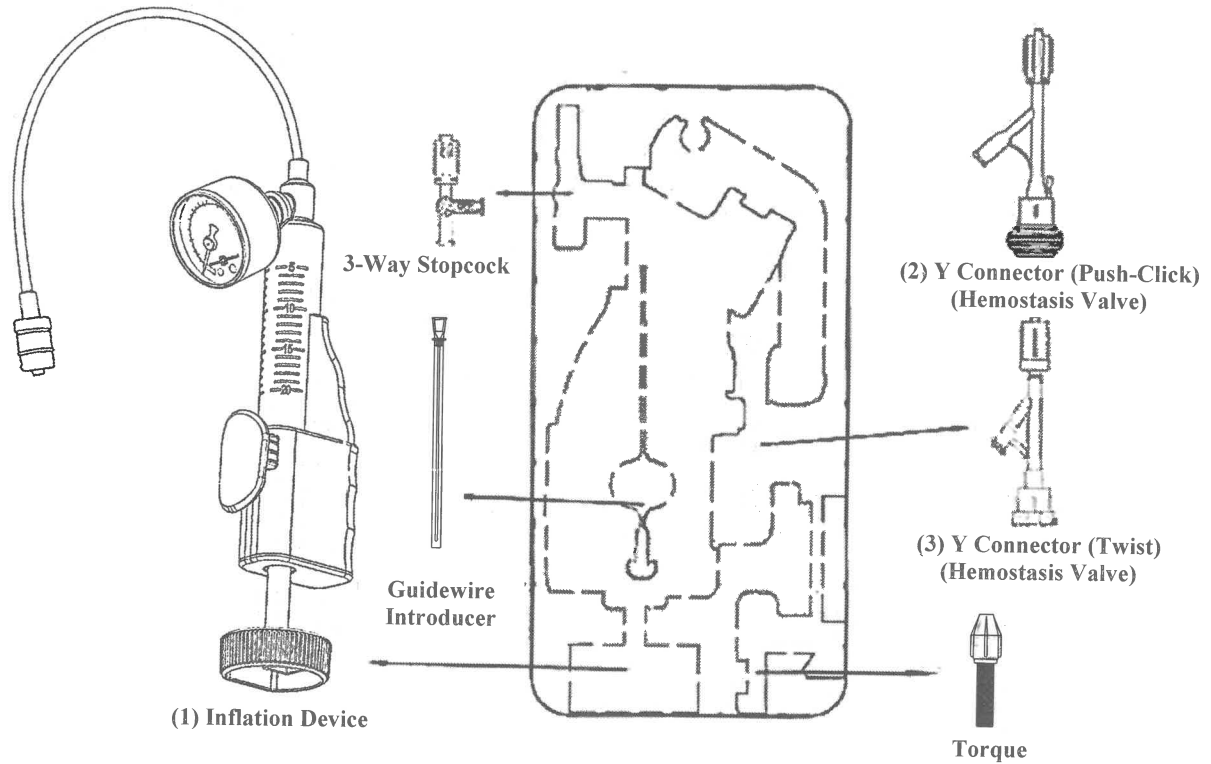


## Instructions For Use

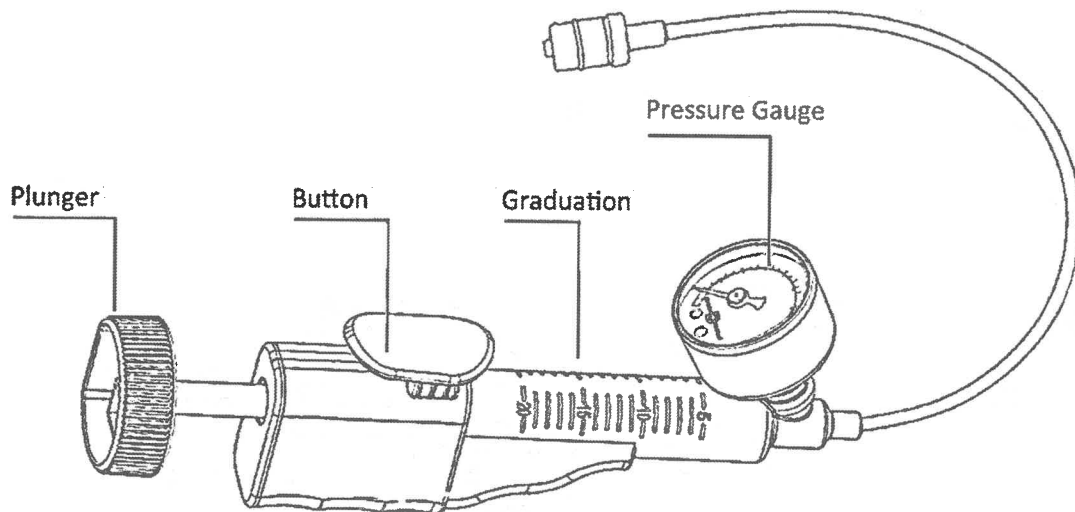
### Interventional Device Set (Inflation Device Pack)



