

The Laryngeal Mask Company Limited. ("LMA")
c/o Teleflex,
IDA Business & Technology Park
Dublin Road, Athlone
Co. Westmeath, Ireland

URGENT - FIELD SAFETY NOTICE

Type of Action:	Recall	
Reference Number:	CP-14-004	
Commercial Name:	Material	Batch
LMA® Supreme (New Cuff) Size 5	175050	HMAUGK

Dear Customer,

Details of affected devices

LMA has initiated a voluntary Field Safety Corrective Action for the above listed products due to a labelling inconsistency.

Description of the problem

LMA is recalling the product referenced above due to receipt of complaints stating that the labelling of units from the affected lot indicate that the product within is a size 5 LMA Supreme (New Cuff) as seen below, but the product within may actually be a size 4 LMA Supreme (New Cuff). It is unlikely that the mislabelling will result in any serious adverse health consequences. LMA is recalling the affected lot in an effort to provide customers and patients with the highest quality product possible



FIELD SAFETY CORRECTIVE ACTION INSTRUCTIONS:

ADVICE ON ACTION TO BE TAKEN BY MEDICAL STAFF

1. We request that you check your inventory for product within the scope of this field action. Users should cease use and distribution of stock of the affected product batch and quarantine immediately.
2. If you do not have stock in scope of this field action as referred to in above table then mark the according checkbox on the Acknowledgement form (Appendix 1) and return the form to the fax number or e-Mail-address mentioned below.
3. If you have stock from the affected product as referred to in above table, mark the according checkbox on the Acknowledgement form (Appendix 1).

4. Contact customer service by calling the phone number mentioned in Section 6 who will issue you with a return number. Write this return number into the respective field in the Acknowledgement form.
5. Complete 'Appendix 1' for all products in your possession and under control. Return this form immediately to Customer Service.
6. LMA (or your local dealer) will issue a credit note upon receipt of the returned affected product.

INSTRUCTION FOR DISTRIBUTORS OF AFFECTED PRODUCT

1. If you are a distributor, provide this field safety notice to all of your customers who have received product in scope of this Field Action. Your customer is then required to complete the acknowledgement form and return this to you.
2. As a Distributor you are required to confirm to LMA that you have completed the field activity outlined above. Upon completion of your actions, please forward the completed Acknowledgement Form to Customer Service.
3. Please be aware that all European Economic Area/Switzerland (EEA/CH) and Turkey Member State Competent Authorities in which LMA distribute directly will be notified by LMA.
4. If you are a distributor and/or have a reporting responsibility within or outside the EEA/CH/TK area, please notify your local Competent Authority of this action. Please forward the notification and all communication with your local competent authority to LMA.
5. **LMA**
LMA informs all customers, employees of LMA and distributors on this Field Action.
6. **Transmission of this Field Safety Notice**
This notice should be passed on to all persons who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. Please consider end users, clinicians, risk managers, supply chain/distribution centers etc. in the circulation of this notice.

Maintain awareness of this notice until all required actions have been completed in your organization

Contact reference person

Should you require any further information or support concerning this issue, please contact:

Customer Service:

Contact: Helen SAUVAGE

FAX: 01494 524650

Telephone: 01494 532761

E-mail: orders.uk@teleflex.com

Please be advised that all European Economic Area/Switzerland (EEA/CH) and Turkey Member State Competent Authorities to which LMA distribute directly will be notified by LMA.

LMA is committed to providing high quality, safe and effective products. We sincerely apologize for any inconvenience this action may cause your operations. If you have any other questions, feel free to contact your local sales representative or Customer Service.

For and on behalf of LMA,



Karen Boylan
VP Global RA/QA

Appendix 1

Customer No: _____

FIELD SAFETY CORRECTIVE ACTION

LMA Ref: CP-14-004

Acknowledgement Form

URGENT ATTENTION REQUIRED

Return completed form immediately to:

FAX: 01494 524650

E-mail: orders.uk@teleflex.com

Please check applicable box:

<input type="checkbox"/> We confirm receipt of this FSN and completed the required actions contained therein. We confirm that our inventory does NOT include products affected by this Field Action.	<input type="checkbox"/> We confirm receipt of this FSN and completed the required actions contained therein. We confirm our inventory DOES include products affected by this Field Action. The use and further distribution of the affected products has been stopped. All products are on hold and the quantity stated below will be returned.
	<div style="border: 2px solid red; padding: 5px; display: inline-block;"> Return Authorisation No _____ </div>

Please CLEARLY print the below return information:

Names of Affected Products:		
LMA® Supreme (New Cuff)		
Product Number	Lot Number	Quantity (Returning)
175050	HMAUGK	

Return Instructions for Warehouse / Pharmacy Personnel:

- Please label product returns as "Field Action Returns".
 - Include a copy of this form (including RAN Number) with product returns.
- Returns excluding ALL necessary documentation **CANNOT** be processed.

Institution Name - (Hospital, Health Care Organisation, etc.)	
Institution Address:	Email Address:
	Phone Number:
Form completed by:	
Print Name:	Institution Stamp:
Signature:	
Date:	