DISRUPTIVE INNOVATION & POLICY IN CERVICAL CANCER SCREENING TECHNOLOGIES

Duke BASS CONNECTIONS

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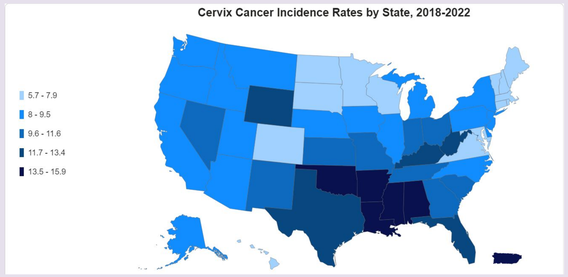
Health Policy & Innovation

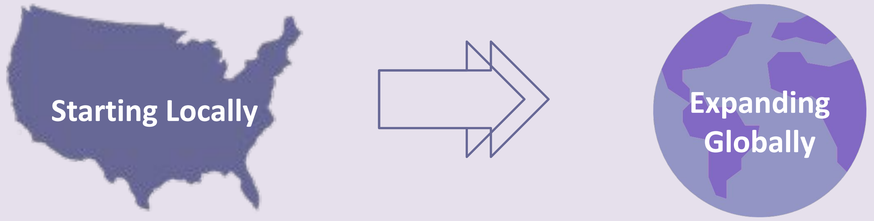
BACKGROUND

- Cervical cancer is the fourth most common cancer in women globally.[1]
- Cervical cancer is 15% less common in urban areas compared to rural areas.[2]



vaccinate → screen (HPV/Pap) → colposcope + biopsy → treatment & follow-up

TARGET MARKET



- Rural primary care providers (~95,000)[3]
- Healthcare deserts (~1,104 U.S. counties without OB or birthing facility)[4]
- Community Health Centers (~6,970)[5]
- Scaling portable colposcopy with HPV screening expansion
- Existing partnerships in Peru and Kenya

Competitive edge: Enables screening outside of clinics, expands use to frontline providers, low-cost and portable device
- 10x lower the cost of traditional colposcopes
- Proven globally with 150 devices in 10 countries with 10,000 patients

CALLASCOPE

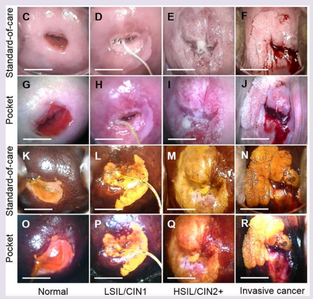
- Callascope: Gen II device that allows for **self-screening** without the use of a speculum.
- Regulatory pathway would track the Pocket Colposcope's, with distinction between provider-use vs. speculum-free self-use.
- Clear path to payment/reimbursement in the U.S. through existing coding

Regulatory Pathway

Clear for provider-use under Traditional 510(k) → Modify label to include self-use

POCKET COLPOSCOPE

- Low-cost, accessible, and hand-held



FDA 510(k)

FINANCIALS

Key Assumptions

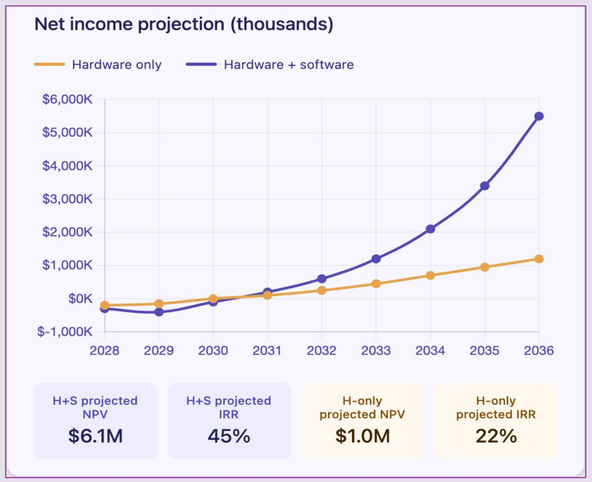
- 10-year project timeline with 12% cost of capital
- Hardware price: $1,500/unit
- Software price: ~$1,200 annual subscription fee

Hardware-only Model

Gross margin:
50% early, ~80% at scale

Hardware + Software Model

Gross margin:
~64% early, ~78% at scale



OBJECTIVES AND TEAMS

- **OBJECTIVE:** To research how the Pocket Colposcope and Callascope can address local gaps that limit access to cervical cancer prevention in the U.S.
- **Teams:** Marketing, Business Strategy, and Regulatory

FUTURE STEPS

- Implement more Pocket Colposcopes, with focus on low-income and rural areas.
- FDA-clear the Callascope.
- Conduct focus groups with Radical Healing to see how the Callascope can work with transgender and non-binary populations.
- Expand to maternal health applications.
- Expand on initial conversations with providers through research surveys.

RADICAL HEALING

Sources:
[1]World Health Organization (Dec. 2, 2025); [2]Indira Zhetpisbayeva, *Annals of Global Health* (Nov. 1, 2023), PMID: 37928103; [3]Health Resources and Services Administration (Dec. 2025); [4]March of Dimes, Nowhere to Go: Maternity Care Deserts Across the U.S. (2024); [5]National Association of Community Health Centers (Dec. 2024)