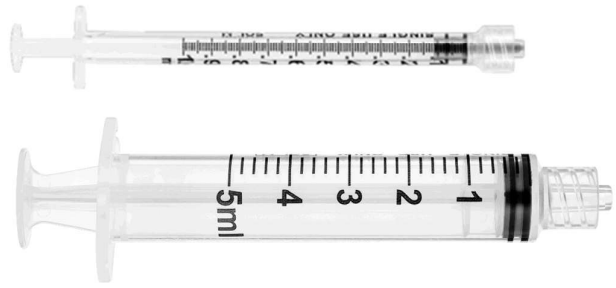


Technical Data Sheet



Product specification

1. Product name	Sol-M™ Luer Lock Syringe without Needle
2. Description	Sol-M™ Luer Lock Syringe without Needle is a sterile, single-use, standard 3-piece hypodermic syringe.
3. Indication for use	The Standard Luer Lock Syringe without Needle is used to inject fluids into, or withdraw fluids from, the body.
4. Intended use	Sol-M™ Luer Lock Syringe without 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
	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)
	P180001	SOL-M 1ml Luer Lock Syringe w/o Needle (PP)
	180001	SOL-M 1ml Luer Lock Syringe w/o Needle (PC)
	180003	SOL-M 3ml Luer Lock Syringe w/o Needle
	P180003	SOL-M 3ml Luer Lock Syringe w/o Needle

180005	SOL-M 5ml Luer Lock Syringe w/o Needle
P180005	SOL-M 5ml Luer Lock Syringe w/o Needle
180010	SOL-M 10ml Luer Lock Syringe w/o Needle
P180010	SOL-M 10ml Luer Lock Syringe w/o Needle
180020	SOL-M 20ml Luer Lock Syringe w/o Needle
P180020	SOL-M 20ml Luer Lock Syringe w/o Needle
180030	SOL-M 30ml Luer Lock Syringe w/o Needle
P180030	SOL-M 30ml Luer Lock Syringe w/o Needle
180060	SOL-M 60ml Luer Lock Syringe w/o Needle
P180060	SOL-M 60ml Luer Lock Syringe w/o Needle
P180050	SOL-M 50ml Luer Lock Syringe w/o Needle

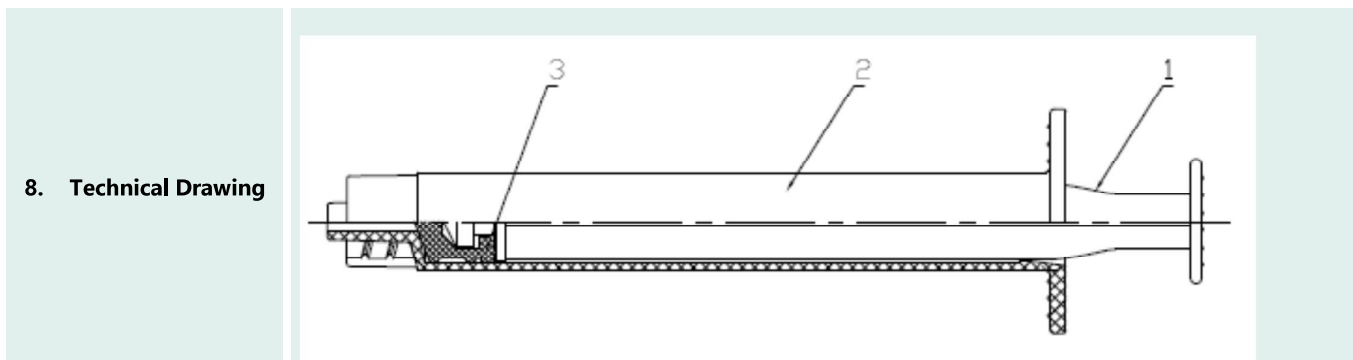
Sol-M™ 1ml Luer Lock Syringe in Low Dead Space Version

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

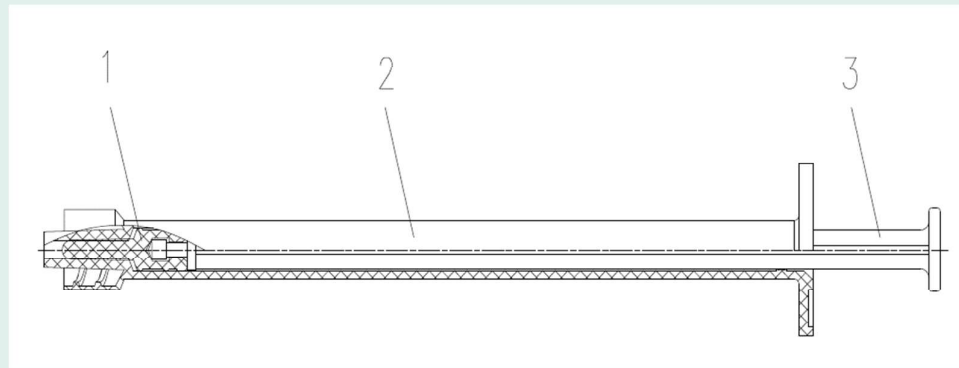
Technical information

1. List of materials	Component name	Material
	Plunger	Polypropylene (PP)
	Barrel	180001 Polycarbonate (PC) All the other sizes Polypropylene (PP)
	Gasket	Latex Free Rubber
	Barrel Lubricant	Silicone oil
2. Latex free	Yes	
3. PHT / DEHP / BPA free	Yes	

