Aspira*

DRAINAGE SYSTEM

Pleural/Peritoneal Drainage Kit

Product Description:

The Aspira* Drainage Bag 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 bag attaches to the implanted catheter and is activated using an in-line siphon pump.

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 Aspira* Drainage Bag is indicated for use only with the Aspira* Drainage Catheter for intermittent drainage.

Contraindications:

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

Warnings:

- 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.
- Accessing the catheter valve with anything other than the Aspira* Drainage Bag, Aspira* Luer Adapter or Aspira* Universal Tubing Adapter may damage the valve.
- Dispose of used product in accordance with accepted medical practice and applicable local, state and federal regulations. Used product may present a potential biohazard.

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.
- Check the packages for damage before opening them.
- Sterilized using ethylene oxide. Do not resterilize.
- 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 Bag, Aspira* Luer Adapter or Aspira* Universal Tubing Adapter.
- A kink or loop in the line can stop flow early. If this occurs, remove the kink or loop and squeeze the siphon pump once again to restart flow.
- The patient should be instructed to contact their physician if :
  - Patient develops a fever (body temperature above 100.5º F [38º 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:

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

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:

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

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. 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. Gently squeeze the siphon pump one time to initiate flow. Place the bag at least arms length below the patient's chest or abdomen.

CAUTION: A kink or loop in the line can stop flow early. If this occurs, remove the kink or loop and gently squeeze the pump once again 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 100.5º F [38º 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. When the fluid flow stops or the bag is full, hold the catheter with one hand and pinch the wings of the white plastic connector until it easily comes away from the catheter.
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.

Revised Date: October 2010

Bard Access Systems, Inc.
605 North 5600 West
Salt Lake City, UT 84116 USA
1-801-522-5000
Home Supply Ordering: 1-866-443-3471
Hospital Ordering Information: 1-800-545-0890
Clinical Information: 1-866-893-2691
www.myaspira.com

Reorder Number:
4992301

0727180 / 1010R