Evidence Navigator: Hysterectomy For Endometrial Cancer

Systematic literature review summary
as of December 31, 2022

INTUITIVE

Purpose

The Evidence Navigator is a slide presentation representing a summary of the meta-analysis of the highest level of evidence available specific to a given procedure and published as of a particular date. It is created by the Global Evidence Management team within Global Access, Value and Economics (GAVE). It includes information that is available in the public domain. It is a systematic review and meta-analysis of the peer-reviewed literature based on a timeframe within which a literature search has been conducted according to a set of concise inclusion and exclusion criteria. The results of the meta-analysis are presented in the form of forest plots summarized for each outcome according to a comparator and surgical approach of interest. The summary results are reflective of a specific period in time and are subject to change with increasing literature. All of the robotic-assisted surgery procedures mentioned within the Evidence Navigator were performed using a da Vinci® surgical system.

Statistical analysis

All summary measures are shown as odds ratios, risk ratios or risk differences when describing binary outcomes, or as weighted mean differences or standardized mean differences when describing continuous outcomes. Weighting is based on the study sample size and variability of the outcome. A random effect model is used if heterogeneity is statistically significant, otherwise a fixed effect model is used. The Mantel Haenszel summary statistic is used for the overall results. The meta-analysis is performed with RevMan 5.4 (Review Manager, Version 5.4. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014) or R software (R Foundation for Statistical Computing, Vienna, Austria.URL https://www.R-project.org/).

Interpretation notes

When the effect size is measured as a standardized mean difference (SMD), or a risk difference (RD), it is not possible to provide a quantitative conclusion. In such cases, a qualitative conclusion is given with reference to its statistical significance. In some instances, studies may contain some overlapping patient populations. A redundancy check is performed in order to minimize this overlap and bias due to over-reporting.

Glossary

RAS	robotic-assisted surgery
Lap	laparoscopic surgery
LOE	level of evidence
HTA	health technology assessment
RCT	randomized controlled trial
OR	odds ratio
MD	mean difference
LNY	lymph node yield
LVSI	lymphovascular space invasion

WMD	weighted mean difference
RD	risk difference
SMD	standardized mean difference
95% CI	95% confidence interval
I^2	test statistic for heterogeneity
EBL	estimated blood loss
LOS	length of hospital stay
PSM	positive surgical margins

Evidence Navigator:
Hysterectomy for endometrial cancer
Summary Slides

Systematic literature review summary
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WHAT DOES THE LITERATURE SHOW?

Systematic literature review: **Hysterectomy for endometrial cancer — clinical outcomes**

Inclusion criteria

Robotic-assisted hysterectomy for endometrial cancer performed with a da Vinci surgical system

January 1, 2010 – December 31, 2022

Level of Evidence = 1b, 2b, 2c

RCT, prospective cohort studies, or large database study (with n≥20 in each cohort)

Exclusion criteria

Not in English

Paper on a pediatric population

Publication is a HTA not published in a peer-reviewed journal

Alternate technique/approach

No stratified analysis by study arm

Hysterectomy data mixed with other procedure(s)

Original research study does not provide quantitative results

Original research publication includes redundant patient population and similar conclusions

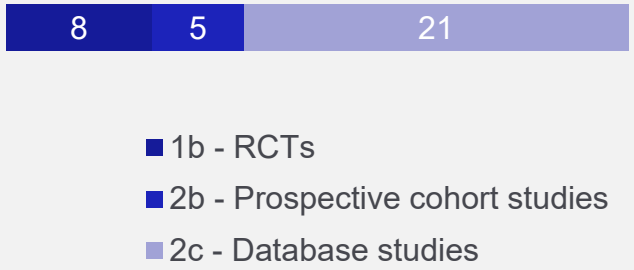
34 publications including

Robotic-assisted patients: **350,460**

Laparoscopic patients: **113,246**

Open patients: **219,787**

Level of evidence



Data collected through: December 31, 2022

WHAT DOES THE LITERATURE SHOW?

Systematic literature review key points:
Robotic-assisted vs. laparoscopic hysterectomy for endometrial cancer

Favors robotic-assisted

- ↓ Conversions by **55%**
- ↓ Estimated blood loss by **24 mL**
- ↓ Length of stay by **0.5 days**
- ↓ 30-day mortality by **37%**

Comparable outcomes

- ≈ Operative time
- ≈ Blood transfusions
- ≈ Lymph node yield
- ≈ Pelvic lymph node yield
- ≈ Para-aortic lymph node yield
- ≈ Positive lymphovascular space invasion
- ≈ Intraoperative complications
- ≈ 30-day postoperative complications
- ≈ 30-day reoperations
- ≈ 30-day readmissions

Favors laparoscopic

None

Data collected through: December 31, 2022

Significant difference favoring robotic-assisted surgery

No significant difference; comparable outcomes

Significant difference favoring laparoscopic surgery

WHAT DOES THE LITERATURE SHOW?

Systematic literature review key points:
Robotic-assisted vs. open hysterectomy for endometrial cancer

Favors robotic-assisted

- ↓ Estimated blood loss by **152 mL**
- ↓ Length of stay by **2.5 days**
- ↓ Blood transfusions by **71%**
- ↓ 30-day postoperative complications by **62%**
- ↓ 30-day reoperations by **92%**
- ↓ 30-day readmissions by **45%**
- ↓ 30-day mortality by **64%**

Comparable outcomes

- ≈ Operative time
- ≈ Lymph node yield
- ≈ Para-aortic lymph node yield
- ≈ Positive lymphovascular space invasion
- ≈ Positive surgical margins
- ≈ Intraoperative complications

Favors open

- ↑ Pelvic lymph yield by **6 nodes**

Data collected through: December 31, 2022

Significant difference favoring robotic-assisted surgery

No significant difference; comparable outcomes

Significant difference favoring laparoscopic surgery

Evidence Navigator:
Hysterectomy for endometrial cancer
Technical Slides

Systematic literature review summary
as of December 31, 2022

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Hysterectomy for Endometrial Cancer: literature search methods

as of December 31, 2022

Monthly searches were conducted in PubMed, Scopus and Embase.

All citations were exported into a reference management system. Duplications were removed. Titles, abstracts and keywords were reviewed for literature review inclusion by Global Evidence Management team.

All robotic-assisted hysterectomies performed with da Vinci® surgical systems. Publications were identified according to inclusion and exclusion criteria described.

Meta-analysis was performed using RevMan or R software.

34 publications

350,460 patients who underwent RAS

113,246 patients who underwent laparoscopic surgery

219,787 patients who underwent open surgery

Level of evidence

- 1b - RCTs
- 2b - Prospective cohort studies
- 2c - Database studies

Criteria phase	Details
Identification phase	Unique records identified from PubMed, Scopus, Embase search N=9,440 to December 31, 2022
Inclusion criteria	
1. Robotic-assisted hysterectomy (radical, total, simple) with or without salpingectomy, oophorectomy, and lymphadenectomy for cancer or other gynecologic oncology procedure	N=2,626 (excluded N=6,814)
2. Year≥2010	N=2,623 (excluded N=3)
3. LOE=1b, 2b, 2c	N=253 (excluded N=2,370)
4. Study is an RCT, prospective study or large database study with comparative cohorts (robotic-assisted vs lap and/or open surgery) and sample size N≥20	N=231 (excluded N=22)
Exclusion criteria	**N=179 excluded publications:**
1. Not in English	N=1 (EC#1)
2. Paper reports on a pediatric population	N=0 (EC#2)
3. Publication is an HTA that was not published in a peer-reviewed journal	N=0 (EC#3)
4. Alternate technique/approach (e.g. single-port)	N=4 (EC#4)
5. No stratified analysis by study arm (e.g. combines results from robotic, laparoscopic and/or open cohorts)	N=113 (EC#5)
6. Hysterectomy cancer data mixed with other procedures (e.g. data from multiple surgical procedures combined)	N=32 (EC#6)
7. Original research study does not provide quantitative results for at least one of the findings relative to the outcomes of interest	N=21 (EC#7)
8. Original research publication includes redundant patient population and similar conclusions	N=8 (EC#8)

Gyn Onc publications: N=52 (34 endometrial cancer)

