

ASEPT[®] 2,000ml Drainage Bag Kit with Procedure Pack

INSTRUCTIONS FOR USE



LS-00134-01-AD 2019-04

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.

ASEPT[®] is a registered trademark of pfm medical, inc.

Tegaderm[®] is a registered trademark of 3M

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

Consult instructions for use

Contains DEHP



Do not reuse



Do not resterilize



Keep dry



Manufacturer



Not made with natural rubber latex

REF

Catalog number



Do not use if package is damaged

Rx only

STERILE EO

Sterilized using ethylene oxide



Keep away from sunlight



Use by

LOT

Batch code

Store at room temperature

Interventional Systems
B | BRAUN

Distributed by:
B. Braun Interventional Systems Inc.
824 Twelfth Avenue
Bethlehem, PA 18018
www.bisusa.org



Manufacturer:
pfm medical, inc.
1916 Palomar Oaks Way,
Suite 150
Carlsbad, CA 92008

Distributed by:
B. Braun Interventional Systems Inc.
824 Twelfth Avenue
Bethlehem, PA 18018
www.bisusa.org

Customer Service, ordering
TEL: (877) 836-2228
FAX: (610) 849-1334
Technical Support
TEL: (800) 443-8362

Assembled and packaged in USA.
Components made in USA and China.

Interventional Systems
B | BRAUN

Instructions for Use

ASEPT® Drainage Bag Kit

PRODUCT DESCRIPTION:-

This product is to be used for peritoneal drainage with the ASEPT® Peritoneal Drainage Catheter only included in the ASEPT® Peritoneal Drainage System. The ASEPT® Drainage Bag Kit is a complete kit with all the items generally required for peritoneal drainage. 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.

THE ASEPT® DRAINAGE BAG KIT CONTAINS- **THE FOLLOWING ITEMS:**

- One 2,000ml Drainage Bag scaled in 100ml increments
- Clear plastic tubing with white pinch clamp
- Luer Lock Connector on the end of the plastic tubing with protective cap
- Release valve on the bottom of the bag

ONE PROCEDURE PACK:

- Four gloves
- Three alcohol pads
- Foam catheter pad
- Six gauze pads
- Tegaderm® Self-adhesive dressing
- Blue emergency slide clamp

INDICATIONS FOR USE:

The ASEPT® Drainage Bag Kit is an accessory to the ASEPT® Peritoneal Drainage System and is used for peritoneal drainage with the ASEPT® Peritoneal Drainage Catheter.

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.

AFTER DRAINING THE FLUID – PLACING A NEW DRESSING:

17. Clamp the pinch clamp on the drain line fully closed and disconnect the drain line from the valve.
18. 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.
19. Disinfect the area around the catheter exit site with the remaining two alcohol pads.
20. 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.
21. 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.
22. Place the gauze pads over the top of the catheter and hold them down.
23. Apply 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.
24. Remove your gloves.

DISPOSAL AFTER USE:

Empty the bag in the toilet or sink by pulling down the release valve on the bottom of the bag. Discard the empty bag.

STERILITY:

The drainage bag with drain line and procedure pack have been sterilized. This product 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 Inc. will not be responsible for any product that is resterilized, nor accept for exchange or credit any product that has been opened by the patient or purchaser but not used.

GENERAL INFORMATION AND WARNINGS:

- Do not reuse. Intended for single patient use.
- 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 blue emergency slide clamp that is included in the procedure pack over the catheter between the patient's body and the cut or leak and push the catheter completely into the small end of the clamp. The clamp will close the catheter.
3. Contact your doctor or nurse immediately.

PRECAUTIONS:

- Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
It is recommended to limit the drainage procedure to 2,000ml from the 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 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 BAG KIT

Use of the ASEPT® Drainage Bag Kit should be easy since you have been fully trained. Follow these step-by-step instructions. 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 one 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. Peel open the drainage bag pouch all the way and leave it on top of the pouch. Open the procedure pack bag by peeling the front and back of the pouch apart, starting at the top.
5. 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.

6. 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 needs to remain sterile.
7. Tear open the three alcohol pads but do not remove the pads from the pouches. Place the pads on the blue wrapping.

CONNECTING THE DRAINAGE BAG TO THE CATHETER:

8. Squeeze the pinch clamp on the drainage line completely closed.
9. Hold the catheter valve end in one hand and vigorously clean the valve surface and around the valve with one of the alcohol pads.
10. Remove the protective cap from the Luer Lock Connector on the drain line and align it in the center of the silicone valve surface.
11. 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 CONNECTION IS TIGHT

DRAINING FLUID INTO THE BAG:

12. Place the drainage bag below your catheter. The drainage bag requires gravity to collect fluid.
13. Release the pinch clamp on the drainage line slowly to begin draining fluid.
14. The fluid will flow into the bag.

NOTE: Should there be leakage on the bottom of the bag check the blue release valve and make sure that it is all the way pushed up towards the bag.

NOTE: If there is no or very little 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 clamp partially closed.
16. The fluid may slow down when the fluid is almost completely drained. When the flow stops or the bag appears to be full close the drain line by squeezing the pinch clamp completely closed.

WARNING: Do not drain more than 2,000ml from your abdomen during any 24 hour period.

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

WARNING: Do not use scissors or other sharp objects near the ASEPT® Drainage Catheter.

WARNING: The blue slide clamp should be used to clamp off the catheter if you accidentally cut the catheter.