

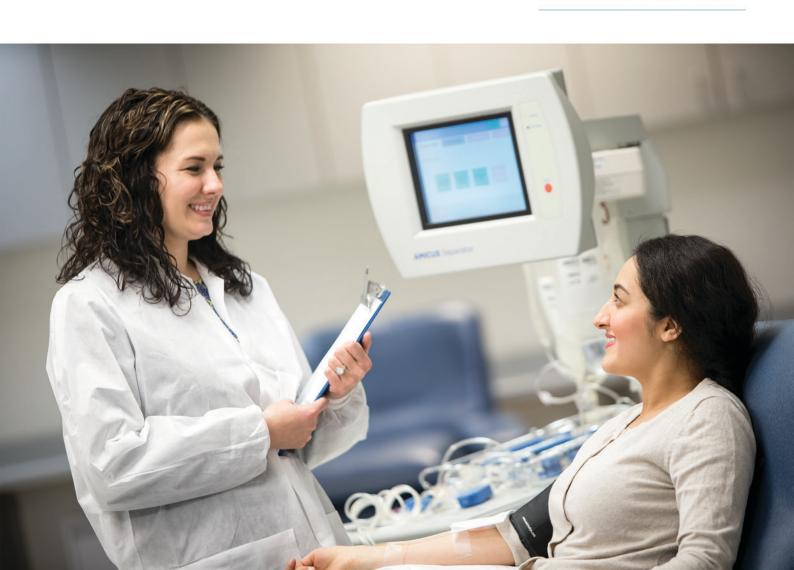
A prospective evaluation of unstimulated donor collections for use in adoptive immunotherapy

Amicus Separator Therapeutic apheresis and cell collection

Amicus had high collection efficiencies for all cell types

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

| Cells | Measure | AMICUS | OPTIA | P-value |
|-------|--------------|---------------|---------------------|---------|
| | | (n=12) | (n=20) | |
| | | Mean ± SD | Mean ± SD | |
| CD45* | Yield (x109) | 5.87 ± 1.16 | | 0.620 |
| | CE (%) | 24.5 ± 4.81 | 18.3 ± 6.3 8 | 0.012 |
| CD34* | Yield (x108) | 6.94 ± 3.47 | 8.22 ± 6.71 | 0.543† |
| | CE (%) | 63.7 ± 14.9 | 55.4 ± 18.9 | 0.495 |
| CD3+ | Yield (x10°) | 2.80 ± 1.00 | 2.36 ± 0.96 | 0.169 |
| | CE (%) | 69.4 ± 7.28 | 44.4 ± 17.6 | <0.001 |
| CD14+ | Yield (x10°) | 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

| Cells | Measure | AMICUS | OPTIA | P-value |
|-------|---------------------------|-------------|-------------|---------|
| | | (n=12) | (n=20) | |
| | | Mean ± SD | Mean ± SD | |
| 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 | <0.00 |

‡ 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.



Fresenius Kabi AG 61346 Bad Homburg Germany

Phone: +49 61 72 608-0 Fax: +49 6172 608-5786 Fresenius Kabi www.fresenius-kabi.com

