BOEHRINGER®

VacPac™ Vacuum Assist Protection Circuit

Indications for Use

VacPac™ provides a sterile interface between the Boehringer Laboratories, LLC (BL) VAVD controller (Model 3931) and the patient circuit during Open Heart Cardiopulmonary Bypass Procedures. The BL Model 3931 was designed to provide accurate control of wall suction from 15-60 mmHg for use in vacuum assisted venous drainage and the removal of waste anesthetic gases in cardiac surgery. The BL 3931 provides a redundant safety device that limits maximum negative pressure to less than 90 mmHg and excess positive pressure.

Contraindications

This device is designed and sold for use only as indicated.

Description

VacPac™ is a sterile, single patient use device. The device is comprised of a cylindrical moisture collection jar which locks into the VAVD controller just below the Adjusting Knob. The upper wall of the collection jar has a protrusion with a flexible tube that connects to the venous drainage reservoir. The collection jar is secured to the VAVD controller by aligning the L-shaped tracks on the jar with the pins on the adapter and then pushing up while twisting counterclockwise until the jar locks into place. For use on a Perfusion Circuit, VacPac™ should only be used with the BL 3931. The BL 3931 provides a redundant safety device that vents excess negative pressure and positive pressure from the patient circuit.

Safety Information

This product is intended for use by or on the order of a physician. It is to be used by individuals who are properly trained in medical suctioning procedures. Please refer to the BL 3931 Instructions for Use for device control description. (BL Publication 3931.003).

Suction regulators must only be attached to central vacuum systems. Do not attach to compressed air, nitrogen, oxygen, or portable suction sources.

DO NOT clamp VacPac™ tubing. Clamping WILL disable the safeties built into the system.

When in the OFF position, the 3931 vents the circuit to atmosphere using a proprietary 5mm vent. When in the REG position, suction is applied to the circuit and all the safety systems are in the circuit.

This device should not be used for clinical procedures requiring greater than 60 mmHg of vacuum.

DO NOT use VacPac™ with any Boehringer Model Regulator other than 3931.

DO NOT use VacPac™ with any other brand of Regulator.

DO NOT cover, obstruct, or occlude the inlet of the interrupter where it is labeled 'Do Not Occlude Vent'. Do not attempt to calibrate this safety device. Return to the manufacturer for appropriate service.

Ensure adapter is securely in place on 3931, and collection jar is properly locked into adapter prior to applying suction. You may ensure unit is fully engaged by feeling a detent.

Clarity of collection jar is intended to be a visual indicator of condensation in the circuit.

VacPac™ is designed to prevent potentially contaminated condensation from returning to the patient circuit. If the VacPac™ collection jar overflows with condensation, water will enter the 3931 unit. Water will not cause permanent damage but will affect the performance, potentially changing the safeties. It must be avoided.

If blood overflows from the circuit, it will accumulate in the VacPac™ collection jar before entering the 3931. Vacuum will continue to be provided to the patient, but the 3931 unit must be returned to BL after the incident for cleaning and calibration.

After patient use, wipe all exterior surfaces of Suction Regulator [including inside of the mounting surface] with an appropriate surface disinfectant. Please refer to BL Publication 3800.044 for a complete list of surface disinfectants.

Always follow the Pre-Use Check detailed in BL Publication 3931.003 before clinical use.

Warnings and Precautions

R_X Only Federal law restricts this device to sale by or on the order of a physician or licensed practitioner. Use of this device should only be performed by persons having adequate training and familiarity with minimally invasive surgical tech-niques, and with the use of this device. Consult medical literature relative to techniques, complications, and hazards prior to use of this device.

⚠ Please read these instructions carefully and refer to Boehringer Laboratories Model 3931 Instructions for Regulator specific questions (BL Publication 3931.003).

The BL Model 3931 VAVD circuit will not be complete without VacPac™. Do not attempt to run Cardiopulmonary Bypass without VacPac™.

This device does not have a shutoff. If the circuit overflows, fluid will enter the unit. Please return the 3931 unit to Boehringer Laboratories if this occurs.

BOEHRINGER®

VacPac™ Vacuum Assist Protection Circuit

STERILE R This device is provided sterile by irradiation.

Do not use if package is open or damaged.

Inspect the device to ensure it has not been damaged before use.

Do not use if package is expired, sterility may be compromised.

