

<b>CE Technical File CE 技术文件</b> <b>产品名称：一次性使用机用采血器</b> <b>Product Name: A.V. Fistula Needle Sets</b>	File No.:S/JS11-CE-C27-2021 (A0) _3.1
	Rev. No: A/0

## Technical Parameters

### 技术参数

#### 1. Models and Specifications

##### 1. 规格型号

Model 型号	Specifications 规格
Type A, Type B A 型、B 型	1.8mm (15G), 1.6mm (16G), 1.4mm (17G), 1.2mm (18G) 1.8mm (15G)、1.6mm (16G)、1.4mm (17G)、1.2mm (18G)

#### 2. Product Structure

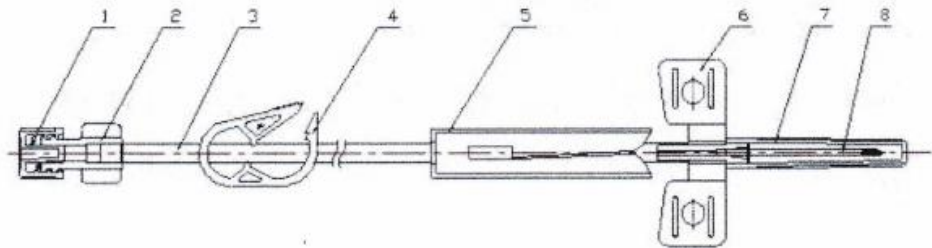
##### 2. 产品结构

This product consists of conical fitting protective cap, blood collection needle protective cap, clamp, conical fitting, needle handle, blood collection tube, protective cap and blood collection needle. The conical fitting protective cap and the blood collection needle protective cap are made from PE and the clamp is made from PP. The conical fitting, needle handle and blood collection tube are made from PVC, the protective cap is made from ABS and the blood collection tube is made from austenitic stainless steel.

本产品由圆锥接头保护套、采血针护套、管夹、圆锥接头、针柄、采血管、保护套、采血针组成，圆锥接头保护套、采血针护套材料为聚乙烯，管夹材料为聚丙烯，圆锥接头、针柄、采血管材料为聚氯乙烯，保护套材料为丙烯腈-丁二烯-苯乙烯，采血针材料奥氏体不锈钢。

The structure diagram is shown in Figure 1.

结构示意图如图 1 所示。



1-1-Protective cap of conical fitting; 2-Conical fitting; 3- Blood collection tube; 4-Protective cap (if any);  
6-Needle handle; 7- Blood collection needle; 8- Protective cap of blood collection needle

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2-圆锥接头保护套；2-圆锥接头；3-采血管；4-管夹；5-保护套（若有）6-针柄；7-采血针；8-采血针护套

Figure 1 Schematic Diagram of A.V. Fistula Needle Set

图 1 采血器示意图

3. Specifications/ Technical Parameters 规格/技术参数

According to the outer diameter, the specifications of A.V. fistula needle set are 1.2mm(18G), 1.4mm(17G), 1.6mm(16G) and 1.8mm(15G). The effective length of the needle tube: 23mm ( $\frac{29}{32}$ " )~32mm( $1\frac{1}{4}$ " ). The needle handle color and needle tube outer diameter are as shown in Table 1 below.

采血器按针管外径分，其规格为 1.2mm(18G)、1.4mm(17G)、1.6mm(16G)、1.8mm(15G), 针管有效长度：23mm ( $\frac{29}{32}$ " )~32mm( $1\frac{1}{4}$ " ),针柄的颜色与针管外径对应如下表 1 所示

Table 1 Color Code

表 1 色标

Specification 规格	15G	16G	17G	18G
Needle handle color 针柄颜色	Blue 蓝色	Green 绿色	Yellow 黄色	Red 红色
Needle tube outer diameter (mm) 针管外径 (mm)	1.8	1.6	1.4	1.2

4.Performance Index Parameters 性能指标参数

See Table 2 for the performance index parameters of A.V. fistula needle set.  
一次性使用机用采血器的性能指标参数见表 2。

Table 2 Performance Index Parameters

表 2 性能指标参数

SN 序号	Performance item 性能项目	Index parameter 指标参数
1	Blood collection tube	The inner diameter should not be less than 2.7 mm, the wall thickness ≥0.65 mm, and the length ≥150mm

