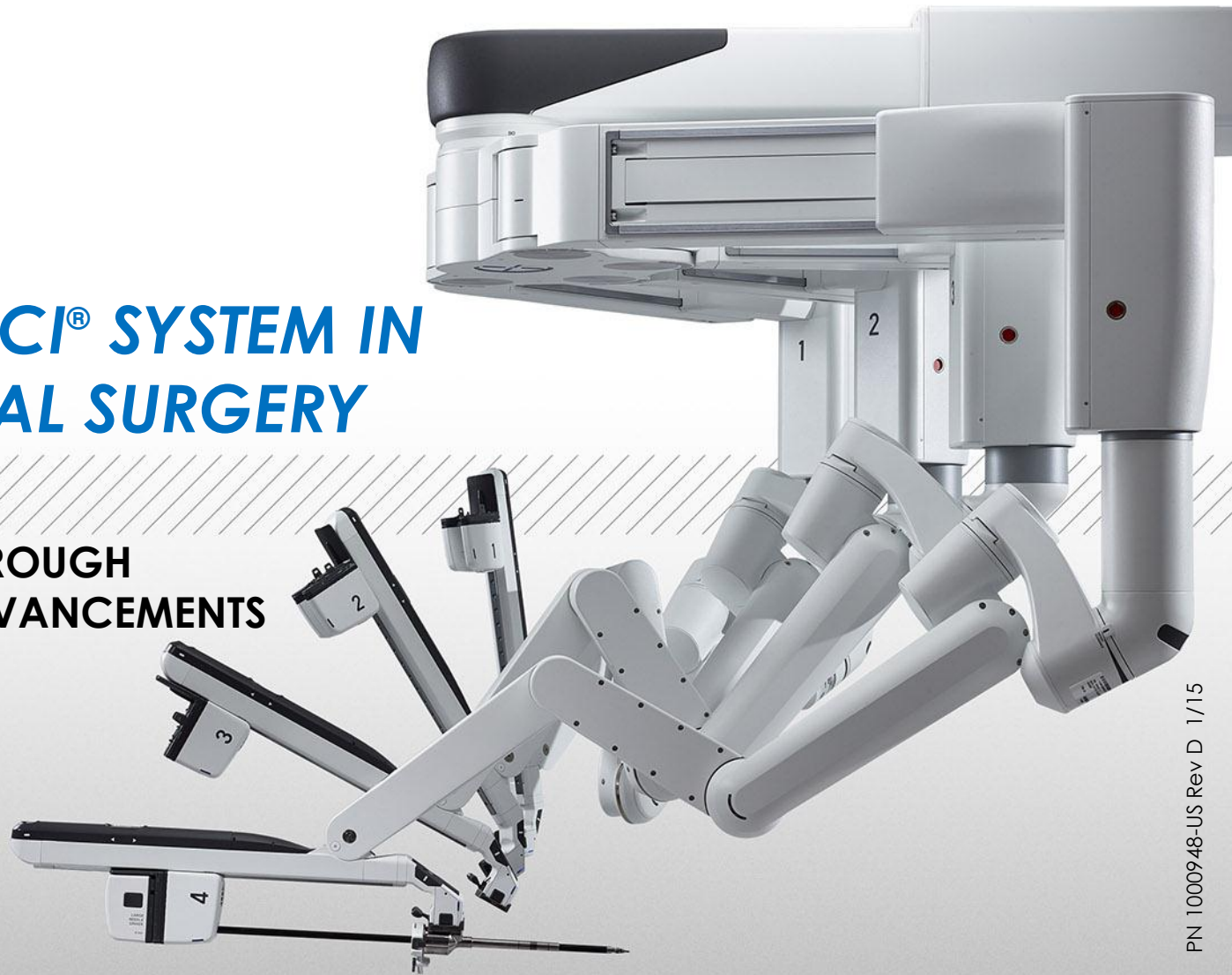


INTUITIVE
SURGICAL®

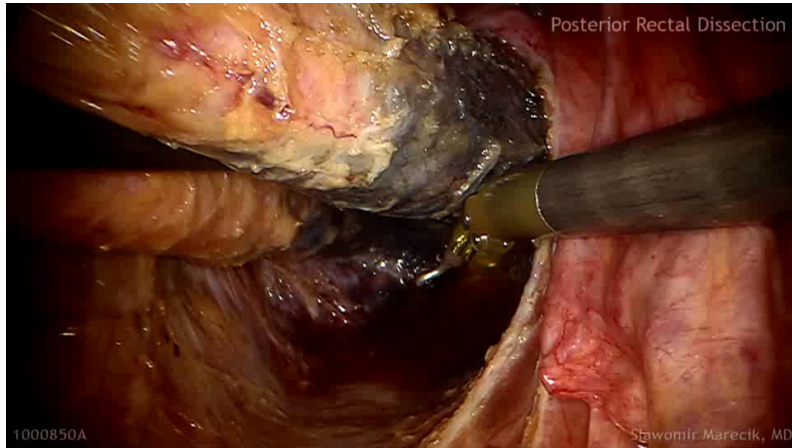
THE DA VINCI® SYSTEM IN COLORECTAL SURGERY

ENABLING MIS THROUGH
TECHNOLOGY ADVANCEMENTS



PN 1000948-US Rev D 1/15

Early Clinical Data Supports Use of the *da Vinci*® System in Rectal Resections



Benefits of using the *da Vinci* System in Rectal Resection:

- Low circumferential positive margin rates¹⁻¹⁷
- Lower conversion rate^{5,14}
- Shorter length of stay^{13,14}
- Less postoperative pain¹³

Highlights from >340 Publications on Robotic Colorectal Surgery

	n	Positive CRM	Conversions	Complications
Pigazzi (2006) ¹	6	NR	0.0%	1.0%
Hellan (2007) ²	39	0.0%	1.0%	5.0%
Baik (2008) ³	18	NR	0.0%	4.0%
Patriti (2009) ⁴	29	0.0%	0.0%	7.0%
Baik (2009) ⁵	56	7.1%	0.0%	3.0%
Park (2010) ⁶	41	1.9%	0.0%	12.0%
Pigazzi (2010) ⁷	143	0.7%	7.0%	59.0%
Bianchi (2010) ⁸	25	0.0%	0.0%	4.0%
Baek (2010) ⁹	64	0.0%	6.0%	23.0%
Baek (2011) ¹⁰	41	2.4%	3.0%	9.0%
Kwak (2011) ¹¹	59	1.7%	0.0%	19.0%
Park (2011) ¹²	52	2.4%	0.0%	10.0%
