Technical Data Sheet

Product specification

1. Product name	SOL-CARE™ Safety Multi-Sample Needle SOL-CARE™ Safety Multi-Sample Needle with Pre-Attached Holder
2. Description	SOL-CARE™ Safety Multi-Sample Needle is a sterile and single-use device, consisting of a safety shield which can be activated to cover the needle immediately after the venipuncture to reduce the risk of accidental needle stick injury. SOL-CARE™ Safety Multi-Sample Needle with Pre-Attached Holder is a sterile, single-use device, pre-assembled with a holder. It consists of a safety shield which can be activated to cover the needle immediately after the venipuncture to reduce the risk of accidental needlestick injury.
3. Indication for use	SOL-CARE™ Safety Multi-Sample Needle is a single-use, sterile device, intended for use in venous blood collection. The device is designed with a safety mechanism that covers the needle after use. In the activated position, the needle cover reduces the possibility of accidental needle stick injuries during normal handling and disposal of the used device. SOL-CARE Safety Multi-Sample Needle is designed for blood collection, not for patient injection. SOL-CARE™ Safety Multi-Sample Needle with Pre-Attached Holder is a single-use, sterile device, intended for use in venous blood collection. The device is designed with a safety mechanism that covers the needle after use. In the activated position, the needle cover reduces the possibility of accidental needle stick injuries during normal handling and disposal of the used device. SOL-CARE Safety Multi-Sample Needle with Pre-Attached Holder is designed for blood collection, not for patient injection.
4. Intended use	Safety multi-sample needle is intended to be used with needle holder as a system in routine venipuncture/ blood collection procedure. In the activated position, the safety shield protects against accidental needle stick injury during normal handling and disposal. Safety multi-sample needle with holder is intended to be used as a system in routine venipuncture/ blood collection procedure. In the activated position, the safety shield protects against accidental needle stick injury during normal handling and disposal.
5. Intended users	Licensed healthcare professionals (HCP).
6. Instructions for Use	Refer to IFU

7. Warning and precautions	1. This device must not be used if unit packaging is damaged or opened before use. 2. If unable to activate the safety mechanism, discard the device immediately into an approved sharps waste container as per facility protocol. 3. Gloves and other personal protective equipment must be used for protection from exposure to bloodborne pathogens in line with facility protocol. 4. Do not forcefully de-activate or re-activate the safety mechanism after it has been activated. 5. This device is single use only. Do not reuse. 6. Do not use the device after expiration date. 7. After use, the device should be treated as clinical sharps waste and disposed of in an appropriate sharps waste container as per facility protocol.
8. Storage information	Keep dry, Keep away from sunlight. Temperature range: 0-40℃; Humidity range: 0-80%.
9. Sizes and REF numbers	

REF.	Sizes
SMSN20125	20G*1 1/4"
SMSN2015	20G*1 1/2"
SMSN21125	21G*1 1/4"
SMSN2115	21G*1 1/2"
SMSN22125	22G*1 1/4"
SMSN2215	22G*1 1/2"
SMSNH20125	with Pre-attached Holder20G*1 1/4"
SMSNH2015	with Pre-attached Holder20Gx1 1/2"
SMSNH21125	with Pre-attached Holder21Gx1 1/4"
SMSNH2115	with Pre-attached Holder21Gx1 1/2"
SMSNH22125	with Pre-attached Holder22Gx1 1/4"
SMSNH2215	with Pre-attached Holder22G*1 1/2"

Technical information

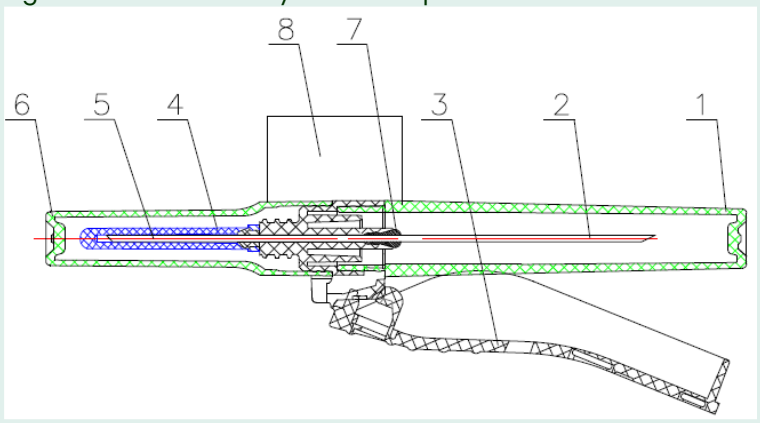
1. List of materials

Component name	Material
Needle cap(L)	High Density Polyethylene
Tube Needle cap(S)	High Density Polyethylene
Needle	SUS 304
Tube Needle	SUS 304
Safety Shield	Polypropylene
Rubber Sleeve	Isoprene Rubber
Adhesive	UV glue
Lubricant	Silicone Oil

