

AMECATH

10. Instructions for Use

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10.1. Suprapubic Cystostomy Set "Cystocath Cannula" With Two Way Foley Catheter Instructions for Use

**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

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.
- 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

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. Inflate the catheter balloon with appropriate volume using sterile saline solution (according to the actual size of the balloon).
9. It is recommended that the balloon's fluid volume be checked periodically and then re-inflate with recommended volume.
10. 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 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.
- 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"](http://www.amecathgroup.com)*

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



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AMECATH

10.2. Suprapubic Cystostomy Set "Cystocath Cannula" With Two Way Foley Catheter Home Care Instructions

SUPRA-PUBIC CYSTOSTOMY SET "CYSTOCATH CANNULA"
With two-way Foley Drainage catheter "total silicon"

AMECATH SUPRA-PUBIC CYSTOSTOMY SET "CYSTOCATH CANNULA"

What is a suprapubic catheter?

A suprapubic catheter is a sterile (germ-free) tube that drains urine out of your bladder. It is inserted through a stoma (created opening) in your abdomen and into your bladder. Suprapubic means that the catheter goes into your body above your pubic bone. The catheter has a small balloon filled with solution that holds the catheter inside your bladder. These catheters are used when you have problems urinating because of a medical condition. A suprapubic catheter is also called an indwelling urinary catheter.

What is a closed drainage system for my suprapubic catheter?

The drainage system consists of your suprapubic catheter and a sterile urine drainage bag attached to the catheter. This forms a pathway that goes from the tip of the catheter inside your bladder to the urine bag. It is a closed drainage system when there are no leaks or disconnections. Your urinary system normally is sterile and a closed drainage system prevents germs from getting into it. Your catheter should **always** be attached to other equipment to form a closed drainage system.

Why is it important to take care of my suprapubic catheter and drainage bag properly?

Urinary catheter-based infections are common and can lead to serious illness and death. An infection can be caused by bacteria (germs) that get inside the catheter or drainage bag tubing when the drainage system is opened. This can happen when the urine bag is changed or when a urine sample is collected. You can also get an infection if the catheter equipment is not cleaned well or if you do not wash your hands. Actions that help prevent catheter-based infections include:

- **Drinking liquids:** Adults should drink about 9 to 13 cups of liquid each day. One cup is 8 ounces. Good choices of liquids for most people include water, juice, and milk. Coffee, soup, and fruit may be counted in your daily liquid amount. Ask your caregiver how much liquid you should drink each day.
- **Good hand washing is the best way to prevent infection.** Always wash your hands with soap and water **before and after** you touch your catheter, tubing, or drainage bag. Do this to remove germs on your hands before you touch these items. Do this after you touch these items to remove germs that may have been on them. Wear clean medical gloves when you care for your catheter or disconnect the drainage bag. This will help stop germs from getting into your catheter. Remind anyone who cares for your catheter or drainage system to wash his or her hands.

Handwashing



- **Always do proper care and cleaning** of the catheter, the insertion site, and the drainage bag.
- Ask your healthcare provider when your catheter will be removed or replaced with a new one. Your risk for infection is greater the longer you have a catheter.
- Keep the catheter drainage system closed.
- Keep the catheter tube secured to your skin or leg so it will drain well.

How do I care for my drainage bag?

- **Use good hand hygiene:** Keep your hands clean and as free of germs as possible. Always wash your hands **before and after** you touch the catheter or the insertion site. Wear clean medical gloves when you care for your catheter.
- **Position the drainage bag and tubing:**
 - **Allow gravity drainage:** Do not loop or kink the tubing so urine can flow out.
 - **Position the drainage bag properly:** Keep the drainage bag below the level of your waist. This helps stop urine from moving back up the tubing and into your bladder.
 - **Keep the bag off the floor:** Do not let the drainage bag touch or lie on the floor.
- **Empty the drainage bag when needed:** The weight of a full drainage bag can pull on and hurt your stoma. Empty the drainage bag every 3 to 6 hours or when it is $\frac{1}{2}$ to $\frac{3}{4}$ full.
 - Place a large container on the floor next to your chair. You may also hold the urine bag over the toilet.
 - Remove the drain spout from its sleeve at the bottom of the urine bag. Do not touch the tip. Open the slide valve on the spout.
 - Let the urine flow out of the urine bag into the container or toilet. Do not let the drainage tube touch anything.
 - Clean the end of the drain spout when the bag is empty. Ask your healthcare provider which cleaning solution is best to use.
 - Close the slide valve and put the drain spout into its sleeve at the bottom of the urine bag. Write down how much urine was in your bag if your healthcare provider has asked you to keep a record.
- **Clean and change the drainage bag as directed:** Ask your healthcare provider how often you should change the drainage bag. You may buy a special solution to clean the drainage bag, or you may make a solution with tap water and household bleach or vinegar. Wear medical gloves if you must disconnect the tubing. Do not allow the end of the catheter or tubing to touch anything. Clean the ends with a new alcohol pad or as directed by your healthcare provider before you reconnect them.

How do I clean my stoma?

