Peritoneal Dialysis

stay•safe® CAPD/DPCA
Training Manual

Fresenius Medical Care
The ultimate system for your safety

stay•safe®
a new generation of CAPD systems

stay•safe® is environmentally friendly

The new Fresenius Medical Care CAPD generation stay•safe® is manufactured from Biofine®, Biofine® is a material from the group of Polyolefines developed by Fresenius Medical Care research.

The Biofine® material for the stay•safe® components is environmentally friendly – from production to use and later disposal. When incinerating, only carbon dioxide and water are produced, which means no hydrochloric acid, dioxins or furans are formed.

stay•safe® is safe and easy to handle

The heart of the new stay•safe® is the revolutionary DISC. This central control switch regulates all treatment steps such as

1. Outflow
2. “Flush”
3. Inflow and inflow rate
4. Automated closing of the system with the PIN

The sequence of the individual steps is controlled by simply turning. Operating errors are essentially excluded. Clamps and breaking cones are not necessary.
The colour coding and the box design with therapy indicators and large wraparound label clearly identify the strengths of glucose and calcium of Fresenius Medical Care's peritoneal dialysis solutions.

A braille system utilising cutouts identifies the different glucose strengths.

Colour coding for glucose strengths

Colour coding for calcium strengths

Coloured caps identify the glucose strength on the bags.

Glucose 1.5%
Glucose 2.3%
Glucose 4.25%
Your instructions for the stay•safe® system

These instructions will provide you with information on how to use the stay•safe® system. It is part of your CAPD-training provided by your dialysis center.

stay•safe® is a CAPD double bag system for single use. It allows you to make a safe disconnection with the catheter adaptor already closed. The proven PIN technology ensures the contamination-safe inline sealing of the system.

The DISC

1. Outflow
2. Flush
3. Inflow and inflow speed
4. Automatic sealing of the system with the PIN

The Organizer

The Organizer can be used on the infusion pole with an appropriate Holder, but also on a table without a support. Four suction cups ensure the secure attachment to the table.

a. Inserted DISC
b. Catheter extension with disinfection cap
c. DISC protection cap
d. New disinfection cap
1. Preparation

Place the disposables and auxiliary materials on the clean work surface

- Wash hands before preparing the material
- Close doors and windows
- Take off woolen clothing, tie, scarf, wrist watch, and jewellery
- Place the infusion pole in position
- Clean the work surface
- Material needed:
  - staysafe® system in outer wrapper, preheated
  - Wrapped disinfection cap
  - Organizer
  - Face mask
  - Hand disinfectant (e.g. Frekasept® 80)
  - Hand wash (e.g. Freka®-SOFT)
- Check the glucose concentration, expiry date and the volume of the solution as well as the bag and the outer wrapper for possible damage

Only use the solution if the outer wrapper is not damaged

2. Opening the outer wrapper

- Put on face mask
- Tear slowly down from the pre cut area on the outer wrapper
- Open outer wrapper carefully to avoid touching the DISC
- Open the packaging of the disinfection cap and leave it in the packaging
- Make catheter extension accessible
3. Washing hands

- Wash your hands thoroughly with a liquid soap (e.g., Freka®-SOFT) paying attention to the areas between the fingers
- Dry thoroughly using disposable towels

4. Checking the solution bag

- Press lightly on the solution bag
- Take the solution bag out of the open outer wrapper and check whether the solution is clear
- Hang the solution bag onto a hook on the infusion pole. Separate the drainage bag from the solution bag

Never use the solution if the bag is damaged or the fluid looks cloudy!

5. Inserting the DISC into the Organizer

- Unroll the line between the solution bag and the DISC
- Press the DISC into the Organizer
- Press the lines into the line guides of the Organizer
- Unroll the line between the DISC and the drainage bag and hang the drainage bag onto the lower hook of the infusion pole
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6. Inserting the disinfection cap

- Insert the disinfection cap into the left-hand Holder of the Organizer
- Make sure that the cap is inserted completely into the Organizer

Left-handed persons place the disinfection cap into the right-hand Holder of the Organizer.

7. Inserting the catheter extension

- Take the catheter extension and insert it into the right-hand Holder of the Organizer
- Ensure that the catheter extension is inserted completely into the Organizer
- Ensure that the clamp is closed

Left-handed persons place the catheter extension into the left-hand Holder of the Organizer.

