



INSTRUCTIONS FOR USE

Thoracic Drainage Catheter (without Trocar)

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

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

PRODUCT DESCRIPTION:

Thoracic Chest/Drainage Catheter (PVC) (SMD 1002): A straight PVC tube without trocar used after cardio thoracic surgery to remove secretions from thoracic cavity.

Thoracic/ Chest Drainage Catheter (Silicone) (SMD 1002 SL): A straight Silicone tube without trocar used after cardio thoracic surgery to remove secretions from thoracic cavity.

Thoracic Drainage Catheter Angled (PVC) (SMD 1002 A): An angled PVC tube used after cardio thoracic surgery to remove secretions from thoracic cavity.

Thoracic Drainage Catheter Angled (Silicone) (SMD 1002 A SL): An angled Silicone tube used after cardio thoracic surgery to remove secretions from thoracic cavity.

INTENDED PURPOSE:

Used for rapid non-operative short term chest drainage.

INDICATIONS:

- Pneumothorax
- Hemothorax
- Pleural effusion
- Empyema

CONTRAINDICATIONS:

- Previous Surgery
- Pulmonary Disease or trauma
- Coagulopathy
- Diaphragmatic hernia

LIMITATION

N/A

INTENDED USER

Trained and registered healthcare professional.

INTENDED PATIENT POPULATIONS

Adults & paediatrics

DIRECTIONS FOR USE:

- Choose the appropriate size of Device.
- Open the package from the peel-open area and remove the device.
- Make a separate stab two inches away from the wound area.
- Insert forceps inside, from the stab towards wound area; hold the tongue connector firmly with forceps.
- Gently pull the catheter from the wound area through the stab hole.
- Place the multiple eyes part of catheter inside the wound area and then close the wound.
- Depth of placement is measured by graduation given at every 2 cm intervals.
- Use the suture to hold the catheter close to the skin.
- Cut the tongue plug and insert the plain end of spare connector in the proximal end of catheter.
- Connect stopper end of connector to the drainage tube of underwater seal drainage kit.
- Discard the device after single use.

WARNING:

#Thoracic Drainage Catheters do not use in placement includes refractory coagulopathy and presence of a diaphragmatic hernia, as well as hepatic hydrothorax and also in scarring in the pleural space.

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 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:

- Lung Injury
- Thoracic vascular injury

CLINICAL BENEFITS:

- Safe, effective, and less expensive
- Successful treatment of thoracic empyema's
- Better Treatment for traumatic haemothorax's
- Minimal invasion
- Less interference with patients' activities and sleep
- No remaining scars

RESIDUAL RISKS:

- Pneumothorax, Haemothorax
- Perforation
- Infection, Chest pain, Bleeding, Blockage

SUPPLY:

Thoracic /Chest Drainage Catheter (PVC): SMD 1002



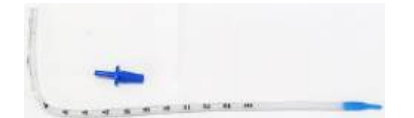
Thoracic/ Chest Drainage Catheter (Silicone): SMD 1002 SL



Thoracic Drainage Catheter Angled (PVC): SMD 1002 A



Thoracic Drainage Catheter Angled (Silicone): SMD 1002 A SL



MATERIAL USED:

Thoracic Drainage Catheter (SMD 1002) /Thoracic Drainage Catheter Angled (PVC) (SMD 1002 A)

Component	Material	Specification/Grade
Catheter	PVC (Poly Vinyl Chloride) Compound	Medical Grade
Connector	ABS (Acrylonitrile Butadiene Styrene)	Medical Grade
Tongue Connector	PVC (Poly Vinyl Chloride) Compound	Medical Grade



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Identifier

Thoracic Drainage Catheter – (SMD 1002 SL) /Thoracic Drainage Catheter
Angled (PVC) – (SMD 1002 ASL)



OBELIS S.A. Bd, General Wahis, 53,
1030, Brussels, Belgium
Email: mail@obelis.net

Component	Material	Specification/Grade
Catheter	100 % Silicone	Medical Grade
Connector	ABS (Acrylonitrile Butadiene Styrene)	Medical Grade
Tongue Connector	PVC (Poly Vinyl Chloride) 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:

The Device 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 Devices may be contaminated with infectious and/or other hazardous materials. Discard used catheters in the container meant for infectious waste. Unused expired catheters 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:

	Catalogue No.		See instructions for Use
	Cautions		Keep Dry
	Do not use it if the packaging is damaged.		Sterile Barrier System
	Single-Use		Do not Re-sterilize
	Batch / Lot No.		Ethylene Oxide Sterilized
	Date of Mfg.		Latex Free
	Date of Exp.		Medical Device
	Avoid Direct Sunlight		Keep in a dry place between 5°C to 45°C
	Phthalate Free		Pyrogen Free
	Unique Device		

Sterimed Group, 501 Ring Road Mall,
21, Manglam Place, Rohini Sec-3 Delhi-85

Manufactured by:

Sterimed Medical Devices Pvt. Ltd.

Plot No. 211A, Sector-16, HSIIDC, Bahadurgarh,
Jhajjar, Haryana - 124507 (INDIA)

Customer Care No.: +91-11-42466196/396

Email : info@sterimedgroup.com

Website : www.sterimedgroup.com

EN ISO 13485:2016 Certified Company

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