Background information

Intent

The intent of this presentation is to provide data from a **single publication.**

This presentation must **not be considered as a substitute for a comprehensive literature review** for inclusion of all relevant outcomes.

We encourage all key stakeholders (e.g., surgeons, hospital executives, hospital robotic coordinators, etc.) to **review all available published materials and their own data** in order to make an informed decision.

Published literature

In order to provide benefit and risk information, Intuitive reviews the **highest available level of evidence** on representative procedures.

Intuitive strives to provide a **complete, fair, and balanced view of the clinical literature.** However, the selected publication 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 physicians to **review the original publications and all available literature** in order to make an informed decision. Clinical studies are available at pubmed.gov.

Clinical outcomes: Published literature

To provide a **complete, fair, and balanced view of the clinical literature**, Intuitive identified the following set of nine standard clinical outcomes to be reported for published literature, along with outcomes pertaining to primary intent of the publication.

Transfusion and/or estimated blood loss

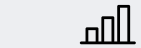
Conversion rate
vs. laparoscopy only

Reoperation rate
30 days or other

Operative time

Complication rate
30 days or other
Intraoperative and/or postoperative

Positive surgical margin rate and/or **lymph node yield** and/or **lymph node upstaging**



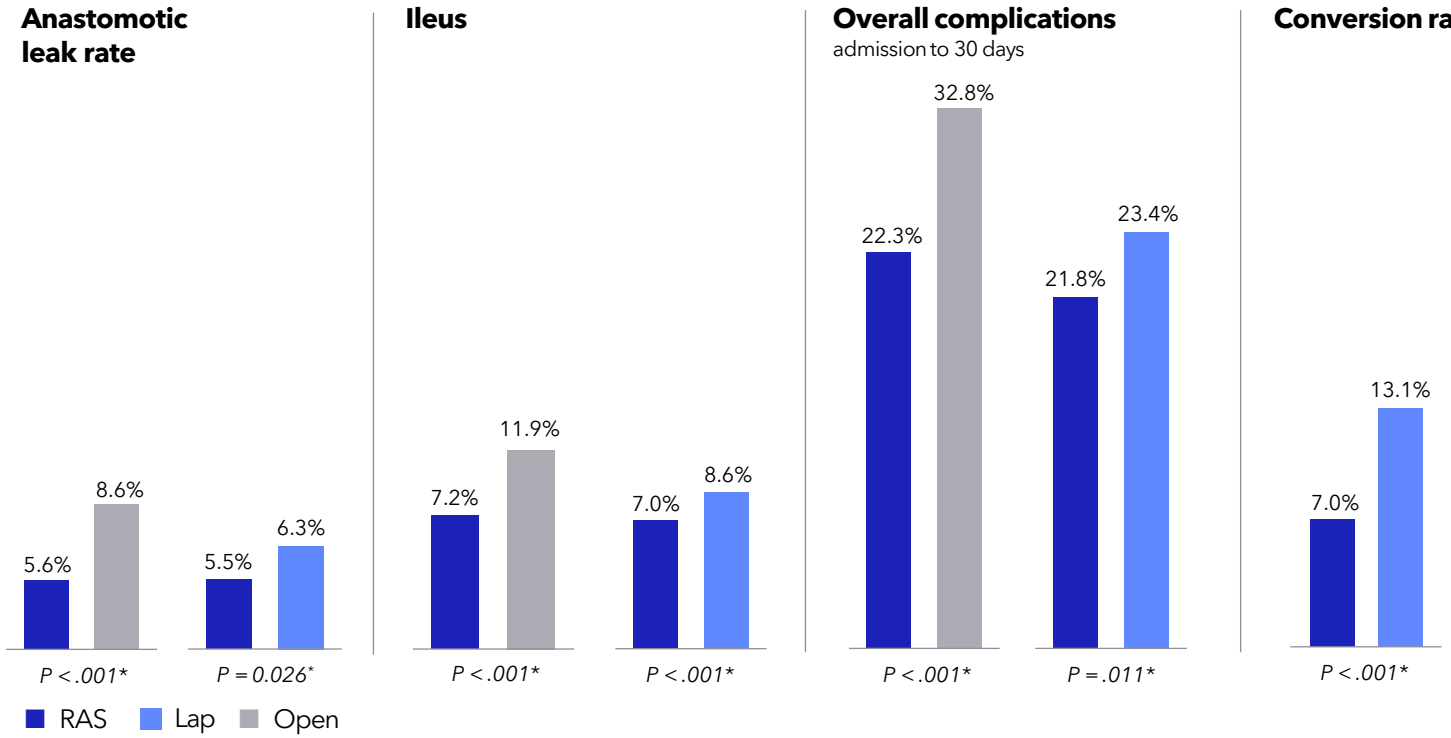
Length of hospital stay

Readmission rate
30 days or other

Perioperative mortality
30 days

Individuals' outcomes may depend on a number of factors, including but not limited to patient characteristics, disease characteristics, and/or surgeon experience. Typical ranges for the clinical outcomes, as reported in the published literature, may be included in this presentation.

Propensity-matched analysis of Premier database shows Robotic-assisted left colectomy (RAS) had lower anastomotic leak, ileus and 30-day overall complication rates when compared with Laparoscopic (LAP) and Open left colectomy



Note: * A *P* value of .05 or less was considered statistically significant.

Compared to laparoscopic left colectomy, additional studies [1,2,3,4] have shown robotic assisted left colectomy is associated with a comparable anastomotic leak rate and ileus, comparable overall complication rate and comparable conversion rates.

Mlambo B, Shih IF, Li Y, Wren SM. The impact of operative approach on postoperative outcomes and healthcare utilization after colectomy. Surgery. 2021 Aug 3:S0039-6060(21)00694-2. doi: 10.1016/j.surg.2021.07.011

Purpose
To evaluate national trends in adoption of different surgical approaches for colectomy and compare clinical outcomes and resource utilization.

Study design
Retrospective database study with propensity-score matched cohorts

Database: Premier Healthcare Database from 2010 to 2019. Propensity matched cohorts selected from 2013 to 2019 data.

Total patients: Total patients: 141,420 (2013 to 2019)

