

Spectra Optia[®] Mononuclear Cell (MNC) Collection

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WHY A NEW PLATFORM?

The Cobe Spectra is used in more than 100,000 MNC collections each year.

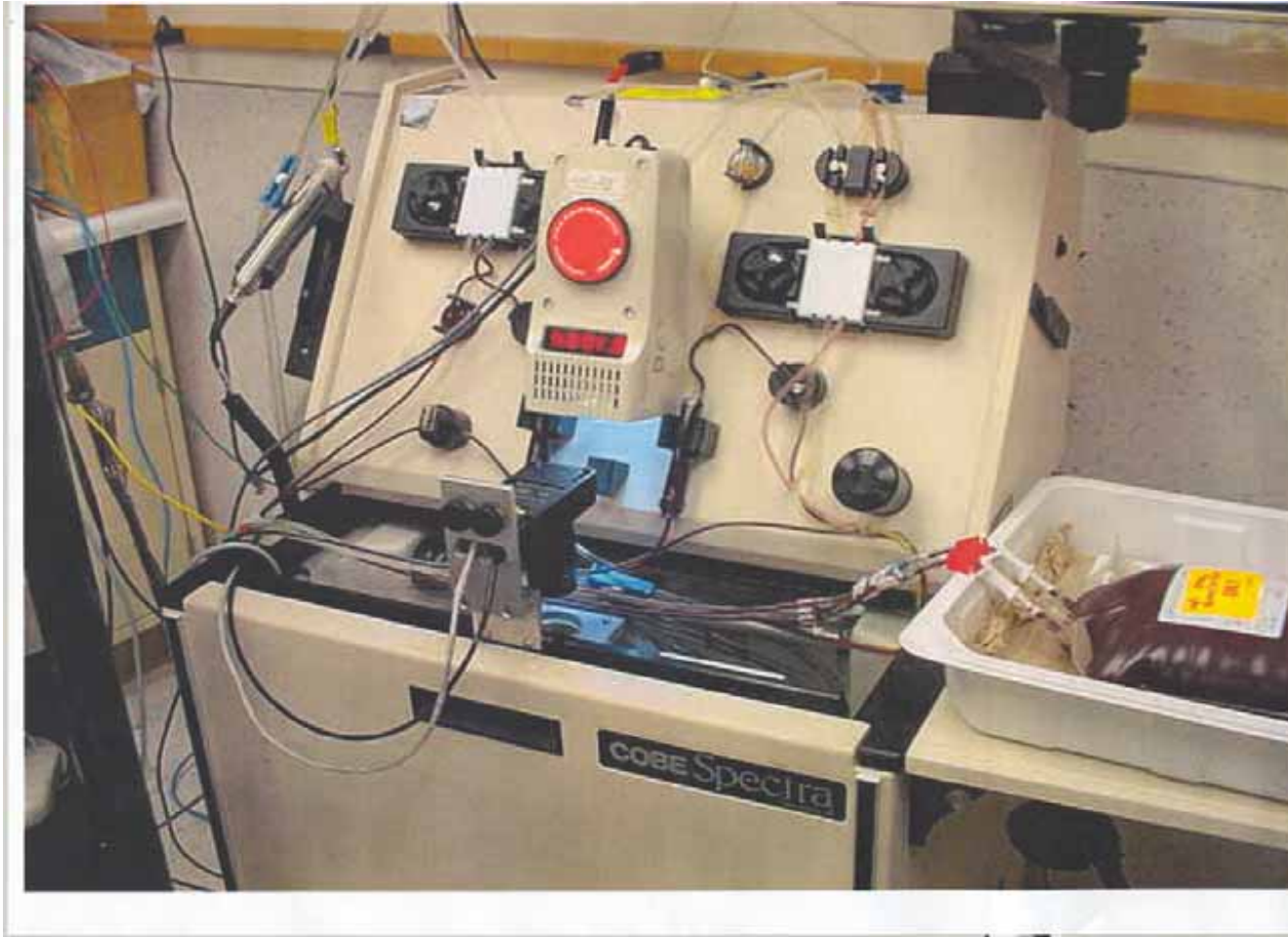
Cobe Spectra is available with two programs MNC and AutoPBSC

Spectra Optia has been designed to replace the current Cobe Spectra apheresis system with the latest technology.

The Spectra Optia MNC protocol combines the relative higher Collection Efficiency (%CE) found on Cobe Spectra's MNC procedure with the relatively higher purity levels associated with the AutoPBSC procedure. And at the same time adding consistency through automation.



