



INSTRUCTIONS FOR USE

Thoracic Drainage Catheter with Trocar (Thoracic Trocar Catheter)

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

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

PRODUCT DESCRIPTION:

Thoracic Trocar Catheter (PVC) (SMD 1001): A straight PVC tube with trocar used for rapid non-operative chest drainage.

Thoracic Trocar Catheter (Silicone) (SMD 1001 SL): A straight Silicone tube with trocar used for rapid non operative chest drainage.

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 right Size of Device.
- Open the package from the peel-open area and remove the device.
- Make a small incision at the location of insertion.
- Insert the Trocar with the catheter through intercostal space with all surgical precautions.
- After reaching pleural cavity hold the Trocar and slide the catheter over the Trocar, then withdraw the Trocar and further the hands before use the device.
- Anchor the catheter to the skin by anchoring stitches.
- Seal the catheter interface by dressing and stitching tape.
- Connect the catheter to the underwater seal drainage system.
- Discard the device after single use.

WARNING:

#Thoracic Drainage Catheters with trocar 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 if the package is opened and damaged.
- 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 Trocar Catheter (PVC): SMD 1001



Thoracic Trocar Catheter (Silicone): SMD 1001 SL



MATERIALS USED:

Thoracic Trocar Catheter (PVC) (SMD 1001):

Component	Material	Specification/Grade
Trocar Needle	Stainless Steel / Aluminium	Medical Grade
Catheter	PVC (Poly Vinyl Chloride) Compound	Medical Grade
Connector	ABS (Acrylonitrile Butadiene Styrene)	Medical Grade
Mouth Code	PVC (Poly Vinyl Chloride) Compound	Medical Grade
Mouth Cap	LDPE (Low Density Poly Ethylene)	Medical Grade
Needle Hub	ABS (Acrylonitrile Butadiene Styrene)	Medical Grade

Thoracic Trocar Catheter (Silicone) (SMD 1001):

Component	Material	Specification/Grade
Trocar Needle	Stainless Steel / Aluminium	Medical Grade
Catheter	100% Silicone	Medical Grade
Connector	ABS (Acrylonitrile Butadiene Styrene)	Medical Grade
Mouth Code	PVC (Poly Vinyl Chloride) Compound	Medical Grade
Mouth Cap	LDPE (Low Density Poly Ethylene)	Medical Grade
Needle Hub	ABS (Acrylonitrile Butadiene Styrene)	Medical Grade

STERILITY:



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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 Identifier		



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EN ISO 13485:2016 Certified Company

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