

Product:

E 01 3591 Disposable Inflation Device

**Distributed by**

Fiagon NA
3913 Todd Lane Suite 101
Austin, Texas 78744 USA
Tel: 512-383-8580
info@fiagon.com

Explanation of symbols

Address of Manufacturer



Date of Manufacture



Reference number/Order number



Production lot/ batch



DO NOT REUSE



Consult instructions for use



STERILIZED USING ETHYLENE OXIDE



Use by date



U.S. Federal law restricts this device to sale by or on the order of a physician



Do not use if the package is broken

1. Device Description

The Inflation Device is an instrument intended to inflate, deflate, and monitor pressure in balloon catheters used in ENT procedures or other medical apparatus and instruments used to control pressure within a balloon. The Inflation Device consists of a syringe, a plunger, a trigger, a shell, a piston seat, a pressure gauge, a tubing, a male rotating adapter, and a stopcock.

Indications for use

It is applied for pressurizing and deflating balloons or other interventional medical apparatus and instruments so as to measure the pressure within the balloon.

2. Contraindication

None

3. Warnings & Precautions

The inflation device is designed to be used only by professional doctors; read the instructions before using.

The inflation device is designed for single use. Do not re-sterilize and/or reuse.

Ethylene oxide sterilization is applied in this product; it belongs to a sterile and non-pyrogenic product, so it is forbidden to be used if the package is damaged; the period of validity of this product is 3 years.

Before using, you must refer to the information related to the maximum bursting pressure specified by the manufacturer for the balloon dilation catheters or other interventional devices. Pressure loss will indicate leakage of the system.

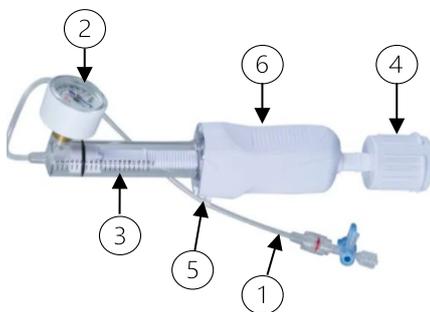
Dispose of the inflation device according to the local law after using.

The Inflation Device should be used within the expiration date indicated on the product label. Manufacturer is not responsible for any incident caused by use of product outside of expiration date.

The product use must be strictly constrained to these instructions and any incident caused by neglect of the Instructions for use will not be Manufacturer's or Distributor's responsibility.

4. Device description

E 01 3591 Disposable Inflation Device



1. Extension Line
2. Pressure Gauge
3. Volume Fill Indicators
4. Syringe Plunger
5. Release Trigger
6. Handle

5. Instructions



The device is provided sterile.

1. Before use, inspect the package and inflation device to insure they are not damaged.
2. Open the packaging containing the inflation device place onto the sterile field. Discard the empty packaging.
3. Priming Procedure
 - a. Obtain sterile water or sterile saline in a sterile bowl or sterile container, around 20 cc maximum.
 - b. Point the distal end of the inflation device downwards and place the tubing end into the sterile fluid.
 - c. While pulling the trigger, pull back on the syringe plunger slowly till you have aspirated 12-15 cc of sterile fluid.
 - d. Turn the inflation device to where it is pointing upwards and hold down the trigger again.
 - e. Push the syringe plunger forward slowly to start purging the air from the inflation device. Release the trigger when air is purged.
 - f. Repeat the process until you have purged as much air as possible and obtain between 8-12 cc of sterile fluid in the inflation device.
4. After preparing the inflation device, connect the inflation device extension line male adapter to the balloon catheter and keep the Pressure gauge dial plate facing directly towards the operator at the same time.
5. Pull the trigger on the inflation device while pointing the inflation device downward and pull back on the syringe plunger to evacuate the residual air inside of the balloon catheter and maintain a vacuum.
6. To dilate point the inflation device downward to ensure any air in the inflation device stays at the top, pull and then release the trigger to release the vacuum. Rotate the plunger clockwise to pressurize the balloon; rotate the plunger counterclockwise to discharge the pressure of the balloon. When the pressure drops to a value lower than 10 atm, pull the trigger to discharge the pressure of the balloon.



Note: Pull the trigger as to pull back or push forward the plunger freely, and the Inflation Device will output negative or positive pressure.

7. When the Inflation Device is kept at a certain pressure, the pressure can be released quickly by pulling the trigger.



NOTE: Over quick release of pressure might result in risks, operate according to clinical conditions.

6. Storage

The Inflation Device should be stored in the environment with a relative humidity lower than 80% and a temperature lower than 40°C without any corrosive gas, and stored in a shady and cool, dry, well-ventilated and clean place.

Manufactured by:

ELITE MEDTEK (JIANGSU) CO., LTD.

No.28 Xiahe Rd, Qianjia Industrial Park, Yanguan Town, Wujin District, Changzhou, 213102,

Jiangsu, P.R.China

TEL: +86-519-88710202