AMECATH

10. INSTRUCTIONS FOR USE

AMECATH ARTERIAL CATHETER Kit

Device Description:
AMECATH ARTERIAL CATHETERS is a sterile single use, radiopaque, single lumen catheter 3, 4, 5 Fr. in diameter and 5 - 20 cm in length.
AMECATH ARTERIAL CATHETERS are made from Pebax material. It is a tipped, marked tube shaft connected to one extension line with over molded hub and flat clamp ended with a female luer hub.
AMECATH ARTERIAL CATHETERS to be cannulated preferably through the radial artery for securing arterial blood and for providing continuous blood pressure (BP) monitoring and arterial blood gas sampling. If the radial artery cannot be cannulated, the femoral artery offers a viable alternative.

*Note: Femoral cannulation provides a pulse contour approximating aortic with minimal thrombotic risk. There is little evidence to show increased incidence of catheter-related systemic infection at this site.

Target patient populations: Adults and paediatrics
Intended user: Health Care Professionals

AMECATH ARTERIAL CATHETER and its accessories:
AMECATH ARTERIAL CATHETER is available in different designs and Kit configurations to cover all customer needs.

Device construction:
List of Accessories:
- Nitinol Guide Wire.
- Introducer Needle
- Disposable Cartridge (DOME)
- Cap

Intended Use:
AMECATH ARTERIAL CATHETERS are indicated for use in attaining arterial access for:
- Arterial blood pressure monitoring.
- Blood gas sampling.

Contraindications:
- The brachial cannulation is contraindicated
- The axillary cannulation is contraindicated.

N.B:
To ensure that Arterial Catheter is performing well in order to achieve its intended use, please:
- If any resistance is encountered in advancing the guide wire, stop advancing the wire, reposition the needle, and attempt to cannulate the vessel again.
- If any resistance to repositioning the guide wire in the needle is met or if the guide wire is stuck in the needle, remove the needle and the wire together and start again.
- If advancement of the catheter becomes difficult, a twisting motion can be used to facilitate catheter passage.
- Do not make a stab incision of the sort used in central line placement; such an incision may damage the underlying artery
- Upon catheter Removal Apply pressure at insertion site after catheter removal to prevent bleeding.

Clinical Benefits
The capability to monitor the arterial blood pressure as well blood gas sampling.

Warnings and Precautions
- For single product and patient use only. Do not re-use, reprocess or re-sterilize.
- Re-use may lead to pyrogenicity, Reprocessing or Re-sterilization may damage the catheter and affect its integrity which may when re-used lead to sever deterioration in health and safety of patients.
- Do not use catheter or accessories if any sign of product damage is visible.
- The catheter does not have any metallic 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.

- Do not use catheter for contrast injection otherwise the catheter may rupture and leak.
- The catheters should not be placed in patient for more than 30 days.
- Implantation must be performed by a competent and experienced catheter insertion team. Inexperienced personnel should not be permitted to perform the implantation except under the direct supervision of an experienced physician or surgeon
- Be sure that you are familiar with the possible complications and that you are aware of emergency measures needed if any complications occur.
- The proper size selection for the catheter size and length is the responsibility of the physician considering the patient's anatomy.
- 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

Complications:

- Hemorrhage
- Sepsis / Infection
- Thrombosis
- Embolism
- Arterial Spasm

How Supplied:

- **AMECATH Arterial Catheter** is a sterile, single-use Medical device.
- **AMECATH Arterial Catheter** Kit is packed PETG hard blister covered with Tyvek.
- Each carton box includes 10 **AMECATH Arterial Catheter** kits.

AMECATH ARTERIAL CATHETERS method of application
General Steps:

*The basic preparation and equipment those are required for arterial cannulation is the same regardless of the route or technique chosen.

❖ Anesthesia:

In an emergency situation or when the patient is unresponsive, anesthesia is not required. In a conscious patient, local anesthesia can be provided by using a small amount of lidocaine 1% at the puncture site to prevent obscuring the site.

