Sterilization Efficacy —

1 Improper Cleaning of Instruments

Cleaning involves the removal of debris and organic material from an instrument prior to sterilization. This type of debris may shield microorganisms from being properly destroyed and ultimately hinders an item from being effectively sterilized.

2 Improper Packaging Materials or Packaging Technique

The type of packaging you choose needs to be compatible with both the items to be sterilized and the chosen method of sterilization. Items need to be packaged according to the manufacturer's instructions for use for both the packaging and items being sterilized. Packaging material must be able to withstand the temperature of your sterilization method. Some common errors include:

- placing a folded peel pouch inside another peel pouch;
- using excessive wrap which may affect steam penetration;
- failure to disassemble instruments; or
- failure to leave hinged instrument in the open position during cleaning and sterilization.

3 Choosing the Incorrect Monitoring Tests for Your Method of Sterilization

Another common error is choosing the incorrect chemical indicators or incorrect biological indicator process challenge device for the method of sterilization used. Once you have chosen the correct monitoring tests for your sterilization process (e.g. *G. stearothermophilus* spores for steam sterilization), plans should be in place in the event of any monitoring failures.

4 Choosing the Incorrect Cycle for Load Contents

Choosing the correct parameters (time, temperature and pressure) for each load is very important. This information can be found in the manufacturer's instructions for the instruments being processed and the type of packaging being used. Inadequate temperature being reached or insufficient time at the recommended temperature could result in incomplete sterilization. Alternatively, temperatures over and above what is recommended by the manufacturer's instructions for the items being sterilized, may adversely affect the integrity and functionality of instruments. Inadequate temperatures may also result from human errors if, for example, the sterilizer door is opened prior to cycle completion. Some sterilizers will have specific cycles for instruments containing lumens, such as a cycle designated for hand pieces.

The 8 Most Common Reasons for Failure

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5 Improper Loading of the Sterilizer

Read the manufacturer's instructions for use for both the sterilizer and packaging you are using. Overloading the sterilizer, placing packages too close together, or incorrect orientation inside the autoclave may prevent adequate air removal and steam penetration around and through the load. If using racks, instrument pouches should be placed on edge and all facing the same direction. Failure to follow proper loading instructions for the method of sterilization may result in incomplete sterilization.

6 Wet Bags from a Completed Cycle

Wet bags can be a result of inadequate drying of instruments prior to wrapping/packaging, overfilling packages, overloading the sterilizer or removing instruments prior to completing the dry cycle. Bags that have come out wet from the sterilizer are not considered sterile and need to be reprocessed.

7 Proper Maintenance of Sterilization Equipment

This includes running appropriate qualifying tests prior to the initial use of a sterilizer in addition to requalifying tests after the sterilizer has had a failure or was sent for repairs. Other issues with maintenance may involve clogged drain lines, clogged steam lines, pressure gauges calibration, worn out door gaskets and seals, and/or malfunctioning valves. If this is the situation, you should check the owner's manual to troubleshoot the problem or send the sterilizer for repairs by a certified technician.

8 Lack of Training for Sterilization Procedures

Anyone involved in processing of reusable medical equipment and devices needs to have device-specific training for any equipment being used and adequate training for the volume and type of instruments to be sterilized. They need to be knowledgeable and trained in how to read sterilization monitoring systems, and to be accountable for logging all necessary monitoring parameters after each load. Lack of knowledge or failure to follow appropriate policies and procedures in any one of the reprocessing steps may result in sterilization failure. CDHO