IFU-ID: G547004 USA

Instructions for Use

Stern-a-Fix Sternal Closure System

Rev.: 2020-06-02

NON STERILE

Rx only

medicon®

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EN

STERN-A-FIX STERNAL CLOSURE SYSTEM

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The directions for use have to be read carefully before clinical use and stored safely and ready to hand. The instructions contained therein must be observed. MEDICON eG assumes no liability for the use until an appropriate introduction has been carried out.

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1. GENERAL NOTES

NON STERILE

The implants and instruments are supplied unsterile and must be disinfected, cleaned and sterilized prior to use. Please observe the following instructions. These will ensure accurate and reliable functioning of the product.

MEDICON implants are manufactured from pure titanium or Titanium alloy.
Both materials are biocompatible, corrosion-proof and nontoxic in the biological environment. They allow imaging virtually free of artifacts.
- conventional x-ray radiography
- computer tomography
- MRI (Magnetic Resonance Imaging).

The surface is chemically passive and the material is antimagnetic.

The MEDICON "Stern-a-Fix Sternal Closure System" may be used only by surgeons with proper experience in cardiothoracic surgery.

2. INDICATIONS FOR USE

The MEDICON "Stern-a-Fix Sternal Closure System" is intended for use in stabilization and fixation of anterior chest wall fractures including sternal fixation subsequent to sternotomy and sternal reconstructive procedures.

3. CONTRAINDICATIONS

Contraindications of the MEDICON "Stern-a-Fix Sternal Closure System" include but are not limited to:
- Active infections
- Patients with insufficient or low-quality of bone, with perfusion problems or latent infections
- Severe osteoporosis
- Limited blood supply
- Other skeletal sections for which it is not intended
- Patients who are unable to comply with the instructions for postoperative care, for example due to psychological, mental or neurological problems
- Patients in an unstable physical and/or mental condition
- Proven allergy to titanium
- Material hypersensitivity, i.e. reaction of the patient to foreign bodies. Here appropriate tests are mandatory before implantation (even in case of mere suspicion!)
- Use with components of other systems.
- Multiple uses

4. POTENTIAL SIDE EFFECTS AND COMPLICATIONS

Possible undesired effects and complications associated with the MEDICON "Stern-a-Fix Sternal Closure System" include:
- Insufficient adaptation of the implants can lead to bone fusion delay or failure.
- Failure of the implants due to nonunion or delayed union
- Failure of the implants due to insufficient bone fusion or insufficient reinforcement of the area operated on and thus absence of mechanically stable conditions
- Complaints, pains, abnormal sensations or palpability of implants.
- Material/foreign-body sensitivity of the patient with allergic reactions.
- Stronger connective-tissue reaction in the fracture region or in the vicinity of the implant
- Delayed or insufficient fracture healing leading to possible implant failure.
- Inadequate healing
- Insufficient bone formation, osteolysis, osteoporosis, reduced revascularization or infection, which can lead to loosening, bending, breakage or rupture of the implants
- Breakage, bending, migration or loosening of the implants
- Reduced bone density due to "stress shielding"
- Loosening of the implants as a result of insufficient screw tightening
- Osseous necrosis, osteoporosis, inhibited revascularization, bone-resorption, and poor bone formation, which can cause premature loss of fixation leading to non-union
- Extreme or repeated bending of the plates in the same area can result in plate breakage
- In the event of a lack of cooperation on the part of the patient or where cooperation cannot possibly be obtained, pseudarthrosis formation and/or implant failure and dislocation may occur
- Loosened implants can lead to secondary irritations or injury to adjacent anatomical structures
- Selection of the wrong size of implants can lead to secondary disorders
- Material/foreign-body hypersensitivity of the patient in the form of allergic reactions
- Discomfort, pain, abnormal sensations due to the implant
- Breaking, bending, migration, loosening of the implant and/or further surgical intervention to remove the system
- Early or late infections
- Neurological damage resulting from the surgical trauma or the presence of the implant
- Vascular damage, above all in the region of the operative access, as a result of surgical trauma

