Instruction for Use

Arterial and Venous Cannula

Arterial Cannula

Dongguan Kewei Medical Instrument Co., Ltd.

CE 2797

Arterial Cannula

Before use, please read this IFU carefully and pay more attention to all the items in Warning and Precautions!

1 Device Description

The arterial cannula consists of an angled or straight plastic tip, a cannula body (wirewound or not), an introducer (provided with certain sizes), a peel cap (provided with certain sizes) and a suture ring (provided with certain sizes).

There are two types of tips for the arterial cannula, which are straight plastic tip and angled plastic tip; and two types of cannula body, which are wirewound or not. An introducer is provided with certain sizes of arterial cannula. Except the sizes with introducer, the other sizes are all provided with peel cap. A suture ring is provided with certain sizes of arterial cannula.

Schematic diagram of the arterial cannula is shown in Figure1.

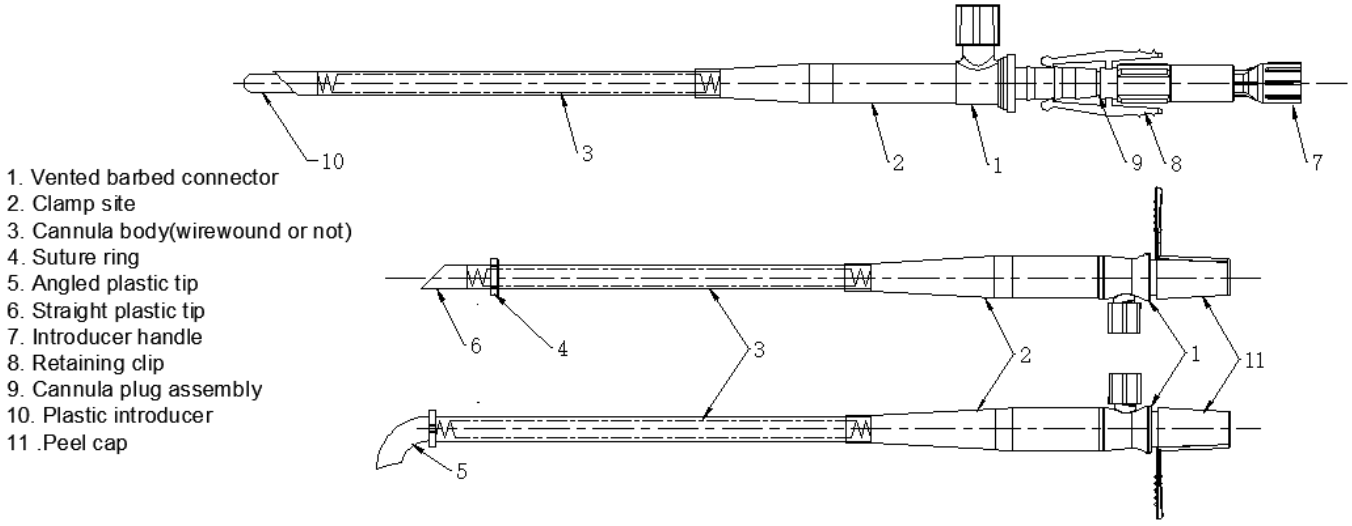


Fig.1 Schematic diagram of the arterial cannula

Available sizes and their corresponding product codes of the arterial cannula are shown in Table 1 and Table 2. For the recommended tubing size of the arterial line compatible with the connector, please refer to Table 3.

Table 1 Available sizes and their corresponding product codes of the arterial cannula

