CENTRAL VENOUS CATHETER KIT

Device Description:

AMECATH **Central Venous Catheters** are Radiopaque and made from polyurethane. The catheter tip is tapered with softer material.

AMECATH **Central Venous Catheters** are single or multilumen catheters for adult and pediatric use.

AMECATH **Central Venous Catheters** are placed centrally or peripherally. The adult catheters range includes catheters that resist high injection pressure.
*Pressure capable catheters feature a pressure resistant lumen (marked PRESSURE)

AMECATH **Central Venous Catheters** recommended to be cannulated centrally through: the right internal and external jugular veins, the left internal and external jugular veins, the subclavian veins; the femoral veins or peripherally.
For Adult Central Venous Catheters: Catheters size ranges between 5 Fr to 9 Fr and length ranges between 15 Cm to 60 Cm.
For Adult Pressure Resistant Central Venous Catheters: Catheters size ranges between 6 Fr to 9 Fr and length ranges between 15 Cm to 20 Cm
For Pediatric Central venous catheters: Catheters size ranges between 2 Fr to 6 Fr and length ranges between 5 Cm to 30 Cm

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

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

Device construction:

Catheter Types:

- Adult Central Venous Catheters
- Pediatric Central Venous Catheters

List of Accessories:

- Introducer Needle
- Syringe
- Guide Wire
- Vessel Dilator
- Scalpel
- Introducer over needle
- Guiding syringe
- Guiding Y connector
- Neutral Valves
- EKG cable (E)
- Fixation wings
- Over the Needle Peel Away Introducer
- Over the Needle Catheter
- Injection Caps
- Caps
- Transparent Catheter Fixation Adhesive
- Peel away over Dilator
- Measuring Tape
- T-connector with Stiffener Wire

Intended Use:

The Central Venous Catheter is a sterile, single use device indicated to permit short term (⩽30 days) central venous access for the treatment of diseases or conditions requiring central venous access.

Indications:

- Lack of usable peripheral IV catheter.
- Central venous pressure monitoring.
- Total parental nutrition (TPN).
- Multiple infusions of fluids, medication, or chemotherapy.
- Frequent blood sampling or receiving blood transfusion/blood products.
- Infusion that are hypertonic, hyperosmolar or infusion that have divergent PH values.
- Powerful injection of contrast media - pressure types ONLY (catheter reference start by the letter PR) where pressure may not exceed 300 psi.

N.B:

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

- Ensure that while flushing before use, there is no leakage from any place on the catheter. Further flushing could result in catheter rupture with possible leakage or immobilization.
- Connection of catheter via it's end to the extension line or the stopcock. And Extension line or stopcock to be connected to the the infusion set should be ensured.
- To avoid Catheter failure and/or tip dislodgement the maximum flow rate of 10 ml/sec or the maximum pressure of power injectors of 300 p.s.i. should not be exceeded.

Clinical Benefits:

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

- Drugs
- Nutrients
- Fluids
- Chemotherapy
- Contrast Media (only with pressure type) Injection for various medical Purposes
- It is also used for Central Venous Pressure monitoring as well as Blood sampling and in Blood Transfusion for various medical purposes.

Contraindications:

The central venous catheters are contraindicated in case of:

- In patients with bleeding disorders
- When the presence of another device related infection, bacteraemia or septicemia is known or suspected
- If severe chronic obstructive lung disease exists
- If previous episodes of venous thrombosis or vascular surgical procedure at the prospective insertion site have occurred
- Local tissue factors which may prevent proper devices stabilization and/or access, like allergic reaction, or any dermatological disease

Warnings and Precautions:

- For single product and patient 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 sever deterioration in health and safety of patients.

