Venous Return Cannula

CE 2797

Dongguan Kewei Medical Instrument Co., Ltd.

Venous Return Cannula

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

1 Device Description

There are two types of venous return cannula, “venous return cannula (single stage)” and “venous return cannula (two stage)”.

The venous return cannula (single stage) is composed of a tip and a wirewound cannula body. Schematic diagram of the venous return cannula is shown in Figure.1.

1. Connection site
2. Clamp site
3. Wirewound body
4. PVC multiport straight tip
5. PVC multiport angle tip
6. Right angle metal tip

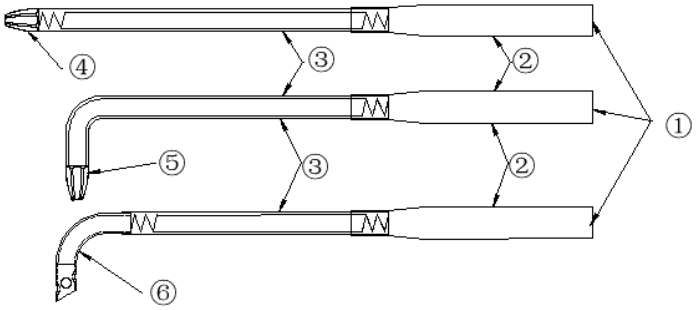


Fig.1 Schematic diagram of the venous return cannula (single stage)

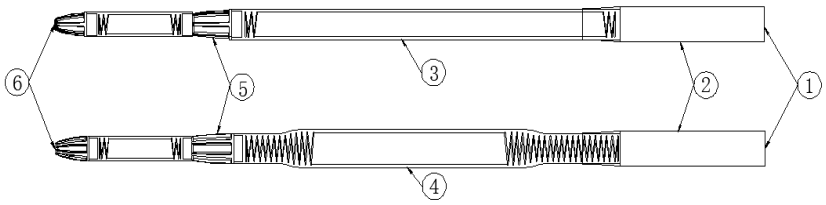
There are three types of venous return cannula (single stage):

1) Cannula with straight plastic tip
2) Cannula with angled plastic tip
3) Cannula with angled metal tip

Tip of the three types of the venous return cannula are with multiple side ports. The cannula body is flexible wirewound body.

The venous return cannula (two stage) is mainly composed of PVC multiport tip, a tapered basket, round or oval wirewound body. Schematic diagram of the venous return cannula (two stage) is shown in Figure.2.

1. Connection site
2. Clamp site
3. Wirewound body
4. Flattended wirewound body
5. Tapered basket
6. PVC multiport tip



Two stage venous return cannula

Fig.2 Schematic diagram of the venous return cannula (two stage)

The cannula body is wirewound body, composed with two models of round lumen and oval lumen.

For the corresponding product codes and available product sizes, please refer to Table 1 and Table 2.

For the recommended tubing size of the venous line using the connector, please refer to Table 3.

Table 1 The corresponding product codes and available product sizes of the venous return cannula

