CE 0123

CARDIOPULMONARY BYPASS CARDIOTOMY SUCTION LINE BLOOD FILTER

(CARDIOTOMY RESERVOIR/BLOOD COLLECTION RESERVOIR)

Instructions for Use

READ ALL PRECAUTIONS AND INSTRUCTIONS CAREFULLY PRIOR TO USE

Spictra

PRODUCT NAME

Cardiopulmonary Bypass Cardiotomy Suction Line Blood Filter (Cardiotomy Reservoir /Blood Collection Reservoir)

BRAND NAME

Spictra

DESCRIPTION

Cardiotomy Reservoir is a container to collect – filter – store the blood around the surgical site during the entire period of cardiopulmonary procedure.

Cardiotomy Reservoir is used for the removal of the following:

- Bone & tissue debris generated while cutting open and accessing the myocardium
- Micro emboli / foams
- Any other surgical debris

INTENDED PURPOSE

Cardiopulmonary Bypass Cardiotomy Suction Line Blood Filter is a container used for collection,filtration, defoaming and storage of blood sucked from thoracic and myocardium during CPB (Cardio Pulmonary Bypass) therapy.

INTENDED USER PROFILE

This Product must be used by perfusionist, cardiac surgeon or other trained and qualified medical professional only.

INTENDED PATIENT POPULATION

The device is intended to be used for patients undergoing cardiopulmonary bypass.

INDICATIONS

Cardiopulmonary Bypass Cardiotomy Suction Line Blood Filter is indicated in the therapy of CPB (Cardio Pulmonary Bypass) for collection, filtration, defoaming and storage of blood during extracorporeal circulation.

DURATION OF CONTACT

< 6 hours

USE ENVIRONMENT

Cardiopulmonary Bypass Cardiotomy Suction Line Blood Filter is used in surgical settings such as operating rooms in hospitals, clinics.

PRINCIPLE OF OPERATION

- Blood from the surgical site is sucked into the device through the inlet ports
- A course defoamer removes bubbles
- A depth filter removes all debris
- A screen filter removes all debris
- A fine defoamer breaks all bubbles
- A transparent container stores and displays level of filtered blood
- Delivery on demand is done through the outlet port in the container bottom

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

- The Cardiotomy Reservoir maintains specified priming volume as well as adapts to dynamic priming requirements across entire operation.
- It is easy to handle during medical procedures
- The cardiotomy reservoir is engineered to collect, filter, and store blood during CPB therapy
- Cardiotomy Reservoir has effective filtration system,
- The inclusion of a defoamer and a large air vent port enables proper air handling and minimizes foaming, enhancing the device's performance and ensuring the safe and reliable management of blood during medical interventions.

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 may cause cross contamination which leads to adverse events such as infections.
- Improper combination or misassembled device with other connecting device leads to performance failure.

LIMITATIONS

The Cardiotomy Reservoir is limited to its designated purpose of blood collection, filtration, and storage during CPB (Cardio Pulmonary Bypass) therapy.

The maximum rated negative pressure of 300 mmHg may limit its use in procedures where higher suction pressure is required.

Proper handling is essential to mitigate these limitations and ensure patient safety during surgical procedures.

PRECAUTIONS

- Store in a dry place away from extremes of temperature. Refer to package labeling for storage temperature requirements.
- A strict anticoagulation protocol should be followed, and anticoagulation should be routinely monitored during all procedures. The benefits of extracorporeal support must be weighed against the risk of systemic anticoagulation and must be assessed by the prescribing physician.
- This product must be used only by trained and qualified medical professional.
- 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 devices. The surgeon can use MediHub 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.

WARNINGS

- 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. The extracorporeal circuit must be continually monitored. Do not use the device if these conditions are observed.

