Technology for Life

Drägerwerk AG & Co. KGaA, 23542 Lübeck

To the Customers of the
Dräger VentStar Flex breathing circuits

February 2025

Important safety notice!!!

Possible leaks due to cracks

Only the products in the attached list are affected!

Dear Sir or Madam,

As part of our global market monitoring, we have become aware of cases in which cracks have formed in the hose. In many cases, the crack was detected before use, for example during the leakage test. In some cases, however, the cracks only formed during application. In no case we were informed of any negative effects on the health of the affected patients. However, this cannot be completely ruled out if this happens again.

In case such cracks form during use, leakage will occur. Depending on the size of the leakage and the selected ventilation pressure, the ventilator / anaesthesia device can compensate for this. If the leakage cannot be compensated for, ventilation is restricted and the patient may experience desaturation/hypoxia. Ventilators according to ISO 80601-2-12 and anaesthesia devices according to ISO 80601-2-13 will generate visual and audible alarms according to the set alarm limits.

Our analyses have shown that the use of certain hose holders or hose holder plates (see Figure 1 below) can cause such cracks due to their flat design. Hose holders with a larger contact surface do not press into individual folds, thus avoiding unfavourable application of force.

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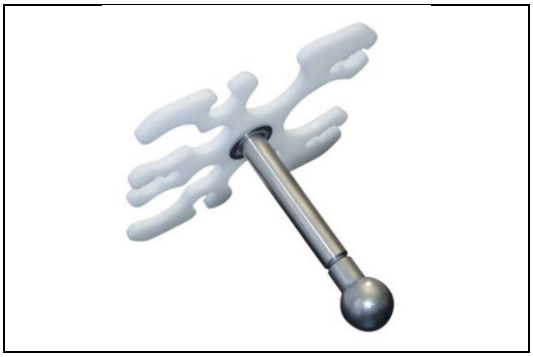

Fig. 1 Hose holder plate with unfavourable design for the affected products

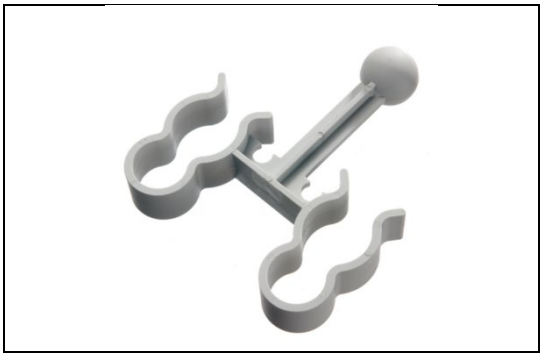

Fig. 2 Hose holder with larger contact surface

For further use of the products, please use hose holders with a larger contact surface (see Figure 2).

We would also like to point out once again that the detection of cracks is improved if the leakage test is only carried out after the extendable hose has been stretched to the required length. In this context, please observe the instructions in the respective instructions for use.

According to our records, you have received affected breathing circuits. Please inform all potential users in your facility.
Please complete and return the attached reply card to confirm this.
If you have forwarded affected products to third parties, please also forward this important safety notice.

We apologize in advance for any inconvenience caused by this measure.

The authorities have been informed about this measure.

Yours faithfully,

Kim Rowold
Product Management
Business Unit Hospital Consumables & Accessories

Oliver Möller
Post Market Surveillance
Quality and Regulatory Affairs

List of affected products

Part no.	Designation	UDI
MP00355	VentStar Flex 220	04048675248996
MP01347	ID Circuit Flex 220	04048675249337
MP02737	Anesthesia Circuit Kit Flex 1	04048675389620
MP02738	Anesthesia Circuit Kit Flex 2	04048675389637
MP02744	Anesthesia Circuit Kit Flex 6	04048675389675
MP02752	Anesthesia Circuit Kit Flex (P)2	04048675389729
MP17103	Anesthesia Circuit Kit Flex HEPA	04048675695660

Dräger

Technology for Life

Reply Card
Please fax or e-mail this form to your Dräger representative!

DRÄGER

To: < To be completed by relevant subsidiaries/dealers >

Department:

Dräger Representative:

Fax:

Phone:

E-mail:

Re: **Important Safety Notice on Dräger VentStar Flex breathing circuits, February 2025**

(Please complete)

CUSTOMER DATA

Hospital:

Customer name:

Phone: Fax:

E-mail:

Address:

Address 2:

Country:

Town/city:

Quantity of affected units:

☐ We acknowledge receipt of the safety notice and that the information contained therein has been brought to the attention of all affected users.

(Please complete and sign)

Title/position:

Name: (Please print in capitals)

Signature: Date: