PRESS RELEASE

Dräger issues recall notification to address potential health risks related to possible separation of breathing hose components in certain breathing circuits

Draeger, Inc., a subsidiary of Drägerwerk AG & Co. KGaA, is initiating a voluntary recall notification for Dräger Coax Ventilation Hoses, Dräger Neo Disposable Breathing Systems, Dräger Pediatric Disposable Breathing Systems, Dräger Seattle PAP plus, and Dräger Set2Go to address the potential risk that glued connections of the breathing circuits may loosen either before or during the ventilation process, which could result in partial or complete detachment of components such as the water trap, y-piece or hose connector. To date, there are no reports of any adverse impacts on the health of patients in connection with this potential risk.

Dräger immediately stopped shipment of affected products once these potential risks were identified. Dräger has since implemented changes to the gluing process used during manufacturing to help address these potential risks. Testing of the updated gluing process has been completed for Seattle PAP (MP02260), and Dräger started distributing Seattle PAP products utilizing this updated gluing process to customers as of March 20, 2023. Testing is still ongoing for the remaining circuits, and all impacted customers have been offered an alternative product as a temporary replacement.

Only the products listed below (all lot numbers) are affected:

Product Name	Material Number	UDI Number
VentStar Anesthesia (N) 180	MP00333	04048675422198
VentStar Basic (P) 180	MP00351	04048675422068
VentStar Basic(P) 250	MP00352	04048675422051
VentStar Basic (N) 180	MP00353	04048675422044
VentStar Watertrap (P) 180	MP00361	04048675422013
VentStar Watertrap (P) 180 w/oLL	MP00362	04048675422006
VentStar Watertrap (N) 180	MP00363	04048675421993

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VentStar Anesthesia WT (P) 180	MP00374	04048675421948
VentStar Coax (P) 150	MP00379	04048675421917
VentStar Bag Set (N) 110	MP00383	04048675421887
VentStar breathing bag Set (P) 110	MP00384	04048675421870
ID Circuit Basic (P) 180	MP01340	04048675421481
Seattle PAP plus*	MP02260*	04048675548904*
Anesthesia Circuit Kit Coax 1	MP02730	04048675412014
Anesthesia Circuit Kit Coax 3	MP02732	04048675412038
Ventstar Coax	MP03373	04048675545552
Ventstar Coax 180	MP03374	04048675545576
ID Coax 180	MP03375	04048675545590
Ventstar Coax 230	MP03376	04048675545613
Anesthesia Set Coax 180	MP03384	04048675552833
VentStar Coax (P) 150	MP00379	04048675421917
Set2Go Ventilation 12 (A)	MP07968	04048675544739
Anesthesia Circuit Kit Coax HEPA	MP17102	04048675695622

* Lot Number 0367.2702.13 Not Affected (Distributed after March 20, 2023)

Potential Patient Impact

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

For Seattle PAP plus (shipped prior to March 20, 2023):
A detachment of system components may cause desaturation of the patient/hypoxia due to a loss of airway pressure caused by a leak. Patient monitoring (such as SpO2) is designed to detect desaturation of the patient.

For Dräger Neo and Dräger Pediatric disposable breathing systems:

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A detachment of system components may 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 (IFU) as being compatible, the devices are designed to detect the leakage and give an alarm with respect to such leakage.

For Dräger Coax ventilation hoses:
A detachment of system components may cause hypoxia due to:

- A leak of the outer hose, leading to a loss of airway pressure,
- 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 IFU as being compatible, a leakage and/or an obstruction will be detected, and the device will give an alarm.

Required Action

If you have received breathing circuits that were shipped prior to March 20, 2023 that may be affected by this issue, please follow the below instructions:

- Stop use of the affected products. Inspect current stock and quarantine/segregate any unused affected products to prevent their use.
- Alternative therapy should be instituted as soon as possible. These alternative therapies may include: nasal continuous positive airway pressure (nCPAP), noninvasive positive pressure ventilation (NIPPV), high flow nasal canula, and invasive mechanical ventilation (last resort).
- Do not depend on any device output (e.g., oxygen desaturation) to make decisions regarding whether to stop using the system.
- Please ensure that all users of the above-mentioned products and other persons within your organization are made aware of this Urgent Medical Device Recall.
- Please keep this information available to all users at least until you have checked your stock and quarantined/segregated any unused affected products to prevent their use.

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

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To replace/return unused products, please contact Dräger Customer Success via phone between the hours of 8:00 AM – 6:00 PM EST Monday through Friday at 1-800-437-2437 (press 2 at the prompt, then 1) or via email at US-Medical@draeger.com. You will also be provided with a Return Material Authorization and pre-paid shipping documents to return the unused product to Dräger.

If you have any questions, you may contact Michael Kelhart between the hours of 8:00 AM – 4:30 PM EST at 267-664-1131 or via email at mike.kelhart@draeger.com.

Adverse reactions or quality problems experienced with the use of these products may be reported to the U.S. Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Online: Complete and submit the report online
- Regular mail or fax: Download the form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Affected customers have been notified. This voluntary medical device recall has been reported to the FDA.

Dräger. Technology for Life®

Dräger is an international leader in the fields of medical and safety technology. Our products protect, support, and save lives. Founded in 1889, Dräger generated revenues of around EUR 3 billion in 2022. The Dräger Group is currently present in over 190 countries and has more than 16,000 employees worldwide. Please visit www.draeger.com for more information.

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