

Optiscan Imaging Ltd

Global Leader in Live Micro Imaging

Confocal Endomicroscope

Notice – Forward Looking Statements



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Optiscan Corporate Snapshot



Capital Structure	Number of Units	% of fully diluted	Notes
Ordinary Shares, ASX Code OIL (million)	376.1	93.7%	
Unlisted Options (million)	25.5	6.3%	Average exercise price \$0.062 (6.2 cents) Average expiry date 30 June 2019
Fully Diluted Shares (million)	401.6	100%	

Share Price Performance – prior 6 months



Market Cap and Liquidity	
Current Market Cap (as at 30 Jun 2017)	A\$36.9 million
Current Share Price	\$0.098
Twelve Month Range	\$0.027 - \$0.13
Average Turnover per day (last three months)	0.35 million

Major Shareholders	
Ian Mann	(11.1%)
Robert Peters	(6.7%)

New Leadership Structure since 2016



Archie Fraser



Alan Hoffman



Peter Delaney

- CEO Archie Fraser (ex Adecco, Inchcape, Cendant, St Kilda FC).
- Chairman Alan Hoffman (ex Shell, Wesfarmers, Coventry)
- CTO Peter Delaney (Founder, Technology and Applications Specialist)
- Strong focus on commercial outcomes from A\$100m historical investment

Value Added to Market Cap Since July 2016



- Jul-16 \$750k raised @2.5c Market Cap \$6.3m
- Stock was suspended on ASX at 2.0c
- Sep-16 \$1.41m raised @2.5c Market Cap \$9.0m
- Stock lifted from suspension and relisted at 2.5c
- Dec-16 \$1.93m raised @5.0c Market Cap \$22.8m
- Apr-17 Market Cap \$48.0m
- 52 Week High Share Price of 13.0c

Confocal Endomicroscope

Who is Optiscan?



- Global leader in live micro imaging through its unique patented confocal laser endomicroscopy technology
- Based in Melbourne, Australia
- Trading on Australian Stock Exchange (ASX Code: OIL)
- Over AUD\$100m invested to date
- Launched 2nd generation Preclinical Research platform late 2016
- Preparing for launch of second-generation Clinical endomicroscope in 2017, in conjunction with Carl Zeiss Meditec (Germany)

Confocal Endomicroscope

Optiscan is a Global Leader in its Field



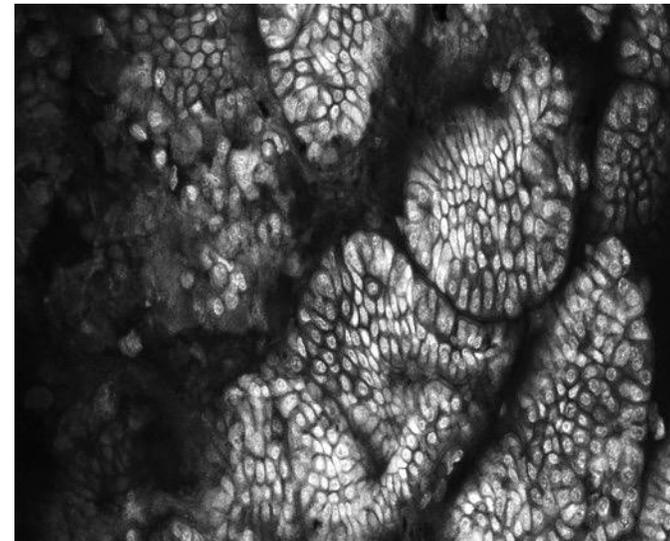
- Founded 1994, IPO on ASX 1997
- World's first confocal laser endomicroscope (CLE), 2001
- Licensed to Pentax (Japan) in 2002, launched globally 2006
- Pentax user base remains in place although product now obsolete
- Patented Point Scanning Confocal delivers stunning images
- Now preparing to launch 70% smaller 2nd generation device

Confocal Endomicroscope

What is a Confocal Laser Endomicroscope?

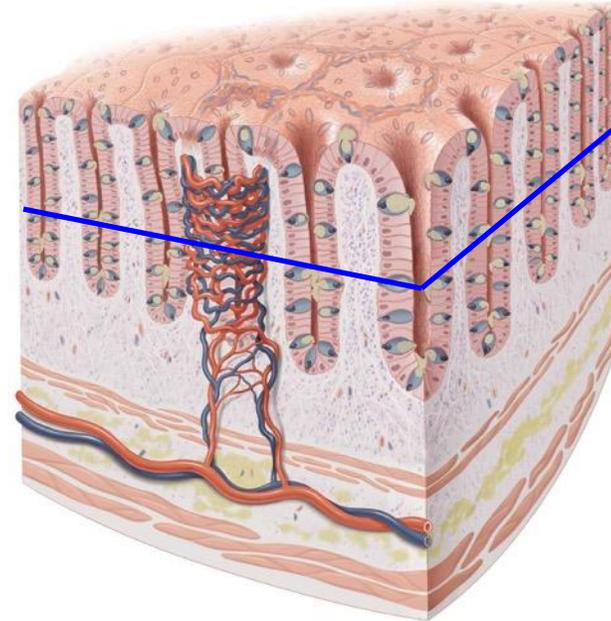
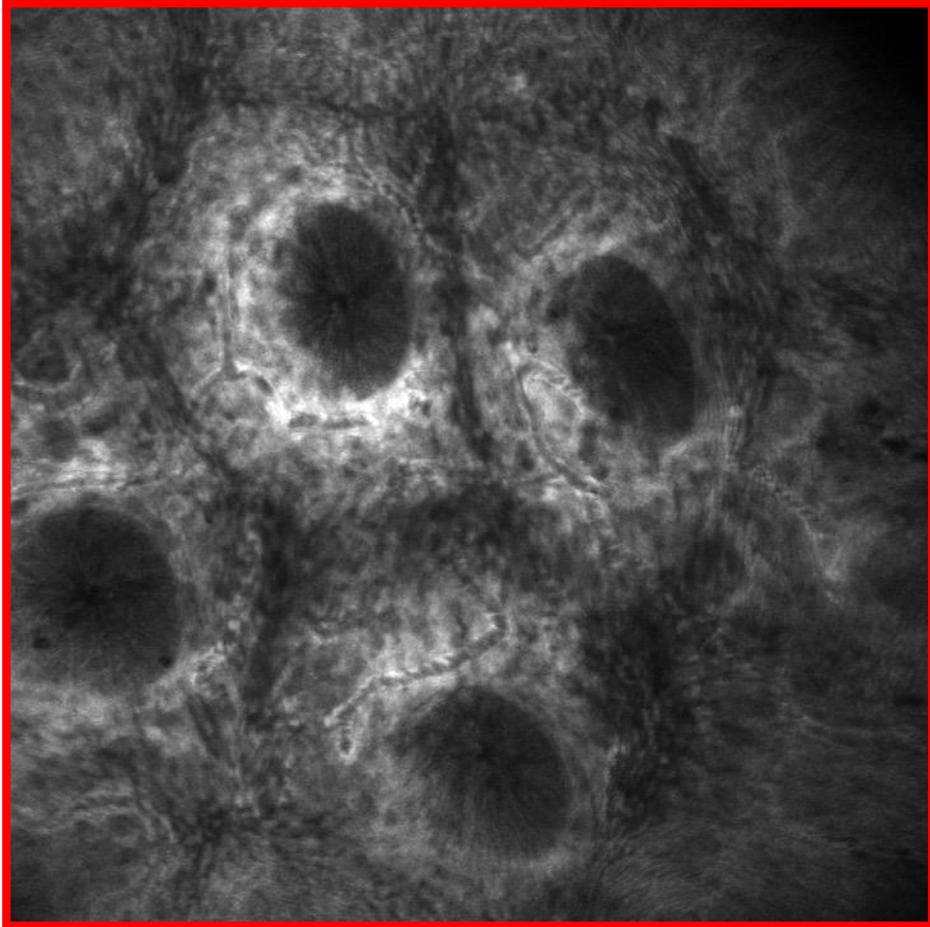


- “endo” = “inside”, so it is a microscope that can be used ***inside*** the living body
- Miniaturised microscope on the end of a flexible **single** optical fibre
- Utilises Confocal Technology
 - ‘Optical Sectioning’
 - Views in-focus structure
 - Rejects out of focus light
 - No physical tissue removal or processing
 - Microscopic imaging **in the living body**
 - Microscopic Imaging ***without biopsy***



Confocal Endomicroscope

Optical Sectioning Feature

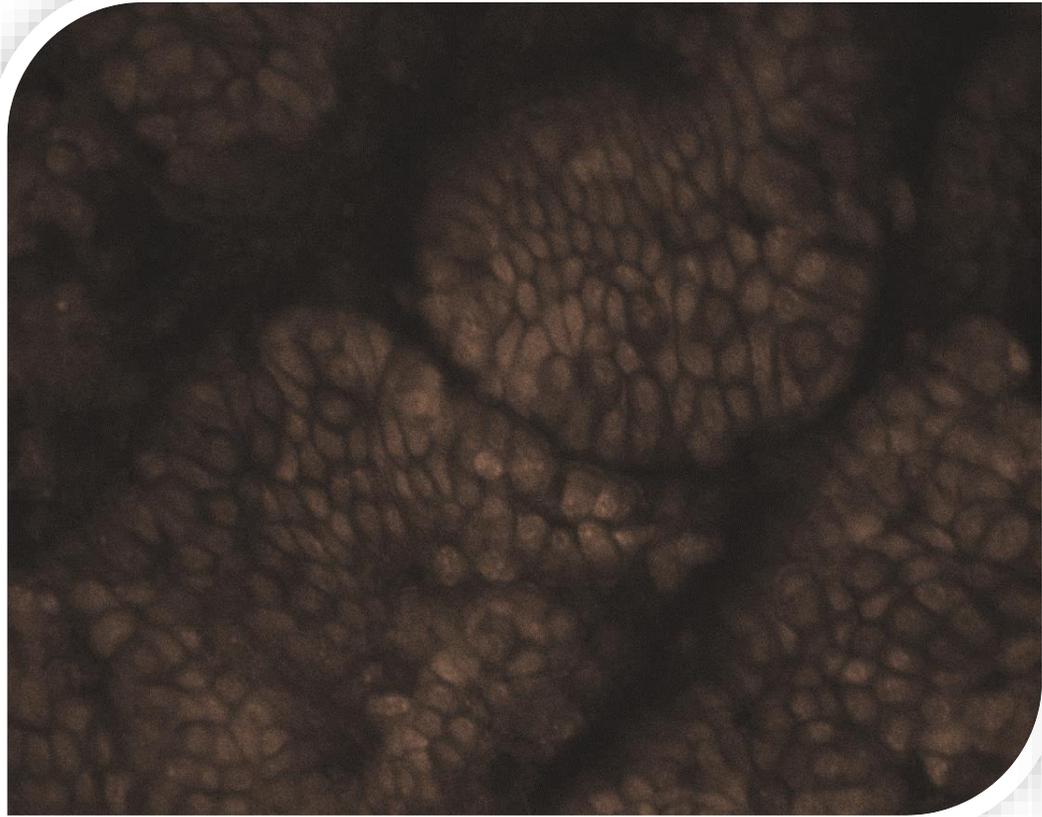


Confocal
Image
Plane

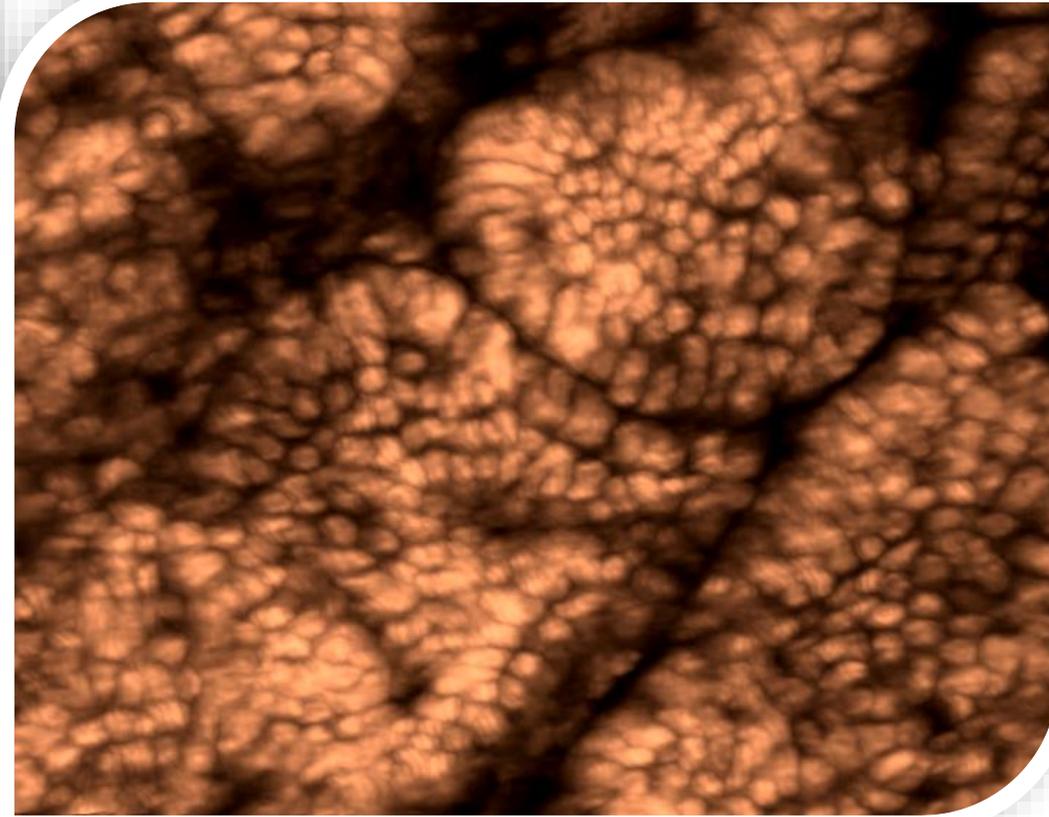
Surface to subsurface cellular imaging



Z-Stack Sequence



3D animation



Confocal Endomicroscope

What Competitors Don't Want You to Know

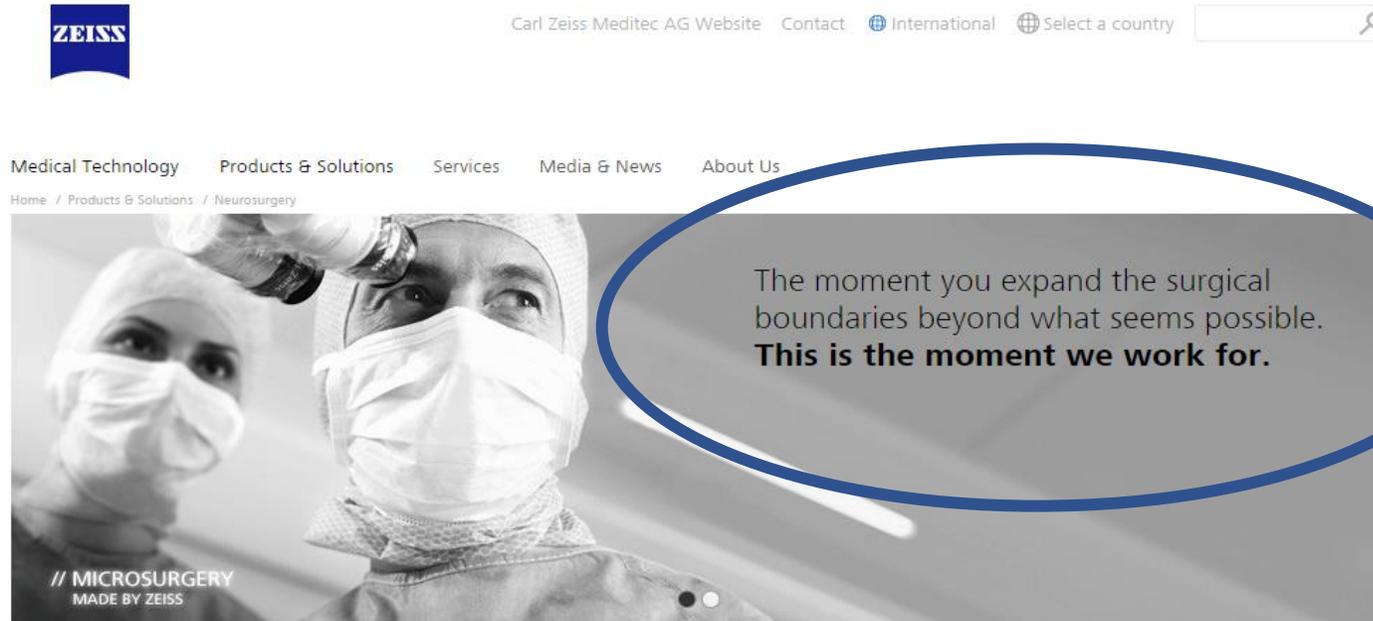
- The term “Endomicroscope” is used **very** broadly
- Nearest competitor offering based on fibre bundles:
 - 60 fold lower image information content
 - Lower resolution
 - Maximum 30,000 optical pixels (0.03 Megapixels), only a few thousand pixels for smaller probes.
 - There are gaps between pixels - like a microwave oven screen door
 - Separate probes must be used to spread this limited information over different magnifications
 - No variable imaging depth capability
- Optiscan’s technology yields full HD (2.1 Megapixels), across a variable field with interactive depth control
- Equivalent bundled fibre probe would be >15mm in diameter, and still would not replace “missing” data between pixels.

Carl Zeiss Meditec Partnership – Microsurgery



- Esteemed in optical imaging

- Market leader in neurosurgical visualisation



Neurosurgery

Countless neurosurgeries worldwide are performed on surgical microscopes from ZEISS – and for good reason. They are designed to suit the high demands of neurosurgery.



Surgical Microscopes

Optical precision, flexibility and ease of use in neurosurgery provided by surgical microscopes from ZEISS.

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Confocal Endomicroscope

Partnership with Carl Zeiss Meditec



- CZM FY16 revenue €1.09bn, EBIT €154m
- Major German optics company (Xetra: AFX), market cap €3.9bn
- No. 1 global player in surgical microscopes through Pentero and other brands (Estimated CZM market share >60%)
- Zeiss chose Optiscan's technology over any other technology available for good reason
- Collaborating on new rigid CLE device for neurosurgical use since mid-2007
- Pre-production systems have been shipped to Zeiss for FDA approval and early customer engagement

Confocal Endomicroscope

- Most critical surgical domain, where small surgical errors can have significant life altering impact
- The goal of surgery is to remove tumour, not brain
- Biopsies are problematic - margins often appear vague
- Real-time visualization with cellular detail creates transformative opportunities in Neurosurgery
- We believe this product will become the new gold standard

