



Instruction for Use



Inflation Device

Variant	: Straight/ Gun Type
Product Class as REGULATION (EU) 2017/745	: Is
Product Class as per Medical Device Rule 2017	: A
Duration of use	: Transient

DESCRIPTION

A digital inflation device specifically designed for dilation balloons. This inflation device is a 20 mL disposable device capable of producing a maximum pressure of 30 ATM.

The major components of the Inflation Device are;

Outer Barrel- PC, Adapter with gauge- PC, Tip of Piston- ABS, Handle-ABS, Inner Slip Rod- Polyoxymethylene, Luer Lock- PC, Extension Line-PU, Rotating Connector-PC

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

Inflation Device is used to inflate & deflate the balloon and measure the pressure.

MODE OF ACTION

The syringe style, single use inflation device for multistage endoscopic balloon dilator supports through its locking mechanism. Balloon pressure & diameters are maintained during dilation without any need to continually reinflate the balloon. Its intuitive design includes a simple plunger locking mechanism that maintains consistent vacuum pressure for rapid, controlled deflation.

INDICATION FOR USE

Pre-application

- Remove the device from the package and place it in the sterile work area using the aseptic technique.
- Syringe solution preparation of contrast media and sterile saline solution.
- Make all aspiration and injection maneuvers with the leur lock, unlocked before use.

Application

- The device is designed for maximum application pressure of 30 bars.
- Hold the device and push the buttons forward to deactivate the lock.
- By keeping the lock in deactivated position, pull the plunger handle back to fill the radiography solution into the device.
- Release the button to activate the lock.
- Plunger handle cannot be pushed or pulled unless the lock is deactivated
- Remove air by pushing plunger handle.
- Connect the Male Luer of Inflation Device to the balloon catheter. Secure the connection. Follows the indications and instructions for balloon catheter procedure as prescribed by the manufacturer.
- Once the balloon catheter is positioned, screw the plunger handle in clockwise direction to increase the pressure and thus, for inflation of the balloon.
- Screwing the plunger handle in anti-clockwise direction will reduce the pressure and thus, for deflation of the balloon.

INTENDED USER

- Product is recommended to use by qualified medical/paramedic staff.

CONTRAINDICATION

- This device is not designed, sold, or intended for use except as indicated.
- The Patient is known or is suspected to be allergic to materials contained in the device.
- Coronary artery spasm in the absence of a significant stenosis.
- Rupturing or dissecting of the wall of the vessel/embolism.

CLINICAL BENEFITS

- used for continuous perfusion of coronary arteries during angioplasty (CPC catheter).
- It helps in the Interventional Cardiology, interventional radiology, peripheral vascular procedures, gastroenterology procedures and urology procedures.

CAUTION/WARNING

- The product is designed for single use only.
 - Do not re-sterilize.
 - If reuse it may lead to cross contamination
 - Do not alter the catheter or guide wire or any other component during insertion, use or removal.
 - Leak test or other necessary testing are advised prior to use.
 - Inspect the syringe tubing and luer lock to ensure that there is no air in the system.
 - Always follow the manufacturer's directions accompanying the balloon dilation catheter for instructions for use, maximum balloon inflation pressure, precautions, and warnings for that device.
- Troubleshooting: User Paramedic staff should be aware & able to troubleshoot the certain complications that may occur during the application of the product such as; He/she should be careful while performing the balloon angioplasty to avoid rupturing or dissecting the vessel wall.

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 guide line 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. Sterilization 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 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








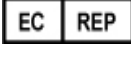






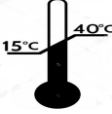





GOODS RETURN POLICY

Refer to the company's return goods policy.

Please contact the branch office or customer service at bls@bllifesciences.com or call +91 11 45100100.

Company Website Link to product IFU: <https://www.bllifesciences.com>

SYMBOLS USED ON PRODUCT LABEL

Symbol			
Meaning	Caution	2460 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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