



October 15, 2015

**Re: INTERCEPT® Blood System for Platelets and Plasma  
Product Codes INT2110B, INT2210B, INT2510B, INT3110B  
Modification to the Contraindication for Neonatal Phototherapy**

Dear Valued Customer,

The FDA has approved a change to the contraindication section of the package inserts for INTERCEPT Platelets and Plasma, in order to improve the clarity for physicians. This communication is intended to inform you of the change as well as the process and timing for availability of new package inserts.

### **Description of the Change**

The new language provides greater specificity on phototherapy devices in the United States that are not compatible with transfusion of INTERCEPT platelet and plasma components for neonatal patients. The contraindication now reads:

*Contraindicated for preparation of plasma/platelet components intended for neonatal patients treated with phototherapy devices that emit a peak energy wavelength less than 425 nm, or have a lower bound of the emission bandwidth <375 nm, due to the potential for erythema resulting from interaction between ultraviolet light and amotosalen.*

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

Existing inventory of processing sets packaged with the previous package insert will continue to be distributed until such inventory is depleted. In the interim, new package inserts can be obtained as follows:

1. Updated package inserts are now available for download from the INTERCEPT website ([www.INTERCEPT-usa.com](http://www.INTERCEPT-usa.com)).
2. Printed package inserts are currently being prepared and are expected to be available by October 15<sup>th</sup>, 2015. Contact Cerus customer service at (855) 835-3523 or [CustomerServices.Americas@cerus.com](mailto:CustomerServices.Americas@cerus.com) to request a supply of printed inserts.

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