1 General Information

1.1 Introduction

This Technical File consists of technical documentation relating to products of Arteriovenous Fistula Needle Sets. It meets the requirements of the Medical Device Directive 93/42/EEC and is requested to bear the CE Marking to enable them to move freely within the European medical market and to be put into service in accordance with its intended purpose.

1.2 Company history

Chengdu OCI Medical Devices Co., Ltd. (hereinafter referred to as OCI Medical) was founded in 2005, which is a high-tech company focusing on the R&D, production and sales of blood purification product series (including hemodialysis machine, Hemodialysis blood tubing sets, Arteriovenous fistula needle sets, Disposable hemoperfutor). The company cooperated with Sichuan University (College of Polymer Science&Engineering) for the production R&D technology of “Polyethersulfone hollow fiber membrane” which was monopolized by the foreign enterprises; with the efforts nearly four years, OCI Medical has broke the technical barrier of foreign enterprises and owned the independent core production technology and intellectual property of the “Polyethersulfone hollow fiber membrane”, with the national invention patent obtained (Patent No. ZL200510020277.1). In December, 2009, after strict clinical trial and review, the product of the company “High flux polyethersulfone hollow fiber hemodialyzer” obtained the Registration Certificate of Medical Equipment Product from State Food and Drugs Administration, became the first enterprise obtaining the registration certificate of polyethersulfone hollow fiber hemodialyzer, and was authorized to produce and sell such products in China. At present, as the leading company, OCI Medical participates and achieved good results in the national project "13th five year plan" of “Key technology development and industrialization of new blood purification materials and wearable artificial kidney”.

So far, OCI Medical have developed more products in blood purification field, including Low-Flux Polyethersulfone Hollow Fiber Hemodialyzer; High-Flux Polyethersulfone Hollow Fiber Hemodialyzer; Hollow Fiber Hemodiafilter; Hollow Fiber Membrane Hemodialyzer; Hemodialysis Blood Tubing Sets; Arteriovenous fistula needle sets; Disposable hemoperfutor. At present, OCI Medical owns 47000m^2 factory and 2000 m^2 cleaning room and two production lines with the annual output of 800,000pcs.

2 Device Description

2.1 Product name

Product name: Arteriovenous Fistula Needle Sets

Business name: Purifier® or OCI®

2.2 Product catalogue

Table 2-1 Product catalogue

Product Name	Model
Arteriovenous Fistula Needle Sets	OCI-14G
	OCI-15G
	OCI-16G
	OCI-17G

2.3 Product specification

Table 2-2 Product Specifications

Specification	Models	Color of needle handle	Back hole area, mm	Length of the tube	Diameter of the needle(mm)	Length of the needle (mm)
OCI-14G	Back-eye needle; Rotated wing 360º rotation	Purple	≥1.6	290mm	2.10±0.01	25±2
					2.10±0.01	32±2
OCI-15G		Beige	≥1.3	290mm	1.85±0.01	25±2
					1.85±0.01	32±2
OCI-16G		Green	≥1.0	290mm	1.65±0.01	25±2
					1.65±0.01	32±2
OCI-17G		Orange	≥0.8	290mm	1.50±0.01	25±2
					1.50±0.01	32±2