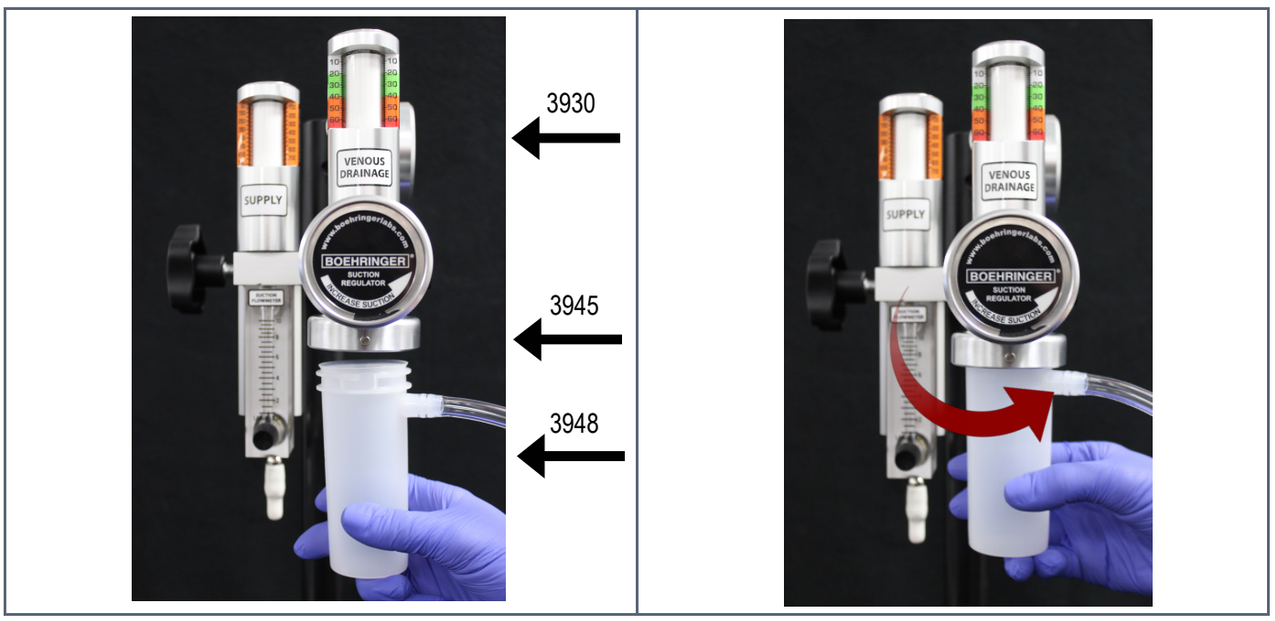
Single patient use. Do not reuse, reprocess or autoclave VacPac™, as this action may compromise the safety, function, and integrity of the device.

Dispose of VacPac™ per your facility's biohazardous waste disposal protocol.

This product is not made with natural rubber latex.

Installation

Refer to BL Publication 3945.007 for VacPac™ Adapter (Model 3945) installation instructions if necessary.



Theory of Operation for VAVD Controller with VacPac™:

OFF Mode: When the Mode Selector Knob of the Model 3931 is in the OFF position, the venous drainage reservoir reverts to atmospheric pressure through a proprietary 5mm vent. This is similar in practice to leaving the leg of a Y-connector open.

REG Mode: With the Model 3931 connected to the vacuum system and to a vacuum capable venous reservoir, rotating the Mode Selector Knob will place the unit into REG mode. Vacuum can now be regulated from 15-60 mmHg. Excess negative pressure is vented through a redundant safety feature built into the 3931. Excess positive pressure is also vented by the 3931.

Specifications

Supplied: Sterile
Length: Jar: 2"; Tubing: 4.5'
Diameter: Tubing: 3/8"
Volume of Trap Bottle : 3oz.
Material: tubing: polyvinyl chloride (PVC); Jar: low-density polyethylene (LDPE)
Packaging: SBS Carton of 10, individually packaged in peel pouches
Shelf Life: 2 years

VacPac™ is both BPA and DEHP free. As such, it is compliant with The State of California's Proposition 65, the Safe Drinking Water and Toxic Enforcement Act.

RxOnly	Found on IFU and packaging labels. Definition: Federal law restricts this device to sale by or on the order of a physician.
STERILE R	Found on IFU and packaging labels. Definition: Sterile
	Found on IFU and packaging labels. Definition: Do not re-use.
LATEX	Found on IFU and packaging labels. Definition: This product is not made with natural rubber latex.
	Found on the IFU and packaging labels. Definition: Manufacturer.
	Found on packaging labels. Definition: Do not use if package is damaged.
	Found on packaging labels. Definition: Consult instructions for use.
REF	Found on packaging labels. Definition: Reorder number.
LOT	Found on packaging labels. Definition: Lot number.
	Found on packaging labels. Definition: Use-by-date.

Boehringer Laboratories, LLC
300 Thoms Drive, Phoenixville, PA 19460
1-800-642-4945 www.boehringerlabs.com Made in USA

3948010 Rev A VacPac™ IFU 34248 Released July 2019