

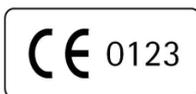
H.E.L.P. Plasmät[®] Futura

Brief Instructions for Use SW 3.0x



H.eparin induced
E.xtracorporeal
L.DL
P.recipitation

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SHARING EXPERTISE



CE-marking according to guideline 93/42/EWG
Technical alterations reserved

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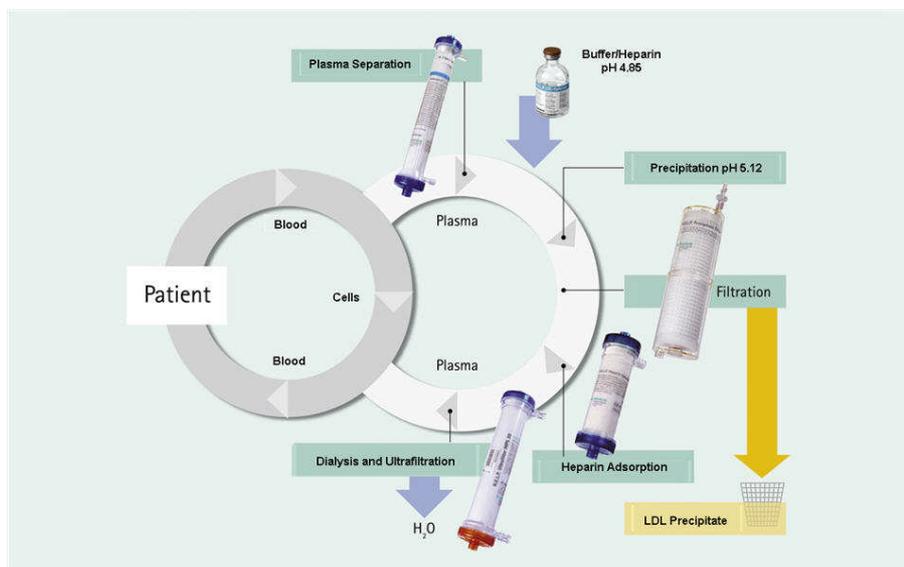
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SHARING EXPERTISE

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Heparin induced Extracorporeal LDL Precipitation



These Brief Instructions for Use are no substitute for the complete Instructions for Use and must only be used considering the information given in the Instructions for Use of H.E.L.P. Plasmac® Futura Set and the Instructions for Use of Plasmac® Futura.

Filters and Lines

1 H.E.L.P. Futura Set consisting of:

- 1 H.E.L.P. Futura Kit
- Base plate with attached venous line, plasma-buffer line, filtrate line, connection line, ultrafiltration line, filter venting line and reinfusion line as well as Haemoselect L 0.5 plasma filter, H.E.L.P. precipitate filter, H.E.L.P. heparin adsorber 400 and H.E.L.P. ultrafilter.
- 1 x 5 l empty bag for rinse solution
- 1 arterial line
- 1 dialysate line
- 3 x 7 l empty bags for dialysate

Solutions

- 1 x 4 l H.E.L.P. acetate buffer (pH 4.85)
- 1 x 40 ml H.E.L.P. heparin sodium (400.000 IU)
- 2 x 3 l H.E.L.P. 0.9 % NaCl saline solution
- 2 x 5 l H.E.L.P. BicEl bicarbonate solution for plasma dialysis
- 1 x 500 ml and 1x 1500 ml H.E.L.P. 0.9 % NaCl bag

Miscellaneous

- Perfusor syringe 30 ml (Omnifix®) for heparin solution
- Heparin 5000 IU/ml
- Puncture needles, cannulas, swabs
- Syringes for blood samples
- Laboratory test tubings, possibly adapters
- Tourniquets, clamps
- Skin disinfectant, gloves

PREPARATION

Machine

- Switch on the machine (main switch on the rear)



An automatic selftest is performed. During this period, neither the pressure transducers nor the load cell may be loaded. The piston pusher of the heparin syringe pump must be lightly pulled back and the clasp must be latched.

- Make sure that you hear the four different alarm signals during the selftest, that you see three rows of figures from 0 to 9, and that the LEDs alongside the screen flash.
- After successful selftest the cursor goes automatically to <End>.
- Press  to go to the Start screen.

Rinse bags

- Each of the 3 l 0.9 % H.E.L.P. NaCl bags must be mixed with 7500 IU heparin.

