Building a Robotic Lung Biopsy Program

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Noah Medical

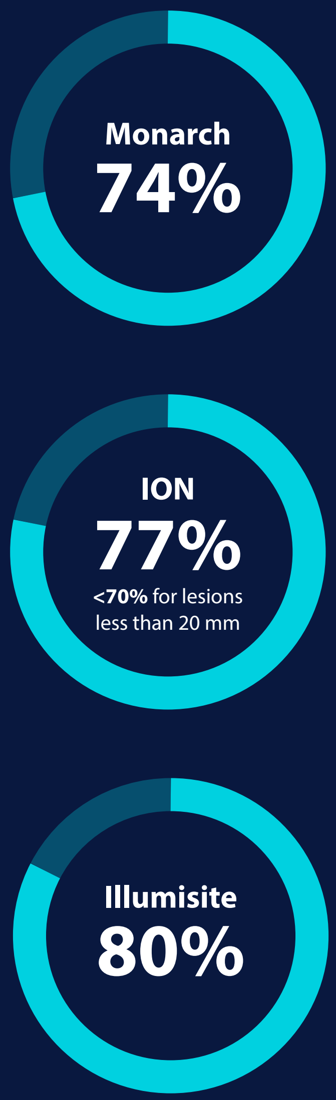
Legacy robotic bronchoscopy platforms and their **disappointing results**

Robotic assisted bronchoscopy (RAB) platforms have gained significant interest for their potential to improve diagnostic yield of peripheral lung nodule biopsies. Advantages of first-generation robotic platforms, ION (Intuitive, Sunnyvale, CA) and Monarch (Ethicon Johnson & Johnson, Redwood City), include enhanced maneuverability, farther reach, and increased stability of the bronchoscope as compared to conventional guided bronchoscopy.[1] Initial cadaveric studies with Monarch's ACCESS and ION's Precision-1 trials, demonstrated promising diagnostic yield of 97% and 80% in cadaveric models, respectively. [2,3]

Unfortunately, diagnostic yields for both first-generation robotic platforms were underwhelming in human studies. The BENEFIT trial using the Monarch robot demonstrated a diagnostic yield of 74%.[4] Low et al compared ION to Illumisite (Medtronic, Minneapolis, MN) digital tomosynthesis platform. The diagnostic yield was 77% (110 /143 lesions) for ION and 80% (158/197 lesions) for Medtronic's Illumisite. Both platforms were comparable with no significant difference in diagnostic yield.[5] Deckel's post-market study of the ION robot demonstrated a diagnostic yield of <70% in lesions less than 20 mm.[6]

Both ION and Monarch are RAB systems and are prone to CT-to-body divergence (CT2BD). CT2BD can lengthen the procedure, frustrate the operator, and ultimately lead to non-diagnostic procedures.

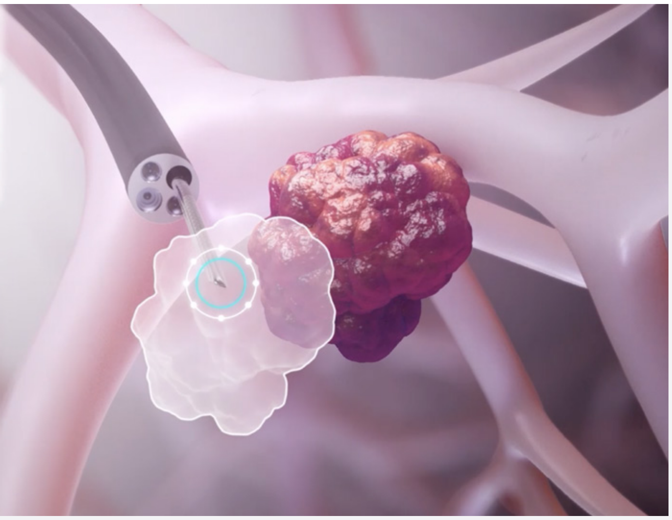
DIAGNOSTIC YIELD



CT-to-Body Divergence Solution with the **Galaxy System**™

To overcome CT2BD, many bronchoscopists are supplementing first generation RAB platforms with advanced imaging devices such as digital tomosynthesis (DT), mobile two-dimensional/three-dimension (2D/3D) cone beam CT (CBCT) systems and fixed CBCT systems with CT augmented fluoroscopy (CT AF). Unfortunately, CBCT solutions are very expensive and not readily available in most bronchoscopy suites.

