CE 0123

CARDIOPULMONARY BYPASS HEAT EXCHANGER (MYOCARDIAL PROTECTION SYSTEM)

Instructions for Use

READ ALL PRECAUTIONS AND INSTRUCTIONS CAREFULLY PRIOR TO USE

Spictra

PRODUCT NAME
Cardiopulmonary Bypass Heat Exchanger
BRAND NAME
Spictra
DESCRIPTION
The SPICTRA Myocardial Protection System is supplied sterile. This system has been designed to instantly cool the Blood Cardioplegia mix in the ratio of 1:1 or 4:1 depending upon the delivery set configuration.
1. The oxygenated arterial blood/crystalloid mix in the proportion of:
a) one crystalloid volume to one arterial blood volume.
OR
b) one crystalloid volume to four arterial blood volume.
2. Initially, only crystalloid is used during the early stages, utilizing the tubing set with a shunt line.
3. The system facilitates controlled reperfusion.
The SPICTRA Myocardial Protection System is supplied in following variants:
1. MPS- Adult
2. MPS- Paediatric
3. MPS- Adult Without RC Line
4. MPS- Adult M20, M22, M23, M24

INTENDED PURPOSE
The Cardiopulmonary bypass heat exchanger is a device intended for the mixing, warming/cooling and delivery of oxygenated blood/cardioplegia solution in a predetermined ratio during cardiac surgery. This system ensures optimal myocardial protection and supports surgical procedures effectively.
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
The Cardiopulmonary Bypass Heat Exchanger is indicated for use in cardiac surgeries with extracorporeal circulation, where cardiac arrest is desired with continuous myocardial perfusion.
DURATION OF CONTACT
<6 hours
USE ENVIRONMENT
Cardiopulmonary Bypass Heat Exchanger is used in surgical settings such as operating rooms in hospitals, clinics.
PRINCIPLE OF OPERATION
This device utilizes a tubular metallic heat exchanger to regulate blood temperature. Blood enters through an inlet port and flows axially over the heat exchanger. Simultaneously, water flows in a counter-current manner inside the tubes, adjusting the blood temperature. The warmed or cooled blood is then mixed with cardioplegia chemicals in the delivery system tubing, ensuring proper temperature and composition for cardiac procedures.

INSTRUCTION FOR USE (To be used with or without Delivery Set)
Open the cover and mount the SPICTRA MPS in HORIZONTAL POSITION in the stand supplied (see figure1)

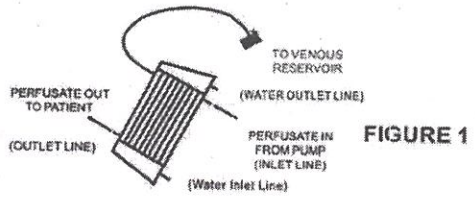

FIGURE 1

1. Connect the Purge Line with 3 ways - 100 cm extension to the Venous Reservoir.
2. Connect the temperature probe firmly in the thermowell provided.
3. Connect the Pressure line (OPTIONAL) in the port provided at the outlet connector.
4. Take delivery set and 4:1 inlet set with shunt line by opening the peel pouch and connect them to the respective INLET &OUTLET 1/4" connectors.
5. Close the clamps in the Crystalloid Cardioplegia line and pierce in both the spikes into the crystalloid Cardioplegia units. Open the clamps only while priming.
6. Connect the 1/4" Blood line in the Y Connector of the delivery set to the oxygenator outlet port.
7. Clamp the outset line and open the 3-way connector of the purge line before priming
8. Prime the lines De-air the Heat Exchanger by tilting the unit to about 30°C for complete de-airing by running the pump at 100ml/min flow rate.
9. Close the 3 ways stop cock in the purge line and open the outlet line.
10. After you had ensured total de-airing, tilt the unit back to normal. so that the unit is now vertical, as seen in Figure 2 (i.e., inlet on the top and outlet in the bottom
11. Connect the water lines from the Hyper Hypothermia unit to the 1/2" Water inlet & Outlet ports of the MPs Ensure that the water pressure does not exceed 40PSI.
12. Temperature of water input to heat exchanger exceeding 42°C get will cause blood damage.
13. Start circulating the water from Hyper-hypothermia unit only after complete priming of the unit is over. Closely observe for leaks. If any leaks are observed stop &remove the system.
14. The system is ready for use
15. The pinch Clamp in the shunt line in the delivery set should be CLOSED while delivering the Blood Cardioplegia mix and by keeping all the other clamps OPEN in the tubing set.
16. If the perfusion technique demands the delivery of only crystalloid at the beginning. Then Close the clamp in the 1/4" Line from oxygenator and keep the pinch clamp in the SHUNT LINE OPEN. Then, if the delivery of Blood Cardioplegia is desired follow step15.

