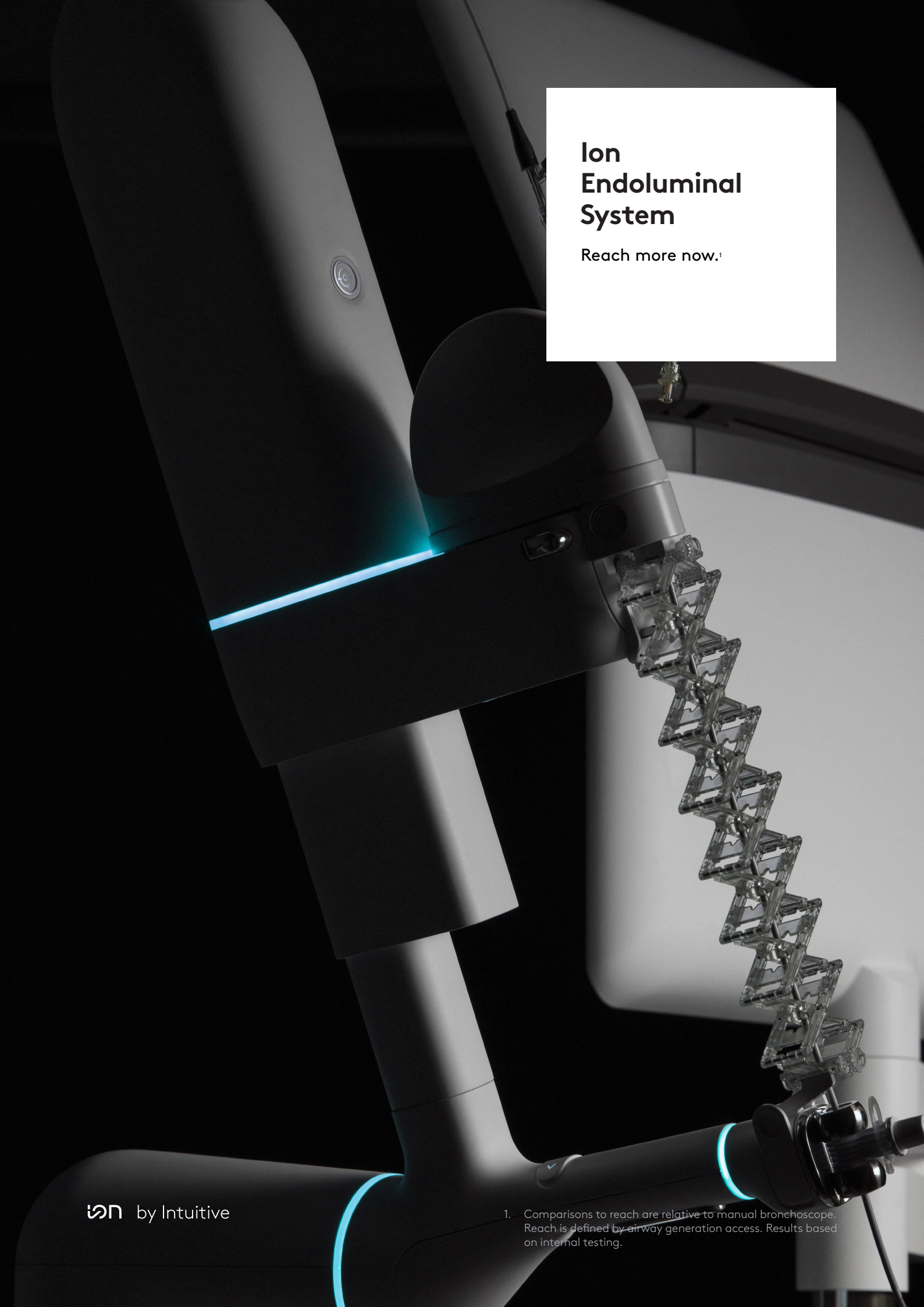


Ion Endoluminal System

Reach more now.[1]

ion by Intuitive

1. Comparisons to reach are relative to manual bronchoscope. Reach is defined by airway generation access. Results based on internal testing.

More precise.[2] More flexible.[3] For more answers.

