IFU of IV Administration Set

Manufactured by Mais India Medical Devices Pvt. Ltd.

General Device Description: The IV administration set is a medical device used to deliver fluids, medications products directly into a patient's bloodstream via intravenous infusion. It typically consists of flexible tubing connected to a fluid container through spike, with features such as drip chambers for monitoring flow rate, needle or micro-needle, tubing, is with or without air vent, flow regulator, connector and filter to ensure controlled fluid delivery. IV Administration Set is used in an aseptic environment. The use of the product is restricted to a qualified doctor or a paramedic.

Product Name: IV Administration Set.

Brand Names: MAISFUSION SET

Variants: (as Applicable)

1. IV Administration Set.
2. IV Administration Set with Y-Site.
3. IV Administration Set with micro drip.
4. IV Administration Set with flow Regulator.
5. IV Administration Set with integrated Three way stop cock.
6. IV Administration Set with flow Regulator with micro needle
7. IV Administration Set with Filter 0.2 micron

Type: (as Applicable)

1. Latex Free
2. DEHP Free
3. Vented/Non-Vented

Intended Use:
IV Administration Set is used for the Intravenous therapy in which drug is directly infused in the veins. The piercing Spike (distal end of I.V. Set) is inserted into the liquid container.

Material of construction: (as Applicable)
Polyvinyl chloride (PVC), Acrylonitrile Butadiene Styrene (ABS), Polycarbonate (PC), Polyethylene (PE), Polypropylene (PP), Is propene & Hi-density Polyethylene (HDPE), Acrylic Copolymer Membrane, LLDPE, Isoprene & Stainless Steel.

Indications:
The IV Administration Set is indicated for:

- Parenteral administration of IV fluids (saline, dextrose, Ringer's lactate, etc.).
- Delivery of intravenous medications and pharmacological agents.
- Nutritional support via parenteral nutrition solutions.
- Electrolyte replacement and fluid resuscitation.
- Pre-operative, intra-operative, and post-operative fluid management.

Contra-indications:
The IV Administration Set is contraindicated in the following situations:

- Administration of blood or blood products through a standard fluid administration set not labelled for blood transfusion.
- Use with infusion pumps for which the set is not validated — always verify pump compatibility
- Product should not be used in patients with known Hypersensitivity to any of the materials used.
- Product not to be used with Photosensitive and Chemotherapy Drugs.

Intended Patient Population:
Adult, paediatric, and neonatal patients requiring intravenous infusion.

Intended User:
Qualified doctor or a paramedic.

Use environment:
Proper healthcare setup.

Size specifications:
Standard.

Instruction for use:

- Inspect the packaging and device for damage. Do not use if the package is open, damaged, or expired.
- Ensure compatibility of the IV Administration Set with the prescribed fluid container.
- Perform hand hygiene and follow aseptic techniques throughout the procedure.
- Close the flow regulator or roller clamp. Remove protective cap from plastic spike without touching the sterile tip& insert the spike completely
- Fill the drip chamberuntil it is half filled.
- Open the flow control device to allow fluid to fill the tubing and expel air completely.
- Remove needle protector holding needle upright.
- Close the flow regulator.
- For integrated three-way stopcock, the molded arrows on the handles indicate the open flow paths in relation to the 3 ports. Turning the stopcock handle to the intermediate position can close all fluid paths.
- For Flow Regulator, Turn the dial or move the slider to the desired flow rate as prescribed by a qualified healthcare professional. After setting the flow rate, monitor the drip chamber and the patient to ensure the fluid is flowing correctly and the patient is tolerating the infusion
- Disinfect the Y-site, for a secondary medication administration or simultaneous infusion of a compatible drug without disconnecting the primary infusion line.
- Connect the distal end of the tubing to the patient's intravenous access device using aseptic technique or Perform vein-puncture holding needle uprightand regulate flow by opening flow regulator gradually to achieve the desired flow rate.
- Once the infusion is complete, Close the flow control device and disconnect the administration set from the patient using aseptic technique.
- Dispose of the used set according to hospital policy and local biomedical waste regulations.

