ANDERSEN STERILIZERS EO GAS REFILL KIT
TECHNICAL DATA SHEET

GENERAL DESCRIPTION

The Andersen EOGas and Anprolene Sterilizer systems have refill kits containing a 20mL cartridge which holds the sterilant, EO Gas. The 20mL cartridge is a unit dose container for Ethylene Oxide (EO). Inside the cartridge, the Ethylene Oxide is in the liquid state within a hermetically sealed glass ampoule. The cartridge cushions the ampoule during shipping and handling and facilitates the safe release of the EO once the glass ampoule is broken. Ethylene Oxide boils at a temperature of 10.7°C (51.3°F), therefore at EOGas sterilization temperatures of 30°C – 55°C (86°F – 131°F), the Ethylene Oxide liquid quickly turns to gas. When the cartridge is activated, 100% Ethylene Oxide gas leaves the cartridge and enters the sterilization bag.

Each EOGas cartridge has an activation trigger secured with a trigger guard, which is in turn secured with green adhesive tape to prevent accidental activation. Once the items to be sterilized are prepared and placed in the sterilization bag, the protective tape and trigger guard are removed, the cartridge is placed in the sterilization bag with the sterilization load, and the bag is sealed. To activate the cartridge, it is manipulated through the flexible wall of the sterilization bag to depress the activation trigger.

INDICATIONS FOR USE

Refer to EOGas Sterilizer User Manuals for Indications for Use.

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DIRECTIONS FOR USE

Items to be sterilized are prepared according to the Instructions for use found in the EOGas Refill Kit and in the EOGas Sterilizer User's Manual which are provided with purchase of the Refill Kit and the Sterilizer.

APPLICATION OF USE

- 20mL cartridges are approved for use only in the EOGas 3, EOGas 4 and Anprolene AN75 sterilization systems.
- The 20mL cartridge is designed to hold a glass ampoule which is filled with varying amounts of EO, depending on the Refill Kit contents as specified below in Specifications.

SPECIFICATIONS

Refill Kit Number	Liquid Ethylene Oxide Contents (grams +/- 5%)*	Refill Kit Contents
AN1004.16	17.6	14 EOGas Cartridges, 14 Dosimeter, 14 Humidichip, 14 Sterilization Bags
AN1006.00	10.5	14 EOGas Cartridges,14 Dosimeter, 14 Humidichip, 14 Sterilization Bags
AN2011.00	10.5	14 EOGas Cartridges
AN2018.00	17.6	14 EOGas Cartridges

*Ethylene Oxide Safety Data Sheet contains safety information and specifications for Ethylene Oxide. This Safety Data Sheet is available from Distributors.

RAW MATERIAL COMPOSITION

Raw material	Material
Cartridge, multiple pieces	See TDS 20ML Cartridge
Glass ampoule	See TDS 20ML Cartridge
Ethylene Oxide	See TDS 20ML Cartridge
Sterilization Bag	See TDS Sterilization Bag
Dosimeter	See TDS Dosimeter
Humidichip	See TDS Humidichip

MANUFACTURING AND DESIGN

- The EOGas and Anprolene Systems are manufactured and designed under a full Quality Management System certified (certificate number 0085440) under MDSAP and registered by Intertek, an MDSAP recognized auditing organization as conforming the requirements of ISO 13485:2016 for the Canadian Medical Device Regulations – Part 1 – SOR 98/282 and the United States USFDA 21CFR 820, 21 CFR 803, 21 CFR 806, 21CFR 807 (EOGas 4 Only, EOGas 3 sterilization cycle validated by commercial user). A Risk Management Program is fully adopted per ISO14971:2019.
- Andersen Sterilizers maintains EC Certification through a full Quality Assurance System certification number 4134704-02 under Directive 93/42/EEC on Medical Devices allowing for the use of CE 0413 marking.

