

Boost Autologous Blood Transfusion Options



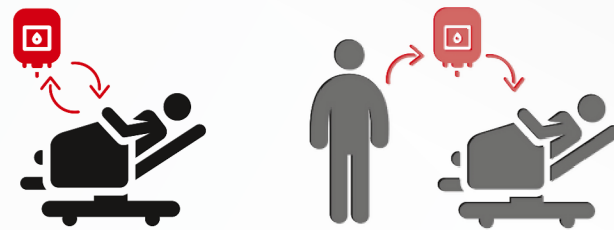
The background

Annually 100 million donor blood transfusions take place worldwide. Despite broad applicability, donor transfusion is still associated with high total costs and health risks resulting in medical complications, longer recovery time, or increased mortality.

Patient Blood Management represents a set of patient-centered strategies aimed at minimizing donor blood use and improving patient outcomes. Part of these strategies is collecting and reinfusing blood lost during surgery, a procedure referred to as autologous blood transfusion. The prerequisite for autologous blood is that it is "washed" before being given back to the patient; valuable blood cells are retained while harmful contaminants are washed out.

The HemoClear blood system is the first out-of-the-box solution for cell recovery. HemoClear generates safe and high-quality autologous, platelet-rich, red blood cells from patients' shed blood. The simple sterile and closed filter procedure takes only 30 minutes and can be performed by anyone in any healthcare setting.

Autologous blood transfusion



Autologous blood transfusion is the reinfusion of blood or blood components to the same individual from whom the blood was collected. There are two types of autologous blood transfusion: patients' blood can be donated and stored for later use, or shed blood can be collected during and after surgery / trauma and reinfused almost immediately. Medical standards recommend and healthcare professionals commonly use autologous blood transfusion during or after surgery / trauma. Autologous blood pre-donation is uncommon and primarily reserved for specific indications and situations like rare blood types or religious considerations.

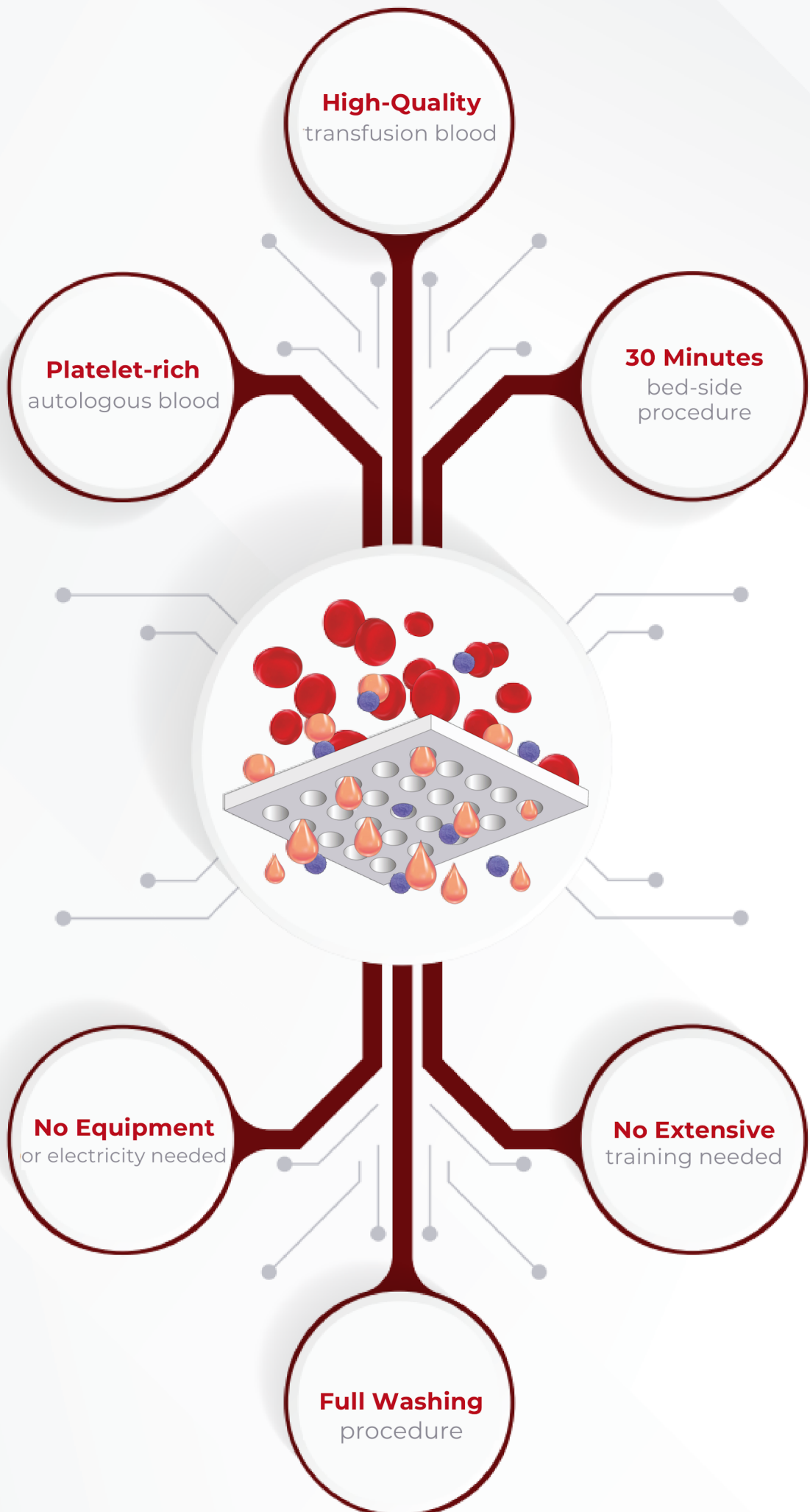
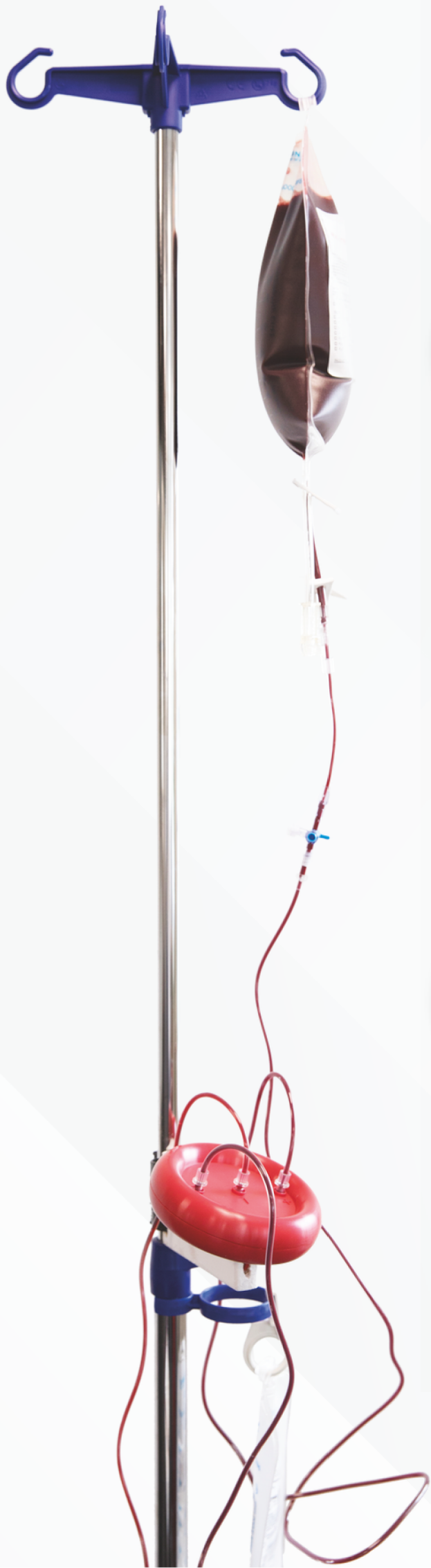
Cell recovery or cell salvage

Cell recovery is the process of enabling autologous blood transfusion by collecting patients' shed blood during or after surgery, washing the shed blood, and reinfusing it into the patient. To safely reinfuse the shed blood, it is a prerequisite that shed blood is prepared before being given back to the patient; valuable blood cells are retained while harmful contaminants are washed out.

