LEUKOTRAP - CP2D SOLUTION- anticoagulant citrate phosphate double dextrose solution
LEUKOTRAP - AS-3 SOLUTION- additive solution - 3 solution
Haemonetics Corporation

Leukotrap RC PL System

CP2D/AS-3 BLOOD BAG UNIT WITH IN-LINE RCM1 AND ATS-LPL FILTERS AND SAMPLING SYSTEM

For collection of blood and preparation of red blood cells, plasma and platelets with pre-storage leukocyte reduction.

Instruction for Use for Systems Containing a Y Sampling Site (YSS) or Sample Diversion Pouch (with or without a pre-attached SampLok™ Vacuum Tube Holder).

Refer to unit foil package label for specific product description being used.

Sterile, non-pyrogenic fluid path. Sterilized by steam.

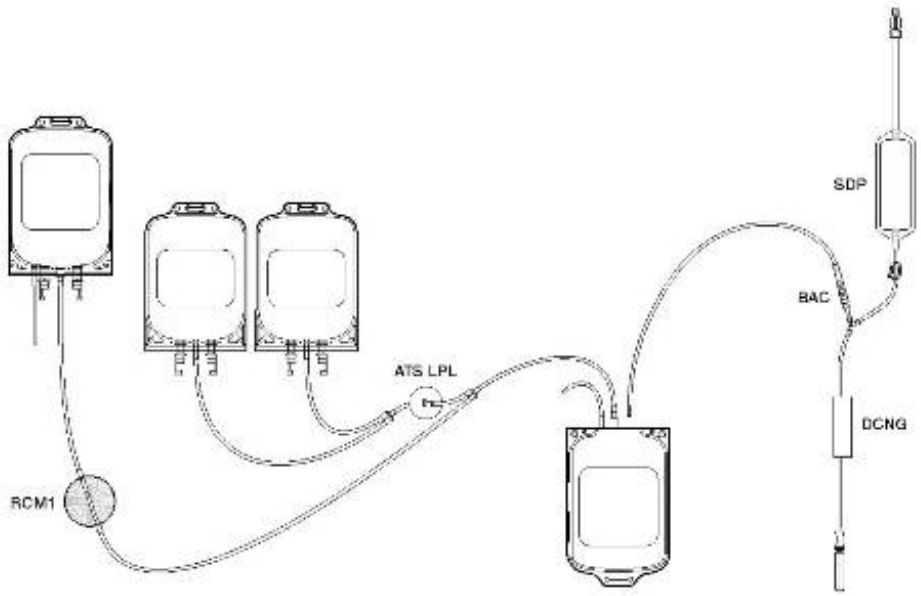
Rx only.

CLINICAL PHARMACOLOGY

This product is free of natural rubber latex.

Illustration

Collection system with sample diversion pouch



INDICATIONS AND USAGE

Whole blood; for use in blood collection.

CONTRAINDICATIONS

None known.

WARNINGS

Failure to achieve and maintain a closed system during processing would result in a product that must be transfused within 24 hours.

GENERAL PRECAUTIONS

Use aseptic technique.

Use only if solutions are clear.

Maximum hard spin conditions for RCM1 filter should not exceed 5000 g.

If using centrifuge cups with filter adapters, the RCM1 filter should not be placed within the adapter when hard spin conditions are used.

Do not exceed maximum head heights as indicated within the processing instructions.

Filtration can begin at room temperature up to 8 hours, or 1—6 °C up to 24 hours post-collection. Filtration must begin within 24 hours of collection.

If preparing a platelet concentrate, the platelet-rich plasma should be separated from the red blood cells within 8 hours after collection.

If preparing fresh frozen plasma, separate from the red cells and place in the freezer at -18 °C or colder within 8 hours after blood collection.

For systems with in-line breakaway closure (BAC), use oval style centrifuge cups.

Increased (mechanical) hemolysis has been associated with stripping when blood is cold and has a higher hematocrit. Do not strip forcefully or frequently against a snap-open closure if re-suspension of segmented tubing is necessary.