The Y Connector (2), (3) is for optional, refer the below specification table.

| Components   | Ref. No | DAS |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
|--|---------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
|  |         | 001 | 002 | 003 | 004 | 005 | 006 | 007 | 008 | 009 | 010 | 011 | 012 | 013 | 014 | 015 | 016 | 017 | 018 | 019 | 020 | 021 |
| Inflation Device   |         | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   |
| 3-way Stopcock (OFF)   |         | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   |
| Twist Y Connector, bypass without extended tube                            |         | ✓   | ✓   | ✓   | ✓   |     |     |     |     |     |     |     |     |     |     |     | ✓   |     |     |     |     |     |
| Push-click Y Connector, bypass without extended tube                       |         |     |     |     |     | ✓   | ✓   | ✓   |     | ✓   | ✓   |     |     |     |     |     |     | ✓   |     |     |     | ✓   |
| Twist Y Connector, bypass with fixed extended tube and 3-way stopcock      |         |     |     |     |     |     |     |     |     |     | ✓   |     |     |     |     | ✓   | ✓   |     |     | ✓   |     |     |
| Push-click Y Connector, bypass with fixed extended tube and 3-way stopcock |         |     |     |     |     |     |     |     |     |     |     | ✓   | ✓   | ✓   |     |     |     |     |     | ✓   | ✓   |     |
| Torque   |         | ✓   | ✓   |     | ✓   | ✓   |     | ✓   | ✓   |     | ✓   | ✓   |     | ✓   | ✓   |     | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   |
| Introducer   |         | ✓   | ✓   |     | ✓   | ✓   |     | ✓   | ✓   |     | ✓   | ✓   |     | ✓   | ✓   |     | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   |
| Pressure Line 15 cm  |         |     | ✓   |     | ✓   | ✓   |     |     |     | ✓   | ✓   |     |     |     |     |     | ✓   | ✓   |     |     |     | ✓   |
| Sticker  |         |     |     |     | ✓   | ✓   |     |     | ✓   |     |     | ✓   |     |     |     |     | ✓   | ✓   | ✓   | ✓   |     | ✓   |
| Gauze  |         |     |     |     | ✓   | ✓   |     |     | ✓   |     |     | ✓   |     |     |     |     | ✓   | ✓   | ✓   | ✓   |     | ✓   |
| Square Box   |         |     |     |     | ✓   | ✓   |     |     | ✓   |     |     | ✓   |     |     |     |     | ✓   | ✓   | ✓   | ✓   |     | ✓   |
| Drape  |         |     |     |     | ✓   | ✓   |     |     | ✓   |     |     | ✓   |     |     |     |     | ✓   | ✓   | ✓   | ✓   |     | ✓   |
| Syringe 2 ml   |         |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     | ✓   | ✓   | ✓   | ✓   |     | ✓   |
| Syringe 5 ml   |         |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     | ✓   | ✓   | ✓   | ✓   |     | ✓   |
| Syringe 10ml Luer Lock   |         |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     | ✓   | ✓   | ✓   | ✓   |     | ✓   |
| Syringe 20 ml  |         |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     | ✓   | ✓   | ✓   | ✓   |     | ✓   |
| Pressure Line 122 cm   |         |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     | ✓   | ✓   | ✓   | ✓   |     | ✓   |
| Infusion Set with Chamber  |         |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     | ✓   | ✓   | ✓   | ✓   |     | ✓   |

## Instructions For Use for Inflation Device (Component 1)



**\* Tecnologia Selok® integrada**

### **Description:**

The Demax Medical Balloon Inflation Device is a 20 mL disposable device capable of producing a maximum pressure of 30 atm/bars. Fitted with a threaded plunger, a flexible high pressure extension tube, and a three-way high pressure stopcock. Inside Selok® technology allows Inflation to generate and monitor pressure over a range of vacuum to 30 atm/bars (441 psi) with accuracy of  $\pm 1$  atm/bar (14.7 psi).

