

da Vinci® Surgical System

Introduction:

With already over 210 devices in use throughout the United States, Europe, and Japan, Intuitive Surgical is the leading company in the field of digital surgery with its da Vinci® Surgical System. Approved in July 2000 to perform advanced surgical techniques such as cutting and suturing, this system is the first operative surgical robotic system to be cleared by the FDA, giving it a first-mover advantage over its competitors. Though Intuitive Surgical has had to overcome many obstacles in order to dominate the digital surgery field, it is now a multimillion-dollar business that continues to grow¹.

System Overview



Making a one-centimeter keyhole incision to perform the operation, the surgeon is able to engage in minimally invasive surgery through this system. According to Ben Gong, Intuitive Surgical's vice president of finance, da Vinci reduces the average 2-3% infection probability to nearly zero². There are four main components to da Vinci: the surgeon console, patient-side cart, EndoWrist Instruments, and Insite Vision System with high resolution 3D Endoscope and Image Processing Equipment.

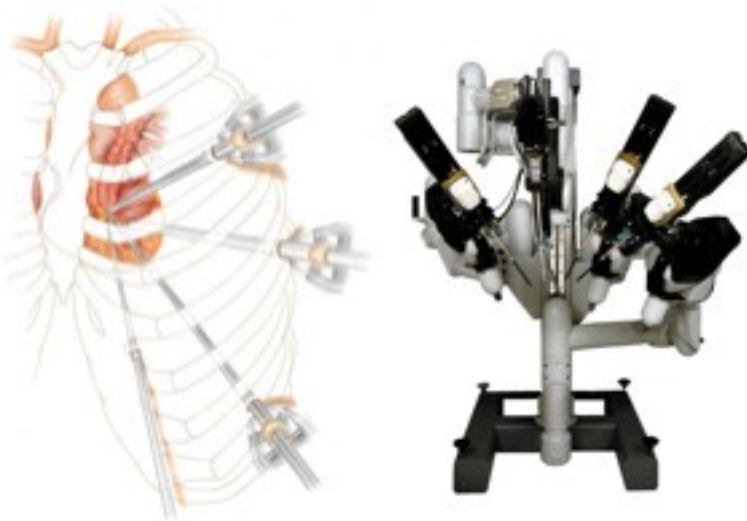
1. Surgeon Console

The surgeon is situated at this console several feet away from the patient operating table. The surgeon has his head tilted forward and his hands inside the system's master interface. The surgeon sits viewing a magnified three-dimensional image of the surgical field with a real-time progression of the instruments as he operates. The instrument controls enable the surgeon to move within a one cubic foot area of workspace.



2. Patient-side Cart

This component of the system contains the robotic arms that directly contact the patient. It consists of two or three instrument arms and one endoscope arm. The feedback as of today is limited to sensing tool-on-tool collision, so the surgeon needs to rely almost solely on the visual field when suturing or contacting soft tissue. As of 2003, Intuitive launched a fourth arm, costing \$175,000, as a part of a new system installation or as an upgrade to an existing unit². It provides the advantages of being able to manipulate another instrument for complex procedures and removes the need for one operating room nurse³.



3. Detachable Instruments (Endowrist® Instruments and Intuitive® Masters)

The Endowrist detachable instruments allow the robotic arms to maneuver in ways that simulate fine human movements. Each instrument has its own function from suturing to clamping, and is switched from one to the other using quick-release levers on each robotic arm. The device memorizes the position of the robotic arm before the instrument is replaced so that the second one can be reset to the exact same position as the first. The instruments' abilities to rotate in full circles provide an advantage over non-robotic arms. The seven degrees of freedom (meaning the number of independent movements the robot can perform) offers considerable choice in rotation and pivoting⁴. Moreover, the surgeon is also able to control the amount of force applied, which varies from a fraction of an ounce to several pounds. The Intuitive Masters technology also has the ability to filter out hand tremors and scale movements. As a result, the surgeon's large hand movements can be translated into smaller ones by the robotic device⁵. Carbon dioxide is usually pumped into the body cavity to make more room for the robotic arms to maneuver.