Intended Clinical Benefits to the patients:

- Controlled, safe, and reliable delivery of intravenous fluids and medications directly into the bloodstream
- Enables precise regulation of flow rate via the roller clamp regulator /flow Regulator.
- The drip chamber allows visual monitoring of the infusion rate without interrupting therapy
- Inline filter (where fitted) reduces the risk of particulate matter and air entering the venous system
- Closed-system design minimises microbial contamination and air embolism risk
- Supports rapid fluid resuscitation in emergency scenarios
- Y site acts as an additional site for secondary infusion without disconnecting the primary infusion line
- Integrated three-way stopcock allows efficient switching between simultaneous different IV lines without leakage or interruption of flow.
- The air vent allows air to enter the container, preventing vacuum formation and ensuring smooth fluid flow.

Clinical Safety:

- IV Administration Set forms a closed system between the fluid container and the patient's bloodstream. This barrier prevents airborne contaminants, skin flora, and other environmental pathogens from entering the fluid pathway.
- The spike is designed to firmly (but safely) engage with the port of the IV fluid bag or bottle, minimizing the risk of dislodgement and contamination.
- Injection Port/Y-Site allow for the safe and sterile intermittent injection of additional medications or secondary infusions without requiring disconnection of the primary line
- Biocompatible product, made with non- toxic and non-pyrogenic material.

Performance characteristics:

- Brings about the immediate treatment effect of the drug-infused into the patient.
- Provides accuracy for measurement of flow rate for rapid infusion i.e. 20 drops= 1ml.
- The tubing of the IV Administration Set is kink resistant that allow uninterrupted infusion.
- Drip Chamber provided with 15-micron filter to trap particulate matter.
- Compatible with all Infusion devices with 6% taper.

Accessories which can be used with the device:
IV Administration Set can used along with the connecting accessories such as I.V. Cannula and other infusion devices.

Warnings:

1. The use of this product is restricted to a qualified doctor or a paramedic
2. Read instructions before use.
3. MAIS INDIA disclaims any responsibility for possible consequences resulting from improper use.
4. The product should not be reprocessed.
5. Visually inspect and carefully check the product and packaging before use.
6. Improper transport and handling may cause structural and/or functional damage to device or packaging.

7. The product is non-toxic, sterile & non-pyrogenic.
8. Do not Clean or resterilise. For single use only. Discard after use.
9. Re-use of single-use devices creates a potential risk (i.e, Bloodstream infection) of patient or user.
10. If the device is reused, then it may cause bacterial infection to the patient, and also may lead to contamination and/or impairment of functional capability which may in turn lead to injury to the patient.
11. If there is any change in expected performance of the device or in case of any malfunction the device should be immediately removed & sent back to supplier for analysis.
12. Store in a cool & dry place.
13. Do not expose to heat or direct sunlight.
14. The product should be used immediately after opening the packaging.

Cautions:

- Do not use if protective caps are loose or missing.
- Do not use for blood transfusion.
- Use Y site only for injection medicine.
- Do not fill drip chamber completely.
- Do not use if package is damaged.
- Discard after single use.

Limitations:

- Duration of Use: IV administration sets are typically designed for short-term use and may not be suitable for prolonged infusion therapy. Prolonged use can increase the risk of complications such as infection, thrombosis, and tissue damage.
- Compatibility: Some medications or fluids may not be compatible with certain types of IV administration sets or materials used in their construction. Compatibility issues can affect the efficacy and safety of the infusion
- Flow Rate Accuracy: The flow rate of IV administration sets may not always be precise, leading to variations in the delivery of medications or fluids.
- Mechanical Failures: IV administration sets can experience mechanical failures such as kinks, occlusions, or disconnections, which can disrupt the flow of fluids or medications and compromise therapy.

