

SPINE SAFETY CAUTIONARY NOTICE:

**Information for Healthcare Professionals:**

**Steris System 1 Processor:**

**FDA Notice and Recommendations-**

**Unapproved Device With Potential for Improper Sterilization and Disinfection**

According to MedWatch, 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](#).

Read the complete MedWatch 2009 Safety summary, including a link to the FDA letter to healthcare facilities, at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm192842.htm>

The North American Spine Society is committed to quality patient care through promotion of patient safety and prevention of medical errors. NASS monitors a variety of government and other resources for patient safety related notices that may be useful to our members. Information from these notices is also archived on the NASS website at <http://www.spine.org/Pages/PracticePolicy/ClinicalCare/SpineSafetyAlerts/Default.aspx>. This information is provided as a service for information and education only.