



Intuitive Surgical Announces Innovative Single Port Platform — the da Vinci SP® Surgical System

May 31, 2018

Allows for narrow access surgery using a single port

SUNNYVALE, Calif., May 31, 2018 (GLOBE NEWSWIRE) -- Intuitive Surgical, Inc. (Nasdaq:ISRG), today announced a new U.S. Food and Drug Administration (FDA) clearance for the da Vinci SP surgical system for urologic surgical procedures that are appropriate for a single port approach.



Intuitive Surgical receives FDA clearance for the da Vinci SP surgical system

The da Vinci SP system provides surgeons with robotic-assisted technology designed for deep and narrow access to tissue in the body. The ability to enter the body through a single, small incision helps surgeons perform more complex procedures. Intuitive anticipates pursuing further regulatory clearances for da Vinci SP, including transoral, transanal, and extraperitoneal applications, broadening the applicability of the SP platform over time.

“The da Vinci SP is the latest in our integrated product family that shows our commitment to improving minimally invasive surgery with technology that can positively impact patient outcomes,” said Gary Guthart, chief executive officer for Intuitive. “Our da Vinci SP compliments da Vinci X[®] and Xi[®] systems by enabling surgeons to access narrow workspaces while maintaining high quality vision, precision, and control that surgeons have come to trust from da Vinci[®] systems.”

The da Vinci SP system includes three, multi-jointed, wristed instruments and the first da Vinci fully wristed 3D HD camera. The instruments and the camera all emerge through a single cannula and are properly triangulated around the target anatomy to avoid external instrument collisions that can occur in narrow surgical workspaces. The system enables flexible port placement and excellent internal and external range of motion (e.g., 360-degrees of anatomical access) through the single SP arm. Surgeons control the fully articulating instruments and the camera on the da Vinci SP system, which uses the same surgeon console as the da Vinci X and Xi systems.

“Intuitive continues to bring tomorrow’s surgery today by addressing surgeon and patient needs, as well as working closely with hospitals to systematically improve the overall experience in the operating room,” said Salvatore J. Brogna, Intuitive executive vice president and chief operating officer.

Since the initial U.S. FDA clearance in April 2014 for the da Vinci SP surgical system, Intuitive invested in important platform refinements. Intuitive plans to launch the da Vinci SP surgical system in the United States in a measured fashion, with customer shipments beginning in the third quarter of 2018.

About Intuitive Surgical, Inc.

Intuitive Surgical, Inc. (Nasdaq:ISRG), headquartered in Sunnyvale, Calif., is the pioneer and a global leader in robotic-assisted, minimally invasive surgery. Intuitive Surgical develops, manufactures and markets the da Vinci[®] surgical system.

About the da Vinci Surgical System

There are several models of the da Vinci surgical system. The da Vinci surgical systems are designed to help surgeons perform minimally invasive surgery. Da Vinci systems are not programmed to perform surgery on their own. Instead, the procedure is performed entirely by a surgeon who controls the system. Da Vinci systems offer surgeons 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.

Representative Uses

The da Vinci SP Surgical System may be used in the following procedures:

- Radical prostatectomy, pyeloplasty, nephrectomy, partial nephrectomy

Surgical Risks

For Important Safety Information, indications for use, risks, full cautions and warnings, please refer to <http://www.davincisurgery.com/safety> and www.intuitivesurgical.com/safety.

Forward Looking Statements

This press release contains forward-looking statements, including statements regarding customers' continued adoption of Intuitive's products into minimally invasive surgery programs. These forward-looking statements are necessarily estimates reflecting the best judgment of the Company's 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, but not limited to, the following: the impact of global and regional economic and credit market conditions on healthcare spending; healthcare reform legislation in the United States and its impact on hospital spending, reimbursement and fees levied on certain medical device revenues; changes in hospital admissions and actions by payers to limit or manage surgical procedures; the timing and success of product development and market acceptance of developed products; the results of any collaborations, in-licensing arrangements, joint ventures, strategic alliances or partnerships; procedure counts; regulatory approvals, clearances and restrictions or any dispute that may occur with any regulatory body; guidelines and recommendations in the healthcare and patient communities; intellectual property positions and litigation; competition in the medical device industry and in the specific markets of surgery in which the Company operates; unanticipated manufacturing disruptions or the inability to meet demand for products; the results of legal proceedings to which the Company is or may become a party; product liability and other litigation claims; adverse publicity regarding the Company and the safety of the Company's products and adequacy of training; the Company's ability to expand into foreign markets; the impact of changes to tax legislation, guidance, and interpretations; and other risk factors under the heading "Risk Factors" in the Company's report on Form 10-K for the year ended December 31, 2017, as updated by the Company's 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. The Company undertakes no obligation to publicly update or release any revisions to these forward-looking statements, except as required by law.

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A photo accompanying this announcement is available at <http://www.globenewswire.com/NewsRoom/AttachmentNg/cec0db92-4a5d-4e93-b159-776724a1d383>

The logo for Intuitive Surgical, featuring the word "INTUITIVE" in a bold, sans-serif font. A small circle is positioned above the letter "I".

Intuitive Surgical, Inc.