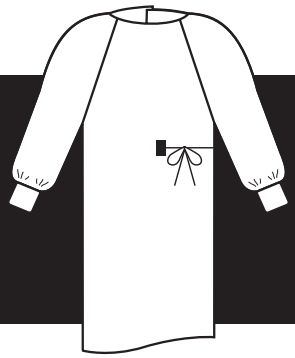
HALYARD*

SURGICAL GOWN



Sterilization Instructions Package Insert

These instructions are provided as a guide for convenience kit assemblers who sterilize non-sterile HALYARD* Surgical Gowns. The Ethylene Oxide (EO) sterilization parameter ranges summarized below represent those used by O&M Halyard for EO sterilization of HALYARD* Surgical Gowns. The EO sterilization cycle has been validated in accordance with Annex B.1.2.(a) Half cycle approach of ANSI/AAMI/ISO 11135:2014 "Sterilization of health care products – Ethylene oxide – Requirements for development, validation, and routine control of a sterilization process for medical devices".

The parameters required for sterilization may vary depending on cycle design, load configuration, and packaging system. The validated sterilization cycle supports HALYARD* Surgical Gowns that:

1) Exhibit case densities less than or equal to 14.08 lbs/ft^3
2) Are packaged in Form-Fill-Seal (FFS) and Clear Header Bag (CHB) sterile barrier systems
3) Are processed in twenty-four (24) and thirty (30) pallet load configurations

O&M Halyard recommends that convenience kit assemblers select and validate their sterile barrier system and packing design in accordance with the requirements of ANSI/AAMI/ISO 11607-1:2019 "Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems" and ANSI/AAMI/ISO 11607-2:2019 "Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes". O&M Halyard also recommends that convenience kit assemblers select and validate their load configuration in accordance with ANSI/AAMI/ISO 11135:2014 "Sterilization of health care products - Ethylene oxide - Requirements for development, validation, and routine control of a sterilization process for medical devices". It is the responsibility of the convenience kit assembler to carefully consider the impact that any processing may have on the kit's components.

HALYARD* Surgical Gowns are qualified for use after two (2) EO sterilization cycles. HALYARD* Surgical Gowns should not be sterilized by any sterilization method other than EO. HALYARD* Surgical Gowns are intended for single use following sterilization.

Sterilization Compatibility:

Method: 100% Ethylene Oxide
Reference Table:

Parameter	Tolerances
Preconditioning Temperature	100–125°F / 38–51°C
Preconditioning Humidity	45-80%
Preconditioning Time	24-48 hours
In-Chamber Temperature	125–145°F / 52–62°C
In-Chamber Humidity	≥ 35%
Maximum Vacuum Depth	1.5 inHgA
Products Vacuum Sensitive	No
Ethylene Oxide Gas Concentration	≥ 230 mg/L
Ethylene Oxide Gas Exposure Time	3 hrs 0 min – 3 hrs 30 min
Aeration Temperature	100–130°F / 38–54°C
Aeration Time	72-120 hours
Ethylene Oxide Residuals[1]	EO ≤ 4 mg/dev; ECH ≤ 9 mg/dev

[1]HALYARD* Surgical Gowns are categorized as limited exposure devices; the EO and ECH residual levels listed above meet the requirements for limited exposure devices per ANSI/AAMI/ISO 10993-7:2008 "Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals" following two (2) sterilization cycles.

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