

Field Safety Notice

stay•safe Disinfection Cap (article no. 2845091, F00005376, F00005996) – potential side effects of hypothyroidism and hypersensitivity

Date: September 25th, 2023

Dear Valued Customer,

Fresenius Medical Care is updating the labeling to our *stay•safe* Disinfection Cap. Label updates include adding additional warnings and contraindications for potential side effects for the use of our *stay•safe* Disinfection Cap.

Based on current literature, it has been recognized that an increased exposure to povidone-iodine, a potent antiseptic present in the *stay•safe* Disinfection Cap used to close the PD catheter extension could lead to iodine-induced hypothyroidism and associated clinical sequelae. This is especially a concern for infants and children with smaller peritoneal fill volumes in which iodine overload could result in secondary hypothyroidism. Fresenius Medical Care is aware of one pediatric-related event of hypothyroidism during PD treatment.

As such, Fresenius Medical Care recommends close monitoring of thyroid function in patients with small peritoneal fill volumes, typically infants and children, when using iodine containing products.

Povidone-iodine could also lead to hypersensitivity. Do not use in case of known povidone-iodine allergy.

Fresenius Medical Care is in the process of updating the labeling to include these medical warnings and contraindications.

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 provide this Safety Notice to all those who need to be aware within your organization.

Please review these warnings and contraindications with your patients.

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

Susanne Renner (Susanne.Renner@fmc-ag.com)

Sincerely yours,

Paula Rogalski

Paula Rogalski
Vice President
Quality & Regulatory, Home Therapies



Marco Zimmer
Vice President
International MD Vigilance & PMS