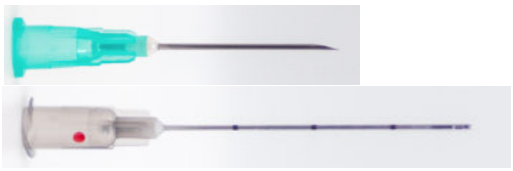
Technical Data Sheet



Product specification

1. Product name	Sol-M ™ Sterile Injection Kit
2. Description	Sol-M ™ Sterile Injection Kit containing: 1 Aesthetic Cannula Needle + 1 Hypodermic needle; All needles are available in various lengths and sizes, and consist of needle hub, needle tube and protective cap.
1. Indication for use	Sol-M™ Sterile Injection Kit is used for the intradermal/hypodermic injection of Sodium hyaluronate based fillers in medical plastic surgery.
2. Intended use	Sol-M™ Sterile Injection Kit is used for the intradermal/hypodermic injection of Sodium hyaluronate based fillers in medical plastic surgery.
3. Intended users	Professional medical staff, including physicians, nurses, therapists and other relevant staff in medical science.
4. Instructions for Use	Please refer to the instructions for use on the box package.
5. Warning and precautions	• Single use only. Do not reuse. • Do Not use if package is damaged.
6. Storage information	Keep dry, Keep away from sunlight
7. Sizes and REF numbers	*Put product REF# and description into the table below.*

REF	Product Description
ACK2215	Sol-M Aesthetic Cannula Kit (Blunt Needle 22G x 1.5″; Pilot Needle 21G x 1″)
ACK2202	Sol-M Aesthetic Cannula Kit (Blunt Needle 22G x 2″; Pilot Needle 21G x 1″)
ACK22275	Sol-M Aesthetic Cannula Kit (Blunt Needle 22G x 2.75″; Pilot Needle 21G x 1″)
ACK2515	Sol-M Aesthetic Cannula Kit (Blunt Needle 25G x 1.5″; Pilot Needle 23G x 3/4″)
ACK2502	Sol-M Aesthetic Cannula Kit (Blunt Needle 25G x 2″; Pilot Needle 23G x 3/4″)
ACK2710	Sol-M Aesthetic Cannula Kit (Blunt Needle 27G x 1″; Pilot Needle 26G x 1″)
ACK2702	Sol-M Aesthetic Cannula Kit (Blunt Needle 27G x 2″; Pilot Needle 26G x 1″)

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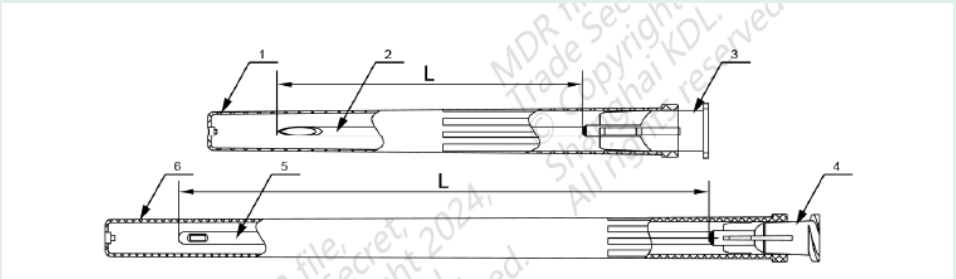
Technical information

1. List of materials		Component name	Material
		Protective Cap of hypodermic needle	PP
		Needle Tube of of hypodermic needle	SUS 304
		Needle Hub of hypodermic needle	PP, BS, and ABS
		Needle Hub of aesthetic cannula	PP, BS, and ABS
		Needle Tube of aesthetic cannula	SUS 304
		Protective Cap of aesthetic cannula	PP, PE
		Lubricant	Silicone oil
		Resin	Epoxy Glue
2. Latex free		Yes	
3. PHT / DEHP Free		Yes	
4. Materials of concern		NA	
5. Shelf life		5 years	
6. Sterilization method		Sterilized with Ethylene Oxide	
7. Packaging Specification	7.1 Sales unit	20 units	Units per box
		1000 units (50 boxes)	Units per case (Boxes per case)

8. Technical Drawing



1.Protective Cap of hypodermic needle ; 2. Needle Tube of of hypodermic needle
3.Needle Hub of hypodermic needle; 4. .Needle Hub of aesthetic cannula
5. Needle Tube of aesthetic cannula 6. Protective Cap of aesthetic cannula

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Quality and Regulatory information

1. Quality certificate	MDL 110045	
2. Product classification	Canada: Class 2	
3. List of standards	**The product is compliant with the following standards and regulations:**	
	Document reference	**Title**
	Q/JKDL-52-2022	Corporate Standards of Sterile Injection Kit
	ISO 7864:2016	Sterile hypodermic Needles for single use
	BS EN ISO 9626:2016	Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods
	IS0 80369-7:2021	Small-bore connectors for liquids and gases in healthcare applications -Part 7: Connectors for intravascular or hypodermic applications
	MEDDEV.2.7.1 Rev.4	Clinical evaluation: Guide for manufacturers and notified bodies
	EN 62366-1:2015	Medical devices -Part 1: Application of usability engineering to medical devices
	EN ISO 20417:2021	Information Supplied by the Manufacturer with Medical Devices
	IS0 15223-1:2021	Medical devices -Symbols to be used with medical device labels, labelling and information to be supplied -Part 1: General requirements
	EN 556-1:2001/ AC:2006	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
	EN ISO 11135:2014	Sterilization of health care products -- Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices
	EN ISO 11737-1:2018	Sterilization of health care products - Microbiological methods - Part 1: termination of a population of microorganisms on products
	EN ISO 11737-2:2020	Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
	EN ISO 11138-1.2017	Sterilization of health care products - Biological indicators - - Part 1: General requirements
	EN ISO 11138-2:2017	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization

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		processes
	EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices - Part 1: Requirements form materials, sterile barrier systems and packaging systems
	EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
	EN ISO 13485:2016	Medical Devices-Quality management system-Requirements for regulatory purposes
	ISO 14698-1:2003	Cleanrooms and associated controlled environments -- Biocontamination control -Part 1: General principles and methods
	IS0 14698-2:2003	Cleanrooms and associated controlled environments -- Biocontamination control -Part 2: Evaluation & Interpretation of Biocontamination Data
	IS0 14644-1:2015	Cleanrooms and Associated Controlled Environments Part 1: Classification and Air Cleanliness
	IS0 14644-2:2015	Cleanrooms and Associated Controlled Environments Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1
	IS0 14644-3:2019	Cleanrooms and associated controlled environments-Part 3: Test methods
	IS0 14971:2019	Medical Devices -Application of Risk Management to Medical Devices
	ISO/TR 24971:2020	Medical devices-Guidance on the application of IS0 14971
	EN ISO10993-1:202	Biological evaluation of medical devices-Part 1 Evaluation and testing within a risk management process
	EN ISO10993-4:2017	Biological evaluation of medical devices-Part 4: Selection of tests for interactions with blood
	EN ISO10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
	EN ISO 10993-7:2008/AC:2009	Biological evaluation of medical devices -Part 7: Ethylene oxide sterilization residuals
	EN ISO10993-10.2021	Biological evaluation of medical devices-Part 10: Tests for irritation and delayed-type hypersensitivity
	EN ISO10993-11:2018	Biological evaluation of medical devices Part 11: Tests for systemic toxicity
	ASTM F1980:2016	Standard guide for accelerate aging of sterile barrier systems for medical device

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This material is dedicated only to healthcare professionals.

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