



POLY MEDICURE LIMITED

TECHNICAL DATA SHEET **Manifold With/without extension Line**



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TECHNICAL DATA SHEET
Manifold with/without extension line

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Product Code	Description Of Product
13034	Manifold with Q-syte and support 2 port
13035	Manifold with Q-syte and support 3 port
13036	Manifold with Q-syte and support 4 port
13037	Manifold with Q-syte and support 5 port
13710	Manifold with Q-syte and support 6 port
13711	Manifold with luer lock 2 port
13712	Manifold with luer lock 3 port
13713	Manifold with luer lock 4 port
13714	Manifold with luer lock 5 port
13715	Manifold with luer lock 6 port
13716	Manifold with Q-syte, conekt plus & support 2 port
13717	Manifold with Q-syte, conekt plus & support 3 port
13718	Manifold with Q-syte, conekt plus & support 4 port
13719	Manifold with Q-syte, conekt plus & support 5 port
13720	Manifold with Q-syte, conekt plus & support 6 port
13721	Manifold with luer lock & conekt plus 2 port
13722	Manifold with luer lock & conekt plus 3 port
13723	Manifold with luer lock & conekt plus 4 port
13724	Manifold with luer lock & conekt plus 5 port
13725	Manifold with luer lock & conekt plus 6 port
13726	Blue Clamp for Manifold (carrier)
13727	Manifold with luer lock, conekt plus and support 2 port
13728	Manifold with luer lock, conekt plus and support 3 port
13729	Manifold with luer lock, conekt plus and support 4 port
13730	Manifold with luer lock, conekt plus and support 5 port
13731	Manifold with luer lock, conekt plus and support 6 port
13732	Manifold with luer lock and support 2 port
13733	Manifold with luer lock and support 3 port
13734	Manifold with luer lock and support 4 port
13735	Manifold with luer lock and support 5 port
13736	Manifold with luer lock and support 6 port
13737	Manifold with luer lock 2 port (Bulk)
13738	Manifold with luer lock 3 port (Bulk)
13739	Manifold with luer lock 4 port (Bulk)
13740	Manifold with luer lock 5 port (Bulk)
13741	Manifold with luer lock 6 port (Bulk)
13742	Manifold with luer lock 2 port with Extension line



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Product Code	Description Of Product
13743	Manifold with luer lock 3 port with Extension line
13744	Manifold with luer lock 4 port with Extension line
13745	Manifold with luer lock 5 port with Extension line
13746	Manifold with luer lock 6 port with Extension line
13747	Manifold with luer lock, conekt plus and support 2 port with Extension line
13748	Manifold with luer lock, conekt plus and support 3 port with Extension line
13749	Manifold with luer lock, conekt plus and support 4 port with Extension line
13750	Manifold with luer lock, conekt plus and support 5 port with Extension line
13751	Manifold with luer lock, conekt plus and support 6 port with Extension line
13753	Manifold, Neofold Pro (2 Port Right)
13754	Manifold, Neofold Pro (3 Port Right)
13755	Manifold Neofold Pro 250psi (2 Port Right OFF)
13756	Manifold Neofold Pro 250psi (3 Port Right OFF)
13757	Manifold Neofold Pro 500psi 2 Port Right OFF
13758	Manifold Neofold Pro 500psi 3 Port Right OFF
13759	Manifold Neofold Pro 500psi 2 Port Right ON
13760	Manifold Neofold Pro 500psi 3 Port Right ON
16350	Manifold, 2ways, coextruded PE/PVC extension tube 50cm, 2,5x4,1mm
16351	Manifold, 2ways, coextruded PE/PVC extension tube 100cm, 2,5x4,1mm
16352	Manifold, 2ways, coextruded PE/PVC extension tube 150cm, 2,5x4,1mm
16353	Manifold, 2ways, coextruded PE/PVC extension tube 200cm, 2,5x4,1mm
16354	Manifold, 3ways, coextruded PE/PVC extension tube 50cm, 2,5x4,1mm
16355	Manifold, 3ways, coextruded PE/PVC extension tube 100cm, 2,5x4,1mm
16356	Manifold, 3ways, coextruded PE/PVC extension tube 150cm, 2,5x4,1mm
16357	Manifold, 3ways, coextruded PE/PVC extension tube 200cm, 2,5x4,1mm
16358	Manifold, 4ways, coextruded PE/PVC extension tube 50cm, 2,5x4,1mm
16359	Manifold, 4ways, coextruded PE/PVC extension tube 100cm, 2,5x4,1mm
16360	Manifold, 4ways, coextruded PE/PVC extension tube 150cm, 2,5x4,1mm
16361	Manifold, 4ways, coextruded PE/PVC extension tube 200cm, 2,5x4,1mm
16362	Manifold, 5ways, coextruded PE/PVC extension tube 50cm, 2,5x4,1mm
16363	Manifold, 5ways, coextruded PE/PVC extension tube 100cm, 2,5x4,1mm
16364	Manifold, 5ways, coextruded PE/PVC extension tube 150cm, 2,5x4,1mm
16365	Manifold, 5ways, coextruded PE/PVC extension tube 200cm, 2,5x4,1mm
16366	Manifold, 2ways, with BD QSYTE valve, carrier, coextruded PE/PVC extension tube 50cm, 2,5x4,1mm
16367	Manifold, 2ways, with BD QSYTE valve, carrier, coextruded PE/PVC extension tube 100cm, 2,5x4,1mm



