Statistical Analysis Plan (SAP)

A Prospective, Multicenter Study of Reflux Management with the LINX® System for Gastroesophageal Reflux Disease after Laparoscopic Sleeve Gastrectomy

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A Prospective, Multicenter Study of Reflux Management with LINX® System for Gastroesophageal Reflux Disease after Laparoscopic Sleeve Gastrectomy

Protocol Version: 4600 Rev 5

The following individuals have reviewed this version of the Statistical Analysis Plan and are in agreement with the content:

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Revision History

Revision Number	Revision Date	Reasons for Revision
1.0	25JUN2021	Original Document
2.0	15SEP2021	Analysis methodology for pH measurements updated to reflect variable number of days reported by subjects in the study; i.e. subjects reported between 1 and 4 days of pH measurement data and to normalize the values across subjects, averages for each subject over the number of days reported for all parameters will be summarized prior to summarization on the overall set of subjects.

Table of Contents

1 Introduction

This is the Statistical Analysis Plan (SAP) for the final analysis of data collected under Protocol 4600 Rev 5. This SAP describes in detail the statistical methodology and statistical analyses for this protocol.

1.1 Study Objectives

The purpose of this study is to evaluate the safety and efficacy of LINX for its approved indication in subjects who have had prior gastric surgery, specifically, Laparoscopic Sleeve Gastrectomy (LSG). The objective of the study is to confirm safety and efficacy after LSG is similar to the outcomes that formed the basis for Premarket Approval (PMA) in order to support modification of the current labeling with a statement that prior gastric surgery with LSG has been evaluated for safety and efficacy.

1.2 Study Design

This is an observational, multicenter, single-arm study with prospective enrollment. Based on the observational status of the study, no formal statistical hypothesis tests will be conducted. Up to 30 subjects meeting the eligibility requirements will be implanted with LINX and followed through 12-months after implant. Up to twelve clinical sites will enroll subjects. Safety evaluations will be ongoing throughout the duration of the study, starting at the implant procedure. Efficacy endpoints will be evaluated at the 12-month visit.

Safety will be assessed by evaluating device and/or procedure related adverse events, perioperative complications, device malfunctions, device removals, and hospital readmissions experienced by subjects post-LINX implant out to 12 months. Esophageal anatomy and functionality will be monitored by performing manometry and barium esophagram at 12-months post-implant. This will allow for identification of any abnormal or atypical findings. Further, device migration will be assessed by confirming device position at the gastroesophageal junction (GEJ) by obtaining upright, bi-plane X-rays and device erosion will be assessed by performing endoscopy at the 12-month visit.

Efficacy will be assessed by evaluating the percentage of subjects reporting at the 12-month follow-up:

- Normalization of total distal acid exposure time or at least 50% reduction in total distal acid exposure time compared to baseline.
- >50% reduction in total GERD-HRQL score compared to baseline (off PPIs).
- >50% reduction in average daily PPI dosage compared to baseline.

2 Treatment Assignment

This is a prospective, multicenter, single-arm, observational study, where subjects serve as their own control.

3 Randomization and Blinding Procedures

This is an observational, single-arm study. No randomization will occur, and no blinding procedures will be needed.

4 Interval Windows

Interval windows are not defined for the purpose of analysis in this study outside of the visit windows that are provided in the Study Schedule and Assessments in the final protocol. There will be no assigning of observations to time points outside of the visit to which they are recorded in the electronic Case Report Forms (eCRFs). Data collected in Unscheduled Visits forms will be listed as such. Observations collected outside of the 12-month protocol-specified visit window may be still be included in the analysis of primary effectiveness and safety endpoints since the device under study is an implant and longer term follow-up (i.e. beyond 12-months) is still considered informative towards evaluating the overall benefit-risk profile of the device in subjects with prior LSG surgery.

5 Levels of Significance

No formal statistical hypotheses are specified for this study. For continuous efficacy parameters, the p-value for a one sample, paired t-test to test if there is statistical evidence that the change from baseline is not equal to zero will be given. All estimation of endpoints will be performed using 95% confidence intervals.

6 Analysis Sets

All subjects who meet the eligibility criteria, provide informed consent, complete baseline assessments and undergo the LINX procedure will represent the study population for analysis. This set of subjects will be labeled as Full Analysis Set (FAS). This set of subjects will be identified by having answered “Yes” to the question “Was the LINX device implanted?” on the Implant Data eCRF.

7 Sample Size Justification

No formal sample size calculation has been performed for this study. The sample size planned for the study is up to 30 eligible subjects recruited from 12 clinical sites and no site will enroll more than 6 subjects without prior written approval provided by the Sponsor. No formal hypothesis has been tested in this study; thus, the sample size is not statistically sized, but rather is considered

sufficient for a descriptive summary of LINX performance for subjects who have had prior gastric surgery with LSG through confidence interval estimation and evaluation of safety and efficacy.

8 Analyses to be Conducted

8.1 General Conventions

Subject data will be summarized in tables and presented in further detail in listings. All eCRF data will be listed per subject for all subjects. Descriptive statistical analyses will be provided for pre-specified study endpoints. Summaries for continuous variables will include a minimum of number of observations (n), mean, standard deviation, median, minimum and maximum. Summaries for categorical variables will include number and frequency.

Analyses will be conducted using SAS software. During the course of programming of tables that are mocked up in this SAP, minor modifications may become necessary. Examples of these minor modifications include, but are not limited to, table title, re-wording of a footnote, addition of a footnote, re-labeling of a column, or addition or removal of a column from a listing. In cases where modifications to tables or listings are not related to a change in statistical analysis methodology or conclusions that could be made on the originally proposed methodology, then no amendment of the SAP is necessary. Any final analyses that differ from what has been specified in this document will be identified within the final statistical output and documented within the clinical study report.

