AMECATH SUPRA-PUBIC CYSTOSTOMY SET “METALLIC CANNULA”

Guides & instruction for use

CAUTION: Federal law (USA) restricts this device to sale by or on the order of physician.

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

CONTRAINDICATION:
- Acute Urinary Retention due to clot retention caused by undiagnosed bladder mass to avoid malignant fistula.
- Previous Supra-pubic Surgery.

WARNING:
- 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 Pyrogencity. 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.

PRECAUTIONS:
Catheter should not left inside the body for more than 30 days except the two ways latex silicon coated catheter must not remain indwelling more than 7 days.

DEVICE DESCRIPTION:
Supra-pubic cystostomy set “metallic cannula” is splittable cystostomy metallic cannula supplied with Polyurethane catheters or two way Foley catheters with their accessories.

The basic set contains the following

I. If the set supplied with Polyurethane catheter:
- Splittable cystostomy metallic cannula.
- Catheter (J type or Malecot) with metal straightener.
- Connection tube (12Fr or 16Fr).
- Fixation wings.
- Stopcock 3 ways.
- Scalpel# 11.
- Urine Bag. (Optional)

II. If the set supplied with two way catheter:
- Splittable cystostomy metallic cannula.
- Two way catheter (total silicon or Latex silicon coated).
- Scalpel# 11.
- Urine Bag. (Optional)

Product range codes:

<table>
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<tr>
<th>Fr. Size</th>
<th>Supra-pubic cystostomy set “metallic cannula” with J type (Pigtail) catheter</th>
<th>Supra-pubic cystostomy set “metallic cannula” with Malecot type catheter</th>
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METHOD OF APPLICATION:

I. Instruction for use the set with polyurethane catheter
- Prepare the catheter before application by advancing the straightener inside the catheter to its end.
- Choose the site of supra-pubic incision.
- After applying the local anesthesia to the selected site, a small 2 cm. incision is done including the skin and subcutaneous tissue.
- Introduce the metallic trocar cannula through the incision until it becomes inside the bladder, urine will come out through the trocar.
- Advance the catheter with the straightener, through the trocar, urine will come through the catheter.
- Remove the straightener.
- Strip the metallic trocar cannula from the catheter.
- Apply the fixation wing to the catheter and fix it to the skin.
- Apply the extension tube to the catheter end and connect it to the urine bag.

**Catheter removal and exchange**
- Disconnect the urine bag, connection tube and fixation wings
- Advance the straightener inside the catheter to the tip end to make it straight.
- Gently withdraw the catheter.
- Apply sterile dressing as needed.
- In long standing cases (> 1 month) the tract, left, is safe to introduce a new catheter through it.

II. **Instruction for use the set with two way catheter**
- Choose the site of supra-pubic incision.
- After applying the local anesthesia to the selected site, a small 2 cm. incision is done including the skin and subcutaneous tissue.
- Introduce the metallic trocar cannula through the incision until it becomes inside the bladder, urine will come out through the trocar.
- Advance the two way catheter through the trocar, urine will come through the catheter.
- Strip the metallic trocar cannula from the catheter. Connect the catheter with urine bag adaptor.
- Inflate the catheter balloon with appropriate volume using sterile saline solution.
- It is recommended the balloon’s fluid volume be checked periodically and then reinflated with recommended volume

**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 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, is safe to introduce a new catheter through it.

**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

**HOW SUPPLIED:**
The devices are sterilized by ethylene oxide. Contents are sterile, non-pyrogenic in unopened or undamaged package. Do not use catheter if package has been damaged or has been opened.

**STORAGE:**
Store at room controlled temperature. 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.

**PRODUCT SAFE DISPOSAL:**
*Used Catheter should be disposed in sanitary container to prevent possible contamination and cross infection.*