MEDICAL DEVICES

Amicus

CELL SEPARATION PLATFORM

When efficiency and comfort matter

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UNIQUE FEATURES DESIGNED FOR OPTIMAL COMFORT AND SAFETY FOR PATIENTS, DONORS AND OPERATORS

Centrifuge compartment:
built-in optical interface detector for fully automated separation allowing operator to focus on donor/patient care

Very low operating noise

- Disposables are sterilized by irradiation to avoid risks related to EtO exposure
- Disposable is primed with saline prior starting collection to maintain donor or patient isovolemic state

- 6 pumps, 5 weight scales for redundant safety control of returned fluid volumes
- 3 cassettes for quick and easy disposable loading

Colored touch screen for smooth operator, patient and donor interaction

Air detector to prevent infusion of air in return fluids

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Cell Separation Platform

When efficiency and comfort matter

PLATELET COLLECTION

- Automated Preparation of Platelet Additive Solution (PAS) Stored Platelets
- Proven Highest Separation Efficiency Records
- Maximized Platelet Yields from Broader Donor Base
- Donor Focused Technology

MONONUCLEAR CELL COLLECTION

- Fully Automated Controls
- High CD34+ Cell Collection Yield
- Low Platelet and Granulocyte Contamination
- Low Product Volume

THERAPEUTIC PLASMA EXCHANGE

- Fully Automated Procedure Control
- High Plasma Removal Efficiency
- Low Platelet Loss
- Accurate Fluid Balance Control

DATA COLLECTION SOFTWARE

- Procedure Summary Report
- Procedure Event Report
- Search and Query Functions

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Cell Separation Platform

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Platelet Collection

- **Automated Preparation of Platelet Additive Solution (PAS) Stored Platelets**
- **Proven Highest Separation Efficiency records**
- **Maximized Platelet Yields from Broader Donor Base**
- **Donor Focused Technology**

The Amicus Cell Separation Platform has long track records in collecting consistently high quality platelet concentrates. Thanks to its unique separation technology, Amicus is able to demonstrate the highest separation efficiency in its category. Moreover, it allows the use and automated transfer of Platelet Additive Solution without impairing the platelet concentrate's quality, increasing blood center's productivity.

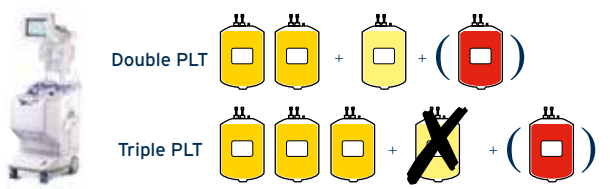
AUTOMATED PREPARATION OF PAS STORED PLATELETS

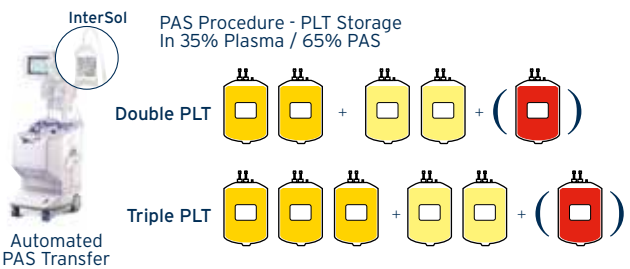
Why use PAS?

- Potential TRALI mitigation strategy
- Additional plasma collection for transfusion
- Substantial reduction of transfusion reactions[1]

Double the Concurrent Plasma collection with PAS

Standard Procedure - PLT Storage in Plasma





Example:
PLT unit = 2.4 x 10^{11}
PLS unit = 200 ml
RBC unit = 200 ml

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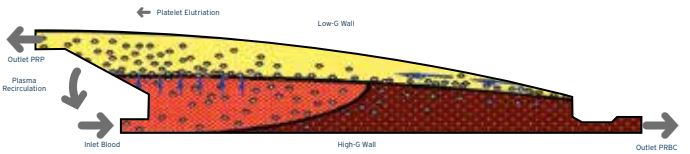
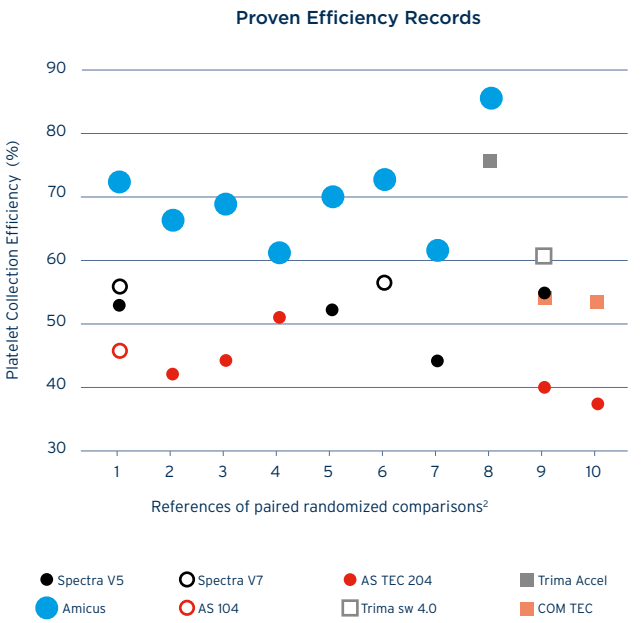
PROVEN HIGHEST SEPARATION EFFICIENCY

Thanks to its unique separation concept, Amicus succeeds to harvest the greatest proportion of the platelets entering the separation chamber, while maintaining low WBC contamination.



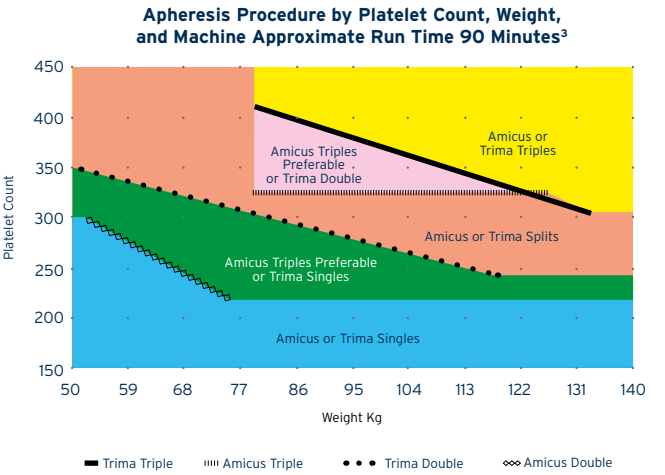


DONOR FOCUSED TECHNOLOGY

- Choice between Single Needle or Double Needle procedure, depending on donor's preference for greater comfort or shorter procedure time
- Redundant safety monitoring of anticoagulant delivery (pumps and weight scales)
- Adjustable flow rates and features to maintain a consistent and reasonable blood flow
- Automatic inflatable pressure cuff and prompt grip
- Saline priming of the disposable to maintain isovolemia
- Irradiation sterilization, to avoid risks associated with EtO exposure
- Donor's safety Notifications Alarms (Post-count, Post-Hematocrit, ECV Limit Exceeded, WB to Process Exceeded, PPP Collect Volume Exceeded, IVD Limit Exceeded)

MAXIMIZED PLATELET YIELDS FROM BROADER DONOR BASE

Great collection performances can be achieved with a large population of donors, including those who would be excluded from other collection platforms.



1 Heddle N.M. - Transfusion 1999;39:231-238. De Wildt-Eggen J. – Transfusion 2000;40:398-403. **2** References of paired randomized comparisons: **2.1** Burgstaler et al, Journ. Clin Aph. 14:163-170 (1999). **2.2** Moog et al, Transfusion 1999; 39:572-7. **2.3-2.4** Moog et al, AABB 1997, Abstract S26 (3=DN, 4=SN). **2.5** Pineda et al, ASFA 1998, Abstract 47. **2.6** Pineda et al, AABB 1998, Abstract S-315. **2.7** Benjamin et al, Transfusion 1999, Vol. 39, 895-899. **2.8** Burgstaler et al, Tansfusion 2004; 44:1612-20. **2.9** Strasser et al, Transfusion 2005; 45:788-797. **2.10** Zingsem et al, Transfusion 2007; 987-994. **3** S enaldi E, et al. Retrospective evaluation of Baxter AMICUS and Trima Accel for platelet collection in the same donor. Transfusion. 2004;44(suppl):S22-030E.

