Important Medical Device Correction

Follow-up Communication: MiniCap Extended Life PD Transfer Sets

February 24, 2025

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. 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 23, 2024, Vantive issued an Important Medical Device Correction to inform impacted patients about a potential patient safety issue related to MiniCap Extended Life PD transfer sets. These transfer sets were manufactured with peroxide-cured silicone tubing 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 exposure to non-dioxin-like (NDL) polychlorinated biphenyl acids (PCBAs) and NDL polychlorinated biphenyls (PCBs). Baxter pre-emptively issued the October 23rd notice to inform patients 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 testing.

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 as available information indicates that NDL PCBAs and NDL PCBs are not detected in medical devices with this modified version of silicone tubing.

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 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.** If you have any questions about your PD therapy, please contact your doctor and/or nurse.

2. Please acknowledge receipt of this notification using one of the two methods detailed on the enclosed Home Patient Reply Form Instruction Sheet. ***This step is required per FDA guidelines.*** 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 Baxter to confirm your receipt of this notification.

3. If you did not receive this notification directly from Vantive, please note that responding via the Home Patient Reply Form Instruction Sheet is not applicable.

Further Information and Support

If you have any questions about your PD therapy, please contact your doctor and/or nurse.

For general questions regarding this communication, please contact Vantive Customer Care at 800-284-4060, option 1, 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

Amy McKernan
Senior Director, Product Quality
Vantive US Healthcare LLC

Enclosures: Vantive Home Patient Reply Form Instruction Sheet
Home Patient Letter dated October 23, 2024