Clean the skin around your stoma every day or as directed by your healthcare provider. Do the following:

1. **Gather the items you will need:**
 - Warm water and soap without lotions or perfumes in it
 - Clean washcloth or sterile gauze bandage
 - Clean towel
 - New gauze bandage for dressing, if used
 - Clean medical gloves
 - Trash can
2. **Prepare the site:**
 - Wash your hands. Put on clean gloves.
 - Gently remove the bandage, if you use one. Hold the skin around the stoma with one hand. With the other hand, gently pull any adhesive tape in the direction of hair growth. Throw the bandage in the trash can.
 - Look for redness, skin injuries, red spots, drainage, and swelling. Report any skin changes to your healthcare provider.
3. **Clean the site:**
 - Throw away your used gloves. Wash your hands and put on clean gloves.
 - Hold the end of the catheter tube near the insertion site so you do not pull it out while you clean your skin.
 - Wash the catheter with a washcloth or sterile gauze bandage as directed to remove blood or other material. Start at the end near your stoma and move up the catheter, away from the stoma.
 - Clean the skin around your stoma by moving your hand in a circle away from the stoma as you clean. Clean off any mucus. Rinse the stoma and the skin around it with the washcloth or sterile gauze bandage.
 - Pat the area gently with a clean towel or gauze bandage to dry it.
4. **Dress the stoma site and secure the catheter:**
 - Throw away your used gloves. Wash your hands. Apply a new bandage if you use one.
 - Secure the catheter tubing with tape or the device that holds the catheter to your leg or abdomen. Do not kink or block the tubing.

Warning:

Changing catheters need well trained health care provider "doctor or nurse". So, patients are not advised to change the catheters themselves.

In case of catheter change either accidentally or end of its required lifetime, please contact your healthcare provider to manage this change.

Special instructions:

- **Blocked tubing or catheter:** Keep the tubing in a straight line when you hang your drainage bag to prevent it from getting blocked. Increase the amount of liquids you drink if you see mucus or sand-like material in your urine. This can block your catheter and increase your risk for infection. You may need to change the position of your drainage bag. You may get bladder stones that can block your catheter.
- **Tissue overgrowth around the stoma:** Too much tissue may grow around your stoma. Move the catheter to a different place on your abdomen to reduce the pressure. This will help keep the tissue from growing too much. Healthcare providers may need to treat you if the tissue keeps growing.
- **Signs of problems related to your catheter:**
 - **Urine leaking from your stoma or urethra:** Wet clothes or a wet bed may be signs that your catheter is not draining as it should. You may get some urine leaking from your stoma or urethra if you have bladder spasms. A lot of urine leaking is not normal. The catheter may be blocked or in the wrong position. The drainage tubing may be blocked or kinked. Leaking urine can also be a sign of infection.
 - **No urine draining from the catheter:** No urine drainage for 6 to 8 hours is a sign that your catheter is not working properly. Pain or fullness in your lower abdomen can also be signs of catheter blockage or infection problems. You may also feel restless. If you have any of these signs, do the following:
 - Check to see if the urine tubing is twisted or bent or if you are lying on the catheter or tubing.
 - Make sure the urine bag and tubing are located below the level of your waist
 - Move to a different position.
 - **Contact your healthcare provider immediately** if there is still no urine draining or if you continue to have pain or fullness or feel restless.

When should I contact my healthcare provider?

- You have a fever.
- You have changes in how your urine looks or smells, or you have blood in your urine.
- Urine keeps draining out of the catheter insertion site or from your urethra.
- You have an overgrowth of skin at the insertion site that is getting larger.
- The closed drainage system has accidentally come open or apart.
- Your catheter keeps getting blocked.
- Lower abdomen pain: This can be a sign of infection. You may also have pain if the catheter is in the wrong place.
- Your catheter came out accidentally and you have replaced it with a new one.

When should I seek immediate care?

- There is less urine than usual or no urine draining into the drainage bag.
- Catheter comes out accidentally
- The catheter comes out and you are not able to put a new catheter in.
- Loss of stoma: Your stoma can start to close if it goes longer than 5 to 10 minutes without a catheter in it.
- Your insertion site is red, has green or yellow discharge, smells bad, or is bleeding more than usual.
- You have pain in your hip, back, pelvis, or lower abdomen.
- You are confused or have other changes in the way that you think.

***In case of any Adverse event, Contact your Local Health Authority immediately**



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AMECATH



10.3. Suprapubic Cystostomy Set "Cystocath Cannula"
With Polyurethane Catheter Instructions for Use

SUPRA-PUBIC CYSTOSTOMY SET "CYSTOCATH CANNULA" (With Polyurethane Drainage Catheter)

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

Device construction:

List of Accessories:

- Splittable cystocath cannula.
- Polyurethane Catheter (J type or Malecot tip) with metal straightener.
- Connection tube (12Fr or 16Fr).
- Fixation wings.
- Stopcock 3 ways.
- Scalpel# 11.

Intended Use:

AMECATH SUPRA-PUBIC CYSTOSTOMY SET "CYSTOCATH CANNULA" with Polyurethane drainage catheters, 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 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.
- Catheter should not be left inside the body for more than 30 days.
- The methods of application are variable and could be modified by the physician according to his own experience.
- The proper size selection for the catheter size and length is the responsibility of the physician.
- 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

Complications:

- Sepsis
- Bleeding
- Pain
- Urine extravasation
- Encrustation

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 polyurethane drainage catheter (J Type or Malecot tip Catheters)

1. Prepare the catheter before application by advancing the straightener inside the catheter to its end.
2. The drainage catheter should be flushed.
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 catheter with the straightener, through the sheath, urine will come through the catheter.
7. Remove the straightener.
8. Strip the cannula sheath from the catheter.
Note: For Grip-lock, peel the sheath away.
9. Apply the fixation wing to the catheter and fix it to the skin.
10. 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.

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-J-K	XX	<ul style="list-style-type: none"> • Splitable Cystocath Cannula. • Catheter J Type XXFr (Pigtail) with Straightener. • Fixation Wings. • Connection Tube. • Stopcock 3 Ways. • Scalpel #11
G-CYST-XX-J-K	XX	<ul style="list-style-type: none"> • Grip-Lock Cystocath Cannula. • Catheter J Type XXFr (Pigtail) with Straightener. • Fixation Wings. • Connection Tube. • Stopcock 3 Ways. • Scalpel #11
CYST-XX-M-K	XX	<ul style="list-style-type: none"> • Splitable Cystocath Cannula. • Catheter Malecot Type XXFr with Straightener. • Fixation Wings. • Connection Tube. • Stopcock 3 Ways. • Scalpel #11
G-CYST-XX-M-K	XX	<ul style="list-style-type: none"> • Grip-Lock Cystocath Cannula. • Catheter Malecot Type XXFr with Straightener. • Fixation Wings. • Connection Tube. • Stopcock 3 Ways. • Scalpel #11

Storage and Product Safe Disposal

- 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.
- 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.***



**Supra-Pubic Cystostomy Set
Technical Documentation****Section: 10****AMECO MEDICAL INDUSTRIES**

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AMECATH



10.4. Suprapubic Cystostomy Set "Cystocath Cannula"
With Polyurethane Catheter Instructions for Home Care

**SUPRA-PUBIC CYSTOSTOMY SET
"CYSTOCATH CANNULA"
(With Polyurethane Drainage Catheter)**

AMECATH SUPRA-PUBIC CYSTOSTOMY SET "CYSTOCATH CANNULA"

What is a suprapubic catheter?

A suprapubic catheter is a sterile (germ-free) tube that drains urine out of your bladder. It is inserted through a stoma (created opening) in your abdomen and into your bladder. Suprapubic means that the catheter goes into your body above your pubic bone. The catheter has a small balloon filled with solution that holds the catheter inside your bladder. These catheters are used when you have problems urinating because of a medical condition. A suprapubic catheter is also called an indwelling urinary catheter.

What is a closed drainage system for my suprapubic catheter?

The drainage system consists of your suprapubic catheter and a sterile urine drainage bag attached to the catheter. This forms a pathway that goes from the tip of the catheter inside your bladder to the urine bag. It is a closed drainage system when there are no leaks or disconnections. Your urinary system normally is sterile and a closed drainage system prevents germs from getting into it. Your catheter should **always** be attached to other equipment to form a closed drainage system.

Why is it important to take care of my suprapubic catheter and drainage bag properly?

Urinary catheter-based infections are common and can lead to serious illness and death. An infection can be caused by bacteria (germs) that get inside the catheter or drainage bag tubing when the drainage system is opened. This can happen when the urine bag is changed or when a urine sample is collected. You can also get an infection if the catheter equipment is not cleaned well or if you do not wash your hands. Actions that help prevent catheter-based infections include:

- **Drinking liquids:** Adults should drink about 9 to 13 cups of liquid each day. One cup is 8 ounces. Good choices of liquids for most people include water, juice, and milk. Coffee, soup, and fruit may be counted in your daily liquid amount. Ask your caregiver how much liquid you should drink each day.
- **Good hand washing is the best way to prevent infection.** Always wash your hands with soap and water **before and after** you touch your catheter, tubing, or drainage bag. Do this to remove germs on your hands before you touch these items. Do this after you touch these items to remove germs that may have been on them. Wear clean medical gloves when you care for your catheter or disconnect the drainage bag. This will help stop germs from getting into your catheter. Remind anyone who cares for your catheter or drainage system to wash his or her hands.

Handwashing



- **Always do proper care and cleaning** of the catheter, the insertion site, and the drainage bag.
- Ask your healthcare provider when your catheter will be removed or replaced with a new one. Your risk for infection is greater the longer you have a catheter.
- Keep the catheter drainage system closed.
- Keep the catheter tube secured to your skin or leg so it will drain well.

How do I care for my drainage bag?

- **Use good hand hygiene:** Keep your hands clean and as free of germs as possible. Always wash your hands **before and after** you touch the catheter or the insertion site. Wear clean medical gloves when you care for your catheter.
- **Position the drainage bag and tubing:**
 - **Allow gravity drainage:** Do not loop or kink the tubing so urine can flow out.
 - **Position the drainage bag properly:** Keep the drainage bag below the level of your waist. This helps stop urine from moving back up the tubing and into your bladder.
 - **Keep the bag off the floor:** Do not let the drainage bag touch or lie on the floor.
- **Empty the drainage bag when needed:** The weight of a full drainage bag can pull on and hurt your stoma. Empty the drainage bag every 3 to 6 hours or when it is $\frac{1}{2}$ to $\frac{3}{4}$ full.
 - Place a large container on the floor next to your chair. You may also hold the urine bag over the toilet.
 - Remove the drain spout from its sleeve at the bottom of the urine bag. Do not touch the tip. Open the slide valve on the spout.
 - Let the urine flow out of the urine bag into the container or toilet. Do not let the drainage tube touch anything.
 - Clean the end of the drain spout when the bag is empty. Ask your healthcare provider which cleaning solution is best to use.
 - Close the slide valve and put the drain spout into its sleeve at the bottom of the urine bag. Write down how much urine was in your bag if your healthcare provider has asked you to keep a record.
- **Clean and change the drainage bag as directed:** Ask your healthcare provider how often you should change the drainage bag. You may buy a special solution to clean the drainage bag, or you may make a solution with tap water and household bleach or vinegar. Wear medical gloves if you must disconnect the tubing. Do not allow the end of the catheter or tubing to touch anything. Clean the ends with a new alcohol pad or as directed by your healthcare provider before you reconnect them.

How do I clean my stoma?

Clean the skin around your stoma every day or as directed by your healthcare provider. Do the following:

5. **Gather the items you will need:**
 - Warm water and soap without lotions or perfumes in it
 - Clean washcloth or sterile gauze bandage
 - Clean towel
 - New gauze bandage for dressing, if used
 - Clean medical gloves
 - Trash can
6. **Prepare the site:**
 - Wash your hands. Put on clean gloves.
 - Gently remove the bandage, if you use one. Hold the skin around the stoma with one hand. With the other hand, gently pull any adhesive tape in the direction of hair growth. Throw the bandage in the trash can.
 - Look for redness, skin injuries, red spots, drainage, and swelling. Report any skin changes to your healthcare provider.
7. **Clean the site:**
 - Throw away your used gloves. Wash your hands and put on clean gloves.
 - Hold the end of the catheter tube near the insertion site so you do not pull it out while you clean your skin.
 - Wash the catheter with a washcloth or sterile gauze bandage as directed to remove blood or other material. Start at the end near your stoma and move up the catheter, away from the stoma.
 - Clean the skin around your stoma by moving your hand in a circle away from the stoma as you clean. Clean off any mucus. Rinse the stoma and the skin around it with the washcloth or sterile gauze bandage.
 - Pat the area gently with a clean towel or gauze bandage to dry it.
8. **Dress the stoma site and secure the catheter:**
 - Throw away your used gloves. Wash your hands. Apply a new bandage if you use one.
 - Secure the catheter tubing with tape or the device that holds the catheter to your leg or abdomen. Do not kink or block the tubing.

Warning:

Changing catheters need well trained health care provider "doctor or nurse". So, patients are not advised to change the catheters themselves.

In case of catheter change either accidentally or end of its required lifetime, please contact your healthcare provider to manage this change.

Special instructions:

- **Blocked tubing or catheter:** Keep the tubing in a straight line when you hang your drainage bag to prevent it from getting blocked. Increase the amount of liquids you drink if you see mucus or sand-like material in your urine. This can block your catheter and increase your risk for infection. You may need to change the position of your drainage bag. You may get bladder stones that can block your catheter.
- **Tissue overgrowth around the stoma:** Too much tissue may grow around your stoma. Move the catheter to a different place on your abdomen to reduce the pressure. This will help keep the tissue from growing too much. Healthcare providers may need to treat you if the tissue keeps growing.
- **Signs of problems related to your catheter:**
 - **Urine leaking from your stoma or urethra:** Wet clothes or a wet bed may be signs that your catheter is not draining as it should. You may get some urine leaking from your stoma or urethra if you have bladder spasms. A lot of urine leaking is not normal. The catheter may be blocked or in the wrong position. The drainage tubing may be blocked or kinked. Leaking urine can also be a sign of infection.
 - **No urine draining from the catheter:** No urine drainage for 6 to 8 hours is a sign that your catheter is not working properly. Pain or fullness in your lower abdomen can also be signs of catheter blockage or infection problems. You may also feel restless. If you have any of these signs, do the following:
 - **Check** to see if the urine tubing is twisted or bent or if you are lying on the catheter or tubing.
 - **Make** sure the urine bag and tubing are located below the level of your waist
 - **Move** to a different position.
 - **Contact your healthcare provider immediately** if there is still no urine draining or if you continue to have pain or fullness or feel restless.

When should I contact my healthcare provider?

- You have a fever.
- You have changes in how your urine looks or smells, or you have blood in your urine.
- Urine keeps draining out of the catheter insertion site or from your urethra.
- You have an overgrowth of skin at the insertion site that is getting larger.
- The closed drainage system has accidentally come open or apart.
- Your catheter keeps getting blocked.
- Lower abdomen pain: This can be a sign of infection. You may also have pain if the catheter is in the wrong place.
- Your catheter came out accidentally and you have replaced it with a new one.

When should I seek immediate care?

- There is less urine than usual or no urine draining into the drainage bag.
- Catheter comes out accidentally
- The catheter comes out and you are not able to put a new catheter in.
- Loss of stoma: Your stoma can start to close if it goes longer than 5 to 10 minutes without a catheter in it.
- Your insertion site is red, has green or yellow discharge, smells bad, or is bleeding more than usual.
- You have pain in your hip, back, pelvis, or lower abdomen.
- You are confused or have other changes in the way that you think.

***In case of any Adverse event, Contact your Local Health Authority immediately**



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**10.5. Suprapubic Cystostomy Set “Metallic Cannula”
With Two Way Foley Catheter Instructions for Use**

SUPRA-PUBIC CYSTOSTOMY SET "METALLIC CANNULA"
(With two-way Foley Drainage catheter "Total Silicon")

Device Description:

AMECATH SUPRA-PUBIC CYSTOSTOMY SET "METALLIC CANNULA" is a sterile, single use device, for adult and pediatric use. It is a splittable cystostomy Plastic cannula supplied with Polyurethane drainage catheters (J Type or Malecot tip Catheters) or with two-way Foley Drainage catheter "total silicon" with their accessories.

Splittable cystostomy metallic cannula: it is split needles for suprapubic bladder puncture. The optimized design provides minimal splitting forces and easy handling.

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 "METALLIC CANNULA" and its accessories:

AMECATH SUPRA-PUBIC CYSTOSTOMY SET "METALLIC CANNULA" is available in different designs and Kit configurations to cover all customer needs

Device construction:**List of Accessories:**

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

Intended Use:

AMECATH SUPRA-PUBIC CYSTOSTOMY SET "METALLIC CANNULA" with two-way Foleys' 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 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.
- Test to make sure that the balloon inflates and deflates properly should not performed while using "METALLIC 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

Complications:

- Skin infection.
- Skin scar

How Supplied:

- Each **AMECATH SUPRA-PUBIC CYSTOSTOMY SET "METALLIC CANNULA"** is packed in a PETG hard blister covered with Tyvek.
- Window pack is applied when **AMECATH SUPRA-PUBIC CYSTOSTOMY SET "METALLIC 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 "METALLIC CANNULA"**