ADVERSE REACTIONS

No adverse reactions specifically attributable to this drug have been reported.

HOW SUPPLIED

* During processing, always observe the following precautions:

1. Sealing should be done in a manner that avoids fluid splatter.

2. Always dispose of blood-contaminated products in a manner consistent with established BIOHAZARD safety procedures

Instructions for Use

I. Blood Collection Instructions for Systems Containing a Y Sampling Site (YSS) Only

1. Load blood agitation device or suspend blood bag on donor scale and adjust donor scale to desired collection gross weight as per manufacturer's instructions.

2. Clamp donor tubing between the DonorCare™ Needle Guard (DCNG) and Y Sampling Site.

3. Secure donor tubing above the Y connector and disinfect site of phlebotomy.

4. If using blood pressure cuff, inflate to not more than 60 mm Hg.

5. Remove donor needle cover and accomplish phlebotomy.

6. Release clamp and ensure there is blood flow. Reduce pressure as required.

7. Slide the DCNG midway over the needle hub and securely tape DCNG to the donor's arm as close to top of the DCNG as possible. ***Note:*** If blood flow is slow, slide DCNG away from the needle hub, adjust and re-engage DCNG. If repeated needle adjustment is necessary, slide DCNG away from the needle hub and re-engage at the end of blood collection.

8. Collect appropriate volume of blood into collection bag, as indicated on packaging. ***Note:*** Mix blood and anticoagulant frequently during collection to avoid possible clot formation. For example: once every 45 seconds and immediately after collection. If blood agitation device is used, follow manufacturer's operating instructions.

9. After required amount of blood has been collected, seal donor tubing between the Y Sampling Site and the collection bag.* ***Note:*** If pre-filtration quality control is to be performed, leave an adequate length (~10 inches) of QC tubing containing anticoagulated blood attached to the collection bag.

10. For blood sampling, remove the Y Sampling Site needle cover. Ensure the protective sheath is in place over the sampling needle.

11. Fasten the vacuum tube holder on to the base of the sampling needle.

12. Collect blood samples into vacuum tubes.

13. Ensure the vacuum tubes are centered within the vacuum holder during sample collection.

14. Maintain forward pressure on the vacuum tubes during sample collection. ***Note:*** After the last tube is collected, it is recommended that the vacuum tube holder be left in place to prevent an accidental needlestick.

15. After blood samples are collected, clamp donor tubing between the Y Sampling Site and DCNG, as close as possible to the DCNG.

16. Release any remaining pressure from the donor's arm.

17. DCNG must be held stationary while the needle is withdrawn into it. While holding sides of DCNG near the front, grasp the tubing below the clamp and pull the needle into the DCNG until it locks into place, and the needle hub engages the bottom of the DCNG.

18. Insert the DCNG into the vacuum tube holder. ***Note:*** It is recommended that the DCNG be inserted securely into the vacuum tube holder, prior to discarding.

19. Seal donor tubing adjacent to DCNG.* Detach and discard needle, DCNG, Y Sampling Site and tubing.*

20. Strip tubing between seal and collection bag.

21. Continue to "Blood Processing and Filtration Instructions," Section IV, Step 1.

II. Blood Collection Instructions for Systems Containing a Sample Diversion Pouch with or without a pre-attached SampLok™ Vacuum Tube Holder

When using systems with a pre-attached SampLok™ vacuum tube holder, follow instructions as noted below, but refer to Section III when indicated to do so.

1. Load blood agitation device or suspend blood bag on donor scale and adjust donor scale to desired collection gross weight as per manufacturer's instructions.

2. Clamp donor tubing between the DonorCare™ Needle Guard (DCNG) and Sampling Site.

3. Secure donor tubing above the Y connector and disinfect site of phlebotomy.

4. If using blood pressure cuff, inflate to not more than 60 mm Hg.

5. Remove donor needle cover and accomplish phlebotomy.

6. Release clamp, and ensure there is blood flow.

7. Slide the DCNG midway over the needle hub and securely tape DCNG to the donor's arm as close to the top of the DCNG as possible. Note: If blood flow is slow, slide DCNG away from the needle hub, adjust and re-engage DCNG. If repeated needle adjustment is necessary, slide DCNG away from the needle hub and re-engage at the end of blood collection.

