



Press Release
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Terumo Blood and Cell Technologies' IMUGARD Platelet Pooling Set cleared by FDA

IMUGARD to help strained US platelet supply meet growing need

Lakewood, Colorado, US, February 14, 2023 – Terumo Blood and Cell Technologies announces US Food and Drug Administration (FDA) clearance and official launch of its IMUGARD(R)WB Platelet Pooling Set, which supports extended shelf life of whole blood-derived platelets from five days to seven days.[1] IMUGARD is the first platelet pooling set approved for seven-day storage in the US and provides an alternate source of platelet supply at a time when demand continues to increase while the supply remains challenged by the lack of blood donors.

Terumo Blood and Cell Technologies is a medical technology company that makes products that collect, process and separate blood and cells. Platelets are a component of human blood that form clots and stop bleeding. They are used to treat many different patients, such as those undergoing chemotherapy, organ transplants and bone marrow transplants. In 2021, more than 2.5 million units of platelets were transfused in the US, up from 2.3 million in 2019, according to the National Blood Collection and Utilization Survey (NBCUS).

Terumo Blood and Cell Technologies' latest innovation aims to increase the availability of platelets for transfusion. IMUGARD enables extended shelf life of platelets from the standard five days to seven days. [1] This can help blood centers better manage supply to meet patient needs and reduce waste.[2][3]

Most of the platelets in the United States are currently collected by apheresis. IMUGARD now gives blood centers another product choice to help them recoup platelets from whole blood donations.

"We continue to invest in innovations that help blood centers to positively impact patients," says Chetan Makam, General Manager, Global Blood Solutions, Terumo Blood and Cell Technologies. "IMUGARD opens the possibility for US blood centers to use the platelets from their whole blood donations to increase the number of platelets available for transfusion. We are the first company to provide seven-day shelf life of both apheresis and whole blood-derived platelets in the US, adding flexibility to the platelet supply. This is especially important now with the increased demand for platelets and the challenges blood centers face with recruiting new apheresis platelet donors."

[1] U.S. Department of Health and Human Services Food and Drug Administration Center for Biologics Evaluation and Research. *Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion*. December 2020. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/bacterial-risk-control-strategies-blood-collection-establishments-and-transfusion-services-enhance>.

[2] Delage G, Bernier F, Beaudoin J, Thibault S, Dion J, Gagné L. Improved bacterial culture of platelet product: preliminary results after implementation of a two-bottle system with 48-hour sampling. *Transfusion*. 2016;56(S4):28A.

[3] Harm SK, Szczepiorkowski ZM, Dunbar NM. Routine use of Day 6 and Day 7 platelets with rapid testing: two hospitals assess impact 1 year after implementation. *Transfusion*. 2018;58(4):938-942.

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About Terumo Blood and Cell Technologies

Terumo Blood and Cell Technologies is a medical technology company. Our products, software and services enable customers to collect and prepare blood and cells to help treat challenging diseases and conditions. Our employees worldwide believe in the potential of blood and cells to do even more for patients than they do today. This belief inspires our innovation and strengthens our collaboration with customers.

Terumo Blood and Cell Technologies' customers include blood centers, hospitals, therapeutic apheresis clinics, cell collection and processing organizations, researchers and private medical practices. Our customers are based in over 130 countries across the globe. We have 750+ granted patents, with more than 150 additionally pending.

We have global headquarters in Lakewood, Colorado, U.S.A., along with five regional headquarters, seven manufacturing sites and six innovation and development centers across the globe. Terumo Blood and Cell Technologies is a subsidiary of Terumo Corporation (TSE: 4543), a global leader in medical technology.