

### UMBILICAL CATHETER KIT

#### Device Description:

**AMECATH Umbilical Catheters** are Radiopaque and made from polyurethane.

**AMECATH Umbilical Catheters** are single, dual or triple catheters End with female luers.

\*Note: The double lumen catheter is used only for insertion into the umbilical vein.

**AMECATH Umbilical Catheters** are for newly born babies use only.

**Umbilical Catheters** size ranges between 2 Fr to 5 Fr.

**Umbilical Catheters** lengths ranges between 25 Cm to 40 Cm.

**AMECATH Umbilical Catheter** is recommended to be used for 10 days.

**AMECATH Umbilical Catheters** are placed in the umbilical vein or artery.

**Target patient populations:** newborn

**Intended user:** Health Care Professionals

**AMECATH Umbilical Catheters** are available in different designs and Kit configurations to cover all customer needs.

#### Device construction:

**List of Accessories may include the following:**

- Scalpel
- Stopcock
- T-connector with Stiffener Wire & Caps ( 2F & 3F ) ONLY
- Injection caps

#### Intended Use:

**AMECATH Umbilical Catheter** is used for short term vascular access through the umbilical vessels.

#### Indications:

- Parenteral nutrition & fluid administration
- Drugs administration
- Venous blood sampling

#### N.B:

To ensure that Umbilical Venous catheter is performing well in order to achieve its intended use, please

- Ensure that if catheter is used intermittently , Catheter lumens should be flushed routinely before and after medications are administered and before and after blood samples are aspirated
- To avoid Catheter rupture, Use a 10 cc or larger syringe to flush lumen in vivo. As Smaller syringes may generate extreme pressure which could rupture the catheter

#### Clinical Benefits:

The Umbilical Central Venous Catheter is used to facilitate the delivery and administration of:

- Drugs
- Parenteral nutrition
- Fluids
- It is also used for venous Blood sampling for various medical purposes.

### Contraindications:

- Patients exhibiting renal, gastrointestinal, cardiac, or periumbilical abnormalities (including clinical indicators for umbilical infection).
- Peritonitis, necrotizing enterocolitis, omphalitis.
- Omphalocele, evidence of local vascular compromise in lower limbs or buttocks area, or portal venous hypertension.

### Warnings and Precautions:

#### General

- For single use only. Do not re-use, reprocess or re-sterilize. Do not use catheter or accessories if any sign of product damage is visible.
- Reprocessing or re-sterilization may damage the catheter and affect its integrity which may, when re-used, lead to severe deterioration in health and safety of patients.
- The catheter does not have any electrically conductive, metallic, nor magnetic components and can be exposed to various environmental conditions including thermal ignition source (during MRI) as long as no metal component is attached to it. (In accordance to ASTM F2503-23).
- The insertion technique has a significant influence on the complications and outcome of the patient. Insertion must be performed by a competent and experienced catheter insertion team. Inexperienced personnel should not be permitted to perform the insertion except under the direct supervision of an experienced physician or surgeon
- Ensure that all connections to the catheter are secure.
- Placement must be determined by X ray.
- Check extremities for discoloration and blanching while the catheter is indwelling.
- If a catheter thrombus is suspected do not flush. Follow hospital protocol and physician orders for aspiration and declotting.
- This device should only be used by, or under the instruction and responsibility of, an appropriately qualified person who's familiar with the product and the clinical procedure.
- The proper size selection for the catheter size and length is the responsibility of the physician considering the patient's anatomy.
- Do not use absolute alcohol or acetone based product on the catheter. 2% chlorhexidine or iodine based solution is recommended as antiseptic solution.
- It is not recommended to use ointments especially antimicrobial ointments or solutions on catheters as it may cause its degradation.

#### Specific

- It may be advisable to pass an NG tube to decompress the stomach prior to catheter insertion.
- Catheter lumens should be flushed routinely if used intermittently, before and after medications are administered and before and after blood samples are aspirated.
- Amount, strength, and frequency of heparin flush should be determined by hospital policy. Most references recommend 10 U of heparin per 1 ml of saline and a volume to slightly exceed the catheter volume.
- Routine umbilical stump care should be administered to help prevent infection.
- To remove catheter, withdraw it slowly.
- Use a 10 cc or larger syringe to flush lumen in vivo. Smaller syringes may generate extreme pressure which could rupture the catheter.
- Directions described herein do not represent all medically acceptable protocols, nor are they intended as a substitute for the physicians experience and judgment in treating any specific patient.
- Exercise caution when using sharp instruments near the catheter.
- Exercise caution when suturing catheter to avoid cutting, indenting, or compromising the catheter in any way.
- Always observe sterile technique when handling the catheter during insertion and when administering routine care to the catheterized umbilical stump.

### Complications:

- **Potential Complications associated with umbilical catheters include:**

- Ischemia
- Thrombosis
- Vasospasm
- Hemorrhage
- Infection
- Vascular perforation
- Air embolism

### How Supplied:

- **AMECATH Umbilical Catheter** is a sterile, single-use Medical device.
- Each **AMECATH Umbilical Catheter** Kit is packed in a PETG hard blister covered with PETG hard blister cover and wrapped together into one soft window bag.
- Each carton box includes 10 **AMECATH Umbilical Catheter** Kits.

