

Facts about *da Vinci*[®] Surgery

- **Safety and Effectiveness:** Over the past decade, more than 1.5 million *da Vinci* surgeries have been performed in major clinical centers around the world. *da Vinci* Surgery is a part of routine surgical practice in several surgical specialties. Through the adoption of *da Vinci* Surgery, surgeons have made significant progress in reducing the number of patients receiving open incisions for conditions found in gynecology, urology, general, cardiac and thoracic surgery (see appendix). Intuitive's highest priority is and always has been to provide patient benefit – creating products that in a surgeon's hands are safe, effective and minimally invasive. As with any surgery, *da Vinci* Surgery is not without risk. The *da Vinci* Surgical System is an advanced tool and is not a substitute for the training, experience and surgical judgment of the surgeon with respect to how a particular surgery should be performed.
- **Clinical Evidence:** There are thousands of peer-reviewed publications discussing the safety and effectiveness of *da Vinci* Surgery. In late 2011 and 2012, several large-scale clinical studies on *da Vinci* Surgery were published and demonstrated the benefits of *da Vinci* Surgery. Since *da Vinci* prostatectomy is the most mature procedure, many of these large studies used population databases to assess the clinical impact of *da Vinci* Surgery for prostatectomy when compared to the prior standard, open surgery. As other clinical areas of *da Vinci* Surgery mature, clinical evidence continues to trend toward lower complication rates compared to open surgery.^{1,2,3,4,5,6} While many studies' findings favor *da Vinci* Surgery, some do not.^{8,9,10} Medical research requires careful analysis of patient populations, appropriate statistical technique and robust data collection. We encourage those interested in clinical evidence on the use of *da Vinci* Surgical Systems to explore relevant literature critically. For examples of such studies, please visit: <http://intuitivesurgical.com/company/clinical-evidence>.
- **Cost of *da Vinci* Surgery:** Cost-effective healthcare is a necessity. The ability to replace an open procedure with a minimally invasive one typically benefits the patient, the hospital and the healthcare system. In procedures such as prostatectomy and hysterectomy for complex conditions, *da Vinci* Surgery can have a positive impact on the clinical outcomes that are significant cost drivers in healthcare, including readmission rates,^{3,11} surgical site infections^{2,6,12,13} and complication rates.^{1,2,3,5,6,12,13} As the Affordable Care Act is implemented in the United States, technologies that improve metrics such as reductions in hospital borne infections, complications, readmissions and patient satisfaction will fare well. It is important to note that the majority of cost studies to date analyzing *da Vinci* Surgery have not accurately captured this downstream cost benefit and typically measure only direct costs of the procedure. Additionally, hospitals do not report costs in a consistent manner, and thus the cost of a given procedure may vary widely from study to study. However, some studies have compared the total cost to treat a patient using *da Vinci* Surgery versus open surgery including both up-front costs and downstream savings. These studies reported that *da Vinci* Surgery enabled surgeons to perform a minimally invasive procedure on a patient who would have previously received an open surgical procedure and that the use of *da Vinci* Surgery reduced the cost of treating some patients.^{13,14,15,16}
- **Medical Device Reports/Adverse Events:** The absolute number of *da Vinci* Surgeries performed has increased from a few thousand per year in 2002 to more than 450,000 in 2012. Total adverse event rates have remained low and in-line with historical trends. As the absolute number of procedures has risen significantly during this period, so has the number of complications and associated MDR reports. As noted above, many studies have reported these complication rates to be significantly lower than open surgery.

- **FDA:** There are many aspects to the FDA's post-market surveillance program, including conducting user surveys and inspections. The FDA has just completed an on-site inspection of Intuitive Surgical that included a quality system review, including Medical Device Reporting (MDR) compliance, surgeon training, human factors, recalls, and design control. The local FDA investigator issued four observations on a form known as FDA Form 483, which notifies the company of conditions that in the opinion of the FDA investigator are not in compliance with FDA requirements. We take our regulatory obligations seriously and have implemented corrective actions for all four observations. Earlier this year, the FDA initiated a small sample survey to gather information from a small number of hospitals regarding their experience with the *da Vinci* Surgical System. The survey is ongoing and the FDA may post its findings from this survey.
- **Litigation:** Intuitive Surgical also responds to legal claims diligently. We trust in the legal system as the proper forum to resolve these matters. Intuitive Surgical does not comment on pending litigation matters. However, Intuitive Surgical has actively engaged with media – responding to queries related to safety, outcomes, data and the value of *da Vinci* Surgery in extending the benefits of minimally invasive surgery to those who can and should benefit from it. In addition, if a hospital requests for us to do so, we will refer clinical experts and company spokespeople to media as an additional reference. If you have a media related question or require assistance please contact Intuitive Surgical's Corporate Communications group at 408-523-7337 or corpcomm@intusurg.com.

