INTUITIVE

How robotic colon surgery helped lower surgical site infections

Background information, study information, congruency and typicality, and safety information

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Intent

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

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

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 all available literature** in order to make an informed decision. Clinical studies are available at pubmed.gov.

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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	**Readmission rate (30 days or other)**
Operative time	**Reoperation rate (30 days or other)**
Length of hospital stay	**Positive surgical margin rate and/or lymph node yield and/or lymph node upstaging**
Conversion rate (versus laparoscopy only)	**Perioperative mortality (30 days)**
Complications (30 days or other) (intraoperative and/or postoperative)	

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.

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Economic outcomes

From a hospital perspective, clinical benefits may result in the potential cost savings discussed here; however, these clinical benefits and costs may vary per hospital, be higher or lower than mentioned during this presentation, and have not been published or peer-reviewed.

The implementation of a da Vinci robotic-assisted surgery (RAS) program is practice- and hospital-specific. Results may vary. Past customer experience does not imply any guarantee of results in practice or program success.

Cost calculations include intraoperative instrument and accessory costs, if indicated. Costs related to da Vinci system acquisition, yearly service costs and other intraoperative and post-operative hospital costs are not included/considered, unless otherwise indicated. All cost estimates have been provided directly by customers, unless otherwise indicated. Results have not been validated by Intuitive.

When considering cost-effectiveness of an advanced technology like the da Vinci system, we recommend that hospitals perform a full cost-benefit analysis, considering not just the operating room costs but also the costs associated with hospital stays, procedure-related complications, and hospital readmissions.

This single center's economic outcome data is not peer reviewed and not published and may or may not be reproducible and is not generalizable. As such, the data reported should be considered informational only and not conclusive.

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Reference #2 Study Information

A case-matched comparative analysis of nationwide data showed minimally invasive colon surgery reduced complications and improved recovery for colon resection

Benlice, C., Aytac, E., Costedio, M., et al. (2016). Robotic, laparoscopic, and open colectomy: a case-matched comparison from the ACS-NSQIP. International Journal of Medical Robotics and Computer Assisted Surgery, 1-6. DOI 10.1002/rcs1783.

Study Design

- Retrospective analysis of American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP, 2013)
- Propensity score matched comparison of robotic, laparoscopic, and open colectomies
- N = 12,790 before propensity score matching
- Database includes 154 different centers within the U.S.

Patient Population

- Subjects with date of surgery in 2013
- Indications for surgery included malignant and benign diagnoses
- Excludes patients with secondary procedures (e.g. creation of ileostomy)

Analysis

- Propensity matched analysis (robotic-assisted vs lap vs open surgery)

Outcomes Measured / Evaluated

- Complications, including surgical site infection (SSI)
- Length of stay
- Operative time
- Transfusions
- Readmissions
- Conversions

Results / Conclusions

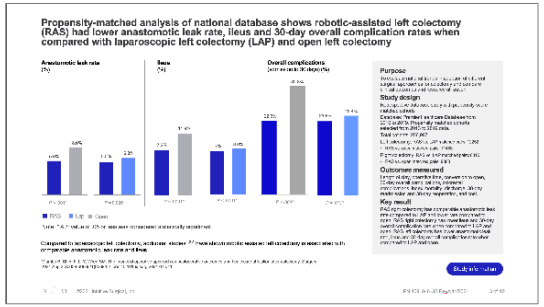
- Robotic-assisted colectomies had the longest operative times, but shortest length of stay and lowest overall morbidity.
- Superficial SSI was lowest in the robotic-assisted group, but rates were similar across modalities for deep and organ space SSIs.
- Transfusion rate was lowest for robotic-assisted cases.
- Readmission rate and mortality were lowest among lap, but differences were not statistically significant.
- Conversion rate was lower in the robotic-assisted group vs lap

Study Limitations

- Retrospective analysis
- Data do not include any hospital or surgeon details

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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.

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.

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 analyzed

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/conclusions

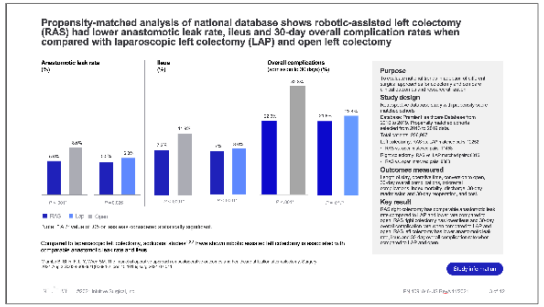
Left colectomy (PSM)

- 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%; $P = .570$)

Results/conclusions continued on next page.

