3. Product descriptions

3.1 Product name

Product Names: Disposable Central Venous Catheter Kit

Trade Name: SAFECATH

3.2 General device description

3.2.1 Indications for use

The single and multiple-lumen catheters permit venous access to the adult and paediatric central circulation for the administration of medicines, blood sampling and pressure monitoring.

3.2.2 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
- ✧ Abnormity at puncture or dissection site such as an enlarged thyroid gland or other tumors
- ✧ Critical condition of emphysema
- ✧ Distinctive aberrance at puncture site, such as burns, etc.

3.2.3 Classification and conformity assessment route

Classification:

Product and accessory	classification	UMDNS- Code
Disposable central venous catheter kit	Class III	16615
Disposable central venous catheter	Class III, Rule 7	10729
guide wire	Class III, Rule 6	11925
Introducer needle	Class IIa, Rule 6	12727
Blue introducer syringe	Class IIa, Rule 6	15256
Dilator	Class IIa, Rule 6	15215
Heparin cap	Class IIa, Rule 2	16081
Scalpel	Class IIa, Rule 6	12252

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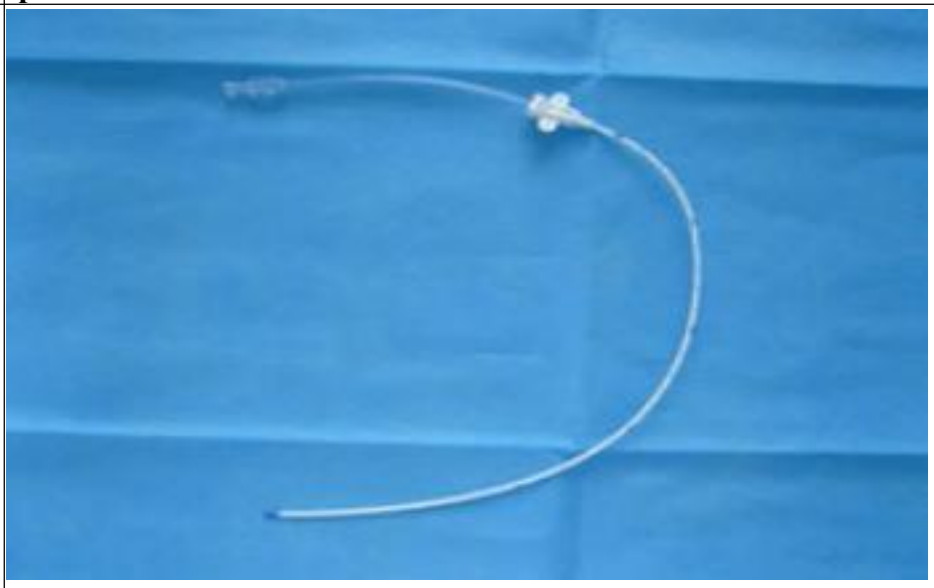
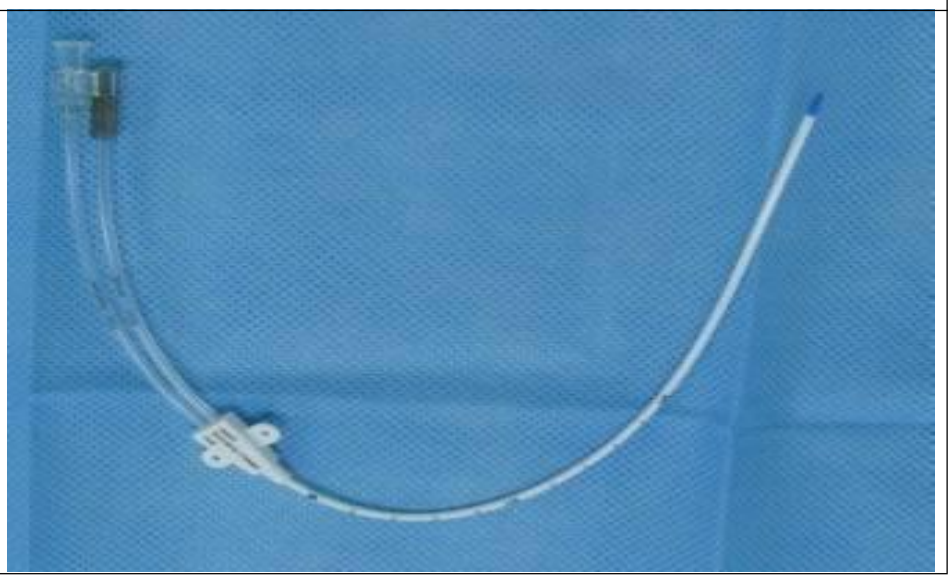
Syringe	Class IIa, Rule 2	13940
Stanch clip	Class I, Rule 1	10875
Catheter clamp	Class I, Rule 1	10875
Rigid fastener	Class I, Rule 1	10875

