Statistical Analysis Plan (SAP)

A Prospective, Single-Arm Multi-Center Study of the ENSEAL® X1 Curved Jaw Tissue Sealer and Generator G11 in Thoracic, Urologic, and Ear, Nose, and Throat (ENT) Procedures

Protocol Number: ENG_2020_04

Protocol Version: Amendment 2, July 28, 2021

SAP Revision: 1
SAP Revision Date: 22Sep2022

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Protocol Version: Amendment 2, July 28, 2021

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Revision History

Revision Number	Revision Date (DDMMMYYYY)	Reasons for Revision
0.1	26Aug2022	First draft
0.2	09Sep2022	Implemented internal comments
1.0	22Sep2022	First version

Table of Contents

1 Introduction

This is the Statistical Analysis Plan (SAP) for the final analysis of data collected under Protocol ENG_2020_04. This SAP describes in detail the statistical methodology and statistical analyses for this protocol.

1.1 **Study Objectives**

The primary objective of this study is to demonstrate the acceptable performance and safety of the ENSEAL X1 and GEN11 devices when used per the instructions for use (IFU).

1.2 **Study Design**

This prospective, single-arm, multi-center study will collect clinical data in a post-market setting by procedure group (thoracic, urologic, and ENT). Investigators will perform each procedure using the device in compliance with their standard surgical approach and the ENSEAL X1 and GEN11 IFUs. Subjects will be consented and screened anytime during a period of 8 weeks prior to the date of surgery. Subjects will be considered enrolled when the ENSEAL X1 device has been attempted to be used for a vessel transection during thoracic, urologic, or ENT procedures. All enrolled subjects will be followed post-operatively through discharge and again at 28 days (± 14 days) post-surgery; therefore, from the surgery date to study exit, the duration will be approximately 6 weeks.

A minimum of 105 subjects enrolled (maximum of 120 subjects enrolled) will be included in the study from up to 12 surgery centers globally with the following procedure targets:

- A minimum of 35 subjects enrolled to a maximum of 40 subjects enrolled for thoracic procedures (e.g., lung resections [branches, no pulmonary artery/pulmonary vein {PA/PV}]).
- A minimum of 35 subjects enrolled to a maximum of 40 subjects enrolled for urologic procedures (e.g., nephrectomy); and
- A minimum of 35 subjects enrolled to a maximum of 40 subjects enrolled for ENT procedures (e.g., thyroidectomy, tonsillectomy, parotidectomy, radical neck).

2 Treatment Assignment

This is a single-arm study where all enrolled subjects will have the ENSEAL X1 device utilized for transection of at least one vessel.

3 Randomization and Blinding Procedures

As this is a single-arm study, no randomization will occur, and no blinding procedures are required.

4 Interval Windows

Interval windows for the purpose of analysis in this study will not be defined outside of those already specified in the protocol for visit scheduling as the collection of data for the primary and secondary performance endpoints occurs intra-operatively. The final visit occurs 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 Schedule of Events specifies a window of 14 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.

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 all performance and safety endpoints will be performed on the set of subjects in whom the ENSEAL X1 device is utilized during the surgical procedure. This will be labeled the ENSEAL Analysis Set. This set of subjects will be identified by having at least one entry in the "Vessel Transected" eCRF or by having answered "Yes" to the question "Was ENSEAL X1 used for tissue cutting or dissection?" on the "ENSEAL X1 Usage" eCRF. The summary of all primary and secondary performance endpoints will be performed by procedure group (thoracic, urologic, and ENT) and on the entire pooled set of subjects. The safety endpoints will be summarized by procedure group and for the entire pooled set of subjects.

7 Sample Size Justification

A sample size of 105 to 120 treated subjects is planned for enrollment in this study. No formal hypothesis is being tested in this study; thus, the sample size was not statistically sized, but rather is considered sufficient for a descriptive summary of performance endpoints within each procedure group. It is expected that at least 1 vessel will be transected within each procedure, providing an expected minimum of at least 35 transections within each procedure group for a total of at least 105 transections.

From a safety perspective on the pooled analysis of 105 subjects and in consideration of rare AEs that may occur (e.g., bleeding requiring blood product transfusion), for an event that has an incidence rate of, for example, 2%, then in a sample of 105 subjects, the probability of observing at least 1 event is 88.0% under a binomial probability model. Thus, this sample size provides a high probability of observing an AE if they do occur and provides reasonable assurance to conclude that

the likelihood of such AEs is less than 3.5% if they do not occur based on the upper limit of an exact 95% confidence interval when 0 events out of 105 subjects are observed.

8 Analyses to be Conducted

8.1 General Conventions

Subject data will be summarized in tables and further details will be provided in listing. 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 total and counts for each category and their corresponding percentages.

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 table or 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 by procedure group (thoracic, urologic, and ENT) and in total using counts and percentages. The number and percentage of subjects in the ENSEAL Analysis Set who completed, screen failure 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, sex, childbearing potential, race, and ethnicity) and vital signs (height, weight, and body mass index) will be presented by procedure group and in total. Background information (primary indication, specific procedure performed, smoking history, and cancer history) will be summarized in a similar manner. Medical history will be summarized by Medical Dictionary for Regulatory Activities (MedDRA) system organ class and preferred term. Surgical characteristics including, at minimum, procedure duration, occurrence of vessel skeletonization, presence of inflamed tissue or calcified tissues/vessels, volume of estimated intra-operative blood loss, and use of ENSEAL X1 for tissue cutting or dissection will be summarized by procedure group and in total.

8.4 Primary and Secondary Endpoints and Associated Hypotheses

No formal hypotheses are specified for the primary and secondary endpoints of this study. The study endpoints are representative of endpoints that are currently reported in the available literature for similar energy devices, and this will allow for comparisons with the results from this study.

8.4.1 Primary Endpoint and Associated Hypotheses

No formal hypotheses are specified for the primary endpoint of this study.

The primary performance endpoint in this study is the number and percentage of vessels where hemostasis (≤ Grade 3) is achieved using the ENSEAL X1 device. The hemostasis grading scale is defined as:

- Grade 1: no bleeding at transection site;
- Grade 2: minor bleeding at transection site, no intervention needed;
- Grade 3: minor bleeding at transection site, mild intervention needed, use of compression, basic energy devices (monopolar and/or bipolar device), and/or touch-ups with ENSEAL X1.
- Grade 4: significant bleeding (e.g., pulsatile blood flow, venous pooling) requiring intervention such as extensive coagulation or use of additional hemostatic measures (e.g., hemoclips, staples, sutures, fibrin sealants, other advanced energy products).

The primary performance endpoint will be summarized at the vessel transection level as multiple vessel transections per subject are expected; that is, the denominator for the primary endpoint will be the total number of vessel transections and the numerator will be the number of vessel transections where hemostasis (≤ Grade 3) is achieved. An exact 95% confidence interval using the Clopper-Pearson method will be estimated. The statistics for the primary performance endpoint will be presented by procedure group and in total.

8.4.2 Secondary Endpoints and Associated Hypotheses

No formal hypotheses are specified for the secondary endpoints of this study.

Counts and percentages will be provided for the following secondary endpoints:

- Satisfaction scores in 5-point scale for the following tasks completed by the ENSEAL X1 device:
    - Adhesion removal or division
    - Lymphatics bundles division
    - Tissue bundles division
    - Tissue grasping
    - Tissue cutting
    - Tissue dissection

- Hemostasis grading scale (1-4) for all vessel transected
- Type, name, and number of additional hemostasis measures required to achieve hemostasis for Grade 4 vessel transections by:
    - Name of vessel transected
    - Number of additional hemostatic measure(s) used to obtain hemostasis
    - Type of additional hemostatic measure(s) used to obtain hemostasis

8.4.3 Additional Endpoints

Summary statistics will be provided for the following endpoints:

- Procedure duration
- Use of any other energy device (basic [monopolar and traditional bipolar], advanced bipolar, ultrasonic) in primary procedure (type, name, and number of device and reason for use)
- Surgeon questionnaire administered once per investigator
- Generator questionnaire after each procedure for each GEN11 used
- Surgical procedure conducted
- Hospital stay duration
- Name and number of vessels that were transected
- Surgeon determination of diameter size range (< 3 mm, 3 to 5 mm, and > 5 to 7 mm)
- Occurrence and location of cancer and occurrence of pre-surgical radiation/chemotherapy within 90 days prior to surgery
- Occurrence of vessel skeletonization
- Presence of inflamed tissue, calcified tissues/vessels, atherosclerotic tissue, fibrotic tissue, or presence of adhesions intraoperatively
- Volume of estimated intra-operative blood loss
- Occurrence of blood transfusion, total required units of blood, and time point of transfusion
- Type of additional mild interventions (use of compression, basic energy devices [monopolar and/or bipolar] and/or touch-ups with ENSEAL X1) required to achieve hemostasis for Grade 3 vessel transections including number of times when ENSEAL X1 touch-ups were used
- Protocol deviation classified as minor or major, rationale for deviation, type of protocol deviation, and outcome of protocol deviation in terms of subject's discontinuation of study

8.5 Safety Analyses

The primary safety endpoint in this study is the occurrence of device-related AEs. As per the study protocol, device-related AEs are those identified as having a relationship of possibly, probably, or causally. AEs unrelated to the study device are recorded as 'not related' on the CRF. Both device-related and procedure-related AEs reported during the study will be coded to MedDRA. All reported AEs will be summarized by MedDRA system organ class and preferred term by the entire pooled subjects. Separate summaries will be provided for device-related and procedure-related AEs. Serious AEs will be summarized in a similar manner. The safety endpoints will be summarized by procedure group and on the entire pooled set of subjects. All reported adverse events will be listed.

Listings will also be provided for blood transfusion details, concomitant procedures, and concomitant medications.

Safety endpoints are as follows:

- All AEs
- Serious AEs
- All AEs related to the study device
- Serious AEs related to the study device
- All AEs related to the study procedure
- Serious AEs related to the study procedure

8.6 Plans for Interim Analysis

No interim analyses are planned for this study.

8.7 Handling of Missing Data

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

8.8 Sensitivity Analyses

The analysis of the primary performance endpoint described above in Section 8.4.1 makes the assumption of independence of vessel transections within a subject in estimation of variance for the confidence interval calculation. If the percentage of subjects with two or more vessel transections exceeds 10% a sensitivity analysis will be performed to account for the potential dependence among vessel transections within a subject. The 95% confidence interval will be estimated using a bootstrap approach. If the percentage of subjects with two or more vessel transections is less than 10% the bias due to assuming independence is expected to be small, and no sensitivity analysis will be conducted.

Bootstrap process:

For each subject, the outcome of each activation will be represented by a vector of 1's (indicating a score of ≤ Grade 3 hemostasis) and 0's (indicating a score of Grade 4 hemostasis). This vector will be re-sampled with replacement to generate a bootstrap sampled vector of observations for each subject. Then, the proportion of observations scored as ≤ Grade 3 hemostasis for the bootstrap sample will be calculated. This process will then be repeated a minimum of 5000 times to generate a sampling distribution for the proportion of activations achieving ≤ Grade 3 hemostasis. The mean of this sampling distribution will be provided as the point estimate of the proportion of activations achieving ≤ Grade 3 hemostasis 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
1	(1, 1, 0, 1, 1)	(1, 0, 1, 0, 1)
2	(1, 1, 1)	(1, 1, 1)
3	(1, 0, 1, 1)	(0, 1, 1, 1)
4	(1, 1, 0, 1, 1)	(1, 1, 1, 1, 1)
5	(1, 1)	(1, 1)
…	…	…
…	…	…
N	(0, 1, 1, 0, 1)	(1, 0, 1, 1, 1)
Summary		Count the number of 1's/Total number of 1's and 0's

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

8.9 Subgroup Analysis

Subgroup analyses are planned to be performed for vessel transection variables collected through the vessel transected form, Grade 3 form, and Grade 4 form for the subjects who had medical history of treatment for cancer (yes or no) by procedure groups and all groups combined. Subjects who had a medical history of treatment for cancer is identified through the treatment history form and those who checked for "Neoadjuvant chemotherapy" or "Neoadjuvant radiation therapy" boxes. These analyses will be exploratory and summary statistics for the procedure-related parameters will be provided for each subgroup.

8.10 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 in this study. All fields collected will be listed.

Table 1
Subject Disposition
All Subjects

	Thoracic n (%)	Urologic n (%)	ENT n (%)	Total n (%)
Signed Informed Consent				xx
Screen Failure				xx
Preoperative/Preprocedural				xx
Intraoperative/Intraprocedural				xx
ENSEAL Analysis Set	xx	xx	xx	xx
Completed the Study	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Discontinued from the Study	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Reason for Discontinuation				
Adverse Event	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Death	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Lost to Follow-up	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Physician Decision	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Site or Study Termination	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Withdrawal by Subject	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)

All percentages are calculated using the number of subjects in the ENSEAL 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
ENSEAL Analysis Set

Characteristic	Thoracic (N = xx)	Urologic (N = xx)	ENT (N = xx)	Total (N = xx)
Age at Consent (yrs)				
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)
Gender, n (%)				
Male	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Female	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ethnicity, n (%)				
Hispanic or Latino	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Hispanic or Latino	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Reported	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Race, n (%)				
Race 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
……	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Childbearing Potential, if female, n (%)				
Of childbearing potential	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Permanently sterilized	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Postmenopausal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Height (cm)				
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)
Weight (kg)				
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)
Body Mass Index (kg/m^2)				
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.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)

Denominator and percentages are based on subjects with non-missing data. For child-bearing potential, denominator is number of females in each group.

Table 3
Medical History by System Organ Class and Preferred Term
ENSEAL Analysis Set

System Organ Class	Preferred Term	Thoracic n (%)	Urologic n (%)	ENT n (%)	Total n (%)
Total		xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
System Organ Class 1		xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Preferred Term 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Preferred Term 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
System Organ Class 2		xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Preferred Term 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
System Organ Class 3		xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Preferred Term 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Preferred Term 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
System Organ Class 4		xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Preferred Term 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Table 4.1
Background Information – Thoracic Procedure Group
ENSEAL Analysis Set

Characteristic	Thoracic n (%)
Primary Indication for the Procedure	
Lung resection (branches, no PA/PV)	xx (xx.x)
Other	xx (xx.x)
Specific Procedure Performed	
Lung carcinoma	xx (xx.x)
Emphysema	xx (xx.x)
Lung infection (TBC, aspergillosis, bacterial)	xx (xx.x)
Other	xx (xx.x)

