POLY MEDICURE LIMITED

TECHNICAL DATA SHEET

Thoracic Drainage Catheter

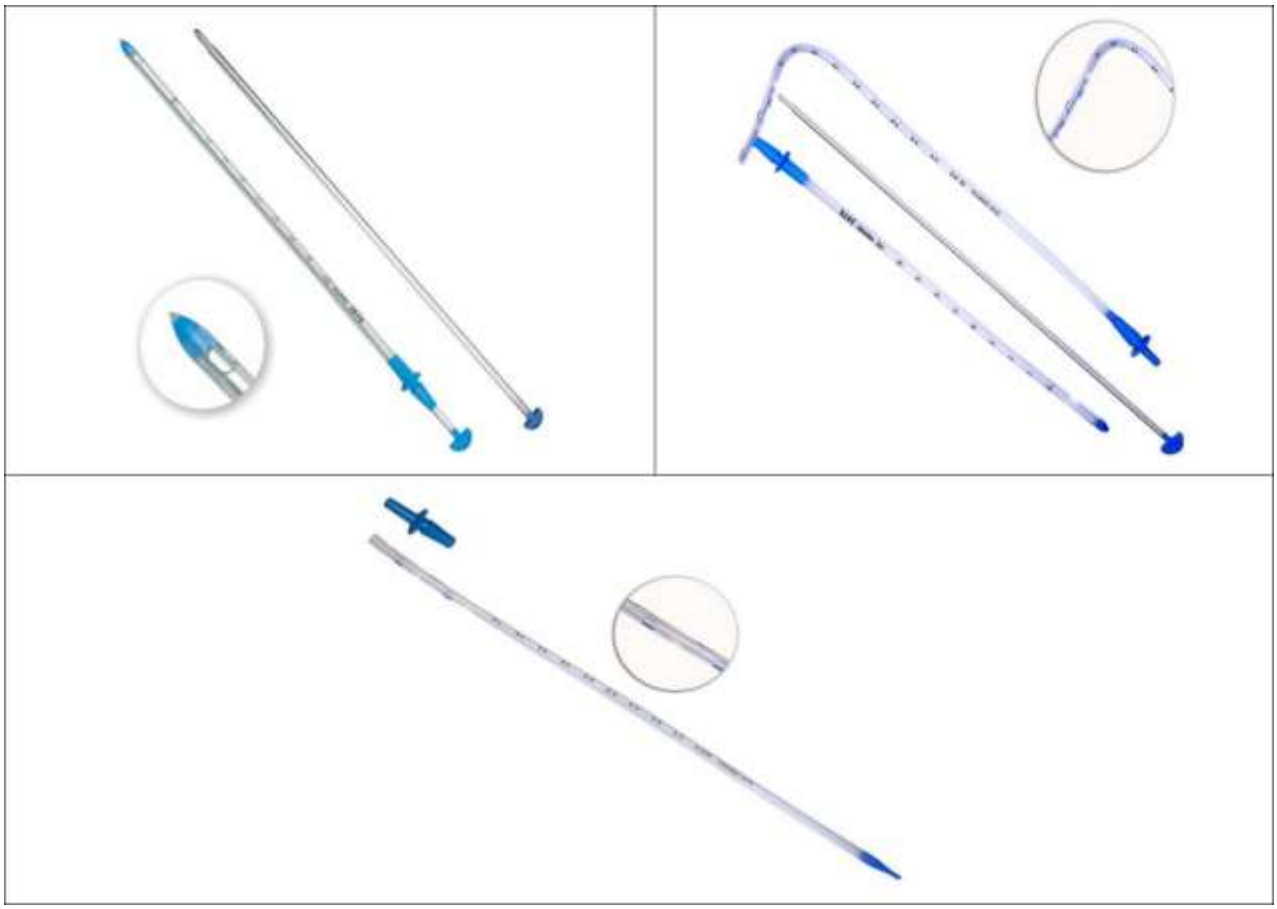
With/without Trocar

Digitally signed by Iarovoi Petru
Date: 2025.05.30 15:40:26 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

PRODUCT CODE	DESCRIPTION OF PRODUCT
90080	Ultra Cath Novo - Straight 8FG
90081	Ultra Cath Novo - Straight 10FG
90082	Ultra Cath Novo - Straight 12FG
90083	Ultra Cath Novo - Straight 14FG
90084	Ultra Cath Novo - Straight 16FG
90085	Ultra Cath Novo - Straight 18FG
90086	Ultra Cath Novo - Straight 20FG
90087	Ultra Cath Novo - Straight 22FG
90088	Ultra Cath Novo - Straight 24FG
90089	Ultra Cath Novo - Straight 28FG
90170	Ultra Cath Novo - Straight 32FG
90171	Ultra Cath Novo - Straight 36FG
90172	Ultra Cath Novo - Straight 40FG
90182	Ultra Cath Novo - Straight 30FG
90183	Ultra Cath Novo - Straight 26FG
90185	Ultra Cath Novo - Straight 34FG
90540	Ultra Cath Novo - angled 8FG
90541	Ultra Cath Novo - angled 10FG
90542	Ultra Cath Novo - angled 12FG
90543	Ultra Cath Novo - angled 14FG
90544	Ultra Cath Novo - angled 16FG
90545	Ultra Cath Novo - angled 18FG
90546	Ultra Cath Novo - angled 20FG
90547	Ultra Cath Novo - angled 22FG
90548	Ultra Cath Novo - angled 24FG
90549	Ultra Cath Novo - angled 28FG
90173	Ultra Cath Novo - angled 32FG
90174	Ultra Cath Novo - angled 36FG
90175	Ultra Cath Novo - angled 40FG
90181	Ultra Cath Novo - angled 30FG
90090	Ultra Cath Novo - trocar 8FG
90091	Ultra Cath Novo - trocar 10FG
90092	Ultra Cath Novo - trocar 12FG
90093	Ultra Cath Novo - trocar 14FG
90094	Ultra Cath Novo - trocar 16FG
90095	Ultra Cath Novo - trocar 18FG
90096	Ultra Cath Novo - trocar 20FG
90097	Ultra Cath Novo - trocar 22FG

PRODUCT CODE	DESCRIPTION OF PRODUCT
90098	Ultra Cath Novo - trocar 24FG
90099	Ultra Cath Novo - trocar 28FG
90176	Ultra Cath Novo - trocar 32FG
90177	Ultra Cath Novo - trocar 36FG
90178	Ultra Cath Novo - trocar 40FG
90179	Ultra Cath Novo - trocar 42FG
90180	Ultra Cath Novo - trocar 30FG
90184	Ultra Cath Novo - trocar 26FG
90186	Ultra Cath Novo - trocar 34FG

Product Image



General Information:

Intended Use

The product is used to collect the post operation fluid from patient in the pleural space or for drainage after cardio-thoracic and thoracic surgery. The product can be used to drain the fluid in the pleural space (area between the chest wall and the lungs) which can occur due to heart failure, lymphatic fluid, a lung tumor, or infections such as tuberculosis and pneumonia.

Legal Manufacturer-
POLY MEDICURE LIMITED
Plot No.: 104-105, Sector 59, HSIIDC Industrial Area, Ballabhgarh,
Faridabad, HARYANA, INDIA - 121004

Manufacturing Site-
POLY MEDICURE LIMITED
Plot No.:104-105, Sector 59, HSIIDC Industrial Area, Ballabhgarh,
Faridabad, HARYANA, INDIA – 121004

European Authorized Representative- Name and address
OBELIS S.A.
Boulevard Général Wahis 53,
B-1030, Brussels,
Belgium

Certification:

Certification	Notified Body
CE Certificate *Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III* ***CE Certificate No.: G10 041938 0011***	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany **Notified Body Number: 0123**
EN ISO 13485:2016/DIN-EN ISO 13485:2016 ***Certificate No.: Q5 041938 0001 Rev.03***	

Device Classification:

As per the "Classification criteria" Annexure-IX of the Council Directive 93/42/EEC as amended by2007/47/EC the Thoracic Drainage catheter is used for more than 60 minutes and less than 30 days. Hence this device is for 'short term use' as per the description in the 1.1 of Annexure IX.
This device penetrates inside the body through surface of body with the aid or in the context of a surgical operation hence it is "Surgically Invasive Device" as per 1.2 of Annexure IX.
As per Rule-7 of Annexure IX of Council Directive 93/42/EEC as amended by 2007/47/EC all surgically invasive devices intended for short-term use are in Class IIa. Hence Thoracic Drainage Catheter is classified as Class IIa Medical Devices.

Device Common Description:

The Thoracic Drainage catheter is provided with soft, frosted and kink resistant thermosensitive PVC tubing (not made with DEHP) with radio-opaque line and markings at specified distance from the last eye to check the tube's position inside chest. The distal end of the catheter is smoothly shaped with soft material. Thoracic drainage catheter is a flexible plastic tube that is inserted through the chest wall and into the pleural space or mediastinum. It is used to remove air in the case of pneumothorax or fluid such as in the case of pleural effusion, blood, chyle, or pus when empyema occurs from the intrathoracic space. The product is sterilized using EO (Ethylene Oxide) gas

Technical Specification:

Based on the application and requirements, various features are incorporated in the Thoracic Drainage Catheter designs as follows –