CONTRAINDICATIONS

- The use of re-infused blood from the product may be contraindicated (e.g., in the presence of sepsis or malignancy). This product used for any other purposes than for the indicated intended use is the responsibility of the user.
- The safe length of time that blood may remain in this reservoir is a medical decision and may vary with each case where intra operative salvage is used.
- DO NOT USE the GAS VENTS for priming
- Do not exceed 200 mmHg pressure/vacuum when used with positive pressure/ vacuum source.Use GAS VENT to pressurize/evacuate. Close all other PORTS while pressuring /evacuating
- The position must be high enough above the oxygenator inlet to provide adequate gravity drainage to the oxygenator.

PRODUCT SPECIFICATION

Housing - Polystyrene
Weight - 530 g. Approx.
Blood Storage Capacity - 2000ml/3000ml
Blood Flow rate - 8 liters per minute, maximum
Prefilter - High Density Polyethylene (HDPE)
Filter- Polyester
Min. efficiency at 37 micron level- 95%
Defoamer - Siliconized HDPE
Max. Rated Negative Pressure - 300 mm Hg
Blood inlet port - 3 nos. 1/4"
Blood outlet port - 3/8" or 1/4"
Air vent port - One large vent for quick suction/ Venting
Priming Port -Two direct and two through filters, all provided with female luer
Sterilization Method - ETO gas Sterilization
Product Used by - 60 Months (5 Years)

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SETUP OF THE CARDIOTOMY RESERVOIR

- Firmly position the SPICTRA CARDIOTOMY RESERVOIR HOLDER TO A POLE ½ – 2" in diameter. Use the screw clamp for tightening.
- The position must be high enough above the oxygenator inlet to provide adequate gravity drainage to the oxygenator.
- Open the sealed outer pouch of the Cardiotomy Reservoir.
- Remove the Reservoir from the bag using aseptic technique.
- Examine the unit for any visual defects.
- Suction lines are covered with blue protective caps.
- Remove the blue protective caps and connect suction lines (1/4") to the sucker in let ports.
- Unused suction ports should be kept closed with its blue cap.
- Outlet is covered with redcap.
- Remove the red cap and connect a 3/8"I.D. tube to the connector. Connect the other end of this tube to the oxygenator's Cardiotomy Reservoir return inlet port.
- Mount the Cardiotomy Reservoir on the HOLDERs of that volume marking is visible Remove the protective caps from the VENTS from the TOP of the Cardiotomy Reservoir.
- Prime the cardiotomy reservoir through the priming ports if needed.
- Do not use the gas vents for priming
- Add 500 ml. of the priming fluid through the prime through filter port and wait 1 to 2 minutes till the fluid appears in the container through the filter.
- use 'quick prime port' only for speedy priming.
- solutions and drugs can be added through any of the ports on the top of the unit except the gasvent
- fluids added through quick prime ports will bypass the defoamer and filter and flow into the oxygenator return line.
- do not exceed 200mmhg pressure/vacuum when used with positive pressure/vacuum source. use gas vent to pressurize/evacuate. close all other ports while pressuring evacuating

MAXIMUM OPERATING VOLUME CAPACITY IS 2000/3000 ml.

DISPOSAL METHOD

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 process.

CONNECTION OF DEVICES

The Cardiotomy Reservoir container is connected to the Oxygenator & Heart lung machine through polymer tubing as per the custom circuit prescribed by the individual hospitals.

USAGE FREQUENCY

This is single-use device

STORAGE CONDITION

Cardiotomy Reservoir shall be stored at 25 °C to 45°C

STERILITY STATE & METHOD OF STERILIZATION

Cardiotomy reservoir 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 LDPE, HDPE cover, medical grade pouch, non-woven cloth, and cartons.

Product	Unit package carton (Initial Packing) in No.	Unit packing carton material (Initial Packing)	Bulk package carton (Master Carton) in No.	Bulk packing carton material (Master Carton)
Cardiotomy Reservoir (CR)	1	Thermocole	6	5 Ply

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

Mfg.L.No.MFG/MD/2021/000327

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.	STERILE EO	Batch Code Indicates the manufacturer's batch code so that the batch or lot can be identified.	LOT

	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 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	37 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
	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
	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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