

To our customers of
Dräger Breathing System Filters
SafeStar55 (MP01790)

Mai 2022

Important Safety Notice

Potentially obstructed breathing system filter

Only the following products are affected:

Breathing System Filter SafeStar 55 (MP01790; GTIN: 04048675420828)
with lot number LT2103 (other lots are not affected)

Dear Sir or Madam,

Within our global vigilance activities, we have become aware of one case in which an obstructed breathing system filter SafeStar 55 was used on a patient during anesthesia. The patient reportedly became hypoxic and had to be reanimated.

To detect obstructions, every filter is subject to a 100% resistance test. If the test fails, the respective filter will automatically be destroyed. Our analyses revealed the obstruction of the SafeStar 55 was due to a human error during a service measure of the manufacturing equipment. During the service measure the automatic destruction had to be deactivated and the filters were sorted manually. During that limited time the filter in question was added to the "passed" box although having failed the resistance test. Our analyses of the supply chain and deliveries indicates that there are most likely no more potentially affected SafeStar 55 in the market – however, it can't be excluded with absolute certainty.

The SafeStar 55 Instructions for Use contain a corresponding warning and advise the user to check all system components for obstructions, damage, and foreign matter before installation.

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Registered office: Lübeck
Commercial register:
Local court Lübeck HRB 7903 HL
General partner: Drägerwerk Verwaltungs
AG
Registered office: Lübeck
Commercial register:
Local court Lübeck HRB 7395 HL

Chairman of the Supervisory
Board for Drägerwerk AG & Co.
KGaA and Drägerwerk
Verwaltungs AG:
Stefan Lauer
Executive Board:
Stefan Dräger (chairman)
Rainer Klug
Gert-Hartwig Lescow
Dr. Reiner Piske

If however, an obstructed filter is used on a patient, ventilation will be restricted and the patient might desaturate. SafeStar 55 is tested and released for the use with devices for both anesthetic and respiratory use. These devices feature both pressure and volume monitoring. In case of an obstruction, corresponding alarms will be generated indicating restricted ventilation of the patient.

Dräger has already taken measures to ensure that all filters are subject to both resistance test AND automatic sorting and automatic destruction of poor parts respectively.

Actions to be taken:

Please check your stock for filters with lot number "LT2103" and return them to Dräger.

Dräger will replace all returned filters free of charge.

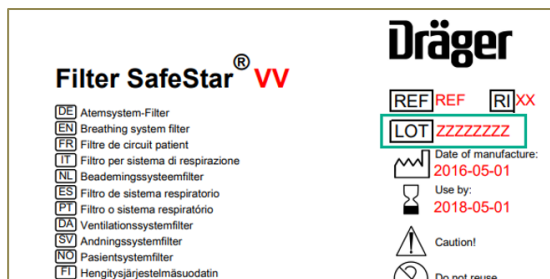
Please ensure that all users of the above-mentioned products and other persons within your organization are made aware of this Important Safety Notice. If you have provided the products to third parties, please forward a copy of this information.

Please keep this information available to all users at least until the you have checked your stock.

The responsible authorities have been notified of this action.

Identification of the affected medical devices:

According to our records you have received potentially affected breathing system filters SafeStar 55 manufactured by Drägerwerk AG & Co. KGaA with lot number LT2103. To identify affected products in your stock, please check the Lot number on the label on the packaging:



Contact:

If you have any questions, please do not hesitate to contact your local Dräger representative.

We apologize for any inconvenience caused by this measure.

We thank you for your support.

Kind regards

Theresa Strampfer

Product Manager
Product Management
Business Unit Hospital Consumables & Accessories
Medical Division