# From Light to Insight: Imaging System Prototyping for MedTech Startups

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# About Optikos

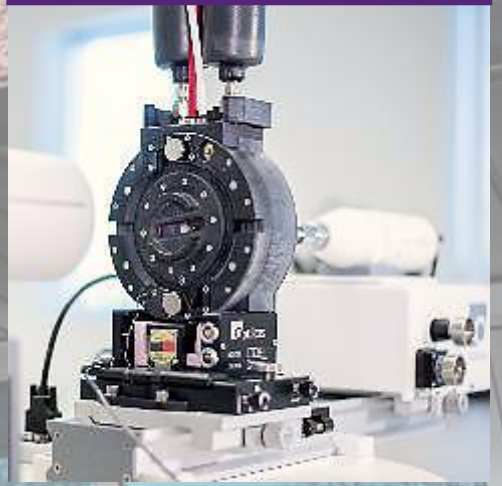
- 40+ Years in business
- Located in Wakefield, MA
- Hardcore optical engineering company
- Products and services
- ISO 9001 and ISO 13485

**Product Development**

**Contract Manufacturing**

**Metrology Products**

**Testing Services**



# About Lumicell and Initial Target

At Lumicell, our mission is to improve the way cancer surgery is performed, starting with breast cancer.

**> 300,000** **women estimated to be diagnosed with breast cancer in US in 2023[1]**

**~ 43,000** **patients will die from breast cancer each year in US[1]**

**> 180,000** **patients undergo lumpectomy each year in US[2]**

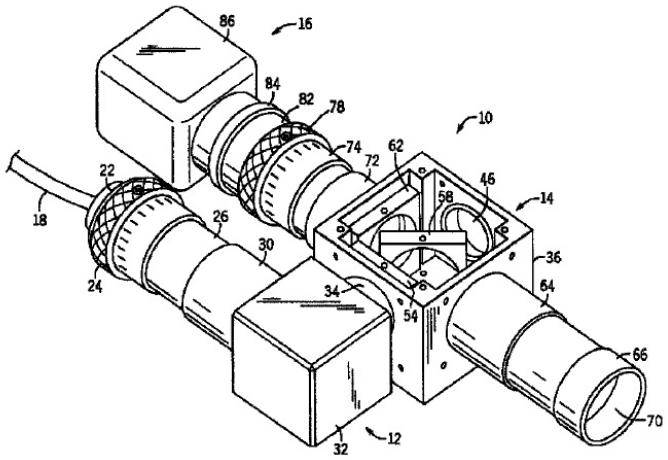
1. American Cancer Society, 2023; 2. National Cancer Database - Accessed 2023

Unmet need: Current tools limited and do not identify extent of tumor accurately enough, making it challenging to achieve complete tumor resection

