

Important Medical Device Correction

Follow-up Communication: MiniCap Extended Life PD Transfer Sets

February 20, 2025

Dear Dialysis Provider:

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. The communication below is a follow-up to the communication you have previously received from Baxter about a product that is now marketed by Vantive. Please note that all future communications related to this issue will come from Vantive and not Baxter.

On October 21, 2024, Vantive issued an Important Medical Device Correction to inform customers about a potential patient safety issue related to MiniCap Extended Life PD transfer sets. These transfer sets were manufactured with peroxide-cured silicone tubing as a fluid pathway component, and Vantive was made aware of several recalls by other manufacturers that used this type of silicone tubing in their devices. Peroxide-cured silicone tubing can result in patients being exposed to non-dioxin-like (NDL) polychlorinated biphenyl acids (PCBAs) and NDL polychlorinated biphenyls (PCBs). Vantive pre-emptively issued the October 21st notice to inform customers of this potential risk, while awaiting the completion of internal testing to determine whether there is an actual patient safety risk.

Vantive has since completed its own evaluation to determine whether these risks are present with Vantive’s MiniCap Extended Life PD transfer sets. These test results demonstrate that there are no PCBs detected when using Vantive’s MiniCap Extended Life PD transfer sets with peroxide-cured silicone tubing, and that the levels of PCBAs are not anticipated to present a safety risk for patients over 6 months of age. Test results for patients younger than 6 months, however, were inconclusive due to the limitations of available test methodology.

Please note that even though the peroxide-cured silicone tubing components in the transfer sets are not anticipated to present a PCBA safety risk for patients older than 6 months, and the PCBA safety risk is inconclusive for patients younger than 6 months, Vantive is still in the process of transitioning from peroxide-cured silicone tubing to platinum-cured silicone tubing for these devices. In the meantime, Vantive continues to advise healthcare providers not to disrupt dialysis treatments for their patients, as peritoneal dialysis systems are critical to patient care.

Affected Product

Product Code	Product Description	Lot Numbers	UDI Number
5C4482	Transfer Set (MiniCap Extended Life PD Transfer Set with Twist Clamp)	All lots within expiry	00085412007731
5C4483	Transfer Set (MiniCap Extended Life PD Transfer Set with Twist Clamp – Extra Short)	Lot H24F17045 and lower	00085412007748

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 test methodology. 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 Customers

1. For patients older than 6 months of age, healthcare providers are advised to continue using both the peroxide-cured silicone tubing version and/or the platinum-cured silicone tubing version of the MiniCap Extended Life PD transfer sets, as neither is anticipated to present safety risks related to PCB/PCBAs.
2. Test results for patients younger than 6 months were inconclusive due to the limitations of available test methodology, therefore, for these patients Vantive is recommending the following actions:
 - a. Healthcare providers should prioritize the use of platinum-cured silicone tubing sets or other alternatives that may be available.
 - b. If no alternatives are available, healthcare providers should continue to connect the peroxide-cured silicone tubing sets and prioritize the use of shorter transfer sets.
 - c. If the patient currently has the peroxide-cured silicone tubing, they do not need to have it replaced early, as data demonstrates that PCBA levels decrease over treatment time.
3. If you received this communication directly from Vantive, please acknowledge receipt of this notification by responding on our customer portal at <https://BaxterFieldActionCustomerPortal.onprocess.com>, even if you do not have any remaining inventory. Log in to the portal using the account number listed in the enclosed reply form instruction sheet. Acknowledging receipt of this notification will prevent you from receiving repeat notices. If you do not complete the acknowledgement, you will receive a phone call from OnProcess Technology on behalf of Vantive to confirm your receipt of this notification.
4. If you purchased this product from a distributor, please note that responding via the Vantive customer portal is not applicable. If a response is requested by your distributor or wholesaler, please respond to the supplier according to their instructions.
5. If you distributed this product to other facilities or departments within your institution, please forward a copy of this communication to them.
6. If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) that distributed any affected product to other facilities, please notify your customers of this Important Medical Device Correction in accordance with your customary procedures and **check the associated box on the customer portal.**

Further Information and Support

For general questions regarding this communication, please contact Vantive Customer Care at 800-284-4060, option 3, between the hours of 7:00 am and 6:00 pm Central Time, Monday through Friday.

The United States Food and Drug Administration (FDA) has been notified of this action. Any product quality complaints or adverse events experienced with the use of these products may be reported using one of the following options:

- Contacting Vantive Product Surveillance by navigating to the Product Feedback Portal at <https://productfeedback.vantive.com>
- Reporting to the FDA MedWatch Serious Injury Reporting Program:
 - **Online:** By completing and submitting the report online at <https://www.accessdata.fda.gov/scripts/medwatch/>
 - **Regular mail or Fax:** Download the form from www.fda.gov/MedWatch/getforms.htm or call 800-332-1088 to request a reporting form, then complete and mail it to the address on the pre-addressed form or submit by fax to 800-332-0178

We apologize for any inconvenience this may cause you and your staff.

Sincerely,



Amy McKernan
Senior Director, Product Quality
Vantive US Healthcare LLC

Enclosures: Vantive Customer Reply Form Instruction Sheet
Dialysis Provider letter dated October 21, 2024
Peritoneal Dialysis Patient Follow-up Letter