Intuitive Announces FDA Clearance of da Vinci Single Port for Transanal Local Excision/Resection

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SUNNYVALE, Calif., May 01, 2025 (GLOBE NEWSWIRE) -- Intuitive (NASDAQ: ISRG), a global technology leader in minimally invasive care and the pioneer of robotic-assisted surgery, announced today that the U.S. Food and Drug Administration (FDA) cleared the da Vinci Single Port (SP) surgical system for transanal local excision/resection, a form of minimally invasive surgery performed through a natural orifice to avoid abdominal surgical incisions for select procedures. This clearance extends the da Vinci SP's capabilities in colorectal surgery, building upon procedures previously cleared by the FDA in November 2024, which include transabdominal procedures - low anterior resection, total mesorectal excision, colectomy, abdominoperineal resection, and sigmoidectomy.

Intuitive engineered the da Vinci SP system to navigate in narrow body cavities requiring precise access, such as lower pelvis and rectal procedures. Its design and architecture support access to rectal anatomy by allowing surgeons to control up to three multi-jointed instruments and a high-definition articulating camera through a single entry point to work freely in the smaller space.

Da Vinci SP also helps mitigate challenges inherent with laparoscopic transanal minimally invasive surgery, such as surgeon ergonomics, reaching lesions in the upper rectum, and working circumferentially, or "upside-down," when needed.

"With FDA's clearance of the da Vinci SP system for transanal local resection, surgeons have a new option in colorectal surgery to positively impact patient outcomes," said Intuitive Executive Vice President and Chief Medical Officer Myriam Curet, MD. "Da Vinci SP represents a major leap forward for minimally invasive colorectal surgery, supporting surgeons in better preserving healthy tissue and accelerating patient recovery."

The da Vinci SP system helps enable surgeons to dissect, suture, and excise through a natural orifice, avoiding external scarring for patients, unlike conventional transabdominal rectal resection, which typically requires multiple incisions and removal of the rectum.

"Using the da Vinci SP will help me adapt some of my transabdominal low anterior resections to transanal surgeries for appropriate lesions," said Laila Rashidi, M.D., of MultiCare Tacoma General Hospital in Tacoma, Wash.

This clearance adds to Intuitive's colorectal portfolio, designed to meet the diverse needs of colorectal surgeons. With da Vinci 5 and da Vinci Xi, Intuitive provides colorectal surgeons with a broad, integrated offering to support a spectrum of colorectal interventions.

A growing body of evidence, including more than 500 peer-reviewed publications to date, supports the safety, efficacy, and outcomes associated with the da Vinci SP system. The FDA has previously cleared the da Vinci SP system for certain urology procedures, including simple prostatectomy, as well as transoral otolaryngology and general thoracoscopic procedures. The da Vinci SP system is also approved for use in Europe, Japan, and Korea for a range of procedures spanning multiple surgical disciplines.

2025 marks Intuitive's 30 th year developing robotic-assisted technology with the goal of improving patient outcomes, improving patient and care team experience, increasing access to minimally invasive care, and lowering the total cost to treat. In Intuitive's first three decades, surgeons have performed nearly 17 million procedures using our technology, and nearly 90,000 surgeons have been trained to use our systems.

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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.

Important Safety Information

For Important Safety Information, indications for use, risks, full cautions, and warnings, please refer to the associated da Vinci user manual(s).



Source: Intuitive Surgical, Inc.