

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 re-sterilize 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.



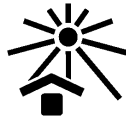
Caution



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 instruction for use



Batch code



Unique device identifier



Authorized representative in the European Community/ European Union



Consult instructions for use or consult electronic instructions for use



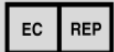
Do not re-sterilize



Medical device



Single sterile barrier system



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