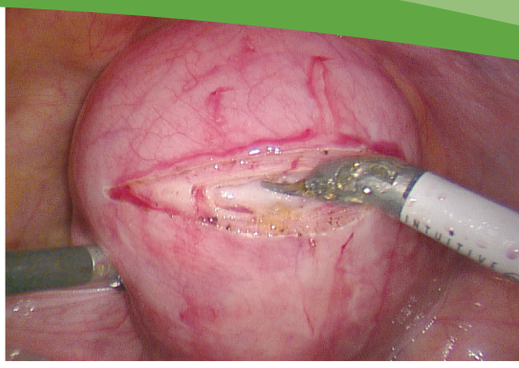
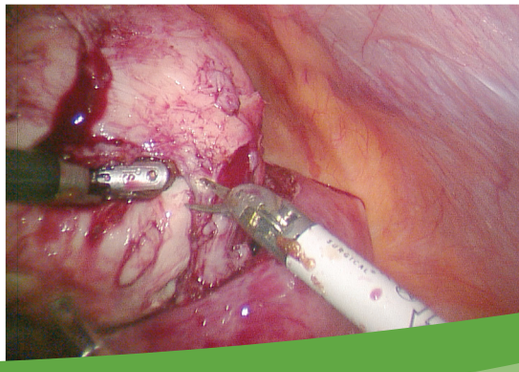
da Vinci®

MYOMECTOMY





Solutions for minimally invasive gynecologic surgery

INTUITIVE SURGICAL®

The *da Vinci* Surgical System

***TilePro*™ Multi-Input Display**
Allows the surgeon and the OR team to view 3D video of the operative field along with up to two additional video sources, such as ultrasound and EKG.

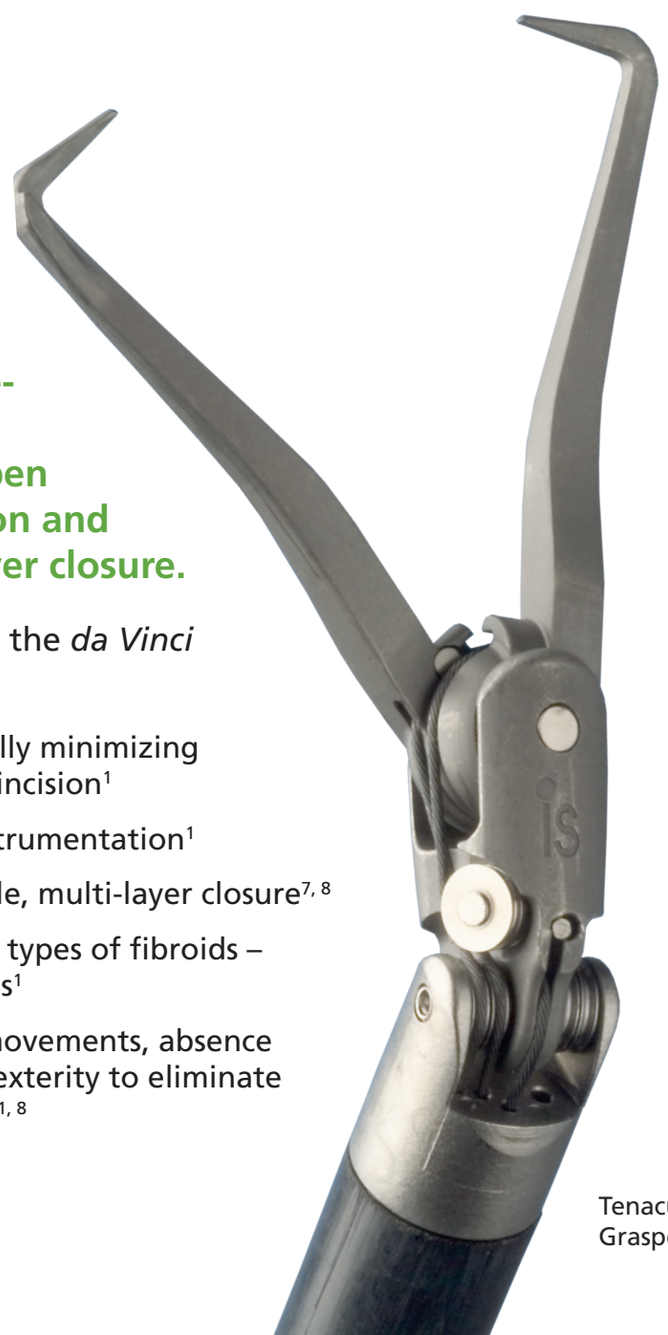
- High-definition 3D vision
- *EndoWrist*® instrumentation
- *Intuitive*® motion

Surgeon Benefits

Enables gynecologists to perform uterine-preserving myomectomies minimally invasively, reproducibly and following open surgical technique – with surgical precision and confidence in the ability to do a multi-layer closure.

