



POLY MEDICURE LIMITED

TECHNICAL DATA SHEET **Closed Wound Suction Unit**



POLY MEDICURE LIMITED
TECHNICAL DATA SHEET
Closed Wound Suction Unit

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Product Code	Description Of Product
90050	Novovac Set 200 ml 6 FG
90051	Novovac Set 200 ml 8FG
90052	Novovac Set 200 ml 10 FG
90053	Novovac Set 200 ml 12 FG
90054	Novovac Set 200 ml 14 FG
90055	Novovac Set 200 ml 16 FG
90056	Novovac Set 200 ml 18 FG
90057	Novovac Set 400 ml 6 FG
90058	Novovac Set 400 ml 8FG
90059	Novovac Set 400 ml 10 FG
90125	Novovac Set 400 ml 12 FG
90126	Novovac Set 400 ml 14 FG
90127	Novovac Set 400 ml 16 FG
90128	Novovac Set 400 ml 18 FG
90129	Novovac Set 600 ml 6 FG
90130	Novovac Set 600 ml 8FG
90131	Novovac Set 600 ml 10 FG
90132	Novovac Set 600 ml 12 FG
90133	Novovac Set 600 ml 14 FG
90134	Novovac Set 600 ml 16 FG
90135	Novovac Set 600 ml 18 FG
90200	Novovac Set 200 ml 10 FG with 175mm trocar (DEHP free Redon Tube)
90201	Novovac Set 200 ml 12 FG with 175mm trocar (DEHP free Redon Tube)
90202	Novovac Set 200 ml 14 FG with 175mm trocar (DEHP free Redon Tube)
90203	Novovac Set 200 ml 16 FG with 175mm trocar (DEHP free Redon Tube)
90204	Novovac Set 200 ml 18 FG with 175mm trocar (DEHP free Redon Tube)
90205	Novovac Set 400 ml 10 FG with 175mm trocar (DEHP free Redon Tube)
90206	Novovac Set 400 ml 12 FG with 175mm trocar (DEHP free Redon Tube)
90207	Novovac Set 400 ml 14 FG with 175mm trocar (DEHP free Redon Tube)
90208	Novovac Set 400 ml 16 FG with 175mm trocar (DEHP free Redon Tube)
90209	Novovac Set 400 ml 18 FG with 175mm trocar (DEHP free Redon Tube)
91064	Novovac Set 500ml 10 FG with 175mm trocar (DEHP free Redon Tube)
91065	Novovac Set 500ml 15 FG with 175mm trocar (DEHP free Redon Tube)
91066	Novovac Set 500ml 19 FG with 175mm trocar (DEHP free Redon Tube)
91050	Novovac-2 Set 200ml - SPRING BELLOW CHAMBER, CONNECTING TUBE (L-100cm, OD-7.0mm, ID-5.0mm), CLAMP & GAUGE CONNECTOR- 6 FG



