Intuitive expands AI and advanced imaging integration in Ion Endoluminal System

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FDA-cleared software release enhances navigation and broadens access to advanced imaging for lung biopsy procedures

SUNNYVALE, Calif., Oct. 08, 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) has cleared software advancements for the Ion endoluminal system (Ion).

Ion, Intuitive's robotic-assisted bronchoscopy platform, features an ultra-thin, shape-sensing catheter designed to navigate deep into the lung. This advanced technology enables physicians to access small, hard-to-reach nodules and precisely position biopsy tools to sample potentially cancerous tissue.

This latest software release introduces artificial intelligence across Ion's entire navigational workflow, while also integrating new advanced imaging capabilities to support accurate and efficient lung biopsies.

Lung cancer has been the leading cause of cancer-related deaths both globally and in the U.S. for over 25 years, with studies showing early diagnosis of lung cancer is associated with a higher five-year survival rate.[1,2,3] A key step in lung cancer management is diagnosis, which often requires a biopsy of complex nodules in challenging locations within the lung.

"These latest Ion software advancements reflect Intuitive's ongoing commitment to advancing lung cancer care through meaningful innovation," said Intuitive Chief Executive Officer Dave Rosa. "By further integrating artificial intelligence with expanded advanced imaging capabilities, we're equipping physicians with smarter tools designed to support early diagnosis and improve access to advanced care for more patients."

AI-powered enhanced navigation

Ion's latest AI-powered enhanced navigation builds on its existing strengths to address a key challenge in lung biopsy known as CT-to-body divergence—when a lung nodule is in a different location during the procedure relative to the pre-procedure CT scan due to movement of the lung. This shift can make it more difficult to reach the target accurately and perform an effective biopsy.

Ion will now use AI to help correct this in real time. By combining computer vision with Ion's shape-sensing technology, the system compares live images to the original plan and adjusts the view along the navigation path as needed—similar to a GPS that reroutes when conditions change. These enhancements are designed to increase workflow efficiency, reduce manual steps, improve accuracy, and could give physicians greater confidence in delivering answers to patients quickly.

Expanding advanced imaging

Intuitive is introducing new and improved advanced imaging capabilities, including integrated tomosynthesis—to broaden access to advanced imaging. This innovation enables real-time imaging updates with a standard 2D C-arm, offering an advanced imaging option where alternatives are limited and providing physicians with multiple options to tailor biopsy workflows to each patient's clinical need.

This diverse offering reflects Intuitive's commitment to supporting a wide range of healthcare environments and providing physicians with the advanced imaging tools they need to find answers for patients—accurately and efficiently.

These software features will initially be introduced through a limited launch to gather insights into performance across a range of clinical and operational environments. A broader launch in the U.S. is planned for 2026.

"We know that early diagnosis can make a life-changing difference for patients with lung cancer," said Federico Barbagli, PhD, Senior Vice President and General Manager, Endoluminal at Intuitive. "That's why we continue to relentlessly innovate—advancing Ion's capabilities to support more efficient, accurate, and personalized procedures across a wide range of healthcare environments. We're committed to equipping care teams with the tools they need to deliver timely answers for patients and improve outcomes where it matters most."

Ion's global footprint

As of June 30, 2025, there were more than 900 Ion systems in place in hospitals across 10 countries.[4] In addition, the body of evidence continues to grow with more than 100 abstracts and publications describing the potential value delivered to patients.[5]

Intuitive is actively sponsoring and supporting a growing portfolio of clinical studies using the Ion endoluminal system, including observational research involving more than 2,000 subjects across the EU and U.S. These studies underscore the company's commitment to generating global evidence across diverse populations—advancing research, informing innovation, and supporting improved patient outcomes worldwide.

These features may not be available in all countries. Product availability is subject to regulatory approval in the specific market. Please contact your local Intuitive representative for product availability in your region.

About Intuitive Surgical, Inc.

Intuitive (Nasdaq: ISRG), headquartered in Sunnyvale, California, is a global leader in minimally invasive care and the pioneer of robotic-assisted 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.

Information provided by the Ion Endoluminal System or its components should be considered guidance only and not replace clinical decisions made by a trained physician.

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

For risks, cautions, and warnings and full prescribing information, refer to the associated Ion System user manual(s) or visit https://manuals.intuitivesurgical.com/market. For summary of the risks associated with bronchoscopy 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, integration 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.

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References:

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2. American Cancer Society, "Key Statistics for Lung Cancer" (Last updated January 2025). Available at: https://www.cancer.org/cancer/types/lung-cancer/about/key-statistics.html. Date accessed: October 2025.
3. Lungevity, "Screening & Early Detection" (Last updated February 2024) Available at: https://www.lungevity.org/lung-cancer-basics/screening-early-detection Date accessed: October 2025.
4. As of Q2 2025. Intuitive data on file.
5. Intuitive data on file for more than 100 abstracts and/or publications.

A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/dca93c95-e8f7-4e35-b4bf-4ce7662221b5

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Source: Intuitive Surgical, Inc.



Ion system during a procedure setup