




VAVD KIT (Vacuum Assisted Venous Drain Kit)

R_X Only

Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Information for Use:

Read Warnings and Precautions prior to use.

 Certain uses of this device require the use of additional equipment or connections in order for it to function properly. Carefully read the Information for Use prior to using the product and ensure that any additional items needed are available before using this device.

Description:

The Vacuum Assisted Venous Drain Kit is used in conjunction with a sealed venous reservoir capable of withstanding up to -125 mmHg (negative) pressure to augment venous return blood. Negative pressure is applied via wall suction through a vacuum regulator and is connected to the vent port on the venous reservoir. A negative pressure of approximately -100mmHg can be obtained via this method. A negative and positive relief valve are included as part of this kit along with tubing required to connect between reservoir, valves and regulator.



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The positive relief valve opens at a maximum 5mmHg and the negative relief valve opens at a maximum of -125mmHg.

Contents:


1 Vacuum Assisted Venous Drain Kit which includes:
- 1 Negative Pressure Relief Valve
- 1 Positive Pressure Relief Valve
- PVC Tubing

Indication:

The NovoSci™ VAVD Kit is designed to function in an extracorporeal circuit. The kit connects the venous reservoir to wall suction therefore augmenting venous return with suction. The kit also includes a positive and negative safety valve.

Contraindications:

This device is not designed, sold, nor intended for use except as indicated.

 **Summary of Warnings and Precautions:**
Read all warnings, precautions, and instructions prior to use.

Warning: This device was designated and built for single use only. Do not reuse or re-sterilize.

Warning: This device should be used by properly qualified and trained personnel.

Warning: This device is sterile if unopened, undamaged package. Inspect the device and package carefully. Do not use if the package and/or device is damaged.

Warning: Do not use chemicals such as ether acetone. These chemicals may cause damage to the device is used in or on the device.

Warning: Retrograde flow is possible in an occlusive pump if not totally occluded; in a centrifugal pump of not using a check valve.

Warning: This device was designated and built for single use only. Do not reuse or re-sterilize.

Warning: Entire CPB circuit is under vacuum. Vent system before infusing drugs, drawing samples, or manipulating tubing/fittings.

Warning: After use, this product should not be considered a biohazard. Handle and dispose in accordance with hospital Policy and local, state, and federal laws and regulations.

Precaution: The NovoSci™ VAVD Kit should not be connected to a vacuum greater than -125mmHg during operating use. Exposure to a level greater than -125mmHg may cause deformation of the reservoir housing.

Precaution: The vacuum regulator is an integral part of the system. Before sure to read its Instructions for Use.

Instructions for Set Up and Operation:

1. Remove the NovoSci™ VAVD Kit from the box and visually inspect the sterile bag for damage. If the package or kit appears to be damaged, do not use.
2. Make all necessary tubing and vacuum line connections using aseptic technique.

Vacuum Regulator Connection:

Attach the long tubing end to the vacuum regulator.

Venous Reservoir Connection:

Remove the vent port cap on the venous reservoir. Attached the long end of the “Y” connection to this port. Ensure that the tubing that connects to the regulator first routes downward to capture vapor in line.

Note: The shorter end of the “Y” connection (atmospheric line) will be clamped when the vacuum augmentation is required. When the clamp is removed, the reservoir will be exposed to the atmosphere and venous augmentation is diminished.

Safety Valve Check:

Clamp the vacuum line to just below the “Y” connector containing the 3/8” safety valve. Increase suction until the valve activates, making an audible noise. Do not use the valve if it fails to open.

Positive Pressure Valve:

Verify that the check valve moves freely in the housing. Do not use valve if the check ball does not move freely.

Place positive pressure valve on reservoir luer fitting.

Initiating Vacuum Augmentation:

1. Check proper operation of vacuum regulator and wall suction per regulator Instructions for Use.
2. Initial bypass using appropriate normal gravity drain perfusion technique.
3. Once bypass has been initiated.

Product Specifications:

Vacuum Augmentation: -95mmHg

Pressure/Vacuum:

Max Positive: 5mmHg
Max Negative: -125mmHg



Contains or Presence of Phthalates: Bis (2-ethylhexyl) phthalates on pregnant/nursing women or children have not been fully characterized and there may be concern for reproductive and development effects.

422190-000 Rev. E