QUANTIFYING THE IMPACT

Clinical Economics References from Thoracic Leading Surgeons

From a hospital perspective, clinical benefits may result in the potential cost reductions noted below; however, these clinical benefits and costs may vary per hospital and be higher or lower than mentioned during this presentation.

Cost estimates seen here have been independently generated by Intuitive Surgical, Inc. using cost modeling methodology based on national averages and have not been published or peer-reviewed. Cost calculations include intraoperative instrument and accessory costs. Costs related to *da Vinci*® System acquisition, yearly service costs and other intraoperative and post-operative hospital costs are not included/considered.

In order to provide benefit and risk information, Intuitive Surgical reviews the highest available level of evidence on representative *da Vinci* procedures. Intuitive Surgical strives to provide a complete, fair and balanced view of the clinical literature. However, a quoted article may not be reflective of the broader literature and our materials should not be seen as a substitute for a comprehensive literature review for inclusion of all potential outcomes. We encourage patients and physicians to review the original publications and all available literature in order to make an informed decision. Clinical studies are available at pubmed.gov.

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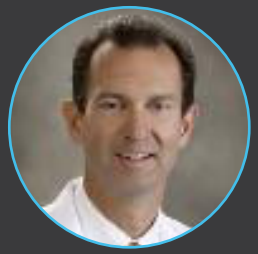
Thoracic Surgery



Robert Douglas Adams, MD, FACS
Owensboro Medical Health System
Owensboro, KY
Featured Procedure:
Lobectomy

Jeffrey A. Hagen, MD, FACS
Keck School of Medicine (USC)
Los Angeles, CA
Featured Procedure:
Lobectomy

G. Kimble Jett, MD
The Heart Hospital Baylor Plano
Plano, TX
Featured Procedure:
Lobectomy

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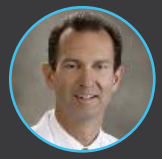
Surgeon Profile



Robert Douglas Adams, MD, FACS
Owensboro Medical Health System
Owensboro, KY

***da Vinci*® System Training:**
2009

Hospital:
Owensboro Medical Health System

Residency:
North Carolina Baptist Hospital (General)
Rush-Presbyterian St. Luke's Medical Center (Thoracic)

Memberships:
American College of Surgeons (ACS)
American Association for Thoracic Surgery (AATS)
Society of Thoracic Surgeons (STS)

Estimated MIS Procedure Volume

15%
Before *da Vinci*® Training

95%
After *da Vinci*® Training

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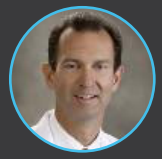
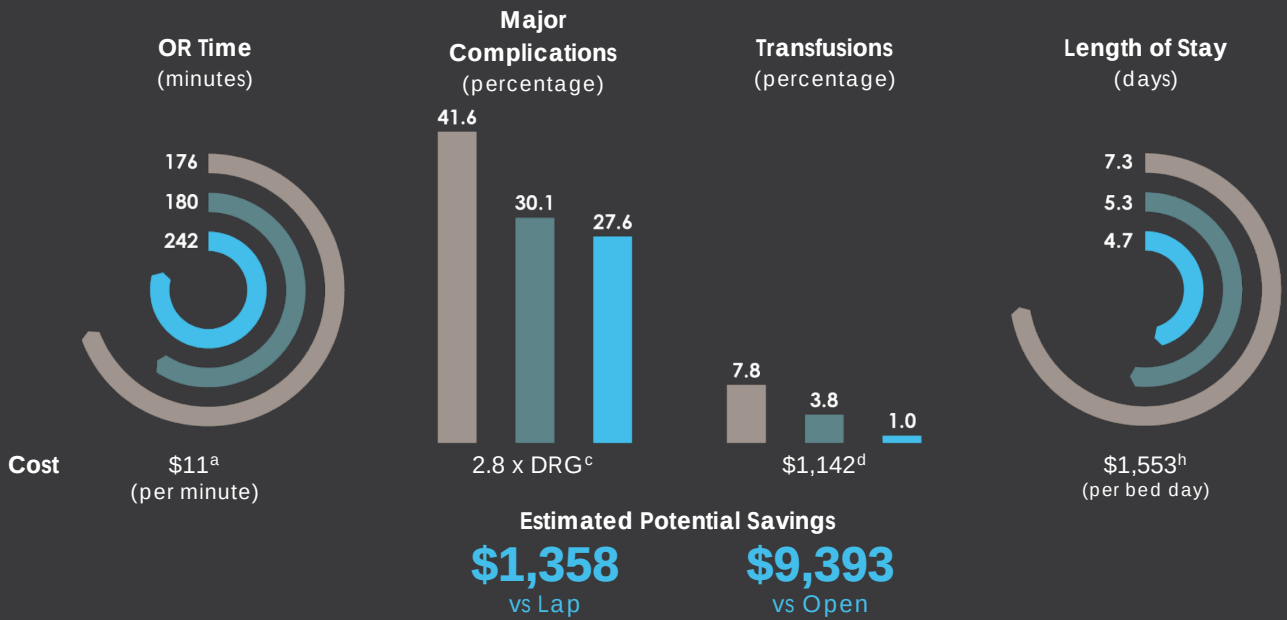
Clinical Outcomes and Potential Cost Savings

