

Compatibility Testing of Healthmark's Translucent Tip Protectors Processed in Steam and Ethylene Oxide Sterilization Cycles

Objective: To evaluate the effects of Ethylene Oxide (EO) and Steam sterilization cycles on the Translucent Tip Protectors produced by Healthmark.

Materials:

Translucent Tip Protectors	Steam Sterilizer	Sterilization Wrap
Chemical Indicators	EO Sterilizer	Surgical Instruments

Procedure:

- Pack Preparation
 - **Steam:** One metal tray (10.5" x 10") containing: 3 surgical instruments with the translucent tip protectors and chemical indicator wrapped individually with sterilization wrap and steam sterilization indicator tape
 - **Ethylene Oxide:** One metal tray (10.5" x 10") containing: 3 surgical instruments with the translucent tip protectors wrapped individually with sterilization wrap and EO sterilization indicator tape
- Sterilization
 - Translucent tip protectors were processed in the sterilization tray.
 - The sterilization cycles were each performed once, and can be see below:

Sterilization Method	Cycle Parameters
Pre-Vacuum Steam Cycle (132°C)	Sterilization Temperature: 132+/-3°C Jacket Temperature: 133.0°C Purge Pressure: 10.0P Purge Time: 2.0 Minutes Pre-Vacuum Level: 27.0" Pre-Vacuum Pulses: 4 Pre-Vacuum Hold: 1.0 Minutes Incremental Charge Time: 2.0 Minutes Final Charge Time: 2.0 Minutes Sterilization Time: 4 Minutes Dry Time: 20 Minutes
Pre-Vacuum Steam Cycle (135°C)	Sterilization Temperature: 135+/-3°C Jacket Temperature: 136.0°C Purge Pressure: 10.0P Purge Time: 2.0 Minutes Pre-Vacuum Level: 27.0" Pre-Vacuum Pulses: 4

	Pre-Vacuum Hold: 1.0 Minutes Incremental Charge Time: 2.0 Minutes Final Charge Time: 2.0 Minutes Sterilization Time: 3 Minutes Dry Time: 16 Minutes
Gravity Displacement Steam Cycle	Sterilization Temperature: 121+/-3°C Jacket Temperature: 122°C Purge Pressure: 10.0P Purge Time: 2.0 Minutes Incremental Charge Time: 0.0 Minutes Final Charge Time: 2.0 Minutes Sterilization Time: 30 Minutes Dry Time: 20 Minutes
100% EO – 37°C Cycle	EO Concentration: 725-735 mg/L Temperature: 37+/-5°C Exposure Time: 180 Minutes (3 Hours) Minimum Aeration Time: 3 Days at ambient room temperature
100% EO – 55 °C Cycle	EO Concentration: 725-735 mg/L Temperature: 55+/-5°C Exposure Time: 60 Minutes (1 Hour) Minimum Aeration Time: 12 hours at ambient room temperature

Post-Sterilization Procedure:

Packs that were steam sterilized were opened and the Chemical Indicators were observed. Each Indicator passed.

Packs that were EO sterilized were opened and aerated for 12 hours and 3 days and then tested for Ethylene Oxide (EO), Ethylene Chlorohydrin (ECH), and Ethylene Glycol (EG) residuals.

All packs were examined for damage.

Results:

- Steam and EO sterilization do not visibly damage the two types of Tip Protectors.
- The EO sterilized samples do not exceed the ISO acceptance criteria for “limited exposure devices” for EO and EC after a 12 hour or longer aeration period.
- Healthmark’s translucent tip protectors are compatible with steam and EO sterilization.