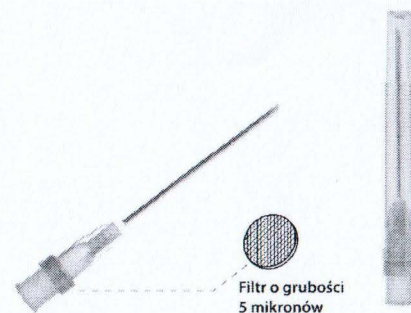


Technical Data Sheet



Product specification

1. Product name **SOL-M Blunt Fill Needle with 5 micron filter**
2. Description **The SOL-M Blunt Fill Needle is designed to replace hypodermic needles currently for withdrawal of medication from rubber- stoppered vials or injection into I.V. Systems and pre-slit septum covering injections sites.**
3. Characteristics **The SOL-M Blunt Fill Needle is used in conjunction with a syringe to penetrate rubber-stoppered medicine vials and pre-slit septum covering injection sites. The cannula is pre-lubricated to reduce septum insertion forces.**
4. Intended use **The SOL-M Blunt Fill Needle is used in conjunction with a syringe as an additive device for aspiration from multi-dose medicine vials or injection into I.V. Systems and pre-slit septum covering injection sites.**
5. Instructions for use **See IFU (11010107-IFU-02, Revision G)**

6. Sizes and REF numbers

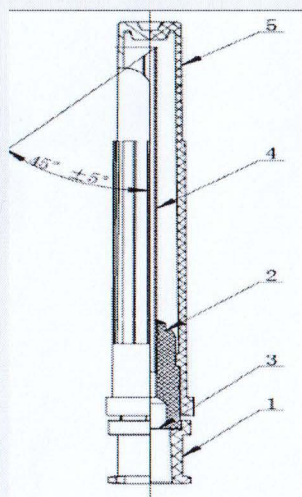
REF	Size
110021F	18GX1''
110022F	18GX1 1/2''
110023F	18GX2''

SOL-MILLENNIUM®

Technical information

1. List of Materials	Component name	Material	
	Luer lock interface	PP: H1500	
	Needle hub	PP: H1500	
	Filter membrane	Versapor	
	Needle tube	Stainless steel: SUS304	
	Needle cap	PP: RP344RK	
	Adhesive	Epoxy: YD-128	
	Needle Silicon	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
		1000	Units per case

7. Technical Drawing



1. Luer lock interface
2. Needle hub
3. Filter membrane
4. Needle tube
5. 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**

The product is compliant with the following standards and regulations:

3. List of standards	Document reference	Title
	ISO 7864:1993	
ISO 9626:1991		Stainless steel needle tubing for the manufacture of medical devices
ISO 594-1:1986		Conical fitting with 6% (Luer) taper for syringes, needles and certain other medical equipment part 1 general requirement
ISO10993-4:2002		Biological evaluation of medical devices part 4
ISO10993-5:2009		Biological evaluation of medical devices part 5
ISO10993-7:2008		Biological evaluation of medical devices part 7
ISO10993-10:2010		Biological evaluation of medical devices part 10
ISO10993-11:2006		Biological evaluation of medical devices part 11
ISO 15223-1:2008		Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied
ISO 11607-1:2006		Packaging for terminally sterilized medical devices Part 1
ISO 11607-2:2006		Packaging for terminally sterilized medical devices Part 2

REV	00	Date	2016-01-28	Signature	PDO Director, Ligang Xue, 
					QA 2016