



LINX® Reflux Management System Surgical Procedure

Step by Step Overview

Principles of LINX® Reflux Management System Technique



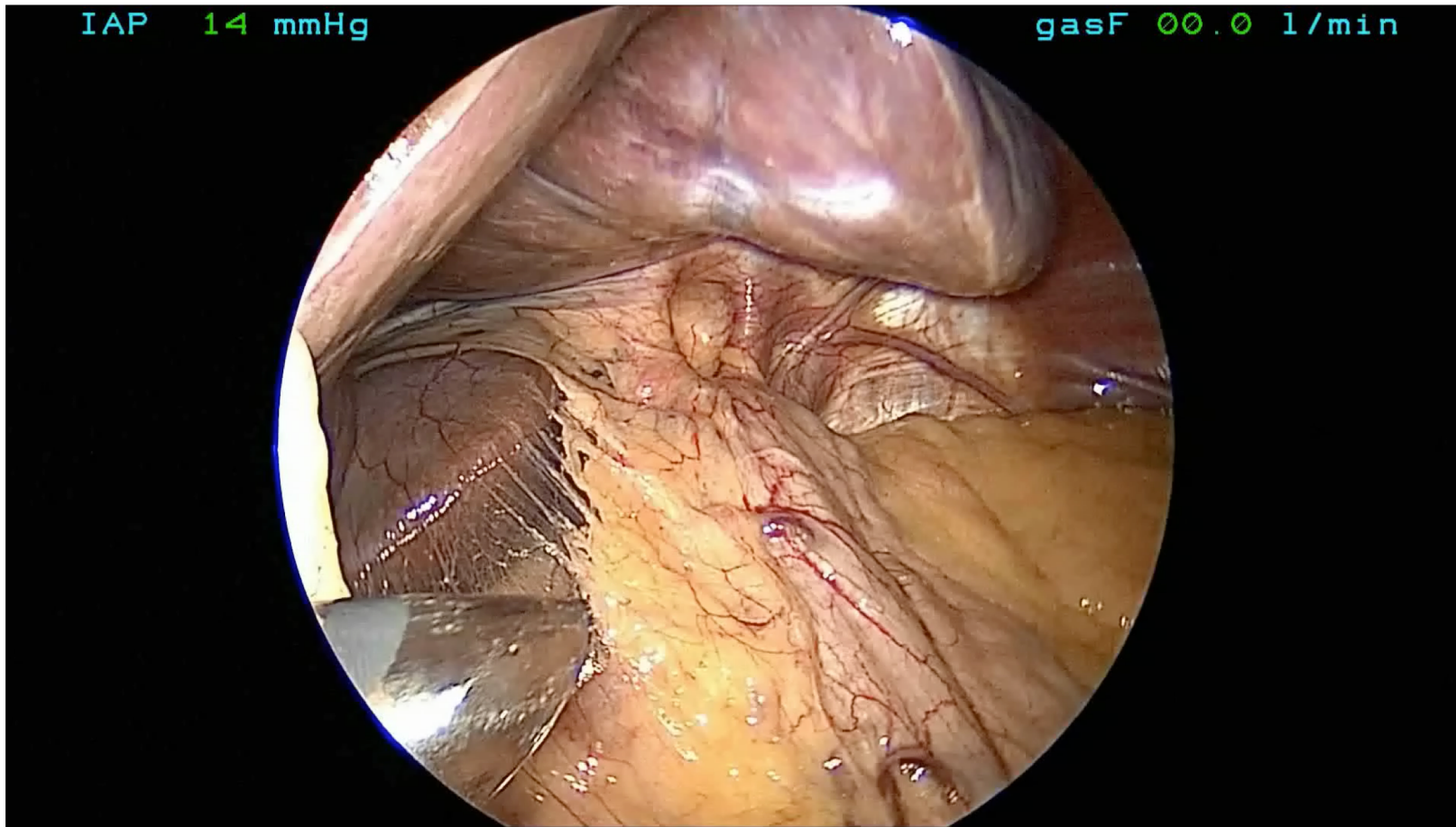
What we have learned in over 7000 cases:

Same fundamentals as Nissen: repair both sphincters

1. Full Hiatal Dissection

- Reduce the HH/Hernia Sac
- Mobilize the esophagus
- 2-3cm of intra-abdominal length
- Crural repair

Full Hiatal Dissection and Crural Repair



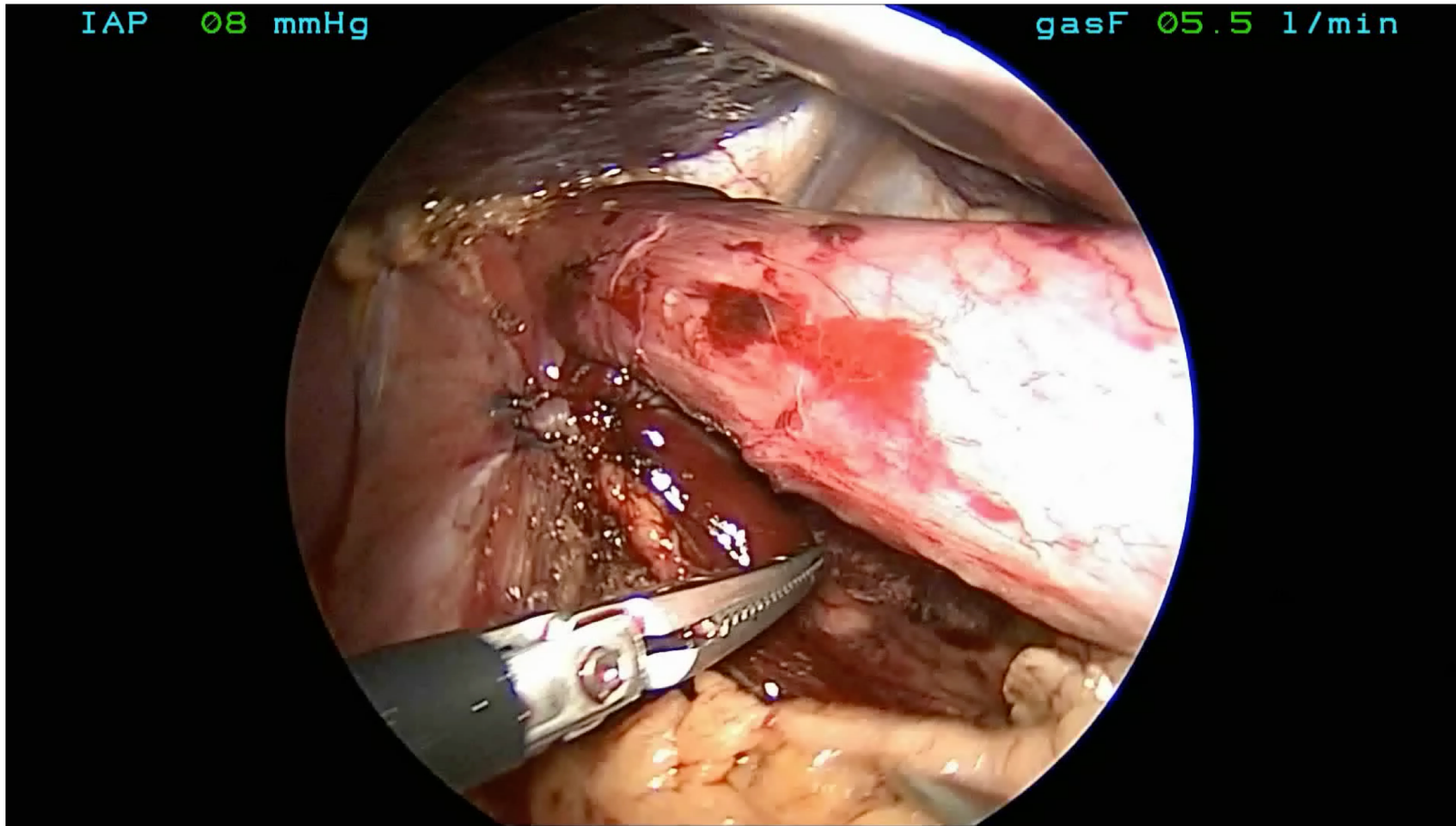
Principles of LINX[®] Reflux Management System Technique



