ANDERSEN STERILIZERS EOGAS 3 STERILIZATION BAGS TECHNICAL DATA SHEET

DEVICE GENERAL DESCRIPTION AND CLASSIFICATION

EOGas 3 sterilization bags are part of the EOGas 3 Sterilization System. Andersen EOGas 3 sterilization bags are Ethylene oxide gas permeable polyethylene bags designed 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 heat-sealed inside the sterilization bag with an appropriate gas cartridge 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 EOGas 3 sterilization system does not come into direct contact with a patient. The system is registered and classified as a Class II medical device in Canada, the UK and the European Union, customers purchasing the system that desire a US FDA clearance do so through a validated sterilization cycle.

INDICATIONS FOR USE

- The EOGas 3 sterilizer is designed for professional use only. It may be used for medical and laboratory sterilization of medical devices. The EOGas 3 sterilizer may be used for commercial sterilization as part of a validated sterilization cycle. The sterilizer is not intended for patient use; the sterilizer is not intended for use on a specific part of the body, it is an active device and is intended to be used for disinfecting invasive devices, as the end point of processing.
- The EOGas 3 sterilizer is designed to sterilize all materials that are compatible with ethylene oxide including metal, glass and plastics. It is designed to sterilize reusable medical devices that are sensitive to moisture, heat, chemical corrosion, or radiation. It is not designed for the sterilization of food or drugs unless it has been determined that they are not altered by contact with ethylene oxide. This compatibility would be determined as part of a validated sterilization cycle.

DIRECTIONS FOR USE

Items to be sterilized are prepared according to the Instructions for use found in the EOGas 3 Refill Kit and in the EOGas 3® Sterilizer User's Manual which are provided with purchase of the Refill Kit and the Sterilizer.

APPLICATION OF USE

- To be used only in Andersen EOGas 3 sterilization system,
  - EOGas 6 bags (PN4646) are specific to the AN1006.00 Refill kit
- To be used with the AN1006.00 Refill kits containing cartridges to activate 10.5 grams of Ethylene Oxide.

SPECIFICATIONS

Part Number	Sterilization System	Material	Thickness (inches)	Dimensions W X L (inches)
4646	EOGas 3	Engineered film structure of polypropylene	0.003 (+/- 0.0005)	22 X 36 (+/- ¼ inch)

RAW MATERIAL COMPOSITION

- Andersen EOGas 3 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

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- The EOGas 3® 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 EOGas 3® 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 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 AN1006.00
  See refill kit technical data sheet for further detail.
- Sterilization bags are available for sale independent of a refill kit, they are securely packaged in a corrugated box with foam inserts to prevent damage during transit.
- 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.

SPECIFICATIONS

Part Number	Sterilization System	Material	Thickness (inches)	Dimensions W X L (inches)
4646	EOGas 3	Polyethylene	0.003 (+/- 0.0005)	22 X 36 (+/- ¼ inch)

QUALITY INSPECTION COMPLETED BY ANDERSEN STERILIZERS

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- Inspection of lot number, date of manufacture, and expiration date printed on the sterilization bags
- Confirmation of sterilization bag dimensions to appropriate tolerances
- Testing for Ethylene oxide gas transmission rate. The method of testing and the specific transmission rate and allowable tolerances are considered proprietary.
- Testing for pin holes or other defects in the polyethylene material
- Testing for heat seal strength and integrity
- Visual inspection of print and heat seal quality

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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PN4646

Heat seal bag here • Thermo-souder le sac ici • Den Beutel hier verschweißen
Termosaldare il sacchetto in questo punto • Selle en caliente la bolsa aquí.

EOGas® 6

Sterilization Liner Bag for use with one **#6 EOGas Cartridge.**
FOR USE ONLY IN A **GENUINE ANDERSEN EOGAS STERILIZER.**

ENGLISH

IMPORTANT: EOGas 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 16 hour cycle at 122°F / 50°C is complete.

Shortening the mandatory 16 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 EOGas sterilizer must be operated according to the detailed instructions available in the Owner's Manual and the Instructions enclosed in each #6 EOGas Refill Kit.

Sac de stérilisation à utiliser avec une **cartouche EOGas #6.**
A UTILISER UNIQUEMENT DANS UN **STERILISATEUR EOGAS ANDERSEN D'ORIGINE.**

FRANÇAIS

IMPORTANT: Le gaz OE 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 16 heures du cycle à 122°F / 50°C.

Raccourcir les 16 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 EOGas doit être utilisé conformément aux instructions détaillées dans le Manuel de l'Utilisateur et aux instructions fournies dans chaque kit de recharges EOGas #6.

Sterilisier-Einsatzbeutel zum Gebrauch mit einer **EOGas-Patronen Nr 6.**
NUR ZUM GEBRAUCH IN EINEM **ECHTEN EOGAS-STERILISATOR VON ANDERSEN.**

DEUTSCH

WICHTIG: EOGas 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 16-Stunden-Zyklus bei 122°F / 50°C geöffnet werden.

Wird der obligatorische 16-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 EOGas-Sterilisator muss gemäß den detaillierten Anleitungen im Handbuch und in der Bedienungsanleitung, die jedem #6 EOGas-Nachfüllkit beiliegen, betrieben werden.

Sacchetto per sterilizzazione destinato esclusivamente all'uso con una **cartuccia di EOGas n. 6.**
DA UTILIZZARE ESCLUSIVAMENTE IN UNA **STERILIZZATRICE AD EOGAS ORIGINALE ANDERSEN.**

ITALIAN

IMPORTANTE: L'EOGas è un gas inflammabile. 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 dei ciclo di 16 ore a 50°C / 122°F.

La riduzione della durata dei ciclo di 16 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 EOGas deve essere azionata attenendosi alle istruzioni dettagliate riportate nel manuale per l'utente ed a quelle allegate a ciascun Kit di riempimento EOGas n. 6.

Bolsa de esterilización para su uso con un **Cartucho de EOGas #6.**
PARA USO SÓLO EN UN **ESTERILIZADOR ANDERSEN EOGAS GENUINO.**

ESPAÑOL

IMPORTANTE: EOGas 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 riesgo para el sistema reproductivo.
No abra esta bolsa antes de que se complete el ciclo de 16 horas a 122°F / 50°C.

Acortar el ciclo obligatorio de 16 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 esterilazión de acuerdo con las instrucciones adjuntas.

El esterilizador de EOGas debe utilizarse de acuerdo con las instrucciones detalladas disponibles en el Manual del Propietario y en las Instrucciones que acompañan cada Juego de Reemplazo de EOGas #6.

EPA Registration No. 69340-6

Liner Bag Manufacture Date: yyyy-mm-dd
Liner Bag Expiration Date: yyyy-mm-dd
LOT M. P. O. No. 323386
REF PN4646_Rev 10

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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.
2022023	1	2022-03-10	Updated to remove all reference(s) to AN1005.00 Refill Kit.

Signatures:

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