VOLUME 1

STERRAD™ SUPERIORITY

A FACTSHEET BY ASP

The Power of Plasma

How do STERRAD™ with ALLClear™ Technology Sterilization Systems Operate?

✓ STERRAD™ with ALLClear™ Technology Sterilization Systems utilise a combination of **hydrogen peroxide (H_2O_2) and low-temperature gas plasma** to rapidly and safely sterilize validated medical devices and materials, without leaving toxic residues.[1]

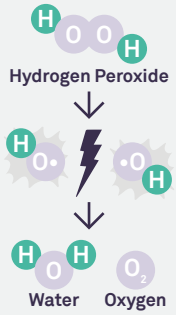
✓ This approach offers **safety and efficiency advantages** over alternative reprocessing modalities such as ethylene oxide (EtO), formaldehyde gas (FO) and other H_2O_2 systems, as described below.

> **"ASP pioneered the use of gas plasma in low temperature sterilizers in the 1990s and has led the market since then."**

How Does Plasma Work?

1. H_2O_2, combined with low-temperature **gas plasma**, results in the production of microbicidal free radicals, such as hydroxyl, which **disrupt essential cell components**

2. Plasma dissociates unreacted H_2O_2 into oxygen and water and **removes any residual H_2O_2** from the load



Safe for the User

Commonly used sterilants, including EtO, FO and H_2O_2, and their residues are associated with acute and long-term toxicities, such as chronic irritation, central nervous system depression, severe allergic reactions and many more.[2,3,4,5,6]

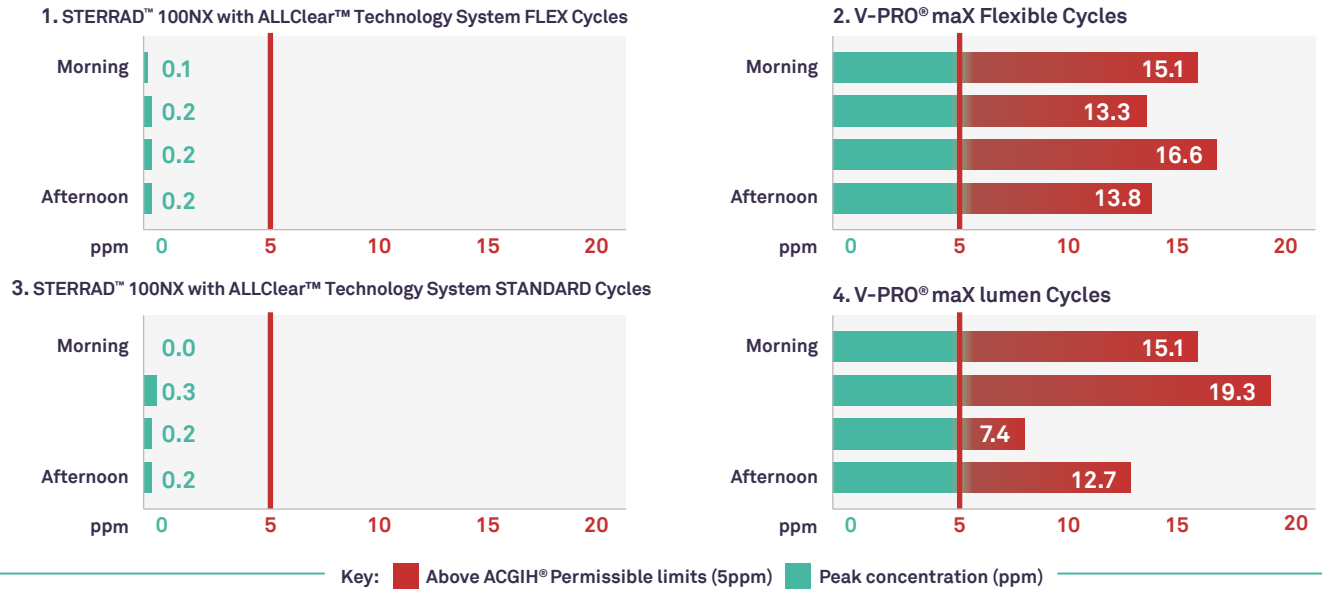
→ Sterilizers which lack gas plasma technology **risk exposing users to such residues** or require **lengthy and disruptive measures** to eliminate them

→ Sterilization with **EtO requires aeration** of the load to help keep staff safe, with typical sterilization cycles lasting **16–17 hours**[7]

→ Sterilization with H_2O_2 does not typically require aeration of the load before handling, however, sterilizer models without gas plasma technology have been shown to produce **H_2O_2 emissions above that deemed safe** by the American Conference of Governmental Industrial Hygienists (ACGIH®)[8]