- Product expiration date is identified on product label.
- Do not use non pressure resistant catheter for contrast media injection otherwise the catheter may rupture and leak. For this special purpose, use a pressure resistant type catheter.
- 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 catheter. 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 emergency measures are known and available if any occur.
- Patient requiring ventilation support is at great risk of pneumothorax during subclavian vein cannulation.
- Over advancement of guide wire can result in serious injuries or arrhythmias.
- Use the marking over the guide wire or over the dispenser to determine the advanced length.
- Do not advance the guide wire or catheter if unusual elastic resistance is encountered. Do not insert or withdraw the guide wire forcibly from any component. The wire could break or unravel, in which case both the catheter and guide wire must be removed simultaneously.
- Over advancement of the catheter can result in serious injury or arrhythmias.
- Use the marking on the catheter to determine the advanced length.
- Use 10 ml or greater syringe to flush the catheter to reduce risk of exceeding the pressure capacity of the catheter. If resistance is felt during flushing, no further attempt should be made. Further flushing could result in catheter rupture with possible leakage or immobilization.
- The pressure CVC is the only catheters to be used for powerful injection. Do not attempt to use the non-pressure multi-lumen catheter in this procedure as it may result in catheter rupture and high risk to the patient. The correct lumen is marked “PRESSURE” i.e.: Use of lumens not marked “Pressure” for power injection of contrast media may cause failure of the catheter.
- Failure to ensure patency of the catheter prior to power injection studies may result in catheter failure.
- Failure to warm contrast media to body temperature prior to power injection may result in catheter failure.
- Power injector machine pressure limiting feature may not prevent over-pressurization of an occluded catheter which may lead to catheter failure.
- Exceeding the maximum flow rate of 10 ml/sec or the maximum pressure of power injectors of 300 p.s.i. may result in catheter failure and/or tip dislodgement.
- In the rare event that a hub or connector separates from any component during the insertion or use, take all necessary steps and Precautions to prevent blood loss or air embolism and remove the catheter immediately.
- The catheters should not be placed in patient for more than 4 weeks.
- Only physician familiar with the technique should perform the catheter removal.
- Always review hospital protocols, possible complications and their treatments, precautions and warning.
- Do not use sharp instruments near the extension line or tubing. Do not use scissors to remove dressing, as this could possibly cut or damage catheter. Do not suture through any part of the catheter. Catheter tubing can tear when subjected to excessive force or rough edges.
- Use only smooth jawed forceps for clamping. Clamping the catheter repeatedly in the same spot could weaken the tubing. Change the position of the clamp regularly to prolong the life of the catheter. Avoid clamping near the adapter and hub of the catheter. Do not clamp the

lumen portion of the catheter. Clamp only the extensions. Examine tubing for damage at the end of each treatment.

- Tape injection caps (or other types used) between treatments to safeguard them against accidental removal.
- It is recommended that only luer lock (threaded) connections be used with the catheter (including syringes, IV tubing, and injection caps). Repeated over tightening of syringes, and caps will reduce connector life and could lead to potential connector failure. Inspect the catheter frequently for nicks, scrapes, cuts, etc. which could impair its performance.
- The position of the tip of any central catheter should be verified
- Always be sure that the catheter tip is in the superior vena cava and has not entered into the right atrium to avoid possible arrhythmias or mural injury.
- Ultrasound should be used in the placement of catheters.
- 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.
- Over tightening of catheter luers may lead to its failure.
- If any resistance is felt, then the needle should be pulled out with the wire still inside and the procedure repeated. This reduces the risk of entangling of the guide wire or its end being cut off by the needle tip.
- The valve of the guiding syringe should be opened by the guide wire advancer tip. Do not attempt passing the guide wire.
- 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 considering the patient's anatomy.

Complications:

Early Potential Complications:

- Arterial puncture
- Bleeding
- Cardiac arrhythmias
- Injury to the thoracic duct
- Injury to surrounding nerves
- Air embolism
- Catheter embolus
- Pneumothorax

Late Potential Complications:

- Venous thrombosis
- Cardiac perforation and tamponade
- Infection
- Hydrothorax

How Supplied:

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

AMECATH **Central Venous Catheter** method of application

Before cannulation, you should consider the following

Patient Evaluation Prior to Access Placement:

Consideration	Relevance
History of previous CVC	Previous placement of a CVC is associated with central venous stenosis.
History of pacemaker use	There is a correlation between pacemaker use and central venous stenosis.

History of diabetes mellitus	Diabetes mellitus is associated with damage to vasculature necessary for internal accesses.
History of anticoagulant therapy or any coagulation disorder	Abnormal coagulation may cause clotting or problems with haemostasis of access site..
History of vascular access	Previously failed vascular accesses will limit available sites for access; the cause of a previous failure may influence planned access if the cause is still present.
History of heart valve disease or prosthesis	Rate of infection associated with specific access types should be considered.
History of previous arm, neck, or chest surgery/trauma	Vascular damage associated with previous surgery or trauma may limit viable access sites.

