### **Problem Background**

# 100,000

Interstitial Lung Disease (ILD) diagnoses in the U.S. annually



Fig 1.

Cryobiopsy is the **only** method that offers the best of current biopsy techniques without the trade-offs.



A challenge slowing the widespread adoption of cryobiopsy:

### The frustrating process of removing extracted tissue from the cryoprobe tip

Current methods include:

- Aggressive shaking in formalin solution
- Scraping with a small hand-held tool

Both are **inefficient** and **time-consuming** according to expert pulmonologists.

With around **15-20 samples taken per procedure**, this is an opportunity for innovation to help cryobiopsy become the **new gold standard** in pulmonary diagnostics.



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# **Novel Device for Streamlining Tissue Retrieval in Lung Cryobiopsy**

Approximately 100,000 people are diagnosed with interstitial lung diseases (ILD) annually in the U.S., and lung cancer remains the leading cause of cancer-related deaths. Together, these burdens highlight the urgent need to innovate for improved pulmonary diagnostics. Lung cryobiopsy is a promising technique that offers the best of both forceps and surgical biopsies, low complication and high-quality samples, without the trade-offs. A challenge slowing widespread adoption of cryobiopsy is the frustrating process of removing extracted tissue from the cryoprobe tip. Current methods include aggressive shaking of the probe in formalin solution and scraping with a small hand-held tool, where both are inefficient and time-consuming according to pulmonologists. The ICOR is a novel device that easily integrates into the existing workflow, adding negligible cost while improving speed and convenience. By overcoming this hurdle, ICOR helps cryobiopsy advance toward becoming the gold standard in pulmonary disease diagnostics.

Pulmonologists need to efficiently **remove extracted tissue** from a cryoprobe to **promote adoption of lung cryobiopsy**, which offers higher diagnostic quality and reduced patient burden.

### We need a solution that...



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Can be operated RELIABLY without causing damage to the tissue or safety concerns for the patient and user.

UNIVERSALLY-COMPATIBLE with all cryoprobe types and sample collection container sizes.



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Can extract tissue samples EFFICIENTLY in few attempts.

Has minimal complexity and EASE OF USE with no added steps to the existing workflow.

Keeps or reduces the AFFORDABILITY of the cryobiopsy procedure.

# **Our Solution: ICOR**

- ✓ Significantly reduces time and frustration to remove tissue samples from the cryoprobe
- ✓ **Intuitive** and easy to set up and use
- Visible improvement in sample quality, integrity, and size compared to notched fork

Testimonials from expert pulmonologists validated that ICOR is better in comparison to the notched fork, making it a viable solution to improve tissue removal during lung cryobiopsy. Dr. Ardian Latifi, Dr. Lonny Yarmus, and Dr. Gaurav Raman say:

"easy and intuitive"

"can one-hand the procedure" References [1] U.S. Department of Health and Human Services. (n.d.). What are interstitial lung diseases?. National Heart Lung and Blood Institute. https://www.nhlbi.nih.gov/health/interstitial-lung-diseases "far faster" [2] WebMD. (n.d.). Deadliest cancers: Lung, breast, colorectal, pancreatic, prostate. WebMD. https://www.webmd.com/cancer/features/top-cancer-killers [Fig.1] Bronchoscopy: MedlinePlus Medical Encyclopedia. Medlineplus.gov. Published 2016. https://medlineplus.gov/ency/article/003857.html [Fig.2] Menezes V, Molina JC, Pollock C, et al. Lung cryobiopsy outside of the Operating Room: A Safe Alternative to surgical biopsy. Innovations: Technology and Techniques in Cardiothoracic and Vascular Surgery. 2021;16(5):463-469. doi:10.1177/15569845211034506 "miles ahead of the fork" [Fig.3] Husnain SM, Sarkar A, Huseini T. Utility and safety of bronchoscopic cryotechniques—a comprehensive review. Diagnostics. 2023;13(18):2886. doi:10.3390/diagnostics13182886cc

"quality of samples is significantly better"

"a lot more convenient"

# **Testing and Setup**

Comparison of sample removal with **ICOR** vs. **notched fork** studied on specimen of various levels of authenticity: **Preserved Pig Lungs** (March 27th, 2025) 2. Live Pig Experiment (April 8th, 2025) 3. Human Patient Procedures (April 2nd, 16th, 18th, 2025)



Fig 2. Endoscopic view of cryoprobe entering the trachea.



**Fig 3.** X-ray view of cryoprobe navigation within the lungs.

## **Results & Conclusions**

ICOR proved to remove tissue samples with **fewer attempts and time** while also preserving a **greater sample size** compared to the notched fork.

#### Workflow Efficiency Comparison



Fig 5. Average number of scrapes and seconds it takes to remove tissue from the frozen cryoprobe using the ICOR vs. notched fork.

#### Average Sample Size Comparison (mm<sup>2</sup>)



Fig 7. Average sample sizes obtained using ICOR vs. the notched fork calculated by width \* length from a top view perspective.



Fig 8. Sample collected using notched fork (~2mm width)

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Fig 4. Cryoprobe with extracted tissue sample stuck to the tip.



Fig 6. Sample removal with the notched fork requires use of both hands and much higher precision and care, so as not to flick the sample out of the cup during removal.

Fig 9. Sample collected using the ICOR (~4mm width)