SeaSpine

CAMBRIA™ NANOMETALENE®

ANTERIOR CERVICAL INTERBODY
SURGICAL TECHNIQUE

CONTENTS

CAMBRIA™ NANOMETALENE®

DESIGN RATIONALE

The Cambria™ NanoMetalene® implant is designed to be your cervical interbody solution. It combines the surface benefits of titanium[1] and the mechanical properties of PEEK[2] to deliver an interbody solution with the best of both materials and design for fusion.

SYSTEM FEATURES

Anatomically Designed Implant

- 6.5° of lordosis
- Multiple footprints to fit varying patient anatomies
- 13 x 12mm, 15 x 13mm, 17 x 13mm
- Maximized graft area for fusion

Simple Instrumentation

- Threaded secure insertion
- Color-coded trials

Description	Measurements
Footprints	13 x 12mm, 15 x 13mm, 17 x 13mm
Heights	5–12mm

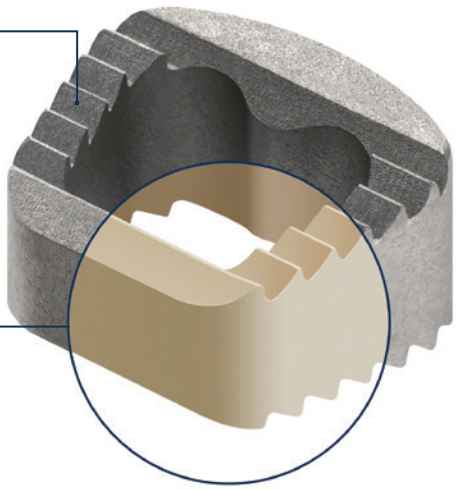
[1]NanoMetalene SEM images on file. TR-0094-19-01
[2]Results from mechanical testing. Data on file. TR-0010-11-01

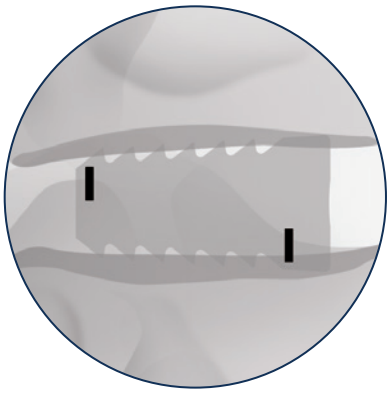
NANOMETALENE® TECHNOLOGY

Submicron titanium layer molecularly bonded to entire PEEK implant

Titanium surfacing resists wear debris[1]

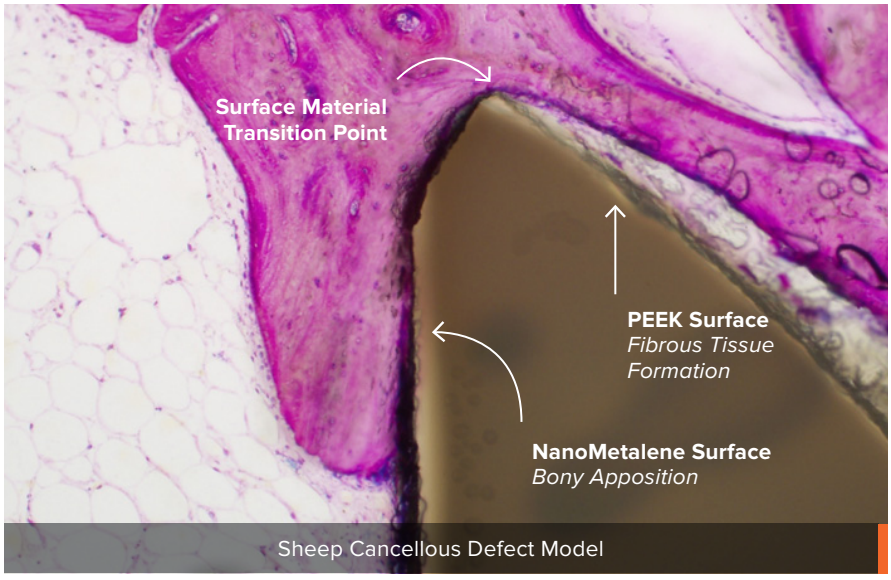
Mechanical properties of PEEK unaltered, providing stiffness on par with bone[1]