2. Identify and Exclude the Posterior Vagus Nerve

- Key procedural landmark
- Identifies LES
- Gently dissect a tunnel between posterior esophagus and posterior vagus nerve
- LINX Reflux Management System must be placed in between posterior vagus nerve and esophagus
- Never dissect out the anterior vagus nerve

Exclusion of Posterior Vagus



Principles of LINX® Reflux Management System Technique

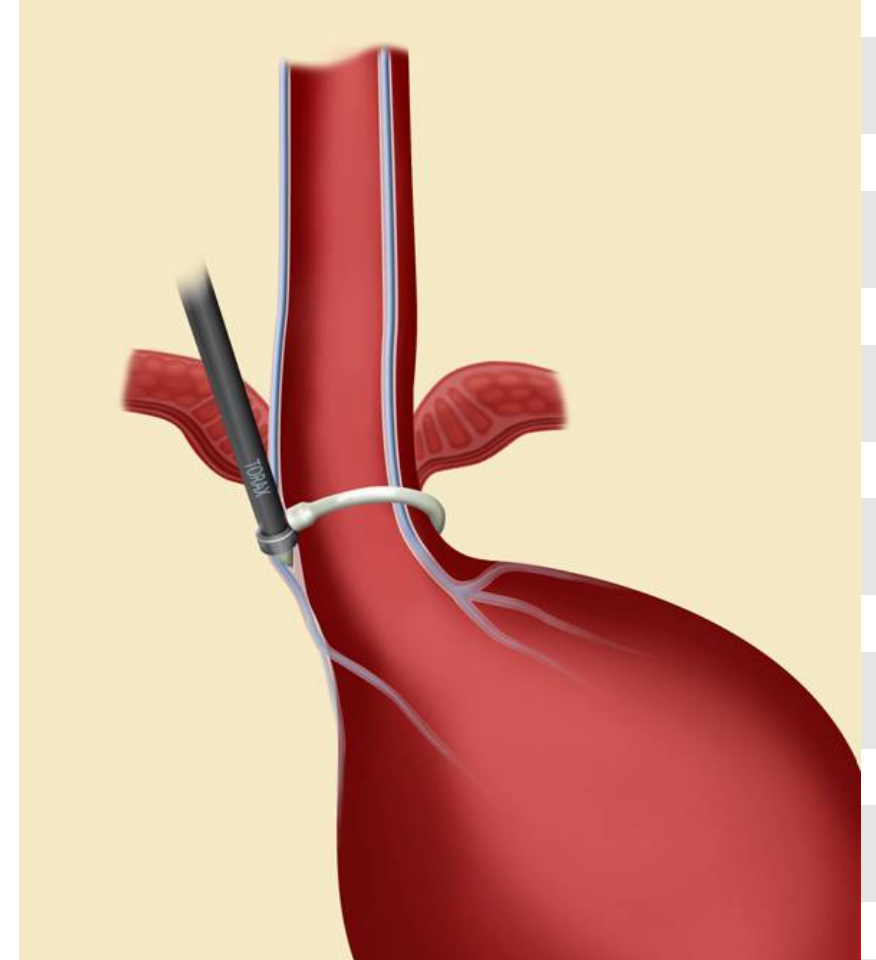


3. Sizing the Esophagus

