Steris System 1 Processor Update

This document updates the FDA Notice: *Concerns about the Steris System 1 Processor, Components, and Accessories, and FDA Recommendations*, issued December 3, 2009.

Dear Healthcare Facility Administrators and Infection Control Practitioners:

The purpose of this document is to inform you that FDA is extending to 18 months from the date of this notice the total recommended time period for transitioning from Steris Corporation's modified System 1 processor (SS1) to legally-marketed alternative devices.

As FDA announced in its December 3, 2009, notice, the Agency has not approved or cleared the SS1 for its labeled claims. Steris Corporation has chosen not to seek FDA clearance of this device and, therefore, its use should be discontinued as soon as practicable.

During a December 10, 2009, stakeholder conference call, FDA stated its view that healthcare facilities should be able to transition from the SS1 to legally-marketed alternative devices in three to six months. That recommendation was based on discussions with a number of outside constituents.

Since then, Agency staff has heard from many other healthcare providers and professional organizations. FDA now understands that a three to six month transition period may present significant difficulties for some healthcare facilities, which could, in turn, adversely affect patient care. FDA's primary objective is that safe and effective alternative reprocessing devices be identified and placed into use as soon as practicable, without compromising either patient care or employee health.

Therefore, FDA is extending to 18 months the recommended period for transitioning from the SS1 to legally-marketed alternative devices. At this time, FDA expects that Steris Corporation will continue to support existing SS1 units throughout the extended transition period, e.g., through provision of currently-marketed components, accessories, and sterilant. During this period, FDA will monitor the availability and supply of legally-marketed replacement products.

FDA does not expect to take regulatory action against healthcare facilities for failing to replace SS1 units within the 18-month transition period. But these facilities should be aware that the current SS1 is a misbranded and adulterated medical device because it has not been cleared by FDA as safe and effective for its labeled claims. Healthcare facilities should therefore transition to alternative reprocessing devices as soon as practicable.

Additional information on this issue may be found at http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm194411.htm [1] and questions can be directed to Candace McManus, DrPH, at the Office of Compliance, CDRH, 10903 New Hampshire Avenue, WO 66, Silver Spring, Maryland 20993, by email at candace.mcmanus@fda.hhs.gov, or by telephone message at 1-877-260-3731.

Sincerely,

Timothy A. Ulatowski Director, Office of Compliance Center for Devices and Radiological Health Food and Drug Administration

In response to this, STERIS wrote:

Dear Valued U.S. Customer:

We want to take this opportunity to update you on SYSTEM 1® matters. On February 2, 2010, the FDA updated its December 10, 2009 information by extending to 18 months the total recommended time period for transitioning from SYSTEM 1 to acceptable alternative devices.

In early December, FDA requested feedback on the timeline and obstacles to transition from SYSTEM 1. Based on that feedback and the difficulties that this transition may present to some healthcare facilities, the Agency has now recommended this extended transition period. FDA also recommends that healthcare facilities continue to transition to alternative reprocessing devices as soon as practicable. As further stated in the February 2nd notice from FDA, the Agency expects that STERIS will continue to support existing SYSTEM 1 units through the extended transition period, and STERIS is committed to continuing to support SYSTEM 1 units throughout the FDA's extension. We thank you for providing your input, and we appreciate the Agency's response to your views and its efforts to support the public health.

In addition, as previously communicated by the FDA and STERIS, STERIS submitted a new premarket notification for an updated STERIS SYSTEM 1. This updated system includes the changes outlined in the May 15, 2008 FDA warning letter as well as other technology updates. STERIS submitted this new 510(k) to FDA on January 5, 2009 and is continuing to seek clearance of this new device.

We also continue to communicate with the FDA about a transition plan for SYSTEM 1 users and we will notify you of further developments as soon as we can. Meanwhile, please direct questions you may have to your STERIS representative, contact STERIS at 1-800-548-4873, or visit www.steris.com/ss1 [2].

Sincerely,

Walt Rosebrough President and Chief Executive Officer STERIS Corporation

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[1] http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm194411.htm
[2] http://www.steris.com/ss1