WHOLE BLOOD PROCESSING AND COMPONENT PREPARATION
UTILIZING THE IMUFLEX® WB-SP BLOOD BAG SYSTEM

Description

Training will consist of:
1. Reading the following documents:
   a. Your institution’s SOP for Whole Blood processing and component production utilizing the IMUFLEX® WB-SP Blood Bag System. Record your institution’s procedure # on the line below in Procedure Review.
   b. The Terumo Instructions for Use (package insert)
2. Presentation and Demonstration by a trainer
3. Practicing the procedure

Procedure Review

Read your institution’s SOP and the Instructions for Use (package insert) for Whole Blood processing and component production utilizing the IMUFLEX® WB-SP Blood Bag System.

If you have any questions, ask them. After reading each document, initial and record the date on the lines below.

Procedure # _______________________
Initials:_____________________ Date:______________________

Instructions for Use

Initials:_____________________ Date:______________________

Demonstration

Observe the procedure being performed by a trainer or designate. Document the observation on the following line.

I observed the procedure performed by ______________________ on __________/________/________.

Practice

• Familiarize yourself with the IMUFLEX® WB-SP Blood Bag System.
• Review the procedure steps and practice by performing each step with all the necessary materials.
• Once you feel comfortable with the procedure arrange to demonstrate the procedure to a trainer or designate.

Self Appraisal

I feel comfortable processing and preparing blood components using the IMUFLEX® WB-SP Blood Bag System.

Employee: ___________________________ Date: ___________________________
### WHOLE BLOOD PROCESSING AND COMPONENT PREPARATION

### DIRECT OBSERVATION

#### Instructions

**FOR TRAINEE:** After completion of training on the use of the IMUFLEX® WB-SP Blood Bag System, arrange to have a trainer observe you process a unit of whole blood.

**FOR TRAINER:** Directly observe performance of each step of the procedure as listed in the table below. For each step that conforms to procedure, a mark should be placed in the YES box. If any step of the procedure is performed incorrectly a mark should be placed in the NO box. If an optional step is not performed at your institution, mark the Not Applicable (NA) box.

<table>
<thead>
<tr>
<th>Component Processing</th>
<th>YES</th>
<th>NO</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Whole Blood Unit Preparation &amp; First Centrifugation</strong></td>
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<tr>
<td>Prepare blood bag system including satellite bags and tubing for centrifugation</td>
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<tr>
<td>Balance blood bags and place any balancing weights between the satellite bags</td>
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<tr>
<td>Mix the unit thoroughly prior to centrifugation</td>
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<tr>
<td>Place blood bag unit into centrifuge cup/cup liner per recommended loading procedure</td>
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<tr>
<td>Place segments horizontally in front of the primary bag</td>
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<tr>
<td>Ensure that blood bags are fully seated at the bottom of the cup by gently tapping the cups against a flat surface</td>
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<tr>
<td>Set the centrifuge to the appropriate settings for the components being prepared</td>
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<tr>
<td>Centrifuge whole blood at the assigned conditions for the component(s) to be prepared</td>
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<tr>
<td>Remove blood bags promptly and carefully at completion of centrifugation</td>
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<tr>
<td><strong>Platelet Rich Plasma (PRP) Expression</strong></td>
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<tr>
<td>Position primary bag into the expressor</td>
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<tr>
<td>Break CLIKTIP® of the primary bag in two directions, away from and toward you, to transfer leukocyte reduced PRP into the XT-612® platelet bag</td>
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<tr>
<td>Express PRP into the XT-612® platelet bag</td>
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<tr>
<td><strong>NOTE:</strong> Express cellular interface to the outlet ports of the bag. Due to leukoreduction, there will NOT be a buffy coat layer. To maximize recovery of platelets, Red Blood Cells may be expressed into tubing but not beyond the “Y”</td>
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<tr>
<td>Clamp transfer tubing of the platelet bag</td>
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<tr>
<td>Break the CLIKTIP of the OPTISOL® solution bag in two directions, away from and toward you, and drain the contents into the primary bag containing the leukocyte reduced packed Red Blood Cells.</td>
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</tbody>
</table>

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TERUMO MEDICAL CORPORATION

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TERUMO TRANSFUSION PRODUCTS

REV. 3/2/2007
Seal tubing of the primary bag in two places, cut between seals and separate primary bag from the XT-612 platelet bag and OPTISOL bag

NOTE: Empty OPTISOL container may now be used for further processing of plasma components following approved regulations and standards

Mix the Red Blood Cells and OPTISOL thoroughly by inversion

Store AS-5 Red Blood Cells, Leukocytes Reduced between 1-6°C for up to 42 days.

Second Centrifugation

Prepare PRP for centrifugation by balancing the blood bag sets and placing two units per centrifuge cup/ cup liner

Place the balanced centrifuge cups/ cup liners into the centrifuge rotor

Set the centrifuge to the appropriate settings for platelet preparation

Remove units promptly and carefully

Platelet Poor Plasma (PPP) Expression

Place unit in the expressor with bag label facing the back of the expressor and the unit at an angle by tilting the bag

Position the bag at an angle with the outlet tubing at the uppermost point of the angled platelet bag

Express PPP until there is about 50mL of plasma remaining on the PC

Remove the unit from the expressor and adjust the final plasma volume to 55-65mL

Seal tubing of each product in two places, cut between seals and separate

Equilibration – Resting Platelets

Rest platelets label side down for 90-120 minutes at 20-24°C without stacking or overlapping

After the rest period, place units on platelet rotator

Store Platelets, Leukocytes Reduced between 20-24°C for up to 5 days

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Trainer:
In my judgment the employee is able to perform the above procedure □ YES □ NO

If NO, corrective action required: ________________________________________________________________

Witness: ________________________________________________________________________________ Date: __________________

Title: ___________________________________________________________________________________ Date: ________________

Reviewed by Employee: ___________________________________________________________________ Date: ________________