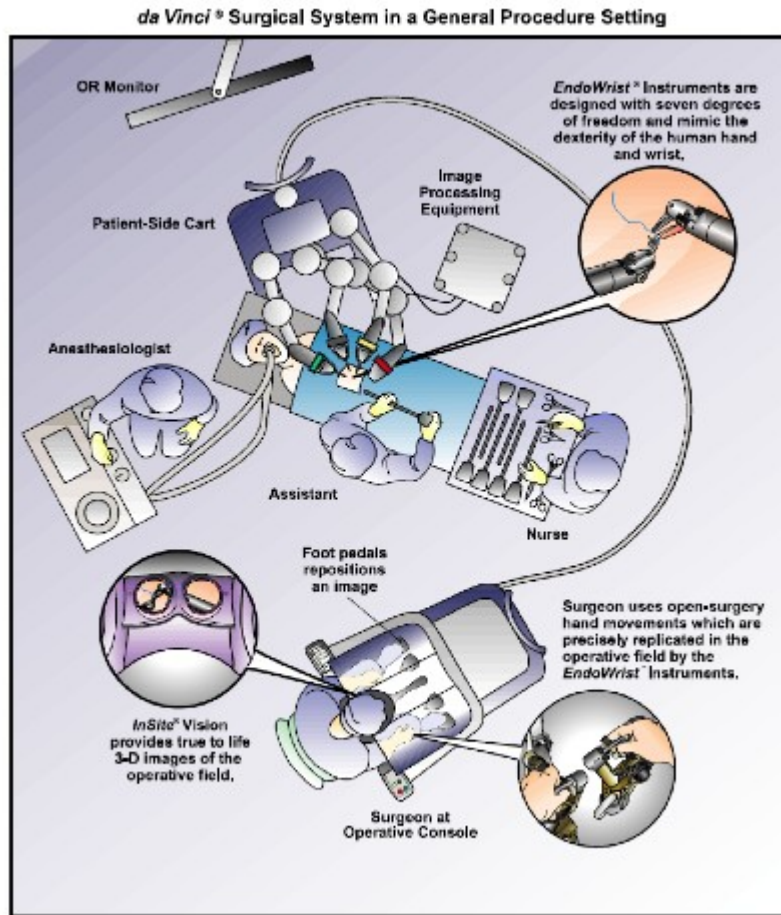


4. 3-D Vision System

(Insite® Vision and Navigator Camera Control)



The camera unit or endoscope arm provides enhanced three-dimensional images. This high-resolution real-time magnification showing the inside the patient allows the surgeon to have a considerable advantage over regular surgery. The system provides over a thousand frames of the instrument position per second and filters each image through a video processor that eliminates background noise. The endoscope is programmed to regulate the temperature of the endoscope tip automatically to prevent fogging during the operation³. Unlike The Navigator Control, it also enables the surgeon to quickly switch views through the use of a simple foot pedal.



Competitors:

Just a few years ago, Intuitive Surgical was in the midst of a fierce legal battle with its competitor, Computer Motion. The series of events was offset by a lawsuit filed by Computer Motion for nine patent infringements. Intuitive Surgical then filed three lawsuits of its own and made a final blow by teaming with IBM to sue its competitor for infringing on its voice-recognition technology. Computer Motion lost the case for this integral component of all its devices including Zeus, its version of da Vinci. It faced a major problem since it would have to stop selling in the event that it could not receive a proper license from its competitor. On March 7, 2003, Intuitive Surgical merged with its main competitor⁶, ending a four-year legal power struggle that detracted from product advancement and funds⁷. Intuitive Surgical paid \$150 million for Computer Motions and laid off around 90% of its employees following the merger². Intuitive now owns and will market Computer Motion's products (Zeus Surgical System, Hermes Control Center, Aesop Robotic Endoscope Positioner, and Socrates Telecollaboration System)⁸.

Market Information of the Robot Surgical Systems

Equipment	Costs	Company	Equipment Descriptions
da Vinci Surgical System	\$1 million	Intuitive Surgical	Robot-assistant, with arms to connect surgical instruments

Zeus Robot Surgical System	\$975,000	Computer Motion*	Robot-assistant, with arms to connect surgical instruments
Aesop 3000	\$80,000	Computer Motion*	Voice-controlled endoscope-positioning robot
Hermes Control Center	Request price quota	Computer Motion*	Centralized system used to network an intelligent OR
Socrates Robotic Telecollaboration System	Request price quota	Computer Motion*	Allows shared control of Aesop 3000 from different locations

*Former Computer Motion systems that are now owned by Intuitive Surgical. Sources: Table 1 from Journal of Healthcare Management 46:4 July/August 2003

Advantages and Disadvantages:

The da Vinci Surgical System reduces hospital stays by about half, reducing hospital cost by about 33%⁹. These fewer days in the intensive care unit are a result of less pain and quicker recovery. Though the size of the device is still not small enough for heart procedures in children, the minimally invasive nature of da Vinci does not leave a large surgical scar and still has some limited applications in children for the time being. Moreover, according to Intuitive Surgical, only 80,000 out of 230,000 new cases of prostate cancer undergo surgery because of the high risk invasive surgery carries, implying that more people may undergo surgery with this evolving technology². The main drawbacks to this technology are the steep learning curve and high cost of the device. Though Intuitive Surgical does provide a training program, it took surgeons about 12-18 patients before they felt comfortable performing the procedure¹⁰. One of the greatest challenges facing surgeons who were training on this device was that they felt hindered by the loss of tactile, or haptic, sensation (ability to “feel” the tissue). The large floor-mounted patient-side cart limits the assistant surgeon’s access to the patient. However, there are also many who are unable to access the da Vinci based on the steep price. In a paper published by The American Journal of Surgery, 75% of surgeons claimed that they felt financially limited by any system that cost more than \$500,000¹¹. As of now, surgery with the da Vinci Surgical System takes 40-50 minutes longer, but the FDA considered this a learning curve variable and expects time to improve with more use of the system¹².

Estimate of Initial Investment and Cost Savings per Heart-Valve Surgery for da Vinci® Market Price

Maintenance/year Physician Training	\$1 million \$100,000 \$250,000
Cost of one inpatient hospital day	\$2,000
Reduced inpatient hospital days for heart procedures	4.5 days
Cost saving per heart procedure due to reduced hospital stay	\$9,000 per heart valve
Extra procedure cost	\$2000 more per operation
Surgical assistance	\$175,000 for fourth arm (Compared to \$80,610 per year for extra OR nurse)

Variable	Open Surgery	Laparoscopic	daVinci®
Number of cases	100	50	100
Average blood loss, millimeters	900	380	<100
Cases with complications	15	10	5
Average days with catheter afterwards	15	8	7
Average days hospitalized	3.5	1.3	1.2

Source: Menon, M. "Robotic Radical Prostatectomy," British Journal of Urology 91(3):175-80. February 2003.

Costs

Though Intuitive Surgical has faced some setbacks during its legal battles with Computer Motion, it has recovered quickly and has been growing at an unprecedented rate since the merger. The total sale for the first year of 2004 was \$138.8 million (a 51% increase from the previous year) with a total of \$60 million in revenue. This includes recurring revenue from instruments, disposable accessories, and services, which have also increased accordingly in response to the larger number of systems installed and greater usage in hospitals. In 2004 alone, 76 da Vinci Systems, each costing about \$1.5 million, were sold¹³.

Reimbursement:

Medical reimbursement by insurance companies is specific to each respective company. However, Medicare reimbursement is available for laparoscopic and thoracoscopic procedures since the da Vinci Surgical System has been FDA approved for commercial distribution in the United States¹⁴.

FDA Approval:

http://www.intuitivesurgical.com/news_room/fda_clear.html

Date	Procedure
April 26, 2005	Gynecological Laparoscopic Procedures
January 30, 2003	Totally Endoscopic Atrial Septal Defect (ASD)
November 13, 2002	Mitral valve repair surgery
November 12, 2002	Thoracoscopically-Assisted Cardiotomy Procedures, K022574
July 11, 2000	General Laparoscopic Surgery (gallbladder, gastroesophageal reflux)

	and gynecologic surgery), K990144
March 5, 2001	Thoracoscopic Surgery (IMA Harvesting for Coronary Artery Bypass and Lung surgery), K002489
May 30, 2001	Laparoscopic Radical Prostatectomy, K011002
July 31, 1997	Surgical Assistance, K965001



Fail Safe Mechanisms

Safety concerns remain the center of focus for Intuitive Surgical. To start the procedure, the surgeon's head must be placed in the viewer. Otherwise, the system will lock and remain motionless until it detects the presence of the surgeon's head once again. During the procedure, a zero-point movement system prevents the robotic arms from pivoting above or at the one-inch entry incision, which could otherwise be unintentionally torn. Included in the power source is a backup battery that allows the system to run for twenty minutes, giving the hospital enough time to reestablish power. Each instrument contains a chip that prevents the use of any instrument other than those made by Intuitive Surgical. These chips also store information about each instrument for more precise control and keep track of instrument usage to determine when it must be replaced.



Future Outlook

Besides the cost, the da Vinci Surgical System still has many obstacles that it must overcome before it can be fully integrated into the existing healthcare system. From the lack of tactile feedback to the large size, the current da Vinci Surgical System is merely a rough preview of what is to come. Spending around \$16.2 million in 2003 alone, Intuitive Surgical has a first-mover advantage over its competitors and continues to lead on as it receives more and more FDA approvals. More improvements in size, tactile sensation, cost, and telesurgery are expected for the future¹⁵.

* = All pictures taken from www.intuitivesurgical.com