BRAND GASEOUS STERILANT FOR ROOM TEMPERATURE ATMOSPHERIC PRESSURE STERILIZATION

Instructions for using Anprolene gas ampules

1. Do not open the plastic bag in which each individual Anprolene ampule is sealed.

Each ampule of Anprolene is surrounded by a plastic break shield. The ampule and shield are sealed in a plastic bag. The plastic bag is a gas diffusion membrane of known permeability which functions by containing the gas given off by the ampule and releasing it at a controlled rate during the sterilization cycle. The plastic shield around the ampule prevents the broken glass of the opened ampule from puncturing the gas release bag.

2. Typical products which may conveniently be processed in Anprolene Sterilizers:

Respirators, corrugated tubing
Bronchoscopes, gastroscopes, fiberscopes of all kinds
Procedure trays
Catheters – plastic, rubber, cloth
Tubing – plastic, rubber, metal, glass, cloth
Anesthesia equipment – endotracheal tubes, masks, rubber tubing
Adhesive tape
Bandages, dressing sets (reuse plastic forceps)
Syringes – plastic, rubber, glass, bulb syringes
Gloves – rubber, plastic, cloth
Surgical instruments – steel, chrome plate, brass, plastic
Optical instruments – scopes, cameras, lenses, mirrors
Electrical equipment – whether autoclaveable or not
Painted equipment – metal, wood
High speed steel – drills, burs, chisels
Airways – plastic, rubber, metal
Fabric – cloth, rubber, plastic, leather
Electric wire – whether autoclaveable or not
Dry cell batteries, battery cases, bulbs
Sutures – plastic, silk, cotton, stainless steel
Thermometers, applicator sticks
Rectal tubes, douche tubes – rubber, plastic
Specula – plastic, metal

four hours. Such a chamber may be made by placing a wet surgical sponge in a liner bag with the [illegible] and twist tying the bag.

B. Water [illegible] may react with the gas and reduce its effect [illegible] items to be sterilized [illegible] Do [illegible] oven.

C. Occlusive caps, plugs or stylets must be removed [illegible] that the gas can [illegible] needles and plastic or rubber tubing must be open at both ends and free from plugs. Syringes must be packaged disassembled, with the plunger out of the barrel.

D. You must wrap all items individually, in cloth or paper, in the manner conventional for steam sterilization, or in Anpro Seal and Peel® Packaging. Anpro Seal and Peel Packaging offers a see-through, peel open, extended shelf-life package, proven to be compatible with the Anprolene [illegible].

Do not pack the liner bag so tightly with cloth or gauze that gas diffusion is slowed.

4. Sterilization method with AN70 or AN72 Anprolene Sterilizer container.

Be certain that all items have been prepared as described in paragraph 3 above. The ambient relative humidity must be at least 35% for Anprolene processing. The user must verify that this minimum exists before processing begins.

Remove one liner bag from the AN71 or AN73 dispenser box. Prepare the bag to receive the wrapped items to be sterilized by opening it and placing it in the sterilizer container with the open end out. Put the wrapped items to be sterilized inside the liner bag.

Remove one Anprolene ampule from the AN71 or AN73 dispenser box. *Do not open the plastic bag in which it is wrapped. Rather, unroll the plastic bag.* Each ampule is prescored around its neck to facilitate releasing the gas. Push the ampule gently to the center of the gas release bag. Grasp the ampule through the bag and protective shield and snap the top of the ampule. This action releases the gas within the gas release bag. Place the activated ampule, still sealed in its plastic bag, inside the liner bag with the material to be sterilized. After loading the liner bag with the gas release bag and the materials to be sterilized, press out any excess air before closing the mouth of the liner bag. If you fail to do this you may experience difficulty in closing the sterilizer due to "pillowing" of the liner bag. Twist the liner bag shut and hold it firmly shut with one of the white twist seal wire closures which are provided in the kit.

Close the sterilizer and lock the cover. The AN70 locks with the two mechanical locks on its cover, while the AN72 locks with a key. The AN72 key must be removed from the sterilizer and remain in the possession of a supervisor. This prevents unauthorized removal of goods from the sterilizer. The sterilizer must be located

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Under the Federal Insecticide, Fungicide and Rodenticide Act for pesticide registered under EPA Reg. No. 9411

PPM ETHYLENE OXIDE (8 Hour Time-Weighted Average).

Aerate the gas absorbent items for at least 24 hours before use (see paragraph 7: Precautions).

After the sterile material has been removed from the liner bag, the used ampule and its bag may be disposed of in ordinary rubbish.

5. Sterilization method using the AN72V ventilated sterilizer container.

Be certain that all items have been prepared as described in paragraph 3 above. The ambient relative humidity must be at least 30% for Anprolene processing. The user must verify that this minimum exists before processing begins.

Remove one liner bag from the AN71 or AN73 dispenser box. Make the bag ready to receive the wrapped items to be sterilized by opening it and placing it in the sterilizer container with the open end out. Put the wrapped items to be sterilized inside the liner bag.

