ANDERSEN STERILIZERS ANPROLENE 75 AND EOGAS 4 STERILIZATION BAGS TECHNICAL DATA SHEET

DEVICE GENERAL DESCRIPTION AND CLASSIFICATION

750004 sterilization bags are part of the Anprolene AN75 and EOGas 4 Sterilization Systems. They are impermeable, designed to contain water vapor (humidity) and Ethylene Oxide gas during sterilization of various load and material types as specified in the Indications for Use. The Ethylene Oxide (EO) gas is introduced into the sterilization bag through the activation of the EO cartridge and removed from the sterilization bag at the end of the sterilization cycle by the sterilizer's purge mechanism.

The sterilization systems do not come into direct contact with a patient. The systems are registered and classified as a Class II medical device in the US and Canada, and a Class IIb device in the UK and European Union.

INDICATIONS FOR USE

The Anprolene AN75 Ethylene Oxide Gas Sterilizer is intended for use in hospitals and other human healthcare settings. It is designed to sterilize reusable medical devices that are sensitive to moisture,heat, chemical corrosion, or radiation.

The 12-hour cycle at 20-29ºC in the Anprolene AN75 Ethylene Oxide Gas Sterilizer is for surface sterilization of medical devices, including mated surfaces. The critical process parameters for the cycleare summarized in Table 1.

Table 1. Critical sterilization cycle parameters in the Anprolene AN75 Ethylene Oxide Gas Sterilizer

EO Amount	Temperature	Relative Humidity	EO Exposure Time	Total Cycle Time
17.6 g =/15%	20-29ºC	35-70%	12 hours	14 hours

Maximum loads of specific materials and devices that have been validated are listed in Table 2. All validated maximum loads were processed without additional devices in the sterilizer.

Table 2. Load and material types validated in the Anprolene AN75 Ethylene Oxide Gas Sterilizer

Device Type	Maximum Load	Device Examples	Required Aeration
Metal	24 lbs. (11kg)	Delicate sharps and surgical instruments, including those with hinges and mated surfaces	Metal instruments do not absorb EO; Follow pouch or wrap manufacturer's instructions (Example: Sterisheet® wraps require ≥ 6 hours at 20-29ºC
Plastic	3.5 lbs. (1.6 kg)	Reusable power cords, trocars	Follow manufacturer's instructions; 24 hours at 20-29°C
Fabric	3.0 lbs. (1.4 kg)	Reusable cloth gowns, towels	Follow manufacturer's instructions; 24 hours at 20-29°C

Reusable medical devices must be aerated following the instructions of device manufacturers and packaging

material manufacturers, then released for use after sterilization based on successful inactivation of an EZTest®- Gas Biological Indicator in the Anprolene SteriTest process challenge device.

The EOGas 4® Ethylene Oxide Gas Sterilizer is intended for use in hospitals and other human healthcare settings. It is designed to sterilize reusable medical devices that are sensitive to moisture, heat, chemical corrosion, or radiation.

The 3-hour cycle at 50°C in the EOGas 4® Ethylene Oxide Gas Sterilizer is for surface sterilization of medical devices as well as for the sterilization of single-lumen flexible endoscopes. The critical process parameters for the cycle are summarized in Table 5-1 below:

Table 5-1. Critical parameters for the 3-hour cycle in the EOGas 4® Ethylene Oxide Gas Sterilizer

EO Amount	Temperature	Relative Humidity	EO Exposure Time	Total Cycle Time
17.6 g ± 5%	50°C ± 3°C	35-70%	3 hours	3.5 hours

Maximum loads of specific materials and devices that have been validated are listed in Table 5-2. All validated maximum loads were processed without additional devices in the sterilizer.

