

Bladder Evacuator



Device Description

Bladder evacuator is bottle like device, Designed for TURP Procedures, Easy to fit connection to resectoscope instrument & Soft easy to squeeze bottle design, allows fast and efficient removal of tissue during TURP.

Intended Purpose

Used for irrigation and tissue collection during transurethral bladder and prostate surgery.

Indications For Use & Contraindications

Indicated to be used for providing irrigation and tissue collection during TURP procedure.

No known contraindications.

Warnings And Precautions

- Intended for single use only. Resue can cause severe infection. Intended purpose may fail on reuse.
- Do not re-sterilize. Reserialization may case the components of the device may fail to work as intended.
- Do not use if package is opened or found defected. Do not use the product if there is suspect that the device is not sterile.
- Device is intended to be used by physicians trained and experienced in the use of urologic procedures with support from qualified technicians using aseptic technique and not intended by unauthorized or untrained personnel. On completion of the procedure, dispose off the device and its components, if any, as per institutional and local regulatory guidelines for bio-hazardous medical waste disposal.

Instructions For Use

To Fill bottle, Evacuate, Emptying and disposal

- Hand tighten screw cap on bottle. Test for leaks by pressing a fingertip over the nozzle opening and then squeezing the bottle. If any leak found after tightening the cap, do not use the device.
- Evacuate the bottle/reservoir before filling the irrigation solution and connect the nozzle to the sheath of the resectoscope, press firmly inward and then fill the appropriate volume of solution required for irrigation.
- Alternatively squeeze the bulb multiple times, to remove the tissue from the bladder. Repeat if required
- Should one filling not be adequate to remove all tissue, the evacuator may be recharged by emptying and refilling with fresh solution.
- To drain the irrigation solution, invert the bottle and gently squeeze. To remove the tissue, unscrew the cap and transfer tissue to a suitable container, or tissue may be transported in the bottle.

Target Population Group

Patients who require irrigation and tissue removal during Trans Urethral Resection of Prostate procedure.

Supply and Storage

The device is packed in primary pack made of polyethylene and the secondary package made of polyethylene and Tyvek. Supplied sterilized by Ethylene Oxide gas in peel open package. Device shall be stored at temperature range from 20°C to 40°C and away from direct sunlight.

Report Any Serious Incident

If problems occur using this device or any serious incidents or adverse events, please contact our customer relations department or call to the contact provided in our manufacturing address and competent authority of the Member State in which the user and/or patient is established.

Symbol Glossory And Definations

Standard Reference:

ISO 15223-1 Medical devices — Symbols to be used with information to be supplied by the manufacturer

Symbol	Symbol Title
	Do not re-sterilize
	Do not use if package is damaged and consult instructions for use
	Consult instructions for use
	Temperature limit
	Keep away from sunlight
	Do not re-use
	Not made with natural rubber latex
	Sterilized using ethylene oxide
	Non-pyrogenic
	Keep dry
	Medical device
	Single sterile barrier system with protective packaging inside
	Does not contain DEHP
	Unique device identifier
	Date of Manufacture
	Use-by date
	Batch code

	Catalogue number
	Authorized Representative in the European Community/ European Union
	Manufacturer
	Caution
	Prescription



- This device is to be sold by/on the directions of a physician. Sterile (ETO) if package is unopened or undamaged.
- Read all the instructions before use.
- On completion of the procedure, dispose off device and its components if any as per institutional and local regulatory guidelines for bio-hazardous medical waste dispose.



Authorized Representative in the European Community
Arazy Group (Ireland) Ltd
19 Baggot Street Lower,
Dublin 2, D02 X658, Ireland
E-mail: Ireland@arazygroup.com



Manufacturer
Blue Neem Medical Devices Pvt Ltd
Plot Nos 270 & 271, Road No 5, Harohalli Industrial Area
II Phase, Kanakapura Taluk, Ramanagara
Karnataka - 562112, India.
Phone: +91 80 29761336
E-Mail: contact@blueneem.com
Website: www.blueneem.com