Every patient's outcome matters to us. Patient safety is our highest priority. Intuitive Surgical remains focused on the mission of extending the benefits of minimally invasive surgery to those patients who can and should benefit from it.

Questions? Please contact Angela Wonson, VP, Communications, (408) 523-8086 regarding media inquiries.

¹Bogges, J. F., et al. (2008). "A comparative study of 3 surgical methods for hysterectomy with staging for endometrial cancer: robotic assistance, laparoscopy, laparotomy." *American Journal of Obstetrics and Gynecology* 199(4): 360 e361-369.

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⁶Tewari A, et al. "Positive Surgical Margin and Perioperative Complication Rates of Primary Surgical Treatments for Prostate Cancer: A Systematic Review and Meta-Analysis Comparing Retropubic, Laparoscopic, and Robotic Prostatectomy." *Eur Urol*. 2012 Feb 24.

⁷Khalifeh A, et al. "Comparative Outcomes and Assessment of Trifecta in 500 Robotic and Laparoscopic Partial Nephrectomies: A Single Surgeon Experience." *J Urol*. 2012 Oct 16. pii: S0022-5347(12)05220-2. doi: 10.1016/j.juro.2012.10.021.

⁸Wright JD, Ananth CV, Lewin SN, et al. "Robotically assisted vs laparoscopic hysterectomy among women with benign gynecologic disease." *JAMA* 2013;309:689-98.

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¹⁰Schroek FR., Krupski TL, Sun L., et al. "Satisfaction and Regret after Open Retropubic or Robot-Assisted Laparoscopic Radical Prostatectomy." *Eur Urol* 2008 Oct; 54(4):785-93.

¹¹After adjusting for potential confounders, Chung et al found that patients undergoing robotic-assisted prostatectomy had a lower risk of 90-day re-admission than patients undergoing open prostatectomy. The odds of being re-admitted \leq 90 days after prostatectomy were comparable in the two groups.

Chung, SD et al. (2012), "Comparison of 90-day re-admission rates between open retropubic radical prostatectomy (RRP), laparoscopic RP (LRP) and robot-assisted laparoscopic prostatectomy (RALP)." *BJU International*, 110: E966-E971.

¹²Tollefson, MK et al. (2011). "Robotic-assisted Radical Prostatectomy Decreases the Incidence and Morbidity of Surgical Site Infections." *Urology*, 78(4):827-831.

¹³Lau, S., et al. (2012). "Outcomes and cost comparisons after introducing a robotics program for endometrial cancer surgery." *Obstetrics and Gynecology*. 119(4): 717-724.

¹⁴Bell, MC et al. (2008). "Comparison of outcomes and cost for endometrial cancer staging via traditional laparotomy, standard laparoscopy and robotic techniques." *Gynecologic Oncology*. Vol. 111, p. 407-411.

¹⁵Elliot, CS et al. (2012). "Robot-Assisted Versus Open Sacrocolpopexy: A Cost-Minimization Analysis." *Journal of Urology*. Vol. 187, 638-643

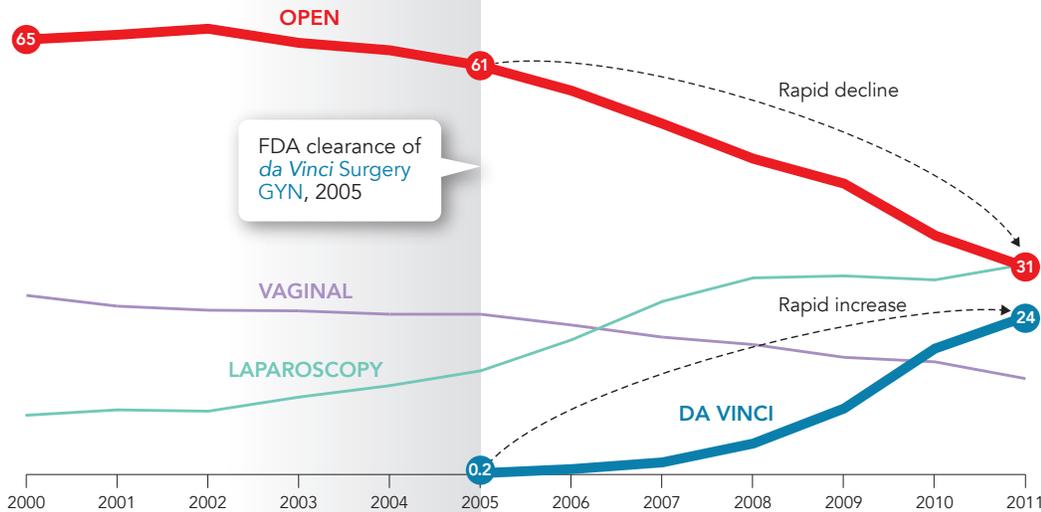
¹⁶Laydner, H et al. (2013). "Single institutional cost analysis of 325 robotic, laparoscopic, and open partial nephrectomies." *Journal of Urology*. Volume 81, Issue 3, March 2013, Pages 533-538.