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Results/conclusions (continued)

- 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)

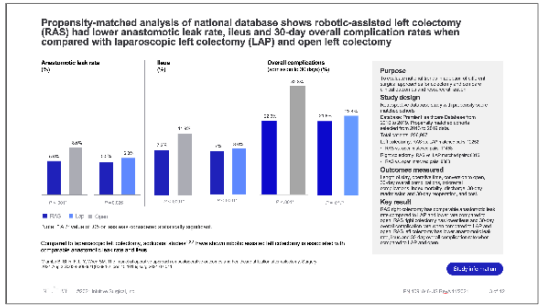
Right colectomy (PSM)

- 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)
- 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)

Results/conclusions continued on next page.

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Results/conclusions (continued)

- 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.

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Congruency for clinical outcomes in colectomy

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

Outcome	Da Vinci RAS compared to Open Surgery	Reference
Operating Time	Comparable	Rausa E et al. Surg Endosc. 2019;33(4):1020-1032. DOI: 10.1007/s00464-018-6592-3
	Longer	Lee YF et al. J Gastrointest Surg. 2018;22(6):1059-1067. DOI: 10.1007/s11605-018-3706-0
Length of Hospital Stay	Shorter	Rausa E et al. Surg Endosc. 2019;33(4):1020-1032. DOI: 10.1007/s00464-018-6592-3
Postoperative Complication Rate	Lower	Rausa E et al. Surg Endosc. 2019;33(4):1020-1032. DOI: 10.1007/s00464-018-6592-3
Mortality Rate (30 day)	Lower	Lee YF et al. J Gastrointest Surg. 2018;22(6):1059-1067. DOI: 10.1007/s11605-018-3706-0
	Comparable	Rausa E et al. Surg Endosc. 2019;33(4):1020-1032. DOI: 10.1007/s00464-018-6592-3
Readmission Rate (30 day)	Lower	Lee YF et al. J Gastrointest Surg. 2018;22(6):1059-1067. DOI: 10.1007/s11605-018-3706-0
	Comparable	Rausa E et al. Surg Endosc. 2019;33(4):1020-1032. DOI: 10.1007/s00464-018-6592-3

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Congruency for clinical outcomes in colectomy

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

Outcome	Da Vinci RAS compared to Laparoscopy	Reference
Operating Time	Comparable	Rausa E et al. Surg Endosc. 2019;33(4):1020-1032. DOI: 10.1007/s00464-018-6592-3
	Longer	Ma S et al. Asian J Surg. 2019;42(5):589-598. DOI: 10.1016/j.asjsur.2018.11.002
Length of Hospital Stay	Shorter	Ma S et al. Asian J Surg. 2019;42(5):589-598. DOI: 10.1016/j.asjsur.2018.11.002
	Comparable	Rausa E et al. Surg Endosc. 2019;33(4):1020-1032. DOI: 10.1007/s00464-018-6592-3
	Longer	Keller DS et al. Surg Endosc. 2014;28(1):212-221. DOI: 10.1007/s00464-013-3163-5
Conversion to Open Surgery Rate	Lower	Ma S et al. Asian J Surg. 2019;42(5):589-598. DOI: 10.1016/j.asjsur.2018.11.002
	Comparable	Rausa E et al. Surg Endosc. 2019;33(4):1020-1032. DOI: 10.1007/s00464-018-6592-3
	Higher	Benlice C et al. Int J Med Robot. 2017 Sep;13(3). DOI: 10.1002/rcs.1783
Postoperative Complication Rate	Lower	Ma S et al. Asian J Surg. 2019;42(5):589-598. DOI: 10.1016/j.asjsur.2018.11.002
	Comparable	Rausa E et al. Surg Endosc. 2019;33(4):1020-1032. DOI: 10.1007/s00464-018-6592-3
Perioperative (Overall) Complication Rate	Comparable	Dolejs SC et al. Surg Endosc. 2017;31(6):2387-2396. DOI: 10.1007/s00464-016-5239-5

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Typical ranges for clinical outcomes in colectomy

Typical ranges report the minimum and maximum values for the most frequently reported metric of a given outcome in the published literature.

