Instruction for Use

AngiX HEMOSTASIS Y

SPECIFICATION & PERFORMANCE CHARACTERISTICS

B L Part#	Variants	Selection of variants by the end user
BHYL-XXXXX	Large Bore rotating, Click Type, Push Pull	Variant selection of Y connector…Large bore, Push Pull or Click Type, is completely the choice of the clinician & and his/her experience. All three variants are intended for the same application except for some modernity in basic design.
Specification & Special Features: 1. Compatible with catheter from 4 FR up to 9 FR and Guide wire from 0.014" to 0.038" diameter, Rated pressure- 480 Psi		

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 the coronary angioplasty procedure, the device play the role of maintaining Hemostasis and is supposed to connect with an arterial catheter.

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

DESCRIPTION

Hemostasis Y is a back bleeding valve for PTCA (percutaneous transluminal coronary angioplasty) procedure. It is used in the diagnostic and interventional procedure. It accepts the standard Guide wire and angioplasty catheters. Provided valve can be shifted between three state open, Semi open and close.

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 introduction of interventional devices.
(Hemostasis Y is used to maintain hemostasis during coronary angioplasty procedure).

PATIENT TARGET GROUP:

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

INTENDED PURPOSE

Hemostasis Y is used to maintain Hemostasis during the introduction, use and withdrawal of diagnostic and interventional devices, used in coronary angiography/angioplasty procedures.
Hemostasis is a physiological process by which bleeding cease.

Duration of use: The device is recommended for short-term use. In general, angiography/Angioplasty procedures takes 30 minutes to 2hrs to perform, during the procedure Hemostasis Y is used as an accessory to maintain Hemostasis. The device is restricted to single use only.

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

- To maintain hemostasis during coronary angioplasty.
  "Hemostasis" is the mechanism that leads to the cessation of bleeding from a blood vessel.

MODE OF ACTION

Hemostasis Y valve provides self-sealing mechanism to limit the backflow of blood or other fluids. Transluminal devices such as guidewire and catheters may be passed through such a conduit.
During application, hemostasis Y connector forms a seal around & and minimize the opening around the diagnostic/ interventional devices, which prevents the backflow of blood.

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:

- Variant selection of Y connector…Large bore, Push Pull or Click Type, is completely the choice of the clinician & and his/her experience. All the three variants are intended for the same application except for some modernity in basic design.
- Peel open the package and remove the Hemostasis Y Connector.
- Connect the device to the angioplasty catheter female connection and lock it with the luer lock (The catheter can be already inserted into the patient's blood vessel at this time).
- Connect the female luer of the side arm to a manifold or automatic injector or inflation device as per set up requirement.
- **Opening of septum and insertion of guidewire:**
  Once the connection is properly locked you can freely aspirate or flush and then insert the guide-wire.
  - For Large bore Turn the knob to open the septum and insert the guidewire.
  - For push-pull type: Push the knob to open the septum and insert the guidewire.

- For Click type: Insert guidewire through the Y-Click Connector by pushing the distal part to the end and opening the device.
- Use guide-wires in diameter between 0.014" and 0.038".

- **For closure of the device:**
  - Standard Rotating: Turn the knob to close the septum to arrest the guidewire movement.
  - For push-pull type: Pull the knob to close the septum to arrest the guidewire movement.
  - Click Type: Press the y-lever and the device will be in a close position to arrest the guidewire movement.

  After inserting the guide wire open the device to the semi-open position by pushing the distal part only for one click, for easy maneuverability of the guiding wire. To close back the device press the y-lever and the device. This additional feature is available only in click type Hemostasis Y.
- For safe insertion of angled and soft guide-wires, balloon and stent catheters fully open the device and afterwards close it back.
- While injecting the contrast media the device should be in the closed position (closed position, i.e. guidewire movement is arrested to clear the passage for contrast media).
- If an automatic contrast media injector is used the following parameters should not exceed: 600 psi & 15 ml/sec.
- Make sure that when the device is under low pressure (arterial pressure) up to 250 mmHg, fluid loss should not exceed 10 drops (monitored manually).

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

- It reduces the complication related to bleeding after 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 & and able to troubleshoot certain procedural complications, side effects/adverse events/ may occur during the application such as; Air embolism.

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@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

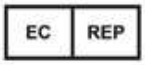

Manufacturer


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 resterilize


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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