Bicarbonate bag

- Prepare the 2 bags with H.E.L.P. BicEl bicarbonate solution by transferring the fluid from the small to the large chamber. Thoroughly mix the solution.

Anticoagulation with heparin

- Prepare heparin solution for perfusor syringe 30 ml (Omnifix®), for example for 20 ml heparin solution with 1000 IU/ml
- Mix 4 ml heparin (1ml = 5000 IU) + 16 ml 0.9% NaCl solution.

IV-pole

- IV-pole with
 - 5 l empty bag (connection to the top)
 - 1 heparinized 3 l NaCl bag
 - Load the 2 bags with 1 x 500 ml/1500 ml NaCl.

Load cell

- Load cell with
 - 3 empty bags
 - 1 heparinized 3 l NaCl bag
 - 2 bicarbonate solution bags

H.E.L.P. Futura Set

Attach the H.E.L.P. Futura Kit. Place the plastic plate onto the bottom support. Press the plate against the front and secure the top seat with the upper holder. From the top to the bottom:

- Insert the pump segments of the plasma buffer pump/ultrafiltration pump into the upper pumps (buffer/plasma segment individually).



The pump segment of the ultrafiltration pump (UFP) is inserted correctly as soon as the white marking of the ultrafiltration line is on the left side of the pump (arrow on the pump to the top). Pay attention to the different color coding of the plasma and buffer line and avoid to cross the lines.

PREPARATION

- Insert the two air chambers (filtrate and precipitation chambers) into the level monitoring devices and secure them.
- Screw on pressure transducers of the plasma line, connection line, precipitate line and filtrate line.
- Insert plasma line coming from plasma filter into blood leak detector (BLD).
- Firmly insert the filtrate line to the heparin adsorber into the heparin adsorber clamp (HAK).
- Check that the venous chamber is placed in the holder at the kit.
- Insert the venous line in the safety air detector (SAD) and in the safety air clamp (SAK); screw on the pressure transducer (PV); connect the venous line to the empty bag on the IV-pole.
- Connect the buffer line to the saline bag on the load cell.
- Connect the ultrafiltration line (3-piece) to the 3 drain bags on the load cell.
- Connect the reinfusion line to the connection of the 1.5 l NaCl bag and fill the line manually. Afterwards close the clamp.
- Insert buffer line into the holder provided on load cell.

Arterial line

- Screw the patient-side connection of the arterial line to the 3 l NaCl bag on the IV-pole.
- Insert the pump segment into the blood pump.
- Insert the air chamber into the holder.
- Screw the pressure transducer in front of the pump segment (PA) to the connector in front of the blood pump.
- Screw the pressure transducer behind the pump segment (PBE) to the connector behind the blood pump.
- Screw on the feeder of the arterial line to the plasma filter.



The pump segment of the blood pump is inserted correctly as soon as the red marking of the arterial line is on the left side of the pump (arrow on the pump to the top).

Heparin syringe

- Screw the prepared heparin syringe onto the heparin line. Vent the line by hand up to the T-piece and insert it into the heparin syringe pump.



Safety brace of the heparin perfusor must latch in!
Avoid tilted position of the syringe!

Dialysate line

- Insert the warming bag of the dialysate line with the blue Hansen connector pointing upward into the plate warmer.



The bag must be placed flat on the heating element. The cover of the heating plate must be completely closed with the safety lock!

- Connect the blue Hansen connector to the upper end of the ultrafilter.
- Connect the connections of the dialysate line with the bicarbonate bags.
- Follow the line and insert the pump segment into the dialysate pump.
- Open the seals of the bicarbonate bags.
- Screw the pressure transducer (PDI) to the connector.
- Insert the feed line to the heating plate into the air detector (DAD).



The pump segment of the dialysis pump (DP) is inserted correctly as soon as the blue marking of the dialysate line is on the left side of the pump (arrow on the pump to the top).

PRIMING

Priming



Check again whether all connections are tight and the seals of all bags are open.

- Press  to change to priming.
- The message <W18: Break seals and open all clamps!> is displayed on the monitor.
Confirm with .
- Press  to start the automatic priming and rinsing.
- The message <W01: Plasma pump starts after pressurization blood side> is displayed.

Filling the dialyzer

- When the message <W04: "Turn dialyzer (blue side down)!"> is displayed, turn the dialyzer and press .



Always ensure that the hose lines are not kinked!

