AN 73

ONE BOX **CONTENTS: 60 Ampules, 60 Liner Bags, 60 Closures**

ANPROLENE®

STERILIZING GAS AMPULES

Active ingredient: Ethylene oxide 84% (by weight)
Inert ingredients: 16% (by weight)
Net contents 60 ampules, 0.16 av. oz. each ampule

DANGER **EXTREMELY FLAMMABLE**

Contains liquid and gas under pressure. Do not use near fire, heated surfaces, or flame. Breathing vapor is harmful.

READ INSERT INSTRUCTIONS & PRECAUTIONS BEFORE USING.

Avoid breathing vapor. Causes irritation of nose, throat, eyes and skin. Avoid contact with skin, eyes and clothing. In case of contact, immediately remove all contaminated clothing and flush affected areas with water. For eyes, get medical attention.

USE ONLY IN ANPROLENE STERILIZER

IMPORTANT:
FOR PROFESSIONAL USE ONLY

■ Air gas sorbent materials before using them ■ Use only in Anprolene Sterilizers ■ Store in a cool place out of direct sunlight ■ Disposal: Do not reuse empty box. Wrap box in newspaper and discard in trash.

ANPRO® ANDERSEN PRODUCTS

P/N 683 REV F 06/01/90

H.W. Andersen Products, Inc.
Health Science Park • P.O. Box 1050 • Chapel Hill, NC 27514 USA

AN 73

ANDERSEN PRODUCTS

ONE BOX

CONTENTS: 60 AMPULES • 60 LINE

ANPROLE

STERILIZING GAS AMPULES

IMPORTANT: FOR PROFESSIONAL USE ONLY.

- *AIR GAS SORBENT MATERIALS BEFORE USING THEM*
- *USE ONLY IN ANPROLENE STERILIZERS*
- *STORE IN A COOL PLACE OUT OF DIRECT SUNLIGHT*
- *DISPOSAL: DO NOT REUSE EMPTY BOX. WRAP BOX IN NEWSPAPER AND DISCARD IN TRASH*

Active ingredient: Ethylene oxide..... 84% (by weight)
Inert ingredients..... 16% (by weight)
Net contents 60 ampules, 0.16 av. oz. each ampule

EPA REGISTRATION NO 9417-1 EPA ESTABLISHMENT NO 9417-MC-001

EXTREM

Contains liquid and gas under pres flame. Breathing vapor is harmful.

READ INSERT INSTRUCTIO

Avoid breathing vapor. Causes irri contact with skin, eyes and clothin contaminated clothing and flush a attention.

MANUFACTURED BY H.W. ANDERSEN PRODUCTS

ACCEPTED
JAN 14 1991
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 9417-1

AN71-AN73

ANPROLENE[R]

BRAND GASEOUS STERILANT
FOR ROOM TEMPERATURE,
ATMOSPHERIC PRESSURE STERILIZATION

FOR USE IN VENTILATED ANPROLENE STERILIZERS ONLY

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 whose function it is to contain the gas given off by the ampule and to release 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, 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, burrs, 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

3. Preparation of Materials for Sterilization.

Materials to be sterilized by Anprolene must first be meticulously

cleaned and towel-dried. Coating of dry protein, such as dry pus, blood, or feces, protect microorganisms and slow the sterilization process. To prevent this possibility, and to be certain that your system meets the highest standard of sterilization, you must:

A. Disassemble and scrub all instruments in detergent and water to the most critical standard of cleanliness possible.

If an item cannot be washed in detergent and water, then presterilization humidification is required. This pretreatment must be done in a chamber having 100% relative humidity at a temperature of at least 68°F (20°C) for at least four hours. Such a chamber may be made by placing an AN1071 Humidichip™ into a liner bag with the item and closing the bag with a twist-tie.

B. Water on instruments at the time of exposure to Anprolene may react with the gas and reduce its effectiveness. Be sure that items to be sterilized are dry before wrapping and processing. Drain or towel-dry instruments. Do not dry them in a hot-air oven.

C. Occlusive caps, plugs, or stylets must be removed from instruments so that the gas can penetrate freely. Hollow-bore needles and plastic or rubber tubing must be open at both ends and free from plugs. Syringes must be packaged disassembled, with the plunger removed from the the barrel.

D. You must wrap all items individually, in cloth or paper, in a manner conventional for steam sterilization, or in Anpro® Seal & Peel® Packaging. Anpro Seal & Peel is a transparent, peel-open, extended shelf-life packaging, proven to be compatible with the Anprolene Sterilizing System.

