



## Sterilization Alternatives

# Ethylene Oxide

A trusted means of sterilization for more than 60 years, usage of Ethylene Oxide (EO) accelerated dramatically in the Seventies when it was discovered that EO is highly compatible with polymer-based, single-use medical devices, procedure kits and surgical trays.

In the intervening years, EO processing has proven to be an effective means of sterilizing a wide variety of healthcare products, one with very few limitations. However, as the healthcare products market evolved and manufacturers adopted practices such as just-in-time (JIT) inventories, faster processing times have become increasingly important.

To meet the challenge, innovations in EO technology emerged—among them Parametric Product Release, Microwave Spectrometry and CyclEOne™ single-chamber sterilization—resulting in faster processing, shorter cycle times and an earlier release of product... thus, adding a new level of relevance to this respected and widely-used sterilization alternative.

### **The Nature of Ethylene Oxide**

Ethylene Oxide (EO) processing sterilizes products by means of an alkylation reaction that destroys an organism's ability to reproduce. The process requires the simultaneous control of four variable, but interdependent, parameters: gas concentration, temperature, relative humidity and time of exposure.

In order for the EO process to be effective, the gas must be able to diffuse throughout freely. Products must be placed in breathable packaging that allows the gas to penetrate the sterile barrier and reach all surfaces of the device.

### **Significantly Improved Performance, Thanks to Emerging Technology**

Historically, EO has required the use of biological indicators (BIs) to confirm the sterility of a product following processing. This procedure, which includes the retrieval and subsequent incubation of the BIs, may add several days to the product's release.

Today's advanced EO technology, however, has significantly reduced incubation time, heightened reliability and dramatically accelerated product release. Chief among these advances are: Parametric Product Release, Reduced Incubation Time Studies (R.I.T.), Microwave Spectrometry and CyclEOne processing with parametric.

### **Parametric Product Release: The Accuracy of BIs without the Cost and Delay**

Approved by the Food and Drug Administration (FDA) and accepted by the Association for the Advancement of Medical Instrumentation (AAMI), Parametric Release brings state-of-the-art speed, convenience and reliability to the EO process.

Sterility is confirmed, not by retrieving and reading BIs, but by establishing processing specifications for each of the key parameters, then monitoring activity in the chamber load to verify that each condition has been met. As soon as all changes have been made, and then documented, the product is ready for release.

The result is assured sterility—based on actual verifiable data rather than empirical data—and freedom from the costly delays associated with the use of BIs.

## Microwave Spectrometer: The Ultimate in Precision

A key parameter in enhancing EO efficiency is the quantifiable introduction of relative humidity (RH) into the chamber. Using advanced and patented hardware, the Microwave Spectrometer not only reads the amount of EO gas in the chamber; it also calculates the amount of humidity present.

The precision is unparalleled. The Microwave Spectrometer self-calibrates before every cycle and calibrates only to the EO molecule, regardless of any similar gases that may be present. The result is increased confidence that each parameter is measured accurately, ensuring a proper release of product.

## Residuals

Under conditions for effective sterilization, EO reacts with moisture and chloride ions to form ethylene glycol and 2-chlorethanol, a non-volatile residue referred to as ethylene chlorohydrin. Because this residue remains after processing, an aeration period is required to allow the gas to dissipate to levels that are safe for handling of the processed product. Typically, this aeration process is complete within 24 hours.

## CycleOne: Sterilization in One Chamber, in One Day

A true revolution in EO sterilization, the Sterigenics CycleOne process preheats, sterilizes and aerates in one chamber—in just one day. No separate pre-treat is required. No separate aeration is required. CycleOne does it all—in just 12 to 24 hours vs. the 10 to 14 days required for conventional EO processing. In just one chamber, in just one day, CycleOne takes 9 to 13 days out of supply chain inventory when used in combination with Parametric Release.

### Key Considerations

	Gamma Radiation	Electron Beam (E-beam)	Ethylene Oxide (EO)
Process Methodology	Continuous or batch	Continuous	Batch
Product Release	Dosimetric release (immediate, no post-sterilization testing is required).	Dosimetric release (immediate, no post-sterilization testing required).	Historically, BIs were required to verify sterility assurance level (SAL). Today, state-of-the-art Parametric Release enables significantly faster product release.
Penetration	Complete penetration	Complete penetration, dependent upon material thickness.	Complete penetration with the use of gas-permeable packaging.
Material Compatibility	Most materials are satisfactory. Considered somewhat incompatible with PVC, PTFE and Acetal.	Most materials are satisfactory.	Nearly all materials are compatible.
Residuals	None	None	Ethylene Chlorohydrin, requiring an aeration period following processing. With advanced CycleOne technology, separate aeration is not required.

## References

- American National Standard, ANSI/AAMI ST27-1988, *Guideline for Industrial Ethylene Oxide Sterilization of Medical Devices*, 1988.
- American National Standard, ANSI/AAMI/ISO 11137-1994, *Sterilization of health care products—Requirements for validation and routine control—Radiation sterilization*, 1994.
- Scholla, M.H. and Wells, M.E. "Tracking Trends in Industrial Sterilization." *Medical Device and Diagnostic Industry*, September 1997, pp.92-95.
- Sordellini, P.J. "Speeding EtO-Sterilized Products to Market with Parametric Release." *Medical Device and Diagnostic Industry*, February 1997, pp. 67-80.

