

Statistical Analysis Plan (SAP)

**A Prospective, Multi-Center Evaluation of a Powered Vascular Stapler in Video-Assisted
Thoracoscopic Lobectomies**

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This is the Statistical Analysis Plan (SAP) for the final analysis of data collected under Protocol ESC-14-006. This SAP describes in detail the statistical methodology and statistical analyses for the above mentioned protocol.

1 Study Overview

1.1 Study Objectives

The primary objective was to demonstrate the effectiveness of the powered vascular stapler (PVS) for transection of the pulmonary artery (PA) and pulmonary vein (PV) during video-assisted thoracoscopic surgery (VATS) lobectomy.

1.2 Study Design

This was a prospective, multi-center study that collected data from the surgeon's use of the PVS for PA/PV transection. Prospective subjects were informed about the nature of the research, given the ICD to read, and if the subject understood the consent, was asked to provide written consent (the ICD).

2 Treatment Assignment

This was a single-arm study where all enrolled subjects underwent VATS lobectomy with the planned usage of PVS for transection of the PA and PV.

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 as the collection of data for the primary performance endpoint occurred intra-operatively and the collection of data for the primary safety endpoint occurred through hospital discharge. The final visit occurred approximately 4 weeks after surgery, thus no interval windows need to be defined given the absence of long-term follow-up in this study. The study protocol specified a window of 5 days around the scheduling of the 4-week follow-up visit, and any information entered in the eCRFs at this visit will correspond to the 4-week visit. There will be no assigning of observations to time points outside of the visit to which they are recorded in the eCRFs. The complete Schedule of Events for this study can be found in the Synopsis of the study protocol.

5 Primary and Secondary Endpoints

5.1 Primary Effectiveness Endpoint

The primary effectiveness endpoint in this study was defined as the occurrence of hemostatic interventions/procedures completed for intra-operative bleeding related to the transection of the PA and PV during VATS lobectomy. Hemostasis interventions or procedures were defined as bleeding detected and controlled intra-operatively (additional stapling, over-sewing, clip placement, compression, use of suture, sealant, and/or buttress, and/or use of energy); or bleeding that occurred intra-operatively requiring blood or blood product transfusion or an additional surgical procedure (e.g. conversion to open). No hemostasis intervention was defined as no bleeding at the staple line or bleeding that stopped after initial blotting of the staple line.

The primary effectiveness endpoint will be summarized at the firing level as multiple firings per subject were expected and observed; that is, the denominator for the primary endpoint will be the total number of firings and the numerator will be the number of firings where an intervention was required.

5.2 Primary Safety Endpoint

The primary safety endpoint was defined as the occurrence of hemostatic interventions/procedures completed for post-operative bleeding related to the transection of the PA and PV during VATS lobectomy. Hemostasis intervention was defined as bleeding that occurred post-operatively requiring blood or blood product transfusion or an additional surgical procedure (related to PA and PV transection). No hemostasis intervention was defined as no interventions needed for post-operative bleeding (related to PA and PV transection). This endpoint was recorded at the subject level as it was based on post-operative interventions and not specific to any individual firing.

5.3 Secondary and Additional Endpoints

Key additional endpoints in this study include: pain score assessments, American Shoulder and Elbow Surgeons Standardized (ASES) Shoulder Assessment, Surgeon Task Load Index, adverse events, and device usability questionnaires.

6 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.

7 Analysis Sets

There will be three analysis sets defined:

- The Full Analysis Set (FAS) will consist of all enrolled subjects who had a procedure completed and provided data on the number of surgical interventions;
- The Per Protocol (PP) Analysis Set will consist of all subjects in the FAS who had no major protocol deviations. Determination of major deviations are conducted by the study Medical Director, Project Manager and Biostatistician. A major deviation is defined as: A departure from the study protocol that has the potential to affect the scientific validity of the study (including deviations that: a) impact the analysis of the primary endpoint, or b) are due to inappropriate enrollment of a subject that does not meet the inclusion/exclusion criteria) or the safety, rights and welfare of the enrolled subject.
- The Safety Analysis Set will consist of all enrolled subjects on whom a procedure was started.