Size	Straight plastic tip					Angled plastic tip	
	Not Wirewound Body, with Peel Cap	Wirewound Body, with Peel Cap	Not Wirewound Body, with Suture Ring, with Peel Cap	Wirewound Body, with Suture Ring, with Peel Cap	Wirewound Body, with Introducer	Not Wirewound Body, with Peel Cap	Wirewound Body, with Peel Cap
8 Fr	IFAC-PSN-08	IFAC-PSR-08	-	-	IFAC-PSR-ST-08	-	-
10 Fr	IFAC-PSN-10	IFAC-PSR-10	-	-	IFAC-PSR-ST-10	-	-
12 Fr	IFAC-PSN-12	IFAC-PSR-12	-	-	IFAC-PSR-ST-12	IFAC-PCN-12	IFAC-PCR-12
14 Fr	IFAC-PSN-14	IFAC-PSR-14	IFAC-PSN-SR-14	IFAC-PSR-SR-14	IFAC-PSR-ST-14	IFAC-PCN-14	IFAC-PCR-14
16 Fr	IFAC-PSN-16	IFAC-PSR-16	IFAC-PSN-SR-16	IFAC-PSR-SR-16	IFAC-PSR-ST-16	IFAC-PCN-16	IFAC-PCR-16
18 Fr	IFAC-PSN-18	IFAC-PSR-18	IFAC-PSN-SR-18	IFAC-PSR-SR-18	-	IFAC-PCN-18	IFAC-PCR-18
20 Fr	IFAC-PSN-20	IFAC-PSR-20	IFAC-PSN-SR-20	IFAC-PSR-SR-20	-	IFAC-PCN-20	IFAC-PCR-20
22 Fr	IFAC-PSN-22	IFAC-PSR-22	IFAC-PSN-SR-22	IFAC-PSR-SR-22	-	IFAC-PCN-22	IFAC-PCR-22
24 Fr	IFAC-PSN-24	IFAC-PSR-24	IFAC-PSN-SR-24	IFAC-PSR-SR-24	-	IFAC-PCN-24	IFAC-PCR-24

Table 2 The outer diameter and length of the arterial cannula

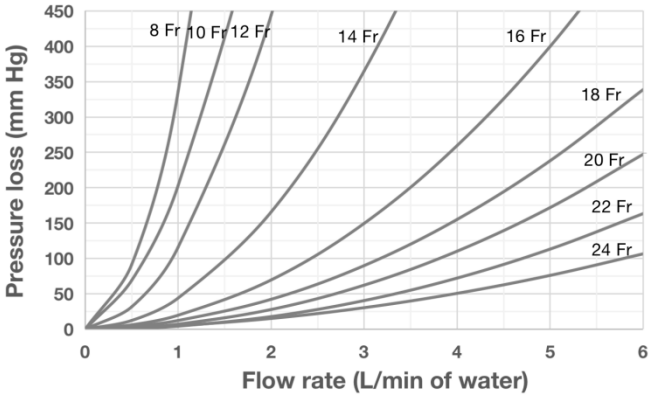
Size	Straight plastic tip		Straight plastic tip		Straight plastic tip		Angled plastic tip	
	Wirewound/Not Wirewound Body, with peel cap		Wirewound/Not Wirewound Body, with Suture Ring, with Peel Cap		Wirewound Body, with Introducer		Wirewound/Not Wirewound Body, with peel cap	
	OD of Tip (mm)	Length (mm)	OD of Tip (mm)	Length (mm)	OD of Tip (mm)	Length (mm)	OD of Tip (mm)	Length (mm)
8 Fr	2.7	211	-	-	2.7	260	-	-
10 Fr	3.3		-	-	3.3		-	-
12 Fr	4.0		-	-	4.0		4.0	223
14 Fr	4.7		4.7	211	4.7		4.7	
16 Fr	5.3		5.3		5.3		5.3	
18 Fr	6.0	255	6.0	255	-	-	6.0	264
20 Fr	6.7		6.7		-	-	6.7	
22 Fr	7.3		7.3		-	-	7.3	
24 Fr	8.0		8.0		-	-	8.0	

Table 3 Required tubing size of the arterial line

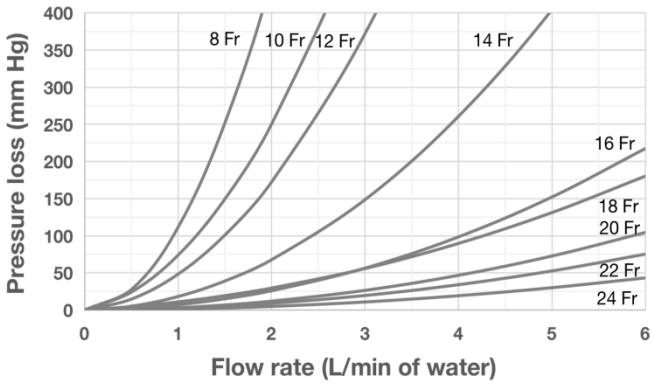
Product size	Connector model	Required tubing size of the arterial line
8 Fr	Ø6	1/4 Inch
10 Fr		
12 Fr		
14 Fr		
16 Fr		
18 Fr	Ø10	3/8 Inch
20 Fr		
22 Fr		
24 Fr		

