LOW-TEMPERATURE STERILIZATION

LEARNING OBJECTIVES
1. Discuss the purpose of low-temperature sterilization
2. Provide an overview of low-temperature sterilization methods
3. Describe important low-temperature sterilization practices
4. Review two special low-temperature sterilization concerns

LOW-TEMPERATURE STERILIZATION IS AN EFFECTIVE MEANS TO process heat and moisture sensitive surgical instrumentation, implants, and general equipment. Before using one of these sterilization modalities, however, it is imperative to check with the device manufacturer, and the required processing steps must always be carefully followed. This module emphasizes these steps.

OBJECTIVE 1: DISCUSS THE PURPOSE OF LOW-TEMPERATURE STERILIZATION
The most cost effective method of processing surgical instrumentation and equipment is steam sterilization; however, heat- and moisture-sensitive items cannot be processed with steam sterilization.

Low-temperature sterilization is typically used to sterilize unique devices with complex designs and/or those made of heat and moisture sensitive materials including fiber optics, polymers on cameras, flexible scopes, and certain plastics that cannot withstand the heat and moisture associated with steam sterilization. Devices may be constructed with electrical or other delicate components, which also are affected by heat and moisture. Low-temperature sterilization methods differ in their mode of action, and the method chosen is based on the process for which the device has been validated by the original equipment manufacturer. Low-temperature sterilants are capable of harming humans. Reactions to exposure can vary depending on the type of exposure. If exposure occurs, employees need to know what to do immediately. An emergency response plan helps to ensure that employees and patients are protected from exposure to chemical sterilants.

OBJECTIVE 2: PROVIDE AN OVERVIEW OF LOW-TEMPERATURE STERILIZATION METHODS
Ethylene Oxide (EtO) was the standard low-temperature sterilization method until the early- to mid-1990s when gas plasma was introduced. While EtO still

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has its place in healthcare sterilization processing, it is not the first option considered in hospital settings today. Reasons include the length of total cycle time and aeration and the potential carcinogenic effects on staff.

Several low-temperature sterilization methods are currently cleared for use in the United States by the U.S. Food and Drug Administration (FDA), and these are noted in Figure 1.

**OBJECTIVE 3: DESCRIBE IMPORTANT LOW-TEMPERATURE STERILIZATION PRACTICES**

Certain sterilization processes do not change regardless of whether the device is processed by steam or low temperature. For example, all devices must be thoroughly cleaned, rinsed and dried. They must be disassembled to ensure the sterilant's contact on all surfaces. The correct chemical and biological monitors must be selected and placed in the correct location within the pack, and the correct packaging materials must be used. The sterilizer must be properly loaded to ensure sterilant contact. At the completion of the sterilization cycle all quality monitors, including physical monitors, must be reviewed to assure that sterilization parameters were met before releasing the load.

The device manufacturer is responsible for ensuring the device can be effectively sterilized, and the device must be processed according to its Instructions for Use (IFU). Chemical sterilization qualification of a device requires microbiological, engineering and toxicological testing. Device labeling should identify specific methods of cleaning and sterilization that have been validated by the manufacturer. *Note: the manufacturer’s written IFU should be kept on file.*

Technicians impact the results of a sterilization process because poor cleaning and disinfection practices and improper sterilizer loading can contribute to process failure. The proper systems and training programs must be in place, evaluated and audited to verify adequate adherence to IFU and to determine future process improvement initiatives.

Mechanical breakdowns can occur, and any sterilizer can break down and require repair. Electrical malfunctions and outages cause machines to shut down or interrupt power and ultimately interfere with cycle parameters. Other utility issues, such as poor water quality leaving sediment on instruments, can also impact processing quality.

Basics of low-temperature processing must be consistently addressed and are now reviewed.

**Physical Environment.** This is a key factor in low- and high-temperature sterilization, for several reasons. The physical environment should be constructed to promote appropriate processing practices. This includes adequate airflow

