ANORECTAL INSTRUCTIONS FOR USE

Product Covered

This IFU covers the product range water perfused anorectal manometry and balloon expulsion catheters.

Intended Use

Intended for use during water-perfusion anorectal manometry and balloon expulsion procedures to study the function of the rectum and anal canal in patients suffering from colonic and anorectal disorders.

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 anorectal manometry and balloon expulsion procedures.

Patient Population

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

Packaging & Sterilisation

Most of the anorectal catheters are supplied non-sterile, for single use only. If the catheters are supplied sterile, they are sterilised via Ethylene Oxide in accordance with ISO 11135. The catheters are not to be sterilised prior to use.

Precautions/contraindications

- Not to be used if the patient has a local infection or physical obstruction of the anorectal canal.
- The device is to be used by a qualified medical professional only.
- The device is to be used with compatible manometry equipment and accessories only.
- The device is single use only. Reuse may cause infection.
- Do not use the device if the packaging or device is damaged.
- Should the balloon rupture or detach during use, care should be taken to ensure that all balloon fragments have been removed from the patient.

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 to the water perfusion 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.

Multi-lumen catheters

Connect the luers to the machinery in the order stated on the catheter diagram present on the device label.

Perfuse the catheters with sterile saline or water prior to insertion 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 anorectal canal. Correctly position the catheter and perform the evaluation according to local clinical procedures and guidelines.

After the procedure is completed and the relevant measurements obtained. Remove the catheter from the patient and disconnect from the 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