Instruction for Use

AngiX® Interventional Systems

CONTROL SYRINGE

SPECIFICATION & PERFORMANCE CHARACTERISTICS

B L Part#	Variants	Selection of variants by the end user
BCSR-XXXXX	6ml, 10ml, 12ml & 20ml – Clear.	Variants shall be selected by the end users, on the basis of patient body weight to fix the dose.
Specification & Special Features: **1.** Available with 10cc ,12cc or 20cc capacity. 2. Available with low friction hub. 3. Available with Bold marking for correct measurement of dosage. 4. Available with Finger Grips for one-hand operation. 5. Available with 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, the device supposed to connect with Manifold.

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

DESCRIPTION

Control Syringes, are a special style of syringe that include finger and thumb rings that are attached to the barrel's proximal end and to the plunger's tip. Control syringes are uniquely designed with a safe space that effectively limits the risk of introducing air bubbles into the catheter.

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: "Tyvek Paper"
  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.
  (Control syringe is used to inject contrast media during a coronary angiography procedure. Contrast media highlights the differences between various parts of the body).

PATIENT TARGET GROUP:

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

INTENDED PURPOSE:

Control syringe is a hand-controlled device used to inject contrast media during the coronary angiography procedure.

Duration of use: The device is recommended for transient use. During the coronary angiography procedure, a device is used to inject contrast media.

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

The patient who requires coronary angiography, during procedure control syringe is used to inject contrast media.
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

Control syringe allows to generate more pressure with less applied force, resulting in improved visualization with less contrast, increased flow through smaller French-sized catheters and decreased hand fatigue.
Device design includes finger grips that facilitate one-hand control during product application. This design also helps in generating more pressure in less applied force: This More pressure generating feature, also promotes the flow in less French size catheters, which carry less amount of contrast and result in clear imaging even after less volume of contrast.

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.

Application

- Push the plunger into barrel to expel air out.
- Connect the male Luer lock to the manifold assembly & secure all connections.
- Flush the system to ensure free-flow channel.
- Once the manifold connection is done push the plunger to ensure the forwarded flow of the contrast media to initiate the Angiography procedure.

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

- Control syringes facilitates precise and accurate administration of contrast media, which improves the quality and reliability of diagnostic and therapeutic interventions.
- Enhance visualization of target tissues, improved success rates of procedures, and reduced risk of complications.
- Minimized Contrast Waste; The precise control over contrast injection can help minimize waste.

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 Paramedic staff should be aware & able to troubleshoot certain procedural complications, side effects/adverse events/ may occur during the product application like Air embolism, vessels damage at the site of application, impacts of dye injection on kidney function (on sensitive/ allergic patients).

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

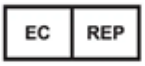
Manufacturer

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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