

## Technical Data Sheet



### Product specification

1. Product name	SOL-CARE™ Safety Needle
2. Description	The SOL-CARE™ Safety Needle is a single use, standard hypodermic needle with a shield to enclose the needle after use.
3. Characteristics	The SOL-CARE™ 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-CARE™ 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. Instructions for use	See current IFU

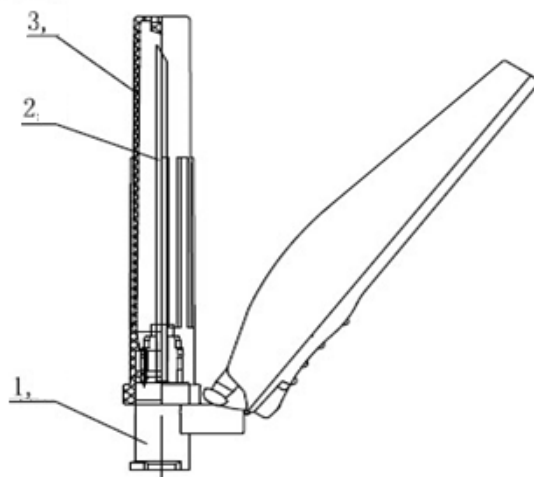
Reference number	Product description	Gauge size	Outer diameter (mm)	Length		Indications*				
				(mm)	(inch)	SC	ID	IM	IV	IA
SN3012	SOL-CARE™ Safety Needle 30G*1/2"	30G	0.3 mm	12.5 mm	1/2"	SC				
SN2715	SOL-CARE™ Safety Needle 27G*1 1/2"	27G	0.4 mm	40 mm	1 1/2"	SC	ID			
SN27125	SOL-CARE™ Safety Needle 27G*1 1/4"	27G	0.4 mm	32 mm	1 1/4"	SC	ID			
SN2734	SOL-CARE™ Safety Needle 27G*3/4"	27G	0.4 mm	18.5 mm	3/4"	SC	ID			
SN2758	SOL-CARE™ Safety Needle 27G*5/8"	27G	0.4 mm	16 mm	5/8"	SC	ID			
SN2712	SOL-CARE™ Safety Needle 27G*1/2"	27G	0.4 mm	12.5 mm	1/2"	SC	ID			
SN2612	SOL-CARE™ Safety Needle 26G*1/2"	26G	0.45 mm	12.5 mm	1/2"	SC	ID			
SN2515	SOL-CARE™ Safety Needle 25G*1 1/2"	25G	0.5 mm	40 mm	1 1/2"	SC	ID	IM		IA
SN2510	SOL-CARE™ Safety Needle 25G*1"	25G	0.5 mm	25 mm	1"	SC	ID	IM		IA
SN2558	SOL-CARE™ Safety Needle 25G*5/8"	25G	0.5 mm	16 mm	5/8"	SC	ID	IM		IA
SN2315	SOL-CARE™ Safety Needle 23G*1 1/2"	23G	0.6 mm	40 mm	1 1/2"			IM	IV	IA
SN23125	SOL-CARE™ Safety Needle 23G*1 1/4"	23G	0.6 mm	32 mm	1 1/4"			IM	IV	IA
SN2310	SOL-CARE™ Safety Needle 23G*1"	23G	0.6 mm	25 mm	1"			IM	IV	IA
SN2358	SOL-CARE™ Safety Needle 23G*5/8"	23G	0.6 mm	16 mm	5/8"			IM	IV	IA
SN2215	SOL-CARE™ Safety Needle 22G*1 1/2"	22G	0.7 mm	40 mm	1 1/2"			IM	IV	IA
SN22125	SOL-CARE™ Safety Needle 22G*1 1/4"	22G	0.7 mm	32 mm	1 1/4"			IM	IV	IA
SN2210	SOL-CARE™ Safety Needle 22G*1"	22G	0.7 mm	25 mm	1"			IM	IV	IA
SN2105	SOL-CARE™ Safety Needle 21G*2"	21G	0.8 mm	50 mm	2"			IM	IV	IA
SN2115	SOL-CARE™ Safety Needle 21G*1 1/2"	21G	0.8 mm	40 mm	1 1/2"			IM	IV	IA
SN21125	SOL-CARE™ Safety Needle 21G*1 1/4"	21G	0.8 mm	32 mm	1 1/4"			IM	IV	IA
SN2110	SOL-CARE™ Safety Needle 21G*1"	21G	0.8 mm	25 mm	1"			IM	IV	IA
SN2015	SOL-CARE™ Safety Needle 20G*1 1/2"	20G	0.9 mm	40 mm	1 1/2"			IM	IV	
SN2010	SOL-CARE™ Safety Needle 20G*1"	20G	0.9 mm	25 mm	1"			IM	IV	
SN1920	SOL-CARE™ Safety Needle 19G*2"	19G	1.1 mm	50 mm	2"			IM	IV	
SN1915	SOL-CARE™ Safety Needle 19G*1 1/2"	19G	1.1 mm	40 mm	1 1/2"			IM	IV	
SN1910	SOL-CARE™ Safety Needle 19G*1"	19G	1.1 mm	25 mm	1"			IM	IV	
SN1820	SOL-CARE™ Safety Needle 18G*2"	18G	1.2 mm	50 mm	2"				IV	
SN1815	SOL-CARE™ Safety Needle 18G*1 1/2"	18G	1.2 mm	40 mm	1 1/2"				IV	
SN1810	SOL-CARE™ Safety Needle 18G*1"	18G	1.2 mm	25 mm	1"				IV	

### 6. Sizes and REF numbers

## Technical information

1. List of Materials	Component name	Material	
	Needle cap	PP: RP344RK	
	Needle tube	Stainless steel: SUS304	
	Needle hub with protective arm	PP: H1500	
	Adhesive	Epoxy: YD-128	
	Needle Lubricant	Silicon oil: Xilikang 201-350cs	
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
		800	Units per case

## 7. Technical Drawing



triple bevel

1. Needle hub with protective arm
2. Needle tube
3. Needle cap

## 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
	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 10993-1:2009/Cor 1:2010	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 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 980:2008	Symbols for use in the labelling of medical devices
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices	

REV

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Date

03.11.2017