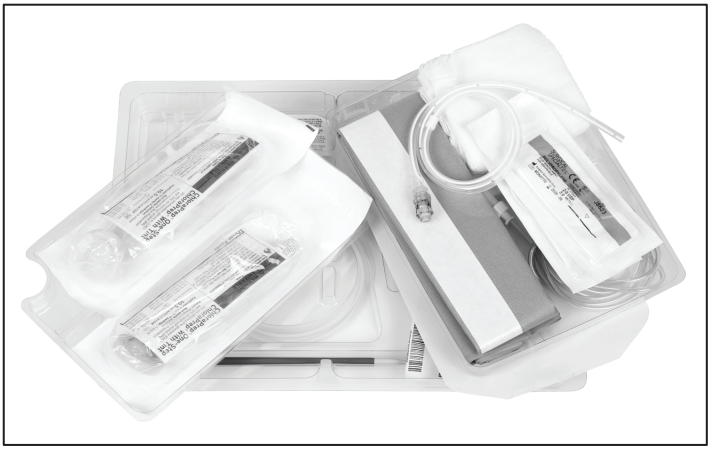
ASEPT®

Peritoneal Drainage System

INSTRUCTIONS FOR USE



LS-00117-01-AD 2023-12

Do not reuse

Do not resterilize

Rx only

15°C 30°C

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.

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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Customer Service, ordering
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Assembled and packaged in U.S.A.

Interventional Systems
B BRAUN

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.

INDICATIONS FOR USE:

The ASEPT® Peritoneal Drainage System is indicated for intermittent, long-term drainage of symptomatic, recurrent, malignant and non-malignant ascites that does not respond to medical management of the underlying disease and for the palliation of symptoms related to recurrent ascites. The use of the ASEPT® Peritoneal Catheter for non-malignant ascites is limited to patients who are intolerant or resistant to maximum medical therapy, refractory to large volume paracentesis (LVP) and are not candidates for trans-jugular intrahepatic portosystemic shunt or LVP. The ASEPT Peritoneal Catheter is indicated for adults only.

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.
- When the patient is known or suspected to be allergic to materials contained in the device.
- When the patient has a medical history of system palliation failure by peritoneal drainage.

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.
- A diagnostic paracentesis should be performed if the patient shows signs or symptoms of possible spontaneous bacterial peritonitis (SBP) such as fever or abdominal pain. If SBP is present, the patient should be treated per institutional guidelines, including systemic antibiotics and repeat diagnostic paracentesis at the end of the antibiotic regimen. For a patient with resolved SBP, the patient should be treated per institutional guidelines, including prophylactic antibiotics to help in the prevention of refractory or recurrent SBP. In the case of refractory or recurrent infections, the catheter should be removed and reinserted at the discretion of the clinician after the SBP has resolved.
- 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 then 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. Appropriate evacuating pressures should be used. Do not exceed a 14.7 mm Hg (20 cm water).
- 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.

- Potential and/or possible complications of access and drainage of the peritoneal cavity include, but may not be limited to, the following: exposure to bodily fluids, discomfort during fluid removal, accidental catheter dislodgment, breakage or removal, leakage around catheter, occlusion around catheter, fluid path blockage, low flow rate/prolonged drainage, catheter or cuff erosion through skin, electrolyte imbalance, sepsis, skin irritation or infection, circulatory collapse, protein depletion, ascites leakage, peritonitis, infection, abdominal wall cellulitis, splenic or hepatic laceration, pain during fluid removal, hemoperitoneum, bowel damage, hematoma.

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 ChloraPrep®.
- 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.
- Prior to placement of the device, drain the peritoneal cavity in a patient with recent SBP and/or patients with a significant amount of ascites fluid (tense ascites).
- The use of this product for refractory non-malignant ascites should be limited to patients who have failed 1 month of maximum medical therapy and 3 LVP procedures within 3 months
- Potential complications of access and drainage of the peritoneal cavity include, but may not be limited to, the following: Wound dehiscence/Poor Wound and Exit Site healing, especially in higher-risk patients such as those who are malnourished, elderly, or debilitated, 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, prolonged bleeding, leakage of peritoneal cavity fluid/ascites, pneumothorax, catheter malposition, venous air embolism, dysrhythmia, visceral injury, infection, skin irritation/inflammation, Urinary or biliary tract calculi if there is contact with salt solutions such as urine in the bile, poor damage, omentum wrapping, catheter migration, hernia, and pain.
- 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.

The ASEPT® Peritoneal Drainage System contains the following:

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

TRAY 1:

- Two - ChloraPrep® 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 GUIDELINES:

1. 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.
2. The site for guidewire insertion should be decided based on patient anatomy, including the location of loculated fluid collections and adhesions. The suggested insertion site is lateral to the midline, 6-10 cm below the costal margin, and above the patient's beltline. Consider ultrasonography to confirm the guidewire insertion site. After insertion of the guidewire, check for aspiration of ascitic fluid.
3. Guidewire insertion site selection should be based upon patient anatomy and presentation with consideration given to any possible adhesions or loculated pockets of fluid. The fenestrated section of the catheter should preferentially be placed low in the peritoneal cavity to maximize access to fluid.
4. The catheter exit site should be 5-8cm from the guidewire insertion site.
5. The fenestrated portion of the catheter should ideally be placed low in the peritoneal cavity in an area absent of omentum to optimize drainage of ascites fluid.
6. In order to ensure the catheter is not placed in a patient with a pre-existing infection, a diagnostic paracentesis evaluating for evidence of infection (such as gram stain and/or Absolute Neutrophil Count) should be performed prior to the placement of the device.

