Drägerwerk AG & Co. KGaA, 23542 Lübeck

To whom it may concern

Our reference
meike.lessau@draeger.com
kreske.brunckhorst@draeger.com

Phone
+49 451 882-0

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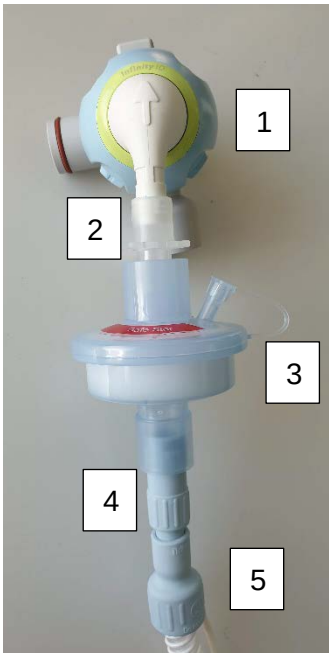
COVID-19: Use of Breathing System Filter & Neonatal Expiratory Valve

Dear customers, dear health care professionals,

The World Health Organization (WHO) declared COVID-19 a pandemic on March 11th, 2020, with over 118,000 cases of the coronavirus illness reported in over 110 countries worldwide. The pandemic has created a high demand for Breathing System Filter (BSF) to avoid cross-contamination. Customers and health care professionals approached us, to obtain information about the possibility to use BSF (especially the SafeStar® family) in combination with a neonatal expiratory valve (8415270 reusable expiratory valve for Babylog® VN500) via connectors similarly as shown in the following picture.



1. 8415270 reusable expiratory valve for Babylog® VN500
2. Standard tube connector 11mm (11ID/15OD-11ID/13OD)
3. Mechanical Filter, e.g. SafeStar 55 MP01790
4. Connector 11ID/15OD–9ID/11OD, e.g. MP02655 (20 pieces)
5. Expiratory limb of the breathing circuit

Due to these exceptional circumstances, we believe it is our responsibility to provide some insights both (I) on the legal and regulatory perspective as well as (II) related to the use of a Dräger BSF in combination with Dräger neonatal expiratory valve.

I. Legal and Regulatory Perspective

WARNING: The following information on the legal and regulatory perspective is limited to the laws in force in the European Union (EU) as of the date of this letter and provides only general guidance.

The intended use of Dräger's Breathing System Filters (BSF) is described in the corresponding instruction for use (IfU). The BSFs are specified for anesthesia or respiratory use. For further information on system compatibilities, see the lists of accessories of the ventilators or other documents issued by Dräger. The installation to the intensive care ventilator must be performed following the respective IfU.
The patient group is defined in the technical data for the respective BSF by the recommended tidal volume range. For the defined patient groups, the BSF can be used at the Y-piece and / or the device side. When combined with active humidifiers or medication nebulizers, the medical device must only be used on the device side and under closer surveillance of a potential increase in expiratory resistance.

Any use of the product outside of the intended use specified in the instructions for use (e.g. using connectors to combine the BSF with a neonatal expiratory valve) constitutes off-label use.

If a product is used off-label, the user recognizes that it is not the intended use of the product and does so in his responsibility and at his own (liability) risk.
However, in a situation in which a user requires a mechanical filter to protect the surrounding for cross-contamination, the benefit of an expiratory filter on a neonatal expiratory valve has to be weighed against the risk of the off-label usage of a BSF. This risk-benefit assessment and the resulting decision must be made by the responsible health care professional based on the circumstances of the individual case.

II. Known Limitations of using a combination of a Dräger Breathing System Filter at a Neonatal Expiratory Valve

WARNING: The following information list is based on our currently available knowledge as of the date of this letter. It does only apply to Dräger products still being marketed. It is most likely not complete and exhaustive. If you detect important points which are missing, please let us know.

WARNING: Dräger as the manufacturer cannot and may not market or promote or sign-off such off-label use of Dräger products. The following information is, therefore provided only to provide a better basis for the decision of the responsible health care professional. If a device is used off-label, the user does so in his own responsibility and at his own (liability) risk.

Additional components in the breathing system, such as a BSF, increase the dead space if attached proximal to the patient or increase the compliance and resistance of the breathing system if applied at the ventilator side. Using the BSF proximally can lead to reduced CO2-removal due to dead space ventilation. Adding further components such as connectors and using incompatible components may additionally increase inspiratory and expiratory resistance of the breathing system and adversely affect the performance of the ventilator. The simultaneous use of 2 filters (on inspiratory and expiratory side of the ventilator) leads to an increased total resistance (pressure drop).

The use of additional components in the patient circuit requires particular care and monitoring!

Check that all connections are securely fitted and tight. After the breathing circuit and filters have been completely installed and before use on the patient, perform a system check and a breathing circuit check after the breathing circuit and filters have been completely installed.

Regularly check the inside of the BSF for liquids (condensed water) or visible soiling (secretion).
If liquids or visible soiling are found, replace the BSF immediately.

An undetected increased expiratory resistance may put the patient at risk and increase the work of breathing. **During invasive ventilation, an increased expiratory resistance may lead to undetected deviations in mean airway pressure and set inspiratory pressures.**
To early detect the occlusion of the filter and the resulting increase in expiratory resistance, closely monitor the following parameters on the ventilator:

- Monitor the flow waveform for a change in resistance in the expiration phase
- Monitor related measurements such as resistance or expiratory time constants
- Monitor an increase of expiratory pressures and related alarms e.g. PEEP high alarm
- Monitor a decreasing tidal volume and minute volume

The BSF SafeStar MP01790 was designed, tested and manufactured **exclusively for single use and a period of use not exceeding 24 hours**. The BSF must not be reused, reprocessed or sterilized. Reuse, reprocessing or sterilization may lead to failure of the medical device and injury to the patient.

If you have any further questions or need any support, please contact Dräger's local service support or sales representative.

Kind Regards,

Marco Ventur
Risk Manager
Business Unit Therapy
Medical Devision

Meike Lessau
Global Product Manager
Business Unit Hospital
Consumables & Accessories
Medical Division

Kreske Brunckhorst
Global Product Manager
Business Unit Therapy
Medical Division