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Product Code	Description Of Product
91051	Novovac-2 Set 200ml - SPRING BELLOW CHAMBER, CONNECTING TUBE (L-100cm, OD-7.0mm, ID-5.0mm), CLAMP & GAUGE CONNECTOR- 8 FG
91052	Novovac-2 Set 200ml - SPRING BELLOW CHAMBER, CONNECTING TUBE (L-100cm, OD-7.0mm, ID-5.0mm), CLAMP & GAUGE CONNECTOR- 10 FG
91053	Novovac-2 Set 200ml - SPRING BELLOW CHAMBER, CONNECTING TUBE (L-100cm, OD-7.0mm, ID-5.0mm), CLAMP & GAUGE CONNECTOR- 12 FG
91054	Novovac-2 Set 200ml - SPRING BELLOW CHAMBER, CONNECTING TUBE (L-100cm, OD-7.0mm, ID-5.0mm), CLAMP & GAUGE CONNECTOR- 14 FG
91055	Novovac-2 Set 200ml - SPRING BELLOW CHAMBER, CONNECTING TUBE (L-100cm, OD-7.0mm, ID-5.0mm), CLAMP & GAUGE CONNECTOR- 16 FG
91056	Novovac-2 Set 200ml - SPRING BELLOW CHAMBER, CONNECTING TUBE (L-100cm, OD-7.0mm, ID-5.0mm), CLAMP & GAUGE CONNECTOR- 18 FG
91057	Novovac-2 Set 400ml - SPRING BELLOW CHAMBER, CONNECTING TUBE (L-100cm, OD-7.0mm, ID-5.0mm), CLAMP & GAUGE CONNECTOR- 6 FG
91058	Novovac-2 Set 400ml - SPRING BELLOW CHAMBER, CONNECTING TUBE (L-100cm, OD-7.0mm, ID-5.0mm), CLAMP & GAUGE CONNECTOR- 8 FG
91059	Novovac-2 Set 400ml - SPRING BELLOW CHAMBER, CONNECTING TUBE (L-100cm, OD-7.0mm, ID-5.0mm), CLAMP & GAUGE CONNECTOR- 10 FG
91060	Novovac-2 Set 400ml - SPRING BELLOW CHAMBER, CONNECTING TUBE (L-100cm, OD-7.0mm, ID-5.0mm), CLAMP & GAUGE CONNECTOR- 12 FG
91061	Novovac-2 Set 400ml - SPRING BELLOW CHAMBER, CONNECTING TUBE (L-100cm, OD-7.0mm, ID-5.0mm), CLAMP & GAUGE CONNECTOR- 14 FG
91062	Novovac-2 Set 400ml - SPRING BELLOW CHAMBER, CONNECTING TUBE (L-100cm, OD-7.0mm, ID-5.0mm), CLAMP & GAUGE CONNECTOR- 16 FG
90070	Polyvac Set 600ml 6 FG
90071	Polyvac Set 600ml 8FG
90072	Polyvac Set 600ml 10 FG
90073	Polyvac Set 600ml 12 FG
90074	Polyvac Set 600ml 14 FG
90075	Polyvac Set 600ml16 FG
90076	Polyvac Set 600ml 18 FG
90077	Polyvac Set 800ml 6 FG
90078	Polyvac Set 800ml 8FG
90079	Polyvac Set 800ml 10 FG
90136	Polyvac Set 800ml 12 FG
90137	Polyvac Set 800ml 14 FG
90138	Polyvac Set 800ml16 FG
90139	Polyvac Set 800ml 18 FG
90043	POLYVAC SET 400ML 6FG
90044	POLYVAC SET 400ML 8FG

Product Code	Description Of Product
90045	POLYVAC SET 400ML 10FG
90046	POLYVAC SET 400ML 12FG
90047	POLYVAC SET 400ML 14FG
90048	POLYVAC SET 400ML 16FG
90049	POLYVAC SET 400ML 18FG
90190	Polyvac Set 600ml 10 FG with 175mm trocar (DEHP free Redon Tube)
90191	Polyvac Set 600ml 12 FG with 175mm trocar (DEHP free Redon Tube)
90192	Polyvac Set 600ml 14 FG with 175mm trocar (DEHP free Redon Tube)
90193	Polyvac Set 600ml 16 FG with 175mm trocar (DEHP free Redon Tube)
90194	Polyvac Set 600ml 18 FG with 175mm trocar (DEHP free Redon Tube)
90195	Polyvac Set 800ml 10 FG with 175mm trocar (DEHP free Redon Tube)
90196	Polyvac Set 800ml 12 FG with 175mm trocar (DEHP free Redon Tube)
90197	Polyvac Set 800ml 14 FG with 175mm trocar (DEHP free Redon Tube)
90198	Polyvac Set 800ml 16 FG with 175mm trocar (DEHP free Redon Tube)
90199	Polyvac Set 800ml 18 FG with 175mm trocar (DEHP free Redon Tube)
91067	Polyvac Set 500ml 10 FG with 175mm trocar (DEHP free Redon Tube)
91068	Polyvac Set 500ml 15 FG with 175mm trocar (DEHP free Redon Tube)
91069	Polyvac Set 500ml 19 FG with 175mm trocar (DEHP free Redon Tube)
90650	Neovac set 6FG
90651	Neovac set 8FG

Product Image



Polyvac set



Novovac set



Neovac set

General Information:

Intended Use

The product is used for closed wound drainage or collection of fluid from surgical wound under negative pressure through a collection tube and collection device (bellow) with an option to operate one or two catheters simultaneously. The negative pressure is generated through bellow.

Legal Manufacturer-

POLY MEDICURE LIMITED

Plot No.: 104-105, Sector 59, HSIIDC Industrial Area, Ballabhgarh,
Faridabad, HARYANA- 121004, INDIA

POLY MEDICURE LIMITED

*Plot No. 17, Sector-3, Integrated Industrial Estate,
Sidcul Haridwar, Uttarakhand 249403, India*

Manufacturing Site-

POLY MEDICURE LIMITED

Plot No.:104-105, Sector 59, HSIIDC Industrial Area, Ballabhgarh,
Faridabad, HARYANA- 121004, INDIA

POLY MEDICURE LIMITED

*Plot No. 17, Sector-3, Integrated Industrial Estate,
Sidcul Haridwar, Uttarakhand 249403, India*

European Authorized Representative- Name and address

OBELIS S.A.

