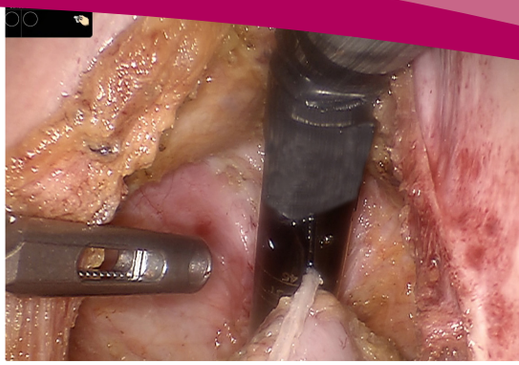
da Vinci®

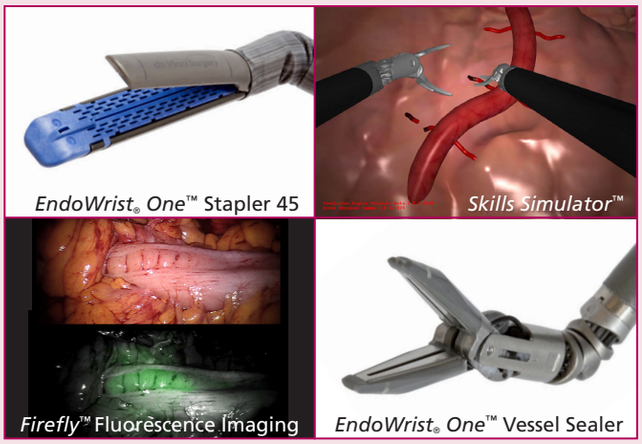
COLORECTAL SURGERY



Solutions for minimally invasive colorectal surgery

INTUITIVE SURGICAL®

The *da Vinci* Surgical System



Advanced *da Vinci* technology
Available exclusively on the *da Vinci*® *Si*™, advanced instrumentation offers a unique level of surgeon autonomy during colorectal procedures.

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

Surgeon Benefits

Maintain the oncological and intraoperative principles of open colorectal surgery using a minimally invasive approach

The visualization, precision, dexterity and control provided by the *da Vinci* Surgical System offers the following potential surgeon benefits:

- Low circumferential positive margin rates[1,2,3,4]
- Lower rate of conversion to open surgery compared to traditional laparoscopy[5,6]
- Shorter length of stay compared to open surgery[4] and traditional laparoscopy[6]
- Quicker recovery of voiding and sexual function compared to traditional laparoscopy[5,7]
- Less postoperative pain compared to open surgery and traditional laparoscopy[4]
- Effective intracorporeal anastomosis[8], shown to reduce intraoperative complications and length of stay[9]
- Equal access to left and right rectal sidewalls[5,10,11]

EndoWrist®
Stapler 45

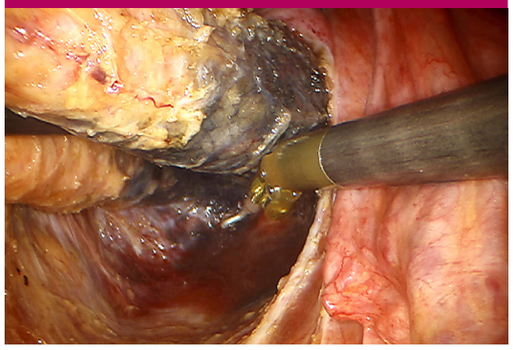
Application Highlights

Six ways *da Vinci* technology facilitates a precise colorectal surgery:

Vascular Control

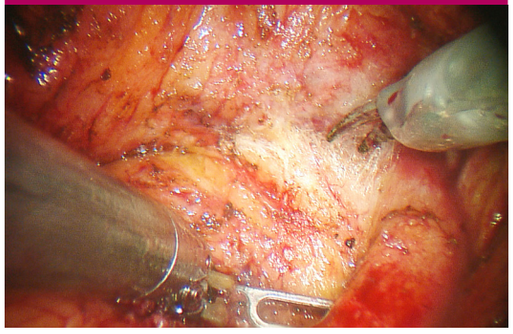
The *EndoWrist*® *One*™ Vessel Sealer offers effective transection of blood vessels and tissue bundles.

