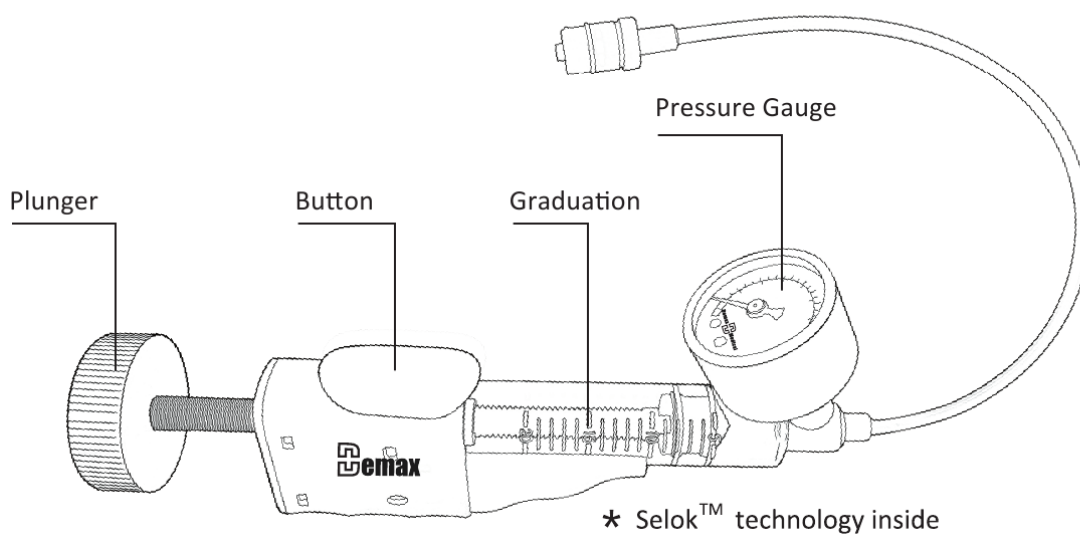


## Balloon In-Deflation Device Instructions for Use

Please read the instructions carefully before use.



### Description:

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

### Indications:

A Balloon In-Deflation 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 and In-Deflation 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 In-Deflation Device to Balloon Dilatation Catheter:

1. Note: Prior to connecting the In-Deflation 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 In-Deflation 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 In-Deflation Device and the Balloon Dilatation Catheter, and tighten the joint securely.

### Operating In-Deflation Device:

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

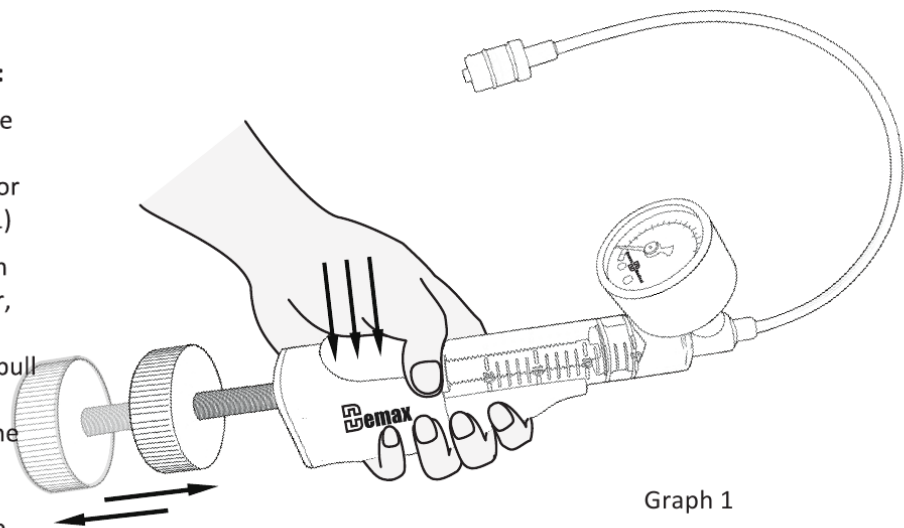
2. To remove any residual air in the Balloon Dilatation Catheter, hold the device upright with Pressure Gauge upward, then pull back the Plunger to generate vacuum pressure while keep the Button held.

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

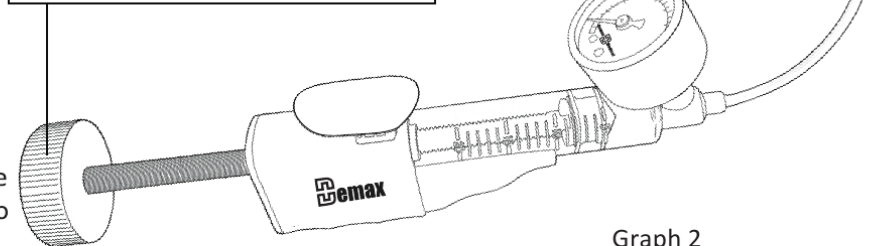
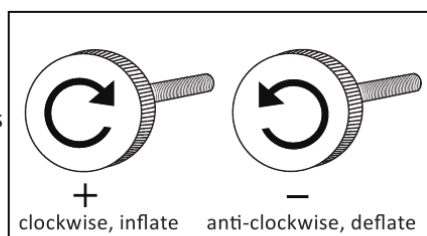
4. Balloon Deflation: Rotate the handle counterclockwise two laps until the pressure reduces to below 10atm. Then press the Button to release the pressure. (Graph 2)

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

6. Vacuum pressure generating: Press the Button and pull back the handle, then release the Button to generate vacuum pressure.



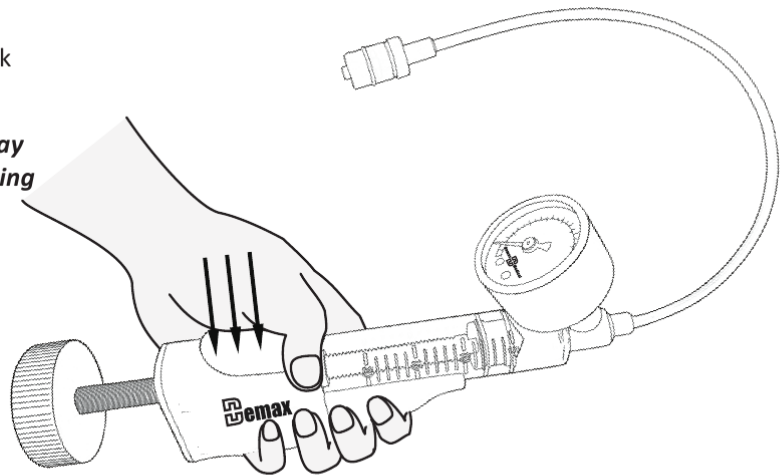
Graph 1



Graph 2

7. Press the Button allows pressure quick release.

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



**Warnings and Precautions:**

1. Don't use it if the package is damaged or unsealed.
2. Please read the introduction firstly before use.
3. The device is designed for single use. Please don't re-sterilize and/or reuse.
4. Don't use it after expiry date.
5. The Luer connector must be securely connected unless there could be leaking or air getting into blood vessel.
6. Please don't increase the pressure over 30atm.
7. Please don't use gas medium to inflate the balloon, eliminate any air out of the system before use.
8. For qualified physician use only.

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

**Signs and Legends:**



Device contains a sterile fluid path that has been sterilized using ethylene oxide.



Use before expiry Date



Do Not Reuse



Manufactured Date



Caution



Manufacturer



Batch Code



Catalogue Number



Qualified physician use



Contents



Authorized Representative in the European Community only

**Storage:**

Store in a dry, dark, cool place.  
Use before expiry date (see label).



Manufacturer Information:

Manufacturer: Beijing Demax Medical Technology Co., Ltd.

Registration Address: First Floor, No.1 Building, No.8 HongDaBeiLu, BDA, Beijing, China

Manufacturing Address: First Floor, No.1 Building, No.8 HongDaBeiLu, BDA, Beijing, China

Tel: +86 (10) 67868057

Fax: +86 (10) 67860415

Postcode: 100176

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

After-Sales Service: Beijing Demax Medical Technology Co., Ltd.

Address: First Floor, No.1 Building, No.8 HongDaBeiLu, BDA, Beijing, China

Tel: +86 (10) 67868057

Fax: +86 (10) 67860415

Postcode: 100176

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



European Representative:

Shanghai International Holding Corp. GmbH (Europe)

Eiffestrasse 80, 20537 Hamburg, Germany

Tel: 0049-40-2513175

Fax: 0049-40-255726