Lobectomy



Robert Douglas Adams, MD, FACS
Owensboro Medical Health System
Owensboro, KY

DA VINCI (n=120[1])
VATS (n=4,612[1])
OPEN (n=5,913[1])



Estimated Potential Savings

$1,358 vs Lap

$9,393 vs Open

Data presented for robotic-assisted surgery reflect a single surgeon experience that may or may not be reproducible and is not generalizable. This data comparison is not case-matched for patient complexity and/or disease status and may not be comparable across these surgical modalities. As such, this data presentation should be considered as informational only and is not conclusive. Cost estimates have been independently generated by Intuitive Surgical, Inc. using cost modeling methodology based on national averages and have not been published or peer-reviewed. Costs related to *da Vinci* System acquisition, yearly service costs and other intraoperative and post-operative hospital costs are not included/considered.

Readmissions are not shown separately since readmission surrogates (i.e., unexpected return to OR and unexpected return to ICU) per STS are shown as parts of major complications.

1. Adams RD, et al. Initial Multicenter Community Robotic Lobectomy Experience: Comparisons to a National Database. Ann Thorac Surg 2014 June;97:1893-900. doi: 10.1016/j.athoracsur.2014.02.043.

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Surgeon Profile

Jeffrey A. Hagen, MD, FACS
Keck School of Medicine (USC)
Los Angeles, CA

***da Vinci*® System Training:**
2011

Hospital:
Keck Hospital of the University of Southern California

Residency:
Creighton University (General)
Washington University (Thoracic)

Memberships:
American College of Surgeons (ACS)
Society of Thoracic Surgeons (STS)
Society of American Gastrointestinal and Esophageal Surgeons (SAGES)

Estimated MIS Procedure Volume

10%
Before *da Vinci*® Training

100%
After *da Vinci*® Training

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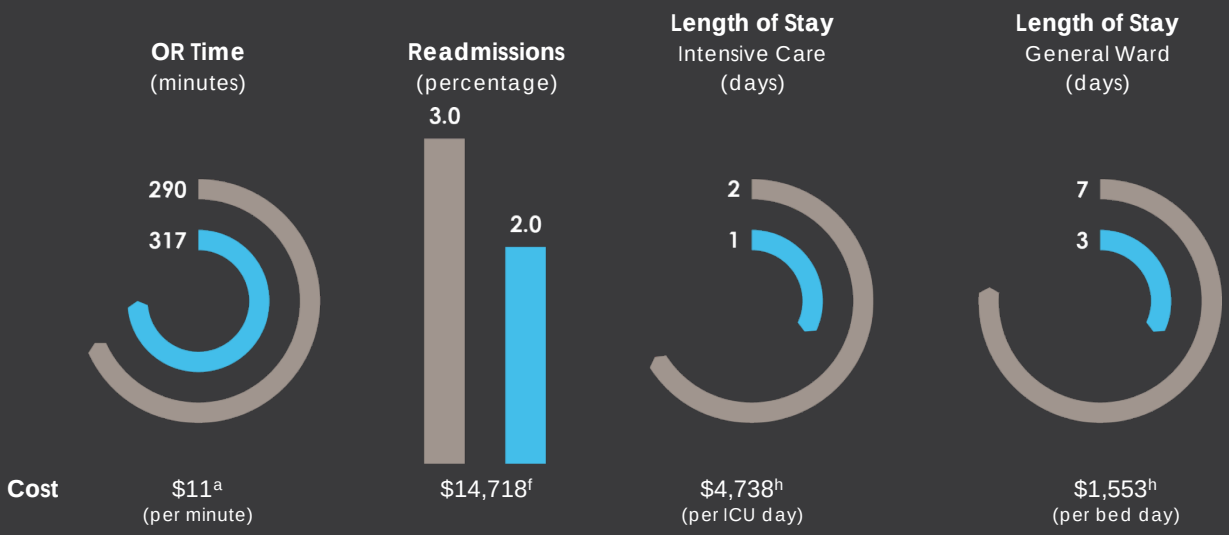
Clinical Outcomes and Potential Cost Savings

