Evidence Navigator: Thymectomy

Systematic literature review & meta-analysis
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
VATS	Video assisted thoracoscopic surgery

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
ICU	intensive care unit

Evidence Navigator: Thymectomy Summary Slides

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WHAT DOES THE LITERATURE SHOW?

Systematic literature review:
Da Vinci robotic-assisted thymectomy

Inclusion criteria

Robotic-assisted thymectomy performed with a da Vinci surgical system

January 1, 2010 – December 31, 2022

Level of Evidence 1b, 2b, 2c, 3b

RCT, large database, prospective and retrospective cohort studies (with n≥20 in each cohort)

Exclusion criteria

Not in English

Paper reports on a pediatric population

Publication is an HTA that was not published in a peer-reviewed journal

Alternate technique/approach (e.g. single-port)

No stratified analysis by study arm

Thymectomy data mixed with other procedures

Original research study does not provide quantitative results for outcomes of interest

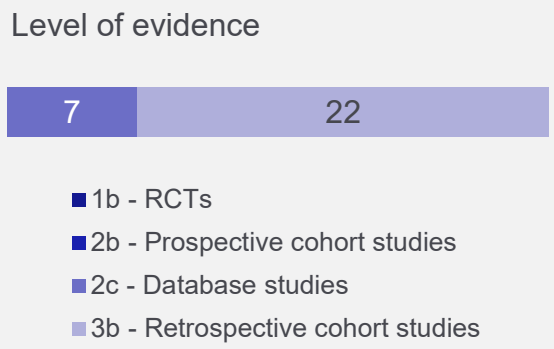
Original research publication includes redundant patient population and similar conclusions

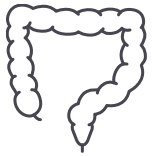
29 publications including:

Robotic-assisted patients: **1,382**

VATS patients: **5,206**

Open patients: **3,951**





WHAT DOES THE LITERATURE SHOW?

Systematic literature review key points: **Robotic-assisted vs. VATS thymectomy**

Favors robotic-assisted

- ↓ Conversions by **55%**
- ↓ Length of stay by **0.75 days**

Comparable outcomes

- ≈ Operative time
- ≈ Estimated blood loss
- ≈ Blood transfusions
- ≈ Lymph node yield
- ≈ Positive surgical margin rate
- ≈ Chest tube drainage
- ≈ Chest tube duration
- ≈ ICU length of stay
- ≈ 30-day postoperative complications
- ≈ 30-day readmissions
- ≈ 30-day reoperations
- ≈ 30-day mortality

Favors VATS

None

Data collected: December 31, 2022

WHAT DOES THE LITERATURE SHOW?

Systematic literature review key points: **Robotic-assisted vs. open thymectomy**

Favors robotic-assisted

- ↓ Estimated blood loss by **208 mL**
- ↓ Positive surgical margin by **19%**
- ↓ Chest tube drainage by **362 mL**
- ↓ Chest tube duration by **1.6 days**
- ↓ ICU admission by **80%**
- ↓ Length of hospital stay by **2.9 days**
- ↓ 30-day postoperative complication by **57%**
- ↓ 30-day reoperation by **56%**

Comparable outcomes

- ≈ Operative time
- ≈ Blood transfusions
- ≈ ICU length of stay
- ≈ Lymph node yield
- ≈ 30-day readmissions
- ≈ 30-day mortality

Favors open

None

Data collected: December 31, 2022

Evidence Navigator: Thymectomy Technical Slides

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Thymectomy: 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 thymectomies 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.

