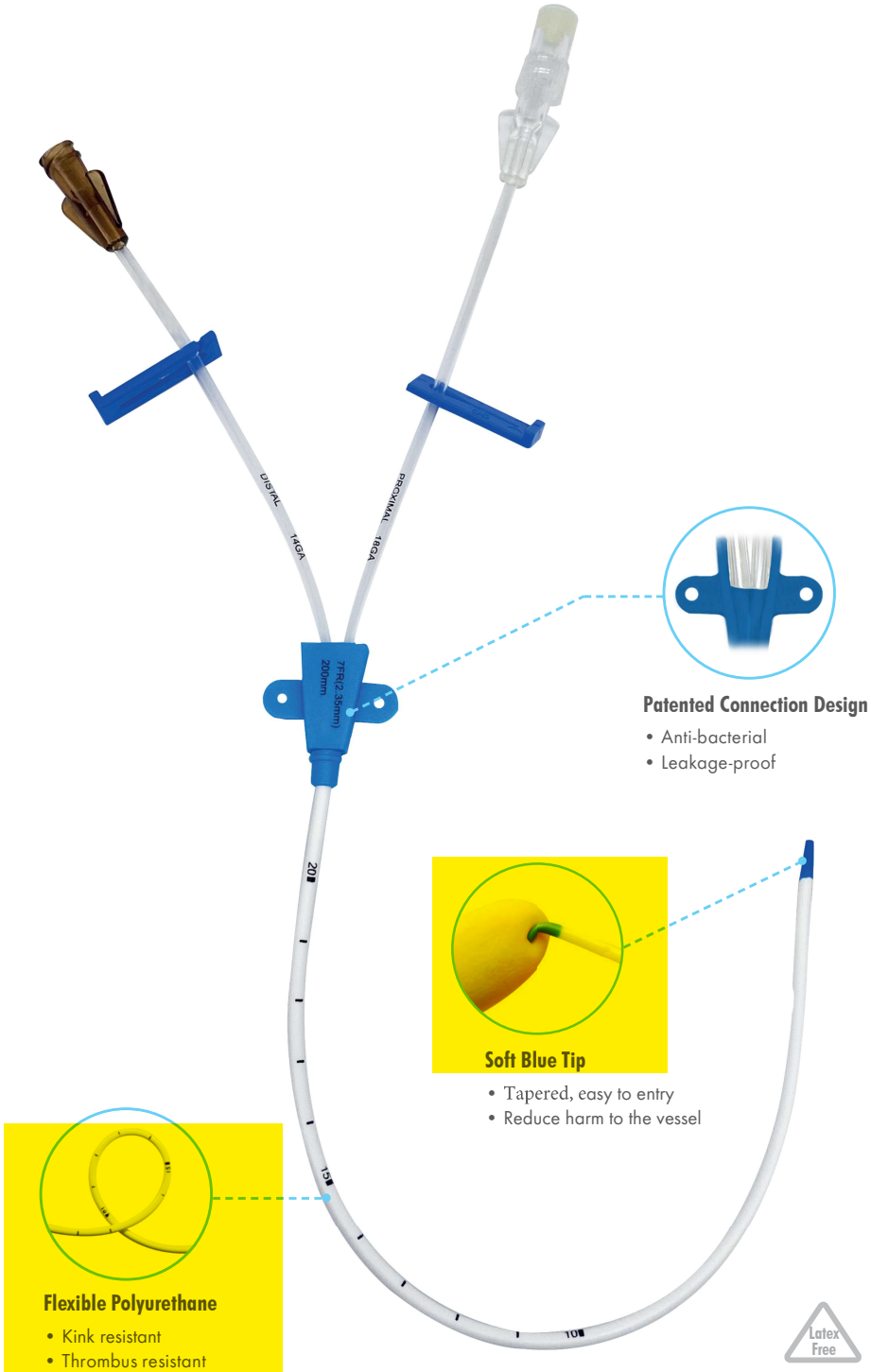
62 pirkimo dalis - CENTRINĖS VENOS 1 KANALO KATETERIO RINKINYS

SAFECATH

Dokumentą elektroniniu parašu pasirašė POVILAS,JANONIS
Data: 2025-04-29 15:34:23

Disposable Central Venous Catheter Kit CE 0123



Patented Connection Design
- Anti-bacterial
- Leakage-proof

Soft Blue Tip
- Tapered, easy to entry
- Reduce harm to the vessel

Flexible Polyurethane
- Kink resistant
- Thrombus resistant
- Radiopaque
- Marked in centimeters

Latex Free

LEPU MEDICAL

Product Information

Features
- Soft blue tip
- Patented connection design
- Flexible polyurethane material
- Latex-free

Ranges
- Single/double/triple lumen
- 5-50cm multi-catheter lengths

Package Componets

Standard Package:

- Catheter (1)
- Guidewire (1)
- Dilator (1)
- Introducer Needle (0/1)
- Y-Introducer Needle (0/1)
- Catheter Clamp (1)
- Rigid Fastener (1)
- Blue Introducer Syringe (0/1)
- Heparin Cap (1/2/3)
- Stanch Clip (1/2/3)
- Syringe (1/2)
- Injection Needle (1)
- Scalpe (1)

Ordering Information

Model	guidewire kink-proof nitinol guidewire, one end straight, the other "J" shaped;		dilator material: PP	blue introducer syringe	introducer needle		Y-introducer needle		fixation clip	number syringes（5ml）	Symbol on thr pakage
	OD/inch	length/mm			OD/G	length/mm	OD/G	length/mm			
MMCVCBJ 1-14-15	0.035	600	8F	5 mL	18	70	/	/	Ø2.1	1	
MMCVCBJ 1-14-20	0.035	600	8F	5 mL	18	70	/	/	Ø2.1	1	
MMCVCBJ 1-14-30	0.035	700	8F	5 mL	18	70	/	/	Ø2.1	1	
MMCVCBJ 1-16-15	0.035	600	7F	5 mL	18	70	/	/	Ø1.5	1	
MMCVCBJ 1-16-20	0.035	600	7F	5 mL	18	70	/	/	Ø1.5	1	
MMCVCBJ 1-16-30	0.035	700	7F	5 mL	18	70	/	/	Ø1.5	1	
MMCVCBJ2-70-15	0.035	600	8.5F	5 mL	18	70	/	/	φ2.3	1	
MMCVCBJ2-70-20	0.035	600	8.5F	5 mL	18	70	/	/	φ2.3	1	
MMCVCBJ2-70-30	0.035	700	8.5F	5 mL	18	70	/	/	φ2.3	1	
MMCVCBJ2-70-50	0.035	700	8.5F	5 mL	18	70	/	/	φ2.3	1	
MMCVCBJ3-70-15	0.035	600	8.5F	5 mL	18	70	/	/	φ2.3	1	
MMCVCBJ3-70-20	0.035	600	8.5F	5 mL	18	70	/	/	φ2.3	1	
MMCVCBJ3-70-30	0.035	700	8.5F	5 mL	18	70	/	/	φ2.3	1	
MMCVCBJY1-14-15	0.035	600	8F	/	/	/	18	70	Ø2.1	2	
MMCVCBJY1-14-20	0.035	600	8F	/	/	/	18	70	Ø2.1	2	
MMCVCBJY1-14-30	0.035	700	8F	/	/	/	18	70	Ø2.1	2	
MMCVCBJY1-16-15	0.035	600	7F	/	/	/	18	70	Ø1.5	2	
MMCVCBJY1-16-20	0.035	600	7F	/	/	/	18	70	Ø1.5	2	
MMCVCBJY1-16-30	0.035	700	7F	/	/	/	18	70	Ø1.5	2	
MMCVCBJY1-18-15	0.021	600	5F	/	/	/	20	38	Ø1.3	2	
MMCVCBJY1-18-20	0.021	600	5F	/	/	/	20	38	Ø1.3	2	
MMCVCBJY1-18-30	0.021	600	5F	/	/	/	20	38	Ø1.3	2	
MMCVCBJY1-20-13	0.021	600	5F	/	/	/	20	38	Ø1.0	2	
MMCVCBJY1-20-20	0.021	600	5F	/	/	/	20	38	Ø1.0	2	
MMCVCBJY2-40-05	0.021	600	5F	/	/	/	20	38	Ø1.3	2	
MMCVCBJY2-40-08	0.021	600	5F	/	/	/	20	38	Ø1.3	2	
MMCVCBJY2-40-13	0.021	600	5F	/	/	/	20	38	Ø1.3	2	
MMCVCBJY2-50-08	0.021	600	6F	/	/	/	20	38	Ø1.7	2	
MMCVCBJY2-50-13	0.021	600	6F	/	/	/	20	38	Ø1.7	2	
MMCVCBJY2-50-20	0.021	600	6F	/	/	/	20	38	Ø1.7	2	
MMCVCBJY2-70-15	0.035	600	8.5F	/	/	/	18	70	Ø2.3	2	
MMCVCBJY2-70-20	0.035	600	8.5F	/	/	/	18	70	Ø2.3	2	
MMCVCBJY2-70-30	0.035	700	8.5F	/	/	/	18	70	Ø2.3	2	
MMCVCBJY2-70-50	0.035	700	8.5F	/	/	/	18	70	Ø2.3	2	
MMCVCBJY3-55-08	0.021	600	6F	/	/	/	20	38	Ø1.7	2	
MMCVCBJY3-55-13	0.021	600	6F	/	/	/	20	38	Ø1.7	2	
MMCVCBJY3-70-15	0.035	600	8.5F	/	/	/	18	70	Ø2.3	2	
MMCVCBJY3-70-20	0.035	600	8.5F	/	/	/	18	70	Ø2.3	2	
MMCVCBJY3-70-30	0.035	700	8.5F	/	/	/	18	70	Ø2.3	2	

62.1

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https://en.lepumedical.com/e-ifu/

Brown=STERILE

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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:

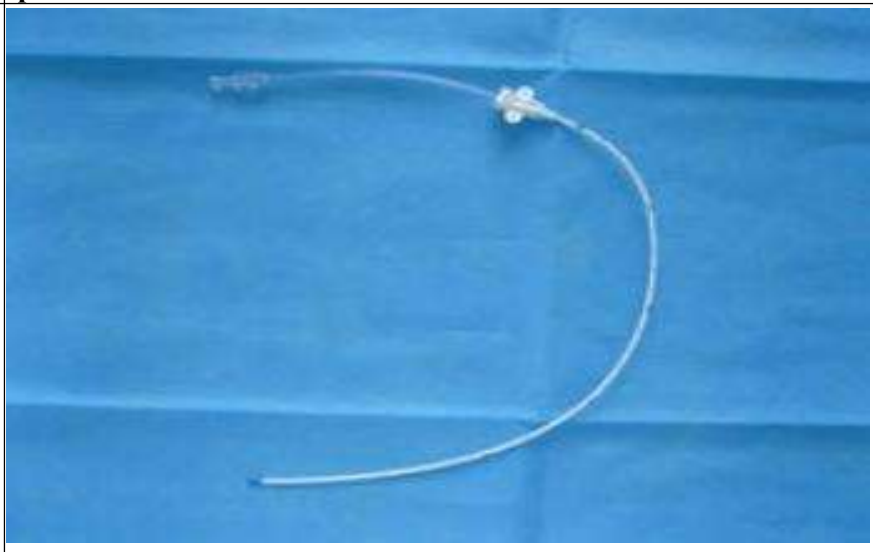
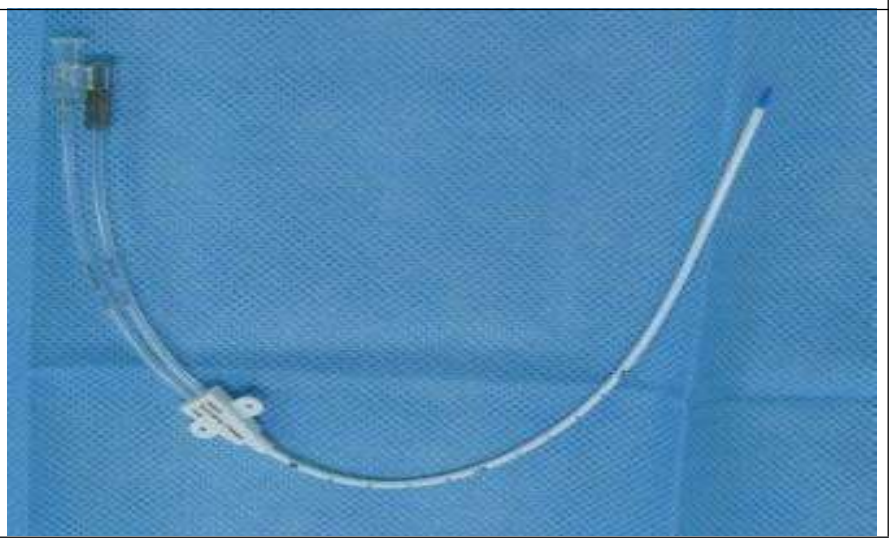
Product and accessory	classification	UMDNS- Code
Disposable central venous catheter kit	Class III	16615
Disposable central venous catheter	Class III, Rule 7	10729
guide wire	Class III, Rule 6	11925
Introducer needle	Class IIa, Rule 6	12727
Blue introducer syringe	Class IIa, Rule 6	15256
Dilator	Class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