ANDERSEN STERILIZERS EO GAS REFILL KIT
TECHNICAL DATA SHEET

- The EOGas and Anprolene Sterilization System is independently certified for safety and effectiveness standards for electrical safety and electromagnetic compatibility as required by international regulations.

TESTING AND INSPECTION

- Verification of Ethylene Oxide fill weights
- Pressure testing of all filled ampoules to ensure ampoule integrity
- Cartridge seal testing on all completed cartridges
- Certificate of Analysis confirming Ethylene Oxide has a purity of 99.99%
- g-shock testing to verify compliance with Federal D.O.T. shipping regulations.
- Visual inspection to confirm all Refill Kit contents and label accuracy
- See TDS Dosimeter, Humidichip and Sterilization Bag for testing

PACKAGING AND LABELING

EO Gas Refill Kits are packaged with protective corrugated dividers inside a corrugated inner box. The inner box is then placed in a larger, corrugate box and labeled with the appropriate device label.

Examples of the inner box and outer box labels is within this technical documentation. Cartridge labels can be found in TDS 20ML Cartridges.

STORAGE CONDITIONS

Store in a cool, well-ventilated area away from heat and direct sunlight. Store in accordance with 28CFR 1910.1047. When properly stored for the stated shelf life, Ethylene Oxide will retain its clear liquid appearance and consistency, comparable to denatured alcohol.

DISPOSAL

Pesticide wastes are toxic. Improper disposal of excess pesticides is a violation of Federal Law. If the waste cannot be disposed of by use according to label instructions, contact Andersen Products Inc. (336-276-3000). Do not puncture or incinerate unused cartridges. Aerate empty cartridges and used sterilization bags according to complete Directions for Use. After aeration, dispose of in sanitary landfill.

SHELF LIFE

The shelf life of an EOGas cartridge depends on the fill weight of the Ethylene Oxide gas within the cartridge. The following table lists the shelf life of the Cartridges and the Refill Kits:

Refill Kit	Cartridge Expiration (Years)	Refill Kit Expiration* (Years)
AN1004.16	5	3
AN1006.00	5	3
AN2011.00	5	5
AN2018.00	5	5

*Expiration of the refill kit is determined by the kit component with the shortest shelf life.

ANDERSEN STERILIZERS EO GAS REFILL KIT TECHNICAL DATA SHEET

AN1006.00/AN2011.00 Inner Box Label

AN1006 AN2011 EOGas®

REF

EO GAS AN1006
Kit **CONTENTS:** 14 Cartridges, 14 liner Bags, 14 Dosimeters, 14 Humidichips
EO GAS AN2011
Kit **CONTENTS:** 14 Cartridges

Each AN1006 / 2011 cartridge contains 0.39 av. Oz. (10.5g) Ethylene Oxide

Active ingredient: Ethylene oxide..... 96%
Inert ingredient:..... 4%
Total:..... 100%

AN 2011 cartridges are for industrial use in a fully validated sterilization system only. It is incumbent on the user to determine the definition of a fully validated sterilization system

Manufactured by:
ANDERSEN STERILIZERS, INC.
3154 Caroline Drive Haw River, NC 27258 USA

Distributed by:
ANDERSEN STERILIZERS, INC.
3202 Caroline Drive Haw River, NC 27258 USA
1-800-523-1276
336-376-3000

EPA Registration No. 69340-6.
EPA Establishment No. 69340-NC-001
EOGas® and Dosimeter® are registered trademarks of Andersen Sterilizers, Inc.

UK REP
H.W. ANDERSEN PRODUCTS, LTD.
808 Fowler Clacton-On-Sea Essex CO15 4AA UK
44-1255-428328

EC REP
H.W. Andersen S.A.R.L.
12 Place Saint-Hubert
59000 - Lille - France

CE 0413

Keep Out of Reach of Children

DANGER

PRECAUTIONARY STATEMENTS

Causes eye and skin burns. May be fatal if inhaled. Do not breath vapor. Do not swallow. Do not get in eyes, on skin, or on clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Wear appropriate protective clothing.

