

## SOLX® System - Instructions for Use

**DRAFT**

### HAEMONETICS Leukotrap® WB System with CPD Anticoagulant and SOLX® Additive Solution

#### Description:

The HAEMONETICS Leukotrap® WB System with CPD Anticoagulant and SOLX® Additive Solution is intended for the collection and leukoreduction of 500 mL CPD Whole Blood and subsequent processing into SOLX® (SOLX® is synonymous with AS-7) RBC and frozen plasma. The fluid pathway is sterile and non-pyrogenic.

#### Each unit consists of:

- Primary bag with 70 mL of Citrate Phosphate Dextrose Solution (CPD), USP
- Satellite bag with 80 mL SOLX® Additive Solution A
- Satellite bag with 30 mL SOLX® Additive Solution B
- Empty bag for storage of SOLX® Red Blood Cells, Leukocytes Reduced
- Empty bag for storage of CPD Plasma, Leukocytes Reduced
- Integral LEUKOTRAP® WB Leukocyte Reduction Filter for Whole Blood
- Sample diversion pouch with integrated blood sampling port (BSP)
- 16 gauge donor needle with cover and needle guard

See **Figure A** for a schematic with labeled components.

#### Indications for Use:

Haemonetics' WB System with CPD Anticoagulant and SOLX® Additive Solution, also known as the "SOLX® System", is indicated for:

- Pre-storage leukocyte reduction of CPD whole blood followed by preparation of AS-7 Red Cells, Leukocytes Reduced prepared at room temperature and placed at 1 – 6° C within 24 hours of collection. AS-7 Red Cells, Leukocytes Reduced, may be stored at 1 – 6° C for up to 42 days after collection.
- Pre-storage leukocyte reduction of CPD whole blood held at 1 – 6° C and preparation of AS-7 Red Cells, Leukocytes Reduced within 72 hours after collection. AS-7 Red Cells, Leukocytes Reduced, may be stored at 1 – 6° C for up to 42 days after collection.
- Preparation of Fresh Frozen Plasma (FFP), Leukocytes Reduced prepared from a whole blood collection and frozen at -18° C or below within 8 hours of collection. FFP, Leukocytes Reduced may be stored at -18° C or colder for up to one year after collection.
- Preparation of Plasma Frozen Within 24 Hours After Phlebotomy (PF24), Leukocytes Reduced prepared from a whole blood collection. The product can be held at room temperature (RT) up to 8 hours after collection, refrigerated at 1 – 6° C until separated, and placed at -18° C or below within 24 hours of whole blood collection. PF24, Leukocytes Reduced may be stored at -18° C or colder for up to one year after collection.

- Preparation of Plasma Frozen Within 24 Hours After Phlebotomy Held at Room Temperature Up to 24 Hours After Phlebotomy (PF24RT24), Leukocytes Reduced prepared from a whole blood collection can be held at room temperature for up to 24 hours after collection, separated, and placed at -18° C or colder within 24 hours of collection. PF24RT24, Leukocytes Reduced may be stored at -18° C or colder for up to one year after collection.

Warnings:

- Do not use if package is damaged.
- Do not use unless solutions are clear.
- Use precautions to avoid accidental needle sticks.
- If a container is entered in a manner that violates the integrity of the system, the component expires 24 hours after entry if refrigerated (1 – 6° C).
- Studies have not been performed to allow irradiation and/or freezing of RBCs prepared with the SOLX® System.
- Do not squeeze the Sample Diversion Pouch during collection to avoid risk of air embolism.

Precautions:

- Do not squeeze the Blood Unit or apply mechanical pressure at any time during the leukoreduction process.
- Do not strip the downstream line while the LEUKOTRAP® WB Filter is attached to the downstream bag.
- Whole blood collected from certain donors may have extended filtration times and the potential for ineffective filtration and leukoreduction.
- The SOLX® System is not intended for manufacture of CPD Whole Blood or CPD packed red blood cells not containing additive solution.
- Platelets cannot be prepared with the SOLX® System.
- Cryoprecipitated AHF must be prepared from plasma products that have been placed in the freezer within 8 hours of collection.
- Dispose of used components using acceptable biohazard disposal methods.
- Collection sets must be used within 4 days of opening outer foil packaging.

Note:

- This product is not made with natural rubber latex.

Removal from Packaging:

- 1) Remove individually packaged collection sets from the outer foil package and inspect for damage. **Warning: Do not use if package is damaged.**  
**Precaution: Collection sets must be used within 4 days of opening outer foil packaging.**
- 2) Remove the collection set from the plastic overwrap. **Note:** Collection sets removed from plastic overwrap may be used for up to 4 days.

