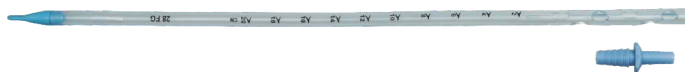


Thoracic catheter

- Suitable for effective drainage after Cardio-Thoracic & thoracic Surgery.
- Atraumatic & rounded open distal end with smooth eyes.
- With radio-opaque line and marking at every 2 cm from the last eye.
- Sizes: 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40 FG
- Soft, frosted and kink resistant PVC Tubing -Matching size connector for easy connection to the drainage system.
- Proximal end is fitted with pull through tapered tongue.
- Qty. in carton (Inner/Master) – 25Pcs/ 150Pcs.



Technical Specifications

Size (FG)	OD (mm)	ID (mm)	Length (mm.)	Reference No.	
				Glocic (without Trocar)	Glocic (with Trocar)
8	2.70	1.70	180	62608A	C62608A
10	3.30	2.15	180	62610A	C62610A
12	4.00	2.70	180	62612A	C62612A
14	4.70	3.00	200	62614A	C62614A
16	5.30	3.70	200	62616A	C62616A
18	6.00	3.70	350	62618A	C62618A
20	6.70	4.80	350	62620A	C62620A
22	7.30	4.90	350	62622A	C62622A
24	8.00	5.50	350	62624A	C62624A
26	8.70	5.60	350	62626A	C62626A
28	9.30	6.60	350	62628A	C62628A
30	10.00	7.60	350	62630A	C62630A
32	10.70	7.60	350	62632A	C62632A
34	11.30	8.20	350	62634A	C62634A
36	12.00	8.20	350	62636A	C62636A
38	12.80	9.00	350	62638A	C62638A
40	13.30	9.50	350	62640A	C62640A

Also available

Glocic™

with
TROCAR

THORACIC CATHETER



Glodrain®

Wound Suction Drainage System

- Suitable to offer surgeons and doctors an effective device for close wound drainage under negative pressure post operatively with the option to use one or two catheters simultaneously.
- Graduated bellow container.
- Redon drain catheters are provided with radio opaque line and satin smooth eyes.
- Connecting tube is kink resistant and is provided with additional strength to withstand the suction.
- Easy to depress chamber to activate the suction of bellow unit by one person.
- Available with different catheter sizes with matching size curved needle to meet moderate to heavy drainage needs.

Unit consists of

- Bellow unit.
- Connecting tube with clamp and "Y" connector.
- Curved needle with matching catheter.
- Spare perforated catheter.

Type Bellow Capacity

- 800 ml.

Supplied As:

- Complete unit packed in a box.
- Sterile, ready for use.

Technical Specifications

Size (FG)	Colour code	O.D of perforated catheter (mm)	Length of perforated catheter (cm)	Capacity of Below container (ml)	Ref. No.
6	Light Green	2.00	50	800	5090065G
8	Blue	2.70	50	800	5090085G
10	Black	3.30	50	800	5090105G
12	White	4.00	50	800	5090125G
14	Green	4.70	50	800	5090145G
16	Orange	5.30	50	800	5090165G
18	Red	6.00	50	800	5090185G

• Qty. in carton (Inner/Outer): 1/30



Surgery

Global Medikit Limited

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Ref. No: TDS – 38, Revision No - 5

TECHNICAL DATA SHEET

Glocic

Thoracic Drainage Catheter

Product Photograph



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GENERAL DESCRIPTION OF DEVICE

BRAND NAME	GLOCIC
DEVICE MODEL	Thoracic Drainage Catheter
DEVICE DESCRIPTION	The Thoracic Drainage Catheter is commonly known as a chest tube. It is used to drain fluid, blood, pus, or air from the space around the lungs. It is a flexible plastic tube that is inserted through the chest wall into the pleural space or mediastinum. The tube is often connected to a suction machine to help with drainage. The tube remains in the chest until all or most of the air or fluid has drained out, usually within a few days.
INTENDED USE	Thoracic Drainage Catheter is intended for drainage of air or fluid from the pleural cavity after cardio-thoracic and thoracic surgery.
CLASSIFICATION	Thoracic Drainage Catheter is a short-term use, surgically invasive device, classified as Class IIa as per Rule 7 of Annex VIII of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR 2017/745).
SIZE AVAILABLE (FG)	8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40
PATIENT POPULATION	Child, Adult

