Central Venous Catheter (CVC) Kit

Instructions for Use

CE 2797

1 Product Name

Central Venous Catheter (CVC) Kit

2 Product Description

Central Venous Catheter (CVC) Kit contains central venous catheter, guide wire, I model/Y model introducer needle, blue introducer syringe, dilator, injection site cap, extension line clamp, fastener, scalpel, hypodermic syringe, and hypodermic needle. The central venous catheter (CVC) is a long, soft, thin, hollow tube placed into a large vein in the neck (internal jugular vein), chest (subclavian vein) or groin (femoral vein). CVC is intended to provide short-term (≤30 days) central venous channel for treatment of patients who requiring central venous channel.

For REF, see also Annex 1.

3 Intended Purpose

Central Venous Catheter (CVC) Kit is used to insert into the central venous system for the infusions of fluids or medications, blood sampling or pressure measurement.

4 Indications

There is no specific disease or medical condition. It is only intended for the diseases or conditions requiring central venous access or lacking usable peripheral IV sites, including but not limited to the following:

- Central venous pressure measurement;
- Blood sampling;
- Total parenteral nutrition (TPN);
- Multiple infusions of fluids, medications or chemotherapy.

5 Clinical benefits

CVC has the ability to gain access to the central circulation system through a single puncture site for applications that include infusion of fluids or medications, blood sampling or pressure measurement.

- CVC could be used for short-term infusions, compared to transient devices.
- Multi-lumen catheters could establish multiple channels compared to single-lumen catheters.

6 Contra-indications

There is no absolute contraindication, but it should be used with caution in patients with known hemorrhagic diseases.

7 Complications

Including but not limited to the following:

- Cardiac tamponade secondary to vascular, atrial or ventricular perforation;
- Pleural (i.e., pneumothorax, hemothorax) and mediastinal injuries;
- Air embolism;
- Catheter embolism;
- Catheter occlusion;
- Thoracic duct lacerations;
- Bacteraemia;
- Septicemia;
- Thrombosis;
- Inadvertent arterial puncture;
- Nerve injury;
- Hematoma;
- Hemorrhage;
- Fibrin sheath formation;
- Exit site infection;
- Vessel erosion;
- Catheter tip malposition;
- Dysrhythmias;
- Extravasation

8 Patient target groups

The device is intended for patients fitting the intended uses. It can be used for the patients over 1yr old (i.e. excluding Neonates and Infants).

9 Intended users

This product can be used by professional doctors, who has been properly trained for this operation.

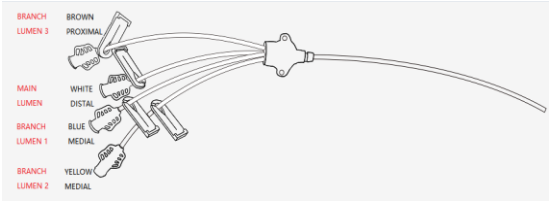
10 Instructions for use

a) Read the instructions for use carefully before use and select the appropriate specification according to the *list of model specifications in Annex 1* and the *list of flow rates of CVC in Annex 2*.

b) Prepare skin for the puncture site and pave sterile sheet;

c) Before surgery, inject normal saline or heparin saline into the lumen to check whether the CVC is abnormal. Then, clamp the extension tube or put a Injection site cap on the extension tube hub, and the extension tube connecting the distal lumen should be kept open to pass through the guide wire.

⚠ **Refer to the following figure for the identification of hub and lumen:**

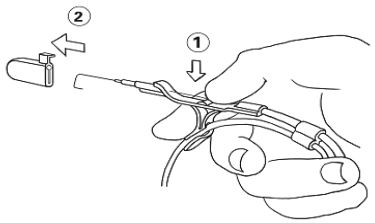


d) Insert the introducer needle into the vein and draw back to confirm that there is good venous blood reflux, but the color of the reflux blood is not always the only dependable

sign to check whether the introducer needle enters into the vein;

e) Advance the guide wire into vein through introducer needle with the aid of control handle until the required depth is met, and the "J" shaped head may need a light twirl to enter. **Do not have any angle between the guide wire and the introducer needle to deliver or withdraw the guide wire;**

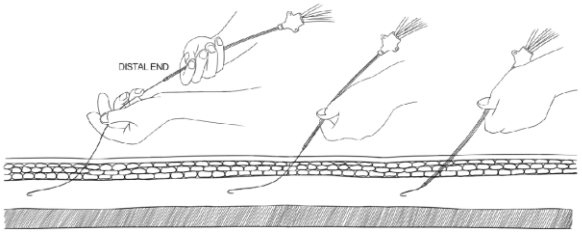
⚠**Before using the control handle, gently press the guide wire at the exposed part of the handle (as shown in figure ① below), and then pull out the protective cap (as shown in figure ② below) to prevent the guide wire from slipping out of the handle; The control handle should be handled with care, do not remove by force.**



f) Hold the guide wire tightly and take out the introducer needle, and hold the guide wire tightly at any time;

g) Insert the dilator into the blood vessel along the guide wire, and turn the dilator, and gently dilate the channel in order to insert the catheter. For withdrawal of the dilator (while inserting and removing the dilator, keep the guide wire fixed), do not leave the dilator in its original position as the indwelling catheter, so as to avoid blood vessel wall perforation;

h) Hold the distal end of the catheter pass through the guide wire, when it is close to the skin, hold tightly the distal end of the catheter and then turn gently it into vein;



i) Advance the catheter into the indwelling position using the length mark on the catheter as a positioning reference, then record the catheter length and check the catheter position regularly;

⚠**Marking system of the catheter: Indicate distance from the distal end. From the first mark, the distance between marks is 1cm.**

j) Pull out the guide wire after the catheter reaches a predetermined depth. When resistance encounters, take it slowly, and if necessary, turn the guide wire at a certain angle to move it away from a certain distance; if it still cannot be taken out, the catheter and the guide wire should be taken out together. Do not take them out forcibly since the guide wire may be broken in the human body. Check whether the guide wire is intact after it is taken out;

k) Connect a syringe to the extension tube hub, and check the catheter position, observe whether the blood flow is unobstructed when taking out, then connect a qualified connecting tube to the extension tube hub as required. Block off the unused catheter lumen with a injection site cap. Stop the blood flow with a Extension line clamp when replacing the connecting tube and Injection site cap;

l) Check the catheter distal tip position with X-ray. Fix the catheter to the patient with sutures through fasteners. Do not suture directly outside the catheter to prevent the catheter from being punctured. Cover the puncture site with medical gauze, and record the length of catheter insertion, and check frequently whether the catheter is moved;

m) Nursing during the catheter indwelling:

1) If the three-way valve or injection site cap used at the connector is found loosening or falling off, remove it immediately, and replace it with a new three-way valve or Injection site cap. All operations at the connector such as infusion, drug administration, blood drawing and connection of infusion pump should strictly comply with aseptic operations to prevent the iatrogenic infection. For patients receiving intravenous high nutrient solution, strengthen the inspection during the period of infusion; after the infusion, flush the lumen with normal saline or replace the infusion tube with a new one before infusing other fluids;

2) When monitoring CVP for a long period of time, the catheter should be flushed with 5 ml (30 u) of dilute heparin solution prepared with saline every 24 h to keep the pressure measurement system unobstructed and reduce the incidence of infection and prevent the formation of fibrin sheath around the catheter distal end;

⚠**The residual catheter track remains the air entry point. When the catheter is successfully placed, the medical dressing used to close the wound should be kept in place until the wound is epithelialized. After the wound is epithelialized, the medical dressing used during catheter indwelling is recommended to be replaced every 24 hours to keep the wound dry and clean.**

⚠**When removing the Injection site cap, holding the flanking part of the catheter hub can effectively reduce the disassembly resistance.**

n) Pay attention to the patient's condition when removing the catheter. If there is a serious infection, use other methods to remove the catheter, such as surgery. Do not forcibly pull out the catheter when removing the catheter in a regular way to prevent the catheter from breaking in the human body.

⚠**Ask patient to take a breath and hold it if removing internal jugular or subclavian catheter.**

11 Performance Characteristics

Central Venous Catheter is accessory devices used during interventional procedures. Clinical performance is determined by whether the catheter successfully placed into the central venous circulatory system.

For the performance characteristics of catheter:

- The catheter is made TPU material with good physical properties, smooth surface, peak tensile force, easy for puncture and placement.

- The catheter is visible under X-ray, accurate positioning.

12 Precautions

a) Avoid repeating insertion, or it might cause hematoma and infection;

b) This product is supplied sterile and sterilized by ethylene oxide. The shelf life of this product is 3 years. Please use it within the shelf life;

c) Please check whether the package is intact before use. Do not use if it is damaged;

d) This product is for single use. Do not reuse, reprocess or resterilize. Reuse of the device poses a potential risk of serious injury and/or infection. Dispose of the product waste as medical waste according to local regulations or hospital management regulations after use.

e) The product can only be used by professional doctors, who has been properly trained for this operation.

f) The product is allowed to be indwelled in human body for 30 days at most, and 14 days the best;

g) The device used together with this product should have a standard luer lock.

h) Adverse side effects: improper care of the puncture site may lead to infection; prolonged indwelling time may lead to phlebitis or thrombophlebitis.

i) Do not press harshly to avoid the device damage;

j) Fragile, handle with care;

k) Store in a ventilated and dry place to avoid moisture as much as possible, and keep away from sunlight to avoid fire or heat deformation of the device;

l) Intended condition of use: this product is use for operating room or catheter room environment. (Temperature range: 21 to 25℃, relative humidity range : 30% to 60% RH, Atmospheric pressure range: 70 to 104 kPa). Please do not use it in the environment beyond the above conditions;

m) Please note that fluid leakage during catheter indwelling may result in blood loss or delay in treatment. Please pay attention to check whether the catheter leakage during indwelling. Replace the catheter immediately once leakage is found.

n) Do not place catheter into or allow it to remain in the right atrium or right ventricle. X-ray exam or other method in compliance with institutional policies and procedures must show catheter tip located in lower 1/3 of the Superior Vena Cava (SVC), in accordance with institutional guidelines.

o) Do not use too much force when clamping. Also avoid repeated clamping in the same location which may weaken the catheter.

p) This product is not for high pressure injection for such application can result in inter-lumen crossover or rupture with potential for injury.

13 Warnings

When selecting nitroglycerin, vitamin K1, paclitaxel, shenmai, fluorouracil and fat emulsion for drug compatibility studies, this product has been proven with good compatibility and no adsorption of drugs, which can ensure the drug efficacy.

The cobalt is above 0.10% w/w in 304 stainless steel of the Guide wire, Blue introducer syringe and Hypodermic needle.

Explanation of graphics, symbols and abbreviations of medical devices used in this product:

CE	CE mark		Manufacturer
EC REP	Authorized representative in the European Community/European Union	REF	Catalogue number
	Use-by date		Keep away from sunlight
	Keep dry		Do not re-use
	Date of manufacture	LOT	Batch code
	Caution		Consult instructions for use or electronic instructions for use
STERILE EO	Sterilized using ethylene oxide		Don't use if package is damaged, and consult instructions for use
MD	Medical device		Do not resterilize
	Fragile, handle with care		Single sterile barrier system
UDI	Unique device identifier		Contains hazardous substances: Cobalt（CAS NO.7440-48-4）

14 Additional Information

The SSCP of this product will be available in the European database on medical devices (Eudamed), where it is linked to the Basic UDI-DI (694242711359FE). The URL to the Eudamed public website is:
https://ec.europa.eu/tools/eudamed

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative and to your national authority. The contacts of national competent authorities (Vigilance Contact Points) and further information can be found on the following European Commission website:
https://ec.europa.eu/growth/sectors/medical-devices/contacts_en

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