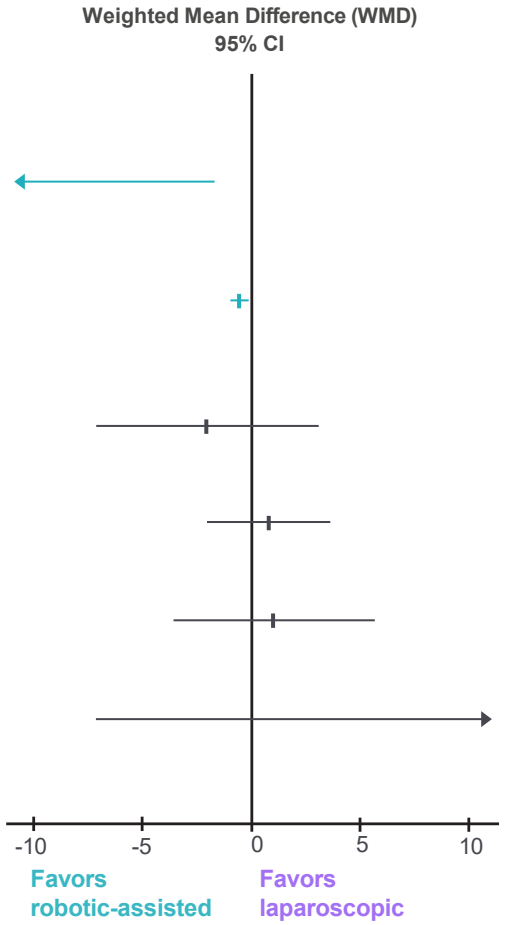
Robotic-assisted vs. laparoscopic hysterectomy for endometrial cancer

Summary as of December 31, 2022

Significant difference favoring robotic-assisted surgery | No significant difference; comparable outcomes | Significant difference favoring laparoscopic surgery

Compared to laparoscopic hysterectomy, the evidence for **robotic-assisted hysterectomy for endometrial cancer** demonstrates:

- Significantly less estimated blood loss by an average of 24 mL
- Significantly shorter hospital length of stay by an average of 0.5 days
- Comparable lymph node yield
- Comparable pelvic lymph node yield
- Comparable para-aortic lymph node yield
- Comparable operative time



Outcome	Robotic-assisted, n	Laparoscopic, n	Effect size 95% CI	P-value
Endometrial cancer continuous variables (to December 31, 2022)				
EBL, mL [6, 16, 17, 21-23, 27]				
Subtotal	826	689	WMD: -23.67 [-45.44, -1.91]	p=0.03
Random, Heterogeneity: p =0.03; I^2 = 53%				
LOS, days [6, 8, 9, 11, 13, 16, 19, 21, 27, 32]				
Subtotal	26570	13786	WMD: -0.53 [-0.90, -0.17]	p<0.01
Random, Heterogeneity: p<0.01; I^2 = 88%				
LNY, n [21, 23, 27]				
Subtotal	128	128	WMD: -1.98 [-7.08, 3.13]	p=0.45
L-R Random, Heterogeneity: p=0.07; I^2 =62%				
Pelvic LNY, n [16, 19, 27]				
Subtotal	203	169	WMD: 0.82 [-1.99, 3.63]	p=0.57
L-R Random, Heterogeneity: p=0.03; I^2 =64%				
Para-aortic LNY, n [16, 19, 27]				
Subtotal	144	147	WMD: 1.01 [-3.56, 5.58]	p=0.66
L-R Random, Heterogeneity: p<0.01; I^2 =91%				
Operative time, min [6, 9, 16, 17, 19, 21, 22, 27]				
Subtotal	2355	2215	WMD: 13.82 [-7.00, 34.63]	p=0.19
Random, Heterogeneity: p<0.01; I^2 = 93%				

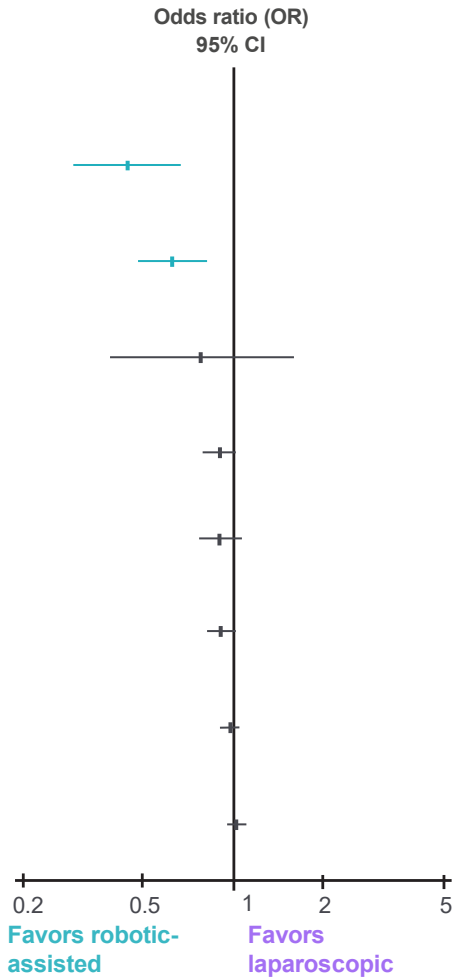
Robotic-assisted vs. laparoscopic hysterectomy for endometrial cancer

Summary as of December 31, 2022

Significant difference favoring robotic-assisted surgery | No significant difference; comparable outcomes | Significant difference favoring laparoscopic surgery

Compared to laparoscopic hysterectomy, the evidence for **robotic-assisted hysterectomy for endometrial cancer** demonstrates:

- 55% less likely to be converted to open surgery
- 37% less likely to experience mortality within 30-days of surgery
- Comparable reoperation rate within 30-days of surgery
- Comparable blood transfusion rate
- Comparable intraoperative complication rate
- Comparable rate of positive lymphovascular space invasion
- Comparable postoperative complication rate within 30-days of surgery
- Comparable readmission rate within 30-days of surgery



Outcome	Robotic-assisted, n	Laparoscopic, n	Effect size 95% CI	P-value
Endometrial cancer binary variables (to December 31, 2022)				
Conversions, n [5-7, 9, 15, 16, 19, 21, 24, 27, 33, 34]				
Subtotal	87685	33816	OR: 0.45 [0.29, 0.67]	p<0.01
Random, Heterogeneity: p<0.01; I^2 = 86%				
Mortality, n [8, 11, 21, 22, 27, 31, 33, 34]				
Subtotal	31824	13897	OR: 0.63 [0.49, 0.82]	p<0.01
Fixed, Heterogeneity: p=0.68; I^2 = 0%				
Reoperations, n [16, 21, 31]				
Subtotal	1620	1177	OR: 0.78 [0.39, 1.57]	p=0.49
Fixed, Heterogeneity: p=0.25; I^2 =25%				
Transfusions, n [6, 9, 10, 16, 19, 21, 30, 31, 33, 34]				
Subtotal	12055	8331	OR: 0.90 [0.80, 1.02]	p=0.10
Fixed, Heterogeneity: p=0.37; I^2 = 8%				
Intraop complications, n [6, 16, 19, 21, 30, 31, 33, 34]				
Subtotal	10096	6696	OR: 0.91 [0.77, 1.07]	p=0.25
Fixed, Heterogeneity: p=0.54; I^2 = 0%				
Positive LVSI, n [1, 5, 8]				
Subtotal	92379	32590	OR: 0.92 [0.83, 1.02]	p=0.11
Fixed, Heterogeneity: p=0.30; I^2=19%				
Postop complications, n [4, 6, 9, 10, 13, 16, 19, 30, 31, 33, 34]				
Subtotal	14007	11930	OR: 0.98 [0.91, 1.06]	p=0.58
Random, Heterogeneity: p<0.01; I^2 = 81%				
Readmissions, n [3, 4, 8, 9, 31]				
Subtotal	141005	48010	OR: 1.03 [0.95, 1.11]	p=0.47
Fixed, Heterogeneity: p=0.16; I^2 =39%				