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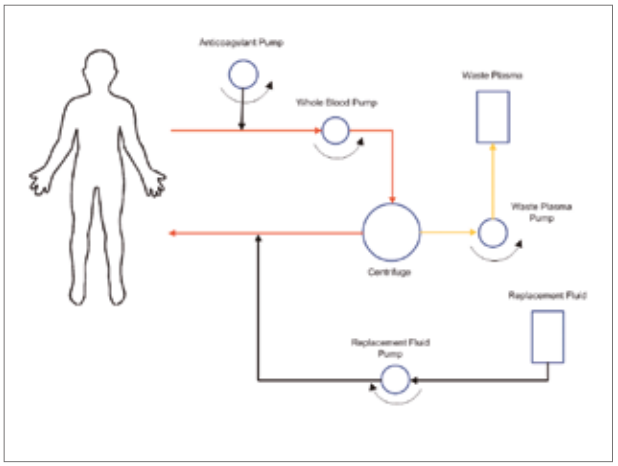
Therapeutic Plasma Exchange

- **Fully Automated Procedure Control**
- **High Plasma Removal Efficiency**
- **Low Platelet Loss**
- **Accurate Fluid Balance Control**

Amicus Cell Separation Platform allows to perform Centrifugal Therapeutic Plasma Exchange, separating plasma from the other blood components using continuous flow centrifugation technology.

Plasma that is removed from the patient is replaced with donated plasma or other replacement fluids, while the cellular components are returned to the patient.

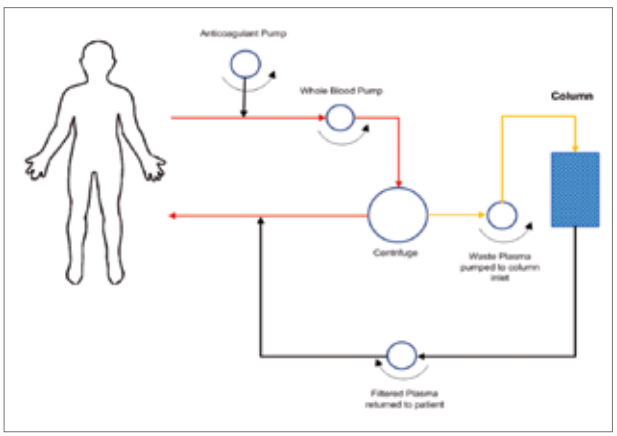


Process flow for a standard TPE procedure

Thanks to its flexibility, the Amicus Cell Separation Platform is also able to accommodate both Passive and Active column procedures.

- **Passive Column Procedure:** Referring to a standard TPE procedure, with a disposable adsorption column attached in-line, by means of luers, through which the plasma will pass through and be returned to the patient.

- **Active Column Procedure:** Referring to a standard TPE procedure, with a separate adsorption column device connected to the Amicus TPE Disposable. The inlet of the column device is attached to the separated plasma container; the outlet of the column device is plugged onto a separate buffer container, allowing Amicus to regulate the return of plasma to the patient.



Process flow for a typical TPE column procedure

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Clinical Evaluation Outcome[1]

Primary Endpoint: Efficiency of Plasma Removal

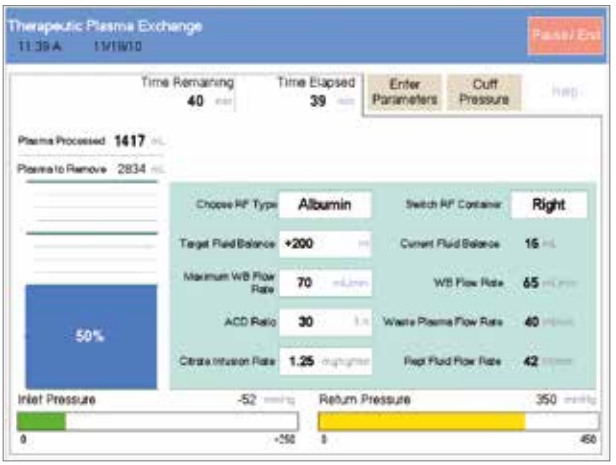
Efficiency of Plasma Removal (EPR)	Amicus	Spectra	Paired Difference	p value
Procedures	30			
Mean (SD)	81.9%* (7.6)	75.2% (6.3)	6.7% (7.3)	0.00001
Minimum	68%	61%	-12%	
Maximum	96%	88%	21%	

* The lower 97.5% one-sided confidence limit on the mean of the paired differences (Test - Control) was greater than 0 and demonstrated that Amicus was statistically superior (p = 0.00001) to Spectra for EPR.

