



Updated June 30, 2011

FDA Guidance Limits STERIS® SYSTEM 1E™ Critical Device Reprocessing

If your facility is considering the STERIS System 1E™ (SS1E) as a replacement for the STERIS System 1® (SS1), you should be aware of recent FDA updates to their Liquid Chemical Sterilization (LCS) Web site. On its site, the FDA recommends that these type of systems be **“limited to reprocessing only critical devices that are heat-sensitive and incompatible with sterilization methods such as steam and gas/vapor/plasma low temperature processes.”**

As a result, most of the commonly used critical devices you processed in the SS1 are not FDA-recommended for processing in the SS1E. The FDA cleared the SS1E as a liquid chemical sterilant processing system, not as a sterilizer.

COMMONLY USED CRITICAL DEVICES*	STERIS SYSTEM 1E: RECOMMENDED BY FDA FOR LCS
Cameras	NO
Rigid telescopes, such as arthroscopes or laparoscopes	NO
Single-channel flexible endoscopes such as choledoscopes and ureteroscopes	NO
Critical stainless steel instruments	NO
Orthopedic drills and saws	NO
Batteries	NO
Defibrillator paddles	NO
Dopplers	NO



*Please also note that semi-critical devices, such as cystoscopes or laryngoscope blades, must also be sterile if they are going to be used in the OR setting in a sterile field.



Sterility Assurance for Your Critical Devices

The deadline to stop using your STERIS System 1[®] is fast approaching. Now is the time to upgrade to ensure there is no disruption in processing your critical devices. Devices that can be processed in steam, EtO or a low-temperature gas plasma process are not recommended for processing in the SS1E.

The STERRAD[®] NX[®] System offers a safe, low-temperature hydrogen peroxide gas plasma technology with the ability to terminally sterilize a wide range of critical devices including the heat-sensitive and heat-stable devices that you depend on every day.

Upgrade to the STERRAD[®] NX[®] System Today

- Offers a Sterility Assurance Level (SAL) of 10^{-6} as required for the clearance of sterilizers
- Uses the STERRAD[®] CYCLESURE[®] 24 Biological Indicator (BI) to monitor sterilization as recommended by AAMI, AORN and the CDC
- Cleared to process the critical devices you depend on every day
- Provides dry, packaged devices that can be used or immediately or stored for later use



Contact ASP for trade-in options on your SS1 or SS1E and for the latest financing alternatives.

Call ASP at 1-888-783-7723, visit www.aspjj.com/alternatives, or contact your local ASP representative for more information about upgrading to the STERRAD[®] NX[®] System.

ADVANCED STERILIZATION PRODUCTS

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