

FDA Alert: Steris System 1 Sterilizers Not Approved for Sterilization

The U.S. Food and Drug Administration (FDA) issued a safety alert on December 3, 2009, urging users of the Steris System 1 (SS1) to find alternative methods of sterilizing and disinfecting instruments and medical devices. The Alert states that “improperly disinfected or sterilized instruments may transmit pathogens to patients and healthcare staff, or expose them to hazardous chemicals.”

The alert recommends that facilities should transition to an alternative method of sterilization and disinfection as soon as possible. Steris disagrees with the safety alert and states that there has not been a documented infection directly caused by the SS1 “when certified health professionals have followed proper guidelines and instructions.” The Steris statement does not include these instructions, nor does it define “certified health professionals.”

Their web site does offer study guides that include care and handling of flexible endoscopes, as well as a two day training seminar, with a “train the trainer” approach that can be scheduled at their training locations, but does not provide any other written guidelines as noted in their statement following the FDA alert.

This alert was issued as Steris significantly modified the SS1, however, the FDA has not determined that the modifications are safe or effective, and has indicated that there is a potential risk to patients if it is utilized as a method of sterilization.

In summary: The FDA determined that the numerous changes to the SS1 since its launch causes it to be a “violating device.” However, they also recommend that “If an acceptable alternative is not readily available, health care facilities should not cancel surgical procedures and may continue using SS1 while preparing a transition plan to be implemented in three to six months.” For more, go to the [“Questions and Answers” document](#) on the FDA website.

The risk management advice presented in this Site is intended as general information of interest to physicians and other healthcare professionals. The recommendations and advice published on this Site do not reflect or establish a standard of care and do not establish rules for the practice of medicine. The publication of this information is not intended as an offer to insure such conditions or exposures, or to indicate that MAG Mutual Insurance Company will underwrite such risks for the reader. Our liability is limited to the specific written terms and conditions of actual insurance policies issued.
