STERILE SPINAL CAGE

◆ Sterile Expandable cage (ENGLISH Ver.)

Sterile Expandable Spinal Cage of CTL Biotec Co., Ltd. is lumbar intervertebral fusion prosthesis manufactured both SLM (Selective Laser Melting) 3D printing technology using powder and by mechanical processing (CNC method). It is used by implanting between the intervertebral bodies to obtain sufficient fusion and mechanical stability.
The entire model has a variable height according to the expansion mechanism. Manufactured from Titanium Alloy Powder (Ti-6Al-4V ELI Alloy), see below for details.

◆ Components

- KLIMT Expandable Cage (Sterile)
  : PLIF (Short Expansion type / Tall Expansion type)
  : TLIF (Short Expansion type / Tall Expansion type)

◆ Indication

Cage-type device used to treat structural abnormalities caused by degenerative intervertebral disc of lumbar spine. It is a expandable spinal cage manufactured using a 3D printer and machining (CNC).

◆ PREPARATIONS BEFORE USE

- This product is supplied in a state of radiation sterilization (Gamma radiation, ISO 11137-1,2,3), so re-sterilization is not allowed, and before use, it must be checked for not only damage of product's packaging but also expiration date.
- The Surgeon should be fully familiar with the characteristics of the implants and instruments, surgical procedures, and precautions through the instructions for use (I.F.U) before use.
- Specialized instruments should be used to ensure accurate implantation of implants (=Cage).
- Before the procedure, you must check the degree of wear or damage of the instruments, and if corrosion, cracks, pinholes, etc. are found during use, stop using them immediately and replace them with other instruments.
- In case of severe impact or dropping to the floor, or if damage or foreign substances are found on the surgical instrument, immediately stop using it in a unclean state and replace it with another instrument.

◆ METHOD OF USE

Use a product of an appropriate size for the patient, and do not forcefully use it for purposes other than the intended purpose.

- The implant size is determined according to the Posterior lumber (PLIF) and Transforaminal lumber (TLIF) surgery methods, and the level of the disc to be operated is checked using X-ray and C-arm.
- After incising the surgical site, open the affected area (upper and lower body) using a retractor etc.
- Remove the damaged disc entire or partially, and secure space for implant's insertion using Paddle distractor, Disc Scraper, etc.
- Using the Trial, determine the appropriate size of the product by checking the height and angle between the vertebrae in the space where the disc has been removed.
- Insert the implant using the Cage Inserter.
- The inserted implant can be expanded as much as the intended range according to the expansion mechanism using the connected instrument, and after confirming the fixation and correction status, the opening instrument (retractor etc.) is removed and the surgical site is sutured.
  At maximum expansion (Final), the 2NM Torque Limit Handle must be used.

◆ STORAGE AND MANAGEMENT METHOD AFTER USE

- **Implants are disposable sterilized medical devices, so reuse is prohibited.**
- Implants are transported packaged and must be undamaged on arrival.
- It must be stored in a place that is clean, dry, and at an appropriate temperature (Room temperature : 1~30℃).

◆ PRE-OPERATIVE PRECAUTION

Implants of CTL Biotec, Co., Ltd. should be used by surgeons who have experience in spinal surgery or have received related training. The surgeon must be careful not to place undue stress on the spine or the implant during the surgery.

The implant should be used in conjunction with assist device(screws, etc.). Therefore, the user should consider specific precautions for the assist device in addition to the corresponding implant.

◆ CONTRAINDICATIONS

Contraindications can be relative or absolute. The selection of particular implants must be carefully considered against the patient's total evaluation. The following may reduce the chances of a successful outcome.

- Patients with active infection or spondylitis
- Patients with inflammatory degenerative diseases
- Hepatitis infected with hepatitis or HIV
- In the event of severe burns, scarring or inflammation to the surrounding soft tissue
- Patients with symptoms of allergy to metallic substances
- Patients with Infected fracture
- Overweight patients
- In case a pregnant woman has not been confirmed the pregnancy
- Patients with osteoporosis
- A person who cannot follow post-operative instructions during the recovery process after surgery
- In case of abnormal loading or auxiliary reaction due to neurological or skeletal musculoskeletal diseases
- Bone immature patients
- Massive inflammation
- Multifaceted infection (due to bleeding at the implant site)
- When the progression of bone absorption or bone destruction spreads at a rapid rate in radiological findings
- A person whose diagnostic name is outside of the use category and the operating surgeon determines that it cannot be used

The above contraindications can be relative or absolute, and must be consulted until the procedure is determined by the surgeon. However, contraindications are not limited to this list.