Thoracic Drainage Catheters without Trocar

- *Suitable for effective drainage after cardio-thoracic & thoracic surgery*
- *Atraumatic & rounded open distal end with smooth eyes for efficient drainage*
- *Proximal end is fitted with pull through tapered tongue connector*
- *With radio-opaque line and markings at every 2 cm for easy and precise positioning*
- *Cross side eyes to prevent tissue aspiration*
- *Matching size connector for easy connection to the drainage system*
- *Soft, frosted and kink resistant PVC tubing*
- *Length: 45 cm*
- *Sizes: 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 36 & 40FG*
- *Not made with DEHP.*
- *Also available with curved (90°) angle for easy aspiration of drainage*

Thoracic Drainage Catheters-With Trocar

- *Suitable for effective drainage after cardio-thoracic & thoracic surgery*
- *Two lateral smooth side eyes for efficient drainage*
- *Sharp trocar tip allows for quick and precise insertion and tight fixation at the end of the catheter. Available with blunt tip*
- *With radio-opaque line and markings at every 2 cm for easy and precise positioning*
- *Proximal end fitted with tapered connector for easy connection to the drainage system*
- *Length: 35 cm*
- *Sizes: 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 36, 40 & 42FG.*
- *Not made with DEHP material.*

Approved Materials of Constructions:

S. No.	Parts Where Material is used	Base Material	CAS Number
1	*Pull through Tongue*	*Polyvinyl chloride*	*9002-86-2*
2	*Catheter Connector (hard Connector / Step connector)*	*ABS*	*9003-56-9*
3	*Tip Connector*	*Polyvinyl chloride*	*9002-86-2*
4	*Protective Cap for tip (butterfly)*	*LDPE*	*9002-88-4*
5	*Straight Cap*	*LDPE*	*9002-88-4*
6	*Catheter (Tube)*	*Polyvinyl chloride*	*9002-86-2*
7	*Trocar Rod*	*Aluminum*	*7429-90-5*
		Stainless Steel	*65997-19-5*
8	*Trocar Handle (Holder)*	*ABS*	*9003-56-9*

Sterilization Method:

Sterilized using Ethylene Oxide

Shelf Life:

Five years from the date of manufacturing

Standards Compliance:

Document Code	Document Description
EN ISO 13485:2016+ A11:2021	*Quality system - Medical Devices - Requirements for the Regulatory Purposes*
EN ISO 14971:2019/ A11:2021	*Application of risk management to medical devices*
IEC 62366-1:2015 / Amd 1:2020	*Medical Devices – Application of usability engineering to medical devices*
EN ISO 11135:2014 /A1:2019	*Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices*
EN ISO 11737-1:2018/A1:2021	*Sterilization of health care products -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products.*
EN ISO 11737-2:2020	*Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process.*
EN ISO 11607-1:2020/ A1:2023	*Packaging for terminally sterilized medical devices – requirements for materials, sterile barrier & packaging systems.*
EN ISO 11607-2:2020/ A1:2023	*Packaging for terminally sterilized medical devices – Validation requirements for forming, sealing and assembly process.*
EN ISO 15223-1:2021	*Symbols to be used with medical devices labels, labeling and information to be supplies*
ISO 20417:2021	*Medical devices — Information to be supplied by the manufacturer*
EN ISO 10993-1:2020	*Biological evaluation of medical devices – Evaluation and testing within a risk management process.*
EN 868-5:2018	*Packaging for terminally sterilized medical devices. Sealable pouches & reels of porous and plastic film construction. Requirements & test methods.*

Reference to QMDS Documents:

Document Title	Polymed Internal Document Reference
Technical File	PML/MD/TF/28
Product Specification	FP/QA/*43*-44
Risk Management	PML/MD/RA/28
Clinical Evaluation	PML/MD/CER/28
DOC	F/QA/176

Packaging Characteristics:

The unit package consists of a medical-grade paper pouch and is designed to maintain a sterility barrier through its seal. The integrity of the package shall not be compromised during normal handling, storage, sterilization, or transportation. The unit package shall open reliably without tearing or generating particulate matter.

One (1) unit package shall be packed into one inner duplex printed cardboard box.

Forty (40) duplex boxes shall be packed into one corrugated shipper box, as per customer requirements.

This packaging system—comprising the unit package, duplex box, and shipper box—shall provide adequate protection during standard shipping, handling, and storage, ensuring the product reaches the end user in optimal condition.

Storage Conditions:

Store in between 5°C to 35°C, *avoid excessive heat, protect from direct sunlight and moisture.*

Materials of Concern:

Not made with natural rubber latex or DEHP plasticizer.

Any substances of animal origin e.g., BSE/TSE are not used during manufacturing.