da Vinci Surgery

Innovating & Expanding Minimally Invasive

THORACIC SURGERY

Samer Kanaan, MD

Pacific Thoracic Surgery

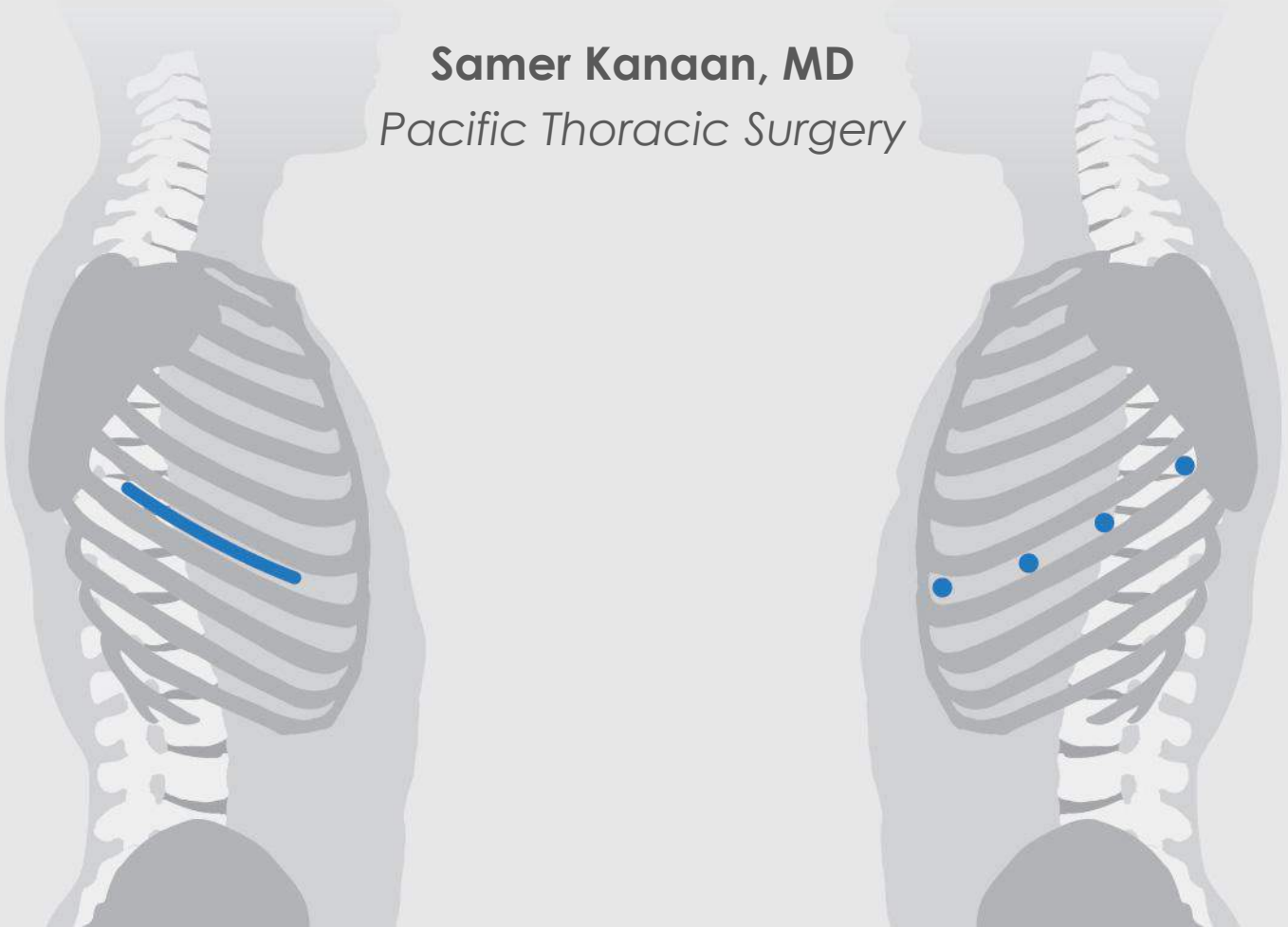


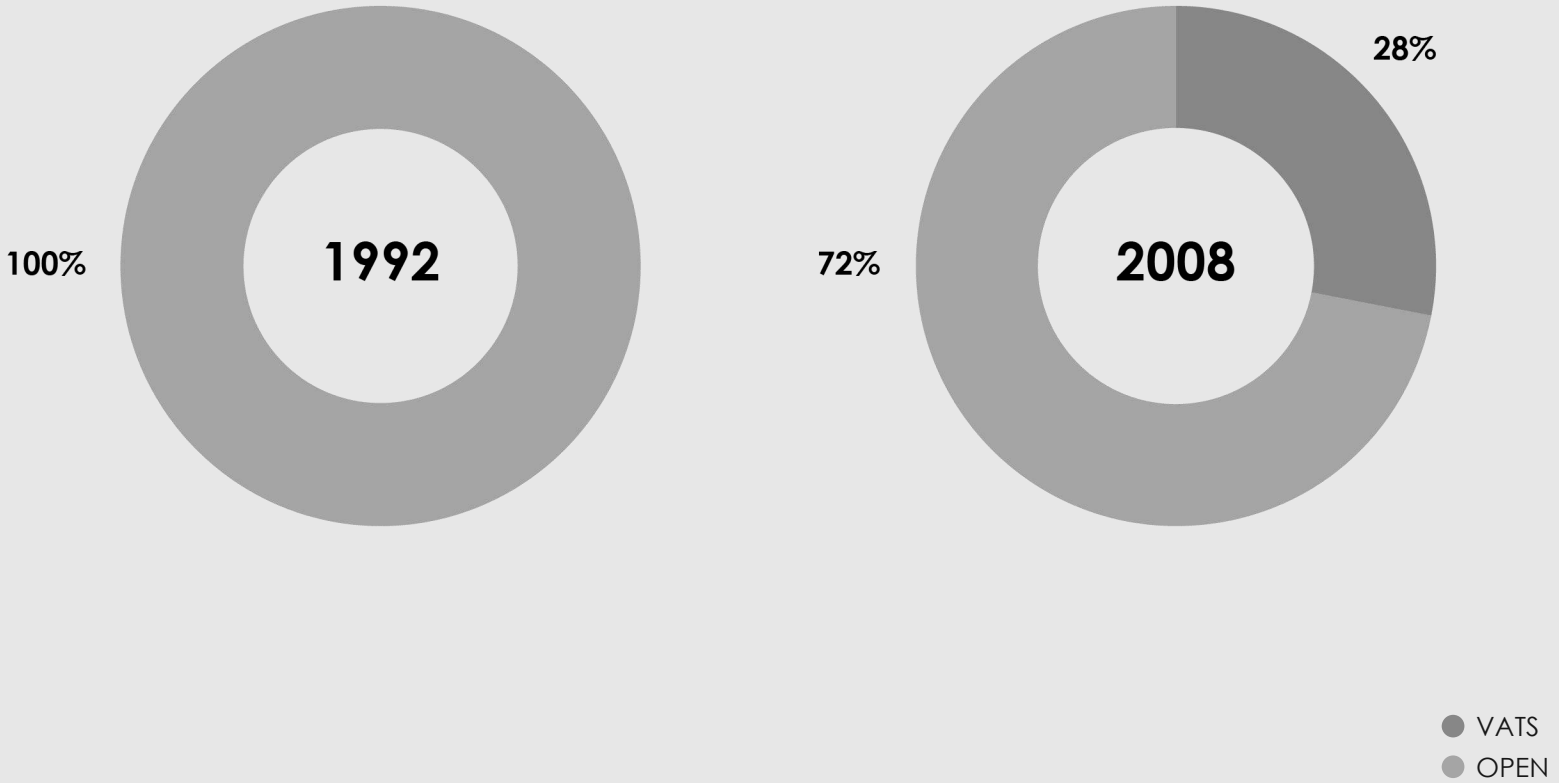
Table of Contents

Vision Presentation

Clinical Data

da Vinci® Xi™

Adoption of VATS Lobectomy* in the US Has Been Slow[1]

