

LEUCOFLEX CGP- anticoagulant citrate phosphate dextrose solution with additive solution as-1

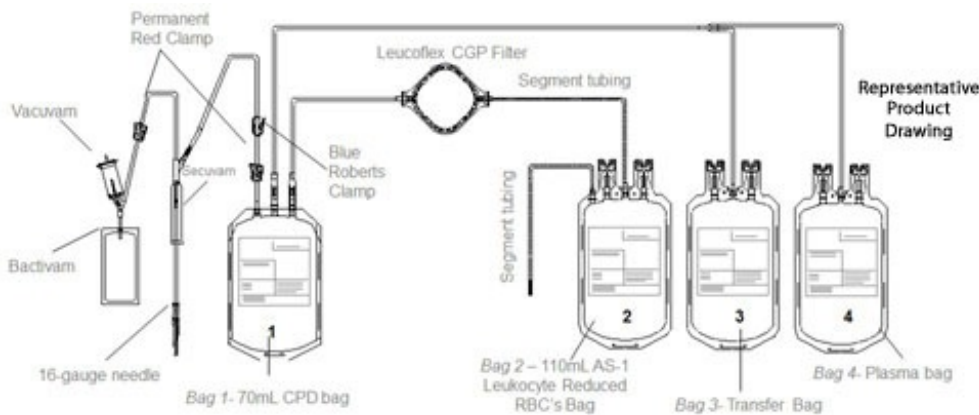
Maco Productions

Anticoagulant Citrate Phosphate Dextrose Solution USP (CPD) With an Integral Container of Additive Solution (AS-1) Preservative, And an Integral Leucoflex CGP Leukocyte Reduction Filter for Red Blood Cells

Description

The Leucoflex CGP product consists of a blood collection system with 70ml of CPD for the collection of 500±50ml of blood and 100ml of AS-1 Additive Solution. They are supplied with sterile, non-pyrogenic fluid pathways. The product as supplied includes an in-line leukocyte reduction filter known as Leucoflex CGP, storage containers for blood components and tubing, a sample diversion pouch (Bactivam), a vacuum tube adapter (Vacuvam), and a protective shield for the used needle (Secuvam).

Representative Product Drawing



Intended Use

The "Leucoflex CGP Leukocyte Reduction Filter" is intended for the leukocyte reduction of Red Blood Cells prepared from whole blood stored at 1-6°C up to 24 hours after collection. The collection set provides for subsequent preparation of AS-1 Red Blood Cells, leukocytes Reduced (adenine saline added) and plasma in a closed system.

The AS-1 Red Blood Cells, leukocytes Reduced and plasma may then be stored for the maximum allowable dating periods.

WARNING

- Avoid contact with sharp objects.
- DO NOT USE if the overwrap or blood bag system shows any signs of deterioration.
- DO NOT USE if the solutions are not clear.
- Dispose of all system components that have been contaminated with blood in a biohazard container as per your institution's SOP.
- Dispose of all sharps as per your institution's SOP.

CAUTIONS

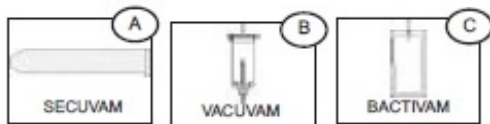
- Do not fold or squeeze the Leucoflex CGP filter. Inappropriate handling may adversely affect filtration.

- Check for kinks in the tubing prior to collection and filtration.
- Rx only.

The protective shield for needle Secuvam (A) and the vacuum tube adapter Vacuvam (B) features of the collection set aid in the safe collection of vacuum tube samples from the sample diversion pouch Bactivam (C) and the disposal of donor needles after blood collection by providing protection from accidental needlestick.

All or part of this medical device is made of PVC plasticized with DEHP. According to some studies, DEHP could potentially be harmful to the reproductive system of male fetuses. The prescriber is solely responsible for choosing to use this device on women who are either pregnant or breast-feeding, or on young male infants. Nevertheless, DEHP-plasticized PVC is in compliance with the European Pharmacopeia.

All manufacturing processes and all components in contact with the donors, the users and the blood components dedicated to the patients are not made with natural rubber latex.



