

**To our customers of
heated breathing circuits and corresponding sets**

March 2019

Important Safety Notice!!!

Possible cracking

***VentStar Helix heated* breathing circuits and *Set2go* products are affected.
Only products found on the attached material number list are affected.**

Dear Madam/Sir,

During the course of our global market surveillance activities, several cases have come to our attention in which cracks have formed in the breathing hose during ventilation. In two cases the patient's health was impacted. In one case the patient required resuscitation, while in another case a patient experienced short-term/reversible tachycardia. In both of these cases the breathing circuits were used in conjunction with devices that we had not declared as compatible. The precise cause of the cracks has not been identified yet. However, our investigation did reveal that a hose material reinforcement that was implemented in March 2018 was not applied to all the breathing circuits that have been manufactured since this time. The difference between a breathing circuit that conforms to the specifications and one that is defective (because it still has the previous hose thickness) is not possible for the customer to identify prior to use.

If a crack forms in the breathing hose during operation, a leak will result that can negatively affect ventilation of the patient. If the breathing circuit is used with devices listed as compatible in the Instructions for Use, any leakages will be detected and the device will give an alarm.

Breathing circuits that we will be shipping in future conform to specifications, i.e. the hose material has been reinforced. We have introduced additional checks to ensure that quality is closely monitored.

According to our records, you have received breathing circuits that may be affected during the past two years (see material number list attached). We will replace any stocks you have not yet used as

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quickly as possible. This will be free of charge. Please contact your local Dräger representative to arrange for this to happen.

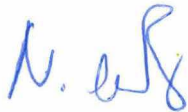
During the transitional period, you can use hoses that pass the leak test prior to use. Make sure to use the hose solely with devices that have been declared as compatible in the Instructions for Use or in the accessories list of the basic device. Ensure that the patient is adequately monitored and select appropriate alarm limits. Make sure to avoid unnecessary pulling during installation and operation and do not use the hoses for longer than stated in the Instructions for Use.

Please notify all potential users in your facility accordingly.

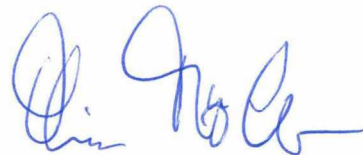
We apologize for any inconvenience that this measure may cause.

The relevant authorities have been notified of this action.

With kind regards



Nicole de Baay
Product Management
Hospital – Generic Supplies & Consumables



Oliver Möller
Post Market Surveillance
Quality and Regulatory Affairs

Attachment:

- List of affected material numbers

Material number list:

Ventilation systems:

Material:	Material name:
MP02606	VentStar Helix dual heated
MP02607	VentStar Helix heated

Set2go:

Material:	Material name:
MP07929	Set2go Ventilation 50 (A)
MP07930	Set2go Ventilation 51 (A)
MP07934	Set2go Ventilation 47 (A)
MP07941	Set2go Ventilation 41 (A)
MP07949	Set2go Ventilation 21 (A)
MP07957	Set2go Ventilation 6 (A)
MP07982	Set2go Ventilation 28 (A)
MP07983	Set2go Ventilation 20 (A)
MP07985	Set2go Ventilation 23 (A)
MP07986	Set2go Ventilation 24 (A)
MP07995	Set2go Ventilation 34 (A)
MP07977	Set2go Ventilation 16 (A)
MP07980	Set2go Ventilation 19 (A)
MP07993	Set2go Ventilation 32 (A)