8. Disinfecting hands

- Disinfect your hands with suitable disinfectant (e.g. Frekasept® 80)
- Rub your hands until they are dry
9. Removing the protection cap of the DISC

- Unscrew the protection cap of the DISC and discard it

10. Connecting to the system

- Unscrew the catheter extension from the disinfection cap and screw onto the DISC

The used disinfection cap (with the used PIN) remains in the Organizer

11. Outflow

- Open the clamp on the catheter extension

The DISC is automatically in the outflow ("\(\bullet\)") position. The outflow procedure starts
12. Flush

- Ensure that the outflow has completed
- Turn the control switch of the DISC clockwise to the position “●●●”

The flush process starts. The flushing is now performed with fresh solution into the drainage bag.

13. Inflow

- Turn the control switch of the DISC clockwise until you reach the position “○●●●”

Turning the control switch of the DISC between the three dots (“○●●●”) makes it possible to control the flow rate:

○ No inflow
● Half inflow rate
●● Full inflow rate

14. Safety lock with PIN – security step

After the inflow has been completed

- Turn the control switch of the DISC to the very end position of the (“●●●●●”)

The PIN will be released and introduced into the catheter extension automatically (safety lock)

- If you have to interrupt the treatment at any step, you can turn the control switch at any time to position “●●●●●” in order to activate the safety lock with the PIN
15. Closing the clamp

- Close the white clamp on the catheter extension.

16. Removing the protection cap

- Unscrew the protection cap from the new disinfection cap
- Screw the protection cap onto the used disinfection cap

17. Disconnecting

- Unscrew the catheter extension of the DISC

The PIN remains firmly in the catheter extension
18. Screwing the catheter extension onto the disinfection cap

- Screw the catheter extension onto the new disinfection cap and immediately
- Remove the catheter extension from the Organizer

The PIN is visible through the transparent cap

19. Closing the DISC

- Take the used disinfection cap out of the Organizer
- Turn the cap and screw the open end onto the DISC

20. Checking the drained dialysate; disposal

- Check the drained dialysate. Refer also to the information of your dialysis center on how to proceed (e.g. weighing of the drained dialysate)
- If the dialysate is cloudy, please contact your dialysis center immediately and keep the dialysate for laboratory analysis
- If the dialysate is clear remove the stay•safe® system from the infusion pole and the Organizer and discard it
21. Prepare the new bag

- Take a new bag
- Check the glucose concentration, expiry date and the volume of the solution as well as the bag and the outer wrapper for possible damage
- Turn the bag around with the drainage bag on top
- Place the bag in the outer wrapper on the heating plate
- Turn on the PD-THERMOSAFE®plus
Information

Composition: 1 litre of the ready-to-use solution contains:

<table>
<thead>
<tr>
<th>Active substances</th>
<th>CAPD/ DPCA 2</th>
<th>CAPD/ DPCA 3</th>
<th>CAPD/ DPCA 4</th>
<th>CAPD/ DPCA 17</th>
<th>CAPD/ DPCA 18</th>
<th>CAPD/ DPCA 19</th>
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</thead>
<tbody>
<tr>
<td>Sodium chloride</td>
<td>5.786</td>
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<td>5.786</td>
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<tr>
<td>Sodium lactate</td>
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<td>3.925</td>
<td>3.925</td>
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<tr>
<td>(as sodium lactate solution)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Calcium chloride 2 H₂O</td>
<td>0.2573</td>
<td>0.2573</td>
<td>0.2573</td>
<td>0.1838</td>
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<tr>
<td>Magnesium chloride 6 H₂O</td>
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<tr>
<td>Anhydrous glucose</td>
<td>15</td>
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<td>22.73</td>
<td>15</td>
<td>42.5</td>
<td>22.73</td>
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<tr>
<td>(as glucose-monohydrate)</td>
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**Active substances (mmol/l)**

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<tr>
<th>Na⁺</th>
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<tbody>
<tr>
<td>Ca²⁺</td>
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<td>1.25</td>
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<tr>
<td>Mg²⁺</td>
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<td>0.5</td>
<td>0.5</td>
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<tr>
<td>Cl⁻</td>
<td>103.5</td>
<td>103.5</td>
<td>103.5</td>
<td>102.5</td>
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<tr>
<td>Lactate</td>
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<td>35</td>
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<tr>
<td>Theoretical osmolarity (mosm/l)</td>
<td>358</td>
<td>511</td>
<td>401</td>
<td>356</td>
<td>509</td>
<td>399</td>
</tr>
</tbody>
</table>

**Excipients:** Water for injections, hydrochloric acid, sodium hydroxide.

**Indications:** End-stage chronic renal failure of any origin treated with peritoneal dialysis.

**Contraindications:**

**Solution related:** Solutions containing 1.75 mmol/l calcium: Hypokalaemia, hypercalcaemia. Solutions containing 1.25 mmol/l calcium: Hypocalcaemia, hypercalcaemia. Solutions containing 2.3% or 4.25% glucose additionally: Reduced body fluids (hypovolaemia) and low blood pressure. A hereditary fructose intolerance must be excluded prior to administration.

