

Da Vinci Si® and da Vinci Xi® Surgical Systems

Thoracic Basic Plus Technology and Surgeon-led Procedure Training TR200.THOR.Si

2 Days at a da Vinci® Training Center

Day One

7:00am

Arrival at Training Center

- Arrive in scrubs or change into scrubs

7:00 – 7:15am

Welcome

- Introductions
- Program Overview
- Objectives
- Offsite da Vinci System Technology Training Waiver/Release

7:15 – 9:00am

da Vinci System Skills Assessment – Inanimate Skills & Simulation

9:00 – 11:00am

da Vinci System Technology Skills Protocol – Wet Lab

11:00 – 11:30am

Lunch – Provided by Intuitive

11:30am – 3:00pm

da Vinci System Skills Protocol – Wet Lab, continued

3:00 pm

Adjourn

Day Two

7:00am

Arrival at Training Center

- Arrive in scrubs or change into scrubs
- Breakfast – Provided by Intuitive

7:00 – 7:30am

Welcome

Da Vinci Si® and da Vinci Xi® Surgical Systems

7:30 – 8:30am	<p>Classroom: Introduction</p> <ul style="list-style-type: none"> • Outline the Day • Define Objectives • Presentation
8:30 – 8:45am	<p>Transition to Lab</p>
8:45 – 11:15am	<p>Laboratory: Session I – Lobectomy Position (left) – Wedge Resection (3 arms)</p> <ul style="list-style-type: none"> • Pre-Session (at bedside) <ul style="list-style-type: none"> ○ Port placement ○ Instrumentation ○ 3rd party staplers ○ Appropriate cases • Cadaver Training <ul style="list-style-type: none"> ○ Wedge resection (3 arms): 45 minutes ○ 3rd party stapler use ○ Specimen extraction <p>Laboratory: Session II – Thoracic Procedural Skills (4 arms)</p> <ul style="list-style-type: none"> • Cadaver Training (continued) <ul style="list-style-type: none"> ○ Skill focus: <ul style="list-style-type: none"> ▪ Inferior anatomic access ▪ Inferior pulmonary ligament mobilization ▪ Lymph node identification and dissection (level 8 & 9) ▪ Lung movement/passive and active retraction ▪ Posterior pleural dissection & level 7 nodes ▪ Superior hilar pleural dissection & level 5/6 nodes ▪ Lymph node extraction ▪ Coordination with bedside assistant ▪ Retrieval of inferiorly placed object ▪ Blunt, monopolar and bipolar dissection ▪ Vascular dissection/stapling ▪ Fissure examination & dissection • Post-Session Debrief <ul style="list-style-type: none"> ○ Q & A
11:15 – 11:45am	<p>Lunch – Provided by Intuitive (informal Q & A)</p>
11:45am – 12:00pm	<p>Program Development Presentation</p> <ul style="list-style-type: none"> • Level 1 cases • Training pathway tips • Anterior mediastinal introduction
12:00 – 12:10pm	<p>Transition to lab</p>

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12:10 – 1:45pm	<p>Laboratory: Session III – Mediastinal Position (Right)</p> <ul style="list-style-type: none"> • Pre-Session (at bedside) <ul style="list-style-type: none"> ○ Port placement ○ Instrumentation ○ Anatomic considerations ○ Appropriate cases • Cadaver Training <ul style="list-style-type: none"> ○ Thymectomy ○ Pericardial window ○ Specimen extraction • Post-Session Debrief <ul style="list-style-type: none"> ○ Cannula differences between procedures ○ Energy differences related to anatomy (phrenic) ○ Choice of sides for mediastinal lesions ○ Q & A
1:45 – 2:15pm	<p>Individual Group Evaluations (conducted as groups finish)</p> <ul style="list-style-type: none"> • Level 1 cases • Training pathway suggestions • What we saw
2:15 – 2:30pm	<p>Wrap up</p>

Indications for Use for the da Vinci Si Surgical System

The Intuitive Surgical® Endoscopic Instrument Control Systems (da Vinci Si Surgical System Model IS3000) is intended to assist in the accurate control of Intuitive Surgical EndoWrist® Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, ultrasonic/harmonic shears, forceps/pick-ups, needle holders, endoscopic retractors, stabilizers, electrocautery and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery, suturing, delivery and placement of microwave and cryogenic ablation probes and accessories, during urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, transoral otolaryngology surgical procedures restricted to benign and malignant tumors classified as T1 and T2 and for benign base of tongue resection procedures, general thoracoscopic surgical procedures, and thoracoscopically assisted cardiomy procedures. The system can be employed with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization. The system is indicated for adult and pediatric use except for transoral otolaryngology surgical procedures. It is intended for use by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Professional Instructions for Use. The safety and effectiveness of this device for use in the treatment of obstructive sleep apnea have not been established.

Indications for Use for the da Vinci Xi Surgical System

The Intuitive Surgical Endoscopic Instrument Control System (da Vinci Surgical System, Model IS4000) is intended to assist in the accurate control of Intuitive Surgical Endoscopic Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, forceps/pick-ups, needle holders, endoscopic retractors, electrocautery and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery, suturing, and delivery and placement of microwave and cryogenic ablation probes and accessories, during urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, general thoracoscopic surgical procedures and thoracoscopically assisted cardiomy procedures.

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The system can also be employed with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization. The system is indicated for adult and pediatric use. It is intended to be used by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Professional Instructions for Use.

Precaution for Representative Uses

The demonstration of safety and effectiveness for the representative specific procedures was based on evaluation of the device as a surgical tool and did not include evaluation of outcomes related to the treatment of cancer (overall survival, disease-free survival, local recurrence) or treatment of the patient's underlying disease/condition. Device usage in all surgical procedures should be guided by the clinical judgment of an adequately trained surgeon

Important Safety Information

Serious complications may occur in any surgery, including da Vinci® Surgery, up to and including death. Examples of serious or life-threatening complications, which may require prolonged and/or unexpected hospitalization and/or reoperation, include but are not limited to, one or more of the following: injury to tissues/organs, bleeding, infection and internal scarring that can cause long-lasting dysfunction/pain. Individual surgical results may vary.

Risks specific to minimally invasive surgery, including da Vinci Surgery, include but are not limited to, one or more of the following: temporary pain/nerve injury associated with positioning; a longer operative time, the need to convert to an open approach, or the need for additional or larger incision sites. Converting the procedure could result in a longer operative time, a longer time under anesthesia, and could lead to increased complications. Contraindications applicable to the use of conventional endoscopic instruments also apply to the use of all da Vinci instruments. You should discuss your surgical experience and review these and all risks with your patients, including the potential for human error and equipment failure. Physicians should review all available information. Clinical studies are available through the National Library of Medicine at www.ncbi.nlm.nih.gov/pubmed.

Be sure to read and understand all information in the applicable user manuals, including full cautions and warnings, before using da Vinci products. Failure to properly follow all instructions may lead to injury and result in improper functioning of the device. Training provided by Intuitive Surgical is limited to the use of its products and does not replace the necessary medical training and experience required to perform surgery. Procedure descriptions are developed with, reviewed and approved by independent surgeons. Other surgical techniques may be documented in publications available at the National Library of Medicine. For Important Safety Information, indications for use, risks, full cautions and warnings, please also refer to www.davincisurgery.com/safety and www.intuitivesurgical.com. Unless otherwise noted, products featured are available for commercial distribution in the U.S. For availability outside the US, please check with your local representative or distributor.

Should meals, transportation, or any other transfer of value be provided by Intuitive Surgical during this course, Intuitive Surgical will comply with the disclosure requirements under the Physician Payment Sunshine Act. In accordance with state law, Intuitive is unable to provide Vermont-licensed physicians a meal at Intuitive-sponsored events.