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Electromagnetic Navigation Bronchoscopy™

A New Treatment for Patients with Peripheral Lung Lesions

Lung Cancer: An Epidemic?

- In the U.S.:
  - #1 cause of cancer-related death[1]
  - Kills more people every year than breast, prostate, colon and pancreatic cancers combined[1]
  - 87% of lung cancer deaths are related to tobacco usage[2]

Sources:
1.Jemal A, et al. CA: A Cancer Journal for Clinicians 2007; 57:43-66
2.American Cancer Society, 2006

Lung Cancer: A Growing Problem

- 2010 estimates for U.S.:
  - >222,000 new cases[1]
  - >157,000 deaths[1]

- 43 million smokers in the U.S.

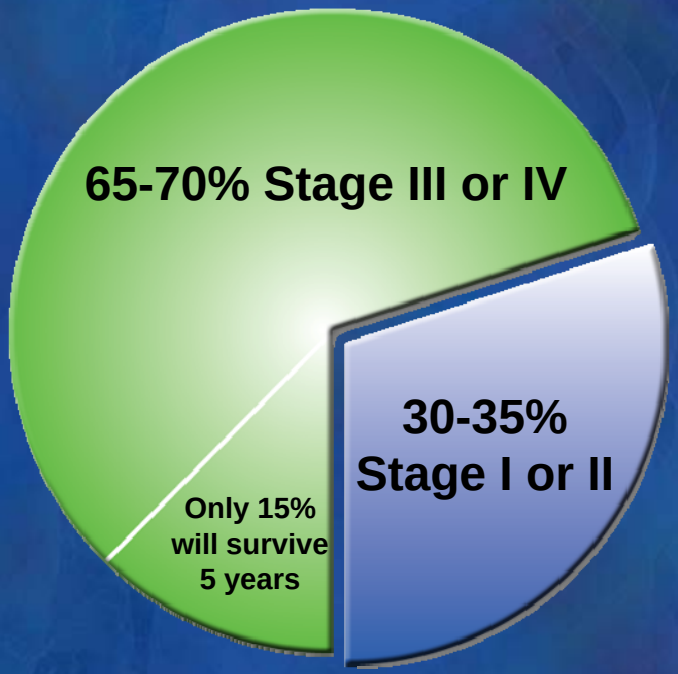
- Lung cancer risk[3]:
  - 20 times higher for male smokers
  - 12 times higher for female smokers

- The population is aging and the incidence of lung cancer will grow[4]

Sources:
1.American Cancer Society, 2010
2.CDC National Health Survey, 2007
3.Ries, L, et al., SEER Cancer Statistics, NCI 2003
4.American Cancer Society, Surveillance Research, 2006

Lung Cancer: A Poor Prognosis

- >75% of new cases have late-stage lung cancer (Stage III or IV)[1]
- 5-year survival rate is only 15%[2]



Sources:
1.Dubey, S., et al, AJRCCM, 2006 Vol 175: 868-874
2.Ries, L, et al, SEER Cancer Statistics, NCI 2003

Early Diagnosis Offers Hope

- If diagnosed at Stage III or IV, 15% survival rate at 5-years[1]
- If diagnosed at Stage I, 88% survival rate at 10-years[1]
- 92% survival rate if immediate removal of lesion[1]
- Yet, only 16% of lung cancer patients are diagnosed at an early, localized stage[2]

Sources:
1.Intl Early Lung Cancer Action Program Investigators, 2006
2.Ries, L, et al., SEER Cancer Statistics, NCI 2003

Early Stage Advantage

STAGE I OR II LESION	STAGE III OR IV LESION
SMALLER (size of pencil eraser)	LARGER (size of golf or tennis ball)
DISTAL LOCATION	PROXIMAL LOCATION
DISCRETE	ORGANIZED & WIDESPREAD
EASIER TO TREAT	TOO LATE FOR EFFECTIVE TREATMENT
SURVIVAL RATE = 88% @ 10 YEARS	LIFE EXPECTANCY +/- 6 MONTHS

