OESOPHAGEAL INSTRUCTIONS FOR USE

Products Covered
This IFU covers the product range water perfused oesophageal manometry catheters.

Intended Use
Intended for use during water-perfusion oesophageal manometry procedures to study the function of the upper gastrointestinal tract. By monitoring pressure and pressure changes to aid the diagnosis and management of upper gastrointestinal 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 oesophageal manometry procedures.

Patient Population
Indicated for use in adults and paediatrics.

Packaging & Sterilisation
The catheters are supplied non-sterile, for single use only. The catheter is 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 oesophagus.
- 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.
- Catheter may double back in a megaoesophagus giving misleading results.

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/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 and use local anaesthetic to aid insertion if clinically indicated. Insert the catheter into the oesophagus. 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