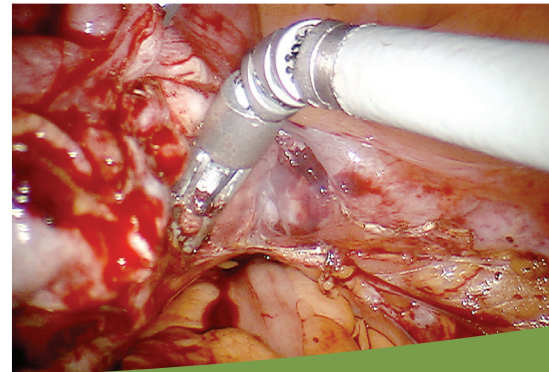
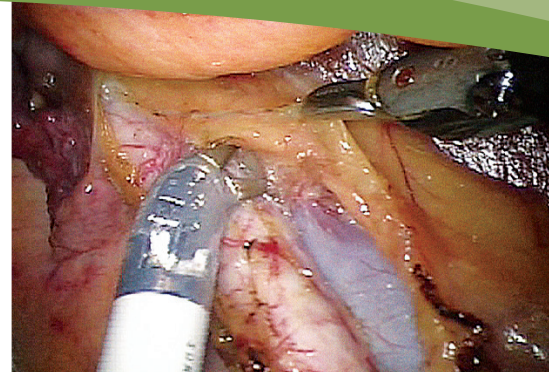


*da Vinci*<sup>®</sup>

# HYSTERECTOMY

FOR EARLY STAGE GYNECOLOGIC CANCER



Solutions for minimally invasive gynecologic surgery

# The *da Vinci* Surgical System



## 3D HD Vision

3D HD visualization facilitates accurate identification of the ureters while accessing the correct anatomical angles.

## Dual Console: Available exclusively on the *da Vinci* Si™

Dual console capability allows an additional surgeon to provide an assist or can facilitate teaching and proctoring by connecting a second surgeon console.

- High-definition 3D vision
- *EndoWrist*® instrumentation
- *Intuitive*® motion

## Surgeon Benefits

### Enables precise, comprehensive minimally invasive surgery for early stage gynecologic cancer

The improved dexterity and excellent visualization provided by the *da Vinci* System allow surgeons to:

- ❖ Offer a safe, reproducible approach for women undergoing surgery for gynecological cancer — even for obese women<sup>1</sup>
- ❖ Perform a comprehensive cancer surgery and staging procedure that preserves radicality<sup>2</sup>
- ❖ Enjoy surgical autonomy and efficiency
- ❖ Simplify postoperative care and reduce length-of-stay by minimizing trauma, pain and complications<sup>3</sup>
- ❖ Expedite the initiation of adjuvant therapy as a result of fast recovery<sup>3</sup>
- ❖ Extend the benefits of minimally invasive surgery to more patients, with excellent outcomes and patient satisfaction



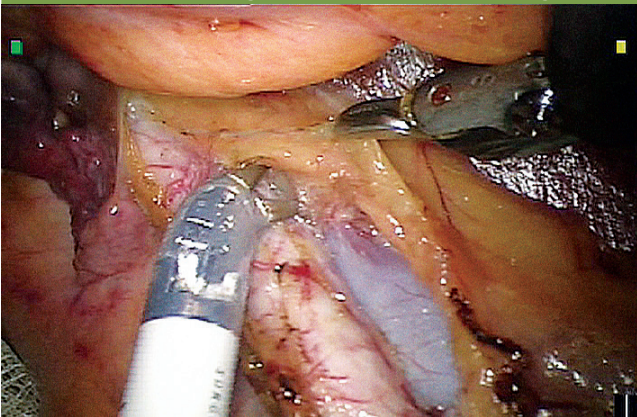
Monopolar  
Hot Shears™



# Application Highlights

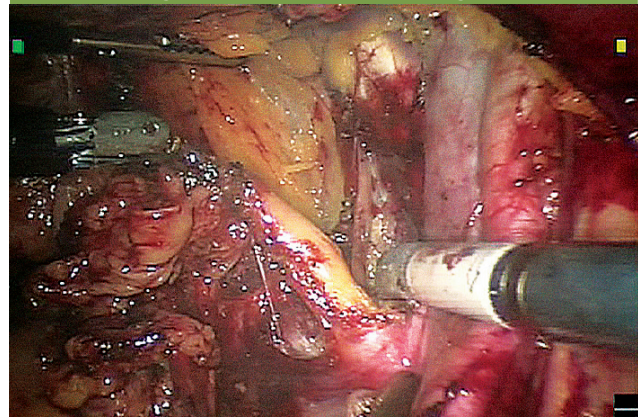
Four ways *da Vinci* technology facilitates a precise hysterectomy for early-stage cancer:

