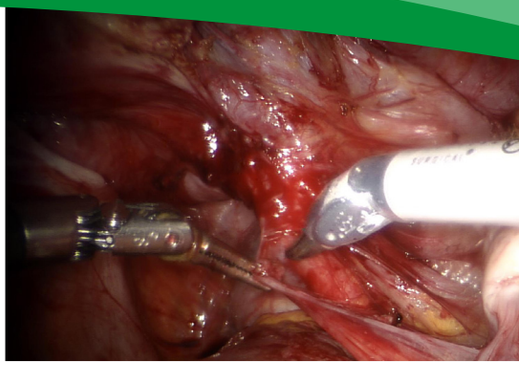
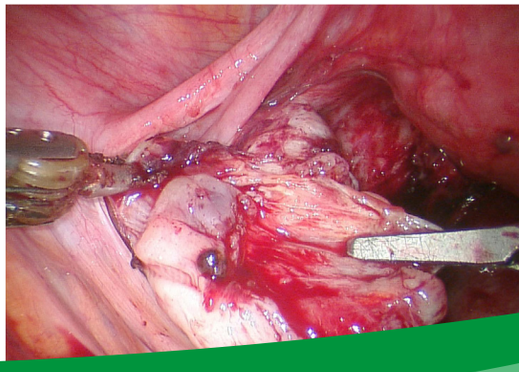
da Vinci®

ENDOMETRIOSIS RESECTION





Solutions for minimally invasive gynecologic surgery

INTUITIVE SURGICAL®

The *da Vinci* Surgical System

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

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

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.

Monopolar
Hot Shears™

Surgeon Benefits

Enables a reproducible surgical approach for complex endometriosis with improved visualization[1,2] for complete resection[3] of endometriotic lesions.

The visualization, depth perception, dexterity and control provided by the *da Vinci* System offer potential for:

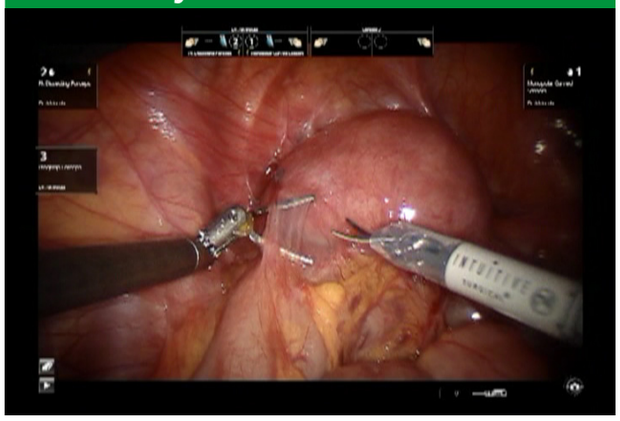
- 3D high-definition visualization of endometriotic lesions[1,2]
- Ability to precisely resect stage IV disease, including deeply infiltrating endometriosis[1,3]
- Extension of a minimally invasive approach to advanced or extensive cases[3]
- Control of the camera and all three operative arms provide excellent surgical autonomy, accuracy and efficiency.

Potential risks of any endometriosis resection procedure include bladder injury, abscess, urinary tract injury and bowel obstruction.

Application Highlights

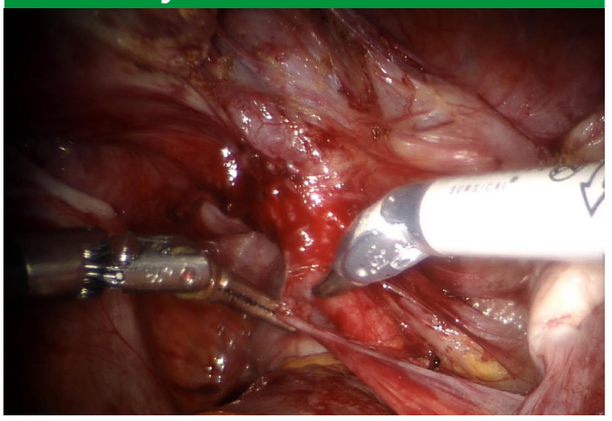
Four ways *da Vinci* technology facilitates a precise endometriosis resection:

Adhesiolysis



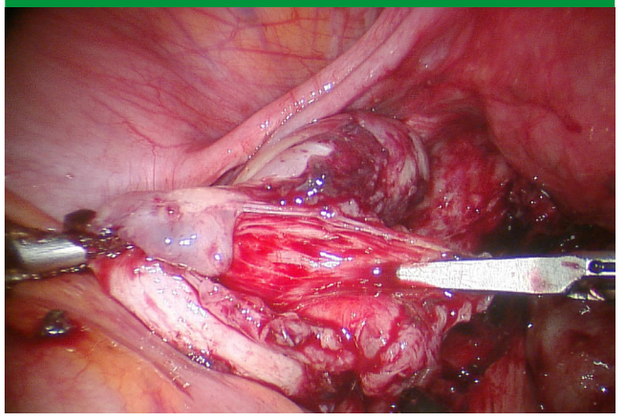
3D HD vision provides improved visualization of tissue planes, making it easy to restore normal anatomy while avoiding injury to ureters, vasculature and other structures. In addition, *Hot Shears*™ (Monopolar Curved Scissors) offers two modes for meticulous freeing of adhesions throughout the pelvic cavity.

