

ONE BOX

CONTENTS: 20 AMPULES • 20 LINER

ANPROL

STERILIZING GAS AM

IMPORTANT: FOR PROFESSIONAL USE ONLY.

- AIR GAS SORBENT MATERIALS BEFORE USING THEM.
- USE ONLY IN ANPROLENE STERILIZER AN-74.
- STORE IN A COOL PLACE.
- DISPOSAL — DISCARD USED AMPULE IN ORDINARY RUBBISH.

Net contents each ampules	0.64 av. oz.
Active ingredient ethylene oxide	97%
Inert ingredients	3%

EPA REGISTRATION NO. 9417-3

3-14-73
9417-3

BOX

CONTENTS: 20 AMPULES • 20 LINER BAGS • 20 CLOSURES

ANPROLENE®

STERILIZING GAS AMPULES

IMPORTANT: FOR PROFESSIONAL USE ONLY.

USE WITH GAS SORBENT MATERIALS BEFORE USING THEM.

USE ONLY IN ANPROLENE STERILIZER AN-74.

STORE IN A COOL PLACE.

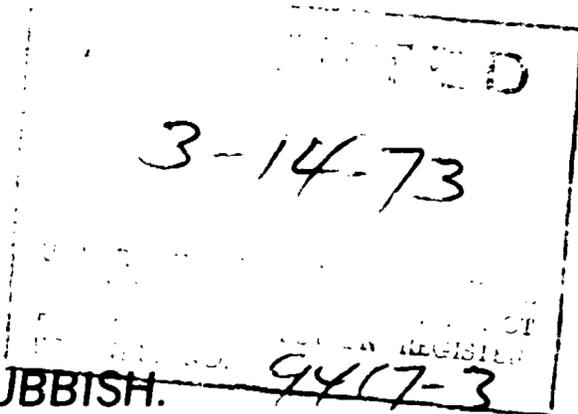
DISPOSAL — DISCARD USED AMPULE IN ORDINARY RUBBISH.

Contents each ampules 0.64 av. oz.

Active ingredient ethylene oxide 97%

Inert ingredients 3%

REGISTRATION NO. 9417-3



DANGER

EXTREMELY FLAMMABLE

KEEP AWAY FROM HEAT, SPARKS AND FLAME

READ INSERT INSTRUCTIONS AND PRECAUTIONS BEFORE USING.

Avoid prolonged or repeated exposure to vapors. 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.

Manufactured by

H. W. ANDERSEN PRODUCTS, INC.

45 East Main Street, Oyster Bay, New York 11771

U.S.A. Patents 3,476,506 3,505,775 3,552,083

Foreign Patents Issued and Pending.

IMPORTANT

DO NOT OPEN THIS BAG

ANPROLENE[®]
STERILIZING GAS

NET CONTENTS EACH AMPULES	0.64 AV. OZ.
ACTIVE INGREDIENT ETHYLENE OXIDE	97%
INERT INGREDIENTS	3%

DANGER

CONTENTS EXTREMELY FLAMMABLE

USE ONLY IN ANPROLENE STERILIZER AN-74

**READ INSERT INSTRUCTIONS
AND DISPENSER BOX LABEL
FOR ADDITIONAL PRECAUTIONS
BEFORE USING**

**DISCARD USED AMPULE
IN ORDINARY RUBBISH**

3-14-73

94123

**AN
79**

ONE BOX CONTENTS 20 AMPULES 20 LINER BAGS 20 CLOSURES

ANPROLENE®

STERILIZING GAS AMPULES

Net contents each ampule	0.64 av. oz.
Active ingredient ethylene oxide	97%
Inert ingredients	3%

DANGER

EXTREMELY FLAMMABLE

KEEP AWAY FROM HEAT, SPARKS AND FLAME

USE ONLY IN ANPROLENE STERILIZER AN-74



3-14-73
FEDERAL BUREAU OF INVESTIGATION
U.S. DEPARTMENT OF JUSTICE
FOLSON REGISTERED
9447-3

H. W. ANDERSEN PRODUCTS, INC.

45 East Main Street, Oyster Bay, New York 11771

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Foreign Patents Issued and Pending EPA Reg. No. 9447-3

**AN
79**

ONE BOX CONTENTS 20 AMPULES 20 LINER BASES 20 STERILIZER

ANPROLENE

STERILIZING GAS AMPULES

Net content Each ampule 0.04 ml
Active ingredient ethylene oxide 97%
Inert ingredients 3%

DANGER

EXTREMELY FLAMMABLE

KEEP AWAY FROM HEAT, SPARKS AND FLAME

USE ONLY IN ANPROLENE STERILIZER

ANPRO

H. W. ANDERSEN PRODUCTS, INC.

45 East Main Street, Oyster Bay, New York 11771

U.S.A. Patents 3,476,506 3,505,775 3,552,083

Foreign Patents Issued and Pending. EPA Reg. No. 9417-3

Anprolene®

Gas diffusion membrane ("Liner Bag").

USE ONLY IN ANPROLENE STERILIZER
AN-74.

IMPORTANT:

The gas within this membrane may be flammable. Keep away from spark and open flame.

Do not open this Liner Bag before the recommended 12 hour cycle time has elapsed.

Failure to adequately air gas absorbing materials may lead to contact chemical burns. Plastic, rubber and other gas absorbing products intended for use in contact with the human body or to be implanted in the human body, must be aired for 24 hours outside of this membrane before use.



AN79

ANPROLENE®

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 has a plastic shield around the ampule. The ampule and shield are sealed in a plastic bag. The plastic bag is a gas diffusion membrane of known permeability whose function is to contain the gas given off by the ampule and release it at a controlled rate during the sterilization cycle. The plastic shield around the ampule prevents broken glass from the opened ampule from puncturing the gas release bag.

2. Typical products which may conveniently be processed in the AN-74 Anprolene Sterilizer.

Respirators, Corrugated tubing
Bronchoscopes, Gastrosopes
Procedure Trays
Catheters-Plastic, rubber, cloth
Tubing—plastic, rubber, metal, glass, cloth
Anesthesia equipment—endotracheal tubes, masks, rubber tubing
Tape (a common source of cross infection)
Bandages, dressing sets (re-use 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, tongue depressors, applicator sticks
Rectal tubes, douche tubes—rubber, plastic
Specula—plastic, metal

3 Preparation of material for sterilization

Material to be sterilized by Anprolene must be surgically clean and dry. Coatings of dry protein, like dry pus, blood or feces protect microorganisms and slow the sterilization process. Washing contaminated instruments with detergent and water prior to exposure to Anprolene rehydrates desiccated spores and is strongly recommended as a routine procedure. If the nature of the material is such that the water treatments specified above are harmful, then a pretreatment in a chamber having a saturated humidity will be necessary for an overall pretreatment routine of at least one hour. (See also Paragraph 6 "Precautions.")

Although Anprolene is a highly dependable gaseous sterilant, nevertheless, occlusive caps, pliers or styles must be removed from instruments so that the gas can penetrate to the tip. Do not pack instruments in a chamber.

8. 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. The liner bag, when properly twist closed, has a 35 liter capacity. It serves as a second gas diffusion membrane, retaining Anprolene long enough to sterilize its contents and then diffusing it into the surrounding room air at a slow enough rate to insure that toxic levels are not reached in the room. Each ampule releases approximately 19 grams of Anprolene at room temperature (68°F., 20°C.) and sea level atmospheric pressure. The AN-79 ampule produces a minimum peak concentration within the liner bag of 500 mgm./1,000 cc. Tests in our laboratory confirm that this configuration will kill the most resistant spores known (providing they have not been desiccated) within the 12 hour cycle.

9. Storage — Shelf Life.

Anprolene must be stored in a cool place out of direct sunshine. 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.

contents each ampule	0.64 av. oz.
Active ingredient ethylene oxide	97%
Inert ingredients	3%

Anprolene® Modular Sterilizing System

- AN-70 Anprolene Cylinder Kit (Includes 1 AN-71)
- AN-71 Anprolene 25 Ampule Refill Dispenser
- AN-72 Anprolene Tray Kit (Includes 1 AN-73)
- AN-73 Anprolene 60 Ampule Refill Dispenser
- AN-74 Anprolene Giant Size Sterilizer (Includes 1 AN-79)
- AN-75 Anprolene 60 Ampule Refill Dispenser (Use with AN-74 only)
- AN-78 Anprolene Aerator Cabinet
- AN-79 Anprolene 20 cc. Ampule Refill Dispenser (Use with AN-74 only)
- AN-80 Steritest™ Biological and Chemical Anprolene Sterilizer Control
- AN-82 2" by 200" Seal and Peel™ Roll Stock
- AN-83 3" by 200" Seal and Peel Roll Stock
- AN-85 Anprolene Exposure Indicator Strips
- AN-87 7" by 200" Seal and Peel Roll Stock
- AN-90 Seal and Peel Electric Impulse Sealer
- AN-92 2" by 20" Seal and Peel Packaging Pouches
- AN-93 3" by 20" Seal and Peel Packaging Pouches
- AN-97 7" by 20" Seal and Peel Packaging Pouches

Anprolene is a registered trademark of H. W. Andersen Products, Inc.

Anprolene is patented in

U.S.A. 3,476,101, 3,538,775 & 3,552,083	Italy 800,999
Argentina 167,939	Mexico 104,930
Belgium 679,293	New Zealand 144,583
Canada 791,915	Pakistan 117,277
France 1,475,394	South Africa 169,066
Great Britain 1,138,512 & 1,138,513	Spain 325,170
India 164,576	Sweden 337,282
	Switzerland 460,253

Other Patents Pending

H. W. ANDERSEN PRODUCTS, INC.
45 EAST MAIN ST. OYSTER BAY, N. Y. 11771
516-922-5100

with cloth or gauze that gas diffusion is slowed. Hollow bore needles and plastic or rubber tubing must be open and free from plugs. Syringes must be packaged disassembled with their plungers out of the barrel.