Noah Medical's Galaxy System™, the next generation in RAB, is a fully image integrated robotic assisted bronchoscopy (iiRAB) solution, with digital tomosynthesis and augmented fluoroscopy, and is designed to be compatible with a variety of C-arms, including standard portable C-arms and cone beam CT systems. This capability allows for two key advantages –

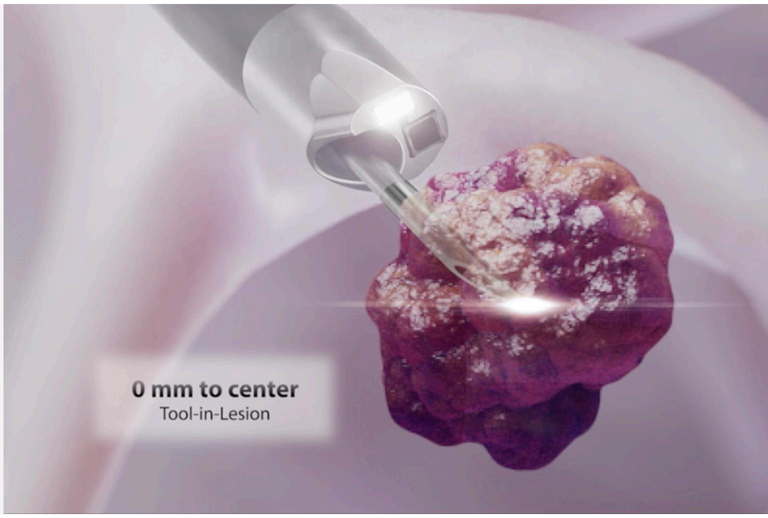


1) Correct for CT-to-Body Divergence

The C-arm is isocentered over the target lesion and a 60-degree fluoroscopic sweep is performed to capture multiplanar images. The images undergo processing through Galaxy's propriety tomosynthesis algorithm which updates the lesion location and activates Galaxy's augmented fluoroscopy feature. This allows a real-time visual of the lesion under live fluoroscopy. The updated lesion with augmented fluoro enables the bronchoscopist to make adjustments to position the scope more accurately.

2) Confirm Tool-in-Lesion

A second tomosynthesis sweep can be performed after inserting a tool (typically a needle) into the lesion. By selecting the lesion and the tip of the needle, a feature called StrikePoint™ is enabled. StrikePoint measures the distance of the needle tip from the center of the selected lesion to provide a quantitative measure of centerstrike and helps to achieve tool-in-lesion confirmation



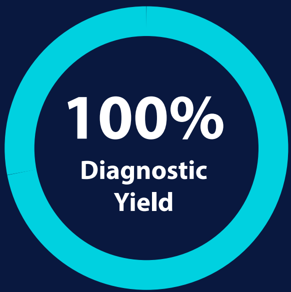
Review of the **Galaxy Data**

“Tool-in-lesion” Accuracy of Galaxy System
A Robotic Electromagnetic Navigation Bronchoscopy with Integrated Tool-in-lesion-Tomosynthesis Technology”

THE MATCH STUDY[7]

J Bronchol Intervent Pulmonol. April 2023; Bhadra, Krish MD; Rickman, Otis B. DO; Mahajan, Amit K. MD; Hogarth, Douglas Kyle MD

In an animal model, the MATCH trial demonstrated 95% tool in lesion confirmation, 5% tool-touch-lesion and 100% diagnostic yield.[7]



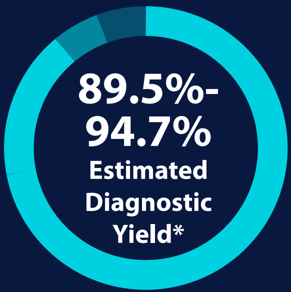
*5% tool-touch-lesion

First-in-Human Clinical Trial of the Galaxy System
Robotic Electromagnetic Navigation Bronchoscopy with Integrated Tool-in-lesion-Tomosynthesis Technology

THE FRONTIER STUDY[8]

Tajalli Saghaie, Jonathan Williamson, Martin Philips, Dona Kafili, Sarika Sundar, Kyle Hogarth and Alvin Ing

The Frontier trial, first-in-human clinical trial, with 18 patients and 19 nodules, demonstrated a 100% successful navigation, 100% tool in lesion confirmation, and between 89.5% to 94.7% diagnostic yield in the study population.[8]



*pending patient follow-up

iiRAB Business Model

Understanding the business of bronchoscopy is vital when approaching the C-suite to purchase a robotic bronchoscopy platform.

