

Peditrol Instruction for Use

Indications

For 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 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 accepted standards for endoscopic procedures.

⚠ Caution

The Peditrol irrigation system for ureterorenoscopy should be assembled and used only by physicians and other qualified medical personnel who are familiar with equipment normally 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 hydrostatics 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.

Intended Use and Disposal

Peditrol Irrigation System for Ureterorenoscopy is intended to be used on an individual patient during a single urological procedure and then disposed of using the hospital's Medical Waste Handling Procedure. It is not intended to be reprocessed and used again.

Instructions for Use

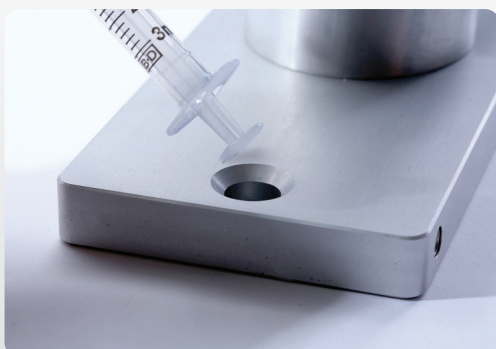
1. Remove the disposable irrigation set from the sterile packaging using an aseptic technique:



2. Connect the Luer Lock syringe to the manifold tightly :



3. Insert the end of the syringe plunger into the round nest at the base of the foot pedal. A slight click should be heard.



4. Make sure that the tubing coming off the manifold is directed away from the foot pedal :



5. Without depressing the foot pedal , hold the tubing close to the manifold and pull the manifold up to its nest.



6. Insert the manifold into its nest . A distinct click should be heard.



7. Attach the female connector of the Peditrol's inlet tube to the irrigation fluid supply.



8. Connect the male connector with blue switch in open position to the ureterorenoscope .



** Make sure that all taps and clamps are in open position. The irrigation fluid should flow spontaneously through the drip chamber of irrigation fluid supply.*

9. Expel the air from the Peditrol tubing by depressing the foot pedal several times.



Caution

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



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