



## DESCRIPTION OF PRODUCT

### SMART BULB URO037



#### DESCRIPTION OF PRODUCT AND INTENDED USE

Smart Bulb is a single use, sterile irrigation system that is used during ureterorenoscopy and endoscopy.

Irrigation during endoscopy helps to maintain a clear visual field by displacing blood, stone fragments, and cellular debris.

The Smart Bulb is designed for controlled irrigation through an endoscope or accessory during urological and / or endoscopic procedures.

The system is capable of producing dual flow i.e. background low intensity flow that is regulated by hydrostatic pressure by adjusting the height of the irrigation fluid reservoir and accelerated flow that depends on the force applied to the device by the hand of the operator. Lowering of the fluid reservoir below the patients' level will cause background flow to cease

Inadvertent effects, such as stone migration caused by pressurized irrigation can complicate ureterorenoscopy but are easily avoided with the use of the Smart Bulb.

The Smart Bulb clears visual field instantly with a flow that is effective even with laser fibre or basket loaded in the working channel and scope fully flexed.

As a low volume system, it is less likely to subject the kidney to excessive intrapelvic pressures.

Smart Bulb is operated by hand and due to its small size, it fits comfortably into operator hand.

The simple connection of the pumping unit to fluid supply provides the urologist with a very sensitive system capable of producing a broad range of flows, thus making both rigid and flexible ureteroscopy and stone treatment much easier.



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#### INDICATIONS

For the use with urological and/or endoscopic surgical procedures requiring irrigation. Only sterile irrigation fluid should be used during urological and/or endoscopic surgical procedures requiring irrigation.

#### CONTRAINDICATIONS

None known

#### POTENTIAL COMPLICATIONS

Any irrigation system may cause the following adverse effects:

- Hydronephrosis
- Excessive distension of urinary tracts
- Extravasation of irrigating fluid.

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

#### CAUTION

The irrigation system for ureterorenoscopy should be assembled and used by suitably trained physician and/or other qualified medical personnel who are familiar with equipment normally used during endoscopic procedures.

#### GMDN CODE

46102: SURGICAL IRRIGATION TUBING SET, SINGLE USE; A collection of sterile, flexible, single-bore, external tubing intended to provide a conduit to deliver a sterile irrigation solution (e.g., saline solution) from its source (e.g., gravity feed bag, feed pump) to a site of surgical intervention and/or endoscopy; it is not intended to navigate through an anatomical lumen. The tubing typically includes associated items such as clamps, filters, spikes, and connectors; it may include a syringe or an integrated manual pump (e.g., a squeeze bulb). It does not include suction tubing and is not intended to aspirate the surgical/endoscopic site (i.e., not an irrigation/aspiration tubing set). This is a single-use device.

#### LIFE OF THE PRODUCT

The Smart Bulb is indicated for a 5-year life based on the sterilisation validation.