Remove one Anprolene ampule from the AN71 or AN73 dispenser box. *Do not open the plastic bag as such it is wrapped. Rather, unroll the plastic bag.* Each ampule is prescored around its neck to facilitate releasing the gas. Push the ampule gently to the center of the gas release bag. Grasp the ampule through the bag and protective shield and snap the top of the ampule. This action releases the gas within the gas release bag. Place the activated ampule, still sealed in its plastic bag, inside the liner bag with the material to be sterilized. After loading the liner bag with the gas release bag and the materials to be sterilized, press out any excess air before closing the mouth of the liner bag. If you fail to do this, you may experience difficulty in closing the sterilizer due to "pillowing" of the liner bag. Put the small plastic purge tube into the mouth of the liner bag. Using one of the white wire closures provided in the Anprolene box, twist tie the liner bag around the purge tube. Close the sterilizer and lock the cover with the key provided. The key must be removed from the sterilizer and remain in the possession of a supervisor. This prevents unauthorized removal of goods from the sterilizer.

Turn the ventilator on and the purge pump off.

DO NOT OPERATE THE PURGE PUMP DURING THE 12 HOUR STERILIZATION CYCLE. FAILURE TO HEED THIS WARNING WILL RESULT IN AN UNSTERILE LOAD.

The temperature of the room must be maintained at no less than 68°F. (20° C.) during the sterilization cycle.

At the end of the twelve-hour sterilization cycle, turn the purge pump on. Leave the ventilator on. Purge the liner bag for 2 hours before opening the sterilizer and removing the sterile items.

FAILURE TO OBSERVE THE ABOVE INSTRUCTIONS MAY EXPOSE THE STERILIZER OPERATOR TO MORE THAN 0.5 PPM ETHYLENE OXIDE (8 Hour Time-Weighted Average).

Aerate the gas absorbent items for at least 24 hours before use (see paragraph 7: Precautions).

After the sterile material has been removed from the liner bag, the used ampule and its bag may be disposed of in ordinary rubbish.

6. Special Problems.

When sterilizing long lengths of plastic or rubber tubing, such as ureteral catheters, heart catheters and coils of drainage tubing, use two ampules and increase the cycle time to 24 hours.

7. PRECAUTIONS.

DANGER: EXTREMELY FLAMMABLE. KEEP OUT OF REACH OF CHILDREN.

Anprolene gas is extremely flammable. Do not use it near fire, heated surfaces, or flame. Do not smoke near the container while loading and unloading it. Remove batteries from electrical instruments being sterilized in Anprolene and wrap them separately to avoid the possibility of an electrical spark igniting the gas during the sterilization cycle.

Never open the container during the sterilization cycle. Avoid breathing Anprolene vapor. Breathing Anprolene vapor is harmful. Anprolene sterilizing gas, in concentrated amounts, is as irritating to the lungs and mucous membranes as is ammonia gas. Like many other chemical vapors, Anprolene has the potential to cause an allergic response in a sensitive individual. Such individuals should not handle Anprolene, and should neither breathe its vapors nor allow materials sterilized in it to come in contact with their skin or mucous membranes.

All users must avoid contact of Anprolene with skin, eyes and clothing. If contact with liquid Anprolene occurs, users must immediately remove all contaminated clothing, including shoes. Flush skin or eyes with plenty of water for at least fifteen minutes. If liquid Anprolene has come in contact with your eyes, see a physician immediately for further treatment.

Failure to adequately air gas absorbing materials may lead to contact chemical burns. All items that may contact living tissues must be aired for 24 hours, at a minimum temperature of 68° F. (20° C.), before being used. Items such as plastic instruments, foam rubber, plastic foams, vinyl tubing, rubber tubing, plastic items, rubber items and sealed air cushioned devices, like some anesthesia masks, must be aired. Instruments need not be removed from cloth or paper wrappings to obtain adequate diffusion of the residual Anprolene vapors.

It is incumbent on the user to determine appropriate aeration parameters for gas absorbent items intended to contact tissue culture, microbial cell culture, spermatocytes, oocytes, embryonic tissue, or the like.

To minimize operator exposure to ethylene oxide vapors and to shorten the above quoted aeration times, use a heated aerator. H. W. Andersen Products, Inc. offers the AN78 Anprolene Aerator to speed aeration. For appropriate aeration times using a heated aerator, consult the manual accompanying the aerator.

Microorganisms and spores which are vacuum dehydrated, crystallized in salt, chemically desiccated, or dried by prolonged exposure to ambient relative humidity below 30% may become highly resistant to sterilization by Anprolene. Rehydration of organisms so changed, and hence reversion to normal sensitivity, occurs only when they have been actually wetted or placed in a 100% relative humidity atmosphere. Do not attempt to sterilize materials which may be carrying dried microorganisms without first scrubbing the articles with water and soap or detergent. If the nature of the material is such that immersion in water is harmful, then pretreatment in a chamber having a saturated humidity and a temperature of at least 68° F. (20° C.) is required for at least four hours.

Anprolene is a potent polymerizing agent. It must not be used for sterilizing foodstuffs or drugs because it may chemically change them in an detrimental manner.

It is absolutely essential that reliable forced ventilation be employed in the room in which the Anprolene Sterilizer is used. This system must be capable of ten air changes per hour, so that operator exposure remains within U.S. government permissable exposure limits.

In a room where the adequacy of ventilation is doubtful, either an AN72V ventilated sterilizer container or an AN77 Anprolene Ventilation Hood or another appropriate ventilation hood, properly connected to the outside, must be used to reduce operator exposure. Such ventilation devices must be tested for efficacy, and serviced at the sterilizer site at least once a year. If you cannot arrange for this locally, you may contact H. W. Andersen Products, Inc. at 1-800-523-1276 for advice regarding testing and service. Nylon and polyester film are virtually impervious to ethylene oxide. The only all-plastic, waterproof wrapping material proven compatible with Anprolene is our Seal and Peel brand pouches. Do not use any other plastic film to wrap items to be sterilized in Anprolene

8. IMPORTANT — The user must not deviate from these instructions.

Do not be fooled by the Anprolene Sterilizing System's apparent simplicity. Its reliable use depends on your adhering precisely to these instructions. AN71 and AN73 Anprolene ampules are designed to be used only in the AN70, AN72 and AN72V Anprolene Sterilizers with the liner bags and twist seals supplied in the refill dispenser. No other container may be used, no matter how similar it seems. You must use a genuine fresh Anprolene liner bag with each load.

9. Technical description of the system.

The Anprolene Sterilizer container serves as a guard against inadvertent ignition of the contents by spark or open flame during the sterilization cycle. In the case of the AN72V sterilizer, the container also serves as a ventilation hood. The liner bag, when properly twist closed, has a 7 liter capacity. It serves as a second gas diffusion membrane, retaining Anprolene long enough to sterilize its contents. Each ampule releases approximately 3.8 grams of Anprolene at room temperature (68° F., 20° C.) and sea level atmospheric pressure. The AN71/73 ampule produces a *minimum* peak concentration within the liner bag of 500 mg/1,000 cc. Tests in our laboratory confirm that this dose will kill the most resistant spores known within the 12-hour cycle, providing they have been rehydrated according to our instructions

10. Storage — Shelf Life.

Anprolene must be stored in a cool place out of direct sunlight. Under normal conditions its shelf life will exceed one year. As long as the material in the ampule is liquid at 68° F. (20° C.), it is sufficiently potent to use.

11. Testing the Efficacy of the Anprolene Sterilizer.

Monitoring sterilization efficacy is extremely important. It is strongly recommended that the user establish a routine for monitoring each cycle. A color change chemical indicator, such as the Anpro AN87 Dosimeter®, placed in the most inaccessible part of the load, will indicate whether or not the gaseous sterilant

penetrated to the core of the load in adequate concentration to assure sterilization. In addition, an appropriate biological control, such as the Anpro AN80 Steritest®, should be used at least once per month to challenge the procedure. It is sensitive to the gas concentration, cycle time and average cycle temperature.

Active ingredient: Ethylene oxide	84%
Inert ingredients:	16%
Net contents each ampule	0.16 av. oz.

Anprolene® Modular Sterilizing System

AN71	Anprolene 25-Ampule Refill Dispenser: use with AN70, or AN72 Sterilizers (includes 25 5cc ampules of Anprolene Sterilizing Gas)
AN72	Anprolene Tray Kit (includes 1 AN73)
AN72V	Ventilated Anprolene Tray Kit with manual cycle controls (includes 1 AN71)
AN73	Anprolene 60-Ampule Refill Dispenser: use with AN70, or AN72 Sterilizers (includes 60 5cc ampules of Anprolene Sterilizing Gas)
AN74	Anprolene High Capacity Sterilizer (includes 1 AN79)
AN74A	Anprolene High Capacity Sterilizer — ventilated sterilizer with automatic cycle timer (includes 1 AN79)
AN74V	Anprolene High Capacity Sterilizer — ventilated sterilizer with manual controls (includes 1 AN79)
AN76	Anprolene Remote Control Accessory (for use with AN72V, AN74V and AN74A sterilizers)
AN77	Anprolene Hood
AN78	Anprolene Aerator Cabinet
AN79	Anprolene 20-Ampule Refill Dispenser. Use with AN74 series Sterilizers only (includes 20 20cc ampules of Anprolene Sterilizing Gas)
AN80	Steritest® biological and chemical controls
AN85	Anprolene Exposure Indicator Strips
AN87	Anprolene Dosimeter®
AN90	Seal and Peel® Electric Impulse Sealer
AN820	2" by 200' Seal and Peel Roll Stock
AN830	3" by 200' Seal and Peel Roll Stock
AN850	5" by 200' Seal and Peel Roll Stock
AN870	7" by 200' Seal and Peel Roll Stock

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