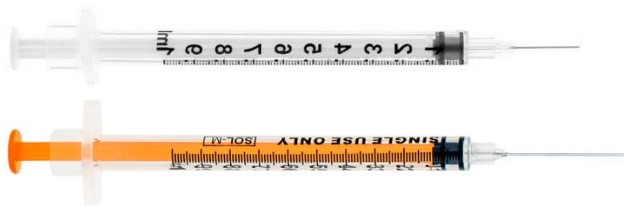


Technical Data Sheet



Product specification

1. Product name	Sol-M™ Syringe with Fixed Needle
2. Description	Sol-M™ Syringe with Fixed Needle is a sterile single-use standard hypodermic syringe with permanently pre-attached needle. It contains the syringe barrel as a container for withdrawn medication and the plunger that helps to adjust medication dose and release it from the syringe through the needle to the patient body.
3. Indication for use	The Standard Syringe with Fixed Needle is used to inject fluids into, or withdraw fluids from, the body.
4. Intended use	Sol-M™ Syringe with Fixed Needle is used to inject fluids into, or withdraw fluids from, the body.
5. Intended users	Licensed healthcare professionals
6. Instructions for Use	N/A
7. Warning and precautions	Single use device. Re-use or use if the package is damaged may lead to infection or other illness/injury.
8. Storage information	Keep dry, Keep away from sunlight, Storage condition: Temperature: 0°C~ 40°C, Humidity: ≤80%

9. Sizes and REF numbers	REF	Product Description
		180523
	181525	SOL-M 0.5ml Syringe with Fixed Needle 25G*5/8"
	180525	SOL-M 0.5ml Syringe with Fixed Needle 25G*1"
	180527	SOL-M 0.5ml Syringe with Fixed Needle 27G*1/2"
	181023	SOL-M 1ml Syringe with Fixed Needle 23G*1"

181025	SOL-M 1ml Syringe with Fixed Needle 25G*5/8"
182025	SOL-M 1ml Syringe with Fixed Needle 25G*1"
181026IDB	SOL-M 1ml Syringe with Fixed Needle 26G*3/8" IDB
181026	SOL-M 1ml Syringe with Fixed Needle 26G*1/2"
181027	SOL-M 1ml Syringe with Fixed Needle 27G*1/2"

Technical information

	Component name	Material
1. List of materials	Needle cap	Polypropylene (PP)
	Cannula	Stainless steel
	Gasket	Latex free rubber
	Barrel	Polypropylene (PP)
	Plunger	Polypropylene (PP)
	Adhesive	UV Adhesive
	Needle Lubricant	Silicone oil
	Barrel Lubricant	Silicone oil
	2. Latex free	Yes
3. PHT / DEHP / BPA free	Yes	
4. Materials of concern	<p>Not contain substances in a concentration that is above 0.1% w/w referred to following:</p> <ul style="list-style-type: none"> 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	6.1 Sales unit	100 units	Units per box
		800 units (8 boxes)	Units per case (Boxes per case)

8. Technical Drawing

1. Needle cap 2. Cannula 3. Gasket 4. Barrel 5. Plunger

Quality and Regulatory information

1. Quality certificate	Quality Management System according to ISO 13485:2016
2. Product classification	USA: Class II EU: Class IIa according to Annex IX of EU MDR 2017/745 (CE2797)

3. List of standards	The product is compliant with the following standards and regulations:	
	Document reference	Title
	EN ISO 13485:2016, EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes
	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 11135:2014, 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, 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 14971:2019, EN ISO 14971:2019/A1:2021	Medical Devices - Application of Risk Management to Medical Devices
EN ISO 10993-1:2018	Biological evaluation of medical devices - Part 1 Evaluation and testing within a risk management process	

EN ISO 10993-12:2021	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
EN ISO 10993-7 :2008/AC:2009	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals
EN ISO 10993-4:2017	Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood
EN ISO10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-10:2021	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 7864:2016	Sterile hypodermic needles for single use – Requirements and test methods
EN ISO 7886-1:2018	Sterile hypodermic syringes for single use – Part 1: Syringes for manual use
EN ISO 9626:2016	Stainless steel needle tubing for the manufacture of medical devices – Requirements and test methods
EN ISO 6009:2016	Hypodermic needles for single use – Colour coding for identification
EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes
ISO 11138-1:2017	Sterilization of health care products -- Biological indicators -- Part 1: General requirements
ISO 11138-2:2017	Sterilization of health care products – Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization processes

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This material is dedicated only to healthcare professionals.

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