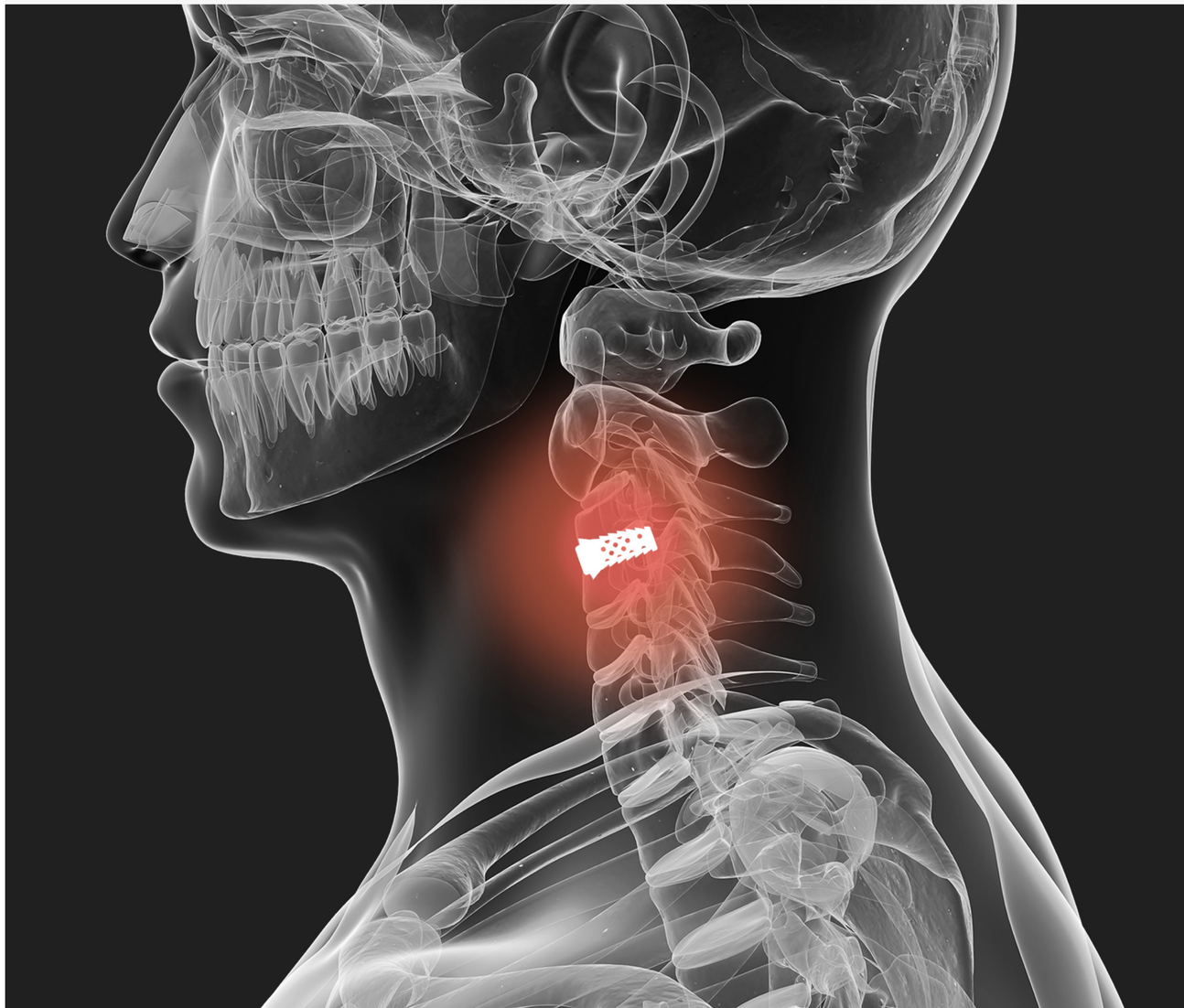
GENOSS
For Patients & Doctors

Rev.0(2205)

Cervical
3d Cage



genoss co., ltd.

