HEMOCONCENTRATOR SET
(HAEMOCONCENTRATOR)

Instructions for Use

READ ALL PRECAUTIONS AND INSTRUCTIONS CAREFULLY PRIOR TO USE

Spictra

INTENDED USE

Haemoconcentrator is used during open heart surgery for the selective separation of water and other fluids from blood using a semi permeable ultra-filtration membrane in order to increase the Hematocrit of blood.

INDICATIONS

The SPICTRA HAEMOCONCENTRATOR is to be used during or after cardiopulmonary procedure for concentration of the cells and proteins from the diluted extra corporeal circulating blood by removing fluids/over hydration. The maximum recommended duration of use is six hours

DESCRIPTION

The SPICTRA HAEMOCONCENTRATOR is supplied sterile & non - pyrogenic. They contain hollow fibers similar to those within a dialysis filter. Blood passes through the inside of hollow fibers and vacuum may be applied on the outside to encourage water removal.
It is an ultra filtration device that consists of semipermeable membrane fibers that remove plasma water and solutes. They function similarly to hemodialysis units but are simpler in that they do not requiread a dialysate solution.
Blood flows through microporous membrane fibers, and since the hydrostatic pressure is higher in side the membrane fibers,effluent fluid permeates the membrane and can be removed.
This IFU is applicable to all the models of HAEMOCONCENTRATOR with drain line supplied by us.Spictra Haemoconcentrators are made in two models with 0.7sq.mtr and 0.3sq.mtr.
The membrane pore sizes are typically less than 55,000 Da, which preserve plasma proteins such as albumin (65,000 Da) and maintain the colloid on cotic pressure.
The ultra filtration rate of a hemoconcentrator is dependent on the hydrostatic pressure gradient across the membrane, blood flow rate through the membrane fibers, membrane pore size, and the hematocrit.
Ultra filtration is useful for increasing hematocrit, reducing high potassium levels after cardioplegia delivery,and removing harmful inflammatory mediators.

DEVICECOMBINATION

1. During cardiac surgery,the function of the heart & lung will be taken over by the Heart–Lungmachine
2. 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.
3. The Cardioplegia device is connected to the Cardioplegia cannula which is used to deliver the Cardioplegia solution to the surgery site.
4. 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.

PRECAUTIONS

- For single use only. Do not re-sterilize or reuse it.
- Do not use if package is open or damaged.
- Personnel trained in extracorporeal procedures only should use the system.
- The operator should be well trained in every procedure described in“instructions of use”
- Ensure to connect the product to the positive pressure side of the pump
- Heparinisation should be carried out depending up on physician’sadvice
- Follow your the atreSOP for the usage procedures.
- If you observe any packaging damages in the system.It should not beused.
- 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 Medi Hub product or other company’s product should be well trained & experienced for
- proper use of the device.

WARNING

- Do not exceed transmembrane pressures of 500mm HG.
- Do not exceed flow through the device more than 500ml perminute.
- Do not use more than 50% Haemocrit concentrates through the product.

CONTRAINDICATIONS

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

SETUP OF THE HAEMOCONCENTRATOR WITH DELIVERY SET

- Priming volume of heat exchanger - 28ml;46ml
- Filter Material - Polyethersulfone
- Shell Material - Polycarbonate
- Top& Bottom cover Material - Polycarbonate
- Surface area of the filter - 0.3&0.7 Sq.M
- Bloodline connector size -1/4”&3/16”
- Filtrate Connector size -1/4”
- Sterilization Process - ETO

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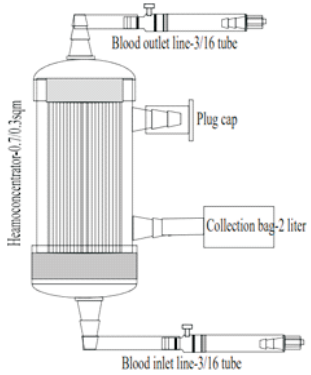
Instructions for Use

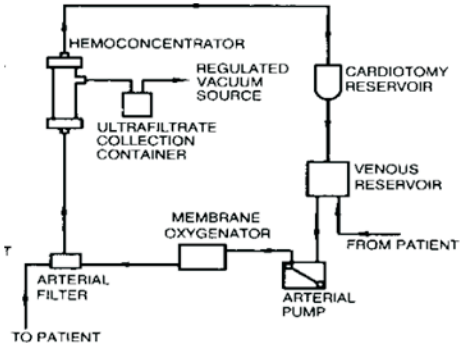
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SETUP OF THE HAEMOCONCENTRATOR WITH DELIVERY SET

- Open the device pack and tubings pack Connect the device with its tubings set supplied as shown in the figure.





- Circulate prime fluid through the unit for few minutes to allow all the air inside to get flushed out.
- Locate the filtrate collection soft bag below the device level.
- Remember to close and open the vacuum connection and filtrate collection lines to achieve desired rate of ultra-filtration and monitor the volume collected, in the collection bag.

DISPOSALMETHOD

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

CONNECTIONOFDEVICES

The HAEMOCONCENTRATOR is connected to the Cardiotomy reservoir, Oxygenator / Arterial blood filter through polymer tubing as per the custom circuit prescribed by the individual hospitals and also if required, it is connected to a regulated vacuum source through waste (filtrate) collection bag connected at the drainports.

STERILITY

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

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/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.
25°C 45°C	**Temperature Limits** Indicates the limit of temperature to which the medical device can be safely exposed.	25% 90%	**Humidity limitation** Indicates the range of humidity to which the medical device can be safely exposed
IN	**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.
	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 medicaldevice 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
MD	**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.	UDI	**Unique Device Identifier** Indicates a carrier that contains Unique Device Identifier information

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