Boulevard Général Wahis 53,
B-1030, Brussels,
Belgium

Certification:

Plant	Certification	Notified Body
POLY MEDICURE LIMITED Plot No.:104-105, Sector 59, HSIIDC Industrial Area, Ballabhgarh, Faridabad, Haryana 121004, INDIA	CE Certificate Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III CE Certificate No.: G10 041938 0011 EN ISO 13485:2016/DIN-EN ISO 13485:2016 Certificate No.: Q5 041938 0001 Rev.03	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany Notified Body Number: 0123
<i>Plot No. 17, Sector-3, Integrated Industrial Estate, SIDCUL Haridwar, Uttarakhand 249403, INDIA</i>	<i>CE Certificate Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III Certificate No.: G20 105486 0001 EN ISO 13485:2016/DIN-EN ISO 13485:2016 Certificate No.: Q5 041938 0001 Rev.03</i>	

Device Classification:

- As per "Classification Criteria" in Annexure VIII of Regulation (EU) 2017/745, the closed wound suction unit 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 1.2 of Annexure VIII.
- This device penetrates inside the surface of body, hence is "Invasive device" as per 2.2 of Annexure VIII. As per the Directive devices which penetrate the body through other than an establish body orifice are surgically invasive devices hence Closed wound suction unit is "Surgically invasive device".
- Closed wound suction unit is classified as Class IIa Medical device following no indent of rule-7 of Annex-VIII of EU MDR 2017/745.

Device Description:

Closed Wound Suction Unit is a medical device, used to drain wounds of fluids, blood, and other foreign material that builds up in the area of the body after surgery. Closed wound suction unit helps to prevent infection and hematomas, therefore enhancing wound healing, reducing inflammation, and providing pain relief. Closed-wound suction is an important part of postoperative treatment, and it is used to create a low negative pressure to drain away undesirable exudates.

The closed-wound suction unit has a thin flexible tube attached to a squeezable container (bellow container). One end of the tube is placed into the patient's surgical site through a small opening near the incision where the fluid is building up. The other end is attached to the bellow. When the bellow is squeezed, a constant gentle suction is created which draws out the excess fluids. It has a curved trocar with very sharp cutting edge on one end and other end is being given as threaded portion to insert flexible Drain.

A Close Wound Suction unit consist with a bellow unit with connector, connecting tube with clamp and Y- connector, curved trocar with catheter and perforated redon drain catheter with radio-opaque line and markings for accurate placement. The product & packaging doesn't contain any constituent of animal origin. Non-toxic. Non-pyrogenic.

Single use Close Wound Suction Unit available in single unit pack.

Polymed provides following variants of Closed wound Suction Unit:

- Novovac Set:** Closed wound drainage system with graduated transparent spring bellow available in sizes 200, 400 500 & 600ml, suitable for drainage under negative pressure post operatively with the options to operate one or two catheters simultaneously.
- Polyvac Set:** Closed wound suction unit with flexible bellow container available in sizes 500, 600 & 800ml, suitable for drainage under negative pressure post operatively with the options to operate one or two catheters simultaneously.
- Neovac Set:** Closed wound suction unit with flexible bellow container available in size 50ml, suitable for minor surgeries.

Technical Specification:

Dimension of trocar needle is as given below-

Size (FG)	Length of Trocar						O.D.
	For 50 ml (Neovac)	For 400ml (Polyvac & Novovac)		For 500ml (Polyvac)	For 600ml (Polyvac)	For 800ml (Polyvac)	
FG 6	90 ± 3mm						2.00 mm
FG 8	90 ± 3mm	90 ± 3mm	90 ± 3mm			90 ± 3mm	2.70 mm

FG 10		132 ± 3mm	175 ± 3mm	175 ± 3 mm	175 ± 3mm	132 ± 3mm	175 ± 3mm	3.30 mm
FG 12		132 ± 3mm	175 ± 3mm		175 ± 3mm	132 ± 3mm	175 ± 3mm	4.00 mm
FG 14		132 ± 3mm	175 ± 3mm		175 ± 3mm	132 ± 3mm	175 ± 3mm	4.70 mm
FG 15				175 ± 3 mm				4.70 mm
FG 16		132 ± 3mm	175 ± 3mm		175 ± 3mm	132 ± 3mm	175 ± 3mm	5.35 mm
FG 18		132 ± 3mm	175 ± 3mm		175 ± 3mm	132 ± 3mm	175 ± 3mm	6.00 mm
FG 19				175 ± 3 mm				6.00 mm

