INTERSURGICAL
COMPLETE RESPIRATORY SYSTEMS
Quality, innovation and choice

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Urgent Field Safety Notice

Device:
Solus Flexible, small paediatric, wire-reinforced laryngeal mask airway 2
Solus Flexible, large paediatric, wire-reinforced laryngeal mask airway 2.5
Solus Flexible, small adult, wire-reinforced laryngeal mask airway 3
Solus Flexible, medium adult, wire-reinforced laryngeal mask airway 4
Solus Flexible, large adult, wire-reinforced laryngeal mask airway 5

NB: Please be aware all other Solus products are unaffected.

REF numbers: 8002001, 8025001, 8003001, 8004001, 8005001

LOT numbers: from 31310139 till 31703855

Manufacturer: Intersurgical Ltd

FSCA-identifier: 164826 **Date:** 28 March 2017

Attention: All clinical staff, managers and users of the above products

Type of action: Quarantine and destroy the above products lot numbers

Description of the problem: Intersurgical has voluntarily initiated a global corrective action of specific product codes and associated LOTs of Solus Flexible wire-reinforced laryngeal mask airways. **All other Solus products are unaffected.**

A manufacturing fault in the tube supplied to Intersurgical for production of the device can result in partial or total occlusion of the airway tube when the cuff is inflated, which may result in partial or total restriction of air delivery to and/or from the patient. The outcome for the patient will depend on a number of variables, including the degree of occlusion and how quickly the source of the problem is identified allowing remedial action to be taken.

An internal assessment of product performance, including a review of customer complaints has confirmed these devices represent a potentially serious risk to patient safety. For this reason and to prevent any potential risk of harm, all of the affected products must not be used and must be destroyed.

Transmission of this Field Safety Notice: This notice should be transmitted to all those who need to be aware within your organisation, or to any organisation where these potentially affected devices have been transferred.
Intersurgical apologises for any inconvenience this may cause. If you have any questions, please contact your distributor or local Intersurgical representative.

The relevant National Authorities have been advised about this Field Safety Corrective Action.
Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Action to be taken by the user:
Stop the use of all affected devices as defined in this document. Ensure that all of the affected devices in stock are quarantined. Check stock and complete the enclosed Response Form and return it to the contact at the top of the Response Form. Destroy all affected products, credit will be arranged as required. Continue to report any adverse events involving this product to Intersurgical at the contact in the header.

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

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Contact details: *[letterhead with regional contacts header]*

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Response Form

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REF numbers: 8002001, 8025001, 8003001, 8004001, 8005001

LOT numbers: *[list]*

FSCA-identifier: 164826 **Date:** X March 2017

Hospital Name: _____

Hospital Address: _____

Please complete the section below, and send it back to the contact above even if no affected products remain in stock, so that we can reconcile affected products supplied to customers.

I confirm that I have quarantined and destroyed the following products and lot numbers.

REF	LOT	Quantity
[add more rows as required]		

Form Completed and Returned From:

Name:
Position:
Phone No / e-mail:
Date (yyyy-mm-dd):