Introducing the Ion™ endoluminal system, Intuitive's new robotic platform for minimally invasive biopsy in the peripheral lung. The system features an ultra-thin[4], ultra-maneuverable[5] catheter that allows navigation far into the peripheral lung[6], and unprecedented stability[7] enables the precision needed for biopsy. With Ion, you can advance your bronchoscopic capabilities.[8]

Reach more now.[1]

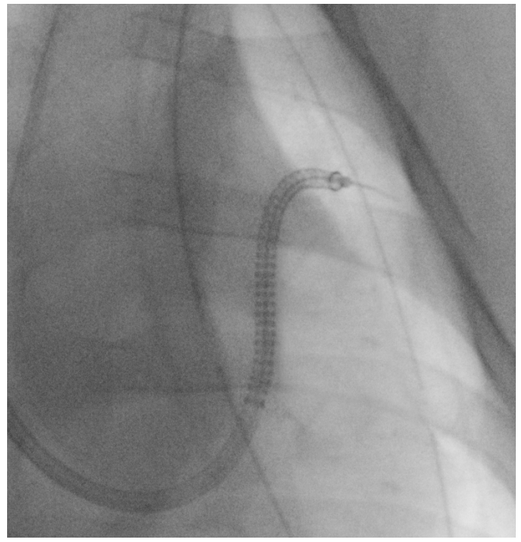
1. Comparisons to reach are relative to manual bronchoscope. Reach is defined by airway generation access. Results based on internal testing.
2. Comparisons of precision are relative to manual techniques. Precision is the ability to place a biopsy tool in a desired location consistently. Results based on internal testing.
3. Comparisons of flexibility is relative to ENB technology. Flexibility is the ability to articulate 180° in all directions. Results based on internal testing.
4. Results based on internal testing.
5. Maneuverability is the ability to articulate 180° in all directions. Results based on internal testing.
6. Results based on internal testing.
7. Comparisons of stability are relative to manual techniques. Stability is enabled by fiber optic sensing technology which maintains active robotic control of catheter position and corrects unwanted tip deflection. Results based on internal testing.
8. Results based on internal testing.

More reach[1]

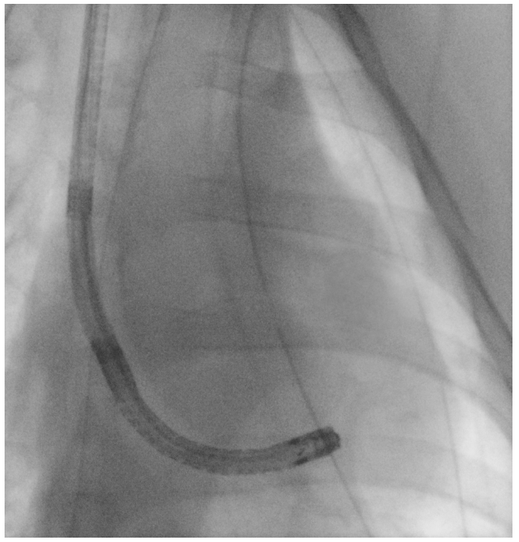
Reaching peripheral nodules in the lung can be challenging. With Ion's ultra-thin robotic catheter[4] and advanced maneuverability[5], you can navigate far into the peripheral lung.[6]

The Ion endoluminal system features a 3.5 mm outer-diameter catheter with a 2.0 mm working channel that can pass through small and tortuous airways.[9] The catheter can articulate 180 degrees in any direction and pass around tight turns, allowing it to reach all 18 segments of the lung.[10, 11]

And, with an integrated vision probe, you will have real-time vision of the airway while navigating to the target.[12]



The Ion fully articulating catheter pictured here is able to reach a target in a challenging location of the right upper lobe. The anatomy pictured is the right upper lobe of a porcine model.



The outer diameter of traditional bronchoscopes (ranging from 4 mm–6 mm) is sometimes too large to reach difficult-to-access segments of the lung, and lacks robotic articulation to navigate. The diagnostic bronchoscope pictured has an outer diameter of 5.3 mm.

1. Comparison to reach are relative to manual bronchoscope. Reach is defined by airway generation access. Results based on internal testing.
4. Results based on internal testing.
5. Comparisons of maneuverability are relative to ENB technology. Maneuverability is the ability to articulate 180° in all directions. Results based on internal testing.
6. Results based on internal testing.
9.-12. Results based on internal testing.

