

SUPRA-PUBIC CYSTOSTOMY SET “CYSTOCATH CANNULA” (With two-way Foley Drainage catheter “total silicon”)

Device Description:

AMECATH SUPRA-PUBIC CYSTOSTOMY SET “CYSTOCATH CANNULA” is a sterile, single use device, for adult and pediatric use.

AMECATH SUPRA-PUBIC CYSTOSTOMY SET “CYSTOCATH CANNULA” range consists of:

1- Splittable Cannula: is Splittable cystostomy plastic cannula sheath over dilator and stainless-steel trocar.

It is composed of three parts; the first part named plastic cannula sheath and made from polyethylene tube welded with ABS hub, the cannula tube able to split. The second part is a dilator made from polyurethane tube welded with ABS Female luer. The third part is a trocar made from stainless steel stylet welded with a cap made from ABS. the trocar end must be trigonal beveled to easy penetration. The three parts are fixed with each other.

2-Grip-lock Cystocath.: It consists of the same 3 parts as Cystocath cannula, but it is also equipped with griplock made of HDPE with its female luer for a firmer lock. Grip-Lock part is peelable for an easier and more secure handling.

AMECATH SUPRA-PUBIC CYSTOSTOMY SET “CYSTOCATH CANNULA” is supplied with Polyurethane drainage catheters (J Type or Malecot tip Catheters) or with two-way Foley Drainage catheter “total silicon ” with their accessories.

Range of size for Cystocath cannula is 10Fr. To 24Fr. Supplied with catheter of size between 8Fr. To 20Fr.

Range of size for metallic cannula is 3.05mm to 5.1mm supplied with catheter of size between 2.0mm to 4.66mm (8Fr. To 14Fr.)

AMECATH SUPRA-PUBIC CYSTOSTOMY SET “CYSTOCATH CANNULA” and its accessories:

AMECATH SUPRA-PUBIC CYSTOSTOMY SET “CYSTOCATH CANNULA” is available in different designs and Kit configurations to cover all customer needs.

Target patient populations: Adults and Paediatric

Intended user: Health Care Professionals

Device construction:

List of Accessories:

- Splittable cystocath cannula.
- Two-way Foley drainage catheter (total silicon).
- Scalpel# 11.

Intended Use:

AMECATH SUPRA-PUBIC CYSTOSTOMY SET “CYSTOCATH CANNULA” with two-way Foley Drainage catheter, is used for:

- Bladder Drainage in case of failure of urethral catheterization or contraindicated urethral catheterization.
- Supra-pubic diversion after some selected urethral surgery.

Contraindications:

- Acute Urinary Retention due to clot retention caused by undiagnosed bladder mass to avoid malignant fistula.

- Previous Supra-Pubic Surgery.

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 and Pyrogenicity. 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.
- Caution should be taken while inserting the cannula / catheter into the bladder to avoid tissue damage or internal hemorrhage
- Test to make sure that the balloon inflates and deflates properly should not performed while using "CYSTOCATH CANNULA".
- The procedure must be carried during complete aseptic technique.
- The catheter is for single use.
- Damage of the pack indicates lost sterility guarantee.
- The silicon type should be used for 30 days or less
- 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 methods of application are variable and could be modified by the HCP according to his own experience. HCP must be experienced or trained on the proper use of the device.
- The proper size selection for the device size and length is the responsibility of the physician considering the patient's anatomy.

Complications:

- Skin infection.
- Skin scar

How Supplied:

- Each **AMECATH SUPRA-PUBIC CYSTOSTOMY SET "CYSTOCATH CANNULA"** is packed in a PETG hard blister covered with Tyvek.
- Window pack is applied when **AMECATH SUPRA-PUBIC CYSTOSTOMY SET "CYSTOCATH CANNULA"** is packed in a PETG hard blister with its PETG tray cover without tyvec lid.
- Each carton box includes 10 **AMECATH SUPRA-PUBIC CYSTOSTOMY SET "CYSTOCATH CANNULA"**.

AMECATH SUPRA-PUBIC CYSTOSTOMY SET "CYSTOCATH CANNULA method of application with two-way Foley drainage catheter (total silicon)

1. Explain the procedure to the patient. Especially if they have never had a catheter before.
2. Apply the sterile gloves. (Be careful not to touch the catheter tube)
3. Choose the site of supra-pubic incision.
4. After applying the local anesthesia to the selected site, a small 2 cm. incision is done including the skin and subcutaneous tissue.

5. Introduce the Cystocath cannula through the incision until it becomes inside the bladder, urine will come when removing the metal stylet from the dilator. It is safe then to remove the whole dilator from the trocar.
6. Advance the two-way Foley drainage catheter (total silicon): through the trocar, urine will come through the catheter.
7. Strip the cannula sheath from the catheter. Connect the catheter with urine bag adaptor.
Note: For Grip-lock, peel the sheath away.
8. It is recommended that the balloon's fluid volume be checked continuously to confirm that urine is drained.
9. Remove gloves, dispose of equipment appropriately, wash hands.

Catheter removal and exchange:

- Disconnect urine bag
- Using syringe aspiration, deflate the balloon
- Gently withdraw the catheter.
- Apply sterile dressing as needed.
- In the event that the retention balloon cannot be deflated, transect the shaft of the catheter, allow balloon to deflate, and remove.
- If more time is needed, the tract, left, then it is safe to introduce a new catheter through it.

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

CATHETER CARE /MAINTENANCE:

- Simple dressing to avoid contact to the skin is recommended
- Catheter should be dependant with frequent checking of patency
- Always ensure good hand hygiene is performed prior to any intervention and use protective equipment e.g., gloves
- Observe the cystostomy site for signs of infection and over granulation.

Product Variants:

For variants of **AMECATH SUPRA-PUBIC CYSTOSTOMY SET "CYSTOCATH CANNULA"**, kindly refer to the catalogue, visit our website on: "www.amecathgroup.com" , or contact your nearest **AMECATH** representative."

Reference	Fr. Size	Contents
CYST-XX-S-K	XX	<ul style="list-style-type: none"> ● Splitable Cystocath Cannula. ● Two Way Total Silicon Catheter XXFr ● Scalpel #11
G-CYST-XX-S-K	XX	<ul style="list-style-type: none"> ● Grip-Lock Splitable Cystocath Cannula. ● Two Way Total Silicon Catheter XXFr ● Scalpel #11

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.
- ☐ N.B. please provide patients by the instructions of home care attached to this document.
 - ☐ In case of any questions or queries, Kindly contact the local Authorised Representative or visit **AMECATH** website on : “ 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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