POLY MEDICURE LIMITED

TECHNICAL DATA SHEET

Under Water Seal Drainage System

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Product Code	Description Of Product
90120	Under water seal drainage bag -1000ml
90320	Under water seal drainage bottle Adult -2000ml
90330	Under water seal drainage bottle Midi -1200ml
90340	Under water seal drainage bottle Kid -500ml
90321	Under water seal drainage bottle with clamp Adult -2000ml

Product Image

General Information:

Intended Use

Under Water Seal Drainage System is used to drain the fluid from body collected due to various reasons like larger pleural effusions, post-operative drainage etc. from a patient. The drainage is facilitated using a catheter and then the catheter is connected with the tube of under water-sealed drainage system. The water-sealed drainage system prevents air from leaking into the pleural space or the operated area. The collection bag/container has marking to indicate the volume of fluid collected.

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 "Classification Criteria" in Annexure VIII of Regulation (EU) 2017/745, the Under Water Seal Drainage System is normally intended for continuous use for between 60 minutes and 30 days. Hence these are for short-term use as per description in the 1.2 of Annexure VIII.
- Under Water Seal Drainage System penetrates inside the surface of body, hence is "Invasive device". The devices which penetrate the body through other than an establish body orifice are surgically invasive devices hence Under Water Seal Drainage System is "Surgically invasive device" as per 2.2 of Annexure VIII.
- As per Rule 7, main paragraph for Classification, all 'Surgically Invasive Devices' intended for short-term use are classified in Class IIa. Hence "Under Water Seal Drainage System" is classified as Class IIa Medical device.

Device Description:

Under Water Seal Drainage System is available in two categories: Under water seal drainage bag and under water seal drainage bottle.
The idea is to create a one-way mechanism that will let air/fluid out of the pleural space and prevent outside air/fluid from entering into the pleural space. This is accomplished by the use of an underwater seal. The distal end of the drainage tube is submerged in 2cm of H_2O. They use flexible plastic tubes which are inserted through the chest wall and into the pleural space between the 5th and 6th intercostal space in the mid-axillary line, venting the space which allows air back out.

Under Water Seal Drainage Bag (Poly Drain)

- Under water seal drainage system for collection of drainage fluid from thoracic cavity.
- Specially designed molded handle for easy carrying and hanging of the bag.
- PVC drainage bag with 1000 ml. capacity.
- Soft and kink resistant PVC tubing.

Under Water Seal Drainage Bottle (Poly Seal)

- Suitable for pleural drainage in conjunction with chest drainage catheters in cardio-thoracic procedures.
- Polyseal adult is a double chamber compact unit having capacity of 2000 ml.
- Clearly marked initial water level to ensure under water seal.
- Clear easy to ready graduations marked on bottle to determine the amount of collection.
- Write on facility on the side of scale helps in monitoring of drain volume.
- Kink resistant large bore tubing facilities unrestricted flow.
- Metallic hangers for easy attachment with bed and floor stand for easy standalone working.
- Separate suction port is provided to connect with suction unit.
- The product is available in three types - Adult, Midi and Kid having capacity of 2000ml, 1200ml and 500ml respectively.
- The product is sterilized with Ethylene Oxide.

Technical Specification:

Mechanical Characteristics of device:

S. No.	***Parameter***	***Specification***
1.	*Tensile Strength of joints*	*NLT 20N*

Physical Characteristics of device:

S. No.	***Test***	***Specifications***
1.	*Integrity of Package*	*Shall be intact*
2.	*Surface finish*	*Tube shall be smooth finish*
3.	*Kinking of Tube*	*Shall be free from kinks or bends*
4.	*Length of soft tubing*	• *200cm ± 3cm for adult* • *150cm ± 3cm for Midi & Kid*
5.	*Length of hard tubing*	• *27 cm ± 1 cm for Adult* • *23 cm ± 1 cm for Midi* • *27 cm ± 1 cm for kid*
6.	*Weight of bottle*	• *360 ± 20gm for Adult* • *260 ± 20gm for midi* • *170 ± 20gm for kid*
7.	*Volume capacity*	• ***Polydrain:****1000ml* • ***Polyseal:*** *2000 ml for Adult, 1200ml for Midi & 500ml for Kid* • *Outer dimension of hard tubing should be 9.00 mm ± 0.1 mm*
8.	*Leakage from joints*	*Shall not be leak up to 0.5 bar air pressure for 15 secs.*

