L'OZONE – LE DERNIER DÉVELOPPEMENT DANS LA STÉRILISATION DES DISPOSITIFS MÉDICAUX

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RÉSUMÉ

Combien de fois avez-vous connu un retard dans une procédure dans la salle d'opération parce que les instruments nécessaires se trouvaient encore dans le stérilisateur? Dans votre rôle d'infirmière de salle d'opération vous connaissez sans doute trop bien la pression ressentie pour rendre disponibles à tout moment les instruments parfois peu nombreux.

En 2003, une société canadienne a développé une procédure de stérilisation unique se servant de l'ozone en tant qu'agent de stérilisation. Cette technologie présente un choix rapide, économe et sans danger qui pourrait remplacer les autres méthodes de stérilisation à basse température et diminuer la pression ressentie lorsque le besoin d'instruments excède leur disponibilité.

Cet article traitera des principes et du cycle du stérilisateur ainsi que des bénéfices de cette technologie.

OZONE - THE LATEST ADVANCE IN STERILIZATION OF MEDICAL DEVICES

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ABSTRACT

How many times have procedures in your operating rooms been delayed because the instruments needed were still in the sterilizer? As Perioperative nurses you are likely to be quite familiar with the constant pressure to ensure that scarce instrumentation is available when needed.

In 2003, a Canadian company developed a unique sterilization process employing ozone as the sterilizing agent. This technology is a safe, rapid and economical alternative to other low temperature sterilization modalities and may relieve some of the pressure experienced when instruments in short supply are in high demand.

This article will discuss the principles of the sterilizer and the cycle and will explore the advantages of using this sterilization technology.

Courtesy TSO3

Ozone Sterilizer

INTRODUCTION

The field of sterilization has recently grown to admit a newcomer in low temperature sterilization technology. A Canadian company, based in Quebec, received Health Canada and FDA clearance in the autumn of 2003 to market a breakthrough technology using ozone as the sterilant. The company's first product is a sterilizer with a four cubic foot (125 litres) chamber capacity.

OZONE

In 1840 C.F. Schonbein, first discovered ozone and took the Greek word ozein as the root for the name. Ozein means 'to smell'[1] which acknowledges ozone's distinctive odour.

Ozone is a molecule composed of three oxygen atoms. In gas and liquid forms, ozone is

metastable, meaning that it is stable for short periods of time. In its gaseous state, ozone is readily soluble in water and is highly oxidative. Oxidation is defined by the United States Environmental Protection Agency as a 'chemical reaction in which oxygen unites or combines with other elements.'[2] Since it is highly oxidative, ozone readily enters into this chemical reaction. This characteristic, combined with its solubility, makes it an excellent candidate for use as a sterilant.

In the earth's atmosphere, ozone is produced naturally from oxygen in the upper stratosphere through the absorption of the sun's ultraviolet radiation.[3] The ozone molecule is heavier than air and falls towards the earth's lower atmosphere, attaching to other airborne particles during its descent. Once attached, the ozone molecule reacts with the particle and oxidizes it, cleaning and purifying the air. It is this action that gives ozone its label as Mother Nature's purifier and gives rise to the clean fresh smell following a rain storm.[4]

When found in the lower atmosphere, ozone is formed by the reaction of solar radiation with noxious gas or hydrocarbons released by factories and automobiles.[3] As a result, it is a component of smog found in highly industrialized and populated areas.

Ozone can also be produced mechanically. A photocopy machine will produce ozone if the machine is copying large quantities.[5] Ozone is also produced by welders when they use an electrical arc. Levels established for ozone toxicity in humans is based on welder's exposure levels to ozone.[6]

Today ozone is employed in many beneficial ways. Ozone has long been recognized as a safe disinfectant for water and food. It is safely used in both gas and liquid forms as an antimicrobial agent in the treatment, storage and processing of foods, including meat and poultry. In addition, there are over 3000 municipalities using ozone technology to purify their water and sewage.[7,8,10] Los Angeles has one of the largest municipal ozone water treatment plants in the world![7,9] Companies selling bottled water use ozonated water to sterilize their containers[7,8] and Olympic organizing committees have used ozone to purify swimming pools since 1984.[9]

