March 2010

Re: INTERCEPT Blood System™ for Platelets & Plasma
Product Codes INT21, 22, 25, and 31
Conformity to DEHP Labeling Requirements

Dear Valued Customer,

This letter is to advise you of changes to INTERCEPT processing set labeling in accordance with the requirements of Medical Device Directive 93/42/EEC as amended by Directive 2007/47/EC.

Label Changes

In accordance with the amended Directive, the following symbol will be applied to the foil pouch labels of all INTERCEPT processing sets:

The symbol indicates the presence of Di(2-ethylhexyl)phthalate (DEHP), a plasticizer (softener) commonly used in polyvinylchloride (PVC) components, including components used in medical devices such as containers for blood or nutrients, tubings and catheters.

It is important to note that within INTERCEPT sets, PVC is present only in tubing components, container ports, and in-line filters. All containers and other parts are PVC-free. Furthermore, by nature of the INTERCEPT treatment process, blood components are in contact with PVC for a limited duration (generally less than 15 minutes). Based on limited surface area contact and minimal contact time, DEHP levels in blood components after treatment with INTERCEPT processing sets are estimated to be well below those resulting from other medical applications containing PVC tubing (such as hemodialysis, intravenous fluid administration, extracorporeal membrane oxygenation and cardiopulmonary bypass procedures). Regulatory agencies have noted that the risk of not doing a needed procedure is far greater than the risk associated with exposure to DEHP. [1,2] In the case of pathogen inactivation with the INTERCEPT Blood System, the risks associated with DEHP released to the blood components must be weighed against the benefits of therapeutic transfusion and inactivation of harmful viruses, bacteria, and other pathogens.

The DEHP symbol, information concerning DEHP, and its use in INTERCEPT processing sets will also be added to the Instructions for Use (IFUs) included within each carton of INTERCEPT sets.

DEHP Information

DEHP can leach out of PVC medical devices into solutions that come in contact with the medical device. Depending on the medical procedure, the amount of DEHP that will leach out varies widely and is a function of the lipid content of the fluid that comes into contact with the medical devices, the PVC surface size, the temperature, the flow rate and the contact time.[1,3]

There were some concerns for potential groups at risk, i.e. male fetuses of pregnant women and male neonates, because the DEHP exposure levels during certain medical procedures are the same as or above those that induce reproductive toxicity in animal studies. However, the

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European Commission Scientific Committee on Emerging and Newly-Identified Health Risks (SCENIHR) concluded that the few follow-up studies after high DEHP exposures in neonates performed so far, did not indicate that there is an effect of DEHP on the development of the human male reproductive system and that there is no conclusive scientific evidence that DEHP exposure via medical treatments has harmful effects in humans.[1]

Implementation

Manufacturing of processing sets with updated labeling for the addition of the DEHP symbol is currently in progress. Existing inventory of processing sets will continue to be distributed until such inventory is depleted. Updated IFUs will be available on the INTERCEPT product website at www.INTERCEPTBloodSystem.com in mid-March.

We appreciate your commitment to safeguarding the blood supply from transfusion-transmitted diseases, and we look forward to continued collaborations with your center in the field of pathogen inactivation.

Contact information

If you have any questions concerning this change, please contact Cerus BV Customer Services:

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With Kind Regards,

Carol M. Moore
Vice President, Regulatory Affairs, Quality and Clinical

[1] Scientific Committee on Emerging and Newly-Identified Health Risks (SCENIHR), Scientific opinion on the safety of medical devices containing DEHP-plasticized PVC or other plasticizers on neonates and other groups possibly at risk. Adopted after public consultation by the SCENIHR during the 22nd Plenary of 6 February 2008. http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_014.pdf

[2] U.S. Food and Drug Administration. FDA Public Health Notification: PVC Devices Containing the Plasticizer DEHP. July 12, 2002. http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm062182.htm

[3] U.S. Food and Drug Administration. Safety Assessment of Di(2- ethylhexyl) phthalate (DEHP) Released from PVC Medical Devices. 2002. Center for Devices and Radiological Health. http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080457.pdf