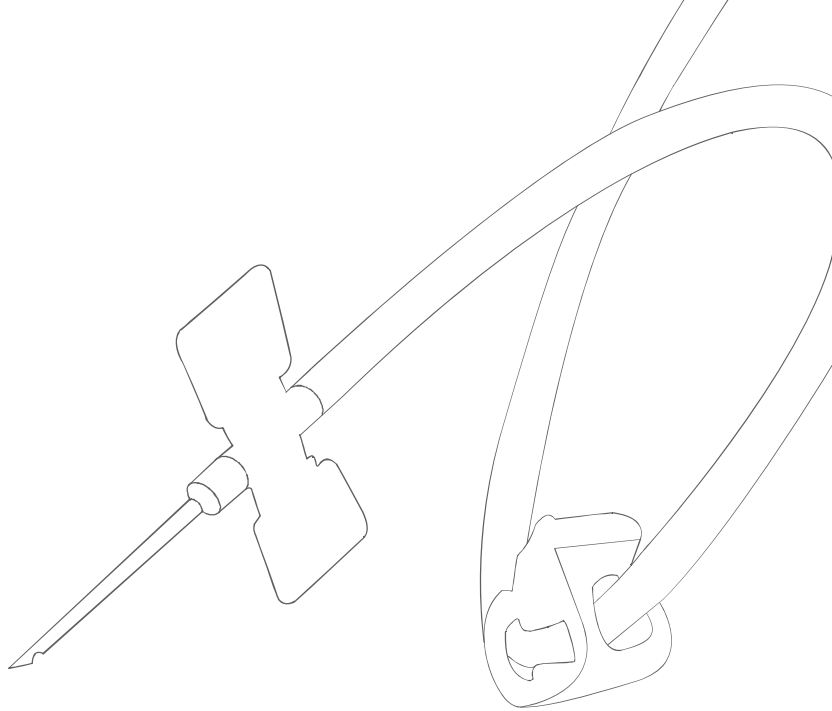


INSTRUCTIONS

A.V. Fistula Needle Sets

EN	A.V. Fistula Needle Sets	PT	Agulhas de Istula A.V.
DE	A.V. Kanüle	RU	Иглы фистульные A.V.
FR	Aiguilles à Fistule A.V.	AR	سوزن فیستولا
ES	Set de Agujas de Fístula A.V.	JP	AVF ニードルセット

WEGO

THE BLOOD PURIFICATION EXPERT

I PRODUCT NAME

A.V. Fistula Needle Sets

II SPECIFICATIONS AND MODELS

1.4×25GD, 1.4×25XD, 1.4×32GD, 1.4×32XD;
1.6×25GD, 1.6×25XD, 1.6×32GD, 1.6×32XD;
1.8×25GD, 1.8×25XD, 1.8×32GD, 1.8×32XD;
1.4×25GS, 1.4×25XS, 1.4×32GS, 1.4×32XS;
1.6×25GS, 1.6×25XS, 1.6×32GS, 1.6×32XS;
1.8×25GS, 1.8×25XS, 1.8×32GS, 1.8×32XS;

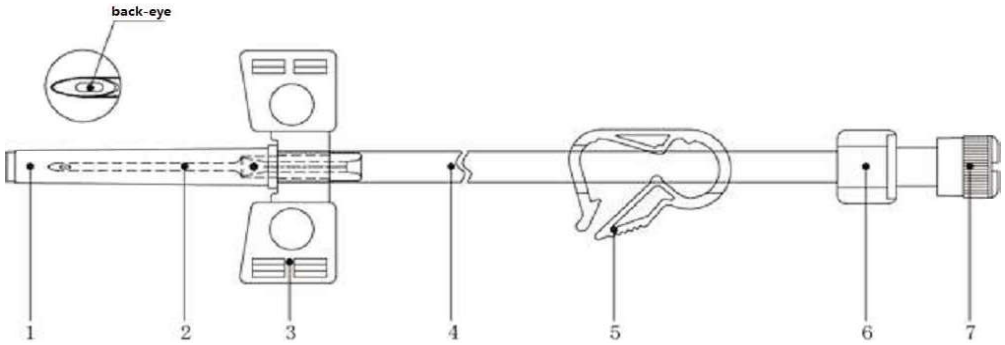
III MANUFACTURER

Weihai Weigao Blood Purification Products Co., Ltd.

