THE DA VINCI® SYSTEM IN COLORECTAL SURGERY

ENABLING MIS THROUGH TECHNOLOGY ADVANCEMENTS
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 rates\textsuperscript{1-17}
- Lower conversion rate\textsuperscript{5,14}
- Shorter length of stay \textsuperscript{13,14}
- Less postoperative pain \textsuperscript{13}

Highlights from >340 Publications on Robotic Colorectal Surgery

<table>
<thead>
<tr>
<th>Study</th>
<th>n</th>
<th>Positive CRM</th>
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*COLOR II Trial Results\textsuperscript{19}

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

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.
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
- Surgeon autonomy
- 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**

- Open: 73%
- Lap: 10%
- da Vinci: 17%

**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

Why?

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

### ROBOTIC COLECTOMIES

~5% adoption in 2014*

<table>
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<tr>
<th>Year</th>
<th>RRCIA n=102</th>
<th>LRCEA n=94</th>
<th>LRCIA n=40</th>
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<td>8.5%</td>
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<td>3**</td>
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<td>LOS (days)</td>
<td>4</td>
<td>7**</td>
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*Based on projections made in Nov 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.

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

References, continued


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 thorascopic surgical procedures, and thorascopically 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 thorascopic surgical procedures and thorascopically 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 electrosurgical instrument cleared for commercial distribution in the U.S. for use with the da Vinci® Si™ Surgical System and the ERBE VIO 300 D electrosurgical 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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