# Instructions for Use

## Suction Catheter

(Vent Catheter)



**Dongguan Kewei Medical Instrument Co., Ltd.**

CE 2797

# Vent Catheter

*Before use, please read this IFU carefully and pay more attention to all the items in Warnings and Precautions.*

## 1. Device Description

There are two models “Suction Catheter with/without stylet” and “Malleable Suction Catheter”.

The Suction Catheter with or without stylet consists of a flexible plastic tube with a perforated distal segment (the Stylet is as a guide introducer to assist surgeon for tube insertion). A small tapered tip is to aid in the insertion of the distal end of the catheter across the mitral valve. Depth markings on the tube indicate insertion depth.

The Malleable Suction Catheter consists of a flexible plastic tube with a perforated distal segment. A malleable stainless steel wire within the catheter tube permits precise shaping. Depth markings on the tube indicate insertion depth.

These catheter fitting is a slip-on connector for 0.6 cm (1/4 in) ID tubing.

The detailed information as below, refer to Figure 1 to Figure 3.

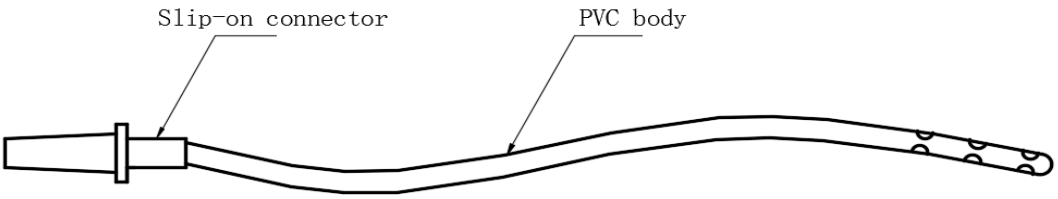


Figure 1 Suction Catheter without stylet

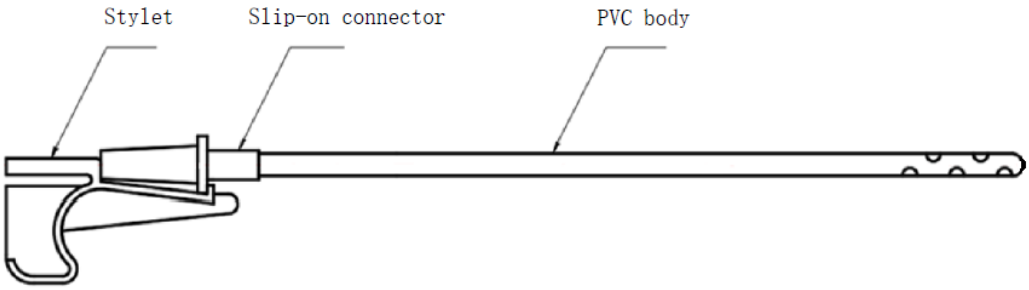

Figure 2 Suction Catheter with stylet

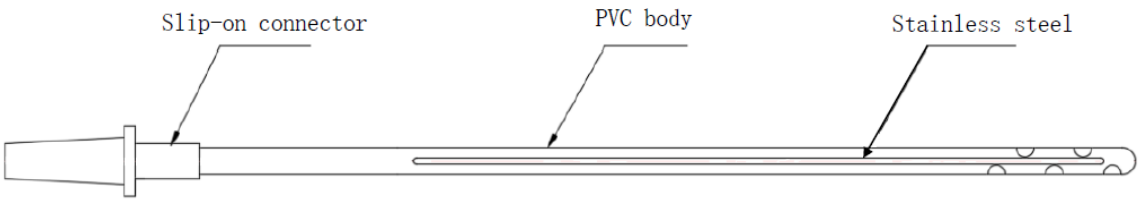


Figure 3 Malleable Suction Catheter

## 2. Device Specification

For available product sizes, please refer to below table.

