

Additional Sheet for the Sera Adsorber Rinsing Kit for the use of Seraph[®] 100 with the multiFiltrate/multiFiltratePRO devices

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**This Additional Sheet contains additional information for using the Seraph[®] 100 adsorber in combination with this kit and the multiFiltrate/multiFiltratePRO devices in CVVHD mode.
The Seraph[®] 100 can only be operated with heparin anticoagulation.**

The Additional Sheet provides instructions for the operator in order to ensure air-free commissioning of the Seraph[®] 100 together with the multiFiltrate/multiFiltratePRO device. Irrespective of this Additional Sheet, the Instructions for Use and, in particular, the warnings and precautions stipulated therein must be observed for the Seraph[®] 100, for the multiFiltrate/multiFiltratePRO device, and for the other products used in the therapy. Observe the information contained in the Seraph[®] 100 Instructions for Use regarding indications, contraindications and side effects.

Treatment using the Seraph[®] 100 is possible with the multiFiltrate device software version 5.41 and multiFiltratePRO software version 5.0.

Usability of Seraph[®] 100

The Seraph[®] 100 must **not** be used if any one of the following circumstances is present:

- The use-by date has passed
- The outer packaging has been damaged or opened
- The Seraph[®] 100 is damaged
- There are loose or missing sealing caps on the Seraph[®] 100

| Consumables | Adsorber Rinsing Kit part no. F00009080 |
|--|--|
| The kit contains: | |
| 1 Adsorber Rinsing System | X |
| 1 rinsing bag, 10 L | X |
| 1 copy of the Instructions for Use for the Adsorber Rinsing System | X |
| 1 copy of the Additional Sheet for the Sera adsorber kit | X |
| The following are also required for treatment: | |
| 1 kit for CVVHD therapy | X |
| 1 Seraph [®] 100 | X |
| 2000 ml 0.9 % NaCl solution for rinsing | X |

| Consumables | Adsorber Rinsing Kit part no. F00009080 |
|--|--|
| 500 ml 0.9% NaCl solution for reinfusion at end of treatment | X |
| 1 additional filter holder for multiFiltrate (part no. 6777921) / multiFiltratePRO (part no. F00007585) | X |
| 1 sterile Luer lock syringe with at least 20 ml NaCl solution | |

◆ **Additional information for the multiFiltrate/multiFiltratePRO Instructions for Use Chapter 4 – Operation**



Note

The Seraph[®] 100 is not pre-filled, and the entry of air **must be prevented during rinsing**.

The instructions provide information for connecting the Seraph[®] 100. If any discrepancies between the screen display and these instructions are encountered during setup, please follow these instructions.

The Seraph[®] 100 **must** be situated upstream of the haemofilter in the blood circuit.

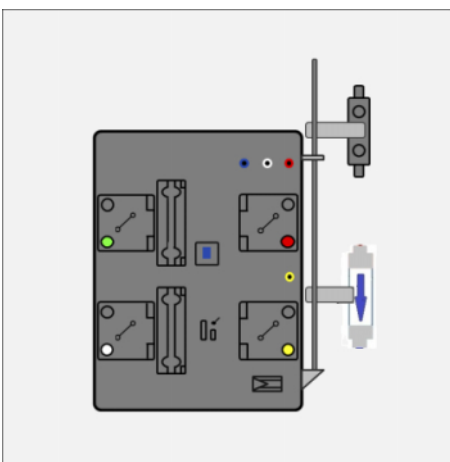
● **Preparing ready for operation/selecting starting conditions**

When preparing ready for operation and selecting the starting conditions, the following settings in particular must be observed:

- Select the treatment mode **CVVHD** and confirm.
- multiFiltrate: Check that the **Reinfusion volume** setting under **System Parameters / Default treatment settings** reads **500 ml** and adjust as needed.
- Complete the starting conditions for the selected treatment mode and confirm.
- Follow the on-screen instructions to set up, fill and rinse the device and start circulation mode.

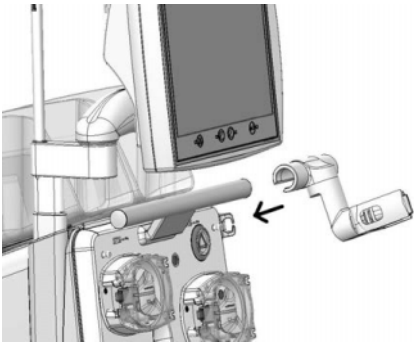
● **Installing an additional filter holder**

multiFiltrate

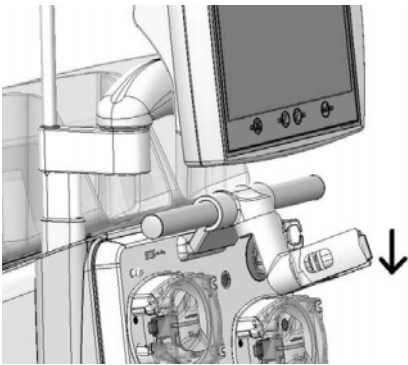


- Attach the additional filter holder for the Seraph[®] 100 to the right IV pole.
- Insert the haemofilter into the upper filter holder.

multiFiltratePRO

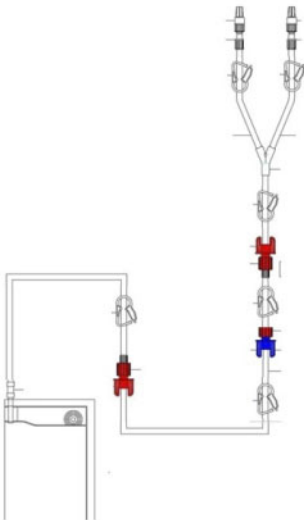


- Slide the holder to the centre of the front handle from the right-hand side.



