LEUKOTRAP WB SYSTEM - CP2D- cp2d/as-3 anticoagulant and additive system solution
LEUKOTRAP WB SYSTEM - AS3- cp2d/as-3 anticoagulant and additive system solution
Haemonetics Corporation

Leukotrap WB System

DESCRIPTION

CP2D/AS-3 Blood Bag Unit with In-Line WBF Filter and Sampling System

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

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

Sterile, nonpyrogenic fluid path. Sterilized by steam.

Rx only.

This product is free of natural rubber latex.

INDICATIONS AND USAGE

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

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. Platelet concentrates are not intended to be made with this product.

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.

STORAGE

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

If AS-3 is not used, whole blood or red blood cells in CP2D alone may be stored at 1—6 °C for up to 21 days.

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 Donor *Care*® 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 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. Collect appropriate volume of blood into collection bag, as indicated on packaging.

Note: Mix blood and anticoagulant frequently during collection, 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 Y Sampling Site 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.

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 tube holder.

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.

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

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 "Filtration Instructions", Step 1.

BLOOD COLLECTION INSTRUCTION FOR SYSTEMS CONTAINING A SAMPLE DIVERSION POUCH WITH OR WITHOUT A PRE-ATTACHED SAMP *LOK* VACUUM TUBE HOLDER

When using systems with a pre-attached Samp *Lok* vacuum tube holder, follow instructions as noted below, but refer to "When Using Systems with a Pre-attached Samp *Lok* Vacuum Tube Holder" 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 Donor *Care* 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 Samp *Lok* vacuum tube holder, go to “When Using Systems with a Pre-attached Samp *Lok* Vacuum Tube Holder”.

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 downwards so that the air rises to the top of the pouch and away from the vacuum tube holder. Note: Drawing air into the vacuum tube may cause hemolysis.

14. Collect blood samples from the sample diversion pouch within approximately four minutes to avoid possible clot formation.

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

16. 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.

17. Collect appropriate volume of blood into collection bag as indicated on packaging.

Note: Mix blood and anticoagulant frequently during collection, for example, once every 45 seconds, and immediately after collection. If blood agitation device is used, follow manufacturer's operating instructions.

18. 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.

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

20. Release any remaining pressure from donor’s arm.

21. 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.

22. 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.

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

24. Strip tubing between seal and collection bag.

25. Continue to "Filtration Instructions", Step 1.

WHEN USING SYSTEMS WITH A PRE-ATTACHED SAMP *LOK* VACUUM TUBE HOLDER

1. To collect blood samples, open lid from Samp *Lok* vacuum tube holder.

2. Open snap-open closure between sample diversion pouch and Samp *Lok* vacuum tube holder.

3. Position the sample diversion pouch downwards so that the air rises to the top of the pouch and away from the Samp *Lok* vacuum tube holder. Note: Drawing air into the vacuum tube may cause hemolysis.

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

5. Ensure the vacuum tubes are centered within the Samp *Lok* vacuum tube holder during sample collection.

6. Maintain forward pressure on the vacuum tubes during sample collection.

7. The lid may be closed on the Samp *Lok* vacuum tube holder after sample collection.

8. Return to "Blood Collection Instruction for Systems Containing a Sample Diversion Pouch with or without a Pre-attached Samp *Lok* Vacuum Tube Holder", Step 17. Note: When collection of unit is complete, and the donor needle is engaged in the DCNG, open the lid of the Samp *Lok* 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.

FILTRATION INSTRUCTION

1. Filter and process whole blood within 72 hours of collection.

2. Mix whole blood/anticoagulant thoroughly.

3. Place empty red cell storage bag on a horizontal surface.

4. Ensure cap of blood recovery vent above the filter is tightly closed.

5. Hang whole blood bag up to 60 inches (1.52 meters) above empty red cell storage bag and ensure filter is vertical. Note: The maximum head height should be 60 inches (1.52 meters) for whole blood filtered at room temperature and at 1—6 °C.

6. Open snap-open closure of whole blood bag. Priming will occur automatically by gravity.

7. After blood fills one side of the air vent below the filter, open snap-open closure immediately below the air vent to begin filtration.

8. Allow blood to filter by gravity. Note: Do not apply mechanical or manual pressure to increase flow rate. Filtration is complete when whole blood bag is empty.

9. Remove cap from blood recovery vent above the filter and allow the upstream side (non-printed side) of the filter to drain.

