POLY MEDICURE LIMITED

TECHNICAL DATA SHEET

Vial Access Spike

(Polyspike, Polyspike V Plus)

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Product Code	Description
13068	Polyspike -Air vented spike with green snap fit cap
13490	Polyspike- Air vented spike with Blue snap fit cap, fluid filter
13491	Polyspike- Air vented chemo spike with Red snap fit cap, fluid filter
13492	Polyspike -Air vented spike with needle free valve
13493	Polyspike- Air vented spike with needle free valve, fluid filer
13494	Polyspike- Air vented chemo spike with needle free valve, fluid filter
13495	Polyspike -Air vented spike with green snap fit cap (air filter 0.1 µm)
13496	Polyspike- Air vented spike with Blue snap fit cap (air filter 0.1 µm), fluid filter (fluid filter 5 µm)
13550	Polyspike - Air Vented Spike With Blue Needle Free Valve, 0.20 µm Filter
13551	Polyspike - Air Vented Spike With Blue Needle Free Valve, 0.45 µm Filter
13552	Polyspike - Air Vented Spike With Blue Snap Fit Cap, 0.20 µm Filter
13553	Polyspike - Air Vented Spike With Blue Snap Fit Cap, 0.45 µm Filter
13554	Polyspike - Air Vented Spike With Green Needle Free Valve, 0.20 µm Filter
13555	Polyspike - Air Vented Spike With Green Needle Free Valve, 0.45 µm Filter
13556	Polyspike - Air Vented Spike With Green Snap Fit Cap, 0.20 µm Filter
13557	Polyspike - Air Vented Spike With Green Snap Fit Cap, 0.45 µm Filter
13558	Polyspike - Air Vented Spike With Red Needle Free Valve, 0.20 µm Filter
13559	Polyspike - Air Vented Spike With Red Needle Free Valve, 0.45 µm Filter
13560	Polyspike - Air Vented Spike With Red Snap Fit Cap, 0.20 µm Filter
13561	Polyspike - Air Vented Spike With Red Snap Fit Cap, 0.45 µm Filter
13565	Polyspike V Plus-R- Air vented spike with 0.20 µm air filter, Red Snap Fit Cap, integrated 2-way valve,5 µm fluid filter
13566	Polyspike V Plus-B- Air vented spike with 0.10 µm air filter, Blue Snap Fit Cap, integrated 2-way valve,5 µm fluid filter
13567	Polyspike V Plus-B Air vented spike with 0.45 µm air filter, Blue Snap Fit Cap, integrated 2-way valve, 5 µm fluid filter
13568	Polyspike V Plus-G- Air vented spike with 0.10 µm air filter, Green Snap Fit Cap, integrated 2-way valve
13569	Polyspike V Plus-G- Air vented spike with 0.45 µm air filter, Green Snap Fit Cap, integrated 2-way valve

Product Image

General Information:

Intended Use

The product is used for steady repeated injection & withdrawals. The product is designed to be used to transfer medication from a vial to a syringe and from syringe to vial.

Legal Manufacturer-

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

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

POLY MEDICURE LIMITED
Plot No.:115, 116 & 117, Sector 59, HSIIDC Industrial Area, Ballabhgarh,
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Manufacturing Site-

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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, INDIA – 121004*	*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***	
Plot No.:115, 116 & 117, Sector 59, HSIIDC Industrial Area, Ballabhgarh, Faridabad, Haryana, INDIA – 121004	*CE Certificate* *Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III* ***CE Certificate No.: G10 105484 0003***	
	EN ISO 13485:2016/DIN-EN ISO 13485:2016 ***Certificate No.: Q5 041938 0001***	

Manufacturing Site	Certification	Notified Body
POLY MEDICURE LIMITED Plot No.: 33-34, Sector 68, IMT, Faridabad- 121004, Haryana, 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**	

Device Classification:

- As per "Classification Criteria" in *Annexure VIII of Regulation (EU) 2017/745,* Vial Access Spike 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".
- As per rule 2 of classification Vial Access Spike is classified as Class Is Medical Device.

Device Description:

Vial Access Spike is a vented dispensing pin for injection & withdrawing fluids from vials or semi-rigid containers. It minimizes the risk of touch contamination of spike & luer- connector. It has an air filter (0.1µ/ 0.2µ/ 0.45µ) and a hydrophilic bacteria retentive filter (5µm), which protect the medication against contamination by bacteria and particles. Low piercing forces even when pricking thick rubber stopper. Good priming characteristics & low priming volume, easy handling through ergonomic design, simple one-hand handling (open & close) or protection against contamination through safety snap cap PVC-free, DEHP free & latex free.

