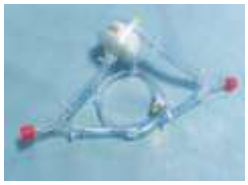
Instruction for Use



PerfX Arterial Filter

SPECIFICATION & PERFORMANCE CHARACTERISTICS

B L Part#	Variants	Selection of variants by the end user
BFL-XXXXX	Adult, Paediatric/Infant With or without purge line	Variants shall be selected by the end users, on the basis of patient body weight.
Specification & Special Features: • Filter Size: 40 micron • Priming volume: - Adult/Paediatric = 90ml, Infant = 35ml • Flow Rate (Ltrs/min): - Adult = 6 LPM, Paediatric = 5 LPM & Infant = 3.2 LPM ➢ Excellent Air Handling ➢ Excellent visibility & easy priming ➢ Available with or without purge line		

Description of the accessories of the device, other device and other products, that are not the device, intended to use in Combination with device:

During on-pump cardiac surgery, the arterial filter is supposed to use an accessory to the extracorporeal circuit and supposed to connect with tubings, connectors, oxygenator outlet, arterial cannula & Venous Reservoir.

The device is Single use, Sterile, Biocompatible & Pyrogen free.

DESCRIPTION

Arterial filters are important component used in cardiopulmonary bypass to remove blockages originating in the perfusion circuit such as gas emboli, fat emboli, and aggregates of platelets, red blood cells, and other debris. Good quality designs offer ease of priming, superior air handling, and efficient filtration.

Device available with purge line having connectors may fit with the way stop cock-makes possible to eliminate the micro-emboli that have been filtered out and to read the operating pressure.

All the material used for the manufacturing of the device & related components are DEHP-free & biocompatible.

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.
- The product is available in three-layer sterile packing.
  Primary Packaging: "Medical Grade Paper /Tyvek pouch /Plastic Pouch"
  Secondary Packaging: "Duplex Box"
  Tertiary Packaging: "Corrugated Box"

INTENDED USERS:

An appropriately trained and qualified perfusionist for extracorporeal circulation during cardiopulmonary bypass.

PATIENTS/BENEFICIARIES:

Patients who are very ill with the condition of heart and lung and who are waiting or recovering from cardiovascular bypass surgery. Arterial Filter is used as an essential part of extracorporeal circuit, to support & maintain the required blood consistency & protect the patient from possible gross embolization.

PATIENT TARGET GROUP:

- **Age Group:** Adult, Paediatric/Infant
- **Gender:** Male & Female both.

INTENDED PURPOSE

The device is indicated to be used in all cardiopulmonary bypass procedure for the removal of micro-emboli greater than 40 microns in size including gas emboli, fat emboli and aggregates composed of platelets, damaged red blood cells and bone chips from sternotomy, flakes of PVC tubing and other debris, from the arterial line.

Duration of use: During procedure, the device should not be used for more than 6 hours.

INDICATION FOR USE (Medical Condition to be diagnosed, treated or monitored)

During cardiovascular bypass surgery, Arterial filter is used as an accessory of extracorporeal circuit, to protect the patient from possible gross air embolization.

MODE OF ACTION

Arterial Filter is assembled on the arterial line of extracorporeal circuit (between oxygenator & aortic cannula). It has a luer lock port at the top which helps in de-airing of the product. It comes with a bypass loop which is primed & kept clamped throughout the surgery. Bypass loop is used to bypass the arterial filter in case of clotting.

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

Note: The device does not come in direct contact with the heart or central circulatory system.

PROCEDURE STEPS:

Pre-application:

- Ensure the proper aseptic conditions arrangements, before the product application.
- Before starting cardiopulmonary bypass, make sure that all the air has been thoroughly removed.
- Leak test or other necessary testing are advised prior to use.

Application:

- The device must be used immediately after being opened.
- The arterial filter is supposed to be positioned on the bloodline closest to the patient.
- Keep a bypass/Purge line in the event an alternate flow path is required, during the procedure.