<table>
<thead>
<tr>
<th>Low-temperature Method</th>
<th>Fast Facts</th>
<th>Cycle Parameters</th>
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<tr>
<td>ETO</td>
<td>- Long chemical expose time required</td>
<td>- Time</td>
</tr>
<tr>
<td></td>
<td>- Aeration needed after sterilization</td>
<td>- Temperature</td>
</tr>
<tr>
<td></td>
<td>- Is human carcinogenic and mutagenic</td>
<td>- Concentration</td>
</tr>
<tr>
<td></td>
<td>- Penetrates well due to light molecular weight</td>
<td>- Relative Humidity</td>
</tr>
<tr>
<td></td>
<td>- Powerful alkylating agent</td>
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| Hydrogen Peroxide Gas Plasma | - Is reactive and unstable in its liquid state | - Time |
|                             | - Powerful oxidizer | - Temperature |
|                             | - Converts safely to H2O and O2 | - Concentration |
|                             | - Has material and lumen size limitations | - Plasma |
|                             |                          | - Vacuum |

| Vapor Phase Hydrogen Peroxide | - Is reactive and unstable in its liquid state | - Time |
|                               | - Powerful oxidizer | - Temperature |
|                               | - Converts safely to H2O and O2 | - Concentration |
|                               | - Has material and lumen size limitations | - Relative Humidity |

| Ozone                   | - Not widely used | - Time |
|                        | - Powerful oxidizer | - Temperature |
|                        | - Converts safely back to O2 after cycle | - Concentration |
|                        | - Has some material limitations | - Relative Humidity |
|                        | - Small sterilizer chamber size | |
|                        | - Long cycle time | |

| Liquid Chemicals* | - Not effective at penetrating biofilm barriers | - Time |
|                  | - Longer exposure times required than other alternatives | - Temperature |
|                  | - After-exposure requirements hinder use | - Concentration |
|                  | - Thorough rinsing needed to prevent disinfectant residues | |

*Note: monitoring liquid chemicals for sterility assurance is not usually possible, so these products are often used as high-level disinfectants.
exchanges, proper sinks, flat processing surfaces, adequate space and lighting, and the appropriate temperature and relative humidity in each processing area.

**Proper Cleaning.** Cleaning is the most critical step in processing surgical instrumentation, equipment, utensils, and other related devices. Without proper cleaning, the items to be sterilized will not be prepared for the process. If the item is not cleaned completely, it cannot be sterilized or high-level disinfected.

Proper cleaning requires clean and soft nylon brushes, baskets, and facility-approved cleaning and disinfectant agents and solutions. Technicians need adequate space, sinks, lighting, and specific instructions to complete their tasks. All cleaning must be completed by following the specific cleaning and sterilization instructions as noted in the IFU for every device. These must be available for technicians who also require the equipment, chemicals and supplies necessary to follow the instructions.

**Instrument Inspection.** The purpose of inspection is to ensure items are appropriately clean, free of remaining visible debris, absent of defects or damage, and in proper working order. An extensive knowledge of instruments and equipment is necessary to successfully inspect the devices to be processed.

Inspection tools include magnifying lenses, scissors testing materials, and pipe cleaners. Adequate time is required to prevent unsuitable instruments, equipment, utensils, and other medical devices from being reused.

**Preparation and Selection of Sterilization Method.** Preparation steps are partly determined by the type of low-temperature sterilization method to be used. For example, instrumentation containing lumens must be completely dry and free of any moisture for gas plasma and EtO sterilization, but for different reasons. Moisture in lumens for a gas plasma load may cause the sterilizer to abort because the sterilizer cannot reduce the vacuum. However, a device with a moist lumen processed in an EtO sterilization cycle will not abort the cycle, but moisture in the presence of EtO produces ethylene glycol which is toxic to humans.

**Packaging.** Sterilization packaging is selected to allow the sterilization of the contents, to maintain the sterility of the contents until the package is opened, and to provide for the removal of the contents without contamination.

**Loading.** Procedures used to load instruments in a low-temperature sterilizer are similar to those used for steam sterilization. The sterilant must be able to reach the devices so loads cannot be packed too tightly, and a technician should be able to place his or her hand in between packages without difficulty.

Each sterilization unit has specific instructions for proper loading that must be consistently followed. Stacking is not permitted unless the equipment manufacturer has cleared the sterilizer to do so. Placing the items and sets away from the sterilizer’s chamber walls will prevent aborted cycles in some sterilizer models.

**Unloading and Release.** While items requiring low-temperature sterilization are not “hot” after sterilization, they are warmer than ambient air temperatures. Care is needed to ensure that they are moved out of the sterilizer to an appropriate cool down area. Placing the items or sets on an open wire rack in a room with proper temperature and humidity before transportation and storage is important.

**Monitoring Devices.** Physical monitors include the sterilizer’s displays, printouts, pressure recorders and gauges, and time and temperature readings. If parameters, such as temperature, are not met for non-EtO sterilizers, the cycle will abort, but a technician should review the information after the cycle is completed. These monitors are needed to show that the sterilizer is functioning properly and help to indicate that sterilization parameters have been achieved. Note: monitoring devices do not “prove” that sterilization has occurred.

