



November, 2008

**Re: INTERCEPT Blood System™ for Platelets
Product Code INT220X: Increase to Maximum Platelet Processing Volume
Product Codes INT210X & INT220X: Packaging Improvement**

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 Platelet Large Volume sets and improvement to the individual pouch packaging for both our Small Volume and Large Volume processing sets.

Volume Expansion – Large Volume Processing Set (INT220X)

The maximum platelet concentrate input volume for processing with the INTERCEPT Blood System Large Volume set has increased from 390 ml to 420 ml. As a result, the new range for processing with the Large Volume set is 300 ml – 420 ml platelets prepared with InterSol solution (plasma content remains unchanged at 32-47%). This label change has been approved by our Notified Body, TÜV SÜD Product Service. The increased volume range will provide your center with additional flexibility to meet the INTERCEPT processing requirements for larger volume concentrates obtained via aphaeresis collections or buffy coat pooling, while maintaining robust pathogen inactivation.

Packaging Improvement – Large & Small Volume Processing Sets (INT210X & INT220X)

Individual INTERCEPT Platelet processing sets will be packaged in a clear protective pouch in lieu of the current red pouch. This change provides the user better visibility to the contents of the pouch without the need to open this layer of packaging. The packaging will now be consistent with the pouch for the INTERCEPT Plasma processing sets. The pouch is for protective purposes only and the modification does not alter the function or performance of the processing sets in any way.

The pictures below depict the changes to the pouch:

PREVIOUS platelet processing set pouch



NEW platelet processing set pouch



Implementation

Inventory of the Large Volume processing sets packaged with the existing Instructions for Use and Large Volume & Small Volume processing sets packaged with the red plastic pouch 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