

**Fresenius Medical Care (UK) Ltd**

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## Field Safety Notice

### *stay•safe* Disinfection Cap (article no. 2845091) – potential side effects of hypothyroidism and hypersensitivity

Date: September 25<sup>th</sup>, 2023

Dear Healthcare Professional,

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.

**Fresenius Medical Care (UK) Limited**



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 ensure all relevant staff are made aware of the content of this letter and that the information is communicated to patients and caregivers.

**Please review these warnings and contraindications with your patients.**

**Call for reporting**

Healthcare professionals are asked to report any suspected adverse reactions to the Yellow Card Scheme electronically. Report via the website <https://www.gov.uk/yellowcard>.

Suspected side effects can also be reported via [VigilanceUK@fmc-ag.com](mailto:VigilanceUK@fmc-ag.com). When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset timing, treatment dates, and product brand name.

**Company contact point**

If you have any questions about this letter or require more information, please contact Fresenius Medical Care UK Limited.

Telephone: 01623 445 100

E-mail: [Press.UK@fmc-ag.com](mailto:Press.UK@fmc-ag.com)

Your faithfully

*Chris Slater*

Chris Slater  
Managing Director  
Fresenius Medical Care UK Ltd

**Fresenius Medical Care (UK) Limited**

## Customer Reply Form

Affected Device: *stay•safe* Disinfection Cap  
(article no. 2845091)

FSN: Potential side effects of hypothyroidism and hypersensitivity

Recipients Name: \_\_\_\_\_  
Hospital Name: \_\_\_\_\_  
Postal Code: \_\_\_\_\_

Please complete for regulatory effectiveness check:

I have read the attached Notification and understand the instructions that I am given:

Signature: \_\_\_\_\_  
Print Name: \_\_\_\_\_  
Date: \_\_\_\_\_

**Please return this customer reply form via one of the following methods:**

- Return this signed form to your Fresenius Medical Care Representative

Email the signed form to [VigilanceUK@fmc-ag.com](mailto:VigilanceUK@fmc-ag.com)