

## Fact Sheet for *da Vinci*<sup>®</sup> Surgery

### What is the *da Vinci* Surgical System?

The *da Vinci* Surgical System is a tool that utilizes advanced, robotic, computer and optical technologies to assist your surgeon with your operation. It does not act on its own and its movements are controlled by your surgeon. The *da Vinci* Surgical System has a 3D high definition (3D-HD) vision system, special instruments and computer software that allow your surgeon to operate with enhanced vision, precision, dexterity and control. The 3D-HD image is highly magnified, so your surgeon has a close-up view of the area he or she is operating on. The *da Vinci* instruments have mechanical wrists that bend and rotate to mimic the movements of the human wrist – allowing your surgeon to make small, precise movements inside your body. And, *da Vinci* software can minimize the effects of a surgeon's hand tremors on instrument movements.

### What is *da Vinci* Surgery and how can it help me?

*da Vinci* Surgery is a less invasive technique than what is referred to as “open” surgery. With *da Vinci* Surgery, the cuts (incisions) made in your body by your surgeon are much smaller than the cut made during open surgery. *da Vinci* Surgery is therefore considered “minimally invasive surgery.” Studies of *da Vinci* Surgery have shown the following benefits in comparison to open surgery:

- A shorter hospital stay<sup>1,2,3,4</sup>
- Less blood loss<sup>2,3,4,5</sup>
- Fewer complications<sup>2,3,4,6,7</sup>
- Less need for narcotic pain medicine<sup>1,6,8,9</sup>
- A faster recovery<sup>1,2,10,11</sup>
- Smaller incisions associated with minimal scarring<sup>3,5,6</sup>

Since its introduction, *da Vinci* Surgery has greatly reduced the number of open surgeries for common operations (such as hysterectomy<sup>12</sup> and prostatectomy<sup>13</sup>). Thanks to *da Vinci* technology, more patients have been offered minimally invasive surgery (MIS) than at any other time in history.

For more information about clinical evidence related to *da Vinci* Surgery, please visit [www.intuitivesurgical.com/company/clinical-evidence](http://www.intuitivesurgical.com/company/clinical-evidence).

NOTE: The referenced studies evaluated an *Si* or earlier model *da Vinci* Surgical System. There are no clinical data currently available for the *da Vinci Xi* Surgical System. The *da Vinci Xi* Surgical System is not cleared for use in transoral otolaryngology surgical procedures and is not specifically cleared for use in prostatectomy. It is cleared for use in urologic surgical procedures.

## **Surgical Risks**

Serious complications may occur in 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

Patients should consider that risks of any surgery also include, but are not limited to, the following:

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

Individual surgical results may vary.

Risks specific to minimally invasive surgery, including *da Vinci* Surgery, include, but are not limited to, the following:

- Temporary pain and/or nerve injury associated with positioning;
- Temporary pain and/or discomfort from the use of air or gas in the procedure;
- A longer operative time and time under anesthesia;
- The need to convert the procedure to an open surgery;
- Converting the procedure could result in a longer operative time, a longer time under anesthesia, and/or the need for additional or larger incisions and/or increased complications.

## **Medical Advice & Surgeon Training**

Patients should talk to their doctor to decide if *da Vinci* Surgery is right for them. Other options may be available and appropriate. Only a doctor can determine whether *da Vinci* Surgery is appropriate for a patient's situation. Patients and doctors should review all available information on both non-surgical and surgical options in order to make an informed decision.

## **About the *da Vinci*® Surgical Systems**

### **The *da Vinci*® Xi™ System**

Launched in April, 2014, the newly refined *da Vinci Xi* Surgical System is the latest addition to the *da Vinci*® product line. The *da Vinci Xi* System has broader capabilities than prior generations of the *da Vinci* System. It can be used across a wide spectrum of minimally invasive surgical procedures and has been optimized for multi-quadrant surgeries (procedures in which instruments must be able to reach up and down and across the abdomen or chest).

