

## Diagnostic Imaging with LINX™

Patients with a LINX device can undergo a wide range of diagnostic imaging tests, including: X-Ray, Ultrasound, PET Scan, CT Scan, and MRI under certain conditions.<sup>1</sup>



### Do you have a LINX device?

It's important to know which LINX device you have. Each version of the device must be scanned under specific MRI conditions. Scanning under different conditions may result in serious injury to you and/or interfere with the magnetic strength of and function of the device. If you are not sure which device you have, please contact your physician.

### How will I know post-implant which LINX device I have?

- Patients **implanted with LINX PRIOR to May 22, 2015** have been implanted with the **0.7T device**.
- If you were **implanted with LINX AFTER May 22, 2015** please check your implant card. Blue card (below) for **1.5T device**; White card (below) for **0.7T device**.
- If you have any questions about which LINX device you have, contact the surgeon who performed your procedure.

#### CURRENT IMPLANT CARD

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

**LINX**  
IMPLANT CARD  
LXM LXC

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

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

[Redacted]

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

4631 Rev 3

#### PREVIOUS IMPLANT 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.

**PLEASE NOTE:** In the event an MRI outside the compatibility of your device is required, and alternative diagnostic procedures cannot be used, the LINX™ device can be removed

## 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 Reflux Management 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. Scanning under different conditions may result in serious injury to you and/or interfere with the magnetic strength and the function of the device. In the event alternative diagnostic procedures cannot be used and MRI is required, the LINX device can be safely removed utilizing a laparoscopic technique that does not compromise the option for traditional anti-reflux procedures. It is recommended that patients receiving the LINX device register their implant with the MedicAlert Foundation ([www.medicalert.org](http://www.medicalert.org)) or equivalent organization.

Failure to secure the LINX device properly may result in its subsequent displacement and necessitate a second operation.

**General Precautions:** The LINX device is a long-term implant. Explant (removal) and replacement surgery may be indicated at any time. Management of adverse reactions may include explantation and/or replacement.

The use of the LINX device in patients with a hiatal hernia larger than 3 cm should include hiatal hernia repair to reduce the hernia to less than 3 cm. The LINX device has not been evaluated in patients with an unrepaired hiatal hernia greater than 3 cm.

The safety and effectiveness of the LINX device has not been evaluated in patients with Barrett's esophagus or Grade C or D (LA classification) esophagitis.

The safety and effectiveness of the LINX device has not been evaluated in patients with electrical implants such as pacemakers and defibrillators, or other metallic, abdominal implants.

The safety and effectiveness of the LINX Reflux Management System has not been established for the following conditions:

- Scleroderma
- Suspected or confirmed esophageal or gastric cancer
- Prior esophageal or gastric surgery or endoscopic intervention with the exception of Laparoscopic Sleeve Gastrectomy (LSG) which has been evaluated for safety and efficacy
- Distal esophageal motility less than 35 mmHg peristaltic amplitude on wet swallows or <70% (propulsive) peristaltic sequences or High Resolution Manometry equivalent, and/or a known motility disorder such as Achalasia, Nutcracker Esophagus, and Diffuse Esophageal Spasm or Hypertensive LES
- Symptoms of dysphagia more than once per week within the last 3 months
- Esophageal stricture or gross esophageal anatomic abnormalities (Schatzki's ring, obstructive lesions, etc.)
- Esophageal or gastric varices
- Lactating, pregnant or plan to become pregnant
- Morbid obesity (BMI >35)
- Age < 21

**Potential Side Effects:** Potential adverse events associated with laparoscopic surgery and anesthesia include adverse reaction to anesthesia (headache, muscle pain, nausea), anaphylaxis (severe allergic reaction), cardiac arrest, death, diarrhea, fever, hypotension (low blood pressure), hypoxemia (low oxygen levels in the blood), infection, myocardial infarction, perforation, pneumonia, pulmonary embolism (blood clot in the lung), respiratory distress, and thrombophlebitis (blood clot). Other risks reported after anti-reflux surgery procedures include bloating, nausea, dysphagia (difficulty swallowing), odynophagia (painful swallowing), retching, and vomiting.

Potential risks associated specifically with the LINX Reflux Management System include achalasia (lower part of esophagus does not relax), bleeding, cough, death, decreased appetite, device erosion, device explant/re-operation, device failure, device migration (device does not appear to be at implant site), diarrhea, dyspepsia (indigestion), dysphagia (difficulty swallowing), early satiety (feeling full after eating a small amount of food), esophageal spasms, esophageal stricture, flatulence, food impaction, globus sensation (sensation of a lump in the throat), hiccups, inability to belch or vomit, increased belching, infection, impaired gastric motility, injury to the esophagus, spleen, or stomach, nausea, odynophagia (painful swallowing), organ damage caused by device migration, pain, peritonitis (inflammation of the peritoneum), pneumothorax (collapsed lung), regurgitation, saliva/mucus build-up, swallow-induced syncope (fainting), stomach bloating, ulcer, vomiting, weight loss, and worsening of preoperative symptoms (including but not limited to dysphagia or heartburn).

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**For more information on the LINX Reflux Management System, contact your physician.**

**For full patient information visit [www.linxforslife.com](http://www.linxforslife.com) or [www.ethicon.com](http://www.ethicon.com).**

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