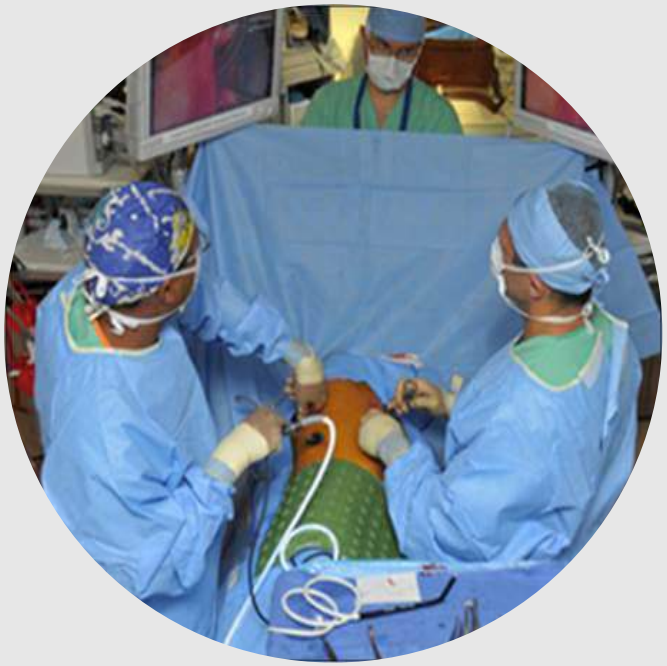


*Includes lobectomy, pneumonectomy, and segmentectomy

[1]AHRQ HCUPnet database

PN 1000710-US Rev D 6/15

VATS is Difficult to Reproduce[1]



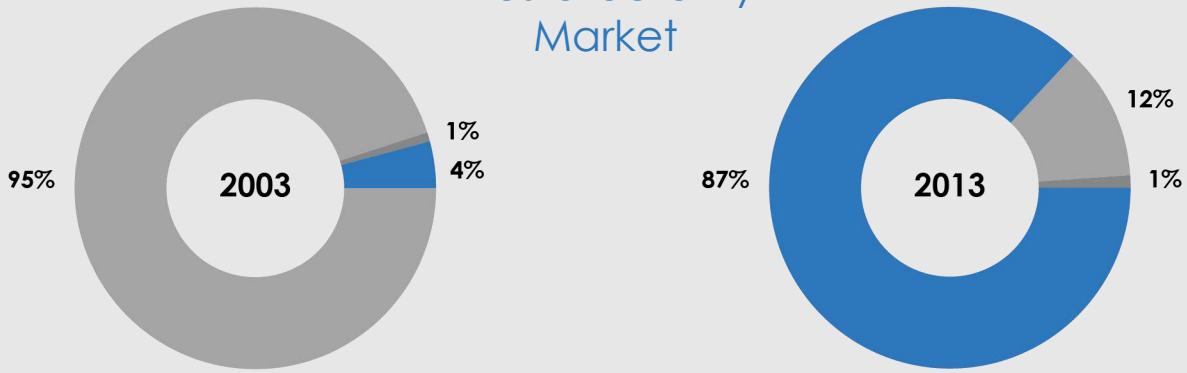
- Counterintuitive orientation
- Rigid instrumentation
- 2D visualization

PN 1000710-US Rev D 6/15

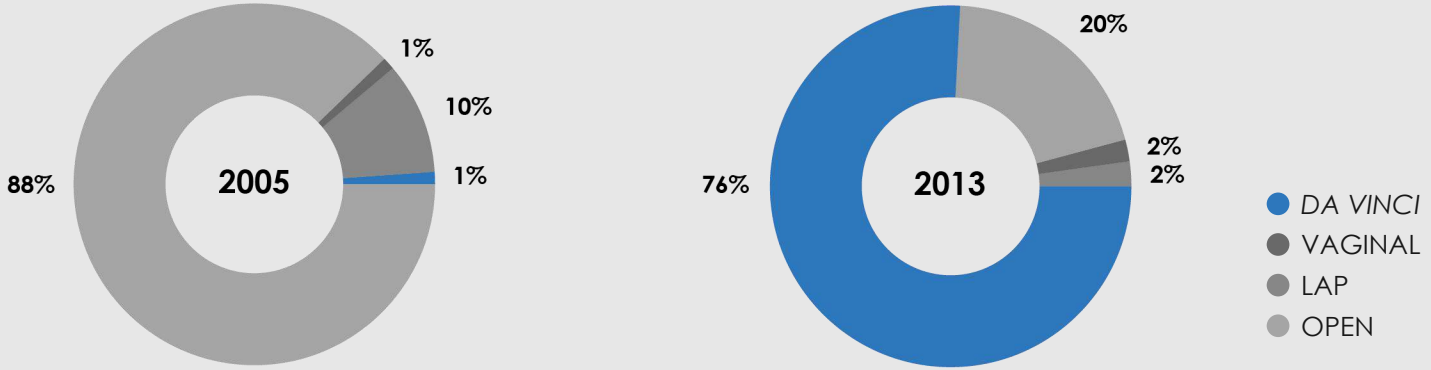
[1]Dylewski, MR, et al. Pulmonary Resection using a Total Endoscopic Robotic Video-Assisted Approach. *Semin in Thoracic Surg*. 2011;23(1) 36-42

da Vinci® Surgery Has Increased Adoption of Minimally Invasive Oncologic Procedures[1]

