INSTRUCTIONS FOR USE

STERIMED UNDER WATER SEALED DRAINAGE SYSTEM

***Please Read All Instructions Carefully before Use(Sterile, for single use only)**

SMDPL/IFU/UWS/01 Rev. No.:00, Dt. 12.08.2023

PRODUCT DESCRIPTION:

Chest drains are surgical drains placed within the pleural space to facilitate removal of unwanted substances (air, blood, fluid, etc.) in order to preserve respiratory functions and hemodynamic stability. Some chest drains may utilize a flutter valve to prevent retrograde flow, but those that do not have physical valves employ a water trap seal design, often aided by continuous suction from a wall suction or a portable vacuum pump. The active maintenance of an intrapleural negative pressure via chest drains builds the basis of chest drain management, as an intrapleural pressure lower than the surrounding atmosphere allows easier lung expansion and thus better alveolar ventilation and gas exchange.

Chest Drainage system /Under Water Seal Drainage system (SMD 1043):

A single-use PVC device that is connected to a patient usually via Drainage Catheter used to provide negative pressure for the removal of large volumes of fluids that have collected within the thorax between the lung and chest wall.

INTENDED PURPOSE:

A single-use short term device that is connected to a patient usually via Drainage Catheter used for the removal of large volumes of fluids that have collected within the thorax between the lung and chest wall.

INDICATIONS:

- Pneumothorax: Open or closed; simple or tension
- Hemothorax
- Hemopneumothorax
- Hydrothorax
- Chylothorax
- Empyema
- Pleural effusion
- Patients with penetrating chest wall injury who are intubated or about to be intubated.

CONTRAINDICATIONS:

Relative contraindications to chest tube placement include pulmonary adhesions from previous surgery, pulmonary disease, and/or trauma. Coagulopathy and diaphragmatic hernias can be a contraindication as well

LIMITATION

Underwater sealed drainage system used for short-term uses.

INTENDED USER

Doctors or trained healthcare professionals only.

INTENDED PATIENT POPULATIONS

Infant, Paediatric and Adult

DIRECTIONS FOR USE:

- Check the packing carefully, if packing is damaged,torned or pierced discard the piece. Wash up and scrub hands and preferably use pre sterile protective gloves.Peel open the pack and remove the device aseptically.
- Make a separate stab two inches away from the wound area.
- Open the hangers, if the bottle is to be hanged on the bed side.
- Use the floor stand, if the bottle is to be placed on the floor.
- Add approximate 200 ml of liquid to fill up the chamber up to the initial lable.Insert the straw into the bottle and screw down the cap ensuring that the bottom of the straw is below the initial level tank.
- Connect the connector to the catheter to start the drainage.
- To start the suction, remove vent cap and connect to the suction source for low vacuum regulated suction.Replace the cap when suction is completed.
- For record of drainage, white side for writing on graduation scale.
- Sterile, individually packed in a box

WARNING:

Researchers have found biofilm has caused a range of serious health problems including Salmonella, Shigella, E. Coli, Campylobacter and Yersinia. Drains are breeding grounds for bacteria that cause illness

PRECAUTIONS AND CAUTIONS:

- Prior to using read entire instructions for use. Failure to do so may result in severe patient injury.
- STERIMED DISCLAIMS ANY RESPONSIBILITY FOR POSSIBLE CONSEQUENCES FROM IMPROPER USE.
- Do not clean or Re-use the device, For single Patient use only.
- Discard after Single use.
- The product should be used immediately after opening the packing.
- Do not use with a stylet or guide wire. Do not use the device after expiry Date mentioned on the Label.
- If the patient is sensitive or allergic to PVC, do not use the device

ADVERSE EFFECTS:

- Trauma to intrathoracic structures, intra-abdominal structures and intercostal muscles.
- Re-expansion pulmonary oedema.
- Haemorrhage

CLINICAL BENEFITS:

- Drainage of large pleural effusions
- Low pressure pulmonary bleeding
- Improves respiratory function
- Prevents pneumothorax
- Facilitate postoperative recovery
- Prevent air re-entry
- Less susceptible to clogging or kinking

RESIDUAL RISKS:

- Pneumothorax
- Infection, Chest Pain

SUPPLY:

Chest Drainage system /Under Water Seal Drainage system- SMD 1043

MATERIAL USED:

Component	Material	Specification/Grade
CDS Bottle	K-Resin	Medical Grade
Bottle Cap	PP (Poly Propylene) Compound	Medical Grade
Connecting Tube	PVC (Poly Vinyl Chloride) Compound	Medical Grade
Connector	ABS (Acrylonitrile Butadiene Styrene) Compound	Medical Grade

STERILITY:

This device is sterilized by ethylene oxide gas. Do not re-sterilize, and do not reuse. Do not use it if the package is opened or damaged. Discard opened, unused Device.

STORAGE:

These products should be stored in their original box in a cool and dry place between 5 to 45° C, preferably away from direct and indirect sources of light and heat. Do not use after expiry.

DEVICE DISPOSAL:

Used Under water sealed systems may be contaminated with infectious and/or other hazardous materials. Discard used catheters in the container meant for infectious waste. Unused expired products should be disposed of as per local regulations.

NOTE: Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established

SYMBOLS:

REF	**Catalogue No.**		**See instructions for Use**
	Cautions		**Keep Dry**
	Do not use it if the packaging is damaged.		**Sterile Barrier System**

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	Single-Use		Do not Re-sterilize
LOT	Batch / Lot No.	STERILE EO	Ethylene Oxide Sterilized
	Date of Mfg.	LATEX	Latex Free
	Date of Exp.	MD	Medical Device
	Avoid Direct Sunlight	45°C 5°C	Keep in a dry place between 5°C to 45°C
PHT DEHP	Phthalate Free		Pyrogen Free
UDI	Unique Device Identifier		

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