



Welch Allyn Limited,
Navan Business Park,
Dublin Road,
Navan,
Co. Meath,
Ireland.

URGENT: Field Safety Notice

WA15-01-01

Welch Allyn KleenSpec® Corded Illumination System
Welch Allyn Ref: WA15-01-01

Dear Welch Allyn KleenSpec® Corded Illumination System Customer:

Details on affected devices:

Applies to Welch Allyn KleenSpec® Corded Illumination System
Models 78810, 78812, 78814 and 78816

We are writing to inform you of a potential misconnection hazard with regard to our KleenSpec® Corded Illumination System and advise 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 C7 type of AC power cord (i.e. IEC 60320) instead of being correctly connected to the illuminator DC power cord connector (as shown in Figure 2 below).

The use of an AC line power cord (any unapproved non-Welch Allyn power cord) may result in a shattered lamp bulb and a potential electric shock hazard. AC line power cords do not have the manufacturer's approved integrated wall transformer. If users incorrectly connect the illumination system to an unapproved, non-Welch Allyn power cord, (e.g., C7 type AC power cord) the AC mains electrical current from the outlet would be directly transferred to the device (i.e., the AC current is not converted to DC current).

There have been no associated injuries, but the misconnection can be reproduced. For example, the illuminator light cord connector may fit into AC power cords from laptops and other such devices that have a C7 or similar type power cord connector.

To help our customers avoid any such occurrences we are providing below some supplementary user precautions which re-emphasise and provide additional specificity to the warnings already on our labelling and packaging.

Affected Devices:

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

Action to be taken by the user:

- **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: (see Figure 1 below). The KleenSpec Corded Illuminator should only be used with the power cord supplied with it and **NOT** any other power cord that may appear to fit the illuminator.



Only use the approved Welch Allyn KleenSpec® Corded Illuminator with the illuminator power cord which has the integrated wall transformer.

Figure 2 below shows the approved/correct assembly. The use of any other AC line power cord may result in a shattered lamp bulb and a potential electric shock hazard.



Welch Allyn Long Term Correction: Welch Allyn will shortly supply users with labels to affix to the two ends of the KleenSpec® Corded Illumination System power cord connector to remind you to only connect the Welch Allyn Illuminator with Welch Allyn corded wall transformer.

Alternate Welch Allyn Illuminator System Options: Welch Allyn also 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*



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work with the 580S (Sheath) Vaginal Specula (PN 58000S, 58001S, 58004S) or the 586 Economy Series Vaginal Specula (PN 58600, 58601).

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)**

**59004-LED only Available on October 7th, 2015

This notice needs to be passed on to all those who need to be aware within your organisation, or to any organisation where the potentially affected devices have been transferred.

If you would like to switch to one of these options, or should you have any questions or concerns, please feel free to contact Welch Allyn Technical Support.

Technical Support:

Denmark +46 (0)858 536 551	Spain +34 91 749 9357	Italy +39 026 968 2425	Austria +49 (0) 695 098 5132
Norway +46 (0)858 536 551	Finland +46 (0)858 536 551	Benelux +31 20 206 13 60	Germany +49 (0) 695 098 5132
Portugal +34 91 749 9357	Sweden +46 (0)858 536 551	France +33 (0) 141 475 656	Switzerland +49 (0) 695 098 5132
UK 0207 +44 (0)365 6780 Option 3	All other EU countries: +44 (0) 207 365 6780	Middle East +44 (0) 207 365 6780	

This notice has been communicated to your local Regulatory Agency.

Yours sincerely,

Paul Reynolds,
Director, International Quality Assurance & Regulatory Affairs