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:
1. 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.

2. Sterilization
   - Translucent tip protectors were processed in the sterilization tray.
   - The sterilization cycles were each performed once, and can be seen below:

<table>
<thead>
<tr>
<th>Sterilization Method</th>
<th>Cycle Parameters</th>
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| 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.