Prostatectomy Market



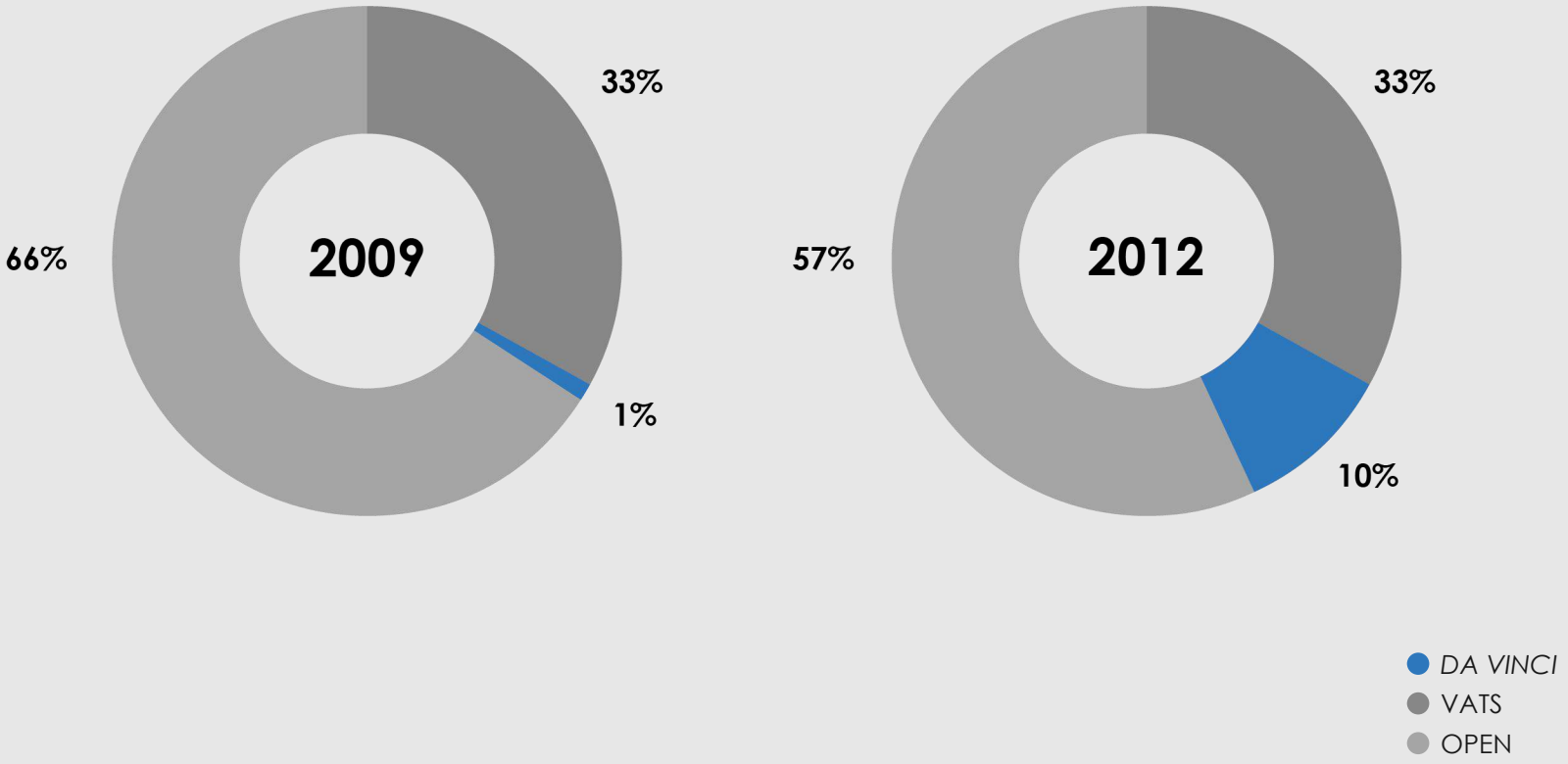
Malignant Hysterectomy Market



[1]Estimates based on Premier Database

PN 1000710-US Rev D 6/15

da Vinci Surgery Is Driving Adoption of Minimally Invasive Pulmonary Resection[1]



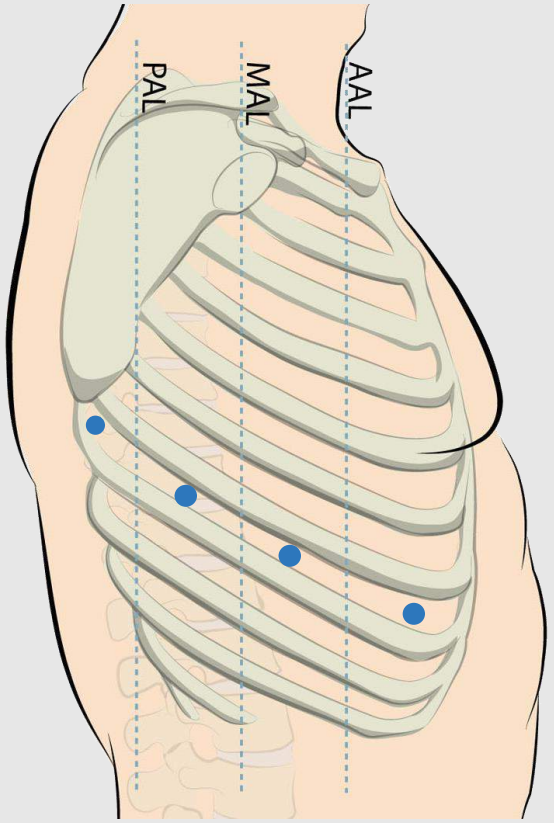
[1]AHRQ HCUPnet database

PN 1000710-US Rev D 6/15

da Vinci Si™ Lobectomy Procedure Features

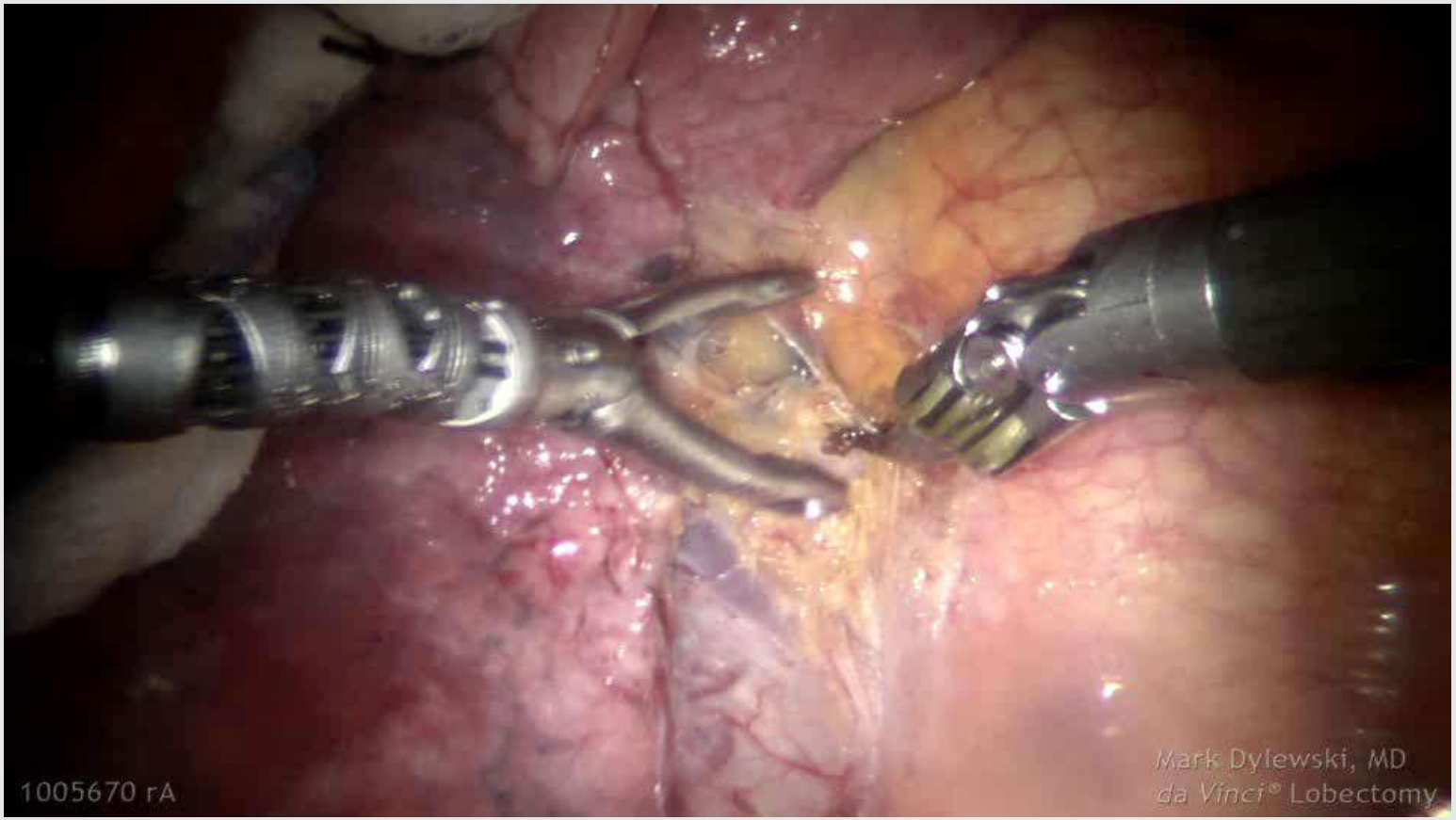
The 4-arm Robotic Lobectomy (CRPL-4):

- Enables access and exposure of upper, middle, and lower lobes
- Single intercostal space
- No rib spreading
- No utility thoracotomy
- CO_2 insufflation



