



# Innovating Prostate & Bladder Cancer Treatment

enCAGE™ Therapy for Prostate Cancer  
i/Blue™ Visualization for Bladder Cancer

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# Imagin\* Business Overview

## *Innovating Prostate & Bladder Cancer Treatment*

- Disruptive products will dramatically improve prostate & bladder cancer treatment
- Option for hospital or physician office treatment improves economics for providers & increases the addressable market
- Over \$1B addressable market
- Development risk mitigated
- 11 issued patents
- Previously successful management team

\* Imagin Medical, Inc. is a development stage company with one 510(k) and does not currently have any other Medical Device Regulatory Approvals or Clearances to market products in any jurisdiction.

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### PROSTATE CANCER

#### **enCAGE Precision Ablation Therapy**

*Minimizes Erectile  
Dysfunction and  
Urinary Incontinence*

### BLADDER CANCER

#### **i/Blue Imaging System**

*Dramatically improves  
visualization, 33% more  
tumors found, recurrence  
rates reduced*



# Prostate Cancer

## U.S. Market Data

- 1 out of 7 men will be diagnosed
- 3.1M living with prostate cancer
- Over 268K new cases/year
- Over 34K deaths/year
- \$5-\$8B/year metastatic prostate cancer cost to Medicare, billions more for initial treatments

Prostate Cancer  
most prevalent  
cancer in men in  
the U.S.

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**Number 2** cancer  
deaths for men

# The New Standard of Care for Prostate Cancer

## Today's Standards of Care



## Today's Challenges:

- Important nerves immediately adjacent to tumors can be damaged
- Difficulty in controlling the treatment energy leads to energy damage beyond the margins of the tumor
- Erectile dysfunction and urinary incontinence are frequent side effects in these modalities

## The New Standard of Care: enCAGE Therapy

- enCAGE Coil creates a Faraday Cage effect “walling off” the delicate structures
- Radio Frequency (RF) energy within the coil, targets only the tumor
- Only the cancer is ablated. Erectile & urinary function are unimpaired
- Minimizes future costs to the healthcare system

## Faraday Cage Effect



# enCAGE Coil Disposable Kit & Generator

Electrodes, Introducer and Guide Template

## enCAGE Coil Electrode

*Contains RF energy within coil*



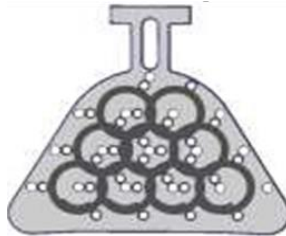
8mm, 10mm,  
12mm & 14mm

## Introducer



Enables better targeting of electrode

## Guide Template



Facilitates movement of electrode from ablation to ablation

## Works with...

### Imagin enCAGE RF Generator



Automated control based on impedance monitoring

*\*Works with commercially available Navigation Systems*



# Imagin Medical enCAGE Therapy

## Clinical Status

Clinical studies completed using current device to ablate prostate tissue. 20 patients evaluated at University College London. Dr. Mark Emberton, Dr. Clement Orczyk.

Editorial Comment from *The Journal of Urology* which said: The clinical data from **early-stage trials of, essentially, a prototype was excellent.** Of particular interest...

*“Coil RFA with the **enCAGE device is a unique option** for focal prostate ablation. With transperineal insertion, and **ablation limited to the coil cage**, treatments can be applied to both anterior and posterior lesions with minimal chance of ablating nearby vital structures.*

*In this series of 20 men with intermediate risk prostate cancer, no grade 3-5 adverse events were reported, and 15 men had complete absence of any cancer at the 6-month biopsy. This is impressive considering that it was the first of its kind experience and post-treatment biopsy was mandated and thorough, with a median of 6 cores from the treatment site, which is beyond the approach of most focal therapy series. The success may in large part be due to the ingenious approach of adding extra needles to pull the energy outside the coil...”*

## FDA Status

- 510(k) clearance for general soft tissue ablation
- Tissue ablation, as a specific indication for prostate ablation requires FDA clearance under Class 11 De Novo
- Pre-Submission meeting with FDA, approved enCAGE DeNovo clinical study plan

## FDA Action

- Submit Special 510(k) for refined enCAGE for soft tissue indication
- Submit formal applications for prostate labeling when verification testing is complete



