INSTRUCTIONS FOR USE

Important Information - Please Read Prior to Use

ENGLISH

CTL Medical Corporation (d/b/a: CTL Amedica)
2052 McKenzie Drive, Building 1, Carrollton, TX 75006
P: 214-545-5820 | E: info@CTLAmedica.com | www.ctlamedica.com

DEVICE SYSTEM NAME:

KLIMT™ Expandable Lumbar Interbody Fusion (LIF) Cage System

DESCRIPTION AND INTENDED USE

The KLIMT Expandable Lumbar Intervertebral Fusion (LIF) Cage System is designed to be implanted in the disc space between vertebral bodies to promote fusion and provide mechanical stability in the lumbar spine. The cage features a vertically expandable design, allowing for height adjustment to facilitate easier implantation and achieve a secure fit that conforms to the patient's anatomy.

The cage components are manufactured using two methods: Selective Laser Melting (SLM) 3D printing technology with medical-grade titanium alloy powder, and CNC machining. These components are then assembled into the final cage unit. The cages are made from titanium alloy powder (ASTM F3001) and titanium alloy (ASTM F136), available in both sterile and non-sterile versions.

All instruments that come into contact with the patient are manufactured from stainless steel (ASTM F899) and are provided in a non-sterile condition, requiring sterilization by the end user prior to use.

All implants and instruments compatible with the system are listed in the respective Surgical Technique Guide (STG), reference STG.367.001. which can be accessed via our company website or requested in printed format through our customer service team.

The KLIMT Expandable Lumbar Interbody Fusion (LIF) Cage System is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion. .

INDICATIONS

The KLIMT™ Expandable LIF Cage is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. The system is to be used with supplemental fixation cleared for use in the lumbar spine. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).This device is to be used with autogenous bone graft. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

CONTRAINDICATIONS

1. Patients with active infection or spondylitis.
2. Patients with inflammatory degenerative diseases. Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
3. Patients infected with hepatitis or HIV.
4. Patients with severe burns, scarring or inflammation to the surrounding soft tissue.
5. Patients with allergies to metallic substances.
6. Patients with Infected fractures.
7. Overweight patients.
8. Pregnant Patients or Patients with unconfirmed pregnancies.
9. Patients with osteoporosis.
10. A person who cannot follow post-operative instructions during the recovery process after surgery.
11. Patients with abnormal loading or auxiliary reactions due to neurological or skeletal musculoskeletal diseases.
12. Patients with Immature Bone Development.
13. Massive inflammation.
14. Multifaceted infection (due to bleeding at the implant site).
15. When the progression of bone absorption or bone destruction spreads at a rapid rate in radiological findings
16. A person whose diagnosis is outside of the use category and the operating surgeon determines that it cannot be used

MATERIALS

A The KLIMT Expandable LIF Cage Systemcomponents are made of Ti-6Al-4V ELI Alloy (Titanium Alloy). Titanium Alloy implants consist of Ti-6Al-4V ELI Alloy that conform to ASTM F136 and ASTM F3001. The KLIMT Expandable LIF Cage System is implanted using a combination of device specific and universal Class I instruments manufactured from stainless steel materials that conform to ASTM F899.

CLEANING AND STERILIZATION

Implants of the KLIMT Expandable LIF Cage System may be provided either sterile or non-sterile and this will be clearly identified on the product labels. Instruments of the KLIMT Expandable LIF Cage System are provided non-sterile. Sterile, single-use implants must not be reprocessed or reused. Non-sterile implants and instruments must be sterilized prior to use in accordance with the processing instructions provided below. Non-sterile implants may be subjected to reprocessing in accordance with these processing instructions but must be discarded following direct patient contact or use.

STERILE IMPLANTS

Implants of the KLIMT Expandable LIF Cage System that are supplied sterile using radiation. The implants are supplied sterile and the contents are sterile unless package is damaged, opened, or the expiration date on the device label has passed. The integrity of the packaging should be checked to ensure that the sterility of the contents is not compromised. Remove implants from packaging using

aseptic technique, only after the correct size has been determined. Remove any packaging materials inside the inner sterile barrier from the implant prior to use.

CAUTION: Do not use the implants if the condition of the package and/or labeling indicates a chance that the devices may not be sterile and must be sterilized per the guidance applicable to the NON-STERILE IMPLANTS AND/OR INSTRUMENTS.

NON-STERILE IMPLANTS AND/OR COMPONENTS

Implants and instruments that are supplied non-sterile must be sterilized by the hospital prior to use. Implants are single use; instruments may be reused. Implants and Instruments must be thoroughly cleaned prior to sterilization. Trained personnel must perform cleaning and mechanical inspection prior to sterilization. Unless just removed from an unopened CTL Medical package, all instruments and implants must be disassembled (if applicable) and cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to CTL Medical.

Whenever possible the automated method should be used. The automated cleaning process is more reproducible and, therefore, more reliable, and staff are less exposed to the contaminated devices and the cleaning agents used. Whichever method is used, staff should always use suitable protective clothing and equipment. In particular, take note of the instructions provided by the cleaning agent manufacturer for correct handling and use of the product.

The guidance provided by the detergent manufacturer concerning concentrations and temperatures shall be observed. If these concentrations and temperatures are exceeded significantly, discoloration or corrosion could occur with some materials. This could also happen if rinsing after cleaning and/or disinfecting is insufficient. CTL Medical does not recommend any specific cleaning and/or disinfection agent. For cleaning or disinfecting reusable instruments, only specifically formulated cleaning agents and/or disinfectants should be used. Do not alter the concentrations specified by the detergent manufacturer. The quality of the water used for diluting cleaning agents and/or disinfectants and for rinsing re-usable instruments should be carefully considered. Application of freshly pre-pared DI water/highly DI water or sterile water for rinsing purposes with less than 100 cfu/ml and Mineral residues from hard water, as well as higher contamination with microorganisms and endotoxins, can result in staining of the device or prevent effective cleaning and decontamination.

CLEANING OF IMPLANTS AND INSTRUMENTS

All instruments and implants must first be cleaned using established hospital methods before sterilization and introduction into a sterile surgical field. Disassemble instruments with removable parts. Methods of cleaning re-usable instruments are provided in these instructions, a manual method and a method using an automated washer disinfector.

CAUTION: Use of sodium hydroxide (NaOH) is prohibited. Use of corrosive products and/or instruments including abrasive sponges and metal brushes should be avoided.

PRE-SURGICAL

1. In a clean metal pan, prepare an enzymatic detergent bath according to the detergent manufacturer's instructions.
2. Allow the devices to soak in enzymatic detergent bath for 20 minutes.
3. While in detergent bath, using a soft bristled brush, gently clean the devices, paying attention to pivots, threads, recesses, crevices, cannulas and other difficult to clean areas, until all visible debris is removed.
4. Remove the devices from the enzymatic detergent bath and rinse with tap water for a minimum of 1 minute.
5. Prepare an enzymatic detergent bath in a sonicator.
6. Ultrasonically clean the individual devices in the enzymatic bath for 10 minutes at 45kHz and 60˚C/140˚F.
7. Remove the sonicator and rinse the devices in DI water for a minimum of 1 minute
8. Verify that the instruments are in operation condition.

Note: Certain cleaning solutions such as those containing bleach or formalin may damage some devices and they must not be used.

All products should be treated with care. Improper use or handling may lead to damage and possible improper functioning of the device.

