July 2012

Re: INTERCEPT Blood System™ for Platelets
Product Code INT25 (Dual Storage Processing Set)
Labeling Extension: Maximum Platelet Input Extended to $8x10^{11}$ with DS Set

Dear Valued Customer:

CERUS is committed to continuously improving our products and services. This letter is to advise you of the most recent project designed to improve treatment of double dose apheresis and buffy coat platelet units by extending the maximum platelet content which can be treated using the INTERCEPT Processing Set with Dual Storage Containers (the DS Set, INT25).

Maximum Platelet Input Extended to $8x10^{11}$ When Using the INTERCEPT Processing Set with Dual Storage Containers

The maximum platelet content approved for treatment with the INTERCEPT DS Set has been extended from $7x10^{11}$ platelets to $8x10^{11}$ platelets when the volume is 375 – 420 mL. Table 1 below specifies the newly approved treatment conditions. This label extension has been reviewed and approved by our Notified Body, TÜV SÜD Product Service.

Table 1. New Treatment Conditions for the DS Set (INT25)

Platelet Count	Volume	Plasma content	Additive Solution Content	RBC Content	CAD Agitation Duration
$2.5 – 7.0×10^{11}$	300 – 420 mL	32-47%	53-68%	$<4×10^6$ RBC/mL	6 to 16 hours
$7.1 – 8.0 × 10^{11}$	**375 – 420 mL**				

Red font indicates label extension

This label extension has no impact on the design of the INTERCEPT disposable sets or the INTERCEPT Illuminator.

Implementation

The INT25 Instructions for Use (IFU) are currently being updated to reflect this new label extension. Upon completion, the new IFU will be available via download from www.INTERCEPTBloodSystem.com or by request from Cerus Europe B.V. Customer Services. Existing inventory of INT25 processing sets packaged with the previous IFU will continue to be distributed until such inventory is depleted.

Some countries may have additional registration requirements which must be met prior to implementation. Implementation of this label extension should proceed according to the internal processes of your blood establishment and in compliance with local regulations and procedures.

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We understand that blood centers are under ever increasing pressure to reduce costs and increase efficiency. To this end, we continue to pursue product improvements and label claims which ensure our customers realize maximum value from the implementation of INTERCEPT. We hope that you find this improvement useful.

Contact information

If you have any questions concerning this change, please contact Cerus BV Customer Services:

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With Kind Regards,

Cerus Europe B.V.

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