PERFUSION TUBING SET/ CUSTOM TUBING PACK

Circuits for Cardiopulmonary bypass, Cardioplegia and other Extracorporeal Support

DESCRIPTION

This device is manufactured to user specifications and may consist of one or all of the following main components: oxygenators, pressure gauge protection chambers, drip chambers, clamps, stop cocks, heat exchangers, bubble traps, etc. according to requirements. The device is single use, non-toxic, pyrogen-free, supplied STERILE. Sterilized by ethylene oxide.

INTENDED USE

This device is manufactured to user specifications and may consist of one or all of the following main components: connectors, check valves, drip chambers, clamps, stopcocks, filters etc. according to requirements. It is intended for use during surgery requiring cardiopulmonary or other surgical procedures which need the extracorporeal support. The medical device is used to channel blood to-and-fro the body and heart lung machine. It can be used together with other devices such as pumps, oxygenators, reservoirs, heat exchanging devices and cannula. It can be used in all patient population as per the different customized circuits.

WARNING

- Store in a cool dry place.
- Only use the unit if it is STERILE. If the device is supplied NOT STERILE (in this case the label is marked "not sterile") contact CSS or its representative to determine the method for sterilization.
- Carefully read the instructions before using the product.
- The device is intended to be used by professionally trained personnel.
- The device must be used in accordance with these instructions for use. CSS is not responsible for problems arising from inexperience or improper use.
- The device must not undergo any further processing.
- The device is sterilized by ethylene oxide. Sterility is guaranteed only if the sterile packaging is not damaged.
- FRAGILE, handle with care.
- Carry out a visual inspection and carefully check the device before use. Transport and/or storage conditions other than those prescribed may have caused damage to the device.
- The product is non-toxic and pyrogen-free.
- For single use and single patient only.
- Do not attempt to re-sterilize or clean the product for further use. The product must be used once only and destroyed after use. Any intention to reuse may cause serious cross contamination and damage to the integrity and proper functioning of the device.
- Avoid conditions of use which expose the blood to a temperature higher than 37°C.
- Always administer and maintain a correct dose and accurately monitor the anticoagulant before, during and after the bypass.
- After use, dispose of the device in accordance with the applicable regulations in force in the country of use.
- Do not use the device if the sterility is not guaranteed.
- Check the expiry date on the label attached. Do not use the device after the date shown.
- The device must be used immediately after opening the sterile packaging.
- The device must be handled aseptically.
- Do not use solvents such as alcohol, ether, acetone, etc. as contact may cause damage to the device.
- Do not allow halogenated liquids such as Halothane and Flurothane to come into contact with the polycarbonate housing of the device.

This could cause damage which may compromise the integrity and proper functioning of the device.

- It is recommended to read the instructions for use of the individual devices included in the packaging.
- Handle all the tubes carefully to prevent damaging them.
- The user is responsible for any changes made either to the set or to the operating procedure which may alter the set.
- Carefully check for leaks before and during use. Leaks may cause loss of sterility or gaseous emboli. Should leakage be observed before or during use, replace the leaking component following good perfusion practice. The use of an arterial filter or bubble trap is recommended in accordance with the manufacturer's instructions in order to reduce the possibility of transmitting gaseous emboli to the patient.
- If the set contains a pre-bypass filter, it must not be exposed to blood or other cellular fluids and must be removed before initiating bypass.
- The effectiveness of myocardial cooling can only be ascertained by measuring the myocardial temperature. It is conditioned by variables such as use and degree of hypothermia, cannulation, surgical technique, anatomy and cardiac pathology.
- For further information and/or in case of complaint contact CSS or the authorized local representative.
- Some general safety information with the aim of advising the user preparing to use the device are mentioned below. In addition, specific safety information is given in the instructions for use at the points in the instructions where this information is relevant for correct operation.
- As the product contains phthalates, it should only be used for short term application in pregnant or nursing women, infants and children. If it needs to be used for long-term, the healthcare providers need to compare the pros and cons of using it.
- The blood to be treated must contain anticoagulant. The device must not be used for longer than 6 hours for CPB. Contact with blood for longer periods is not advisable

SETUP

1) If this set is used with a peristaltic pump, observe the following:

a) Check that the tubes are undamaged before installing them in the pump. During use constantly check for any signs of wear, cracks, leaks or air intake and take the appropriate action.

b) Adjust pump occlusion prior to each procedure in accordance with the manufacturer's instructions for use. Improper occlusion may cause deterioration of the under-pump tubes, excessive wear, hemolysis and inaccurate blood flow reading.

c) Position the tubes in the peristaltic pump maintaining the natural curvature of the tube and avoid twisting it.

d) Use the right size tube clamp inserts to prevent damage and to securely lock them.

2) If the set contains a coil, do not use saline or alcohol solutions in order to prevent the temperature from going down to below 0°C, since this might harm the patient.

a) Remove the set from the package using a sterile technique.
b) Make all the connections using an aseptic technique.
c) Connect the Luer-locks without tightening them excessively but ensure that the connection is secure.
d) Close the stopcocks.
e) Connect the set to the oxygenator, heat exchangers, filters and other components in accordance with the specific instructions for use.
f) Secure the connections with clamps.
g) Ensure that the one-way valves in the set are in the correct position.
h) Prime the circuit in accordance with the instructions for use of the circuit components.
i) Ensure that there are no air bubbles in the circuit and the components.
j) Ensure that there are no leaks.
k) Initiate the bypass in accordance with the instructions for use of the oxygenator and following good perfusion practice.

DEVICE REPLACEMENT

A spare device must always be available during perfusion.
After 6 hours of use with blood or in particular situations which may lead the perfusionist to believe that the safety of the patient may be jeopardized, replace the device.

Note: Use a sterile technique during the entire replacement procedure.

IMPORTANT

SILICONE PUMP SEGMENT

The silicone of which the pump segment/s of this extracorporeal circuit is made originates from a material batch that has undergone tests such that it may be defined chemically and physically suitable for use as "PUMP SEGMENT" for heart-lung machines roller type in custom pack for extracorporeal circulation

The silicone tubes may be inserted in the custom packs for extracorporeal circulation and can be used both as pump segment and as component to complete the circuit. They may not be used for longer than 6 hours and it is therefore unadvisable to use them in the case of ECMO.

Pump occlusion must be adjusted following the instructions provided by the pump manufacturer. Incorrect calibration or improper use of the pump may cause damage to the pump segment for which CSS cannot be held responsible.

ONE-WAY VALVE

The main function of the one-way valve that may be present in this circuit is to prevent air intake into the cardiac cavities in the event of incorrect installation of the under-pump tube or accidental inversion of the roller pump rotation direction.

The valve also allows limiting the negative pressure in case of excessive air intake through the tube connected to it.
Finally, in the event of excessive positive pressure in the tube connected to it, the device allows releasing the excess air.

Indications for use

The Vacuum Relief Check Valve is intended to be used during cardiopulmonary bypass surgery to prevent build-up of excessive pressure of the heart or the surgical field during aspiration, and to prevent accidental air flow to the heart.

Warnings

1. Carefully check for the absence of blood or air leaks from the valve before and during use. Immediately remedy any leaks caused by an incorrect direction of flow or excessive positive pressure downstream of the valve.
2. This valve is designed to draw air into the connected tube in order to limit the vacuum pressure. The valve must be properly oriented to ensure that the blood returns to an open venous or cardiotomy reservoir suitable for air removal.
3. Do not obstruct the vent openings.
4. Ensure that the valve is fitted on the vent or suction line and the direction of flow is correct.

Operating procedures

1. Remove the valve from its package using an aseptic technique.
2. The valve must be inserted correctly, referring to the direction of flow indicated by the arrow.

LIMITED WARRANTY

This Limited Warranty is in addition to any statutory rights of the Purchaser pursuant to applicable law.
CSS warrants that all reasonable care has been taken in the manufacture of this medical device, as required by the nature of the device and the use for which the device is intended.
CSS warrants that the medical device is capable of functioning as indicated in the current instructions for use when used in accordance with them by a qualified user and before any expiry date indicated on the packaging.
However, CSS cannot guarantee that incorrect diagnosis or therapy and/or the particular physical and biological characteristics of an individual patient do not affect the performance and effectiveness of the device with damaging consequences for the patient, even though the specified instructions for use have been respected.
CSS, whilst emphasizing the need to adhere strictly to the instructions for use and to adopt all the precautions necessary for the correct use of the device, cannot assume any responsibility for any loss, damage, expense, incidents or consequences arising directly or indirectly from improper use of the device. CSS undertakes to replace the medical device in the event that it is defective at the time of placing on the market or whilst being shipped by CSS up to the time of delivery to the final user unless such defect has been caused by mishandling by the purchaser. The above replaces all other warranties explicit or implicit, written or verbal, including warranties of merchantability and fitness for purpose.
No person, including any representative, agent, dealer, distributor or intermediary of CSS or any other industrial or commercial organization is authorized to make any representation or warranty concerning this medical device except as expressly stated herein. CSS disclaims any warranty of merchantability and any warranty for purpose with regard to this product other than what is expressly stated herein.

The purchaser undertakes to comply with the terms of this Limited Warranty and in particular agrees, in the event of a dispute or litigation with CSS not to make claims based on alleged or proven changes or alterations made to the Limited Warranty by any representative, agent, dealer, distributor or other intermediary.

The existing relations between the parties to the contract (also in the case where it is not drawn up in writing) to whom this Warranty is given as well as every dispute related to it or in any way connected to it as well as anything related to it or any dispute concerning this Warranty, its interpretation and execution, nothing excluded and/or reserved.
In the case of any serious incident happened in related to the device (outside Europe), the users and/or patients are advised to report to the manufacturer, CSS through the contract details stated. If any serious incident is occurred in member states, please also report to the authorized representative (WMDE B.V.) and related competent authority.

Contact CSS or an authorized representative if any difficulties occur.

ADDRESSES

Manufacturer
Contract Sterilization Services Pte. Ltd
2 Tukang Innovation Grove, #08-03/04/05 JTC MedTech Hub,
Singapore 618305
Tel : +65 67107529
Fax : +65 67107427
Email : sales@css-medical.com
Website : www.css-medical.com

EU Representative
WMDE B.V.
Bergerweg 18, 6085 AT Horn, The Netherlands.
Tel : +31-(0) 475-58 22 85
Fax : +31-(0) 475-58 22 78
Email : office@wmde.nl
Website : www.wmde.nl

DEFINITIONS OF SYMBOLS

	This way up		Consult instructions for use
REF	Product Name	PHT DEHP	Contains or presence of Phthalates
LOT	Lot Number		Do not use if package is damaged
SGP	Country of manufacturing & Date of manufacturing		Manufacturer
	Use by date		Do not reuse
STERILE EO	Single sterile barrier system, Sterilized by ethylene oxide	2 STERILIZE	Do not re-sterilize
EC REP	Authorized representative in the European Community/European Union		Fragile, handle with care
	Keep away from sunlight		Keep dry
MD	Medical Device	UDI	Unique Device Identifier
#	Model Number		

Lê Thu Hà
Trưởng phòng đăng ký và quản lý chất lượng

LÊ THU HÀ
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