

Hemanext ONE[®]

DEVICE DESCRIPTION:

Blood container set used to process and store CPD/PAGGSM Red Blood Cells, Leukocytes Reduced, and O₂/CO₂ Reduced.

Each system consists of:

- One Oxygen Reduction Bag (ORB): empty oxygen impermeable container for processing of CPD/PAGGSM Red Blood Cells, Leukocytes Reduced
- One Hemanext Storage Bag (HSB): empty oxygen impermeable container for storage of CPD/PAGGSM Red Blood Cells, Leukocytes Reduced, and O₂/CO₂ Reduced
- One Leukocytes Reduced, Red Blood Cell (LR RBC) blood line
- Three flow control blood line clamps

TUBE WELDING COMPATIBILITY

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

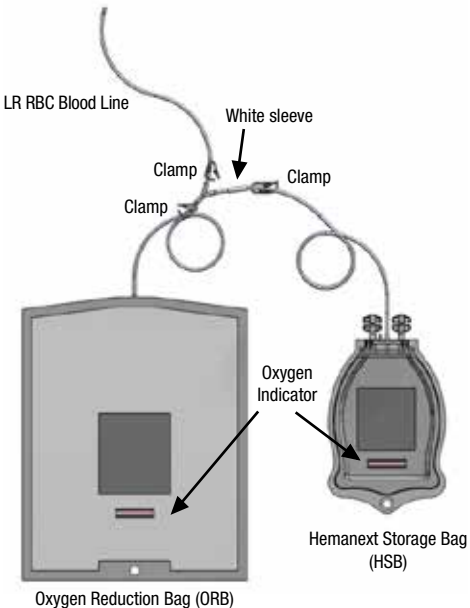


Figure 1: HEMANEXT ONE[®]

INDICATIONS FOR USE:

Blood container set used to process and store Red Blood Cells Leukocytes Reduced, O₂/CO₂ Reduced. HEMANEXT ONE is intended to process and store CPD/PAGGSM Red Blood Cells, Leukocytes Reduced (LR RBC) that have been prepared and processed with the HEMANEXT ONE system within 24-hours of collection. The HEMANEXT ONE system limits the O₂ and CO₂ levels in the storage environment. Red Blood Cells Leukocytes Reduced, O₂/CO₂ 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.

WARNING:

- Use aseptic technique for proper connection of disposable tubing.
- Do not use if:
 - Product is expired
 - The package is damaged
 - 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

PRECAUTIONS:

- HEMANEXT ONE is only intended to process CPD/PAGGSM whole blood derived, leukocyte reduced Red Blood Cells.
- HEMANEXT ONE is designed to process up to 350mls of LR RBC.
- Processing with the HEMANEXT ONE system must be completed with red cells at room temperature prior to refrigeration.
- HEMANEXT ONE must be used within 24-hours of opening its individual packaging.
- Do not use the HEMANEXT ONE system if the O₂ indicator(s) are purple or bluish-gray.
- Tubing between 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.

ENGLISH

- 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:

- Red Blood Cells collected in solutions other than CPD/PAGGSM
- Non-leukocyte reduced Red Blood Cells
- Apheresis derived Red Blood Cells
- Washed or frozen Red Blood Cells
- Red Blood Cells intended to be transported in a pneumatic tube system
- Red Blood Cells processed with Pathogen Reduction Technology
- Split Red Blood Cell components

STORAGE AND HANDLING OF DISPOSABLE SET PRIOR TO USE

- Store at room temperature
- 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 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 color indicators on the ORB and HSB are not purple or bluish-gray.
Caution: If indicator is purple or bluish-gray, do not use the product.

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

- 1) Confirm all clamps on the HEMANEXT ONE system are closed.
- 2) Ensure incoming CPD/PAGGSM Leukocytes Reduced RBC blood line is not segmented.
(Caution: LR RBC unit must be no more than 350 ml)
- 3) Confirm that the O₂ indicator of the ORB is not purple or bluish-gray.
- 4) Using a sterile connecting device (SCD), sterile dock the CPD/PAGGSM, 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 180 cm (72 inches.)

- 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 RBC's have transferred to the ORB, close the clamp on the ORB blood line.
Note: ORB O₂ indicator may change color during transfer and processing due to the presence of oxygen in the LR RBC. This is normal, and there is no need to stop processing.
- 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 RBC's 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: 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.

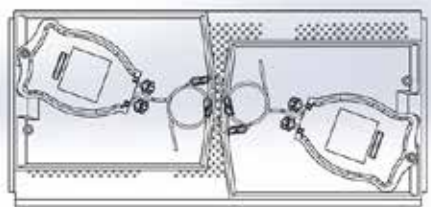


Figure 2

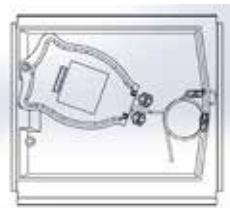


Figure 3

- 3) Make sure the agitator shelf is fully closed. If applicable, make sure the incubator doors are closed. Start the shaking of the 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 3 hours +/- 15 minutes for O₂/CO₂ reduction.
- 5) After 3 hours, remove the HEMANEXT ONE system from the agitator shelf.

TRANSFER OF LR RBC O₂/CO₂ REDUCED FROM THE ORB TO THE HSB (HEMANEXT STORAGE BAG)

- 1) At room temperature (20-26°C), hang the ORB bag at a head height of no greater than 180 cm (72 inches).
- 2) Open 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 clamp on the ORB blood line to initiate transfer of the LR RBC O₂/CO₂ reduced from the ORB into the HSB.
- 5) Upon completion of the transfer of the LR RBC's from the ORB to the HSB, expel any air from the HSB and close clamp. Heat seal the HSB blood line after the clamp and the HSB, leaving the desired length of HSB bloodline tubing. **Caution: Do not close 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 bloodline as needed.
- 8) Place the HSB into cold storage at 1 to 6° C for up to 42 days after collection.
- 9) Prior to transfusion, confirm that the O₂ indicator in the HSB is not purple or bluish-gray.























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SYMBOL LEGEND	
	Symbol for Manufacturer
	Symbol for Catalog Number
	Symbol for Use By Date
	Symbol for Batch Code
	Symbol for Sterile Fluid Path
	Symbol for Single Use Only
	Symbol for Refer to Instructions for Use
	Do Not Vent
	Symbol for Keep Dry
	Keep Away from Extreme Temperatures
	Symbol for Caution
	Symbol for Non-Pyrogenic
	Symbol for Contains or Presence of Phthalate
	Symbol for Do Not Use If Package is Damaged
	Symbol for Blood or Blood Component Container Volume
	Symbol for Red Blood Cell Container
	Symbol for Processing Bag
	Symbol for Authorized Representative in the European Community
	CE Mark
	Do Not Use If There is Any Visible Sign of Deterioration