Conformity assessment route: Annex IX of MDD 93/42/EEC

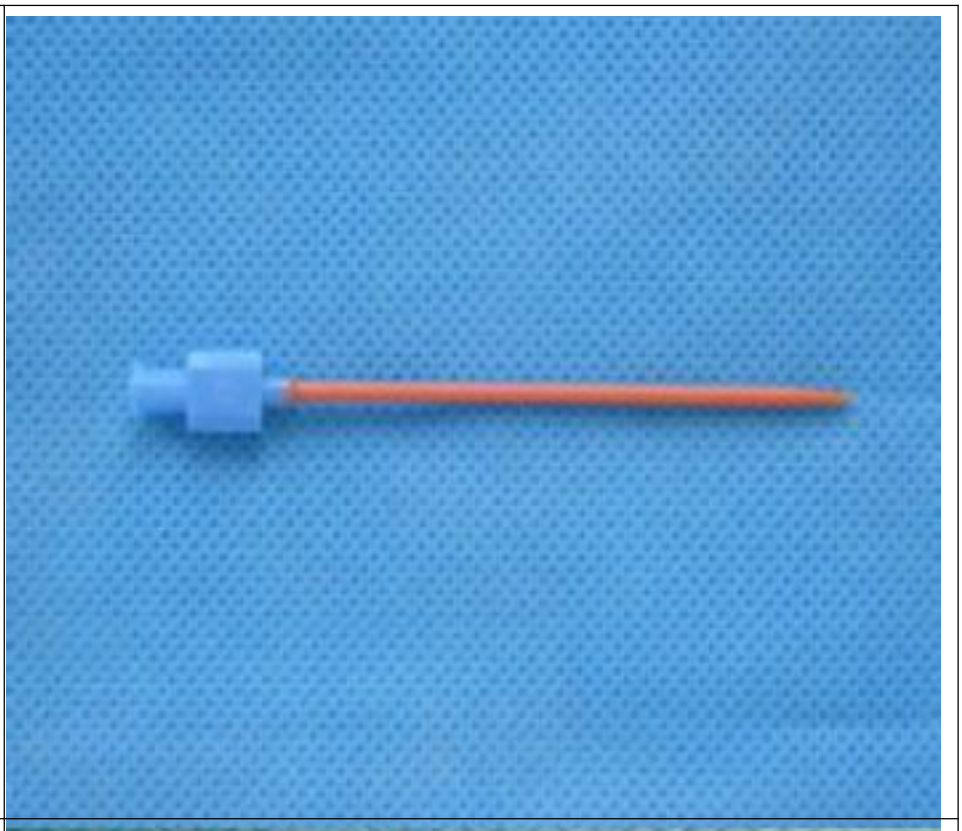
3.2.4 Photographs of Product

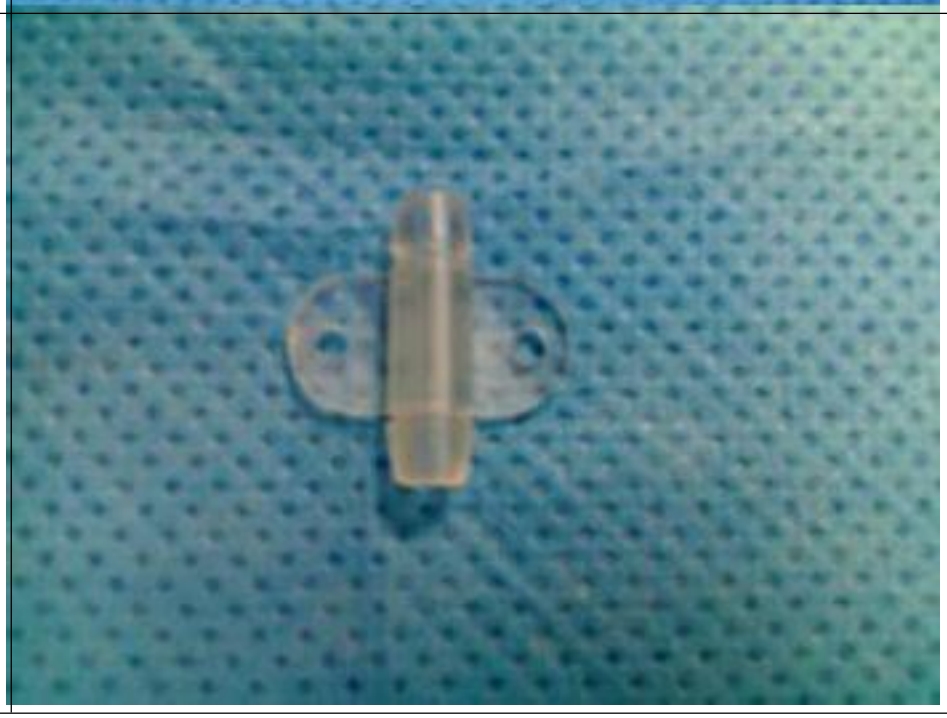
Disposable Central Venous Catheter Kit contains Disposable Central Venous Catheter,Guide wire,Blue introducer syringe,Introducer needle,Dilator,Heparin cap,Stanch clip,Catheter clamp, Rigid fastener,Scalpel and Syringe.

name	picture
Disposable central venous catheter single lumen OD:1.05~2.1mm Effective length130~600mm	
Disposable central venous catheter Double lumen OD: 1.35~3.85mm Effective length：50~300mm	

Disposable central venous catheter Multi lumen OD: 1.85~2.35mm Effective length：80~300mm	
guide wire OD: 0.46~0.97mm Length:450~700mm	

blue introducer syringe 5ml	
Introducer needle MMN1870 External diameter：1.25mm； Effective length：70mm MMN2038 External diameter：0.9mm； Effective length：38mm	

Dilator External diameter： 5F 1.65mm 6F 2.00mm 7F 2.30mm 8F 2.70mm 12F 4.00mm	
Heparin cap	

Stanch Clip	
Catheter Clamp	

Rigid fastener	
Scalpel Model：11#	

Syringe Syringe size：5ml Needle size：7#	

3.2.5 Principle of operation

Such catheters are typically introduced using percutaneous entry techniques, such as the well-known Seldinger techinique. After skin disinfection, local anesthetic is applied if required. The location of the vein is then identified by landmarks and the introducer needle assembled the Blue introducer syringe filled with normal saline is introduce into the selected vein. Once puncture is confirmed, then the guide wire is inserted from the end of the Blue introducer syringe and passed to required position, after which the introducer needle should be withdrawn. A dilator may be passed over the guidewire to slightly enlarge the tract, and the catheter itself is then passed over the guidewire, which is then removed. Transfusion can be performed immediately after the end of the catheter is connected with the port.

3.2.6 Variants

3.2.6.1 Model names and configurations

The specification model of the central venous catheter kit are classified by the central venous catheters.