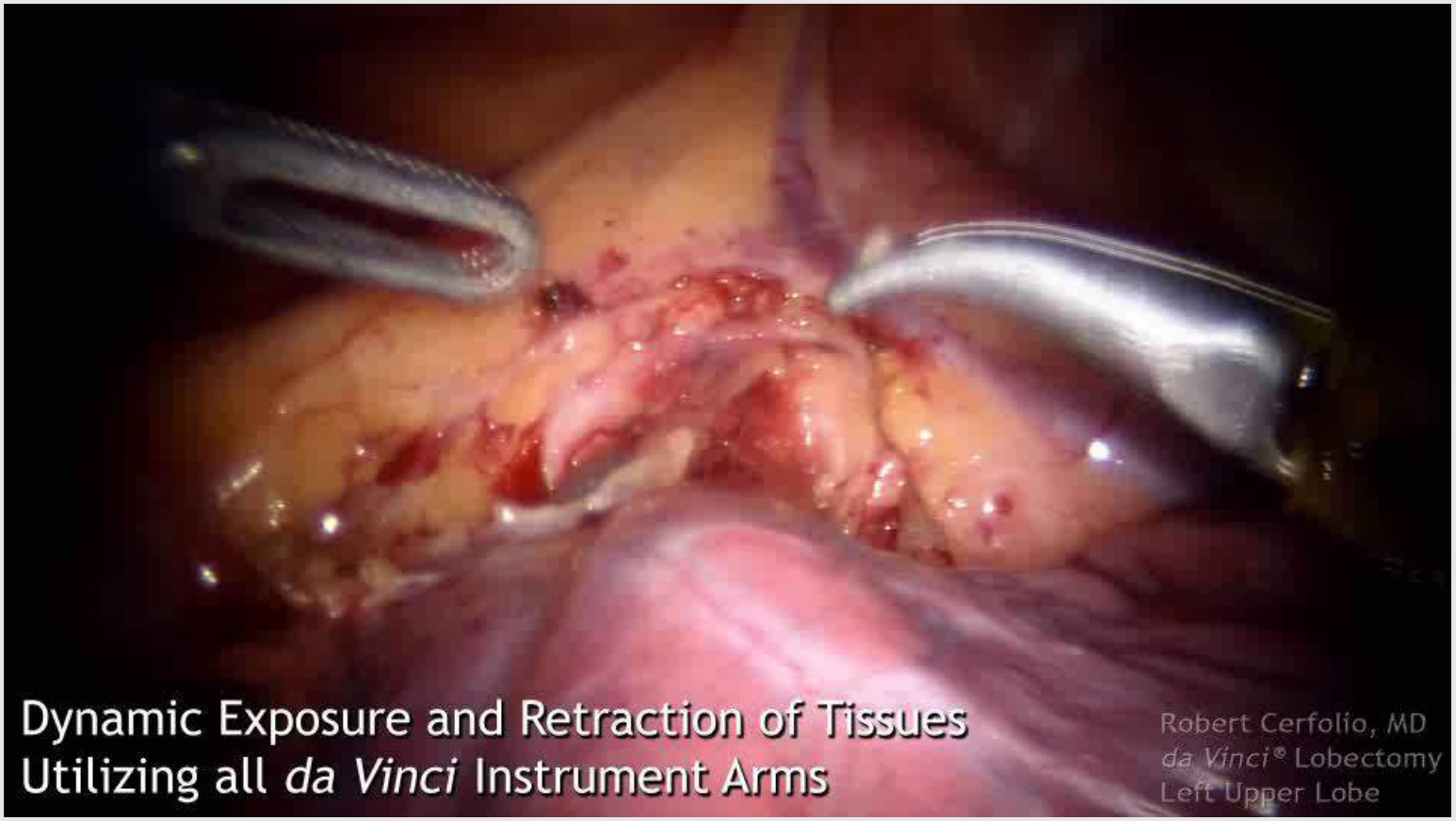
PN 1000710-US Rev D 6/15

Mediastinal & Hilar Lymph Node Dissection



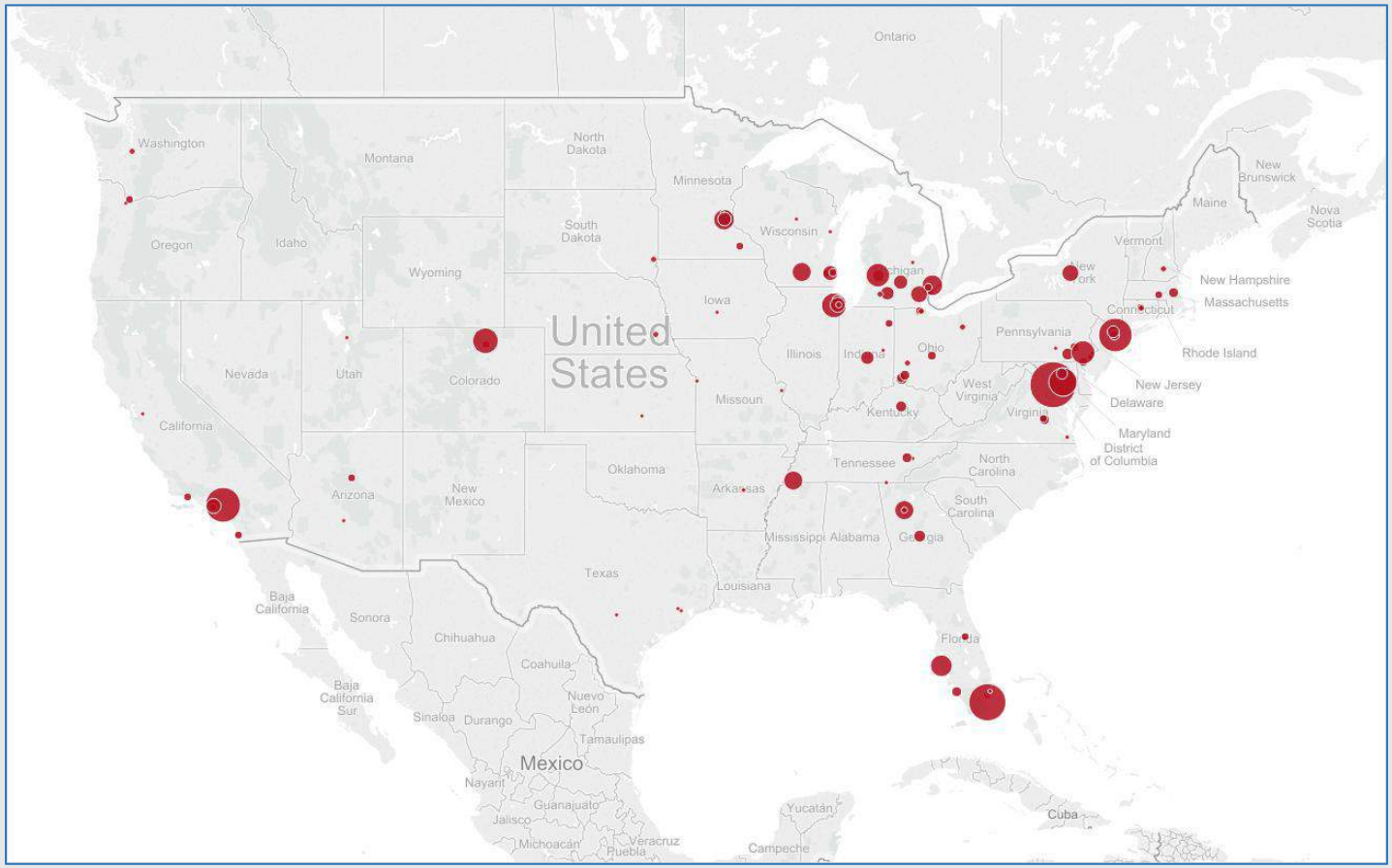
PN 1000710-US Rev D 6/15

Dynamic Exposure & Retraction



PN 1000710-US Rev D 6/15

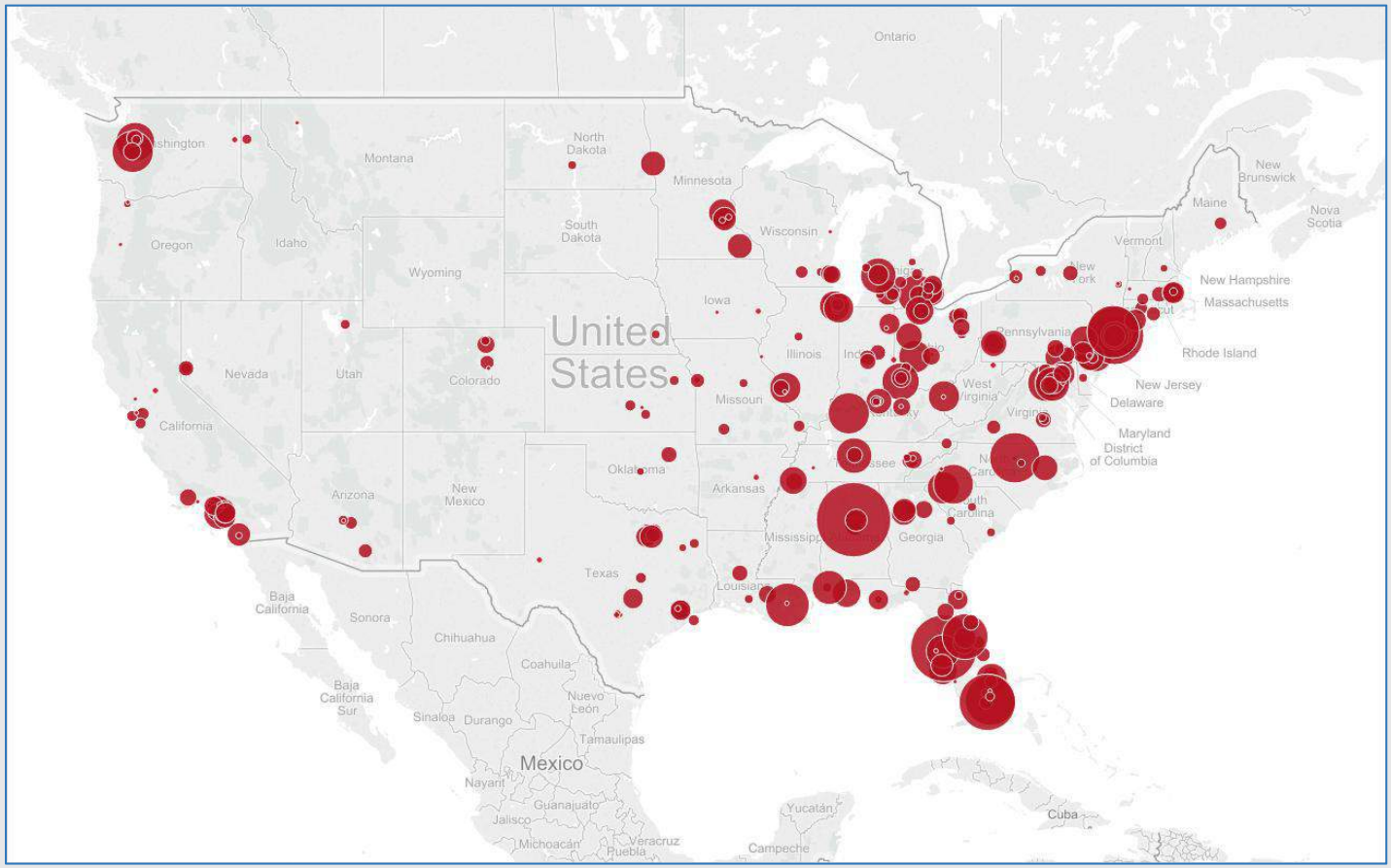
Adoption of *da Vinci* Thoracic Surgery: 2008



100 cases

PN 1000710-US Rev D 6/15

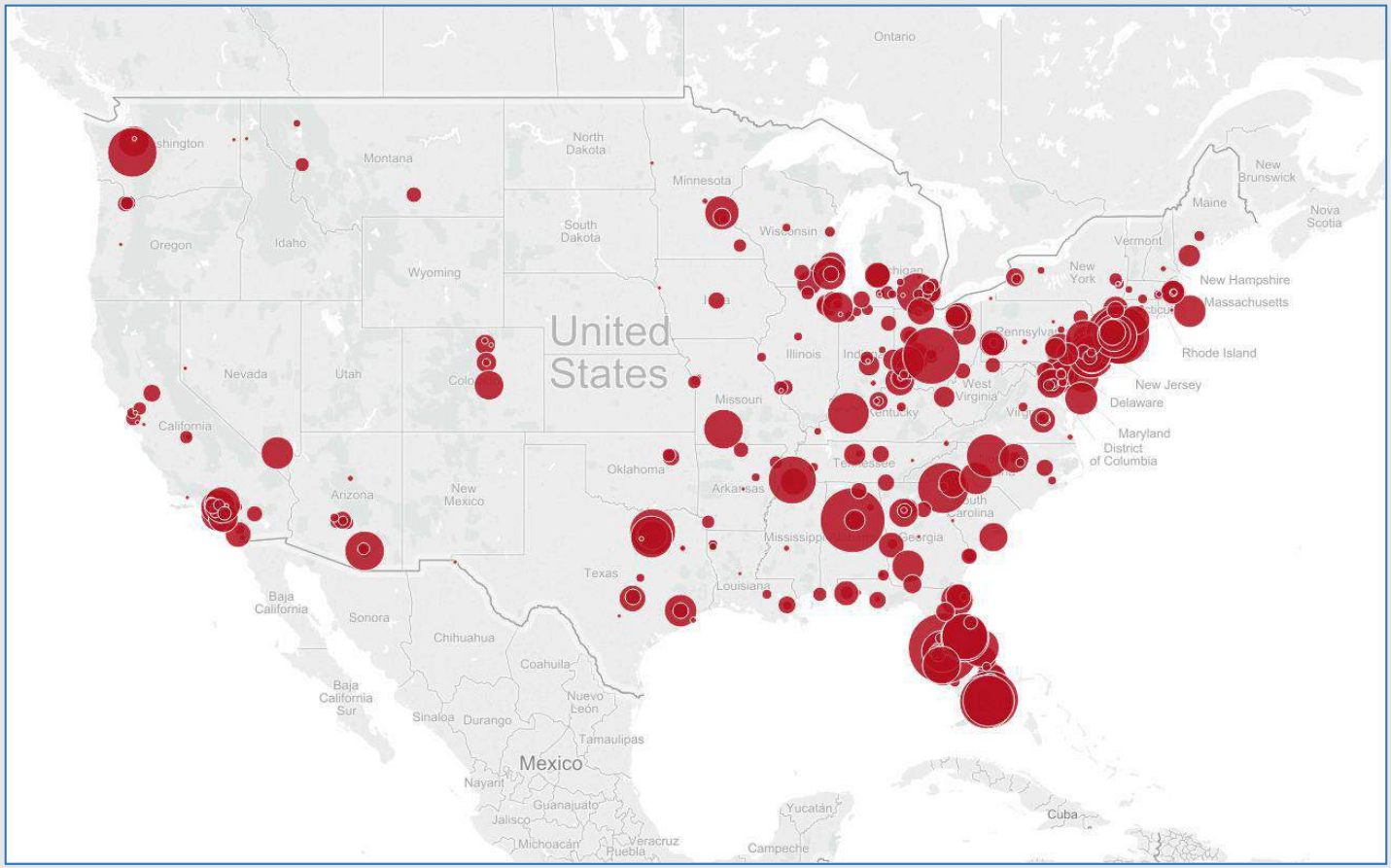
Adoption of *da Vinci* Thoracic Surgery: 2011



100 cases

PN 1000710-US Rev D 6/15

Adoption of *da Vinci* Thoracic Surgery: 2014

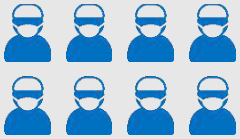


100 cases

Year-to-Year Growth of AATS Robotics Fellowship Program

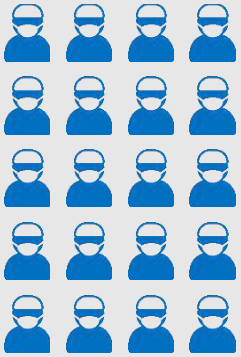
Residents Trained in 2014

8



Residents Trained in 2015

20



da Vinci Si

CLINICAL DATA

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, 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.