10. When the upstream side of the filter is empty, clamp tubing below the filter. Note: 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.

11. Seal tubing just below the snap-open closure.

12. Detach and discard collection bag and filter. Note: Do not strip tubing prior to sealing the tubing distal to the filter. If it is desired to strip blood from numbered tubing, do so only after tubing has been sealed close to the snap-open closure and detached.

13. If desired, seal at or adjacent to "X" marks on the tubing to provide numbered segments of anticoagulated blood for typing or crossmatching. Notes: 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.

PROCESSING INSTRUCTIONS

1. Load filtered blood and remaining bags into centrifuge cup, ensuring that the tubing stays in the top half of the cup.

2. Centrifuge at appropriate conditions to produce desired components.

3. Carefully remove the unit from the centrifuge and place the red cell storage bag in the plasma expressor.

4. Clamp tubing to extra satellite bags, if present.

5. Gently apply expressor pressure.

6. Open snap-open closure to satellite bag and express plasma.

7. After plasma is expressed, clamp tubing between red cell storage bag and Y connector, and release expressor pressure.

8. Clamp tubing between the Y connector and plasma bag.

9. Hang AS-3 bag above red cell storage bag and remove clamp from tubing to the red cell storage bag.

10. Open snap-open closure on the bag containing the AS-3 additive solution and transfer to the bag containing the red cells. Note: AS-3 solution should be added to the packed red blood cells immediately after removal of plasma. Transfer AS-3 solution under one of the following processing conditions:

a. within 8 hours of collection if whole blood is held at room temperature.

b. within 72 hours of collection if whole blood is refrigerated.

11. Seal tubing and detach the bag containing packed red cells, and set aside plasma for further processing.** Note: If quality control is to be performed on postfiltration sample, leave an adequate length (~10 inches) of tubing attached to the bag containing red cells.

12. Gently mix packed red cells and AS-3 solution.

13. Store CP2D/AS-3 preserved red blood cells at 1—6 °C for up to 42 days and use as indicated. Note: If AS-3 is not used, whole blood or red blood cells in CP2D alone may be stored at 1—6 °C for up to 21 days.

HOW SUPPLIED

Each shipping case contains 6 foil envelopes. Within each foil envelope resides 3 clear pouches containing an individual collection system. Each collection system consists of CP2D/AS-3 500 ml, Double Blood Bag Collection System with Sample Diversion Pouch.

REFERENCES

Haemonetics Corporation. Donor *Care* and Samp *Lok* are registered trademarks of ITL Corporation, Canberra, Australia.

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

PRINCIPAL DISPLAY PANEL

CP2D 500 ANTICOAGULANT CITRATE PHOSPHATE DOUBLE DEXTROSE SOLUTION

Approx. 500 ml plus 70ml 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. VOLUNTEER DONOR. This product may transmit infectious agents. Rx only. PROPERLY IDENTIFY INTENDED RECIPIENT.

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.

Double 500ml CP2D/AS-3

AS-3 RED BLOOD CELLS

Adenine – Saline Added, Leukocyte Reduced

16.5 mEq sodium added. From 500 ml CP2D Whole Blood. Store at 1-6 ºC. 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.

LEUKOTRAP ® WB SYSTEM

CP2D/AS-3 Double Blood Bag Unit with In-Line WBF Filter and Sample Diversion Pouch

For collection of 500 ml of blood and preparation of red blood cells and plasma 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 one empty bag. 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.

HAEMONETICS®

WBF 500 ml
Triple CP2D/AS-3

LEUKOTRAP® WB SYSTEM

CP2D/AS-3 Triple Blood Bag Unit with In-Line WBF Filter* and Sample Diversion Pouch

For collection of 500 ml of blood and preparation of red blood cells and plasma 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 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.