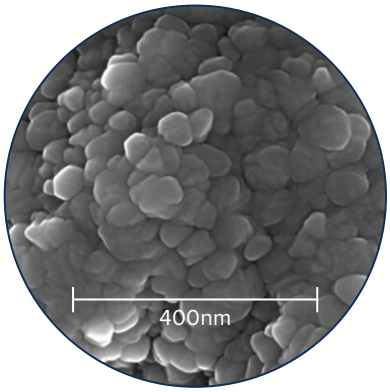




Radiolucent for post-op fusion assessment[2]

Preclinical results show greater bone ongrowth on NanoMetalene® vs. PEEK[3,†]





Rough submicron topography encourages integration[3,4]

†Preclinical testing, such as animal studies, may not be indicative of human results.
[1]Results from mechanical testing. Data on file. TR-0010-11-01
[2]Results from imaging study. Data on file. TR-0010-11-01
[3]Walsh, et al. The in vivo response to a novel Ti coating compared with polyether ether ketone: evaluation of the periphery and inner surfaces of an implant. Spine Journal 2018 Jul; 18(7): 1231-1240
[4]NanoMetalene SEM images on file. TR-0094-19-01

STEP 1. ACCESS

Access the appropriate level(s) of the anterior cervical spine using standard ACDF approach technique (FIG. 1).

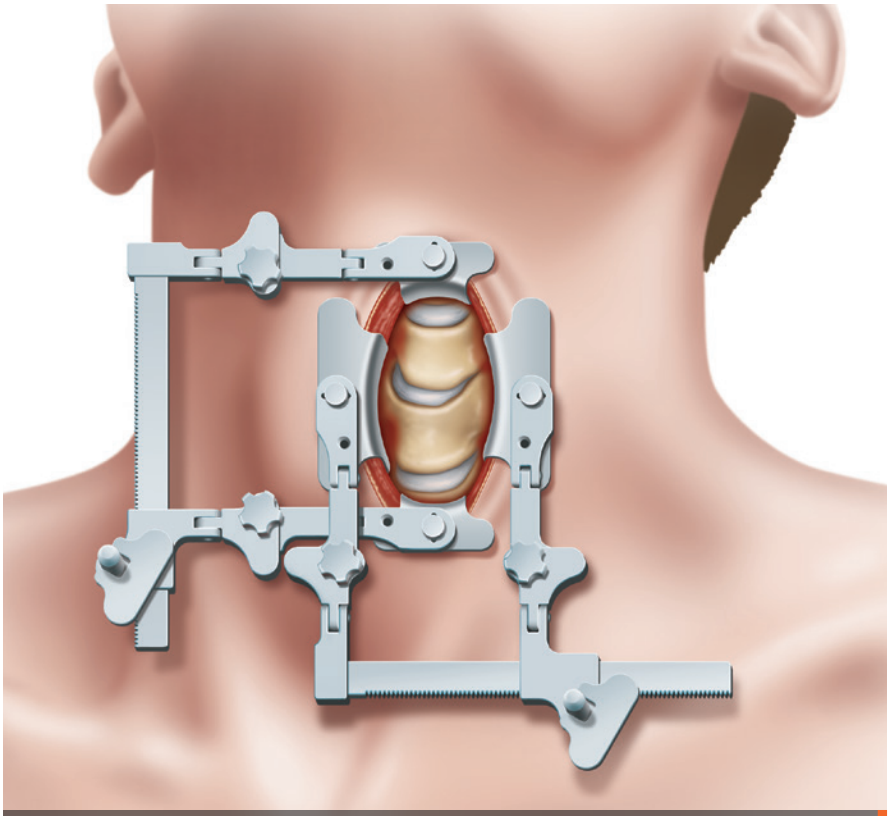


FIG. 1

STEP 2. DISCECTOMY & ENDPLATE PREPARATION

Remove the disc material and cartilaginous endplates as required to prepare the implantation site and create space for the Cambria™ NanoMetalene® implant.

A rasp may be used to help prepare the endplates (FIG. 2).

CAUTION
Excessive removal of the endplates may compromise construct strength and increase the potential for subsidence.

