

February 24, 2010

GYRUS ACMI STATEMENT CONCERNING STERIS SYSTEM 1 ADDITIONAL INFORMATION

As a follow up to our statements published on December 22, 2009 and January 7, 2010 concerning the FDA's actions with respect the STERIS System 1 (SS1), Gyrus ACMI would like to advise you of the following additional information.

FDA

As noted in our January 7, 2010 statement, FDA has posted several documents regarding the SS1 matter. These documents can be found at

<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm194411.htm>. The documents include a transcript of the conference call with healthcare facilities hosted by FDA on December 10, 2009, a Questions and Answers document and a document listing legally marketed alternative sterilization methods to replace the SS1. If you haven't done so already, we strongly urge you to review the documents posted by FDA in order to get a more complete understanding of this situation.

Among other things, FDA states in these documents that STERIS Corporation (STERIS) has significantly modified the SS1 and that FDA has not approved or cleared this modified product. Accordingly, FDA has not determined whether the SS1 is safe or effective for its labeled claims, including claims that it sterilizes medical devices.

In a letter dated February 22, 2010 to endoscope manufacturers, including Gyrus ACMI, that have devices labeled for use with the SS1, FDA states:

“If your devices are labeled for use with the SS1, you should revise your labeling to correct these violations as soon as possible by removing all statements indicating that your devices may be reprocessed with the SS1 and by specifying only legally-marketed reprocessing devices. FDA anticipates that you should be able to do this within one year.”

FDA's letter also recommends that endoscope manufacturers take additional actions. A copy of this letter may be found through the link indicated above.

In accordance with FDA's direction, Gyrus ACMI will be undertaking an effort to remove references to the SS1 in our product labeling within the next year. Additionally, Gyrus ACMI will be expediting our efforts to identify and validate additional suitable reprocessing methods.

REPROCESSING ALTERNATIVES FOR GYRUS ACMI ENDOSCOPES

As noted in our December 22 and January 7 statements, there are device sterilization alternatives to the SS1 to reprocess Gyrus ACMI endoscopes. Two methods that are often cited are steam sterilization and hydrogen peroxide gas vapor (or STERRAD) processes.

Steam sterilization is the most prevalent method for device sterilization and is frequently more cost-effective than the “per cycle” cost of other alternatives. Whether using gravity-displacement or pre-vacuum cycles, Gyrus ACMI offers a range of autoclavable products, such as M3™Gold Telescopes, SlimLine™ MRO™-7 Series Autoclavable Ureteroscopes, and Elite 2 Resectoscope Sheath Systems, that can withstand the rigors of the steam autoclave process.

For devices that are heat labile (including most flexible endoscopes), a suitable alternative may be the STERRAD® NX Sterilization System, manufactured by Advanced Sterilization Products (ASP). This system offers healthcare facilities a viable option for low-temperature sterilization of heat-labile endoscopes that may have traditionally been sterilized using ethylene oxide or liquid chemical sterilization methods. Gyrus ACMI offers several flexible endoscopes that are compatible with the STERRAD® NX Sterilization System.

For further information on these and other alternative sterilization methods, please consult the Instructions for Use that accompany each Gyrus ACMI device, or contact a Technical Support Specialist at 800-852-9361.

This statement supersedes the statements previously issued by Gyrus ACMI on December 22, 2009 and January 7, 2010.

We trust that this additional information provides value to your facility as you transition from the STERIS System 1 to another sterilization method. Gyrus ACMI looks forward to partnering with you to meet your reprocessing needs.