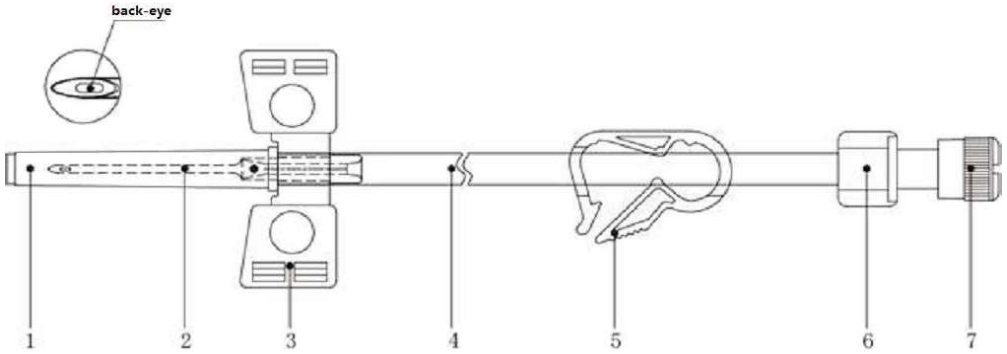
IV STRUCTURE AND PERFORMANCE OF PRODUCT

Structure: Disposable fistula needle consists of needle, needle guard, needle handle, clamp, flexible tube, female conical fitting and connector protective cap.

Performance: Good sharpness, flexibility, clean and neat appearance, and good transparency.



1-needle guard 2-needle 3-needle handle 4-flexible tube 5-clamp
6-female conical fitting 7-connector protective cap
Figure1 Structure of a fixed-wing fistula needle



1-needle guard 2-needle 3-needle handle 4-flexible tube 5-clamp
6-female conical fitting 7-connector protective cap
Figure2 Structure of a rotary-wing fistula needle

V PRODUCT MAINTENANCE AND CARE

The product is disposable and does not require special maintenance or care.

VI PRODUCTION DATE AND EXPIRATION DATE

See the inner package.

VII STORAGE CONDITIONS

Required temperature is 0℃-40℃, this product can be stored in 20%~80% relative humidity place without corrosive gas, and away from direct sunlight. Avoid pressing heavily and hitting and getting wet in the rain or snow in transit.

VIII STERILIZATION METHOD

The product is supplied sterile and non-pyrogen after ethylene oxide sterilization.

IX INTENDED USE

This product is designed for use with hemapheresis consumables for collection of human blood components. Vascular access cannulation for blood purification.

X CONTRAINDICATIONS

None.

PRECAUTIONS AND WARNINGS

01 Read this user manual carefully before using the product.
02 This product is for single use only and should be disposed after usage.
03 Do not use product if the package is damaged or damp.
04 This product should be used promptly after unwrapping internal package.
05 The product is intended to be used with hemapheresis consumables.
06 To remove the needle sleeve, pull it straightly along the needle. Otherwise, the needle tip may be damaged.
07 Before using the product, disinfect the skin where the needle will puncture.
08 Be careful not to be hurt by the needle when using or disposing it.
09 Do not squeeze, push, pull, or bend the product with too much force.
10 Before using the product, check whether any part of it is abnormal, especially the needle tip, clamp, and joint. If any abnormity is found, replace the product.
11 When using the product, do not touch the needle tip directly with your hands or other parts of your body.
12 When using the clamp, ensure that the flexible tube is correctly fixed in the clamp and functions properly.
13 When connecting the female conical fitting of the product to a disposable extracorporeal blood circuit for blood purification, do not insert the joint too tight.
14 When the product is connected to a disposable extracorporeal blood circuit, periodically check the joint during the use. If any abnormity is found on the joint, take appropriate measures for the treatment and replace the product immediately.
15 Repeated puncturing will damage the vascular endothelium and activate the exogenous coagulation pathway to form thrombus, which will block the hemodialyzer.
16 After hemodialysis is finished, the puncture point will continue bleeding because the anticoagulant is still effective. We recommend that you press the puncture point for a longer time. Follow the clinician's advice for this issue.
17 The product needs to be used with a disposable extracorporeal blood circuit for blood purification.
18 The disposable extracorporeal blood circuit used with the product must have a registration certificate conforming to the related requirements.
19 The PVC passage can interact with the drug infused, causing a change of the drug's effect.