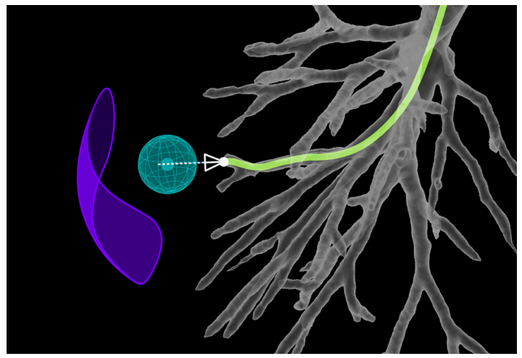
More stability[7]

Embedded in the catheter wall, the Ion fiber optic shape sensor measures the full shape of the catheter hundreds of times per second, providing precise location and shape information throughout the whole navigation and biopsy process.[13] The fiber optic shape sensor is thin, flexible, and not sensitive to metal objects.[14]

Illustration of the Ion Fully Articulating Catheter

Fiber optic shape sensor

Combining these real-time measurements with robotic control algorithms allows the Ion catheter to hold its position once the target nodule is reached.[7]



Force is applied to the four pull wires integrated into the catheter to maintain the stability of the tip as a biopsy tool is passed through.[15]

These design features help the catheter hold its position, even if you attempt to deflect the tip with your finger.

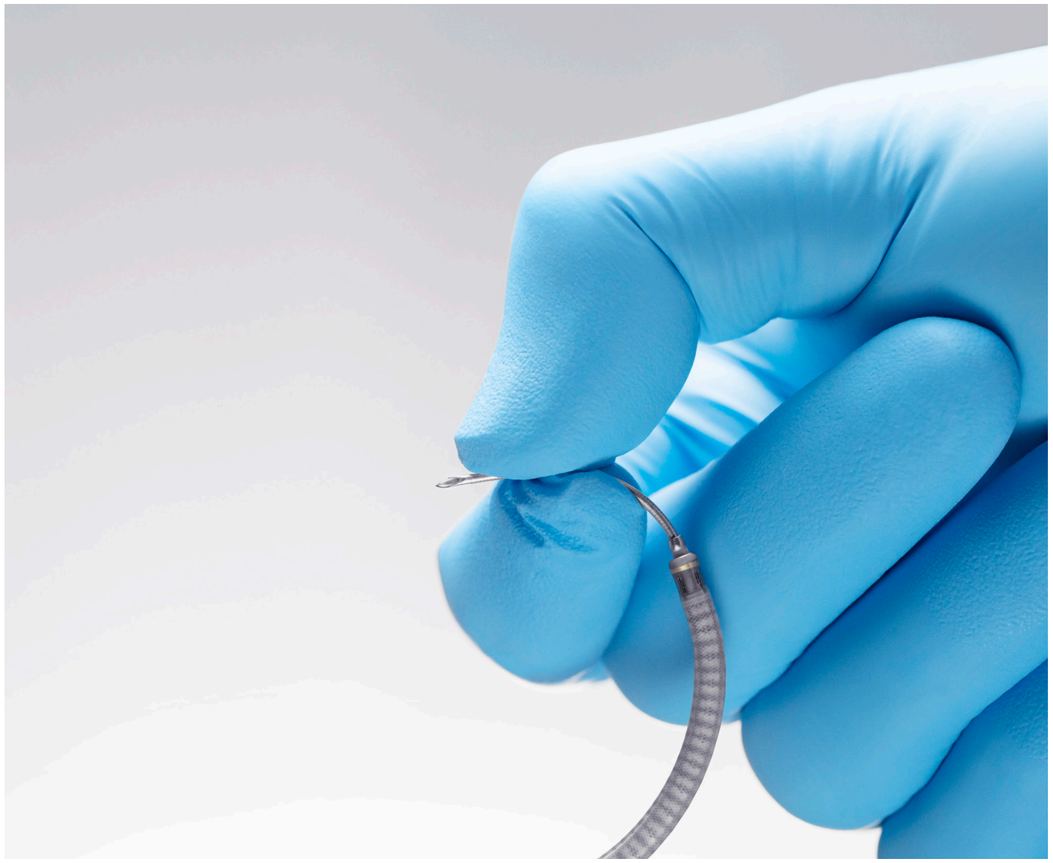
7. Comparisons of stability are relative to manual techniques. Stability is enabled by fiber optic sensing technology which maintains active robotic control of catheter position and corrects unwanted tip deflection. Results based on internal testing.
13. Results based on internal testing.
14. Poeggel S., et al. Sensors (Basel). 2015 Jul 15;15(7):17115-48. doi: 10.3390/s150717115.
15. Results based on internal testing.

