PRODUCT NAME

Blood Transfusion Set(BT Set)

BRAND NAME

UMAFLOW

VARIANTS

- Blood Transfusion Set-Economy
- Blood Transfusion Set- Standard
- Blood Transfusion Set- Y Injection Site
- Blood Transfusion Set-Vented

GENERAL DEVICE DESCRIPTION

A sterile Blood Transfusion Set (BT set) contains a long transparent tube made of polyvinyl chloride with an infusion chamber and a spike at one end for introducing blood and its derivatives into the device, and a syringe needle at the other end. Strong, bevel shaped make penetration easier. Flexible dual drip chambers facilitate visual access and quick liquid level adjustment.
Drip formation rate 20 drops = { 1.0± 0.1 ml (1.0 ± 0.1 g) } 10 cm2 area Blood filter of 200 micron.

INTENDED PURPOSE

Blood Transfusion Set(BT Set) is used to administer blood or blood components to patient's vascular system through vascular access device.

MATERIAL OF CONSTRUCTION

Components	Parts	Materials
Chamber with spike	ABS Spike	Acrylonitrile Butadiene Styrene (ABS)
	PVC Drip Chamber	Nontoxic Polvinyl Chloride(PVC)
	BT Filter	High Density Poly Ethylene (HDPE)
	Air vent	Polvinyl Chloride (PVC)
	Air vent filter	Glass Fibre

Components	Parts	Materials
PVC Tube		Nontoxic Polvinyl Chloride(PVC)
Flow Regulator	Regulator Body	Polypropylene(pp), Acrylonitrile Butadiene Styrene(ABS)
	Rill	Polypropylene(PP), Acrylonitrile Butadiene Styrene (ABS), High Density Poly Ethylene (HDPE)
Injection Site	"Y Site"	Acrylonitrile Butadiene Styrene(ABS)-Transparent, Latex Free Rubber
	Bulb Latex	Natural Rubber
	Tube latex	Natural Rubber
Adopter	Fixed Luer Connector	Acrylonitrile Butadiene Styrene(ABS)-Transparent
	Rotating Luer Connector	Acrylonitrile Butadiene Styrene(ABS)-Transparent
	Luer Slip	Polypropylene(PP)
Needle with cover	Needle(Cannula)	SS-304
	Needle Hub	Polypropylene(PP)
	Needle Cover	Polypropylene(PP)
Cap		High Density Poly Ethylene(HDPE)

INDICATIONS

- Blood Transfusion Set(BT Set) are used to administer blood or blood components to patients with acute or chronic blood loss, thrombocytopenia, haemorrhage and anaemia.

MEDICAL CONDITIONS

- Patients With Acute Or Chronic Blood Loss
- Anaemia
- Haemorrhage

- Thrombocytopenia

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, paediatrics, adults and old age patients) with consideration given to adequacy of vascular anatomy.

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

PERFORMANCE CHARACTERISTICS

- Filters are used to retain blood clots and other debris from blood components.
- Sharp spike vented for better penetration.
- Available without air-vent feature to prevent air embolism.
- Efficient flow regulator for the better flow control.

CLINICAL BENEFITS

- The device helps to provide fresh blood cells for easy transfer of oxygen to tissues.

- Maintaining blood requirement during surgery and excessive blood loss.
- The device helps to provide blood for patients with severe anaemia and bleeding to ensure proper blood circulation.
- Microfilters of Blood transfusion set(BT Set) reduces the risk caused by small blood clots, plaques, and degenerated platelets during transfusion.
- Blood transfusion set are used for safe and easy transfusion of blood and blood components in indicated patients vascular system

CLINICAL SAFETY

- DEHP Free (Applicable only for DEHP free variants)
- Blood transfusion set (BT set) reduces the risk caused due to small blood clots, debris, and degenerated platelets.
- The medical-grade PVC tubing's provide a soft, transparent, and flexible means for users to detecting any air bubbles.
- It is a single use, non-pyrogenic, sterile disposable device.
- The product is made of materials which are not leachable, ensuring blood is safely administered and the filter present as part of device, filter offs the unwanted substances and ensure safe transfusion.

PRINCIPLE OF OPERATION

The device is used to administer blood to a patient's vascular system by gravity-controlled flow administration method

- **Gravity-controlled flow:** Gravity-controlled flow in a blood transfusion set relies on the force of gravity to deliver blood from an elevated reservoir (typically an blood bag or bottle) to a patient's bloodstream. The 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. Higher placement of the container increases the flow rate, while lowering it decreases the flow rate.