**Treatment related:** Recent abdominal surgery or injury; severe abdominal burns; extensive inflammation of the abdominal skin (dermatitis) in the region of the catheter; peritonitis; abdominal perforation; a history of multiple operations with adhesions or fibrous adhesions; inflammatory bowel diseases (Crohn’s disease, ulcerative colitis, diverticulitis), intra-abdominal tumours; ileus; umbilical, inguinal or other abdominal hernia; internal or external abdominal fistulae; pulmonary disease, esp. pneumonia; sepsis; lactacidosis; extreme malnutrition (cachexia) and weight loss, particularly in cases in which an adequate protein supplement is not guaranteed; in rare cases of uraemia, which cannot be managed by PD, extreme hyperlipidaemia; in patients who are physically or mentally incapable of performing peritoneal dialysis as instructed by the doctor. Please note that premature discontinuation of peritoneal dialysis therapy may have life-threatening consequences, if no other renal replacement therapy is carried out. Pregnancy and breast-feeding: Only after evaluation of benefit versus risk for mother/child by the treating doctor. Children: The dialysate volume should be reduced in accordance with age, size and body weight. Elderly patients: The increased incidence of hernia should be taken into account.

**Side effects:** Possible treatment related side effects: Peritonitis; infections of the catheter exit site and tunnel; sepsis; Peritoneal loss of proteins (5–15 g/day), amino acids (1.2–3.4 g/day) and water-soluble vitamins, hypoproteinaemia; transport characteristics of the peritoneal membrane may change during long-term peritoneal dialysis primarily indicated by a loss of ultrafiltration. Abdominal distension; in- and outflow disturbances of the dialysis solution; hernia; shoulder pain; breathing difficulties caused by elevation of the diaphragm, diaphragm and constipation. Possible solution related side effects: Disturbances of electrolyte balance such as hypercalcaemia (solutions containing 1.75 mmol/l calcium), hypocalcaemia (solutions containing 1.25 mmol/l calcium), hypercalcaemia. Low blood pressure and hypovolaemia (solutions containing 2.3% or 4.25% glucose); hyperhydration and dehydration; hyperglycaemia; dyslipoproteinaemia; increase in body weight.

**Drug interactions:** The use of these peritoneal dialysis solutions can lead to a loss of efficacy of other medicinal products if these are dialysable through the peritoneal membrane. A distinct reduction of serum-potassium-level can increase the frequency of digitalis-associated adverse reactions. For solutions containing 1.75 mmol/l calcium the concomitant administration of calcium-containing medicinal products or vitamin D may cause hypercalcaemia. The use of diuretic agents may result in water and electrolyte imbalances. In diabetic patients the daily dose of blood sugar reducing medication must be adjusted to the increased glucose load.

**Warnings and precautions:** Do not use unless solution is clear and container undamaged. Any unused portion of the solution is to be discarded. Do not store above 25°C. Do not refrigerate or freeze. Keep out of the reach of children. Addition of medication to the dialysis solution is only to be undertaken on the instructions of a doctor. Aseptic conditions must be maintained during exchange of the dialysate bag. Levels of serum electrolytes, blood sugar, serum protein, parathyroid hormone and concentrations of creatinine and urea as well as acid-base balance and fluid balance should regularly be monitored.

**Date:** January 2004

**Fresenius Medical Care Deutschland GmbH**

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This training manual is intended as an aid in supporting the training and education of PD patients. It is intended as a support and is not intended to replace the judgement or experience of the attending physician and nurse. The peritoneal dialysis treatment as well as the decisions concerning specific patient treatments are within the sole responsibility of the attending physician and nurse.

This training manual has been developed by Fresenius Medical Care Deutschland GmbH (Germany) and is now offered to clinics to use it for their patients as a tool or aid in caring for dialysis patients.

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