

Thank you for using the Anprolene® sterilization system.

The active ingredient in Anprolene is ethylene oxide (EtO or EO), a chemical that can be hazardous if not handled properly. To ensure that you fully understand the safe operation of your sterilizer, we strongly encourage you to take advantage of our Key Operator certification program.

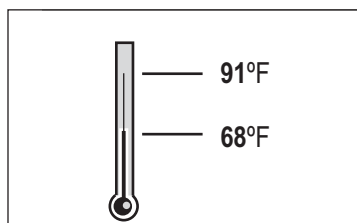
To begin Key Operator training, please read through this study guide thoroughly. If you do not understand any of the information in the guide, please call Andersen Customer Service for assistance. Once you are familiar with the study guide, please call us at (800) 523-1276 to schedule a test.

The test will take approximately 20 minutes. The Key Operator test is also an excellent opportunity to ask your Andersen Representative any questions you may have about the Anprolene system or ethylene oxide.

When you successfully complete the test, you will receive a certificate and a registered key ring. We look forward to hearing from you.

Key Operator training is free of charge for the lifetime of your sterilizer. Please have all operators of your Anprolene sterilizer contact us for training before they use the system.

Environmental Considerations



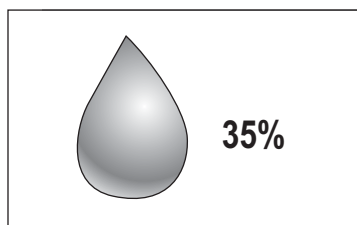
① Temperature

Store your Anprolene gas refill kits in a cool, secure area. We recommend storage below 70°F.

The sterilizer must be used in an area where the temperature is not less than 68°F or more than 91°F. This temperature range must be maintained during the entire sterilization cycle.



EtO FACTS: At sea level, ethylene oxide is a liquid below 51°F. Above 51°F, EtO begins to boil and converts into a gas. EtO does not become an effective sterilant until 68°F. Make sure that the room where your Anprolene sterilizer is installed remains above 68°F during the entire sterilization cycle. This is especially important during the winter months!



② Humidity

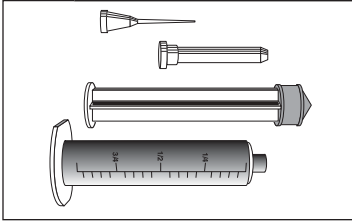
Humidity is very important to the Anprolene process. Relative Humidity (RH) must be at least 35% in the room where item preparation and sterilization take place. Spores that might be on the instruments may become desiccated and resistant to Anprolene if the RH is below 35%.

The simplest way to humidify items is to wash them.

It is necessary to humidify items which cannot be washed by enclosing them in a plastic bag with a damp sponge for four hours prior to sterilization, or you may use an Andersen Humidichip®.

Preparing the items for sterilization

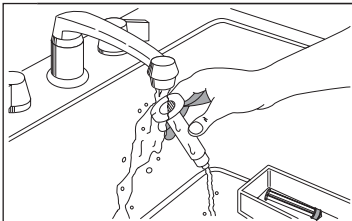
Four basic steps must always be followed when preparing items for sterilization:



1 Disassemble

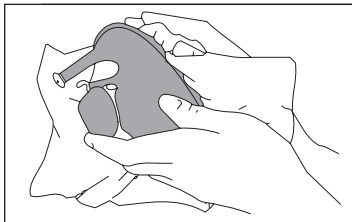
Items containing removable parts such as syringes must be taken apart before washing, drying, and wrapping them to allow the Anprolene an unobstructed path.

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.



2 Wash

Items must be washed surgically clean prior to sterilization. For cleaning, we recommend using a detergent.



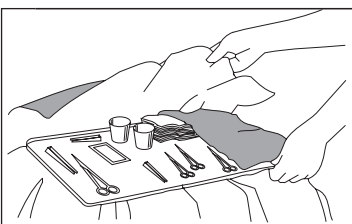
3 Dry

Two accepted ways to dry any item prior to sterilization with Anprolene 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 Anprolene because it will dehydrate or desiccate bacteria spores making them more resistant to the ethylene oxide gas.

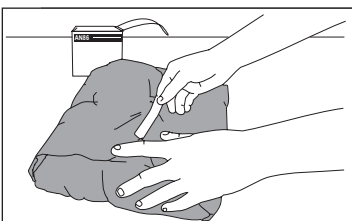
WARNING: Any water left on items may react with ethylene oxide. Please air dry instruments thoroughly.