The primary effectiveness endpoint analysis will be performed on the Full Analysis Set. The primary effectiveness endpoint analysis will also be performed on the PP set as a sensitivity analysis to the results on the FAS. A summary of additional endpoints will also be performed on the Full Analysis Set. Analysis of the primary safety endpoint and adverse events summaries will be performed on the Safety Analysis Set.

8 Sample Size Justification

Approximately 50 subjects were enrolled in the study. No formal sample sizing was performed for this study as it is a single-arm study without a hypothesis. Historical clinical study data on a similar powered surgical stapler demonstrated a need for staple line interventions in approximately 6% of firings on the pulmonary artery or pulmonary vein. This data also showed an average of 2.6 to 2.9 firings per subject, and it is expected, given differences in device design, that each subject will require 3 to 4 firings on the pulmonary vein or pulmonary artery in the current study with PVS. Therefore, assuming an average of 3.5 firings per subject, a sample size of 50 subjects should provide approximately 175 firings. Assuming a 6% proportion of firings which require an intra-operative hemostatic intervention/procedure background rate, then the proposed sample size should control the margin of error for a 95% confidence interval to be no more than 3.5% and provide adequate precision for evaluating the performance of PVS and allow for qualitative comparisons to additional trials involving this device.

9 Data Monitoring Committee (DMC)

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

10 Analyses to be Conducted

10.1 General Conventions

Subject data will be summarized using listings and tables. 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 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 version 9.4 or higher. During the course of analysis 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.

10.2 Disposition of Study Subjects

Subject disposition will be summarized in total using counts and percentages. The number and percentage of subjects in each analysis set will be tabulated. Additionally, the number and percentage of subjects completed and discontinued will be tabulated along with the specific reasons for discontinuation.

10.3 Demographic, Baseline, and Surgical Characteristics

Summary statistics of subject demographics (age, gender, race, and ethnicity) will be presented in total for the Full Analysis Set. Surgical characteristics including, at minimum, lobe location, calcified hilar lymph node presence, number of ports used, number of pulmonary arteries transected, number of chest tubes placed, ASA physical status, estimated blood loss, conversion to open, requirement for blood transfusion, procedure duration, and number of chest tubes will be summarized in total. Results of tumor assessments performed by the pathology laboratory (including tumor stage, maximum tumor diameter, maximum tumor depth, primary TNM classification, presence of distant metastasis, and confirmation of non-small cell lung cancer) will also be summarized.

10.4 Primary Endpoint Analyses

For the primary performance endpoint, summary statistics and a 95% confidence interval will be provided for the number and percentage of interventions for the FAS. To account for the potential dependence among firings within a subject, the 95% confidence interval will be estimated using a

bootstrap approach. For each subject, the outcome of each firing will be represented by a vector of 0's (indicating no intervention needed) and 1's (indicating an intervention was needed). This vector will be re-sampled with replacement to generate a bootstrap sampled vector of observations for each subject. Then, the proportion of observations requiring intervention for each subject will be calculated from this bootstrap vector. After obtaining a sample proportion of firings requiring intervention for each subject, the mean of these sample proportions will be calculated across all 50 subjects to provide an estimated sample proportion of firings requiring intervention based on 1 iteration of the bootstrap process. This process will then be repeated a minimum of 5000 times to generate a sampling distribution for the proportion of firings requiring intervention. The mean of this sampling distribution will be provided as the point estimate of the proportion of firings requiring intervention and the 95% confidence interval will be estimated by the lower 0.025 and upper 0.975 percentiles of this sampling distribution.

The table below demonstrates 1 iteration of this bootstrap process.

Subject ID	Observed Data Vector	Bootstrap Sampled Vector	Bootstrap-Based Sample Proportion
1	(0, 0, 1, 0, 0)	(0, 1, 0, 1, 0)	0.40
2	(0, 0, 0)	(0, 0, 0)	0.0
3	(0, 1, 0, 0)	(1, 0, 0, 0)	0.25
4	(0, 0, 1, 0, 0)	(0, 0, 0, 0, 0)	0.0
5	(0, 0)	(0, 0)	0.0
...
...
50	(1, 0, 0, 1, 0)	(0, 1, 0, 0, 0)	0.20
Summary			Average of above proportions to get 1 observation in the sampling distribution of the proportion of firings requiring intervention.

