

# US clinical evaluation of collection protocol in G-CSF mobilized donors

## Amicus Separator Therapeutic apheresis and cell collection



### Study Parameters

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- Ten healthy subjects participated in 20 procedures resulting in 19 evaluable procedures
- Five males and five females ranging in age from 19 to 58 years (median of 29 years) participated in the study

### Key Outcomes

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MNC and CD34+ collection efficiencies and product quality were evaluated. The study demonstrated that collections on Amicus were safe and efficient:

- MNC and CD34+ collection efficiencies were comparable to historical data (CS-3000)
- Product contained high viability with low platelet and red cell contamination
- Subject vital signs and hematology parameters were safely maintained
- No serious adverse events were reported

Table 1

Amicus achieved high collection efficiencies with low RBC and platelet contamination in the product

HEALTHY DONOR PARAMETERS				
	Median	Minimum	Maximum	N
Total Blood Volume (mL)	4276	3256	6203	10
Pre-WBC x 10 <sup>9</sup> /mL	38	17	55	19
Pre-CD34+/μL	7	1	63	19
Pre-Platelets x 10 <sup>6</sup> /mL	192	130	298	19
Weight (kg)	66	53	106	10

PROCEDURE VARIABLES				
	Median	Minimum	Maximum	N
Number of Cycles	6	4	8	19
Cycle Volume (mL)	1400	1000	1400	19
Whole Blood Processed (mL)	8313	6590	11173	19
Procedure Time (hours)	3.4	2.9	4.3	19

MNC COLLECTION RESULTS				
	Median	Minimum	Maximum	N
CD34+ x 10 <sup>6</sup> /kg	2.8	1.3	7.0	18
Viability (%)	100	95	100	15
Platelets x 10 <sup>11</sup>	0.6	0.4	0.8	18
Granulocyte (%)	14	4	30	19
Hct (%)	3.8	2.0	7.5	14
Volume (mL)	160	122	293	18

PROCEDURE RESULTS				
	Median	Minimum	Maximum	N
CD34+ CE1 (%)	82	35	100	18
MNC CE1 (%)	70	40	113	17
Subject Platelet Loss (%)	7	4	11	18
Platelet CE1 (%)	4	0	6	19

Source: FCRP-0297: Investigational Plan for the Harvesting of PBSC in G-CSF and Chemotherapy Mobilized Patients Using the Amicus Separator, December, 2000 and Post Hoc Analysis for FCRP-0297, March, 2014. Data on file.

$$CE1\% = \frac{\text{Cells collected}}{\text{Avg. (pre and post) cell concentration} \times (\text{Vol. WB processed} - \text{Vol. AC used})}$$

