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Disposable Central Venous Catheter Kit Instruction for use

(Trademark: Safecath)

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Single and multiple lumen central venous catheter kit Product Description

Disposable Central Venous Catheter Kit contains Catheter, Guidewire, Introducer Needle, Blue introducer Syringe/Y-introducer needle, Dilator, Catheter Clamp, rigid fastener, Heparin Cap, stanch clip, syringe, Scalpel.

The specification of disposable catheter kit is defined by the catheter in the kit, Take MMCVCBJ1-16-20 for example ,it means the single-lumen central venous catheter kit manufactured by Target Medical, the catheter in this kit is single lumen, with diameter of 16G and effective length of 20cm.

The central venous catheter has single lumen, double-lumen, and triple-lumen. Detail information as below:

Single lumen: 14G(2,10mm), 16G(1,70mm), 18G(1,30mm), 20G(1,05mm)

Double lumen: 4F(1.35mm)~7F(2.35mm) Triple lumen: 5.5F(1.85mm)~7F(2.35mm)

Effective length: 50~500mm

Intended use:

The single and multiple-lumen catheters permit venous access to the adult and paediatric central circulation for the administration of medicines, blood sampling and pressure monitoring.

Intended user:

The device should be used by competent physicians and nurses who have the training of central venous catheter management. The physician must be aware of complications associated with central vein catheters,

Indications:

Common use of central venous catheter kit is including but not limited to following conditions:

To give IV medications over a long period of time (no more than 15 days) because a large vein can tolerate an IV catheter for a longer time than a small vein.

Examples of such medications are antibiotics and chemotherapy,

To rapidly deliver large amounts of fluid or blood, for example when a person is in shock.

To provide extra IV sites when patients lacking of usable peripheral IV sites.

To directly measure blood pressure in a large or central vein. This can help manage how much fluid a person needs.

To take frequent blood samples (more than once each day) without being "stuck" many times.

To deliver nutrition directly into the blood when food or liquids cannot be given through the mouth, stomach, or intestine.

Contraindications

Infection in the puncture site, a serious bleeding tendency, such as coagulation disorder and the ongoing anti-coagulation treatment.

Persistent shock Impeded or injured puncture channel Abnormity at puncture or dissection site such as an enlarged thyroid gland or other tumors Critical condition of emphysema Distinctive aberrance at puncture site, such as burns, etc.

Potential adverse events

Adverse events associated with the use of the central venous catheter kit include, but are not limited to: Vascular puncture (including vascular tear, puncture, perforation)
Cardiac arrhythmias Bleeding/hematoma Infection Catheter-related sepsis Hemathorax Pneumothorax Myocardial perforation/cardiac tamponade Malposition Biocompatibility
reaction (allergy, poisoning, carcinogenesis, tumorigenesis, gene muta-tion and even fetal malformation) Catheter-related thrombosis Air embolism Catheter occlusion

Leakage/extravasation injury Accidental catheter removal Death Product components damage or rupture.

Combination Using Products

The list of accessories intended to be used in combination with the Disposable Central Venous Catheter Kit is as below:

- · Heparin cap
- · Needless connector
- · Disposable infusion set
- Syringe
- · Disposable blood pressure transducer
- Guide wire

Marnings and precautions:

1. Warning: (a) It is strongly recommended you do not place the catheter into or allow it to remain in the right atrium or right ventricle. Failure to follow these instructions can result in severe patient injury or death, Read instructions, Statement on Cardiac Tamponade below.

2. Warnings: The physician should be aware that certain complications may occur during subclavian insertion such as hemathorax, pneumothorax, and hematoma.

3. Warning: Do not cut the catheter to alter length.

4.Warning: Do not cut guidewire to alter length. Do not withdraw guidewire against needle bevel to avoid possible severing or damaging of guidewire.

5. Warning: Do not leave dilator in place as an indwelling catheter to avoid possible vessel wall perforation.

6. Warnings: Do not clamp the multi-lumen body of the catheter,

7.Precaution: The colour of the blood aspirated is not always a reliable indicator of venous access,

8. Precaution: Catheter clamp and rigid fastener must not be attached to catheter until guidewire is removed.

9. Precaution: To avoid damage to lumen extensions from excessive pressure, each stanch clip must be opened prior to infusing through that lumen.

10.Precaution: For central venous placement, x-ray exam must show catheter tip located in right side of mediastinum in the superior vena cava (SVC) above its junction with tight atrium and parallel to vessel wall and its distal tip positioned at a level above either azygos vein or carina of the trachea, whichever is better visualized. If catheter tip is malpositioned, reposition and reverify. Secure catheter to patient using integral hub suture holes of catheter clamp and rigid fastener.

11.Precaution: Do not suture directly against the catheter tubing to avoid cutting or damaging the catheter or impeding catheter flow.

12, Precaution: Maintain the insertion site with regular meticulous redressing using aseptic technique,

13, Precaution: Alcohol & Acetone can weaken the structure of polyurethane materials, Check the contents of preparation fluids and swabs for Alcohol or Acetone content,

Acetone: Do not use acetone on the catheter surface. Acetone may be applied to the skin, but must be allowed to dry completely prior to applying a dressing.

Alcohol: Do not use alcohol to soak catheter surface or to restore catheter patency. Care should be taken when infusing drugs containing a high alcohol concentration.

A Iways allow alcohol to dry completely prior to applying dressing.

14.Precaution: there is no evidence that shows the ordinary drugs can weaken the structure of polyurethane materials. However, if the catheter is used to infusion new drug, doctors should consider whether this drug can weaken the structure of polyurethane materials.

15.Precaution: The produce should be centrally collected with medical wastes and disposed according to environmental requirement.

16.Precaution: The recommended cleaning agent is heparin or saline.

17.Precaution: The clinical safety and performance of the product in prematures, neonates, pregnant women have not been demonstrated.

18. Precaution: Special attention should be paid when the product is applying to children population.

19. Precaution: Please report to the manufacturer and the competent authority of the member state in which the user and/or patient is established in case of any serious incident that has occurred in relation to the device.

20.The device is not tested for MRI-Safety. Considering the catheter does not have any metal parts, it can be exposed to the environmental conditions of MRI as long as there

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- are no metal parts attached to it.
- 21. The materials of guidewire contain nickel, which may cause allergic reaction.
- 22. The device contains Cobalt (CAS No.7440-48-4), which may pose a risk of carcinogenic and toxic of reproduction. Special attention should be paid when used for pediatric patients,

Safety and efficacy considerations

The product is designed for single use only. If use repeatedly, the product may not keep the original design properties and have the risk of contamination.

Do not use if sterile packaging is damaged or opened. Do not alter the catheter,guidewire, or any other kit/set component during insertion,use,or removal.Cetntral vascular catheterization must be performed by trained personnel, well versed in anatomical landmarks, safe technique and potential complications.

Cardiac tamponade

Cardiac tamponade, a condition resulting from an abnormally excessive amount of fluid in the pericardium, compressing the heart and impairing diastolic filling and functioning of the heart.

Central venous catheter insertion instructions

- 1. Use sterile technique.
- 2. Degrease, sterilize (iodophor) and local anesthesia the puncture site.
- 3. Prepare the catheter for insertion by flushing each lumen per directions approved by your institution. Clamp extension lines or attach heparin caps to the appropriate lumen extensions. Leave the distal lumen extension uncapped for guidewire passage.
- Warning: Do not cut the catheter to alter length.
- 4. The blue introducer syringe is attached to introducer needle that will permit passage of the guidewire, (If a Y-introducer needle is used, a syringe is attached to Y-introducer needle that will permit passage of the guidewire), The introducer needle is inserted into the identified vein, then pump back to ensure a good venous reflux (Tip: the color of the pumped back blood is not always a reliable sign of the vein).
- Precaution: The colour of the blood aspirated is not always a reliable indicator of venous access. Because of the potential for inadvertent arterial placement, verify venous access via a wave form obtained by a calibrated pressure transducer. If hemodynamic monitoring equipment is not available to permit transducing a central venous wave form, disconnect the syringe and check for pulsatile flow. Pulsatile flow is usually an indicator of inadvertent arterial puncture.
- 5.Using the guidewire(Diameter.0.021-0.035inches.Length:60-70cm) dispenser, advance guidewire spring through introducer needle into vein.
- Advance guidewire to required depth. Advancement of "J" tip may require a gentle rotating motion.
- Warning: Do not cut guidewire to alter length, Do not withdraw guidewire against needle bevel to avoid possible severing or damaging of guidewire.