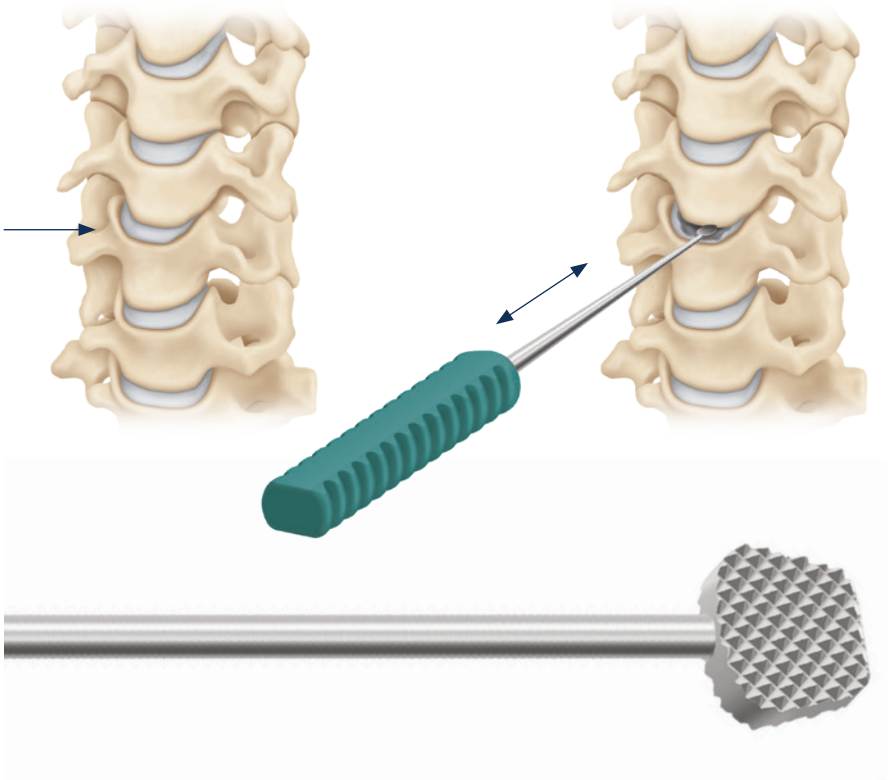


FIG. 2

STEP 3. IMPLANT SIZING

Select the appropriate trial for the desired implant footprint. Insert the trial into the disc space to determine the appropriate height implant (FIG. 3).

The trials have built-in stops to set the final implant depth at 2mm sub-flush to the anterior surface of the vertebral body (FIG. 4).

NOTE
The trials are color-coded for easy reference.

