












ASEPT[®]

600ml-OR-1,000ml Drainage Kit

INSTRUCTIONS FOR USE



LS-00115-01-AE 2022-03

 Do not reuse	 Do not resterilize	 Do not use if package is damaged	Store at room temperature	 Keep away from sunlight	 Consult instructions for use	 Catalog number
 Sterilized using ethylene oxide		Rx only	 Not made with DEHP	 Keep dry	 Use by	 Batch code

This product contains dry natural rubber

WARNING: This product contains chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.

ASEPT[®] is a registered trademark of PFM Medical, Inc.
Tegaderm[®] is a registered trademark of 3M Company

Interventional Systems
B | BRAUN

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Assembled and packaged in U.S.A.

Interventional Systems
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Instructions for Use

ASEPT® 600ml or ASEPT® 1,000ml Drainage Kit

Contents of unopened, undamaged package are:

STERILE

Disposable - This device is intended for one use only.
Do not reuse or resterilize. Sterilized with Ethylene Oxide.

PRODUCT DESCRIPTION:

The ASEPT® Drainage Kit is a complete vacuum bottle kit with all the items generally required for either pleural or peritoneal drainage.

The following instructions are for the ASEPT® 600ml Drainage Kit or the ASEPT® 1,000ml Drainage Kit.

Before using this product make sure that you have been fully trained on the correct use of the items in this kit. If you have any questions or problems in regards to draining fluid, please contact your doctor or nurse.

Depending on your prescription you have been provided with the ASEPT® 600ml Drainage Kit or the ASEPT® 1,000ml Drainage Kit.

The ASEPT® 600ml Drainage Kit or ASEPT® 1,000ml Drainage Kit contains the following items:

One 600ml or 1,000ml vacuum bottle set with the following features:

- Bottle scaled in 10ml increments
- Green vacuum indicator plastic cap
- Clear plastic tubing with pinch clamp
- Green tube with vacuum release clamp
- Luer lock connector with protective cap

One Procedure Pack including:

- One - CSR Wrap
- Four - Gloves
- Three - Alcohol Pads
- One - Foam Catheter Pad
- Six - Gauze Pads, 4"x4"
- One - Tegaderm® Self Adhesive Dressing
- One - Emergency Slide Clamp

ADVICE TO PATIENTS:

If you still feel shortness of breath, or if the bottle appears to be filled with more than 2/3 of fluid, all the fluid may not have drained. Use a second bottle kit if advised by your physician to do so or contact your doctor or nurse.

Disposal after Use

Take a pair of scissors, cut off the green rubber tube connected to the drainage line as well as the vacuum indicator. Empty the bottle into the toilet or sink. Discard the bottle.

STERILITY:

This device has been sterilized, **is for single use only, and is not to be reused.** As long as the packaging remains sealed and uncompromised the contents within each package are sterile. B. Braun Interventional Systems will not be responsible for any products that are reesterilized, nor accept for exchange or credit any product that has been opened but not used by the patient or purchaser.

WARRANTY: B. BRAUN INTERVENTIONAL SYSTEMS INC. WARRANTS THAT THIS PRODUCT WAS MANUFACTURED ACCORDING TO APPLICABLE STANDARDS AND SPECIFICATIONS. PATIENT CONDITION, CLINICAL TREATMENT AND PRODUCT MAINTENANCE MAY AFFECT THE PERFORMANCE OF THIS PRODUCT. USE OF THIS PRODUCT SHOULD BE IN ACCORDANCE WITH THE INSTRUCTIONS PROVIDED AND AS DIRECTED BY THE PRESCRIBING PHYSICIAN.

WARNING: Do not drain more than 1,000ml from your chest at any one drainage procedure; no more than 2,000ml from your abdomen during any 24 hour period.

Warning: Follow your physician's instructions in regards to frequency and amount of fluid drainage.

WARNING: Do not use scissors or other sharp objects near the ASEPT® Drainage Catheter. The slide clamp should be used to clamp off the catheter if you accidentally cut the catheter.

AFTER DRAINING THE FLUID – PLACING A NEW DRESSING:

16. Clamp the pinch clamp on the drainage line fully closed and disconnect the drain line from the valve.
 17. Put on the second pair of gloves included in the procedure pack. Pick up one glove by the wrist and put it on. Pick up the other glove by the wrist and put it on the other hand. Both gloves fit either hand. Be careful not to let the outside of the gloves come in contact with anything non-sterile for example, clothing or skin.
 18. Disinfect the area around the catheter exit site with the remaining two alcohol pads.
 19. Remove and discard the framed center panel of the self adhesive dressing.
- NOTE: The framed center panel is on the opposite of the printed side. Put the dressing back on the blue wrapping.**
20. Place the foam catheter pad around the catheter. Curl the catheter around in a circle and place it on top of the foam pad. **Be very careful not to kink the catheter.**
 21. Place the gauze pads over the top of the catheter and hold them down.
 22. Applying the dressing: Peel the dressing from the printed paper backing, exposing the adhesive surface. View the area where the dressing is to be applied through the film and center the dressing over the wound. Press it down. Do not stretch the dressing during the application. Slowly remove the remaining paper frame by peeling it off on the split section while smoothing down the dressing edges. Once removed smooth the entire dressing from the center toward the edges and firmly push down the dressing.
 23. Remove your gloves and discard.