Table 5-2. Load and material types validated in the EOGas 4® Ethylene Oxide Gas Sterilizer

Device Type	Maximum Load	Device Examples	Required Aeration
Metal	24 lbs (11 kg)	Surgical instruments, delicate sharps, including those with hinges and mated surfaces	Metal instruments do not absorb EO; Follow pouch or wrap manufacturer's instructions for aeration requirements (Examples: Tyvek® pouches and Sterisheet® wrap require ≥ 6 hours aeration at 50°C).
Plastic	7.0 lbs (3.2 kg)	Reusable power cords, trocars	24 hours at 50°C; Follow manufacturer's instructions
Fabric	6.1 lbs (2.8 kg)	Reusable cloth gowns, towels	
Single-lumen Endoscope(s)	One (1) ≥ 2.0 mm internal diameter ≤ 1100 mm length; No additional devices	Gastrovideoscopes, gastrointestinal videoscopes	12 hours at 50°C; Follow manufacturer's instructions

Reusable medical devices must be aerated following the instructions of the device manufacturer and the packaging material manufacturer, then released for use after sterilization based on successful inactivation of an EZTEST®- Gas Biological Indicator in the Andersen EOGas 4 SteriTest process challenge device.

DIRECTIONS FOR USE

Items to be sterilized are prepared according to the Instructions for use found in the Refill Kits and in the Anprolene AN75 Sterilizer User's Manual and the EOGas 4 Sterilizer user's Manual which are provided with purchase of the Refill Kit and the Sterilizer.

ANDERSEN STERILIZERS ANPROLENE 75 AND EOGAS 4 STERILIZATION BAGS TECHNICAL DATA SHEET

APPLICATION OF USE

- To be used in Andersen Anprolene AN75 Sterilizers and EOGas 4 Sterilizers.
- To be used only with the Refill Kits containing cartridges to activate 17.6 grams of Ethylene Oxide.

SPECIFICATIONS

Andersen Part Number	Sterilization System	Material	Thickness (inches)	Dimensions W X L (inches)
750004	Anprolene AN75 EOGas 4	Engineered film structure of polypropylene and nylon	0.003 (+/- 0.0005)	22 X 36 (+/- ¼ inch)

RAW MATERIAL COMPOSITION

- Andersen 750004 sterilization bags are manufactured from a proprietary engineered film structure of polyethylene-nylon 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 sterilization 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. 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 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:

UL 61010-1, 3rd Ed.: 2012
CAN/CSA C22.2 No. 61010.1-12, 3rd Ed.
IEC 61010-2-40, 2nd Ed.
IEC 61326-1: 2012 (120VAC)
EN 61326-1: 2013 (230VAC)
47 CFR Part 15 Subpart B (120VAC)
ICES-003 Issue 6, January 2016 (120VAC)

ANDERSEN STERILIZERS ANPROLENE 75 AND EOGAS 4 STERILIZATION BAGS TECHNICAL DATA SHEET

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 impermeability to EO gas and humidity.
- Functional Testing for pin holes or other defects in the polyethylene – nylon material
- Functional Testing for seal strength and integrity

PACKAGING AND LABELING

- Sterilization bags are packaged with Ethylene Oxide Refill kits AN7514.00 and AN4000.16. See refill kit technical data sheet for further detail.
- Sterilization bags have printed labeling 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.

ANDERSEN STERILIZERS ANPROLENE 75 AND EOGAS 4 STERILIZATION BAGS TECHNICAL DATA SHEET

PN750004 Sterilization Bag Label

ANDERSEN STERILIZERS ANPROLENE 75 AND EOGAS 4 STERILIZATION BAGS TECHNICAL DATA SHEET

Revision History

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.
2022001	1	2022-02-09	Update artwork PN750003 to PN750004 (sterilization bag). Combined EOGas 4 sterilization system information within this TDS.
2022001	2	2022-02-16	Additional change in Sterilization System column of specification section to add EOG 4.

Signatures:

Content Approval:	I have approved the content of this document		
Name:	**Ethan Marshall** **emarshall** Ethan Marshall	Title:	**Director of Operations / Senior Manufacturing Engineer**
Electronically Signed in	M-Files	Timestamp	2022-02-18 18:25:46 (UTC+00:00)

Controlled Quality Document Authorized for Release:	I authorize this controlled quality document for release.		
Name:	**Faith Rios** **ANDERSEN\Faith.Rios** Faith Rios	Title:	**Director of Quality Assurance and Regulatory Affairs**
Electronically Signed in	M-Files	Timestamp	2022-03-07 15:03:47 (UTC+00:00)