GENOSS™ 3d Cage Lumbar

A DEVICE DESCRIPTION

The 3d Cage is a device designed for usage in the posterior/transforaminal lumbar inter-body fusion procedures. It consists of block made of titanium alloy.

B MATERIAL

The 3d Cage is made from titanium 6-aluminum 4-vanadium ELI, ASTM F3001.

C INDICATION FOR USE

The 3d Cage is an intervertebral body fusion device indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-L5. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six months of non-operative therapy. The device is intended to be used with supplemental fixation system and autograft bone.

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)
7. Severe instabilities
8. Vertebral body fractures
9. Spinal tumours
10. Systemic and metabolic diseases
11. Dependency on pharmaceutical drugs, drug abuse, or alcoholism resulting in a lack of patient cooperation

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. Expose and approach to the affected disc and adjacent vertebral bodies.
2. Distract the segment with the Lumbar distractor.
3. Connect the selected implant to the holder.
4. Pack the inner hole of cage with autogenous bone.
5. Orient implant and holder in the correct alignment and carefully insert the implant into the distracted segment.
6. Release the distractor and remove all instruments.
7. Verify and confirm the position of cage.
8. Close the wound carefully.

* 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
   1) Rinse the contaminated device with cold tap water for 2 minutes.
   2) Use a soft brush or cloth to remove contaminants from the device.
      * Do not use metal brushes or steel wool for cleaning
   3) The enzyme detergent is mixed with water at a ratio of 1: 250.
   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.
   5) Rinse in flowing water for 2 minutes.
   6) Immerse the device completely into the new diluted detergent solution and perform the ultrasonic cleaning at 40 kHz for 10 min.
   7) Rinse the device thoroughly with clean tap water for 2 minutes to remove the detergent.
   8) Finally, rinse with purified water for 2 minutes.
   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℃)	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. Avoid excessive shock when inserting the implant.
2. Protect the operation site safely for a certain period for ensuring stable fusion.
3. Only the surgeons specially trained in the 3d Cage or similar devices should perform the operation.
4. Surgical plan should be prepared before operation through radiography.
5. Severe adverse effects can occur when
   1) Implantation site is not appropriate anatomically.
   2) Selected implant is excessively large compared to the disc space.
   3) Dislocation of vertebral body occur due to the inadequate modification during implantation.
   4) Surgical tools are misused.
   5) Implantation site is fractured by excessive load.
6. If any part of the implant is damaged during operation, the implant should be replaced. If damaged product is used. severe adverse effects can occur.
7. If the surgeon doesn't follow the instructions in package insert, adverse effects can occur.
8. If any problem happens in the implanted product, pain can be caused and re-operation might be required.
9. Radiological examination should be executed periodically after the operation.
10. Imperfect fusion may cause the extrusion or fracture of the implant.
11. Excessive load to the implant or surrounding tissue may cause the extrusion or fracture of the implant.
12. Do not use this product in the case of pseudo-arthrosis with pain due to the failure of previous fusion.
    * Federal law restricts this device to be used, or sold by or on the order of a physician.

I POTENTIAL ADVERSE EFFECTS

1. Delayed union of the fusion
2. Non fusion
3. Pseudarthrosis
4. Neurologic complications
5. Paralysis
6. Tissue lesions
7. Pain as sequel to the operation
8. Implant migration
9. Superficial and deep infection of signs/symptoms of infection
10. Implant material sensitivity ofallergic reaction
11. Implant creep into the vertevbra during placement
12. Breakage of implant
13. Bone resorption
14. Loss of disc height
15. Injury or damage to adjacent bones, discs, or soft tissues (Carotid or vertebral artery, nerves, esophagus or trachea)
16. Death (In worst case)

Note : This list of adverse events is by no means complete. Additional surgery may be necessary to correct these potential adverse effects.

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

N PRESERVATION

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

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