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Medical Information Memorandum (December 2014)

Re: MRI Safety of the Lap-Band® System

Dear Health Care Professional:

You are receiving this memorandum based on a request received through Apollo Endosurgery Medical Information regarding the magnetic resonance (MR) imaging safety profile of the Lap-Band System.

Non-clinical testing demonstrated that the Lap-Band System* is MR Conditional. A patient with the Lap-Band System devices noted below can be scanned safely immediately after placement under the following conditions:

- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of 720 Gauss/cm or less
- Maximum MR system-reported, whole-body-averaged specific absorption rate (SAR) of 3-W/kg for 15 minutes of scanning.

In non-clinical testing, the Lap-Band System produced a maximum temperature rise of 0.5° C at a maximum MR system-reported whole-body-averaged specific absorption rate (SAR) of 3-W/kg for 15 minutes (per pulse sequence) of MR scanning in a 3-Tesla MR system using a transmit/receive body coil (Excite, Software G3.0-052B, General Electric Healthcare, Milwaukee, WI).

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the Lap-Band System devices. Therefore, optimization of MR imaging parameters to compensate for the presence of the Lap-Band System may be necessary.

Thank you for contacting Medical Information at Apollo Endosurgery. We appreciate your inquiry and commitment to provide the best care for your patient.

A handwritten signature in black ink, appearing to read "Laura LeBoeuf", written in a cursive style.

Laura LeBoeuf
Vice President, Quality, Regulatory, Clinical Affairs

*For the purposes of this memorandum only, "Lap-Band System" is limited to the Lap-Band device, Access Port I, Access Port II, and RapidPort Tack. Apollo Endosurgery, Inc. is currently pursuing updates to the information presented on the website www.MRIsafety.com to be consistent with this memorandum.