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Viper I Vacuum Heart Stabilizer

Product Code	Description
STB-50CVS	Viper I Vacuum Heart Stabilizer



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VIPER I Vacuum Heart Stabilizer

Product Description:

The VIPER I Vacuum Heart Stabilizer has an articulating arm, two malleable, vacuum foot pads and a mounting base that fastens onto a sternal Retractor. The arm is tightened or loosened by a knob. Once the foot pads are placed at the anastomotic site, suction is applied to stabilize the heart tissue.

Sterile, Disposable, Single use only

Note: The mounting base has been designed for the Chase Medical FasTract Sternal Retractor (sold separately).

Indication for Use:

The VIPER I Vacuum Heart Stabilizer is intended for use during performance of beating heart coronary artery bypass surgery through a sternotomy incision approach. It is used to stabilize and minimize the motion of selected areas of the beating heart to facilitate coronary anastomosis.

Contraindications:

This product is not intended for use except as indicated above. Do not position the Viper I Heart Stabilizer over a coronary artery, newly infarcted or aneurysmal heart tissue.

Warnings and Precautions:

- Carefully read instructions prior to use.
- The instructions for use are furnished for information purposes only.
- Proper surgical procedures and techniques are the responsibility of the medical professional. The surgical team must evaluate the appropriateness of the procedure based on their experience, and patient's heart condition and other issues. The outcome is dependent on many variables, including patient anatomy, pathology, surgical technique and anesthesia management.
- Although product has been carefully designed, manufactured and inspected or tested prior to sale, the product may fail to perform its intended function satisfactorily for a variety of reasons. Warnings contained in the product labeling and in this document provide more detailed information and should be read by the user prior to use of product.
- Do not exceed (-) 300 mmHg. Excessive negative pressure may damage tissue.
- Over-bending of malleable feet may restrict or block air flow. Repeated or excessive bending may cause the metal tube to fracture or limit performance.
- When loosening the articulating arm, do not turn the large plastic knob counterclockwise more than 3 complete turns. Doing so may cause the device to malfunction.
- Product is Ethylene Oxide sterilized.
- **Do not reuse or resterilize.** Reuse or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- Sterile unless package is opened or damaged.

CAUTION: Federal U.S. laws restrict this device to sale, distribution, and use, by or on the order of a physician.

Adverse Effects:

None known.

Directions for Use:

1. Inspect all packaging, Viper I Vacuum Heart Stabilizer and Tubing for damage and expiration date prior to opening the package.
2. If undamaged and unexpired, open the package and transfer the product onto the sterile field utilizing aseptic technique.

Suction Circuit Assembly

1. Attach Tubing (not included) from the operating room suction wall source to the back of the hospital's vacuum regulator. Turn regulator on and set vacuum to (-) 300 mmHg.
2. Connect Tubing *with Filter* (not included) from the hospital's vacuum regulator to a fluid collection canister (not included).
3. Utilizing aseptic technique, connect the stopcock fitting of the Viper I Vacuum Heart Stabilizer to the Tubing with Luer Fitting (included). Attach the other end of the tubing to the same fluid collection canister (not included).
4. Ensure the stopcock is in the closed-air position.

Attach Viper I Vacuum Heart Stabilizer to the Retractor

1. Ensure the locking lever metal knob is positioned underneath the large plastic knob.
2. Mount the Viper I Vacuum Heart Stabilizer base onto the retractor using a toe-to-heel approach, assuring the base is flush with the Retractor. Slide the locking lever metal knob to the left or right until it locks.

Note: The protruding hook on the left side of the base is used to help lock the base with one hand by placing the left forefinger over the hook while using the left thumb to slide the metal knob on the locking lever to the left or right.

Viper I Vacuum Heart Stabilizer Use, Removal and Disposal

1. Adjust the stabilizer arm and place the vacuum foot pads onto the designated anastomotic site.
2. Turn the large plastic knob **clockwise to tighten** the articulating arm. Turn the large plastic knob **counterclockwise to loosen** the articulating arm.
Caution: When loosening the articulating arm, do not turn the large plastic knob counterclockwise more than 3 complete turns. Doing so may cause the device to malfunction.
3. If motion is detected between the links in the articulating arm after tightening, ensure the vacuum foot pads are still correctly positioned on the heart, then continue turning the large plastic knob **clockwise** until all motion in the articulating arm is eliminated.
4. Gently shape the malleable vacuum foot pads at the desired location on the heart.
Caution: Do not exceed a 25 degree bend in the vacuum foot pads in any direction. Repeated bending may compromise device performance.
5. Apply vacuum pressure by opening the stopcock.
6. To terminate suction, support the heart and turn the stopcock to the off-to-vacuum position. To loosen the arm, turn the large plastic knob counter-clockwise, not more than 3 turns, and gently lift the vacuum foot pads from the heart.
7. To remove the Viper I Vacuum Heart Stabilizer from the Retractor, reposition the locking lever metal knob under the large plastic knob.
8. When finished, discard the Viper I Vacuum Heart Stabilizer according to approved hospital procedures.