Robotic Surgery-
Weighing the Benefits and Risks

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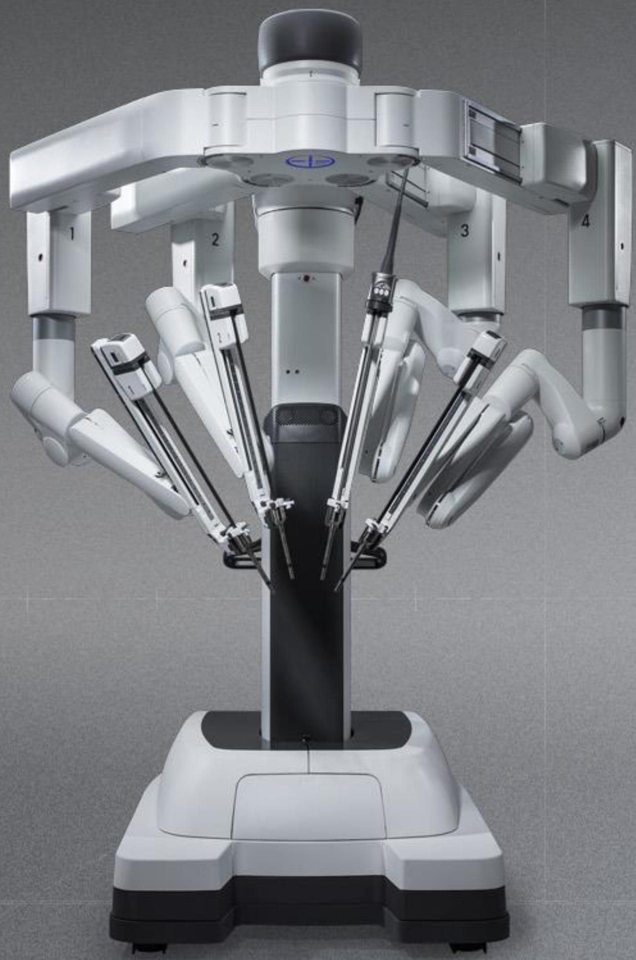
Director, Surgical Weight Loss
Director, Nonsurgical Weight Loss

PN 1018713-US Rev H 03/2018


3000
da Vinci


3000
da Vinci
3,000
Robotic Cases!
Dr Toder

4th Generation *DA VINCI XI* SURGICAL SYSTEM



Revolutionary Anatomical Access

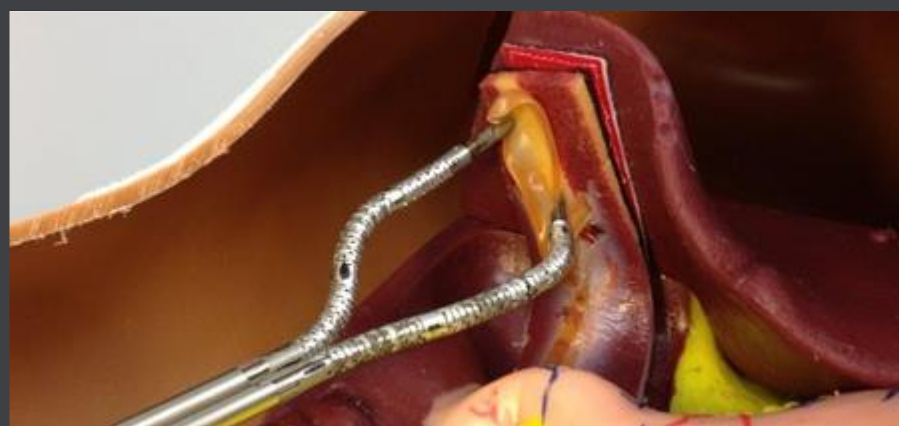
Crystal-clear 3D HD vision

Platform for Advanced Technologies

PN 1006780 Rev A 3/14

TITAN MEDICAL INC.

SPORT tm Tackles Complex Surgical Tasks



No 510 clearance from the FDA

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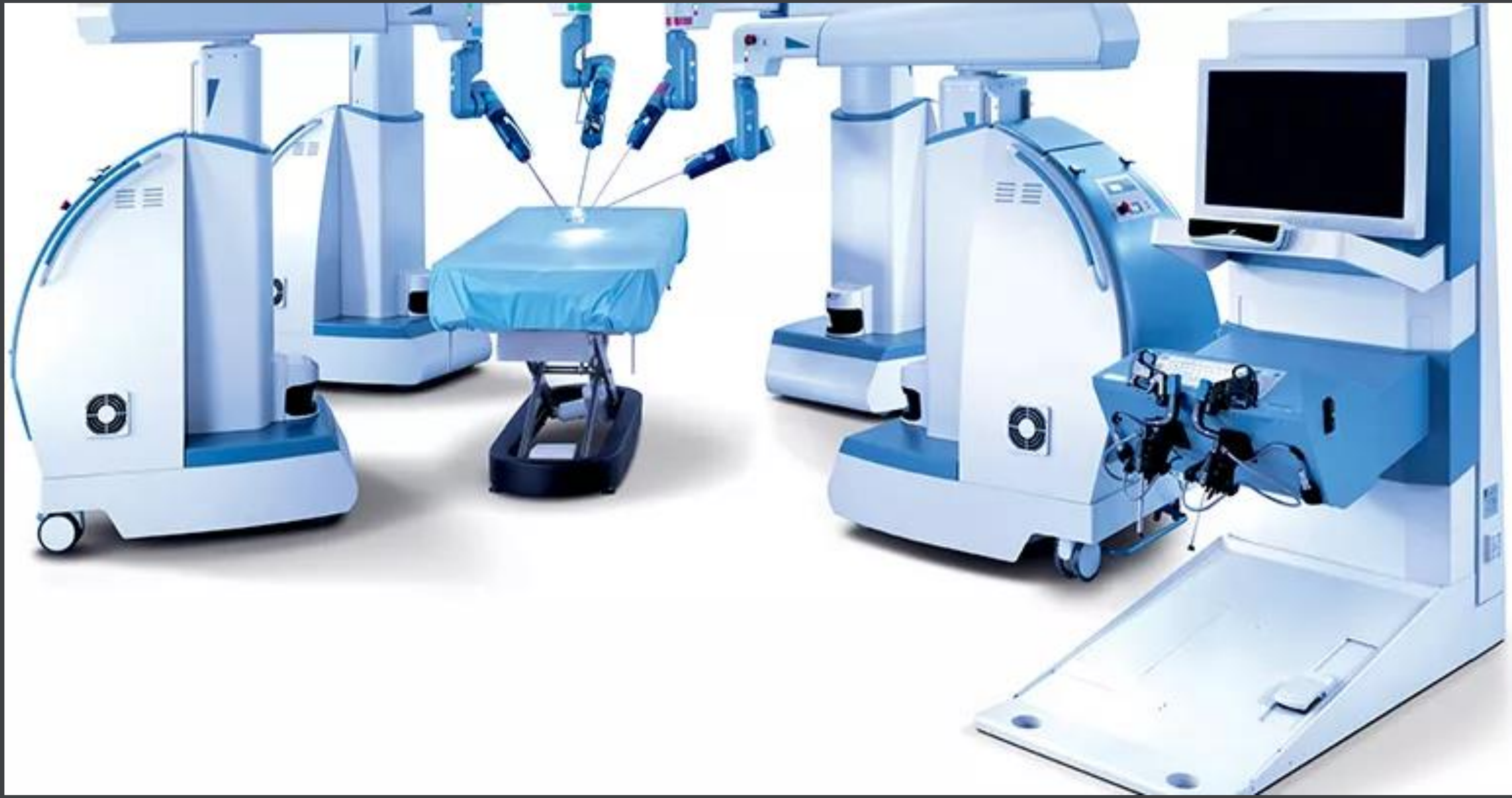
TransEnterix®