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

4. Sterilization Method with the AN70 or AN72 Anprolene Sterilizer and the AN77 Ventilation Hood.

Be certain that all items have been prepared as described in section 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.

Turn on the AN77 Ventilation Hood. 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 into the sterilizer container, open end out. Put the wrapped items to be sterilized into 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. Push the ampule gently to the center of the gas-release bag. While holding the gas-release bag away from the face and eyes, grasp the ampule through the bag and protective shield and snap the top of the ampule. Each ampule is prescored around its neck to facilitate this action. Snapping off the top of the ampule activates it, i.e., releases the sterilant gas within the gas-release bag. Immediately place the activated ampule, still sealed in its plastic bag, inside the liner bag along with the material 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 closed and hold it firmly shut with one of the white twist-seal wire closures provided in the Anprolene kit.

Close and lock the sterilizer. The AN70 locks with the two mechanical locks on its cover, while the AN72 locks with a key. The key must be removed from the AN72 sterilizer and remain in the possession of a supervisor to prevent unauthorized removal of goods during the sterilization cycle. The sterilizer must be located in a clean, well-ventilated area, away from sparks or flame. The temperature of the room must be maintained at no less that 68°F (20°C).

At the end of the twelve-hour cycle, unlock the sterilizer. Remove the twist seal from the liner bag and open it. Leave the opened liner bag and wrapped items in the ventilation hood for an additional fifteen minutes before removing them. This procedure allows residual gas in the liner bag to dissipate before the products are handled.

FAILURE TO OBSERVE THE ABOVE INSTRUCTIONS MAY EXPOSE THE STERILIZER OPERATOR TO MORE THAN 0.5 PPM ETHYLENE OXIDE (The OSHA Established Action Level Measured as an Eight-Hour Time-Weighted Average).

Aerate gas-absorbent items for at least 24 hours prior to use (see section 7: Precautions).

After the sterile materials have been removed from the liner bag, the exhausted and empty gas-release ampule and its bag may be disposed of in ordinary rubbish.

5. Sterilization Method Using the AN72C or AN72V Ventilated Anprolene Sterilizer.

Be certain that all items have been prepared as described in section 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. Prepare the bag to receive the wrapped items to be sterilized by opening it and placing it into the sterilizer container, 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.* Push the ampule gently to the center of the gas-release bag. While holding the gas-release bag away from the face and eyes, grasp the ampule through the bag and protective shield and snap the top of the ampule. Each ampule is prescored around its neck to facilitate this action. Snapping off the top of the ampule activates it, i.e., releases the sterilant gas within the gas-release bag. Immediately the activated ampule, still sealed in its plastic bag, inside the liner bag along with the material 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. Locate the flexible, plastic purge tube that protrudes into the interior of the sterilizer tray. Place the purge tube into the mouth of the liner bag. Using one of the white, wire closures provided in the Anprolene kit, twist-tie the liner bag around the purge tube.

Close and lock the sterilizer. The key must be removed from the sterilizer and remain in the possession of a supervisor to prevent unauthorized removal of goods during the sterilization cycle.

Turn the ventilator on. If you are using an AN72V sterilizer, be sure that the purge pump is turned off. If you are using an AN72C sterilizer, press the CYCLE START button.

DO NOT OPERATE THE (AN72V) PURGE PUMP DURING THE TWELVE-HOUR STERILIZATION CYCLE. FAILURE TO HEED THIS WARNING WILL RESULT IN AN UNSTERILE LOAD.

The sterilizer must be located in a clean, well ventilated area, away from sparks or flame. 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, the AN72C will automatically begin a two-hour purge cycle and a green indicator light will signal when you may open the sterilizer and remove the load. If you are using an AN72V, turn the purge pump on and purge the liner bag for two 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. The OSHA Established Action Level, Measured as an Eight-Hour Time-

Weighted Average).

Aerate gas-absorbent items for at least 24 hours prior to use (see section 7: Precautions).

After the sterile material has been removed from the liner bag, the exhausted and empty gas-release 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 double the cycle time.

If you are using an AN70 or AN72 sterilizer in an AN77 Ventilation Hood, increase the cycle time to 24 hours. (Be sure to permit residual sterilant gas to dissipate from the liner bag for fifteen minutes before removing the sterile items at the end of the cycle.) If you are using an AN72V sterilizer, increase the cycle time to 24 hours, and purge the liner bag for two hours. With an AN72C, load the sterilizer with the items for sterilization and the two activated gas-release bags, but then wait twelve hours before pushing the START button. Before loading the sterilizer, be sure that the ventilator is running. The ventilator must continue to run during the entire augmented cycle.

