English

CE 0197

Disposable A.V. Fistula Needle Sets

Instruction for Use

Manufacturer has been granted certificate of ISO 13485
Performed standard is ISO 1135-4

1. Material

The major components of this product are made from medical-grade PVC, PP, PC and other medical-grade macromolecule materials and stainless steel, this product is free of latex.

2. Product configuration and Feature

Specification	14G, 15G, 16G, 17G
Components	Protective cap, Cannula, Wing, Clamp, Female Luer Lock, etc.

3. Indication for use

This product is intended to be used as vein puncture for the hemodialysis treatment. It is applicable to all dialysis patients.

4. Recommended usage method

1) Take out needle from pouch.
2) Disinfect the skin which is intended to be punctured.
3) Screw off cap from female luer lock, and fill up tubing with physiological saline to exclude air inside.
4) Hold the wing, take off the needle cap, then puncture the vein, clamp tubing once blood fills up the tubing.
5) Fix the cannula at the puncture site by medical adhesive tape.
6) Connect with bloodline for hemodialysis.
7) After the treatment and blood returned to patient, withdraw the needle from patient, and discard it into the designated sharps collection container.

5. Transportation and storage

Please avoid crash and exposure to rain, snow or direct sunlight during transportation. The storage temperature is 0°C~40°C, please store it indoors with relative humidity no more than 80%, well ventilated and without corrosive gases. Do not store this product in warehouse together with chemicals and moist articles.

6. Precautions in use

1) Using the product should be supervised by a physician or adequately trained personnel, in accordance with aseptic technique throughout the entire procedures. The validity period of sterilization is three years, please check expiration date prior to use to prevent contamination or infection, do not use any expired product.
2) The products is fully sterilized by irradiation, sterility and non-pyrogenicity. Do not use the product if pouch is damaged. Assure that there are no flattened portions or kinks, and protective caps are not detached before use.
3) Open pouch and take out fistula needle carefully.
4) If fistula needle not be properly connected, or there is any fluid leakage or air bubbles, treatment or readjustment should be performed. In case of no improvement, please replace with another new fistula needle.
5) This product is for single use only and reuse is forbidden. Reuse or reprocessing of this product may lead to adverse reaction to patient and/or device failure. It should be discarded according to laws and regulations relevant to disposal of infectious medical waste to prevent infection.
6) This product contains DEHP (Di-2-ethylhexyl phthalate). Attention should be paid when this product is used for pregnant women, lactating women, infants and children.
7) All of the disinfectant used for this product have no special contraindications.
8) This product is intended to be used with bloodline, which should be equipped with standard luer lock.
9) If abnormal conditions arise during the dialysis, such as bubbles, foreign matter, blood leakage, or clotting, etc., proper measures shall be taken according to doctor's advice.
10) If serious incident occurs, please inform the manufacturer or local competent authority.
11) There are no known contraindications of this product. General contraindications for hemodialysis apply.
12) Please refer to the actual labeling for the model, shelf life, batch code, etc.

7. After sales service

Please keep the original packaging for any investigation on product quality.

8. Symbol

	Do not re-use	STERILE R	Sterilized using irradiation
	Date of manufacture		Manufacturer
LOT	Batch code		Use-by date
REF	Catalogue number		Keep dry
	Do not use if package is damaged		Keep away from sunlight
	Caution		Handle with care
	Consult instructions for use		Humidity limitation
	Non-pyrogenic	PHT DEHP	Contains or presence of phthalate
	Temperature limit	EC REP	Authorized representative in the European Community
CE	CE marking		This end up

EC REP <EU Representative>
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Keep this Instruction for use until all of the products in this carton are used up.

Date: 2022-12-20 Made in China

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