



Instructions for Use

PRIME™

Arterial Filter

Description:

PRIME™ Arterial Filter is intended to filter micro emboli, larger than the specified micron size, from circulating blood during cardiopulmonary bypass (CPB) surgery. During the CPB surgery, blood flows into the device from the tee connector and then runs through the blood inlet tube. The micro emboli are removed when the blood passes through the filter mesh to the blood outlet tube into the patient's body. Under normal conditions the bypass tube is clamped with a clip in order to avoid blood flow into this pathway. The bypass is used in case there is any obstruction in the filter or there is no need to filter the blood.

Indications for Use:

This device is indicated for use in cardiopulmonary bypass procedures for the removal of particulate and gaseous micro emboli.

Contraindications:

- 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. The use of certain solvents may compromise the integrity of the device.
7. Gas emboli must be cleared from the extracorporeal circuit before initiating bypass. Gas emboli are hazardous to the patient.
8. 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.

Instructions for Use:

Set Up

Note: Refer to the CPB pump speed controller Instructions for Use for details related to system setup, priming, operating parameters, and emergency back-up equipment.

1. Remove the device from the packaging carefully to ensure a sterile fluid pathway.
2. Insert the arterial filter into the arterial line. The use of tie bands is recommended. Ensure proper direction of fluid flow.
3. Place the arterial filter in a stable position and make sure the blood outlet port pointing down.
4. A filter bypass line may be used to facilitate priming and to provide an alternate blood flow path around the filter.

Priming

Note: To aid priming, 100% medical grade CO₂ may be used to displace air.

5. Prime the filter per institutional protocol.
6. The filter may be tapped gently to aid in removal of air.
7. Visually inspect the filter and ensure that there is no air present before the initiation of bypass.

8. Double check all connections and visually inspect for leaks.

Caution: Before blood is introduced into any extracorporeal circuit, the use of a pre-bypass filter should be considered.

Operation

9. Check for adequate levels of anticoagulation before initiating bypass.

10. During extracorporeal circulation, the three-way switch should be operated in the open position

Caution: The stopcock of the arterial purge line must be closed when the pump is stopped to prevent retrograde blood flow from the patient through the purge line.

Disposal:

11. The device 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	Adult	Child	Infant
Prime Volume (ml)	≤190	≤140	≤45
Maximum Blood Flow Rate (ml/min)	6000	3000	1500
Filter area (cm ²)	≥660	≥400	≥120
Screen Size (µm)	40		
Blood Inlet Tube Inner Diameter (mm)	10	10	6
Blood Outlet Tube Inner Diameter (mm)	10	10	6
Tee Connector (mm)	10x10x10	10x10x10	6x6x6
Piezometer Tube Inner Diameter (mm)	10x10x10	10x10x10	6x6x6
Exhaustion Tube Inner Diameter (mm)	3		





Potential Complications / Adverse Effects









Arterial Filters 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. Vessel damage and complications at the puncture site may occur if the instructions for use are not followed.


Warranty and Limitations

Arterial Filters 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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