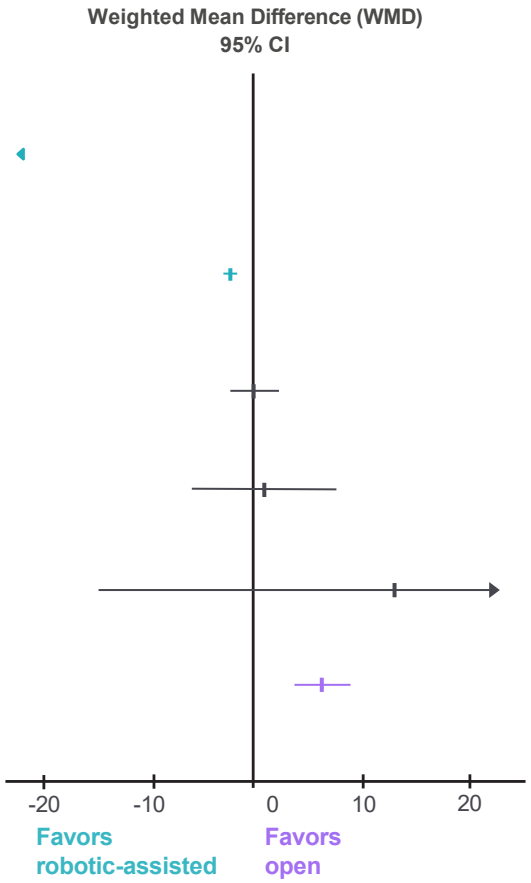
Robotic-assisted vs. open hysterectomy for endometrial cancer

Summary as of December 31, 2022

- Significant difference favoring robotic-assisted surgery
- No significant difference; comparable outcomes
- Significant difference favoring open surgery

Compared to open hysterectomy, the evidence for **robotic-assisted hysterectomy for endometrial cancer** demonstrates:

- Significantly less estimated blood loss by an average of 152 mL
- Significantly shorter hospital length of stay by an average of 2.5 days
- Comparable para-aortic lymph node yield
- Comparable lymph node yield
- Comparable operative time
- Significantly lower pelvic lymph node yield by an average of 6 nodes



Outcome	Robotic-assisted, n	Open, n	Effect size 95% CI	P-value
Endometrial cancer continuous variables (to December 31, 2022)				
EBL, mL [6, 12, 20, 23, 26, 28]				
Subtotal	580	2843	WMD: -151.99 [-225.83, -78.14]	p<0.01
Random, Heterogeneity: p<0.01; I^2 = 96%				
LOS, days [6, 8, 9, 11, 13, 18, 12, 19, 20, 26, 28, 32]				
Subtotal	30284	35697	WMD: -2.50 [-3.06, -1.93]	p<0.01
Random, Heterogeneity: p<0.01; I^2 = 97%				
Para-aortic LNY, n [6, 19, 26]				
Subtotal	274	751	WMD: -0.22 [-2.33, 1.89]	p=0.84
O-R Random, Heterogeneity: p =0.12; I^2 =53%				
LNY, n [6, 12, 23, 26, 28]				
Subtotal	347	805	WMD: 0.74 [-5.85, 7.32]	p=0.83
O-R Random, Heterogeneity: p<0.01; I^2 =93%				
Operative time, min [6, 9, 12, 19, 20, 26]				
Subtotal	3083	5373	WMD: 12.97 [-14.63, 40.56]	p=0.36
Random, Heterogeneity: p<0.01; I^2 = 94%				
Pelvic LNY, n [6, 19, 26]				
Subtotal	274	751	WMD: 6.36 [-3.61, 9.11]	p<0.01
O-R Random, Heterogeneity: p =0.09; I^2 =59%				

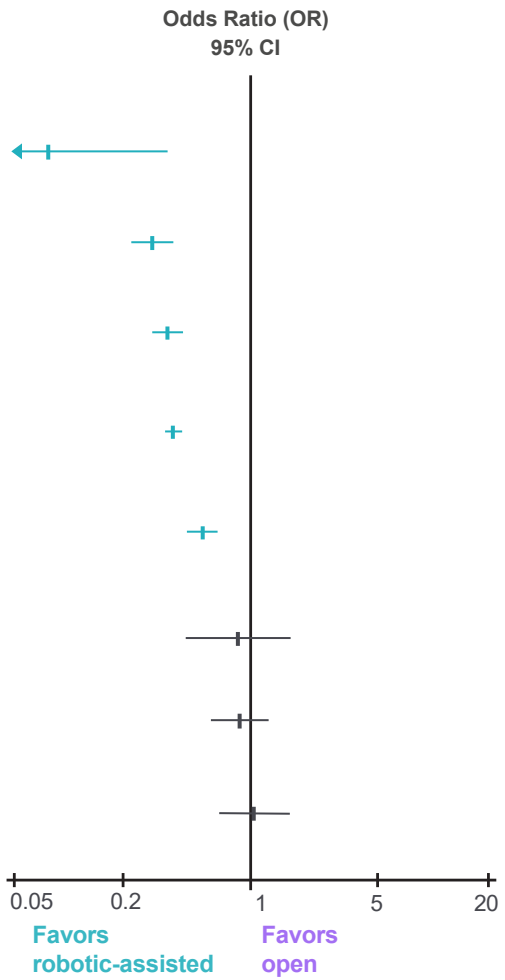
Robotic-assisted vs. open hysterectomy for endometrial cancer