Comparative Data: Perioperative Outcomes in Lobectomy

Study (n)	Comparator	LOS, days (*p* value vs. robotic)	Chest tube duration, days (*p* value vs. robotic)	Overall Complications % (*p* value vs. robotic)	30 day Mortality % (*p* value vs. robotic)
Kent 2013[1]					
Open (1,233)	SID (national database)	8.2 (<.0001)	NA	54.1 (.003)	2.0 (.016)
VATS (1,233)		6.3 (NS)	NA	45.3 (NS)	1.1 (NS)
Robotic (411)		5.9	NA	43.8	0.2
Farivar 2014[2]					
Open (4,612)	STS database	7.3 (<.0001)	4.8 (<.0001)	NA	2.0 (<.0001)
VATS (5,913)		5.3 (<.0001)	3.7 (.0005)	NA	0.9 (<.0001)
Robotic (181)	2 centers	3.2	2.9	NA	0
Cerfolio 2011[3]					
Open (318)	Single center	4.0 (.02)	3.0 (<.001)	38.0 (.05)	3.0 (NS)
Robotic (106)		2.0	1.5	27.0	0

[1]Kent M, Wang T, et al.; Open, Video-Assisted Thoracic Surgery, and Robotic Lobectomy: Review of a National Database. *The Society of Thoracic Surgeons.* 2013; 97(1):236-244; [2]Farivar, AS, Cerfolio, RJ, et al.; Comparing Robotic Lung Resection With Thoracotomy and Video-Assisted Thoracoscopic Surgery Cases Entered Into The Society of Thoracic Surgeons Database. *Innovations*.2014; 9(1):1-6. [3]Cerfolio, RJ; Bryant, AS, et al.; Initial consecutive experience of completely portal robotic pulmonary resection with 4 arms. *The Journal of Thoracic and Cardiovascular Surgery*.2011;142(4)740-746.

PN 1000710-US Rev D 6/15

Comparative Data: Nodal Upstaging

Study	n	Hilar upstaging % (*p* value vs. VATS)	Mediastinal upstaging % (*p* value vs. VATS)	Overall upstaging % (*p* value vs. VATS)
Boffa 2012[1]				
Open	7,137	9.3 (<.001)	5.0 (NS)	14.3 (<.001)
VATS	4,394	6.7	4.9	11.6
Licht 2013[2]				
Open	796	13.1 (<.001)	11.5 (<.001)	24.6 (<.001)
VATS	717	8.1	3.8	11.9
Merritt 2013[3]				
Open	69	17.4 (NS)	7.2 (NS)	24.6 (.05)
VATS	60	8.3	1.8	10
Park 2012[4]				
Robotic	325	NR	NR	24.0 (N/A)

[1]Boffa, DJ; Kosinski, AS, et al.; Lymph Node Evaluation by Open or Video-Assisted Approached in 11,500 Anatomic Lung Cancer Resections. *The Annals of Thoracic Surgery*. 2012;94(2):347-353. [2]Licht PB; Jorgensen, OD, et al.; A National Study of Nodal Upstaging After Thoracoscopic Versus Open Lobectomy for Clinical Stage I Lung Cancer. *The Society of Thoracic Surgeons*.2013;96(3):943-950. [3]Merritt, RE; Hoang, CD, et al.; Lymph Node Evaluation Achieved by Open Lobectomy Compared With Thoracoscopic Lobectomy for N0 Lung Cancer. *The Annals of Thoracic Surgery*.2013;96(4):1171-1177. [4]Park BJ; Melfi, F, et al.; Robotic lobectomy for non-small cell lung cancer (NSCLC): Long-term oncologic results. *The Journal of Thoracic and Cardiovascular Surgery.2012;143(2):383-389*

PN 1000710-US Rev D 6/15

Performing Robotic Lobectomy and Segmentectomy: Cost, Profitability, and Outcomes[1]

	Clinical Outcomes			Economic Outcomes	
	LOS (days)	Major Morbidity	30-day Mortality		Median Cost
Cerfolio 2014[1]					
Robotic	2.0	9.6%	0.25%	Direct Cost	$9,853
(n = 394)				Indirect Cost	$5,587
				Total Expense per Patient	$15,440
				Medicare Reimbursement	$18,937
				Profit Margin per Patient	$3,497

Limitations of the Study

- Single surgeon, single institution analysis of cases from single payer (Medicare)
- Effect of surgeon experience and patient selection not taken into account
- Non-accounted advances leading to improved results

PN 1000710-US Rev D 6/15

[1]Cerfolio RJ, et al. Performing Robotic Lobectomy and Segmentectomy: Cost, Profitability, and Outcomes. *The Annals of Thoracic Surgery*. 2014;98(1) 203-209.

da Vinci Xi Indications for Use

THORACIC PROCEDURES

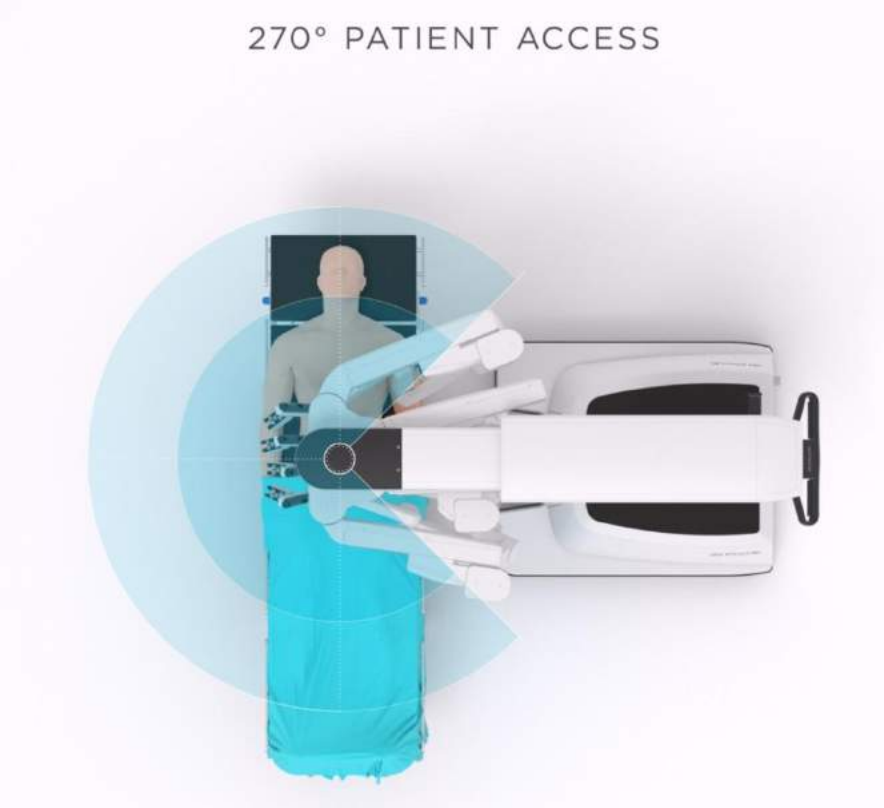
General thoracoscopic surgical procedures and thoracoscopically-assisted cardiotomy procedures

Representative use for the *da Vinci Xi* (IS4000):

