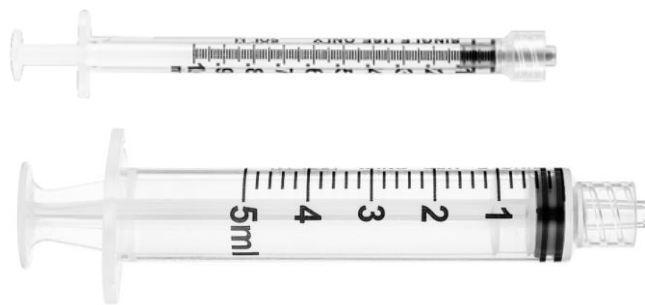


# Technical Data Sheet



## Product specification

<b>1. Product name</b>	Sol-M™ Luer Lock Syringe without Needle
<b>2. Description</b>	Sol-M™ Luer Lock Syringe without Needle is a sterile, single-use, standard 3-piece hypodermic syringe.
<b>3. Indication for use</b>	The Standard Luer Lock Syringe without Needle is used to inject fluids into, or withdraw fluids from, the body.
<b>4. Intended use</b>	Sol-M™ Luer Lock Syringe without Needle is used to inject fluids into, or withdraw fluids from, the body.
<b>5. Intended users</b>	Licensed healthcare professionals
<b>6. Instructions for Use</b>	N/A
<b>7. Warning and precautions</b>	Single use device. Re-use or use if the package is damaged may lead to infection or other illness/injury.
<b>8. Storage information</b>	Keep dry, Keep away from sunlight, Storage condition: Temperature: 0°C~ 40°C, Humidity: ≤80%

<b>9. Sizes and REF numbers</b>	<b>REF</b>	<b>Product Description</b>
	180001PP	SOL-M 1ml Luer Lock Syringe w/o Needle (PP) (low dead space)
	P180001PP	SOL-M 1ml Luer Lock Syringe w/o Needle (PP) (low dead space)
	180001	SOL-M 1ml Luer Lock Syringe w/o Needle (PC)
	180003	SOL-M 3ml Luer Lock Syringe w/o Needle
	180005	SOL-M 5ml Luer Lock Syringe w/o Needle

180010	SOL-M 10ml Luer Lock Syringe w/o Needle
180020	SOL-M 20ml Luer Lock Syringe w/o Needle
180030	SOL-M 30ml Luer Lock Syringe w/o Needle
180060	SOL-M 60ml Luer Lock Syringe w/o Needle
P180050	SOL-M 50ml Luer Lock Syringe w/o Needle

## Sol-M™ 1ml Luer Lock Syringe in Low Dead Space Version

### 1. Description

Sol-M™ 1ml Luer Lock Syringe without Needle (in low dead space version) is designed with ultra-long tip gasket, featuring much less medication residual. The average measured waste space value reaches 0.005ml.

