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Plastic Blood Bags For Single Use Instruction for use				Issue Dep.		Technical Dep.	
Editor/Date				Comptroller/Date			
Approval/Date				Implementation Date		2018. 07. 20	
Issue to		/					
Revision status							
Revision Date							

## 1.0 Product Name

Plastic Blood Bag for Single Use.

## 2.0 Manufacturer and Address

### 2.1 Manufacturer

Shandong Weigao Group Medical Polymer Co., Ltd

### 2.2 Manufacturer's address

No.18 Xingshan Road, High-tech Industrial Development Zone, Weihai, Shandong Province, China

### 2.3 Production address

No.10 Junshan Road, High-tech Industrial Development Zone, Weihai, Shandong Province, China

## 3.0 Representative and address of the European Union

### 3.1 EU Representative

Shanghai International Holding Corp.GmbH(Europe)

### 3.2 Address

Eiffestrasse 80, 20537 Hamburg Germany

## 4.0 Product Instruction

4.1 The product is a closed system consisting of blood collection needle, tube, transfusion connector and bag body, sterile, non-toxic, non-pyrogen.

4.2 This product contains maintenance solution CPDA-1, which is suitable for collecting the whole blood and the clinical transfusion of blood or separation of blood components.

4.3 This product is sterilized by High temperature steam. The validity period is 2 years.

4.4 Packing bag of the product is a high temperature resistant composite membrane packing bag.

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## 5.0 Instruction

5.1 Instruction for use of plastic blood bag for single use.

5.1.1 Selection of puncture site for blood collection

5.1.2 Tie the tourniquet and disinfect the puncture site.

5.1.3 Close the stop clamp of blood bag blood, rotate and open the protective cap of blood collection needle (pay attention to not touch the needle when opening). After the disinfectant is dried, venipuncture is carried out at the puncture site, and the blood collection needle is fixed.

5.1.4 Put the blood bag on the swing scale.

5.1.5 When using the blood bag with safety sampling device, the break-away cannula connected with the sampling device is opened to make the blood flow into the sampling bag of the sampling device. After the sampling, the stop clamp on the sampling device is closed.

5.1.6 Open the stop clamp on the blood bag, and make the blood flow into the blood bag.

5.1.7 When the blood collection volume reaches the requirement, loosen the tourniquet, close the tourniquet clip on the blood bag tubing, take out the blood collection needle and handle the puncture site according to the requirement.

5.1.8 If using the blood bag without safety device, the used venipuncture needle can be inserted into the vacuum blood collection tube to collect blood samples.

5.1.9 When the blood bag with needle protection device is used, the needle can be completely covered by the needle protection cap along the direction of the catheter after the blood collection, and the catheter can be fixed at the end of the needle protection device.

5.1.10 Heat sealing and separate the catheter of blood collection needle and dispose of the used blood collection needle according to the prescribed requirements.

5.1.11 when using the blood bag with a sampling device, heat sealing and separate the sampling device after the end of blood collection, and the blood collection tube can be collected from the sampling device according to the requirements.

5.1.12 Store the blood bags at the prescribed temperature.

5.1.13 Separation, transfer and storage of blood components are performed as required.

## 5.2 Attention :

5.2.1 Products use must conform to the requirements of blood stations operating norms and

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relevant laws and regulations related, is limited to the training of blood stations personnel.

5.2.2 Single use, destroyed after use.

5.2.3 Forbid to use, if the accessories fall off, displace or defect, the anticoagulant solution is turbid or there is foreign body in it.

5.2.4 Forbid to use, if the products is broken, polluted or has solution leakage.

5.2.5 When the bags are in frozen condition, Vibration should be avoided to prevent bags or tube fracture, before use, the liquid inner bag should be melt into a liquid state.

### 5.3 Special attention:

5.3.1 This product is valid for two years. The bags must be used to collect the blood in 35 days before the expiration of blood bags.

5.3.2 When breaking the break cannula, we should break the stopper to make it into dissociative condition to make ensure the blood flow smoothly.

5.3.3 The condition of store whole blood will be 2℃-6℃ with 35 days

5.3.4 The products are PVC soft plastic container, No ventilation is required during transfusion

5.3.5 This product is made of PVC material containing phthalate two formic acid two (2- ethyl) ester (DEHP) plasticized, and the product contains DEHP, and children are prohibited from using it.

### 6.0 Document Change Record

No.	Reasons for change	Description	Previous edition	
			Edition	Implementation Date
1	Updated the production address	Updated from No.10 Mashan Road, High-tech Industrial Development Zone, Weihai, Shandong Province, China to No.10 Junshan Road, High-tech Industrial Development Zone, Weihai, Shandong Province, China	D/1	2017.04.20