Salvaged Blood Filtration

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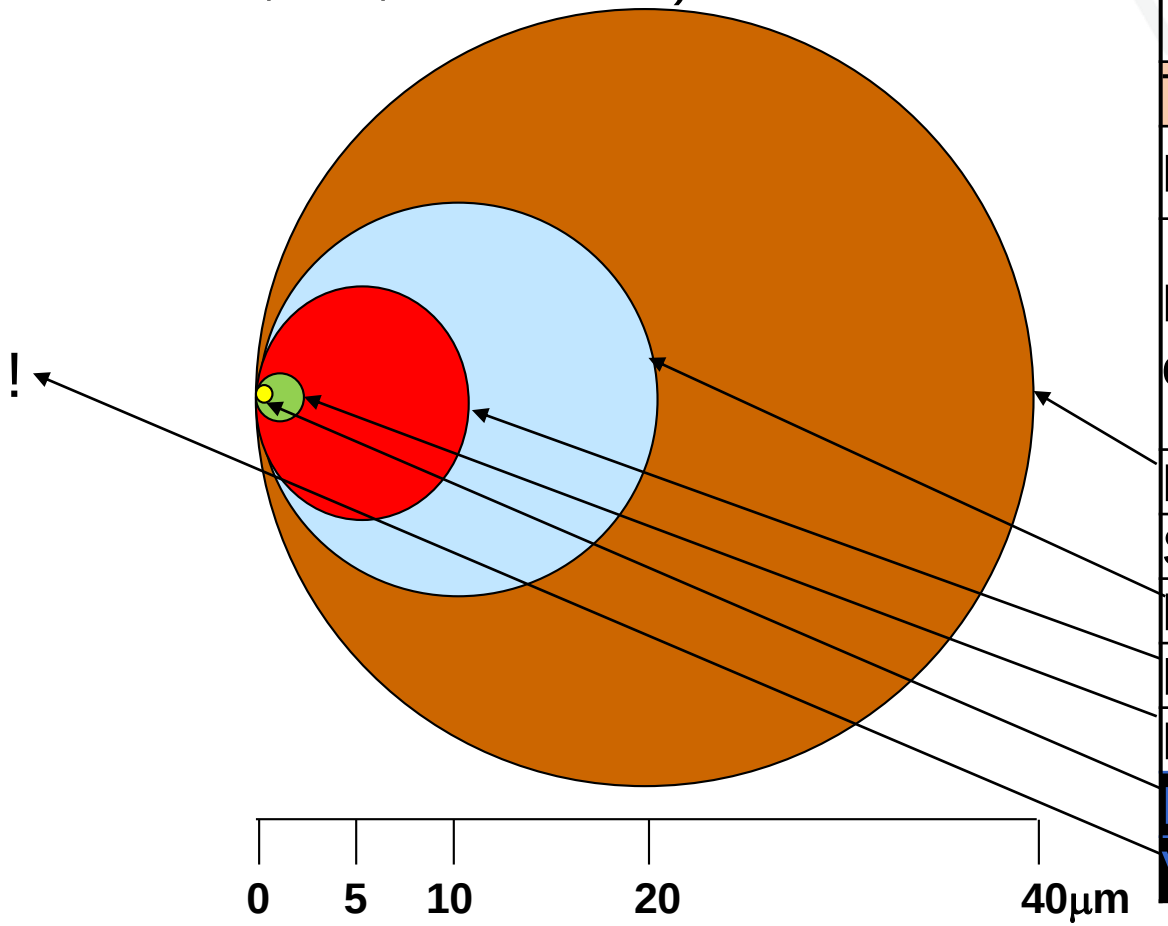
Sizes of Cells and Contaminants

- Micron (1/1000 mm
  = 1/1,000,000 meter)



Item	Size (microns, μm)
Tea Leaf	100-2000
Microaggregate	40 - >4000
Bone shaving, metal swarf, cancer cell, squamous cell	? **Mostly > 10 μm**
Human hair (40 μm dia & microaggregate)	20-180
Silica particle	20
Leucocyte	12-20
Red blood cell	6-8
Platelet	2-4
Bacterium	0.2
Virus	0.02 (20nm)

0.020 μm = 20 nm

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Content

- Summary of filters used for blood filtration

- Filtration of stored donor blood
- Microaggregates
- SQ40 general purpose filter

- Filtration of autologous / salvaged blood
- SB1 Lipiguard filter
- RS1 Leucodepletion filter

- Cell Salvage and Filtration

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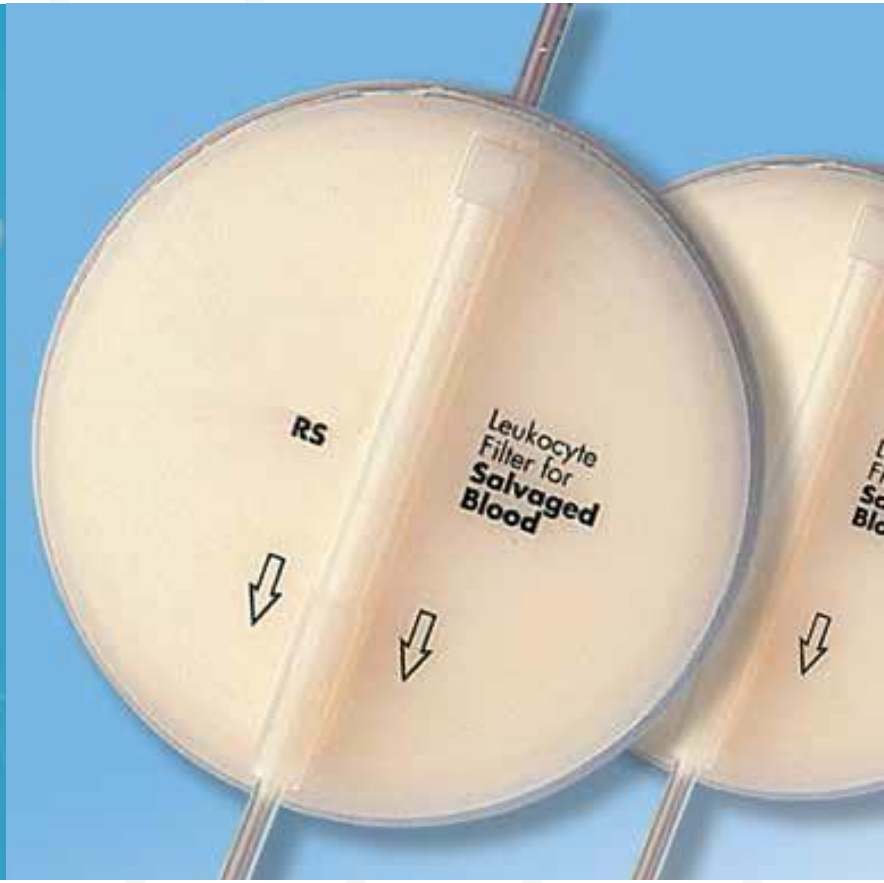
A Series of filters for different applications

