ART AN4761.00W EOG3 Instructions for Use and Safety Information Rev 2

ECOGas® 3

Instructions and Safety Information

EO-FCT STERILIZATION

ETHYLENE OXIDE
FLEXIBLE CHAMBER TECHNOLOGY

AN333

AN310

ANDERSEN STERILIZERS

Sterilization redefined.

EOGAS STERILIZERS - SERIES 3 SAFETY INFORMATION

This manual applies to models manufactured in 2018 or more recently:

AN310.11	220-240V - 50/60Hz
AN333.11	220-240V - 50/60Hz

All models include a label printer, AN5200.72 extractor unit, and have three (3) operating modes. See power rating label on rear of each unit.

CAUTIONS AND WARNINGS

Food and drugs may not be sterilized because Ethylene Oxide may change their chemical composition. If you are not certain about an item's suitability for Ethylene Oxide sterilization, please contact an Andersen Customer Service Representative.

Les aliments et les médicaments ne doivent pas être stérilisés, car l'oxyde d'éthylène risque de modifier leur composition chimique. Si vous n'êtes pas sûr qu'un article est compatible avec la stérilisation à l'oxyde d'éthylène, veuillez contacter un représentant du service client Andersen.

This EOGas sterilizer must be installed and operated as specified by Andersen in the Owner's Manual and Installation Instructions. Failure to do so may significantly impair the sterilization efficacy and the protections provided by the equipment.

Ce stérilisateur EOGas doit être installé et utilisé comme spécifié par Andersen dans le mode d'emploi et les instructions d'installation. L'efficacité de la stérilisation et des protections fournies par l'équipement risque de se dégrader considérablement si ces consignes ne sont pas respectées.

Ethylene oxide vapors are extremely flammable and are readily ignited by static charge, sparks and flames at concentrations above 2.6%. Operate away from open flame and remove all batteries from electrical devices and wrap them separately before exposing to ethylene oxide to avoid ignition.

Les vapeurs d'oxyde d'éthylène à des concentrations supérieures à 2,6 % sont extrêmement et facilement inflammables par des charges d'électricité statique, des étincelles et des flammes. Faites fonctionner l'appareil loin des flammes nues, retirez toutes les piles des appareils électriques et enveloppez-les séparément avant de les exposer à l'oxyde d'éthylène pour éviter toute inflammation.

Ethylene Oxide is a Cancer and Reproductive hazard. Refer to SDS starting on page 77 and EPA approved labeling on all EOGas refill kits for complete instructions and warnings. Additional local exhaust ventilation may be required in storage areas for refill kits containing EO.

DANGER *L'oxyde d'éthylène est cancérigène et peut avoir des effets négatifs sur le système de reproduction. Reportez-vous à la fiche de sécurité (SDS), pages 77-93, et aux étiquettes de conformité EPA apposées sur tous les kits de recharges EOGas pour prendre connaissance des instructions et des avertissements fournis. Une ventilation par aspiration locale supplémentaire peut être nécessaire dans les zones de stockage pour les kits de remplissage contenant de l'OE.*

DANGER **In case of emergency,** please call Andersen Products Customer Service at 336-376-3000 during regular business hours (EST). After business hours, please contact 800-255-3924.

IMPORTANT Please call **Customer Service at 800-523-1276 or 336-376-3000** for technical support or repair services. Outside the United States and Canada, please contact your local distributor. Refer to Appendix E for additional contact information.

IMPORTANT Documentation must be consulted in all cases where a triangle symbol enclosing an exclamation mark is displayed on the sterilizer, extractor or accessories in order to understand the nature of the potential hazards and any actions which may be taken to avoid them.

IMPORTANT This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

IMPORTANT Changes or modifications to the equipment not expressly approved in writing by an executive officer of Andersen Sterilizers, Inc. (the party responsible for compliance) could void the user's authority to operate the equipment.