2.4 Photographs of products

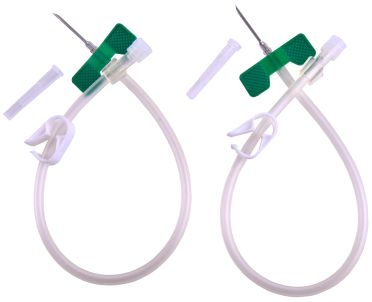


Fig. 2-1 Arteriovenous Fistula Needle Sets

2.5 Device structure diagram

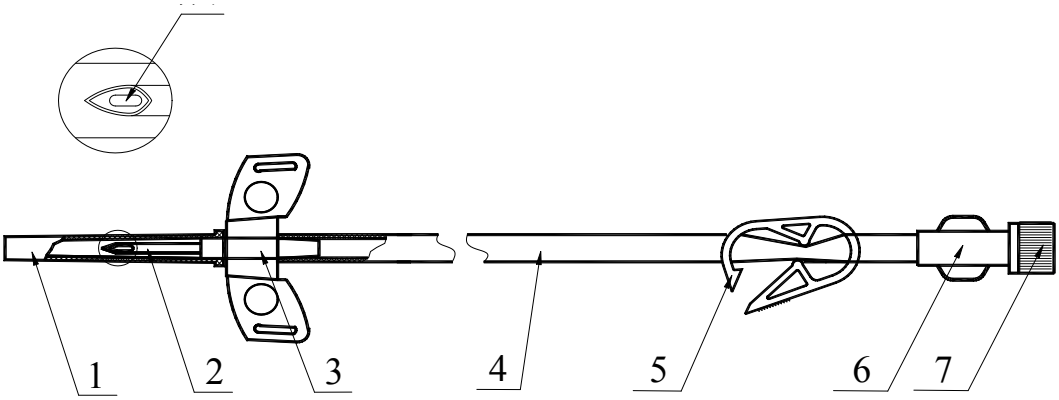


Fig. 2-2 1－Needle protector； 2－Needle； 3－Needle handle；
4－Tube； 5－Clamp； 6－Inner cone joint； 7－Joint protector

2.6 Key description of the devices

2.6.1 Product name

Arteriovenous Fistula Needle Sets

2.6.2 Intended use

(1) Indication: Arteriovenous Fistula Needle Sets is designed for arteriovenous puncture in

conducting blood purification.

(2) Name of disease: Arteriovenous puncture in blood purification treatment.

(3) Patient population: adults. The safety and efficacy of the pregnant patients have not been established.

(4) Intended users: the device should be used by trained doctors or nurses.

(5) Body fluid contact with the device: human blood.

(6) Duration use: 4h

(7) Use environment: This device is suitable for clinical departments that need to establish extracorporeal circulation for hemodialysis treatment.

This device is designed to be used in medical institutions. Since the dialysis machine is used as the power source of extracorporeal circulation, there are requirements for the power supply system of medical institutions. Medical institutions are required to provide dual power supply to ensure the safety of patients treated in case any accidental power failure during treatment. Dialyzers should be used in the treatment process, and dialyzers should comply with ISO 8637. The dialysate should also be used in the treatment process, and the water for dialysate preparation should comply with ISO 13959. Therefore, the dialysis machine must be equipped with corresponding water producing equipment and water source, so as to avoid affecting the dialysate quality, thus affecting the treatment effect and safety of patients.

(8) Operation principle: the operation should obey the instruction for use.

2.6.3 Intended users

Arteriovenous Fistula Needle Sets is designed to use by trained doctors or nurses.

2.6.4 Intended patient population

Arteriovenous Fistula Needle Sets is designed for adults.

The safety and efficacy for pregnant patients have not been established.

2.6.5 Medical status to be treated

Acute and chronic renal failure.

2.6.6 Contraindications/Precautions/Warnings/Side effects

(1)Contraindications:

The contraindications of this product are unclear now.

(2)Precautions:

1.This product is compatible with other existing brands and models of hemodialysis bloodline on the market at present.

3. This product is sterilized by ethylene oxide, it is sterile, pyrogen free and valid for 3 years.

2. 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.

(3)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.

(4)Side effects:

Aneurysm, AVF thrombosis/occlusion, AVF stenosis, Infection, Bleeding/hematoma/infiltration, Needlestick injury (NSI), Needle dislodgment, Oedema, Allergic Reactions, Leakage, Seperation between needle and line

2.6.7 Working principle and mechanism

The working principle of Arteriovenous Fistula Needle Sets is to use its stainless steel needle to puncture the arteriovenous vein. Under the function of blood pressure, the blood is introduced into the extracorporeal circulation bloodline, and then the extracorporeal circulation channel of blood is established.

2.6.7 Medical Performance Claim

This product is a sterile disposable device, which support the use of hemodialysis machine, hemodialyser and extracorporeal circulation tube, apply to hemodialysis therapy of patients with acute or chronic renal failure, function as arteriovenous puncture in conducting blood purification.

2.6.8 Innovative confirmation

There is no innovative materials, technologies or clinical uses. There are already equivalent products with same materials, technologies or clinical uses exist in the market.

