

Field Safety Corrective Action

7th October 2014

Device details

Tubular Slide Sheets
Flat Slide Sheets
Transfer Sheets

Subject: Change to Instruction For Use (IFU)

Dear Customer,

Our records show that you have historically been a customer of Cromptons Healthcare, purchasing slide sheets from us. The purpose of this communication is to advise you of a change to the product Instruction For Use.

Background

Recently, a patient undergoing laparoscopic appendicectomy in a head-down, left-sided tilt (normal position), whilst the transfer sheet was retained beneath the patient, started to slide off the operating table.

Change to Instructions For Use (IFU)

The above reported incident identified a potential hazard in the event that a transfer sheet or slide sheet is retained underneath the patient during surgical procedures where the operating table is inclined. As a precautionary measure, Cromptons Healthcare have amended the product IFU to include reference to this risk.

Amendment to IFU

"Inclined Operating Table Hazard – a potential hazard will exist if the operating table is inclined while the transfer sheet or slide sheet is retained beneath the patient, if inclined sufficiently there is a risk the patient will slide off the operating table. Local risk analysis should consider this possibility when reviewing slide sheet/transfer sheet use within theatres."

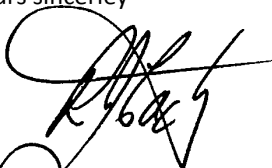
The full revised IFU is available on the Cromptons Healthcare web site at - www.cromptons.co.uk

Please distribute this information to all appropriate personnel in your operating theatres, and forward this information to all parties that may use this product.

We would also be most grateful if you would return the response form below to acknowledge receipt of this letter, this will allow us to positively monitor the effectiveness of this notice.

If you have any questions or need assistance please contact Cromptons Healthcare Limited: Phone: 01256 400620 Email: sales@cromptons.co.uk

Yours sincerley



Roger Cackett
Sales Director

FSN acknowledgement

Device details

Patient transfer sheet

Item code: JC100

Description: Disposable patient transfer sheet

Subject: Change to Instruction For Use (IFU)

I acknowledge receipt of this JC100 Transfer Sheet Field Safety Notice

Name of Hospital	
Department	
Contact Name	
Contact Title	
Contact Telephone No.	

Please complete this form and

Fax: 01256 400622

or

email sales@cromptons.co.uk