



URGENT DEVICE CORRECTION
STERRAD® NX™ System and STERRAD® 50 System

March 9, 2009

Dear Director of Risk Management:

On April 23, 2008, Advanced Sterilization Products (ASP) initiated a device correction notification related to certain models of STERRAD® Sterilization Systems that have the potential to emit oil mist due to a premature mechanical failure in the oil mist filter and/or filter assemblies. All affected STERRAD Systems have been corrected since the notification was issued.

Recently, a secondary, lower-occurring cause of oil mist has been identified within the STERRAD NX System and STERRAD 50 System oil fill plugs. Your facility's STERRAD NX System and/or STERRAD 50 System may potentially have defective oil fill plugs. Less than 1% of the installed STERRAD NX Systems have been affected. ASP has received 18 complaints in 10 months related to this failure for the STERRAD NX System. We have not received any complaints related to this issue for the STERRAD 50 System. As of December 22, 2008, ASP has been actively replacing the plugs in these systems with stainless steel plugs during service calls. We will continue to replace the oil fill plugs until all affected units are corrected.

Please circulate this letter to any STERRAD NX System or STERRAD 50 System users within your facility and also to the Chief Administrative Officer, Director of Biomedical Engineering, Director of Materials Management and Chief of Nursing.

What Defect Occurs with the Oil Fill Plugs?

The oil fill plugs in the STERRAD NX System vacuum pump are made of nylon 6-6, which is a material that can degrade over time if exposed to hydrogen peroxide. Because the plugs are exposed to hydrogen peroxide vapor that is evacuated by the vacuum pump, a hole may form following prolonged exposure and contribute to the emission of oil mist from the sterilizer.

Although no complaints have been received to date for the STERRAD 50 System, it contains the same nylon plugs as the STERRAD NX System. Accordingly, the STERRAD 50 System oil fill plugs, in addition to the STERRAD NX System oil fill plugs, will be proactively replaced as part of the device correction.

Please note that the oil fill plug failure condition is independent of the requirements to achieve sterility. You can be confident that sterility is achieved if instruments are reprocessed in a complete cycle and according to the instructions in the User's Guide for your STERRAD System.

What Should I Do if I Experience Oil Mist?

There is a risk of symptoms, such as nausea, shortness of breath, dry throat, burning, watery and blurry eyes, and headache occurring if customers inhale oil mist. If you see mist, haze or smoke in the room or detect an oil odor, personnel should complete the following:

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- Cancel the cycle if the sterilizer is running and as always, do not use instruments from an incomplete cycle
- Leave the room
- Avoid working in the room until the mist has cleared
- **Discontinue use of the STERRAD System until the system is repaired**

Please note that all STERRAD Systems should be used and installed in a well-ventilated environment. The “Installation Requirements and Product Specification” document for each STERRAD System model call for environmental conditions that include a minimum of 10 air exchanges per hour. Please contact ASP immediately at **(888) 783-7723 (select option 2)** to schedule on-site service.

What is Oil Mist?

The chemical composition of the mist is primarily airborne mineral oil with trace amounts of other compounds. The oil mist originates from the vacuum pump in the STERRAD Sterilizer. Test results¹ for the airborne mineral oil mist and the other compounds indicate that the levels are well below the respective OSHA Permissible Exposure Limit (PEL) and National Institute for Occupational Safety and Health (NIOSH) Recommended Exposure Limit, Time Weighted Average (TWA) and Short Term Exposure Limit (ST). Based upon these results, any respiratory symptoms; e.g., eye, nose and throat irritation, should only last minutes to a few hours after exposure ceased. **Any user experiencing adverse health effects following exposure to oil mist should immediately consult with a health care professional.** Oil mist exposure may, theoretically, pose an increased risk to people with certain respiratory conditions, such as asthma, and they should take special precaution not to be exposed to oil mist. Continuing to run additional cycles in the unit after observing this condition may result in an accumulation of the mist that could exceed the thresholds described above, especially in areas not adequately ventilated. **Therefore, you should follow the instructions in the “What Should I Do If I Experience Oil Mist?” section above if you experience this condition with your sterilizer.**

Actions We Are Taking to Meet Your Needs

We value you as a customer and appreciate your patience. On December 22, 2008, ASP began replacing the nylon oil fill plugs with stainless steel plugs during service calls for STERRAD NX Systems and STERRAD 50 Systems. If you have had service on your unit since December 22, 2008, your oil plugs have already been updated; if not, ASP will replace the oil fill plugs at no charge during your next service call. All updates will be completed no later than July 31, 2009.

If you observe oil mist before ASP can replace the oil fill plug on your sterilizer, follow the instructions in the “What Should I Do if I Experience Oil Mist?” section above.

Our Clinical and Technical Support staff is available 24 hours a day to answer additional questions you may have at (888) 879-4613.

Sincerely,

A handwritten signature in blue ink that reads 'Mark Johnson'.

Mark Johnson

Vice President, Worldwide Quality Assurance, Regulatory Affairs and Process Excellence

¹ Tests Included: Airborne Mineral Oil Mist, Hydrogen Peroxide Vapor by OSHA method, Total Aerosol Mass, Respirable Dust, Sulfur Dioxide, Polynuclear Aromatic Hydrocarbons (PAHs), Quartz Silica, Heavy Metals, Carbon Monoxide, and Total Hydrocarbon Vapor.