A Prospective, Multi-Center Investigation of the *da Vinci SP*® Surgical System in Pulmonary Lobectomy and Thymectomy for Benign and Malignant Disease

Protocol Summary

NCT05150210

Date: 8/15/2024

SPONSOR:
Intuitive Surgical, Inc.
1020 Kifer Road
Sunnyvale, CA 94086
Telephone: (408) 523-2100
Facsimile: (408) 523-1390

Study #	dV SP – Thoracic-01
Title	A prospective, multi-center investigation of the *da Vinci SP*® Surgical System in pulmonary lobectomy and thymectomy for benign and malignant disease
Study Design	A prospective, multi-center, single-arm clinical investigation
Study Center	Up to six institutions will be included in the United States.
Number of Subjects	Up to N=36. The study will enroll a minimum of 18 pulmonary lobectomy cases, and a minimum of 10 thymectomy cases will additionally be enrolled. The study will be conducted in a staged approach, starting with enrollment of 10 thymectomy cases in the first stage and followed by enrollment of lobectomy cases upon FDA approval to begin enrollment in the second stage.
Study Objective	To confirm the safety and performance of the *da Vinci SP* Surgical System, Instruments and Accessories in pulmonary lobectomy, and in thymectomy procedures
Premarket Study Endpoints	<u>Primary Performance:</u> • The primary performance endpoint will be assessed as the ability to complete the planned *da Vinci SP*-assisted thoracic procedure without conversion to an alternate approach. Conversion to an alternate approach comprises undocking of the *da Vinci SP* to complete the planned procedures using other methods, such as open, VATS, or multiport robotic (da Vinci Si or X/Xi) <u>Primary Safety:</u> • The primary safety endpoint will be assessed as the incidence of all intra-operative and post-operative adverse events that occur through the 30-day follow-up period <u>Primary Pathology (malignant cases only):</u> The primary pathologic endpoint will be assessed as the rate of complete resection (R0) at all surgical resection margins (for lung cancer: bronchial, parenchymal, vascular margins and for thymoma: pleural margins).

Pre-market Data Collection	➢ Pre-operative Assessment: demographics (age, gender, race, ethnicity), patient characteristics (e.g. BMI, ASA class, functional status- Zubrod score), and medical history (e.g. tobacco use, occupational exposure, steroid use, comorbidities such as hypertension, cardiopulmonary disease, diabetes, pulmonary arterial hypertension), standard imaging and lab tests, pulmonary function tests (FEV1% predicted, DLCO% predicted), neo-adjuvant therapy, prior cardiothoracic surgery, pre-operative tumor characteristics (tumor size, location, clinical tumor staging) ➢ Intra-operative Assessment: Operative time (wheels-in, wheels-out, robotic procedure time (docking time, console time), anesthesia time, primary procedure performed, secondary (concomitant) procedures performed, chest tube placement, estimated blood loss, blood transfusions, conversions, intraoperative adverse events ➢ Post-operative (to discharge) Assessment: Post-operative adverse events, in-hospital mortality, length of hospital stay (LOS), patient disposition immediately after surgery (ICU, intermediate care unit, ward), length of intermediate care unit stay, length of ICU stay, chest tube duration, reason for prolonged placement, if applicable, amount of daily chest tube drainage, discharge disposition (such as another health care facility, nursing care, home, etc.), unplanned procedure-related reoperations ➢ Post-operative (14 ± 3 days) Assessment: Unplanned procedure-related reoperations or readmissions, mortality, post-operative adverse events, chest tube duration, reason for prolonged placement, and total amount of chest tube drainage, if applicable, pathologic tumor staging, surgical margins, number of harvested lymph nodes, lymph node stations ➢ Post-operative (30 days ± 7 days) Assessment: Unplanned procedure-related reoperations or readmissions, mortality, post-operative adverse events, chest tube duration, reason for prolonged placement, and total amount of chest tube drainage, if applicable
Post-Market Assessment	Long-term data out to 5 years will be collected from study subjects that underwent lobectomy for primary lung cancer or thymectomy for thymoma. The post-market long term data collection will include information on long-term cancer outcomes such as local recurrence, disease free survival, overall survival, adverse events related to the index procedures, and any administered adjuvant therapy
Study Eligibility Criteria	**<u>General Inclusion Criteria:</u>** • Age >21 years • BMI ≤ 35 • ASA ≤ 3

	• Willing and able to provide a written informed consent. • Willing and able to comply with the study protocol requirements including follow-up examinations at 14 days and 30 days post-operatively, and post-market long term follow-up on an annual basis through 5 years **<u>Lobectomy Inclusion Criteria:</u>** • Clinical stage I or II primary lung cancer or other suspected lung malignancy; or benign lung disease requiring resection; primary tumor ≤ 5 cm diameter **<u>Thymectomy Inclusion Criteria:</u>** • Masaoka clinical stage I or II thymoma; or thymectomy for myasthenia gravis; thymic mass ≤ 5 cm diameter **<u>General Exclusion Criteria:</u>** • Clinical or radiological evidence of mediastinal or systemic metastatic disease • Life expectancy < 6 months • Subjects with a known bleeding or clotting disorder • Subjects actively receiving therapeutic-dose anticoagulation or anti-platelet medications at the time of operation • Uncontrolled systemic illness 6 months prior to planned surgical procedure including, but not limited to ongoing or active infection, symptomatic congestive heart failure, unstable angina pectoris, cardiac arrhythmia, or psychiatric illness/social situations that would limit compliance with study requirements • Previous chemotherapy, immunotherapy and/or radiation therapy for treatment of the cancer to be resected • Subject has a contraindication for general anesthesia or surgery • Subjects under active immunomodulatory or immunosuppressive regimen (e.g. transplant patient, high-dose steroid requirement) within 30 days prior to the planned surgical procedure. For myasthenia patients, if steroids are weaned down to prednisone ≤5 mg/day prior to day of surgery, the patient may be enrolled • Previous sternotomy • Subject belongs to vulnerable population • Subject is pregnant or suspected to be pregnant or breastfeeding

	<u>Lobectomy Exclusion Criteria:</u> • Tumor involving carina or any airway requiring sleeve resection, bronchoplasty • Tumor requiring resection of local structures (e.g. chest wall) or extended resection such as bilobectomy • History of pulmonary hypertension • Previous ipsilateral thoracic surgery or radiotherapy **<u>Thymectomy Exclusion Criteria:</u>** • Uncontrolled myasthenia gravis symptoms at the time of scheduled surgery • Tumor requiring resection of local structures (except pericardium) • Confirmed thymic carcinoma **<u>Intraoperative Exclusion Criteria:</u>** • Anatomy determined intra-operatively to be unsuitable for minimally invasive surgery
Study Devices	System: *da Vinci SP* Surgical System Instruments: The EndoWrist SP Instruments available include: a needle driver, medium-large clip applier, monopolar curved scissors, monopolar cautery instrument, fenestrated bipolar forceps, Maryland bipolar forceps, Cadiere forceps, round tooth retractor and the Camera Instrument. Accessories available: The SP Accessories include: Cannula, Obturator, Entry Guide Kit, Sheaths for Camera and Instruments, tips for Monopolar Curved Scissors, Cautery Hook and Cautery Spatula, Instrument Arm Drape and cautery cords, SP Access Port Kit (Small Incision) and SP Access Port Kit (Large Incision)
Sample Size Considerations	The planned number of subjects in this confirmatory study (N=36) comprises a minimum of eighteen (n=18) lobectomy cases based on the anticipated intra-operative and post-operative lobectomy adverse event rate from prior literature, and includes a minimum of 10 cases of thymectomy. 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 animal and cadaver testing.
Data Analysis	All 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 through 30 days of follow-up.

Study Enrollment & Follow Up	Enrollment is anticipated to take approximately 13 – 15 months. ***Premarket Assessment:*** Subjects will be followed postoperatively at 14 days (± 3 days) and at 30 days (± 7 days). ***Post market Assessment (for malignant patients only):*** Subjects will be followed on a semiannual basis for the first two years and annually afterwards out to 5 years (± 90 days) post-operatively following National Comprehensive Cancer Network (NCCN) guidelines.