Spectra Optia Summer 2002



Spectra Optia January 2003



Spectra Optia

April 2007: CE-marked for Therapeutic Plasma Exchange (Optia TPE)

August 2007 : FDA approval for TPE in the US

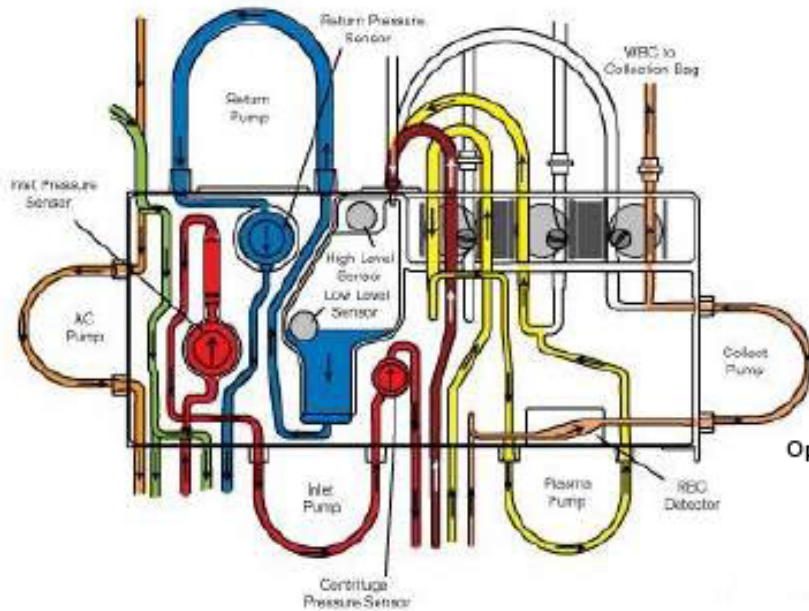
Today: TPE is sold in more than 40 countries all over the world.

Optia TPE is fast, easy and safe.

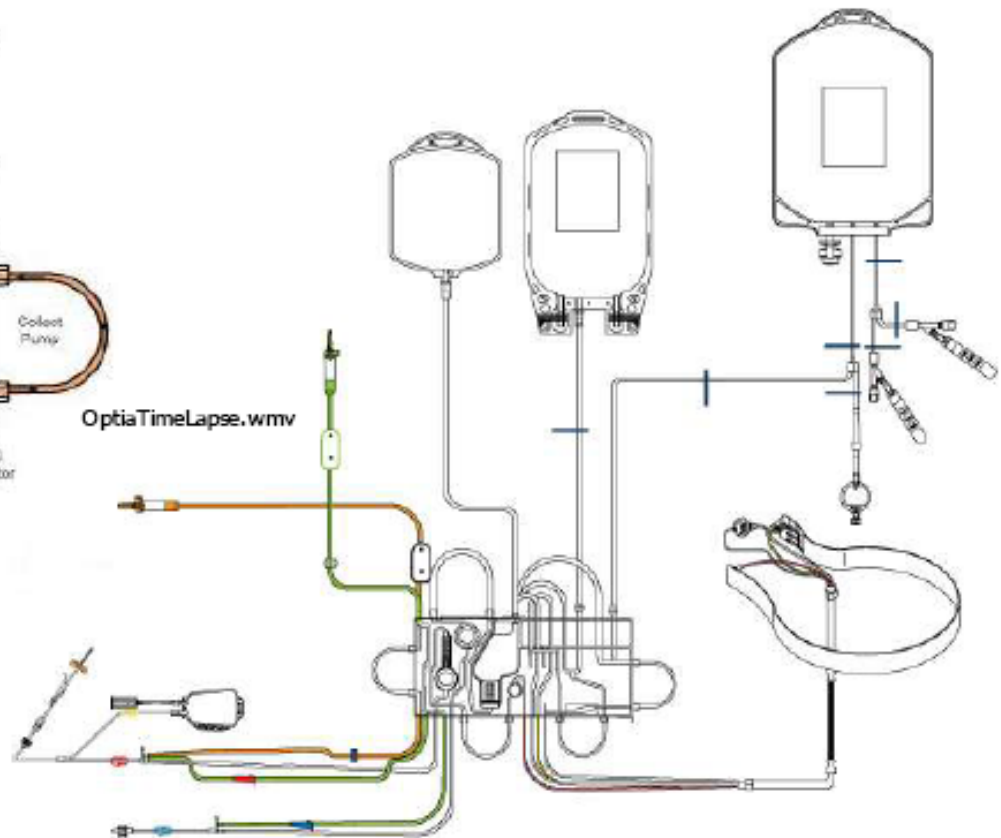
January 2008: CE –marked for White Blood Cell Collection (Optia MNC), and September start MNC clinical trial in Europe



