

### 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 Catheter** 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 soft blister medical paper pouch.
- 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:

|            |                      |
|------------|----------------------|
| <b>UD:</b> | Urodynamic catheter. |
| <b>L:</b>  | Number of lumens.    |
| <b>XX:</b> | Catheter size in Fr. |

| Reference  | Contents  |
|--|---|
| UD-L-XX  | <ul style="list-style-type: none"> <li>Dual Lumen Urodynamic Catheter.</li> </ul> |
| <ul style="list-style-type: none"> <li>For Dual Lumen Pigtail Cystometry Catheter add "J" (UD-L-XX-J)</li> </ul> |   |

#### Kit Code Structure: UD-L-XX-KD:

|            |   |
|------------|---|
| <b>UD:</b> | Urodynamic catheter.                    |
| <b>L:</b>  | Number of lumens.                       |
| <b>XX:</b> | Catheter size in Fr.                    |
| <b>KD:</b> | The Catheter with Disposable Cartridge. |

| Reference   | Contents   |
|---|--|
| UD-L-XX-KD  | <ul style="list-style-type: none"> <li>Dual Lumen Urodynamic Catheter.</li> <li>Disposable Cartridge.</li> </ul> |
| <ul style="list-style-type: none"> <li>For Dual Lumen Pigtail Cystometry Catheter add "J" (UD-L-XX-KD-J)</li> </ul> |  |

### B. Triple lumen Profilometry Urodynamic Catheter & Kits

#### Code Structure: UD-L-XX:

|            |                      |
|------------|----------------------|
| <b>UD:</b> | Urodynamic catheter. |
| <b>L:</b>  | Number of lumens.    |
| <b>XX:</b> | Catheter size in Fr. |

| Reference  | Contents  |
|--|---|
| UD-L-XX  | <ul style="list-style-type: none"> <li>Triple Lumen Profilometry Catheter.</li> </ul> |
| <ul style="list-style-type: none"> <li>For Triple lumen Profilometry Urodynamic Kits including Disposable Cartridge add "KD" (UD-L-XX-KD)</li> </ul> |   |

### C. Rectal Urodynamic Catheter & Kits

#### Code Structure: UD-RL-XX-N:

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

| Reference   | Contents  |
|---|---|
| UD-RL-XX-N  | <ul style="list-style-type: none"> <li>Rectal Urodynamic catheter.</li> </ul> |
| <ul style="list-style-type: none"> <li>For Rectal Urodynamic Catheter Kits including Disposable Cartridge add "KD" (UD-RL-XX-N-KD)</li> </ul> |   |

### 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.
- ☐ Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established



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