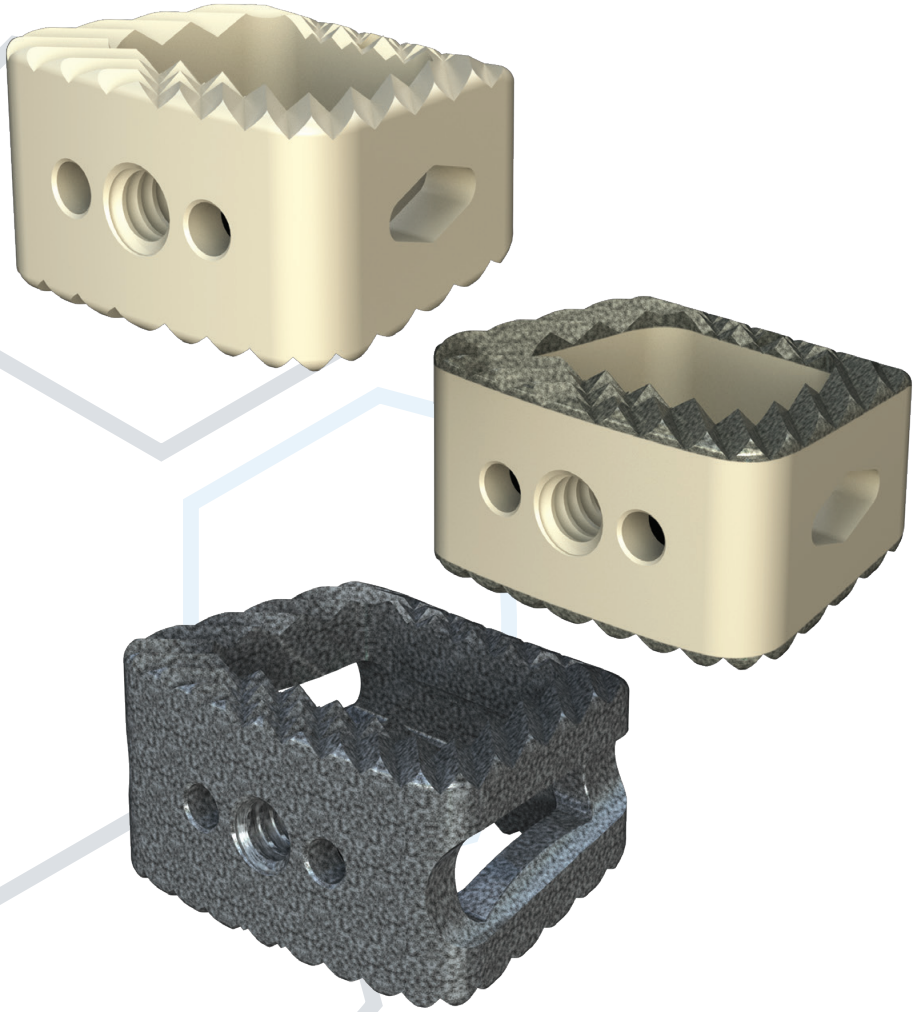
SAGE™ CERVICAL INTERBODY FUSION SYSTEM



CERVICAL INTERBODY

Surgical Technique Guide

CURITEVA®

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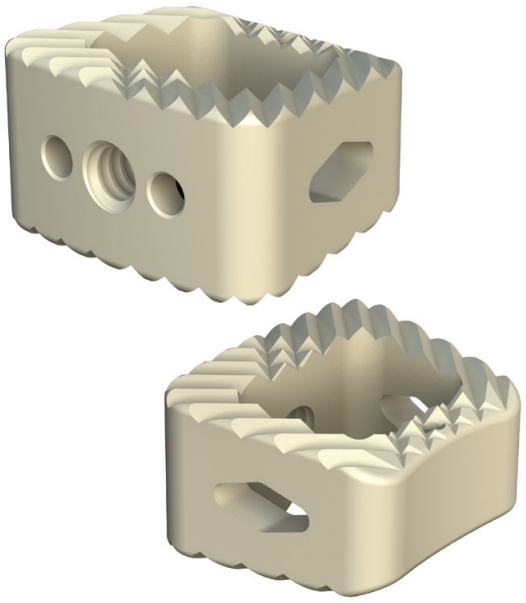
SAGE™
CERVICAL INTERBODY FUSION SYSTEM

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.

SAGE™ PEEK CERVICAL INTERBODY FUSION SYSTEM

Sage Cervical Interbody Fusion System is designed to support cervical loads while maximizing surface contact between the implant and the vertebral bodies. The interbody is offered in four footprints to accommodate individual patient anatomy while the streamlined instrumentation is designed to aid in consistent and accurate implant placement.



