Hemosep

Revolutionary Cell Salvage

Training Manual

Concentrating **all blood components** from salvaged autologous blood.

Contents

Introducing Hemosep®

Cell salvage is an important part of patient blood management in hospitals. There are a number of technologies available to undertake cell salvage, the most common being centrifugal cell savers, which salvage only red blood cells (RBC). These devices are complex and require specialist technical knowledge to operate.

When designing Hemosep, the objective was to develop a haemoconcentrating cell salvage technology that does not require centrifugation and can be used easily without complex technical knowledge or skills. It was also important to manufacture a system that could salvage all blood components including red blood cells (RBC), platelets and clotting factors.

Hemosep uses a modified separation technique concentrating the blood through a membrane controlled superabsorber. The resulting product can be transfused back to the patient.

Introduction to Blood Transfusion

Composition of Blood

Blood has both cellular and non-cellular components. The cellular components include red blood cells (RBC), white blood cells (WBC) and platelets. The non-cellular component of blood is plasma, which contains proteins such as albumin, clotting factors, electrolytes and immunoglobulins.

Size of cells

The sizes of the cell species found in blood vary:
- Red blood cells 7µm
- White blood cells 7-20µm
- Platelets 2-5µm

Allogenic blood transfusion

Allogenic (donor) blood is a valuable but limited resource and although potentially lifesaving, is not without risks e.g. wrong blood incidents, transmission of infection and immunosuppression.

Autologous blood transfusion

Patients can receive their own blood back in a number of ways including:
- Pre-operative autologous donation
- Post-operative cell salvage (from surgical drains)
- Intra-operative cell salvage

Hemosep is an intra-operative cell salvage device.

Benefits of autologous blood transfusion

- No disease transmission (e.g. HIV, Hepatitis etc.)
- Usually an acceptable answer to religious beliefs surrounding blood transfusion
- No transfusion reactions
- No requirement for blood compatibility testing
- Eliminates the risk of the wrong patient receiving the wrong blood
- Supports the efforts to manage the blood supply more effectively due to concerns over blood shortages

Common reasons for transfusion

Red blood cells (RBC)
- To increase the haemoglobin levels of the blood

Platelets
- The prevention and treatment of bleeding due to:
    - Thrombocytopenia associated with large volume blood transfusions
    - Consumption due to disseminated intravascular coagulation (DIC)

Fresh Frozen Plasma
- Multiple coagulation factor deficiencies & disseminated intravascular coagulation (DIC)
- Abnormal Haemostasis following massive blood transfusion or surgery
- Reversal of Warfarin effect
- Haemostatic defects associated with liver disease if bleeding/invasive procedure

Cryoprecipitate
- Bleeding associated with hypofibrinogenaemia most commonly occurring in:
    - Disseminated intravascular coagulation (DIC)
    - Massive transfusion

Religious and cultural concerns over blood products and transfusions

Some people regard blood as sacred due to their religious beliefs, for example, Jehovah's Witnesses, or for cultural reasons. Based on these core beliefs, they often decline treatment with allogenic (donor) blood (red cells, white cells, platelets and plasma). However, they will usually accept their own blood and blood products via autologous transfusion. Hemosep can be used in the usual way, although some patients may request the system is set up to allow a continuous loop.

Hemosep has an advantage over traditional cell salvage as patients not only receive their own red blood cells but also vital platelets and clotting factors.

