



**VIPER™ II VACUUM APICAL LIFT
INSTRUCTIONS FOR USE**

Catalog Number	Description
API-700VS	Viper II Vacuum Apical Lift, M Base
API-800VS	Viper II Vacuum Apical Lift, Q Base

Explanation of Symbols on Packaging Label

	Sterilized using Ethylene Oxide		SKU / Catalog Number
	Manufacturer		Lot Number
	Date of Manufacture	Rx only	Prescription only / Caution: Federal (US) law restricts this device to sale by or on the order of a physician
	Use-by Date		Consult Electronic Instructions for Use
	Do Not Re-Use		Contains Phthalates

Product Description:

The VIPER II Vacuum Apical Lift features an articulating arm with a conforming silicone suction apparatus and a mounting base that fastens onto a sternal Retractor or Retractor Platform Rails. The arm is tightened or loosened by a knob. The suction apparatus is placed at the apex of the left ventricle. Vacuum pressure is applied through a regulated vacuum source at (-) 250 mmHg.

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 Apical Lift is intended for use during performance of beating heart coronary artery bypass surgery through a sternotomy incision approach. It is used for positioning the heart.

Contraindications:

This product is not intended for use except as indicated above. Do not position the Viper II Vacuum Apical Lift 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 (-) 250 mmHg. Excessive negative pressure may damage tissue.
- The Viper II Vacuum Apical Lift is to be used only on the apex and on the left ventricle immediately proximal to the apex.
- Do not use on atrial tissue or on the right ventricle.
- 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.

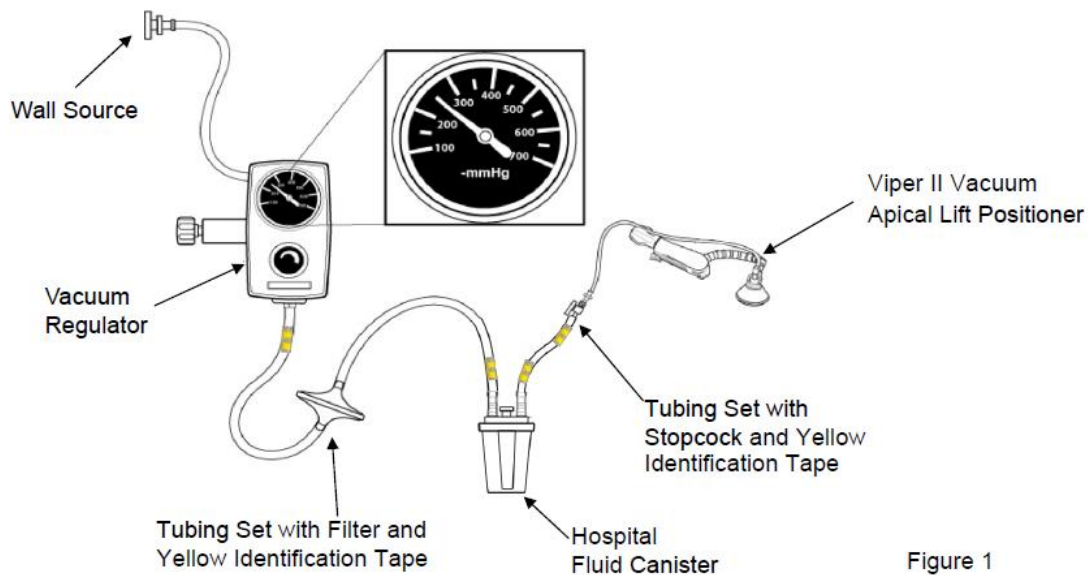
Adverse Effects:

None known.

Instructions for Use:

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 (-) 250 mmHg.
3. Utilizing aseptic technique, connect the luer lock fitting of the Viper II Vacuum Apical Lift to the stopcock fitting of the Tubing Set with Stopcock and Yellow 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 Apical Lift Tubing Set *with Filter* and Yellow Identification Tape (included) from the same fluid collection canister to the hospital's vacuum regulator.



VIPER II Vacuum Apical Lift (all models)

1. Utilizing aseptic technique, attach and secure the Viper II Vacuum Apical Lift to the Retractor or Retractor Platform Rails using the toe to heel approach.
2. Use the locking lever on the mounting base to secure the Viper II Vacuum Apical Lift to the Retractor or Platform Rails.
3. Prior to turning on the vacuum, place the suction apparatus on the apex or on the left ventricle immediately proximal to the apex.
4. Turn the vacuum on by turning the stopcock to the "on" position. Position the heart only after the device has reached full vacuum of (-) 250 mmHg.
5. Position the heart by holding onto the headlink with one hand while supporting the heart with the other hand.
6. To terminate suction and remove the Viper II Vacuum Apical Lift, 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 device from the heart.
7. Reposition the locking lever underneath the knob to remove the Viper II Vacuum Apical Lift from the Retractor or Retractor Platform Rails.
8. When finished, discard the Viper II Vacuum Apical Lift according to approved hospital procedures.

LIMITED WARRANTY AND DISCLAIMER OF LIABILITY

Chase Medical products (“Product”) are manufactured under carefully controlled conditions and Chase Medical warrants the Product will perform in accordance with its labeling and will be free from defects in material and workmanship under normal use for one year from the date of shipment.

Chase Medical’s sole liability shall be limited to replacement of, or credit for, any Product returned to Chase Medical and which Chase Medical determines, in its sole discretion, to have been defective in either material or workmanship at the time of shipment.

Chase Medical has no control over the conditions under which the product is handled or used by third parties, and specifically assumes no liability with respect to instruments reused, reprocessed or resterilized, in contraindication to the warnings in this document. THEREFORE, CHASE MEDICAL DISCLAIMS ALL WARRANTIES, BOTH EXPRESS AND IMPLIED, WITH RESPECT TO THE PRODUCT, INCLUDING BUT NOT LIMITED TO ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. CHASE MEDICAL SHALL NOT BE LIABLE TO ANY PERSON OR ENTITY FOR ANY MEDICAL EXPENSES OR DAMAGES CAUSED BY ANY USE, DEFECT, FAILURE OR MALFUNCTION OF THE PRODUCT, WHETHER A CLAIM FOR SUCH DAMAGES IS BASED UPON WARRANTY, CONTRACT, TORT OR OTHERWISE. NO PERSON HAS ANY AUTHORITY TO BIND CHASE MEDICAL TO ANY REPRESENTATION OR WARRANTY WITH RESPECT TO THE PRODUCT.

The exclusions and limitations above are not intended to and should not be construed as intending to contravene mandatory provisions of applicable law. If any part of this Limited Warranty and Disclaimer of Liability is held to be unenforceable or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions shall be enforced as if this Limited Warranty and Disclaimer of Liability did not contain the part held invalid.



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>