The sharp, thin, piercing spike permits easy penetration of rubber stoppered vials / bags. The luer design maintains a secure closure between the product and the syringe. The hinged cap and easy-gripping spike holder help maintaining sterilization before use, minimize "touch" contamination and ensure a closed system for disposal.

Technical Specification:

Vial Access Spike is designed with various features as listed below.

- *The sharp, thin, piercing spike permits easy penetration of rubber stoppered vials / bags. The luer design maintains a secure closure between the product and the syringe. The hinged cap and easy-gripping spike holder help maintaining sterilization before use, minimize "touch" contamination and ensure a closed system for disposal.*
- *Uniform smooth bore throughout permits maximum infusion flow.*
- *Leak-proof up to 1 bar liquid pressure.*
- *Threaded Spike holder facilitates safe and secure connection to luer of other system.*
- *Female fitting of device is provided with 6% luer taper for leak proof connection with other devices as per ISO 80369-7:2021.*
- *Integrated two-way valve made of silicone material prevents back flow of infusion fluid towards the spike when it is used in inverted position.*
- *The product is sterilized using EO (Ethylene Oxide) gas.*
- *The product and packaging don't contain any constituent of animal origin.*

Approved Materials of Constructions:

S. No.	Parts Where Material is used	Base Material	CAS No.
1	Spike small	Acrylonitrile Butadiene Styrene	9003-56-9
	Spike small red ABS	*Acrylonitrile Butadiene Styrene*	*9003-56-9*
	Spike small red	*Copolymer*	-
2	Spikes cover small	Polypropylene	9010-79-1
3	Spike holder	Acrylonitrile Butadiene Styrene	9003-56-9
	Spike holder red	Copolymer	-
4	Filter Shield Red	Acrylonitrile Butadiene Styrene	9003-56-9
	Filter Shield	ABS/Copolymer	9003-56-9
5	Air filter (0.1µ, 0.2µ, 0.45µ)	PTFE Membrane	9002-84-0
6	Fluid Filter (5.0µ)	Polyethylene Terephthalate (PET)	25038-59-9
7	Filter Housing	Acrylonitrile Butadiene Styrene	9003-56-9
8	Valve	Silicon	68083-18-1
9	Valve Housing	Polypropylene	9010-79-1
10	Polyspike Cap Connector	Acrylonitrile Butadiene Styrene	9003-56-9
11	Snap cap	Polypropylene	9010-79-1
12	Swabable Valve	Polycarbonate + Silicon	25037-45-0+ 68083-18-1

Sterilization Method:

Sterilized using Ethylene Oxide.

Shelf Life:

Polyspike – The Finished products of Vial Access Spike variant, Polyspike conform to the specifications and functional requirements for five years from the date of manufacturing.

Polyspike V Plus – The Finished products of Vial Access Spike variant, Polyspike V Plus shall conform to the specifications and functional requirements for three years from the date of manufacturing.

Standards Compliance:

Document Code	Document Description
ISO 13485:2016+A11:2021	Quality system Medical Devices - Requirements for the Regulatory Purposes
EN ISO 14971:2019/A11:2021	Application of Risk Management for Medical Devices
IEC 62366-1:2015/Amd1:2020	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.*

Document Code	Document Description
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	Medical Devices-Symbols to be used with medical devices labels, labeling and information to be supplied Part 1: General requirements
EN 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.
ISO 10993-7:2008/Amd 1:2019	Biological evaluation of medical devices – Ethylene oxide sterilization residuals
EN ISO 80369-7:2021	Small bore connectors for liquids and gases in healthcare applications. Connectors for Intravascular or hypodermic applications.
EN 868-5:2018	Packaging for terminally sterilized medical devices. Sealable pouches & reels of porous and plastic film construction. Requirements & test methods.
ISO 14644-1:2015	Cleanroom and associated controlled environments – Classification of air cleanliness

Reference to QMDS Documents:

Document Title	Polymed Internal Document Reference
Technical File	PML/MD/TF/2.75
Product Specification	*FP/QA/5.112, FP/QA/5.213*
Risk Management	PML/MD/RA/2.75
Clinical Evaluation	PML/MD/CER/75
DOC	F/QA/176

Packaging Characteristics:

One unit package. Unit package of Vial Access Spike shall be a clear PP+PE film, sealed with a printed lid of medical grade/non-toxic lacquered paper. 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. Unit package shall open reliably without tearing and particulate matter generation.

- Hundred (100) pcs of unit packages shall be packed into one Inner Duplex printed cardboard box.
- Ten (10) Duplex boxes shall be packed into one corrugated shipper box, as per customer requirement.

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.