



Intuitive Surgical Announces Clearance to Expand Use of Fluorescence Imaging in Gallbladder Surgery

September 23, 2013

Offers Surgeons Enhanced Imaging During Minimally Invasive Robotic-Assisted Procedures

SUNNYVALE, Calif., Sept. 23, 2013 (GLOBE NEWSWIRE) -- Intuitive Surgical, Inc. (Nasdaq:ISRG), the global leader in minimally invasive robotic-assisted surgery, today announced it received FDA 510(k) clearance for expanded use of its *da Vinci*[®] Fluorescence Imaging Vision System (*Firefly*[™]) for the *da Vinci*[®] Surgical System. *Firefly* imaging can now be used during gallbladder surgery.

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 during minimally invasive surgical procedures. When a surgeon uses the *Firefly* camera, blood appears green and tissue without blood flow appears gray.

In addition to providing the ability to view blood flow through vessels and tissue, the expanded use now includes real-time imaging of bile ducts (cystic duct, common bile duct and common hepatic duct). The *Firefly* imaging system is intended for use along with normal white light in imaging of the bile ducts and is not intended for standalone use.

Injuries to the common bile duct represent a serious and challenging surgical complication, and most often occur during laparoscopic gallbladder removal.¹ This occurs when the common bile duct is mistaken for the cystic duct, resulting in clipping and division of the common duct, which is then resected with the gallbladder.² It is therefore beneficial in minimally invasive surgery to have the ability to properly identify the biliary duct.

"As a surgeon, real time and precise images during surgery are enormously helpful in achieving good patient outcomes," said Dr. Myriam Curet, Chief Medical Advisor, Intuitive Surgical. "Intuitive Surgical has been committed to surgical innovation for more than a decade, providing surgeons with not only improved surgical dexterity, but enhanced visualization during surgery. We will continue to innovate and enhance the *da Vinci* Surgical System to provide surgeons with tools that help deliver optimal patient outcomes."

For information on regulatory clearances, visit: <http://www.intuitivesurgical.com/company/regulatory-clearance.html>.

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 improved surgical capabilities. By providing surgeons with superior visualization, enhanced dexterity, greater precision and ergonomic comfort, the *da Vinci* Surgical System makes it possible for skilled surgeons to perform more minimally invasive procedures involving complex dissection or reconstruction. For more information about clinical evidence related to *da Vinci* Surgery, please visit www.intuitivesurgical.com/company/clinical-evidence/.

All surgery presents risk, including *da Vinci* Surgery. Results, including cosmetic results, may vary. 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. Temporary pain or nerve injury has been linked to the inverted position often used during abdominal and pelvic surgery. Patients should understand that risks of surgery include potential for human error and potential for equipment failure. Risk specific to minimally invasive surgery may include: a longer operative time; the need to convert the procedure to an open approach; or the need for additional or larger incision sites. Converting the procedure to open could mean a longer operative time, long time under anesthesia, and could lead to increased complications. Research suggests that there may be an increased risk of incision-site hernia with single-incision surgery. Patients who bleed easily, have abnormal blood clotting, are pregnant or morbidly obese are typically not candidates for minimally invasive surgery, including *da Vinci* Surgery. Other surgical approaches are available. Patients should review the risks associated with all surgical approaches. They should talk to their doctors about their surgical experience and to decide if *da Vinci* is right for them. For more complete information on surgical risks, safety and indications for use, please refer to <http://www.davincisurgery.com/safety>.

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding our medical device reporting practices, related device malfunction filings, product performance and the speed at which instrument changes can be accomplished. 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 the following: the impact of global and regional economic and credit market conditions on health care spending; health care reform legislation in the United States and its implications on hospital spending, reimbursement and fees which will be levied on certain medical device revenues; timing and success of product development and market acceptance of developed products; procedure counts; regulatory approvals, clearances and restrictions; guidelines and recommendations in the health care and patient communities; intellectual property positions and litigation; competition in the medical device industry and in the specific markets of surgery in which we operate; unanticipated manufacturing disruptions or the inability to meet demand for products; the

results of legal proceedings to which we are or may become a party; our ability to expand into foreign markets; and other risk factors under the heading "Risk Factors" in our report on Form 10-K for the year ended December 31, 2012, 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 to reflect events or circumstances after the date of this press release or to reflect the occurrence of unanticipated events.

¹ McPartland KJ, Pomposelli JJ (2008). "Iatrogenic biliary injuries: classification, identification, and management." *Surgical Clinics of North America* Dec 88(6):1329-43.

² Branum G, Schmitt C, Baillie J, Suhocki P, Baker M, Davidoff A, Branch S, Chari R, Cucchiaro G, Murray E, et al (1993). "Management of major biliary complications after laparoscopic cholecystectomy." *Annals of Surgery* 217(5):532-40; discussion 540-1.

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