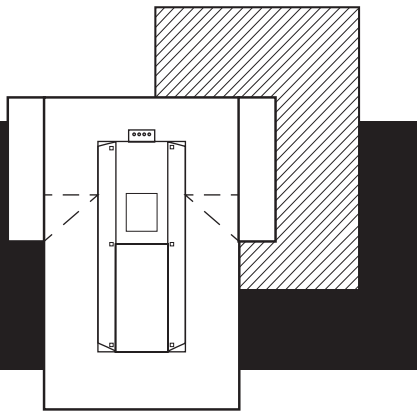
HALYARD*

# 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:

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 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. HALYARD* Surgical Drapes and Equipment Covers 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 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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