常美医疗
Changmei Medtech

Instruction for Use of Balloon Inflator

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【Product name】

Balloon Inflator

【Product structure and components】

The Balloon Inflator can be divided into A type and B type. Balloon Inflator (A type) consists of connecting pipe, pressure gauge, plunger, sheath, screwed tube, elastic pulling rod, pushing rod, connector and 3-way valve. It can be divided into several specifications according to nominal capacity and syringe features.

【Materials】

No.	Name	Materials
1	Plunger, 3-way valve, pushing block, shell body	ABS+PC
2	Sheath, screwed tube, connector, pushing rod	PC
3	Elastic pulling rod	POM
4	Pressure gauge	Standard accessories
5	Connecting pipe	PU

【Specification】

Specification	Product model	Nominal capacity（ml）	Max. pressure（atm）	Syringe features
BI-20（25，30，35，40）A（B）-（10，15，20，25）	A: Balloon Inflator(A type) B: Balloon Inflator(B type)	20 25 30 35 40	30	None: without syringe 10: with 10ml syringe 15: with 15ml syringe 20: with 20ml syringe 25: with 25ml syringe

【Packaging list】

Inner package: Blister box, 1pcs/box

Middle package: Paper box, 1pcs/box

Outer package: Corrugated box

【Intended use】

Mainly used for hydraulic pressure on balloons to achieve the

function of balloon dilation. Sterile, for single-use.

【Contraindication】

There is no absolute contraindications under the correct use of doctors.

【Notice】

1. Users should be trained doctors.
2. Do not use the instrument when the package is damaged.
3. Do not use the instrument when the valid period is exceeded.
4. Do not use the instrument when extravasation or leakage occurred.
5. Do not use the instrument when the indicator doesn't move.
6. Do not use air as medium when inflate or dilate the balloon.
7. The pressure cannot exceed the maximum value of pressure gauge.
8. Single use only, discards after use. Do not reuse.

【Usage】

a) Preoperative preparation

1. Remove the package, if it is damaged, do not use.
2. Pumping operation of Balloon Inflator (A type):

   Pull the elastic rod of the Balloon Inflator, then pull back out of the piston. Inhaling the right amount of contrast media or

normal saline. Connect 3-way valve to Balloon Inflator. Keep the Balloon Inflator straight up and eliminate the internal air.

Pumping operation of Balloon Inflator (B type):

Pull forward the pushing block of the Balloon Inflator, then pull back out of the piston. Inhaling the right amount of contrast media or normal saline. Connect 3-way valve to Balloon Inflator. Keep the Balloon Inflator straight up and eliminate the internal air.

Operation of syringe: Use syringe to inhale enough contrast media or normal saline and keep it upright. Connect 3-way valve and clockwise tighten the front end of the syringe. Rotate the 3-way valve knob, then make sure the Balloon Inflator and syringe are in connection. Pull back out of the piston, and inhale the contrast media or normal saline from syringe.

3. Connect the 3-way valve of Balloon Inflator with the filling connector of Dilation Balloon Catheter. Rotate the pushing rod to pressure on the balloon. Check whether the Balloon Inflator is properly sealed, whether the pressure gauge is working normally, whether the balloon is complete.
4. After confirming the balloon inflator and the balloon, draw out the contrast media or normal saline from the balloon.

b) Instructions

1. Insert the dilation balloon catheter into the lesions, under the

X-ray, slowly inject the contrast media or normal saline into the balloon, and then pressure on the balloon.

2. After completing the balloon dilation, draw out the contrast media or normal saline, and then remove the balloon from working channel.

Note:

This product does not enter into the incision, only in vitro and connect with dilation balloon catheter.

c) Postoperative disposal of the equipment

Dispose the equipment in accordance with generally accepted standards of hospital waste treatment. Single use only, discards after use. Do not reuse.

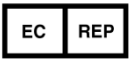
【Storage & Transport】

1. The instrument should be placed in the environment with relative humidity of less than 80% and without corrosive gas. Store the device at cool, dry, clean room of good ventilation.
2. Do not store the sterile instrument in places where it will become damaged, wet or improperly sealed. Otherwise, the sterility of the instrument may be compromised, which could pose a risk of infection control or cause infection in affected part of patients.
3. The inner package is blister box, middle is the box, and outer is the corrugated carton. Transportation should maintain clean,

dry and sealed.

4. Transportation conditions: It should prevent stress and could not be transported together with sand, metal fragments, glasses or keen-edged stuff, nor with the poisonous, corrosive or flammable stuff. Slinging of packages when loading and unloading, insulation under the sun or drenching in rain are all prohibited.

【Signs & Symbols】

	Disposable		Sterilized by EO
	Date of manufacture		Expiration date
	Do not use the instrument when the package is damaged.		Read instructions before use
	Lot number		Note that refer to attached documents
	EU representative		Manufacturer
	CE certified by TUV SUD		

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【**Validity Period**】3 years

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