

Central Venous Catheter Kit

CAUTION

Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications.

DEVICE DESCRIPTION

The central venous catheter kit is a sterile, single-use, non-pyrogenic and disposable device that is made for the use of intravenous infusion (of drugs or solutions), blood sampling, central venous monitoring. This device consists of 9 parts if inner packaging material is included: the central venous catheter, scalpel, introducer needle, guide wire, dilator, syringe, catheter clamp, injection cap, inner packaging material(plastic tray)(see figure 1). Central venous catheter with different lumen is shown in figure 2. The size information of central venous catheter is shown in figure 3. And Table 1 shows the content in a CVC kit.

Figure 1 Central venous catheter kit

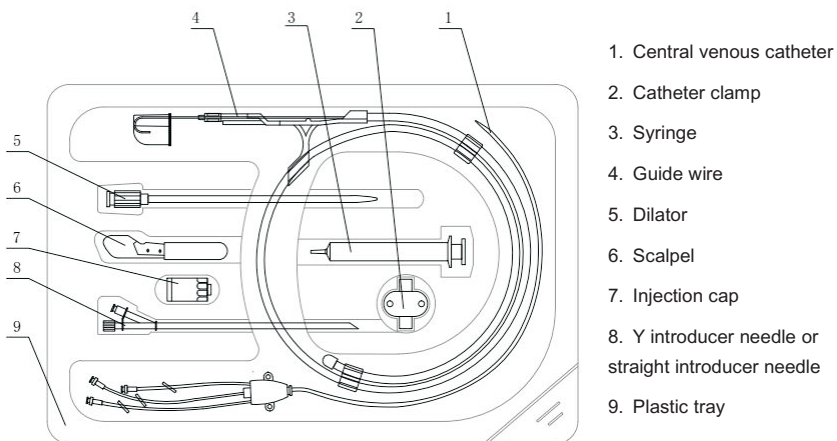


Figure 2 Schematics of a single, double, triple and quad lumen catheters.

1. Tip 2. Catheter tube 3. Neck 4. Connecting tube 5. Connector

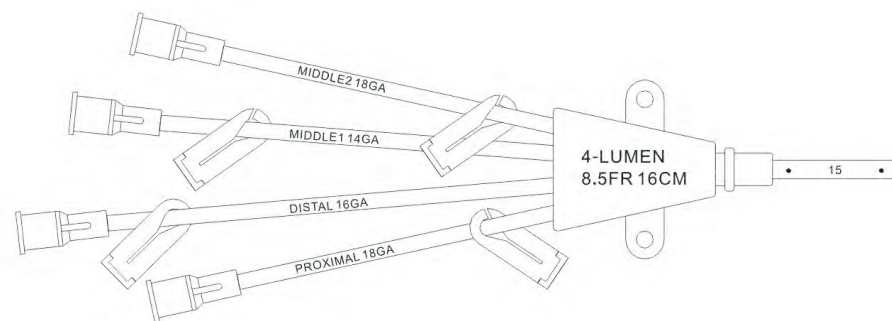
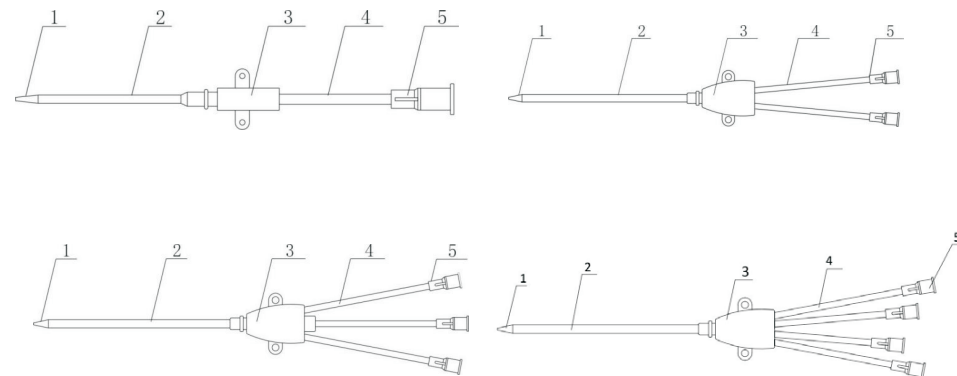


Table 1 Contents of the CVC kit

No.	Name	Quantity	Dimension
1	Central venous catheter	1	See label
2	Catheter clamp	1	/
3	Syringe	1	5ml
4	Guide wire	1	See label
5	Dilator	1	See label
6	Introducer needle	1	See label
7	Scalpel	1	11#
8	Injection cap	Depends on CVC model	/
9	Plastic tray	1	165mm*240mm*20mm

