Molina Clinical Policy
Image-Guided Bronchoscopy Evaluation of Pulmonary Lesions
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DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Lung cancer is the leading cause of cancer-related deaths in the United States, and pathological findings remain the benchmark for diagnosis. Biopsy via bronchoscopy is a minimally invasive alternative to needle biopsy with a generally lower risk profile by avoiding puncture of the chest wall. Image-guided bronchoscopy consists of several techniques, such as virtual navigation bronchoscopy, electromagnetic navigation bronchoscopy, and robotic-assisted bronchoscopy. The primary goal of using image-guided bronchoscopy is to serve as an additional tool in the biopsy of peripheral pulmonary lesions as they are difficult to reach and biopsy using conventional flexible bronchoscopy alone (Ishida et al. 2011; Hayes; 2018; Shepherd 2025).

Virtual bronchoscopy (VB) is a non-invasive method of generating 3D images of the tracheobronchial tree that extend to the seventh generation of airways. The 3D images are reconstructed using a computed tomography (CT) chest scan with specific protocols for imaging. A primary benefit of VB is that it may provide important information about the condition of the distal airway beyond an obstruction that a flexible bronchoscope cannot pass. In addition, it can provide information about the location of other structures, such as lymph nodes or blood vessels, that surround the airways. While VB is a non-invasive imaging tool, it lacks the ability to sample lesions and is therefore often combined with or used prior to navigational bronchoscopy, which involves the use of a virtual or electromagnetic navigational system to guide an instrument (e.g., flexible or ultrathin bronchoscope) through the airways to a target lesion (Islam 2025; Shepherd 2025).

Virtual navigation bronchoscopy (VNB) is a procedure that utilizes VB imaging to guide a bronchoscope to a target peripheral lesion in the lung. First, CT scan images are obtained and a virtual pathway to the target lesion is created, which is typically performed on the same day or a few days ahead of the planned biopsy procedure. During the procedure, an ultrathin bronchoscope is inserted and advanced through the airways following virtual guidance by matching the airway from the 3D imaging with the real-time images obtained through the bronchoscope (Shepherd 2025).

Electromagnetic navigation bronchoscopy (ENB) is similar to VNB in that 3D images of the tracheobronchial tree are created using VB. However, ENB systems also use an electromagnetic field board or generator that allows for real-time tracking during the guidance and biopsy phases of the procedure. A catheter with a sensor probe is inserted into the working channel of a regular flexible bronchoscope and guided through the distal airways beyond the third generation of airways. ENB systems are limited in that they cannot directly visualize the lesion. Due to this, radial probe endobronchial ultrasound (EBUS) is often used in conjunction with ENB to verify the lesion location. ENB systems allow the operator to plan a path while also suggesting an alternative path (Shepherd 2025; Islam 2025).

Robotic-assisted bronchoscopy (RAB) is a newer image-guided bronchoscopy technique that involves using a robotic platform, similar to those used during robotic surgeries, to control a catheter as it is navigated through the airways without requiring the operator to directly touch the bronchoscope. The catheter used for navigation is smaller than a bronchoscope, allowing for navigation to the much smaller airways that are not normally accessible by a traditional bronchoscope. Another benefit of using a RAB system is the ability to lock the catheter in place once the lesion is reached. There are currently two RAB systems available with both requiring thin-slice CT scans (similar to

VNB) and one system utilizing an electromagnetic field similar to ENB. Two important limitations for the currently available RAB systems include a lack of "tactile feedback to the operator [for both systems] and one system does not offer actual visualization at the time of biopsy" (Shepherd 2025). Secondary confirmation of correct placement can also be confirmed using radial probe EBUS, fluoroscopy, and cone-beam CT (Islam 2025).

Regulatory Status

The FDA regulates image-guided bronchoscopy systems as Class II devices under the 510(k) premarket notification process. In 2019, the FDA cleared the ILLUMISITE Platform (manufactured by Covidien LLC), an ENB system that replaces its predicate device, the superDimension Navigation System, originally cleared in 2004. The device is indicated for displaying images of the tracheobronchial tree to aid physicians in guiding endoscopic tools in the pulmonary track and to enable marker placement within soft lung tissue. It does not make a diagnosis, is not an endoscopic tool, and is not for pediatric use. The ig4 Image Guided System, an ENB system originally FDA cleared in 2009 and which had several subsequent models, was recalled in 2023 by its manufacturer, Olympus Corporation of the Americas. Other notable FDA clearances include the LungPoint System in 2009, the bf-NAVI System in 2010, and the LungVision System in 2017, all of which are VBN systems. Additionally, the Monarch Endoscopy Platform and the Ion Endoluminal System are RAB devices that were FDA cleared in 2018 and 2019 respectively. More information about FDA cleared ENB, VNB, and RAB devices can be found in the FDA 510(k) premarket notification database under product codes JAK, LLZ, and EOQ.

COVERAGE POLICY

Electromagnetic navigational bronchoscopy (ENB)* may be **considered medically necessary** for Members who require a pathological diagnosis of pulmonary lesions when ONE of the following are met:

1. Pulmonary lesions are inaccessible by standard bronchoscopy approaches
2. Pulmonary lesions are inaccessible by a transthoracic biopsy approach

*Note: Endobronchial Ultrasound (EBUS) may be performed in conjunction with ENB to diagnose and stage lung cancer

Virtual navigation bronchoscopy (VNB) and robotic-assisted bronchoscopy (RAB) for the evaluation of pulmonary lesions are considered **investigational, experimental, and unproven** due to insufficient evidence published in the peer-reviewed medical literature to establish long-term safety, efficacy, and effect on net health outcomes

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

Virtual Navigation Bronchoscopy

Randomized Controlled Trials

Asano et al. (2013) conducted a prospective, multicenter, randomized controlled trial (RCT) to investigate whether virtual bronchoscopic navigation (VBN) combined with ultrathin bronchoscopy improves the diagnostic yield for peripheral pulmonary lesions. The study enrolled 350 adult patients with peripheral pulmonary lesions ≤ 30 mm in diameter and suspected to be malignant but not yet pathologically confirmed. After exclusions, 334 patients were analyzed (167 in the VBN-assisted group and 167 in the non-VBN-assisted group). All procedures used a 2.8 mm ultrathin bronchoscope, with the VBN group guided by virtual images generated from preprocedural CT scans, while the control group relied only on axial CT images only. The primary outcome, overall diagnostic yield, was not significantly different between the two groups (67.1% in the VBN group vs. 59.9% in the non-assisted group; p = 0.173). Subgroup analyses revealed statistically significant diagnostic yield improvements with VBN for specific lesion categories: right upper lobe (81.3% vs. 53.2%; p = 0.004), peripheral third of the lung (64.7% vs. 52.1%; p = 0.047),

and lesions invisible on posterior-anterior radiographs (63.2% vs. 40.5%; p = 0.043). For lesions ≤ 20 mm, the VBN-assisted group demonstrated similarly improved yields in these subgroups. Secondary outcomes included technical metrics and procedural efficiency. The VBN group achieved higher rates of fluoroscopic confirmation that the biopsy instrument reached the lesion (92.8% vs. 83.8%; p = 0.011), reduced time to initial sampling (median 6.4 vs. 6.8 minutes; p = 0.021), and shorter fluoroscopy time before sampling (1.2 vs. 2.2 minutes; p < 0.001). Despite these procedural advantages, diagnostic yield per sampling modality did not significantly differ between groups. Adverse events were rare and not significantly different between groups. The study noted sources of potential bias and limitations, such as reliance on fluoroscopy, which may misrepresent instrument position due to two-dimensional imaging, and variability among bronchoscopic system and specimen handling techniques which could influence generalizability. The authors concluded VBN-assisted ultrathin bronchoscopy does not significantly improve overall diagnostic yield for peripheral pulmonary lesions, but improves yield for lesions in certain subcategories, particularly the right upper lobe, invisible, and peripheral third lesions.

Systematic Reviews and Meta-Analyses

Giri et al. (2021) conducted a systematic review and meta-analysis of six RCTs to evaluate the diagnostic yield and safety of virtual bronchoscopic navigation assisted (VBNA) versus non-virtual bronchoscopic navigation-assisted (NVBNA) bronchoscopy for the diagnosis of peripheral pulmonary lesions (PPLs). The review included a total of 1,626 patients, evenly split with 813 in the VBNA group and 813 in the NVBNA group. Primary outcomes assessed were total diagnostic yield and total examination time. Secondary outcomes included complication rates and diagnostic yield stratified by lesion characteristics. Pooled analysis found no statistically significant difference in the overall diagnostic yield between VBNA (74.17%) and NVBNA (69.51%), with a risk ratio of 1.07 (95% CI: 0.98-1.17; p = 0.13). The VBNA group had a shorter total examination time by approximately four minutes (MD = -3.94 minutes, 95% CI: -6.57 to -1.36; p = 0.003). Subgroup analysis found VBNA had superior diagnostic yield than NVBNA for PPLs ≤ 20 mm in diameter (RR = 1.18, 95% CI: 1.05-1.32; p = 0.005), but no difference was found for lesions > 20 mm (RR 1.01, 95% CI 0.96-1.06). Additionally, no significant differences in diagnostic yield were observed when stratified by lesion nature (malignant vs. benign), location within the lung lobe, distance from the hilum, or with the presence or absence of a bronchus sign. Complication rates between groups were similar (RR = 0.84, 95% CI: 0.42-1.67), with pneumothorax and hemorrhage being the most common adverse events. The authors concluded that VBNA does not improve the overall diagnostic yield compared with NVBNA bronchoscopy for PPLs but may have better performance with small lesions (≤ 20 mm) and may yield a shorter total examination time.

Shen et al. (2021), in a systematic review and meta-analysis, found that diagnostic yield was similar in VNB-assisted and non-VNB-assisted groups. A sub-analysis of data found that the diagnostic yield was higher in the VNB-assisted group when peripheral pulmonary lesion size was ≤ 20 mm. It was also noted that the total examination time was significantly shorter in the VNB-assisted group despite similar diagnostic yields. Other factors noted to impact diagnostic yield were related to VNB software utilized for reconstructing the airways.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Hiddinga et al. (2023) reported on the first cohort of the NAVIGATOR single-center, prospective, observational cohort study. The goal of the NAVIGATOR study is “to evaluate the performance of [VNB] to obtain a diagnosis of [solitary pulmonary nodules] in a real-world clinical setting.” A total of 35 patients underwent a VNB procedure for pulmonary nodules “that were not otherwise accessible or for which other diagnostic procedures were considered less successful or less safe.” Inclusion criteria included age > 18 years with a pulmonary nodule or nodules with a diameter > 6 mm and located > 5 mm from the parietal pleura and within the parenchymal tissue. Nodules also had to be considered accessible by VNB. Exclusion criteria included any contraindication to a bronchoscopic procedure, inability to stop anticoagulant or antiplatelet medications, pregnant or breastfeeding women, moderate to severe pulmonary fibrosis, and severe emphysema with bullae > 5 cm in the vicinity of the target nodule or tunnel. All eligible patients received a high-resolution computed tomography scan before undergoing the VNB. Results showed a median age of 68 years (range 45-80 years) with 18 male patients and 17 female patients. Approximately 15 patients underwent VNB for a pulmonary nodule without a history of solid malignancy, 13 had a history of solid malignancy other than lung cancer, and 7 were being considered for a relapse or progression of prior lung cancer. A total of 13 patients underwent a diagnostic procedure before undergoing a VNB (n = 9 diagnostic bronchoscopy; n = 2 EBUS with fine needle aspiration; n = 1 endoscopic ultrasound with fine needle aspiration; n = 3 computed tomography-guided transthoracic biopsy; n = 1 thoracoscopy). In terms of pulmonary nodule morphology, 33 were solid, one was subsolid, and one was ground glass opacity. Approximately 12 pulmonary nodules were ≤ 20 mm in diameter and 23 were > 20 mm in diameter and the median nodule size was 25 mm (range 10-57 mm). A visible bronchus sign was present in 22 nodules. The overall

diagnostic yield was 77% with yield being "dependent on [pulmonary nodule] size and chosen path, with highest yield in lesions with an airway path on [computed tomography] imaging 89% (15/18 lesions), and 78% in [pulmonary nodules] with a diameter > 20 mm (18/23 lesions)." Of note, median diagnostic yield for nodules with a diameter ≤ 20 mm was only 37% and those with a tunnel path was 62%. A diagnosis was obtained in 27 cases with 22 of those being malignant and five being benign. Adverse events occurred in a total of 10 patients with hemorrhage occurring in nine patients and one case of self-limiting subcutaneous emphysema in the neck region three days after the VNB procedure. Of those that experienced hemorrhage, only two experienced grade 3 hemorrhage that required additional bronchoscopic hemostasis. Researchers noted that "the performance of [the] first cohort of VNB procedures was comparable to other studies." Researchers plan to continue the study with additional patients to make the data more robust.

Giri et al. (2022) completed a review of 6 RCTs comparing VNB-assisted to non-VNB-assisted and other forms of guided bronchoscopy. One RCT included in the review found no significant difference in diagnostic yield between VNB-assisted and non-VNB-assisted groups. Another RCT compared VNB-assisted to x-ray fluoroscopy-assisted groups and found no significant difference in diagnostic yield. Another RCT of 1,010 participants compared VNB-assisted to other forms of guided bronchoscopy. It was noted that VNB combined with endobronchial ultrasound (EBUS) produced higher diagnostic yields. However, it was also noted that there was no significant difference in diagnostic yield between VNB combined with EBUS and standard EBUS. Overall data showed a higher diagnostic yield when peripheral pulmonary lesion size was > 20 mm.

Electromagnetic Navigation Bronchoscopy

Randomized Controlled Trials

Bondue et al. (2023) conducted a single-center, prospective RCT to compare the diagnostic yield of electromagnetic navigation bronchoscopy (ENB) with cone beam computed tomography (CBCT) versus standard x-ray fluoroscopy in traditional endoscopy suite. Eligible participants were adults with pulmonary nodules ≤ 30 mm in diameter requiring biopsy, with 49 patients randomized into two separate groups. Both groups underwent ENB with fluoroscopic and radial endobronchial ultrasound (rEBUS) guidance, followed by six trans-bronchial biopsies and one trans-bronchial lung cryobiopsy unless deemed unnecessary. The CBCT-guided ENB procedure demonstrated a significantly higher diagnostic yield (80%) compared to those performed in a standard endoscopy suite (42%) (p = 0.023). Adverse events were minimal and similar between three groups, with pneumothorax occurring in three patients (6%) overall. All bleeding events were either mild or moderate. The authors concluded that ENB procedures for small pulmonary nodules (< 2 mm) performed under CBCT guidance significantly improve diagnostic yield and accuracy compared to those performed under standard fluoroscopic guidance. The study was registered with ClinicalTrials.gov (NCT05257382).

Zheng et al. (2022) conducted a prospective, multicenter, RCT to evaluate the diagnostic efficacy and safety of a novel ENB system used in conjunction with endobronchial ultrasound and a guide sheath (EBUS-GS) versus EBUS-GS for diagnosing peripheral pulmonary nodules (PPNs). A total of 400 participants were enrolled, with 385 included in the final analysis. Participants were adults with PPNs suspicious for malignancy between 8 mm and 30 mm in diameter, with lesions located beyond the segmental bronchi and not visible through standard bronchoscopy. The primary outcome was diagnostic yield, defined as the proportion of patients in whom bronchoscopy yielded a definitive diagnosis that matched the final clinical or surgical diagnosis. Diagnostic yield was significantly higher in the ENB-EBUS-GS group at 82.9% (95% CI: 77.6-88.2%) compared to 73.4% (95% CI: 67.2-79.7%) in the EBUS-GS only group, with an adjusted difference of 9.0% (95% CI: 2.3-15.8%). Diagnostic yield was higher for malignant lesions (90.3% vs. 78.7%) and for nodules with a bronchus sign leading to the lesion on CT. ENB-EBUS-GS required significantly less time to locate lesions (213.2 ± 145.6 seconds) than the EBUS-GS group (264.8 ± 189.5 seconds; p = 0.003). However, there was no statistically significant difference in the total procedure time between groups. Adverse events were comparable between groups, with moderate intraoperative hemorrhage occurring in 3.6% of patients in the ENB-EBUS-GS group and 3.1% in the EBUS-GS group. No patients required additional intervention. Multivariate analysis identified lesion nature (malignant vs. benign), presence of a bronchus sign, type of anesthesia, and group assignment as significant factors influencing diagnostic success. The authors concluded that the addition of the novel ENB system to EBUS-GS significantly improves the diagnostic yield for PPNs without increasing complication rates. The RCT was registered with ClinicalTrials.gov (NCT03569306).

Systematic Reviews and Meta-Analyses

Folch et al. (2020) conducted a systematic review and meta-analysis to evaluate the diagnostic performance and safety of ENB for PPLs suspected of lung cancer. The review included 40 studies with a total of 3,342 participants.

Outcomes included the sensitivity of ENB for detecting malignancy, adequacy of tissue samples collected, and procedure related complications. The pooled sensitivity of ENB for diagnosing malignancy was 77% (95% CI: 72-82%), with high heterogeneity (I^2 = 80.6%). Specificity was 100% (95% CI: 99-100%; I^2 = 0%), and overall diagnostic accuracy was found to be excellent. ENB was also successful in obtaining adequate tissue samples for ancillary testing in 90.9% of cases (95% CI: 84.8%-96.9%; I^2 = 80.7%). The risk of pneumothorax was low at 2.0% (95% CI: 1.0-3.0%; I^2 = 45.2%). The authors concluded that ENB is very safe and has good sensitivity for diagnosing malignancy in patients with PPLs. However, the generalizability of the results is limited due to high heterogeneity and predominant use of a single device platform (superDimension navigation system) across most studies.

McGuire et al. (2020) conducted a systematic review and meta-analysis to compare the diagnostic accuracy, sensitivity for malignancy, and safety profiles of rEBUS and ENB in sampling PPLs identified by chest CT and suspicious for early-stage lung cancer. The review included a total of 41 original studies, for a total of 3204 patients and 2988 lung nodules (2102 sampled using rEBUS and 886 using ENB. The pooled sensitivity for detecting cancer was 70.7% (95% CI: 67.2-74.0), with nearly identical results for rEBUS at 70.5% (95% CI: 66.1-74.8) and ENB at 70.7% (95% CI: 64.7-76.8). Pooled overall diagnostic accuracy was 74.2% (95% CI: 71.0-77.3), with again, similar results for rEBUS at 72.4% (95% CI: 68.7-76.1) and ENB at 76.4% (95% CI: 70.8-82.0). Both modalities had comparative safety profiles with < 2% complication rates. The authors concluded that both rEBUS and ENB have a high proportion of successful PPL localization and have similar sensitivity for malignancy and accuracy.

