BLOOD TRANSFUSION FILTER

Instructions for Use

READ ALL PRECAUTIONS AND INSTRUCTIONS CAREFULLY PRIOR TO USE

INTENDED USE

Blood transfusion filter is used for filtration of blood and transfusion. The blood transfusion filter serves as a meticulous gatekeeper during the journey of blood from donor to recipient.

INDICATION

Removes clots, Micro aggregates and particulate debris from Blood and High filtering capacity designed for the administration of multiple blood. Hold-up volume is Just 4 ml.

DESCRIPTION

The Blood Transfusion Filter is used for the removal of Micro aggregates, Particulate Debris & Clots. It comes EtO Sterilized & non-pyrogenic and is disposable.

- Depth filtration maximizes flow & throughput
- Traps at surface the Micro aggregate, clots & particulate debris and also through the media
- Hard spike allows easy penetration of Blood Bags
- Meets emergency situations by handling multiple units of blood with high flow rates
- The integrated administration set quickens setup
- Very low held-up volume maximizes recovery

DEVICE COMBINATION

The device includes tubing, a flow regulator, a drip chamber, an infusion line filter and a hollow spike to penetrate and connect the tubing to a pouch.

PRECAUTIONS

- Use aseptic technique
- The product must be used only by the trained and qualified medical personnel.
- Do not use if package is open or damaged.
- For single use only. Do not re-sterilize or reuse it.
- Open the cover and take out the product.
- In blood bag, open the membrane port protective covering. Remove the spike cap and spike the BTF into the port. Spike the Intravenous line into the Siliconadapter.

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- Keep the filter in a position that blood bag at the bottom side and filter at thetop.

  Slowly squeeze the blood for air removal.
- The drip chamber should never be squeezed.
- The filter should not be flushed with saline after filtration
- The cap on the drip chamber must not be loosened or removed during the transfusion.
- After air removal, hang the blood bag in the stand and allow the drip chamberlevel

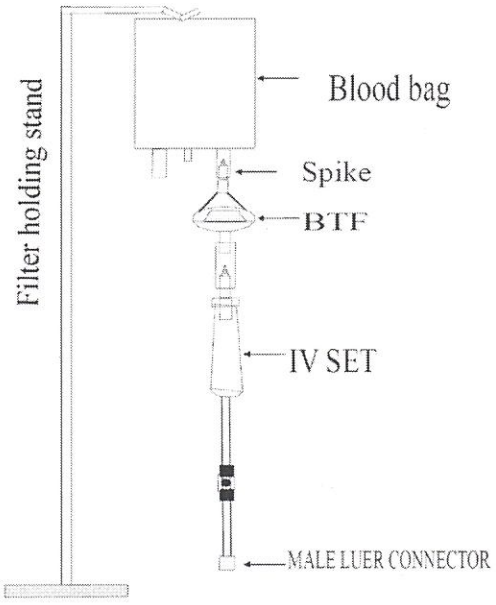
  to fill then adjust the flow rate of the blood-using controller.

SETUP OF BLOOD TRANSFUSION FILTER

1. Prepare Set and Blood Bag.
   - Gently shake the blood bag and suspend it on the stand.
   - Ensure the vented spike is firmly closes.
   - Close the upstream filter clamp and ensure the protective cap is hanging free.
   - Close administration set roller cap.
   - Insert the spike into blood bag using a twisting motion.

2. Prime Filter and Administration Set.
   - Open the filter clamp.
   - Allow the filter and drip chamber to prime under gravity.

3. Blood Cell Recovery.
   - On completion of the transfusion, open vented spike and allow upstream side of the filter to drain.



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WARNING

Do not allow the reservoir to empty as this could deliver air to the patient. Gas emboli are hazardous to the patient.

If leaks are observed during priming and/or operation, this may result in air embolism to the patient and /or fluid loss. Do not use the device if these conditions are observed.

CONTRAINDICATIONS

A standard blood filter needs to be changed every 12 hours; however, if there is a noticeable slowing down in the blood flow rate, you can change the filter earlier than 12 hours.

If a filter for infusion of red blood cells, do not use it again for infusing platelets. The trapped red blood cells in the filter may block the effective filtration of platelets.

To prevent the blockage in the flow of blood in the filter, you can flush the standard blood filters with normal saline.

We can use each standard blood filter for up to 4 units of blood. Thus, changing the filter could be affected when 12-hour use has been reached or when it has been used for four units of blood, whichever comes first.

DISPOSAL METHOD

The used device must be disposed of as per local regulatory requirements and corresponding hospital disposal procedures for biohazard materials.

CONNECTION OF DEVICES

The Blood transfusion filter is connected from Storage blood bag to the patient through tubing as per the custom circuit prescribed by the individual hospitals.

STERILITY

Three years from the sterilization date. Sterile if the package is not damaged.

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Manufacturer Information

Medihub Sciencetec Private Limited.,

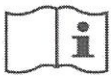
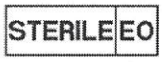
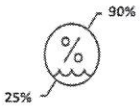
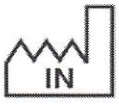
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Email: enquiry@spictra.com

Information on Symbols

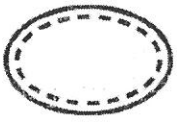
	**Do not resterilize** Indicates a medical device that is not to be resterilized.		**Use-by date** Indicates the date after which the medical device is not to be used
	**Consult Instructions for Use** Indicates the need for the user to consult the instructions for use.		**Do not re-use** Indicates a medical device that is intended for one use or for use on a single patient during a single procedure.
	**Sterilized using ethylene oxide** Indicates a medical device that has been sterilized using ethylene oxide.		**Batch Code** Indicates the manufacturer's batch code so that the batch or lot can be identified.
	**Temperature Limits** Indicates the limit of temperature to which the medical device can be safely exposed.		**Humidity limitation** Indicates the range of humidity to which the medical device can be safely exposed
	**Date of Manufacture along with Country of manufacture** Indicates the date when the medical device was manufactured.		**Keep away from Sunlight** Indicates a medical device that needs protection from light sources.

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	**Manufacturer** **Medihub Sciencetec Private Limited.,** Plot no.4, NH-7, MMDA Industrial Estate, Maraimalainagar-603 209 Tamilnadu, India. **Telephone No.:** 044-47400484. **Website:** www.spictra.com **Email:** enquiry@spictra.com		**Caution** Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	**Fluid Path** Indicates the presence of a fluid path		**Single sterile barrier system with protective packaging inside** Indicates Single sterile barrier system with protective packaging inside
	**Medical Device** Indicates the item is a medical device		**Do not use if package is damaged** Indicates a medical device that should not be used if the package has been damaged or opened.
	**Non-pyrogenic** Indicates a medical device that is non-pyrogenic		**Keep dry** Indicated a medical device that needs to be protected from moisture
	**Model number** Indicates the model number or type number of a product.		

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