8.2 Disposition of Study Subjects

Subject disposition will be summarized using counts and percentages. The number and percentage of subjects in the Full Analysis Set (FAS) who completed and withdrawal will be tabulated along with the specific reasons for withdrawal.

8.3 Demographic, and other Baseline Characteristics

Demographic and other baseline characteristics will be summarized descriptively for subjects in the FAS.

The following demographic variables will be summarized:

- Age
- Gender
- Race
- Height
- Weight
- Body Mass Index (BMI) at baseline
- Ethnicity

8.4 Surgical Characteristics

Basic surgical characteristics will be summarized using count and frequency.

The following variables will be summarized:

- Documentation of LSG and GERD History (time had GERD, PPI taking history, GERD status, duration between LSG surgery and LINX surgery, and BMI at time of LINX surgery).
- Implantation, including surgical duration, device size, concomitant surgical procedure, and perioperative complications.

8.5 Efficacy

Efficacy will be measured by a comparison of GERD control before and after placement of the LINX Reflux Management System defined by esophageal pH measurements, GERD-HRQL score and PPI use. The change from baseline by follow-up will be calculated and summarized.

8.5.1 Esophageal Acid Exposure

Testing will be performed with subjects off PPIs. The subject's total distal esophageal acid exposure time at baseline will serve as the control and will be compared to results at the 12-month visit. Normalization for total distal ambulatory esophageal pH testing is defined as pH< 4 for < 4.5% of the time. If longer pH evaluations are received, the total distal acid exposure time will be recorded as a 24-hour average (e.g. 48-hour Bravo testing).

The proportion of subjects achieving pH normalization or at least a >50% reduction from baseline to the result at the 12-months will be summarized descriptively for the FAS. Two-sided 95% CI will also be constructed using exact Clopper-Pearson method.

8.5.2 Quality of Life

Subjects GERD-HRQL (Health Related Quality of Life) scores will be assessed off all GERD medications. The subject's baseline GERD-HRQL score will serve as the control and be compared to the subject's GERD-HRQL 12 months post implantation.

Summary statistics will be provided for the GERD-HRQL questionnaire. Subjects are asked to rate 10 specific symptoms in addition to assessing how satisfied they are with their present condition. Each symptom is scored on a 0 to 5 scale. Summaries will also be provided for an overall score which is calculated as the average of the ten components for each subject.

Counts and percentages will be provided for responses to the GERD-HRQL questionnaire.

8.5.3 Use of PPIs

Subject's average daily dose of PPI will be evaluated. The subject's baseline average daily dosage will serve as the control and be compared to the subject's average daily dosage 12 months post-procedure.

The proportion of subjects with at least 50% reduction in daily PPI use from baseline at 12 months will be reported. In addition, a two-sided 95% CI will be provided for the proportion of success (>=50% reduction achieved).

8.6 Safety Analyses

Safety will be assessed by the rate of AEs and SAEs (number and percentage of subjects experiencing). Similar summaries will also be provided for AEs and SAEs related to the study device, as well as for AEs and SAEs related to the study procedures. Related events are those where the event relatedness is indicated as Yes/Probably/Possibly, or Unknown. Esophageal anatomy and functionality will be monitored by performing manometry and barium esophagram at 12-months post-implant. A summary and change from baseline of manometry and motility results will be provided which includes LES length, LES residual pressure, LES intra-abdominal length, LES basal mean pressure, percent peristaltic sequences, distal amplitude, distal contractile integral, percent ineffective swallows, and percent fragmented swallow. Count and percentages will be provided for barium esophagram in the number of subjects who have normal swallow function, number of subjects who have a dilated proximal pouch, number of subjects who have evidence of a hiatal hernia, and if any abnormalities occurred. This will allow for identification of any abnormal or atypical findings. Further, device migration will be assessed by confirming device position at the GEJ by obtaining upright, bi-plane X-rays and device erosion will be assessed by performing an endoscopy at the 12 months visit.

8.7 Additional Analyses

- Summary statistics will be provided for components of the DeMeester score at 12 months, which includes total % time, upright % time, supine % time, reflux episodes, reflux episodes > 5 min, and longest episode (min). For each of the individual components listed above as well as the overall DeMeester score, the average within a subject will first be calculated given that the number of days reported for each subject varies between 1 and 4. The 'Total' value reported in the database will not be utilized, and the average score for each parameter at each visit will be summarized in the overall value.
- Counts and percentages will be presented for subjects who discontinue daily PPI use at 3, 6 and 12 months.
- Counts and percentages will be provided for subjects with esophagitis by endoscopy at 12 months (using L.A. Classification). Additional endoscopic results provided will include: evidence of device erosion, hiatal hernia size and gastroesophageal junction morphology using Hill Grade. Summary statistics will also be provided for hiatal hernia size.

- Counts and percentages for responses to the Foregut Symptoms Questionnaire (FSQ) will be provided for subjects who meet the following criteria at 3, 6, and 12 months.
    - Subjects who eliminate moderate or severe regurgitation
    - Subjects with extra-esophageal symptoms or lung problems (Recurrent cough, Nocturnal cough, Recurrent Pneumonitis, Asthma, and Change of voice)
    - Subjects with ability to belch
    - Subjects with ability to vomit

8.8 Plans for Interim Analysis

No formal interim analyses were planned in the protocol that would have the intent of altering the study design. However, given the lower than anticipated follow-up that was initially observed in the study, reviews of data for completeness of endpoint data were performed when the initial study enrollment of 30 subjects was completed. The intent of these analyses and data reviews were to attempt to assess the overall completeness of the dataset.

8.9 Handling of Missing Data

All summaries will be performed only on enrolled subjects and only observed data will be summarized. There will be no imputation of data for early terminated subjects or for missing data within the database.

8.10 Subgroup Analysis

No subgroup analysis will be performed.

8.11 Assessment of Site Homogeneity

No summaries or adjustments by study site are planned for this study.

9 Data Monitoring Committee (DMC)

No Data Monitoring Committee was planned or utilized during this study.

Appendix: Table Shells and List of Listings to be Generated

Table shells are provided below for all summaries to be generated for this study. These shells are a guide to the general layout of data to be presented. Minor modifications can be made to suit existing programs or macros that are available. Additionally, a list of all listings to be created is provided corresponding to the eCRFs that are used during this study. All fields collected will be listed.

Table 1
Subject Disposition
All Subjects

Characteristics	Total
Signed Informed Consent	xx
Full Analysis Set	xx
Consented Screen Failure	xx
Device not implanted	
Completed the Study [1]	xx (xx.x%)
Withdrawal from the Study [1]	xx (xx.x%)
Reason for Withdrawal [2]	
Withdrawal of consent	xx (xx.x%)
Adverse Event	xx (xx.x%)
Death	xx (xx.x%)
Lost to Follow-up	xx (xx.x%)
Site or Study Termination	xx (xx.x%)
Other	xx (xx.x%)

[1] Percentages are based on the number of subjects who enrolled and implanted as the denominator.
[2] Percentages are based on the number of subjects who discontinued from the study as the denominator.

<Programming note: Only categories observed in the database need to be displayed for Reason for Withdrawal.>

Table 2
Subject Demographics and Physical Examination
Full Analysis Set

Characteristic	Total (N = ##)
Age at Consent (years)	
n	xx
Mean (SD)	xx.x (xx.x)
Median (Min, Max)	xx.x (xx, xx)
Gender, n (%)	
Male	xx (xx.x%)
Female	xx (xx.x%)
Ethnicity, n (%)	
Hispanic or Latino	xx (xx.x%)
Not Hispanic or Latino	xx (xx.x%)
Not Reported	xx (xx.x%)
Race, n (%)	
American Indian or Alaska Native	xx (xx.x%)
Asian	xx (xx.x%)
Black or African American	xx (xx.x%)
Native Hawaiian or Other Pacific Islander	xx (xx.x%)
White or Caucasian	xx (xx.x%)
Other	xx (xx.x%)
Height (cm)	
n	xx
Mean (SD)	xx.x (xx.x)
Median (Min, Max)	xx.x (xx, xx)
Weight (kg)	
n	xx
Mean (SD)	xx.x (xx.x)
Median (Min, Max)	xx.x (xx, xx)
Body Mass Index (kg/m^2) at Baseline	
n	xx
Mean (SD)	xx.x (xx.x)
Median (Min, Max)	xx.x (xx, xx)

Denominator and percentages are based on subjects with non-missing data.
<Programming note: Only categories observed in the database need to be displayed for Ethnicity and Race>

Table 3
GERD Medications
Full Analysis Set

Characteristic	Baseline (N = ##)	3 Months Follow-Up (N = ##)	6 Months Follow-Up (N = ##)	12 Months Follow-Up (N = ##)
Currently Taking PPI				
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
PPI Medications				
Omeprazole	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Aspirin/Omeprazole	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Omeprazole/Sodium bicarbonate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lansoprazole	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Dexlansoprazole	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Rabeprazole	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Pantoprazole	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Esomeprazole	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Currently Taking H2 Blocker				
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
H2 Blocker Medication				
Nizatidine	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Famotidine	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Cimetidine	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Ranitidine	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Currently Taking Antacids				
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Denominator and percentages are based on subjects with non-missing data.

<Programming note: Only categories observed in the database need to be displayed for PPI and H2 medications>

Table 4
LSG and GERD History
Full Analysis Set

Characteristic	Total (N = ##)
GERD new-onset after LSG or pre-existing	
Pre-existing	xx (xx.x%)
New-onset	xx (xx.x%)
Duration of having GERD (years)	
n	xx
Mean (SD)	xx.x (xx.x)
Median (Min, Max)	xx.x (xx, xx)
Duration of taking PPIs (years)	
n	xx
Mean (SD)	xx.x (xx.x)
Median (Min, Max)	xx.x (xx, xx)
BMI on date of LSG (kg/m^2)	
n	xx
Mean (SD)	xx.x (xx.x)
Median (Min, Max)	xx.x (xx, xx)
Time between LSG surgery and LINX implant (days)	
n	xx
Mean (SD)	xx.x (xx.x)
Median (Min, Max)	xx.x (xx, xx)

Denominator and percentages are based on subjects with non-missing data.

Table 5
Characteristics of pH Results (Off PPI)
Full Analysis Set

Characteristic	Baseline (N = ##)	12 Months Follow-Up (N = ##)
Was GERD Medications discontinued at least 7 days prior to test?		
Yes	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)
Type of pH Testing Method Used		
Bravo capsule	xx (xx.x%)	xx (xx.x%)
5 cm above manometry upper border of the LES	xx (xx.x%)	xx (xx.x%)
6 cm above endoscopically visualized SCJ	xx (xx.x%)	xx (xx.x%)
Trans-nasal catheter	xx (xx.x%)	xx (xx.x%)
Trans-nasal with impedance catheter	xx (xx.x%)	xx (xx.x%)
pH Test Duration (days)		
n	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median (Min, Max)	xx.x (xx, xx)	xx.x (xx, xx)

Denominator and percentages are based on subjects with non-missing data.

