Technology Overview
Ethylene Oxide
The STERIS AST Ethylene Oxide processing service offers:

- Cycle optimisation
- Improved turnaround times
- Flexible validation options
- Parametric release
- Research & development chamber
- Reduced incubation studies

Additional services available:

- Cross line / cross plant contingency
- Distribution and logistics
- Consultancy service
- Flexible service solutions
- Small batch release processing for small volumes/clinical trial units
- Product adoptions
- Residual testing
- DNA inactivation
- Reprocessing of surgical equipment

For more information on ethylene oxide processing please contact our team of specialist

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www.synergyhealthplc.com/ethylene-oxide
What is Ethylene Oxide (EO)

EO is a gas widely used for the sterilization of healthcare devices and instruments. The process involves exposing products to EO under vacuum in a sealed chamber. The EO penetrates the packaging and sterilizes all accessible surfaces of the product to render products STERILE by alkylation of proteins essential for cell reproduction.

Approximately 50% of all sterile single use medical devices are sterilized using EO. In recent years the technology has come under pressure as a sterilization method from a number of sources including alternative sterilization methods, tighter regulatory and environmental controls. Even with these challenges, EO remains, and will continue to be, an important method of sterilization for the medical device industry.

Examples of products processed

EO can penetrate multiple layers of packaging, making it suitable for the sterilization of a wide range of medical devices and healthcare products:

- Assembled complex devices
- Catheters
- Custom procedure packs
- Equipment with integrated-electronics
- Multi-lumen tubing products
- Stents
- Woundcare dressings

Traditional EO sterilisation is typically completed in three phases:

1. Pre-conditioning:
   Products are heated and humidified to aid the effectiveness of the sterilant gas to optimise the sterilization process

2. Sterilization:
   The EO gas is introduced to the products under vacuum in a sealed chamber and held for a predefined dwell time validated to deliver a Sterility Assurance Level (SAL) of 10^-6

3. De-Gassing:
   This final stage uses circulated heated air to remove residual EO from the product to ensure that it meets specified EO residual limits outlined in ISO10993-7

While the above are often carried out in separate chambers, they can be all combined into a single “all in chamber” process.
Rely on our expertise

The treatment of medical devices by EO has been one of the principal methods of sterilization in the healthcare industry since the introduction of the concept of single use, sterile, disposable medical devices in the 1960s.

The increased regulatory and environmental demands since that time have led to the process becoming increasingly sophisticated, which is evidenced by the increased complexity and technical demands of operating EO plants.

When selecting a sterilization partner, medical device manufacturers need to choose a contractor who has the flexibility and technical capability to meet the demands of the specific devices.
Global Site locations

Since opening its first EO site over 20 years ago, STERIS AST has expanded significantly and now operates EO facilities in 4 continents, with many different sized vessels allowing processing of single devices to a full truckload or container volumes at one time.

Why STERIS AST?

As a leading sterilization and decontamination specialist, STERIS ASR has over 40 years experience in providing safe and effective sterilization and decontamination.

- Varying sizes of chambers
- Large portfolio of cycles
- Large range of encompassing solutions

Prior to routine sterilization a complex validation study is undertaken to ensure that the chosen sterilization cycle is effective in the routine processing of products. All our EO facilites are certified to ISO13485 & ISO11135 and operate in accordance with FDA QSR’s and specific local enviromental & safety regulations

Qualification protocol generation

Throughout the product qualification process, our technical team can assist our Customers with preparation of written validation qualification protocols to support the production-related activities which are carried out in our service centres.

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Validation Support

From simply validating an existing process from another site or contractor to developing and validating a new EO process, the technical teams in each our EO processing sites work with our Customers to ensure that the process is validated in line with Customer requirements and the associated international standards.

With our extensive network of laboratories, we can also coordinate and carry out all the laboratory testing associated with the validation of an EO process to provide a fully integrated validation solution.

Our validation services include:

- Coordination of sample testing
- Protocol execution
- Protocol generation
- Review of results
- Report generation
- Temperature and humidity profiling

“STERIS AST provide regulatory compliant and cost effective Ethylene Oxide sterilization solutions for the healthcare industry.”
Our Vision

To build a lasting reputation as the trusted experts in global health-related markets by differentiating our services and products through the way we work.

Achievement
We believe our success comes from our focus on exceeding expectations and our commitment to go that extra mile, however small the difference may seem.

Accountability
We take personal responsibility for our actions and are equipped to take the right course of action.

Integrity
We believe that the way we work is as important as what we do. We care deeply about the quality of our work and inspire trust by delivering on promises.

Innovation
We achieve the best possible results by working with Customers to develop new ways of solving problems and reducing risk.