

Intuitive Surgical Receives FDA Clearance for First 60mm Stapler

July 5, 2018

A new breed of da Vinci® stapling compatible with the da Vinci Xi and X surgical systems

SUNNYVALE, Calif., July 05, 2018 (GLOBE NEWSWIRE) -- Intuitive Surgical, Inc. (Nasdaq:ISRG), the pioneer and a global technology leader in robotic-assisted, minimally invasive surgery, today announced that the U.S. Food and Drug Administration granted clearance for the company's fully wristed, 60mm stapler.

SureForm 60™, a single-patient use 60mm stapler, offers 120 degrees of fully wristed articulation – an industry first. Surgeons control SureForm 60 through the da Vinci surgeon console, creating an immediate connection between clinical decision-making and instrument action. Combining da Vinci's tremor filtration with SureForm 60's tip stability and 120 degrees of articulation in all directions may help provide surgeons with precise stapler manipulation and placement.

SureForm 60 uses SmartFire™ technology—integrated software that optimizes stapler and staple line performance. SmartFire measures tissue compression before and during staple firing, making automatic adjustments to the firing process as staples are formed and the transection is made. SmartFire makes more than 1,000 measurements per second, helping to ensure a more consistent staple line, while helping prevent tissue damage, across a range of tissue thicknesses.

"Intuitive continues our minimally invasive innovation with our 60mm stapler, rooted in extensive research and development and an understanding of surgeons' needs," said Sal Brogna, Intuitive executive vice president and chief operating officer.

SureForm 60 has general, thoracic, gynecologic, urologic, and pediatric indications. It is compatible with the da Vinci Xi and X surgical systems. The SureForm 60 extends the da Vinci stapling portfolio to cover all required staple line lengths. It expands and evolves Intuitive's da Vinci stapling portfolio, which includes 30 and 45mm stapler instruments.

About Intuitive Surgical, Inc.

Intuitive Surgical, Inc. (Nasdaq:ISRG), headquartered in Sunnyvale, Calif., is the pioneer and a global technology leader in robotic-assisted, minimally invasive surgery. Intuitive develops, manufactures and markets the da Vinci surgical system. The company strives to make surgery more effective, less invasive and easier on surgeons, patients and their families.

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 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.

© 2018 Intuitive Surgical, Inc. All rights reserved. Intuitive Surgical®, da Vinci®, da Vinci S®, da Vinci Si™, da Vinci Xi®, da Vinci X®, OnSite® and EndoWrist® are trademarks or registered trademarks of Intuitive Surgical, Inc.

For more information, please visit the company's web site at www.intuitivesurgical.com.

Important Safety Information

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 the flexible robotics platform as a safe and feasible approach to sample lung tissue, the ability of platform application in the lungs to enable early lung cancer diagnoses, the strong safety profile of the platform, and enabling physicians to start care plans for patients earlier and offer curative treatments. 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, 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 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; product liability and other litigation claims; adverse publicity regarding the Company and the safety of our products and adequacy of training; 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, 2016, as updated by 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.

Contact

Global Public Affairs

Intuitive Surgical
Email: corp.comm@intusurg.com
U.S. Tel: +1 408.523.7337

 Primary Logo

Intuitive Surgical, Inc.