Qian et al. (2020) completed a meta-analysis to compare the diagnostic yield and accuracy of ENB versus VNB for pulmonary nodules. The meta-analysis included 32 studies (16 each for ENB and VNB) with a total of 1981 patients. The meta-analysis revealed that ENB had an advantage over VNB in terms of specificity (0.81 vs 0.65). There were no differences noted between sensitivity (0.80 vs 0.80). It was noted that ENB had a higher detection ability with larger lesions. Limitations that were noted in the meta-analysis were the lack of RCTs comparing ENB to VNB.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence
Kim et al. (2023) completed a retrospective analysis to determine the diagnostic accuracy and safety of ENB with transthoracic needle biopsy. A total of 32 patients were enrolled at a single center in South Korea. Inclusion criteria included adults aged ≥ 18 years with a peripheral pulmonary lesion ≥ 10mm that was “accessible by an anterior or lateral chest percutaneous approach.” The Veran SPiNperc System was used for all procedures. Bronchoscopy instruments (e.g., introducer needle, biopsy needle) were the same size for every procedure. Outcomes measured included the mean size of pulmonary lesions, the median distance from the pleura, the diagnostic accuracy, pathological outcomes, and adverse events. The introducer needle was passed only once in all cases. Mean pulmonary lesion size was 36.9±17.4mm with six patients having a lesion 10-20mm in size, six patients having a lesion 21-30mm in size, and 20 patients having a lesion > 30mm in size. The median distance from the pleura was 15.5mm with the right upper and left lower lobes being the most prevalent locations of lesions. A total of 14 patients were diagnosed with a malignant lesion (adenocarcinoma = 12, squamous cell carcinoma = 1, small cell lung cancer = 1). Eighteen of the cases were initially determined to be negative, but further analysis following the procedure revealed that seven of those cases were false negatives (squamous cell carcinoma = 3, adenocarcinoma = 3, metastatic carcinoma from colorectal cancer = 1). The total diagnostic accuracy was 75.0% with a diagnostic yield for lung cancer 66.7% (excluding false negatives) and 50% (including false negatives). Sensitivity was 66.7% (excluding false negative cases) with a low estimate of 56.0% and a high estimate of 66.7%. The specificity was 100% at all points (excluding false negatives and low and high estimates). The only reported adverse event was one case of hemoptysis. Researchers determined that the diagnostic accuracy and rate of adverse events demonstrated in this study were similar to other studies, adding further evidence to support the safety and efficacy of ENB.

Yutaka et al. (2022) completed a retrospective study to compare the results of ENB transbronchial lung biopsies to VNB transbronchial lung biopsies at a single institution. The study included 100 ENB samples and 50 VNB samples. Overall results showed improved diagnostic yield in ENB as compared to VNB (64.0% vs 46.0%). A positive bronchus sign was a significant factor in successful diagnostic yield. An 81.0% diagnostic yield was noted in ENB with positive bronchus sign compared to a 60.0% diagnostic yield in VNB.

Folch et al. (2019) completed the NAVIGATE study, a prospective, multicenter, cohort study evaluating ENB using the superDimension navigation system. A total of 1215 participants were enrolled at 29 participating sites between April 2015 and August 2016. Individual physician judgement was utilized in determining candidacy for an elective ENB and there were no protocol-specified restrictions for tools, imaging, or procedural technique, including completion of a

lymph node staging EBUS before, during, or after ENB. Fluoroscopy was noted to be used in 91% of cases and radial probe EBUS in 57% of cases. Approximately 1157 participants underwent lung lesion biopsy and tissue was successfully obtained in 94.4% of those participants. Follow-up post-ENB was completed at 1 month in 98.9% of participants and at 12 months in 80.3% of participants. The 12-month diagnostic yield was noted to be 73%, consistent with other published estimates of 65% to 73%.

Robotic-Assisted Bronchoscopy

Systematic Reviews and Meta-Analyses

Zhang et al. (2024) conducted a systematic review and meta-analysis to evaluate the diagnostic yield and safety of robotic assisted bronchoscopy (RAB) in the evaluation of PPLs. The review included 10 eligible studies, including 5 prospective studies and 5 retrospective studies using either the Ion or Monarch RAB platforms, for a total of 725 lesions. The pooled diagnostic yield of RAB was 80.4% (95% CI: 75.7-85.1%), with individual study yields ranging from 70.0% to 90.0%. The pooled complication rate was low at 3.0% (95% CI: 1.6-4.4%), with pneumothorax being the most common adverse event (1.8%). No deaths were reported. Subgroup analysis revealed that lesions larger than 30 mm had significantly higher diagnostic yields (92.4% vs. 79.5%, p =0.03, as did lesions with a bronchus sign (82.9% vs. 71.9%, p – 0.02) and those with a concentric rEBUS view (89.4% vs. 79.8%, p = 0.01). Lesions ≤ 20 mm had a yield of 78.0% (95% CI: 72.0-84.1%), which was higher than historical benchmarks for earlier guided bronchoscopy techniques. The use of cryoprobes in one study significantly improved diagnostic yield (90.0%, 95% CI: 83.2-94.7%) compared to conventional methods (79.9%, 95% CI: 75.8-82.2%, p < 0.01), suggesting cryobiopsy may be a contributing factor; however, the limited number of studies using cryoprobes and differences in study designs restrict broader conclusions. No significant differences in diagnostic yield were observed based on lesion appearance (solid vs. nonsolid), location (upper vs. non-upper lobe), robotic platform (Ion vs. Monarch), or use of cone beam CT (CBCT). Despite theoretical advantages of CBCT and new technologies for tool-in-lesion confirmation, these did not show a statistically significant effect on yield in the analysis. Two studies were found to have an unclear risk of bias for patient selection, and one study was judged to have a high risk of bias in reference standard due to reliance on imaging alone. In conclusion the authors found that RAB is both an effective and safe technique for diagnosing PPLs. However further high-quality prospective studies still need to be conducted.

