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www.welchallyn.ca



October 16, 2015

URGENT MEDICAL DEVICE CORRECTION

Welch Allyn KleenSpec® Corded Illumination System
Models 78800, 73410, 73412, 73414, 73416, 78810, 78812, 78814 and 78816

Dear Welch Allyn KleenSpec® Corded Illumination System Customer:

Purpose of Letter: I am writing to inform you of a potential hazard associated with the KleenSpec® Corded Illumination System and to inform you of alternative Welch Allyn illumination system options.

Problem Description: Welch Allyn has been made aware that the KleenSpec® 788 Corded Illuminator has the potential to be incorrectly connected to a commonly available AC power cord instead of the illuminator low voltage transformer power cord which is supplied with the illuminator. This may result in a shattered lamp bulb and a potential electric shock hazard. Commonly available AC line power cords do not have an integrated wall transformer and therefore, the electrical current from the outlet is fully transferred into the device. There have been no associated injuries, but the misconnection can be reproduced. For example, the illuminator cord connector may fit into AC power cords from common consumer equipment, such as laptop computers and other medical devices that have similar power cord connector.

To help our customers avoid any such occurrences we are providing supplementary User Precautions which reemphasize safe use of this product and providing additional specificity to the warnings already on our labeling and packaging.

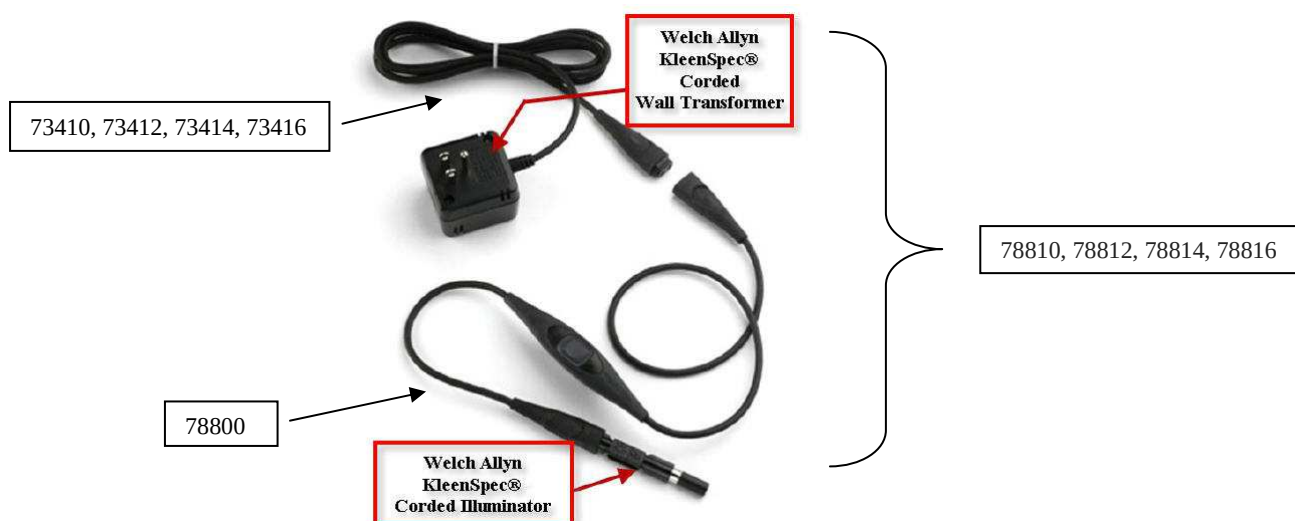
Affected Devices: All KleenSpec® Corded Illumination Systems can be affected, regardless of lot.

User Precautions:

- **DO NOT** connect the KleenSpec® Corded Illuminator directly into AC line power cord. The AC line power cords do not have an integrated wall transformer.



- Use the KleenSpec® Corded Illuminator only with the illuminator power cord with the integrated wall transformer that was provided with the illuminator unit.



Welch Allyn Long Term Correction: For units that are currently in your possession, Welch Allyn will supply labels to affix to the two ends of the KleenSpec® Corded Illumination System power cord connector to remind users to only connect the Welch Allyn Illuminator with the Welch Allyn corded wall transformer.

Alternate Welch Allyn Illuminator System Options: Welch Allyn has the following options that may be used as an alternative to the KleenSpec® 788 Corded Illuminator:

- **KleenSpec® Cordless Illumination System for the 590 series Vaginal Specula**

Corded Illumination System	*Cordless Illumination System Cross Reference
PN 78810	PN 79910
PN 78812	PN 79912
PN 78814	PN 79914
PN 78816	PN 79916

**Please note customers must be using or switch to the 590 Series Vaginal Specula (PN 590XS, 59000, 59001, 59004, 59005, 59006) in order to use the KleenSpec® Cordless Illumination System. Cordless illuminators will not work with the 580S (Sheath) Vaginal Specula (PN 58000S, 58001S, 58004S) or the 586 Economy Series Vaginal Specula (PN 58600, 58601).*



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OR

- **KleenSpec® Single Use LED Vaginal Specula** – Vaginal Specula with an Integrated light source that is ready to use out of the package, no other light source is needed.
PN 590XS-LED (x-small), 59000-LED (small), 59001-LED (medium), 59004-LED (large)

If you would like to switch to one of these options, or should you have any questions or concerns, please contact Welch Allyn Technical Support at 1-800-561-8797 with reference to this letter.

Note: Please ensure this letter is shared with the appropriate personnel in your organization, or to any organization where the potentially affected devices have been transferred.

Regards,

A handwritten signature in black ink that reads "Brian Cousins".

Brian Cousins
VP, Quality Assurance/Regulatory Affairs
Welch Allyn, Inc.