

# Instruction for Use



**SPECIFICATION & PERFORMANCE CHARACTERISTICS**

B I Part#	Variants	Selection of variants by the end user
BHL-TB-XXXXX	PVC (Poly Vinyl Chloride)/Silicon/Silicon Replacement & Coated tubing	Variants shall be selected by the end users, on the basis of end user requirement.
<b>Specification &amp; Special Features:</b> Available with the Length of (1ft to 12 ft) USP Class VI compliant tubings Kinked resistant/Transparent/Clear Tubing		

**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 device supposed to form an extracorporeal circuit.

During procedure device supposed to connect with Connectors, Arterial Filter, Hemoconcentrator, Cardioplegia Delivery System/ Heat Exchanger, Oxygenator, Heart Lung Machine etc.

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

**DESCRIPTION**

Medical grade tubing, to carry blood to & from the patient to the Heart Lung machine/Oxygenator.

PVC/Silicon, Silicon Replacement/Coated tubing, are used as an accessory to form extracorporeal circuit supposed to connect with Heart Lung Machine, during on pump cardiac surgery.

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 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, ill with the condition of heart and lung and waiting or recovering from cardiovascular bypass surgery.

**PATIENT TARGET GROUP:**

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

**INTENDED PURPOSE**

Tubings are spare tubings sterile medical grades provided to be used as an accessory in extra-corporeal circulation. These are the accessories to Heart Lung pack.

**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)**

- Especially on-pump cardiopulmonary bypass (CPB).
- When extensive or complex revascularization is needed.
- CPB allows the heart to be stopped and blood to be diverted for a bloodless surgical field.
- Tubing are used as an accessory in extra-corporeal circulation circuit.

**MODE OF ACTION**

PVC Tubing interconnects all of the main components of the circuit during cardiopulmonary bypass surgery.

**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.
- Only use standard Luer connection devices.

**Application**

- Open the undamaged sterile pouch in sterile area.
- Start the setup.
- While setting up the tubing system, do take care to avoid kinking and damage of the component of the circuit.

#### **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**

- Tubings provide sterile blood flow path for the blood circulation which reduces the systemic inflammatory responses in extracorporeal circuit required for Cardiopulmonary bypass (CPB).

#### **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.

#### **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 Failure/rupture of tubing, hemodilution etc.

#### **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@blllifesciences.com](mailto:blls@blllifesciences.com) or call +91 11 45100100

Company Website Link to product IFU: <https://www.blllifesciences.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 re-sterilize



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.blifesciences.com](http://www.blifesciences.com)  
 Tel: +91 11 45100100  
 Email: [blis@blifesciences.com](mailto:blis@blifesciences.com)  
 Device Basic UDI-DI: 8903283BHL-TBSU

**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](mailto:mail@obelis.net)