ARIX Sternal System
Bone Screw / Bone Plate

INSTRUCTIONS FOR USE

CE 1639

Manufacturer:
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[DESCRIPTION]
ARIX Sternal 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 to aid in the alignment and stabilization of bone. Instrumentation has been designed specifically for use with this system of implants.
Plates are manufactured from titanium (ASTM F67) and Screw are manufactured from titanium alloy (ASTM F136). The Plate & Screw are provided a packaging as sterilized by gamma irradiation.

[INDICATIONS]
The ARIX Sternal 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, to promote fusion.

[DIRECTIONS FOR USE]

1. The first step in the successful application of the ARIX Sternal system is to dissect all soft tissue from the surface of the sternum to allow for complete visualization of the bone. Optimally the soft tissue is dissected to reveal the costal cartilage on both sides of the sternum. Performing this step before the sternotomy decreases the likelihood of off mid-line sternotomy, a potential precursor to dehiscence. This step should also be followed in revision cases where wire is removed due to sternal non-union or for re-operation. In addition to dissecting the soft tissue from the sternum in the revision patient, bony calluses should also be removed from the midline and sternal surface to allow for proper anatomical reduction and plate placement.
2. Complete the intended surgical procedure.
3. Examining the sternum before closure: Closely examine the sternum before anatomical reduction to identify transverse fractures. Marking all transverse fractures before reduction of the sternotomy allows for easy fracture identification after anatomical reduction is performed.
4. Precise sternal depth measurements should also be taken at this time. Measurements should be recorded at the anticipated plate locations before bone reduction to insure the selection of appropriate screws.
5. The sternum should be reduced using the bone reduction forceps found in the Instrument tray. To reduce the sternotomy at the body of the sternum, place the approximating ends of the reduction forceps in the intercostals spaces on either side of the sternum and slowly bring the sternum together. During this process be careful to observe the midline for protruding internal tissue and proper bony alignment. Be careful not to place the reduction forceps in the area of a fracture line. Placing the reduction forceps at the Manubrium and the Xyphoid can attain proper anatomical reduction. Maintain static compression on the sternum by locking the reduction forceps in place. The forceps can be rotated to allow for easy access to all sternal regions.
Alternate Reduction: The sternum can be reduced with the assistance of appropriate sized Stainless Steel suture at the Xyphoid and Manubrium. Reduction forceps are used in the mid-body of the sternum to ensure full approximation. CAUTION: Putting dissimilar metals and alloys in contact with each other may be detrimental to the patient and/or function of the implant(s).
The ARIX Sternal system offers plate options to accommodate anatomical variation. The typical sternum is plated using a four-hole "L" plate on the Manubrium, an eight hole "X" plate in the body of the sternum and an eight-hole "X" plate as inferiorly as possible near the Xyphoid. The "L" plate is typically used to fixate transverse fractures where the larger shapes are not anatomically appropriate. Place the first "X" plate in the body of the sternum with the cuttable cross-sections running perpendicular to and across the sternotomy line. Care should be taken to keep the plate centered over the sternotomy. The "X" plate can be placed over the sternotomy either lengthwise or across the sternum with four holes on each side of the sternotomy. With the plate positioned on the sternum, check for conformity to the sternal surface. It may be necessary to adapt the plate to provide for better fit to the sternum. However, it is not necessary for the plates to conform perfectly to the sternal surface. Should plate bending be necessary, benders are located in the Instrument tray.
Experience has shown that the following plate configurations are usually standard:
Manubrium: 1 L Plate
Body of Sternum: 1 vertical X-Plate
Lower Sternum: 1 vertical X-Plate
6. Using the measurements recorded during the examination of the sternum, select the appropriate screw length for that location of the plate. Screw length is chosen by adding, at the most, 2mm to the full thickness of the selected sternal region. Please refer to the chart below for a summary of suggested screw lengths to use based on measured sternal depth. (NOTE: If using the ARIX Sternal System Screw Sizer to measure sternal depth, the 2mm maximum length has already been added to the screw length marking on the sizer. Evaluate the size of screw to use accordingly, as appropriate for the patient.) With the plate in position, place the selected screw by turning clockwise to insert the screw. Be sure to keep the screw as perpendicular as possible to the plate to ensure proper fixation. DO NOT fully seat the first screw at this time; tightening the first screw in each plate will cause the plate to rotate. Pressure should be applied to the plate during the insertion of the screws to assure the plate's full contact with the bony surface.

