

**Urgent Field  
Safety Notice**

**MiniCap Extended Life PD Transfer Sets**

**FA Number:** FAV-2024-007

**Manufacturer:** Baxter Healthcare SA (CH-MF-000026124)

**Type of Action:** Correction

09 June 2025 (Updated 10.06.25)

Dear Peritoneal Dialysis Patient:

In February 2025, Vantive, formerly the Baxter Kidney Care segment, launched as a new standalone company. Vantive will continue to design, manufacture and distribute lifesaving and life-sustaining pharmaceutical and medical devices products for kidney dialysis and other organ support therapies. Please note that any future communications related to this issue will come from Vantive and not Baxter.

On October 23, 2024, Vantive issued a communication to inform Healthcare Providers about potential safety risks related to MiniCap Extended Life PD transfer sets while Vantive was performing an internal evaluation.

Vantive has since completed the evaluation to determine whether these risks are present. These test results show that there are no non-dioxin like (NDL) polychlorinated biphenyls (PCBs) detected when using Vantive's MiniCap Extended Life PD transfer sets with peroxide-cured silicone tubing, and that the levels of NDL polychlorinated biphenyl acids (PCBAs) are not anticipated to present a safety risk for patients over 6 months old. Test results for patients younger than 6 months old, however, were inconclusive due to the limitations of available testing.

**Affected Product**

Product Code	Product Description	Lot Numbers
R5C4482	Transfer Set (MiniCap Extended Life PD Transfer Set with Twist Clamp)	All lots within expiry
R5C4483	Transfer Set (MiniCap Extended Life PD Transfer Set with Twist Clamp)	
R5C4484	Transfer Set (MiniCap Extended Life PD Transfer Set with Twist Clamp)	

### Hazard Involved

Although Vantive's testing results demonstrate that the peroxide-cured silicone tubing components in Vantive's MiniCap Extended Life PD transfer sets are not anticipated to present a hazard for patients over 6 months of age, the test results for patients younger than 6 months remain inconclusive due to the limitations of available testing. Therefore, Vantive does not have data to definitively conclude whether there is a PCBA safety risk for patients younger than 6 months. To date, Vantive has not received any complaints related to this issue.

### Actions to be Taken by Patients

1. **Please continue your prescribed PD therapy.** Your dialysis provider has been informed of this issue and has been provided with a copy of this letter. If you have any questions about your PD therapy, please contact your healthcare team.

### Further Information and Support

For general questions regarding this communication or any product issue you are experiencing, contact your healthcare team.

Sincerely,



Yvonne Garcia  
PD Product Manager UK & Ireland,  
Vantive Ltd