

Document Description: CSB Sterilization KleenSpec 590 Series	Document Number: 80021546 Version: A
	
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<h2 style="margin: 0;">Customer Service Bulletin</h2>			
Product: KleenSpec® 590 Series Vaginal Speculum		Date: 2016-07-22	
Subject: Ethylene Oxide (EO) & Vaporized Hydrogen Peroxide (VHP) Sterilization Instructions			
HW Version(s) Affected: Part Numbers - 590XS, 59000, 59001, 59004, 59005, 59006, 590XS-LED, 59000-LED, 59001-LED, 59004-LED, 58000S, 58001S, 58004S		SW Version(s) Affected: N/A (no software in device)	
Serial Numbers Affected: N/A (applies to all serial numbers for models listed)		Lot or Date Code Affected: N/A (applies to all lot/date codes for models listed)	
Classification: As Needed			
Distribution:			
<input checked="" type="checkbox"/> Customer Care		<input checked="" type="checkbox"/> Product Service	<input checked="" type="checkbox"/> Field Service
<input checked="" type="checkbox"/> ASPs <input checked="" type="checkbox"/> Distributors		<input checked="" type="checkbox"/> Customers	<input type="checkbox"/> Company Confidential

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**Not applicable for Customer Service Bulletins*

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: 55C +/- 3C
 - Exposure time: 60 minutes
 - Relative humidity: 30 to 80%
 - Aeration: 50C - 55C 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

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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.

Version	Sec, Pg, Para Changed	Change Made	Date Version Created	Version Created By (initials)
A	N/A	Initial Release	2016-07-22	KMC

Rev.	Description of Change (for FCD-1482 template)
K	Administrative change.