April 2014

Re: INTERCEPT Blood System™ for Platelets and Plasma
Product Codes INT21, INT22, INT25, INT31
Processing Set Label Changes

Dear Valued Customer:

CERUS is committed to continuously improving our products and maintaining compliance with international standards. This letter is to advise you of changes to the labeling associated with the INTERCEPT processing sets. These changes are being made in order to comply with ISO 15223-1 and the Medical Device Directive.

Table 1 provides a description of the changes and the impacted INTERCEPT labels.

Table 1 Description of Label Changes

Change	Symbol or Example	Impacted Label(s)
Add symbol for "Do not resterilize."		Foil pouch Instructions for Use (IFU)
Add the following text: "Set is single use only. Do not reuse. Do not resterilize. This product is not designed for reuse. Misuse can result in adverse reactions, including severe illness and possibly death."	Not Applicable	Instructions for Use (IFU)
Add the INTERCEPT processing set lot number in barcode format		Foil pouch

These label changes have no impact on the design of the INTERCEPT processing sets or the INTERCEPT Illuminator.

Implementation

These label changes are in the process of being implemented in newly manufactured processing sets. Existing inventory of sets packaged with the previous labeling will continue to be distributed until such inventory is depleted.

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With kind regards,

Cerus Europe BV