STERIS

January 20, 2009

IMPORTANT NOTICE

Dear Valued SYSTEM 1 Customer:

On May 15, 2008, the United States Food and Drug Administration ("FDA") sent a warning letter to STERIS stating its view, among other things, that STERIS made changes or modifications to the STERIS System 1 requiring STERIS to submit to FDA a new premarket notification ("510(k)") and obtain marketing clearance for the changed device. Accordingly, FDA stated that the currently marketed device does not have a cleared premarket notification. The regulations require a new 510(k) when changes are made to a legally marketed device that "could significantly affect the safety or effectiveness of the device" (21 CFR 807.81(a)(3)(i)).

The changes or modifications identified in the warning letter occurred between 1988 and 2002, and are as follows:

- The centrifugal circulation pump's impeller was changed from a mechanically coupled to a magnetically driven impeller;
- The high pressure pump used to circulate sterilant to and through device lumens was changed: the original pump had a flow rate of 800 mls/min and the modified pump's flow rate was 3500 mls/min: also a pressure switch was added to monitor high pressure pump leakage;
- System 1 software was changed to limit the operation of the high pressure pump to avoid high pressure pump alarms related to low facility water pressure;
- The connector design was changed from separate components to groupings of tethered components intended for use with specified endoscopes, and new connectors were developed to facilitate the adaptation of the flow unit to the instrument intended for processing;
- The chamber size of the System 1 was made larger than the test chamber referenced in the original System 1 510(k), and the STERIS 20 sterilant formula was changed to maintain the FDA-cleared sterilant concentration to accommodate the larger chamber volume; and
- Additional inert ingredients were added to STERIS 20 sterilant, *i.e.*, water, sodium hydroxide, sodium polyacrylate, EDTA and NTA.

On July 31, 2008, STERIS provided a written response to FDA disagreeing with the agency's assessment that a new 510(k) was required under the agency's regulations. Subsequently, STERIS and FDA met to discuss the warning letter. Although the parties continue to disagree about the statements in the warning letter, STERIS agreed to submit a new premarket notification for an updated STERIS System 1, which includes the changes referenced above and other technology updates. STERIS submitted this new 510(k) to FDA on January 5, 2009.

In conjunction with the submission of the 510(k) for the updated STERIS System 1, STERIS is discontinuing sales in the U.S. of the System 1 Processor that is the subject of the warning letter, except for sales related to product replacement. STERIS will continue to support existing System 1 Processors for at least two years from the date of this notice. This support will consist of selling accessories and STERIS 20 sterilant, providing service and parts, and selling replacement units on a one-for-one basis. STERIS will work with customers on a timetable to transition to the purchase of a replacement for its System 1 product.

As always, Customers should report any serious adverse event that you suspect is associated with the use of the STERIS System 1 to STERIS 1-800-548-4873 and FDA (see http://www.fda.gov/medwatch/report/hcp.htm).

If you have any questions, please contact STERIS Customer Service at 1-800-548-4873 or www.steris.com.

Sincerely,

Rosemary Niewolak

Rosemary Niewolak
Product Manager, SYSTEM 1
STERIS Corporation