Optiscan's technology extends the boundary of neurosurgical visualisation

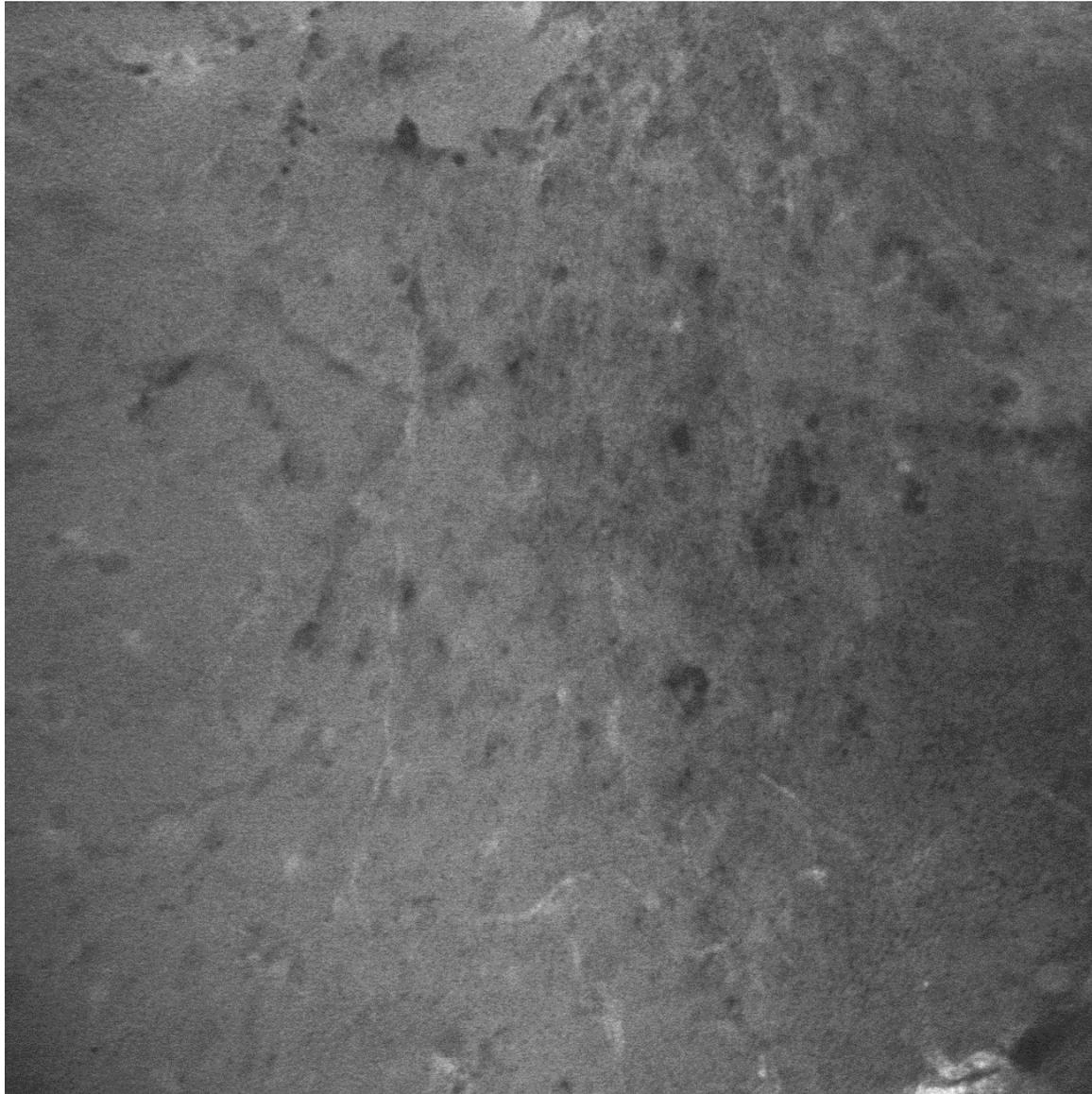


- By adding Optiscan's technology, the surgeon's armamentarium is extended to offer cellular detail
- This is unprecedented and perfectly aligned with Zeiss's mission

*Real-time microscopy provides the surgeon views of the cellular makeup of particular sites of interest during surgery **before** choosing sites for biopsy or finalising an assessment of tumour margins*

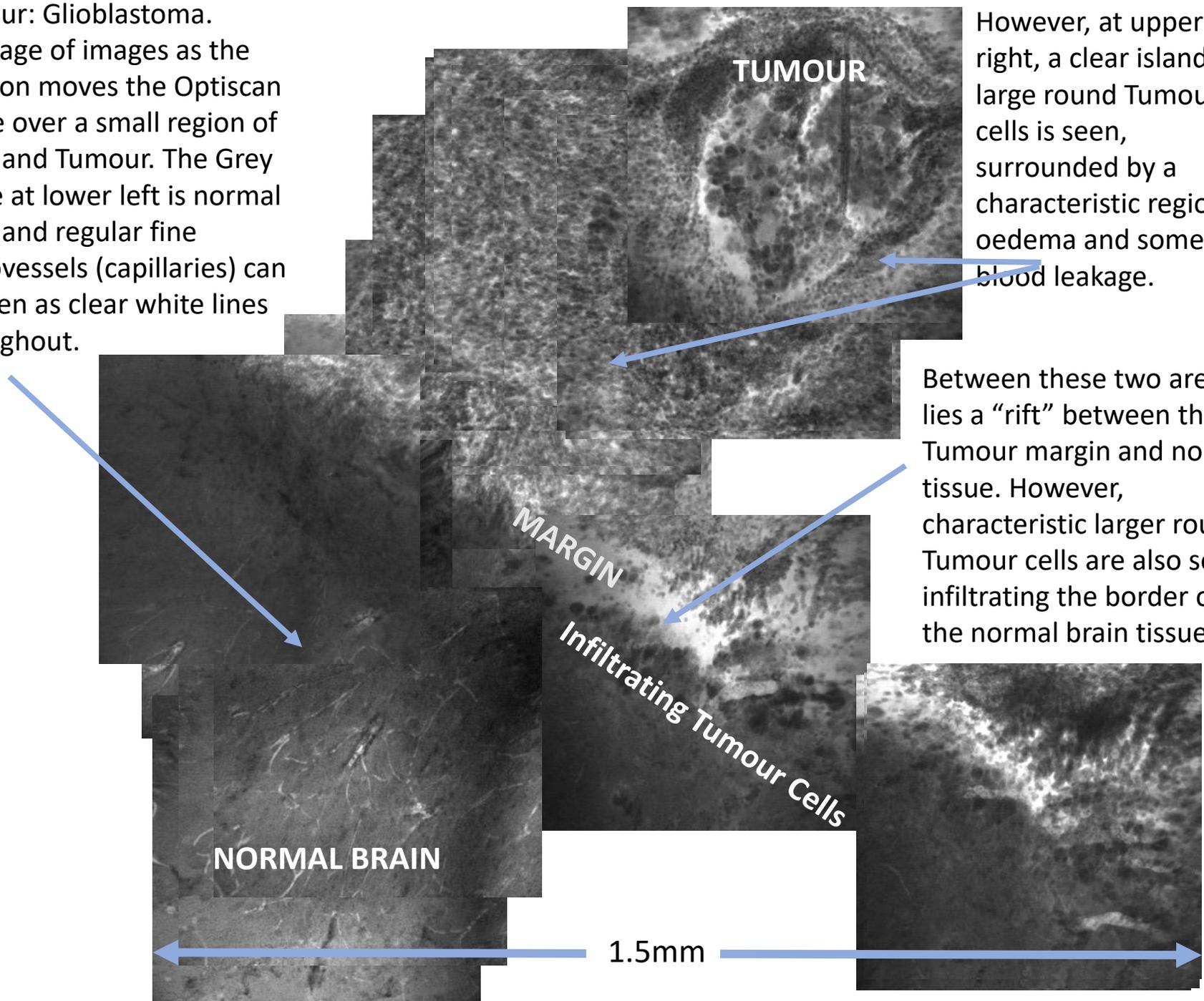
- The device is a rigid endoscope or hand-held probe placed directly onto tissue of interest
- Development details and specifications remain confidential
- Pre-clinical and clinical investigations have been published

Confocal Endomicroscope



- Video of live imaging
- Probe is moved across tissue
- Initially, tissue is normal
- Then, an island for cancer cells (glioblastoma) is clearly observed
- Finally, the surgeon moves between the two and finds the infiltrating margin of the tumour

Tumour: Glioblastoma.
Montage of images as the surgeon moves the Optiscan probe over a small region of brain and Tumour. The Grey tissue at lower left is normal brain and regular fine microvessels (capillaries) can be seen as clear white lines throughout.



However, at upper right, a clear island of large round Tumour cells is seen, surrounded by a characteristic region of oedema and some blood leakage.

Between these two areas lies a "rift" between the Tumour margin and normal tissue. However, characteristic larger round Tumour cells are also seen infiltrating the border of the normal brain tissue.