Specification of CVC

Central venous catheter				
CVC-01 (Single lumen)				
Size	Effective Length (cm)	Lumen	Lumen Flow rate (ml/min)	Code No.
24Ga	5	Single	9	609128
	8	Single	7	609129
	9	Single	7	609151
	13	Single	5	609130
	15	Single	4	609131
	20	Single	3	609132
22Ga	5	Single	13	609123
	8	Single	10	609124
	13	Single	7	609125
	15	Single	6	609126
	20	Single	5	609127
	5	Single	15	609118
	8	Single	11	609119
	13	Single	8	609111

20Ga	15	Single	7	609112	
	16	Single	7	609117	
	20	Single	6	609113	
18Ga	12	Single	27	609110	
	13	Single	26	609107	
	15	Single	24	609108	
	16	Single	23	609116	
	20	Single	18	609109	
17Ga	20	Single	50	609121	
16Ga	15	Single	85	609104	
	16	Single	83	609115	
	20	Single	73	609105	
	30	Single	60	609106	
14Ga	14	Single	145	609120	
	15	Single	140	609101	
	16	Single	138	609114	
	20	Single	120	609102	
	30	Single	110	609103	
4Fr	5	Single	35	609133	
	10	Single	30	609134	
	15	Single	24	609135	
	20	Single	18	609136	
	25	Single	14	609137	
	30	Single	11	609138	
5Fr	5	Single	120	609139	
	10	Single	105	609140	
	15	Single	90	609141	
	20	Single	80	609142	
	25	Single	70	609143	
	30	Single	60	609144	
8Fr	5	Single	315	609145	
	10	Single	290	609146	
	15	Single	275	609147	
	20	Single	250	609148	
	25	Single	230	609149	
	30	Single	215	609150	
CVC-02 (Double lumen)					
Size	Effective Length (cm)	Lumen	Lumen Flow rate (ml/min)	Code No.	
4Fr	5	Double	Distal	P: 13	609218
	8		Distal	P: 10	609219

	13	Double	D:12	P: 7	609220
5Fr	8	Double	D:25	P: 13	609201
	10	Double	D:21	P: 11	609215
	13	Double	D:18	P: 10	609202
	15	Double	D:17	P: 9	609213
	16	Double	D:16	P: 9	609210
7Fr	20	Double	D:13	P: 7	609203
	15	Double	D:100	P: 55	609204
	16	Double	D:98	P: 53	609211
	18	Double	D:93	P: 48	609221
8Fr	20	Double	D:85	P: 45	609205
	30	Double	D:65	P: 30	609206
	11	Double	D:115	P: 110	609208
	15	Double	D:110	P: 98	609214
11.5Fr	16	Double	D:108	P: 97	609212
	20	Double	D:105	P: 85	609207
	30	Double	D:90	P: 65	609209
	5	Double	D:290	P: 320	609222
12Fr	10	Double	D:260	P:280	609223
	15	Double	D:250	P: 250	609224
	20	Double	D:240	P: 225	609225
	25	Double	D:225	P: 205	609226
	30	Double	D:200	P: 195	609227
12Fr	5	Double	D:300	P: 305	609228
	10	Double	D:270	P: 280	609229
	15	Double	D:250	P: 270	609230
	20	Double	D:240	P: 250	609231
	25	Double	D:220	P: 230	609232
30	Double	D:210	P: 210	609233	

CVC-03 (Triple lumen)

Size	Effective Length (cm)	Lumen	Lumen Flow rate (ml/min)			Code No.
			Distal	Proximal	Middle	
4Fr	5	Triple	D: 30	P: 11	M:11	609317
	10	Triple	D: 24	P: 9	M:9	609318
	15	Triple	D: 19	P: 6	M:6	609319
	20	Triple	D: 17	P: 4	M:4	609320
	25	Triple	D: 14	P: 3	M:3	609321
	30	Triple	D: 11	P: 3	M:3	609322
5Fr	13	Triple	D: 40	P: 7	M:7	609315
	8	Triple	D: 58	P: 10	M:11	609301
	13	Triple	D: 50	P: 8	M:8	609302

5.5Fr	15	Triple	D: 45	P: 7	M:7	609303
	16	Triple	D: 42	P: 7	M:7	609309
	20	Triple	D: 37	P: 6	M:6	609313
7Fr	15	Triple	D: 67	P: 40	M:36	609304
	16	Triple	D: 65	P: 38	M:35	609310
	18	Triple	D: 60	P: 36	M:32	609314
	20	Triple	D: 56	P: 31	M:28	609305
	30	Triple	D: 54	P:23	M:22	609306
8Fr	20	Triple	D: 105	P: 34	M:34	609316
8.5Fr	15	Triple	D: 130	P: 43	M:43	609312
	16	Triple	D: 130	P: 42	M:42	609311
	20	Triple	D: 115	P: 36	M:36	609307
	30	Triple	D: 110	P:27	M:27	609308
11.5Fr	5	Triple	D: 105	P: 280	M:220	609323
	10	Triple	D: 95	P: 250	M:205	609324
	15	Triple	D: 88	P: 210	M:190	609325
	20	Triple	D: 83	P:185	M:180	609326
	25	Triple	D: 70	P: 175	M:170	609327
12Fr	30	Triple	D: 60	P: 168	M:160	609328
	5	Triple	D: 110	P: 290	M:230	609329
	10	Triple	D: 95	P: 250	M:210	609330
	15	Triple	D: 90	P: 210	M:190	609331
	20	Triple	D: 85	P:190	M:180	609332
	25	Triple	D: 75	P: 175	M:170	609333
30	Triple	D: 65	P: 170	M:165	609334	