$$\text{Plasma removal efficiency \%} = 100 \times \frac{\text{Plasma removed (mL)}}{\text{Total plasma processed (mL)}}$$

Secondary Outcomes:
No significant Platelet Loss or Hemolysis
High Fluid Balance Accuracy

Parameter	n	Mean (SD)	Median	Min	Max	p value
Platelets in waste plasma (x 10^{10}/L)						
Amicus	26	1.15 (0.62)	1.09	0.1	2.5	N.S.
Spectra	26	1.07 (0.79)	0.95	0.0	2.7	
Plasma Hemoglobin in waste plasma (mg/dL)						
Amicus	29	0.5 (0.6)	0.2	0.2	2.7	N.S.
Spectra	29	0.8 (2.0)	0.3	0.2	11.3	
Fluid Balance Accuracy (%)						
Amicus	30	98.8 (0.2)	99.9	99.2	100.0	<0.05
Spectra	30	98.8 (1.8)	99.4	92.9	100.0	



Typical Procedure Run Screen

Routine Use Performances

Standard TPE Procedure
University Clinic Transfusion Blood Center, Innsbruck, Austria
Per abstract accepted at ESFH 2012

Procedure #	19
Patient #	6
Plasma Removal Efficiency (%)	82 +/- 7
Flow Rate (ml/min)	71 +/- 16
Removed Plasma volume (ml)	3196 +/- 692
Procedure Time (min)	92 +/- 16
Patient PLT pre (x10E3/↔l)	146 +/- 63
Patient PLT post (x10E3/↔l)	139 +/- 62 (not statistically different from PLT pre)

Passive Colum Procedure
German Hemapheresis Centrum, Köln, Germany
Per abstract accepted at ESFH 2012

Procedure #	6
Patient #	5 (4 Hypercholesterolemia, 1 age-related macular degeneration)
Column Type	Kawasumi Evaflux
Column Max. Pressure (mmHg)	450
Plasma Flow Rate (ml/min)	24 - 35
WB Flow Rate (ml/min)	40 - 85
WB processed (L)	11 [5.7 - 22.4]
Treated Plasma Volume (L)	3,9 [2.2 - 6.5]
Procedure Time (min)	154 [79 - 292]
Patient PLT pre (x10E3/↔l)	216 +/- 49
Patient PLT post (x10E3/↔l)	212 +/- 50

Comprehensive training programs tailored to your institution needs, combined with responsive clinical and technical support make the adoption of Amicus very smooth.

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1 Data from clinical evaluation on file.

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iTrace Data Collection Software

for Amicus Cell Separation Platform

GREATER EASE AND CONFIDENCE WITH iTRACE SOFTWARE

iTrace is the advanced software application that transfers and stores apheresis data from the Amicus separator. Yet easy to learn and use, iTrace software offers, in addition to the Summary and Event Reports, powerful tools to meet your future needs, such as the Entries Report, Search Function, Query Module and data export.

Save time with a system that streamlines productivity, quality and efficiency:

- The Summary Report replaces manual documentation and archiving of procedure summary screen parameters
- The Event Report enables efficient trouble shooting of component and device failures
- The Entries Report expands your electronic database and enables electronic queries
- The Search function offers you direct access to data whenever needed
- The Query module facilitates analysis of selected key performance indicators

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MANAGE YOUR NEEDS

iTrace software improves staff productivity and reduces time for

. Manual documentation and archiving
. Fixing illegible and incomplete records
. Data retrieval
. Electronic reporting
. Troubleshooting

iTrace software efficiency reports help to easier monitor apheresis operations

. Procedure efficiency and discard rate trends
. Device performance
. Staff productivity and training needs

iTrace software improves donor base management

. Immediate access to historical donation records contributes to a satisfying donor experience
. Donor base productivity reports
. Efficient donor scheduling

iTrace software enhances traceability for regulatory compliance

iTrace software standardizes your apheresis procedure records and reduces writing errors and incomplete reports

. Electronic Summary Report
. Barcode scanners for operator and donation IDs, disposable and solution lot numbers

Technical Specifications

Licence
Wireless Data Access point
iTrace software
Barcode scanner
Amicus WiFi module / Auto-C Bridge

The iTrace system includes:

Hardware	**Operating Systems**
Pentium III or Higher	MS Windows 2000 Professional Edition SP4
1GHz or Higher	MS Windows XP Professional edition SP2
RAM: 512 Mb or Higher	MS Windows VISTA Business
Hard Disk: 1Gb free	
Ethernet Connection	
CD Drive	