REVIEW OF ETHYLENE OXIDE STERILIZATION

The Basics of Ethylene Oxide Sterilization
with the Andersen EOGas 3 Sterilization System

There are seven parameters of Ethylene Oxide (EO) sterilization to consider. Most of these parameters are under the control of the operator, so it is vital to keep them in mind when using any Ethylene oxide sterilization system. Care must be taken to properly prepare items for sterilization and assure the sterilizer is functioning properly. The parameters are:

1. *Required Sterility Assurance Level*
2. *Ethylene Oxide Dose (Concentration)*
3. *Time*
4. *Temperature*
5. *Humidity*
6. *Load Characteristics*
7. *Aeration*

1) Required Sterility Assurance Level

The Sterility Assurance Level, or SAL, is the probability of microorganism survival after a sterilization cycle. In testing, 1 million (10^6) organisms with high resistance to the sterilization process are included on a spore strip in a worst-case load. Ability to inactivate all microorganisms on the spore strip requires (at a minimum) a 6 log reduction in organisms. For Ethylene Oxide sterilization in healthcare settings, the required Sterility Assurance Level is 10^{-6}, or a 12 log reduction in microorganisms highly resistant to the sterilant.

2) Ethylene Oxide Dose

The EOGas 3 system uses a cartridge containing an ampoule of liquid EO. The #6 Cartridge and ampoule contains 10.5 grams of EO, about 10% of the volume our competitors use. However, this is enough gas to sterilize the typical contents of the sterilization bag during a 16 hour cycle.

The advantages of using less Ethylene oxide are:

1. Less gas means less absorption of gas into absorbent materials.
2. Less gas allows abatement (capture) of the effluent gas more easily after the cycle.
3. Less gas reduces the risk of operator exposure.

A vacuum sealer is required to increase the concentration of EO in the load, by removing excess air from the sterilization bag before the cartridge is activated at the beginning of the cycle. The smaller the volume of air in the sterilization bag, the higher the concentration of EO and the quicker the microorganisms will be inactivated.

EO is a gas at room temperature. It boils at 10 ºC (50 ºF). As soon as the cartridge is activated, the liquid EO boils and is released from the cartridge. The gas exits the ampoule and cartridge and disperses throughout the sterilization bag. The gas moves from areas of higher concentration to lower concentration until an equilibrium is reached. Therefore, the gas penetrates into all areas of the sterilization bag. It can pass through many plastics by dissolving in the plastic material. This allows the gas to get into the center of many hollow plastic tubes (such as intravenous tubing) by going through the wall of the tube. However, this also implies that the EO is contained within the wall of the tubing and must be allowed to elute after the cycle. This is the reason gas absorbent materials like rubber and some types of plastic must be aerated after sterilization.

3) Time

The longer time devices remain in contact with EO, the higher the likelihood that microorganisms will be inactivated. The typical cycle time of sixteen (16) hours in the Andersen EOGas 3 systems provides 12 log sterilization (SAL 10^{-6}) of our standard test load at 50ºC (122ºF).

4) Temperature

At higher temperatures, EO becomes more active and sterilization occurs more quickly. As a rule of thumb, a 10 degree increase in temperature decreases the time needed for sterilization by half. Of course, there is a practical limitation to increasing or decreasing the temperature. At higher temperature, the load may be damaged by the heat, and conversely, at lower temperature, the required sterility assurance level may not be achieved within the standard 16 hour cycle. The standard EOGas 3 cycle temperature of 50ºC (122ºF) provides sterilization and the requisite sterility assurance level for most products. Depending on the particular product and load configuration, the sterilizer cycle temperature may be adjusted anywhere from 40ºC (104ºF) to 55ºC (131ºF).

5) Humidity

Some bacteria and fungi become more resistant to sterilization in a dry environment. When there is ample humidity, the microorganisms are in their active or vegetative state. When the humidity drops too low, the organisms become dormant, forming what is called a spore. Spores are much more difficult to destroy than vegetative organisms. The minimum recommended relative humidity for EO sterilization is 35%.

The humidity is relative to temperature, so a relative humidity of 35% at room temperature equates to a lower humidity as the temperature rises. To maintain humidity at an appropriate level for sterilization, some water must be added to the system as the temperature increases. In some sterilizers, water is injected into the sterilization chamber. In the EOGas 3 system, a Humidichip is used for the same purpose. The Humidichip contains 4.3 grams of water, which is sufficient to maintain the relative humidity during the sterilization cycle.

The best way to humidify the load is to clean and dry (towel or drip-dry) the items to be sterilized. Do not use hot air drying, as it may cause some microorganisms to enter the dormant spore state making them resistant to sterilization.

Devices that may be damaged by immersion in water, or a sterilization load that contains a large amount of material that will absorb moisture (dry paper and cloth), will require pre-humidification. This can be accomplished within the sterilizing bag prior to the cycle as follows:

Manual Pre-Humidification Using an EOGas 3 Sterilization bag

1. Confirm the sterilizer is switched on so that it heats to 50 ºC (122 ºF)
2. Prepare the items in the load for sterilization.
3. Place the prepared items along with a Humidichip® and EOGas cartridge inside a sterilizing bag. Remove excess air and hermetically seal the sterilization bag.
4. Place the sealed sterilization bag in the sterilizer for 2 hours, then remove the bag from the sterilizer for an additional 2 hours to allow for cooling.
5. WARNING **DO NOT ACTIVATE THE CARTRIDGE AT ELEVATED TEMPERATURE**.
6. AVERTISSEMENT **NE PAS ACTIVER LA CARTOUCHE À TEMPÉRATURE ÉLEVÉE.**
7. After the 2 hours of cooling, the sterilization bag may be placed in the sterilizer and the cycle started normally. This process is more fully explained on page 25 of this manual.

6) Load Characteristics

The characteristics of the load placed in the sterilizer will also affect cycle lethality. Overloading the sterilization bag may make some parts of the load less accessible to the gas. A very dry (low humidity) load such as a large quantity of paper may need to be humidified to ensure sterility (as discussed above). All occlusive caps, plugs, and stylets must be removed from instruments and tubing so that the gas can penetrate freely. For example, a glass vial with a tightly-closed metal cap will not allow the gas to penetrate into the vial. Hollow bore needles and plastic or rubber tubing must be open and free from stylets and plugs. Syringes must be packaged with the plungers removed. Long or narrow tubing, defined as a lumen smaller than 1 mm or a length greater than 90 cm (3 feet) requires longer sterilization time at elevated temperatures of 50 ºC or higher.

7) Aeration

Glass and metal do not absorb EO. Therefore glass and metal items may be used immediately at the end of the sterilization cycle. Many plastics and rubber readily absorb EO and require aeration prior to use on a patient. The danger is that a plastic or rubber device that is not properly aerated and is left in prolonged contact with the patient may cause a contact chemical burn. As an example, an anesthesia mask that is not properly aerated may cause a contact chemical burn where the mask contacts the face during a procedure. In general, 24 hours aeration is adequate for most rubber and plastic items. Additional aeration is recommended for devices that will come into contact with very sensitive tissues such as cell cultures.

CAUTION **All packaged devices must be aerated before handling.** It is the responsibility of the individual **device manufacturer** to provide specific information on the use and processing of reusable devices. The manufacturer of the medical device should provide sterilization and aeration parameters in writing to health care facilities. Device manufacturers are in the best position to: (1) identify the maximum temperature that the device can withstand, and (2) evaluate the effects that changes in raw materials, processing or configuration can have on aeration times.

ATTENTION **Tous les articles emballés doivent être aérés avant d'être manipulés.** Il incombe au **fabricant d'un appareil** individuel de fournir des informations spécifiques sur l'utilisation et le traitement des éléments réutilisables. Le fabricant de l'appareil médical doit fournir par écrit les paramètres de stérilisation et d'aération aux établissements de soins de santé. Les fabricants d'appareils sont les mieux placés pour : (1) identifier la température maximale que l'élément peut supporter, et (2) évaluer les effets que des changements de matières premières, de traitement ou de configuration peuvent avoir sur les temps d'aération.

PROCESSING REVIEW

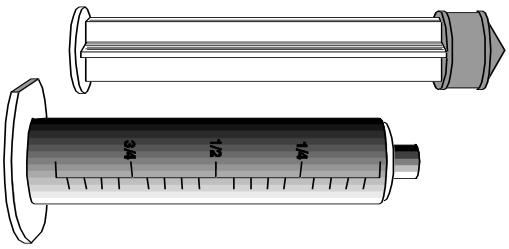
Devices to be sterilized using EO must be meticulously cleaned and dried. Coatings of dry protein like dry pus, blood, or feces, protect microorganisms and slow the sterilization process. You must always take the following precautions before sterilizing with EOGas:

