

**URGENT FIELD SAFETY NOTICE – Ref: 150914**

**Voluntary Recall**

**Affected Product:** Laryngeal Suction Tube with Soft Tip

**Product Reference:** NL-0025 Proximal 80 degrees, 250mm 9FG/CH

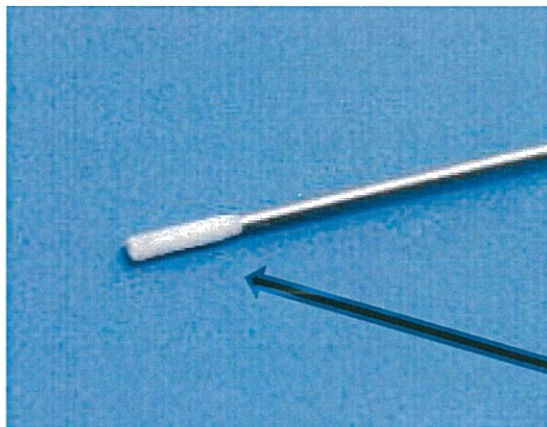
**Affected Batch Numbers:** All batches

14<sup>th</sup> September 2015

Dear Customer,

Our records indicate that you have received the above mentioned device.

**Issue:** Through post production experience activities we have identified that there is a potential for the soft tip to become detached from the suction tube. If this were to happen during a procedure, it is possible that the tip could be aspirated by the patient.



Soft tip may become detached.

**Action:**

1. Identify and quarantine all devices which are still in stock.

2. Liaise with Pennine, or your distributor, to arrange the return of the affected devices.
3. Please complete the attached reply form to confirm that you have read and understood the contents of this Field Safety Notice.
4. Maintain awareness of this Field Safety Notice until all stock of the affected devices have been returned.

At this time, Pennine are unable to offer replacements for the affected devices.

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.

We confirm that this Field Safety Notice has been notified to the appropriate national competent authorities.

Yours sincerely

Print Name: Gareth Hazlewood

Signed:

Position: Deputy Quality Manager

Date:

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### Customer Reply Form

Name			
Address			
Please indicate below the quantity and batch numbers of any stock under your control.			
Batch		Quantity	
Batch		Quantity	
Batch		Quantity	
I hereby confirm that I have read and understood the contents of this Field Safety Notice.			
Sign			
Date			

Please scan and return the completed reply form to:  
[regaffairs@penninehealthcare.co.uk](mailto:regaffairs@penninehealthcare.co.uk)