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	采血管	内径应不小于 2.7 mm,壁厚 $\geq 0.65$ mm,长度 $\geq 150$ mm
2	Needle tube 针管	The lateral area of the back hole shall be no less than 1mm <sup>2</sup> 背孔侧面积应不小于 1mm <sup>2</sup>
3	Effective length of needle tube 针管有效长度	Nominal value $\pm 2$ mm 标称值 $\pm 2$ mm
4	Lubricant 润滑剂	The amount of lubricant on the surface of the needle tube per square centimeter should not exceed 0.25mg 每平方厘米针管表面上润滑剂的用量不宜超过 0.25mg
5	Clamp 管夹	When the clamp is closed, it should be capable to block the gas above the atmospheric pressure 50kPa without leakage for 1 minute 管夹关闭时应能阻断高于大气压强 50kPa 的气体 1min 无泄漏
6	Particle contamination 微粒污染	It shall not exceed contamination index when tested according to Annex A. 按附录 A 试验时, 应不超过污染指数
7	Leak proof 密封性	One end of the A.V. fistula needle set is sealed, and the other end is introduced with gas 50kPa higher than atmospheric pressure, and it is immersed in water at 20°C~30°C for 2min. There should be no signs of gas leakage. 采血器一端封口, 另一端通入高于大气压 50kPa 的气体, 浸入 20°C~30°C 的水中检查 2min, 应无气体泄漏迹象
8	Connection strength 连接强度	The joints of the various components of the A.V. fistula needle set (excluding the protective cap and the blood collection needle protective cap) should be able to withstand a static axial tension of not less than 15N or an elongation of 50% (whichever comes first) for 10s without breaking or falling off. 采血器各组件的连接处(不包括保护套、采血针护套)应能承受不小于 15N 或伸长为 50% 的静态轴向拉力(取先达到者)持续 10s, 不得断裂和脱落。
9	Flow rate 流量	The A.V. fistula needle set should output no less than 1000ml of blood within 30min at (23 $\pm$ 2)°C under a pressure difference of 10kPa. Under a pressure of 30kPa higher than the atmospheric pressure, the A.V. fistula needle set should also output no less than 500ml of blood within 2 minutes. 采血器在 10kPa 压差下, 在 (23 $\pm$ 2)°C 下 30min 内应输出不少于 1000ml 的血液。在高于大气压强 30kPa 的压力下, 采血器还应在 2min 内输出不少于 500ml 的血液。
10	Reducing substances 还原物质	The difference in the volume of potassium permanganate [c(KMnO <sub>4</sub> )=0.002mol/L] between the test solution of the A.V. fistula needle set and the blank solution should not exceed 2.0mL 采血器检验液和空白液消耗高锰酸钾[c(KMnO <sub>4</sub> )=0.002mol/L]的体积之差应不超过 2.0mL
11	Metal ion 金属离子	1. When the atomic absorption spectrophotometry (AAS) is used for testing, the total content of barium, chromium, copper, lead, and tin in the test solution of the A.V. fistula needle should not exceed 1 $\mu$ g/mL. The content of cadmium should not exceed 0.1 $\mu$ g/mL 2. When the colorimetric method is used for determination, the color of the test solution of the A.V. fistula needle should not exceed the mass

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		concentration $\rho$ ( $Pb^{2+}$ ) = 1 $\mu$ g/mL standard control solution 1.当用原子吸收分光光度法(AAS)进行检测时, 采血器检验液中钡、铬、铜、铅、锡的总含量应不超过 1 $\mu$ g/mL。镉的含量应不超过 0.1 $\mu$ g/mL 2.当用比色法进行测定时, 采血器检验液呈现的颜色应不超过质量浓度 $\rho$ ( $Pb^{2+}$ ) = 1 $\mu$ g/mL 的标准对照液
12	PH value 酸碱度	The difference of the pH value between the test solution of the A.V. fistula needle and the blank solution should not exceed 1.5 采血器检验液与空白液 pH 值之差应不超过 1.5
13	Residue after evaporation 蒸发残留	The total amount of evaporation residue should not exceed 2mg 蒸发残渣的总量应不超过 2mg
14	Ultraviolet absorbency 紫外吸光度	The absorbency of the test liquid of the blood sampling device should not be greater than 0.1 in the range of 250nm~320nm 采血器检验液的吸光度在 250nm~320nm 范围内应不大于 0.1
15	EO residue 环氧乙烷残留	The EO residue of each set of A.V. fistula needle set shall not be greater than 0.5 mg 每套采血器环氧乙烷残留量应不大于 0.5mg
16	Bacterial endotoxin 细菌内毒素	The bacterial endotoxin shall be less than 0.5EU/mL 细菌内毒素含量应小于 0.5EU/mL
17	Hemolysis 溶血	The hemolysis rate of the A.V. fistula needle set should be less than 5% 采血器溶血率应小于 5%

