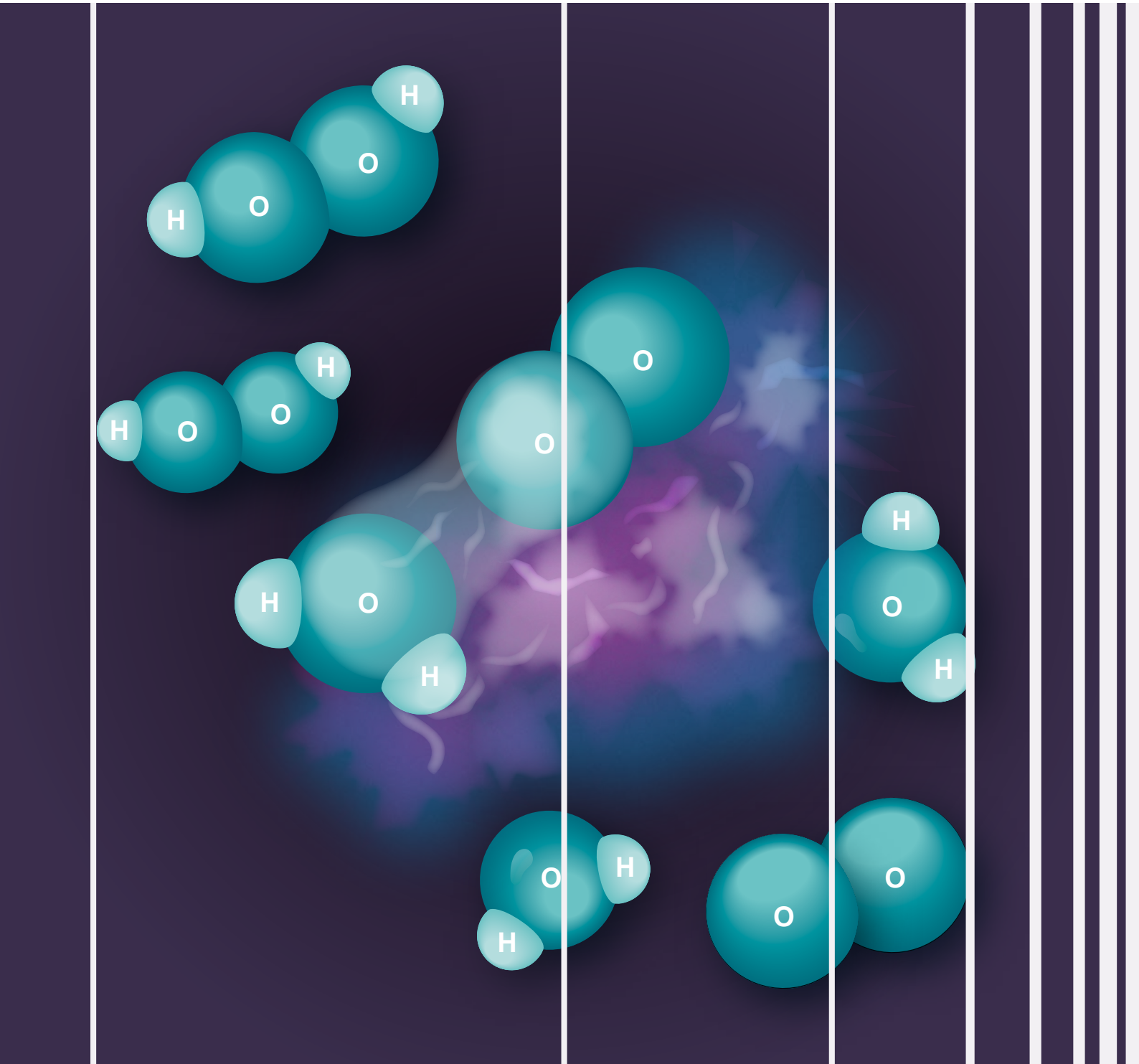
Protecting Users, Patients and the Environment

ASP™ Advanced Sterilization Products

A summary of the risks and burden associated with commonly used sterilization modalities



Protecting Users, Patients and the Environment

The Risks and Burden Associated with Commonly Used Sterilization Modalities

Sterilization offers the greatest margin of safety to device reprocessing, yet conventional high-temperature methods such as steam are not suitable for all devices. The materials that comprise advanced surgical instruments, and their complex design, necessitates the use of low-temperature sterilization (LTS) to maintain device integrity. Commonly utilised LTS modalities include ethylene oxide (EtO), formaldehyde gas (FO) and hydrogen peroxide (H_2O_2), however, each is associated with potential hazards, to users, patients and the environment.

