

## 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 gauge (16-23G & 25G) of thin wall needles is designed to allow the use of a smaller gauge size with increased flow rates over regular walled needles (26-30G & 24G).
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. Instructions for use	N/A

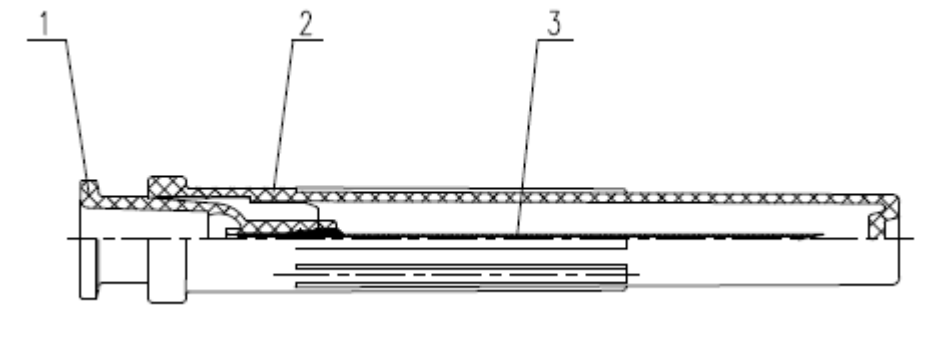
6. Sizes and REF numbers	<table border="1"> <thead> <tr> <th>REF</th> <th>Size</th> </tr> </thead> <tbody> <tr><td>1114318</td><td>14G*3 1/8”</td></tr> <tr><td>111615</td><td>16G*1 1/2”</td></tr> <tr><td>111810</td><td>18G*1”</td></tr> <tr><td>1118125</td><td>18G*1 1/4”</td></tr> <tr><td>111815</td><td>18G*1 1/2”</td></tr> <tr><td>111820</td><td>18G*2”</td></tr> <tr><td>111910</td><td>19G*1”</td></tr> <tr><td>111920</td><td>19G*2”</td></tr> <tr><td>111915</td><td>19G*1 1/2”</td></tr> <tr><td>112010</td><td>20G*1”</td></tr> <tr><td>112015</td><td>20G*1 1/2”</td></tr> <tr><td>112110</td><td>21G*1”</td></tr> <tr><td>112115</td><td>21G*1 1/2”</td></tr> <tr><td>112120</td><td>21G*2”</td></tr> <tr><td>1121318</td><td>21G*3 1/8”</td></tr> <tr><td>1122125</td><td>22G*1 1/4”</td></tr> <tr><td>112210</td><td>22G*1 ”</td></tr> <tr><td>112215</td><td>22G*1 1/2”</td></tr> <tr><td>112310</td><td>23G*1”</td></tr> <tr><td>112315</td><td>23G*1 1/2”</td></tr> <tr><td>1123125</td><td>23G*1 1/4”</td></tr> </tbody> </table>	REF	Size	1114318	14G*3 1/8”	111615	16G*1 1/2”	111810	18G*1”	1118125	18G*1 1/4”	111815	18G*1 1/2”	111820	18G*2”	111910	19G*1”	111920	19G*2”	111915	19G*1 1/2”	112010	20G*1”	112015	20G*1 1/2”	112110	21G*1”	112115	21G*1 1/2”	112120	21G*2”	1121318	21G*3 1/8”	1122125	22G*1 1/4”	112210	22G*1 ”	112215	22G*1 1/2”	112310	23G*1”	112315	23G*1 1/2”	1123125	23G*1 1/4”	<table border="1"> <thead> <tr> <th>REF</th> <th>Size</th> </tr> </thead> <tbody> <tr><td>112334</td><td>23G*3/4”</td></tr> <tr><td>112506</td><td>25G*5/8”</td></tr> <tr><td>112410</td><td>24G*1”</td></tr> <tr><td>112510</td><td>25G*1”</td></tr> <tr><td>112515</td><td>25G*1 1/2”</td></tr> <tr><td>112612</td><td>26G*1/2”</td></tr> <tr><td>112638</td><td>26G*3/8”</td></tr> <tr><td>112658</td><td>26G*5/8”</td></tr> <tr><td>112705</td><td>27G*1/2”</td></tr> <tr><td>112734</td><td>27G*3/4”</td></tr> <tr><td>112905</td><td>29G*1/2”</td></tr> <tr><td>113005</td><td>30G*1/2”</td></tr> <tr><td>113010</td><td>30G*1”</td></tr> <tr><td>113112</td><td>31G*1/2”</td></tr> </tbody> </table>	REF	Size	112334	23G*3/4”	112506	25G*5/8”	112410	24G*1”	112510	25G*1”	112515	25G*1 1/2”	112612	26G*1/2”	112638	26G*3/8”	112658	26G*5/8”	112705	27G*1/2”	112734	27G*3/4”	112905	29G*1/2”	113005	30G*1/2”	113010	30G*1”	113112	31G*1/2”
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# SOL-MILLENNIUM®

## Technical information

	Component name	Material
1. List of Materials	Needle hub	PP: H1500
	Needle cap	PP: RP344RK
	Cannula	Stainless steel: SUS304
	Adhesive	Epoxy: YD-128
	Needle Lubricant	Silicon oil: Xilikang 201-350cst
	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	100	Units per box
		1000	Units per case

7. Technical Drawing			
	<p>1. Needle hub 2. Needle cap 3. Cannula</p>		

## 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:**

3. List of standards	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	05	Date	15.03.2019
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