

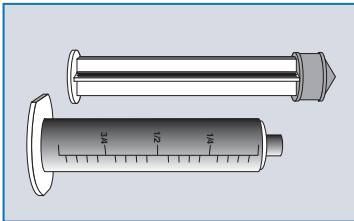
Thank you for using the EOGas Sterilization System.

The active ingredient in EOGas is Ethylene oxide (EtO or EO). To ensure that you and/or your staff are properly educated and informed about the safe and proper use of this system, we have developed a training program that covers the basics of EtO sterilization and the EOGas Sterilizer: our Key Operator Certification program. This offer applies to all operators of EOGas Sterilizers and is free of charge.

Please call Andersen Products at 800-523-1276 to schedule the 20-minute test with one of our customer service representatives. You should study the information in this guide prior to scheduling your test. When you have successfully completed the test, you will receive an EOGas Key Operator certificate. We look forward to hearing from you!

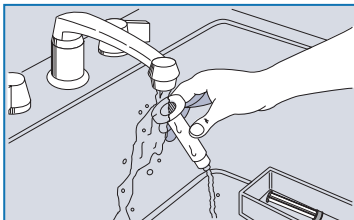
Preparing the items for sterilization

Four basic steps must always be followed when preparing items for sterilization:



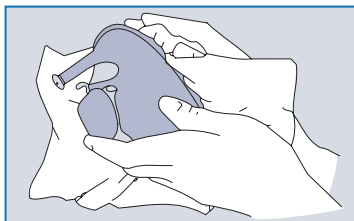
1 Disassemble

Items containing removable parts such as syringes must be taken apart before washing, drying, and wrapping them to allow the EOGas an unobstructed path.



2 Wash

Items must be washed surgically clean prior to sterilization.



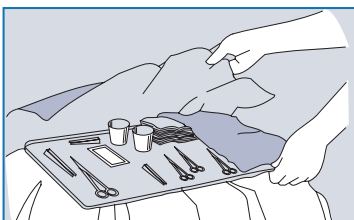
3 Dry

Two accepted ways to dry any item prior to sterilization with EOGas are:

1. Towel drying
2. Drain drying (air drying)



WARNING: Heat or hot air should never be used to dry an item prior to sterilizing it with EOGas because it will desiccate, dehydrate or dry out spores making them more resistant to the ethylene oxide gas.



4 Wrap

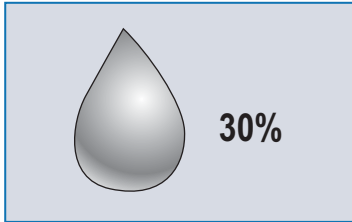
Types of wrapping material that are recommended for use with Anprolene:

1. Andersen Seal and Peel Packaging (which is airtight and waterproof and greatly extends the shelf life when heat sealed at both ends).
2. Cloth, like CSR wrap, has an estimated sterile shelf life of 30 days.
3. Paper (self-seal pouches) has a shelf life of 30 days.
4. Tyvek-paper pouches.



WARNING: Instruments which contain batteries should be taken apart and the batteries removed and wrapped separately to protect against a spark occurring and igniting the ethylene oxide gas.

Role of Humidity



Humidity is very important to the EOGas process. Relative Humidity (RH) must be at least 30% in the room where preparation and sterilization take place.



Spores that might be on the instruments may become dry if the RH is below 30% which makes them resistant to EOGas.

1 Wash: The simplest way to humidify items is to wash them.

2 Or Humidify:

Items that cannot be washed (like laptops, cameras, and delicate electronics) should be humidified by the following method: seal the products in a sterilizing bag with a Humidichip, Dosimeter and the appropriate size cartridge. Place the bag in the EOGas sterilizer for 4 hours at 50°C. Then remove the bag to room temperature for an additional 4 hours prior to activating the EOGas cartridge to begin sterilization.



