Prymax Perfusion

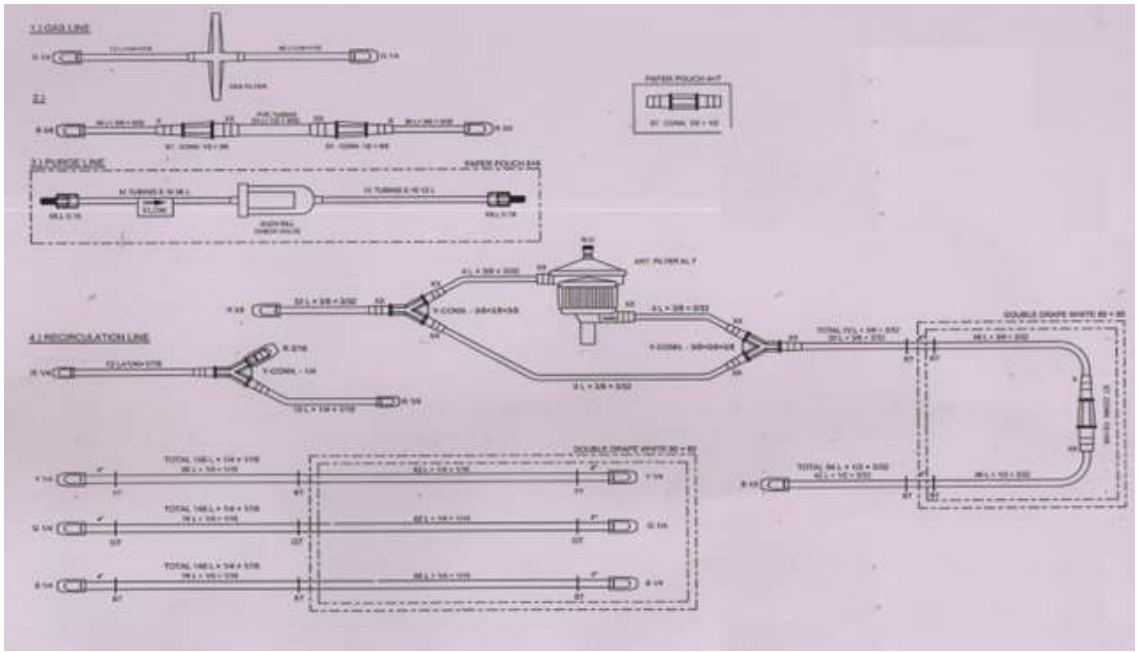
Heart Lung pack

DEVICE DESCRIPTION:

Prymax Healthcare supplies Heart lung pack in the form of adult, infant and neonatal which are further available in different combinations as per the requirement like with or without Arterial filter, different tubing sizes etc.

A standard Heart lung pack includes (1) Tubings, (2) St. Connector, (3) Y-Connector, (4) Purge Line (5) Gas Line Filter (6) Arterial Filter (7) Rapid Prime Line. Although Device can be customized as per the requirement of customer.

Drawing of product:



This is a sample drawing. Drawings can be modified as per the customer requirements.

CONTENTS:

- Pump head line
- Arterial Filter
- Purge line,
- Gas line,
- Rapid Prime Line

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- Perfusion connectors etc.

Above mentioned contents are for standard kit. Additional components can be provided with the kit as per the user requirement.

MATERIAL USED:
Poly vinyl chloride, Polycarbonate, Polyester, Polypropylene, Cyrolite, Acrylonitrile butadiene styrene, Polyoxymethylene

INTENDED PURPOSE:
INTENDED USE: Heart Lung Pack/ Perfusion Pack 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.

INTENDED USER: The device is intended to be used only by a qualified medical professional.

INTENDED PATIENT POPULATION: All patient population irrespective of age and gender

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

CONTRAINDICATIONS:
- 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. Do not use the device if allergic / hypersensitive to material used in device

CLINICAL BENEFITS & PERFORMANCE CHARACTERISTICS

Clinical Benefits:
Allowed Heart to undergo surgical procedure by maintaining extra-corporeal circuit. The clinical outcomes are measured by performance and safety characteristics

PERFORMANCE CHARACTERISTICS
- Kink resistant tubing
- Maximum blood flow in the Adult Arterial filter
- Priming volume

INSTRUCTION FOR USE:
Pre-application
- Open the product in sterile environment.

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- Visually inspect the product & packing for any visual defects. Improper transportation & handling can cause structural/functional damage to the device or packaging.
- 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 0^0C, 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.

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- Product must not be reserialized. The resterilization of the device will alter mechanical and chemical properties, inappropriate of intended use and also increase the EO residue on device.

  operating procedure
- 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.

WARNING & PRECAUTIONS:

- Do not use if the sterile pack is opened or damaged.
- 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.
- The use of this product is restricted to a qualified doctor or a surgeon trained in the techniques of vascular catheterizations.
- Read all the information mentioned in instruction for use. Failure to do so may result in severe patient injury or death. The product should be used according to the instructions for use.
- The product is guaranteed, sterile till the package has not been opened or damaged within the expiry date.
- Sterile, Single use: Do not reuse, reprocess or re-sterilize. Reuse of device creates a potential risk of serious injury and/or infection which may lead to death.

ADVERSE EFFECTS:

Bleeding, Blood clot (thromboembolism), Infection, Loss of blood in hands, feet or legs (limb ischemia), Anaphylactic reaction, Blood damage & haemolysis and Hyperglycaemia

RE-USE HAZARDS:

Transmission of infection from one patient to another.

PACKAGING:

The device is packed in Header Pouch, which is further packed in inner carton & master carton.

STERILIZATION:

Device is EO sterilized, and sterilization is done in-house.

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STORAGE CONDITION:
Temperature Limit: 15^{o}C to 40^{o}C.

DEVICE SHELF LIFE: 3 Year

Country Code: - 356

DISPOSAL
After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal law and regulation.

REPORTING OF ADVERSE EVENTS:
In case of any serious adverse event please report the same to info@prymaxhealthcare.com & gloizou@compliancems.com.au.

Note: For product used in EU also report to the competent authority of the Member State in which the user and/or patient is established.

GOODS RETURN POLICY
Refer to the company's return good policy.
Please contact the branch office or customer service at info@prymaxhealthcare.com or call +91 129 4011818.

SYMBOLS USED ON PRODUCT LABEL

Lot number


Do not re-use

Sterilized by Ethylene Oxide


Manufacturing date


Use-by date


Caution


Non-pyrogenic

Do not resterilize

Catalogue number


Manufacturer

Storage Temperature Range

Conformité Européenne

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Do not use if package is damaged

Consult instructions for use

Single Sterile Barrier System

Medical Device

UDI Carrier

Country of Manufacturer

Manufactured By:

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53/17, Industrial Area NIT, Faridabad,
Haryana, INDIA -121001
www.Prymaxhealthcare.com

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