PEEK Interbody

Part Number: C204-XXXXYY-7
XXXX - Interbody Footprint, YY - Interbody Height

- PEEK construction
- Footprints (mm): 12W x 11D, 14W x 12D, 16W x 13D, and 18W x 14D
- Heights: 5-12mm, offered in 1mm increments
- Lordosis: 7°

Sage Features

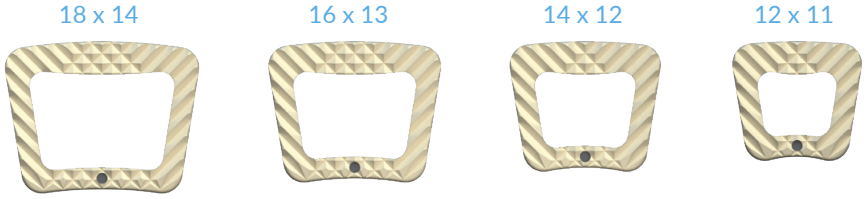
- Modulus of elasticity between cortical and cancellous bone for optimal load sharing
- Designed to ensure a high degree of compressive strength and dimensional stability
- Tantalum radiopaque markers to optimize visibility and placement
- Multi-directional, aggressive teeth designed to prevent implant migration
- Robust inserter engagement features to facilitate implant insertion
- Large, central graft cavity for packing bone graft to facilitate fusion
- Lateral windows provide vascularization to the fusion site
- Self-distracting leading edge to facilitate implant insertion
- Crescent shaped tamp for implant positioning
- Color-coded instruments for easy identification

SAGE™ PEEK CERVICAL INTERBODY FUSION SYSTEM

PEEK Cervical Interbodies					
Catalog Number	Description (W x D x H)	Graft Volume	Catalog Number	Description (W x D x H)	Graft Volume
C204-121105-7	12 x 11 x 5mm	.16cc	C204-161305-7	16 x 13 x 5mm	.34cc
C204-121106-7	12 x 11 x 6mm	.20cc	C204-161306-7	16 x 13 x 6mm	.42cc
C204-121107-7	12 x 11 x 7mm	.24cc	C204-161307-7	16 x 13 x 7mm	.50cc
C204-121108-7	12 x 11 x 8mm	.28cc	C204-161308-7	16 x 13 x 8mm	.58cc
C204-121109-7	12 x 11 x 9mm	.32cc	C204-161309-7	16 x 13 x 9mm	.66cc
C204-121110-7	12 x 11 x 10mm	.36cc	C204-161310-7	16 x 13 x 10mm	.74cc
C204-121111-7	12 x 11 x 11mm	.39cc	C204-161311-7	16 x 13 x 11mm	.82cc
C204-121112-7	12 x 11 x 12mm	.43cc	C204-161312-7	16 x 13 x 12mm	.91cc
C204-141205-7	14 x 12 x 5mm	.25cc	C204-181405-7	18 x 14 x 5mm	.44cc
C204-141206-7	14 x 12 x 6mm	.31cc	C204-181406-7	18 x 14 x 6mm	.55cc
C204-141207-7	14 x 12 x 7mm	.37cc	C204-181407-7	18 x 14 x 7mm	.66cc
C204-141208-7	14 x 12 x 8mm	.43cc	C204-181408-7	18 x 14 x 8mm	.77cc
C204-141209-7	14 x 12 x 9mm	.49cc	C204-181409-7	18 x 14 x 9mm	.88cc
C204-141210-7	14 x 12 x 10mm	.55cc	C204-181410-7	18 x 14 x 10mm	.99cc
C204-141211-7	14 x 12 x 11mm	.61cc	C204-181411-7	18 x 14 x 11mm	1.10cc
C204-141212-7	14 x 12 x 12mm	.67cc	C204-181412-7	18 x 14 x 12mm	1.21cc

Interbody Details

- 2mm side wall thickness
- .5mm tooth depth (.025")

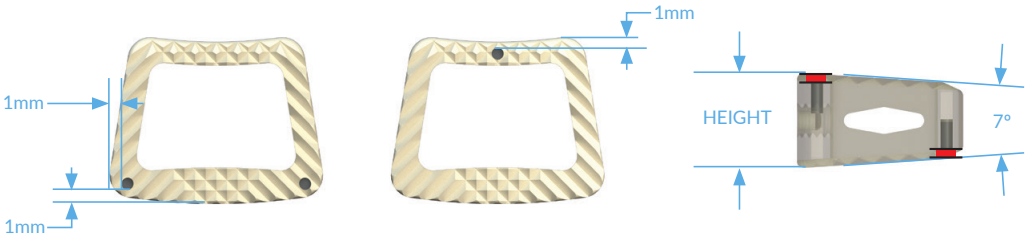


Radiographic Markers

- 3 Pins per interbody – 2 anterior/cephalad (top) & 1 posterior/caudal (bottom)
- Pin length: 2.5mm; 1mm diameter
- Pins offset .5mm (tooth depth) from endplate (identified in red below)
- Pins are 1mm from edges of interbody (measured from external edge of pin)