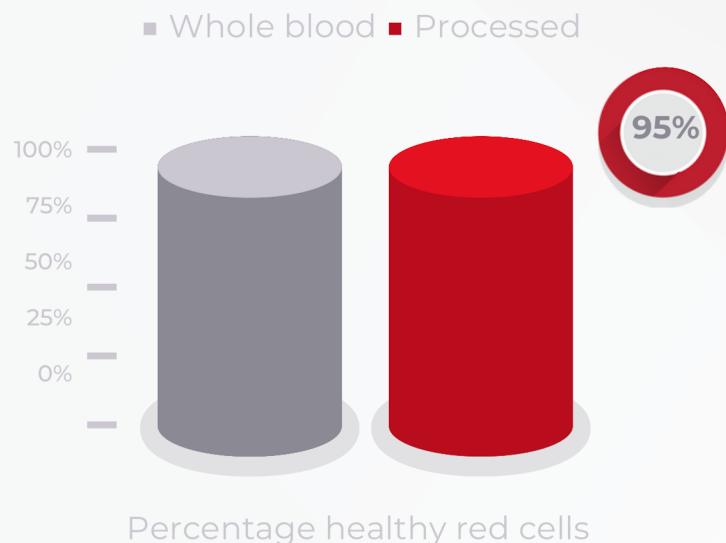


Introducing

the first micro-filtration
cell recovery solution

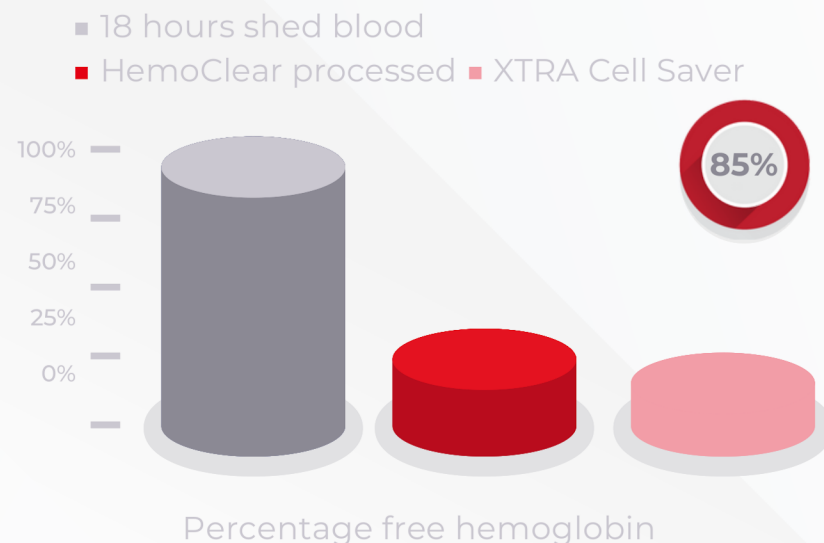


Recuperates Healthy Red Blood Cells



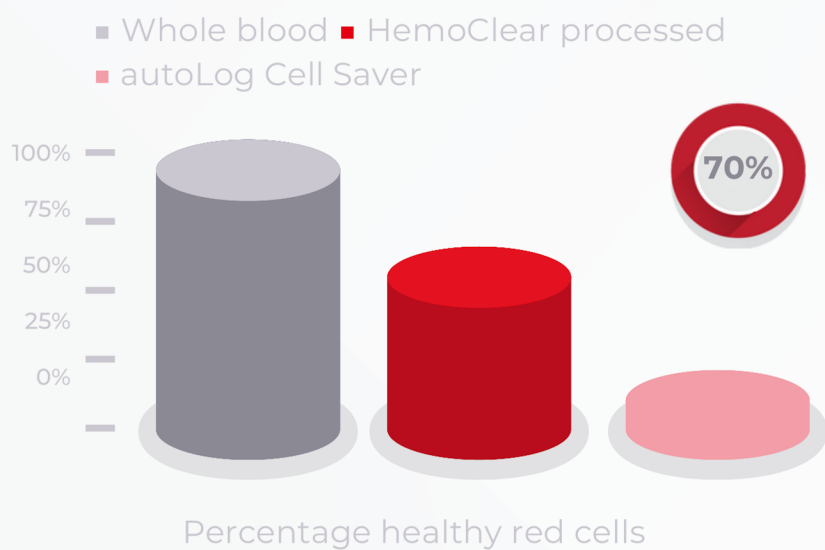
RBC morphology was determined after fixation of the cells and using a light microscope, RBCs were visually analysed and described as either well-shaped discocytes (smooth biconcave discs without defined spicules) or echinocytes (crenated cells with defined spicules, including spherocytes).

