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广东百合医疗科技股份有限公司  
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## Technical Data for Hemodialysis Catheter

### Product code

Ref. Code	Product name
FR-2116	Double Lumen Catheter, for elderly persons, magistral blood vessels catheterization, 11.5F, L-200mm
FR-2612	Double Lumen Catheter, pediatric, magistral blood vessels catheterization, 6,5F, L-75mm
FR-2613	Double Lumen Catheter, pediatric, magistral blood vessels catheterization, 6,5F, L-100mm
FR-2614	Double Lumen Catheter, pediatric, magistral blood vessels catheterization, 6,5F, L-120mm
FR-2913	Double Lumen Catheter, pediatric, magistral blood vessels catheterization, 8F, L-100mm
FR-291912	Double Lumen Catheter, pediatric, magistral blood vessels catheterization, 8,0 F, L-120mm
FR-291915	Double Lumen Catheter, pediatric, magistral blood vessels catheterization, 8,0 F, L-150 mm

### Key contents

Each HC kit contains:

- Hemodialysis catheter
- Introducer needle
- Introducer syringe
- Guidewire with advancer
- Dilator



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- Injection Cap
- Medical dressing
- Scalpel
- Needle with Suture

## Components

Description

TPU  
Silicone/TPU  
POM/ABS  
PC/PBT alloy

## Catheter

Tube  
Hub  
Extension Line  
Flat Clamps  
Female Luer Hub

PC  
Stainless Steel  
PE

## Introducer Needle

Hub  
Cannula  
Protective Tube

Polypropylene  
ABS  
Silicone rubber  
Silicone  
Stainless Steel

## Introducer Syringe

Barrel  
Plunger  
Seal  
Safety valve  
Tube

## Guidewire with advancer

Guidewire  
Dispenser  
Dispenser Clips  
Advancer  
Advancer cap

## Raw Material

Stainless Steel or Nitinol Core Guidewire  
PP  
PP  
PP  
PP

TPU

## Dilator

Female Luer Hub  
Tube

PC/PBT alloy  
PP

## Injection Cap

Shell

PET



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Core	Rubber
<b>Medical dressing</b>	Spin
<b>Scalpel</b>	Stainless Steel/PE
<b>Needle with Suture</b>	Stainless Steel/Silk

### **Packaging**

Single units: Kits packed in blister with Tyvek paper.

	Number of pieces	Dimensions
Unit Box	10	350*215*165mm
Shipping Carton	80	540*450*850mm

### **Sterilization**

With ethylene oxide to a Sterility Assurance Level of at least  $10^{-6}$

### **Storage**

Shelf life of 3 years.

- The lot number and expiry date are printed on the label put on the blister pack.
- Do not store at extreme temperature and humidity.

### **Precautions of use**

Do not use if sterile packaging is damaged or opened.  
For single use only.  
Dispose of safely after single use to avoid risk of infection.

### **Quality tests**

#### **Structural tests**

- Surface
- Corrosion resistance
- Force at break
- Force at break at soft tip
- Force at break of catheter



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- Freedom of leakage
  - Hubs
  - Flowrate

### **Biological tests**

ISO Maximization Sensitization Study

ISO AMES Mutagenicity Study of a Saline Extract

ISO 10993.11 Systemic Toxicity Study Extract

ISO 10993.4 IN VITRO Hemolysis Study Modified ASTM-EXTRACTUIN Method

ISO Test for IN VITRO Cytotoxicity

ISO Mouse Bone Marrow Micronucleus Study

Intracutaneous Reactivity Study In the Rabbit Conducted In according with the provision of the

ISO10993.10

Genotoxicity:In Sperm Aaberration Study in the mouse conducted in according with the provision of the ISO 10993.3(Extracts)

### **Chemical tests**

- ETO residual