



Intuitive Surgical Announces U.S. Clearance for da Vinci Xi EndoWrist Stapler 30 Instruments and Reloads

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Stapler 30 for the da Vinci Xi System expands the company's EndoWrist Stapler portfolio

SUNNYVALE, Calif., March 14, 2016 (GLOBE NEWSWIRE) -- Intuitive Surgical, Inc. (Nasdaq:ISRG), the global leader in robotic-assisted minimally invasive surgery, today announced that the United States Food and Drug Administration has provided 510(k) clearance for the company's *da Vinci*® *Xi*™ EndoWrist Stapler 30 (30mm) instruments and reloads.

Availability of the Stapler 30 for the *da Vinci Xi* Surgical System expands the company's *EndoWrist* Stapler portfolio through the offering of new curved and straight tip instruments and four reloads. With General Surgery, Thoracic, Gynecologic and Urologic surgery indications, the Stapler 30 Curved-Tip instrument provides enhanced placement and visualization around tenuous vasculature. The Stapler 30 instruments and reloads — ranging from gray (0.75mm closed) to green (2.0mm closed) — provide a robust offering of 30mm stapling options for the *da Vinci Xi* Surgical System.

"Combined with the *da Vinci Xi* Surgical System's 3DHD vision, access, and surgeon control and autonomy, the *EndoWrist* Stapler 30 naturally expands the *da Vinci* stapling portfolio," said Sal Brogna, Executive Vice President, Product Operations, Intuitive Surgical. "This clearance further underscores the progress we've made in developing a broad suite of tools and resources for surgeons spanning several specialties, including thoracic and general surgery."

The *da Vinci Xi* Surgical System design enables control of stapling from the surgeon console, creating a more direct relationship between clinical decision-making and instrument action. Other features include:

- **Surgeon Control and Autonomy:** Places control of the stapler directly in the hands of the surgeon. Positioning, grip, clamp and fire are fully controlled by the surgeon through the *da Vinci* surgeon console.
- **Fully Wristed Articulation:** The *EndoWrist* Stapler has the greatest side-to-side articulation currently available, with a range of 108° total side-to-side. The *EndoWrist* Stapler articulates through a range of 54° total up-and-down, providing a fully-wristed cone of articulation.
- **SmartClamp Feedback:** Reduces the guesswork associated with conventional, handheld stapling by detecting whether the jaws can adequately close on the target tissue for the given staple height.

The Stapler 30 product is immediately available for order, with rollout occurring in Q1 of 2016.

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.

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.

Indications for 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 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.

The Intuitive Surgical EndoWrist® Stapler 30 Instrument and Stapler 30 Reloads are intended to be used with the *da Vinci* Surgical System (Model IS4000) for resection, transection and/or creation of anastomoses in General, Thoracic, Gynecologic, and Urologic surgery. The device is indicated for adult and pediatric use. The device can be used with staple line or tissue buttressing material.

Important Safety Information

Serious complications may occur in any surgery, including *da Vinci* Surgery, up to and including death. Risks include, but are not limited to, injury to tissues and organs and conversion to other surgical techniques. If your doctor needs to convert the surgery to another surgical technique, this could result in a longer operative time, additional time under anesthesia, additional or larger incisions and/or increased complications. Individual surgical results may vary. Patients who are not candidates for non-robotic minimally invasive surgery are also not candidates for *da Vinci* Surgery. Patients

should talk to their doctors to decide if *da Vinci* Surgery is right for them. Patients and doctors should review all available information on non-surgical and surgical options in order to make an informed decision. Please also refer to www.daVinciSurgery.com/Safety for Important Safety Information.

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, 2015, 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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