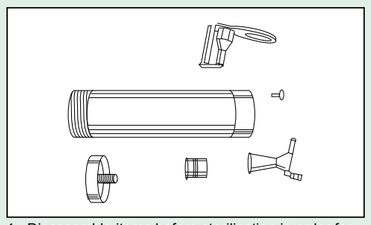
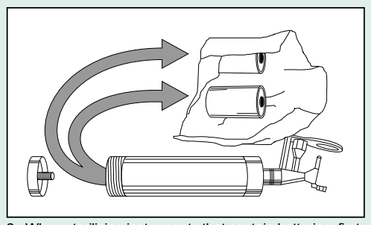
Anprolene® gas sterilization

Instructions for Anprolene® sterilizers 100% Ethylene Oxide (EtO)

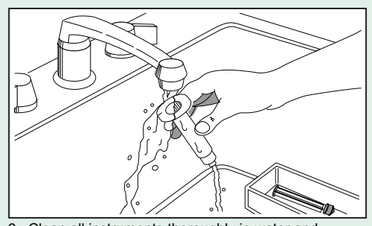
PREPARATION



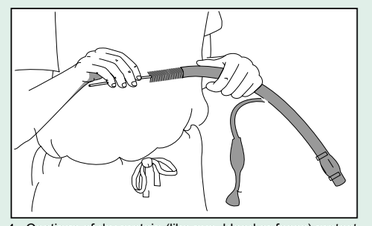
1. Disassemble items before sterilization in order for the Anprolene gas to penetrate freely.



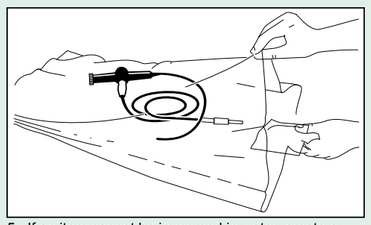
2. When sterilizing instruments that contain batteries, first remove the batteries, then wrap them separately. This ensures no sparks or flames will occur.



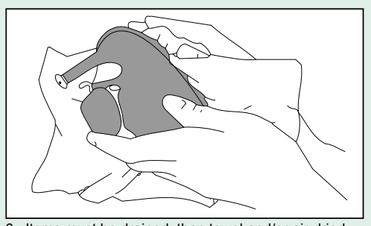
3. Clean all instruments thoroughly in water and detergent to loosen protein & residues.



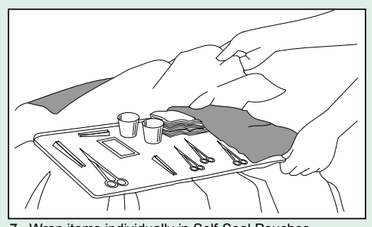
4. Coatings of dry protein (like pus, blood or feces) protect microorganisms and slow the sterilization process. Therefore, scrub instruments to a "surgically clean" standard before sterilizing.



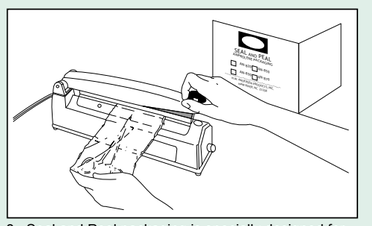
5. If an item cannot be immersed in water, create a humidification chamber by placing a Humidichip® (AN1071) in a liner bag with the item, and twist-tie the bag closed. Leave the item in the bag for four hours.



6. Items must be drained, then towel and/or air-dried completely before processing. Do not dry them with hot-air. Heat can desiccate bacterial spores, making them more resistant to sterilization.

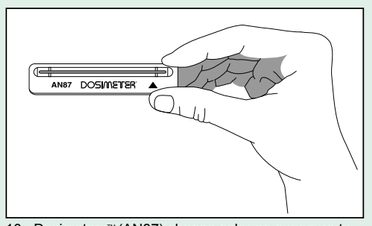


7. Wrap items individually in Self-Seal Pouches (AN2310 through to AN2350), Seal and Peel® (AN820-AN870), CSR wrap or other approved packaging.

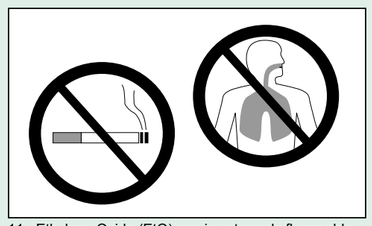


8. Seal and Peel packaging is specially designed for use with Anprolene and allows you to create see-through, peel-open, extended shelf-life pouches.

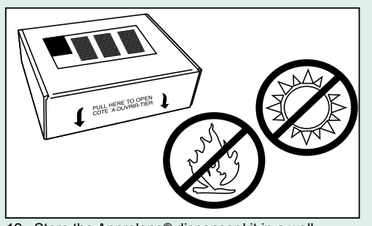
9. Apply one self-adhering chemical indicator to the outside of each package to be sterilized. Andersen Package Closure Indicator Strip (AN85/AN86) is a chemical indicator which verifies exposure to Anprolene gas. Unlike biological indicators they do not signify sterility.



10. Dosimeters™ (AN87) change color on exposure to Anprolene gas in proportion to the length of time and the temperature within the cabinet. If the yellow crystals turn to blue from left to right as far as the triangular mark (▲), you can be certain that the sterilization parameters for properly prepared items have been met.

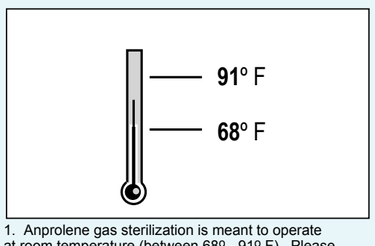


11. Ethylene Oxide (EtO) gas is extremely flammable. Do not smoke in the vicinity of the sterilizer while loading or unloading. Avoid breathing EtO vapors. EtO is irritating to the lungs and mucous membranes.

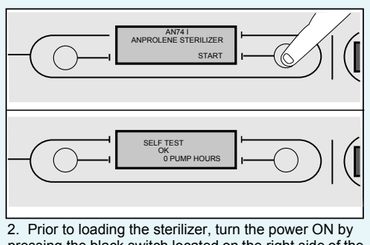


12. Store the Anprolene® dispenser kit in a well ventilated room between 59° and 86° F, away from direct sunlight. Keep the box lid closed when not in use. Keep the Humidichip jar tightly closed to prevent drying of the chips.

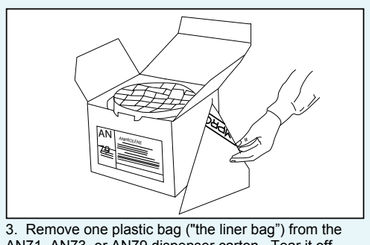
STERILIZATION



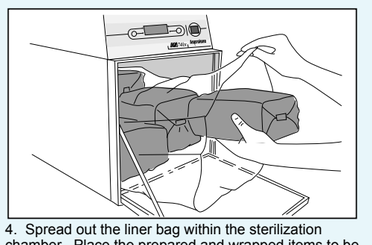
1. Anprolene gas sterilization is meant to operate at room temperature (between 68° - 91° F). Please ensure that the location of the unit guarantees the minimum temperature for the entire sterilization cycle.



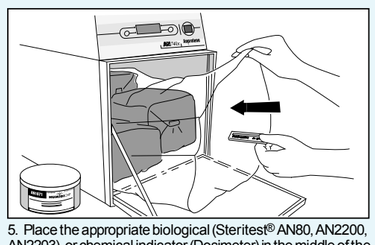
2. Prior to loading the sterilizer, turn the power ON by pressing the black switch located on the right side of the Control Panel. Press the button to the right of START on the display screen to initiate the SELF-TEST.



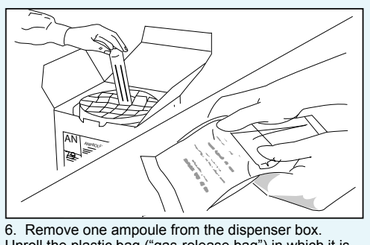
3. Remove one plastic bag ("the liner bag") from the AN71, AN73, or AN79 dispenser carton. Tear it off carefully at the perforation.



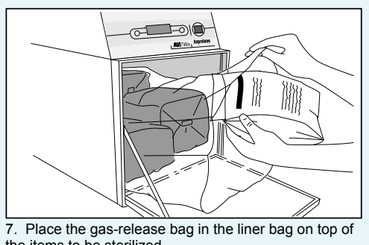
4. Spread out the liner bag within the sterilization chamber. Place the prepared and wrapped items to be sterilized in the liner bag.



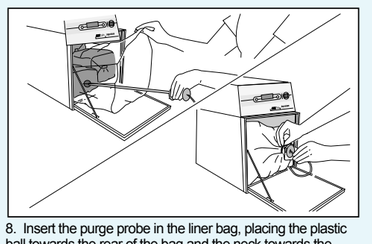
5. Place the appropriate biological (Steritest® AN80, AN2200, AN2203), or chemical indicator (Dosimeter) in the middle of the liner bag. If you cannot verify that the relative humidity is at least 35%, place a Humidichip inside a Humiditube (AN1072) and insert into the liner bag to ensure that the minimum humidity level is met.



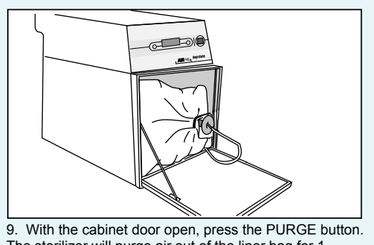
6. Remove one ampoule from the dispenser box. Unroll the plastic bag ("gas-release bag") in which it is sealed. Gently push the ampoule to the center of the gas-release bag.



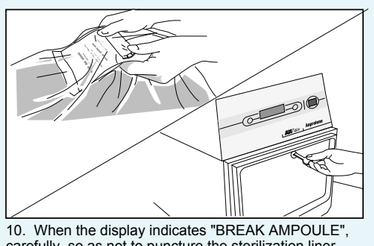
7. Place the gas-release bag in the liner bag on top of the items to be sterilized.



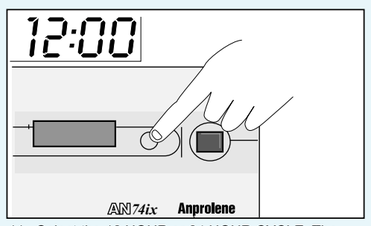
8. Insert the purge probe in the liner bag, placing the plastic ball towards the rear of the bag and the neck towards the opening. Then, gather the open end of the liner bag around the neck of the purge tube. Secure using the Velcro® strap.



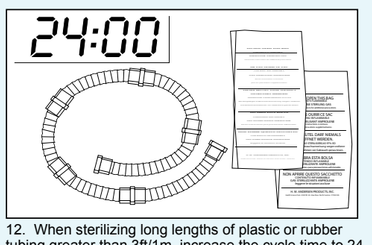
9. With the cabinet door open, press the PURGE button. The sterilizer will purge air out of the liner bag for 1 minute, 30 seconds.



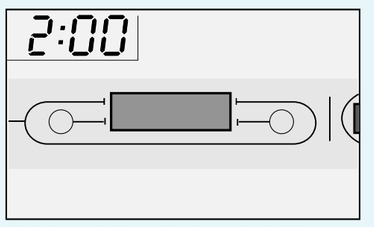
10. When the display indicates "BREAK AMPOULE", carefully, so as not to puncture the sterilization liner bag, grasp the ampoule through the sterilization liner bag and activate it by snapping off the top. **CLOSE AND LOCK DOOR**.



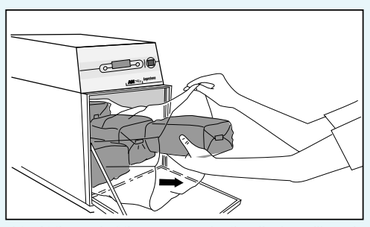
11. Select the 12 HOUR or 24 HOUR CYCLE. The display will begin counting down.



12. When sterilizing long lengths of plastic or rubber tubing greater than 3ft/1m, increase the cycle time to 24 hours. In these cases, a second ampoule may be necessary.

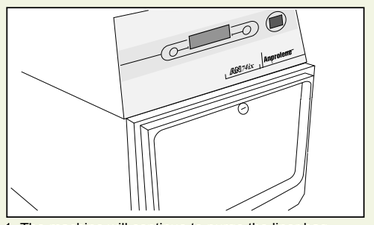


13. At the end of the sterilization cycle, the 2 hour purge phase will start and begin counting down.

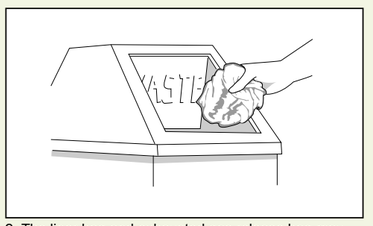


14. At the end of the purge cycle, the display will read "UNLOAD STERILIZER." The sterilizer will continue to purge the liner bag every 2 minutes until the operator unloads the sterilizer, closes the door, and presses the EXIT button.