Eliminates Non-cellular Components



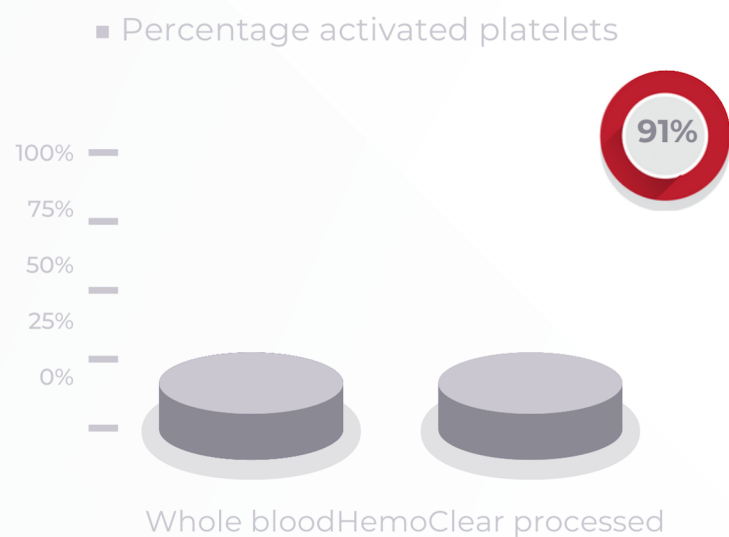
Free haemoglobin was equally washed out by the two devices to a mean level of less than 15% of the total baseline load. Total loads of complement C3, complement C4, and D-dimer were reduced by over 15-fold after the HemoClear washing procedure.

Recuperating Functioning Platelets



The washing procedure yielded platelets of at least $68 \pm 10\%$. Washing by one filtration round, two consecutive rounds or the entire washing protocol did not significantly increase haemolysis.

Filtration Does Not Activate Platelets



Immediately after separation of the whole blood, activation of the platelets was measured by percentage CD62P display. Platelet function was assessed using TEG. Parameters indicate that separation has minimal influence on platelet functionality.

Research Article

An In Vitro Pilot Study Comparing the Novel HemoClear Gravity-Driven Microfiltration Cell Salvage System with the Conventional Centrifugal XTRA™ Autotransfusion Device

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Abstract

Background :

In 2013, the World Health Organization reported a shortage of 17 million red blood cell units, a number that remains growing. Acts to relieve this shortage have primarily focused on allogeneic blood collection. Nevertheless, autologous transfusion can partially alleviate the current pressure and dependence on blood banking systems. To achieve this, current gold standard autotransfusion devices should be complemented with widely available, cost-efficient, and time-efficient devices. The novel HemoClear cell salvage device (HemoClear BV, Zwolle, Netherlands), a gravity-driven microfilter, potentially is widely employable. We evaluated its performance in the cardiac postoperative setting compared to the centrifugal XTRA device.

Methods :

In a split-unit study (n= 18), shed blood collected 18 hours after cardiothoracic surgery was divided into two equal volumes. One-half was processed by the XTRA paired set-up, equal washing volumes were used for both methods. Washing effectivity and cellular recovery were determined by the XTRA device and the other with the HemoClear blood separation system. In this measuring of complete blood count, free hemoglobin, complement C3, complement C4, and D-dimer in both concentrate as filtrate. Also, processing times and volumes were evaluated.

Results :

The HemoClear and XTRA™ devices showed equal effectiveness in concentrating erythrocytes and leucocytes. Both methods reduced complement C3, complement C4, and D-dimer by ≥90%. The centrifugal device reduced solutes more significantly by up to 99%. Free hemoglobin load was reduced to 12.9% and 15.5% by the XTRA red blood cells comparably to the conventional centrifugal XTRA™ and HemoClear, respectively.

Conclusion:

The HemoClear device effectively produced washed concentrated™ autotransfusion device. Although the centrifugal XTRA™ device achieved a significantly higher reduction in contaminants, the HemoClear device achieved acceptable blood quality and seems promising in settings where gold standard cell savers are unaffordable or unpractical.

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Research Article

Recovery of platelet-rich red blood cells and acquisition of convalescent plasma with a novel gravity-driven blood separation device

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Abstract

Objectives and Background :

Our objectives were to determine the separation characteristics and blood product quality of a gravity-driven microfiltration blood separation system (HemoClear, The Netherlands).

A range of centrifugal blood separation devices, including intraoperative cell salvage devices (cell savers) and apheresis machines, are available to assist in preparing both allogenic and autologous blood products. These devices are expensive to operate and require extensive training.

