

**Medical Device Product Notification:  
Reminder to Follow The User's Guide When Opening Chamber Door  
of The STERRAD NX® Sterilization System.  
P/N 10033, 10033-002 (STERRAD NX® Sterilization System)**

17<sup>th</sup> Jan 2017

Dear Valued Customers,

Advanced Sterilization Products (ASP) has identified that in a rare sequence of events following an external power outage, the system door interlock can become disengaged during system reboot for a 20-second duration. ASP is sending this letter to remind customers to follow the instructions in the STERRAD NX® System User's Guide. Specifically, after cycle initiation, the user should only open the chamber door of the STERRAD NX® System when prompted by the Graphical User Interface (GUI) per the User's Guide.

**Product Intended Use**

The STERRAD NX® Sterilization System is a general purpose, low temperature sterilizer which uses the STERRAD NX® process to inactivate microorganisms on a broad range of medical devices and surgical instruments. When used as directed by the instructions in the user's guide, the STERRAD NX® Sterilization System will sterilize both metal and nonmetal medical devices at low temperatures. The STERRAD NX® sterilization process is a multiphase sterilization process that utilizes a combination of exposure to hydrogen peroxide vapor and plasma to affect sterilization.

**What The Customer/User Needs To Know**

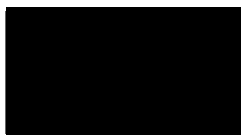
- Follow the instructions in the User's Guide, Chapter 5 for normal operation. Specifically, after cycle initiation, the user should only open the chamber door of the STERRAD NX® System when prompted by the GUI per the User's Guide. Reference Appendix I of this letter for specific images of the GUI.
- Ensure that anyone in your facility impacted by this notification reads this letter carefully.
- Maintain a copy of this communication where the STERRAD NX® Sterilization System is located.
- Please complete and return the attached Customer Acknowledgement Form for your acknowledgement within 3 business days of receipt of this notification letter.

**Why You Are Being Contacted**

You are receiving this letter because our records indicate you have owned/purchased a STERRAD NX® Sterilization System. To report any complaints or suspected problems with STERRAD NX® Sterilization System product related to this letter, please contact your local ASP Representative. For questions regarding the Customer Acknowledgement Form, please contact your local ASP Representative.

We appreciate your cooperation in this matter and value you as our customer. ASP is committed to maintaining your confidence in the safety and quality of our products.

Yours sincerely,



Lee Ching Hwee

Associate Manager, Regulatory Affairs

### Appendix I

Below are the screen images of the Graphical User Interface (GUI) displayed to the user the open door messages.

- When a cycle is completed



- When a cycle is cancelled