Left colectomy: RAS vs. LAP matched pairs: 12,252

- RAS vs. Open matched pairs: 11,458

Right colectomy: RAS vs. LAP matched pairs: 8,815

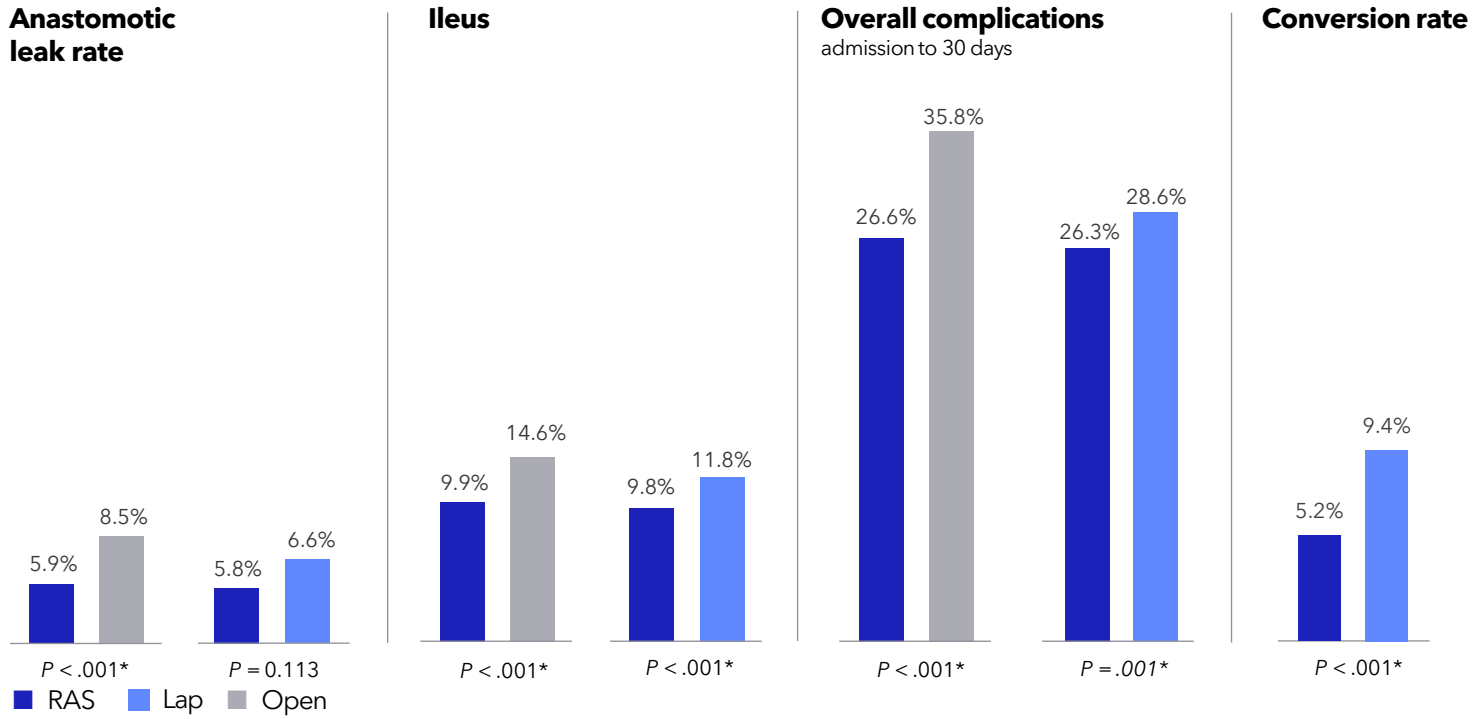
- RAS vs. Open matched pairs: 8,383

Outcomes measured
Length of stay, operative time, conversion to open, 30-day overall complications, colorectal complications, index mortality, discharge, 30-day readmission and 30-day reoperation, and cost.

Key result
RAS left colectomy had lower anastomotic leak rate, ileus and 30-day overall complication rate when compared to LAP Left colectomy and open left colectomy surgery.

Study information

Propensity-matched analysis of Premier database shows Robotic-assisted right colectomy (RAS) had lower ileus and 30-day overall complication rates when compared with Laparoscopic (LAP) and Open right colectomy. RAS had lower anastomotic leak rate compared to Open surgery and comparable rate to LAP



Note: * A *P* value of .05 or less was considered statistically significant.

Compared to laparoscopic right colectomy, additional studies have shown robotic assisted right colectomy is associated with a comparable anastomotic leak rate and ileus, and lower or comparable overall complication rate and lower and comparable conversion rates.

Please refer to congruency and typical range table for additional information.

Mlambo B, Shih IF, Li Y, Wren SM. The impact of operative approach on postoperative outcomes and healthcare utilization after colectomy. Surgery. 2021 Aug 3:S0039-6060(21)00694-2. doi: 10.1016/j.surg.2021.07.011.

