MONET™

Anterior Cervical Interbody Fusion Cage System with supplementary fixation plate

INDICATIONS FOR USE

PURPOSE

MONET™ Anterior Cervical Interbody Fusion Cage System with Supplementary Fixation Plate is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2 to the C7 disc.

DESCRIPTION

MONET™ Anterior Cervical Interbody Fusion Cage System with Supplementary Fixation Plate is intended for use as an interbody fusion cage device and is to be used with additional supplemental fixation systems that have been cleared for use in the cervical spine. The devices are available in a variety of different sizes and configurations to accommodate anatomical variation in different vertebral levels and/or patient anatomy. The devices are made of either PEEK with tantalum markers or Titanium Alloy. MONET™ Anterior Cervical Interbody Fusion Cage System with Supplementary Fixation Plate devices are designed for an anterior approach.

INDICATIONS

MONET™ Anterior Cervical Interbody Fusion Cage System with Supplementary Fixation Plate is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. MONET™ Anterior Cervical Interbody Fusion Cage System with Supplementary Fixation Plate is used to facilitate intervertebral body fusion in the cervical spine at the C2 to C7 disc levels using autograft bone. MONET™ Anterior Cervical Interbody Fusion Cage System with Supplementary Fixation Plate could be used with additional supplemental fixation systems that have been cleared for use in the cervical spine. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

CONTRAINDICATIONS

1. MONET™ Anterior Cervical Interbody Fusion Cage System with Supplementary Fixation Plate is not intended for posterior surgical implantation.
2. Contraindications include, but are not limited to:
   - Any case needing to mix metals from different components.
   - Any case not described in the indications.
   - Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
3. Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
4. Any patient unwilling to co-operate with postoperative instructions.
5. Fever or leukocytosis.
6. Infection, local to the operative site.
7. Mental illness.
8. Morbid obesity.
9. Pregnancy.
10. Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction and/or the amount of mechanical fixation.
11. Signs of local inflammation.
12. Suspected or documented metal allergy or intolerance.
13. These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth.
14. Contraindications of this device are consistent with those of other spinal systems.

POTENTIAL ADVERSE EVENTS

All of the possible adverse events or complications associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of possible adverse events or complications includes, but is not limited to:

1. Bone loss or decrease in bone density, possibly caused by stress shielding.
2. Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex
3. Deficits, arachnoiditis, and/or muscle loss.
4. Cessation of any potential growth of the operated portion of the spine. Loss of spinal mobility or function. Inability to perform the activities of daily living.
5. Change in mental status.
6. Death.
7. Development of respiratory problems, e.g., pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
8. Disassembly, bending, and/or breakage of any or all of the components.
9. Dural tears, pseudo-meningocele, fistula, persistent CSF leakage, meningitis.
10. Early or late loosening of the components. Implant migration.
11. Foreign body (allergic) reaction to the implants, debris, corrosion products, including metallosis, staining, tumor formation and/or autoimmune disease.
12. Fracture, micro fracture, resorption, damage, penetration, and/or retropulsion of any spinal bone, of the autograft, or at the bone graft harvest site - at, above, and/or below the level of surgery.
13. Gastrointestinal complications.
14. Graft donor site complications including pain, fracture, infection, or wound healing problems.
15. Hemorrhage, hematoma, occlusion, seroma, edema, embolism, stroke, excessive bleeding, phlebitis, damage to blood vessels, or cardiovascular system compromise. Wound necrosis or wound dehiscence.
16. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
17. Infection.
18. Loss of neurological function, including paralysis (complete or incomplete), dysesthesia, hyperesthesia, anesthesia, paraesthesia, appearance or radiculopathy, and/or the development or continuation of pain, numbness, neuroma, tingling sensation, sensory loss and/or spasms.
19. Non-union (or pseudoarthrosis). Delayed union. Mal-union.
20. Postoperative change in spinal curvature, loss of correction, height, and/or reduction.
21. Scar formation possibly causing neurological compromise around nerves and/or pain.

22. Subsidence of the device into vertebral body (ies).
23. Tissue or nerve damage, irrigation, and/or pain caused by improper positioning and placement of implants or instruments.
24. **OPTIONAL - IMPLANT REMOVAL NOTE: Additional surgery may be necessary to correct some of these anticipated adverse events.** The insertion instruments can be used to engage the implant securely. The implant can then be extracted by following the implantation process in the reverse order.

WARNING(S)

- 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. MONET™ Anterior Cervical Interbody Fusion Cage system must be used with Anterior Cervical Plate System to augment stability. Use of this product without autograft may not be successful. No spinal implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device(s) will eventually occur. Do not use implants and instruments that you find any deterioration, such as surface discoloration or corrosion and please inform to distributor or manufacturer immediately.

- Preoperative and operating procedures, including knowledge of surgical techniques, proper selection and placement of the implant and good reduction are important considerations in the success of surgery.

- Never reuse an internal fixation device under any circumstances. Even when a removed device appears undamaged, it may have small defects or internal stress patterns that may lead to early breakage. Damage of the thread will reduce the stability of the instrumentation.

- Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spine fusion. Proper patient selection is important as fatigue testing and device mechanical performance cannot account for all possible in-vivo conditions.

- MRI Safety Information: MONET™ Anterior Cervical Interbody Fusion Cage System with Supplementary Fixation Plate has not been evaluated for safety and compatibility in the MRI environment. MONET™ Anterior Cervical Interbody Fusion Cage System with Supplementary Fixation Plate has not been tested for heating, migration or image artifact in the MRI environment. The safety of the MONET™ Anterior Cervical Interbody Fusion Cage System with Supplementary Fixation Plate in the MRI 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.

PRECAUTION(S)

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 intervertebral body fusion device.