Tea Strainer
(700µm)
Stops leafy tea

Clot Screen
(170-220µm)
Stops needle blocking

SQ40
Microaggregate
Filter
(40µm)

SB1 Lipid &
Leucocyte filter
(40µm + 8µm)



RS1 Leucocyte filter
(~8µm)

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Summary of Haemonetics Surgical Filters

Filter	Nominal Pore size	Indications	Where to use
Tea Strainer	700µm	Leaf tea (Not tea bags)	Kitchen or Drawing Room
Clot Screen	170-200µm	Prevent infusion needle / IV line blockage Included in CS Elite 00205-00 hard reservoir (150µm)	All transfusions – **in blood giving set**
SQ40	40µm	All types of blood product (RC, PLT, Plasma) Multiple units depending upon quality (Stop when blocked)	Universal transfusion usage
20 µm reservoir		Small pore 20 µm screen in Orthopaedic reservoir	Orthopaedic surgery
SB1	~ 10-20 µm	1 unit of intraoperatively or post-operatively salvaged blood Washed or Unwashed Wound drainage blood	Surgery Orthopaedic General (Where fat is a concern)
RS1	~ 8µm	450mL of washed intra-operatively salvaged washed blood for re infusion or 1000mL of unwashed intra-operatively salvaged blood for re infusion	Surgery -Orthopaedic -Cardiac -General Obstetrics

40µm screen filtration – Haemonetics SQ40SE

Blood Filtration – SQ40

Microaggregate Filtration:

- Removal of microaggregates
- Removal of any particulate >40µm
- Filter connects between giving set spike and blood pack
- *Compare to 20µm reservoir screen*

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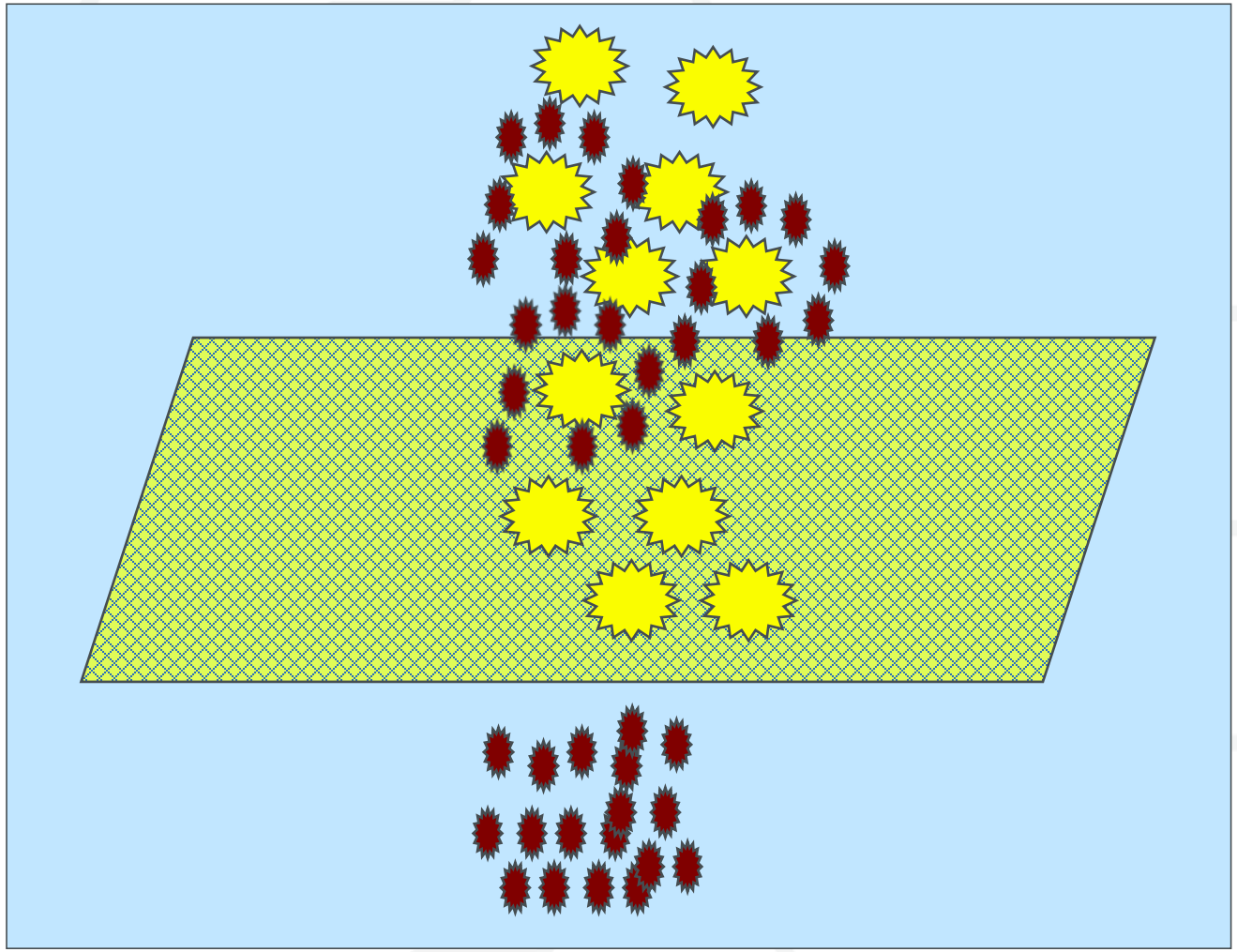
Preventing the passage of microaggregates

Screen Filtration with SQ40

- 40µm pore size
- Absolute filter
  - Lock woven mesh screen
- Large surface area obtained by using a pleated membrane
- Polyester screen



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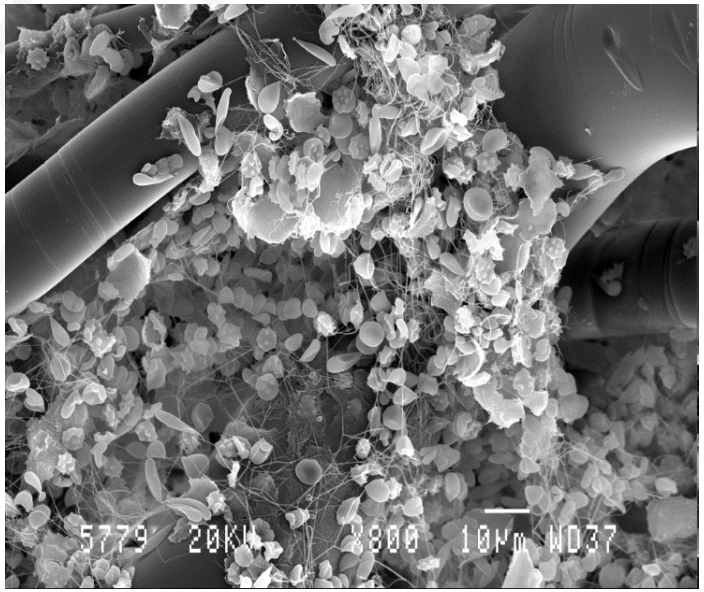
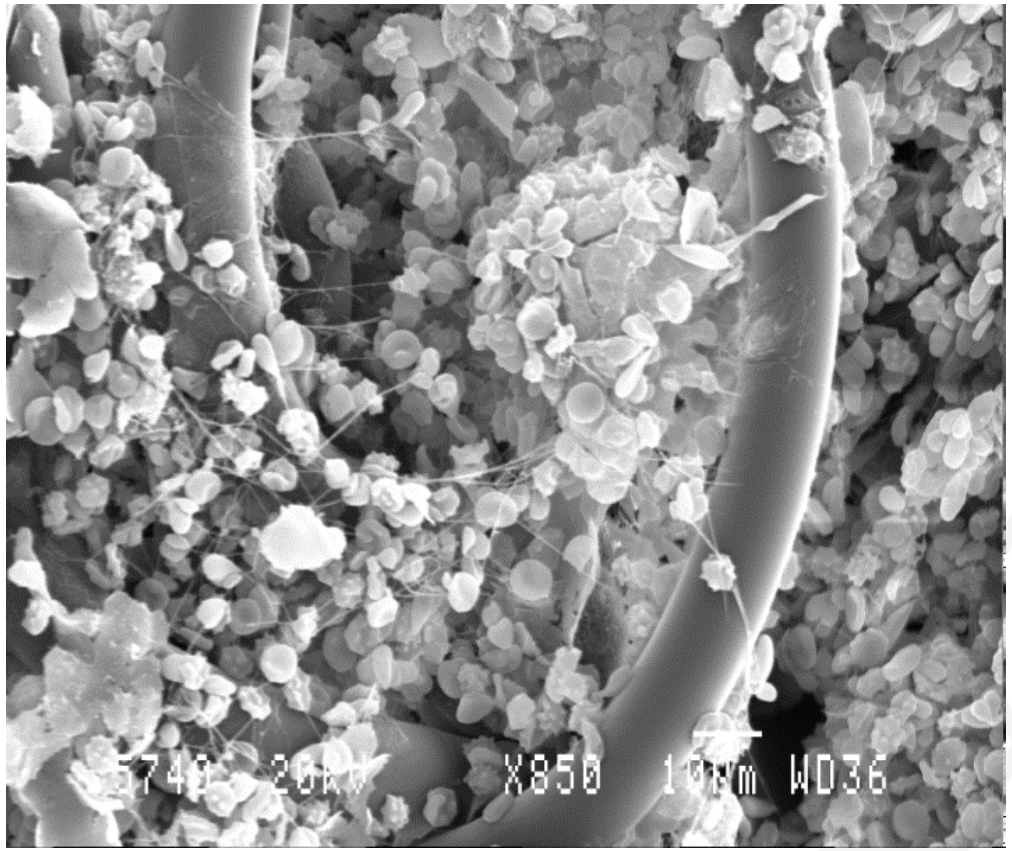
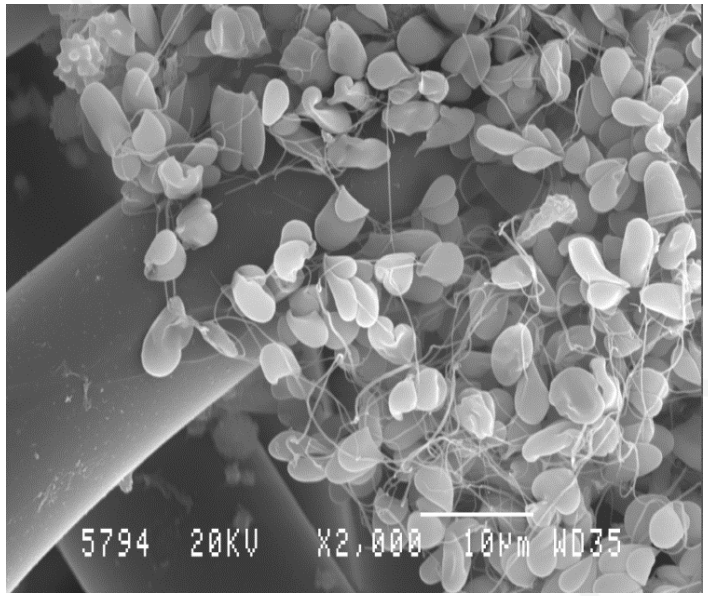
Microaggregates, platelets and WBCs removed by depth filters







- Platelets
- Leucocytes
- Fibrin Filaments

Adhered to depth filter fibres

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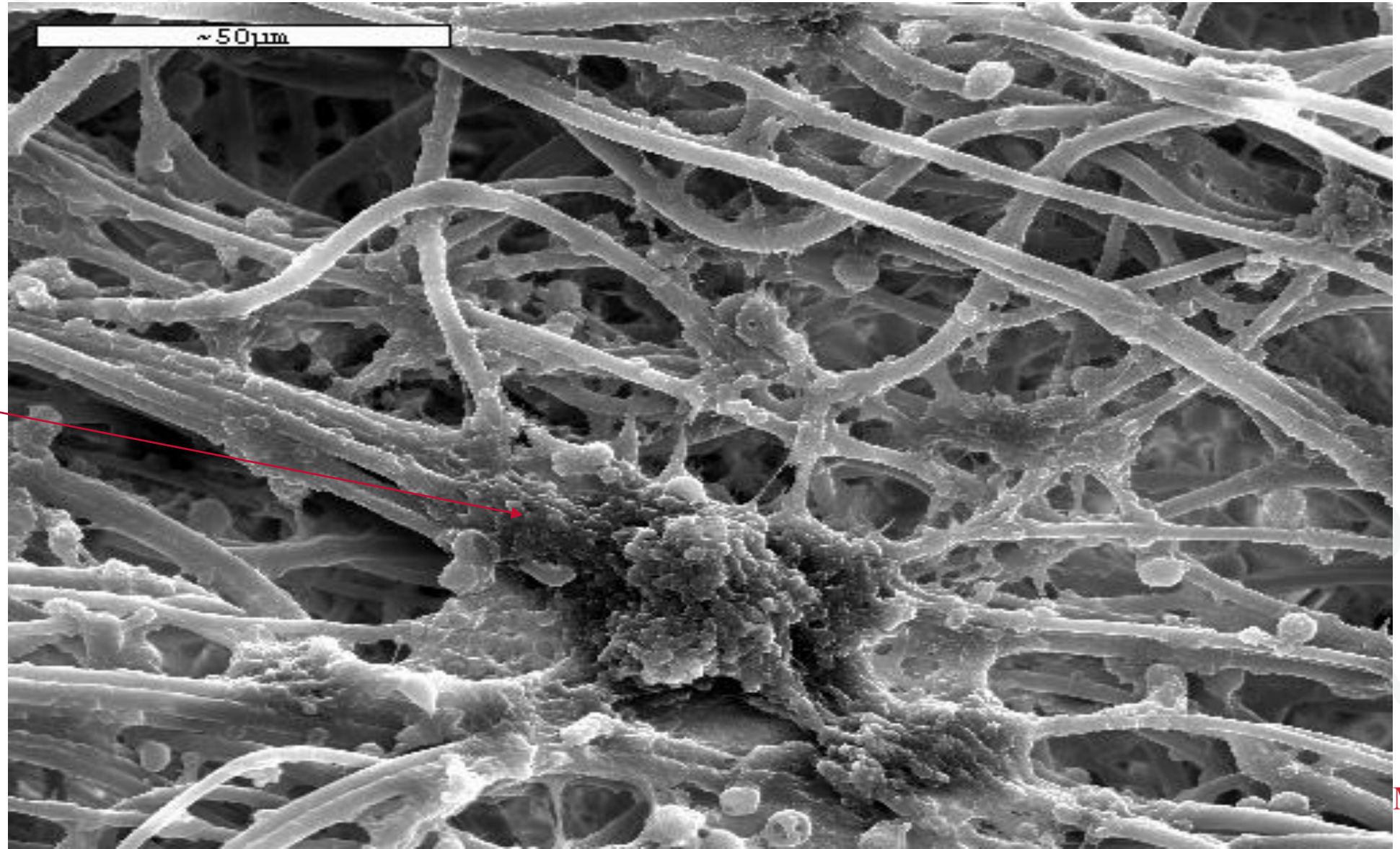
Fat, Fibrin and Cellular material trapped on Depth filter (such as RS1)



Filtration of Autologous Salvaged Blood

The best blood for the patient is their own blood

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Quality of Cell Salvaged Blood (Washed) from Cell Saver ELITE

Parameter	Units	225 mL bowl	125 mL bowl	70 mL bowl
Product Hct	%	50.4	45.4	40.6
RBC recovery	%	95.1	93.9	91.1
FHgb washout	%	96.1	97.8	95.0
Heparin washout	%	98.1	99.6	98.9
Albumin washout	%	96.5	99.5	98.9
WBC removal	%	22.4	19.6	22.7
Platelet removal	%	85.2	90.7	90.4
Cycle time, cycle-1	mm:ss	6:15	8:07	7:29
Cycle time, cycle-2	mm:ss	6:10	7:40	7:05

*Results may vary based on the incoming hematocrit and level of free hemoglobin that is collected into the reservoir.
References: TR-CLN-100049 (RBC recovery); TR-CLN-100177 (all other parameters)

Cell Washing

- Excellent for reduction of solutes e.g. Heparin

- Inefficient for WBC and platelet reduction

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Cell Washing vs. Filtration:

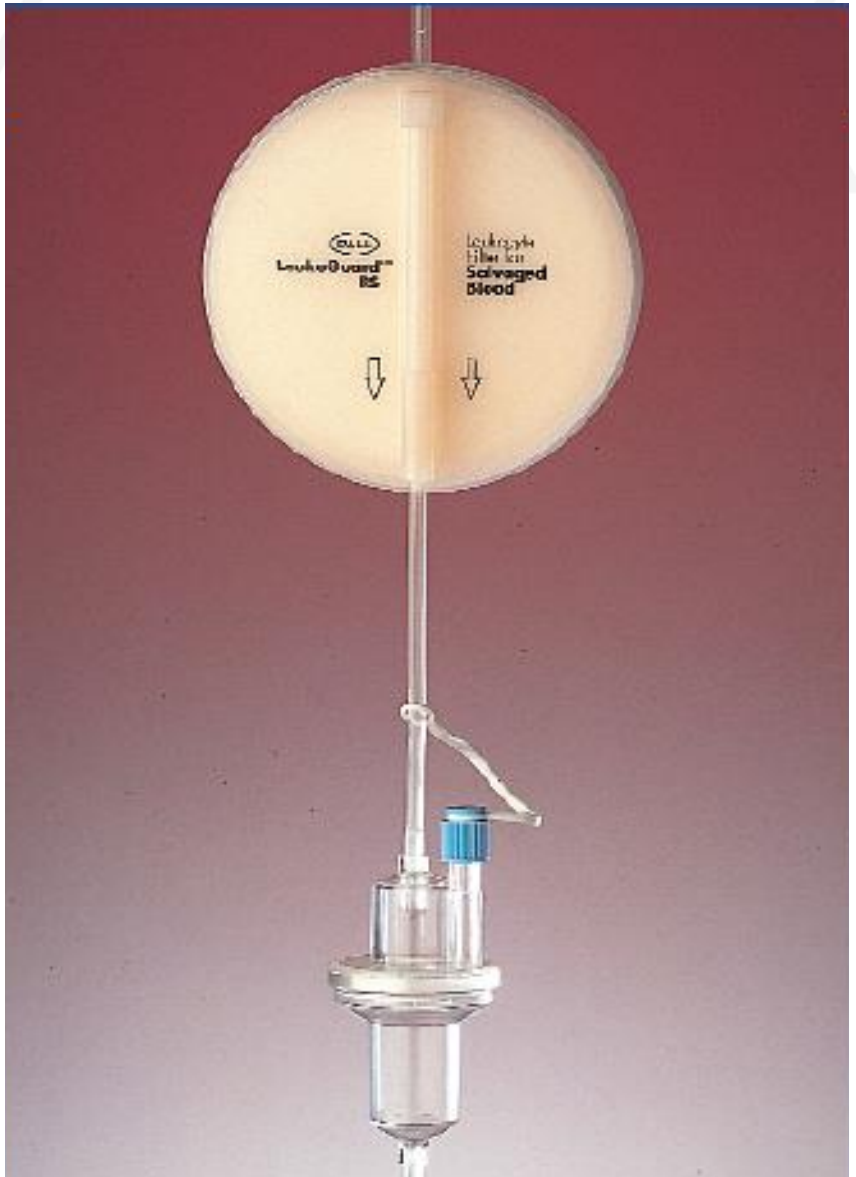
Cell Wash:

