Technical Data Sheet

Product specification

1. Product name	Sol-M™ Hypodermic Needle
2. Description	Sol-M™ Hypodermic Needle is a sterile, single use, standard hypodermic needle. The device is available in 16G to 31G and in length from 3/8″ to 2″. In addition, the needle tip is available in a regular or short bevel.
3. Indication for use	The Standard Hypodermic Needle is used to withdraw blood or other fluids from the body as well as inject medications into the body.
4. Intended use	Sol-M™ Hypodermic Needle is used to withdraw blood or other fluids from the body as well as inject medications into the body.
5. Intended users	Licensed healthcare professionals
6. Instructions for Use	N/A
7. Warning and precautions	Single use device. Re-use or use if the package is damaged may lead to infection or other illness/injury.
8. Storage information	Keep dry, Keep away from sunlight, Storage condition: Temperature: 0℃~ 40℃, Humidity: ⩽80%
9. Sizes and REF numbers	

REF	Product Description
111610	SOL-M Hypodermic Needle 16G*1″
111615	SOL-M Hypodermic Needle 16G*1 1/2"
111810	SOL-M Hypodermic Needle 18G*1"

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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
112234	SOL-M Hypodermic Needle 22G*3/4"
112210	SOL-M Hypodermic Needle 22G*1"
1122125	SOL-M Hypodermic Needle 22G*1 1/4"
112215	SOL-M Hypodermic Needle 22G*1 1/2"
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

Sol-M™ Hypodermic Needle in Low Dead Space Version

1. Description

Sol-M™ Hypodermic Needle featuring low dead space hub is available in 23 and 25 gauge and in lengths from 5/8'' to 1 1/2''. In addition, the needle tip is available in a regular bevel. The gauges 23G & 25G are offered with thin wall.

2. REF & Dead Space Volume

REF	Description	Average Dead Space Volume
112358LDS	SOL-M Hypodermic Needle 23G*5/8"	less than 0.030ml, with the needle tightly assembled on the syringe
112334LDS	SOL-M Hypodermic Needle 23G*3/4"	
112310LDS	SOL-M Hypodermic Needle 23G*1"	
1123125LDS	SOL-M Hypodermic Needle 23G*1 1/4"	
112315LDS	SOL-M Hypodermic Needle 23G*1 1/2"	
112506LDS	SOL-M Hypodermic Needle 25G*5/8"	
112510LDS	SOL-M Hypodermic Needle 25G*1"	
112515LDS	SOL-M Hypodermic Needle 25G*1 1/2"	

Note: Must be used with Sol-M 1ml LDS syringe to achieve dead space less than 0.030ml

Sol-M™ Hypodermic Needle in Individually Separated Blister Pack

1. Description

Sol-M™ Hypodermic Needle (individually separated blister pack) is a sterile, single use, standard hypodermic needle.

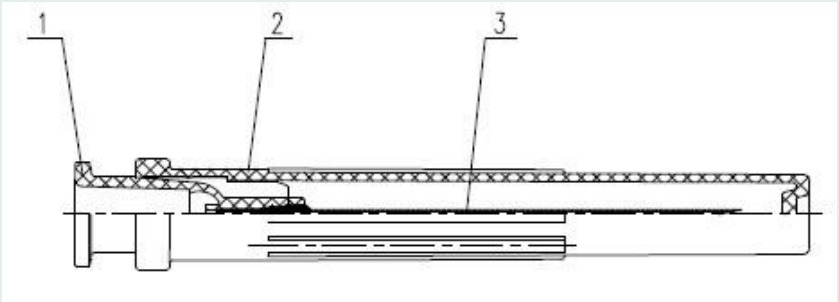
2. Sizes and REF numbers

REF	Product Description
113005VB	SOL-M Hypodermic Needle 30G*1/2"
112215I	SOL-M Hypodermic Needle 22G*1 1/2"

Technical information

1. List of materials		Component name	Material
		Needle hub	Polypropylene (PP)
		Needle cap	Polypropylene (PP)
		Cannula	Stainless steel
		Adhesive	Epoxy
		Needle Lubricant	Silicone oil
2. Latex free		Yes	
3. PHT / DEHP / PVC free		Yes	
4. Materials of concern		Not contain substances in a concentration that is above 0.1% w/w referred to following: • Substances which are carcinogenic, mutagenic or toxic to reproduction (CMR), of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament • Endocrine-disrupting substances identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (SVHC) or once a delegated act has been adopted by the Commission pursuant to the first subparagraph of Article 5(3) of Regulation (EU) No 528/2012 of the European Parliament and the Council in accordance with the criteria that are relevant to human health amongst the criteria established therein.	
5. Shelf life		5 years	
6. Sterilization method		Sterilized with Ethylene Oxide	
7. Packaging specification	7.1 Sales unit	100 units	Units per box
		1000 units (10 boxes)	Units per case (Boxes per case)

8. Technical Drawing



1. Needle hub 2. Needle cap 3. Cannula

Quality and Regulatory information

1. Quality certificate	Quality Management System according to ISO 13485:2016
2. Product classification	USA: Class II EU: Class IIa according to Annex VIII of EU MDR 2017/745

3. List of standards

The product is compliant with the following standards and regulations:

Document reference	Title
EN ISO 13485:2016, EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2019, EN ISO 14971:2019/A11:2021	Medical Devices - Application of Risk Management to Medical Devices
EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
EN ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer
EN ISO 780:2015	Packaging. Distribution packaging. Graphical symbols for handling and storage of packages
EN ISO 11135:2014, EN ISO 11135:2014/A1:2019	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
EN ISO 11737-1:2018, EN ISO 11737-1:2018/A1:2021	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2:2020	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 11138-1:2017	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes
EN ISO 11138-2:2017	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes
ASTM F1886/F 1886M – 16	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
ISTA 3A 2018	General Simulation Performance Tests, Procedure 3A: Packaged-Products for Parcel Delivery System Shipment 70kg (150 lb) or Less

	ASTM F1980-21	Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices
	ASTM F1929-2015	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
	ASTM F88/F88M-21	Standard Test Method For Seal Strength Of Flexible Barrier Materials
	EN868-5：2018	Packaging for terminally sterilized medical devices -Part 5: Sealable pouches and reels of porous materials and plastic film construction – Requirement and test methods (excluding clause 4.3.2)
	ASTM F2825-18	Standard Practice For Climatic Stressing Of Packaging Systems For Single Parcel Delivery
	EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1 Evaluation and testing within a risk management process
	EN ISO 10993-4:2017	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
	EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
	EN ISO 10993-7:2008/A1:2022	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals Amendment 1: Applicability of allowable limits for neonates and infants
	EN ISO 10993-10:2023	Biological evaluation of medical devices - Part 10: Tests for skin sensitization
	EN ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
	EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation
	EN ISO 7864:2016	Sterile hypodermic needles for single use - Requirements and test methods
	EN ISO 9626:2016	Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods
	EN ISO 80369-1:2018	Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements
	EN ISO 80369-7:2021	Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications
	EN ISO 80369-20:2015	Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods

	EN ISO 6009:2016	Hypodermic needles for single use - Colour coding for identification
	EN ISO 11607-1:2020/A11:2022	Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems
	EN ISO 11607-2:2020/A11:2022	Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes

This material is dedicated only to healthcare professionals.

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