Lobectomy

Jeffrey A. Hagen, MD, FACS
Keck School of Medicine (USC)
Los Angeles, CA

DA VINCI (n=43[1])
OPEN (n=88[1])



Estimated Potential Savings

$10,800

vs Open

Data presented a single surgeon experience that may or may not be reproducible and is not generalizable. This data comparison is not case-matched for patient complexity and/or disease status and may not be comparable across these surgical modalities. As such, this data presentation should be considered as informational only and is not conclusive. Cost estimates have been independently generated by Intuitive Surgical, Inc. using cost modeling methodology based on national averages and have not been published or peer-reviewed. Costs related to *da Vinci* System acquisition, yearly service costs and other intraoperative and post-operative hospital costs are not included/considered.

OR time for *da Vinci* Lobectomy represent median OR time for the last 22 cases of the study.

1. Oh DS, Cho I, Karamian B, DeMeester SR, Hagen JA. Early adoption of robotic pulmonary lobectomy: feasibility and initial outcomes. Am Surg. 2013 Oct;79(10):1075-80.

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Surgeon Profile

G. Kimble Jett, MD
The Heart Hospital Baylor Plano
Plano, TX

***da Vinci*® System Training:**
2011

Hospital:
The Heart Hospital Baylor Plano

IDN System:
Baylor Scott and White Health

Residency:
Massachusetts General Hospital (General)
Emory University (Thoracic)
National Heart Institute, NIH (Cardiac)

Memberships:
Society of Thoracic Surgeons (STS)

Estimated MIS Procedure Volume

60%
Before *da Vinci*® Training

95%
After *da Vinci*® Training

THO

LOB

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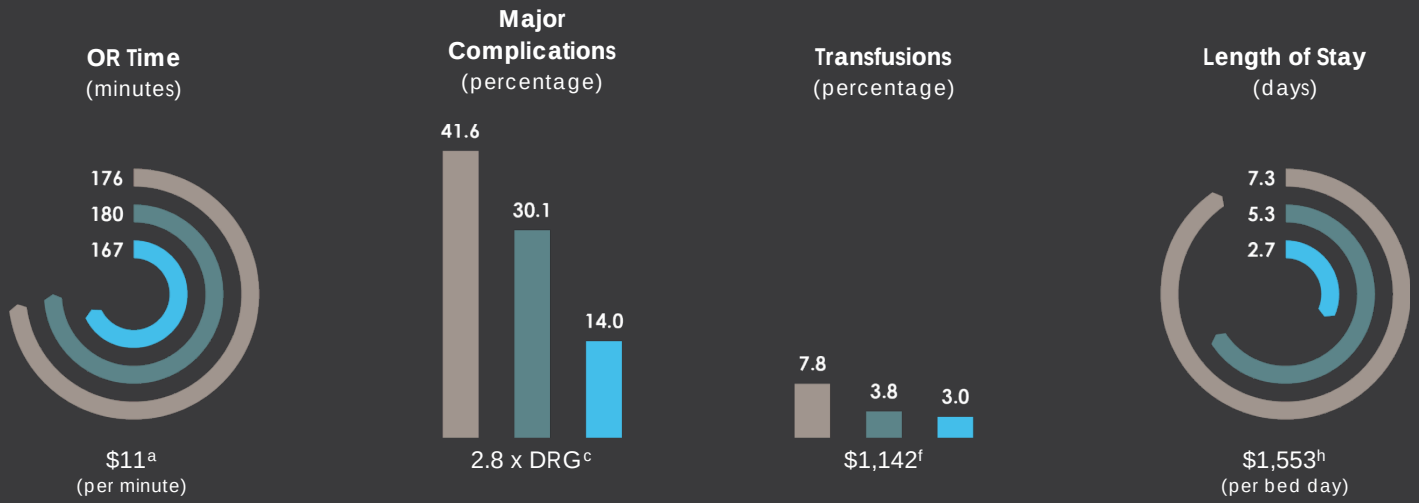
Clinical Outcomes and Potential Cost Savings

