CE 0197

Brun Medical Co., Ltd.

GRA-403002,Rev.02

Balloon Inflation Device [INSTRUCTION FOR USE]

1. INTENDED USE

The device is intended to pressurize the balloon dilatation catheters in PTCA that create pressure in the balloon to dilate the blood vessel or indwelling stent in the blood vessel by professional physician.

2. INTENDED USER

Intended users are the competent physicians who have the training in interventional treatment.

3. INTENDED PATIENT POPULATION

Patients needing interventional treatment.

4. CONTRAINDICATION

No absolute contraindications when used correctly by medical personnel.

5. HANDING AND STORAGE

Stored in the relative humidity of not more than 80%, non-corrosive gases, a common, dry, well-ventilated and clean environment.

6. STRUCTURE AND SPECIFICATIONS

The device is consist of the luer connector, connecting tubing, pressure gauge, syringe barrel, handle and three-way stopcock.

Specifications:

specification	Volume(ml)	Pressure(atm)
BR-BID-I30	20	30
BR-BID-I40	20	40
BR-BID-I30L	30	30
BR-BID-I40L	30	40
BR-BID-II26	20	26
BR-BID-II30	20	30
BR-BID-III30	20	30
BR-BID-IV30	20	30

7. PRODUCT PERFORMANCE

The Balloon Inflation Devices can create and monitor pressure in the balloon, and can deflate the balloon quickly.

8. INSTRUCTION FOR USE

1. Remove the packaging, do not use if the package damaged.
2. Attach connecting tube to luer port of the prepared balloon catheter. Pressure can be increased by pushing the plunger handle, to check whether the device is leakage, or pressure gauge is working correctly, or balloon is broken.
3. Aspirate contrast agent into syringe, and eliminate any air that may have collected in the luer port. Create pressure in the balloon though injection of contrast agents.

9. PRODUCT LABEL AND PACKAGING (See the label or packaging)

1.Product name, model and specification.
2.Production date, batch lot.
3.Sterilization expiry date.

10. CAUTION

- Procedure must be performed by trained medical personnel.
- Sterilization is valid for three years, please confirm date of sterilization prior to use, do not use if expiry.
- Do not use if pressure gauge doesn't work when pressuring.
- Under working conditions the pressure difference should not exceed the full-scale value of the gauge.
- It's forbidden to use gas as a medium for creating the pressure in the balloon.
- The device is designed and intended for ONE-TIME USE ONLY.
- Do not resterilize and/or reuse, otherwise patients could get the risk of infection.
- After use dispose of product and packaging in accordance with infectious medical waste disposal method.


Caution


Use-by date


Keep dry


Keep away from sunlight

Catalogue number


Date of manufacture


Manufacturer


Do not re-use

Sterilized Using ethylene oxide


Do not use if package is damaged and consult instrction for use

Batch code

Unique device identifier

Authorized representative in the European Commutity/ European Union


Consult instructions for use or consult electronic instructions for use

Do not resterilize

Medical device


Single sterile barrier system

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