



January 2016

Subject: Treatment of Platelets Suspended in Additive Solutions (CE Mark)

INTERCEPT™ Processing Sets for Platelets
Product Codes: INT21 Small Volume (SV) Set
INT22 Large Volume (LV) Set
INT25 Dual Storage (DS) Set

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 Processing Sets for platelets. Platelets suspended in T-PAS+, manufactured by Terumo BCT, Inc., and Grifols® PAS III M, manufactured by Grifols, can now be treated with any of the INTERCEPT Processing Sets for platelets.

Combined with the prior CE Mark approvals to treat platelets suspended in 100% plasma, InterSol® and SSP+, this approval further broadens the INTERCEPT system's compatibility with platelet collection practices. Cerus has completed the requisite in vitro testing to verify that INTERCEPT is effective for platelets suspended in T-PAS+ and Grifols® PAS III M. This label expansion has been approved by our Notified Body, TÜV SÜD Product Service.

This communication is intended to inform you of the change, as well as the process and timing for availability of new instructions.

Description of the Change

The Instructions for Use (IFU) now note:

Platelet additive solutions approved for use with INTERCEPT: InterSol®, SSP+, T-PAS+, Grifols® PAS III M.

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 T-PAS+ and Grifols® PAS III M are equivalent to the parameters for platelets suspended in InterSol and SSP+.

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Implementation

This label claim expansion requires that we update the Instructions for Use for the INTERCEPT Platelet Small Volume, Large Volume, and Dual Storage Processing Sets (INT21, INT22, and INT25, respectively). Updated IFUs which incorporate this expanded label claim are currently being prepared. Existing inventory of processing sets packaged with the previous IFUs will continue to be distributed until such inventory is depleted. In the interim, new instructions for use can be obtained from the INTERCEPT Blood System website, 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.

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.

INTERCEPT and INTERCEPT Blood System are trademarks of CERUS Corporation
InterSol is a trademark of Fenwal Corporation
T-PAS+ is a trademark of Terumo BCT, Inc.
Grifols® PAS III M is a trademark of Grifols

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