



Drainage Bottle Kit

Product Description:

The Aspira* Drainage Bottle accesses the Aspira* Drainage Catheter to drain accumulated fluid in the pleural (chest) or peritoneal (abdomen) cavity to relieve symptoms associated with pleural effusions or malignant ascites. The drainage bottle attaches to the implanted catheter and is activated by moving the slide clamp. The Aspira* Drainage System provides patients with a convenient, compassionate way to relieve pleural effusion or malignant ascites symptoms at home.

Indications For Use:

The drainage collection device is indicated for use only with the Aspira* Drainage Catheter for intermittent drainage.

Contraindications:

- None known when used with the Aspira* Drainage System.

Warnings:

- Do not invert the bottle and/or hold it above the catheter exit site, this could result in collected fluid flowing back into the catheter.
- Intended for single use. DO NOT REUSE. Reuse and/or repackaging may create a risk of patient or user infection, compromise the structural integrity and/or essential material and design characteristics of the device, which may lead to device failure, and/or 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.
- Do not use scissors or other sharp objects near the catheter.
- Accessing the catheter valve with anything other than the Aspira* Drainage System approved devices may damage the valve.
- Handle the bottle with caution. Do not drop the bottle on hard surfaces.
- Dispose of used product in accordance with accepted medical practice and applicable local, state and federal regulations. Used product may present a potential biohazard.
- Do not use if package is damaged.
- Do not use if product is damaged.

Precautions:

- Federal (USA) law restricts this device to sale by or on the order of a physician.
- Carefully read and follow instructions prior to using this device.
- Do not drain more than 1,000 mL from the chest or 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 catheter valve using only the Aspira* Drainage System approved devices.
- The pinch clamp on the drainage line must be completely closed when not draining or the vacuum in the bottle may be lost.
- A kink or loop in the line can stop flow early. If this occurs, remove the kink or loop to restart flow.
- 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 isn't 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.) changes significantly between drainages.

Possible Complications:

Pleural and peritoneal fluid drainage may result in any of the following complications:

- Accidental catheter dislodgement, breakage or removal
- Exposure to bodily fluids
- Fluid path-way blockage
- Hypotension (low blood pressure) subsequent to drainage
- Infection
- Leakage
- Low flow rate/prolonged drainage
- Occlusion
- Pain during fluid removal
- Skin irritation

CHEST:

- Re-expansion pulmonary edema (swelling or fluid build up in the lung due to rapid re-expansion of the lung) is an additional complication that may result from draining pleural fluid.

ABDOMEN: The following are additional complications that may result from draining peritoneal fluid:

- Electrolyte imbalance
- Loculation of peritoneal cavity
- Peritonitis
- Protein depletion

Drainage Instructions:

NOTE: Before beginning this procedure, read the "Contraindications," "Warnings," "Precautions" and "Possible Complications" sections of these instructions for use.

1. Remove and discard catheter valve cap from the catheter valve.
2. Wipe the end of the valve with an alcohol pad.
3. Clamp the drainage line completely closed using the clamp found on the drainage bottle tubing. 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.

CAUTION: The pinch clamp on the drainage line must be completely closed when not draining or the vacuum in the bottle may be lost.

4. Place the bottle on a table by the patient. Push the white slide clamp over until it no longer pinches the tube on the drainage bottle.

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

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 isn't 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.
5. Release the pinch clamp on the drainage line to begin draining fluid. When the fluid flow stops or the bottle is full, reclamp the tubing attached to the bottle and then detach the bottle tubing by holding the catheter with one hand and pinching the wings of the white plastic connector until it easily comes away from the catheter.
NOTE: The clamp can be used to slow the rate of fluid removal down if the patient experiences pain associated with the drainage.
 6. Wipe the catheter valve with a new alcohol pad. Place the new valve protector cap over the catheter valve.

An issued or revision date for these instructions is included for the users information. In the event two years have elapsed between this date and the product's use, the user should contact **Bard Access Systems, Inc.** to see if additional product information is available.

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www.myaspira.com

Drainage Bottle Kit
(Dressing Kit Included)
Reorder Number:

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