CE 0123

PERFUSION CUSTOM PACK

Instructions for Use

READ ALL PRECAUTIONS AND INSTRUCTIONS CAREFULLY PRIOR TO USE

Spictra

PRODUCT NAME
Perfusion Custom Pack

BRAND NAME
Spictra

DESCRIPTION
The Perfusion custom pack are used for extra corporeal circuit is for use during open Heart Surgery to interconnect the Patient and the Products. It is supplied ETO Sterilized & Non-Pyrogenic and is disposable. This IFU is applicable to all the models of Perfusion Custom Pack supplied by us.

INTENDED PURPOSE
Perfusion custom packs that are tubing and connection set during the surgery to interconnect to the patient and product through the heart lung machine. These are made as per customer requirement.

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.

INDICATION
Perfusion Custom Pack are used to interconnect vascular system and extra corporeal device.

DURATION OF CONTACT
<6 hours

USE ENVIRONMENT
Perfusion Custom Pack is used in surgical settings such as operating rooms in hospitals, clinics.

PRINCIPLE OF OPERATION
- Tubing of various diameter and lengths are cut as per needs
- The tubing are interconnected as per needs using connectors
- The setso made is packed as per needs in sub packs

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 oxygenatorfor blood oxygenation.
- The Cardioplegia device is connected to the Cardioplegia cannula which is used to deliver theCardioplegia solution to the surgery site.
- The Hemoconcentrator is connected to the heart lung machine which is used to maintain thehaematocrit 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 machineand 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
- Perfusion Custom Packs are tubing and connector sets used during the surgery to interconnect the patient and products through the heart lung machine. These are made as per the customer requirement.
- It is easy to handle during medical procedures.
- It is made up of biocompatible polymers.

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
Perfusion Custom Packs are tubing and connector sets used during the surgery to interconnect the patient and products through the heart lung machine. These are made as per the customer requirement.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 kink or restrictions that may alterblood flow and build pressure inside.
- Check the circuit design with the drawing enclosed prior to use.
- Use aseptic technique.
- 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 another 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.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.

WARNING
- When a circuit is coated with a bio surface, 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 systematic anticoagulation and must be assessed by the prescribing physician. Secure connections need to be verified before use.

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

PRODUCT SPECIFICATION
Perfusion Custom Packs are tubing and connector sets used during the surgery to interconnect the patient and products through the heart lung machine. These are made as per the customer requirement.It is made of up biocompatible polymers. It is sterile, pyrogen free, single use device.It is a customized product which configures different tubes and different connectors configured by the users themselves. It is available in 1/4" Tubing 12 feet, 3/8"Tubing 10 feet & 1/2" Tubing 10 Feet.

PRE-APPLICATION
Check that the tubes are undamaged before installing them in the pump. During use constantlycheck for any signs of wear, cracks, leaks or air intake and take the appropriate action.
Adjust pump occlusion prior to each procedure in accordance with the manufacturer's instructions for use. Improper occlusion may cause deterioration of the pump head tubes,excessive wear, hemolysis and inaccurate blood flow reading.

SYSTEM SETUP AND USE
1. Remove the pack from the shipping carton.
2. Before removing the pack from its sterile packaging, visually inspect the packaging for any damage or an opened seal.
3. Remove and discard the sterile packaging as appropriate for your pack.
4. Visually inspect the pack for any obvious defects in materials or assembly and ensure all protective caps are in place.
5. Remove protective caps.

CE 0123

PERFUSION CUSTOM PACK

Instructions for Use

READ ALL PRECAUTIONS AND INSTRUCTIONS CAREFULLY PRIOR TO USE

Spictra

6. Tighten the luer locks or luer fittings to the desired components finger-tight. Make sure that the connections are secure. Do not over-tighten.

7. Connect the perfusion pack to the oxygenator, filters, heat exchangers, and other components as appropriate.

8. Prevent leaks or tubing disconnections by pushing the proper size tubing at least 1/4 inch past the apex of the innermost barb of the connector and tie wrap if appropriate (see Figure 1). It is recommended to make tie banding on the tubing to all barbed connectors and component ports.

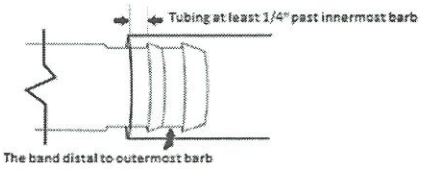


Figure1

9. Prime the extracorporeal circuit in accordance with the instructions accompanying the oxygenator and other components of the extracorporeal circuit.

10. Visually inspect to make sure the circuit is free of air bubbles and leaks.

11. Initiate cardiopulmonary bypass in accordance with oxygenator instructions.

COMPONENT SETUP AND USE

1. For Stopcocks use, observe the following:
- Stopcocks are indicated for infusion of fluids or obtaining samples of blood or other fluids.
- Position the stopcock handles over the port to be closed. The remaining ports will be open.

2.For Non-Return valve use, connect the valve as per the flow direction given in the valve.

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 perfusion custom packs connect with cardiac surgery devices and connect them to Heart lung machine as per the custom circuit prescribed by individual hospitals.

USAGE FREQUENCY

This is single-use device

STORAGE CONDITION

Perfusion Custom Pack shall be stored at 25 °C to 45°C

STERILITY STATE & METHOD OF STERILIZATION

Perfusion Custom Pack 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
Perfusion Custom Pack	1	43x14x43	4	46x46x59
	40-1/4 tube	-	-	38x37.5x32.5
	25-3/8 tube	-	-	38x37.5x32.5
	20-1/2 tube	-	-	38x37.5x32.5

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/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.
	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 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 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	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.

Doc No. SPT-IFU-PCP

Revision Date: 06.08.2026

Revision No.: 06