

Smart Bulb Instructions for Use



Indications

For use during urological and/or endoscopic procedures that require irrigation. Only sterile irrigation fluid should be used during urological or other endoscopic procedures.

Contraindications

None.

Potential Complications

Any irrigation product may cause the following adverse effects:

- Excessive distension of urinary tract and hydronephrosis
- Extravasation of irrigating fluid and fornix rupture, flank pain
- Postoperative fever, urinary tract infection, sepsis and septic shock
- Transient haematuria, subcapsular haematoma

The patient should be routinely monitored in accordance with the accepted standards for endoscopic procedures.



Caution

The Smart Bulb Irrigation System for Ureterorenoscopy should only be assembled and used by physicians and other qualified medical personnel, who are familiar with equipment used during endoscopic procedures.

It is important to provide adequate drainage from the kidney during endoscopic procedure when irrigation is used. The source of irrigation fluid should ideally be placed at patient's kidney's level to avoid generation of distending hydrostatic pressure. The volume of the delivered boluses of irrigation fluid should be kept as low as possible and enough time allowed between boluses delivery to avoid rise in intrarenal pressure.

Preparation for Use

Inspect the package for any mechanical damage.



Do not use if package is damaged



Caution

All necessary manipulations during the preparation and intervention, must be carried out under sterile conditions.

Intended Use and Disposal: The Smart Bulb Irrigation System for Ureterorenoscopy is intended to be used on an individual patient, during a single urological procedure, and thereafter disposed of according to the hospital's medical waste handling procedure. It is not intended to be re-processed and re-used.

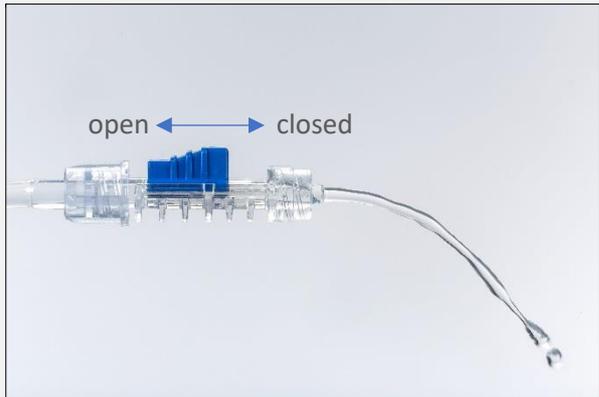
Instructions For Use

1. Using the aseptic technique, open the sterile packaging and remove the unit.

2. Attach the female connector of the Smart Bulb to the irrigation fluid supply.



3. Ensure that the switch is in the open position, by moving the blue slider away from the fluid outflow.



4. Compress the Bulb to expel the air. Then release, to fill the Bulb with the irrigation fluid. Repeat as required.



5. Connect the In-line Flow Switch to the scope. Compress the Bulb to deliver the desired volume of irrigation fluid. Release the Bulb to refill the unit.



SMART BULB EXTENSION

The Smart Bulb unit is supplied with an extension for the user's convenience. This can be inserted between the In-Line Flow Switch and an endoscope, if an assistant is required to operate the unit.

| REF | DESCRIPTION | QUANTITY |
|---------|-------------|----------|
| URO 037 | SMART BULB | 10 |



Wismed CC
71 Princess Alice Avenue,
Durban, 4001, South Africa
Tel: +27 31 206 0177
orders@wismed.co.za
www.wismed.co.za



TNMC Devices (Llc)
Ulica Franje Krezme 1
10000 Zagreb, Croatia
Tel: +38 59 1622 9658
tnmchr@tnmc.biz

