

Technical Data Sheet



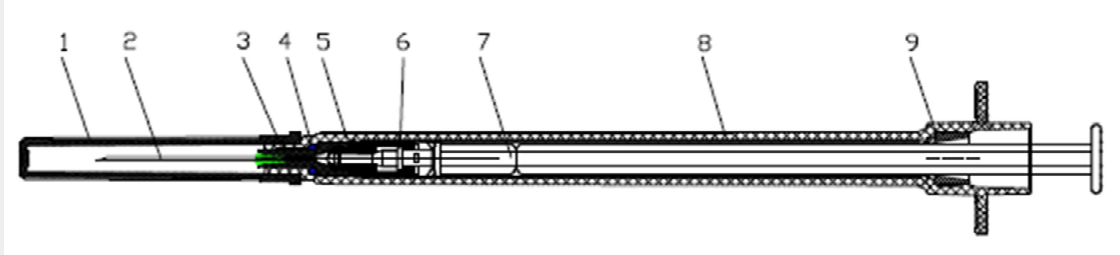
Product specification

1. Product name	SOL-CARE™ Insulin Safety Syringe U-100 Insulin Only
2. Description	The SOL-CARE™ 50 and 100 unit Insulin Safety Syringe U-100 Insulin Only is used to inject insulin into the body. The Insulin Safety Syringe U-100 Insulin Only is designed to aid in the prevention of needle stick injuries.
3. Characteristics	After use, the health care professional fully depresses the plunger to engage the Luer Assembly. Once the Luer Assembly is engaged, pulling back the plunger causes the Adapter and the attached needle to be withdrawn into the safety of the barrel. In this position against the flange, lateral pressure on the plunger results in a controlled fracture of the plunger. Both the syringe and plunger are discarded in a Sharps container.
4. Intended use	The Insulin Safety Syringe U-100 Insulin Only is used to inject insulin into the body. In addition, the Insulin Safety Syringe U-100 Insulin Only is designed to aid in the prevention of needle stick injuries.
5. Instructions for use	See IFU

6. Sizes and REF numbers	<table border="1"> <thead> <tr> <th>REF</th> <th>Size</th> </tr> </thead> <tbody> <tr> <td>100002B</td> <td>0.5ml 29G*1/2"</td> </tr> <tr> <td>100089B</td> <td>0.5ml 30G*5/16"</td> </tr> <tr> <td>100097B</td> <td>0.5ml 30G*15/64"</td> </tr> <tr> <td>100001IM</td> <td>0.5ml 30G*1/2"</td> </tr> <tr> <td>100002IM</td> <td>0.5ml 29G*1/2"</td> </tr> <tr> <td>100089IM</td> <td>0.5ml 30G*5/16"</td> </tr> <tr> <td>100095IM</td> <td>0.5ml 30G*15/64"</td> </tr> <tr> <td>100017B</td> <td>1ml 29G*1/2"</td> </tr> <tr> <td>100020B</td> <td>1ml 30G*5/16"</td> </tr> <tr> <td>100017IM</td> <td>1ml 29G*1/2"</td> </tr> <tr> <td>100081IM</td> <td>1ml 30G*1/2"</td> </tr> </tbody> </table>	REF	Size	100002B	0.5ml 29G*1/2"	100089B	0.5ml 30G*5/16"	100097B	0.5ml 30G*15/64"	100001IM	0.5ml 30G*1/2"	100002IM	0.5ml 29G*1/2"	100089IM	0.5ml 30G*5/16"	100095IM	0.5ml 30G*15/64"	100017B	1ml 29G*1/2"	100020B	1ml 30G*5/16"	100017IM	1ml 29G*1/2"	100081IM	1ml 30G*1/2"	<table border="1"> <thead> <tr> <th>REF</th> <th>Size</th> </tr> </thead> <tbody> <tr> <td>100020IM</td> <td>1ml 30G*5/16"</td> </tr> <tr> <td>100071IM</td> <td>1ml 28G*1/2"</td> </tr> <tr> <td>100094IM</td> <td>1ml 30G*15/64"</td> </tr> <tr> <td>100091IM</td> <td>1ml 31G*5/16"</td> </tr> </tbody> </table>	REF	Size	100020IM	1ml 30G*5/16"	100071IM	1ml 28G*1/2"	100094IM	1ml 30G*15/64"	100091IM	1ml 31G*5/16"
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Technical information

1. List of Materials	Component name	Material		
	Needle cap	HDPE:2911		
	Cannula	Stainless steel: SUS304		
	Needle hub	PP: 5250T		
	O ring	Medical Silicone		
	Locating ring	ABS: HI121		
	Gasket	TPE:181W-57		
	Plunger	PP: 5250T		
	Barrel	PP: 5250T		
	Locking ring	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	0.5ml&1ml	100	Units per box
		0.5ml &1ml	1000	Units per case

7. Technical Drawing				
	1. Needle cap	7. Plunger	8. Barrel	9. Locking ring
	2. Cannula			
	3. Needle hub			
	4. O ring			
	5. Locating ring			
	6. Gasket			

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

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 7886-4:2006	Sterile hypodermic syringes for single use-Part 4: Syringes with re-use prevention feature
ISO 9626:1991/Amd1:2001	Stainless steel needle tubing for the manufacture of medical devices
ISO 10993-1:2009/Cor1:2010	Biological evaluation of medical devices
ISO10993-4:2002	Biological evaluation of medical devices—part 4
ISO10993-5:2009	Biological evaluation of medical devices—part 5
ISO10993-7:2008/Cor1:2009	Biological evaluation of medical devices—part 7
ISO10993-10:2010	Biological evaluation of medical devices—part 10
ISO 15223-1:2012	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied
ISO 11607-1:2006/Amd1:2014	Packaging for terminally sterilized medical devices—Part 1
ISO 11607-2:2006	Packaging for terminally sterilized medical devices—Part 2
ISO 11737-2:2006/Amd1:2014	Sterilization of medical devices-Microbiological methods-Part 2: Tests of sterility performed in the validation of a sterilization process
EN 980:2008	Symbols for use in the labelling of medical devices
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices

3. List of standards

REV	02	Date	04.10.2016
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