General preparation to obtain central access

The basic preparation and equipment that is required for venous cannulation is the same regardless of the route or technique chosen. Clinicians who insert central venous catheter should be taught the technique by an experienced colleague.

Equipments required for venous access

- Sterile pack and antiseptic solution
- Local anesthetic; e.g. 5ml lignocaine 1% solution
- Appropriate CV catheter
- Syringes and needles
- Saline or heparinized saline to prime and flush the line after insertion
- Suture 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 massive hairs (especially the femoral)
- Facility for Chest X-ray

General technique for all routes
General Steps:

Catheterize the patient in the usual manner.
Central Venous Catheters to be connected via its end to the extension line or the stopcock.
Extension line or stopcock to be connected to the infusion set.

1. Confirm that central venous access is needed and select the most appropriate route. Explain the procedure to the patient.

2. Shave the needle insertion area if very hairy.

3. Using a strict aseptic technique, prepare and check all the equipment for use. Read instructions with the catheter.

4. Sterilize the skin and drape the area.

5. Infiltrate the skin and deeper tissues with local anaesthetic. In cases where difficulty is anticipated use the small local anaesthetic needle to locate the vein before using the larger needle. This reduces the risk of trauma to other structures.

6. Position the patient as for the specific route described - avoid long periods of head down, particularly in patients with difficulty in breathing.

7. Identify the anatomical landmarks for the chosen route and insert the needle at the recommended point. After the needle has penetrated the skin, aspirate gently whilst advancing the needle as directed until the vein is entered.

   7.1 If the vein is not found, slowly withdraw the needle whilst gently aspirating; often the vein has been collapsed and transfixed by the entry of the needle.

   7.2 In case of using an over needle catheter, pull out the needle and leave the catheter in place inside the vein.

8. Advance a guidewire (Seldinger technique), into the needle (or catheter if used) to the vein, flexible J-shape end first, then remove the needle (or the catheter) leaving the guide wire in the vein. Please monitor the marks on the guide wire to know the length of its advanced part.

   8.1 If any resistance is felt then the needle should be pulled out with the wire still inside, and the procedure repeated. This reduces the risk of entangling of the guide wire or its end being cut off by the needle tip.

9. Advance the guide wire equivalent length to the desired position of the catheter tip

   9.1 An EKG lead attached to the end of the guide wire can confirm its tip location at the right atrium through monitoring of an elevation of the P wave.

   *In case of using the guide wire syringe: while maintaining a firm grip on the syringe, push the guide wire advancer tip into the syringe until it passes through the valve. Once the advancer tip opens the valve, advance the guide wire all through the syringe (to the inside of the attached introducer needle.

   *In case of using the guide wire Y connector, the connector is to be connected between the needle and the syringe. Push the guide wire advancer tip into the connector valve arm until it passes through the valve. Once the advancer tip opens the valve, advance the guide wire to the inside of the attached introducer needle.

   9.2 The valve of the guide wire syringe or guide wire Y connector should be opened by the guide wire advancer tip. Do not attempt passing the guide wire before opening the valve by the advancer tip otherwise the wire may be kinked or destroyed.

10. It is necessary to dilate up the hole in the skin. Use the scalpel, with the blade facing away from the guide wire, and make a small incision in the skin and fascia where the guide wire enters the patient. Thread the dilator over the wire into the vein with a twisting motion. Excessive force should not be needed. Remove the dilator taking care not to dislodge the guide wire.

11. Thread the CV catheter over the guide wire until the end of the wire protrudes from the end of the catheter and whilst holding the wire still advance the catheter into the vein. Attention should be taken not to allow the wire to be pushed further into the vein whilst advancing the catheter. Advance the catheter to the length determined anatomically or to the length determined through the use of EKG lead if used. Remove the guide wire

once the catheter is fully advanced. The catheter position should be confirmed with chest X-ray.

12. Check that blood can be aspirated freely from all lumens of the catheter and flush with saline.

13. Secure the catheter in place with the suture and cover with a sterile dressing. Tape any redundant tubing carefully avoiding any kinking or loops which may snag and pull out the catheter.