| Model/ Specification | Suction catheter with stylet | Suction catheter without stylet | Malleable Suction Catheter |
|---|---|---|---|
| 18 Fr | SCA-18 | / | SCB-18 |
| 14 Fr | SCA-14 | / | SCB-14 |
| 12 Fr | / | SCA-12 | SCB-12 |

## 3. Performance Characteristics

The tip of vent catheter is soft and porous, which can increase the area of the suction drainage and prevent the damage of the endocardium. The flexible tube can be freely bent and can effectively conduct left ventricular drainage. The body is transparent and with depth marking. The plastic stylet support inner core for insertion and placement. The malleable stainless steel wire within the catheter body permits precise shaping. These catheter fitting is a slip-on connector for 0.6 cm (1/4 in) ID tubing.

## 4. How Supplied

**STERILE: FOR SINGLE USE ONLY.** This product is sterilized with ethylene oxide (EtO). Non-pyrogenic.

- Do not use if the package is opened or damaged.
- Do not use if labeling is incomplete or illegible.
- Do not re-sterilize.

## 5. Indications for Use

The Vent Catheter is intended for use in venting the left heart during cardiopulmonary bypass surgery up to six hours or less.

## 6. Contraindications

The device is not intended for use except as indicated above.

## 7. Intended User

The device should be operated by professional surgeons, who shall be well trained and be operating the device under the instruction of an eligible medical person who is familiar with the common benefit and risk during the operation of the catheter.

## 8. Patient Population

The catheter can be used for the patients who need to undergo Cardiopulmonary bypass (CPB) surgery to treat heart disease.

## 9. Clinical Benefits

The catheter is used to vent the left heart during Cardiopulmonary bypass (CPB) surgery to treat heart disease. The catheter is an integral part of cardiopulmonary bypass devices. CPB can be used during surgery for congenital heart disease (atrial septal defect, ventricular septal defect, patent foramen ovale, pulmonary arterial hypertension, Right Ventricular Outflow Tract Obstruction (RVOTO), Ebstein deformity, etc.), rheumatic heart disease (aortic valve stenosis or/with insufficiency, mitral valve stenosis or/and insufficiency, tricuspid stenosis or/and insufficiency, etc.), coronary heart disease, tetralogy of fallot; aortic dissecting aneurysm, myxoma of the left atrium, etc.

## 10. Warnings

- Gravity drainage is suggested in procedures where the left heart is kept closed in order to minimize the possibility of air embolism and over-distention of the left ventricle.
- Gravity drainage is not suggested where relatively high flows may be encountered.

## 11. Precautions

- Note: Proper surgical procedures and techniques are the responsibility of the medical profession. The described procedure is furnished for information purposes only. Surgeons must evaluate the appropriateness of the procedure based on their own medical training and experience, the type of surgical procedure, and the type of suction systems utilized.
- The PVC body will stiffen at cold temperatures. Necessary care must be taken when manipulating the heart to avoid inadvertent trauma to delicate cardiac tissues.
- When removing the catheter, withdraw it completely before tightening the purse string suture to prevent catching the suture in the perforated distal tip of the catheter.
- The catheter is designed and intended for single use only. DO NOT REUSE.
- Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.
- When the surgical procedure is completed, dispose of the catheter according to hospital policy.
- **Due to the presence of di(2-ethylhexyl) phthalate (DEHP) in the product, the clinician must weigh the benefits of product use against the drawbacks of phthalate exposure for male children and pregnant or nursing women.**

## 12. Adverse Effects

This device, as do all extracorporeal blood system devices, has possible side effects which include, but are not limited to, myocardial damage, infection, blood loss, tissue injury, and thrombus. Vessel damage and complications at the puncture site may occur if the Instructions for Use are not followed.

