POLY MEDICURE LIMITED

TECHNICAL DATA SHEET

Three Way Stop Cock

Digitally signed by Iarovoi Petru
Date: 2025.06.08 19:18:22 EEST
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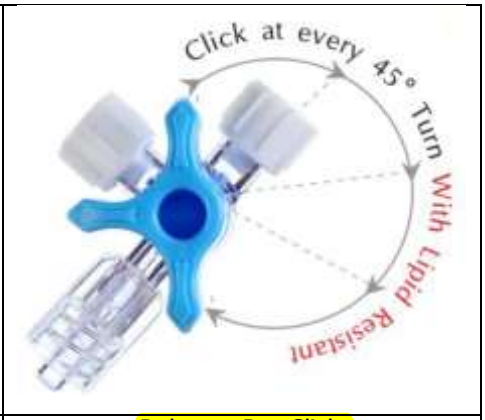
Product Code	Description Of Product
13001 – 13012,13507	Three Way Stop Cock
13013- 13015	Three Way Stop Cock with 45º click
13016-13022,13040-13045,13056, 13099,13601-13602, 13605-13608,	Three Way Stop Cock with Extension Tube
13023-13025	Three Way Stop Cock with Lipid Resistant
13026,13058, 13600, 13603, 13230-13235	Three Way Stop Cock with Lipid Resistant & 45° click
13027-13033,13050-13055,13610-13611	Three Way Stop Cock lipid resistant with Extension Tube
13038	High Pressure stop cock
13039	Three way stopcock Lipid resistant without Screw Cap (Rotator) with Blue handle
13046-13047	Three Way Stop Cock
13048-13049,13498-13499,13505-13506	Three Way Stop Cock with Lipid Resistant
13066	Three way stop cock with blue handle
13069	Three way stop cock, white handle, With Luer Slip in paper pack
13098	Three Ways Stopcock (lipid resistant), swabable valve with PVC Extension tube 10 cm and rotating luer lock
13604	Three way stop cock Lipid resistant, Light Blue handle, With Needle-free connector
13609	Three way stop cock Lipid resistant, Light Blue handle, With 2 Needle-free connector
13599	Enteral stopcock (white handle) with soft blister pack
13500-13502	Three way stop cock BPA free with click
13503	Three way stop cock with lipd resistant BPA free with click
13504	Three way stop cock BPA free with click
13540-13543	Three way stop cock BPA free with DEHP free extension tube
13615-13620	Three way stop cock click with DEHP free extension tube
16194	Three way stopcock with white handle lipid resistance
13236	Three way stopcock Lipid resistant click, White Handle, with DEHP free PVC extension tube (12 cm), Two Halkey Robert Needle free connector, Rotating Luer Lock, PE cap with Filter
13060-13065,13210-13215	Three way stop cock with click , UV & PVC free extension tube
13220-13225	Three way stop cock lipid resistant with click , UV & PVC free extension tube
13070-13075, 13090-13095,	Three way stop cock click with DEHP free extension tube
13800-13806	Three way stop cock lipid resistant with extension tube with needle free connector
13810-13818	Three way stop cock lipid resistant with extension tube with two needle free connector
13820-13822	Three way stopcock Lipid resistant click, DEHP free PVC extension tube, Back check valve, Rotating Luer Lock, PE cap without Filter, Paper packed
13965-13995, 16000-16024	Three way stop cock with co-extruded extension line
16025-16038, 16040-16091	Three way stop cock lipid resistant with co-extruded extension line
13208	Three way with extension line ALP-TR3RS

Product Image

		
Polyway	Polyway Pro	Polyway Pro Click

General Information:

Intended Use

The product is used to deliver Intravenous fluid and medicines into human circulating system to maintain hydration and/ or correct dehydration in patients who are unable to take sufficient volume of oral fluids. The Three Way Stop Cock family is designed to provide access into IV Cannula system for administration of two fluids or drugs at a time.

Legal Manufacturer-

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

POLY MEDICURE LIMITED
Plot No.: 33-34, Sector 68, IMT,
Faridabad, Haryana- 121004, INDIA

POLY MEDICURE LIMITED
Plot No. PA-010-018, PA-010-019, Mahindra World City
(Jaipur) Ltd., Multi-Product SEZ, Jaipur, Rajasthan 302037, INDIA

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

Manufacturing Site-

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Sidcul Haridwar, Uttarakhand 249403, India

European Authorized Representative- Name and address
OBELIS S.A.
Boulevard Général Wahis 53,
B-1030, Brussels,
Belgium

Certification:

Manufacturing Site	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***	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***	
POLY MEDICURE LIMITED *Plot No.: 33-34, Sector 68, IMT, Faridabad, Haryana- 121004, INDIA*	*CE Certificate* *Medical Device Directives 93/42/EEC- Annex II* ***CE Certificate No.: G1 105485 0007 (CL 105485 0010)***	
	EN ISO 13485:2016/DIN-EN ISO 13485:2016 ***Certificate No.: Q5 105485 0006***	
POLY MEDICURE LIMITED *Plot No. PA-010-018, PA-010-019, Mahindra World City (Jaipur) Ltd., Multi-Product SEZ, Jaipur, Rajasthan 302037, INDIA*	*CE Certificate* *Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A* ***CE Certificate No.: G20 105735 0009***	
	EN ISO 13485:2016/DIN-EN ISO 13485:2016 ***Certificate No.: Q6 105735 0006***	
POLY MEDICURE LIMITED *Plot No. 17, Sector-3, Integrated Industrial Estate,* *Sidcul Haridwar, Uttarakhand 249403, India*	*CE Certificate* *Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A* ***CE Certificate No.: G20 105486 0001***	
	EN ISO 13485:2016/DIN-EN ISO 13485:2016 ***Certificate No.: Q5 0419380001***	

