

SELF-STUDY SERIES

LESSON NO. 83

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Ozone Sterilization

LEARNING OBJECTIVES:

1. Explain the properties of ozone that make it an attractive low-temperature sterilization alternative.
2. Review the brief history of ozone sterilization.
3. Discuss advantages of using ozone sterilization.
4. Summarize basic procedures required for ozone sterilization.
5. Present background information about the safety of the ozone sterilization process.
6. Note materials, items, and packaging that *are* or *are not* recommended for use with the ozone sterilization system.

New surgical devices that help physicians perform modern miracles are constantly being introduced by medical technology. These new devices also create new challenges for the Central Service (CS) technicians who must process them for reuse. Because of their effectiveness and cost efficiency, steam sterilization units have long been the preferred method for reprocessing surgical devices. The materials used to construct many of the newest surgical instruments, however, become damaged when they are processed in a heat or moisture environment and so, these devices require a low-temperature sterilization process.

Ethylene oxide (EtO) has become the most popular low-temperature alternative because of the wide range of materials with which it can be used and because of its effectiveness in destroying microorganisms. Other popular alternatives include hydrogen peroxide gas plasma, liquid peracetic acid, and glutaraldehyde systems¹.

An emerging technology for low-temperature sterilization involves the use of ozone. The application of this system within a specific facility must be carefully analyzed and may or may not be applicable today, or in the future. Ozone sterilization must be considered, however, and so this Self-Study Lesson presents the background information to do so.

Objective 1: Explain the properties of ozone that make it an attractive low-temperature sterilization alternative.

Most people are familiar with ozone. They may know about its benefits in the earth's upper atmosphere, where it protects us from the sun's harmful ultraviolet [UV] rays, and at ground level where it is a very powerful oxidizing agent. Ozone has also been used as a germicide to sterilize foods, air, and drinking water that

contain organic matter such as fungi, viruses, and bacterial spores. In CS applications, only electricity, water, and medical-grade oxygen are needed to produce ozone in a sterilization system. Because these components are readily available in hospitals, devices to be sterilized at an extremely cost-effective rate.²

In addition to low cost, ozone sterilization offers another significant advantage in employee safety. Because the ozone sterilizer produces its own sterilizing agent, the sterilant does not require any transportation or physical contact by technicians. It also releases only oxygen and water vapor into the environment. In the event of an ozone leak in the sterilizer, the distinct smell of the sterilant would be apparent before a dangerous exposure level for humans is reached.

Objective 2: Review the brief history of ozone sterilization.

Ozone is a pale-blue gas with a characteristic pungent odor. It condenses to a dark blue liquid at -170° F (-112° C) and freezes at -315° F (-193° C). It has been used for medicinal applications since the late 1800s, when it was used to therapeutically purify blood. By the early 1900s, ozonated water was being used to treat numerous diseases including anemia, diabetes, influenza, and even canker sores. During World War I, ozone was used to treat wounds, gangrene, and the after-effects of poisonous gas.

The ozone sterilization system marketed today evolved from a concept submitted at a 1991 meeting about the use of ozone for water treatment. By 1999, clinical trials had begun, and the ozone sterilizer was licensed by Canada in 2002 and by the U.S. Food and Drug Administration in 2003.³



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Objective 3: Discuss advantages of using ozone sterilization.

Ozone's ability to destroy pathogens at low cost in a worker-safe environment was noted briefly above. By contrast, EtO is a mutagen (a substance or agent that causes an increase in the rate that genes change), a carcinogen (a cancer-causing substance), and a reproductive hazard. It is also explosive and dangerous to handle, and the Occupational Safety and Health Administration (OSHA) has indicated a desire to ban its use. In addition to all these drawbacks, Instruments sterilized with the EtO process must be aerated for 12 to 24 hours, which requires a relatively large inventory of medical devices. The residual level of EtO released into the environment must also be monitored carefully to assure that no environmental problems are created.

The cost of sterilizing with ozone is much less than with EtO. For example, the ozone required for one sterilization cycle costs less than ten cents; the same sterilization cycle with EtO has a sterilant cost of more than \$7.35. Another economic advantage to the use of ozone sterilization arises from the ability to use the instruments as soon as they complete the sterilization process, requiring a smaller instrument inventory than with the EtO process.

Extensive testing has suggested the possibility that ozone sterilization may deactivate prions, the infectious protein that causes Creutzfeldt-Jakob Disease (CJD) in humans. This disease can be transmitted between patients when contaminated surgical instruments are used even after the devices have been processed with today's common sterilization methods. While further testing—incorporating a relatively long timeframe—is required, ozone sterilization's potential for reducing the spread of CJD from contaminated instruments is exciting. The manufacturer of the ozone sterilizer is now developing a test device to help determine whether prions are destroyed during the sterilization cycle.⁴

Objective 4: Summarize the basic procedures required for ozone sterilization.

Instruments to be sterilized with ozone must be prepared for sterilization according to the guidelines issued by regulatory or professional organizations and from the applicable

instrument manufacturers. All infection control practices and procedures used by the CS department for processing instruments by any other method should also be used for ozone sterilization.

