

Medtronic

The future is in motion.

ILLUMISITE™ fluoroscopic navigation platform

Discover the complete platform designed to do more.

With real-time visualization that enhances nodule imaging and adjusts to a dynamic environment,^{1,2} the ILLUMISITE™ platform provides greater confidence when you biopsy.



Compensate for CT-to-body divergence.

- Corrects for the discrepancy between the static CT scan and the dynamic breathing lung¹⁻³
- Enhances the visibility of the lesion¹⁻³



Maintain a bullseye view.

- Makes continued target alignment possible across multiple tool uses – without the need to reinsert the locatable guide^{2,3}
- Allows for multidirectional sampling for a thorough biopsy



Target acquired. Even off the airway.

- Locate hard-to-reach lesions – even outside of visible airways – with the CrossCountry™ transbronchial access tool.
- With just over 50% of nodules not located in a visible airway,⁴ the CrossCountry™ transbronchial access tool can access lung nodules without a bronchus sign.^{†,‡}

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

[‡]Based on NAVIGATE study: a large prospective observational multicenter study of 1388 subjects (NAVIGATE).

Accuracy is no longer a moving target.

Fluoroscopic navigation technology

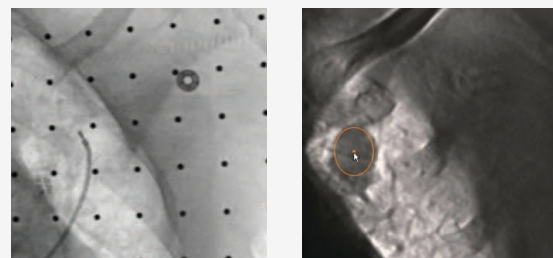
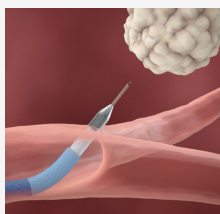
With fluoroscopic navigation technology, you'll have the tools you need to biopsy with greater confidence. Perform local registration with 3-D tomosynthesis input from an existing C-arm and enhance the nodule's visibility to adjust for CT-to-body divergence.⁵

Continuous guidance

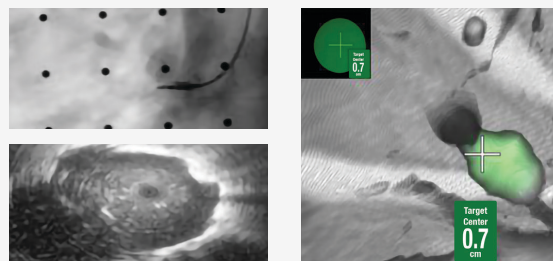
Staying on target means everything when it comes to enhancing procedural performance. That's the power of continuous guidance. The embedded sensor in the catheter tip provides positional data while you biopsy, so you can ensure alignment on the target even after the locatable guide is removed. Sample multi-directionally for a thorough biopsy and potentially improved procedural outcomes when used with fluoroscopic navigation technology.^{2,3}

CrossCountry™ transbronchial access tool

Travel outside the airways to access lesions. The CrossCountry™ transbronchial tool is designed to allow access to lung lesions without a bronchus sign and enable access to more lesions to extend the benefit of ENB procedures.



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



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

Expanded fluoroscopic capability, for new possibilities.

The ILLUMISITE™ fluoroscopic navigation platform is now compatible with digital fluoroscopes, delivering expanded fluoroscopic capability during lung biopsy procedures. This is device innovation that promotes operational efficiency to facilitate diagnosis and treatment.



Imaging compatibility powers access.

The ILLUMISITE™ platform gives you new ways to expand your imaging compatibility with digital fluoroscopy. Increasing your access to fluoroscopic navigation technology, which uses digital tomosynthesis, means more certainty that you are in the right location before you biopsy.^{2,3,6,7,†}



Integrated imaging – for accuracy you can rely on.

Achieving the navigation accuracy you need to reach the target nodule requires high-quality, real-time imaging. The ILLUMISITE™ platform features integrated imaging that is clinically proven to accurately navigate to lung nodules^{2,3,6,7,†} and correct for CT-to-body divergence.^{2,3,6,7,†,‡}



Maximize your imaging investment.

Explore how expanded fluoroscopic capability may amplify the clinical and economic value of your imaging investment. With digital compatibility, you can unlock the full potential of the ILLUMISITE™ platform – enabling CT-to-body divergence correction.^{2,3,6,7,†,‡}

Not for use in pediatric patients or those with unstable hemodynamic status. Specific risks include but not limited to: bleeding, pneumothorax, and respiratory failure.

†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.

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

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.

1. 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. doi: 10.1097/LBR.0000000000000687.
2. 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*. Published online September 03, 2021. doi: 10.1159/000518009.
3. Dunn BK, Blaj M, Stahl J, Speicher et al. Evaluation of electromagnetic navigational bronchoscopy using tomosynthesis-assisted visualization, intraprocedural positional correction and continuous guidance for evaluation of peripheral pulmonary nodules. *J Bronchology Interv Pulmonol*. 2022.
4. 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): 445-58. doi: 10.1016/j.jtho.2018.11.013.
5. Based on test report DGR00596, ILLUMISITE™ platform summative survey results. March 2019.
6. 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. doi: 10.21037/jtd.2020.01.35
7. 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.

For more information
about our Lung Health
portfolio, visit
**medtronic.com/
ILLUMISITEexperience.**