8. The donor blood will be automatically diverted to the sample diversion pouch. Once the sample diversion pouch is filled, close clamp immediately on tubing between the sample diversion pouch and Y connector. ***Warning:*** To avoid risk of air embolism to donor, do not squeeze sample diversion pouch while tubing is open.

9. Open snap-open closure between the Y connector and the collection bag to initiate blood collection. Reduce pressure as needed.

10. Permanently seal tubing between the sample diversion pouch and the Y connector to maintain sterility of the system prior to collecting blood samples.* ***Note:*** When using systems with a pre-attached SampLok™ vacuum tube holder, go to Section III.

11. For blood sampling, remove the Sampling Site needle cover. Ensure the protective sheath is in place over the sampling needle.

12. Fasten the vacuum tube holder on to the base of the sampling needle.

13. Position the sample diversion pouch downward so that the air rises to the top of the pouch and away from the vacuum tube holder.

Notes:

• Drawing air into the vacuum tube may cause hemolysis.

• Collect blood samples from the sample diversion pouch into vacuum tubes within approximately four minutes to avoid possible clot formation.

14. Ensure the vacuum tubes are centered within the vacuum tube holder during sample collection.

15. Maintain forward pressure on the vacuum tube during sample collection. ***Note:*** After the last tube is collected, it is recommended that the vacuum tube holder be left in place.

16. Collect appropriate volume of blood into collection bag as indicated on packaging. ***Note:*** Mix blood and anticoagulant frequently during collection to avoid possible clot formation, for example, once every 45 seconds, and immediately after collection. If blood agitation device is used, follow manufacturer's operating instructions.

17. After required amount of blood has been collected, seal donor tubing between snap-open closure and collection bag.* ***Note:*** If pre-filtration quality control is to be performed, leave an adequate length (~10 inches) of QC tubing containing anticoagulated blood attached to the collection bag.

18. Clamp donor tubing between the Y connector and DCNG, as close as possible to the DCNG.

19. Release any remaining pressure from donor's arm.

20. DCNG must be held stationary while the needle is withdrawn into it. While holding sides of DCNG near the front, grasp the tubing below the clamp and pull the needle into the DCNG until it locks into place, and the needle hub engages the bottom of the DCNG.

21. Insert the DCNG into the vacuum tube holder, if desired. ***Note:*** It is recommended that the DCNG be inserted securely into the vacuum tube holder, prior to discarding.

22. Seal donor tubing adjacent to DCNG.* Detach and discard needle, DCNG, sample diversion pouch, and tubing.*

23. Strip tubing between seal and collection bag.

24. Continue to "Blood Processing and Filtration Instructions", Section IV, Step 1.

III. When Using Systems with a Pre-attached SampLok Vacuum Tube Holder

1. To collect blood samples, open lid from SampLok™ vacuum tube holder.

2. Open snap-open closure between sample diversion pouch and SampLok™ vacuum tube holder.

3. Position the sample diversion pouch downward so that the air rises to the top of the pouch and away from the SampLok™ vacuum tube holder.

Notes:

• Drawing air into the vacuum tube may cause hemolysis.

• Collect blood samples from the sample diversion pouch into vacuum tubes within approximately four minutes to avoid possible clot formation.

4. Ensure the vacuum tubes are centered within the SampLok™ vacuum tube holder during sample collection.

5. Maintain forward pressure on the vacuum tube during sample collection.

6. The lid may be closed on the SampLok™ vacuum tube holder after sample collection.

7. Return to Section II, Step 17. Note: When collection of unit is complete, and the donor needle is engaged in the DCNG, open the lid of the SampLok™ vacuum tube holder and insert the DCNG into the holder. Twist until it locks into place. An audible click will confirm that it is locked.