**Warning: Do not use unless solutions are clear.**

- 3) Smooth out any kinks observed in the tubing prior to collection and filtration.

Blood Collection:

- 1) Use aseptic technique throughout the collection process.
- 2) Adjust blood collection scale/mixer to desired collection settings.
- 3) Place Collection Bag on the blood collection scale/mixer.
- 4) Ensure the Sampling Line Clamp is open.
- 5) Apply tourniquet or pressure cuff on donor's upper arm to assist in locating a vein. Disinfect the site of phlebotomy using an approved method.
- 6) Remove Needle Cover as per instructions below. The black line in the Needle Hub indicates the bevel side:
  - a. Grasp Needle Hub and Cover firmly near the connection and twist Cover.
  - b. Pull Needle Cover straight off, being careful not to drag the cover across the needle tip.
- 7) Insert needle into vein with bevel up. Blood will flow into the Sample Diversion Pouch (SDP). After completion of blood collection into the SDP, close the Sampling Line Clamp and conduct blood sampling using the integrated Blood Sampling Port (BSP).
- 8) To conduct blood sampling with the integrated Blood Sampling Port (BSP):
  - a. Position the Sample Diversion Pouch downward so that air is at the top (opposite to the connection of the SDP and BSP) of the Sample Diversion Pouch.
  - b. Avoid collection of entrapped air by positioning the BSP above the bottom of the SDP, i.e. while keeping the Sample Diversion Pouch downward, angle the BSP upwards, without restricting blood flow, and insert vacuum test tube into the BSP to collect undiluted blood. Multiple samples may be collected by exchanging vacuum test tubes. The blood collection tubes should be appropriately labeled.
- 9) After samples are collected, ensure the Sampling Line Clamp is closed. Hermetically seal the tubing leading to the Sample Diversion Pouch (SDP) between the SDP and the Y-junction.

**Warning: Do not proceed with the subsequent steps unless the tubing leading to the Sample Diversion Pouch is hermetically sealed between the Sample Diversion Pouch and the Y-junction.**

- 10) After tubing leading to Sample Diversion Pouch is sealed, open the Donor Clamp and break the Donor Snap-open Closure to initiate blood flow into the Collection Bag.
- 11) Mix blood and anticoagulant in the Collection Bag continuously or at sufficient intervals to ensure thorough mixing with anticoagulant throughout the collection process.
- 12) Collect the required amount of blood (500 mL ± 50 mL). Close the Donor Clamp to stop blood flow when the collection is complete.

**Precaution: Once the desired blood volume is collected, complete steps 13-16 within approximately 4 minutes to avoid possible clot formation in tubing.**

- 13) Release pressure on the donor's arm. Remove needle and apply pressure to the venipuncture site. Follow site specific procedures to complete donor care.
- 14) Pull Donor Needle into the protective Phlebotomist Protection Device (PPD) to prevent needle stick injury.
- 15) Heat seal the Donor Line at the desired length and discard the tubing containing the Donor Needle, SDP and BSP into a properly designated container.
- 16) Strip contents of the Donor Line into the Collection Bag using facility specific procedures.
- 17) Thoroughly mix the whole blood with anticoagulant after collection.

Leukoreduction:

- 1) Thoroughly mix the whole blood prior to leukoreduction.  
**Note:** When whole blood is at room temperature, filter within 24 hours of collection.  
**Note:** When whole blood is at 1 – 6° C, filter within 72 hours of collection.
- 2) Ensure the Bypass Clamp and Downstream Clamp are open.
- 3) Suspend the LEUKOTRAP® SOLX® System from the LEUP® of the Collection Bag.
  - a. Suspend room temperature whole blood at a height of approximately 35.4 inches (0.9 meters) between the top of the Collection Bag and the top of the RBC Transfer Bag. Keep the LEUKOTRAP® WB Filter vertical and suspend the RBC Transfer Bag vertically using the Suspension Islet(s) near the Snap-open Closure.
  - b. Suspend whole blood stored at 1 – 6° C at a height of approximately 54 inches (1.4 meters) between the top of the Collection Bag and the top of the RBC Transfer Bag. Keep the LEUKOTRAP® WB Filter and RBC Transfer Bag vertical and straighten tubing. The RBC Transfer Bag hangs freely.
- 4) Initiate blood flow into the LEUKOTRAP® WB Filter by breaking the Lower Snap-open Closure on the Collection Bag and breaking the Upper Snap-open Closure on the Collection Bag to enable the auto-drain feature of the LEUKOTRAP® SOLX® System.  
**Precaution: The LEUKOTRAP® WB Filter is self-priming. Do not squeeze the Blood Unit or apply mechanical pressure at any time during the leukoreduction process.**
- 5) Allow blood to completely drain into the RBC Transfer Bag. This occurs automatically.
- 6) Check the Collection Bag to ensure the entire unit was filtered and that no additional volume is present.
- 7) When filtration is complete close the Downstream Clamp near the LEUKOTRAP® WB Filter. If the entire unit is not filtered, check unit volume and WBC count. Products not meeting leukocyte reduction standards should be discarded.  
**Precaution: Do not strip the Downstream Line while the LEUKOTRAP® WB Filter is attached to the downstream bag.**
- 8) Expel excess air (if present) from the RBC Transfer Bag by gently squeezing the RBC bag in an upright position and close the Bypass Clamp. Separate the Collection Bag and LEUKOTRAP® WB Filter from the RBC Transfer Bag with associated satellite bags by heat-

