

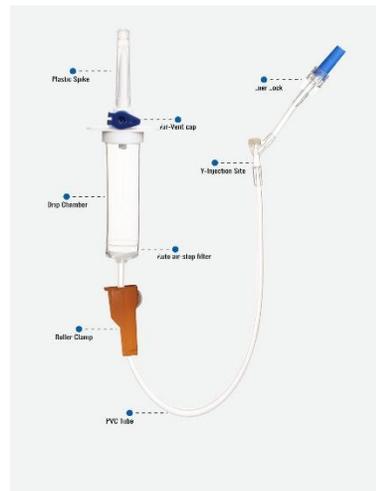
Follow manufacturer's instructions for use and institutional procedures for IV Infusion Set

**Product Name- IV Infusion Set**

**DESCRIPTION**

The 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. The I V Infusion Sets are not used for the administration of Blood and Blood related Components to the patient.

**IMAGE OF THE DEVICE**



**Models:**

IV Infusion Set (with/without air vent, with/without Y site, with/without needle free Y site, with /without air safe feature, with/without dial flow regulator, with/without purge filter, with/without accessories)

**INTENDED PURPOSE**

The IV Infusion Set is intended to administer fluids such as nutrients, medications, or blood products to a patient's vascular system through a needle or catheter inserted into a vein.

<p><u>N. R. Dukare.</u></p>	<p><u>Shawda</u></p>	<p><u>SK</u></p>
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<p><b>Prepared By Senior Executive- QA</b></p>	<p><b>Reviewed By QA- MR</b></p>	<p><b>Approved By Manager- RA/QA</b></p>

**INDICATIONS FOR USE**

- Infusion of IV Fluids
- To prevent/ treat dehydration
- Infusion of IV Drug Administration

**INTENDED PATIENT POPULATION**

Patients of all age groups requiring continuous or intermittent intravenous administration of fluids, medications, or nutrients under clinical supervision.

**INTENDED USER**

The intended users for IV Infusion Set are healthcare professionals trained in performing Infusion.

**INTENDED USE ENVIRONMENT**

IV Infusion Set is intended to be used in hospitals and clinics.

**CLINICAL BENEFITS**

**IV Infusion Set** improves clinical care by providing secure and consistent intravenous access, reducing the need for frequent line replacements and minimizing infection risks. It ensures efficient fluid management and patient safety.

**PRINCIPLE OF OPERATION**

The IV Infusion Set is used for the controlled administration of intravenous fluids or medication directly into the bloodstream. The set includes a drip chamber, tubing, flow regulator, and needle. The flow of liquid is maintained through gravity, where the fluid is administered from an elevated container and regulated using a manual clamp or roller to adjust the flow rate.

**PERFORMANCE CHARACTERISTICS:**

- Smooth fluid regulation with accurate flow control
- Minimal dead space
- Leak-proof spike and luer lock connection

**MATERIALS USED**

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S. NO.	Components	Material	Type of Body Contact
1	Spike Cap	Poly Propylene	No contact
2	Spike	ABS	Indirect contact with blood path
3	Drip Chamber	PVC	Indirect contact with blood path
4	Button Filter	Nylon	Indirect contact with blood path
5	P.V.C. Tube	P.V.C.	Indirect contact with blood path
6	Latex Bulb	Latex	Indirect contact with blood path
7	Roller Body	Polypropylene	No contact
8	Roller	ABS	No contact
9	Male Connector	Poly Propylene	Indirect contact with blood path
10	Vent Cap	Poly Propylene	No contact
11	Flow Regulator	ABS	Indirect contact with blood path
12	Purge Filter	PC	Indirect contact with blood path
13	Micro Pin	SS	Indirect contact with blood path

**CONTRAINDICATIONS**

- Do not use if the patient has a known allergy to any of its components. It may lead to an allergic response resulting in anaphylaxis.
- Do not use in patients with active infections or conditions that increase infection risk, using a contaminated IV Infusion Set could exacerbate their condition
- Avoid using the IV Infusion Set for fluids or medications that are incompatible with the materials of the set, as this could lead to chemical reactions or reduced efficacy.
- 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 (Phthalates and other related substances) to any of the materials used.

**POTENTIAL COMPLICATIONS**

- Possible complications associated with the use of IV Infusion Sets may include

		
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infections (localized/systemic), sepsis, air embolism, particulate embolism, thrombophlebitis, and catheter occlusion.

- Leakage from the set may expose patients and healthcare providers to hazardous fluids.
- Inappropriate handling, failure to maintain sterility, or improper technique can lead to infusion-related complications such as infiltration, extravasation, erythema, swelling, and pain.
- Use of non-sterile or contaminated fluids may result in serious infections or life-threatening conditions, including sepsis or death.

**INSTRUCTIONS FOR USE**

- Peel open the product & take out the infusion set.
- Remove protector 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 the flow regulator. Squeeze drip chamber till it is half filled.
- Open flow regulator & allow solution to pass till all air bubble 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.