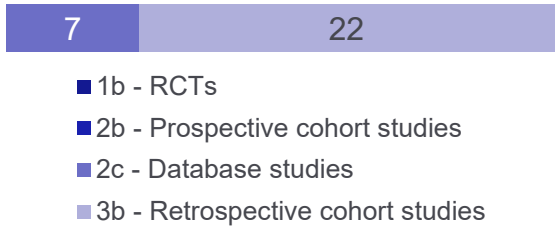
29 publications

1,382 patients who underwent RAS

5,206 patients who underwent VATS surgery

3,951 patients who underwent open surgery

Level of evidence



Criteria phase	Details
Identification phase	All robotics publications (library generated from monthly search process) N=35,023 library size at the time of search December 31, 2022
Inclusion criteria 1. Robotic-assisted thymectomy procedure	Robotic Thymectomy N = 461 (excluded N = 34,562)
2. Year ≥ 2010	Articles published ≥ 2010 N = 408 (excluded N = 53)
3. LOE = 1b, 2b, 2c, 3b	Articles with LOE= 1b, 2b, 2c, 3b N = 63 (excluded N = 345)
4. RCT, large database, retrospective or prospective studies with comparative cohorts (robotic-assisted vs. VATS and/or open surgery) and sample size ≥ 20 in each cohort	Comparator cohorts N = 45 (excluded N = 18)
Exclusion criteria	**N = 16 excluded publications:**
1. Not in English	N = 0 (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 = 0 (EC#4)
5. No stratified analysis by study arm (e.g., combines results from robotic, laparoscopic, and/or open cohorts)	N = 13 (EC#5)
6. Thymectomy data mixed with other procedures	N = 0 (EC#6)
7. Original research study does not provide quantitative results for the outcomes of interest	N = 2 (EC#7)
8. Original research publication includes redundant patient population and similar conclusions	N = 1 (EC#8)

Thymectomy publications: N = 29

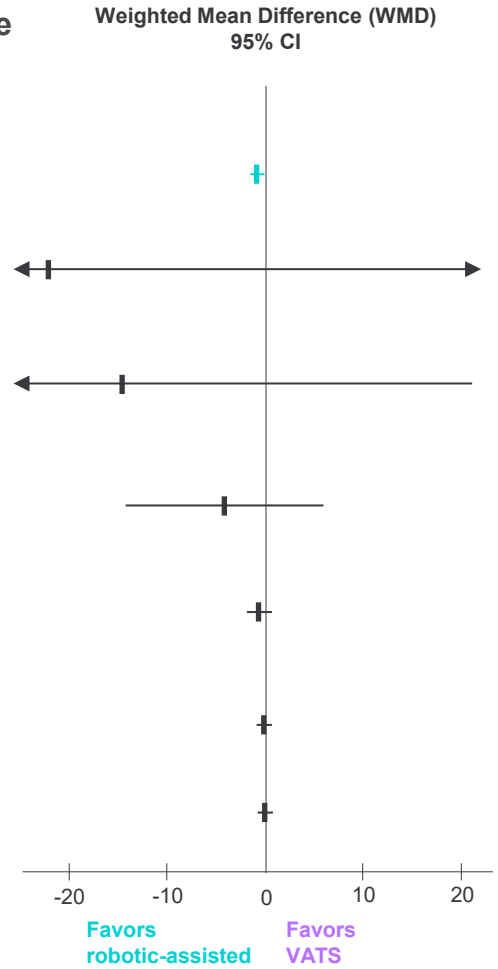
Robotic-assisted vs. VATS thymectomy

Summary as of December 31, 2022

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

Compared to VATS thymectomy, the evidence for **robotic-assisted thymectomy using the da Vinci surgical system** demonstrates:

- Significantly shorter hospital length of stay by an average of 0.75 days
- Comparable chest tube drainage
- Comparable estimated blood loss
- Comparable operative time
- Comparable chest tube duration
- Comparable ICU length of stay
- Comparable lymph node yield



Outcome	Robotic-assisted, n	VATS, n	Effect Size WMD, 95%CI	P-value
Thymectomy Continuous Variables (to December 31, 2022)				
LOS, days [4,7,8,9,10,13,15,19,23,24,27,28]				
Subtotal	1293	1349	-0.75 [-1.36, -0.13]	p=0.02
Random, Heterogeneity: p<0.01; I^2=89%				
Chest tube drainage, mL [8,15,19,23]				
Subtotal	193	155	-22.12 [-251.86, 207.63]	p=0.85
Random, Heterogeneity: p<0.01; I^2=97%				
EBL, mL [4,8,13,19,23,28]				
Subtotal	235	243	-14.56 [-34.36, 5.25]	p=0.15
Random, Heterogeneity: p=0.01; I^2=65%				
Operative Time, min [4,8,9,13,15,19,21,23,28]				
Subtotal	478	539	-3.98 [-14.00, 6.04]	p=0.44
Random, Heterogeneity: p<0.01; I^2=66%				
Chest tube duration , days [4,8,9,15,19,23,28]				
Subtotal	289	277	-0.66 [-1.56, 0.24]	p=0.15
Random, Heterogeneity: p<0.01; I^2=93%				
ICU LOS, days [7,9]				
Subtotal	109	157	-0.14 [-0.44, 0.15]	p=0.35
Fixed, Heterogeneity: p=0.48; I^2=0%				
LNY, n [10,27]				
Subtotal	274	274	-0.01 [-0.60, 0.58]	p=0.97
(VATS-R) Fixed, Heterogeneity: p=0.46; I^2=0%				