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

Table 4.2
Background Information – Urologic Procedure Group
ENSEAL Analysis Set

Characteristic	Urologic n (%)
Primary Indication for the Procedure	
Partial Nephrectomy	xx (xx.x)
Nephrectomy	xx (xx.x)
Radical prostactectomy	xx (xx.x)
Cystectomy	xx (xx.x)
Adrenalectomy	xx (xx.x)
Other	xx (xx.x)
Specific Procedure Performed	
Partial Nephrectomy primary indication	
Benign disease suspicion	xx (xx.x)
Bilateral tumors	xx (xx.x)
Cystic nephroma	xx (xx.x)
Solitary kidney	xx (xx.x)
Complex cyst	xx (xx.x)
Von Hippel-Lindau disease	xx (xx.x)
Bourneville syndrome	xx (xx.x)
Angiomyolipoma	xx (xx.x)
Familial RCC	xx (xx.x)
Oncocytoma	xx (xx.x)
Graft kidney	xx (xx.x)
Lithiasis	xx (xx.x)
Arterial stenosis	xx (xx.x)
Borderline renal function	xx (xx.x)
Chronic pyelonephritis	xx (xx.x)
Hypertension/diabetes	xx (xx.x)
Nephrectomy primary indication	
Renal cancer	xx (xx.x)
Severe renal trauma	xx (xx.x)
Symptomatic hydronephrosis	xx (xx.x)
Chronic infection	xx (xx.x)
Polycystic kidney disease	xx (xx.x)
Shrunken kidney	xx (xx.x)
Hypertension	xx (xx.x)
Renal calculus	xx (xx.x)
Other	xx (xx.x)

Radical prostactectomy primary indication	
Prostate cancer	xx (xx.x)
Other	xx (xx.x)
Cystectomy primary indication	
Bladder cancer	xx (xx.x)
Other	xx (xx.x)
Adrenalectomy primary indication	
Malignancy suspicion or malignant tumors	xx (xx.x)
Non-functional tumors with the risk of malignancy	xx (xx.x)
Functional adrenal tumors	xx (xx.x)
Other	xx (xx.x)
Other indication	xx (xx.x)

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

Table 4.3
Background Information – ENT Procedure Group
ENSEAL Analysis Set

Characteristic	ENT n (%)
Primary Indication for the Procedure	
Thyroidectomy	xx (xx.x)
Tonsillectomy	xx (xx.x)
Parotidectomy	xx (xx.x)
Adenoidectomy	xx (xx.x)
Radical neck dissection	xx (xx.x)
Other	xx (xx.x)
Specific Procedure Performed	
Thyroidectomy primary indication	
Thyroid cancer	xx (xx.x)
Goiter	xx (xx.x)
Hyperthyroidism	xx (xx.x)
Indeterminate or suspicious thyroid nodules	xx (xx.x)
Other	xx (xx.x)
Tonsillectomy primary indication	
Adenotonsillar hyperplasia with obstructive sleep apnea, failure to thrive, or abnormal dentofacial growth	xx (xx.x)
Suspicion of malignant disease	xx (xx.x)
Hemorrhagic tonsillitis	xx (xx.x)
Adenotonsillar hyperplasia with upper airway obstruction, dysphagia, or speech impairment, and halitosis	xx (xx.x)
Recurrent or chronic pharyngotonsillitis	xx (xx.x)
Peritonsillar abscess	xx (xx.x)
Streptococcal carriage	xx (xx.x)
Other	xx (xx.x)
Parotidectomy primary indication	
Malignant tumors	xx (xx.x)
Benign tumors	xx (xx.x)
Inflammatory conditions (chronic parotitis, deep salivary calculi, or parotid abscess)	xx (xx.x)

Salivary duct stones	
Sialorrhea	xx (xx.x)
Other	xx (xx.x)
Radical neck dissection primary indication	
Head and neck cancer	xx (xx.x)
Other	xx (xx.x)
Adenoidectomy primary indication	
Adenotonsillar hyperplasia with obstructive sleep apnea, failure to thrive, or abnormal dentofacial growth	xx (xx.x)
Suspicion of malignant disease	xx (xx.x)
Adenotonsillar hyperplasia with upper airway obstruction, dysphagia, or speech impairment, and halitosis	xx (xx.x)
Otitis media	xx (xx.x)
Recurrent or chronic rhinosinusitis or adenoiditis	xx (xx.x)
Other	xx (xx.x)
Other indication	xx (xx.x)

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

Table 5
Additional Background Information
ENSEAL Analysis Set

Characteristic	Thoracic (n = xx)	Urologic (n = xx)	ENT (n = xx)	Total (n = xx)
Current Smoking Status, n (%)				
Current smoker	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Former smoker	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Never smoked	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Years Since Stopped Smoking				
n	xx	xx	xx	xx
Mean (SD)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Median (Min, Max)	xx.x (xx, xx)	xx.x (xx, xx)	xx.x (xx, xx)	xx.x (xx, xx)
ASA Score, n (%)				
Completely healthy fit	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Mild systemic disease	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Severe systemic disease not incapacitating	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Severe systemic disease that is a constant threat to life	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Moribund patient who is not expected to survive	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Table 6
Treatment History
ENSEAL Analysis Set

Characteristic	Thoracic n (%)	Urologic n (%)	ENT n (%)	Total n (%)
Is the Indication for the Subject's Surgery Due to a Cancer Diagnosis?				
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)
Type of treatment within 90 days prior to surgery[1]				
None	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Observation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Neoadjuvant chemotherapy	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Neoadjuvant radiation therapy	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