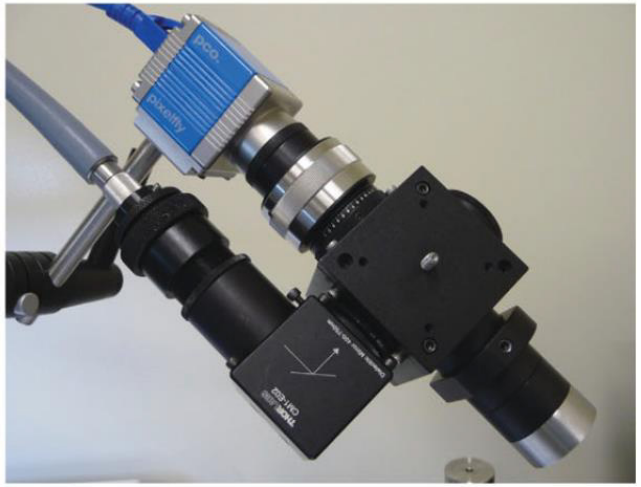
# Lumicell Approach

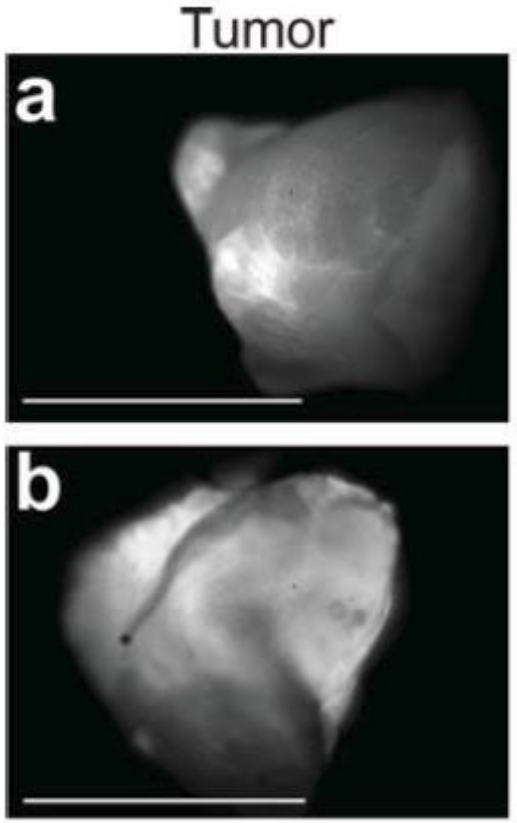
Develop fluorescent imaging agent to target tumor and imaging device to collect its signal to direct surgeons to cancer that would be left behind

- Early concept borne out of MIT: off-the-shelf components for mouse studies




Patent 8983581 (MIT)