Source:
1. *Intl Early Lung Cancer Action Program Investigators, 2006*
2. *American Cancer Society, Surveillance Research, 2006*

Failure of Bronchoscopy

- 500,000 bronchoscopies performed annually in the U.S.[1]
- 65% of bronchoscopies fail to reach peripheral lesions[2]
- Failure of bronchoscopy often leads to more invasive diagnostic procedures
  - TTNA
  - Surgical Biopsy

Sources:
1. Ernst et al., Chest 123: 1693-1717, 2003
2. Schwarz Y et al., Chest Apr 2006; 129:988-994

Current Approaches to Diagnosis

Method	Limitations
Watchful Waiting	Malignant CANCER can ADVANCE stage
Sputum, CXR, CT, PET	No tissue collection
Bronchoscopy	Limited reach and low diagnostic yield
Transthoracic Needle Aspiration (TTNA)	Pneumothorax Not all patients are candidates
Surgery	Non-therapeutic thoracotomy Highly invasive Not all patients are candidates

INVASIVE

Electromagnetic Navigation Bronchoscopy (ENB)

- Using the patient's natural airways, the i·Logic System provides the ability to diagnose, stage, and prepare to treat distal lung lesions in one procedure
- Provides safe and efficient access for non-operable patients
- Carries a 3% or less risk of pneumothorax[1]

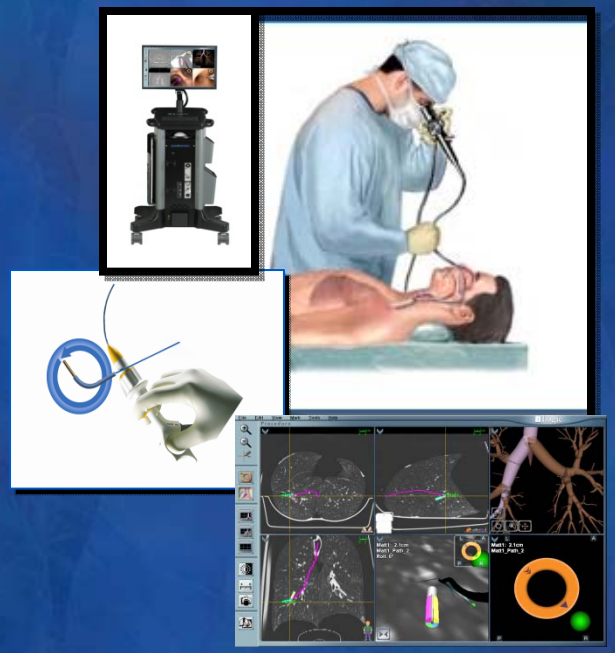
Source:
Eberhardt, R, et al, CHEST June 2007: 1800-1805