POST-SURGICAL/ POINT OF USE CARE

1. Ensure that no instruments or implants are left in the surgical site prior to closure as patient injury may result
2. Implants removed from a patient or that contact bodily tissues or fluids should never be reused. All single-use devices and materials should be removed and discarded in compliance with hospital policies.
3. Remove excess body fluids and tissue from instruments with a disposable, non-shedding wipe.
4. Place devices in a tray of distilled water or cover with damp towels.
5. Devices should be cleaned within 30 minutes of use to minimize the potential for drying prior to cleaning.
6. The drying of gross soil (blood, tissue, and/or debris) on devices following surgical use should be avoided. It is preferred that gross soil is removed from devices immediately following use and in can be removed using sponges, cloths, or soft brushes. Water and/or cleaning detergents labeled for use on medical devices may be used.
7. Flush all lumens, blind holes, small clearances, and moving and intricate parts with water or detergent solution to prevent the drying of soil and/or debris.
8. If gross soil cannot be removed at the point of use, the devices should be transported to prevent drying (e.g., covered with a towel dampened with purified water) and cleaned as soon as possible at a designated processing area. Delays may create conditions favorable to microbial growth, which may increase the challenge to subsequent steps such as cleaning and disinfection/sterilization. Organic contamination may inactivate or prevent full penetration of a disinfectant or sterilant. Used instruments and implants pulled from the sterile field must be transported to the central supply in closed or covered containers to prevent unnecessary contamination risk

.PREPARATION BEFORE CLEANING

1. Symbols or specific instructions (if any) etched on instruments or instrument trays and cases should be strictly followed.
2. Where applicable, multi-component instruments should be disassembled for appropriate cleaning.
3. Disassembly, where necessary, is generally self-evident. Care should be exercised to avoid losing small screws and components.
4. All cleaning agents should be prepared at the use-dilution and temperature recommended by the manufacturer. Softened tap water may be used to prepare cleaning agents. Use of recommended temperatures is important for optimal performance of cleaning agents.

Note: Fresh cleaning solutions should be prepared when existing solutions become grossly contaminated (bloody and/or turbid).

CLEANING & DISINFECTION OPTIONS

1. Manual - Enzymatic soak and scrub followed by sonication.
2. Combination Manual/Automated - Enzymatic soak and scrub followed by an automated washer/disinfector cycle.
3. Automated cycle - Not recommended without manual precleaning.

Note: If stainless steel instruments are stained or corroded, an acidic, anti- corrosion agent in an ultrasonic cleaner may be sufficient to remove surface deposits. Care must be taken to thoroughly rinse acid from devices. Acidic, anti-corrosion agents should only be used on an as needed basis

MANUAL- ENZYMATIC SOAK AND SCRUB FOLLOWED BY SONICATION

1. Completely submerge device in enzyme solution and allow it to soak for 20 minutes. If visible soil is evident, scrub using a soft-bristled, nylon brush to gently clean the device.

Note: The enzyme solution should be changed on a regular basis in order to ensure its effectiveness.

2. Remove the device from the enzyme solution and rinse in tap water for a minimum of 3 minutes. Thoroughly flush lumens, holes and other difficult to reach areas.
3. Place prepared cleaning agents in sonication unit. Completely submerge device in cleaning solution and sonicate for 10 minutes at 45kHz and 60˚C/140˚F.
4. Rinse device in DI water thoroughly for at least 3 minutes or until there is no sign of blood or soil in the rinse stream. Thoroughly and aggressively flush lumens, holes and other difficult to reach areas.
5. Repeat the sonication and rinse steps above.
6. Remove excess moisture from the device with a clean, absorbent and non-shedding wipe.

COMBINATION MANUAL/AUTOMATED CLEANING STEPS

1. Completely submerge device in enzyme solution and allow to soak for 20 minutes. If visible soil is evident, scrub using a soft-bristled, nylon brush to gently clean the device. Particular attention must be given to crevices, lumens, mated surfaces connectors and other hard-to-clean areas. Lumens should be cleaned with a long, narrow, soft nylon-bristled brush.
2. Remove devices from the enzyme solution and rinse in DI water for a minimum of 1 minute. Thoroughly and aggressively flush lumens, holes and other difficult to reach areas.
3. Place devices in a suitable washer/disinfector basket and place basket in ultrasound cleaner.
4. Ultrasonically clean the individual devices in the enzymatic bath for 10 minutes at 45kHz and 60˚C/140˚F.
5. Remove the sonicator and rinse the devices in DI water for a minimum of 1 minute.
6. Dry with a sterile gauze, clean cloth and/or clean compressed air. Inspect instruments for cleanliness, function, and residual moisture. Any device that is not visually clean must be reprocessed.

Note: Use of a sonicator at 45kHz will aid in thorough cleaning of devices.

