

Building a Robotic **Lung Biopsy Program**

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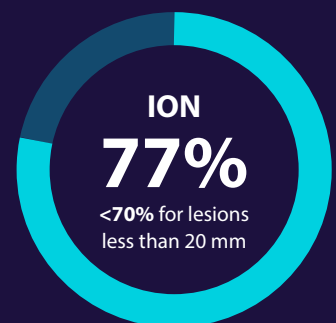
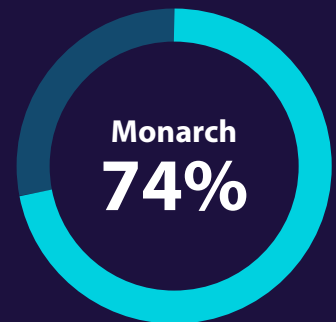
Legacy robotic bronchoscopy platforms and their **disappointing results**

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, CA), 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 the 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.

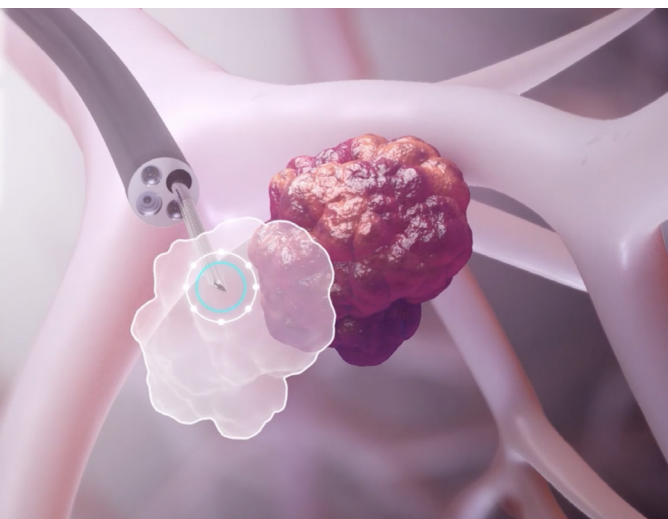
DIAGNOSTIC YIELD



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:

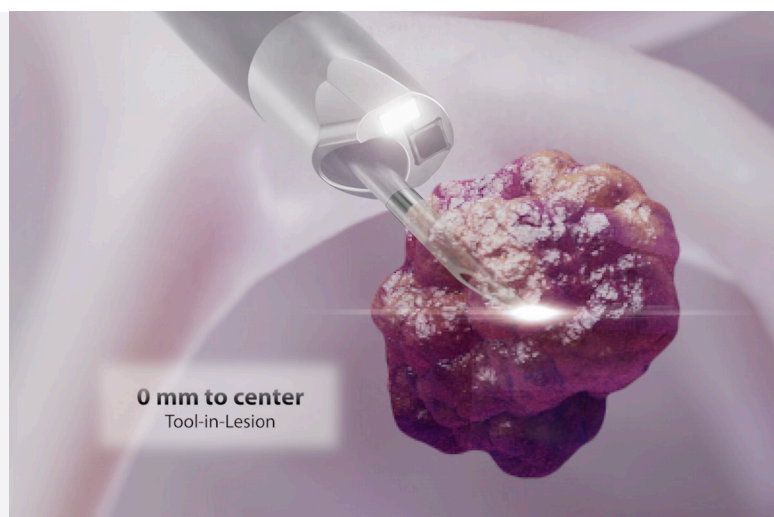


1) Correct for CT-to-body divergence

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 System's propriety tomosynthesis algorithm, which updates the lesion location and activates Galaxy System'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 System™** data

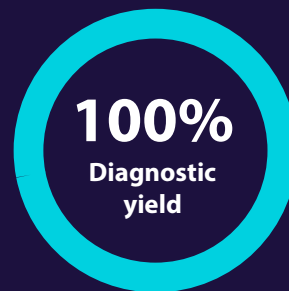
“Tool-in-Lesion” Accuracy of Galaxy System

A Robotic Electromagnetic Navigation Bronchoscopy with Integrated Tool-in-lesion-Tomosynthesis Technology

THE MATCH STUDY⁷

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

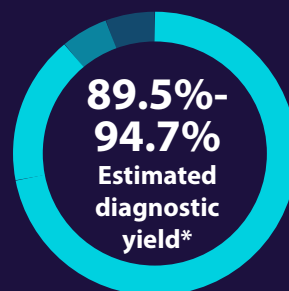
First-in-Human Clinical Trial of the Galaxy System

Robotic Electromagnetic Navigation Bronchoscopy with Integrated Tool-in-lesion-Tomosynthesis Technology

THE FRONTIER STUDY⁸

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

The FRONTIER trial, a 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.