IV. Blood Processing and Filtration Instructions

1. Load unit into centrifuge cup [for systems with in-line breakaway closure (BAC), use oval style centrifuge cups], ensuring that the tubing stays in the top half of the cup. Position the platelet (smaller) filter on top of the tubing assembled inside the cup. Place the red blood cell (larger) filter in a horizontal position on top of the entire assembly and secure with tape or Leukotrap Strap. If using centrifuge cups with filter adapters, follow manufacturer's instructions for use.

2. Centrifuge unit per standard protocol.

3. Carefully remove the unit from the centrifuge and place the collection bag in the plasma expressor.

4. Gently apply expressor pressure.

5. Place platelet (smaller) filter on work surface or in Pall® PL holder ensuring that the side labeled "OUT" faces up. Clamp tubing between the red blood cell (larger) filter and the Y connector.

6. Clamp tubing to extra satellite bag.

7. Open snap-open closure of the collection bag and express platelet-rich plasma into a satellite bag.

8. When the outlet side of the platelet filter turns pink, or red blood cells are visible in the tubing between the filter outlet and the Y connector closest to the satellite bags, clamp tubing between the filter and the Y connector closest to the satellite bags. Release expressor pressure.

Notes:

• Do not apply extra pressure to increase flow rate.

• The ATS-LPL filter will not prevent red blood cells from passing into the satellite bag during expression.

9. Seal tubing between platelet filter and the Y connector closest to the satellite bags.* Detach and set aside the platelet-rich plasma for further processing.*

10. Seal tubing between platelet filter and the remaining Y connector.* Detach and discard the platelet filter and tubing.*

11. Hang the AS-3 red blood cell bag in a manner ensuring the filter is in a vertical position. Remove clamp near red blood cell filter. Open snap-open closure of the bag containing Nutricel AS-3 additive

solution, and transfer additive solution to the collection bag. ***Note:*** Nutricel AS-3 solution should be added to the collection bag immediately after platelet-rich plasma removal.

12. Transfer AS-3 solution under one of the following conditions:

A. Within 8 hours of collection if whole blood is held at room temperature.

B. Within 24 hours of collection if whole blood is refrigerated.

13. Clamp tubing close to the collection bag in order to avoid the introduction of air into the filter.

14. Mix red blood cells gently and thoroughly.

15. Hang the collection bag at one of the following heights, while ensuring that the filter is hanging in the vertical position:

A. No more than 60 inches for blood stored and filtered at room temperature.

B. No more than 76 inches for blood stored and filtered at 1—6 °C.

16. Remove clamp to allow red blood cells to gravity flow through the filter and into the red cell storage bag.

Notes:

• Do not apply mechanical or manual pressure to increase flow rate.

• If unit has not completely filtered by 8 hours post-collection at room temperature, filtration must be completed at 1—6 °C.

• Filtration at maximum head height may shorten filtration times.

• Filtration of red cells can be unattended.

• Filtration times can be influenced by collection and processing conditions and biological variability of donors. Experimental data with some filter products indicate that a prolonged filtration can be an indication of sub-optimal leukocyte reduction.

17. Clamp tubing near red cell storage bag and seal tubing below the filter.* The numbered tubing downstream of the filter will not drain.

Notes:

• If the filter housing (downstream side) and numbered tubing below the filter have drained (emptied) after filtration, it is recommended to perform QC on the unit.

• Do not strip tubing prior to sealing the tubing below the filter. If it is desired to strip blood from numbered tubing, do so only after tubing has been sealed close to the filter and detached.

• If it is necessary to strip blood from numbered tubing for re-suspension, care should be taken when stripping is performed. Increased (mechanical) hemolysis has been associated with stripping when blood is cold and has a higher hematocrit. Do not strip forcefully or frequently against a snap-open closure.

18. Detach and discard collection bag and filter.*

19. If desired, seal at or adjacent to "X" marks on tubing to provide numbered segments of anticoagulated blood for typing or cross matching.* If quality control is to be performed on post-filtration sample, use the attached QC line on the bag containing red cells.