More precision[2]

The Ion Fully Articulating Catheter
Use the distal tip articulation to aim at small targets—even those located outside airways.[16]

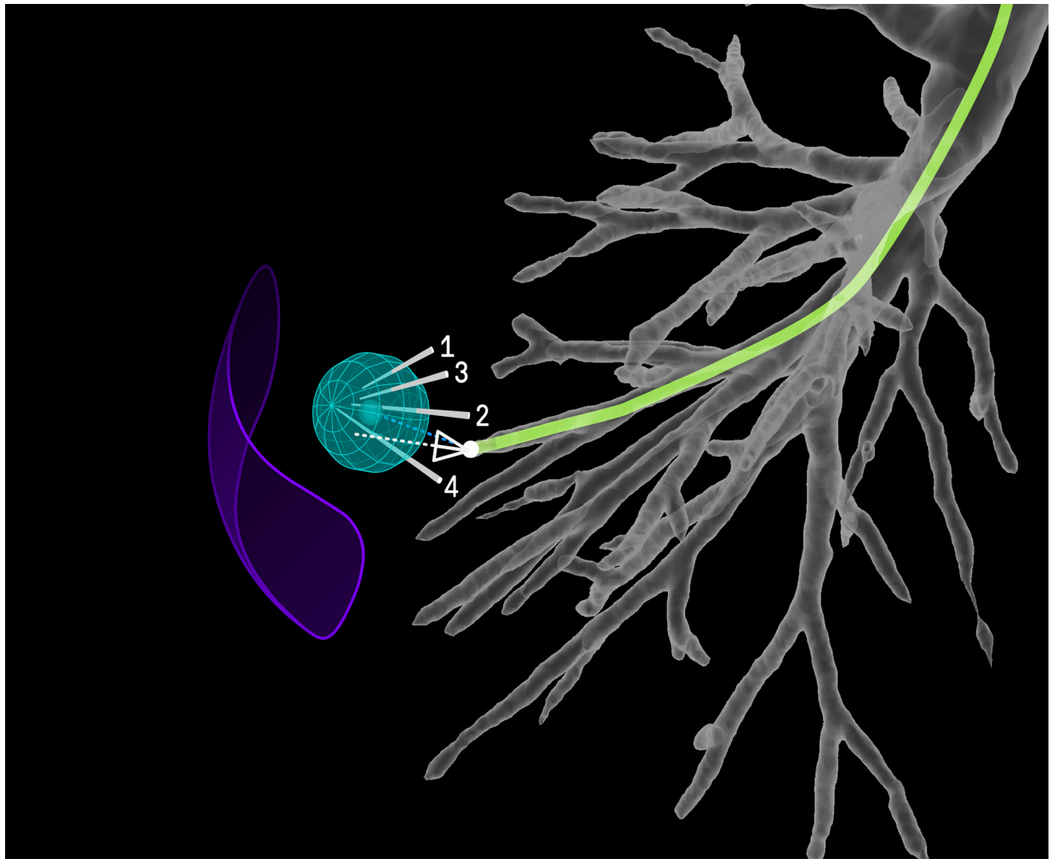
The Fiber Optic Shape Sensor
The shape sensor provides real-time positioning and orientation information.[17]

The Ion Flexision™ Needle
The Ion Flexision needle is flexible and able to pass through the catheter even when positioned in tortuous airways. After advancing the needle around tight bends, the needle still deploys into the target location on a straight path.[18]



Cloud biopsy approach
Ion's Biopsy Marker feature lets you systematically indicate multiple biopsy attempts, and can help you visualize different biopsy needle trajectories.[19]

If real-time confirmation of a representative tissue sample is available during the procedure, you can systematically redirect subsequent biopsy attempts into the confirmed target area. This approach is referred to as cloud biopsy.