Appendix

U.S. BENIGN HYSTERECTOMY MARKET BY MODALITY

Estimated Adoption of Minimally Invasive Surgery (MIS)

Percentage of all procedures



IMPACT OF ROBOTIC-ASSISTED SURGERY:

Prior to the introduction of robotics, many hysterectomies were performed via open incision. A number of complexities can prevent patients from receiving a traditional MIS approach.

Surgical complexities may include:

- High patient BMI
- Size of uterus
- Scarring from prior surgeries
- Multiple C-sections

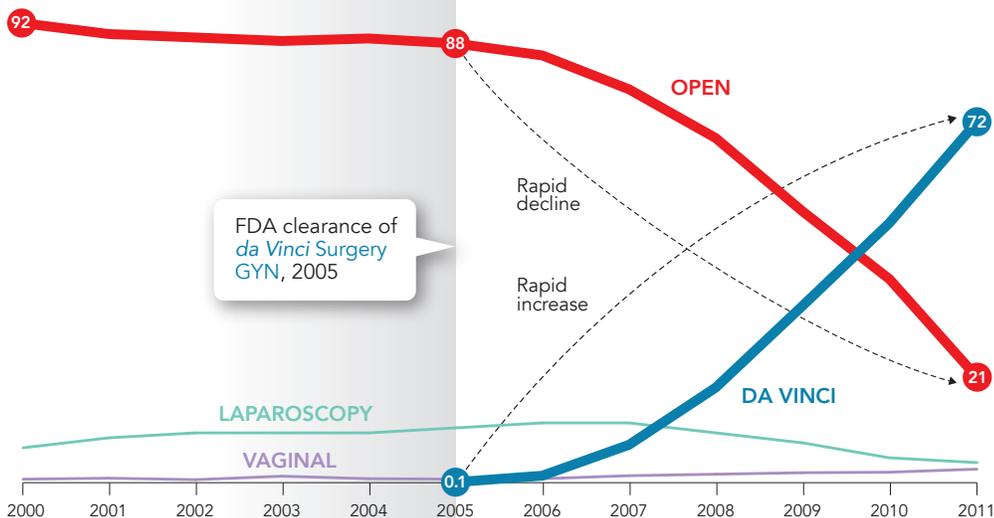
The enhanced visualization, precision, and control of the *da Vinci* Surgical System helps experienced surgeons overcome these complexities and has enabled this shift in the market.

1. Inpatient data: Nationwide Inpatient Sample (NIS), Healthcare Cost and Utilization Project (HCUP), Agency for Healthcare Research and Quality
 2. Outpatient data: Solucient® Database - Truven Health Analytics (Formerly Thomson-Reuters) 3. *da Vinci* data: ISI Internal Estimates

U.S. MALIGNANT HYSTERECTOMY MARKET BY MODALITY

Estimated Adoption of Minimally Invasive Surgery (MIS)

Percentage of all procedures



IMPACT OF ROBOTIC-ASSISTED SURGERY:

Since 2012, more than 70% of U.S. gynecologic cancer patients now receive a minimally invasive procedure.

Prior to robotic-assisted surgery, less than 15% of these patients received a minimally invasive surgical option.

A number of complexities can prevent patients from receiving a traditional MIS approach.

