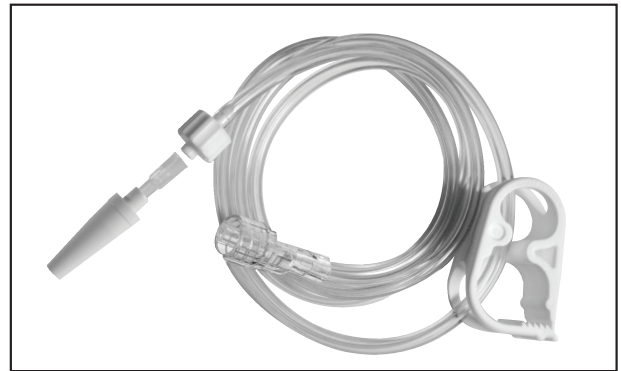










ASEPT[®] Drainage Line Set

INSTRUCTIONS FOR USE



LS-00136-01-AE 2021-07

		Rx only			REF
Do not reuse	Do not re-sterilize		Keep away from sunlight	Consult instructions for use	Catalog number
Store at room temperature					LOT
STERILE EO	Do not use if package is damaged	Not made with DEHP	Not made with natural rubber latex	Keep dry	Use by
Sterilized using ethylene oxide					Batch code

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

Interventional Systems
B | BRAUN

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

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



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: 1-(877)-836-2228
FAX: 1-(610)-849-1334
Technical Support
TEL: 1-(800)-443-8362
Made in U.S.A.

Interventional Systems
B | BRAUN

Instructions for Use

ASEPT® Drainage Line Set

STERILE

Disposable – This device is intended for one use only.

Do not reuse or resterilize, Sterilized with Ethylene Oxide.

PRODUCT DESCRIPTION:

The ASEPT® Drainage Line is used for connecting the ASEPT® Pleural or Peritoneal Drainage Catheter to wall suction or standard fluid collection equipment. This is a guide to aid in the assembly of the ASEPT® Drainage Line set to the ASEPT® Pleural Drainage System or the ASEPT® Peritoneal Drainage System. For more information please read and refer to the ASEPT® Drainage System Instructions for Use.

INDICATIONS FOR USE:

The ASEPT® Drainage Line is an accessory to the ASEPT® Pleural or Peritoneal Drainage System that is used for connecting the ASEPT® Catheter to wall suction or standard fluid collection equipment. The ASEPT® Pleural or Peritoneal Drainage Catheter is the main component of the ASEPT® Pleural or Peritoneal Drainage System.

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.

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.
- 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.
- Do not use if package is opened or damaged.

APPLICATION:

1. Make sure the pinch clamp on the ASEPT® Drainage Line 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. (An adapter that may be used with different types of collection equipment is included in this kit.) Use extra caution when using wall suction.
4. Open the pinch clamp on the drain line when ready for draining fluid.

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.