



Guangdong Baihe Medical Technology Co., Ltd.
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广东百合医疗科技股份有限公司
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Technical Data

1. Product Description

1.1 Generic name: Disposable Fistula Needles

1.2 Trademark 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 IIa, 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 Compatible With Devices in Use

1.10 Warnings, caution and contraindications

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.



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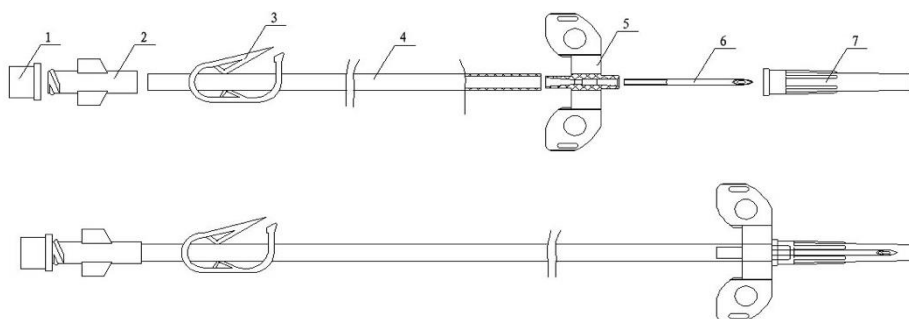
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- ◆Single use only. Any re-sterilization or reuse of the products can result in hazard to the patients.
- ◆The treatment should be conducted in strict asepsis circumstance.
- ◆The product is sterilized by Ethylene Oxide and has no pyrogen.
- ◆Ensure 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



- 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 Steel	Yes
Needle cover	PP	No



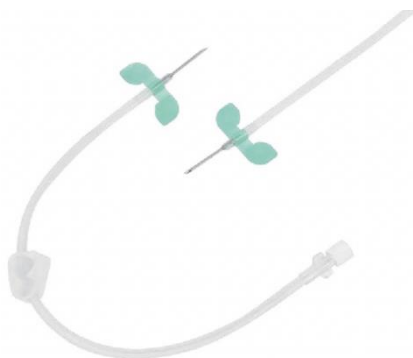
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Feature

- ◆ Both arterial and venous fistula needles are equipped with lateral holes.
- ◆ Integrated clips are equipped by fistula needles.
- ◆ 360° Rotatable wing and fixed wing available to choose.
- ◆ Different colors of clamps can be used to distinguish the purposes of the needles (arterial/venous. puncture).

2. Product Photo



3. Product Specification

Single pack	Double pack	Needle size	Needle Length	Tube Length	Color of Clamp
FN-1411S	FN-1411D	14G	25	150	Red/ Blue/White
FN-1511S	FN-1511D	15G/1,8mm	25	150	Red/Blue/White
FN-1611S	FN-1611D	16G/1,6mm	25	150	Red/Blue/White
FN-1711S-R	FN-1711D	17G/1,5mm	25	150	Red/Blue/White
FN-1412S	FN-1412D	14G	25	300	Red/Blue/White
FN-1512S	FN-1512D	15G/1,8mm	25	300	Red/Blue/White
FN-1612S	FN-1612D	16G/1,6mm	25	300	Red/Blue/White
FN-1712S	FN-1712D	17G/1,5mm	25	300	Red/Blue/White
FN-1421S	FN-1421D	14G	32	150	Red/Blue/White
FN-1521S	FN-1521D	15G/1,8mm	32	150	Red/Blue/White
FN-1621S	FN-1621D	16G/1,6mm	32	150	Red/Blue/White
FN-1721S	FN-1721D	17G/1,5mm	32	150	Red/Blue/White
FN-1422S	FN-1422D	14G	32	300	Red/Blue/White
FN-1522S	FN-1522D	15G/1,8mm	32	300	Red/Blue/White
FN-1622S	FN-1622D	16G/1,6mm	32	300	Red/Blue/White
FN-1722S	FN-1722D	17G/1,5mm	32	300	Red/Blue/White
FN-1411ZS	FN-1411ZD	14G	25	150	Red/Blue/White
FN-1511ZS	FN-1511ZD	15G/1,8mm	25	150	Red/Blue/White
FN-1611ZS-R	FN-1611ZD	16G/1,6mm	25	150	Red



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FN-1611ZS-B	FN-1611ZD	16G/1,6mm	25	150	Blue
FN-1711ZS-R	FN-1711ZD	17G/1,5mm	25	150	Red
FN-1711ZS-B	FN-1711ZD	17G/1,5mm	25	150	Blue
FN-1412ZS	FN-1412ZD	14G	25	300	Red/Blue/White
FN-1512ZS	FN-1512ZD	15G/1,8mm	25	300	Red/Blue/White
FN-1612ZS	FN-1612ZD	16G/1,6mm	25	300	Red/Blue/White
FN-1712ZS	FN-1712ZD	17G/1,5mm	25	300	Red/Blue/White
FN-1421ZS	FN-1421ZD	14G	32	150	Red/Blue/White
FN-1521ZS	FN-1521ZD	15G/1,8mm	32	150	Red/Blue/White
FN-1621ZS	FN-1621ZD	16G/1,6mm	32	150	Red/Blue/White
FN-1721ZS	FN-1721ZD	17G/1,5mm	32	150	Red/Blue/White
FN-1422ZS	FN-1422ZD	14G	32	300	Red/Blue/White
FN-1522ZS	FN-1522ZD	15G/1,8mm	32	300	Red/Blue/White

4. 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 3 years.