

URGENT FIELD SAFETY NOTICE

Laryseal Laryngeal Mask

Ref: FSN 2018-001

Date: 13th December 2018

Type of Action: Integrity test required by end user prior to use
Attention: All end users of Flexicare Laryseal Laryngeal Masks

Details on affected devices:

038-94-450 LarySeal Laryngeal Mask Airway Size 5 Lot: 140801295

038-94-520 LarySeal Laryngeal Mask Airway Size 2 Lot: 140300628

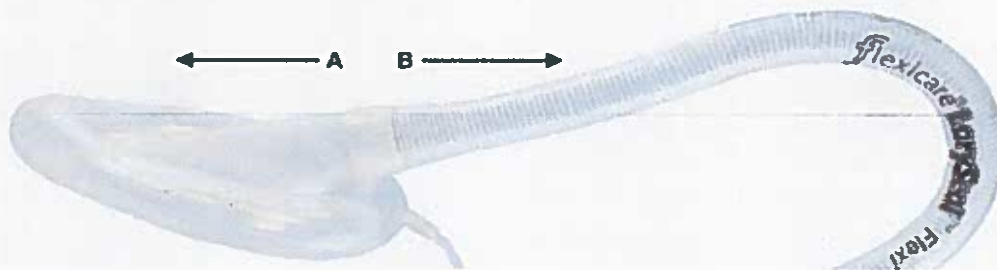
038-94-540 LarySeal Laryngeal Mask Airway Size 4 Lot: 131201439, 140200107, 170401960

038-94-550 LarySeal Laryngeal Mask Airway Size 5 Lot: 140100438

Description of the problem: Potential for the Laryngeal shell to detach from the tube on removal of the device from the patient.

Advice on action to be taken by the user:

Check the integrity of the bond between the tube and the cuff shell prior to use by pulling A (the shell) and B (the tube) in opposite directions using minimal force.



Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Contact reference person:

Tracy Best Quality Assurance Manager

Telephone: +44 (1443) 474647

Email: Tracy.best@flexicare.com

I confirm that this notice has been notified to the appropriate Regulatory Agency

A handwritten signature in black ink that reads "Tracy Best". The signature is written in a cursive style.

Signature
Quality Assurance Manager

FIELD SAFETY NOTICE – ACKNOWLEDGEMENT FORM

Laryseal Laryngeal Mask

PRODUCT CODE	DESCRIPTION	LOT
038-94-450	LarySeal MRI Laryngeal Mask Airway Size 5	140801295
038-94-520	LarySeal Flexi Laryngeal Mask Airway Size 2	140300628
038-94-540	LarySeal Flexi Laryngeal Mask Airway Size 4	131201439 140200107 170401960
038-94-550	LarySeal Flexi Laryngeal Mask Airway Size 5	140100438

I acknowledge receipt and understanding of this field safety notice and have identified that we do not have any of the listed product lot numbers

I acknowledge receipt and understanding of this field safety notice and have communicated this field safety notice to all end users

Customer Name: _____

Address: _____

Telephone: _____

Email: _____

Please complete this form by and return to the Quality Department at quality@flexicare.com by *date*.