Compared to prior *da Vinci* Systems, the *da Vinci Xi* System's key features include:

- A new overhead instrument arm architecture designed to facilitate anatomical access from virtually any position.
- A new endoscope digital architecture that creates a simpler, more compact design with improved visual definition and clarity.

- An ability to attach the endoscope to any arm, providing flexibility for visualizing the surgical site.  
Smaller, thinner arms with newly designed joints that offer a greater range of motion than ever before.
- Longer instrument shafts designed to give surgeons greater operative reach.

#### **About the *da Vinci*® *Si*™ System:**

Launched in April 2009, the *da Vinci Si* Surgical System offers several enabling features, including:

- Dual surgeon-console capability to support training and collaboration during minimally invasive surgery.
- High-definition 3D vision
- An updated user interface for streamlined setup and OR turnover
- Extensibility for digital OR integration

#### ***da Vinci* Technology**

More recent models of *da Vinci* Systems all retain and build on the core technology at the heart of prior-generation *da Vinci* Systems:

- Advanced 3D-HD visualization, which provides a highly magnified, immersive view of the operative field
- *EndoWrist* instrumentation, which offer dexterity and range of motion far greater than even the human hand
- *Intuitive*® motion technology, which preserves natural eye-hand-instrument alignment and intuitive instrument control

Together, these technological advancements provide surgeons unparalleled precision, dexterity and control for the performance of minimally invasive surgery. As with all *da Vinci* Systems, the newly redesigned *da Vinci Xi* Surgical System offers numerous features designed to provide the following potential benefits:

- Surgeon control and ergonomic comfort
- Patient safety
- OR efficiency
- Integrated technology and data

#### ***Firefly*™ Fluorescence Imaging Vision System**

The *Firefly* Fluorescence Imaging Vision System enables surgeons to use a special video camera and glowing dye to view blood flowing in vessels, and tissue or bile moving through ducts during minimally invasive surgical procedures. When a surgeon uses the *Firefly* camera, healthy structures appear green but those without blood flow appear gray.

The *da Vinci* Fluorescence Imaging Vision System 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

extrahepatic 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 use 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.

*Firefly* Fluorescence Imaging Vision System is not currently cleared for use with the *da Vinci Xi Surgical System*.

*For a complete list of product features and benefits, please visit [intuitivesurgical.com](http://intuitivesurgical.com).*

#### **Clinical evidence:**

- With thousands of peer-reviewed publications examining the use of the *da Vinci* Surgical System in a wide range of surgeries, the breadth and depth of literature on surgery using the *da Vinci Si* or prior-generation systems is extensive. For a list of key studies, please visit [www.intuitivesurgical.com/company/clinical-evidence](http://www.intuitivesurgical.com/company/clinical-evidence). There are no clinical data currently available for the *da Vinci Xi* Surgical System.
- A growing body of research studying the *da Vinci Si* and/or prior-generation systems suggests that *da Vinci* Surgery is a cost-effective approach for a growing number of surgical procedures. Numerous studies demonstrate the cost benefits of robotic-surgery for appropriate procedures, as compared to open surgery. For more information, please visit [www.intuitivesurgical.com/company/media/backgrounders/cost](http://www.intuitivesurgical.com/company/media/backgrounders/cost). There are no clinical data currently available for the *da Vinci Xi* Surgical System.
- Recent clinical literature studying the *da Vinci Si* and/or prior-generation systems includes several studies that use national databases to evaluate thousands of patient's surgical outcomes. These studies compare *da Vinci* Surgery to non-robotic-assisted approaches for specific procedures, such as prostatectomy (removal of the prostate) and hysterectomy (removal of the uterus). There are no clinical data currently available for the *da Vinci Xi* Surgical System. The *da Vinci Xi* System is not specifically cleared for use in prostatectomy. It is cleared for use in urologic surgical procedures.
- For prostatectomy, two larger representative studies on the *da Vinci Si* and/or prior-generation systems<sup>14,15</sup> demonstrate that *da Vinci* Prostatectomy is safer than the prior standard of open surgery across a large number of patients. These studies show that complications, death, blood loss, and length of hospital stay are all substantially better for *da Vinci* Prostatectomy by a statistically significant margin. There are no clinical data currently available for the *da Vinci Xi*

Surgical System. The *da Vinci Xi* System is not specifically cleared for use in prostatectomy. It is cleared for use in urologic surgical procedures.