Guidewire dispenser instructions

- 6.Straighten the " J" by retracting the guidewire into the dispenser tip straightener. When the tip is straightened, the guidewire is ready for insertion. Centimeter marks are referenced from " J" end.One band indicated 10cm, two bands 20cm, and three bands 30cm,
- 7. Hold guidewire in place and remove introducer needle.
- Precaution: Maintain firm grip on guidewire at all times. Use centimeter markings on guidewire to adjust indwelling length according to desired depth of indwelling catheter placement.
- 8. Enlarge percutaneous puncture site with cutting edge of scalpel positioned away from guidewire.
- Precaution: Do not cut guidewire. Use tissue dilator to enlarge site as required.
- Warning: Do not leave dilator in place as an indwelling catheter to avoid possible vessel wall perforation.
- 9.Thread tip of catheter over guidewire. (Sufficient guidewire length must remain exposed at hub end of catheter to maintain a firm grip on guidewire). Grasping near

- skin,advance catheter into vein with slight twisting motion.
- Precaution: Catheter clamp and rigid fastener must not be attached to catheter until guidewire is removed.
- 10.Using cm marks on catheter as positioning reference points, advance catheter to final indwelling position. Record, indwelling catheter length on patient's chart and check position routinely,
- 11, Hold catheter at desired depth and remove guidewire,
- Caution:Although the incidence of guidewire failure is extremely low, user should be aware of the potential for breakage if undue force is applied to the wire. The catheter included in this product has been designed to freely pass over the guidewire. If resistance is encountered when attempting to remove the guidewire after catheter placement, the guidewire may be kinked about the tip of the catheter within the vessel. In this circumstance, pulling back on the guidewire may result in undue force being applied resulting in guidewire breakage. If resistance is encountered, withdrawn the cather relative to the guidewire about 2-3cm and attempt to remove the guidewire and catheter simultaneously.
- 12. Verify that the entire guidewire is intact upon removal.
- 13. Check lumen placement by attaching a syinge to each lumen extension and aspirate until free flow of blood is observed. Connect all lumen extensions to appropriate Luer-Lock line(s) as required. Unused port(s) may be "locked" through heparin cap(s) using standard hospital protocol. Slide stanch clips provided on lumen extensions to occlude flow through each lumen during line and heparin cap changes.
- Precaution: To avoid damage to lumen extensions from excessive pressure, each stanch clip must be opened prior to infusing through that lumen.
- 14. Secure and dress catheter temporarily.
- 15. Verify catheter tip position by chest x-ray immediately after placement.
- Precaution: For central venous placement, X-ray exam must show the catheter tip located in the tight side of mediastinum in the superior vena cava (SVC) above its junction with tight atrium and parallel to vessel wall and its distal tip positioned at a level above either azygos vein or carina of the trachea, whichever is better visualized.

 If catheter tip is malpositioned, reposition and reverify. Secure catheter to patient using integral hub suture holes of catheter clamp and rigid fastener.
- Precaution: Do not suture directly against the catheter tubing to avoid cutting or damaging the catheter or impeding catheter flow.

Catheter clamp and Rigid fastener instructions

After guidewire has been removed and the necessary lines have been connected or locked, spread catheter clamp and position on catheter as required to ensure proper tip location,

Snap rigid fastener onto catheter clamp. Secure catheter to patient by suturing the suture wing to the skin, using side wings to prevent catheter migration.

- 16.Dress puncture site per hospital protocol.
- Precaution: Maintain the insertion site with regular meticulous redressing using aseptic technique.
- 17.Record on the patient's chart the indwelling catheter length as to centimeter markings on catheter where it enters the skin. Frequent visual reassessment should be made to ensure that he catheter has not moved.

⚠ Warnings

Do not clamp the multi-lumen body of the catheter. Clamp only the extension lines and use only the stanch clips provided. Never use serrated forceps to clamp the extension lines

The physician should be aware that certain complications may occur during subclavian insertion such as hemathorax, pneumothorax, and hematoma.

! Insertion cautions

- 1.Central venous catheters should be positioned so that the distal tip of the catheter is in the mediastinum in the SVC above the junction of the SVC and the right atrium and lies parallel to the vessel wall.
- Warning: DO NOT place the catheter into or allow it to remain in the right atrium or right ventride. For femoral vein approach the catheter should be advanced into the vessel

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- so that the catheter tip lies parallel to the vessel wall.
- 2. Physicians must be aware of complications associated with central vein catheters including cardiac tamponade secondary in vessel wall, atrial or ventricular perforation, air embolism, catheter embolism, catheter-related sepsis, vascular puncture, haemothorax, pneumothorax, etc.
- 3,Do not apply excessive force in removing guidewires or catheters. If withdrawal cannot be easily accomplished, a chest x-ray should be obtained and further consultation requested.
- 4.The colour of the blood aspired is not always a reliable indicator of venous access, Verify centra venous placement via a wave form obtained by a calibrated pressure
- Note: If hemodynamic monitoring equipment is not available to permit transducing a centra venous waveform, check for pulsatile flow.Pulsatile flow is usually an indicator of inadvertent arterial puncture.
- 5.To lessen the risk of air embolism during catheter insertion the patient should be positioned in a slight trendelenburg position as tolerated. The physician must be aware of potential air embolism problems associated with leaving open needles or catheter in central venous puncture sites or as a consequence of inadvertent diaconnects,
- 6.Care should be exercised in passing guidewire. Use of excessive length of the guidewire into the right heart can cause arrhythmias, and vessel wall, arterial or ventricular
- 7.Do not suture directly to the outside diameter of the catheter to avoid cutting or damaging the catheter or impeding catheter flow.



Maintenance, care and removal cautions

- 1, This product is designed for single use only, Do not re-sterilise or reuse, This product must be used within the 3-year validity of sterilization,
- 2, Indwelling catheter should be routinely inspected for desired flow rate, security of dressing, correct catheter position and for proper luer-lock connection, Use cemtimeter markings to identify if the catheter position has changed,
- 3, Only x-ray examination of the catheter placement can insure that the catheter tip has not entered the heart or no longer lies parallel to the vessel wall. If catheter position has changed, immediately perform chest x-ray examination to confirm catheter tip position.
- 4.Due to a higher risk of contamination with femoral access sites, the physician should evaluate the length of time the catheter is left in place.
- 5. Maintain the insertion site with regular meticulous redressing using aseptic technique.
- 6.To lessen the risk of air embolism or blood loss due to disconnects, only luer-lock tubing should be used with this device.
- Follow standard hospital protocol to guard against air embolism for all subsequent catheter maintenance.
- 7.Air embolism can occur after the removal of a central venous catheter; thus the wound must be covered by a dressing impermeable to air.
- 8.To avoid cutting of the cathete, do not use scissors to remove the dressing.
- 9.Upon removal of the catheter, inspect the catheter to make sure that the entire catheter length has been removed.
- 10. For blood sampling, temporarily shut off remaining port (s) through which solutions are being infused.
- 11.Due to the risk of exposure to HIV(Human Immunodeficiency Virus) or other blood-borne pathogens, health care workers should routinely use "universal blood and body-fluid precautions"in the case of all patients,
- 12, There should be anticoagulant in the whole process of sealing tube, Use 5ml heparin to seal tube under positive pressure, Draw the needle back when only 1ml heparin left to keep the positive pressure and to avoid thrombosis at the end of the catheter, If the catheter is partially blocked, the nurse can use 3~5 ml urokinase (1000 u/ml) to seal the tube for 3~5h and then draw the blood clot when the clot becomes flexible thrombus into the blood vein.



⚠ Caution

Catheter should not be left in place longer than 15 days.

Summary of Safety and Clinical Performance (SSCP)

The summary of safety and performance for the device is available on the website of EUDAMED: https://ec,europa,eu/tools/eudamed

E-IFU

Software and hardware requirements needed to display the instructions for use in electronic form are shown as:

Computer:

Configuration item		Requirements
Hardware configuration	CPU	Intel Pentium 4 and above
	RAM	256 M and above
	Hard disk space	20 G and above
Systems platform		Windows platform (compatible with Windows XP, Windows 7, Windows 8&8.1, Windows 10, compatible with 32-bit & 64-bit)
Required software		Adobe Acrobat Reader or pdf reader software of the same type

Mobile phone:

Configuration item	Requirements	
Systems platform	Android 4.0 and above or IOS 5.0 and above	
Required software	Adobe Acrobat Reader or pdf reader software of the same type	

The exact same pdf version e-IFU can also be found on the website: https://en.lepumedical.com/e-ifu/

When the manufacturer's instruction for use is updated, it will be uploaded timely. For it is difficult to trace to every end user to inform the change, so we advise the customer to browse and check it regularly.

EXPLANATION OF SYMBOLS







USE BY DATE











MANUFACTURER



TEMPERATURE LIMIT



DO NOT USE IF THE PACKAGE IS DAMAGED



Cobalt (CAS NO, 7440-48-4) PRESENTS IN THE DEVICE







SINGLE STERILE BARRIER SYSTEM AND STERILIZED USING ETHYLENE OXIDE



IN THE EUROPEAN COMMUNITY/ EUROPEAN UNION



WARNING: DO NOT PLACE THE CATHETER INTO OR ALLOW IT TO REMAIN IN THE RIGHT ATRIUM OR RIGHT VENTRICLE. FAILURE TO FOLLOW THESE INSTRUCTIONS CAN RESULT IN SEVERE PATIENT INJURY OR DEATH.

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