Senhance surgical robotic system

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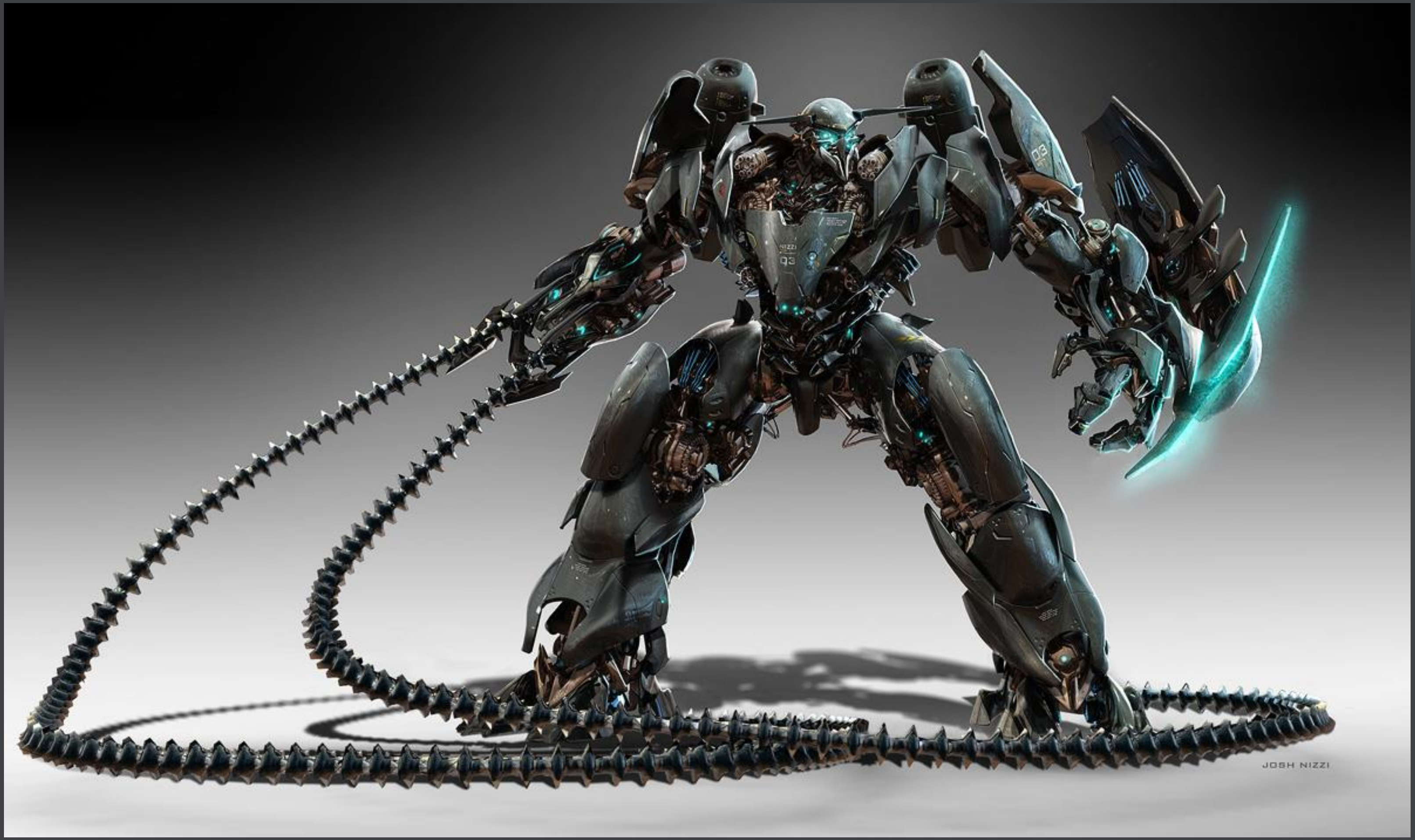
Alphabet


Medtronic
COVIDIEN

Who is my audience?



Why robotics in 2005

- Increasing **volume**
- Increasing **BMI**
- Multiple events converged
- Physical limitations herniated disc
- Adequate **access** to a system
- Trained **OR staff** eager to use their new skills

Pros and Cons

- Increase quality
- Decrease cost
- Create a better patient experience
- Will become the mainstay of surgical practice particularly with penetration in residencies

- No demonstrable difference in quality
- Increase cost
- No demonstrable change in patient experience
- Will be replaced by machine learning and AI

Robotic Weight Loss Surgery

2013 Mar-Apr;9 SOARD
Robotic-assisted Roux-en-Y gastric bypass: update from 2 high-volume centers.
Tieu K1, Allison N, Snyder B, Wilson T, Toder M, Wilson E.
BACKGROUND:
Laparoscopic Roux-en-Y gastric bypass (RYGB) is a challenging operation in the most experienced hands. Robotic surgery allows the capabilities of the minimally invasive surgeon to be extended. An increasing number of robotic gastric bypasses are being performed each year with the assumption that the complication rates are decreased. **The objectives of the present study were to review the results of robotic-assisted RYGB (RARYGB) from 2 high-volume centers, including 1 university and 1 private practice.**

METHODS:

We report the most recently compiled, **largest series of RARYGB in the world to show the effectiveness, morbidity, and mortality of this method. Databases were searched for patients undergoing RARYGB from 2002 to 2010, and the endpoints were recorded.**

RESULTS:

A total of **1100** RARYGBs matched our search. The patients had a mean preoperative age of **46.9 years**, mean weight of 131.9 kg, and mean body mass index of **47.9 kg/m(2)**. The mean operative time was **155 minutes. There were no conversions**. The mean body mass index was 39.8 kg/m(2) at 3 months postoperatively (79% follow-up). Complications were few, and included **2 cases of pulmonary embolism (.19%), 3 cases of deep venous thrombosis (.27%), 1 case of gastrojejunal anastomotic leak (.09%), and 9 cases of staple line bleeding (.82%). No patients died.**

CONCLUSION:

RARYGB is safe and effective. Although the operative time might be increased, the **complication rates, most notably of anastomotic leak, are extremely low.**

The ROLARR Randomized Clinical Trial

Effect of Robotic-Assisted vs Conventional Laparoscopic Surgery on Risk of Conversion to Open Laparotomy Among Patients Undergoing Resection for Rectal Cancer

David Jayne, MD1; Alessio Pigazzi, PhD2; Helen Marshall, MSc3; et al Julie Croft, BSc3; Neil Corrigan, MSc3; Joanne Copeland, BSc3; Phil Quirke, FMedSci4; Nick West, PhD4; Tero Rautio, PhD5; Niels Thomassen, MD6; Henry Tilney, MD7; Mark Gudgeon, MS7; Paolo Pietro Bianchi, MD8; Richard Edlin, PhD9; Claire Hulme, PhD10; Julia Brown, MSc3
Author Affiliations Article Information

JAMA. 2017

Question Does robotic-assisted laparoscopic surgery, as compared with conventional laparoscopic surgery, reduce the risk of conversion to laparotomy among patients undergoing surgery for rectal cancer?

Design, Setting, and Participants **Randomized clinical trial comparing robotic-assisted vs conventional laparoscopic surgery among 471 patients with rectal adenocarcinoma suitable for curative resection** conducted at 29 sites across 10 countries, including 40 surgeons. Recruitment of patients was from January 7, 2011, to September 30, 2014, follow-up was conducted at 30 days and 6 months, and final follow-up was on June 16, 2015.

Interventions Patients **were randomized to robotic-assisted (n = 237) or conventional (n = 234) laparoscopic rectal cancer resection**, performed by either high (upper rectum) or low (total rectum) anterior resection or abdominoperineal resection (rectum and perineum).

Main Outcomes and Measures The primary outcome was conversion to open laparotomy. Secondary end points included intraoperative and postoperative complications, circumferentia resection margin positivity (CRM+) and other pathological outcomes, quality of life (36-Item Short Form Survey and 20-item Multidimensional Fatigue Inventory), bladder and sexual dysfunction (International Prostate Symptom Score, International Index of Erectile Function, a Female Sexual Function Index), and oncological outcomes.