USER SAFETY RECOMMENDATIONS

Users should remove clothing / PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

OTHER POSSIBLE DELAYED HEALTH EFFECTS: Cancer and reproductive hazard. May cause nervous system damage, cataracts, adverse reproductive effects, chromosomal and mutagenic changes. May cause irritation of respiratory tract, chest tightness, headache, nausea, vomiting, diarrhea, light headed feeling, dizziness, weakness, drowsiness, cyanosis, loss of coordination, coma, delayed lung injury (fluid in lungs), immediate or delayed skin irritation and blisters, allergic skin.

PEL: 1 PPM-TWA Ethylene Oxide (OSHA-29 CFR1910.1047).

EL: 5 PPM-excursion limit, 15 minutes.

Store and use with adequate ventilation in accordance with 29 CFR 1910.1047.

FIRST AID

In all cases of exposure, get medical attention immediately. Take person to a doctor or emergency treatment facility at once.

Have the product container or label with you when calling the Emergency Contact number or doctor, or going for treatment.

IF INHALED: Move exposed person to fresh air. Keep warm. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth to mouth method. If breathing is at all labored, give oxygen. Call a doctor even if no symptoms are present for further treatment advice. Keep under medical observation. Symptoms may be delayed.

IF IN EYES: Hold eyelids open and flush eyes with a steady, gentle stream of water for at least 15 to 20 minutes. Remove contact lenses, if present, after the first 5 minutes and then continue rinsing the eyes. Get immediate medical treatment.

IF ON SKIN: Immediately wash skin for 15-20 minutes with plenty of water while removing contaminated clothing and shoes. Call Emergency Contact number or a doctor for treatment advice. Aerate, wash, or clean contaminated clothing and discard leather goods.

IF SWALLOWED: Call the Emergency Contact number or a doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by an Emergency Contact responder or a doctor. Do not give anything to an unconscious person.

NOTE TO PHYSICIAN

Ethylene oxide is a liquefied gas. Skin exposure from contact with fabric, rubber, or plastic containing residual ethylene oxide will commonly result in skin irritation with extensive blister formation. At high concentrations severe conjunctivitis can occur. Irritation of the respiratory tract may occur, but without acute lung edema. Symptoms of systemic intoxication are headache, nausea, vomiting, lack of coordination, and cardiac irregularities. Treatment is symptomatic.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

A material that is chemical resistant to this product is butyl rubber.

All handlers must wear at a minimum:

- Long-sleeved shirt and long pants.
- Shoes plus socks.
- Chemical-resistant gloves and
- when the ambient ETO concentration is 1 to 50 ppm, full-facepiece respirator with ETO approved canister, front or back mounted,
- when the ambient ETO concentration is 50 to 2,000 ppm, (1) positive-pressure supplied-air respirator equipped with full-facepiece, hood, or helmet; or (2) continuous-flow supplied-air respirator (postive-pressure) equipped with hood, helmet, or suit,
- when the ambient ETO concentration is >2,000 ppm or unknown (e.g., emergency situations), (1) positive-pressure self-contained breathing apparatus equipped with full-facepiece; or (2) positive-pressure full facepiece supplied-air respirator equipped with an auxiliary positive-pressure self-contained breathing apparatus.

When handlers could have eye or skin contact with ETO or ETO solutions, such as during maintenance and repair, vessel cleaning, or cleaning up spills, they must wear:

- Chemical-resistant attire, such as apron, protective suit, or footwear that protects the area of the body that might contact ETO or ETO solutions, and
- Face-sealing goggles, a full-face shield, or a full-face respirator.