CONTRAINDICATION

- Administration of highly viscous.
- It is not intended for delivery of drugs and IV Fluids.
- Do not use in patients with known hypersensitivity to any of the materials used.
- Do not use if there is inflammation or infection present at the insertion site.
- Blood Transfusion Set (BT Set) which contains DEHP should not be used for the treatment of pregnant or nursing women, infants, or children.

LIMITATION

Use for blood transfusion only.

WARNINGS

- Do not use if packaging or product is damaged or contaminated or if protective caps are loose or missing.
- Re-use of device creates a potential risk to patient or user.
- It is recommended not to use the supplied needle for vein puncture during blood transfusions.

PRECAUTIONS

- Device should be immediately used after the opening of the package.
- Do not store in direct sunlight, at extreme temperature or in high humidity.
- Monitor all connections for tightness over the whole transfusion procedure.
- This product is sterilized for single use only, discard after single use. Please do not repeat sterilization, do not clean, do not reuse.

DIRECTIONS FOR USE

1. Check valid period and completeness of product before use.
2. Open the package from the peel side and take out the product.
3. Take of the protective cap, close the flow regulator and insert the spike into the blood bag.

4. Fix the cone fitting with the needle firmly to make sure there is no blood leakage.
5. Release the flow regulator, the blood flows into the tube and exhaust air completely, close the flow regulator.
6. Operate normal venous puncture, open the flow regulator and do blood transfusion as required.
7. After transfusion, pull out the needle and insert it into the empty bottle which has done the transfusion before.

POTENTIAL SIDE EFFECTS/ POTENTIAL ADVERSE REACTION

- Local and systemic infection
- Intravascular and extravascular hemolysis
- Febrile non-hemolytic complications
- Urticaria & Purpura
- Edema
- Allergic reaction
- Embolism
- Leakage
- Particle contamination and kinking
- Mechanical hemolysis and bacterial 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 Bag, Ribbon Pouch, Paper pouch, Soft Blister

For Secondary Packaging: Poly Bag, FBB Box(when primary packaging is paper pouch & Soft Blister)

For Shipper 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

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:

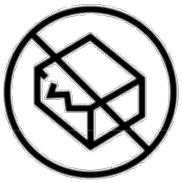
ROYAL SURGICARE PRIVATE LIMITED,

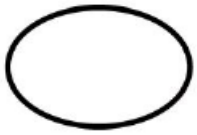
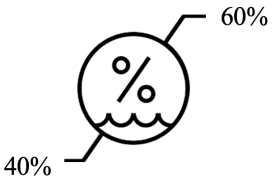
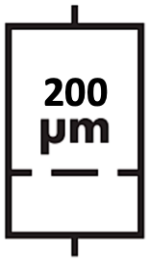
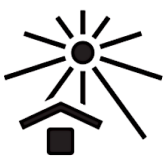
Plot No.832 Near Ganesh Rubber, Prima Automation Lane, Santej-382721, Ta: Kalol, Dist.: Gandhinagar (Gujarat) India

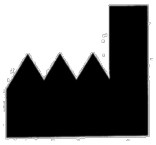
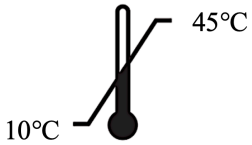
Email ID: royalsurgicare@gmail.com

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.	 MM/YYYY	**Country of Manufacture** Note: This symbol is accompanied by the date that the device was manufactured. The date could be year, year and month, or year, month and day, as appropriate.
	**Unique device Identifier** Indicates a carrier that contains Unique Device Identifier information		**Sterilized using ETO** Indicates a medical device that has been sterilized using Ethylene Oxide.

Symbol	Description	Symbol	Description
	**Single sterile barrier system** Indicates Single sterile barrier system		**Single sterile barrier system with protective packaging outside** To indicate that there is a single sterile barrier system with protective packaging outside.
	**Drops per Millilitre** Indicates the number of drops per millilitre.		**Humidity limitation** Indicates the range of humidity to which the medical device can be safely exposed.
	**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.		**Non-pyrogenic** Indicates a medical device that is non-pyrogenic.
	**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:** info@meddevices.net		CE marking with Notified Body Number
	**Keep Away from Sunlight** The symbol denotes the medical device that needs protection from light sources.		**Keep Dry** Indicates a medical device that needs to be protected from moisture.

Symbol	Description	Symbol	Description
	**Do not resterilize** Indicates a medical device that is not to be resterilized.		**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 - 97268665503 **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.
	**Temperature limit** Indicates the temperature limits to which the medical device can be safely exposed. Storage Conditions: Temperature:10°C to 45°C		