



March 18, 2016

**Re: INTERCEPT® Blood System for Platelets  
Product Codes INT2110B, INT2210B, INT2510B  
Trima Platelet Components Suspended in 100% Plasma**

Dear Valued Customer,

The FDA has approved the use of the INTERCEPT Blood Systems for Platelets (SV, LV and DS set configurations) with Trima apheresis platelets suspended in 100% plasma. This communication is intended to inform you of the associated changes in the package inserts as well as the timing for availability of the new inserts.

**Description of the Changes in the Package Inserts**

- Trima platelets suspended in 100% plasma may now be treated with the INTERCEPT Blood System for Platelets, including the Small Volume (SV), Large Volume (LV) and Dual Storage (DS) Sets.
- The Intended Use has been expanded and now reads:

*The INTERCEPT Blood System for platelets is intended to be used for ex vivo preparation of pathogen-reduced Amicus apheresis platelet components suspended in 65% PAS-3/35% plasma, and Trima apheresis platelet components suspended in 100% plasma in order to reduce the risk of transfusion-transmitted infection (TTI), including sepsis, and to potentially reduce the risk of transfusion-associated graft versus host disease (TA-GVHD).*

- Specifications are included for platelet collection and processing for Trima apheresis platelets suspended in 100% plasma. These differ from those for Amicus platelets suspended in PAS-3.
- For Dual Storage sets, additional details are provided in the Instructions for Use section of the package insert as to when to store in two containers, including differences for platelets suspended in PAS-3 versus 100% plasma.
- New data has been added to the package inserts to support the use of pathogen reduction for apheresis platelets suspended in 100% plasma, including pathogen reduction results, *in vitro* characterization studies and clinical experience data from outside the US.



### **Availability of New Package Inserts**

- New package inserts (dated March 15, 2016) are now available for download from the Cerus website at <http://intercept-usa.com/resources/package-inserts>.
- For the next several months, there will be a transition phase and shipments of SV, LV and DS sets will continue to include copies of the prior package inserts inside the shipping carton. Cerus will also send you copies of the new package inserts along with each order.
- Once the existing Cerus inventory is depleted, we will no longer send you the new package insert separately.
- For existing customers with product inventory on hand, Cerus Customer Service will send you copies of the new package inserts to go with your current inventory.
- If additional copies are needed, you can contact Cerus customer service at (855) 835-3523 or [CustomerServices.Americas@cerus.com](mailto:CustomerServices.Americas@cerus.com) to request additional supply.

Thank you for choosing INTERCEPT for pathogen reduction. If you have any additional questions, please contact your Cerus representative or our Customer Service department.

Sincerely,

Cerus Corporation