Steam, hydrogen peroxide and peracetic acid are also examples of sterilization technologies that are based on oxidative capabilities. Ozone's oxidative capacity is greater than hydrogen peroxide and peracetic acid, thus making it a stronger and more effective sterilant. Substances such as fluorine, fluorine dioxide, hydroxyls radicals, and atomic oxygen have higher oxidative potential than ozone but to date a method for harnessing them for productive use has not been developed.[11]

Establishing the efficacy of the technology

In order to bring a new sterilization technology to the market in North America, the product's capabilities must be demonstrated under certain conditions.[12, 13] The primary requirement is to demonstrate the sterilizer's capacity to kill microorganisms. The required tests are:

- Achieve a Sterility Assurance Level (SAL) of 10?[6]
- Pass the American Association of Official
- Analytical Chemists (AOAC) sporicidal test, originally developed for a liquid chemical sterilant.
- Conduct simulated use tests
- Demonstrate ability to sterilize narrow stainless steel lumens and items with complex geometry such as hinges etc.
- Sterilize actual medical devices in hospital environments ('in-use testing').

The company that developed ozone sterilization technology passed all these required tests and has demonstrated the ozone sterilizer's excellent capacity to achieve sterilant contact between mated surfaces.

Generating the ozone

Ozone is relatively easy to generate artificially. In 1857, von Siemens developed the first industrial ozone generator based on coronal discharge.[14] The ozone sterilizer uses this principle to generate ozone for use as the sterilant.

Glass rods are filled with oxygen gas and a high voltage electrical current is applied to the space between the rods. An electrostatic plasma field is formed, exciting the oxygen molecules and causing them to break apart and recombine as ozone.[14]

The sterilizer cycle

The ozone sterilizer requires water, oxygen and electricity. The sterilization cycle is composed of four phases – vacuum phase, humidification, injection, and exposure. Each phase is run twice, followed by a ventilation phase. The cycle time is approximately 4 1/2 hours.[15]

When the door of the chamber is closed and the cycle is started, the chamber and contents are warmed to a uniform temperature. When this pre-conditioning is completed the first phase of the sterilization cycle begins.

The first phase is the **Vacuum phase**. A vacuum of approximately 1 Torr (Torr - a unit of pressure equal to 133.3 pascals or 1/760 of an atmosphere[14]) is drawn in the chamber.

The next phase is **Humidification**. The load is humidified with approximately 60 milliliters of water vapour to facilitate the action of ozone on microorganisms. This is followed by the Injection phase where ozone is injected into the chamber. The concentration of ozone is controlled to 160 – 200 mg/L.

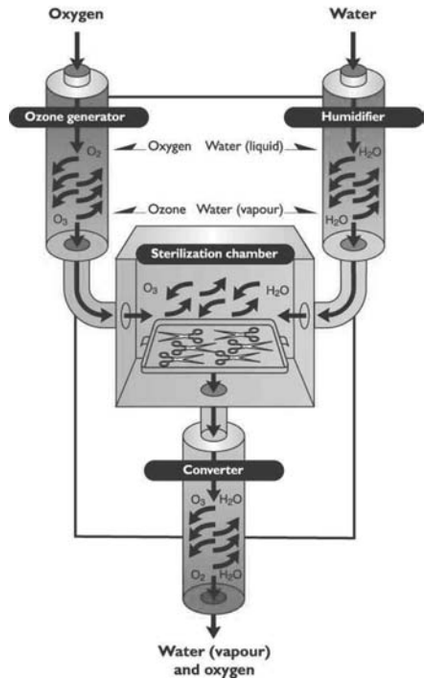
The instruments are exposed to ozone for a fixed time period during the **Exposure phase**. This sequence, vacuum, humidification, injection and exposure are repeated. At the completion of the second exposure phase, the sterilizer moves into the ventilation phase to remove ozone from the devices and the chamber.[15]

During the **Ventilation phase** a catalytic convertor converts the ozone to oxygen and any residual humidity to water vapour. These are safely exhausted into the room through an outlet on the side of the machine. No abatement is necessary.[15]

The cycle operates between 25 and 35°C (the coldest low temperature sterilization technology available today). Instruments are ready for use at the end of the cycle. They do not require a cool down period or any aeration time before they can be handled or used.