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16368	Manifold, 2ways, with BD QSYTE valve, carrier, coextruded PE/PVC extension tube 150cm, 2,5x4,1mm
16369	Manifold, 2ways, with BD QSYTE valve, carrier, coextruded PE/PVC extension tube 200cm, 2,5x4,1mm
16370	Manifold, 3ways, with BD QSYTE valve, carrier, coextruded PE/PVC extension tube 50cm, 2,5x4,1mm
16371	Manifold, 3ways, with BD QSYTE valve, carrier, coextruded PE/PVC extension tube 100cm, 2,5x4,1mm
16372	Manifold, 3ways, with BD QSYTE valve, carrier, coextruded PE/PVC extension tube 150cm, 2,5x4,1mm
16373	Manifold, 3ways, with BD QSYTE valve, carrier, coextruded PE/PVC extension tube 200cm, 2,5x4,1mm
16374	Manifold, 4ways, with BD QSYTE valve, carrier, coextruded PE/PVC extension tube 50cm, 2,5x4,1mm
16375	Manifold, 4ways, with BD QSYTE valve, carrier, coextruded PE/PVC extension tube 100cm, 2,5x4,1mm
16376	Manifold, 4ways, with BD QSYTE valve, carrier, coextruded PE/PVC extension tube 150cm, 2,5x4,1mm
16377	Manifold, 4ways, with BD QSYTE valve, carrier, coextruded PE/PVC extension tube 200cm, 2,5x4,1mm
16378	Manifold, 5ways, with BD QSYTE valve, carrier, coextruded PE/PVC extension tube 50cm, 2,5x4,1mm
16379	Manifold, 5ways, with BD QSYTE valve, carrier, coextruded PE/PVC extension tube 100cm, 2,5x4,1mm
16380	Manifold, 5ways, with BD QSYTE valve, carrier, coextruded PE/PVC extension tube 150cm, 2,5x4,1mm
16381	Manifold, 5ways, with BD QSYTE valve, carrier, coextruded PE/PVC extension tube 200cm, 2,5x4,1mm
16382	Manifold, 6ways, with BD QSYTE valve, carrier, coextruded PE/PVC extension tube 50cm, 2,5x4,1mm
16383	Manifold, 6ways, with BD QSYTE valve, carrier, coextruded PE/PVC extension tube 100cm, 2,5x4,1mm
16384	Manifold, 6ways, with BD QSYTE valve, carrier, coextruded PE/PVC extension tube 150cm, 2,5x4,1mm
16385	Manifold, 6ways, with BD QSYTE valve, carrier, coextruded PE/PVC extension tube 200cm, 2,5x4,1mm
16386	Manifold, 2ways, with carrier, coextruded PE/PVC extension tube 50cm, 2,5x4,1mm
16387	Manifold, 2ways, with carrier, coextruded PE/PVC extension tube 100cm, 2,5x4,1mm
16388	Manifold, 2ways, with carrier, coextruded PE/PVC extension tube 150cm, 2,5x4,1mm
16389	Manifold, 2ways, with carrier, coextruded PE/PVC extension tube 200cm, 2,5x4,1mm
16390	Manifold, 3ways, with carrier, coextruded PE/PVC extension tube 50cm, 2,5x4,1mm
16391	Manifold, 3ways, with carrier, coextruded PE/PVC extension tube 100cm, 2,5x4,1mm



