GENOSS™ 3d Cage Cervical

A 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-4VELI.

B MATERIAL

The 3d Cage Cervical is made from titanium 6-aluminum 4-vanadium alloy(ASTM F3001).

C INDICATION 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 main diseases that the medical device is applicable are shown below.

1) Degenerative cervical disc
2) Spondylolysis
3) Spinal stenosis
4) Cervical disc herniation

D 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)

E PRECAUTION

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.

F DIRECTIONS FOR USE

1. After the initial incision, carefully proceed with surgical incision in soft tissue area and appoach to the surgical site.
2. Open spinal segment using distrator.
3. Remove the cartilaginous layer.
4. Select the trial based in 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 materialin 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

For the best results, the same type of 3d Cage instruments as used for implantation should be used for implant removal purposes. Cage holder is available to adapt to the removal drive sizes in a fixation screws. It should be noted that where excessive bone or fibrous growth has occurred from the first surgery, there may be added stress on the removal instruments and the implants. Both instrument and implant may be prone to possible breakage. In this case it is necessary to first remove the bone and/or tissue from around the implants.

G 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 instruVment 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 flowing 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 1)~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	Exposure Time	Dry Time
Steam	Gravity	270°F(132°C)	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 Infromation
   1) Cleaning Agent Information: Manufacturer used the following cleaning agents during validation of reprocessing (ENDOZIME AW TRIPLE PLUS with APA)
   2) Instument 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.
   3) Instrument sterilization process are available until 20 times of using, recommend changing instruments after using more than 20 times.
   4) It is recommended to using an FDA cleared sterilization wraps for sterilization.

H ⚠ CAUTION

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 dusion 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 occured 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 resued under any circumstance. Otherwise, adverse effects (Section 1) Can be caused. Also, when indications in the description are inaccurately followed, adverse effects (Section 1) 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 physician.

I 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 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 instumentation are possible. Listing of possible adverse events or complications includes, but it is not limited to :

1) Delayed union of the fusion
2) Non fusion
3) Pseudarthrosis
4) Neurologic complications
5) Paralysis
6) Tissue lesion
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
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 on cage
20) Death(In cas of serious situation)

Note : Side effects other than listed above could appear and an additional operation would be need if the effects are shown.

J EXPIRY DATE

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

K MAGNETIC RESONANCE(MR) COMPATIBILITY

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

L WARNING

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.

M SYMBOLS

REF	Catalogue number	STERILE R	Sterilized using irradiation		Date of manfacture
	Do not reuse		Consult instructions for use		Use-by date
	Caution	EC REP	Authorized representative		Manufacturer
	Temperature limit		Do not use if package is damaged		Distributor
	Do not resterlize	LOT	Batch code		

N PRESERVATION

Store this product in a dry place at room temperature. (1°C ~ 30°C)

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