### **Indications:**

A Balloon Inflation Device is used for the inflation and deflation of a balloon dilatation catheter, to dilate the vessel or implant a stent.

### **Preparation:**

1. Check the package of Inflation Device to insure they are not damaged.
2. Push the Plunger to the 0 (zero) graduation to eliminate the air out of this syringe while pressing the Button.
3. Submerge the male rotating adapter into prepared contrast medium, then hold down the Button and draw back the plunger. When the contrast medium has reached the amount required, release the Button.
4. Connect the device with the stopcock securely. Hold the device upright with pressure gauge upward, push the plunger forward while pressing the Button to remove the inside air. Slightly tap the syringe in order to eliminate to residual air if necessary.
5. Switch off the liquid path of stopcock, test the gauge indicator by increasing or decreasing the pressure.

### **Connecting Inflation Device to Balloon Dilatation Catheter:**

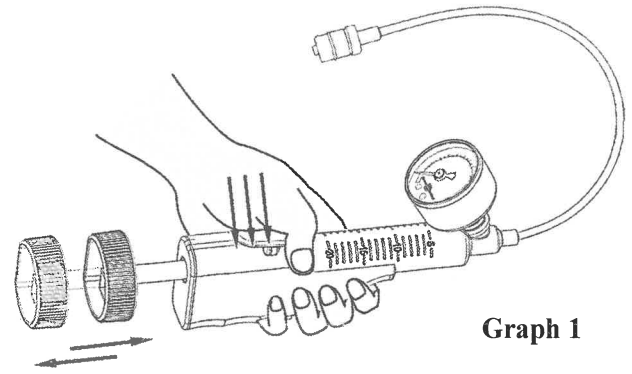
1. Note: Prior to connecting the Inflation Device, Balloon Dilatation Catheter should be prepared and tested according to the manufacturer's instructions.
2. Remove the stopcock from the male rotating adapter of the Inflation Device.

**⚠ Caution:** Failure to remove the stopcock could result in allowing the air to enter the system and/or contrast solution leak out Inflation pressure may not be maintained.

3. Create a fluid-fluid connection between the male rotating adapter of the Inflation Device and the Balloon Dilatation Catheter, and tighten the joint securely.

### Operating Inflation Device:

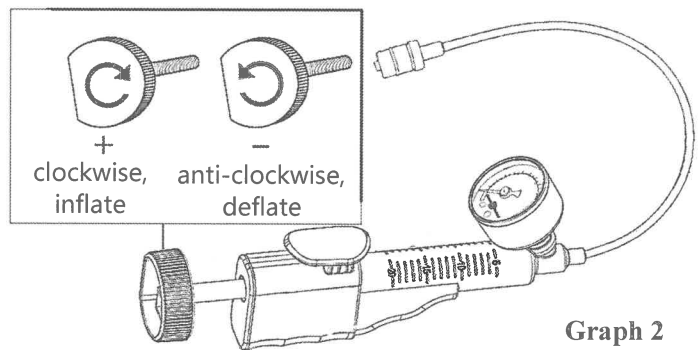
1. Holding the Button to release Selok® mechanism to allows freely push or pull of plunger for inflation or deflation. (Graph 1)



Graph 1

2. To remove any residual air in the Balloon Dilatation Catheter, hold the device upright, then pull back the plunger to generate vacuum pressure while keep Button held.

3. Balloon Inflation: Rotate the handle clockwise to increase the pressure. (Graph 2)



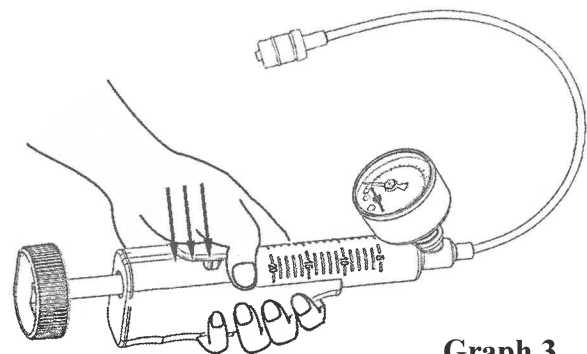
Graph 2

4. Balloon Deflation: Rotate the handle counterclockwise two laps until the pressure reduces to below 10atm. Then press the Button to release the pressure. (Graph 2)

