

November 10, 2008

URGENT: PRODUCT CORRECTION
STERRAD® 100S Sterilizer

Dear Risk Manager:

Advanced Sterilization Products (ASP) is notifying you of two situations that, under rare circumstances, could cause your STERRAD® 100S Sterilizer to malfunction. This letter is to inform you of these situations and what ASP will do to correct them. **Please distribute this information to all STERRAD® 100S System users in your facility.**

The first situation involves the failure of the STERRAD 100S System to detect when an injection takes place without hydrogen peroxide having been transferred to the vaporizer bowl. This can occur under combinations of the following conditions:

- the pneumatic pressure is low on the machine, OR
 - the injector valve has a small leak,
- AND
- a cassette fails to advance, OR
 - a used cassette is re-inserted into the sterilizer.

This situation can result in a cycle completion with insufficient hydrogen peroxide. Based upon ASP's Risk Assessment, it has been determined that the likelihood of this condition occurring during sterilizer operation is remote. This means that the chance of this incidence occurring is much less than one in 1,000,000 which is well below the Sterility Assurance Level (SAL) of 1×10^{-6} for any sterilization modality. Therefore, ASP is not aware of any current risk to patients by continued use of the STERRAD 100S Sterilizer.

The second situation involves the failure of the STERRAD 100S System to detect an obstruction in the door travel path while the door is closing. Under some conditions, the door sensors may become mechanically unsecured/disconnected and will not detect an obstruction. This situation can result in an operator's hand becoming pinched and bruised while the door is closing.

Actions ASP is Taking to Correct These Situations

To correct both situations above, ASP has revised the software and is making physical hardware additions to the STERRAD 100S System. These updates and additions will be installed in your STERRAD 100S Sterilizer(s) at the time of your next maintenance visit starting the first week in December 2008. All updates will be completed no later than August 31, 2009.

The software enhancements and hardware additions will ensure that your STERRAD® 100S Sterilizer properly does the following:

1. detects the transfer of liquid from the cassette to the vaporizer bowl;
2. confirms functionality of the door sensor when the door is in motion;
3. helps ensure that your STERRAD 100S System functions solely with genuine STERRAD 100S Cassettes made by or on behalf of ASP. Among other things, this will help avoid potential safety concerns and compatibility issues you may experience with other products.

Based upon the risk assessments mentioned above, ASP has determined that the likelihood of either of these conditions occurring during sterilizer operation is remote. To help mitigate any remaining risks:

1. please make sure to follow the directions in your User's Guide and always use STERRAD® Chemical Indicators in the load, and
2. do not place hands or any object in the travel path of the door while the door is in motion.

ASP is always working to continuously improve our systems and ensure the products you use with your STERRAD® Sterilizer are appropriate and optimized for best performance. We regret any inconvenience these product corrections may cause you or your staff. If you have any questions or need assistance, please call the ASP Customer Care Center at 800-370-4632.

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

Sincerely,



Mark Johnson
Vice President, Quality Assurance, Regulatory Affairs and Process Excellence