Equipment's required for Arterial access:

- Patient on a tilting bed, trolley or operating table
- Sterile pack and antiseptic solution
- Local anaesthetic - e.g. 5ml lidocaine 1% solution
- Appropriate catheter for age/purpose
- Syringes and needles
- Suture material in case of fixation by suturing is determined- e.g. 2/0 silk on a straight needle
- Sterile dressing
- Shaving equipment for the area if very hairy (especially the femoral)

Precaution:

Clinicians who insert Arterial catheter should be trained on the technique by an experienced physician. If this is not possible then the access routes associated with the fewest complications are the radial artery.

❖ **Positioning:**

- **For radial artery cannulation**; the patient is placed in the supine position. The arm is placed up on a flat surface in neutral position, with the palm up and the wrist adequately exposed. The wrist is dorsi-flexed to 30-45° and supported in this position with a towel or gauze under its dorsal aspect.

Precaution:

Hyper dorsiflexion must be avoided because it may compress the radial artery, making cannulation more difficult. This position is maintained by an assistant holding the patient's hand or by taping the hand and fingers to the work surface.

- **For femoral artery cannulation**; the patient is also placed in the supine position, with the hip in mild external rotation. The artery is palpated at the midpoint between the anterior superior iliac spine and the pubic tubercle.

Arterial line placement can be performed via multiple methods. The choice of methods is determined by location, operator preference, and available equipment. The most commonly used methods are the following.

- Catheter over needle
- Catheter over wire (including direct Seldinger and modified Seldinger techniques)

WARNING:

- Arterial cut-down for arterial access is not recommended. It should be considered a last resort, to be performed only by physicians with sufficient training and skill to perform the procedure and manage complications.
- For radial artery cannulation, either the catheter-over-needle technique or the catheter-over-wire technique may be used. The catheter-over-wire technique is more common in adults and older children; while the catheter-over-needle technique is more common in infants and neonates as the diameter of the vessel is too small to allow easy advancement of the guide wire.
- As a last resort, a surgical cut-down can be performed for cannulation of the radial artery.
- For femoral artery cannulation, the catheter-over-wire technique is preferred.
  The puncture site for the femoral artery should be below the inguinal ligament to allow control of bleeding and prevention of bleeding into the pelvis.
- The catheter-over-needle technique can also be used for femoral artery cannulation, either alone or in combination with an over-the-wire technique (ie, Seldinger) if a longer indwelling catheter is desired.
- With either the catheter-over-needle approach or the catheter-over-wire approach, meticulous attention must be paid to preparing the cannulation site with chlorhexidine to minimize the risk of infection and to firmly securing the final intra-arterial catheter with sutures.
- As with central venous line placement, real-time ultrasonographic guidance can decrease the number of attempts and amount of time required to place an arterial line.

❖ **Catheter-Over-Wire Technique:**

The over-wire method (Seldinger and modified Seldinger techniques) is the main commonly used method for superficial arteries placement (e.g. the radial artery) and are preferred for the femoral artery. Both Seldinger and modified Seldinger techniques are similar in entering the artery with a needle through which the wire is advanced into the artery. The main difference is that the modified Seldinger technique uses an integrated needle-catheter-wire system.

❖ **Seldinger technique:**

- **Radial artery:**
  Catheterization

1. Position, prepare, and drape the patient as previously described. Inject local anesthetic. Open the arterial line kit, and check the guide wire to make sure that it flows freely through the introducer needle. Palpate the artery with the second and third digits of the non-dominant hand.
2. Attach the finder needle to a syringe. Puncture the skin proximal to your fingers over arterial pulsations, advancing the needle at a 30-45° angle toward the pulsation.
3. Advance the needle with slight negative pressure until free return of blood is visualized in the syringe. If initial return of blood is observed but the flow then ceases, the posterior wall of the vessel may have been punctured. Withdraw the needle slightly to try to restore blood flow to the needle.
4. Once free flow of blood is obtained, remove the syringe, and advance the guide wire into the artery.

4.1. If any resistance is encountered in advancing the guide wire, stop advancing the wire, reposition the needle, and attempt to cannulate the vessel again. If any resistance to repositioning the guide wire in the needle is met or if the guide wire is stuck in the needle, remove the needle and the wire together and start again.

