

Thank you for using the Anprolene[®] sterilization system.

The active ingredient in Anprolene is ethylene oxide (EtO or EO). EtO is a powerful anti-microbial agent; it can also be dangerous if not handled correctly. To help ensure that your sterilizer is operated safely, all personnel who operate or maintain the equipment need to be properly trained.

The Andersen Anprolene Key Operator Certification Program provides instruction in the following areas:

- Environmental considerations for Anprolene sterilization
- Preparation of items to be sterilized
- Operation of the sterilizer
- Sterility Assurance
- Operator Exposure Testing and Emergency Procedures

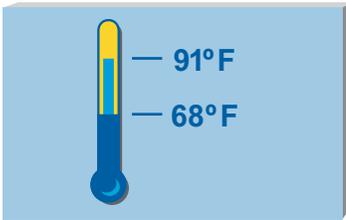
The Andersen Anprolene Key Operator Certification Program is available free of charge for the lifetime of your sterilizer. We recommend that all operators at your facility are trained before they use the sterilizer for the first time.

The information in this study guide should be carefully reviewed. The Key Operator test is conducted over the telephone and requires 20 minutes. When you are ready, please call Andersen Customer Service at (800) 523-1276 to schedule your test. Shortly after completing your test, you will receive a registered training certificate. We look forward to hearing from you!

**Overview of the Anprolene[®] sterilization system.**

- 1 The Anprolene system is a room temperature Ethylene Oxide (EtO) sterilizer. This sterilization system must be installed and operated in an environment that maintains a temperature of no less than 68°F to be effective.
- 2 The usual Anprolene cycle is 12 hours, plus a two hour bag ventilation (Aeration) cycle.
- 3 Because it takes longer for EtO to penetrate small, long lumens, the Anprolene system also offers a 24 hour cycle. Use this cycle for any lumen longer than 3 feet in length.
- 4 Humidity is critical for successful EtO sterilization. The Andersen Humidichips will help to ensure adequate humidity during sterilization.
- 5 The AN87 Dosimeter provides an immediate indication at the end of a cycle of whether the conditions for sterilization have been met. A sterility indicator should be used with every cycle.

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!



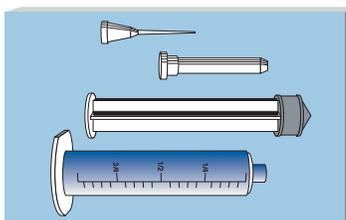
② Humidity

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 an Andersen Humidichip[®] or a damp sponge for four hours prior to sterilization.

Preparing the items for sterilization

Four basic steps must always be followed:



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.

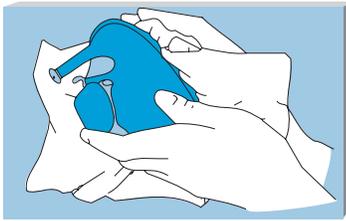


WARNING: Instruments which contain batteries should be taken apart and the batteries removed and wrapped separately to protect against a spark occurring and igniting the ethylene oxide gas.



② Wash

Items must be washed surgically clean prior to sterilization using detergent and water.



3 Dry

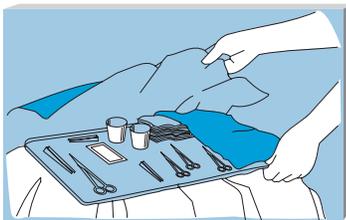
Two accepted ways to dry any item prior to sterilization with Anprolene are:

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.



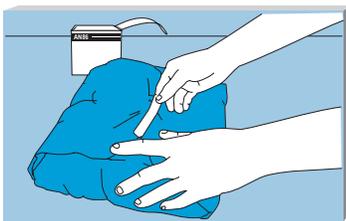
4 Wrap

The following types of wrapping material 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 / plastic and Tyvek[®] / plastic pouches - follow manufacturer's guidelines for shelf life.



HINT: Exposure indicators such as the Andersen AN85 or AN86 are used to seal or label items. Indicators will change color in the presence of EtO, helping to later identify items that have been sterilized. Exposure indicators **DO NOT** indicate sterility.