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## Annex A: Particle Contamination Test

### 附录 A：微粒污染试验

#### A.1 Principle 原理

By flushing the surface of the liquid channel in the lumen of the blood collection device, the particles on the filter membrane are collected and counted with a microscope.  
 通过冲洗采血器内腔液体通道表面，收集滤膜上的微粒，并用显微镜进行计数。

#### A.2 Reagents and Materials 试剂和材料

Distilled water (filtered with a membrane with a pore size of 0.2μm), powder-free gloves, and a vacuum filter membrane (with a pore size of 0.45μm).  
 蒸馏水（用孔径 0.2μm 的膜过滤）、无粉手套、真空滤膜（孔径 0.45μm）。

#### A.3 Steps 步骤

Before the test, use distilled water to fully clean the filter device, filter membrane and other appliances.  
 试验前应用蒸馏水充分清洗过滤装置、滤膜及其他器具。  
 Under the condition of laminar flow, take 10 A.V. fistula needle sets for use, wash the inner cavity with 500ml distilled water each, and then pass each eluate through a vacuum filter membrane, place the grid filter membrane under the microscope (incident illumination). Measure it under 50-times magnification, and count according to the size classification given in Table A.1.  
 在层流条件下，取 10 支供用状态的采血器，各用 500ml 蒸馏水冲洗内腔，然后使各洗脱液通过一个真空滤膜，将该格栅滤膜置于显微镜下（入射照明）在 50 倍放大倍数下对其进行测量，并按表 A.1 所给尺寸分类进行计数。

Table A.1 Particle Contamination Evaluation  
 表 A.1 微粒数污染评价

Parameter 参数	Size classification 尺寸分类		
Particle size/μm 微粒大小/μm	20~50	51~100	> 100
Mean number of particles in 10 A.V. fistula needle sets 10 支采血器中平均微粒数	N <sub>a1</sub>	N <sub>a2</sub>	N <sub>a3</sub>
Mean number of particles in the blank control solution 空白对照液中平均微粒数	n <sub>b1</sub>	n <sub>b2</sub>	N <sub>b3</sub>
Evaluation coefficient 评价系数	0.1	0.2	5

#### A.4 Results Determination 结果确定

Each A.V. fistula needle set tested (at least 10 pcs) is tested only once, and the average particle count of each A.V. fistula needle set in three sizes is used as the analysis result.  
 各供试采血器（至少 10 支）只进行一次试验，以每支采血器三个尺寸分类的平均微粒计数作为分析结果。  
 The test report should record the measured values of the blank control solution (using the same test device rather than the test samples; mean number of particles is measured with 10 equal parts of 500ml water sample when classified according to the 3 size classifications given in Table A.1) to calculate the contamination index.

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试验报告中应记录测得的空白对照液的各值（用同样的试验装置，但不通过供试样品，按表 A.1 给出的 3 个尺寸分类测得的 10 等份 500ml 水样的平均微粒数），用以计算污染指数。

The number of blank particles  $N_b$  should not exceed 9. Otherwise, the test device should be disassembled and cleaned again, and the background test should be performed again. The test report should indicate the blank determination value.

空白的微粒数  $N_b$  应不超过 9。否则应拆开试验装置重新清洗，并重新进行背景试验。试验报告中应注明空白测定值。

Calculate the contamination index as follows:

按以下计算污染指数：

Multiply the mean number of particles in the 10 A.V. fistula needle sets of each size by the evaluation coefficient, and add the results to obtain the number of particles in the A.V. fistula needle set,  $N_a$ . Then, multiply the mean number of particles in the blank control sample classified in each size by the evaluation coefficient, and add the results to obtain the number of particles in the blank sample,  $N_b$ . The contamination index is obtained by subtracting  $N_a$  from  $N_b$ .