The ozone sterilization process uses two identical half-cycles. After the chamber is loaded with instruments, the door is closed, and the cycle begins. First, a vacuum is created within the chamber, followed by a humidification phase. Ozone is then injected into the chamber and the sterilization process begins. After the half-cycle is reached, the previous steps are repeated. A final ventilation phase is used to remove ozone from the chamber and the packaging within it.

During the sterilization cycle, a catalytic agent is used to transform the ozone into oxygen. There are no toxic/hazardous residues or waste products associated with the process, and no toxic gas is vented into the environment.

Mechanical, biological, and chemical indicators are used to complete the sterilization assurance monitoring process.⁵ Typical process (mechanical) functions are monitored during the cycle and, at the end of each cycle, process parameters are printed for review and retention. During the sterilization cycle, if a parameter is not reached, the cycle will abort, and the reason for the interruption will be displayed on a screen and printout.

For routine process monitoring, a sterilization test pack is placed directly in the load. This test pack should be used in each sterilization cycle. A biological indicator is placed in a syringe with a catheter tip, followed by a chemical indicator. The plunger diaphragm is inserted into the syringe which, in turn, is placed in a sterilization pouch before being sealed. (A routine ozone test pack closely resembles an Association for Advancement of Medical Instrumentation [AAMI] routine EtO test pack.) The syringe serves as an ozone absorber, and the biological indicator is a microbial challenge. Concurrent biological monitoring is done, using *geobacillus stearothermophilus* in a self-contained vial, to provide a sterility assurance level (SAL) of 10⁻⁶. The chemical indicator resembles a small sticker and contains

chemicals that change color when the parameters required for sterilization have been met.

The sterilization cycle lasts approximately four and one-quarter hours at temperatures from 85° - 94° F (30° - 35° C).

Objective 5: Present background information about the safety of the ozone sterilization process.

Excessive exposure to any sterilant can be a health and safety hazard. At low levels, ozone can be a respiratory irritant, and it causes more serious effects at higher levels. OSHA has established a short-term exposure limit of no greater than 0.3 parts per million (ppm) over a fifteen-minute period, and an exposure limit of no greater than 0.1 ppm as an eight hour time-weighted average.

The human nose can detect ozone at levels of approximately 0.003 ppm, so a Central Service technician will typically be aware of ozone in the environment long before a hazard exists. In addition, because the sterilizer creates a negative pressure chamber during the processing cycle, any leaks would enter the chamber and the ozone would be diluted before entering the environment.

The manufacturer recommends that the sterilizer unit be placed in a room with at least ten air exchanges per hour.⁶

Objective 6: Note materials, items, and packaging that are or are not recommended for use with the ozone sterilization system.

All medical devices should always be processed by following the device manufacturer's recommendations. Instructions provided by the manufacturer of the sterilization equipment that apply specifically to the sterilization process should also be followed carefully.

Because of the wide variety of heat-sensitive devices and changes in instrument model designs, material and device compatibility must be identified on an individual basis. Many devices containing the following materials *can* be sterilized with ozone:

- rigid polyvinyl chloride (PVC)
- nylon
- polypropylene

- polyetherimide Teflon
- silicone
- Plexiglas
- stainless steel
- low-density polyethylene
- high-density polyethylene
- Pyrex glass
- anodized aluminum

The process can also be used with lumens of specified diameter and length:

- inside diameter of 2 mm (0.08 inches) or larger and a length of 250 mm (9.8 inches) or shorter
- inside diameter of 3 mm (0.12 inches) or larger and a length of 470 mm (18.5 inches) or shorter
- inside diameter of 4 mm (0.16 inches) or larger and a length of 600 mm (23.6 inches) or shorter

The process can also be used for items with diffusion-restricted spaces, including the hinged portion of hemostats, forceps, and serrated surfaces.

Items that should *not* be used in this process include those containing:

- natural rubber
- latex
- textile fabrics
- copper
- brass
- bronze
- zinc
- nickel

Items that cannot withstand a vacuum, implants, flexible endoscopes, glass or plastic ampoules, and liquids are not recommended. Packaging made of woven fabric or metal foillis also inappropriate for use with the process. Packaging that creates a solid barrier—such as hermetically sealed (air-tight) packs or any other packaging not

specifically recommended by the manufacturer—likewise should not be used.⁷ Rigid (anodized aluminum) containers, however, *are* approved for use with the process.

It is very important that CS professionals interested in this technology carefully research approved alternatives. For instance, staff may find that it is inefficient to stock packaging materials that are not compatible with the sterilizers in current use, and increases the possibility of error for end users.

Conclusion

Central Service managers will find that there are many options as they analyze the most effective way to meet their facility's low-temperature sterilization needs. Numerous factors—including sterilization efficiency; employee, patient, and environmental safety; cost-effectiveness; and the impact on instrument inventories—must be assessed when determining sterilization methods most appropriate for the specific facility.