The serial numbers of the central venous catheter kit are as follows

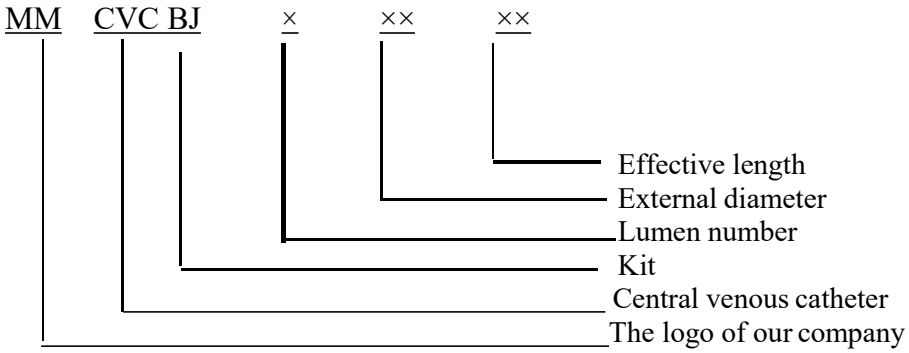


Fig1 Classification methods of central venous catheter kit

According to lumen numbers of catheters, the kits are classified into signal-lumen, double-lumen and triple-lumen central venous catheter kits.

Model name(s)	Model No(s)	Variant(s)
Single Lumen Catheter	MMCVCBJ1	——
Two-Lumen Catheter	MMCVCBJ2	——
Triple Lumen Catheter	MMCVCBJ3	——

3.2.6.2 Functional component

A central venous catheter (CVC) is a long, soft, thin, hollow tube placed into a large vein in the neck (internal jugular vein), chest (subclavian vein) or groin (femoral vein). A central venous catheter is much like an intravenous (IV) catheter that is placed in a small vein in an arm, except that a central venous catheter is longer and is placed in a large vein leading to the heart. It is used to administer medication or fluids, obtain blood tests (specifically the "mixed venous oxygen saturation"), and directly obtain cardiovascular measurements such as the central venous pressure. Certain medications, such as inotropes and amiodarone, are preferably given through a central line. Intensive treatment of patients with onc-hematological diseases often relies on the use of venous access devices, expecially in pediatric age, when the positioning of CVC represents an essential step in the management of these patients to allow the infusion of chemotherapy agents, blood products, total parenteral nutrition(TPN), intensive care, therapeutic drugs and to perform blood sampling.

A central venous catheter is made up of three main parts, including body, extension line and adapter. Polyurethane(PU), is high degree of biocompatibility, makes up the body of the

catheters. The body is radiopaque to help confirm catheter tip location in the patient by chest X-ray. To reduce the chance for vessel trauma, and have a special soft-tip which is more pliant than the rest of the catheter. The extension line is also made up of PU, the end of which is linked to a female Luer adapter.

Dependent on its use, the catheter is monoluminal, biluminal or triluminal, dependent on the actual number of extension line or lumens (1, 2 and 3 respectively).

This kind Central Venous Catheter kit possesses the following features:

Central Venous Catheter reduces the risk and vascular trauma due it specially formulated and biocompatible Polyurethane material which provides strength during insertion and also softens at body temperature to conform to the body tissues.

Soft flexible guide wire provides good torque to ensure firm insertion and also prevents vessel perforation .

Specially designed soft & beveled tip for smooth & easy insertion of catheter. Clear and definite marking facilitates correct placement of catheter tip.

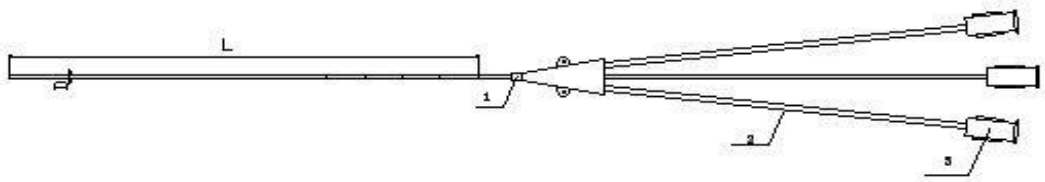
Radio-opaque Catheter.