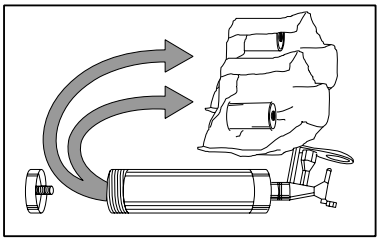
DISASSEMBLY

EO diffuses readily through many materials. However, occlusive caps, plugs, or stylets must be removed from instruments so that the gas can penetrate freely. Syringes must be disassembled for sterilization**.**

WARNING **Batteries must be removed from electrical devices, wrapped and sterilized separately to prevent electrical sparks.**

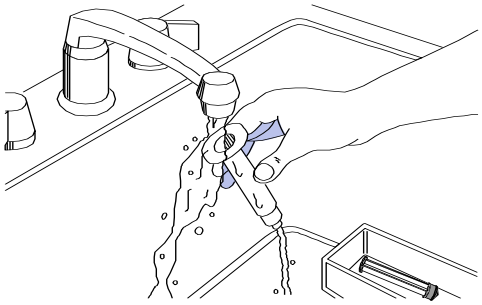
AVERTISSEMENT **Les piles doivent être retirées des appareils électriques, emballées et stérilisées séparément pour éviter la formation d'étincelles électriques.**

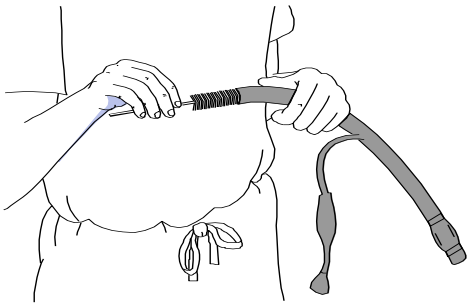




CLEANING

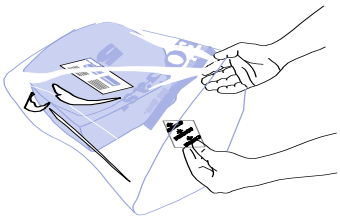
Disassemble and scrub all instruments in detergent and water to the most critical standard of

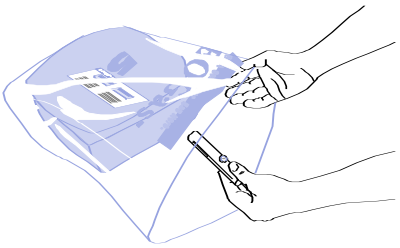


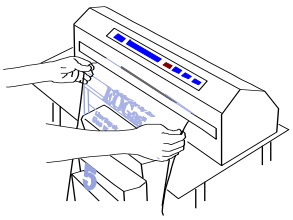


HUMIDIFICATION

If cleaning in water will damage the items to be sterilized, pretreat for 4 hours in a sterilization bag with saturated humidity. To humidify the contents of the sterilization bag, wrap the devices individually in paper or cloth in the usual manner. Place them in a sterilization bag along with a Humiditube, Humidichip, Dosimeter, and an EOGas cartridge (Remove the cartridge trigger guard but **DO NOT ACTIVATE THE EOGas CARTRIDGE AT THIS TIME**). Complete the provided Dosimeter card, then place it in the sterilization bag. Use color change chemical indicators, if desired, for further visual assurance of exposure to EO at the end of the cycle.







Remove excess air and heat seal the sterilization bag

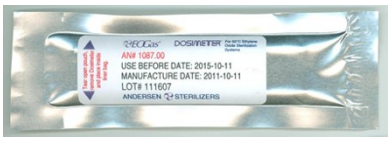
Place the sealed sterilization bag into the sterilization cabinet, and start a Preconditioning Cycle.

After the Preconditioning Cycle, remove the sterilization bag from the sterilizer and allow it to cool to room temperature. After the sterilization bag and its contents have reached room temperature, place it back inside the sterilization cabinet, press the activation pin to release the EO, and start a normal length, 16 hour sterilization cycle.

AN1072 Humiditube The AN1072 Humiditube, shown above, provides an open space between the Humidichip and the surrounding devices in the sterilization bag, allowing adequate and full release of AN1071 Humidichip moisture. The tube does not affect the sterilization and aeration process.

