

ASEPT® 2,000ml Drainage Bag

INSTRUCTIONS FOR USE



Picture for reference only.

LS-00132-01-AB REV 2016-04

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

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.

Interventional Systems
B | BRAUN

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



Manufacturer:
pfm medical, inc.
1815 Aston Ave.,
Suite 106
Carlsbad, CA 92008

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

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

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

Interventional Systems
B | BRAUN

Instructions for Use

ASEPT® Drainage Bag

PRODUCT DESCRIPTION:

The ASEPT® Drainage Bag is to be used for peritoneal drainage with the ASEPT® Peritoneal Drainage Catheter only. 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 CONTAINS THE FOLLOWING ITEMS:

- One 2,000ml Drainage Bag scaled in 100 ml 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

GENERAL INFORMATION AND WARNINGS:

- **If drainage is done with the ASEPT® Drainage Bag in a setting other than a hospital where not all the dressing change items are readily available, the ASEPT® Procedure Pack is required.**

PATIENT/CAREGIVER:

Do not perform drainage unless you have the ASEPT® Procedure Pack.

Note: ASEPT® Single Drainage Bag does not include Procedure Pack, use ASEPT® Procedure Pack provided with Drainage Bag Kit or ASEPT® Drainage Bottle Kit.

ONE PROCEDURE PACK INCLUDES:

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

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 has 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 reesterilized, nor accept for exchange or credit any product that has been opened by the patient or purchaser but not used.

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

Use of the ASEPT® Drainage Bag 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.

PATIENT/CAREGIVER:

Do not perform drainage unless you have the ASEPT® Procedure Pack.

MEDICAL PROFESSIONAL:

We recommend using the ASEPT® Procedure Pack with the use of this product only. If the ASEPT® Procedure Pack is not readily available and you need to substitute with other items ensure that you have all items that come with with the procedure pack and follow sterile procedure.

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.

READY TO BEGIN:

4. Peel open the drainage bag pouch all the way and leave the drainage bag 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.

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.

INDICATION:

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

Indications for Use - 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.