



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
I05105	5Fr, 49cm, female connector
I05106	6Fr, 49cm, female connector
I05108	8Fr, 49cm, female connector
I05110	10Fr, 49cm, female connector
I05131	5Fr, 125cm, female connector
I05132	6Fr, 125cm, female connector
I05134	8Fr, 125cm, female connector
I05135	10Fr, 125cm, female connector
I05204	4Fr, 40cm, male connector
I05205	5Fr, 48cm, male connector
I05206	6Fr, 48cm, male connector
I05208	8Fr, 48cm, male connector
I05210	10Fr, 48cm, male connector
I05220	4Fr, 80cm, male connector
I05221	5Fr, 80cm, male connector
I05222	6Fr, 80cm, male connector
I05224	8Fr, 80cm, male connector
I05225	10Fr, 80cm, male connector
I05232	6Fr, 125cm, male connector
I05234	8Fr, 125cm, male connector
I05235	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
3. 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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We will return these products as instructed.

Name: _____ Signature: _____

Title: _____

Telephone number: _____ Date: _____

Email: _____

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

Orla Carr

Irish Hospital Supplies Ltd.

Email: ocarr@ihs.ie

Phone: 01-2829016

Fax: 01-2829957

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