

## **URGENT FIELD SAFETY NOTICE – Ref: 180215**

### **Voluntary Recall**

**Affected Product:** OSC-1210/48, Clear Graduated Oppo-Cath Suction Catheter, 10ch/48cm.

**Affected Batch:** 24J15

18<sup>th</sup> February 2016

Dear Customer,

You are receiving this letter as our records indicate that you have received the above mentioned device.

**Issue:** Through post production experience activities we have identified that there is a small possibility that the suction catheter may be blocked. A blocked suction catheter would mean that suctioning could not be performed. There is a potential for serious harm should an alternative suction catheter not be available. Due to this risk we have taken the decision to voluntarily recall the affected batch.

**Action:**

1. Identify and quarantine all stock of the affected batch.
2. Complete the attached reply form to confirm that you have read and understood the contents of this Field Safety Notice.
3. Upon receipt of the completed reply form, Pennine Healthcare will arrange for the return or destruction of the affected product.
4. Replacements will be provided for the affected stock which you are holding.
5. Maintain awareness of this Field Safety Notice until all stock of the affected batch has been destroyed or returned to Pennine Healthcare.

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

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

Yours sincerely

Print Name: Gareth Hazlewood

Signed:

Position: Deputy Quality Manager

Date:

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**Customer Reply Form**

Name	
Position	
Company/Institute	
Address	

We do not have any stock of the affected batch

Quantity of affected device in stock

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)