

Field Safety Notice

stay•safe Catheter Extensions - Silicone Tubing and PCBAs

Date: February 15th, 2024

Dear Valued Customer,

Fresenius Medical Care is sending you this letter because your clinic has been identified as one that treats patients with the *stay•safe* Catheter Extension, which are manufactured using peroxide cross-linked silicone tubing.

The *stay•safe* Catheter Extension enables effluent to drain out of, and dialysate to flow into, the patient's peritoneum during peritoneal dialysis treatment. The *stay•safe* Catheter Extension are available in different tube lengths (25 cm, 32 cm, 40 cm, 60 cm, see Tab. 1).

| Product Name | Product Code |
|--|---------------------|
| <i>stay•safe</i> Catheter Extension Luer-Lock 32 cm | 2843181 |
| <i>stay•safe</i> Catheter Extension Luer-Lock 25 cm | F00005375 |
| <i>stay•safe</i> Catheter Extension Luer-Lock 25 cm | 2843241 |
| <i>stay•safe</i> Catheter Extension Luer-Lock 40 cm | 2843251 |
| <i>stay•safe</i> Catheter Extension Luer-Lock 60 cm | 2843191 |

Table 1. Available stay•safe Catheter Extension Sets and corresponding Product Code

Fresenius Medical Care has determined through testing that non-dioxin-like polychlorinated biphenyl acids (PCBAs) could leach from the *stay•safe* Catheter Extension, which are manufactured using peroxide cross-linked silicone tubing. Please note that PCBAs are chemically different from polychlorinated biphenyls (PCBs), which were not identified. To date, Fresenius Medical Care has not received any complaints related to PCBAs.

PCBA levels decrease with shorter *stay•safe* Catheter Extension and decrease over the treatment time.

While a review of the medical literature has not identified any health effects related to PCBA exposure, toxicologically relevant thresholds may be exceeded in patients with lower body weights. However, patients with a body weight > 40 kg are not affected.

Until an updated silicone catheter extension material is available, as a measure of precaution, Fresenius Medical Care recommends that healthcare providers do the following:

Use only the shortest *stay•safe* Catheter Extension length (e.g. 25 cm) for patients weighing less than 40 kg.

Fresenius Medical Care is in the process of updating the catheter extension silicone to PCBA-free material by the end of June 2025.

We sincerely apologize for any inconvenience this may cause. Fresenius Medical Care is committed to ensure that our products and services consistently meet the highest standards of quality and safety for patients and healthcare providers.

Please distribute this Safety Notice to all those within your organization who need to be aware of it.

In case of any further questions do not hesitate to contact:

Name (*Please adapt locally*)

Telephone (*Please adapt locally*)

E-mail XXX@freseniusmedicalcare.com (*Please adapt locally*)

Sincerely yours,

Name and Signature (*please adapt locally*)