1 Cumulative percentage may exceed 100 as multiple responses are recorded
2 Denominator represents patients receiving neoadjuvant chemotherapy or neoadjuvant radiation therapy

Table 7
Intra-Operative and Post-Operative Information
ENSEAL Analysis Set

Characteristic	Thoracic n (%)	Urologic n (%)	ENT n (%)	Total n (%)
Occurrence of Vessel Skeletonization?				
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)
Was there prophylactic use of clips or sutures as standard of surgical care **before** vessel transection?				
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)
Presence of Inflamed Tissue or Calcified Tissues/Vessels				
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)
Presence of Calcified Tissues/Vessels				
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)
Presence of Atherosclerotic Tissue				
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)
Presence of Fibrotic Tissue				
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)
Presence of Adhesions				
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)
Was an Ethicon trocar used with ENSEAL X1 (if applicable)?				
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)
Surgical Approach				
Open	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Laparoscopic	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Conversion to Open				
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)
Was ENSEAL X1 Used for Tissue Cutting or Dissection?				
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)
Procedure Duration (hours)				
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)
Procedure Duration (hours)				
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)
Volume of Estimated Intra-operative Blood Loss (mL)				
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 8
ENSEAL X1 Usage
ENSEAL Analysis Set

Characteristic	Thoracic n (%)	Urologic n (%)	ENT n (%)	Total n (%)
Were adhesions removed or divided by ENSEAL X1?				
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)
Surgeon's satisfaction with the adhesion removal or division by ENSEAL X1?[1]				
Very dissatisfied	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)
Neither Satisfied or Dissatisfied	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Satisfied	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Very satisfied	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Were lymphatics bundles divided by ENSEAL X1?				
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)
Surgeon's satisfaction with the lymphatics bundles divide by ENSEAL X1?[1]				
Very dissatisfied	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)
Neither Satisfied or Dissatisfied	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Satisfied	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Very satisfied	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Were tissue bundles divided by ENSEAL X1				
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)
Surgeon's satisfaction with the tissue bundle divide by ENSEAL X1?[1]				
Very dissatisfied	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)
Neither Satisfied or Dissatisfied	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Satisfied	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Very satisfied	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Was the ENSEAL X1 used for tissue grasping?				

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)
Surgeon's satisfaction with the tissue grasping by ENSEAL X1?[1]				
Very dissatisfied	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)
Neither Satisfied or Dissatisfied	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Satisfied	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Very satisfied	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Was the ENSEAL X1 used for tissue cutting?				
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)
Surgeon's satisfaction with the tissue cutting by ENSEAL X1?[1]				
Very dissatisfied	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)
Neither Satisfied or Dissatisfied	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Satisfied	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Very satisfied	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Was the ENSEAL X1 used for tissue dissection?				
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)
Surgeon's satisfaction with the tissue dissection by ENSEAL X1?[1]				
Very dissatisfied	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)
Neither Satisfied or Dissatisfied	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Satisfied	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Very satisfied	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Was there use of any other energy device (monopolar, traditional bipolar, advanced bipolar, ultrasonic) during the primary procedure?				
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)
Type of any other energy device used				
None	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Monopolar	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Traditional bipolar	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Advanced bipolar	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Ultrasonic	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

[1] Denominator represents the corresponding usage of ENSEAL X1

Table 9
Vessel Transection Summary – Original Procedure
ENSEAL Analysis Set

Characteristic	Thoracic (n = xx)	Urologic (n = xx)	ENT (n = xx)	Total (n = xx)
Total Number of Vessels Transected	xx	xx	xx	xx
Hemostasis Grading Scale				
Grade 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Hemostasis Achieved (Grade 3 or lower)				
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
95% Confidence Interval (exact method)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
95% Confidence Interval (bootstrap method – sensitivity analysis)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
Surgeon determination of diameter size range				
< 3 mm	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3 to 5 mm	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
> 5 to 7 mm	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Was an image captured with the vessel in an open jaw of the ENSEAL X1 device perpendicular to the vessel?				
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)
Determination of vessel diameter size from image				
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)
Name of Vessel Transected				
Name 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Name 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Name 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…				
Grade 3 Vessels Using Compression [3]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Grade 3 Vessels Using Monopolar Touch-up [3]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Number of Touch-up of Grade 3 Vessels Using Monopolar Device [3]				
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)
Grade 3 Vessels Using Bipolar Touch-ups [3]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Number of Touch-up of Grade 3 Vessels Using Bipolar Device [3]				
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)
Grade 3 Vessels Using ENSEAL X1 Touch-up [3]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Number of ENSEAL X1 Touch-ups of Grade 3 Vessels [3]				
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)
Vessels transected as Grade 4 [4]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Name of Vessel Transected as Grade 4 [4]				
Name 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Name 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Name 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
…				
Number of Additional Hemostatic Measure Used to Obtain Hemostasis for Grade 4 Vessels [4]				
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)
Type of additional hemostatic measure(s) used to obtain hemostasis for Grade 4 Vessels [2]				
Hemoclips	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Staples	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Sutures	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Fibrin Sealants	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Adjunctive Topical Hemostats (except Fibrin Sealants)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other advanced energy products	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)