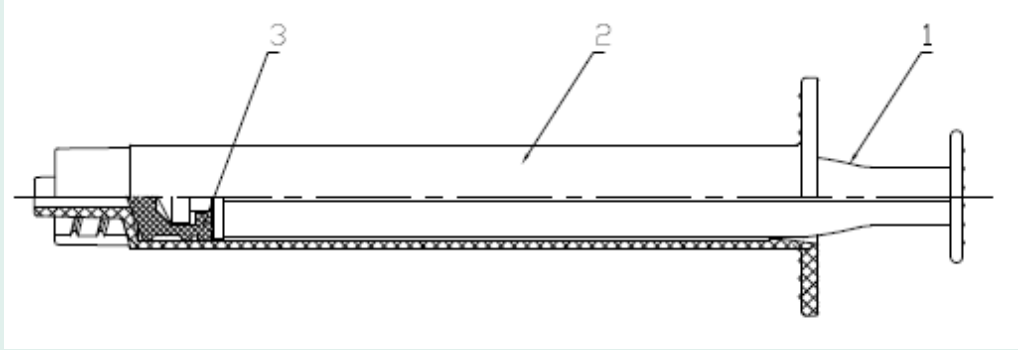
### 2. REF & Dead Space Volume

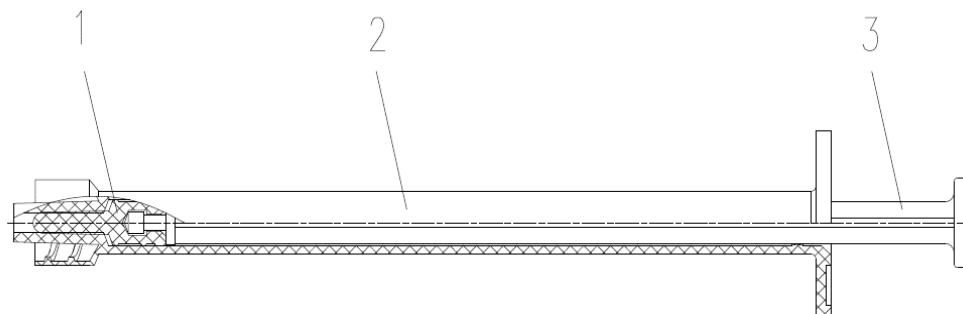
REF	Description	Average (ml)	Minimum (ml)	Maximum (ml)
P180001PP	SOL-M 1ml Luer Lock Syringe w/o Needle (PP) (low dead space)	0.005	0.002	0.008
180001PP	SOL-M 1ml Luer Lock Syringe w/o Needle (PP) (low dead space)	0.005	0.002	0.008

## Technical information

<b>1. List of materials</b>	Component name	Material
	Plunger	Polypropylene (PP)
	Barrel	180001 Polycarbonate (PC) All the other sizes Polypropylene (PP)
	Gasket	Latex Free Rubber
	Barrel Lubricant	Silicone oil
<b>2. Latex free</b>	Yes	
<b>3. PHT / DEHP / BPA free</b>	Yes	
<b>4. Materials of concern</b>	<p>Not contain substances in a concentration that is above 0.1% w/w referred to following:</p> <ul style="list-style-type: none"> <li>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</li> </ul>	

		· 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.		
<b>5. Shelf life</b>		5 years		
<b>6. Sterilization method</b>		Sterilized with Ethylene Oxide		
<b>7. Packaging specification</b>	6.1 Sales unit	180001PP, P180001PP, 180001	100 units	Units per box
		180003, 180005	100 units	
		180010, 180020	100 units	
		180030	75 units	
		180060	40 units	
		P180050	30 units	
		P180001PP, 180001	800 units (8 boxes)	Units per case (Boxes per case)
		180001PP	3200 units (32 boxes)	
		180003	2700 units (27 boxes)	
		180005	1800 units (18 boxes)	
		180010	1200 units (12 boxes)	
		180020	800 units (8 boxes)	
		180030	600 units (8 boxes)	
		180060	320 units (8 boxes)	
		P180050	240 units (8 boxes)	

<b>8. Technical Drawing</b>			
	1. Plunger	2. Barrel	3. Gasket



Sol-M™ 1ml Luer Lock Syringe (in low dead space version)

1. Gasket                      2. Barrel                      3. Plunger

## Quality and Regulatory information

<b>1. Quality certificate</b>	Quality Management System according to ISO 13485:2016	
<b>2. Product classification</b>	USA: Class II EU: Class Is+m according to Annex IX of EU MDR 2017/745 (CE2797)	
<b>3. List of standards</b>	<b>The product is compliant with the following standards and regulations:</b>	
	<b>Document reference</b> <b>Title</b>	
	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/A11:2021	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 7886-1:2018	Sterile hypodermic syringes for single use – Part 1: Syringes for manual use
EN ISO 80369-7:2017	Small-bore connectors for liquids and gases in healthcare applications – Part 7: Connectors for intravascular or hypodermic applications
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
EN ISO 80369-20:2015	Small-bore connectors for liquids and gases in healthcare applications – Part 20: Common test methods

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This material is dedicated only to healthcare professionals.

REV	11	Date	2023.06.22
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