Further preparations

- While the machine rinses fully automatically and performs various tests, the following can be prepared:
 - Add 400,000 IU H.E.L.P. heparin sodium to the buffer bag and mix thoroughly.
 - Complete the treatment protocol.
 - Take blood samples (e.g. cholesterol and coagulation status before and after the treatment).
 - Prepare puncture instruments and initial heparin.
 - If required, set therapy parameters.

Rinsing

- When the minimum rinsing volume of 2400 ml is reached after fully automatic rinsing, all pumps stop.
- Confirm the message <W14: Rinsing completed. For further rinsing set new value!> with .
- The <Therapy> function is active in the menu selection (black labeling).
- Confirm the message <W32: Activate therapy mode?> with .

Buffer bag

- Hang the buffer bag onto the load cell and connect the buffer line.
- Remove the NaCl bag from the load cell.

Venous line

- Connect the venous line to the 3 l NaCl bag on the IV-pole.
- Remove the empty bag with the rinse fluid from the IV-pole.

THERAPY

Connecting the patient

- Take the weight and blood pressure of the patient.
- Puncture with the arterial needle, check for correct seating, fix it in place, take blood samples, rinse.
- Puncture with the venous needle, check for correct seating, fix it in place, administer the initial heparin, rinse.
- Confirm the message <W15: Connect buffer, check if seal and clamp are open ! > with .
- Connect the arterial line to the patient.
- Start the blood pump (preset value is 40 ml/min).



Monitor the arterial pressure (PA) as well as the inlet pressure of the blood into the plasma filter (PBE)!

- When the blood circuit has been filled with blood, stop the blood pump.
- Connect the venous line to the patient. Start the blood pump.



Monitor the venous pressure (PV)!
The pressure should be within the range 20 - 60 mmHg.

- Circulate the blood for at least 2 minutes in the plasma filter. In doing so adjust the blood flow step by step monitoring PA, PBE and PV.



CAUTION

Ideal plasma separation without hemolysis

- To avoid hemolysis and to receive ideal plasma separation only start therapy as soon as enough plasma is in the compartment of the plasma filter.

Running the therapy

- Start the therapy with <Start Therapy> and enter the time.
- Adjust the plasma flow step by step monitoring PV and PPL.



RULES:

The plasma flow should be approximately 30% of the blood flow but should not exceed 35 ml/min.

Changes of PPL and TMP must be taken into account when adjusting the plasma flow !

This ensures that the separation of plasma is performed spontaneously.

- Record the values in the log, repeat the recording during the therapy every 30 minutes.



CAUTION

Avoid filter clotting and/or control heparinization.

- The anticoagulation (heparinization) should be controlled with coagulation checks (ACT or PTT)!
- The testing should be done every 30 minutes.
- The sample can be taken from the port of the arterial line.

- At the end of the therapy, the machine switches automatically to the bypass mode.
- Record the time, the treated plasma amount and the therapy time in the log.
- Confirm the message <W06: Therapy completed!> with  and change to the reinfusion mode.
- Press  to confirm when asked <W35: Activate reinfusion?>.

REINFUSION AND TERMINATION

Preparation

- The message <W11: 1) Connect reinfusion and buffer lines to saline solution 2) Clamp plasma line at out of plasma filter 3) Turn plasma and precipitate filters 4) Turn heparin adsorber> is displayed.
- Confirm the performance of the individual steps with .



The blood pump continues running with 40 ml/min. All other pumps stopped.

Plasma reinfusion

- Start the plasma reinfusion by selecting the <Start Plasma> menu item in the menu bar and pressing .
- The default setting of the plasma buffer pump for reinfusion is 30 ml/min.



The blood pump should always turn at least 10 ml/min faster than the reinfusion flow to ensure an imbalance between corpuscular parts and plasma parts during reinfusion process.



If a pressure rise of the PPF and/or PDF occurs, the reinfusion flow has to be reduced.
The blood pump speed can be adjusted independent of the reinfusion flow.

- The machine stops the plasma-side pumps when a reinfusion volume of 400 ml (default setting) has been reached.
- The following message is displayed: <W12: Plasma Reinfusion completed! For Blood Reinfusion stop Blood Pump (do not press 'OK') or for further Plasma Reinfusion press  to proceed.>.



The reinfusion volume can be manually increased up to 1000 ml, if necessary.

