



February 2, 2009

**URGENT: PRODUCT CORRECTION**  
**Specific STERRAD® 50 Sterilizers**

Dear Sir or Madam::

Advanced Sterilization Products (ASP) is notifying you of a remote circumstance that could cause a capacitor in the vacuum pump component within your STERRAD® 50 System to overheat and potentially create a hazardous condition inside of the system, resulting in smoke and/or fire. Based on our risk assessment, there is a low possibility of this malfunction occurring, as ASP is aware of only two such incidents since the system was released in 1997.

This condition only impacts STERRAD 50 Systems with serial numbers listed on page two of this notification. You are being informed of this situation because our records indicate that your facility has one of the affected STERRAD 50 Systems.

Please distribute this notification to all STERRAD 50 System users in your facility.

**Actions Required if Malfunction Occurs**

If you see smoke or smell a burning odor in or around your STERRAD 50 System, ASP strongly recommends that you follow your facility's safety protocols and if possible, immediately disconnect the STERRAD 50 System from its electrical source. Please contact ASP to schedule an onsite visit to investigate the issue. If the issue is caused by a malfunctioning capacitor in the vacuum pump, we will replace the malfunctioning component right away.

**Actions We Are Taking**

To correct this situation, an ASP Field Service Engineer (FSE) will be visiting your facility within sixty days to replace the capacitor in the vacuum pump on your affected STERRAD 50 System with a capacitor of a different design. Your Field Service Engineer (FSE) will contact you as soon as possible to schedule this visit.

We regret any inconvenience this product correction may cause you or your staff. If you have any questions or need assistance, please call our ASP representative at +6012-288 7330

Thank you for your valued partnership and continued support of STERRAD Sterilization Systems.

Sincerely,

Ong Yean Ting  
Regulatory Affairs Manager

3 Technology Drive, Irvine, CA 92618. Tel: 949.581.5799. Fax: 949.581.5997

**ADVANCED STERILIZATION PRODUCTS**

Division of Ethicon, Inc.  
a **Johnson & Johnson** company