DEVICE SPECIFICATIONS**Technical Specifications:**

Size (FG)	OD (mm)	ID (mm)	Thoracic Drainage Catheter					
			Straight without trocar		Straight with trocar		Curved without trocar	
			Length ± 5 (mm)	Number of Eyes	Length ± 5 (mm)	Number of Eyes	Length ± 5 (mm)	Number of Eyes
8	2.70 \pm 0.1	1.70 \pm 0.1	450	4	180	2	450	4
10	3.30 \pm 0.1	2.15 \pm 0.1	450	4	180	2	450	4
12	4.00 \pm 0.1	2.70 \pm 0.1	450	4	180	2	450	4
14	4.70 \pm 0.1	3.00 \pm 0.1	450	4	200	2	450	4
16	5.30 \pm 0.1	3.70 \pm 0.1	450	4	200	2	450	4
18	6.00 \pm 0.1	3.70 \pm 0.1	450	4	350	2	450	4

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20	6.70±0.2	4.80±0.2	450	4	350	2	450	4
22	7.30±0.2	4.90±0.2	450	4	350	2	450	4
24	8.00±0.2	5.50±0.2	450	6	350	2	450	6
26	8.70±0.2	5.60±0.2	450	6	350	2	450	6
28	9.30±0.2	6.60±0.2	450	6	350	2	450	6
30	10.00±0.2	7.60±0.2	450	6	350	2	450	6
32	10.70±0.2	7.60±0.2	450	6	350	2	450	6
34	11.30±0.2	8.20±0.2	450	6	350	2	450	6
36	12.00±0.2	8.20±0.2	450	6	350	2	450	6
38	12.80±0.2	9.00±0.2	450	6	350	2	450	6
40	13.30±0.2	9.50±0.2	450	6	350	2	450	6

Features

- Suitable for effective drainage after Cardio-Thoracic & thoracic Surgery.
- Atraumatic & rounded open distal end with smooth eyes.
- With radio-opaque line and marking at every 2 cm from the last eye.
- Size Available (FG): 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 36, 38 and 40.
- Soft, frosted and kink resistant PVC Tubing -Matching size connector for easy connection to the drainage system.
- Proximal end is fitted with pull through tapered tongue.
- Sterile, Non-Pyrogen & Non toxic
- Comes with sharp Tip

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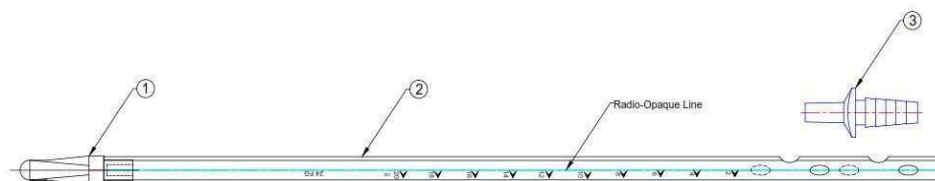


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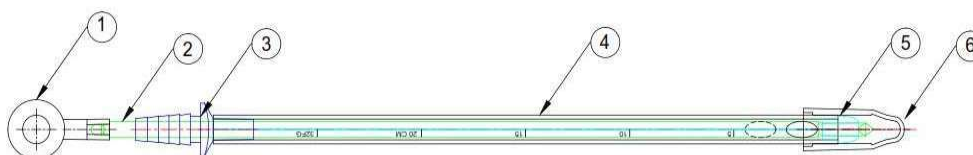
DEVICE DRAWING

Thoracic Drainage Catheter Straight without Trocar

1. Taper tongue connector
2. Catheter tube with radio opaque line
3. Step connector

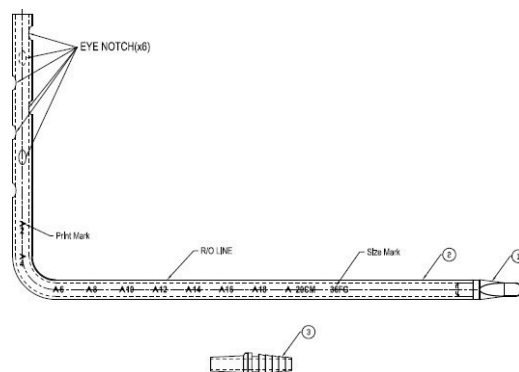


Thoracic Drainage Catheter Straight with Trocar



1. Trocar handle
2. Trocar
3. Step connector
4. Catheter tube with radio opaque line
5. Tip connector
6. Trocar cover

Thoracic Drainage Catheter Curved without Trocar



1. Taper tongue connector
2. Curved catheter tube with radio opaque line
3. Step connector

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APPROVED MATERIAL OF CONSTRUCTION