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

- Minimally invasive access to the myoma, potentially minimizing complications associated with a large abdominal incision[1]
- Precise dissection of myomas using *EndoWrist* instrumentation[1]
- Precise suturing of the uterine defect for a durable, multi-layer closure[7, 8]
- Extending a minimally invasive approach to more types of fibroids – larger, more numerous and less accessible myomas[1]
- 3D vision, improved ergonomics, wide range of movements, absence of the fulcrum effect and improved instrument dexterity to eliminate most of the limitations of traditional laparoscopy[1, 8]

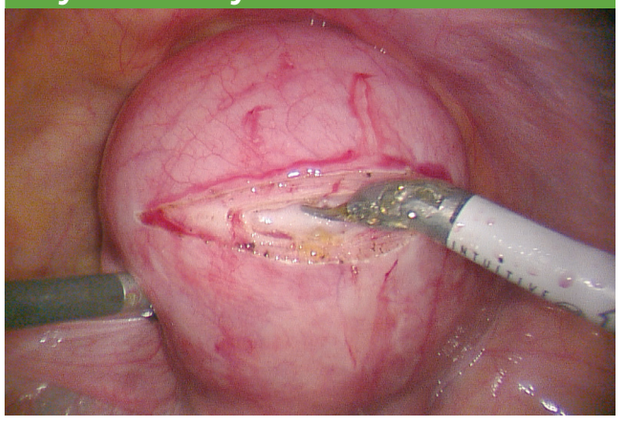


Tenaculum Grasper

Application Highlights

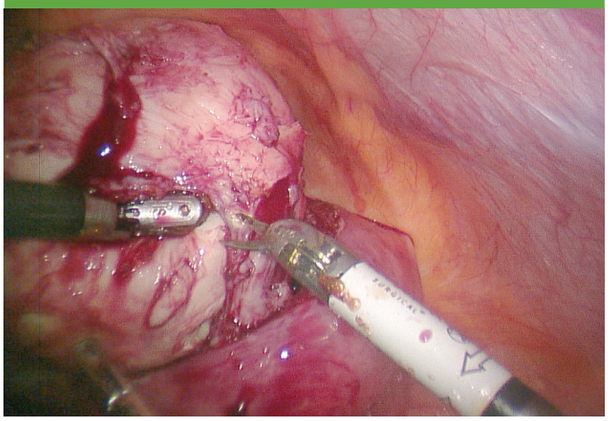
Four ways *da Vinci* technology facilitates a precise myomectomy:

Hysterotomy



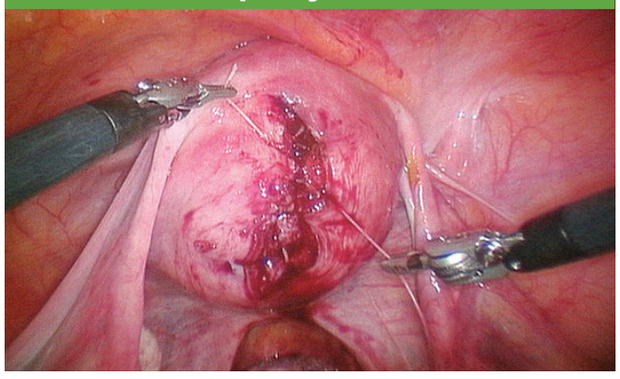
The Permanent Cautery Hook allows for a strategically placed horizontal or vertical incision, based upon the location of the pathology, while avoiding excessive divots or tunneling within the myometrium surrounding the myoma. The *PK*™ Dissecting Forceps retract the incised myometrium and provide improved coagulation with minimal thermal spread to facilitate deliberate perpendicular cuts down to the myoma capsule.

Enucleation



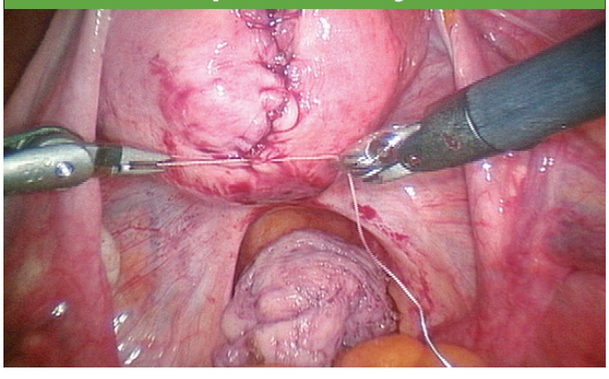
Consistent, careful counter traction can be attained by utilizing the *EndoWrist*® Tenaculum Forceps while avoiding entrance into the endometrial cavity or premature avulsion of the myoma. The *PK* Dissecting Forceps facilitate development of the correct dissection plane surrounding the myoma while also providing more site-specific counter traction, facilitating a more precise dissection. The *HotShears* is used to peel the myoma free of all attachments. Coagulation with the *PK* Dissecting Forceps should be prudently used to preemptively deal with vascular attachments.