- Washing is very good at adjusting Hct and exchanging solution
  - Washes out soluble contaminants
- Poor discrimination of cells, particles, metal shards, swab fibres, hair etc.

Filtration:

- Haemonetics filters are very good at removing large cells and particulates
  - RS1 allows red cells to pass at high efficiency
- Filters offer poor reduction of solutions or solutes
- Filters and washing are complementary and synergistic technologies

RS1 Leucocyte Removal Filter for Salvaged Blood



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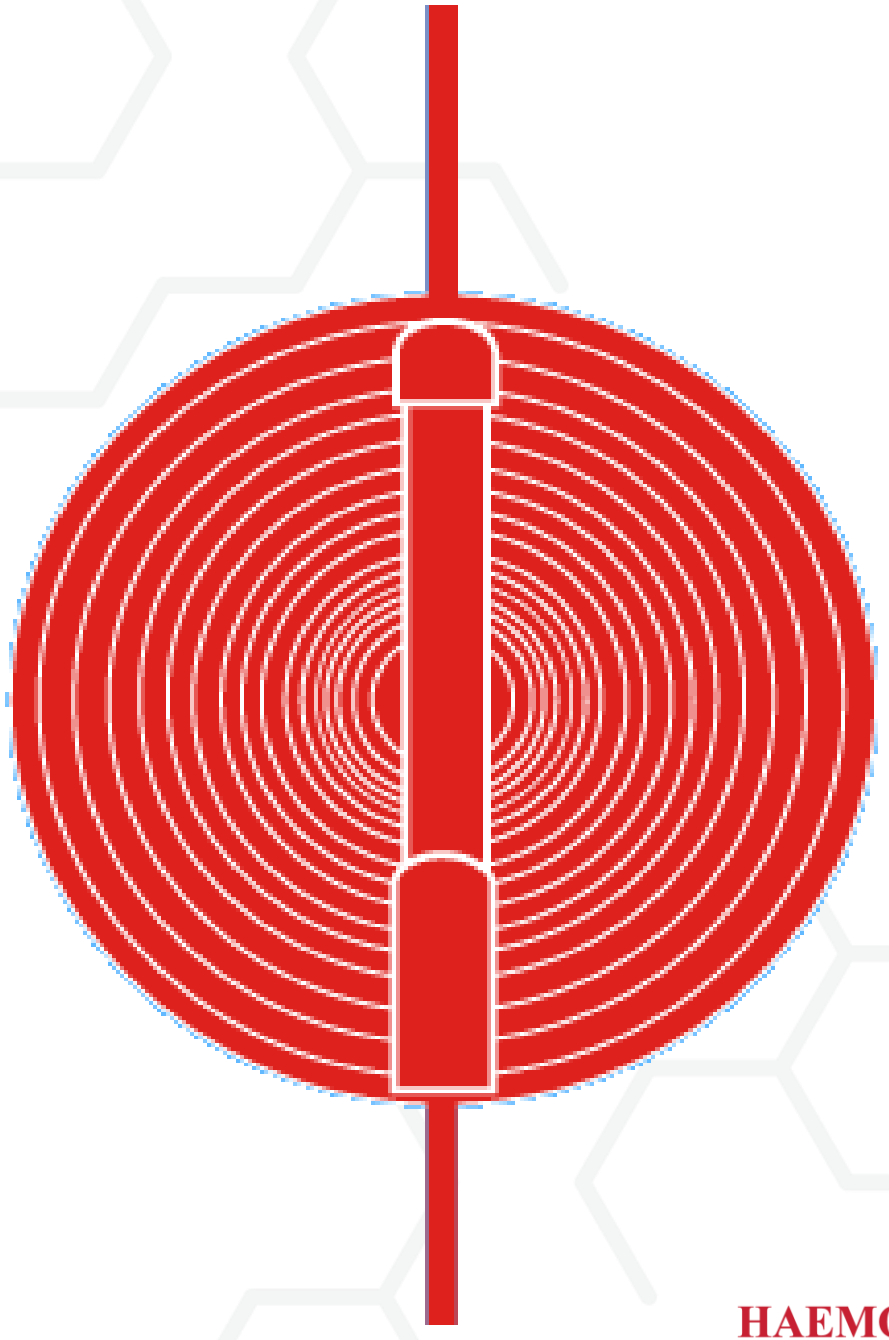
RS1 Filter Priming