S.No.	PART NAME	MATERIAL USED
1	Catheter tube	Poly Vinyl Chloride (PVC)
2	Taper tongue connector	Poly Vinyl Chloride (PVC)
3	Tip connector	Poly Vinyl Chloride (PVC)
4	Step connector	Polypropylene (PP)
5	Trocar	Aluminum/stainless steel
6	Trocar handle	Polypropylene (PP)
7	Trocar cover	Polypropylene (PP)

PACKING SPECIFICATIONS

The Device is individually packed in Poly Polyester Film sealed with Medical grade 60gsm paper pouch pack, such 25 PCs. are packed in Inner carton i.e. Kraft pull Paper & such 6 inner cartons are packed in master carton i.e. Kraft pull Paper.

Packing Details:

Individual Packing Size	600 x110 mm
Inner carton size	550 x 110 x 120 mm
No. of blister packed pieces in an inner carton	25 pcs
Master carton size	555 x 345 x 255 mm
No. of inner cartons in a master carton	6 nos
No. of blister packed pieces in a master carton	150 pcs

STERILIZATION

The device is supplied sterile, sterilized by ethylene oxide.

STORAGE CONDITION

5°C to 25°C, away from moisture, direct light heat sources.

SHELF LIFE

Shelf life of the finished product 5 years from the date of sterilization.

STANDARDS COMPLIANCE

ISO 20697:2018	Sterile drainage catheters and accessory devices for single use
ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-7:2008	Biological evaluation of medical devices - Part 7: Ethylene oxide

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	sterilization residuals
ISO 11607-1:2019	Packaging for terminally sterilized medical devices – part 1: requirements for materials, sterile barrier systems and packaging systems
ISO 11607-2:2019	Packaging for terminally sterilized medical devices – part 2: validation requirements for forming, sealing and assembly processes
ISO 15223-1:2021	Medical devices – symbols to be used with medical device labels, labelling and information to be supplied – part 1: general requirements
ISO 11135-1:2014	Sterilization of health care products – ethylene oxide – part 1: requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 13485:2016	Medical devices - Quality management systems –Requirements for regulatory purposes.
ISO 14971:2019	Medical devices - Application of risk management to medical devices

Date: 5 May 2023

Samar Keshari Jena
Regulatory Affairs Manager
Global Medikit Limited

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.

DEVICE SHELF LIFE:

5 YEARS

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:

- Prior to using read entire instructions for use.
- 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.
- In the event of malfunction of the device or changes in its performance that may affect the safety of the patient, carefully remove the device from the patient's body.
- Discard the malfunctioning device and use a new device.

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.

CLINICAL BENEFITS:

Drainage of the fluid or air contents from the thoracic region to restore the negative pressure in the pleural space.

PERFORMANCE CHARACTERISTICS:

- The Thoracic Drainage Catheter is available in following dimensions –
- The variant straight without trocar is available in sizes (FG) 8-40, having length of 450 (±5) mm and 4 eyes in each size.
- The variant straight with trocar is available in sizes (FG) 8-40, lengths of 180 - 350 (±5) mm and 2 eyes in each size.
- The variant Curved without trocar is available in sizes (FG) 8-40, having length of 450 (±5) mm and 4 eyes in each size.
- The device is radiopaque.
- The trocar provided with the catheter must be corrosion free, when removed for use.



	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

Global Medikit Limited

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Tel: +32 (2) 73 25 954 | Fax: +32 (2) 73 26 003
E-mail: regulatory@obelis.net

Revision : 06 Date : 09/09/2024

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

Artworks No.:GML/IFU/14/001 **Revision No:** 06, **Revision Date:** 09/09/2024