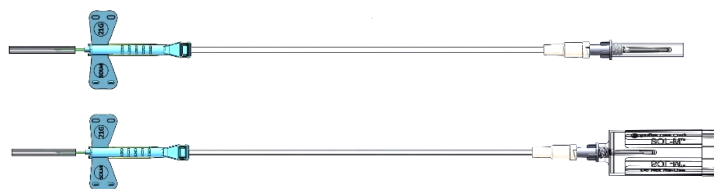


Technical Data Sheet



Product specification

1. Product name	SOL-CARE™ Safety Blood Collection Needle & SOL-CARE™ Safety Blood Collection Needle with Pre-attached Holder.
2. Description	SOL-CARE™ Safety Blood Collection Needle is a sterile winged blood collection needle with tubing and Luer adapter with a non-patient needle end. The safety Blood Collection Needle is used for blood collection and/or short-term infusion of intravenous fluids. SOL-CARE™ Safety Blood Collection Needle with Pre-attached Holder is a sterile winged blood collection needle with tubing and Luer adapter with a non-patient needle attached with a holder.
3. Characteristics	The device contains a sliding shield that covers the needle point after use. In the activated position the needle cover guards against accidental needlesticks during normal handling and disposal.
4. Intended use	SOL-CARE™ Safety Blood Collection Needle and SOL-CARE™ Safety Blood Collection Needle with Pre-attached Holder is a sterile, multiple-sample, single-use winged blood collection set intended for venipuncture to obtain blood specimens from patients and/or short-term infusion of intravenous fluids. The device is designed with an integral safety sliding shield that provides a safety feature intended to cover the intravenous (IV) end of the needle after the needle is withdrawn from the patient aids in the prevention of needlestick injury.
5. Instructions for use	See IFU:

6. Sizes and REF numbers	REF Numbers	Sizes
	110201030030	with Luer Adapter 21G* 3/4 *7"
	110201030031	with Luer Adapter 21G* 3/4*12"
	110201030032	with Luer Adapter 23G* 3/4*7"
	110201030033	with Luer Adapter 23G* 3/4*12"
	110201030034	with Luer Adapter 25G* 3/4"*7"
	110201030035	with Luer Adapter 25G* 3/4*12"
	110201030036	with Luer Adapter 22G*3/4" 7inch
	110201030037	with Luer Adapter 22G*3/4" 12inch
	110201030002	with Pre-attached Holder 21G* 3/4*12"
	110201030004	with Pre-attached Holder 21G* 3/4*7"
	110201030006	with Pre-attached Holder 23G* 3/4*12"
	110201030008	with Pre-attached Holder 23G*3/4*7"
	110201030010	with Pre-attached Holder 25G*3/4*12"
	110201030012	with Pre-attached Holder 25G* 3/4*7"