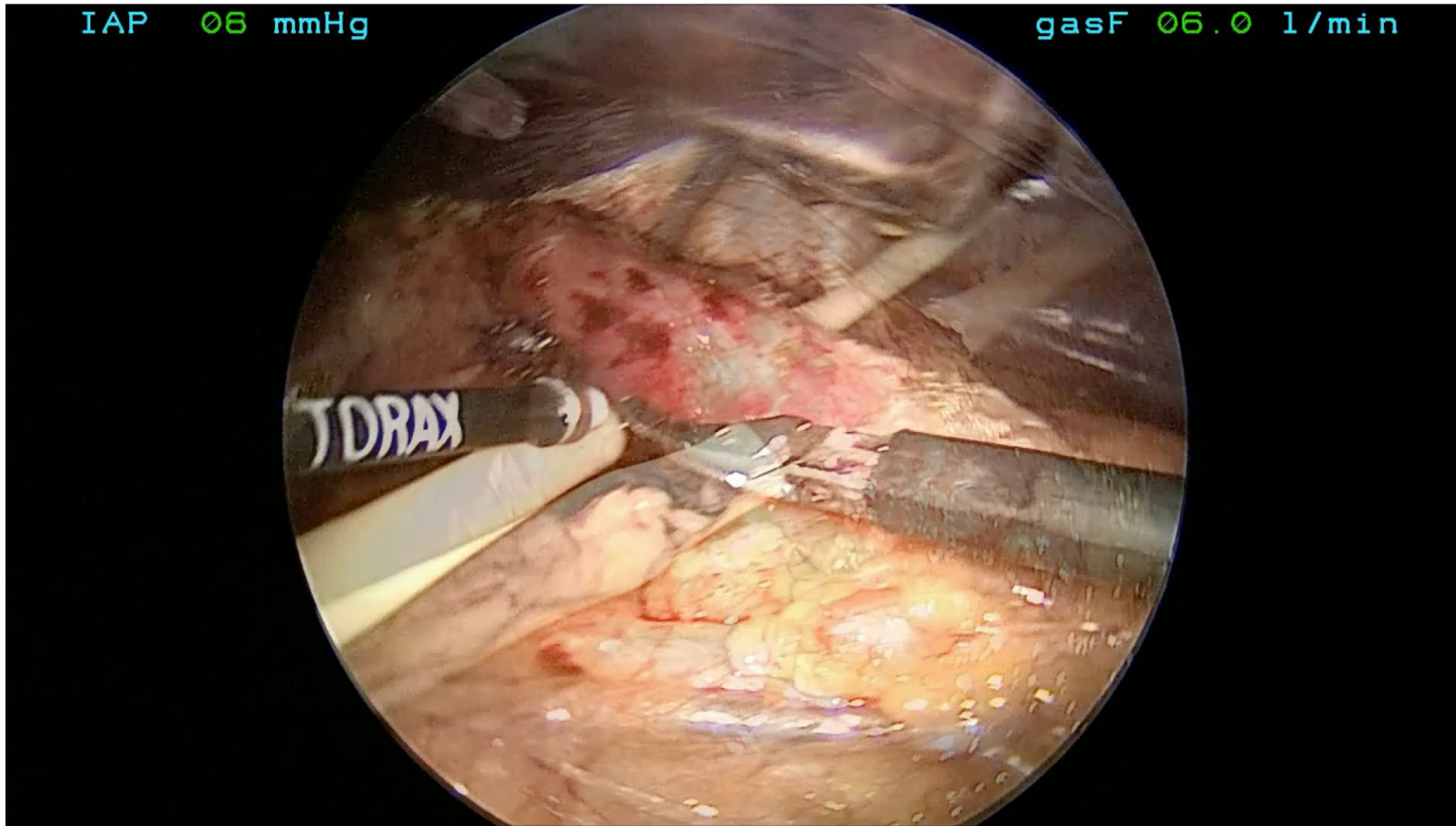


Lap Sizing Tool:

- Single use device
- Matches device to esophageal diameter
- Introduced laparoscopically
- Placed through the dissected eyelet on posterior esophagus
- White inner tube wraps around esophagus and reconnects to magnet on the black outer tube
- Surgeon tightens white inner tube to point that it does not shift when black outer tube is rotated
- Size is indicated on scale on device handle



Sizing the Esophagus

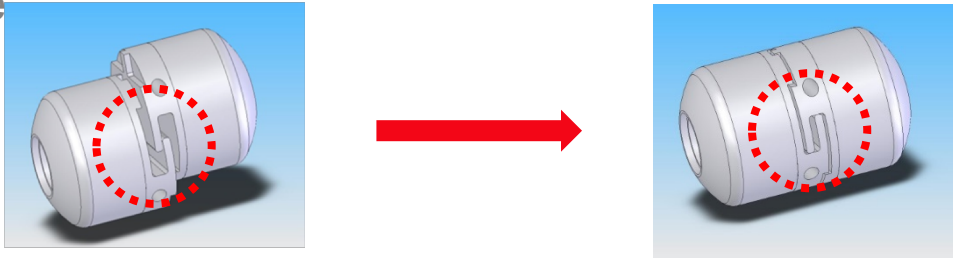


Principles of LINX[®] Reflux Management System Technique



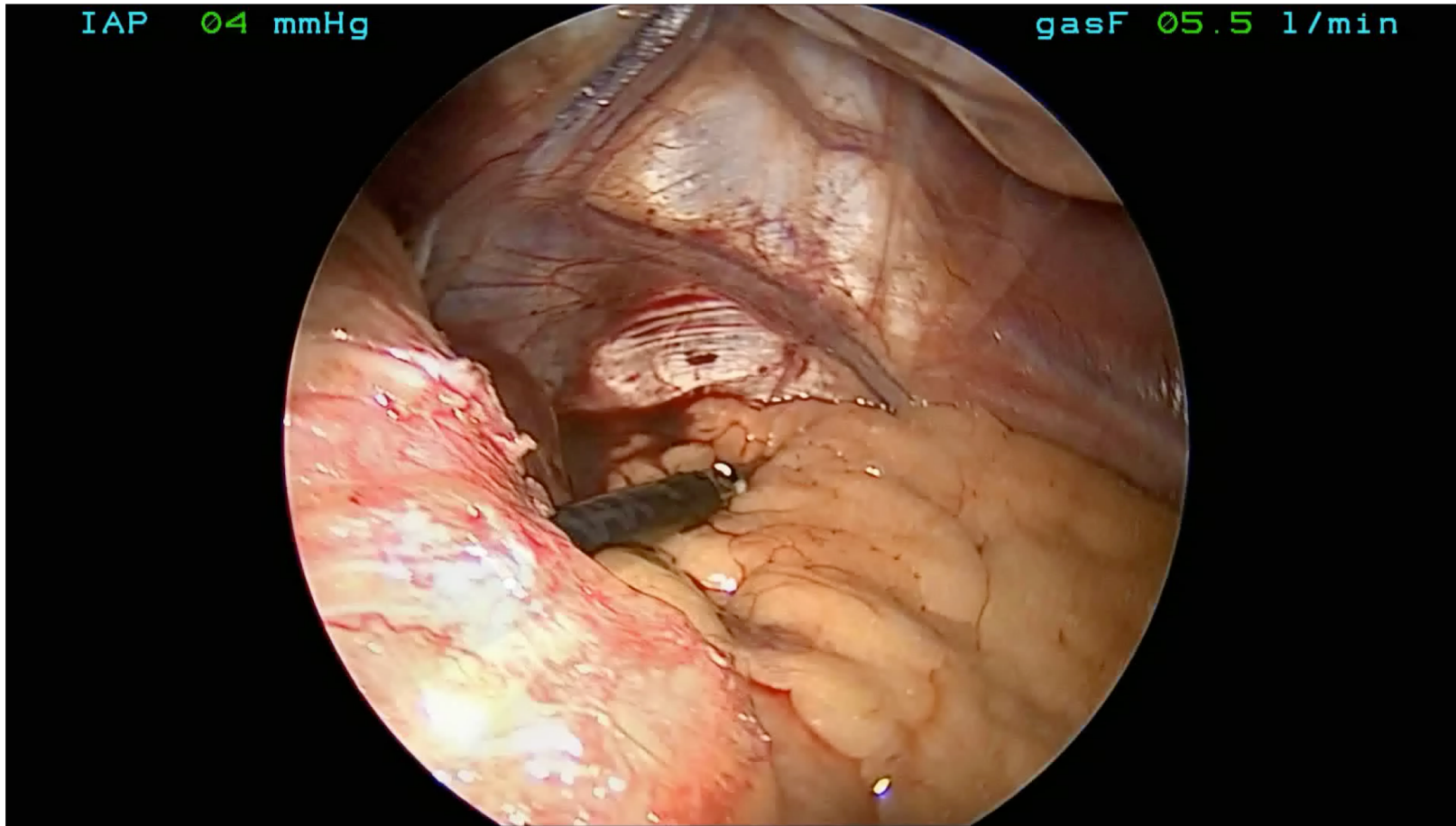
4. Place LINX Reflux Management System and Lock the Clasp Device

