



## Intuitive Surgical Receives CE Mark for the da Vinci(R) Xi(TM) Surgical System

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SUNNYVALE, Calif., June 25, 2014 (GLOBE NEWSWIRE) -- Intuitive Surgical, Inc. (Nasdaq:ISRG), the global leader in robotic-assisted minimally invasive surgery, today announced it has received a CE Mark for its [da Vinci Xi Surgical System](#). Achieving this milestone allows the company to market the Xi System in Europe and other countries that require the CE Mark. In April, the da Vinci Xi System received clearance from the U.S. Food and Drug Administration (FDA) and is now commercialized in the United States.

The da Vinci Xi System is intended to be a technological leap forward in replacing large-incision open surgeries with a minimally invasive approach. Intuitive Surgical designed the new da Vinci Xi System to optimize ease-of-use. For example, the da Vinci Xi System can help simplify procedures requiring access to multiple areas of the pelvis, abdomen or chest. For more than a decade, da Vinci Surgical Systems have enabled surgeons to offer a minimally invasive alternative to open surgery that aims to reduce many of the costs and complications associated with open procedures.

"We are pleased to bring the da Vinci Xi System to market in Europe and other countries that rely on the CE Mark for marketing authorization," said Henry Charlton, Intuitive Surgical Vice President, Sales and Marketing, Europe, Middle East, India and Africa (EMEIA), Latin America, Canada and Australia. "With the CE Mark, we're expanding our customer base that has access to this exciting new technology. The da Vinci Xi System represents the most advanced option available to date as we strive to make minimally invasive surgery the global standard of care."

With the U.S. and European introductions underway, Intuitive Surgical is seeking additional regulatory clearances to market the da Vinci Xi System around the world. These include clearances for advanced technologies such as vessel sealing, stapling and fluorescence imaging, which are designed to enhance the capabilities of the da Vinci Xi System. This month, Intuitive Surgical received the first of these clearances from the FDA to market the *EndoWrist® One™* Vessel Sealer instrument for the da Vinci Xi System in the United States.

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

By enabling efficient access throughout the pelvis, abdomen and chest, the da Vinci Xi System expands upon the core da Vinci System features, which include 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 with a highly magnified view, virtually extending their eyes and hands into the patient.

Compared with 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.

### 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 fluorescence imaging, advanced instruments and anatomical access, as well as future innovations.

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/).

### Intended Use

The *da Vinci Xi* System is CE Marked in the EU for the following Intended Use:

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 during urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, general thoracoscopic surgical procedures and thoracoscopically assisted cardiomy 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.

#### **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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