

**10. INSTRUCTIONS FOR USE**


URODYNAMIC CATHETERS
Device Description:

CREO Urodynamic Catheter is a sterile, single-use device, for short-term use (up to 90 minutes), 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.

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

CREO 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

CREO 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

Device construction:
Catheter Types
•Urodynamic Catheter

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

•Rectal Urodynamic Catheter

- Rectal double lumen urodynamic catheter

List of Accessories

Disposable Cartridge (Domes)

Intended Use:

- **CREO Urodynamic Catheter** "urethral" is used for installation of fluids in the urinary bladder during urodynamic examination. Also, **CREO 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:

- **CREO Urodynamic Catheter** is a sterile, single use medical device
- Each **CREO Urodynamic Catheter** / **Urodynamic catheter kit** is packed in a soft blister medical paper pouch.
- Each carton box includes 10 **CREO Urodynamic Catheter** / **Urodynamic Catheters kits**

CREO Urodynamic Catheter method of application



Urodynamic Catheter and Kit Technical Documentation

Section: 10

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 **Creo Urodynamic Catheter**, Kindly refer to the catalogue, visit our website on "www.creomedical.com", or contact your nearest **CREO MEDICAL** representative.

A. Double lumen Cystometry Urodynamic Catheter and Kits

Reference	Description
4126AE	Urodynamic Catheter 2 lumens cystometry 40cm O.D. 3.0mm

B. Triple lumen Profilometry Urodynamic Catheter & Kits

Reference	Description
4125AE	Urodynamic catheter 3 lumens 9Fr 40cm O.D. 3.0mm pk10

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

Reference	Description
4114AE	Rectal Urodynamic catheter 2 lumens 10Fr 30cm O.D. 3.33mm pk10

D. List of accessories supplied with Urodynamic Catheters

Reference	Description
00002787C	Disposable Dome Male / Male Luer Locks
00002787B	Disposable Dome Clip-on Female / Male Luer Lock
00002787A	Disposable Cartridge Female / Male Luer Lock

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 **CREO** website on : ["www.creomedical.com"](http://www.creomedical.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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