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Cervical 3d Cage
Products Information

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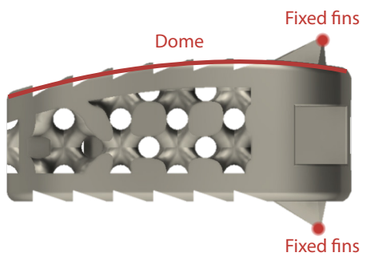

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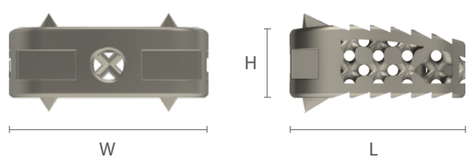
16	14	5~12



Stabilizing & Fixed Fins

Upper and lower fins improve primary stability

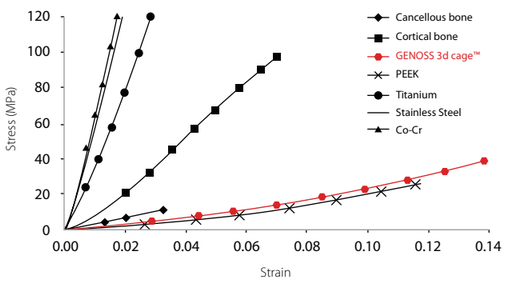
Anatomical Shape (Dome & Lordosis)

It was designed in the most similar shape to Disc through Lordosis and Dome shape.
By increasing the contact area with the endplate, stress dispersion and fixing force are improved to prevent subsidence.

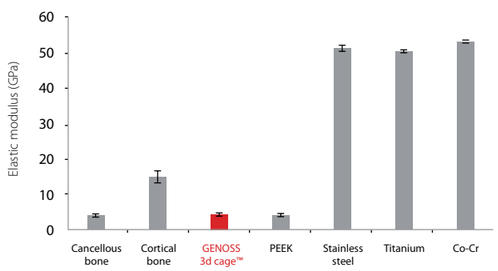
No Subsidence

No subsidence due to similar elastic modulus to cancellous bone
GENOSS 3d Cage™ Cervical demonstrated better resistance to subsidence than different materials.

Stress vs Strain



Elastic modulus under compressive forces



Surgical Procedure

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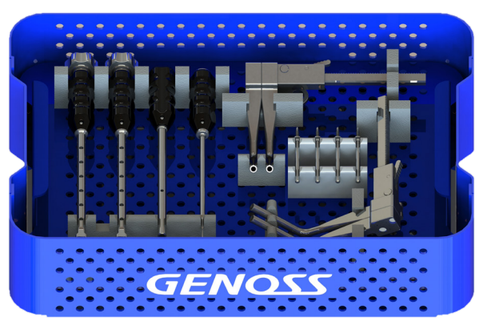
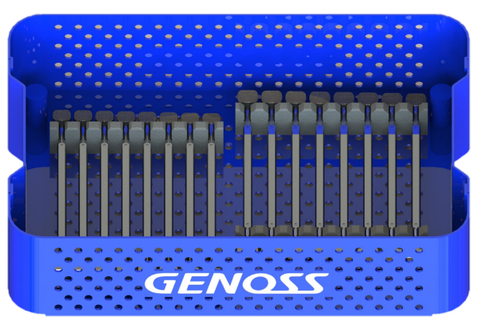




Cage Holder

Supporting Screw Driver

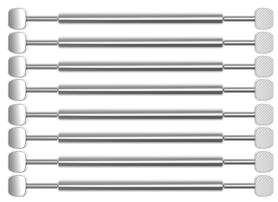
AWL

Supporting Screw

Retractor RT/LT

Trial

RASP



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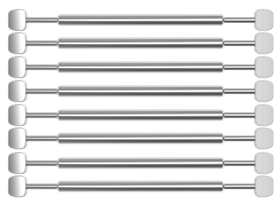