Vascular damage may lead to life-threatening or fatal hemorrhages. Incorrectly positioned implants in the vicinity of large blood vessels may erode these vessels and lead to life-threatening hemorrhaging in the late postoperative period. If the MEDICON "Stern-a-Fix Sternal Closure System" remains in the body after full recovery, in rare cases the following complications may occur, either individually or collectively:
- Corrosion with localized tissue reaction or pain
- Changes in the position of the implant with consequent injuries
- Risk of additional injuries due to postoperative trauma
- Bending, loosening and/or fracture, making follow-up operations more difficult
- Pain, discomfort or non-physiological sensations due to the presence of the product
- Potentially increased risk of infection
- Bone loss caused by stress shielding

This surgical procedure may cause not only the above-mentioned side effects and complications but also problems such as injuries to nerves, infections, pain etc., which are not necessarily caused by the implant.

In the selection of patients, the following factors should be observed that promote possible adverse events and complications:

Patient weight:
- Excess body weight or obesity of a patient can increase the load on the implant in such a way that failure is more likely.

Occupation or activity of the patient:
- Heavy lifting, severe muscle strain, strong turning, twisting and bending and manual labor should be avoided in private or professional activities until to the bones have healed completely. Even after complete healing, the patient may no longer be able to successfully perform the activities listed above.

Senility, mental illness, alcoholism or drug abuse:
- These circumstances may contribute to the patient ignoring certain restrictions or precautions that the implant calls for. This can lead to failure of the implant or other complications.

Sensitivity to foreign bodies:
- Preoperative testing may not entirely exclude hypersensitivity or allergy. Such complications may occur even if the implant has already been in the body for some time.

Smoking:
- In smokers, a higher rate of pseudarthroses was found after surgical procedures where bone implants were used. Smoking-induced progressive degeneration of adjacent segments can lead to later clinical failure (intermittent pain), even if initially successful stiffening of the bone has occurred and clinical improvement has been demonstrated.

In addition to the undesirable effects and complications already mentioned, the surgical procedure can lead to other problems such as nerve damage, infections, pain etc. that cannot be attributed to the implant.

5. SINGLE-USE PRODUCT

Implants are intended and designed for single use on one patient only and may not be reused.

Under no circumstances may a removed implant be reused. Even if the implant appears to be intact or fully functional, there may be wear, minor defects and attrition due to overuse that are not visible to the naked eye.
As the impact of the forces and conditions inside the body on the stability, function and material quality of an implant cannot be anticipated, re-implantation of a removed implant would entail the risk of premature wear or failure and is therefore unacceptable. The user will be held liable if the operating instructions are not observed.

6. CT AND MRI INSTRUCTIONS

Implants:
The safety, compatibility, and heating of the implants in the MR environment have not been tested. The responsible physician is responsible to inform the patient that they carry an implant that has not been tested under MR conditions. It is then the responsibility of the patient to inform the treating physician prior to an MR examination.
We recommend the surgeon to provide the patient with an implant passport after completion of the implantation. The implant passport can be requested from MEDICON. The patient hands the implant passport to the responsible personnel, who can use it as a source of information.

Instruments:

MR

The instruments intended for use with the MEDICON "Stern-a-Fix Sternal Closure System" present a risk in the vicinity of CT or MRI scanners. The individual instruments must not be in the vicinity of these devices during application of these procedures.

7. IMPLANT SELECTION

The surgeon is responsible for the correct selection of implants.

The following aspects are critical for the correct selection of implants:
- indication,
- body weight of the patient,
- physical condition, age and activity level of the patient

