

Medtronic

The future is
in motion.



ILLUMISITE™
fluoroscopic
navigation platform



Don't let lung motion put biopsy at a standstill.

Reliance on a static image in a dynamic environment can make nodule biopsies using lung navigation technology challenging.

CT-to-body divergence – the discrepancy between the static pre-op CT scan and the dynamic, breathing lung – impacts the accuracy of peripheral lung biopsies in a number of ways:¹

- Static CT image in dynamic lung environment^{1,2}
- Changes from anesthesia^{1,2}
- Tissue distortion due to robotic and flexible scopes^{1,2}

That's why you need a lung navigation platform that corrects for CT-to-body divergence during procedures. So you can biopsy with greater confidence to facilitate diagnosis and treatment, and move lung care forward.





The ILLUMISITE™ platform – the leading electromagnetic lung navigation platform that corrects for CT-to-body divergence.^{2,3}

Correct for CT-to-body divergence

With the complete platform designed to do more.

Not only is the ILLUMISITE™ platform the first to correct for CT-to-body divergence – it's the only platform that uses digital tomosynthesis to do so.^{1,3}



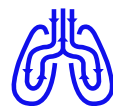
See the real target.

As the first lung navigation solution to correct for CT-to-body divergence, the ILLUMISITE™ platform is clinically proven to help you accurately navigate lung nodules.^{1,3,5,†} With its unique fluoroscopic navigation technology utilizing digital tomosynthesis,^{2,4} you'll have greater confidence that you're in the right spot before you biopsy.



Lock on in real time.

At every stage of the biopsy procedure, you'll remain on target with ongoing guidance. The precision of continuous guidance makes continued target alignment possible across multiple tool uses – without the need to reinsert the locatable guide.^{4,†} And it's designed for multidirectional sampling for a more thorough biopsy.



Travel outside the airways.

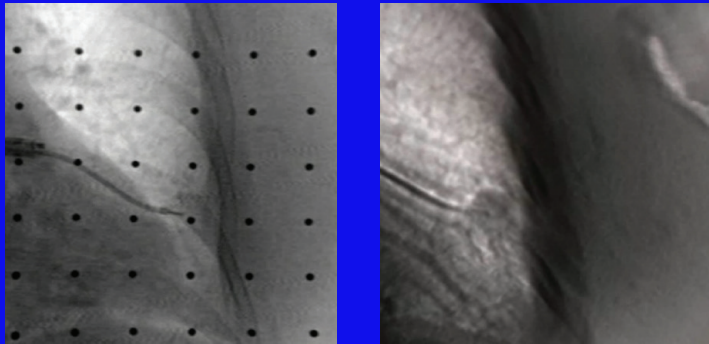
New possibilities for lung disease detection and management are within reach when you can extend the reach of bronchoscopy. Locate hard-to-reach lesions – especially outside of visible airways⁶ – with the CrossCountry™ transbronchial access tool.

[†]Based on evidence from a single-center prospective study including a total of 82 consecutive patients.

Accuracy is no longer a moving target.

With fluoroscopic navigation technology, you can biopsy with greater confidence.

Perform local registration with 3-D tomosynthesis-like input from an existing C-arm and enhance the nodule's visibility. Adjust for CT-to-body divergence with alignment of the catheter to the nodule throughout the procedure.

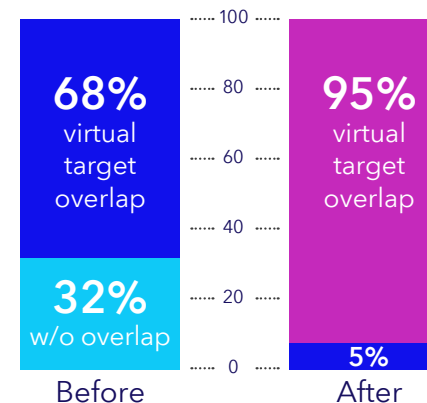


Using fluoroscopic navigation technology, compare the 2-D fluoroscopic image (left) to a slice of the 3-D reconstruction of the exact same nodule (right).

In a single-center retrospective cohort study, use of fluoroscopic navigation technology resulted in a nearly **25-point increase[†]** in diagnostic yields⁷



[†]25-percentage point increase using fluoroscopic navigation (79%, 53/67) versus standard navigation (54%, 55/101).



95% success rate[‡]

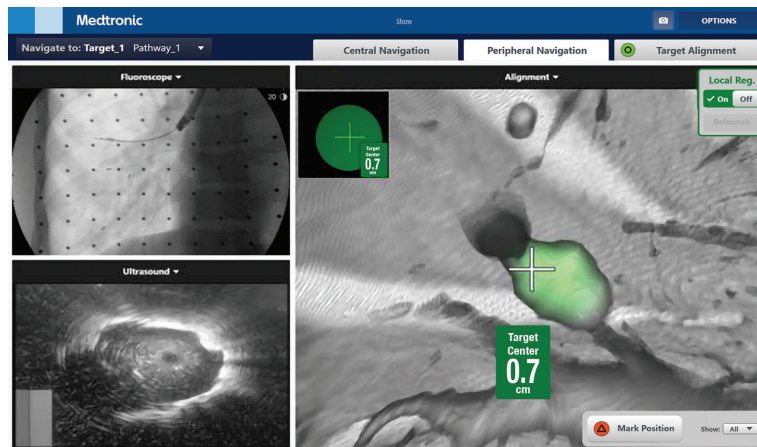
of the virtual target overlapping the actual lesion after using fluoroscopic navigation technology²

[‡]Cases with evaluable videos (n=41).

Maintain a bullseye view.

**Staying on target means everything when it comes to enhancing biopsies.
That's the power of continuous guidance.**

The sensor embedded in the catheter tip provides positional data, so you can maintain alignment to the target even after the locatable guide is removed.^{4,†} Sample multi-directionally for a thorough biopsy. Improvement in diagnostic yield has been reported when using fluoroscopic navigation technology.^{4,5,7,†,‡}



With the locatable guide removed, radial ebus confirms successful navigation to the nodule. Continuous guidance shows the alignment to the nodule.

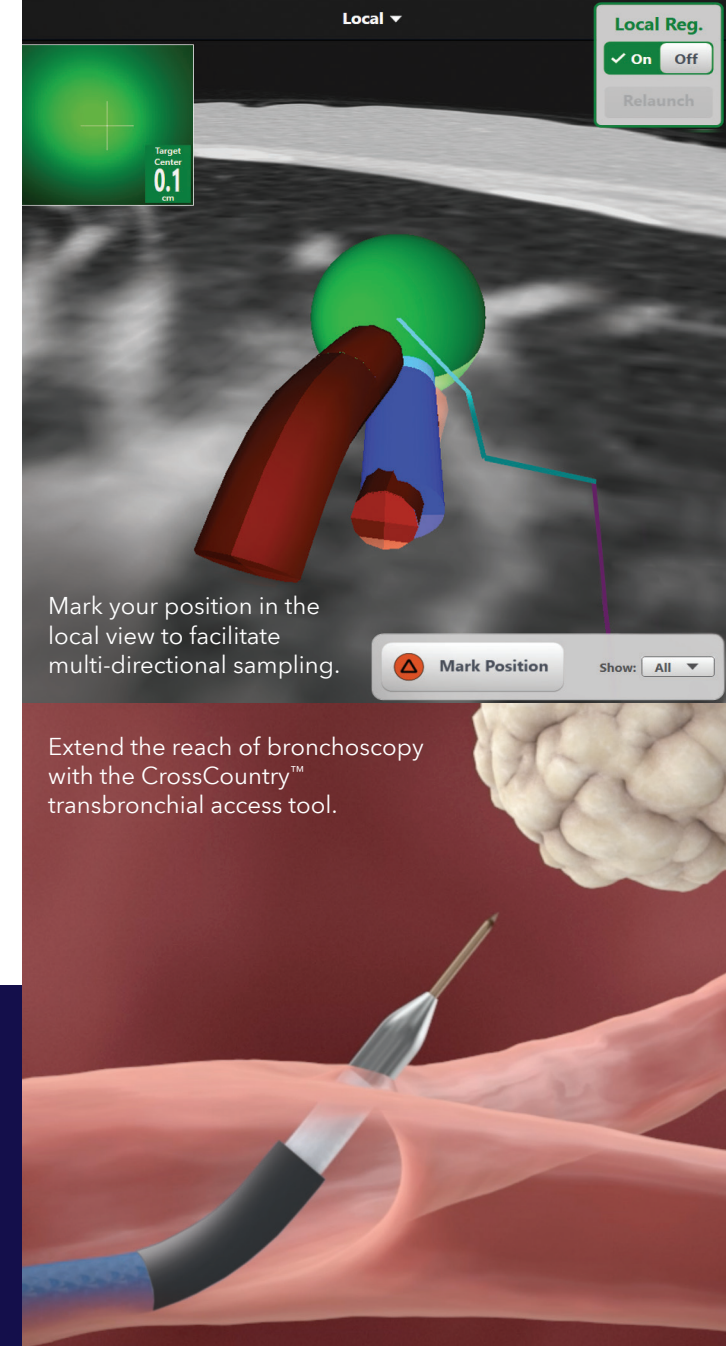
Target acquired. Even off the airway.

With just over 50 percent of nodules not located in a visible airway,⁶ the CrossCountry™ transbronchial access tool is designed to access lung nodules without a bronchus sign.[§]

†Based on evidence from a single-center prospective study including a total of 82 consecutive patients.

‡Based on evidence from a single-center retrospective study including a total of 72 consecutive patients.

§For more information regarding the CrossCountry™ transbronchial access tool, please contact your account manager or clinical education specialist.



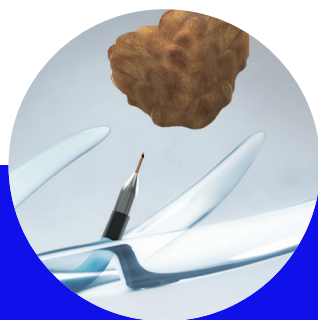
Tools that take aim at lung challenges

Drive confidence and move lung health forward with our portfolio of lung health tools.



Sensing catheters

A sensor coil embedded in the distal tip generates continuous positional data, so you can maintain alignment on the target even after the locatable guide is removed.



CrossCountry™ trans-bronchial access tool

This tool extends the reach of bronchoscopy and enable more patients to benefit from navigation procedures. Now you can access nodules outside of the airway.



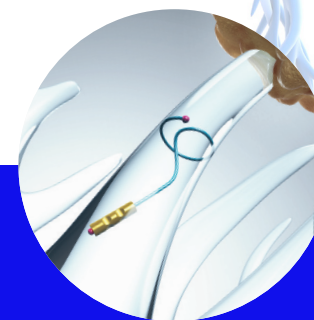
Arcpoint™ pulmonary needle

Features a braided sheath for trackability and maneuverability tapered for ease of sampling. The short, rigid metal needle maximizes flexibility. There is also an optional stylet for additional rigidity if needed.



GenCut™ core biopsy system

Using a proprietary blade design, this tool helps you obtain core tissue samples for molecular genetic analysis and enables continuous sampling.



SuperLock™ nitinol coil fiducial markers

With shape memory designed to secure the marker and minimize migration, these markers conform to the contours of the anatomy and enable nodule localizing during stereotactic body radiation therapy (SBRT/XBRT).

A new movement for lung cancer care



Staying one move ahead of lung cancer takes innovative surgical products, minimally invasive techniques, and continuous collaboration.

With the Medtronic Lung Health Program, we are dedicated to moving lung cancer care forward.

We apply the full power of partnership to empower you to improve clinical outcomes, leaning on our industry relationships and clinical connections to pioneer innovation across the care continuum.

All focused on our vision to transform lung cancer from a terminal illness into a manageable and potentially curable condition.

Indications for use

ILLUMISITE™ Platform: The ILLUMISITE™ Platform is indicated for displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools or catheters in the pulmonary tract and to enable marker placement within soft lung tissue. It does not make a diagnosis and is not an endoscopic tool. Not for pediatric use.

WARNING: The ILLUMISITE™ platform may only be used by a qualified bronchoscopist.

CONTRAINDICATIONS:

Flexible bronchoscopy should be performed only when the relative benefits outweigh the risks. Absolute contraindications include, but are not limited to:

- Absence of consent from the patient or his /her representative, unless a medical emergency exists and the patient is not competent to give consent
- Lack of adequate facilities and personnel to care for emergencies such as cardiopulmonary arrest, pneumothorax, or bleeding
- Inability to adequately oxygenate the patient during the procedure
- For large patients, inability to place all three patient sensors within the sensing volume

The danger of a serious complication from bronchoscopy is especially high in patients with the disorders listed below. These conditions are usually considered absolute contraindications, unless risk-benefit assessment warrants the procedure:

- Coagulopathy or bleeding diathesis that cannot be corrected
- Severe obstructive airways disease
- Severe refractory hypoxemia
- Unstable hemodynamic status including dysrhythmias

Relative contraindications or conditions involving increased risk for Fiber-optic Bronchoscopy in adults include but are not limited to:

- Recent myocardial infarction or unstable angina
- Uremia and pulmonary hypertension (possibility of serious hemorrhage after biopsy)
- Lung abscess (danger of flooding the airway with purulent material)
- Respiratory failure requiring mechanical ventilation
- Known or suspected pregnancy (because of radiation exposure)

CrossCountry™ transbronchial access tool

The CrossCountry™ transbronchial access tool is to be utilized through a flexible endoscope with an extended working channel by physicians who are trained in endoscopic techniques to puncture the tracheobronchial wall and facilitate access of additional endobronchial tools for patients with endobronchial lesions, peripheral lung nodules, or lung masses.

Arcpoint™ pulmonary needle

The Arcpoint™ pulmonary needle is utilized through a flexible endoscope or with the superDimension™ navigation system or ILLUMISITE™ platform by physicians who are trained in endoscopic techniques for retrieving specimens from patients with endobronchial lesions, peripheral lung nodules, or lung masses.

GenCut™ core biopsy system

The GenCut™ core biopsy system is utilized through a flexible endoscope or with the superDimension™ navigation system or ILLUMISITE™ platform by physicians who are trained in endoscopic techniques for retrieving specimens from patients with endobronchial lesions, peripheral lung nodules, or lung masses.

SuperLock™ fiducial marker - (US)

The SuperLock™ fiducial marker is intended to be used to radiographically mark soft tissue for future surgical or therapeutic purposes.

SuperLock™ fiducial marker - (EU)

The SuperLock™ fiducial marker is intended to be used to radiographically mark soft lung tissue for future surgical or therapeutic purposes.

References

1. Pritchett MA, Bhadra K, Calcutt M, Folch E. Virtual or reality: divergence between preprocedural computed tomography scans and lung anatomy during guided bronchoscopy. *J Thorac Dis* 2020;12(4):1595-1611.
2. Pritchett MA, Bhadra K, Mattingley JS. Electromagnetic navigation bronchoscopy with tomosynthesis-based visualization and positional correction: three-dimensional accuracy as confirmed by cone-beam computed tomography. *J Bronchology Interv Pulmonol*. 2021; 28(1):10-20.
3. Medtronic financial and market analysis as of November 2021 of ENB and robotic lung navigation systems in market demonstrating Medtronic leading market share as defined by percentage of capital system sales.
4. Avasarala SK, Roller L, Katsis J, et al. Sight unseen: diagnostic yield and safety outcomes of a novel multimodality navigation bronchoscopy platform with real-time target acquisition. *Respiration*. 2022;101(2):166-173.
5. Dunn BK, Blaj M, Stahl J, Speicher J, Anciano C, Hudson S, Kragel EA, Bowling MR. Evaluation of electromagnetic navigational bronchoscopy using tomosynthesis-assisted visualization, intraprocedural positional correction and continuous guidance for evaluation of peripheral pulmonary nodules. *JBronchology Interv Pulmonol*. 2022.
6. 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;14(3): 445-458.
7. Aboudara M, Roller L, Rickman O, et al. Improved diagnostic yield for lung nodules with digital tomosynthesis-corrected navigational bronchoscopy: Initial experience with a novel adjunct. *Respirology*. 2020;25(2):206-213. doi:10.1111/resp.13609.

Always refer to the instructions for use included with the product for complete indications, contraindications, warnings, and precautions.

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the ILLUMISITE™
platform, visit
illumisite.com.



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