Kang (2013) ¹³	165	4.2%	0.6%	21.0%
D'Annibale (2013) ¹⁴	50	0.0%	0.0%	10.0%
Kim (2014) ¹⁵	48	0.0%	0.0%	18.8%
Ielpo (2014) ¹⁶	56	0.0%	3.5%	26.8%
Baek (2014) ¹⁷	182	5.0%	NR	16.5%
Shiomi (2014) ¹⁸	113	0.0%	0.0%	19.5%
<i>da Vinci</i>®	1187	2.2%	2.0%	21.0%
Lap*	981	11.0%	21.0%	38.0%
Open*	496	11.0%	N/A	37.0%

*COLOR II Trial Results¹⁹

Studies selected based on highest quality of available literature. No statistical analysis has been performed; analysis may confirm that numerical differences are not statistically significant.

Data presented pertains to the *da Vinci S™/Si™* Systems

Advancements in Technology for Colon and Rectal Procedures

EndoWrist® Vessel Sealer



Full suite of products optimized for Colon and Rectal surgeries:

- Operative efficiency
- Surgeon autonomy
- Computer-assisted decision making

Advancements in Technology for Colon and Rectal Procedures

EndoWrist® Stapler 45

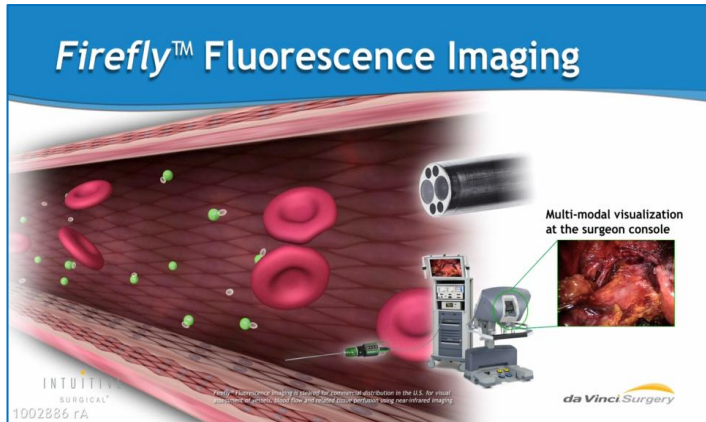


Full suite of products optimized for Colon and Rectal surgeries:

- Operative efficiency
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- Computer-assisted decision making

Advancements in Technology for Colon and Rectal Procedures

Firefly™ Fluorescence Imaging

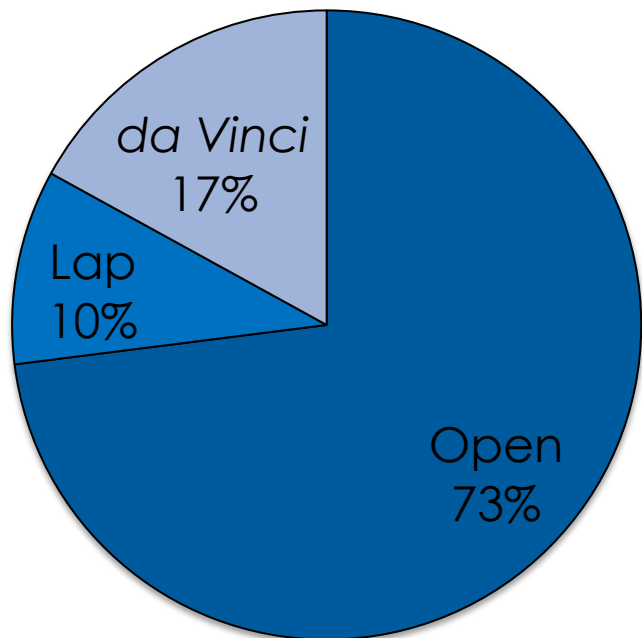


Full suite of products optimized for Colon and Rectal surgeries:

- Operative efficiency
- Surgeon autonomy
- Computer-assisted decision making

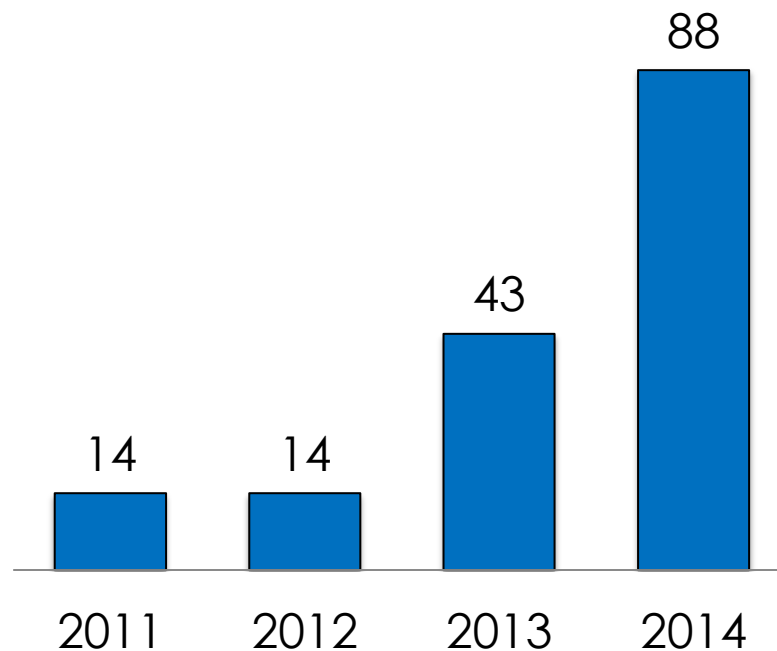
Rectal Resection Adoption Is Increasing, with Training on the Rise in Fellowship Programs

RECTAL RESECTION MARKET SHARE, 2014



WHAT WILL THE FUTURE HOLD?

