Hemanext ONE®

DEVICE DESCRIPTION

Blood container set used to process and store CP2D/AS-3 Red Blood Cells, Leukocytes Reduced, and O_2/CO_2 Reduced.

Each system consists of:

- One Oxygen Reduction Bag (ORB): empty oxygen impermeable container for processing of CP2D/AS-3 Red Blood Cells, Leukocytes Reduced (LR RBC)
- One Hemanext Storage Bag (HSB): empty oxygen impermeable container for storage of CP2D/AS-3 Red Blood Cells, Leukocytes Reduced, and O_2/CO_2 Reduced
- One Leukocytes Reduced, Red Blood Cell (LR RBC) blood line
- Three flow control blood line clamps

TUBE WELDING COMPATIBILITY

PVC, OD 0.161 in (4.1 mm), ID 0.118 in (3 mm), Wall Thickness (0.55 mm)

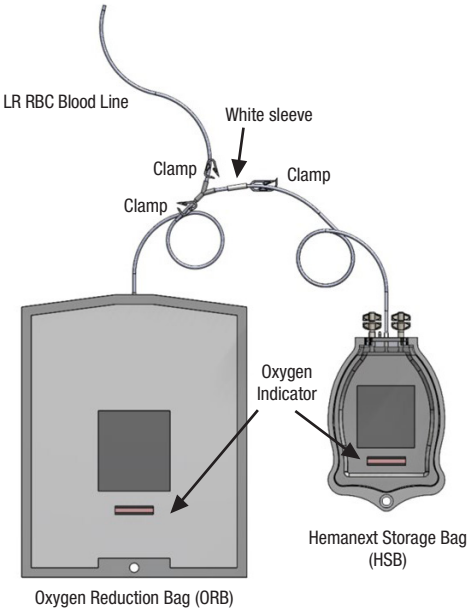

Figure 1: HEMANEXT ONE® SYSTEM

INDICATIONS FOR USE

Blood container set used to process and store Red Blood Cells Leukocytes Reduced, O_2/CO_2 Reduced.

HEMANEXT ONE is intended to process and store CP2D/AS-3 Red Blood Cells, Leukocytes Reduced (LR RBC) that have been prepared within the standard 8-hour hold time. Processing of Red Blood Cells with the HEMANEXT ONE system must be initiated within 8 hours of collection and completed within 12 hours of collection. The Red Blood Cells must be processed at room temperature (20-26°C). The HEMANEXT ONE system limits O_2 and CO_2 levels in the storage environment. Red Blood Cells Leukocytes Reduced, O_2/CO_2 Reduced may be stored for up to 42 days at 1-6°C. HEMANEXT ONE is used for volumes no greater than 350 mL of LR RBC.

CONTRAINDICATIONS

Sickle Cell Trait blood cannot be used for HEMANEXT ONE RBC processing. Donors whose blood will be processed with the HEMANEXT ONE system should be tested for Sickle Cell Trait.

WARNING

- Use aseptic technique for proper connection of disposable tubing.
- Do not use if:
  - The product is expired
  - The package is damaged
  - The tamper evident package has been opened
  - Signs of deterioration are visible on the HEMANEXT ONE system
  - The fluid path closures are loose or not intact
  - The ORB, which contains RBC, is dropped on a hard surface (e.g. floor, lab bench, etc.)
  - There is a blood leak in ORB or HSB during processing
- If a closed system has not been maintained due to a breach in the ORB or HSB, discard the device and do not use.
- If the closed system has been breached during processing or storage, discard the LR RBC.

PRECAUTIONS

- The HEMANEXT ONE system is only intended to process CP2D/AS3 whole blood derived, leukocyte reduced Red Blood Cells.
- The HEMANEXT ONE system is designed to process up to 350 mL of LR RBC.
- Processing with the HEMANEXT ONE system must be completed with Red Blood Cells at room temperature prior to refrigeration.
- The HEMANEXT ONE system must be used within 24-hours of opening its individual packaging.
- Do not use the HEMANEXT ONE system if the oxygen indicator(s) are purple or bluish-gray.
- Tubing between the ORB and HSB should not be cut or sterile docked to any other product.
- Dispose of used components using acceptable biohazard disposal methods.
- Do not use the HEMANEXT ONE system if the LR RBC line has been segmented.
- The HEMANEXT ONE ORB contains an oxygen absorbing material that generates heat if breached. Do not disassemble or remove ORB components.