The Market Opportunity - Neurosurgery



- Expected to be ~27,110 new brain cancer cases per annum in the US and 80,000 new tumour cases overall⁴
- There are ~700,000 people living with a brain tumour in the USA⁴
- Brain metastases tend to double the cost of cancer care²
- Five year survival for brain cancer only averages ~35%³, so demand for new treatment modalities is strong

1 American Cancer Society, Cancer Facts and Figures; 2 Breast Cancer Res Treat. 2008 Mar;108(2):297-305. Epub 2007 Jun 19; 3 American Cancer Society, Cancer Facts and Figures. 4 American Brain Tumor Association

Incidence according to type

Overall incidence (new cases) of Primary Brain Tumour is 14 per 100,000 people or ~49,000 new cases per year in the USA (malignant and benign).

Meningiomas	36.6%	5 per 100,000 people
Gliomas	24.7%	3 to 4cases per 100,000
Glioblastoma	14.9%	2 cases per 100,000
Nerve Sheath Tumours e.g. Schwannomas	8.2%	1.2 per 100,000
Pituitary	14%	2 per 100,000

Prevalence according to type

- Overall prevalence (all people living with a tumour) of Primary Brain tumours is ~200 cases per 100,000 capita in the US¹ (~700,000 people)

Meningiomas	36.6%	73 per 100,000
Gliomas	24.7%	49 per 100,000
Glioblastoma	14.9%	30 per 100,000
Nerve Sheath Tumours e.g. Schwannomas	8.2%	10 per 100,000
Pituitary	14%	28 per 100,000

- Optiscan's technology is applicable to:
 - Meningiomas
 - Gliomas
 - Glioblastoma
 - Nerve sheath tumours
- These represent 84% of all tumour types

1. American Brain Tumor Association

The New Zeiss/Optiscan Collaboration Device

- Product development and early clinical work completed
- 130 clinical cases performed and data published
- Zeiss expects early uptake from key opinion leaders
- Optiscan will manufacture the confocal microscope components for sale to Zeiss

Confocal Endomicroscope

The Market Opportunity – Neurosurgery Summary

- Overall incidence of Primary Brain Tumour is 14 per 100,000
- Overall prevalence of 700,000 brain tumour cases in 2017, we estimate approximately 240,000* surgical procedures per annum are eligible to benefit from Optiscan's technology.
- Total Surgical Procedures in the USA is 67.7million per annum
- Total Procedure Volumes USA Neurosurgery of 1,150,900 per annum
- Neurosurgery procedure volume is just 1.7% of all surgical procedures carried out in the USA per annum
- * Based on 84.4% of craniotomy for tumour estimates of 285,000 procedures pa, and proportion of tumour surgeries against estimates of global neurosurgical procedure volumes.
- Refer: Barrow Neurological Institute

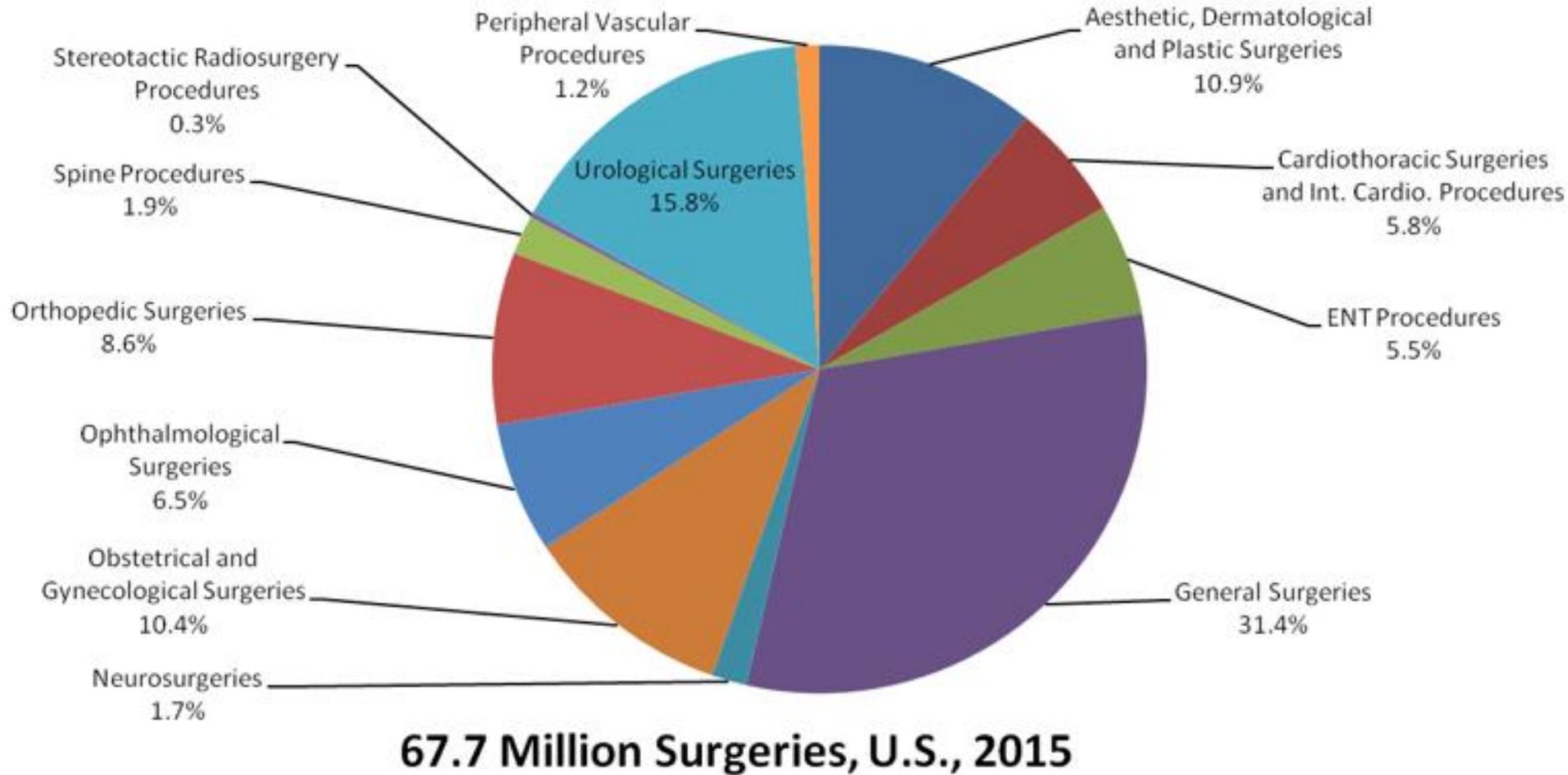
Neurosurgery Systems Estimates



- In the USA there are ~5,000 major surgical facilities
- In the USA there are ~1.15 million Neurosurgery procedures per annum
 - To cover the annual procedures volume in the USA @200 procedures per system, per annum, estimated that 5,754 fully operational systems would be required
- In the USA there are 1,276 dedicated Neurosurgery Centers
 - Estimated each would require between 2 to 4 systems each and 4 to 8 probes in each center
- In the USA there are 30 dedicated Neurosurgery Super Centers
 - Estimated each would require between 10 to 15 systems and 20 to 30 probes in each center
- Global Neurosurgery Market is estimated as potentially requiring between 8,556 and 16,662 systems
- Total Potential Major Market Estimates in Systems:

• US market	High 5,554	Low 2,852
• Europe market	High 5,554	Low 2,852
• Asia market	<u>High 5,554</u>	<u>Low 2,852</u>
• Total Potential Market Size	High 16,662	Low 8,556

Global Surgical Procedure Volumes*



** Excludes Gastrointestinal Endoscopy
(not surgically invasive)*

Gastrointestinal (GI) Endoscopy

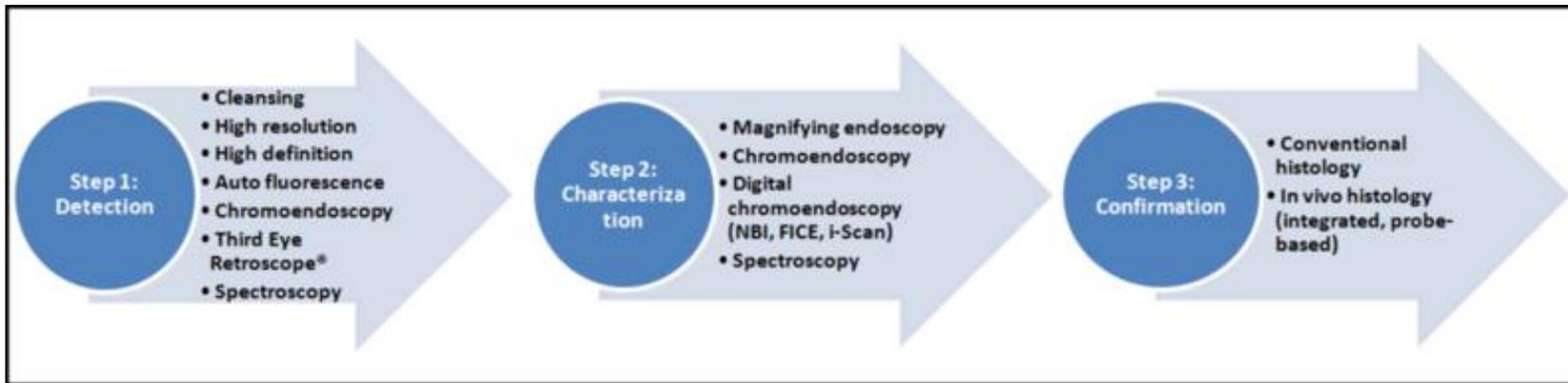


- GI endoscopy is considered outside of surgery (less invasive)
- Up to 14 million US procedures pa
- 2002: Optiscan partnered with Pentax (Japan)
 - AUD\$18M deal (3 equal components: up-front; license; equity)
 - Exclusive rights for flexible GI scopes
 - Based on Optiscan's first generation
- Product (Pentax ISC-1000) released 2006
- 100's clinical studies published with compelling clinical data
- 2007/8 Pentax was acquired and merged into Hoya, who did not take up Optiscan's 2nd generation system
- Stopped supplying in 2009 after ~150 systems installed globally

Confocal Endomicroscope

Endoscopic Process and Medical Need

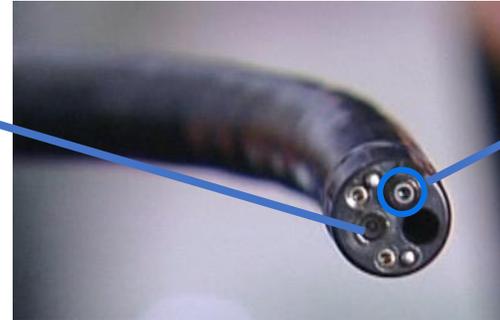
- Common endoscopic procedures involve 3 key steps:
 1. Detection of an area of interest
 2. Characterisation (i.e. a closer look)
 3. Confirmation – a firm cellular diagnosis



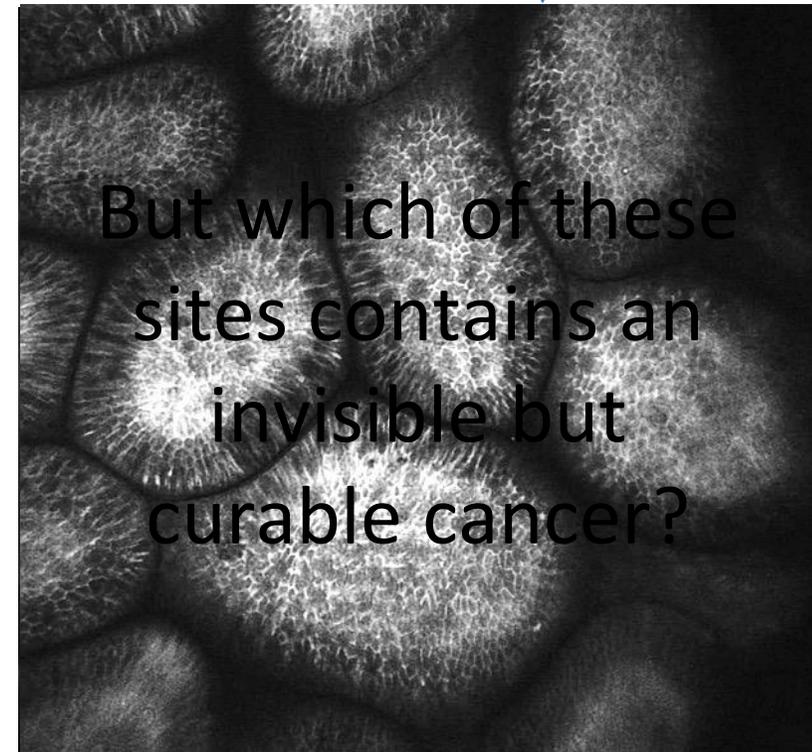
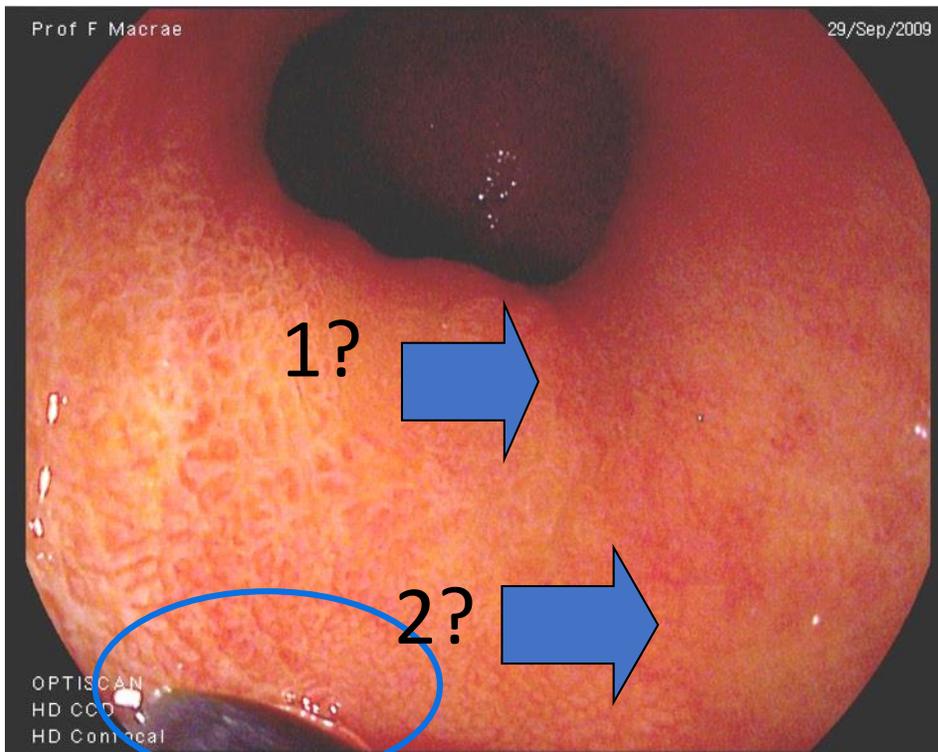
- Multiple techniques have crowded into the first two steps, but only endomicroscopy offers a cellular view comparable to conventional biopsy and histology

