PRODUCT NAME

INFUSION SET(IV SET)

VARIANTS & BRAND NAMES

Variants	Brand Name	Reference Number
Infusion Set With Y SITE	SAFE N Flow	T-7101
Infusion Set with Airvent	1UP Vented	T-7104
Infusion Set Non Vented	IV FLO	T-7117
Infusion Set Economy	TOP	T-7102
Infusion Set With T Shape Spike	SEF-T	T-7103
Infusion Set with Dial Flow Regulator	UMAFlOW	T-7113
Infusion Set with Micro Filter	UMAFlOW	T-7124
Infusion Set With Drip Chamber	Y MICRO	T-7105
Infusion Set With Micro Drip Chamber	Micro Drip	T-7106

GENERAL DEVICE DESCRIPTION

Infusion Set(IV Set) consists of a tubing set with sharp piercing spike for easy insertion in IV container, a drip chamber, fluid filter, one injection site, adaptor, and a flow regulator to control the flow. It is recommended to use Infusion Set(IV Set) with IV cannula. The device is a sterile and comes with drip chamber having flow rate; 20 drops/minute and 60 drops/minute.

Needle size: 16G to 23G

Length: 150cm to 250cm

INTENDED PURPOSE

Infusion Set(IV Set) is intended for intravenous infusion of IV Fluids and parenteral drugs from bags to a patient's vascular system.The device is used in gravity feed IV therapy, when an extended fluid path is required for administration.

MATERIAL OF CONSTRUCTION

COMPONENTS	PARTS	MATERIAL OF CONSTRUCTION
Drip Chamber with Spike	ABS Spike	Acrylonitrile Butadiene Styrene (ABS)
	Spike Cover	Polypropylene (PP)
	PVC Drip Chamber	Nontoxic Polyvinyl Chloride (PVC)
	Micro Drip	Stainless Steel (SS-304)
	Fluid Filter	High-Density Polyethylene (HDPE) + Nylon
	Air vent	Polyvinyl Chloride (PVC)
	Air vent Filter	Glass Fibre
PVC Tube	--	Nontoxic Polyvinyl Chloride(PVC)
Needle with cover	Needle(Cannula)	Stainless Steel (SS-304)
	Needle hub	Polypropylene (PP)
	Needle cover	Polypropylene (PP)
Flow regulator	Regulator Body	Polypropylene (PP), Acrylonitrile Butadiene Styrene (ABS)
	Rill	Polypropylene (PP), Acrylonitrile Butadiene Styrene (ABS), High-Density Polyethylene (HDPE)
Injection Site (Used as per the variant)	"Y" Site	Acrylonitrile Butadiene Styrene (ABS)-Tranparent-507, Latex Free Rubber
	Bulb Latex	Natural Rubber

COMPONENTS	PARTS	MATERIAL OF CONSTRUCTION
	Tube Latex	Natural Rubber
Adapter (Used as per the variant)	Fixed Luer Connector	Acrylonitrile Butadiene Styrene (ABS)-Tranparent-507
	Rotating Luer connector	Acrylonitrile Butadiene Styrene (ABS)-Tranparent-507
	Luer Slip	Polypropylene (PP)
Cap	Luer Lock Cap	High-Density Polyethylene (HDPE)

INDICATIONS

- The Infusion Sets are used to administer Intravenous fluid and medicines into human circulating system at controlled infusion rates
- To deliver the fluid in the patient who are unable to take through oral route
- Fluid loss related to decreased intake, surgery, vomiting, diarrhea, the patient may require IV therapy.

MEDICAL CONDITIONS

- Dehydration
- Electrolyte imbalance
- Specialized medication delivery

DURATION OF CONTACT

Short Term (Intended to be used for less than 24 Hours)

POINT OF CONTACT

Indirect contact with blood

USAGE FREQUENCY

Single use device.

INTENDED PATIENT POPULATION

This device is used for any patient population (such as neonates, pediatrics, adults and old age patients) with consideration given to adequacy of vascular anatomy and appropriateness for the solution being infused and duration of therapy.

INTENDED USER

The device is intended to be used by Healthcare professional.(Generalist medical practitioners, Specialist medical practitioners, Nursing professionals, Paramedical practitioners, emergency room staff and critical care staff).

USE ENVIRONMENT

Healthcare Setting

ACCESSORIES PROVIDED WITH THE DEVICE

- Three way Stopcock
- Scalp Vein Set

PERFORMANCE CHARACTERISTICS

- Infusion Set(IV Set) is intended for continuous delivery of IV fluids at controlled infusion rates.
- In infusion set with airvent, the air filter maintains a constant fluid level in fluid delivery tube and reduces the possibility of air entering the line when the IV bottle/bag is empty.
- The fluid filter in the Infusion Set(IV Set) is intended to filter particulates.

- Specially designed roller clamp for better flow control & precise adjustment of infusion rate.
- Kink resistant tubing
- Transparent chamber for easy visualization of flow.

CLINICAL BENEFITS

- Infusion sets allow for the controlled and precise delivery of medications or fluids into a patient's bloodstream, ensuring that the prescribed dosage is administered.
- Infusion Set(IV Set) improves patient comfort, compliance and overall experience as medication can be administered through the same site via rubber injection port and Y injection port.
- IV administration avoids the first-pass metabolism effect resulting in direct entry of electrolyte/fluid into the systemic circulation which results in immediate effect.
- The device is a sterile device which is used for intravenous infusion of IV Fluids to correct dehydration, electrolyte imbalances and to deliver medications.

CLINICAL SAFETY

- DEHP Free (Applicable only for DEHP free variants)
- Specially designed cylindrical collapsible drip chamber with bacteria barrier hydrophobic filter to visualize the flow rate.
- Provided with Y Injection Site for additional medication.
- Infusion sets are designed to be sterile single use, non-pyrogenic, non-toxic hence, reducing the risk of infection and contamination during treatment.
- The product is made of materials which are not leachable, ensuring fluid, medications are safely administered and the filter present as part of device, filter offs the unwanted substances and ensure safe infusion.

PRINCIPLE OF OPERATION

The device is used for to administer IV fluid to a patient's vascular system by gravity-controlled flow. Gravity-controlled flow in an infusion set relies on the force of gravity to deliver fluids or medications from an elevated reservoir (typically an IV bag or bottle) to a patient's bloodstream. The IV container (usually a bag or bottle) is hung above the patient's level, creating a height difference between the container and the patient. The greater the height difference, the faster the flow rate, as it increases the gravitational force. The flow rate is controlled by adjusting the height of the IV container or by using a flow rate regulator. Higher placement of the container increases the flow rate, while lowering it decreases the flow rate.

CONTRAINDICATION.

- Administration of highly viscous fluids.
- Not to be used in patients with known hypersensitivity to any of the materials used.
- It is not intended for the delivery of whole blood, blood components.
- Infusion Set(IV Set) which contains DEHP should not be used for the treatment of pregnant or nursing women, infants, or children.

KNOWN CHARACTERISTICS OF DEVICE IN CASE OF RE-USE.

- Blockage of filter or air vents.
- Any infectious disease can transfer
- Tube kink

LIMITATION

The device is not intended to be used with blood or blood components.

WARNINGS

- For single use only. Do not re-sterilize and reuse.
- Read instructions before use.
- Check expiry date prior to use.

- Not to be used for blood or blood components.
- Visually inspect and carefully check the product and packaging before use. Improper transport and handling may cause structural or functional damage to device or packaging.
- The product is guaranteed non- toxic, sterile & non- pyrogenic if the package has not been opened or damaged.
- Ensure proper disposal of product and packing after use.
- Use the product immediately after opening the individual packing.
- The product should not be reprocessed.
- Attached needle to be used for puncture of bottle and shall not be inserted into circulating blood / veins.

PRECAUTIONS

- Do not use if protective caps are detached.
- Do not use if package is damaged.
- Use rubber part only for injecting medicine.
- Discard the set after single use. Reusing can be associated with Cross infection, Device Malfunction and Reactions to endotoxins as sterilization will not inactivate toxins produced by the breakdown of Gram-negative bacteria even if the bacteria themselves are killed.
- Do not store in direct sunlight, at extreme temperature or in high humidity
- Keep away from getting wet.
- Avoid direct contact with the needle / sterile part of accessory.
- Inspect all the connections of the device before use.

DIRECTIONS FOR USE

1. Close the roller Clamp.
2. Remove the protective cap and insert the piercing device straight into the top of the bottle up to its full length.

3. Turn the bottle upside down and hang it at suitable height.
4. Squeeze the drip chamber until it is half-filled.
5. Remove needle protector. Open roller clamp and allow solution to pass until all air bubbles in the tube are removed. Now close the roller clamp.
6. Perform veni puncture and adjust the roller clamp to achieve desired flow rate.
7. Flow can be adjusted to desired flow rate by adjusting roller clamp.
8. Designed to deliver 20 or 60 drops/minute.

POTENTIAL SIDE EFFECTS/ POTENTIAL ADVERSE REACTION

- Malfunction due to leakage or blockage
- Infiltration
- Extra Vascular drug administration
- Embolism
- Allergic reactions
- tissue necrosis
- Phlebitis
- Thrombophlebitis & blistering
- Hematoma
- Infection

STERILIZATION

The device is a single use device supplied in a sterile condition and it is sterilized by ETO Sterilization Method.

PACKAGING

For Primary Packaging: HM printed bag/ Ribbon pouch/Paper Pouch/Soft Blister

For Secondary Packaging: Inner Box, and Poly Bag

For Tertiary Packaging: Carton (Corrugated box)

STORAGE CONDITION

Store in cool and dry place. Protect from excessive heat or direct sunlight.