Basic Principles of the MNC Procedure






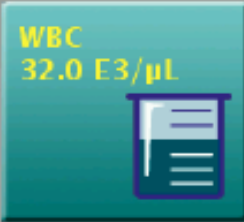





OptiaTimeLapse.wmv



ECV = 191 ml

Patient Data

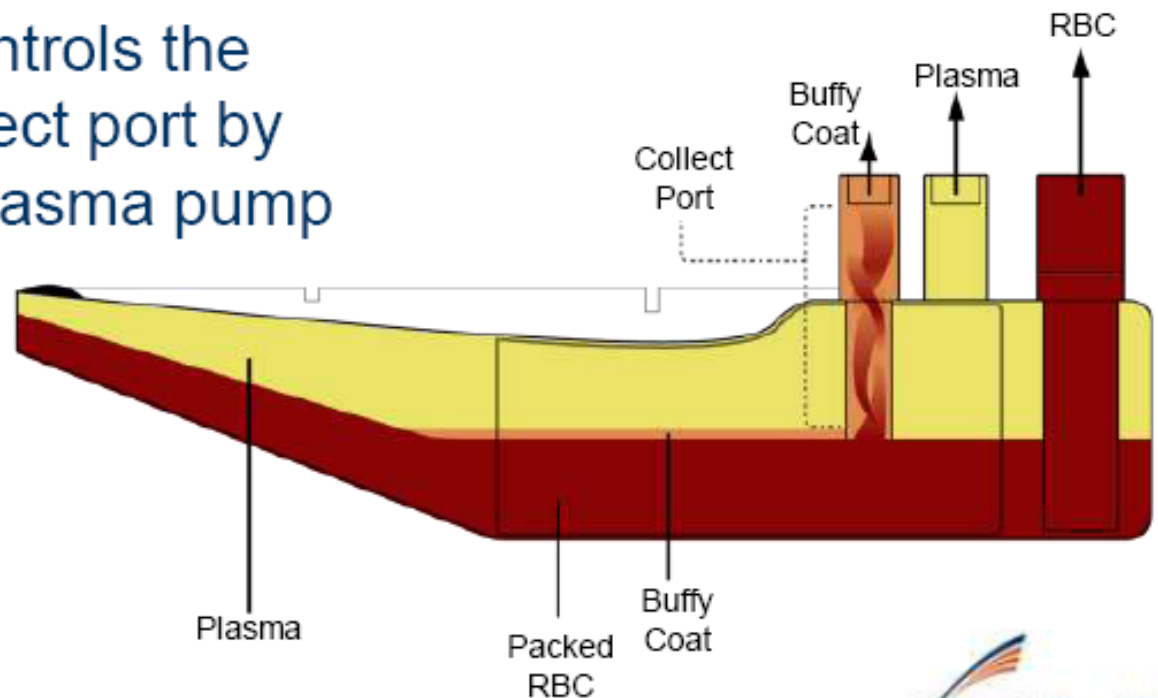
Config	Data	Run	End Run
	Height 173 cm 	Weight 79 kg 	TBV 5047 mL 
	Hct 28% 	WBC 32.0 E3/ μ L 	Platelet 185 E3/ μ L 
17:47 10-06-2008	Confirm		 MNC



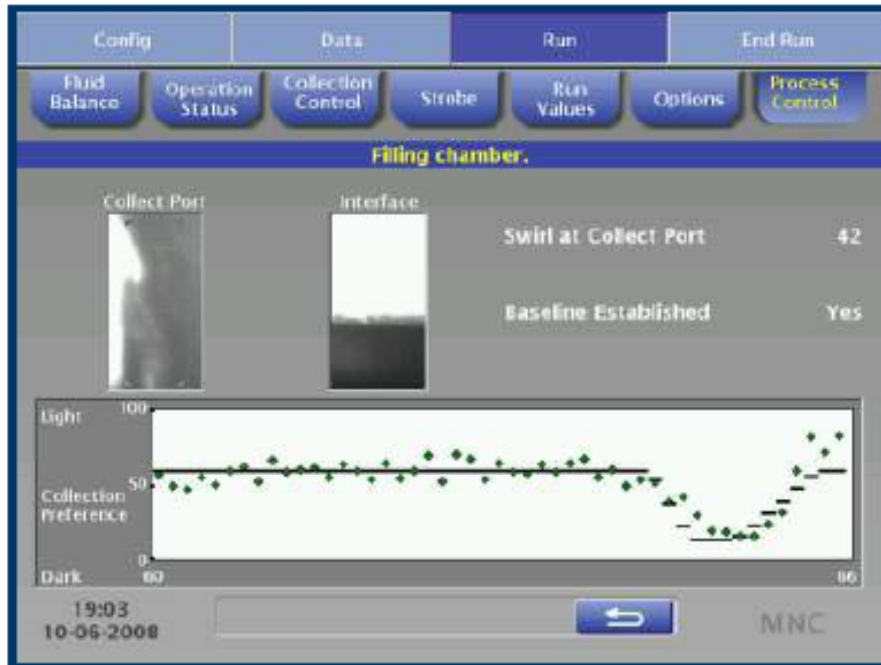
Separation in the Connector

Primary separation:

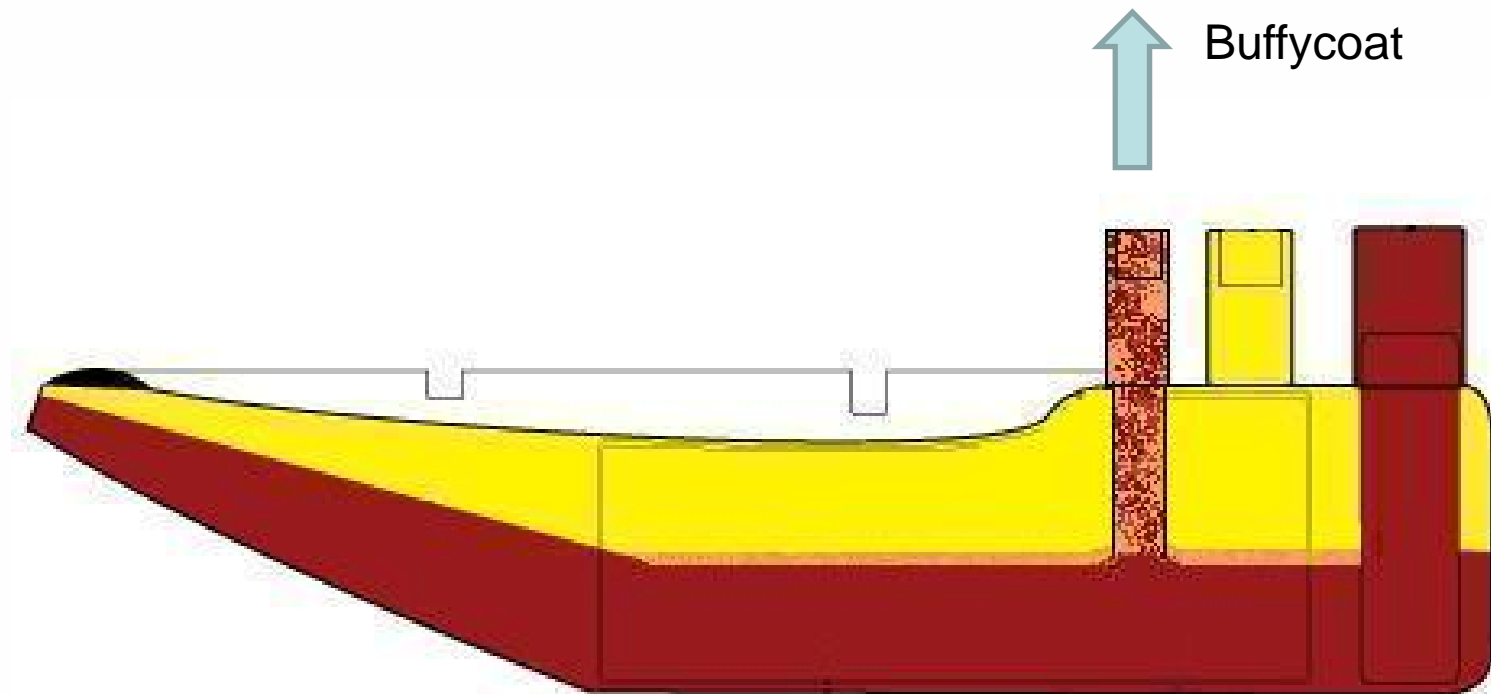
- Cells are separated based on specific gravity.
- AIM system controls the swirl in the collect port by adjusting the plasma pump flow rate.



Process Control Screen



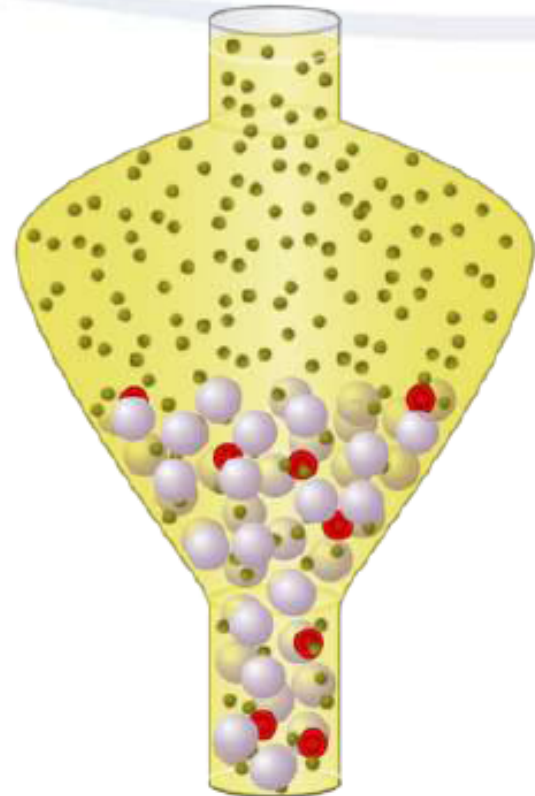
- Collect port
- Interface
- Swirl at Collect Port
- Baseline Established
- Graph



Separation in the Chamber

Secondary separation:

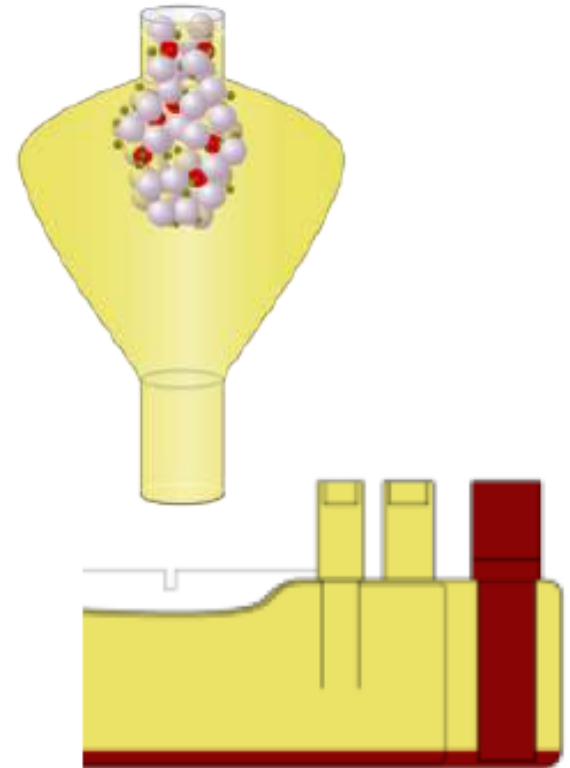
- Cells are separated by size.
- Platelets are continuously pumped to the reservoir.
- Chamber is filled with cells.
- When the chamber is full, the chamber contents are collected.



