| Health Technology Review | |
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| **Technology Ref.:** | HTA24023 |
| **Applicant's contact Email: Mobile no:** | Person Name: Mohammad Hamdan<br>Company Name: Johnson and Johnson Middle East Inc.<br>Email: mhamdan@its.jnj.com<br>Contact Number: 0588991531 |
| **Technology Name/Version/Model:** | LINX™ REFLUX MANAGEMENT SYSTEM |
| **Approvals by International Bodies (year):** | Approved by MOHAP/ FDA / CE Marked |
| **Manufacturer/ Company name, country of Origin** | TORAX MEDICAL INC, UNITED STATES OF AMERICA/ USA |
| **Agent in UAE:** | modern pharmaceutical company [Abu Dhabi; United Arab Emirates |
| **Class/ Type** | Class 3 / Implant |
| **Licensed Indications** | The LINX® Reflux Management System is indicated for:<br>- Treating gastroesophageal reflux disease (GERD).<br>- Strengthening a weak lower esophageal sphincter (LES).<br>- Preventing the backflow of stomach acid into the esophagus.<br>- Reducing or eliminating GERD symptoms. |
| **Cost and Comparisons with standard of Care** | Estimated price of the LINX® Reflux Management System, including different bead sizes (LXMC13, LXMC14, LXMC15, LXMC16, LXMC17) and the Sizer (LST), is approximately 25,500 AED.<br>• LINX Reflux Management System (13-17 Bead sizes): 23,000 AED each<br>• Laparoscopic Esophagus Sizing Tool: 2,500 AED |
| **Administration/ Use** | For administrative use, the LINX® Reflux Management System is:<br>- An implantable medical device.<br>- Specifically designed for managing gastroesophageal reflux disease (GERD).<br>- Comprising titanium beads with magnetic cores connected by titanium wires.<br>- Available in multiple sizes to match different esophagus sizes.<br>- Used in conjunction with a sizing tool to ensure proper fit and function. |

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| **Short Description of the Technology:** | • **Introduction:**<br>The LINX® Reflux Management System is a medical device designed for patients diagnosed with pathologic gastroesophageal reflux disease (GERD). GERD is characterized by chronic symptoms and abnormal pH testing, indicating a weak lower esophageal sphincter (LES). The LINX® system aims to provide relief for patients who continue to experience GERD symptoms despite maximum medical therapy. This innovative treatment has been endorsed by various international clinical societies, reflecting its efficacy and safety in managing GERD. |

- **Mechanism of Action:**

The LINX® Reflux Management System consists of a series of titanium beads with magnetic cores, connected by independent titanium wires to form an annular shape. The magnetic attraction between the beads is designed to augment the strength of the LES, keeping it closed to prevent acid reflux. During swallowing, the magnetic beads separate, allowing the esophagus to distend and enable the passage of food. This dynamic action helps maintain a barrier to reflux while permitting normal esophageal function.

- **Clinical Evidence/ Efficacy:**

Validation of the LINX® Reflux Management System technology is supported by peer-reviewed studies in scientific journals and endorsed by various medical societies, including:
1. Journal of the American College of Surgeons
2. National Institute for Health and Care Excellence (NICE,
2. Annals of Thoracic Surgery
3. Surgical Endoscopy
4. Clinical Gastroenterology and Hepatology
5. Therapeutic Advances in Gastroenterology

- **Clinical Trials:**

Randomized controlled trial showed 89% of LINX patients achieved elimination of moderate to severe regurgitation compared to 10% in the double-dose PPI group.
- Systematic Reviews and Meta-Analyses:
High percentage of patients achieved PPI cessation.
Significant improvement in GERD-related quality of life (GERD-HRQL) scores.
-Long-Term Outcomes:
5-year follow-up studies showed sustained symptom relief.
Significant reduction in the need for PPIs post-procedure.
-Device Removal: The 7-year cumulative risk of device removal was 4.81%.
-Erosion:
Risk of erosion at 4 years after implantation was 0.3%.

Various medical societies endorse the LINX® Reflux Management System for treating chronic GERD symptoms.
It's seen as an effective alternative to fundoplication, offering equivalent outcomes and safety.
Clinical evidence supports its efficacy, highlighting benefits like minimal surgical dissection and reduced side effects.

- **Safety/ Risk issues:**

There was one recall it was related to the lot and it was completed and pulled from the market in USA.
Risks:

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| | - Device Removal: The 7-year cumulative risk of device removal was 4.81%.<br>Erosion:<br>- Risk of erosion at 4 years after implantation was 0.3%.<br>- Safety<br>Patients with specific contraindications, such as large hiatal hernias (greater than 3 cm), Barrett's esophagus, or severe esophagitis (Grade C or D), should be excluded from using this product<br><br>• **Place in therapy/ diagnosis:**<br>LINX is primarily indicated for patients diagnosed with Gastroesophageal Reflux Disease (GERD) who continue to have chronic symptoms despite maximum medical therapy, including those intolerant to or seeking an alternative to proton pump inhibitors (PPIs).<br>It's offered in specialized gastroenterology or surgical clinics within hospitals.<br>These clinics may include:<br>1. Gastroenterology Clinics<br>2. Esophageal Disorders Clinics<br>3. Surgical Clinics<br>4. Reflux Centers |

| **Health Technology Assessment Team Recommendation:** | **Approve** |
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**Summary of Review:**

The LINX® Reflux Management System is a laparoscopic, fundic-sparing anti-reflux procedure that augments the weak esophageal sphincter using magnetic beads. It is designed as an alternative to proton pump inhibitors for GERD patients, offering a minimally invasive and reversible solution without anatomical alteration. The technology has been reviewed favorably by multiple international bodies, including NICE and the American College of Gastroenterology.

We recommend an **approval of using this technology** for Market entry with the following conditions:

1. Surgeons performing the LINX® procedure should be specifically trained in laparoscopic anti-reflux surgery and familiar with the unique aspects of the LINX® device to ensure proper placement and minimize the risk of complications.
2. Patients with specific contraindications, such as large hiatal hernias (greater than 3 cm), Barrett's esophagus, or severe esophagitis (Grade C or D), should be excluded from receiving the LINX® Reflux Management System.
3. Ensure that patients with a history of allergic reactions to titanium, stainless steel, nickel, or ferrous materials are thoroughly screened before considering the LINX® device, as the sizing tool used during the procedure contains nickel. Patients with allergies to these materials should be excluded from using the LINX® system
4. Ensure robust monitoring for adverse events by establishing a regular follow-ups for patients with the LINX® device to promptly identify and manage any complications, such as device migration or dysphagia, ensuring patient safety and timely intervention.
5. Establishing a proper quality monitoring process and reporting of any adverse events or

unwarranted consequences including safety issues of employees.

6. Provision of regular updates and reports about the product to DOH upon request.

**Moreover,** DOH has the right to stop the product at any stage if deemed necessary, initial conditions and any subsequent conditions must be satisfied before obtaining final approval. Failure to do so will reflect in provoking the approval.

**Technology Image**

Figure 1 – Illustration of Implant, Closed

Figure 2 – Illustration of Implant, Open

**Population, setting and intended user for Technology "LINX™ REFLUX MANAGEMENT SYSTEM"**

- **Population/ Intended User**; The LINX® Reflux Management System is 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.

- **To be performed by**: Implantation of the LINX® device should only be performed by a surgeon who has experience in laparoscopic anti-reflux procedures and has received product-specific training.

- **Clinical Setting:** The procedure is performed in a clinical setting that requires laparoscopic surgery capabilities.

- **Condition of use:** The LINX® Reflux Management System is intended for single use only, and it is crucial that the device is placed correctly around the esophagus, excluding the posterior vagus nerve bundle. The device should not be used if sterility or performance is compromised.

- **Exclusion criteria:** The LINX® device is not evaluated for use in patients with a hiatal hernia larger than 3 cm, Barrett's esophagus, severe esophagitis (Grade C or D), or in patients with electrical implants like pacemakers , patients with a history of allergic reactions to titanium, stainless steel,

nickel, or ferrous materials are thoroughly screened before considering the LINX® device, as the sizing tool used during the procedure contains nickel. Patients with allergies to these materials should be excluded from using the LINX® system. and other exclusion patients to be determined by the physicians