CLOSED WOUND SUCTION SET	SAFE-VAC



Fig.: Closed Wound Suction Set (Safe-Vac)

1. PRODUCT DESCRIPTION

"Closed Wound suction set consist of a plastic bellow, a perforated suction tube and a stainless steel trocar. The plastic bellow is used for creating suction and perforated tube (radon tube) is used for secretion of excess fluid after operation. It is a single use device.

Duration of Use: Short term.

Material of Composition: SS, PVC, ABS, PP or Silicon."

2. DEVICE CLASSIFICATION AND RULE

The device is classified as Class IIa/Rule 7, medical device (classification as per ANNEX–VIII of (EU) MDR 017/745) and Class II as per 21 CFR 880.5200 (USFDA Classification).

3. INTENDED USE

Closed Wound Suction Set is used for continuous evacuation of wound secretions and reduces postoperative edema and hematoma formation, decrease the possibility of infection, and minimize the chance of external contamination of the surgical site.

4. PRODUCT FEATURES

- Closed Wound Suction Set is used for continuous evacuation of wound secretions and reduces postoperative edema and hematoma formation, decrease the possibility of infection, and minimize the chance of external contamination of the surgical site.
- The U-connector connects different sections of tubing or allows for the connection of the drainage tube to the collection chamber. It is shaped like a "U" and helps to maintain an airtight seal in the system.
- Transparent in appearance including redon tube.
- Chamber volume 400-600ml = 500 ML.
- Low aspiration pressure.
- Possibility to connect to drainage 6-18CH.
- With expandable PVC bellow chamber that creates and maintains vacuum

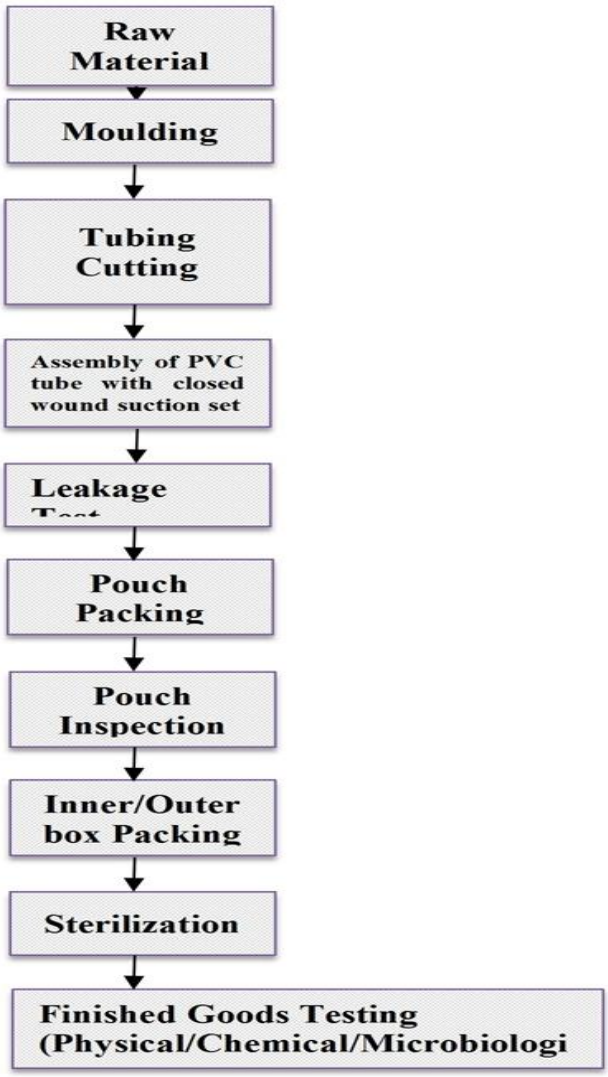
5. REFERNCE CODES:

Closed wound suction set- 8FG	CWS9
Closed wound suction set- 10FG	CWS10
Closed wound suction set- 12FG	CWS11
Closed wound suction set- 14FG	CWS12
Closed wound suction set- 16FG	CWS13
Closed wound suction set- 18FG	CWS14

6. MATERIAL OF CONSTRUCTION

S. No	Component Description	Material used
1.	Bellow Chamber	PVC (Polyvinyl Chloride)
2.	Plain Bellow cap	PP (Polypropylene)
3.	Bellow cap Connector	PVC Flex
4.	Redon Tube	PVC Flex
5.	Perforated Tube	PVC Flex
6.	U Connector	PVC (Polyvinyl Chloride)
7.	Nozzle	ABS (Acrylonitrile Butadiene Styrene)
8.	Perforated Tube (with R/O line)	PVC Flex
9.	Trocar Needle	SS 304 Stainless Steel
10.	Hanger	LDPE (Low density polyethylene)
11.	Nozzle cap	PVC Soft
12.	C-Clamp	POM
13.	Trocar Needle Cover	PVC (Polyvinyl Chloride)

7. PROCESS FLOW CHART



8. PACKAGING DETAILS AND SPECIFICATIONS

Packaging Type	Packed Quantity			Packing Material / Specification
	Unit	Inner Carton (units)	Master Carton (units)	

Hard Blister (Unit Pack)	01	100	1000	**1. Hard Blister – 134 X 27 MM** – PVC Film – MKP 60 GSM **2. Inner Carton (Duplex Board)** 168X136X150 **3. Master Carton (CorrugatedBox)** – 698X320X178 – 3 Ply Corrugated box – 2 X 180 GSM Virgin (Inner &Outer) – 1x150 GSM Semi kraft (Middle) – Copper wire stitching – Interlocking flaps on Top &Bottom

Note: Labels conform to requirements of EC Medical Device Directive (MDD) 2007/47/EC and international labelling standards. Labelling and packaging specifications may be different for custom branding.