### AMECATH Umbilical Catheter method of application

**Use strict aseptic technique when handling and introducing the product. Disinfect carefully the umbilical cord and the abdominal wall. Place a sterile drape with central opening.**

1. Elevate the cord vertically using toothed forceps. Cut the cord horizontally 1 cm above the skin with a scalpel blade.
2. Remove the clots which may obstruct the vessel lumen. Control any bleeding by gentle tension on the umbilical tape.
3. Grasp the stump of the cord and hold it upright. Identify the vessels.
4. Prime the catheter with saline solution.
5. Carefully dilate the vessel in which the catheter will be inserted.
6. Insert the catheter into the vessel with forceps and advance the catheter directing it toward the pelvis.
7. Use the cm markings on the catheter to note the length of catheter inserted.
8. Place a suture in the wall of the cord taking care not to puncture the catheter.
9. Dress the catheter according to your local policies.

### Control of positioning:

- Always check the location of the catheter by radiography.
- For arterial catheterization, the catheter tip should be placed in the lower abdominal aorta below the origin of the renal and inferior mesenteric arteries and above the bifurcation of the aorta (i.e., at the bottom of, or just below, the 3rd lumbar vertebra).
- For venous catheterization, the catheter tip should be placed beyond the ductus venosus in the central venous system (inferior vena cava)

**\* Note:** In emergency situations, the catheter can be inserted 2-3 cm (until blood is returned) and emergency meds can be given. The catheter should not be left in this placement and should be removed after giving emergency medications.

**Nursing care:**

The catheter and insertion site should be inspected daily for any indications of a developing complication. Signs and symptoms at the insertion site include warmth, redness, swelling, pain or tenderness, circulatory compromise, discharge, etc....  
If any of these are present, notify the appropriate doctor and record in the nursing records. The catheter's general condition should also be noted.

**PRECAUTION:**

- Catheter dressing policy should follow the protocol adopted by the institution involved.
- N.B for further information on luer connections, please refer to latest version of BS EN ISO 80369-7**

**Catheter Removal:**

- The catheter insertion site should be cleaned carefully prior to catheter withdrawal.
- The catheter is removed by gentle sustained traction close to the exit site (2-3 cm). Do not over stretch the catheter. After removal, inspect the catheter to confirm its integrity.

**Description of marking system:**

The catheter tube is marked for effective length in numerical number every 1 centimetre and dot every one 5 centimetres. However, the first 4 cm is not marked.  
**Tip ----- 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 ----- hub**

**Product Variants:**

For variants of **AMECATH Umbilical Catheters**, Kindly refer to the catalogue, visit our website on **“www.amecathgroup.com”** , or contact your nearest **AMECATH** representative.

**UMBILICAL CATHETER KIT:**

























**Code Structure: CnLC-xxII-KU:**







- N:** number of Lumens  
**S:** for Single Lumen Catheter      **D:** for Dual Lumen Catheter      **T:** for Triple Lumen Catheter  
**XX:** for Catheter size in Fr.  
**LI:** for Catheter Length in cm.

Reference	Contents
CnLC-xxII-KU	<ul style="list-style-type: none"><li>● Single/Multi Lumen Umbilical Catheter</li><li>● Injection Caps</li><li>● Way Stopcock</li></ul>
For sizes 2 and 3 Fr. only, add T-connector with Stiffener Wire & Caps	

### 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.
  - Used Catheter should be disposed as hospital protocol or 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) ”
- ☐ You can find a copy of this IFU in a PDF format on 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
- ☐ For Summary of Safety and Clinical Performance “SSCP” please visit EUDAMED website on : <https://ec.europa.eu/tools/eudamed/eudamed> (BASIC UDI-DI: 6221139INV-CVC-03CE).

Information with Symbols	
 <b>Manufacturer information</b>	 <b>EC Representative information</b>
 <b>CE Mark</b>	 <b>Medical Device</b>
 <b>Date of Manufacturing</b>	 <b>Keep Dry</b>
 <b>Expiry Date</b>	 <b>Storage temperature</b>
 <b>Reference</b>	 <b>Keep away from sunlight</b>
 <b>Lot number</b>	 <b>Unique device identifier</b>
 <b>Country of manufacture</b>	 <b>Sterilization Method</b>
 <b>Don't Re-sterilize</b>	 <b>Don't Re-use</b>
 <b>Fragile</b>	 <b>Do not use if package is damaged</b>
 <b>Latex Free</b>	 <b>Phthalate Free</b>
 <b>Contains Latex</b>	 <b>Consult instructions for use</b>
 <b>Importer</b>	 <b>Distributor</b>

 <b>Patient identification</b>	 <b>website</b>
 <b>Health care center or doctor</b>	 <b>Date</b>
<b>B.N. Batch Number</b>	 <b>(Package Orientation (Upright</b>
 <b>MRI Safe</b>	



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