Blood reinfusion Part 1

- Stop the blood pump (as long as the blood pump is running the blood reinfusion is not active).
- Under reinfusion type, select <Blood Reinfusion> and confirm by pressing .
- The message <W21: Connect art. line to saline solution bag. Connect reinfusion line to venous chamber> is displayed.
- After having performed these handling steps confirm with .
- Take blood samples.
- Start the blood pump.



After a reinfusion volume of 150 ml, the warning <W41: Open plasma clamp and close venous clamp.> will be displayed.

REINFUSION AND TERMINATION

Blood reinfusion Part 2

- Open the clamp of the plasma line behind the plasma filter and close the clamp on the venous line behind the plasma filter.



The saline is now pressed through the membrane = plasma-side rinsing of the plasma filter.

- When a blood reinfusion volume of 300 ml (default setting) has been reached, the blood pumps stop.
- Remove the venous line from the patient.
- Take the weight and blood pressure of the patient.
- Change to the Start screen by selecting <New Therapy> in the <Additional Functions> menu and confirmation with . The machine can now be used for the next therapy or it can be switched off.

TABLE OF H.E.L.P. PLASMAT FUTURA PRESSURE VALUES

	Work Range ¹ mmHg	Limits ² mmHg	* Function: • Cause of Alarm
Blood-Side Pressures			
PA Arterial pressure	-60 - +10	-150 ÷ +100 (m = -350/+200)	* Monitors the arterial needle • When ↓↓: Hypotension? Needle? In v.v. treatment congestion, muscle pump, local warmth? If necessary, reduction of blood flow
PBE Plasma filter pre-pressure	+90 - +140	PBEref-60 ÷ PBEref+80	* Monitors the plasma filter • When ↑↑: VP? Coagulation? If necessary, reduction of blood and/or plasma flow, rinse plasma filter, change plasma filter • When ↓↓ (rare): VP? Hypotension?
PV Venous pressure	+20 - +50	PVref-20 ÷ PVref+40 (m = window)	* Monitors the venous needle * Should not exceed 60 mmHg • When ↑↑: Needle? Coagulation? Coagulation in ven. chamber? • When ↓↓: Hypotension? Disconnection?
Plasma-Side Pressures			
PPL Plasma pressure	+20 - +50	-10 ÷ +200 (m = -20)	* Regulates the plasma flow: If the pressure sinks below the set PPL threshold, the plasma flow will be reduced. • When ↓↓: Coagulation? Reduce plasma flow, rinse plasma filter, change plasma filter
TMP Transmembrane pressure	+10 - +50	-450 ÷ +70 (m = +200)	* TMP=(PBE+PV)/2-PPL applies * Monitors the plasma filter * Should not exceed 100 mmHg • When ↑↑: Coagulation? If necessary, reduction of blood and/or plasma flow, rinse plasma filter, change plasma filter
PPF Precipitate filter pressure	+150 - +300	-20 ÷ +450 (m = -50)	* Monitors the precipitate filter * Monitors the buffer bag and line • When ↑↑: Air filter of precipitate filter? Precipitate filter? PDF↑? Dialyzer? • When ↓↓: Buffer bag? Buffer line?
PDF Dialyzer pressure	+120 - +270	-50 ÷ +350 (m = +350)	* Monitors the dialyzer • When ↑↑: Plasma flow? Dialyzer? If necessary, reduce plasma flow, change dialyzer. • When ↓↓ (rare): Plasma flow? Dialyzer leak?
PDPA Prec./adsorber pressure drop	+0 - +150	-450 ÷ +350 (m = 200)	* PDPA=PPF-PDF applies * Monitors the precipitate filter and the heparin adsorber • When ↑↑: Precipitate filter? Heparin adsorber?
PDI Dialysate pressure	+60 - +80	-50 ÷ +450	* Monitors the dialysate flow • When ↑↑: Warming bag? Dialysate line? Empty bag? • When ↓↓ (rare): Bicarbonate bag?

