DOC # LBL-016 Rev: B

CircumFix™ Solutions, Inc.

For the Attention of the Operating Surgeon:

IMPORTANT INFORMATION

ON THE CircumFix Solutions™

VariTrax Sternal CircumFixator™ System

Description

The VariTrax Sternal CircumFixator System consists of polyetheretherketone (PEEK) locking bands with detachable, stainless-steel needles and a buttress plate (PEEK). The VariTrax implants are placed in parasternal fashion through the intercostal space, with the help of the detachable needle. Once inserted, the needle is removed and the VariTrax implants are attached and locked to the VariTrax buttress plate then tightened and secured in place to provide stable fixation of the sternum. The VariTrax implants can be cut and removed for emergent, or long-term, re-entry through the sternum.

INDICATIONS

The VariTrax Sternal CircumFixator system is indicated for primary or secondary closure/repair of the sternum following sternotomy or fracture of the sternum to stabilize the sternum and promote fusion.

CONTRAINDICATIONS

The VariTrax Sternal CircumFixator implants are not intended for use in:

1. The presence of Sternal Infections

2. Conditions where it is felt to be unsafe because of insufficient quality of bone

3. Patients who are unwilling or incapable of following postoperative care instructions

WARNINGS

VariTrax Sternal CircumFixator implants are for SINGLE USE only. Do not attempt to re-sterilize.

• The use of VariTrax Implants is only appropriate with a midline sternotomy

• Do not use VariTrax Implants trans-sternally. The system is intended for intercostal space application only

PRECAUTIONS

- Do not damage the implant teeth and locking head by manipulating with instruments
- The VariTrax Implants are not intended to be used without a properly sized VariTrax buttress plate
- Use the provided template to ensure the proper buttress plate length is selected
- Ensure the VariTrax buttress plate is properly oriented such that the undersurface contacts the sternum
- Irrigate thoroughly
- The surgeon should instruct the patient about postoperative sternal precautions
- Do not resterilize the VariTrax Implants
- Ensure that the locking head of the implant is free of soft tissue and/or surgical material that could prevent locking of the implant
- Handle implants carefully, especially needles, to avoid damaging critical anatomical structures, soft tissue and/or hand gloves

POSSIBLE ADVERSE EFFECTS

1. Poor bone formation, osteoporosis, osteolysis, osteomyelitis, inhibited revascularization, or infection can cause loosening, bending, or breakage of the device

2. Non-union or delayed union which may lead to breakage of the implant

3. Loosening or migration of the implant

4. Decrease in bone density due to stress shielding

5. Pain, discomfort, abnormal sensation, or palpability due to the presence of the device

6. Increased fibrous tissue response around the fracture site and/or the implant

7. Necrosis of bone

8. Infection, nerve damage, or pain

STERILIZATION

The implant set and templates are provided **sterile through gamma radiation**, validated to a Sterility Assurance Level (SAL) of 10^{-6}. The packaged implant set and templates are considered sterile for up to 1 year unless the packaging has been opened or damaged.

The instruments are provided non-sterile for sterilization prior to use. It is recommended to place instruments individually in an FDA cleared self-sealing sterilization pouch for use in healthcare facilities. The recommended sterilization process is pre-vacuum steam autoclave at 121°C, with a cycle time of 30 minutes, and minimum drying time of 30 minutes. This process has been validated to a Sterility Assurance Level (SAL) of 10^{-6}.

