BEFORE USING PRODUCT, READ THE FOLLOWING IMPORTANT INFORMATION.

THIS IS NOT A REFERENCE FOR SURGICAL TECHNIQUE. SEE MKT-76-3215.

CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE AND USE BY, OR ON THE ORDER OF, A PHYSICIAN.

DEVICE DESCRIPTION

The SternaFuse® Fixation System implants are composed of 316 LVM implant quality stainless steel plates, links, and screws intended to stabilize and fixate fractures of the anterior chest wall. The components include various sizes to facilitate customization according to the requirements of the anterior chest wall repair. Self-drilling locking screws come in two diameters, 3.0mm and 3.3mm, and lengths of 10mm, 13mm, and 16mm. Multiple plates may be used in one anterior chest wall repair. Variable Assemblies can be configured, and the Links articulated for optimum fixation. Implants are designed with centralized saddles to aid in intra-operative contouring, to facilitate cutting during postoperative emergent re-entry, and to provide a location for stainless steel wire.

All implants are provided sterile with a five-year shelf-life. The implants should never be reused under any circumstance.

The SternaFuse® Fixation System also includes single-use, disposable surgical instrumentation to assist with implantation. The driver bits are provided sterile with a five-year shelf life.

INDICATIONS FOR USE

Indicated for use in the stabilization and fixation of fractures of the anterior chest wall including sternal fixation following sternotomy, sternal fractures, and sternal reconstructive surgical procedures to promote fusion.

CONTRAINDICATIONS

Contraindications may include, but are not limited to:

- 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.
- Patients with limited blood supply; insufficient quantity or quality of bone including severe osteopenia and/or osteoporosis, 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.

POTENTIAL ADVERSE EVENTS

- 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, 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 due to improper placement of cerclage wires and/or improper assembly of this system's components.
- Selection of screws which are longer than the depth of the sternum or anterior ribs may cause possible impingement on structures internal to chest wall including vessels, pleura, and other structures.

Apart from these adverse effects there are always possible complications of any surgical procedure such as, but not limited to, infection, nerve damage, and pain which may not be related to the implant. It may be necessary to perform additional surgery in order to correct some of the adverse effects or reactions that may or may not be related to this system.

WARNINGS
The subject device is intended for use only as indicated.

The implantation of the SternaFuse® Fixation System should be performed only by experienced surgeons with specific training in the use of this system as this is a technically demanding procedure presenting a risk of serious injury to the patient.

Internal fixation devices 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. Internal fixation devices are internal splints, or load sharing devices that align the fracture until normal healing occurs. 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, insufficient quantity or quality of bone, and adherence to load bearing instructions may have an effect on 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.

Single use device – do not reuse implants under any circumstances. While an implant may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant. Do not treat patients with implants that have been even momentarily placed in a different patient. If reused, single use devices may not perform as intended and could cause serious injury.

Do not intermix implants with different metallic alloy types. Implant materials are subject to corrosion. Implanting metals and alloys will subject 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 cut or modify implants. Bending or contouring of the unassembled Ring or Snap elements of the Variable Assemblies is not permitted, as it will increase the risk of Snap/Ring misalignment and of implant fracture or separation.

Moderate bending or contouring across the saddles of the Classic plate implants is permitted.

Minimal bending of Variable Base components and/or Links components across the saddles is permitted only after assembly of the Snap/Ring construct, according to the instructions found in the surgical technique.

Do not implant this device without the appropriate number of screws to achieve bone fixation. All Link implants require screw fixation both (proximally) at the Snap/Ring junction and (distally) for all remaining screw holes not associated with the Snap/Ring junction. Implantation without the appropriate number of screws may compromise device function and increase the risk of migration or failure.

Do not implant screws into any single Ring element, without having first assembled a Snap to that Ring. Rings do not contain threads for a screw head to lock into.

Do not implant a screw into any single Snap element, without having first assembled a corresponding Ring element to that Snap.

Intraoperative fracture of screws can occur if excessive force (torque) is applied while seating bone screws.

Implants may be removed after fracture or other bony non-union has healed. Implants can loosen, fracture, corrode, migrate, cause pain, discomfort, abnormal sensations; and increase the risk of infection. 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.

Do not use if packaging/implant/instrument is damaged or opened prior to use.

This device is not intended to be capable to withstand sudden dynamic loads associated with accidents or falls.

Do not place the SternaFuse® plates or Links over any other implants such as, but not limited to, plates, Links, wires, screws or cables.

Use of an undersized screw, plate, or Link in areas of high functional stresses may lead to implant fracture and failure.

Plates and screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.

Excessive bending of the plate or Link may cause weakening and could result in implant fracture and failure.

Use of excessive force during insertion of screws may lead to implant failure.

PRECAUTIONS

Single-use, disposable instruments are available for the SternaFuse® Fixation System to aid in the accurate implantation of these internal fixation devices. Instruments, which have experienced extensive use or excessive force, are susceptible to fracture. Fusion Innovations recommends that all instruments be regularly inspected for wear and disfigurement.

