INSTRUCTIONS FOR USE

Important Information - Please Read Prior to Use

ENGLISH

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DEVICE SYSTEM NAME:

Anterior Cervical Interbody Fusion Cages

which includes:

MATISSE/MATISSE-NITRO ACIF Cage System
MONET/MONET-NITRO ACIF Cage System
VALEO C/VALEO C+CSC/VALEO-II C ACIF Cage System

DESCRIPTION

Anterior Cervical Interbody Fusion Cage System is intended for use as an interbody fusion cage device and must be used with supplemental fixation. 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 Silicon Nitride (Si3N4), PEEK with marker pins made of tantalum, Titanium, or a hybrid of Titanium and PEEK. Anterior Cervical Interbody Fusion Cage system devices are designed for an anterior approach. Titanium and hybrid Titanium-PEEK cages feature TiCro™ surface technology.

INDICATIONS

Anterior Cervical Interbody Fusion Cage System 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 or two contiguous levels. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Anterior Cervical Interbody Fusion Cage System is used to facilitate intervertebral body fusion in the cervical spine at the C3 to C7 disc levels using autograft bone. Anterior Cervical Interbody Fusion Cage System is to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

CONTRAINDICATIONS

1. The Anterior Cervical Interbody Fusion Cage System 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.

PATENTIAL ADVERSE EVENTS

All 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 deficits, arachnoiditis, and/or muscle loss.
3. Cessation of any potential growth of the operated portion of the spine.
4. Loss of spinal mobility or function.
5. Inability to perform the activities of daily living.
6. Change in mental status.
7. Death.
8. Development of respiratory problems, e.g., pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
9. Disassembly, bending, and/or breakage of any or all of the components.
10. Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
11. Early or late loosening of the components. Implant migration.

12. Foreign body (allergic) reaction to the implants, debris, corrosion products, including metallosis, staining, tumor formation and/or autoimmune disease.

13. Fracture, microfracture, 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.

14. Gastrointestinal complications.

15. Graft donor site complications including pain, fracture, infection, or wound healing problems.

16. Hemorrhage, hematoma, occlusion, seroma, edema, embolism, stroke, excessive bleeding, phlebitis, damage to blood vessels, or cardiovascular system compromise. Wound necrosis or wound dehiscence.

17. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.

18. Infection.

19. Loss of neurologial 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.

20. Non-union (or pseudarthrosis). Delayed union.

21. Malunion.

22. Postoperative change in spinal curvature, loss of correction, height, and/or reduction.

23. Scar formation possibly causing neurological compromise around nerves and/or pain.

24. Subsidence of the device into vertebral body/bodies.

25. Tissue or nerve damage, irrigation, and/or pain caused by improper positioning and placement of implants or instruments.

    NOTE: Additional surgery may be necessary to correct some of these anticipated adverse events.

WARNINGS

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. The Anterior Cervical Interbody Fusion Cage System must be used with an approved 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 circum- stances. 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. And Proper patient selection is important as fatigue testing and device mechanical performance cannot account for all possible in-vivo conditions.

MRI Safety Information: The Anterior Cervical Interbody Fusion Cage System has not been evaluated for safety and compatibility in the MR environment. The Anterior Cervical Interbody Fusion Cage System has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Anterior Cervical 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.

PRECAUTIONS

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

FOR US AUDIENCES ONLY CAUTION: 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. 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.

PREOPERATIVE

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.

INTRAOPERATIVE

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. 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.

POSTOPERATIVE

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 Corporation.

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 unfunctional.

STORAGE & HANDLING

Anterior Cervical Interbody Fusion Cage System should be stored in a dry environment, protected from direct sunlight and at an ambient temperature in their original packaging.

CLEANING & STERILIZATION

Implants of the Cervical Interbody Fusion System may be provided either sterile or non-sterile and this will be clearly identified on the product labels. Instruments of the Cervical Interbody Fusion 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 Cervical Interbody Fusion System that are supplied sterile are sterilized 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.

PRECAUTION: Do not use the implants if the condition of the package and/or labeling indicates a chance that the devices may not be sterile. Implants supplied sterilized from the manufacturer must not be resterilized.

NON-STERILE IMPLANTS AND INSTRUMENTS: 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 Corporation 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 Corporation.

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 Corporation 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/Disinfection Options

All instruments and implants must first be cleaned using established hospital methods before sterilization and introduction into a sterile surgical field. Disassemble instruments with re-movable 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 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.

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 Corporation representative for a replacement.
4. If corrosion is noted, do not use and contact your CTL Medical representative for a replacement.

STERILIZATION

The Cervica Interbody Fusion Cage 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 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 dissembled. 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.

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 Corporation 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 performance, should notify the distributor or CTL Medical Corporation. 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 Corporation 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.

DISPOSAL INSTRUCTIONS

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

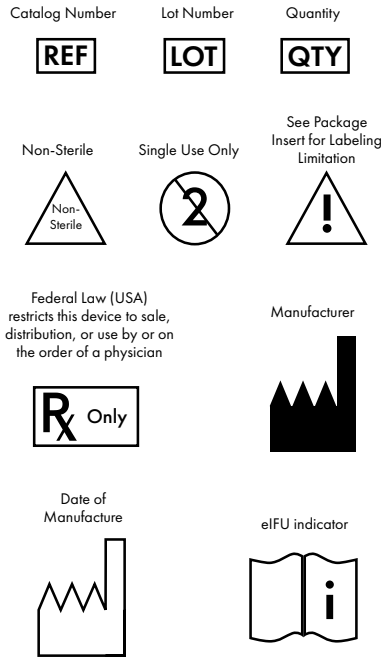
LIMITED WARRANTY

CTL Medical Corporation 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 Corporation 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 Corporation.

SYMBOL TRANSLATION



CTL AMEDICA
rethink what's possible®

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