June, 2009

Re: INTERCEPT Blood System™ for Platelets
Product Code INT220X: Treatment of Platelets Suspended in 100% Plasma

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 Large Volume (LV) processing set.

INTERCEPT Treatment of Platelets Suspended in 100% Plasma

Platelet concentrates suspended in 100% plasma can now be treated with the INTERCEPT Blood System utilizing the LV processing set. As a result of this label expansion, blood centers can now choose to treat platelets suspended in 100% plasma or suspended in InterSol based on the method most aligned to the centers' operations.

The design of the LV disposable set is unchanged as a result of this label expansion; however, some processing parameters associated with treating platelets suspended in 100% plasma are different from those for treating platelets suspended in InterSol. Table 1 provides a comparison of the processing parameters.

Table 1: Comparison of Processing Parameters for Platelets Suspended in 100% Plasma and Platelets Suspended in InterSol Using the INTERCEPT LV Set

Processing Parameter	Platelets Suspended in 100% Plasma	Platelets Suspended in 35% Plasma / 65% InterSol
Platelet Count	2.5 – 7.0x10^{11}	2.5 – 7.0x10^{11}
Volume	**255 – 390 mL***	300 – 420 mL
RBC Content	< 4x10^{6} RBC/mL	< 4x10^{6} RBC/mL
CAD Agitation Duration	**16 – 24 hours***	6 – 16 hours
WBC Content	Leukoreduced per local requirements	Leukoreduced per local requirements
Approved Storage Duration	**5 days***	7 days

***Bold** text indicate processing parameters that are different when processing platelets suspended in 100% plasma as compared to processing platelets in InterSol

Please note that this expanded label claim applies only to the Large Volume platelet processing sets (INT2201B, INT2203B, and INT2204B). Platelet concentrates treated using the Small Volume (SV) or Dual Storage (DS) processing sets must continue to be suspended in InterSol prior to INTERCEPT treatment (approximately 35% plasma/65% InterSol).

Because platelets suspended in 100% plasma yield similar pathogen inactivation (PI) results as those seen when applying INTERCEPT treatment to plasma, the approved pathogen inactivation claims associated with INTERCEPT Platelets in 100% plasma are largely equivalent to those for INTERCEPT Plasma. Please reference the INTERCEPT Platelets Technical Data Sheet (www.INTERCEPTBloodSystem.com) for the approved PI claims.

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Plasma supernatant in platelet concentrates has been linked to a higher number and increased severity of transfusion reactions[1]. Data indicate that the use of platelet additive solutions to replace a portion of this plasma decreases the number of transfusion reactions by approximately 56%[2]. Use of additive solutions also has the additional benefit of increasing the availability of plasma for fractionation or transfusion. However, Cerus understands that for some blood centers, the transition to platelet additive solution may not be feasible at this time. In order to afford these blood centers the safety benefits associated with INTERCEPT pathogen inactivation, the requisite testing has been completed to verify that INTERCEPT is effective for platelets suspended in 100% plasma. This label expansion has been approved by our Notified Body, TÜV SÜD Product Service within the processing parameters delineated in Table 1.

Implementation

This label claim expansion requires that we update the Instructions for Use (IFU) of the INTERCEPT Platelet LV Processing Set. Updated IFUs, which incorporate this expanded label claim, are currently being printed. Inventory of LV 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.

We trust you will find this change useful and are available should you need any further information.

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

1. Heddle NM, Klama L, Singer J, et al. *N Engl J Med.* 1994; Sep 8;331(10):625-8
2. Kerkhoffs JL, Eikenboom JC, Schipperus MS, et al. *Blood* 2006; 108(9):3210-5