- Lock the holder in place.

● Preparing the rinsing system

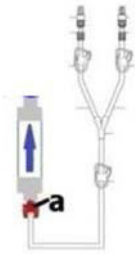


- Hang 2000 ml NaCl solution on the IV pole.
- Insert the Seraph[®] 100 into the filter holder (arrow pointing down).
- Hang the rinsing bag on scales III and IV.
- Tighten all connectors on the rinsing system.
- Close all clamps.
- Connect the rinsing system to the NaCl solution.
- Connect the rinsing system to the rinsing bag.
- Clip the rinsing system into the tube holder on the filter holder.

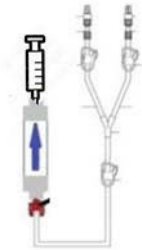
● **Filling the Seraph® 100**



- Connect rinsing system connector (a) (red) to the Seraph® 100 inlet. Keep the sealing cap on the Seraph® 100 outlet closed.



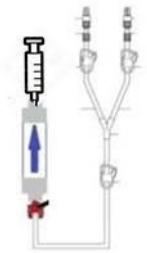
- Turn the Seraph® 100 (arrow pointing up).
- Remove the sealing cap from the Seraph® 100 outlet.
- Open the clamps between the Seraph® 100 and the NaCl bag.
- If necessary, break the cones on the solution bag.
- Fill the Seraph® 100 until NaCl solution comes out of the Seraph® 100.
- Close all clamps.



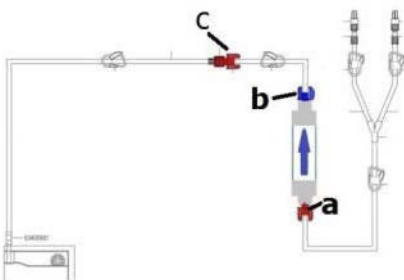
- Place a sterile syringe (Luer lock) containing at least 20 ml NaCl solution on the Seraph® 100 and ensure that it is free from air.



- Turn the Seraph® 100 (arrow pointing down).
- Open the clamps between the Seraph® 100 and the NaCl solution.
- Using the syringe, push any remaining air bubbles into the NaCl bag.
- Close all clamps between the Seraph® 100 and the NaCl solution.

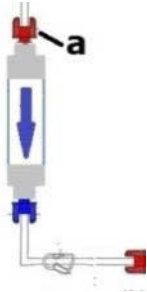


- Turn the Seraph® 100 (arrow pointing up).
- Remove the syringe.

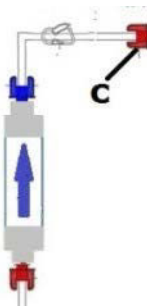


- Connect rinsing system connector (b) (blue) to the Seraph® 100 outlet.
- Open all clamps.
- Rinse the Seraph® 100 with at least 1000 ml NaCl solution.
- Using your hand, knock gently to remove any residual air.
- Once the rinse volume has been reached, close **all** clamps.

- **Connecting the Seraph® 100**



- Stop the blood pump.
- Turn the Seraph® 100 (arrow pointing down).
- Remove rinsing system connector (a) (red) from the Seraph® 100.
- Remove the filter connector (red) from the haemofilter and connect it to the Seraph® 100.



- Turn the Seraph® 100 (arrow pointing up).
- Connect the rinsing system connector (c) (red) to the haemofilter.
- Open the clamp (white) between the Seraph® 100 and the haemofilter.
- Remove the NaCl solution, rinsing system and rinsing bag from the device.
- If necessary, start the blood pump and continue circulation.

- **Connecting the patient**

- Follow the on-screen instructions to connect the patient.

- **Treatment**

The following information must be observed when starting the treatment:

- A blood flow of 100 – 350 ml/min is recommended.



Note

TMP discrepancies will occur if adsorbers are used in the blood circuit of a dialysis treatment.

The displayed TMP will be higher than the value shown in a standard CVVHD treatment. Balancing and ultrafiltration are carried out in accordance with the treatment specifications.

In addition to the causes which occur within the scope of a dialysis treatment, an incipient coagulation in the Seraph® 100 may also cause a gradual increase in the TMP and/or filter inlet pressure.

- **Terminating the treatment**

The end of treatment must be initiated after no more than 5 hours.



Note

In the event that blood reinfusion is not possible due to coagulation, proceed with an end of treatment **without blood reinfusion**.

The following must be observed:

- Hang 500 ml NaCl solution on the IV pole.
- Turn the Seraph[®] 100.
- Perform reinfusion.
- If necessary, reset the default treatment settings for the next treatment.