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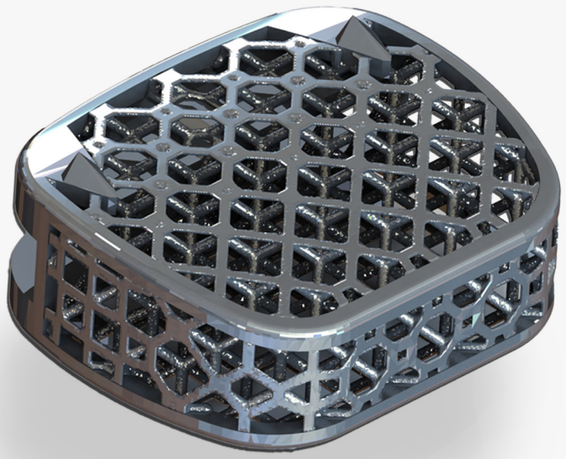
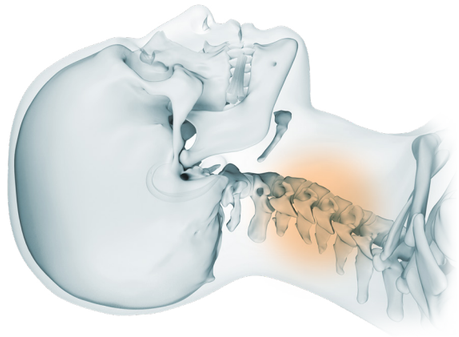


Cervical
3d Cage

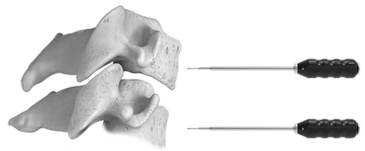
Surgical Technic



Step 1

Exposure

- Position the patient on a surgical table while under anesthesia.
- Patient must be draped in the usual sterile manner for posterior fusion with supplemental fixation.
- A transverse or oblique incision parallel to the skin creases of the neck is recommended.

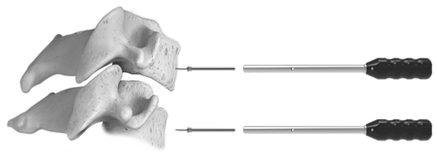


First

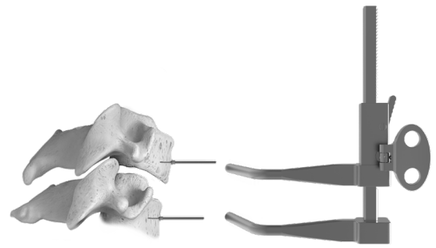
Step 2

Discectomy

- Complete resection is performed using preferred surgical instruments.
- The supporting screw is combined with the supporting screw driver to place the screw in an appropriate position for spinal segmentation.
- Use Distractor to open the vertebral segment.
- Remove the Cartilaginous Layer from the longitudinal surface of the adjacent vertebrae.



Second



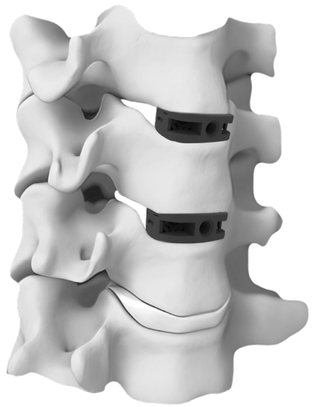
Third

Supporting Screw Driver

AWL

Supporting Screw

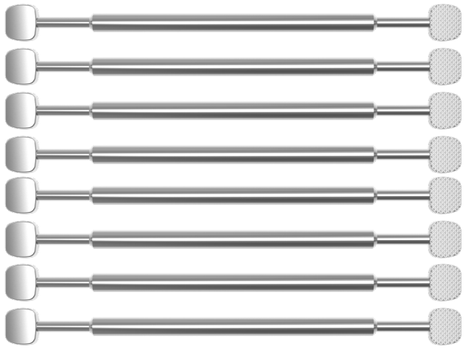
Distractor-RT Distractor-LT



Step 3

Endplate Preparation

- Use RASP to remove the surface layer of the end plate sequentially.
- Appropriate end plate preparation will optimize surface contact with the selected interbody.
- This will aid in creating bleeding bone to promote spinal fusion.

