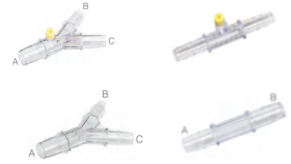
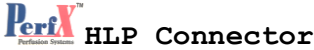


Instruction for Use



SPECIFICATION & PERFORMANCE CHARACTERISTICS

B L Part#	Variants	Selection of variants by the end user
BCN-XXXXX	Straight/ Y Connector - with or without Luer Locks & cap	Straight Connector- Used to join two tubings/components/other medical devices when uni-directional liquid flow is required.
Specification & Special Features: Available with secure Luer leak-proof connection.		Y connector- Provide liquid flow diversion to multiple channels at a time.
		Straight/ Y Connector with Luer port- Facilitates de-airing and provide connecting port to add another medical devices if required to perform application.

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

In order to form an extracorporeal circuit, connector is supposed to connect with tubings, as per requirement. The device is Single use, Sterile, Biocompatible & Pyrogen free.

DESCRIPTION

It is used as an accessories of Heart lung pack. Connectors are made up of Polycarbonate and is used to connect the different size tubing with each other.

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

HLP connectors are used to connect the two perfusion tubing to each other. These are the accessories of 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.
- Connectors are used to connect the different size tubing with each other in order to form an extracorporeal circuit.

MODE OF ACTION

Connectors are used to connect different sizes of tubings and other components in a Heart Lung Pack to assemble them together. The shape & size of the connector is according to the respective tubing.

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.

Application

- Select the appropriate size and variant of connector.
- Set the setup as per the requirement and initiate the application.

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

- Facilitating leak proof & sterile connection between different size tubing required to create extracorporeal circuit, during cardiopulmonary 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.
- 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.
- Leak test or other necessary testing are advised prior to use.

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 blood loss due to use of multiple connectors.

Note: The user medical staff should have good knowledge to select appropriate size and required connections to form extracorporeal circuit to circulate the blood during cardiac surgery.

The irrelevant tube length and multiple connections to form extracorporeal circuit can cause blood component's damage/blood loss, which is caused due to mechanical force generated by multiple connections.

HLP connectors are supposed to join two tubings, if there are multiple connections, multiple connectors will be required to join them. During bypass surgery, when blood circulate inside this extracorporeal circuit, due to multiple connectors extra mechanical force will be generated & damage the blood components and increase the chances of blood loss.

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 bls@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 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	



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