sealing the downstream line near the LEUKOTRAP® WB Filter and heat-sealing the Bypass Line near the RBC Transfer Bag.

- 9) If unit is designated for quality control testing, a well-mixed, representative sample of the blood unit must be obtained. Thoroughly mix the filtered Whole Blood prior to obtaining quality control samples. **Note:** Quality assurance programs with a scientifically sound sampling plan should confirm <5% nonconformance rate with 95% confidence that units prepared contain <math>5 \times 10^6</math> residual leukocytes and yield a  $\geq 85\%$  recovery of the original Whole Blood content.
- 10) Retain RBC Transfer Bag (containing the leukocyte reduced whole blood) with associated satellite bags (Plasma Bag, Additive Bag A and Additive Bag B) and appropriately discard the empty Collection Bag with attached LEUKOTRAP® WB Filter and tubing assemblies into a properly designated container.

Processing Blood Components:

- 1) Place the RBC Transfer Bag, satellite bags and associated tubing into centrifuge cups.  
**Note:** It is recommended that the bags and associated tubing fit snugly into the cup and that contact with rigid components be avoided.  
**Note:** Follow AABB recommended guidelines for heavy spin centrifugation for component preparation. For optimal red blood cell (RBC) quality do not exceed 5000g.

Preparing Plasma:

- 1) Centrifuge filtered Whole Blood using a “hard spin” method.  
**Precaution: Platelets cannot be prepared with the SOLX® System.**
- 2) After centrifugation, place the RBC Transfer Bag into a plasma extractor, break the RBC Transfer Bag Snap-open Closure and transfer substantially all separated plasma from the RBC bag into the plasma bag.
- 3) Externally clamp the RBC Line after plasma is transferred.
- 4) Clamp or heat-seal the Plasma Line and disconnect the Plasma Bag from the remaining set.  
**Note:** Clamp line if plasma will be further manufactured into Cryoprecipitate AHF.
- 5) If unit is designated for quality control testing, a well-mixed, representative sample of the Plasma unit must be obtained. Thoroughly mix the Plasma unit prior to obtaining the quality control samples.  
**Note:** Quality assurance programs with a scientifically sound sampling plan should confirm <5% nonconformance rate with 95% confidence that units prepared contain <math>5 \times 10^6</math> residual leukocytes.
- 6) Label plasma with the appropriate component designation and place in frozen storage.  
**Note:** FFP should be separated from RBC and placed in a freezer at  $-18^{\circ}$  C or colder within 8 hours after Whole Blood (WB) collection.

**Note:** PF24 Leukocytes Reduced should be prepared from a whole blood collection that is held at room temperature (RT) up to 8 hours after collection, refrigerated at 1 – 6° C until separated, and placed at -18° C or below within 24 hours of whole blood collection.

**Note:** PF24RT24 should be prepared from Whole Blood (WB) collections. The product can be held at room temperature for up to 24 hours after collection and separated from RBC and frozen at -18° C or colder within 24 hours of whole blood collection.

