

山东五洲医疗器械有限公司

Shandong Wuzhou Medical Equipment Co., Ltd.

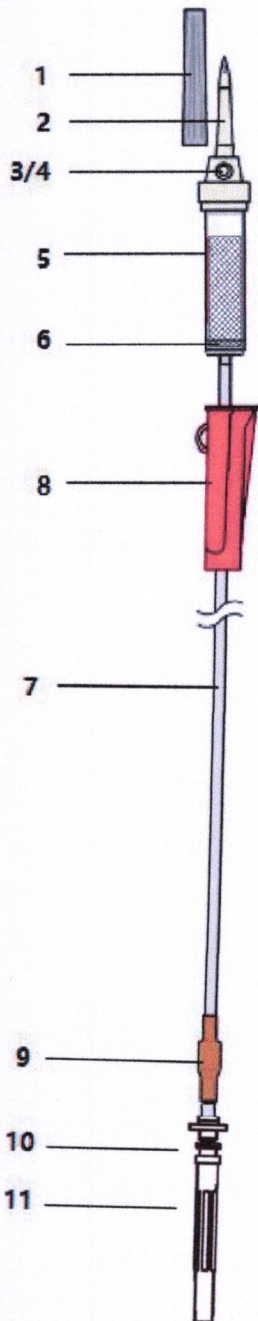
Address: Dingtao(Yantai)Industrial Area, Heze, 274100 Shandong, P.R. China.

Technical File of Blood Transfusion Set

Product Introduction:

Ref code: BTS-ST01

Drawing



Description:

1. Spike cap
2. Spike
3. Air filter
4. Air inlet cap
5. Drip chamber
6. Filter
7. Tube
8. Roller clamp
9. Injection site
10. Luer slip connector
11. In vein needle

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山东五洲医疗器械有限公司

中国 山东
CHINA SHANDONG
Zhang Wen

Document No:	TEF-BTS-ST01	Revision No:	V.002	Date of Revision:	2022.04.27
Responsible:	ZHANGWEN	Signature:			

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Address: Dingtao(Yantai)Industrial Area, Heze, 274100 Shandong, P.R. China.

Description	Disposable Blood Transfusion Set, 155 cm, with needle 18G*11/2"		
Type	Vented, Luer Slip		
Composition		Material	Details
Components	Spike Cap	Polyethylene (PE)	
	Spike	Acrylonitrile Butadiene Styrene (ABS)	
	Air Inlet Cap	Polyvinyl Chloride (PVC)	Red
	Drip Chamber	Polyvinyl Chloride (PVC)	98mm, Transparent, Flexible
	Filter	Nylon and ABS	Micron: 200µm
	Tube	Polyvinyl Chloride (PVC)	Min.150cm, Transparent, Kink resistant
	Roller Clamp	Polyethylene (PE)	
	Injection Site	Rubber	Latex
	Luer Slip Connector	ABS	
	Needle	PP and Stainless Steel	18G*11/2"
Intended Use		For intravenous blood transfusion	
Drop Factor		20 drops of distilled water at $(20 \pm 2) ^\circ\text{C}$ and at a flow rate of (50 ± 10) drops/min deliver $(1 \pm 0,1)$ ml $[(1 \pm 0,1) \text{ g}]$.	
Sterilization		Ethylene Oxide (E.O.)	
Shelf Life		60 months	
Product Standards		ISO1135-4:2012	
Classification		MDD 93/42/EEC, Class IIa	
Certificates		CE, ISO13485, FSC	
Packaging		Single PE bag, 25 pcs. per middle bag, 500 pcs. per carton	

Features:

- Non-toxic;
- Non-pyrogenic;
- Packed in sterile unit packages.

Operation Instruction:

1. Open the individual packing and take out the blood transfusion set.
2. Insert plastic spike into container.
3. Open roller clamp.
4. Control the liquid level on 1/2~1/3 of dripping chamber.
5. Expel the air.
6. Adjust flow rate by roller clamp.
7. Open air inlet if use glass container and close the air inlet if use soft container.
8. Dispose properly as medical waste after use.

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Storage:

Store in relative humidity less than 80%, no corrosive gas, cool, dry, well ventilated, clean environment.

Cautions:

1. Check the batch number and validity before use.
2. Tighten the needle before use.
3. It is strictly prohibited to use if the single packing damaged or needle cap.
4. Drop off.
5. For single use only, use immediately after unsealed, destroy after use.
6. It is strictly prohibited to reuse.
7. Specially designed for transfusion of blood and blood components, not recommended for regular IV infusion.

Product picture:



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Label design:

包装尺寸:225x100mm 颜色要求: 红色PT032C

Blood Transfusion Set	
TO USE TRANSFUSION SET • Close the roller clamp • Remove the cover from plastic lancet • Punch the lancet into the fluid container • Fix the metal needle to the vein part • Open the roller clamp and expel the air bubbles • Close the roller clamp • Apply the vein needle to the patient • Adjust the flow rate Manufactured by: Shandong Wuzhou Medical Equipment Co., Ltd. Add:Dingtao (Yantai) Industrial Area, Heze City, 274100 Shandong,P.R.China	20drops=1mL±0.1mL L: 155cm 18Gx1 ½" CAUTION • Do not resterilize • Sterile unless package has been opened or damaged • Do not use if the package is opened or damaged • Discard after single use • Do not store in direct sunlight, at extreme temperature, or in high humidity Please use this pouch to replace the enclosed medical device after use STERILE EO CE 0197 ISO 13485 MADE IN CHINA REF: BTS-ST01 LOT 20230320 20230320 20280320 TEAR OPEN
30mm	8mm

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