

August, 2007

**Re: INTERCEPT Blood System™ for Platelets Disposables–  
INTERCEPT™ Processing Set for Large and Small Volume Platelet Units  
Labeling Changes.  
INTERCEPT UVA Illuminator Product Code Change.**

Dear Valued Customer,

CERUS is committed to providing you with quality products and services. This letter is to inform you of changes that are being implemented in our INTERCEPT Blood System product line. We are pleased to advise you of upcoming improvements to labeling of the Platelet Processing Sets, which have been made in response to your feedback. These product improvements bring further flexibility for platelet process timing, increased maximum platelet yields prior to treatment, and a few labeling adjustments. Although the treatment sets themselves are identical to the former products delivered under the Baxter labels, we would like to inform you that the product reference and ordering codes have changed. The changes are described in the Product Reference Table below. We are providing you with this letter 30 days prior to release of the new sets to allow sufficient time for implementation planning. We trust you will find these improvements useful and are available for any questions or enquiries.

## **Background**

The current Platelet Products consist of the Aphaeresis (R5628B) and Buffy Coat (R5629B) Processing Sets manufactured by Baxter Healthcare Corporation. CERUS obtained commercial rights to the INTERCEPT Blood System for platelets and plasma effective February 1, 2006. As part of the transition, CERUS notified TÜV Product Service GmbH on July 13<sup>th</sup>, 2006 of the label change as well as the additional changes to the Platelet Processing Sets as described in detail below.

## **Details of Improvements**

CERUS will offer the INTERCEPT Processing Sets for Small Volume (255-325 ml) and Large Volume (300-390 ml) Units.

1. Change in manufacturer from Baxter Healthcare to CERUS Corporation.
2. Platelets derived from aphaeresis or by pooling buffy coats collection can be used in either the Large Volume or for Small Volume Sets.
3. The maximum delay before processing platelets with INTERCEPT has been extended to the end of day 1 after collection.
4. The platelet yield upper limit for the Large Volume Set has been increased from  $6.0 \times 10^{11}$  to  $7.0 \times 10^{11}$ . Processing to the upper limit must be in accordance with local regulations.

## Product References

### INTERCEPT Processing Set Ordering Codes

New Sets	UK	French	ISBT	Multilingual
Small Volume*	INT2101B	INT2102B	INT2103B	INT2104B
Large Volume*	INT2201B	INT2202B	INT2203B	INT2204B
Current Sets				
Aphaeresis	FGR5628B	DGR5628B	KGR5628B	RGR5628B
Buffy Coat	FGR5629B	DGR5629B	KGR5629B	RGR5629B

\*The instructions for use and labels will be changed according to the table above.

The UVA Illuminator product code also changed as part of the transition from Baxter to CERUS. The CERUS UVA Illuminator product code is INT100.

## Implementation Details

The INTERCEPT Processing Sets for Aphaeresis and Buffy Coat Platelets are no longer manufactured and will be discontinued in late 2007. During the transition period, Buffy Coat and Aphaeresis along with Large and Small Volume Sets will be available. CERUS will maintain an overlap inventory of existing Aphaeresis and Buffy Coat Platelet Sets until the supply is no longer available. CERUS requests that our customers plan for this transition by working with their CERUS representative to first utilize their current inventory of sets and then implement the Processing Sets for Small and Large Volume Platelets. Your Cerus representative will contact you shortly to stream line an effective transition to the new labels. CERUS will not offer refunds of unused Aphaeresis and Buffy Coat Processing Sets.

An authorized technical representative will enter new set codes into the INTERCEPT Illuminator during scheduled Preventive Maintenance or CERUS BV Technical Service will contact you to schedule a service.

CERUS B.V. Customer Service will provide you with a new; INTERCEPT Illuminator Operating Manual: MAN-00001 and if applicable an IDMS User manual MAN-00003.

## Contact information

If you have any questions concerning these changes or when receiving the new products, please contact CERUS BV Customer Service:

Kastanjelaan 1	Phone:	+31 33 496 0600
3833 AN Leusden	Fax:	+31 33 496 0606
The Netherlands	Email:	customer_services@cerus.com

With Kind Regards,

*Cerus Europe BV*