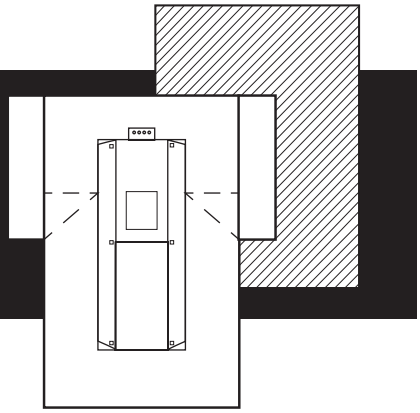
HALYARD*

SURGICAL DRAPES AND EQUIPMENT COVERS



Sterilization Instructions Package Insert

These instructions are provided as a guide for convenience kit assemblers who sterilize non-sterile HALYARD* Surgical Drapes and Equipment Covers. The Ethylene Oxide (EO) sterilization parameter ranges summarized below represent those used by O&M Halyard for EO sterilization of HALYARD* Surgical Drapes and Equipment Covers. 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 Drapes and Equipment Covers that are packaged in Form-Fill-Seal (FFS) and/or Clear Header Bag (CHB) sterile barrier systems. 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". 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 Drapes and Equipment Covers are qualified for use after two (2) EO sterilization cycles. HALYARD* Surgical Drapes and Equipment Covers should not be sterilized by any sterilization method other than EO.

Sterilization Compatibility:
Method: 100% Ethylene Oxide
Reference Table:

Parameter	Tolerances
Preconditioning Temperature[1]	100–125°F / 38–51°C
Preconditioning Humidity[1]	45-80%
Preconditioning Time[1]	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[1]	100–130°F / 38–54°C
Aeration Time[1]	48-96 hours
Ethylene Oxide Residuals[1]	EO ≤ 4 mg ECH ≤ 9 mg

[1]HALYARD* Surgical Drapes and Equipment Covers 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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