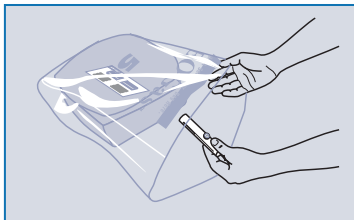
The pre-humidification should take place for 4 hours inside the EOGas sterilizer at

EOGas Sterilization Cycle

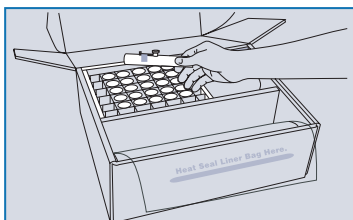
The usual EOGas sterilization and aeration cycle is 16 hours, plus a 5-minute purge cycle. Sterilization and aeration must take place in the EOGas cabinet at a temperature that is not less than 50 C (122°F).

The following are the recommended steps for a complete EOGas sterilization cycle on Standard Operating Mode:

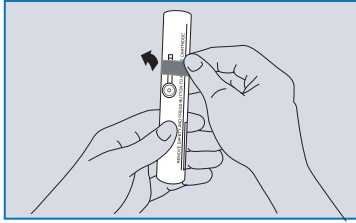
1 Bag Preparation



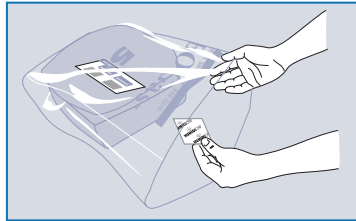
a) Place prepared, wrapped items into a medium (#5) or large (#6) EOGas sterilizing bag.



b) Match the EOGas cartridge size (#5 or #6) with the number on sterilizer bag. Each cartridge contains the precise amount of ethylene oxide needed to sterilize the contents of the corresponding sterilization bag. Mismatching the bag and cartridge size may result in a non-sterile load or over-saturation of product and/or gas exposure issues.



c) Remove safety trigger on the cartridge and place the cartridge in sterilizing bag without activating the cartridge.

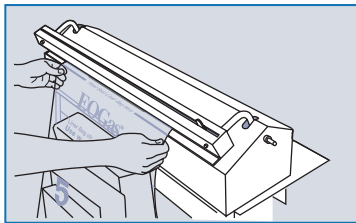


d) Place a Dosimeter and Humiditube with a Humidichip inside of the EOGas sterilizing bag.

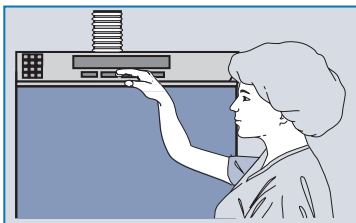
e) Insert a biological control (optional).

f) Press excess air out of the loaded bag.

g) Heat seal or vacuum seal the sterilizing bag.

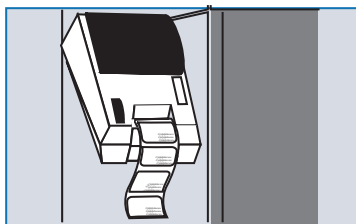


2 Loading the Sterilizer



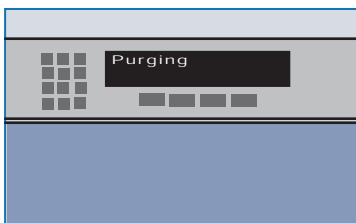
a) Have your EOGas bags prepared and heat-sealed.

b) When loading an empty sterilizer confirm that the sterilizer has power and is switched "on". Once the display reads "Standby" press the "Load" key. This will allow the sterilizer to reach a temperature of 50 degrees. (If required, key in your operator code and press "Enter".)

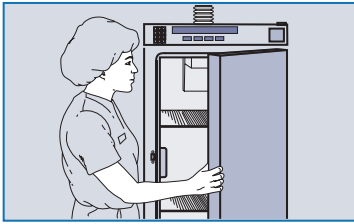


c) On the keypad, enter the number of bags you are placing in the sterilizer. Look at the display to check that that number matches your entry and press "Enter" to confirm.

d) Two labels will print for each bag. Place one on the sterilizing bag and one in your sterilization logbook. The labels provide a tracking number, along with a record of the time when the bag was inserted into the sterilizer and the cycle length.