Endomicroscopy Workflow

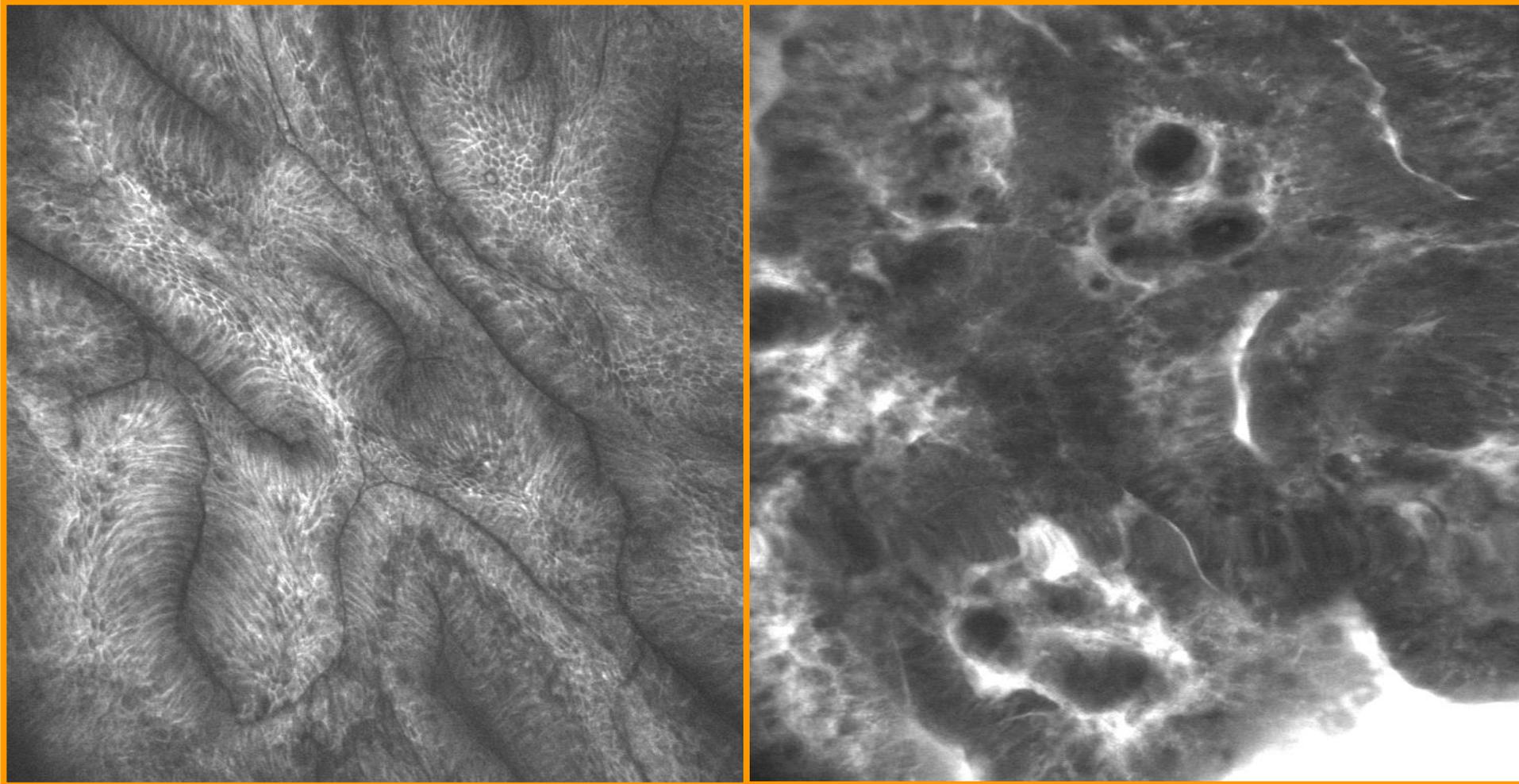
Conventional endoscopic view provides detection of areas of interest and initial characterisation



Optiscan's endomicroscope scanner provides fast scanning and ultra-high definition "virtual biopsies"



Barrett's Oesophagus and Barrett's Cancer



Site 1: Normal Barrett's Oesophagus

Site 2: Barrett's carcinoma (early cancer)

Images courtesy of Dr Ralf Kiesslich, Mainz University Hospital, Germany

Investor presentation - July 2017

Confocal Endomicroscope

Barrett's Oesophagus – a major opportunity



- >20% of the US population complain of regular heartburn
- >10% will suffer chronic heartburn (~34m people)
- Of these 10% will develop Barrett's oesophagus, requiring endoscopic surveillance due to increased cancer risk
- Sites of early cancer (while still curable) are difficult to identify
- So, many biopsies were required
 - Standard of care was for 2cm quadrant biopsy
 - **inefficient & ineffective**
- Opportunity = ~3.4 million procedures pa
- Optiscan's technology has changed clinical practice...

Changing Clinical Practice (Barrett's Oesophagus)



ARTICLE IN PRESS

ORIGINAL ARTICLE

In vivo endomicroscopy improves detection of Barrett's esophagus-related neoplasia: a multicenter international randomized controlled trial (with video)

Marcia Irene Canto, MD, MHS,¹ Sharmila Anandasabapathy, MD,² William Brugge, MD,³ Gary W. Falk, MD,⁴ Kerry B. Dunbar, MD, PhD,⁵ Zhe Zhang, PhD,⁶ Kevin Woods, MD, MPH,⁷ Jose Antonio Almario, BS, MHS,⁸ Ursula Schell, BS,⁹ John Goldblum, MD,⁹ Anirban Maitra, MD,¹⁰ Elizabeth Montgomery, MD,¹⁰ Ralf Kiesslich, MD, PhD,⁸ for the Confocal Endomicroscopy for Barrett's Esophagus or Confocal Endomicroscopy for Barrett's Esophagus (CEBE) Trial Group
Baltimore, Maryland, USA

Background: Confocal laser endomicroscopy (CLE) enables in vivo microscopic imaging of the GI tract mucosa. However, there are limited data on endoscope-based CLE (eCLE) for imaging Barrett's esophagus (BE).