95% of 2014 CR Fellows Have Been Trained on the *da Vinci*® System*

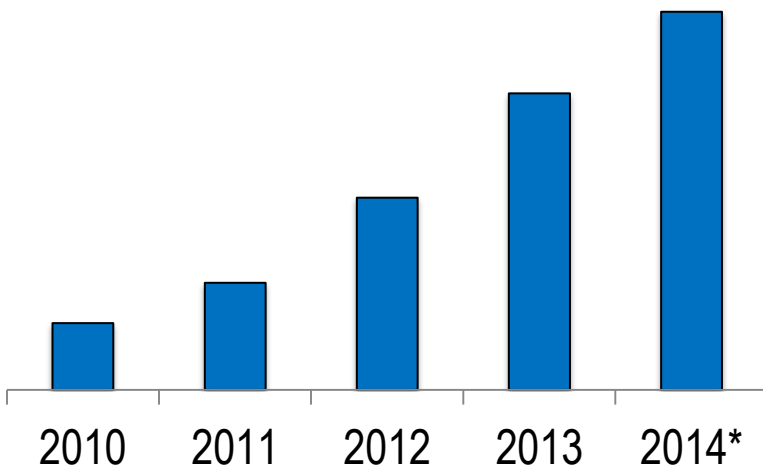


*2014 program organized by Association of Programs Directors in Colon and Rectal Surgery (APDCRS)

The da Vinci® System is Becoming More Widely Utilized in Segmental Colectomies

ROBOTIC COLECTOMIES

~5% adoption in 2014*



*Based on projections made in Nov 2014

Why?

- Increased adoption among General and Colorectal surgeons
- Improved outcomes with advanced MIS techniques, such as intracorporeal anastomosis

	RRCIA n=102	LRCEA n=94	LRCIA n=40
Conversions	3.9%	8.5%	15%
First Flatus (days)	2	3**	4**
LOS (days)	4	7**	5.5

Retrospective analysis. Trastulli, *et al.* Surg Endoscopy. Epub Oct 11, 2014.

Statistical significance vs. RRCIA (p<0.05)

RRCIA: robotic right colectomy with intracorporeal anastomosis.

LRCEA: laparoscopic right colectomy with extracorporeal anastomosis.

LRCIA: laparoscopic right colectomy with intracorporeal anastomosis.

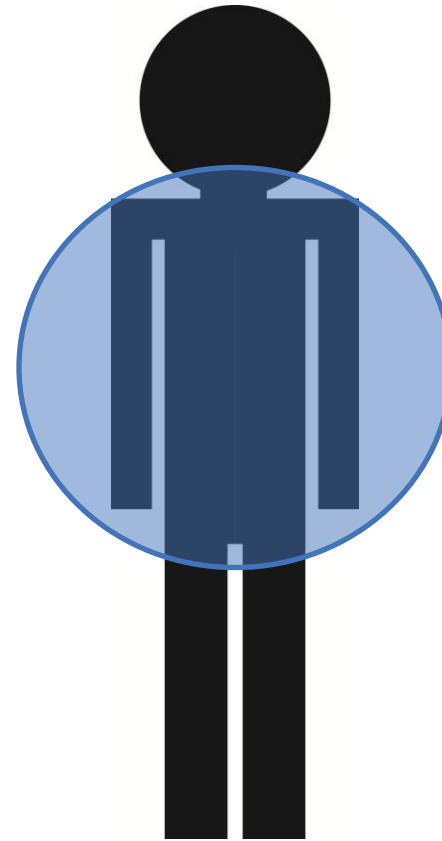
da Vinci Xi[®] System: Multi-Quadrant Access to Further Optimize Robotic Colorectal Surgery

ANATOMICAL ACCESS

da Vinci[®] Si[™] System



da Vinci Xi System



da Vinci Xi[®] System: Multi-Quadrant Access to Further Optimize Robotic Colorectal Surgery



