

Technical Data Sheet



Product specification

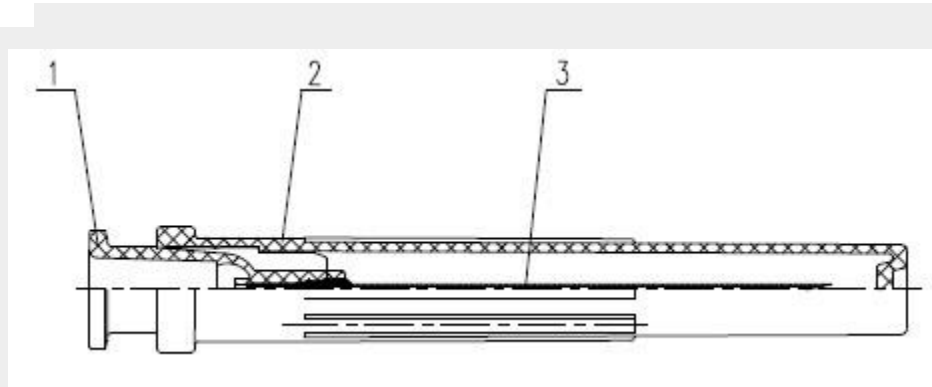
1. Product name	SOL-M™ Hypodermic Needle																																
2. Description	The SOL-M™ Hypodermic Needle is a sterile, single use, standard hypodermic needle. The device is available in 16 to 31 gauge and in lengths from 3/8" to 2". In addition, the needle tip is available in a regular bevel. The gauges 16-23G & 25G are offered with thin wall.																																
3. Characteristics	The SOL-M™ Hypodermic Needle's device consists of a stainless steel cannula sealed with epoxy glue into a polypropylene hub. The assembly has a protective polypropylene needle cap/shield.																																
4. Intended use	The SOL-M™ Hypodermic Needle is sterile hypodermic needle intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin.																																
5. GMDN number	59230																																
6. Instructions for use	N/A																																
7. Storage and handling	Store at room temperature. Keep dry. Keep away from sunlight. Sharp: Avoid needle stick injuries.																																
8. Sizes and REF numbers	<table border="1"> <thead> <tr> <th>Label code</th><th>Description</th></tr> </thead> <tbody> <tr><td>111610</td><td>SOL-M Hypodermic Needle 16G*1"</td></tr> <tr><td>111615</td><td>SOL-M Hypodermic Needle 16G*1 1/2"</td></tr> <tr><td>111810</td><td>SOL-M Hypodermic Needle 18G*1"</td></tr> <tr><td>1118125</td><td>SOL-M Hypodermic Needle 18G*1 1/4"</td></tr> <tr><td>111815</td><td>SOL-M Hypodermic Needle 18G*1 1/2"</td></tr> <tr><td>111820</td><td>SOL-M Hypodermic Needle 18G*50mm</td></tr> <tr><td>111910</td><td>SOL-M Hypodermic Needle 19G*1"</td></tr> <tr><td>111915</td><td>SOL-M Hypodermic Needle 19G*1 1/2"</td></tr> <tr><td>112010</td><td>SOL-M Hypodermic Needle 20G*1"</td></tr> <tr><td>112015</td><td>SOL-M Hypodermic Needle 20G*1 1/2"</td></tr> <tr><td>112110</td><td>SOL-M Hypodermic Needle 21G*1"</td></tr> <tr><td>112115</td><td>SOL-M Hypodermic Needle 21G*1 1/2"</td></tr> <tr><td>112120</td><td>SOL-M Hypodermic Needle 21G*50mm</td></tr> <tr><td>112210</td><td>SOL-M Hypodermic Needle 22G*1"</td></tr> <tr><td>1122125</td><td>SOL-M Hypodermic Needle 22G*1 1/4"</td></tr> </tbody> </table>	Label code	Description	111610	SOL-M Hypodermic Needle 16G*1"	111615	SOL-M Hypodermic Needle 16G*1 1/2"	111810	SOL-M Hypodermic Needle 18G*1"	1118125	SOL-M Hypodermic Needle 18G*1 1/4"	111815	SOL-M Hypodermic Needle 18G*1 1/2"	111820	SOL-M Hypodermic Needle 18G*50mm	111910	SOL-M Hypodermic Needle 19G*1"	111915	SOL-M Hypodermic Needle 19G*1 1/2"	112010	SOL-M Hypodermic Needle 20G*1"	112015	SOL-M Hypodermic Needle 20G*1 1/2"	112110	SOL-M Hypodermic Needle 21G*1"	112115	SOL-M Hypodermic Needle 21G*1 1/2"	112120	SOL-M Hypodermic Needle 21G*50mm	112210	SOL-M Hypodermic Needle 22G*1"	1122125	SOL-M Hypodermic Needle 22G*1 1/4"
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112358	SOL-M Hypodermic Needle 23G*5/8"
112334	SOL-M Hypodermic Needle 23G*3/4"
112310	SOL-M Hypodermic Needle 23G*1"
1123125	SOL-M Hypodermic Needle 23G*1 1/4"
112315	SOL-M Hypodermic Needle 23G*1 1/2"
112506	SOL-M Hypodermic Needle 25G*5/8"
112510	SOL-M Hypodermic Needle 25G*1"
112515	SOL-M Hypodermic Needle 25G*1 1/2"
112410	SOL-M Hypodermic Needle 24G*1"
112638	SOL-M Hypodermic Needle 26G*3/8"
112610	SOL-M Hypodermic Needle 26G*1"
112612	SOL-M Hypodermic Needle 26G*1/2"
112658	SOL-M Hypodermic Needle 26G*5/8"
112705	SOL-M Hypodermic Needle 27G*1/2"
112734	SOL-M Hypodermic Needle 27G*3/4"
112905	SOL-M Hypodermic Needle 29G*1/2"
113005	SOL-M Hypodermic Needle 30Gx1/2"
113010	SOL-M Hypodermic Needle 30G*1"
113112	SOL-M Hypodermic Needle 31G*1/2"
111920	SOL-M Hypodermic Needle 19G*50mm

Technical information

	Component name	Material
1. List of Materials	Needle hub	PP
	Needle cap	PP
	Cannula	Stainless steel: SUS304
	Adhesive	Epoxy
	Needle Lubricant	Silicon oil
2. Latex free	YES	
3. PHT / PVC free	YES	
4. Shelf life	5 years	
5. Sterilization method	Sterilized using Ethylene Oxide	
6. Packaging specification	6.1 Sales unit	100 Units per box
		1000 Units per case

7. Technical Drawing



1. Needle hub
2. Needle cap
3. Cannula

Quality and Regulatory information

1. Quality certificate	Quality Management System according ISO 13485	
2. Legal manufacturer	Sol-Millennium Medical Inc. 1735 North Brown Road, Suite 120, Lawrenceville, GA 30043, USA	
3. Importer/ distributor	N/A	
4. Product classification	Europe: Class IIa according to Annex IX of MDD 93/42/EEC USA: Class II	
5. Regulatory information	Europe: CE Marked USA: FDA 510k cleared	
6. List of standards	The product is compliant with the following standards and regulations:	
	Document reference	Title
	ISO 7864:2016	Sterile hypodermic needles for single use - Requirements and test methods
	ISO 9626:2016	Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods
	ISO 6009:2016	Hypodermic needles for single use - colour coding for identification
	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 10993-11:2017	Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity
	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
	EN 1041:2008+A1:2013	Information supplied by the manufacturer with medical devices

REV

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Date

20.04.2021