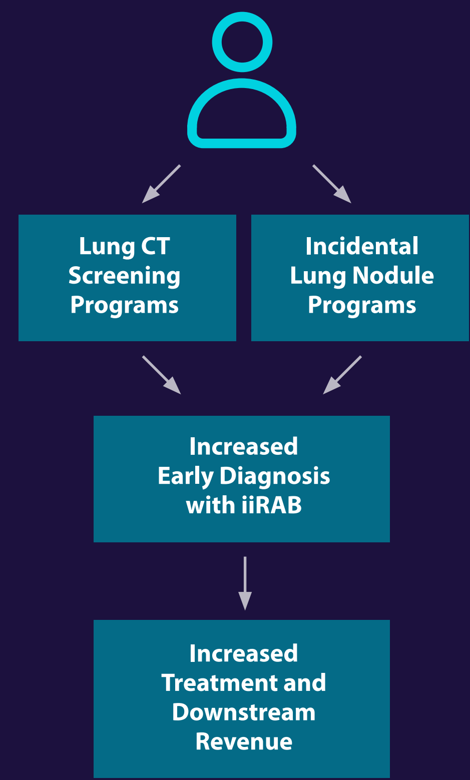
1) Lung nodule identification

There are two programs that are needed for a robust lung nodule program – lung CT screening programs and incidental lung nodule programs (IPN).

Lung CT screening programs: The United States Preventative Task Force has recommended that high risk patients undergo Lung CT Screening. Adults aged 50 to 80 years who have a 20 pack-year smoking history and currently smoke or have quit within the past 15 years are eligible for annual low-dose computed tomography (CT).

CT screenings are non-invasive and can help save more lives per screening than mammography, PSA testing and colonoscopies all combined.[9]

Incidental Lung Nodule Programs (IPN): IPN programs account for the bulk of nodule detection. Radiology tagging with Fleischner guidelines is a helpful way to remind the ordering physician the importance of follow up, further imaging and consideration of biopsy. A lung nodule clinic, nurse navigators, key role players such as radiology, pathology, oncology specialists and thoracic surgeons and administrators are important to include as you develop your IPN program. Electronic Medical Record systems for lung nodule tracking may be beneficial.



Downstream revenue

~$24,000

per patient[10]

As your program grows, mobile CT lung screening buses and electronic medical programs for lung nodule management can be considered.

2) Procedural coding and reimbursement

Reimbursement for peripheral navigational bronchoscopy is increasing for bronchoscopy. It is paramount to ensure correct billing and coding for both the physician and institution. Failure to code properly can lead to lost revenue and reduce the impact of your business case. See Tables 1 and 2 for physician coding and institutional reimbursement.

3) Downstream revenue

Downstream revenue includes subsequent imaging, office visits, chemotherapy, radiation and thoracic surgery. Studies on the economics of new technology for lung biopsy indicate that each new patient can generate on average ~$24,000 per patient.[10]

Why **Galaxy**

1) Increased procedural volume

The Tool-in-lesion confirmation, along with augmented fluoroscopy capability, allows physicians to more confidently biopsy smaller lung nodules. The increased number of navigational bronchoscopies may lead to increased overall contribution margin.

2) Avoid significant capital expenditure to correct for CT-to-body divergence

The Galaxy system integrates with most existing fluoroscopy C-arms to enable tomosynthesis capability, which helps correct for CT-to-Body Divergence. Other robotic platforms, to make this same correction, require either an additional navigation system or CBCT imaging system – leading to significantly higher capital expenditure.

3) Stage shift and downstream revenue

The biopsy of smaller lung nodules results in increased diagnosis of early-stage lung cancer. Patients with stage 1 lung cancer, the earliest form of lung cancer, typically undergo high contribution margin procedures such as thoracic surgical resection or stereotactic body radiation therapy (SBRT).

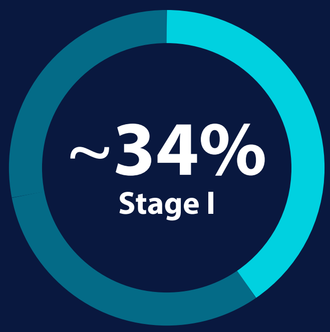
Per a study analyzing Small Cell Lung Cancer data from the SEER Database, between 20% to 34% of patients with Stage I and Stage II cancers received surgical treatment, while just ~3% of patients with Stage III received surgery.[10]

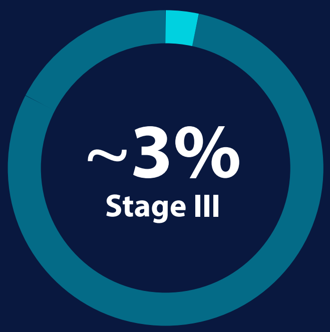
Thoracic surgery could generate ~$7,500 in revenue per procedure.[11] Additional revenue could be realized through other adjunct therapies (chemotherapy, radiotherapy), follow-up imaging and physician consults.

4) Halo effect

Providers are more likely to refer to a hospital that has innovative technology such as the Galaxy System. The halo effect strengthens the overall image of the hospital and reputation. This halo effect creates a competitive advantage and increases the number of referrals. These referrals may not be limited to lung nodules. They may include other complex pulmonary conditions.

Percentage of patients with Stages I - III cancers that received surgical treatment[10]





5) Less costly complications

Navigational bronchoscopy reduces expensive complications compared to CT guided FNA. Bronchoscopy has a better safety profile than CT guided FNA.[12] Pneumothorax complication rates with bronchoscopic biopsy are 83% less than with CT guided TTNA.[13,14] Patients in the United States receiving non-robotic assisted biopsy undergo 1.7 biopsy attempts for a diagnosis.[15] Galaxy's ability to provide visual tool-in-lesion confirmation may improve the negative predictive value. Patients may not need to undergo multiple biopsies.

83%

decrease in pneumothorax rates vs percutaneous biopsy[13, 14]

6) Avoid the hidden costs of sterile processing associated with reusable scopes

Reusable scopes come with several hidden disadvantages, such as sterilization costs, cross contamination complications, negative environmental impact, hands-on staff time, need for sterilization equipment such as the Steris Endo 1 and "critical" water etc.,

1) Reprocessing one flexible endoscope requires approximately 76 mins of hands-on staff time and incurs a cost of

$114 to **$280**[16]

2) Reusable bronchoscopes are estimated to result in 2.8%[17] infection rate, with an average estimated cost of treating infection at

~$12,000[18]

3) Reusable bronchoscopes can have substantially higher negative environmental impact than single use bronchoscopes.[19]

90% more

energy required

A Disposable scope can offer several key advantages –

1) Avoid repair costs or hassle of dealing with replacements.
2) Optimize workflow.
3) Mitigate cross-contamination risk.
4) Reduce waste – reprocessing produces more solid waste.

Speaking with Your Hospital CEO

Remember the biopsy of small peripheral lung nodules and overcoming the challenge of CT-to-Body Divergence is the biggest problem in improving your diagnostic yield and increasing biopsy volumes and downstream revenue. Take the health care CEO into your world and explain the benefits of the Noah Galaxy Robot and how it can help you expand your thoracic oncology program.

Time to prepare for your first meeting

1) Start with an initial 5 minutes of small talk to help build a connection. Small talk topics could include weather, family, or vacations. Stay positive.
2) Do not apologize for being there.
3) Keep the discussion more conversational – Do not bring a PowerPoint or stack of paper. Less is more.
4) Elaborate your problem: the biopsy of small lung nodules, CT2BD, and how achieving higher diagnostic yields with earlier diagnosis of cancer can drive further downstream revenue. Explain how the Galaxy system can help provide confidence in accessing hard-to-reach nodules, and also avoid unnecessary and expensive additional imaging equipment.
5) Allow sufficient time for questions.
6) Do not over promise and be realistic.
7) Summarize the meeting and set a date or plan for follow up.

Insights from a first generation robotic user

1) First generation robotic bronchoscopy systems still require additional imaging support to help overcome CT2BD that can often get in the way of a successful biopsy. Learn as much as you can about the differences in the technologies. Make an informed decision and do what is right for your patients.
2) Galaxy is designed to integrate with a variety of 2D and 3D CBCT imaging systems, including 2D/3D CIOS systems, to enable tomosynthesis capability within the robotic platform.
3) Reusable scopes from first generation devices lead to costly sterilization processing that requires labor. There could also be a challenge with scope performance after multiple sterilizations – this could lead to a hassle, and possibly a cost, to secure a replacement.
4) Space in the Bronchoscopy suite and OR suite is very valuable and can be limited – first generation robotic bronchoscopy systems occupy a much larger footprint than the Galaxy System.

Bibliography

1) **Current Novel Advances in Bronchoscopy.**
Jeffrey Jiang, Stephanie H. Chang, Amie J. Kent, Travis C. Geraci, and Robert J. Cerfolio. PMID: 33304923

2) **Accuracy of a Robotic Endoscopic System in Cadaver Models with Simulated Tumor Targets: ACCESS Study**
Alexander C Chen, Nicholas J Pastis, Michael S Machuzak, Thomas R Gildea, Michael J Simoff, Colin T Gillespie, Amit K Mahajan, Scott S Oh, Gerard A Silvestri PMID: 31805570

3) **A Prospective Randomized Comparative Study of Three Guided Bronchoscopic Approaches for Investigating Pulmonary Nodules: The PRECISION-1 Study**
Lonny Yarmus, Jason Akulian, Momen Wahidi, Alex Chen, Jennifer P Steltz, Sam L Solomon, Diana Yu, Fabien Maldonado, Jose Cardenas-Garcia, Daniela Molena, Hans Lee, Anil Vachani; Interventional Pulmonary Outcomes Group (IPOG) PMID: 31678307

4) **Robotic Bronchoscopy for Peripheral Pulmonary Lesions: A Multicenter Pilot and Feasibility Study (BENEFIT)**
Alexander C Chen, Nicholas J Pastis Jr, Amit K Mahajan, Sandeep J Khandhar, Michael J Simoff, Michael S Machuzak, Joseph Cicenia, Thomas R Gildea, Gerard A Silvestri PMID: 32822675

5) **Shape-Sensing Robotic-Assisted Bronchoscopy vs Digital Tomosynthesis-Corrected Electromagnetic Navigation Bronchoscopy: A Comparative Cohort Study of Diagnostic Performance**
See-Wei Low, Robert J Lentz, Heidi Chen, James Katsis, Matthew C Aboudara, Samuel Whatley, Rafael Paez, Otis B Rickman, Fabien Maldonado

6) **Shape-Sensing Robotic-Assisted Bronchoscopy in the Diagnosis of Pulmonary Parenchymal Lesions**
Or Kalchiem-Dekel, James G Connolly, I-Hsin Lin, Bryan C Husta, Prasad S Adusumilli, Jason A Beattie, Darren J Buonocore, Joseph Dycoco, Paige Fuentes, David R Jones, Robert P Lee, Bernard J Park, Gaetano Rocco, Mohit Chawla, Matthew J Bott PMID: 34384789

7) **"Tool-in-lesion" Accuracy of Galaxy System – A Robotic Electromagnetic Navigation Bronchoscopy With Integrated Tool-in-lesion-Tomosynthesis Technology: The MATCH Study**
Krish Bhadra, MD, Otis B. Rickman, DO, Amit K. Mahajan, MD, and Douglas Kyle Hogarth, MD PMID: 37072895

8) **AABIP 2023 Abstract presentation by Dr Tajalli Saghaie (August 25th 2023) - Preliminary results of the FRONTIER STUDY: First Human Use of a New Robotic Electromagnetic Navigation Bronchoscopy with Integrated Tool-in-Lesion Tomosynthesis (TiLT) Technology (Galaxy System™) for Small Peripheral Pulmonary Nodules**

8) **U.S. Preventive Task Force. (2021). Lung cancer: screening. Retrieved from https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/lung-cancer-screening**

9) **Survival Outcomes for Patients with Surgical and Non-Surgical Treatments in Stages I-III Small-Cell Lung Cancer**
Keying Che, Hongchang Shen, Xiao Qu, Zhaofei Pang, Yuanzhu Jiang, Shaorui Liu, Xudong Yang, and Jiajun Du PMID: 29721052

10) **Understanding the economic impact of introducing a new procedure: calculating downstream revenue of endobronchial ultrasound with transbronchial needle aspiration as a model**
Pastis et al

11) **Where's the Money? Revenues associated with 3000 Lung Cancer Screens**
John Handy, Jr., Courtney Wood, Erika Rauch, Kevin Olson, Roshanthi Weerasinghe, Rachel Sanborn, Micheal Skokan

12) **Navigational bronchoscopy with biopsy versus computed tomography-guided biopsy for the diagnosis of a solitary pulmonary nodule: a cost-consequences analysis**
Christopher R Dale, David K Madtes, Vincent S Fan, Jed A Gorden, David L Veenstra PMID: 23207529

13) **Electromagnetic Navigation Bronchoscopy for Periphreal Pulmonary Lesions: One-Year Results of the Prospective, Multicenter NAVIGATE Study.**
Journal of Thoracic Oncology, Volume 14, Issue 3, 445-458 Folch, Erik E., Anciano, Carlos et al.

14) **Complication rates of CT-guided transthoracic lung biopsy:** meta-analysis. *Eur Radiol.* 2017;27(1):138–148. doi:10.1007/s00330-016-4357-8. Heerink WJ, de Bock GH, de Jonge GJ, Groen HJ, Vliegenthart R, Oudkerk M.

15) **Biopsy frequency and complications among lung cancer patients in the United States**
Yichen Zhang , Lizheng Shi , Michael J Simoff, Oliver J Wagner & James Lavin PMID: 33318758

16) **Ofstead, et al. 2017. A glimpse at the true cost of reprocessing endoscopes: Results of a pilot project. In International Journal of Healthcare Central Service Material Management.**
Available at https://www.bostonscientific.com/content/dam/bostonscientific/uro-wh/portfolio-group/LithoVue/pdfs/Sterilization-Resource-Handout.pdf

17) **A systematic review and cost effectiveness analysis of reusable vs. single-use flexible bronchoscopes**
J M Mouritsen, L Ehlers, J Kovaleva, I Ahmad, K El-Boghdadly PMID: 31701521

18) **Economic costs of respiratory tract infections in the United States**
R E Dixon PMID: 4014287

19) **Comparative Study on Environmental Impacts of Reusable and Single-Use Bronchoscopes (2018)**
Birgitte Lilholt Sørensen, Henrik Grüttner

Table. 1 Frequently Used CPT codes for Bronchoscopy

Code	Frequently Used CPT codes for Bronchoscopy
	Bronchoscopy Procedures
31623	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with brushing or protected brushings
31624	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial alveolar lavage
31628	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transbronchial lung biopsy(s), single lobe
31629	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transbronchial needle aspiration biopsy(s), trachea, main stem and/or lobar bronchus(i)
31641	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with destruction of tumor or relief of stenosis by any method other than excision (eg, laser therapy, cryotherapy)
	Multiple Procedures
+31632	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transbronchial lung biopsy(s), each additional lobe (List separately in addition to code for primary procedure) *
+31633	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transbronchial needle aspiration biopsy(s), each additional lobe (List separately in addition to code for primary procedure)
	Endobronchial Ultrasound
31652	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (eg, aspiration[s]/ biopsy[ies]), one or two mediastinal and/or hilar lymph node stations or structures
31653	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (eg, aspiration[s]/ biopsy[ies]), 3 or more mediastinal and/or hilar lymph node stations or structures
+31654	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transendoscopic endobronchial ultrasound (EBUS) during bronchoscopic diagnostic or therapeutic intervention(s) for peripheral lesion(s)
	Computer Assisted Navigation and Cone Beam Guidance
+31627	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with computer-assisted, image-guided navigation (List separately in addition to code for primary procedure[s])
77012	Computed tomography guidance for needle placement (eg, biopsy, aspiration, injection, localization device), radiological supervision and interpretation
77377	3D post-processing is performed on a separate independent workstation
	Placement of Fiducial or Dye Markers
31626	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with placement of fiducial markers, single or multiple

Reimbursement & complexity adjustments

Hospital Outpatient complexity adjustment pairings[2]

Primary CPT®[1] code	Primary short descriptor[9]	Secondary CPT®[1] code	Secondary short descriptor[9]	Complexity adjusted APC assignment[2]	Complexity adjusted CY23 OPPS rate[2]
31622	Dx bronchoscope/wash	+31627	Navigational bronchoscopy	5154	$3,334
31624	Dx bronchoscope/lavage	31624	Dx bronchoscope/lavage	5154	$3,334
31624	Dx bronchoscope/lavage	+31627	Navigational bronchoscopy	5154	$3,334
31625	Bronchoscopy w/biopsy(s)	31624	Dx bronchoscope/lavage	5154	$3,334
31625	Bronchoscopy w/biopsy(s)	+31627	Navigational bronchoscopy	5154	$3,334
31625	Bronchoscopy w/biopsy(s)	+31654	Bronch ebus ivntj perph les	5154	$3,334
31629	Bronchoscopy/needle bx each	31628	Bronchoscopy/lung bx each	5155	$6,187
31629	Bronchoscopy/needle bx each	31652	Bronch ebus sampling 1/2 node	5155	$6,187
31653	Bronch ebus sampling 3/> node	31628	Bronchoscopy/lung bx each	5155	$6,187
31653	Bronch ebus sampling 3/> node	31629	Bronchoscopy/needle bx each	5155	$6,187

Table contains CPT®[1] codes and their short descriptions

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