Table 6
Bravo pH Normalization or >= 50% Reduction Compared to Baseline (Off PPI)
Full Analysis Set

Parameter	Baseline	12 Months Follow-Up	Change from Baseline to 12 Months Follow-Up	% Successful at 12 Months Follow-Up [1]
Total % Time				
n	xx	xx	xx	
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	
Median (Min, Max)	xx.x (xx, xx)	xx.x (xx, xx)	xx.x (xx, xx)	
95% Confidence Interval			(xx.xxx, xx.xxx)	
p-value[2]			0.xxx	
Number of Subjects were Successful				xx (xx.x%)
Number of subjects with pH normalization (<=4.5 %)				xx (xx.x%)
Number of subjects with >= 50% reduction in total distal acid exposure				xx (xx.x%)

Denominator and percentages are based on subjects completed baseline and 12 months follow-up.
[1] % Successful is defined as number of subjects meeting the success criterion of pH normalization or at least 50% reduction in total distal acid exposure.
[2] From one-sample, paired t test against the change from baseline is equal to zero.

Table 7
Summary of DeMeester Score Components
Full Analysis Set

Parameter	Baseline	12 Months Follow-Up	Change from Baseline to 12 Months Follow-Up
Daily Average of Total % Time			
n	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median (Min, Max)	xx.x (xx, xx)	xx.x (xx, xx)	xx.x (xx, xx)
Daily Average of Upright % Time			
n	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median (Min, Max)	xx.x (xx, xx)	xx.x (xx, xx)	xx.x (xx, xx)
Daily Average of Supine % Time			
n	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median (Min, Max)	xx.x (xx, xx)	xx.x (xx, xx)	xx.x (xx, xx)
Daily Average of Number of Reflux Episodes (pH <4)			
n	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median (Min, Max)	xx.x (xx, xx)	xx.x (xx, xx)	xx.x (xx, xx)
Daily Average of Number of Reflux Episodes > 5 mins			
n	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median (Min, Max)	xx.x (xx, xx)	xx.x (xx, xx)	xx.x (xx, xx)
Daily Average of Longest Reflux Episode (min)			
n	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median (Min, Max)	xx.x (xx, xx)	xx.x (xx, xx)	xx.x (xx, xx)

Note: For all parameters, the within subject average of the values within a visit is first calculated prior to summarizing across all subjects at the given visit.

Table 7
Summary of DeMeester Score Components
Full Analysis Set

Parameter	Baseline	12 Months Follow-Up	Change from Baseline to 12 Months Follow-Up
Daily Average of DeMeester Score			
n	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median (Min, Max)	xx.x (xx, xx)	xx.x (xx, xx)	xx.x (xx, xx)
Number of Subjects with Normal DeMeester Score based on Daliy Average (≤ 14.72)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: For all parameters, the within subject average of the values within a visit is first calculated prior to summarizing across all subjects at the given visit. Subjects with simultaneous zero as pH measurements are not included in dalily average calculation.

<Programming Note: Records with all pH parameters: reflux episodes (PHRESRE), reflux episodes > 5 min (PHRESREM), longest episode (PHRESLE), total % time (PHRESTT), upright % time (PHRESUT), supine % time (PHRESST) and DeMeester score (PHRESDS) as zero, should be excluded in daily average calculation.>

Table 8
Summary of Manometry/Motility Results
Full Analysis Set

Characteristic	Baseline	12 Months Follow-Up	Change from Baseline to 12 Months Follow-Up
LES Length (cm)			
n	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median (Min, Max)	xx.x (xx, xx)	xx.x (xx, xx)	xx.x (xx, xx)
LES Residual Pressure (mmHg)			
n	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median (Min, Max)	xx.x (xx, xx)	xx.x (xx, xx)	xx.x (xx, xx)
LES Intra-Abdominal Length (cm)			
n	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median (Min, Max)	xx.x (xx, xx)	xx.x (xx, xx)	xx.x (xx, xx)
LES Basal Mean Pressure (mmHg)			
n	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median (Min, Max)	xx.x (xx, xx)	xx.x (xx, xx)	xx.x (xx, xx)
Percent Peristaltic Sequences (%)			
n	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median (Min, Max)	xx.x (xx, xx)	xx.x (xx, xx)	xx.x (xx, xx)
Distal Amplitude (mmHg)			
n	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median (Min, Max)	xx.x (xx, xx)	xx.x (xx, xx)	xx.x (xx, xx)
Distal Contractile Integral (mmHg·s·cm)			
n	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median (Min, Max)	xx.x (xx, xx)	xx.x (xx, xx)	xx.x (xx, xx)
Percent Ineffective Swallows (%)			
n	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median (Min, Max)	xx.x (xx, xx)	xx.x (xx, xx)	xx.x (xx, xx)

Table 8
Summary of Manometry/Motility Results
Full Analysis Set

Characteristic	Baseline	12 Months Follow-Up	Chane from Baseline to 12 Months Follow-Up
Percent Fragmented Swallows (%)			
n	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median (Min, Max)	xx.x (xx, xx)	xx.x (xx, xx)	xx.x (xx, xx)

Table 9
Endoscopy Summary
Full Analysis Set

Characteristic	Baseline (N = ##)	12 Months Follow-Up (N = ##)
Hiatal Hernia Size		
None	xx.x (xx.x%)	xx.x (xx.x%)
1 cm	xx.x (xx.x%)	xx.x (xx.x%)
2 cm	xx.x (xx.x%)	xx.x (xx.x%)
3 cm	xx.x (xx.x%)	xx.x (xx.x%)
Any Evidence of Device Erosion?		
Yes		xx (xx.x%)
No		xx (xx.x%)
Number of Subjects with Reported Esophagitis	xx (xx.x%)	xx (xx.x%)
Esophagitis L.A. Classification		
None	xx (xx.x%)	xx (xx.x%)
Grade A	xx (xx.x%)	xx (xx.x%)
Grade B	xx (xx.x%)	xx (xx.x%)
Grade C	xx (xx.x%)	xx (xx.x%)
Grade D	xx (xx.x%)	xx (xx.x%)
Change in Esophagitis Grade [1]		
Improvement		xx (xx.x%)
No Change		xx (xx.x%)
Worsening		xx (xx.x%)
Hill Grade		
N/A	xx (xx.x%)	xx (xx.x%)
Grade I	xx (xx.x%)	xx (xx.x%)
Grade II	xx (xx.x%)	xx (xx.x%)
Grade III	xx (xx.x%)	xx (xx.x%)
Grade IV	xx (xx.x%)	xx (xx.x%)

Denominator and percentages are based on subjects with non-missing data.
[1] Denominator and percentages are based on subjects completed baseline and 12 months follow-up.

