

## Safety



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## MedWatch The FDA Safety Information and Adverse Event Reporting Program

## Safety Information

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## Steris System 1 Processor: FDA Notice and Recommendations

**Audience:** Hospital risk managers, surgical service managers, infection control professionals

[UPDATED 04/20/2010] FDA Obtains Consent Decree to Stop Marketing of Unapproved Sterilization System-STERIS System 1 Processor (SS1).

[UPDATED 02/02/2010] FDA is extending to 18 months the total recommended time period for transitioning from Steris Corporation's modified System 1 processor (SS1) to legally-marketed alternative devices.

[UPDATED 12/17/2009] Alternatives to STERIS System 1 (FDA-cleared sterilization and disinfection products) added to web site.

[Posted 12/03/2009] FDA notified healthcare facility administrators and infection control healthcare professionals of important information regarding the regulatory status of the STERIS System 1 Processor (SS1) used in surgical and endoscopy suites for reprocessing, i.e., sterilizing or disinfecting, medical devices.

STERIS has significantly modified the SS1 and FDA has not approved or cleared this modified product. Thus, FDA has not determined whether the SS1 is safe or effective for its labeled claims, including claims that it sterilizes medical devices. Use of a device that is promoted to sterilize or disinfect a medical or surgical device, but that does not properly perform these functions, poses risks to patients and users. Improperly disinfected or sterilized instruments may transmit pathogens to patients and healthcare staff, or expose them to hazardous chemicals. Improper sterilization or disinfection may also adversely affect the quality and functionality of reprocessed instruments. FDA has received some reports of malfunctions of the SS1 that had the potential to cause or contribute to serious injuries to patients, such as infections. There have also been reports of injuries, mostly burns from exposure to the sterilant solution, to healthcare facility staff operating the device.

FDA recommends that if a facility has an acceptable alternative to the SS1 to meet sterilization and disinfection needs, the facility should transition to that alternative as soon as possible to ensure continued patient safety. If an acceptable alternative to the SS1 is not available, the facility should promptly assess its patient-care needs and sterilization and disinfection requirements and take steps to obtain legally-marketed substitutes for the SS1.

User facilities, including hospitals, are required to report suspected device-related deaths to FDA and the manufacturer, and serious injuries to the manufacturer or to FDA, if the manufacturer is unknown (see <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm>). Also, FDA solicits voluntary reports of adverse events from healthcare professionals. Adverse events may be submitted online.

[04/20/2010 - [FDA News Release](#) - FDA]

[02/02/2010 - [Extension of Recommended Time Period for Healthcare Facilities](#) - FDA]

[12/17/2009 - [Alternatives to STERIS System 1: FDA-cleared sterilization and disinfection products](#) - FDA]

[12/03/2009 - [Dear Healthcare Facility Letter](#) - FDA]

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