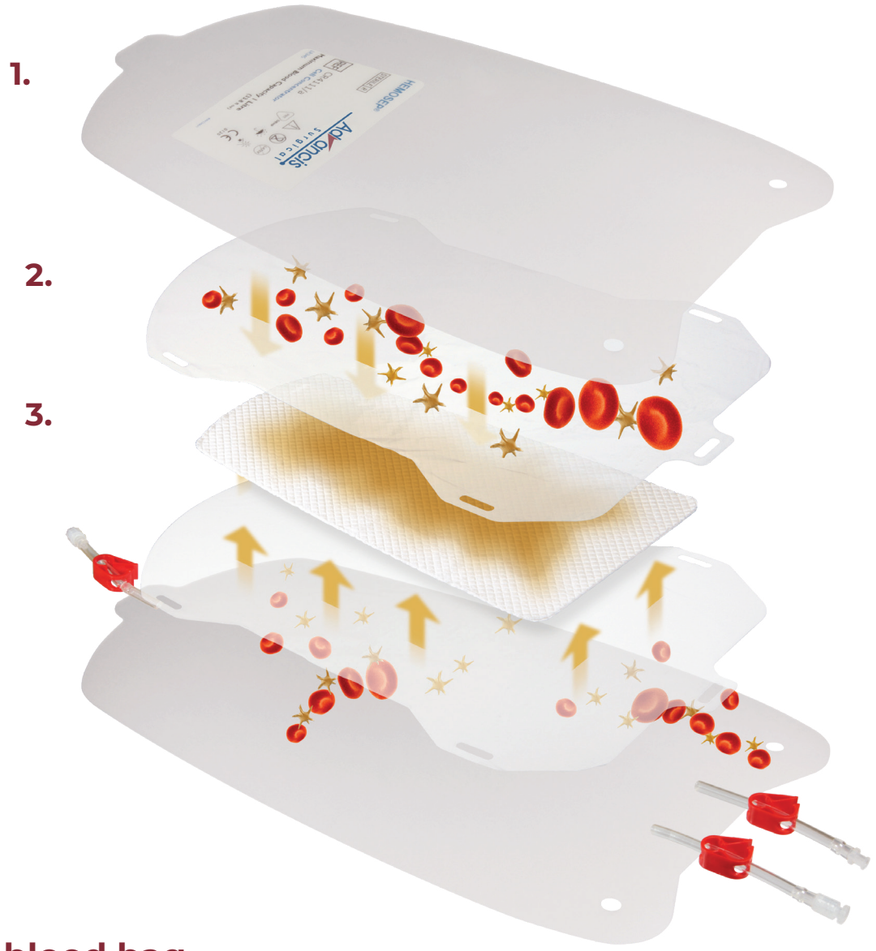
The Hemosep device

Components:

Hemosep®: Revolutionary Cell Salvage

Hemosep Technology

The Hemosep Cell Concentrator Bag is the active processer of the device and consists of three parts:



1. The blood bag
Houses the technology (filter membrane and superabsorbent pad) and blood whilst it is filtered.

2. Filter membrane
A unique size pore structure to control what is able to pass through during filtration means that no cellular components can pass into the superabsorbent pad.

3. Superabsorbent pad
The excess plasma and blood detriments that pass through the filter membrane are absorbed and turned into a gel-like substance. This allows for easy biohazard disposal.

Priming the bag ‘wets’ the superabsorber opening channels that allow the absorption of the unwanted plasma.

The bag must not be primed more than 3 minutes before filling the bag with collected blood as the saline will form cross links in the superabsorber, rendering it inactive and resulting in no concentration of the blood taking place.

The Hemosep Shaker rotates at 120rpm. This speed has been specifically calculated to ensure there is no shearing of cells. It produces an efficient wave pattern within the bag that moves the blood across the surface of the filter membrane, optimising the efficiency of the concentration process.

The filter membrane in the Hemosep Cell Concentrator Bag has a unique pore size and structure. It allows plasma to travel through and into the superabsorber core but the pore size is too small for RBC, WBC and platelets to pass through. The result is a haemoconcentrated mix of all cell species in the outer section of the Hemosep Cell Concentrator Bag.

Operation of Hemosep®

Set-up for blood collection

Step 1 Place the collection reservoir into the holder on the side of the Hemosep Shaker ensuring the clamp at the bottom outlet is closed.

Step 2 Attach one end of the vacuum suction line to main suction port on the reservoir and connect the other end to the theatre suction unit.

Step 3 Pass the sterile aspiration & anticoagulant (A & A) suction line to the scrub practitioner to open aseptically. Have them pass the end of the A & A suction line out of the sterile field and attach it to the inlet port on the collection reservoir.

