



U.S. FDA clears first stapler designed for single-port robotic surgery

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Intuitive's SureForm 45 stapler available for thoracic, colorectal, and urology procedures

SUNNYVALE, Calif., April 10, 2025 (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 SP SureForm 45 stapler for use with its da Vinci SP surgical system in thoracic, colorectal, and urologic procedures.

Like its multiport counterparts, the SP SureForm 45 features SmartFire technology, which continuously monitors tissue compression before and during firing. This real-time optimization helps surgeons enhance staple line integrity and reduce the risk of tissue damage across varying thicknesses.

"Being able to use a SureForm 45 stapler in single-port robotic surgery helps provide surgeons with more control of their procedures from the da Vinci surgeon console, without the need to rely on an assistant to fire a stapler. This kind of control can help save valuable operating time," said Intuitive Chief Medical Officer Myriam Curet, M.D.

The da Vinci SP system provides surgeons with robotic-assisted technology, enabling them to perform procedures with innovative approaches that help promote faster patient recovery and reduce postoperative pain.

These innovative surgical approaches are made possible by surgeon control of up to three wristed instruments and a high definition (HD), three-dimensional (3D) camera. The instruments—including the SureForm 45 stapler—and camera enter through a single access point and triangulate inside the body, helping eliminate external instrument collisions that can occur in small surgical workspaces.

The da Vinci SP surgical system is approved for use across a variety of surgical procedures in Europe, Japan, Korea, and Taiwan. In the U.S., the FDA has cleared the da Vinci SP surgical system for urology, transoral otolaryngology, colorectal, and thoracic procedures. The SP SureForm 45 stapler has received FDA clearance for thoracic, colorectal, and urology procedures, though it is not cleared for transoral otolaryngology procedures.

Da Vinci SP is part of Intuitive's portfolio of surgical systems. The da Vinci 5, Xi, and X are Intuitive's multi-port surgical systems, now in its fifth generation of innovative technology.

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About Intuitive

Intuitive (NASDAQ:ISRG), headquartered in Sunnyvale, California, is a global leader in minimally invasive care and the pioneer of robotic surgery. Our technologies include the da Vinci surgical system and the Ion endoluminal system. By uniting advanced systems, progressive learning, and value-enhancing services, we help physicians and their teams optimize care delivery to support the best outcomes possible. At Intuitive, we envision a future of care that is less invasive and profoundly better, where disease is identified early and treated quickly, so that patients can get back to what matters most.

About da Vinci Surgical Systems

There are several models of the da Vinci surgical system. The da Vinci surgical systems are designed to help surgeons perform minimally invasive surgery and 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 product intended use and/or indications for use, risks, cautions, and warnings and full prescribing information, visit <https://manuals.intuitivesurgical.com/market>. For summary of the risks associated with surgery refer to www.intuitive.com/safety.

Forward-Looking Statements

This press release contains forward-looking statements which relate to expectations concerning matters that are not historical facts. Statements using words such as "estimates," "projects," "believes," "anticipates," "plans," "expects," "intends," "may," "will," "can," "could," "should," "would," "targeted," "potential," and similar words and expressions are intended to identify forward-looking statements. These forward-looking statements are necessarily estimates reflecting the judgment of Intuitive's management and involve a number of risks and uncertainties that could cause actual results or impacts on its operations, financial performance, and business position to differ materially from those suggested by the forward-looking statements. These forward-looking statements include, but are not limited to, statements related to research and development of products and services, manufacturing of products, obtaining of regulatory approvals, technical and other performance of products and services, and making products and services available to more patients and health care professionals. These forward-looking statements should be considered in light of various important factors and involve known and unknown risks, uncertainties, and other factors, which may cause the actual results, performance, or achievements of Intuitive, or industry results, to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements. Important factors that could cause actual results to differ materially from those anticipated in the forward-looking statements include, among others, economic conditions in the geographic markets in which we operate, changes in governmental regulations, regulatory approval priorities, resources, and timelines, regulatory enforcement priorities, governmental investigations and civil litigation, and other factors discussed in Intuitive's Annual Reports and other filings with relevant securities regulators.

Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release and

which are based on current expectations and are subject to risks, uncertainties, and assumptions that are difficult to predict, including those risk factors identified under the heading "Risk Factors" in Intuitive's Annual Report on Form 10-K for the year ended December 31, 2024, as updated by its other filings with the U.S. Securities and Exchange Commission. Intuitive's actual results may differ materially and adversely from those expressed in any forward-looking statements, and it undertakes no obligation to publicly update or release any revisions to these forward-looking statements, except as required by law.



Source: Intuitive Surgical, Inc.