Incorrect implant selection can lead to premature implant loss and cause loosening, deformations and fractures of the implants. Failure to use the proper component to maintain adequate blood supply and provide rigid fixation may result in loosening, bending or fracturing of the product and/or bone.
The success of an operation also depends on how the implants are handled. The plates must be bent carefully and cautiously, avoiding repeated and extensive deformation. Damage and scratches reduce the stability of the implants and result in early fatigue of the implant material. MEDICON implants and instruments have been designed for being used together. Using implants or instruments from other manufacturers in conjunction with MEDICON products entails unpredictable risks since the products will not be matched to each other. This may also cause danger to the patient, the surgeon or third parties. Post-operative care and the patient's ability to follow instructions are important aspects of any successful bone healing. Prior to applying the products, the surgeon must thoroughly discuss with the patient the intended outcome of the operation. The patient must be aware of the temporary limitations enforced by the implant and be instructed to avoid or limit any physically strenuous activities, especially lifting and turning movements, as well as participation in sporting activities. The patient must be aware that a metal implant is not as strong as a normal, healthy bone and that excessive strain – particularly with incomplete healing of the bone – can result in loosening, bending and/or breaking.
The patient must also be informed that a loss of function of the implants may still occur, even if he or she follows these instructions. Displaced or damaged implants may migrate and damage the nerves or blood vessels. Active, weakened or demented patients who are unable to follow post-operative instructions properly are particularly at risk during post-operative rehabilitation. Due to the limited stability of the fixation, the patient must be informed that the fixation site must not be put under the full body weight.
The patient must be instructed to inform the surgeon immediately if they notice unusual changes in the situs. The patient must be monitored carefully if there is a manifest change in the fixation region. The surgeon must consider possible consequences, e.g. implant failure, and discuss with the patient any necessary measures for further healing. In cases of failed, delayed or insufficient fracture union, the incidence of implant bending, implant failure or implant breakage cannot be excluded.
The MEDICON Stern-a-Fix Sternal Closure implants serve as internal fixation devices until bony fusion has occurred. The implants are intended to temporarily reinforce a segment of the sternum until the bone has fused and may not last indefinitely due to anatomical limitations and modern surgical materials.
We can therefore assume liability for the implants only until healing is fully completed. The decision whether the implants should remain in the body or be removed after full healing is the responsibility of the surgeon and has to be made by the surgeon after weighing up the risks and benefits. After implant removal the risks have to be minimized through adequate post-operative care.
The risk from implants remaining in the body can be increased in active patients. After implant removal the surgeon is responsible for disposing of the implants according to the standard. It cannot be excluded that implants will break, loosen, corrode, migrate through tissue and cause pain. The packaging label carries a Lot Number. We recommend copying this Lot Number to the patient records as this number allows tracing the production history of the implant back to the raw material.

8. APPLICATION AND HANDLING OF PLATES

Before being implanted, all implants must be checked for function, deformation and mechanical integrity. Damaged implants must be replaced, as they can lead to a reduction in or even loss of function. Always choose the implants that best suit the specific situation and indication. The plates have to be adapted to the natural or planned bone contours as precisely as possible. For adapting the plates, use the instruments provided by MEDICON. Cold straining of the material occurs during the plate bending procedure, under which the titanium increases in hardness, but simultaneously loses deformability. Therefore, it is absolutely necessary to achieve the required plate shape in as few bending steps as possible. Excessive bending can lead to postoperative plate breakage. Overly aggressive application of bending instruments can result in visible damage of the plates. When such damage has occurred, a new plate must be selected and adapted more cautiously.
Deformed plate holes for the screws entail not only an increased risk of breakage at the location of the holes; they also damage the locking function and compromise the precise seating of the screw head in the plate. It is recommended to use the intended bending protection screws during the plate bending process to avoid deformation of the plate holes and threads. Deformed plates must be inspected for notches, deformed threads and screw holes and other mechanical damage prior to application. Make sure that implants are positioned correctly with the aid of imaging procedures. If subjected to great stress, the implant can become overloaded and break. Solid and correct connection between the plates and screws must be checked and ensured during surgery. The MEDICON "Stern-a-Fix Sternal Closure System" can become loose and subsequently displaced in the screws are not fastened properly. A displaced implant can migrate and damage nerves or blood vessels.