Potential Side Effects:

- If the IV Administration Set is used for an extended period of time there are chances, phlebitis and thrombophlebitis
- Infection
- Air Embolism
- Fluid overload
- Allergic reactions like rash, difficulty breathing, and confusion.

Disposal Instructions:

The unused device can safely be disposed of as normal hospital waste in a 'Sharps' container. The used device should be disposed of as 'hospital contaminated waste'- typically incinerated or as per safe hospital practices as improper disposal can lead to bio-hazard.

Duration of use:

Short-term duration (Normally intended for continuous use for between 60 minutes and 30 days) [*Note: Generally, to be used for up to 72 hours for best performance*].

Storage Conditions:

Store in a Cool & Dry Place.
Keep away from sunlight.
Temperature: 10° C to 40° C.

Shelf life: 5 Years.

Type of Sterilization:

ETO sterilization.

Notice to Users and/ or Patients:

Any serious incident that has occurred in relation to the device, should be reported to the Manufacturer and the Competent Authority of the Member State in which the user and/or patient is established.

Explanation of symbols used:

Symbols	Title of the Symbol	Symbols	Title of the Symbol
	Consult instructions for use (Indicates the need for the user to consult the instructions for use)	CE 0123	CE Mark (CE Marking with Notified Body Number)
	Caution (To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.)		Manufacturer (Indicates the medical device manufacturer) Manufacturing Unit: 525P, Sector-37, Pace City II, Gurgaon, Haryana-122001, India. Contact Details.: +91 8527589990 Fax No.: 0124 404 7533 Email ID: info@maisindia.com Website:www.maisindia.com

Symbols	Title of the Symbol	Symbols	Title of the Symbol
STERILE EO	Sterilized using ethylene oxide (Indicates a medical device that has been sterilized using ethylene oxide)	REF	Reference number (Indicates the manufacturer's catalogue number so that the medical device can be identified)
STERILE EO	Single sterile barrier system (Indicates a single sterile barrier system)	LOT	Batch Number (Indicates the manufacturer's batch number so that the batch or lot can be identified)
2 STERILIZE	Do not re-sterilize (Indicates a medical device that is not to be re-sterilized)		Date of manufacture (Indicates the date when the medical device was manufactured)
	Do not re-use (Indicates a medical device that is intended for one single use only)		Use-by date (Indicates the date after which the medical device is not to be used)
	Do not use if packaging is damaged and consult instructions for use. (Indicates a medical device that should not be used if its packaging has been damaged or opened, and that the user should consult the instructions for use for additional information)	EU REP	Authorized representative in the European Union / European Community (Indicates the authorized representative in the European Union / European Community OBELIS S.A. Boulevard Général Wahis 53, 1030 Brussels, Belgium Contact Number: +32(2)73 25 954 Email ID: regulatory@obelis.net Website: www.obelis.net
	Keep dry (Indicates a medical device that needs to be protected from moisture)		Keep away from sunlight (Indicates a medical device that needs protection from light sources)
	Non-pyrogenic (Indicates a medical device that is non- pyrogenic)	IN	Country of manufacture (To identify the country of manufacture of products)
NOT DEHP	Indicates product that does contain the phthalate plasticizers DEHP.	MD	Medical device (Indicates the item is a medical device)
LATEX	Latex free (Indicates a medical device that is Latex free)	40°c 10°c	Temperature limit (Indicates the temperature limits to which the medical device can be safely exposed.
UDI	Unique Device Identifier (Indicates a carrier that contains Unique Device Identifier information)		Fragile, handle with care (Indicates a medical device that can be broken or damaged if not handled carefully)
20 ml	Drops per millilitre		This way up

Manufactured by:
Mais India Medical Devices Pvt. Ltd.
525-P, Sector-37, Pace City-II,
Gurgaon, Haryana-122001 (INDIA)
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EU REP **Obelis S.A.**
Boulevard Général Wahis 53, 1030 Brussels, Belgium.

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