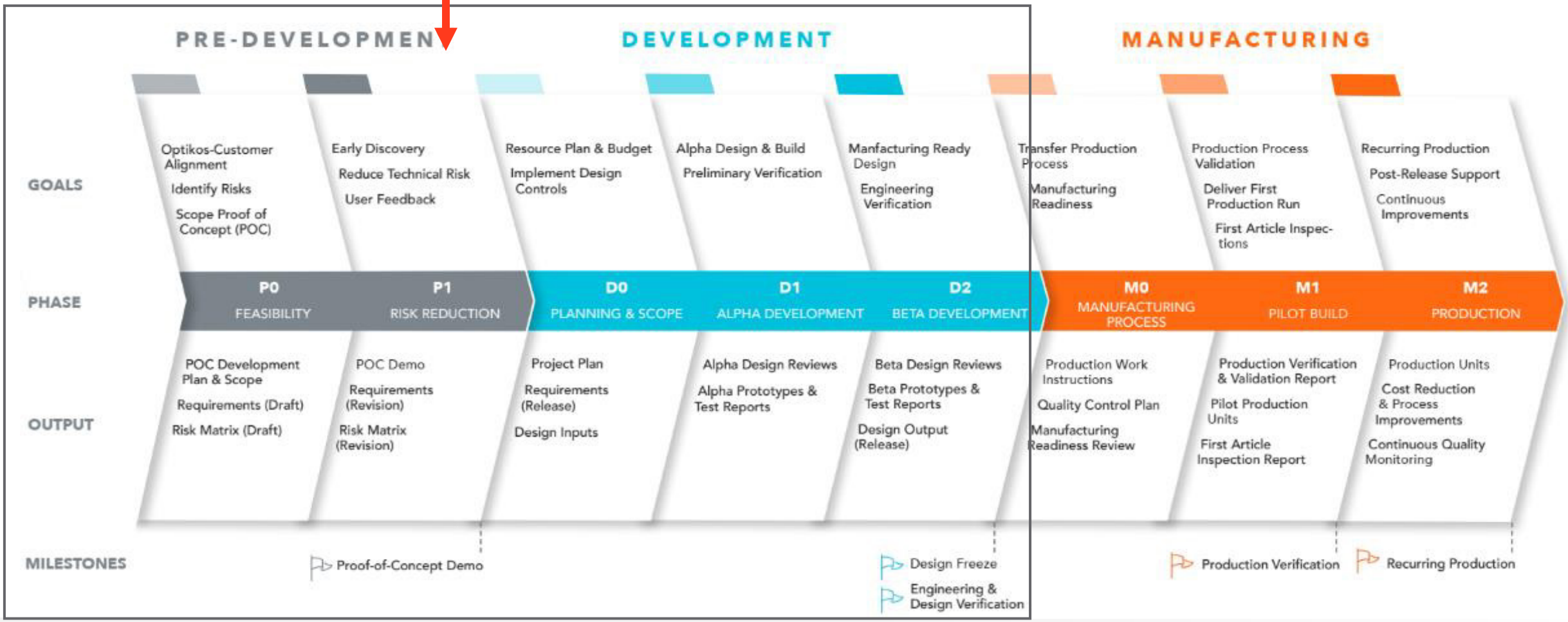

Mito, et al., Cancer; 2012

# Working with Lumicell – Development of the Handheld Device

Lumicell

Optikos Engagement

Optikos & Lumicell

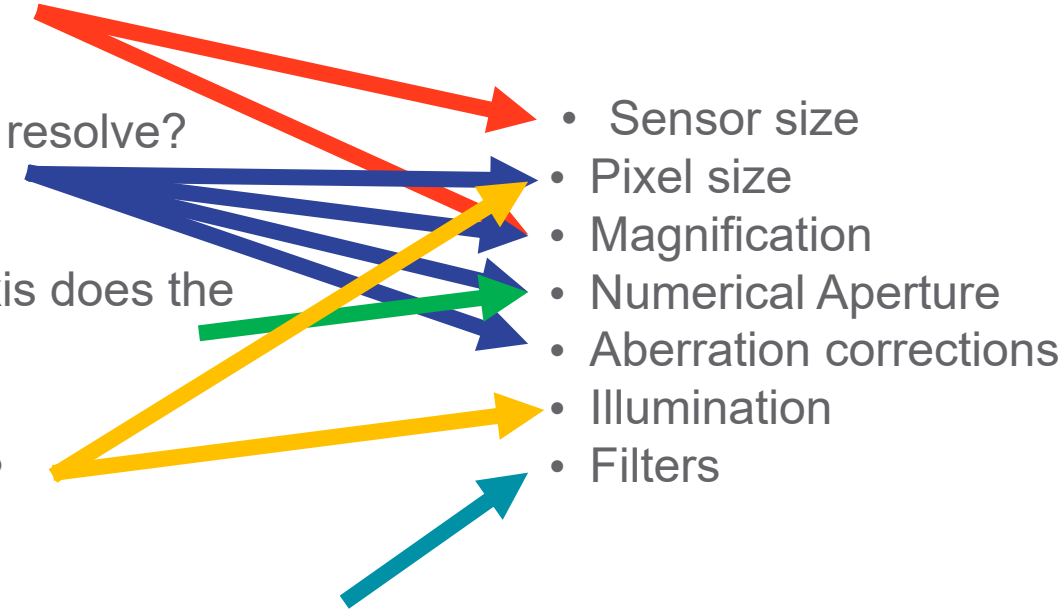


# First Order Optical Design Considerations

Brief overview of some basic optical concepts

# First Order Performance Goals

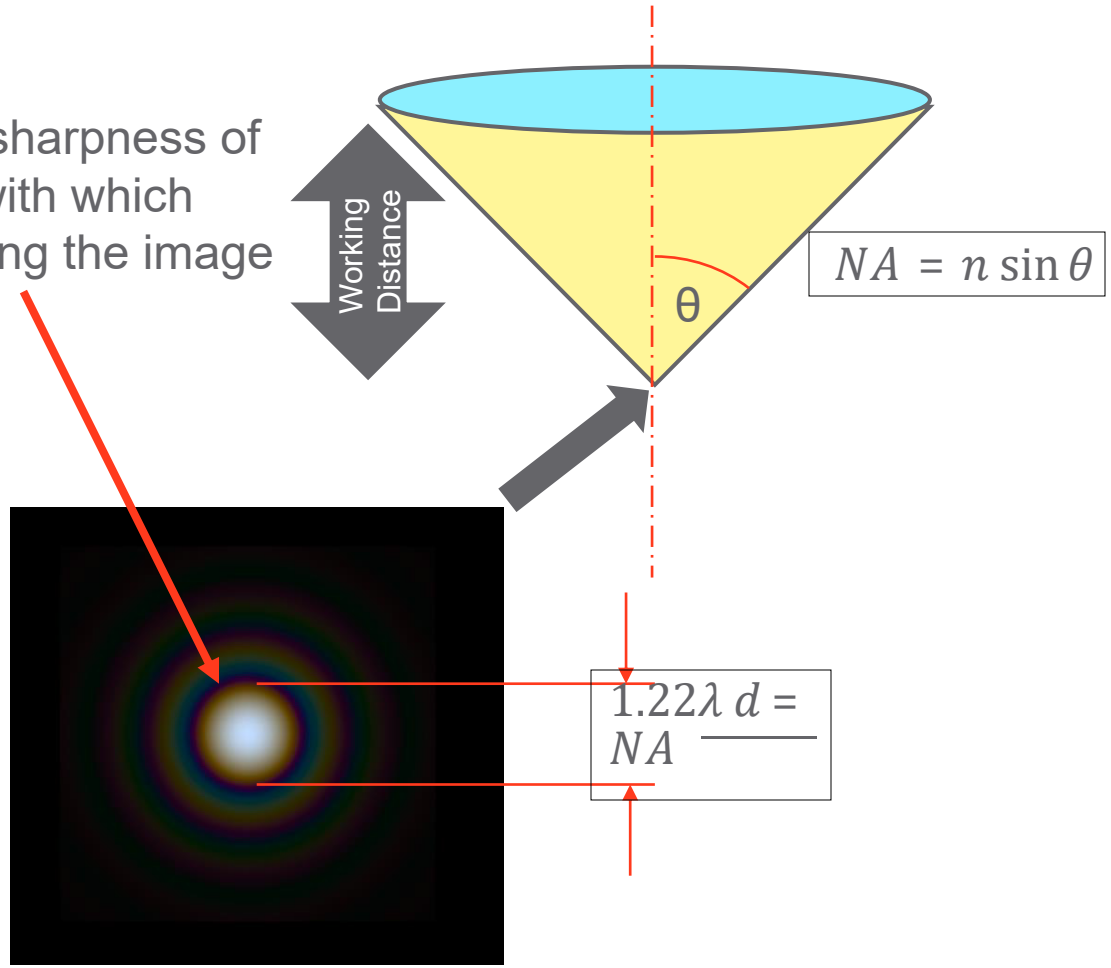
- Field of view How big is the area that we want to image?
- Resolution What is the smallest detail 7 we need to resolve?
- Depth of field — How far along the optical axis does the resolution need to hold up?
- Sensitivity — What is the photon budget?