9. REFERENCE COMPLIANCE STANDARD

Sr. No.	Title	Standard Ref. No.
1.	6% Luer- Small-bore connectors for liquids and gases in healthcare applications	EN ISO 80369-7:2017
2.	Medical suction equipment — Part 3: Suction equipment powered from a vacuum or positive pressure gas source	ISO 10079-3:2022
3.	Medical devices – Quality management systems –Requirements for regulatory purposes	EN ISO 13485:2016
4.	Medical devices – application of risk management to medical devices	EN ISO 14971:2019
5.	Sampling Procedure For Inspection By attributes	ISO 2859-1:2026
6.	Medical devices - Symbols to be used with medical devicelabels, labeling and information to be supplied - Part 1: General requirements	EN ISO 15223-1:2021
7.	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routinecontrol of a sterilization process for medical devices	EN ISO 11135:2014/A1:2019
8.	Sterilization of health care products - Biological Indicators - Part 1: General requirements	EN ISO 11138-1:2017
9.	Sterilization of health care products - Biological indicators for ethylene oxide sterilization processes	EN ISO 11138-2:2017
10.	Clean Rooms And Associated Controlled Environments: Classification of air cleanliness by particle concentration	EN ISO 14644-1:2015
11.	Clean Rooms And Associated Controlled Environments : Monitoring to provide evidence of clean room performance related	EN ISO 14644-2:2015

	to air cleanliness by particle concentration	
12.	Sterilization of health care products- Microbiological methods- Part 1: Determination of a population of microorganisms on products	EN ISO 11737-1:2018/ A1:2021
13.	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	EN ISO 11607-1:2020/ A1:2023
14.	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	EN ISO 11607-2:2020/ A11:2022
15.	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	EN ISO 10993-1:2025
16.	Biological evaluation of medical devices - Part 3: Tests for Genotoxicity, carcinogenicity and reproductive toxicity	EN ISO 10993-3:2014
17.	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood (ISO 10993-4:2017)	EN ISO 10993-4:2017
18.	Biological evaluation of medical devices - Part 5: Tests for in vitro Cytotoxicity	EN ISO 10993-5:2009/ A11:2025
19.	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	EN ISO 10993-10:2023
20.	Biological evaluation of medical devices - Part 11 : Tests for systemic toxicity	EN ISO 10993-11:2018
21.	Biological evaluation of medical devices - Part 12 : Sample preparation and reference materials	EN ISO 10933-12:2021
22.	Biological evaluation of medical devices - Part 17: Toxicological risk assessment of medical device constituents	EN ISO 10993-17:2023
23.	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process	EN ISO 10993-18:2020
24.	Medical devices - Part -1: Applications of Usability engineering to the medical devices.	IEC 62366-1:2015/Amd 1:2020
25.	Medical Devices- Post market Surveillance for manufacturers	ISO 20416:2020
26.	Clinical Evaluation Assessment Report Template	MDCG 2020-13
27.	Medical Devices Regulations Clinical Evidence Requirements	MEDDEV 2.7.1 Rev 4,
28.	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	ASTM-F1980
29.	Medical devices - Information to be supplied by themanufacturer	ISO 20417:2021

10. OTHER DETAILS

10.1. **Intended Use:** Closed Wound Suction Set is used for continuous evacuation of wound secretions and reduces postoperative edema and hematoma formation, decrease the possibility of infection, and minimize the chance of external contamination of the surgical site

10.2. **Storage:** store in a cool and dry place and keep away from direct sunlight and extreme heat.

10.3. **Method of Sterilization:** sterilized using ethylene oxide.

10.4. **Shelf life:** 05 years from the month / date of sterilization.

10.5. **Testing and Analysis:** Testing for sterility, pyrogen content and physical characteristics (leakage testing, flow rate of lumen, penetration force, packaging integrity, etc.) is performed on each batch before release.

10.6. **Biocompatibility:** The product is tested as per the international standard ISO 10993-1 and parts applicable, and evaluation results are found conform to the standard requirements. The report from the actual study is available with Quality Assurance and will be available for review on request.

10.7. **Disposal:** Dispose of the used product in to biohazard container / clinical wastage bag or according to hospital and country specific protocol.

11. COMPLIANCE INFORMATION

Manufacturer 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**,** TUV SUD Product Service GmbH
CEMarking: TUV SUD Product Service GmbH, EC Notified body No. 0123
Basic UDI-DI: ++G401CWSS8
GMDN Code: 35824

12. ABBREVIATIONS

QMS – Quality Management System
GMDN – Global Medical Device Nomenclature