

# Technical Data Sheet



## Product specification

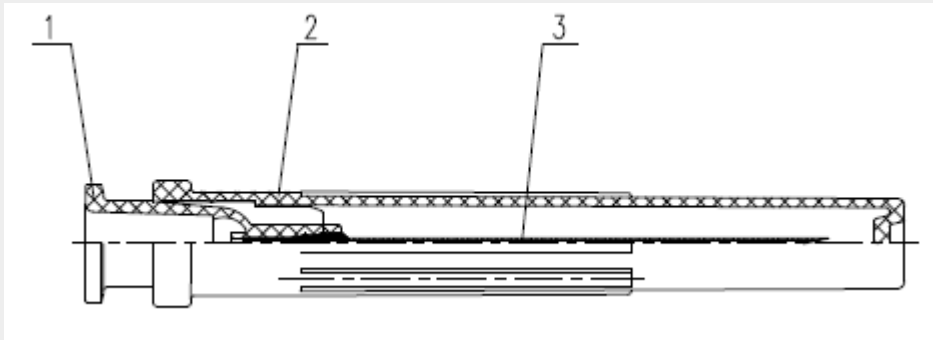
1. Product name	SOL-M™ Hypodermic Needle
2. Description	The SOL-M™ Hypodermic Needle is a sterile, single use, standard hypodermic needle. The device is available in 16 to 31 gauge and in lengths from 3/8" to 2". In addition, the needle tip is available in a regular bevel. The gauge (16-23G & 25G) of 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

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"

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"

Technical information

1. List of Materials	Component name		Material	
	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				
	1. Needle hub 2. Needle cap 3. Cannula			

## 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	<b>The product is compliant with the following standards and regulations:</b>	
	<b>Document reference</b>	<b>Title</b>
	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

15.03.2019