Figure 1 provides an illustration of how ozone is generated, water is humidified and how both are converted into oxygen and water vapour.

Figure 1 – Flow Diagram



Courtesy TSO3

A) Water in liquid form is heated until it becomes water vapour and enters the chamber during the humidification phase.
B) Medical grade oxygen is released into the ozone-generator and subjected to an electrical current, causing the oxygen to convert to ozone. The ozone is released into the chamber during the Injection phase and is held for a set period of time during the Exposure phase.
C) During Ventilation a convertor catalyses residual ozone into oxygen and exhausts both oxygen and residual water vapour into the room.

Monitoring the cycle for quality assurance

As the cycle progresses through each phase the display screen located on the front of the sterilizer provides a graphic read-out. In addition, a printout of the cycle parameters is provided at the completion of each cycle. Should the sterilizer detect and diagnose a malfunction, it will abort

the cycle. The printout will indicate that the cycle was aborted and the cause. See Figure 2 for a completed cycle printout. The operator can also manually abort a cycle. A sample printout of this event is shown in Figure 3.

Figure 2

125L-03-0025

Date: 2004/07/05
Cycle number: 000171
Load ID: 000000

Cycle start at: 16:18:52 hms

1 VACUUM PHASE: Pressure: 0001 torr
Duration: 00:42:28 hms

2 HUMID. PHASE: Pressure: 0035 torr
Duration: 00:50:01 hms

3 INJECT. PHASE: O3 conc.: 0186 mg/L
Pressure: 0421 torr
Duration: 00:39:52 hms

4 EXPOS. PHASE: Pressure: 0421 torr
Duration: 00:15:00 hms

5 VACUUM PHASE: Pressure: 0001 torr
Duration: 00:21:53 hms

6 HUMID. PHASE: Pressure: 0035 torr
Duration: 00:50:00 hms

7 INJECT. PHASE: O3 conc.: 0187 mg/L
Pressure: 0418 torr
Duration: 00:39:48 hms

8 EXPOS. PHASE: Pressure: 0418 torr
Duration: 00:15:02 hms

9 VENT. PHASE: Duration: 00:18:43 hms

Door unlocked at: 21:11:43 hms
Total cycle duration: 04:52:51 hms

OPERATOR I.D.: 0000

Name:

Cycle Completed: 21:11:43 hms
Cycle number: 000171

Courtesy TSO_3

Printout of a complete sterilization cycle

Figure 3

125L-02-0004

Date: 2004/07/08
Cycle number: 004486
Load ID: 000000

Cycle start at: 14:00:38 hms

1 VACUUM PHASE: Pressure: 0001 torr
Duration: 00:42:10 hms

2 HUMID. PHASE: Pressure: 0001 torr
Duration: 00:08:50 hms

9 VENT. PHASE: Duration: 00:15:44 hms

Door unlocked at: 15:07:27 hms
Total cycle duration: 01:06:49 hms

OPERATOR I.D.: 0000

Name:

Manually Aborted: 15:07:27 hms
Cycle number: 004486

Courtesy TSO_3

Printout generated in a cycle aborted by the operator

INDICATORS

Chemical and biological indicators are available for quality assurance monitoring of the cycle (see Figure 4 & 5). The chemical indicator (CI) is provided on a roll and has covered adhesive backing. There are two options for application.

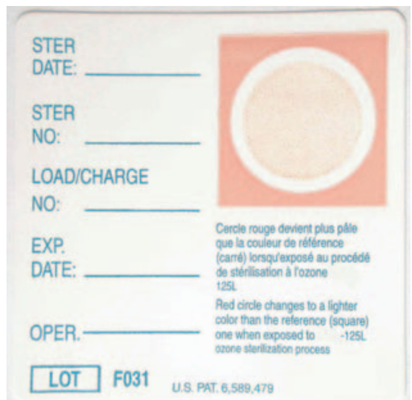
The CI can be applied to the peel pouch or wrapper by removing the adhesive cover. Alternatively, the backing can be left in place and the CI can be positioned on the outside of a rigid container, or inside a pouch and/or container.

