



Intuitive receives FDA clearance for 8 mm SureForm 30 Curved-Tip Stapler

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First 8 mm robotic stapler with 120-degree articulation and SmartFire technology

SUNNYVALE, Calif., Dec. 15, 2021 (GLOBE NEWSWIRE) -- Intuitive (Nasdaq: ISRG), a global technology leader in minimally invasive care and the pioneer of robotic-assisted surgery, today announced that the U.S. Food & Drug Administration (FDA) cleared the company's fully wristed, 8 mm SureForm 30 Curved-Tip Stapler and reloads (gray, white, and blue) for use in general, thoracic, gynecologic, urologic, and pediatric surgery.

The 8 mm SureForm 30 stapler is expected to launch in the U.S. in 2022, with other countries to follow. It has been designed to help surgeons better visualize and reach anatomy through a combination of the 8 mm diameter instrument shaft and jaws, 120-degree cone of wristed articulation, and the curved tip. As it fits through the 8 mm da Vinci surgical system instrument cannula, the stapler allows different angles for surgeons to approach patient anatomy.

"In working with our customers, we identified an opportunity to provide better access and visibility during stapling procedures. The 8 mm SureForm 30 curved tip stapler achieves this while providing stapling performance surgeons have grown to trust," said Bob DeSantis, Intuitive's executive vice president and chief product officer. "We continue to innovate our systems and instruments by listening to our customers and enhancing capabilities, products, and services."

"Having an 8 mm diameter stapler option—especially during complex procedures—will give surgeons more choices to access target anatomy with confidence," said Dr. William Tisol, a thoracic surgeon based in Wisconsin.

As with the other SureForm staplers, the 8 mm SureForm 30 Curved-Tip Stapler integrates SmartFire technology — software that optimizes staple line performance by measuring tissue compression before and during staple firing.

The SmartFire technology makes automatic adjustments to the firing process as staples are formed and the transection is made. The technology makes more than 1,000 measurements per second, helping achieve a consistent staple line.

About Intuitive

Intuitive (Nasdaq: ISRG), headquartered in Sunnyvale, California, is a global technology leader in minimally invasive care and the pioneer of robotic-assisted surgery. As part of our mission, we believe that minimally invasive care is life-enhancing care. Through ingenuity and intelligent technology, we expand the potential of physicians to heal without constraints.

Intuitive brings more than two decades of leadership in robotic-assisted surgical technology and solutions to its offerings and develops, manufactures, and markets the da Vinci Surgical System and the Ion endoluminal system.

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For more information, please visit the Company's website at www.intuitive.com.

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.

For more information, please visit the company's website at www.intuitive.com.

Important Safety Information

For Important Safety Information, indications for use, risks, full cautions and warnings, please refer to www.intuitive.com/safety.

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding the launch and performance of the 8 mm SureForm 30 stapler and the company's leadership in the advancement of minimally invasive care. These forward-looking statements are based on current expectations and estimates 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 company's ability to successfully commercialize the 8 mm SureForm 30 stapler, risks that the 8 mm SureForm 30 stapler does not perform as expected; the impact of global and regional economic and credit market conditions on healthcare spending; reimbursement and fees levied on certain medical device revenues; 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; and other risk factors under the heading "Risk Factors" in the company's annual report on Form 10-K for the year ended December 31, 2020, as updated by the company's other filings with the Securities and Exchange Commission. 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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Source: Intuitive Surgical, Inc.