Results Among 471 randomized patients (mean [SD] age, 64.9 [11.0] years; 320 [67.9%] men), 466 (98.9%) completed the study. The overall rate of conversion to open laparotomy was 10.1 19 of 236 patients **(8.1%) in the robotic-assisted laparoscopic group** and 28 of 230 patients **(12.2%) in the conventional laparoscopic group** (unadjusted risk difference = 4.1% [95% CI, −1.4% to 9.6%]; adjusted odds ratio = 0.61 [95% CI, 0.31 to 1.21]; P = .16). The overall CRM+ ra was 5.7%; **CRM+ occurred in 14 (6.3%) of 224 patients in the conventional laparoscopic group** and 12 **(5.1%) of 235 patients in the robotic-assisted laparoscopic group** (unadjusted risk difference = 1.1% [95% CI, −3.1% to 5.4%]; adjusted odds ratio = 0.78 [95% CI, 0.35 to 1.76]; P = .56). Of the other 8 reported prespecified secondary end points, **including intraoperative complications, postoperative complications, plane of surgery, 30-day mortality, bladder dysfunction, and sexual dysfunction, none showed a statistically significant difference** betwe groups.

Conclusions and Relevance Among patients with rectal adenocarcinoma suitable for curative resection, robotic-assisted laparoscopic surgery, as compared with conventional laparoscopic surgery, did not significantly reduce the risk of conversion to open laparotomy. These findings suggest that robotic-assisted laparoscopic surgery, **when performed by surgeons with varying experience with robotic surgery, does not confer an advantage in rectal cancer resection**.

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Inguinal Hernias

Minimally invasive inguinal hernia repair is superior to open: a national database review.
Pokala B1,2, Armijo PR2, Flores L2,3, Hennings D1,2, Oleynikov D4,5.
PURPOSE:
Many publications have focused on single-surgeon or single-center data, comparing surgical approach in inguinal hernia repair. **This study evaluated outcomes in patients who underwent open (OIHR), laparoscopic (LIHR) or robotic (RIHR) inguinal hernia repair using a national database.**
METHODS:
The Vizient clinical database was queried using ICD-9 and ICD-10 procedure and diagnosis cod for RIHR, LIHR, and OIHR from **2013 to 2017**. Elective procedures classified as minor or moderate risk severity were included. **Complications, 30-day readmission, mortality, LOS, and intra-hospital opiate utilization were analyzed** using IBM SPSS v.23.0.

RESULTS:

3547 patients (OIHR: N = 2413, LIHR: N = 540, RIHR: N = 594) were included in the study. **Majority were male** (OIHR 84.1%, LIHR 80.4%, RIHR 95.3%), **≥ 51 years** (OIHR 81.5%, LIHR 81.7 RIHR 95.3%), and **Caucasian** (OIHR 75.7%, LIHR 77.0%, RIHR 81.5%). RIHR had the least overall complications (0.67%) compared to LIHR (4.44%) and OIHR (3.85%), $p < 0.05$. **OIHR had the highest postoperative infection rate** (8.33%), versus LIHR (0.56%) and RIHR (0.0%), $p < 0.05$. **OIHR had longer length of stay** (3.57 ± 4.1 days) when compared to both groups (LIHR 2.2 ± 2. days, RIHR 1.75 ± 1.62 days), $p < 0.001$. **OIHR had higher 30-day readmission rates** (3.61%) compared to RIHR (0.84%), $p = 0.001$. Mortality was similar between groups (OIHR 0.21%, LIHR 0.19%, RIHR 0.17%), $p = 0.081$. **Opiate use was higher with OIHR** (96.0%), compared to both LIHR (93.1%), and RIHR (93.8%), $p = 0.004$.

CONCLUSION:

RIHR outcomes were improved compared to OIHR or LIHR. OIHR had the highest rate of opiat use, there was no difference between LIHR and RIHR. Further studies are needed to determin the role of RIHR and to assess whether surgeon or patient selection contributes to outcomes.

KEYWORDS:

Cost; Inguinal hernia; Minimally invasive surgery; Open surgery; Opiate use; Outcomes

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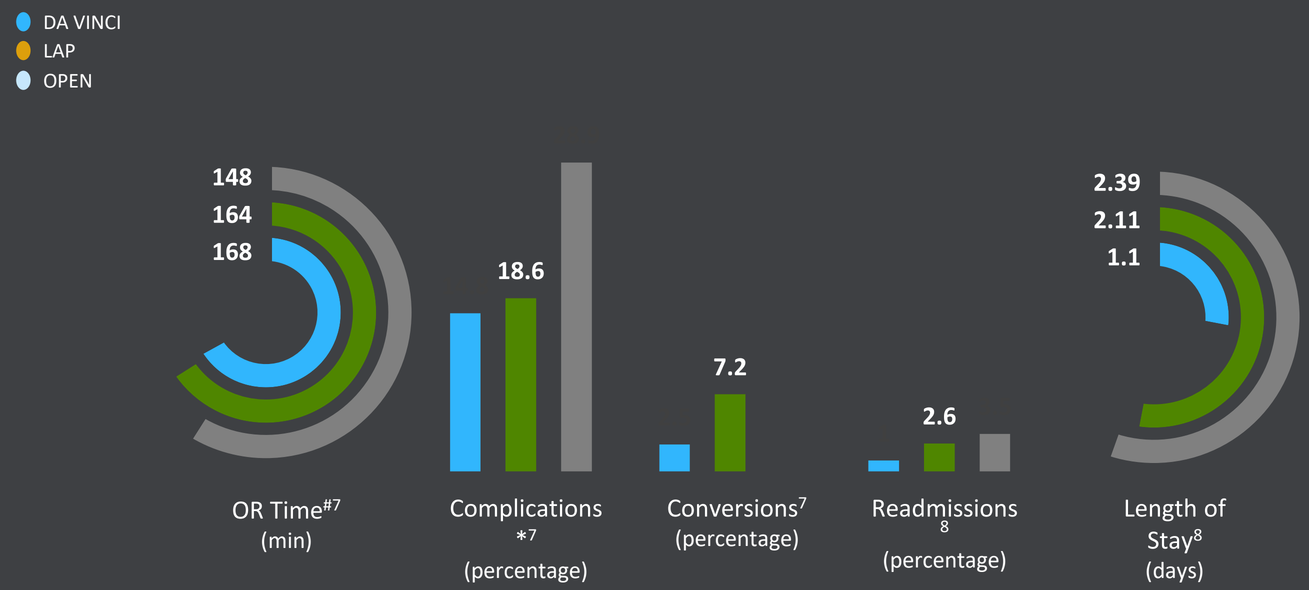
Clinical Outcomes – Benign Hysterectomy

and Potential Cost Offsets^+



^ Data for surgical site infections not reported.
+ 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.
# Surgery time decreased with progressive experience, falling below three hours after 100 cases (2.8 hours for the last 25 cases).
* Complications: Based on blended rate for Benign Hysterectomy DRG; $7,263 (2016 CMS Inpatient Facility Reimbursement); Overall complications calculation based on 0.5 x DRG