Table1-Technical data of Central Venous Catheter

Model (MMCVCBJ)	External diameter (GorF)	Outer Diameter (mm)	effective length (mm)	Lumen numbers	Nominal flowrate (ml/min)	Peak Tensile of Catheter body(N)	Peak Tensile of Soft tip(N)
1-14-15	14G	2.1	150	1	110	≥15	≥5
1-14-20	14G	2.1	200	1	100	≥15	≥5
1-14-30	14G	2.1	300	1	95	≥15	≥5
1-16-15	16G	1.7	150	1	54	≥10	≥4
1-16-20	16G	1.7	200	1	52	≥10	≥4
1-16-30	16G	1.7	300	1	40	≥10	≥4
1-18-15	18G	1.3	150	1	21	≥10	≥4
1-18-20	18G	1.3	200	1	18	≥10	≥4
1-18-30	18G	1.3	300	1	14	≥10	≥4
1-20-13	20G	1.05	130	1	20	≥5	≥4
1-20-20	20G	1.05	200	1	15	≥5	≥4
1-40-45	4F	1.35	450	1	6	≥10	≥4
1-40-60	4F	1.35	600	1	5	≥10	≥4
1-50-45	5F	1.70	450	1	4	≥10	≥4

1-50-60	5F	1.70	600	1	3	≥10	≥4
2-40-05	4F	1.35	50	2	20/14	≥10	≥4
2-40-08	4F	1.35	80	2	17/11	≥10	≥4
2-40-13	4F	1.35	130	2	15/8	≥10	≥4
2-50-08	5F	1.7	80	2	38/17	≥10	≥4
2-50-13	5F	1.7	130	2	36/13	≥10	≥4
2-50-20	5F	1.7	200	2	30/10	≥10	≥4
2-70-15	7F	2.35	150	2	90/24	≥15	≥5
2-70-20	7F	2.35	200	2	83/18	≥15	≥5
2-70-30	7F	2.35	300	2	75/12	≥15	≥5
2-70-50	7F	2.35	500	2	68/7	≥15	≥5
$2\text{-}11_{5}\text{-}13$	11.5F	3.85	130	2	120/110	≥15	≥5
$2\text{-}11_{5}\text{-}20$	11.5F	3.85	200	2	113/90	≥15	≥5
$2\text{-}11_{5}\text{-}16$	11.5F	3.85	160	2	120/100	≥15	≥5
3-55-08	5.5F	1.85	80	3	53/6/6	≥15	≥5
3-55-13	5.5F	1.85	130	3	21/7/8	≥15	≥5
3-70-15	7F	2.35	150	3	64/28/28	≥15	≥5
3-70-20	7F	2.35	200	3	50/18/17	≥15	≥5
3-70-30	7F	2.35	300	3	43/12/11	≥15	≥5

The basic structure is as follows:



D- Outside diameter L- Effective length 1- Delta 2- Extension line 3- Hub

Introduction of the guide wire

The Disposable guide wire is mainly used in the process of interventional therapy for guiding and orienting when the medical and implant devices enter the human organs. It is composed of core wire, safety wire and spring coil, which are made of 304 stainless steel.

Guide wire can be divided into fixed and movable – core guide wire based on its structure. The internal core of fixed core wire is fixed and welded at both ends. So the hardness, soft length and shape of the wire head are not movable. There are two kinds of head shapes, erect and J. The erect guide wire has changed soft length on its head, from 3.0 cm to 3.5 cm, so that it can be divided into soft erect, long soft erect, long long soft erect and especially long soft erect wire. The bending radius of J type guide wire head is generally 1- 15 mm. Since the core wire of movable core guide wire is only welded and fixed on its tail but not head, the softness, soft length and shape of the wire head are changeable when pulling back the internal core. This kind of guide wire is especially convenience for super-selective catheterization or passing acute angle of the blood vessel division.

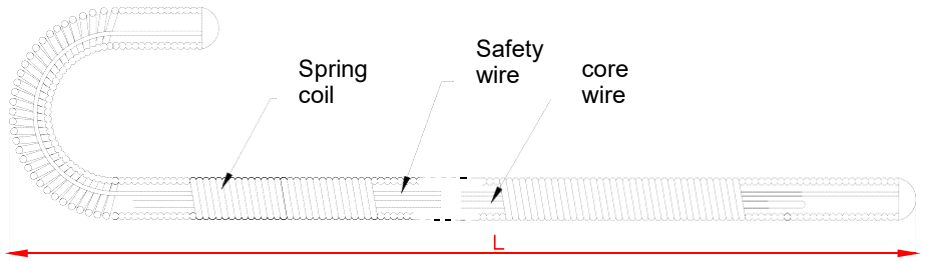
The diameter of the guide wire is generally around 0.018- 0.038 inches (0.45- 0.97 mm). Most thin wire is 0.010 inches and most thick one is 0.052 inches. The length varies from 40 to 450 cm according to different functions. Guide wire fit for central venous catheter is fixed, with its external diameter around 0.018- 0.038 inches and length 45~70cm.

Table2-The technical data of Guide wire:

Model (MMNJF)	Outer Diameter (mm)	length (mm)	Peak Tensile (N)
18045	0.018 (0.46)	45	-
18060	0.018 (0.46)	60	-
18070	0.018 (0.46)	70	-
21045	0.021 (0.53)	45	-

21060	0.021 (0.53)	60	-
21070	0.021 (0.53)	70	-
25045	0.025 (0.64)	45	≥5
25060	0.025 (0.64)	60	≥5
25070	0.025 (0.64)	70	≥5
32045	0.032 (0.81)	45	≥10
32060	0.032 (0.81)	60	≥10
32070	0.032 (0.81)	70	≥10
35045	0.035 (0.89)	45	≥10
35060	0.035 (0.89)	60	≥10
35070	0.035 (0.89)	70	≥10
38045	0.038 (0.97)	45	≥10
38060	0.038 (0.97)	60	≥10
38070	0.038 (0.97)	70	≥10

The basic structure is as follows:

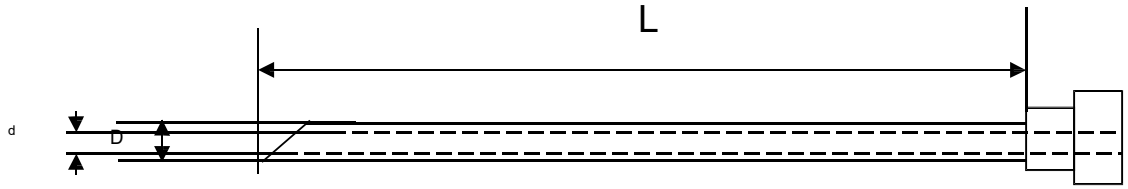


MMNJF guide wire

Introduction for the introducer needle

The disposable introducer needle is mainly used for interventional diagnosis and therapy. It punctures anterior wall of the blood vessel and guides the guide wire into blood vessels. As the central venous catheter puncture sites are usually at subclavian vein, internal jugular vein, it can reduce the damage and hemorrhage to structures near to blood vessel, using introducer needle. The needle is 3.8~ 7 cm long and its external diameter is from NO. 18- 21 (0.8~ 1.25 mm).The needle is made of 304 stainless steel and its injection adapter is made from polycarbonates.

The basic structure is as follows:

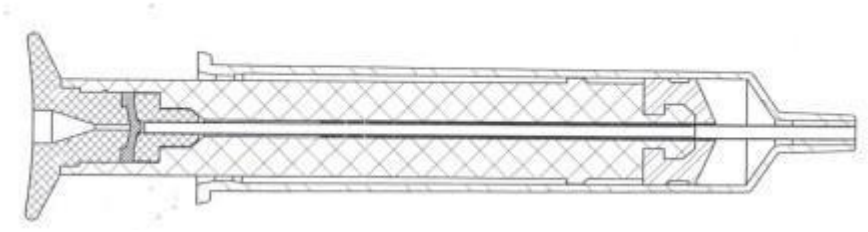


MMN introducer needle

Introduction of Blue introducer syringe

Blue introducer syringe for the introduction of a catheter guide wire into a patient's body, said introduction syringe comprises a hollow syringe barrel including a fluid chamber, a plunger movable between an advanced position defining a distal end and retracted position defining a proximal end and slidably disposed within said fluid chamber, a guide passage means formed longitudinally through and engaged with a distal end of said hollow syringe barrel and said plunger, said guide passage means including an aperture disposed within said fluid chamber and a valve assembly disposed in operative relationship relative to said guide passage means to prevent passage of fluid through said guide passage means during flushing or aspirating of said catheter introduction syringe or during the introduction or withdrawal of catheter guide wire through said guide passage means and to permit fluid to flow from the patient's body into said fluid chamber through said aperture, said guide passage means being configured to maintain the catheter guide wire in a substantially straight configuration while the catheter guide wire is disposed within said guide passage means.

