



February, 2009

**Re: INTERCEPT Blood System™ for Plasma
Product Code INT310X: Expanded Processing Window for Plasma**

Dear Valued Customer,

CERUS is committed to providing you with quality products and services. In response to your feedback, we have made improvements to our INTERCEPT Blood System product line. We are pleased to advise you of an expansion to the approved labeling for the INTERCEPT Plasma processing sets.

Expanded Processing Window for Plasma

The processing window for INTERCEPT treatment of apheresis and pooled whole blood derived plasma has been extended from 8 hours to 20 hours. This label change has been approved by our Notified Body, TÜV SÜD Product Service. As a result, the entire process from collection to freezing can now be completed within a 20-hour timeframe, thereby providing your center with additional flexibility to meet the INTERCEPT processing requirements for your whole blood derived and apheresis plasma collections. With this label claim expansion, when using the INTERCEPT Blood System you will be able to simplify your processing logistics. Whole blood from mobile donor drives can be collected in the afternoon, held overnight, and then processed into plasma components the following day. This change may also allow for blood typing results to become available prior to INTERCEPT processing.

Implementation

This label claim expansion changes the Instructions for Use (IFU) of the INTERCEPT Plasma Processing Set. Updated IFUs which incorporate the expanded processing window are currently being printed. Inventory of INTERCEPT Plasma processing sets packaged with the existing IFU will continue to be distributed until such inventory is depleted.

Implementation of this label claim 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 improvement useful and are available for any questions or inquiries.

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