Ureterolysis



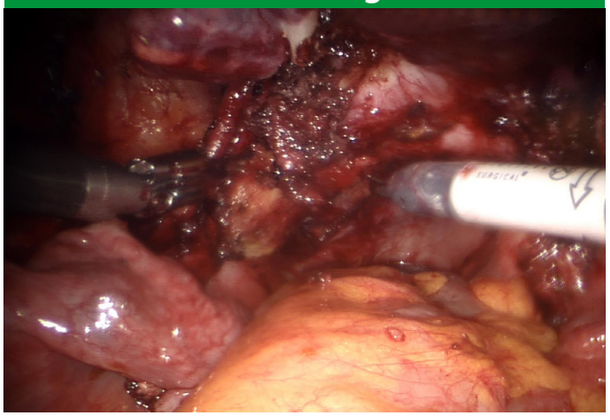
EndoWrist® instruments facilitate careful ureterolysis, even when the ureters are hidden by scar tissue and nodular disease. Wristed instrumentation also enables precise resection of lesions that have deeply infiltrated structures such as bowel and ureters. Surgical autonomy can be achieved utilizing the 3rd instrument arm to assist in tissue manipulation or retraction.

Excision of Ovarian Endometrioma



Excellent visualization for better tissue plane identification.[2] This may help avoid damage to the ovary and to preserve ovary functionality by improved identification of the ovary / endometrioma wall. The *PK*™ Dissecting Forceps and Long-Tip Forceps can be used together to provide traction/retraction for effective removal of the endometrioma.

Resection of Rectovaginal Nodules



Stable and magnified visualization, scaling of movements, and fully articulating instrumentation enables the surgeon to identify and resect lesions and nodules throughout the pelvic cavity, including deep in the pelvis and in the posterior cul-de-sac. The *EndoWrist* instrumentation also facilitates easy and efficient access to intraperitoneal and retroperitoneal anatomy for excision of all nodules.

For technology videos visit

www.daVinciSurgeryCommunity.com

Clinical Data

Retrospective analysis of robot-assisted versus standard laparoscopy in the treatment of pelvic pain indicative of endometriosis[2]

John F. Dulemba, MD, Cyndi Pelzel, MD and Helen B. Hubert, Journal of Robotic Surgery, June 2012.

Operative time (77 vs. 72 min), blood loss (29 vs. 25 mL), and complication rates (1.1% vs. 0%) in robot-assisted and standard laparoscopy were low and similar for both approaches. Differences were apparent in biopsies confirming endometriosis (80% robot-assisted vs. 56.8% traditional laparoscopy, p<0.001). Most patients reported improved postoperative pain at the first follow-up visit with no differences between the surgical approaches (85% vs. 80%, p = 0.365). This finding suggests that robot-assisted techniques, compared to standard laparoscopy, may provide more accurate visualization and, thus, excision of existing endometriosis. There are small subtle changes in the terrain of the peritoneum that cannot be seen with the 2-dimensional components of the traditional laparoscopic equipment. The authors experienced better tissue plane visualization with robot-assisted compared to conventional laparoscopic surgery due to the very stable and magnified views with scaling of movements. Limitations of this study are that it lacked validated and longer-term outcome measures needed to address symptom and fertility outcomes and that further investigation is required to evaluate the cost of acquiring and using robotic equipment versus the potential benefits.

	Robot-assisted	Laparoscopy	*p* Value
Operative Time (minutes)	77.4	72.3	0.23
Patients w/ confirmed endometriosis	80.0%	56.8%	<0.001
Appendectomy	23.3%	30.0%	0.32
Appendix positive for endometriosis	28.6%	3.3%	0.02
Complications	2 (1.1)*	0	0.54

**1 intraoperative cystotomy, 1 postoperative MRSA umbilicus*

Peri-operative outcomes of patients with stage IV endometriosis undergoing robotic-assisted laparoscopic surgery[3]

Lorna Brudie, MD and Rob Holloway, MD, Journal of Robotic Surgery, October 2011.

Stage IV endometriosis with a "frozen pelvis" presents surgical challenges that often exceed many oncology operations because of distorted anatomy and risks of damage to normal tissues. This is a large reported series of peri-operative and short-term post-operative outcomes of 80 patients with stage IV endometriosis who underwent surgery with the *da Vinci* Surgical System. Managing advanced stage endometriosis was feasible with few laparotomy conversions and low complications during the authors' "learning-curve," sparing many patients from the morbidity of laparotomy. Resolution of endometriosis-related pain at least 2 months following surgery was excellent. Limitations of this study include the retrospective design, the lack of long-term follow-up for recurrence of pain and endometriosis and that all data were retrieved from chart review without formal pain-score assessments.