Depth of Sternum where Plate will be Placed	Recommended Screw Length
6.0-7.0 mm	8.0 mm
8.0-9.0 mm	10.0 mm
10.0-11.0 mm	12.0 mm
12.0-13.0 mm	14.0 mm
14.0-15.0 mm	16.0 mm
16.0-17.0 mm	18.0 mm
18.0 mm or deeper	20.0 mm

Pairing the SMARTO Power driver (111-ED-051/050/052) with the ARIX Sternal System bone screws greatly facilitates screw placement and reduces overall closure time.
After placing the first screw the remaining screws can be placed and fully seated. Return to the first screw at this time and ensure that it is fully seated into the plate.
Typically one "X" Plate is placed in the body of the sternum first, at that time the reduction forceps may be removed and the remaining plates are placed in the manubrium and xyphoid.
7. Plate options and locations should be chosen to best fit the anatomy of each patient. 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

• **Plate & Screw Removal**
In instances where the removal of ARIX Sternal System is required, after normal surgical exposure the ARIX Sternal System Plates & Screws may be dislodged by using a driver shaft and other instruments. If the removal of ARIX Sternal System Plates & Screws is required, they should be removed, inventoried and discarded. Do not reuse. The surgical site is now re-sutured.

• **Emergent Reentry**: If emergent reentry is necessary, the ARIX Sternal System plate can be cut with most non-scissor type heavy wire cutters found in the operating room or a crash cart. Should emergent reentry be necessary and no plate cutter is available, place a curved elevator under one side of the sternal plate and lift the plate off of the sternum for removal.

• **Disclaimer:** As the manufacturer of the ARIX Sternal System, Jeil Medical Corporation does not practice medicine and does not recommend this or any other product or surgical technique for use on a specific patient. The surgeon who performs any sternal closure procedure must determine the appropriate closure method and surgical procedure for each individual patient. The surgical technique portion of this insert is not intended for patients.

[MATERIAL]
Bone Screw: Titanium Alloy (ASTM F 136)
Bone Plate: Titanium (ASTM F 67)

[WARNING]
① 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).
② Correct handling of implants is extremely important. Implants should be modified only when necessary. Modifications or excessive contouring of implants may weaken the implant and contribute to breakage. Notches or scratches put in the implant during the course of surgery may contribute to breakage.
③ Intraoperative fracture of screws can occur if excessive force (torque) is applied while seating bone screws.
④ Implants may be removed after fracture or other bony non-union has healed. Implants can loosen, fracture, corrode, migrate, or cause pain. 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. 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.
⑤ Adequately instruct the patient. Postoperative care is important. 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. The patient is to be instructed in the use of external supports and braces that are intended to immobilize the site of the fracture or other non-union and limit load bearing. The patient is to be made fully aware and warned that the device does not replace normal healthy bone, and that the device can break, bend or be damaged as a result of stress, activity, load bearing or inadequate bone healing. The patient is to be made aware and warned of general surgical risks, complications, possible adverse effects, and to follow the instructions of the treating physician. The patient is to be advised of the need for regular postoperative follow-up examination as long as the device remains implanted.
⑥ Plate position shall not extend across both costal margins. (When plating the sternum, long straight plates should be placed vertically.)

[CAUTION]
① Improper fixation of the plate and screw may result in the formation of a ridge.
② Always follow appropriate safety precautions.
③ Select the appropriately sized plate and screw for the patient.
④ Responsibility for proper selection of patients, adequate training, experience in the choice and placement of plate & screw and the decision to leave or remove plate and screw postoperatively, rests with the surgeon.
⑤ Once applied, never reuse this device.
⑥ Delayed healing, nonunion or subsequent bone resorption or trauma may cause excessive stress on this device and result in loosening or fracture.
⑦ It is recommended that the implant be removed after use for up to 16 weeks, which is the period of completion of bone healing, unless medical attention is required.

[PRECAUTIONS]
① **Sterilized Single Use Device**: Check the package before using if it is torn or damaged. Never use implants if the package is damaged.
② Inspect each device to ensure they are not bent or damaged.
③ Instruments are available for each implant system to aid in the accurate implantation of internal fixation devices. Surgical instruments are subject to wear with normal usage. Instruments, which have experienced extensive use or excessive force, are susceptible to fracture. Jeil Medical Corporation recommends that all instruments be regularly inspected for wear and disfigurement.
④ Surgical instruments must be used only for the device systems for which they are designed. Use of other manufacturer instruments can involve incalculable risks for the implant and instrument, thereby potentially endangering the patient, user, or third party.
⑤ The surgeon should operate carefully to prevent problems such as implant failure, wound infection, elective removal for noninfected wound sinus, sterile soft tissue dehiscence, nonunion, instability, infection, mediastinitis, pain, narcotic use.
⑥ The physician should take the appropriate action for the patient after the operation. Otherwise implant failure, wound infection, elective removal for noninfected wound sinus, sterile soft tissue dehiscence, nonunion, instability, infection, mediastinitis, pain, narcotic use.

⑦ **IMPLANTS IN THE MAGNETIC RESONANCE (MR) ENVIRONMENT**
The effects of the MR environment have not been determined for this device. This device has not been tested for heating or migration in the MR environment.

