



November, 2008

**Re: INTERCEPT Blood System™ for Plasma
Product Code INT310X: Previously Frozen Plasma & Frozen Plasma Stability
Expiry Dating Label Expansions**

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.

Previously Frozen Plasma

Original labeling required plasma to be INTERCEPT treated prior to freezing. A new label claim now allows fresh frozen plasma to be thawed then treated with the INTERCEPT Blood System for plasma. This label claim has been approved by our Notified Body, TÜV SÜD Product Service, and is supported by pathogen inactivation and coagulation factor analyses.

When using fresh frozen plasma as the starting material, the plasma should be thawed in accordance with local regulations and immediately treated with INTERCEPT. The treated plasma may then be transfused or refrozen. We hope that this addition to the labeling will provide your center with increased flexibility to integrate INTERCEPT treatment into your routine operations regardless of whether you choose to utilize INTERCEPT before or after freezing.

Frozen Plasma Stability Expiry Dating

The expiration dating of the INTERCEPT treated frozen plasma has been extended to the following:

Storage Conditions	Storage Duration
-18°C to -25°C	12 months
Below -25°C	24 months

This expiration extension has been approved by our Notified Body and will result in a longer shelf life of your INTERCEPT treated frozen plasma.

Implementation

INTERCEPT Blood System for Plasma Instructions for Use will be updated to reflect the changes described above; however, existing inventory of processing sets packaged with the current Instructions for Use will continue to be distributed until such inventory is depleted.

We trust you will find these improvements 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