

IMPORTANT NOTICE TO STERIS SYSTEM 1® STERILE PROCESSING UNIT
USERS IN EUROPE, MIDDLE EAST AND AFRICA

December 8, 2009

To our valued SYSTEM 1 Customer:

On December 3, 2009, the United States Food and Drug Administration (FDA) issued a notice to healthcare facility administrators in the USA regarding the domestic US regulatory status of the STERIS SYSTEM 1 Sterile Processing System (SYSTEM 1) and actions recommended to US users of this medical device. The FDA has stated that if US users have an acceptable alternative to the SYSTEM 1 processor to meet their sterilization needs, they should transition to that alternative.

This FDA notice may be found here:

<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm191585.htm>

STERIS disagrees with the FDA's December 3, 2009 notice. The SYSTEM 1 Sterile Processing System is safe and effective when used as directed. We are engaged in dialogue with the FDA about this matter.

The FDA Notice is applicable only to SYSTEM 1 devices marketed in the USA and has no effect on CE marking of SYSTEM 1 and its conformity to the European Essential Requirements. STERIS will continue to sell, service and support SYSTEM 1, STERIS 20™ Sterilant Concentrate, related accessories and service parts without restriction to all international users.

STERIS unequivocally stands behind the performance of SYSTEM 1. Its 20+ year contribution to healthcare speaks for itself:

- More than 23,000 units have been sold and used safely and effectively;
- More than 300 million medical devices have been processed in SYSTEM 1;
- Each STERIS Process cycle is monitored by the device and biological indicators;
- Performance of the unit has been verified independently;
- There has not been a documented case of infection directly caused by SYSTEM 1 sterile processing when proper guidelines and instructions are followed by certified health professionals.
- In addition to review and approval by STERIS Corporation's European Notified Body BSI, the technical documentation demonstrating the safety and effectiveness of STERIS SYSTEM 1 has been independently reviewed by the Australian Therapeutic Goods Administration and included on the Australian Register of Therapeutic Goods, reviewed and approved by Health Canada, as well as the medical device regulatory approval agencies of a number of other countries.

STERIS is notifying European Competent Authorities of this action in order to address any questions they may have. If you have any questions, please contact your local STERIS Customer Service. STERIS values our relationship with you as a Customer and we want to assure you of our continuing support of SYSTEM 1 in your area.

Sincerely,

John Mills
Marketing Director, STERIS Europe