References

1. Pigazzi A, Ellenhorn JD, Ballantyne GH, et al. Robotic-assisted laparoscopic low anterior resection with total mesorectal excision for rectal cancer. *Surg Endosc.* 2006;20:1521-1525.
2. Hellan M, Anderson C, Ellenhorn JD, et al. Short-term outcomes after robotic-assisted total mesorectal excision for rectal cancer. *Ann Surg Oncol.* 2007;14:3168-3173.
3. Baik SH, Ko YT, Kang CM, et al. Robotic tumor-specific mesorectal excision of rectal cancer: short-term outcome of a pilot randomized trial. *Surg Endosc.* 2008;22:1601-1608.
4. Patrìti A, Ceccarelli G, Bartoli A, et al. Short- and medium-term outcome of robot-assisted and traditional laparoscopic rectal resection. *JLS.* 2009;13:176-183.
5. Baik SH, Kwon HY, Kim JS, et al. Robotic versus laparoscopic low anterior resection of rectal cancer: short-term outcome of a prospective comparative study. *Ann Surg Oncol.* 2009;16:1480-1487.
6. Park JS, Choi GS, Lim KH, Jang YS, Jun SH. Robotic-Assisted versus Laparoscopic Surgery for Low Rectal Cancer: Case-Matched Analysis of Short-Term Outcomes. *Ann Surg Oncol.* 2013; DOI 10.1245/s10434-010-1162-5
7. Pigazzi A, Luca F, Patrìti A, et al. Multicentric study on robotic tumor specific mesorectal excision for the treatment of rectal cancer. *Ann Surg Oncol.* 2010;17:1614-1620.
8. Bianchi PP, Ceriani C, Locatelli A, et al. Robotic versus laparoscopic total mesorectal excision for rectal cancer: a comparative analysis of oncological safety and short-term outcomes. *Surg Endosc.* 2010;24: 2888-2894.
9. Baek JH, McKenzie S, Garcia-Aguilar J, et al. Oncologic outcomes of robotic-assisted total mesorectal excision for the treatment of rectal cancer. *Ann Surg.* 2010;251:882-886.
10. Baek JH, Pastor C, Pigazzi A. Robotic and laparoscopic total mesorectal excision for rectal cancer: a case-matched study. *Surg Endosc.* 2011;25:521-525.
11. Kwak JM, Kim SH, Kim J, et al. Robotic vs laparoscopic resection of rectal cancer: short-term outcomes of a case-control study. *Dis Colon Rectum.* 2011;54:151-156.
12. Park JS, Choi GS, Lim KH, et al. S052: a comparison of robot-assisted laparoscopic, and open surgery in the treatment of rectal cancer. *Surg Endosc.* 2011;25:240-248.

References, continued

13. Kang J, Yoon KL, 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 a 3-Arm Comparison—Open, Laparoscopic, and Robotic Surgery. *Ann Surg*. 2013; 257:95-101
14. 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; 27:1887-1895
15. Kim JC, Kwak JY, Yoon YS, Park IJ, Kim CW. A comparison of the technical and oncologic validity between robot-assisted and conventional open abdominoperineal resection. *Int J Colorectal Dis*. 2014 Aug;29(8):961-9.
16. Ielpo B, Caruso R, Quijano Y, Duran H, Diaz E, Fabra I, Oliva C, Olivares S, Ferri V, Ceron R, Plaza C, Vicente E. Robotic versus laparoscopic rectal resection: is there any real difference? A comparative single center study. *Int J Med Robot*. 2014 Sep;10(3):300-5.
17. Baek SJ, Kim CH, Cho MS, Bae SU, Hur H, Min BS, Baik SH, Lee KY, Kim NK. Robotic surgery for rectal cancer can overcome difficulties associated with pelvic anatomy. *Surg Endosc*. 2014 Aug 27. [Epub ahead of print]
18. Shiomi A, Kinugasa Y, Yamaguchi T, Tomioka H, Kagawa H. Robot-assisted rectal cancer surgery: short-term outcomes for 113 consecutive patients. *Int J Colorectal Dis*. 2014 Sep;29(9):1105-11.
19. van der Pas MHGM, Haglind E, Cuesta MA, Fürst A, Lacy AM, Hop WCJ, Bonjer HJ. Laparoscopic versus open surgery for rectal cancer (COLOR II): short-term outcomes of a randomised, phase 3 trial. *Lancet Oncol*. 2013; 14:210-218

Important Safety Information

Labeling Information for Surgeons

Surgical Risks

Surgeons should counsel their patients that serious complications may occur with any surgery, including *da Vinci* Surgery, up to and including death. Examples of serious and life-threatening complications, which may require prolonged and/or unexpected hospitalization and/or reoperation, include but are not limited to, one or more of the following:

- Injury to tissues and/or organs
- Bleeding
- Infection
- Internal scarring that can cause long-lasting dysfunction or pain.

Surgeons should discuss these and all risks associated with surgery with their patients, including but not limited to the following:

- Potential for human error
- Potential for equipment failure
- Potential for anesthesia complications

Individual surgical results may vary.

Risk specific to minimally invasive surgery, including *da Vinci*[®] Surgery, include but are not limited to:

- Temporary pain or nerve injury associated with positioning;
- A longer operative time;
- The need to convert the procedure to an open approach;
- Converting the procedure could mean a longer operative time, a longer time under anesthesia, and/or the need for additional or larger incisions and/or increased complications.

Surgeons should counsel their patients that there are other surgical approaches available. You should discuss your surgical experience and review these and all risks with your patients. Patients and physicians should review all available information on non-surgical and surgical options in order to make an informed decision. Clinical studies are available through the National Library of Medicine at www.ncbi.nlm.nih.gov/pubmed.