INSTRUCTIONS FOR USE

1. Reduce sternal halves

2. Use the Varitrax Template to properly measure for the appropriate VariTrax buttress plate

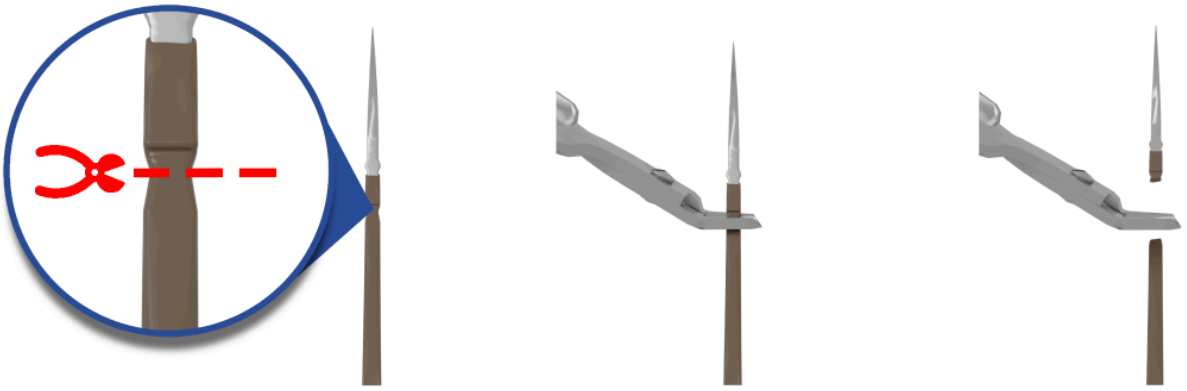
Apply the single-use pre-sterilized template directly to the patient's sternum, superior end towards the sternal notch. Bend over the distal end of the template at the closest marked end towards the xiphoid process.

Select the correct VariTrax Implant Kit with the appropriate size buttress plate as determined in Step 2.

3. Place VariTrax locking bands through intercostal spaces

Caution: Take care to avoid injury to or impingement upon the internal mammary artery and intercostal vessel and nerve bundles. Avoid clamping of implant in the area of the teeth or excessive bending/twisting of the band, as this may lead to implant failure. Ensure that the needle is attached to the implant body before being inserted into the intercostal space.

4. Remove VariTrax locking band needle



Caution: Cut the implant directly below the notch on the band. Removing the needle by bending or twisting will cause a deformed end that may damage the locking head during insertion. Always ensure that the implant end is cut and not deformed. If the implant is not cut, implant failure may occur.

5. Insert remaining VariTrax locking bands and remove all needles

Caution: Use VariTrax locking bands, one per intercostal space, to achieve stable fixation in a full midline sternotomy.

6. Attach VariTrax locking bands to buttress plate

Push the locking heads of the Varitrax locking bands into the center oblong holes of the buttress plates. Locking band heads should be initially pushed forward and then in a downwards motion.

An audible “click” may be heard to indicate proper seating. To verify, slide the locking head along the track rails of the buttress plate to ensure proper placement.

7. Insert and tension VariTrax locking bands

Once locking band attachment to the plate has been completed, insert the cut end of the locking band through the corresponding slot located on the locking band head and tension with the tensioning pliers provided with the set until desired provisional tension is achieved. Repeat with all locking bands until desired tension is achieved.

Caution: Care should be taken to control band tension in patients with poor bone quality to prevent additional injuries. Tension the locking bands using only the application instrument until the sternum reduction is achieved and the implant is properly positioned. If intercostal space is not suitable for VariTrax Implants, use alternative methods for closure. ***Do not cut the locking bands until all bands have been fully tensioned since bands cannot be further tensioned once cut.***

Caution: To avoid damage to the locking head, stainless steel needles must be removed before closing the VariTrax implants. It is necessary to remove the needle from the implant body before proceeding to insert the next implant. Prior to insertion of the cut end, ensure the VariTrax locking band is properly oriented such that the toothed undersurface contacts the sternum. Align the cut end with the locking head during insertion. Do not insert at an angle. Use the provided tensioning instrument. Avoid excessive force when tightening the implants. Do not use forceps to tighten the implant. Damage resulting from excessive force or forceps may cause implant failure. Ensure that the locking band body is not twisted while passing the cut end through the locking head. Ensure the implant body follows the bony anatomy of the sternum. The VariTrax locking band should only be inserted once into the locking head.

Note: Do not attempt to contour the buttress plate using instrumentation. The plate will conform to the shape of the bone when locking bands are tensioned. Attempts to contour the plate using metal instruments can result in damage to the plate and potential system failure including plate breakage.

Caution: Upon tensioning the locking bands, the buttress plate will conform to the shape of the anterior aspect of the sternal body. Be sure to perform visual and tactile inspection of each band before removing excess band material with the cutting pliers provided with the set. Do not trim individual bands until all bands are optimally tensioned and inspected. Once engaged though the locking mechanism in the slot of the locking band head, be sure to pull locking bands across the chest wall. Do not pull locking bands in an upward direction.