Multi-Layered Suture Closure of Defect – *Deep Layers*



The *SutureCut*™ Needle Driver securely holds CT-2 needles as they pass through the myometrial layers while providing integrated cutting following knot tying for improved operative efficiency. The *EndoWrist* Large Needle Driver allows for interrupted figure-ofeight or running sutures to be thrown and tied intracorporeally for a deep multi-layer closure. The unsurpassed visualization of the camera allows for accurate placement of imbricated stitches in additional layers and superior ability to reconstruct the uterine defect.

Multi-Layered Suture Closure of Defect – *Superficial Layer*



All *EndoWrist* Needle Drivers are fully wristed, enabling quick and efficient knot tying. The Long Tip Forceps is used to perform a running baseball stitch with an SH needle, in order to close any dead space and avoid serosal pull-through. The *SutureCut* Needle Driver is used to manipulate the tissue for needle bite placement and to cut the suture upon completion of stitching for added surgical autonomy and operative efficiency.

For technology videos visit

www.daVinciSurgeryCommunity.com

Clinical Data

Robotic-assisted, Laparoscopic, and Abdominal Myomectomy: A Comparison of Surgical Outcomes

Barakat E, Bedaiwy MA, Zimberg S, Nutter B, Nosseir M, and Falcone T. Robotic-assisted, laparoscopic, and abdominal myomectomy: a comparison of surgical outcomes. Obstet Gynecol, 2011;117:1–1.

Robotic-assisted myomectomy is associated with decreased blood loss and length of hospital stay compared with traditional laparoscopic and open myomectomy. Robotic technology could increase the utilization of a minimally invasive approach for the surgical management of symptomatic myomas.

Limitations of this study are its lack of analysis of the relationship between the surgeon's experience and surgical outcomes and the study's retrospective nature.

	Abdominal	Laparoscopic	*da Vinci*	Overall P
Surgical Time (min)	126.00	155.00	181.00	<.001[1]
Myoma Weight (g)	263.00	96.65	223.00	<.001[2]
Estimated Blood Loss (mL)	200.00	150.00	100.00	<.001[3]
Hemoglobin Drop (g/dL)	2.00	1.55	1.30	<.001[4]
Length of Stay (days)	3.00	1.0	1.00	<.001[5]

[1] Abdominal compared with laparoscopic, P=.142; abdominal compared with robotic, P=.003; laparoscopic compared with robotic, P=.083.
[2] Abdominal compared with laparoscopic, P<.001; abdominal compared with robotic, P=.360; laparoscopic compared with robotic, P=.021.
[3] Abdominal compared with laparoscopic, P<.001; abdominal compared with robotic, P<.001; laparoscopic compared with robotic, P=.818.
[4] Abdominal compared with laparoscopic, P=.061; abdominal compared with robotic, P<.001; laparoscopic compared with robotic, P=.431.
[5] Abdominal compared with laparoscopic, P<.001; abdominal compared with robotic, P<.001; laparoscopic compared with robotic, P=.506.

Pregnancy Outcomes Following Robot-Assisted Myomectomy Clinical Data

Michael C. Pitter, MD, Antonio R. Gargiulo, MD, Leo M. Bonaventura, MD, J. Stefano Lehman, MD, and Serene S. Srouji, MD. Pregnancy outcomes following robot-assisted myomectomy. Hum Repro, 2013; 28(1): 99-108.

Despite a high prevalence of women with advanced maternal age, obesity and multiple pregnancies in the cohort, the outcomes with *da Vinci* Myomectomy are comparable to those reported in the literature for laparoscopic myomectomy.

Limitations of this study are its retrospective and single-armed nature. Due to the high prevalence of infertility patients in this cohort, the data cannot be used to counsel women who are undergoing robotic-assisted myomectomy about fertility rates after surgery. No statistical analysis of the data being compared was provided.

First Author (n, year)	Mean Size of Largest Myoma (cm)	Time to Pregnancy (months)	SAB <20 weeks (%)	Live Term Births (%)	Uterine Rupture (%)
Robotic Laparoscopy					
Pitter *(107, present study)*	7.5	12.9 - *mean*	18.9	59.8	1.1
Conventional Laparoscopy					
Seraccholi *(127, 2006)*	5.4	17.9 - *mean*	27.2	65.8	0
Dubuisson *(98, 2000)*	4.8	16.0 - *median*	26.4	59.7	1

For additional data pertaining to these studies visit

www.daVinciSurgeryCommunity.com

Potential Patient Benefits & Risks

POSSIBLE BENEFITS COMPARED TO OPEN SURGERY:

- Less blood loss[1,2,3]
- Shorter hospital stay[1,2,3,4]
- Less need for narcotic pain medicine[4]
- Small incisions for minimal scarring[5]

POSSIBLE BENEFITS COMPARED TO TRADITIONAL LAPAROSCOPIC SURGERY:

- Minimally invasive removal of heavier, more numerous and more difficult to access fibroids[1]
- Fewer complications during surgery[6]

POSSIBLE RISKS INCLUDE:

- Weakening of the uterus during labor
- Pre-term birth
- Tears or perforations in the uterine wall

In addition to the above risks, there are risks related to minimally invasive surgery, including *da Vinci* Myomectomy, such as pulmonary embolism (blocked lung artery).[1]

EndoWrist® Instruments Optimized for *da Vinci*® Myomectomy

	STANDARD/*S,Si* PNs	FEATURES
	***PK*™ Dissecting Forceps** **400227/420227** **Requires Instrument Cords** **400228 (PK/SP)** **400229 (G400)**	- *PK* technology advantage - Audio and video impedance indicator
	***Hot Shears*™ (Monopolar Curved Scissors)** **400179/420179** **Requires Tip Cover** **400180**	- Combined scissors and monopolar cautery - Tapered tip profile
	**Long Tip Forceps** **400048/420048**	- Grasping and tissue handling - Delineating border of myomas
	**Tenaculum Forceps** **400207/420207**	- Smooth, rounded 90° nerve hook design

	STANDARD/*S,Si* PNs	FEATURES
	***SutureCut*™ Needle Driver** **400209/420209**	- Integrated scissor blades - Strong grasping force - Tapered outer jaw profile
	**Maryland Bipolar Forceps** **400172/420172**	- Grasping, dissecting and coagulating
	***Cobra*™ Grasper** **400190/420190**	- Counter traction of myoma during enucleation - Manipulation of fibroid uterine mass
	***ProGrasp*™** **400093/420093**	- Grasping, retraction & dissection

INTUITIVE SURGICAL®

Taking Surgery Beyond the Limits of the Human Hand.™

This material has been developed with, reviewed and approved by an independent surgeon, who is not an Intuitive Surgical employee. All surgeries carry risks of adverse outcomes. 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 U.S., 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.

All materials will eventually become obsolete. When referencing printed or digitally replicated materials, please note the revision date located near the part number (PN), located on the material. Consult your *da Vinci* representative or visit the *da Vinci* Online Community for the latest revision.

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[1] Barakat EE, Bedaiwy MA, Zimberg S, Nutter B, Nosseir M, Falcone T. Robotic-assisted, laparoscopic, and abdominal myomectomy: a comparison of surgical outcomes. Obstet Gynecol. 2011 Feb;117(2 Pt 1):256-65. [2] Ascher-Walsh CJ, Capes TL. Robot-assisted laparoscopic myomectomy is an improvement over laparotomy in women with a limited number of myomas. J Minim Invasive Gynecol. 2010 May-Jun;17(3):306-10. Epub 2010 Mar 19. [3] Sangha R, Eisenstein D, George A, Munkarah A, Wegienka G. Surgical outcomes for robotic-assisted laparoscopic myomectomy compared to abdominal myomectomy. Journal of Robotic Surgery, Volume 4, Number 4, December 2010 , pp. 229-233(5). [4] Nash K, Feinglass J, Zei C, Lu G, Mengesha B, Lewicky-Gaupp C, Lin A. Robotic-assisted laparoscopic myomectomy versus abdominal myomectomy: a comparative analysis of surgical outcomes and costs. Arch Gynecol Obstet. 2012 Feb;285(2):435-40. Epub 2011 Jul 22. [5] Advincula AP, Song A, Burke W, Reynolds RK. Preliminary experience with robot-assisted laparoscopic myomectomy. J Am Assoc Gynecol Laparosc.2004 Nov;11(4):511-8 (see figure 2). Alternatively, see Myomectomy Procedure Guide, PN 871798. [6] Bedient CE, Magrina JF, Noble BN, Kho RM. Comparison of robotic and laparoscopic myomectomy. Am J Obstet Gynecol. 2009 Dec;201(6):566.e1-5. Epub 2009 Aug 15. [7] Michael C. Pitter, MD, Antonio R. Gargiulo, MD, Leo M. Bonaventura, MD, J. Stefano Lehman, MD, and Serene S. Srouji, MD. Pregnancy outcomes following robot-assisted myomectomy. Hum Repro, 2013; 28(1): 99-108. [8] Pundir, J., Pundir, V., Walavalkar, R., Omanwa, K., Lancaster, G., Kayani, S.Robotic-Assisted Laparoscopic vs Abdominal and Laparoscopic Myomectomy: Systematic Review and Meta-Analysis. Journal of Minimally Invasive Gynecology; v:20 i:3 p:335-345; May, 2013