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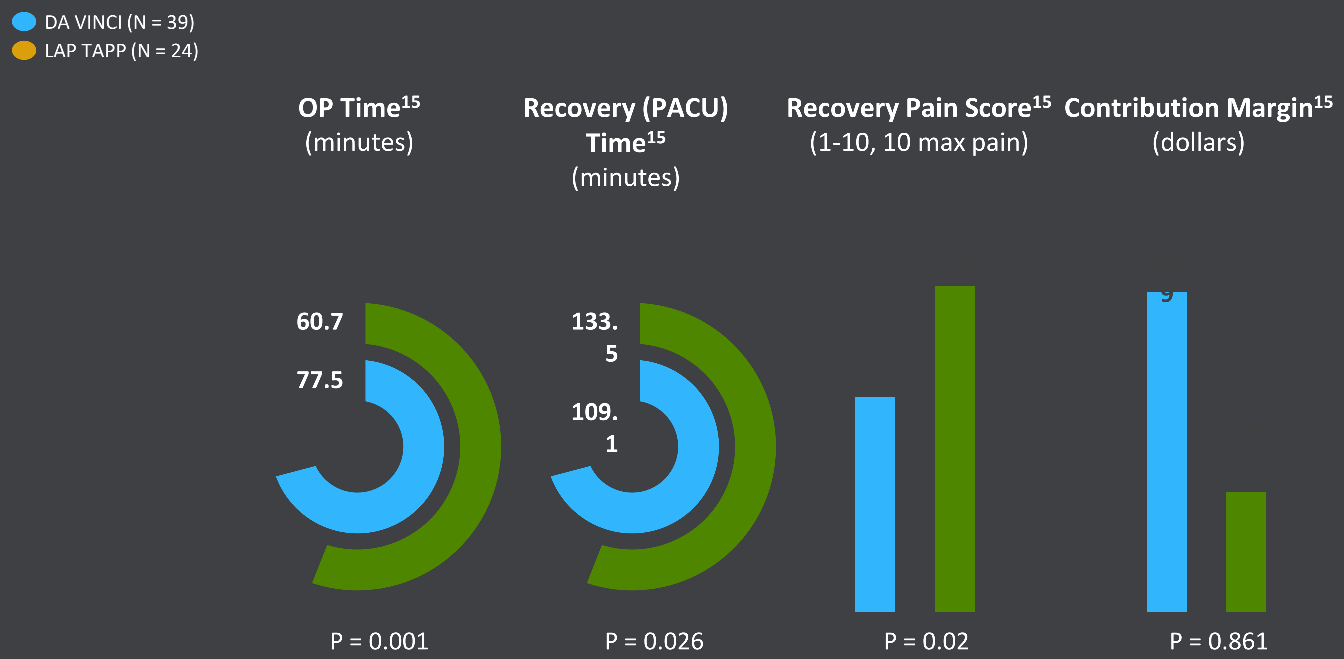
Clinical Outcomes – Inguinal Hernia Repair

and Impact on Contribution Margin*



- Longer operative times with da Vinci® inguinal hernia were offset by shorter amount of time in the PACU
- Pain scores were less in the PACU with da Vinci inguinal hernia compared to TAPP laparoscopic patients
- Contribution margins were noted to be nearly equivalent

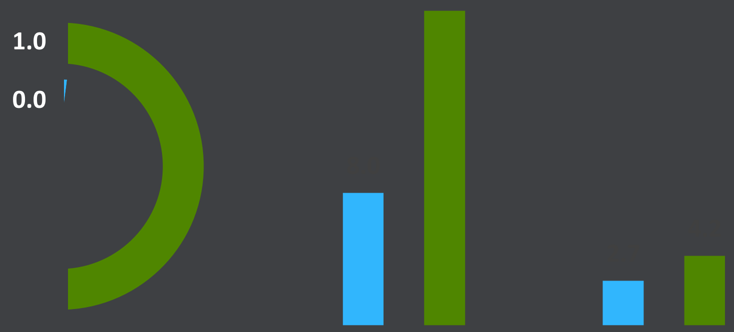
* Not statistically significant

Clinical Outcomes – Incisional Hernia

and Potential Cost Offsets^

DA VINCI (n = 186)
LAP (n = 452)

Length of Stay (days)	**Complications** (percentage)	**Readmission** (percentage)



Length of Stay[14] (days)	Complications*[14] (percentage)	Readmission[14] (percentage)
p <0.001	p <0.001	p = 0.4*

^ Data for surgical site infections, OR time and conversions were not reported in the manuscript.
* Not statistically significant

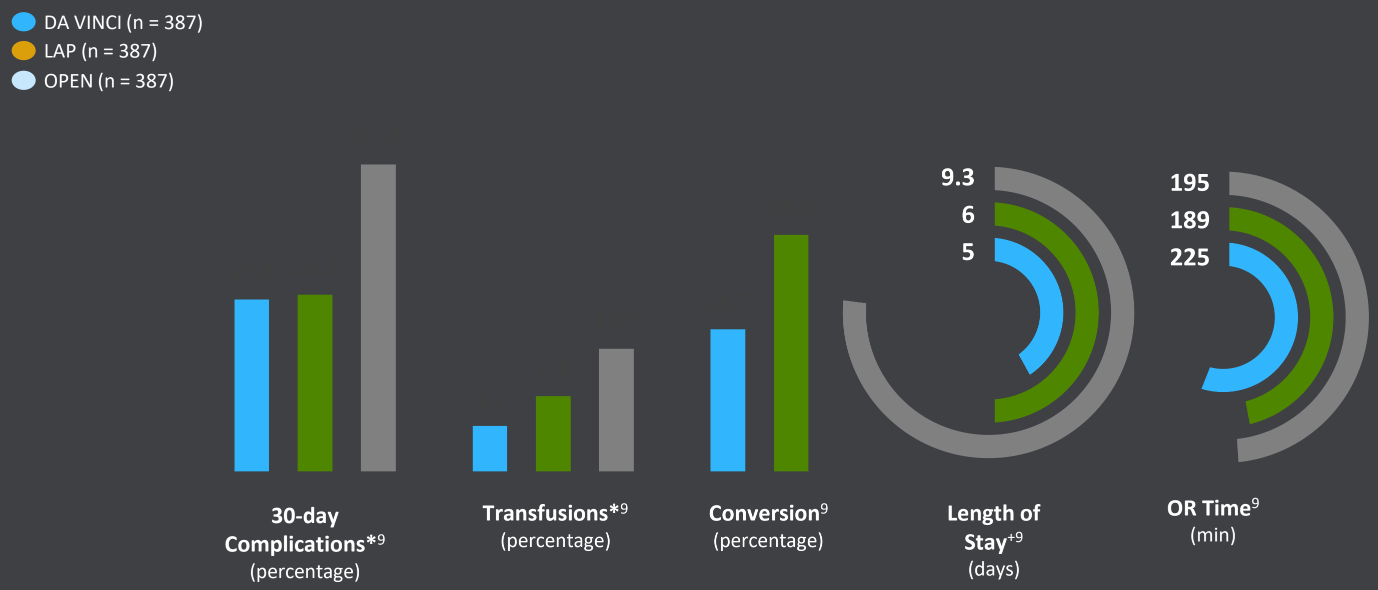
Clinical Outcomes – Complex Ventral Hernia Robotic & Open Transverse Abdominis Release[13]

and Potential Cost Offsets

* Not statistically significant

Clinical Outcomes – Colon Resection

and Potential Cost Offsets^



^ Data for readmission and surgical site infections not reported in the peer reviewed manuscript.

* Complications: Based on blended rate for Colon Resection DRG; $15,901 (2016 CM6 Inpatient Facility Reimbursement); overall complications calculation based on 0.5 x DRG.

+ Outcomes comparisons were made among unmatched patient populations.

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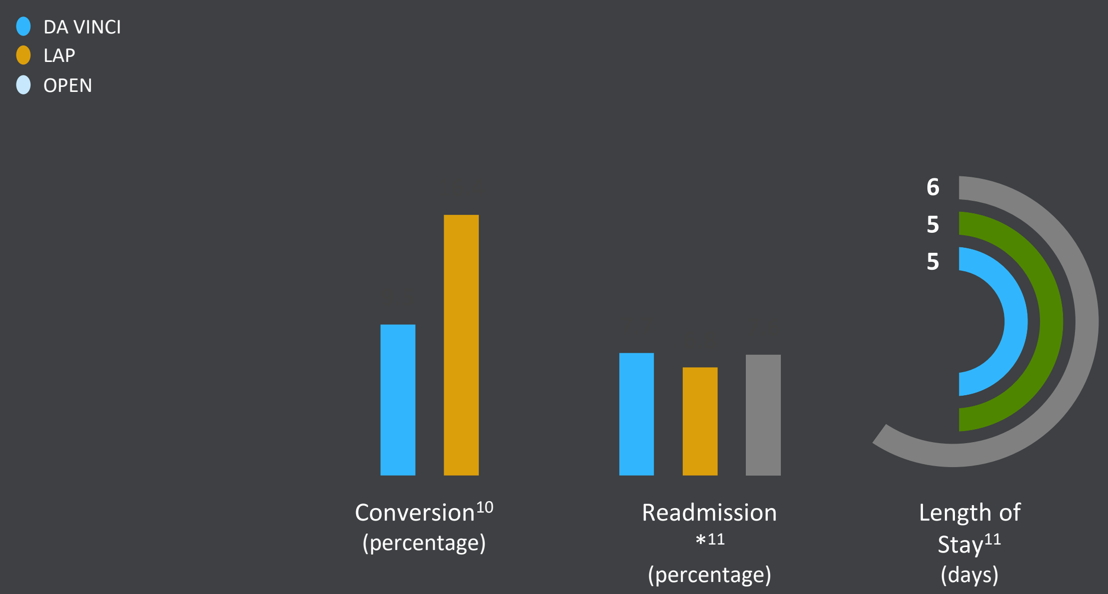
Clinical Outcomes – Rectal Resection

and Potential Cost Offsets^



^ Data for complications, SSI and operative time not reported in the peer reviewed manuscript.