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Product Code	Description Of Product
16392	Manifold, 3ways, with carrier, coextruded PE/PVC extension tube 150cm, 2,5x4,1mm
16393	Manifold, 3ways, with carrier, coextruded PE/PVC extension tube 200cm, 2,5x4,1mm
16394	Manifold, 4ways, with carrier, coextruded PE/PVC extension tube 50cm, 2,5x4,1mm
16395	Manifold, 4ways, with carrier, coextruded PE/PVC extension tube 100cm, 2,5x4,1mm
16396	Manifold, 4ways, with carrier, coextruded PE/PVC extension tube 150cm, 2,5x4,1mm
16397	Manifold, 4ways, with carrier, coextruded PE/PVC extension tube 200cm, 2,5x4,1mm
16398	Manifold, 5ways, with carrier, coextruded PE/PVC extension tube 50cm, 2,5x4,1mm
16399	Manifold, 5ways, with carrier, coextruded PE/PVC extension tube 100cm, 2,5x4,1mm
16400	Manifold, 5ways, with carrier, coextruded PE/PVC extension tube 150cm, 2,5x4,1mm
16401	Manifold, 5ways, with carrier, coextruded PE/PVC extension tube 200cm, 2,5x4,1mm
16402	Manifold, 6ways, with carrier, coextruded PE/PVC extension tube 50cm, 2,5x4,1mm
16403	Manifold, 6ways, with carrier, coextruded PE/PVC extension tube 100cm, 2,5x4,1mm
16404	Manifold, 6ways, with carrier, coextruded PE/PVC extension tube 150cm, 2,5x4,1mm
16405	Manifold, 6ways, with carrier, coextruded PE/PVC extension tube 200cm, 2,5x4,1mm
30600	Manifold with luer lock 2 port with Extension line 100cm, 2,5x4,1mm
30601	Manifold with luer lock 2 port with Extension line 150cm, 2,5x4,1mm
30602	Manifold with luer lock 2 port with Extension line 200cm, 2,5x4,1mm
30603	Manifold with luer lock 3 port with Extension line 100cm, 2,5x4,1mm
30604	Manifold with luer lock 3 port with Extension line 150cm, 2,5x4,1mm
30605	Manifold with luer lock 3 port with Extension line 200cm, 2,5x4,1mm
30606	Manifold with luer lock 4 port with Extension line 100cm, 2,5x4,1mm
30607	Manifold with luer lock 4 port with Extension line 150cm, 2,5x4,1mm
30608	Manifold with luer lock 4 port with Extension line 200cm, 2,5x4,1mm
30609	Manifold with luer lock 5 port with Extension line 100cm, 2,5x4,1mm
30610	Manifold with luer lock 5 port with Extension line 150cm, 2,5x4,1mm
30611	Manifold with luer lock 5 port with Extension line 200cm, 2,5x4,1mm
30612	Manifold, 2ways, with BD QSYTE valve, carrier, extension tube 50cm, 2,5x4,1mm
30613	Manifold, 2ways, with BD QSYTE valve, carrier, extension tube 100cm, 2,5x4,1mm
30614	Manifold, 2ways, with BD QSYTE valve, carrier, extension tube 150cm, 2,5x4,1mm
30615	Manifold, 2ways, with BD QSYTE valve, carrier, extension tube 200cm, 2,5x4,1mm
30616	Manifold, 3ways, with BD QSYTE valve, carrier, extension tube 50cm, 2,5x4,1mm
30617	Manifold, 3ways, with BD QSYTE valve, carrier, extension tube 100cm, 2,5x4,1mm
30618	Manifold, 3ways, with BD QSYTE valve, carrier, extension tube 150cm, 2,5x4,1mm
30619	Manifold, 3ways, with BD QSYTE valve, carrier, extension tube 200cm, 2,5x4,1mm
30620	Manifold, 4ways, with BD QSYTE valve, carrier, extension tube 50cm, 2,5x4,1mm
30621	Manifold, 4ways, with BD QSYTE valve, carrier, extension tube 100cm, 2,5x4,1mm
30622	Manifold, 4ways, with BD QSYTE valve, carrier, extension tube 150cm, 2,5x4,1mm



