

ANORECTAL MANOMETRY CATHETERS

INSTRUCTIONS FOR USE

Intended Purpose

The Anorectal Catheters are used in water perfused or air-filled anorectal manometry and in balloon expulsion procedures to study the function of the lower GI tract by monitoring pressure and pressure changes.

Indications for Use

For use in adults and paediatrics when the measurement of the physiological pressures in the anorectal canal are indicated to aid the diagnosis and monitoring of patients with symptoms of anorectal 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 Anorectal Manometry procedures.

Clinical Benefits

These devices aid in the diagnosis, monitoring and treatment of patients with symptoms of lower GI motility dysfunction.

Performance Characteristics

These devices work in conjunction with manometry equipment to facilitate the measurement of pressure changes during manometry testing to allow for the study of the function of the lower GI tract and to aid in patient diagnosis. The devices are available in multiple configurations, are flexible and easy to insert, allowing for accurate placement and reliable pressure measurements.

Packaging & Sterilisation

The catheters are supplied non-sterile, for single use only. The catheter is not to be sterilised prior to 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

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

Warnings and Precautions

- The device should be used by a qualified healthcare professional only.
- Care should be taken when performing anorectal manometry and balloon expulsion procedures on pregnant patients, especially within the first and second trimesters and must only be performed when considered acceptable according to local clinical procedures and guidelines.

- The healthcare professional should brief the patient on the contraindications and precautions associated with this device.
- The device is to be used with compatible manometry 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.
- For water perfused catheters, to ensure that there are no air bubbles, blockages, or leaks in the catheter, perfuse using sterile saline or water during setup. In the event of leaks or blockages being detected, do not continue the procedure using the device and contact the manufacturer.
- Should the balloon rupture or become detached during use, care should be taken to ensure that all balloon fragments are removed from the patient.
- Ensure the balloon is fully deflated before removal.

Instructions For Use

1. For water perfusion catheters, connect the catheter to the 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.
2. For air-filled catheters, connect the pressure measurement luers to compatible low dead space pressure transducers.
3. Connect luers to equipment in the order stated on the catheter diagram present on the device label.
4. 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.
5. 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 anorectal canal. Correctly position the catheter and perform the evaluation according to local clinical procedures and guidelines.
6. 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.
























Note:

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

ANORECTAL MANOMETRY CATHETERS

INSTRUCTIONS FOR USE

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>

 **Advena Ltd**
 Tower Business Centre, 2nd Floor, Tower Street, Swatar, BKR 4013, Malta.
 Tel: +356 2546 6689
 Email: info@advena.mt

Malvern Medical Developments Ltd (also trading as PB Medical Limited)
 Unit 10 Northbrook Close, Worcester, WR3 8BP, UK.
 Tel: +44 (0) 1905 731343
 Email: sales@malmed.co.uk