Buffy Coat

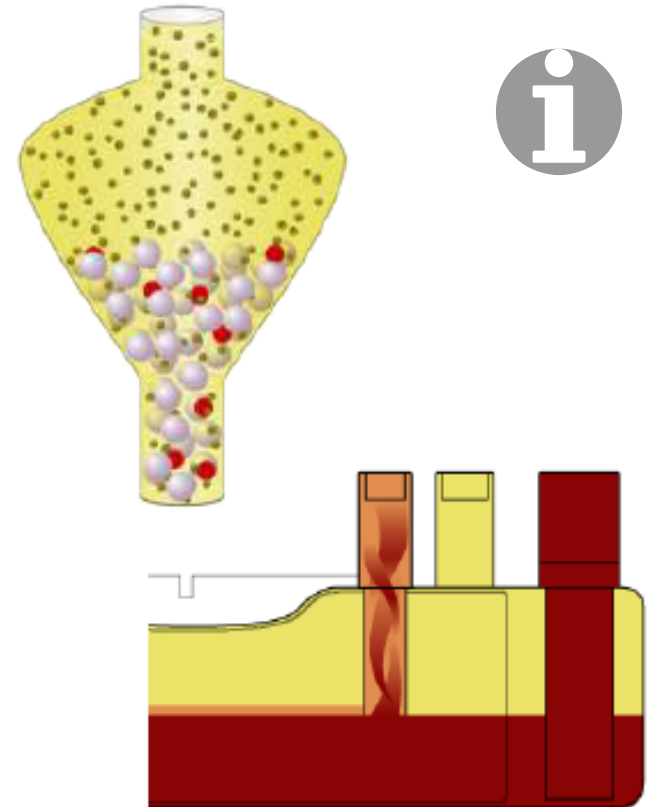
Collection Phase: First Stage

1. Collect valve opens.
2. Plasma pump stops.
3. Packing factor decreases to 7.
4. Collect pump flow rate increases.
5. Plasma is used to flush the chamber contents to the collection bag.



Collection Phase: Second Stage

1. Collect pump stops.
2. Packing factor increases to 20.
3. Plasma pump restarts to re-establish the interface.
4. Collect pump restarts to flush cells in the collect line past the collect valve.
5. Collect valve closes.



Optia MNC study Procedure data summary

What are the communicated core needs?

Top Customer needs

- Versatility – MNC is the second (of many) protocols
- Flexibility – Operator control, variety of patients
- Automate to eliminate errors- identifies and corrects process variations
- Ease of Use
- Cell Viability/Functionality – Do the cells engraft?
- Performance – Cells in the Bag, Efficiency, Purity

Validation Metrics

Collection efficiency and yield

Purity

Viability of the CD34+ cells and engraftment

System Performance in Patient Environment

Final product volume.

Operator Usability / Trainability

EUT 4 Data

- N=15 runs
- Patients from three sites from 09.09.08 – 02.10.08
- Diagnosis included
 - Multiple Myeloma
 - Non-Hodgkin's Lymphoma
 - Burkitt's Lymphoma
 - Hodgkin's Disease

Patient data - Median (Range)

- Body weight 74kg (45 – 105)
- TBV 4500mL (3024 – 5854)
- Blood processed 11406mL (5466 – 15752)
- Pre WBC. $9.7 \times 10^6/\text{mL}$ (3.3 – 55.8)
- Pre PLT $93 \times 10^6/\text{mL}$ (21 – 234)
- Pre CD34+ 73/uL (15 – 314)
- TBV Processed 2.30 (1.39 – 4.18)

