



GUANGDONG BAIHE MEDICAL TECHNOLOGY CO., LTD.  
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## Technical Data for Hemodialysis Catheter

### Key contents

Each HC kit contains:

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

### Components

### Raw Material

Description

#### Catheter

Tube	TPU
Hub	TPU
Extension Line	Silicone/TPU
Flat Clamps	POM/ABS
Female Luer Hub	PC/PBT alloy

#### Introducer Needle

Hub	PC
Cannula	Stainless Steel
Protective Tube	PE

#### Introducer Syringe

Barrel	Polypropylene
Plunger	ABS
Seal	Silicone rubber
Safety valve	Silicone
Tube	Stainless Steel



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### **Guidewire with advancer**

Guidewire	Stainless Steel or Nitinol Core Guidewire
Dispenser	PP
Dispenser Clips	PP
Advancer	PP
Advancer cap	PP

### **Dilator**

Female Luer Hub	PC/PBT alloy
Tube	PP

### **Injection Cap**

Shell	PC
Core	Rubber

### **Medical dressing**

Spin

### **Scalpel**

Stainless Steel/PE

### **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.



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## **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

ISO10993.10

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

of the ISO 10993.3(Extracts)

### **Chemical tests**

- ETO residual