Instruction for Use

iPeX™ Invasive Pressure Systems

Extension Line/Multiple Extension Line

SPECIFICATION & PERFORMANCE CHARACTERISTICS

B L Part#	Variants	Selection of variants by the end user
BEX-XXXXX BEXIL-XXXXX	With or without Single /Double /Triple /Quadruple lumen. Extension line with Stopcock.	Variants shall be selected by the end users, on the basis of patient body weight to fix the dose.
Specification & Special Features: Sizes: • 2.80 mm • 3.56 mm • 4.07 mm • 2mm/2.5mm - with Stopcock/Luer Locks or Needle free sampling site to avoid cross-contamination. USP Class VI compliant, DEHP free tubings. Luer fitting in compliance to ISO 80369-7		

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 sampling syringes, stopcocks, infusion lines/infusion sets or pumps and with vascular access devices.

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

DESCRIPTION

The device is available with needleless valve and DEHP free fluid path with luer connectors. The device is supplied sterile, non-toxic and pyrogen-free.

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/ Tyvek paper"
  Secondary Packaging: "Duplex Box"
  Tertiary Packaging: "Corrugated Box"

INTENDED USERS:

Product is recommended to use by qualified medical/paramedic staff who are experienced in IV infusion therapy.

PATIENTS/BENEFICIARIES:

Patients of operating room, critical care units, Catheterization lab, General ward & inpatient wards, who are considered to the procedure being performed and fluid being infused.

PATIENT TARGET GROUP:

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

INTENDED PURPOSE:

Extension Line/Multiple Extension Lines are used as an extension between patient's vascular access site and the main infusion or monitoring devices to ensure free flow of the fluid & medications & blood sampling procedure. Multiple Extension Lines/ports offers, administration of multiple drugs or fluids simultaneously or sequentially, with the ability to stop one line while running another.

Duration of use: During application, device does not recommend to use more than 24 hours. Device restricted to single use only.

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

Extension line/Multiple extension lines can be used for:

- Intermittent infusion or continuous infusion to delivering fluids, medications & blood products.

  Multi-Extensions line supports in administering multiple drugs or fluids simultaneously or sequentially.
  Sampling ports: Drawing blood samples without disconnecting infusion lines.

MODE OF ACTION

Extension Line/Multiple Extension lines provide an extension to the IV fluid pathway for blood, infusion therapy or medication in all age group of patients 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.
- Ensure all luer locks are tighten properly.

Application

- Inspect the package and product for damage. If undamaged, open the package and transfer the product into the sterile field utilizing an aseptic technique.
- Connect the line as per need & indication. Avoid coiling multiple lines, prefer straight run and gentle curves.

- Flush and fill the line with saline to ensure bubble free priming.
- Prior to every access, disinfect the top of needleless valve using antiseptic solution and allow to dry.
- Flush the valve after each use as per the hospital protocol if it is not cleared during flushing, replacement is recommended.

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).
- High viscous liquid and large blood transfusion is not recommended because of a combination of flow-rate limitations, safety concerns, and risk of complications related to:
    - ❖ Reduced Flow Rate
    - ❖ Clot Formation and Occlusion
    - ❖ Air Embolism & Leak Risks
- Do not use for enteral therapies.
- The Patient is known or is suspected to be allergic to materials contained in the device.

CLINICAL/BENEFITS

- Allows clinician access sites of monitoring points without repositioning the patient in operating room, critical care units, Catheterization lab, General ward & inpatient wards.
- Supports patient mobility, particularly in long-term infusion therapy or monitoring.

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 that may occur during the application of the product like Blood backflow, air embolism and infection due to disconnection or loose connections etc.

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

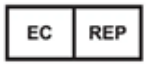
Manufacturer

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

B L Lifesciences Pvt. Ltd.
28-D, Sector-31, Ecotech-I, Greater Noida
Gautam Buddha Nagar, Uttar Pradesh (India)-201306
www.bllifesciences.com
Tel: +91 11 45100100
Email: blls@bllifesciences.com
Device Basic UDI-DI: 8903283BEXH5

Obelis s.a
Bd. Général Wahis 53
1030 Brussels, Belgium.
Tel: +(32)2.732.59.54
Fax: +(32)2.732.60.03
E-Mail: mail@obelis.net