# Customer Service Bulletin

**Product:** KleenSpec® 590 Series Vaginal Speculum  
**Date:** 2016-07-22

**Subject:** Ethylene Oxide (EO) & Vaporized Hydrogen Peroxide (VHP) Sterilization Instructions

<table>
<thead>
<tr>
<th>HW Version(s) Affected:</th>
<th>Part Numbers - 590XS, 59000, 59001, 59004, 59005, 59006, 590XS-LED, 59000-LED, 59001-LED, 59004-LED, 58000S, 58001S, 58004S</th>
<th>SW Version(s) Affected:</th>
<th>N/A (no software in device)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serial Numbers Affected:</td>
<td>N/A (applies to all serial numbers for models listed)</td>
<td>Lot or Date Code Affected:</td>
<td>N/A (applies to all lot/date codes for models listed)</td>
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</table>

**Classification:** As Needed

**Distribution:**
- [x] Customer Care
- [x] Product Service
- [x] Field Service
- [x] ASPs
- [x] Distributors
- [x] Customers
- [ ] Company Confidential
Training Required:  ☐ Yes  ☒ No

Summary: For requests for sterilization instructions for KleenSpec® 590 Series Vaginal Specula, the following methods have been validated. These instructions are for new Vaginal Specula and assume the bioburden load of a new unit. There are no cleaning instructions and these remain single use devices. The performance validation is based on one sterilization cycle only. (Particular sterilization packaging used and the subsequent expiration date of sterilization is the responsibility of the sterilization processor)

**These instructions are for those trained in processing sterile devices for the proper use of the sterilization equipment selected. This training is not provided by Welch Allyn and the responsibility of the sterilization processor.**

**Ethylene Oxide Sterilization (EO): (Part Numbers - 58000S, 58001S, 58004S, 590XS, 59000, 59001, 59004, 59005, 59006)**

1. Remove the specula from its bag.
2. Place the specula in the EO chamber as appropriate to allow best exposure of EO. Double wrap as appropriate. 100% EO chamber parameters are as follows:
   - Concentration: 725 mg/L +/- 30 mg/L
   - Temperature: 55°C +/- 3°C
   - Exposure time: 60 minutes
   - Relative humidity: 30 to 80%
   - Aeration: 50°C - 55°C for 12 hours
3. Load should be monitored using biological and chemical indicators approved for EO Sterilization

**WARNING:** Always examine for physical integrity after sterilization and prior to use. Sterilize 1 time only and do not re-sterilize.

**Vaporized Hydrogen Peroxide Sterilization:** (Part Numbers- 58000S, 58001S, 58004S, 590XS, 59000, 59001, 59004, 59005, 59006, 590XS-LED, 59000-LED, 59001-LED, 59004-LED)

1. Remove the specula from its bag and place into a sealed pouch approved for VHP Sterilization
2. Sterilize using STERRAD 100NX for a full cycle
3. Load should be monitored using biological and chemical indicators approved for VHP Sterilization
WARNING: Always examine for physical integrity after sterilization and prior to use. Sterilize 1 time only and do not re-sterilize.

**(Internal Welch Allyn Note) Training is required if the document includes information on how to change/repair/fix the product - and only applies to TSBs.

<table>
<thead>
<tr>
<th>Version</th>
<th>Sec, Pg, Para Changed</th>
<th>Change Made</th>
<th>Date Version Created</th>
<th>Version Created By (initials)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>N/A</td>
<td>Initial Release</td>
<td>2016-07-22</td>
<td>KMC</td>
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**Rev. Description of Change (for FCD-1482 template)**

K Administrative change.