2 Performance Characteristics

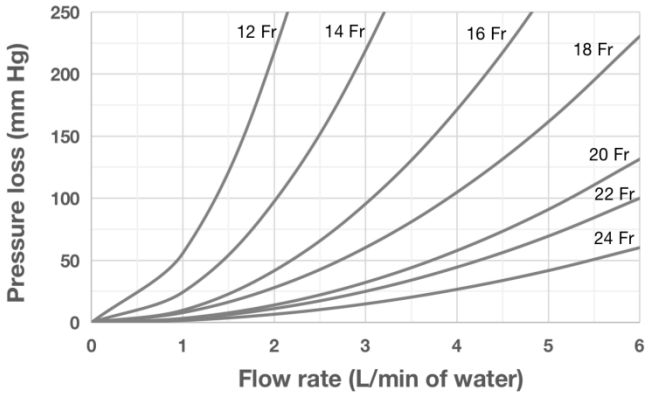
The bodies of the arterial cannulae are available with reinforced and non-reinforced. The tip types are available with straight and curved, which completely meet every operational requirement. The construction allows for higher flow rates with minimal pressure differential. The Pressure loss/Flow rate curve for each size are shown in Figure.2- Figure.5.



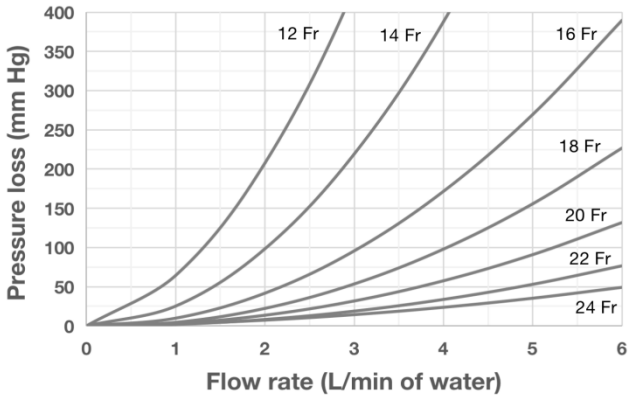
Firgure.2 Straight plastic tip, Not Wirewound Body with Peel Cap/ with Suture ring, with Peel Cap



Firgure.3 Straight plastic tip, Wirewound Body with Peel Cap/ with Suture ring, with Peel Cap/ with Introducer



Firgure.4 Angled plastic tip, Not Wirewound Body, with Peel Cap



Firgure.5 Angled plastic tip, Wirewound Body, with Peel Cap

3 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.

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

4 Indication for Use

These cannulae are intended for perfusion of the ascending aorta during cardiopulmonary bypass surgery up to six hours or less.

5 Contraindications

This device is not intended for use except as indicated.
This device is contraindicated for long-term use. DO NOT USE FOR EXTENDED TERMS SUCH AS VENTRICULAR ASSIST PROCEDURES.

6 Intended User

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

7 Patient Population

The cannula can be used for adult, children and infant, who need to undergo Cardiopulmonary bypass(CPB) surgery to treat heart disease.

8 Clinical Benefits

The cannula is used to provide access points for blood perfusion during Cardiopulmonary bypass (CPB) surgery to treat heart disease. The cannula 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 and so on), rheumatic heart disease (aortic valve stenosis or/with insufficiency, mitral valve stenosis or/and insufficiency, tricuspid stenosis or/and insufficiency and so on), coronary heart disease, tetralogy of fallot; aortic dissecting aneurysm, myxoma of the left atrium and so on.