AN1071 Humidichips, shown above, ensure that humidification requirements for EO sterilization are met. AN1071 Humidichips measure 1.75" x 1.75" (45 mm x 45 mm) and contain 4.3 grams of water. One Humidichip per sterilizing bag per cycle is usually sufficient for standard humidification needs.

EO INDICATORS

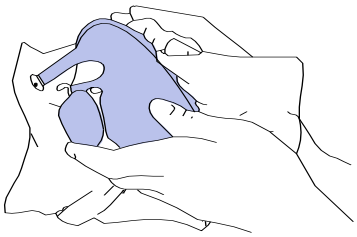
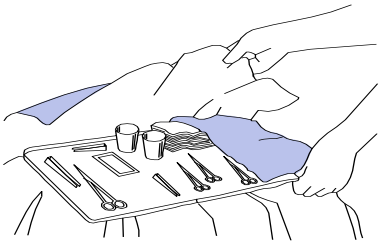


AN1087 Dosimeters are designed to change color from yellow to blue when exposed to EO. Dosimeters integrate the effects of time, temperature, and EO. For processed devices to be considered sterile, the color change from yellow to blue must extend past the triangular mark on the Dosimeter. No laboratory testing is required; the information is available immediately at the end of a sterilization cycle.

AN85 Color Change Indicators indicate exposure to EO by turning color from yellow/green to blue. They indicate that there has been exposure to EO, but do not indicate the actual dose. The convenient self-stick backing adheres to conventional paper or cloth wrapping.

DRYING

Be sure devices to be sterilized are physically dry before wrapping and processing. Towel drying or drain drying is sufficient. Do not use hot air drying. Water on instruments at the time of exposure to EO may react with the gas and reduce its effectiveness. Hollow bore needles and plastic or rubber tubing must be open and free from stylets and plugs. Syringes must be disassembled with their plungers out of the barrel before they are wrapped for sterilization.

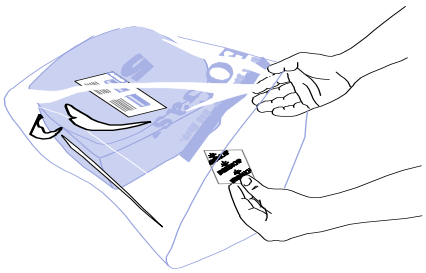
WRAPPING

All devices to be sterilized must be wrapped in cloth or paper sterilization wraps appropriate for use with EO. Plastic film packaging materials may not be used with EO unless the materials have been validated for adequate EO gas permeability. Polyamide (Nylon) and polyester (Mylar) films are known to be impermeable to EO. Do not pack the sterilizing bag so tightly that gas diffusion is slowed.

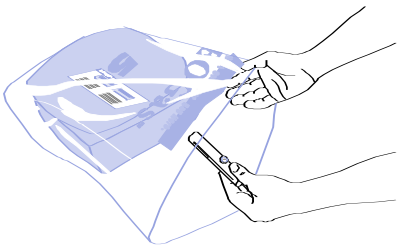
DESCRIPTION OF AN EOGAS CYCLE

Prepare items to be sterilized as described under **"Processing Review"** .

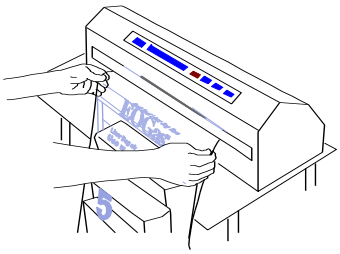
Remove a Dosimeter card from the dispenser box. Write the date and the time sterilization and aeration will be complete on the card. Place the dosimeter in the core of the load. Take a sterilization bag from the EOGas dispenser box and place the wrapped devices in the sterilization bag, along with one AN1071 Humidichip and the Dosimeter indicator card. Place the Humidichip inside the HumidiTube, then place the HumidiTube in the sterilization bag.