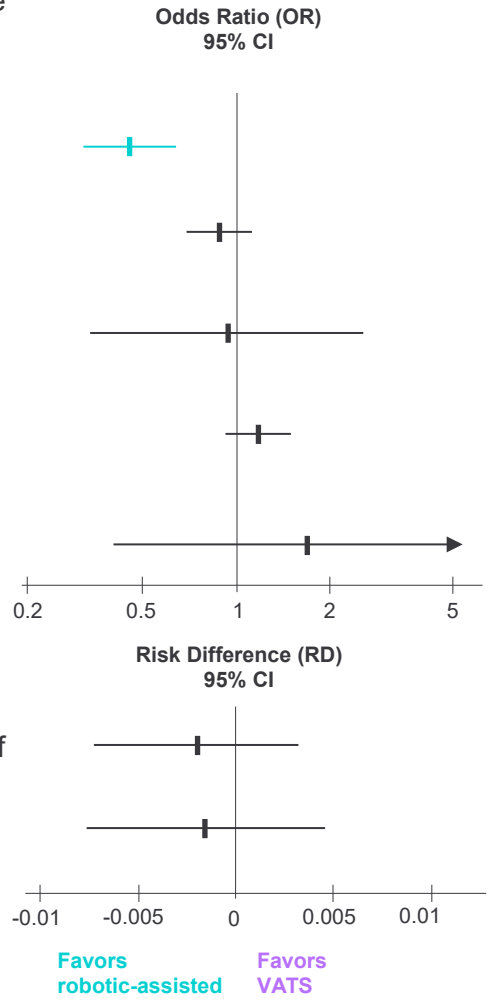
Robotic-assisted vs. VATS thymectomy

Summary as of December 31, 2022

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

Compared to VATS thymectomy, the evidence for **robotic-assisted thymectomy using the da Vinci surgical system** demonstrates:

- 55% less likely to have a conversion to open surgery
- Comparable positive surgical margin rate
- Comparable reoperations rate within 30-days of surgery
- Comparable postoperative complications rate within 30-days of surgery
- Comparable readmissions rate within 30-days of surgery
- Comparable mortality rate within 30-days of surgery
- Comparable blood transfusions rate



Outcome	Robotic-assisted, n	VATS, n	Effect size OR/RD 95% CI	P-value
Thymectomy Binary Variables (to December 31, 2022)				
Conversions, n [8,10,13,15,19,20,21,22,28]				
Subtotal	1621	1586	0.45 [0.32, 0.63]	p<0.01
Fixed, Heterogeneity: p=0.22; I²=26%				
Positive surgical margin, n [2,7,8,10,22,27]				
Subtotal	860	985	0.89 [0.70, 1.13]	p=0.33
Fixed, Heterogeneity: p=0.15; I²=41%				
Reoperations 30-day, n [7,20,13]				
Subtotal	783	730	0.93 [0.34, 2.58]	p=0.90
Fixed, Heterogeneity: p=0.72; I²=0%				
Postoperative complications 30-day, n [4,8,9,15,19,20,21,23,24,28]				
Subtotal	1647	1518	1.17 [0.93, 1.48]	p=0.19
Fixed, Heterogeneity: p=0.98; I²=0%				
Readmissions 30-day, n [7,10,22]				
Subtotal	576	557	1.72 [0.41, 7.20]	p=0.46
Random, Heterogeneity: p=0.04; I²=69%				
Mortality 30-day, n [4,6,8,10,13,15,19,21,22,23,24]				
Subtotal	1647	1744	-0.0019 [-0.0072, 0.0034]	p=0.49
Fixed, Heterogeneity: p=1.00; I²=0%				
Blood transfusions, n [20,28]				
Subtotal	689	572	-0.0015 [-0.0076, 0.0046]	p=0.62
Fixed, Heterogeneity: p=0.56; I²=0%				