20. Store CP2D/AS-3 preserved red blood cells at 1—6 °C for up to 42 days and use as indicated.

MANUFACTURER

Manufactured for: Haemonetics Corporation

400 Wood Road

Braintree, MA 02184, USA

By: Haemonetics Manufacturing Inc.

1630 Industrial Park Street

Covina, CA 91722, USA

Visit us at www.haemonetics.com

Phone: 888-489-5938

PACKAGE LABEL – PRINCIPAL DISPLAY PANEL

Leukotrap® RC System

CP2D/AS-3 Triple Blood Bag Unit with In-Line RCM1 and ATS-LPL Filters and Sample Diversion Pouch

For collection of 500 ml of blood and preparation of red blood cells, plasma or platelets with pre-storage leukocyte reduction of red blood cells.

Each unit consists of a collection bag with 70 ml of CP2D solution, an additive bag with 110 ml of AS-3 solution, and two empty CLX® satellite bags. Each 70 ml of CP2D solution contains 3.57 g dextrose (monohydrate), USP; 1.84 g sodium citrate (dihydrate), USP; 0.229 g citric acid (monohydrate), USP; and 0.155 g monobasic sodium phosphate (monohydrate), USP. Each 110 ml of AS-3 solution contains 1.21 g dextrose (monohydrate), USP; 0.647 g sodium citrate (dihydrate), USP; 0.451 g sodium chloride, USP; 0.304 g monobasic sodium phosphate (monohydrate), USP; 0.046 g citric acid (monohydrate), USP; and 0.033 g adenine, USP.

Sterile, nonpyrogenic fluid path. Sterilized by steam. See accompanying directions for use. Rx only. Store at room temperature. Unused bags in opened pouches may be kept 30 days by folding and SECURING open end of pouch to prevent possible loss of moisture.

3 Units

Code 123-93

Collection Date	Unit Number	EXPIRES

84

ANTICOAGULANT
CITRATE
PHOSPHATE
DOUBLE DEXTROSE
SOLUTION

CP2D RED BLOOD CELLS

04080

Approx. 500 ml
plus 70 ml CP2D.
Store at 1—6 °C.

70 ml Anticoagulant Citrate Phosphate Double Dextrose Solution for collection of 500 ml of blood. Each 70 ml of CP2D solution contains 3.57 g dextrose (monohydrate), USP; 1.84 g sodium citrate (dihydrate), USP; 0.229 g citric acid (monohydrate), USP; and 0.155 g monobasic sodium phosphate (monohydrate), USP. Use only if solution is clear.

See circular of information for indications, contraindications, cautions and methods of infusion.

670123933

VOLUNTEER DONOR

This product may transmit infectious agents. **Rx only.**

PROPERLY IDENTIFY INTENDED RECIPIENT.

CP2D
500

Affix
Collection/Processing
I.D. Label Here

123-93 LOT #######

Manufactured for:
Haemonetics Corporation
400 Wood Road
Braintree, MA 02184, USA

Insert Barcode Here

1HE0012393

000#######

Collection Date	Unit Number	EXPIRES

04

Store platelets
5 days at 20—24 °C.
Leukocytes
reduced.

Place Product Label
here after bag is filled.

CLX® Container

675123933

CP2D
500

See circular of information for indications, contraindications, cautions and methods of infusion.

VOLUNTEER DONOR

This product may transmit infectious agents. **Rx only.**

PROPERLY IDENTIFY INTENDED RECIPIENT.

123-93 LOT #######

Manufactured for:
Haemonetics Corporation
400 Wood Road
Braintree, MA 02184, USA

Insert Barcode Here

6HE0012393

000#######

Collection Date	Unit Number	EXPIRES

84

AS-3 RED BLOOD CELLS
ADENINE - SALINE ADDED
LEUKOCYTES REDUCED

16.5 mEq sodium added. 04730

From 500 ml
CP2D Whole Blood.
Store at 1—6 °C.

