

# Arteriovenous Fistula Needle Sets

## Operation Instruction

**Single use, NOT FOR REUSE**

**DO NOT use the product if the packing bag is damaged**

**Read the Instruction for use before usage**

**Validity: three years**

### [General Information]

**INDICATION:** Arteriovenous Fistula Needle Sets is designed for arteriovenous puncture in conducting blood purification.

**CONTRAINDICATIONS:** The contraindications of this product are unclear now.

**PRECAUTIONS:** (1) This product is compatible with other existing brands and models of hemodialysis bloodline on the market at present. (2) This product is sterilized by ethylene oxide, it is sterile, pyrogen free and valid for 3 years. (3) Before using this product, please check the package and the product integrity; It is forbidden to use if the package or the product is damaged. (4) The operation of the product should only be limited to trained medical personnel. (5) After use, all the blood in the tube should be back flow to the patient, then all clamps shall be closed. Finally, remove the Arteriovenous Fistula Needle Sets and other accessories. All of them shall be placed in a special waste container and destroyed according to the clinical regulations. (6) Don't store in high temperature, direct sunlight and humid environment. (7) The duration of device life use is 4h. (8) Read the operation instruction carefully before use.

**WARNING:** (1) Pay attention to avoid being hurt by the needle when using or discarding, which may cause injury or infection. (2) When connecting with the hemodialysis bloodline, it should be inserted straight and tightened. If it is inserted at an angle, there will be risk of blood leakage or blood pressure decrease. (3) Do not infuse drugs incompatible with PVC. It may change the drug efficacy that caused by the interaction. (4) The infusion of alcohol will cause cracks and leakage. (5) The maximum positive pressure for this product is not more than +66.6kPa, the maximum negative pressure is not more than -66.6kPa.









**SIDE EFFECTS:** Aneurysm, AVF thrombosis/occlusion, AVF stenosis, Infection, Bleeding/hematoma/infiltration, Needlestick injury (NSI), Needle dislodgment, Oedema, Allergic Reactions, Leakage, Separation between needle and line.

**STORAGE:** the packed products shall be stored in a clean environment with temperature between 0~40°C, relative humidity no more than 80%, with clean, ventilated, no corrosive gas, and shall not be extruded.

### [Usage]

1. Disinfect the puncture site according to the operation procedures of dialysis treatment.
2. Confirm the package is not damaged before use, take out the product from the package and remove the needle protector.
3. Hold the needle handle and puncture the blood vessel at the disinfected site.
4. After the blood flows into the catheter, close the clamp.
5. Fix the needle with tape.
6. Puncture the second needle according to the above steps.
7. Unscrew the connector protector, connect it with the hemodialysis bloodline, open the clamp, start the blood circulation.
8. After the treatment, close the clamp, remove the tape, pull out the needle, and dispose it according to the regulations of medical waste.

**[Refer to the label for]**

	Batch code		Expiring date		Representative of European Community
	Do not reuse		Refer to the instructions for use		Don't use if the package is damaged
	Caution		Sterilized by ethylene oxide		

**[Warranty and limitation of liability]**

1. The manufacturer guarantees that the products are manufactured in accordance with the product technical requirements and the requirements of YY0267.
2. If the product has problems within the validity period, According to the production date, you can contact to replace the product.
3. The manufacturer is only responsible for the quality of the product when it is firstly used in accordance with the requirements of the product operation manual. The manufacturer shall not be liable for any direct or indirect damage to the product or any damage to the product caused by the user's failure to operate in accordance with the instructions.

**[Manufacturers information]**

Manufacturers: Chengdu OCI medical devices CO., LTD.

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**[European authorized representative]**

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**[Specifications]**

Model	Type	OD (mm)	Length (mm)	Color Code
OCI-14G	Back needle	2.10±0.01	25±2	purple
		2.10±0.01	32±2	
OCI-15G		1.85±0.01	25±2	beige
		1.85±0.01	32±2	
OCI-16G		1.65±0.01	25±2	green
		1.65±0.01	32±2	
OCI-17G		1.50±0.01	25±2	orange
		1.50±0.01	32±2	