Posterior Rectal Dissection



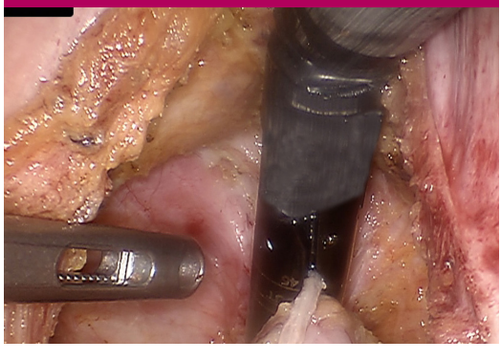
Excellent exposure, reach and dexterity facilitate dissection in the proper avascular plane down to the pelvic floor.

Anterior Rectal Dissection



Use of three *EndoWrist* instruments in concert enables exposure and countertraction during dissection in the confined space of the anterior rectal plane.

Distal Rectal Division

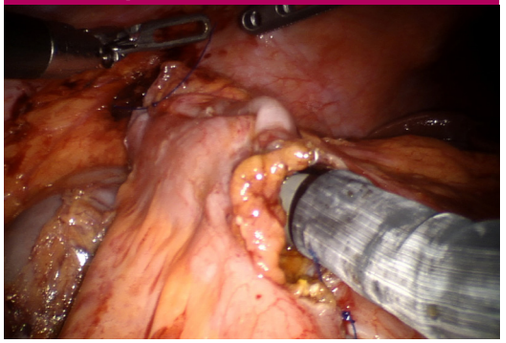


The surgeon-controlled and fully wristed *EndoWrist* Stapler 45 offers access to critical anatomy and provides confidence when stapling deep in the pelvis with *SmartClamp*™ Feedback.

Tissue Perfusion Assessment

Firefly™ Fluorescence Imaging offers unique visualization of ischemic boundaries in the proximal colon to impact decision-making at the surgeon console.

Intracorporeal Anastomosis



Fully wristed instruments allow for efficient suturing and stapling when performing an intracorporeal anastomosis.

For technology videos visit

www.daVinciSurgeryCommunity.com

Clinical Data

Outcomes of minimally invasive versus open surgery for rectal cancer

Kang J, Yoon KJ, Min BS, Hur H, Baik SH, Kim NK, Lee KY. The impact of robotic surgery for mid and low rectal cancer: A case-matched analysis of 3-arm comparison – open, laparoscopic, and robotic surgery. Ann Surg. 2013 Jan; 257(1):95-101.

	Open (n=165)	Laparoscopic (n=165)	Robotic (n=165)
Positive margin*	10.3%	6.7%	4.2%
Wound infection*	4.8%	1.2%	0.6%
Time to first flatus, days+	3.0	2.4	2.2
Time to resumed soft diet, days+	6.4	5.2	4.5
Estimated blood loss, mL*	275.4	140.1	133.0

Limitations include but are not limited to: application of preoperative chemoradiotherapy; disproportionate surgical experience between approaches

Outcomes of laparoscopic versus robotic surgery for rectal cancer

D'Annibale A, Pernazza G, Monsellato I, Pende V, Lucandri G, Mazzocchi P, Alfano G. Total mesorectal excision: a comparison of oncological and functional outcomes between robotic and laparoscopic surgery for rectal cancer. Surg Endosc. 2013 Jan 5.

	Laparoscopic (n=50)	Robotic (n=50)	*p*-value
Operative time (mins)	280 (240-350)	270 (240-315)	0.863
CRM (<2mm)‡	6	0	0.022
Conversions‡	6	0	0.011
Length of stay (days)‡	10 (8-14)	8 (7-11)	0.034
IPSS at 1 month (measure of voiding function)‡	7.08 ± 3.5	6.71 ± 5.9	0.012
No erectile dysfunction at 1 year (no. of patients)‡	10	17	0.045

Limitations include but are not limited to: low number of performed procedures; not randomized and based on a single-center experience

Outcomes of low anterior resection with and without near infrared (NIR) and indocyanine green (ICG)

Jafari MD, Lee KH, Halabi WJ, Mills SD, Carmichael JC, Stamos MJ, Pigazzi A. The Use of Indocyanine Green Fluorescence to Assess Anastomotic Perfusion During Robotic Assisted Laparoscopic Rectal Surgery. Surg Endosc. 2013 Feb 13.