Sterilization Cycle

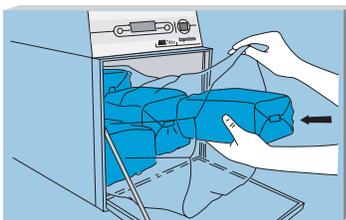
Preparing the Sterilization Liner Bag

1 Place prepared items in a new sterilization liner bag.

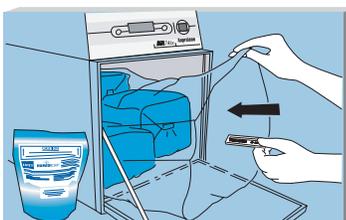


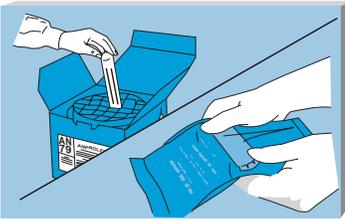
WARNING: Do not reuse sterilization liner bags. Even a tiny pinhole in a liner bag can allow gas to escape and cause cycle failure!

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.

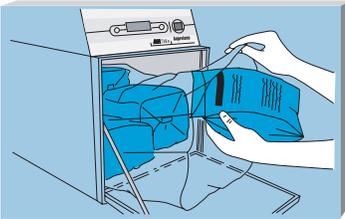


2 Insert appropriate controls such as a Dosimeter[®] (chemical integrator) or a Steritest[®] (biological & chemical indicator) into the least accessible part of the sterilization liner bag. Add a Humidichip to the Humiditube[®] and insert into the sterilization liner bag.



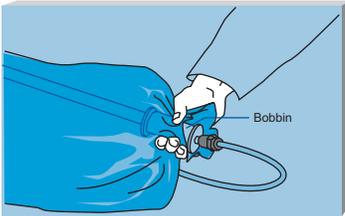


- 3 Unroll the gas release bag containing the gas ampoule and, without opening it, gently move the ampoule to the center of the gas release bag. Place on top of items in the sterilization liner bag where it will be easy to break. In order to prevent liquid from coming into contact with the skin and prevent gas from escaping too quickly to achieve sterilization, never open the gas release bag.

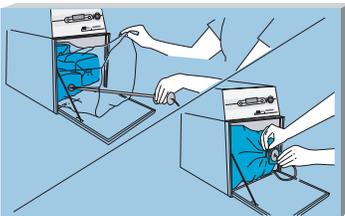


WARNING: Reasons why the gas release bag containing the ampoule should never be opened:

- 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 bobbin 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.

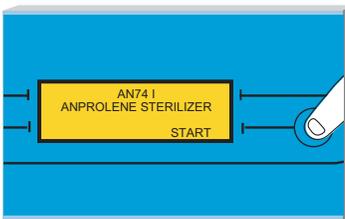


- 5 Connect the quick release connector to the purge probe, if it is not already connected.

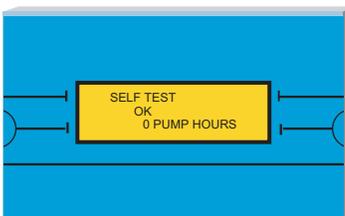


HINT: The sterilization liner bag may be loaded and sealed away from the sterilizer cabinet, and connected to the purge probe once you are ready to start a cycle.

Starting the Cycle



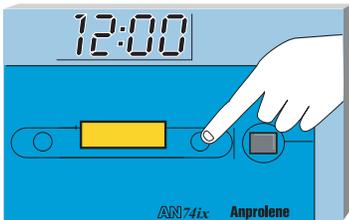
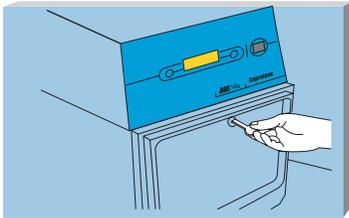
- 1 Make sure the sterilizer power cord is connected. Press the top part of the power switch. Wait to see the "(model #) ANPROLENE STERILIZER" and the "START" message to appear on the cabinet display.



- 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.



Selecting Cycle Length



- 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.

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



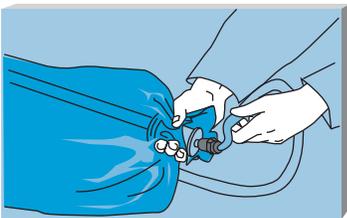
WARNING: The usual Anprolene sterilization cycle is 12 hours, plus a 2-hour purge cycle. When sterilizing lengths of tubing 3 feet or longer, or a full load of gas absorbent items, it may be necessary to increase the cycle time to 24 hours with the "24 HOUR CYCLE" button.

- 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.

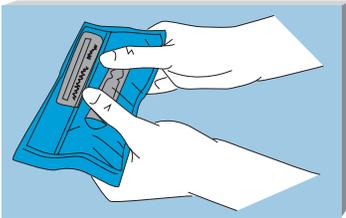
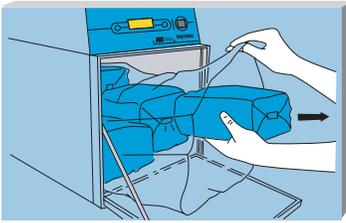
Unloading the Sterilizer and Determining Sterility



- 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 additional aeration 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.

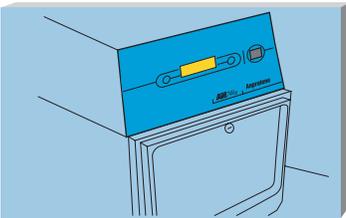


- 2 Press **EXIT** to **end the cycle** and return the sterilizer to standby state.
- 3 **Unload** the liner bag and check the sterility chemical integrator &/or biological indicator.
 - **Biological Indicators** (BI's) such as the **Steritest** reliably verify that sufficient concentration of EtO killed one million *B. Atrophaeus* spores. After incubation, color change from blue-green to yellow would distinctly indicate a positive culture.
 - **Chemical Exposure Integrators**, such as the **Dosimeter** provide immediate visual confirmation that time, temperature, and EtO concentration were sufficient for sterilization to occur.
 - **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.



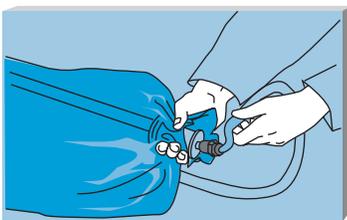
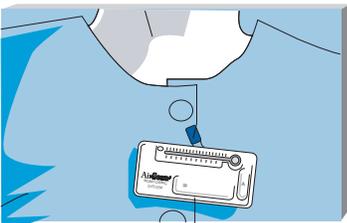
WARNING: Never remove items before the full 2-hour purge cycle has completed. The purge cycle is designed to aerate most products sufficiently to meet the OSHA short-term exposure level (STEL) of 5.0 ppm over the 15 minutes.

Aeration



- 1 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 and the exit button is pressed, ending the cycle. A count-up timer will keep track of additional aeration since the standard cycle was completed.
- 2 Extended aeration can also take place **outside of the sterilizer**. After removing items from the sterilization liner bag, aeration should take place in a well-ventilated area that provides at least 10 fresh air exchanges per hour so that unsafe concentrations of gas will not develop.
- 3 Metal and glass **do not** require additional aeration.
- 4 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 is retained in an item and came in contact with skin or mucosa, it can cause a chemical contact burn. Examples of gas absorbing items include rubber, silicone, and soft plastics.

Safety Precautions



Ethylene Oxide Safety

- 1 Do not allow open flame or sparks near the sterilizer during the sterilization cycle. 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 (15 min.) and TWA (8 hour) badges. EtO exposure levels should be checked upon installation of the sterilizer. We recommend that exposure testing be performed on an annual basis or whenever a sterilizer is relocated.
- 7 If an ampoule is accidentally activated outside of the bag, immediately place it in the sterilization cabinet and start a cycle.

Reasons for locking the Anprolene sterilizer:

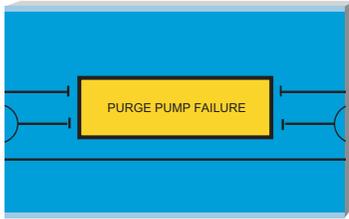
- To protect the contents from spark or flame.
- To protect the liner bag from puncture.
- To ensure the Anprolene sterilizer exhausts the ethylene oxide through the ventilation system to the outside.



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

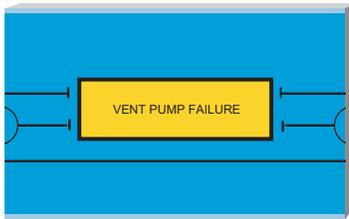
Reasons why the gas release bag containing the ampoule should never be opened:

- 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.