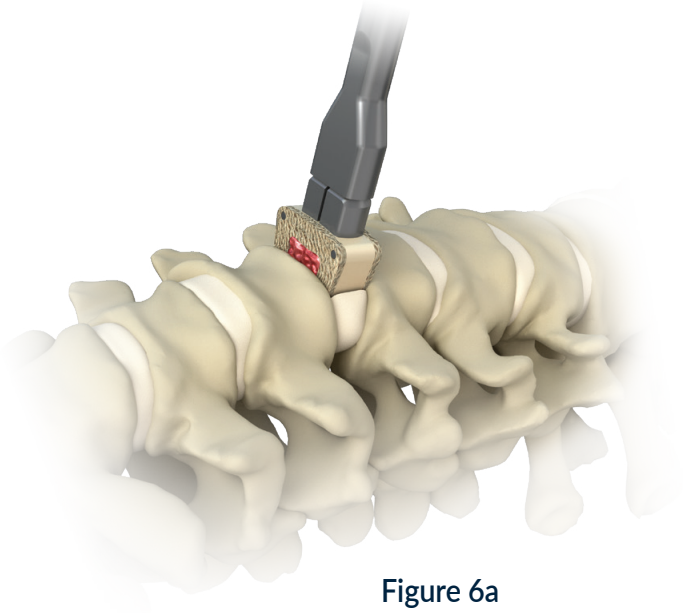


Figure 6a

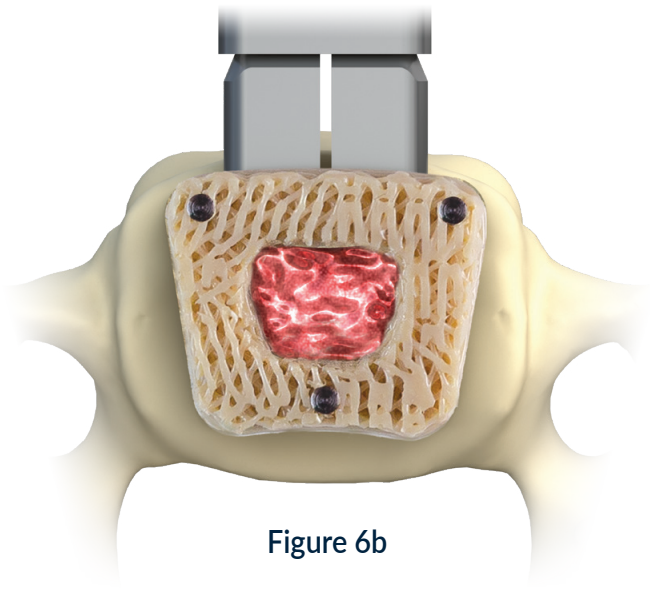


Figure 6b

Step 7: Tamp Implant to Final Position

The Cervical Tamp (C205-200) can be used for implant adjustments and for tamping the implant into final position. Radiographic markers enable intraoperative fluoroscopic assessment for the final implant position. **(Figure 7)**

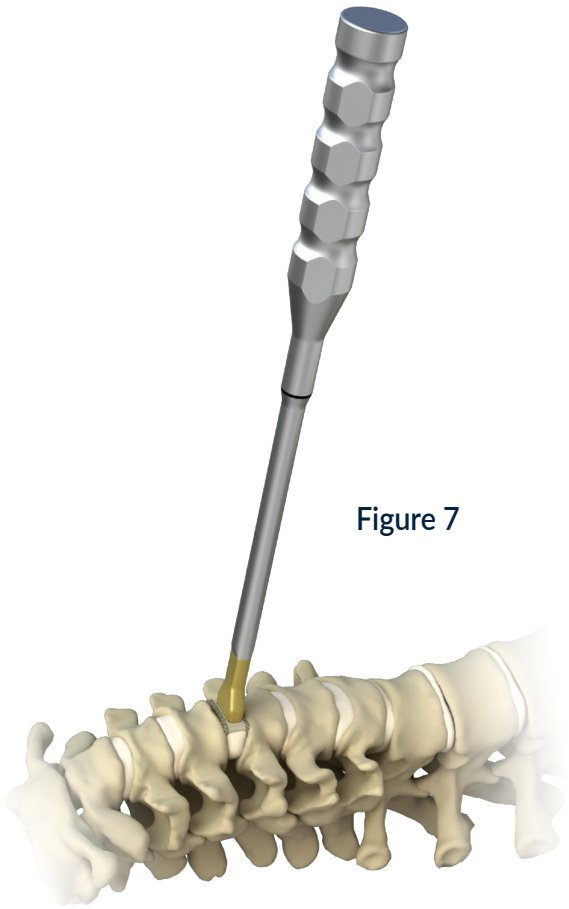


Figure 7

Step 8: Implant Removal (optional)

If the implant needs to be removed, insert the two prongs of the Inserter into the corresponding holes on the interbody device until the face of the instrument is flush with the implant. Then secure the implant to the Inserter by rotating the proximal knob clockwise. Gently remove the implant from the disc space.

Indications for Use:

The INSPIRE Cervical Interbody Fusion System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level (C2 – T1 inclusive). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. Implants are intended to be used with autograft and/or allograft bone (comprised of cancellous and/or corticocancellous bone graft) and supplemental spinal fixation systems that have been cleared for use in the cervical spine. Patients should receive at least six (6) weeks of non-operative treatment prior to treatment with the device.

Contraindications:

Contraindications for the INSPIRE Cervical Interbody Fusion System are similar to those of other systems of similar design, and include, but are not limited to:

- Patients with probable intolerance to the materials used in the manufacture of this device.
- Patients with infection, inflammation, fever, tumors, elevated white blood count, obesity, pregnancy, mental illness and other medical conditions which would prohibit beneficial surgical outcome.
- Patients unwilling or unable to follow post- operative restrictions on movement, especially in athletic and occupational activities.
- Use with components from other systems.
- Grossly distorted anatomy caused by congenital abnormalities.
- Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
- Rapid joint disease, bone absorption, osteopenia. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, and/or the amount of mechanical fixation.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
- Any case not described in the indications for use.
- Reuse or multiple uses.

Cautions, Precautions and Warnings:

Cautions:

Mixing of dissimilar metals can accelerate the corrosion process. Stainless steel and titanium components must NOT be used together.

Do not use components of the SAGE Cervical Interbody Fusion System with components from any other manufacturer.

Care must be taken to protect the components from being marred, nicked or notched as a result of contact with other objects. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.

As with all orthopedic implants, none of the SAGE Cervical Interbody Fusion System components should ever be reused under any circumstances.

Precautions:

The implantation of properly selected and placed system implants and components should be performed only by experienced spinal surgeons with specific training in the use of this spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Patients who smoke have been shown to have an increased incidence of non- union. These patients should be advised of this fact and warned of the consequences. Other poor candidates for spine fusion include obese, malnourished, those with poor muscle and bone quality, and nerve paralysis patients.

Due to the presence of implants, interference with roentgenographic, CT and/or MR imaging may result. The SAGE Cervical Interbody Fusion System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the SAGE Cervical Interbody Fusion System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Warnings:

This device system is not intended to be the sole means of spinal support. It's use without a bone graft or in cases that develop into a non-union will not be successful. No spinal implant can withstand the loads of the body without maturation of a solid fusion mass, and in this case, bending, loosening or fracture of the implant will eventually occur. The proper selection and compliance of the patient will greatly affect the results.

The implantation of spinal systems should be performed only by spinal surgeons fully experienced in the surgical techniques required for the use of such implants. Even with the use of spinal implants, a successful result in terms of pain, function, or fusion is not always achieved in every surgical case.

The physician is the learned intermediary between the company and the patient. The indications, contraindications, warnings, and precautions given in this document must be conveyed to the patient. If requested, additional information, including surgical technique manuals, may be obtained through corporate sales representatives.

CURITEVA®
POWER TO HEAL

Toll Free: 877.9CURITEVA
Phone: 256.213.1057
www.curiteva.com
customersupport@curiteva.com

QMSF-1239 Rev 2.0