

URODYNAMIC INSTRUCTIONS FOR USE

Products Covered

This IFU covers the product range urodynamic catheters, urodynamic catheter sets, and urodynamic catheter accessories.

Intended Use

Intended for use during water-perfusion urodynamic procedures to study the function of the bladder and urethra during filling and voiding. By monitoring pressure and pressure changes to aid in the diagnosis and management of lower urinary tract dysfunction.

Intended User

The devices are intended to be used by suitably qualified medical professionals with training and knowledge of the indications and techniques required for urodynamic procedures.

Patient Population

Indicated for use in adults and paediatrics. Catheters suitable for paediatric urodynamic investigation are identified via the label.

Packaging & Sterilisation

The bladder/urethral catheters and accessories are supplied sterile, for single use only. They are sterilised via Ethylene Oxide in accordance with ISO 11135. The rectal/vaginal catheters are supplied non-sterile, for single use only.

Precautions/contraindications

- Not to be used when the patient has a local infection of the urinary tract, vagina, or anorectal canal.
- Not to be used when the patient has a urethral, vaginal, or rectal blockage.
- Not to be used if the patient is pregnant.
- The device is to be used by a qualified medical professional only.
- The device is to be used with compatible urodynamic equipment and accessories only.
- The device is single use only. Reuse may cause infection.
- Do not use the device if the packaging or device are damaged.

Storage

- To be stored under normal ambient conditions.
- Keep away from direct sunlight and must be kept dry.
- The shelf-life of the product is stated on the label.

Disposal

Dispose of the catheter in accordance with local clinical disposal instructions.

Instructions

Connect the catheter and/or accessories to the urodynamic equipment using the luer connectors. The specific setup/sequence and calibration of equipment, accessories and catheters should be performed according to local clinical procedures and guidelines.

Bladder catheter setup

When attaching the double and triple lumen catheters, the clear lines are for filling the bladder and the coloured lines are for pressure measurements.

Perfuse the catheters and accessories with sterile saline or water prior to insertion/use to check for any leaks or blockages and carefully purge any air bubbles present.

Apply any lubricant to the catheters as required prior to insertion. Insert the catheters into the bladder and/or rectum/vagina. Correctly position the catheter(s) and perform the urodynamic evaluation according to local clinical procedures and guidelines.

After the procedure is completed and the relevant measurements obtained. Remove the catheter(s) from the patient and disconnect from the urodynamic equipment along with the accessories and dispose of according to local clinical disposal instructions.

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Affix device label

Affixing the device label ensures the IFU meets the requirements of the medical device directive 93/42/eec, annex 1 essential requirements, section 13.6.



Affix Label here