

# A prospective evaluation of unstimulated donor collections for use in adoptive immunotherapy

## Amicus Separator Therapeutic apheresis and cell collection

Amicus had high collection efficiencies  
for all cell types

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Cross-cellular contamination was low  
with Amicus

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Amicus had significantly lower donor  
platelet loss when compared to Optia

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## Study Parameters

- Comparative evaluation of different continuous flow apheresis devices
- Subjects were healthy, non-cytokine stimulated donors
- Data was collected to analyze product quality, collection efficiency, cross-cellular contamination and donor response

## Key Outcomes

- Amicus delivered high collection efficiencies for all cell types\*
- Cross-cellular contamination was low on Amicus
- Donor platelet loss was significantly lower on Amicus
- No serious adverse events were reported

\*Amicus is cleared for MNC collection. Further analysis was performed on collected MNC product using multiparameter flow cytometry; results may vary depending on analysis method.

Table 1  
Amicus delivered high collection efficiencies for all cell types

HIGH COLLECTION EFFICIENCIES				
Cells	Measure	AMICUS (n=12) Mean ± SD	OPTIA (n=20) Mean ± SD	P-value
CD45 <sup>+</sup>	Yield (x10 <sup>9</sup> )	5.87 ± 1.16	5.66 ± 1.87	0.620
	CE (%)	<b>24.5 ± 4.81</b>	<b>18.3 ± 6.38</b>	<b>0.012</b>
CD34 <sup>+</sup>	Yield (x10 <sup>6</sup> )	6.94 ± 3.47	8.22 ± 6.71	0.543†
	CE (%)	<b>63.7 ± 14.9</b>	<b>55.4 ± 18.9</b>	<b>0.495</b>
CD3 <sup>+</sup>	Yield (x10 <sup>9</sup> )	2.80 ± 1.00	2.36 ± 0.96	0.169
	CE (%)	<b>69.4 ± 7.28</b>	<b>44.4 ± 17.6</b>	<b>&lt;0.001</b>
CD14 <sup>+</sup>	Yield (x10 <sup>9</sup> )	1.20 +/- 0.37	1.64 +/- 0.70	0.002
	CE (%)	<b>66.8 +/- 17.6</b>	<b>67.1 +/- 16.4</b>	<b>0.221</b>

† Differences between apheresis devices used the dependent two-sample t-test for normally distributed data and the Wilcoxon signed-rank test for non-normal distribution.

Table 2  
Cross-cellular contamination was low with Amicus

LOW CROSS-CELLULAR CONTAMINATION				
Cells	Measure	AMICUS (n=12) Mean ± SD	OPTIA (n=20) Mean ± SD	P-value
PLTs	Yield (x10 <sup>9</sup> )	46.2 ± 14.7	114 ± 48.3	<0.001
	CE (%)	<b>3.55 ± 1.31</b>	<b>8.25 ± 4.77</b>	<b>0.009†</b>
RBCs‡	Yield (x10 <sup>9</sup> )	53.0 ± 15.1	16.8 ± 7.44	0.002†
	HCT	9.6 ± 2.6	3.1 ± 0.7	<0.001

‡ The maximum RBC volumes on Amicus and Spectra Optia were 7.5 and 4.0 mL, respectively.

Source: Steininger PA, Strasser EF, Weiss D, Achenbach S, Zimmerman R, Ekstein R. First comparative evaluation of a new leukapheresis technology in non-cytokine-stimulated donors. Vox Sanguinis 2013; DOI 10.1111/VOX. 12102.