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

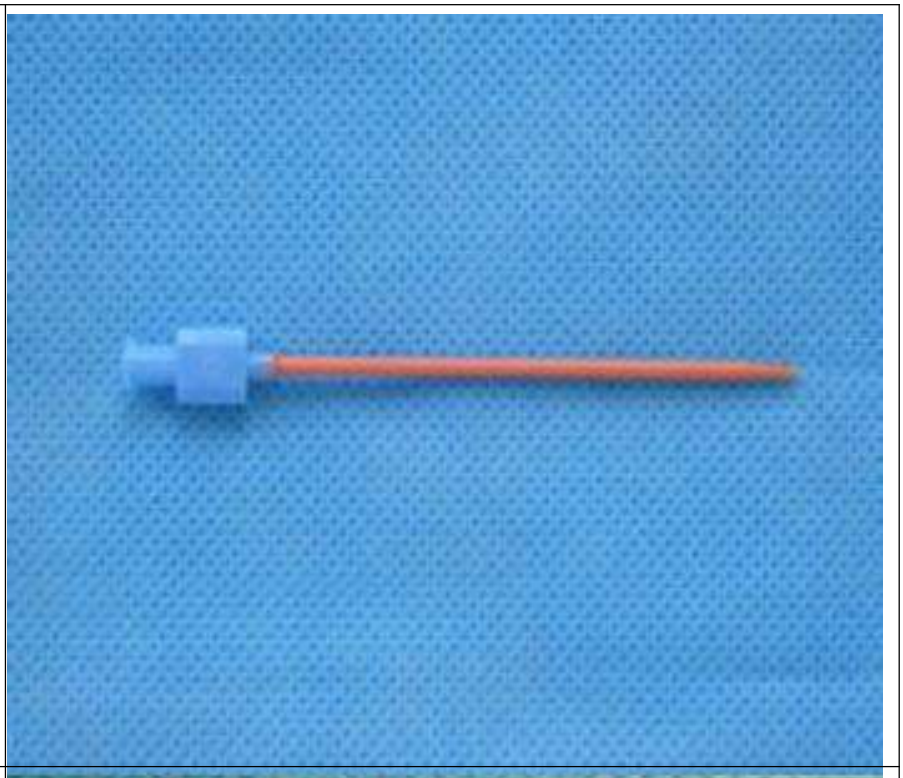
Disposable Central Venous Catheter Kit contains Disposable Central Venous Catheter,Guide wire,Blue introducer syringe,Introducer needle,Dilator,Heparin cap,Stanch clip,Catheter clamp, Rigid fastener,Scalpel and Syringe.

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	

62 pirkimo dalis - CENTRINĖS VENOS 1 KANALO KATETERIO RINKINYS

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

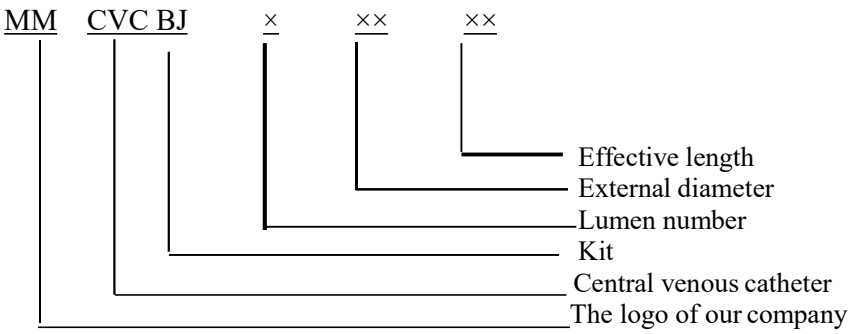


Fig1 Classification methods of central venous catheter kit

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 .

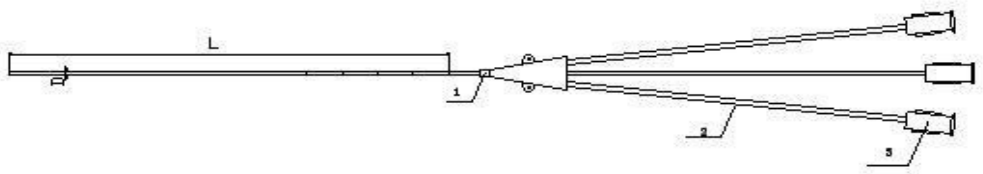
Radio-opaque Catheter.

Table1-Technical data of Central Venous Catheter

Model (MMCVCJ)	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
62.1. 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
62.2. 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	-

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62 pirkimo dalis - CENTRINĖS VENOS 1 KANALO KATETERIO RINKINYS

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

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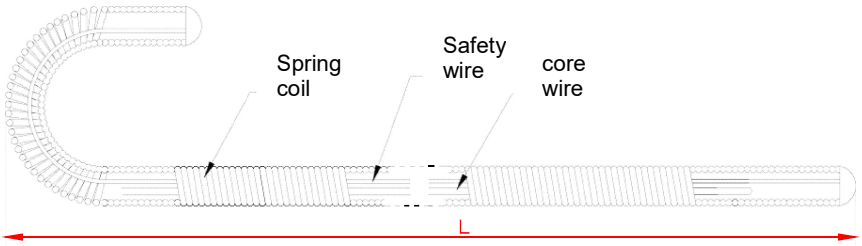
The basic structure is as follows:



MMNJF guide wire