IFU of Blood Transfusion Set

Manufactured by Mais India Medical Devices Pvt. Ltd.

General Device Description: The Blood Transfusion Setis a sterile, single-use device designed for the safe and controlled transfer of blood or blood components from a blood bag to a patient. It consists of a spike, drip chamber, tubing, flow Regulator with roller body, a patient-end needleand integrated blood filter to remove clots and debris. The Blood Transfusion Set ensures precise flow control, maintains sterility, and minimizes risks such as contamination or haemolysis. The Air vent (with a hydrophobic filter) present in Vented Blood Transfusion set allows controlled entry of sterile air ensures smooth, uninterrupted flow while maintaining sterility and preventing air entry.

Product Name: Blood Transfusion Set

Brand Names: Blood Transfusion Set

Variants:

1. Blood Transfusion Set (Vented)
2. Blood Transfusion Set (Non-Vented)

Intended Use:

Blood Transfusion Set is used to administer blood from a container (plastic bag or glass bottle) to a patient's vascular system through a needle or catheter inserted into a vein.

Material of Construction:

Component		Material	Nature of Contact (Direct or Indirect contact)	Duration of Contact
Drip chamber with Filter & Spike (Vented or Non-Vented)	Spike Cover	(Polypropylene) PP	Does not come in direct or indirect contact with human body	Short-term
	Drip Chamber	Polyvinyl Chloride (PVC)		
	BT Filter	NYLON+ABS		
	Spike	ABS		
	Hydrophobic Filter (For vented)	(Polypropylene) PP Paper		
	Air vent Cap (For vented)	LLDPE		
TUBE(Length:150 cm, ID-2.8, OD-3.8)		Polyvinyl Chloride(PVC)	Does not come in direct or indirect contact with human body	Short-term
Regulator with roller body (Standard in Red)	Roller body Roller	Acrylonitrile butadiene styrene (ABS)	Does not come in direct or indirect contact with human body	Short-term
Latex Free Bulb		ISOPRENE	Does not come in direct or indirect contact with human body	Short-term
Male Luer Slip		Acrylonitrile butadiene styrene (ABS)	Does not come in direct or indirect contact with human body	Short-term
Needle with hub & cover (18 G in red)	Needle with Hub	SS 304+ PP	Direct Contact with circulating blood	Short-term
	Needle Cover	(Polypropylene) PP	Does not come in direct or indirect contact with human body	Short-term

Indications:

Blood transfusion set is a disposable medical device indicated for the transfusion of whole blood, red blood cells, platelets, plasma, or other blood derivatives, as prescribed by a healthcare provider.

Contra-indications:

- Product should not be used in patients with known Hypersensitivity to any of the materials used.
- Product not to be used for infusion of medications, Photosensitive and Chemotherapy Drugs.
- The device is not suitable for use with infant and pregnant women if device label does not claim DEHP-free.
- If "DEHP Free" is not claimed on the unit pack of device it means, the device should not be considered as Phthalates free during intended use.

Intended Patient Population:

All Patient age groups such as – Neonates, Paediatrics & Adults.

Intended User:

Qualified doctor or a paramedic.

Use environment:

Proper healthcare setup.

Instruction for use:

1. Verify package integrity and Remove Set from Package with clean and sanitized hands.
2. Close the flow regulator and Prepare Blood Container.
3. Remove the spike Cover and insert the spike firmly into the blood container port without touching sterile surfaces.
4. Ensure the vent is opened to allow proper air entry and continuous flow.
5. Squeeze the drip chamber to fill it halfway.
6. Open the roller clamp briefly to prime the tubing and expel all air, then close the clamp once priming is complete.
7. Remove the needle protector and connect the needle using sterile technique.
8. Adjust the roller clamp to regulate the desired flow rate and monitor the patient
9. After transfusion, close the clamp, disconnect the set, and dispose of all components in accordance with biomedical waste regulations.

Intended Clinical Benefits to the patients:

- Ensures Safe,Faster & Controlled Transfusion
- Built-in Filter Improves Patient Safety
- Maintains Sterility Throughout Transfusion
- Compatible with Blood Components
- Drip Chamber and flow Regulator Improves Flow Accuracy
- Air-Vent Options Improve Ease of Use and Proper Flow
- Reduces Risk of Air Embolism.