Mitral Valve Repair

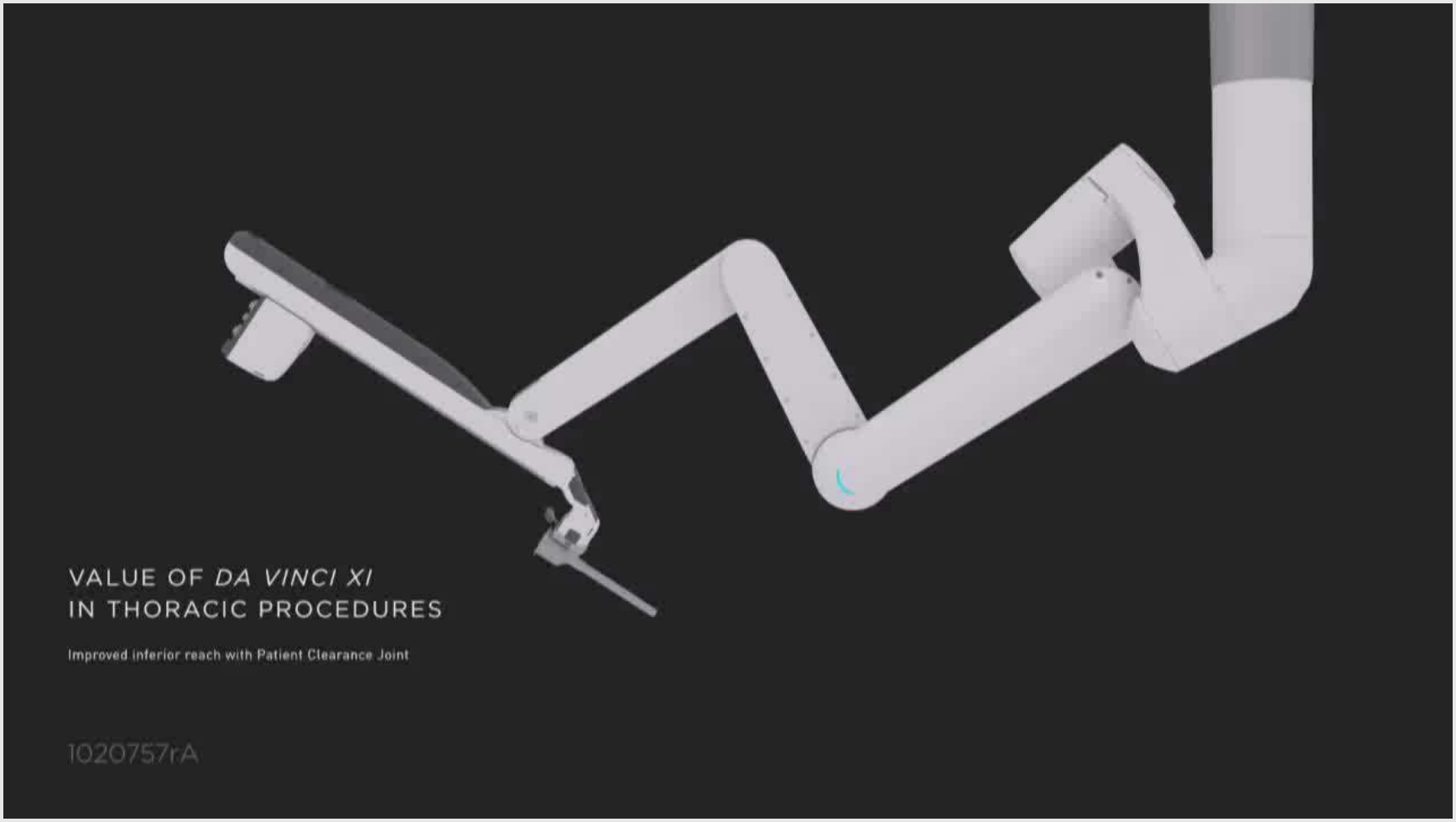
Anatomical Access From Virtually Any Position

- Improved access for anesthesia and bedside assist
- Place ports for a variety of procedures from one patient cart position



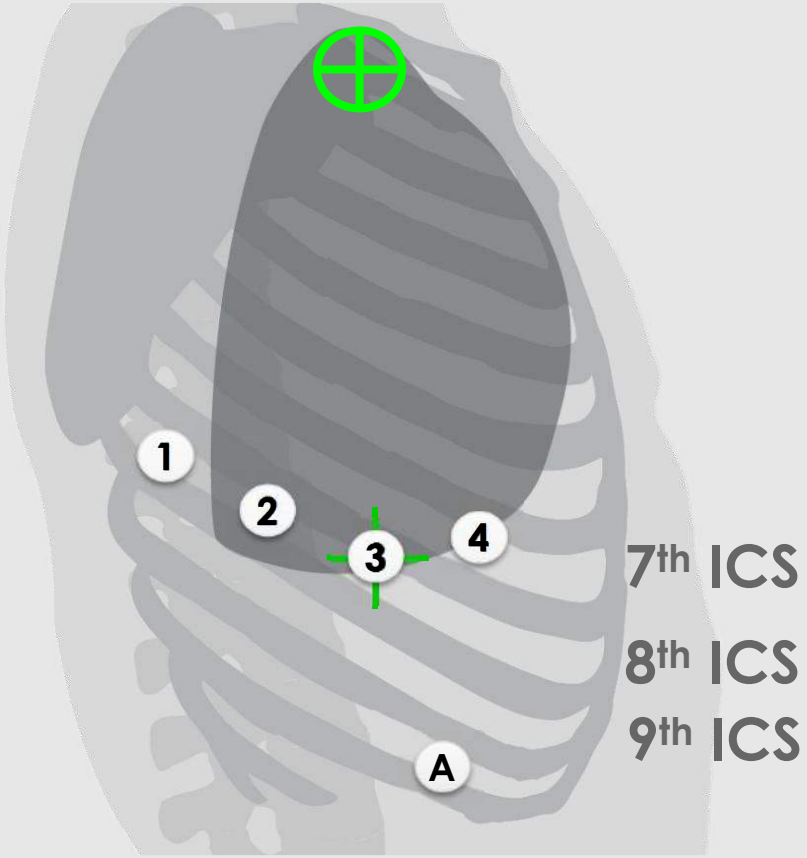
PN 1000710-US Rev D 6/15

Improved Inferior Reach



Place Ports with Confidence

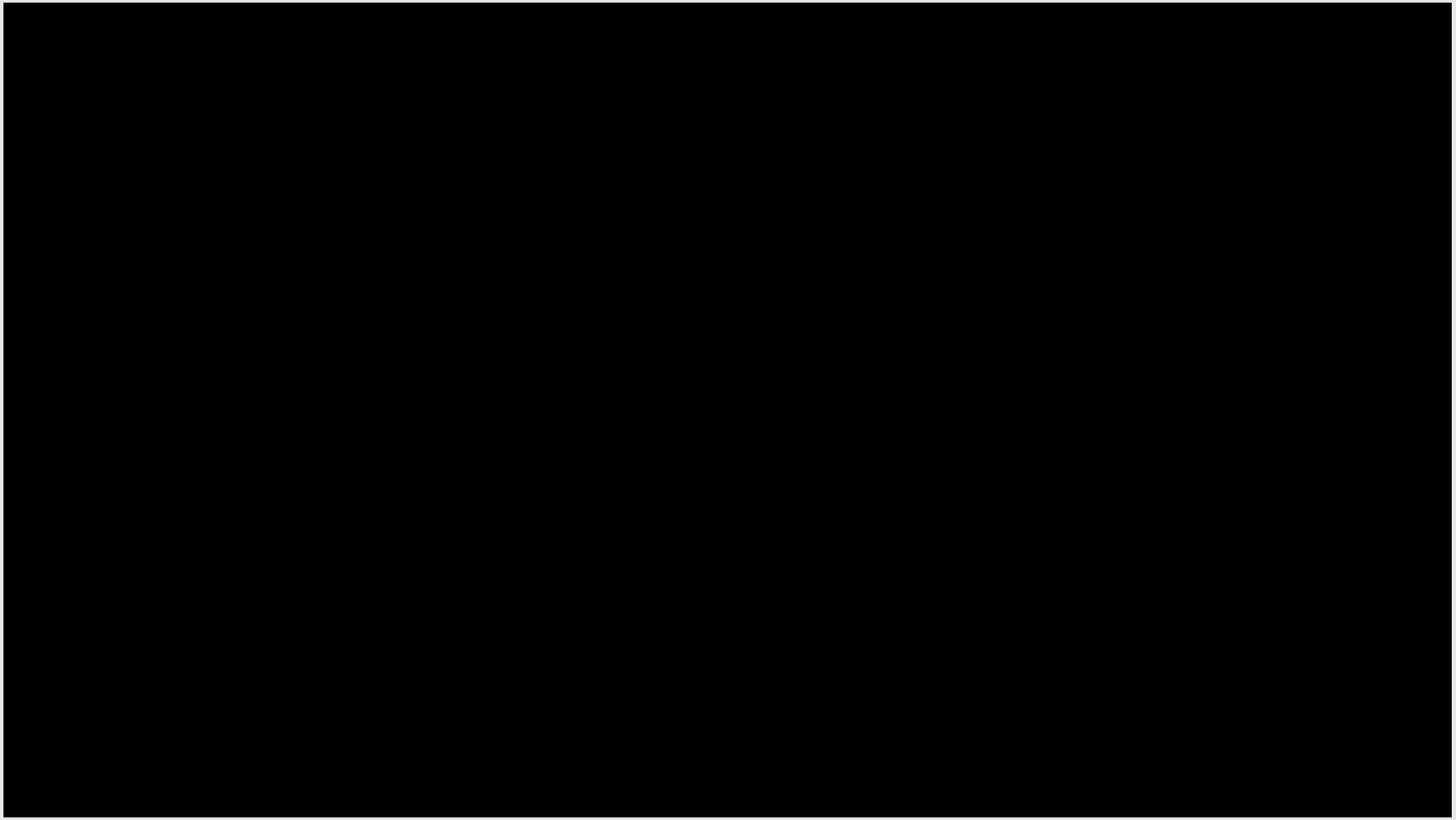
- 6 cm spacing between ports
- Port hop scope to optimize access to anterior and posterior mediastinum