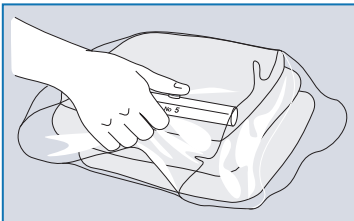
e) Check the display. If there are no bags in the sterilizer, the display will read "Warm Up". If other bags have been previously loaded, it will read "Purge".



f) When the "Door Unlocked - OK to Open" message appears, open the door. The EOGas Sterilizer always goes through a 5 minute purge cycle before the door may be opened to assure that the operator is not exposed to levels of EO beyond OSHA's acceptable short term limit of five parts per million. (5.0 ppm 15 minute STEL). The door will remain unlocked for 3 minutes.



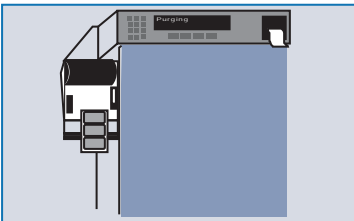
g) Immediately place the sterilizing bag(s) into the EOGas cabinet. Do not over pack the sterilizer; air must be able to circulate around the bags.



h) Activate each EOGas cartridge within the sealed sterilization bag(s) by depressing the trigger button. Make sure that the trigger button is fully depressed.

i) Close the door and confirm that it is locked.

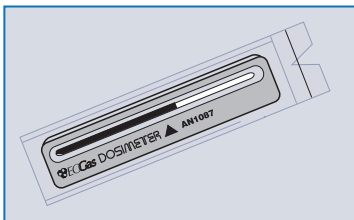
3 Unloading the Sterilizer



a) To unload bag(s) after the full cycle, press the "Unload" button. Key in your operator code if requested. The sterilizer will begin a five-minute purge cycle before the door will unlock.

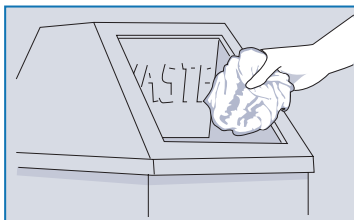


b) When the "Door Unlock - OK to Open" message appears, open the door. Confirm which sterilization bags should be unloaded by using the up and down keys on your display. Match your log numbers to bag numbers to determine which have completed the 16-hour cycle. Slit each appropriate bag down the center to aerate. With the door still open, press "0" for a 5-minute additional aeration. Close the door.



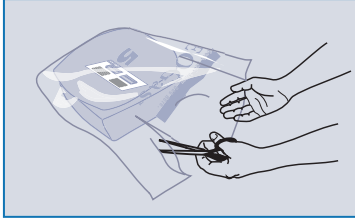
c) After the 5-minute additional purge, press "unload". Remove slit bags from cabinet.

d) Remove the sterilized items and check the Dosimeter. Make sure the blue line has progressed up to or beyond the triangular mark.



e) The items may be removed from the EOGas sterilization bag. Discard the sterilization bag, Humidichip, and spent cartridge with ordinary trash. Incubate Biological Indicator, if using one. Retain Humiditube to use again

4 Extended Aeration Procedure



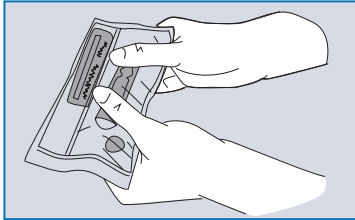
The 16-hour EOGas cycle at 50 C includes an aeration period adequate for most EO absorbing materials.



Large gas absorbent items, especially implants, or devices that will contact blood or living tissue, require additional post sterilization aeration. For these, simply cut open the bag while it is still in the sterilizer, close the door to the sterilizer, and leave it in there for an additional 4-6 hours.