Bone Plates
⑧ Bone plates may need to be contoured to the surface of the bone by bending the plates with a bending instrument.
⑨ Care must be taken to achieve the appropriate contour with as few bends as possible. Repeated bending of titanium increases the risk of fracture.
⑩ Sharp angles and small bending radii must be avoided to reduce the risk of device breakage.
⑪ The bending instruments must be used with care because they can cause damage to the implant. The operating surgeon should always inspect the implant after bending for damage which may include dents or deformed screw holes. These defects can lead to breakage of the implant. Deformed screw recesses due to bending may impair the proper fit of the screw head.
⑫ Cutting bone plates may increase the risk of failure of the implant. If the operating surgeon elects to cut a plate, care must be taken to cut in such a way to maintain adequate strength, support, and fixation for the intended use. Cutting a plate between the screw holes is a preferred method to maintain strength characteristics. Sharp edges should be smoothed to avoid soft tissue damage or irritation. When cutting a plate, extra care must be taken to prevent the portion being cut from projecting towards the patient, user or third party.

Bone Screws
⑬ 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.
⑭ Incorrect alignment or fit of the screwdriver to the screw head may increase the risk of damage to the implant or screwdriver.
⑮ Excessive torque can cause the screw to fracture.

[POSSIBLE ADVERSE EFFECTS]
① Poor bone formation, Osteoporosis, Osteolysis, Osteomyelitis, inhibited revascularization, or infection can cause loosening, bending, cracking or fracture of the device.
② Nonunion or delayed union which may lead to breakage of the implant.
③ Migration, bending, fracture or loosening of the implant.
④ Metal sensitivity, or allergic reaction to a foreign body.
⑤ Decrease in bone density due to stress shielding.
⑥ Pain, discomfort, abnormal sensation, or palpability due to the presence of the device.
⑦ Increased fibrous tissue response around the fracture site and/or the implant.
⑧ Necrosis of bone.
⑨ Inadequate healing.
⑩ 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.

[CONTRAINDICATIONS]
① Active infection
② Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation.
③ Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.

[CLEANING & STERILITY]
ARIX Sternal System Bone Plate/ Bone Screw are packaged individually and sterilized by gamma radiation. They don't need any Cleaning process or Sterilization.

• Cleaning
ARIX Sternal System's accessories (surgical instruments) can be reused after cleaning and sterilizing.
They must be cleaned before reuse. Cleaning and Sterilization instructions are recommended for cleaning;
※ Please refer to the Cleaning and Sterilization Guide.

1) Pre-cleaning
① Disassemble the device where possible.
② Remove gross soil using paper wipes and solution of cleaning agent.
③ Immerse the device in solution of cleaning agent for the time recommended by the detergent's manufacturer.
④ Using suitable brushes (never metal brushes or steel wool) cleaning the device thoroughly.
⑤ Rinse in running water until all traces of cleaning solution are removed.
⑥ Visually inspect for any remaining soil and repeat the steps above if necessary.
2) Cleaning
① Immerse the device completely in solution of cleaning agent and activate the ultrasonic bath at the concentration and temperature specified in the detergent manufacturer's instructions.
② Follow the same as the clause ④ ~ ⑥ of instructions for pre-cleaning.

• Sterilization
ARIX Sternal System's accessories (surgical instruments) must be sterilized before use. Following instructions are recommended;
① Place the devices in the appropriate block (kit or tray) using forceps and/or powder-free gloves to avoid contamination and any other negative effect on the surface of device.
② Wrap the block with a surgical drape.
③ Sterilize in the autoclave validated and maintenanced in accordance with ISO 17665 and ANSI AAMI ST79. Following parameters are validated in accordance with ISO 17665-1 and recommended for sterilization;

Cycle	Temperature	Exposure Time	Load Characteristics	Drying Time
Gravity	132°C	15 min.	Wrapped*	30 min.
Pre-vacuum	132°C	4 min.	Wrapped*	30 min.

* In the case of load characteristics, we recommend usage of an FDA cleared wrap to ensure that the device is actually sterile prior to implantation.
④ Caution: Plates & Screws are disposable (single use only). Do not re-use. Devices labeled for single-use only should never be reused. Reuse of these devices may potentially result in serious patient harm. Examples of hazards related to the reuse of these devices include, but are not limited to the following: significant degradation in device performance, cross-infection, and contamination.

An implant should never be re-sterilized or reused after contact with body tissues or fluids, but rather should be discarded. Jeil Medical Corporation does not take any responsibility for the use of implants re-sterilized after contact with body tissues or fluids.

[EXPIRATION DATE] 5 years from Manufacture date

[STERILE BY GAMMA IRRADIATION]

[PACKAGING]
All ARIX Sternal System Bone Screw / Bone Plate are packaged individually. This device is manufactured and sold by Jeil Medical Corporation.

[SYMBOL DESCRIPTIONS]

REF	Catalogue number
LOT	Batch code
	Do not re-use
STERILIZE	Do not restrilize
	Date of manufacture
	Manufacturer
	Use-by date
STERILE R	Sterilized using irradiation
	Caution
	Consult instruction for use
	Do not use if package is damaged
EC REP	Authorized representative in the European Community

EC REP **EMERGO EUROPE**
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