ASEPT®
Replacement Valve

INSTRUCTIONS FOR USE

LS-00138-01-AB REV 2016-04

Do not reuse

Do not resterilize

Rx only

Keep away from sunlight

Consult instructions for use

REF
Catalog number

Store at room temperature

STERILE | EO
Sterilized using ethylene oxide

Do not use if package is damaged

DEHP
Not made with DEHP

LATEX
Not made with natural rubber latex

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.

Interventional Systems
B BRAUN

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Manufacturer:
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Made in U.S.A.

Interventional Systems
B BRAUN

Instructions for Use

ASEPT® Replacement Valve

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® Replacement Valve is used for replacing the valve attached to the ASEPT® Pleural or Peritoneal Drainage Catheter in case of occlusion or malfunction. This is a guide to replace the ASEPT® Valve. Please read and refer to the ASEPT® Pleural Drainage System or the ASEPT® Peritoneal Drainage System Instructions for Use for more information on the operation of either system.

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.

INDICATION:

The ASEPT® Replacement Valve is used for replacing the valve attached to the ASEPT® Pleural or Peritoneal Drainage Catheter in case of occlusion or malfunction. 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.

APPLICATION:

Before beginning to replace the valve please have the following items:

- Scissors
- Forceps with rubber-shods
- Alcohol Pads

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. Remove the forceps.

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.