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.

Rx only

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

MR

MR Conditional

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

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, the devices can be implanted 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 monofilament 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 22Cr-13Ni-5Mn stainless steel (ASTM F1314). Non-implantable needles, used to guide the cable around the sternum are manufactured from 420 or Custom 470 stainless steel.

Thorecon Rigid Fixation System devices are all single-use. The plates, complete with the necessary screws and instruments (screw driver 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.

WARNINGS
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 attaining these goals, they cannot be expected to replace normal healthy 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 in the medical and surgical aspects of the implant, 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 device function 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 be removed after fracture or other bony 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 refracture or recurrence of non-union 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 refracture 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 plates 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 with cuttable sections over 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 retrieving the fragments.
    - If the fragment is retained 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-sternal 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 facilitate emergent reentry, 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. Screws must be fully seated to verify their connection to the plate. Unseated 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-filament strands may fray.

POTENTIAL ADVERSE EFFECTS
These effects may or may not be device related:
- Poor bone formation, osteoporosis, osteolysis, osteomyelitis, inhibited revascularization, nonunion, delayed union, or infection 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 dislocation.
- 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.

- Pain, discomfort, abnormal sensation, or palpability due to the presence of the device.
- Necrosis of bone, cessation of growth of the operated portion of the bone, possible neurovascular compromise, disruption of blood circulation, and/or vessel damage due to improper cable placement and/or improper assembly of the system's components.
- Selection of screws which are longer than the depth of the sternum may cause possible impingement on structures internal to chest wall including vessels, pleura and other structures.

MAGNETIC RESONANCE IMAGING (MRI) SAFETY INFORMATION

Non-clinical testing and MRI simulations were performed to evaluate the entire family of Thorecon Rigid Fixation System devices. Non-clinical testing demonstrated the entire family of these products are MR Conditional. A patient with this implant can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 T and 3 T, only
- Maximum spatial field gradient of 1440 gauss/cm (14.4 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of <2 W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode

Under the scan conditions defined, an implant from this device system is expected to produce a maximum temperature rise of 5.7°C after 15-minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the image artifact caused by an implant from this device system extends approximately 15 mm from this device when imaged with a gradient echo pulse sequence and a 3-Tesla MR system.

POSTOPERATIVE CARE

Adequately instruct the patient of the benefits and risks of the system, general surgical risks, complications, possible adverse effects and to follow the instructions of the treating physician, prior to, and after the surgery. Postoperative care is important as is providing clear directions and warnings and obtaining the utmost compliance from the patient postoperatively. The patient's ability and willingness to follow instructions is one of the most important aspects of successful management of fracture or other non-union. Patients with senility, mental illness, alcoholism, or drug abuse may be at higher risk of device failure since these patients may ignore instructions and activity restrictions. If appropriate, restrict patient's mobility at the fusion region, and instruct the patient in the use of external supports and braces that are intended to immobilize the site of the fracture. Provide the patient with load bearing restrictions. General information that may be provided to the patient on the use and limitation of these devices include the following:

- The device does not replace normal healthy bone and that the device can fracture, bend or be damaged because of stress, activity, load bearing or inadequate bone healing.
- The medical device cannot withstand dynamic loads from falls or accidents.
- Regular postoperative follow-up examination is required as long as the device remains implanted.
- If the sternum does not heal, the device will not remain intact indefinitely; the device may fracture.
- Contact the physician immediately if they experience unusual pain, severe discomfort, or fever.
- The implant is a temporary device designed to stabilize/ secure the bone fracture(s) and augment the process of healing after which time, if conditions are unfavorable, the device may be removed.
- Warn patient against sudden changes in position, strenuous activity, falls, smoking, consuming alcohol or drugs not prescribed by the physician, steroids, non-steroidal anti-inflammatory agents, aspirin, and mechanical vibrations that may loosen the devices.
- The implanted components are comprised of 316L Stainless steel and 22Cr-13Ni-5Mn Stainless steel.

GENERAL INSTRUCTIONS FOR USE

It is important to read and understand the following instructions prior to clinical use. Improper preparation technique may adversely affect the success of the surgical procedure.

- 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.
- Inspect the product, including all packaging and labeling materials carefully:
  - 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 or (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.

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	Pre-vacuum (Wrapped)	132° C (270° F)	4 Minutes	30 Minutes

LIMITED WARRANTY

THIS LIMITED WARRANTY GIVES THE ORIGINAL PURCHASER SPECIFIC LEGAL RIGHTS. THE ORIGINAL PURCHASER MAY HAVE ADDITIONAL OR ALTERNATIVE LEGAL RIGHTS UNDER CONTRACT OR STATUTE, WHICH VARY FROM JURISDICTION TO JURISDICTION. NOTHING IN THIS LIMITED WARRANTY SHALL BE CONSTRUED AS LIMITING SUCH 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, WHICHEVER IS LESS (THE "LIMITED WARRANTY PERIOD"). WITH RESPECT TO ANY SUCH MALFUNCTIONS OR DEFECTS OCCURRING IN THE PRODUCT DURING THIS LIMITED WARRANTY PERIOD, THE ORIGINAL PURCHASER'S REMEDY SHALL BE LIMITED AS FOLLOWS: THE MANUFACTURER, IN ITS SOLE DISCRETION, WILL EITHER: (A) REPAIR OR REPLACE SUCH PRODUCT (OR PART THEREOF) AT NO CHARGE; OR (B) REFUND TO THE ORIGINAL PURCHASER THE PURCHASE PRICE PAID FOR SUCH PRODUCT. UNDER THIS LIMITED WARRANTY, ALL OTHER EXPRESS AND IMPLIED WARRANTIES FOR THE PRODUCT, INCLUDING BUT NOT LIMITED TO ANY 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 HAS ITS 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 other written correspondence sent to the address listed below. It is important to note that when filing 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
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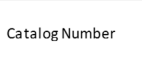
Farmingdale, NJ 07727 USA
www.aemedical.com

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

Symbol Definitions			
	Catalog Number		Batch Code
	Contains or Presence of		Do Not Reuse
	Do Not Use if Package is Damaged		Caution, consult instructions for use
	Use-By Date		Manufacturer
	Non-Sterile	STERILE R	Sterilized using irradiation
	MR Conditional	Rx only	Prescription Only
	Do not resterilize		