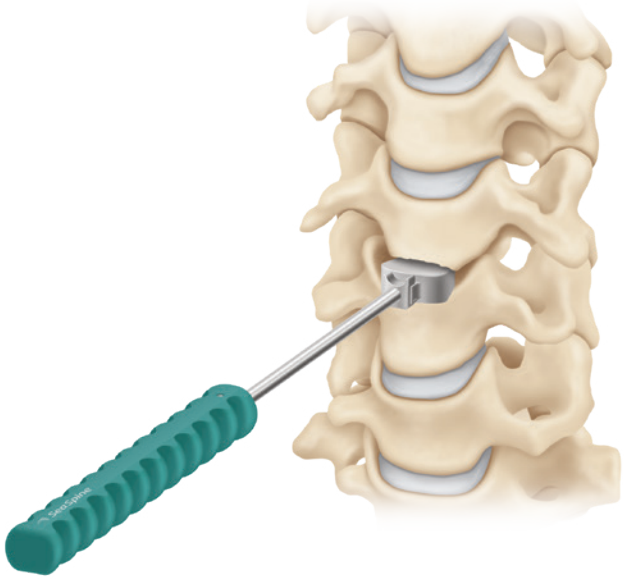


FIG. 3

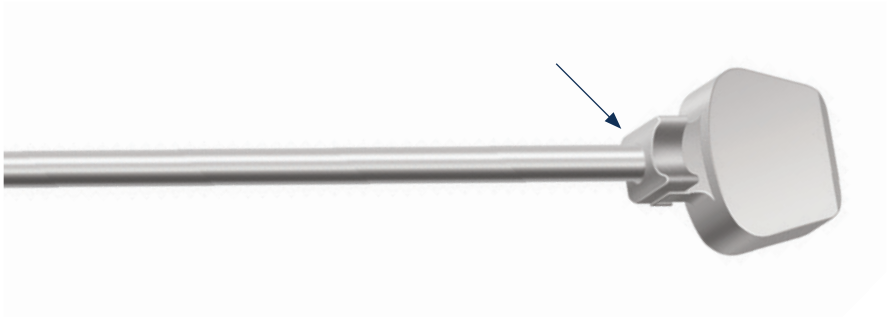


FIG. 4

COLOR-CODED TRIALS

STEP 4. IMPLANT SELECTION

Cambria™ NanoMetalene® implants come sterile packaged. Review the box and ensure the tamper seal is intact. Also, review the label for correct footprint and height prior to opening (FIG. 5).

CAUTION
Due to sterile contents, once package seal has been broken, it cannot be returned to the manufacturer.

Once the box is opened, refer to the IFU for handling and transfer of implant to sterile field.

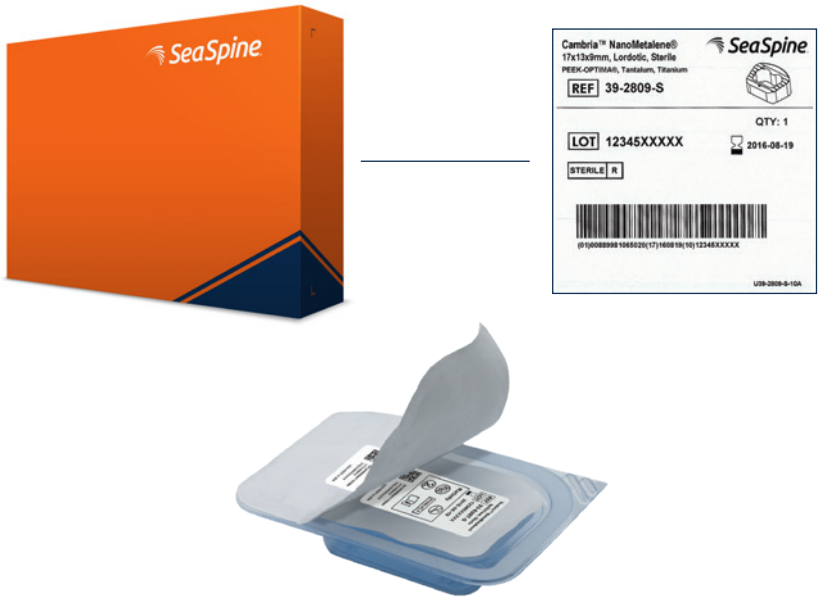


FIG. 5

STEP 5. BONE GRAFTING

Place the appropriate Cambria™ NanoMetalene® implant into the graft packing block and insert bone graft into the central cavity.

The graft tamp may be used to further pack the graft material (FIG. 6).

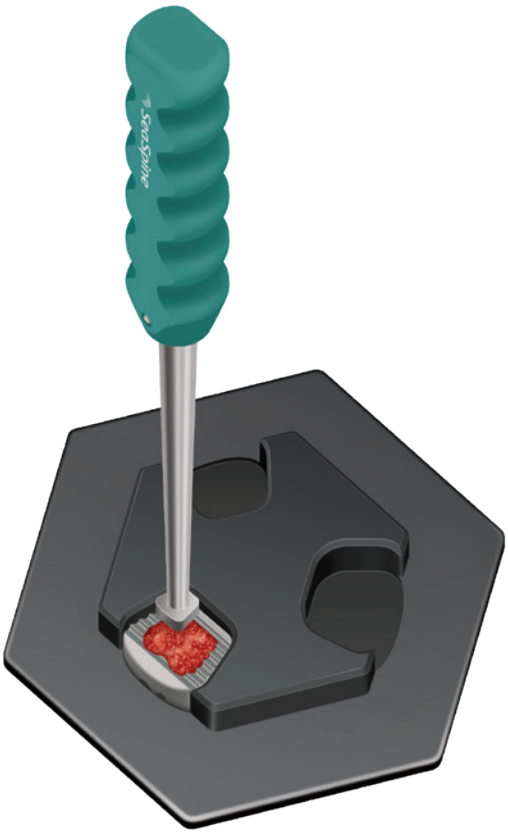


FIG. 6

STEP 6. IMPLANT INSERTION

Thread the inserter into the appropriate implant by rotating the wheel at the top of the handle clockwise until implant is secure. (FIG. 7). Next, turn the knurled knob on the proximal end of the inserter clockwise until the implant is fully engaged. Do not over-tighten. Gently impact the implant into the disc space.

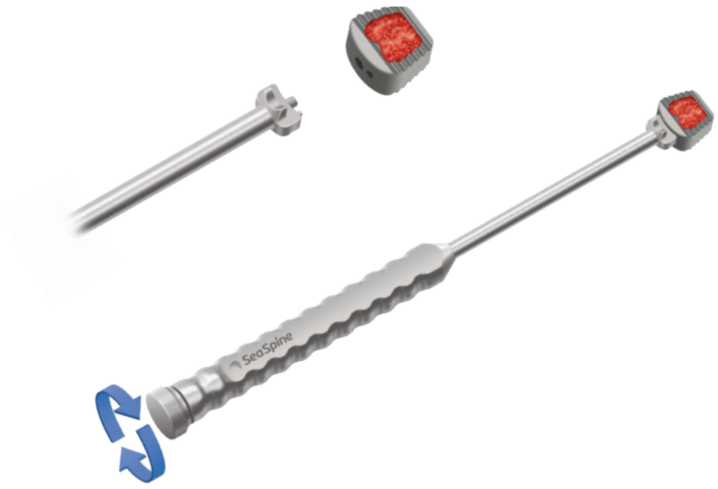


FIG. 7

TIP
The inserter has a built-in stop to set the final implant depth at 2mm sub-flush to the anterior surface of the vertebral body (FIG. 8).

After the implant has been properly positioned, turn the inserter knob counterclockwise to disengage the inserter. The graft impactor tool may be used to further adjust implant position if needed. Fluoroscopic imaging may be used to confirm final implant positioning (FIG. 9).

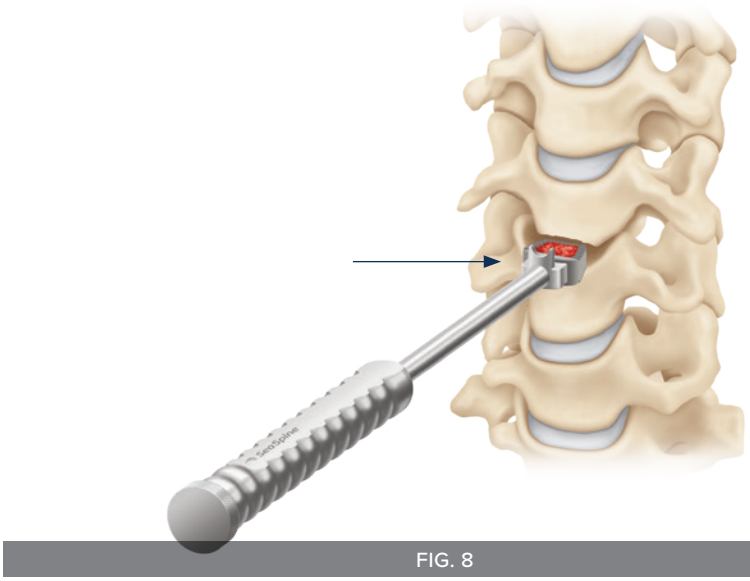


FIG. 8

TIP
The Cambria™ NanoMetalene® implant has three titanium markers (two anterior, one posterior) to help verify implant placement.

