ANDERSEN STERILIZERS ANPROLENE AN 74 STERILIZATION BAGS TECHNICAL DATA SHEET

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 ^{10}-6) of up to twelve (12) pounds of metal devices such as stainless-steel surgical instruments with mated surfaces, including scissors, 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 ^{10}-6) 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

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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 (+/- ¼ inch)

RAW MATERIAL COMPOSITION

- Anprolene 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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P/N 822 Printed Bag Label

ANPROLENE®

Sterilization Liner Bag for use only with **Anprolene**
USE ONLY IN A **VENTILATED ANDERSEN ANPROLENE STERILIZER**

ENGLISH

IMPORTANT: Anprolene gas is flammable. Do not use near fire, heated surfaces or flame.
Keep out of reach of children.
Cancer hazard and reproductive hazard.
Do not open this bag before the 14 hour cycle at or above 68°F / 20°C is complete.

Shortening the mandatory 14 hour cycle may lead to unacceptable operator exposure to ethylene oxide and chemical burns to the patient. Aerate gas absorbing materials outside of the Sterilization Liner Bag according to the enclosed instructions.

The Anprolene sterilizer must be operated according to the detailed instructions available in the Owner's Manual and the Instructions enclosed in each Anprolene Refill Kit.

FRANÇAIS

Sac de stérilisation à n'utiliser qu'avec **l'Anprolene**
A UTILISER UNIQUEMENT DANS UN **STERILISATEUR VENTILE ANPROLENE ANDERSEN**

IMPORTANT: Le gaz de l'Anprolene est inflammable. Ne pas utiliser près d'un feu, de surfaces chauffées ou d'une flamme.
Conserver hors de portée des enfants.
Risques de cancer et de maladie reproductive.
Ne pas ouvrir ce sac avant la fin des 14 heures du cycle à 68°F / 20°C ou plus.

Raccourcir les 14 heures obligatoires du cycle peut conduire à une exposition inacceptable de l'opérateur à l'oxyde d'éthylène et à des brûlures chimiques sur le patient. Aérer les matériels absorbant le gaz en dehors du sac de stérilisation, selon les instructions fournies.

Le stérilisateur Anprolene doit être utilisé conformément aux instructions détaillées dans le Manuel de l'Utilisateur et aux instructions fournies dans chaque kit de rechargea Anprolene.

DEUTSCH

Sterilisier-Einsatzbeutel nur zum Gebrauch mit **Anprolene**
NUR IN EINEM **BELÜFTETEN ANPROLENE-STERILISATOR VON ANDERSEN VERWENDEN.**

WICHTIG: Anprolene-Gas ist brennbar. Nicht in der Nähe von Feuer, beheizten Flächen oder Flammen verwenden.
Nicht in Reichweite von Kindern aufbewahren.
Krebsrisiko und Gefährdung der Fortpflanzungsorgane.
Dieser Beutel darf nicht vor Ablauf des 14-Stunden-Zyklus bei oder über 68°F / 20°C geöffnet werden.

Wird dieser obligatorische 14-Stunden-Zyklus gekürzt, kann dies zu einem nicht akzeptablen Kontakt des Bedieners mit Ethylenoxid und zu chemischen Verbrennungen am Patienten führen. Belüften Sie das Gas absorbierende Material gemäß den beiliegenden Anleitungen außerhalb des Sterilisier-Einsatzbeutels.

Der Anprolene-Sterilisator muss gemäß den detaillierten Anleitungen im Handbuch und in der Bedienungsanleitung, die jedem Anprolene Nachfüllkit beiliegen, betrieben werden.

ESPAÑOL

Bolsa para esterilización para su uso sólo con **Anprolene**
UTILÍCESE SÓLO EN UN **ESTERILIZADOR VENTILADO ANDERSEN ANPROLENE.**

IMPORTANTE: El gas Anprolene es inflamable. No lo utilice cerca del fuego, de superficies calientes o de llamas.
Manténgase fuera del alcance de los niños.
Riesgo de cáncer y para el sistema reproductor.
No abra esta bolsa antes de que se complete el ciclo de 14 horas a 20°C / 68°F o temperatura superior.

Acortar este ciclo obligatorio de 14 horas puede producir una exposición inaceptable del operador a óxido de etileno y quemaduras químicas en el paciente. Airee los materiales que absorben gas fuera de la bolsa de esterilización de acuerdo con las instrucciones adjuntas.

El esterilizador de Anprolene debe utilizarse de acuerdo con las instrucciones detalladas disponibles en el Manual del Propietario y en las Instrucciones que acompañan a cada caja de Anprolene.

ITALIANO

Sacchetto per sterilizzazione destinato esclusivamente all'uso con **Anprolene**
DA UTILIZZARE ESCLUSIVAMENTE IN UNA
STERILIZZATRICE AD ANPROLENE ANDERSEN DI TIPO VENTILATO.

IMPORTANTE: L'Anprolene è un gas infiammabile. Evitare di utilizzarlo in prossimità di fuochi, superfici riscaldate o fiamme.
Tenere lontano dalla portata dei bambini.
Pericolo di cancro e di anomalie riproduttive.
Non aprire questo sacchetto prima del completamento del ciclo di 14 ore a temperature pari o superiore a 20°C / 68°F.

La riduzione della durata obbligatoria del ciclo di 14 ore può essere causa di esposizione inaccettabile dell'operatore ad ossido di etilene e di ustioni di origine chimica per il paziente. Aerare i materiali di assorbimento gas all'esterno del sacchetto per sterilizzazione in conformità con le istruzioni allegate.

La sterilizzatrice ad Anprolene deve essere azionata attenendosi alle istruzioni dettagliate riportate nel manuale per l'utente ed a quelle allegate a ciascun Kit di riempimento di Anprolene.

EPA Registration No. 69340-2

CE 0413

EPA Est No. 69340-NC-001

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LOT M.P.O No. xxxxxx
REF PN822_Rev 7

Liner Bag Manufacture Date: yyyy-mm-dd
Liner Bag Expiration Date: yyyy-mm-dd

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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.

Signatures:

Content Approval:	I have approved the content of this document		
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Controlled Quality Document Authorized for Release:	I authorize this controlled quality document for release.		
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