* Not statistically significant.

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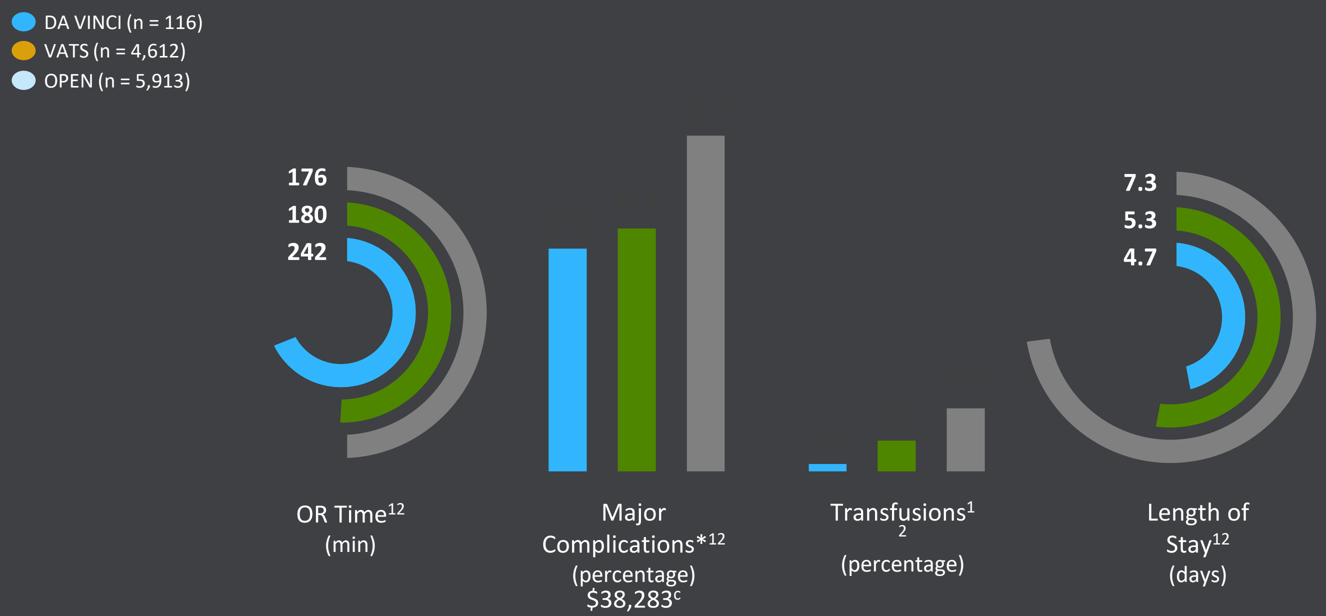
Clinical Outcomes – Lobectomy

and Potential Cost Offsets^+



^ Data for readmissions, surgical site infections and VATS conversions to open surgery not reported in the peer reviewed manuscript.

+ 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.

* Not statistically significant.

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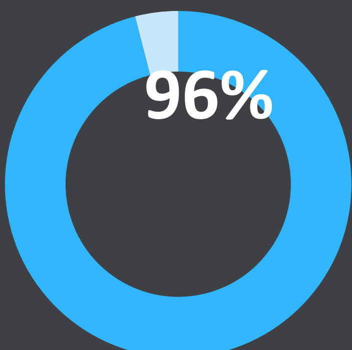
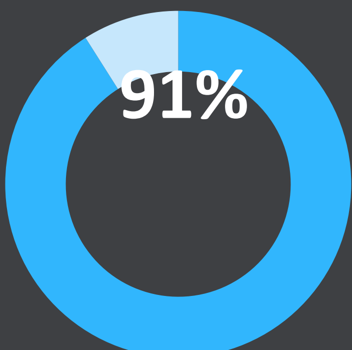
Attracting the Next Generation of Surgeons

Proliferation of da Vinci® Surgery in Residency and Fellowship Programs[21-24]

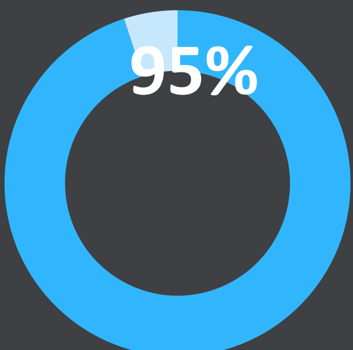
Urology Residency Programs with da Vinci Surgery[21]*



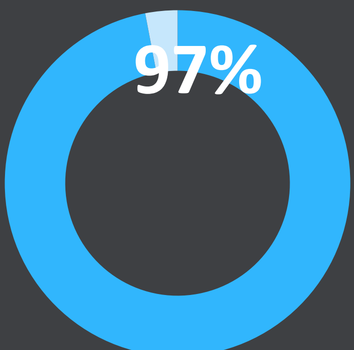
GYN Residents Reporting Staff Surgeons Performing da Vinci Surgery for GYN[22]



GYN-Oncology Fellowships with da Vinci Training[23]



U.S. Colorectal Fellowship with da Vinci Basic Training[24]



*Source: ISI internal analysis based on 2014 Premier data. The data have not been peer-reviewed and have not been published.

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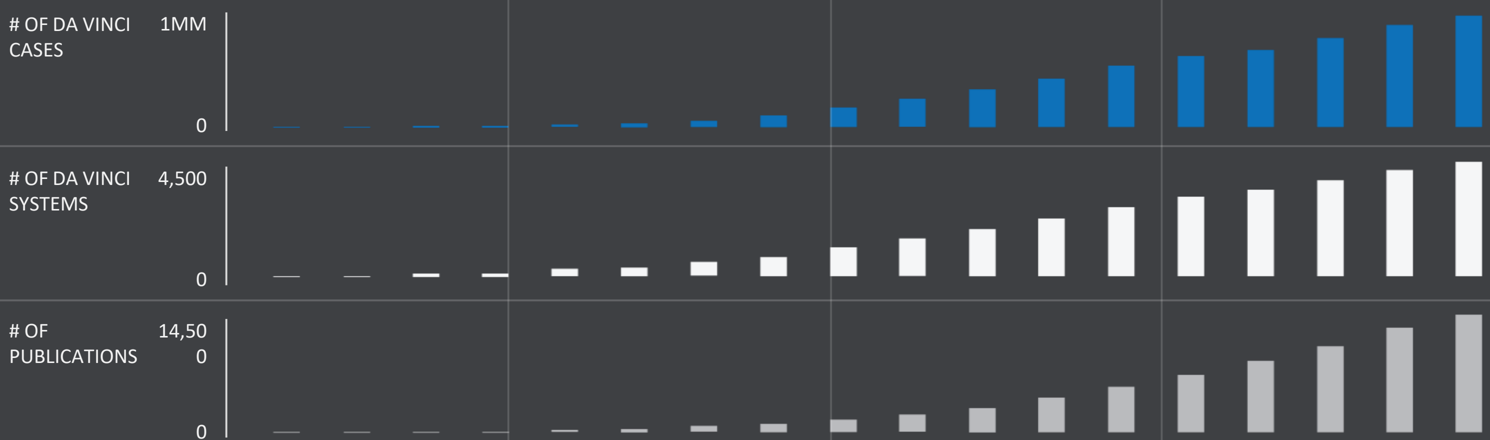
Evolution of Da Vinci® Ecosystem by Intuitive