Final Word: Important Notes About EOGas

1 Sterility Indicators

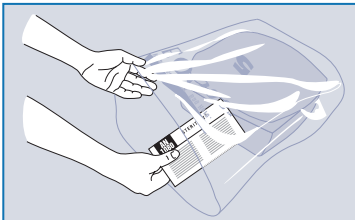


a) The methods to check that the sterilization cycle was successful are the Dosimeter® or the Steritest or other biological indicator.

b) The EOGas Dosimeter is an indication that sterilization conditions have been achieved in the sterilization bag.



AN85 exposure indicator strips and AN86 package closure indicator tape do not prove sterilization; they only change color to show that the items were exposed to ethylene oxide.

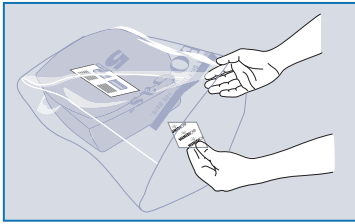


c) Biological Indicators or Steritest are the best indicators that your load is sterile. They work by showing that over one million spores of the most resistant bacteria to ethylene oxide (*Bacillus Athrophaeus*) were killed.

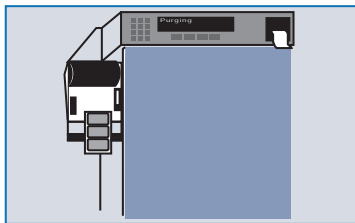


d) Personnel exposure to EO can be monitored with the Airscan Monitoring badges to measure that the operator is not being exposed to more than the government permitted level of 5.0 ppm in a 14-minute period while the sterilizer is being unloaded.

2 Humidichip

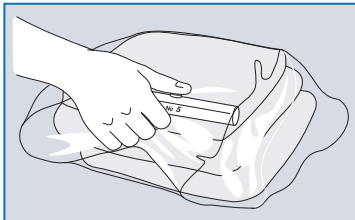


- a) The Humidichip and Humiditytube ensure that humidity requirements for EO sterilization are maintained within the sterilization bag.
- b) To assure that adequate humidity conditions are maintained within the EOGas sterilization bag, put one Humidichip (in a Humiditytube) in the sterilization bag before sealing it.
- c) Humiditytubes can be re-used. Humidichips should be discarded after use.



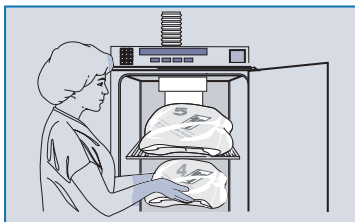
3 Why locking EOGas Sterilizer:

The ventilation and purge features of the EOGas sterilizer prevent operator exposure to levels of ethylene oxide in excess of OSHA regulations.



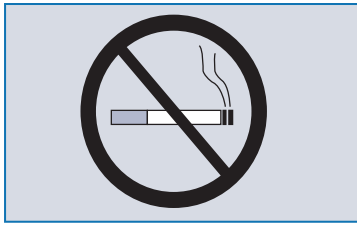
4 Two reasons for never activating the EOGas cartridge without first sealing it in the sterilization bag are:

- a) This would expose the operator to levels of EO in excess of OSHA regulations.
- b) It will decrease the amount of ethylene oxide available for sterilization and might result in a non-sterile load.



5 Three consequences of opening the EOGas bag before the 16 hour cycle are:

- a) The load might not be sterile.
- b) The sterilization bag might still contain high levels of EO.
- c) The load might not be adequately aerated. If used on a patient, the items might cause a serious chemical contact burn.



6) Other warnings:

- a) You should not smoke near EOGas because it is flammable.
- b) Food and drugs must not be sterilized in EO because it can change their chemical composition.
- c) If liquid ethylene oxide comes into contact with a part of the body you should wash thoroughly for at least 15 minutes.



- 7) Rubber and plastic items that absorb gas, especially implants and devices that will contact blood or living tissue, may require additional aeration time after sterilization.

- a) For any device that will be implanted or used inside of the human body, please contact the manufacturer or Andersen Customer Service for recommendations for proper aeration.

EMERGENCY CONTACT INFORMATION



**In case of emergency, please contact
Chemtel at 800-255-3924.**