Instructions for Use

PRIME™

Hemofilter

Description:

PRIME™ Hemofilter is designed to be used in cardio-pulmonary bypass (CPB) surgeries, in which the blood is greatly diluted. It can separate excessive water out in a relatively short time. Thus, concentrating the effective constituents of red blood cells and plasma proteins, etc. It can meanwhile clear away complement and inflammatory mediums in the extracorporeal circuit. This is beneficial for the recovery of cardiac and pulmonary functions in the post-operation period.

The device is a Hollow Fiber Hemofilter, and is composed of an upper cover (blue), lower cover (red), shell, hollow fiber ultrafiltration membrane and tubing.

Indications for Use:

The Hemofilter is indicated to concentrate diluted blood during cardio-pulmonary bypass (CPB) surgeries.

Contraindications:

- Please strictly follow the clinician's requirement if anti-coagulation or other medicines are needed to be added into the blood
- The device is to be used only as indicated

Warnings and Precautions:

1. Please read all packaging insert warnings, precautions, and instructions before use. Failure to do so may result in severe patient injury or death.
2. Warning: Sterile by EO, Single Use: Do not reuse, reprocess or re-sterilize under any circumstance.
3. Warning: Do not use if the packaging is damaged or opened unintentionally before use. This will lead to loss of sterility.
4. Warning: Rx Only. The device must be used by trained physicians only
5. Precaution: Aseptic techniques must be used wherever possible, especially during removal from packaging.
6. If leaks are observed during priming and/or operation, this may result in air embolism to the patient and /or fluid loss. The extracorporeal circuit must be continually monitored. Do not use the device if these conditions are observed.
7. During the pre-filling process, check the Hemofilter and each connector to see whether there's leakage. If abnormal, a reinstallation is needed. Replace Hemofilter if necessary.
8. When ultra-filtering, the flow rate should be not lower than 100ml/min to prevent blood clotting. Monitor ACT throughout the whole process.
9. Ensure that blood flow rate is not over 500 ml/min for 0.8m²(type adult), 300 ml/min for 0.3m²(children), and transmembrane pressure is not over 500 mmHg (adults) or 300mmHg (children) throughout the ultrafiltration process.
10. If there's red substance in the filtration fluid during ultra-filtering process, it indicates that ultrafiltration membrane has broken, please replace Hemofilter in this case.
11. The filtration fluid bag should lie under the Hemofilter to prevent the backflow of the filtration fluid.
12. The blood flows from bottom to top (from red end to blue end).
13. In the extracorporeal circulation operation, the concentrated blood can enter human body or venous blood bank. If it directly enters human body, please pay attention to preventing bubbles getting inside human body.

14. The Hemofilter has strong permeability, so that it is easy to concentrate the active ingredients of blood. However, attention needs to be paid that the filtered haematocrit should not be over 50%

Instructions for Use:

1. Take out the product from the internal package bag and check the integrity of the connection tube and lids.
2. Determine the installation location of the Hemofilter according to the oxygenator type.
3. Fix the Hemofilter vertically onto the pump frame with a special stand, make sure that the blood inlet orients downward, and blood circulation is from bottom to top, rather than vertical installation, which will weaken the ultrafiltration performance.
4. Blue cover (blood outlet) connects with φ6 tube and the other end connects with venous blood reservoir.
5. Red cover (blood inlet) connects with φ6 tube and the other end connects with extracorporeal circulation tube. Control the maximum flow, it should not be over 500 ml/min for 0.8m² (adults) Hemofilter, and 300 ml/min for 0.3m²(paediatric) Hemofilter
6. The filtration outlet at the flank of the Hemofilter near the blue cover connects with φ6 tube and the other end connects with fluid bag. The Fluid bag should lye below the blood Hemofilter to prevent backflow of the fluid.
7. If negative pressure is generated based on siphon principle, the fluid bag should be kept under the Hemofilter.
8. The Hemofilter can be primed by normal saline. Loosen the filtration outlet tube clip gradually as the pre-filling process continues. As the filtration tube shows air exhaustion, turn off the pump and tighten the tube clip immediately. When air is out, incarcerate blood outlet and turn on filtration tube. If a roller pump is used for extracting filtration fluid, please slightly loosen the blood outlet tube to prevent the situation happening that the transmembrane pressure is over 500mmHg (adults) or 300mmHg (children). While the filtration tube and the ultrafiltration chamber are full of fluid, turn off the pump and clip the blood inlet, blood outlet as well as the filtration fluid outlet and get ready for use.
9. As the extracorporeal circulation initiates, incarcerate filtration tube to make blood flow into the Hemofilter, and turn on blood outlet tube gradually. When air is out, loosen filtration tube and begin blood concentration.

Disposal:

10. A Hemofilter can be a biological hazard if disposed incorrectly. They should be disposed using recognised medical procedures and industry best practices. Local laws and regulations should be taken into account during disposal

Specifications:

Specification		**0.3m² (Paediatric)**			**0.8m² (Adult)**				
Ultrafiltration membrane area		0.3 ±20% m²			0.8±20% m²				
Blood chamber capacity		12 ml±10ml			37 ml±10ml				
Priming volume		30ml			58ml				
Pressure drop of the blood channel	Blood Flow Rate ml/min	100	200	300	100	200	300	400	500
	Pressure Drop	≤4.1kPa	≤5.3kPa	≤7.5kPa	≤2.6kPa	≤4.0kPa	≤7.0kPa	≤9.6kPa	≤12.6kPa
The largest filtration molecular diameter		65000 Dalton							
Filter coefficients		Total protein screening coefficient is not greater than 0.2							

Potential Complications / Adverse Effects:

Hemofilters are used in extracorporeal circuits. This device, as with all extracorporeal blood system devices, has possible side effects which include, but are not limited to, infections, blood loss, thrombus formation, embolic events and dislocation.

Warranty and Limitations

Hemofilters are sold in 'as is' condition. The entire risk as to the quality and performance of the product is with the buyer. ALSPL disclaims all warranties, expressed or implied, with respect to its products, including but not limited to, any implied warranty of merchantability or fitness for a particular purpose. ALSPL shall not be liable to any person for any medical expenses or any direct or consequential damages resulting from the use of any product or caused by any defect, failure, or malfunction of any product, whether a claim for such damages is based upon warranty, contract, tort, or otherwise. No person has any authority to bind ALSPL to any representation or warranty with respect to its products.

Symbols Glossary

	Caution, Consult Indications for Use
	Date of Manufacture
	Do not re-use
	Do not use if package is damaged
	Sterilized using ethylene oxide
	Keep away from sunlight
	Batch code
	Catalogue Number
	Manufacturer
	Use-by date
	Keep dry
	Temperature Limit

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