

December 4, 2023

**Medical Device - Customer Notification****STERRAD™ 100NX Sterilizers and STERRAD NX™ Sterilizers  
Product Codes:****STERRAD™ 100NX Sterilizer** (10104, 10104-002, 10104-003, 10104-004)**STERRAD™ 100NX Sterilizer with ALLClear™ Technology** (10104-005, 10104-006, 10104-007, 10104-008)**STERRAD NX™ Sterilization System** (10033, 10033-002)**STERRAD NX™ Sterilization System with ALLClear™ Technology** (10033-004)

Advanced Sterilization Products, Inc. (ASP) has determined that certain STERRAD 100NX Sterilizers and STERRAD NX Sterilizers (hereinafter “STERRAD Sterilization Systems” or “sterilization system”), manufactured after September 2019, contain a UV lamp power supply that may experience a short circuit, causing the power supply to fail. If this short circuit condition occurs, the sterilization system will be unable to detect the UV light and the system will not start the sterilization cycle. If the short circuit occurs during a sterilization cycle, the cycle will cancel and display a cancelation message. In 0.37% of these identified sterilization systems, a power supply failure leading to overheating has occurred, and in 0.15% of the overheating occurrences there were reports of the sterilizer emitting an electrical burning odor and smoke was visible. If an odor or smoke is observed, power off the unit and contact ASP for service.

The STERRAD Sterilization Systems can continue to be used in accordance with the user’s guide. The sterilization systems are designed and tested to meet IEC 61010-1 Electrical safety standards and use self-extinguishing components. ASP is implementing a correction to eliminate the possibility of overheating and the potential for burning odor and smoke and will service impacted STERRAD Sterilization Systems during the next service calls starting in November 2023.

**WHY ARE YOU BEING CONTACTED**

ASP records indicate your facility has a STERRAD™ 100NX Sterilizer and/or a STERRAD NX™ Sterilizer that may be impacted by this issue. Users can still operate the sterilization systems in accordance with their respective user’s guide pending the correction.

**CUSTOMER ACTIONS REQUIRED**

- Maintain a copy of this Customer Notification at your facility and ensure it remains available to Healthcare Workers.
- Ensure Healthcare Workers who operate the sterilizers have read and understood this Customer Notification.
- Complete and return the Customer Reply Form within five (5) business days of receipt of this notification.
- If your facility observes this issue, contact your local ASP representative with the STERRAD Sterilization System serial number.

ASP is committed to providing safe and effective products around the world. For questions regarding this notification, please contact your ASP representative.

Sincerely,

DocuSigned by:  
Marcelo Trevino  
Signer Name: Marcelo Trevino  
Signing Reason: I approve this document  
Signing Time: 04-Dec-2023 10:31 AM PST  
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**Marcelo Trevino**  
ASP Vice President,  
Global Regulatory Affairs & Quality Assurance