MNC Data Summary Sheet

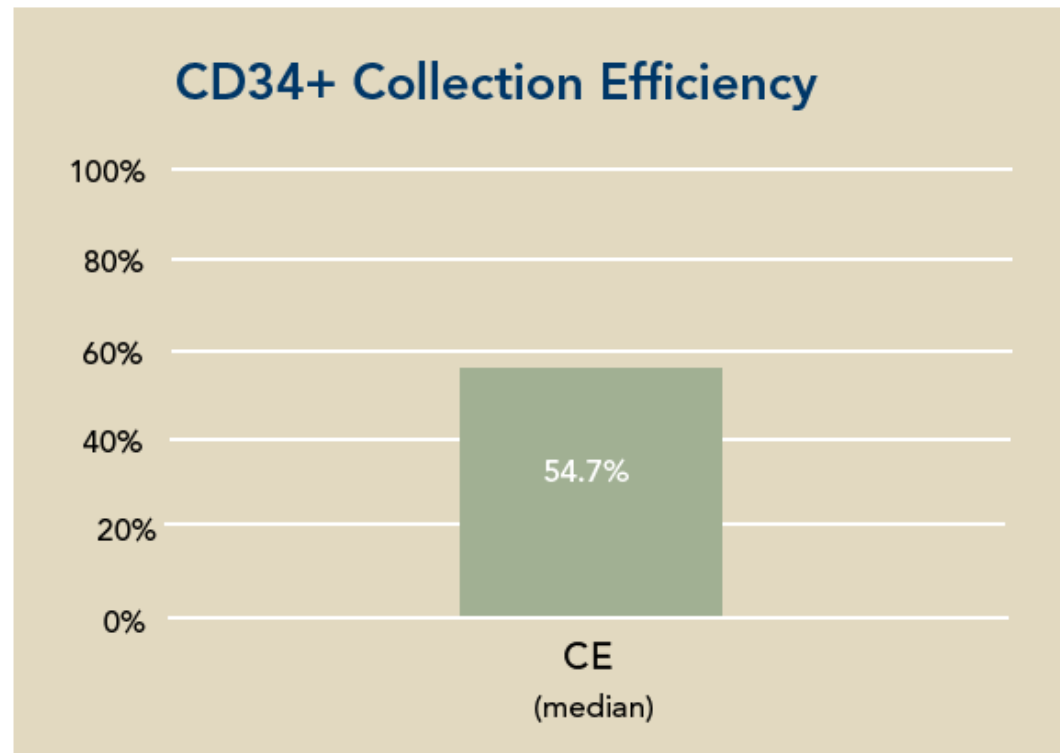
Interim results of Spectra Optia® Mononuclear Cell (MNC) Collection study on chemotherapy

Table 1. Data summary

Patient Data Pre-Count	N= 15	Median	Min	Max
TBV (ml)		4500	3024	5854
WBC x 10 ³ /μL		9.7	3.3	55.8
CD34+ /μL		73	14.9	314.2
Platelets x 10 ³ /μL		93	21.0	234.0
<hr/>				
Product				
CD34+ Collection Efficiency		54.7%	31.9%	70.3%
Hct%		2.2%	0.0%	4.0%
Granulocytes %		17.2%	0.0%	51.2%
Platelets x 10 ³ /μL		613	50	1240
Volume (ml)		200	129	320