9. APPLICATION AND HANDLING OF SCREWS

Self-drilling screws usually do not require to drill a hole. If the bone is very dense and hard, it may be necessary to drill holes. To apply the drill holes, only use the respective drill designated by MEDICON for the specific screw, so that the correct drill hole diameter for the screw is obtained. Only use drill bits with sharp cutting edges. During drilling, there is a risk of heat damage to the bone. Therefore, only work with a low drill speed and always ensure sufficient cooling during the drilling procedure. Excessive

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application of force during the drilling procedure can lead to drill breakage, endangering the patient, the surgeon and others. If, due to a failed drilling procedure or a slack drill hole, the screw cannot be anchored firmly in the bone, the emergency screws intended for this purpose must be used. To ensure that the screwdriver blade is firmly seated in the screw head, axial force must be applied when inserting the screwdriver into the screw head. This ensures the correct axial alignment of screw and screwdriver, and prevents slipping of, or damage to the screw head or the screwdriver blade. Application of excessive fore in tightening the screws can lead to screw breakage during the procedure.
Wear of the screwdriver blade will impair the firm connection between blade and screw. Whenever such wear is detected, the screwdriver blade must be replaced. Screws have a locking mechanism. Once the implantation has been completed, the secure connection between every screw and plate must be checked. If necessary, retighten the screws. Prior to implant removal, all screw heads must be cleaned carefully, using a scalpel or another suitable instrument, so that the screwdriver can be optimally seated in the screw head.

10. APPLICATION AND HANDLING OF INSTRUMENTS

The instruments intended for application of the system are subject to wear and tear and mechanical strains even when used normally, but even more so when applied with excessive force. To prevent failure of, or mechanical damage to the instruments during the operation, prior to each use the instruments must be inspected to make certain they are mechanically intact, not deformed, and fully functional. Do not use instruments that were found to be damaged, deformed or not fully functional.

11. DECONTAMINATION, CLEANING, STERILIZATION

Instruments made of stainless steel must not be placed in physiological saline solution (NaCl solution) as prolonged contact leads to corrosion such as pitting and stress corrosion cracking.
Only cleaned and disinfected implants and instruments may be sterilized.

Location of use:
Implants that have been contaminated by blood and/or secretions or are suspect to be contaminated must not be placed back in the storage tray and reprocessed. They have to be disposed in a suitable with contaminations caused by blood and/or secretions must not be placed back into the implant storage tray. These must be disposed in a suitable container. Instruments that have been contaminated by blood and/or secretions or are suspect to be contaminated must not be cleaned in the implant/instrument tray. They have to be cleaned separately and after proper cleaning they can be placed in the implant/instrument storage tray.

Limitations on reprocessing:
The implants may only be brought in contact with a patient once and must not be reprocessed. Instruments can be reprocessed using the following validated methods described below. Frequent reprocessing has little effect on these instruments.
These instruments should not be processed together with other contaminated/soiled instruments and materials.

Preparation for decontamination:
Before manual/machine cleaning the instruments have to be taken out of the implant/instrument tray storage tray. The screwdriver blade has to be removed from the screwdriver handle. Place the lid back onto the implant/instrument tray.
The implant/instrument storage tray must be placed in instrument holders suitable for machine cleaning. The instrument holders (e.g. wire basket) must allow subsequent cleaning in a sonication unit or in the cleaning and disinfection device (CDD) when they are not impeded by acoustic or rinsing shadows. Instruments should be cleaned as soon as practical to ensure ease of cleaning according to the health care facility's infection control and hazardous waste management procedures.

Manual Cleaning:
Implant tray:
- Rinse the products under cold running water to remove visible soil.
- Use a soft bristled brush and lumen brush to aid in removal of visible soil while rinsing.
- Using a syringe, flush hard to reach areas while rinsing.
- Prepare Enzol® enzymatic detergent at 1oz. per gallon warm tap water.
- Immerse the tray to soak for 1 minute into Enzol® enzymatic detergent.
- Following the soak time, brush the implant tray with a soft bristled brush and lumen brush for a minimum of 1 minute to remove soil residuals.
- Using a syringe, flush hard to reach areas with the detergent solution.
- Remove the implant tray from the enzymatic detergent solution and rinse under running tap water to remove detergent residuals.
- Prepare a neutral detergent Valsure® neutral in a sonication unit at ¼ oz. per gallon of warm (37 - 40 °C / 98.6 - 104 °F) tap water. Immerse in the sonication unit and actuate.
- Allow the implant tray to sonicate for 10 minutes.
- Remove the implant tray from the sonication unit and rinse it under cold distilled water to remove detergent residuals.
- Dry the implant tray completely using medical compressed air and disposable, lint-free cloths.

