

# The Olympus Solutions for Lung Cancer Diagnosis and Staging

Proven Precision. Deeper Insight.



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## The Problem: Lung Cancer

Lung cancer accounts for approximately 1 in 4 cancer deaths - more than all breast, colorectal and prostate cancer deaths combined.<sup>1</sup> An estimated 1-2 million people die each year from lung cancer, a trend that could be significantly reduced with preemptive lung cancer screening.<sup>2,3</sup>



## Lung Cancer Screening Eligibility: Earlier Detection, Better Outcomes

As of March 2021, The U.S. Preventative Services Task Force (USPSTF) has reduced the recommended age range and pack-years for low-dose computed tomography (CT) lung cancer screening – increasing the number of eligible US adults.<sup>4</sup> The Centers for Medicare and Medicaid Services (CMS) also recommend more proactive lung cancer screening in individuals at high risk of lung cancer.<sup>5</sup>

The increase in patient screening is expected to result in:

- A greater number of patients with solitary pulmonary lesions that require follow-up care
- An increase in patients that require endobronchial ultrasound transbronchial needle aspiration (EBUS-TBNA) and bronchoscopic sampling of suspicious lesions

Consequently, there is a clear need for direct and accurate diagnosis of malignancy using safe, minimally invasive methods.

USPSTF Recommendations for CT Lung Cancer Screening		
•	•	
Old Recommendations	New Recommendations	
Age range: 55-80	Age range: 50-80	
Pack-year history: 30	Pack-year history: 20	





Is your institution equipped to handle the estimated **79% increase** in demand for more accurate and efficient methods for assessing central and peripheral regions of the second second

# Outdated Staging Methods May Lead to Suboptimal Patient Outcomes

With an increase in the population eligible for preemptive lung cancer screening, it's important to have a comprehensive diagnosis and staging program in place. Reliance on clinical staging alone can lead to an incorrect diagnosis and increased mortality. Additionally, clinical staging using CT alone can markedly differ from invasive staging, reducing the accuracy of clinical diagnosis.<sup>9-11</sup>

(i) Effective invasive staging is required for the most accurate diagnosis and treatment assessment.<sup>10</sup>

### Accuracy of Clinical Staging of Stage I-III a Non-Small Cell Lung Cancer<sup>23</sup>



## Inaccurate Staging of Mediastinal Lymph Nodes

When relying on PET-CT results alone, physicians falsely overstage mediastinal lymph nodes in approximately 19% of patients and falsely understage in approximately 13% of patients.<sup>9, 15, 16</sup>





# The Solution: Comprehensive Tools to Diagnose and Stage Lung Cancer Across All Regions of the Lung

With increased focus on early lung cancer detection and more aggressive, preemptive screening, diagnostic methods to stage and then treat the disease are more critical than ever before.

A dynamic and complete solution that allows effective sampling across the entire lung is imperative. EBUS-TBNA is the guideline-recommended best first test for lung cancer diagnosis and staging.<sup>7</sup> However, when a diagnosis with EBUS-TBNA proves elusive, an effective approach for accessing and sampling the periphery is critical.

## The 2013 ACCP guidelines recommend: <sup>7</sup>

- EBUS-TBNA as the best first test over surgery for mediastinal staging
- Radial EBUS for patients with a peripheral lesion and when tissue diagnosis is required due to uncertainty of diagnosis

<ul> <li>In patients with peripheral lung lesions that are</li> </ul>
difficult to reach with conventional bronchoscopy,
electromagnetic navigation guidance is recommended
if the equipment and the expertise are available

# Effective Staging Helps Guide Successful Therapy

When comparing available sampling methods, it's important to weigh the risk of complications with sensitivity and specificity.

#### Sensitivity/Specificity of Select Staging Methods<sup>9-14</sup>

CT*	50%-70%	63%-86%
PET-CT*	50%-85%	74%-93%
Mediastinoscopy	≈78%	100%
Video mediastinoscopy	≈89%	100%
EBUS	≈89%	100%
EUS	≈89%	100%
Olympus Solutions for Lung Cancer Diagnosis and Staging	≈91%	100%

Sensitivity

The use of invasive staging before making treatment decisions is crucial to obtain the most accurate assessment for appropriate therapy and proper prognosis.<sup>12</sup>

## Lung Cancer Molecular Subtypes May Help Determine Treatment Options

The molecular basis of lung cancer is complex and heterogeneous.<sup>21</sup> Understanding the molecular biology of lung cancer through adequate tissue sampling is necessary for determining the best course of treatment.<sup>21</sup>

The list of approved therapies for lung cancer continues to grow. However, without obtaining an adequate tissue sample, many of these therapies may be unavailable to your patients.



Other genes	27.3%	<i>RET</i> fusion
KRAS	29.1%	MET amplification
EGFR	14.2%	• ERBB2 amplification
BRAF	7.2%	MAP2K1
NF1 truncation	6.3%	• NRAS
ERBB2	1.8%	• HRAS
MET splice	1.4%	RIT1
ALK fusion	0.8%	• FGFR1 or FGFR2
ROS1 fusion	0.9%	

Advanced testing drives the need for more tissue collected during sampling. Does your institution have a precise, reliable method of collecting sufficient tissue samples?

0.3%

1.7%

1.6%

2.2%

0.5%

0.5% 1.6%

2.6%

Specificity



# Maintaining Control from Pathway to Nodule Identifying Limitations in Emerging Bronchoscopic Technology

Consistently obtaining diagnostic samples in the outer third region of the lung can be challenging without augmenting your procedure with navigational guidance or supportive imaging and visualization.<sup>19</sup> Some physicians have turned to robotic-assisted systems to attempt to address these challenges. However, when compared to a more physician-directed approach using the Olympus Solutions for Lung Cancer Diagnosis and Staging, robotic-assisted approaches may not address all needs.

# Physician-Directed vs. Robotic-Assisted Diagnosis and Staging Systems <sup>24, 25</sup>

The recent arrival of robotic-assisted bronchoscopy promises physicians a simple way to maneuver into the peripheral lung. While robotic bronchoscopy systems make it easier to access these areas in some cases, they offer few distinct advantages over the superior, physician-directed approach.

#### Physician-Directed Bronchoscopy

- Puts capable physicians in control with advanced navigational guidance, tip tracked spatial awarene and high-resolution imaging
- Precise sampling under respiratory motion in the periphery and other regions of the lung
- Seamlessly transition from a navigated bronchosco to a navigated TTNA in a single procedure
- ✓ Always-On Tip Tracked<sup>™</sup> instruments eliminate "blind sampling" and make additional modalities such as fluoroscopy unnecessary

	Robotic-Assisted Bronchoscopy	
SS	<ul> <li>Robotic-assisted bronchoscopy provides a simple way to maneuver into the periphery</li> </ul>	
	Ineffective sampling of lung nodules in the peripheral region during respiratory motion	
ру	Inability to transition patient to TTNA during the same procedure	
	X Lack of visualization at the time of biopsy results in "blind sampling"	



The Olympus Solutions for Lung Cancer Diagnosis and Staging

Proven Precision. Deeper Insight.

Together, Olympus and Veran combine the power of real-time, proven precision with advanced navigational agility throughout the lung — offering a comprehensive portfolio with EBUS and navigation that empowers quality patient care and cutting-edge treatment.<sup>24</sup>

## The Next Generation of EBUS-TBNA is Here

#### Allowing Staging and Diagnosis of Difficult to Reach Lymph Nodes and Lesions

The Olympus EBUS Solution offers everything you need to perform real-time sampling and staging in one revolutionary system designed for efficiency and enhanced patient care. With more than 1,600 proven clinical studies, Olympus continues to innovate and partner with pulmonologists to offer patients the gold standard in diagnosis and staging lung cancer. The BF-UC190F, the next generation of Olympus EBUS bronchoscope, provides enhanced access and control to allow staging and diagnosis of even difficult-to-reach lymph nodes and lesions.<sup>26</sup>



#### BF-UC190F <sup>26</sup>

The BF-UC190F represents the next generation of EBUS innovation from Olympus with a thin outer diameter, decreased forward oblique viewing angle for easy intubation and endoscopic observation and increased angulation for enhanced maneuverability.