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. When sterilizing battery-operated instruments, remove the batteries and wrap them separately to avoid the possibility of an electrical spark igniting the gas during the sterilization cycle.

Never open the sterilizer 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, neither should they breathe its vapors or allow materials sterilized in it to come in contact with their skin or mucous membranes.

All users must avoid allowing Anprolene to contact skin, eyes, and clothing. If contact with liquid Anprolene occurs, the user must

immediately remove all contaminated clothing, including shoes. Flush skin or eyes copiously with 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 at least 24 hours, at a minimum temperature of 68°F (20°C), prior to use. Items such as plastic instruments, foam rubber, plastic foams, vinyl tubing, rubber tubing, plastic items, rubber items, and sealed air-cushioned devices (for instance, 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 upon the user to determine appropriate aeration parameters for gas-absorbent items intended to contact tissue cultures, microbial cell cultures, spermatocytes, oocytes, embryonic tissue, or the like.

To minimize operator exposure to ethylene-oxide vapors, and to shorten the aeration times quoted above, use a heated aerator. For this purpose, H.W. Andersen Products, Inc. offers the AN78 Anprolene Aerator. Consult the manual accompanying the aerator for aeration times appropriate when using a heated 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, hence reversion to normal sensitivity, occurs only when the organisms have been actually soaked in water or treated in an atmosphere of 100% relative humidity. Do not attempt to sterilize materials which may be carrying dried microorganisms without first scrubbing the articles with water and soap or detergents. 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.

Nylon and polyester films are virtually impervious to ethylene oxide. The only all-plastic, waterproof wrapping material proven compatible with Anprolene is our Seal & Peel brand roll stock. Do not use any other plastic film to wrap items to be sterilized in Anprolene.

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

It is absolutely essential that reliable forced ventilation be

employed in the room where 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 permissible exposure limits.

Either an AN72C or an AN72V ventilated sterilizer or an AN70 or AN72 used with an AN77 Anprolene Ventilation Hood or another appropriate ventilation hood, properly connected to the outside, must be used to assure the operator is not exposed to toxic levels of ethylene oxide. Such ventilation devices must be tested for efficacy and serviced at the sterilizer site at least once a year. Contact H.W. Andersen Products, Inc. at 1-800-523-1276 for advice regarding testing and service of these devices.

Note: the AN70, AN72, AN72V, AN74, AN74V, and AN74A Anprolene Sterilizers, as well as the AN77 Anprolene Ventilation Hood, are no longer available. Instructions for their use are included here to accommodate the existing user. It is the responsibility of the user to upgrade the non-ventilated AN70, AN72, and AN74 Anprolene sterilizers to current safety standards. The user should be aware that local or state regulations may forbid the use of Anprolene sterilizers not having an integral ventilation and purge unit.

8. IMPORTANT - The User Must Not Deviate from these Instructions.

Do not be fooled by the apparent simplicity of the Anprolene Sterilizing System. Its reliable use depends upon precise adherence to these instructions. AN71 and AN73 Anprolene ampules are designed to be used only in the AN70, AN72, AN72C, 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. Liner bags must not be reused: use only 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 a spark or open flame during the sterilization cycle. In the case of the AN72C and AN72V sterilizers, the container also serves as a ventilation hood. When using the AN70 and AN72 sterilizers, a separate AN77 Ventilation Hood is required. The liner bag, when properly closed with a twist-tie, has a 7 liter capacity. It is a second gas-diffusion membrane that serves to retain Anprolene long enough to sterilize its contents and releases it into the surrounding vent hood at a rate slow enough to ensure that toxic levels are not reached in a properly ventilated room. Each ampule releases approximately 3.8 grams of Anprolene at room temperature (68°F/20°C) and sea-level atmospheric pressure. The AN71/AN73 ampule produces a *minimum* peak concentration within the liner bag of 500 mg/1000 cc. Tests in our laboratory confirm that this dose will kill the most resistant spores known within the twelve-hour cycle,

providing they have been rehydrated according to instructions (see section 3A: Preparation of Materials for Sterilization).

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. The AN80 Steritest 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

Anpro®, Anprolene®, Dosimeter®, Humidichip™, Seal & Peel®, and Steritest® are trademarks of H.W. Andersen Products.

Manufactured by

H.W. Andersen Products, Inc.
Health Science Park
Box 1050-Chapel Hill, NC 27514 USA

EPA Registration No. 9417-1 EPA Establishment No. 9417-NC-001

ACCEPTED

JUN 4 1991

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 9417-1