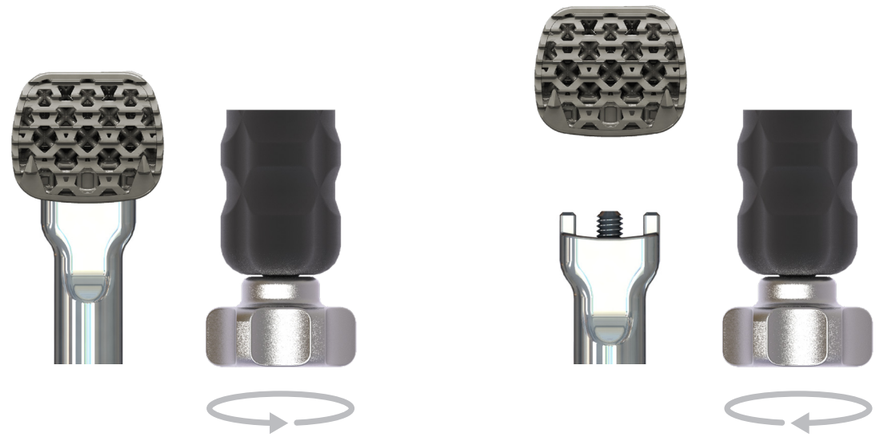


Trial & RASP

Step 4

Implant Size Selection

- Selection of the trial depends on the height, width, depth of the intervertebral space.
- Based on preoperative imaging and surgical technique, select a Trial of appropriate height.

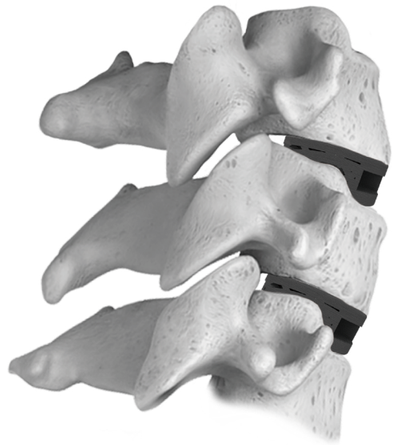


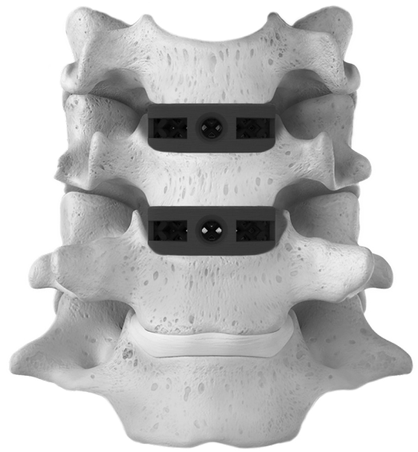
Step 5

Cage Preparation

- Prepare Cervical 3d Cage that has the same size Trial.
- Assemble Cervical 3d Cage with the Cage Holder.

- **Assemble :**
  Connect the cage to grip type holder assembly by rotating the knob.
- **Disassemble :**
  Position and aligned the cage between the intervertebral bodies. Rotated the knob in the opposite direction to disassemble the tap type holder form the cage if desired cage positioning is achieved.





Step 6

Cage Insertion

- Insert cage in opened disc space with spike sides facing endplates.
- Compact the Autograft bone in space between cages and vertebral body wall after removing the holder.

Device Description

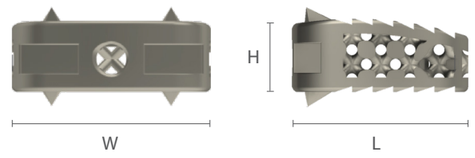
The Cervical Cage is a Cervical interbody spacer, which is surgically use for anterior cervical spinal fusion procedures. It consists of block made of Titanium alloy.

