Thorecon® Rigid Fixation System

Read this entire package insert carefully prior to use.

Implants and instruments are for single patient use only, on a single occasion. If re-used, single use devices may not perform as intended and could cause serious injury.

United States federal law restricts the use of this device on the order of a physician.

MR Conditional

STERILE, SINGLE-USE IMPLANTS AND INSTRUMENTS
NON-STERILE, SINGLE-USE INSTRUMENTS

IMPORTANT
This information is intended to aid in using this system and is not a reference for surgical technique. Refer to the surgical technique manual for instructions for implantation.

DESCRIPTION
The Thorecon Rigid Fixation System is designed to enhance the stability and strength of traditional sternal closure techniques. Utilizing a unique load-sharing concept, this device can be implant to distribute lateral force across the osteotomy. The devices may be implanted via an open or minimally invasive approach. Where additional stability is desired, devices can be used with traditional monofillament wire or Sternal Cable of similar material.

The Thorecon Rigid Fixation System includes plates (some with integrated cable subassemblies) manufactured from 316L stainless steel (ASTM F138) and screws comprised of 220-13N-5M stainless steel (ASTM F1314). Non-implantable needles and cables to guide the cable around the sternum are manufactured from 420 or Custom 470 stainless steel.

The Thorecon Rigid Fixation System devices are all single-use. The plates, complete with the recommended screws and instruments (screwdriver and tensioner/cutter) required for completion of the surgery, are provided sterile in a kit. Sterile screw multi-packs and a non-sterile cable/plate cutter instrument are also available as replacements and for use during emergent re-entry, if necessary. The devices should be implanted using only the manual surgical instruments designed specifically for the implants in the system.

INDICATIONS FOR USE
The Thorecon Rigid Fixation System is intended for use in the stabilization and fixation of fractures of the anterior chest wall including sternal fixation following sternotomy and sternal reconstructive surgical procedures. The system is intended for use in patients with normal and/or poor bone quality.

CONTRAINDICATIONS
The system is contraindicated, including but not limited to patients with the following:

- Active infection.
- Foreign body sensitivity, allergy, or intolerance. Where material sensitivity is suspected, testing is to be completed prior to implantation.
- Inadequate tissue coverage of implant site.
- Limited blood supply, rapid bone absorption, metabolic bone disease, cancer, tumor, or tumor like condition of the bone, end stage malignant disease, latent infection, or other unexplained disease.
- Severely comminuted fractures.
- Any patient unwilling or incapable of following postoperative care instructions.

WARNING
The same medical/surgical conditions or complications that apply to any surgical procedure may also occur during or following implantation of this device system, including but not limited to infection, nerve damage, and pain which may not be related to the implant. The surgeon is responsible for informing the patient of the potential risks associated with treatment, including complications and adverse reactions. The surgeon may need to perform additional surgery to address any complications or adverse reactions, which may or may not be device related.

Internal fixation devices are internal splints, or load sharing devices that align the fracture until normal healing occurs and aid the surgeon in the alignment and stabilization of bone in the anterior chest wall for fixation of fractures and reconstructive procedures. While these devices are generally successful in obtaining these goals, they cannot be expected to replace normal bone or withstand the unsupported stress placed upon the device by full load bearing. If there is delayed union, nonunion, or incomplete healing of bone; the implant can be expected to bend, break, or fracture. Therefore, it is important that immobilization of the bony segments be maintained until firm bony union (confirmed by clinical and radiographic examination) is established. The size and shape of bones and soft tissue place limitations on the size and strength of implants. Surgical implants are subject to repeated stresses in use, which can result in fatigue fracture. Factors such as the patient’s activity level and adherence to load bearing instructions can affect the service life of the implant. The surgeon must be thoroughly knowledgeable not only of the mechanical aspects of the surgical implants but also must be aware of the mechanical and metallurgical aspects of the surgical implants. If nonunion occurs, revise/remove the system.

