IMUFLEX WB-RP BLOOD BAG SYSTEM WITH INTEGRAL WHOLE BLOOD LEUKOCYTE REDUCTION FILTER (REMOVING PLATELETS) WITH DIVERSION BLOOD SAMPLING ARM ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE (CPD) AND OPTISOL (AS-5) RED CELL PRESERVATIVE - anticoagulant citrate phosphate dextrose (cpd) and as-5 red cell preservative
Terumo Corporation

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IMUFLEX® WB-RP BLOOD BAG SYSTEM WITH INTEGRAL WHOLE BLOOD LEUKOCYTE REDUCTION FILTER (REMOVING PLATELETS) WITH DIVERSION BLOOD SAMPLING ARM® CPD/OPTISOL® SOLUTION

Issued 01/06
N-WR-OP-A-DB 1

IMUFLEX® WB-RP BLOOD BAG SYSTEM WITH INTEGRAL WHOLE BLOOD LEUKOCYTE REDUCTION FILTER (REMOVING PLATELETS) WITH DIVERSION BLOOD SAMPLING ARM® CPD/OPTISOL® SOLUTION

Read these instructions carefully before use. Rx ONLY.

Integral filter unit intended for leukocyte reduction of Whole Blood up to 8 hours after blood collection when Whole Blood is stored at ambient temperature or cooled towards 1–10°C (transport temperature). Preparation of leukocyte reduced red blood cells and plasma units may be accomplished with this set. The leukocyte reduced blood components may then be stored for the maximum allowable dating period as indicated in the section INSTRUCTIONS FOR COMPONENT SEPARATION.

• For single use only. Sterile and non-pyrogenic fluid path. Sterilized by steam.
• Intended for the collection, processing and preservation of human blood and components.

PRECAUTIONS
• Do not use unless the solutions are clear.
• Avoid excessive heat and direct sunlight. Protect from freezing.
• Recommended storage conditions: Room Temperature (15-30°C/59-86°F).

CAUTION Do not use a dielectric tube sealer to seal the tubing while the needle is connected to the donor's body unless it is approved for such a purpose.

INSTRUCTIONS FOR BLOOD COLLECTION: Use aseptic technique
(See Fig. 1, Fig. 2 and Fig. 3)

Materials Needed:
VENOJECT ll Tube Holder (code P-1316R) or equivalent
VENOJECT ll Multi-Sample Luer Adapter (code MN *2000T) or equivalent
Evacuated Blood Collection Tubes

1. Prepare the blood bag following your institution's standard operating procedures.
2. Make a loose knot in the donor tubing below the "Y" and CLIKTIP (inline closure device) unless alternate methods are used to seal the tubing at the end of collection.
3. Temporarily clamp the donor tubing between the phlebotomy needle and the "Y".

4. Close the White Clamp below the diversion pouch.

5. Tube Holder/Luer Adapter Assembly:
a) Connect the VENOJECT Multi-Sample Luer Adapter to the VENOJECT Tube Holder (or equivalent) (Fig.1).
b) Twist and snap to remove the blue port cap at the end of the Diversicn Blood sampling Arm (Fig. 2a).
c) Insert the Holder/Luer assembly in the female luer port. (Fig. 2b)
NOTE: Alternatively, steps a, b and c (above) may be performed at any time during bag preparation or after the blood is collected into the diversion pouch.

Insert Fig. 2a and 2b here
6. Suspend the collection bag as far as possible below the donor's arm.

7. Apply blood pressure cuff or tourniquet to donor's arm. Disinfect site of phlebotomy. If blood pressure cuff is used, inflate to approximately 60 mmHg.

8. Remove the needle cover and perform phlebotomy. Remove the temporary clamp on the donor tubing to permit blood flow into the Diversion Blood Sampling Arm pouch.

**CAUTION** Do not touch the needle after removing the needle protector. Assure that the White Clamp below the pouch is closed prior to initiating phlebotomy.

9. Secure the needle safety device in place following the manufacturer's instructions.

10. Secure donor tubing to donor's arm.

11. Position the diversion pouch with the notches up and the Tube Holder/Luer Adapter assembly (or port cap) down. When the level of blood in the pouch is approximately in line with the notches, the diversion pouch is full. (Fig. 3a)

**NOTE:** The approximate fill volume of the pouch at the notches is 35 mL.

12. **Permanently seal the tubing between the "Y" and the diversion pouch to maintain a closed system using an aluminum clip or a tube sealer approved for use with tubing connected to a donor. (Fig. 3b)**

13. To initiate blood flow into the collection bag, break the CLIKTIP between the "Y" and the collection bag.

14. **To avoid clot formation, collect samples as soon as possible from the diversion pouch as follows (Fig. 3b)**

**CAUTION** Do not collect donor test samples until the tubing between the "Y" and the diversion pouch is permanently sealed.

- a) Open the White Clamp on the tubing below the pouch to open the pathway for sampling.
- b) Position the diversion pouch with the notches up and the Tube Holder/Luer Adapter assembly downward. Assure that any air in the pouch is at the top and will not enter the blood collection tubes.
- c) Insert blood collection tube firmly into the tube holder; when full, remove sample tube from holder. Repeat to collect additional samples.
NOTE: The pouch may be removed after the donor test samples are collected. A second seal must be made between the diversion pouch and the permanent seal prior to removing the pouch.