2000 — 2006 — 2009 — 2014 — 2017

	2000	2006	2009	2014
INNOVATION & INTEGRATION	▪ (2000) GEN 1 - da Vinci® System ▪ (2004) 4th arm upgrade	▪ (2006) GEN2 - da Vinci S® System ▪ (2007) 3DHD Vision	▪ (2009) GEN3 - da Vinci Si® System ▪ (2009) Dual Console ▪ (2011) Single-Site® technology ▪ (2011) Firefly® imaging ▪ (2013) Advanced instruments	▪ (2014) GEN4 - da Vinci® Xi System ▪ (2014) Integrated energy ▪ (2015) Integrated table motion ▪ (2016) Expanded instrument portfolio ▪ (2017) da Vinci X® System GEN4 integration
TRAINING & EDUCATION*	▪ Hands-on technology training ▪ Online training ▪ Peer-to-peer education ▪ Continuing education	▪ Hands-on technology training ▪ Online training ▪ Peer-to-peer education ▪ Continuing education ▪ Fellowship training ▪ Research grant support	▪ Hands-on technology training ▪ Online training ▪ Peer-to-peer education ▪ Continuing education ▪ Remote mentoring and case observations ▪ Skills Simulator	▪ Hands-on technology training ▪ Online training ▪ Peer-to-peer education ▪ Continuing education ▪ Sterile reprocessing Support ▪ Enhanced remote proctoring program
SUPPORT & ANALYTICS	▪ 24/7/365 technical support ▪ Clinical support representative ▪ Field engineering support	▪ Automated technical support system ▪ 24-hour critical part replacement	▪ da Vinci OnSite predictive maintenance ▪ Technology integration & OR optimization	▪ Sterile reprocessing support ▪ Program benchmarking ▪ Procedure economics ▪ Flexible acquisition models ▪ Healthcare economics analytics



*Training offered by Intuitive is limited to the use of its products and does not replace the necessary medical training and experience required to perform surgery. Intuitive additionally facilitates various educational and training opportunities conducted by licensed medical professionals.

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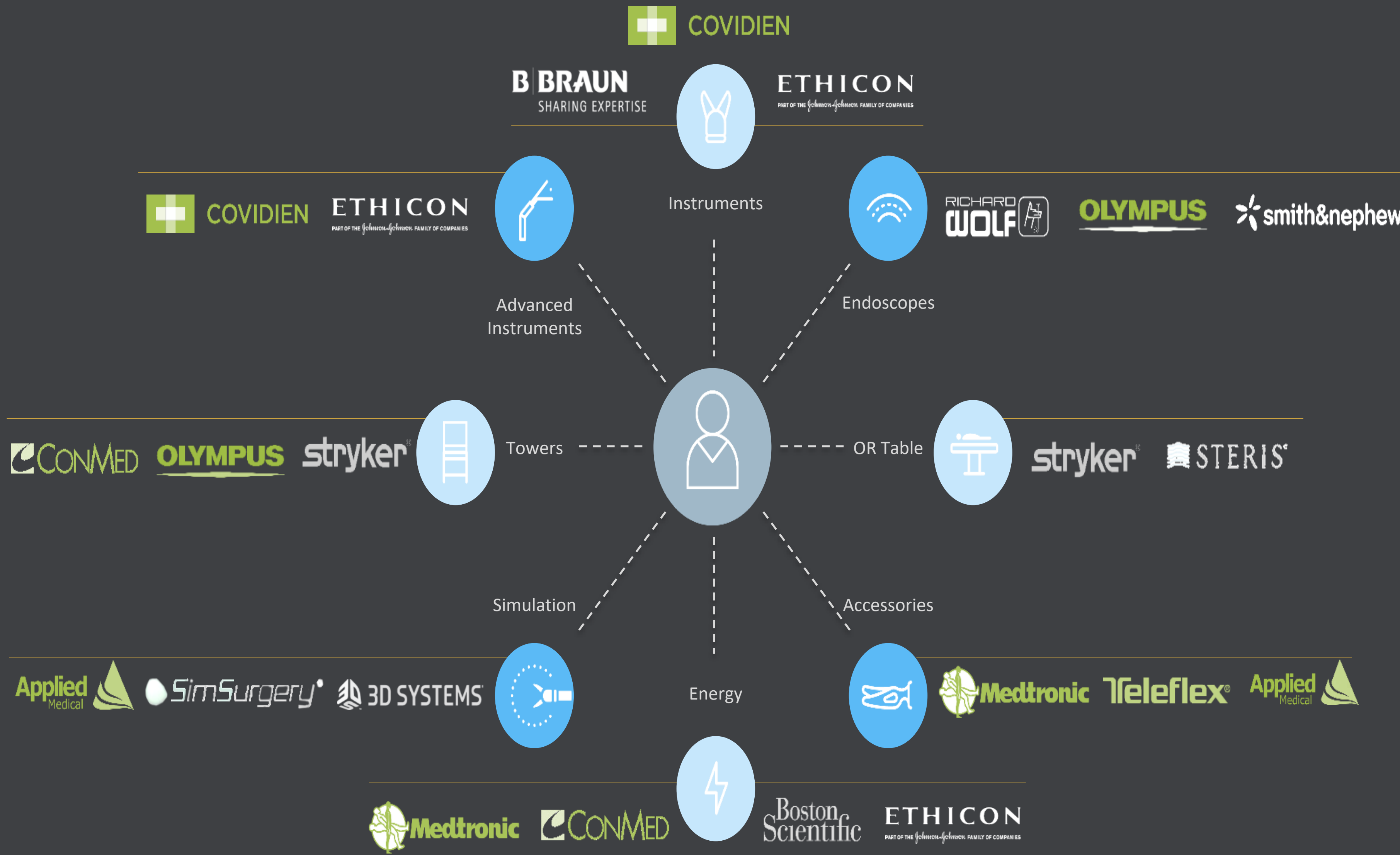
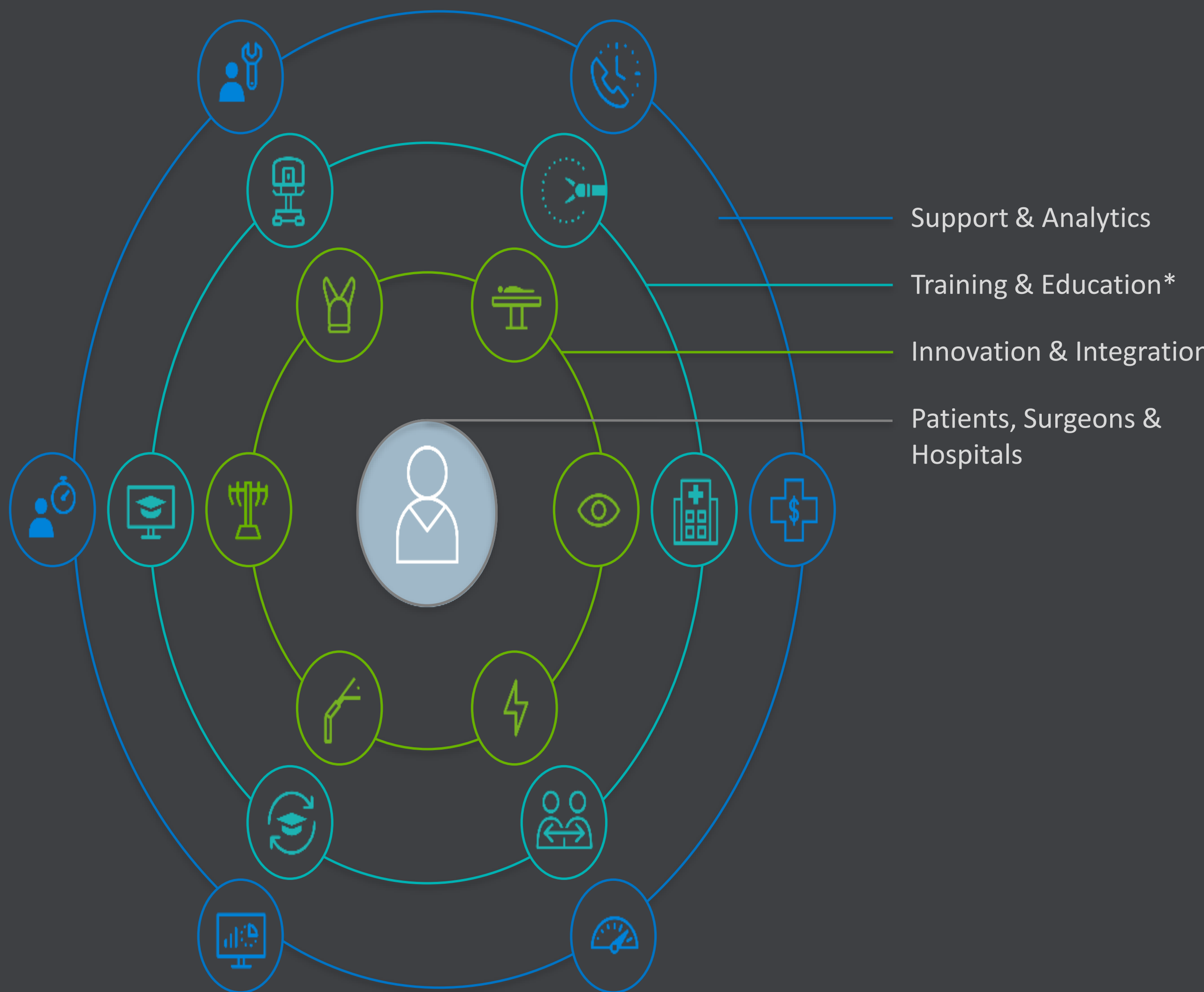
A Disconnected Environment
Laparoscopy