Humidity limit: 40% to 60 %

Temperature limit: 10℃ to 45℃

SHELF LIFE

5 years

DISPOSAL METHOD/ INSTRUCTIONS

Discard the needle in proper waste container & dispose off the product in accordance with accepted medical practice and applicable local, state and country laws and regulations for handling of bio-medical waste.

NOTICE TO THE USER AND/OR PATIENT

In the event of malfunction of the device or changes in its performance that may affect safety, or 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.

FOR FURTHER INFORMATION

For Further Information, please contact:

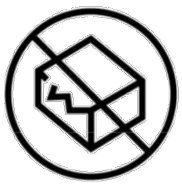
ROYAL SURGICARE PRIVATE LIMITED,

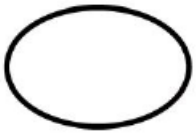
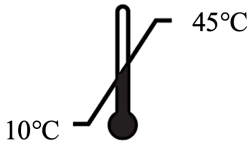
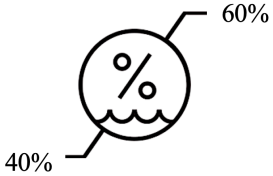
Plot No.832 Nr. Ganesh Rubber, Prima Automation Lane, Tal: Kalol, Dist.: Gandhinagar, Santej, Gujarat-382721, India

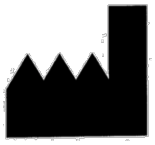
Email ID: royalsurgicare@gmail.com

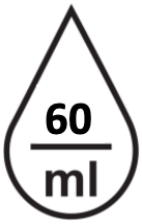
Website: http:www.umaflowindia.com

SYMBOLS AND DESCRIPTION

Symbol	Description	Symbol	Description
	**Medical Device** Indicates the item is a medical device		**Manufacturers Company Logo**
	**Consult Instructions For Use** Note: This symbol advises the reader to consult the operating instructions for information needed for the proper use of the device.		**Do not re-use** Single use or use only once
	**Catalogue Number** Note: This symbol be accompanied by the catalogue number relevant to the device bearing the symbol.		**Batch Code** Note: This symbol should be accompanied by the batch code relevant to the device bearing the symbol.
	**Do Not Use If Package Is Damaged** Do not use, if the packaging is compromised.		**Caution** This symbol is to denote that there some warning or precautions associated with device, which are not otherwise found on labels
	**Use-by date** Indicates the date after which the medical device is not to be used.		**Country of Manufacture** Note: This symbol is accompanied by the date that the device was manufactured. The date could be

Symbol	Description	Symbol	Description
			year, year and month, or year, month and day, as appropriate.
UDI	**Unique device Identifier** Indicates a carrier that contains Unique Device Identifier information	STERILE EO	**Sterilized using ETO** Indicates a medical device that has been sterilized using Ethylene Oxide.
	**Single sterile barrier system** Indicates Single sterile barrier system		**Temperature Limit** Indicates the temperature limits to which the medical device can be safely exposed. Storage Conditions: Temperature: 10°C to 45°C
	**Non-pyrogenic** Indicates a medical device that is non-pyrogenic.		**Keep Dry** Indicates a medical device that needs to be protected from moisture.
EU REP	**Authorized Representative in the European Community** MED DEVICES LIFESCIENCES B.V. **Address:** Keizersgracht 482 1017 EG Amsterdam, The Netherlands **Contact No.:** +31-202254558 **Email ID:**		**Humidity limitation** Indicates the range of humidity to which the medical device can be safely exposed.

Symbol	Description	Symbol	Description
	info@meddevices.net		
	**Do not resterilize** Indicates a medical device that is not to be resterilized.		**Keep Away from Sunlight** The symbol denotes the medical device that needs protection from light sources.
CE 0123	CE marking with Notified Body Number		**ROYAL SURGICARE PRIVATE LIMITED** Plot No.832 Nr. Ganesh Rubber, Prima Automation Lane, Tal: Kalol, Dist.: Gandhinagar, Santej, Gujarat-382721, India **Customer Care No.:** +91 - 9724312823 +91 - 9726865503 **Email ID:** royalsurgicare@gmail.com **Website:** http:www.umaflowindia.com
	**Latex free** (Indicates a medical device that is Latex free)		**Contains or presence of natural rubber latex**
	**Does not contain DEHP** Contains less then 0.1% Phthalates—DEHP		**DEHP** Contains or presence of phthalate plasticizers DEHP.

Symbol	Description	Symbol	Description
	**Drops per Millilitre** Indicates the number of drops per millilitre.		**Drops per Millilitre** Indicates the number of drops per millilitre.
	**Liquid filter with pore size** Indicates an infusion or transfusion system of the medical device that contains a filter of a particular nominal pore size.		**Single sterile barrier system with protective packaging outside** To indicate that there is a single sterile barrier system with protective packaging outside.