

# Instruction for Use



## INTRODUCER NEEDLE



### SPECIFICATION & PERFORMANCE CHARACTERISTICS

B L Part#	Variants	Selection of variants by the end user
BIN-XXXXX	18Gx7cm, 20GX4cm, 20GX7cm, 21GX4cm.	Variants shall be selected by the end users, on the basis of patient body weight and vessels sizes.
<b>Specification &amp; Special Features:</b> <ol style="list-style-type: none"><li>High precise atraumatic bevel tip needle.</li><li>OD for 18G-1.30 ±0.2mm, Length-70mm±2mm.</li><li>OD for 20G-0.9 ±0.2mm, Length-40mm±2mm.</li><li>OD for 20G-0.9 ±0.2mm, Length-70mm±2mm.</li><li>OD for 21G-0.81 ±0.2mm, Length-40mm±2mm.</li></ol>		

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 stand-alone works, to perform the intended application. During procedure, guidewire supposed to go inside the vein through introducer needle.

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

### DESCRIPTION

Introducer Needle is a composite unit, stainless-steel cannula over molded on hub. The introducer needle provides an access.

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.

(Introducer needle provide path to enter the interventional devices into the vessel during coronary angiography).

### PATIENT TARGET GROUP:

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

### INTENDED PURPOSE

Introducer Needle is a device indicated to use to create an incision in the skin or vessel to facilitate other devices to enter into the body (during coronary angiography).

**Duration of use:** The device is recommended for transient use, just to create an incision in the skin or vessel. The device is a disposable single-use device.

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

Vessel incision/percutaneous introduction of surgical devices (during coronary angiography).

### MODE OF ACTION

Introducer needle is inserted at the site in aseptic manner & the blood vessel is punctured. Syringe is attached to the needle & aspirated to assure proper placement. Guidewire is introduced as per hospital procedure.

**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:

- Preparation of application site.
- To be pre-decided. Correct size of needle 18, 20 or 21 Ga as per user's protocol.

#### Application:

- Connect the proximal port of the introducer needle to a syringe
- Ensure that the connection is secured properly and free of air bubble.
- Flush with saline to prime the device.
- Target the selected vessel and insert it to make passage to enter interventional devices through it.

### 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

- During the intended application, the Introducer needle provides stable and atraumatic percutaneous vascular access to facilitate other devices entering the body (during coronary angiography).

### 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; Mechanical complications associated to the device at the puncture site, Hematoma & 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](mailto: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



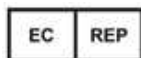
Use-by date



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



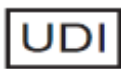
Stacking limit by number



Contents



Medical device



Unique Device Identifier



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