Instruments:
- Rinse instruments under cold running tap water for at least one minute to remove visible soil and actuate movable parts while rinsing. Use a soft bristled brush and lumen brush to aid in removal of soil while rinsing and actuate movable parts while brushing. Use a syringe to flush the lumen (internal spaces, threads, and holes) with rinse water.
- Prepare Enzol® enzymatic detergent at 1 oz. per gallon of warm tap water and immerse instruments to soak for at least one minute.
- Following the soak time, brush the instruments with a soft bristled brush and lumen brush for a minimum of one minute to remove soil residuals.
- Using a syringe, flush internal spaces, threads, and holes with the enzymatic detergent solution.
- Remove the instruments from the enzymatic detergent solution and rinse under running tap water to remove detergent residuals.
- Prepare a neutral detergent Valsure® neutral in a sonication unit at ¼ oz. per gallon of warm (37 - 40 °C / 98.6 - 104 °F) tap water. Immerse in the sonication unit and actuate.
- Allow the instruments to sonicate for at least 10 minutes.
- Remove the instruments from the sonication unit and rinse them under cold distilled water to remove detergent residuals.
- Dry the instruments completely using medical compressed air and disposable, lint-free cloths.

Machine Cleaning:
Implant tray and Instruments:
- Rinse the products under cold running tap water to remove visible soil.
- Use a soft bristled brush and lumen brush to aid in removal of visible soil while rinsing.
- Using a syringe, flush hard to reach areas while rinsing.
- Prepare a neutral detergent Valsure® neutral in a sonication unit at ¼ oz. per gallon of warm (37 - 40 °C / 98.6 - 104 °F) tap water. Immerse in the sonication unit and actuate.
- Using a syringe, flush hard to reach areas with the detergent solution and then allow the implant tray and instruments to sonicate for 10 minutes.
- Transfer the implant tray and the instruments in the cleaning and disinfection device (CDD) and choose the following cycle parameter:

Phase	Time (minutes)	Temperature	Detergent
Pre-Wash 1	2:00	Cold tap water	N/A
Enzyme Wash	2:00	Hot Tap water	Enzol enzymatic (1 oz/gallon)
Wash 1	2:00	65.5 °C / 150 °F	ValSure neutral (¼ oz/gallon)
Rins 1	0:15	Distilled water	N/A
Drying	6:00	98.8 °C / 210 °F	N/A

Maintenance, Inspection and Testing:
After cleaning, the implants and instruments must be macroscopically clean; free from visible residues and soiling. Inspection is performed visually. Insufficiently cleaned implants and instruments must be cleaned again and then adequately rinsed and dried. Deformed or damaged implants and instruments must be removed and disposed of, as they can no longer be guaranteed to be safe to use.

Packaging:
The implant tray and instruments must be placed in a suitable sterile barrier system. The sterile barrier system must meet the following criteria:
- The implant tray and instruments may be wrapped in standard medical grade, steam sterilization wrap using the AAMI double wrap method or equivalent.

The packaging for terminally sterilized medical devices should fulfill the following requirements:
- AAMI/ANSI/ISO 11607
- Suitable for steam sterilization (temperature resistance up to at least 141 °C / 286 °F, sufficient steam permeability).
- Sufficient protection of the implant tray and instruments as well as of the sterilization packaging to mechanical damage.
- Sterilization equipment and sterilization wrapping must match both the wrap contents and the employed sterilization method.

Sterilization:
The following sterilization instructions are applicable for all implants and instruments of the MEDICON "Stern-a-Fix Sternal Closure System". All implants and Instruments are provided non-sterile and must be sterilized prior to use. The implants and instruments should be placed in the appropriate sterilization case in the designated location for each implant/instrument. Use the following sterilization procedure and parameters to achieve effective sterilization:

Cycle type	Temperature	Exposure Time	Dry time
Pre-vacuum (steam)	132 °C / 270 °F	4 minutes	30 minutes

It is essential to attain a sterility assurance level of 10^{-6}.