<Programming note:
Change in Esophagitis Grade will be performed for subjects who have esophagitis evaluated at both baseline and 12 months. Improvement is defined as going from higher grade to lower grade (i.e. from Grade D at baseline to Grade B at 12 months). Worsening is defined as going from lower grade to higher grade (i.e. from Grade A at baseline to Grade C at 12 months). The numeric grade can be found in ENDOSCOPYESOP_STD>

Table 9.1
Endoscopy Summary
Full Analysis Set

Characteristic	Baseline (N = ##)	12 Months Follow-Up (N = ##)
Hiatal Hernia Size (cm)		
n	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median (Min, Max)	xx.x (xx, xx)	xx.x (xx, xx)

Table 10
Implantation
Full Analysis Set

Characteristic	Total (N = ##)
Surgery Duration (minutes)	
n	xx
Mean (SD)	xx.x (xx.x)
Median (Min, Max)	xx.x (xx, xx)
Device Size	
12-Bead	xx (xx.x%)
13-Bead	xx (xx.x%)
14-Bead	xx (xx.x%)
15-Bead	xx (xx.x%)
16-Bead	
17-Bead	
Concomitant Surgical Procedures	
None	xx (xx.x%)
Hiatal hernia/crural repair	xx (xx.x%)
Cholecystectomy	xx (xx.x%)
Other	xx (xx.x%)
Perioperative Complications Occurred	
Yes	xx (xx.x%)
No	xx (xx.x%)
Length of Hospitalization (days)	
n	xx
Mean (SD)	xx.x (xx.x)
Median (Min, Max)	xx.x (xx, xx)

Denominator and percentages are based on subjects with non-missing data.

<Programming note: Only device size and concomitant surgical procedures observed need be displayed. Length of stay is defined as discharge date (from discharge page) minus hospital admission date. >

Table 11
Barium Esophagram Summary
Full Analysis Set

Characteristic	Baseline (N = ##)	Implant/Discharge (N = ##)	12 Months Follow-Up (N = ##)
Number of subjects have normal swallow function	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of subjects have a dilated proximal pouch	xx (xx.x%)		xx (xx.x%)
Number of subjects have evidence of a hiatal hernia	xx (xx.x%)		xx (xx.x%)
Any Abnormalities?			
Yes	xx (xx.x%)	xx (xx.x%)	
No	xx (xx.x%)	xx (xx.x%)	

Denominator and percentages are based on subjects with non-missing data.

Table 12
Summary of GERD-HRQL Questionnaire at Baseline (On PPI)
Full Analysis Set

Characteristic	Baseline
Number of Subjects Completed Questionnaires per Protocol Requirements	xx
How bad is your heartburn?	
0 - No symptoms	xx (xx.x%)
1 - Symptoms noticeable, but not bothersome	xx (xx.x%)
2 - Symptoms noticeable and bothersome, but not every day	xx (xx.x%)
3 – Symptoms bothersome every day	xx (xx.x%)
4 – symptoms affect daily activities	xx (xx.x%)
5 – Symptoms are incapacitating, unable to do activities	xx (xx.x%)
Heartburn when lying down?	
0 - No symptoms	xx (xx.x%)
1 - Symptoms noticeable, but not bothersome	xx (xx.x%)
2 - Symptoms noticeable and bothersome, but not every day	xx (xx.x%)
3 – Symptoms bothersome every day	xx (xx.x%)
4 – symptoms affect daily activities	xx (xx.x%)
5 – Symptoms are incapacitating, unable to do activities	xx (xx.x%)
Heartburn when standing up?	
0 - No symptoms	xx (xx.x%)
1 - Symptoms noticeable, but not bothersome	xx (xx.x%)
2 - Symptoms noticeable and bothersome, but not every day	xx (xx.x%)
3 – Symptoms bothersome every day	xx (xx.x%)
4 – symptoms affect daily activities	xx (xx.x%)
5 – Symptoms are incapacitating, unable to do activities	xx (xx.x%)
Heartburn after meals?	
0 - No symptoms	xx (xx.x%)
1 - Symptoms noticeable, but not bothersome	xx (xx.x%)
2 - Symptoms noticeable and bothersome, but not every day	xx (xx.x%)
3 – Symptoms bothersome every day	xx (xx.x%)
4 – symptoms affect daily activities	xx (xx.x%)
5 – Symptoms are incapacitating, unable to do activities	xx (xx.x%)

Denominator and percentages are based on subjects completed questionnaires per protocol requirements.

