Heart/Lung Perfusion Packs

DESCRIPTION

A Sorin Group USA, Inc. Heart/Lung Perfusion Pack is either a customized tubing pack built to user specifications or a stock tubing pack, designed for use during surgery requiring cardiopulmonary bypass. It is not designed for long-term use (greater than six hours).

Perfusion Packs labeled as SMARxT® contain components that have an additive to improve blood compatibility. Non-SMARxT packs may contain some SMARxT tubing and/or connectors depending on the customer requirements.

- SMARxT tubing is polymeric material containing a surface-modifying additive to improve blood compatibility. The tubing is designed for use in the arterial blood pump head (3/32-inch wall thickness tubing only) and for interconnecting the oxygenator and other components of the cardiopulmonary bypass circuit.

- SMARxT connectors are molded from polymeric material containing a surface modifying additive to improve blood compatibility. Connectors are provided in various sizes, with and without a luer lock port.

Contents of this pack have been sterilized by ethylene oxide gas and have nonpyrogenic fluid pathways.

Another component that can be present inside the PTS is the HeartLink™ card.

The HeartLink™ card is made of cardboard and of standard credit card size; it contains an RFID tag to be used in conjunction with the HeartLink™ reader to enable dedicated functions in Sorin|Connect.

The HeartLink™ card is positioned inside the custom pack tray, inside a transparent pouch attached to a wall of the tray. To utilize it, please remove the card from the pouch, being careful not to damage it, and position it close to the logo present on the upward side of the HeartLink™ reader.

Please refer to Sorin|Connect user manual to obtain further information on the HeartLink™ usage.

INDICATIONS FOR USE

This Heart/Lung Perfusion Pack is indicated for use in surgical procedures requiring extracorporeal support for periods of up to six hours.

CONTRAINDICATIONS

There are no known contraindications for this product.

WARNINGS

1. SINGLE PATIENT USE ONLY. Discard after single use. Do not resterilize any part of this pack, including the sterile packaging.

2. Carefully examine this pack for leaks before and during use. Leakage may result in loss of sterility, blood loss, or air embolism. If leakage is observed before or during use, replace the leaking component or retighten the leaking connection.

3. Check all pumps and components to ensure that they are set up for proper flow direction prior to initiating bypass.

4. If this pack contains a Sorin Group USA, Inc. Bubble Trap with an integral temperature well, observe the following:
   - Fluid levels in the Bubble Trap should be maintained above the top of the screen. Failure to do so may allow transmission of air bubbles to the patient. Fluid levels should be monitored at all times.
   - Do not exceed 500 mL/min flow rate through the system. Flows in excess of 500 mL/min may generate and allow transmission of air bubbles to the patient. Flow rates should be monitored at all times.

5. If this pack contains a Sorin Group USA, Inc. Bubble Trap without an integral temperature well, observe the following:
   - Fluid levels in the Bubble Trap should be maintained above the BLOOD LEVEL mark. On packs without the BLOOD LEVEL mark, maintain the fluid level above the top of the screen. Fluid levels should be monitored at all times.
   - Do not exceed 300 mL/min flow rate through the system. Infusate flows in excess of 300 mL/min may generate and allow transmission of air bubbles to the patient. Flow rates should be monitored at all times.

6. If this pack contains a Sorin Group USA, Inc. Vacuum Relief Check Valve, observe the following:
   - The valve must be properly oriented to ensure that blood returns to an open venous or cardiotomy reservoir suitable for air handling. The valve is designed to draw air into the line to which it is attached to prevent excessive vacuum pressure. Incorrect orientation or direction of flow can result in air embolism.
   - Carefully observe for leakage of air or blood from the over-pressure relief band before and during use. Leakage from the over-pressure relief band may result from excessive positive pressure downstream of the valve due to
incorrect direction of flow. Incorrect direction of flow must be remedied immediately. Leakage from the valve embodiment may result in loss of sterility or air embolism. If leakage from the embodiment is observed before or during use, replace the valve.

7. When using this pack and tubing with a roller-type blood pump, observe the following:

- When using an arterial blood pump for delivering fluid, the pump occlusion should be adjusted prior to each procedure in accordance with the pump manufacturer’s recommendations. Unless otherwise recommended, adjust the occlusion to a one-inch fall per minute in a thirty-inch column of fluid. Failure to maintain proper occlusion of the roller pump can lead to premature pump head tubing failure, resulting in leaks, contamination, and air emboli.

- Only use 3/32” wall thickness PVC or S P A R T A tubing in an arterial blood pump head tubing application as it is susceptible to premature failure.

- Use appropriate tubing inserts for installing pump head tubing. Maintain the natural curvature of the tubing when placing it in the pump raceway. Adjust the length in the pump head so that a slight gap exists between the tubing and raceway, except where the pump roller contacts the tubing. Adjust the tubing clamps such that the tubing is firmly held and does not creep along the raceway. Failure to properly install the pump head tubing in the pump head may result in a flow rate that is different from the rated value.

- Use care to avoid damaging the tubing when adjusting the tubing clamps and while handling the tubing. Cuts or nicks in tubing can lead to premature pump head tubing failure, resulting in leaks, contamination, and air emboli.

- If a pump head tubing failure occurs, immediately terminate bypass by normal procedures. Examine the extracorporeal circuit for air, remove air, replace pump head tubing, and resume bypass per normal procedures.

- Do not lubricate pump tubing segments. This may result in premature failure caused by swelling and weakening of the tubing.

- Do not use co-extruded striped tubing in a pump head application as the color stripes will prevent proper occlusion setting. This could lead to premature tubing failure. Striped tubing that has the stripe printed on the tubing is acceptable for pump header applications.

- Routine maintenance of pump roller bearings and tubing guides in accordance with the manufacturer’s instructions is recommended to prevent increased tubing wear which could cause premature pump head tubing failure.

**PRECAUTIONS**

1. Carefully read these and all other enclosed Instructions for Use before using this product. When using packs with other manufacturers’ components, contact them for their Instructions for Use, and read them also.

2. It is recommended that one pack be set up and evaluated in a laboratory or bench test prior to first clinical use.

3. This pack is intended for use by trained personnel only.

4. Do not use this pack if it is damaged, if the sterile packaging is damaged or opened, or if the protective caps are not in place. Check for loose connections on preassembled packs.

5. Use proper aseptic technique while handling this pack.

6. To aid in the detection and prevention of gas or particulate embolization, Sorin Group USA, Inc. recommends the use of safety devices, including level sensors, bubble detectors, vented arterial filters, and prebypass filters, for all cardiopulmonary bypass procedures.

7. All Sorin Group USA, Inc. Perfusion Packs should be adequately primed and debubbled before use.

8. Adequate anticoagulation is essential when using this pack.

9. The following maximum pressure limitations should not be exceeded:

- All Sorin Group USA, Inc. components and Sorin Group USA, Inc. connections: 500 mmHg (10 psi), unless superseded by the individual component Instructions for Use.

- Certain connections to Pall® filters may not meet the 500 mmHg pressure rating.

10. If the pack contains a pre-bypass filter, it must be removed before initiating cardiopulmonary bypass.

11. All luer connections should be finger-tight. Over-tightened connections may result in cracks or leaks. Wet connections promote over-tightening by lubricating the ports.

12. When infusing solutions from bags, remove all air from the bag during setup. This prevents air from entering the patient’s vascular system when the bag is emptied.

13. If using a Sorin Group USA, Inc. Transducer Protector, the protector must be changed if contacted by fluid. Once wetted, it will not allow air passage, thus preventing proper pressure transmission.

14. When using a Sorin Group USA, Inc. SAT/HCT® connector for the Sorin Group USA, Inc. SAT/HCT Monitor, note that the SAT/HCT Monitor has not been characterized for accuracy in the presence of fetal hemoglobin, so the accuracy of values obtained in the presence of fetal hemoglobin is unknown.

15. When using a Sorin Group USA, Inc. Vacuum Relief Check Valve, do not obstruct vent openings. Occluded vent openings prevent the valve from limiting the vacuum pressure. Ensure the valve is placed in the vent or suction line with the correct direction of flow. Incorrect direction of flow can result in air embolism.

16. Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.
PROCEDURES FOR USE

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.
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. If using a Sorin Group USA, Inc. tubing connector, 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).
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. If using Sorin Group USA, Inc. Stopcocks, observe the following:
   • Sorin Group USA, Inc. 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. When using a Sorin Group USA, Inc. Pre-Bypass Filter, observe the following:
   • The Sorin Group USA, Inc. Pre-Bypass Filter is indicated for use during priming of the extracorporeal circuit to remove contaminants larger than 5 microns.
   • Aseptically place the filter in the extracorporeal circuit in accordance with the direction of flow indicated on the filter. Tubing should extend at least 1/4 inch past the innermost barb of the filter.
   • Recirculate the priming fluid through the circuit, gradually increasing to full flow. Do not exceed 6 lpm flow rate.
   • Stop the pump, clamp the tubing proximal and distal to the filter, and remove the filter from the circuit.
   • Do not utilize blood or cellular primes with the Sorin Group USA, Inc. Pre-Bypass Filter.
3. When using a Sorin Group USA, Inc. Gas Filter, observe the following:
   • The Sorin Group USA, Inc. Gas Filter is intended to be used to remove debris and other contaminants greater than 0.3 micron from oxygen and other medical gases prior to their introduction into an oxygenator.
   • Place the filter in the oxygen inflow line of the oxygenator.
   • Connect the gas source to the filter.
   • Make sure that the tubing extends at least 1/4 inch past the barbs of the filter connectors.
4. When using a one-way valve in an arterial filter purge line:
   • The one-way valve must point in the direction of intended flow.
   • Connect the inlet of the one-way valve purge line to the vent port on the arterial filter or to a stopcock attached to the vent port of the arterial filter.
   • Attach the outlet of the one-way valve purge line to a nonfiltered, nonpressurized port, such as a vented cardiotomy reservoir or oxygenator reservoir. See reservoir manufacturer’s Instructions for Use.
5. When using a Sorin Group USA, Inc. SAT/HCT connector for the Sorin Group USA, Inc. SAT/HCT Monitor, observe the following:
   • The Sorin Group USA, Inc. SAT/HCT connector for use with the Sorin Group USA, Inc. SAT/HCT Monitor is a straight flow through connector with two luer ports (with the exception of 1/4 x 1/4 connectors) and one SAT/HCT fitting. The two luer ports may be used for the placement of a thermistor probe or for blood access.
   • If desired, connect the Sorin Group USA, Inc. SAT/HCT Monitor to the SAT/HCT fitting on the connector. For complete instructions, refer to the Operator’s Manual for the monitor.
6. When using a Sorin Group USA, Inc. Vacuum Relief Check Valve, observe the following:
   • The Sorin Group USA, Inc. Vacuum Relief Check Valve is intended to be used to help prevent the buildup of excess vacuum pressure when suctioning from the heart or surgical field, and to help prevent the inadvertent flow of air into the heart.
   • If not preconnected, insert the valve into the vent or suction line between the cannula and suction pump. Arrows on the valve indicate the direction of flow. The valve can be attached to 1/4” ID tubing at the inlet and 1/4” or 3/8” ID tubing at the outlet.
• The valve must be inserted in the vent or suction line with the direction of flow arrow pointing toward the suctioning pump.

COMPONENT SPECIFICATIONS

1. Sorin Group USA, Inc. Vacuum Relief Check Valve: maximum vacuum pressure approximately -170mmHg; positive pressure relief approximately 450mmHg.

2. Sorin Group USA, Inc. Pre-Bypass Filter: 5 micron filter media pore size.

3. Sorin Group USA, Inc. Gas Filter: 0.3 micron filter media pore size.

For Customers Outside the United States

If for any reason this product must be returned please contact your sales representative for specific instructions.

If the product has been in contact with blood or body fluids, it must be thoroughly cleaned and disinfected before packing. It should be shipped in either the original carton, or an equivalent carton, to prevent damage during shipment.

CAUTION
It is the responsibility of the health care institution to adequately prepare and identify the product for return shipment. Do not return products that have been exposed to blood borne infectious diseases.

DEFINITION OF SYMBOLS
(as used in product labeling)

- ATTENTION, SEE INSTRUCTIONS FOR USE
- DO NOT REUSE
- METHOD OF STERILIZATION USING ETHYLENE OXIDE
- CATALOG NUMBER
- BATCH CODE
- USE BY DATE
- CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.
- NON PYROGENIC FLUID PATHWAY
- QUANTITY
- DO NOT USE IF PACKAGE IS DAMAGED
- DO NOT RESTERILIZE

RETURN OF USED PRODUCT

For Customers within the United States

If for any reason this product must be returned to Sorin Group USA, Inc., a returned goods authorization (RGA) number is required from Sorin Group USA, Inc., prior to shipping.

If the product has been in contact with blood or body fluids, it must be thoroughly cleaned and disinfected before packing. It should be shipped in either the original carton, or an equivalent carton, to prevent damage during shipment; and it should be properly labeled with an RGA number and an indication of the biohazardous nature of the contents of the shipment.

Instructions for cleaning and materials, including appropriate shipping containers, proper labeling, and an RGA number may be obtained from the Sorin Group USA, Inc., Returned Goods Coordinator, Quality Assurance Department (800-650-2623).

CAUTION
It is the responsibility of the health care institution to adequately prepare and identify the product for return shipment. Do not return products that have been exposed to blood borne infectious diseases.

The shipping address for returned goods is:

Sorin Group USA, Inc.
Returned CV Products
14401 West 65th Way
Arvada, CO 80004-3599 USA
ADDRESSES:

Manufacturer:
Sorin Group USA, Inc.
14401 W. 65th Way
Arvada, CO 80004 USA
Telephone: 800-221-7943
Telephone: 303-425-5508
Fax: 303-467-6584

Distributor in Canada:
Sorin Group Canada, Inc.
280 Hillmount Road Unit 8
Markham Ontario L6C 3A1
Telephone: 416-751-8787
Fax: 416-751-9849

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