

INSTRUCTIONS FOR USE LEAFLET

THORACIC DRAINAGE CATHETER WITH & WITHOUT TROCAR

Medicic/Glocic

THORACIC DRAINAGE CATHETER CURVED (WITHOUT TROCAR)

Medicic Curved/Glocic curved

INSTRUCTIONS FOR USE

DEVICE DESCRIPTION:

The device "Thoracic Catheter" simply has a length of PVC tubing attached to the connector that is inserted through the chest wall and into the pleural space or mediastinum. It is used to remove air, fluid or pus from the intrathoracic space.

MATERIAL:

PP,PVC, Aluminium, SS

INTENDED PURPOSE:

Thoracic Drainage Catheter is intended for drainage of air or fluid from the pleural cavity after cardio-thoracic and thoracic surgery.

INTENDED USER:

The device is intended to be used by a qualified respiratory physician (Pulmonologist) or cardiothoracic surgeon.

INTENDED PATIENT POPULATION:

All patient population irrespective of age and gender.

INDICATION:

The Thoracic Drainage Catheter is intended for remove air (pneumothorax), blood (hemothorax), fluid (pleural effusion or hydrothorax), chyle (chylothorax), or purulence (empyema) from the intrathoracic space

CONTRAINDICATIONS:

- Not to be used in patients allergic/hypersensitive to materials used in device

INSTRUCTIONS FOR USE:

- Verify the integrity of sterile barrier packaging.
- Open the outer sterile barrier pack from the area of peel and place the inner sterile barrier pack on the sterile field.
- Open the inner sterile barrier pack and remove the device for use.
- Inspect the catheter visually. It should not have any cut and the connector should not have any crack.
- Ensure that the eyes on catheter are proper and does not have blockage.
- Select and mark appropriate site of insertion using medical knowledge on the chest wall and apply local anesthesia.
- For thoracic catheter without trocar: Make an incision at the insertion site using appropriate medical tool and insert the catheter tube into the pleural cavity through chest wall.
- For thoracic catheter with trocar: With care, remove the trocar cover just before use only and insert catheter

tube with trocar from tip connector into pleural cavity through chest wall. Withdraw the trocar carefully.

- After inserting the device in pleural cavity, ensure the correct position of the device inside patient using radiopaque line and appropriate medical technique.
- After confirming the correct position of the catheter inside pleural cavity, secure catheter near insertion site using suture.
- For thoracic catheter without trocar: Then attach the taper tongue connector with drainage system for removal of air or fluid.
- For Thoracic Drainage Catheter with trocar: Attach the step connector with drainage system for removal of air or fluid.

For Thoracic Drainage Catheter straight/curved without trocar:

- If required to shorten the length of catheter tube, cut the tube from opposite end of the eyes and attach tightly the step connector provided additionally with the product and then attach the step connector with drainage system for removal of air or fluid.

PRECAUTIONS:

- Open the outer and inner sterile barrier pack only under aseptic conditions.
- Withdraw the device carefully to avoid any patient injury.
- The use of this product is restricted to a qualified respiratory physician (Pulmonologist) or cardiothoracic surgeon.
- Do not use if the sterile pack is opened or damaged.
- Dispose after single use.
- This product is for single use only; re-use could cause infection or cross-contamination.
- Store in a cool and dry place. Keep away from sunlight and rain.
- Exposure to elevated temperature and ultraviolet light to be avoided.

WARNINGS:

- The product should not be reprocessed.
- Global Medikit will not be responsible for any structural and functional damage to the device or packing caused due to improper transportation and material handling.
- The product is guaranteed, sterile till the package has not been opened or damaged within the expiry date.
- Do not clean or re-sterilize.
- The trocar cover must be opened only when required.

- Ensure the correct position of catheter inside the body prior to catheter securement.
- Ensure the securement of the device to body before further use.

ADVERSE EFFECTS:

Pharyngeal discomfort, pain, sore throat, epistaxis, gastritis, allergic reaction from hypersensitivity to materials used in the device, infection, otitis media, sinusitis

HAZARDS OF RE-USE:

Transmission of infection from one patient to another.

PACKAGING:

The device is packed in PP+PEcopolymer film sealed with medical grade paper, inner carton i.e. 3-ply box & master carton i.e. craft pulp paper.

STERILIZATION:

Device is EO sterilized and sterilization is done by Global Medikit Limited.

STORAGE CONDITION:

Temperature Limit: 5°C to 25°C

DISPOSAL:

After use, this product may be a potential Biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal law and regulation.

REPORTING OF ADVERSE EVENTS:

In case of any serious adverse event please report the same to info@globalmedikit.in or regulatory@obelis.net
Note: For product used in EU also report to the competent authority of the Member State in which the user and/or patient is established.



	Manufacturer
	Authorised representative in the European Community
	Date of manufacture
	Use by / Expiry Date
	Batch code
	Catalogue number
	Sterilized using ethylene oxide
	Do not resterilize
	Temperature limit
	Do not reuse
	Consult instructions for use
	Do not use if package is damaged and consult instructions for use
	Caution
	Medical Device
	CE marking
	Unique Device Identifier
	Double sterile barrier system
	Non-Pyrogenic
	Keep Dry
	Keep Away from Sunlight

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IFU

Device Name : THORACIC DRAINAGE CATHETER (WITH & WITHOUT TROCAR)

Brand Name : MEDICIC & GLOCIC

Dimension : Length 203 x width 140mm

Colour : BLACK

Material : Chromo art paper 70gsm

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