COLLECTION AND SAMPLING PROCEDURE

INSTRUCTION FOR USE

Before Donation

- 1) Peel open the transparent overwrap (D) using the corner flap.
- 2) Support blood bag system as far as possible below donor arm, ideally on an automated blood mixer.

Note: it is recommended that the primary bag on the mixer lies with the tubing on the lower side of the mixer holding plate.

- 3) Apply tourniquet or pressure cuff (inflate to approximately 60 mm Hg).
- 4) Prepare venipuncture site as per your SOP.
- 5) Ensure that the donor line is not twisted or tangled.

Venipuncture

- 1) Open the needle cap (E1) using the following procedure:
 - a) Twist the needle cap, thus breaking the seal.
 - b) Lift the cap off of the needle (E2) in a straight line taking special care not to touch the needle in the process (F). Keep hands behind the needle at all times during set use and disposal.
- 2) Perform the venipuncture.
- 3) After the needle has been inserted, introduce the Secuvam onto the hub of the needle.
- 4) Tape the Secuvam onto the donor's arm.

Note: if the Secuvam causes discomfort to the donor or decreases the blood flow because of the angle of the needle, leave the Secuvam on the tubing, behind the needle hub (G) during collection. Secure the needle into the Secuvam at the end of the donation (H).

After Venipuncture

- 1) Ensure that the clamp between the Bactivam pouch and the donation line is open.
- 2) Ensure that the Bactivam pouch is held below the level of the venipuncture site, and is supported at

all times.

3) Allow blood to run into the Bactivam pouch until the pouch fills (approximately 30ml) (I).

4) Close the red clamp (I1) on the transfer line to the Bactivam pouch, by holding the clamp in one hand and squeezing the two edges together, until it locks (a click may be heard).

Note: the red clamp cannot be opened after it has snapped shut.

5) Break the break-away cannula (I2) on the donor line by holding the cannula in one hand and the plastic Y-junction in the other and snapping the cannula both left and right to ensure a clean break. Allow the donation procedure to continue, ensuring that the blood bag is mixed immediately when blood flows into the primary bag.

Note: This step may be done prior to venipuncture if the Blue Roberts clamp (I3) on the donor line is closed prior to breaking the break-away cannula.

6) If using an automated mixer, open the mixer clamp and start the mixer at this point.

Note: it is recommended that the primary bag on the mixer lies with the tubing on the lower side of the mixer holding plate.

7) After approximately 50 ml of blood enters the primary bag, mix thoroughly (when possible).

Note: Collect the quantity of blood stated on the blood bag label.

Sampling Procedure

Note: this is done during the donation. Avoid air in the collection of sample tubes from the diversion pouch to ensure adequate sample volume and avoid hemolysis.

1) Hold the Bactivam pouch with the Vacuam below it (J), to ensure good blood flow from the pouch to the sampling device, and no introduction of air into the sampling tubes.

2) Remove the cap of the Vacuam sampling device, and retain for later use (when possible).

3) Introduce a vacuum sampling tube by holding the barrel of the Vacuam and directing the sample tube cap directly onto the needle inside the device (J1).

4) Blood is drawn automatically into the sampling tube, stopping at the appropriate volume.

5) When the sample tube stops filling, withdraw the tube, ensuring that the tube is pulled out of the barrel in a straight line.

6) Repeat the sampling procedure steps (3 to 5) with all remaining sampling tubes.

7) When all samples have been taken, replace the Vacuam cap to prevent accidental access to the interior needle (when possible).

8) Mix the blood in the primary bag regularly (approximately every 100 ml or every minute).

After Donation

1) Once the required volume of blood has been collected, close the red clamp on the donor line (J2), at least 12 inches above the primary bag.

Note: if necessary, place a Hemostat on the collection line just below the Secuam.

2) Release the pressure cuff or tourniquet, and immediately mix the whole blood in the primary bag.

Note: if the needle was taped to the arm, and not the Secuam, remove the tape from the needle before pulling the needle into the Secuam (disregard step 3).

3) Remove the tape holding the Secuam in place.