Studies have not been performed on any of the following and should not be processed with the Hemanext ONE system:

- Refrigerated Red Blood Cells
- Red Blood Cells collected in solutions other than CP2D/AS3
- Non-leukocyte reduced Red Blood Cells

Precautions *continued on next page ...*

PRECAUTIONS (continued)

Studies have not been performed on any of the following and should not be processed with the Hemanext ONE system:

- Apheresis derived Red Blood Cells
- Irradiated Red Blood Cells
- Washed or frozen Red Blood Cells
- Red Blood Cells processed with Pathogen Reduction Technology
- Split Red Blood Cell components

Studies have not been performed on:

- Red Blood Cells irradiated after processing and storage with the Hemanext ONE system.

PRECAUTIONS – TRANSPORTATION

- Studies have not been completed on Red Blood Cells intended for transportation in a pneumatic tube system. **Note: In the case that a facility wishes to transport Hemanext ONE Red Blood Cells in a pneumatic tube system, the facility should complete an internal validation.**

STORAGE AND HANDLING OF DISPOSABLE SET PRIOR TO USE

- Store at room temperature (20-26°C)
- Avoid exposure to excessive heat
- Protect from freezing

INSTRUCTIONS FOR USE

REMOVAL FROM PACKAGING

1) Tear open the individual foil overwrap of the HEMANEXT ONE system using the tear-away strip at the top of the overwrap.
2) Remove the HEMANEXT ONE system from the overwrap. Remove and discard the white cardboard surrounding the pack and inspect for damage. **Warning: Do not use if overwrap or disposable set is damaged.**
3) Smooth out any kinks observed in the tubing prior to processing.
4) Close clamps on the LR RBC and the ORB blood lines. **Note: The clamp leading from the Y-connector to the HSB bag will already be closed upon removal from the overwrap.**
5) Confirm the oxygen indicators on the ORB and HSB are not purple or bluish-gray. **Caution: If either indicator is purple or bluish-gray, do not use the product.**

TRANSFER OF LR RBC TO THE ORB (OXYGEN REDUCTION BAG)

1) Prior to transfer, confirm all clamps on the HEMANEXT ONE system are closed.
2) Ensure the incoming CP2D/AS-3 Leukocytes Reduced RBC blood line is not segmented. **Caution: LR RBC unit must be no more than 350 mL.**
3) Confirm that the oxygen indicator of the ORB is not purple or bluish-gray. If either indicator is purple or bluish-gray, do not use the product.
4) Using a sterile connecting device (SCD), sterile dock the CP2D/AS-3, LR RBC bag to the LR RBC blood line.
5) At room temperature (20-26°C), hang the LR RBC bag at a head height of no greater than 72 inches (180 cm).
6) Open the clamps on the LR RBC blood line and ORB blood line.
7) Transfer the LR RBC by gravity to the ORB by pinching open the sterile weld on the LR RBC blood line. This will allow the Red Blood Cells to begin to flow into the ORB.
8) Once all the LR RBCs have transferred to the ORB, close the clamp on the ORB blood line. **Note: The ORB oxygen indicator may change color during transfer due to the presence of oxygen in the LR RBC. This is normal, and there is no need to stop transferring.**
9) Close clamp on the LR RBC blood line.
10) Using a tube sealer, heat seal the LR RBC blood line between the Y-connector and the LR RBC bag.
11) Separate the LR RBC bag and discard accordingly.

