Instructions for Use

Suction Catheter
(Suction Wand)

Dongguan Kewei Medical Instrument Co., Ltd.

CE 2797

Suction Wand

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 “Rigid Suction Catheter” and “Flexible Suction Catheter”, each model has two categories different from size or length.

The Rigid Suction Catheter is consisted of a stainless steel body with comfortable hand grip, a fluted tip attached to the distal end, and fitting with a 0.6 cm (1/4 in) slip-on connector.

The Flexible Suction Catheter is consisted of a fluted tip which is attached to a PVC body, and fitting a connector for 0.6 cm (1/4 in) ID tubing.

The detailed information as below, Refer to Figure 1 and Figure 2:

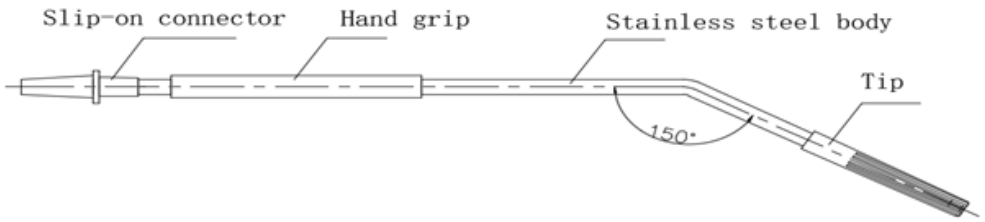

Figure 1 Rigid Suction Catheter

Figure 2 Flexible Suction Catheter

2. Device Specification

The device specification is shown as following table.

Model/ Specification	Rigid Suction catheter	Flexible Suction catheter
18 Fr	SCR-18	SCF-18
14 Fr	SCR-14	SCF-14

3. Performance Characteristics

The types of rigid and flexible suction wand are available, their body is made of rigid stainless steel or flexible plastic tube separately. The suction wand offers a fluted tip to minimize the possibility of tissue occlusion while maintaining an opportunity for drainage. These catheter fitting is a slip-on connector or 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 suction wand is intended for use in draining the excess fluid from pericardial sac or the cardiac chambers during cardiopulmonary bypass surgery up to six hours or less.

6. Contraindication

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 draining the excess fluid from pericardial sac or the cardiac chambers 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

- The proposed device shall be used under sterile operation strictly and by professional surgeon;
- The negative pressure shall not be too high in open heart surgery to cause endocardium damage, blood damage or blocking of the suction hole;
- The tip hole or side hole blocking will cause a difficult suction, the suction catheter position shall be adjusted appropriately;
- The shelf life is three years, please check the package and expire date, a damaged package or out of date product shall be prohibited to use;
- The product is for single use and to be disposed as per local regulations;

11. Precautions

- Proper surgical procedures and techniques are the responsibility of the medical professional. The described procedure is furnished for information purposed only. Surgeons must evaluate the appropriateness of the procedure based on their own medical training and experience, and the type of surgical procedure being performed.
- 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. Catheter sizes must be selected appropriately.
2) Connect the 1/4 inch connector to the suction tubing provided in the extracorporeal circuit.
3) Insert the fluted tip into the surgical field. Place the fluted tip into the liquid filled area. When completely draining removing the excess fluid liquid, withdraw the tip from the surgical wound. If needed, repeat the operation.
4) After the procedure, remove the suction catheter from the circuit.

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 suction wand. 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

Dongguan Kewei Medical Instrument Co., Ltd.
Add: No.1 Tongqing Road, Dongcheng District, Dongguan City, Guangdong, 523127, China
Tel: (86) (769) 39001000
Fax: (86) (769) 22250971
Email: kewei@microport.com
Website: www.kewei.com

EC REP
MicroPort Medical B.V.
Add: Paasheuvelweg 25
1105BP Amsterdam, The Netherlands
Tel: +31 (0)20 545 0100 ext. 8 Fax: +31 (0)20 545 0109

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