Summary as of December 31, 2022

Significant difference favoring robotic-assisted surgery | No significant difference; comparable outcomes | Significant difference favoring open surgery

Compared to open hysterectomy, the evidence for **robotic-assisted hysterectomy for endometrial cancer** demonstrates:

- 92% less likely to experience a reoperation within 30-days of surgery
- 71% less likely to experience a blood transfusion
- 64% less likely to experience mortality within 30-days of surgery
- 62% less likely to experience a postoperative complications within 30-days of surgery
- 45% less likely to experience a readmission within 30-days of surgery
- Comparable positive surgical margins
- Comparable rate of positive lymphovascular space invasion
- Comparable intraoperative complication rate



Outcome	Robotic-assisted, n	Open, n	Effect size 95% CI	P-value
Endometrial cancer binary variables (to December 31, 2022)				
Reoperations, n [18, 26]				
Subtotal	2850	14226	OR: 0.08 [0.02, 0.35]	p<0.01
Fixed, Heterogeneity: p=0.18; I^2 = 41%				
Transfusions, n [6, 9, 10, 12, 16, 19, 20, 26]				
Subtotal	6331	20198	OR: 0.29 [0.22, 0.38]	p<0.01
Random, Heterogeneity: p=0.04; I^2 = 49%				
Mortality, n [8, 11, 18, 25, 26]				
Subtotal	50057	47634	OR: 0.36 [0.29, 0.43]	p<0.01
Fixed, Heterogeneity: p=0.35; I^2 = 10%				
Postop complications, n [4, 6, 9, 10, 12, 13, 18, 19, 20, 26, 28]				
Subtotal	8398	23399	OR: 0.38 [0.34, 0.42]	p<0.01
Fixed, Heterogeneity: p=0.06; I^2 = 41%				
Readmissions, n [3, 4, 8, 9, 12, 25, 26]				
Subtotal	164527	101938	OR: 0.55 [0.46, 0.66]	p<0.01
Random, Heterogeneity: p<0.01; I^2 = 85%				
Positive surgical margins, n [1, 25]				
Subtotal	25106	21418	OR: 0.86 [0.45, 1.62]	p=0.63
Random, Heterogeneity: p=0.01; I^2 = 84%				
Positive LVSI, n [1, 5, 8]				
Subtotal	92379	60497	OR: 0.87 [0.60, 1.26]	p=0.46
Random, Heterogeneity: p<0.01; I^2 = 99%				
Intraop complications, n [6, 12, 18, 19, 26, 28, 30]				
Subtotal	4530	21858	OR: 1.04 [0.66, 1.64]	p=0.85
Random, Heterogeneity: p<0.01; I^2 = 78%				

Hysterectomy for endometrial cancer: bibliography (1 of 2)

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Hysterectomy for endometrial cancer: bibliography (2 of 2)

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Disclosures

Important Safety Information

(US) Serious complications may occur in any surgery, including da Vinci surgery, up to and including death. Serious risks include, but are not limited to, injury to tissues and organs and conversion to other surgical techniques which could result in a longer operative time and/or increased complications. For summary of the risks associated with surgery refer to www.intuitive.com/safety.

Da Vinci Xi®/da Vinci 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), except for radical prostatectomy which was evaluated for overall survival, 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.

(EU) Da Vinci X & Xi Surgical Systems

The Intuitive Surgical Endoscopic Instrument Control Systems (da Vinci X and da Vinci Xi Surgical Systems) are intended to assist in the accurate control of Intuitive Surgical Endoscopic Instruments during urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, general thoracoscopic surgical procedures, and trans-oral otolaryngology surgical procedures restricted to benign tumors and malignant tumors classified as T1 and T2, and for benign base of tongue resection procedures. The systems are indicated for adult and pediatric use (except for trans-oral otolaryngology surgical procedures). They are intended to be used by trained physicians in an operating room environment.

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