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Red Blood Cell Exchange

Amicus Separator

Therapeutic apheresis and cell collection

The Amicus Separator provides precision red cell removal for exchange, depletion/exchange and depletion procedures.[2]

- Low extracorporeal volume (160 mL)
- Automatic bag switching for replacement fluid
- Partial custom prime option for lower blood volume patients
- Same hardware and disposable kit for RBCx and TPE

Three different procedure options[1] give physicians the flexibility to provide patient treatment to achieve individualized outcomes

Exchange	Removes the patient's RBCs and replaces them with compatible donor RBCs to achieve a target FCR, target End Hct, and target Fluid Balance.
Depletion	Removes the patient's excess RBCs and replaces them with a prescribed replacement fluid, typically colloid and/or crystalloid solutions, to achieve a target End Hct.
Depletion/Exchange	Performs an RBC Depletion procedure quickly followed by an RBC exchange.

Target FCR and End hematocrit accuracy

The Amicus RBC exchange procedure accurately removes the patient's red blood cells (RBCs) while simultaneously infusing healthy donor cells with the intent of reaching a target hematocrit (Hct), fraction of cells remaining (FCR), and fluid balance.

Parameter	N[1]	Mean (SD)[1]	Median[1]
Calculated Target End Hct Accuracy	16	0.96 (0.07)	0.97
Target Fraction of Cells Remaining (%)	8	53.0 (8.3)	56.0
Actual FCR (%)	8	46.12 (9.07)	46.33
Pre-Procedure HbS (%)	8	32.21 (11.82)	30.10
Post-Procedure HbS (%)	8	14.80 (6.66)	12.15
Calculated Actual:Target FCR Ratio	8	0.87 (0.08)	0.87

The mean actual to target FCR Ratio was 0.87 and the mean target end hematocrit values were 96% accurate. In RBC Exchange and RBC Depletion/Exchange subjects, the mean hemoglobin S was reduced from 32.21% to 14.80%. This was comparable to the mean hemoglobin S reduction from 37.79 to 13.88 reported by Quirolo (2014)[3] in a Spectra Optia study.

Source:

[1] Plan for Evaluation of the Amicus Red Blood Cell Exchange System: Summary of RBCx System Procedures from the AMIC-003-CMD and AMIC-004-CMD Protocols.

[2] Information included in Amicus Clinical Evaluation Report 345-CER-000008 for CE Mark of Amicus RBCx System.

[3] Quirolo K et al. The evaluation of a new apheresis device for automated red blood cell exchange procedures in patients with sickle cell disease. Transfusion 2014; doi: 10.1111/trf.12891.

Low extracorporeal kit volume

Amicus employs a kit design with a low extracorporeal volume (ECV) of 160 mL. A low kit ECV helps to reduce the percent of patient total blood volume used to prime the kit.

Automated partial custom prime

For patients with lower total blood volume or lower hematocrit, Amicus offers a partial custom prime option:

- Allows priming from replacement fluid line through return line. This can save a unit of blood that is typically used for priming the entire kit.
- Amicus has the ability to mix saline with the prime source fluid to achieve a desired hematocrit in the return line.
- Helps ensure the patient remains isovolemic at the start of the procedure with minimal hematocrit fluctuations.

Sterilization using irradiation

Sterilization of apheresis kits with irradiation avoids the risk of reactions related to patient exposure to residual ethylene oxide and eliminates the need for double priming the kit.

The RBCx system is CE marked for distribution in EU. It is not cleared for market in the United States.

Precision design to help you achieve more

Refer to Amicus Operator's Manual for a full list of warnings and cautions associated with the use of the Amicus device.

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Fresenius Kabi AG
61346 Bad Homburg
Germany

Phone: +49 61 72 608-0
Fax: +49 6172 608-5786

Fresenius Kabi
www.fresenius-kabi.com

Amicus Therapeutics
www.fk-therapeutic-apheresis.com
amicus@fresenius-kabi.com