Important Safety Information

Appropriate Use of the *da Vinci* System

There are several models of the *da Vinci* System. Below are the cleared indications for use in the US for the various models. Important Safety Information, Instructions for Use, Contraindications, Warnings, and Precautions are included in the product instructions for use provided with the system, instruments and accessories.

da Vinci S, Si-e and Si System Models

The Intuitive Surgical Endoscopic Instrument Control Systems (*da Vinci*, *da Vinci S* and *da Vinci Si* Surgical Systems Models IS1200, IS2000, IS3000) are intended to assist in the accurate control of Intuitive Surgical *EndoWrist* Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, ultrasonic/harmonic shears, forceps/pick-ups, needle holders, endoscopic retractors, stabilizers, electrocautery and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery, suturing, delivery and placement of microwave and cryogenic ablation probes and accessories, during urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, transoral otolaryngology surgical procedures restricted to benign and malignant tumors classified as T1 and T2, general thoracoscopic surgical procedures, and thoracoscopically assisted cardiotomy procedures. The system can be employed with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization. The system is indicated for adult and pediatric use except for transoral otolaryngology surgical procedures. It is intended for use by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Professional Instructions for Use.

da Vinci Xi System Model

The Intuitive Surgical Endoscopic Instrument Control System (*da Vinci* Surgical Systems Model IS4000) is intended to assist in the accurate control of Intuitive Surgical Endoscopic Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, forceps/pick-ups, needle holders, endoscopic retractors, electrocautery and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery, suturing and delivery and placement of microwave and cryogenic ablation probes and accessories, during urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, general thoracoscopic surgical procedures and thoracoscopically assisted cardiotomy procedures. The system can be employed with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization. The system is indicated for adult and pediatric use. It is intended for use by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Professional Instructions for Use.

Contraindications applicable to the use of conventional endoscopic instruments also apply to the use of all *da Vinci* instruments.

Product Availability

Unless otherwise noted, products featured are available for commercial distribution in the U.S. Some products may not be available worldwide and may not be used for all applications. For availability outside the US, please check with your local representative or distributor.

Important Safety Information

Intuitive-Provided Instruction

Training provided by Intuitive Surgical is limited to the use of the *da Vinci* Surgical System and does not replace the necessary medical training and experience required to perform surgery. The *da Vinci* Surgical System should be used only by surgeons who have received specific training in the use of the *da Vinci* Surgical System.

Intuitive Surgical facilitates peer-to-peer clinical teaching. Intuitive Surgical does not teach surgery, nor does it provide or evaluate surgical credentialing. Procedure descriptions are developed with, reviewed and approved by independent surgeons.

Intuitive Surgical-sponsored presentations, instruction and promotional materials are intended for general information only and are not intended to substitute for formal medical training or certification. *da Vinci*® Surgical System training programs are not replacements for hospital policy regarding surgical credentialing. Certification, OR access and hospital privileges are the responsibility of the surgeon and their institutions, not that of Intuitive Surgical.

Any demonstration during Intuitive Surgical-sponsored training or instructional material on how to use the system to perform a particular technique or procedure is not the recommendation or "certification" of Intuitive Surgical as to such technique or procedure, but rather is merely a sharing of information on how other surgeons may have used the system to perform a given technique or procedure. Clinical information and opinions expressed by training participants, including any inaccuracies or mistakes, belong to the individual. Information and opinions are not necessarily those of Intuitive Surgical, Inc.

User Responsibilities

Before performing any *da Vinci*® procedure, physicians are responsible for receiving sufficient training and proctoring to ensure that they have the skill and experience necessary to protect the health and safety of their patients.

da Vinci® users must follow all instructions for use supplied with the system, instruments and accessories. Use of *da Vinci* instruments for tasks other than that for which they were designed may result in damage or breakage. Unless stated in the instructions, do not use *EndoWrist* Instruments on cartilage, bone or hard objects. Failure to follow instructions may lead to serious injury or surgical complications for the patient, including death. Electrosurgical energy may cause burns, serious injury or complications to the patient, including death. It is important to fully understand the *da Vinci* System energy user interface, not exceed recommended energy levels and use caution when working near critical anatomy.