***Preparing SOLX® Red Blood Cells:***

- 1) Open the SOLX® Additive Bag B Snap-open Closure and completely drain contents of Additive Bag B into SOLX® Additive Bag A. Upon complete fluid transfer, clamp the Additive Mix line close to Additive Bag A. **Note:** It is essential that the contents of Additive Bag B be drained into Additive Bag A as completely as possible.
- 2) Thoroughly mix the contents of Additive Bag A (combined solutions A and B).
- 3) Open the Additive Bag A Snap-open Closure and completely drain the contents of Additive Bag A (combined solutions A and B) into the RBC Transfer Bag.
- 4) Mix contents of the RBC Transfer Bag thoroughly and heat seal RBC line.
- 5) If unit is designated for quality control testing, a well-mixed, representative sample of the RBC unit must be obtained. Thoroughly mix the RBC unit prior to obtaining quality control samples. **Note:** Quality assurance programs with a scientifically sound sampling plan should confirm <5% nonconformance rate with 95% confidence that units prepared contain <5 x 10<sup>6</sup> residual leukocytes and yield a ≥ 85% recovery of the original RBC content.
- 6) Store SOLX® RBC, Leukocytes Reduced, between 1 – 6° C for up to 42 days after collection.  
**Note:** SOLX® Red Blood Cells (RBC), Leukocytes Reduced can be prepared at room temperature and placed at 1 – 6° C within 24 hours of collection.  
**Note:** SOLX® RBC, Leukocytes Reduced can also be prepared at 1 – 6° C within 72 hours of collection and stored at 1 – 6° C.  
**Warning: If a bag is entered in a manner that violates the integrity of the system, the component expires 24 hours after entry if refrigerated (1 – 6° C).**
- 7) Appropriately discard Additive Bag A, Additive Bag B, associated tubing and Y-connector in a properly designated container.
- 8) If desired, sterile dock an empty transfer bag in conjunction with Fresh Frozen Plasma (FFP) to further manufacture into Cryoprecipitate AHF.

**Quality Control Testing:**

Percent recovery should be determined by following FDA Guidance entitled “ Guidance for Industry - Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion”, published in September 2012.

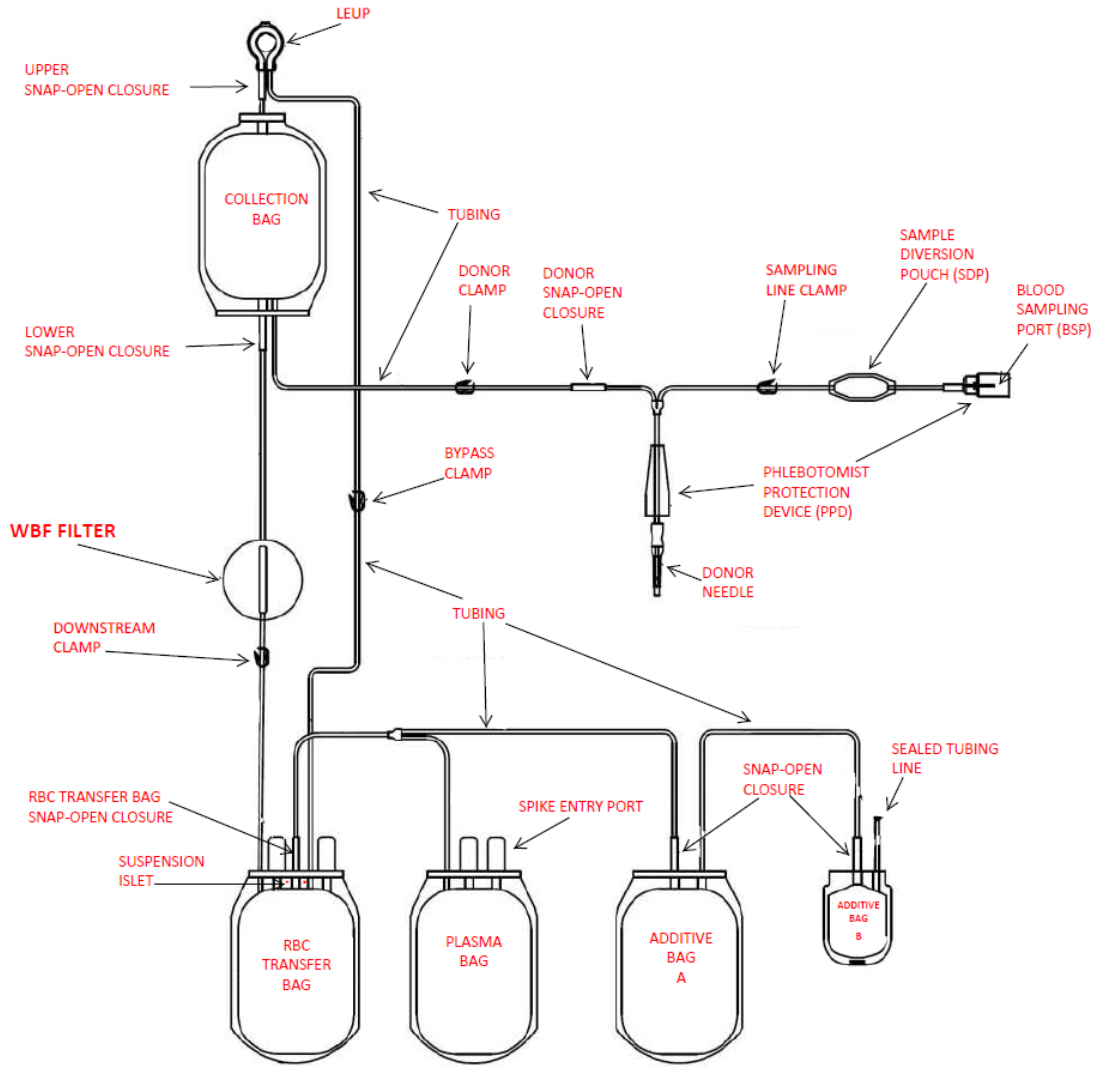
**Table 1 FFP and PF24RT24 Unit Constituents Post Storage**