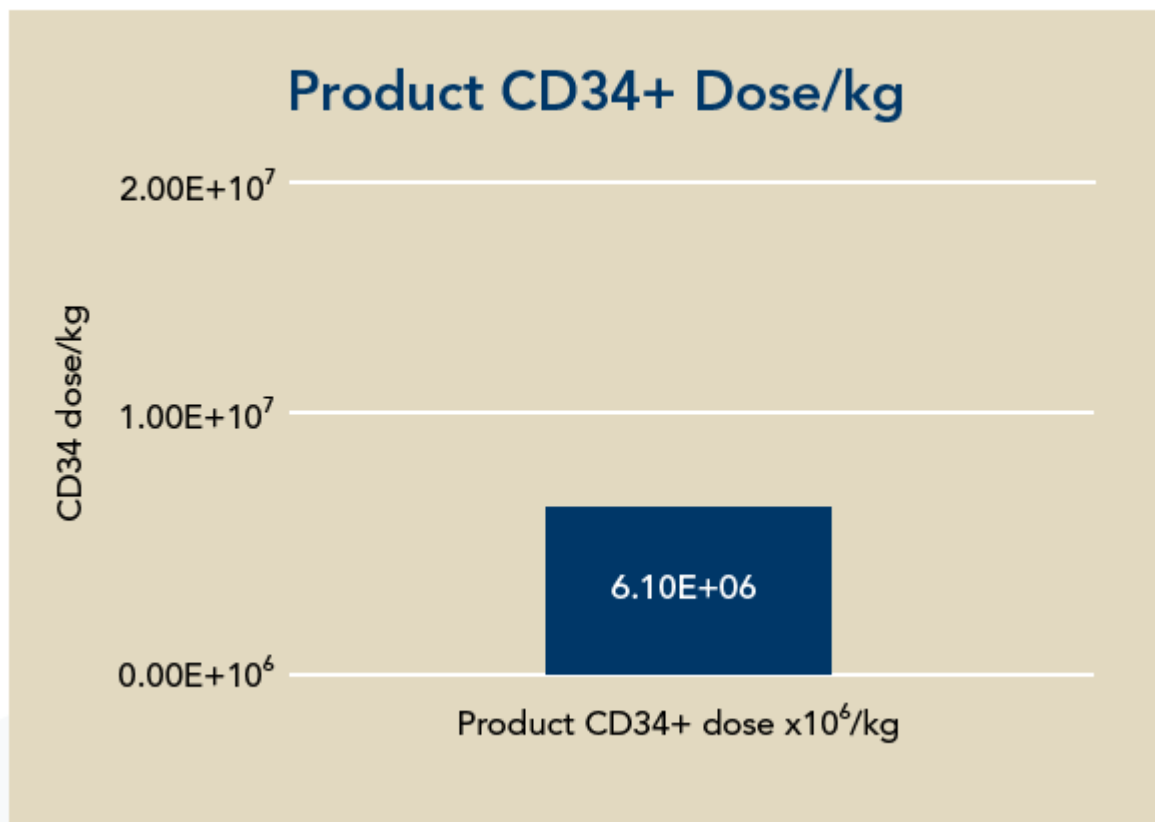
CD34+ Collection Efficiency

Chart 1. Performance



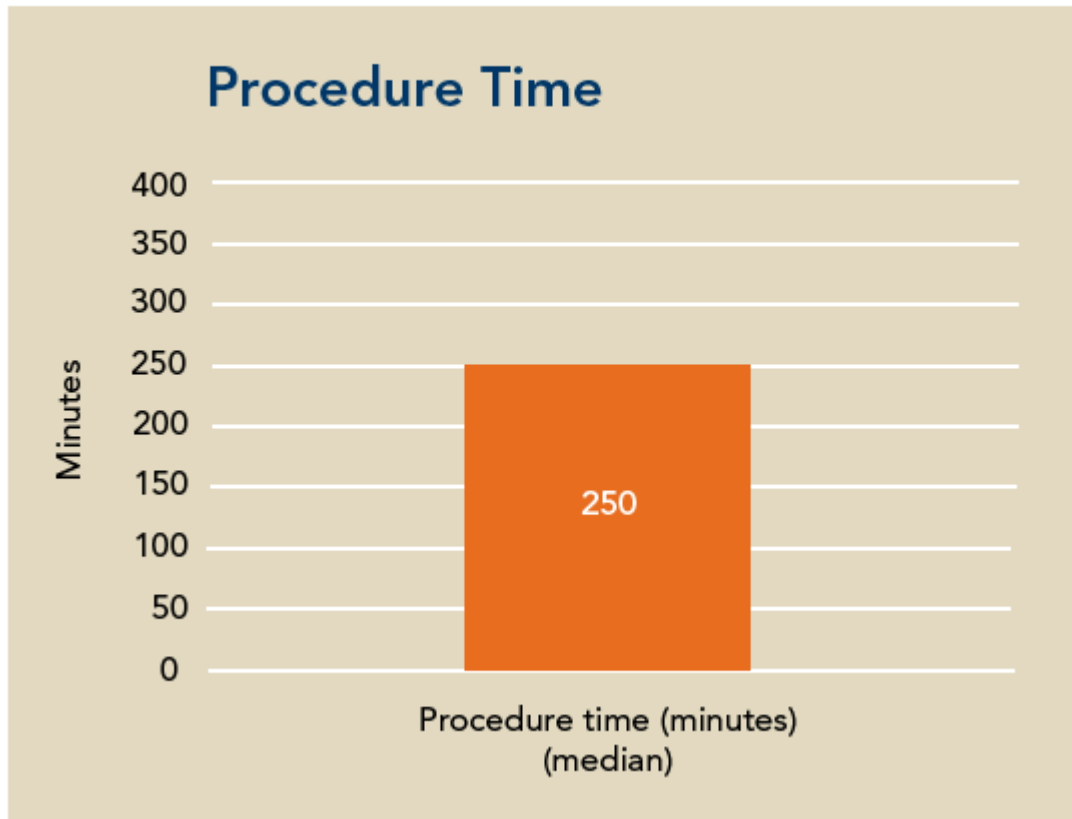
Product CD34+ Dose/kg

Chart 2. Final product



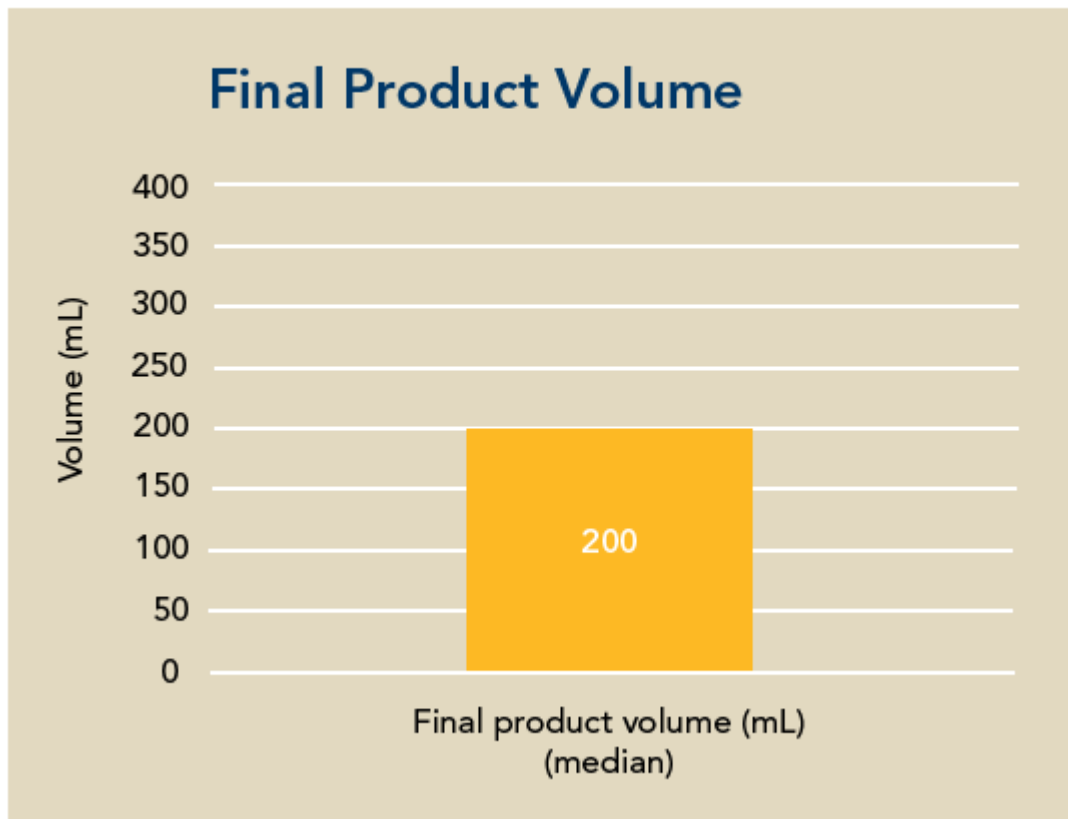
Procedure Time

Chart 3. Processing: Total time



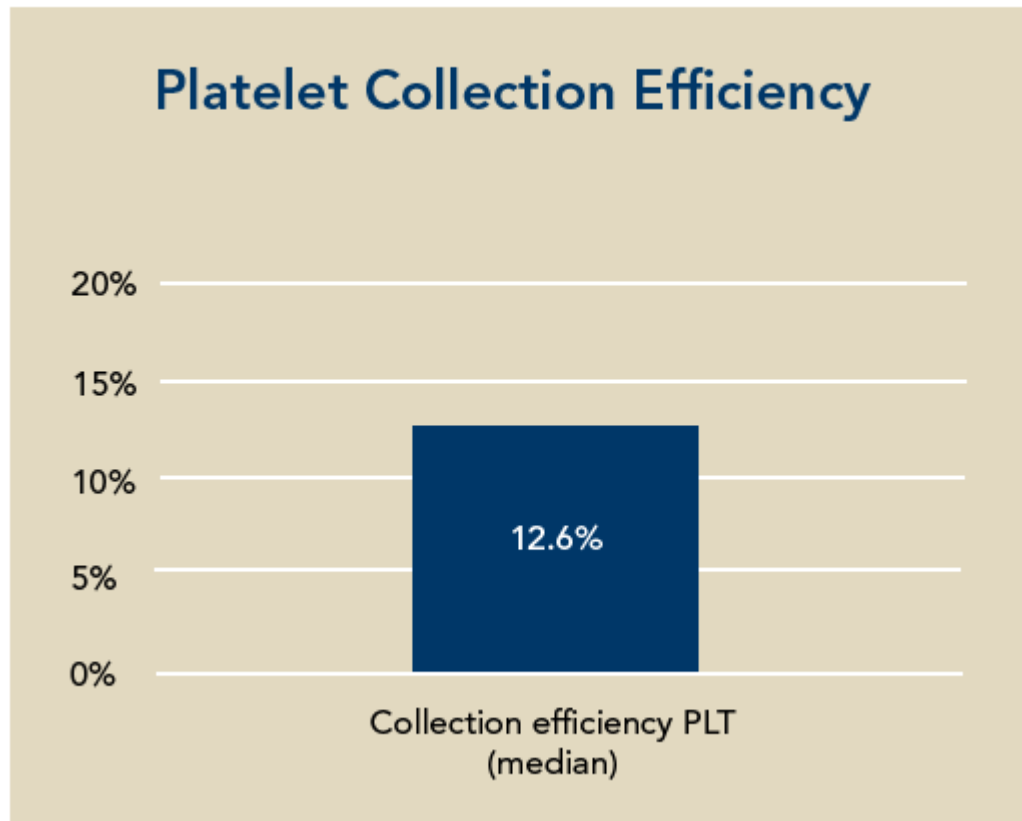
Final Product Volume

Chart 4. Final Product: Volume



Platelet Collection Efficiency

Chart 5. Performance: Platelet collection efficiency



RBC Residuals

Chart 6. Performance: RBC residuals



Mobilized Donor Data summary

Table 1. Mobilized donor data summary

Pre-Count	N=21	Median	Min	Max
TBV (ml)		5629	4292	7876
WBC x 10 ³ /μL		41	23	78
CD34+ /μL		43	9	115
Platelets x 10 ³ /μL		237	126	334
Product				
LY+MO Eff.		65.9%	34.2%	148.4%
CD34+ Eff.		60.5%	33.5%	101.9%
Platelets x 10 ³ /μL		970	548	1945
Hct%		0.6%	0.0%	1.7%
Granulocyte %		4.0%	1.0%	28.7%
Volume (ml)		239	125	373

- Preliminary performance from initial feasibility study performed on mobilized donors
- Data updated since presentation at EBMT (March 2008) and ASFA (April 2008)
- Donors mobilized using 10mcg/kg GCSF x 3 days

Spectra Optia

“ The MNC protocol brings the value of **efficiency, purity, and consistency** to cell collections - ultimately benefiting patients, clinicians and laboratory processes.”

Thank you.

We welcome you in our booth for more information.