* WBF2

3 Units **Code 126-93**

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

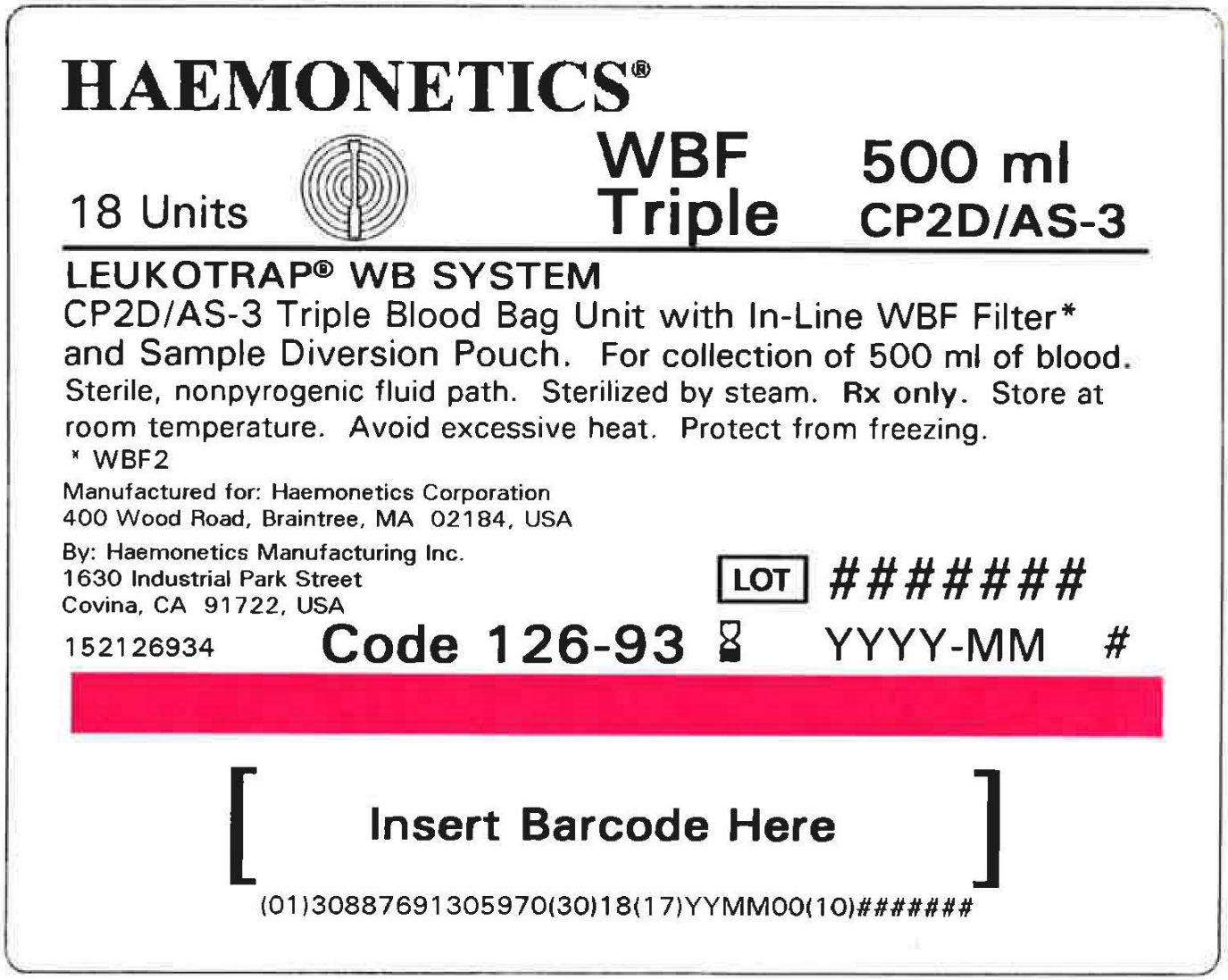
LOT #######

YYYY-MM #

151126935

[Insert Barcode Here]

(01)20887691305973(30)03(17)YYMM00(10)#######



LEUKOTRAP WB SYSTEM - CP2D

cp2d/as-3 anticoagulant and additive system solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:53157-126
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

Inactive Ingredients	
Ingredient Name	**Strength**
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)	

WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53157-126-92	6 in 1 BOX		
1		3 in 1 POUCH		
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	BN820915	10/07/2015	

LEUKOTRAP WB SYSTEM - AS3

cp2d/as-3 anticoagulant and additive system solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:53157-106
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53157-106-92	6 in 1 BOX		
1		3 in 1 POUCH		
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	BN820915	10/07/2015	

Labeler - Haemonetics Corporation (057827420)

Establishment

Name	Address	ID/FEI	Business Operations
Haemonetics Manufacturing Inc		078598396	manufacture(53157-126, 53157-106) , sterilize(53157-126)

Revised: 1/2020 Haemonetics Corporation