

# Instruction for Use



## AngiX™

### Angio kit

Variant : with/without Manifolds-2 gang kit/3 gang kit-with/without Drapes & Surgical instruments.

Product Class REGULATION (EU) 2017/745 : IIa

Product Class as per Medical Device Rule-2017 : B

Duration of use : Short Term

### DESCRIPTION

Angio kit used during Cardiac & Vascular Catheterization in order to diagnose the possible blockage in an artery or vessel. This is a complete Angiography kit made per 'open & use' concept to save assembling time during acute Cardiac arrest.

The major components of the Angio Kit are;

Manifold 2 gang kit/ 3 gang kit- HDPE, Manifold 2/3, 4/5 core right on/ off- HDPE, Introducer needle-SS, Hemostasis Y click/Large Bore/Push Pull-PC, Insertion tool/Blunt Needle-20G, 10cm-SS, Torque device-ABS, High pressure tubing- 25/50/120cm- PU, Control syringe-10/12/20ml- PC & TPR, Inflation device- 30ml-PC/ABS, High Pressure Stopcock-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

It is used during Angiography or Angioplasty to diagnose/treat cardiac blockages. kits are assembled including all the angiographic accessories indicated to be used during Cardiac & Vascular Catheterization/radiology procedures.

### MODE OF ACTION

Angio Kit is a combination of manifolds, control syringes, inflation device, needle, insertion tool, torque device, Hemostasis Y, tubings & other accessories together, under controlled & monitored conditions, to form a functional unit.

### INDICATION FOR USE

#### Pre-application

- Site preparation for the access of guidewire.
- Sometimes an artery in the groin is used as the access point instead of Arm.
- Numbing Medicine (Anesthesia)
- Patient is given medicines to relax but will stay awake the entire procedure.

#### Application

- Open the Angio pack containing sterile disposable Angio kit. Check all the fittings & connections to minimize any possibility of air embolism & infection.
- Prepare Cath Lab protocol under sterile conditions.
- Cover the patients with drape to initiate the procedure. if decided to perform femoral Angio, use fenestrated drapes.
- Connect IV-line, Contrast line & PM Line of pre-fitted manifold assembly to the respective sources.
- Flush the kit with heparinized saline.
- Check for leakage, if any.
- Drape and Puncture the targeted site pre-decided for performing Angiography using aseptic technique.
- Proceed with Angiography procedure under the supervision of Interventional Cardiologist who is familiar of possible complications, may arise during the catheterization.
- Locate & spot the blockage in the vessel.
- Remove the whole kit once procedure is over.

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.
- Patient weight that exceeds the angiography table limit (150 kg mostly). Overweight patients might prohibit the use of angiography equipment because of technical safety concerns.
- Pregnancy or possible pregnancy (unless there is life-threatening hemorrhage or threat of same e.g. bleeding from placenta accreta).
- Significant previous allergic reactions to iodinated contrast medium injection e.g. iohexol, iopamidol. These includes acute breathlessness due to bronchospasm, laryngospasm, and swelling of the tongue and oropharynx, cardiovascular collapse, and any reaction requiring emergency medical resuscitation (certain previous allergic reactions can be managed by pre-treatment with steroids and antihistamines, or by using carbon dioxide angiography).
- Renal impairment or dehydration. Additional contrast medium burden might lead to a deterioration in renal function.
- Coagulopathy (especially INR > 2, aPTT ratio > 2, platelet count < 50,000 x 10<sup>6</sup>). This could be a consequence of chemotherapy, liver disease or hematological disease. With the advent of artery closure devices, the contraindications of underlying coagulopathy are fewer than was historically the case.
- Antiplatelet or blood thinning medication.
- In diabetic patients treated with metformin who have pre-existing renal impairment or might have large doses of contrast medium during the procedure, there is an increased risk of deteriorating renal function and lactic acidosis after angiography. Metformin should be stopped on the day of the procedure until 48 hours after angiography (using other treatments to control the patient's diabetes). It can then be restarted if blood tests show no deteriorating renal function (see: RANZCR Guidelines for Iodinated contrast administration, 2009).
- Excessive anxiety (might require general anesthesia).
- Inability to lie flat or still (might require general anesthesia).
- The Patient is known or is suspected to be allergic to materials contained in the device.

**CLINICAL BENEFITS**

- Angiography may eliminate the need for surgery. If surgery remains necessary, it can be performed more accurately.
- Angiography may give more precise anatomical detail than other imaging, particularly in small blood vessels.
- Heart and vascular angiography is faster, non-invasive and has fewer complications.
- There is also potentially less discomfort because contrast material is injected into an arm vein.
- No radiation remains in a patient's body after heart and vascular angiography.

**CAUTION/ WARNING**

- Do not use the product if the package is damaged or open.
- Ensure all additional warnings and/or cautions contained in this IFU.
- It is strongly recommended that you do not place the Catheter/Guidewire into or allow it to remain in the vessel. Failure to follow these instructions can result in to serve patient's injury.
- The physician should be aware that certain complications might occur during insertion.
- Observe all additional warnings and/or cautions contained in the Directions for Use.
- Do not advance or withdraw the Guidewire against resistance.
- Product must not be re-sterilized. The re-sterilization of the device will alter mechanical and chemical properties, inappropriate of intended use and also increase the EO residue on device.
- Troubleshooting: User Paramedic staff should be aware & able to troubleshoot the certain complications may occur during the application of the product such as; Sudden loss of aortic pressure, Improper flow, Leakage etc. related to the device.

**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 guidelines 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. 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. 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**



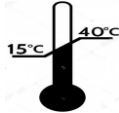







Refer to the company's return goods policy.

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


Company Website Link to product IFU: <https://www.blifesciences.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 re-sterilize	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	



  
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