

Urgent Field Safety Notice

Crystal ® Metal Miller Disposable Blades (sizes 0 and 00)

7th March 2011

NOTIFICATION TO THEATRE STAFF, STORES PERSONNEL & RISK MANAGERS

Attention: Theatre Staff, Stores Personnel & Risk Managers

Details of affected devices:

Product: Disposable Laryngoscope Blade

Brand Name: Crystal ® Metal Miller Disposable Blades (sizes 0 and 00)

Description of the problem:

Penlon is aware of two isolated incidents where disposable laryngoscope blade cartons have been incorrectly labelled. The affected batches have been identified and this notice is issued as a precautionary measure.

Penlon has determined that this poses a low risk to the user. It is anticipated that prior to use, the user will recognise that the blade is not the size stated on the carton. Penlon has taken action to ensure that this will not occur in the future.

Advise on action to be taken by the user:

All theatre staff and stores personnel should check their stock with expiry dates between August 2010 to July 2015 and ensure that the sizes written on the blades, inner plastic bags, and the carton all match. Please complete the reply form below and send to the address provided. If you have any stock where the sizes on the bags, blades, and carton do not match, quarantine the blades and contact Penlon using the information below.

Transmission of this Field Safety Notice: (if appropriate)

Distribute this notice to all personnel who need to be aware within your organisation, and to any organisation where the potentially affected devices have been transferred.

Contact reference person:

Angela Dunford

Regulatory & Quality Manager

Penlon Ltd

Abingdon Science Park

Barton Lane

Abingdon

OX14 3PH

UK

Telephone: 44 1235 547093

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agencies.

Angela Dunford, Penlon Ltd

REPLY FORM

NAME: _____

HOSPITAL: _____

ADDRESS: _____

We confirm that we have checked our stock of Penlon Crystal[®] Disposable laryngoscope blades with expiry dates between August 2010 and July 2015.

Please tick in the appropriate box below.

We **are not** affected:

We **are** affected:

Lot Number and blade sizes are:

LOT NUMBER	BLADE SIZE

Signed:

Date: