



KleenSpec® Corded Vaginal Illumination System Field Safety Action Overview

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Field Safety Notice (FSN) - Background

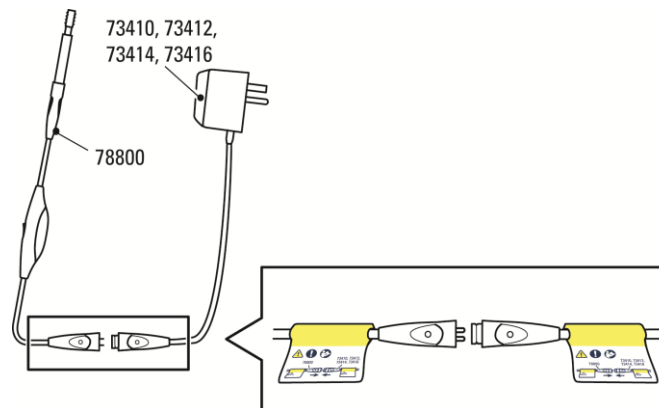
What is the issue?

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.

- **Field Safety Action (Global)**
- **Low risk issue**
- **Expected Remediation Time: over a year (approx. 6-12 months)**

Welch Allyn Plan for 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 in approximately 4-6 weeks.



Customer Contact / Impacted Customers

- US Distributors
 - Initial mailing to Big 5 US Distributors (Cardinal, McKesson, Owen's & Minor, Henry Schein and Medline) via a formal Customer Notification (Field Safety Notice) letter via UPS mailed on October 2, 2015
 - CA mailing to Big 4 Distributors - letters going out towards end of next week
 - Other US/C Dist consignees will receive letter in a few weeks- around 10/26
- International Letters will go out in next 3 weeks (approximately)
- There will be a webpage with info on wa.com - in progress
- End User letters will go out, with labels included, around mid November when labels are available
- Stop ship on 7881X to be lifted once labels are available (mid November)

Number of Impacted Customers and Devices by Country

Region	Country	# Customers	# Units
US/C	Canada	60	11,281
	United States	3,681	179,401

Region	Country	# Customers	# Units
EU	Belgium	9	34
	Cyprus	2	15
	Denmark	3	95
	France	10	35
	Germany	9	110
	Greece	1	3
	Iceland	1	2
	Netherlands	12	27
	Poland	2	3
	Spain	1	1
	Switzerland	1	4
	United Kingdom	17	96
Region	Country	# Customers	# Units
Europe/Middle East	Bahrain	1	17
	Egypt	1	1
	Israel	1	4
	Kenya	1	1
	Kuwait	1	4
	Norway	1	18
	Oman	1	1
	Russian Federation	3	11
	Saudi Arabia	3	83
	Serbia	1	18
	Turkey	1	13
	United Arab Emirates	1	13

Region	Country	# Customers	# Units
JAPACA	Australia	39	451
	Cambodia	1	1
	China	11	1,380
	Guam	2	28
	Hong Kong	2	405
	India	6	222
	Japan	5	17
	Malaysia	1	10
	Namibia	1	23
	New Zealand	5	411
	Singapore	3	9
	South Africa	8	125
	Sri Lanka	1	7
	Thailand	1	2
Region	Country	# Customers	# Units
SA/LA	Bahamas	1	1
	Bermuda	1	1
	Guatemala	1	2
	Honduras	1	1
	Mexico	8	66
	Panama	1	2
	Peru	1	1
	Philippines	1	5
	Puerto Rico	2	3

Next Steps

- As part of this training, you will be requested to review the FAQs, Customer Letters and applicable materials will be posted as a Spotlight in the Knowledge Center
 - Search by part number (eg 78810, 78812) or for “Vag Illuminator”
- Additional training on RMA process to capture Customer requests for additional labels, once label part number is released (Mid November)

The screenshot shows the WelchAllyn Knowledge Center interface. At the top, the WelchAllyn logo is on the left, and a search bar contains the text '78810' with a 'Search' button to its right. Below the search bar, a message states 'Your query has been expanded. [Show Expansions](#)'. A navigation bar below this contains three tabs: 'PRODUCT INFORMATION' (which is active), 'PRODUCT IMAGES', and 'QUALITY SYSTEM (COMING SOON)'. Below the navigation bar, there is a 'Sort by:' section with 'Date' and 'Relevancy' options. On the left side, there are three expandable sections: 'Refinements', 'Source', and 'Product Category'. The 'Refinements' section is currently expanded, showing a list of sources: 'WelchAllyn.com (19)', 'INTL.WelchAllyn.com (12)', 'Intranet (8)', and 'Product Catalog (1)'. The 'Source' section is also expanded, showing 'Physical Exam (12)'. The 'Product Category' section is expanded, showing 'Document Type'. The main content area on the right displays the search results for '78810'. It shows a date '2015-10-02' and a title 'Corded Vaginal Illuminator Field Action'. Below the title, it lists 'Affected Materials: 78800, 78801, 78810, 78812, 78814, 78816'. There are two links: 'EPIC' and 'Overview'. Below these links, there are three sections: 'Internal FAQs', 'External FAQs (may be sent to customer on request)', and 'U/S/C Customer Letter'. At the bottom, there is a link to 'SAP Quick Reference for Additional labels (coming Nov 2015)'.

Key Contacts

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