Technical Data Sheet

Product specification

1. Product name	Sol-M™ Blunt Fill Needle w/Filter
2. Description	Sol-M™ Blunt Fill Needle w/Filter is designed to replace hypodermic needles currently for withdrawal of medication from ampoules.
3. Indication for use	The Blunt Fill Needle w/Filter is used in conjunction with a syringe as an additive device for aspiration from multi-dose medicine vials.
4. Intended use	Sol-M™ Blunt Fill Needle w/Filter is used in conjunction with a syringe as an additive device for aspiration from multi-dose medicine vials.
5. Intended users	Licensed healthcare professionals
6. Instructions for Use	Instruction icon printed on shelf box
7. Warning and precautions	Single use device. Re-use or use if the package is damaged may lead to infection or other illness/injury. Not for patient injection.
8. Storage information	Keep dry, Keep away from sunlight, Storage condition: Temperature: 0℃~ 40℃, Humidity: ≤80%
9. Sizes and REF numbers	

REF	Product Description
110021F	Sol-M Blunt Fill Needle w/Filter 18G*1"
110022F	Sol-M Blunt Fill Needle w/Filter 18G*1 1/2"

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110023F	Sol-M Blunt Fill Needle w/Filter 18G*50mm
110051F	Sol-M Blunt Fill Needle w/Filter 19G*1”
110052F	Sol-M Blunt Fill Needle w/Filter 19G*1 1/2”

Sol-M™ Blunt Fill Needle w/Filter in Individually Separated Blister Pack

1. Description

Sol-M™ Blunt Fill Needle w/Filter (individually separated blister pack) is designed to replace hypodermic needles currently for withdrawal of medication from ampoules.

2. Sizes and REF numbers

REF	Product Description
110021FI	Sol-M Blunt Fill Needle w/Filter 18G*1”
110022FI	Sol-M Blunt Fill Needle w/Filter 18G*1 1/2”
110023FI	Sol-M Blunt Fill Needle w/Filter 18G*50mm

Technical information

1. List of materials	Component name	Material
	Luer lock interface	Polypropylene (PP)
	Needle hub	Polypropylene (PP)
	Filter membrane	Versapor®
	Needle tube	Stainless steel
	Needle cap	Polypropylene (PP)
	Adhesive	Epoxy
	Needle Lubricant	Silicone oil
2. Latex free	Yes	
3. PHT / DEHP / PVC free	Yes	
4. Materials of concern	Not contain substances in a concentration that is above 0.1% w/w referred to following:	

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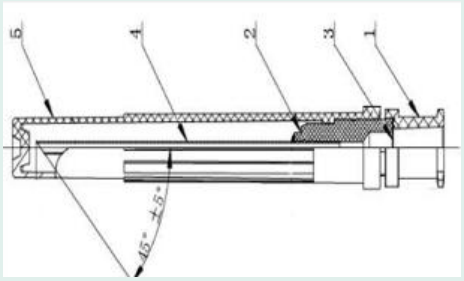
		• Substances which are carcinogenic, mutagenic or toxic to reproduction (CMR), of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament • Endocrine-disrupting substances identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (SVHC) or once a delegated act has been adopted by the Commission pursuant to the first subparagraph of Article 5(3) of Regulation (EU) No 528/2012 of the European Parliament and the Council in accordance with the criteria that are relevant to human health amongst the criteria established therein.	
5. Shelf life		5 years	
6. Sterilization method		Sterilized with Ethylene Oxide	
7. Packaging specification	7.1 Sales unit	100 units	Units per box
		1000 units (10 boxes)	Units per case (Boxes per case)

8. Technical Drawing



1. Luer lock interface
2. Needle hub
3. Filter membrane
4. Needle tube
5. Needle cap

Quality and Regulatory information

1. Quality certificate	Quality Management System according to ISO 13485:2016	
2. Product classification	USA: Class I EU: Class Is according to EU MDR 2017/745	
3. List of standards	**The product is compliant with the following standards and regulations:**	
	Document reference	**Title**
	EN ISO 13485:2016, EN ISO	Medical devices - Quality management systems - Requirements for regulatory purposes

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	13485:2016/A11:2021	
	EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
	EN ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer
	EN ISO 780:2015	Packaging. Distribution packaging. Graphical symbols for handling and storage of packages
	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	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 11138-1:2017	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes
	EN ISO 11138-2:2017	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes
	ASTM F1886/F 1886M - 16	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
	ISTA 3A 2018	General Simulation Performance Tests, Procedure 3A: Packaged-Products for Parcel Delivery System Shipment 70kg (150 lb) or Less
	ASTM F1980-21	Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices
	ASTM F1929-23	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
	ASTM F88/F88M-23	Standard Test Method For Seal Strength Of Flexible Barrier Materials
	EN868-5：2018	Packaging for terminally sterilized medical devices -Part 5: Sealable pouches and reels of porous materials and plastic film construction – Requirement and test methods (excluding clause 4.3.2)
	ASTM F2825-18	Standard Practice For Climatic Stressing Of Packaging Systems For Single Parcel Delivery
	EN ISO 14971:2019	Medical Devices - Application of Risk Management to

		Medical Devices
	EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1 Evaluation and testing within a risk management process
	EN ISO 10993-4:2017	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
	EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
	EN ISO 10993-7:2008/A1:2022	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals Amendment 1: Applicability of allowable limits for neonates and infants
	EN ISO 10993-10:2023	Biological evaluation of medical devices - Part 10: Tests for skin sensitization
	EN ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
	EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation
	EN ISO 9626:2016	Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods
	EN ISO7864: 2016	Sterile hypodermic needles for single use -- Requirements and test methods
	EN ISO 80369-1:2018	Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements
	EN ISO 80369-7:2021	Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications
	EN ISO 11607-1:2020/A11:2022	Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems
	EN ISO 11607-2:2020/A11:2022	Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes

This material is dedicated only to healthcare professionals.

REV	08	Date	2024.10.30

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