		Tube Holder		Polypropylene
2.	**Latex free**	Yes		
3.	**PHT / DEHP / BPA 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	Safety Multi-Sample Needle 48	Units per box
			Safety Multi-Sample Needle with Holder 50	
			Safety Multi-Sample Needle 480	Units per case
			Safety Multi-Sample Needle with Holder 400	

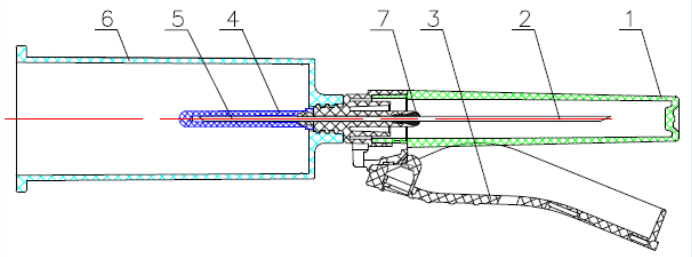
8. Technical Drawing

Figure1 SOL-CARE Safety Multi-Sample Needle



1. Needle cap(L) 2. Needle3. Safety shield 4. Rubber sleeve 5. Tube needle 6. Tube Needle cap(S) 7. Adhesive 8. Label

Figure2 SOL-CARE Safety Multi-Sample Needle with Pre-attached Holder



1. Needle cap(L) 2. Needle 3. Safety shield 4. Rubber sleeve 5. Tube needle 6. Tube Holder 7. Adhesive

Quality and Regulatory information

1. Quality certificate	Quality Management System according to ISO 13485:2016
2. Product classification	EU: Class IIa device according to European Medical Device Directive 93/42/EEC USA: Class II according to FDA 21 CFR 880.5570 Canada: Class II according to Rule 1(1) CMDR SOR /98-282
3. List of standards	**The product is compliant with the following standards and regulations:**

Document reference	**Title**
ISO 13485:2016	Medical devices -- Quality management systems -- Requirements for regulatory purposes
ISO 14971: 2019	Medical Devices – Application of Risk Management to Medical Devices
Council Directive 93/42/EEC (MDD)	COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical device
(EU) 2017/745 Medical Devices Regulation (MDR)	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices
21 CFR Part 820	Quality system regulation
Canada Medical Devices Regulations	Canada Medical Devices Regulations SOR/98-282
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 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 15223-1:2021	Medical devices -- Symbols to be used with information to be supplied by the manufacturer -- Part 1: General

		requirements
	ISO 15223-2:2010	Medical devices -- Symbols to be used with medical device labels, labelling, and information to be supplied -- Part 2: Symbol development, selection and validation.
	ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer
	ISO 6009:2016	Hypodermic needles for single use. Color coding for identification.
	ISO11135:2014/Amd 1:2018	Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices -- Amendment 1: Revision of Annex E, Single batch release (ISO 11135:2014/DAmd 1:2018)
	ISO 11737-1:2018/Amd 1:2021	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products- AMENDMENT 1
	ISO11737-2:2019	Sterilization of health care products – Microbiological methods – parts2 Tests of sterility performed in the definition, validation and maintenance of a sterilization process.
	ISO 11138-1:2017	Sterilization of health care products -- Biological indicators -- Part 1: General requirements
	ISO 11138-2:2017	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes
	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.
	ASTM F1886/F1886M-16	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
	ASTM F1980-21	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
	ISTA 3A 2018	General Simulation Performance Tests, Procedure 3A: Packaged-Products for Parcel Delivery System Shipments 70kg (150 lb) or Less (standard, small, flat or elongated)
	ISO 780: 2015	Packaging -- Distribution packaging -- Graphical symbols for handling and storage of packages
	EN 868-5:2018	Packaging for terminally sterilized medical devices -Part 5: Sealable pouches and reels of porous materials and plastic film construction – Requirement and test methods

	ASTM F1929-2015	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
	ASTM F88/F88M-23	Standard test method for Seal strength of flexible barrier materials
	ASTM F2825-18	Standard Practice For Climatic Stressing Of Packaging Systems For Single Parcel Delivery
	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/AMD 1:2019	Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals Amendment 1: Applicability of allowable limits for neonates and infants
	ISO 10993-10:2021	Biological evaluation of medical devices — Part 10： Tests for skin sensitization.
	ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation
	ISO 10993-11:2017	Biological evaluation of medical devices — Part 11: Tests for systemic toxicity.

This material is dedicated only to healthcare professionals.

REV	05	Date	2023/11/07