## Para-aortic Lymphadenectomy



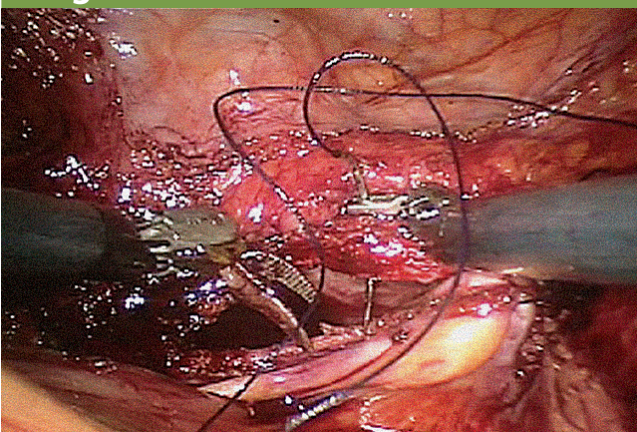
The visualization and dexterity provided by the *da Vinci* System facilitate anatomical tissue plane dissection and pedicle isolation. This provides greater precision and control when dissecting the lymph node bundle off the internal iliac and vena cava. The result is excellent lymph node harvest with greater surgical ease compared to open and conventional laparoscopic technique.<sup>2</sup>

## Pelvic Lymphadenectomy



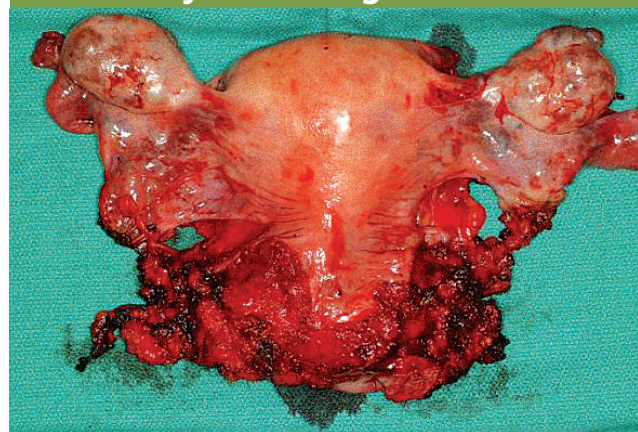
A precise, controlled dissection of the lymph node bundle can be achieved off the external iliac artery, out to the pelvic side wall and psoas muscle, and into the obturator space. This facilitates a complete en bloc lymphadenectomy, increasing lymph node yield for pathology evaluation.<sup>2</sup>

## Vaginal Cuff Closure



*EndoWrist* instrument articulation provides surgeons with greater dexterity, precision and control to suture the vaginal cuff closed compared to conventional laparoscopy.<sup>7,8</sup>

## Radicality and Margins



The 3D visualization and up to 10X magnification combined with wristed instruments allow surgeons to perform comprehensive, radical dissections to achieve desired margins for complete cancer removal.<sup>7,8</sup>

For technology videos visit  
[www.daVinciSurgeryCommunity.com](http://www.daVinciSurgeryCommunity.com)

# Clinical Data

## Surgical Outcomes In Gynecologic Oncology In The Era Of Robotics: Analysis Of First 1000 Cases

Paley et al., Am J Obstet Gynecol.2011; 551.e1-551.e9

This prospective study examines outcomes from the first 1000 women who underwent *da Vinci* hysterectomy at a tertiary care center in Seattle, WA. 377 women who underwent *da Vinci* hysterectomy for endometrial cancer staging (ECS) were compared with a historical data set of 131 who underwent ECS via laparotomy. Despite a steady and significant rise in average patient BMI and an increasing proportion of women with medical comorbidities and prior pelvic surgeries throughout the study period, the authors found no concomitant rise in major complications or conversions, and a steady decline in the rate of vaginal cuff dehiscence. Limitations of this study included its retrospective, nonrandomized design, potentially introducing selection bias.

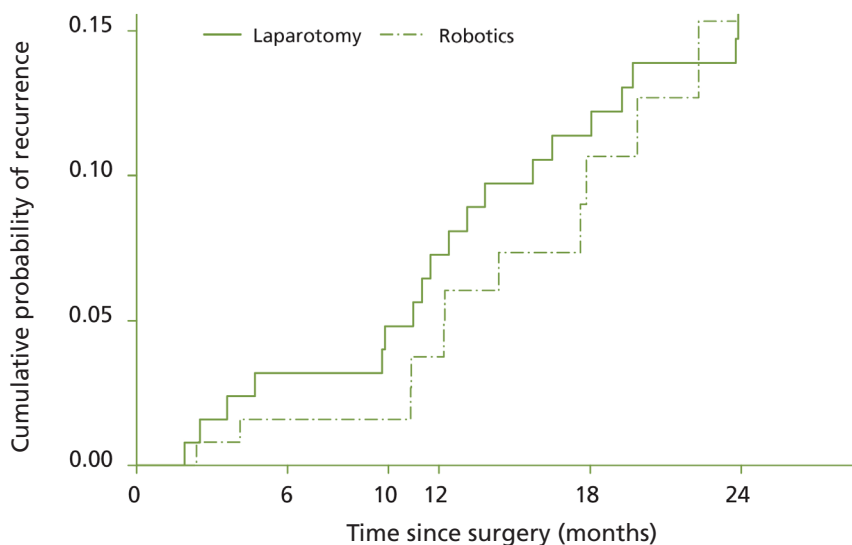
	<i>da Vinci</i> (n=377)	Laparotomy (n=131)	P-value
Age (yrs)	62.1	63	0.08 (NS)
BMI (kg/m <sup>2</sup> )	31.3	32.2	0.47 (NS)
Surgical Time (mins)	184	139	<0.0001
EBL (mL)	46.9	197.6	<0.0001
Node Counts	15.4	13.1	0.007
LOS (day)	1.4	5.3	<0.0001
Major complications (%)	6.4	20.6	<0.0001
Major complications <sup>a</sup> , Obese subset	(n=5/136) 3.7%	(n=15/47) 31%	<0.0001

<sup>a</sup>Includes infection, wound dehiscence, anemia requiring transfusion, pulmonary, cystostomy, myocardial infarction, atrial fibrillation, acute renal failure and ureteral injury.

## Outcomes and Cost Comparisons After Introducing a Robotics Program for Endometrial Cancer Surgery

Lau et al., Obstet Gynecol. 2012 Apr;119(4):717-24.

A key factor in evaluating any cancer treatment procedure is oncologic outcome. In this study, a follow-up of 2 years after robotic surgery indicates a lower recurrence rate compared with the historical cohort (p <.001). There were 19 recurrent cases in the historic cohort (solid line) and 11 recurrences in the robotics cohort (dotted line) within 2 years of surgery. A limitation of this study relates to the retrospective nature of the data collection for the historical cohort.



For additional data pertaining to these studies visit  
[www.daVinciSurgeryCommunity.com](http://www.daVinciSurgeryCommunity.com)



# Potential Patient Benefits & Risks

## POSSIBLE BENEFITS COMPARED TO OPEN SURGERY:

- ❖ More precise removal of cancerous tissue (based on two year follow-up)<sup>4</sup>
- ❖ Fewer complications<sup>2,3,4,5,6,7,8</sup>
- ❖ Less blood loss<sup>1,2,3,4,5,6,7,8,9</sup>
- ❖ Less pain<sup>8,10</sup>
- ❖ Quicker recovery<sup>3</sup>
- ❖ Shorter hospital stay (one day in many cases)<sup>2,4,5,6,7,8,9</sup>
- ❖ Small incisions for minimal scarring

## POSSIBLE BENEFITS COMPARED TO TRADITIONAL LAPAROSCOPY:









- ❖ Similar or fewer complications,<sup>3</sup> including major complications<sup>11,12</sup>
- ❖ Fewer conversions to open surgery<sup>9,10,13</sup>
- ❖ Less blood loss<sup>2,6,11</sup>
- ❖ Less need for narcotic pain medicine<sup>14</sup>
- ❖ Shorter hospital stay<sup>2,9,11</sup>
- ❖ Quicker recovery<sup>3</sup>