4) Remove the needle by gently pulling the needle into the barrel of the Secuam while supporting the Secuam with one hand (a click may be heard).

Note: if necessary, step 4 may be done before step 3.

5) Remove and discard the cap (if relevant) from the barrel of the Vacuvam, into an appropriate container.

6) Insert the Secuvam needle protector into the barrel of the Vacuvam sampling device.

7) After removing the blood from the mixer/trip scale, mix the blood unit thoroughly.

8) If the donor line is to be used for quality control, strip the line as per procedure (at least 3 times), heat-seal (place clips) and cut (between the clips), leaving sufficient line for testing purposes.

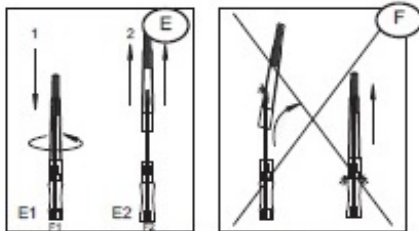
Note: if it is necessary to strip the donor line, it is recommended to strip within 4 minutes of the end of the donation, in order to avoid introducing clots into the blood bag.

9) Ideally, heat-seal the donor line as close as possible to the pack (~1 inch). Alternatively, place clips close to the blood pack and cut between the clips. Mix thoroughly during and immediately after the procedure.

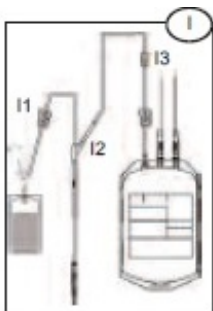
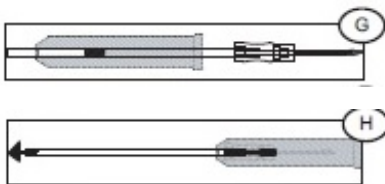
Note: this is an in-line filter system; there is no need to keep the donor line for cross-matching segments.

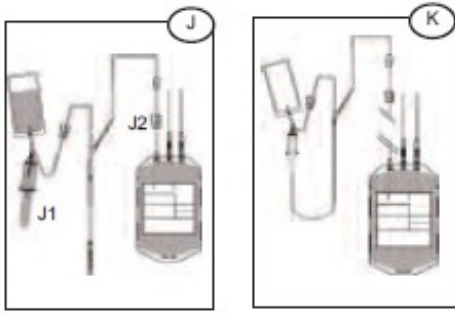
10) Remove and discard the donor line (K) with the two red clamps, Blue Roberts clamp, Bactivam, Vacuvam and Secuvam as per SOP.

Note: the completely protected needle after securing the Secuvam inside the rigid Vacuvam sleeve can be disposed of in general biowaste vs. a sharps container.



Opening needle cap





COMPONENT PREPARATION GENERAL

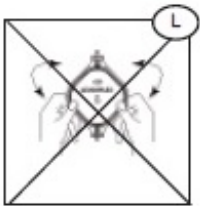
CAUTION:

Do not fold or manhandle the filters (L).

Do not apply pressure, either mechanical or human, to increase the flow rate of the filter.

- Units with decreased or extended filtration times may not be adequately leukoreduced, and should be evaluated for residual leukocytes and red blood cell recovery before release. Consult training materials for more information on expected length of filtration times and the applicable hold periods in clinical study data.
- Failure to achieve and maintain a closed system throughout processing results in a product that must be stored at 1 to 6 C and transfused within 24 hours.
- The AS-1 additive solution must be added to the red blood cells without delay after the separation of the plasma. Whole blood in CPD alone may be stored at 1 to 6 C for up to 21 days.
- The filter has been designed and validated to meet the criteria of a leukocytes reduction filter for Red Blood Cells. The filter's performance must be validated using your facility's standard operating procedure (SOP) on component preparation and handling. Any filtration that fails to meet the filtration specifications established by the facility's validation should be evaluated for residual leukocytes and red blood cell (RBC) recovery after filtration.

Note that unusual attributes such as sickle cell trait, cold agglutinins, blood clotting and gel formation, and poor mixing during collection and processing of components can contribute to the failure of a filtration to meet filtration specifications. Failure to adequately mix RBC with Additive Solution thoroughly prior to filtration can result in blocked filters.

