



## Intuitive Surgical Announces New da Vinci(R) Xi(TM) Surgical System

April 1, 2014

SUNNYVALE, Calif., April 1, 2014 (GLOBE NEWSWIRE) -- Intuitive Surgical, Inc. (Nasdaq:ISRG), the global leader in robotic-assisted minimally invasive surgery, today announced the FDA clearance and U.S. introduction of the *da Vinci Xi* Surgical System, a technological leap forward in replacing large-incision abdominal surgeries (open surgery) with a minimally invasive approach.

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 complex, multi-quadrant surgeries.

For more than a decade, *da Vinci* Surgical Systems have provided patients with a minimally invasive alternative to open surgery that reduces many of the costs and complications associated with open procedures. Intuitive Surgical designed the new *da Vinci Xi* System with the goal of further advancing the technology used in minimally invasive surgery for complex diseases and conditions in gynecology, urology, thoracic, cardiac, and general surgery.

"Our goal is to develop technology that enhances surgical performance," said Gary Guthart, Intuitive Surgical President and Chief Executive Officer. "The *da Vinci Xi* System's new overhead architecture means that multi-quadrant surgery can be performed without repositioning the system, an innovation long sought by surgeons who perform complex procedures. We strive to provide the most advanced, least invasive option for surgery, and we are working hard to make minimally invasive surgery the standard of care."

With the U.S. introduction now underway, Intuitive Surgical will be seeking regulatory clearances to market the *da Vinci Xi* System around the world.

### Efficient Anatomical Access, Crystal Clear 3D-HD Visualization

By enabling efficient access throughout the abdomen and chest, the *da Vinci Xi* System expands upon core *da Vinci* System features, including wristed instruments, 3D-HD visualization, intuitive motion, and an ergonomic design. As with all *da Vinci* Surgical Systems, the *da Vinci Xi* System's immersive 3D-HD vision system provides surgeons a highly magnified view, virtually extending their eyes and hands into the patient.

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.

In addition, the *da Vinci Xi* System is built to be compatible with Intuitive Surgical's *Firefly*™ Fluorescence Imaging System. While it is not currently available, we plan to seek regulatory clearance for use of *Firefly* Imaging with the *da Vinci Xi* System. This technology is currently available as an option with the *da Vinci Si*™ model, and it is used to provide the surgeon with additional visual information in a variety of surgical procedures by enabling real-time visualization and assessment of vessels, bile ducts and tissue perfusion.

### A System Designed For the Future

The *da Vinci Xi* System is an expandable technology platform that is designed to accommodate and seamlessly integrate a range of current technologies in areas such as imaging, advanced instruments and anatomical access, as well as future innovations.

To provide hospitals with choices to match their needs, Intuitive Surgical will continue to offer the current *da Vinci Si* System, which addresses a broad span of procedure complexity, and the *da Vinci Si-e*™ System, a lower-cost system suited for less complex surgeries.

For more information about the *da Vinci Xi* Surgical System, visit [intuitivesurgical.com](http://intuitivesurgical.com).

### About Intuitive Surgical, Inc.

Intuitive Surgical, Inc. (Nasdaq:ISRG), headquartered in Sunnyvale, Calif., is the global leader in robotic-assisted, minimally invasive surgery. Intuitive Surgical develops, manufactures and markets the *da Vinci*® Surgical System. Intuitive Surgical's mission is to extend the benefits of minimally invasive surgery to those patients who can and should benefit from it.

### About the *da Vinci* Surgical System

The *da Vinci* Surgical System is a surgical platform designed to enable complex surgery using a minimally invasive approach. The *da Vinci* Surgical System consists of an ergonomic surgeon console or consoles, a patient-side cart with three or four interactive arms, a high-performance vision system and proprietary *EndoWrist*® instruments. Powered by state-of-the-art technology, the *da Vinci* Surgical System is designed to scale, filter and seamlessly translate the surgeon's hand movements into more precise movements of the *EndoWrist* instruments. The net result is an intuitive interface with advanced surgical capabilities. By providing surgeons with superior visualization, enhanced dexterity, greater precision and ergonomic comfort compared to other surgical approaches, the *da Vinci* Surgical System makes it possible for skilled surgeons to perform minimally invasive procedures involving complex dissection or reconstruction.

All surgery presents risk, including *da Vinci* Surgery and other minimally invasive procedures. Serious complications may occur in any surgery, up to and including death. Examples of serious and life-threatening complications, which may require hospitalization, include injury to tissues or organs, bleeding, infection, and internal scarring that can cause long-lasting dysfunction or pain. For more complete information on risks, considerations, safety, and indications for use, please refer to [www.davincisurgery.com](http://www.davincisurgery.com). 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/).

#### **Indications for Use for the *da Vinci*<sup>®</sup> *Xi*<sup>™</sup> Surgical System**

The Intuitive Surgical Endoscopic Instrument Control System (*da Vinci* Surgical System, 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 also be employed with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization. The system is indicated for adult and pediatric use. It is intended to be used by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Professional Instructions for Use.

#### **Indications for use for *Firefly*<sup>™</sup> Fluorescence Imaging for the *da Vinci Si* Surgical System**

The *da Vinci*<sup>®</sup> Fluorescence Imaging Vision System (*Firefly*<sup>™</sup> 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.

#### **Forward-Looking Statement**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding regulatory clearances to market the *da Vinci Xi* System around the world. These forward-looking statements are necessarily estimates reflecting the best judgment of our management and involve a number of risks and uncertainties that could cause actual results to differ materially from those suggested by the forward-looking statements. These forward-looking statements should, therefore, be considered in light of various important factors, including those under the heading "Risk Factors" in our annual report on Form 10-K for the year ended December 31, 2013, as updated from time to time by our quarterly reports on Form 10-Q and our other filings with the Securities and Exchange Commission. Statements using words such as "estimates," "projects," "believes," "anticipates," "plans," "expects," "intends," "may," "will," "could," "should," "would," "targeted" and similar words and expressions are intended to identify forward-looking statements. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. We undertake no obligation to publicly update or release any revisions to these forward-looking statements, except as required by law.

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