da Vinci. LOBECTOMY



Solutions for minimally invasive thoracic surgery



The da Vinci Surgical System



Dual Console

Dual console capability allows an additional surgeon to provide an assist or can facilitate teaching and proctoring by connecting a second surgeon console.

- High-definition 3D vision
- EndoWrist® instrumentation
- Intuitive® motion

Surgeon Benefits

Represents the state-of-the-art approach for surgical removal of primary malignant, metastatic and benign lesions of the peripheral and central lung.

da Vinci lobectomy maintains the oncologic principles of open lobectomy while providing the benefits of a minimally invasive approach. da Vinci lobectomy enables precise anatomical resection, along with complete mediastinal lymph node dissection - the gold standard treatment for non-small cell lung cancer (nSCIC).

The unsurpassed visualization, precision, dexterity and control provided by the *da Vinci* Surgical System offers the following potential surgeon benefits:

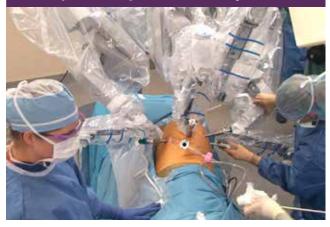
- Autonomous control of the camera and instruments
- ❖ Dynamic exposure and retraction of tissues by utilizing all da Vinci instrument arms, which furthermore increases reproducibility and teachability²
- ★ Complete and simple resection of all mediastinal (N2) and hilar (N1) lymph nodes in the aortopulmonary window, hilar, subcarinal and paratracheal area^{2,3}
- Low conversions and simplification of minimally invasive thoracic surgery³
- * Improved capability for performing complex pulmonary resection surgery on large tumors (7-9 cm) and as such, extending the benefits of minimally invasive surgery to a broad base of patients^{2,4}



Application Highlights

Four ways da Vinci technology facilitates a precise lobectomy:

Portal Technique Maintains Oncologic Principles of Open Lobectomy



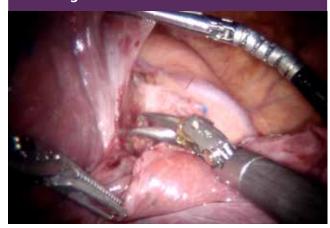
Using a posterolateral, single intercostal port placement and the unparalleled dexterity provided by *EndoWrist®* instrumentation enables access to and exposure of upper, mid and lower lobes during resection. A 15-mm assistant port is employed to enable effective ligation of vascular and bronchial structures as well as specimen retrieval (extended to 2-3 cm) at the conclusion of the surgery.

Comprehensive Lymph Node Dissection



3D HD vision and *EndoWrist* instrumentation enable complete capsular resection of mediastinal (N2) and hilar (N1) lymph nodes in the aortopulmonary window, hilar, subcarinal and paratracheal area.

Dynamic Exposure & Retraction of Tissues Utilizing all *da Vinci* Instrument Arms



4th arm assistance combined with new *EndoWrist* instrumentation designed specifically for pulmonary resection surgery facilitates manipulation of lung and tumor mass and enables an accurate dissection – limiting blood loss⁵ and enabling precise isolation of vascular and bronchial structures.

Superior Access without Utility Thoracotomy



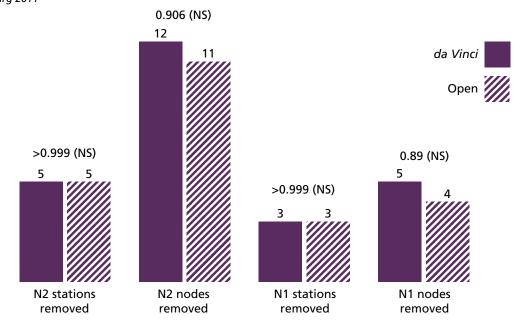
Patient-side assistance, including stapling vascular and bronchial structures, is primarily performed through a 15-mm assistant port in the 9th/10th interspace, with sufficient distance from all *da Vinci* instrument arms to limit internal and external interferences. Specimen retrieval is performed by extending the assistant port to a 2-3 cm incision without rib spreading.

Clinical Data

Retrospective Comparison of da Vinci Lobectomy versus Open Lobectomy

da Vinci surgery enables complete lymph node dissection

- Robotic surgery enables an equivalent lymph node dissection, compared to open
- Taken from Cerfolio, et al. Initial consecutive experience of completely portal roboticpulmontary resection with 4 arms. J Thorac Cardiovasc Surg 2011



da Vinci Lobectomy has shorter hospital stay and better quality of life than rib- and nervesparing thoracotomy.

Compared to open surgery, robotic lobectomy resulted in less blood loss, shorter hospital stay, and shorter chest tube duration. *J Thorac Cardiovasc Surg 2011*

	da Vinci	Open	P value
Est. blood loss	30+/-26	90+/-22	0.03
Verbal pain score	2.5 (0-7)	4.4 (0-8)	.04
Hospital stay	2	4	0.01
Chest tube duration	1.5	3.0	< 0.001
Morbidity (no.)	28 (27%)	120 (38%)	.05
Operative mortality (no.)	0	11(3%)	.11

Limitations of this study include, but are not limited to:

- Single institution
- Procedure underwent modifications during first 20 operations
- Potential for patient bias regarding pain scores and QOL surveys



Potential Patient Benefits & Risks

POSSIBLE BENEFITS COMPARED TO OPEN SURGERY:

- ★ Reduced pain due to a port-only approach

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- Less blood loss⁵
- ★ Shorter length of stay⁵
- Reduced chest tube duration⁷
- ★ Low risk of wound infections⁶
- ★ Shorter length of stay⁵
- **※** Low conversion rate³

POSSIBLE RISKS INCLUDE:

- Abnormal heartbeat following surgery
- Bronchopleural fistula (abnormal passageway develops between lung airways and the membranes that line the lungs)
- Blood loss requiring transfusion⁸



EndoWrist® Instruments Optimized for da Vinci® Lobectomy



STANDARD/S,Si PNs

FEATURES

5 mm Thoracic Grasper NA/420343

- * Ring profile grip
- × Blunt tip



STANDARD/S,Si PNs

FEATURES

Cadiere Forceps 400049/420049 ★ Short fenestrated jaw



8 mm Curved Bipolar Dissector NA/420344 ※ Curved dissecting tip



Permanent Cautery Spatula 400184/420184 Lymph node dissection



Maryland Bipolar Forceps 400172/420172 Dissecting jaw profile



Stapler Cannula Kit NA/420295

- Integrated 8 mm Cannula Reducer
- da Vinci System-guided instrument trajectory



Fenestrated Bipolar Forceps 400205/ 420205

- Bipolar energy device
- Fenestrated wide jaw profile



INTUITIVE SURGICAL®

Taking Surgery Beyond the Limits of the Human Hand.™

The friable nature of pulmonary tissue enhances the risk of patient injury when using this device. Published clinical experience as well as clinical studies performed to support this marketing clearance have demonstrated that even surgeons considered expert in laparoscopy/thoracoscopy have learning curves of 10 to 12 cases ((Falk, et al., Total endoscopic computer enhanced coronary artery bypass grafting, Eur J Cardiothorac Surg 2000; 17: 38-45.)).

All surgeries carry risks of adverse outcomes. Results, including cosmetic results, may vary. Serious complications may occur with da Vinci Surgery, up to and including death. Contraindications applicable to the use of conventional endoscopic instruments also apply to the use of all da Vinci instruments, including Single-Site Instrumentation. General contraindications for endoscopic surgery include bleeding diathesis, morbid obesity and pregnancy. Be sure to read and understand all information, particularly caution and warning information, found in the applicable user manuals before using these products. Failure to properly follow all instructions, including those in the da Vinci Si Surgical System user manual, and instructions supplied with accessory devices like generators, may lead to injury and result in improper functioning of the device. Unless otherwise noted, products featured are cleared for commercial distribution in the U.S. and bear the CE mark. For availability and clearances outside the US, please check with your local representative or distributor. For complete technical and labeling information, including indications, contraindications, warnings, precautions and safety information, please refer to the documentation provided with the da Vinci® System and its instruments and accessories.

While clinical studies support the use of the da Vinci Surgical System as an effective tool for minimally invasive surgery, individual results may vary. Before performing any clinical procedure utilizing the System, physicians are responsible for receiving sufficient training and proctoring to ensure that they have the requisite training, skill, and experience necessary to protect the health and safety of the patient. For technical information, including full cautions and warnings on using the da Vinci System, please refer to the System User Manual. Read all instructions carefully. Failure to properly follow instructions, notes, cautions, warnings, and danger messages associated with this equipment may lead to serious injury or complications for the patient. All people depicted unless otherwise noted are models.

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1Submissions for da Vinci System 510Ks, on file with Intuitive Surgical. 2Cerfolio RJ, Bryant AS, Skylizard L, Minnich DJ. Results of, and technical advancements to, completely portal robotic pulmonary resection using 4 arms (CPRL-4). Submitted to JTCVS April 2011. 3 Kernstine KH, Anderson CA, Falabella A. Robotic lobectomy. Operative techniques in thoracic and cardiovascular surgery, 2008:204.e1- 204.e23. Dylewski MR, Ohaeto AC, Pereira JF: Pulmonary resection using a total endoscopic robotic video-assisted approach. Seminars in Thoracic and Cardiovascular Surgery, 2011. In-press. SVeronesi G, Galetta D, Maisonneuve P, Melfi F, Schmid RA, Borri A, Vannucci F, Spaggiari L. Four-arm robotic lobectomy for the treatment of early-stage lung cancer. J Thorac Cardiovasc Surg, 2010;140(1):19-25. eSrivastava S, Gadasalli S, Agusala M, Kolluru R, Naidu J, Shroff M, Barrera R, Quismundo S, Srivastava V. Use of bilateral internal thoracic arteries in CABG through lateral thoracotomy with robotic assistance in 150 patients. Ann Thorac Surg, 2006 March;81(3):800-6; discussion 806. Perfolio RJ, Bryant AS, Skylizard L, Minnich DJ. Initial consecutive experience of completely portal robotic pulmonary resection with 4 arms. J Thorac Cardiovasc Surg. 2011 Oct;142(4):740-6. doi: 10.1016/j.jtcvs.2011.07.022. Epub 2011 Aug 15.