



Guangdong Baihe Medical Technology Co., Ltd  
No. 89, Taoyuan East Road, Nanhai, Foshan, 528225  
Guangdong Province, China  
Tel: 86-757-81207300 Fax:86-757-81207311  
www.baihemedical.com/en/

广东百合医疗科技股份有限公司  
广东省佛山市南海区桃园东路89号  
电话: 86-757-81207300 传真: 86-757-81207311  
网址: www.baihemedical.com/ch/  
邮箱: able@baihemedical.com

## 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  <b>Luer-Lock connector with clamps</b> <b>Puncture needle 17G ID 1.16 x 70 mm</b> <b>Metal safety guide 0.038" Ø 0.95 x 600 mm</b> <b>Dilator 12&amp;10 F</b> <b>Blood flow rate ≥ 190 ml / min.</b>
FR-2612	Double Lumen Catheter, pediatric, magistral blood vessels catheterization, 6,5F, L-75mm  <b>Luer-Lock connector with clamps</b> <b>Puncture needle 20G ID 0,68 x 38 mm</b> <b>Metal safety guide 0.021" Ø 0,53 x 500 mm</b> <b>Dilator 7 F</b> <b>Blood flow rate ≥ 100 ml / min.</b>
FR-2613	Double Lumen Catheter, pediatric, magistral blood vessels catheterization, 6,5F, L-100mm  <b>Luer-Lock connector with clamps</b> <b>Puncture needle 20G ID 0,68 x 38 mm</b> <b>Metal safety guide 0.021" Ø 0,53 x 500 mm</b> <b>Dilator 7 F</b> <b>Blood flow rate ≥ 100 ml / min.</b>
FR-2614	Double Lumen Catheter, pediatric, magistral blood vessels catheterization, 6,5F, L-120mm  <b>Luer-Lock connector with clamps</b> <b>Puncture needle 20G ID 0,68 x 38 mm</b> <b>Metal safety guide 0.021" Ø 0,53 x 500 mm</b> <b>Dilator 7 F</b> <b>Blood flow rate ≥ 100 ml / min.</b>
FR-2913	Double Lumen Catheter, pediatric, magistral blood vessels catheterization, 8F, L-100mm  <b>Luer-Lock connector with clamps</b> <b>Puncture needle 19G ID 0.74 x 45 mm</b> <b>Metal safety guide 0.025" Ø 0,64 x 500 mm</b> <b>Dilator 9 F</b> <b>Blood flow rate ≥ 150 ml/min.</b>



Guangdong Baihe Medical Technology Co., Ltd  
No. 89, Taoyuan East Road, Nanhai, Foshan, 528225  
Guangdong Province, China  
Tel: 86-757-81207300 Fax: 86-757-81207311  
www.baihemedical.com/en/

广东百合医疗科技股份有限公司  
广东省佛山市南海区桃园东路89号  
电话: 86-757-81207300 传真: 86-757-81207311  
网址: www.baihemedical.com/ch/  
邮箱: able@baihemedical.com

FR-291912	Double Lumen Catheter, for elderly persons, magistral blood vessels catheterization, 8,0 F, L-120mm  <b>Luer-Lock connector with clamps</b> <b>Puncture needle 19G ID0.74 x 45 mm</b> <b>Metal safety guide 0.025'' Ø 0,64 x 500 mm</b> <b>Dilator 9 F</b> <b>Blood flow rate ≥ 150 ml/min.</b>
FR-291915	Double Lumen Catheter, pediatric, magistral blood vessels catheterization, 8,0 F, L-150 mm  <b>Luer-Lock connector with clamps</b> <b>Puncture needle 19G ID0.74 x 45 mm</b> <b>Metal safety guide 0.025'' Ø 0,64 x 500 mm</b> <b>Dilator 9 F</b> <b>Blood flow rate ≥ 150 ml/min.</b>

## Key contents

Each HC kit contains:

- Hemodialysis catheter
- Introducer needle
- Introducer syringe
- Guidewire with advancer
- Dilator
- Injection Cap
- Medical dressing
- Scalpel
- Needle with Suture

## Components

Description

### Catheter

Tube  
Hub  
Extension Line  
Flat Clamps

Female Luer Hub

### Introducer Needle

Hub  
Cannula  
Protective Tube

### Introducer Syringe

Barrel  
Plunger  
Seal



Guangdong Baihe Medical Technology Co., Ltd  
No. 89, Taoyuan East Road, Nanhai, Foshan, 528225  
Guangdong Province, China  
Tel: 86-757-81207300 Fax: 86-757-81207311  
www.baihemedical.com/en/

广东百合医疗科技股份有限公司  
广东省佛山市南海区桃园东路89号  
电话: 86-757-81207300 传真: 86-757-81207311  
网址: www.baihemedical.com/ch/  
邮箱: able@baihemedical.com

Safety valve  
Tube

Polypropylene  
ABS  
Silicone rubber  
Silicone  
Stainless Steel

## Raw Material

TPU  
TPU  
Silicone/TPU  
POM/ABS  
PC/PBT alloy

PC  
Stainless Steel  
PE

## Guidewire with advancer

Guidewire  
Dispenser  
Dispenser Clips  
Advancer  
Advancer cap

Stainless Steel or Nitinol Core Guidewire  
PP  
PP  
PP  
PP

## Dilator

Female Luer Hub  
Tube

PC/PBT alloy  
PP

## Injection Cap

Shell  
Core

PET  
Rubber

## Medical dressing

Spin

## Scalpel

Stainless Steel/PE

## Needle with Suture

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



Guangdong Baihe Medical Technology Co., Ltd  
No. 89, Taoyuan East Road, Nanhai, Foshan, 528225  
Guangdong Province, China  
Tel: 86-757-81207300 Fax: 86-757-81207311  
www.baihemedical.com/en/

广东百合医疗科技股份有限公司  
广东省佛山市南海区桃园东路89号  
电话: 86-757-81207300 传真: 86-757-81207311  
网址: www.baihemedical.com/ch/  
邮箱: able@baihemedical.com

---

## **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
- 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



Guangdong Baihe Medical Technology Co., Ltd  
No. 89, Taoyuan East Road, Nanhai, Foshan, 528225  
Guangdong Province, China  
Tel: 86-757-81207300 Fax: 86-757-81207311  
www.baihemedical.com/en/

广东百合医疗科技股份有限公司  
广东省佛山市南海区桃园东路89号  
电话: 86-757-81207300 传真: 86-757-81207311  
网址: www.baihemedical.com/ch/  
邮箱: able@baihemedical.com

---

ISO10993.10

Genotoxicity: In Sperm Aberration Study in the mouse conducted in accordance with the provision

of the ISO 10993.3(Extracts)

### **Chemical tests**

- ETO residual