

Instruction for Use



HIGH PRESSURE TUBING



SPECIFICATION & PERFORMANCE CHARACTERISTICS

B L Part#	Variants	Selection of variants by the end user
BHPT-XXXXX	10", 20", 48" (Tube Length)	Variants shall be selected by the end users, on the basis of application requirement on patients.
Specification & Special Features: 1. 1200 PSI rating 2. Rotating Male Luer Lock		

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 is supposed to connect with the Hemostasis Y connector & manifold.

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

DESCRIPTION

High Pressure Tubing is the combination of PU tubing, MLL, FLL connectors. It is used to carry the fluid/contrast media to the patient during coronary angiography.

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"
Secondary Packaging: "Duplex Box"
Tertiary Packaging: "Corrugated Box"

INTENDED USERS:

- An interventional cardiologist/Interventional radiologists and vascular surgeons.

PATIENTS/BENEFICIARIES:

- Patients, requires to do a coronary angiogram procedure.
(High Pressure Tubings support carrying the Fluid/contrast media to the patient).

PATIENT TARGET GROUP:

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

INTENDED PURPOSE:

High Pressure Tubing is the tubing to carry the fluid / contrast media to the patient during coronary angiography procedure.

Duration of use: The device is recommended for short-term use. During the coronary angiography procedure, device used to carry fluid/contrast media. In general, angiography procedure takes 30 minutes to 2hrs. Device restricted to single use only.

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

During coronary angiography, High Pressure Tubing is used to transport the contrast agent into the patient's vessels under extreme pressure (1200 PSI).

MODE OF ACTION

During coronary angiography procedure, the smallest ramifications of the blood vessels, a contrast agent is required which is injected in to the body with high pressure via the tubes. During the application, the high-pressure tubing must withstand the forceful injection reliably, while remaining kink-free and flexible.

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:

- Confirm the appropriate size of the tubing prior to use as per requirement. It is available in 10", 20" & 48" as standard lengths.

Application

- This is PU material tubing, designed to handle pressure upto 1200 psi.
- Open the undamaged sterile pouch in sterile area.
- Remove the caps. Connect the female luer end to the manifold. Connect the male luer end toward the patient via suitable device.
- Make sure that entire system is de-aired before use.

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).

CLINICAL/BENEFITS

- High pressure stability during coronary angiographic procedure.

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 the certain complications may occur during the application of the product such as; bruising and soreness 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 blis@bllifesciences.com or call +91 11 45100100

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

SYMBOLS USED ON PRODUCT LABEL



Caution



2460

Conformity of European Norm with Notified Body Number



Manufacturer



Do not re-use



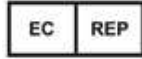
Use-by date



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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