## POSSIBLE RISKS INCLUDE:

- ❖ Separation of the vaginal incision<sup>2</sup>
- ❖ Blocked lung artery<sup>2</sup>
- ❖ Urinary tract injury<sup>2</sup>



## EndoWrist<sup>®</sup> Instruments Optimized for *da Vinci*<sup>®</sup> Hysterectomy for Cancer

STANDARD/S,Si PNs	FEATURES	STANDARD/S,Si PNs	FEATURES
 <p><b>Fenestrated Bipolar Forceps (Bipolar Cadiere)</b> 400205/420205</p>	<ul style="list-style-type: none"> <li>❖ Bipolar energy device</li> <li>❖ Fenestrated wide jaw profile</li> </ul>	 <p><b>Large Needle Driver</b> 400006/420006</p>	<ul style="list-style-type: none"> <li>❖ Carbide-insert style jaws</li> <li>❖ Diamond pattern jaw profile</li> </ul>
 <p><b>Hot Shears<sup>™</sup> (Monopolar Curved Scissors)</b> 400179/420179 Requires Tip Cover: 400180</p>	<ul style="list-style-type: none"> <li>❖ Combined scissors and monopolar cautery</li> <li>❖ Tapered tip-profile</li> </ul>	 <p><b>EndoWrist PK<sup>™</sup> Dissector</b> 400227/420227</p>	<ul style="list-style-type: none"> <li>❖ Grasping, dissection, and coagulation</li> </ul>
 <p><b>ProGrasp<sup>™</sup></b> 400093/420093</p>	<ul style="list-style-type: none"> <li>❖ Grasping, retraction &amp; dissection</li> </ul>	 <p><b>Maryland Bipolar Forceps – Fenestrated</b> 400172/420172</p>	<ul style="list-style-type: none"> <li>❖ Grasping, dissection, and coagulation</li> </ul>
 <p><b>Mega SutureCut<sup>™</sup> Needle Driver</b> 400309/420309 <b>Large SutureCut<sup>™</sup> Needle Driver</b> 400296/420296</p>	<ul style="list-style-type: none"> <li>❖ Strong grasping force</li> <li>❖ Scissor blades at the base</li> <li>❖ Tapered, smooth outer jaw</li> </ul>	 <p><b>Vessel Sealer</b> 410322</p>	<ul style="list-style-type: none"> <li>❖ Fully wristed articulation</li> <li>❖ Dual-hinged jaw opening</li> </ul>



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To contact a representative or receive additional information, visit [www.intuitivesurgical.com](http://www.intuitivesurgical.com) or call Intuitive Surgical Customer Service in the U.S. at 1.877.408.3872, in Europe at +41 21 821 20 00 or +800 0 821 20 20 or in the rest of the world, 1.408.523.2100.

While clinical studies support the use of the *da Vinci*® Surgical System as an effective tool for minimally invasive surgery for specific indications, individual results may vary. Contraindications applicable to the use of conventional endoscopic instruments also apply to the use of all *da Vinci* instruments, including *Single-Site* Instrumentation. General contraindications for endoscopic surgery include bleeding diathesis, morbid obesity and pregnancy. Be sure to read and understand all information in the applicable user manuals, including full cautions and warnings, before using *da Vinci* products. Failure to properly follow all instructions may lead to injury and result in improper functioning of the device. Unless otherwise noted, products featured are cleared for commercial distribution in the U.S. and bear the CE mark. For availability and clearances outside the US, please check with your local representative or distributor. We encourage patients and physicians to review all available information. Clinical studies are available through the National Library of Medicine at [www.ncbi.nlm.nih.gov/pubmed](http://www.ncbi.nlm.nih.gov/pubmed).