## 13. Instruction for Use

1) Inspect the package and product for damage and expiration date. If undamaged and unexpired, open the package and transfer the catheter onto the sterile field utilizing an aseptic technique.
2) For the Malleable Catheter, bend the catheter into the desired shape prior to insertion. And make certain that the wire within the catheter body is on the inside of the formed angle to avoid kinking or occluding the lumen of the catheter. Avoid forming abrupt angles.
3) Retract the right atrium and place a purse string suture at the cannulation site in the right superior pulmonary vein adjacent to its junction with the left atrium. Draw the suture through a tourniquet/ligature tube. Make an incision within the purse string suture.

4) Moisten the catheter in sterile 0.9% sodium chloride or heparinized 0.9% sodium chloride before inserting. Insert the tip of the catheter just through the wall of the right superior pulmonary vein and advance into the left atrium.

   **Note:** It is recommended that the aorta be cross clamped prior to the insertion of the vent catheter.

5) Insert the catheter at least past the last hole on the distal tip of the catheter or at least to the first line on the catheter. During insertion, palpate the left ventricle to insure proper positioning of the catheter across the mitral valve.

6) Tighten the tourniquet and secure to the vent catheter at a convenient site. Remove the stylet (if included). Connect the vent catheter to the suction tubing provided in the perfusion circuit.

7) After the procedure, remove the vent catheter from the heart and tie the purse string suture (see Precautions).

**NOTES to Users:**

The product shall be performed under sterile condition rigorously from unpacking to application;

The product shall be assembled and used under the direction of professional surgeon, non-professional shall be prohibited to use.

## 14. Transportation and Storage Conditions

Protected from pressure, light and wet rain during transportation.

**STORAGE**: Store in a dry, dark and cool place.

## 15. Shelf Life

Under store requirements conditions, the shelf life of the suction catheter is 3 years.

## 16. Supplementary Information

The summary of safety and clinical performance (SSCP) is available in the European database on medical devices (Eudamed), please refer to (Place holder for the link of Eudamed).

## 17. WARRANTY AND LIMITATIONS

Dongguan Kewei Medical Instrument Co., Ltd. has committed itself to the manufacture of the vent catheter. Dongguan Kewei Medical Instrument Co., Ltd. warrants that all the products shall be free of defects in materials and workmanship upon receipt. Dongguan Kewei Medical Instrument Co., Ltd. will not to be liable for any incidental, special, or consequential loss, damage,

or expense resulting, directly or indirectly, from use of its product.

Dongguan Kewei Medical Instrument Co., Ltd. indicates definitely that this device is intended for one time use only and makes no warranty, representation or condition of any kind, whether expressed or implied (including any warranty of merchantability, suitability or fitness for a particular purpose) respecting the reuse of this product. Moreover, Dongguan Kewei Medical Instrument Co., Ltd. assumes no responsibility or liability for incidental or consequential damages which may result from such reuse. Contact Kewei directly with any other questions related to the products.

Any serious incident that has occurred in relation to the device, the user should report to the manufacturer and the competent authority of the Member State in which the user is established.

## 18. Graphical Symbols for Medical Device Labelling

| | | |
|---|---|---|
| 1) |  | Manufacturer |
| 2) |  | Authorized representative in the European Community |
| 3) |  | Date of manufacture |
| 4) |  | Use-by date |
| 5) |  | Batch code |
| 6) |  | Catalogue number |
| 7) |  | Sterilized Using Ethylene Oxide |
| 8) |  | Do not resterilize |
| 9) |  | Do not use if package is damaged |
| 10) |  | Keep away from sunlight |
| 11) |  | Keep dry |
| 12) |  | Do not re-use |
| 13) |  | Consult instructions for use |

| | | |
|---|---|---|
| 14) |   | CONTENT: 1 |
| 15) |   | Contains di(2-ethylhexyl)phthalate (DEHP) |
| 16) |  | Caution! Observe the warnings and safety precautions given in the accompanying documentation |
| 17) |  | Non-pyrogenic |
| 18) |   | Sterile Barrier System |
| 19) |   | Medical device |

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