USER SAFETY REQUIREMENTS

When wearing respirators:

1. Follow the respirator manufacturer's user's instructions for changing canisters.
2. Respirators must be fit-tested and fit-checked using a program that conforms to OSHA's requirements (see 29CFR Part 1910.134).
3. Respirator users must be trained using a program that conforms to OSHA's requirements (see 29CFR Part 1910.134).
4. Respirator users must be examined by a qualified medical practitioner to ensure physical ability to safely wear the style of respirator to be worn. A qualified medical practitioner is a physician or other licensed health care professional (PLHCP) who will evaluate the ability of a worker to wear a respirator. The initial evaluation consists of a questionnaire that asks about medical conditions (such as a heart condition) that would be problematic for respirator use. If concerns are identified, then additional evaluations, such as a physical exam, might be necessary. The initial evaluation must be done before respirator use begins. It does not need to be repeated unless the health status or respirator use conditions change (see 29CFR Part 1910.134).

Follow manufacturer's instructions for cleaning / maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

EMERGENCY CONTACT: 1-800-255-3924 PHYSICAL AND CHEMICAL HAZARDS

Ethylene oxide gas is extremely flammable. Do not use near flame, electrical sparks, hot surfaces, or allow sources of ignition near the sterilization area. Ground all equipment to prevent static sparks.

Contents under pressure. Do not puncture or incinerate container. Exposure to temperatures above 130 °F (54°C) may cause bursting.

ODOR: Ether-like in high concentrations. Exposure to toxic levels may occur without warning or detection by the user.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Employees in facilities that use ETO must comply with all of the requirements for ETO use specified in 29CFR 1910.1047.This product may be used only in EOGas® sterilizers, and only for hospital, medical, and veterinary sterilization.

In hospitals and healthcare facilities, and contract sterilization facilities treating medical equipment and supplies, sterilization/fumigation with ETO must be performed only in vacuum or gas tight chambers designed for use with ETO. After February 28, 2010, a single chamber process is required for ETO treatment (sterilization and aeration are to occur in the same chamber) in hospitals and healthcare facilities.

During the treatment cycle, the sterilization bag may contain hazardous concentrations of ETO. Do not open the sterilization bag until the sterilization, ventilation, and aeration portions of the treatment cycle are complete.

Safety and awareness training is required for all employees including office staff. Information and training must be provided to all employees in the facility at the time of initial assignment and annually thereafter. The safety training must include, at a minimum, the following information:

1. the most recent monitored ambient levels of ETO in the facility; 2. the potential health effects from the levels of ETO in the facility; 3. the emergency response plan and how to respond in an emergency; 4. the availability of the Material Safety Data Sheet and other materials related to the health hazards of exposure to ETO. In order to reduce ambient levels of ethylene oxide, lengthy facility aeration is encouraged. Achieving an ambient level of 0.25 ppm (measured as a daily time-weighted average) greatly reduces potential long-term risks to employees not directly involved in the ETO applications. Air monitoring should include the entire facility including office space, break areas, and loading/unloading areas. Employers in facilities that use ETO must comply with all the requirements for ETO use specified in 29CFR 1910.1047.
1. Prepare items to be sterilized. Remove one Dosimeter® and card from the dispenser box. Write the date and time sterilization will begin and the date and time sterilization and aeration will be complete on the label. Attach the Dosimeter® to its card. Take one sterilizer bag from the EOGas dispenser box and place the wrapped items to be sterilized into the sterilizer bag.
2. Place the Dosimeter® in the core of the load. Place the Humidichip® inside the HumidiTube and place the HumidiTube in the sterilization bag. Select one EOGas cartridge from the dispenser box. Confirm that the number printed on the EOGas cartridge corresponds with the number printed on the sterilizer bag. Remove the cartridge trigger guard (secured with green tape) and place the cartridge on top of the devices near the open end of the sterilization bag, but do not activate the cartridge at this time.
3. Remove excess air with a vacuum sealer or press the excess air out of the sterilization bag and heat seal the open end of the sterilization bag. Initiate the sterilization cycle by pressing the LOAD key on the front of the EOGas sterilizer cabinet and follow the directions for loading.
4. After the cabinet has purged for 5 minutes, "DOOR UNLOCKED" will be displayed and door will unlock. Place the sterilization bag on a shelf in the sterilizer.
5. Without opening the sterilization bag, grasp the EOGas cartridge through the wall of the sterilization bag and press the plunger (trigger button) firmly to activate the cartridge. Press it all the way so that the trigger reaches the cartridge wall. This action releases the gas instantly from the cartridge into the sterilizer bag.
6. Close the sterilizer door securely. It will lock automatically at the end of the 3-minute countdown displayed on the screen. Leave the sterilizer bag undisturbed in the sterilizer cabinet for 16 hours, the sterilizer bag may then be removed. To accomplish this, initiate a 5-minute purge cycle by pressing the UNLOAD button. The sterilizer will begin purging (high volume ventilation to remove any residual EO from the cabinet). At the end of the 5-minute purge cycle, the sterilizer will unlock the door for 10 minutes. The door may be opened at any time during this 10-minute window. Once the door is opened the operator has a 3-minute window to remove sterilization bags.
7. When unloading multiple sterilization bags or loads which absorb a large amount of EO, some operators prefer to cut open the end of the sterilization bag while it is still in the cabinet, then shut the door and repeat the PURGE cycle. This minimizes the chance of xposure to residual EO within the sterilization bag.
8. After the sterile material has been removed from the sterilizer bag, wrap the empty cartridge and bag in paper and discard according to disposal instructions. DO NOT REUSE EMPTY BOX, EMPTY CONTAINERS (Cartridges), OR LINER BAGS.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