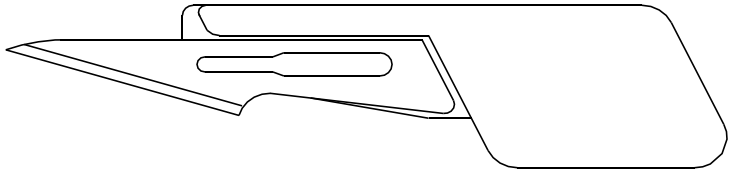
The basic structure is as follows:



Introduction of Scalpel

Scalpel consisted of hilt，sheath and blade，The material of blade is 304 stainless steel， the module is 11#，Hilt material is ABS，Sheath material is PP. Scalpel mainly used for percutaneous central venous catheter the epidermis when speak, the calpel is the whole

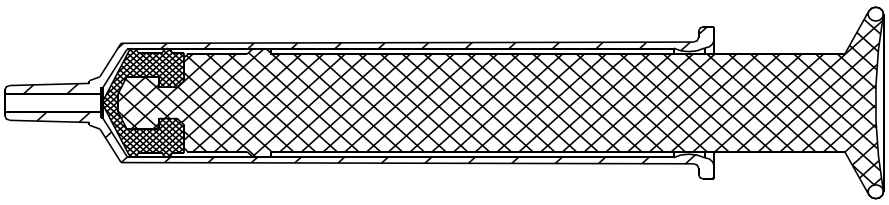
process of catheter auxiliary parts required application, Can also be used to for catheter kit without shear equipment accessories use, catheter after completing suture fixation of cutting work relict.



Scalpel

Introduction of Syringe

Syringe mainly component are barrel, core bin and piston. Barrel and core bin are made of PP.Piston material is Synthetic rubber. The main purpose of the product:1. Used for washing catheter before placed catheter. Central venous catheter percutaneous catheter ago, first to catheter flushing work, flush to check the pod unblocked, each chamber catheter from internal air, thoroughly wash catheter inside possible particles. 2. when the puncture equipment of CVC Kit is Y needle, syringe and Y needle combination percutaneous ,and in the process of taking back the puncture blood, used to determine the correct tip into the vascular site. 3.
When successful and percutaneous catheter through the puncture site to complete the work place, the application of the syringe on the catheter withdrawing the cavity inspection to ensure proper catheter placement in the bloodstream. 4. Complete the catheter placement is confirmed, with all cavity catheter syringe of saline or heparin saline flush and drain the blood in the catheter memory to ensure catheter prior to use in the absence of the normal flow of the cavity with and without thrombosis. 5. May need to be administered to patients when the work.



Syringe

Insertion

Generally, a central venous catheter is surgically inserted into a major vein, such as the superior vena cava. Such catheters are typically introduced using percutaneous entry techniques, such as the well-known Seldinger techinique. In the Seldinger technique, the skin is cleaned, and local anesthetic applied if required. The location of the vein is then identified by landmarks or with the use of a small ultrasound device. A hollow needle is advanced through the skin until blood is aspirated; the color of the blood and the rate of its flow help distinguish it from arterial blood (suggesting that an artery has been accidentally punctured).

A blunt guidewire is passed through the needle, and the needle is then removed. A dilating device may be passed over the guidewire to slightly enlarge the tract, and the catheter itself is then passed over the guidewire, which is then removed. All the lumens of the line are aspirated (to ensure that they are all positioned inside the vein) and flushed.