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- RAS vs. open matched pairs: 8,383

Outcomes measured
Length of stay, operative time, conversion to open, 30-day overall complications, colorectal complications, index mortality, discharge, 30-day readmission and 30-day reoperation, and cost.

Key result
RAS right colectomy had comparable anastomotic leak rate compared to LAP and lower rate compared to open surgery. RAS right colectomy has lower ileus and 30-day overall complication rate when compared to LAP and open surgery.

Study information

References

1. Casillas MA Jr, Leichtle SW, Wahl WL, Lampman RM, Welch KB, Wellock T, Madden EB, Cleary RK. Improved perioperative and short-term outcomes of robotic versus conventional laparoscopic colorectal operations. Am J Surg. 2014 Jul;208(1):33-40. doi: 10.1016/j.amjsurg.2013.08.028.

2. Xu M, Zhao Z, Jia B, Liu R, Liu H. Perioperative and long-term outcomes of robot-assisted versus laparoscopy-assisted hemicolectomy for left-sided colon cancers: a retrospective study. Updates Surg. 2021 Jun;73(3):1049-1056. doi: 10.1007/s13304-020-00959-4.

3. Al-Temimi MH, Chandrasekaran B, Agapian J, Peters WR Jr, Wells KO. Robotic versus laparoscopic elective colectomy for left side diverticulitis: a propensity score-matched analysis of the NSQIP database. Int J Colorectal Dis. 2019 Aug;34(8):1385-1392. doi: 10.1007/s00384-019-03334-x.

4. Bradley R, Davis et al. Robotic-Assisted Versus Laparoscopic Colectomy: Cost and Clinical Outcomes. JSLS : Journal of the Society of Laparoendoscopic Surgeons. 2014 Jun; 18(2): 211–224. doi: 10.4293/108680813X13753907291035.

Congruency for clinical outcomes in right colectomy

Additional recent studies comparing robotic-assisted surgery to traditional laparoscopic surgery have shown the following results:

Outcome	RAS compared to laparoscopic surgery	Reference
Anastomotic leakage	**Comparable**	Rausa, E et al. Surg Endosc 2018; 33(4): 1020-1032. DOI: 10.1007/s00464-018-6592-3
Ileus	**Comparable**	Ma, S. et al. Asian J Surg 2018; 42(5): 589-598. DOI: 10.1016/j.asjsur.2018.11.002
Overall complication rate	**Lower**	Trastulli S et al. PLoS One 2015; 10(7): e0134062 DOI: 10.1371/journal.pone.0134062
	Comparable	Rausa, E et al. Surg Endosc 2018; 33(4): 1020-1032. DOI: 10.1007/s00464-018-6592-3
Conversion Rate	**Lower**	Ma, S. et al. Asian J Surg 2018; 42(5): 589-598. DOI: 1016/j.asjsur.2018.11.002
	Comparable	Rondelli, F. et al. Int J Surg 2015; 18: 75-82.DOI : 10.1016/j.ijsu.2015.04.044

* References represent the most recently reported study for each outcome and comparative finding combination.

Typical ranges for clinical outcomes in right colectomy

Typical ranges report the minimum and maximum value for the most frequently reported metric for a given outcome.

Range of statistical metric for robotic-assisted surgery

Robotic-assisted surgery vs. Laparoscopic surgery for right colectomy

Outcome	Statistical metric	Value	Reference
Anastomotic leakage	Min OR	**0.55**	Xu, H. et al. World J Surg Oncol 2014; 12(1): 274. DOI: 10.1186/1477-7819-12-274
	Max OR	**1.82**	Rondelli, F. et al. Int J Surg 2015; 18: 75-82. DOI: 10.1016/j.ijsu.2015.04.044
Ileus	Min OR	**0.52**	Petrucciani, N. et al. Journal of Minimal Access Surgery 2015; 11(1): 22-28. DOI: 10.4103/0972-9941.147678
	Max OR	**2.22**	Rondelli, F. et al. Int J Surg 2015; 18: 75-82. DOI: 10.1016/j.ijsu.2015.04.044
Overall complication rate	Min OR	**0.62**	Xu, H. et al. World J Surg Oncol 2014; 12(1): 274. DOI: 10.1186/1477-7819-12-274
	Max OR	**1.65**	Rondelli, F. et al. Int J Surg 2015; 18: 75-82. DOI: 10.1016/j.ijsu.2015.04.044

*OR = Odds Ratio: A measure of the strength of an association between a surgical approach and outcome when compared to the same outcome seen with a different surgical approach. The OR represents the odds that an outcome will occur with a particular approach, compared to the odds of the outcome occurring in another approach. A OR >1 means there is a higher odds of a given outcome with the approach.

Study information: The impact of operative approach on postoperative outcomes and healthcare utilization after colectomy

Citation

Mlambo B, Shih IF, Li Y, Wren SM.
The impact of operative approach on postoperative outcomes and healthcare utilization after colectomy. Surgery. 2021 Aug 3:S0039-6060(21)00694-2. doi: 10.1016/j.surg.2021.07.011.

Study design

A retrospective database study of right and left colectomies using propensity-score matched cohorts to study national trends of surgical approach adoption and compare the clinical outcomes of robotic-assisted (RAS) versus open surgery (open) and laparoscopic surgery (LAP)

Data Source: Premier Healthcare Database

Dates: 2010 to 2019. PSM cohorts selected from 2013 to 2019.

Patient population

Total patients: Total patients: 141,420 (2013 to 2019)

Left colectomy:

RAS vs. LAP matched pairs: 12252; RAS vs. open matched pairs: 11458

Right colectomy:

RAS vs. LAP matched pairs: 8815; RAS vs. open matched pairs: 8383

Outcomes measured

Operation time; conversion to open surgery rate (RAS vs. LAP); length of hospital stay; ileostomy and colostomy rates; discharge rates; index mortality rates; complication rates (30-day overall complications, colorectal complications and other); bleeding rates; surgical site complication rates;
30-day reoperation rate. 30-day readmission rate; 30-day encounters rate; cost

Results / conclusion:

Left colectomy (PSM)

- Length of stay was lower for RAS when compared to open (5.3 vs.
7.1 days; P < .001) and when compared to LAP (5.3 vs 5.6; P < .001).
- Operation time was longer for RAS when compared to open (333.6 vs 241.9; P < .001) and when compared to LAP (329.2 vs 252.5; P < .001)
- Conversion rate was lower for RAS when compared to LAP (7% vs 12.8%; P < .001).
Conversion rate in open cohort was 7.2% for RAS.
- Index mortality rate for RAS was lower when compared to open (0.3% vs 0.5%; P = .010)
and comparable when compared to LAP (0.3% vs 0.3%;
P = .430)
- Discharge home rate for RAS was higher when compared to open (84.8% vs 75.3%; P < .001) and comparable when compared to LAP (85% vs 85.5%; P = .434)
- Overall complication rate was lower for RAS when compared to open (22.3% vs 32.8%; P <.001) and when compared to LAP (21.8% vs 23.4%;
P = .011)
- Colorectal complications rate was lower for RAS when compared to open (16.6% vs 24.2%; *P* <.001
and when compared to LAP (16.2% vs 17.6%; *P* = .008)
- Bleeding rate was lower for RAS when compared to open (7.5% vs 10%;
P < .001) and comparable when compared to LAP (7.4% vs 7.1%; *P* = 0.477)
- Anastomotic leak rate was lower for RAS when compared to open (5.6% vs 8.6%; *P* < .001)
and when compared to LAP (5.5% vs 6.3%; *P* = .026)
- Ureteral injury rate was lower for RAS when compared to open (0.3% vs 0.7%; *P* < .001)
and comparable when compared to open (0.3% vs 0.3%;
P = .570)

Study highlight

Study information: The impact of operative approach on postoperative outcomes and healthcare utilization after colectomy

- Surgical site infection rate was lower for RAS when compared to open (3.2% vs 4.9%; *P* < .001) and comparable for LAP (3.1% vs 3.3%; *P* = .427)
- Ileus rate was lower for RAS when compared to open (7.2% vs 11.9%; *P* < .001) and when compared to LAP (7% vs 8.6%; *P* < .001)
- Other complications rate was lower for RAS when compared to open (11.7% vs 18.3%; *P* < .001) and comparable when compared to LAP (11.4% vs 11.9%; *P* = .437)
- 30-day reoperation rate was lower for RAS when compared to open (5.3% vs 7.1%; *P* < .001) and comparable when compared to LAP (5.2% vs 5.2%; *P* = .828)
- 30-day readmission rate was lower for RAS when compared to open (5.9% vs 7.8%; *P* < .001) and comparable when compared to LAP (5.8% vs 6.3%; *P* = .105)
- 30-day encounters rate was lower when compared to open (20.7% vs 25.7%; *P* < .001) and when compared to LAP (20.3% vs 22.6%; *P* < .001)
- Index cost was higher for RAS when compared to open ($20993 vs $19332; *P* <.001) and compared to LAP ($20880vs $17155; *P* < .001)
- Index + 30-day cost was higher for RAS when compared to open ($21992 vs $20801; P <.001) and compared to LAP ($21934 vs $18402; P < .001)

Right colectomy (PSM)

- Length of stay was lower for RAS when compared to open (4 vs. 5.1 days; *P* < .001) and when compared to LAP (4 vs 3.6 days; *P* < .001).
- Operation time was longer for RAS when compared to open (314.9 vs 195.9; *P* < .001) and when compared to LAP (311.2 vs 200.5; *P* < .001)
- Conversion rate was lower for RAS when compared to LAP (5.2% vs 9.4%; *P* < .001). Conversion rate in open cohort was 5.2% for RAS.
- Index mortality rate for RAS was comparable when compared to open (0.5% vs 0.8%; *P* = .073) and when compared to LAP (0.5% vs 0.5%; *P* = .872)
- Discharge home rate for RAS was higher when compared to open (83.7% vs 77%; *P* < .001) and comparable when compared to LAP (84.1% vs 85%; *P* = .113)
- 30-day overall complication rate was lower for RAS when compared to open (26.6% vs 35.8%; *P* <.001) and when compared to LAP (26.3% vs 28.6%; *P* = .001)
- Colorectal complications rate was lower for RAS when compared to open (19.9% vs 26.2%; *P* <.001) and when compared to LAP (19.7% vs 21.6%; *P* = .002)

Study highlight

Study information: The impact of operative approach on postoperative outcomes and healthcare utilization after colectomy

