ASP™ Advanced Sterilization Products

Now is the Right Time to Go EtO Free

As medical equipment becomes more complex and sensitive, the need for low temperature dry sterilization is increasing. Due to the toxicity of ethylene oxide (EtO) and the burden it can impose on staff, patients and the environment, there are four clear benefits for Going EtO Free with STERRAD™:

Protecting Staff and Patients:
Producing no toxic residues, STERRAD™ offers peace of mind. EtO is a known carcinogen and can affect neurological and reproductive health

Convenience of use:
EtO is strictly regulated and operators must comply with local and international guidelines. STERRAD™ provides a versatile, safe and simple-to-use approach to sterility assurance

Protect the Environment:
EtO persists in the atmosphere, and EtO sterilizers consume more natural resources

Economic Benefits:
STERRAD™ has a faster turnaround time, reducing your inventory requirements. STERRAD™ avoids many costs associated with regulating and reducing the toxicit of EtO

Is EtO Sterilization still a Responsible Choice?

What is EtO Sterilization?

EtO is a colorless gas used for low temperature sterilization of sensitive instruments and devices.[1]

EtO re-processing typically lasts 16–18 hours; the majority of which is required to aerate instruments of toxic EtO residues.[2, 3]

Is it fair to expose staff and patients to EtO?

→ There are acute and chronic health risks associated with exposure to EtO and by-products for both staff and patients (Figure 1).[4-13]

→ Sterilization facilities must ensure that staff and patients are protected from the harmful effects of EtO.

Extensive regulations govern the use of EtO for sterilization

→ Due to the health, safety and environmental concerns associated with EtO, sterilization facilities must comply with strict regulations (Box 1).[14-18]

→ Air monitors, alarm systems, safety equipment, and specialized EtO storage facilities may all be required.

→ In the US, staff exposed to EtO require regular health checks; medical surveillance records need to be kept for 30 years.[19]

→ In the US, the attitude to the tolerable risk of EtO is changing; discussions of restricting EtO for sterilization are ongoing.[20]

Box 1: Restrictions and regulations for EtO

Many countries have recognized the danger of EtO and have issued regulations governing its use to limit exposure to staff and patients. In many markets, EtO is not being used due to these regulations.

France: EtO sterilization should only be used if no appropriate alternative exists.[14]

Brazil: EtO exposure is prohibited for minors, pregnant women, or women of child bearing age.[15]

Tunisia: EtO is banned for use in sterilization.[16]

Turkey: Extensive health and safety guidelines for managers of EtO sterilization facilities.[17]

US: Partial loads are not allowed to be sterilized using EtO unless managers provide justification that it is a 'medical necessity'.[18]

Figure 1: Health risks associated with EtO sterilization

Risks to Staff

Toxicity of EtO

- Acute exposure to EtO gas: Irritation to eyes, skin and airways and effects on the central nervous system.[4,5]
- Exposure to liquid EtO: Severe chemical burns and blistering to the eyes and skin.[5]
- Exposure to high EtO concentrations can be fatal.[4,5]

Toxic by-products

- EtO breaks down to form the toxic products ethylene glycol and ethylene chlorohydrin.

Carcinogenicity

- EtO is recognized as a carcinogen by many regulatory agencies.[4,5]
- Increased cancer rates and mortality have been reported from a cohort of more than 18,000 employees exposed to EtO, mainly in sterilization processes.[6]

Explosive and highly flammable

- Explosions due to EtO have caused death, severe injury and damage to sterilization facilities.[5]

Risks to Patients

Patient exposure to EtO residue

- Poorly aerated devices can expose patients to toxic residues of EtO and its breakdown products.
- EtO exposure can result in avoidable complications such as allergic reactions, severe burns and toxic anterior segment syndrome.[7-11]

Instruments damaged by EtO

- Patients are at risk of harm from instruments damaged by EtO sterilization.[12,13]

Going EtO Free with STERRAD™

Protect staff and patients

- With STERRAD™, instruments are sterilized with hydrogen peroxide (H_2O_2), which degrades to the non-toxic by-products water and oxygen.
- H_2O_2 is non-carcinogenic or mutagenic and is not a fire hazard.
- By Going EtO Free with STERRAD™, it is possible to avoid exposing staff and patients to unnecessary health risks.

