

Technical Data Sheet



Product specification

1. Product name	SOL-M™ Insulin Syringe with Fixed Needle
2. Description	The SOL-M™ Insulin Syringe with Fixed Needle is used to inject insulin into the body.
3. Characteristics	SOL-M™ Insulin Syringe with Fixed Needle is 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	The Insulin Syringe is used to inject insulin into the body.
5. Instructions for use	N/A

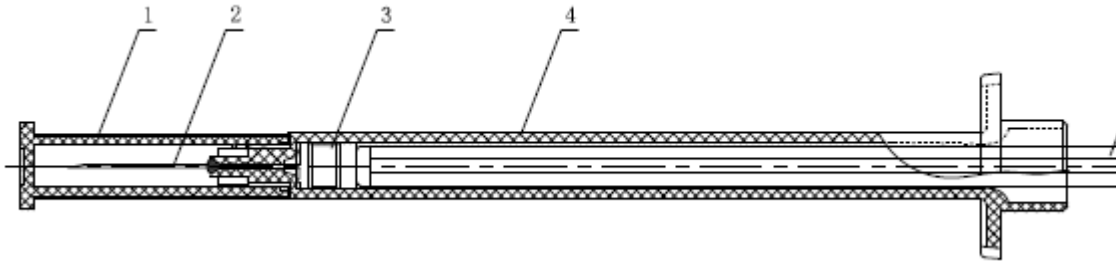
6. Sizes and REF numbers

REF	Size
1632912B	0.3ml 29G*1/2"
1633012B	0.3ml 30G*1/2"
1633051B	0.3ml 30G*5/16"
1633151B	0.3ml 31G*5/16"
1652912B	0.5ml 29G*1/2"
1653012B	0.5ml 30G*1/2"
1653051B	0.5ml 30G*5/16"
1653151B	0.5ml 31G*5/16"
1612912B	1ml 29G*1/2"
1613012B	1ml 30G*1/2"
1613051B	1ml 30G*5/16"
1613151B	1ml 31G*5/16"

REF	Size
1632912	0.3ml 29G*1/2"
1633012	0.3ml 30G*1/2"
16330516	0.3ml 30G*5/16"
1652912	0.5ml 29G*1/2"
1653012	0.5ml 30G*1/2"
16530516	0.5ml 30G*5/16"
1612912	1ml 29G*1/2"
1613012	1ml 30G*1/2"
16130516	1ml 30G*5/16"
1612512	1ml 25G*1/2"

SOL-MILLENNIUM®

Technical information

1. List of Materials	Component name		Material	
	Needle cap		PP: 5250T	
	Cannula		Stainless steel: SUS304	
	Gasket		Latex free rubber	
	Barrel		PP: 5250T	
	Plunger		PP: 5250T	
	Adhesive		Loctite: 3321	
	Needle Lubricant		Silicon oil: Alpha 12500cst	
	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	0.3ml\0.5ml1ml	100	Units per box
		0.3ml\0.5ml1ml	800	Units per case
7. Technical Drawing				
	<ol style="list-style-type: none"> 1. Needle cap 2. Cannula 3. Gasket 4. Barrel 5. Plunger 			

Quality and Regulatory information

1. Quality certificate	Quality Management System according ISO 13485	
2. Product classification	Class IIa 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 8537:2016	Sterile single-use syringes, with or without needle, for insulin
	ISO 9626:2016	Stainless steel needle tubing for the manufacture of medical devices -- Requirements and test methods
	ISO 10993-1:2009/Cor 1:2010	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
	ISO10993-4:2002/Amd 1:2006	Biological evaluation of medical devices -- Part 4: Selection of tests for interactions with blood
	ISO10993-5:2009	Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
	ISO10993-7:2008/Cor 1:2009	Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals
	ISO10993-10:2010	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 11607-1:2006/Amd 1:2014	Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems
	ISO 11607-2:2006/Amd 1:2014	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
	EN980:2008	Symbols for use in the labelling of medical devices
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices	

REV	03	Date	03.01.2017
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