Step 4 Prepare your anti-coagulant solution. If using heparinised saline, you will need to add 30,000 IU of unfractionated heparin to a 1L bag of N/Saline 0.9%.

Connect the anti-coagulant to the prime through filter and run until 50ml of anti-coagulant is in the suction reservoir, then connect to the purple line on the suction wand lines.

Hemosep®: Revolutionary Cell Salvage

Step 5 Hang up the bag of anti-coagulant solution on a drip stand and attach it via a giving set to the purple tubing of the A & A suction line. Once connected the blue anticoagulant tube line should be primed thoroughly.

Leave the anticoagulant drip switched off, using the switch on the anticoagulant tube where it enters the suction wand, until suctioning blood from the surgical field. This will avoid filling up the collection reservoir with excess anticoagulant and diluting collected blood.

Step 6 When ready to aspirate blood from the surgical field, turn on the main theatre suction and switch on the anticoagulant drip.

! Important

- Surface skimming (aspirating blood mixed with large quantities of air from the surgical field) should be minimised to prevent haemolysis of the cells
- The drip rate should be 1 drip per second
- The suction pressure should not be set higher than 150mmHg to avoid haemolysis of red blood cells
- When the aspiration suction is not in use, switch off the anticoagulation drip using the switch on the anticoagulant line at the suction wand end to prevent over filling of the collecting reservoir with the anticoagulation solution. This will prevent over-diluting the contents of the reservoir

Prepare the Hemosep cell concentrator bag

Step 7 Close clamps B and C on the Hemosep Cell Concentrator Bag.
A. Clamp/ line A. For priming
B. Clamp/ line B. For connection to collection reservoir
C. Clamp/ line C. For connection to the Hemosep blood collection bag

Step 9 Gently rock (do not fold or crumple) the Hemosep Cell Concentrator Bag for around 30 seconds to achieve an even coverage of saline across the superabsorbent pad. The white pad will turn a light grey colour when all the saline has been absorbed.

! Important

DO NOT prime the Hemosep Cell Concentrator Bag any longer than 3 minutes before filling with blood. Priming earlier will result in the superabsorber becoming inactive, resulting in no concentration of the blood.

Step 8 Prime the Hemosep Cell Concentrator Bag with 100ml of normal saline 0.9%. Draw up the saline in a syringe or via an IV giving set and add to the Hemosep cell concentrator bag via line A.

Process the collected blood

Step 10 Place the Hemosep Cell Concentrator Bag in the top compartment of the Hemosep Shaker. Ensure the clamps are closed.

Step 11 Connect the Hemosep Cell Concentrator Bag via line B to the collection reservoir's line.

Step 13 Press the run/stop button once to start the Hemosep Shaker. The Hemosep Shaker is pre-set to an optimum cycle of 120rpm.

! Important

Do not place more than one bag in the shaker as this will reduce the wave effect on the collected blood.

Step 12 Open the clamps between the reservoir and the Hemosep Cell Concentrator Bag. Allow a maximum of 500ml of the collected blood to drain into the Hemosep Cell Concentrator Bag. Close the connector clamps once full.

! Important

Filling the bag with more than 500ml will result in less efficient concentration of the blood.

Step 14 The Hemosep Shaker will run for 20 minutes. A processing time of 20 minutes will return a PCV level of around 38-40% from a starting haematocrit level of around 20%.

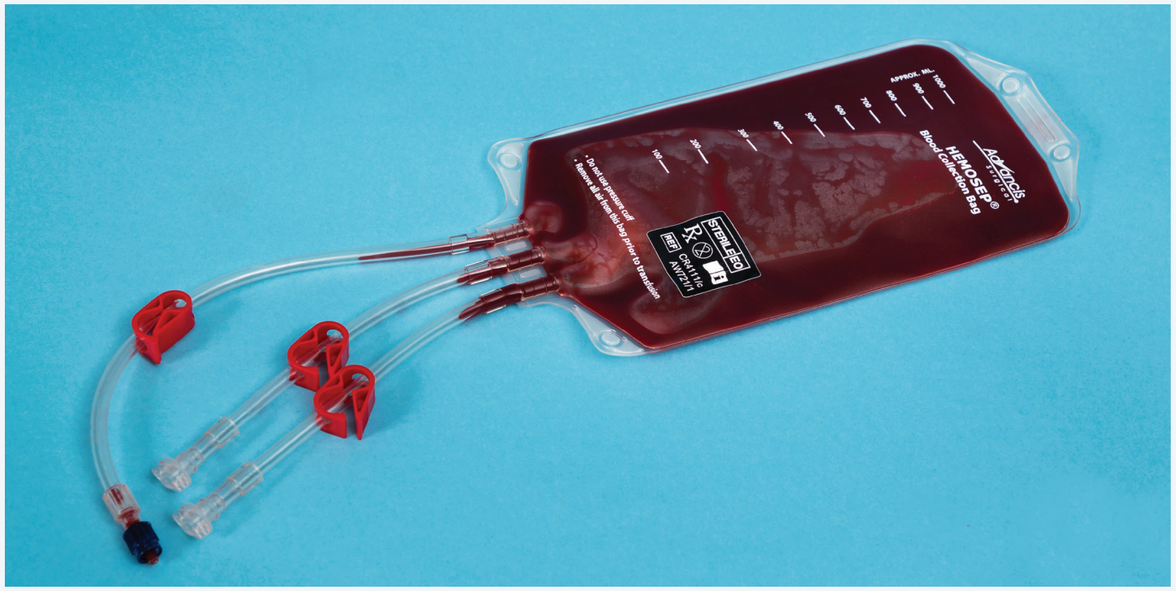
Step 15 Connect the Hemosep Blood Collection Bag to the Hemosep Cell Concentrator Bag via line C. Open the clamps between the bags. Lift the Hemosep Cell Concentrator Bag off the Hemosep Shaker and hold up to allow the concentrated blood to gravity feed into the Hemosep Blood Collection Bag.

Step 16 When all the concentrated blood has drained into the Hemosep Blood Collection Bag, close the clamps and disconnect. Place the used Hemosep Cell Concentrator Bag into the clinical waste as per local protocol.

Note: If you have processed more than one bag of blood (steps 10-14), you can also add this to the same blood collection bag (steps 15 -16)

The blood is now ready for transfusion back into the patient.

Prepare for transfusion



Step 17 Connect the Hemosep Blood Collection Bag to the patient, using your departments' normal blood giving set & filters as per local protocol.
Label the Hemosep Blood Collection Bag with the date, time collected and patient's details.
Begin autologous transfusion.

Indications, contraindications and cautions

The decision to collect blood is based on a number of factors including:
- Anticipated blood loss for a particular surgical procedure
- Risk factors for bleeding
- Low preoperative haemoglobin
- Religious or other objections to receiving allogeneic (donor) blood.

Patient selection for Hemosep cell salvage is at the discretion of the surgeon and anaesthetist caring for the patient.

Each organisation should refer to its local policy for use of intraoperative cell salvage.

Indications for use

The use of Hemosep for intraoperative cell salvage is recommended in a variety of medium to high blood loss procedures including cardiac, orthopaedic, spinal, renal and vascular surgeries. Patient selection for Hemosep cell salvage is at the discretion of the surgeon and anaesthetist caring for the patient.
Each organisation should refer to its local policy for use of intraoperative cell salvage.

Contraindications

Hemosep cell salvage should not be used in the following situations:
- Bowel contents in the surgical field (the surgical field may be irrigated with copious normal saline (0.9% NaCl) before resuming Hemosep cell salvage).
- During obstetric surgery due to the risk of amniotic fluid in the surgical field.
- Heparin induced thrombocytopenia if heparin is the only available anticoagulant (a citrate anticoagulant solution may be used instead).

Cautions

- Pleural effusions should not be aspirated and should be drained prior to Hemosep cell salvage.
- The decision to use Hemosep cell salvage in patients with abnormal red cell disorders, such as sickle cell disease, should be made by a clinician on an individual patient basis.
- The use of Hartmann's Solution will inhibit the action of citrate based anticoagulants (e.g. ACD) if used as an irrigant.
- Where possible, all air in the Hemosep blood collection should be evacuated prior to reinfusion. Do not use a pressure cuff as there is a risk of air embolus.
- The decision to use blood that is potentially contaminated with malignant cells should be made by the clinicians caring for the patient, taking into account the latest evidence, considering the risk and benefits for the individual patient. Clinicians should consider using a leucoreduction filter to reinfuse the blood.[1]
- During high blood loss periods, it may become necessary to increase the suction at the request of the surgical team. The vacuum should be returned to standard level (100-150mmHg) as soon as bleeding is under control. This will minimise damage to the RBC and haemolysis.[1]
- Where possible the tip of the wand should be immersed in blood and NOT skimmed across the surface of tissues or pools of blood. Skimming results in a large quantity of air mixing with the aspirated blood, which increases haemolysis and therefore reduces the number of viable RBC for reinfusion.[1]
- When substances not licensed for intravenous (IV) use are used within the surgical field and could potentially be aspirated into the collection reservoir. In this instance, a separate standard theatre suction should be used to aspirate the surgical field. The surgical field should then be irrigated with copious normal saline (0.9% NaCl) before resuming Hemosep cell salvage. Examples of non-IV materials that should not be aspirated into the Hemosep cell salvage system include: antibiotics not licensed for IV use, Iodine, topical clotting agents, methyl methacrylate (orthopaedic bone cement).
- The presence of infection may result in contamination of the salvaged blood. The decision to use blood that is potentially contaminated with bacteria should be made by the clinicians caring for the patient, taking into account the latest evidence, considering the risk and benefits for the individual patient.
- Where gastric/pancreatic secretions could be aspirated into the system as they may cause enzymatic haemolysis.

References

1. Section 8 – Intraoperative Cell Salvage Education Workbook. https://transfusionguidelines.org/transfusion-practice/uk- cell-salvageaction- group/intraoperative-cell-salvage-education

Contaminants and their potential effects

Potentially Harmful Substance	Potential Effects	Recommendations
Alcohol	Will cause haemolysis. May cause serious reaction if administered intravenously.	Do not aspirate into system.
Antibiotics not licensed for parenteral use	Potential serious reactions. May be delivered at higher than normal concentrations.	Do not aspirate into system. Irrigate area before resuming blood salvage.
Avitene (absorbable collagen haemostat)	May stimulate coagulopathy if administered intravenously. May clot in collection reservoir.	Do not aspirate into system.
Betadine	Will cause haemolysis.	Do not aspirate into system.
Clotting adjuncts (microfibrillar products, topical thrombin)	May stimulate coagulopathy if administered intravenously, May clot in collection reservoir.	Do not aspirate into system.
Faecal contamination	Sepsis	Do not aspirate into system.
Fibrin Glue	May activate clotting. May clot in collection reservoir.	Do not aspirate into system. Irrigate area before resuming blood salvage.
Gastric fluids	Contains proteolytic enzymes that may activate clotting. May clot in collection reservoir. May cause haemolysis.	Do not aspirate into system. Irrigate area before resuming blood salvage.
Hydrogen Peroxide	Will cause haemolysis.	Do not aspirate into system.
Methyl methacrylate (bone cement)	May cause heat produced haemolysis. May cause circulatory collapse. Possible clogging of the system.	Do not aspirate into system. Irrigate area before resuming blood salvage.
Sterile water	Will cause haemolysis.	Do not aspirate into system.
Tumour cells	Possible potential for metastasis.	Tumour cell aspiration and transfusion of blood containing tumour cells is a decision to be made by the physician in charge of the case.