5. If necessary, please repeat steps 3 and 4.

6. Vacuum pressure generating: Press the button and pull back the handle to generate vacuum pressure.

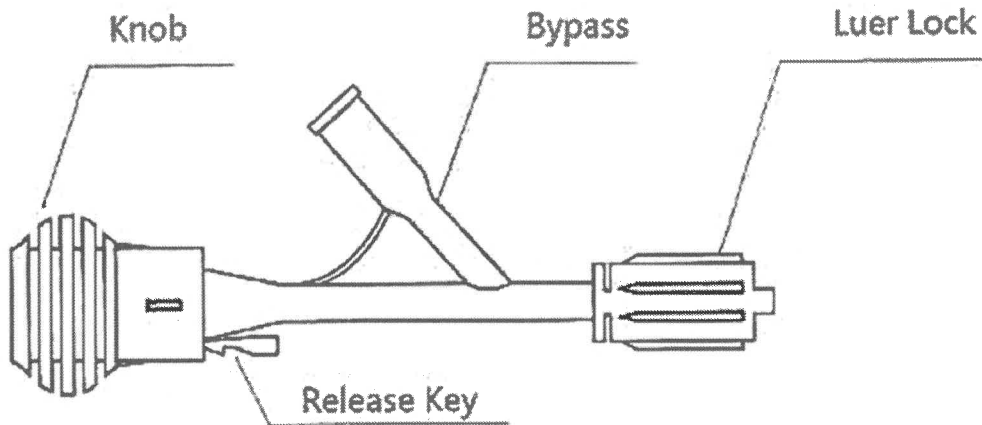
7. Press the Button allows pressure quick release.(Graph 3)



Graph 3

**⚠ Caution: Fast pressure release may cause risk to patient. Please use according to clinical requirement.**

## Instructions For Use for Y Connector (Push-Click) (Component 2)

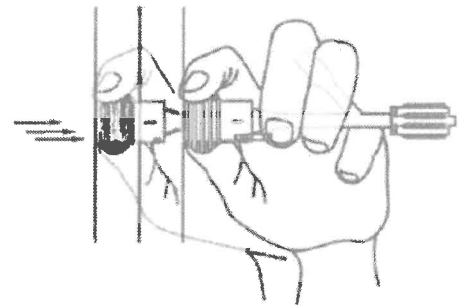


### Indications:

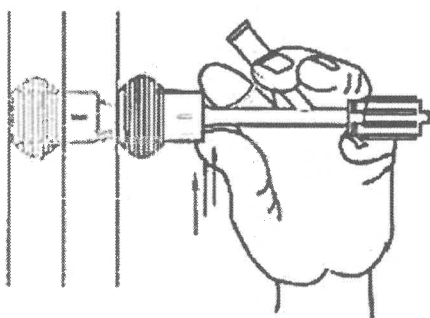
Y Connector intends to provide two tunnels into the blood vessel, this can introduce the contrast and Guide-wire or catheters during the interventional surgery. Y Connector Valve intends to prevent blood lost. Guidewire Introducer inserts the valve of Y connector, making a tunnel for guidewire to get through and protecting Guidewire tip. Guidewire Torquer holds Guidewire and makes Guidewire move easier.

### Operating Y Connector (Push-Click):

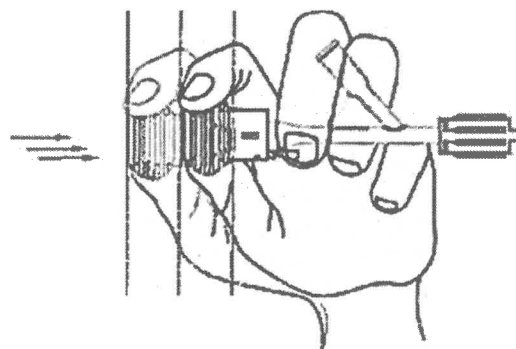
1. Check that the package is well sealed and without any damage.
2. Flush the devices with standard saline before use.
3. Connect the removable 3-way stopcock with bypass if necessary.
4. Securely connect the distal luer lock with catheter or other devices.
5. Press the knob to the end to keep the valve in "Open" position ("click" sound shall be heard) (see Graph 4)
6. When the valve is in "Open" position, devices including guidewire, balloon catheter can pass through.
7. Press the release key will rest the valve to "Close" position. (see Graph 5)
8. Press knob by fingers between "Open" and "Close" can adjust the valve from full open to full close which may help the device through with minimum blood lost. (see Graph 6)
9. Devices can move through the Y connector even when valve is closed.
10. Guidewire Introducer can help the insertion of guidewire.
11. Using Guidewire Torquer is recommended to help controlling guidewire.