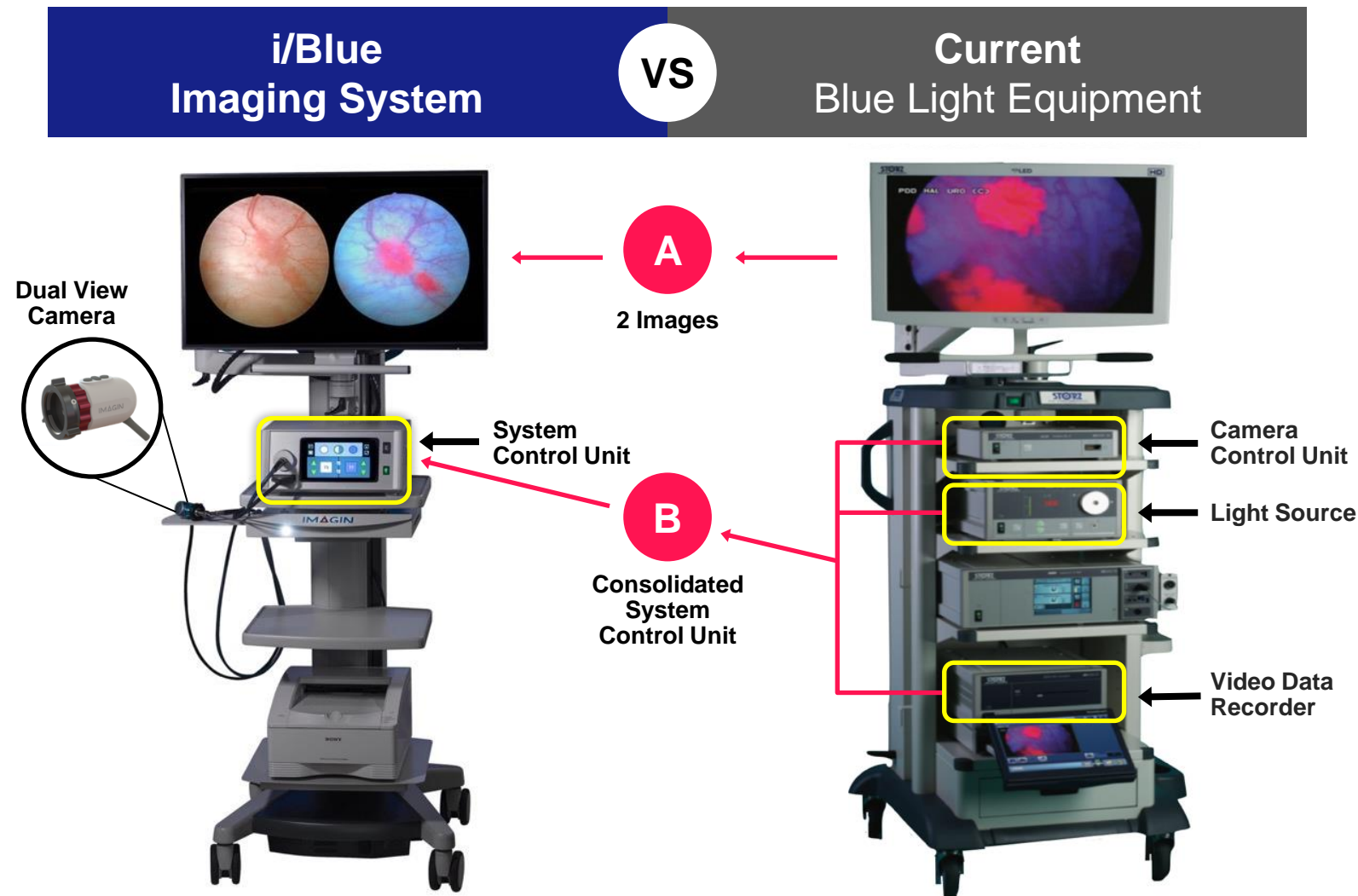
# i/Blue™ Imaging System for Bladder Cancer

## Next Program

# i/Blue Imaging System vs. Current Systems

## Exceptional Clinical & Economic Value Proposition

- Enables physician to view two images on one monitor vs having to switch back forth. Improves clinical results & reduces procedure time (A)
- i/Blue miniaturizes and consolidates System Control Unit into one state-of-the-art optical system (B)
- Leads to significantly reduced manufacturing & acquisition cost
- Attaches to most endoscopes on the market, enabling hospitals to use equipment they already own, saving significant cost



# Imagin\* Business Overview

## Who We Are

### Management Team

**Jim Hutchens**

President & CEO

**Boston  
Scientific**

**Smith+Nephew**

**Venture Capital  
Early-Stage**

**John Vacha, CPA**

CFO

**Deloitte  
& Touche**

**intact™**

(sold to Medtronic)

**Mike Vergano**

Director of Operations

**Boston  
Scientific**

**Corning  
Diagnostic**

**Microsurge**  
(all phases of project  
management)

**Sheila Heyer, J.D.**

Consultant QA/RA

**Boston  
Scientific**

**FDA**

### World Class Medical Advisors & SAB

- **Mark Emberton, MD, University College London**  
*Dean of faculty, Professor of Interventional Oncology, 500 peer reviewed papers, leading focal therapy proponent*
- **Ashish Kamat, MD, MD Anderson Cancer Center**  
*Professor of Urological Oncology, 300 peer reviewed papers, Expertscape rated #1 in bladder cancer*

# Thank You!

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