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Amicus MNC Bibliography

Amicus compared to Spectra

Comparison of Hematopoietic Progenitor Cell Collections Using the COBE Spectra Version 7 and Amicus Version 3.1 for Patients with AL Amyloidosis. Edwin A. Burgstaler and Jeffrey L. Winters*, Division of Transfusion Medicine, Mayo Clinic, Rochester, Minnesota, **Journal of Clinical Apheresis, 2011**

Automated programs for collection of mononuclear cells and progenitor cells by two separators for peripheral blood progenitor cell transplantation: comparison by a randomized crossover study. Kazuhiko Ikeda, Hitoshi Ohto, Takahiro Kanno, Takashi Ogata, Hideyoshi Noji, Kazuei Ogawa, and Yukio Maruyama, **Transfusion, 2007**

Procedure Settings

Use of Various Offset Settings in the Amicus during Hematopoietic Progenitor Cell Collection to Increase Lymphocyte Yield and Reduce Cross cellular Contamination. Edwin A. Burgstaler, Luis F. Porrata, Svetomir N. Markovic, and Jeffrey L. Winters, **Journal of Clinical Apheresis, 2010**

Recommendations for optimized settings of the Amicus Crescendo cell separator for the collection of CD34+ progenitor cells. Dirk Hartwig, Isabel Dorn, Holger Kirchner, and Peter Schlenke, **Transfusion, 2004**

Manual Color Monitoring to Optimize Hematopoietic Progenitor Cell Collection on the Amicus. Edwin A. Burgstaler and Jeffrey L. Winters*, Division of Transfusion Medicine, Mayo Clinic, Rochester, Minnesota, **Journal of Clinical Apheresis, 2011**

Pediatric collections

Collection efficiencies of MNC subpopulations during autologous CD34+ peripheral blood progenitor cell (PBPC) harvests in small children and adolescents. Witt V, Fischmeister G, Scharner D, Printz D, Pottschger U, Fritsch G, et al., **J Clin Apher 2001;16(4):161-8.**

Performance of a new separator system for routine autologous hematopoietic progenitor cell collection in small children.
Witt V, Beiglbock E, Ritter R, Wurth M, Peters C, Ladenstein R, et al.,**J Clin Apher 2007;22(6):306-13.**

Training courses for pediatric apheresis on site; how apheresis technology transfer can be performed. Volker Witt, St. Anna Kinderspital, Kinderspitalgasse 6, 1090 Vienna, Austria, **Transfusion and Apheresis Science 43 (2010) 223-225**

Dendritic cells

Large-scale generation of autologous dendritic cells for immunotherapy in patients with acute myeloid leukemia. Anita Schmitt, Peter Reinhardt, Iwona Hus, Jacek Tabarkiewicz, Jacek Roliński, Thomas Barth, Krzysztof Giannopoulos, Anna Dmoszyńska, Markus Wiesneth, and Michael Schmitt, **Transfusion 2007;47:1588-1594.**

Bone marrow processing

Bone marrow processing with the AMICUS separator system. V. Witt1,*, E. Beiglböck1, G. Fritsch2, **Journal of Clinical Apheresis, 2011**

Unstimulated donor collection

Optimization of Unstimulated Mononuclear Cell Collections Using the Amicus Continuous-Flow Apheresis Device. SF Leitman, Y Yau, CL Matthews, JA Hopkins, K Min, **AABB Abstract, 2009**

Photopheresis

Mononuclear Cell Collection in Patients Treated with Extracorporeal Photochemotherapy by Using the Off-Line Method: A Comparison Between COBE Spectra AutoPbsc Version 6.1 and Amicus Cell Separators. Paolo Perseghin* and Arianna Incontri, Department of Clinical Pathology, Therapeutic Apheresis Unit and Immunohematology, Ospedale San Gerardo, Monza, Italy, **Transfusion, 2010**

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Mononuclear Cell Collections

- **Fully Automated Controls**
- **High CD34+ Cell Collection Yield**
- **Low Platelet and Granulocyte Contamination**
- **Low Product Volume**

The use of MNCs as a therapy is well established and new therapeutic applications continue to emerge.

The Amicus separator is an easy-to-use, automated system that consistently collects MNCs with high yields and purity.

Amicus separator can help you prepare your MNC collection program to meet current and future demands - safely and simply.