- Do not intermix implants of different metallic alloy types. Implant materials are subject to corrosion. Implanting metals and alloys subjects them to constant changing environments of salts, acids, and alkalis that can cause corrosion. Putting dissimilar metals and alloys in contact with each other may be detrimental to the patient and/or function of the implant(s).
- Do not bend, contour, cut, or modify implants unless instructed to do so in the surgical technique manual. Bending or other modifications made to the implant or its component parts increase the risk of fracture or separation.
- Do not implant this device without the appropriate number of screws to achieve bone fixation. Use without the appropriate number of screws may compromise fracture union and increase the risk of migration, dehiscence, patient pain or possible revision surgery.
- Do not use if sterile packaging/implant is damaged or opened prior to use.
- Intraoperative fracture of screws can occur if excessive force (torque) is applied while seating bone screws.
- Avoid over tensioning cables as they may break or fray and may cut through soft bone that is not protected and immobilized.
- Implants may remain in fracture or other non-union has healed. Implants can loosen, fracture, corrode, migrate, cause pain, discomfort, abnormal sensations. If an implant remains implanted after complete healing, the implant may cause stress shielding, which may increase the risk of fracture or recurrence of nonunion in an active patient or due to trauma. The surgeon should weigh the risks versus benefits when deciding whether to remove the implant. Adequate postoperative management to avoid fracture or recurrence of non-union should follow implant removal.
- For plates with integrated cable subassemblies, do not cut or remove cable unless instructed to do so in the surgical technique manual; these plates are not intended for use without cable.
- This device is not intended to withstand sudden dynamic loads associated with accidents or falls.
- Do not place the plate over any other implants such as, but not limited to, plates, wires, screws, or cables.
- Plate position shall not extend across both costal margins. When plating only the sternum, long straight plates should be placed vertically. When extending to anterior rib, the long straight plates may be placed horizontally or at a 45 degree angle to the fracture.
- Instruments are subject to damage during use which may result in significant risks to safety and/or inability to function as intended.
- If instruments are damaged or broken during use, metal fragments can be viewed by radiographic assessment. It is the surgeon’s responsibility to carefully consider the risks and benefits of removing the fragments.
- The fragment resection in the patient, it is recommended that the surgeon advise the patient of specific information regarding the fragment material, including size and location and the potential risks associated with the retained fragment.

PRECAUTIONS
Prior to surgery, consider preoperative and operating procedures, including knowledge of surgical techniques, proper selection and placement of the implant.

It is important to be aware of the overall stability of the closure and use as many devices as necessary to achieve adequate fixation based on a surgeon’s assessment for each patient. It is recommended to use a minimum of five cross-stermal elements (e.g., plate cross members, cable cerclages, or wires) when fusing after a sternotomy.

Sterile, single-use implants and instruments should not be re-sterilized or re-used. The non-sterile, single-use cable/plate cutter must be sterilized before use but cannot be re-sterilized or re-used.

Instruments are available for the implant system to aid in the accurate implantation of internal fixation devices. Use of other manufacturer instruments can involve unevaluated risks for the implant and instrument, thereby potentially endangering the patient, user, or third party.

Damage, including notches or scratches to the implant during the course of surgery, may contribute to breakage. If the plate is bent, scratched, or if the cables cannot be properly applied, discard the implant and replace with a new implant. It is important to be aware of the overall stability of the closure and use as many devices as necessary to achieve adequate fixation based on a surgeon’s assessment for each patient.

Bone Plates
Ensure adequate approximation and alignment of bony anatomy prior to final cable and screw fixation. When plating transverse fractures, take care to avoid placing screws on or near the fracture line. Span the fracture with a plate that appropriately fits the anatomy.

To minimize emergent re-operation, avoid placing non-cuttable portions of the sternal plates over the sternotomy line. The cerclage area should not be cut.

Bone Screws
The screwdriver which has been designed for a particular system of screws must always be used to be sure that proper screwdriver/screw head connection is achieved. Incorrect alignment or fit of the screwdriver to the screw head may increase the risk of damage to the implant or screwdriver. Screw head must be removed if necessary to verify their connection to the plate. The recommended screws may increase the risk of screw backout or compromise their intended function. Excessive torque can cause the screw to fracture.

