FRESENIUS MEDICAL CARE

April 10, 2024

IMPORTANT MEDICAL DEVICE CORRECTION

stay•safe® Catheter Extension/Luer Lock Sets & stay•safe®/Luer Lock Adapter Peroxide Catalyst Tubing and PCBAs
(FA-2023-15-R-1)

Dear Valued Customer,

This letter has important information on the use of the stay•safe® Catheter Extension Sets and Adapter. You are receiving this letter because your clinic has been identified as one that treats pediatric patient(s) with the stay•safe Catheter Extension sets and Adapter, which are manufactured using peroxide cross-linked silicone tubing.

The catheter extension set enables effluent to drain out of, and dialysate to flow into, the patient's peritoneum during Peritoneal Dialysis treatment. The stay•safe® Catheter Extension Sets come in three (3) tubing lengths (6-inch, 12-inch, and 18-inch). The Adapter is used to connect a catheter extension set to a medical device with a Luer-Lock connection.

FMCRTG has determined through testing that non-dioxin-like polychlorinated biphenyl acids (PCBAs) could leach from the stay•safe Catheter Extension sets and Adapter, which are manufactured using peroxide cross-linked silicone tubing. Please note that PCBAs are chemically different from polychlorinated biphenyls (PCBs) which were not identified. No complaints have been reported.

PCBA levels decrease with shorter catheter extension sets and decrease over the treatment time. Therefore, FMCRTG recommends use of the shortest catheter extension set length (6-inch) with patients <40kg.

While review of the medical literature has not identified any health effects related to PCBA exposure, toxicologically relevant thresholds may be exceeded for lower weight patients. Specifically:

- Patients with body weight <10 kg: when using the 6-inch Catheter Extension Set, PCBA levels are above the threshold during the first seven (7) days of treatment.
- Patients with body weight <10 kg: when using the 4-inch Adapter in combination with the 6-inch Catheter Extension Set, PCBA levels are above the threshold during the first fourteen (14) days of treatment.
- Patients with body weight between 10kg and 40kg: when using the 4-inch Adapter in combination with the 6-inch Catheter Extension Set, PCBA levels are above the threshold during the first four (4) days of treatment.

Patients with body weight > 40kg are not impacted.

FMCRTG recommends the following for Healthcare providers until an update to the catheter extension silicone material becomes available:

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- **Use only the shortest length extension set (6-inch, Part No. 050-95013) when treating patients with a body weight below 40 kg, including infants and Neonates and if possible, avoid using the adapter.**

This is for both existing patients and patients about to initiate peritoneal dialysis.

Remain alert for further updates and recommendations from the FMCRTG and FDA.

- Please report any complaints or adverse events to product.complaints@fmc-na.com or FDA MedWatch at https://www.fda.gov/safety/medical-product-safety- information/medwatch-forms-fda-safety-reporting.
- Please post the attached poster in the offices of the Medical Director/ PD Nurse Manager and supply room.

For any clinical or medical questions, please contact the Global Medical Information and Education Office at 1-855-616-2309.

This notification serves as important medical device information. FMCRTG is not requesting the return of any product.

FMCRTG is working diligently to update the Catheter Extension sets and expects release in Q1 2025. The health and safety of your patients continue to be our highest priority.

Thank you for your cooperation.

Sincerely,

Linda Jalbert

Linda Jalbert
SVP Medical Safety and Post Market Systems

Please forward this notice to providers who may use these products for pediatric use. Place this notification with the device to ensure awareness.

Product code	Description	UDI Information
050-95001	stay•safe /Safe Lock Catheter Ext. 12 in	Bag GTIN and QR-Code: 00840861100767 Case GTIN and QR-Code: 10840861100764
050-95004	stay•safe /Luer Lock Catheter Ext. 12 in	Bag GTIN and QR-Code: 00840861100781 Case GTIN and QR-Code: 10840861100788
050-95005	stay•safe /Luer Lock Catheter Ext. 18 in	Bag GTIN and QR-Code: 00840861100798 Case GTIN and QR-Code: 10840861100795
050-95013	stay•safe /Luer Catheter Ext. 6 in	Bag GTIN and QR-Code: 00840861100804 Case GTIN and QR-Code: 10840861100801
050-95003	stay•safe /Luer Lock Adapter 4 in	Bag GTIN and QR-Code:00840861100774 Case GTIN and QR-Code:10840861100771

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FMCRTG recommends the following for Healthcare providers until an update to the catheter extension silicone material becomes available:

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This is for both existing patients and patients about to initiate peritoneal dialysis.

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For any clinical or medical questions, please contact the Fresenius Medical Care Global Medical Information and Education Office at 1-855-616-2309.