During controlled reperfusion close both the clamps near the Spike in the Crystalloid line and KEEP OPEN the clamps in the SHUNT LINE & 1/4" Blood Line from the oxygenator, thus enabling the delivery of blood alone.

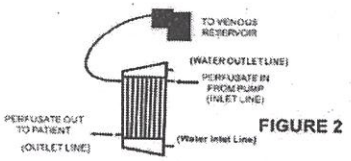

FIGURE 2

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 hematocrit 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.

PERFORMANCE CHARACTERISITCS
- The device regulates temperature of blood to be delivered to body.
- The device allows for easy mixing of blood with cardioplegia solution.

CLINICAL BENEFIT
The Cardiopulmonary bypass heat exchanger is vital for minimizing tissue damage, ensuring temperature control, providing ischemic protection, optimizing warming and cooling processes with customized perfusion, thereby enhancing surgical success.
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.
RESIDUAL RISKS
Allergic reactions ,Tissue damage, Thrombus, Hypovolemia
Systemic inflammatory response syndrome,Hypothermia,Hyperthermia, Electrolyte imbalance,Minor neurological events,Air/Gas embolism, Physiological blood damage, Ischemia, Sepsis, Deep hypothermic arrest Stroke, Hemolysis, Air entrainment, Thermal injury
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.

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LIMITATIONS

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

PRECAUTIONS

- For single use only. Do not re-sterilize or reuse it.
- Do not use if package is open, damaged or expiration date has passed.
- This product must be used only by specified intended user only.
- To stop the infusion, clamp in the infusion line and simultaneously remove the clamp on the reservoir inlet line.
- 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.
- To avoid air emboli, verify that all air is purged from all lines before infusing the patient.
- A Fully occlusive roller head pump must be used. Check the pump for proper flow direction. Fill the reservoir with adequate Cardioplegia solution
- Do not exceed a flow rate above 750ml/min.

WARNINGS

- 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.
- Test for the presence of cold agglutinins in the patient's blood prior to use. The temperature of the blood/Cardioplegia solution should never fall below the temperature at which negative cold agglutinins were determined.
- Do not allow water temperature to exceed 42 °C as physiological blood damage may occur.

CONTRAINDICATIONS

- Do not let anesthetic liquid as isoflurane, come in contact with this device as they might affect its integrity.

PRODUCT SPECIFICATION

Housing Material - Polycarbonate
Heat Exchanger Material - Anodized Aluminium
Cardioplegia Solution inlet -1/4"
Water port ½"Priming Volume 40 ml
Heat exchanger Straight tubes
Sterilization Method ETO gas Sterilization
Product Used by 60 Months (5 Years) after sterilization

SETUP OF THE MYOCARDIAL PROTECTION SYSTEM

WARNING: The setup and use of the SPICTRA Myocardial Protection System is the responsibility of the attending clinician using the device.

- Do not let anesthetic liquid as isoflurane, come in contact with this device as they might affect its integrity.
- After removing the System components from the packaging, inspect the packaging and product for damage.

DISPOSAL INSTRUCTIONS

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

UDI DETAILS

UDI is provided on the product label for traceability purposes.

CONNECTION OF DEVICES

The Myocardial Protection System is connected with the Oxygenator & Heart lung machine through polymer tubing as per the custom circuit prescribed by the individual hospitals.
Myocardial Protection System is also connected with the Hyper Hypothermia unit using the connectorsat the "Water in" and "Water out" ports and an equivalent model Y.S.I. series 400 compatible probe to the Temperature port.

USAGE FREQUENCY

This is single-use device.

STORAGE CONDITION

Myocardial Protection System shall be stored at 25 °C to 45°C

STERILITY STATE & METHOD OF STERILIZATION

Myocardial Protection System 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 carton (Initial Packing) in	Unit packing carton material (Initial Packing)	Bulk package carton (Master Carton) in No.	Bulk packing carton material (Master Carton)
Myocardial Protection System	1	Thermocole	8	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
License Number: 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
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.

25% 90%	**Humidity limitation** Indicates the range of humidity to which the medical device can be safely exposed	25°C 45°C	**Temperature Limits** Indicates the limit of temperature to which the medical device can be safely exposed.
EU REP	**Authorized Representative in the European Community** Indicates the Authorized representative in the European Community. **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		**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
	Keep dry Indicated a medical device that needs to be protected from moisture	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.		

Doc No. SPT-IFU-MPS

Revision Date: 06.08.2026

Revision No.: 04