Pesticide Storage: Store in a cool, well ventilated area away from heat and direct sunlight. Store in accordance with 29 CFR 1910.1047.

Pesticide Disposal: Pesticide wastes are toxic. Improper disposal of excess pesticides (unwanted or expired EOGas cartridges) is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact Andersen Sterilizers, Inc. (336.376.3000), or your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal: Do not puncture or incinerate unused cartridges. Aerate empty cartridges and used sterilization bags according to the complete Directions for Use. After aeration, dispose of in sanitary landfill.

AN2854.00 Rev 0

AN1004.16/AN7514.00/AN2018.00 Inner Box Label

AN1004 / AN7514 / AN2018

AN1004 EOGas 4®
CONTENTS: 14 Sterilization Bags, 14 AN1036 Dosimeter®, 14 Humidichip®, 14 Cartridges with ampoules

AN7514 Anprolene®
CONTENTS: 14 Sterilization Bags, 14 AN87 Dosimeter, 14 Cartridges with ampoules

AN2018 EOGas® 3
CONTENTS: 14 Cartridges with ampoules

Contents of Cartridges: each ampoule contains 0.64 av. oz. (17.6 g) Ethylene Oxide

Activeingredient:Ethyleneoxide.....97.0%
Inert ingredient:..... 3.0%
Total:..... 100%

For use in the following Andersen Sterilizers Ethylene Oxide Gas Sterilization Systems:

Anprolene AN74i/ix/j EOGas 4
Anprolene AN75i/j EOGas 3

Manufactured by:
ANDERSEN STERILIZERS, INC.
3154 Caroline Drive
Haw River, NC 27258 USA

Distributed in the U.S. by:
ANDERSEN STERILIZERS, INC.
3202 Caroline Drive
Haw River, NC 27258 USA
1.800.523.1276
336.376.3000

Authorized UK Representative:
H. W. ANDERSEN PRODUCTS, LTD.
808 Fowler Clacton-On-Sea
Essex • CO15 4AA • UK
44.1255.428328

Authorized EU Representative:
H.W. Andersen S.A.R.L.
12 Place Saint-Hubert
59000 • Lille • France

EPA Registration No. 69340-7.
EPA Establishment No. 69340-NC-001

CE 0413

Keep Out of Reach of Children

DANGER

PRECAUTIONARY STATEMENTS

Causes eye and skin burns. May be fatal if inhaled. Do not breath vapor. Do not swallow. Do not get in eyes, on skin, or on clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Wear appropriate protective clothing.

