

Instruction for Use



Pressure Monitoring Line



SPECIFICATION & PERFORMANCE CHARACTERISTICS

B L Part#	Variants	Selection of variants by the end user
BPT-XXXXX BRPT-XXXXX BBPT-XXXXX BYPT-XXXXX BPPT-XXXXX	Plain, Red, Blue, Yellow & Paediatric	USP Class VI compliant, DEHP free tubings. Luer fitting in compliance to ISO 80369-7.
Specification & Special Features: Sizes: OD: 2.80 mm ID: 1.27mm, 0.9mm Thickness: 0.78mm		

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 application, device supposed to connect with Arterial Catheter/ Central venous Catheter, Pressure Transducers, syringes & stopcock.

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

DESCRIPTION

The pressure monitoring Line is made of medical grade PVC. It is available with male to male and male to female connectors.

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: "Paper Pouch/ Tyvek paper"

Secondary Packaging: "Duplex Box"

Tertiary Packaging: "Corrugated Box"

INTENDED USERS:

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

PATIENTS/BENEFICIARIES:

Patients in operating room, critical care units, and catheterization lab, who requires to monitor their continuous and accurate invasive blood pressure.

PATIENT TARGET GROUP:

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

INTENDED PURPOSE:

The Pressure Monitoring Lines are indicated to be used for the transmission of waves of Invasive Blood Pressure of the patient to the vital sign monitoring during OT/critical units & catheterization labs.

Duration of use: During application, device does not recommend to use more than 24 hours. Device restricted to single use only.

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

- Intravascular Blood pressure monitoring.

MODE OF ACTION

Pressure monitoring lines come with Male/Female luer lock connection. They help to connect the site of pressure to be monitored to the pressure transducer or other parts of the Pressure Monitoring Kit.

This functional unit is sterilized by 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

- Inspect the package and product for damage. If undamaged, open the package and transfer the product into the sterile field utilizing an aseptic technique.
- Connect the Male port of the Pressure Monitoring Line to the patient end.
- Connect the Female port of the Pressure Monitoring Line to the transducer end.
- Flush and fill the line with saline to ensure bubble free priming.
- Red line may be indicated for Arterial use and Blue for Venous line for easy identification.

CONTRAINDICATIONS

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).
- The Patient is known or is suspected to be allergic to materials contained in the device.
- High viscous liquid and large blood transfusion.

CLINICAL/BENEFITS

Pressure Monitoring Lines provide sterile path to allow continuous beat to beat blood pressure monitoring that is useful in patients who are likely to display sudden changes in blood pressure (e.g. vascular 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.
- 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.

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 back flow and air bubble in pressure monitoring line.

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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