Welch Allyn KleenSpec® Corded Illumination System Field Action FAQ’s

What is wrong with the KleenSpec® Corded Illumination System?
There is nothing wrong with the KleenSpec® Corded Illumination System as long as you use it as intended.

Can I still use my KleenSpec® Corded Illumination System?
Yes, you can still use your KleenSpec® Corded Illumination System as long as you use the correct power supply cord that comes with the system. You can verify the correct power supply cord by confirming the model number on the transformer. Part Number 73410, 73412, 73414, 73416 (Welch Allyn 4.7 V Power Transformer for KleenSpec Corded Illumination System)

Why did I receive this letter?
You received a letter because we want you to be aware of a potential misconnection hazard with regard to our KleenSpec® Corded Illumination System and to let you know of alternative Welch Allyn illuminator system options.

Which devices are affected?
All KleenSpec® Corded Illumination Systems can be affected, regardless of lot. The part numbers are, 78800, 73410, 73412, 73414, 73416, 78810, 78812, 78814 and 78816

What is the issue?
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 that ships with the product. This may result in a shattered lamp 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.

What are the risks associated with this issue?
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 laptops, and other medical devices that have similar power cord connector. This may result in a shattered lamp and a potential electric shock hazard.
Has Welch Allyn received any field complaints relating to issue?
We have received only a total of 2 complaints for this issue from the field since the product’s introduction in 2003.

Have there been any injuries? No.

Is this a mandated correction by FDA, a Competent Authority, or other regulatory agency? No. This is a voluntary notice to customers

If I have never used the KleenSpec® Corded Illumination System, do I need to do anything? No, this information only applies if you use the KleenSpec® Corded Illumination System

What does Welch Allyn plan to do about the affected devices?
In order to help our customers avoid plugging in the incorrect power supply, we will be supplying labels for existing customers to apply to both ends of the corded illumination system. We will be distributing a letter to customers who have purchased the KleenSpec® Corded Illumination System describing the issue and documenting the additional precautions for users of the KleenSpec® Corded Illumination System once the labels are available, approximately mid-December 2015, and continuing over the next few months.

What if I need additional labels?
If you need additional labels, Welch Allyn will supply them at no charge. Labels will be available in mid-December 2015.