



## VISION SCIENCES® STATEMENT REGARDING STERIS SYSTEM 1

Vision-Sciences, Inc. | 40 Ramland Road | Orangeburg, NY 10962 USA | 845-365-0600 | 845-365-0620 | [www.visionsciences.com](http://www.visionsciences.com)

January 22, 2010

### FDA STERIS NOTIFICATION

In May of 2008 the FDA issued a Warning Letter concerning the STERIS System 1 (SS1). This Warning Letter specifically concerned changes that had been made to the STERIS System 1 over a period of five years from 1998 to 2002. When this Warning Letter was issued, STERIS had agreed to submit a new 510(k) specifying the changes to the System 1.

More recently, on December 3<sup>rd</sup>, 2009 the FDA released a Notice and List of Recommendations focused on the STERIS System 1 questioning its claims of being an effective medical device sterilizer. This notice and list of recommendations cautions healthcare facilities that the 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 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.

While the FDA has stated that procedures should not be interrupted, it does state that healthcare facilities should make a timely transition to alternatives to the STERIS System 1 within three to six months.

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

### ON ENDOSHEATH® TECHNOLOGY

EndoSheath® Technology is an FDA-cleared sterile, disposable solution for flexible endoscopy. Designed as a durable microbial barrier that provides each patient with a sterile insertion tube and a contaminant-free system, EndoSheath® Technology can provide an alternative to conventional high level disinfection processes such as STERIS System 1. EndoSheath®-based endoscopy offers rapid equipment turnaround, ensured sterility for all patient contact components, limited exposure to toxic chemicals, simplified staff training, and cost effective capital equipment implementation compared to conventional endoscopy.

Please visit the Products/Catalogs section of [www.visionsciences.com](http://www.visionsciences.com) to find out more about EndoSheath® Technology and how you can become an EndoSheath® Endoscopy practice or facility. Vision Sciences® EndoSheath® Technology is FDA-cleared, features CE Mark and is currently marketed for use in areas such as flexible cystoscopy, flexible bronchoscopy, flexible esophagoscopy, and flexible laryngoscopy.

### FOR OUR ENDOSCOPE CUSTOMERS

While Vision-Sciences endoscopes have been declared functionally and materially compatible with the STERIS System 1, we urge you to review the FDA notification and information on the situation so that the appropriate actions can be taken regarding your reprocessing needs, including finding an alternative to the use of the System 1. If you need assistance in finding acceptable alternatives or require any information or technical service on any Vision Sciences® products, please contact Vision-Sciences Customer Service at 800-874-9975.