CARDIOPULMONARY BYPASS HEAT EXCHANGER
(CARDIOPLEGIA DELIVERY SYSTEM)

CE 0123

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 Cardioplegia Delivery System consists of 2 Litre Reservoir with integrated cooling warming coil in one pack. The capacity of the reservoir is 2 liters, P.V.C. tube, polycarbonate connectors,stopcock and other specific accessories as per order configured in separate pack. This customer specific perfusion set if ordered separately will be packed with the main system. Cardioplegia chemicals and blood are delivered into a container. The mixture is filmed and flown over tubular metallic heat exchanger with counter current water flow inside the tubes. The warm/cool mixture is re-circulated and stored and displayed with levels in the container. On demand the mixture is delivered through the outlet port.
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.
PRIMING THE SYSTEM
• Remove the cap from the reservoir quick prime port. This port provides access into the reservoir for the addition of priming and Cardioplegia solutions.
• Inter connect Y connector with reservoir's outlet (TO PUMP), Inlet (FROM PUMP) and Table infusion line with 1/4" tubings
• Load the 1/4" tube connecting the Outlet (TO PUMP) and Y-connector into a roller pump head.Connect a 3-way stopcock to sampling port if you propose to do sampling.

WARNING: A Fully occlusive roller head pump must be used. Check the pump for proper flow direction. Fill the reservoir with adequate Cardioplegia solution.
CAUTION: Verify that there are no leaks. Do not use if leaks are observed.
• Initiate the roller pump at a flow rate of 50 ml/min or less.
• Keep priming the reservoir until all the air bubbles escape.
• Fill the reservoir with Cardioplegia solution to the desired level for the procedure
RESERVOIR RECIRCULATION
• Clamp the infusion line at the Y connector point.
WARNING: Ensure that the reservoir not caped.
• To recirculate the Cardioplegia solution in the reservoir, start the pump and set the pump at the desired recirculation line.
CAUTION: Do not exceed a flow rate above 750ml/min.
PRIMING THE INFUSION LINE
• Clamp the 1/4" reservoir inlet (FROM PUMP) and set the pump to 100 ml/min recirculation flowrate.
• Slowly start the pump and run all air bubbles are eliminated from the infusion line and stop the pump.
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
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
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.

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PRODUCT SPECIFICATION
Shell Material - Polystyrene
Heat Exchanger Material - Anodised Aluminium
Inlet/outlet connector of blood solution in the heat exchanger - 1/4"
Inlet/outlet connector of Water in the heat exchanger - 1/2"
Volume of heat exchanger - 2 Litre
Heat exchanger - Helical Coil
Sterilization Method - ETO gas Sterilization
Product Used by - 60 Months (5 years)

SETUP OF THE CARDIOPLEGIA DELIVERY SYSTEM
WARNING: The setup and use of the SPICTRA Cardioplegia Delivery 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 biohazard materials.

UDI DETAILS
UDI is provided on the product label for traceability purposes.

CONNECTION OF DEVICES
The Cardioplegia delivery system is connected with the Oxygenator & Heart lung machine through polymer tubing as per the custom circuit prescribed by the individual hospitals.Cardioplegia delivery system is also connected with the Hyper Hypothermia unit using the connectors at 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
Cardiopulmonary Bypass Heat Exchanger shall be stored at 25 °C to 45°C.

STERILITY STATE & METHOD OF STERILIZATION
Cardioplegia Delivery 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 No.	Unit packing carton material (Initial Packing)	Bulk package carton (Master Carton) in No.	Bulk packing carton material (Master Carton)
Cardioplegia Delivery System	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
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		**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

	Fluid Path Indicates the presence of a fluid path	CE 0123	**CE marking with Notified Body Number**
MD	**Medical Device** Indicates the item is a medical device		**Single sterile barrier system with protective packaging inside** Indicates Single sterile barrier system with protective packaging inside
UDI	**Unique Device Identifier** Indicates a carrier that contains Unique Device Identifier information		**Do not use if package is damaged** Indicates a medical device that should not be used if the package has been damaged or opened.
	Keep dry Indicated a medical device that needs to be protected from moisture	200 µm	**Liquid filter with pore size** Indicates an infusion or transfusion system of the medical device that contains a filter of a 200-micrometer pore size
	Non-pyrogenic Indicates a medical device that is non-pyrogenic	#	**Model number** Indicates the model number or type number of a product.

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