February 2015

Re: INTERCEPT Blood System™ for Platelets
Product Code INT22 (Large Volume Set) and INT25 (Dual Storage Set)
Labeling Extensions for Platelets in 100% Plasma

Dear Valued Customer:

CERUS is committed to continuously improving our products and services. This letter is to advise you of the most recent labeling extensions designed to further facilitate treatment of platelets suspended in 100% plasma.

Dual Storage Set Approved for Use with Platelets in 100% Plasma

The Dual Storage (DS) processing set is now approved for treatment of platelets suspended in 100% plasma. Approved processing ranges for treatment of platelets in 100% plasma using the DS set are shown in Table 1.

Table 1 Processing Ranges for Platelets in 100% Plasma with 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**	**100%**	**0%**	**<4×10^{6} RBC/mL**	**16 to 24 hours**
7.1 – 8.0×10^{11}	**375 – 420 mL**				

Red font indicates label extension

Large Volume Set Input Extended to 420mL for Platelets in 100% Plasma

The maximum treatment volume for platelets suspended in 100% plasma using the Large Volume (LV) set has been increased from 390 mL to 420 mL. Refer to Table 2 for the approved processing ranges for platelets in 100% plasma.

Table 2 Processing Ranges for Platelets in 100% Plasma with the LV Set (INT22)

Platelet Count	Volume	Plasma Content	Additive Solution Content	RBC Content	CAD Agitation Duration
$2.5 – 7.0\times10^{11}$	300 – **420** mL	100%	0%	$<4\times10^{6}$ RBC/mL	16 to 24 hours

Red font indicates label extension

Platelets in 100% Plasma Approved for 7 Day Shelf Life

The shelf life for platelets suspended in 100% plasma has been extended to 7 days from the day of collection using either the LV or DS set.

These label extensions have been reviewed and approved by our Notified Body, TÜV SÜD Product Service.

These changes have no impact on the design of the INTERCEPT disposable sets or the INTERCEPT Illuminator.

Implementation

The INT22 and INT25 Instructions for Use (IFU) are currently being updated to reflect these changes. 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 INT22 and 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.

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.

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Contact information

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With Kind Regards,

Cerus Europe B.V.