English

Aspira® DRAINAGE SYSTEM

Drainage Kit

INSTRUCTIONS FOR USE

PRODUCT DESCRIPTION

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

INDICATIONS FOR USE

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

CONTRAINDICATIONS

None known when used with the Aspira Valve Assembly.

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.
- 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

- ℞ 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 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 100.5° 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 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.

POTENTIAL COMPLICATIONS

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

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

PLEURAL (CHEST)

- 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.

PERITONEAL (ABDOMEN)

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

DRAINAGE INSTRUCTIONS

NOTE: Before beginning this procedure, read the "Contraindications", "Warnings", "Precautions" and "Potential 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. Place the bag on a flat service at least arm's length below the patient's chest or abdomen. Gently squeeze the pump one time. It will slowly re-expand as fluid fills the pump. Let fluid drain until the bag is full or the fluid stops flowing.

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 100.5° 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. When fluid flow stops or the bag 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.
6. Wipe the catheter valve with a new alcohol pad. Place the new valve protector cap over the catheter valve.

SYMBOL	DESIGNATION
	Use By: YYYY-MM-DD
LOT	Lot Number
REF	Catalog Number
	Do Not Re-sterilize
	Do Not Use If Package is Damaged and Consult Instruction for Use
	Single Use
	Caution
STERILE EO	Sterilized Using Ethylene Oxide
℞ ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician
	This product can expose you to chemicals including Di(2-ethylhexyl)phthalate, (DEHP), which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.
MD	Medical Device
UDI	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
EC REP	Authorized Representative in European Community
	Manufacturer

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