USER SAFETY RECOMMENDATIONS

Users should remove clothing / PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

OTHER POSSIBLE DELAYED HEALTH EFFECTS: Cancer and reproductive hazard. May cause nervous system damage, cataracts, adverse reproductive effects, chromosomal and mutagenic changes. May cause irritation of respiratory tract, chest tightness, headache, nausea, vomiting, diarrhea, light headed feeling, dizziness, weakness, drowsiness, cyanosis, loss of coordination, coma, delayed lung injury (fluid in lungs), immediate or delayed skin irritation and blisters, allergic skin.

PEL: 1 PPM-TWA Ethylene Oxide (OSHA-29 CFR1910.1047).

EL: 5 PPM-excursion limit, 15 minutes.

Store and use with adequate ventilation in accordance with 29 CFR 1910.1047.

FIRST AID

In all cases of exposure, get medical attention immediately. Take person to a doctor or emergency treatment facility at once. Have the product container or label with you when calling the Emergency Contact number or doctor, or going for treatment.

IF INHALED: Move exposed person to fresh air. Keep warm. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth to mouth method. If breathing is at all labored, give oxygen. Call a doctor even if no symptoms are present for further treatment advice. Keep under medical observation. Symptoms may be delayed.

IF IN EYES: Hold eyelids open and flush eyes with a steady, gentle stream of water for at least 15 to 20 minutes. Remove contact lenses, if present, after the first 5 minutes and then continue rinsing the eyes. Get immediate medical treatment.

IF ON SKIN: Immediately wash skin for 15-20 minutes with plenty of water while removing contaminated clothing and shoes. Call Emergency Contact number or a doctor for treatment advice. Aerate, wash, or clean contaminated clothing and discard leather goods.

IF SWALLOWED: Call the Emergency Contact number or a doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by an Emergency Contact responder or a doctor. Do not give anything to an unconscious person.

NOTE TO PHYSICIAN

Ethylene oxide is a liquefied gas. Skin exposure from contact with fabric, rubber, or plastic containing residual ethylene oxide will commonly result in skin irritation with extensive blister formation. At high concentrations severe conjunctivitis can occur. Irritation of the respiratory tract may occur, but without acute lung edema. Symptoms of systemic intoxication are headache, nausea, vomiting, lack of coordination, and cardiac irregularities. Treatment is symptomatic.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

A material that is chemical resistant to this product is butyl rubber.

All handlers must wear at a minimum:

- Long-sleeved shirt and long pants.
- Shoes plus socks.
- Chemical-resistant gloves and
- when the ambient EO concentration is 1 to 50 ppm, full-facepiece respirator with EO approved canister, front or back mounted,
- when the ambient EO concentration is 50 to 2,000 ppm, (1) positive-pressure supplied-air respirator equipped with full-facepiece, hood or helmet; or (2) continuous-flow supplied-air respirator (postive-pressure) equipped with hood, helmet, or suit,
- when the ambient EO concentration is >2,000 ppm or unknown (e.g., emergency situations), (1) positive-pressure self-contained breathing apparatus equipped with full-facepiece; or (2) positive-pressure full facepiece supplied-air respirator equipped with an auxiliary positive-pressure self-contained breathing apparatus.

When handlers could have eye or skin contact with EO or EO solutions, such as during maintenance and repair, vessel cleaning, or cleaning up spills, they must wear:

- Chemical-resistant attire, such as apron, protective suit, or footwear that protects the area of the body that might contact EO or EO solutions, and
- Face-sealing goggles, a full-face shield, or a full-face respirator.

