

## Instruction for Use

### Bladder Evacuator

#### Device Description

The Bladder Evacuator is provided for use in Urology procedures during transurethral prostate or bladder surgery. The device is delivered in sterile peel-open package. Intended for single use. No contact with the body. The configurations available include:

Family	Height (Cm)	Width (Cm)	Catalogue Number
Bladder Evacuator (BE)	14	6.3	AMPLGP003

#### Intended Purpose

Bladder Evacuators are intended to be used for evacuating irrigation solutions, Blood clots, tissue collection and/or straining functions during prostate surgery or bladder surgery.

#### Performance Characteristics of the device

Single nozzle to adapt for use with Storz, Wolf and Olympus Resectoscopes. Provides throw and suction. Designed for single-hand use for better eye-hand co-ordination.

#### Indications

Evacuating irrigation solutions, blood clots, tissue collection and straining functions during prostate surgery or bladder surgery

#### Contraindications

No known contraindications

#### Precautions & Warnings

Carefully read all instructions for use and product labeling. 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:

- Each physician is responsible for using the appropriate technique and deciding on the indication for use of this device based on his own experience, training and medical judgement. The doctor must be trained in the proper use of the device.
- The Intended user of the device must be a Urologist specializing in the treatment of urinary system disorders and related urological procedures.
- Do not use the device if there is any indication that the sterility of the device has been compromised.

##### Warnings:

- The device is for single use only.
- Dispose of all components as infectious waste. Users of this device have an obligation and responsibility to provide the highest degree of infection control to patients, co-workers and themselves. To avoid cross-contamination, follow infection control policies established by your facility.
- The product must not be re-used. Reusing single-use devices can lead to potentially serious consequences for the patient: Bio-contamination due to release of infectious agents from device into the body which further may result in Urinary Infections.
- This device should be administered to humans only by physicians authorized by the Competent Authority of the country in which the Physician is practicing.

#### Intended Patient Population

- Bladder evacuator is used after bladder or prostate surgery in conditions such as Urinary Retention, Hematuria, Urinary Tract Infections, Bladder Stones, Bladder wall damage, renal dysfunction.
- Bladder evacuator is used in patients of all age groups (infants, children and adults).

#### Shelf-life and Storage Condition of the Product

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

Store the Bladder Evacuator at a temperature between 12°-35°C and a Humidity range of 30%-75%.

Store in a dry, cool place. Avoid extended exposure to sun light.

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

- The Bladder Evacuator has 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 in the Urinary System.
- If the sterile package is damaged or possibly opened, do not use. Contact “Manufacturer or Distributor” and replace the product.
- The Bladder Evacuators packed single. Product in each pack must be utilized immediately when opened. Product should not be re-sterilized.

#### Directions for Use

- Open the package at the Chevron Side (‘V’ Notch) of the pouch.
- Suggested instructions for using Bladder Evacuator:
- Select corresponding adapter end for use with either Storz, Wolf, Olympus resectoscopes. Attach opposite end of adapter to surgical tubing.
- Attach surgical tubing to port. Ensure tubing insecure.
- Collection basket connects to the filtration tube.
- Cap securely attaches to flask by turning clockwise.
- Fill device with fluid. Prior to use, purge all air from device which can be achieved in several ways.
- No contact with the body.

#### Removal Instructions

## Instruction for Use


















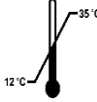


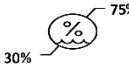
### Bladder Evacuator

To disassemble, remove flask from cap by turning counter clockwise while holding device over basin.

#### 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
	Catalogue Number		CE Mark		Do not Re sterilize		Country of Manufacture		Medical Device
	Manufacturer		Date of manufacture		Keep Dry		Caution		Single Sterile barrier system with protective packaging inside
	Batch Code		Use by Date		Keep Away from Sunlight		Do not re-use		Unique Device Identifier
	Sterilized using ethylene oxide		Consult Instructions for Use		Temperature Limit		Do Not Use if Package is Damaged		Authorized Representative in the European community
	Humidity Limit								

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- 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.