AMECATH SUPRA-PUBIC CYSTOSTOMY SET "METALLIC CANNULA" method of application:

with two-way Foley drainage catheter (total silicon)

11. Explain the procedure to the patient. Especially if they have never had a catheter before.
12. Apply the sterile gloves. (Be careful not to touch the catheter tube)
13. Choose the site of supra-pubic incision.
14. After applying the local anesthesia to the selected site, a small 2 cm. incision is done including the skin and subcutaneous tissue.
15. Introduce the metallic trocar 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.
16. Advance the two-way Foley drainage catheter (total silicon): through the trocar, urine will come through the catheter.
17. Strip the metallic trocar cannula from the catheter. Connect the catheter with urine bag adaptor.
18. Inflate the catheter balloon with appropriate volume using sterile saline solution (according to the actual size of the balloon).
19. It is recommended that the balloon's fluid volume be checked periodically and then re-inflate with recommended volume.
20. 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 dependent 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 "METALLIC CANNULA"**, Kindly refer to the catalogue, visit our website on "www.amecathgroup.com", or contact your nearest **AMECATH** representative.

Reference	Fr. Size	Contents
SUP-XX-S-K	XX	<ul style="list-style-type: none"> • Splitable Cystostomy Metallic Cannula. • Two Way Total Silicon Catheter XXFr • Scalpel #11

Storage and Product Safe Disposal

- 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.
- 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.



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10.6. Suprapubic Cystostomy Set “Metallic Cannula”
With Two Way Foley Catheter Instructions for Home Care

SUPRA-PUBIC CYSTOSTOMY SET "METALLIC CANNULA"

(With two-way Foley Drainage catheter "total silicon")

AMECATH SUPRA-PUBIC CYSTOSTOMY SET "METALLIC CANNULA"

What is a suprapubic catheter?

A suprapubic catheter is a sterile (germ-free) tube that drains urine out of your bladder. It is inserted through a stoma (created opening) in your abdomen and into your bladder. Suprapubic means that the catheter goes into your body above your pubic bone. The catheter has a small balloon filled with solution that holds the catheter inside your bladder. These catheters are used when you have problems urinating because of a medical condition. A suprapubic catheter is also called an indwelling urinary catheter.

What is a closed drainage system for my suprapubic catheter?

The drainage system consists of your suprapubic catheter and a sterile urine drainage bag attached to the catheter. This forms a pathway that goes from the tip of the catheter inside your bladder to the urine bag. It is a closed drainage system when there are no leaks or disconnections. Your urinary system normally is sterile and a closed drainage system prevents germs from getting into it. Your catheter should **always** be attached to other equipment to form a closed drainage system.

Why is it important to take care of my suprapubic catheter and drainage bag properly?

Urinary catheter-based infections are common and can lead to serious illness and death. An infection can be caused by bacteria (germs) that get inside the catheter or drainage bag tubing when the drainage system is opened. This can happen when the urine bag is changed or when a urine sample is collected. You can also get an infection if the catheter equipment is not cleaned well or if you do not wash your hands. Actions that help prevent catheter-based infections include:

- **Drinking liquids:** Adults should drink about 9 to 13 cups of liquid each day. One cup is 8 ounces. Good choices of liquids for most people include water, juice, and milk. Coffee, soup, and fruit may be counted in your daily liquid amount. Ask your caregiver how much liquid you should drink each day.
- **Good hand washing is the best way to prevent infection.** Always wash your hands with soap and water **before and after** you touch your catheter, tubing, or drainage bag. Do this to remove germs on your hands before you touch these items. Do this after you touch these items to remove germs that may have been on them. Wear clean medical gloves when you care for your catheter or disconnect the drainage bag. This will help stop germs from getting into your catheter. Remind anyone who cares for your catheter or drainage system to wash his or her hands.

Handwashing



- **Always do proper care and cleaning** of the catheter, the insertion site, and the drainage bag.
- Ask your healthcare provider when your catheter will be removed or replaced with a new one. Your risk for infection is greater the longer you have a catheter.
- Keep the catheter drainage system closed.
- Keep the catheter tube secured to your skin or leg so it will drain well.

How do I care for my drainage bag?

- **Use good hand hygiene:** Keep your hands clean and as free of germs as possible. Always wash your hands **before and after** you touch the catheter or the insertion site. Wear clean medical gloves when you care for your catheter.

- **Position the drainage bag and tubing:**
 - **Allow gravity drainage:** Do not loop or kink the tubing so urine can flow out.
 - **Position the drainage bag properly:** Keep the drainage bag below the level of your waist. This helps stop urine from moving back up the tubing and into your bladder.
 - **Keep the bag off the floor:** Do not let the drainage bag touch or lie on the floor.
- **Empty the drainage bag when needed:** The weight of a full drainage bag can pull on and hurt your stoma. Empty the drainage bag every 3 to 6 hours or when it is $\frac{1}{2}$ to $\frac{3}{4}$ full.
 - Place a large container on the floor next to your chair. You may also hold the urine bag over the toilet.
 - Remove the drain spout from its sleeve at the bottom of the urine bag. Do not touch the tip. Open the slide valve on the spout.
 - Let the urine flow out of the urine bag into the container or toilet. Do not let the drainage tube touch anything.
 - Clean the end of the drain spout when the bag is empty. Ask your healthcare provider which cleaning solution is best to use.
 - Close the slide valve and put the drain spout into its sleeve at the bottom of the urine bag. Write down how much urine was in your bag if your healthcare provider has asked you to keep a record.
- **Clean and change the drainage bag as directed:** Ask your healthcare provider how often you should change the drainage bag. You may buy a special solution to clean the drainage bag, or you may make a solution with tap water and household bleach or vinegar. Wear medical gloves if you must disconnect the tubing. Do not allow the end of the catheter or tubing to touch anything. Clean the ends with a new alcohol pad or as directed by your healthcare provider before you reconnect them.