Venous return cannula		
Product	Single stage	Two stage

size	Straight plastic tip	Angled plastic tip	Angled metal tip	Round lumen	Oval lumen
12Fr	VC-PSR-12	VC-PCR-12	VC-MCR-12	/	/
14Fr	VC-PSR-14	VC-PCR-14	VC-MCR-14	/	/
16Fr	VC-PSR-16	VC-PCR-16	VC-MCR-16	/	/
18Fr	VC-PSR-18	VC-PCR-18	VC-MCR-18	/	/
20Fr	VC-PSR-20	VC-PCR-20	VC-MCR-20	/	/
22Fr	VC-PSR-22	VC-PCR-22	VC-MCR-22	/	/
24Fr	VC-PSR-24	VC-PCR-24	VC-MCR-24	/	/
26Fr	VC-PSR-26	VC-PCR-26	VC-MCR-26	/	/
28Fr	VC-PSR-28	VC-PCR-28	VC-MCR-28	/	/
30Fr	VC-PSR-30	VC-PCR-30	/	/	/
32Fr	VC-PSR-32	VC-PCR-32	/	/	/
34Fr	VC-PSR-34	VC-PCR-34	/	/	/
36Fr	VC-PSR-36	VC-PCR-36	/	/	/
38Fr	VC-PSR-38	VC-PCR-38	/	/	/
40Fr	VC-PSR-40	VC-PCR-40	/	/	/
42Fr	VC-PSR-42	VC-PCR-42	/	/	/
24/28Fr	/	/	/	VC-TSR-2428	VC-TSO-2428
28/36Fr	/	/	/	VC-TSR-2836	VC-TSO-2836
30/38Fr	/	/	/	VC-TSR-3038	VC-TSO-3038
32/38Fr	/	/	/	VC-TSR-3238	VC-TSO-3238
34/38Fr	/	/	/	VC-TSR-3438	VC-TSO-3438
34/40Fr	/	/	/	VC-TSR-3440	VC-TSO-3440
34/46Fr	/	/	/	VC-TSR-3446	VC-TSO-3446
34/48Fr	/	/	/	VC-TSR-3448	VC-TSO-3448
36/46Fr	/	/	/	VC-TSR-3646	VC-TSO-3646
36/50Fr	/	/	/	VC-TSR-3650	VC-TSO-3650
38/50Fr	/	/	/	VC-TSR-3850	VC-TSO-3850

Note: "/" not available.

Table 2 The outer diameter and length of the venous return cannula

Size	Single stage						Size	Two stage		
	straight plastic tip		angled plastic tip		angled metal tip			Round/Oval lumen		
	OD of tip (mm)	Length (mm)	OD of tip (mm)	Length (mm)	OD of tip (mm)	Length (mm)		OD of tip (mm)	OD of the middle cannula body (mm)	Length (mm)
12 Fr	4.0	380	4.0	350	4.0	395	24/28 Fr	8.0	9.3	390
14 Fr	4.7		4.7		4.7		28/36 Fr	9.3	12.0	

16 Fr	5.3		5.3		5.3		30/38 Fr	10.0	12.7	
18 Fr	6.0		6.0		6.0		32/38 Fr	10.7	12.7	
20 Fr	6.7		6.7		6.7		34/38 Fr	11.3	12.7	
22 Fr	7.3		7.3	370	7.3	425	34/40 Fr	11.3	13.3	
24 Fr	8.0		8.0		8.0		34/46 Fr	11.3	15.3	
26 Fr	8.7		8.7		8.7		34/48 Fr	11.3	16.0	
28 Fr	9.3		9.3		9.3		36/46 Fr	12.0	15.3	400
30 Fr	10.0	400	10.0		-	-	36/50 Fr	12.0	16.0	
32 Fr	10.7		10.7		-	-	38/50 Fr	12.7	16.0	
34 Fr	11.3		11.3	355	-	-	-	-	-	-
36 Fr	12.0		12.0		-	-	-	-	-	-
38 Fr	12.7		12.7		-	-	-	-	-	-
40 Fr	13.3		13.3		-	-	-	-	-	-
42 Fr	14.0		14.0		-	-	-	-	-	-

Note: "-" not available.

Table 3 Recommended connector size of the venous return cannula

Product size	Single stage		Two stage
	Cannula with angled/straight plastic tip	Cannula with angled metal tip	Round Lumen and Oval Lumen
12 Fr	1/4 Inch	1/4 Inch	/
14 Fr	1/4 Inch	1/4 Inch	/
16 Fr	1/4 Inch	1/4 Inch	/
18 Fr	5/16 Inch	5/16 Inch	/
20 Fr	5/16 Inch	5/16 Inch	/
22 Fr	5/16 Inch	5/16 Inch	/
24 Fr	5/16 Inch	5/16 Inch	/
26 Fr	5/16 Inch	5/16 Inch	/
28 Fr	3/8 Inch	3/8 Inch	/
30 Fr	3/8 Inch	/	/
32 Fr	3/8 Inch	/	/
34 Fr	3/8 Inch	/	/
36 Fr	1/2 Inch	/	/
38 Fr	1/2 Inch	/	/
40 Fr	1/2 Inch	/	/
42 Fr	1/2 Inch	/	/
24/28 Fr	/	/	3/8 Inch
28/36 Fr	/	/	1/2 Inch
30/38 Fr	/	/	1/2 Inch
32/38 Fr	/	/	1/2 Inch
34/38 Fr	/	/	1/2 Inch
34/40 Fr	/	/	1/2 Inch
34/46 Fr	/	/	1/2 Inch
34/48 Fr	/	/	1/2 Inch
36/46 Fr	/	/	1/2 Inch
36/50 Fr	/	/	1/2 Inch
38/50 Fr	/	/	1/2 Inch

Note: "/" not available.

