CE 0123

ARTERIAL LINE BLOOD FILTER
(ARTERIAL BLOOD FILTER)

Instructions for Use

READ ALL PRECAUTIONS AND INSTRUCTIONS CAREFULLY PRIOR TO USE

Spictra

PRODUCT NAME
Arterial Line Blood Filter
BRAND NAME
Spictra
DESCRIPTION
The arterial blood filter for extra corporeal circuit is for use during open Heart surgery (<6 hours). It comes ETO sterilized & non-Pyrogenic and is disposable. It removes micro emboli greater than 40 m in size. Including gas emboli. Fat emboli, aggregates, and other surgical debris, from entering the artery.
This IFU is applicable to all the models of Arterial blood filter with bypass loop supplied by us.
INTENDED PURPOSE
Arterial Blood filter is use for removal of air micro aggregates. Surgical debris & particles, without any damage to the blood components.
INTENDED USER PROFILE
This product must be used by perfusionist, cardiac surgeon or other trained and qualified medical professional only.
INTENDED PATIENT POPULATION
Applicable for patients undergoing cardiopulmonary bypass.
INDICATION
The Arterial Blood Filter is indicated for use in open heart surgeries to remove emboli, aggregates and other surgical debris from entering the artery for uninterrupted blood flow.
DURATION OF CONTACT
<6 hours
USE ENVIRONMENT
Arterial Blood Filter is used in surgical settings such as operating rooms in hospitals, clinics.
PRINCIPLE OF OPERATION

- A sterile, porous device intended to be used in the arterial line of an extracorporeal circuit, during a cardiopulmonary bypass procedure, to trap and remove potentially harmful gaseous emboli, aggregated blood constituents, and particulate matter (e.g., greater than 40 microns) to prevent them from flowing into the bloodstream and obstructing extracorporeal circulation.

DEVICE COMBINATION

- During cardiac surgery, the function of the heart & lung will be taken over by the Heart – Lung machine.
- Deoxygenated blood will be taken up by the Arterial cannula from the aorta. The arterial cannula is connected to bubble trap which traps the bubbles and the blood is transferred to the oxygenator for blood oxygenation.
- The Cardioplegia device is connected to the Cardioplegia cannula which is used to deliver the Cardioplegia solution to the surgery site.
- The Hemoconcentrator is connected to the heart lung machine which is used to maintain the haematocrit level. The blood moves to the Arterial blood filter and then the blood in the oxygenator enters the venous reservoir & the blood is oxygenated and transferred to the heart lung machine and oxygenated blood is given back to the patient.
- Our products are designed such a way that match the product specification of the connected devices & are compatible with the devices used in the circuit

CLINICAL BENEFIT
The device used in cardiopulmonary surgery ensures patient safety by effectively preventing fatal air bubbles, reducing the risk of embolisms and enhancing surgical outcomes.
PERFORMANCE CHARACTERISITCS

- Arterial Blood filter is use for removal of air micro aggregates, surgical debris & particles, without any damage to the blood components.
- It is easy to handle during medical procedures.
- Arterial Blood filter has effective filtration system.
- Extra corporeal Blood just before entry into the arterial system is passed through the device
- The blood passes through a multi stage filtration system consisting of depth and screen media in the arterial blood filter .
- The filtered blood is pumped into the arterial system from the outlet port using heart lung machine.

POTENTIAL SIDE-EFFECTS
The concerned product is not associated with severe or adverse life threatening side-effects. However, the precautions and contraindication are clearly mentioned in IFU of the product.
USABILITY & INFORMATION HAZARDS

- Use of the device under improper environmental conditions leads to clinical malfunctions such as injury to patient.
- Reuse or Re-sterilization of the Product leads to adverse events such as infections & cross contamination
- Improper combination or misassembled device with other connecting device leads to performance failure.

LIMITATIONS
Arterial Blood filter is limited to use for removal of air micro aggregates, surgical debris & particles, without any damage to the blood components during CPB (Cardio Pulmonary Bypass) therapy.Proper handling is essential to mitigate these limitations and ensure patient safety during surgical procedures.
PRECAUTIONS

- Tubing should be attached in such a manner as to prevent kinks or restrictions that may alter blood flow and build pressure inside.
- All blood tubing connections should be banded to get firm engagement as fluid pressures are high.
- In a three-way stopcock one line should be installed to monitor the pressure drop during the use and another line for air outlet and recirculation to the Membrane oxygenator venous reservoir or the Bubble Oxygenator.
- The device should be installed in the arterial line with a bypass line. So that the bypass line can be diverted in case the pressure drops in the filter is high.
- Ensure that the extra corporeal circuit has been de bubbled prior to CPB.
- This Arterial Blood Filter must be used only by a trained and qualified medical perfusionist.
- For single use only. Do not re-sterilize or reuse it.
- Do not use if package is open or damaged.

- The device is used in combination with other medical device. The surgeon can use MediHub's or other company's combination device. The surgeon using the device in combination with MediHub product or other company's product should be well trained & experienced for proper use of the device.
- Do not exceed the blood flow rate more than 8 LPM.

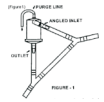
WARNING

- The use of certain solvents may compromise the integrity of the device.
- Gas emboli must be cleared from the extracorporeal circuit before initiating bypass. 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. The extracorporeal circuit must be continually monitored. Do not use the device if these conditions are observed.

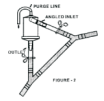
CONTRAINDICATIONS
This device used for any other purposes than for the indicated use is the responsibility of the user.
PRODUCT SPECIFICATION

Device	Model	Priming Volume, (ml)	Max Blood Flow Rate (LPM)	Filter size
Arterial Blood Filter	Adult	120	8	40

SETUP OF THE ARTERIAL BLOOD FILTER
1. Remove the device from the box and inspect visually for abnormalities i e. breach sterile barrier, cracks, broken ports, etc. WARNING: DO NOT USE IF APPEARANCE IS ABNORMAL.
2. Using aseptic technique and ensuring the sterile fluid path is maintained, connect the arterial blood filter and the arterial line. WARNING: CHECK FOR PROPER DIRECTION OF FLOW.
3. Place the arterial blood filter securely into its holder.
4. A filter bypass line should be used to facilitate priming and to provide an alternate blood flow path around the arterial blood filter. (Figure1)
5. It is recommended that a purge line with stopcock and one way valve to be used to vent the Arterial line filter. (Figure1)



Warning: Always purge the arterial blood filter through the vent port to a low pressure area to prevent back flow of air through the arterial blood filter purge line.
Warning: The stopcock of the arterial blood filter purge line must be closed when the pump is stopped to prevent blood flow from the arterial side through the purge line. To prevent this purge line with one way valve may be used.
PRIMING THE ARTERIAL BLOOD FILTER
NOTE: Refer to Figures when performing the priming procedure.
1. Clamp the tubing both on the inlet and outlet sides of the device.
Fill the bypass loop and the remainder of the circuit with prime solution.(figure2)



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2. Open vent port on the arterial filter. Run the pump at low speed (100-200ml/min) and remove the outlet tubing clamp and place it below the outlet "Y" connector (figure 3). With retrograde flow, the device may be tilted and gently tapped to aid de-bubbling.

3. With pump still running at slow speed remove the clamp in inlet line & then clamp the bypass loop and remove any air trapped at the inlet. Remove outlet clamp (figure 4) and increase pump to clinical flows.

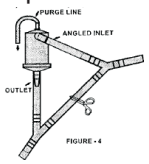


FIGURE - 4

4. Close the stop cock and invert the device. With pump running and device is inverted position, tap gently to remove any air on the outlet side of the device. Stop the pump.

5. Return the device to upright position in its holder and secure, with seating mechanism on holder.

6. Visually inspect device and be certain that device is completely de-bubbled prior to the initiation of bypass.

7. Check all connections visually inspect for leaks.

8. The filter is now ready for use.

DISPOSAL INSTRUCTIONS

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

UDI DETAILS

UDI is provided on the product label for traceability purposes.

CONNECTION OF DEVICES

Arterial blood filter is connected with the Oxygenator through polymer tubing as per the custom circuit prescribed by the individual hospitals.

USAGE FREQUENCY

This is single-use device

STORAGE CONDITION

Arterial blood filter shall be stored at 25 °C to 45°C

STERILITY STATE & METHOD OF STERILIZATION

Arterial blood filter is proposed to be marketed in sterile form. It is sterilized using Ethylene Oxide (EtO) sterilization.

SHELF LIFE

5 years

LIFETIME OF DEVICE

<6 hours

PACKING

This includes:

Product	Unit Package (Initial Packing) Cartons In nos.	Unit packing carton size (LxWxH) in cms	Bulk Package (Final Packing) Cartons in Nos	Bulk Package carton size (LxWxH) in cms
Arterial Blood Filter	3 (with loop)	20x20x32	18	62.5x41.2x36
	5 (without loop)	30x19.5x16	40	62.5x41.2x36

A NOTICE TO THE USER

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

Manufacturer Information

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

License Number: MFG/MD/2022/000710

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
STERILE EO	**Sterilized using ethylene oxide** Indicates a medical device that has been sterilized using ethylene oxide.	LOT	**Batch Code** Indicates the manufacturer's batch code so that the batch or lot can be identified.
90% 25%	**Humidity limitation** Indicates the range of humidity to which the medical device can be safely exposed	45°C 25°C	**Temperature Limits** Indicates the limit of temperature to which the medical device can be safely exposed.
EU REP	**Authorized Representative in the European Union.** Indicates the Authorized representative in the European Union. **MEDDEVICES LIFESCIENCES B.V** Keizersgracht 482, 1017EG Amsterdam, Netherlands Email: nk@meddevices.net Phone: +31202254558 Web site: www.meddevices.net		**Keep away from Sunlight** Indicates a medical device that needs protection from light sources.
IN	**Date Of Manufacture along with Country of manufacture** Indicates the date when the medical device was manufactured.		**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 medicaldevice itself.
	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		**Single sterile barrier system with protective packaging inside** Indicates Single sterile barrier system with protective packaging inside

	Do not use if package is damaged Indicates a medical device that should not be used if the package has been damaged or opened.	CE 0123	**CE marking with Notified Body Number**
UDI	**Unique Device Identifier** Indicates a carrier that contains Unique Device Identifier information		**Keep dry** Indicated a medical device that needs to be protected from moisture
	Processing container On medical devices or blood process application to indicate that the processing of final container is used for the achievement of a process	MD	**Medical Device** Indicates the item is a medical device
	Fluid Path Indicates the presence of a fluid path		**Non-pyrogenic** Indicates a medical device that is non-pyrogenic
#	**Model number** Indicates the model number or type number of a product.	40 µm	**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

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