Medical Device Advisory Notice
Anesthesia and Respiratory Product line

24 May 2023

Dear Valued Customer,

This letter is being sent to notify you of an Advisory Notice for our Anesthesia and Respiratory product line. This advisory notice is for all lots of product codes 6126(CircuitGuard Filter, ThermoFlo Heat and Moisture Exchanger, Elbow), 6131(CircuitGuard Filter, ThermoFlo Heat and Moisture Exchanger, Integrated Elbow), and 7056 (CircuitGuard, Bacterial/Viral filter with Elbow) received prior to 5/26/2023. This Advisory Notice does not affect the quality of the product and no customer actions are required.

This advisory notice was issued to inform our customers that you received the product codes mentioned above where there was no IFU (Instructions for use) in each case.

The product codes mentioned above should have been shipped with an IFU (Instructions for use) in each case. Moving forward all cases will contain an IFU (Instructions for use). Please see the attached IFU for product code 6126, 6131, and 7056. You can also find our IFU for the product codes mentioned above on our website at https://www.typenex.com/products/operating-room/breathing-circuit-filters/hmes-and-filters/ under the resources tab.

We kindly request that you send documented acknowledgement of receipt of advisory notice. Please continue to reach out to your sales representative for product inquiries or issues.

The contents of this advisory notice constitute "Confidential Information." We request that you hold the Confidential Information in strict confidence by not forwarding the same and using that degree of care used in safeguarding your own similar information or material, but in no event less than a reasonable degree of care, to prevent the unauthorized disclosure of the same. We further request that you not disclose such Confidential Information to any third party except as specifically authorized herein, by law, or as specifically authorized by us in writing, and, in the case of a disclosure to any third party, to ensure that such third party abides by the same nondisclosure obligations as stated herein prior to any such disclosure of Confidential Information.

If you have any questions pertaining to this advisory notice please contact Typenex Medical's Director, Quality and Regulatory Affairs: Mr. Michael D. Choquette at mchoquette@typenex.com or at 312-888-4064. Thank you for your continued commitment to Typenex Medical.

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