#### Radial EBUS 27

Radial EBUS provides a 360-degree image of the airway wall and surrounding structures external to the airway. The real-time ultrasound image supports direct visualization of the exact position of the lesion for sampling.



# Access and Sample the Mid- and Outer-Third Regions of the Lung with the SPiN Thoracic Navigation System™

The SPiN System<sup>™</sup> uses respiratory gating technology to track nodule movement in real-time on a 3D map based on inspiration/expiration CT scans. The SPiN System is currently the only EMN platform that offers the flexibility to seamlessly transition from navigated bronchoscopy to navigated TTNA in one procedure.





Armed with the SPiN System's accurate 3D roadmap and respiratory gating technologies, you can reach challenging targets — even as they move during respiration. <sup>24</sup>





When you're in control of bronchoscopic yields, the answers are in your hands.



Always-On Tip Tracked Instruments provide precision guidance for dve injection and hook wires for localization, as well as navigation during localization via endobronchial or transthoracic approaches.

Visualize all the way to the nodule using

any of the SPiN System's Always-On

flexibility to switch to a percutaneous

approach in a single procedure.

Tip Tracked<sup>™</sup> Instruments and gain the



# All Options are on the Table

### Transition from Navigated Bronchoscopy to TTNA Seamlessly

Olympus' SPiN Perc<sup>™</sup> system allows for a seamless transition from navigated bronchoscopy to navigated transthoracic needle aspiration (TTNA) in the same procedure.

## **Timeline for SPiN System Percutaneous Approach**







SPiN Perc Needle: Always-On Tip Tracked<sup>™</sup> SPiN Perc is designed to provide safe navigation and sampling Access lung nodules percutaneously with SPiN Perc. 28, 29



#### We believe this highlights the outstanding potential

...in allowing minimally invasive diagnoses for patients with SPN in a single procedural setting, which traditionally has not been available. The ability to perform simultaneous EBUS mediastinal staging along with bronchoscopy and TTNA under EMN guidance during the same procedure may reduce time to treatment and cost of care and increase diagnostic yield and convenience for patients."4

Roy W. Semaan, MD, et al. / Johns Hopkins University School of Medicine

## A Successful Diagnosis Starts With A Better Map











**3D Road Map:** SPiN System<sup>™</sup> is currently the only 3D road map generated from inspiration/expiration CT scans.



SPiN<sup>™</sup> software communicates with the vPad<sup>™</sup> to update respiratory movement 20x per second

SPiN Software: Monitors respiration as the patient breathes to track nodule motion during inspiration and expiration.



while eliminating the need for fluoroscopy.



## Olympus Solutions for Lung Cancer Diagnosis and Staging

#### **EVIS EXERA™ III Endoscopy Platform**



This powerful endoscopy platform is compatible with a wide range of endoscopes across specialties to provide easy data management and cost efficiencies.

#### SPiN Thoracic Navigation System<sup>™</sup>



The SPiN System<sup>™</sup> uses respiratory gating technology to track nodule movement in real-time on a 3D map and is an EMN platform that enables seamless transitions from navigated bronchoscopy to navigated TTNA in one procedure.

BF-P190 38

#### BF-UC190F <sup>26</sup>



The BF-UC190F EBUS bronchoscope supports enhanced access and control to allow staging and diagnosis of even difficult-to-reach lymph nodes and lesions.

#### BF-MP190F 36

The rotatable, ultra-slim design is

compatible with the radial EBUS probe and

an array of sampling devices to expand

access to smaller, more distal airways.





The rotatable, slim design, and additional tip angulation, enhances maneuverability to provide access in peripheral airways.

#### ViziShot<sup>™</sup> | EBUS-TBNA Needles



The ViziShot 21 G and 22 G needles are designed to improve visibility on ultrasound images to support direct visualization of the needle as it penetrates the lymph node.<sup>30</sup>

#### ViziShot 2 FLEX | EBUS-TBNA Needle



The 19 G FNB EBUS-TBNA needle features spiral laser cuts on the surface designed to to deliver flexibility and angulation. The 19 G needle has been shown to obtain sufficient tissue to perform mutational analysis and/or immunocytochemical analysis.<sup>20, 32</sup>

#### **EU-ME2<sup>™</sup> Ultrasound Processor**

## Guide Sheath<sup>™</sup> Kit 2



This versatile system allows real-time visualization of the targeted area for precise sampling of lymph nodes and pulmonary lesions. Its unique design supports electronic and mechanical scanning for both curvilinear and radial EBUS in one compact box.34



diagnostic yield.33

## ViziShot 2 | EBUS-TBNA Needles



The ViziShot 2 EBUS-TBNA needles offer improved features compared to Vizishot, including added flexibility, enhanced puncture capabilities, and a colored sheath. Available in 21 G, 22 G and 25 G sizes.31

### **Radial EBUS Probes**



Convenient insertion directly through the bronchoscope, or use with the Olympus guide sheath. The real-time, 360-degree ultrasound image enables direct visualization to determine lesion location for accurate sampling.27

Provides a versatile method for reaching and sampling peripheral lesions in the lung. When combined with radial EBUS, the Guide Sheath Kit may help to improve the

#### **PeriView FLEX<sup>™</sup> TBNA** Needle



This 21 G needle provides flexibility and versatility to improve access. Compatible with the full line of Olympus guide sheaths and bronchoscopes with an instrument channel 1.7 mm and above.35



# Focus on Your Patient

With the click of a button, connect with our team of Clinical Support Specialists so you can continue taking care of your patient. We can assist you remotely with the SPiN System<sup>™</sup> and the SPiN Planning<sup>™</sup> station to support you directly in your procedure.

# vSupport<sup>™</sup> Connect

vSupport Connect is a secure, HIPAA-compliant platform that provides on-demand, secure screen sharing for live physician-directed clinical support with the SPiN System and the SPiN Planning Laptop Workstation.

### **Services Offered**

Our U.S. based, live clinical support team can assist with:

- Case planning
- Live procedure support
- Troubleshooting
- Post procedure analysis

#### vSupport Access

Simply click on the icon to connect with a Clinical Support Specialist.

To get connected with a vSupport specialist outside of the platform, call or email today.

- **§** 1-866-508-9675
- Vsupport@olympus.com





# Olympus Services: Dedicated Support Beyond Products

Olympus is more than a provider of advanced medical equipment. We provide reliable end-to-end support - from the purchasing process to the procedure and reprocessing services - to maintain a relationship of lasting trust.

Your success with our industry-leading products means that you can focus on comprehensive diagnostics and a reliable treatment plan for your patients. We are always here as a resource to help you move forward with precision, confidence and simplicity.



## Field Service and Clinical Support

#### **Endoscopy Support Specialists**

Perform on-site training on reprocessing, care and handling, and asset management.

#### **Clinical Endoscopy Specialists**

Field-based nurses or technicians with advanced clinical experience in our suite of products.

#### **Field Service** Engineers

Install your product and conduct in-service training for your clinical staff to get up and running.

#### Clinical **Educators**

Healthcare Professionals providing clinical support on safe and effective use training for Olympus products and procedures.

#### **Respiratory Territory** Managers

Consultants for all your Olympus respiratory product and service needs.

#### **Clinical Application Specialists**

Registered diagnostic medical sonographers providing support for EUS and EBUS products.

#### **Executive Respiratory Account Managers**

Consultants for all your Olympus respiratory SPiN capital needs.

## **Customer Service Contact Information**



#### vSupport<sup>™</sup> Connect

vSupport Connect is a secure, HIPAA-compliant platform that provides on-demand secure screen sharing for live physician-directed clinical support. With the click of a button, connect with our team of Clinical Support Specialists who can assist you remotely with the SPiN System<sup>™</sup> and the SPiN Planning<sup>™</sup> station from our St. Louis office. To get connected with a vSupport specialist, call or email today.

Section 1-866-508-9675

Vsupport@veranmedical.com

#### **Olympus Technical Assistance Center (TAC)**

Specialists are available Monday-Friday 7 am to 8 pm EST to respond to calls and assist you in diagnosing and troubleshooting your entire range of Olympus products.

