

URODYNAMIC CATHETERS INSTRUCTIONS FOR USE

Intended Purpose

This IFU provides guidance for the safe use of urodynamic catheters and associated accessories. It covers the following products:

- Urodynamic Catheters
- Urodynamic Catheter Sets
- Set Guards
- Pump Tube Sets
- Rectal Catheters
- Extension Lines

The Urodynamic Catheter Devices and Urodynamic Pump Tube Devices intended purpose is to help study the function of the lower urinary tract during filling, storage and voiding by either (a) facilitating the measurement of pressure in the bladder, urethra, vagina or rectum during water filled/perfused urodynamic procedures or (b) facilitating the external filling / irrigation of the bladder.

Indications for Use

The devices are indicated for use in adults when the measurement of physiological pressures in the lower urinary tract (LUT) and abdominal cavity (vagina /rectum) coupled with optional external fluid filling of the bladder are indicated to aid in the diagnosis and monitoring of patients with symptoms of LUT dysfunction.

Intended Users

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

Clinical Benefits

These devices aid in the diagnosis and monitoring of patients with symptoms of lower urinary tract dysfunction.

Performance Characteristics

Urodynamic catheters and associated accessories work in conjunction with urodynamic equipment to support accurate assessment of lower urinary tract function. They are provided in various configurations and are designed to support patient comfort during use.

Packaging & Sterilisation

Refer to product packaging and associated symbols to determine the device's sterilisation status. Devices are for single use only. They are not to be sterilised after use.

Storage

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

Contraindications

There are no known contraindications for extension lines, pump tube sets and set guards. The contraindications for the urodynamic catheters are as follows:

- Not to be used if the patient has a local infection or obstruction of the urinary tract, vagina or anorectal canal.
- Not to be used if the patient is pregnant.

Warnings and Precautions

- The device should be used by qualified healthcare professionals only.
- The qualified healthcare professional should brief the patient on the contraindications and precautions associated with this device.
- The device is to be used with compatible urodynamic equipment and accessories only.
- The device is single use only. Reuse of the device may cause risk of infection to the patient.
- Do not use the device if the packaging or device has been opened or is damaged.

Instructions For Use
























1. Connect the catheter/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.
2. When setting up a bladder catheter, the clear lumens on double and triple lumen catheters are used for filling the bladder, while the coloured lumens are designated for measuring pressure.
3. Perfuse the catheter and, if used, the extension line with sterile saline or water prior to insertion/use to check for any leaks or blockages and carefully purge any air bubbles present.
4. 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 bladder and/or rectum/vagina. Correctly position the catheter and perform the evaluation according to local clinical procedures and guidelines.
5. 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.

Note:

The urodynamic catheters are fitted with standard luers which are compatible with urodynamic equipment such as connecting luers, external transducers, perfusion / infusion pumps and computerised systems. These are widely available and not supplied with the device.

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Key for Symbols and Labels

	Catalogue / Product Ref.		Legal Manufacturer
	Batch / LOT Number		Keep dry
	Medical Device		Keep out of sunlight
	Sterilised using Ethylene Oxide		Sterilised using Gamma Irradiation
	Do not re-sterilise		Single sterile barrier system
	Single sterile barrier system with protective packaging		Expiry Date
	Non-sterile		Single Use
	Date and Country of Manufacture		Do not use if packaging is damaged
	Importer into the EU or Swiss market		Distributor
	Authorised Representative in the European Community		Swiss Authorised Representative
	UKCA Marking		CE Marking
	Electronic Instructions for Use		


Complaints / Incidents


In the event of a serious incident related to this device, please contact the manufacturer and the competent authority of the member state in which you are based.

Accessing Previous versions of this publication

Previous versions of this Instructions for use are available on Malvern Medical Developments website.

<https://www.malmed.co.uk>

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