



## Technical File for Disposable Blood Lines

### 1. Product Description

#### 1) Intended Use

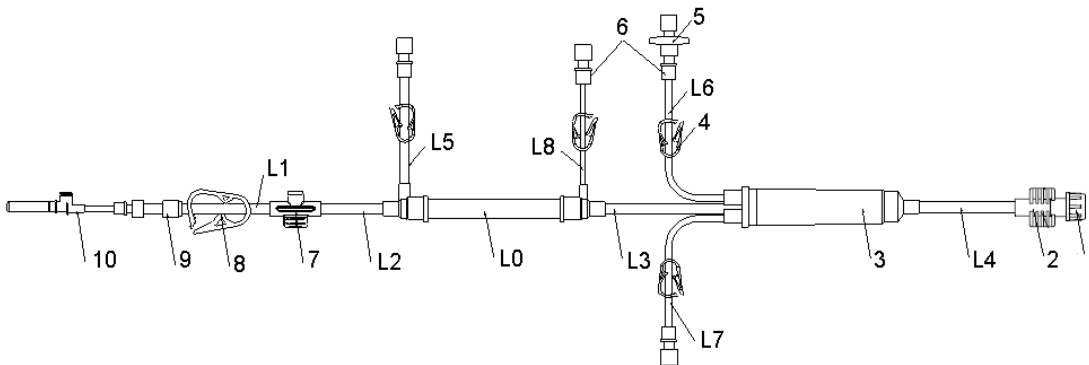
The Disposable Blood Lines are intended to establish blood circulating path outside human body. It can match all dialysis machines

#### 2) Main Parts

##### 2.1 Device Description

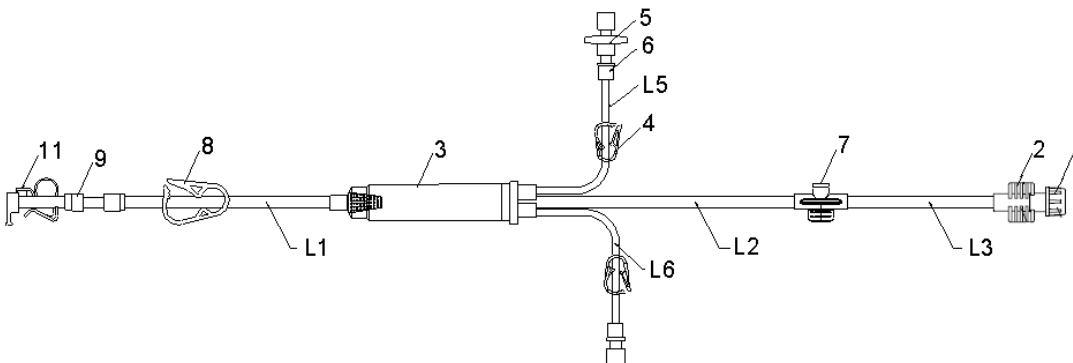
The Disposable Blood Lines are consisting of Red Arterial line, Blue Venous line, and some selected accessories. The Venous line is consisting of Main tube, Monitor tube, Chamber (including filter), cap of dialyser connector, On-off clamp, Injection port, Transducer protector (Disposable filter), Female luer lock, male luer lock, Speikes; Selection of accessories include: Disposable infusion sets, disposable Drainage bags.

##### 2.1.1 Arterial Blood Line



1-Protective cap ; 2- Dialyzer Connector ; 3- Drip Chamber ; 4- Pipe Clamp ; 5- Transducer Protector ; 6-Female Luer Lock ; 7- Sampling Port ; 8- Pipe Clamp ; 9-Male Luer Lock ; 10- Speikes

##### 2.1.2 Venous Blood Line



1-Protective cap ; 2- Dialyzer Connector ; 3- Drip Chamber ; 4- Pipe Clamp ; 5- Transducer Protector ; 6-Female Luer Lock ; 7- Sampling Port ; 8- Pipe Clamp ; 9-Male Luer Lock ; 11- Circulating Connector



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2.2 Precautions, restrictions, warnings, special care  
Refer to Attach 1 Instruction For Use

2.3 Use method  
Refer to Attach 1 Instruction For Use

### 3) Product Photo



Venous line



Arterial line

## 2. Classification

Class II a, according to MDD Annex IX, rule 2



### 3. Product Specification

The blood line is divided into below specification according to the length segment of each pipe.

Table 1 Pipe length of the arterial line Unit (mm)

Arterial line ±20										
Code	L0	L1	L2	L3	L4	L5	L6	L7	L8	Priming volume (ml)
A001	350	1600	350	600	850	80	80	0	600	90
A002	350	1600	350	600	850	500	80	0	600	90
A003	350	1600	350	600	850	500	80	100	600	90
A004	350	1750	250	700	1000	80	80	100	600	95
A005	350	400	125 0	500	600	500	450	0	600	80
A006	350	1000	600	750	750	80	80	0	600	84
A101	350	1600	350	600	850	80	80	0	600	89
A102	190	1600	350	600	850	80	80	0	600	84
A103	350	1600	350	600	850	500	80	100	600	89
A104	190	1600	350	600	850	80	80	100	600	84

Table 2 Pipe length of the Venous line Unit (mm)

Venous Line±20						
Code	L1	L2	L3	L5	L6	Priming volume (ml)
V01	1600	450	450	500	80	55
V02	1800	450	450	610	80	80
V03	1950	200	800	500	80	87
V04	500	1400	800	500	0	58
V05	1800	450	450	600	80	58
V11	1600	460	450	500	80	55
V12	1300	750	450	500	80	55

**Note:** L0, L1, L2.....is the pipe of the blood line, L0, L1, L2 can refer to the drawing of the point 2.1.1 & 2.1.2.

Therefore, there're 38 models of the blood line

There're 30 models of the blood line for the pump size of  $\Phi 12.1/\Phi 7.9$ , they're as follow:

FB-A001V01, FB-A001V02, FB-A001V03, FB-A001V04, FB-A001V05, FB-A002V01, FB-A002V02, FB-A002V03, FB-A002V04, FB-A002V05, FB-A003V01, FB-A003V02, FB-A003V03, FB-A003V04, FB-A003V05, FB-A004V01, FB-A004V02, FB-A004V03, FB-A004V04, FB-A004V05, FB-A005V01, FB-A005V02, FB-



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A005V03, FB-A005V04, FB-A005V05, FB-A006V01, FB-A006V02, FB-A006V03, FB-A006V04 and FB-A006V05

There're 8 models of the blood line for the pump size of  $\Phi 9.75/\Phi 6.4$ , they're as follow:

FB-A101V11, FB-A101V12, FB-A102V11, FB-A102V12, FB-A103V11, FB-A103V12, FB-A104V11, and FB-A104V12

#### 4. Product Flowchart

Refer to attach 2 Product flowchart for bloodline.

#### 5. Description of Packaging

- Large outer package (craft carton).
- Unit package (PA/PE film & Adhesive paper).

The package for single unit is thermally sealed by pneumatic thermal sealing machine.

#### 6. Bill of material

Parts	Materials	Contact blood or not?
Dialyzer Connector, Self-ejecting Patient Connector	PVC	Yes
Drip Chamber	PVC	Yes
Pump Tube, Main tube, Monitor tube, Heparin tube	PVC	Yes
Sampling Port(Blood Injection Site)	PVC	Yes
Female Luer Lock	PVC	Yes
ON-off Clamp	PP	No
Recirculating Connector	PP	No

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Date: 13<sup>th</sup> October, 2017