

Instruction for Use



SPECIFICATION & PERFORMANCE CHARACTERISTICS

B L Part#	Variants	Selection of variants by the end user
BMN-XXXXX	2 Core/3 Core - Right ON/OFF.	Variants shall be selected by the end users, on the basis of application requirement on patients.
Specification & Special Features: <ol style="list-style-type: none"> 1. Available with coloured handle 2. Clear material for easy detection of bubbles. 3. Large bore for max. flow 500 Psi 4. Manifold facilitate rotation of the catheter & Administration of contrast/ medicine during coronary angiography procedure. 5. Handle available with right on/off features. <ul style="list-style-type: none"> - "ON" handle facilitates flow of movement by rotating the handle at right direction. - "OFF" handle stops the flow by rotating the handle at right direction. 		

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 High Pressure Tubing, control Syringe & other infusion devices.

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

DESCRIPTION

Manifold used during coronary angiography and angioplasty and it is compatible with all commons fluids (contrast, saline) used during the procedure.

It is providing airless rotator that enhance patient safety by minimizing the possibility of trapped air and create more space for user.

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.
(Manifold is used to infuse the contrast media during a coronary angiography procedure).

PATIENT TARGET GROUP:

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

INTENDED PURPOSE:

Manifold is a hand-controlled device used during the injection of contrast media during coronary angiography procedure.

Duration of use: The device is recommended for short-term use. Device is used as channeling device, to inject contrast media, during coronary angiography procedure. The whole angiography procedure takes 30 minutes to 2hrs for the completions. Device restricted to single use only.

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

To infuse the contrast media, during the coronary angiography procedure.
Contrast media highlights the differences between various parts of the body, including those parts that have a similar composition. This provides a clearer image of how the body is working, or if there is any disease or abnormality present.

MODE OF ACTION

During the coronary angiography procedure, the manifold is supposed to connect with Y connector (Hemostasis Y connector) via high-pressure tubing and on another side, connected to the syringe (or an automated injection-device) for radiocontrast application, and on its side arms to the saline infusion, to the transducer for invasive blood pressure monitoring. Through the manifold, the operator controls the contrast injection, blood pressure, injections of heparinized saline if necessary, etc.

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

- Open the undamaged sterile pouch in sterile area.
- Remove the caps. Connect the manifold to the required items.
- At distal end, control syringe may be attached. At lateral ports, contrast media set and IV line / pressure monitoring line may be attached. The proximal male luer to be attached toward patient via high pressure tubing and similar device.
- Make sure that entire system is de-aired.

- To ensure that there is no air or clot within the coronary catheter, a syringe is connected to the catheter to aspirate and discard at least some 5 ml of blood. This is the approximate volume of the catheter lumen/or allow a small 'bleed back' from the catheter, after which the catheter is connected to the three-port manifold.

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 facilitates the entire closed system, during coronary angiography to avoid the cross-contamination.

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 may occur during the application of the product 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 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



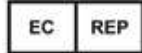
Use-by date



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



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Medical device



Unique Device Identifier



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