A Prospective, Multicenter Investigation of the *da Vinci*® *SP*™ Surgical System in TORS Procedures for Resection of Malignant Tumors

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Study #	dV SP-TORS -#01/ G160251
Title	A prospective, multicenter investigation of the *da Vinci*® *SP*™ Surgical System in Transoral Robotic Surgery (TORS) procedures for malignant tumors
Study Design	A prospective, multicenter, single-arm clinical investigation
Study Enrollment and Follow-Up	Enrollment is anticipated to take approximately 8 months and subjects will be followed for 7 weeks post-operatively
Study Center(s)	Three institutions in the United States – see Appendix II for study centers and participating investigators
Number of Subjects	The study will enroll a maximum of 33 subjects. This includes 30 evaluable subjects and an assumed rate of 10% for subjects lost to follow-up.
Study Objective	To evaluate the safety and clinical performance of the *da Vinci SP* Surgical System, instruments, and accessories in TORS procedures for malignant oropharyngeal tumors classified as T1 and T2.
Study Endpoints	**Primary Endpoints:** • The primary performance endpoint is the conversion rate from *da Vinci SP* to an open approach required to complete the indicated procedure. • The primary safety endpoint is the incidence of device-related serious adverse events. **Secondary Endpoint:** • Rate of final positive surgical margins.
Subject Study Assessments	**Pre-operative Assessment**: Subject demographics, diagnostic tests to determine disease status and subject eligibility for TORS, pathology and dysphagia assessment by MD Anderson Dysphagia Inventory (MDADI) questionnaire **Intra-Operative Assessments**: Assessment of ability to complete surgical tasks and procedures (conversion to open approach), total operative time, robotic procedure time, estimated blood loss, incidence of blood transfusions, intra-operative adverse events, pathology report to assess surgical margins by immediate "frozen-section" technique **Post-Operative (prior to discharge) Assessment**: Length of hospital stay, CTCAE grading of hemorrhage, pathology to determine final surgical margins, adverse events, feeding tube dependency, return to oral diet, dysphagia assessment by MDADI questionnaire **Post-Operative (14 ± 2 days) Assessment:** Surgical margin status on final pathology report, adverse events, CTCAE grading of hemorrhage,

	feeding tube dependency (if administered), return to oral diet, dysphagia assessment by MDADI questionnaire **Post-Operative (7 weeks ±7 days) Assessment:** Adverse events, CTCAE grading of hemorrhage, return to oral diet, feeding tube dependency, any re-hospitalization since discharge, dysphagia assessment by MDADI questionnaire
Study Inclusion and Exclusion Criteria	**Inclusion Criteria:** • Subject is 18 years or older • Subject clinically diagnosed with malignant oropharyngeal tumor classified as T1 or T2 • Subject with an oropharyngeal tumor that is accessible and amenable to transoral resection • Subject without previous treatment for the index tumor (previous biopsy or excisional lymph node biopsy or neck dissection is allowed) • Subject is willing and able to provide written informed consent • Subject is willing and able to comply with the study protocol requirements **Exclusion Criteria** • Subject has been clinically diagnosed with T3 or T4 stage tumor • Subject has had previous radiation treatment to the head and neck, with or without chemotherapy • Subject with evidence of other primary cancers or distant metastasis or subject with synchronous primary tumor excluding skin cancers • Subject with pre-operative expectation of needing microvascular soft-tissue ("free-flap") reconstruction • Subject with a tumor that invades and/or abuts the internal and/or external carotid artery • Subject with a retropharyngeal carotid artery coincident with a tonsillar cancer or posterior pharyngeal wall cancer • Subject with evidence of mandibular invasion of tumor • Subject with Eastern Cooperative Oncology Group (ECOG) Performance Status score greater than or equal to 2 • Subject on a medication that interferes with clotting, including but not limited to Coumadin, Lovenox, or Plavix that cannot be stopped prior to surgery • Subject is contraindicated for general anesthesia or surgery • Subject is mentally handicapped or has a psychological disorder or severe systemic illness that would preclude compliance with study requirements or ability to provide informed consent

	• Subject is pregnant or suspected to be pregnant
Study Devices	*da Vinci SP* Surgical System & Instruments and Accessories
Data Management	Data management will be performed by Intuitive Surgical Inc. (Sponsor) or its appointed designee.
Statistical Considerations & Data Analysis	The recommended number of evaluable subjects in this confirmatory study (N=30) is not based on a formal sample size calculation. It is intended to provide a measure by which the performance and safety of the *da Vinci SP* Surgical System in a clinical setting can be confirmed based on demonstrating equivalence with the da Vinci Si Surgical System via animal and cadaver testing. All evaluable subjects will be included for analysis regardless of the completeness of their data. Analyses will be based on pre-operative characteristics, intra-operative and post-operative characteristics, and outcomes. Standard univariate and bivariate techniques, where applicable, will be used to describe the clinical results of the study. Continuous variables will be described as a mean, standard deviation, and 95% confidence interval (i.e., total operative time, length of hospital stay, estimated blood loss). Discrete variables will be described as a rate and a proportion of the total (i.e., conversions, complications). The data will be stratified by institution to understand the similarities and differences across patients and procedures. A comparison of the results among institutions as well as the overall results will be described. Where appropriate, the data will also be stratified by the representative procedures. Methods appropriate for analyzing data where the outcome is time until the occurrence of an event, such as the case for resumption of swallowing function, return to oral diet, and feeding tube dependency, will be utilized. The results of this study will be compared to the results of the previous clinical study for TORS (K090993). While formal statistical inference will not be made, the two studies will be compared on the basis of the 95% confidence intervals for each outcome of interest.