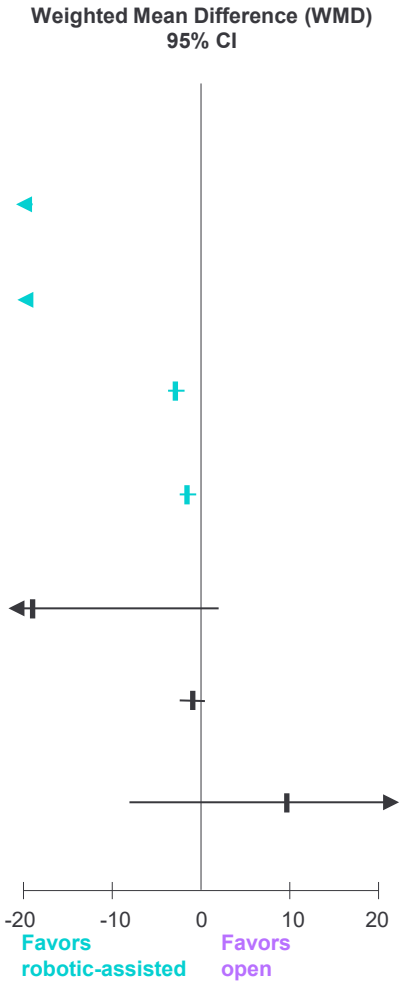
Robotic-assisted vs. open thymectomy

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 Thymectomy, the evidence for **robotic-assisted thymectomy using the da Vinci surgical system** demonstrates:

- Significantly less chest tube drainage by an average of 362 mL
- Significantly less estimated blood loss by an average of 208 mL
- Significantly shorter hospital length of stay by an average of 2.9 days
- Significantly shorter chest tube duration by an average of 1.6 days
- Comparable operative time
- Comparable ICU length of stay
- Comparable lymph node yield



Outcome	Robotic-assisted, n	Open, n	Effect Size WMD, 95%CI	P-value
Thymectomy Continuous Variables (to December 31, 2022)				
Chest tube drainage, mL [8,19,25, 29]				
Subtotal	169	157	-362.14 [-546.48, -177.80]	p<0.01
Random, Heterogeneity: p<0.01; I^2=98%				
EBL, mL [1,5,8,11,12,14,19,26,29]				
Subtotal	456	443	-208.27 [-292.50, -124.04]	p<0.01
Random, Heterogeneity: p<0.01; I^2=97%				
LOS, days [1,3,5,7,8,10,11,12,14,16,17,18,19,20,25,26,27,29]				
Subtotal	1863	3414	-2.91 [-3.68, -2.13]	p<0.01
Random, Heterogeneity: p<0.01; I^2=100%				
Chest tube duration , days [5,8,11,14,17,19,25,26,29]				
Subtotal	350	396	-1.62 [-2.34, -0.91]	p<0.01
Random, Heterogeneity: p<0.01; I^2=95%				
Operative time, min [1,3,5,7,8,11,12,14,16,17,19,25,26]				
Subtotal	666	668	-18.90 [-40.15, 2.35]	p=0.08
Random, Heterogeneity: p<0.01; I^2=95%				
ICU LOS, days [7,16,26]				
Subtotal	170	240	-0.96 [-2.39, 0.47]	p=0.19
Random, Heterogeneity: p<0.01; I^2=87%				
LNY, n [10,27]				
Subtotal	448	1178	9.56 [-7.29, 26.42]	p=0.27
L-R, Random, Heterogeneity: p<0.01; I^2=99%				