- Spectral considerations — What is the bandwidth and separation of the excitation and emission spectra?



- Sensor size
- Pixel size
- Magnification
- Numerical Aperture
- Aberration corrections
- Illumination
- Filters

# Optical Resolution Tradeoffs – Numerical Aperture (NA)

This is the sharpness of the pencil with which we're drawing the image



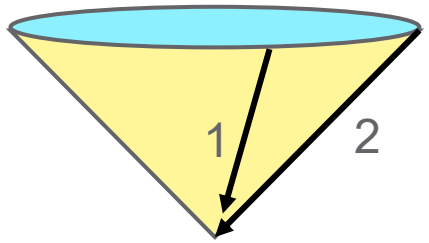

Higher NA → Higher Resolution


NA=0.95 (θ=72°, d=0.70μm @ 546nm)

At the image plane, d= 40 x 0.70μm = 28μm

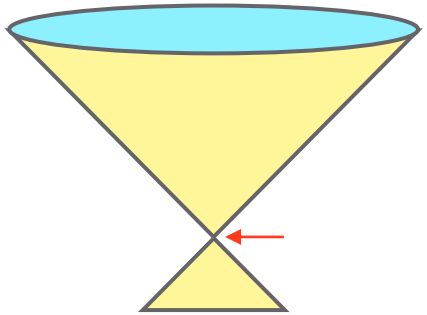
# Why Not Just Make All Lenses High NA and High Resolution?

