

January 9, 2010

Summary: *Steris System 1* is the subject of an FDA Notice stating the current piece of equipment has not gained appropriate pre-market FDA clearance for several modifications made to the system *over many years*. *The FDA recommends customers evaluate their operations which utilize the System 1 and **transition to alternative methods** (based on the manufacturers' recommendations for the devices being sterilized or processed in the System 1) **over a transition period of 3-6 months**.*

To read the FDA notice go to: www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm191585.htm

We strongly recommend customers follow FDA guidance to evaluate and transition to alternatives, and they consult the manufacturer's specifications/recommendations to assist in making their decisions. There is no single solution for every member. **MCHC will assist our members as they evaluate new equipment or manufacturers to determine the best alternative contracted sources.**

During the evaluation process it is important to note that:

- Specific requirements are needed to make recommendations.
- Customers use these units for different reasons, although many are using it for scope processing.
- There are 'sterilizers' and 'high level disinfectant' type units. Often what is used is procedurally driven by the customer and the device manufacturer's stated recommendations (which can vary by type and brand).
- There are varying levels of automation. If other instruments are sterilized in the System 1 that are not temperature sensitive, there are alternative cleaning and sterilization methods that might be a substitute.

MedAssets, MCHC's national group purchasing partner, has contracted suppliers with various types of *FDA approved* infection control equipment using different methodologies and products. ASP has similar low temperature sterilization devices (i.e. Sterrad) as well as endoscope reprocessors for high level disinfecting. We also have various high temperature sterilizers, other instrument washers, disinfectors etc. on contracts with Getinge and Belimed.

Steris has several other products not affected by this notice which could be suitable. Some customers may have other suitable alternatives already available in their facilities. For those customers with staff adequately trained in manual cleaning and disinfecting of scope type devices, there are FDA approved products on contract for this as well, although that is probably not the best choice.

MedAssets has developed a CDQuick Contract Template for Sterile Processing that provides additional information and product resources. If you have access to CDQuick, this template can be viewed on CDQuick under *Reports: Contract Templates: Sterile Processing*.

MedAssets also has information posted in “Alerts – Important Information” in CDQuick.

There are non-contracted alternatives, and customers should evaluate and choose the method and products that are best suited to them.

We understand the seriousness of **any** FDA recommendations to manufacturers, **and our expectation is that medical supplies and equipment will have FDA approval for their particular type of product.**

Steris sent a number of customer communications addressing the situation, providing updates, and is working with customers to transition to alternative methods or products. One is posted at www.mchc.org for reference. In addition, STERIS has a public web site to communicate information and updates to their customers. The transcript of FDA conference calls around this notice is also posted.

The FDA document has a FAQ section that addresses how each individual facility should evaluate their utilization practices to determine what alternatives exist for their type of operation and device, and provides guidance on a number of methodologies. Also included is a list of approved medical devices for this purpose and a list of alternative solutions. This information can also be found at www.mchc.org.

Since the STERIS System 1 is not currently approved as it is configured, and is not available for sale, MedAssets has pulled this equipment off contract with STERIS. We agree with the recommendations the FDA set forth in their letter, and will continue to utilize our **tools** to assist in the communication of this issue and all actions taken by the supplier. We expect and support STERIS’ efforts to work diligently to assess their operations and evaluate alternative methods.

For question, or assistance contact Ron Michalak, Manager of Supply Chain Solutions, at 312-906-6122.

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