4 Wrap

The following types of wrapping material that are recommended for use with Anprolene:

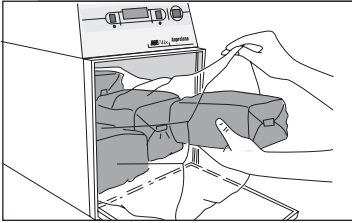
1. Andersen Seal and Peel® Packaging (which is airtight and waterproof and greatly extends the shelf life when heat sealed at both ends).
2. Cloth, like CSR wrap, has an estimated sterile shelf life of 30 days.
3. Paper (self-seal pouches) has a shelf life of 30 days.
4. Tyvek-paper pouches.



HINT: Exposure indicators such as the Andersen AN85 or AN86 will change color in the presence of EtO, helping to later identify items that have been sterilized. Seal or label items with exposure indicators such as the AN85 or AN86. These indicators will change color when exposed to EtO. Exposure indicators do not prove sterility.

Sterilization Cycle

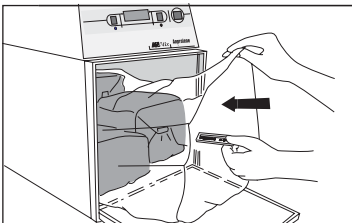
Preparing the Sterilization Liner Bag



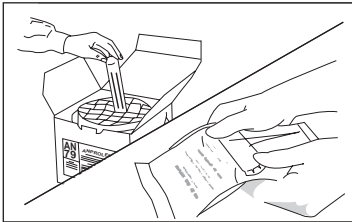
- 1 Place prepared items in a new sterilization liner bag.

WARNING: Do not reuse sterilization liner bags. Even a tiny pinhole in a liner bag can allow gas to escape and cause cycle failure!

WARNING: Do not sterilize liquids, foods or drugs in the Anprolene sterilizer. If you have any questions about whether an item may be sterilized using Anprolene, please call Andersen Customer Service.



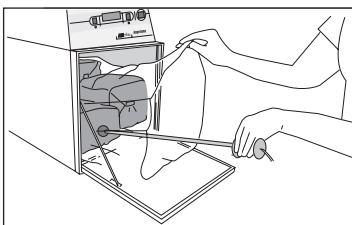
- 2 Insert appropriate controls such as a Dosimeter® (chemical indicator) or a Steritest® (biological & chemical indicator) into the least accessible part of the sterilization liner bag. Add a Humidichip to the Humiditube® and insert into the sterilization liner bag.



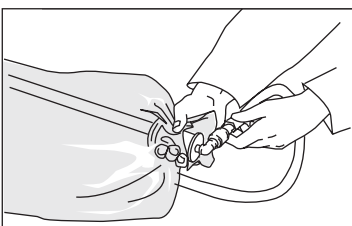
- 3 Unroll the **gas release bag** containing the gas ampoule and, without opening it, gently move the ampoule to the center of the gas release bag if it's not already there. Place on top of items in the sterilization liner bag where it will be easy to break. In order to prevent liquid from coming into contact with the skin and prevent gas from escaping too quickly to achieve sterilization, never open the gas release bag.

WARNING: Reasons why the gas release bag containing the ampoule should never be opened:

- To prevent the liquid ethylene oxide from coming in contact with the user or the items to be sterilized.
- To prevent the gas from escaping too quickly to achieve sterilization.



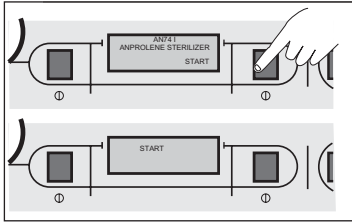
- 4 Insert the **purge probe** into the sterilization liner bag with the neck and quick release fitting at the open end. Place the black Velcro® strap around the sterilization liner bag and the bobbin of the purge probe, and pull it snug through its loop to completely close the sterilization liner bag. The strap must secure the sterilization liner bag tightly around the purge probe in order to keep gas from escaping.



- 5 Connect the **quick release connector** to the purge probe, if it is not already connected.

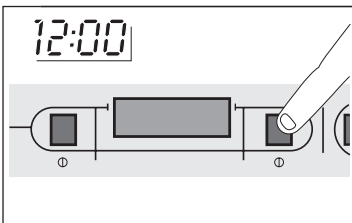
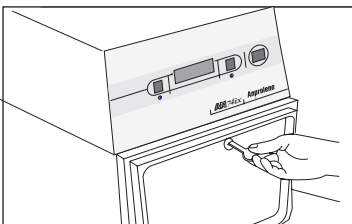
HINT: The sterilization liner bag may be loaded and sealed away from the sterilizer cabinet, and connected to the purge probe once you are ready to start a cycle.

Starting the Cycle



- ① Make sure the sterilizer power cord is connected. Press the top part of the **power switch**. Wait to see the "**(model #) ANPROLENE STERILIZER**" and the "**START**" message to appear on the cabinet display.
- ② Push the button to the right of **START**.
- ③ Wait for the **SELF TEST** and number of elapsed PUMP HOURS to appear.
- ④ Press the button next to the **PURGE** message on the right of the display and wait for 1 minute 30 seconds until the display reads '00:00:00'. The sterilization liner bag should vacuum down as excess air is removed.
- ⑤ When the display indicates "**BREAK AMPOULE**", carefully, so as not to puncture the sterilization liner bag, grasp the ampoule through the sterilization liner bag and activate it by snapping off the top.

Selecting Cycle Length



- ① **Close** the door.
- ② **Lock** the sterilizer and remove the key.
- ③ **SELECT CYCLE LENGTH.** (Right button = 12 Hour, Left button = 24 Hour).



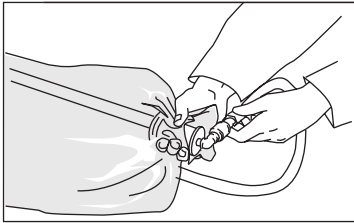
WARNING: The usual Anprolene sterilization cycle is 12 hours, plus a 2-hour purge cycle. When sterilizing lengths of tubing 3 feet or longer, or a full load of gas absorbent items, it may be necessary to increase the cycle time to 24 hours with the "24 HOUR CYCLE" button.

- ④ If an electronic beep sounds, it is an alert that 5 seconds have elapsed and the sterilizer is awaiting a cycle time selection.
- ⑤ Log sterilization data if required.




WARNING: Never interrupt a cycle once the gas ampoule has been activated. An alarm will sound if the door is opened during the cycle.

Unloading the Sterilizer and Determining Sterility



- 1 Remove the sterilized items only after the sterilization cycle and 2-hour purge cycle have been completed and the display indicates "**UNLOAD STERILIZER**". The sterilizer will continue to aerate items that are not removed immediately. A count-up timer on the display will indicate the time that has lapsed since the final 2-hour purge cycle ended.

 **HINT:** To unload the sterilization liner bag away from the sterilizer, simply detach the purge probe hose from the bag using the quick release fitting at the base of the probe.

- 2 Press EXIT to **turn off** the sterilizer.
- 3 **Unload** the liner bag and check the sterility (chemical &/or biological) indicators.
 - Steritest provides an immediate indication of the success of the cycle (via the Dosimeter), and later proves sterility by showing that active spores have been killed. (Spores will require at least 48 hours of incubation to provide results).
 - The Dosimeter shows whether time, temperature and gas concentration parameters have been met. It proves an immediate chemical indication that the cycle was successful. Dosimeters should not be used in place of B.I.s to prove sterility.
 - Chemical exposure indicators, such as the AN85 or AN86, do not prove sterilization. They only change color to show that the items have been exposed to ethylene oxide.

Aeration

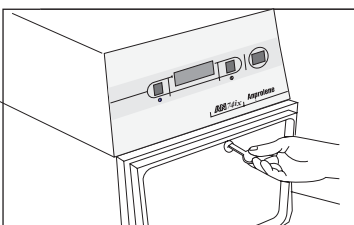
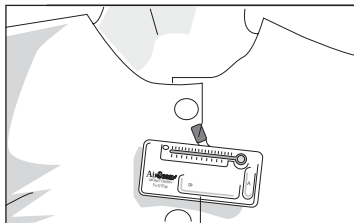
- 1 The **cabinet ventilator should be running** during the entire sterilization cycle to prevent personnel from being exposed to more than the OSHA permitted levels of ethylene oxide. [1.0 ppm (parts per million) over an 8 hour time weighted average (TWA)] Do not remove items before the full 2-hour purge cycle. Aeration should take place in a well-ventilated area that provides at least 10 fresh air exchanges per hour so that high concentrations of gas will not build up while aerating. The purge cycle is designed to aerate most products sufficiently to meet the short-term exposure level (STEL) of 5.0 ppm for the 15 minutes (during unloading of the liner bag).
- 2 Metal and glass **do not** require additional aeration.
- 3 Items made of **gas absorbent material** must be aerated at a minimum room temperature of 68° F for at least 24 hours prior to use. If EtO were retained in an item and came in contact with skin or mucosa, it could cause a chemical contact burn.
- 4 The sterilizer can be used for **extended aeration**. After the regular cycle is finished, the sterilizer will continue to ventilate and purge the liner bag until the door is opened, the exit button is selected, and the cycle has ended. A count-up timer will keep track of the time that has passed since the standard cycle was completed.
- 5 Extended aeration can also take place **outside of the sterilizer** after removing items from the sterilization liner bag. In this case, aeration should take place in a well-ventilated area that provides at least 10 fresh air exchanges per hour so that high concentrations of gas will not build up while aerating.