1. The aberrations in Ray 2 are more difficult to correct than those in Ray 1



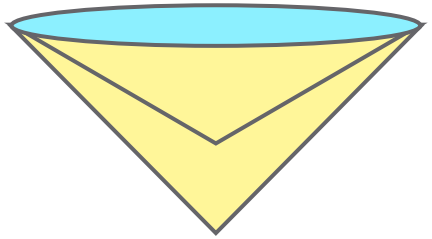

- More Expensive!
- More complicated design (more elements)
- Higher precision lens alignment required to achieve performance

2. The depth of field is shallower in high NA lenses



The spot diameter increases more rapidly with defocus for a larger cone angle/NA

3. Working distances get shorter or optics get larger in diameter with higher NA lenses



# How do I Build an Optical Assembly?


## Optics Sourcing

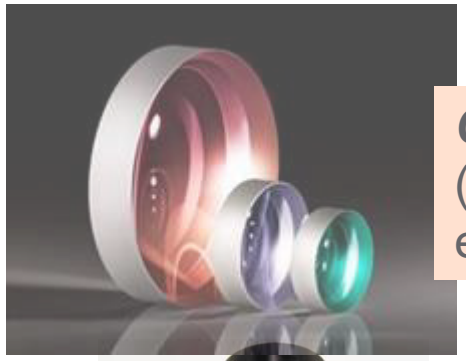
***Catalog lens assemblies***
(Photographic lenses, microscope objectives etc.)

## Pros

- Reasonable cost
- Rapid delivery
- Convenient precision

## Cons

- Fixed form factor
- Fixed optical parameters
- Mixed performance



***Catalog components***
(singlets, doublets, mirrors etc.)

- Modest cost
- Rapid delivery
- Flexible assembly options

- Limited design performance
- Modest fabricated performance
- Limited offerings

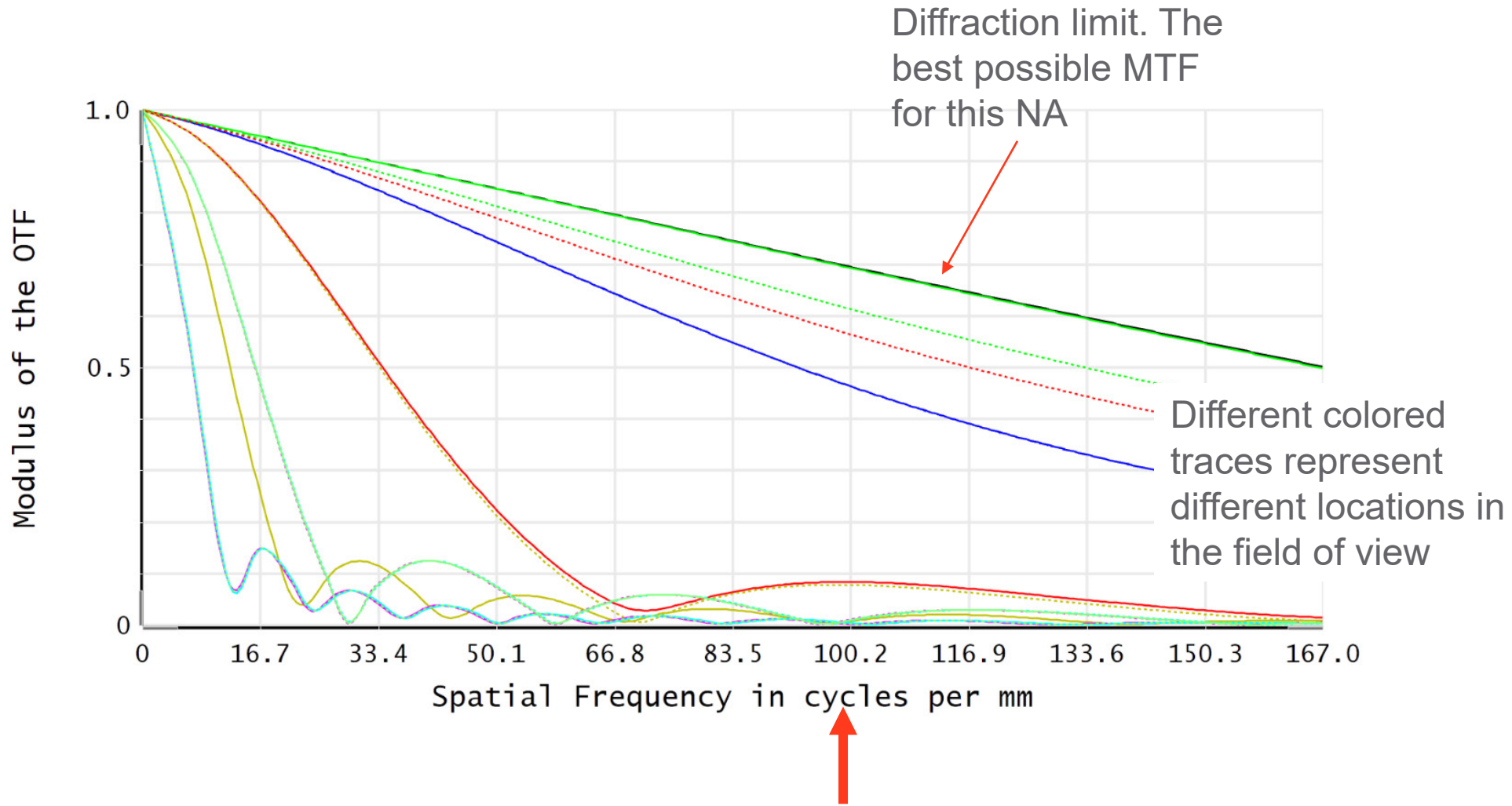

***Custom lens assemblies***

- Designed for purpose
- Assembled performance is controlled
- Potentially molded optics

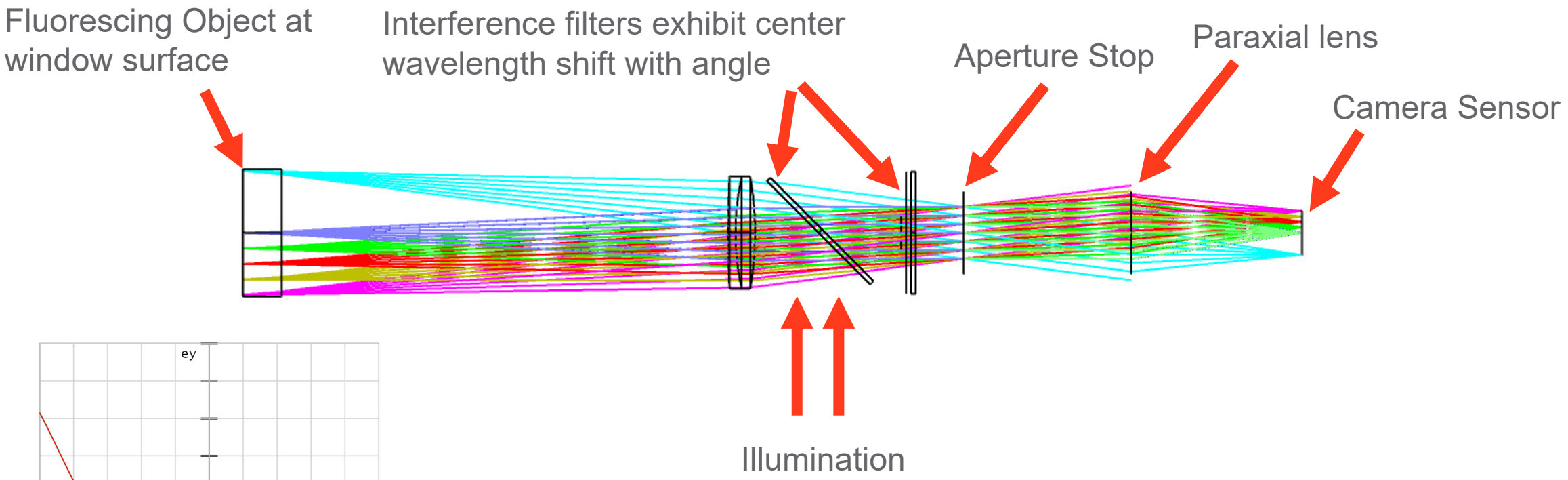
- Expensive in low volumes
- Long lead times