**HOW SUPPLIED**

The IV Infusion Set is supplied in EO sterile, single-use Paper pouch packaging, complete with instructions for use and necessary accessories like measuring scale and dressing material.

**WARNINGS**

- For Professional Use Only: This device must be used only by trained healthcare professionals

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- Sterile Packaging: Do not use if the packaging is damaged or opened prior to use.
- Single Use Only: The warn is designed for single use. Do not reuse or re-sterilize.
- Proper Handling: Handle with care to avoid damage to the device, which could compromise its sterility and functionality
- Allergic Reactions: Check patient history for allergies to materials in the warn.
- Inspect Before Use: Ensure all components are present and undamaged before use
- Follow Instructions: Carefully follow the included instructions for use to avoid complications
- Dispose Properly: Dispose of the device in accordance with local regulations for medical waste

**PRECAUTIONS**

- Follow Manufacturer’s Guidelines: Adhere strictly to the manufacturer's instructions for proper use and maintenance.
- Inspect Before Use: Check the IV Infusion Set for any damage or defects before connecting.
- Avoid Over-tightening: Do not over-tighten connections to prevent damage or leaks.
- Regular Inspection: Routinely inspect the IV Infusion Set during use for signs of wear, kinking, or other issues.
- Proper Storage: Store the IV Infusion Set in a clean, dry environment to maintain sterility and functionality.
- Proper Disposal: Dispose of the IV Infusion Set according to institutional protocols and environmental regulations to prevent contamination.

**CAUTIONS:**

- Store in a cool and dry place
- Discard after single uses
- Do not use if the package is open or damage
- Do not store at extreme temperature and humidity
- Dispose the blood contaminated product as per local applicable laws

**STORAGE**

Store the product at room temperature 10-40 °C keeping out of direct sunlight, high humidity and exposure to water.

**EXPIRATION PERIOD**

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### INSTRUCTIONS FOR USE

Doc. No.: SPM/TF- CE/ IV Set/ 03. - Rev. 02 Date: 26-05-2025



The device has a shelf life of 5 years from the date of manufacturing. The product should not be used after the indicated sterility expiration date.

#### **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.

#### **DISPOSAL OF THE USED DEVICE**

- Disposal of the used product should be done according to hospital procedures, State Regulations, national legislation or regional legislation.
- Device should be disposed after use on individual patient during a single procedure.
- Disposal of the packaging material should be done as biomedical waste.
- Any open packaging should be disposed as biomedical waste.
- Leftover products should be disposed as biomedical waste

#### **REPORTING**

In case of any 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 occurrence, contact the manufacturer or authorized representative and competent authority of the member state where the user and/or patient is established.

<b><u>LEGAL MANUFACTURER AND MANUFACTURING FACILITY</u></b>	
 <b>Manufacturer:</b> <b>SPM Medicare Pvt, Ltd</b> B-40, Phase-II, Noida, Gautam Buddha Nagar, Uttar Prades-201305, India. <b>Manufacturing Site 1-</b> B-40, Phase-II, Noida, Gautam Buddha Nagar, Uttar Prades-201305, India. <b>Manufacturing Site 2-</b> Industrial Building Plot no 26, Sector 158, Noida, Gautam buddha, Nagar, Uttar Pradesh, 201305 India. Customer care: No.: +91-840-7070-718 Email: <a href="mailto:info@spmmedicare.com">info@spmmedicare.com</a> Web Site: <a href="http://www.spmmedicare.com">www.spmmedicare.com</a>	<b><u>AUTHORIZED REPRESENTATIVE</u></b> <div style="border: 1px solid black; display: inline-block; padding: 2px; margin-bottom: 5px;">EC REP</div> MEDDEVICES LIFESCIENCES B. V. Kraijenhoffstraat, 482, 1017 EG Amsterdam, Netherlands. Customer Care No.: +31 202254558 Email: <a href="mailto:info@meddevices.net">info@meddevices.net</a>

#### **EXPLANATION OF SYMBOLS**

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Symbol	Explanation	Symbol	Explanation
	Caution		Catalogue Number
	Manufacturer		Batch code
	Date & Country of manufacturer		Use-by date
	Do not re-sterilize		Temperature Limit
	Consult instructions for use		Do not use if package is damaged and consult <i>instructions for use</i>
	Keep away from sunlight		Non-Pyrogenic
	Do not re-use		Sterilized using EO
	This side up		Handle with care
	Do not use hook		Maximum stacking
	Medical Device		Model number
	Unique Device Identifier		Single Sterile Barrier System
	Single Sterile Barrier System with protective packaging outside		Sterile
	Authorized representative in the European Community		Keep dry

		
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Symbol	Explanation	Symbol	Explanation
	Biological risks		Recycling

		
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