Note: Use of a syringe or water jet will improve flushing of difficult to reach areas and closely mated surfaces.

CAUTION: Use of corrosive products and/or instruments including abrasive sponges and metal brushes should be avoided.

INSPECTION

1. Carefully inspect each instrument to ensure all visible blood and soil has been removed.
2. Inspect instruments and instrument cases for damage. Check action of moving parts to ensure proper operation, and ensure disassembled instruments readily assemble with mating components.
3. If damage or wear is noted that may compromise the proper function of the instrument or instrument case, do not use and contact customer service or your CTL Medical representative for a replacement.
4. If corrosion is noted, do not use and contact your CTL Medical representative for a replacement.

STERILIZATION

The KLIMT Expandable LIF Cage System instruments are provided non-sterile and are delivered to the customer in a surgical kit, which is comprised of instrument trays and cases. All instruments used in surgery must be sterilized by the hospital prior to use. The following moist heat sterilization cycle, which results in a SAL of 10-6, was validated for use in accordance with applicable standards, including ANSI/AAMI ST79:

METHOD	Steam	Steam
Cycle	Gravity	Pre-Vacuum
Temperature	132°C(270°F)	132°C(270°F)
Exposure Time	15 minutes	4 minutes
Dry Time	45 minutes*	45 minutes*

Wrap: 2 times utilizing FDA-cleared wrap

*(15 Min Open Door Time + 30 Min Cool-Down Time)

It is important to note that an FDA-cleared sterilization wrap, package, sterilization container system should be used to enclose the case or tray in order to maintain sterility. Instruments should be positioned to allow the steam to come into contact with all surfaces. All jointed instruments should be in the open or unlocked position with ratchets not engaged. Instruments composed of more than one part or with sliding pieces or removable parts should be disassembled. Remove all packaging material prior to sterilization. Only sterile implants and instruments should be used in surgery. Instruments used in surgery should be re-sterilized after surgery. Implants should not be used as templates in surgery.

POST-OPERATIVE MOBILIZATION

The surgeon should advise the patient to be careful not to place significant loads on the spine for the first three months after surgery. The surgeon may advise the patient to limit their activity or wear a brace.

Careful management of the load will enable the fusion mass to heal and reduce the likelihood of non-union. Radiographic confirmation of a mature fusion mass may be used as a guide in the lifting of these restrictions.

WARNINGS

Following are specific warnings, precautions, and adverse effects that should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that can occur with surgery in general but are important considerations particular to spinal fixation devices. General surgical risks should be explained to the patient prior to surgery.

1. Patients with prior spinal surgery at the levels to be treated may have different clinical outcomes compared to those without previous surgery.
2. PATIENT SELECTION. In selecting patients for internal fixation devices, the following factors can be of extreme importance to the eventual success of the procedure:
    I. A patient may have multiple pain generators due to advanced degeneration of the spine (e.g. intervertebral disc, facets or bony stenosis). These conditions may be present at the index level or adjacent levels. Careful review of the clinical record, including radiographic studies and applicable diagnostic tests, should be performed to make the appropriate diagnosis. Concomitant conditions may reduce the effectiveness of the surgery, and this should be discussed with the patient.
    II. The patient's weight. An overweight or obese patient can produce loads on the device that can lead to failure of the implant or subsidence.
    III. The patient's occupation or activity. If the patient is involved in an occupation or activity that includes substantial walking, running, lifting or muscle strain, the resultant forces can cause failure of the implant or subsidence.
    IV. Patients that are non-compliant with postoperative guidance may place too much stress on the implant in the early postoperative period and compromise the maturing fusion mass.
    V. Smoking. Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used.
    VI. Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.