Device Classification:

- As per "Classification Criteria" in Annexure VIII of Regulation (EU) 2017/745 the Three Way Stop Cock and Three Way Stop Cock with Extension Tube 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, Three Way Stop Cock with/without Extension Tube is classified as class IIa Medical Device.

Device Description:

The stopcocks 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, resistant to disinfectants for skin tissues used in hospitals and clinics. Three-way stopcocks are used to deliver Intravenous fluid and medicines into human circulating system. The Stop Cock family is designed to provide access into IV Cannula system for administration of two fluids or drugs at a time. For multiple infusions.

- Uniform smooth bore throughout permits maximum infusion flow and prevents turbulence as well as formation of air bubbles.
- Rotating male luer and two female luer connectors. Colored handle. 360° Rotation.
- Approximate Priming volume in three way stop cock with/without lipid resistance is 0.23 ml, three way stop cock with 45º click is 0.26 ml.
- Extension Tube length: 7, 10, 15, 20, 25, 30, 50, 80, 100, 150 & 200cm.
- Stopcock without extension line is leak-proof up to 4.5 bars for non-lipid resistant & 5.5 bars for lipid resistant variant and Stopcock without extension line is leak-proof up to 2.0 bars and can withstand the pressure applied in procedure without affecting smooth rotation of red, blue or white handle.

Technical Specification:

Test characteristics	Specification
Tensile Strength between stop cock and tube joints	Not less than 15 N
Flow Rate	Not less than 350 ml /minute
Male / female Connector	Complies with ISO 80369-3 and/or ISO 80369-7.
Leakage from handle & channel joint	Should not leak when tested at 3.0 to 3.2kpa liquid pressure
Leakage from channel & tube joint	Should not leak when tested at 2 bar liquid pressure
Tube Outer dimension	4.1mm ± 0.1mm
Tube Inner dimension	3.0mm ± 0.1mm

Approved Materials of Constructions:

S. No.	Parts Where Material is used	Base Material	CAS No.
1	Handle	HDPE	9002-88-4
2	Channel	PC	103598-77-2
3	Channel Housing (BPA Free)	Copolymer	-
4	Screw cap	PC	103598-77-2
5	Cock cap	PP	9003-07-0
6	Luer lock	HDPE	9002-88-4
		ABS	9003-56-9
7	DEHP free Tubing	DEHP Free PVC	9002-86-2
8	PVC free Tubing	Meliflex	9002-86-2

S. No.	Parts Where Material is used	Base Material	CAS No.
9	Male luer connector	Polycarbonate	103598-77-2
		ABS	9003-56-9
		RPVC	9002-86-2
10	MLL cap	HDPE	9002-88-4
11	Purge filter cap	ABS	9003-56-9
12	Hinge Connector	LDPE	9002-88-4
13	Enteral Channel Male Connector	ABS	9003-56-9
14	Enteral Channel Female Connector	ABS	9003-56-9
15	Gluing Agent	Cyclohexanone	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*
EN ISO 10993-1:2020	*Biological evaluation of medical devices – Evaluation and testing within a risk management process.*
EN ISO 8536-4:2020	*Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed*
EN ISO 8536-10:2015	*Infusion equipment for medical use - Part 10: Accessories for fluid lines for single use with pressure infusion equipment*

Document Code	Document Description
EN ISO 80369-7:2021	*Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications*

Reference to QMDS Documents:

Document Title	Polymed Internal Document Reference
Technical File	PML/MD/TF/1.02
Product Specification	FP/QA/02
Risk Management	PML/MD/RA/1.02
Clinical Evaluation	PML/MD/CER/02
DOC	F/QA/176

Packaging Characteristics:

The bottom of the unit package shall be a clear blister formed from PVC or PP+PE film. It shall be sealed with a printed lid made of Tyvek or medical-grade paper.

The unit package shall maintain a sterility barrier through its seal. The integrity of the package shall not be compromised during normal handling, storage, sterilization, or transportation.

Packaging Configurations:

- ***Standard Configuration:*** *Fifty (50) unit packages shall be packed into one duplex box, as per requirement. Ten (10) or twenty (20) duplex boxes shall be packed into one corrugated shipper box, containing a total of 500 or 1,000 units, respectively.*
- ***Variable Configuration (Based on Tube Length or Customer Requirement):*** *Thirty-five (35) to seventy-five (75) unit packages shall be packed into one duplex box. Ten (10) such duplex boxes shall be packed into one corrugated shipper box, containing a total of 350 to 750 units.*

This packaging system—comprising the unit package, duplex box, and shipper box—provides adequate product protection during normal shipping, handling, and storage, ensuring the product reaches the end user in optimal condition.

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.