Indication

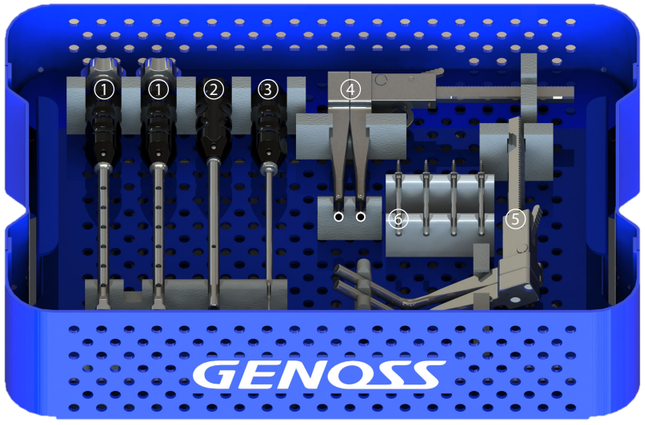
The Cervical Cage is a medical device indicated for anterior cervical interbody fusion procedure. Patients with cervical disc disease accompanying radicular symptoms at one level from C2 to C7 are objectives for the treatment.

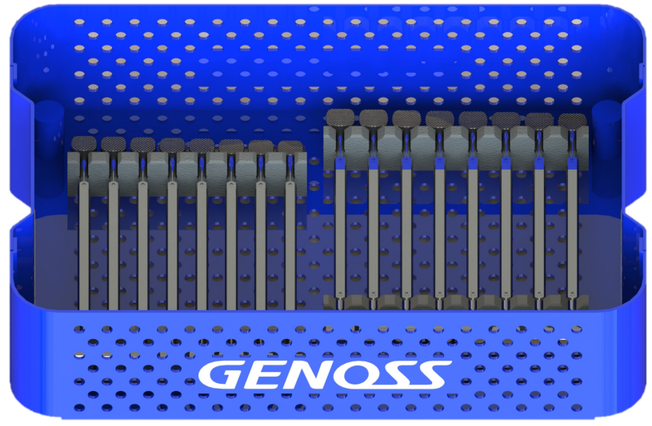
Order Information

Width(mm)	Length(mm)	Height(mm)
14	12	5~12
16	14	5~12



Cervical 3d Cage Tray





Cervical 3d Cage

Upper Tray

4 _ Retractor RT

1_ Cage Holder

2_ Supporting Screw Driver

5_ Retractor LT

3_ AWL

6_ Supporting Screw

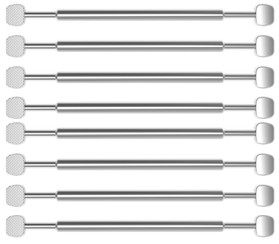
Trial & RASP

Lower Tray

Trial

RASP

Width	Height	Length
12	05~12	14
14	05~12	16



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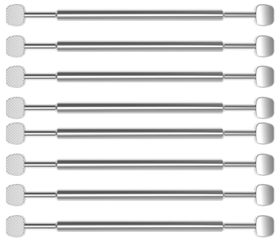

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IMPORTANT INFORMATION ON THE TRELLOSS POROUS TI INTERBODY SYSTEM

Device Description
The 3d Cage™ Cervical is a cervical interbody spacer, which is surgically used for anterior cervical spinal fusion procedures. The 3d Cage™ Cervical is made of Ti-6Al-4V ELL.

Material
The 3d Cage™ Cervical is made from titanium 6-aluminum 4-vanadium alloy (ASTMF3001).

Indications For Use
The 3d Cage™ Cervical is a medical device indicated for anterior cervical interbody fusion procedure. Patients with cervical disc disease accompanying radicular symptoms at one level from C2 to C7 are objectives for the treatment. The man diseases that the medical device is applicable are shown below
1) Degenerative cervical disc
2)Spondylolysis
3)Spinal stenosis
4)Cervical disc herniation

Contraindications
1. Acute or chronic infections
2. Major bone defects in the vertebral bodies
3. Severe osteoporosis
4. Previous interbody fusion site
5. Allergy to Titanium alloy
6. Excessive stresses on bone and implants (severe obesity, pregnancy)

Precautions
1. Open the package after selecting the appropriate size of implant.
2. Check any damage in the package or product.
3. Surgeons should be fully aware of the surgical technique, indications, and contra-indications.
4. Check any biological or biomechanical factors which might make bad surgical result.
5. Read the instructions in the package thoroughly before usage.