General Information and Warnings:

WARNINGS:

- Do not reuse. Intended for single patient use only. The reuse of this single-use device can affect safety, performance and effectiveness, exposing patients and staff to unnecessary risk.
- It is not uncommon to feel some pain or cough when draining fluid. If you feel pain when draining, clamp the drainage line to slow or stop the flow of fluid for a few minutes. If you don't feel better after doing this, contact your nurse or doctor and withhold further drainage.
- Do not use scissors or other sharp objects near the ASEPT® Drainage Catheter.
- Keep the valve on your ASEPT® Drainage Catheter clean and the end connector of the drainage line sterile.
- This product and its packaging have been sterilized with Ethylene Oxide. Ethylene Oxide is a chemical known to the State of California to cause cancer, birth defects, or reproductive harm.

If the catheter gets punctured or cut follow the instructions below:

1. Pinch the catheter closed between your fingers.
2. Push the emergency slide clamp (included in the procedure pack) over the catheter between the patient's body and the cut or leak, then push the catheter completely into the small end of the clamp. The clamp will close the catheter.
3. Contact your doctor or nurse immediately.

INDICATIONS FOR USE:

The ASEPT® Drainage Kit is a non-powered, single patient, portable suction device used to aspirate, remove or sample body fluids.

Indications for Use – ASEPT® Peritoneal Drainage System

The ASEPT® Peritoneal Drainage System is indicated for periodic drainage of recurrent and symptomatic malignant ascites. The catheter is intended for long term access of the peritoneal cavity in order to relieve symptoms such as dyspnea.

Indications for Use – ASEPT® Pleural Drainage System

The ASEPT® Pleural Drainage System is intended for long term, intermittent drainage of symptomatic, recurrent, pleural effusions, including malignant pleural effusions and other pleural effusions that do not respond to treatment of the underlying disease.

PRECAUTIONS:

- Federal (USA) law restricts this device to sale by or on the order of a physician.
- This product contains dry natural rubber.
- It is recommended to limit drainage to no more than 1,000ml from your chest at any one drainage procedure; 2,000ml from your abdomen during any 24 hour period. The volume of fluid removed should be based on directions from the treating physician.
- Potential complications of access and drainage of the pleural cavity include, but may not be limited to, the following: re-expansion pulmonary edema, pneumothorax, laceration of lung or liver, bleeding, hypotension/circulatory collapse, wound infection, and empyema.
- Potential complications of access and drainage of the abdomen include, but may not be limited to, the following: laceration of liver or bowel, hypotension/circulatory collapse, electrolyte imbalance, protein depletion, ascites leakage, peritonitis, wound infection, tumor growth in the catheter tunnel, and loculation of the peritoneal space.

APPLICATION:

Using the ASEPT® Drainage Kit

Use of the ASEPT® Drainage Kit should be easy since you have been fully trained. Follow these step-by-step directions. You should drain fluid every one or two days or as directed by your doctor.

BEFORE BEGINNING WITH THE DRAINAGE PROCEDURE:

1. Locate a clean and uncluttered workspace.
2. Wash your hands with soap and water for at least 1 minute.
3. Remove the adhesive dressing, gauze pads and foam catheter pad from over your catheter. Check for any redness, tenderness, swelling or fluid around the catheter.

If you see any signs of infection, do not continue with the drainage procedure and contact your doctor or nurse.

4. Pick up the bag that contains the ASEPT® Drainage Kit. Look at the green vacuum indicator on the top of the bottle. This indicator tells you if there is a vacuum in the bottle. The indicator should be down, not up. If the indicator is up discard and use another drainage kit.
5. Peel open the drainage kit pouch all the way and remove the procedure pack. Leave the ASEPT® bottle set on top of the pouch. Open the procedure pack bag by peeling the front and back of the pouch apart, starting at the top.

6. Place the procedure pack on your workspace. Remove the tape and unfold the blue wrapping. Leave the enclosed items on the wrapping.

The items and the inside of the wrapping are sterile, don't touch them with your ungloved hands or other non-sterile items.

7. Pick up one glove by the wrist and put it on. Pick up the other glove by the wrist and put it on the other hand. Both gloves fit either hand. Be careful not to let the outside of the gloves come in contact with anything non-sterile for example, clothing or skin. The outside of the gloves need to remain sterile.
8. Tear open the three alcohol pads but do not remove the pads from the pouches. Place the pads on the blue wrapping.
9. Remove the twist tie that holds together the drainage line. Put the bottle back on the open pouch. Do not remove the protective cap on the end of the drainage line yet.

CONNECTING THE DRAINAGE BOTTLE TO THE CATHETER:

10. Squeeze the pinch clamp on the drainage line completely closed.
11. Hold the catheter valve end in one hand and vigorously clean the valve surface and around the valve with one of the alcohol pads.
12. Remove the protective cap from the luer lock connector on the drain line and align it in the center of the silicone valve surface.
13. Push the luer lock connector into the silicone valve and twist to close. The connection must be tight to open the valve and allow the flow of fluid.

WARNING: Make sure the connectors are tight

DRAINING FLUID INTO THE BOTTLE:

14. Release the white vacuum release clamp until it no longer pinches the green tube closed. Release the pinch clamp on the drainage line slowly to begin draining fluid. The fluid will flow into the vacuum bottle.

Note: If there is little or no fluid flow, check and ensure that the connection between the luer lock connector and the valve is tight.

15. Remove your gloves and discard. You adjust the flow by squeezing the pinch clamp on the drainage line partially closed.

Note: The fluid may slow down when the fluid is almost completely drained. When the flow stops or the bottle kit is filled with about 2/3 of fluid or more close the drainage line by squeezing the pinch clamp completely closed. The drainage will usually take 10-15 minutes.

WARNING: It is not uncommon to feel some pain or cough when draining fluid. Clamp the drainage line to slow or stop the flow of the fluid for a few minutes for symptom relief. If you don't feel better after doing this, stop the drainage procedure and contact your doctor or nurse.