FRESENIUS KABI

Red Blood Cell Exchange

Amicus Separator

Therapeutic Apheresis and Cell Therapy

The Amicus Separator device provides precision red cell removal for exchange, depletion/exchange, and depletion procedures.[1, 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, 2] 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.

AMIC-003-CMD[1] (Exchange and Depletion/Exchange Procedures)

Parameter Evaluable Procedures (n=59)		Mean (SD)
Actual HbS (%)	Pre-Procedure	38.39 (12.155)
	Post-Procedure	14.92 (6.369)
Actual FCR (%)		38.97 (11.015)
Target FCR (%)		40.2 (10.25)
Actual Hct (%)	Pre-Procedure	27.3 (4.37)
	Post-Procedure	29.61 (2.665)
Target Hct (%)		30.0 (1.97)
Calculated Target end Hct (%) Accuracy		1.19 (0.817)
Calculated A:T FCR Ratio		0.978 (0.1933)

The AMIC-003-CMD[1] study (Exchange and Depletion/Exchange Procedures only) had a total of 59 procedures in 37 adult subjects (age ≥ 22 years) and 22 pediatric subjects (age ≤ 22 years).

The mean Actual to Target (A:T) FCR Ratio was 0.978 and the mean hemoglobin S was reduced from 38.39% to 14.92%. The mean Calculated Target End Hematocrit accuracy was 1.19%.

AMIC-004-CMD[2] (Depletion Procedures)

Parameter Evaluable Procedures (n=36)	Mean (SD)
Subject Post-Procedure Hct (%)	34.6 (2.79)
Target End Hct (%)	35.8 (2.25)
Calculated Actual:Target Hct	1.0 (0.05)

The AMIC-004-CMD[2] study (Depletion Procedures only) had a total of 36 evaluable procedures. The mean actual subject post-procedure Hct was reported as 34.6%. The mean Target End Hct was 35.8.% Therefore, the mean calculated actual to target (A:T) End Hct ratio was 1.0 with a 95% CI of 0.95 to 0.98.

Source:
1. AMIC-003-CMD: Evaluation of the AMICUS Red Blood Cell Exchange (RBCx) System in Sickle Cell Patients
2. AMIC-004-CMD: Evaluation of the AMICUS Red Blood Cell Exchange (RBCx) System

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 the patient remain isovolemic at the start of the procedure with minimal hematocrit fluctuations.

Sterilization using irradiation

Sterilization of apheresis kits with irradiation eliminates the need for double priming the kit.

Red Blood Cell Exchange

Precision design
to help you achieve more

This marking reflects compliance with the applicable CE Marking requirements for medical devices. CE 0123

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

FRESENIUS KABI

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