Remove an EOGas cartridge from the dispenser box. Confirm that the number printed on the EOGas cartridge corresponds with the number printed on the sterilization bag. Remove the trigger guard (secured with green tape) and place the EOGas cartridge on top of the devices near the open end of the sterilization bag in a horizontal orientation (long edge of cartridge as parallel to the floor as possible) , but **do not activate the cartridge at this time.**

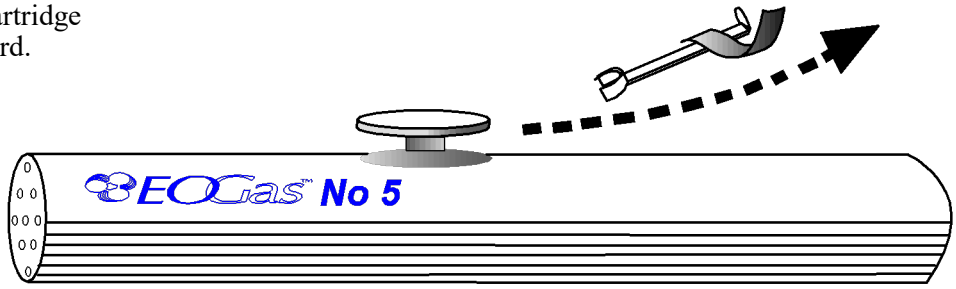


Remove excess air with a vacuum sealer or press the excess air out of the sterilization bag before heat sealing, then initiate the sterilization cycle by pressing the LOAD key on the front of the EOGas sterilizer cabinet and follow the directions for loading.

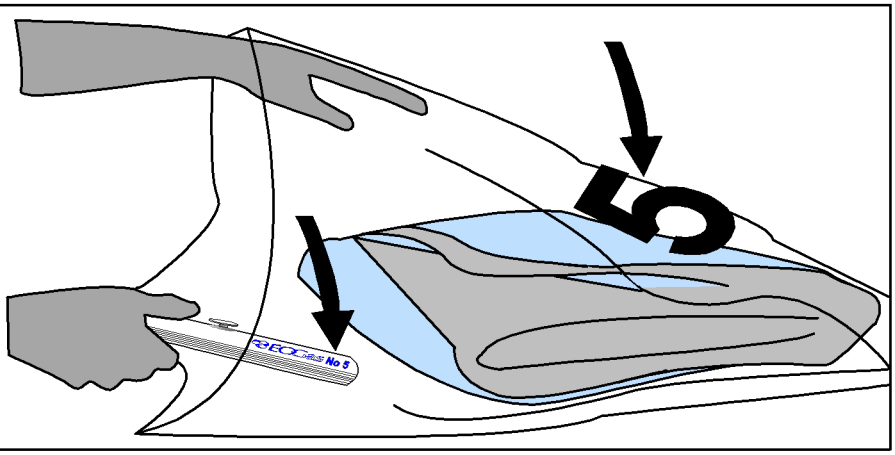


Activating the EOGas Cartridge

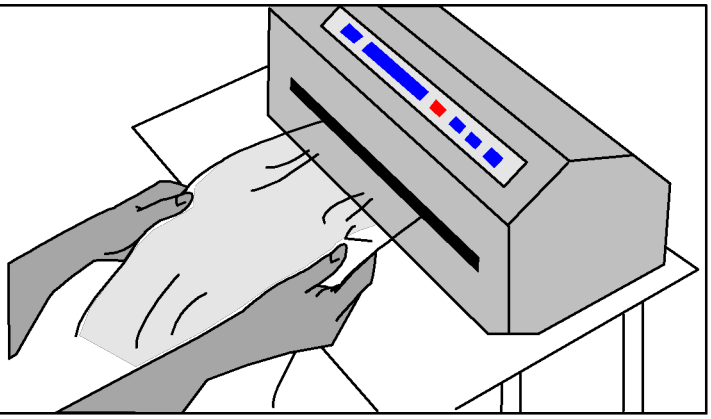
1. Remove cartridge trigger guard.



2. Be sure cartridge number matches sterilizing bag number. Place cartridge into loaded bag (see Processing Review: Description of an EOGas Cycle.)

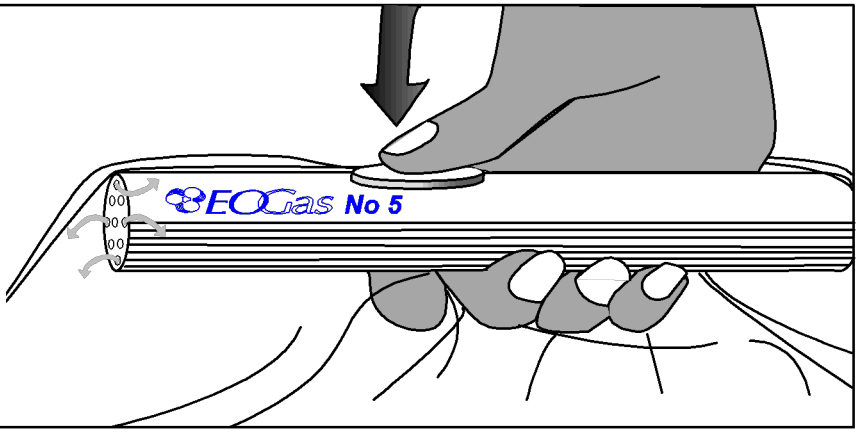


3. Remove excess air from bag and heat seal.

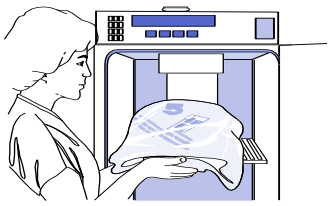


4. After the sterilization cabinet has been purged for 5 minutes, place the bag into the sterilization cabinet.

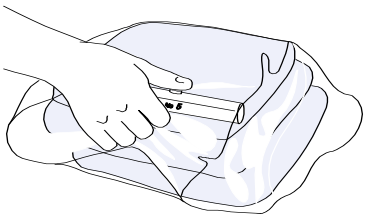
Firmly grasp the cartridge through the bag and depress the trigger completely to release EO, then close the door of the sterilizer.



After the cabinet has been purged for 5 minutes, "DOOR UNLOCKED" will be displayed and the door will unlock. Place the sterilization bag on a shelf in the sterilizer.



Without opening the sterilization bag, grasp the EOGas cartridge through the wall of the sterilization bag and press the plunger to activate the cartridge.



Close the door securely and the door will lock automatically at the end of the 3 minute countdown displayed on the screen.

Leave the sterilization bag undisturbed in the sterilizer cabinet for 16 hours. After the sterilization cycle is complete, the contents of the sterilization bag may be removed. To accomplish this, initiate a 5 minute purge cycle by pressing the UNLOAD button. The sterilizer will begin purging (high volume ventilation to remove any residual EO from the cabinet).

At the end of the 5 minute purge cycle, the sterilizer will unlock the door for 10 minutes. The door may be opened at any time during this 10 minute window. Once the door is opened, the operator has a 3 minute window during which time the processed sterilization bags may be removed. Once the 3 minute timer counts down to zero, an alarm will sound if the door is still open. If the door is closed, the door lock will engage. As explained further on page 35, when unloading multiple sterilization bags or loads which absorb a large amount of EO, some operators prefer to cut open the end of the sterilization bag while it is still in the cabinet, then shut the door and repeat the PURGE cycle. This minimizes the chance of exposure to residual EO within the sterilization bag.

After wrapped devices have been removed from the sterilization bag, the empty EOGas cartridge and the sterilization bag may be disposed of in ordinary trash. The trash receptacle must be located in a well-ventilated area.

CAUTION It is incumbent on the user to confirm that gas absorbent items sterilized in EOGas have been adequately aerated before they contact living tissue. This is particularly important for plastic or rubber items that will contact tissue culture preparations, microbial cell cultures, spermatocytes, oocytes, embryonic tissue, etc. Failure to adequately aerate EO-absorbent materials may lead to contact chemical burns.

ATTENTION Il incombe à l'utilisateur qui stérilise des articles dans un stérilisateur EOGas de s'assurer que les articles qui absorbent le gaz ont été correctement aérés avant d'être mis en contact avec des tissus vivants. Ceci est particulièrement important pour les articles en plastique ou en caoutchouc qui entreront en contact avec des préparations de culture tissulaire, des cultures de cellules microbiennes, des spermatocytes, des ovocytes, des tissus embryonnaires, etc. L'absence d'aération adéquate des matériaux qui absorbent l'EO peut provoquer des brûlures chimiques.

Gas absorbent items like breast implants and plastic extracorporeal blood filters may require additional aeration before they can be safely implanted or used. Aeration will progress more rapidly outside of the sterilization bag and at elevated temperature. Customers may obtain assistance in determining aeration times by contacting the Manufacturer of the medical device being sterilized.