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<sup>1</sup> Lau S, Vaknin Z, Ramana-Kumar AV, Halliday D, Franco EL, Gottlieb WH. Outcomes and cost comparisons after introducing a robotics program for endometrial cancer surgery. *Obstet Gynecol.* 2012 Apr;119(4):717-24. doi: 10.1097/AOG.0b013e31824c0956. <sup>2</sup> Paley PJ, Veljovich DS, Shah CA, Everett EN, Bondurant AE, Drescher CW, Peters WA 3rd. Surgical outcomes in gynecologic oncology in the era of robotics: analysis of first 1000 cases. *Am J Obstet Gynecol.* 2011 Jun;204(6):551.e1-9. Epub 2011 Mar 16. <sup>3</sup> Estape R, Lambrou N, Estape E, Vega O, Ojea T. Robotic-assisted total laparoscopic hysterectomy and staging for the treatment of endometrial cancer: a comparison with conventional laparoscopy and abdominal approaches. *J Robotic Surg* 2009 DOI 10.1007/s11701-011-0290-7. <sup>4</sup> DeNardis SA, Holloway RW, Bigsby GE, Pikaart DP, Ahmad S, and Finkler NJ. Robotically assisted laparoscopic hysterectomy versus total abdominal hysterectomy and lymphadenectomy for endometrial cancer. *Gynecologic Oncology* 2008;111:412-417. <sup>5</sup> Boggess JF, Gehrig PA, Cantrell L, Shafer A, Ridgway M, Skinner EN, and Fowler WC. A comparative study of 3 surgical methods for hysterectomy with staging for endometrial cancer. *Am J Obstet Gynecol* 2008. (For port placement, see figure 3) <sup>6</sup> Bell MC, Torgerson J, Seshadri-Kreaden U, Suttle AW, and Hunt S. Comparison of outcomes and cost for endometrial cancer staging via traditional laparotomy, standard laparoscopy, and robotic techniques. *Gynecologic Oncology* 2008;111:407-411. <sup>7</sup> Halliday D, Lau S, Vaknin Z, Deland C, Levental M, McNamara E, Gottlieb R, Kaufer R, How J, Cohen E, Gottlieb W. Robotic radical hysterectomy: comparison of outcomes and cost. *J Robotic Surg* (2010) 4:211-216 DOI 10.1007/s11701-010-0205-z <sup>8</sup> Magrina JF, Zanagnolo V, Giles D, Noble BN, Kho RM, Magtibay PM. Robotic surgery for endometrial cancer: comparison of perioperative outcomes and recurrence with laparoscopy, vaginal/laparoscopy and laparotomy. *Eur J Gynaecol Oncol.* 2011;32(5):476-80. <sup>9</sup> Lowe MP, Hoekstra AV, Jairam-Thodla A, Singh DK, Buttin BM, Lurain JR and Schink JC. A comparison of robot-assisted and traditional radical hysterectomy for early-stage cervical cancer. *Journal of Robotic Surgery* 2009:1-5. <sup>10</sup> Lim PC, Kang E, Park do H. A comparative detail analysis of the learning curve and surgical outcome for robotic hysterectomy with lymphadenectomy versus laparoscopic hysterectomy with lymphadenectomy in treatment of endometrial cancer: a case-matched controlled study of the first one hundred twenty two patients. *Gynecol Oncol.* 2011 Mar;120(3):413-8. Epub 2010 Dec 30. <sup>11</sup> Jason D. Wright, MD, Cande V. Ananth, PhD, MPH Sharyn N. Lewin, MD William M. Burke, MD Yu-Shiang Lu, MS, Alfred I. Neugut, MD, PhD Thomas J. Herzog, MD, Dawn L. Hershman, MD. Robotically assisted vs laparoscopic hysterectomy among women with benign gynecologic disease. *JAMA*, February 20, 2013—Vol 309, No. 7 689. <sup>12</sup> Scandola M, Grespan L, Vicentini M, Fiorini P. Robot-assisted laparoscopic hysterectomy vs traditional laparoscopic hysterectomy: five metaanalyses *J Minim Invasive Gynecol.* 2011 Nov-Dec;18(6):705-15. <sup>13</sup> Martino MA, Shubella J, Thomas MB, Morcrette RM, Schindler J, Williams S, Boulay R. A cost analysis of postoperative management in endometrial cancer patients treated by robotics versus laparoscopic approach. *Gynecol Oncol.* 2011 Dec;123(3):528-31. Epub 2011 Oct 2. <sup>14</sup> A detailed analysis of the learning curve: robotic hysterectomy and pelvic-aortic lymphadenectomy for endometrial cancer. Seamon LG, Fowler JM, Richardson DL, Carlson MJ, Valmadre S, Phillips GS, Cohn DE. *Gynecol Oncol.* 2009 Aug;114(2):162-7.