Statistical Analysis Plan (SAP)

A Prospective, Multi-Center Evaluation of the ECHELON CIRCULAR Powered Stapler in Left-Sided Colorectal Anastomoses

Protocol Number: ESC-16-002

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Revision History

Revision Number	Revision Date	Reasons for Revision
1.0	28JAN2020	Original Document
2.0	05FEB2020	Addition of Adverse Event tables to support the submission to NMPA for registration in China. These include differentiation of intraoperative (day of surgery) versus postoperative (strictly after surgery) and are described in mock-up Tables 29 to 33. Additional text has also been added to Section 8.5 to describe these tables.

Table of Contents

1 Introduction

This is the Statistical Analysis Plan (SAP) for the final analysis of data collected under Protocol ESC-16-002. This SAP describes in detail the statistical methodology and statistical analyses for this protocol.

1.1 Study Objectives

The primary objective of this study was to prospectively evaluate the intra-operative performance of the powered circular stapler in a post-market setting using the ECHELON CIRCULAR™ Powered Stapler device per its Instruction For Use (IFU). Secondary objectives include surgeon workload, surgeon satisfaction, and proactive surveillance of safety of the powered circular stapler used in left colectomy procedures in a post-market setting.

1.2 Study Design

This was a prospective open-label, multi-center clinical study designed to evaluate the intra-operative performance of the powered circular stapler in left colectomy procedures in a post-market setting. Investigators were to perform the procedure using the device in compliance with their standard surgical approach and the ECHELON CIRCULAR™ Powered Stapler IFU.

Each site utilized consecutive screening and enrollment in an effort to generate a random and representative patient population sample. Patients satisfying the entry criteria will be consented and screened. Subjects will be considered enrolled at the time of the first attempted anastomosis using the ECHELON CIRCULAR™ Powered Stapler device during their procedure. Procedures were performed either open or via minimally invasive surgery (MIS) according to institutional standard-of-care (SOC). Use of a hand port and robotic assistance were permissible providing the powered circular stapler was used to create the anastomosis. Conversion from MIS to open surgery is permissible under the protocol at the surgeon's discretion for the patient's safety. Follow-up care was documented post-operatively to confirm healing of the anastomosis. The final scheduled study visit was to occur 28 days post-procedure (routinely scheduled follow-up with the surgeon). Follow-up by phone for subjects was allowed when an on-site visit is not planned or was more than six weeks post-operative.

A total of 165 eligible subjects were planned to be enrolled in up to 12 sites (United States and Europe) to ensure at least 150 subjects complete the study. The planned maximum number of subjects enrolled at any site was not to exceed 20% of the total number of subjects enrolled in the study.

2 Treatment Assignment

This was a prospective, open label, single-arm study where all enrolled subjects were to have the ECHELON CIRCULAR™ Powered Stapler device utilized for anastomosis of left-sided colon resection. The original design of this study planned to have two treatment arms including commercially available manual staplers and the powered circular stapler. Enrollment was to be sequential within each site where manual cases would be performed first and then transitioning to enrollment of powered cases. As part of amendment 3 to the study protocol, a business decision was made to move to a single-arm study for expeditious trial completion. The objective of the study was revised and the planned comparison of the manual stapler to the powered stapler was removed. The objective of the study was restated to evaluate the intra-operative performance of just the powered stapler. The study design herein is described as a single-arm study. Prior to this amendment, a total of 22 subjects had been enrolled and had procedures performed with a manual circular stapler. Data from these subjects has been maintained in the study database and this data is included in the listings generated as part of the final analysis for this study.

3 Randomization and Blinding Procedures

This was a single-arm, open-label study. No randomization occurred and no blinding procedures were required.

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 Schedule of 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) and data collected in Unscheduled Visit forms will be listed as such.

5 Levels of Significance

No hypotheses are specified for this study and no p-values are being calculated, therefore no level of significance is specified. All estimation of endpoints will be performed using 95% confidence intervals.

6 Analysis Sets

The summary of safety and effectiveness endpoints will be performed on the set of enrolled subjects in whom an anastomosis was attempted with the ECHELON CIRCULAR™ Powered Stapler. This will be labeled the Full Analysis Set. This set of subjects will be identified by having answered "Yes" to the question "Was anastomosis attempted?" on the Intraoperative Data eCRF.

The summary of effectiveness endpoints will be repeated on the set of subjects in the Full Analysis Set who also have no major protocol deviations. This will be labeled the Per Protocol Set.

7 Sample Size Justification

A total of 165 eligible subjects was planned to be enrolled in up to 12 sites to ensure at least 150 subjects complete the study. No formal hypothesis was being tested in this study, thus the sample size was not statistically sized, but rather was considered sufficient for a descriptive summary of stapler performance issues through confidence interval estimation and evaluation of safety. The sample size of 165 subjects was consistent with the amount of information that was planned to be collected on the powered stapler in the original study design and provides acceptable precision for estimation of the rate of stapler performance issues. Available literature suggests that stapler performance issues are observed in 15% to 20% of subjects in whom a circular stapler is used, and a sample size of 165 subjects will provide a margin of error for a one-sided 95% confidence interval that does not exceed 5.1% for estimation of the true rate of stapler performance issues.

Further, in consideration of rare AEs that may occur, for an event that occurs at a rate of, for example, 1.5%, then in a sample of 165 subjects, the probability of observing at least 1 event is greater than 90% under a binomial probability model. Thus, this sample size provides a high probability of observing rare events if they do occur and provides reasonable assurance that the absence of such events in the study is not a result of too few subjects being studied, should none be observed.

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 percentage.

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, 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 who completed and discontinued will be tabulated along with the specific reasons for discontinuation.

8.3 Demographic, Baseline, and Surgical Characteristics

Summary statistics of subject demographics (age, gender, race, height, weight, body mass index, and ethnicity) and pre-operative surgical characteristics (bowel preparation and administration of antibiotics) will be presented for the Full Analysis Set. Medical History (ASA score, surgery indication, level of anastomosis, clinical stage, and smoking history) will be summarized in a similar manner. Surgical characteristics including procedure duration, splenic flexure mobilization, surgical approach, anastomosis details, stapler used, and conversion to open will also be summarized.

8.4 Primary and Secondary Endpoints and Associated Hypotheses

8.4.1 Primary Endpoint and Associated Hypotheses

No formal hypotheses are specified for this study. The study endpoints are representative of endpoints that are currently reported in the available literature for stapler performance and this will allow for qualitative comparisons with the results from this study.

The primary performance endpoint in this study is the percentage of subjects who experienced a failure of the ECHELON CIRCULAR™ Powered Stapler to perform per its IFU. This includes but is not limited to difficulty placing or removing the stapler, stapler misfire/failure of the device to fully fire, staple line defects, incomplete or thin donuts, tissue damage, positive intraoperative leak test, detached components, unformed staples, or any other device failures.

The denominator for the primary endpoint will be the total number of subjects where an anastomosis was attempted and the numerator will be the number of subjects who experienced a stapler performance issue. An exact 95% confidence interval using the Clopper-Pearson method will also be estimated.

8.4.2 Secondary Endpoints and Associated Hypotheses

Summary statistics will be provided for the Surgery Task Load Index (Surg-TLX). Surgeons are asked to rate 6 specific components after each surgery performed. The 6 components are – mental fatigue, physical fatigue, hurried/rushed pace, procedure complexity, anxious while performing procedure, and distracting operating environment. Each component is scored on a 0 to 100 scale with lower scores representing a ‘Low’ response on that component and higher scores indicating a ‘High’ response on that component. Summaries will also be provided for an overall score which is calculated as the average of the six components for each surgery.

Counts and percentages will be provided for responses to the surgeon satisfaction questionnaire.

8.4.3 Additional Endpoints

Counts and percentages will be provided for results of the intra-operative leak test. The requirement for any blood transfusion and reason of the transfusion will be summarized with counts and percentages. Summary statistics will be provided for length of stay and discharge details will be listed. All protocol deviations recorded during the study will be classified as minor or major. Counts and percentages will be provided for the type of deviation, the rationale for the deviation, and classification (minor or major). As indicated in Section 3.19 of the protocol, photos of the anastomotic donuts were to be taken if possible. These photos were to be reviewed and assessed by the Sponsor to evaluate the quality of the donuts created and determine if either donut appeared thin or incomplete. No summary analyses were planned for the results of these assessments in the protocol and none are specified here. The results of the Sponsor assessment will be listed.

8.5 Safety Analyses

Safety will be assessed through the incidence of AEs and SAEs, which will be coded using the Medical Dictionary for Regulatory Activities (MedDRA). The number and percentage of subjects reporting AEs and SAEs will be summarized at the MedDRA system organ class and preferred term level. 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 procedure. Related events are those where the relationship is indicated as Unlikely, Possibly, Probably, or Causal. Summaries will also be provided for AEs, device-related AEs and SAEs where the start date of the event is equal to the day of surgery (intraoperative AEs). Similar summaries will be generated for AEs and device-related AEs where the start date of the event is strictly after the day of surgery (postoperative AEs). All reported adverse events will be listed. Listings will also be provided for concomitant procedures and concomitant medications.

8.6 Plans for Interim Analysis

No interim analyses were planned or performed for this study.

8.7 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.

8.8 Subgroup Analysis

Subgroup analyses of the primary performance endpoint are planned to be performed surgical approach (open or laparoscopic as identified on the Intraoperative Procedure eCRF) and by surgery indication (diverticulitis, neoplasm, etc identified on the Medical History eCRF).

8.9 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

	Overall
Signed Informed Consent	xx
Full Analysis Set	xx
Completed the Study	xx (xx.x%)
Discontinued from the Study	xx (xx.x%)
Reason for Discontinuation	
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%)

All percentages are calculated using the number of subjects in the Full Analysis Set as the denominator.

Programming note: Only categories actually observed in the database need to be displayed for Reason for Discontinuation.

Table 2
Subject Demographics and Vital Signs
Full Analysis Set

Characteristic	Overall (N = ##)
Age at Consent (yrs)	
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 (%)	
Race 1	xx (xx.x%)
……	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)	
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 3
Medical History By System Organ Class and Preferred Term
Full Analysis Set

System Organ Class	Preferred Term	Overall (N = ##)
Total		xx (xx.x%)
System Organ Class 1		xx (xx.x%)
	Preferred Term 1	xx (xx.x%)
	Preferred Term 2	xx (xx.x%)
	Preferred Term 3	xx (xx.x%)
System Organ Class 2		xx (xx.x%)
	Preferred Term 1	xx (xx.x%)
	Preferred Term 2	xx (xx.x%)
System Organ Class 3		xx (xx.x%)
	Preferred Term 1	xx (xx.x%)
	Preferred Term 2	xx (xx.x%)
	Preferred Term 3	xx (xx.x%)
System Organ Class 4		xx (xx.x%)
	Preferred Term 1	xx (xx.x%)
	Preferred Term 2	xx (xx.x%)

Table 4
Medical History
Full Analysis Set

Characteristic	Overall (N = ##)
ASA Score	
I	xx (xx.x%)
II	xx (xx.x%)
III	xx (xx.x%)
Surgery Indication	
Colorectal carcinoma	xx (xx.x%)
Ulcerative colitis	xx (xx.x%)
Diverticulitis	xx (xx.x%)
Crohn's disease	xx (xx.x%)
Colorectal polyps or polyp syndrome	xx (xx.x%)
Other	xx (xx.x%)
Estimated Anastomosis Level	
Sigmoid colon	xx (xx.x%)
Upper rectum	xx (xx.x%)
Mid rectum	xx (xx.x%)
Lower rectum	xx (xx.x%)
Colorectal Carcinoma Clinical Stage	
Clinical T	
x	xx (xx.x%)
…	xx (xx.x%)
Clinical N	xx (xx.x%)
x	
…	
Clinical M	
x	
…	

Programming note: Only categories actually observed in the database need to be displayed for colorectal carcinoma clinical stage

Table 4
Medical History
Full Analysis Set

Characteristic	Overall (N = ##)
Smoking Status	
Current smoker	xx (xx.x%)
Former smoker	xx (xx.x%)
Never smoked	xx (xx.x%)

Table 5
Pre-Procedure Information
Full Analysis Set

Characteristic	Overall (N = ##)
Pre-Operation Bowel Preparation	
Yes	xx (xx.x%)
No	xx (xx.x%)
Type of Pre-Operation Bowel Preparation	
Mechanical bowel preparation	xxx
Antibiotic	xxx
Enema	xxx
Other	xxx
Pre-operative Antibiotics (IV) Administered	
Yes	xx (xx.x%)
No	xx (xx.x%)

Table 6
Intra-Operative Information
Full Analysis Set

Characteristic	Overall (N = ##)
Surgeon Gender	
Male	xx (xx.x%)
Female	xx (xx.x%)
Surgeon Height (cm)	
n	xx
Mean (SD)	xx.x (xx.x)
Median (Min, Max)	xx.x (xx, xx)
Surgeon Weight (kg)	
N	xx
Mean (SD)	xx.x (xx.x)
Median (Min, Max)	xx.x (xx, xx)
Surgeon Hand Length (cm)	
N	xx
Mean (SD)	xx.x (xx.x)
Median (Min, Max)	xx.x (xx, xx)
Surgeon Grip Strength (kg)	
n	xx
Mean (SD)	xx.x (xx.x)
Median (Min, Max)	xx.x (xx, xx)

Programming note: For surgeon gender, height, weight and hand length only one summary per surgeon should be included recognizing that surgeons will perform multiple surgeries. This will be accomplished through a nodupkey sort on surgeon initials within a study site.

Table 6
Intra-Operative Information
Full Analysis Set

Characteristic	Overall (N = ##)
Number of Previous Cases on Day of Procedure	
n	xx
Mean (SD)	xx.x (xx.x)
Median (Min, Max)	xx.x (xx, xx)
Procedure Duration (hours)	
n	xx
Mean (SD)	xx.x (xx.x)
Median (Min, Max)	xx.x (xx, xx)
Was the Splenic Flexure Mobilized?	
Yes	xx (xx.x%)
No	xx (xx.x%)
Number of Linear Firings	
n	xx
Mean (SD)	xx.x (xx.x)
Median (Min, Max)	xx.x (xx, xx)
Surgical approach	
Open Laparotomy	xx (xx.x%)
Hand-assisted MIS	xx (xx.x%)
Laparoscopy	xx (xx.x%)
Robotic	xx (xx.x%)
Was Anastomosis Attempted?	
Yes	xx (xx.x%)
No	xx (xx.x%)
Type of Anastomosis	
End to End	xx (xx.x%)
Side to End	xx (xx.x%)
Side to Side	xx (xx.x%)
Anastomosis not completed	xx (xx.x%)
Type of Stapler Used	
ECHELON CIRCULAR Power Stapler (diameter 29 mm)	xx (xx.x%)
ECHELON CIRCULAR Power Stapler (diameter 31 mm)	xx (xx.x%)

Programming note: Denominator for Conversion to open is number of subjects with surgical approach of hand-assisted MIS, laparoscopy, and robotic.

Table 6
Intra-Operative Information
Full Analysis Set

Characteristic	Overall (N = ##)
Estimated Distance of Anastomosis From Anal Verge	
n	xx
Mean (SD)	xx.x (xx.x)
Median (Min, Max)	xx.x (xx, xx)
Adjunct used	
Yes	xx (xx.x%)
No	xx (xx.x%)
Type of Adjunct used	
Seamguard	xxx
Evicel fibrin sealant	xxx
Other fibrin sealant	xxx
Surgifoam hemostat	xxx
Surgicel hemostat	xxx
Oversew	xxx
Other	xxx
Intra-op Leak Test Result	
Leak	xx (xx.x%)
No Leak	xx (xx.x%)
Conversion to Open Procedure?	
Yes	xx (xx.x%)
No	xx (xx.x%)
Relationship of Conversion to Study Device?	
None	xx (xx.x%)
Possibly related	xx (xx.x%)
Possibly related	xx (xx.x%)

Programming note: Denominator for Conversion to open is number of subjects with surgical approach of hand-assisted MIS, laparoscopy, and robotic.

Table 7
Technical Issues Summary
Full Analysis Set

Characteristic	Overall (N = ##)
Number of Subjects With At Least One Technical Issue [1]	
Yes, n (%)	xx (xx.x%)
95% Exact Confidence Interval	xx.x%, xx.x%
Number of Technical Issues Observed	xxx
Technical Issue Category [2]	
Difficulty placing the stapler	xx (xx.x%)
Difficulty coupling anvil to stapler	xx (xx.x%)
Stapler misfire	xx (xx.x%)
Difficulty removing the stapler	xx (xx.x%)
Staple line defects	xx (xx.x%)
Incomplete or thin donuts	xx (xx.x%)
Tissue damage	xx (xx.x%)
Positive intraoperative leak test	xx (xx.x%)
Detached components	xx (xx.x%)
Malformed/unformed staples	xx (xx.x%)
Other device failure	xx (xx.x%)
Technical Issue Related to an Adverse Event?	
Yes	xx (xx.x%)
No	xx (xx.x%)
Intra-operative Related complications	
Yes	xx (xx.x%)
No	xx (xx.x%)

[1] Percentage is calculated using total number of subjects where anastomosis was attempted as the denominator.
[2] Percentage is calculated using number of technical issues observed as the denominator.

Programming note: Only technical issue categories actually observed need be displayed.

Table 8
Surg-TLX Questionnaire
Full Analysis Set

Characteristic	Overall (N = ##)
Overall Score	
n	xx
Mean (SD)	xx.x (xx.x)
Median (Min, Max)	xx.x (xx, xx)
Mentally Fatiguing	
n	xx
Mean (SD)	xx.x (xx.x)
Median (Min, Max)	xx.x (xx, xx)
Physically Fatiguing	
n	xx
Mean (SD)	xx.x (xx.x)
Median (Min, Max)	xx.x (xx, xx)
Hurried or Rushed Pace	
n	xx
Mean (SD)	xx.x (xx.x)
Median (Min, Max)	xx.x (xx, xx)
Procedure Complexity	
n	xx
Mean (SD)	xx.x (xx.x)
Median (Min, Max)	xx.x (xx, xx)
Anxious During Procedure	
n	xx
Mean (SD)	xx.x (xx.x)
Median (Min, Max)	xx.x (xx, xx)
Distracting Environment	
n	xx
Mean (SD)	xx.x (xx.x)
Median (Min, Max)	xx.x (xx, xx)

Table 9
Surgeon Satisfaction Questionnaire – Echelon Circular Powered Stapler
Full Analysis Set

Characteristic	Overall (N = ##)
Number of Questionnaires Completed	xx
Easier Firing Versus Manual	
Strongly disagree	xx (xx.x%)
Slightly disagree	xx (xx.x%)
Neutral	xx (xx.x%)
Slightly agree	xx (xx.x%)
Strongly agree	xx (xx.x%)
Less Force To Fire Versus Manual	
Strongly disagree	xx (xx.x%)
Slightly disagree	xx (xx.x%)
Neutral	xx (xx.x%)
Slightly agree	xx (xx.x%)
Strongly agree	xx (xx.x%)
Increased Confidence for Reduced Variation	
Strongly disagree	xx (xx.x%)
Slightly disagree	xx (xx.x%)
Neutral	xx (xx.x%)
Slightly agree	xx (xx.x%)
Strongly agree	xx (xx.x%)
Fully Fired	
Strongly disagree	xx (xx.x%)
Slightly disagree	xx (xx.x%)
Neutral	xx (xx.x%)
Slightly agree	xx (xx.x%)
Strongly agree	xx (xx.x%)
Less Movement	
Strongly disagree	xx (xx.x%)
Slightly disagree	xx (xx.x%)
Neutral	xx (xx.x%)
Slightly agree	xx (xx.x%)
Strongly agree	xx (xx.x%)

Percentages are calculated using the total number of questionnaires completed as the denominator.

Table 10
Post-operative Anastomotic Leak Assessment and Length of Stay Summary
Full Analysis Set

Characteristic	Overall (N = ##)
Any Post-operative Anastomotic Leak ?	
Yes	xx (xx.x%)
No	xx (xx.x%)
Grading of Anastomotic Leakage	
Grade A	xx (xx.x%)
Grade B	xx (xx.x%)
Grade C	xx (xx.x%)
Discharge Location	
Home	xx (xx.x%)
Skilled nursing facility	xx (xx.x%)
Long-term care	xx (xx.x%)
Hospice care	xx (xx.x%)
Other	xx (xx.x%)
Length of Stay (days)	
n	xx
Mean (SD)	xx.x (xx.x)
Median (Min, Max)	xx.x (xx, xx)

Table 11
All Adverse Events by System Organ Class and Preferred Term
Full Analysis Set

System Organ Class	Preferred Term	Overall (N = ##)
Total		xx (xx.x%)
System Organ Class 1		xx (xx.x%)
	Preferred Term 1	xx (xx.x%)
	Preferred Term 2	xx (xx.x%)
	Preferred Term 3	xx (xx.x%)
System Organ Class 2		xx (xx.x%)
	Preferred Term 1	xx (xx.x%)
	Preferred Term 2	xx (xx.x%)
System Organ Class 3		xx (xx.x%)
	Preferred Term 1	xx (xx.x%)
	Preferred Term 2	xx (xx.x%)
	Preferred Term 3	xx (xx.x%)
System Organ Class 4		xx (xx.x%)
	Preferred Term 1	xx (xx.x%)
	Preferred Term 2	xx (xx.x%)

The following tables will have the same format as Table 11:

Table 12	All Serious Adverse Events by System Organ Class and Preferred Term Full Analysis Set
Table 13	Adverse Events Related to the Study Device by System Organ Class and Preferred Term Full Analysis Set
Table 14	Serious Adverse Events Related to the Study Device by System Organ Class and Preferred Term Full Analysis Set
Table 15	Adverse Events Related to the Study Procedure by System Organ Class and Preferred Term Full Analysis Set
Table 16	Serious Adverse Events Related to the Study Procedure by System Organ Class and Preferred Term Full Analysis Set

Table 17
Protocol Deviations
Full Analysis Set

Characteristics	Overall (N = ##)
Total Number of Protocol Deviations	xxx
Specific Types of Protocol Deviations [1]	
Informed Consent Process	xx (xx.x%)
Inclusion/Exclusion Criteria	xx (xx.x%)
Study Procedure	xx (xx.x%)
Visit Out of Window	xx (xx.x%)
Other	xx (xx.x%)
Sponsor Assessment of Protocol Deviations [1]	
Minor	xx (xx.x%)
Major	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.

The following tables will have the same format as Table 7:

Table 18	Technical Issues Summary Per Protocol Analysis Set
Table 19	Technical Issues Summary Surgical Approach – Open Laparotomy Full Analysis Set
Table 20	Technical Issues Summary Surgical Approach – Hand-assisted MIS Full Analysis Set
Table 21	Technical Issues Summary Surgical Approach – Laparoscopy Full Analysis Set
Table 22	Technical Issues Summary Surgical Approach – Robotic Full Analysis Set
Table 23	Technical Issues Summary Surgical Indication – Colorectal Carcinoma Full Analysis Set
Table 24	Technical Issues Summary Surgical Indication – Ulcerative Colitis Full Analysis Set
Table 25	Technical Issues Summary Surgical Indication – Diverticulitis Full Analysis Set
Table 26	Technical Issues Summary Surgical Indication – Crohn's Disease Full Analysis Set
Table 27	Technical Issues Summary Surgical Indication – Colorectal polyps or polyp syndrome Full Analysis Set
Table 28	Technical Issues Summary Subjects With Any Potential Anastomotic Leak Risk Factor From Medical History eCRF Full Analysis Set

The following tables will have the same format as Table 11:

Table 29	All Adverse Events With a Start Date on the Day of Surgery by System Organ Class and Preferred Term Full Analysis Set
Table 30	All Device-Related Adverse Events With a Start Date on the Day of Surgery by System Organ Class and Preferred Term Full Analysis Set
Table 31	All Adverse Events With a Start Date Strictly After the Day of Surgery by System Organ Class and Preferred Term Full Analysis Set
Table 32	All Device-Related Adverse Events With a Start Date Strictly After the Day of Surgery by System Organ Class and Preferred Term Full Analysis Set
Table 33	All Serious Adverse Events With a Start Date on the Day of Surgery by System Organ Class and Preferred Term Full Analysis Set

The following listings will be generated for this study:

Listing 1	Inclusion/Exclusion Criteria All Subjects
Listing 2	Demographics All Subjects
Listing 3	Health Economic Data All Subjects
Listing 4	Medical History All Subjects
Listing 5	Past Medical History Log All Subjects
Listing 6	Abdominal Surgical History All Subjects
Listing 7	Pre-Procedure Data All Subjects
Listing 8	Intraoperative Data All Subjects
Listing 9	Anastomosis Assessment All Subjects
Listing 10	Additional Intraoperative Details All Subjects
Listing 11	Technical Issues With Stapler All Subjects
Listing 12	Surgery Task Load Index (SURG-TLX) All Subjects
Listing 13	Surgeon Satisfaction Questionnaire (Echelon Circular Powered Stapler) All Subjects
Listing 14	Discharge All Subjects

Listing 15	Postoperative Visit All Subjects
Listing 16	Additional Procedures All Subjects
Listing 17	Postoperative Anastomotic Leak Assessment All Subjects
Listing 18	Adverse Events All Subjects
Listing 19	Concomitant Medications All Subjects
Listing 20	Protocol Deviations All Subjects
Listing 21	Completion/Withdrawal All Subjects
Listing 22	Unscheduled Visit All Subjects