CTL MEDICAL®

RENOIR™

POSTERIOR CERVICO-THORACIC FIXATION SYSTEM

IMPORTANT NOTE
Before using a product placed on the market by CTL Medical, the operating surgeon should study carefully the following recommendations, warnings and instructions, as well as the available product-specific information (e.g., product literature, written surgical technique). CTL Medical is not liable for complications arising from the use of the device outside of its indicated uses, surgical technique or judgment, product selection, and similar matters outside the control of CTL Medical.

Compatibility between all CTL Medical Spine product lines, including acquisitions of pre-existing product lines, has not been estalished. Only authorized combinations of products should be used. Only use as indicated in the Instructions for Use (Package Insert) and/or the Surgical Technique.

DEVICE DESCRIPTION
The RENOIR™ Posterior Cervical Fixation System is a top-loading, multiple component, posterior (cervical-thoracic) spinalfixation system which consists of polyaxial screws, semi-reduction poly screws, reduction poly screws, straight rods, curved rods, set screws, hooks and set screws.
Materials: All products are made of titanium alloy (Ti-6Al-4V ELI/ in conformance with ASTM F136) approved for medical use.

INDICATIONS
The RENOIR™ Posterior Cervical Fixation System is indicated for the following:
· DDD (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
· Spondylolisthesis
· Spinal stenosis
· Fracture/dislocation
· Failed previous fusion
· Tumors
The implants are intended to provide stabilization as an adjunct to fusion when used with autogenous bone graft or allograft following the reduction of fractures/dislocations or trauma in the spine.
Hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1 –T3) spine.
The pedicle screws are limited to placement in T1 -T3 in treating thoracic conditions only. The pedicle screws are not intended to be placed in or treat conditions involving the cervical spine.

GENERAL CONDITIONS OF USE
1. The implants must be implanted only by surgeons having undergone the necessary training in spinal surgery. Their use in implantation must be decided upon in accordance with the surgical and medical indication, the potential risks and limitations related to the this type of surgery, the contra-indications, side effects, and precautions defined, and in the knowledge of the nature and metallic, metallurgic and biological characteristics of the implants to be used.
2. It is recommended the RENOIR™ Posterior Cervical Fixation System should not be used together with implants from a different source, a different manufacturer, or made from a different material. If this should occur, CTL Medical. declines all responsibility.
3. Under no circumstances may the implants be re-used; although the device may appear infect on removal, internal modifications due to the stresses and strains placed on it, or small defects may exist, which may lead to the fracture of the implant.

CONTRA-INDICATIONS
Contraindications include, but are not limited to:
1. Infection, systemic, spinal or localized
2. Morbid obesity
3. Signs of local inflammation
4. Fever or leukocytosis
5. Metal sensitivity/allergies to the implant materials
6. Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count
7. Grossly distorted anatomy due to congenital abnormalities
8. Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis (osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of the bone graft)
9. Any case not needing a bone graft and fusion or where fracture healing is not required
10. Any case requiring the mixing of metals from different components
11. Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock,bone quality, or anatomical definition
12. Any case not described in the indications
13. Any patient unwilling to cooperate with the postoperative instructions
14. Any time implant utilization would interfere with anatomical structures or expected physiological performance.

POTENTIAL ADVERSE EFFECTS AND COMPLICATIONS
Possible adverse effects include, but are not limited to:
1. Bending, loosening or fracture of the implants or instruments
2. Loss of fixation
3. Sensitivity to a metallic foreign body, including possible tumor formation
4. Skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which may result in skin breakdown and/or wound complications
5. Nonunion or delayed union
6. Infection
7. Nerve or vascular damage due to surgical trauma, including loss of neurological function, dural tears, radiculopathy, paralysis and cerebral spinal fluid leakage
8. Gastrointestinal, urological and/or reproductive system compromise, including sterility, impotency and/or loss of consortium
9. Pain or discomfort
10. Bone loss due to resorption or stress shielding, or bone fracture at, above or below the level or surgery (fracture of the vertebra)
11. Hemorrhage of blood vessels and/or hematomas
12. Malalignment of anatomical structures, including loss of proper spinal curvature, correction, reduction and/or height
13. Bursitis
14. Bone graft donor site pain
15. Inability to resume activities of normal daily living
16. Reoperation
17. Death

PRECAUTIONS
MRI Safety Information: RENOIR™ Posterior Cervical Fixation System has not been evaluated for safety and compatibility in the MR environment. RENOIR™ Posterior Cervical Fixation System has not been tested for heating, migration or image artifact in the MR environment. The safety of the RENOIR™ Posterior Cervical Fixation System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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 posterior cervical fixation system. The implantation of the posterior cervical fixation system 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.

