HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

LAP-BAND Adjustable Gastric Banding System and Accessories

Priority 3 – Advisory

HPRA Safety Notice: SN2020(13)

Issue Date: 24th September 2020

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Apollo Endosurgery, Inc.	V44632

ISSUE

Apollo Endosurgery, Inc. has issued a Field Safety Notice (FSN) advising that the MRI information section of the LAP-BAND Directions For Use (DFU) and the LAP-BAND Patient ID Card were updated. These updates were to remove the use of outdated MRI terminology and to state that the implantable portion of the system is "***MRI Conditional***." The DFU was also updated to specify under what conditions a LAP-BAND patient can safely undergo an MRI.

Imaging centre staff and radiographers are advised to review the MRI conditions specified in the accompanying FSN when reviewing any implant card for a LAP-BAND Adjustable Gastric Banding System.

Centres provided with affected products supplied since 2018 will receive an updated Directions for Use (DFU) and updated implant cards to reflect the device(s) as being MR Conditional. However, it should be noted devices which were supplied prior to 2018 also have the potential to be affected by this issue and implant cards provided to patients previously will contain the outdated terminology.

Please see the accompanying FSN for further details.

ACTION OR RECOMMENDATIONS

The HPRA advises that **Implanting Centres:**

1 Refer to the accompanying FSN and follow the instructions provided.

2 Ensure the updated Patient ID Card is provided to the patient.

3 Review your inventory to determine if you hold any affected product.

4 Forward a copy of this Safety Notice, the FSN, and Patient ID Card (where applicable), to all relevant personnel within your organisation, or to any organisation/persons to which/whom these devices have been transferred/implanted.

5 Report any adverse incidents associated with these devices to the manufacturer and to the HPRA.

The HPRA advises that **Imaging Centre Staff:**

1 Refer to the accompanying FSN and follow the instructions provided.

2 Review the MRI conditions listed in the attached FSN when presented with Patient ID card for device(s) affected by this FSN.

3 Forward a copy of this Safety Notice, the FSN, to all relevant personnel within your organisation.

4 Report any adverse incidents associated with these devices to the manufacturer and to the HPRA.

The HPRA advises that **patients:**

1 Review the accompanying FSN.

2 Review your implant card, if the implant card indicates *MRI Compatible,* be aware that this term is outdated. The correct term is *MRI Conditional*.

3 If undergoing an MRI highlight this information to your healthcare professional.

4 Report any adverse incidents associated with these devices to the manufacturer and to the HPRA.

TARGET GROUPS	
All surgical wards and theatres Clinical Engineers Clinical Nurse Managers Directors of Nursing Emergency Department Consultants Gastroenterologists Gastrointestinal surgeons Hospital Managers / CEOs ICU Staff Imaging Centre Staff Medical Physicists	Nuclear Medicine Technologists Patients Procurement / Purchasing Managers Radiographers Radiologists Risk Managers Stores / Supplies Staff Supplies managers Theatre Managers Theatre Staff

BACKGROUND

Prior to the updates highlighted above, the LAP-BAND DFU stated that the system had "been proven to be MRI Safe per testing when exposed to 3T or lower MRI scans" and the Patient ID Card indicated that the system was "MRI Compatible." These terms were once compliant with international standards, however, this MRI terminology and their definitions were updated in subsequent revisions of the standard to provide clarity. The corresponding changes were not implemented within the LAP-BAND DFU or Patient Card following the publication of these updated standards.

Apollo Endosurgery, Inc. have indicated that although unlikely, it is possible that this discrepancy could lead to a LAP-BAND patient being exposed to MRI conditions outside of those proven to be safe and as a result, potentially lead to adverse events such as tissue damage, device migration and/or device malfunctions (e.g., fluid leaks). It has been outlined that there have been zero (0) reports of LAP-BAND patients being exposed to MRI conditions outside of those shown to be safe as a result of this issue, to date.

A HPRA Information Notice was published in 2017 which relates to MR Imaging of Patients with Implantable Medical Devices, which is available at the following link: IN201705

The HPRA is issuing this Safety Notice to raise awareness of this issue.

MANUFACTURER INFORMATION

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

Apollo Endosurgery, Inc
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Bldg.1, Ste. 300
Austin, TX 78746
USA

Telephone: (281) 513-5110
E-mail: evelyn.kile@apolloendo.com

Or

ReShape Lifesciences, Inc
1001 Calle Amanecer
San Clemente, CA 92673
USA

Telephone: (949) 429-6680
E-mail: tmeraz@reshapelifesci.com

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
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie