

SINCE 1977

太平洋醫材股份有限公司 Pacific Hospital Supply Co.,Ltd

台北市112北投區大業路160號4樓 4F., NO. 160, Daye Road, Beitou Dist. Taipei 112, Taiwan

Tel:+886-2-2895-5050 Fax:+886-2-2897-8282

# **Urgent Field Safety Notice**

Commercial name of the affected product: Pediatric Enteral Feeding Tube

FSCA-identifier: CP1040031

Type of action: Recall of PVC feeding tube

Date: 2015.9.18

**Attention: End Users** 

#### **Details of affected products:**

Product Code	Specifications
105105	5Fr, 49cm, female connector
105106	6Fr, 49cm, female connector
105108	8Fr, 49cm, female connector
105110	10Fr, 49cm, female connector
105131	5Fr, 125cm, female connector
105132	6Fr, 125cm, female connector
105134	8Fr, 125cm, female connector
105135	10Fr, 125cm, female connector
105204	4Fr, 40cm, male connector
105205	5Fr, 48cm, male connector
105206	6Fr, 48cm, male connector
105208	8Fr, 48cm, male connector
105210	10Fr, 48cm, male connector
105220	4Fr, 80cm, male connector
105221	5Fr, 80cm, male connector
105222	6Fr, 80cm, male connector
105224	8Fr, 80cm, male connector
105225	10Fr, 80cm, male connector
105232	6Fr, 125cm, male connector
105234	8Fr, 125cm, male connector
105235	10Fr, 125c, male connector



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To whom it may concern,

Pacific Hospital Supply Co., Ltd. (hereinafter referred to PAHSCO) is conducting an urgent product recall of all PVC Pediatric Enteral Feeding Tubes. This voluntary recall is being conducted with the knowledge of the relevant Regulatory Agencies.

#### Description of the problem:

The manufacturer became aware of an incident that occurred in Norway where bleeding occurred in a premature infant resulting in abdominal surgery. The PVC feeding tube was found to be very stiff, deformed and discoloured. The root cause for the resulting stiffness of the PVC is under investigation.

#### Advice on action to be taken by the hospital:

- 1. Immediately stop using and quarantine all inventory of PAHSCO PVC feeding tubes with the above product codes
- 2. Perform a count of affected product currently in inventory
- Complete and return the attached Product Response Form by email to your local distributor, Irish Hospital Supplies Ltd;
  Orla Carr ocarr@ihs.ie

#### Transmission of this Urgent Field Safety Notice:

This Field Safety Notice needs to be passed on to all personnel who need to be aware within your organisation or to any organisation/persons where the potentially affected feeding tubes have been transferred.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of this Field Safety Notice.



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## **Product Response Form**

Please complete this form to acknowledge receipt of the Field Safety Notice CP1040031 and to identify whether or not your facility is in possession of PAHSCO PVC Pediatric Enteral Feeding Tubes with article numbers; <u>I05105 / I05106 / I05108 / I05110 / I05131 / I05132 / I05134 / I05135 / I05136 </u> 105206 / 105208

Hosp	oital			
Addr	ess			
City				
Country				
		1		
Please	e check ALL approp	riate boxes.		
	Yes, I have read and understand the recall instructions provided in the Urgent Field Safety Notice CP1040031			Safety
	My facility <u>has no</u> PVC pediatric enteral feeding tubes available for return.			
	My facility <u>has</u> PVC pediatric enteral feeding tubes available for return			
	(If box is checked	d, please complete the table b	elow)	
REF		Number of units received	Number of units to be returned	



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We will return these products as instructed.

Fax:

01-2829957

Signature:				
Date:				
Please return this Product Response Form as soon as possible to:				

P.S. A copy of this form might be forwarded to the Competent Authority in your country.