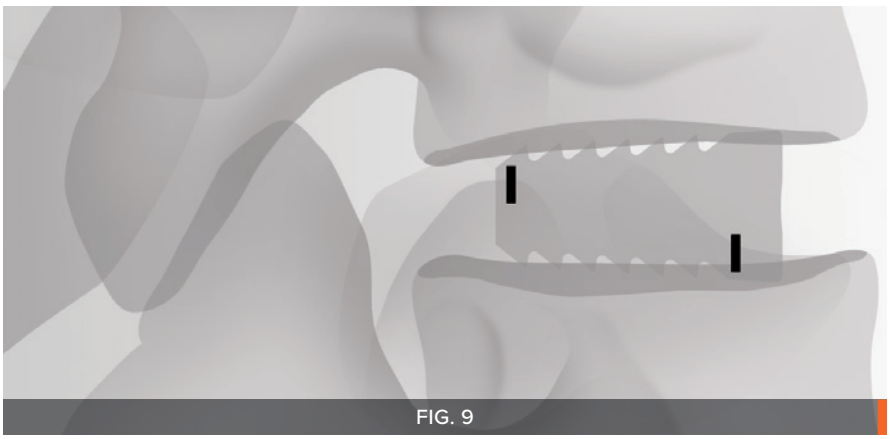


FIG. 9

STEP 7. FINAL STEPS

Removal Option

If removal of the implant is desired, align the anti-rotation pin on the distal end of the inserter with the anti-rotation hole on the face of the Cambria™ NanoMetalene® implant. (FIG. 10). Next, turn the knurled knob on the proximal end of the inserter clockwise until the implant is fully engaged (FIG. 11). Once the implant is fully re-engaged with the inserter, simply remove it by gently pulling upward away from the spine.

TIP
A gentle medial to lateral movement may help to loosen and remove the implant from a tight disc space (FIG. 12).