Water on instruments at the time of exposure to Anprolene may react with it and reduce its effectiveness. Be sure that items to be sterilized are dry before wrapping and processing.

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 and controlled to be compatible with the Anprolene Sterilizing System.

4. Sterilization method with AN-74 Anprolene Sterilizer.

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 gusseted liner bag from the AN-79 dispenser box, open it up ready to receive the wrapped items to be sterilized and place it in the AN-74 sterilizer open end out. Place the wrapped items to be sterilized inside the liner bag.

Remove one large size Anprolene ampule from the AN-79 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. Grasp the ampule through the bag and protective shield and snap the top of the ampule. This action releases the gas within the ampule. Place the activated ampule, still wrapped in its sealed plastic bag, inside the liner bag on top of the material to be sterilized. After loading the liner bag with the gas release bag and the materials to be sterilized, it is advisable to press any excess air out of the liner bag before closing the mouth of the liner bag. If you fail to do this, you may experience difficulty in closing the AN-74 container due to "pillowing" of the liner bag.

Twist the liner bag shut and hold the seal with one of the twist seal closures which are provided in the kit.

Close the door of the AN-74 Sterilizer and turn the time lock in a clockwise fashion for one complete revolution. By doing so, the sterilizer door is locked for a period of 12 hours and it is impossible to interrupt the sterilization cycle without permanently damaging the time lock.

The AN-74 Sterilizer must be located in a bacteriologically clean, well ventilated area, away from flame or spark. Room temperature must be at least 68 F (20 C). The position of the time lock at any given time during the cycle will indicate the amount of time remaining before the 12 hour sterilization cycle is complete.

At the end of the 12 hour cycle the time lock will release automatically and the AN-74 Sterilizer may be opened. Remove the twist seal from the liner bag and open it. Allow five minutes for the diffusion of any residual free gas and then remove the sterilized materials.

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.

5 Special Problems.

When sterilizing long lengths of plastic or rubber tubing, for example, Ureteral Catheters, Heart Cath-

ters, I.V. Extension Tubes, increase the cycle time to 24 hours.

6. PRECAUTIONS.

DANGER: KEEP OUT OF REACH OF CHILDREN.

Anprolene gas is extremely flammable, keep away from heat, sparks and flame. Do not smoke near the container while loading or 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.

Keep container closed, avoid breathing Anprolene vapor. In concentrated amounts Anprolene sterilizing gas is as irritating to the lungs and mucus membranes as is ammonia gas. As with other chemical vapors, there is a chance of an occasional allergic response to Anprolene in a sensitive individual. Such individuals should not handle Anprolene, nor breathe its vapors nor allow materials sterilized in it to come in contact with their skin or mucus membranes. All users should avoid contact with skin, eyes and clothing. If contact with liquid Anprolene occurs, users should immediately remove all contaminated clothing, including shoes. Flush skin or eyes with plenty of water for at least fifteen minutes. For eyes get medical attention.

Failure to adequately air gas absorbing materials may lead to contact chemical burns. Foam rubber, plastic foams and sealed air cushioned devices like some anesthesia masks must be aired 24 hours before use. Gas absorbing materials, like rubber or plastic, which are to be implanted or used on or in the human body should be aired 24 hours before use. It is not necessary to remove such material from cloth or paper wrappings to obtain adequate diffusion of the residual Anprolene vapors.

The above aeration times can be shortened by using a heated aerator. For appropriate aeration times using a heated aerator consult the manual accompanying the aerator.

Vacuum dehydration, chemical desiccation or prolonged exposure to ambient relative humidity below 30% have been demonstrated to produce spores highly resistant to sterilization by Anprolene. Rehydration of spores so changed and hence reversion to normal sensitivity does not seem to occur until they have been actually wetted or placed in essentially 100% relative humidity. Do not attempt to sterilize materials which may be carrying dried spores without first soaking them in water or washing the articles with water, soap, or detergents. If the nature of the material is such that the water treatments specified above are harmful, then a pretreatment in a chamber having a saturated humidity will be necessary for an overall pretreatment routine of at least one hour.

Anprolene is a potent polymerizing agent. It should not be used for sterilizing food-stuffs or drugs.

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 AN-85 placed in the most inaccessible part of the load will verify whether or not the gaseous sterilant penetrated to the core of the load. In addition a good biological control such as the ANPRO AN-80 Steritest® should be used at least once per month to challenge the procedure.

7. IMPORTANT — Variations from these instructions.

The user must not deviate from these instructions. AN-79 Anprolene ampules are designed to be used only in the AN-74 Anprolene Sterilizer utilizing the AN-79 liner bags and twist seal supplied in the AN-79 refill dispenser. You must use a fresh liner bag with each load.