Ali et al. (2023) completed a systematic review and meta-analysis "to determine the diagnostic performance and safety profile of RAB." A total of 25 studies were included with 20 studies including both diagnostic and safety analyses and 5 studies only reporting safety analyses. The included studies were a mix of prospective and retrospective studies and different RAB systems, leading to high heterogeneity (I^2 = 65.6%). A total of 1779 lesions were included in analyses across all 20 studies with a pooled diagnostic yield of 84.3%. Increased diagnostic yield was noted when lesion size was > 2 cm, there was a positive bronchus sign, and a concentric radial EBUS view was used in conjunction with RAB. Adverse event rates were comparable with pneumothorax occurring in 2.3% of cases and 1.2% of cases requiring a chest tube for treatment of pneumothorax. Significant hemorrhage occurred in 0.5% of cases. Researchers concluded that RAB can significantly [increase] the diagnostic yield of navigational bronchoscopy compared [to] conventional systems such as [ENB], but well-designed prospective studies are needed to better understand the impact of various factors…on the diagnostic yield of RAB."

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Khan et al. (2023) completed a retrospective analysis of patients that underwent a RAB at three community hospitals between January 2019 and March 2020. All procedures were performed using the Monarch Platform. Patients were included in analysis if they were ≥ 21 years of age. A total of 264 patients were included in the analysis. Primary pulmonary lesion characteristics were collected and the characteristics of one secondary lesion were collected if applicable. "Diagnostic yield was calculated at the index RAB and using 12-month follow-up data. At index, all malignant and benign (specific and non-specific) diagnoses were considered diagnostic. After 12 months, benign non-specific cases were considered diagnostic only when follow-up data corroborated the benign result. An alternative definition at index classified benign non-specific results as non-diagnostic, while an alternative 12-month definition categorized index non-diagnostic cases as diagnostic if no malignancy was diagnosed during follow-up." Results showed a median patient age of 69.5±10.5 years. Approximately 56.8% of patients were female, 11% had a history of lung cancer, and 52% had chronic obstructive pulmonary disease. Of note, 62.5% of patients had a single lesion (range 1-22 lesions) and 48.2% of "patients had a pre-procedure probability of malignancy ≥ 65%." A total of 264 primary and 48 secondary lesions were biopsied with a median lesion size of 19.3 mm. Approximately 58.9% of lesions were located in the peripheral outer third of the lung and 22% of primary lesions were subsolid. "Tissue samples were successfully obtained at the index RAB procedure in all but one case, which was classified as non-diagnostic [and] the

index RAB procedure led to a malignant diagnosis in 115 patients (43.6%)" with the most common diagnosis being adenocarcinoma (46.1%). Overall diagnostic yield at index procedure was 85.2% (range 80.9-89.5%) and at 12-months was 79.4% (range 74.4-84.3%) using the first definition of diagnostic yield. The diagnostic yield for the index procedure was 58.7% (range 52.8-64.7%) and 89.0% (range 85.1-92.8%) at 12-months using the alternative definition of diagnostic yield. A total of 20 patients had device- or procedure-related complications with the most common being pneumothorax (n= 15). Ten of the patients that developed a pneumothorax required chest tube placement. Researchers noted that the rate of pneumothorax was much higher when the RAB procedure was completed by a thoracic surgeon (15.8%) versus an interventional pulmonologist (4.0%). Bleeding occurred in four patients and all four patients required treatment to stop the bleeding. Researchers noted that this study "demonstrated a high diagnostic yield…despite representing a real-world community population with a relatively low pre-procedure probability of malignancy and where traditionally challenging lesions, such as those < 20 mm, peripherally located, and without a bronchus sign on [computed tomography] scan, were in the majority." Researchers recommended additional studies comparing diagnostic yields across bronchoscopic technologies.

Chen et al. (2021) completed a prospective, multicenter pilot and feasibility study to determine the safety and feasibility of RAB with radial probe EBUS in patients with peripheral pulmonary lesions. The primary goals of the study were to determine the localization and adverse event rates. A standard flexible bronchoscopy was performed prior to RAB with radial probe EBUS to exclude the presence of endobronchial disease and to provide topical anesthesia based on the discretion of the bronchoscopist. Peripheral pulmonary lesion size in the study ranged from 1 to 5 cm with a median size of 2.3 cm. The study initially enrolled 55 patients. However, one patient withdrew study consent and EBUS imaging was only available in 53 cases, leaving 53 cases for inclusion. Lesion localization was achieved in 96.2% of cases and diagnostic yield was approximately 74.1%. Researchers noted this is higher than the diagnostic yield of 40% to 60% in other guided bronchoscopic approaches. Adverse events occurred in 3.7% of cases which is comparable to standard bronchoscopy. Larger prospective studies are needed to confirm the results of this study.

Bronchoscopic Technique Comparisons

Kops et al. (2023) completed a systematic review and meta-analysis to determine the diagnostic yield and safety of the available types of navigation bronchoscopy. A total of 95 studies were included with a total of 10,381 patients and 10,682 lesions. Of the 95 included studies, 63 were found to have a "high risk of bias or applicability concerns in at least one domain…[with] most risk of bias…found in the 'flow and timing' for diagnostic yield (n = 47 studies)." Subgroup analysis was completed by comparing navigation type (ENM, VNB, RAB, cone beam computed tomography [CBCT], and CBCT multimodality), length of time the navigation technique had been established (recent or longer established), strictness of definition of diagnostic yield (strict, intermediate, liberal, not reported), median nodule size (< 20 mm or ≥ 20 mm), publication year (before 2012 or after 2012), and additional navigation tools in ENB (no additional tools, additional tools, or tomosynthesis guided ENB). Further explorative subgroup analysis was completed by comparing individual nodule size (< 20 mm or ≥ 20 mm) and bronchus sign (positive or negative). The overall diagnostic yield was 70.9%. Diagnostic yield for ENB was 70.3% (n = 5669, range 66.0-74.2%), VNB was 69.4% (n = 3628, range 65.3-73.2%), RAB was 76.5% (n = 558, range 68.4-82.9%), CBCT was 78.2% (n = 371, range 71.5-83.7%), and CBCT multimodality was 77.4% (n = 456, range 70.7-82.9%) (p = 0.091). Median diagnostic yield for recent navigation techniques was 77.5% (n = 1926, range 74.7-80.1%) and longer established navigation techniques was 68.8% (n = 8756, range 65.9-71.6%) (p < 0.001). The median diagnostic yield based on the strictness of the definition of diagnostic yield was 67.6% for "strict," 72.9% for "intermediate," 70.7% for "liberal," and 72.4% for "not reported" (p = 0.255). When comparing median nodule size, median diagnostic yield was 72.1% (range 67.2-76.6%) for nodules < 20 mm (n = 2843) and 70.4% (range 67.5-73.2%) for nodules ≥ 20 mm (n = 7839) (p = 0.506). These results differed when comparing individual nodule size in explorative subgroup analysis as an individual nodule size ≥ 20 mm produced a median diagnostic yield of 79.4% (n = 3744, range 76.0-82.4%) compared to a median diagnostic yield of 67.4% (n = 3499, range 63.1-71.5%) when individual nodule size was < 20 mm (p < 0.001). Based on publication year, median diagnostic yield was 73.9% (n = 1489, range 69.0-78.3%) for studies before 2012 and 70.2% (n = 9193, range 67.3-72.9%) for studies after 2012 (p = 0.254). Median diagnostic yield was improved with the use of additional navigation tools (70.9%, n = 3109, range 63.5-77.4%) and tomosynthesis-guided ENB (79.5%, n = 541, range 65.4-88.8%) compared to no additional navigation tools (64.0%, n = 1508, range 61.8-73.1%) (p = 0.154). A positive bronchus sign produced a much higher median diagnostic yield (73.7%, n = 3302, range 69.4-77.6%) compared to a negative bronchus sign (54.1%, n = 1826, range 48.5-59.6%) (p < 0.001). The overall adverse event rate was 5.6% (n = 547) with the most common adverse event being pneumothorax (n = 246) with 115 of those patients requiring intervention. Bleeding was another common adverse event and occurred in approximately 205 patients. Less common adverse events included pneumonia/infection (n = 17), respiratory insufficiency/hypoxemia (n = 31), arrhythmia (n = 2), minor

