VIPER™ II VACUUM HEART STABILIZER
INSTRUCTIONS FOR USE

Catalog Number	Description
STB-700VS	Viper II Vacuum Heart Stabilizer, M Base
STB-800VS	Viper II Vacuum Heart Stabilizer, Q Base

Explanation of Symbols on Packaging Label

	**Sterilized using Ethylene Oxide**
	**Manufacturer**
	**Date of Manufacture**
	**Use-by Date**
	**Do Not Re-Use**

	**SKU / Catalog Number**
	**Lot Number**
Rx only	**Prescription only / Caution: Federal (US) law restricts this device to sale by or on the order of a physician**
	**Consult Electronic Instructions for Use**
	**Contains Phthalates**

Product Description:

The VIPER II Vacuum Heart Stabilizer has an articulating arm, two malleable, vacuum foot pads and a mounting base that fastens onto a sternal Retractor or Retractor Platform Rails. 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.

All Models: Sterile, Disposable, Single use only.

Note: The mounting base has been designed to be compatible with a range of adult sternal Retractors. Compatibility should be confirmed prior to beginning the procedure.

Indication for Use:

The VIPER II 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 II Heart Stabilizer over a coronary artery, newly infarcted or aneurysmal heart tissue.

Warnings and Precautions:

- Carefully read instructions prior to use.
- 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 (-) 400 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.
- If Retractor Platform Rails are in use, do not adjust or move while pericardial sutures are engaged in the platform.
- Suture holder features are designed for "0" size sutures.
- Product is Ethylene Oxide sterilized. Do not reuse or resterilize.
- 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.

Instructions for Use:

Retractor Platform Rails Use and Removal (STB-800VS model only)

1. Inspect the packages and products for damage and expiration date. If undamaged and unexpired, open the packages and transfer the devices onto a sterile field utilizing aseptic techniques.
2. Utilizing aseptic technique, insert the Retractor Platform Rails onto an Activator Drive Mechanism (not included), matching the correct left and right rails to the correct drive attachment side. Ensure the rails are fully engaged.
3. Ensure the rails are properly seated on the sternum.
4. Turn the drive handle counter-clockwise to begin spreading the sternum to the desired opening.
5. If using sutures, slide the sutures into the suture holder slots. Engage only one suture strand per slot to ensure proper hold. Release engaged suture from the platform by concurrently pulling back and up on the suture while pulling the suture through the suture holder slot.
6. To remove the Retractor Platform Rails from the Activator Drive Mechanism, turn Release Latches on the Platform in the direction of the arrows and pull the Rails away from the drive mechanism.
7. When finished, discard the Retractor Platform Rails according to approved hospital procedures.

Suction Circuit Assembly (all models)

1. Inspect the packages and products for damage and expiration date. If undamaged and unexpired, open the packages and transfer the devices onto a sterile field utilizing aseptic techniques.
2. Per Figure 1, attach tubing (not supplied) from the operating room suction wall source to the back of the hospital's vacuum regulator. Turn regulator on and set vacuum to (-) 400 mmHg.
3. Utilizing aseptic technique, connect the luer lock fitting of the Viper II Vacuum Heart Stabilizer to the stopcock fitting of the Tubing Set with Stopcock and Blue Identification Tape. Attach the other end of the Tubing Set with Stopcock to a fluid collection canister (not supplied). Ensure the Stopcock is in the closed-air position.
4. Connect the Vacuum Heart Stabilizer Tubing Set *with Filter* and Blue Identification Tape (included) from the same fluid collection canister to the hospital's vacuum regulator.

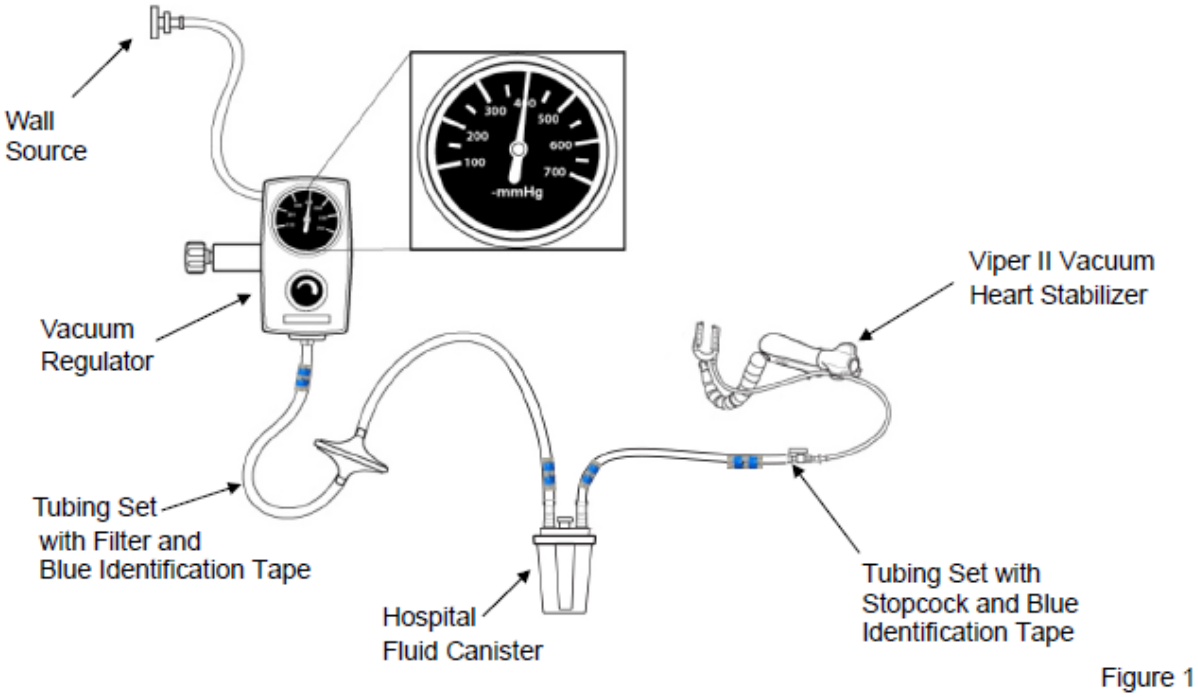

Figure 1

VIPER II Heart Stabilizer Use and Removal (all models)

1. Utilizing aseptic technique, attach and secure the Viper II Vacuum Heart Stabilizer to the Retractor or Retractor Platform Rails using the toe to heel approach.
2. Use the locking lever to secure the Viper II Vacuum Heart Stabilizer to the Retractor or Platform Rails.
3. Gently position and shape the malleable foot pads at the desired location on the heart. Caution: Do not exceed a 25 degree bend in the foot pads in any direction. Repeated bending may compromise device performance.
4. While holding the malleable foot pads in position, turn the knob clockwise to tighten the articulating arm.
5. Apply vacuum pressure by opening the stopcock.
6. To terminate suction and remove the Viper II Vacuum Heart Stabilizer, support the heart and turn the stopcock to the off-to-vacuum position. Turn the knob counter-clockwise to loosen the arm, and gently lift the Stabilizer from the heart.
7. Reposition the locking lever underneath the knob to remove the Viper II Vacuum Heart Stabilizer from the Retractor or Retractor Platform Rails.
8. When finished, discard the Viper II Vacuum Heart Stabilizer according to approved hospital procedures.

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CHASE MEDICAL

800 E. Campbell Road
Suite 252
Richardson, Texas 75081 USA
(972) 783-7005 Tel
(844) 272-6624 Toll Free Fax
Email: info@ChaseMedical.com
https://chasemedical.com/IFU