Parameters	Results
Cases (n)	80
Operative time (min)	115 ± 46
Estimated blood loss (ml)	88 ± 67
Blood transfusions	0
Hospital length of stay (days)	1.0 ± 0.37
Pain relief at 8 weeks post-operative	79 (98.8%)

For additional data pertaining to these studies visit

www.daVinciSurgeryCommunity.com

Potential Patient Benefits & Risks

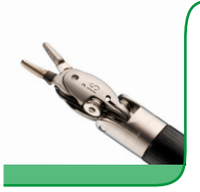
POSSIBLE BENEFITS SIMILAR TO TRADITIONAL LAPAROSCOPY:

- Low blood loss[2,3]
- Low conversion rate to open surgery[2,3]
- Low rate of complications[1,2]
- Short hospital stay[3]
- Small incisions for minimal scarring

POSSIBLE RISKS INCLUDE[4]:

- Bladder injury
- Abscess
- Urinary tract injury
- Bowel obstruction

EndoWrist® Instruments Offered for ***da Vinci***® Endometriosis Resection

	STANDARD/*S,Si* PNs	FEATURES
	***Hot Shears***™ **(Monopolar Curved Scissors)** **400179/420179**	⁘ Combined scissors and monopolar cautery ⁘ Tapered tip profile
	***PK***™ **Dissecting Forceps** **400214/420214** **Tip Cover Accessory** **400180**	⁘ *PK* advanced bipolar technology ⁘ Audio impedance indicator
	**Long-Tip Forceps** **400048/420048**	⁘ Long-tip jaw design ⁘ Increased jaw spacing
	**Large *SutureCut***™ **Needle Driver** **400296/420296**	⁘ Tapered, smooth outer jaw ⁘ Scissor blades at the base

	STANDARD/*S,Si* PNs	FEATURES
	**5 Fr. Introducer** **400225/420225** **Laser Sheath** **400009/NA**	⁘ Precise manipulation of a validated laser fiber ⁘ Precise excision and coagulation of tissue
	**Maryland Bipolar Forceps** **400172/420172**	⁘ Grasping, coagulation & dissection
	**Small *Graptor***™ **(Grasping Retractor)** **NA/420318**	⁘ Firm, yet atraumatic grasping of bowel and other delicate structures
	**Cadiere Forceps** **400049/420049**	⁘ Grasping and resecting ⁘ Atraumatic retraction

INTUITIVE SURGICAL®

Taking Surgery Beyond the Limits of the Human Hand.™

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.

The Intuitive Surgical *EndoWrist* 5 Fr. Introducer is intended to be used as a conduit through which compatible surgical laser fibers may be held and directed in conjunction with *da Vinci, da Vinci S*, or *da Vinci Si* surgical systems. At this time, only the following surgical laser system is compatible for use with the *da Vinci, da Vinci S*, and *da Vinci Si* systems: LISA laser RevoLix® jr. The Laserscope Aura-XP system is only compatible with the *da Vinci* and *da Vinci S* systems because a disposable sterile adapter with filter is not available for the *da Vinci Si* System. The *EndoWrist* 5 Fr. Introducer may also be used to perform blunt dissection when the laser fiber is retracted or not within the instrument.

The *PK*® Dissecting Forceps and *PK* instrument cords are intended to be used with the *da Vinci* and *da Vinci S/Si* Surgical System for endoscopic manipulation of tissue including: grasping, dissecting, approximation, coagulation, retraction and ligation. The *PK* Dissecting Forceps may only be used on soft tissue. Do not use it on cartilage, bone or hard objects. Doing so may damage the instrument or make it impossible to remove from the cannula. The *PK* Dissecting Forceps is not intended for contraceptive coagulation of the fallopian tube, but may be used to achieve hemostasis following transection of the fallopian tube. The *PK* Dissecting Forceps is classified as a BF applied part. This instrument is hence not suitable for direct cardiac applications. For complete instructions for use, indications, contraindications, warnings and precautions, and safety information, please refer to the Instruments and Accessories User Manual, PN 550675.

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[1] Nezhat C, Lewis M, Kotikela S, Veeraswamy A, Saadat L, Hajhosseini B, Nezhat C. Robotic versus standard laparoscopy for the treatment of endometriosis. Fertil Steril. 2010 Dec;94(7):2758-60. Epub 2010 May 26. [2] Dulemba J.F. , Pelzel C. and Hubert H., Retrospective Analysis of Robot-Assisted Versus Standard Laparoscopy in the Treatment of Pelvic Pain Indicative of Endometriosis. Journal of Robotic Surgery, June 2012. [3] Brudie, L. and Holloway, R., Peri-operative outcomes of patients with stage IV endometriosis undergoing robotic-assisted laparoscopic surgery. Journal of Robotic Surgery, October 2011. [4] Endometriosis.org Global forum for news and information. "Surgery". Available from: http://endometriosis.org/treatments/endometriosis-surgery/