

IMPORTANT INFORMATION

For the blood services customers of Versiti



Blood Services

UPDATE

Blood Bag Shortage and Expedited Conversion

10/31/2022

There is an unprecedented nationwide shortage of bag sets for the collection and processing of whole blood precipitated by manufacturing and supply chain deficiencies (see attached letter from Fresenius Kabi). We have exhausted all other options that would not impact our customers (e.g., qualifying additional bag types, exploring alternate vendors, etc.). While Versiti strives to proactively communicate changes impacting our customers well before implementation, the urgency of this shortage requires us to take immediate action to ensure uninterrupted collection and distribution of blood products. Without such action we will exhaust our inventory of blood bags in the very near future. Since every blood center is under the same supply constraints, there is no opportunity to obtain additional bags from another source.

To ensure that we can continue operations, Fresenius Kabi (manufacturer of our current bag) obtained an Emergency Use Authorization (EUA) from FDA for a bag manufactured and in use in Europe. We have purchased and are currently validating this bag (CompoSelect). **At this time the bag is approved for red cell storage for 35 days**, although FDA is currently reviewing a request and data submitted to extend expiration to 42 days.

Hospitals should prepare to receive products in these bags as early as November 7th. This bag will be used for red blood cells and plasma components.

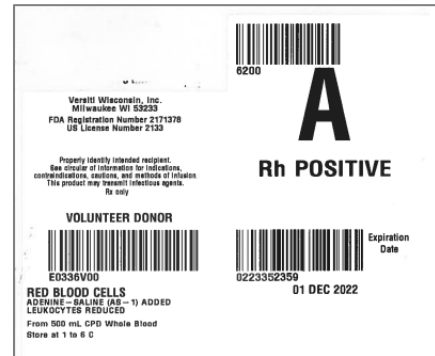


Differences Between the Bioflex (current) and CompoSelect (new) bags

- Under the current EUA, **the CompoSelect bags are approved for 35 day expiration rather than the current 42 day expiration.** There is active review at FDA that is intended to extend shelf life to 42 days. The timeline for review completion is unknown.
- Bag feels different because it is DEHP-free (surface feels rougher)
- Different way of accessing ports (see nursing education)
- Tubing Dimensions differ
 - Bioflex: 0.118" ID x 0.025" WL (0.168" OD)
 - CompoSelect: 0.122" ID x 0.022" WL (0.166" OD)

What is not changing

- All product codes will remain the same
- There are no changes to the additive solutions
- Product volume will remain the same



Implementation

The CompoSelect bag will be initially implemented for whole blood collection in the state of Wisconsin. We anticipate the remaining Versiti states will quickly follow as the shortage continues. Thus, the new bag will be used for a significant portion of the overall Versiti inventory. **Hospitals should prepare to receive red cells and plasma in these bags as early as November 7th.** Cryoprecipitate will follow, likely by the end of November. Please note that collection bags for apheresis (red cells, plasma and platelet) collections will NOT be changing at this time.

Impact Mitigation Measures and Training

- In anticipation of reduced inventory due to shelf life and product transition, **we will immediately reduce fill rates for all RBC orders to accommodate short-term shortages.**
- You should also anticipate more short-dated products than typical as we work to maximize the management of the community inventory.
- Returned products continue to require >10 days of remaining shelf life.
- Empty bags and tubing are available upon request for training and validation
- Versiti is validating the following tube sealers and sterile docker with the new bags, our validations are available upon request.
 - Genesis BPS Rapid Seal II SE530
 - Genesis Rapid Seal Tube Sealer SE200 RS
 - Genesis Rapid Seal Tube Sealer SE250 RS
 - SEBRA REF 1105 (hand sealer)
 - Terumo TSCD-II

- We have attached educational materials for nursing staff
- We are currently planning a hospital meeting to further discuss this change. Look for a meeting invitation coming soon.

We do not take the impact of this change, nor the short lead time for implementation lightly. We are committed to help you in any way that we can to integrate these changes. Please do not hesitate to reach out with any questions or requests. As stated earlier, this is an unprecedented situation, and we will continue to evaluate and communicate new information as we receive it. We will continue to announce updates to our inventory levels and make allocation changes when appropriate. Above all, we are committed to being a strong partner in patient care and will do what is necessary to serve our communities with you. Please reach out to Hospital Relations Specialist, Ashley Root, anwood@versiti.org, with any questions and concerns.