














ASEPT®

Peritoneal Drainage System

INSTRUCTIONS FOR USE



LS-00117-01-AC 2021-07

 Do not reuse	 Do not resterilize	Rx only	 Store at controlled room temperature 15°-30°C (59°-86°F)	 Keep away from sunlight	 Consult instructions for use	 REF Catalog number
 STERILE EO Sterilized using ethylene oxide	 Do not use if package is damaged	 LATEX Not made with natural rubber latex	 DEHP Not made with DEHP	 Keep dry	 Use by	 LOT Batch code

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.
ChlorPrep® is a registered trademark of Carefusion 2200, Inc.
Tegaderm® is a registered trademark of 3M

Interventional Systems
B | BRAUN

Manufactured for:
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

Manufactured for:
B. Braun Interventional Systems Inc.
824 Twelfth Avenue
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Technical Support
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Assembled and packaged in U.S.A.

Interventional Systems
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Instructions for Use

ASEPT® Peritoneal Drainage System

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® Peritoneal Drainage System is a tunneled, indwelling catheter used to drain accumulated fluid from the abdomen.

The catheter is placed in the patient's peritoneal cavity enabling the patient to perform periodic peritoneal drainage at home or in the hospital. The primary components of the system are the indwelling ASEPT® Peritoneal Catheter and the ASEPT® Drainage Kit. The end of the indwelling catheter has a valve attached that will allow the flow of fluid only when accessed. The valve should only be connected to the ASEPT® Drainage Line connected to the drainage bottle kit. Although the ASEPT® Drainage Line, which is part of the Peritoneal Drainage System and also available separately, may be connected to other fluid collection equipment we strongly recommend using the ASEPT® Drainage Kit only. The ASEPT® Peritoneal Drainage System provides patients with a convenient way to relieve malignant ascites symptoms at home.

CATHETER REMOVAL PROCEDURE

It may be appropriate and/or necessary to remove the ASEPT® Peritoneal Drainage catheter. Three successive attempts to drain fluid that result in less than 50 ml of fluid removed may indicate one of the following: 1) the catheter is located away from the fluid 2) the catheter is occluded 3) the ascites has resolved

1. Place the patient in an appropriate position.
2. Aseptically clean the patient's abdomen around the catheter exit site.
3. Anesthetize the site.
4. Remove the sutures.
5. Using forceps, dissect around the cuff to free it from the ingrowth. Ensure that the cuff is completely free within the tunnel.
6. Grasp the catheter in one hand and pull with a firm constant pressure.
7. Cover the site as appropriate.

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 resterilized, 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.

The ASEPT® Peritoneal Drainage System contains the following:

- One - ASEPT® Drainage Catheter
- One - CSR Wrap

TRAY 1:

- Two - ChloroPrep® 10.5mL Tint
- One - Synthetic Suture, 2-0 Straight Needle
- One - Synthetic Suture, 3-0 Curved Needle

TRAY 2:

- Two - 5cc Syringes
- One - 10cc Syringe
- One - 22 GA. x 1.5" Needle
- One - 25 GA. x 1.0" Needle
- One - 18 GA. Guidewire Introducer Needle
- One - J-Tip Guidewire
- One - Safety Scalpel
- One - 16F Tear Away Introducer
- One - 12F Dilator
- One - 8F Dilator
- One - Tunneler
- One - Forceps

TRAY 3:

- One - Fenestrated Drape
- One - 16 GA. x 1.0" Needle
- One - 5-in-1 Drainage Line Adapter
- One - ASEPT® Drainage Line with Protective Cap
- One - Foam Catheter Pad
- Six - Gauze Pads 4" x 4"
- One - Tegaderm® Self Adhesive Dressing

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.
- Accessing the catheter with anything other than the ASEPT® Drainage Line connector may damage the valve.
- Dispose of the used product in accordance with applicable local, state and federal regulations. Used product may present a potential biohazard.
- When using the ASEPT® Drainage Line to access the catheter, ensure that the pinch clamp is fully closed prior to connecting.
- When using the ASEPT® Drainage Line to access the catheter for drainage with equipment other than the ASEPT® Drainage Kit, the adapter that is included in the kit may be utilized.
- Use caution when using wall suction or drainage equipment other than the ASEPT® Drainage Kit. It is strongly recommended to use the ASEPT® Drainage Kit only.
- Do not pass a wire, needle or other device through the valve.
- Do not flush or attempt to clear an occluded catheter with a syringe smaller than 10 ml.
- 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.