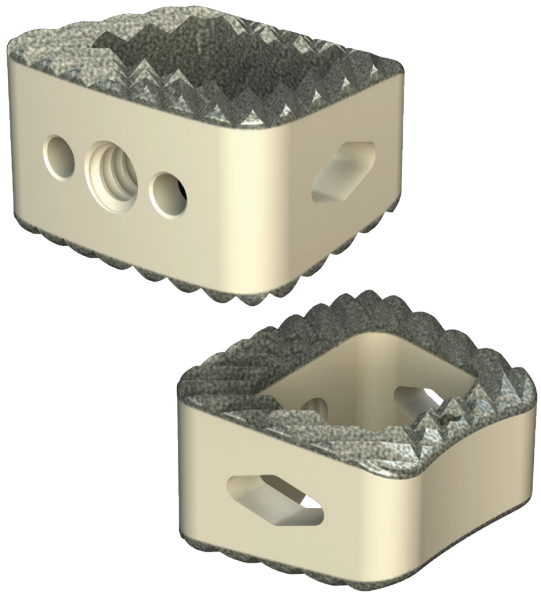
Lateral Window

- 5 & 6mm – No Window
- 7 – 10mm – Single Window
- 11 & 12mm – Split Window



SAGE™ PEEK CERVICAL INTERBODY FUSION SYSTEM
Featuring Titanium Plasma Coating

Sage Titanium Plasma Coated Interbody system is designed to offer immediate stability with a friction fit design. The interbody is manufactured out of PEEK with a titanium plasma spray coating. The interbody is offered in four footprints to accommodate individual patient anatomy while the streamlined instrumentation is designed to aid in consistent and accurate implant placement. The titanium plasma coating will add approximately 0.25mm thickness to the overall height of the interbody.



PEEK Interbody with Coating

Part Number: C224-XXXXYY-7CT
XXXX - Interbody Footprint, YY - Interbody Height

- PEEK Construction with Plasma Coating
- Footprints (mm): 12W x 11D, 14W x 12D, 16W x 13D, and 18W x 14D
- Heights: 5-12mm, offered in 1mm increments
- Lordosis: 7°

Sage Features

- Surface topography produces superior implant contact and construct stability
- Optimal Radiolucency
- Long-Term Fixation
- Modulus of elasticity between cortical and cancellous bone for optimal load sharing
- Designed to ensure a high degree of compressive strength and dimensional stability
- Tantalum radiopaque markers to optimize visibility and placement
- Multi-directional, aggressive teeth designed to prevent implant migration
- Robust inserter engagement features to facilitate implant insertion
- Large, central graft cavity for packing bone graft to facilitate fusion
- Lateral windows provide vascularization to the fusion site
- Self-distracting leading edge to facilitate implant insertion
- Color-coded instruments for easy identification

SAGE™ PEEK CERVICAL INTERBODY FUSION SYSTEM
Featuring Titanium Plasma Coating

Titanium Plasma Coated PEEK Cervical Interbodies

Catalog Number	Description (W x D x H)	Graft Volume
C224-121105-7CT	12 x 11 x 5mm	.16cc
C224-121106-7CT	12 x 11 x 6mm	.20cc
C224-121107-7CT	12 x 11 x 7mm	.24cc
C224-121108-7CT	12 x 11 x 8mm	.28cc
C224-121109-7CT	12 x 11 x 9mm	.32cc
C224-121110-7CT	12 x 11 x 10mm	.36cc
C224-121111-7CT	12 x 11 x 11mm	.39cc
C224-121112-7CT	12 x 11 x 12mm	.43cc
C224-141205-7CT	14 x 12 x 5mm	.25cc
C224-141206-7CT	14 x 12 x 6mm	.31cc
C224-141207-7CT	14 x 12 x 7mm	.37cc
C224-141208-7CT	14 x 12 x 8mm	.43cc
C224-141209-7CT	14 x 12 x 9mm	.49cc
C224-141210-7CT	14 x 12 x 10mm	.55cc
C224-141211-7CT	14 x 12 x 11mm	.61cc
C224-141212-7CT	14 x 12 x 12mm	.67cc