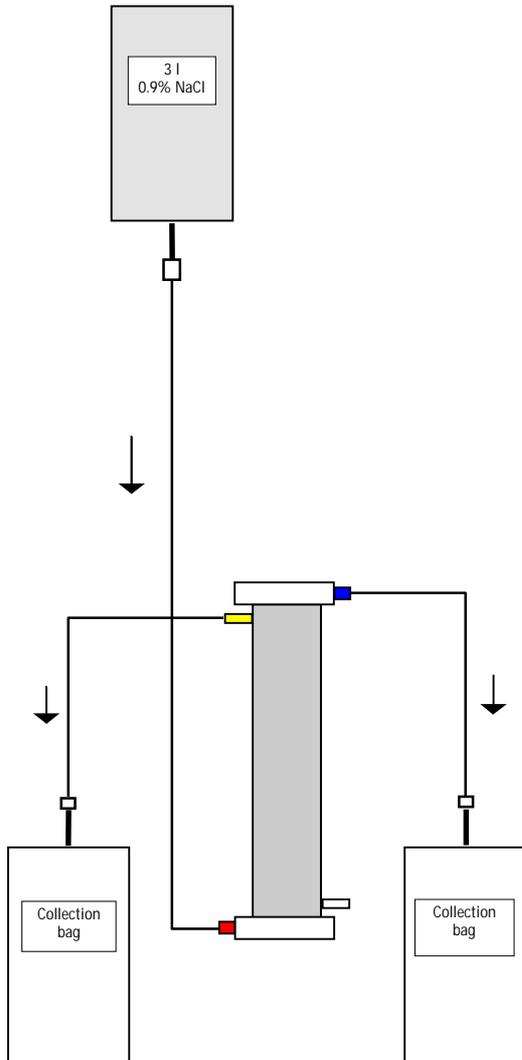
¹ These pressure values are valid for a normal hematocrit, blood flow 60-120 ml/min and plasma flow 20-35 ml/min

² Above the limits, the max. system pressure is still at 450 mmHg

m= these parameters can still be set individually by the user.

Changing the Plasma Filter

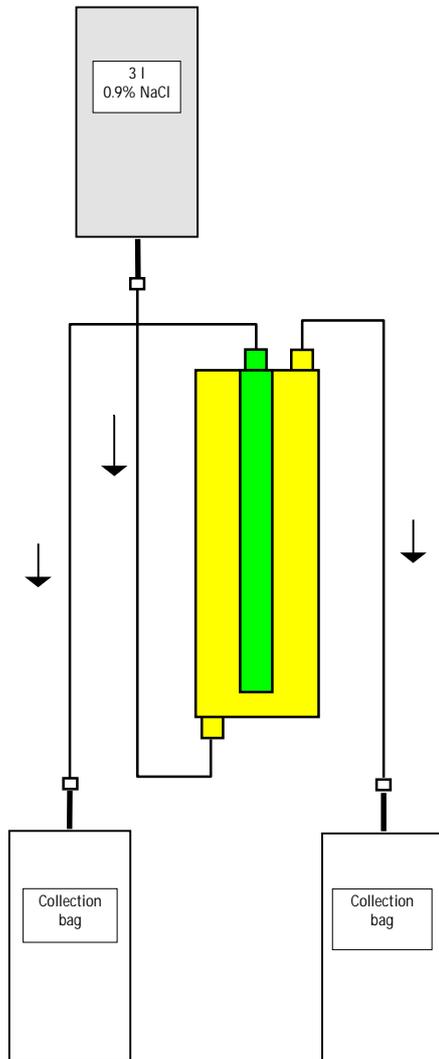
Material	Article number
Haemoselect L 0,5	7061007C
2 x collection bags	7210929
3 l H.E.L.P. 0.9% NaCl solution	4107
3 connection lines	7210934
7500 IE Heparin	



- Mix 7500 IU heparin into the H.E.L.P. 0.9% NaCl solution.
- Attach a connection line to the NaCl solution, fill the line and connect it with the blood-side inlet of the filter.
- Attach the remaining connection lines and the collection bags as shown in the figure with the plasma and blood side of the filter and clamp shut the line on the plasma side.
- Allow the rinse solution to flow by means of gravity into the blood-side collection bag.
- Hold the filter so that it is filled from the bottom to the top and thoroughly vented in the process.
- Open the plasma-side line when approximately half of the rinse solution has flown into the blood-side collection bag and clamp shut the blood-side line. Continue to rinse.
- Clamp shut all connection lines when the remaining rinse solution has flown through (be careful that no air enters the filter!) and remove the bags.
- Stop the blood pump, clamp shut the arterial and the venous plasma line, remove the old filter and connect it with the new plasma filter in the correct orientation. Close the old filter with the connection lines.
- Reopen the blood and plasma lines and start the blood pump.

