



**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		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.

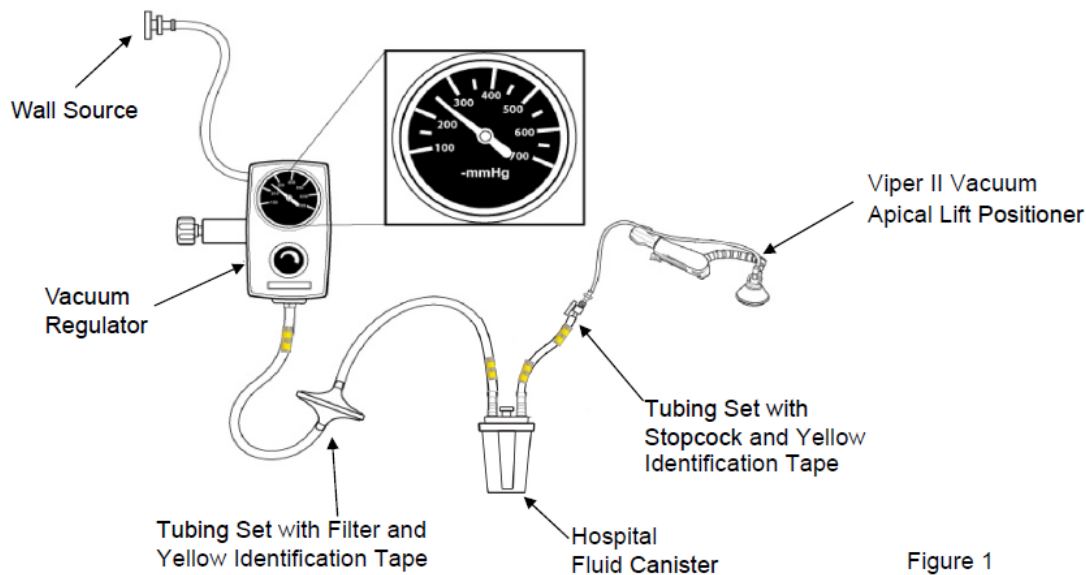


Figure 1

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.

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