Safety Precautions

Ethylene Oxide Safety



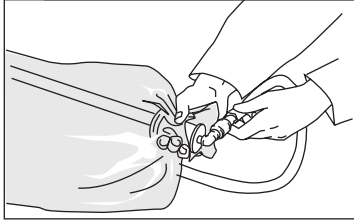
- ① Do not allow open flame or sparks near the sterilizer during the sterilization cycle because ethylene oxide gas is highly flammable in concentrations above 3.0% (30,000 ppm).
- ② If you come in contact with liquid Anprolene, you should wash the effected area with water thoroughly for at least 15 minutes. Consult MSDS for further reference.
- ③ Never interrupt a cycle in progress.
- ④ Sterilization liner bags should never be reused because they may have a puncture or tear.
- ⑤ The 12 and 24-hour sterilization cycles both end with a 2-hour purge cycle, which flushes fresh air around the products in the sterilization load.
- ⑥ Personnel exposure to ethylene oxide can be monitored by using the personal exposure badges, such as the Andersen AN93 AirScan® Badges. The AN93 AirScan Kit has both STEL and TWA badges. EtO exposure levels should be checked upon installation of the sterilizer. We recommend that exposure testing be performed on an annual basis.
- ⑦ If an ampoule is accidentally activated outside of the bag, immediately place in sterilization cabinet and start cycle



Reasons for locking the Anprolene sterilizer:

- To protect the contents from spark or flame.
- To protect the liner bag from puncture.
- To ensure the Anprolene sterilizer exhausts the ethylene oxide through the ventilation system to the outside.

Note: No other container or sterilizer can be used with Anprolene sterilizing gas.



Reasons why the gas release bag containing the ampoule should never be opened:

- To prevent the liquid ethylene oxide from coming in contact with the user or the items to be sterilized.
- To prevent the gas from escaping too quickly to achieve sterilization.

Malfunctions and Power Failures

In the event of a purge pump failure, the vent pump will continue to ventilate the interior of the cabinet, exhausting gas as it diffuses through the sterilization liner bag. A PURGE PUMP FAILURE error message will be displayed, and the sterilizer will add 24 hours of aeration before the display indicates that you may remove your products. (If this happens, please call Customer Service for assistance, (800) 523 -1276).

In the event of a VENT PUMP FAILURE, the cycle will be aborted, and the purge pump will evacuate the liner bag of any remaining gas. (If this happens, please call Customer Service for assistance, (800) 523 -1276).

If a power outage occurs during any part of the cycle, the sterilizer is equipped with a battery back up to the circuit board that will keep track of elapsed cycle time. When power is restored, the cycle will continue. Do not open the door of the sterilizer until power is restored and the vent/purge systems have removed any residual gas from the liner bag.



HINT: In the case of any sterilizer malfunction or power failure, you can determine whether sterilization was achieved by examining the sterility indicators (biological indicator, Steritest with Dosimeter) included in the load.

Here is what you should know after reading this study guide:

- *The minimum temperature needed in the room for the entire sterilization cycle*
- *The length (in time) of the standard cycle*
- *Why the ventilation system is running during the entire cycle*
- *Why the sterilization liner bag is purged*
- *The desired relative humidity in the room where the items are prepared*
- *How to prepare items for sterilization*
- *The types of indicators that are used in the Anprolene system*
- *Ethylene oxide safety and precautions*
- *Basic operation of your Anprolene sterilizer from start to finish*

When you feel comfortable with answers to these subjects, please give Andersen Products a call at 1-800-523-1276 and schedule your Key Operator Certification exam. The test will take approximately 20 minutes.

Money saving uses for Anprolene®

electric



rubber items



scopes



disposable items



non-sterile

Things that CAN be sterilized with Anprolene:

ELECTRICAL DEVICES

- Flashlights
- Drills
- Dremmel drills
- Microdrills

SURGICAL DEVICES

- Scalpels & sharps
- Scissors
- Clamps & crimpers
- Saws
- Rulers
- Forceps
- Biopsy punches
- Dermal punches
- Dilators
- Skin staplers
- Specula
- Needles
- Neuter clips
- IV sets
- Marking pens

ENDOSCOPES

- Endoscopes
- Cameras
- Fiberoptic scopes

Things that CAN be sterilized with Anprolene but that require additional aeration:

CLOTH ITEMS

- Gauze
- Gowns
- Bandages
- Cotton balls
- Masks
- Drape materials

TUBES

- Suction tubes
- Liposuction tubes
- Catheters
- Endotracheal tubes
- Feeding tubes
- Nasal tubes

IMPLANTS

- Pacemakers
- Nylon implants
- Implants

OTHER ITEMS

- Toothbrushes
- Rubber bands
- Rubber tourniquets
- Sponges

Things that CANNOT be sterilized with Anprolene:

Liquids, food, and drugs should not be sterilized in ethylene oxide because it may change their chemical composition.