

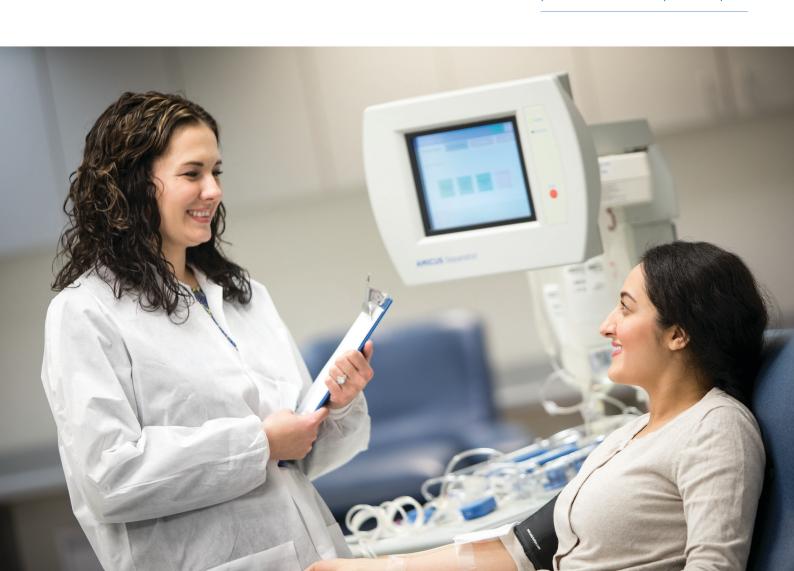
A prospective evaluation of unstimulated donor collections for use in adoptive immunotherapy

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

Table 1

all cell types

- 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.

Amicus delivered high collection efficiencies for

HIGH COLLECTION EFFICIENCIES						
Cells	Measure	AMICUS (n=12) Mean ± SD		P-value		
CD45 ⁺	,	5.87 ± 1.16				
	CE (%)	24.5 ± 4.81		0.012		
CD34 ⁺		6.94 ± 3.47				
	CE (%)	63.7 ± 14.9		0.495		
CD3+	,	2.80 ± 1.00				
	CE (%)	69 .4 ± 7.28		<0.001		
CD14+		1.20 +/- 0.37	•	0.002		
	CE (%)		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°)	46.2 ± 14.7	114 ± 48.3	<0.001		
	CE (%)	3.55 ± 1.31	8.25 ± 4.77	0.009†		
RBCs‡	Yield (x10°)	53.0 ± 15.1	16.8 ± 7.44	0.002†		
	НСТ	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 10.1111VOX. 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.





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