	NIR + ICG (n=16)	Control (n=22)
Revision of Transection Point	19%	5%
Anastomotic leak rate	6%	18%
Median level of anastomosis	3.5 cm	5.5 cm

Limitations include but are not limited to: retrospective study with a small sample size; surgical decision-making processes are unknown

*Significant difference between open and robotic
+Significant difference between open, laparoscopic and robotic
‡Significant difference between laparoscopic and robotic

For additional data pertaining to these studies visit
www.daVinciSurgeryCommunity.com

Potential Patient Benefits & Risks

POSSIBLE BENEFITS INCLUDE:

- Less blood loss[4,13*]
- Less pain[2,4+]
- Shorter hospital stay[2,4*]
- Quicker return of bowel function[2*]
- Quicker return to a normal diet[2*]
- Faster recovery[5‡]
- Small incision for minimal scarring

*Significant difference between open and robotic
+Significant difference between open, laparoscopic and robotic
‡Significant difference between laparoscopic and robotic

POSSIBLE RISKS OF ANY COLORECTAL SURGERY INCLUDE:

- Anastomotic leak
- Ileus
- Pulmonary embolism
- Abscess
- Urinary problems

EndoWrist® Instruments Optimized for *da Vinci*® Colorectal Surgery

	STANDARD/*S,Si* PNs	FEATURES
	***Hot Shears***™ **(Monopolar Curved Scissors) 400179/420179 Requires Tip Cover: 400180**	⁘ Combined scissors and monopolar cautery ⁘ Tapered tip profile
	**Monopolar/ Permanent Cautery Hook 420183**	⁘ Dissecting and coagulating
	**Fenestrated Bipolar Forceps 400205/420205**	⁘ Fenestrated wide jaw profile ⁘ Bipolar energy
	**Cadiere Forceps 400049/420049**	⁘ Atraumatic grasping and retraction
	***Small Graptor***™ **(Grasping Retractor) 420318**	⁘ Atraumatic grasping and retraction

	STANDARD/*S,Si* PNs	FEATURES
	***EndoWrist***® **Stapler 45 410298**	⁘ Surgeon control ⁘ Fully wristed articulation ⁘ *SmartClamp*™ feedback ⁘ Blue and green reloads
	***EndoWrist*® *One***™ **Vessel Sealer 410322**	⁘ Fully wristed articulation ⁘ Dual-hinged jaw opening ⁘ Up to 7mm vessels
	***EndoWrist*® *One***™ **Suction Irrigator 410299**	⁘ Articulating carbide tip ⁘ Snake Wrist architecture ⁘ Surgeon console or bedside control
	***Harmonic***™ **Curved Shears 400174/420147**	⁘ Ultrasonic energy ⁘ Curved jaw design
	**Large Clip Applier 400230/420230**	⁘ High grip strength ⁘ Serrated jaw design

INTUITIVE SURGICAL®

Taking Surgery Beyond the Limits of the Human Hand.™

www.IntuitiveSurgical.com
www.daVinciSurgery.com

To contact a representative or receive additional information, visit www.intuitivesurgical.com or call Intuitive Surgical Customer Service
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Labeling Information

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.

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. Temporary pain or nerve injury has been linked to the inverted position often used during abdominal and pelvic surgery. Risk specific to minimally invasive surgery may include a longer operative time, the need to convert to an open approach, or for additional or larger incision sites. Converting the procedure could mean a longer operative time, a long time under anesthesia, and could lead to increased complications. Research suggests that there may be an increased risk of incision-site hernia with single-incision surgery. We encourage you to discuss your surgical experience and review these and all risks with your patients, including potential for human error and for equipment failure. We encourage patients and physicians to review all available information on surgical options and treatment in order to make an informed decision. Clinical studies are available through the National Library of Medicine at www.ncbi.nlm.nih.gov/pubmed.

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. Training provided by Intuitive Surgical is limited to the use of the *da Vinci* System. Intuitive is not responsible for teaching surgeons how to perform surgery. Procedure descriptions are provided by independent surgeons. For complete technical information, including warnings and cautions, please refer to the product documentation. 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.

The *Harmonic* Curved Shears Instrument is designed to be used in conjunction with both the *da Vinci* System (Standard, *S* and *Si* models) and a compatible *Ethicon* Endo-Surgery Generator and Hand Piece. It is intended for soft tissue incisions when bleeding control and minimal thermal injury are desired.