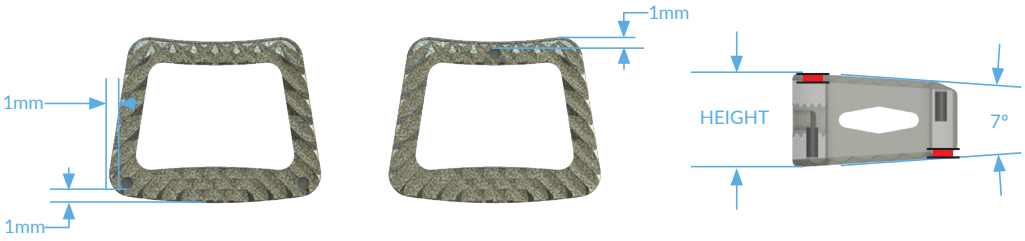
Catalog Number	Description (W x D x H)	Graft Volume
C224-161305-7CT	16 x 13 x 5mm	.34cc
C224-161306-7CT	16 x 13 x 6mm	.42cc
C224-161307-7CT	16 x 13 x 7mm	.50cc
C224-161308-7CT	16 x 13 x 8mm	.58cc
C224-161309-7CT	16 x 13 x 9mm	.66cc
C224-161310-7CT	16 x 13 x 10mm	.74cc
C224-161311-7CT	16 x 13 x 11mm	.82cc
C224-161312-7CT	16 x 13 x 12mm	.91cc
C224-181405-7CT	18 x 14 x 5mm	.44cc
C224-181406-7CT	18 x 14 x 6mm	.55cc
C224-181407-7CT	18 x 14 x 7mm	.66cc
C224-181408-7CT	18 x 14 x 8mm	.77cc
C224-181409-7CT	18 x 14 x 9mm	.88cc
C224-181410-7CT	18 x 14 x 10mm	.99cc
C224-181411-7CT	18 x 14 x 11mm	1.10cc
C224-181412-7CT	18 x 14 x 12mm	1.21cc

Interbody Details

- 2mm side wall thickness
- .5mm tooth depth (.025")

Radiographic Markers

- 3 Pins per interbody – 2 anterior/cephalad (top) & 1 posterior/caudal (bottom)
- Pin length: 2.5mm; 1mm diameter
- Pins offset .5mm (tooth depth) from endplate (identified in red below)
- Pins are 1mm from edges of interbody (measured from external edge of pin)

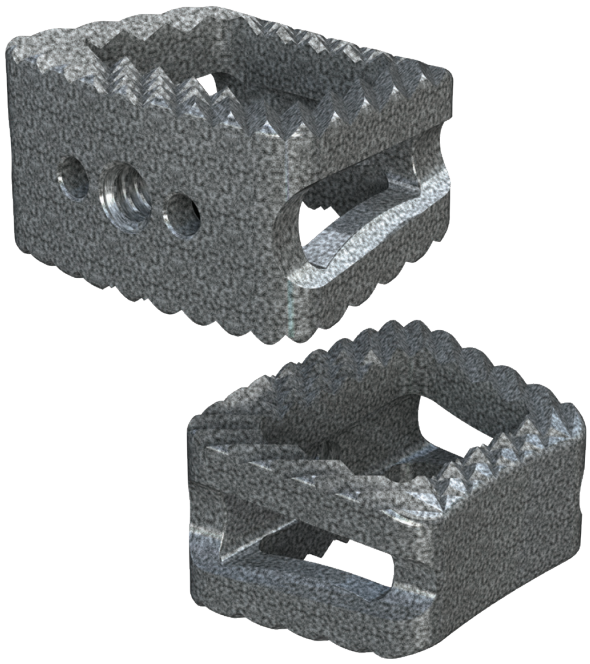


Lateral Window

- 5 & 6mm – No Window
- 7 – 10mm – Single Window
- 11 & 12mm – Split Window

SAGE™ Titanium CERVICAL INTERBODY FUSION SYSTEM Featuring TRU-LOK® Technology

Sage Titanium Interbody System features TRU-LOK®. The TRU-LOK® surface technology results in a proprietary, micro-textured surface intended to provide an improved osteogenic environment while minimizing the potential for implant migration. The micro-scale roughness of the TRU-LOK® surface technology is intended to reduce the potential for implant migration and to encourage enhanced osseointegration. The interbody is offered in four footprints to accommodate individual patient anatomy while the streamlined instrumentation is designed to aid in consistent and accurate implant placement.



Titanium Interbody with TRU-LOK®

Part Number: C214-XXXXYY-7

XXXX - Interbody Footprint, YY - Interbody Height

- Titanium construction with surface texturing
- Footprints (mm): 12W x 11D, 14W x 12D, 16W x 13D, and 18W x 14D
- Heights: 5-12mm, offered in 1mm increments
- Lordosis: 7°

Sage Features

- Open Architecture
- Surface topography promotes superior osteoblast differentiation and enhanced osseointegration
- Micro-roughness surface texturing produces superior implant contact and construct stability
- Designed to ensure a high degree of compressive strength and dimensional stability
- Multi-directional, aggressive teeth designed to prevent implant migration
- Robust inserter engagement features to facilitate implant insertion
- Large, central graft cavity for packing bone graft to facilitate fusion
- Lateral windows provide vascularization to the fusion site
- Self-distracting leading edge to facilitate implant insertion
- Color-coded instruments for easy identification

