Intuitive and Siemens Healthineers enhance scanning integration for Ion Endoluminal procedures

June 30, 2022

Intuitive's Ion System and Siemens Healthineers Cios Spin FDA clearance offers seamless cone beam CT scans during robotic bronchoscopy procedures

SUNNYVALE, Calif., June 30, 2022 (GLOBE NEWSWIRE) -- Intuitive (Nasdaq: ISRG), a global technology leader in minimally invasive care and the pioneer of robotic-assisted surgery, today announced the U.S. Food and Drug Administration has cleared the integration of a mobile cone-beam CT (CBCT) imaging technology and the Ion Endoluminal System used for robotic-assisted bronchoscopy.

Siemens Healthineers Cios Spin mobile imaging offers integrated functionality with Ion to provide 2D and 3D imaging during procedures to help physicians gain confidence around refining Ion's catheter positioning and help improve biopsy tool placement.

Early studies have shown Ion enables a diagnostic yield of approximately 80% in studies with a relatively small average nodule size. 3D imaging is used in peripheral nodule biopsies to confirm that biopsy tools are appropriately placed in a suspicious nodule. An initial single center study demonstrated an improvement in diagnostic yield of up to approximately 10%[1] when the Cios Spin was used with the Ion platform.

This new imaging integration could help improve the accuracy of biopsy procedures, a key step in how lung cancer gets diagnosed. Lung cancer kills more people annually than any other cancer[2] and early diagnosis can improve survival rates. The integration enhances a physician's ability to provide minimally invasive lung biopsy with the Ion system, which can give patients answers sooner.

"Since launching Ion we have continued to make improvements to our system, tools and user interface with a view of making robotic-assisted lung biopsy the standard of care," said Charlie Dean, senior vice president of Endoluminal at Intuitive. "With the Siemens Healthineers integration we are raising that bar further by enabling our physicians to even more accurately and repeatably biopsy small lesions deep within the lung. With this clearance, we hope to help physicians continue to improve patient outcomes."

Ion will continue to evolve with the potential inclusion of other technology collaborators to enhance its ecosystem in ways physicians and care teams find valuable.

"The integration between Ion and Siemens Healthineers' Cios Spin provides additional information that may help physicians gain more confidence that they are collecting tissue at the right location," said Dr. Oliver Wagner, vice president and Ion's medical officer. "There's clear patient benefit in these technologies working together to help improve accuracy, which could help get answers sooner."

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[1] Definitions of diagnostic yield may vary across publications. Information provided is directional in nature and is not conclusive, and may not be reproducible or generalizable.

[2] https://seer.cancer.gov/statfacts/html/lungb.html

https://www.lung.org/lung-health-diseases/lung-disease-lookup/lung-cancer/resource-library/lung-cancer-fact-sheet

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.

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

About the Ion Endoluminal System

The Ion Endoluminal System (Model IF1000) assists the user in navigating a catheter and endoscopic tools in the pulmonary tract using endoscopic visualization of the tracheobronchial tree for diagnostic and therapeutic procedures. The Ion Endoluminal System enables fiducial marker placement. It does not make a diagnosis and is not for pediatric use.

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.

About Siemens Healthineers Cios Spin

Cios Spin is a compact and mobile cone-beam CT (CBCT) which is capable of 2D and 3D X-ray imaging of the lung and other organs. It enables visualization of certain pulmonary lesions in relation to biopsy tools during interventions. Cios Spin supports tool-in-lesion confirmation in interventional bronchoscopy.

For more information, please visit the company's website at https://www.siemens-healthineers.com/en-us/clinical-specialities/surgery/surgical-disciplines/lung-care.

Important Safety Information

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

Ion is for sale in the U.S.
Outside of the U.S., Ion is not CE Marked and not for human use. Ion cannot be placed on the market or put into service. Ion may not have regulatory approvals in all markets. Please check with your local Intuitive representative.

Important Safety Information - Bronchoscopy
Risk associated with bronchoscopy through an endotracheal tube and under general anesthesia are infrequent and typically minor, and may include but are not limited to: sore throat, hoarseness, respiratory complications including dyspnea or hypoxemia, airway injury, bronchospasm, laryngospasm, fever, hemoptysis, chest or lung infection including pneumonia, lung abscess or an adverse reaction to anesthesia.

Although rare, the following complications may also occur: bleeding, pneumothorax (collapsed lung), cardiac related complications, respiratory failure, air embolism, or death. As with other medical procedures, there may be additional risks associated with the use of general anesthesia and/or endotracheal intubation which are not listed above; you should consult a health care professional regarding these and other potential risks.

Procedures using the Ion endoluminal system may be associated with longer procedure and/or longer anesthesia time.

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding the integration of a mobile cone-beam CT (CBCT) imaging technology and the company's Ion Endoluminal System and how this integrated offering advances 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 companies' ability to successfully commercialize the integrated offering, risks that the integrated offering 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, 2021, 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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