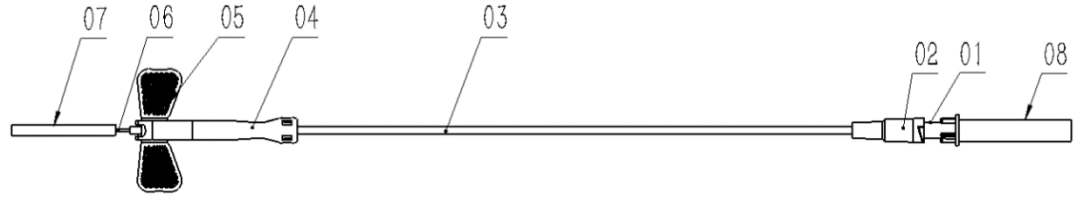
Technical information

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		Component name	Material	
1. List of materials		Blood collection composition	Isoprene Rubber, Stainless steel SUS304, Polypropylene	
		Female luer adapter	Polyvinyl Chloride	
		Tubing	Polyvinyl Chloride	
		Safety shield	Polypropylene	
		Butterfly wings (21G, 23G, 25G)	Polyvinyl Chloride	
		Needle	Stainless steel SUS304	
		Needle protector	Low Density Polyethylene	
		Non-patient Needle protector	Low Density Polyethylene	
		Holder	Polypropylene	
		Adhesives (Between needle and butterfly wings)	Epoxy glue	
		Adhesives (Between tubing and female Luer adapter)	Cyclohexanone	
		Adhesives (Non-patient needle)	Epoxy resin	
		Lubricant	Silicone oil	
	2. Latex free	YES		
3. PHT / DEHP / free	YES			
4. Shelf life	5 years			
5. Sterilization method	Sterilized using Ethylene Oxide			
6. Packaging specification	6.1 Sales unit	with Luer Adapter	50	Units per box
		with Pre-attached Holder	25	
		with Luer Adapter	200	Units per case
		with Pre-attached Holder	200	

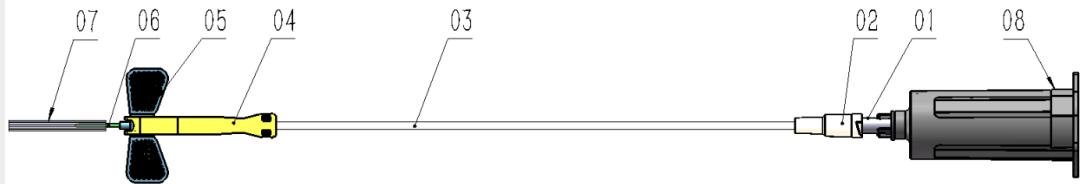
7. Technical Drawing

SOL-CARE™ Safety Blood Collection Needle



- | | |
|----------------------------------|---------------------------------|
| 1. Blood collection compositions | 5. Safety wings |
| 2. Female Luer Adapter | 6. Needle |
| 3. Tubing | 7. Needle protector |
| 4. Safety shield | 8. Non-patient Needle Protector |

SOL-CARE™ Safety Blood Collection Needle with Pre-attached Holder



- | | |
|----------------------------------|---------------------|
| 1. Blood collection compositions | 5. Safety wings |
| 2. Female Luer Adapter | 6. Needle |
| 3. Tubing | 7. Needle protector |
| 4. Safety shield | 8. Holder |

Quality and Regulatory information

1. Quality certificate

Quality Management System according to ISO 13485

2. Product classification

Class IIa according to Annex IX of MDD 93/42/EEC

3. List of standards

The product is compliant with the following standards and regulations:

Document reference	Title
ISO 7864:2016	Sterile hypodermic needle for single use
ISO 8536-4:2019	Infusion equipment for medical use, Part 4 Infusion sets for single use, gravity feed
ISO 9626:2016	Stainless steel needle tubing for the manufacture of medical devices
ISO 80369-7:2016	Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors with 6% taper for intravascular or hypodermic applications
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
EN 1041:2008+A1:2013	Information Supplied by the Manufacturer with Medical Devices
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 6009:2016	Hypodermic needles for single use -- Colour coding for identification
ISO 780:2015	Packaging. Distribution packaging. Graphical symbols for handling and storage of packages

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ISO 11135:2014/Amd 1:2018	Sterilization of health care products -- Ethylene oxide -- Requirements for development, validation and routine control of a sterilization process for medical devices
ISO 11737-1:2018	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on product
ISO 11737-2:2019	Sterilization of medical devices -- Microbiological methods -- Part 2: 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 11607-2:2019	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 11607-1:2019	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN 868-5:2009	Packaging for terminally sterilized medical devices Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods
IEC 62366-1:2015/Cor 1:2016	Medical devices -- Part 1: Application of usability engineering to medical devices
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
ISO10993-5:2009	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
ISO10993-11:2017	Biological evaluation of medical devices — Part 11: Tests for systemic toxicity

REV

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Date

2022.06.08