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Medical Devices

STERIS System 1E (SS1E) Liquid Chemical Sterilant - K090036

This is a brief overview of information related to FDA's clearance to market this product. See the links below to the 510(k) Summary for more complete information on this product and its indications for use.

Product Name: STERIS System 1E (SS1E) Liquid Chemical Sterilant Processing System

510(k) Applicant: STERIS Corporation.

Address: 5960 Heisley Road, Mentor, OH 44060, USA.

Clearance Date: April 5, 2010

Clearance Letter and 510(k) Summary with Indications for Use:

http://www.accessdata.fda.gov/cdrh_docs/pdf9/K090036.pdf¹

What is it? The STERIS System 1E (SS1E) is a liquid chemical sterilant processing system. The SS1E can be used to process reusable heat-sensitive devices such as endoscopes and their accessories that cannot be processed using thermal methods.

How does it work? First, the SS1E uses the S40 chemical sterilant, a peracetic acid germicide, to process the devices. At this point, the device is considered to be liquid chemically sterilized. Next, the SS1E rinses the processed devices with extensively treated water to remove the chemical residues to ensure the processed devices are safe for the intended use.

The rinse water is tap (potable) water that has been filtered and exposed to ultraviolet rays. It is treated to minimize any bioburden that may be naturally occurring in the water. Because the rinse water is not sterile, devices processed using liquid chemical sterilization cannot be assured to be sterile.

The processed devices should be used immediately or stored in a manner similar to that of high level disinfected endoscopes. Users should be aware that currently all liquid chemical sterilant processing systems have the same limitations in that the final devices emerge wet and unwrapped from the processor.

For more information on the differences between traditional sterilization and liquid chemical sterilization, see [Liquid Chemical Sterilization](#)².

When is it used? Healthcare providers should evaluate the above description of the SYSTEM 1E's liquid chemical sterilant processing and rinse water elements and determine how the device fits within their infection control programs.

What will it accomplish? The SS1E provides processing for heat-sensitive semi-critical and critical devices that are compatible with the S40 sterilant and processing system, and which cannot be sterilized by other legally marketed, validated, traditional sterilization methods.

When should it not be used? The SS1E should NOT be used unless the process has been validated for the specific device(s). The SS1E should NOT be used on devices that must be sterile, unless they cannot be sterilized by other legally marketed, traditional, validated sterilization methods.

Additional information:

As healthcare facilities and infection control practitioners are aware, another STERIS product, the STERIS System 1 (SS1), available on the U.S. market, is adulterated and misbranded. For this reason, FDA advised hospitals to transition away from the [STERIS System 1](#)³.

The SS1E may be considered as an alternative to the SS1 for processing compatible heat-sensitive devices, as healthcare facilities transition away from the SS1. Users should be aware of the following, if they choose to use the SS1E:

- SS1E should be used only for processing heat-sensitive semi-critical and critical devices that are compatible with the S40 sterilant and processing system and cannot be sterilized by other legally marketed traditional sterilization methods validated for that type of device.
- Devices that are not validated for processing in the SS1E should not be processed in the SS1E.
- Following processing, the devices should be used immediately.
- The S40 sterilant used in the SS1E has not been validated for use with the SS1 and should not be used in the SS1.

Links on this page:

1. http://www.accessdata.fda.gov/cdrh_docs/pdf9/K090036.pdf
2. <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/ucm208018.htm>
3. <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm194411.htm>