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Product Code	Description Of Product
30623	Manifold, 4ways, with BD QSYTE valve, carrier, extension tube 200cm, 2,5x4,1mm
30624	Manifold, 5ways, with BD QSYTE valve, carrier, extension tube 50cm, 2,5x4,1mm
30625	Manifold, 5ways, with BD QSYTE valve, carrier, extension tube 100cm, 2,5x4,1mm
30626	Manifold, 5ways, with BD QSYTE valve, carrier, extension tube 150cm, 2,5x4,1mm
30627	Manifold, 5ways, with BD QSYTE valve, carrier, extension tube 200cm, 2,5x4,1mm
30628	Manifold, 6ways, with BD QSYTE valve, carrier, extension tube 50cm, 2,5x4,1mm
30629	Manifold, 6ways, with BD QSYTE valve, carrier, extension tube 100cm, 2,5x4,1mm
30630	Manifold, 6ways, with BD QSYTE valve, carrier, extension tube 150cm, 2,5x4,1mm
30631	Manifold, 6ways, with BD QSYTE valve, carrier, extension tube 200cm, 2,5x4,1mm
30632	Manifold, 2ways, with carrier, extension tube 50cm, 2,5x4,1mm
30633	Manifold, 2ways, with carrier, extension tube 100cm, 2,5x4,1mm
30634	Manifold, 2ways, with carrier, extension tube 150cm, 2,5x4,1mm
30635	Manifold, 2ways, with carrier, extension tube 200cm, 2,5x4,1mm
30636	Manifold, 3ways, with carrier, extension tube 50cm, 2,5x4,1mm
30637	Manifold, 3ways, with carrier, extension tube 100cm, 2,5x4,1mm
30638	Manifold, 3ways, with carrier, extension tube 150cm, 2,5x4,1mm
30639	Manifold, 3ways, with carrier, extension tube 200cm, 2,5x4,1mm
30640	Manifold, 4ways, with carrier, extension tube 50cm, 2,5x4,1mm
30641	Manifold, 4ways, with carrier, extension tube 100cm, 2,5x4,1mm
30642	Manifold, 4ways, with carrier, extension tube 150cm, 2,5x4,1mm
30643	Manifold, 4ways, with carrier, extension tube 200cm, 2,5x4,1mm
30644	Manifold, 5ways, with carrier, extension tube 50cm, 2,5x4,1mm
30645	Manifold, 5ways, with carrier, extension tube 100cm, 2,5x4,1mm
30646	Manifold, 5ways, with carrier, extension tube 150cm, 2,5x4,1mm
30647	Manifold, 5ways, with carrier, extension tube 200cm, 2,5x4,1mm
30648	Manifold, 6ways, with carrier, extension tube 50cm, 2,5x4,1mm
30649	Manifold, 6ways, with carrier, extension tube 100cm, 2,5x4,1mm
30650	Manifold, 6ways, with carrier, extension tube 150cm, 2,5x4,1mm
30651	Manifold, 6ways, with carrier, extension tube 200cm, 2,5x4,1mm



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Product Image



General Information:

Intended Use

The product is used to deliver Intravenous fluid and medicines into human circulating system. Manifolds are used in angioplasty procedures in which fluids are administered under pressure. The product can also be used for monitoring blood pressure.

Legal Manufacturer-

POLY MEDICURE LIMITED

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

POLY MEDICURE LIMITED

*Plot No.: 33-34, Sector 68, IMT,
Faridabad, Haryana- 121004, INDIA*

Manufacturing Site-

POLY MEDICURE LIMITED

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

POLY MEDICURE LIMITED

*Plot No.: 33-34, Sector 68, IMT,
Faridabad, Haryana- 121004, INDIA*

European Authorized Representative- Name and address

OBELIS S.A.

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



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Certification:

Manufacturing Site	Certification	Notified Body
POLY MEDICURE LIMITED Plot No.:104-105, Sector 59, HSI IDC Industrial Area, Ballabhgarh, Faridabad, Haryana- 121004, INDIA	CE Certificate Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III <u>CE Certificate No.: G10 041938 0011</u>	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany <u>Notified Body Number: 0123</u>
	EN ISO 13485:2016/DIN-EN ISO 13485:2016 <u>Certificate No.: Q5 041938 0001 Rev.03</u>	
POLY MEDICURE LIMITED Plot No.: 33-34, Sector 68, IMT, Faridabad, Haryana- 121004, INDIA	CE Certificate Medical Device Directives 93/42/EEC- Annex II <u>CE Certificate No.: G1 105485 0007 (CL 105485 0010)</u>	
	EN ISO 13485:2016/DIN-EN ISO 13485:2016 <u>Certificate No.: Q5 105485 0006 Rev.02</u>	

Device Classification:

- As per "Classification Criteria" in Annexure VIII of Regulation (EU) 2017/745 the Manifold with/without Extension line is normally **intended for continuous use for more than 60 minutes and less than 30 days**. Hence it is for short-term use as per description in the 1.2 of Annexure VIII.
- This device does not penetrate inside the body, hence is "Non-invasive device".
- The product intended for channeling or storing blood, body liquids or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are in Class IIa. So as per rule 2 of classification, Manifold with/without Extension line is classified as class IIa Medical Device.