How do I clean my stoma?

Clean the skin around your stoma every day or as directed by your healthcare provider. Do the following:

- **Gather the items you will need:**
 - Warm water and soap without lotions or perfumes in it
 - Clean washcloth or sterile gauze bandage
 - Clean towel
 - New gauze bandage for dressing, if used
 - Clean medical gloves
 - Trash can
- **Prepare the site:**
 - Wash your hands. Put on clean gloves.
 - Gently remove the bandage, if you use one. Hold the skin around the stoma with one hand. With the other hand, gently pull any adhesive tape in the direction of hair growth. Throw the bandage in the trash can.
 - Look for redness, skin injuries, red spots, drainage, and swelling. Report any skin changes to your healthcare provider.
- **Clean the site:**
 - Throw away your used gloves. Wash your hands and put on clean gloves.
 - Hold the end of the catheter tube near the insertion site so you do not pull it out while you clean your skin.
 - Wash the catheter with a washcloth or sterile gauze bandage as directed to remove blood or other material. Start at the end near your stoma and move up the catheter, away from the stoma.
 - Clean the skin around your stoma by moving your hand in a circle away from the stoma as you clean. Clean off any mucus. Rinse the stoma and the skin around it with the washcloth or sterile gauze bandage.
 - Pat the area gently with a clean towel or gauze bandage to dry it.
- **Dress the stoma site and secure the catheter:**
 - Throw away your used gloves. Wash your hands. Apply a new bandage if you use one.
 - Secure the catheter tubing with tape or the device that holds the catheter to your leg or abdomen. Do not kink or block the tubing.

Warning:

Changing catheters need well trained health care provider "doctor or nurse". So, patients are not advised to change the catheters themselves.

In case of catheter change either accidentally or end of its required lifetime, please contact your healthcare provider to manage this change.

Special instructions:

- **Blocked tubing or catheter:** Keep the tubing in a straight line when you hang your drainage bag to prevent it from getting blocked. Increase the amount of liquids you drink if you see mucus or sand-like material in your urine. This can block your catheter and increase your risk for infection. You may need to change the position of your drainage bag. You may get bladder stones that can block your catheter.
- **Tissue overgrowth around the stoma:** Too much tissue may grow around your stoma. Move the catheter to a different place on your abdomen to reduce the pressure. This will help keep the tissue from growing too much. Healthcare providers may need to treat you if the tissue keeps growing.
- **Signs of problems related to your catheter:**
 - **Urine leaking from your stoma or urethra:** Wet clothes or a wet bed may be signs that your catheter is not draining as it should. You may get some urine leaking from your stoma or urethra if you have bladder spasms. A lot of urine leaking is not normal. The catheter may be blocked or in the wrong position. The drainage tubing may be blocked or kinked. Leaking urine can also be a sign of infection.
 - **No urine draining from the catheter:** No urine drainage for 6 to 8 hours is a sign that your catheter is not working properly. Pain or fullness in your lower abdomen can also be signs of catheter blockage or infection problems. You may also feel restless. If you have any of these signs, do the following:
 - Check to see if the urine tubing is twisted or bent or if you are lying on the catheter or tubing.
 - Make sure the urine bag and tubing are located below the level of your waist
 - Move to a different position.
 - **Contact your healthcare provider immediately** if there is still no urine draining or if you continue to have pain or fullness or feel restless.

When should I contact my healthcare provider?

- You have a fever.
- You have changes in how your urine looks or smells, or you have blood in your urine.
- Urine keeps draining out of the catheter insertion site or from your urethra.
- You have an overgrowth of skin at the insertion site that is getting larger.
- The closed drainage system has accidentally come open or apart.
- Your catheter keeps getting blocked.
- Lower abdomen pain: This can be a sign of infection. You may also have pain if the catheter is in the wrong place.
- Your catheter came out accidentally and you have replaced it with a new one.

When should I seek immediate care?

- There is less urine than usual or no urine draining into the drainage bag.
- Catheter comes out accidentally
- The catheter comes out and you are not able to put a new catheter in.
- Loss of stoma: Your stoma can start to close if it goes longer than 5 to 10 minutes without a catheter in it.
- Your insertion site is red, has green or yellow discharge, smells bad, or is bleeding more than usual.
- You have pain in your hip, back, pelvis, or lower abdomen.
- You are confused or have other changes in the way that you think.

***In case of any Adverse event, Contact your Local Health Authority immediately**



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10.7. Suprapubic Cystostomy Set “Metallic Cannula” With Polyurethane Catheter Instructions for Use

SUPRA-PUBIC CYSTOSTOMY SET "METALLIC CANNULA"
(With Polyurethane Drainage Catheter)

Device Description:

AMECATH SUPRA-PUBIC CYSTOSTOMY SET "METALLIC CANNULA" is a sterile, single use device, for adult and pediatric use. It is a splittable cystostomy metallic cannula supplied with Polyurethane drainage catheters (J Type or Malecot tip Catheters) or with two-way Foley Drainage catheter "total silicon " with their accessories.

Splittable cystostomy metallic cannula: it is split needles for suprapubic bladder puncture. The optimized design provides minimal splitting forces and easy handling.

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 "METALLIC CANNULA" and its accessories:

AMECATH SUPRA-PUBIC CYSTOSTOMY SET "METALLIC CANNULA" is available in different designs and Kit configurations to cover all customer needs

Device construction:**List of Accessories:**

- Splittable METALLIC cannula.
- Polyurethane Catheter (J type or Malecot tip) with metal straightener.
- Connection tube (12Fr or 16Fr).
- Fixation wings.
- Stopcock 3 ways.
- Scalpel# 11.

