

		Customer Service Bulletin																									
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Welch Allyn, Inc.[®] 4341 State Street Road Skaneateles Falls, New York 13153-0220 USA		Bulletin Type: INFORMATION ONLY																									
Tel: 1-800-535-6663 Fax: 1-315-685-3361 www.WelchAllyn.com		Manufacturer: Welch Allyn																									
Date: 2014-12-05		SAP DIR #: 80019880																									
Subject:		CSB-LARYNGOSCOPE HANDLES CLEANING, DISINFECTION and “STERILIZATION” INSTRUCTIONS																									
Distribution Scope:		Welch Allyn Global Technical Support, Product, Field & Customer Service teams and WA Customers, ASP's, and Distributors																									
Product(s) Referenced:		Laryngoscope Fiber Optic and/or Standard Handles <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">P/N</th> <th style="text-align: left;">DESCRIPTION</th> </tr> </thead> <tbody> <tr><td>60200</td><td>LG HOOK-ON LARYNGOSCOPE HANDLE</td></tr> <tr><td>60300</td><td>MED HOOKON-LARYNGOSCOPE HANDLE</td></tr> <tr><td>60305</td><td>STUBBY LARYNGOSCOPE HANDLE-STD</td></tr> <tr><td>60400</td><td>HOOK ON HANDLE ASSY-PENLIGHT</td></tr> <tr><td>60710</td><td>RCHG HOOK-ON-HANDLE UL & CSA</td></tr> <tr><td>60720</td><td>RECHARGEABLE HOOK-ON-HNDLE-IEC</td></tr> <tr><td>60713</td><td>LIGHTWEIGHT RCHGBL F/O LARYNGO</td></tr> <tr><td>60813</td><td>LIGHTWEIGHT F/O LARYNGOSCOPE</td></tr> <tr><td>60814</td><td>LIGHTWEIGHT F/O LARYNGOSCOPE</td></tr> <tr><td>60815</td><td>STUBBY F/O LARYNGOSCOPE HANDLE</td></tr> <tr><td>60835</td><td>3.5V RECHG F/O LARYNGO HANDLE</td></tr> </tbody> </table>		P/N	DESCRIPTION	60200	LG HOOK-ON LARYNGOSCOPE HANDLE	60300	MED HOOKON-LARYNGOSCOPE HANDLE	60305	STUBBY LARYNGOSCOPE HANDLE-STD	60400	HOOK ON HANDLE ASSY-PENLIGHT	60710	RCHG HOOK-ON-HANDLE UL & CSA	60720	RECHARGEABLE HOOK-ON-HNDLE-IEC	60713	LIGHTWEIGHT RCHGBL F/O LARYNGO	60813	LIGHTWEIGHT F/O LARYNGOSCOPE	60814	LIGHTWEIGHT F/O LARYNGOSCOPE	60815	STUBBY F/O LARYNGOSCOPE HANDLE	60835	3.5V RECHG F/O LARYNGO HANDLE
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Summary:		Provide clarification of instructions for cleaning, disinfecting, and additional instructions for “sterilization” for the above referenced Laryngoscope Handles.																									
Issue:		Clarification of customer questions																									
The following actions pertain to the Directions For Use listed in the table below:																											
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Action: Please refer to Laryngoscope Handle Directions For Use for complete cleaning, disinfection, disassembly, assembly, and maintenance instructions.

Note: For all laryngoscope handles listed in Product(s) Referenced section on page 1.

In the “Cleaning and intermediate level disinfection instructions” section of the laryngoscope handle DFUs, there are three statements describing the appropriate type of cleaner/disinfectant. The intention is to instruct users on which cleaner/disinfectant chemical families they could choose from. Our analysis and testing showed the cleaner/disinfectants from the quaternary ammonium and alcohol families performed the best with the devices (both in compatibility and efficacy).

These three statements include the incorrect wording “...quaternary ammonium isopropanol...”. The correct wording is “.....quaternary ammonium and/or isopropanol....”

Action: Please refer to Laryngoscope Handle Directions For Use for complete cleaning, disinfection, disassembly, assembly, and maintenance instructions.

Note: For all laryngoscope handles listed in Product(s) Referenced section on page 1 with the exception of 60710, 60720, 60713, and 60835.

Hydrogen peroxide “sterilization” methods for the laryngoscope handles are not included in the released DFUs. Since the release of the DFUs, marketing has received requests for laryngoscope handle hydrogen peroxide “sterilization” methods. These validated methods are provided below.

Steris® Amsco® V-PRO® low temperature “sterilization”: Follow equipment manufacturer and facility procedures in the set-up and operation of Steris® Amsco® V-PRO® low temperature sterilization equipment. Unwrapped V-PRO® sterilization settings are as follows:

- V-PRO 1: Lumen cycle
- V-PRO 1 PLUS: Lumen cycle, non-Lumen cycle
- V-PRO maX: Lumen cycle, non-Lumen cycle, Flexible cycle

STERRAD® hydrogen peroxide gas plasma “sterilization”: Follow equipment manufacturer and facility procedures in the set-up and operation of the STERRAD® hydrogen peroxide gas plasma sterilization equipment. Unwrapped STERRAD® hydrogen peroxide gas plasma sterilization systems and cycles are as follows:

- STERRAD 100S: Standard (short) cycle
- STERRAD 100S: Long cycle (outside of US only)
- STERRAD NX: Standard, Advanced cycles
- STERRAD 100NX: Express, Standard cycles

Notes:

1. Contact Welch Allyn regarding any questions or concerns from this or other issues.
2. Drawings, illustrations, and part numbers in this document are for reference purposes only and subject to change.

End of Bulletin

Revision History

Version	Description	Change #	Init	Release Date	Appr
A	Initial Release	D*	MEB	D*	D*

D* SEE SAP DIR FOR CHANGE NUMBER, APPROVER NAME AND DATE OF APPROVAL