& 800-848-9024, ext 1

#### OlympusConnect.com

OlympusConnect.com is a web portal for Olympus customers to access corporate intelligence in order to improve business and clinical operations. This passwordprotected site contains a vast amount of resources including case studies, product catalogs and businessbuilding marketing materials.

olympusconnect.com

## **Financing Options**

For more than 20 years, Olympus has been providing lease financing programs that are affordable, flexible and customized for our healthcare technology users.

☑ fisfrsteam@olympus.com

#### **Service Agreements**

Olympus provides comprehensive coverage for all covered endoscope repairs, whether caused by daily use or accidental damage. Our 24/7 technical support provides on-site options to meet your facility's needs.

**&** 800-401-1075

Service.contracts@olympus.com

#### **Reimbursement Guidelines Hotline**

Olympus has a full collection of reimbursement materials to help healthcare providers be more informed and to make better economic decisions. Coding experts are available to help answer your reimbursement questions.

Section 866-794-4331

☐ olympusreimbursement@priahealthcare.com

#### **Olympus Continuum**

Product training and education programs provide safe and effective product use training on Olympus equipment and devices to healthcare professionals (HCPs), particularly physicians and nurses.

Section 800-231-0016

□ olympuscontinuum.com

# Physician Directed vs. Robotic Assisted <sup>37</sup>

	Branchessens Competite III.
	Bronchoscope Compatibility
	Diagnaphia (4.9, 5, 5 mm)
	Diagnostic (4.0-5.5MM)
	*Scopes can be starilized at your facility reducing th
Access: Endobronchial	need to be sent off to a third-party sterilization vent
	SPiN Access Catheter
	2.7mm OD
	Navigate Steerable Catheter Access
	(No bronchoscope required)
	SPiN Vision Scopes
	SPiN Perc™
Access: Transthoracic	Allows for a seamless transition from navigated bronchoscopy to navigated TTNA in the same procedure to help speed time to diagnosis
	Always-On Tip Tracked® instruments allow for continual guidance when you need it the most, at t
	time of biopsy.
	and are compatible with a 2.0mm WC, or larger.
Navigated Sampling	Available Always-On Tip Tracked® Biopsy Tools
	Forceps (Serrated and Oval)
	Needles (19ga & 21ga)
	SPIN Flex™ 22ga Needle
	Aways-on hp nacked® inple Needle Brush Brush
	SPiN Xtend™ 1-4cm Adiustable Needle
	Allows for transluminal approach
	Airway map is based on proprietary 3D map based
	on both inspiration and expiration CT scans: YES
Procedural Map	
	Respiratory gating technology: YES
	System compatible with referral CT scans: YES
	Endobronchial Approach: YES
	Fiducial* Placement
	Dye Marking
	Transthoracic Approach: YES
ocalization Modalities	SPiN Perc™
	Allows for percutaneous placement of localization
	devices
	devices SPiN Perc™ Localization Needles
	devices SPiN Perc <sup>™</sup> Localization Needles Allows for percutaneous dye marker placement
	devices SPiN Perc <sup>™</sup> Localization Needles Allows for percutaneous dye marker placement Time-consuming procedural set-up: <b>NO</b>
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	devices SPiN Perc <sup>™</sup> Localization Needles Allows for percutaneous dye marker placement Time-consuming procedural set-up: <b>NO</b> Anesthetic regimen General anesthesia: <b>YES</b>
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System Versatility	devices SPiN Perc <sup>™</sup> Localization Needles Allows for percutaneous dye marker placement Time-consuming procedural set-up: NO Anesthetic regimen General anesthesia: YES Moderate sedation: YES Conscious sedation: YES
System Versatility	Allows for percutaneous placement of rotalization devices SPiN Perc <sup>™</sup> Localization Needles Allows for percutaneous dye marker placement Time-consuming procedural set-up: NO Anesthetic regimen General anesthesia: YES Moderate sedation: YES Conscious sedation: YES Patient positioning for procedure
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System Versatility Cost	Another between the intervention of recent and the devices SPiN Perc™ Localization Needles Allows for percutaneous dye marker placement Time-consuming procedural set-up: NO Anesthetic regimen General anesthesia: YES Moderate sedation: YES Patient positioning for procedure Supine: YES Prone: YES Prone: YES Lateral Decubitus: YES Capital cost under \$250k: YES Problished clinical data supporting high diagnostic yield: YES 92% Yarmus et al. (Hopkins) Average lesion size: 2.0cm
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System Versatility Cost System Performance	Allows for percutaneous placement of rocalization devices SPiN Perc <sup>™</sup> Localization Needles Allows for percutaneous dye marker placement Time-consuming procedural set-up: <b>NO</b> <b>Anesthetic regimen</b> General anesthesia: <b>YES</b> Moderate sedation: <b>YES</b> <b>Patient positioning for procedure</b> Supine: <b>YES</b> <b>Patient positioning for procedure</b> Supine: <b>YES</b> <b>Patient positioning for procedure</b> Supine: <b>YES</b> Prone: <b>YES</b> Lateral Decubitus: <b>YES</b> Capital cost under \$250k: <b>YES</b> Procedural cost under \$250k: <b>YES</b> Procedural cost under \$2k: <b>YES</b> Published clinical data supporting high diagnostic yield: <b>YES</b> <b>92% Yarmus et al. (Hopkins)</b> Average lesion size: 2.0cm Veran System + Linear EBUS: 92% <b>90.2% Flenaugh</b> Average lesion size: 2.2cm Pneumothorax: 0%
System Versatility Cost System Performance	Anomotor percentaneous placement of rocalization devices SPiN Perc <sup>™</sup> Localization Needles Allows for percutaneous dye marker placement Time-consuming procedural set-up: <b>NO</b> <b>Anesthetic regimen</b> General anesthesia: <b>YES</b> Moderate sedation: <b>YES</b> <b>Patient positioning for procedure</b> Supine: <b>YES</b> <b>Patient positioning for procedure</b> Supine: <b>YES</b> Prone: <b>YES</b> Lateral Decubitus: <b>YES</b> Capital cost under \$250k: <b>YES</b> Procedural cost under \$250k: <b>YES</b> Procedural cost under \$2k: <b>YES</b> Procedural cost under \$2k: <b>YES</b> Published clinical data supporting high diagnostic yield: <b>YES</b> <b>92% Yarmus et al. (Hopkins)</b> Average lesion size: 2.0cm Veran System + Linear EBUS: 92% <b>90.2% Flenaugh</b> Average lesion size: 2.2cm Pneumothorax: 0% Chest tube: 0%
System Versatility Cost System Performance	Allows for percutaneous placement of rotalization devices         SPiN Perc™ Localization Needles         Allows for percutaneous dye marker placement         Time-consuming procedural set-up: NO         Anesthetic regimen         General anesthesia: YES         Moderate sedation: YES         Patient positioning for procedure         Supine: YES         Prone: YES         Lateral Decubitus: YES         Capital cost under \$250k: YES         Procedural cost under \$250k: YES         Procedural cost under \$250k: YES         Published clinical data supporting high diagnostic yield: YES         92% Yarmus et al. (Hopkins)         Average lesion size: 2.0cm         Veran System + Linear EBUS: 92%         90.2% Flenaugh         Average lesion size: 2.2cm         Pneumothorax: 0%         Chest tube: 0%         83.3% Raval
System Versatility Cost System Performance	Allows for percutaneous placement of localization         devices         SPiN Perc™ Localization Needles         Allows for percutaneous dye marker placement         Time-consuming procedural set-up: NO         Anesthetic regimen         General anesthesia: YES         Moderate sedation: YES         Patient positioning for procedure         Supine: YES         Prone: YES         Lateral Decubitus: YES         Procedural cost under \$250k: YES         Procedural cost under \$250k: YES         Procedural cost under \$250k: YES         Published clinical data supporting high diagnostic yield; YES         92% Yarmus et al. (Hopkins)         Average lesion size: 2.0cm         Veran System + Linear EBUS: 92%         90.2% Flenaugh         Average lesion size: 2.2cm         Pneumothorax: 0%         Chast tube: 0%         83.3% Raval         Average lesion size: 1.9cm
System Versatility Cost System Performance	Allows for percutaneous placement of localization devices         SPiN Perc™ Localization Needles         Allows for percutaneous dye marker placement         Time-consuming procedural set-up: NO         Anesthetic regimen         General anesthesia: YES         Moderate sedation: YES         Patient positioning for procedure         Supine: YES         Prone: YES         Lateral Decubitus: YES         Procedural cost under \$250k: YES         Published clinical data supporting high diagnostic yield: YES         92% Yarmus et al. (Hopkins)         Average lesion size: 2.0cm         Veran system: 87%         Veran System + Linear EBUS: 92%         90.2% Flenaugh         Average lesion size: 2.2cm         Pneumothorax: 0%         Chest tube: 0%         83.3% Raval         Average lesion size: 1.9cm         Pneumothorax: 2%