Surgical complexities include:

- Stage of disease
- High patient BMI
- Size of uterus

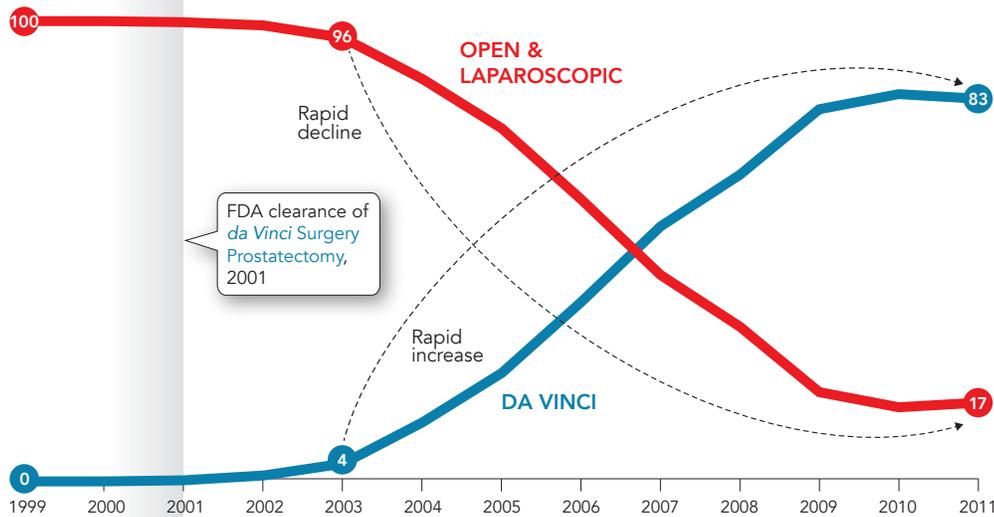
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 2. Outpatient data: Solucient® Database - Truven Health Analytics (Formerly Thomson-Reuters) 3. *da Vinci* data: ISI Internal Estimates

U.S. PROSTATECTOMY MARKET BY MODALITY

Estimated Adoption of Minimally Invasive Surgery (MIS)

Percentage of all procedures



1. Prostatectomy prevalence data: Nationwide Inpatient Sample (NIS), Healthcare Cost and Utilization Project (HCUP), Agency for Healthcare Research and Quality & Solucient® Database - Truven Health Analytics (Formerly Thomson-Reuters) 2. MIP percentage prior to introduction of robotic prostatectomy: Premiere Prospective Database 2004-2010 as cited by Davis et. Al. BJUI 2013 (accepted for publication) 3. da Vinci® Prostatectomy data: ISI Internal Estimates

IMPACT OF ROBOTIC SURGERY:

Since 2010 over 85% of men in the United States who undergo a prostatectomy benefit from a minimally invasive approach to the procedure. In 2004, prior to the widespread adoption of robotic surgery, less than 5% of men in the United States undergoing a prostatectomy received a minimally invasive approach via traditional laparoscopy².

A number of complexities can limit the patients who may benefit from minimally invasive procedures including:

- Prior abdominal surgery
- High Body Mass Index
- Enlarged prostate gland
- Advanced stage of disease

The enhanced visualization, precision, and control of the *da Vinci* Surgical System helps experienced surgeons to overcome these complexities and has enabled this shift in the market.

Important Information for Patients

Potential risks of any hysterectomy procedure include: Separation of the vaginal incision, blocked lung artery and urinary tract injury. In addition to these risks, there are risks related to minimally invasive surgery, including *da Vinci* Hysterectomy, such as hernia (bulging tissue at incision site).¹

Potential risks of any prostatectomy procedure include: Urinary and/or sexual dysfunction due to nerve damage, rectal or bowel injury, blocked artery in the lung, blocked bowel. In addition, there are risks related to minimally invasive surgery, including *da Vinci* Prostatectomy, such as hernia (bulging tissue/organ) at incision site.^{2,3}

All surgery presents risk, including *da Vinci* Surgery. Results, including cosmetic results, may vary. Serious complications may occur in any surgery, up to and including death. Examples of serious and life-threatening complications, which may require hospitalization, include injury to tissues or organs; bleeding; infection, and internal scarring that can cause long-lasting dysfunction or pain. Temporary pain or nerve injury has been linked to the inverted position often used during abdominal and pelvic surgery. Patients should understand that risks of surgery include potential for human error and potential for equipment failure. Risk specific to minimally invasive surgery may include: a longer operative time; the need to convert the procedure to other surgical techniques; the need for additional or larger incision sites; a longer operation or longer time under anesthesia than your surgeon originally predicts. Converting the procedure to open could mean a longer operative time, long time under anesthesia, and could lead to increased complications. Research suggests that there may be an increased risk of incision-site hernia with single-incision surgery. Patients who bleed easily, have abnormal blood clotting, are pregnant or morbidly obese are typically not candidates for minimally invasive surgery, including *da Vinci* Surgery. Other surgical approaches are available. Patients should review the risks associated with all surgical approaches. They should talk to their doctors about their surgical experience and to decide if *da Vinci* is right for them. For more complete information on surgical risks, safety and indications for use, please refer to

<http://www.davincisurgery.com/safety>.

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