

Drägerwerk AG & Co. KGaA, 23542 Lübeck

To our customers of

- **Dräger Seattle PAP plus**
- **Dräger Neo disposable breathing systems**
- **Dräger Coax ventilation hoses**
- **Dräger Pediatric disposable breathing systems**
- **Dräger Set2Go & Pack2Go**

March 2023

Important Safety Notice!!!

Possible separation of breathing hose components

Only the products listed in the attached list are affected

Dear Madam/Sir,

During the course of our global market surveillance activities, we have become aware of cases in which glued connections of the breathing circuits loosened either before or during the ventilation process resulting in partial or complete detachment of components such as watertrap, y-piece or hose connector. There were no reports of any adverse impact on the health of the patients in question.

Our investigations have shown that the adhesive joint did not conform to specification due to a manufacturing error.

If system components become loose and/or detach from the hose during use, ventilation of the patient will be restricted.

For Seattle PAP plus:

A detachment of system components might cause desaturation of the patient/ hypoxia, due to a loss of airway pressure caused by a leak. A desaturation will be detected by the patient monitoring (such as SpO₂).

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

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For Dräger Neo and Dräger Pediatric disposable breathing systems

A detachment of system components might cause hypoxia, due to a loss of airway pressure caused by a leak. If the breathing systems are 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.

For Dräger Coax ventilation hoses:

A detachment of system components might also cause hypoxia due to either...

- a leak of the outer hose, leading to a loss of airway pressure, or
- a leak of the inner hose, leading to rebreathing of exhaled gas, or
- torsion of the inner hose, leading to an obstruction.

If Dräger Coax ventilation hoses are used with devices that are listed in the Instructions for Use as being compatible, a leakage and/or an obstruction will be detected, and the device will give an alarm.

Dräger has immediately stopped further shipment of affected products and has started implementing improvements to ensure a reliable gluing process.

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

Please stop use of the affected products.

If you have affected products in your inventory, please contact your local Dräger representative who will be happy to provide you with information regarding alternative products and arrange replacement.

We apologize for any inconvenience caused by this measure.

The authorities have been notified of this action.

With kind regards



Meinhard Braedel
Head of Product Management
Business Unit Hospital Consumables & Accessories



Oliver Möller
Post Market Surveillance
Quality and Regulatory Affairs

List of affected products

Dräger Seattle PAP plus

| Part No. | Description |
|----------|------------------|
| MP02260 | Seattle PAP plus |

Dräger Neo disposable breathing systems

| Part No. | Description |
|----------|---|
| MP00333 | VentStar Anesthesia (N) 180 |
| MP00353 | VentStar Basic (N) 180 |
| MP00363 | VentStar Watertrap (N) 180 |
| MP00383 | VentStar Bag Set (N) 110 |
| MP01327 | ID Circuits Basic (N) 180 |
| MP01328 | ID Circuits Watertrap (N) |
| MP01329 | ID VentStar Bag Set (N) |
| MP16020 | VentStar Bag Set (N) 110 (Cone OD22) |
| MP16032 | VentStar Anesthesia (N) 180 (Cone OD22) |

Dräger Pediatric disposable breathing systems

| Part No. | Description |
|----------|--|
| MP00351 | VentStar Basic (P) 180 |
| MP00352 | VentStar Basic (P) 250 |
| MP00361 | VentStar Watertrap (P) 180 |
| MP00362 | VentStar Watertrap (P) 180 w/o LL |
| MP00374 | VentStar Anesthesia WT (P)180 |
| MP00375 | VentStar Anesthesia WT (P)180 w/o LL |
| MP00384 | VentStar Bag Set |
| MP01340 | ID Circuit Basic (P) 180 |
| MP01341 | ID Circuit Watertrap (P) 180 |
| MP16021 | VentStar breathing bag Set (P) 110 (Cone 22OD) |
| MP16037 | VentStar Anesth WT (P)180 (BC OD22) |
| MP16038 | VentStar Anesth WT(P) 180 w/oLL (Cone 22OD) |
| MP01343 | ID Bag Set (P) 110 |

Dräger Coax ventilation hoses

| Part No. | Description |
|-----------------|---|
| MP00315 | Vent Set, coax. |
| MP00316 | Vent Set COAX with Holder |
| MP00342 | ID Circuit Coax w. holder |
| MP00356 | VentStar Coax 180 |
| MP00357 | Ventstar ID coax GSL 230 |
| MP00358 | Anesthesia Set Coax GSL 230 |
| MP00359 | Anesthesia Set Coax WT GSL 210 |
| MP00367 | Ventstar ID coax WT GSL 210 |
| MP00368 | Anesthesia ID Set Coax GSL 230 |
| MP00370 | Anesthesia ID Set Coax WT GSL 210 |
| MP00373 | Coax Watertrap 210 |
| MP00378 | ID Coax Watertrap 210 |
| MP00379 | Coax (P) |
| MP03373 | Ventstar Coax |
| MP03374 | Ventstar Coax 180 |
| MP03375 | ID Coax 180 |
| MP03376 | Ventstar Coax 230 |
| MP03377 | ID Coax 230 |
| MP03378 | Ventstar coax GSL 230 |
| MP03379 | Ventstar Coax WT GSL 210 |
| MP03381 | Anesthesia Set Coax Watertrap 210 |
| MP03383 | Anesthesia Set Coax 230 |
| MP03384 | Anesthesia Set Coax 180 |
| MP16041 | Anesthesia Set Coax 180 (Bag Cone OD22) |
| MP16042 | Anesthesia Set Coax 230 (Bag Cone OD22) |
| MP16044 | Anesthesia Set Coax WT 210 (Bag Cone OD22) |
| MP16045 | Anesthesia Set ID Coax WT 210 (Bag Cone OD22) |
| MP16049 | Anesthesia Set Coax GSL 230 (Bag Cone OD22) |
| MP16050 | Anesthesia Set Coax WT GSL 210 (Bag Cone OD22) |
| MP16051 | Anesthesia ID Set Coax GSL 230 (Bag Cone OD22) |
| MP16052 | Anesthesia ID Set Coax WT GSL 210 (Bag Cone OD22) |
| MP02730 | Anesthesia Circuits Kit Coax 1 |
| MP02732 | Anesthesia Circuits Kit Coax 3 |
| MP17102 | Anesthesia Circuits HEPA Coax |

Set2Go & Pack2Go

| Part No. | Description |
|-----------------|--------------------------------|
| MP01673 | Savina invasive VentPack Coax |
| MP01676 | Evita inv VentPack/Coax CO2Cuv |
| MP01677 | Evita inv VentPack/Coax |
| MP07200 | Set2Go Anesthesia 23 (A) |
| MP07201 | Set2Go Anesthesia 24 (A) |
| MP07207 | Set2Go Anesthesia 28 (P) |
| MP07209 | Set2Go Ventilation 77 (A) |
| MP07214 | Set2Go Ventilation 79 (A) |
| MP07217 | Set2Go Anesthesia 32 (A) |
| MP07219 | Set2Go Anesthesia 33 (P) |
| MP07220 | Set2Go Anesthesia 34 (N) |
| MP07223 | Set2Go Anesthesia 36 (A) |
| MP07224 | Set2Go Ventilation 84 (A) |
| MP07232 | Set2Go Ventilation 85 (A) |
| MP07903 | Set2Go Anesthesia 20 (A) |
| MP07906 | Set2Go Anesthesia 21 (N) |
| MP07910 | Set2Go Anesthesia 19 (A) |
| MP07912 | Set2Go Ventilation 66 (A) |
| MP07914 | Set2Go Ventilation 64 (A) |
| MP07920 | Set2Go Ventilation 57 (A) |
| MP07921 | Set2Go Ventilation 56 (A) |
| MP07922 | Set2Go Ventilation 53 (A) |
| MP07926 | Set2Go Ventilation 54 (A) |
| MP07927 | Set2Go Ventilation 55 (A) |
| MP07928 | Set2Go Anesthesia 17 (A) |
| MP07946 | Set2Go Anesthesia 14 (A) |
| MP07950 | Set2Go Ventilation 1 (A) |
| MP07951 | Set2Go Ventilation 2 (A) |
| MP07952 | Set2Go Ventilation 3 (A) |
| MP07954 | Set2Go Ventilation 5 (A) |
| MP07958 | Set2Go Anesthesia 7 (A) |
| MP07959 | Set2Go Anesthesia 8 (A) |
| MP07960 | Set2Go Anesthesia 9 (A) |
| MP07961 | Set2Go Anesthesia 10 (A) |
| MP07962 | Set2Go Anesthesia 3 (A) |
| MP07963 | Set2Go Ventilation 7 (A) |
| MP07968 | Set2Go Ventilation 12 (A) |

Set2Go & Pack2Go

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|---------|--|
| MP07969 | Set2Go Anesthesia 4 (A) |
| MP07970 | Set2Go Anesthesia 5 (A) |
| MP07972 | Set2Go Ventilation 14 (A) |
| MP07975 | Set2Go Anesthesia 11 (A) |
| MP07984 | Set2Go Ventilation 22 (A) |
| MP07990 | Set2Go Anesthesia 13 (A) |
| MP07998 | Set2Go Ventilation 37 (A) |
| MP07999 | Set2Go Ventilation 38 (A) |
| MP20375 | Pack2Go invasive Vpack Coax |
| MP20377 | Pack2Go Evita inv. Vpack Coax/CO2 Cuv. |
| MP20378 | Pack2Go Evita invasive Vpack Coax |