Dimension of the Collection tube / Main tube should be as per below table: -

Description	Dimension	Tolerance
Length	1000 mm	±10 mm
	1200 mm	±20 mm
Outer Diameter	7.4 mm	± 0.1 mm
Inner Diameter	5.3 mm	± 0.1 mm

Drainage catheter (Redon tube) dimensional parameters are as per below table:

Size	O.D. ± 0.10 (mm)	I.D. ± 0.10 (mm)	Marking ±1.0 (cm)	Perforated Length ±1.0 (cm)		No. of Perforations		Length of Perforation gap
				50cm Tube	120cm Tube	50±1.0 cm Tube	120±1.0 cm Tube	
FG 6	2.00 mm	1.10 mm	5 cm	14 cm	30 cm	26 pairs	52 pairs	1 cm
FG 8	2.70 mm	1.60 mm	5 cm	14 cm	30 cm	24 pairs	52 pairs	1 cm
FG 10	3.33 mm	2.10 mm	5 cm	14 cm	30 cm	24 pairs	48 pairs	1 cm
FG 12	4.00 mm	2.50 mm	5 cm	14 cm	30 cm	24 pairs	48 pairs	1 cm
FG 14	4.70 mm	2.90 mm	5 cm	14 cm	30 cm	24 pairs	52 pairs	1 cm
FG 15	5.00 mm	3.20 mm	5 cm	14 cm	30 cm	26 pairs	52 pairs	1 cm
FG 16	5.33 mm	3.60 mm	5 cm	14 cm	30 cm	26 pairs	52 pairs	1 cm
FG 18	6.00 mm	4.20 mm	5 cm	14 cm	30 cm	26 pairs	52 pairs	1 cm
FG 19	6.30 mm	4.20 mm	5 cm	14 cm	30 cm	26 pairs	52 pairs	1 cm

Approved Materials of Constructions:

S. No.	Parts Where Material is used	Base Material	CAS Number
1.	Trocar	Stainless Steel	65997-19-5
2.	Collection / Main Tube	PVC	9002-86-2
3.	Non-Return Valve	Silicon	7440-21-3
4.	Trocar Needle cover	PVC	9002-86-2
5.	Drainage catheter (Redon tube)	PVC	9002-86-2
6.	U-connector	PVC	9002-86-2
7.	Bellow cap (Neovac)	RPVC	9002-86-2
8.	Gauge connector	RPVC	9002-86-2
9.	Hanger	HDPE+LDPE	9002-88-4+ 9002-88-4
10.	Hanger clamp	ABS	9003-56-9
11.	Pouring point connector	PVC	9002-86-2
12.	Novo Y- connector	PVC	9002-86-2
13.	Suction point connector	PVC	9002-86-2
14.	Enclosure Cap	PVC	9002-86-2
15.	Green connector	PVC	9002-86-2
16.	Bellow cap (Polyvac)	RPVC	9002-86-2

S. No.	Parts Where Material is used	Base Material	CAS Number
17.	Snap Cap	ABS	9003-56-9
18.	Snap cap inner plug	PVC	9002-86-2
19.	Click Clamp	PP	9010-79-1
20.	Bellow (Polyvac)	LDPE	9002-88-4
21.	Bellow (Neovac)	LDPE	9002-88-4
22.	PVC Sheet (Novovac)	PVC	9002-86-2
23.	Upper Cap	RPVC	9002-86-2
24.	Lower Cap	RPVC	9002-86-2
25.	Inner Plug	PVC	9002-86-2
26.	Spring	Stainless Steel	65997-19-5

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.



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Reference to QMDS Documents:

Document Title	Polymed Internal Document Reference
Technical File	PML/MD/TF/1.18
Product Specification	FP/QA/35
Risk Management	PML/MD/RA/1.18
Clinical Evaluation	PML/MD/CER/18
DOC	F/QA/176

Packaging Characteristics:

The unit packaging comprises a medical-grade paper pouch that functions as a sterile barrier system, maintaining sterility through a secure seal. The integrity of the pouch is designed to remain uncompromised during routine handling, storage, sterilization, and transportation. It is constructed to open reliably without tearing or generating particulate matter, ensuring aseptic presentation.

Each individual unit pouch is placed into a duplex printed cardboard inner box, providing additional protection and product identification. Subsequently, forty (40) such inner boxes are packed into a single corrugated shipper box, in accordance with customer requirements.

This multi-layered packaging configuration including the unit pouch, inner duplex box, and outer corrugated shipper ensures comprehensive product protection throughout normal shipping, handling, and storage conditions, maintaining package integrity and sterility until 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.
- Any substances of animal origin e.g., BSE/TSE are not used during manufacturing.