<p>4. Materials of concern</p>	<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. 																																							
<p>5. Shelf life</p>	<p>5 years</p>																																							
<p>6. Sterilization method</p>	<p>Sterilized with Ethylene Oxide</p>																																							
<p>7. Packaging specification</p>	<table border="1"> <tr> <td data-bbox="396 644 613 1505" rowspan="20"> <p>6.1 Sales unit</p> </td> <td data-bbox="618 644 1198 676"> <p>180001PP, P180001PP, P180001, 180001</p> </td> <td data-bbox="1203 644 1477 676"> <p>100 units</p> </td> <td data-bbox="1203 644 1477 898" rowspan="7"> <p>Units per box</p> </td> </tr> <tr> <td data-bbox="618 682 1198 714"> <p>180003, P180003, 180005, P180005</p> </td> <td data-bbox="1203 682 1477 714"> <p>100 units</p> </td> </tr> <tr> <td data-bbox="618 720 1198 751"> <p>180010, P180010, 180020, P180020</p> </td> <td data-bbox="1203 720 1477 751"> <p>100 units</p> </td> </tr> <tr> <td data-bbox="618 758 1198 789"> <p>180030</p> </td> <td data-bbox="1203 758 1477 789"> <p>75 units</p> </td> </tr> <tr> <td data-bbox="618 795 1198 827"> <p>P180030</p> </td> <td data-bbox="1203 795 1477 827"> <p>50 units</p> </td> </tr> <tr> <td data-bbox="618 833 1198 865"> <p>180060</p> </td> <td data-bbox="1203 833 1477 865"> <p>40 units</p> </td> </tr> <tr> <td data-bbox="618 871 1198 903"> <p>P180060, P180050</p> </td> <td data-bbox="1203 871 1477 903"> <p>30 units</p> </td> </tr> <tr> <td data-bbox="618 909 1198 940"> <p>P180001PP, P180001, 180001</p> </td> <td data-bbox="1203 909 1477 940"> <p>800 units (8 boxes)</p> </td> <td data-bbox="1203 909 1477 1505" rowspan="13"> <p>Units per case (Boxes per case)</p> </td> </tr> <tr> <td data-bbox="618 947 1198 978"> <p>180001PP</p> </td> <td data-bbox="1203 947 1477 978"> <p>3200 units (32 boxes)</p> </td> </tr> <tr> <td data-bbox="618 984 1198 1016"> <p>P180003, P180005</p> </td> <td data-bbox="1203 984 1477 1016"> <p>800 units (8 boxes)</p> </td> </tr> <tr> <td data-bbox="618 1022 1198 1054"> <p>180003</p> </td> <td data-bbox="1203 1022 1477 1054"> <p>2700 units (27 boxes)</p> </td> </tr> <tr> <td data-bbox="618 1060 1198 1092"> <p>180005</p> </td> <td data-bbox="1203 1060 1477 1092"> <p>1800 units (18 boxes)</p> </td> </tr> <tr> <td data-bbox="618 1098 1198 1129"> <p>180010, P180010</p> </td> <td data-bbox="1203 1098 1477 1129"> <p>1200 units (12 boxes)</p> </td> </tr> <tr> <td data-bbox="618 1136 1198 1167"> <p>180020, P180020</p> </td> <td data-bbox="1203 1136 1477 1167"> <p>800 units (8 boxes)</p> </td> </tr> <tr> <td data-bbox="618 1173 1198 1205"> <p>180030</p> </td> <td data-bbox="1203 1173 1477 1205"> <p>600 units (8 boxes)</p> </td> </tr> <tr> <td data-bbox="618 1211 1198 1243"> <p>P180030</p> </td> <td data-bbox="1203 1211 1477 1243"> <p>400 units (8 boxes)</p> </td> </tr> <tr> <td data-bbox="618 1249 1198 1281"> <p>180060</p> </td> <td data-bbox="1203 1249 1477 1281"> <p>320 units (8 boxes)</p> </td> </tr> <tr> <td data-bbox="618 1287 1198 1318"> <p>P180060, P180050</p> </td> <td data-bbox="1203 1287 1477 1318"> <p>240 units (8 boxes)</p> </td> </tr> </table>	<p>6.1 Sales unit</p>	<p>180001PP, P180001PP, P180001, 180001</p>	<p>100 units</p>	<p>Units per box</p>	<p>180003, P180003, 180005, P180005</p>	<p>100 units</p>	<p>180010, P180010, 180020, P180020</p>	<p>100 units</p>	<p>180030</p>	<p>75 units</p>	<p>P180030</p>	<p>50 units</p>	<p>180060</p>	<p>40 units</p>	<p>P180060, P180050</p>	<p>30 units</p>	<p>P180001PP, P180001, 180001</p>	<p>800 units (8 boxes)</p>	<p>Units per case (Boxes per case)</p>	<p>180001PP</p>	<p>3200 units (32 boxes)</p>	<p>P180003, P180005</p>	<p>800 units (8 boxes)</p>	<p>180003</p>	<p>2700 units (27 boxes)</p>	<p>180005</p>	<p>1800 units (18 boxes)</p>	<p>180010, P180010</p>	<p>1200 units (12 boxes)</p>	<p>180020, P180020</p>	<p>800 units (8 boxes)</p>	<p>180030</p>	<p>600 units (8 boxes)</p>	<p>P180030</p>	<p>400 units (8 boxes)</p>	<p>180060</p>	<p>320 units (8 boxes)</p>	<p>P180060, P180050</p>	<p>240 units (8 boxes)</p>
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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

1. Quality certificate	Quality Management System according to ISO 13485:2016	
2. Product classification	USA: Class II EU: Class Is+m 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/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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