For Important Safety Information, including indications for use and full cautions and warnings, please also refer to the product instructions for use. Read all instructions carefully. Failure to properly follow instructions, notes, cautions, warnings and danger messages associated with this equipment may lead to serious injury or complications for the patient, including death.

In the event that the *da Vinci* System, instruments, or accessories do not work as expected or if you are aware of a product deficiency or adverse event, please contact Intuitive Surgical Customer Service immediately. Please refer to the Customer Service contact information in the product instructions for use.

Intuitive Surgical promotes and facilitates the use of the *da Vinci* System for commercial use only in conjunction with on-label procedures set forth in the Instructions for Use. Intuitive Surgical recommends consulting your institutional policy regarding the use of cleared medical devices for off-label procedures prior to utilizing the *da Vinci* System.

Important Safety Information

Indications, Contraindications & Warnings for *da Vinci*® Technologies

Instrument & Accessory Care

It is the responsibility of the owner of the *da Vinci* Surgical System to properly train and supervise its personnel to ensure that the instruments and accessories are properly cleaned, disinfected and sterilized as required by the User's Manual. The *da Vinci* products should not be used in a clinical setting unless the institution has verified that these products are properly processed in accordance with the *da Vinci* System User's Manual.

EndoWrist® Stapler 45

The Stapler 45 is compatible for use with the *da Vinci Si* Surgical System; it is not compatible for use with the *da Vinci* or *da Vinci S* Surgical Systems. The *EndoWrist*® Stapler 45 System and Stapler 45 Reloads are intended to be used with the *da Vinci Si* Surgical System (IS3000) for resection, transection and/or creation of anastomoses in general, gynecologic and urologic surgery. The device can be used with staple line or tissue buttressing materials (natural or synthetic). Commercial clearance (US) is for blue and green 45 mm reloads only. The Stapler 45 System and Stapler 45 Reloads should not be used on tissue such as the liver or spleen, where tissue compressibility is such that clamping of the instrument would be destructive. Do not use the Stapler 45 System or Stapler 45 Reloads on the aorta.

EndoWrist® Stapler Cannula Seal

The *EndoWrist* Stapler Cannula Seal is intended to maintain insufflation, and serves as a port of entry when used with the compatible *Intuitive Surgical* Cannulae.

Important Safety Information

Firefly™ Fluorescence Imaging

The *da Vinci*® Fluorescence Imaging Vision System (*Firefly*™ Fluorescence Imaging) is intended to provide real-time endoscopic visible and near-infrared fluorescence imaging. The *da Vinci* Fluorescence Imaging Vision System enables surgeons to perform minimally invasive surgery using standard endoscopic visible light as well as visual assessment of vessels, blood flow, and related tissue perfusion, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct and common hepatic duct), using near infrared imaging.

Fluorescence imaging of biliary ducts with the *da Vinci* Fluorescence Imaging Vision System is intended for adjunctive use only in conjunction with standard of care white light and, when indicated, intraoperative cholangiography. The device is not intended for standalone use for biliary duct visualization.

Intuitive's ICG packs are available for sale in the US ONLY. Intuitive's ICG packs are cleared for commercial distribution in the U.S. for use in combination with the fluorescence-capable *da Vinci Si* HD vision system and *Firefly* integrated hardware. Intuitive-distributed ICG contains necessary directions for use of ICG with *Firefly* Fluorescence Imaging. Using generic ICG with *Firefly* Fluorescence Imaging is considered off-label and is not recommended. Anaphylactic deaths have been reported following ICG injection during cardiac catheterization. Total ICG dosage should not exceed 2 mg/kg per patient. Anaphylactic or urticarial reactions have been reported in patients with or without histories of allergy to iodides.

EndoWrist® One™ Vessel Sealer (from 551027 Vessel Sealer I&A Addendum)

The *EndoWrist*® One™ Vessel Sealer is a bipolar electro-surgical instrument cleared for commercial distribution in the U.S. for use with the *da Vinci*® *Si*™ Surgical System and the ERBE VIO 300 D electro-surgical generator. It is intended for grasping and blunt dissection of tissue and for bipolar coagulation and mechanical transection of vessels up to 7 mm in diameter and tissue bundles that fit in the jaws of the instrument. The *EndoWrist One* Vessel Sealer has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these procedures. The Vessel Sealer is intended for use only with the *da Vinci*-configured ERBE VIO 300 D generator. **Use of the Vessel Sealer with other generators could result in injury to the patient or surgical team, or cause damage to the instrument.**

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