

# One-Vac™ Evacuated Drainage Bottle

## INSTRUCTIONS FOR USE

### PRODUCT DESCRIPTION

The One-Vac™ Evacuated Drainage Bottle is used to collect fluid from patients during drainage procedures. The bottle contains a vacuum that's activated by turning the handle counterclockwise to allow the vacuum in the bottle to remove fluid.

### INDICATIONS FOR USE

The One-Vac Evacuated Drainage Bottle is indicated for use to aspirate, remove, or sample body fluids.

### CLINICAL BENEFITS

The One-Vac Evacuated Drainage Bottle is made from shatter resistant plastic, provides fast fluid removal and provides a means to easily remove the fluid contents.

### CONTRAINDICATIONS

- None known.

### WARNINGS

- For single patient use only. Do not reuse, reprocess or sterilize. Reuse, reprocessing or sterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- This product is non-sterile.
- After use, dispose of device in a manner consistent with standard protocols for biohazard waste disposal.
- In the EU, any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the applicable Member State.

### PRECAUTIONS

- RX Only Caution - Federal law (USA) restricts this device to sale by or on the order of a physician.
- Inspect the One-Vac Evacuated Drainage Bottle to ensure there is no damage.

### POTENTIAL COMPLICATIONS

Potential complications (in alphabetical order) of removing fluid include, but are not limited to any of the following complications:

- Electrolyte imbalance
- Exposure to bodily fluids
- Hypotension (low blood pressure) subsequent to drainage
- Loculation of fluid cavity
- Low flow rate/prolonged drainage
- Pain during fluid removal
- Pneumothorax
- Protein depletion
- Re-expansion pulmonary edema (swelling or fluid buildup in the lung due to rapid re-expansion of the lung) is an additional complication that may result from draining pleural fluid.

### DRAINAGE INSTRUCTIONS

1. Connect appropriate drainage tubing to the female luer of the One-Vac Evacuated Drainage Bottle.
2. Connect the other end of the drainage tubing to the drainage catheter.
3. Place the bottle upright on a flat surface with the bottle handle accessible.
4. Open the bottle by rotating the handle counterclockwise until the arrow in the handle lines up with the tubing (approximately half a turn). Let fluid drain until the bottle is full or the fluid stops flowing. **NOTE:** If drainage is to be stopped for any reason prior to the bottle becoming full or full evacuation of fluid, rotate the handle clockwise until the handle stops (approximately half a turn). To begin drainage again, rotate the handle counterclockwise until the arrow in the handle lines up with the tubing (approximately half a turn).

**CAUTION:** While the bottle is connected to the catheter, do not rotate the handle past where the arrow in the handle lines up with the tubing (approximately half a turn) until you are ready to empty the bottle. If the handle is rotated too far while connected to the catheter, air could enter the system causing a pneumothorax. If air enters the system, disconnect the tubing from the catheter and use another bottle.

**NOTE:** When rotating the handle a bump may be felt. This is an indication to stop rotating the handle until ready to remove the handle completely. Do not rotate the handle past this feature until the bottle has been disconnected from the catheter and you are ready to empty the contents of the bottle.

**CAUTION:** A kink or loop in the line can stop flow early. If this occurs, remove the kink or loop.

**CAUTION:** If fluid does not flow, check the catheter and tubing for kink(s) or loops. If there are no kinks or loops, the patient may need to adjust positions to move fluid to the catheter drainage holes. If fluid still does not flow, replace the One-Vac Evacuated Drainage Bottle with a new one.

**NOTE:** To slow fluid flow, the handle may be rotated clockwise. It may be better to regulate flow with a mechanism (such as a roller clamp) on the tubing.

5. When fluid flow stops or the bottle is full, disconnect the drainage tubing from the One-Vac Evacuated Drainage Bottle.
- NOTE:** Rotate the handle counterclockwise until it stops before disconnecting the drainage tubing. This will prevent fluid from leaking.
6. To empty fluid from the bottle, rotate the handle counterclockwise until it detaches from the bottle. Empty the fluid in accordance with accepted physician instructions and standard protocols for biohazard waste disposal.
7. To replace the handle, rotate the handle clockwise.

SYMBOL	DESIGNATION
	Use By: YYYY-MM-DD
	Lot Number
	Catalog Number
	Do Not Use If Package is Damaged and Consult Instructions for Use
	Single Use
	Caution
	Non-sterile
<b>RX ONLY</b>	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician
	Medical Device
	Unique Device Identifier
	Consult Instructions for Use For electronic copy scan QR code, or go to <a href="http://www.merit.com/ifu">www.merit.com/ifu</a> and enter IFU ID. For printed copy, call U.S.A. or EU Customer Service
<b>EC REP</b>	Authorized Representative in European Community
	Manufacturer
	Date of Manufacture: YYYY-MM-DD



#### Manufacturer:

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