EtO, FO and H_2O_2, and their residues, are linked with acute and long-term toxicities,[1-3] while the former two sterilants are considered carcinogenic by the World Health Organization (WHO),[4, 5] putting staff and patients at an avoidable risk of harm. Many countries have recognised the danger of EtO and FO and have issued strict regulations governing their use – to limit exposure to staff, patients and the environment – which sterilization facilities must comply with.[6-10] The use of EtO and FO has declined rapidly since the start of the century, and in some markets has completely stopped, due to these regulations.[11]

Where they are still used, various precautions, such as the use of air monitors, alarm systems and safety equipment, must be taken by sterilization facilities. Such measures are associated with substantial financial burden, incurred both directly and indirectly, the former through infrastructure, equipment and training costs, and the latter through a negative impact on efficiency. For example, EtO reprocessing typically lasts 16–17 hours, and FO reprocessing ~3 hours, the majority of which is required to aerate instruments of toxic residues;[12] this, in turn, impacts instrument turnover, requiring a large number of instrument sets to be held in hospitals' inventories, which in itself is costly.[13]

Some sterilization processes, such as steam and EtO, have also been shown to damage surgical devices, necessitating their repair or replacement and putting patients at risk of further harm.[14, 15] Steam and EtO are also associated with substantial energy and water consumption, which incurs significant costs and carries additional burden on natural resources.[16, 17]

Protecting Users

There are acute and chronic health risks associated with exposure to EtO, FO and H_2O_2, and their by-products, which pose a hazard to user safety (Table).

➡ Acute exposure to EtO can lead to vomiting and bronchitis, as a result of irritation to the gastrointestinal system and lungs, respectively, and neurological disorders, due to central nervous system depression.[1] Long-term, repetitive exposure has been shown to be associated with reproductive disorders, cataracts and neurological disorders.[1] In addition, EtO is considered carcinogenic by many regulatory agencies;[4] increased cancer rates and mortality have been reported from a cohort of more than 18,000 employees exposed to EtO, mainly in sterilization processes.[18]

➡ Acute exposure to FO is highly irritating to the skin, eyes and respiratory tract.[2] Even low concentrations of FO can rapidly irritate, causing cough, chest pain, shortness of breath and wheezing. Higher concentrations can result in significant inflammation, resulting in swelling of the throat and accumulation of fluid in the lungs, potentially leading to pulmonary injury. Repeat exposure can cause severe allergic reactions in sensitized persons, manifesting as asthma or contact dermatitis.[2]

FO is also considered carcinogenic by WHO and, in humans, FO exposure has been associated with increased risk of nasal cancer.[5]

➡ H_2O_2 is less toxic than EtO and FO and is not considered carcinogenic, however, exposure to the sterilant is still associated with health risks.[3] Acute exposure can lead to upper airway irritation, inflammation of the nose and shortness of breath. Because H_2O_2 is rapidly decomposed in the body, it is unlikely to cause chronic toxicity. Nevertheless, repeated exposures to H_2O_2 vapour may cause chronic irritation of the respiratory tract.

EtO, FO and H_2O_2 are associated with acute and long-term toxicities, putting users at risk of health complications.

Explosions due to EtO have caused death, severe injury and damage to sterilization facilities.[19]

Steam sterilization also poses an explosion risk, and pressure and heat in the chamber can escape rapidly, potentially causing serious injury.[20]

Health risks associated with EtO, FO and H_2O_2

Sterilant	EtO	FO	H_2O_2
Acute exposure	Irritation, central nervous system depression	Irritation	Irritation
Long-term exposure	Reproductive disorders, neurological disorders, cataracts	Severe allergic reactions	Chronic irritation
Carcinogenic	✓	✓	✗

Measures that are Necessary to Protect Users Negatively Impact the CSSD and Surgeons

Due to the health, safety and environmental concerns associated with EtO and FO, the CSSD must comply with strict regulations.[6-10] Air monitors, alarm systems, safety equipment and specialised storage facilities may all be required, and staff exposed to EtO or FO require regular health checks; in the US, medical surveillance records for staff exposed to EtO need to be kept for 30 years.[21]

Many countries recognise the danger of EtO and FO and issue regulations to limit exposure to staff and patients.[6-10] In many markets, EtO and FO are not used due to these regulations.

