

medical device  
manufacturing  
100% EtO  
sterilization

 **EO Gas**<sup>TM</sup>

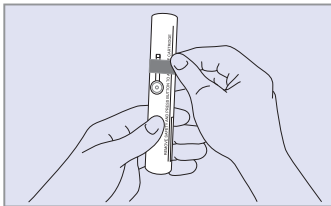


 **ANDERSEN  
PRODUCTS**  
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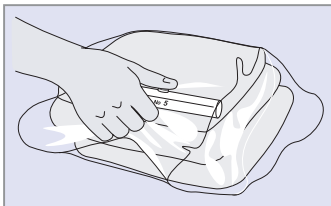
*Andersen Products has been in the gas sterilization business for over three decades. Our sterilizers are the most technically advanced on the market with a proven track record for reliability and effectiveness.*



*Health Science Park, Haw River, NC*



*Remove trigger guard.*



*Load cartridge in bag w/ product.*



*Load bag in sterilizer and activate cartridge.*

### Unique Gas Diffusion Technology

The EOGas® Series 3 Plus sterilizer utilizes 100% ethylene oxide gas (EtO) diffusion technology developed by Andersen Products. This unique process introduces gas directly into a polyethylene film bag containing the load. It eliminates stratification, which is a common problem with industrial vessels. Since gas diffusion employs a low vacuum, low temperature and low humidity, it is the gentlest sterilization method available, and suitable for most delicate devices.

### Dose-Specific Gas Usage

Our system matches the unit dose of EtO to the load size to ensure parameters for sterilization are met without using excess gas. Flexible gas diffusion technology allows ethylene oxide use based not on the chamber size, but on the actual volume of the items being sterilized, making it ideal for small lots. No other gas sterilization system allows for such efficient processing.



AN306

AN333

AN310

**Temperature Control:**

- ▶ EOGas sterilizers maintain a controlled environment at 50°C. Through many years of research, we have determined that this is the optimum temperature to maximize both the speed and effectiveness of the sterilization cycle, while minimizing possible product damage. Please note that the EOGas overall sterilization cycle includes aeration, unlike our competitors.

**Less Gas Consumption:**

- ▶ EOGas sterilizers utilize unit dosed gas cartridges containing 100% ethylene oxide. This allows matching the gas dosage to the load size rather than the chamber size. The result is a system that uses over 80% less gas than the competition.

**Shorter Cycle Time:**

- ▶ The standard cycle time of an EOGas sterilization system is around 16 hours, including aeration. Additionally, there is the added convenience of having sterilization and aeration take place in the same cabinet. Critical items that readily absorb ethylene oxide may require additional aeration, which may be performed inside the EOGas sterilizer chamber.



*"We like being smaller than the competition"- is our motto.  
Our system utilizes over 80% LESS gas than our closest competitor.*

### Installation Requirements

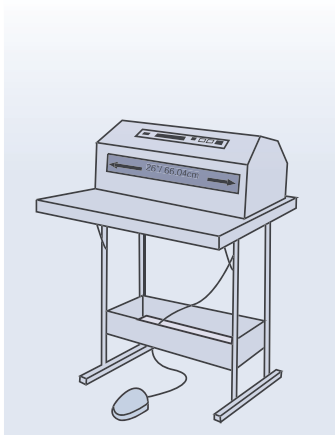
EOGas sterilization systems require only a standard 110V or 240V outlet and a 3" ventilation connection to the outside, compared to many competitors that require outside water and vacuum sources.

We require that the installation and initial calibration of the EOGas system be performed by an Andersen factory representative. The installation consists of unpacking the sterilizers and hooking it up to a dedicated exhaust that has been provided by your facility. All pre-usage testing, calibration, and certification of your EOGas systems will be performed at the time of installation.



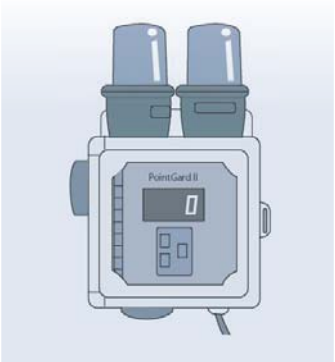
### EOGas® Series 3 Plus Sterilizers

The AN306 has a six cubic foot chamber capacity, the AN310 has a ten cubic foot chamber capacity, and the AN333 has a thirty-three cubic foot chamber capacity. Unit-dose gas cartridges tailored to exact load volume eliminate dangerous ethylene oxide holding tanks and reduce ethylene oxide use by up to 80%. The temperature controlled chamber allows for complete sterilization and aeration. Power outage protection maintains negative pressure in the cabinet in case of electrical failure reducing the risk of cycle interruption. The unit is manufactured by Andersen Sterilizers, an ISO 9001 company.



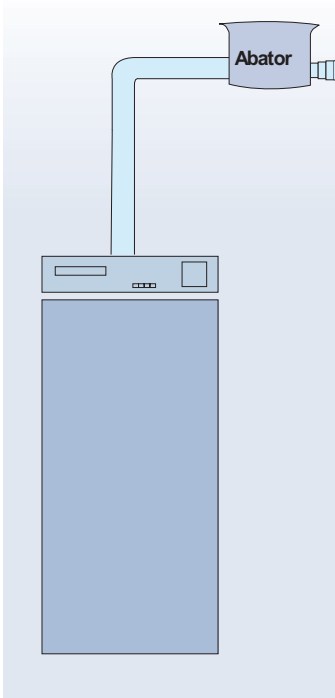
**AN5026 Vacuum Sealer**

The Andersen AN5026 vacuum sealer is a self-contained unit that removes excess air from the sterilization bag, producing a higher gas concentration and more reliable process. Vacuum-sealed packaging promotes faster aeration and provides visual guarantee of sterility prior to opening. Digital controls and displays are easy to operate, reducing the risk of operator error. Dual safety sensors minimize the chance for mishaps during sealing operations.



**AN2750 Pointgard Ethylene Oxide Monitoring System**

The monitoring system measures and displays gas concentrations accurately to the nearest part per million. Gas detection control unit can be mounted in the sterilization room and provides audible alarms if concentration reaches determined caution levels. Self-test functions continuously monitor the sensor for quality and alert the operator when the sensor needs calibration or replacing.



**Ethylene Oxide Abator**

The Abator is a high-volume dry bed filter used to safely destroy ethylene oxide, leaving no toxic or hazardous by-products. The patented chemical reactant material destroys the ethylene oxide on a 1:1 ratio. The spent reactant is completely safe, and can be easily disposed of in non-hazardous landfills. The Abator produces no hazardous by-products, does not require water or drains, and operates at room temperature. The Abator requires no additional utilities other than a power outlet for the blower.

### Key Operator Certification

All employees working in the area of the EOGas unit will have the opportunity to partake in a "Key Operator" certification program from Andersen Products. Our Key Operator training focuses on instrument preparation, packaging, basic sterilizer operation, and safety issues. We will schedule a visit by a representative of Andersen Products who will provide on site training and demonstrations of proper operating procedure.



*Our best selling product at Andersen Products is service. Personalized follow-up, attention to detail and a commitment to quality are standard features of every sterilizer we sell.*

### Routine Maintenance

Andersen Products provides the option of a "Maintenance and Service Contract" for all of its equipment. Our "Maintenance and Service Contract" includes annual service calls and prompt response in the case of emergency problems with the system.

### Validation

Daryl Woodman, the General Manager of Andersen Scientific, will develop the sterilization validation protocols according to applicable portions of ANSI/AAMI/ISO 11135 – Medical Devices – Validation and routine control of ethylene oxide sterilization (the internationally accepted sterilization standard.) Paragraph 1.4 of this guidance expressly excludes sterilization either by the technology of injecting ethylene oxide or its mixtures directly into the individual product packages or continuous sterilization process since this guideline was written specifically for pressure/vacuum sterilization chambers where the chamber is vacuumed down before ethylene oxide and humidity are injected. Such functions are not incorporated into the gas diffusion process (EOGas). For more information, call 336-376-3000 or send an email to [ANSCI@mindspring.com](mailto:ANSCI@mindspring.com).