- For hysterectomy, two representative studies on the *da Vinci Si* and/or prior-generation systems<sup>16,17</sup> show that *da Vinci* Hysterectomy is safer than hysterectomy performed through an open incision and as safe as laparoscopy. These studies also show a shorter length of hospital stay for the group of women who were qualified to have a minimally invasive hysterectomy performed with either laparoscopy or *da Vinci* Surgery. There are no clinical data currently available for the *da Vinci Xi* Surgical System
- Today, studies of the *da Vinci Si* and/or prior-generation systems show that *da Vinci* Surgery is clearly displacing traditional open surgery and reducing the complications and costs associated with it. There are no clinical data currently available for the *da Vinci Xi* Surgical System. For more information on the safety of *da Vinci* Surgery, please visit [www.intuitivesurgical.com/company/media/backgrounders/safety](http://www.intuitivesurgical.com/company/media/backgrounders/safety).

### ***da Vinci* System Description**

There are several models of the *da Vinci* Surgical System. The *da Vinci* Surgical Systems are designed to help doctors perform minimally invasive surgery. The *da Vinci* Surgical System is not programmed to perform surgery on its own. Instead, the surgery is performed entirely by a doctor, who controls the system. *da Vinci* Systems offer doctors high-definition 3D vision, a magnified view, and robotic and computer assistance. They use specialized instrumentation, including a miniaturized surgical camera and wristed instruments (i.e., scissors, scalpels and forceps) – that are designed to help with precise dissection and reconstruction deep inside the body.

### **When is the *da Vinci* System Used?**

One or more of the *da Vinci* Surgical System models are commercially available for use in the following specialty areas:

- Urologic surgery
- General laparoscopic surgery
- Gynecologic surgery
- Trans-oral robotic surgery restricted to benign (non-cancer) and malignant tumors (cancer) classified as T1 and T2 (early stage cancer)\*
- Thoracic surgery
- Some types of heart surgery

\* *Not cleared for use with the da Vinci Xi Surgical System.*

*da Vinci* Systems are used on adults in the specialty areas described above. They are also used in pediatric surgery (on children), except for conditions affecting the head and neck (transoral surgery). They are intended for use by trained medical professionals in an operating room environment and according to the manufacturer's product documentation.

*da Vinci* Surgery with *Single-Site*<sup>®</sup> Instruments is cleared for use with the *da Vinci Si*<sup>™</sup> System for use in gallbladder removal, and for hysterectomy and ovary removal for benign conditions.

Talk to your doctor about whether they use the *da Vinci* System within these specialty areas, and visit [daVinciSurgery.com](http://daVinciSurgery.com) for more information. Please consult your surgeon for questions about the model of the *da Vinci* System to be used in your procedure. For further information on the use of the *da Vinci* System, please visit [www.intuitivesurgical.com/company/indications-for-use.html](http://www.intuitivesurgical.com/company/indications-for-use.html).

### **When the *da Vinci* System is *not* used**

Patients who are not candidates for non-robotic minimally invasive surgery are also not candidates for *da Vinci* Surgery.

### **More information about the *da Vinci* System and locating a doctor**

If you have questions about the *da Vinci* System or *da Vinci* procedures, consult with a qualified surgeon. Surgeons experienced with the *da Vinci* System can be found using the Surgeon Locator at [www.davincisurgery.com](http://www.davincisurgery.com). Intuitive Surgical provides surgeons training on the use of the *da Vinci* System but does not certify, credential or qualify the surgeons listed in the Surgeon Locator.

