CPAC ENVIRONMENTAL SOLUTIONS

SterilizerNews

JULY 2024

Risks of Using Steam for Immediate Use

Steam Sterilization – Not the best method for immediate-use reprocessing of medical instruments

The absence of a clear alternative to Immediate-Use Steam Sterilization (IUSS) has contributed to the long debate among infection control and sterile processing professionals over its use. Using IUSS as a method for rapid turnaround of a critical surgical instrument involves shortcuts to FDA-prescribed sterility assurance procedures that shift much of the regulatory and civil legal responsibility from the steam sterilizer and surgical instrument manufacturer to the healthcare facility. This article discusses the risks and liabilities of using IUSS and how an alternative is currently available to eliminate those risks and liabilities.

The healthcare facility is confronted with the stark reality that in-house protocols for IUSS can compromise the performance standards prescribed by the FDA and other regulatory bodies. This raises a crucial question: Can the healthcare facility realistically conform to established sterility performance standards within their IUSS protocols when they reduce or eliminate a steam sterilizer's dry cycle and compromise instrument packaging? The importance of maintaining these established standards cannot be overstated, as any compromise could lead to potential safety and liability issues.

Significant points frequently discussed by standards and practices professionals regarding the use of IUSS:

- Legitimate deployment of IUSS should only be conducted when specific criteria have been met, keeping IUSS to a minimum as stated in facility or department-specific protocols.
- Assurance that sufficient regulatory documentation is maintained for each IUSS event.
- Healthcare facilities must document and validate IUSS cycle times and temperatures to meet at least a 6-Log_{10} spore reduction[1], preferably the demonstration of a 12-Log_{10} spore reduction[2] as required by FDA and AAMI/ANSI standards for meeting the Sterility Assurance Level (SAL) for each instrument type that may require the use of IUSS.
- Assurance that wet instruments retrieved from the steam sterilizer are protected from environmental contamination and aseptically transferred to the point of use.
- Only sterile packaging cleared by the FDA is to be used to ensure the maintenance of sterility.
- Ability to perform IUSS at a site closest to surgery with readily available instrument cleaning, sanitary water, and drainage resources.

1. Assure that the biological indicators utilized contain > 6 Log_{10} of recommended bacterial spores.
2. Provide internal documentation of ½-cycle studies and the determination of the number of minutes required for the additional SAL requirement.

RAPIDHEAT
PRO 9 AND PRO 11 HVHA STERILIZERS

Mitigation or elimination of these concerns can be accomplished by utilizing an alternative FDA-cleared sterilization technology that can provide safe, effective, and rapid instrument turnaround for "Immediate Use" of surgical instruments. RapidHeat™ sterilizers manufactured by CPAC Equipment, Inc. employing High-Velocity Hot Air (HVHA™) technology meet this requirement.

FDA-cleared RapidHeat technology utilizes HVHA that recirculates>200 air exchanges per minute at a chamber temperature of 375°F. With pre-set cycles for wrapped and unwrapped instruments, handpieces, and instrument cassettes, RapidHeat sterilizers provide the flexibility necessary for various instrument sizes and types, including instruments with narrow lumens. Since there is no steam and no drying cycle, total processing times are equal to or shorter than those of steam sterilizers. All cycles meet or exceed the 12-Log_{10} spore reduction to meet sterility and additional Sterility Assurance Level requirements.

Features and Benefits

CPAC manufactures tabletop RapidHeat Sterilizers in two sizes. They feature a rectangular chamber for uniform capacity with a touch-screen operation for ease of use.

FEATURE	BENEFIT
Dry Sterilizing Environment	Eliminates Instrument Corrosion & Wet Loads
Simple Mechanical Design	Easy Operation with Minimal Maintenance and Repair
High Temperature Cycles	Fast Turnaround for Immediate-Use
Low Temperature Cycles	Option for Heat-Sensitive Instruments
Environmentally Sustainable	Uses 65% Less Energy than Steam & NO Water

RapidHeat HVHA sterilizers fall within the category of thermal sterilization and, like steam, can process medical devices that have been process validated using heat sterilization. Manufacturer IFUs that specify sterilization by steam do not automatically rule out the use of RapidHeat HVHA (dry heat sterilization) when it is not explicitly excluded in the IFU. In the absence of a manufacturer's specific validation, the FDA allows the use of dry heat sterilization (RapidHeat HVHA) when there has been a determination made by the device manufacturer, sterilizer manufacturer, or the informed end-user that its use for sterile processing will NOT significantly affect the device's performance, safety, and effectiveness. The nominal temperature difference of 80°F between a wrapped medical device exposed to HVHA at 350°F and exposed to steam at 270°F has been proven through RapidHeat HVHA testing to be of no consequence in the performance of metallic surgical instruments including metallic instruments containing high-temperature resistant polymers and surface coatings.

Hospital ORs and Outpatient Surgery Centers must seriously consider using RapidHeat HVHA tabletop sterilizers to provide "Immediate Use" of those critical surgical instruments and surgeon-specific devices that have been inadvertently contaminated. A considerable advantage of HVHA technology is that it can accomplish fast instrument turnaround without residual wetness. Since there is no moisture or steam to contend with, instruments whether wrapped or unwrapped come out dry, thus eliminating the opportunity for the wicking of any environmental contamination. Strategically located in or near surgical suite areas with access to enzymatic cleaning and an electrical outlet is all that is required. Transporting the instrument safely to the point of use can be further enhanced through the use of RapidHeat FDA-cleared, non-porous dry-heat sterilization nylon pouches.

Further information on RapidHeat HVHA sterilization can be obtained online from CPAC Equipment, Inc. (www.cpac.com) or by calling 800-828-6011.