

Instruction for Use
Urodynamic Catheter

Device Description

The Urodynamic Catheters are provided for use in Urology procedures for cystometry and urethral pressure profilometry. Duration of Contact with the body is short term. The configurations available include:

Family	Size (Fr.)	Length (cm)	Tip	Catalogue Number
Urodynamic Catheter (UDC)	6	40	Straight Tip (ST) Pigtail Tip (PT)	AMPLCT011
		45		
		50		

Intended Purpose

Urodynamic Catheters are used to estimate the changes that occur inside the bladder and or the urethra during filling or voiding.

Performance Characteristics of the Device

Dual Lumen Catheter is designed for over-the-wire placement, providing two separate working channels for second wire placement or injection. The two lumens aids in the cystometric pressure change monitoring and allows patient catheterization with simultaneous bladder filling and pressure measurement.

Indications

- Urinary Incontinence
- Lower Urinary tract symptoms.
- Repeated urinary infections.

Contraindications

- Do not use catheter if there is damage to the urethra or bladder
- In the presence of cystitis or bacterial infection.
- Patient refusal/ Uncooperative Patient

Precautions & Warnings

Carefully read all instructions for use and product labeling. Do not use this product without reading and understanding the complete instructions enclosed herein. The device shall only be applied for its intended use and in accordance with these instructions. Observe all cautions and warnings throughout these instructions. Failure to do so may result in complications.

Precautions

- The intended user of the device must be a Urologist specializing in the treatment of urinary system disorders and related urological procedures authorized by the Competent Authority of the country in which the physician is practicing.
- Each physician is responsible for using the appropriate technique and deciding on the indication for use of this device.
- Confirm the information on the label and that the product has not reached its expiration date and there is no damage to the packaging or device.
- Device is not recommended for use in patients with the above-mentioned contraindicated conditions.
- Store the Urodynamic Catheter at a temperature between 12-35°C and a Humidity range of 30-70%.
- Store in a dry, cool place. Avoid extended exposure to sunlight.

Warnings:

- All components of the Urodynamic Catheters are for single use only.
- The product must not be re-used. Reusing single-use devices can lead to potentially serious consequences for the patient such as bio-contamination due to release of infectious agents from device into the body which further may result in Urinary Infection.
- Do not use the device if there is any indication that the sterility of the device has been compromised. If the sterile package is damaged or possibly opened, do not use. Contact "Manufacturer or Distributor" and replace the product.
- Do not reprocess or re-sterilize, reprocessing or re0sterilization may compromise the structural integrity of the device and/or lead to failure which, in turn, may result in patient injury.

Intended Patient Population

The device is intended for use in patients of all age groups.

Shelf-life

The shelf life of the Urodynamic Catheter is 3 years (Indicated on product label with the following use-by date symbol).

Sterility – This product is Sterile unless the package has been opened or damaged

- The Urodynamic Catheters have been sterilized by exposure to Ethylene Oxide. Sterility indicators are on each package. The imprinted label will change color from blue to brown after ethylene oxide exposure. Do not use the product unless the sterility indicators are the correct color.
- Exposure to high levels of Ethylene Oxide may result in presence of residual ETO which leads to Toxic Reaction in the body resulting in tissue damage of Urinary System.
- The Urodynamic Catheters are packed single. Product in each pack must be utilized immediately when opened.

Directions for Use

Open the package from the Chevron Side ('V' Notch) of the pouch. Suggested instructions for using Urodynamic Catheters:

- Under aseptic technique, Catheterize the patient in the usual manner.
- Connect the urodynamic measuring equipment to the appropriate lumen. Proceed with the urodynamic study.
- Prior to filling, ask the patient to cough so that the traces can be observed. The spikes on the intravesical and intra-abdominal lines should be identical. Any necessary adjustments should be made and the cough repeated.
- Record the fill rate.
- Ask the patient to cough every minute to ensure continued subtraction. If the lines slip, then stop the filling and rectify the problem.
- Complete test form with the number of millimeters at which the patient reports first, normal and strong desire to urinate, pain and volume leaked.
- Total volume in the bladder at the end of filling should be recorded.
- Detail any rise in detrusor pressure with or without urgency.
- At the end of filling, the large catheter used for filling the bladder is removed.

Instruction for Use
Urodynamic Catheter

- Upon completion of the study, dispose of the catheter.













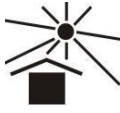




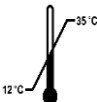



Removal Instructions

- Retrieve cystoscopically by gently pulling on Catheter or retrieval line with grasping forceps or equivalent.
- If resistance is encountered during removal of the Catheter, stop and determine cause of resistance before proceeding.

Disposal Instructions

Dispose of all equipment, in appropriate containers. After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

Explanation of symbols used on label

Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol
	Catalogue Number		CE Mark		Do not Re sterilize		Country of Manufacture		Medical Device
	Manufacturer		Date of manufacture		Keep Dry		Caution		Single Sterile barrier system with protective packaging inside
	Batch Code		Use by Date		Keep Away from Sunlight		Do not re-use		Unique Device Identifier
	Sterilized using ethylene oxide		Consult Instructions for Use		Temperature Limit		Do Not Use if Package is Damaged		Authorized Representative in the European community
	Humidity Limit								

	<p>Aster Medispro Pvt. Ltd S.P.181, 10th Main, 1st Stage, DR. B. R. Ambedkar Industrial Estate (KSSIDC) Jigani Industrial area, Jigani, Bangalore- 560105, Karnataka, India. Tel: +91 80-42062716 Email: info@astermedispro.net Web: www.astermedispro.net</p>		<p>M/sCMC Medical Devices & Drugs S.L. located in C/Horacio Lengo N° 18, CP29006, Málaga, Spain Tel : +34951214054, Fax: +34952330100 E-mail : mmateos@cmcmedicaldevices.com Web : www.cmcmedicaldevices.com</p>
--	--	--	--

Bibliography

- Single Use Medical Device:
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/956268/Single_use_medical_devices.pdf
- EN ISO 15223-1:2021 – Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
- EN ISO 20417:2020 – Medical Devices – Information to be supplied by the manufacturer.