Representative use for the *da Vinci Xi* (IS4000):
Mitral Valve Repair

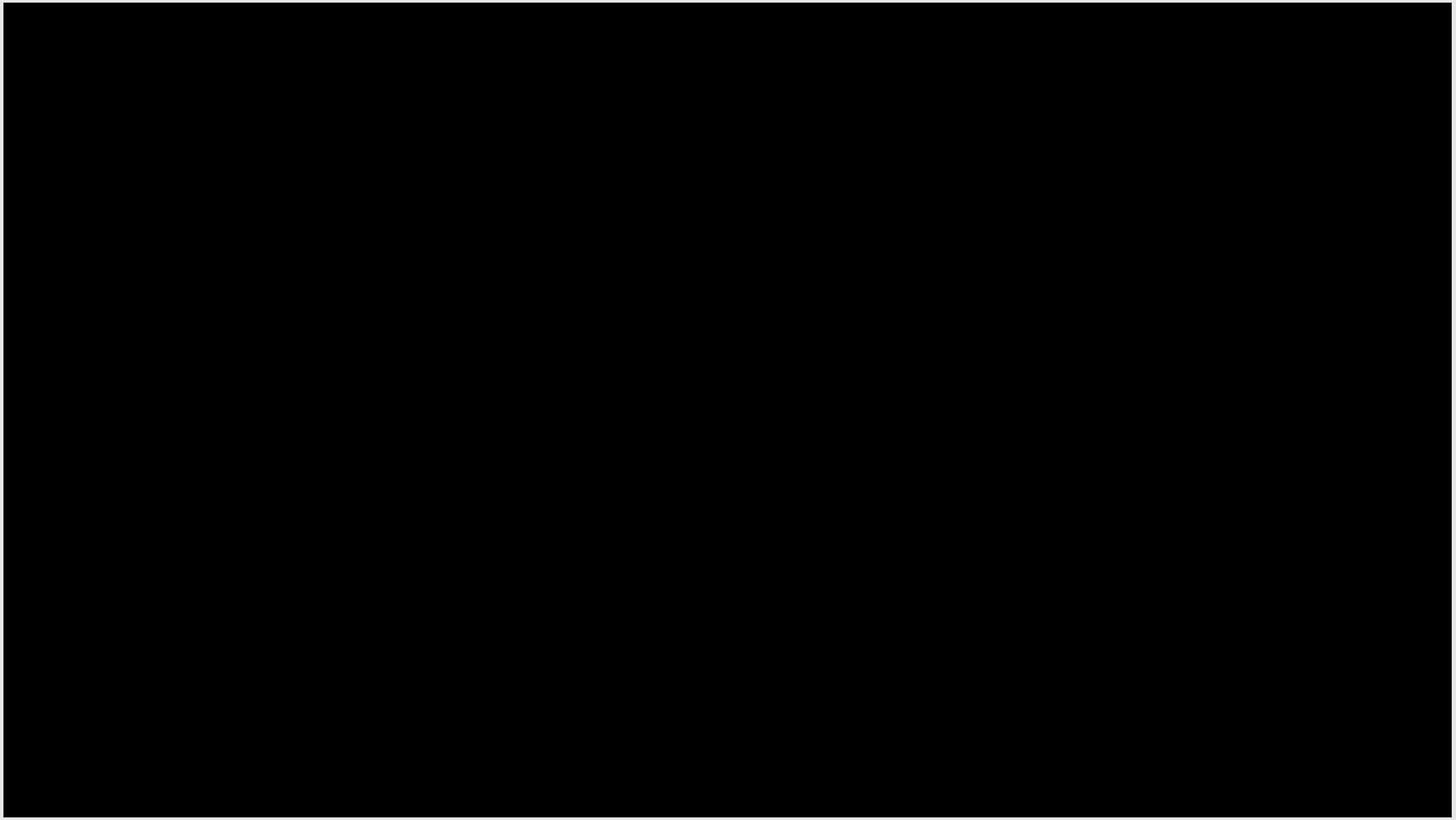
PN 1000710-US Rev D 6/15

Fully Wristed, Surgeon Controlled Stapling



PN 1000710-US Rev D 6/15

Fully Wristed, Surgeon Controlled Stapling



PN 1000710-US Rev D 6/15

Important Safety Information

Risks associated with pulmonary resection (wedge resection, segmentectomy, lobectomy) include persistent air leak, pneumonia, prolonged ventilation >48 hours, atrial fibrillation, acute respiratory distress syndrome (ARDS), chylothorax, re-intubation, arrhythmias, bronchopleural fistula, phrenic nerve injury, esophageal injury, recurrent laryngeal nerve injury leading to vocal cord dysfunction.

Risks associated with esophagectomy include anastomotic leak, pneumonia, cardiac complications (infarction, failure, atrial fibrillation), recurrent laryngeal nerve injury, chyle leak.

Risks associated with mediastinal mass resection include prolonged ventilation >48 hours, persistent air leak, pericardial effusion, mixed respiratory syndrome, chylothorax, pneumothorax, re-intubation, pneumonia, acute respiratory distress syndrome (ARDS), atrial fibrillation, cardiac injury, conversion to sternotomy, recurrent laryngeal nerve injury leading to vocal cord dysfunction, phrenic nerve injury.

Risks associated with mitral valve repair include failed repair requiring replacement or repair, embolic stroke, ischemic heart failure, aortic dissection, prolonged ventilation >48 hours, prolonged time for: a heart-lung bypass, extracorporeal membrane oxygenation, intraaortic balloon pump or other cardiac assist systems, pulmonary edema, acute limb ischemia, valve infection, arrhythmia requiring pacemaker implantation, post-pericardiotomy syndrome (low grade fever and chest pain up to 6 months), pericarditis, persistent coagulopathy, heart attack, pericardial tamponade, memory loss and/or loss of mental clarity, arterial dissection, circumflex coronary artery injury, inadequate closure

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

PN 1000710-US Rev D 6/15

Important Safety Information

Individual surgical results may vary.

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,

PN 1000710-US Rev D 6/15

Important Safety Information

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 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.

PN 1000710-US Rev D 6/15

Important Safety Information

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

PN 1000710-US Rev D 6/15

Important Safety Information

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* 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.

The *EndoWrist*® Stapler for the *da Vinci*® *Xi*™ System (IS4000) is not compatible for use with the *da Vinci*, *da Vinci S*, or *da Vinci Si* Surgical System. The *EndoWrist* Stapler, *EndoWrist* Stapler Reloads and other Stapler accessories for the *da Vinci Xi* System are intended to be used with the *da Vinci Xi* Surgical System (IS4000) for resection, transection, and/or creation of anastomoses in General, Thoracic, Gynecologic and Urologic surgery. The device can be used with staple-line or tissue-buttressing materials (natural or synthetic). Commercial clearance (U.S.) is for white, blue, and green 45 mm reloads only. The *EndoWrist* Stapler and *EndoWrist* Stapler Reloads for the *da Vinci Xi* System should not be used on tissue such as the liver or spleen, where tissue compressibility is such that clamping of the instrument would be destructive. Do not use the *EndoWrist* Stapler or *EndoWrist* Stapler Reloads for the *da Vinci Xi* System on the aorta.

The friable nature of pulmonary tissue enhances the risk of vascular, bronchiolar or other injury that will be difficult to control 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).

PN 1000710-US Rev D 6/15

PN 1000710-US Rev D 6/15