SAGE™ Titanium CERVICAL INTERBODY FUSION SYSTEM Featuring TRU-LOK® Technology

Titanium Cervical Interbodies with TRU-LOK® Technology

Catalog Number	Description (W x D x H)	Graft Volume
C214-121105-7	12 x 11 x 5mm	.16cc
C214-121106-7	12 x 11 x 6mm	.20cc
C214-121107-7	12 x 11 x 7mm	.24cc
C214-121108-7	12 x 11 x 8mm	.28cc
C214-121109-7	12 x 11 x 9mm	.32cc
C214-121110-7	12 x 11 x 10mm	.36cc
C214-121111-7	12 x 11 x 11mm	.39cc
C214-121112-7	12 x 11 x 12mm	.43cc
C214-141205-7	14 x 12 x 5mm	.25cc
C214-141206-7	14 x 12 x 6mm	.31cc
C214-141207-7	14 x 12 x 7mm	.37cc
C214-141208-7	14 x 12 x 8mm	.43cc
C214-141209-7	14 x 12 x 9mm	.49cc
C214-141210-7	14 x 12 x 10mm	.55cc
C214-141211-7	14 x 12 x 11mm	.61cc
C214-141212-7	14 x 12 x 12mm	.67cc

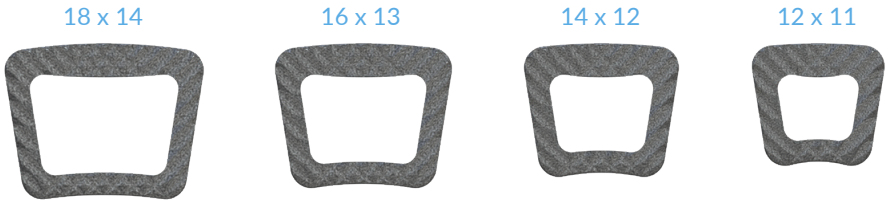
Catalog Number	Description (W x D x H)	Graft Volume
C214-161305-7	16 x 13 x 5mm	.34cc
C214-161306-7	16 x 13 x 6mm	.42cc
C214-161307-7	16 x 13 x 7mm	.50cc
C214-161308-7	16 x 13 x 8mm	.58cc
C214-161309-7	16 x 13 x 9mm	.66cc
C214-161310-7	16 x 13 x 10mm	.74cc
C214-161311-7	16 x 13 x 11mm	.82cc
C214-161312-7	16 x 13 x 12mm	.91cc
C214-181405-7	18 x 14 x 5mm	.44cc
C214-181406-7	18 x 14 x 6mm	.55cc
C214-181407-7	18 x 14 x 7mm	.66cc
C214-181408-7	18 x 14 x 8mm	.77cc
C214-181409-7	18 x 14 x 9mm	.88cc
C214-181410-7	18 x 14 x 10mm	.99cc
C214-181411-7	18 x 14 x 11mm	1.10cc
C214-181412-7	18 x 14 x 12mm	1.21cc

Interbody Details

- 2mm side wall thickness
- .5mm tooth depth (.025")

Lateral Window

- 5 & 6mm – No Window
- 7 – 12mm – Single Window



Instrument Guide

C205-100	Inserter

C205-200	Cervical Tamp

C205-300	Graft Packing Block

C205-310	Graft Packer

C205-500	Parallel Rasp

C205-615	5 and 6mm Dual-Headed Trial, 12 x 11mm, Lordotic
C205-616	7 and 8mm Dual-Headed Trial, 12 x 11mm, Lordotic
C205-617	9 and 10mm Dual-Headed Trial, 12 x 11mm, Lordotic
C205-618	11 and 12mm Dual-Headed Trial, 12 x 11mm, Lordotic
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
C205-635	5 and 6mm Dual-Headed Trial, 16 x 13mm, Lordotic
C205-636	7 and 8mm Dual-Headed Trial, 16 x 13mm, Lordotic
C205-637	9 and 10mm Dual-Headed Trial, 16 x 13mm, Lordotic
C205-638	11 and 12mm Dual-Headed Trial, 16 x 13mm, 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

SAGE™
Surgical Technique

Disclaimer

Each surgical step applies to all material types but the illustrations only show PEEK.

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)**

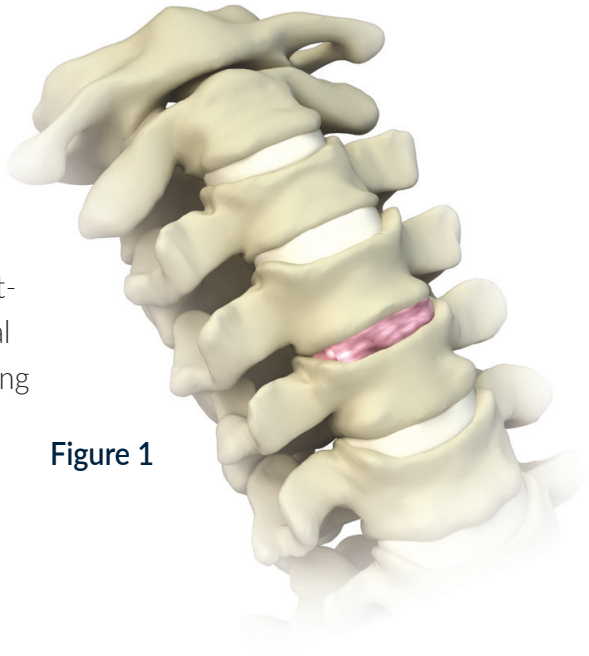


Figure 1

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)**

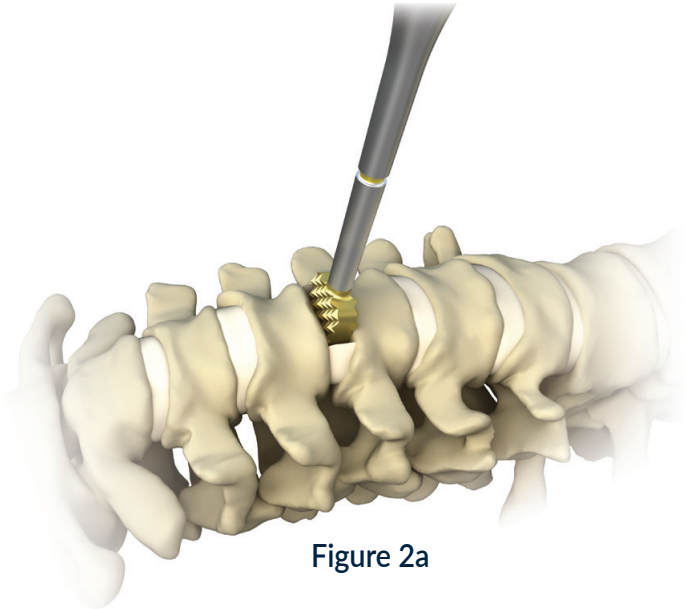


Figure 2a

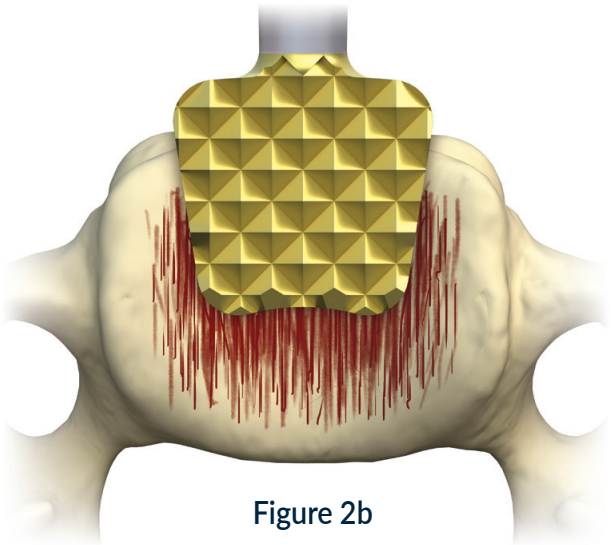


Figure 2b

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 teeth.

