

# First locally owned and produced non-polyvinyl chloride (PVC) packed peritoneal dialysis (PD) solution in Malaysia, Soft Flow SC®: Evaluation of clinical performance and safety in peritoneal dialysis patients

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## ABSTRACT

**Introduction:** Locally manufactured Fresenius and Baxter peritoneal dialysis (PD) systems contain PVC despite known environmental and health hazards. Peritone Health uses a safer alternative called polypropylene, to manufacture Soft Flow SC® PD bags and tubes. **Methods:** This was a prospective, multicenter observational study involving 13 centres. The primary endpoint was the peritonitis rate. Secondary endpoints were clinical effectiveness and device deficiencies. The duration of the evaluation was a minimum of 1843.2 patient months. **Results:** Among 212 patients, mean age was 50.0 (14.9) years and 52.8% were male. The main renal pathology was diabetic nephropathy (60%), hypertensive nephropathy (20%) and glomerulonephritis (9%). Existing patients (35.3%) and new patients (63.7%) were recruited. Two-thirds were on continuous ambulatory PD (72.9%) while the remaining were on automated PD (27.1%). Peritonitis rate was 1 episode in 31.9 patient-months or 0.037 episode/patient-month. Peritonitis risk factors were diabetes mellitus, modality of PD and centre effect. Peritonitis rate varied between centres. Centre factors associated with peritonitis were the patient-to-staff ratio and culture-negative rate. Peritonitis rates of existing and de-novo patients were comparable. Average Kt/V and creatinine clearance were 2.0, 1.9 and 58.6, 63.4L/week at baseline and month 6, respectively. The rigidity of polypropylene contributed to 58 device deficiencies in the initial phase. The drop-out rate was 29.2%. **Conclusion:** Soft Flow SC® is comparable to existing multinational PD Systems in Malaysia based on clinical performance and safety. Peritonitis rate of 0.037 per episode/patient-month is above the target peritonitis rate as per ISPD recommendation.