



Balloon Inflation Device

[Instruction For Use]

1. Intended use

Balloon inflation device is used in cardiovascular interventional operation and connected with balloon catheter. The balloon on the catheter can be accurately expanded and contracted by controlling the pressure value displayed on pressure gauge.

2. Structure and material

- The balloon inflation device is composed of Pump barrel, Trigger, Pressure pump spring, Screw rod, Back cover, Push block, Screw sleeve, Piston head, Piston, Pressure gauge, Balloon inflation device sleeve, Extension tube, High pressure connector.
 The stopcock is composed of male tapered joint, the main body and the handle.
 The hemostasis valve set is composed of Y-shaped connector, torque and insertion tool.
- Pump barrel is made of polycarbonate(PC); trigger is made of acrylonitrile butadiene styrene copolyme(ABS); pressure pump spring is made of stainless steel; screw rod, back cover, push block and screw sleeve are made of acrylonitrile butadiene styrene copolyme(ABS); piston head is made of polycarbonate(PC); piston is made of silicone; extension tube is made of polyurethane(PU); balloon inflation device sleeve is made of polyvinyl chloride(PVC); the main body of stopcock is made of polycarbonate(PC); the handle of stopcock is made of acrylonitrile butadiene styrene copolyme(ABS). Y-shaped connector is mainly made of polycarbonate and silicone; torque is made of polypropylene, acrylonitrile-butadiene -styrene and stainless Steel; Insertion tool is made of polycarbonate, polypropylene and stainless steel.

3. Contraindication

None

4. Warning

- This product is EO sterilized. The package should be checked before using. No use if unsealing, gas leakage or breakage are found.
- > This product must be used before expiry date.
- > The product has multiple specifications, select the appropriate specification according to the patient's situation.
- > The device should be used immediately after opening the package.
- The device should be disposed in proper way after use in accordance with local laws or hospital regulations.
- > The product is single use product, no repeat sterilization or reuse, it may cause cross infection.



5. Instruction for use

5.1 Model and description

BID1

- > 25ML.30ATM
- 3-way stopcock
- > Hemostasis valve
- Insertion tool:20G*10CM
- > Torque device

BID2

- > 25ML.40ATM
- > 3-way stopcock
- > Hemostasis valve
- > Insertion tool:20G*10CM
- Torque device

5.2 Balloon inflation device

- Inhale saline or contrast medium into the balloon inflation device, to exhaust residual gas;
- > Connect the extension tube of balloon inflation devices with balloon catheter;
- Observe pressure gauge and rotate the screw rod to reach the appropriate pressure, or observe the size of balloon catheter by angiography and pressure the balloon to the desired size;
- > Pull the trigger to release pressure;
- Observe whether the vascular lesion position is unobstructed by angiography;
- Withdraw the balloon catheter or indwell the stent in the blood vessel.

Note: Connect the three-way stopcocks with the interface of tubes for multi-way infusion or direction switch

5.3 Hemostasis valve sets

- > Connect the Y-shaped connector with the catheter connector,
- Insert the insertion tool into the Y connector main body through valve, and then insert the quidewire into the insertion tool;
- > Fix the distal end of guidewire with torque, tighten and push rotate torque handle to guide the guidewire reach the position for surgery;
- Y-shaped side arm connector can be connected to the infusion device for infusion.

6. Mark on label

USE BY ® DO NOT REUSE STERILIZED USING ETHYLENE OXIDE

REF REFERENCE NO EC REP EUROPEAN AURHORIZED REPRESENTATIVE

TEMPERATURE LIMITATION ADDRESS OF MANUFACTURER

LOT NO. M DATE OF MANUFACTURE 🚳 DO NOT USE IF THE

PACKAGE IS DAMAGED





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7. Package and Storage

- > The unit package of the product is TYVEY Paper+small box or PVC Plastic, inner package and outer package are corrugated carton for transportation.
- > This product should be stored in a dry environment, avoid direct sunlight.

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