



Refer to the device directions for use for complete instructions on device use.

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

REF

M00501970, M00501971, M00501972



Sterilization Instructions

- Place gown in an ethylene oxide (EO) sterilization pouch prior to sterilization.
- Time and temperature parameters required for sterilization may vary according to sterilizer, cycle design and packaging material.
- Do not exceed 20 gowns per sterilization cycle.



Caution

- The contents of this package may burn if exposed to a flame or extremely hot object. Avoid contact with an open flame or high intensity heat source. Gown materials meet Class I Normal Flammability as defined in CPSC 16 (FR Part 1610.
- Do not steam sterilize: Steam sterilization may damage the gown.
- EO sterilization only.
- Sterilize prior to operating room use for surgical procedures.

Parameters for Ethylene Oxide (E) Sterilization

EO	Chamber	Exposure	Relative	Aeration	Aeration
Concentration	Temperature	Time	Humidity	Temperature	Time
759 mg/L	131°F	60 Minutes	60%	125°F - 145°F	12 Hours