Parameters		Mean (SD)		Median		(Min, Max)		Mean Difference (PF24RT24 - FFP)	
		FFP * (n=63)	PF24RT24 ** (n=63)	FFP (n=63)	PF24RT24 (n=63)	FFP (n=63)	PF24RT24 (n=63)	(95% CI)	P-Value
Intrinsic & Extrinsic Coagulation Pathways	aPTT (secs)	30.25 (2.257)	30.89 (2.237)	30	31	(26.00, 36.00)	(27.00, 36.00)	0.63 ( 0.21, 1.06)	0.0040
	PT (secs)	11.79 (0.821)	12.05 (0.901)	11.9	12	( 9.90, 13.50)	(10.30, 14.00)	0.26 ( 0.11, 0.41)	0.0011
Coagulation Factors	Factor V (%)	85.14 (16.54)	81.87 (17.18)	82	79	(53.00, 129.0)	(55.00, 132.0)	-3.27 ( -6.63, 0.09)	0.0561
	Factor VIII (%)	81.00 (22.44)	68.60 (19.71)	78	67	(46.00, 148.0)	(34.00, 118.0)	-12.40 (-16.50, -8.30)	<.0001
	Factor XI (%)	97.02 (11.93)	97.68 (14.04)	98	97	(63.00, 122.0)	(62.00, 137.0)	0.67 ( -1.51, 2.84)	0.5420
	vWF/Rco Activity (%)	110.4 (46.88)	103.9 (46.21)	96	89	(45.00, 295.0)	(48.00, 270.0)	-6.48 (-15.24, 2.28)	0.1445
Coagulation Inhibitors	Protein S Activity (%)	80.43 (16.38)	74.24 (15.89)	85	73	(36.00, 112.0)	(39.00, 115.0)	-6.19 ( -8.68, -3.70)	<.0001
	Protein C Activity (%)	117.5 (26.22)	118.3 (24.80)	114	113	(72.00, 193.0)	(68.00, 200.0)	0.84 ( -4.91, 6.59)	0.7709
	Antithrombin III (mg/dL)	25.63 (2.471)	25.62 (2.406)	26	26	(19.00, 30.00)	(19.00, 32.00)	-0.02 ( -0.54, 0.51)	0.9520
Markers of Activation	Factor VIIa (µg/mL)	0.02 (0.023)	0.02 (0.018)	0.013	0.014	( 0.01, 0.18)	( 0.01, 0.14)	0.00 ( -0.00, 0.01)	0.5125
	TAT Complex (µg/L)	4.35 (8.532)	3.05 (2.901)	2.4	2.3	( 2.00, 60.00)	( 2.00, 18.10)	-1.30 ( -3.57, 0.97)	0.2565
	Fibrinogen (mg/dL)	324.2 (58.93)	310.7 (62.80)	319	305	(203.0, 552.0)	(81.00, 427.0)	-13.57 (-30.15, 3.01)	0.1068

\* FFP (control group) – manufactured from WB anticoagulated with CP2D and leukoreduced with Haemonetics WBF filter.

\*\* PF24RT24 (investigational group) - manufactured from WB anticoagulated with CPD and leukoreduced with Haemonetics WBF filter.

**Figure A:** LEUKOTRAP® WB System with CPD Anticoagulant and SOLX® Additive Solution



**Rx ONLY**



STERILE FLUID PATH



DO NOT USE IF PACKAGE IS DAMAGED

STORE AT ROOM TEMPERATURE

NON-PYROGENIC FLUID PATH

PROTECT FROM FREEZING

AVOID EXCESS HEAT AND DIRECT SUNLIGHT

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