



INSTRUCTIONS FOR USE

Doc. No.: SPM/IFU/03, Rev. No.: 02, Rev. Date: 23-10-2023

STERILE IV INFUSION SET FOR SINGLE USE

APPLICABLE MODELS/VARIANTS

S. No.	Product Description	Component Specification
1.	IV Infusion Set-Airsafe Elite	Tube Length-180cm with Y-Site
2.	IV Infusion Set-Standard	Tube Length-150cm with Latex Bulb
3.	IV Infusion Set-Turk	Tube Length-150cm with Latex Bulb with luer lock
4.	IV Infusion Set-Airsafe Regular	Tube Length-150cm without Y-Site
5.	IV Infusion Set-Micro	Tube Length-150cm with Non Vented with Latex Bulb
6.	IV Infusion Set-Connect	Tube Length-150cm Tube Length-150cm with Vented with Y port
7.	IV Infusion Set-Purge	Tube Length-150cm Vented with Purge Filter with Y Injection Site
8.	IV Infusion Set-Dial	Tube Length-150cm Vented with flow regulator with Y Injection Site

DESCRIPTION

SPM's Infusion Sets are used to administer Intravenous fluid and medicines into human circulating system by using intravenous catheter or cannula. The I.V. Set is used in aseptic environment. The product is sterilized using EO (Ethylene Oxide) gas. The use of the product is restricted to a qualified doctor or a paramedic.

INTENDED USE / INDICATION FOR USE

Infusion Set are intended for administer intravenous fluid and/or medication to a patient intravenously.

TARGET AGE GROUP:

Use All Age Groups

DURATION OF USE:

Short term Use (Less than 30 Days).

STORAGE CONDITIONS:

Store at specified temperature and humidity (Temperature in between 10°C to 40°C and Humidity in between 55%Rh to 75% Rh).

CONTRAINDICATIONS/WARNINGS:

- Device must not be used other than as indicated in intended use
- Device should not be used for administration of blood and blood components
- Device should not be used in patients with known hypersensitivity to any of the materials used.
- The instructions should be followed carefully before use.
- DO NOT re-sterilize and /or reuse.
- Re use of single use device creates a potential risk for patient on use. It may lead to contamination and /or impairment of functional capability.
- Do not use on injured or infected surface.
- Visually inspect and carefully check the product and packaging before use.



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INDICATION/INTENDED APPLICATION:

To prevent or treat dehydration.

MODE OF ACTION:

This is a disposable IV Infusion Set of different variants. This device is supplied sterile in paper pouch. Based on stability studies, the shelf life for sterile products is recommended to 5 years from the date of sterilization/manufacturing. The product life is mentioned on the product label.

HOW SUPPLIED:

IV Infusion Set is supplied sterile, packed in individual paper pouch. Hundred (100) such individuals are enclosed within a printed duplex box. The overall packing contains ten (10) duplex boxes and external identification stickers.

MATERIALS USED:

Polypropylene (PP), Acrylonitrile butadiene styrene (ABS), Poly Vinyl Chloride (PVC), Natural Latex, Stainless Steel (SS), Nylon.

⚠ CAUTIONS:

- Store in a cool and dry place.
- Discard after single use.
- Do not use if package is open or damaged.
- Do not store at extreme temperature and humidity.
- Do not use with blood and blood components.
- Do not use device after shelf life expires.

PRECAUTIONS

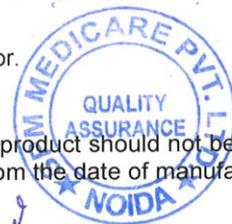
- When handling the product care should be taken to avoid damage from handling. Avoid crushing and crimping damage to the product due to application of surgical instruments such as forceps etc.

INSTRUCTIONS FOR USE

- Peel open the pouch and take out the infusion set.
- Remove protective cap from piercing spike.
- Insert the piercing spike to its full length into the top of the container.
- Open air vent of piercing spike.
- Close flow regulator and squeeze drip chamber till it is half filled.
- Open flow regulator & allow solution to pass till all air bubbles in the tube are removed.
- Close the flow regulator.
- Remove the priming stop cap from luer lock connector.
- Connect the set to intended device and regulate flow by using flow regulator.
- Use Y-injection site for extra medicament.
- For intermittent use put the prime stop cap back in luer connector.

DEVICE LIFE

The expiration date of the product is the sterility expiration date. The product should not be used after the indicated sterility expiration date. Recommended shelf life of the product is 05 years from the date of manufacturing.



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INSTRUCTIONS FOR USE

RETURN OF DAMAGED PRODUCT:

Return the product in its original packing identified by the batch number, purchase information, your reference and reason for return. Please contact your local distributor office regarding product return/exchange.

REPORTING

Adverse events and/or potentially sight-threatening complications that may reasonably be regarded as product related and that were not previously expected in nature, severity or incidence must be report to SPM Medicare Pvt.Ltd. B-40, Phase-II, Noida, Gautam Buddha Nagar, UP-201305.

DISPOSAL OF THE USED DEVICE

After use device should be disposed off in compliance with the local, state and country laws & regulations.

EXPLICATION OF SYMBOLS

Symbol	Meaning	Symbol	Meaning
	Caution/Warning (Read instruction before use)		Catalogue Number
	Manufacturer Logo		Batch/Lot Number
	Date and country of manufacturer		Date of Expiry
	Do not re-sterilize		Temperature Limitation
	Humidity Limitation		Do not use if package damaged
	Consult IFU		Keep Dry
	Keep away from sunlight		Non Pyrogenic
	Don't re-use		Sterilized using EO
	This side up		Handle with care



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INSTRUCTIONS FOR USE

	Do not use hook		Maximum stacking
	Medical Device		Conformity of European Norm with Notified Body Number
	Unique Device Identifier		Model Number
	Single Sterile Barrier System with protective packaging outside		Single Sterile Barrier System
	Authorized European Representative		

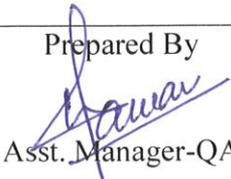
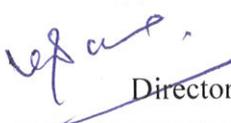
SPM Medicare Pvt. Ltd.
 B-40, Phase-II, Noida, Gautam Budh Nagar,
 UP-201305
 Customer Care No.: +91-840-7070-718
 Email: info@spmmedicare.com
 Web Site: www.spmmedicare.com



MEDDEVICES LIFESCIENCES B.V.
 Keizersgracht 482
 1017 EG Amsterdam,
 The Netherlands
 Email: info@meddevices.net
 Phone: +31-202254558



Handwritten signature

Prepared By  Asst. Manager-QA	Reviewed By  Head Quality / MR	Approved By  Director
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