VOLUNTARY PRODUCT RECALL
KimVent* Subglottic Suctioning Endotracheal Tubes
EMEA4321

November 24th, 2014

Dear Valued Halyard Health Customer:

«Name»
«Address»
«City», «State» «Zip»
ATTENTION: xxx

This letter is to notify you of a Voluntary Product Recall initiated by Halyard Health, Inc. (formerly known as Kimberly-Clark Health Care).

Which Products are impacted?

The five codes and associated lot numbers are provided in the following table. Please note that all affected lots were shipped between December 20th 2013 and October 30th 2014.

Product Code	Product Description/Size	Lot Numbers
13220	KimVent* Microcuff* Subglottic Suctioning Endotracheal Tube, **7.0 mm**	AA3213, AA3227, AA3227V01 AA3245, AA3245V02, AA3253V02, AA3269V01 AA3274V01, AA4038, AA4038V03, AA4038V04, AA4038V06, AA4062, AA4062V01 AA4104V02, AA4111V01, AA4113V01, AA4134V01 AA4146V01, AA4146V04, AA4174V01
13221	KimVent* Microcuff* Subglottic Suctioning Endotracheal Tube, **7.5 mm**	AA3213, AA3213V01, AA3231, AA3231V01 AA3249, AA3249V02, AA3253, AA3253V01 AA3274, AA3274V03, AA4062, AA4062V02 AA4062V06, AA4097, AA4097V01, AA4097V03 AA4125V01, AA4134V02 AA4140, AA4140V01, AA4142, AA4142V01 AA4146V02, AA4167V03 AA4170, AA4170V02
13222	KimVent* Microcuff* Subglottic Suctioning Endotracheal Tube, **8.0 mm**	AA3213, AA3213V03, AA3227, AA3227V01 AA3239, AA3239V01, AA3245, AA3245V02 AA3249, AA3249V01, AA3249V03 AA3253V02, AA3269V01 AA3274, AA3274V01, AA3274V04 AA4038, AA4038V03, AA4038V04, AA4038V06 AA4062, AA4062V01, AA4062V03, AA4062V04 AA4083, AA4083V02 AA4097, AA4097V02, AA4097V04 AA4104V01, AA4104V02 AA4111, AA4111V01, AA4111V02 AA4113V01, AA4125V03, AA4134V01 AA4146V01, AA4146V04 AA4155V03, AA4167V01 AA4170V01, AA4174V01 AA4217V01, AA4226V01

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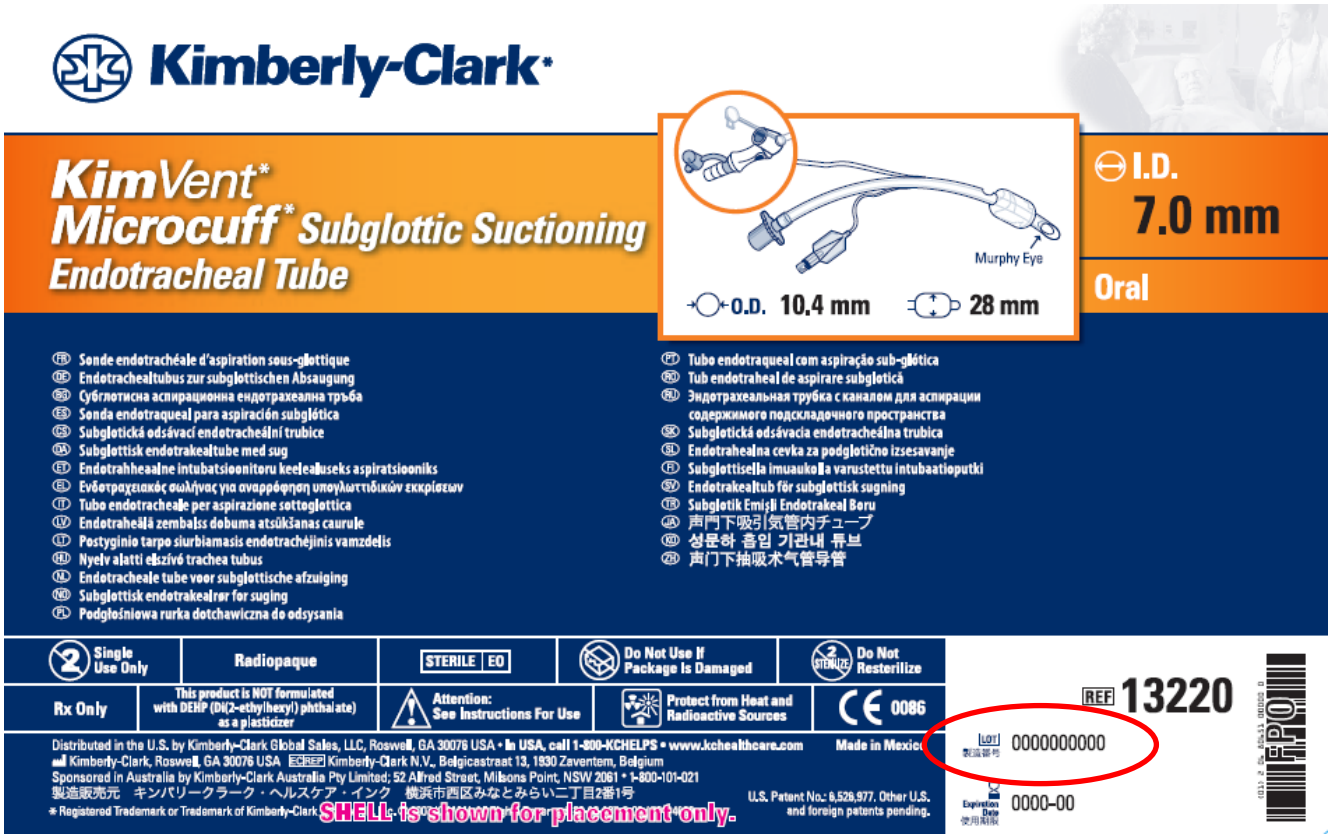
Product Code	Product Description/Size	Lot Numbers
13223	KimVent* Microcuff* Subglottic Suctioning Endotracheal Tube, **8.5 mm**	AA3203V03 AA3234, AA3234V01 AA3260, AA3260V01 AA4038, AA4038V01, AA4038V02, AA4038V05 AA4077, AA4077V01 AA4083, AA4083V01 AA4092V01 AA4125V02
13224	KimVent* Microcuff* Subglottic Suctioning Endotracheal Tube, **9.0 mm**	AA3274, AA3274V02 AA4062, AA4062V05 AA4092V02 AA4104V01 AA4111V03 AA4174V02 AA4190V01
Note: The STANDARD KimVent* Microcuff* Endotracheal Tubes are NOT impacted.		

Representative Product Label (Location of LOT # is highlighted below with a red oval):



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What is the reason for this Voluntary Product Recall?

Halyard Health's Quality Assurance processes have identified that the inflation line of certain KimVent* Microcuff* Subglottic Suctioning Endotracheal Tubes (i.e., currently occurring at a rate of less than 0.5%) may detach from the endotracheal tube during use (i.e., if pulled, tugged, or excess tube/patient movement occurs). Detachment of the inflation line leads to gradual deflation of the endotracheal tube cuff potentially leading to respiratory circuit air leak between the cuff and tracheal wall.

In most reported cases, detachment of the inflation line was identified immediately, while in other cases, eventual decrease in ventilator circuit pressure triggered ventilator alarms. In the majority of occurrences, re-intubation of the patient was required to re-establish the desired pressure in the ventilator circuit. One suspected case of ventilator associated pneumonia was reported after inflation line detachment, which was resolved with standard antibiotic treatment. No other patient injury has been reported to date associated with this issue.

When will the products be available again?

Halyard Health is currently working on corrective actions to solve this issue. We will come back to you once these are implemented and products are available for sale.

What should you do in response to this Voluntary Product Recall?

1. **Please evaluate your facilities' unused inventory** of KimVent* Microcuff* Subglottic Suctioning Endotracheal Tubes to determine if any of the impacted product lots remain within your facility.

    - If present, please quarantine and discontinue use.
    - Please complete the attached **Distributor Product Recall Response Form** and **fax** it at **+32 (0)2 711 26 91 or e-mail** to **piq.emea@hyh.com** within 5 business days of receipt of this notice, even if you have no inventory left.
    - Upon completion of the Distributor Product Recall Response Form, please physically destroy quarantined products using your facility's standard non-contaminated medical device destruction process. Halyard Health will issue to your facility a credit note for the destroyed products. If you have any questions about your credit note, please contact Halyard Health et piq.emea@hyh.com.

2. Please review your distribution records to **identify** all customers who were shipped any of the impacted products.
3. Please **notify** each of your customers, as soon as possible, who were shipped any of the impacted products.
   See attached an example of **Customer Letter** which Halyard Heath is using with its direct customers regarding this Important Voluntary Product Recall along with the **Customer Product Recall Response Form**.
4. Please **notify** the Competent Authority for Medical Device of your country of this recall.

Product currently used on patients

- **NOTE** – If any of these affected codes are currently being used on a patient, please instruct your customer to use the physician's discretion to determine any appropriate actions. If there are questions, please contact Halyard Health at piq.emea@hyh.com.

If you require further assistance please contact Halyard Health at piq.emea@hyh.com.

Halyard Health is dedicated to manufacturing and distributing superior quality products and apologizes for any inconvenience this voluntary product recall may cause you.

Thank you for your assistance.

Sincerely,

Olivier Zarza
Quality and Regulatory Affairs Manager EMEA
On behalf of Thomas Kozma, PhD
Director, Regulatory Affairs

Attachment 1 - Distributor Product Recall Response Form
Attachment 2 - example of Customer Letter used Halyard Heath

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Distributor Product Recall Response Form

Please FAX a copy of this form to +32 (0)2 711 26 91, or send it via email at piq.emea@hyh.com, within 5 business days of receipt of this notice.

Facility: «Name»
«Address»
«City», «State» «Zip»

Our records indicate that you may have received certain impacted products identified below. IF IMPACTED PRODUCT IS STILL WITHIN YOUR EXISTING INVENTORY/CONTROL, please indicate below the quantity of units. Enter "0" to indicate no inventory of the impacted product lots remain within your facility.

Product code	Product Description	Qty of Units for Return (Check Units or Cases)
13220	KimVent* Microcuff* Subglottic Suctioning Endotracheal Tube, 7.0 mm	_____ ( ) Individual units _____ ( ) Cases*
13221	KimVent* Microcuff* Subglottic Suctioning Endotracheal Tube, 7.5 mm	_____ ( ) Individual units _____ ( ) Cases*
13222	KimVent* Microcuff* Subglottic Suctioning Endotracheal Tube, 8.0 mm	_____ ( ) Individual units _____ ( ) Cases*
13223	KimVent* Microcuff* Subglottic Suctioning Endotracheal Tube,8.5 mm	_____ ( ) Individual units _____ ( ) Cases*
13224	KimVent* Microcuff* Subglottic Suctioning Endotracheal Tube, 9.0 mm	_____ ( ) Individual units _____ ( ) Cases*
*Each case includes 10 individually packaged units		

[ ] Please check this box if you have no inventory of impacted product.

I certify that the product codes and lot numbers in the corresponding quantities above will be destroyed in accordance with our facility's standard non-contaminated medical device destruction process.
I certify that the competent authority for medical devices of my country has been informed of this voluntary product recall.

_____
(Signature) (Date)

_____
(Name – print)

_____
(Title – print)