



Instruction For Use

DESCRIPTION and INTENDED USE:

The CEZANNE II™ Interbody Fusion System is offered in various device configurations based on surgical approach and patient anatomy, and consist of:

CEZANNE II™ lumbar interbody fusion device(s), which may be implanted

- as a single device via a direct lateral (XLIF) approach;
- as a single device via a transforaminal (TLIF) approach; or
- as a single device via an anterior (ALIF) approach

CONTRAINDICATIONS:

1. Active systemic infection or infection localized to the site of the proposed implantation are contraindications to implantation.
2. Known sensitivity to PEEK material.
3. Severe osteoporosis is a relative contraindication because it may result in implant subsidence and loss of fixation.
4. Any condition that significantly affects the likelihood of fusion may be a relative contraindication (e.g. cancer, diabetes, osteomalacia, heavy smoker, morbid obesity) and the surgeon must evaluate the relative risks and benefits individually with each patient.
5. Other relative contraindication may include mental illness, drug abuse or alcoholism as these may cause the patient to be non-compliant with post-operative guidance (e.g. bracing and physical therapy).
6. Prior fusion at the levels to be treated.
7. Any condition not described in the indications for use.

MATERIALS:

The CEZANNE II™ Interbody Fusion System implant components are made of polyether ether ketone (PEEK Optima LT1) that conforms to ASTM F2026. Additionally, the devices contain tantalum markers (ASTM F560) to assist the surgeon with proper placement of the device. The CEZANNE II™ Interbody Fusion 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 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 removable parts. Specifically, the inserter instrument provided with the CEZANNE II™ System is intended to be disassembled for cleaning and sterilization. To disassemble the inserter, twist handle in clockwise direction to disengage threads. Two methods of cleaning CEZANNE II™ re-usable instruments are provided in these instructions, a manual method and a method using an automated washer disinfectant. 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 re-usable 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 prepared 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.

Pre-Cleaning

1. Remove gross soil using wipes and solution of cleaning agent.
2. Immerse re-usable instrument in solution of cleaning agent.
3. Ensure that all surfaces are thoroughly wetted.
4. Use a syringe to ensure that the cleaning solution reaches all parts of cannulations.
5. Ensure that air is not trapped within features of the device when immersing in the solution.
6. Soak for minimum recommended time by the detergent manufacturer's instructions.
7. Using suitable soft bristle brushes, clean the re-usable instrument thoroughly, paying particular attention to rough surfaces and features where soil may be impacted or shielded from the cleaning process.
8. Use a firm bristle brush for cleaning bone-cutting features such as drill tips broaches.
9. Use a bottle brush of appropriate diameter and length for cannulations. Ensure that the brush passes the whole length of each cannulation.
10. Caution: Never use metal brushes or steel wool for cleaning.
11. Operate articulating devices and those with moving parts.
12. Rinse in running water until all traces of cleaning solution are removed.
13. Pay particular attention to cannulations and blind holes, as well as hinges and joints, between mating parts.
14. Visually inspect for any remaining soil and repeat the steps above if necessary.
15. Allow to drain on absorbent paper or transfer immediately to cleaning step.

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/disinfectant cycle.
3. Automated cycle - Not recommended without manual pre-cleaning.

Manual Cleaning and Disinfection

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.

Procedure for Cleaning:

1. Completely submerge instruments in enzyme solution and allow to soak for minimum of 20 minutes. Scrub using a soft-bristled, nylon brush until all visible soil has been removed.
2. Remove the device from the enzyme solution and rinse in tap water for minimum of 3 minutes. Thoroughly and aggressively flush lumens, holes and other difficult to reach areas.
3. Place prepared cleaning agents in the sonication unit. Completely submerge device in cleaning solution and sonicate for 10 minutes at 45-50 kHz.
4. Rinse instrument in purified water for at least 3 minutes or until there is no sign of blood or soil on the device or 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.

Automated Cleaning and Disinfection

Procedure for automated cleaning/disinfection:

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°C for 3 minutes.
 - ii. Perform the ultrasound rinsing repeatedly subjected 3 times for 3 minutes using the purified water at 35-45°C.
 - iii. Dry at 100°C (±5°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.

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:

The CEZANNE II™ Interbody Fusion System is provided non-sterile and is delivered to the customer in a surgical kit, which is comprised of implant caddies, instrument trays and cases. All implants and 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	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.

POSTOPERATIVE 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 a 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:

- a) 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.
- b) 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.
- c) 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.
- d) 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.
- e) Smoking. Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used.
- f) 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 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 CEZANNE II™ System has not been evaluated for safety and compatibility in the MR environment. The CEZANNE II™ System has not been tested for heating, migration or image artifact in the MR environment. The safety of the CEZANNE II™ 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.

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 EFFECTS

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

1. Pseudarthrosis (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. Infection.
8. Decrease in bone density due to stress shielding.
9. Pain, discomfort, or abnormal sensations due to the presence of the device.
10. Loss of proper spinal curvature, correction height and/or reduction.
11. Vascular and/or nerve damage due to surgical trauma or presence of the device.
12. Visceral injury.
13. Neurological injury, including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, and paraesthesia.
14. Paralysis.
15. Death.
16. Erosion of blood vessels due to the proximity of the device, leading to hemorrhage and/or death.

Single Use/Limits on Processing:

Products intended for single use must not be reused. 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.

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.

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

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SYMBOL TRANSLATION

CATALOG
NUMBER

LOT NUMBER

QUANTITY

REF

LOT

QTY

NON-STERILE



SINGLE USE
ONLY



See package insert for
labeling limitation



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



MANUFACTURER



DATE OF
MANUFACTURE



eIFU indicator



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