

From: NC Statewide Program in Infection Control and Epidemiology (SPICE)  
December 23, 2009

On December 3rd, the FDA disseminated a notice to healthcare facilities stating that Steris significantly modified the Steris System 1 processor and the FDA has not approved or cleared this modified product. Thus, the FDA has not determined whether this processor is safe or effective for its labeled claims including claims that it sterilizes medical devices. The FDA recommends that users find an acceptable alternative to the product as soon as possible to ensure continued patient safety.

SPICE recommendations are:

- Evaluate what medical/surgical equipment you sterilize (or HLD) by Steris System 1 (SS1) and what alternatives are available now and plan to transition to the alternative technologies. We recommend healthcare facilities use the following references as guidance on alternative technologies: the CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 ([www.cdc.gov/ncidod/dhqp/pdf/guidelines/Disinfection\\_Nov\\_2008.pdf](http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Disinfection_Nov_2008.pdf)); the FDA website (<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm194429.htm>) for information about high-level disinfectants/chemical sterilants and alternate sterilization technologies; manufacturer's written recommendations (e.g., medical device material [polypropylene, brass, polyamide], restrictions based on lumen length and diameter); and articles in the scientific literature. In general, you must minimally high-level disinfect a semicritical instrument (i.e., instruments that contact mucous membranes such as GI endoscope, laryngoscopes) and sterilize a critical instrument (objects that contact sterile tissue or the vascular system such as surgical instruments, laparoscopes, arthroscopes). All devices may not be able to be reprocessed by the same sterilization technology.
- We know of no demonstrated risk of disease transmission associated with the use of this system if used as recommended. To our knowledge, there have been no reports of sterilization failure and no apparent risk of infections with the SS1 in the scientific literature, except for one report in MMWR in 1999 when bronchoscopes were inadequately reprocessed when inappropriate channel connectors were used and when there were inconsistencies between the reprocessing instructions provided by the manufacturer of the bronchoscope and the manufacturer of the automatic endoscope reprocessor.
- We do not interpret the recent FDA information to represent an immediate and urgent risk of infections.
- We believe healthcare facilities do not need to discontinue their use of the SS1 immediately but they should evaluate options and plan to transition to alternative technologies within 3-6 months (may be outliers based on capital equipment funds, availability of alternative sterilization technology, etc).