Intended Use:

AMECATH SUPRA-PUBIC CYSTOSTOMY SET "METALLIC CANNULA" with Polyurethane drainage catheters, 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 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.
- Catheter should not be left inside the body for more than 30 days.
- The methods of application are variable and could be modified by the physician according to his own experience.
- The proper size selection for the catheter size and length is the responsibility of the physician.
- 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

Complications:

- Sepsis
- Bleeding
- Pain
- Urine extravasation
- Encrustation

How Supplied:

- Each **AMECATH SUPRA-PUBIC CYSTOSTOMY SET "METALLIC CANNULA"** is packed in a PETG hard blister covered with Tyvek.
- Window pack is applied when **AMECATH SUPRA-PUBIC CYSTOSTOMY SET "METALLIC 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 "METALLIC CANNULA"**

AMECATH SUPRA-PUBIC CYSTOSTOMY SET "METALLIC CANNULA" method of application:

with polyurethane drainage catheter (J Type or Malecot tip Catheters)

1. Prepare the catheter before application by advancing the straightener inside the catheter to its end.
2. Choose the site of supra-pubic incision.
3. After applying the local anesthesia to the selected site, a small 2 cm. incision is done including the skin and subcutaneous tissue.
4. Introduce the metallic trocar cannula through the incision until it becomes inside the bladder, urine will come out through the trocar.
5. Advance the catheter with the straightener, through the trocar, urine will come through the catheter.
6. Remove the straightener.
7. Strip the metallic trocar cannula from the catheter.
8. Apply the fixation wing to the catheter and fix it to the skin.
9. 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.

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 dependent 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 "METALLIC CANNULA"**, Kindly refer to the catalogue, visit our website on "www.amecathgroup.com", or contact your nearest **AMECATH** representative.

Reference	Fr. Size	Contents
SUP-XX-J-K	XX	<ul style="list-style-type: none"> • Splitable Cystostomy Metallic Cannula. • Catheter J Type (Pigtail) XXFr with Straightener. • Fixation Wings. • Connection Tube. • Stopcock 3 Ways. • Scalpel #11
SUP-XX-M-K	XX	<ul style="list-style-type: none"> • Splitable Cystostomy Metallic Cannula. • Catheter Malecot Type XXFr with Straightener. • Fixation Wings. • Connection Tube.

- Stopcock 3 Ways.
- Scalpel #11

Storage and Product Safe Disposal

- 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.
- 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"](http://www.amecathgroup.com)*

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

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10.8. Suprapubic Cystostomy Set “Metallic Cannula”
With Polyurethane Catheter Instructions for Home Care

SUPRA-PUBIC CYSTOSTOMY SET "METALLIC CANNULA" (With Polyurethane Drainage Catheter)

AMECATH SUPRA-PUBIC CYSTOSTOMY SET "METALLIC CANNULA"

What is a suprapubic catheter?

A suprapubic catheter is a sterile (germ-free) tube that drains urine out of your bladder. It is inserted through a stoma (created opening) in your abdomen and into your bladder. Suprapubic means that the catheter goes into your body above your pubic bone. The catheter has a small balloon filled with solution that holds the catheter inside your bladder. These catheters are used when you have problems urinating because of a medical condition. A suprapubic catheter is also called an indwelling urinary catheter.

What is a closed drainage system for my suprapubic catheter?

The drainage system consists of your suprapubic catheter and a sterile urine drainage bag attached to the catheter. This forms a pathway that goes from the tip of the catheter inside your bladder to the urine bag. It is a closed drainage system when there are no leaks or disconnections. Your urinary system normally is sterile and a closed drainage system prevents germs from getting into it. Your catheter should **always** be attached to other equipment to form a closed drainage system.

Why is it important to take care of my suprapubic catheter and drainage bag properly?

Urinary catheter-based infections are common and can lead to serious illness and death. An infection can be caused by bacteria (germs) that get inside the catheter or drainage bag tubing when the drainage system is opened. This can happen when the urine bag is changed or when a urine sample is collected. You can also get an infection if the catheter equipment is not cleaned well or if you do not wash your hands. Actions that help prevent catheter-based infections include:

- **Drinking liquids:** Adults should drink about 9 to 13 cups of liquid each day. One cup is 8 ounces. Good choices of liquids for most people include water, juice, and milk. Coffee, soup, and fruit may be counted in your daily liquid amount. Ask your caregiver how much liquid you should drink each day.
- **Good hand washing is the best way to prevent infection.** Always wash your hands with soap and water **before and after** you touch your catheter, tubing, or drainage bag. Do this to remove germs on your hands before you touch these items. Do this after you touch these items to remove germs that may have been on them. Wear clean medical gloves when you care for your catheter or disconnect the drainage bag. This will help stop germs from getting into your catheter. Remind anyone who cares for your catheter or drainage system to wash his or her hands.

Handwashing



- **Always do proper care and cleaning** of the catheter, the insertion site, and the drainage bag.
- Ask your healthcare provider when your catheter will be removed or replaced with a new one. Your risk for infection is greater the longer you have a catheter.
- Keep the catheter drainage system closed.
- Keep the catheter tube secured to your skin or leg so it will drain well.

How do I care for my drainage bag?

