Important Medical Device Correction

Follow-up Communication: MiniCap Extended Life PD Transfer Sets

February 2025

Dear Dialysis Providers and Peritoneal Dialysis Patients:

Vantive previously 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 previous 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.

Affected Product

Please be aware that the table below is a complete list of all products globally impacted by this field action and may include more products than those applicable to your country. For information on the specific products affected in your country, please refer to the Affected Product section in the notification you received.

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
5C4482EJ	Transfer Set (MiniCap Extended Life PD Transfer Set with Twist Clamp)	All lots including and manufactured after H20A30068	00085412489643
5C4482S	Transfer Set (MiniCap Extended Life PD Transfer Set with Twist Clamp)	All lots including and manufactured after H19J11055	00085412476261
R5C4482	Transfer Set (MiniCap Extended Life PD Transfer Set with Twist Clamp)	All lots including and manufactured after H19J22078	00085412008776
R5C4482E	Transfer Set (MiniCap Extended Life PD Transfer Set with Twist Clamp)	All lots including and manufactured after H19K04041	GTIN 5413760005379
R5C4483	Transfer Set (MiniCap Extended Life PD Transfer Set with Twist Clamp)	All lots including and manufactured after H19J21062	GTIN 0085412008783

R5C4484	Transfer Set (MiniCap Extended Life PD Transfer Set with Twist Clamp)	All lots including and manufactured after H20B11116	GTIN 0085412050768
T5C4482	Transfer Set (MiniCap Extended Life PD Transfer Set with Twist Clamp)	All lots including and manufactured after H20F09053	04987456422906
T5C4484	Transfer Set (MiniCap Extended Life PD Transfer Set with Twist Clamp)	All lots including and manufactured after H20B11074	04987456422890

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. At the time the field action was initiated, Vantive had not received any complaints related to this issue.

Actions to be Taken by Customers and/or Patients

For information on the specific actions to be taken, please refer to the applicable section in the notification distributed in your country.

Further Information and Support

For further information and support, please refer to the applicable section in the notification distributed in your country.

Sincerely,

Amy McKernan

Amy McKernan
Senior Director, Product Quality
Vantive US Healthcare LLC