ANPROLENE AN75
GAS STERILIZATION

Instructions for Hospital Use

The reusable medical device manufacturer determines the compatibility of the device with ethylene oxide, including the appropriate aeration requirements after sterilization. A resource regarding material compatibility with ethylene oxide is the current version of Annex B of AAMI TIR17, titled "Compatibility of Materials Subject to Sterilization". See Appendix H of this manual for additional information.

The sterile reprocessing area of the Hospital must be properly designed following the recommendations of the current version of ANSI/AAMI ST41 "Ethylene oxide sterilization in health care facilities: Safety and effectiveness", Section 3 (Design Considerations). See Appendix I of this manual for additional information. Specific consideration must be given to maintaining and monitoring temperature, relative humidity, and appropriate ventilation in the sterile reprocessing area.

Recommendations included in the Standard are:

1. "General work areas should have a temperature controlled between 20°C and 23°C (68°F and 73°F). The decontamination area should have a temperature controlled between 16°C and 18°C (60°F and 65°F). The temperature in sterilization access rooms should be controlled between 24°C and 29°C (75°F and 85°F) or as recommended by the equipment manufacturer."
2. "Relative humidity should be controlled between 30% and 60% in all work areas except the sterile storage area, where the relative humidity should not exceed 70%."
3. "A minimum of 10 total air exchanges per hour is recommended for areas housing EO sterilizers and aerators."

The Anprolene AN75 sterilizer must be installed in a "sterilization access room", therefore the ANSI/AAMI ST41 guidance recommends a temperature that is monitored and controlled between 24°C and 29°C (75°F and 85°F). Following this recommendation results in ideal conditions for Anprolene AN75 sterilization. However, the validation of the Anprolene AN75 sterilizer was completed at a temperature of 23°C±3°C, in other words, at a minimum temperature of 20°C (68°F). Therefore, the Anprolene AN75 sterilizer may be used in a monitored and controlled temperature between 20°C and 29°C (between 68°F and 84°F).

Devices may be sterilized in individual Tyvek® pouches or wrapped in sterilization wraps. Devices may be grouped or stacked in the sterilization bag, with or without a containment method (such as a tray or basket). Approved wrapping materials for the Anprolene AN75 sterilization system are Tyvek® Sterilization Pouches (Amcor Flexibles) and Sterisheet® Sterilization Wrap (Arjowiggins Healthcare).

After medical devices to be sterilized are cleaned, dried, and wrapped according to device manufacturers' instructions and healthcare facility protocols, they are inserted into a sterilization bag. The bag is placed inside the sterilizer with the following accessories:

1. Ethylene oxide process indicators (AN85 EO Indicator) to differentiate exposed from unexposed wrapped devices after sterilization
2. One AN87 Dosimeter, a chemical indicator that measures cumulative ethylene oxide gas exposure (confirms adequate gas concentration and time during sterilization)
3. One AN7514 cartridge containing 17.6 grams ethylene oxide
4. One biological indicator (EZTEST® Biological Indicator, SGM Biotech, Inc., Bozeman, MT) placed in the BI receptacle of the purge probe (the process challenge device for routine cycle monitoring). See the section in the manual titled "Preparing the Sterilization Bag".

The purge probe is inserted into the sterilization bag with the probe sitting on top of the load. The open end of the bag is gathered around the purge assembly and secured with the included Velcro strap. A ninety second initial purge is performed and the sterilization cycle is initiated.

After the sterilization and ventilation phases of the cycle are complete, additional aeration of gas absorbent medical devices may be required. Devices may be left inside the sterilizer after the ventilation cycle is complete for additional aeration of the sterilization load. 24 hours of additional aeration after each cycle may be selected in the supervisor setup for the sterilizer, and a count down timer will display the remaining aeration time. A count up timer on the screen displays elapsed additional aeration time after the sterilization, ventilation, and aeration (if selected) phases of the cycle are complete.

The AN87 Dosimeter should be evaluated as soon as practical after the cycle to make sure the blue line passed the triangular calibration mark. Because the AN87 Dosimeter responds to time and ethylene oxide concentration and does not respond to the other critical parameters for ethylene oxide sterilization (temperature and relative humidity), it is not a replacement for a biological indicator.

IMPORTANT - Release of sterilized reusable medical devices for patient use after each cycle in the Anprolene AN75 sterilizer is based on the successful inactivation of the EZTEST® Biological Indicator in the Andersen Anprolene SteriTest process challenge device.

CAUTION - All personnel operating the Anprolene AN75 sterilizer must be trained on the safe disposal of an inadvertently activated Anprolene gas cartridge. Instructions for the Accidental Release Containment Mechanism (ARCM) begin on page **Error! Bookmark not defined.** of this manual; these instructions should be made readily available to all users of the sterilizer.

Warnings and Cautions

CAUTION - Food and drugs may not be sterilized because ethylene oxide may change their chemical composition. A resource regarding material compatibility with ethylene oxide is Annex B of AAMI TIR17, titled "Compatibility of Materials Subject to Sterilization". See Appendix H of this manual for additional information.

If you are not certain about a particular medical device's suitability for ethylene oxide sterilization, please contact an Andersen Customer Service Representative and/or the device manufacturer.

WARNING - If the Anprolene AN75 sterilizer is not installed and operated in the manner specified by Andersen Sterilizers, the protection provided by the equipment may be seriously impaired.

ATTENTION *- Si le stérilisateur Anprolene AN75 n'est pas installé et utilisé de la manière indiquée par Andersen Sterilizers, la protection fournie par l'équipement pourrait être gravement compromise.*

WARNING - Ethylene oxide is a cancer and reproductive hazard. Refer to the SDS in Appendix D and EPA approved labeling on all Anprolene AN75 refill kits for complete instructions and warnings.

WARNING - Exposed high voltage connections are present inside the top cabinet enclosure. Only Qualified Persons may perform this work. Do NOT remove the top cover of the sterilizer until after you have first: (a) turned OFF the power switch on the rear of the sterilizer; (b) disconnected power from the sterilizer by removing the power cord from the rear of the sterilizer; and (c) have observed applicable lockout / tag out protocols.

ATTENTION – *Des connexions exposees à haute tension sont présentes à l'intérieur de l'enceinte de l'armoire supérieure. NE PAS retirer le couvercle supérieur du stérilisateur avant d'avoir : (a) désactivé l'interrupteur derrière le stérilisateur ; (b) débranché l'alimentation du stérilisateur en déconnectant le cordon d'alimentation ; et (c) observé les protocoles de lock-out et d'étiquetages.*

IMPORTANT – This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of FCC Riles. 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 – This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.

- Increase the separation between the equipment and receiver.

- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

- Consult the dealer or an experienced radio/TV technician for help.

Revision Table		
ECN	Revision	Date
2025012	3	2025-01-20