

## Intended Purpose

This IFU covers a range of urology accessories, including perfusion and irrigation sets as well as voiding adaptors. These accessories are intended for use alongside urodynamic equipment to support the diagnosis of lower urinary tract dysfunction.

## Indications for Use

For use on adult and paediatric patients to support urodynamic procedures in order to assess bladder and urethral function during filling and voiding, supporting the diagnosis and monitoring of lower urinary tract dysfunction.

## Intended Users

The devices are intended for use only by suitably qualified healthcare professionals with the training and knowledge required for the indications and techniques associated with urology accessories used in urodynamic procedures.

## Clinical Benefits

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

## Performance Characteristics

The urology accessories are intended for reliable use during urodynamic procedures to support the diagnosis of lower urinary tract dysfunction and are compatible with standard urodynamic equipment.

## Packaging & Sterilisation

The voiding adaptors are supplied non-sterile, for single use only. They are not to be sterilised prior to use.

The irrigation and perfusion sets are sterilised using Ethylene Oxide (EO) and are single use only. They are not to be re-sterilised after use. Refer to product packaging and associated symbols to determine the device's sterilisation status.

## 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

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

## Warnings and Precautions

- The device should be used by a qualified healthcare professional only.
- The 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. Voiding Adaptors

Position the funnel of the voiding adaptor near the external urethral opening, ensuring patient comfort. Direct the tubing into a collection device, such as a uroflow meter, if urinary flow measurement is required.
























After the procedure is complete and the relevant measurements obtained, dispose of the voiding adaptor according to local clinical disposal instructions.

### 2. Irrigation / Perfusion Sets

Remove the protective cap from the distal end of the perfusion/irrigation set. Insert the spike firmly into the fluid bag. Perform priming, air removal, and connection of the proximal end according to local clinical procedures and guidelines.

After the procedure is complete, disconnect from the equipment and dispose of the set according to local clinical disposal instructions.

## 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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