USER SAFETY REQUIREMENTS

When wearing respirators:

1. Follow the respirator manufacturer's user's instructions for changing canisters.
2. Respirators must be fit-tested and fit-checked using a program that conforms to OSHA's requirements (see 29 CFR Part 1910.134).
3. Respirator users must be trained using a program that confirms to OSHA's requirements (see 29 CFR Part 1910.134).
4. Respirator users must be examined by a qualified medical practitioner to ensure physical ability to safely wear the style of respirator to be worn. A qualified medical practitioner is a physician or other licensed health care professional (PLHCP) who will evaluate the ability of a worker to wear a respirator. The initial evaluation consists of a questionnaire that asks about medical conditions (such as a heart condition) that would be problematic for respirator use. If concerns are identified, then additional evaluations, such as a physical exam, might be necessary. The initial evaluation must be done before respirator use begins. It does not need to be repeated unless the health status or respirator use conditions change (see 29 CFR Part 1910.134).

Follow manufacturer's instructions for cleaning / maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

EMERGENCY CONTACT: 1.800.255.3924 PHYSICAL AND CHEMICAL HAZARDS

Ethylene oxide gas is extremely flammable. Do not use near flame, electrical sparks, hot surfaces, or allow sources of ignition near the sterilization area. Ground all equipment to prevent static sparks.

Contents under pressure. Do not puncture or incinerate container. Exposure to temperatures above 130 °F (54°C) may cause bursting.

ODOR: Ether-like in high concentrations.

Exposure to toxic levels may occur without warning or detection by the user.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Employees in facilities that use EO must comply with all of the requirements for EO use specified in 29 CFR 1910.1047.

This product may be used only in Andersen AN74, AN75, EOGas 3, and EOGas 4 sterilizers for commercial, hospital, medical and veterinary sterilization.

In hospitals, healthcare facilities, and contract sterilization facilities treating medical equipment and supplies, sterilization/fumigation with EO must be performed only in vacuum or gas tight chambers designed for use with EO. After February 28, 2010, a single chamber process is required for EO treatment (sterilization and aeration are to occur in the same chamber) in hospitals and healthcare facilities.

During the treatment cycle, the sterilization bag may contain hazardous concentrations of EO. Do not open the sterilization bag until the sterilization and ventilation portions of the sterilization cycle are complete.

Safety and awareness training is required for all employees including office staff. Information and training must be provided to all employees in the facility at the time of initial assignment and annually thereafter. The safety training must include, at a minimum, the following information: 1. the most recent monitored ambient levels of EO in the facility; 2. the potential health effects from the levels of EO in the facility; 3. the emergency response plan and how to respond in an emergency; 4. the availability of the Material Safety Data Sheet and other materials related to the health hazards of exposure to EO. To reduce ambient levels of EO, lengthy facility aeration is encouraged. Achieving an ambient level of 0.25 ppm (measured as a daily time-weighted average) greatly reduces potential long-term risks to employees not directly involved in the EO applications. Air monitoring should include the entire facility including office space, break areas, and loading/unloading areas. Employers in facilities that use EO must comply with all the requirements for EO use specified in 29 CFR 1910.1047.

Sterilization Process:

- Remove one sterilization bag from the dispenser box. Place wrapped devices to be sterilized inside the sterilization bag along with required accessories (Humidichip, chemical indicators, biological indicator).
- Remove one cartridge from the dispenser box. Remove the adhesive tape, then the trigger guard. Place the cartridge on top of the wrapped items near the open end of the bag where it is accessible for cartridge activation. **DO NOT ACTIVATE THE CARTRIDGE.**
- On sterilizers with sterilization bag purge, insert the purge probe into the sterilization bag. Gather the open end of the sterilization bag around the purge probe and wrap the blue strap around both the sterilization bag opening and the purge probe, tightening it to completely seal the sterilization bag. On sterilizers without a purge probe (EOGas 3), the bag must be sealed with a heat sealer after removing excess air from the sterilization bag.
- Place the sealed sterilization bag inside the sterilizer. On sterilizers with sterilization bag purge, connect the quick release connector on the purge probe to the purge probe tubing. In the AN75 and EOGas 4 sterilizers, include a biological indicator in the BI receptacle on the purge probe.
- In Anprolene and EOGas 4 sterilizers with a purge probe, evacuate excess air from the sterilization bag using the initial bag purge, then follow the cycle selection and cycle verification prompts.
- **ACTIVATE THE CARTRIDGE:** grasp the cartridge through the wall of the sealed sterilization bag and fully depress the trigger button on the side of the cartridge to release EO into the sterilization bag.
- Close the door to the sterilizer and start the sterilization cycle.
- Always lock the door of the sterilizer to prevent unauthorized removal of devices during the sterilization and ventilation portions of the cycle.
- After the sterilization and ventilation portions of the cycle in sterilizers without a purge probe (EOGas 3), open the sterilization bag while it is still in the cabinet, then shut the door and continue aeration. This will improve aeration efficiency and minimize the chance of exposure to residual EO within the sterilization bag.
- After the sterile devices have been removed from the sterilization bag, discard the sterilization bag and empty cartridge according to disposal instructions. **DO NOT REUSE EMPTY BOX, EMPTY CARTRIDGES OR LINER BAGS.**

