## DEVICE GENERAL DESCRIPTION AND CLASSIFICATION

Anprolene AN74 sterilization bags are part of Andersen Anprolene AN74 system. Sterilization bags are Ethylene oxide gas permeable polyethylene bags used to control the Ethylene oxide dose and relative humidity during sterilization. The bags are impermeable to humidity, but permeable to Ethylene oxide. Items to be sterilized and sterilization accessories are placed inside the sterilization bag with an appropriate Anprolene gas release mechanism containing Ethylene oxide. During the sterilization cycle, Ethylene oxide released from the cartridge elutes through the wall of the sterilization bag at a known rate, maintaining parameters necessary for sterilization, but allowing the Ethylene oxide gas level to diminish by the end of the cycle.

The Anprolene, AN74 sterilization system does not come into direct contact with a patient. The system is registered and classified as a Class II medical device in the UK and the European Union, it is marketed in the veterinary market in the U.S., and not registered as a medical device with the USFDA.

# INDICATIONS FOR USE

The Anprolene, AN74 sterilization system is designed for professional use only. It may be used for medical, and laboratory sterilization of medical devices, and veterinary hospital (Outside US) and veterinary hospital use only in the U.S. It is designed to achieve:

- 12-log sterilization of (SAL <sup>10-</sup>6) of up to twelve (12) pounds of metal devices such as stainless-steel surgical instruments with mated surfaces, including seissors, forceps, clamps, rongeurs, needle holders, and pliers were from Sontec Instruments (Centennial, CO) or Codman & Shurtleff Inc. (Raynham, MA). Each instrument was individually pouched in a Dupont Tyvek package approximately 12"x12", 7.5"x12", or 4"x12" in size and indicated for use in EO sterilizers. The metal instruments were loaded with no other devices for processing.
- 12-log sterilization of (SAL <sup>10-6</sup>) of up to three (3) pounds of cloth (100% cotton) items, such as reusable 16"x26" operating room (OR) towels were purchased from Med-Vet International (Mettawa, IL). Each OR towel was folded in half twice (4 layers), 5 pieces (20 layers) were stacked one on top of one another, and then wrapped in CSR wrap. Fabric loads were processed without any other devices.

## **DIRECTIONS FOR USE**

Items to be sterilized are prepared according to the Instructions for use found in the Anprolene AN7916.00 Refill Kit and in the Anprolene AN74 Sterilizer User's Manual which are provided with purchase of the Refill Kit and the Sterilizer.

# **APPLICATION OF USE**

- To be used only for use only in Anprolene AN74 Sterilizers
- To be used only with the Anprolene AN7916.00 Refill Kit containing ampoules to activate 17.6 grams of Ethylene Oxide

### **SPECIFICATIONS**

Part Number	Sterilization System	Material	Thickness (inches)	Dimensions W X L (inches)
822	Anprolene	Engineered film structure of polypropylene	0.003 (+/- 0.0005)	22 X 36 (+/- 1/4 inch)

### RAW MATERIAL COMPOSITION

- An prolene AN74 sterilization bags are manufactured from a proprietary engineered film structure of polyethylene material.
- The sterilization bags are latex-free and DEHP free.
- Andersen Sterilizer systems have no components or raw materials which come in direct contact with the patient.

## MANUFACTURING AND DESIGN

- The Anprolene AN74 System is 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. 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.
- The Anprolene Sterilization System is independently certified for safety and effectiveness standards for electrical safety and electromagnetic compatibility as required by international regulations per the following table:

MDD 93/42-EEC (230 VAC)
UL 61010A-1, 1st Ed. (R 2002) (115VAC)
CSA C22.2 No. 1010-1, -92 (R 1999) (115VAC)
UL 61010A-2-042, 1st Ed. (115VAC)
EN 61010-1: 2010 (230VAC)
EN 61010-2-040: 2005 (230VAC)
IEC 61010-2-42: 1997 (230VAC)

# **TESTING AND INSPECTION**

Visual inspection for print contents and print quality/legibility, holes or other visual defects

- Dimensional inspection to appropriate tolerances
- Functional testing of EO gas transmission rate
- Functional Testing for pin holes or other defects in the polyethylene material
- Functional Testing for seal strength and integrity

# **PACKAGING AND LABELING**

- Sterilization bags are packaged with Ethylene Oxide Refill kits AN7916.00. See AN7916.00 refill kit technical data sheet for further detail.
- Sterilization bags have printed labeling with multi-language instructions to include date of manufacture and date of expiration. A sample is included in this technical data sheet.

# STORAGE CONDITIONS

Store sterilization bags at room temperature and away from exposure to direct sunlight.

### **DISPOSAL**

- Sterilization bags are not reusable and must be discarded after each sterilization cycle.
- Used and unused sterilization bags may be discarded in ordinary trash

## SHELF LIFE

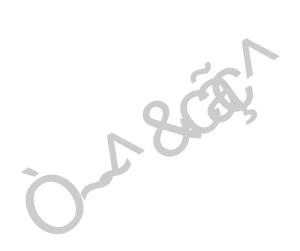
Sterilization bags may be used up to 5 years after the date of manufacture.



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# ANDERSEN STERILIZERS ANPROLENE AN 74 STERILIZATION BAGS TECHNICAL DATA SHEET

ECN Number	Revision	Effective Date	Reason for Change
2021078	0	2021-11-16	Updated to include data
			requested by international
			customers. Created as
			controlled documents under
			revision control in document
			management system.



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