

**10. INSTRUCTIONS FOR USE**

URODYNAMIC CATHETERS

Device Description:

AMECATH Urodynamic Catheter is a sterile, single-use device made of medical radiopaque polyurethane which provides high compatibility and less irritation. Polyurethane is a soft thermos-labile material that increases the patient comfort allowing minimum fallacious results.

AMECATH Urodynamic Catheter is a thin tube designed with single, dual or triple lumens.

AMECATH Urodynamic Catheters are divided into two types:

- Urodynamic catheter.
- Rectal Urodynamic Catheter.

Range of size between 4 to 12 FR

For Urodynamic catheter: the catheter active length is 40 cm

For Rectal Urodynamic Catheter: The catheter active length is 30 cm

AMECATH Urodynamic Catheter is connected with the urodynamic machine sensors through a (Dome which is a disposable part of transducer used to monitor invasive Fluid pressure) to elicit pressure change either in the bladder or the urethra during filling or voiding.

Target patient populations: Adults and Children

Intended user: Health Care Professionals

AMECATH Urodynamic Catheter is supplied either single catheter or in kits.

AMECATH Urodynamic Catheter and its accessories:

AMECATH Urodynamic Catheter is available in different designs and Kit configurations to cover all customer needs

Device construction:**Catheter Types**• **Urodynamic Catheter**

- Double lumen Cystometry Urodynamic catheter
- Triple lumen Profilometry Urodynamic Catheter

• **Rectal Urodynamic Catheter**

- Rectal single lumen urodynamic catheter
- Rectal double lumen urodynamic catheter

List of Accessories

Disposable Cartridge

Caps (for rectal the feeding cap should be opened)

Intended Use:

- **AMECATH Urodynamic Catheter** "urethral" is used for installation of fluids in the urinary bladder during urodynamic examination. Also, **AMECATH Urodynamic Catheter** is used to estimate changes that occur inside the bladder and or the urethra during filling or voiding
- Rectal Urodynamic Catheter is used to estimate abdominal pressure changes during filling or voiding.

Contraindications:

- Impassable urethral structure.
- Bleeding tendencies.

Warnings and Precautions

- For single product and patient use only.
- Do not use catheter if any sign of product damage is visible.
- Do not re-use, reprocess or re-sterilize. Reuse may lead to infection. Reprocessing or Re-sterilization may damage the catheter and affect its integrity which when re- used may lead to possible deterioration in health and safety of patients.
- Trauma to the urethra could occur during insertion
- Procedures should be aborted if any difficulties observed during insertion
- It is not recommended to use antimicrobial ointments on catheters as it may cause its degradation.
- Do not use absolute alcohol or acetone-based product on the catheter. 2% chlorhexidine or Iodine based solution is recommended as antiseptic solution
- The proper size selection for the catheter size is the responsibility of the physician considering the patient's anatomy.

How Supplied:

- **AMECATH Urodynamic Catheters** is a sterile, single use medical device
- Each **AMECATH Urodynamic Catheter / Urodynamic catheter kit** is packed in a pouch made of PE blister covered with medical paper.
- Each carton box includes 10 **AMECATH Urodynamic Catheters / Urodynamic Catheters kits**

AMECATH Urodynamic Catheter method of application

1. Catheterize the patient in the usual manner.
2. Urodynamic Catheter to be connected via its end to the extension line or the stopcock.
3. Extension line or stopcock to be connected to the disposable Cartridge (Dome)
4. Disposable Cartridge will help monitoring fluid pressure either with Urodynamic Catheter or Rectal Urodynamic Catheter.

N.B for further information on luer connections, please refer to latest version of BS EN ISO 80369-7

Product Variants:

For variants of **AMECATH Urodynamic Catheter**, Kindly refer to the catalogue, visit our website on

["www.amecathgroup.com"](http://www.amecathgroup.com), or contact your nearest **AMECATH** representative.

A. Double lumen Cystometry Urodynamic Catheter and Kits
Catheter Code Structure UD-L-XX

UD:	Urodynamic catheter
L:	Number of lumens
XX:	Catheter size in Fr.

Reference	Contents
UD-L-XX	Dual Lumen Urodynamic Catheter
For Dual Lumen Pigtail Cystometry Catheter add "J" (UD-L-XX-J)	

Kit Code Structure UD-L-XX-KD

UD:	Urodynamic catheter
L:	Number of lumens
XX:	Catheter size in Fr.
KD:	The Catheter with Disposable Cartridge

Reference	Contents
UD-L-XX-KD	Dual Lumen Urodynamic Catheter Disposable Cartridge
For Dual Lumen Pigtail Cystometry Catheter add "J" (UD-L-XX-J-KD)	

B. Triple lumen Profilometry Urodynamic Catheter & Kits
Code Structure UD-L-XX

UD:	Urodynamic catheter
L:	Number of lumens
XX:	Catheter size in Fr.

Reference	Contents
UD-L-XX	Triple Lumen Profilometry Catheter
For Triple lumen Profilometry Urodynamic Kits including Disposable Cartridge add "KD" (UD-L-XX-KD)	

C. Rectal Urodynamic Catheter & Kits
Code Structure UD-RL-XX-N

UD-R:	Rectal Urodynamic catheter
L:	Number of lumens
XX:	Catheter size in Fr.
N:	Non-Latex Balloon Material
KD:	The Catheter with Disposable Cartridge

Reference	Contents
UD-RL-XX-N	Rectal Urodynamic catheter
For Rectal Urodynamic Catheter Kits including Disposable Cartridge add "KD" (UD-RL-XX-N-KD)	

Storage and Product Safe Disposal

- Store between 5°C to 30°C.
- Do not expose to organic solvents, ionizing radiation or ultraviolet light.
- Rotate inventory so that catheters are used prior to expiration date on the package label.
- Used product should be disposed in sanitary container to prevent possible contamination and cross infection.

❖ *In case of any questions or queries, Kindly contact the local Authorised Representative or visit **AMECATH** website on : ["www.amecathgroup.com"](http://www.amecathgroup.com)*

❖ *In case of any Adverse event, Contact your local Health Authority immediately.*



AMECO MEDICAL INDUSTRIES
Industrial Zone B4 - Plot II9 East.
10th of Ramadan City - Egypt
Tel: +20 5545 01321/2 - Fax: +20554501224
support@amecathgroup.com | www.amecathgroup.com



OBELIS S.A
Bd. Général Wahis, 53
1030 Brussels - BELGIUM
Tel: +32.2.732.59.54 | Fax: +32.2.732.60.03
mail@obelis.net | www.obelis.net