

Fig.1: THORACIC DRAINAGE CATHETER

1. PRODUCT DESCRIPTION

The device is suitable for post-operative drainage after Thoracic surgery. Distal end open with smooth large eyes to maximize the drainage from the chest without causing trauma to the delicate lung tissues. Proximal- end fitted with specially designed tapered tongue to provide excellent grip to the forceps and enable non-traumatic insertion. Tubes marked at 2 cm from the last eye to ascertain the depth of placement. One loose connector provided to facilitate immediate connection of catheter with the drainage set. Manufactured from non-toxic Medical Grade PVC with Radio Opaque Line throughout its length. Duration of Use: Short term.

2. DEVICE CLASSIFICATION AND RULE

Thoracic Drainage Catheter falls under Class-IIa, Rule 7 device as per EU MDR 2017/745 Annexure VIII.

3. PRODUCT CHARACTERISTICS & INTENDED USE

INTENDED USE:

Thoracic catheter set is intended for effective drainage after thoracic surgery. The catheter is placed intraoperatively, removes gas and fluid deposits from the pleural cavity and helps to restore and maintain pressure.

Features:

- Suitable for effective drainage after cardio-thoracic & thoracic surgery
- Atraumatic & rounded open distal end with smooth eyes
- Proximal end is fitted with pull through tapered tongue
- With radio-opaque line and markings at every 2 cm from the last eye
- Cross side eyes to prevent tissue aspiration
- Matching size connector for easy connection to the drainage system

4. PRODUCT VARIANTS

Following variants are available for the products

S.No.	Product	GMDN Code	Classification
1.	Thoracic Drainage Catheter	36247	Rule-7, Class-IIa

Prepared by:	Reviewed by:	Approved by:	Issued by:	
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5. MATERIAL OF CONSTRUCTION

S. No.	Component Description	Material used
1.	Thoracic Plain Tip	SS & Aluminium
2.	Thoracic Tube	PVC Soft
3.	Tube Connector	ABS
4.	Trocar Tip	PVC Soft
5.	Thoracic Cover	LDPE
6.	Thoracic Handle	ABS

6. TECHNICAL SPECIFICATIONS:

S. No.	Size (Fr)	Outer Diameter (mm)	Length	Typical use
1.	08 Fr	4.0 mm	28-30 cm	Pediatric / Small drainage
2.	10 Fr	4.0 mm	28-30 cm	Pediatric / Small drainage
3.	12 Fr	4.0 mm	28-30 cm	Pediatric / Small drainage
4.	14 Fr	4.0 mm	28-30 cm	Pediatric / Small drainage
5.	16 Fr	5.3 mm	28-30 cm	Pediatric / Moderate drainage
6.	20 Fr	6.7 mm	36-40 cm	Adult – small pneumothorax
7.	22 Fr	6.7 mm	36-40 cm	Adult – small pneumothorax
8.	24 Fr	8.0 mm	36-40 cm	Adult – pleural effusion
9.	28 Fr	9.3 mm	36-40 cm	Adult – hemothorax
10.	30 Fr	9.3 mm	36-40 cm	Adult – hemothorax
11.	32 Fr	10.7 mm	36-40 cm	Adult – empyema, drainage of thick fluid
12.	36 Fr	12.0 mm	36-40 cm	Adult – massive hemothorax
13.	40 Fr	13.3 mm	36-40 cm	Adult – large bore drainage

7. REFERENCE COMPLIANCE STANDARD

S No.	Name of Standard	Number
CLOSED IV CANNULA		
1.	Sterile drainage catheters and accessory devices for single use	ISO 20697:2018
General		
2.	Sampling procedures for inspection by attributes Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection	ISO 2859-1:1999
3.	Clean Rooms And Associated Controlled Environments: Classification of air cleanliness by particle concentration	EN ISO 14644-1:2015
4.	Clean Rooms And Associated Controlled Environments : Monitoring to provide evidence of clean room performance related to air cleanliness by particle concentration	EN ISO 14644-2:2015
5.	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General	EN ISO 15223-1:2021

	requirements	
6.	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices Amendment 1: Revision of Annex E, Single batch release	ISO 11135:2014/Amd 1:2018
7.	Sterilization of health care products - Biological indicators - Part 1: General requirements	EN ISO 11138-1:2017
8.	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products	EN ISO 11737-1:2018
9.	Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems Amendment 1: Application of risk management	ISO 11607-1:2019/Amd 1:2023
10.	Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes Amendment 1: Application of risk management	ISO 11607-2:2019/Amd 1:2023
11.	Biological evaluation of medical devices –part 1, Evaluation and testing within a risk management process	EN ISO 10993-1:2025
12.	Biological evaluation of medical devices — Part 3: Tests for Genotoxicity, carcinogenicity and reproductive toxicity	EN ISO 10993-3:2014
13.	Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood	EN ISO 10993-4:2017
14.	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	EN ISO 10993-5:2009
15.	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals - Amendment 1: Applicability of allowable limits for neonates and infants (ISO 10993-7:2008/Amd 1:2019)	EN ISO 10993-7:2008/A1:2022
16.	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	EN ISO 10993-10:2023
17.	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	EN ISO 10993-11:2018
18.	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials	EN ISO 10993-12:2021
19.	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances	EN ISO 10993-17:2023
20.	Clean rooms and associated controlled environments- bio-contamination control- general principles and methods	EN ISO 14698-1:2003
21.	Clean rooms and associated controlled environments- bio-contamination control- evaluation and interpretation of bio-contamination	EN ISO 14698-2:2003
22.	Medical devices -- Quality management systems -- Requirements for regulatory purposes	ISO 13485:2016
23.	Medical devices – application of risk management to medical devices	EN ISO 14971:2019
24.	European council directive concerning medical devices	MDR 2017/745
25.	Medical devices - Quality Management Systems - Requirements for regulatory purposes	EN ISO 13485:2016

8. PACKAGING DETAILS AND SPECIFICATIONS

ITEM	MATERIAL
Individual Sterile Packing	Paper Pouch
Inner Carton	3 Ply Corrugation White Box
Master Carton	5Ply Corrugation

9. COMPLIANCE INFORMATION

Manufacturing Site Information: Disposafe Health and Life Care Ltd., Plot No. 1 & 2,Sec-59, Phase-II, Ballabhgarh, Faridabad-121004, Haryana (INDIA)
Drug Manufacturing License No.: MFG/MD/2019/000106
QMS Certification: EN ISO 13485:2016
CE Marking: TUV-SUD Product Services GmbH 0123
GMDN: 36247