



**URGENT: PRODUCT CORRECTION**  
**Automatic Endoscope Reprocessor (AER)**

February 19, 2010

Dear Valued Customer:

Advanced Sterilization Products (ASP), the distributor of the Automatic Endoscope Reprocessor (AER) manufactured by Minntech Corporation (Minntech), is notifying you that we have received three customer reports of elevated temperature of the high-level disinfectant solution used in the ASP AER as a result of a possible temperature monitoring system malfunction. This communication is to advise you that if high-level disinfectants are exposed to elevated temperatures, fumes may occur and result in reported incidents of respiratory reactions, dizziness, burning eyes and headaches to the healthcare worker. According to the MSDS for CIDEX<sup>®</sup> OPA, additional reactions from inhalation may cause irritation, including but not limited to, discharge, coughing, wheezing, tightness of chest and throat, difficulty breathing, stinging sensation in nose and throat, tingling of mouth and lips, headache, loss of smell and dry mouth.

ASP is working with Minntech to identify the root cause related to the temperature elevation, and is working towards a potential long-term solution. While the incident rate is below 1 percent, please immediately take the following precautionary steps to ensure continued safe operation of the ASP AER and avoid the potential for elevated high-level disinfectant temperatures.

**Until further notice, please distribute this information to all ASP AER users in your facility and ensure they immediately follow the instructions below.**

**Actions Required to be Taken Immediately**

- **CIDEX<sup>®</sup> OPA Solution Users:** If you are using CIDEX<sup>®</sup> OPA Solution, you must disconnect the heater and use the CIDEX<sup>®</sup> OPA Solution in accordance with its label directions of 12 minute immersion time at 20° C. The heater can be disconnected by having your technician follow the enclosed instructions. ASP recommends that the user check the solution temperature in the basin on a regular basis per institutional guidelines.
- **Users of Other High-Level Disinfectants:** If you are currently using a disinfectant that must be used at 25° C or higher, you must immediately discontinue using the ASP AER with that disinfectant. Instead, you must process your endoscopes by another method in accordance with the Instructions for Use (IFU) for that particular disinfectant. **If you plan to continue to use the ASP AER,** you must disconnect the heater and obtain a high-level disinfectant that does not require heating above room temperature. Information on high-level disinfectants cleared for use by the FDA can be obtained from the website: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofSingle-UseDevices/UCM133514>.

