June 2009

Re: INTERCEPT Blood System™ for Platelets
Product Code INT21, INT22, INT25: Treatment of Platelets Suspended in SSP+ Additive Solution

Dear Valued Customer:

CERUS is committed to providing you with quality products and services. In response to your feedback, we are pleased to advise you of an expansion to the approved labeling for the INTERCEPT Platelet processing sets.

INTERCEPT Treatment of Platelets Suspended in SSP+ Additive Solution

Platelet concentrates suspended in SSP+ additive solution can now be treated with any of the INTERCEPT Platelet processing sets. Combined with the May 2009 approval to treat platelets in suspended in 100% plasma, this SSP+ approval further broadens INTERCEPT's compatibility with platelet collection practices.

SSP+, manufactured by MacoPharma, Mouvaux, France is a CE Marked commercially available platelet additive solution (PAS) designed to partially replace plasma in apheresis and buffy coat platelet collections; it is a modification to the third generation PAS formulation (PAS-IIIM).

In order to afford blood centers the benefits associated with treating platelets in SSP+, and to provide customers a choice in platelet additive solutions, Cerus has completed the requisite in vitro testing to verify that INTERCEPT is effective for platelets suspended in SSP+. This label expansion has been approved by our Notified Body, TÜV SÜD Product Service.

The design of the platelet processing sets (Small Volume, Large Volume, and Dual Storage) is unchanged as a result of this label expansion. The processing parameters for platelets suspended in SSP+ are equivalent to the parameters for platelets suspended in InterSol. As a result, future Instructions for Use (IFU) will denote the processing parameters for platelets in PAS with a note specifying the approved additive solutions. Table 1 below provides an overview of the approved processing parameters for each of the INTERCEPT Platelet processing sets.

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Table 1 INTERCEPT Platelet Processing Parameters

Processing Parameter	Small Volume (INT21)	Large Volume (INT22)		Dual Storage (INT25)
	Platelets in PAS*	Platelets in 100% Plasma	Platelets in PAS*	Platelets in PAS*
Platelet Count	$2.5 – 6.0x10^{11}$	$2.5 – 7.0x10^{11}$	$2.5 – 7.0x10^{11}$	$2.5 – 7.0x10^{11}$
Volume	255 – 325 mL	255 – 390 mL	300 – 420 mL	300 – 420 mL
Plasma Content	32 – 47%	100%	32 – 47%	32 – 47%
RBC Content	$< 4x10^6$ RBC/mL	$< 4x10^6$ RBC/mL	$< 4x10^6$ RBC/mL	$< 4x10^6$ RBC/mL
CAD Agitation Duration	4 – 16 hours	16 – 24 hours	6 – 16 hours	6 – 16 hours
WBC Content	Leukoreduced per local requirements	Leukoreduced per local requirements	Leukoreduced per local requirements	Leukoreduced per local requirements
Approved Storage Duration	7 days	5 days	7 days	7 days

*Approved Platelet Additive Solutions: InterSol, SSP+

Pathogen inactivation results for platelets suspended in SSP+ are generally equivalent or better than those seen with InterSol; as a result, the approved pathogen inactivation (PI) claims are the same for platelets treated in either additive solution. A listing of the approved PI claims can be found in the INTERCEPT Platelets Technical Data Sheet located at www.INTERCEPTBloodSystem.com.

Implementation

This label claim expansion requires that we update the IFU of the INTERCEPT Platelet SV, LV, and DS Processing Sets (INT21, 22, and 25 respectively). Updated IFUs which incorporate this expanded label claim are currently being prepared. Inventory of processing sets packaged with the existing IFU will continue to be distributed until such inventory is depleted. An electronic version of the updated IFU is available at www.INTERCEPTBloodSystem.com.

Implementation of this label expansion should proceed according to the internal processes of your blood establishment and in compliance with local regulations and procedures.

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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 BV