Da Vinci® Ecosystem by Intuitive



*Training offered by Intuitive is limited to the use of its products and does not replace the necessary medical training and experience required to perform surgery. Intuitive additionally facilitates various educational and training opportunities conducted by licensed medical professionals.

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Why robotics in 2019

- **Optics.** Three dimensional HD image, ability to magnify without moving the telescope minimizing crowding in confined spaces
- **Wrists.** Handsewn anastamoses minimize stricture and leak rates
- **Standardize.** Reproduce surgery for a broad range of BMI and abdominal wall contours
- **Complexity.** Meticulous dissection and suturing facilitates the complex surgeries being done minimally invasively
- **Ergonomics.** Dramatically improves surgeon ergonomics minimizing fatigue and musculoskeletal strain
- **Leveraging technology**. Expensive computer assisted surgery is not going away. Robotics in the OR will continue to disrupt the way we do surgery in many positive ways.

The goal is to make MIS an option for even complex procedures with help from computers and mechanics.

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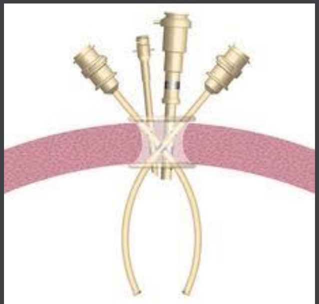
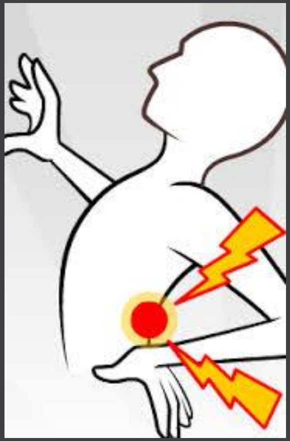
Wrists/Dexterity

Emerging enhancements

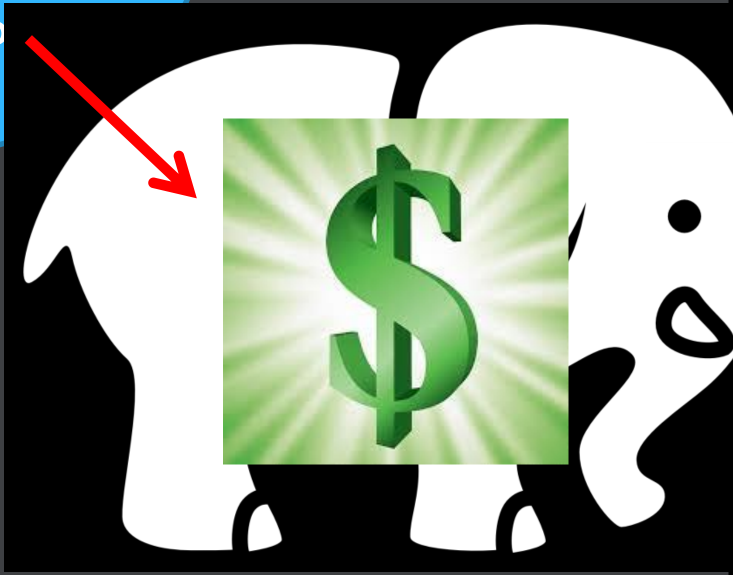


Shouldn't everyone be doing Robotic surgery?



ergonomics

3D high def imaging



April 30, 2019 JAMA

Is It Time for Safeguards in the Adoption of Robotic Surgery?

Kyle H. Sheetz, MD, MSc1,2; Justin B. Dimick, MD, MPH1,2

On February 28, 2019, the US Food and Drug Administration (FDA) released a safety communication that cautioned patients, surgeons, and health care organizations about the use of robotic-assisted surgical systems for the management of breast cancer and other cancers.1 This safety communication cited **concerns that evidence to support the use of robotic-assisted surgery for the management of these cancers was limited and may even be associated with shorter long-term survival compared with other surgical approaches.**

Trends in the Use of Robotic-Assisted Surgery

Several broader shifts in surgical practice make this FDA warning particularly timely. The use of robotic-assisted surgery has **increased more than 3-fold in the past decade**, and the United States is now the largest market for t technology in the world—procedure volumes exceeded 600 000 in 2017 alone.2 The diffusion of robotic-assisted surgical procedures is concentrated within the fields **of urology, gynecology, and general surgery**. For these specialties, the technology is often marketed as a tool to mitigate some of the technical or anatomic challenges associated with specific surgical procedures. An additional justification for robotic-assisted surgery is that it **increases patient access to safer, minimally invasive operations.**

Existing Evidence of Questionable Benefits

To date, **most studies demonstrating potential benefits of robotic-assisted surgery have been small, single-centered reports without rigorous controls. There remains little robust evidence to suggest that robotic-assisted surgical procedures are superior** to existing open or minimally invasive (laparoscopic) approaches. For example, ROLARR trial randomized 471 patients to undergo either laparoscopic or robotic-assisted low anterior resection f rectal cancer.3 This study found no differences in the rates of complications, conversions to open procedures, or quality of oncologic resection between the groups. A large observational study published in 2017 involving 23 75 patients undergoing radical nephrectomy also found no significant differences in complications, blood transfusio or length of hospital stay between laparoscopic and robotic-assisted surgery, despite robotic-assisted surgery bei associated with almost $3000 higher 90-day direct hospital costs.4

Emerging Evidence of Potential Harm

The FDA's safety communication is also timely in the context of 2 complementary studies published in 2018 (1 randomized trial and 1 observational study) that **suggested that minimally invasive radical hysterectomy and robotic-assisted surgery, in particular, were associated with shorter overall survival in patients with cervical cancer**.5,6 Using population-based data, Melamed and colleagues5 demonstrated that in just 5 years (2006-2010 the rapid adoption of minimally invasive surgery was associated with a significant decline in 4-year relative surviv rates for early-stage cervical cancer among all women undergoing radical hysterectomy.

In the FDA's safety communication, **the agency encouraged numerous groups, including research institutions, clinical societies, and device manufacturers, to work collaboratively to develop better data on the safety and efficacy of robotic-assisted surgery**. The FDA also encouraged patients and surgeons to have more open dialogue about the risks and benefits of robotic-assisted surgery, particularly within the context of surgeon experience wit robotic technologies. However, several additional short- and long-term priorities deserve greater attention.