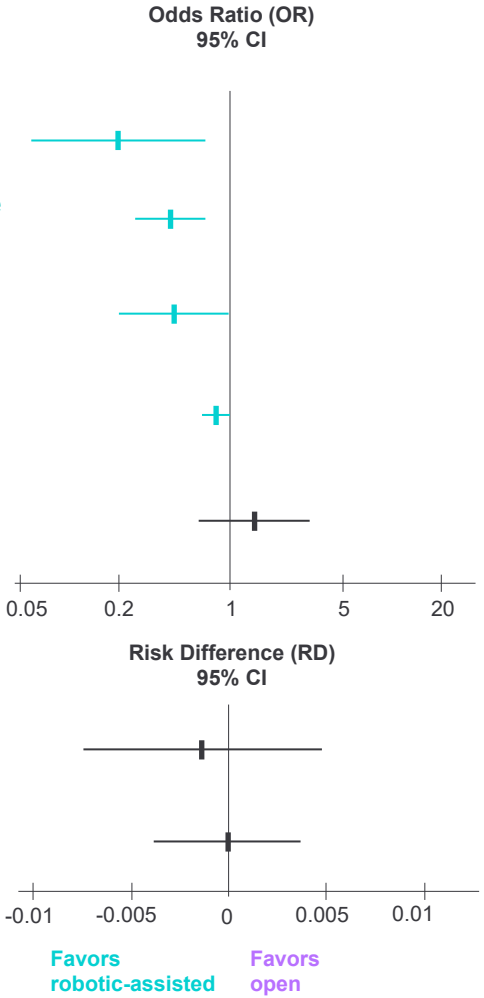
Robotic-assisted vs. open thymectomy

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 thymectomy, the evidence for **robotic-assisted thymectomy using the da Vinci surgical system** demonstrates:

- 80% less likely to be admitted to ICU
- 57% less likely to experience a postoperative complication within 30-days of surgery
- 56% less likely to be reoperated within 30-days of surgery
- 19% lower likelihood of a positive surgical margin
- Comparable readmissions rate within 30-days of surgery
- Comparable mortality rate within 30-days of surgery
- Comparable blood transfusions rate



Outcome	Robotic-assisted, n	Open, n	Effect size OR/RD 95% CI	P-value
Thymectomy Binary Variables (to December 31, 2022)				
ICU Admissions, n [3, 25,26]				
Subtotal	121	172	0.20 [0.06, 0.70]	**p=0.01**
Fixed, Heterogeneity: p=0.15; I²=48%				
Postoperative complications 30-day, n [1,3,8,11,12,14,16,17,18,19,20,25,26,29]				
Subtotal	1322	2139	0.43 [0.25, 0.72]	**p<0.01**
Random, Heterogeneity: p<0.01; I²=55%				
Reoperations 30-day, n [7,20,26]				
Subtotal	781	1728	0.44 [0.20, 0.98]	**p=0.04**
Fixed, Heterogeneity: p=0.62; I²=0%				
Positive surgical margin, n [2,3,5,8,10,12,14,22,27,				
Subtotal	1163	5113	0.81 [0.68, 0.97]	**p=0.02**
Fixed, Heterogeneity: p=0.09; I²=44%				
Readmissions 30-day, n [7,10,22,26]				
Subtotal	710	2116	1.41 [0.63, 3.18]	p=0.40
Random, Heterogeneity: p=0.07; I²=57%				
Mortality 30-day, n [5,6,8,10,12,14,17,19,22,25,26]				
Subtotal	1104	4610	-0.0013 [-0.0076, 0.0050]	p=0.69
Fixed, Heterogeneity: p=1.00; I²=0%				
Blood transfusions, n [20,29]				
Subtotal	691	1596	0.0000 [-0.0038, 0.0038]	p=1.00
Fixed, Heterogeneity: p=1.00; I²=0%				

Thymectomy: bibliography

December 31, 2022

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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.

The da Vinci X and da Vinci Xi Surgical Systems are class IIb medical devices CE marked (CE 2460) under the European Medical Devices Directive (93/42/EEC), manufactured by Intuitive Surgical, Inc. Refer to Instructions For Use before use.

For product intended use and/or indications for use, risks, cautions, and warnings and full prescribing information, refer to the associated user manual(s) or visit https://manuals.intuitivesurgical.com/market. Some products, features or technologies may not be available in all countries. Product availability is subject to regulatory approval in the specific market. Please contact your local Intuitive representative for product availability in your region.

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

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