- **Use good hand hygiene:** Keep your hands clean and as free of germs as possible. Always wash your hands **before and after** you touch the catheter or the insertion site. Wear clean medical gloves when you care for your catheter.
- **Position the drainage bag and tubing:**
 - **Allow gravity drainage:** Do not loop or kink the tubing so urine can flow out.
 - **Position the drainage bag properly:** Keep the drainage bag below the level of your waist. This helps stop urine from moving back up the tubing and into your bladder.
 - **Keep the bag off the floor:** Do not let the drainage bag touch or lie on the floor.
- **Empty the drainage bag when needed:** The weight of a full drainage bag can pull on and hurt your stoma. Empty the drainage bag every 3 to 6 hours or when it is $\frac{1}{2}$ to $\frac{3}{4}$ full.
 - Place a large container on the floor next to your chair. You may also hold the urine bag over the toilet.
 - Remove the drain spout from its sleeve at the bottom of the urine bag. Do not touch the tip. Open the slide valve on the spout.
 - Let the urine flow out of the urine bag into the container or toilet. Do not let the drainage tube touch anything.
 - Clean the end of the drain spout when the bag is empty. Ask your healthcare provider which cleaning solution is best to use.
 - Close the slide valve and put the drain spout into its sleeve at the bottom of the urine bag. Write down how much urine was in your bag if your healthcare provider has asked you to keep a record.
- **Clean and change the drainage bag as directed:** Ask your healthcare provider how often you should change the drainage bag. You may buy a special solution to clean the drainage bag, or you may make a solution with tap water and household bleach or vinegar. Wear medical gloves if you must disconnect the tubing. Do not allow the end of the catheter or tubing to touch anything. Clean the ends with a new alcohol pad or as directed by your healthcare provider before you reconnect them.

How do I clean my stoma?

Clean the skin around your stoma every day or as directed by your healthcare provider. Do the following:

- **Gather the items you will need:**
 - Warm water and soap without lotions or perfumes in it
 - Clean washcloth or sterile gauze bandage
 - Clean towel
 - New gauze bandage for dressing, if used
 - Clean medical gloves
 - Trash can
- **Prepare the site:**
 - Wash your hands. Put on clean gloves.
 - Gently remove the bandage, if you use one. Hold the skin around the stoma with one hand. With the other hand, gently pull any adhesive tape in the direction of hair growth. Throw the bandage in the trash can.
 - Look for redness, skin injuries, red spots, drainage, and swelling. Report any skin changes to your healthcare provider.
- **Clean the site:**
 - Throw away your used gloves. Wash your hands and put on clean gloves.
 - Hold the end of the catheter tube near the insertion site so you do not pull it out while you clean your skin.
 - Wash the catheter with a washcloth or sterile gauze bandage as directed to remove blood or other material. Start at the end near your stoma and move up the catheter, away from the stoma.
 - Clean the skin around your stoma by moving your hand in a circle away from the stoma as you clean. Clean off any mucus. Rinse the stoma and the skin around it with the washcloth or sterile gauze bandage.
 - Pat the area gently with a clean towel or gauze bandage to dry it.
- **Dress the stoma site and secure the catheter:**
 - Throw away your used gloves. Wash your hands. Apply a new bandage if you use one.
 - Secure the catheter tubing with tape or the device that holds the catheter to your leg or abdomen. Do not kink or block the tubing.

Warning:

Changing catheters need well trained health care provider "doctor or nurse". So, patients are not advised to change the catheters themselves.

In case of catheter change either accidentally or end of its required lifetime, please contact your healthcare provider to manage this change.

Special instructions:

- **Blocked tubing or catheter:** Keep the tubing in a straight line when you hang your drainage bag to prevent it from getting blocked. Increase the amount of liquids you drink if you see mucus or sand-like material in your urine. This can block your catheter and increase your risk for infection. You may need to change the position of your drainage bag. You may get bladder stones that can block your catheter.
- **Tissue overgrowth around the stoma:** Too much tissue may grow around your stoma. Move the catheter to a different place on your abdomen to reduce the pressure. This will help keep the tissue from growing too much. Healthcare providers may need to treat you if the tissue keeps growing.
- **Signs of problems related to your catheter:**
 - **Urine leaking from your stoma or urethra:** Wet clothes or a wet bed may be signs that your catheter is not draining as it should. You may get some urine leaking from your stoma or urethra if you have bladder spasms. A lot of urine leaking is not normal. The catheter may be blocked or in the wrong position. The drainage tubing may be blocked or kinked. Leaking urine can also be a sign of infection.
 - **No urine draining from the catheter:** No urine drainage for 6 to 8 hours is a sign that your catheter is not working properly. Pain or fullness in your lower abdomen can also be signs of catheter blockage or infection problems. You may also feel restless. If you have any of these signs, do the following:
 - Check to see if the urine tubing is twisted or bent or if you are lying on the catheter or tubing.
 - Make sure the urine bag and tubing are located below the level of your waist
 - Move to a different position.
 - **Contact your healthcare provider immediately** if there is still no urine draining or if you continue to have pain or fullness or feel restless.

When should I contact my healthcare provider?

- You have a fever.
- You have changes in how your urine looks or smells, or you have blood in your urine.
- Urine keeps draining out of the catheter insertion site or from your urethra.
- You have an overgrowth of skin at the insertion site that is getting larger.
- The closed drainage system has accidentally come open or apart.
- Your catheter keeps getting blocked.
- Lower abdomen pain: This can be a sign of infection. You may also have pain if the catheter is in the wrong place.
- Your catheter came out accidentally and you have replaced it with a new one.

When should I seek immediate care?

- There is less urine than usual or no urine draining into the drainage bag.
- Catheter comes out accidentally
- The catheter comes out and you are not able to put a new catheter in.
- Loss of stoma: Your stoma can start to close if it goes longer than 5 to 10 minutes without a catheter in it.
- Your insertion site is red, has green or yellow discharge, smells bad, or is bleeding more than usual.
- You have pain in your hip, back, pelvis, or lower abdomen.
- You are confused or have other changes in the way that you think.

***In case of any Adverse event, Contact your Local Health Authority immediately**



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