FDA Approves CERUS INTERCEPT Blood System for Platelets and Plasms

In December 2014 the U.S Food and Drug Administration (FDA) approved the INTERCEPT platelet and plasma system for use in the United States. The INTERCEPT Platelet system is approved for *ex vivo* preparations of pathogen reduced apheresis platelet components in order to reduce the risk of transfusion-transmitted infection (TTI), including sepsis , and to potentially reduce the risk of transfusion-associated graft versus host disease (TA-GVD). At the same time the INTERCEPT Plasma system was also approved by the FDA for *ex vivo* preparation of plasma in order to reduce the risk of transfusion-transmitted infection (TTI) when treating patients requiring therapeutic plasma transfusion.

This is the first time that a system that inactivated pathogens in platelets components or plasma will be available in the United States.

The INTERCEPT Blood System inactives a broad spectrum of enveloped viruses, non-enveloped viruses, Gram-positive and Gram-negative bacteria, spirochetes and parasites. While screening tests for a select number of pathogens has lowered the risks from transfusion-transmitted infections, they are reactive approaches requiring the identification of specific pathogens for which tests need to be developed and implemented. Pathogen inactivation by contrast is a proactive safety measure inactivating pathogens independently of whether they have been identified in a specific blood supply.

ABOUT THE INTERCEPT BLOOD SYSTEM

The INTERCEPT Blood System is comprised of single-use platelets or plasma processing sets and an ultraviolet (UVA) illumination device for the *ex vivo* preparation and storage of pathogen inactivated platelet components of whole blood derived or apheresis plasma. The safety and efficacy of the INTERCEPT Blood System has been evaluated in six clinical trials for plasma and 10 controlled clinical trials for platelets. Routine use of INTERCEPT Plasma has been monitored in over 50’000 INTERCEPT Plasma components to almost 10’000 patients in an active hemovigilance study conducted by CERUS Europe and additionally in over 150’000 INTERCEPT Plasma components through France’s national hemovigilance reporting system in 2009 and 2011. INTERCEPT processed platelets have been monitored actively through the national hemovigilance reporting system in France (since 2009) and Switzerland (since 2010).

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