Suggested Catheter Placement Procedure

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. Check for aspiration of ascitic fluid.
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.
12. 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.

13. 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.

14. 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.

15. Remove the guidewire and dilator from the sheath leaving the sheath in place. Immediately place your thumb over the sheath.
16. 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.
17. 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.
18. Close the incision at the initial insertion site.
19. Close the second incision site and suture the catheter to the skin without restricting the diameter of the catheter.
20. 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.
21. 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.

DRAINAGE PROCEDURE:

The drainage procedure can be performed using:

1. ASEPT Vacuum Bottle(s)
2. Lockable Drainage Line with glass vacuum bottle(s)
3. Wall Suction inside the hospital setting

If using ASEPT Vacuum Bottle(s), refer to the ASEPT Drainage Kit Instructions for Use.

Caution: In 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 6L in the first 24 hours.

Caution: 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 intraperitoneal adhesion, tumor growth in the catheter tunnel, and loculation of the peritoneal cavity.

Caution: Removal of chylous ascites could exacerbate protein depletion or related nutritional complications.

Connecting the Drainage Line to Wall Suction

Caution: Keep the valve on the catheter and the lockable access tip on the drainage line clean. Keep them away from other objects to help avoid contamination.

1. The pinch clamp located on the ASEPT Drainage Line must be closed. To do so, pinch both sides of the clamp together until it is in the closed position.

Caution: The pinch clamp must be fully closed to occlude the drainage line. When not connected to a suction source, make sure the clamp attached to the drain line is fully closed, otherwise the drainage line may allow fluid to leak out that is caught in between the ASEPT catheter valve and the drainage line.

2. When holding the drainage line, remove the protective cap of the female luer by twisting away from luer, push and twist the luer into the valve attached to the ASEPT Peritoneal Drainage Catheter to a tight fit.
3. Attach the 5-in-1 adapter to the opposite end of the drainage line at the male luer end, fitting tightly on the drainage line.
4. Using the 5-in-1 adapter, connect the drainage line to the wall suction source.

Caution: Make sure the valve is securely attached to the drain line. If they are accidentally separated, they may become contaminated. If this occurs, clean the valve with an alcohol pad and use a new drainage line to avoid potential contamination.

Caution: Precautions should be taken to ensure the drainage line is not tugged or pulled.

Caution: If wall suction is used, it must be regulated to no greater than -60 cm H2O, or to drain no more than 400 ml of fluid per minute. (-60 cm H2O = -1.7 in Hg = - 44 mm Hg = - 0.8psi)

Caution: Never use a drainage bottle exceeding –24 inHg.

Connecting the Drainage Line to Glass Vacuum Bottle(s)

Caution: Keep the valve on the ASEPT Catheter and the luers on the drainage line clean. Keep them away from other objects to help avoid contamination.

Caution: When draining with glass vacuum bottles, do not use a needle larger than 17G.

The pinch clamp located on the ASEPT Drainage Line must be closed. To do so, pinch both sides of the clamp together until it is in the closed position.

Caution: The pinch clamp must be fully closed to occlude the drainage line. When not connected to a suction source, make sure the clamp attached to the drain line is fully closed, otherwise the drainage line may allow fluid to leak out that is caught in between the ASEPT catheter valve and the drainage line.

Caution: When connecting to a glass vacuum bottle, make sure the pinch clamp on the drainage line is fully closed. Otherwise, it is possible for some or all of the vacuum in the bottle to be lost.

1. Attach the 16G needle to the male luer fitting on the drainage line.
2. Connect the 16G needle to the glass vacuum bottle.
3. Insert and twist the female luer on the drainage line securely into the ASEPT Peritoneal catheter valve. When holding the ASEPT Catheter Valve in place, you will insert the luer into the valve and twist firmly one half of a turn.

Caution: Make sure the ASEPT valve and luer on the drainage line are securely connected when draining. If they are accidentally separated, they may become contaminated. If this occurs, clean the valve with an alcohol pad and use a new drainage line to avoid potential contamination.

Caution: Precautions should be taken to ensure the drainage line is not tugged or pulled.

Draining Fluid

1. Open and release the pinch clamp on the ASEPT Drainage Line when ready for draining fluid.
2. Adjust the flow by squeezing the pinch clamp on the drain line partially closed.

Caution: It is normal for the patient to feel some discomfort or pain when draining fluid. If discomfort or pain is experienced when draining, pinch the clamp towards the closed position to slow or stop the flow of fluid for a few minutes. Pain may be an indication of infection.

3. When the flow of fluid stops, or the desired amount of fluid has been completed, completely close the pinch clamp on the drainage line.

4. If you need to change the glass vacuum bottle/canister/water seal device or suction source for any reason, remove the drainage line from the suction source and connect to a new suction source. Open the pinch clamp again on the drainage line to resume draining.

Finish Drainage

1. Close the pinch clamp on the drainage line.
2. To unlock the ASEPT Catheter Valve from the drainage line, twist the luer attached to the ASEPT Catheter valve so that it becomes unlocked from the ASEPT Peritoneal Insertion Catheter. Set the used drainage line down.
3. Clean the ASEPT Peritoneal Catheter valve with an alcohol pad. Discard the alcohol pad. Do not try to push anything through the valve as damage to the valve may occur.
4. The ASEPT Peritoneal Catheter valve is a self-sealing valve that does not need a cap or covering. Do not cover the ASEPT valve with anything, otherwise the valve could be punctured or damaged and would need to be replaced.

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

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

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