2. Comparisons of precision are relative to manual techniques. Precision is the ability to place a biopsy tool in a desired location consistently. Results based on internal testing.

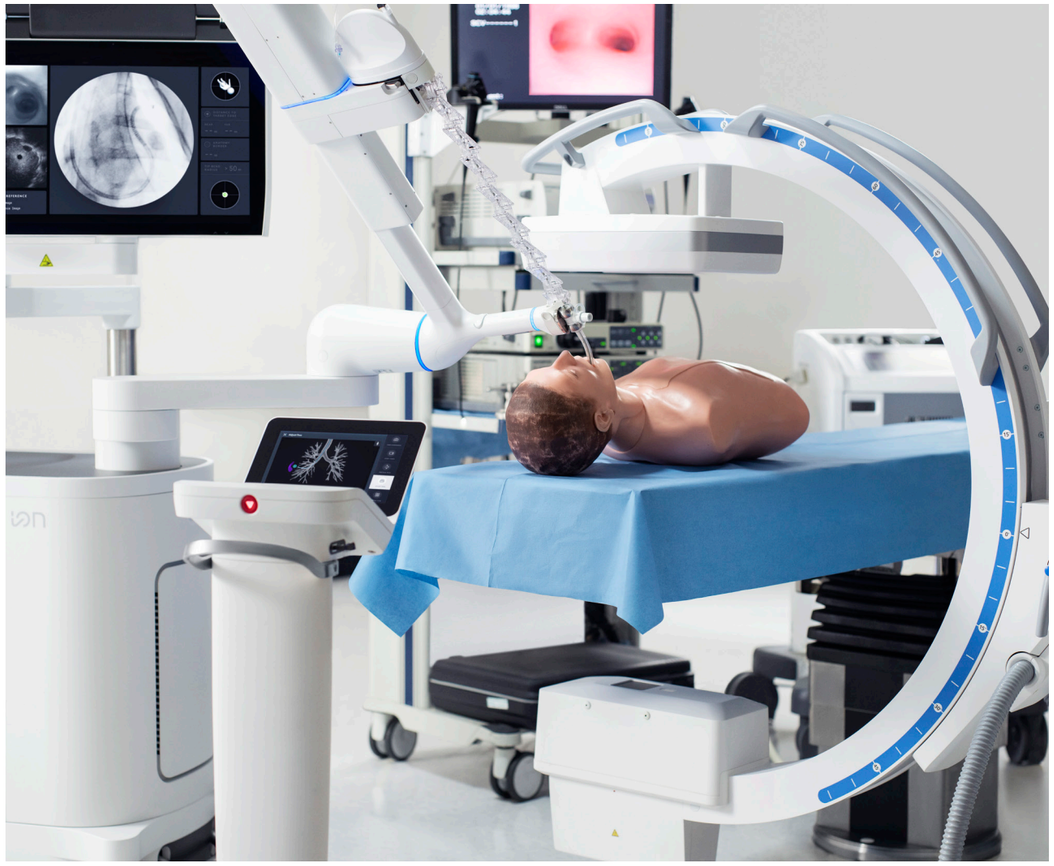
16.-18. Results based on internal testing.

19. Results based on internal testing.

Seamless integration[20]

The Ion system is designed to fit easily into a bronchoscopy suite and integrate with existing technologies.[20] Physical proximity has been taken into account with a design that keeps you close to the patient's airways throughout the procedure.

Although the Ion system does not require the use of cone beam CT for nodule biopsy, we designed Ion to be compatible with this technology.[21]



20.-21. Results based on internal testing.

