CTL MEDICAL®

CEZANNE™

LUMBAR INTERBODY FUSION CAGE SYSTEM

Instruction For Use

PURPOSE

This device is a PEEK (POLYETHERETHERKETONE) fusion device intended for stabilization use and to promote bone fusion during the normal healing process following surgical correction of disorders of the spine. The product should be implanted only by a physician who is thoroughly knowledgeable in the implant's material and surgical aspects and who has been instructed as to its mechanical and material applications and limitations.

DESCRIPTION

The CEZANNE™ Lumbar Interbody Fusion Cage System's implants are interbody fusion devices intended for use as an aid in spinal fixation. These hollow, rectangular implants are offered in a variety of widths, lengths, heights and lordotic angles designed to adapt to a variety of patient anatomies. They have serrations on the superior and inferior surfaces designed for fixation, ergonomically shaped anterior edges, and flat posterior edges. Radiopaque markers have been embedded within the implants, which are designed to allow for visualization in radiographic images.

Surgical approach

- PLIF(Posterior Lumbar Interbody Fusion) PEEK Cage System is to be implanted via posterior approach.
- TLIF(Transforaminal Lumbar Interbody Fusion) PEEK Cage System is to be implanted via transforaminal approach.
- ALIF(Anterior Lumbar Interbody Fusion) PEEK Cage System is to be implanted via anterior approach.
- DLIF (Direct Lateral Interbody Fusion) PEEK Cage System is to be implanted via direct lateral approach. It can be used in an open approach and a percutaneous approach with MIS instrumentation.

INDICATIONS

CEZANNE™ Lumbar Interbody Fusion Cage System 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. 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 bonegraft.Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

CONTRAINDICATIONS

This device is not intended for cervical spine use.
Contraindications include, but are not limited to:
1. Infection, local to the operative site
2. Signs of local inflammation,
3. Fever or leukocytosis,
4. Morbid obesity,
5. Pregnancy,
6. Mental illness,
7. Any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of segmentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
8. Suspected or documented allergy or intolerance to composite materials
9. Any case not needing a fusion,
10. Any case not described in the indications,
11. Any patient unwilling to cooperate with postoperative instructions.
12. Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery.
13. These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth.
14. Spondylolisthesis unable to be reduced to Grade 1.
15. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
16. Any case that requires the mixing of metals from two different components or systems.
17. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
18. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
19. Prior fusion at the level to be treated.

Although not absolute contraindications, conditions to be considered as potential factors for not using this device include:

1. Severe bone resorption.
2. Osteomalacia.
3. Severe osteoporosis

POTENTIAL ADVERSE EFFECTS

Adverse effects may occur when the device is used either with or without associated instrumentation. The potential risk of adverse effects as a result of movement and non-stabilization may increase in cases where associated complementary support is not employed. Potential adverse events include but are not limited to:
1. Implant migration.
2. Breakage of the device(s).
3. Foreign body reaction to the implants including possible tumor formation, auto immune disease, and/ or scarring.
4. Pressure on the surrounding tissues or organs.
5. Loss of proper spinal curvature, correction, height, and/ or reduction.
6. Infection.
7. Bone fracture or stress shielding at, above, or below the level of surgery.
8. Non-union (or pseudoarthrosis).
9. Loss of neurological function, appearance of radiculopathy, dural tears, and/or development of pain. Neurovascular compromise including paralysis temporary or permanent retrograde ejaculation in males, or other types of serious injury. Cerebral spinal fluid leakage.
10. Haemorrhage of blood vessels and/or hematomas.
11. Discitis, arachnoiditis, and/or other types of inflammation.
12. Deep venous thrombosis, thrombophlebitis, and/or pulmonary embolus.
13. Bone graft donor site complication.
14. Inability to resume activities of normal daily living.
15. Early or late loosening or movement of the device(s).
16. Urinary retention or loss of bladder control or other types of urological system compromise.
17. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
18. Fracture, microfracture, resorption, damage, or penetration of any spinal bone (including the sacrum,-pedicles, and/or vertebral body) and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery. Retropulsed graft.
19. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
20. Loss of or increase in spinal mobility or function.
21. Reproductive system compromise, including sterility, loss of consortium,and sexual dysfunction.
22. Development of respiratory problems, e.g. pulmonary-embolism, atelectasis, bronchitis,pneumonia,etc.
23. Change in mental status.
24. Cessation of any potentialgrowth of the operated portion of the spine.
25. Death.