Troubleshooting

Processed blood hasn't reached expected PCV levels	1. Ensure Hemosep Cell Concentrator Bag is primed no more than 3 minutes in advance. Priming the Hemosep Cell Concentrator Bags with saline more than 3 minutes in advance of collected blood being added will inactivate the superabsorber. The saline will form cross links in the superabsorber and it will not work. 2. Ensure the Hemosep Cell Concentrator Bag contains no more than 500ml of blood. Over filling the bags will make them less effective. It is better to use multiple bags. 3. Do not stack Hemosep Cell Concentrator Bags on top of each other whilst on the Hemosep Shaker. This reduces the specially calculated wave form that the Hemosep Shaker is producing to move the blood across the membrane making it less efficient. 4. Do not over dilute the collected blood with either anti-coagulant, or by suctioning up large volumes of wash from the surgical site. A lower starting haematocrit level will result in lower PCV post processing.
Suction inlet port is blocked	Change to the other suction inlet port and cap off blocked port.
Suction wand blocked	Use second suction wand supplied in intraoperative kit.
Clots in reservoir	Check to make sure the anti-coagulant is running. Change reservoir for a new one and discard blood with clots.
Visible fat in patient blood bag	Consider using a Lipiguard transfusion filter.
Substance of concern suctioned into collection reservoir	Stop cell salvage and use alternative suction to clear the area then irrigate area with copious amounts of normal saline. Replace reservoir and suction aspiration line and continue salvage.
Temporary loss of power to machine	Blood processing will continue while the Hemosep Shaker is static during a temporary loss of power although at a much slower rate. Make a note of how long the bag has been processed for as the Hemosep Shaker timer will reset after 5 seconds without power. When power is restored, continue to process the blood on the Hemosep Shaker for the remainder of the original time.
Anti-coagulation solution spilling into the surgical field	Check the suction is on and the suction line is not blocked. Check the suction port at the reservoir is patent.

Hemosep®: Revolutionary Cell Salvage

Frequently asked questions

In which surgical procedure is Hemosep best suited?

Hemosep is recommended in a variety of medium to high blood loss procedures including cardiac, orthopaedic, spinal, renal and vascular surgeries.

What is the overall quality of blood returned to the patient?

The blood product returned after concentration is very similar to that of the pre-surgical blood. In relation to plasma free haemoglobin, we have not detected any significant levels of haemolysis with this device.

How is white blood cell (leukocyte) activation managed?

White blood cell dynamics associated with Cardio Pulmonary Bypass result in a high white blood cell population, but these are largely in an inactivated state. If there are concerns about the white blood cell population of the concentrate, the blood can be leukocyte filtered.

Will Hemosep aid in the reduction of post-operative bleeding?

With traditional cell salvage, only red blood cells are salvaged and therefore there is a reduction in clotting factors. Hemosep retains all blood components, retaining the residual clotting factors in the concentrate, therefore helping in the reduction of post-operative bleeding (see table 1).

Table 1: *Levels of post-operative bleeding following use of Hemosep*

	Hemosep® (N=52)	Control (N=50)
Postoperative Bleeding (24 h) (cc)	545±180	725±200

Will Hemosep remove damaged red blood cells and white blood cells as with traditional cell salvage?

Hemosep will remove damaged or fragmented cells below the pore size.

Do you have details of the effect of activated platelet levels and any potential issues surrounding it?

There is no suggestion that platelets are activated by the process.

What is the micron size of clotting factors?

Clotting factors are proteins in general and are sub-micron in size.

Can Hemosep recycle the clotting factors as these are below the pore size?

Proteins involved in the clotting cascade will be removed by the device as these are less than the unique pore size. However, there are residual clotting factors in the concentrate in proportion to the amount of plasma left in the mix.

Does the bag filter out the anticoagulant?

The level of anticoagulant in the concentrate for transfusion is fairly low and has no apparent impact on effects of transfusion observed in clinical trials. However the activated clotting time (ACT) is reduced and should be monitored with any appropriate action taken.

What procedures are available to quality assure the processed blood?

Measure PCV and do a full blood count if deemed necessary. There are no other methods for this.

What trials and safety tests have been undertaken?