Seamless integration[20]

Ion leverages existing imaging technologies with radial endobronchial ultrasound (rEBUS), fluoroscopic, virtual, and live views of the lung unified in a single system.[20]

20. Results based on internal testing.

First human use study* evaluates safety and feasibility[22]

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	30 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

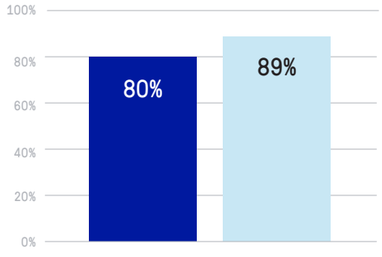
Nodule location
Number of airway generations
Mean ± SD (range):
6.7 ± 1.3 (3.0-9.0)

Lesion locations
66.7% UL
10% RML
23.3% LL

CT Bronchus sign present
40% negative
60% present

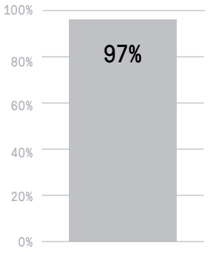
Nodule size
Axial plane: 12.3 ± 4.2 mm
Coronal plane: 12.3 ± 3.2 mm
Sagittal plane: 11.6 ± 4.1mm

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

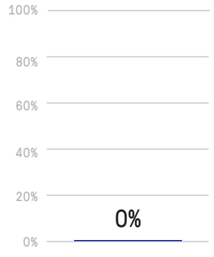


Diagnostic yield trends
Overall
Malignancy

Primary endpoints
Feasibility



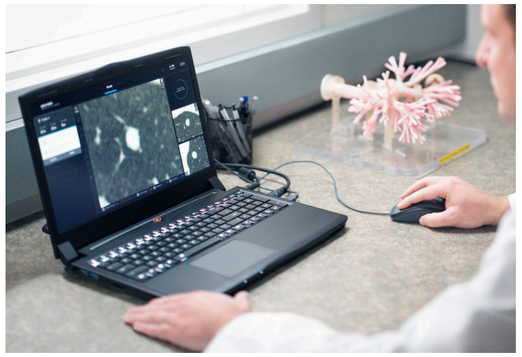
Safety: pneumothorax or excessive bleeding rate



* Study sponsored by Intuitive
Radial EBUS was used at the end of navigation

22. Fielding D, Bashirzadeh F, Son J et al. First Human Use of a New Robotic-Assisted Navigation System for Small Peripheral Pulmonary Nodules Demonstrates Good Safety Profile and High Diagnostic Yield. Chest. 2017;152(4):A858. doi:10.1016/j.chest.2017.08.892. Presented results at the 2017 CHEST Annual Meeting.

The Ion workflow



Planning
Begin by uploading a CT scan of the lung to create a roadmap with PlanPoint software.

Navigation
Next, using the controller, navigate the Ion articulating catheter along the preplanned pathway to the desired location.

Biopsy
Once the target is reached, you are able to lock the catheter in place to perform a nodule biopsy.

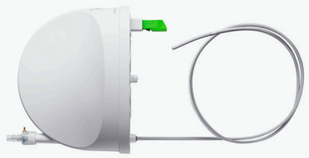
Ion PlanPoint software

PlanPoint software uses a patient's CT scan to generate 3D airway trees. The simple and intuitive user interface allows you to precisely identify a target and create a path to it.

PlanPoint also enables you to create anatomy borders and can help you identify critical structures to reference during the procedure.[23]

23. Results based on internal testing.

Instruments and accessories



The Ion fully articulating catheter has a working channel that allows for insertion of the Ion peripheral vision probe, the Ion Flexision biopsy needle, rEBUS and a range of third-party tools that are compatible with a 2 mm tool channel and have a minimum length of 100 cm.*

Ion Fully Articulating Catheter

1 unit	490105

3.5 mm outer diameter and a 2.0 mm working channel

Ion Peripheral Vision Probe

2 units	490106

Fits within the tool channel of the Ion Fully Articulating Catheter

The Ion Flexision biopsy needles are made of laser-etched stainless steel. The needle is protected by a flexible retractable sheath, with a stylet for support during insertion. The needle and sheath tip are radiopaque. The needle stop allows the user to control the needle length up to 3 cm.

19G Flexision™ Biopsy Needle

5 units	490104

21G Flexision™ Biopsy Needle

5 units	490103

23G Flexision™ Biopsy Needle

5 units	490102

* Compatible forceps: must be Cook Captura Disposable Bronchoscope Biopsy Forceps (Model G53006) only.

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.

PN1051118-US RevA 03/2019


Navigate
85°