

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

Amicus Separator

Amicus had high collection efficiencies
for all cell types

Cross-cellular contamination was low
with Amicus

Amicus had significantly lower donor
platelet loss when compared to Optia



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 ⁺	Yield (x10 ⁹)	5.87 ± 1.16	5.66 ± 1.87	0.620
	CE (%)	24.5 ± 4.81	18.3 ± 6.38	0.012
CD34 ⁺	Yield (x10 ⁶)	6.94 ± 3.47	8.22 ± 6.71	0.543†
	CE (%)	63.7 ± 14.9	55.4 ± 18.9	0.495
CD3 ⁺	Yield (x10 ⁹)	2.80 ± 1.00	2.36 ± 0.96	0.169
	CE (%)	69.4 ± 7.28	44.4 ± 17.6	<0.001
CD14 ⁺	Yield (x10 ⁹)	1.20 +/- 0.37	1.64 +/- 0.70	0.002
	CE (%)	66.8 +/- 17.6	67.1 +/- 16.4	0.221

† 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 ⁹)	46.2 ± 14.7	114 ± 48.3	<0.001
	CE (%)	3.55 ± 1.31	8.25 ± 4.77	0.009†
RBCs [‡]	Yield (x10 ⁹)	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.

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

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