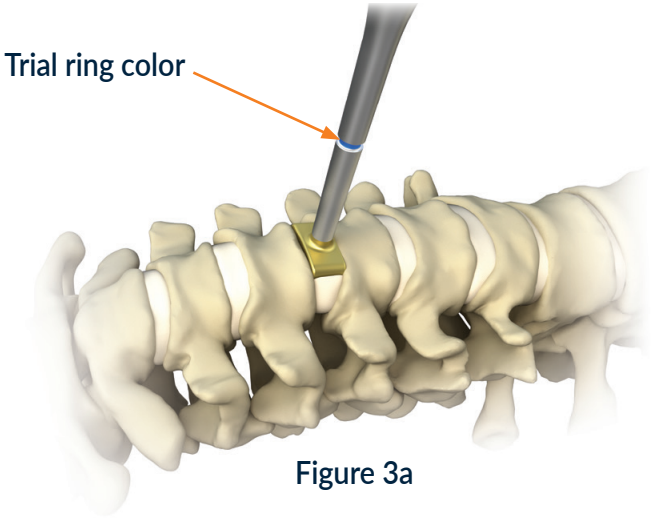


Figure 3a

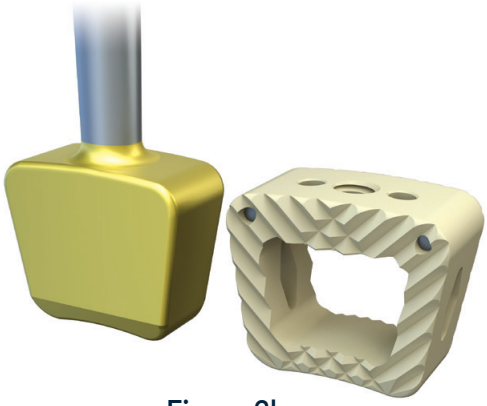


Figure 3b

Step 4: Load the Selected Implant

Thread the assembled Inserter (C205-100) onto the selected interbody device until the face of the instrument is flush with the implant. Ensure the two prongs on the Inserter are properly mated to the corresponding holes on the interbody. **(Figure 4a, 4b)**

Note: The implant can be loaded directly from the Interbody Caddy.

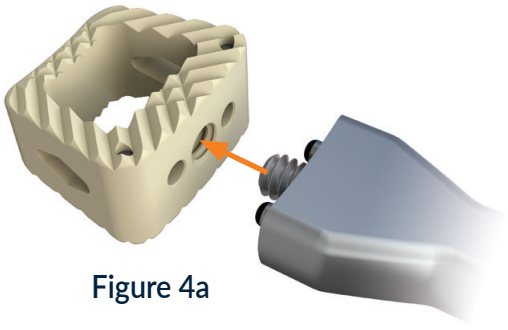


Figure 4a

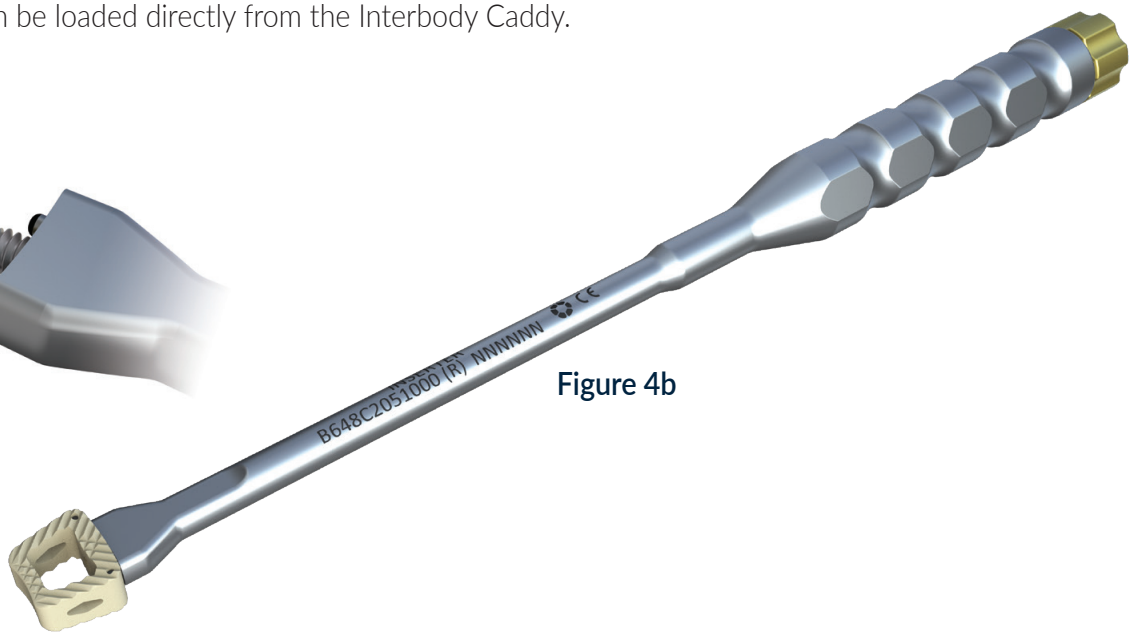


Figure 4b

Step 5: Pack the Implant with Grafting Material

Place the interbody into the appropriate window of the Graft Packing Block (C205-300). Firmly pack autograft and/or allograft material into the graft area of the interbody using the Graft Packer (C205-310). To ensure optimal contact with endplates, pack the interbody until the graft material overflows from the graft area. **(Figure 5)**