Lobectomy

G. Kimble Jett, MD
The Heart Hospital Baylor Plano
Plano, TX

DA VINCI (n=100; Kimble Jett)
VATS (n=4,612, Adam et al 2014[1])
OPEN (5,913, Adam et al 2014[1])



Estimated Potential Savings

$11,091 vs Lap

$19,126 vs Open

Data presented reflect a single center experience (data is not collected under formalized study, DATA IS NOT PEER REVIEWED AND NOT PUBLISHED) that may or may not be reproducible and is not generalizable. This data comparison is not case-matched for patient complexity and/or disease status and may not be comparable across these surgical modalities. As such, this data presentation should be considered as informational only and is not conclusive. Cost estimates have been independently generated by Intuitive Surgical, Inc. using cost modeling methodology based on national averages and have not been published or peer-reviewed. Costs related to *da Vinci* System acquisition, yearly service costs and other intraoperative and post-operative hospital costs are not included/considered.

Readmissions are not shown separately since readmission surrogates (i.e., unexpected return to OR and unexpected return to ICU) per STS are shown as parts of major complications.

1. Adams RD, et al. Initial Multicenter Community Robotic Lobectomy Experience: Comparisons to a National Database. Ann Thorac Surg 2014 June;97:1893-900. doi: 10.1016/j.athoracsur.2014.02.043.

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Supply Cost Comparison

Lobectomy

G. Kimble Jett, MD
The Heart Hospital Baylor Plano
Plano, TX

Cost calculations include intraoperative instrument and accessory costs. Costs related to *da Vinci* System acquisition, yearly service costs and other intraoperative and post-operative hospital costs are not included/considered.

	da Vinci®		VATS
Total	**$1,012**		**$150**
Instrument			
Cadiere Forceps	$200	Dennis Dissector	$7
Curved Bipolar Dissector	$270	Node Grasper	$7
Thoracic Grasper	$240	Debakey Forcep	$10
Small Clip Applier	$42	Disp. Thoracic Grasper	$60
Drape Kit – 4 Arm	$260	Thoracotomy Drape	$66

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Cost Modeling Methodology

Ref.	Clinical Metric	Resource(s)	Calculation Method	Published Value	Value Adjustment
a	Operative Time	Chatterjee A, Payette MJ, Demas CP, et al. Opportunity cost: a systematic application to surgery. Surgery 2009;146:18-22.	Opportunity Cost	$9/min	2009-2014 Medical Services Consumer Price Index
NOTE: Published value is based on laparoscopic ventral hernia repair.					
b	Conversions	Intuitive Surgical, Inc. analysis of 2013 Premier Database for robotic and laparoscopic conversion costs.	Weighted Average	n/a	2013-2014 Medical Services Consumer Price Index
NOTE: Analysis and data, including ICD-9 codes, are on file at Intuitive Surgical.					
c	Complications				
	DRG multiplier	Vonlanthen R, Slankamenac K, Breitenstein S, et al. The impact of complications on costs of major surgical procedures: a cost analysis of 1200 patients. Ann Surg. 2011;254(6):907-913.	$\frac{\text{Cost of complication} - \text{Cost of surgery w/o complications}}{\text{Cost of surgery w/o complications}}$	n/a	n/a
	DRG value	FY2016 Final Rule Tables. Center for Medicare and Medicaid Services.	Weighted Average*	Hyst-Benign DRG-742 (32%*) - $8,527.10 / DRG-743 (9%*) - $5,521.30 APC-5362 (59%*) - $6,861.00 Lobectomy DRG-163 (18%*) - $27,177.90 / DRG-164 (56%*) - $14,031.26 DRG-165 (26%*) - $9,861.00 Colon Resection DRG-329 (25%*) - $27,177.90 / DRG-330 (47%*) - $13,942.36 DRG-331 (41%*) - $9,005.93 Rectal Cancer DRG-332 (12%*) - $24,848.85 / DRG-333 (47%*) - $13,256.36 DRG-334 (41%*) - $9,018.50 Ventral Hernia Repair DRG-353 (3%*) - $15,953.33 / DRG-354 (11%*) - $9,109.79 DRG-355 (13%*) - $6,765.38 / APC-0132 (73%*) - $4,001.00 Inguinal Hernia Repair DRG-350 (3%*) - $13,655.39 / DRG-351 (1%*) - $7,707.73 DRG-352 (4%*) - $5,346.93 / APC-0131 (92%*) - $4,038.82	n/a

