Protecting Lives Against Infection™

MAINTAINING DEVICE STERILITY

Groups such as FDA, AORN and APIC define a sterilized device as one that has been processed in a system that delivers a sterility assurance level of 10^{-6}, which is a one in a million chance of a non-sterile occurrence. The requirement for sterilization is that all viable microorganisms be inactivated including bacteria, fungi, virus, and bacterial endospores. The device is packaged in a manner that will preserve its sterility and allow the device to be transferred to a sterile operating field without contamination. This type of process is called "terminal sterilization" and is the best practice for devices intended for use in an operating room setting where the device may touch normally sterile tissue.

Steris System 1E (SS1E) was recently cleared by FDA as a "Liquid Chemical Sterilant Processing System." At the conclusion of the "sterilization phase" the device is rinsed to remove residual chemical sterilant. The SS1E utilizes "extensively treated" rinse water (510(k) - K090036).[1] The extensive rinse water treatment includes the following steps specified in the FDA-cleared indications for use:

1. **Pre-filtration through two pre-filters:**
   - Pre-filter 1 is a gross depth filter that removes approximately 5 micron or larger particles/contaminants.
   - Pre-filter 2 is a surface filter that removes particles/contaminants > 0.1 micron.
2. **UV Irradiation:**
   - During transit through the UV Water Treatment Chamber, a UV dose sufficient to achieve a ≥ 6-log reduction of MS2 virus is delivered to the water.
3. **0.1 micron filtration:**
   - The water prepared by pre-filtration and UV irradiation is filtered through redundant, 0.1 micron (absolute rated) membranes to remove bacteria, fungi, and protozoa > 0.1 micron.

Filtration and Rinsing Facts

Filtration removes particulates and contaminating microorganisms by physical retention. The water flows through the filter while the particulate or contaminating microorganism may not pass through the filter. There are two critical issues for effective filtration:

Filter rating[2]:

Filter rating is generally stated as the physical size of a particle that will be retained by the filter. For example, a 0.1 micron filter will retain particles of that size or larger.

Efficiency[3]:

The efficiency of a filter is a statement of what proportion of particles at or above the rating size that will be retained. For example, a 0.1 micron filter might have an efficiency rating of 99.9%. The 99.9% efficiency rating indicates that a high percentage of 0.1 micron or larger particles will be retained and a small percentage will be allowed to pass through the filter.

Filtration has been utilized in many applications for reduction of bioburden but has not been generally recognized (including FDA) as a sterilization method capable of delivering a 10^{-6} sterility assurance level. Thus sterility cannot be assured for sterilized instruments rinsed with water not sterilized to a 10^{-6} sterility assurance level.

Another consideration in the use of a filter is that the filter does not inactivate microorganisms, but physically traps the organism on or within the filter.

Live organisms on or within the filter raise a concern. The microorganisms may eventually penetrate the filter, thus contaminating the downstream portion of the filter and also the water passing through the filter. If this situation occurs the internal fluid path (water path) of the system may become contaminated. An additional consideration is that dead organisms on or in the filter may also release endotoxins, contaminating the water passing through the filter.[4]

> "Because the rinse water is not sterile, devices processed using liquid chemical sterilization cannot be assured to be sterile."[6]

Even the best available filters (0.1 micron) are not capable of retaining viruses. In order to reduce the potential for viral contamination, the SS1E has a built-in UV treatment chamber. Ultraviolet (UV) light has been used to treat water in a number of applications but is not commonly recognized as a sterilization method. As noted in the Steris Webcast the week of May 10, the SS1E was shown to inactivate at least 10^6 MS2 viruses (6-log reduction) as a surrogate for the other virus. The Webcast also noted that a 6-log reduction of MS2 was equivalent to a 4-log reduction of adenovirus. A 4-log reduction is the typical requirement for a surface disinfectant rather than a sterilization process.[5]

As noted in FDA's Web posting of April 12, 2010, "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." While the use of multiple filters and UV irradiation extensively treats the rinse water, neither filtration nor UV treatment has been recognized as a means to sterilize water to a 10^{-6} sterility assurance level. Because the rinse water is not sterile, devices processed using liquid chemical sterilization cannot be assured to be sterile."[6]

ADVANCED STERILIZATION PRODUCTS
Division of Ethicon, Inc.
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REFERENCES:
[1] 510(k) - K090036
[2] PALL Life Sciences brochure PN 33377
[3] S. Block, *Disinfection, Sterilization, and Preservation*, Fifth Edition, page 815
[4] S. Block, *Disinfection, Sterilization, and Preservation*, Fifth Edition, page 800
[5] EN 14476, Chemical disinfectants and antiseptics -Virucidal quantitative suspension test for chemical disinfectants and antiseptics used in human medicine - Test method and requirements (phase 2, step 1)
[6] STERIS System 1E (SS1E) Liquid Chemical Sterilant - K090036 http://www.accessdata.fda.gov/cdrh_docs/pdf9/K090036.pdf (accessed on May 28, 2010)

Please contact ASP at 888-783-7723, or visit www.aspjj.com if you have any questions.

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