2 Performance Characteristics

The bodies of the venous return cannulae are made as wire reinforced to resist kink. The tip types are available in straight plastic, angled plastic and angled metal, 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.3- Figure.7.

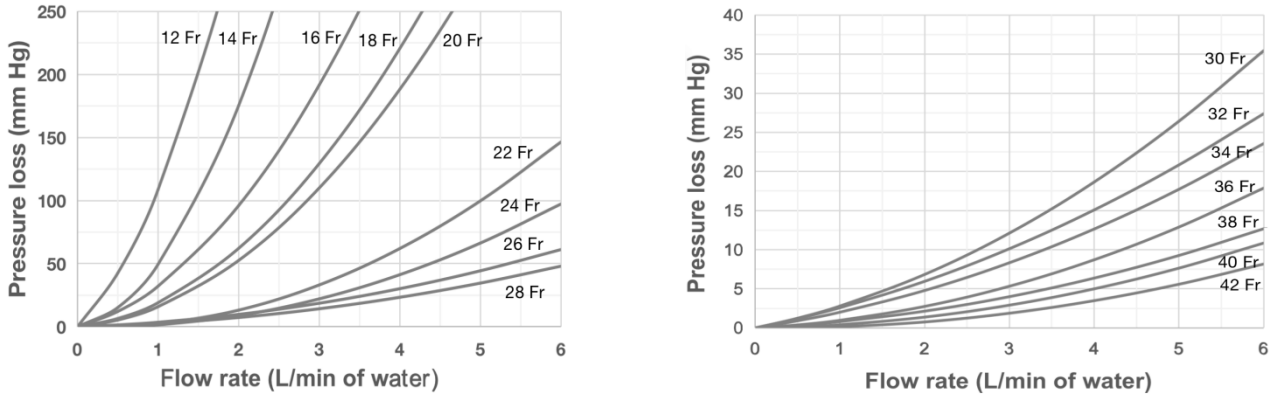


Figure.3 Single stage, Straight plastic tip

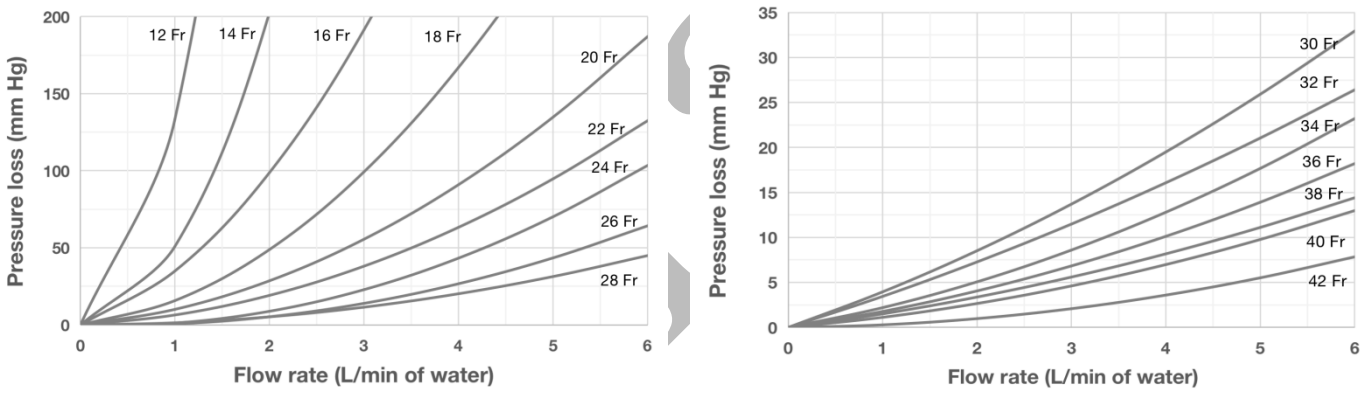


Figure.4 Single stage, Angled plastic tip

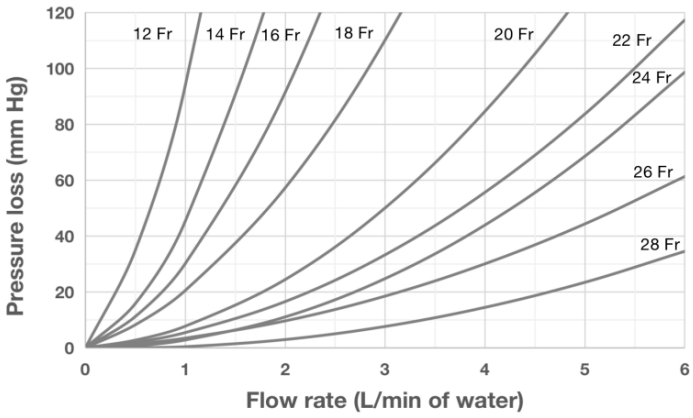


Figure.5 Single stage, Angled metal tip

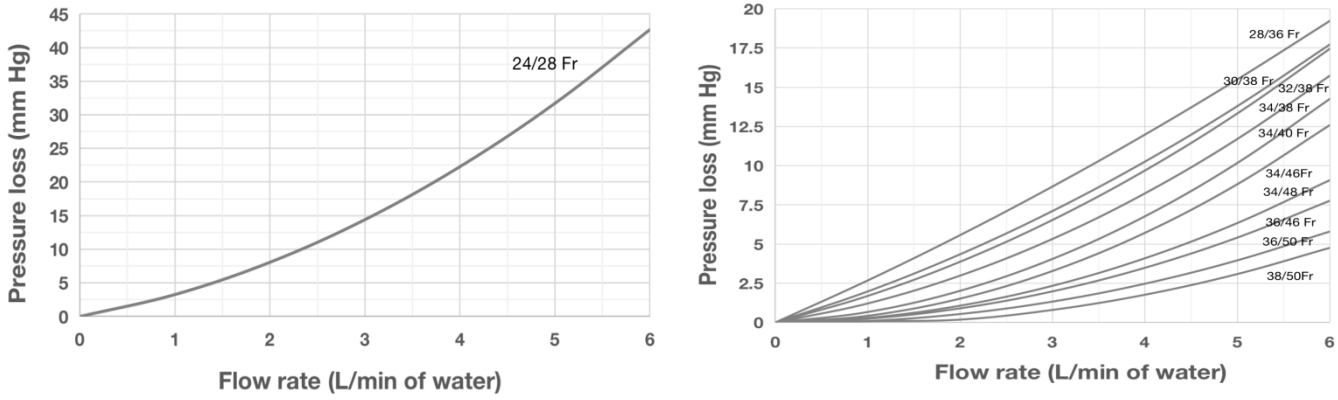


Figure.6 Two stage, Round lumen

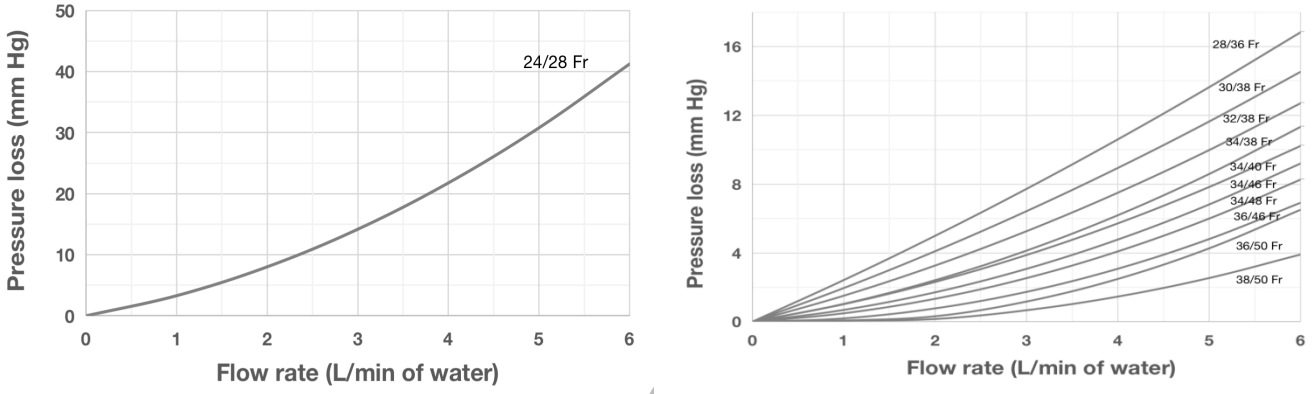


Figure.7 Two stage, Oval lumen

3 How Supplied

STERILE: FOR SINGLE USE ONLY. This product is sterilized with ethylene oxide (EO). 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 Indications for Use

These cannulae are intended for drainage of venous blood from the right side of the heart via the superior and inferior vena cava during cardiopulmonary bypass surgery up to six hours or less.

5 Contraindications

This device is not intended for use except as indicated above.
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 single stage venous return cannula can be used for adult, children and infant and the two stage venous return cannula can be used for adult only, who need to undergo Cardiopulmonary bypass (CPB) surgery to treat heart disease.

8 Benefit

The cannula is used to provide access points for blood drainage 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

- Cannula sizes must be selected to provide adequate venous return rates for a given size patient.
- Do not clamp the cannula over the reinforcing spring.
- Cannula should be operated by medical professional.

10 Precautions

This device is designed for one time use only. Do not reuse, reprocess, or resterilize this product. 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.

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.

This device can only be used by physicians who have received appropriate training.

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

- Select a cannula size which will provide adequate venous return rates for a given size patient. 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.

- After ensuring adequate systemic heparinization has been obtained, place a purse string suture at the desired cannulation site. Draw the purse string suture through a ligature tube/tourniquet.

For Venous Return Cannula (single stage)

1) Make an appropriately sized incision to receive the cannula tip within the purse string suture.
2) Dilate the incision to proper size for the cannula. Place a finger over the incision after dilation.
3) Insert the cannula tip into the incision. Guide the cannula gently into the vena cava. Palpate the vena cava to ensure proper cannula location during insertion.
4) Tighten the purse string suture and tie or clamp the tourniquet at a convenient site. Secure the cannula or venous return line to the surgical field to maintain proper tip orientation and prevent cannula dislodgment or excessive tension on the cannula.
5) Once the cannula and venous lines are primed and de-aired, clamp the cannula at the clamping site, connect the cannula with the venous line. Tubing size of the venous line should choose as recommended in Table 3.
6) Remove the clamp prior to initiating cardiopulmonary bypass.
7) After initiating total cardiopulmonary bypass, secure a caval tape around both vena cavae and cannulae tips to prevent entrainment of air into the venous drainage system.
8) After cessation of bypass, remove the cannula from the vena cava and close the suture line.
9) When the surgical procedure is completed, dispose of the cannula according to hospital policy.

For Venous Return Cannula (two stage)

1) Isolate the appendage with a vascular clamp. Incise the appendage to create an atriotomy.
2) Open the atriotomy with forceps or traction sutures and partially insert the cannula. Release the occluding vascular clamp and simultaneously insert the cannula into the atrium and toward the inferior vena cava. Do not over insert cannula or insufficiently insert cannula.
3) Insert the cannula smoothly and quickly to minimize blood loss. Advance the distal portion of the tip into the inferior vena cava. Position the atrial basket(s) in the right atrium. Remove clamps or traction sutures.
4) Tighten the purse string and secure the ligature tube to the cannula. Connect the cannula to the venous line from the extracorporeal circuit. Do not clamp on reinforced areas. Remove all clamps from the cannula and lines before initiating cardiopulmonary bypass.
5) After the procedure, remove the cannula gently and tie the purse string suture.
6) 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 venous return 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 Venous Return 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 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)		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

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

Distributor:
CORMED Medizintechnik GmbH & Co. KG
Add: Südstraße 1 - 59602 Rüthen, Germany
Email: info@cormed.de
Website: www.cormed.de

Document No.: KW/B08CE039
Version: A
Revise date: November 2021