PRECAUTIONS

1. The implantation of spinal fixation devices should be performed only by experienced surgeons with specific training in the use of such devices. This is a technically demanding procedure presenting a risk of serious injury to the patient.
2. Based on the dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact the performance of the intervertebral body fusion device.
3. Proper sizing of the implants is important. The surgeon should use trials to determine the appropriate implant to use. The implant should be tall enough to provide segmental distraction and stability. The implant should be wide enough to maintain contact with the cortical rim of the vertebral body, or else the risk of subsidence may increase.
4. Surgical implants must never be reused. An explanted Spinal fixation device should never be re-implanted. Even though the device may appear undamaged, it may have small defects and internal stress patterns that may lead to early breakage.
5. Correct handling of the implant is extremely important. The operating surgeon should avoid any notching or scratching of the device during surgery. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.
6. Adequately instruct the patient. Postoperative care and the patient's ability and willingness to follow instructions are one of the most important aspects of successful bone healing. The patient must be made aware of the body's response to the implant and how the fusion mass is expected to develop. A patient that is noncompliant with post-operative guidance is particularly at risk during the early postoperative period.
7. Magnetic resonance (mr) environment. The Klimt expandable lif cage system has not been evaluated for safety and compatibility in the mr environment. The klimt expandable lif cage system has not been tested for heating, migration, or image artifact in the mr environment. The safety of the klimt expandable lif cage system in the mr environment is unknown. Scanning a patient who has this device may result in patient injury. Mixed metals such as titanium and stainless-steel components should not be used together. Components of this system should not be used with components of any other system or any other manufacturer.
8. Based on the fatigue testing results, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of the interbody fusion device. The implantation of the interbody fusion device should be performed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient.

POSSIBLE ADVERSE SIDE EFFECTS

Potential risks identified with the use of this device system, which may require additional surgery, include:

1. Pseudoarthrosis (i.e. non-union), delayed union.
2. Bending or fracture of implant.
3. Loss of fixation.
4. Fracture of the vertebra.
5. Anterior or posterior migration of the implant.
6. Allergic reaction to a foreign body.
7. Allergic reaction to the Ti-6Al-4V ELI alloy. Foreign body (allergic) reaction to implants, debris, corrosion products, including metallosis, staining, tumor formation and/or autoimmune disease.
8. Infection.
9. Decrease in bone density due to stress shielding.
10. Pain, discomfort, or abnormal sensations due to the presence of the device.
11. Loss of proper spinal curvature, correction height and/or reduction.
12. Vascular and/or nerve damage due to surgical trauma or presence of the device.
13. Visceral injury.
14. Neurological injury, including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, and paraesthesia.
15. Paralysis.
16. Death.
17. Erosion of blood vessels due to the proximity of the device, leading to hemorrhage and/or death.
18. Bone graft donor site complications.
19. Deep vein thrombosis, thrombophlebitis, and/or pulmonary embolism.
20. Development of respiratory problems e.g. atelectasis,

bronchitis, pneumonia, etc.

21. Change in mental status.
22. Cerebrospinal fluid leakage.

SINGLE USE/LIMITS ON PROCESSING

Products intended for single use must not be reused. Single use instruments are identified with marking "SINGLE USE" or with the associated symbol on the device and/or packaging. Reuse of a single use device that has come in contact with blood, bone, tissue or other body fluids may lead to patient or user injury, illness or death. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure, material degradation, potential leachables, and transmission of infectious agents. Repeated processing cycles that include ultrasonic, mechanical washing and sterilization have minimal effects on CTL Medical implants and instruments.

DISPOSAL INSTRUCTION

If product return is not possible then the affected product shall be maintained and/or disposed of according to the policies of the user facility.

LIMITED WARRANTY

CTL Medical products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed. If more than 2 years have elapsed between the date of issue/revision of this document, and the date of patient consultation, contact CTL Medical for current information.

PRODUCT COMPLAINTS

Any Health Care Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor or CTL Medical. Further, if any of the implanted spinal system component(s) ever malfunctions, (i.e. does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor or CTL Medical should be notified immediately. If any CTL Medical product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor or CTL Medical should be notified immediately by telephone, fax or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

FURTHER INFORMATION

Recommended directions for use of this system are available at no charge upon request. If further information is needed or required, please contact CTL Medical.

Manufactured by:

CTL Medical Corporation (d/b/a: CTL Amedica). All rights reserved.
2052 McKenzie Drive, Building 1, Carrollton, TX 75006
P: 214-545-5820 | E: info@CTLAmedica.com | www.ctlamedica.com

SYMBOL TRANSLATION