Insert Fig. 3a and 3b here

15. Mix blood with anticoagulant in the collection bag and continue to mix at several intervals during collection and immediately after collection. If using an automated mixer, follow manufacturer's instructions.
16. Collect labeled volume of blood (±10%).
17. When the desired amount of blood has been collected, seal the tubing or tighten the loose knot (white knot) prepared in step 2. Make a second seal between the first seal or knot and the CLIKTIP below the “Y”. Various methods may be used to seal tubing.
18. Release pressure on the donor's arm and remove the needle into the needle safety device following the manufacturer's instructions. Sever the donor tubing between the two seals
previously made below the CLIKTIP and "Y".

CAUTION Discard the Diversion Blood Sampling Arm and phlebotomy needle/donor tubing according to institutional procedures.

19. Seal and remove donor tubing from collection bag or strip donor tubing as follows:
   a) To obtain a quality control prefiltration sample, strip blood from donor tubing into collection bag, mix well, and allow tubing to refill; repeat once. Leave an adequate length of tubing containing the well-mixed anticoagulated whole blood attached to the collection bag.
   OR
   b) To maximize collection recovery, strip the tubing, mix well and seal tubing close to the collection bag without refilling. Remove tubing from collection bag.

INSTRUCTIONS FOR BLOOD FILTRATION
(See Fig. 4)
NOTE: Wait 30 minutes after collection before filtering. Filtration can be accomplished at room temperature for units maintained at room temperature and filtered within 8 hours of collection. Filtration can also be performed with units cooled towards 1-10°C within 8 hours of collection (e.g. during transport). If any unit has not completely filtered by 8 hours post collection, filtration must be completed at 1-6°C. Filtration can be unattended.

Insert Fig. 4 here

1Red blood cells collected from certain donors may have extended filtration times and the potential for ineffective filtration and leukoreduction.

1. Mix the unfiltered whole blood unit by inverting the collection bag #1 (pre-filter bag) several times.
2. Hang the collection bag #1 and extend the filtration set to full length. Verify that the filter is vertical and ensure all tubing is freely suspended without kinks.

3. Break the CLIKTIP at the outlet of the collection bag #1.
   a) The filter housing will begin to fill with blood and expand on the non-textured side.
   b) Blood will flow across the filter pads and expand the textured side of the filter housing.
   c) Air from the bag and filter will be forced into the primary bag #2 (post-filtration bag).
   **CAUTION** Do not squeeze or apply pressure on the filter while it is attached to the bag containing the filtered blood.

4. Filtration ends when the filter has emptied and the housing has collapsed onto the filter pads.
   **NOTE:** Verify that collection bag #1 and pre-filtration tubing has emptied.

5. Gently squeeze the primary bag #2 to expel the air in the bag up the numbered segment tubing line and into the filter.

6. Fill the numbered segment tubing with blood while expelling the air.

7. Clamp the blood filled tubing before blood enters the filter.

8. Seal the tubing as close as possible to the filter outlet and properly dispose of the filter and collection bag #1.

9. Strip the post filter tubing into the primary bag #2, mix well, and allow tubing to refill; repeat once. Make an appropriate number of segments necessary for testing by sealing on or near the X marks. Leave segments attached to the filtered whole blood unit.

**INSTRUCTIONS FOR COMPONENT SEPARATION**

**NOTE:**
- Production of Platelet concentrates is not intended with this product.
- Fresh Frozen Plasma should be separated from the Red Blood Cells and placed in a freezer at -18°C or colder within 8 hours of collection,
- OPTISOL should be added to the Red Blood Cells immediately after removal of the plasma. If plasma is not separated from the Red Blood Cells within 8 hours, OPTISOL may be added within 72 hours of collection if Whole Blood is refrigerated.
- Other components may be prepared following approved regulations and standards.

1. Follow your institution's standard component processing procedures to prepare components.
2. Centrifuge filtered whole blood unit to separate red cells from plasma.
3. Break the CLIKTIP of primary bag #2 and transfer leukocytes-reduced plasma into satellite bag #3. Clamp transfer tubing of satellite bag.
4. Break the CLIKTIP of OPTISOL Solution bag #4 and drain contents into primary bag #2 containing red blood cells. Seal tubing of primary bag in two places, and cut between seals and separate from satellite bag(s).
   **NOTE:** Empty OPTISOL container may be used for further component preparation.
5. Invert the red cell- OPTISOL mixture several times to insure the final product is well suspended.
6. Store AS-5 Red Blood Cells, Leukocytes Reduced between 1-6°C for up to 42 days.
   **NOTE:** Whole Blood or Red Blood Cells in CPD may be stored for up to 21 days at 1-6°C.