Electromagnetic Navigation Bronchoscopy (ENB) Procedure Overview

CT-Scan → DICOM CD

Planning Software → Planned Pathway File

Navigation → Biopsy → Treatment



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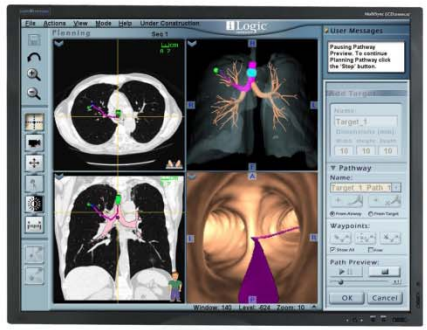
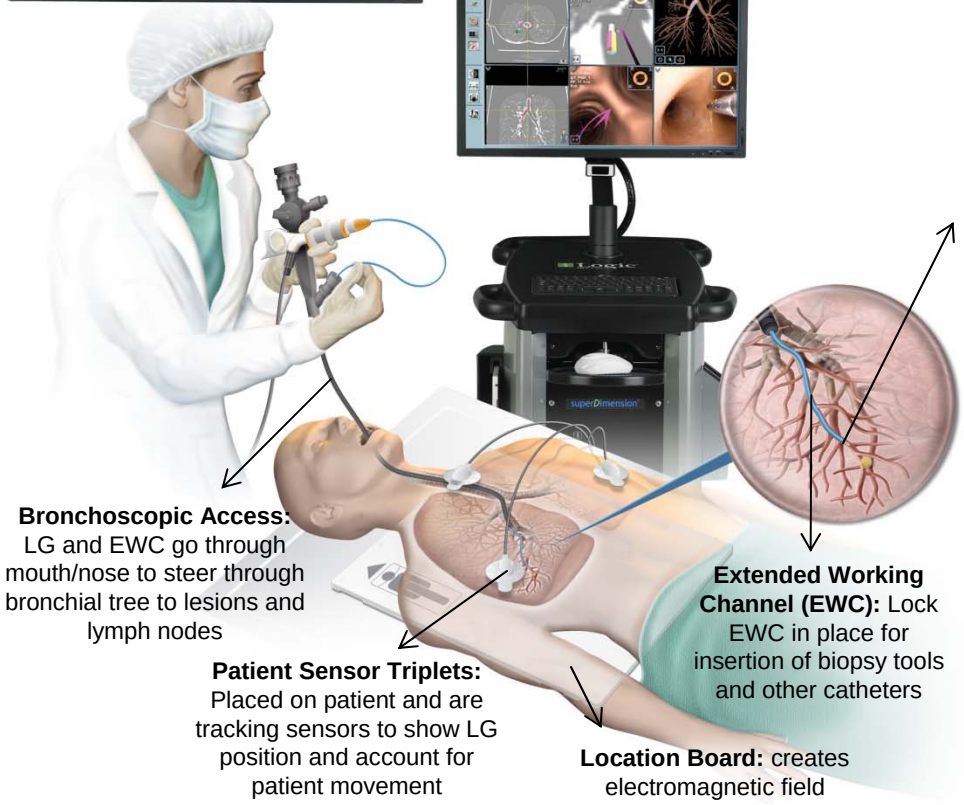


Planning Screen



Locatable Guide (LG): 360° steerability for navigation to lesions and lymph nodes

Bronchoscopic Access: LG and EWC go through mouth/nose to steer through bronchial tree to lesions and lymph nodes

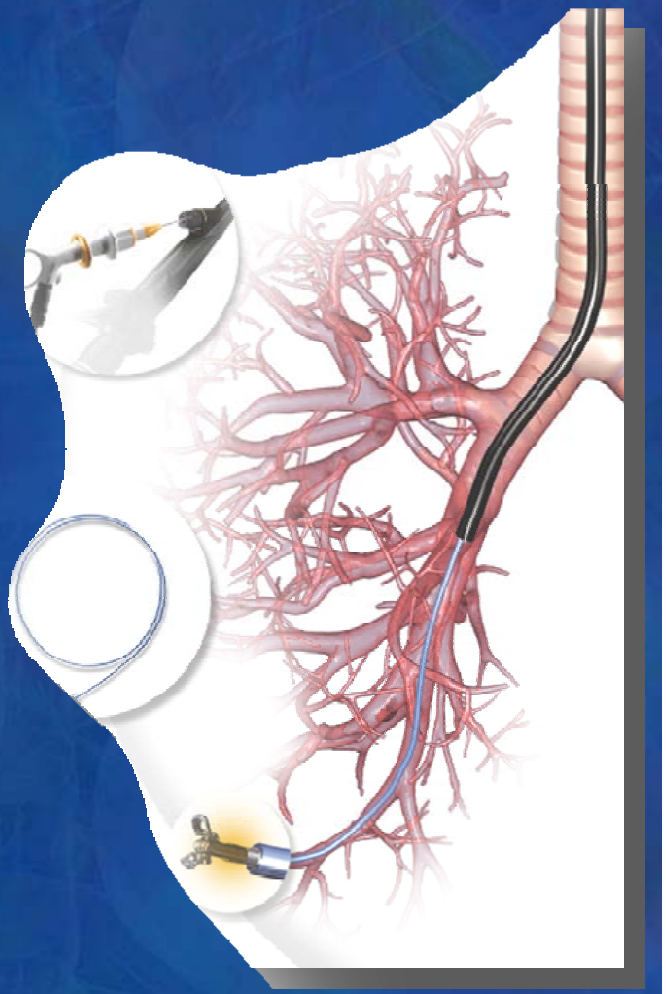
Extended Working Channel (EWC): Lock EWC in place for insertion of biopsy tools and other catheters