Changing the H.E.L.P. Precipitate Filter

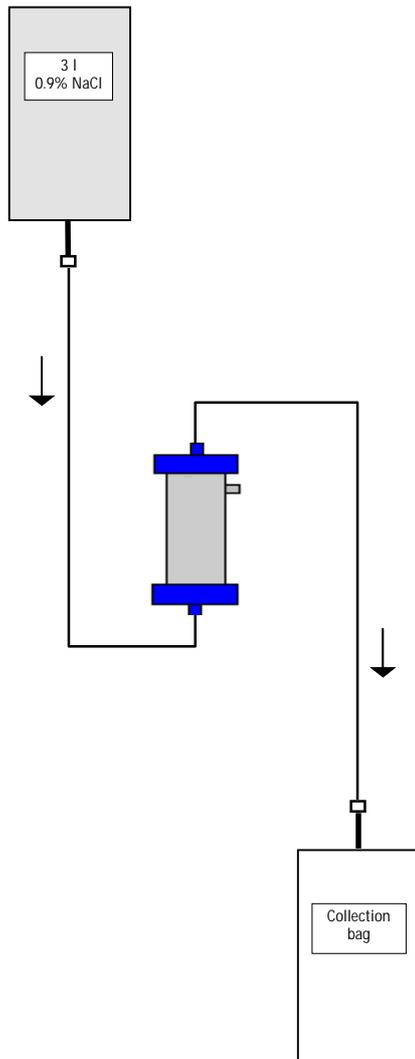
Material	Article number
H.E.L.P. precipitate filter	7210931
2 x collection bags	7210929
3 l 0.9% H.E.L.P. NaCl solution	4107
3 connection lines	7210934



- Attach a connection line with the NaCl solution, fill the line and connect it with the bottom, precipitate-side filter opening.
- Attach the remaining connection lines and the collection bags as shown in the figure with the upper precipitate and filtrate-side opening of the filter and clamp shut the line on the filtrate side.
- Allow the rinse solution to flow by means of gravity into the precipitate-side collection bag.
- Hold the filter so that it is filled from the bottom to the top and thoroughly vented in the process.
- Open the filtrate-side line when approximately half of the rinse solution has flown into the precipitate-side collection bag and clamp the precipitate-side line. Continue to rinse.
- Clamp shut all connection lines when the remaining rinse solution has flown through (be careful that no air enters the filter!) and remove the bags.
- Switch the machine to bypass mode by selecting <Stop Priming> or <Stop Therapy> in the menu bar and confirm with .
- Clamp shut the filtrate line and the circulation line on both sides of the old precipitate filter, remove the old filter and then connect the new filter in the correct orientation with the lines. Close the old filter with the connection lines.
- Reopen the circulation and filtrate lines and continue the interrupted phase by selecting <Start Priming> or <Start Therapy> and confirm with .
- Retain the exchanged filter until the end of the therapy, providing it has no leak. Connect it again in the reinfusion phase and then return the plasma. Increase the reinfusion volume accordingly.

Changing the H.E.L.P. Heparin Adsorber

Material	Article number
H.E.L.P. heparin adsorber 400	7211089
1 x collection bag	7210929
3 l H.E.L.P. 0.9% NaCl solution	4107
2 connection lines	7210934



- Attach a connection line with the NaCl solution, fill the line and connect it with the inlet side of the heparin adsorber.
- Attach the second connection line and the collection bag as shown in the figure with outlet side of the heparin adsorber.
- Allow the rinse solution to flow by means of gravity into the collection bag.
- Hold the adsorber so that it is filled from the bottom to the top and thoroughly vented in the process.
- Clamp shut all connection lines when the remaining rinse solution has flown through (be careful that no air enters the filter!) and remove the bags.
- Switch the machine to bypass mode by selecting <Stop Priming> or <Stop Therapy> in the menu bar and confirm with .
- Clamp shut the filtrate and the connection line on the adsorber, remove the old adsorber and connect the new adsorber in the correct orientation with the filtrate and the connection line (observe the flow direction!). Connect the old adsorber with the connection lines on rinse solution and collection bag.
- Reopen the filtrate and connection lines and continue the interrupted phase by selecting <Start Priming> or <Start Therapy> and confirm with .



CAUTION

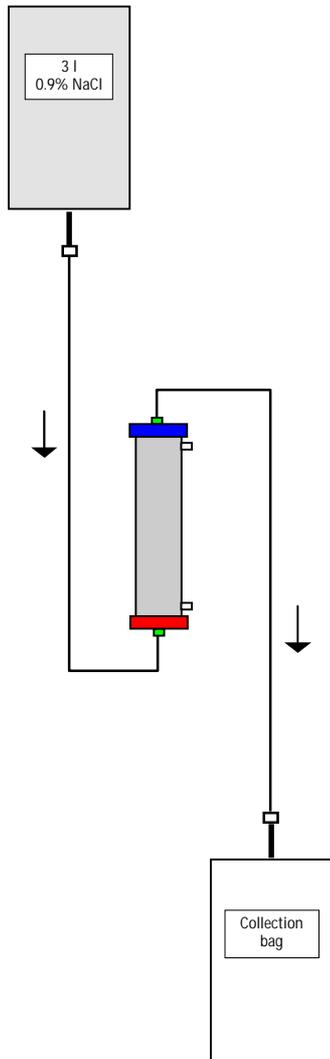
Perform the filling and rinsing of the heparin adsorber considering the flow direction shown by the red arrow at the adsorber's label.

A false flow direction and an upside-down positioning of the heparin adsorber during rinsing and treatment will cause a loss of heparin binding capacity.

- Don't rinse the saline solution too fast into the heparin adsorber to ensure a complete deaeration of the capillaries to avoid remaining air. Air residues within the capillaries will reduce the active surface and therefore decrease the heparin binding capacity.

Changing the H.E.L.P. Ultrafilter

Material	Article number
H.E.L.P. Ultrafilter HIPS 20	7211101
1 x collection bag	7210929
3 l H.E.L.P. 0.9 % NaCl solution	4107
2 connection lines	7210934



- Attach a connection line with the NaCl solution, fill the line and connect it with the red, plasma-side filter opening.
- Attach the second connection line and the collection bag as shown in the figure with the blue, plasma-side filter opening.
- Hold the filter so that it is filled from the bottom to the top and thoroughly vented in the process.
- Clamp shut all connection lines when approximately 1 l rinse solution has flown through (be careful that no air enters the filter!) and remove bags.
- Switch the machine to bypass mode by selecting <Stop Priming> or <Stop Therapy> in the menu bar and confirm with .
- Clamp shut the connection and reinfusion line leading to the dialyzer, remove the old filter and connect the new filter in the correct orientation to the connection and reinfusion line. Connect the old filter with the connection lines to rinse solution and collection bag.
- Plug the Hansen connectors from the old to the new filter (hold old filter horizontally!). Observe the color marking. Insert the new filter with the blue end down into the holder.
- Fill the dialysate side of the filter by manually turning the dialysate pump.
- Reopen the connection and reinfusion lines and continue the interrupted phase by selecting <Start Priming> or <Start Therapy> and confirm with .



Observe the necessary hygienic precautions when preparing, performing and terminating the therapy and when changing parts of the treatment unit.

H.E.L.P. – Futura

Patient:	Treated since:
Date:	Treatment No.:
Physician in charge:	Nurse in charge

Set (Batch no.) BicEL (Batch no.)

Acetate buffer (Batch no.) H.E.L.P. heparin sodium 40 ml (Batch no.).....

Access Initial heparin IU Heparin rate. UI/h

Parameter Overview						
Therapy time h:min						
Plasma volume ml						
Patient Balance g						
Blood flow ml/min						
Plasma flow ml/min						
Dialysate flow ml/min						
Heparin flow ml/h						
Heparin bolus ml						
Heparin quantity ml						
Temperature °C						
PA mmHg						
PBE mmHg						
PV mmHg						
PPL mmHg						
TMP mmHg						
PPF mmHg						
PDF mmHg						
PDPA mmHg						
PDI mmHg						
PPL Threshold mmHg						
Ratio Dial./Plasma						

RR/Pulse before

RR/Pulse after.....

Weight before kg

Weight afterkg

Weight difference kg

Beginningh:min

End..... h:min

Therapy time h:min

Target plasma quantity ml

Actual plasma quantity..... ml

Balance reset: g

Autostop heparin:..... min.

Heparin solution:.....IU/1 ml NaCl

Fibrinogen before mg/dl

Fibrinogen after mg/dl

1. ACT/aPTT:..... sec./time

2. ACT/aPTT:..... sec./time

3. ACT/aPTT:..... sec./time

Quick before..... %

Quick after..... %

INR before:.....

INR after:.....

Complaints after last therapy

Remarks