NOTE:

- Surgical complications classified as Clavien-Dindo Grade I constitute “Minor Complications” for the purposes of this analysis. The DRG multiplier featured (0.3) is an average of the calculated values from column 4 for each of these classifications.
- Surgical complications classified as Clavien-Dindo Grade IIIb, IVa and IVb constitute “Major Complications” for the purposes of this analysis. The DRG multiplier featured (2.8) is an average of the calculated values from column 4 for each of these classifications.

*Based on 2014 Premier Database inpatient/outpatient procedure mix and DRG mix.

Cost Modeling Methodology (cont'd.)

Ref.	Clinical Metric	Resource(s)	Calculation Method	Published Value	Value Adjustment
d	Transfusions	Shander A, Hofmann A, Ozawa S, et al. Activity-based costs of blood transfusions in surgical patients at four hospitals. Transfusion 2010;50(4):753-765.	$1,183.32 + $726.05 / 2 = $955	$1,183.32 / $726.05	2008-2014 Medical Services Consumer Price Index
NOTE: Per-unit blood cost is based on the average of the two hospitals of the four studied that are based in the US, specifically, EHMC and RIH (the other two are in Europe).					
e	Surgical Site Infections	Zimlichman E, Henderson D, Tamir O. Health care-associated infections: a meta-analysis of costs and financial impact on the US health care system. JAMA Intern Med. 2013 Dec 9-23;173(22):2039-46.	n/a	$20,785	n/a
f	Readmissions	Agency for Healthcare Research and Quality. HCUPnet: A tool for identifying, tracking, and analyzing national hospital statistics. All patient readmissions within 30 days. National statistics, 2012. Index stay - 124 Hysterectomy, abdominal and vaginal.	n/a	$14,718	2012-2014 Medical Services Consumer Price Index
g	Recurrences	Poulose BK, Shelton J, Phillips S, et al. Epidemiology and cost of ventral hernia repair: making the case for hernia research. Hernia. 2012 Apr;16(2):179-83.	n/a	$15,899	n/a
h	Length of Stay	Halpern NA, Pastores SM. Critical care medicine in the United States 2000-2005: an analysis of bed numbers, occupancy rates, payer mix, and costs. Crit Care Med 2010;38(1):65-71.	n/a	$1,153/day (general ward) $3,518/day (intensive care)	2005-2014 Medical Services Consumer Price Index

Important Safety Information

Risks associated with pulmonary resection / lobectomy (removal of part of lung): air leaks from lungs, lung infection, lengthy time on a breathing machine of 48 hours or more, abnormal/irregular heartbeat, breathing tube needs to be re-inserted, abnormal path between lung airways and lining, lung failure lymph fluid collects around lungs, abnormal vocal cord function.

Surgeons should counsel their patients that serious complications may occur with any surgery, including *da Vinci* Surgery, up to and including death. Examples of serious and 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 and/or organs
- Bleeding
- Infection
- Internal scarring that can cause long-lasting dysfunction or pain.

Surgeons should discuss these and all risks associated with surgery with their patients, including but not limited to the following:

- Potential for human error
- Potential for equipment failure
- Potential for anesthesia complications

Individual surgical results may vary.

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Important Safety Information

Risk specific to minimally invasive surgery, including *da Vinci*® Surgery, include but are not limited to:

- Temporary pain or nerve injury associated with positioning
- A longer operative time
- The need to convert the procedure to an open approach.

Converting the procedure could mean a longer operative time, a longer time under anesthesia, and/or the need for additional or larger incisions and/or increased complications.