The above re-sampling process will then be repeated a minimum of 5000 times to estimate the sampling distribution.

A secondary estimate of the proportion of firings requiring intervention will be provided under the assumption of independence of firings within a subject. This will be performed based on the total number of firings and the percentage will be calculated as the number of firings requiring an intervention divided by the total number of firings. The 95% confidence interval will be estimated using exact Binomial methods.

Additional summaries will be provided to tabulate the total number of vessels transected as well as the specific type of vessel that was transected – pulmonary artery or pulmonary vein. The specific types of interventions that were performed will also be tabulated.

The same analysis will be replicated for the primary safety endpoint for the occurrence of hemostatic interventions/procedures completed for post-operative bleeding related to the transection of the PA and PV during VATS lobectomy at the subject level. Here, the percentage will be calculated as the number of subjects requiring a post-operative intervention divided by the total number of subjects. The 95% confidence interval will be estimated using exact Binomial methods.

10.5 Plans for Interim Analysis

No interim analyses were planned or performed for this study.

10.6 Handling of Missing Data

All summaries will be performed only on subjects undergoing the VATS procedure 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.

10.7 Sensitivity Analyses

Analyses of the primary effectiveness and safety endpoints will be replicated on the Per Protocol Set to assess the primary results in the set of subjects with no major protocol violations. Exploratory analyses of the primary endpoint data will be performed where measurements within a subject are assumed to be correlated. Given the smaller sample size of this study, data from this protocol may be combined with data from Protocol ESC-15-001 to allow for a more robust analysis. Binomial models utilizing generalized estimating equations to account for repeated measures within a subject will be applied to the data to estimate whether correlation exists and to provide estimates for the rate of interventions as a sensitivity analysis to the primary results.

10.8 Subgroup Analysis

No subgroup analyses are planned for this study.

10.9 Assessment of Site Homogeneity

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

10.10 Additional Endpoint Analyses

Device usage details will be summarized with counts and percentages for subjects in whom the device was articulated during the surgical procedure. Similar summaries will also be provided for the surgeon satisfaction questionnaire and the surgeon device questionnaire.

Post-operative pain is assessed at Visit 3 and Visit 4. Subjects are asked to rate their pain on a scale ranging from 0 (no pain) to 10 (worst possible pain). Subjects will rate pain relating to three sites – trocar site, incisional site, and chest tube site. Summary statistics at each pain site will be provided at Visits 3 and 4, as well as the change from Visit 3 to Visit 4.

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.

The ASES Shoulder Assessment is a patient reported outcome designed to measure functional limitations and pain of the shoulder and has been adapted to this study to measure upper body functionality following VATS lobectomy. The assessment utilizes 10 questions that are answered with: unable to do = 0, very difficult to do = 1, somewhat difficult to do = 2, and not difficult = 3. Scores for each subject are obtained by summing the responses to the 10 questions and thus range from 0 to 30. Summary statistics will be provided for the ASES Shoulder Assessment at Visit 1 (prior to surgery), Visit 3 (after surgery, prior to discharge), and Visit 4 (approximately 4 weeks after surgery). Summary statistics will also be provided for the change from Visit 1 to Visit 3, and for the change from Visit 1 to Visit 4.

The total number of protocol deviations will be tabulated. Specific types of protocol deviations will also be summarized with counts and percentages. The number and percentage of subjects with at least one protocol deviation will also be summarized.

10.11 Safety Analyses

Safety will be assessed through the incidence of adverse events (AEs) and serious adverse events (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 Possibly, Related, or Unknown. The incidence of AEs will also be summarized by maximum severity. All reported adverse events will be listed.

Appendix: Table Shells and List of Listings to be Generated

Table shells are provided below for all summaries to be generated for this study. Additionally, a list of all listings to be created is provided corresponding to the eCRFs that were used during this study. All fields collected will be listed.

