

# MRI Safety Information

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

- Static magnetic field **1.5-Tesla (1.5 T)**
- Maximum spatial field gradient of 1,715 gauss/cm (17.15 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4 W/kg (First Level Controlled Operating Mode)
- The LINX device contains permanent magnets. The patient may feel pressure around the Lower Esophagus. Should the patient experience pain, immediately discontinue the scan and remove the patient from the MR environment.



**PLEASE NOTE:** The MRI information in this document pertains only to the 1.5 T LINX device. Some patients may have been treated with an earlier version of the LINX device that is MR conditional only up to 0.7 Tesla (0.7 T). Patients implanted with the 0.7 T version cannot undergo testing in a magnetic resonance imaging system above 0.7 T. If the patient has a 0.7T device, please contact customer support at **513-337-8901** for imaging information.

## RF Heating

In non-clinical testing, with body coil excitation, the LINX device produced a temperature rise of less than 4.0°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 1.5 T Siemens Espree (MRC30732) MR scanner with SYNGO MR B19 software.

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 1.5 T system with gradient-echo sequencing, the shape of the image artifact follows the approximate contour of the device and extends radially up to 10.4 cm from the implant.

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

Implant Cards

Each LINX™ device package contains a LINX Implant Card to be provided to the patient at the time of surgery. If a patient is in need of a replacement LINX Implant Card, please reach out to your LINX representative directly or contact the Ethicon Resource Department (1-877-384-4266) to submit a replacement request.

CURRENT IMPLANT CARD

Attention: This patient has a magnetic implant in the area of the gastroesophageal junction.

LXMC CARD IMPLANT LXM

The patient should not be exposed to the MRI environment greater than 1.5 Tesla (1.5T). MRI scanners exceeding 1.5 Tesla could cause serious injury to the patient and/or interfere with the magnetic strength and the function of the device.

STOP MRI IMMEDIATELY if patient experiences pain during the MRI procedure

For more information about LINX™ and MRI: Use contact information inside card

Front/Back

For medical questions regarding this device please contact the implanting physician:

or the manufacturer Torax Medical, Inc.:  
Phone: 877.384.4266  
+ 1.513.337.8901 (English)  
Email: customersupport@eesus.jnj.com  
www.toraxmedicalmri.com

Although this device should not interfere with airport or event security, it is advised that this card be available to authorities in the event of security issues.

Place Implant Sticker Here

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Inside

PREVIOUS CARD VERSIONS

LINX IMPLANT CARD

Attention: This patient has a magnetic implant in the area of the gastroesophageal junction.

The patient should not be exposed to an MRI environment greater than 1.5 Tesla (1.5T). MRI scanners exceeding 1.5 Tesla could cause serious injury to the patient and/or interfere with the magnetic strength and the function of the device.

LINX IMPLANT CARD

Attention: This patient has a magnetic implant in the area of the gastroesophageal junction.

The patient should not be exposed to an MRI environment greater than 0.7-Tesla (0.7T). The MRI environment could cause serious injury to the patient and/or interfere with the magnetic strength and the function of the device.

MRI Compatibility Reference Chart

Product Code	Availability	MRI Compatibility	Description	Implant Card	Instructions for Use Document #
LXMC13 LXMC14 LXMC15 LXMC16 LXMC17	Current device being sold	1.5T	Clasp to close the device	Blue	7374
LXC12 LXC13 LXC14 LXC15 LXC16 LXC17	No longer sold	0.7T	Clasp to close the device	White	3720
LS12 LS13 LS14 LS15 LS16 LS17	No longer sold	0.7T	Suture to close the device	White	3089

**LINX™ Reflux Management System Important Safety Information**

The LINX Reflux Management System is a laparoscopic, fundic-sparing anti-reflux procedure indicated for patients diagnosed with Gastroesophageal Reflux Disease (GERD) as defined by abnormal pH testing, and who are seeking an alternative to continuous acid suppression therapy (i.e. proton pump inhibitors or equivalent) in the management of their GERD. **Rx Only. Contraindications:** Do not implant the LINX system in patients with suspected or known allergies to titanium, stainless steel, nickel, or ferrous materials. **Warnings:** The LINX device is considered MR Conditional in a magnetic resonance imaging (MRI) system up to either 0.7 Tesla (0.7T) or 1.5 Tesla (1.5T), depending on the LINX model implanted. Laparoscopic placement of the LINX device is major surgery. **General Precautions:** The LINX device is a long-term implant for use in patients 21 years or older. Medical management of adverse reactions may include explantation and/or replacement. Potential Risks Associated with LINX System: belching, decreased appetite, device erosion, device migration (device does not appear to be at the implant site), dysphagia (difficult swallowing), flatulence, hiccups, inability to belch or vomit, infection, nausea, odynophagia (painful swallowing), pain regurgitation, stomach bloating, weight loss, swallow-induced syncope (fainting), and worsening of preoperative symptoms. Your physician can help you determine if LINX is right for you. Patient results may vary. For full patient information visit [www.linxforlife.com](http://www.linxforlife.com) or [www.ethicon.com](http://www.ethicon.com).

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Manufactured by:  
Torax® Medical, Inc.  
4545 Creek Rd.  
Cincinnati, OH 45242

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