

# Instruction for Use



## THORACIC DRAINAGE CATHETER

Variant	: Straight/Angled
Product Class as per REGULATION (EU) 2017/745	: IIa
Product Class as per Medical Device Rule	: B
Duration of use	: Short Term



### **DESCRIPTION**

It is a flexible plastic tube that is inserted through the chest wall and into the pleural space or mediastinum.

The major components of the thoracic Drainage Catheters are;

Pull Connector-PVC, Tubings-PVC & Step Connector-ABS

The device does not contain;

- DEHP
- medicinal substance, including a human blood or plasma derivative,
- tissues or cells, or their derivatives, of human origin
- tissues or cells of animal origin, or their derivatives.

Patient Target Group: All Age groups

### 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.

### **INTENDED USE**

A thoracic drainage catheter is intended to drain the thoracic cavity during the surgery.

### **MODE OF ACTION**

A thoracic drainage catheter is used to drain fluid and air, prevent these from returning back into the pleural cavity, and restore the negative pleural pressure facilitating lung expansion. This may be into a bag or jug for fluid, or into air or a tube inserted into a bottle under water acting as a one-way seal to prevent air being entrained.

### **INDICATION FOR USE**

#### **Pre-Application**

- Examine the product before applying for the color, consistency, amount, and if there are any clots present.

#### **Application**

- Peel open the package and remove the B L thoracic catheter using sterile technique.
- Users should be familiar with thoracic surgical procedures and techniques before using BL thoracic catheters. Only qualified healthcare practitioners should insert, manipulate and remove thoracic catheters.
- The insertion technique, location and catheter size are at the discretion of the physician to optimize drainage efficiency. Care must be taken when inserting the thoracic catheter to avoid puncturing the lung and/or other organs.
- The thoracic catheter should be secured properly in place to avoid accidental dislodgement or removal.
- Patient tube connections, insertion site and catheter patency should be checked regularly to confirm proper operation.
- Care should be taken during catheter removal from the patient to avoid damaging the catheter.

#### INTENDED USERS

- Product is recommended to use by qualified medical/paramedic staff.

### **CONTRAINDICATION**

- This device is not designed, sold, or intended for use except as indicated.
- Allergy to the material contained in the device.
- Patient with a suspected coagulopathy or other hemorrhagic tendency.
- Pulmonary bullae.
- Pulmonary, pleural, or thoracic adhesions.
- Pulmonary abscess.
- Loculated pleural effusion or empyema.

### **CLINICAL BENEFITS**

- Chest tube can be effective at draining fluid and air from pleural space.
- The withdrawal of thoracic drainage has been found to be comfortable, safe and well tolerated by patients.
- The radiopaque catheter material enhances the radiopaque visualization during X-ray.

### **CAUTION/WARNING**

- Do not use the product if the package is damaged or open.
- Skin infection at the chest-tube insertion site.
- The product is designed for single use only.
- Heparin infusions for cardiac patients should not be discontinued prior to drain removal
- Troubleshooting The physician should be aware that certain complications may occur during the application of the product such as; Pneumothorax, Bleeding at the drain site, Infection at insertion site.

**RISKS OF RE-USE**

- A device designated, as 'single-use' must not be reused. It should only be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used again, even on the same patient.
- The reuse of single-use devices can affect their safety, performance and effectiveness, exposing patients and staff to unnecessary risk.
- The reuse of single-use devices has legal implications:
  - anyone who reprocesses or reuses a device intended by the manufacturer for use on a single occasion, bears full responsibility for its safety and effectiveness;
  - anyone who reprocesses a single-use device and passes it to a separate legal entity for use, has the same legal obligations under the Medical Devices Regulations as the original manufacturer of the device.
- Reprocessing a single-use device may alter its characteristics so that it no longer complies with the original manufacturer's specifications and, therefore, the performance may be compromised.
- If re-used it may lead, but not limited to cross-infection.

**STORAGE**

Based on the stability study report as per ICH guide line the Recommended storage condition in between Temp 15°C to 40°C and maintaining the relative humidity condition 50 to 75%. In case of any tempering in the packaging the product condition may be affected even incase store at above defined condition. Sterilization is valid for three years from the manufacturing of the product.

**DISCLAIMER**

The condition of the device must be verified prior to use. B L is not responsible for any damage to person, property, etc. from any inappropriate or recommended use of the device, including reuse. Reuse could cause infection or serious health issues.

**DISPOSITION**

Dispose off/Discard the used Device, in accordance with your country's health care and safety regulations.















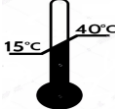
**GOODS RETURN POLICY**

Refer to the company's return goods policy.

Please contact the branch office or customer service at [bls@bllifesciences.com](mailto:bls@bllifesciences.com) or call +91 11 45100100.

Company Website Link to product IFU: <https://www.bllifesciences.com>

**SYMBOLS USED ON PRODUCT LABEL**

Symbol			
Meaning	Caution	Conformity of European Norm with Notified Body Number	Manufacturer
Symbol			
Meaning	Do not re-use	Use-by date	Date of Manufacture
Symbol			
Meaning	Batch/Lot Number	Authorized representative in the European Community	Sterilized using ethylene oxide Single sterile barrier system
Symbol			
Meaning	Do not resterilize	Consult Instruction for use	Non-pyrogenic
Symbol			
Meaning	Do not use if package is damaged	Catalogue number	Temperature Limit

Symbol



Meaning

Fragile, handle with care



Keep dry



This way up

Symbol



Meaning

Keep away from sunlight



Stacking limit by number

Symbol



Meaning

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: [bls@blifesciences.com](mailto:bls@blifesciences.com)



**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)

Device UDI-DI 2890328300633