In the fast-paced world of Central Service, existing sterilization equipment and methods are constantly being improved and updated, and new technology is being introduced. One, ozone sterilization, holds promise as an alternative to process the ever-increasing number of medical devices requiring low-temperature sterilization. CS personnel must understand the basics of ozone sterilization and evaluate the factors associated with its use to determine its usefulness to their department.

Endnotes

- ¹ For more information about low-temperature sterilization alternatives in common use today, see: Joyce Dickerson and Betty Strickland. *Low-Temperature Sterilization*. Chapter 10 in: Jack Ninemeier (editor). *Central Service Technical Manual*. Sixth Edition. Chicago, Illinois. International Association of Healthcare Central Service Materiel Management. 2003.
- ² Jason Simon. *Germ Free: 21st-Century Sterilization Options for Healthcare Facilities*. *Managing Infection Control*. May, 2004.
- ³ For more information about the history of ozone use for medical purposes, see: Bryant Broder. *Ozone Low-Temperature Sterilization: The Sky's Not the Limit Anymore*. *Managing Infection Control*. January, 2004.
- ⁴ Information about advantages to the use of ozone sterilization is found in: Company Obtains FDA Authorization to Commercialize Ozone Sterilizer and Chemical Indicator. www.tso3.com/nouvelles_lecture.asp?118.
- ⁵ Information about operation of the ozone sterilizer are found in: Mark Chaunet, et al. *The Sterilization Technology for the 21st Century*. TSO3, Inc. Sainte-Foy (Quebec), Canada. No Date.
- ⁶ Marimargaret Reichert and Janet Schultz. *Is New Ozone Sterilizer Right for Your OR?* *OR Manager*, Vol. 19, No. 11. November, 2003.
- ⁷ Skytron & TSO₃. *Recommended Materials*. Sainte-Foy (Quebec). Canada. No date.

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Kimberly-Clark

Examination No. 83

CIRCLE THE CORRECT ANSWER.

Objective 1.

- Which of the following is/are needed to produce ozone in a sterilization system?
 - electricity
 - water
 - medical-grade oxygen
 - all of the above
- Which of the following is/are released into the environment as part of the ozone sterilization process?
 - oxygen
 - water vapor
 - electricity
 - a and b above
- Ozone sterilant _____ be detected by its odor before the exposure danger level for humans is reached.
 - would
 - would not

Objective 2.

- Which of the following statements is correct?
 - Ozone is a dark blue gas.
 - Ozone condenses to a liquid at -315°F (-193°C).
 - Ozone was never used for medical applications before 1980.
 - None of the above is correct.
- The ozone sterilization system marketed today evolved from a concept about the use of ozone for
 - water treatment
 - purification
 - influenza treatment
 - diabetes treatment

Objective 3.

- Which of the following sterilization processes allows medical devices to be reused most quickly?
 - EtO
 - ozone

- Which of the following sterilization agents is *least* carcinogenic?
 - EtO
 - ozone
- Which of the following statements about ozone sterilization is *incorrect*?
 - It is more cost-effective than EtO.
 - A smaller instrument inventory is needed than with EtO.
 - It is more explosive and dangerous to handle than EtO.
 - All of the above statements are correct.
- Ozone sterilization may _____ prions.
 - deactivate
 - kill
 - reduce
 - eliminate

Objective 4.

- During the sterilization process, a _____ phase allows the creation of _____.
 - humidification; vacuum
 - vacuum; humidification
- Which of the following is the last step in ozone sterilization?
 - creation of a vacuum
 - ventilation
 - humidification
 - generation of electricity
- During the sterilization cycle, ozone is transformed into oxygen by
 - electricity
 - water
 - a catalytic agent
 - sterilization residue
- What type of indicator(s) is/are used as part of the ozone sterilization assurance monitoring process?
 - mechanical
 - biological
 - chemical
 - all of the above

- How frequently should a sterilization test pack be used for routine process monitoring?
 - with each sterilization cycle
 - once daily
 - once weekly
 - It depends upon the type of devices being processed.
- The ozone sterilization cycle lasts approximately _____ hours.
 - $2\frac{1}{2}$
 - $3\frac{1}{2}$
 - $4\frac{1}{2}$
 - $5\frac{1}{2}$

Objective 5.

- OSHA has established a short-term exposure limit of no greater than _____ ppm over a _____ minute period.
 - 0.1; 15
 - 0.3; 15
 - 0.1; 8
 - none of the above
- The ozone sterilizer unit should be placed in a room with _____ air exchanges per hour.
 - 6
 - 8
 - 10
 - 12

Objective 6.

- Devices containing which of the following materials *cannot* be sterilized with ozone?
 - latex
 - PVC
 - nylon
 - Plexiglas
- Devices containing which of the following materials can be sterilized with ozone?
 - textile fabrics
 - nickel
 - zinc
 - stainless steel
- Which of the following is/are examples of inappropriate packaging materials for ozone sterilization?
 - woven fabrics
 - metal foil
 - hermetically sealed packs
 - all of the above

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