Comprehensive training programs tailored to your institution needs, combined with responsive clinical and technical support make the adoption of Amicus very smooth.

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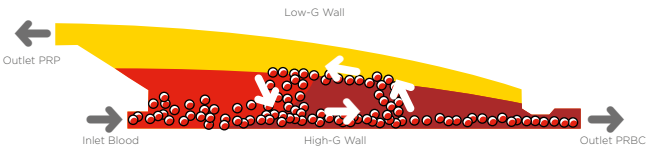
Operator-Friendly Control

Setting parameters is as easy as entering values on the touch screen

Amicus separator provides automated controls that tailor collections to meet patient characteristics and allows operators availability to focus their attention on the patient.

Amicus separator provides operator-friendly touch screens for entry of key parameters.
Parameters may be stored for use in all procedures and modified for a single collection.



Automated separation and collection technology

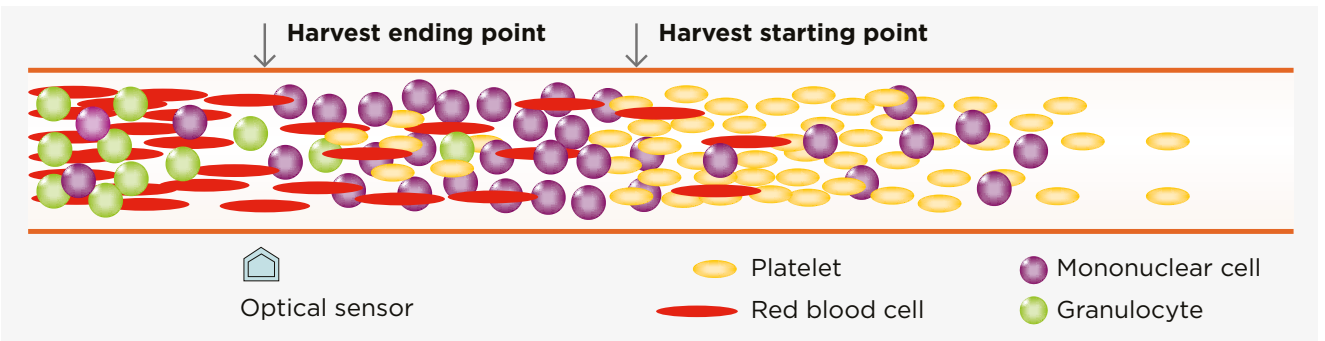
Mononuclear cells (MNCs) are automatically transferred to a storage container at intervals during a procedure. An optical sensor measures light transmission through fluid that is being transferred in tubing. The light transmission corresponds to changing cell layers.

When the user-defined parameter (MNC offset) is reached, harvest begins. It continues until the second parameter (RBC offset) is reached. MNCs are alternately separated from whole blood and harvested until the selected number of cycles is completed.

Red blood cells, plasma and saline are returned to the patient or donor during the procedure for safety and comfort.

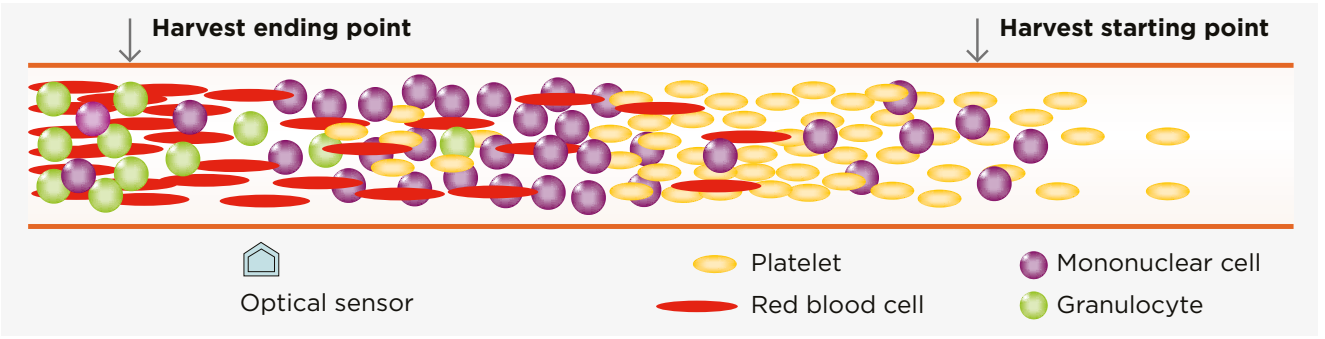
Target Higher Purity - Narrow Harvest

When a high purity product is indicated for a patient, parameters are entered to begin harvest later and/or end **earlier,** resulting in increased purity and somewhat lower MNC yields.