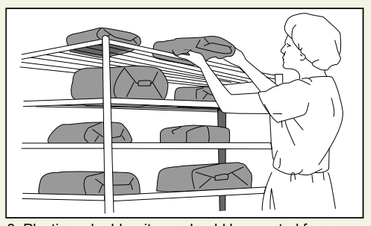
POST STERILIZATION



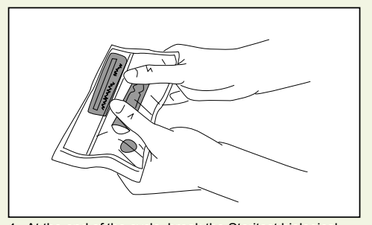
1. The machine will continue to purge the liner bag every 2 minutes until the operator unloads the sterilizer, closes the door, and presses the EXIT button. This allows for aeration within the cabinet. A timer will keep track of additional aeration.



2. The liner bag and exhausted gas release bag may be disposed of in trash. Do not re-use the liner bag.

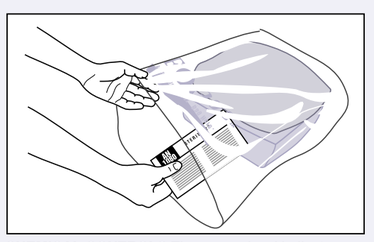


3. Plastic and rubber items should be aerated for an additional 24 hours at 68ºF or warmer before use. Metal and glass do not require additional aeration. The room utilized for aeration must have at least ten air changes per hour.

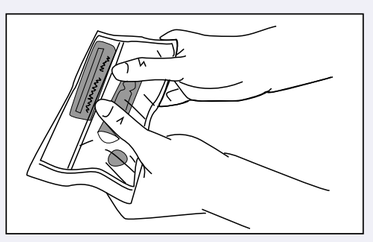


4. At the end of the cycle, break the Steritest biological control through the intact pouch, or activate self contained BI. Incubate in an AN810 and check for a color change in the culture medium at 24 and 48 hours. Please refer to complete package instructions.

CONTROLS & MONITORS

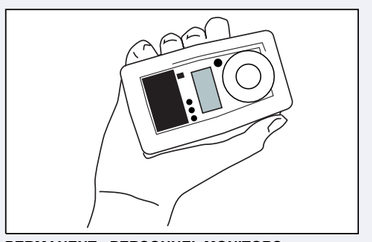


CHEMICAL CONTROLS These are visual indicators that the sterilization package has come into contact with the EtO. They do not replace BI's. Adhere a chemical indicator (AN85, AN86) to the outside of the package at Preparation - Step 9 or insert an Anprolene Dosimeter at the point of Sterilization - Step 5.



BIOLOGICAL INDICATORS (BI's) A self-contained BI (such as the AN80 Steritest, AN2200, or AN2203) should be used on a regular basis to test the procedure. It should be placed in the most challenging area of the load; Refer to Sterilization - Step 5. At the end of the cycle, incubate the culture medium in an AN810 incubator. Check for a 24 - and 48 - hour color change. BI's are sensitive to gas concentration, cycle time, and average cycle temperature. Please refer to complete instructions packaged with BI's.

SINGLE USE - PERSONNEL MONITORING Airscan® Monitors (AN91, AN92, & AN93) measure personnel exposure to airborne concentrations of EtO. The badge is worn by the operator for the prescribed time (15 minutes to obtain the STEL level or 8 hours to obtain the TWA level). Badges are sensitive to smoke, perfume, and sunlight. These may provide a false reading. Refer to complete package instructions.



PERMANENT - PERSONNEL MONITORS Available as hand-held (AN2700) EtO Monitor featuring an audible alarm when gas levels in the ambient air are too high.

Key Operator Certification and Training

Free operator training is provided for the life of the machine. Training focuses on instrument preparation, packaging, sterilizer operation and safety.

- Call for a Key Op Study Guide. (also available at www.anpro.com)
- Call Andersen Customer Service to schedule your 20 minute test.
- Key Operator Certificate provided upon completion.

To speak with an Andersen Representative, please call:

800-523-1276

After business hours, in case of emergency please call:

800-255-3924

www.anpro.com

ANPRO ANDERSEN PRODUCTS

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