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RS1 Filter *in situ*

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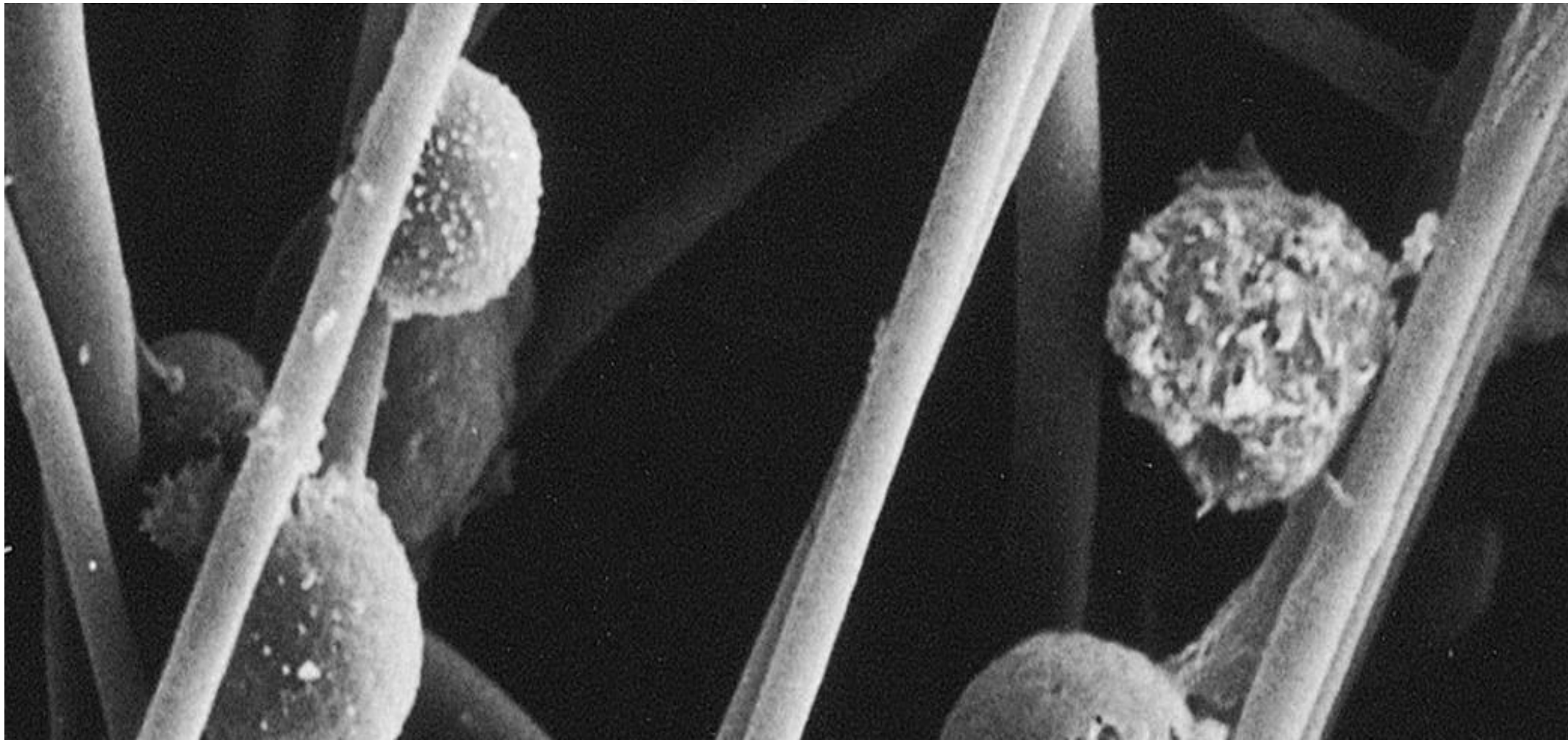
Leucocytes (and a few platelets) adhered to and trapped c polyester depth media



Product Features

- Gravity (or squeeze) prime
  - Use of a pressure cuff must comply with the cell washer manufacturers' instructions for use
- Many, including Haemonetics contraindicate the use of a pressure cuff

- Vented spike on RS1VAE

- Auto priming, self levelling drip chamber on RS1VAE
- No need for saline prime or flush
- No need to squeeze bag

RS1 Indicated Application

- Indicated for the removal of leucocytes, fat particles and microaggregates from:

- 450 mL of washed intra-operative salvaged blood intended for reinfusion

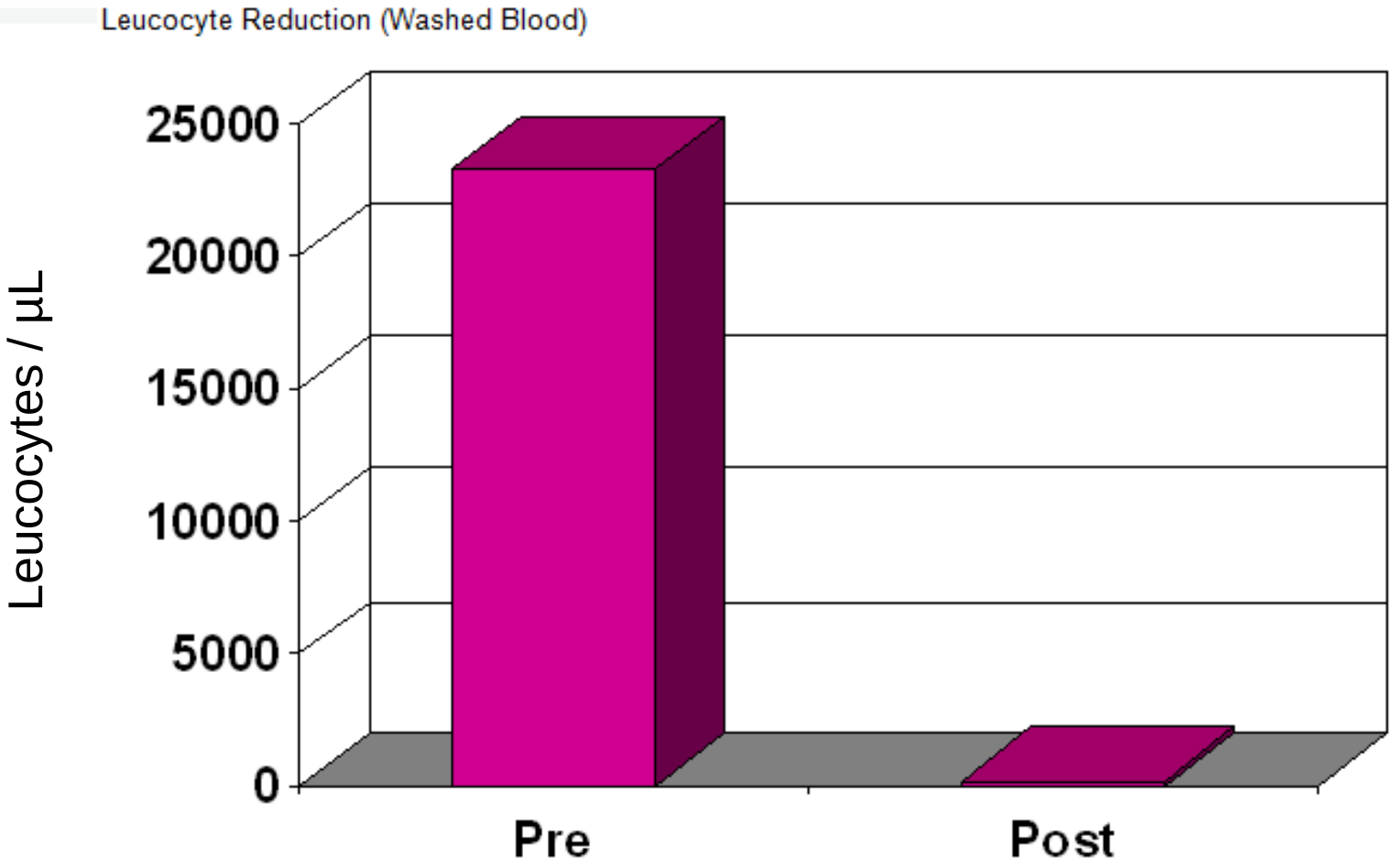
or

- Up to 1 L of unwashed intra-operative salvaged blood intended for reinfusion

Performance Characteristics – RS1 clinical evaluations

Leucocytes and lipid particles were studied from both washed and unwashed salvaged blood obtained from patients undergoing coronary artery bypass procedures and valve replacements or repairs.

RS1 Leucocyte Reduction (Washed Blood)

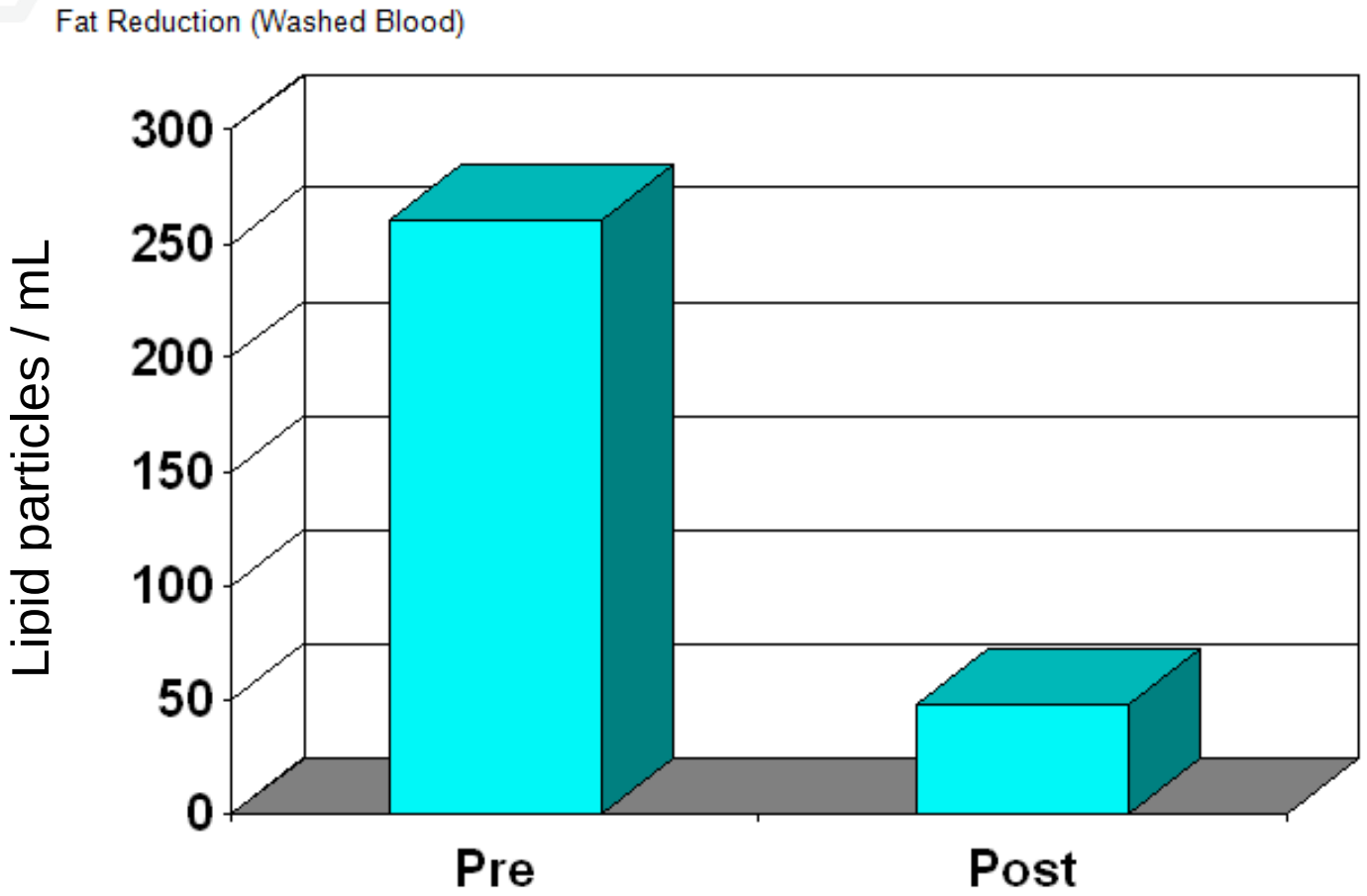


Leucoreduction

= 99.2 ± 0.2%

P < 0.001

RS1 Fat Reduction (Washed Blood)