Table 12
Summary of GERD-HRQL Questionnaire at Baseline (On PPI)
Full Analysis Set

Characteristic	Baseline
Does heartburn change your diet?	
0 - No symptoms	xx (xx.x%)
1 - Symptoms noticeable, but not bothersome	xx (xx.x%)
2 - Symptoms noticeable and bothersome, but not every day	xx (xx.x%)
3 – Symptoms bothersome every day	xx (xx.x%)
4 – symptoms affect daily activities	xx (xx.x%)
5 – Symptoms are incapacitating, unable to do activities	xx (xx.x%)
Does heartburn wake you from sleep?	
0 - No symptoms	xx (xx.x%)
1 - Symptoms noticeable, but not bothersome	xx (xx.x%)
2 - Symptoms noticeable and bothersome, but not every day	xx (xx.x%)
3 – Symptoms bothersome every day	xx (xx.x%)
4 – symptoms affect daily activities	xx (xx.x%)
5 – Symptoms are incapacitating, unable to do activities	xx (xx.x%)
Do you have difficulty swallowing?	
0 - No symptoms	xx (xx.x%)
1 - Symptoms noticeable, but not bothersome	xx (xx.x%)
2 - Symptoms noticeable and bothersome, but not every day	xx (xx.x%)
3 – Symptoms bothersome every day	xx (xx.x%)
4 – symptoms affect daily activities	xx (xx.x%)
5 – Symptoms are incapacitating, unable to do activities	xx (xx.x%)
Do you have pain with swallowing?	
0 - No symptoms	xx (xx.x%)
1 - Symptoms noticeable, but not bothersome	xx (xx.x%)
2 - Symptoms noticeable and bothersome, but not every day	xx (xx.x%)
3 – Symptoms bothersome every day	xx (xx.x%)
4 – symptoms affect daily activities	xx (xx.x%)
5 – Symptoms are incapacitating, unable to do activities	xx (xx.x%)

Denominator and percentages are based on subjects completed questionnaires per protocol requirements.

Table 12
Summary of GERD-HRQL Questionnaire at Baseline (On PPI)
Full Analysis Set

Characteristic	Baseline
Do you have bloating or gassy feelings?	
0 - No symptoms	xx (xx.x%)
1 - Symptoms noticeable, but not bothersome	xx (xx.x%)
2 - Symptoms noticeable and bothersome, but not every day	xx (xx.x%)
3 – Symptoms bothersome every day	xx (xx.x%)
4 – symptoms affect daily activities	xx (xx.x%)
5 – Symptoms are incapacitating, unable to do activities	xx (xx.x%)
If you take medication, does this affect your daily life?	
0 - No symptoms	xx (xx.x%)
1 - Symptoms noticeable, but not bothersome	xx (xx.x%)
2 - Symptoms noticeable and bothersome, but not every day	xx (xx.x%)
3 – Symptoms bothersome every day	xx (xx.x%)
4 – symptoms affect daily activities	xx (xx.x%)
5 – Symptoms are incapacitating, unable to do activities	xx (xx.x%)
How satisfied are you with your present condition?	
Satisfied	xx (xx.x%)
Neutral	xx (xx.x%)
Dissatisfied	xx (xx.x%)
GERD-HRQL Total Score	
n	xx (xx.x%)
Mean (SD)	xx.x (xx.xx)
Median(Min, Max)	xx.x (xx, xx)
95% Confidence Interval	(xx.xxx, xx.xxx)

Denominator and percentages are based on subjects completed questionnaires per protocol requirements.

Table 13
Summary of GERD-HRQL Questionnaire (Off PPI)
Full Analysis Set

Characteristic	Baseline	3 Months Follow-Up	6 Months Follow-Up	12 Months Follow-Up
Number of Subjects Completed Questionnaire per Protocol Requirements	xx	xx	xx	xx
How bad is your heartburn?				
0 - No symptoms	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 - Symptoms noticeable, but not bothersome	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 - Symptoms noticeable and bothersome, but not every day	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Symptoms bothersome every day	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 – symptoms affect daily activities	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
5 – Symptoms are incapacitating, unable to do activities	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Heartburn when lying down?				
0 - No symptoms	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 - Symptoms noticeable, but not bothersome	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 - Symptoms noticeable and bothersome, but not every day	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Symptoms bothersome every day	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 – symptoms affect daily activities	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
5 – Symptoms are incapacitating, unable to do activities	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Heartburn when standing up?				
0 - No symptoms	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 - Symptoms noticeable, but not bothersome	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 - Symptoms noticeable and bothersome, but not every day	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Symptoms bothersome every day	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 – symptoms affect daily activities	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
5 – Symptoms are incapacitating, unable to do activities	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Heartburn after meals?				
0 - No symptoms	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 - Symptoms noticeable, but not bothersome	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 - Symptoms noticeable and bothersome, but not every day	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Symptoms bothersome every day	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 – symptoms affect daily activities	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
5 – Symptoms are incapacitating, unable to do activities	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Denominator and percentages are based on subjects completed questionnaires per protocol requirements.

Table 13
Summary of GERD-HRQL Questionnaire (Off PPI)
Full Analysis Set

Characteristic	Baseline	3 Months Follow-Up	6 Months Follow-Up	12 Months Follow-Up
Does heartburn change your diet?				
0 - No symptoms	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 - Symptoms noticeable, but not bothersome	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 - Symptoms noticeable and bothersome, but not every day	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Symptoms bothersome every day	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 – symptoms affect daily activities	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
5 – Symptoms are incapacitating, unable to do activities	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Does heartburn wake you from sleep?				
0 - No symptoms	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 - Symptoms noticeable, but not bothersome	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 - Symptoms noticeable and bothersome, but not every day	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Symptoms bothersome every day	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 – symptoms affect daily activities	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
5 – Symptoms are incapacitating, unable to do activities	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Do you have difficulty swallowing?				
0 - No symptoms	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 - Symptoms noticeable, but not bothersome	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 - Symptoms noticeable and bothersome, but not every day	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Symptoms bothersome every day	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 – symptoms affect daily activities	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
5 – Symptoms are incapacitating, unable to do activities	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Do you have pain with swallowing?				
0 - No symptoms	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 - Symptoms noticeable, but not bothersome	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 - Symptoms noticeable and bothersome, but not every day	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Symptoms bothersome every day	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 – symptoms affect daily activities	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
5 – Symptoms are incapacitating, unable to do activities	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Denominator and percentages are based on subjects completed questionnaires per protocol requirements.