The implantation of the intervertebral body 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.

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 *(FOR US AUDIENCES ONLY):* FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN

CHOICE OF IMPLANTS

The selection of the proper size, shape, and design of the implant for each patient is crucial to the success of the procedure. Particularly, plastic polymer implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause material fatigue and consequent breakage, bending or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

PRE-OPERATIVE

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Care should be used in the handling and storage of the implant components. The implants should not be scratched or damaged. Implants and instruments should be protected during storage especially from corrosive environments.
4. Further information on the use of this system will be made available on request.
5. Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present- before the surgery begins.
6. The type of construct to be assembled for the case should be determined prior to beginning the surgery. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.
7. Unless sterile packaged, all parts should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

INTRA-OPERATIVE

1. The instructions in any available applicable surgical technique manual should be carefully followed.
2. At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
3. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
4. To assure proper fusion below and around the location of the instrumentation, autograft should be used. Autograft must be placed in the area to be fused and graft material must extend from the upper to the lower vertebrae being fused.
5. When using the MONET™ Anterior Cervical Interbody Fusion Cage with Supplementary Fixation Plate, autograft should be used.
6. Bone cement should not be used since this material will make removal of the components difficult or impossible. The heat generated from the curing process may also cause neurologic damage and bone necrosis.

POST-OPERATIVE

The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.

1. Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening or breakage of the device are complications which can occur as a result of excessive weight bearing or muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated, demented or otherwise unable to use crutches or other weight supporting devices. The patient should be warned to avoid falls or sudden jolts in spinal position.
2. To allow the maximum chances for a successful surgical result, the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke or consume excess alcohol during the bone healing process.
3. The patients should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
4. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening, or breakage of the device. It is important that immobilization of the union is established and confirmed by roentgenographic examination. Where there is a non-union, or if the components loosen, bend, and/or break, the device should be revised and/or removed immediately before serious injury occurs.
5. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible.

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/or instruments. Any damaged packaging and/or product must be returned to CTL Medical.

EXAMINATION

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 location holes or cannulations, and the presence of any cracks, bending, bruising or distortion, 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 non-functional.

STORAGE AND HANDLING

MONET™ Cervical Interbody Fusion Cage with Supplementary Fixation Plate implants should be stored in a dry environment, protected from direct sunlight and at an ambient temperature in their original packaging.

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.

MANUAL CLEANING PROCEDURE

1. Use the neutral pH enzyme soaking solution that has been prepared.
2. Completely submerge the instrument in enzyme solution and allow it to soak for 20 minutes (water temperature: 35-45°C). Use a soft-bristled brush to gently clean the device (particular attention shall be given to crevices, lumens, mated surfaces and other hard-to-clean areas) until all visible soil has been removed. Lumens should be cleaned with a long, narrow, soft-bristled brush (i.e. pipe cleaner brush). Note: Any assembled instruments such as Caspar retractor, please disassemble the parts of retractor both blades, legs, and body before submerge. And reassemble it before disassemble. **Note: The enzyme solution should be changed on a regular basis in order to ensure its effectiveness**.
3. Remove the device from the enzyme solution and rinse in purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled) for a minimum of 3 minutes. Thoroughly flush lumens, holes and other difficult to reach areas (water temperature: 35- 45°C).
4. Prepare the neutral pH cleaning (detergent) solution and place in a sonication unit.
5. Completely submerge device in cleaning solution and sonicate for 10 minutes, preferably at 45-50 kHz.
6. Rinse instrument in purified water (from one or any combination of the following processes: ultra- filter, RO, DI and/ or distilled) thoroughly for at least 3 minutes or until there is no sign of blood or soil in the rinse stream.
7. Repeat Steps 5 and 6 with freshly prepared cleaning solution.
8. Dry the instrument with a clean, disposable, absorbent, non-shedding wipe.
9. Visually inspect the devices under normal room lighting condition to verify all foreign debris has been removed thoroughly clean. Verify that the devices are visually clean

AUTOMATED CLEANING PROCEDURE

Automated washer/disinfector systems are not recommended as the sole cleaning method for complex surgical instruments. These instruments should be cleaned following the manual cleaning procedure above. An automated system may be used as a follow-up method but is not required.

CAUTION:

- Use of corrosive products and/or instruments including abrasive sponges and metal brushes should be avoided.
- Visually inspect the devices under normal room lighting condition to verify all foreign debris has been removed thoroughly clean.
- Verify that the instruments are in visually clean.

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:

It is important to note that a sterilization wrap, package or sterilization 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 re-sterilized.

Method	Type	Temperature	Exposure Time	Dry Time	Open-Door Time	Cool-Down Time
Steam	Gravity	132°C (270° F)	15 min	45 min	15 min	30 min
Steam	Pre-Vacuum	132°C (270° F)	4 min	30 min	15 min	15 min

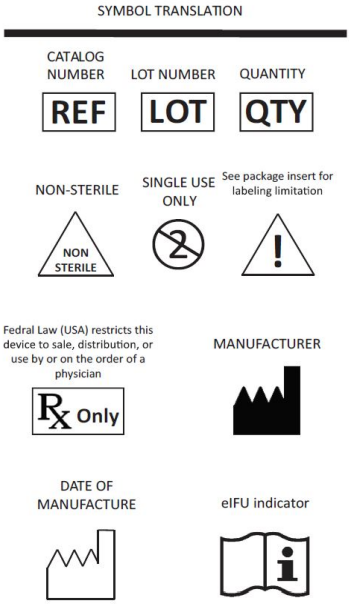
PRODUCT COMPLAINTS

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 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 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 at:

CTL Medical Corporation
4550 Excel Parkway Suite 300
Addison, TX 75001
Telephone: 214-545-5820



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