P³ – A new approach to Peritoneal Dialysis

P³ is a comprehensive PD programme specifically designed to improve your patients’ quality of life whilst extending their time on PD.

P³ allows you to prescribe individual therapy programmes, monitor patient conditions, and precisely adjust therapy when needed – in an efficient and optimised way.

P³ features three integrated categories:
- **Protect**: unique and easy-to-understand PD systems
- **Preserve**: ultra-low GDP fluids with neutral pH
- **Prolong**: individual state-of-the-art therapies for fluid balance control and guided prescription modelling

**Protect** is designed to reach beyond a standard level of care with innovative systems that simplify procedures, increase compliance and maximise safety.

**Protect is designed:**
- to minimise the risk of contamination
- to improve patient compliance
- from PVC-free, environmentally friendly materials
Protect your patients against risk of contamination

Peritonitis is a common complication of PD and is associated with significant morbidity and mortality. Fresenius Medical Care has targeted specific risk factors for infection and modified the standard connectology to intervene. Our unique connectology used in both the stay•safe® and sleep•safe systems helps to minimise contamination risk enabling low peritonitis rates.1-3

PIN technology
PIN technology, with its patent-protected method of in-line closing, gives additional security to your patients. Use of the PIN technology eliminates up to 75% of risk steps (see below).

- The unique PIN system automatically closes the catheter extension before disconnection.
- The disinfection cap ensures decontamination of the catheter extension during dwell times.

Risk step analysis
The calculations below show that PIN technology eliminates up to 75% of risk steps compared with conventional systems, thus contributing to a lower risk of contamination.

<table>
<thead>
<tr>
<th>System:</th>
<th>stay•safe®</th>
<th>Other systems</th>
</tr>
</thead>
<tbody>
<tr>
<td>Connections/day:</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Disconnections/day:</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Risk steps/year:</td>
<td>1,460</td>
<td>2,920</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>System:</th>
<th>sleep•safe</th>
<th>Other systems</th>
</tr>
</thead>
<tbody>
<tr>
<td>Connections/day:</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Disconnections/day:</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Bag connections/day:</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Risk steps/year:</td>
<td>365</td>
<td>1,460</td>
</tr>
</tbody>
</table>

* Calculated on basis of a 4 bags per day prescription

** Calculated on basis of 2 bags of 5 litre (6 litre for other systems) per day per prescription
Built-in guidance improves patient compliance

The *stay•safe®* and *sleep•safe* systems have been specifically designed to help patients with their daily self-care treatment by guiding them through the therapy process in a simple and convenient way.

**stay•safe® in CAPD**

**DISC & PIN technology:**

- Reduces contamination risk
- Improves patient compliance
- Facilitates education and training

The Organizer brings all parts of the system into a central place. Convenient and designed to maintain maximum hygiene, the Organizer contributes to successful therapy.

**sleep•safe in APD**

*sleep•safe* is a highly versatile system with a wide range of benefits such as:

- **Ease of use**
  Using a large colour touch-screen, patients are navigated step-by-step through the procedure.

- **Solution verification feature**
  Bar coded bag connectors are validated to ensure the solution matches the prescription.

- **Automatic bag connection**
  Automatic bag connection eliminates potential patient contamination.

- **Patient Card**
  Records all treatments to assist with therapy analysis.

Designed for simplicity and convenience during operation, the *stay•safe®* system reduces patient errors with a guided, 4-step operation.

- The DiSC control switch regulates all treatment steps. Your patients will not have to worry about clamping the wrong lines or forgetting where they are in the sequence.

This innovation has resulted in improved safety levels, patient compliance, excellent clinical results, as well as reduced training time.

![Diagram of stay•safe® and sleep•safe systems](image-url)
Protect your patients and the environment

Stay\-safe and Sleep\-safe disposables are available in Biofine®, an award-winning material developed from Fresenius Medical Care research. This innovative material protects both the patient and the environment.