14. Connect catheter to a bag of intravenous fluid or flush both lumen with appropriate anti thrombotic.

Checks before using the catheter

- Ensure fluid runs in freely and that blood flows freely back.
- If available, take a chest X-ray (ideally erect) to check the position of the catheter tip and to exclude a pneumo, hydro or haemothorax. An early radiograph may not show up abnormalities and it may be best to wait 3-4 hours unless symptoms develop.
- Ensure that the patient will be nursed and their catheter can be supervised. Give appropriate written instructions regarding how, and what it is to be used for, and who to contact if there is a problem.

Checks before using the Pressure CVC Catheter (catheter reference start by the letter PR) for contrast media injection:

- Attach a 10 ml or larger syringe filled with sterile normal saline.
- Aspirate for adequate blood return and vigorously flush the catheter with the full 10 ml of sterile normal saline.
- Detach the syringe.
- Attach the power injection device to the catheter pressure tube identified by color and marked “pressure”
- Contrast media should be warmed to body temperature prior to power injection.
- Use only lumens marked “Pressure” for power injection of contrast media.
- Complete power injection study taking care not to exceed the flow rates. Do not exceed the maximum flow rate of 10 ml/sec.
- Disconnect the power injection device.
- Flush the catheter with 10 ml of sterile normal saline, using a 10 ml or larger syringe. In addition, lock each lumen of the catheter with heparinized saline. Usually 1 ml per lumen is adequate.

Practical problems common to most techniques of insertion

Arterial puncture	Usually obvious, but it may be missed in a patient who is hypoxic or hypotensive. Arterial pulsation might be seen in the inner lumen of the guiding syringe. If unsure, connect a length of manometer tubing to the needle / catheter and look for blood flow which goes higher than 30cm vertically or is strongly pulsatile. Withdraw the needle and apply firm direct pressure to the site for at least 10 minutes or longer if there is continuing bleeding. If there is minimal swelling then retry or change to a different route.
Suspected pneumothorax	If air is easily aspirated into the syringe (note that this may also occur if the needle is not firmly attached to the syringe) or the patient starts to become breathless, abandon the procedure at that site. Obtain a chest radiograph and insert an intercostal drain if pneumothorax is confirmed. If central access is absolutely necessary, then try another route ON THE SAME SIDE or either femoral vein. DO NOT attempt either the subclavian or jugular on the other side in order to avoid bilateral pneumothoraxes

Arrhythmias during the procedure	Usually from the catheter or the wire being inserted too far (into the right atrium or ventricle. It is advisable to select the proper length for each patient. Slight withdrawal of the wire or catheter usually stops arrhythmias.
Air embolus	This can occur, especially in the hypo-volaemic patient who is breathing spontaneously, if the needle is left in the vein whilst open to the air. It is easily prevented by ensuring that the patient is positioned in the Trendelenburg position (for jugular and subclavian routes) and that the guidewire is passed down the needle promptly.
The wire will not thread down the needle	Check that the needle is still in the vein. Flush it with saline. Try angling the needle so the end of it lies more along the plane of the vessel. Rotate the needle in case the end lies against a vessel wall. Reattach the syringe and aspirate to check that you are still in the vein. If the wire has gone through the needle but will not pass down the vein it should be very gently pulled back. **If any resistance is felt, then the needle should be pulled out with the wire still inside and the procedure repeated. This reduces the risk of the tip of the wire being cut off by the needle tip..**
Persistent bleeding at the entry side	Apply firm direct pressure with a sterile dressing. Bleeding should usually stop unless there is a coagulation abnormality. Persistent severe bleeding may require surgical exploration if there is an arterial or venous tear.

Causes of Early Catheter Dysfunction

- Mechanical compression (pinch off syndrome in subclavian catheter)
- Malposition of catheter tip
- Kinks
- Side holes' occlusion due to clotting or fibrin sheath formation or stuck to vein wall.
- Drug precipitation (some antibody locks or IV IgG)
- Loss of catheter integrity by infection

Methods that should be used to treat a dysfunctional or nonfunctional catheter include:

- Repositioning of a malpositioned catheter.
- Use of thrombolytic, as per hospital protocol.
- All catheter-related infections, except for catheter exit-site infections, should be addressed by initiating parenteral treatment with an antibiotic(s) appropriate for the organism(s) suspected.
- Definitive antibiotic therapy should be based on the organism(s) isolated.
- Catheters should be exchanged as soon as possible and within 72 hours of initiating antibiotic therapy in most instances, and such exchange does not require a negative blood culture result before the exchange. Follow-up cultures are needed 1 week after cessation of antibiotic therapy.