Cable
Prior to removing tensioner, care should be taken to ensure that the set screw has been fully seated according to the operative technique. To remove excess cable after crimping, use the driver to advance the cable cutting lever of the tensioner. When using electrocautery, e.g. “Bovie,” to suppress bleeding near the sternum, be mindful not to touch the cables as the multi-flament strands may fray.

POSSIBLE ADVERSE EFFECTS
These effects may or may not be device related:

- Poor bone formation, osteoprosis, osteolysis, osteomyelitis, inhibited revascularization, neurovascular, or infections can lead to loosening, bending, backout, or fracture of the implant.
- Migration, bending, cracking, fracture, fraying, kinking, disassembly, backout, or loosening of the implant with or without related loss of fracture reduction or control.
- Metal sensitivity, or allergic reaction to a foreign body.
- Irritation or inflammation of soft tissue structures surrounding implant.
- Increased fibrous tissue response around the fracture site and/or the implant.
- Bone formation surrounding the implant making removal difficult.
- Foreign body reaction causing possible tumor-like condition.
- Decrease in bone density due to stress shielding.
- Infection.
- Inadequate healing.
• Use implants and instruments on a single occasion for a single patient only. Once sterile implants and instruments are opened, they must be used for the current procedure or discarded.
• Do not use past expiration date specified on the product label.
• Do not use if the implant is scratched, notched or altered.
• Do not use if packaging is damaged.
• Do not use if there are discrepancies in label information.
• Promptly report all product defects and patient adverse events to the manufacturer (See Complaints Section).

STERILIZATION
The system implants and instruments, (except for the cable/plate cutter) are provided sterile by gamma irradiation. Sterile implants and instruments must not be re-sterilized.

See Association of Operating Room Nurses (AORN) recommended practices and ISO 8828 for guidelines related to proper care and handling of surgical devices while sterilizing per the provided instructions.

Cable/plate cutter (Non-sterile instrument):
• Instrument is provided clean if taken directly from an unopened package and must be sterilized per the below instructions prior to introduction into a sterile surgical field (if applicable) return to the manufacturer.
• Unless just removed from an unopened package, the instrument must not be sterilized.
• Prior to and during use, including sterilization, inspect instrument for:
  - Damage such as, but not limited to, discoloration, corrosion, cracking, fracture, or unrecognizable markings.
  - Proper function including, but not limited to, sharpness, movement of hinges and couplings, joint stability, and legible markings.
• An instrument that shows signs of damage or an inability to function should not be used and should be returned to the manufacturer.

ISO 8828 or AORN recommended practices for in-hospital sterilization should be followed for all instruments. Use of an FDA cleared (or equivalent) wrap is recommended to ensure product sterility.

Steam sterilization (moist heat) is the only method permitted for sterilization. Other sterilization methods are not permitted. The values specified here (duration / temperature) can achieve a Sterility Assurance Level (SAL) of at least 10^-6.

Independent testing has shown the following minimum conditions to be effective.

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LIMITED WARRANTY
THIS LIMITED WARRANTY GIVES THE ORIGINAL PURCHASER SPECIFIC LEGAL RIGHTS. THE ORIGINAL PURCHASER MAY HAVE ADDITIONAL OR ALTERNATIVE LEGAL RIGHTS. THE LEGAL MANUFACTURER OF THE PRODUCT, AS REFLECTED ON THE PRODUCT LABEL (THE “MANUFACTURER”), EXTENDS THIS LIMITED WARRANTY TO THE ORIGINAL PURCHASER OF THE PRODUCT. SUCH WARRANTY DOES NOT EXTEND TO ANY SUBSEQUENT TRANSFEREE OF THE PRODUCT. THIS LIMITED WARRANTY COVERS MALFUNCTIONS OR DEFECTS IN MATERIALS AND WORKMANSHIP FOR A PERIOD OF ONE (1) YEAR FROM THE DATE OF PURCHASE, OR FOR THE REMAINING SHELF LIFE, WHICHERSOEVER IS LESS (THE “LIMITED WARRANTY PERIOD”). WITHIN SUCH TIME, ANY SUCH MALFUNCTIONS OR DEFECTS OCCURRING IN THE PRODUCT DURING THIS LIMITED WARRANTY PERIOD, THE ORIGINAL PURCHASER’S REMEDY SHALL BE LIMITED AS FOLLOWS:

1. A PRODUCT REPAIR REPAIR SUCH PRODUCT (OR PART THEREOF) AT NO CHARGE; OR (B) REPAIR THE ORIGINAL PURCHASER THE PURCHASE PRICE PAID FOR SUCH PRODUCT. UNDER THIS LIMITED WARRANTY, THE MANUFACTURER ALSO EXPRESSLY DISCLAIMS ALL IMPLIED WARRANTIES AND CONDITIONS OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE SPECIFICALLY EXCLUDED. IF AND TO THE EXTENT A JURISDICTION DOES NOT ALLOW EXCLUSION OF IMPLIED WARRANTIES IN A LIMITED WARRANTY, THE MANUFACTURER ADDITIONALLY LIMITS THE DURATION OF ANY IMPLIED WARRANTY TO THE DURATION OF THE LIMITED WARRANTY PERIOD. UNDER THIS LIMITED WARRANTY, NO WARRANTIES WHETHER EXPRESS OR IMPLIED, WILL APPLY AFTER THE LIMITED WARRANTY PERIOD HAS EXPIRED. THE MAXIMUM AMOUNT OF THE MANUFACTURER’S LIABILITY UNDER THIS LIMITED WARRANTY WILL BE NO MORE THAN THE PURCHASE PRICE PAID FOR THE PRODUCT THAT IS THE SUBJECT OF ANY CLAIM UNDER THIS LIMITED WARRANTY. UNDER THIS LIMITED WARRANTY, THE MANUFACTURER DOES NOT ACCEPT ANY LIABILITY BEYOND THE REMEDIES PROVIDED IN THIS LIMITED WARRANTY, OR FOR CONSEQUENTIAL OR INCIDENTAL DAMAGES, INCLUDING, WITHOUT LIMITATION, ANY LIABILITY FOR THIRD-PARTY CLAIMS FOR DAMAGES, THIS LIMITED WARRANTY IS SUBJECT TO THE LAWS OF THE COUNTRY (WITHOUT REFERENCE TO ITS CONFLICTS OF LAW RULES) WHERE THE MANUFACTURER OF THE PRODUCT IS REGISTERED SEAT OF BUSINESS. ANY AND ALL DISPUTES IN RELATION TO THIS LIMITED WARRANTY SHALL BE EXCLUSIVELY CONFERRED TO THE COURTS IN SUCH REGISTERED SEAT OF BUSINESS OF THE MANUFACTURER.

COMPLAINTS
Complaints or dissatisfaction with this device concerning quality, safety, reliability, durability, effectiveness and/or performance, brought forth by a health care professional, whether via a customer or user of the device, should be immediately conveyed to the attention of the manufacturer via telephone, fax or written correspondence sent to the address listed below. It is important to note that when filling a complaint, the following information must be included for the manufacturer to properly respond to the complaint:

Name and address; nature of the complaint; the device(s) trade name and catalog number; applicable lot number(s); effect on the patient; and notification of if a written response and report from the manufacturer is being solicited.

FURTHER INFORMATION
Recommended surgical operative techniques and uses for the products are available at no charge upon request. Should subsequent information be requested or required, please contact the manufacturer.

MANUFACTURER
A&E MEDICAL CORPORATION
5206 Asbury Road, P.O. Box 758
Farmingdale, NJ 07727 USA
www.aemedical.com

The Instructions for Use and a comprehensive symbol glossary can be found at http://www.aemedical.com/quality

SYMBOL DEFINITIONS

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*Caution, consult instructions for use*