Insurance Coverage

While there is disagreement regarding the benefits of robotic-assisted surgery, considerable evidence suggests th these procedures are more expensive than other approaches. Although some may suggest that these costs are le relevant to patients because they are largely borne by hospitals, it will remain difficult to completely shield patier from higher overall costs as robotic-assisted surgery continues to diffuse at a rapid rate. Higher hospital costs will eventually be transferred to patients in the form of higher insurance premiums.

With unclear clinical benefits and even potential harms, payers should emphasize evidence-based coverage of emerging robotic-assisted procedures. The FDA and the Centers for Medicare & Medicaid Services should exercis their ability to provide coverage with evidence development.7 This action has been previously applied to unprove procedural interventions, such as carotid artery stenting, when questions about their effectiveness were accompanied by concern for patient harm. This approach could facilitate the **creation of registries that could be used to monitor the allocation and safety of robotic-assisted surgical procedures**. It also may allow Medicare ar other payers to make coverage decisions that stipulate certain criteria from surgeons and hospitals (eg, proficienc volume, or participation in clinical trials).

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Surgeon Credentialing

Developing clinical registries will take time. For now, **the patient safety imperative lies within hospitals that credential surgeons to perform robotic-assisted surgical procedures**.8 At many institutions, surgeons are granted global privileges for robotic-assisted surgery. After voluntary skills courses or hands-on proctoring from other surgeons, they are free to use the robotic surgical technology at their discretion. Historically, surgeons who completed proctoring in as few as 2 robotic-assisted surgical procedures could begin to integrate robotic-assisted surgery into their practice.

This approach to credentialing is problematic for 2 reasons. First, it does not consider the full scope of procedures that surgeons m choose to perform robotically. The training of surgeons generally focuses on individual operations (eg, rectal cancer surgery). As a result, some surgeons may lack sufficient experience in other clinical domains or anatomic regions in which robotic-assisted surge is technically feasible. Second, this method of credentialing ignores learning curves, which may place patients in unsafe situations surgeons fail to eclipse their learning curve. It also groups surgeons under common learning curves that do not account for their p experience with that specific procedure or with minimally invasive surgical techniques in general. To address these issues, hospita and health care systems should ensure that surgeons are credentialed to perform a narrow scope of robot-assisted surgical procedures for which they have attained proficiency-based benchmarks.

Transparency and Informed Consent

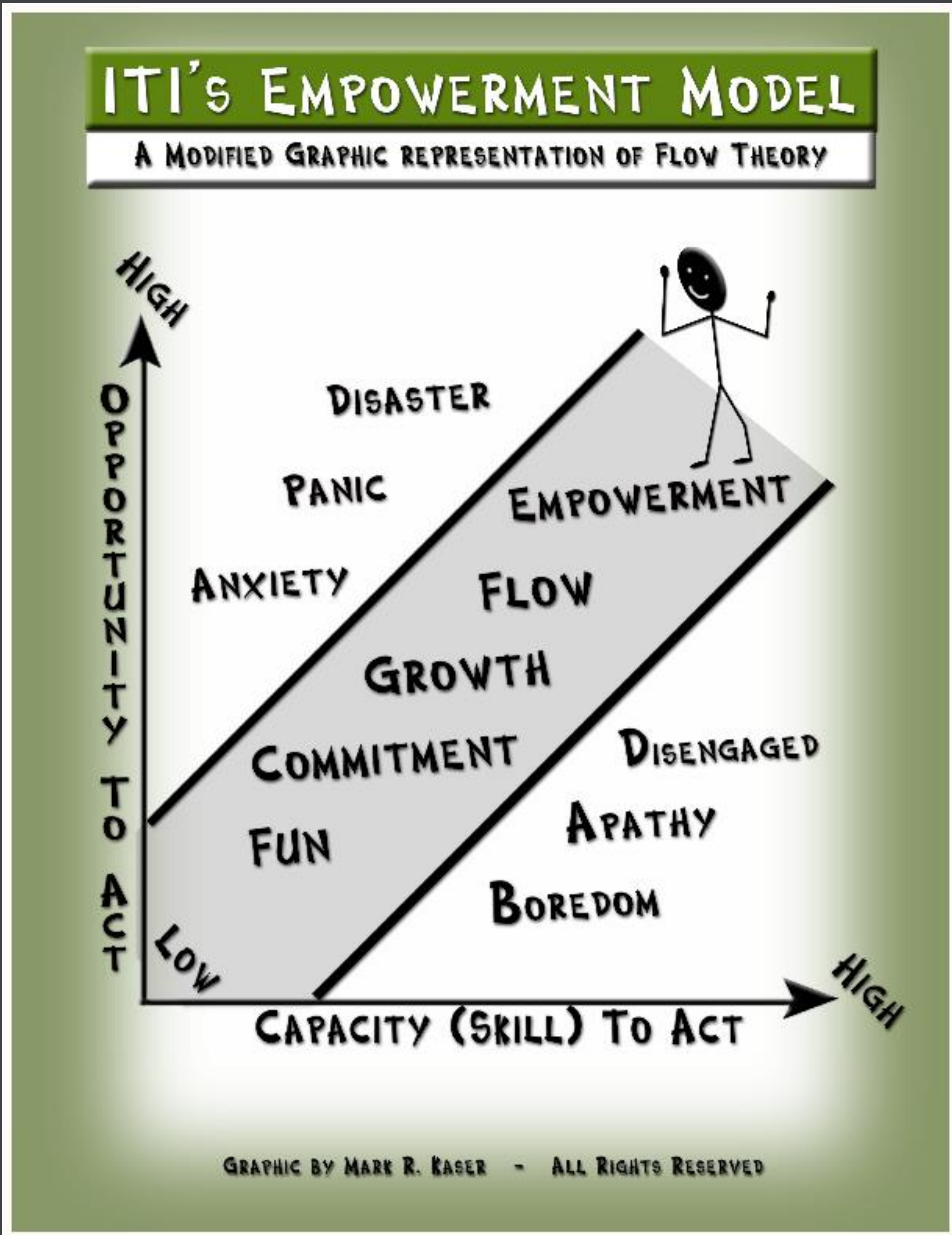
A common trend that is rarely discussed is that when hospitals acquire robotic systems, surgeons will often enhance their robotic surgical skills by "practicing" with less complex procedures. While manufacturers market robotic approaches to more complex operations, such as radical hysterectomy and low anterior resection for rectal cancer, many surgeons apply robot-assisted techniq across myriad procedures.

For example, a general surgeon may earn robotic privileges based on his or her experience performing rectal cancer surgical procedures. To increase skill or broaden the scope of robotic-assisted practice, the surgeon may start to perform other, less compl operations robotically. These procedures might include cholecystectomy, inguinal hernia repair, or appendectomy. Few would argu that there are any real benefits derived from performing these procedures robotically. Aside from the expense, it remains unknow whether this approach increases the risk of harm to the patient.

Within reason, hospitals and health care systems should require procedure-specific training and proctoring for surgeons looking to expand the scope of their robotic-assisted practice. In addition, as written in the FDA safety communication,1 surgeons should disclose information on the overall effectiveness of robotic procedures relative to other approaches and their specific experience performing robotic surgery to patients when obtaining informed consent.

Conclusions

The FDA's safety communication is particularly important and timely given the rapid diffusion of robotic-assisted surgery. However several important factors have the potential to diminish the value and safety of common surgical procedures. **Payers, hospitals, and surgeons can take immediate steps to ensure that certain safeguards remain in place until the evidence for or against the use of robotic-assisted surgery has time to mature.**



***Mike Smith**
Maine Winter Sports Center

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Robotic Steering Committee

- Participate in developing and following credentialing guidelines
- Follow progress of new adopters or the addition of new procedures for experienced robotic surgeons
- Review outcomes
- Use senior mentors regularly
- Include service line champions-Uro, Gyn, General, Bariatric, Colorectal, Thoracic, ENT

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How to Sustain your Program

“This company believes in sustainable development. We don’t think yours is.”

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100 Cases!!!

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