Indications for Use

Form Approved: OMB No. 0910-0120
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See PRA Statement below.

510(k) Number *(if known)*
K192978

Device Name
EOGas 4 Ethylene Oxide Gas Sterilizer

Indications for Use *(Describe)*

The EOGas 4 Ethylene Oxide Gas Sterilizer is designed to sterilize reusable medical devices that are sensitive to moisture, heat, chemical corrosion, or radiation. The critical process parameters for the two available cycles are summarized below:

Table 1. EOGas 4 Ethylene Oxide Sterilizer cycle parameters

EO Exposure Time	Total Cycle Time	EO Amount	Temperature	Relative Humidity
3 hours	3.5 hours	17.6 g ± 5%	50°C ± 3°C	35-70%
6 hours	7 hours			

The differences between the two options are the length of EO gas exposure and the length of mandatory ventilation after gas exposure; the gas exposure is chosen based on the devices to be sterilized. The appropriate purge probe and process challenge device (PCD) must be used: EOGas 4 SteriTest for a 3-hour gas exposure, EOGas 4 Endo-SteriTest for a 6-hour gas exposure.

The EOGas 4 Ethylene Oxide Gas Sterilizer 3-hour gas exposure is used for surface sterilization of medical devices, including instruments with diffusion-restricted spaces (hinges or mated surfaces), as well as for the sterilization of endoscopes with working length shorter than 1100 mm as specified in the labeling. The EOGas 4 SteriTest PCD is used with the 3-hour gas exposure.

The EOGas 4 Ethylene Oxide Gas Sterilizer 6-hour gas exposure is used for sterilization of duodenoscopes and colonoscopes with working length longer than 1100 mm as specified in the labeling. The EOGas 4 Endo-SteriTest PCD is used with the 6-hour gas exposure.

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

Device Type	Maximum Load	Device Examples	Required Aeration
3-Hour EO Exposure, EOGas 4 SteriTest PCD (Blue Purge Probe)			
Metal	24 lbs (11 kg)	Surgical instruments, delicate sharps, including those with hinges and mated surfaces	No additional aeration required; Follow pouch or wrap manufacturer's instructions (Example: Tyvek pouches require ≥ 6 hours at 50°C)
Plastic	7.0 lbs (3.2 kg)	Reusable power cords, trocars, and similar devices	24 hours at 50°C; Follow manufacturer's instructions
Fabric	6.1 lbs (2.8 kg)	Reusable cloth gowns, towels, and similar devices	
≤ 1100 mm Working Lumen Length Endoscopes	One (1) ≥ 2.0 mm ID biopsy channel ≤ 1100 mm working length	Gastrovideoscopes, gastrointestinal videoscopes, and similar devices	8 hours at 50°C; Follow manufacturer's instructions
	Four (4) ≥ 1.2 mm ID biopsy channel ≤ 700 mm working length	Bronchoscopes, bronchovideoscopes, cystoscopes, ureteroscopes, choledocoscopes, and similar devices	
6-Hour EO Exposure, EOGas 4 Endo-SteriTest PCD (Gold Purge Probe)			
>1100 mm Working Lumen Length Endoscopes	Two (2) Duodenoscopes* ≥ 2.0 mm ID biopsy channel ≤ 1250 mm working length ≥ 1.2 mm ID, ≤ 3530 mm maximum length of any channel	Olympus TJF-Q180V, Olympus TJF-Q160VF , Olympus TJF-Q190V, Olympus PJF-160, Fujifilm ED-530XT, Pentax ED34-i10T2, Pentax ED-3490TK	6 hours at 50°C for Olympus and Pentax endoscopes in Sterisheet 8 hours at 50°C for Fujifilm endoscopes in Sterisheet
	Two (2) Colonoscopes* ≥ 3.7 mm ID biopsy channel ≤ 1700 mm working length ≥ 1.2 mm ID, ≤ 3530 mm maximum length of any channel	Olympus CF-Q180AL, Fujifilm EC-600HL, Pentax EC-3490Li	Follow manufacturer's instructions

* One (1) duodenoscope may also be paired with one (1) colonoscope

Reusable medical devices must be aerated following the instructions of the device manufacturer and the packaging material manufacturer. Devices are released for use after sterilization based on successful inactivation of a biological indicator (BI) in the Andersen EOGas 4 SteriTest (3-hour gas exposure) or EOGas 4 Endo-SteriTest (6-hour gas exposure) process challenge devices.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

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