Table 1
Subject Disposition
All Subjects

	Total
Signed Informed Consent	xx
Safety Set	xx (xx.x%)
Full Analysis Set	xx (xx.x%)
Completed the Study	xx (xx.x%)
Discontinued from the Study	xx (xx.x%)
Reason for Discontinuation	
Withdrawal of consent	xx (xx.x%)
Surgical	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%)

Note: All percentages are based on the number of subjects in the Safety Set as the denominator.

Table 2
Subject Demographics
Full Analysis Set

Characteristics	Overall (N = ##)
Race	
White	xx (xx.x%)
Black or African American	xx (xx.x%)
American Indian or Alaska Native	xx (xx.x%)
Native Hawaiian or Other Pacific Islander	xx (xx.x%)
Asian	xx (xx.x%)
Other	xx (xx.x%)
Ethnicity	
Han	xx (xx.x%)
Other	xx (xx.x%)
Subject did not want to disclose	xx (xx.x%)
Age (years)	
n	xx
Mean	xx.x
Standard Deviation	x.xxx
Median	xx.x
Minimum, Maximum	xx.x, xx.x
Gender	
Male	xx (xx.x%)
Female	xx (xx.x%)

Table 3
Protocol Deviations
Safety 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.

Table 4
Surgical Characteristics
Full Analysis Set

Characteristics	Overall (N = ##)
Location of Affected Lobe	
Left Lung, Superior Lobe	xx (xx.x%)
Left Lung, Inferior Lobe	xx (xx.x%)
Left Lung, Multiple Lobes	xx (xx.x%)
Right Lung, Superior Lobe	xx (xx.x%)
Right Lung, Middle Lobe	xx (xx.x%)
Right Lung, Inferior Lobes	xx (xx.x%)
Right Lung, Multiple Lobes	xx (xx.x%)
Calcified Hilar Lymph Nodes Present?	
Yes	xx (xx.x%)
No	xx (xx.x%)
Number of Pulmonary Arteries Transected	
0	xx (xx.x%)
1	xx (xx.x%)
2	xx (xx.x%)
3	xx (xx.x%)
Number of Ports	
1	xx (xx.x%)
2	xx (xx.x%)
3	xx (xx.x%)
4	xx (xx.x%)
Number of Chest Tubes Placed Intraoperatively	
0	xx (xx.x%)
1	xx (xx.x%)
2	xx (xx.x%)
ASA Physical Status	
Class I	xx (xx.x%)
Class II	xx (xx.x%)
Class III	xx (xx.x%)

Table 4
Surgical Characteristics
Full Analysis Set

Characteristics	Overall (N = ##)
Estimated Blood Loss (mL)	
n	xx
Mean	xx.x
Standard Deviation	x.xxx
Median	xx.x
Minimum, Maximum	xx.x, xx.x
Transfusion of Blood or Blood Product Required?	
Yes	xx (xx.x%)
No	xx (xx.x%)
Procedure Converted to Open?	
Yes	xx (xx.x%)
No	xx (xx.x%)
Procedure Duration (min)	
n	xx
Mean	xx.x
Standard Deviation	x.xxx
Median	xx.x
Minimum, Maximum	xx.x, xx.x
Chest Tube Duration (nights)	
n	xx
Mean	xx.x
Standard Deviation	x.xxx
Median	xx.x
Minimum, Maximum	xx.x, xx.x

Programming Note: Chest tube duration is calculated from date of surgery to date of final chest tube removal

Table 5
Tumor Assessment – Pathology Lab
Full Analysis Set

Characteristics	Overall (N = ##)
Tumor Stage, Confirmed by Pathology	
Stage 0	xx (xx.x%)
Stage IA	xx (xx.x%)
Stage IB	xx (xx.x%)
Stage IIA	xx (xx.x%)
Stage IIB	xx (xx.x%)
Stage IIIA	xx (xx.x%)
Stage IIIB	xx (xx.x%)
Stage IV	xx (xx.x%)
Maximum Tumor Diameter (cm)	
n	xx
Mean	xx.x
Standard Deviation	x.xxx
Median	xx.x
Minimum, Maximum	xx.x, xx.x
Maximum Tumor Depth (cm)	
n	xx
Mean	xx.x
Standard Deviation	x.xxx
Median	xx.x
Minimum, Maximum	xx.x, xx.x
Primary Tumor TNM Classification	
TX	xx (xx.x%)
T0	xx (xx.x%)
Tix	xx (xx.x%)
T1	xx (xx.x%)
T1a	xx (xx.x%)
T1b	xx (xx.x%)
T2	xx (xx.x%)
T3	xx (xx.x%)
T4	xx (xx.x%)

Table 5
Tumor Assessment – Pathology Lab
Full Analysis Set

Characteristics	Overall (N = ##)
TNM Classification for Regional Lymph Node	
NX	xx (xx.x%)
N0	xx (xx.x%)
N1	xx (xx.x%)
N2	xx (xx.x%)
N3	xx (xx.x%)
Distant Metastasis Present?	
Yes	xx (xx.x%)
No	xx (xx.x%)
Tumor Confirmed by Pathology as Non-Small Cell Lung Cancer?	
Yes	xx (xx.x%)
No	xx (xx.x%)

Table 6
Intra-Operative Interventions on Pulmonary Artery or Pulmonary Vein
Full Analysis Set

Characteristics	Overall (N = ##)
Total Number of Vessels Transected	xxx
Pulmonary Artery	xxx
Pulmonary Vein	xxx
Bootstrap Based Summary Statistics	
Bootstrap Mean	xx.x%
95% Confidence Interval from Bootstrap Sampling Distribution	xx.x%, xx.x%
Number of Vessel Transections Requiring Intervention [1]	
n (%)	xx (xx.x%)
95% Confidence Interval for Percent	xx.x%, xx.x%
Type of Intervention, n (%) [2]	
Additional Stapling	xx (xx.x%)
Over-sewing	xx (xx.x%)
Compression	xx (xx.x%)
Use of Suture	xx (xx.x%)
Sealant	xx (xx.x%)
Buttress	xx (xx.x%)
Use of Energy	xx (xx.x%)
Clip Placement	xx (xx.x%)
Blood Product Transfusion	xx (xx.x%)
Additional Surgical Procedure	xx (xx.x%)
Other Intervention	xx (xx.x%)

[1] Denominator for calculation of percentage is the total number of vessels transected. Confidence interval based on exact Binomial method.

[2] Denominator for calculation of percentage is the total number of vessels requiring intervention.

Table 7
 Post-Operative Interventions or Procedures Related to Pulmonary Artery or Pulmonary Vein Bleeding
 Safety Set

Characteristics	Overall (N = ##)
Number of Subjects Requiring Post-Operative Intervention Related to Pulmonary Artery or Pulmonary Vein Bleeding	
n (%) [1]	xx (xx.x%)
95% Confidence Interval for Percent	xx.x%, xx.x%
Type of Intervention, n (%) [2]	
Blood Product Transfusion	xx (xx.x%)
Additional Surgical Procedure	xx (xx.x%)
Other Intervention	xx (xx.x%)

[1] Denominator for calculation of percentage is the total number of subjects in that group.

[2] Denominator for calculation of percentage is the total number of subjects requiring intervention in that group.

Table 8
Device Usage Details
Full Analysis Set

Characteristics	Overall (N = ##)
Number of Subjects Where Device Was Articulated	xxx
Did Articulation Make it Easier to Perform Surgery? [1]	
Yes	xx (xx.x%)
No	xx (xx.x%)
Was Articulation Essential to Performing the Surgery? [1]	
Yes	xx (xx.x%)
No	xx (xx.x%)
Was the Angle Range of the Device Sufficient? [1]	
Yes	xx (xx.x%)
No	xx (xx.x%)

1. Denominator used is the total number of subjects in whom the device was articulated.

Table 9
Surgery Task Load Index (SURG-TLX)
Full Analysis Set

Characteristic	Overall (N = ##)
Overall Score	
n	xx
Mean	xx.x
Standard Deviation	x.xxx
Median	xx.x
Minimum, Maximum	xx.x, xx.x
Mentally Fatiguing	
n	xx
Mean	xx.x
Standard Deviation	x.xxx
Median	xx.x
Minimum, Maximum	xx.x, xx.x
Physically Fatiguing	
n	xx
Mean	xx.x
Standard Deviation	x.xxx
Median	xx.x
Minimum, Maximum	xx.x, xx.x
Similar summaries for remaining components:	
Hurried/Rushed Pace	
Procedure Complexity	
Anxious While Performing Procedure	
Distracting Operating Environment	

Note: Each component is scored on a 0 to 100 scale with lower scores representing a 'Low' response and higher scores representing a 'High' response.

Table 10
 Surgeon Satisfaction Questionnaire
 Full Analysis Set

Characteristics	Overall (N = ##)
How Satisfied Were You With Device Usability?	
Very Unsatisfied	xx (xx.x%)
Unsatisfied	xx (xx.x%)
Neutral	xx (xx.x%)
Satisfied	xx (xx.x%)
Very Satisfied	xx (xx.x%)
Amount of Tissue Slippage	
No Tissue Slippage	xx (xx.x%)
Some Tissue Slippage	xx (xx.x%)
Extensive Tissue Slippage	xx (xx.x%)

Table 11
Post-Operative Pain Score
Full Analysis Set

Pain Component	Time Point Statistic	Overall (N = ##)
Trocar Pain	Visit 3	
	n	xx
	Mean	xx.x
	Standard Deviation	x.xxx
	Median	xx.x
	Minimum, Maximum	xx.x, xx.x
	Visit 4	
	n	xx
	Mean	xx.x
	Standard Deviation	x.xxx
	Median	xx.x
	Minimum, Maximum	xx.x, xx.x
	Change From Visit 3 to Visit 4	
	n	xx
	Mean	xx.x
	Standard Deviation	x.xxx
	Median	xx.x
	Minimum, Maximum	xx.x, xx.x
Same summary will be repeated for:		
Incisional Pain		
Chest Tube Pain		

Programming note: Change from Visit 3 to Visit 4 will be calculated as Visit 4 value minus Visit 3 value.

Note: For each pain component, the subject is asked to rate his or her pain today on a scale from 0 (no pain) to 10 (worst possible pain).

Table 12
Surgeon Device Questionnaire
Full Analysis Set

Question Response	Overall (N = ##)
The ECHELON FLEX Powered Vascular Stapler with Advanced Placement Tip enables easier placement of the device on vessels compared to your current standard of care device:	
Strongly Disagree	xx (xx.x%)
Slightly Disagree	xx (xx.x%)
Neutral	xx (xx.x%)
Agree	xx (xx.x%)
Strongly Agree	xx (xx.x%)
The ECHELON FLEX Powered Vascular Stapler with Advanced Placement Tip has the potential to reduce the amount of dissection required (otomy) around the vessel to place the stapler compared to your current standard of care device:	
Strongly Disagree	xx (xx.x%)
Slightly Disagree	xx (xx.x%)
Neutral	xx (xx.x%)
Agree	xx (xx.x%)
Strongly Agree	xx (xx.x%)
The ECHELON FLEX Powered Vascular Stapler with Advanced Placement Tip has the potential to reduce the surgeon stress during the most challenging step of the procedure, which is the pulmonary artery / pulmonary vein transection, compared to your current standard of care device:	
Strongly Disagree	xx (xx.x%)
Slightly Disagree	xx (xx.x%)
Neutral	xx (xx.x%)
Agree	xx (xx.x%)
Strongly Agree	xx (xx.x%)
The ECHELON FLEX Powered Vascular Stapler with Advanced Placement Tip allows for the precise control and placement of the end effector on the target vessel compared to your current standard of care device:	
Strongly Disagree	xx (xx.x%)
Slightly Disagree	xx (xx.x%)
Neutral	xx (xx.x%)
Agree	xx (xx.x%)
Strongly Agree	xx (xx.x%)