2.6.9 Technical data

The following table shows the technical data of the product:

Specification	Models	Color of needle handle	Back hole area, mm	Length of the tube	Diameter of the needle(mm)	Length of the needle (mm)
OCI-14G	Back-eye needle; Rotated wing 360°rotation	Purple	≥1.6	290mm	2.10±0.01	25±2
					2.10±0.01	32±2
OCI-15G		Beige	≥1.3	290mm	1.85±0.01	25±2
					1.85±0.01	32±2
OCI-16G		Green	≥1.0	290mm	1.65±0.01	25±2
					1.65±0.01	32±2
OCI-17G		Orange	≥0.8	290mm	1.50±0.01	25±2
					1.50±0.01	32±2

Model	10 kPa flow, ml/min	30kPa flow, ml/min
OCI-14G	≥45	≥380
OCI-15G	≥38	≥320
OCI-16G	≥30	≥250
OCI-17G	≥24	≥200

2.3 Connecting parts

Below is a list of devices or equipment intended to be used in combination with the device system.
Hemodialysis machine
Extracorporeal Circulation Bloodline
Hemodialyzer
Dialysate or Dialysis Powder

2.4 Accessories

N/A

2.5 Classification & rationale

Classification: According to Annex IX, Rule 2 of the MDD 93/42/EEC as amended by 2007/47/EC, Arteriovenous Fistula Needle Sets is in class IIa.
Rule 3:
All non-invasive devices intended for modifying the biological or chemical composition of blood, other body liquids or other liquids intended for infusion into the body are in Class IIa.

2.6 Conformity assessment route

Conformity Assessment Route: MDD 93/42/EEC, Annex II (excluding Section 4)

2.7 Specified pack shelf life

The shelf life of the Arteriovenous Fistula Needle Sets is 3 years.

2.8 Specified device life in use.

The dialysis treatment time are 4 hours.

2.9 Statements on absence/presence of medicinal substances

We declare the Arteriovenous Fistula Needle Sets do not contain any medicinal substances and free from medicinal substances.

2.10 Statements on absence/presence of human blood derivatives

We declare the Arteriovenous Fistula Needle Sets do not contain any raw materials produced from or substances derived of human blood derivatives and free from human blood derivatives.