**BLISTER PACKAGE**

(See Fig. 5)
To open blister package, peel cover film back four fifths of its length. After opening, unused bags may be stored for 30 days by returning cover film to original position and sealing with tape to prevent possible loss of moisture.
CAUTIONS
• The AGELESS packet contained in this package absorbs oxygen and generates heat on removal. Do not open and handle it with care.
• Dispose of the AGELESS packet with the tray.
• Do not dispose with wastes containing volatile or flammable materials.

TERUMO® MANUFACTURED BY: TERUMO CORPORATION 44-1, 2-CHOME, HATAGAYA, SHIBUYA-KU, TOKYO, JAPAN MADE IN JAPAN © TERUMO CORPORATION 2006 06A30

Tray/Case Label
IMUFLEX® WB-RP BLOOD BAG SYSTEM WITH INTEGRAL WHOLE BLOOD LEUKOCYTE REDUCTION FILTER (REMOVING PLATELETS) WITH DIVERSION BLOOD SAMPLING ARM®

CPD WITH OPTISOL® RED CELL PRESERVATIVE SOLUTION FOR COLLECTION OF 500mL OF BLOOD

Each unit consists of a collection bag containing 70mL of Anticoagulant CPD solution, with a satellite bag containing 111mL of OPTISOL Red Cell Preservative Solution.
Each 70mL Anticoagulant CPD solution USP contains 1.79g Dextrose (monohydrate) USP, 1.84g Sodium Citrate (dihydrate) USP, 209mg Citric Acid (anhydrous) USP, 156mg Monobasic Sodium Phosphate
(monohydrate) USP. Each 111mL OPTISOL Red Cell Preservative Solution contains 974mg Sodium Chloride USP, 1.00g Dextrose (monohydrate) USP, 583mg Mannitol USP, 33.3mg Adenine USP.
STERILE, NON-PYROGENIC FLUID PATH.
DO NOT USE UNLESS ANTICOAGULANT IS CLEAR.

CODE

LOT No.

EXPIRY

UNITS

DONOR NEEDLE 16G x 1 1/2” (1.60 x 38mm)

Rx ONLY
RECOMMENDED STORAGE: Room Temperature (15-30°C/59-86°F).
Avoid excessive heat. Protect from freezing.

After opening, unused bags may be stored for 30 days by returning cover film to original position and sealing with tape to prevent possible loss of moisture.
See Instructions For Use.

Manufactured by: TERUMO CORPORATION Tokyo, Japan
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Issued 01/06
B-4-HR6-A2 1
Place Label here
IMUFLEX WB-RP BLOOD BAG SYSTEM WITH INTEGRAL WHOLE BLOOD LEUKOCYTE REDUCTION FILTER (REMOVING PLATELETS) WITH DIVERSION BLOOD SAMPLING ARM ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE (CPD) AND OPTISOL (AS-5) RED CELL PRESERVATIVE SOLUTION FOR COLLECTION OF 500mL OF BLOOD

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STERILE, NON-PYROGENIC FLUID PATH.
DO NOT USE UNLESS ANTICOAGULANT IS CLEAR.

CODE
LOT No.
EXPIRY
500 UNITS
DONOR NEEDLE 16G x 1 1/2” (1.60 x 38 mm)

Rx ONLY

RECOMMENDED STORAGE: Room Temperature (15-30 °C / 59-86 °F).
Avoid excessive heat. Protect from freezing.

After opening, unused bags may be stored for 30 days by returning cover film to original position and sealing with tape to prevent possible loss of moisture.
See Instructions for Use.

Manufactured by TERUMO CORPORATION Tokyo, Japan
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Issued 01/08)
**PRESERVATIVE**
anticoagulant citrate phosphate dextrose (cpd) and as-5 red cell preservative kit

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### Quantity of Parts

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### Part 1 of 2

**ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE (CPD)**

anticoagulant citrate phosphate dextrose (cpd) solution

### Product Information

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### Active Ingredient/Active Moiety

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<tr>
<td><strong>Trisodium Citrate Dihydrate</strong> (UNII: B22547B95K) (Citric Acid - UNII:2968PHW8QP)</td>
<td>Trisodium Citrate Dihydrate</td>
<td>26.3 g in 1000 mL</td>
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<td><strong>Sodium Phosphate, Monobasic</strong> (UNII: 3980JH2SW) (Phosphoric Acid - UNII:4GA8884NN)</td>
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<td>2.22 g in 1000 mL</td>
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<td><strong>Dextrose Monohydrate</strong> (UNII: LX22YL083G) (Dextrose - UNII:Y9XDZ35W2)</td>
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<td><strong>Anhydrous Citric Acid</strong> (UNII: XF417D3PSL) (Citric Acid - UNII:2968PHW8QP)</td>
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### Inactive Ingredients

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### Packaging
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**Part 2 of 2**

**OPTISOL RED CELL PRESERVATIVE**
as-5 red cell preservative solution

**Product Information**

**Route of Administration**

**ACTIVE INGREDIENT/ACTIVE MOIETY**

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<td>Mannitol (UNII: 3OWL53L36A)</td>
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<td>Adenine (UNII: JAC85A2161)</td>
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**INACTIVE INGREDIENTS**

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Revised: 6/2011

Terumo Corporation