**Graph 4**

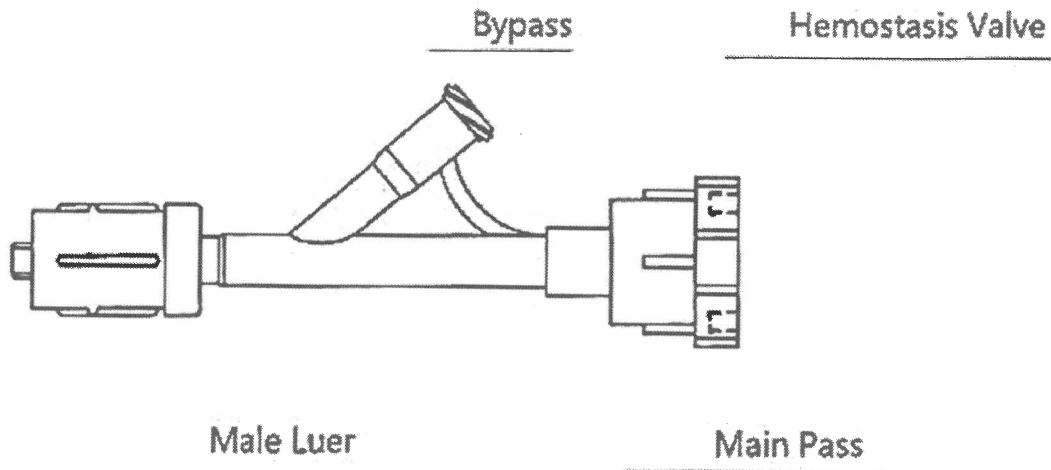


**Graph 5**



**Graph 6**

# Instructions For Use for Y Connector (Twist) (Component 3)



## Indications:

Y Connector intends to provide two tunnels into the blood vessel; this can introduce the contrast medium and Guidewire or catheters during the interventional surgery. Y Connector valve intends to prevent blood lost. Guidewire Introducer inserts the valve of Y connector, making a tunnel for Guidewire to get through and protecting Guidewire tip. Guidewire torque holds Guidewire and makes Guidewire move easily.

## Operating Y Connector(Twist):

1. Check that the package is well sealed and without any damage.
2. Connect the distal luer connector with catheter.
3. Insert guide wire introducer into the valve on the proximal end of Y connector, and then tighten the valve.
4. Insert guide wire through guide wire introducer into catheter.
5. Remove guide wire introducer; screw close the valve of Y connector until no visible blood return.
6. Using guide wire torque to push the guide wire is suggested.

## Warnings:

1. Read the instructions before use.
2. The device is designed for single use only. Do not de-sterilize and/or reuse.
3. Do not use it after the expiry date.
4. Do not use it if the package is damaged or not well sealed.
5. Luer connector must be well connected, and the valve must be closed. Incorrect connection, lose connection or the valve not being closed properly may cause leaking or air getting into blood vessel.
6. Please don't increase the pressure of the inflation device over 30 atm.
7. Please don't use gas medium to inflate the balloon, eliminate any air out of the system before use.
8. Do not inject air into the blood vessel.
9. Suggested working pressure for Push-click Y Connector is under 400 Kpa.
10. Suggested working pressure for Y Connector (Twist) is under 2068 Kpa.
11. For qualified physicians use only.
12. The inner cavity of the manometer will be in contact with the contrast medium, and a color change of the contrast medium may occur. If color changes occur, it is forbidden to use this product to continue the operation.
13. Please dispose the device after use, according to the local legislation.



**Caution:** Please dispose the device after use according to local laws and regulations.

### Signs and Legends:



Sterilized using ethylene oxide



Use By



Do Not Reuse



Date of Manufacture



Caution



Manufacturer



Batch Code



Catalogue Number



Authorised Representative in the European Community



Contents



Contains or Presence of Phthalates



Keep Away from Sunlight



Do Not Use if Package Is Damaged



Keep Dry



CE Marking of Conformity



This Side Up



Temperature Limit



Humidity Limitation

### Storage:

Store in a dry, dark, cool place.

The use before date (expiry date) see label.

### Transportation condition:

Keep away from heavy and sunshine, keep dry.

Temperature limit: -18°C ~ 55°C

Humidity limitation: 0 ~ 85%

### Customer Service:

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Demax Medical PTY LTD

Address: Suite 241, 117 Old Pittwater Road, Brookvale, NSW 2100 (Sydney), Australia

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Email: [csau@demaxmedical.com](mailto:csau@demaxmedical.com)

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