Care of the Central Venous Catheter

- Use an aseptic technique when inserting the catheter and any subsequent injections or changing fluid lines.
- Keep the entry site covered with a dry sterile dressing.
- Ensure the line is well secured to prevent movement (this can increase risks of infection and clot formation).
- Change the catheter if there are signs of infection at the site.
- Remember to remove the catheter as soon as it is no longer needed. The longer the catheter is left in, the greater the risks of sepsis and thrombosis.
  Some people suggest changing a catheter every 7 days to reduce the risks of catheter related sepsis and thrombosis. However, providing that the catheter is kept clean (sterile injections and connections) and there are no signs of systemic sepsis, routine replacement

may not be necessary. Repeated cannulation to change lines on a routine basis, rather than based on clinical need, can increase the risks to the patient.

Catheter removal:

Warnings:

- Only physician familiar with the technique should attempt the removal.
- Always review hospital protocols, possible complications and their treatments, precautions and warning.
  Remove any dressing and suture material. Ask the patient to take a breath and fully exhale. Remove the catheter with a steady pull while the patient is in breath holding and apply firm pressure to the puncture site for at least 5 minutes to stop the bleeding. Excessive force should not be needed to remove the catheter. If it does not come out, try rotating it whilst pulling gently. If this still fails, cover it with a sterile dressing and ask an experienced person for advice.

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

Description of marking system:

- The catheter tube is marked for effective length in numerical number every 5 centimeters and dot every one centimeter however the first 5 cm is not marked.
Tip • • • • • 5 • • • • 10 • • • • 15 • • • • 20 • • • • hub

Product Variants:

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

1. Adult Central Venous Catheter Kits

Code Structure: CnLC-xxll-K0000

N: number of Lumens
S: for Single Lumen Catheter **D:** for Dual Lumen Catheter **T:** for Triple Lumen Catheter
Q: for Quadra Lumen Catheter **P:** for Penta Lumen catheter

Xx: for Catheter size in Fr.

Ll: for Catheter Length in cm.

0000: Variable Kit Configurations with Different Contents as per below table.

Reference	Contents
CnLC-xxll -KN	• Single/Multi Lumen Adult Central Venous Catheter • Introducer Needle xx G yy CM • 5 cc Syringe • Nitinol Guide Wire XX" YY cm with Dispenser • Scalpel XX • Vessel Dilator XX • Fixation Wing • Caps
• Pressure resistant catheters are available. Please add PR before the code (PRCnLC-xxll-KN) • Guide wire with advancer is available. Please add A after the code (CnLC-xxll-KN-A / PRCnLC-xxll-KN-A)	

CnLC- xxll-KGSN	• Single/Multi Lumen Adult Central Venous Catheter • Introducer Needle xx G yyCM • 5 cc Guiding Syringe • Nitinol Guide Wire XX" YY cm With Dispenser • Scalpel XX • Vessel Dilator XX • Fixation Wing • Caps
• Pressure resistant catheters are available. Please add PR before the code (PRCnLC-xxll-KGSN) • Guide wire with advancer is available. Please add A after the code (CnLC-xxll-KGSN-A/PRCnLC-xxll-KGSN-A)	
CnLC- xxll -KGYN	• Single/Multi Lumen Adult Central Venous Catheter • Introducer Needle xx G yyCM • 5 cc Syringe • Nitinol Guide Wire XX" YY cm With Dispenser • Scalpel XX • Vessel Dilator XX • Fixation Wing • Guiding Y Connector • Caps
• Pressure resistant catheters are available. Please add PR before the code (PRCnLC-xxll-KGYN) • Guide wire with advancer is available. Please add A after the code (CnLC-xxll-KGYN-A/PRCnLC-xxll-KGYN-A)	
CnLC- xxll-KGSNO	• Single/Multi Lumen Adult Central Venous Catheter • Over the Needle Catheter • Introducer Needle xx G yyCM • 5 cc Guiding Syringe • Nitinol Guide Wire XX" YY cm With Dispenser • Scalpel XX • Vessel Dilator XX • Fixation Wing • Injection Cap • Transparent Catheter Fixation Adhesive
• Pressure resistant catheters are not available for KGSNO kit • Catheter available in single, dual and triple lumen only. • Guide wire with advancer is available. Please add A after the code (CnLC-xxll-KGSNO-A)	