1. SURGCAL IMPLANTS MUST NEVER BE REUSED.
An explanted metal implant should never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage. 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.

2. CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT. Contouring of metal implants should be done only with proper equipment. The operating surgeon should avoid any notching, scratching or reverse bending of the devices when contouring. Alterations will produce defects in surface finish and internal stresses that may become the focal point for eventual breakage of the implant.

3. BENDING THE CONSTRUCT.
Titanium alloy components should never be bent sharply or reverse bent. If a construct is over-contoured it is recommended that a new construct is contoured correctly rather than reverse bending the over-contoured construct.

4. REMOVAL OF THE IMPLANT AFTER HEALING.
If the device is not removed after the completion of its intended use, any of the following complications may occur: (1)Corrosion, with localized tissue reaction or pain; (2) Migration of implant position resulting in injury; (3) Risk of additional injury from post-operative trauma; (4) Bending, loosening, and/or breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; and (7) Bone loss due to stress shielding. The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture or deformity. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risks involved in a second surgery.

5. ADEQUATELY INSTRUCT THE PATIENT.
Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant, and instructed to limit and restrict physical activities, especially lifting and twisting motions and participating in any type of sports. The patient should understand that a metallic implant is not as strong as normal healthy bone and could loosen, bend and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may migrate and damage the nerves or blood vessels. An active, debilitated, or demented patient who cannot properly use weight supporting devices may be particularly at risk during postoperative rehabilitation.

WARNING
In using metallic surgical implants, the surgeon should be aware of the following:
1. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape and design of the implant. The size and shape of the human spine presents limiting restrictions of the size and strength of implants. No implant can be expected to withstand the unsupported stresses of full weight bearing.
2. The surgeon must ensure that all necessary implants and instruments are on hand prior to surgery. The device must be handled and stored carefully, protected from damage, including corrosive environments. They should be carefully unpacked and inspected for damage prior to use.
3. Correct handling of the implant is extremely important. Contouring of the metal devices is to be avoided.
4. All implants and instruments must be cleaned and sterilized prior to surgery.
5. Mixing of dissimilar metals can accelerate the corrosion process. Stainless steel and titanium implants must NOT be used together. The RENOIR™ Posterior Cervical Fixation System should not be used with components from any other system or manufacturer.
6. As with all orthopaedic implants, the RENOIR™ Posterior Cervical Fixation System should never be reused under any circumstances.

7. Proper implant selection and patient compliance to postoperative precautions will greatly affect surgical outcomes. Patients who smoke have been shown to have an increased incidence of nonunion. Therefore, these patients should be advised of this fact and warned of the potential consequences.
8. Postoperative care is important. The patient should be instructed in the limitations of his/her metallic implant and should be cautioned regarding weight bearing and body stress on the appliance prior to secure bone healing.
9. Correct handling of the implant is extremely important. Contouring of the metal devices is to be avoided.
10. The RENOIR™ Posterior Cervical Fixation system has not been evaluated for safety and compatibility in the MR environment. The RENOIR™ Posterior Cervical Fixation system has not been tested for heating or migration in the MR environment.

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 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 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 AND HANDLING
CTL Medical RENOIR™ Posterior Cervical Fixation System 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.

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. Methods of cleaning RENOIR™ 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 pre-cleaning.

Manual Cleaning/Disinfection Procedure
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 brush to gently clean the device until all visible soil has been removed.
2.Remove the device from the enzyme solution and rinse in purified water for a minimum of 3 minutes. Thoroughly flush lumens, holes and other difficult to reach areas.
3.Place prepared cleaning agents in a 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.

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 nylonbristled 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.

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.
•Verify that the instruments are in operation condition.

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 FDA recognized consensus standards such as "ANSI/AAMI ST79 "Comprehensive guide to steam sterilization and sterility assurance in health care facilities" for details regarding the common steam sterilization parameters available on FDA cleared sterilizers used in health care facilities" 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 an FDA-cleared 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 resterilized. Repeated processing cycles that include ultrasonic, mechanical washing and sterilization have minimal effects on CTL Medical implants and instruments.

CAUTION
Federal (USA) Law restricts this device to sale by or on the order of a physician.

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 or surgical technique manual of this system are available at no charge upon request. If further information is needed or required, please contact CTL Medical.

SYMBOL TRANSLATION

CATALOG NUMBER — REF
LOT NUMBER — LOT
QUANTITY — QTY

NON-STERILE — 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 — Rx Only
MANUFACTURER

DATE OF MANUFACTURE
eIFU indicator

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

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

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