

First human use of a new robotic-assisted fiber optic sensing navigation system* for small peripheral pulmonary nodules¹

Study Design	Single-arm, single-center study with 2 proceduralists
Timeframe	2016-2017
Study registration	Australia New Zealand Clinical Trial Registry (ANZCTR) #ACTRN12616001185459. System evaluated was an earlier iteration of the presented system. Core technology and clinical workflow were similar to that of the presented system.
Primary endpoints	Feasibility Facilitate sampling of small pulmonary nodules (SPNs) ≥ 10 mm to < 30 mm in largest diameter Safety Pneumothorax and excessive bleeding
Sample size	29 patients (consecutive cases)
Follow-up	Up to 6 months
Exclusion	Central pulmonary nodules located within the first 3 airway generations
Subject Eligibility	Presented exclusion criteria was one (1) of the key eligibility criteria. The study population was selected based on other factors including those commonly associated bronchoscopy procedures or other safety reasons. Subjects were not selected based on bronchus sign or nodule location. Full eligibility criteria can be found on trial registration page indicated above (ANZCTR).
Limitations	Single center experience with a selected population. Study is not designed as a performance study.

Nodule location

Number of airway generations

Mean $\pm$ SD (range):

6.7 $\pm$ 1.4 (3.0-9.0)

Lesion locations

69% UL

6.9% RML

24.1% LL

CT Bronchus sign present

41.4% absent

58.6% present

Nodule size (mm)

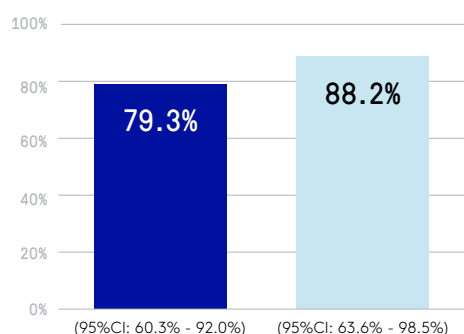
Axial plane: 12.2 $\pm$ 4.2 (6.7-22.0)

Coronal plane: 12.3 $\pm$ 3.3 (5.9-21.1)

Sagittal plane: 11.7 $\pm$ 4.1 (4.5-26.4)

Early performance trends

Overall yield and yield for malignancy trends for up to 6 months of follow-up

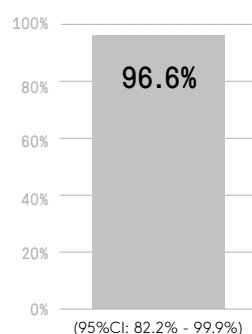


Diagnostic yield trends

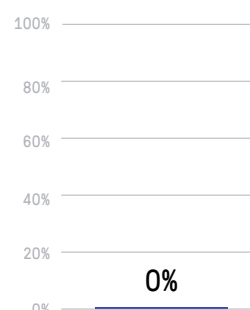
■ Overall ■ Malignancy

Primary endpoints

Feasibility



Safety: pneumothorax or excessive bleeding rate



*Study sponsored by Intuitive

Radial EBUS was used at the end of navigation

1 Fielding D, I, K, Bashirzadeh F, Son J, H, Todman M, Chin A, Tan L, Steinke K, Windsor M, N, Sung A, W: First Human Use of a New

Robotic-Assisted Fiber Optic Sensing Navigation System for Small Peripheral Pulmonary Nodules. Respiration 2019;98:142-150. doi: 10.1159/000498951

Ion is for sale in the US.

Outside of the US, 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

Risks 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.

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