Target Higher Yield - Wide Harvest

When a high yield product is indicated, parameters are entered to begin harvest earlier and/or end **later,** resulting in a harvest deeper into the RBC layer to capture more MNCs.
More platelets and granulocytes are harvested, so the level of purity decreases.



High Efficiency

Published studies have shown Amicus separator yields consistently high MNC collection efficiency from an automated procedure. When yields are high, the required cell dose may be achieved with fewer procedures.

Amicus separator produces high yields

Automated collection, in paired patient and donor procedures[1]

	Amicus Mean ± SD	Spectra SW V. 6.1 Mean ± SD	p Value
Products	22	22	
MNCs			
Per procedure (x 10^{10})	1.32 ± 0.65	1.01 ± 0.38	< 0.02
Per liter (x 10^{10})	0.16 ± 0.08	0.13 ± 0.05	< 0.05
Efficiency (Per procedure)	112.8% ± 46.8	91.1% ± 50.0	< 0.02
CD34+ Peripheral Blood Progenitor Cells (PBPC)			
Per procedure (x 10^{8})	2.66 ± 3.46	1.83 ± 2.61	< 0.03
Per liter (x 10^{8})	0.31 ± 0.37	0.24 ± 0.31	< 0.03
Efficiency (Per procedure)	103.1% ± 34.6	77.2% ± 27.2	< 0.0002

$$\text{Collection efficiency} = \frac{\text{Number of cells collected} \times 100}{\text{Cell count of donor/patient} \times \text{Blood volume of donor/patient}}$$

High Purity

Amicus separator can provide MNC collections with low platelet contamination

Hematopoietic Progenitor Cell (HPC) Yields and Platelet Content[2]

	Automated	Manual	
	Amicus SW V. 3.1 Median	Spectra SW V. 7 Median	p Value
Collections	50	52	
CD34+ Cells			
Per procedure (x 10^{6})	261.4	126.9	< 0.05
Platelet Content			
Per procedure (x 10^{11})	2.3	3.9	< 0.05

1 Ikeda K, et al. Automated programs for collection of mononuclear cells and progenitor cells by two separators for peripheral blood progenitor cell transplantation: comparison by a randomized cross over study. Transfusion 2007;47:1234-1240. **2** Burgstaler E, Winters J, Comparison of hematopoetic progenitor cell (HPC) collections using the Cobe Spectra Version 7 versus Amicus Version 3.1 for patients with amyloidosis. Presented at ASFA Meeting, 2010.

Patient Safety

When fewer platelets are collected, patient platelet levels are better maintained.

Amicus apheresis kits are sterilized using irradiation to avoid the risk of patient exposure to residual ethylene oxide.

Low product volume may better fit pediatric patient therapy.

Thanks to its separation concept, the final MNC product volume can be programmed to be very low, which allows to respond to specific patient needs and reduces post-collection processing costs.

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Mobility Accessories

MAKE TRANSPORTATION EASIER

- **Increased Mobility**
- **Protection from the Elements**
- **More Compact Height**

Amicus Separator's mobility accessories allow for easier transport between sites and instrument protection.

The accessories include a new wheel configuration, a cover and a foam support for the touch screen and solution pole.

Increased Mobility in Challenging Conditions

New wheel configuration	**Support foam**	**Water-resistant, padded cover**
Enhanced manoeuvrability Easier to roll over uneven surfaces like elevator entrances or pavement. Improved Stability	Decreases stress on the display arm during transport Lower solution pole improves visibility	Protects electronics from exposure to most elements Provides professional presence at customer locations
Part # 0112680023	Part # 0212680035*	Part # 0212680034*
Modifications	**Modifications**	
Install heavy-duty wheel base Move existing larger wheels to front New rear wheels will have casters with brakes	Modify solution pole 12 cm lower for transport	Modify solution pole 12 cm lower for transport

*Foam support and padded cover fit lower solution pole position.
New machines will not require this modification.

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RELY ON US...

Fresenius Kabi offers you a variety of training programs that can be tailored to your institution needs. Fresenius Kabi supports the Amicus Cell Separation Platform with experienced therapeutic apheresis clinical consultants and service engineers.

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