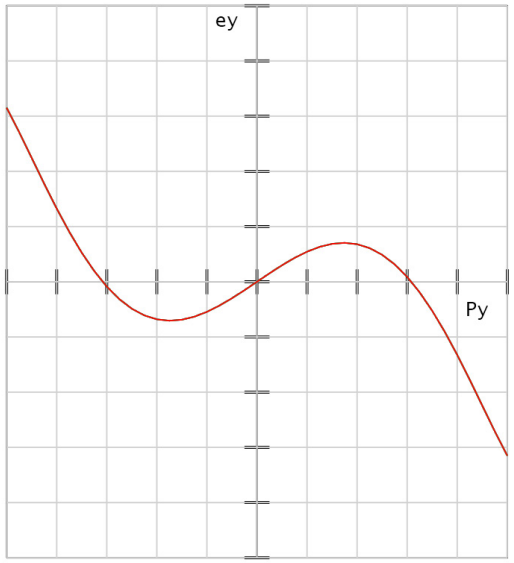
# Lens Resolution and MTF (Modulation Transfer Function)

MTF (often expressed as a percentage)



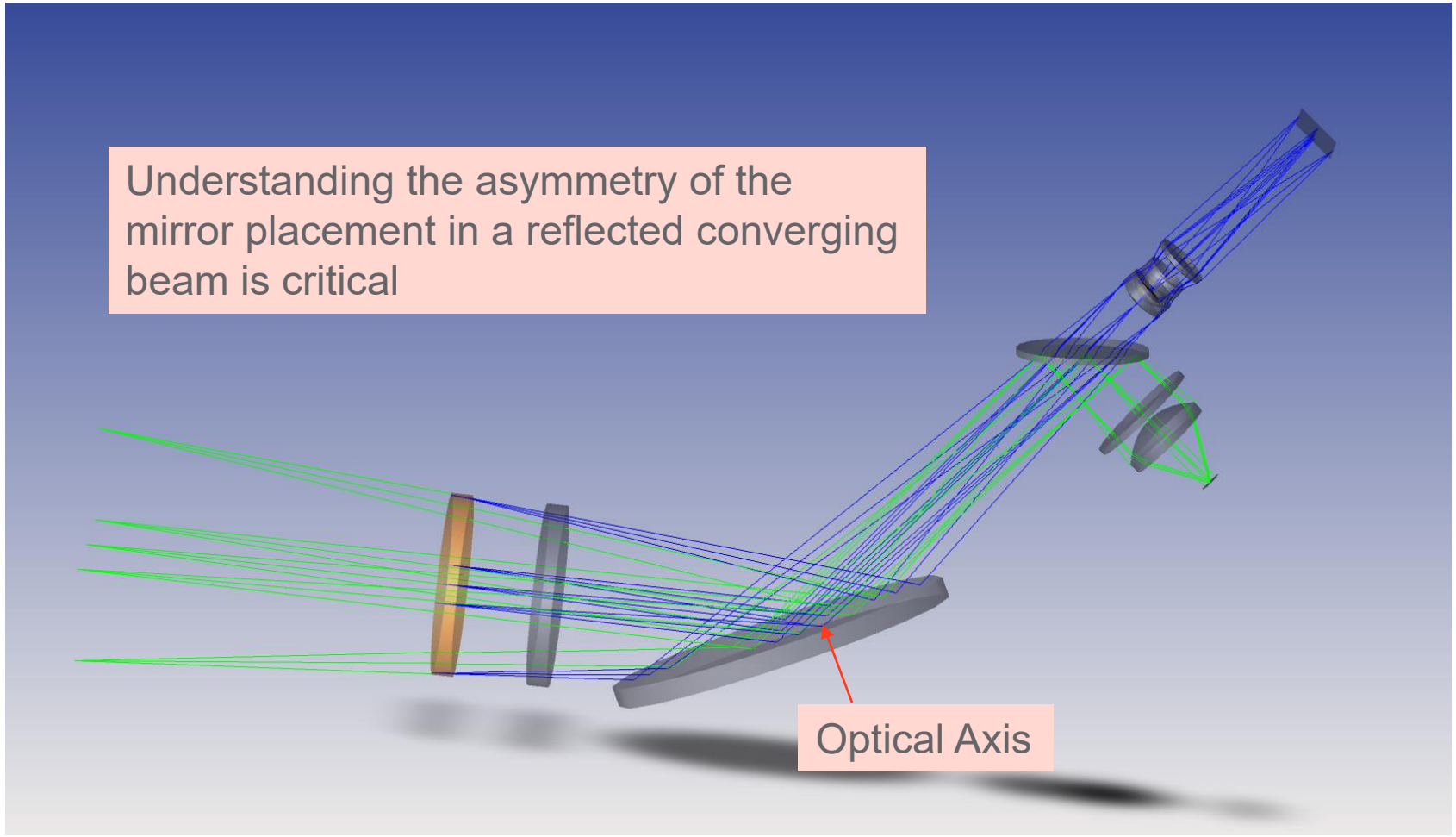
# Some Interesting Aspects of the Lumicell Optical Design




Beware plano parallel windows in converging beam – spherical aberration!

# Beam Folding in the Lumicell Optical Design



# Prototyping and Prep for Clinical Trials

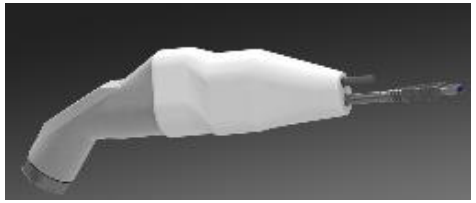
# Clinical Trial Readiness and Regulatory Path

- Transitioning from prototype to a clinically viable system
- Intended use to guide resections: Class III device (higher risk)
- No predicate device + Class III = PMA regulatory path
- Follow Design Controls Process, FDA guidance documents, regulations
  - Detailed documentation of design history files, user needs, design inputs, design outputs, verification, validations, risk evaluation, clinical trial reports, benefit-risk assessment
- Final submission: 11 volumes, several hundreds of thousands of [electronic] pages

# Development Process





2013 2014 2015 2016 2017 2018 2019 2020

Phase A + B (Jun 2015-Oct 2017)

Phase C (Feb 2018–Jun 2019)

Pivotal (Nov 2019-2022)

# Current State of Product (2025)

- Drug and Device FDA-approved since April 17, 2024!
- Initial commercial launch – currently in use at 11 hospitals across the US

## LUMISIGHT

### *Find*

Optical imaging agent that produces fluorescence signal at sites of residual cancer

## Lumicell Direct Visualization System (DVS)

+

### *Detect*

Hand-held imaging probe inserted into breast cavity to identify residual cancer

### *Guide*

Real-time cancer detection software guides surgeon to remove residual cancer

# Key Takeaways

- Partnering early in the development process was important
- Clear division of responsibilities based on capabilities and strengths
- Open sharing of information was very helpful
- Identifying what most was important in the instrument helped focus the design effort

Thank you!

# Q&A