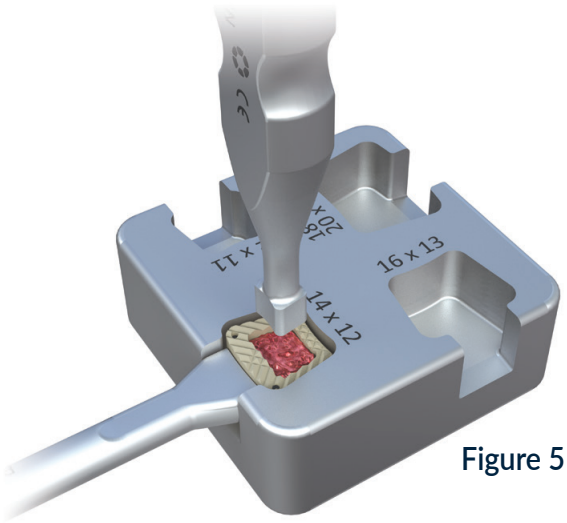


Figure 5

Step 6: Insert Implant

Insert the implant gently into the disc space towards its final position. Once inserted to the proper depth, unthread the Inserter from the implant. **(Figure 6a, 6b)**

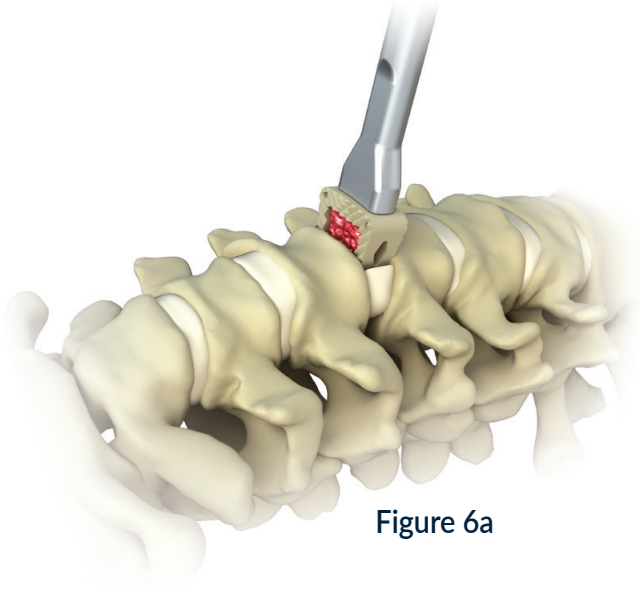


Figure 6a

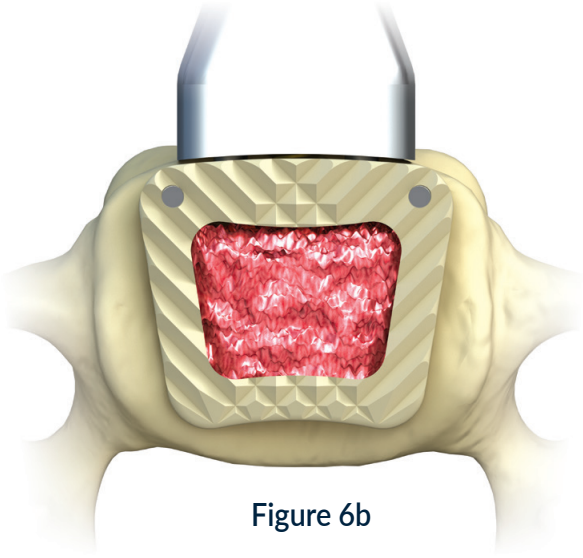


Figure 6b

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)**

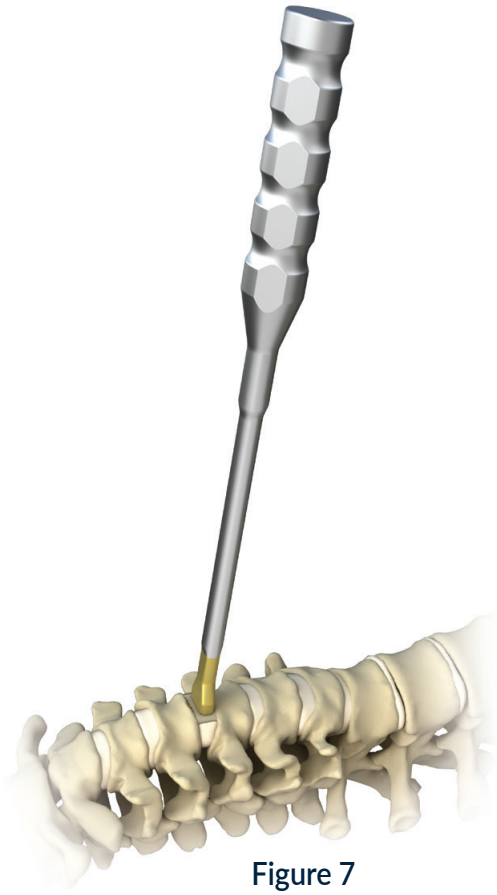


Figure 7

Step 8: Implant Removal (optional)

If the implant needs to be removed, thread the Inserter onto the implant until the face of the instrument is flush with the implant. Ensure the two prongs on the Inserter are properly mated to the corresponding holes on the interbody. Gently remove the implant from the disc space.

Indications for Use:

The SAGE 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 SAGE 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.

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