110 ml of preservative AS-3 solution contains 1.21 g dextrose (monohydrate), USP; 0.647 g sodium citrate (dihydrate), USP; 0.451 g sodium chloride, USP; 0.304 g monobasic sodium phosphate (monohydrate), USP; 0.046 g citric acid (monohydrate), USP; and 0.033 g adenine, USP. Use only if solution is clear.

679123933

See circular of information for indications, contraindications, cautions and methods of infusion.

VOLUNTEER DONOR

This product may transmit infectious agents. **Rx only.**

PROPERLY IDENTIFY INTENDED RECIPIENT.

CP2D
500

Affix
Collection/Processing
I.D. Label Here

123-93 LOT #######

Manufactured for:
Haemonetics Corporation
400 Wood Road
Braintree, MA 02184, USA

Insert Barcode Here

5HE0012393

000#######

HAEMONETICS®

RC PL 500 ml Triple CP2D/AS-3

LEUKOTRAP® RC PL SYSTEM

CP2D/AS-3 Triple Blood Bag Unit with In-Line RCM1 and ATS-LPL Filters and Sample Diversion Pouch

For collection of 500 ml of blood and preparation of red blood cells, plasma and platelets with pre-storage leukocyte reduction

Each unit consists of a collection bag with 70 ml of CP2D solution, an additive bag with 110 ml of AS-3 solution, and two empty CLX® satellite bags. Each 70 ml of CP2D solution contains 3.57 g dextrose (monohydrate), USP; 1.84 g sodium citrate (dihydrate), USP; 0.229 g citric acid (monohydrate), USP; and 0.155 g monobasic sodium phosphate (monohydrate), USP. Each 110 ml of AS-3 solution contains 1.21 g dextrose (monohydrate), USP; 0.647 g sodium citrate (dihydrate), USP; 0.451 g sodium chloride, USP; 0.304 g monobasic sodium phosphate (monohydrate), USP; 0.046 g citric acid (monohydrate), USP; and 0.033 g adenine, USP.

Sterile, nonpyrogenic fluid path. Sterilized by steam. See accompanying directions for use. **Rx only.** Store at room temperature. Unused bags in opened pouches may be kept 30 days by folding and SECURING open end of pouch to prevent possible loss of moisture.

US Pats. 5,968,619; 5,721,024; 6,060,138; 5,690,815

3 Units **Code 123-93**

Manufactured for: Haemonetics Corporation
400 Wood Road
Braintree, MA 02184, USA

By: Haemonetics Manufacturing Inc.
1630 Industrial Park Street
Covina, CA 91722, USA

www.haemonetics.com
888-489-5938

LOT #######

YYYY-MM #

151123936

[Insert Barcode Here]

(01)20887691305508(30)03(17)YYMM00(10)#######

LEUKOTRAP - CP2D SOLUTION

anticoagulant citrate phosphate double dextrose solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:53157-123
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXTROSE (UNII: IY9XDZ35W2) (DEXTROSE - UNII:IY9XDZ35W2)	DEXTROSE	3.57 g in 70 mL

Product Characteristics			
Color	yellow (anticoagulant)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:53157-123-01	6 in 1 POUCH		
1	NDC:53157-123-00	70 mL in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	BN820915	11/09/1983	

LEUKOTRAP - AS-3 SOLUTION

additive solution - 3 solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:53157-124
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXTROSE (UNII: IY9XDZ35W2) (DEXTROSE - UNII:IY9XDZ35W2)	DEXTROSE	1.21 g in 110 mL
ADENINE (UNII: JAC85A2161) (ADENINE - UNII:JAC85A2161)	ADENINE	0.033 g in 110 mL

Product Characteristics

Color	yellow (additive)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53157-124-01	6 in 1 POUCH		
1	NDC:53157-124-00	110 mL in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	BN820915	11/09/1983	

Labeler - Haemonetics Corporation (057827420)

Establishment

Name	Address	ID/FEI	Business Operations
Haemonetics Manufacturing Inc		078598396	manufacture(53157-123, 53157-124)

Revised: 1/2020 Haemonetics Corporation