



January 20, 2016

**Urgent Medical Device Field Correction****3M™ Steri-Vac™ Gas Sterilizer/Aerator  
Models 5XL and 8XL**

Dear Valued 3M Customer:

This letter provides information regarding a field correction involving 3M™ Steri-Vac™ Gas Sterilizer/Aerators Models 5XL and 8XL. The field correction involves units manufactured between May 20, 2015, and December 2, 2015, and units serviced between June 3, 2015, and December 2, 2015. It is important that you read this letter completely and follow the instructions provided.

**Reason for Field Correction**

Recently, during inspection of incoming components from a supplier, 3M discovered a valve with incorrectly labeled “input” and “output” orientation. Identified in a single lot of 100 valves, this defect can result in the valve being installed backwards, creating a remote possibility of valve failure. Because one of the uses for these valves is to admit air into the sterilizer chamber, and also prevent EO from escaping, a failure may result in EO being vented outside the sealed chamber during a limited period (< 1 minute) in the EO injection phase of the cycle.

**Probability of Occurrence**

3M believes the probability of failure is extremely low. While this failure is theoretically possible, 3M has tested all 17 of the valves from the affected lot currently in our possession, and we have not observed this failure. Additionally, 3M has not received any reports related to this issue.

**Potential Hazard**

If the vent valve were to fail, there is a potential for the user to be exposed to EO.

**Action to be Taken**

If you have received this notice from 3M, then our records indicate you have a sterilizer within the scope of the field correction. These units may have an improperly labeled valve.

<b>Sterilizer Models 5XL and 8XL</b>	<b>From Date</b>	<b>To Date</b>
Manufactured by 3M	May 20, 2015	December 2, 2015

3M Service will be contacting you to schedule an appointment to inspect the subject valve in your unit(s). There is no reliable method for an untrained individual to determine if a sterilizer is affected; a trained service technician must assess the valve in person. In the meantime, you may continue using your sterilizer(s).

We apologize for any inconvenience this field correction may cause. Please be assured that 3M is committed to the highest level of safety and customer service and we are proud of our long-standing safety record for 3M™ Steri-Vac™ Gas Sterilizer/Aerators.

For Further Information

If you have any questions, please contact the 3M Health Care Service Line at 1-800-228-3957 or your local 3M representative.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael J. Besser". The signature is fluid and cursive, with a long horizontal stroke at the end.

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Michael J. Besser  
Division Quality Manager  
3M Infection Prevention Division  
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St. Paul, MN 55144, USA