AGITATION OF LR RBC IN THE ORB AT ROOM TEMPERATURE

1) Once LR RBCs have been transferred to the ORB, place the HEMANEXT ONE system on a flatbed platelet agitator shelf at room temperature (20-26°C). **Note: The platelet agitator should operate at a nominal value of 72 cycles/min (CPM).**
2) When placing on the flatbed platelet agitator shelf, be sure to place no more than two HEMANEXT ONE systems per shelf with the ORB parallel to the axis of motion and the HSB on top of the ORB as shown in the diagram below (Figure 2). If only one system can fit per shelf refer to Figure 3. **Note: The ORB must lie flat on shelf surface. Ensure HSB and tubing are positioned completely within the shelf. Ensure that the two HEMANEXT ONE systems do not overlap. Ensure that system and tubing do not catch on the shelf above.**

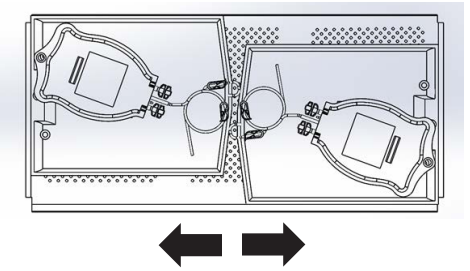

Figure 2

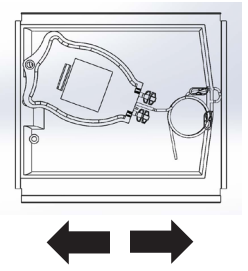

Figure 3

3) Make sure the agitator shelf is fully closed. If applicable, make sure the incubator doors are closed. Start the flatbed platelet agitator.
Note: Limit the amount of times the agitator doors are opened and remain open during processing.
4) Leave the HEMANEXT ONE system on the agitator shelf for at least 3 hours but no longer than 3 hours 15 minutes for O_2/CO_2 reduction.
5) After 3 hours, but no longer than 3 hours 15 minutes, remove the HEMANEXT ONE system from the flatbed platelet agitator shelf.
Note: The ORB oxygen indicator may change color during processing due to the presence o f oxygen in the LR RBC. This is normal, and there is no need to stop the processing of LR RBCs.

TRANSFER OF LR RBC O_2/CO_2 REDUCED TO THE HSB (HEMANEXT STORAGE BAG)

1) At room temperature (20-26°C), hang the ORB at a head height of no greater than 72 inches (180 cm).
2) Open the clamp on the HSB blood line and slide the clamp towards the HSB.
3) Slide the white sleeve over the area where the HSB clamp has pinched the tubing. The white sleeve will ensure that the tubing pathway is fully open.
4) Open the clamp on the ORB blood line to initiate transfer of the LR RBC O_2/CO_2 reduced from the ORB into the HSB.
5) Upon completion of the transfer of the LR RBCs from the ORB to the HSB, expel any air from the HSB and close the clamp. Heat seal the HSB blood line beyond the white sleeve on the tubing section in between the clamp and the HSB, leaving the desired length of HSB blood line tubing.
Caution: Do not close the clamp on the white sleeve section. Do not heat seal tubing in the white sleeve section.
6) Separate the ORB and dispose accordingly.
7) Segment the HSB blood line as needed.
8) Place the HSB into cold storage at 1-6°C for up to 42 days after collection.

PRIOR TO TRANSFUSION – HSB VISUAL INSPECTION

1) Prior to transfusion, confirm that the oxygen indicator on the HSB is not purple or bluish-gray.
Caution: If the indicator is purple or bluish-gray, discard the Red Blood Cells.
2) Prior to Transfusion, confirm that the HSB is not leaking.
Warning: If there is a leak in the HSB, discard the Red Blood Cells.

SYMBOL LEGEND	
	Manufacturer
REF	Catalog Number
	Use By Date
LOT	Batch Code
STERILE R	Sterile Fluid Path Using Irradiation
	Single Use Only
	Consult Instructions for Use
	Do Not Vent
	Keep Dry
	Keep Away from Extreme Temperatures
	Caution
	Non-Pyrogenic Fluid Path
PHT DEHP	Contains or Presence of DEHP
	Do Not Use if Package Is Damaged
350 mL	Blood or Blood Component Container Volume
	Red Blood Cell Container
	Processing Container
Rx Only	US: Prescription Use Only
	Do Not Use if There Is Any Visible Sign of Deterioration

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