

# Inflation Devices

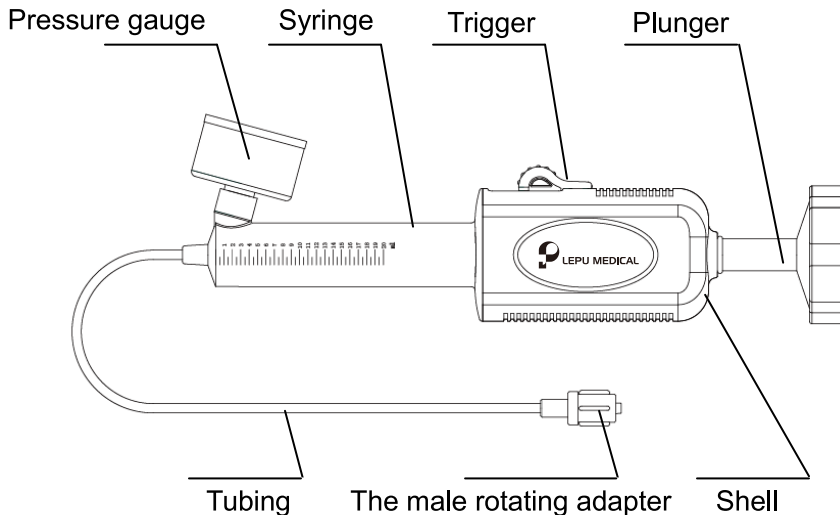
## Instruction for Use

Please read the instructions carefully before use!

### 1. Product Description

Inflation Devices is a kind of device which is used in PTCA operation for pressurizing on the balloon dilation catheter to make the balloon expand so as to realize the goal of expanding the blood vessel or retaining a stent inside the blood vessel.

The Inflation Devices is mainly consisted of a Syringe, a plunger, a Trigger, Shell, a piston seat, a Pressure gauge, a Tubing a male rotating adapter and stopcock (optional).



### 2. Indication for Use

The inflation device is applied to inflate/deflate balloon catheters and monitor pressure within the balloon.

### 3. Contraindications

None

### 4. Instructions

1. Before use, check the package and inflation devices to insure they are not damaged.
2. Push forward the Trigger and pull backward the plunger at the same time. Release the Trigger with the dilution contrast medium (or other liquid) reaching the designated amount.
3. Put the Inflation Devices straight up and push forward the Trigger, and push forward the plunger at the same time to discharge the residual air within the Syringe; if necessary, release the Trigger and rotate the plunger appropriately to discharge the residual air within the Syringe.
4. Connect the male rotating adapter of the Inflation Devices and the balloon catheter and keep the Pressure gauge dial plate facing directly towards the operator at the same time.
5. Push forward the Trigger and pull backward the plunger at the same time to evacuate the residual air inside the balloon catheter.
6. Release the Trigger, and rotate the plunger clockwise to pressurize the balloon; rotate the plunger anticlockwise to discharge the pressure of the balloon. When the pressure drops to a value lower than 10atm, push forward the Trigger to discharge the pressure of the balloon. (Note: push forward the Trigger so as to pull back or push forward the plunger freely, and the Inflation Devices will output negative pressure or positive pressure)
7. Push forward the Trigger, and pull backward the plunger at the same time. Release the Trigger to form negative pressure inside the balloon.
8. When the Inflation Devices is kept at a certain pressure, the pressure can be released quickly by pushing

forward the Trigger.

Note: Over quick release of pressure might result in risks, please operate according to clinical conditions.

#### 5. Notes:

- It is used only by professional doctors; read the instructions before using;
- The device is designed for single use. Please do not re-sterilize and/or reuse.
- Ethylene oxide sterilization is applied in this product; it belongs to a kind of sterile and non-pyrogenic product, so it is forbidden to be used if the package is damaged; Use prior to the USE-BY DATE.
- Before using, you must refer to the information related to the maximum bursting pressure specified by the manufacturer for balloon dilation catheters or other interventional devices. Pressure loss will indicate leakage of the system.
- Federal law restricts this device to sale or on the order of a physician.















#### 6. Storage:

It should be stored in the environment with the relative humidity lower than 80% and the temperature lower than 40°C without any corrosive gas, and stored in a shady and cool, dry, well-ventilated and clean place.

#### 7. Disclaimer of Warranty and Limitation of Remedy

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#### 8. Signs and legends:

SYMBOL	DESCRIPTION
	CATALOGUE NUMBER
	BATCH CODE
	USE-BY DATE
	STERILIZED USING ETHYLENE OXIDE
	DO NOT RE-USE
	CAUTION
	DO NOT USE IF PACKAGE IS DAMAGED
	CONSULT INSTRUCTIONS FOR USE
	MANUFACTURER
	KEEP DRY
	KEEP AWAY FROM SUNLIGHT
	THIS WAY UP
	FRAGILE, HANDLE WITH CARE
	UPPER LIMIT OF TEMPERATURE

 **LEPU MEDICAL TECHNOLOGY (BEIJING) CO., LTD.**

No.37 Chaoqian Road, Changping District, Beijing

102200, P.R. China

Tel: +86-10-80120666 Fax: +86-10-80120600

USA-ID-IN-0001 Rev.02

2018/10/24