

Technical Data Sheet



Product specification

1. Product name	SOL-GUARD™ Safety Needle
2. Description	The SOL-GUARD™ Safety Needle is a single use, standard hypodermic needle with a shield to enclose the needle after use.
3. Characteristics	The SOL-GUARD™ Safety Needle contains a mechanism that covers the needle point after use. In the activated position, the needle cover guards against accidental needle stick during normal handling and disposal of the used needle/syringe combination.
4. Intended use	The SOL-GUARD™ Safety Needle is used for general purpose injection and aspiration of fluids from vials, ampules and parts of the body below the surface of the skin.
5. GMDN number	59230
6. Instructions for use	See current IFU
7. Storage and handling	Store at room temperature. Keep dry. Keep away from sunlight. Sharp: Avoid needle stick injuries.

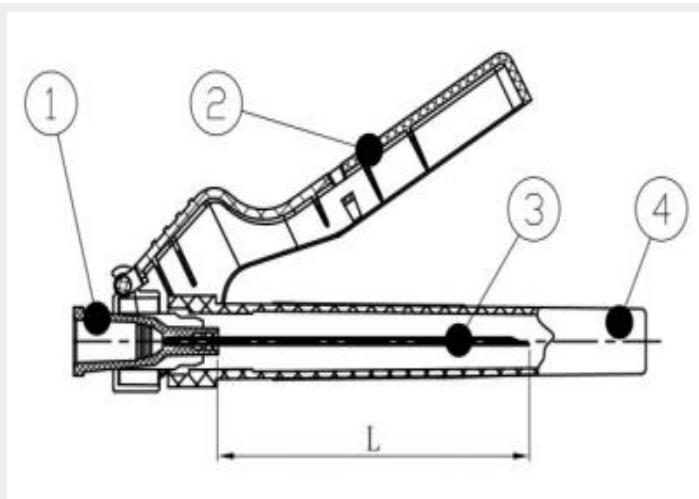
8. Sizes and REF numbers	EMEA Market Only	
	Label code	Product Description
	SND479	SOL-GUARD™ Safety Needle 18G x 1 1/2"
	SND483	SOL-GUARD™ Safety Needle 19G x 1"
	SND484	SOL-GUARD™ Safety Needle 19G x 1 1/2"
	SND482	SOL-GUARD™ Safety Needle 20G x 1"
	SND494	SOL-GUARD™ Safety Needle 20G x 1 1/2"
	SND495	SOL-GUARD™ Safety Needle 21G x 1"
	SND480	SOL-GUARD™ Safety Needle 21G x 1 1/2"
	SND497	SOL-GUARD™ Safety Needle 22G x 1 1/4"
	SND496	SOL-GUARD™ Safety Needle 22G x 1/2"
	SND478	SOL-GUARD™ Safety Needle 23G x 1"
	SND498	SOL-GUARD™ Safety Needle 23G x 1 1/4"
	SND499	SOL-GUARD™ Safety Needle 24G x 1"
	SND477	SOL-GUARD™ Safety Needle 25G x 5/8"
	SND481	SOL-GUARD™ Safety Needle 25G x 1"
	SND500	SOL-GUARD™ Safety Needle 26G x 1/2"
	SND502	SOL-GUARD™ Safety Needle 27G x 1/2"
SND501	SOL-GUARD™ Safety Needle 27G x 1"	
SND503	SOL-GUARD™ Safety Needle 27G x 1 1/2"	

NACA Market Only	
Product REF	Product Description
SND492	SOL-GUARD™ Safety Needle 18G x 1 1/2"
SND491	SOL-GUARD™ Safety Needle 21G x 1"
SND490	SOL-GUARD™ Safety Needle 21G x 1 1/2"
SND489	SOL-GUARD™ Safety Needle 22G x 1"
SND488	SOL-GUARD™ Safety Needle 22G x 1 1/2"
SND487	SOL-GUARD™ Safety Needle 25G x 1 1/2"
SND486	SOL-GUARD™ Safety Needle 25G x 5/8"
SND485	SOL-GUARD™ Safety Needle 27G x 1/2"
SND476	SOL-GUARD™ Safety Needle 23G x 1"
SND493	SOL-GUARD™ Safety Needle 23 x 1 1/2"
SND475	SOL-GUARD™ Safety Needle 25G x 1"

Technical information

1. List of Materials	Component name	Material	
	Needle hub	PP	
	Safety protection cap	PP	
	Needle tube	Stainless steel 304	
	Needle cap	PP	
	Adhesive	Epoxy resin	
	Needle Lubricant	Silicone oil	
2. Not made with natural rubber latex	YES		
3. Not made/ does not contain PHT / DEHP / PVC / BPA	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. Safety protection cap
3. Needle tube
4. Needle cap

Quality and Regulatory information

1. Quality certificate	Quality Management System according ISO 13485	
2. Legal manufacturer	AnHui Hongyu Wuzhou Medical Manufacturer Co., Ltd No.2 Guanyin Road, Economic Development Zone, Taihu County, 246400 Anqing, Anhui PEOPLE'S REPUBLIC OF CHINA	
3. Importer/ distributor	Sol-Millennium Europe Sp. z o.o., Twarda 18,00-105 Warsaw, Poland	
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	
3. 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
	ISO 9626:2016	Stainless steel needle tubing for the manufacture of medical devices
	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 10993-7:2008	Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals	

	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 validation of a sterilization process
	ISO 11135:2014	Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices
	ISO 11138-2:2017	Sterilization of health care products — Biological indicators — Part 2: Biological indicators for ethylene oxide sterilization processes
	ISO 23908:2011	Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling
	ISO 11737-1:2018	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products
	ISO 80369-1:2016	Small-bore connectors for liquids and gasses in healthcare applications - Part 1: General requirements
	ASTM F88-F88M-2015	Standard Test Method for Seal Strength of Flexible Barrier Materials
	ASTM F1886-F1886M-2016	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
	ASTM F1929-2015	Standard test method for detecting seal leaks in porous medical packaging by dye penetration

REV	00	Date	12.14.2020
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