Figure 4

Courtesy TSO_3

Chemical indicator – unexposed. Inner circle is darker than outer square.

Figure 5



Courtesy TSO_3

Chemical indicator – exposed. Inner circle is lighter than outer square.

BIOLOGICAL INDICATORS

The self-contained biological indicator (BI) used for the ozone sterilization process contains spores of *Geobacillus stearothermophilus* which have been found to be most resistant to the sterilant. The BI can be used alone or inside a

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test pack for routine testing purposes. The vial must be incubated at 56°C for 48 hours to obtain a final indicator result.[15,16]

Figure 6

Courtesy TSO3

Biological Indicator – unexposed/no growth. Colour is purple.

Figure 7

Courtesy TSO3

Biological Indicator – evidence of growth. Colour changes to yellow.

Safety and the Ozone Sterilizer

The sterilizer's design limits the worker's risk of exposure to the sterilant. There is no handling of toxic chemicals since a fresh supply of ozone is produced by the sterilizer during each cycle run. Additionally, the chamber is under negative pressure during the cycle. If there is a leak, air will flow into the chamber; ozone will not flow out. No special protective respiratory equipment is required when working around the sterilizer.[15] Software has been developed to control the electromechanical components of the sterilizer, the touch screen and the printer. The sterilizer is controlled by a programmable logic controller (PLC). All critical process parameters are monitored during the cycle and if one of the critical parameters is not reached, the cycle will abort.

Once a cycle is aborted, whether by the operator or automatically by the sterilizer; the cycle will move into the ventilation phase to remove any ozone in the chamber, convert it to oxygen before unlocking the chamber door and permit access to the load. The sterilizer possesses a single standard cycle for all medical devices to reduce the risk of operator error.

The by-products of the cycle are oxygen and water vapour. There are no toxic residuals produced; therefore, there is no danger that toxic residuals could remain on instrumentation and potentially harm patients or staff.[15]

Since oxygen and water are the only by-products there is no need to recapture and scrub the exhausted gases with expensive equipment. The environment is not harmed by the oxygen released at the end of the cycle. The process is safe for technicians, patients, devices and the environment.[15]

Operating costs for the ozone sterilizer

The unit requires oxygen, water and electricity to operate. The sterilizer can be connected to the hospital's existing oxygen network or to oxygen cylinders. The electrical requirement is 240 volts AC 60 hertz, 20 amperes dedicated circuit.[16]

Water quality requirements of the ozone sterilizer correspond to the feed water quality requirements used for steam production in steam sterilization processes. Consumption of water and electricity are minimal per cycle and the cost of the oxygen is minimal per load. Since there is no need to purchase sterilant, the cost per cycle is the most economical low temperature process available today.

Costs for consumable items such as chemical and biological indicators and packaging materials are comparable to existing products on the market.

Ozone (cont.)

There is no requirement for environmental monitoring equipment or waste gas scavenging systems.

Materials compatible with the ozone sterilizer

The ozone process is compatible with most heat sensitive reusable medical items currently sterilized by other technologies. Sterilizing sealed ampoules, liquids, natural rubber, latex, and textile fabrics are not recommended. Sterilization of implants and flexible endoscopes has not been validated at this time.[15,16]

The ozone process is compatible with current packaging such as uncoated nonwoven material/polyethylene pouches and commercially available anodized aluminum containers using disposable filters.[15] It has been validated for medical devices having a single stainless steel rigid lumen with the following internal diameters and lengths:[15,16,17]

Internal diameter	Length
0.5 mm	45 cm
1 mm	50 cm
2 mm	57.5 cm
3 mm	65 cm
4 mm	70 cm

Conclusion

In today's fast paced surgical suites the ability to turn much needed instrumentation around more rapidly would be a real asset. Perioperative Nurses are certainly no strangers to budget restraints and having to make do with less. This new technology may offer an alternative and in so doing help to relieve the pressures associated with increased caseloads and too few resources.

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