

Drainage Bottle Kit

INSTRUCTIONS FOR USE

PRODUCT DESCRIPTION

The Aspira® Drainage Bottle accesses the Aspira Valve Assembly to drain accumulated fluid in the pleural (chest) or peritoneal (abdominal) cavity to relieve symptoms associated with pleural effusions or malignant ascites. The Aspira Drainage Bottle attaches to the implanted catheters Aspira Valve and is activated by turning the handle counterclockwise.

INDICATIONS FOR USE

The Aspira Drainage Bottle is indicated for use only with the Aspira Valve Assembly for intermittent drainage.

CLINICAL BENEFITS

Rather than the need for a patient to travel to a healthcare facility to have the drainage procedure performed, the Aspira Drainage Bottle allows patients to drain unwanted fluid as prescribed by a healthcare provider in a location convenient to the patient.

CONTRAINDICATIONS

- None known.

WARNINGS

- For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization 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 resterilization 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.
- Do not use excessive force on the valve or catheter. Excessive force or incorrect usage may damage the device or cause accidental catheter dislodgement.
- Accessing the Aspira Valve Assembly with anything other than approved devices may damage the valve.
- The connection on the end of the Aspira Drainage Bottle drainage line is made specifically to only attach to the Aspira Valve.
- 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.
- Do not drain more than 1,000 mL from the chest or more than 2,000 mL from the abdomen in any one drainage session.
- Follow a clean procedure when accessing the catheter.
- Inspect kit to ensure all components are included.
- Make sure the drainage line is securely connected to the valve before initiating drainage.
- Do not drain fluid through a damaged catheter.
- Do not use scissors or any sharp instruments on the catheter as that may damage the catheter.
- If damage to the catheter does occur, place the supplied slide clamp between the catheter damage and exit site and contact the patient's physician.
- Access the Aspira Valve Assembly using only Aspira approved devices.
- A kink or loop in the line can stop flow early. If this occurs, remove the kink or loop.
- The patient should be instructed to contact their physician if:
 - Patient develops a fever (body temperature above 100.5° F [38° C]), notice redness, swelling, oozing or has pain at the exit site. These may be signs of infection that may require treatment.
 - Shortness of breath is not relieved after draining 1,000 mL from the chest or 2,000 mL from the abdomen at one time.
 - The patient continues to experience symptoms, but little or no fluid drains from the catheter.
 - Less than 25-50 mL drains in 3 drainage procedures in a row.
 - The appearance (color, thickness, etc.) of the fluid changes significantly between drainages.

POTENTIAL COMPLICATIONS

Potential complications (in alphabetical order) of draining the pleural or peritoneal space include, but are not limited to any of the following complications:

- Accidental catheter dislodgement, breakage or removal
- Electrolyte imbalance
- Exposure to bodily fluids
- Hypotension (low blood pressure) subsequent to drainage
- Loculation of peritoneal 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. Remove and discard catheter valve cap from the catheter valve.
2. Wipe the end of the valve with an alcohol pad.
3. Pick up the connecting end of the drainage line and push it onto the end of the catheter until you hear or feel a click. Gently tug on the drainage line to make sure the connection is secure.
4. Place the bottle upright on a flat surface with the bottle handle accessible.
5. Open the bottle by rotating the handle counterclockwise until the arrow in the handle lines up with the drainage line (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 drainage line (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 drainage line can stop flow early. If this occurs, remove the kink or loop.

CAUTION: If fluid does not flow, check the catheter and drainage line for kink(s) or loops. If there are no kinks or loops, check that the roller clamp on the drainage line is open. If the roller clamp is closed, open the roller clamp. If the roller clamp is open and fluid is not flowing, the patient may need to adjust positions to move fluid to the catheter drainage holes. If fluid still does not flow, replace the Aspira Drainage Bottle with a new one.

CAUTION: Do not drain more than 1,000 mL from the chest or more than 2,000 mL from the abdomen in any one drainage session.

CAUTION: The patient should be instructed to contact their physician if:

- Patient develops a fever (body temperature above 100.5° F [38° C]), redness, swelling, oozing or has pain at the exit site. These may be signs of infection that may require treatment.
- Shortness of breath is not relieved after draining 1,000 mL from the chest or 2,000 mL from the abdomen at one time.
- The patient continues to experience symptoms, but little or no fluid drains from the catheter.
- Less than 25-50 mL drains in 3 drainage procedures in a row.
- The appearance (color, thickness, etc.) of the fluid changes significantly between drainages.

















NOTE: To slow fluid flow, adjust the roller on the drainage line to pinch the drainage line down.

NOTE: If there is pain while draining, adjust the roller on the drainage line to pinch the drainage line down. The bottle may also be closed by turning the handle clockwise (approximately half a turn).

6. When fluid flow stops or the bottle is full, hold the catheter with one hand and pinch the wings of the connector with the other hand until the connector easily comes away from the catheter.


NOTE: To prevent fluid from leaking, close the roller clamp prior to disconnecting the Aspira Drainage Bottle from the catheter.

7. Wipe the catheter valve with a new alcohol pad. Place the new valve protector cap over the catheter valve.
8. To empty fluid from the bottle, rotate the handle counterclockwise until it detaches from the bottle (approximately two full turns). Empty the fluid in accordance with accepted physician instructions and standard protocols for biohazard waste disposal.

SYMBOL	DESIGNATION
	Use By: YYYY-MM-DD
	Lot Number
	Catalog Number
	Do Not Re-sterilize
	Do Not Use If Package is Damaged and Consult Instructions for Use
	Single Use
	Caution
	Sterilized Using Ethylene Oxide
	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician
	Medical Device
	Unique Device Identifier
	Single Sterile Barrier
	Consult Instructions for Use For electronic copy scan QR code, or go to www.merit.com/ifu and enter IFU ID. For printed copy, call U.S.A. or EU Customer Service
	Authorized Representative in European Community
	Manufacturer
	Date of Manufacture: YYYY-MM-DD


For a copy of this device's current European Summary of Safety and Clinical Performance (SSCP), please go to www.merit.com/EU-SSCP.




www.merit.com



Manufacturer:
Merit Medical Systems, Inc.
1600 West Merit Parkway,
South Jordan, Utah 84095 U.S.A.
1-801-253-1600
U.S.A Customer Service 1-800-356-3748



Authorized Representative:
Merit Medical Ireland Ltd,
Parkmore Business Park West,
Galway, Ireland
EU Customer Service +31 43 358 82 22

406997001EN_002 ID 2021-02-27