CVC-04

Size	Effective Length (cm)	Lumen	Lumen Flow rate (ml/min)				Code No.
			Distal	Proximal	Middle 1	Middle 2	
8.5Fr	15	Quad	D:60	P:35	M1:90	M2:35	609401
	20	Quad	D:58	P:30	M1:80	M2:30	609402
	30	Quad	D:46	P:23	M1:70	M2:22	609403

INTENDED USE

The central venous catheter kit is intended for the purpose of providing short term access (no more than 30 days) to the central venous vascular system for the infusion of fluids, monitoring of central venous pressure and sampling of blood.

INDICATIONS

It's not limited to special disease, Patients that need having the CVC inserted are mostly treated at ICU, commonly used puncture pathways include the internal jugular vein, subclavian vein, femoral vein, CVC kit are used for:

- Parenteral nutrition, especially in chronically ill persons.
- Intravenous antibiotics.
- Chemotherapy central venous pressure measuring.(such as at bone marrow transplantation)
- Frequent blood draws
- Frequent or persistent requirement for intravenous access
- Need for intravenous therapy when peripheral venous access is impossible

Blood

Medication

Rehydration

- Monitoring of the central venous pressure (CVP) in acutely ill people to quantify fluid balance.

PATIENT POPULATION

The populations include adults, children, infants and etc., the age range from 1 month - 103 years old.

MODE OF ACTION

Modified Seldinger technique: The catheter is guided into the vascular system by the exchange of puncture needles, guidewires, catheters, etc.

Measurement of central venous pressure: the pressure signal in the blood vessel or cardiac cavity is transmitted to the pressure transducer through the salt-water column in the catheter cavity, which is converted into an electrical signal and synchronously displayed on the monitor, indicating the pressure curve and the data of pressure measurement.

Infusion: the catheter is indwelling in the central venous system to establish a long-term infusion channel for patients who need long-term infusion and large amount of rehydration to avoid repeated puncture.

Hemodialysis: double-lumen catheters are more commonly used. Catheters are combined with other devices to establish extracorporeal circulation. Two cavities in the catheter are used for human blood outflow and purified blood inflow respectively.

INTENDED USER

The Intended users are the competent surgeon who have the training of Central Venous Catheter management.

REPEAT APPLICATION

The product is applicable to repeat application. After the the product is applied to the patient, a few months or years later, some patients may have the same disease. When the doctor determines according to the patient's physical condition that the patient needs the same operation to treatment, this product can be used on these patients again.

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;
- Abnormality at unction or dissection site such as an enlarged thyroid or other tumors;
- Critical condition of emphysema;
- Distinctive aberrance at puncture site, such as burns, etc.
- Pregnant

WARNINGS

- Complications due to the use of this device can cause serious injury or death; catheter tip can erode or perforate vascular walls
- Every effort must be made to ascertain proper tip position to prevent erosion or perforation of central venous system, other vessels and myocardium. Tip position should be verified by x-ray and monitored routinely. Lateral view x-ray can be used to assess tip location in relation to vessel wall. Tip position should be shown to be parallel to vessel wall.
- To avoid vascular injury, do not use excessive force when advancing dilators. Use the smallest size suitable dilator. Guide wire must always lead dilator by several centimeters. Do not insert dilator more than a few centimeters into the vessel.

- Do not attempt to advance or withdraw guide wire, catheter, or other components through the introducer needle or dilator if resistance is felt. Continued advancement or retraction against resistance may result in major bleeding, vessel damage, serious injury to the patient, or damage to/breakage of the guide wire, catheter or other components.
- Do not power inject fluids through catheter. Catheter rupture may happen.
- Do not use pure ethyl alcohol or other organic solvents to flush or soak the central venous catheter.
- Do not use scalpel, needle and other shapes scratched the catheter.