* CHOICE OF IMPLANTS
The implant is chosen by its height, width, length and angle depends on each Size and shape of patient's bone structures. These features are crucial to success of the surgery so surgeon is responsible for this choice. Notice that patients with overweight may responsible for additional stresses and strains on device. This can cause implant's fatigue fracture more faster and/ or deformation of the implants. After implantation, implants are exposure to stresses and strains. Surgeon should consider those surrounding environments, while selecting implant and postoperative follow up period. Otherwise, if implants been damaged by fracture or deformation before complete synostosis, it may result in further side effects or necessitate the early removal of the implants

Precautions
1) After the initial incision, carefully proceed with surgical incision in soft tissue area and approach to the surgical site.
2)Open spinal segment using distractor.
3)Remove the cartilaginous layer.
4)Select the trial based on the height of cage and patient's anatomic structure as the pre-operative plan.
5)Check the size if it is appropriate or not by inserting the trial.
6)Combine cage, the same size as the selected trial, to the holder.
7)Put auto-graft or bone graft material in the lumen area of the cage.
8)After correctly align the cage and holder, insert the cage into the place where anterior cervical fusion is removed.
9)Loosen the distractor and remove all surgical instruments.
10)Check the position of the inserted cage.
11)Suture the surgical site.
* REMOVAL OF IMPLANTS
The 3d Cage™ Cervical may be removed using the holder. Attach the holder to the 3d Cage™ Cervical with the retention by features on the holder.

IMPORTANT INFORMATION ON THE TRELLOSS POROUS TI INTERBODY SYSTEM

After the implant is securely attached to the holder, carefully temove the 3d Cage™ Cervical.

Directions For Use
1) After the initial incision, carefully proceed with surgical incision in soft tissue area and approach to the surgical site.
2) Open spinal segment using distractor.
3) Remove the cartilaginous layer.
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The 3d Cage™ Cervical may be removed using the holder. Attach the holder to the 3d Cage™ Cervical with the retention by features on the holder. After the implant is securely attached to the holder, carefully remove the 3d Cage™ Cervical.Instruments sterilization

Instruments Sterilization
* It is the responsibility of the user to clean and disinfection in an appropriate method if manufacturer recommendations cleaning and disinfection methods are not followed. Only sterile products should be placed in the operative field. Unless marked sterile and clearly labeled as such in an unopened sterile package provided by the company, all instruments used in surgery must be sterilized by the hospital prior to use. Carry out the sterilization process as below.
1) Remove all packaging materials
2) Cleaning
2.1 Rinse the contaminated device with cold tap water for 2 minutes.
2.2 Use a soft brush or cloth to remove contaminants from the device.
* Do not use metal brushes or steel wool for cleaning
2.3 The enzyme detergent is mixed with water at a ratio of 1: 250.
2.4 Soak the surgical instrument thoroughly for 5 minutes in prepared(diluted) detergent. And then wipe out gently with a soft brush until the visible contamination is completely removed.
2.5 Rinse in owing water for 2 minutes.
2.6 Immerse the device completely into the new diluted detergent solution and perform the ultrasonic cleaning at 40 kHz for 10 min.
2.7 Rinse the device thoroughly with clean tap water for 2 minutes to remove the detergent.
2.8 Finally, rinse with purified water for 2 minutes.
2.9 Remove excess moisture from the device with a clean, soft, lint-free cloth or clean compressed air.
Note: Above cleaning process 2.1~2.9 is applied to re-usable instruments.
3) Sterilization
These products are recommended to be sterilized by the hospital using the following validated cycle parameters:

Method	Pressure	Temperature
Steam	Gravity	270°F(132°C)

Dry Time	Exposure Time
30 Minutes	30 Minutes

* ANSI/AAMI/ISO 17665- 1:2006/(R)2013
Note: Because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process(e.g., temperatures, times) used for their equipment.
Note: The instruments can be re-sterilized a maximum of hundred times.
4) Additional Information

4.1 Cleaning Agent Information: Manufacturer used the following cleaning agents during validation of reprocessing (ENDOZIME AW TRIPLE PLUS with APA)
4.2 Instrument Cleaning Accessories Information: It is recommended that the cleaning brush should be at least 4mm in diameter and at least 15mm in length. If have to clean for difficult area like lumens and channels.
4.3 Instrument sterilization process are available until 20 times of using, recommend changing instruments after using more than 20 times.
4.4 It is recommended to using an FDA cleared sterilization wraps for sterilization.

