

December 22, 2009

## **GYRUS ACMI STATEMENT CONCERNING STERIS SYSTEM 1**

FDA issued a Warning Letter to STERIS in May 2008 concerning the System 1 and changes that had been made to the System 1 between 1998 and 2002. As part of the resolution of the Warning Letter, STERIS agreed to submit a new 510(k) to FDA detailing the changes to the System 1 as well as to facilitate existing users of the System 1 to other modalities.

Since that time, FDA made an announcement concerning STERIS System 1 and a recommendation to seek alternative sterilization methods. Our analysis of these events suggests that FDA's position is largely based on concerns that STERIS has not made enough progress on the corrective actions promised in response to the Warning Letter. It does not appear that FDA's concerns necessarily stem from reports of an inability of the System 1 to adequately process devices, merely that changes have been implemented to the System 1 over time that FDA has not had an opportunity to assess. Please note that in its December 10, 2009 briefing to healthcare facilities, FDA specifically stated that it is not directing that use of the System 1 immediately stop. FDA also stated that diagnostic and therapeutic procedures using devices processed in a System should not be interrupted until suitable reprocessing alternatives are in place at health care facilities.

Gyrus ACMI includes reprocessing instructions in the Instructions for Use that accompany each endoscope and accessory the company manufactures. The STERIS System 1 has been one of several recommended modalities for reprocessing Gyrus ACMI endoscopes for many years. Since Gyrus ACMI is a manufacturer, any statements made in our labeling, including the Instructions for Use must be substantiated by supporting data.

Where the use of the System 1 is recommended, you may take assurance that Gyrus ACMI has conducted testing to support the reprocessing of Gyrus ACMI endoscopes in currently fielded System 1 units. Validation data, which included microbiological challenges, is on file which demonstrates that the System 1 is capable of adequately reprocessing these Gyrus ACMI devices.

While Gyrus ACMI presently recommends other sterilization modalities in addition to the System 1 to reprocess Gyrus ACMI endoscopes, Gyrus ACMI also seeks to provide its customers with the greatest flexibility in choosing reprocessing options. Gyrus ACMI supports the identification of other suitable sterilization modalities, but in the interim Gyrus ACMI will continue to support the use of the STERIS System 1 to reprocess Gyrus ACMI endoscopes.