Patient Sensor Triplets: Placed on patient and are tracking sensors to show LG position and account for patient movement

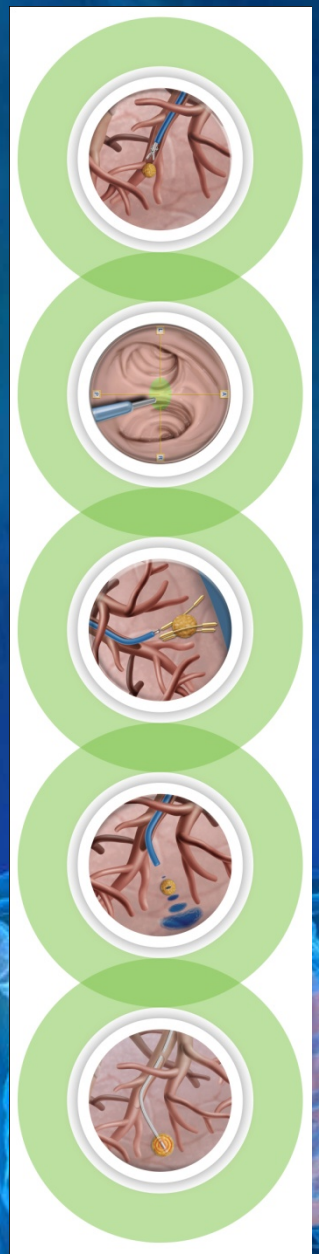
Location Board: creates electromagnetic field

Close Up of Navigation Phase

- Position locatable guide (LG) catheter near the target
- Lock extended working channel (EWC) in place and remove LG catheter
- Insert endobronchial instruments through EWC for tissue sampling



Advantages of i·Logic – Extended Reach



Navigate to peripheral lesions and biopsy for diagnosis

Stage lymph nodes for diagnosis and pre-operative planning

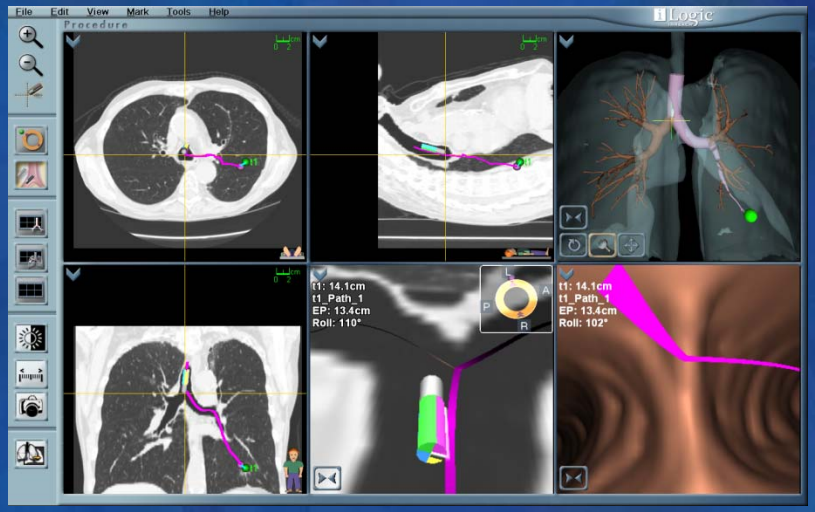
Place fiducial markers in and around tumors for radiation therapy

Place markers to facilitate VATS localization

Guide high dose radiation catheters

Advantages of i·Logic – Greater Clarity

- Virtual 3D bronchial tree extends deep into the lungs reaching 17+ airway generations
- Multiple guidance and navigation views enhance lung lesion and vessel visualization
- Diagnostic yield of 70%-74%[1,2] for lesions and 100% for lymph nodes[1]

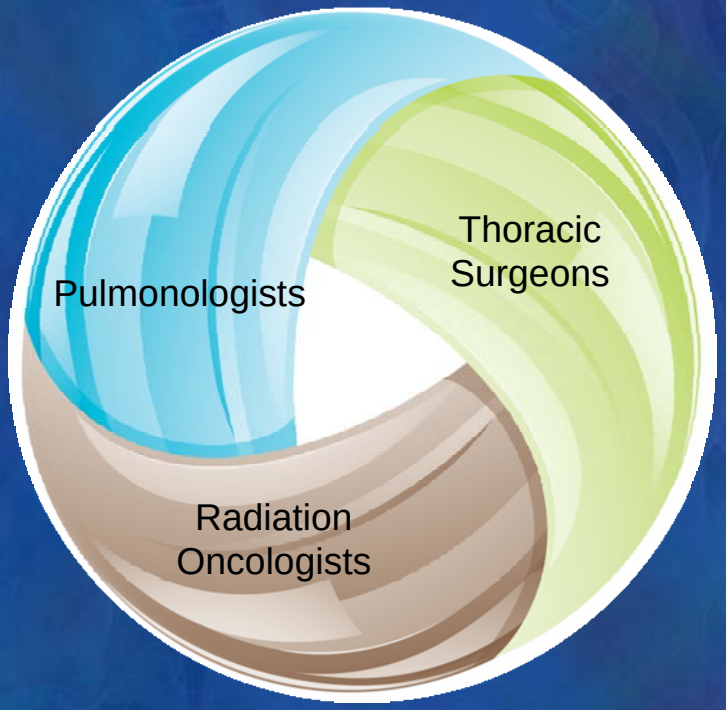


Sources:
1.Gildea, T, et al, AJRCCM 2006; 174: 982-989
2.Wilson, D., et al, JOB Oct 2007; 14(4): 227-232

Advantages of i·Logic – Multi-Specialty

•Electromagnetic Navigation Bronchoscopy (ENB) provides advantages for several specialties:

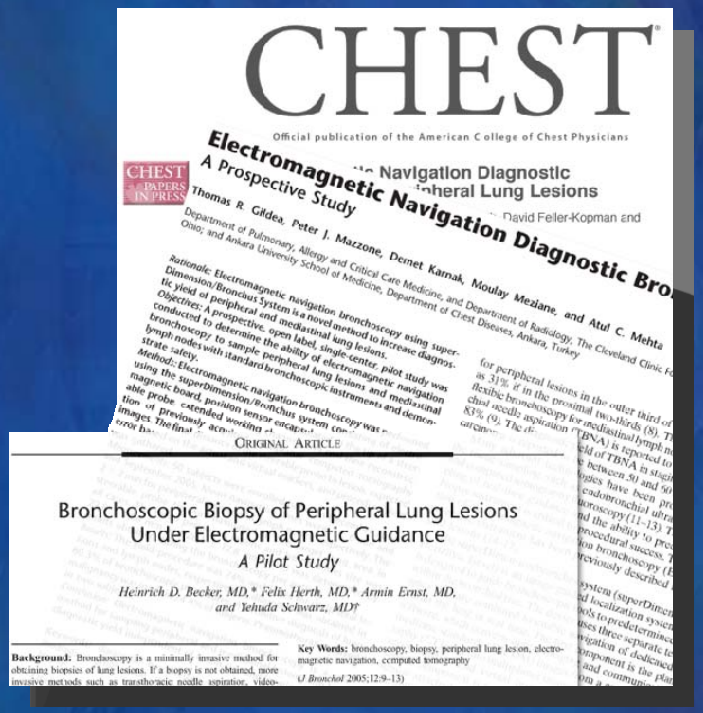
- •Diagnose lesions
- •Stage lymph nodes
- •Place fiducial markers for radiation therapy
- •Place markers to guide VATS
- •Guide high dose radiation catheters



Clinical Results - Effective

- Successful diagnosis of peripheral lesions in 70–74% of ENB cases[1,2]

- High success rates for lymph node staging


CHEST

Official publication of the American College of Chest Physicians

Electromagnetic Navigation Diagnostic Bro

A Prospective Study

Thomas R. Gildea, Peter J. Mazzone, Deinet Karnak, Moulay Mezlane, and Atul C. Mehta

ORIGINAL ARTICLE

Bronchoscopic Biopsy of Peripheral Lung Lesions Under Electromagnetic Guidance

A Pilot Study

Heinrich D. Becker, MD,* Felix Herth, MD,* Armin Ernst, MD, and Yehuda Schwarz, MD†

Sources:
1.Gildea, T, et al, AJRCCM 2006; 174: 982-989
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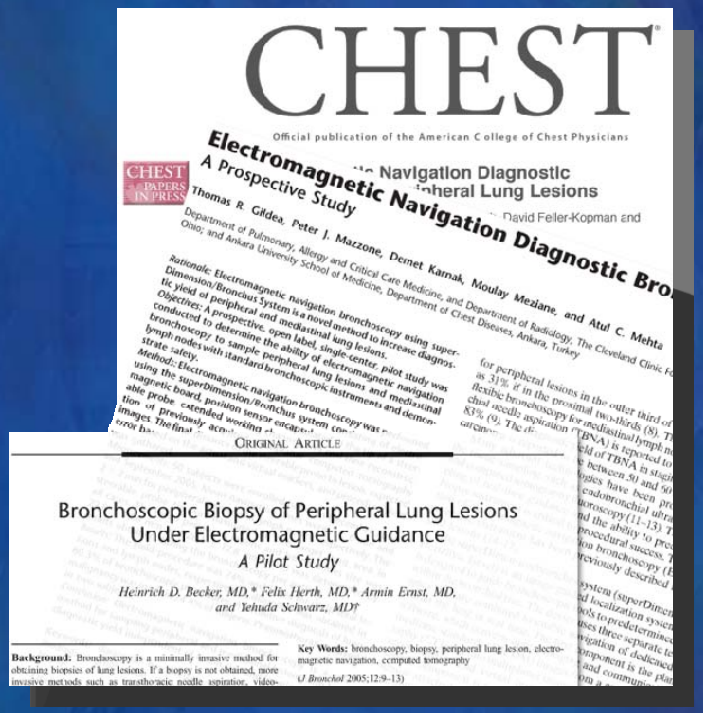
Clinical Results – Safe

- Pneumothorax rate of 2-3%[1,2]
- Over 20 published papers
- >19,000 patient cases worldwide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Why i·Logic Benefits Patients

- Minimally-invasive and uses the patient's natural airways
- Enables earlier diagnosis and earlier treatment decisions
- Potential for lower complication rates

Why i·Logic Benefits Physicians

- Expanded options for accessing lung lesions
- Improved steering through 17+ generations of airways
- Ability to diagnose and stage lymph nodes in one procedure
- Improve patient care with minimally invasive procedure
- Faster route from diagnosis to treatment

Why i·Logic Benefits Hospitals

- Improves patient care – shortens time between diagnosis and treatment
- May reduce complications often associated with more invasive procedures
- Retains patients for treatment and other services:
  - Radiation Oncology
  - Thoracic Surgery
  - Medical Oncology
  - Other Ancillary Services

Closing Comments

Thank You for Coming!

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