ASTER MEDISPRO PRIVATE LIMITED

Instruction for Use

Inflation Device

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 stopcock. The configuration available include:

Family	Volume (cc)	Rate Burst Pressure
Inflation Device	20 30 50 60	30 ATM

Intended Purpose

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

Intended User

This device should be administered to humans only by physicians authorized by the Competent Authority of the country in which the physician is practicing.

Medical Conditions to Be Treated

- Urinary retention
- Urethral obstruction
- Need for urine output monitoring in critically ill/injured patients
- Prostate conditions (e.g., BPH, prostate cancer)
- Urethral stricture (narrowing of the urethra)

Performance Characteristics of the device

- Quick deflation of every balloon regardless of the size with the 30cc
- Precise pressure increases up to 30ATM
- Ensures accurate inflations up to 20ml volume

Indications

- Urinary Retention
- Obstruction in Urethra
- Urine Output monitoring in a critically ill or injured person.
- Patients having conditions such as (prostate hypertrophy, prostate cancer or narrowing of the urethra.

Contraindications

No known contraindications

Precautions & Warnings

Carefully read all instructions for use and product labeling. Do not use this product without reading and understanding the complete instructions enclosed herein. The device shall only be applied for its intended use and in accordance with these instructions. Observe all cautions and warnings throughout these instructions. Failure to do so may result in complications.

Precautions:

- The intended user of the device must be a Urologist specializing in the treatment Urology disorders and related urinary disorders who is authorized by the Competent Authority of the country in which the physician is practicing.
- Each Physician is responsible for using the appropriate technique and deciding on the indication for use of this device.
- Confirm the information on the label and that the product has not reached its expiration date and there is no damage to the packaging or device.
- Store the Inflation Device at a temperature between 12-35^{0}C and a Humidity range of 30-70%.
- Store in a dry, cool place. Avoid extended exposure to sun light.
- Inspect the product for correct assembly and functionality.

Warnings:

- The device is intended for single use only.
- The product must not be re-used. Reusing single-use devices can lead to potentially serious consequences for the patient such as bio-contamination due to release of infectious agents from device into the body which further may result in Infection.
- Do not use the device if there is any indication that the sterility of the device has been compromised. Inspect the device, prior to procedure, to verify functionally and lack of damaged parts. If the sterile package is damaged or possibly opened, do not use. Contact “Manufacturer or Distributor” and replace the product.
- Do not reprocess or re-sterilize, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to failure which, in turn, may result in patient injury.
- If the instrument accidently becomes dirty before treatment, it must be disposed of immediately. No cleaning agents may be applied.
- Do not use after expiration date.

Intended Patient Population

Instruction for Use

Inflation Device

Inflation Device is used in adult patients. The device can be used in both male and female patients.

Shelf-life

The shelf life of the Inflation Device is 3 years (Indicated on product label with the following use-by symbol).

Sterility – This product is Sterile unless the package has been opened or damaged

- The Inflation Device have been sterilized by exposure to Ethylene Oxide. Sterility indicators are on each package. The imprinted label will change color from blue to brown after ethylene oxide exposure. Do not use the product unless the sterility indicators are the correct color.
- Exposure to high levels of Ethylene Oxide may result in presence of residual ETO which leads to Toxic Reaction in the body resulting in tissue damage of the Urinary System.
- If the sterile package is damaged or possibly opened, do not use. Contact "Manufacturer or Distributor" and replace the product.
- Inflation Device are packed single. Product in each pack must be utilized immediately when opened. Product should not be re-sterilized.

Directions for Use

- Priming Procedure
  - Obtain sterile water or sterile saline in a sterile bowl or sterile container, around 20 cc maximum.
  - Point the distal end of the inflation device downwards and place the tubing end into the sterile fluid.
  - While pulling the trigger, pull back on the syringe plunger slowly till you have aspirated 12-15 cc of sterile fluid.
  - Turn the inflation device to where it is pointing upwards and hold down the trigger again.
  - Push the syringe plunger forward slowly to start purging the air from the inflation device. Release the trigger when air is purged.
  - 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.
- 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.
- 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.
- 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 counter clock wise 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.
- When the Inflation Device is kept at a certain pressure, the pressure can be released quickly by pulling the trigger.

Removal Instructions

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

Disposal Instructions

Dispose of all equipment, in appropriate containers. After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

Explanation of symbols used on label

Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol
REF	Catalogue Number	UDI	Unique Device Identifier		Do not re sterilize		Country of Manufacture	MD	Medical Device
	Manufacturer		Date of manufacture		Keep Dry		Caution		Single Sterile barrier system with protective packaging inside
LOT	Batch Code		Use by Date		Keep Away from Sunlight		Do not re-use	75% 30%	Humidity Limit
STERILE EO	Sterilized using ethylene oxide		Consult Instructions for Use	35 °C 12 °C	Temperature Limit		Do Not Use if Package is Damaged		

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Bibliography

- Single Use Medical Device: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/956268/Single_use_medical_devices.pdf
- EN ISO 15223-1:2021 – Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
- EN ISO 20417:2020 – Medical Devices- Information to be supplied by the manufacturer.