In France, EtO sterilization should only be used if no appropriate alternative exists.[6] In the US, partial loads are not allowed to be sterilized using EtO unless managers provide justification that it is a medical necessity.[9]

FO sterilization has not been cleared by the Food and Drug Administration for use in healthcare facilities in the US, due to its toxic effects.[10]

While the risks associated with EtO and FO sterilization can be mitigated, putting these measures in place can have the consequence of negatively impacting the CSSD and surgeons.

> Lengthy aeration periods required to remove toxic residues following sterilization with EtO result in a low rate of instrument turnover, potentially delaying operations, and increasing the demand for large and costly device inventories.[13]

> EtO and FO sterilization require ventilation and abatement systems, and staff must be undergo extensive training, as well as regular health checks, incurring significant costs.[22]

Although H_2O_2 is less toxic than EtO and FO, it is also strictly regulated.[23] Sterilization with H_2O_2 does not typically require aeration of the load before handling, however, sterilizer models that do not properly manage the removal of sterilant and residues have been shown to produce H_2O_2 emissions above that deemed safe by the American Conference of Governmental Industrial Hygienists (ACGIH®).[24] STERIS V-PRO® sterilizers have been shown to produce instantaneous peak measurements of H_2O_2 up to 20 ppm at the user's breathing zone level, contributing to a more hazardous working environment.[24]

Protecting Patients

Sterilants, including EtO, FO and H_2O_2, can leave toxic or irritating residues on medical devices, despite aeration.[25-29] Exposure to these sterilants or their by-products puts patients at risk of serious health complications such as allergic reactions, burns and toxic anterior segment syndrome (TASS).[26]

Concentrations of unchanged EtO have been measured in sterilized devices.[25]

1–2% EtO

TASS has occurred as a result of EtO-sterilized vitrectomy packs. No TASS cases were observed with non-EtO-sterilized packs.[26]

19/893 eyes

had TASS

Instruments damaged by sterilization can also put patients at risk of harm. Surgical devices have been demonstrated to show signs of wear after sterilization with both EtO and steam.[14, 15]

> In an assessment of arthroscopic shaver blades sterilized using EtO, all of the reprocessed blades showed some level of damage or wear.[14] Further, tissue cut using EtO-sterilized blades showed rougher edges than tissue cut using new blades. In clinical practice, this may compromise the success of certain surgical procedures, especially where the viability of tissue borders is critical to the repair process.

A higher percentage of irregularities was observed in tissue cut with EtO-sterilized blades.[14]

5.8–20.0%

vs 3.3–7.1% for new blades

High-temperature reprocessing modalities, such as steam, damage delicate, heat- and moisture-label devices and even damage heat- and moisture-stable devices over time.

> Microsurgical scissors have been demonstrated to exhibit signs of corrosion of the stainless steel cutting surface, suggesting severe oxidation, after 30 cycles of steam sterilization.[15] Damaged surfaces act as hot spots for biofilm formation, and can lead to hospital-acquired infection (HAI) outbreaks, putting patients at further risk of harm.[30]

Liquid sterilization is not a direct substitute for terminal sterilization.[31] Devices reprocessed in this manner must be used within a short time period. Otherwise, they carry a risk of infection if used in a patient. If unused, they require repeat reprocessing, wasting money and time, and requiring larger inventories to ensure availability.

There is an increasing pressure from hospital operating rooms (ORs) to maintain medical device availability for planned and unplanned procedures, whilst ensuring patient safety.[32] However, some reprocessing modalities, such as EtO and FO, are slow to turnaround instruments due to lengthy cycle times, the majority of which comprises aeration of the load, to remove toxic residues.[12] Lengthy turnaround times may delay operating schedules due to unavailability of surgical instruments, compromising patient safety.[33]

Protecting the Environment

Commonly used LTS modalities, including H_2O_2, EtO and FO, can have a toxic impact on the environment.

EtO is an air pollutant and is associated with ozone depletion.[34, 35] While H_2O_2, after being broken down to form highly reactive free radicals, can have a toxic effect on marine life.[36] Similarly, although FO readily biodegrades, it breaks down in sunlight to form carbon monoxide and formic acids; the former being a greenhouse gas, and the latter contributing to acid rain,[37] which can have harmful effects on plants, aquatic animals and infrastructure.[38]

EtO and FO emissions are strictly regulated, in order to minimise their impact on the environment.[6-10] Sterilization facilities must therefore comply with these regulations. For example, sterilization with EtO necessitates the use of air monitors, alarm systems, safety equipment and specialised storage facilities. Such measures can negatively impact upon the CSSD and surgeons, as described above.

Some reprocessing modalities, such as steam, EtO and FO are also associated with substantial water consumption and electricity usage, further impacting upon the environment, while incurring substantial costs.[16, 17]

Costs Associated with Water Consumption

An audit of water use by The Veteran Affairs Hospital in Oregon, US revealed that EtO sterilization was consuming far more water than other equipment in the hospital (14 million litres per year).[17] Due to this audit, the hospital found that simply eliminating EtO sterilization was predicted to save $9,000 annually.

In a separate analysis, steam sterilization was shown to require 26.5 litres of water per minutes of operation, and a single steam sterilizer to use 180,000 litres of water annually.[16]

High Energy Usage

EtO and FO also require exhaust fans to aerate the chamber and operating area for lengthy periods (8–12 hours at 50–60°C), resulting in a large power usage.[10] An analysis estimated that a single steam sterilizer uses 32 kWh of electricity annually.[16]

STERRAD™ Systems Help Protect Users, Patients and the Environment

STERRAD™ Systems rapidly and safely sterilize medical devices and materials, avoiding exposing users and patients to unnecessary health risks by utilising a combination of H_2O_2, which is non-carcinogenic, and gas plasma, which eliminates H_2O_2 residues to leave only water and oxygen.

With no toxic emissions, STERRAD™ Systems avoid the need for expensive ventilation and abatement systems, and adherence to strict regulatory guidelines associated with preventing and detecting exposure, such as for EtO and FO.[22] Moreover, by utilising gas plasma technology to remove residual H_2O_2, STERRAD™ Systems reduce exposure to potentially harmful residues to safe levels.[24]

Sterilization Systems' H_2O_2 emissions, at the user's breathing zone level, are up to 67 times lower than for STERIS V-PRO sterilizers.[24]

The V-PRO® maX showed concentration peaks ranging from 7 ppm to as high as 20 ppm.

The STERRAD™ 100NX and STERRAD NX™ Systems never registered a value above 0.3 ppm.

STERRAD™ Systems' H_2O_2 emissions, at the user's breathing zone level, are up to 67 times lower than for STERIS V-PRO sterilizers.[24]

STERRAD™ Systems also consume less energy and water than alternative sterilization modalities, sparing natural resources and reducing costs.[16, 17]

Compared to steam sterilization, STERRAD™ consumes less natural resources each year, which translates into a reduced economic burden.[16]

68–87% less energy

180,000 litres less water

€8,700 cost savings each year per sterilizer

STERRAD™ Systems enable faster instrument turnover, as they do not require lengthy aeration and offer a rapid sterilization cycle (24–60 minutes), saving time and increasing efficiency. This means that instruments can be re-used much sooner, alleviating the costs associated with holding a large number of instrument sets in inventory.[13]

Furthermore, EtO chambers are typically large, and given that the restrictions in some countries prohibit partial loads,[9] the turnaround time can be even longer if waiting for a full load. In contrast, STERRAD™ Systems are available in a range of sizes so can be run efficiently without needing to wait for as many devices to be returned for reprocessing.

STERRAD™ Systems are able to reprocess over ten times more instruments than EtO in a given time, meaning they are ready for re-use much quicker.[39]

STERRAD™ Systems can cause less damage than EtO and steam to certain materials,[15, 40] reducing the need for repair and replacement of damaged devices, and associated costs.

58% risk reduction of damage[41]

50% reduction in replacement rate[42]

33% reduction in repair costs[43]

compared with steam sterilization.

Summary

Commonly used sterilization modalities, including H_2O_2, EtO and FO are associated with acute and long-term toxicities, and can leave residues on medical devices, putting users and patients at risk of harm.

Due to the health, safety and environmental concerns associated with EtO and FO, the CSSD must comply with strict regulations, leading to lengthy cycle times and incurring substantial costs.

STERRAD™ Systems permits rapid and safe sterilization of medical devices without exposing users and patients to unnecessary health risks, and reduces the costs associated with infrastructure, equipment and training, as well as those incurred as a result of damaged devices.

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