BK990025

COBE Trima Automated Blood Component System

Summary of Safety and Effectiveness

COBE Trima RBC + Plasma Collections

Manufacturer:	COBE BCT, Incorporated 1201 Oak Street Lakewood, Colorado 80215
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Date of Summary Preparation:	August, 1999
Trade Name of Device:	The COBE Trima Automated Blood Component Collection System.
Common Name:	Automated Blood Component Collection System
Classification Name:	Automated Blood Cell Separator (21 CFR 864.9245)
Predicate Devices:	COBE Spectra Apheresis System (510(k)'s BK870022, BK900002, BK900004, BK920036, BK950056) COBE Trima System (510(k)'s BK970002, BK970023)

Device Description

The COBE Trima System is an automated blood cell separator intended for use in collecting blood components for transfusion. It can collect, as defined by country specific standards (new protocols are bolded):

- Single Donor Platelets (SDP, > 3×10^{11} in the U.S)
- Double Platelet Products (DPP, > 6×10^{11} in the U.S.)
- Triple Platelet Products (TPP, > 9×10^{11} in the U.S.)
- SDP, DPP, TPP and a Unit of Plasma
- SDP or DPP and a unit of Packed Red Blood Cells
- SDP or DPP, a Unit of plasma, and a unit of Packed Red Blood Cells
- **Double RBC Product (DRBC)**
- **DRBC and Unit of Plasma**
- **RBC and Unit of Plasma**
- **Unit of Plasma alone**

The products collected are dependent on the size (total blood volume), hematocrit, platelet count, and blood type of the donor. This allows the blood center to manage their blood component inventory based on the specific needs of the prescribing physicians in their hospital or community.

Intended Use:

This device is intended for the collection, pre-storage leukoreduction, and storage of platelet products. Packed red blood cell products are collected as either single or double units and stored for 42 days at 4 °C. Concurrent plasma products are also collected depending on the needs of the blood center and the weight, total blood volume and hematocrit of the donor.

Technological Comparison:

The COBE Trima System disposable tubing set is equivalent to the sets used with the COBE Spectra Apheresis System. It generally uses the same materials, including the platelet and plasma storage bags, as used in the current COBE Spectra Extended Life Platelet Sets. The packaging and sterilization process are the same, and both sets are manufactured in comparable GMP-controlled medical manufacturing areas in the same plant.

The COBE Trima System equipment uses the same centrifugal separation concept as the COBE Spectra. The COBE Trima equipment is approximately 42 inches tall and 21 inches wide, and weighs less than 200 pounds, making it easy to transport. This automated system separates whole blood into its major components: platelets, plasma, and red blood cells. The COBE Trima System uses a disposable tubing set with a cassette that automatically loads the tubing into the pumps, valves, and sensors. The touch screen display is designed to lead the Operator through the setup and operating procedures, and provide her/him with detailed alarm messages to assist in troubleshooting procedures.

The equipment uses five peristaltic pumps located on the front panel. Blood is drawn from the donor and into the system by the inlet pump during the collection process. AC and whole blood are mixed at the configured inlet to AC ratio as a result of the inlet and AC pump speeds. The blood and AC mixture then enters the separation channel in the centrifuge. As the whole blood is separated, platelets and plasma are removed by the collect and plasma pumps. RBCs are pushed from the channel into the collect bag or reservoir by the pressure created from the inlet pump forcing more blood into the channel. Components not collected are directed to a reservoir on the cassette.

When the reservoir contains a sufficient volume of uncollected RBCs, plasma and platelets, a sensor is triggered which activates the return pump. The return pump interrupts the flow of incoming blood by pumping the return blood back

through the single needle access to the donor until the level in the reservoir reaches the lower level sensor. During platelet and plasma collection the inlet pump remains at a constant speed, forcing a small amount of blood back through the inlet line and into the channel. This recirculated blood allows the COBE Trima System to maintain a continuous flow of blood through the channel, which stabilizes the separation process. During RBC collection, blood is not recirculated to avoid diluting the incoming donor blood.

A saline replacement fluid option is available on the COBE Trima for the DRBC, RBC plus Plasma, and Plasma Only protocols. It is not available when platelet products are collected. This option can be activated at the discretion of the blood center's Medical Director or medical staff.

Discussion of Clinical Data:

The safety and efficacy of the COBE Trima System were validated to collect DRBC, RBC plus plasma units, and plasma only in a series of studies. Feasibility studies concentrated on demonstrating safety for the blood component donor. These studies were followed by collection and storage studies that continued to look at donor safety, and evaluated red cell and plasma quality following appropriate storage. *In vitro* measurements of RBC and plasma quality were also done in these studies.

Donor Safety

Donor safety for the COBE Trima System was evaluated with clinical procedures. Blood trauma testing was done on donor blood samples drawn before and after clinical procedures, and the results compared. There were no adverse events recorded, other than the expected reactions to the ACD-A anticoagulant, during the procedures performed as part of this study.

No significant blood trauma was seen as measured by donor blood chemistry, complement activation, and clotting factor activation. Donor safety was assessed with pre and post procedure blood pressure and pulse measurements which showed no clinically significant differences. The optional use of saline replacement fluid also did not affect adverse reactions, or blood pressure and pulse results.

Plasma Product Quality

The results from plasma component assays demonstrate that the COBE Trima System can collect concurrent plasma during red cell collection procedures, or with plasma units collected alone. The studies comparing the plasma products collected on the COBE Trima System to those collected on COBE Spectra showed that the plasma products were comparable, with no clinically significant

differences. The mean levels of Factor VIII were well above the 50 International Units per product required by the AABB standards. These plasma units were also shown to be leukoreduced, meeting both U.S. F.D.A. and European standards for leukoreduced blood components.

Packed Red Blood Cell Unit Quality

Packed red cell units can be collected as single or double units using the COBE Trima System. Samples were collected from pRBC units and analyzed with *in vitro* red cell function assays. These results showed less than 1% hemolysis, with appropriate retention of the ATP concentration known to correlate with red cell recovery and survival. Individual red cell units collected during a double red cell collection were shown to be equivalent to each other. These units were also shown to be equivalent to units collected with a concurrent plasma unit, and units collected following a platelet collection procedure.

Conclusion

Donor blood trauma measurement taken before and after the collection procedures, and adverse events recorded for all procedures, demonstrate that the safety of the COBE Trima System is comparable to other Automated Blood Cell Separators currently available for sale in the United States. The data collected during the COBE Trima System clinical studies evaluating the collection, storage and transfusion of red cell and plasma products predict that these products will be safe and effective when transfused. The results from the concurrent plasma products collected during these procedures showed that there were no clinically significant differences when compared to products collected using the COBE Spectra. The *in vitro* red cell function assays demonstrate that the pRBC units collected using the COBE Trima System are equivalent to similar units processed from whole blood collections.

These data, along with data submitted in earlier 510(k) submissions, demonstrate that the COBE Trima Automated Blood Component Collection System can safely and effectively collect combinations of platelet, plasma, and RBC products. These products are equivalent to those processed from whole blood, and the automated collection process can replace the need to collect whole blood units.