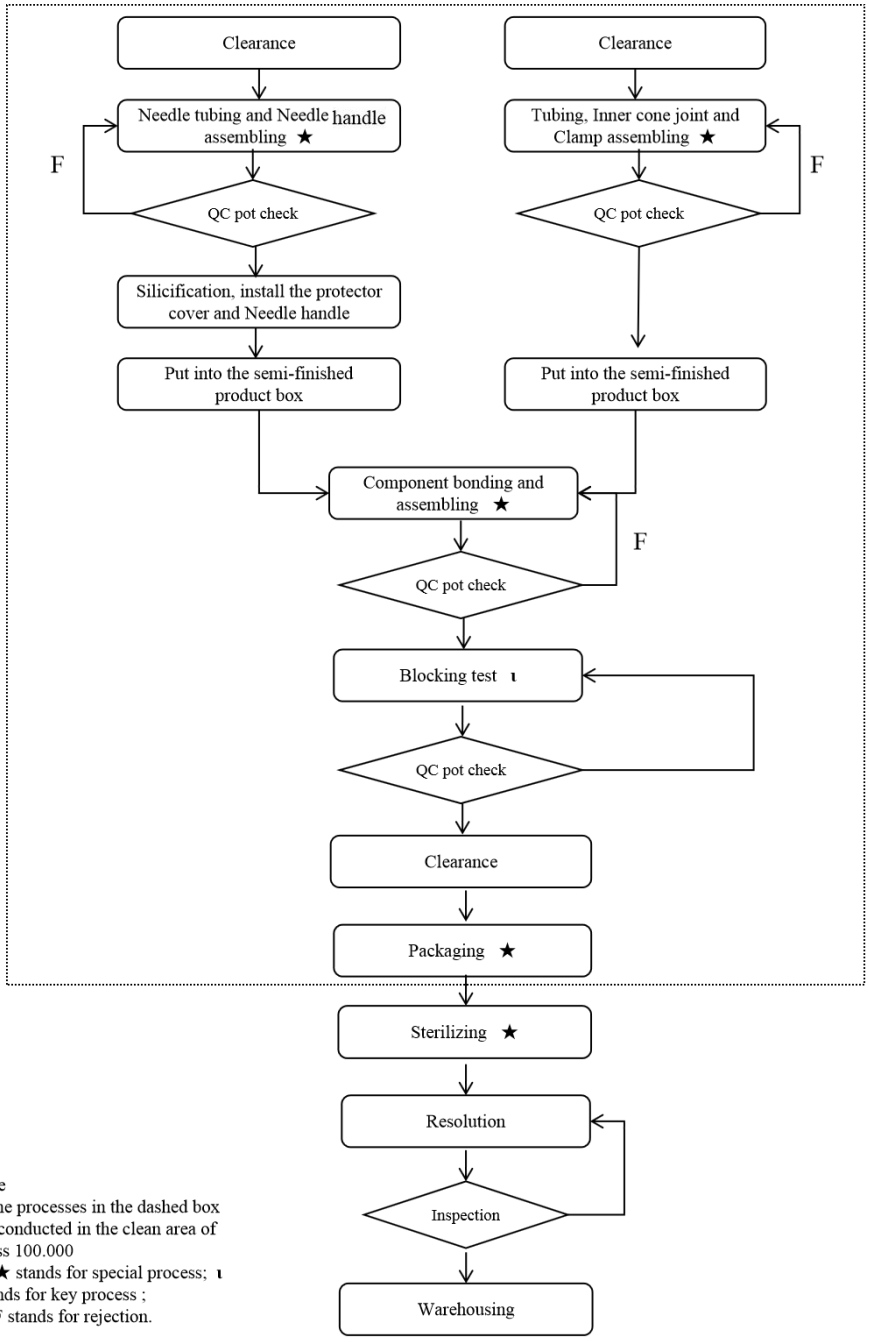
2.11 Details of the EU representative

European representative:
Lepu Medical (Europe) Cooperatief U.A.
Abe Lenstra Boulevard 36, 8448 JB, Heerenveen, The Netherlands
Tel: +31-515-573399 Fax: +31-515-760020
OCI Medical and EU representative have signed the <EU representative agreement>, File No: NO. OCI20190222 on Feb.,22th, 2019, the validation of this agreement is subject to the validation of CE Certificate for the products under it, or is within five years after the signing of the agreement.

3 Manufacturing Processes

3.1 Production Process

The production process of Arteriovenous Fistula Needle Sets mainly consists of 3 parts: bonding and assembling, packaging, sterilization. The flow chart of Arteriovenous Fistula Needle Sets is shown in Fig 9-1.



Note
1.The processes in the dashed box are conducted in the clean area of Class 100.000
2 . ★ stands for special process; ι stands for key process ;
3 . F stands for rejection.

Fig.3-1 Flow chart of A.V. Fistula Needle Sets

3.2 Materials and Suppliers

Table 3-1 Materials of Arteriovenous Fistula Needle Sets

Components	Materials
Needle	Austenitic stainless steel
Needle handle core	Polyvinyl chloride
Tubing	Polyvinyl chloride
Inner cone joint	Polyvinyl chloride
Needle protector	Polyethylene
Needle handle	Polyvinyl chloride
Clamp	Polypropylene
Joint protector	Polyethylene

The quality of materials purchased by OCI medical is guided by OCI/QP7-4<Purchasing control procedure>, and the procurement process and suppliers are effectively controlled, including procurement process, selection of qualified suppliers, evaluation and re-evaluation regulations, requirements for inspection or verification of purchased goods, so as to ensure that the purchased materials meet the specified requirements in terms of quality requirements, delivery and service.
The qualification, certificate, bio-compatibility, MSDS and COA of the main materials, such as Austenitic stainless steel, Polyvinyl chloride have been evaluated. It can be purchased only if it meets the requirements, inspected and put into storage for production.

3.3 Quality control measures

3.3.1 Quality assurance

OCI Medical has set up quality management system of design and development, production, sales, service according to ISO13485:2016, etc. The quality policy is “strengthen the management in product process and pursue excellence quality”.
All the quality system documentation such as Quality manual, Quality Procedure, Relevant records are located at Document Control Room of OCI.

3.3.2 Process quality control

The production quality control includes technology control, test control and environmental control. Technology control contains process flow, critical process and specific process. Test control contains process test, final inspection of product and control of nonconforming product. Environmental control contains the management of personnel, articles and sanitation, and the detection of surroundings, process water and gas. By these measures, finished products are ensured to meet the requirements of registration certificate for product. Besides, our company regularly entrusts authoritative medical equipment test organization, which are from Guangzhou, etc, to periodically test the product and further monitor product quality efficiently.