In contrast, by utilising gas plasma technology to remove residual H_2O_2, STERRAD™ with ALLClear™ Technology Sterilization Systems **reduce exposure to harmful residues, to safe levels**

In line with this, STERRAD™ with ALLClear™ Technology 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:[9]



STERIS V-PRO® sterilizers showed instantaneous peak measurements of H_2O_2 reached up to 20ppm at the user's breathing zone level, contributing to a more hazardous working environment[9]

Safe for the Patient

✓ Sterilizing agents, including EtO, FO and H_2O_2, can **leave toxic residues on medical devices**,[10,14] putting patients at risk of health complications[10,11]

✓ **By utilising gas plasma technology, STERRAD™ with ALLClear™ Technology Sterilization Systems leave medical devices free from toxic residues[1], ensuring that they are safe for the patient**

✓ In addition, **lengthy instrument turnover times**, such as those associated with EtO, may **delay operating schedules** due to unavailability of surgical instruments, compromising patient safety[15]

1-2% EtO[10]
Concentrations of unchanged EtO have been measured in sterilized devices.

19/893 eyes had TASS[11]
TASS has occured as a result of EtO-sterilized vitrectomy packs. No TASS cases were observed with non-EtO sterilized packs.

EtO and H_2O_2 can have a **toxic impact on the environment** and so need ✓ to be strictly regulated in order to reduce their environmental impact[16,17]
Gas plasma eliminates potentially harmful emissions, allowing ✓ efficiency without compromising the environment

Safe for the Environment

Key TAKEAWAYS

✓ **STERRAD™ Sterilization systems with ALLClear™ Technology minimize exposure to harmful sterilizing agents residues by utilizing plasma.**

✓ **Other sterilizers, which utilize H_2O_2 without gas plasma technology, produce H_2O_2 emissions that exceed recommended exposure thresholds. STERRAD™ Sterilization systems with ALLClear™ Technology reduce these emissions to safe levels, ensuring that users, patients and the environment are protected, without the need of weekly chamber leak tests or quarterly gasket inspection required.**

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1. Advanced Sterilization Products. STERRAD 100NX™ User Guide (page 8). 2. Agency for Toxic Substances & Disease Registry. Medical Management Guidelines for Ethylene Oxide. 3. IARC Working Group on the Evaluation of Carcinogenic Risk to Humans. Ethylene Oxide. Chemical Agents and Related Occupations. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, No. 100F., 2012. 4. Agency for Toxic Substances & Disease Registry. Medical Management Guidelines for Formaldehyde. 5. IARC Working Group on the Evaluation of Carcinogenic Risk to Humans. Formaldehyde. Chemical Agents and Related Occupations. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, No. 100F., 2012. 6. Agency for Toxic Substances & Disease Registry. Medical Management Guidelines for Hydrogen Peroxide. 7. Kanemitsu K, Imasaka T, Ishikawa S, et al. A comparative study of ethylene oxide gas, hydrogen peroxide gas plasma, and low-temperature steam formaldehyde sterilization. Infection control and hospital epidemiology 2005;26:486-489. 8. ACGIH®. Hydrogen Peroxide: TLV® Chemical Substances 7th Edition Documentation. 9. Advanced Sterilization Products. Comparison Study of Environmental Hydrogen Peroxide Levels of STERRAD™ Systems and STERIS V-PRO® Low Temperature Sterilizers Reveals Striking Differences. 10. World Health Organization. Ethylene Oxide. 11. Ari S, Caca I, Sahin A, et al. Toxic anterior segment syndrome subsequent to pediatric cataract surgery. Cutan Ocul Toxicol 2012;31:53-7. 12. Kanemitsu K, ®Kunishima H, Saga T, et al. Residual formaldehyde on plastic materials and medical equipment following low-temperature steam and formaldehyde sterilization. J Hosp Infect 2005;59:361-4. 13. Vink P. Residual formaldehyde in steam-formaldehyde sterilized materials. Biomaterials 1986;7:221-224. 14. Ikarashi Y, Tsuchiya T, Nakamura A. Cytotoxicity of medical materials sterilized with vapour-phase hydrogen peroxide. Biomaterials 1995;16:177-183. 15. McIsaac DI, Abdulla K, Yang H, et al. Association of delay of urgent or emergency surgery with mortality and use of health care resources: a propensity score-matched observational cohort study. Cmaj 2017;189:E905-e912. 16. Lesser MP. OXIDATIVE STRESS IN MARINE ENVIRONMENTS: Biochemistry and Physiological Ecology. Annual Review of Physiology 2006;68:253--278. 17. Environmental Protection Agency. Hazardous Air Pollutants: Ethylene Oxide, 2020.

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