◆ GENERAL CONDITIONS OF USE

Implantation of spinal implants is a procedure that requires specific skills due to the risk of serious injury to the patient and should only be performed by experienced surgeons or those with the specific training necessary for the use of these systems.

The information contained in the attached user manual or website is essential but not sufficient for the use of this implant. That it, This information shall not be regarded as an unconditional indicator in determining the following contents, such as surgeons skills or experiences for patient choice, professional judgment, preoperative planning and implant selection, anatomical and biomechanical knowledge of the spine, understanding the mechanical properties and raw materials of the used implants, training and techniques for spinal surgery, the method of use other implants involved in implantation, the thing of guarantee patient cooperation in following postoperative care programs and of performance additional scheduled postoperative care.

This implant has not been evaluated for safety and suitability in the magnetic resonance (MR) environment. Safety in the magnetic resonance environment is unknown, as no tests have been performed for heating, migration, and imaging defects in that environment. Scanning the patient with this medical device inserted may be cause damage to the patient.

◆ INFORMATION FOR PATIENTS

The surgeon should discuss with the patient all physical and psychological limitations resulting from the use of this implant. This includes rehabilitative medications, physical therapy, and wearing appropriate aids as prescribed by your surgeon.

Surgeon must provide the patient with information about the risks and potential side effects of the operation, and they should warn to patients that implants cannot actually reproduce the flexibility, strength, reliability or durability of normal healthy bones, can be broken or damaged by intense activity or trauma, and may need to replace to new one in the future.

If the patient engages in occupations or activities that could place excessive stress on the implant (ex : strenuous walking, running, heavy lifting, or muscle strain), The surgeon should warn the patient before surgery that the force generated by such behavior can lead to surgery failure. If a patient with a degenerative disease has a rapid progression of the disease at the time of implantation, the life expectancy of the implant can be significantly reduced.

◆ SURGICAL INSTRUMENTS

Specialized instruments are provided by our head office (CTL Biotec Co., Ltd.) and must be used to ensure correct implantation of the implant. To reduce the risk of breakage to the implant, care must be taken to avoid twisting, nicking, striking or scraping the implant with instruments. Although rare, breakage or fracture of instruments may occur during the surgery Instruments that have been used excessively or applied with excessive force.
Prior to the surgery, the instruments must be inspected for wear or damage, and Extreme caution is required when the instrument is used around vital organs, nerves or blood vessels.

◆ REUSE

Implants should never be reused. Although the used implants may appear intact, may have defects and have potential damage to integrity can result in reduced use life.

◆ IMPLANT SELECTION AND USE

Choosing the right implant size for each patient is critical to the success of the surgery. surgeons are responsible for making the right choice for each patient. Excessive patient weight can place additional stress and strain on the implant, which can lead to rapid metal fatigue and/or failure or deformation of the implant.

Once implanted, the implant is affected by stress and deformation. This repeated stress on implants is a consideration for surgeon when selecting implants, which applies not only during the surgery but also during the post-treatment period. In fact, stresses and strains on implants can lead to metal fatigue loads and fracture and deformation of implants before complete fusion of the bone graft. This can lead to additional side effects or accelerate the removal of bone-fusion implants.

Improper selection, placement, positioning, and fixation of implants can result in unusual compression, which can reduce the life of the implant. The surgeon must be thoroughly familiar with the surgical procedure, surgical instruments, and characteristics of the implant prior to surgery. Regular additional examinations are recommended to check the condition or location of the implant and the condition of the adjacent bone.

◆ SUITABILITY OF SYSTEM

Some corrosion in all metal and alloys implanted can be accelerated when dissimilar metals come into contact. The presence of corrosion can accelerate damage of implants due to fatigue and can also increase the amount of metal composites that spread throughout the body system. Because each manufacturer uses different materials, different durability and manufacturing requirements, and different design parameters, the components of the system should not be mixed with products from any other manufacturer. CTL Biotec Co., Ltd. does not take any responsibility for the performance caused by the mixed use of these implants.

◆ EXPIRATION DATE

3 years from the date of manufacture

◆ COMPLAINTS

Upon receiving any complaints or complaints regarding the quality, identity, durability, reliability, validity, and/or performance of the product, medical professionals should notify CTL Biotec Co., Ltd. or their local representative.
Furthermore, If our products or instruments are not functioning properly, cause by patient serious injury, death, or contribute to some extent, please inform CTL Biotec Co., Ltd. or local representative by phone, fax and documentation as soon as possible.
Please fill out the following when receiving all complaints.
-Manufacturing number of components (Lot. Number)
-Product name / model No.
-Name and address to be contacted
-Explain the cause of the complaint in detail

For additional information or complaints, please contact :

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