对各尺寸分类的 10 个采血器中平均微粒数分别乘以评价系数，各结果相加即得出采血器的微粒数， $N_a$ 。再对各尺寸分类的空白对照样品中的平均微粒数分别乘以评价系数，各结果相加即得空白样品中的微粒数， $N_b$ 。 $N_a$  减  $N_b$  即得污染指数。

Number of particles in the A.V. fistula needle set:  $N_a = n_{a1} \cdot 0.1 + n_{a2} \cdot 0.2 + n_{a3} \cdot 5$

Number of particles in the blank samples:  $N_b = n_{b1} \cdot 0.1 + n_{b2} \cdot 0.2 + n_{b3} \cdot 5$

Contamination index:  $N = N_a - N_b \leq 90$ .

采血器中微粒数:  $N_a = n_{a1} \cdot 0.1 + n_{a2} \cdot 0.2 + n_{a3} \cdot 5$

空白样品中的微粒数:  $N_b = n_{b1} \cdot 0.1 + n_{b2} \cdot 0.2 + n_{b3} \cdot 5$

污染指数:  $N = N_a - N_b \leq 90$ 。

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## Summary of A.V. Fistula Needle Set

Type	Specification	Gauge	Needle OD	Hub Color	Clamp Color	Needle Length	Tube Length	Package
A-01	Rotated Wing	15G	1.8mm	Blue	Red/Blue	25mm	300mm	100pcs/box,10boxes/carton
A-02	Rotated Wing	16G	1.6mm	Green	Red/Blue	25mm	300mm	100pcs/box,10boxes/carton
A-03	Rotated Wing	17G	1.4mm	Yellow	Red/Blue	25mm	300mm	100pcs/box,10boxes/carton
A-04	Rotated Wing	18G	1.2mm	Red	Red/Blue	25mm	300mm	100pcs/box,10boxes/carton
A-05	Rotated Wing	15G	1.8mm	Blue	Red/Blue	25mm	285mm	100pcs/box,10boxes/carton
A-06	Rotated Wing	16G	1.6mm	Green	Red/Blue	25mm	285mm	100pcs/box,10boxes/carton
A-07	Rotated Wing	17G	1.4mm	Yellow	Red/Blue	25mm	285mm	100pcs/box,10boxes/carton
A-08	Rotated Wing	18G	1.2mm	Red	Red/Blue	25mm	285mm	100pcs/box,10boxes/carton
A-09	Rotated Wing	15G	1.8mm	Blue	Red/Blue	25mm	150mm	100pcs/box,10boxes/carton
A-10	Rotated Wing	16G	1.6mm	Green	Red/Blue	25mm	150mm	100pcs/box,10boxes/carton
A-11	Rotated Wing	17G	1.4mm	Yellow	Red/Blue	25mm	150mm	100pcs/box,10boxes/carton
A-12	Rotated Wing	18G	1.2mm	Red	Red/Blue	25mm	150mm	100pcs/box,10boxes/carton
B-01	Fixed Wing	15G	1.8mm	Blue	Red/Blue	25mm	300mm	100pcs/box,10boxes/carton
B-02	Fixed Wing	16G	1.6mm	Green	Red/Blue	25mm	300mm	100pcs/box,10boxes/carton
B-03	Fixed Wing	17G	1.4mm	Yellow	Red/Blue	25mm	300mm	100pcs/box,10boxes/carton
B-04	Rotated Wing	18G	1.2mm	Red	Red/Blue	25mm	300mm	100pcs/box,10boxes/carton
B-05	Fixed Wing	15G	1.8mm	Blue	Red/Blue	25mm	285mm	100pcs/box,10boxes/carton
B-06	Fixed Wing	16G	1.6mm	Green	Red/Blue	25mm	285mm	100pcs/box,10boxes/carton
B-07	Fixed Wing	17G	1.4mm	Yellow	Red/Blue	25mm	285mm	100pcs/box,10boxes/carton
B-08	Rotated Wing	18G	1.2mm	Red	Red/Blue	25mm	285mm	100pcs/box,10boxes/carton
B-09	Fixed Wing	15G	1.8mm	Blue	Red/Blue	25mm	150mm	100pcs/box,10boxes/carton
B-10	Fixed Wing	16G	1.6mm	Green	Red/Blue	25mm	150mm	100pcs/box,10boxes/carton
B-11	Fixed Wing	17G	1.4mm	Yellow	Red/Blue	25mm	150mm	100pcs/box,10boxes/carton
B-12	Rotated Wing	18G	1.2mm	Red	Red/Blue	25mm	150mm	100pcs/box,10boxes/carton