Check packaging of sterile products. For product that is provided sterile, do not use if sterile package has been opened or damaged. If sterile package has been opened or damaged, return the product to Fusion Innovations. Do not use implants after expiration date, as specified.

Correct handling of implants is extremely important. Modifications including improper bending and contouring of implants, especially the unassembled Snap and Ring elements, may cause misalignment of the Snap/Ring construct. This may contribute to weaken the implant, cause migration, breakage, or failure. These implants may be contoured or bent at or across the saddle regions, according to the surgical technique, and only after proper assembly of the Snap/Ring construct. Damage including notches or scratches to the implant during the course of surgery may contribute to breakage. If the plate or Link is notched or scratched, discard the implant, and replace with a new implant. If any Ring or Snap element of a Variable Base or Link component is bent or distorted prior to or after assembly, discard 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. See Surgical Technique for more recommendations, including minimum implant quantity requirements, for various closures.

Classic Fixation Plates:

Ensure adequate approximation and alignment of bony anatomy prior to screw fixation. Classic Plates do not contain a Ring element and are not capable of being connected to a Link. Classic Plates are designed with cuttable transverse saddle sections for re-entry that are intended to span across the midline of the sternotomy or fracture line. Cuttable saddle sections should be aligned over the fracture and a minimum of two screws must be implanted on each side of the fracture. Straight Plate (76-2506) position shall not extend across both costal margins, but may extend across one costal margin, or be implanted on the sternum vertically.

Variable Fixation Assemblies:

Ensure adequate approximation and alignment of bony anatomy prior to screw fixation. Variable Assemblies are constructed by combining the Ring elements of a Variable Base component to the Snap element of the desired Link components. The Variable Base components are also designed with cuttable transverse saddle sections that are intended to span across the midline of the sternotomy or fracture line. However, the Variable ParaMedian Recon Base component (76-2001) is not intended to span the midline of a sternotomy or across any other fracture, but should only be implanted in a vertical orientation on the sternum. Associated Links with more than two terminal screws can be connected to 76-2001, and may be used to span a fracture at the costal/chondral margins. The Variable Transverse Recon Base component (76-2502) should also not span the midline of the sternotomy, but may be used in a vertical orientation to span a transverse sternal fracture.

Screws must be implanted into all available screw holes when using Variable Fixation Assemblies. Certain Variable Base components contain standard screw holes (not associated with a snap/ring construct) in addition to Ring elements. Screw placement into these standard screw holes is required to adequately supplement and distribute forces when associated Links are connected as part of the construct assembly. Unassembled Rings are **not** screw holes and must first have a Snap element of a Link component assembled to the Ring, prior to screw insertion.

Links:

Links are intended to aid the placement of screws in the best available bone, by means of varying the angle of the link about the snap/ring construct. A SternaFuse® implant can be defined as a Link due to the incorporated Snap element, which is intended to be assembled to a corresponding Ring element. No Link should ever be implanted, without prior assembly to a Ring element of an appropriately indicated Variable Base component. Links are designed with saddles, which may be used to aid intra-operative contouring and in the placement of stainless steel wire, when additional fixation is desired. No Link is designed or permitted to span across the midline of the sternotomy. Saddles may serve as a cut point for postoperative emergent re-entry.

Terminal Links are designed with one proximal screw hole location (associated with the Snap), and one or more distal terminal screw hole locations.
Limo Terminal Links, containing two or more terminal screw holes, may be used to span a fracture gap (not sternotomy), as part of a Variable Base assembly, as long as all screws attain adequate bone purchase. Saddle should be placed over the fracture and a minimum of two screws shall be placed on each side of fracture.

Bridge Links are designed with one Snap and one Ring element. Only one Bridge Link may be used to connect between a particular Variable Base component and another Terminal Link component. No Bridge Link may cross any fracture gap. Bridge Links assembled consecutively with one another is not permitted.

Double-Snap Links are designed with two Snap elements which may be used to connect two separate Variable Base components. Double-Snap Links are not intended to span the midline of the sternotomy or any other fracture. Saddles may still serve as a cut point for postoperative emergent re-entry.

Bone Screws:

The driver bits which have been designed for this 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 driver bit 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 or cause stripping of the threads in the corresponding screw holes.

Screws are intended to be driven and locked perpendicular to the axis of the plate or Link screw hole. Screws that are driven at an off-axis angle may cause stripping at, or otherwise may not adequately lock to the corresponding screw hole. Screws driven off-axis into a proximal Snap screw hole, may cause the Snap/Ring construct to separate. Screws may not be driven with any power driver that has a torque exceeding 2Nm. Refer to Surgical Technique or contact Fusion Innovations for a list of approved power drivers available to the US market. Final locking and tightening must be done using the hand driver.
Screws associated with any Link must be driven and locked by hand driver only. Screws used in the ribs should not exceed 10mm in length.

PREOPERATIVE WARNINGS

- Patient condition and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
- Care should be used in the handling and storage of the implants. The implants should not be scratched or damaged. Implants and instruments should be protected during storage and from corrosive environments and excessive temperatures.
- Inspect all components for damage before use.
- Care should be used during surgical procedures to prevent damage to the device(s) and injury to the patient.
- The size of the device for the case should be determined prior to beginning the surgery. An adequate inventory of implant sizes should be available at the time of the surgery, including sizes larger and smaller than those expected to be used.

INTRAOPERATIVE

- The instructions in the surgical technique guide should be carefully followed.
- Breakage, slippage, or misuse of instruments or implants may cause injury to the patient or operative personnel.
- To assure proper fixation of bones, the correct implants must be carefully selected.

POST-OPERATIVE INSTRUCTIONS

Adequately instruct the patient of the benefits and risks of the system 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 instruction 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 patient is to be made aware and warned of the following:

- Device does not replace normal healthy bone and that the device can fracture, bend or be damaged as a result of stress, activity, load bearing or inadequate bone healing.
- Device cannot withstand dynamic loads from falls or accidents.
- Know general surgical risks, complications, possible adverse effects and follow the instructions of the treating physician.
- There is a need for regular postoperative follow-up examination 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 their 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.
- 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 may loosen the devices.
- The implants are comprised of stainless steel.

IMPLANT REMOVAL

The SternaFuse® screws can be removed using the SternaFuse® driver or any standard T10 screwdriver. Insert the driver into the head of the screw and rotate counter-clockwise while exerting slight downward pressure. Surgeon may use standard wire cutters to remove any sternal wires that cross over the plate implants. All Classic plates and Variable Assemblies including Links can be explanted following screw removal. Following implant removal, surgeon should confirm the complete removal of all intended implants with an X-ray prior to closure.

EMERGENT RE-ENTRY

The SFS Classic plates and Variable Assemblies have been designed with centralized saddles across the transverse aspect that can be easily cut in an emergency. Saddles can be cut with standard wire cutters, commonly located in the open heart operating room. All Link components, though not intended to span across the sternotomy midline, may still be cut at the saddle sections in an emergency. It is recommended to use a larger, heavy wire cutter or the SternaFuse plate cutter, part 76-9007. After plate separation, surgeon may use any SternaFuse T10 driver to remove the screws. If the SternaFuse® T10 drivers are not available, it is recommended to locate a specialized screw removal tray (Stryker screw removal set) that is standard to orthopedic operating rooms.

MAGNETIC RESONANCE SAFETY INFORMATION

The SternaFuse® Fixation System implants are manufactured using non-ferromagnetic 316 Stainless Steel. The implants have not been evaluated for safety and compatibility in the MR environment. The implants have not been tested for heating, migration, or image artifact in the MR environment. The safety of the SternaFuse® Fixation System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

PACKAGING

The SternaFuse® Fixation System is supplied pre-packaged and sterile. The integrity of the packaging should be checked to ensure that the sterility of the contents is not compromised. Remove the device from the packaging using aseptic technique, only after the correct size has been determined.

The implants and driver bits are packaged in a single device configuration, in a single-use container, intended to allow for aseptic transfer of the devices from the packaging to the sterile field. For additional packaging information and instructions please see Surgical Technique.

STORAGE
Store in a temperate, dry and clean place away from direct sunlight and high humidity.

Packages for each of the components should be intact upon receipt. All implants and instruments should be carefully examined for completeness, and for lack of damage, prior to use. Damaged packages or products should not be used and should be returned to Fusion Innovations.

HANDLING OF THE IMPLANTS
Before removing the implants from the package, make sure that the protective packaging is unopened and undamaged. If the packaging is damaged, the implants must be considered as NON-STERILE and may not be used. Upon removal from the package, compare the descriptions on the label with the package contents (product number and size).

Note the STERILE expiry date. Implants with elapsed STERILE expiry dates must be considered as non-sterile.

Take particular care that aseptic integrity is assured during removal of the implant from the inner packaging.

STERILIZATION
All implants are provided sterile. No additional sterilization is required prior to use. Once the seal on the package has been broken, the product should not be re-sterilized.

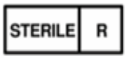
ADDITIONAL INFORMATION
To provide complaint information to the company, obtain Surgical Technique Guide (MKT-76-3215), or should any information regarding the products or their uses be required, please contact your local representative or Fusion Innovations directly at 1-888-316-7627.

You may also email: info@sternafuse.com

MANUFACTURER INFORMATION

Fusion Innovations
341 N. Maitland Ave. Ste. 270
Maitland, FL 32751 USA

SYMBOL LEGEND

	Refer to instructions for use before implantation		Manufacturer
	Single Use Only		Single sterile barrier system with protective packaging inside
REF	Reference Number		Sterilized using radiation
LOT	LOT Number		Do not use if package is damaged
	Use by date		Do not re-sterilize
Rx	For Prescription Use Only		