INDICATION:

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.

CONTRAINDICATIONS:

- When the peritoneal cavity is infected.
- When there is coagulopathy.
- When the peritoneal cavity is multi-loculated, and drainage of the single loculation may not provide relief of all associated symptoms.

SUBSEQUENT DRAINAGE PROCEDURES:

Subsequent drainage procedures are to be performed using the ASEPT® Drainage Kit. Each drainage kit contains the necessary drainage line, vacuum bottle, and other necessary items to perform the drainage procedure. Standalone drainage lines with 5-in-1 adapters are also available for drainage performed by medical personnel only.

It is vital that patients and/or caregivers are fully instructed on how to use the kit to drain malignant ascites. The person(s) responsible for drainage must be able to demonstrate that they are capable of performing the procedure.

If the patient/caregiver is not able or willing to drain at home, a medical professional should perform the drainage.

It is recommended that the patient is periodically contacted or seen by a clinician to evaluate treatment regimen, assess need for possible albumin supplementation, and evaluate catheter function status.

CATHETER VALVE REPLACEMENT:

In case the catheter valve becomes damaged or blocked it may be necessary to replace the valve. Make sure you have a new valve replacement kit opened and ready before changing the valve. Follow sterile technique procedures.

1. Clamp the ASEPT® catheter to prevent air from entering the catheter. Use rubber-shods in between the forceps to prevent damage to the catheter and cut the ASEPT® catheter between the forceps and the connector.
2. Using proper aseptic technique, wipe the surface of the replacement connector that will be inserted into the catheter with an alcohol pad.
3. Insert the valve connector all the way into the catheter tubing.

DRAINAGE PROCEDURE:

The drainage procedure can be done using the ASEPT® Drainage Kit or standard hospital drainage equipment. An adapter is included in the kit that can be attached to the drainage line. It is strongly recommended to drain with one of the ASEPT® Drainage Kits. If peritoneal drainage is practiced using devices other than with one of the ASEPT® Drainage Kits follow procedures or refer to the Manufacturer's Instructions for Use. The ASEPT® Drainage Kits have a drainage line attached that can only be used with the ASEPT® Drainage Catheter.

Caution: In malignant ascites patients, paracentesis-related hypotension is uncommon but has been documented. Use of IV fluid replacement and/or administration of colloidal agents can reduce the risk of hypotension. Initial drainage should be no more than 6 L during the first 24 hours. Drainage procedures thereafter should be limited to no more than 1,500 ml. DO NOT USE WALL SUCTION DIRECTLY!

DRAINAGE PROCEDURE USING THE DRAINAGE LINE INCLUDED IN THE KIT:

1. Make sure the pinch clamp on the ASEPT® Drainage Line set is in the closed position.
2. Remove the protective cap from the Luer Lock Connector, push into the valve on the end of the catheter and twist the connection to a tight fit.
3. Remove the protective cap from the male luer lock of the drainage line set and connect to collection equipment. If using an evacuated glass container that uses a 16 Ga. needle, the needle can be connected to the drainage line. If using an evacuated plastic bottle, connect the drainage line directly to the bottle. If using wall suction, use the 5-in-1 adapter to connect to the drainage line. **Use extra caution when using wall suction.**
4. Open the pinch clamp on the drainage line when ready for draining fluid.

Note: When draining fluid with the ASEPT® Drainage Kit carefully read and refer to the Instructions for Use included with every case.

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. Refer to enclosed instructions for use for ChlorPrep®.
- Insertion or removal of this device is only to be done by qualified health professionals.
- Sterile technique should be used when placing and draining the catheter.
- Sterilized by Ethylene Oxide. Do not resterilize.
- Exercise care when placing the catheter to prevent it from coming into contact with surfaces such as drapes or towels. Silicone rubber is highly electrostatic and attracts airborne particles and surface contaminants.
- Care must be taken when inserting the guidewire needle (commonly referred to as "Seldinger needle") to avoid puncturing or lacerating intra-abdominal organs.
- Exercise care when placing ligatures to avoid cutting or occluding the catheter.
- Use rubber-shod instruments when handling the catheter. Possible cuts or tears can occur if rubber-shod instruments are not used.
- Do not use forceps on the introducer to break its handle and/or peel the sheath.
- In malignant ascites patients, paracentesis-related hypotension is uncommon but has been documented. Use of IV fluid replacement and/or administration of colloidal agents can reduce the risk of hypotension. Additionally, initial drainage should be no more than 6 L during the first 24 hours.
- Potential complications of access and drainage of the peritoneal cavity 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.
- Removal of chylous malignant ascites could exacerbate protein depletion or related nutritional complications.
- Individual patient anatomy, such as thin or weak abdominal wall, may require special care and treatment.