Biofine®:
- Free from PVC and plasticisers (such as DEHP)
- Environmentally friendly, degrading simply to carbon dioxide and water when incinerated
- Can be recycled

Nordic Ecolabel
“One of the most important environmental benefits of Ecolabelled bags is that they are free of PVC and harmful phthalates. If current dialysis bags and packaging are replaced by Nordic Ecolabelled products, the use of phthalates can be lowered by 100 tonnes per year in the Nordic countries.”⁹

“Phthalates have been shown to affect reproductive capabilities during animal testing and it is believed that humans would be similarly impacted. (…) Phthalates are also believed to alter hormonal balance.”¹⁰

First health care company certified by Nordic Ecolabel (SWAN)

Less material = lower environmental burden
Protect, Preserve, and Prolong work together to improve survival

At Fresenius Medical Care, we work continuously to improve peritoneal dialysis treatment and therapy. Our work has been validated by numerous studies demonstrating the benefits and advantages of our products, devices and software. The P3 programme allows you to provide your patients with a therapy that Protects, Preserves and Prolongs their time on PD.

To learn more about the P3 categories Preserve and Prolong please contact your local sales representative.

The P3 programme is available only from Fresenius Medical Care.
**Information**

**balance 1.5% glucose, 1.75 mmol/l calcium, solution for peritoneal dialysis, balance 2.3% glucose, 1.75 mmol/l calcium, solution for peritoneal dialysis, balance 4.25% glucose, 1.75 mmol/l calcium, solution for peritoneal dialysis, balance 1.5% glucose, 1.25 mmol/l calcium, solution for peritoneal dialysis, balance 2.3% glucose, 1.25 mmol/l calcium, solution for peritoneal dialysis, balance 4.25% glucose, 1.25 mmol/l calcium, solution for peritoneal dialysis.**

These solutions are delivered in a double chamber bag. One chamber contains the alkaline lactate solution, the other chamber contains the acidic glucose-based electrolyte solution. Mixing of both solutions by opening the middle seam between the two chambers results in the neutral ready-to-use solution. **Composition:**

1 litre of the neutral ready-to-use solution contains: balance 1.5% glucose, 1.75 mmol/l calcium: sodium chloride 5.640 g, sodium lactate (as sodium lactate solution) 3.925 g, calcium chloride dihydrate 0.2573 g, magnesium chloride hexahydrate 0.1017 g, glucose, anhydrous (as glucose monohydrate) 22.73 g, balance 2.3% glucose, 1.75 mmol/l calcium: sodium chloride 5.640 g, sodium lactate (as sodium lactate solution) 3.925 g, calcium chloride dihydrate 0.2573 g, magnesium chloride hexahydrate 0.1017 g, glucose, anhydrous (as glucose monohydrate) 42.5 g, balance 1.5% glucose, 1.25 mmol/l calcium: sodium chloride 5.640 g, sodium lactate (as sodium lactate solution) 3.925 g, calcium chloride dihydrate 0.1838 g, magnesium chloride hexahydrate 0.1017 g, glucose, anhydrous (as glucose monohydrate) 22.73 g, balance 4.25% glucose, 1.75 mmol/l calcium: sodium chloride 5.640 g, sodium lactate (as sodium lactate solution) 3.925 g, calcium chloride dihydrate 0.2573 g, magnesium chloride hexahydrate 0.1017 g, glucose, anhydrous (as glucose monohydrate) 42.5 g, 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 hypercalcaemia. Solutions with 1.5%/2.3%/4.25% glucose, 1.25 mmol/l calcium: Severe hypokalaemia and severe hypocalcaemia. Solutions with 4.25% glucose: Additionally hypovolaemia and arterial hypotension. **Treatment related:** Recent abdominal surgery or injury, burns, hernia, 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 for solutions containing 1.25 mmol/l calcium Overactivity of the parathyroid gland with potential disorders of the bone metabolism. **Metabolism and nutrition disorders:** Increased blood sugar and fat levels; increase in body weight due to the continuous uptake of glucose from the peritoneal dialysis solution. **Cardiac and vascular 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, swellings, 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. **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. The ready-to-use solution must be used within 24 hours after mixing. Do not store below 4°C. **Date:** December 2010.

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