When sterilizing several products at the same time in one steam sterilizer:
- Make sure that the maximum allowable load capacity of the steam sterilizer, as specified by the manufacturer, is not exceeded.

Storage:
After sterilization, the medical devices must be stored in the sterilization packaging in a dry, dark, cool and semi-sterile place, protected from dust and free from vermin. To avoid the development of condensation, major temperature fluctuations should be avoided during storage. Chemicals must not be stored together with instruments and implants. The walls, floors, and ceilings of the storage room should be smooth and easy to clean and disinfect. Shelves must be at least 30 cm off the floor. The duration of storage permitted depends on the type of sterile barrier system employed and storage condition. This storage period must me established by the operating authority. Sterile packaging should be carefully examined prior to opening to ensure that package integrity has not been compromised.

Disposal:

National regulations have to be considered when disposing the products, its components and its packaging.

Further information on reprocessing:
Validated machine cleaning and disinfection is always preferred over manual cleaning because of the greater certainty of the method. Good cleaning helps to preserve value and us a precondition of successful sterilization. During machine processing, the following points should be noted:
- Correct loading of the storage trays for rinsing is a precondition for effective machine processing. Storage trays must not be overloaded.
- Rinsing shadows due to large instruments must be avoided.

The times and temperatures specified in these reprocessing instructions are minimum requirements and must not be less than those stated here. If they are to be reduced for technical reasons, this must be validated by the operating authority. Exceeding the stated times and temperatures is always possible but leads to increased stress on the material, which may result in premature ageing of the instruments. The use of other sterilization methods is outside our responsibility.

Information on validation processing:
Validation was performed with the following equipment, materials, and chemicals:

Cleaning/Disinfection Device (CDD):	Steris Genfore washer/disinfector
Cleaning agent:	Enzol® enzymatic
Neutralizer:	Valsure® Neutral detergent
Ultrasonic bath:	Bronson sonicator
Sterilizer:	Steris AMSCO LV250
Wrapping:	Kimguard KC600
Additional equipment:	Lumen brushes, soft bristled brushes, syringes

Legally marketed and validated washers/disinfectors with the specified cycle parameters/conditions can be used optionally.

Note:
The user is responsible for the actual processing achieving the desired results with the equipment, materials, and staff employed in the processing facility. Usually, this requires validation and routine monitoring of the method. If the previously described equipment, materials, and chemicals are not available, it is the responsibility of the user to validate his method accordingly. Please note the instructions and regulations of the relevant national regulations and standards and any instructions for use accompanying the medical device. MEDICON eG reserves the right to modify these instructions whenever new information is obtained.

11. LIABILITY
The information in these instructions for use applies only to the product with which the instructions for Use is supplied. Only the latest revision of the instructions for use applies. Due to constant technical development the contents of these MEDICON instructions for use are updated regularly. Please use the
MEDICON extranet: www.MEDICON.de/extranet
to ensure that you are using the current version. The current version date is printed on each edition of the instructions for use. MEDICON eG assumes no liability for damages caused by improper use, care or maintenance or non-compliance with the restrictions for use, non-observance of post-operative instructions and other guidelines in the instructions for use. The liability for defects by MEDICON eG is also not applicable in case of changes or repairs to the product without prior written consent from MEDICON eG as well as in case of repairs which were not carried out by workshops authorized by MEDICON eG or the MEDICON Repair Service (MRS). Please contact MEDICON eG if you have further questions concerning the implants or instruments.

13. SIGNS AND SYMBOLS

	Consult instructions for use
	Caution
	Single use
	Manufacturer
MR	Not suitable for use in MRI
NON STERILE	Non-sterile
Rx only	Prescription use only (US Federal Law)
LOT	Batch number
REF	Item number

Caution: for USA, federal law restricts this device to purchase by or on behalf of a physician or hospital.

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