Methods and Materials :

Nine whole blood units were collected under standard conditions and analysed for haematological parameters, thromboelastographic properties, platelet morphology and activation, and red blood cell (RBC) deformability and morphology. Three whole blood units were separated by means of the HemoClear device, into a liquid and cellular component. The cellular component was diluted with SAGM and cold stored for 14 days. To simulate cell salvage six whole blood units were diluted with isotonic saline, followed by multiple HemoClear separation rounds.

Results :

The recovery of both RBCs ($100 \pm 1.6\%$) and white blood cells ($99 \pm 4.5\%$) after undiluted filtration were very high, while platelet recovery was high ($83 \pm 3.0\%$). During the filtration, and cold storage after filtration storage both the non-deformable RBC fraction and the RBC maximum elongation remained stable. Parameters of thromboelastography indicated that platelets remain functional after filtration and after 7 days of cold storage. In the cell salvage simulation the total protein load in the cellular fraction was reduced by $65 \pm 4.1\%$ after one washing round and $84 \pm 1.9\%$ after two consecutive washing rounds.

Conclusion :

The novel blood filter studied effectively separates whole blood into diluted plasma and platelet-rich RBCs. Moreover, the device effectively washed diluted whole blood, driving over 80% of proteins to the liquid component.

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OR

Frequently Asked Questions

Intended use

HemoClear is intended for use in the washing and reinfusion of autologous blood. Such areas of application may include, but are not limited to:

- General, cardiovascular, orthopedic, vascular, plastic/reconstructive, obstetric/gynecologic, and neurosurgical surgery
- Postoperative treatment areas

The HemoClear micro-filtration objectives

HemoClear reduces the load of non-cellular debris and, brings the hematocrit in the filtered concentrate to normal levels ($\geq 40\%$). To reduce the load of non-cellular debris the collected lost blood will be diluted with NaCl 0,9% to wash out these components. To increase the hematocrit and platelet concentration, 2 filter cycles are advised.

Removed non-cellular debris include:

- Lipids and fats
- Cellular debris
- Plasma-free hemoglobin
- Irrigation solutions
- Pharmacologic agents
- Activated clotting factors

Consumables

All procedure necessities are included in a HemoClear-box, except for a dripping pole and isotonic saline (0.9% sodium chloride solution). Convenient clamps to fixate the filter and bags to a dripping pole will be separately provided.

Contraindications and warnings

Do NOT use if the wound field contains; Betadine/ chlorhexidine, hydrogen peroxide, alcohol, distilled water, antibiotics not for parental use, and fibrin adhesives. Do NOT use with patients with sickle cell disease and other red cell disorders. The use of blood from the HemoClear device for reinfusion may be contraindicated in the case the blood may contain amniotic fluid, bacteria, or tumor cells. This blood could be considered, provided a leucocyte in-line blood filter is used when reinfused.

Single-use device

Use a filter exclusively for one patient.

Duration/time

The device set-up takes approximately 3-5 minutes. The microfiltration procedure takes on average 30 minutes. Medical guidelines restrict the processing time of autologous blood handling and the use of autologous devices, typically between 4-6 hours.

Volume

There're no minimum volume requirements. Under normal conditions, the filter generates up to 4 liter autologous transfusion blood in 4 hours. Reinfusion can start within 30 minutes after the first shed blood is collected and connected to the HemoClear filter.

Ref	In box	Component	Positioning	Final Configuration
1	Yes	Blood bag 1 liter	Placed at the top of the dripping pole	
2	No	Saline bag 2 liter	Placed at the top of the dripping pole	
3	No	Clamp	Place clamp 1m below top of the dripping pole, hook facing upwards	
4	Yes	Red blood cell recovery device	Place the HemoClear filter in the HemoClear clamp	
5	Yes	Extension line Y-connector	Connect blood bag and saline to the blood inlet on the filter	
6	Yes	Blood transfer bag 1 liter	Placed on the hook of the HemoClear clamp	
7	Yes	Female to female luer lock	Connect the blood transfer bag to the remaining filter blood inlet	
8	No	Clamp	Place an extra clamp 1m below the filter, hook facing upwards	
9	Yes	Waste bag 2 liter	Placed on the hook of the clamp	

Product Information

HemoClear Kit

Blood Filter
2 Blood Bags
1 Waste Bag
3 Extension lines

Minimum Quantity: 10 Kits

Product Demonstration

Would you feel more comfortable if we demonstrate how to use the filter?

Let us know at

demo@hemoclear.com

or call us at

+31 (0) 38 303 26 30

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