Full clinical trials have taken place. Following publication of the initial data, validation sources were used such as NHS Blood and Transplant (NHSBT). Full CE approval was granted for the medical device following initial assessments and positive trial outcomes showing no adverse responses to the filtration process.

Hemosep®: Revolutionary Cell Salvage

Hemosep cell salvage training record

Trainee name	
Trainer name	
Hospital	
Department	
Job title	
Date of training	

Topics:	Trainee Signature	Trainer Signature
Introduction to cell salvage & blood:		
The Hemosep Device		
Operation of Hemosep		
Set-up for blood collection		
Preparing Hemosep Cell Concentrator Bag		
Processing the collected blood		
Indications, contraindications and cautions		
Indications		
Contraindications		
Cautions		
Contaminants and their potential effects		
Troubleshooting		
Understanding reasons expected PCV is not reached		
Additional trouble shooting		

Supervised Clinical Training record in Hemosep cell salvage

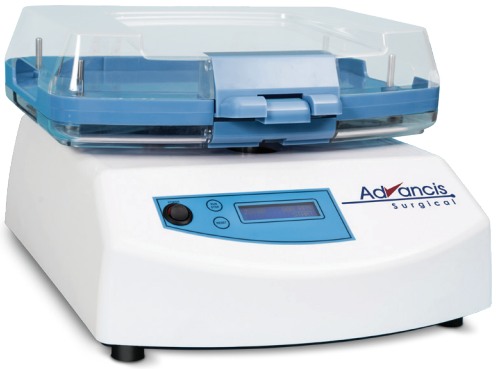
Trainee name: .....

Case no	Date	Operation type	Set up and collection	Process and transfuse	Supervisor comment / signature
1					
2					
3					
4					
5					
6					
7					
8					

Hemosep®: Revolutionary Cell Salvage

Notes

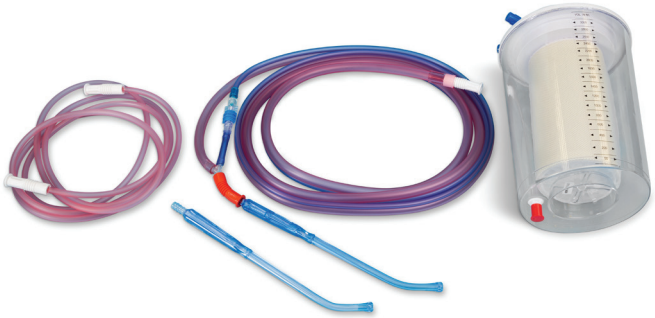
Hemosep Ordering Information



Shaker Code: **CR4213**

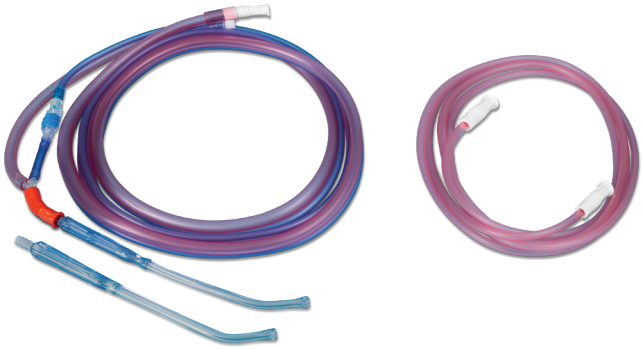
Cell Concentrator Pack Code: **CR4226**

Including: Blood collection bag & cell concentrator bag



Intra-Operative Kit Code: **CR4428**

Including: Blood Reservoir, Wand Set & Tubing



Suction Kit Code: **CR4434**

Including: Spare Wand Set and Tubing

Intra-Operative Stand Code: **CR4429**

MADE IN THE UK

Advancis Surgical is a trading name of Brightwake Ltd.
Lowmoor Business Park, Kirkby-in-Ashfield,
Nottingham, NG17 7JZ, England

Tel: +44 (0)1623 751500
Fax: +44 (0)871 264 8238
Email: info@advancissurgical.com

Advancis Surgical

www.advancissurgical.com

MAR499/v4