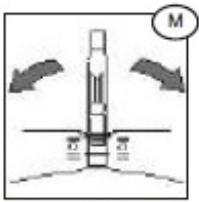


BLOOD COMPONENTS SEPARATION

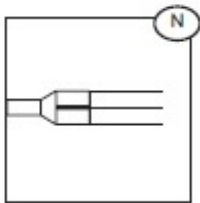
- 1) Obtain collected Whole Blood from 1-6 C storage container.
- 2) Mix the Whole Blood thoroughly.
- 3) Pack the collection system into a centrifuge as per your facility's standard operating procedure (SOP).
- 4) Centrifuge the blood, satellite bag, and additive solution bag together under conditions designed to

produce a separation of plasma and red blood cells.

- 5) Place the centrifuged blood carefully into an extractor, and gently release the pressure plate.
- 6) Break the break-away cannula (M) on the tubing leading to the plasma bag by bending the cannula with a side-to-side motion.
- 7) Express Plasma into appropriate container.
- 8) If preparing Cryoprecipitate AHF (Anti-Hemophilic Factor) from this Plasma, place a temporary clamp between the 'Y' connector (N) and the bag for the final storage of plasma otherwise, add a permanent clamp.
- 9) If required, express the air from the plasma back into the RBC bag.
- 10) Heat seal and disconnect the Plasma bag. (If Cryoprecipitate is manufactured heat seal the tubing 1 inch before the Y connector).



Breaking the cannula



RED BLOOD CELLS LEUKOCYTES REDUCTION

- 1) Lift the additive solution (AS-1) bag above the RBC bag on the filtration rack or drip stand.
- 2) Break the break-away cannula on the RBC bag by bending the cannula with side-to-side motion.
- 3) Allow the additive solution to drain completely through the Leucoflex CGP filter into the RBCs without delay.

☐Note: Some additive solution will be left in the filter. DO NOT squeeze the filter in order to maximize the additive transfer to the RBCs.

- 4) Place a Hemostat on the tubing between the filter and the AS-1 RBCs bag.
- 5) Thoroughly, mix the AS-1 with the Red Blood Cells.
- 6) Hang the AS-1 RBCs bag on a filtration rack so that the outlet tubing of the Leucoflex CGP filter and the Leukocyte Reduced (LR) AS-1 RBC bag inlet tubing is fully extended and the LR AS-1 RBCs bag is freely hanging.
- 7) Remove the Hemostat and allow the blood to flow by gravity through the Leucoflex CGP filter into the LR AS-1 RBCs bag.

☐Note: Determine the status of the filtration as follows: if there is no blood flowing from below the filter, the filter is flat and the filter media is visible on the inlet side, filtration is complete.

- 8) Heat seal the segment tubing 1 inch below the Leucoflex CGP filter, and all along the segment tubing between the printed numbers.

9) Disconnect and discard the empty transfer bag, Leucoflex CGP filter, and tubing as per SOP.

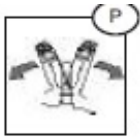
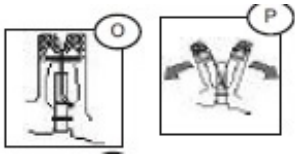
10) Store the LR AS-1 Red Blood Cells, at 1-6 C for up to 42 days.

WARNING: if unit is spiked for any reason, storage is limited to 24 hours at 1 to 6 C before transfusion.

NOTE: If either face of the filter remains white, the Red Cell Concentrate has not been leucoreduced and must be discarded.

HANDLING OF PORT PROTECTORS

- 1) Using both hands tear the port protector as indicated. (O)
- 2) Hold down the port protector pieces with one hand. (P)
- 3) Using the free hand, take the spike and engage into the port. (Q)
- 4) Twist the spike to secure fully in port. (Q)



LABELS

Bag 1 Anticoagulant Citrate Phosphate Dextrose Solution, USP; Bag 2 Additive Solution AS-1; Overwrap; Carton

Anticoagulant Citrate Phosphate Dextrose Solution, USP - Bag 1 Label

Collection Date

Donation Number

EXPIRES

ANTICOAGULANT
CITRATE PHOSPHATE
DEXTROSE SOLUTION, USP

Place Product Label here
after container is filled

70 mL Anticoagulant Citrate Phosphate Dextrose

Solution USP for collection of 500mL of blood.

