

Drägerwerk AG & Co. KGaA, 23542 Lübeck

**To our customers of
Dräger Neo disposable breathing systems
and corresponding sets**

January 2021

Important Safety Notice!!!

Possible detachment of Y-piece

Only the following products are affected:

- **MP00333 VentStar Anesthesia (N) 180**
- **MP00353 VentStar Basic (N) 180**
- **MP00363 VentStar Watertrap (N) 180**
- **MP01327 ID Circuit Basic (N) 180**
- **MP01328 ID Circuit Watertrap (N) 180**

Dear Madam/Sir,

During the course of our global market surveillance activities, we have become aware of cases in which the Y-piece became detached from the ventilation hose either before or during the ventilation process. There were no reports of any adverse impact on the health of the patients in question.

Our investigations have shown that the Y-piece in question and the associated adhesive joint did not conform to specification. A random sample of our stocks revealed that the Y-pieces in question can become detached from the hose even when pulled very slightly. Further analyses determined that the Y-pieces, due to a manufacturing error, can in some cases become disconnected at tensile forces below what is specified. Consequently, some of the referenced breathing circuits that have been shipped since 01.01.2018 may potentially show a limited lifetime of the adhesive joint.

If the Y-piece becomes detached from the hose during use, a leak will be caused that can hinder ventilation of the patient. If the breathing circuit is used with devices that are listed in the Instructions for Use as being compatible, any leakage will be detected and the device will give an alarm.

Future breathing circuits shipped conform to specifications. We have also introduced additional controls to ensure product quality.

Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23558 Lübeck, Deutschland
Postanschrift:
23542 Lübeck, Deutschland
Tel. +49 451 882-0
Fax +49 451 882-2080
info@draeger.com
www.draeger.com
UID-Nr. DE135082211

Bankverbindungen:
Commerzbank AG, Lübeck
IBAN: DE95 2304 0022 0014 6795 00
Swift-Code: COBA DE FF 230
Sparkasse zu Lübeck
IBAN: DE15 2305 0101 0001 0711 17
Swift-Code: NOLADE21SPL

Sitz der Gesellschaft: Lübeck
Handelsregister:
Amtsgericht Lübeck HRB 7903 HL
Komplementär: Drägerwerk Verwaltungs AG
Sitz der Gesellschaft: Lübeck
Handelsregister:
Amtsgericht Lübeck HRB 7395 HL

Vorsitzender des Aufsichtsrats der
Drägerwerk AG & Co. KGaA und
Drägerwerk Verwaltungs AG: S
.....
Vorstand:
.....
.....
.....
.....

Please check the quality of the adhesive joint before use by holding the Y-piece with one hand and then pulling (not twisting) each of the two hoses one after another so that the hose just starts to stretch visibly.

Hoses that you have tested in this manner can be used, provided that they pass the leakage test before use.

Only use the hoses with devices that we have declared compatible in the Instructions for Use or accessories list of the basic device. Ensure that the patient is adequately monitored and select suitable alarm limits. During installation and operation, make sure to avoid any unnecessary tensile forces, and do not use the hoses for longer than is specified in the Instructions for Use.

According to our records, you have received breathing circuits in the last two years that may be affected by this issue. Please inform all potential users at your facility.

If you wish, we will be happy to replace any of your unused stocks that were manufactured between 01.01.2018 and 13.11.2020. Please contact your local Dräger representative.

We apologize for any inconvenience caused by this measure.

The authorities have been notified of this action.

With kind regards

.....
.....
.....

.....
.....
.....