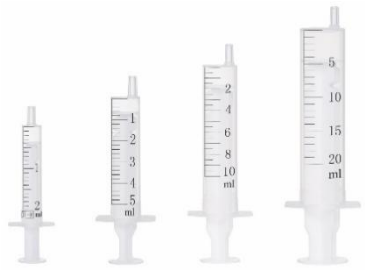
Technical Data Sheet



Product specification

1. Product name	Sol-M Syringe, 2-piece
2. Description	Sol-M Syringe, 2-piece is a sterile hypodermic syringe for single use. The device complies with ISO 7886-1: • Luer Slip Tip: ▫ Concentric (2 ml) ▫ Eccentric (5, 10 and 20 ml) • High barrel transparency – for good visualization of syringe content. • White plunger. • Black graduation – for ideal contrast and readability. • Safe plunger backstop – reduced sliding force.
3. Indication for use	The 2-piece Syringe is used in human skin, muscle and intravenous injections or liquid extraction under normal operation.
4. Intended use	Sol-M Syringe, 2-piece is used in human skin, muscle and intravenous injection or liquid extraction under normal operation.
5. Intended users	Licensed healthcare professionals
6. Instructions for Use	Refer to eIFU
7. Warning and precautions	Lubricant particles can be visible. Single use device. Re-use or use if the package is damaged may lead to infection or other illness/injury.
8. Storage information	Sterilized products should be stored in a relative humidity less than 70%, noncorrosive gas, ventilated room.
9. Sizes and REF numbers	

REF	Product Description
HS2Z02	Sol-M 2ml Syringe w/o Needle, 2-piece
HS2Z05	Sol-M 5ml Syringe w/o Needle, 2-piece

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Sol-Millennium Medical, Inc.
311 S Wacker Drive, Suite 4100
Chicago, Illinois, 60606,
UNITED STATES
www.solm.com

HS2Z10	Sol-M 10ml Syringe w/o Needle, 2-piece
HS2Z20	Sol-M 20ml Syringe w/o Needle, 2-piece

Technical information

1. List of materials		Component name	Material
		Barrel	Polypropylene (PP)
		Plunger	High-density polyethylene (HDPE)
2. Latex free		YES	
3. PHT / DEHP / PVC / BPA free		YES	
4. Materials of concern		Not contain substances in a concentration that is above 0.1% w/w referred to following: • 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		3 years	
6. Sterilization method		Sterilized using Ethylene Oxide	
7. Packaging specification	7.1 Sales unit	100 units	Units per box
		2ml — 2500 units (25 boxes)	Units per case (Boxes per case)
		5ml — 1800 units (18 boxes)	
		10ml — 1200 units (12 boxes)	
		20ml — 800 units (8 boxes)	

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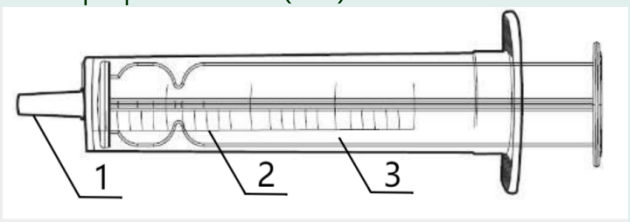
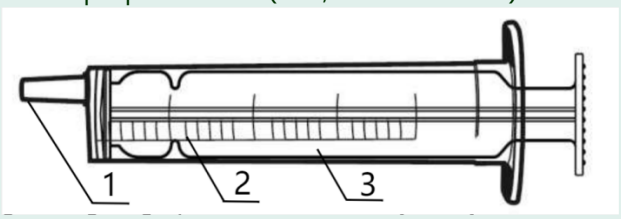
8. Technical Drawing	Luer Slip Tip concentric (2ml)  Luer Slip Tip eccentric (5ml, 10ml and 20ml)  From left to right in sequence: 1. Barrel 2. Scale Printing 3. Plunger

Quality and Regulatory information

1. Quality certificate	Quality Management System according to ISO 13485	
2. Product classification	Class Is according to MDR, Annex VIII Rule 2	
3. List of standards	**The product is compliant with the following standards and regulations:**	
	Document reference	**Title**
	ISO 7886-1:2017	Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
	ISO 80369-7:2021	Small-bore connectors for liquids and gases in healthcare applications -- Part 7: Connectors for intravascular or hypodermic applications
	ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
	ISO 10993-4:2017	Biological evaluation of medical devices -- Part 4: Selection of tests for interactions with blood
	ISO 10993-5:2009	Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
	ISO 10993-7:2008/Cor1: 2009	Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals
	ISO 10993-10:2021	Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization

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	ISO 10993-11:2017	Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity
	ISO 10993-12:2021	Biological evaluation of medical devices -- Part 12: Sample preparation and reference materials
	ISO 11607-1:2019	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
	ISO 11607-2:2019	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
	ISO 11737-2:2019	Sterilization of medical devices -Microbiological methods - Part 2: Tests of sterility performed in the validation of a sterilization process
	ISO 11135:2014/Amd1:2018	Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices
	ISO 15223-1:2021	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
	ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices
	EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices

This material is dedicated only to healthcare professionals.

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