Auris	lon
Robotic Endoscope	Robotic Endoscope
Monarch Bronchoscope Sheath: 6.0mm	Ion Robotic Bronchoscope: 3.5mm
Monarch Broncoscope: 4.4mm	
*Requires third-party sterilization vendor	
NONE	NONE
Robot Kinetics	Positional Awareness
Electromagnetics, optical pattern recognition and robotic kinematic data – to triangulate bronchoscope location during the procedure and provide accurate positional data to physicians performing a bronchoscopy.	Embedded within Ion's ultra-thin catheter, the shape sensor measures the full shape of the catheter hundreds of times per second,1 providing precise location, shape, and orientation information
Airway map is based on proprietary 3D map based on both inspiration and expiration CT scans: <b>NO</b>	Airway map is based on proprietary 3D map based on both inspiration and expiration CT scans: <b>NO</b>
*Airway map is based on previously acquired TLC scan	Airway map is based on previously acquired TLC scan
Respiratory gating technology: NO	Respiratory gating technology: NO
System compatible with referral CT scans: YES	System compatible with referral CT scans: YES
Endobronchial Approach: YES	Endobronchial Approach: YES
Fiducial* Placement	Fiducial* Placement
Dye Marking	Dye Marking
Transthoracic Approach: NO	Transthoracic Approach: NO
Ime-consuming procedural set-up: YES	I ime-consuming procedural set-up: YES
Anestnetic regimen	
General anestnesia: YES	General anestnesia: YES
Conscience sedation: NO	
Patient positioning for procedure	Patient positioning for procedure
	Prone: NO
Lateral Decubitus: NO	Lateral Decubitus: NO
Capital cost under \$500k: NO	Capital cost under \$500k: NO
Procedural cost under \$2k; NO	Procedural cost under \$2k: UNKNOWN
Published clinical data supporting high diagnostic vield: <b>NO</b>	Published clinical data supporting high diagnostic vield: <b>NO</b>
69.1% Chaddha et al. (Multi-center)	No clinical data supporting diagnostic capabilities of system
Average lesion size: 2.5cm	
Pneumothorax: 4%	
Chest tube: 2%	

- 1. American Cancer Society. Cancer Facts & Figures 2018. Atlanta, GA: American Cancer. Society; 2018.
- 2. World Health Organization. Cancer. WHO website. www.who.int/ news-room/fact-sheets/detail/cancer. Accessed June 18, 2018.
- 3. Paskett ED, et al. Cancer. 2015;121(suppl 17):3052-3054.
- U.S. Preventive Services Task Force. Lung Cancer. USPSTF Website. https://www.uspreventiveservicestaskforce.org/uspstf/ recommendation/lung-cancer-screening. Accessed March 9, 2022.
- Centers for Medicare & Medicaid Services. Decision Memo. CMS Website. https://www.cms.gov/medicare-coverage-database/view/ ncacaldecision-memo.aspx?proposed=N&NCAId=274. Accessed March 9, 2022.
- 6. Walter, Joan E., et al. Journal of Thoracic Oncology. 2018.05.006.
- 7. Detterbeck, Frank C., et al. Chest, vol. 143, no. 5. 2-2377.
- Herth FJF, et al. Endobronchial ultrasound-guided transbronchial needle aspiration of lymph nodes in the radiologically normal mediastinum. Eur Respir J. 2006;28(5):910-914.
- 9. Harders SW, et al. Cancer Imaging. 2014;14:23.
- 10. Silvestri GA, et al. Chest. 2013;143(5 suppl):e211S-e250S.
- 11. Heineman DJ, et al. Ther Adv Med Oncol. 2017;9(9):599-609.
- 12. Steinfort DP, et al. Medicine (Baltimore). 2016;95(8):e2488.
- 13. Rami-Porta R, et al. Eur Respir J. 2018;51:1800190.
- 14. Schmidt-Hansen M, et al. Cochrane Database Syst Rev. 2014;(11): CD009519.
- 15. El-Osta H, et al. Ann Am Thorac Soc. 2018;15(7):864-874.
- 16. Li S, et al. PLOS One. 2013;8(10):e78552-e78558.
- Henderson LM, et al. Broadened Eligibility for Lung Cancer Screening: Challenges and Uncertainty for Implementation and Equity. doi:10.1001/jama.2020.26422
- Targeting Mutations That Drive Lung Cancer." Nature News, Nature Publishing Group, https://www.nature.com/articles/d42473-020-00479-0.
- Wang Memoli JS, Nietert PJ, Silvestri GA. Meta-analysis of guided bronchoscopy for the evaluation of the pulmonary nodule. Chest. 2012 Aug;142(2):385-393. doi: 10.1378/chest.11-1764. PMID: 21980059; PMCID: PMC3425336.

