1120 S. Capital of TX Hwy, Bldg.1, Ste.300
Austin, Texas 78746
USA

Urgent Field Safety Notice

LAP-BAND Adjustable Gastric Banding System
FSN-20-001
Field Safety Notice (FSN) – Labeling Update (MRI Safety Information)

Date:

Attention: Customers

Details on affected devices:
This notice is applicable to all patients implanted with the LAP-BAND Adjustable Gastric Banding System. Actively distributed products IDs affected by this Field Safety Notice, corresponding product names and Directions For Use (DFU) are referenced in the table below:

Product ID	Product Name	Directions For Use Number (Revision)
C-20360 C-20365	LAP-BAND AP® Adjustable Gastric Banding System with RapidPort® EZ and OMNIFORM™	GRF-00217-00 (R05)
C-20304 C-20306	RapidPort® EZ Access Port Kit	GRF-00216-00 (R05)
N/A	LAP-BAND AP System Patient ID Card	GRF-00284-00 (R02)

Description of the problem:
The purpose of this notification is to inform you that the MRI information section of the LAP-BAND DFU and the LAP-BAND Patient ID Card were updated in July 2019 and January 2020 respectively, to remove the use of outdated MRI terminology and to state that the implantable portion of the system is "*MRI Conditional*." Additionally, the DFU was updated to specify under what conditions a LAP-BAND patient can safely undergo an MRI (previously this information was available upon request).

Specific changes made to the aforementioned DFU are described below. The same changes have been made to each of the two Directions for Use leaflets.

MRI SAFETY INFORMATION
Non-clinical testing demonstrated that the Apollo Endosurgery LAP-BAND AP® System with RapidPort ® EZ (C-20360, C-20365) and RapidPort® EZ Access Port Kit (C-20304, C-20306) is MR Conditional. A patient with this device can be scanned safely in an MR system immediately after placement under the following conditions:

- *Static magnetic field of 1.5-Tesla and 3-Tesla, only*
- *Maximum spatial gradient magnetic field of 3000 Gauss/cm or less*
- *Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning in the Normal Operating Mode of operation for the MR system*
- *Under the scan conditions defined, the Apollo Endosurgery LAP-BAND AP® System with RapidPort ® EZ (C-20360, C-20365) and RapidPort® EZ Access Port Kit (C-20304, C-20306) is expected to produce a maximum temperature rise of 1.7°C after 15-minutes of continuous scanning.*

ARTIFACT INFORMATION
In non-clinical testing, the image artifact caused by the Apollo Endosurgery RapidPort® EZ Access Port extends approximately 20 mm from this implant when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

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Prior to this update, 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". Additionally, the Patient ID Card indicated that the system was "*MRI Compatible*." Though these terms were once compliant with international standards, 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.

Though 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). To date, 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.

Advise on action to be taken by the user:
Please note that no product return or rework is required as a result of this notification. It is recommended that physicians continue their standard practice as it relates to both new and existing LAP-BAND patients.

Please communicate this information to those inside or outside your clinic that may be performing MRI imaging on LAP-BAND patients. MRI facilities may contact Reshape Lifesciences, Inc., the current proprietary owner of the LAP-BAND Adjustable Gastric Banding System, or visit https://www.lapband.com/mri-information for recommended MRI conditions or with any questions related to this issue.

Please complete and return the "Acknowledgement Form" below as soon as possible, indicating 'UNDERSTOOD' in the subject line (in lieu of a signature). The completed Acknowledgement Form should be e-mailed to:

LAP-BAND_FSN_20-01@apolloendo.com

Alternatively, you can print this e-mail and return the completed/signed Acknowledgement Form to Apollo Endosurgery, Inc by mail. By returning the completed Acknowledgement Form by email or mail, you acknowledge that you have read and understood this Field Safety Notice.

Your prompt confirmation will prevent repeat notifications.

Transmission of this Field Safety Notice:
This notice should be passed on to applicable individuals within your organization and/or transferred to other organizations in which this action has an impact (e.g. MRI Facilities).

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Call for Reporting

The LAP-BAND product line was purchased by ReShape Lifesciene, Inc. in December 2018. Physicians should report the occurrence of any LAP-BAND related adverse events or device malfunctions directly to ReShape Lifesciences, Inc.

ReShape Lifesciences, Inc.
1001 Calle Amanecer
San Clemente, CA 92673 USA
www.reshapelifesciences.com

Telephone: (844) 937-7374
Fax: (949) 276-6910

Company Contact Points for this Notice:

Apollo Endosurgery, Inc.	ReShape Lifesciences, Inc.
Evelyn Kile 1120 S. Capital of TX Hwy, Bldg.1, Ste. 300 Austin, TX 78746 USA E-Mail: evelyn.kile@apolloendo.com Phone: (281) 513-5110	Tania Meraz 1001 Calle Amanecer San Clemente, CA 92673 USA E-Mail: tmeraz@reshapelifesci.com Phone: (949) 429-6680

The undersign confirms that this notice has been communicated to the appropriate Regulatory Agency.

Sincerely,

David M. Hooper, Ph.D.
Vice President, Quality Assurance and Regulatory Affairs
Apollo Endosurgery, Inc.

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Austin, Texas 78746
USA

Acknowledgement Form:

Complete and return this completed table by e-mail to the following address e-mail address (preferred):

LAP-BAND_FSN_20-01@apolloendo.com

or mail to:

Evelyn Kile
1120 S. Capital of TX Hwy,
Bldg.1, Ste. 300
Austin, TX 78746

Please check the two boxes below.

☐ I confirm that I have received and read this Field Safety Notice (FSN-20-001) and acknowledge the updated MRI Safety Information for LAP-BAND Adjustable Gastric Banding System.

☐ I hereby acknowledge that all required personnel have been notified of this MRI Safety Information,

Name of Institution: _____

Address: _____

Telephone Number: _____

Email: _____

Name: _____ **Title**: _____

Signature (If printed): _____ **Date**: _____

We thank you for your cooperation.