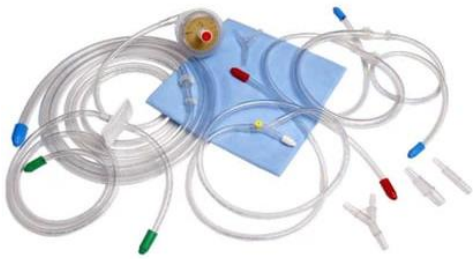
Instruction for Use

Heart Lung Pack and Accessories

Variant : With or without Arterial Filter
Product Class as REGULATION (EU) 2017/745 : IIa
Product Class as per Medical Device Rule 2017 : C
Duration of use : Short Term



DESCRIPTION

Heart Lung Pack/Perfusion Pack with Accessories are a combination of Medical Grade PVC (DEHP Free) Tubing & Connectors.
The major components of the Heart Lung Pack & Accessories are;
Arterial Filter-PC & Polyester (Adult or Pediatric), PVC Tubing -PVC/silicon, Cap-PVC etc.

The device does not contain;

- DEHP
- medicinal substance, including a human blood or plasma derivative,
- tissues or cells, or their derivatives, of human origin
- tissues or cells of animal origin, or their derivatives.

Patient Target Group: All Age groups.

Product Packaging

- The product is available in non-toxic, medical-grade, sterile packing, that allows for maintaining product sterility to the point of use and to maintaining aseptic presentation.
- The product is a single-use device.

INTENDED USE

Heart Lung Pack/ Perfusion Pack with Accessories is intended to be used as a combination of PVC (DEHP FREE) Tubing & Connectors as an extracorporeal circuit to carry blood to & from the patient to the Heart Lung machine.

MODE OF ACTION

Heart Lung Pack includes accessories such as PVC Tubing Connector, Arterial filters, Heat Exchanger System & Hemoconcentrator Lines, which are all interconnected under controlled & monitored conditions, to form a functional unit.

This functional unit is sterilized by Ethylene Oxide, as a "single unit sterile pack".

Heart Lung Pack are used for extracorporeal (The circulation of blood outside the body during Open heart Surgeries) circulation with the help of Heart Lung machine.
Heart Lung Machine consist of Roller Pumps which are used for positive displacement/ pumping the extracorporeal blood. The Heart Lung Pack is connected to the patient's circulatory system with the help of cannula.

Venous blood is drained into the extracorporeal system via a venous cannula which is connected to Superior venacava, Inferior venacava or Right atrium of the Heart. The venous blood is oxygenated and delivered back to the patient via an arterial cannula which is connected to the Aorta.
Note : Heart Lung Machine & Cannulas are not the part of BL's Heart Lung Pack.

INDICATION FOR USE

Pre-application

- 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.
- 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.

Application

If this set is used with a peristaltic pump, ensure the following:

- Position the tubes in the peristaltic pump maintaining the natural curvature of the tube and avoid twisting it.
- Use the right size tube clamp inserts to prevent damage and to securely lock them.

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.

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

  Duck Bill Check Valve
  The Duck Bill Check Valve that may be contained in this set is a valve designed to prevent excessive vacuum pressure, release excessive positive pressure and prevent retrograde flow, thereby reducing the possibility of air flowing to the heart.
- 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.
- 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 treatment.
- Do not obstruct the vent openings.
- Ensure that the valve is fitted on the vent or suction line and that the direction of flow is correct.
- Product must not be resterilized. The resterilization of the device will alter mechanical and chemical properties, inappropriate of intended use and also increase the EO residue on device.
  operating procedures
- Remove the valve from its package using an aseptic technique.
- Insert the valve into the vent or suction line between the cannula and the suction pump. The arrows on the valve indicate the direction of flow. The valve can be fitted on a tube of 1/4" (6.4 mm) inside diameter at the inlet and on tubes of 1/4" (6.4mm) or 3/8" (9.5 mm) inside diameter at the outlet.
- The valve must be inserted in the vent or suction tube with the duckbill and arrow indicating the direction of flow pointing toward the suction pump.
- The **Blood to be treated must contain anticoagulant. The device must not be used for longer than 6 hrs. Contact with blood for longer periods is not advisable.**

INTENDED USERS:

- Product is recommended to use by qualified medical/paramedic staff.

CONTRAINDICATION

- This device is not designed, sold, or intended for use except as indicated.
- The Patient is known or is suspected to be allergic to materials contained in the device.

CLINICAL BENEFITS

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- Heart Lung pack/perfusion pack has greater safety for sensitive or allergic patients.
- Greater Efficiency; Heart Lung pack's use reduces the procedures' lay-up times freeing up valuable nursing time for other activities. By reducing set-up time for the theater, the pack allows for more time to be dedicated to patient care. Fewer errors will, most likely, be made in setting up as well. The tools included can cater to the preference of the surgeon.

CAUTION/WARNING

- Do not use the product if the package is damaged or open.
- 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.

RISKS OF RE-USE

- A device designated, as 'single-use' must not be reused. It should only be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used again, even on the same patient.
- The reuse of single-use devices can affect their safety, performance and effectiveness, exposing patients and staff to unnecessary risk.
- The reuse of single-use devices has legal implications:
  - anyone who reprocesses or reuses a device intended by the manufacturer for use on a single occasion, bears full responsibility for its safety and effectiveness;
  - Anyone who reprocesses a single-use device and passes it to a separate legal entity for use, has the same legal obligations under the Medical Devices Regulations as the original manufacturer of the device.
- Reprocessing a single-use device may alter its characteristics so that it no longer complies with the original manufacturer's specifications and, therefore, the performance may be compromised.
- If re-used it may lead, but not limited to cross-infection.
- Troubleshooting: User Paramedic staff should be aware & able to troubleshoot the certain complications may occur during the application of the product such as;

STORAGE

Based on the stability study report as per ICH guidelines the recommended storage condition in between Temp 15˚C to 40˚C and maintaining the relative humidity condition 50 to 75%. In case of any tempering in the packaging, the product condition may be affected even incase store at above defined condition.
Product Sterility is valid for three years, from the manufacturing of the product.

DISCLAIMER

The condition of the device must be verified prior to use. BL is not responsible for any damage to person, property, etc. from any inappropriate or recommended use of the device, including reuse. Reuse could cause infection or serious health issues.

DISPOSITION

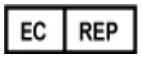
Dispose off/Discard the used Device, in accordance with your country's health care and safety regulations.

GOODS RETURN POLICY

Refer to the company's return goods policy.
Please contact the branch office or customer service at blls@bllifesciences.com or call +91 11 45100100

Company Website Link to product IFU: https://www.bllifesciences.com

SYMBOLS USED ON PRODUCT LABEL

Symbol			
Meaning	Caution	2460 Conformity of European Norm with Notified Body Number	Manufacturer
Symbol			
Meaning	Do not re-use	Use-by date	Date of Manufacture
Symbol			
Meaning	Batch/Lot Number	Authorized representative in the European Community	Sterilized using ethylene oxide Single sterile barrier system
Symbol			
Meaning	Do not resterilize	Consult Instruction for use	Non-pyrogenic
Symbol			
Meaning	Do not use if package is damaged	Catalogue number	Temperature Limit

Symbol			
Meaning	Fragile, handle with care	Keep dry	This way up
Symbol			
Meaning	Keep away from sunlight	Stacking limit by number	
Symbol	MD	UDI	
Meaning	Medical device	Unique Device Identifier	

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