WARNINGS AND PRECAUTIONS

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where other patient conditions may compromise the results. Use of this product without bone graft or in cases that do not develop a union will not be successful. Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and correct selection and placement of the implants are important considerations in the successful utilization of the system by the surgeon.

Further, the proper selection and the compliance of the patient will greatly affect the results. Patients who smoke have been shown to have a reduced incidence of bone fusion.
These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/ or alcohol / drug abuse patients and those with poor muscle and bone quality and / or nerve paralysis are also poor candidates for spinal fusion.

MRI Safety Information: The CEZANNE™ Lumbar Interbody Fusion Cage System has not been evaluated for safety and compatibility in the MR environment. The CEZANNE™ Lumbar Interbody Fusion Cage System has not been tested for heating, migration or image artifact in the MR environment. The safety of the CEZANNE™ Lumbar Interbody Fusion 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. Patients with previous spinal surgery at the levels to be treated may have different clinical outcomes compared to those with a previous surgery.

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 lumbar interbody fusion cage system. The implantation of the lumbar interbody fusion cage system should be performed only by experienced spinal surgeons with specific training in the use of the device because this is a technically demanding procedure presenting a risk of serious injury to the patient.

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

THE CHOICE OF IMPLANTS

The choice of proper shape, size and design of the implant for each patient is crucial to the success of the surgery. The surgeon is responsible for this choice which depends on each patient. Patients who are overweight may be responsible for additional stresses and strains on the device which can speed up implant fatigue and/or lead to deformation or failure of the implants. The size and shape of the bone structures determine the size, shape and type of the implants. Once implanted, the implants are subjected to stresses and strains. These repeated stresses on the implants must be taken into consideration by the surgeon at the time of the choice of the implant, during implantation as well as in the post-operative follow-up period. Indeed, the stresses and strains on the implants may cause fatigue or fracture or deformation of the implants, before the bone graft has become completely consolidated. This may result in further side effects or necessitate the early removal of the osteosynthesis device.

INFORMATION FOR PATIENTS
The surgeon must discuss all physical and psychological limitations inherent to the use of the device with the patient. This includes the rehabilitation regimen, physical therapy, and wearing an appropriate orthosis as prescribed by the physician. Particular discussion should be directed to the issues of premature weight bearing, activity levels, and the necessity for periodic medical follow-up.

The surgeon must warn the patient of the surgical risks and made aware of possible adverse effects. The surgeon must warn the patient that the device cannot and does not replicate the flexibility, strength, reliability or durability of normal healthy bone, that the implant can break or become damaged as a result of strenuous activity or trauma, and that the device may need to be replaced in the future.

If the patient is involved in an occupation or activity which applies inordinate stress upon the implant (e.g., substantial walking, running, lifting, or muscle strain) the surgeon must advice the patient that resultant forces can cause failure of the device. Patients who smoke have been shown to have an increased incidence of non-unions. Surgeons must advise patients of this fact and warn of the potential consequences.

For diseased patients with degenerative disease, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. In such cases, orthopaedic devices may be considered only as a delaying technique or to provide temporary relief. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

PREOPERATIVE PRECAUTIONS
The surgical indication and the choice of implants must take into account certain important criteria such as:
• Patients involved in an occupation or activity that applies excessive loading upon the implant (e.g., substantial walking, running, lifting, or muscle strain) may be at increased risk for failure of the fusion and/or the device.
• Surgeons must instruct patients in detail about the limitations of the implants, including, but not limited to, the impact of excessive loading through patient weight or activity, and be taught to govern their activities accordingly. The procedure will not restore function to the level expected with a normal, healthy spine, and the patient should not have unrealistic functional expectations.
• A condition of senility, mental illness, chemical dependence or alcoholism. These conditions among others may cause the patients to ignore certain necessary limitations and precautions in the use of the implant, leading to failure and other complications.
• Foreign body sensitivity. Where material sensitivity is suspected appropriate tests must be made prior to material implantation.
• Surgeons must advise patients who smoke have been shown to have an increased incidence of non-unions. Such patients must be advised of this fact and warned of the potential consequences.
• Care must be taken to protect the components from being marred, nicked, or notched as a result of contact with metal or abrasive objects.

INTRAOPERATIVE PRECAUTIONS
• The insertion of the implants must be carried out using instruments designed and provided for this purpose and in accordance with the specific implantation instructions for each implant. Those detailed instructions are provided in the surgical technique brochure supplied by CTL Medical.
• Discard all damaged or mishandled implants.
• Never reuse an implant, even though it may appear undamaged.

POSTOPERATIVE PRECAUTIONS
Prior to adequate maturation of the fusion mass, implanted spinal instrumentation may need additional help to accommodate full load bearing. External support may be recommended by the physician from two to four months postoperatively or until x-rays or other procedures confirm adequate maturation of the fusion mass; external immobilization by bracing or casting be employed. Surgeons must instruct patients regarding appropriate and restricted activities during consolidation and maturation for the fusion mass in order to prevent placing excessive stress on the implants which may lead to fixation or implant failure and accompanying clinical problems. Surgeons must instruct patients to report any unusual changes of the operative site to his/her physician. The physician must closely monitor the patient if a change at the site has been detected. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

IMPLANT REMOVAL
If fusion / bone graft growth occurs, the device will be deeply integrated into the bony tissues. As a result, the CEZANNE™ Lumbar Interbody Fusion Cage System is not intended to be removed unless the management of a complication or adverse event requires the removal. Any decision by a physician to remove the device should take into consideration such factors as:
• The risk to the patient of the additional surgical procedure as well as the difficulty of removal.
• Migration of the implant, with subsequent pain and/or neurological, articular or soft tissue lesions.
• Pain or abnormal sensations due to the presence of the implants.
• Infection or inflammatory reactions.
• Reduction in bone density due to the different distribution of mechanical and physiological stresses and strains.

STORAGE AND HANDLING
CTL Medical CezanneTM Lumbar Interbody Device should be stored In a dry environment, protected from direct sunlight and at an ambient temperature in their original packaging.

PACKAGING
Components should only be accepted if received with the factory packaging and labeling intact. All sets should be carefully inspected before use. In particular, check for completeness of the set and integrity of the components and/orinstruments. Any damaged packaging and/or product must be returned to CTL Medical.

EXAMINATION FOR GENERAL INSTRUMENTS
Instruments must always be examined by the user prior to use in surgery. Examination should be thorough, and in particular, should take into account a visual and functional inspection of the working surfaces, pivots, racks, spring or torsional operation, cleanliness of locationholes or cannulations, and the presence of any cracks, bending, bruising ordistortion, and that all components of the instrument are complete.

Never use instruments with obvious signs of excessive wear, damage, or that are incomplete or otherwise unfunctional.

CLEANING AND STERILIZATION
Implants are supplied non-sterile and are for single use only. So all implants used in surgery must be sterilized by the hospital prior to use. Otherwise, Instruments are supplied non-sterile and may be re used. 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.

Cleaning of Instruments:
Clean all instruments prior to use, and as soon as possible after use. Do not allow blood and debris to dry on the instruments. If cleaning must be delayed, place instruments in a covered container with appropriate detergent or enzymatic solution to delay drying. Disassemble instruments with re-movable parts. Specifically, the inserter instrument provided with the CEZANNE™ System is intended to be disassembled for cleaning and sterilization. To disassemble the inserter, twist handle in clockwise direction to disengage threads. Methods of cleaning CEZANNE™ re-usable instruments are provided in these instructions, a manual method and a method using an automated washer disinfector.

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 use suitable protective clothing and equipment at all times. 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 purified water/highly purified 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 and Decontamination
•All instruments and implants must first be cleaned using established hospital methods before sterilization and introduction into a sterile surgical field.
•CAUTION: Use of sodium hydroxide (NaOH) is prohibited. Use of corrosive products and/or instruments including abrasive sponges and metal brushes should be avoided
•Implants removed from a patient or that contact bodily tissues or fluids should never be reused.
•In a clean metal pan, prepare an enzymatic detergent bath according to the detergent manufacturer's instructions.
•Allow the devices to soak in enzymatic detergent bath for 20 minutes.
•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.
•Remove the devices from the enzymatic detergent bath and rinse with tap water for a minimum of 1 minute.
•Prepare an enzymatic detergent bath in a sonicator.
•Ultrasonically clean the individual devices in the enzymatic bath for ten (10) minutes.
•Remove from sonicator and rinse the devices in DI water for a minimum of 1 minute.
•Dry the devices with a clean, soft cloth.
•Visually inspect the devices under normal room lighting condition to verify all foreign debris has been removed.
•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.

Cleaning Instructions:
Point of Use
•Remove excess body fluids and tissue from instruments with a disposable, non-shedding wipe.
•Place devices in a tray of distilled water or cover with damp towels.
•Instruments should be cleaned within 30 minutes of use to minimize the potential for drying prior to cleaning.
•Used instruments must be transported to the central supply in closed or covered containers to prevent unnecessary contamination risk.

Preparation Before Cleaning
•Symbols or specific instructions etched on instruments or instrument trays and cases should be strictly followed.
•Where applicable, multi-component instruments should be disassembled for appropriate cleaning.
•Disassembly, where necessary is generally self-evident. Care should be exercised to avoid losing small screws and components.
•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 Cleaning Steps:
1. Completely submerge the instrument in enzyme solution and allow it to soak for 20 minutes. Scrub using a soft-bristled, nylon brush to gently clean the device until all visible soil has been removed. 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 45-50kHz.
4. Rinse instrument in purified 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 instrument with a clean, absorbent and non-shedding wipe.

Combination Manual/Automated Cleaning Steps:
1. Completely submerge the instruments in enzyme solution and allow to soak for 10 minutes. Use a soft nylon-bristled brush to gently scrub the device until all visible soil has been removed. 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 purified water for a minimum of 1 minute. Thoroughly and aggressively flush lumens, holes and other difficult to reach areas.
3. Place instruments in a suitable washer/disinfector basket and process through a standard washer/disinfector instrument cycle:
   i. Rinse 3 times using tap water for 30 seconds after wash using the enzymatic detergent in the ultrasound cleaner at 35-45^{o}C for 3 minutes.
   ii. Perform the ultrasound rinsing repeatedly subjected 3 times for 3 minutes using the purified water at 35-45^{o}C.
   iii. Dry at 100^{o}C (±5^{o}C) for 30 minutes.

Note: Use of a sonicator at 45-50kHz 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 customer service or your CTL Medical representative for a replacement.

Sterilization
All implants and instruments used in surgery must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field. Sterilization: recommended method to achieve a degree of sterility equal to at least 10^{-6}.The gravity displacement sterilization parameters we suggested comply with AAMI ST79. CTL Medical recommends the following parameters:

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

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

It is important to note that a FDA-cleared sterilization wrap, package or steriliza-tion container system should be used to enclose the case or tray in order to maintain sterility. Although the treatment of the instrument, materials used, and details of sterilization have an important effect, for all practical purposes, there is no limit to the number of times instruments can be resterilized.

LIMITS ON REPROCESSING
Repeated processing cycles that include ultrasonic, mechanical wash-ing and sterilization have minimal effects on CTL Medical implants and instruments.

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 peperformance, 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 per-formance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immedi-atately. If any CTL Medical product ever “malfunctions” and may have caused or contributed to the death or serious injury of a patient, the distributor 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.

Manufactured by CTL Medical
4550 Excel Parkway, Suite 300 Addison, TX 75001
Phone: 214-545-5820 Fax: 888.831.4892
www.CTLMed.com

SYMBOL TRANSLATION

CATALOG NUMBER

LOT NUMBER

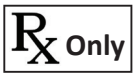
QUANTITY

NON-STERILE

SINGLE USE ONLY

See package insert for labeling limitation

Fedral Law (USA) restricts this device to sale, distribution, or use by or on the order of a physician



MANUFACTURER

DATE OF MANUFACTURE

eIFU indicator

EC	REP

EUROPE:
EC Rep Ltd
Healthcare & Education Centre
The Church, Portland Street,
Southport, PR8 1HU,UK
Phone: +44 1704 544 944
Fax: +44 1704 544 050;
Email: info@ecrep.com

CE 0197