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<sup>1</sup> Park JS, et al. 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

<sup>2</sup> Poston RS, et al. Comparison of economic and patient outcomes with minimally invasive versus traditional off-pump coronary artery bypass grafting techniques. *Ann Surg.* 2008 Oct;248(4):638-46

<sup>3</sup> Health Information and Quality Authority (HIQA), reporting to the Minister of Health-Ireland. Health technology assessment of robot-assisted surgery in selected surgical procedures, 21 September 2011

<sup>4</sup> Landeen LB, et al. Clinical and cost comparisons for hysterectomy via abdominal, standard laparoscopic, vaginal and robot-assisted approaches. *S D Med.* 2011 Jun;64(6):197-9, 201, 203 passim

<sup>5</sup> de Souza AL, et al. A comparison of open and robotic total mesorectal excision for rectal adenocarcinoma. *Dis Colon Rectum.* 2011 Mar;54(3):275-82

<sup>6</sup> Cerfolio RJ, et al. Initial consecutive experience of completely portal robotic pulmonary resection with 4 arms. *J Thorac Cardiovasc Surg.* 2011 Oct;142(4):740-6. Epub 2011 Aug 15

<sup>7</sup> Shaligram A, et al. How does the robot affect outcomes? A retrospective review of open, laparoscopic, and robotic Heller myotomy for achalasia. *Surg Endosc.* 2012 Apr;26(4):1047-50. doi: 10.1007/s00464-011-1994-5. Epub 2011 Oct 25

<sup>8</sup> Lowe MP, et al. A comparison of robot-assisted and traditional radical hysterectomy for early-stage cervical cancer. *Journal of Robotic Surgery* 2009:1-5

<sup>9</sup> Menon M, et al. Prospective comparison of radical retropubic prostatectomy and robot-assisted anatomic prostatectomy: the Vattikuti Urology Institute experience. *Urology.* 2002 Nov;60(5):864-8

<sup>10</sup> Bell MC, et al. Comparison of outcomes and cost for endometrial cancer staging via traditional laparotomy, standard laparoscopy, and robotic techniques. *Gynecologic Oncology* 2008:407-411

<sup>11</sup> Miller J, et al. Prospective evaluation of short-term impact and recovery of health related quality of life in men undergoing robotic assisted laparoscopic radical prostatectomy versus open radical prostatectomy. *J Urol.* 2007 Sep;178(3 Pt 1):854-8; discussion 859. Epub 2007 Jul 16

<sup>12</sup> Market share data on file at Intuitive Surgical

<sup>13</sup> National Cancer Institute. NCI Cancer Bulletin. Tracking the Rise of Robotic Surgery for Prostate Cancer. Aug. 9, 2011 Vol. 8/Number 16; from [www.cancer.gov](http://www.cancer.gov), URL:

<http://www.cancer.gov/ncicancerbulletin/080911/page4>. Sample. Eur Urol. 2012 Jun;61(6):1239-44.  
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<sup>14</sup> Liu et. al., "Perioperative Outcomes for Laparoscopic and Robotic Compared with Open Prostatectomy Using the National Surgical Quality Improvement Program (NSQIP) Database," European Urology (2013), doi:10.1016/j.eurouro.2013.03.080

<sup>15</sup> Kowalczyk et. al., "Temporal National Trends of Minimally Invasive and Retropubic Radical Prostatectomy Outcomes from 2003 to 2007: Results from the 100% Medicare Sample," European Urology (2011), doi:10.1016/j.eurouro.2011.12.020

<sup>16</sup> Lau et. al. "Outcomes and Cost Comparisons After Introducing a Robotics Program for Endometrial Cancer Surgery," Obstetrics & Gynecology (2012), DOI: 10.1097/AOG.ob013e31824c0956

<sup>17</sup> Wright et. al. "Robotically Assisted vs. Laparoscopic Hysterectomy Among Women With Benign Gynecologic Disease," JAMA 2013;309(7):689-698