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

Pesticide Storage: Store in a cool, well ventilated area away from heat and direct sunlight. Store in accordance with 29 CFR 1910.1047.

Pesticide Disposal: Pesticide wastes are toxic. Improper disposal of excess pesticides (unwanted or expired ampoules) is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact Andersen Sterilizers, Inc. (336.376.3000), or your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal: Do not puncture or incinerate unused ampoules. After aeration, dispose of empty ampoules and used sterilization bags in sanitary landfill.

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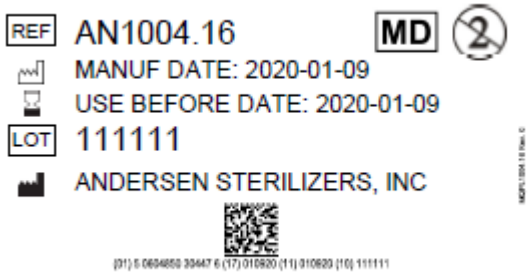
ANDERSEN STERILIZERS EO GAS REFILL KIT
TECHNICAL DATA SHEET

AN1004.16 Outer Box Label

AN1006.00 Outer Box Label

AN2011.00 Outer Box Label


ANDERSEN STERILIZERS EO GAS REFILL KIT
TECHNICAL DATA SHEET

AN 2018.00 Outer Box Label

ANDERSEN STERILIZERS EO GAS REFILL KIT
TECHNICAL DATA SHEET

Revision History			
ECN Number	Revision	Effective Date	Reason for Change
2021078	0	2021-12-28	Updated to include data requested by international customers. Updated for shelf-life changes. Created as controlled documents under revision control in document management system.
2021078	1	2022-04-12	Update to replace AN1004, AN7514, AN2018 EPA label (combined label).
2021078	2	2022-09-14	Remove AN2018 standalone EPA label, update AN14.00.
2023031	3	2023-04-28	Update AN2014 EPA label.
2024003 2024005	4	2024-03-11	Remove AN2014.00 references Update AN1004.16/AN7514.00/AN2018.00 Inner Box Label
2023053 2023054 2023092	5	2025-04-15	Update AN1006.00/AN2011.00 Inner Box Label and AN1004.16/ AN7514.00/AN2018.00 Inner Box Label. Replaced refill kit image.

Signatures:

Content Approval:	I have approved the content of this document		
Name:	**Ethan Marshall emarshall**	Title:	**Director of Operations**
	Ethan Marshall		2025-04-15 12:13:54 (UTC+00:00)
Electronically Signed in	M-Files	Timestamp	

Controlled Quality Document Authorized for Release:	I authorize this controlled quality document for release.		
Name:	**Faith Rios ANDERSEN\Faith.Rios**	Title:	**Director of Quality Assurance and Regulatory Affairs**
	Faith Rios		2025-04-15 18:28:08 (UTC+00:00)
Electronically Signed in	M-Files	Timestamp	