

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 SpO<sub>2</sub>).**

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Sitz der Gesellschaft: Lübeck  
Handelsregister:  
Amtsgericht Lübeck HRB 7903 HL  
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.

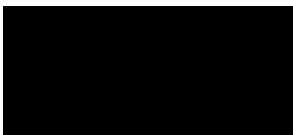
**Please stop use of the affected products.**

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.

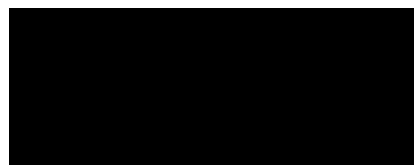
We apologize for any inconvenience caused by this measure.

The authorities have been notified of this action.

With kind regards



Head of Product Management  
Business Unit Hospital Consumables & Accessories



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**

<b>Part No.</b>	<b>Description</b>
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**

<b>Part No.</b>	<b>Description</b>
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**

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