



## Diagnostic Imaging with the LINX® Reflux Management System

**Patients with a LINX device can undergo the following diagnostic imaging tests:**

- CT scan (Computed Tomography)
- Ultrasound (Echocardiography)
- X-ray (Radiography / Fluoroscopy / Angiography)
- PET scan (Positron Emission Tomography)
- MRI (Magnetic Resonance Imaging) up to 0.7-Tesla (0.7T)

**For patients requiring MRI:**

Non-clinical testing has demonstrated that the LINX device is MR Conditional and can be scanned safely in a static magnetic field up to 0.7-Tesla (0.7T). In the event an MRI is required above 0.7-Tesla (0.7T) or alternative diagnostic procedures cannot be used, the LINX device can be safely removed utilizing a laparoscopic technique that does not compromise the option for traditional anti-reflux procedures.

**Guidance for patients considering LINX:**

The LINX device is considered MR Conditional in a magnetic resonance imaging (MRI) system up to 0.7-Tesla (0.7T). Scanning under different conditions may result in serious injury to the patient and/or interfere with the magnetic strength and function of the device. You should discuss the MRI conditions with your doctor prior to deciding on treatment with the LINX System.

Full MRI safety information is attached and available at [www.toraxmedical.com](http://www.toraxmedical.com) or contact Torax Medical, Inc. at (651) 361-8900.

## MRI Safety Information



Non-clinical testing has demonstrated that the LINX® System is MR Conditional. This device can be scanned safely under the following conditions:

- Static magnetic field **0.7-Tesla (0.7 T)**
- Spatial gradient field of up to 364 G/cm (3.64 T/m)
- Maximum whole body averaged specific absorption rate (SAR) of 4.0 W/kg for 15 minutes of scanning in First Level Controlled Mode
- The LINX® System contains permanent magnets. Should the patient experience discomfort or pain, immediately discontinue the scan and remove the patient from the MR environment.

### **RF Heating**

In non-clinical testing, with body coil excitation, the LINX® System produced a temperature rise of 0.6°C at a maximum whole body averaged specific absorption rate (SAR) of 4.0 W/kg, as assessed by calorimetry for 15 minutes of scanning in a 0.7 T Hitachi Altaire Open MR scanner with software version 5.1H-1.

Caution: The RF heating behavior does not scale with static field strength. Devices which do not exhibit detectable heating at one field strength may exhibit high values of localized heating at another field strength.

### **MR Artifact**

In testing using a 0.7 T system with gradient-echo sequencing, the shape of the image artifact follows the approximate contour of the device and extends radially up to 10.3 cm from the implant.

Torax Medical recommends that the patient register the MR conditions disclosed in this IFU with the MedicalAlert Foundation ([www.medicalert.org](http://www.medicalert.org)) or equivalent.



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