

Distributed by:



Technical Data Sheet



Product specification

1. Product name	SOL-M™ Luer Lock Syringe with Exchangeable Needle
2. Description	SOL-M™ 1,3,5,10,20,30,60ml Standard Luer Lock Syringe with Exchangeable Needles are used to inject medicines and vaccines into, or withdraw fluids from, the body.
3. Characteristics	SOL-M™ Luer Lock Syringe with Exchangeable Needles are sterilized by Ethylene Oxide Gas. Each Blister Pack, Dispenser Box and Case are labeled with the contents and the appropriate information per the FDA's Quality System Regulation and Labeling requirements.
4. Intended use	SOL-M™ Luer Lock Syringe with Exchangeable Needles are used to inject medicine or vaccines into, or withdraw fluids from, the body.
5. Instructions for use	N/A

6. Sizes and REF numbers

REF	Size
18012010	1ml 20G*1"
18012912	1ml 29G*1/2"
012912PC	1ml 29G*1/2" PC
REF	Size
1832310	3ml 23G*1"
1832510	3ml 25G*1"
1832515	3ml 25G*1 1/2"
1832558	3ml 25G*5/8"
1832110T	3ml Tray 21G*1"
1832210T	3ml Tray 22G*1"
1832310T	3ml Tray 23G*1"
1832315	3ml 23G*1 1/2"
1832515	3ml 25G*1 1/2"
REF	Size
1812010	10ml 20G*1"
1812015	10ml 20G*1 1/2"
1812110	10ml 21G*1"
1812115	10ml 21G*1 1/2"
1812210	10ml 22G*1"
110101120011	10ml Tray 20G*1"
110101120012	10ml Tray 21G*1"

REF	Size
1831815	3ml 18G*1 1/2"
1832010	3ml 20G*1"
1832015	3ml 20G*1 1/2"
1832110	3ml 21G*1"
1832115	3ml 21G*1 1/2"
1832210	3ml 22G*1"
1832215	3ml 22G*1 1/2"
18322125	3ml 22G*1 1/4"
REF	Size
1852210	5ml 22G*1"
1852010	5ml 20G*1"
1852015	5ml 20G*1 1/2"
1852110	5ml 21G*1"
1852115	5ml 21G*1 1/2"
1852215	5ml 22G*1 1/2"
1852110T	5ml Tray 21G*1"
1852010T	5ml Tray 20G*1"
1852110T	5ml Tray 21G*1"

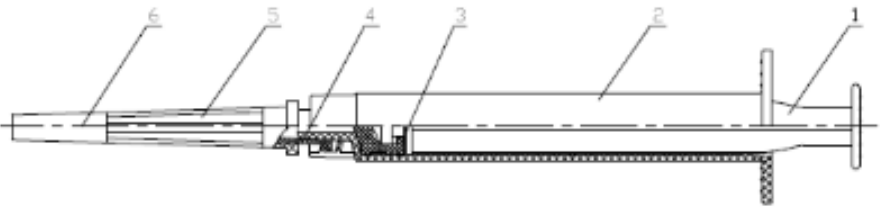
REF	Size
1822115S	20ml 22G*1 1/2" SIDE

Distributed by:



800-826-8302 nelsonjameson.com

Technical information

		Component name	Material
1. List of Materials		Plunger	PP: 5250T
		Barrel	PP: 5250T
			PC IR2200
		Gasket	Latex free rubber
		Needle hub	PP: H1500
		Needle cap	PP: RP344RK
		Cannula	Stainless steel: SUS304
		Adhesive	Epoxy: YD-128
		Needle Lubricant	Silicon oil: Xilikang 201-350cst
		Barrel Lubricant	Silicon oil: DC 360 12500cst
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	1ml\3ml\5ml \10ml\20ml	100
		30ml	50
		60ml	30
		1ml\3ml\5ml	800
		10ml	1200
		20ml	800
		30ml SIDE	400
		60ml SIDE	240
7. Technical Drawing			
	1. Plunger 5. Needle cap 2. Barrel 6. Cannula 3. Gasket 4. Needle hub		

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	The product is compliant with the following standards and regulations:	
	Document reference	Title
	ISO 7886-1:2017	Sterile hypodermic syringes for single use-Part 1: Syringes for manual use
	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 6009:2016	Hypodermic needles for single use -- Colour coding for identification
	ISO 80369-7:2016	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment -- Part 1: General requirements
	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/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 15223-1:2016	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
	ISO 11607-1:2006/Amd 1:2014	Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems
	ISO 11607-2:2006/Amd 1:2014	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 definition, validation and maintenance of a sterilization process
	ISO 11135-1:2014/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
	EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices

REV	02	Date	12.07.2019
-----	----	------	------------

Signature Manifest

Document Number: TDS-0025

Revision: 02

Title: TDS SOL-M Luer Lock Syringe with Exchangeable Needle

Effective Date: 07 Aug 2019

All dates and times are in Greenwich Mean Time.

approval

Record Release Name/Signature	Title	Date	Meaning/Reason
Adam Mickiewicz (AMICKIEWICZ)	QARA Manager	03 Aug 2018, 05:17:10 PM	Approved

TDS_SOL-M Luer Lock Syringe with Exchangeable Needle_ENG

Record Release Name/Signature	Title	Date	Meaning/Reason
Adam Mickiewicz (AMICKIEWICZ)	QARA Manager	07 Aug 2019, 09:16:44 PM	Approved