Surgeons should counsel their patients that there are other surgical approaches available. You should discuss your surgical experience and review these and all risks with your patients. Patients and physicians should review all available information on non-surgical and surgical options in order to make an informed decision. 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/safety. Unless otherwise noted, products featured are available for commercial distribution in the U.S. For availability outside the U.S., please check with your local representative or distributor.

There are several models of the *da Vinci* System. Below are the cleared indications for use in the U.S. for the various models. Important Safety Information, Instructions for Use, Contraindications, Warnings, and Precautions are included in the product instructions provided with the system, instruments and accessories. Contraindications applicable to the use of conventional endoscopic instruments also apply to the use of all *da Vinci* instruments.

The Intuitive Surgical Endoscopic Instrument Control Systems (*da Vinci*, *da Vinci* S and *da Vinci Si* Surgical Systems Models IS1200, IS2000, IS3000) are 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

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Important Safety Information

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 cardiotomy 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.

The Intuitive Surgical Endoscopic Instrument Control System (*da Vinci* Surgical Systems 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 cardiotomy 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. 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.

Unless otherwise noted, products featured are available for commercial distribution in the U.S. Some products may not be available worldwide and may not be used for all applications. For availability outside the U.S., please check with your local representative or distributor.

Training provided by Intuitive Surgical is limited to the use of the *da Vinci* Surgical System and does not replace the necessary medical training and experience required to perform surgery. The da Vinci Surgical System should be used only by surgeons who have received specific training in its use.

Intuitive Surgical facilitates peer-to-peer clinical teaching. Intuitive Surgical does not teach surgery, nor does it provide or evaluate surgical credentialing. Procedure descriptions are developed with, reviewed and approved by independent surgeons.

Intuitive Surgical-sponsored presentations, instruction and promotional materials are intended for general information only and

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Important Safety Information

are not intended to substitute for formal medical training or certification. da Vinci Surgical System training programs are not replacements for hospital policy regarding surgical credentialing. Certification, OR access and hospital privileges are the responsibility of the surgeon and their institutions, not that of Intuitive Surgical.

Any demonstration during Intuitive Surgical-sponsored training or instructional material on how to use the system to perform a particular technique or procedure is not the recommendation or "certification" of Intuitive Surgical as to such technique or procedure, but rather is merely a sharing of information on how other surgeons may have used the system to perform a given technique or procedure. Clinical information and opinions expressed by training participants, including any inaccuracies or mistakes, belong to the individual. Information and opinions are not necessarily those of Intuitive Surgical, Inc.

Before performing any *da Vinci*® procedure, physicians are responsible for receiving sufficient training and proctoring to ensure that they have the skill and experience necessary to protect the health and safety of their patients.

Users of the *da Vinci* System must follow all instructions for use supplied with the system, instruments and accessories. Use of *da Vinci* instruments for tasks other than that for which they were designed may result in damage or breakage. Unless stated in the instructions, do not use *EndoWrist* instruments on cartilage, bone or hard objects. Failure to follow instructions may lead to serious injury or surgical complications for the patient, including death. Electrosurgical energy may cause burns, serious injury or complications to the patient, including death. It is important to fully understand the da Vinci System energy user interface, not exceed recommended energy levels and to use caution when working near critical anatomy.

For Important Safety Information, including indications for use and full cautions and warnings, please also refer to the product instructions for use. 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, including death.

In the event that the da Vinci System, instruments, or accessories do not work as expected or if you are aware of a product deficiency or adverse event, please contact Intuitive Surgical Customer Service immediately. Please refer to the Customer Service contact information in the product Instructions for Use.

Intuitive Surgical promotes and facilitates the use of the *da Vinci* System for commercial use only in conjunction with on-label procedures set forth in the Instructions for Use. Intuitive Surgical recommends consulting your institutional policy regarding the use of cleared medical devices for off-label procedures prior to utilizing the *da Vinci* System.

It is the responsibility of the owner of the da Vinci Surgical System to properly train and supervise its personnel to ensure that the instruments and accessories are properly cleaned, disinfected and sterilized as required by the User's Manual. The da Vinci

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Important Safety Information

products should not be used in a clinical setting unless the institution has verified that these products are properly processed in accordance with the *da Vinci* System User's Manual.

When considering cost-effectiveness of an advanced technology like the *da Vinci* System, we recommend that hospitals perform a full cost-benefit analysis, considering not just the operating room costs but the costs associated with hospital stays, procedure-related complications and hospital re-admissions.

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