		Range of Statistical Metric for Robotic-Assisted Surgery			
Outcome	**Statistical Metric**	**Da Vinci Robotic-Assisted Colectomy v. Open Colectomy**		**Da Vinci Robotic-Assisted Colectomy v. Laparoscopic Colectomy Surgery**	
Operating Time	Min Minutes Mean ± SD	225 ± 114	Benlice C et al. Int J Med Robot. 2017 Sep;13(3). DOI: 10.1002/rcs.1783	195 ± 41	Park JS et al. Br J Surg. 2012;99(9):1219-1226. DOI: 10.1002/bjs.8841
	Max Minutes Mean ± SD	235.9 ± 103.3	Mungo B et al. World J Surg. 2017;41(8):2143-2152. DOI: 10.1007/s00268-017-4001-z	262.2 ± 93	Davis BR et al. JSLS. 2014;18(2):211-224. DOI: 10.4293/108680813X13753907291035
Length of Hospital Stay	Min Days Mean ± SD	4.7 ± 3.6	Mungo B et al. World J Surg. 2017;41(8):2143-2152. DOI: 10.1007/s00268-017-4001-z	4 ± 2	Dolejs SC et al. Surg Endosc. 2017;31(6):2387-2396. DOI: 10.1007/s00464-016-5239-5
	Max Days Mean ± SD	5 ± 3.5	Benlice C et al. Int J Med Robot. 2017 Sep;13(3). DOI: 10.1002/rcs.1783	7.9 ± 4.1	Park JS et al. Br J Surg. 2012;99(9):1219-1226. DOI: 10.1002/bjs.8841
Conversion to Open Surgery Rate	Min %	N/A		0%	Park JS et al. Br J Surg. 2012;99(9):1219-1226. DOI: 10.1002/bjs.8841
	Max %			24.5%	Benlice C et al. Int J Med Robot. 2017 Sep;13(3). DOI: 10.1002/rcs.1783

Legend:
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.

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Typical ranges for clinical outcomes in colectomy

Typical ranges report the minimum and maximum values for the most frequently reported metric of a given outcome in the published literature.

		Range of Statistical Metric for Robotic-Assisted Surgery			
Outcome	**Statistical Metric**	**Da Vinci Robotic-Assisted Colectomy v. Open Colectomy**		**Da Vinci Robotic-Assisted Colectomy v. Laparoscopic Colectomy Surgery**	
Postoperative Complication Rate	Min % / Odds Ratio (95% CI)	15.68%	Mungo B et al. World J Surg. 2017;41(8):2143-2152. DOI: 10.1007/s00268-017-4001-z	0.612 (0.42 – 0.92)	Xu H et al. World J Surg Oncol. 2014;12:274. Published 2014 Aug 28. DOI: 10.1186/1477-7819-12-274
	Max % / Odds Ratio (95% CI)	23.90%	Moghadamyeghaneh Z et al. Surg Endosc. 2016;30(7):2792-2798. DOI: 10.1007/s00464-015-4552-8	1.65 (1.09 – 2.50)	Rondelli F et al. Int J Surg. 2015;18:75-82. DOI: 10.1016/j.ijsu.2015.04.044
Readmission Rate (30 day)	Min Odds Ratio (95% CI)/ %	0.735 (0.566 – 0.954)	Lee YF et al. J Gastrointest Surg. 2018;22(6):1059-1067. DOI: 10.1007/s11605-018-3706-0	2.8%	Park JS et al. Surg Endosc. 2019;33(9):2975-2981. DOI: 10.1007/s00464-018-6563-8
	Max Odds Ratio (95% CI) / %	1.05 (0.83 – 1.33)	Mungo B et al. World J Surg. 2017;41(8):2143-2152. DOI: 10.1007/s00268-017-4001-z	9.3%	Schootman M et al. J Gastrointest Surg. 2017;21(8):1296-1303. DOI: 10.1007/s11605-017-3460-8

Legend:
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.

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Important safety information

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 the da Vinci surgical 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 the da Vinci surgical 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, indications for use, risks, full cautions, and warnings, please also refer to intuitive.com/safety.

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 specific procedure(s) discussed in this material was based on evaluation of the device as a surgical tool and 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.

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