



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

### 1. Product Description

1.1 Generic name: Disposable Fistula Needles

1.2 Trade-mark of medical device: Able

1.3 Commercial presentation:

1.3.1 CE Certification:

Disposable Fistula Needles have obtained the CE certificate issued by TUV since 2010.

1.3.2 Registration Certificate of China

Disposable Fistula Needles have obtained the Registration Certificate of China since 2012

1.4 Industrial manufacturer name: Guangdong Baihe Medical Technology Co., Ltd.

1.5 Shelf life: 3 years

1.6 Risk-related classification: Class II a, according to MDD Annex IX, rule 7

1.7 Indications and uses

Disposable Fistula Needle is available to professional doctors and nurses.

This product is to connect with the hemodialysis dialyzer and blood circuit in clinical, and together with them to build a temporary access road in vitro blood circulation.

1.8 UMDNS Code: 12729

1.9 Warnings, caution and contraindications



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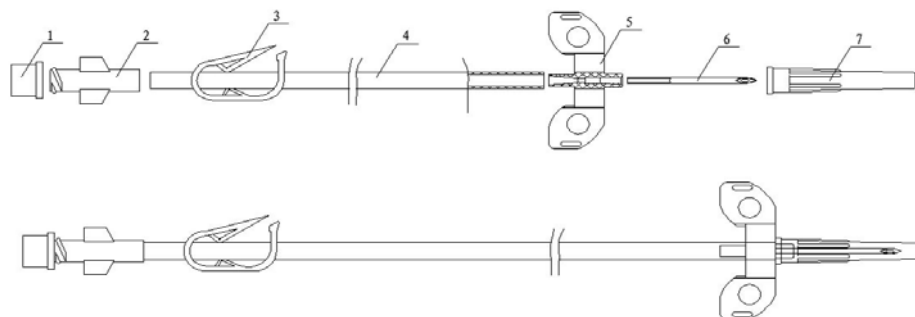
### Warning and caution

- ◆ The product could only be handled by qualified nursing staff.
- ◆ Do not use if the package has been previously opened or damaged.
- ◆ Read the instruction prior to use.
- ◆ Single use only. Any re-sterilization or reuse of the products can result in hazard to the patients.
- ◆ The treatment should be conducted in strict asepsis circumstance.
- ◆ The product is sterilized by Ethylene Oxide and has no pyrogen.
- ◆ Ensure that the products connect with other medical devices is correct, safe and reliable.
- ◆ Attention should be paid when this product is used for pregnant women, breastfeeding mothers, infants and children. Try to use alternatives.

### Contraindications

No absolute contraindication. But Coagulation dysfunction was used with caution.

### 2. Main Parts of the device





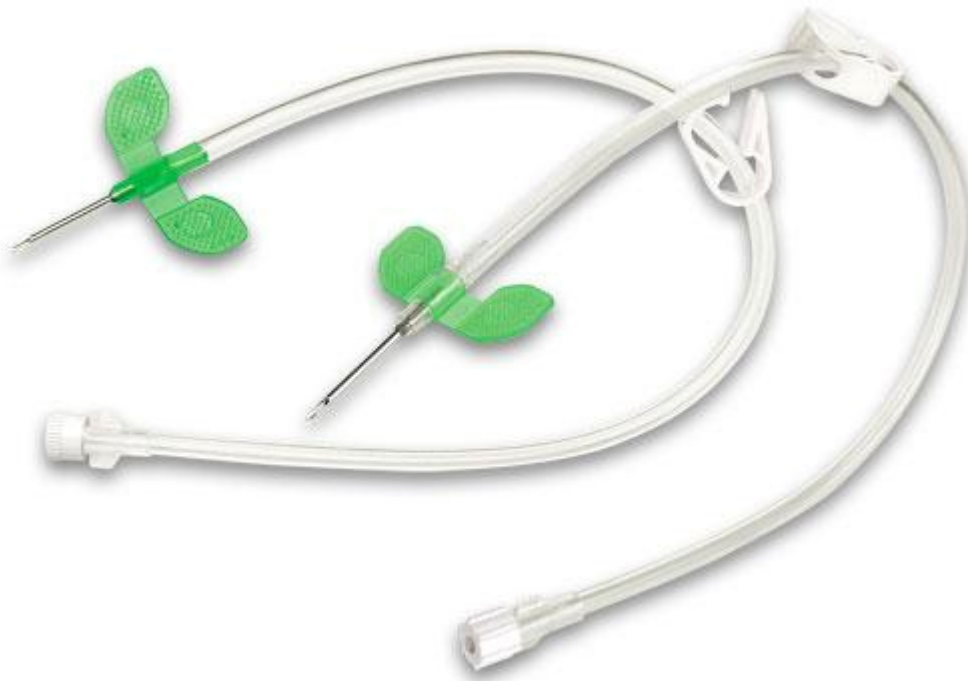
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- ①protect cap      ②connector      ③pipe clamps      ④catheter  
 ⑤catheter adapter      ⑥needle tubing      ⑦needle cover

Parts	Materials	Contact blood or not?
Protect cap	PP	No
Connector	PVC	Yes
Pipe clamps	POM	No
Catheter	PVC	Yes
Catheter adapter	PVC	No
Needle tubing	Stainless Stell	Yes
Needle cover	PP	No

### 3.Product Photo



### 4. Product Specification

Single	Double	Needle Specification	Needle Length	Catheter Length
FN-1411S	FN-1411D	14G	25	150
FN-1511S	FN-1511D	15G	25	150



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FN-1611S	FN-1611D	16G	25	150
FN-1711S	FN-1711D	17G	25	150
FN-1412S	FN-1412D	14G	25	300
FN-1512S	FN-1512D	15G	25	300
FN-1612S	FN-1612D	16G	25	300
FN-1712S	FN-1712D	17G	25	300
FN-1421S	FN-1421D	14G	32	150
FN-1521S	FN-1521D	15G	32	150
FN-1621S	FN-1621D	16G	32	150
FN-1721S	FN-1721D	17G	32	150
FN-1422S	FN-1422D	14G	32	300
FN-1522S	FN-1522D	15G	32	300
FN-1622S	FN-1622D	16G	32	300
FN-1722S	FN-1722D	17G	32	300
FN-1411ZS	FN-1411ZD	14G	25	150
FN-1511ZS	FN-1511ZD	15G	25	150
FN-1611ZS	FN-1611ZD	16G	25	150
FN-1711ZS	FN-1711ZD	17G	25	150
FN-1412ZS	FN-1412ZD	14G	25	300
FN-1512ZS	FN-1512ZD	15G	25	300
FN-1612ZS	FN-1612ZD	16G	25	300
FN-1712ZS	FN-1712ZD	17G	25	300
FN-1421ZS	FN-1421ZD	14G	32	150
FN-1521ZS	FN-1521ZD	15G	32	150
FN-1621ZS	FN-1621ZD	16G	32	150
FN-1721ZS	FN-1721ZD	17G	32	150
FN-1422ZS	FN-1422ZD	14G	32	300
FN-1522ZS	FN-1522ZD	15G	32	300



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## 5.Storage:

The product must be stored in a cool, ventilated and dry environment, at a temperature between 0°C to 40°C and a relative humidity between 30% to 80%. Protect the packed products from exposure to direct sunlight and rodent infestation.

Sterilization is valid for three years.