APPLICATION:

Suggested Catheter Placement Procedure

Before beginning this procedure, read the 'Contraindications, Warnings and Precautions' sections of this manual. Proper procedures are the responsibility of the physician. The appropriateness of any procedure must be based upon good medical judgment and the needs of the patient. The following placement procedure should be used as general guideline only; actual procedures may differ and are the responsibility of the physician.

1. Place the patient appropriately to access the desired catheter insertion site.
2. Identify the appropriate insertion site through which to place the catheter.
3. Aseptically clean all around the planned insertion site.
4. Place the fenestrated drape with the opening located over the planned insertion and tunneling site.
5. Proceed with local anesthesia. Aspirate Lidocaine HCl 1% into a small syringe with a 25 Ga. needle and raise a skin wheal. Attach the 22 Ga. needle to the large syringe aspirating additional Lidocaine to complete infiltration of the access site and tunnel track.
6. Insert the guidewire needle (Commonly referred to as "Seldinger Needle") attached to a (small) syringe, obliquely through the abdominal wall at the desired insertion site. Ensure free aspiration of ascitic fluid. Remove the syringe, leaving the guidewire needle in place.

Caution: Care must be taken when inserting the guidewire needle to avoid puncturing any of the intra-abdominal organs.

7. Leaving the guidewire needle in place, insert the guidewire through the needle, advancing it into the peritoneal cavity. Ensure that no resistance is encountered.
8. Remove the guidewire needle. Leave the guidewire in place.
9. Make a 1 cm incision at the guidewire insertion site.
10. Make a 1-2 cm incision approximately 5 cm away from the first incision site.
11. Remove the protective tubing on the tunneler and attach the fenestrated end of the catheter onto the tunneler.

Caution: Exercise care when placing the catheter to prevent the catheter from coming into contact with non-sterile surfaces or particles. Silicone rubber is highly electrostatic and attracts airborne particles and surface contaminants.

Caution: Use rubber-shod instruments when handling the catheter. Possible cuts or tears can occur if rubber-shod instruments are not being used.

APPLICATION: (continued)

12. Pass the tunneler and the catheter subcutaneously from the second incision site through and out through the incision at the guidewire insertion site. Continue to draw the catheter through the tunnel until the polyester cuff passes about 1 cm beyond the upper incision. Remove the tunneler from the catheter.

Note: If the cuff is advanced further into the tunnel, it can make later removal of the catheter difficult.

Note: An 8F and a 12F Dilator are included in the kit that can be used to dilate the insertion site over the guidewire prior to using the 16F Dilator with sheath.

13. Pass the 16F dilator with sheath over the guidewire and into the peritoneal space.

Caution: Avoid excessive manipulation of the sheath when the dilator is not inserted. Do not kink the sheath as it may make it difficult to pass the catheter through.

14. Remove the guidewire and dilator from the sheath leaving the sheath in place. Immediately place your thumb over the sheath.
15. Insert the fenestrated end of the catheter into the sheath advancing it until all the fenestrations are within the peritoneal space. This can be verified under fluoroscopy as fenestrations are located along the barium stripe.
16. Peel away the sheath, taking care to keep the catheter in place within the peritoneal space. Adjust the catheter so that it lies flat in the tunnel and has no kinks as it passes into and through the abdominal wall.
17. Close the incision at the initial insertion site.
18. Close the second incision site and suture the catheter to the skin without restricting the diameter of the catheter.
19. If needed, proceed with the drainage procedure via the drainage line included in this kit (see instructions in the following section) or with one of the ASEPT® Drainage Kits.
20. Place the soft, foam catheter pad around the catheter. Wind the catheter on top of the foam pad, cover with gauze pads and secure to the patient with the self adhesive dressing.

Caution: Exercise care when placing ligatures to avoid cutting or occluding the catheter.

Caution: The ASEPT® Catheter Valve is for drainage only! Care should be taken to ensure its proper use.