Each 70 mL of anticoagulant contains:

Sodium Citrate (dihydrate) USP 1.84 g

Dextrose (monohydrate) USP 1.78 g

Citric Acid (anhydrous) USP 209 mg

Mono basic Sodium Phosphate (monohydrate) USP 155 mg

pH may have been adjusted with Sodium Hydroxide.

Use only if solution is clear, Sterile and non pyrogenic
fluid pathway.

ETUSA001F

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

CAUTION: Refer to instructions for use.

VOLUNTEER DONOR

This product may transmit infectious agents.
Caution: Rx Only

Affix
Collection / Processing
ID Label Here

PROPERLY IDENTIFY INTENDED RECIPIENT



MACOPRODUCTIONS S.A.S.
200, Chaussée Fernand Forest
59200 TOURCOING - FRANCE



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






1MALQE7230LD



12345678AM

Additive Solution AS-1 - Bag 2 Label

Collection Date	Donation Number	EXPIRES
Place Product Label here after container is filled		ADDITIVE SOLUTION AS-1 Each 110 mL containing: Dextrose (monohydrate) USP 2.42 g Sodium Chloride USP 990 mg Mannitol USP 825 mg Adenine USP 30 mg Contains 16.9 mEq of Sodium. Use only if solution is clear. Sterile, nonpyrogenic fluid pathway. CAUTION: Refer to instructions for use.
See circular of information for indications, contraindications, cautions and methods of infusion.		Processing Center name if different from collection center
VOLUNTEER DONOR This product may transmit infectious agents. Caution: Rx Only		Affix Collection / Processing ID Label Here
PROPERLY IDENTIFY INTENDED RECIPIENT		
 MACOPRODUCTIONS S.A.S. 200, Chaussée Fernand Forest 59200 TOURCOING - FRANCE	     	
 REF 2MALQE7230LD	2	 LOT 0123414A01

OVERWRAP LABEL

CARTON LABEL

LQE	yy/mm/dd 00:00:00	12 RED CELL CONCENTRATE
		QUADRUPLE BAGS FILTERS CGP
		CPD/AS1 500 ML
		YYYY-MM
	REF LQE7230LD	LOT XXXXXXXXXM
		
	0MALQE7230LD 0	XXXXXXXXXXM

LEUCOFLEX CGP

anticoagulant citrate phosphate dextrose solution with additive solution as-1 kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:14498-002
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14498-002-01	1 in 1 KIT		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BAG	70 mL
Part 2	1 BAG	110 mL

Part 1 of 2**ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION**

anticoagulant citrate phosphate dextrose solution injection, solution

Product Information

Route of Administration	INTRAVENOUS
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM CITRATE (UNII: 1Q73Q2JULR) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	SODIUM CITRATE	1.84 g in 70 mL
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE MONOHYDRATE	1.78 g in 70 mL
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	209 mg in 70 mL
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN) (PHOSPHATE ION - UNII:NK08V8K8HR)	SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE	155 mg in 70 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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	BN040083		

Part 2 of 2

ADDITIVE SOLUTION AS-1

additive solution as-1 injection, solution

Product Information

Route of Administration INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE MONOHYDRATE	2.42 g in 110 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM CHLORIDE	990 mg in 110 mL
MANNITOL (UNII: 3OWL53L36A) (MANNITOL - UNII:3OWL53L36A)	MANNITOL	825 mg in 110 mL
ADENINE (UNII: JAC85A2161) (ADENINE - UNII:JAC85A2161)	ADENINE	30 mg in 110 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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	BN040083		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	BN040083	05/31/2013	

Labeler - Maco Productions (265492868)

Registrant - Maco Productions (265492868)

Establishment

Name	Address	ID/FEI	Business Operations
Maco Productions		265492868	manufacture(14498-002)