- Wahidi MM, Davidson K, Shofer S, Mahmood K, Cheng G, Giovacchini C, Jones C, Jug R, Pavlisko EN, Wang X, Gu L, Weimholt C, Zhou Z, Chen A. Pilot Study of the Performance of 19-G Needle in Endobronchial Ultrasound-guided Transbronchial Aspiration for the Diagnosis and Testing of Molecular Markers in Lung Cancer. J Bronchology Interv Pulmonol. 2021 Jul 1;28(3):209-214. doi: 10.1097/LBR.00000000000736. PMID: 33273249.
- 21. J Thorac Dis. 2013 Oct 5 Suppl 5(Suppl 5):S479-90. doi: 10.3978/j. issn.2072-1439.2013.08.03.
- Chen A, Pastis N, Furukawa B, Silvestri GA. The effect of respiratory motion on pulmonary nodule location during electromagnetic navigation bronchoscopy. Chest. 2015 May;147(5):1275-1281. doi: 10.1378/chest.14-1425. PMID: 25357229.
- 23. Navani N, et al. Chest. 2019;155:502
- Furukawa BS, Pastis NJ, Tanner NT, Chen A, Silvestri GA, Comparing Pulmonary Nodule Location During Electromagnetic Bronchoscopy with Predicted Location Based on Two Virtual Airway Maps at Different Phases of Respiration, CHEST (2017), doi: 10.1016/ j.chest.2017.06.004.
- 25. Semaan, Roy W, et al. Electromagnetic guidance for the diagnosis of pulmonary nodules: don't put the nail in the coffin. American Journal of Respiratory and Critical Care Medicine. 2016.
- 26. Data on File (K183525) September 2019
- 27. Data on File (K944610) April 1995
- 28. Data on file (K170023) May 2017
- 29. Data on file (K093995) January 2010
- 30. Data on File (K050503) May 2005
- 31. Data on File (K160098) March 2016
- 32. Data on File (K163469) December 2016
- 33. Data on File (K060243) June 2006
- 34. Data on File (K203128) November 2020
- 35. Data on File (K171232) September 2017
- 36. Data on File (K172726) April 2018
- 37. Information obtained from company websites, brochures, and published IFUs.
- 38. Data on file (K201758) January 2021

Complications from extraluminal ultrasound-guided needle aspiration may include infection, bleeding, perforation and tumor seeding. Extraluminal fine needle aspiration of cystic lesions has a higher risk of complication from infection and bleeding.

Complications from bronchoscopy are rare and most often minor, but if they occur, may include breathing difficulty, vocal cord spasm, hoarseness, slight fever, vomiting, dizziness, bronchial spasm, infection, low blood oxygen, bleeding from biopsied site, or an allergic reaction to medications. Some patients may experience rare but more serious complications such as collapsed lung, respiratory failure, heart attack, and/or cardiac arrhythmia.

Competitor Information obtained from company websites, brochures, and published IFUs.

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