Device Description:

The Manifold are a short-term use device and is being used as medical device for many years under different brands. Components of the product are made from the **biocompatible Polycarbonate & Polyethylene materials**, which are widely used in hospitals and clinics. Manifolds are used to deliver Intravenous fluid and medicines into human circulating system. The Manifold family is designed to provide access into IV Cannulation system for administration of two fluids or drugs at a time.

- Uniform smooth bore throughout permits maximum infusion flow and prevents turbulence as well as formation of air bubbles.
- Extension tube length: 150cm**. For pressure up to 4.5 bars (65 psi). **Priming volume: 6.46 ml/meter.**
- Minimum priming volume required for accurate drug administration.
- Product is manufactured from non-toxic medical grade Polycarbonate and Polyethylene.
- Leak-proof up to 2 bars liquid pressure for 15 minutes and 0.5 bar air pressure for 15 seconds, can withstand the pressure applied in procedure without affecting smooth rotation handle.



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- Male or female fitting of device is provided with 6% luer taper for leak proof connection with other devices as per ISO 80369-7:2021.
- Extension tube is made from Non-toxic medical grade DEHP Free PVC material and coextruded PE/PVC material.

Technical Specification:

Mechanical Characteristics of device:

Test characteristics	Specification
Tensile Strength b/w handle & channel joint	Not less than 15 N
Tensile Strength B/W Tube & male Luer (Left)	Not less than 20 N
Tensile Strength B/W Tube & Male luer (Right)	Not less than 20 N
Leakage from joints (Liquid leakage Tube)	Liquid pressure for tube up to 4.5bar
Liquid Leakage	No leakage at 2.0 bar liquid pressure for 15 min.
Air Leakage	No leakage at 0.5 bar air pressure for 15 sec.
Tube Inner dimension	2.5mm \pm 0.1mm
Tube Outer dimension	4.1mm \pm 0.1mm

Physical Characteristics of device

S. No.	Test	Specifications
1	Description	Single Use Manifold
2	Printed Matter	Shall be legible & Visible
3	Integrity of Package	Shall be intact
4	Particulate Matter	Shall be free from particles
5	Components	Should be well assembled
6	Movement	Handle Movement shall be Smooth
7	Fitment between Handle and Manifold (all type)	Should not be loose
8	Color Code	Shall complies as per color identification chart below
9	Transparency	Transparency of tube shall comply
10	6 % taper	Shall Complies
11	Inner Diameter of tube	Tube Diameter 2.5 \pm 0.1mm
12	Outer Diameter of tube	Tube Diameter 4.1 \pm 0.1mm
13	Effective Length	For example we have 150cm Extension line, Effective length should be 150 \pm 2CM

Approved Materials of Constructions:

S. No.	Parts Where Material is used	Base Material	CAS Number
1	Channel (Manifold)	Polycarbonate	103598-77-2
2	Handle	HDPE	9002-88-4
3	Luer Lock with Hole	HDPE	9002-88-4



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S. No.	Parts Where Material is used	Base Material	CAS Number
4	Male Luer without hole	HDPE	9002-86-2
5	Clamp	ABS	9003-56-9
6	Screw	Nylon	9012-28-6
7	Clip	Nylon	9012-28-6
8	Q - Syte	Silicon + PC	103598-77-2
9	Connek Plus	HDPE	9002-88-4
10	Extension line	DEHP Free PVC	9002-86-2
11	Fixed Male Luer Lock (Extension Line)	RPVC	9002-86-2
12	PE Cap	LDPE	9002-88-4
13	Filter	Porous Filter	N/A
14	Lubricating Agent	Silicone Oil	63148-62-9
16	Gluing Agent	Cyclohexanone	N/A
17	LD Sleeve	PE Film	N/A

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



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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/80
Product Specification	FP/QA/5.133
Risk Management	PML/MD/RA/80
Clinical Evaluation	PML/MD/CER/80
DOC	F/QA/176

Packaging Characteristics:

The unit packaging consists of a clear blister formed from polypropylene and polyethylene (PP+PE) film, serving as the bottom component, and is sealed with a printed lid made of medical-grade paper. This configuration functions as a sterile barrier system, maintaining sterility through a validated sealing process. The integrity of the package is designed to remain intact and uncompromised during standard handling, storage, sterilization, and transportation. Each unit package is packed into a corrugated shipper box, with 25 units per box or as specified by customer requirements. This packaging system ensures the product remains protected and sterile until it 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.