Instruction for Use

Hemoconcentrator Kit

SPECIFICATION & PERFORMANCE CHARACTERISTICS

B L Part#	Variants	Selection of variants by the end user
BHC-XXXXX	Adult, Pediatric & Infant	Variants shall be selected by the end users, on the basis of patient body weight.

Specification & Special Features
Adult: Flow rate: max 500 ml, filter size: (200 micron), Priming volume (Hemoconcentrator): 75 ml. TMP specification 500 mmHg.
Paediatric: Flow rate: max 200 ml, filter size: (200 micron), Priming volume (Hemoconcentrator): 49 ml. TMP specification 500 mmHg.
Infant: Flow rate: max 200 ml filter size: (200 micron), Priming volume (Hemoconcentrator): 21 ml. TMP specification 500 mmHg.

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

Device use as an accessory, in order to form an extracorporeal circuit, required in cardiac procedure. During procedure device supposed to connect with oxygenator outlet, Heart Lung Machine pump port & venous reservoir.

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

DESCRIPTION

The Hemoconcentrator is manufactured with hollow fibers made from special polysulfone, and designed for haemofilteration application. It is only allowed to use them in combination with volume controlling machine.

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: "Film – LDPE GSM 100, Medical Grade Paper/ Tyvek 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, During the CPB Hemoconcentrator kit helps in reduction in the concentration of normal blood constituents & inflammatory responses.

PATIENT TARGET GROUP

- **Age group:** Adult Paediatric and Infants.
- **Gender:** Male & Female both.

INTENDED PURPOSE
Hemoconcentrator Kit is designed as single use device for haemofiltration.

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

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

- In Cardiac surgery (Hemoconcentrator kit helps in reduction in the concentration of normal blood constituents & inflammatory responses).
- Heart failure
- In Modified ultrafiltration (a technique to remove excessive water from the body after restoration of the native circulation, but before removal of the cannulas used for bypass).

MODE OF ACTION
Hemoconcentrator is assembled in the Extracorporeal/Bypass Circuit. It has arterial (inlet) port which is connected to the high-pressure area (post oxygenator) & venous (outlet) port which is connected to the low-pressure area (venous oxygenator). Diluted blood enters the Hemoconcentrator, it is filtered & the concentrated blood is sent back to the extracorporeal circuit. The filtrate is collected in the drainage bag via the filtrate port.

Hemoconcentration is a technique used to separate extra fluid from the plasma and other formed cellular elements. The procedure involves the selective removal of fluid and its dissolved solutes by ultrafiltration. During the Process plasma water and small and medium-sized solutes are removed in a controlled manner from the vascular space while conserving the cellular elements and proteins in the circulating blood. The Technique of hemofiltration is applied to the blood which is hemodiluted during a cardiopulmonary bypass procedure. Hemofiltration is the result of a hydrostatic pressure gradient that exists across the semipermeable membrane. The gradient is achieved by the positive blood pressure supplied by the blood pump and negative filtrate pressure is achieved by vacuum suction.

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:
Band all the tubing connections, to make ready the setup, by using aseptic techniques.

Applications:

HEPARINIZATION
It is recommended to heparinise the extracorporeal circuit during priming. During haemofiltration the dosage of continuous heparin and the mode of application is decided on by the attending physician. Coagulation time must be checked on a regular base.

PREPARATION FOR HAEMOFILTRATION

Priming of the hemofiltration line with sterile heparinized IV solution.

- **Filling of blood compartment**
  - Remove haemofilter from the sterile packaging and attach to the holder in vertical position.
  - Connect the arterial and venous system to the machine. Strictly observe that the connectors remain sterile.
  - Remove blood connector caps of the haemofilter and connect the arterial and venous bloodlines aseptically (arterial connection lower side, venous connection upper side of the haemofilter).
  - Connect patient line of arterial blood-tubing-system to a bag with sterile, heparinized IV Solution.
  - Prime complete system with heparinized IV Solution (using pump setting approx. 150 ml/min, or with gravity IV fluid pressure bag. Remove air completely by short clamping of the arterial bloodline.
- **Filling of filtrate compartment**

  Hemofiltration:
  - Turn haemofilter so that the arterial blood-line points upwards and the venous blood-line points downwards.
  - Remove closure cap from upper filtrate connector and connect a haemofiltrate-collecting-bag with a suitable tubing-system. Keep lower filtrate connector closed with the cap (see drawing).
  - Start blood pump. Filter rest of IV Solution partly across the membrane and prime filtrate compartment and filtrate system.
  - The patient can be connected when blood compartment is completely filled and deaerated.
- **Performance of haemofiltration**

  In order to achieve the listed performance data, the haemofilter must be used in a vertical position. The blood inlet and the filtrate outlet are fixed in the upper part and the blood outlet is located in the lower part.
- **Connection of the patient**
  - Connect arterial blood line to the patient's circulation. Avoid the intake of air.
  - Let blood enter into tubing system and haemofilter (pump speed at approx. 100 ml/min) until a substantial part of the IV solution has been displaced. Discard as much rinsing solution as possible.
  - Connect venous tubing system to the patient.
  - Set blood flow at required value.
  - Circulate blood for approx. 3 minutes without filtration.
- **Setting of filtrate flow**
  - Titrate the flow slowly to achieve the desired filtrate rate.
  - The maximum filtrate flow should amount to 30% of the set blood flow, otherwise an excessive thickening of the blood in the capillaries (hemoconcentration) may occur.
  - Monitor weight loss, loss of the weight of patient will be corresponding to fluid removed during hemofiltration.
- **Action in case the air enters the haemofilter**
  - During hemodialysis the last air possible should be present in the extracorporeal circuit, otherwise:
  - Set lowest possible filtrate flow.
  - Remove air by repeated clamping of arterial blood line.
  - Reset UF-rate to desired value.
- **Action in case the blood pump stops (e.g. alarm)**
  - Set UF-rate as low as possible to avoid excessive thickening of the blood in the capillaries.
  - Reset UF-rate to required value several minutes after restarting the blood pump.
- **Action in case of blood leakage**

  Each haemofilter is tested for leakage during manufacturing. Should a blood leakage occur, proceed as instructed:
  - Set UF-rate as low as possible.
  - Set blood flow at approx. 100ml/min.

  Smaller blood leaks usually clog within 10 minutes. In case of a larger blood leak the haemofilter must be exchanged. The necessity of a retransfusion depends on the size of the blood leak and must be decided upon by the attending physician.
- **To terminate haemofiltration**
  - Set UF-rate as low as possible approximately 5 min. before terminating haemofiltration.
  - Switch off the blood pump!
  - Clamp arterial blood line to patient connection, remove from patient and connect to a bag with 250 ml of sterile, IV Solution. Ensure that no air enters into the extracorporeal system.
  - Release clamp and reinfuse blood at 100-200 ml/min. The "drawing" of blood into the arterial line can be reduced by repeated squeezing of the tube with a clamp.
  - Once IV Solution flows into the haemofilter it is of advantage to repeat clamping the arterial tube briefly until all blood is removed from the haemofilter.
  - Reinfuse patient blood completely.
  - Clamp venous blood-line at patient connector and remove from the patient.

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

- Provides optimum blood management for the patient's benefits during Cardio Bypass Surgery with physiological hemoconcentration characteristics.

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.
- Do not lubricate silicone rubber pump headers with silicone or silicone grease. Failure may result due to swelling and weakening of the tubing.
- Ensure that only devices for haemofiltration are used, which ensure an exact balancing of the filtrate- and substitutes volume.
- The Hemoconcentrator Kit, is nontoxic, sterile, and free from pyrogen.
- 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 damaged or missing components.
- It is recommended to carefully check the product before application. Construction and function of the Hemoconcentrator Kit may be affected by the transport. Manufacturer can therefore not guarantee the full function of the haemofilter 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.
- Hemoconcentrator Kit has to be vented before starting extracorporeal circulation.
- Perform the procedure to Check and use the Hemoconcentrator Kit, as described in this product IFU.

- To ensure an optimal function additional devices or connections are required at specific application modes. It is recommended to read this Product IFU, carefully before, the device is applicated. Ensure that all necessary equipment is at hand before the application of the haemofilter.
- Do not use solvents such as alcohol, ether, acetone and fluid-and gaseous inhalation- anaestetics (e.g. halothan, enfluran); these products may damage the haemofilter on the in- and outside.
- The maximal blood flow rate must not be exceeded.
- The maximal transmembrane pressure (TMP) must not be exceeded.
- A correct heparinization and an exact control of the anticoagulance level has to be provided.
- Hemofiltration may affect the effective concentration and clearance of concomitant drug and medication. So the close monitoring of hemofiltration therapy, must be required by the prescribed medical staff.

Device-Associated Possible Complications/Side Effects/Adverse Events

Troubleshooting: User medical staff should be aware & able to troubleshoot certain complications that may occur during the application of the product like leakage of filter membrane that can cause blood leakage and mix up, air embolism.

- Reactions of hypersensitivity may occur in rare cases during haemofiltration. In severe cases the haemofiltration must be discontinued and the appropriate medication must be initiated.

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

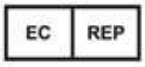

Manufacturer


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

B L Lifesciences Pvt. Ltd.
28-D, Sector-31, Ecotech-I, Greater Noida
Gautam Buddha Nagar, Uttar Pradesh (India)-201306
www.bllifesciences.com
Tel: +91 11 45100100
Email: blls@bllifesciences.com
Device Basic UDI-DI: 8903283BHCG4

Obelis s.a
Bd. Général Wahis 53
1030 Brussels, Belgium.
Tel: +(32)2.732.59.54
Fax: +(32)2.732.60.03
E-Mail: mail@obelis.net