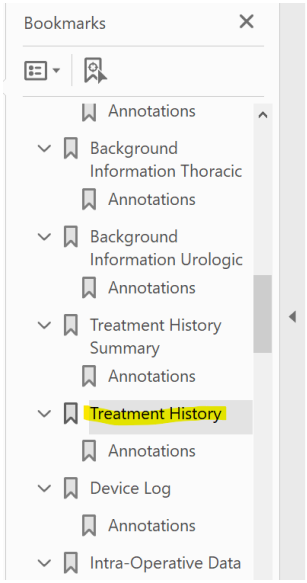
1 Denominator and percentages are based on number of vessels transected in each group.
2 Multiple responses are collected
3 The denominator is number of Grade 3 vessel transections
4 The denominator is number of Grade 4 vessel transections

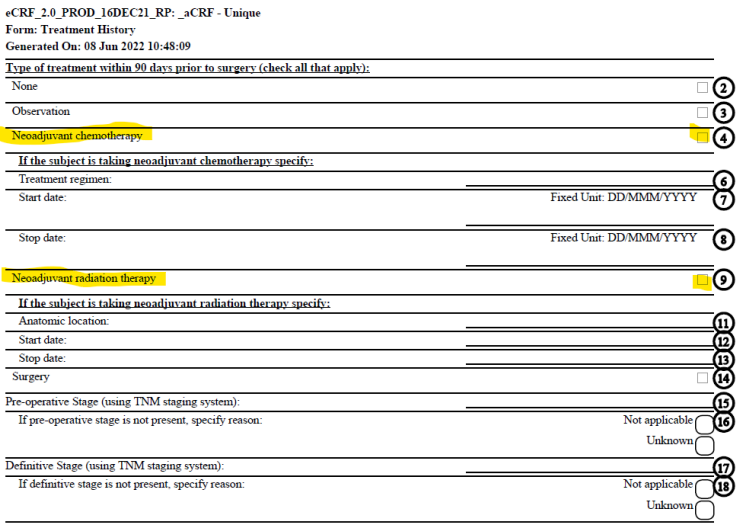
Programming notes:

1. *Only records indicated as "Original procedure" will be summarized in this table.*
2. *For number of vessels using touch up questions, the number presented will be the number of times "yes" is answered to the corresponding CRF question (VTMONO or VTENS); For summary statistics on number of touch-ups, the variables VTTUP and VTTUPS will be summarized*

The following tables will have the same format as Table 9:

Table 10.1	Vessel Transection Summary – Original Procedure ENSEAL Analysis Set Subjects With Medical History for Treatment of Cancer **Programming note:** Subgroup of subjects who had medical history of treatment for cancer is identified from "Treatment History Form" for patients who checked the "neoadjuvant chemotherapy" or "neoadjuvant radiation".



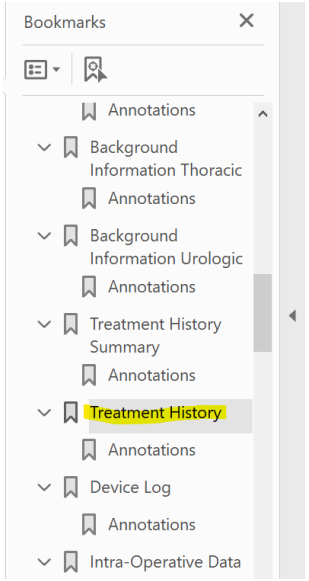


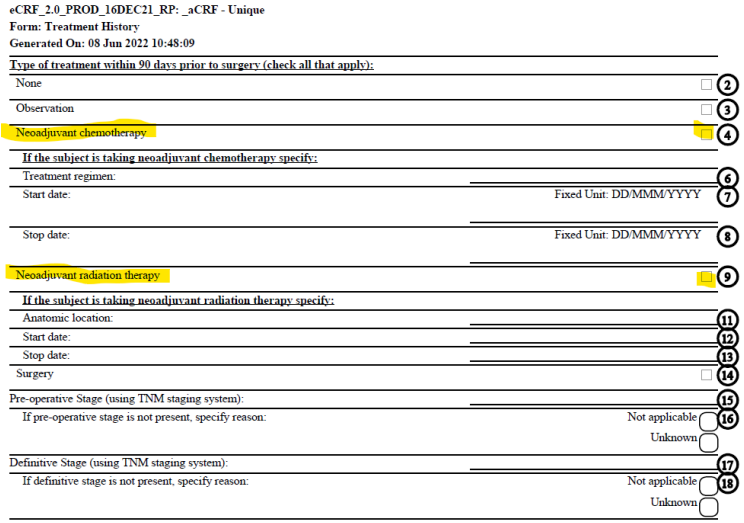
eCRF_2.0_PROD_16DEC21_RP: _aCRF - Unique
Form: Treatment History
Generated On: 08 Jun 2022 10:48:09