complaints such as headache or nausea (n = 37), and other (n = 8). The overall rates of adverse events were similar in all navigation techniques with a rate of 6.3% for ENB, 4.8% for VNB, 5.7% for RAB, and 4.0% for CBCT and CBCT multimodality combined. Researchers concluded that navigational bronchoscopies are safe "with the potential for high diagnostic yield, in particular using newer techniques such as [RAB], CBCT, and tomosynthesis-guided [ENB]." However, "studies showed a large amount of heterogeneity, making comparisons difficult."

Tsai et al. (2023) completed a single-center, retrospective study to compare the diagnostic performance of ENB to VNB. A total of 35 patients were included in the study with 19 undergoing ENB and 16 undergoing VNB. Inclusion criteria included "age ≥ 18 years, pulmonary lesions of unknown origin, failure to have the tumor tissue pathologically diagnosed after evaluation in an interdisciplinary setting, and willingness to undergo the novel navigation bronchoscopy by both patients and their families." Exclusion criteria included "inability to tolerate general anesthesia, presence of coagulopathies, long-term use of anticoagulants, abnormal platelet counts and function, history of airway bleeding, and incomplete medical records." Both procedures were completed according to manufacturer's instructions for each navigation system. The ENB procedures were completed without the use of fluoroscopy, radial EBUS, or other procedural techniques (e.g., cytology brushing or bronchoalveolar lavage). Mean distance to the lesion from the pleural space was 16.1±11.7mm (range 1.0-41.0mm). Approximately 32 lesions had a positive air-bronchus sign. Researchers noted that success rate was higher in the VNB group (93.8%) compared to the ENB group (78.9%). No procedure-related complications or mortality occurred. This study showed that VNB "is a clinically feasible alternative to ENB…[and] the adoption of cone-beam CT may increase the navigation success rate, irrespective of the presence of the [positive] bronchus sign." However, researchers noted that only one operator performed the VNB procedures, increasing the potential for bias due to experience.

A study (NCT05739695) is currently being completed to compare VNB to radial EBUS and a combination of both bronchoscopic techniques. The primary outcomes measured will be the diagnostic efficacy and safety of each method. The study is scheduled to be completed in March 2025 (ClinicalTrials.gov 2024).

A study (NCT05358041) is being completed to compare CBCT-guided ENB to CBCT-guided RAB for peripheral and central lung lesions. The primary outcomes measured will be the difference in diagnostic yield between both approaches and "the sensitivity of ENB with fixed angle catheter versus robotic shape sensing bronchoscopy with articulating catheter." The study had an estimated completion date of November 2022. No data has currently been published (ClinicalTrials.gov 2022).

National/Specialty Organizations

The **Scottish Intercollegiate Guidelines Network (SIGN)** (2014), in a National Clinical *Guideline (No. 137) for the Management of Lung Cancer*, note that flexible bronchoscopy has a lower diagnostic sensitivity for peripheral lesions compared with central lesions. Even though fluoroscopy may improve the diagnostic yield, results are still poor compared to percutaneous fine needle aspiration (FNA) biopsy. Advanced bronchoscopic techniques, such as VBN or EBN, may have a role in obtaining diagnostic material from primary tumors in some patients, but there is insufficient evidence that it provides a higher diagnostic yield than traditional image guidance approaches and fiber optic bronchoscopy. The guideline emphasizes that percutaneous FNA biopsy should be considered as the preferred diagnostic technique in patients with peripheral lesions. The use of advanced bronchoscopic techniques should be considered in patients with tumors where sampling with traditional approaches has failed to provide sufficient diagnostic material.

The **American College of Chest Physicians (ACCP)** published *Diagnosis and Management of Lung Cancer: Evidence-Based Clinical Practice Guidelines (3rd ed.).* In patients suspected of having small cell lung cancer based on the radiographic and clinical findings, it's recommended that the diagnosis be confirmed by the least invasive method (sputum cytology, thoracentesis, fine needle aspiration, or bronchoscopy including transbronchial needle aspiration, as dictated by the patient's presentation. In patients with peripheral lung lesions difficult to reach with conventional bronchoscopy, electromagnetic navigation guidance is recommended if the equipment and the expertise are available. The procedure can be performed with or without fluoroscopic guidance and may be performed with radial probe ultrasound. If electromagnetic navigation is not available, transthoracic needle aspiration is recommended.

The guidelines also note that the diagnostic yield of bronchoscopy decreases for peripheral lesions. Lesions < 2 cm in diameter have shown a sensitivity of 34% and lesions > 2 cm have shown a sensitivity of 63%. Electromagnetic navigation is an emerging technology for the diagnosis of peripheral lung cancer, with a diagnostic yield of 71%. In

comparison, transthoracic needle aspiration has a diagnostic sensitivity of 90% but has a lower sensitivity for lesions < 2 cm and is associated with a higher rate of pneumothorax when compared to bronchoscopic procedures (Rivera et al. 2013).

