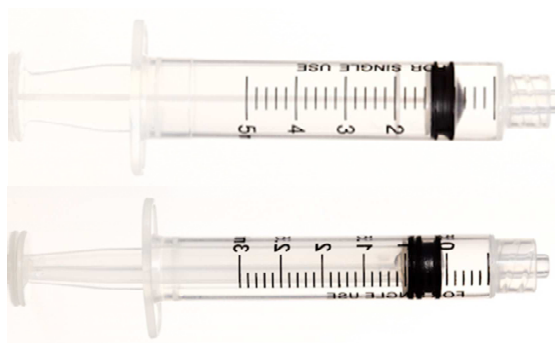


Technical Data Sheet



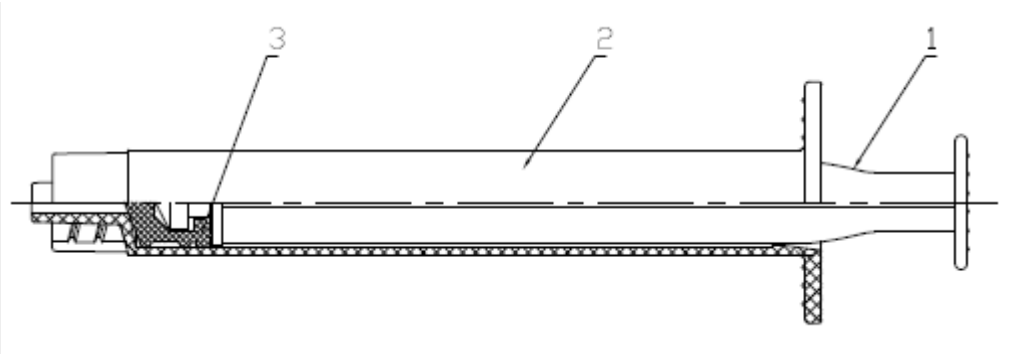
Product specification

1. Product name	SOL-M™ Luer Lock Syringe without Needle
2. Description	SOL-M™ Luer Lock Syringe without Needles are used to inject medicines and vaccines into, or withdraw fluids from, the body.
3. Characteristics	SOL-M™ Luer Lock Syringe without Needles are sterilized by Ethylene Oxide Gas. Each Blister Pack, Dispenser Box and Case are labeled with the contents and the appropriate information per the FDA's Quality System Regulation and Labeling requirements.
4. Intended use	SOL-M™ Luer Lock Syringe without Needles are used to inject medicine or vaccines into, or withdraw fluids from, the body.
5. Instructions for use	N/A

6. Sizes and REF numbers	<table border="1"> <thead> <tr> <th>REF</th> <th>Size</th> </tr> </thead> <tbody> <tr> <td>180001PP</td> <td>1 ml</td> </tr> <tr> <td>P180001PP</td> <td>1 ml</td> </tr> <tr> <td>180001T</td> <td>1 ml</td> </tr> <tr> <td>180001TPC</td> <td>1 ml</td> </tr> <tr> <td>180001</td> <td>1 ml</td> </tr> <tr> <td>180003</td> <td>3 ml</td> </tr> <tr> <td>P180003</td> <td>3 ml</td> </tr> <tr> <td>180005</td> <td>5 ml</td> </tr> <tr> <td>P180005</td> <td>5 ml</td> </tr> <tr> <td>180010</td> <td>10 ml</td> </tr> <tr> <td>P180010</td> <td>10 ml</td> </tr> <tr> <td>180020</td> <td>20 ml</td> </tr> <tr> <td>P180020</td> <td>20 ml</td> </tr> <tr> <td>180030</td> <td>30 ml</td> </tr> <tr> <td>P180030</td> <td>30 ml</td> </tr> <tr> <td>180060</td> <td>60 ml</td> </tr> <tr> <td>P180060</td> <td>60 ml</td> </tr> </tbody> </table>	REF	Size	180001PP	1 ml	P180001PP	1 ml	180001T	1 ml	180001TPC	1 ml	180001	1 ml	180003	3 ml	P180003	3 ml	180005	5 ml	P180005	5 ml	180010	10 ml	P180010	10 ml	180020	20 ml	P180020	20 ml	180030	30 ml	P180030	30 ml	180060	60 ml	P180060	60 ml
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SOL-MILLENNIUM®

Technical information

	Component name	Material		
1. List of Materials	Plunger	PP: 5250T		
	Barrel	PP: 5250T PC: IR2200		
	Gasket	Latex free rubber		
	Barrel Lubricant	Silicon oil: DC 360 12500cst		
2. Latex free	YES			
3. PHT / DEHP / PVC / BPA free	YES			
4. Shelf life	5 years			
5. Sterilization method	Sterilized using Ethylene Oxide			
6. Packaging specification	6.1 Sales unit	180001, 180001PP, P180001PP 180030, P180030 180060, P180060	100 50 30	Units per box
		180001PP, P180001PP, 180001 180001T 180003, P180003, 180005, P180005, 180020, P180020 180010, P180010 180030, P180030 180060, P180060	800 1000 800 1200 400 240	Units per case
		180001T(1ml), 180001TPC(1ml)	25	Units per tray
7. Technical Drawing	 <p>1. Plunger 2. Barrel 3. Gasket</p>			

Quality and Regulatory information

1. Quality certificate	Quality Management System according ISO 13485	
2. Product classification	Class Is+m according to Annex IX of MDD 93/42/EEC	
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 80369-7:2016	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/Cor 1:2009	Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals
	ISO 10993-10:2010	Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
	ISO 15223-1:2016	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
	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 11737-2:2009	Sterilization of medical devices -- Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
	ISO 11135-1:2014/Amd 1:2018	Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices	

REV	07	Date	12.07.2019
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