Cautions

1) Do not apply too much force to the product during the operation.
2) Protect the surgical site for a certain amount of time until cervical fusion process is stabilized.
3) Only experienced and specialized surgeons to a spinal surgery are allowed to use the product.
4) Set up a pre-operative plan before surgery through the radiograph of surgical area.
5) If any problems occurred with the implanted product, the patient could feel unexpected pain. In this case, anterior cervical fusion process needs to be performed again.
6) Perform a periodical radiograph evaluation on the surgical site.
7) In case of incomplete fusion in the surgical site, the collapse or crack might be caused.
8) When an excessive force is applied to the product, the collapse or crack might be caused.
9) The surgery should not be performed against a patient who had a previous failed surgery which ended up with pseudoarthrosis accompanying pain.
10) The 3d Cage™ Cervical should not ever be reused under any circumstance. Otherwise, adverse effects (Section I) can be caused.

Also, when indications in the description are inaccurately followed, adverse effects (Section I) could be caused.
* This product is limited to a specialized and experienced surgeon for use and sale.
* Federal law restricts this device to be used, or sold by or on the order of a physician.

Potential Adverse Effects

If an unstable fixation occurred during or after surgery, spinal cord or nerve root injuries might be caused, which may lead to paraplegia and serious nerve root damage that will never be recovered from its loss of function. The possible conditions during or after surgery are as below:
1) Implanted site is not anatomically suitable
2) Size of selected product for the surgery is too big for a patient
3) Causing spondylolisthesis due to inappropriate manipulation during implantation of the product
4) Misuse of surgical instruments such as Awl or Screw driver
5) Break down of implanted part due to the loaded weight All of events or complications associated with spinal fusion surgery with or without instrumentation are possible. Listing of possible adverse events or complications includes, but is not limited to:

1) Delayed union of the fusion
2) Non fusion
3) Pseudarthrosis
4) Neurologic complications
5) Paralysis
6) Tissue lesions
7) Post operative pain
8) Implant migration
9) Skin infection and skin subcutaneous infection or thesymptoms.
10) Sensitive reaction or allergic to the implant
11) Migration of cage to vertebra column

IMPORTANT INFORMATION ON THE TRELLOSS POROUS TI INTERBODY SYSTEM

12) Reduction of bone density due to stress shielding effect
13) Occurrence of neuropathy and spinal epidural
14) Occurrence of cage abrasion or degradation
15) Damage on other spinal columns
16) Damage on cage
17) Bone absorption
18) Reduction in height of cervical plate
19) Damage of adjacent tissue
20) Death (In case of serious situation)
Note : Side effects other than listed above could appear and an additional operation would be need if the effects are shown.
Instruments Sterilization

Expiry Date

The expiry date is described on the container and packaging. Do not use the device if the expiration date has passed.

Magnetic Resonance(MR) Compatibility

The Cervical 3d Cage™ 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 3dCage™ Cervical in the MR environment is unknown. Scanning a patient who has this device may result in patient injury

Warnings

1) Do not use if package is opened or damaged
2) These devices are to be used as indicated. The safety and effectiveness when implanted in the spine for any other indications has not been established.
3) When more than two involved spinal levels are treated, longer operative times and higher blood loss are likely to occur.

Symbols

REF	Catalogue number	30 °C / 1 °C / (33.8–86 °F)	Temperature limit
	Do not re-use		Consult instructions for use
	Caution		Do not use if package is damaged
STERILE EO	Sterilized using ethylene oxide	Rx only	By prescription only
EC REP	Authorized representative		Use by date
LOT	Batch code		Manufacturer
	Date of manufacture	CE 2195	CE Mark

Preservation

Store this product in a dry place at room temperature.

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