Fat particle reduction

83.9 ± 3.9%

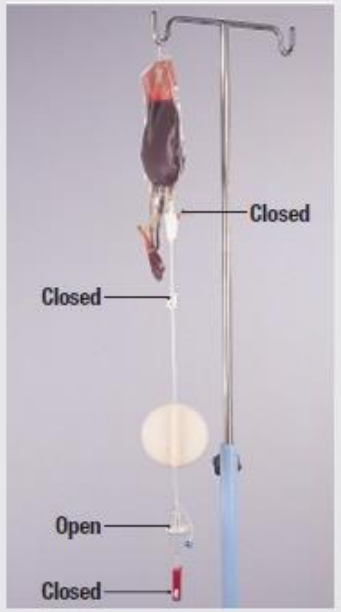
P< 0.001

Supporting Literature: RS1VAE Priming Chart

Instructions for Use

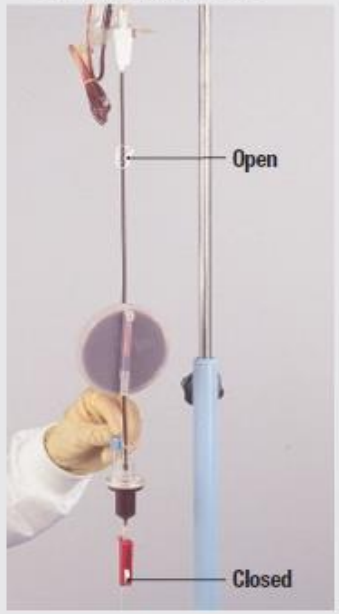
Reorder Code RS1VAE

1 Prepare Set and Blood Bag



- Agitate the salvaged blood bag and hang on stand.
- Ensure red cap (A) on vented spike is firmly closed.
- Close upstream filter clamp (B) and ensure tethered protective cap (C) is hanging free.
- Close administration set roller clamp (D).
- Insert filter spike into blood bag using a twisting motion.

2 Prime Filter and Administration Set



- Open filter clamp (B).
- Allow filter and drip chamber to prime under gravity.

OR

- Apply constant pressure to blood bag by squeezing. Once blood exits the filter, release pressure and allow drip chamber to fill under gravity.
- When blood flow into drip chamber stops, place tethered protective cap (C) on drip chamber air vent and tighten.
- Prime administration set, regulate flow with roller clamp (D) and connect to patient.

3 Red Cell Recovery

- On completion of transfusion, open red cap (A) on vented spike and allow upstream side of filter to drain.

NOTES:

- The drip chamber should never be squeezed.
- Saline priming is not required.
- The filter should not be flushed with saline after filtration.
- The cap on the drip chamber must not be loosened or removed during the transfusion.
- This product is free of natural rubber latex.

Note: Do not insert spike beyond shoulder

Visit us at www.haemonetics.com

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Product Claims and Performance

- WBC Reduction: Averaging > 99% (> 2 log)
- Lipid particle reduction: Averaging 84%
- Filter hold up volume: 31 mL (after recovery)

RS1 Features and Benefits

Feature	Benefit
Clinically proven media technology - CE mark for Salvaged red cells	Patient protection
Unique - Specifically designed cell salvage filter technology	Safe and compatible with salvaged blood
Gravity prime and self levelling drip chamber	Easy and convenient to use
Low hold up volume	High red cell recovery
High flow rates under gravity	Allows rapid infusion

Cell Salvage and filters combined, our claims.

Residual levels for washed red cells from Cell Saver Elite: (The concentration and washing cycles of the device reduce the levels to the following):

- Fat content: N/A
  - Wash-out unknown

- Leucocytes: 2,925,000,000 = 2.92 x 10^9 /500ml
  - Wash-out 22%
  - Washed contains 2,900 times more than EU allogeneic WBC guideline

Cell Salvage and filters combined, our claims.

Residual levels for cell salvage RBC after wash and filtration

With RS1:

- Fat content: 1,920,000 1.92 x 10^6 fat globules/lipid particles / 500ml
  - Reduction 84%
- Leucocytes: 8,775,000 = 8.75 x 10^6 / 500ml
  - **Reduction 99%**

Summary

Cell Salvage and Blood Filtration How it comes together.

RS1 filtration results in salvgaed red cells with equivalent residual WBC to an Allogeneic unit

The EU standard is < $1x10^6$ total residual leucocytes in one unit of Allogeneic red cells.

	Whole Blood (Non Washed) Average concentration/mL		Whole Blood (Non Washed) Total WBC in 500 mL		Washed Blood (Cell saver Elite) Washout average 22%		After wash AND Filter SB1 70% reduction		After wash AND Filter RS1 99% reduction*	
Leucocytes	7500000	7,50E+06	3 750 000 000	3,75E+09	2 925 000 000	2,93E+09	877 500 000	8,78E+08	8 775 000	8,78E+06

*This level of leucoreduction has been shown by Gu, *et a*l, to reduce post-perfusion syndrome in post surgical cardiac patients.

	Whole Blood (Non Washed) Average concentration/mL		Whole Blood (Non Washed) Total particles in 500 mL		Washed Blood (Cell saver Elite) Washout unknown		After wash AND Filter SB1 84% reduction		After wash AND Filter RS1 84% reduction	
Fat Particles**	24000	2,40E+04	12 000 000	1,20E+07	N/A	N/A	1920000	1,92E+06	1920000	1,92E+06

** Average concentration of fat globules/lipid particles per mL, 16 patients from Cardiac surgery case example.
There is no standard for fat particle removal.

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Guidelines / Endorsements:

NICE Obstetrics:

- A leukocyte depletion filter may also be used in this process to reduce the number of leukocytes in transfused blood which may reduce adverse reactions to re-infused blood and limit disease
- https://www.nice.org.uk/guidance/ipg144
- NICE - Intraoperative red blood cell salvage during radical Prostatectomy or radical cystectomy Prostectomy:
- https://www.nice.org.uk/guidance/ipg258
- *"A leukocyte depletion filter is nearly always used; this is thought to minimise the risk of reinfusion of malignant cells that may be present in the aspirate."*

Association of Anaesthetists guidelines: cell salvage for peri-operative blood conservation 2018

- *https://associationofanaesthetists-publications.onlinelibrary.wiley.com/doi/full/10.1111/anae.14331*

- "The use of leucodepletion filters should be considered during re-infusion of salvaged blood in cancer surgery and when blood is salvaged from an infected surgical field. There is mixed evidence of the benefit of leucocyte depletion filters in obstetrics."
- "The number of malignant cells in salvaged blood can be reduced by the use of LDFs, with no apparent adverse effect on the quality of the product 52"

Guidelines / Endorsements (2):

- SHOT Report 2020 Ch. 22 Cell Salvage

“Reinfusion of salvaged red cells should be undertaken using an administration set designed to filter particles that are potentially harmful to the patient. The use of a more specialised filter, such as a leucocyte depletion filter, should be considered in relation to clinical need and policy.”

Thank You!

Questions?

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