CE 0197

Brun Medical Co., Ltd.

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Balloon Inflation Device Sets [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 three-way stopcock , Y connector, guide wire insertion tool and torque device.

Specifications:

specification	Volume(ATM)	Pressure(ml)	specification	Volume(ATM)	Pressure(ml)
BR-BID-I30A	20	30	BR-BID-I30D	20	30
BR-BID-I30B	20	30	BR-BID-I30DL	30	30
BR-BID-I30AL	30	30	BR-BID-II26D	20	26
BR-BID-I30BL	30	30	BR-BID-II30D	20	30
BR-BID-II26A	20	26	BR-BID-III30D	20	30
BR-BID-II26B	20	26	BR-BID-I30E	20	30
BR-BID-II30A	20	30	BR-BID-I30EL	30	30
BR-BID-II30B	20	30	BR-BID-II26E	20	26
BR-BID-III30A	20	30	BR-BID-II30E	20	30
BR-BID-III30B	20	30	BR-BID-III30E	20	30
BR-BID-I30C	20	30	BR-BID-I30F	20	30
BR-BID-I30CL	30	30	BR-BID-I30FL	30	30
BR-BID-II26C	20	26	BR-BID-II26F	20	26
BR-BID-II30C	20	30	BR-BID-II30F	20	30
BR-BID-III30C	20	30	BR-BID-III30F	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

Balloon Inflation Device

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.

Y Connector Set

1.Remove the packaging, do not use if the package damaged.
2.Connect Y-connector with catheter's port, insert guide cannula.
3.Push guide wire into the catheter by using torque.

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.
- Sterilized by ethylene oxide. Do not use if the package damaged.

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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