

Terumo Blood and Cell Technologies' Reveos(R) Automated Whole Blood Processing System cleared by FDA for US commercial use

Reveos is positioned to help U.S. blood centers supplement the platelet supply, reduce labor and costs, and improve overall operational efficiency

LAKEWOOD, Colorado, US, August 1, 2023 – Terumo Blood and Cell Technologies (Terumo BCT) announces US Food and Drug Administration (FDA) clearance of the Reveos Automated Whole Blood Processing System, the first whole blood automation device available in the US that processes whole blood into platelets and other components in a single centrifugation cycle. Automated processing of whole blood on the Reveos system, the only device of its kind globally, will enhance the blood and platelet supply for patients in the US.

Platelets are used to treat patients with many conditions, including trauma and cancer. Today, 94 percent of platelets available for transfusion in the U.S. come from apheresis[1], a process that draws a donor's blood, isolates desired components from it, and returns the rest of the blood to the donor, using platforms such as Terumo BCT's Trima Accel(R) Automated Blood Collection System.

Apheresis donations are not projected to keep up with increases in platelet usage[2]. FDA's clearance of the automated Reveos system gives blood centers the added capacity to collect platelets from existing whole blood donations efficiently.

In Reveos, Terumo BCT brings to the US a platform with an established track record following deployment in 52 countries over the past decade. Reveos is the only automated device to process whole blood into platelets, plasma and red blood cell (RBC) components in a single centrifugation cycle.

Terumo BCT continues making investments to support blood centers. In 2022, FDA cleared its IMUGARD WB Platelet Pooling Set, which supports the extended shelf life of platelets from five days to seven days. As part of the Reveos clearance, Terumo BCT obtained an intended use statement for the IMUGARD WB Platelet Pooling Set that includes platelets prepared by Reveos; these platelets can be pooled on day one or day two after collection — providing even more flexibility to blood centers using Reveos.

"Reveos will help blood centers maximize the use of whole blood donations while increasing the availability of platelets for patients in need," said Bill Block, President and CEO of Blood Centers of America, the largest blood supply network in the US. "We look forward to deploying this technology within our membership and at our blood center partners across the country later this year."

By automating whole blood processing, Reveos can reduce the working hours needed by laboratory staff by up to 30 percent[3]. Whole blood is collected from donors and has traditionally been separated into components using manual methods that take as many as 18 or 20 steps. Reveos simplifies this process and eliminates over half the steps[4].

"Reveos has a long-standing track record for helping blood centers globally meet the critical needs of patients while creating efficiencies in their operations," said Antoinette Gawin, President and CEO of Terumo BCT. "We continue to invest significantly in innovation for the future and in supporting blood centers. Reveos and IMUGARD together target the growing and critical need for platelets. These are just more examples of our holistic work focused on blood centers."

About the Reveos(R) Automated Blood Processing System

Reveos is the first and only device of its kind. This easy-to-use automated system integrates the manual steps of whole blood processing. Whole blood units are collected from donors and have traditionally been separated into components — platelets, plasma and red blood cells — using a semi-automatic and manual method that takes up to 20 steps. Reveos simplifies this process and eliminates over half of the steps. The system aims to help blood centers manage staffing, reduce costs and improve overall efficiency by obtaining more blood products from the same number of donors. It has been used in 52 countries for more than a decade. Reveos is expected to help U.S. blood centers meet the growing

demand for platelets, which control bleeding and are used to treat patients facing trauma, cancer and chronic conditions, among others.

Up to four units of whole blood are loaded into the Reveos system. The rotor begins to spin, and the whole blood is separated into components. Plasma, platelets, red blood cells, and residual leukocytes are expressed into their respective product bags, and each bag is sealed. After the procedure, the data is recorded.

Availability varies by region and country.

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 150 countries across the globe. We have 750+ granted patents, with more than 150 additionally pending.

We have global headquarters in Lakewood, Colorado, US, 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.

[1] Jones et al. Has the trend of declining blood transfusions in the United States ended? Findings of the 2019 National Blood Collection and Utilization Survey. Transfusion. 2021;61:S1–S10

[2] U.S. Department of Health and Human Services. Adequacy of National Blood Supply. Report to Congress 2020

[3] Fernandez et al. Automation in Blood Bank Processing: Where We Go? Transfusion. 2017.57:S3.

[4] Data on file at Terumo Blood and Cell Technologies. BC-REVE-00278