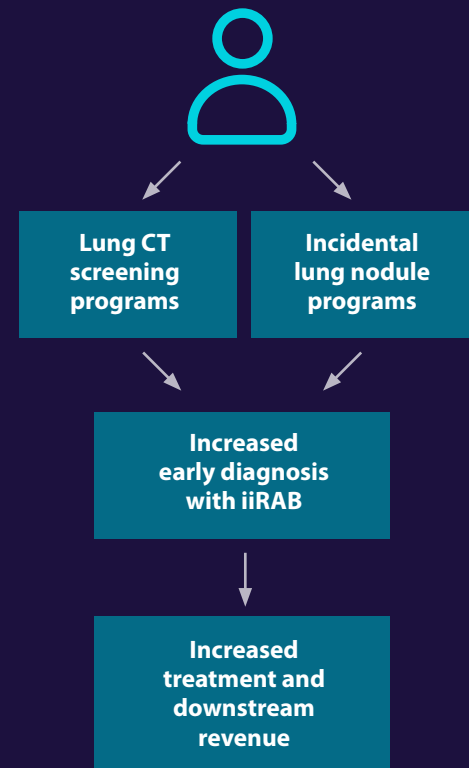
1) Lung nodule identification

There are two programs that are needed for a robust lung nodule program – lung computed tomography (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 CT screening.

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 also be beneficial.



Downstream
revenue
~\$24,000
per patient¹⁰

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 System™

Increase procedural capabilities and thereby volumes

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.

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.

Diagnose earlier and expand use of adjunct therapy and revenue

The biopsy of smaller lung nodules results in increased diagnosis of early-stage lung cancer. Patients with stage I 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).

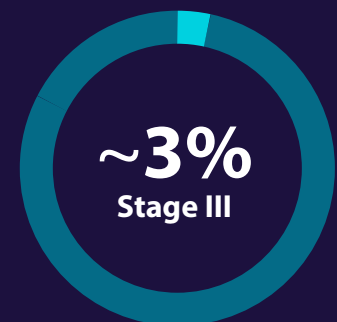
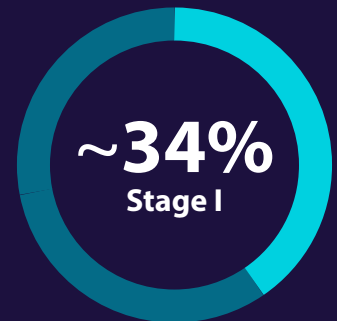
Per a study analyzing small cell lung cancer data from the Surveillance, Epidemiology, and End Results (SEER) Database, between 20% to 34% of patients with stage I and stage II cancers received surgical treatment, while just ~3% of patients with stage III received surgery.¹⁰

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.

Innovate to strengthen your reputation and expand network of care

Providers are more likely to refer to a hospital that has innovative technology such as the Galaxy System. This halo effect strengthens the overall image and reputation of the hospital and creates a competitive advantage that can increase 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 treatment¹⁰



Reduce the incidence and cost of complications

Navigational bronchoscopy reduces expensive complications and has a better safety profile when compared to CT-guided fine needle aspiration (FNA).¹² Pneumothorax complication rates with bronchoscopic biopsy are 83% less than with CT-guided transthoracic needle aspiration (TTNA).^{13,14} Patients in the United States receiving non-robotic-assisted biopsy undergo 1.7 biopsy attempts for a diagnosis.¹⁵ Galaxy System's ability to provide visual Tool-in-Lesion Confirmation may improve the negative predictive value and eliminate the need for patients to undergo multiple biopsies.

83%

decrease in pneumothorax rates
vs percutaneous biopsy^{13, 14}

Eliminate reprocessing costs and increase operational efficiency

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

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

\$114 to \$280¹⁶

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

~\$12,000¹⁸

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:

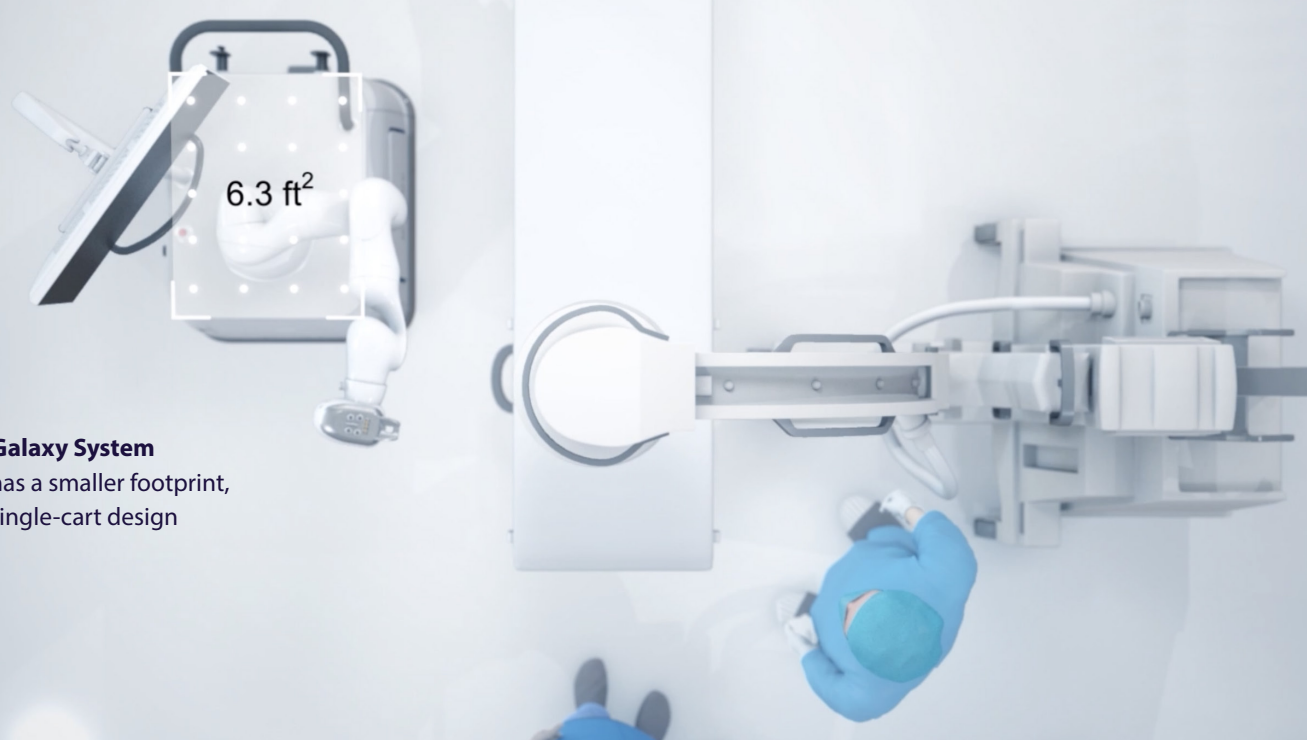
- Avoid repair costs or hassle of dealing with replacements.
- Optimize workflow.
- Mitigate cross-contamination risk.
- Reduce waste that comes from reprocessing.



Insights from a first-generation robotic user

Capturing the biopsy of small peripheral lung nodules while overcoming the challenge of CT-to-body divergence has historically been the biggest problem in improving your diagnostic yield and volume of biopsies in a lung nodule program. Bring the healthcare executives into your world and share how the Galaxy System™ can help expand your thoracic oncology program.

- 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 System™ is designed to integrate with a variety of 2D Fluoroscopy C-arm and 3D CBCT imaging 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 – leading 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 require a much larger footprint than the Galaxy System.



Galaxy System
has a smaller footprint,
single-cart design

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

Select CY 2024 hospital outpatient complexity adjustment pairings²⁰

Primary CPT® code	Primary short descriptor	Secondary CPT® code	Secondary short descriptor	Complexity adjusted APC assignment	Complexity adjusted APC payment rate
31622	Dx bronchoscope/wash	+31627	Navigational bronchoscopy	5154	\$3,572
31624	Dx bronchoscope/lavage	31624	Dx bronchoscope/lavage	5154	\$3,572
31624	Dx bronchoscope/lavage	+31627	Navigational bronchoscopy	5154	\$3,572
31625	Bronchoscopy w/biopsy(s)	31624	Dx bronchoscope/lavage	5154	\$3,572
31625	Bronchoscopy w/biopsy(s)	+31627	Navigational bronchoscopy	5154	\$3,572
31625	Bronchoscopy w/biopsy(s)	+31654	Bronch ebus ivntj perph les	5154	\$3,572
31629	Bronchoscopy/needle bx each	31628	Bronchoscopy/lung bx each	5155	\$6,528
31629	Bronchoscopy/needle bx each	31652	Bronch ebus sampling 1/2 node	5155	\$6,528
31653	Bronch ebus sampling 3/> node	31628	Bronchoscopy/lung bx each	5155	\$6,528
31653	Bronch ebus sampling 3/> node	31629	Bronchoscopy/needle bx each	5155	\$6,528

Table contains CPT®¹ codes and their short descriptions



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