Approved Materials of Constructions:

Under Water Seal Drainage System (POLYSEAL)			
S. No.	**Parts where material is used**	**Base Material**	**CAS No.**
1.	Bottle	K-Resin	9003-55-8
2.	Bottle Cap (Red/ Sky Blue)	PP	9003-07-0
3.	Bottle Cap (White)	LDPE	9002-88-4
4.	Bottle Stand	PP	9003-07-0
5.	Bottle Stand	Card Board	9/7/8050
6.	Flexible Plastic Pipe	LDPE	9002-88-4
7.	Hanger	SS	65997-19-5
8.	Hard Connector (Stepped) 32FG	ABS	9003-56-9
9.	Inlet Cap	PP	9003-07-0
10.	Inlet Connector 27FG	ABS	9003-56-9
11.	Inner Cap (Big)	PVC	9002-88-4
12.	Inner Cap (Midi)	PVC	9002-88-4
13.	Insert	PVC	9002-88-4
14.	PP Clamp	PP	9003-07-0
15.	Red Snap Cap	PVC	9002-88-4
16.	SS Ball	SS	65997-19-5
17.	Tikki PVC	PVC	9002-88-4
18.	Tube 36FG, 150cm (Midi/ Kid)	PVC	9002-88-4
19.	Tube 27FG Hard Rod	RPVC	9002-88-4
20.	Tube 27FG Midi	PVC	9002-88-4

S. No.	Parts where material is used	Base Material	CAS No.
21.	Tube 36FG (Adult)	PVC	9002-88-4

Under Water Seal Drainage System (POLYSEAL)			
S. No.	**Parts where material is used**	**Base Material**	**CAS No.**
1.	Poly Drain Bag Sheet Clear	PVC	9002-86-2
2.	Poly Drain Hard Tube	PVC	9002-86-2
3.	Urimeter Hanger	PP	9003-07-0
4.	Sleeve	PVC	9002-86-2
5.	Port Cap	PVC	9002-86-2
6.	Port Cap Stopper	HDPE	9002-88-4
7.	Slide Flide	ABS	9003-56-9
8.	Tube 27FG, 100cm	PVC	9002-86-2
9.	Inlet Connector	ABS / RPVC	9003-56-9 / 9002-86-2
10.	Inlet Cap	PP	9003-07-0
11.	Nylon Dori	Nylon	25038-54-4

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*

Document Code	Document Description
EN ISO 10993-1:2020	*Biological evaluation of medical devices – Evaluation and testing within a risk management process.*

Reference to QMDS Documents:

Document Title	Polymed Internal Document Reference
Technical File	PML/MD/TF/1.29
Product Specification	FP/QA/49
Risk Management	PML/MD/RA/1.29
Clinical Evaluation	PML/MD/CER/29
DOC	F/QA/176

Packaging Characteristics:

The Under Water Seal Drainage System is individually packed in a clear polypropylene and polyethylene (PP+PE) film and sealed with a printed lid made of medical-grade lacquered paper. This unit packaging is designed to function as a sterile barrier system, maintaining sterility through a validated seal. The integrity of the packaging is ensured under normal conditions of handling, storage, sterilization, and transportation, preventing any compromise to the sterile barrier. The unit package is engineered to open reliably, allowing for aseptic presentation without tearing or generating particulate matter.

Polydrain 1000 ml (Kid) units are packed 20 per box, Polydrain 500 ml (Midi) units 10 per box, and Polyseal 1200 ml (Adult), Polyseal 2000 ml, and both Domestic and Export 1000 ml units are packed individually, one per box.

For tertiary packaging, these duplex boxes are further packed into 5-ply corrugated shipper boxes. Each shipper box contains 80 duplex boxes for Polydrain 1000 ml (Kid), 40 for Polydrain 500 ml (Midi), 15 for Polyseal 1200 ml (Adult), 12 for Polyseal 2000 ml, and 8 each for Domestic and Export 1000 ml units.

The combination of shipper box/duplex box/unit packaging system shall provide adequate product protection during normal shipping, handling and storage, till the product reaches the end user.

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.