FIG. 10

FIG. 11

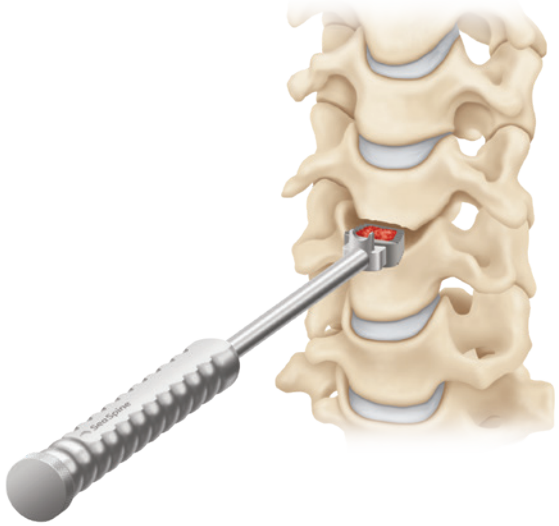


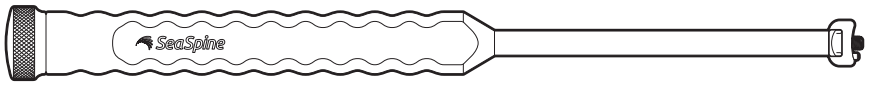
FIG. 12

ORDERING INFORMATION

INSTRUMENTATION CAMNMIMP: CAMBRIA™ NANOMETALENE® INSTRUMENTS

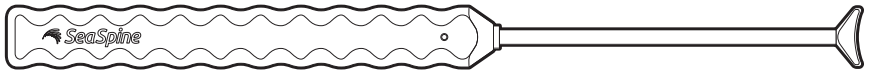
Inserter

PN 93-9830



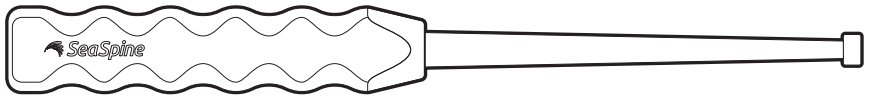
Impant Tamp

PN 93-9831



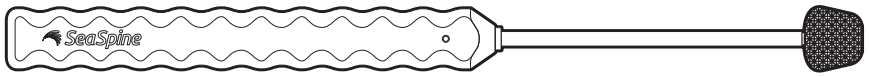
Graft Packer

PN 93-9832



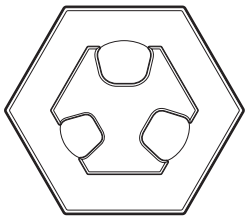
Rasp

PN 93-9833



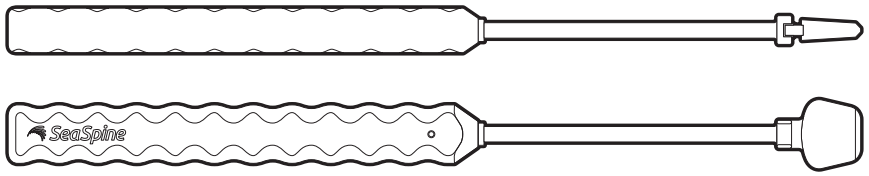
Packing Block

PN 93-9834



Trials with Depth Stops
13 x 12 x 5–12mm
15 x 13 x 5–12mm
17 x 13 x 5–12mm

PN 93-98XX



PRODUCTS SHOWN NOT TO SCALE

INTERBODY TOTES CAMBRIA™ NANOMETALENE® INTERBODIES

CAMNMS: Cambria™ NanoMetalene® Implants – 13 x 12mm

Part Number	Part Description
39-2405-S	5mm, Flat, Lordotic, Sterile
39-2406-S	6mm, Flat, Lordotic, Sterile
39-2407-S	7mm, Flat, Lordotic, Sterile
39-2408-S	8mm, Flat, Lordotic, Sterile
39-2409-S	9mm, Flat, Lordotic, Sterile
39-2410-S	10mm, Flat, Lordotic, Sterile
39-2411-S	11mm, Flat, Lordotic, Sterile
39-2412-S	12mm, Flat, Lordotic, Sterile

CAMNMM: Cambria NanoMetalene Implants – 15 x 13mm

Part Number	PartDescription
39-2605-S	5mm, Flat, Lordotic, Sterile
39-2606-S	6mm, Flat, Lordotic, Sterile
39-2607-S	7mm, Flat, Lordotic, Sterile
39-2608-S	8mm, Flat, Lordotic, Sterile
39-2609-S	9mm, Flat, Lordotic, Sterile
39-2610-S	10mm, Flat, Lordotic, Sterile
39-2611-S	11mm, Flat, Lordotic, Sterile
39-2612-S	12mm, Flat, Lordotic, Sterile

CAMNML: Cambria NanoMetalene Implants – 17 x 13mm

Part Number	Part Description
39-2805-S	5mm, Flat, Lordotic, Sterile
39-2806-S	6mm, Flat, Lordotic, Sterile
39-2807-S	7mm, Flat, Lordotic, Sterile
39-2808-S	8mm, Flat, Lordotic, Sterile
39-2809-S	9mm, Flat, Lordotic, Sterile
39-2810-S	10mm, Flat, Lordotic, Sterile
39-2811-S	11mm, Flat, Lordotic, Sterile
39-2812-S	12mm, Flat, Lordotic, Sterile

INSTRUCTIONS FOR USE

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Indications For Use

The SeaSpine® Cambria™ NanoMetalene® System with NanoMetalene surface technology is intended to be used as an adjunct to spinal fusion procedures at one or two contiguous levels (C3–C7) in skeletally mature patients with degenerative disc disease (defined as neck pain with discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Patients should have received at least six weeks of non- operative treatment prior to treatment with the device. Devices are intended to be implanted via an open, anterior approach and used with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone and supplemental fixation, such as an anterior plating system.

Contraindications

Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery is a contraindication. The following conditions may reduce the chance of a successful outcome and should be taken into consideration by the surgeon. This list is not exhaustive:

Absolute contraindications:

- Infection in or around the operative site
- Allergy or sensitivity to implant materials
- Any case not described in the indication

Relative contraindications:

- Local inflammation
- Morbid obesity
- Pregnancy
- Fever or leukocytosis
- Prior fusion at the level(s) to be treated
- Grossly distorted anatomy due to congenital abnormalities
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis
- Elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count
- Any case not requiring bone graft and fusion or where fracture healing is not required
- Patients having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality or anatomical definition
- Unsuitable or insufficient bone support
- Bone immaturity
- The patient's activity level, mental condition, occupation and/or a patient unwilling to cooperate with the post-operative instructions
- Any case where implant utilization would interfere with anatomical structures or expected physiological performance
- Use of incompatible components and/or materials from other systems

INSTRUCTIONS FOR USE

Sterilization for NanoMetalene® Implants

NanoMetalene® implants in the Cambria™ system are supplied "STERILE." Refer to the IFU for handling and transfer of implant to sterile field.

Sterilization for Instruments

Instruments are supplied "NON-STERILE" and must be decontaminated and sterilized before use. Refer to the IFU for details.

CAUTION Federal law restricts this device to sale by or on the order of a physician or practitioner.

Please refer to the following website for other important labeling information:
www.seaspine.com/eIFU
QF-10-01-104-ENGL

SeaSpine® Orthopedics Corporation does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any procedure is responsible for determining and using the appropriate technique in each patient.

CAMBRIA™ NANOMETALENE®

ANTERIOR CERVICAL INTERBODY

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