This instrument 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 instrument is not intended for contraceptive tubal occlusion. This instrument should not be used in Cardiac or Central Nervous System applications. The use of the *Harmonic* Curved Shears Instrument in conjunction with the standard *da Vinci*® and *da Vinci*® *S*™ (Models IS1000 and IS1200) is contraindicated for pediatric patients. In case of Emergency Stop or fault condition, the Instrument Arm may move due to gravity. Should this movement occur when the instrument is in contact with tissue, unintended injury may result.

[1] Hellan M, Anderson C, Ellenhorn JD, Paz B, Pigazzi A. Short-term outcomes after robotic-assisted total mesorectal excision for rectal cancer. Ann Surg Oncol. 2007 Nov;14(11):3168-73. Epub 2007 Sep 1. [2] Park JS, Choi GS, Lim KH, Jang YS, Jun SH. S052: a comparison of robot-assisted, laparoscopic, and open surgery in the treatment of rectal cancer. Surg Endosc. 2011 Jan;25(1):240-8. Epub 2010 Jun 15. [3] Patel CB, Ragupathi M, Ramos-Valadez DI, Haas EM. A three-arm (laparoscopic, hand-assisted, and robotic) matched-case analysis of intraoperative and postoperative outcomes in minimally invasive colorectal surgery. Dis Colon Rectum. 2011 Feb;54(2):144-50. [4] Kang J, Yoon KJ, Min BS, Hur H, Baik SH, Kim NK, Lee KY. The impact of robotic surgery for mid and low rectal cancer: A case-matched analysis of 3-arm comparison – open, laparoscopic, and robotic surgery. Ann Surg. 2013 Jan; 257(1):95-101. [5] Baik SH, Kwon HY, Kim JS, Hur H, Sohn SK, Cho CH, Kim H. Robotic versus laparoscopic low anterior resection of rectal cancer: short-term outcome of a prospective comparative study. Ann Surg Oncol. 2009 Jun;16(6):1480-7. Epub 2009 Mar 17. [6] D'Annibale A, Pernazza G, Monsellato I, Pende V, Lucandri G, Mazzocchi P, Alfano G. Total mesorectal excision: a comparison of oncological and functional outcomes between robotic and laparoscopic surgery for rectal cancer. Surg Endosc. 2013 Jan 5. [Epub ahead of print] [7] Kim JY, Kim NK, Lee KY, Hur H, Min BS, Kim JH. A comparative study of voiding and sexual function after total mesorectal excision with autonomic nerve preservation for rectal cancer: laparoscopic versus robotic surgery. Ann Surg Oncol. 2012 Aug;19(8):2485-93. Epub 2012 Mar 21. [8] Luca F, Cenciarelli S, Valvo M. Full Robotic Left Colon and Rectal Cancer Resection: Technique and Early Outcome. Annals of Surgical Oncology. May 2009, Vol. 16, No. 5: 1274-1278. [9] Grams J, Tong W, Greenstein A, Salky, B. Comparison of intracorporeal versus extracorporeal anastomosis in laparoscopic-assisted hemicolectomy. Surgical endoscopy. January 2010. [10] D'Annibale A, Morpurgo E, Fiscon V, Trevisan P, Sovernigo G, Orsini C, Guidolin D. Robotic and laparoscopic surgery for treatment of colorectal diseases. Dis Colon Rectum. 2004 Dec;47(12):2162-8. [11] Ng K, Lim Y, Ho K, Ooi B, Eu K. Robotic-Assisted Surgery for Low Rectal Dissection: From Better Views to Better Outcomes. Singapore Med J. 2009 50(8); 763. [12] Jafari MD, Lee KH, Halabi WJ, Mills SD, Carmichael JC, Stamos MJ, Pigazzi A. The Use of Indocyanine Green Fluorescence to Assess Anastomotic Perfusion During Robotic Assisted Laparoscopic Rectal Surgery. Surg Endosc. 2013 Feb 13. [Epub ahead of print] [13] deSouza AL, Prasad LM, Ricci J, Park JJ, Marecik SJ, Zimmern A, Blumetti J, Abcarian H. A comparison of open and robotic total mesorectal excision for rectal adenocarcinoma. Dis Colon Rectum. 2011 Mar;54(3):275-82.