2. Pediatric Central Venous Catheter Kits

Code Structure: CnLC-xxll-KP000

N: number of Lumens

S: for Single Lumen Catheter **D:** for Dual Lumen Catheter

T: for Triple Lumen Catheter **Q:** for Quadra Lumen Catheter

Xx: for Catheter size in Fr.

LL:for Catheter Length in cm.

000: Variable Kit Configurations with Different Contents as per below table

CnLC- xxll -KP	• Pediatric Single/Multi Lumen Lumen Central Venous Catheter • Introducer Needle xx G yyCM • 5 cc Syringe • J - End Nitinol Guide Wire XX" YY cm With Dispenser • Scalpel XX • Vessel Dilator XX • Fixation Wing • Injection Caps
• Guide wire with advancer is available. Please add A after the code (CnLC-xxll-KP-A)	
CSLC- xxll -KP*	• Pediatric Single Lumen Central Venous Catheter • Peel Away Over the Needle • Measuring Tape • T-Connector With Stiffener Wire • Injection Caps
• Single lumen catheter only available.	

CnLC- xxll-KP**	• Pediatric Single / Dual Lumen Central Venous Catheter • Introducer Needle xx G yyCM • 5 cc Syringe • J-End Nitinol Guide Wire XX" YY cm With Dispenser • Peel Away Over Dilator • Measuring Tape • T-Connector With Stiffener Wire • Injection Caps
• Catheter available in single and dual lumen only. • Guide wire with advancer is available. Please add A after the code (CnLC-xxll- KP**-A)	
CnLC- xxll -KPO	• Pediatric Single/Multi Lumen Central Venous Catheter • Over the Needle Catheter • 5 cc Syringe • J-End Nitinol Guide Wire XX" YY cm With Dispenser • Scalpel XX • Vessel Dilator XX • Fixation Wing • Injection Caps
• Guide wire with advancer is available. Please add A after the code (CnLC-xxll- KPO-A)	
CnLC- xxll -KPGY	• Pediatric Single/Multi Lumen Central Venous Catheter • Introducer Needle xx G yyCM • 5 cc Syringe • J-End Nitinol Guide Wire XX" YY cm With Dispenser • Scalpel XX • Vessel Dilator XX • Fixation Wing • Guiding Y Connector • Injection Caps
• Guide wire with advancer is available. Please add A after the code (CnLC-xxll- KPGY-A)	
CnLC- xxll -KP-V	• Pediatric Single/Multi Lumen Central Venous Catheter • Introducer Needle xx G yyCM • 5 cc Syringe • J - End Nitinol Guide Wire XX" YY cm With Dispenser • Scalpel XX • Vessel Dilator XX • Fixation Wing • Neutral Valves
• Catheter available in single, dual and triple lumen only. • Guide wire with advancer is available. Please add A after the code (CnLC-xxll- KPV-A)	

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** "

❒ You can find a copy of this IFU in a PDF format on AMECATH website on : " **www.amecathgroup.com** "

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

❒ **Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established**

❒ 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	
Manufacturer information	EC REP EC Representative information
CE Mark 2797	MD Medical Device
Date of Manufacturing	Keep Dry
Expiry Date	Storage temperature
REF Reference	Keep away from sunlight
LOT Lot number	UDI Unique device identifier
Country of manufacture	Sterilization Method
Don't Re-sterilize	Don't Re-use
Fragile	Do not use if package is damaged
Latex Free	PHT Phthalate Free
Contains Latex	Consult instructions for use
Importer	Distributor
Patient identification	website
Health care center or doctor	Date
B.N. Batch Number	Package Orientation (Upright)
MR MRI Safe	

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