3.3.3 Environmental control

To assure product quality, OCI Medical has set up qualified GMP clean workshop according to Chinese standard of YY 0033 <Standards for Quality Control of sterile Medical Equipment> (similar to EN ISO 14644 series standards), established < The requirement of cleaning room and inspection operation method>, < Work Instruction for Operation of bioburden>, < Management system for cleaning>, < hygienic management system in cleaning room>, <Clean and maintenance the clarification system, disinfect system and lighting device in cleaning room>and conducted static and dynamical detection in accordance with the requirements of each degree of cleanliness. Sichuan Medical Device Testing Center statically detects class 100000 production clean rooms and clean bench of class 100 each year, to make sure that production environment is up to the standards. To ensure cleanliness of production environment, quality control department monitors routinely for these indexes such as dust quantity of clean workshop, colony forming unit content or airborne viable particles content, ventilation rate, static pressure difference, temperature, relative humidity, and so on.

3.3.4 Quality trace management for after-sale

To ensure the control of process related to customers after the delivery of products, meet the quality requirement of product sales and service and guarantee that OCI Medical can provide safe, effective, high-qualified products, provide good service for each link of product sales, timely trace product information and get hold of product quality, OCI Medical has established particular product quality tracking system. Each department assumes corresponding responsibility. By clarifying the special identification, establishing UDI and defining administrative standard for batch number, quality control department unifies and coordinates to establish product traceability management system, timely deal with customer feedback and carry out the improvement of product performance and technology optimization.

Through the lot number, OCI Medical ensures that every customer feedback or complain can be handled quickly and efficiently. OCI Medical also has established procedure to monitor serious quality accident and adverse reaction. Whenever any problems were discovered, OCI Medical would

timely inform the authorities and deal with them efficiently.

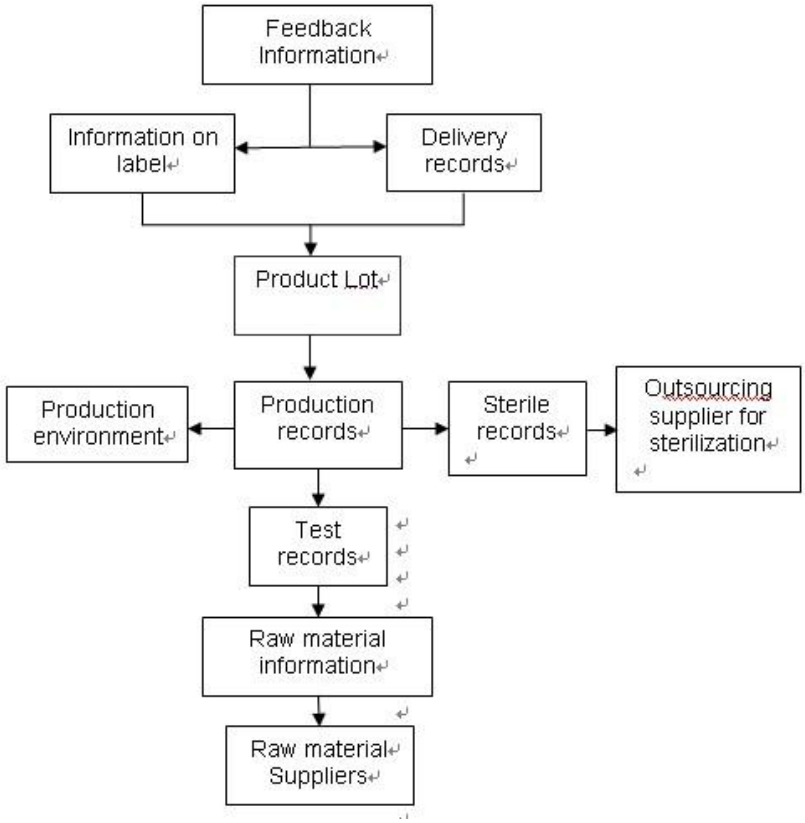


Fig.3-2 Track Back Route of Product

Through the batch number, OCI ensures that every customer feedback or complain can be handled quickly and efficiently. OCI also has established procedure to monitor serious quality accident and adverse reaction. Whenever any problems were discovered, OCI would timely inform the authorities and deal with them efficiently.