- Insert device and pass posteriorly using the suture on the ends of the device
- Close three dimensional lock. Visually confirm that there is only one window visible on device



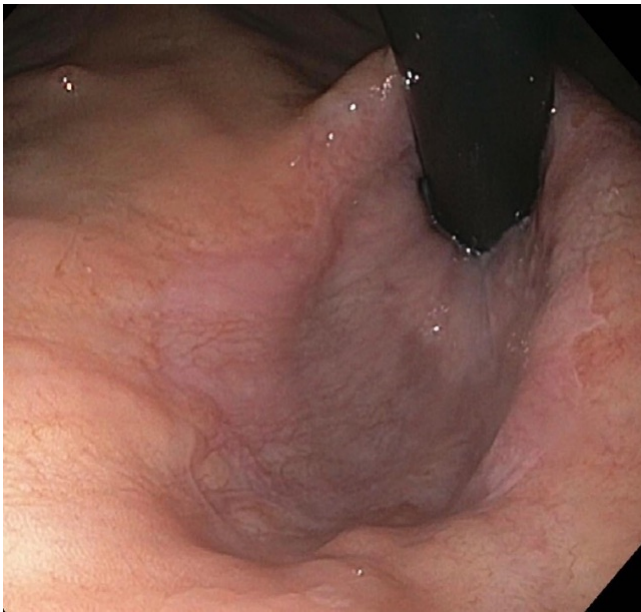
- Pull suture ends in opposite directions to confirm device is locked
- Cut and remove all suture when complete

Place LINX[®] Reflux Management System and Lock the Clasp Device

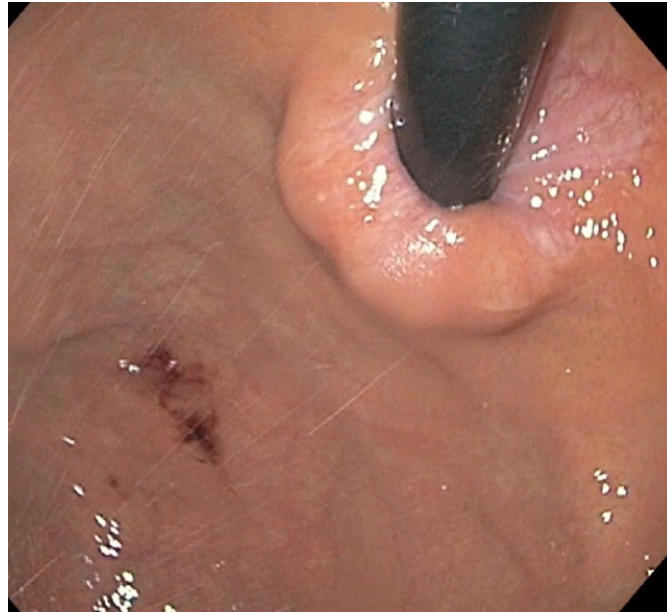


Intra-operative EGD

(optional at end of case)



Before LINX®



After LINX®

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) or equivalent organization.

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

Laparoscopic placement of the LINX device is major surgery and death can occur.

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.

(continued on next slide)

LINX[®] Reflux Management System

Important Safety Information

- 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
- 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, stomach bloating, ulcer, vomiting, weight loss, and worsening of preoperative symptoms (including but not limited to dysphagia or heartburn).