HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

LMA® Mucosal Atomization Devices and LMA® MAD Nasal™ Intranasal Mucosal Atomization Devices

Priority 2 – Warning

HPRA Safety Notice: SN2016(45) **Issue Date: 15 December 2016**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Teleflex Medical	V29751, V29753

ISSUE
Teleflex Medical is voluntarily recalling certain lots of the products listed above (see the attached field safety notices for affected product code and batch/lot numbers) as they may not deliver a fully atomized plume of medication. Teleflex Medical has received complaints advising that the affected lots produced a straight stream instead of an atomized spray. Teleflex Medical has advised that this may result in inadequate topical anaesthesia which may lead to some discomfort, further attempts to deliver topical anaesthesia, or the use of alternative methods of anaesthesia. This can also lead to serious injury or death in certain emergency situations, such as where the device is used in an off-label manner for needle-free delivery of drugs for reversal of life threatening narcotic overdose, reversal of life threatening hypoglycaemia, or treatment of epileptic seizures.

ACTION OR RECOMMENDATIONS

The HPRA advises that users:

(1) Ensure that you read and follow the instructions provided in the manufacturer's field safety notices (FSNs).

(2) Discontinue use of the products listed in the FSNs that are affected by this recall.

(3) Acknowledge receipt of the FSNs and return the affected product batches if you have not already done so.

(4) Report any concerns regarding these devices to the manufacturer and the HPRA.

The HPRA advises that healthcare professionals:

(5) Ensure that relevant personnel receive a copy of the attached FSNs.

(6) Cease use and distribution of stock from the affected product batches, quarantine and return to manufacturer immediately.

(7) Forward this HPRA safety notice and attached FSNs to all those who need to be made aware within your organisation or to any organisation/person where these devices have been transferred.

(8) Report any concerns regarding these devices to the manufacturer and the HPRA.

TARGET GROUPS

Ambulance Services	Medical Device Distributors
Civil Defence	Pharmacists
Fire Brigade	Primary Healthcare Centres
Members of the public	Purchasing / Procurement / Material Managers
Hospitals	Risk Managers
Hospices	Paramedics / Advanced Paramedics
Carers	Public Health Nurses
Nursing Homes	

BACKGROUND

The Teleflex Medical LMA® Mucosal Atomization Devices and MAD Nasal™ Intranasal Mucosal Atomization Devices are used for the delivery of topical anaesthesia via an atomized spray to the oral, nasal, pharyngeal or laryngeal mucosa.

Teleflex Medical is recalling these products as they may produce a straight stream instead of a fully atomized plume of medication. The failure of the device to deliver an atomized plume may impair the effectiveness of the medication with which it is used.

Teleflex Medical has advised that a variety of medications are delivered with these devices for emergency treatment in an off-label manner for needle-free delivery of drugs for reversal of life threatening narcotic overdose, reversal of life threatening hypoglycaemia, or treatment of epileptic seizures.

Failure of the device that is somewhere between full atomization and a simple stream with no atomization will result in a graded degree of impairment of all of the above scenarios, ranging from complete failure of therapy through partial failure of therapy or delay in full effect of therapy.

Any queries regarding these products or this recall should be addressed to Teleflex by email at: recalls.intl@teleflex.com or by phone at +353 (0) 90 646 0869.

MANUFACTURER / DISTRIBUTOR CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

Teleflex Medical,
IDA Business and Technology Park,
Dublin Road,
Athlone,
Ireland

Telephone: +353 (0) 90 646 0869
E-mail: recalls.intl@teleflex.com
Website: http://www.teleflex.com/en/

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie