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Update - Field Safety Notice

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

Date: 28th January 2026

Dear Valued Customer,

In October 2023 you received a Field Safety Notice (FSN) informing you of the potential side effects of hypothyroidism and hypersensitivity in relation to the use of *stay•safe* Disinfection Cap. Reference No: 2845091.

As a follow-up to this communication, we are now providing updated labelling information to support effective use of the *stay.safe* Disinfection Cap, specifically in relation to the management of potential side effects associated with hypothyroidism and hypersensitivity. The following sections of the product labelling have been updated accordingly.

“Side effects: Hypersensitivity to any of the materials in the device. Risk of thyroid dysfunction by uptake of iodine.

Medical Warnings and precautions (to prevent side effects): Disinfection cap with povidone-iodine. Risk of thyroid dysfunction by uptake of iodine. Closely monitor thyroid function in patients with small peritoneal fill volume, typically infants and children.

Contraindications: Do not use in case of known povidone-iodine allergy.”

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Please review these warnings and contraindications with your patients.

We request to pass this update to all those who need to be aware of within your organisation.

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@freseniusmedicalcare.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@freseniusmedicalcare.com

Your faithfully

Signed by:

A handwritten signature in black ink that reads 'Kiran Hiriyannaiah'.

6821AF6BDAC147D...

Kiran Hiriyannaiah
Regulatory Affairs & UK Responsible Person
Fresenius Medical Care UK Ltd

Fresenius Medical Care (UK) Limited