en Instructions for Use

Irrigation Set

BLUENEEM®
Clinicians Trust. Patients Wellbeing

Device description
Irrigation set is a collection of flexible, non-invasive, single-lumen tubing and associated items intended to provide a conduit to deliver a sterile irrigation solution from its source to a instrument during a surgical procedure, it is not intended to navigate through an anatomical lumen. The tubing set includes devices such as clamps, spikes, and Y-piece connectors, this is a single-use device.
Available in Straight and Y-type models.

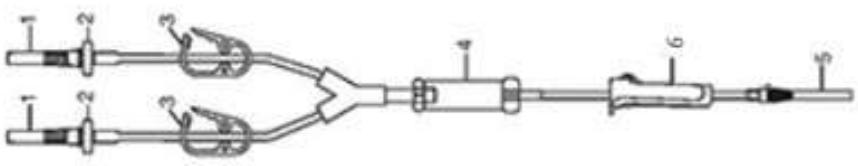
Intended Purpose & Duration
Intended to be used for endoscopic irrigation during transurethral resection of prostate gland up to a period of 60 minutes.

Contraindications
No known contraindications.

Potential Complications
No known Potential complications.

Warnings And Precautions
- Do not reuse the device. Reuse or resterlization can compromise the structural integrity of the device and may cause serious harm to the patient. It can also cause severe patient infection and harm due to contamination.
- Do not use if package is opened or damaged or expired. Do not use the product if there is suspect that the device is not sterile. Device is not intended for long term use.
- Product use should not be carried out by untrained personnel. Product should be used by trained physician with support from qualified technicians using aseptic technique. 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
1. Close the pinch clamps (3). Hang fluid bags.
2. Remove protective caps (1) from spikes of the Irrigation Set and insert the spikes (2) into fluid bags using aseptic technique.
3. To use the irrigation line, invert flexible chamber (4) and open the pinch clamps (3) until the fluid flows out through the tubing Y adaptor, checking that all air has been expelled.
4. Close pinch clamps (3).
5. Connect and secure by attaching the silicone tubing adaptor (5) to the inline port on the endoscope/instrumentation sheath.
6. Control flow rate using the pinch clamps (3) until desired flow rate is achieved.
7. Routine flow can be regulated using flow control adapter (6).

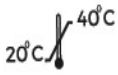


Supply and Storage
The device is packed in primary pack made of polyethylene and the secondary package made of polyethylene and Tyvek. Supplied sterilized by Ethylene Oxide gas in peel open package. Device shall be stored at temperature range from 20^0C to 40^0C and away from direct sunlight.

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