For jugular and subclavian lines, a chest X-ray is typically performed to ensure the line is positioned inside the superior vena cava and, in the case of insertion through the subclavian vein, that there is no resultant pneumothorax.

3.2.6.3 Materials

In Table 3-1 is a list of materials used and if in direct contact with blood or tissues.

The Disposable central venous catheter kit manufactured by Target selects 304 stainless steel, PP, nylon, and polycarbonate with good biocompatibility, which is commonly used in clinic for several years.

Table 3-1 Main Raw Materials & Suppliers

Products	Assembly unit	Materials	Supplier
Central venous catheter	Blue soft tube	TPU	Lepu Medical Technology (Beijing) Co., Ltd
	Catheter body	TPU	
	Delta	PVC	
	Extension line	TPU	
	Stanch clip	ABS	
	Catheter clamp	PVC	
	Rigid fastener	PP	

Guide wire	Guide wire	304 stainless steel	Shenzhen Haikangda Technology Co., Ltd.
	Coil and protection	PE	Lepu Medical Technology (Beijing) Co., Ltd
	Coil booster	PP	
	Pipe card	PP	
	Protection cap	PE	

3.2.6.4 Drawings

The main Drawing list of Disposable Central Venous Catheter Kit is shown as Table 3-2:

Table 3-2 Main drawing list of disposable central venous catheter kit

Products	Assembly unit	Item number
Central venous catheter	Central venous catheter	MMCVC-I-00
	Blue soft tube	MMCVC-I-01
	Tube	MMCVC-I-02
	Extension Line	CVC-01
	Delta	CVC-02
	Catheter Clamp	CVC-03
	Hub	CVC-04
	Delta block-triple lumen	CVC-05
	Delta block-single lumen	CVC-06
	Delta block-double lumen	CVC-07
	Stanch clip	CVC-08
Introducer needle	Needle	MMN-I-001
	Injection adapter	MMN-I-002
Guide wire	Guide wire	GW-0
	Coil and protection tube	GW-1
	Double-link Tube clamp	GW-2
	Triple-link Tube clamp	GW-3
	Protection cap	GW-4
	Coil booster	GW-5
Dilator	Tube seat	KZG-1
	Tube	MMCVC-1-1.02
	Bar	LZG-00
	Large cap	LZG-01

	Inside and outside pipe	LZG-02
	Black rubber plug	LZG-04
	Bobbin	LP0709001
Heparin cap	Main subject	LP08020
	End cover	LP08021
Syringe	Barrel	CVCB-ZSQ-01
	Core Bin	CVCB-ZSQ-02
	Piston	CVCB-ZSQ-03
Needle	Needle hub	CVCB-ZSZ-01
	Needle tube	CVCB-ZSZ-02
Scalpel	Blade	CVC-PPT-01
	Hilt	CVC-PPT-02
	Sheath	CVC-PPT-03

3.2.7 Joint use devices

Below is a list of accessories, adapters, and other devices or equipments intended to be used in combination with the Disposable Central Venous Catheter Kit.

- Heparin cap
- Needless connector
- Disposable infusion set
- Syringe
- Disposable blood pressure transducer
- Guide wire

The Essential Requirements are met when the device is attached or used with these accessories. Reference documents see ***Appendix 3.1 CE-CVCB-048 Statement of joint use medical device of Disposable Central Venous Catheter Kit***

4 Market history

Lepu Medical Technology (Beijing) Co., Ltd is a Sino-America joint-venture established in 1999, which was certified as a high- tech enterprise by the Beijing Municipal Science and Technology Commission. It is mainly engaged in development, production and sale of the medical equipments. Beijing Target Medical Technologies, Inc. is a wholly owned subsidiary company of Lepu Medical Technology (Beijing) Co., Ltd.

Beijing Target Medical Technologies, Inc. is the first manufacture in China engaged in development, production and sale of the central venous catheters. In 2000, it readily got its registration certificate authorized by State Food and Drug Administration. Beijing Target Medical Technologies, Inc. is the only company who own the Hot Melt Adhesive Technique in China. It is a high- tech enterprise with standard management and reliable quality certified by the Beijing