20 When using a disposable extracorporeal blood circuit with the product, follow the operation instructions in the user manual of the disposable extracorporeal blood circuit.
21 In case an emergency occurs during proper use of the product, stop the use and replace the product immediately. Meanwhile, ask the clinician to check the patient immediately and take appropriate measures according to related regulations. Keep the replaced product and contact us as soon as possible.
22 Try to use alternative products for high-risk patients, such as neonates, prepubescent males, and pregnant and lactating women.
23 The product cannot be used to infuse fat emulsion or other liposoluble liquids or drugs.
24 The products contain DEHP.
25 Do not use the product to infuse PVC-incompatible drugs.
26 The used product must be disposed of as biohazardous waste in accordance with operation guidelines for medical institutions, and applicable laws and regulations.
27 The product can only be used by trained doctors or nursing personnel in accordance with operation guidelines for medical institutions, and applicable laws and regulations.
28 Avoid shocks and collisions during handling and storage.
29 Keep the needle away from the protector when removing the protector, when the needle inserted into the protector, change a new device.
30 Do not cap the needle again, it may cause needle stick.
31 During hemodialysis, do not cover the tubes with anything, it may cause failure to discover a dislodgement.
32 The shelf-life is 3 years for sterility.

INTERACTION

Replace the product for the problems that may occur when the product is used with an extracorporeal blood circuit, including but not limited to unsmooth liquid flow due to different interfaces of the extracorporeal blood circuit, circuit breaking or splitting.

INSTRUCTIONS FOR INSTALLATION AND USE

01 Take out the fistula needle from the package only before use.
02 It is recommended to insert patient's blood vessel with fistula needle filling with normal saline.

03 When connecting a priming blood circuit to the product, check carefully to ensure that the joint is connected securely and prevent ingress of air into the circuit.

04 Given that the product contacts with the blood,used needle must be disposed separately from general waste.

05 Follow the direction from the physician to provide treatment after everything is ready.

ADVERSE REACTIONS

For the symptoms or reactions that may occur on the patient while using the product, including but not limited to chest pain and back pain, observe the patient carefully and take appropriate measures. If the symptom is not alleviated, stop hemodialysis.

For the symptoms or reactions that may occur on the patient, including but not limited to itchy skin, urticaria, coughing, sneezing, runny nose, abdominal pain, diarrhea, dyspnea, and shock, stop hemodialysis immediately.

WARRANTY

01 WEGO promises that all the fistula needle products meet the requirements of the quality management system for medical devices.

02 If a fistula needle is found damaged, send it back to WEGO. We will provide a free replacement. WEGO is not liable for any damage (such as broken package, needle damage, and missing accessories) found after the buyer signs to acknowledge the receipt.

03 WEGO is not liable for the injuries or hazards that occur on patients or other personnel during the use of WEGO fistula needle products but cannot be definitely attributed to defects of the products.

04 WEGO is not liable for the hazards or negative reactions on patients or other personnel caused by reuse of WEGO fistula needle products.

05 WEGO is not liable for the hazards on patients or other personnel caused by the use of WEGO fistula needle products beyond the sterilization effective period.

06 WEGO is not liable for the injuries or hazards on patients or other personnel caused by damaged or broken fistula needles or accessories that cannot be separated from the needles during misuse or improper treatment.

CE 0123 CE Mark

WGFN-AV1.0

Do not re-use

Caution

STERILE EO Sterilization using ETO

Date of manufacture

Use-by date

LOT Batch code

Do not use if package is damaged

Consult instructions for use

Temperature limit

EC REP Authorized representative in the European community

Manufacturer

Do not resterilize

Contains or presence of phthalate

EC REP **MedNet EC-REP GmbH**
Borkstrasse 10, 48163 Muenster GERMANY.

Weihai Weigao Blood Purification Products Co., Ltd.
No. 20, Xingshan Road, Weihai Torch Hi-tech Science Park,264210 Weihai,
Shandong Province, PEOPLE'S REPUBLIC OF CHINA.
Tel: +86-631-5660598 Fax: +86-631-5660598