

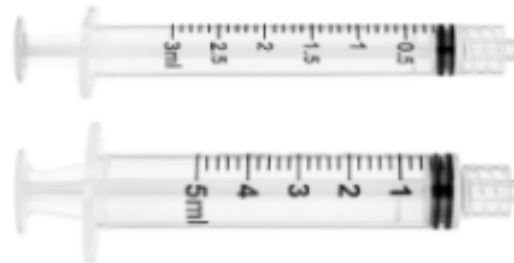
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INC.

Technical Data Sheet



Product specification

1. Product name	SOL-M™ Luer Lock Syringe without Needle
2. Description	SOL-M™ Luer Lock Syringes without Needles are used to inject medicines and vaccines into, or withdraw fluids from, the body.
3. Characteristics	SOL-M™ Luer Lock Syringes 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 Syringes 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

REF	Size
180001PP	1 ml
P180001PP	1 ml
P180001	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
P180050	50 ml

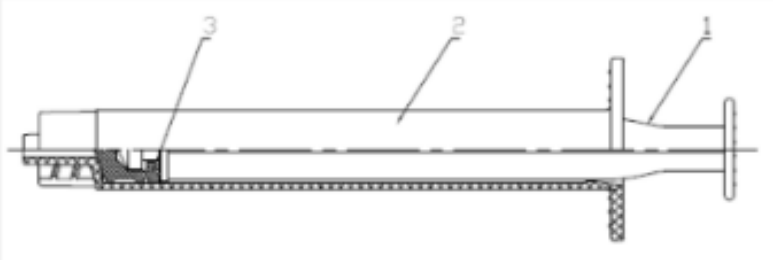
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Technical information

1. List of Materials	Component name	Material		
	Plunger	Polypropylene (PP)		
	Barrel	180001TPC & 180001 All the other sizes	Polycarbonate (PC) Polypropylene (PP)	
	Gasket	Latex Free Rubber		
	Barrel Lubricant	Silicone oil		
2. Latex free	YES			
3. PHT /DEHP /PVC free	YES			
4. Shelf life	5 years			
5. Sterilization method	Sterilized using Ethylene Oxide			
6. Packaging specification	6.1 Sales unit	180001, 180001PP, P180001PP, P180001	100	Units per box
		180003, P180003, 180005, P180005	100	
		180010, P180010, 180020, P180020	100	
		180030, P180030	50	
		180060, P180060, P180050	30	
		180001T, 180001TPC	25	Units per tray
		180001, 180001PP, P180001PP, P180001	800	Units per case
		180001T, 180001TPC	1000	
		180003, P180003, 180005, P180005	800	
		180010, P180010	1200	
		180020, P180020	800	
		180030, P180030	400	
		180060, P180060, P180050	240	
7. Technical Drawing				
	1. Plunger 2. Barrel 3. Gasket			

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Quality and Regulatory information

1. Quality certificate	Quality Management System according to ISO 13485	
2. Product classification	Class Is+m according to Annex V 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 80369-7:2021	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 10993-10:2010	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

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EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
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