- Bleeding rate was lower for RAS when compared to open (9.8% vs 11.2%; *P* = .008) and comparable when compared to LAP (9.7% vs 9.6%; *P* = .959)
- Anastomotic leak rate was lower for RAS when compared to open (5.9% vs 8.5%; P < .001 and comparable when compared to LAP (5.8% vs 6.6%; P = .113)
- Ureteral injury rate was comparable for RAS when compared to open (0.1% vs 0.1%; *P* = .644) and when compared to LAP (0.1% vs 0.0%; *P* = .090)
- Surgical site infection rate was lower for RAS when compared to open (2.7% vs 4%; *P* < .001) and comparable for LAP (2.7% vs 2.5%; *P* = .330)
- Ileus rate was lower for RAS when compared to open (9.9% vs 14.6%; *P* < .001) and when compared to LAP (9.8% vs 11.8%; P < .001)
- Other complications rate was lower for RAS when compared to open (13.6% vs 19.4%; *P* < .001) and comparable when compared to LAP (13.2% vs 13.9%; *P* = .353)
- 30-day reoperation rate was lower for RAS when compared to open (6.0% vs 6.9%; *P* = .012) and comparable when compared to LAP (5.9% vs 5.6%; *P* = .318)
- 30-day readmission rate was lower for RAS when compared to open (6.4% vs 9.1%; *P* < .001) and comparable when compared to LAP (6.3% vs 6.9%; *P* = .114)
- 30-day encounters rate was lower when compared to open (21.3% vs 27.3%; *P* < .001) and when compared to LAP (20.9% vs 24.3%; *P* < .001)
- Index cost was higher for RAS when compared to open ($20271 vs $17963; *P* < .001) and compared to LAP ($20192 vs $15496; P < .001)
- Index + 30-day cost was higher for RAS when compared to open ($21475 vs $19665; P < .001) and compared to LAP ($21370 vs $16815; P < .001)

Study limitations

- Administrative coding inaccuracies may introduce misclassification bias.
- Premier Health data only tracks patients in the same hospital, limiting the ability to capture post-discharge health service utilization and costs outside the index hospital and may therefore underestimate the complication rates, postsurgical services and healthcare costs.
- Due to its observational and retrospective nature study has a selection bias regarding patients and surgical approach selection.

Study highlight

Important safety information

Financial disclosure
This study database acquisition and analysis were funded by Intuitive Surgical, Inc, Sunnyvale, CA, USA. Busisiwe Mlambo and Sherry M. Wren received no funding or financial support related to this research and article. I-Fan Shih and Yanli Li are employed by Intuitive Surgical, Inc, and have not received any funding/financial support beyond their salary related to this research. Busisiwe Mlambo and Sherry M. Wren serve as consultants for Intuitive Surgical, Inc. I-Fan Shih and Yanli Li are employed by Intuitive Surgical, Inc.

Surgical risks
Bowel Resection and Other Colorectal Procedures (Colectomy, Sigmoidectomy, Low Anterior Resection, Abdominopelvic resection (APR), Intersphincteric Resection, Proctectomy, Rectopexy): anastomotic leak, anastomotic stricture, colorectal or anorectal dysfunction

Important safety information
Serious complications may occur in any surgery, including surgery with a da Vinci system, up to and including death. Examples of serious or 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/organs, bleeding, infection and internal scarring that can cause long-lasting dysfunction/pain.

Risks specific to minimally invasive surgery,including surgery with a da Vinci system, include but are not limited to, one or more of the following: temporary pain/nerve injury associated with positioning; a longer operative time, the need to convert to an open approach, or the need for additional or larger incision sites. Converting the procedure could result in a longer operative time, a longer time under anesthesia, and could lead to increased complications. Contraindications applicable to the use of conventional endoscopic instruments also apply to the use of all da Vinci instruments.

For important safety information, including surgical risks and considerations, please also refer to www.intuitive.com/safety. For a product's intended use and/or indications for use, risks, full cautions and warnings, please refer to the associated User Manual(s).

Individual outcomes may depend on a number of factors, including but not limited to patient characteristics, disease characteristics and/or surgeon experience.

Da Vinci Xi/X system precaution statement
The demonstration of safety and effectiveness for the representative specific procedures did not include evaluation of outcomes related to the treatment of cancer (overall survival, disease-free survival, local recurrence) or treatment of the patient's underlying disease/condition. Device usage in all surgical procedures should be guided by the clinical judgment of an adequately trained surgeon.