Type of treatment within 90 days prior to surgery (check all that apply):
None ☐ 2
Observation ☐ 3
Neoadjuvant chemotherapy ☐ 4
If the subject is taking neoadjuvant chemotherapy specify:
Treatment regimen: 6
Start date: Fixed Unit: DD/MMM/YYYY 7
Stop date: Fixed Unit: DD/MMM/YYYY 8
Neoadjuvant radiation therapy ☐ 9
If the subject is taking neoadjuvant radiation therapy specify:
Anatomic location: 11
Start date: 12
Stop date: 13
Surgery ☐ 14
Pre-operative Stage (using TNM staging system): 15
If pre-operative stage is not present, specify reason: Not applicable ☐ 16
Unknown ☐
Definitive Stage (using TNM staging system): 17
If definitive stage is not present, specify reason: Not applicable ☐ 18
Unknown ☐

The following tables will have the same format as Table 9:

Table 10.2	Vessel Transection Summary – Original Procedure ENSEAL Analysis Set Subjects Without Medical History for Treatment of Cancer **Programming note:** Subgroup of subjects who had medical history of treatment for cancer is identified from "Treatment History Form" for patients who checked the "neoadjuvant chemotherapy" or "neoadjuvant radiation". Subjects **without** Medical History for Treatment of Cancer is identified who did not change any of the boxes from "Treatment History Form" of the questions "neoadjuvant chemotherapy" and "neoadjuvant radiation".




eCRF_2.0_PROD_16DEC21_RP: _aCRF - Unique
Form: Treatment History
Generated On: 08 Jun 2022 10:48:09

Type of treatment within 90 days prior to surgery (check all that apply):
None 2
Observation 3
Neoadjuvant chemotherapy 4
If the subject is taking neoadjuvant chemotherapy specify:
Treatment regimen: 6
Start date: Fixed Unit: DD/MMM/YYYY 7
Stop date: Fixed Unit: DD/MMM/YYYY 8
Neoadjuvant radiation therapy 9
If the subject is taking neoadjuvant radiation therapy specify:
Anatomic location: 11
Start date: 12
Stop date: 13
Surgery 14
Pre-operative Stage (using TNM staging system): 15
If pre-operative stage is not present, specify reason: Not applicable 16
Unknown
Definitive Stage (using TNM staging system): 17
If definitive stage is not present, specify reason: Not applicable 18
Unknown

Table 11
Surgeon Questionnaire – ENSEAL X1
ENSEAL Analysis Set

Characteristic	Thoracic n (%)	Urologic n (%)	ENT n (%)	Total n (%)
Number of Questionnaires Completed	xx	xx	xx	xx
What advanced bipolar device(s) did you previously use (check all that apply)[1]				
None	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ENSEAL® Trio Tissue Sealers	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ENSEAL® Round Tip Tissue Sealer	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ENSEAL® G2 Curved and Straight Tissue Sealer	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ENSEAL® G2 Articulating Tissue Sealer	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ligasure Maryland	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ligasure Blunt Tip	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Thunderbeat	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)
I experienced less hand fatigue using the ENSEAL® X1 device compared to previous advanced bipolar device use				
Strongly disagree	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Slightly disagree	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)
Slightly agree	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Strongly agree	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
The cut and seal buttons were easily distinguishable on the ENSEAL® X1 device				
Strongly disagree	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Slightly disagree	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)
Slightly agree	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Strongly agree	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
The ENSEAL® X1 device reduced the need for instrument exchanges during surgery compared to previous advanced bipolar device use				
Strongly disagree	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Slightly disagree	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)
Slightly agree	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Strongly agree	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

The ENSEAL® X1 device was easier to use compared to previous advanced bipolar device use				
Strongly disagree	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Slightly disagree	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)
Slightly agree	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Strongly agree	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Overall, on the most critical tasks in the cases, the ENSEAL® X1 device performed better than my previous advanced bipolar device				
Strongly disagree	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Slightly disagree	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)
Slightly agree	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Strongly agree	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Percentages are calculated using the total number of questionnaires completed in each group as the denominator.
1 Multiple response are collected.

Table 12
Surgeon Questionnaire – Generator
ENSEAL Analysis Set

Characteristic	Thoracic n (%)	Urologic n (%)	ENT n (%)	Total n (%)
Software version used in the generator				
2013-1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2014-1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2016-1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2016-1.1	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)
What instrument was used with the generator?				
Study device (ENSEAL X1 Curved Jaw)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
HARMONIC instrument	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other ENSEAL instrument	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Were there any specific generator-related alarms generated?				
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)
Type of generator-related alarms generated (select all that apply)				
Reactivate	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Restart generator	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Press OK to continue	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Please contact your sales representative	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Generator overheating	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Software upgrade required to run instrument	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)
The generator performed as intended				
Strongly disagree	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Slightly disagree	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)
Slightly agree	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Strongly agree	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
The touchscreen allowed for easy set-up and operation				
Strongly disagree	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Slightly disagree	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)
Slightly agree	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Strongly agree	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

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

Programming note: If fewer than 10 surveys are completed in total, results will only be listed.

Table 13
Blood Transfusion Summary
ENSEAL Analysis Set

Characteristic	Thoracic (n = xx)	Urologic (n = xx)	ENT (n = xx)	Total (n = xx)
Blood Transfusion Required?, n (%)				
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)
Total required units of blood				
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)
Time Point of Transfusion, n (%)				
Intra-operatively	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Prior to discharge	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
After discharge	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Percentages for time point of transfusion are calculated using the number of subjects requiring a blood transfusion as the denominator.

Table 14
All Adverse Events by System Organ Class and Preferred Term
ENSEAL Analysis Set

System Organ Class	Preferred Term	Thoracic		Urologic		ENT		Total	
		Subject n (%)	Events	Subject n (%)	Events	Subject n (%)	Events	Subject n (%)	Events
Total Number of AE			xx		xx		xx		xx
Number of Subjects With at Least 1 AE		xx (xx.x)		xx (xx.x)		xx (xx.x)		xx (xx.x)	
System Organ Class 1	Total	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
	Preferred Term 1	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
	Preferred Term 2	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
	Preferred Term 3	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
System Organ Class 2	Total	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
	Preferred Term 1	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
	Preferred Term 2	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
System Organ Class 3	Total	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
	Preferred Term 1	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
	Preferred Term 2	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
	Preferred Term 3	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
System Organ Class 4	Total	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
	Preferred Term 1	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx
	Preferred Term 2	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx	xx (xx.x)	xx

If a subject has multiple occurrences of an AE, it is counted only once in the respective subject column for the corresponding AE. Percentages are calculated as (n/N)*100 where N represents total number of subjects in the column header.
If a subject has multiple occurrences of an AE, all events are counted in the respective event column for the corresponding AE.

The following tables will have the same format as Table 14:

Table 15	All Serious Adverse Events by System Organ Class and Preferred Term ENSEAL Analysis Set
Table 16	Adverse Events Related to the Study Device by System Organ Class and Preferred Term ENSEAL Analysis Set **Footnote:** Related AEs include those having a relationship of possibly, probably, or causally
Table 17	Serious Adverse Events Related to the Study Device by System Organ Class and Preferred Term ENSEAL Analysis Set **Footnote:** Related AEs include those having a relationship of possibly, probably, or causally
Table 18	Adverse Events Related to the Study Procedure by System Organ Class and Preferred Term ENSEAL Analysis Set **Footnote:** Related AEs include those having a relationship of possibly, probably, or causally
Table 19	Serious Adverse Events Related to the Study Procedure by System Organ Class and Preferred Term ENSEAL Analysis Set **Footnote:** Related AEs include those having a relationship of possibly, probably, or causally

Table 21
Protocol Deviations
ENSEAL Analysis Set

Characteristic	Thoracic n (%)	Urologic n (%)	ENT n (%)	Total n (%)
Total Number of Protocol Deviations	xxx	xxx	xxx	xxx
Specific Types of Protocol Deviations[1]				
AE/SAE Reporting	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Assessment Related	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Consent Related	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Inclusion/Exclusion Criteria	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Procedure Related	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Visit Related	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)
Did this deviation result in the subject's discontinuation of study?				
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)
Primary rationale for deviation				
To protect the subject's rights, safety, or well-being	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Site staff error	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subject physically unable to have / complete test	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Due to subject / physician unavailability	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subject refused	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)
Sponsor Assessment of Protocol Deviations[1]				
Minor	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Major	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Number (%) of Subjects With at Least 1 Protocol Deviation[2]	xx (xx.x)	xx (xx.x)	xx (xx.x)	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 listings will be generated for this study:

Listing 1	Inclusion/Exclusion Criteria All Subjects
Listing 2	Demographics All Subjects
Listing 3	Vital Signs All Subjects
Listing 4	Medical History All Subjects
Listing 5	Surgical History All Subjects
Listing 6	Background Information All Subjects
Listing 7.1	Background Information ENT All Subjects
Listing 7.2	Background Information Thoracic All Subjects
Listing 7.3	Background Information Urologic All Subjects
Listing 8	Treatment History All subjects
Listing 9	Intra-Operative Data All Subjects
Listing 10	ENSEAL X1 Usage All Subjects
Listing 11	Vessel Transected All Subjects
Listing 12	Prophylactic Clip/Suture Use All Subjects
Listing 13	Grade 3 Form

	All Subjects
Listing 14	Grade 4 Form All Subjects
Listing 15	Device Log All Subjects
Listing 16	X1 Curved Jaw Surgeon Questionnaire All Subjects
Listing 17	Generator Questionnaire All Subjects
Listing 18	Blood Transfusion Detail All Subjects
Listing 19	Discharge All Subjects
Listing 20	Subject Completion/Discontinuation All Subjects
Listing 21	Protocol Deviations All Subjects
Listing 22	Concomitant Procedures All Subjects
Listing 23	Prior Concomitant Medications All Subjects
Listing 24	Adverse Events All Subjects
Listing 25	Study Visits All Subjects

Signature Page for VTMF-17865130, V-TMF Version: 1.0
ENG_2020_04---Statistical Analysis Plan-28 Sep 2022

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Signature Meaning:
To verify that the content is accurate and true to the best of my knowledge.