Table 13
ASES Shoulder Assessment
Full Analysis Set

Shoulder Side	Time Point Statistic	Overall (N = ##)
Right	Visit 1	
	n	xx
	Mean	xx.x
	Standard Deviation	x.xxx
	Median	xx.x
	Minimum, Maximum	xx.x, xx.x
	Visit 3	
	n	xx
	Mean	xx.x
	Standard Deviation	x.xxx
	Median	xx.x
	Minimum, Maximum	xx.x, xx.x
	Change From Visit 1 to Visit 3	
	n	xx
	Mean	xx.x
	Standard Deviation	x.xxx
	Median	xx.x
	Minimum, Maximum	xx.x, xx.x
	Visit 4	
	n	xx
	Mean	xx.x
	Standard Deviation	x.xxx
	Median	xx.x
	Minimum, Maximum	xx.x, xx.x
	Change From Visit 1 to Visit 4	
	n	xx
	Mean	xx.x
	Standard Deviation	x.xxx
	Median	xx.x
	Minimum, Maximum	xx.x, xx.x

Same summary will be repeated for: Left Side

Programming note: Change from Visit 1 to Visit 3 will be calculated as Visit 3 value minus Visit 1 value.

Table 14
Adverse Events by System Organ Class and Preferred Term
Safety 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 14:

Table 15	Serious Adverse Events by System Organ Class and Preferred Term Safety Set
Table 16	Adverse Events Related to the Study Device by System Organ Class and Preferred Term Safety Set
Table 17	Serious Adverse Events Related to the Study Device by System Organ Class and Preferred Term Safety Set
Table 18	Adverse Events Related to the Study Procedure by System Organ Class and Preferred Term Safety Set
Table 19	Serious Adverse Events Related to the Study Procedure by System Organ Class and Preferred Term Safety Set

Table 20
Adverse Events by System Organ Class, Preferred Term and Maximum Severity
Safety Set

System Organ Class	Preferred Term	Overall (N = ##)
Total		xx (xx.x%)
Mild		xx (xx.x%)
Moderate		xx (xx.x%)
Severe		xx (xx.x%)
System Organ Class 1		xx (xx.x%)
Mild		xx (xx.x%)
Moderate		xx (xx.x%)
Severe		xx (xx.x%)
	Preferred Term 1	xx (xx.x%)
	Mild	xx (xx.x%)
	Moderate	xx (xx.x%)
	Severe	xx (xx.x%)
	Preferred Term 2	xx (xx.x%)
	Mild	xx (xx.x%)
	Moderate	xx (xx.x%)
	Severe	xx (xx.x%)
System Organ Class 2		xx (xx.x%)
Mild		xx (xx.x%)
Moderate		xx (xx.x%)
Severe		xx (xx.x%)
	Preferred Term 1	xx (xx.x%)
	Mild	xx (xx.x%)
	Moderate	xx (xx.x%)
	Severe	xx (xx.x%)

The following listings will be generated for this study:

Listing 1	Inclusion/Exclusion Criteria All Subjects
Listing 2	Demographics All Subjects
Listing 3	Medical History All Subjects
Listing 4	Surgical History All Subjects
Listing 5	Inclusion/Exclusion at Surgery and ASA Status All Subjects
Listing 6	Procedure Details All Subjects
Listing 7	Procedure Time Duration All Subjects
Listing 8	Intra-Operative Interventions on Pulmonary Artery and Pulmonary Vein All Subjects
Listing 9	Bronchus and Parenchyma Transections All Subjects
Listing 10	Intra-Operative Interventions Not on Pulmonary Artery and Pulmonary Vein All Subjects
Listing 11	Device Usage Details All Subjects
Listing 12	Tumor Assessment Log All Subjects
Listing 13	Surgeon Device Questionnaire All Subjects
Listing 14	Surgery Task Load Index All Subjects
Listing 15	Surgeon Satisfaction Questionnaire All Subjects

Listing 16	Post-Operative Interventions on Pulmonary Artery and Pulmonary Vein All Subjects
Listing 17	Pain Score Assessment All Subjects
Listing 18	Chest Tube Details Log All Subjects
Listing 19	Adverse Events All Subjects
Listing 20	Concomitant Medications All Subjects
Listing 21	Concomitant Procedures/Interventions All Subjects
Listing 22	Protocol Deviations All Subjects
Listing 23	Completion/Withdrawal All Subjects
Listing 24	Study Visits All Subjects