The proven advantages

stay•safe® balance, a further development of the proven stay•safe® system

The new pH-neutral balance solution

The solution is packaged in a new type of double chamber bag. The separation of the glucose solution containing electrolytes and the buffer solution allows steam sterilization of the glucose at a very low pH value and thus a considerable reduction of glucose degradation products.

The mixing of both chambers shortly before the inflow results in a pH-neutral solution. balance contributes to protect the peritoneum.
Safe application by means of the \( \lambda \)-shaped seam

Light pressure on one of the chambers opens the innovative \( \lambda \)-shaped seam from the top to the bottom in direction of the inflow line. This ensures that only the completely mixed solution can be applied.

The proven advantages of the \textit{stay\textbullet safe\textsuperscript{®}} system

All components of the system are made of the PVC-free Biofine\textsuperscript{®} material specially developed by Fresenius Medical Care, a synthetic material which belongs to the group of polyolefines.

The DISC, the central element of the \textit{stay\textbullet safe\textsuperscript{®}} system, controls all operating steps by simple rotation. Operating errors are essentially excluded. Clamps and breaking cones are not necessary. The proven PIN technology ensures the contamination-safe inline sealing of the system.
The colour codes

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:
  - balance system in outer wrapper, preheated
  - Wrapped disinfection cap
  - Organizer
  - Face mask
  - Hand disinfectant (e.g. Frekasept® 80)
- 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. Opening the peel seam

a. Check that the peel seam is intact before opening it
b. Roll up the bag from one of the upper ends until the middle seam opens

The solutions in the two chambers are mixed automatically

c. Now roll up the bag from the upper edge, until the peel seam of the lower triangle is completely opened
5. 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!

6. 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

7. 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
8. 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

9. Disinfecting hands

- Disinfect your hands with suitable disinfectant (e.g. Frekasept® 80)
- Rub your hands until they are dry

10. Removing the protection cap of the DISC

- Unscrew the protection cap of the DISC and discard it
11. Connecting to the system

- Unscrew the catheter extension from the disinfection cap and screw it on the DISC

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

12. Outflow

- Open the clamp on the catheter extension

The DISC is automatically in the outflow (“”) position. The outflow procedure starts

13. 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
14. 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

15. 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

16. Closing the clamp

- Close the white clamp on the catheter extension.
17. Removing the protection cap

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

18. Disconnecting

- Unscrew the catheter extension of the DISC

The PIN remains firmly in the catheter extension

19. 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
20. Closing the DISC

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

21. 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 balance system from the infusion pole and the organizer and discard it

22. 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
Informationen

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<th>balance</th>
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<td>42.5</td>
<td>15</td>
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</table>

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

- Anhydrous glucose (as glucose-monohydrate): 15 g/l
- Sodium lactate: 3.925 g/l
- Sodium chloride: 5.640 g/l
- Calcium chloride: 0.2573 g/l
- Magnesium chloride: 0.1017 g/l
- Anhydrous glucose: 15 g/l

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

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

**Contraindications:**
- Solution related:
  - Solutions with 1.5%/2.3%/4.25% glucose, 1.75 mmol/l calcium: Severe hypokalaemia and severe hypercalcemia.
  - Solutions with 1.5%/2.3%/4.25% glucose, 1.25 mmol/l calcium: Severe hypokalaemia and severe hypercalcemia.
- Solutions with 4.25% glucose: Additionally hypokalaemia and arterial hypertension.

**Treatment related:** Recent abdominal surgery or injury, burns, hemia, inflammatory abdominal skin reaction (dermatitis), inflammatory bowel diseases (Crohn's disease, ulcerative colitis, diverticulitis), peritonitis, non-healing weeping wounds (abdominal fistulae), intra-abdominal tumours, intestinal obstruction (ileus), lung diseases (especially pneumonia), metabolic disorders (lactic acidosis), generalised blood poisoning (sepsis), extreme weight loss ( cachexia), particularly when adequate nutrition is impossible, in cases of accumulation of uraemic toxins in the blood (uraemia) the elimination of which can not be managed by peritoneal dialysis, very high levels of fat in the blood (hyperlipidaemia).

**Undesirable effects:**
- Infections: Peritonitis (very common); skin exit site and tunnel infections (very common) in very rare cases sepsis.
- Disorders of the hormone balance: Increased blood sugar and fat levels; increase in body weight due to the continuous uptake of glucose from the peritoneal dialysis solution.
- Cardiovascular disorders: Frequent pulse; decreased or increased blood pressure.
- Respiratory disorders: Shortness of breath due to elevation of the diaphragm, shoulder pain.
- Gastrointestinal disorders: Diarrhoea; constipation; hernia (very common); abdominal distension and sensation of fullness.
- Renal disorders: Electrolyte disturbances, e.g. decreased potassium levels (very common), increased calcium levels in combination with an increased calcium uptake, e.g. by the administration of calcium containing phosphate binders or decreased calcium levels for solutions containing 1.25 mmol/l calcium.
- General disorders and administration/catheter site conditions: General malaise; redness, oedema, exudations, crusts and pain at the catheter exit site; dizziness; oedema: disturbances in hydration indicated either by a rapid decrease (dehydration) or increase (overhydration) in body weight. Severe dehydration might occur when using solutions of higher glucose concentration.
- Peritoneal dialysis procedure related disorders: Cloudy effluent; in- and outflow disturbances of the dialysis solution.
- 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 dose adjustment might be necessary. The frequency of digitals-associated adverse drug reactions can be increased due to reduced serum potassium levels. The use of diuretic agents may result in water and electrolyte imbalances. In diabetic patients the daily dose of insulin or oral hypoglycaemic medicinal products must be adjusted to take account of the increased glucose load. For solutions containing 1.75 mmol/l calcium the concomitant administration of calcium-containing medicinal products or vitamin D may cause hypercalcemia.
- Warnings and Precautions: Do not use unless solution is clear and container undamaged. For single use only. Any unused portion of the solution is to be discarded. Do not use before mixing both solutions. Do not store below 4°C. Keep out of the reach and sight of children.

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**Note:** We reserve the right to perform technical modifications without special prior notice. The availability in the individual countries depends on the pharmaceutical product approval.
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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