9 Warnings

During cannulation, extreme caution should be exercised if there is a possibility of tissue dissection of the aorta. Avoid directing the cannula tip toward the branch arteries of the aortic arch to minimize inadvertent embolization into the arteries or causing increased intracranial blood pressure. Cannula sizes must be selected appropriately for a given size patient.

10 Precautions

Note: This device can only be used in the operating room.

Proper surgical procedures and techniques are the responsibility of the medical professional. 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 and the type of surgical procedure being performed. Exercise care during the connection of the cannula and the perfusion line to insure that no air is trapped in the perfusion line.

Placement, location, and orientation of the sutures in the aorta is critical to proper positioning of the cannula. Once the cannula is firmly secured with the sutures, it is difficult to change the position of the cannula.

Do not clamp the cannula in the wirewound section as this can make the movement of the introducer difficult.

Connect 0.48 cm (3/16 in) barbed connector models only to 0.48 cm (3/16 in) I.D. tubing.

Please tighten luer caps before using.

These cannulae are 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 cannula according to hospital policy.

11 Adverse Events

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

12 Instructions for Use

Instructions for use for the arterial cannula are as following. For products with introducer or peel cap, specific steps for the introducer or peel cap are pointed out. Cannula sizes must be selected appropriately for a given size patient.

1) Inspect the package and product for damage and expiration date. If undamaged and unexpired, open the package and transfer the cannula onto the sterile field utilizing aseptic technique.
2) (For products with introducer) Advance the introducer into the cannula until the cannula plug is seated in the barbed connector and the retaining clip engages the second barb on the connector.
3) (For products with introducer) Test the introducer assembly for smooth function (see steps 8-9). Adjust introducer tip to desired length by gently pushing introducer handle into plug assembly.
4) Place a purse string suture in the anterior aspect of the distal ascending aorta at the desired location. Place a tourniquet over this purse string. Place a second outer purse string 1 to 2 mm beyond the first purse string. Excise the adventitia from within the inner purse string suture and place a tourniquet on the free ends.
5) Insure adequate systemic heparinization has been obtained. Make an incision within the confines of the inner purse string using a number 11 blade. Place the cannula tip against the side of the blade and slide the cannula into the aorta to the desired depth. Remove the blade.
6) Rotate the cannula so the tip is directed distally and the orientation line on the cannula body faces toward the aortic valve.
7) Tighten the purse strings and secure the tourniquet to the cannula body.
8) (For products with introducer) Disengage the introducer from the plug assembly by pulling the introducer handle straight back. DO NOT DISENGAGE THE RETAINING CLIP AT THIS TIME. Slowly withdraw the introducer through the plug until it stops, allowing the cannula to fill and air to vent. After full prime is achieved, clamp the cannula body at the clamp site.
9) While supporting the cannula, squeeze the retaining clip to disengage from the barbed connector. Slowly rotate the clip and plug together to remove the plug from the connector.
10) (For products with peel cap) Prior to attaching the cannula to the arterial line, when full prime is achieved, clamp the cannula body. Then remove peel cap from the cannula. Attach the cannula to the arterial line. Inspect the line and remove any air before removing the tube clamp. The arterial cannula has a luer port on the connector which can be used to remove air from the line or monitor line pressure.
11) Secure the cannula to the skin or reactor with a suture to provide strain relief and prevent inadvertent movement. Position the cannula and arterial line so that the cannula has a gentle curve

and enters the aorta perpendicularly. Secure the arterial line to the superior drape.

12) The cannula should be carefully removed from the vessel. The entry site should be closed using standard medical procedures.

13) When the surgical procedure is completed, dispose of the cannula according to hospital policy.

13 Shelf life

Under store requirements conditions, the shelf life of the arterial cannula is 3 years.

14 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).

15 WARRANTY AND LIMITATIONS

Dongguan Kewei Medical Instrument Co., Ltd. has committed itself to the manufacture of the Arterial Cannula. 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.

16 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 by 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)		Caution! Observe the warnings and safety precautions given in the accompanying documentation
16)		Non-pyrogenic
17)		Sterile Barrier System
18)		The device is a medical device

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