Internal and external chemical indicators are required for all packages regardless of the sterilization method selected. However, indicators must be specific to the sterilization method and chemical and must be used according to IFU developed by the manufacturer of the chemical indicator, including those related to indicator storage between uses.

Only three classes of the six available chemical indicators are used for low-temperature sterilization:

- **Process indicators** (Class 1; also called external CIs) are used with individual units such as packs and containers to indicate that the unit has been exposed to the sterilization process and to distinguish between processed and unprocessed units.

- **Multi-variable indicators** (Class 4) react to two or more of the critical variables and indicate exposure to a sterilization process at stated values of the chosen variables.

- **Integrating indicators** (Class 5) react to all critical variables with the stated values having been generated to be equivalent to, or exceed, the performance requirements given in the ISO 11140 series for CIs. Integrating indicators follow the death curve for a biological indicator and only reach their end point if all sterilization parameters are achieved. Therefore, they provide a good indication that a BI in the same load will be killed.

The selection of biological indicators (BIs) depends on the sterilization method used and the manufacturer’s guidelines for the low-temperature sterilizer. They indicate whether a cycle was capable of achieving sterilization. A negative result does not prove sterilization has occurred but, instead, indicates that the conditions for sterilization were met.

BIs should be run with every implant; however, with the exception of EtO, processing implants in low-temperature sterilizers is limited or not validated, depending on the manufacturer.
Transportation and Storage. These steps are where items are most likely to become compromised and rendered unfit for use. The use of closed or covered carts and tables are required for within-facility transportation of processed devices to reduce the potential for contamination. Some Central Service (CS) managers use third-party processing entities or other facilities within their organizational system, and appropriate closed transportation containers are required to move items between facilities.

Temperature in storage areas should be approximately 24°C (75°F). There should be at least 4 air exchanges per hour, and relative humidity should be controlled and not exceed 70%. Traffic must be controlled to limit access to sterile items to persons that know how to handle sterile packages. Sterile packages should be stored at least 8 to 10 inches from the floor, 18 inches below the level of sprinkler heads, and at least 2 inches from any outside walls. There should be a barrier on the lowest shelf on open wire shelving to limit dust and contamination when the floor is cleaned.

Closed or covered storage cabinets are recommended, and items should be positioned so they are not crushed, bent, compressed, or punctured while in storage. Wrapped packages should not be stored on top of others because compression and weight can potentially damage the wrappers.

Shelf life relates to the ability to reuse a reprocessed item after it has been in storage. Event-related sterility indicates that reuse depends on the item’s condition rather than the storage time. The longer an item is stored, the more opportunities will occur for the package to be compromised.

**OBJECTIVE 4: REVIEW TWO SPECIAL LOW-TEMPERATURE STERILIZATION CONCERNS**

User facility personnel must ensure and verify that devices requiring sterilization have been validated for use in the sterilizers available at their facility. This verification must confirm that the devices can be sterilized with available sterilization processes. Not every device on the market can be sterilized by every sterilization process; certain devices may be cleared for sterilization in a specific type of low-temperature sterilization unit that the facility does not have. Note: CS representatives should be involved in reusable instrument purchase decisions to ensure on-site processing will be possible.

CS personnel must be aware of some relatively recent changes relating to the use of EtO sterilants. First, two types of EtO have historically been used for sterilization. One is a blend of HCFC (oxyfume) and EtO, which makes the EtO non-flammable. This type of EtO has been eliminated for use in healthcare instrument reprocessing. The other type of EtO is 100% EtO. This type is supplied in single-dose containers, which are classified as flammable liquids and must comply with the National Fire Protection Association (NFPA) 30 standard, including those relating to flammable liquid storage.²

Since 2010, EtO has been re-registered as a pesticide by the Environmental Protection Agency (EPA), and this has changed how EtO can be used in hospitals. Loads can no longer be removed from an EtO sterilizer and then be transferred into the aerator. Also, only single chambers may be used for EtO sterilization and aeration.

**IN CONCLUSION**

Low-temperature sterilization continues to evolve with ever-changing healthcare environments and complex innovations. Devices still pose processing challenges for CS departments. It is important to partner with suppliers and manufacturers who can lend assistance in reducing these challenges and mitigating risks. Instrument processing advancements will continue, and they will include those relating to low-temperature sterilization. ☞

**REFERENCES**


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