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

Code	Description
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])

HCPCS (Healthcare Common Procedure Coding System)

Code	Description
C7509	Bronchoscopy, rigid or flexible, diagnostic with cell washing(s) when performed, with computer-assisted image-guided navigation, including fluoroscopic guidance when performed
C7510	Bronchoscopy, rigid or flexible, with bronchial alveolar lavage(s), with computer-assisted image-guided navigation, including fluoroscopic guidance when performed
C7511	Bronchoscopy, rigid or flexible, with single or multiple bronchial or endobronchial biopsy(ies), single or multiple sites, with computer-assisted image-guided navigation, including fluoroscopic guidance when performed

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APPROVAL HISTORY

06/11/2025	Policy reviewed, no changes to coverage criteria.
06/12/2024	Policy reviewed, no changes to criteria.
06/14/2023	Policy reviewed, changes to coverage criteria include electromagnetic bronchoscopy now medically necessary and inclusion of robotic-assisted bronchoscopy as experimental/investigational/unproven. Updated Overview, Summary of Medical Evidence, and References. Formatting updates to Disclaimer section and "Documentation Requirements" disclaimer in Coverage Policy section. Supplemental Information section removed. Codes C7509, C7510, and C7511 added. Policy reviewed on May 12, 2023, by a practicing, board-certified physician in the areas of Pulmonary Disease, Critical Care, and Internal Medicine.
06/08/2022	Policy reviewed, no changes.
06/09/2021	Policy reviewed, no changes.
06/17/2020	Policy reviewed, no changes, updated references.
06/19/2019	Policy reviewed, no changes, updated references.
07/10/2018	Policy reviewed, no changes.
09/19/2017	Policy reviewed, no changes.
09/15/2016	Policy reviewed, no changes.
12/16/2015	Policy reviewed, no changes.
08/25/2014	New policy.

REFERENCES

1. Ali MS, Ghori UK, Wayne MT, et al. Diagnostic performance and safety profile of robotic-assisted bronchoscopy: A systematic review and meta-analysis. Ann Am Thorac Soc. 2023 Dec;20(12):1801-1812. Doi: 10.1513/AnnalsATS.202301-075OC. PMID: 37769170.
2. Asano F, Shinagawa N, Ishida T, Shindoh J, Anzai M, Tsuzuku A, et al. Virtual bronchoscopic navigation combined with ultrathin bronchoscopy. A randomized clinical trial. Am J Respir Crit Care Med. 2013 Aug 1;188(3):327-33. doi: 10.1164/rccm.201211-2104OC. PMID: 23600452.
3. Bondue B, Taton O, Tannouri F, Van de Velde N, Remmelink M, Leduc D. High diagnostic yield of electromagnetic navigation bronchoscopy performed under cone beam CT guidance: results of a randomized Belgian monocentric study. BMC Pulm Med. 2023 May 27;23(1):185. doi: 10.1186/s12890-023-02492-7. PMID: 37245012; PMCID: PMC10224575.
4. Chen AC, Pastis NJ Jr, Mahajan AK, et al. Robotic bronchoscopy for peripheral pulmonary lesions: A multicenter pilot and feasibility study (BENEFIT). Chest. 2021 Feb;159(2):845-852. Doi: 10.1016/j.chest.2020.08.2047. Epub 2020 Aug 19. PMID: 32822675; PMCID:

PMC7856527.
5. ClinicalTrials.gov. A trial of radial ebus versus vbn for the peripheral pulmonary lesions [NCT05739695]. National Library of Medicine. Updated February 6, 2024. Accessed April 16, 2025. www.clinicaltrials.gov.
6. ClinicalTrials.gov. Cone beam CT guided robotic navigational bronchoscopy (CBCTRNB) [NCT05358041]. National Library of Medicine. Updated May 5, 2022. Accessed April 16, 2025. www.clinicaltrials.gov.
7. Folch EE, Labarca G, Ospina-Delgado D, Kheir F, Majid A, Khandhar SJ, et al. Sensitivity and Safety of Electromagnetic Navigation Bronchoscopy for Lung Cancer Diagnosis: Systematic Review and Meta-analysis. Chest. 2020 Oct;158(4):1753-1769. doi: 10.1016/j.chest.2020.05.534. Epub 2020 May 23. PMID: 32450240.
8. Folch EE, Pritchett MA, Nead MA, et al. Electromagnetic navigation bronchoscopy for peripheral pulmonary lesions: One-year results of the prospective, multicenter NAVIGATE study. J Thorac Oncol. 2019;Mar;14(3):445-458.
9. Giri M, Dai H, Puri A, Liao J, Guo S. Advancements in navigational bronchoscopy for peripheral pulmonary lesions: A review with special focus on virtual bronchoscopic navigation. Front Med (Lausanne). 2022 Oct 10;9:989184. Doi: 10.3389/fmed.2022.989184. PMID: 36300190; PMCID: PMC9588954.
10. Giri M, Puri A, Wang T, Huang G, Guo S. Virtual bronchoscopic navigation *versus* non-virtual bronchoscopic navigation assisted bronchoscopy for the diagnosis of peripheral pulmonary lesions: a systematic review and meta-analysis. Ther Adv Respir Dis. 2021 Jan-Dec;15:17534666211017048. doi: 10.1177/17534666211017048. PMID: 34057861; PMCID: PMC8172954.
11. Hayes. Virtual bronchoscopic navigation for evaluation of peripheral pulmonary lesions. Health Technology Assessment. Published December 11, 2014. Updated December 4, 2018. Accessed April 10, 2025. https://evidence.hayesinc.com
12. Hiddinga BI, Slebos DJ, David Koster T, et al. The additional diagnostic value of virtual bronchoscopy navigation in patients with pulmonary nodules – The NAVIGATOR study. Lung Cancer. 2023 Mar;177:37-43. Doi: 10.1016/j.lungcan.2023.01.012. Epub 2023 Jan 24. PMID: 36708592.
13. Ishida T, Asano F, Yamazaki K, Shinagawa N, Oizumi S, Moriya H, et al. Virtual bronchoscopic navigation combined with endobronchial ultrasound to diagnose small peripheral pulmonary lesions: a randomised trial. Thorax. 2011 Dec;66(12):1072-7. doi: 10.1136/thx.2010.145490. Epub 2011 Jul 11. PMID: 21749984; PMCID: PMC3221323.
14. Islam S. Flexible bronchoscopy in adults: Overview. Updated February 03, 2025. Literature review current through March 2025. Accessed April 10, 2025. https://www.uptodate.com
15. Khan F, Seaman J, Hunter TD, et al. Diagnostic outcomes of robotic-assisted bronchoscopy for pulmonary lesions in a real-world multicenter community setting. BMC Pulm Med. 2023 May 9;23(1):161. Doi: 10.1186/s12890-023-02465-w. PMID: 37161376; PMCID: PMC10170714.
16. Kim S, Kim N, Chung S, et al. Diagnostic accuracy and safety of electromagnetic navigation transthoracic needle biopsy under moderate sedation for the diagnosis of peripheral pulmonary lesions. Transl Lung Cancer Res. 2023 Jul 31;12(7):1496-1505. Doi: 10.21037/tlcr-23-111. Epub 2023 Jul 24. PMID: 37577320; PMCID: PMC10413044.
17. Kops SEP, Heus P, Korevaar DA, et al. Diagnostic yield and safety of navigation bronchoscopy: A systematic review and meta-analysis. Lung Cancer. 2023 Jun;180:107196. Doi: 10.1016/j.lungcan.2023.107196. Epub 2023 Apr 19. PMID: 37130440.
18. McGuire AL, Myers R, Grant K, Lam S, Yee J. The Diagnostic Accuracy and Sensitivity for Malignancy of Radial-Endobronchial Ultrasound and Electromagnetic Navigation Bronchoscopy for Sampling of Peripheral Pulmonary Lesions: Systematic Review and Meta-analysis. J Bronchology Interv Pulmonol. 2020 Apr;27(2):106-121. doi: 10.1097/LBR.0000000000000645. PMID: 31985505.
19. Rivera MP, Mehta AC, Wahidi MM. Establishing the diagnosis of lung cancer: Diagnosis and management of lung cancer, 3rd ed: American College of Chest Physicians evidence-based clinical practice guidelines. Chest. 2013 May;143(5 Suppl):e142S-e165S. doi: 10.1378/chest.12-2353. PMID: 23649436.
20. Scottish Intercollegiate Guidelines Network (SIGN). Management of lung cancer. Published February 2014. Accessed April 11, 2025. https://www.sign.ac.uk/our-guidelines/management-of-lung-cancer/
21. Shen YC, Chen CH, Tu CY. Advances in diagnostic bronchoscopy. Diagnostics (Basel). 2021 Oct 26;11(11):1984. Doi: 10.3390/diagnostics11111984. PMID: 34829331; PMCID: PMC8620115.
22. Shepherd W. Image-guided bronchoscopy for biopsy of peripheral pulmonary lesions. Updated February 24, 2025. Literature review current through March 2025. Accessed April 10, 2025. https://www.uptodate.com
23. Tsai YM, Kuo YS, Lin KH, et al. Diagnostic performance of electromagnetic navigation versus virtual navigation bronchoscopy-guided biopsy for pulmonary lesions in a single institution: Potential role of artificial intelligence for navigation planning. Diagnostics (Basel). 2023 Mar 16;13(6):1124. doi: 10.3390/diagnostics13061124. PMID: 36980432; PMCID: PMC10047187.
24. United States Food and Drug Administration (FDA). 510(k) premarket notification. BF-NAVI. Product code JAK. 510(k): (K093810). Accessed April 15, 2025. https://www.fda.gov
25. United States Food and Drug Administration (FDA). 510(k) premarket notification. IG4 IMAGE GUIDED SYSTEM (multiple approvals). Product code JAK. 510(k): (K093146). Accessed April 15, 2025. https://www.fda.gov
26. United States Food and Drug Administration (FDA). 510(k) premarket notification. ILLUMISITE Platform. Product code JAK. 510(k): (K191394). Accessed April 15, 2025. https://www.fda.gov
27. United States Food and Drug Administration (FDA). 510(k) premarket notification. Ion Endoluminal System. Product code EOQ. 510(k): (K182188). Accessed April 15, 2025. https://www.fda.gov
28. United States Food and Drug Administration (FDA). 510(k) premarket notification. LUNGPOINT PROCEDURE PLANNING. Product code LLZ. 510(k): (K093423). Accessed April 15, 2025. https://www.fda.gov
29. United States Food and Drug Administration (FDA). 510(k) premarket notification. Lung Vision. Product code LLZ. 510(k): (K163622). Accessed April 15, 2025. https://www.fda.gov
30. United States Food and Drug Administration (FDA). 510(k) premarket notification. Monarch Endoscopy Platform. Product code EOQ. 510(k): (K173760). Accessed April 15, 2025. https://www.fda.gov
31. United States Food and Drug Administration (FDA). 510(k) premarket notification. SUPERDIMENSION/BRONCHUS (multiple approvals). Product code JAK. 510(k): (K042438). Accessed April 15, 2025. https://www.fda.gov
32. United States Food and Drug Administration (FDA). Class 2 device recall IG 4 image guided system. Published September 29, 2023. Accessed April 15, 2025. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=202824
33. Yutaka Y, Sato T, Isowa M, et al. Electromagnetic navigation bronchoscopy versus virtual bronchoscopy navigation for improving the diagnosis of peripheral lung lesions: analysis of the predictors of successful diagnosis. Surg Today. 2022 Jun;52(6):923-930. doi: 10.1007/s00595-021-02398-z. Epub 2021 Oct 27. PMID: 34705111.

34. Zhang C, Xie F, Li R, Cui N, Herth FJF, Sun J. Robotic-assisted bronchoscopy for the diagnosis of peripheral pulmonary lesions: A systematic review and meta-analysis. Thorac Cancer. 2024 Mar;15(7):505-512. doi: 10.1111/1759-7714.15229. Epub 2024 Jan 29. PMID: 38286133; PMCID: PMC10912532.
35. Zheng X, Cao L, Zhang Y, Xie F, Yang H, Liu J, et al. A Novel Electromagnetic Navigation Bronchoscopy System for the Diagnosis of Peripheral Pulmonary Nodules: A Randomized Clinical Trial. Ann Am Thorac Soc. 2022 Oct;19(10):1730-1739. doi: 10.1513/AnnalsATS.202109-1071OC. PMID: 35679184.