8. Confirm integrity and stability of closure

9. Remove excess band length material

Excess length of band should be elevated 30° and then cut with the provided cutting instrument as close as possible to the locking head.

Warning: Do not cut the excess length of the locking band under tension. Ensure that the implant is properly placed, that it does not cut through the bone and that the locking function is preserved to confirm the integrity of the final construct.

Caution: Ensure that the cutting instrument is placed approximately 30° to the locking head and is touching the locking head during cutting to avoid sharp edges. The VariTrax locking band cannot be further tensioned after it is cut.

10. Close soft tissues overlying the implant

11. Postoperative consideration

Caution: Standard sternal precautions are recommended for 6 weeks after surgery, including: patient should not lift more than 10lbs. (4.5 kg). Patients should not raise arms greater than 90°. A patient should press a pillow against his/her chest in the event of a strong cough. Do not pull or lift the patient by the arms. Avoid trunk twisting. See Technique Guide for full Instructions for use.

IMPLANT REMOVAL:

1. Cut VariTrax locking bands with a wire/pin cutter or the cutting instrument provided

2. Carefully remove the VariTrax implants by pulling on the buttress plate or locking band body

Caution: Avoid multiple cuts so that the implants can be removed more easily to ensure all fragments are removed.

MRI INFORMATION

The VariTrax Sternal CircumFixation implants are MR Safe according to the terminology in ASTM F 2503-08, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. MR Safe – an item that poses no known hazards in all MR environments. Note 1 – MR Safe items include nonconducting, nonmagnetic items such as a plastic Petri dish. An item may be determined to be MR Safe by providing a scientifically based rationale rather than test data.

No displacement, torque, or heating will occur during MRI when the nonmetallic and non-conductive PEEK VariTrax is used for stable fixation of the sternum. The amount of MRI artifact is considered negligible for this nonmetallic PEEK implant and is not expected to compromise diagnostic MR imaging capability. Caution: MR Safe after needle removal. The ferromagnetic needle must be removed prior to placing it in the vicinity of a MR scanner, and/or anywhere in the MR procedure room, or using in an interventional MRI procedure.

CAUTION:

FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

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Symbols Glossary

Symbol	Title of Symbol & Reference Number	Explanatory Text	Title & Designation Number
	Manufacturer Ref # 5.1.1.	Indicates the medical device manufacturer	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements unless otherwise noted below, ISO 15223-1: 2021
	Date of manufacture Ref # 5.1.3.	Indicates the date when the medical device was manufactured	
	Use by date Ref # 5.1.4.	Indicates the date after which the medical device is not to be used	
	Batch code Ref # 5.1.5.	Indicates the manufacturer's batch code so that the batch or lot can be identified	
	Catalog number Ref # 5.1.6.	Indicates the manufacturer's Catalog number so that the medical device can be identified	
	Sterilized using irradiation Ref # 5.2.4.	Indicates a medical device that has been sterilized using irradiation	
	Do not resterilize Ref # 5.2.6.	Indicates a medical device that is not to be resterilized	
	Key dry Ref # 5.3.4.	Indicates a medical device that needs to be protected from moisture	
	Do not use if package is damaged and consult instructions for use Ref # 5.2.8.	Indicates that a medical device that should not be used,if the package has been damaged or opened and that the user should consult the instructions for use for additional information	
	Do not reuse Ref # 5.4.2.	Indicates a medical device that is intended for one single use only	
	Consult instructions for use or consult electronic instructions for use Ref # 5.4.3.	Indicates the need for the user to consult the instructions for use	
	Caution Ref # 5.4.4.	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences	
	Unique device identifier Ref # 5.7.10.	Indicates a carrier that contains unique device identifier information	

	Magnetic Resonance (MR) safe Ref # Table 2: 7.4.6.1; Fig. 6, 7	An item that poses no known hazards resulting from exposure to any MR environment. MR Safe items are composed of materials that are electrically non conductive, non metallic, and nonmagnetic.	Standard practice for making medical devices and other item for safety in the magnetic resonance environment, ASTM F2503