PRECAUTIONS

- Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications.
- Only surgeons who have received appropriate training and are familiar with the principles, clinical applications, side effects and hazards should use this device.
- Do not alter this device.
- Do not cut the guide wire to alter the length.
- Catheter should not be used for long-term (more than 30 days) applications.
- The device is designed for single use only, do not reuse or re-sterilize.
- If lumen flow is impeded, do not force injection or withdrawal of fluids. Notify competent attending surgeon immediately.
- Select puncture site and required length of catheter by assessing patient anatomy and condition.
- Patient movement can displace catheter tip. Use should be limited to properly controlled hospital environment.
- The device is operated under sterile environment.
- Do not use this device after expiry date printed on the label.
- Do not use this device if the package is damaged.
- After use, dispose the device according to hospital, administrative or government policies.

COMPLICATIONS/POTENTIAL ADVERSE EVENTS

- Cardiac tamponade secondary in vessel wall,
- Atrial or ventricular perforation,
- Pleural and mediastinal injuries,
- Air embolism, catheter embolism,
- Thoracic duct laceration, bacteremia,
- Septicemia, thrombosis,
- Inadvertent arterial puncture,
- Nerve damage, hematoma formation,
- Haemorrhage, dysrhythmia, hemothorax,
- Pneumothorax,
- Catheter rupture,
- Catheter malposition, catheter occlusion,
- Hydrothorax/pleural effusion,
- Chylothorax,
- Hemomediastinum and hydromediastinum

HOW SUPPLIED

The central venous catheter kit is supplied sterile and non-pyrogenic for single use only.

STORAGE

- Store the central venous kit in a clean, dry and dark place to avoid extended exposure to light and moisture.
- Storage environment should be rat-proof and moth-proof in order to keep the integrity of package.
- Keep it from contacting corrosion gas.
- Storage temperature: 0 °C to 40 °C
- Storage humidity: 80%

INSTRUCTIONS FOR USE

1. Chose appropriate model device, Remove the device from package and ensure that all components are integral and unbroken before use.
2. Flush the catheter lumens and the dilator with saline, make sure that the dilator connecting the distal lumen should be open for the purpose of thread through.
3. Use aseptic technique and adopt local anesthesia to prepare and drape the insertion site as required.
4. Puncture the intended vein by the introducer needle.
5. After successful puncture, use the guide wire advancer to advance the guide wire through the introducer needle into vein. During advancing guide wire, no resistance should be felt if the tip of introducer needle correctly goes into the vein. Otherwise, the tip of introducer needle is in the vascular peripheral tissue or the vessel wall. At this time, the resistance felt will become larger due to the advance of the guide wire. The J-shape tip of the guide wire can help avoid perforating wound. In this condition, please hold the introducer needle to softly withdraw the guide wire toward outside.

Caution: If the guide wire is tightly twisted, it cannot be pulled back solely from the introducer needle, in this case, please draw them out together, and replace and choose new puncture site for CVC insertion.

6. After the guide wire tip has gone into the vessel to the required depth, hold guide wire in place and remove the introducer needle.
7. Insert the dilator from its tip into the vessel along the guide wire, then rotate it softly to enlarge the vessel for easy access of catheter, then remove it.

Caution: Do not let the dilator in the place for longer than necessary in case of the perforation of vessel wall.

8. Insert the central venous catheter, starting from the blue tip, go through the guide wire, when the blue tip touches skin, hold the catheter, then softly rotate and advance it.
9. Check the "cm" mark on the catheter as positioning reference, advance the catheter to the central venous tip position and record its length. Hold the catheter to withdraw the guide wire if the catheter has reached the required depth.



















Caution: Although the possibility of breaking guide wire is very small, operator must understand that overexertion may cause tensile failure. The specially designed guide wire should be smooth in and out, if resistance is felt when drawing it back, it may twist in the head of catheter, in this case, overexertion may result in tensile failure. So please draw back the catheter for 2 or 3 centimeters while keeping guide wire in its original position. Then withdraw the guide wire only. If there is still resistance, please withdraw both the catheter and guide wire out together.

10. After extracting guide wire, check its integrity.
11. Use syringe to connect the catheter hub and draw back and push the syringe piston for inspecting that the flow rate of central venous catheter is normal and there is no barrier.
12. Then remove the syringe and connect proper injection cap selected with catheter hub.
13. If necessary, please use X-ray to determine position the catheter.
14. Suture the catheter clamp to fix the catheter on patient's body.

Caution: do not suture directly on the peripheral part of catheter in case of cutting and breaking it.

15. Make sure the central venous catheter kit does not stay in patient's body for more than 30 days.
16. After use, dispose the device according to hospital, administrative or government policies.

DIFINITIONS

	Caution		Keep dry
	Batch code		Non-pyrogenic
	Do not re-sterilize		Do not use if package is damaged.
	Use-by date		Do not re-use
	Sterilized using ethylene oxide		Date of manufacture
	Catalogue number		Consult instructions for use
	Manufacturer		Keep away from sunlight
	Temperature limit		Authorized representative in the European Community
	CE Marking		Notified ID number



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