5. Before removing the needle, make a small skin incision with a scalpel at the site of needle entry into the skin. Do not make a stab incision of the sort used in central line placement; such an incision may damage the underlying artery.
6. Remove the needle while holding the guide wire in place, then advance a catheter over the wire into the artery. If advancement of the catheter becomes difficult, a twisting motion can be used to facilitate catheter passage. Once the catheter is in place, remove the guide wire. Appropriate positioning of the catheter is confirmed by return of pulsatile blood from the catheter hub.
7. Secure the catheter in place with sutures, tape or occlusive dressing.
8. DOME / Disposable Cartridge Preparation

   8.1 Assemble the Disposable Cartridge/ Pressure transducer with the arterial line in way that one of transducer's 2 ports is connected to the Saline bag (pressurized to 300 mm HG). The other port is to be connected to the arterial line ending with the arterial catheter.

   8.2 Priming is done by releasing saline into the arterial line, Transducers ports should be opened during priming in order to remove air bubbles from the pressure transducer. Once removal of air bubbles is ensured, transducers' ports should be closed.

   8.3 Priming of arterial line is presumed, in order to remove the air bubbles from the remaining part of the arterial line (this part will be connected to the arterial catheter).

8.4 Ensure that there are no air bubbles in the whole arterial line. Only then, you can connect the arterial catheter to the arterial line tubing extremity.

8.5 Connect the pressure transducer cable to the pressure measuring device.

- **Femoral artery:**
  Catheterization

1. Prepare and anesthetize the skin, locate the vessel, and insert the needle as previously described for the catheter-over-needle technique). Because of the real deep location of the femoral artery, the needle should be inserted at a 45° angle.
2. Once the needle is in the artery, use a guide wire insertion adapter to advance the wire through the lumen of the needle. Ensure that the guide wire passes easily, without resistance.
3. After the guide wire has been advanced to within several centimeters of the end of the needle, remove the needle over the wire, taking care never to let go of the wire.
4. Make a small nick in the skin at the site of guide wire insertion to facilitate passage of the catheter through the skin.
5. Make sure that the wire fits tightly into the end of the catheter; so that the catheter will enter the arterial lumen smoothly (this may be problematic, especially in patients with synthetic femoral grafts and in patients with advanced atherosclerosis). Advance the catheter over the guide wire and into the vessel.
6. Remove the guide wire, leaving the catheter in place. Successful artery cannulation is confirmed by pulsatile blood flow from the catheter when the wire is removed.
7. Suture the catheter in place to ensure immobilization. Apply a sterile dressing, labeled with the date of placement, over the catheter.
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Catheter Removal

1. In an antiseptic environment, remove sutures, tape or occlusive dressing, only after stopping the arterial line infusion.
2. Remove the Catheter Slowly.
3. Do not exert excessive effort while removing the catheter, if resistance is found, stop and follow hospital instructions.
4. Caution should be taken as exposure of the arterial site to the atmospheric pressure may lead to air entry into blood circulation.
5. Apply pressure at insertion site after catheter removal to prevent bleeding.
6. Cover site with sterile occlusive dressing.

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

Product Variants:

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

Code Structure: AL-XXLL-K00

AL: Arterial catheter.
XX : Size in Fr.
LL : Catheter length.
K00: **KS** For Seldinger technique kit,
KSD For Seldinger technique kit with Disposable Cartridge (Dome)

Reference	Contents
AL-XXLL-KS	• Arterial Catheter • Introducer Needle • Straight End Nitinol Guide Wire Guide Wire • Cap
AL-XXLL-KSD	• Arterial Catheter • Introducer Needle • Straight End Nitinol Guide Wire Guide Wire • Disposable Cartridge • Cap

Storage and Product Safe Disposal

- Store between 5°C to 30°C.
- Do not expose to organic solvents, ionizing radiation or ultraviolet light.
- Rotate inventory so that catheters are used prior to expiration date on the package label.
- Used product should be disposed in sanitary container to prevent possible contamination and cross infection.

❖ *In case of any questions or quiries, 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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