Table 13
Summary of GERD-HRQL Questionnaire (Off PPI)
Full Analysis Set

Characteristic	Baseline	3 Months Follow-Up	6 Months Follow-Up	12 Months Follow-Up
Do you have bloating or gassy feelings?				
0 - No symptoms	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 - Symptoms noticeable, but not bothersome	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 - Symptoms noticeable and bothersome, but not every day	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Symptoms bothersome every day	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 – symptoms affect daily activities	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
5 – Symptoms are incapacitating, unable to do activities	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
If you take medication, does this affect your daily life?				
0 - No symptoms	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
1 - Symptoms noticeable, but not bothersome	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
2 - Symptoms noticeable and bothersome, but not every day	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
3 – Symptoms bothersome every day	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
4 – symptoms affect daily activities	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
5 – Symptoms are incapacitating, unable to do activities	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
How satisfied are you with your present condition?				
Satisfied	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Neutral	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Dissatisfied	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
GERD-HRQL Total Score				
n	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mean (SD)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx.x (xx.xx)
Median(Min, Max)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx.x (xx, xx)
95% Confidence Interval	(xx.xxx, xx.xxx)	(xx.xxx, xx.xxx)	(xx.xxx, xx.xxx)	(xx.xxx, xx.xxx)

Denominator and percentages are based on subjects completed questionnaires per protocol requirements.

Table 14
GERD-HRQL Total Score (Off PPI)
Full Analysis Set

Parameter	Baseline	12 Months Follow-Up	Change from Baseline to 12 Months Follow-Up	% Successful at 12 Months Follow-Up [1]
GERD-HRQL Total Score				
n	xx	xx	xx	
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	
Median (Min, Max)	xx.x (xx, xx)	xx.x (xx, xx)	xx.x (xx, xx)	
95% Confidence Interval			(xx.xxx, xx.xxx)	
Number of Subjects with at Least 50% Reduction on GERD-HRQL				xx (xx.x%)

Denominator and percentages are based on subjects completed baseline and 12 months follow-up per protocol requirements.
[1] % Successful is defined as number of subjects meeting the success criterion of at least 50% reduction on GERD-HRQL at 12 months follow-up compared to baseline off PPI.

Table 15
Daily PPI Medication Use from Baseline to 12 Months
Full Analysis Set

Parameter	Baseline	12 Months Follow-Up	Change from Baseline to 12 Months Follow-Up	% Successful at 12 Months Follow-Up [1]
PPI Use (mg) [2]				
n	xx	xx	xx	
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	
Median (Min, Max)	xx.x (xx, xx)	xx.x (xx, xx)	xx.x (xx, xx)	
95% Confidence Interval			(xx.xxx, xx.xxx)	
Number of Subjects with at Least 50% Reduction in Daily Use				xx (xx.x%)

Denominator and percentages are based on subjects completed baseline and 12 months follow-up.
[1] % Successful is defined as number of subjects meeting the success criterion of at least 50% reduction in daily PPI use from baseline at 12 months.
[2] PPI Use is defined by the evaluation of subject's daily dose of PPI.

<Programming note those PPI administrated as PRN will not be included in daily dose calculation..>

Table 16
Abdominal/Chest X-Ray at 12 Months Follow-Up
Full Analysis Set

Characteristic	12 Months Follow-Up (N = ##)
Is the LINX device at the gastroesophageal junction?	
Yes	xx.x (xx.x)
No	xx.x (xx.x)
Any Evidence of Device Migration?	
Yes	xx (xx.x%)
No	xx (xx.x%)

Denominator and percentages are based on subjects with non-missing data.

Table 17
Foregut Symptoms Questionnaire by Visit (Off PPI)
Full Analysis Set

Characteristic	Baseline (N = ##)	3 Months Follow-Up (N = ##)	6 Months Follow-Up (N = ##)	12 Months Follow-Up (N = ##)
Regurgitation Frequency				
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lung Problems				
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Recurrent cough	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Nocturnal cough	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Recurrent pneumonitis	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Asthma	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Change of voice	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Ability to Vomit				
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No need to vomit	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Ability to belch				
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Denominator and percentages are based on subjects with non-missing data.

Table 18
Regurgitation Severity Elimination from Severe and Moderate (Off PPI)
Full Analysis Set

Change from Baseline	3 Months Follow-Up (N = ##)	6 Months Follow-Up (N = ##)	12 Months Follow-Up (N = ##)
Eliminate severe (to moderate, mild or none) [1]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Eliminate moderate (to mild or none) [2]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Column header counts represent the number of subjects who complete the FSQ form at the given visit.
[1] Percentages are calculated using the number of subjects with severe regurgitation at baseline and who complete the FSQ form at the given visit.
[2] Percentages are calculated using the number of subjects with moderate regurgitation at baseline and who complete the FSQ form at the given visit.

Table 19
Regurgitation Frequency Summary (Off PPI)
Full Analysis Set

Frequency	Baseline (N = ##)	3 Months Follow-Up (N = ##)	6 Months Follow-Up (N = ##)	12 Months Follow-Up (N = ##)
Regurgitation (times/week)				
n	xx	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median (Min, Max)	xx.x (xx, xx)	xx.x (xx, xx)	xx.x (xx, xx)	xx.x (xx, xx)

Table 20
Adverse Events Summary
Full Analysis Set

Adverse Event Category	Number of Subjects (N = ##)	Number of Events
Any Adverse Events	xx (xx.x%)	xx
Serious Adverse Events	xx (xx.x%)	xx
AE related (Yes/Probably/Possibly or Unknown) to Study Device	xx (xx.x%)	xx
AE related (Yes/Probably/Possibly or Unknown) to Implant Procedure	xx (xx.x%)	xx
SAE related (Yes/Probably/Possibly or Unknown) to Study Device	xx (xx.x%)	xx
SAE related (Yes/Probably/Possibly or Unknown) to Implant Procedure	xx (xx.x%)	xx

All percentages are calculated using the number of subjects in the FAS as the denominator.

