

December, 2008

Re: INTERCEPT Blood System[™] Platelet Processing Set (Product Codes INT210X and INT220X) Label Claim Expansion & Processing Set Label Modifications

Dear Valued Customer,

CERUS is committed to providing you with quality products and services. This letter is to inform you of changes that are being implemented in our INTERCEPT Blood System product line. We are pleased to advise you of an expansion to our label claims and improvements to the INTERCEPT Platelet processing set labeling.

New Product Claims

The INTERCEPT Blood System for platelets can be used as an alternative to gamma irradiation to prevent transfusion-associated graft-versus-host disease (TA-GVHD) in at-risk patients (subject to local regulations and requirements). This label claim expansion has been approved by our Notified Body, TÜV SÜD Product Service, based on leukocyte inactivation data and clinical experience with INTERCEPT. The INTERCEPT Blood System for platelets Technical Data Sheet has been updated and a copy can be requested through your local sales representative or Cerus BV Customer Services.

Processing Set Improvements

The following modifications to the processing set labels have been made:

- 1. Removal of amotosalen solution expiry dating on the amotosalen solution container label. The expiry dating on the amotosalen container label was removed to avoid set expiry dating confusion. The processing set expiry dating can be found on the aluminum foil pouch label and the shipping carton.
- 2. The lot logo symbol on the amotosalen container has been removed. The lot logo symbol was removed to avoid customer confusion regarding the lot number of the set. The lot number of the processing set can be found on the aluminum foil pouch, storage container and shipping carton labels.

The pictures below depict the changes:

PREVIOUS platelet processing set amotosalen label*



NEW platelet processing set amotosalen label*



*Pictures reflect Small Volume (SV) platelet processing set amotosalen labels; changes also apply to Large Volume (LV) platelet set amotosalen labels

Existing inventory of processing sets packaged with the previous labels 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