Go green with STERRAD™

- STERRAD™ by-products do not harm the environment; eliminating the need for expensive ventilation and abatement systems, and adherence to strict regulatory guidelines.
- Going EtO Free with STERRAD™ can also help save natural resources, since less electricity is used per cycle and no water supply or drainage is required.

Increased convenience and simplicity

- With no toxic emissions, STERRAD™ avoids many of the regulatory requirements associated with preventing and detecting exposure to EtO.
- The STERRAD™ sterilization cycle is faster than EtO sterilizers (24–60 minutes) and instruments do not require lengthy aeration, saving time and increasing efficiency.
- There is no requirement for a dedicated area for sterilization or aeration. Combined with its small size, this allows STERRAD™ to plug and play within any hospital infrastructure.

Key fact:

Re-processing with STERRAD™ is **over ten times faster** than EtO, so less electricity is used with STERRAD™

Economic benefits

- The faster turnover of STERRAD™ means that instruments can be re-used much sooner **(Figure 2)**. Being able to re-process instruments multiple times per day relieves costs associated with holding a large number of instrument sets in inventory.[21]
- STERRAD™ can cause less damage than EtO to certain materials,[22] reducing the need for repair and replacement of damaged devices.
- By Going EtO Free, the infrastructure, equipment, operational and training costs associated with the toxicity of EtO can all be reduced.[23]

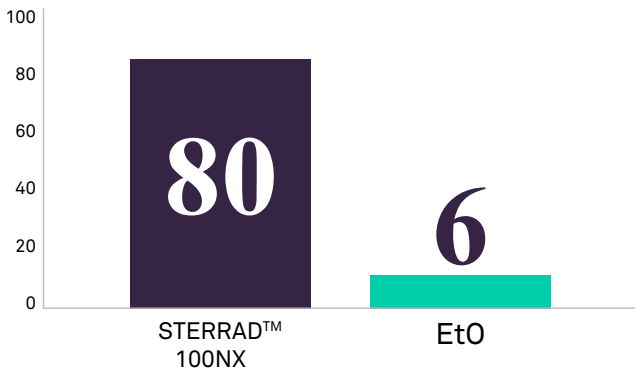
Key fact:

STERRAD™ is able to re-process over ten times more instruments than EtO in a given time, meaning they are ready for re-use much quicker.

Case Study: Cutting costs with STERRAD™: The Veteran Affairs Hospital in Oregon, US

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 liters per year).[24] Due to this audit, the hospital found that simply eliminating EtO sterilization was predicted to save $9,000 annually.[24]

Figure 2: STERRAD™ instrument throughput



Number of trays sterilized per 16 hours*

*Number of trays processed is based on the most commonly used APTIMAX™ Trays (for STERRAD™ 100NX and EtO); trays times the numbers of loads completed within 16 hours.

Table 1: Summary of EtO compared with STERRAD™

	EtO	STERRAD™
Sterilant	→ Known carcinogen → Acute exposure can severely impact health, and can be fatal at high concentrations → Highly explosive and extremely flammable	→ Hydrogen peroxide is a mild irritant → Hydrogen peroxide is not classed as environmentally hazardous
Breakdown products	Toxic and carcinogenic (ethylene glycol and ethylene chlorohydrin)	Harmless (water and oxygen)
Chamber volumes	114–224 liters	30–93.4 liters
Re-processing time	16–17 hours	24–60 minutes
Storage	Dedicated room for sterilization, aeration and storage of sterilant	No requirement for dedicated storage area
Operation	Dedicated water supply and ventilation equipment needed	Plug in to standard electricity socket
Training	Extensive training must be given to staff	Simple to use, little training required
Safety equipment and health precautions	→ Alarms → Air monitors → Exhaust gas neutralizer → Staff personal monitoring devices → Medical surveillance records for staff	→ Chemical indicator strip on sterilant cassette indicates possible leakage → No substantial health precautions required

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