- Remove the cap from the IN-inlet port.
- Connect the Arterial Filter line coming from the oxygenator to the IN-inlet port.
- Remove the cap from the outlet connector.
- Connect the arterial blood line running to the patient the OUT-outlet connector.
- To use the vent line/bypass/Purge line remove the vent port connector & and install the line. The vent line having a duckbill check valve (one-way valve) and three-way tap, should be installed between the filter vent port and oxygenator or another unpressurized location for continuous, automatic venting.
- If a check valve is not installed, position the filter so that it will be below the patient's midline and at or below the level of oxygenator during use.
- Orient filter in mounting bracket with inlet port horizontal & uppermost, the outlet port vertical & down.
- After filter is installed in arterial line, with vent uppermost and closed, clamp inlet tubing between filter and Y-Connector, prime rest of the circuit through bypass line at a flow of between 3-5 L / min.
- While maintaining flow open the vent line allow filter to fill. When liquid reaches the top of the filter remove inlet clamp completely and clamp bypass line.
- Remove filter from mounting bracket invert and tap with heel of your palm or rubber and of a percussion hammer to help dislodged any bubbles on downstream side of filter.
- The Blood to be treated must contain an anticoagulant. The device must not be used for longer than 6 hrs. Contact with blood for longer periods is not advisable.

CONTRAINDICATION

Conditions under which the device should not be used because the risk of use clearly outweighs any possible benefit;

- This device is not designed, sold, or intended for use except as indicated (off label use).

CLINICAL BENEFITS

- Patient's safety: prevention from micro-emboli either being particulate or micro air from reaching the patient's blood circulation.
- Uninterrupted blood flow over the course of bypass surgery.

CAUTION/WARNING

- Do not reuse, do not resterilize, do not reprocess. Reprocessing, Re-sterilizing or reusing the device may compromise the sterility, biocompatibility and functional integrity of the device.
- Carefully inspect the unit package to make sure that no damage to the sterile barrier has occurred. The device should be used immediately after opening the unit package. Do not use if the unit package is damaged.
- Sterility is only guaranteed if the packaging is undamaged.
- Pay attention to the date of expiry.
- Do not expose to any kind of heating source.
- Check for the device package contents, carefully for any damage.
- It is recommended to carefully check the product before application. Construction and function of the device may be affected by the transport. Manufacturer can therefore not guarantee the full function of the device when transport damages occur. The firm fitting of the end caps must be tested and have to be corrected if necessary.
- Product and equipment have to be used under aseptic conditions, immediately after the protection caps have been removed.
- Perform the procedure to Check and use the device as described in this product IFU.
- Do not use metal objects to strike the filter during priming.
- Before using with blood, check that the A.C.T (activated clotting time) is equal to or greater than 480 seconds.
- Never let the device come into contact with solvents such as alcohol, ether & acetone, etc.

Device-associated Possible Complications/side effects/adverse events

Troubleshooting: User medical staff should aware and able to troubleshoot certain complications that may occur during the application of the product like failure of arterial filter during procedure, air embolism & Thrombus formation.

STORAGE

Based on the stability studies, the recommended storage condition is between Temperature 15˚C to 40˚C. In case of any tampering in the packaging, the product condition may be affected even if 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 not recommended use of the device, including reuse.

DISPOSITION

The Device is biohazardous and contaminated with blood. Dispose off/ Discard the used Device, immediately after use, in accordance with your country's health care and safety regulations.

NOTICE TO THE USERS

If during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative and to your national authority.

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

Caution

Conformity of European Norm with Notified Body Number

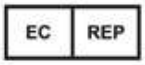
Manufacturer

Do not re-use

Use-by date

Mfg. Date/Country of manufacture

Batch/Lot Number



Authorized representative in the European Community

Sterilized using ethylene oxide
Single sterile barrier system

Do not resterilize

Consult instructions for use or consult electronic instructions for use

Non-pyrogenic

Do not use if package is damaged

Catalogue number

Temperature Limit

Fragile, handle with care

Keep dry

This way up

Keep away from sunlight

Stacking limit by number

Contents

Medical device

Unique Device Identifier

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