Clinical Safety:

- Preventing Transfusion-Related Risks and Complications.
- Device Design and Material Safety.
- Biocompatible products,
- our device is a single use deviceto Avoid Cross-Contamination,
- Filtration of Clots and Particulates.
- our product is non-toxic, sterile & non-pyrogenic.

Performance characteristics:

- Flow Rate Control.
- Priming and Air Venting.
- Sterility and Infection Control.
- Filtration Efficiency
- Biocompatibility
- Leak Resistance
- Tensile Strength and Durability
- Haemolysis Prevention
- Compatibility with Blood Bags
- Resistance to Kinking

Accessories which can be used with the device:

Blood Transfusion Set does not have any accessories provided along with the device but It is to be used with a blood bag, which serves as the source of the blood component to be transfused.

Warnings:

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

• The product is non-toxic, sterile & non-pyrogenic.
• Do not Clean or resterilized. For single use only. Discard after use.
• Re-use of single-use devices creates a potential risk (i.e, Bloodstream infection) of patient or user.
• 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.
• 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.
• Store in a cool & dry place.
• Do not expose to heat or direct sunlight.
• The product should be used immediately after opening the packaging.

Cautions:
• Do not use if package is damaged.
• Discard after single use.

Limitations:
• Duration of Use: Blood Transfusion 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.
• Transfusion and allergic Reactions: Despite careful screening and testing, transfusion reactions can still occur, ranging from mild allergic reactions to life-threatening haemolytic reactions.
• Volume Limitations: Blood transfusion sets have a limited capacity, which may restrict the volume of blood or blood products that can be administered in a single transfusion. This can be a limitation in cases where large volumes of blood are needed, such as in massive haemorrhage scenarios.
• Temperature-related effects: Cold blood can cause chills or discomfort if not warmed appropriately (the set itself doesn't regulate temperature).

Potential Side Effects:
• Infection risk
Not from the sterile set itself, but from breaks in aseptic technique during setup or connection.

• Flow obstruction
Clots trapped in the filter can cause slow or halted flow, which may lead to delayed therapy.

• Leakage or disconnection
Improper connections between tubing, needle, or blood bag ports can lead to spills or contamination

Disposable instructions
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 of 04 hours for best performance)

Storage Conditions:
Store in a Cool & Dry Place.
Keep away from sunlight
Temperature: +10℃ to +40℃
Humidity: 50 ± 10%

Shelf life:
5 Years

Life Time:
Once uses started, normally intended for continuous use of 04 hours.

Type of Sterilization:
EO 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)		Latex free (Indicates a medical device that is Latex free)
	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.)		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)
	Sterilized using ethylene oxide (Indicates a medical device that has been sterilized using ethylene oxide)		Single sterile barrier system (Indicates a single sterile barrier system)

Symbols	Title of the Symbol	Symbols	Title of the Symbol
	Date of manufacture (Indicates the date when the medical device was manufactured)		Use-by date (Indicates the date after which the medical device is not to be used)
	Reference number (Indicates the manufacturer's catalogue number so that the medical device can be identified)		Batch Number (Indicates the manufacturer's batch number so that the batch or lot can be identified)
	Do not re-sterilize (Indicates a medical device that is not to be re-sterilized)		CE Mark
	Do not re-use (Indicates a medical device that is intended for one single use only)		Keep away from sunlight (Indicates a medical device that needs protection from light sources)
	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		Authorized representative in the European Community / European Union (Indicates the authorized representative in the European Community / European Union) 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)		Non-pyrogenic (Indicates a medical device that is non- pyrogenic)
	Unique Device Identifier (Indicates a carrier that contains Unique Device Identifier information)		Medical device (Indicates the item is a medical device)
	Humidity limitation (Indicates the range of humidity to which the medical device can be safely exposed.		Temperature limit (Indicates the temperature limits to which the medical device can be safely exposed.
	Fragile, handle with care (Indicates a medical device that can be broken or damaged if not handled carefully)		Country of manufacture (To identify the country of manufacture of products)
	This way up		Drops per millilitre
	Indicates product that does contain the phthalate plasticizers DEHP.		Contains or presence of phthalate plasticizers DEHP

Manufactured by:
Mais India Medical Devices Pvt. Ltd.
525-P, Sector-37, Pace City-II,
Gurgaon, Haryana-122001 (INDIA)

EC REP **Obelis S.A.**
Boulevard Général Wahis 53, 1030 Brussels, Belgium.

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