Table 21
All Adverse Events
Full Analysis Set

Adverse Event Category	Number of Subjects (N = ##)	Number of Events
Total	xx (xx.x%)	xx
Achalasia	xx (xx.x%)	xx
Allergic reaction	xx (xx.x%)	xx
Anaphylaxis	xx (xx.x%)	xx
….	xx (xx.x%)	xx

All percentages are calculated using the number of subjects in the FAS as the denominator.

<Programming note: Only adverse event observed need be displayed. Sort the AE types by Number of Events descending.>

The following tables will have the same format as Table 21:

Table 22	All Serious Adverse Events Full Analysis Set
Table 23	Adverse Events Related to the Study Device Full Analysis Set
Table 24	Serious Adverse Events Related to the Study Device Full Analysis Set
Table 25	Adverse Events Related to the Study Procedure Full Analysis Set
Table 26	Serious Adverse Events Related to the Study Procedure Full Analysis Set

Table 27
Protocol Deviations
Full Analysis Set

Characteristics	Overall (N = ##)
Total Number of Protocol Deviations	xxx
Major Protocol Deviations	xx
Minor Protocol Deviations	xx
Specific Types of Protocol Deviations [1]	
Informed Consent Issue	xx (xx.x%)
Subject Did Not Meet Inclusion Criteria	xx (xx.x%)
Subject Did Not Meet Exclusion Criteria	xx (xx.x%)
Visit Performed Out of Window	xx (xx.x%)
…..	xx (xx.x%)
Number (%) of Subjects With at Least 1 Protocol Deviation [2]	xx (xx.x%)

[1]. Denominator used is the total number of protocol deviations reported.
[2]. Denominator used is the total number of subjects in the column header.

Table 28
Summary of Device Explants
Full Analysis Set

Category Statistic	Total (N = ##)
Subjects Experiencing Explant	
n (%)	xx (xx.x%)
95% Exact Confidence Interval	(xx.xxx, xx.xxx)
Time to Explant (months)	
n	xx (xx.x%)
Mean (SD)	xx.x (xx.xx)
Median (Min, Max)	xx.x (xx.x, xx.x)
Categorical Summary of Time to Explant [1]	
0 to <= 6 months	xx (xx.x%)
6 months to <= 1 year	xx (xx.x%)
>1 year	xx (xx.x%)

Note: Explants are identified from the Adverse Event case report form under the Healthcare Utilization section and have intervention_explant checked, or in the case of Subject 07-16-009, the device explant is identified in the subject withdrawal form where the reason for withdrawal identifies an explant date of 26MAR2020 (see Listing 19).
[1] Denominator is the total number of subjects experiencing an explant.

< Programming note: Explants are identified from the Adverse Event case report form under the "EXPLANT" checked (variable name AEEXPLANT), or in the Subject Withdrawal/Study Completion case report form under the "Reason for Withdrawal/Completion is Investigator withdrawal" selected "Device explant" (variable name DSINVESWIT=1). Time to explant in months is calculated based on either the date of explant from the AE form and the date of original implant = (AEINTERDAT1 – IMPLANTSURGDAT)/30.4375; or the date of explant mentioned in detailed reason for withdrawal/completion = (explant date derived from DSREAS1 – IMPLANTSURGDAT)/30.4375. >

Table 29
Daily PPI Use
Full Analysis Set

Characteristic	3 Months Follow-Up (N = ##)	6 Months Follow-Up (N = ##)	12 Months Follow-Up (N = ##)
Discontinue Daily PPI Use			
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Percentages are calculated using the total number of subjects completed the 3 months, 6 months, and 12 months follow-up.

< Programming note: Discontinue Daily PPI Use is defined as subjects who reported PPI medication usage at screening/baseline but no PPI usage in each follow-up visit. (GERDMEDPPI =Yes and MEDFUPPI = No)>

The following listings will be generated for this study:

Listing 1	Inclusion/Exclusion Criteria All Subjects
Listing 2	Demographics Full Analysis Set
Listing 3	Study Visit Assessment Full Analysis Set
Listing 4	Physical Examination Full Analysis Set
Listing 5	pH Results Full Analysis Set
Listing 6	Manometry/Motility Results Full Analysis Set
Listing 7	Endoscopy Data Full Analysis Set
Listing 8	Implantation Data Full Analysis Set
Listing 9	Barium Esophagram Data Full Analysis Set
Listing 10	GERD Medications Full Analysis Set
Listing 11	LSG and GERD History Full Analysis Set
Listing 12	Motivation for Surgery Full Analysis Set
Listing 13	GERD-HRQL Questionnaire (on PPI) Full Analysis Set
Listing 14	GERD-HRQL Questionnaire (off PPI) Full Analysis Set
Listing 15	Abdominal/Chest X-Rays Data Full Analysis Set

Listing 16	Discharge Full Analysis Set
Listing 17	Follow-Up GERD Medications Full Analysis Set
Listing 18	GERD-HRQL Questionnaire Full Analysis Set
Listing 19	Foregut Symptoms Questionnaire Full Analysis Set
Listing 20	Adverse Event Full Analysis Set
Listing 21	Protocol Deviations All Subjects
Listing 22	Subject Withdrawal/Study Completion All Subjects
Listing 23	Unscheduled Visit All Subjects