

FDA clears seven-day platelet storage, wireless option, 10/15

Terumo BCT has received 510(k) clearance for a labeling change, extending the storage of platelets in plasma from five days to seven days, as well as offering wireless capability for the software applications used with Terumo BCT's Trima Accel Automated Blood Collection System. This clearance adds to the flexibility and productivity of the Trima Accel system, a device that offers single-needle procedures for a more comfortable donation experience.

The platelet storage conditions have been verified for the standard Terumo BCT extended life platelet storage bag for up to seven days post-collection in 100 percent plasma and up to five days in Isoplate Solution (PAS-F). This is a two-day extension from previous standards for storage of platelets in plasma. For platelet storage up to seven days, the clearance requires that every product be tested with a bacterial detection device cleared by the FDA and labeled as a "safety measure."

The wireless feature connects the Trima Accel system to software applications such as the Cadence Data Collection System and the Vista Information System through a blood center's or hospital's existing wireless network. This enables access to electronic donor information and reporting capabilities, streamlining collections and simplifying data management.

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