Objective: To compare high-definition white-light endoscopy (HDWLE) alone with random biopsy (RB) and HDWLE + eCLE and targeted biopsy (TB) for diagnosis of BE neoplasia.

Design: Multicenter, randomized, controlled trial.

Setting: Academic medical centers.

Patients: Adult patients with BE undergoing routine surveillance or referred for early neoplasia.

Intervention: Patients were randomized to HDWLE + RB (group 1) or HDWLE + eCLE + TB (group 2). Real-time diagnoses and management plans were recorded after HDWLE in both groups and after eCLE in group 2. Blinded expert pathology diagnosis was the reference standard.

Main Outcome Measurements: Diagnostic yield, performance characteristics, clinical impact.

Results: A total of 192 patients with BE were studied. HDWLE + eCLE + TB led to a lower number of mucosal biopsies and higher diagnostic yield for neoplasia (34% vs 7%; $P < .0001$), compared with HDWLE + RB but with comparable accuracy. HDWLE + eCLE + TB tripled the diagnostic yield for neoplasia (22% vs 6%; $P = .002$) and would have obviated the need for any biopsy in 65% of patients. The addition of eCLE to HDWLE increased the sensitivity for neoplasia detection to 96% from 40% ($P < .0001$) without significant reduction in specificity. In vivo CLE changed the treatment plan in 36% of patients.

Limitations: Tertiary-care referral centers and expert endoscopists limit generalizability.

Conclusion: Real-time eCLE and TB after HDWLE can improve the diagnostic yield and accuracy for neoplasia and significantly impact in vivo decision making by altering the diagnosis and guiding therapy. (Clinical trial registration number: NCT01124214.) (Gastrointest Endosc 2013; **■**:1-11.)

Gastrointestinal Endoscopy, 2013

- GI User base has used the Optiscan-Pentax product to change clinical practice
- American Society for Gastrointestinal endoscopy (ASGE) funded landmark trial (see at left)
- 2013 – results published in GIE (level 1 evidence)
- 2014 – 3 category I CPT codes put in place
- 2014 – Reimbursement established for CPT codes
- 2015 - ASGE evaluates Optiscan's technology vs competitors as the only Endomicroscope meeting their PIVI (acceptance) guidelines
- 2016 ASGE releases new Barrett's esophagus practice guidelines recommendation for adoption



Confocal Endomicroscope

GI Endomicroscopy

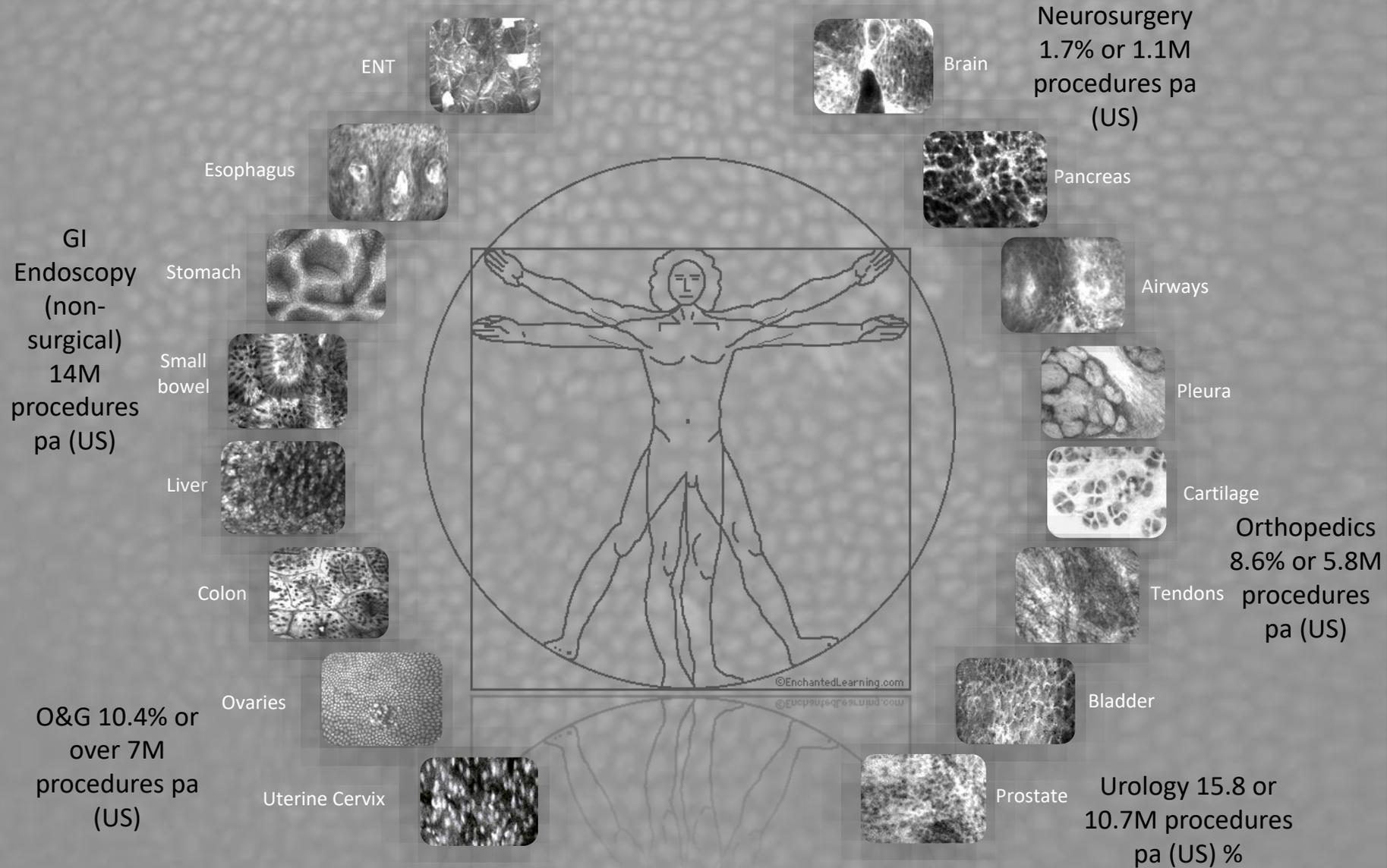


- Largest market opportunity for Optiscan
- Multiple clinical indications for use
- **3 Category 1 CPT codes in place**
- Reimbursement in place
- Optiscan offers compelling technical leadership
- Highest level clinical results support Optiscan's technology



Confocal Endomicroscope

- Platform Technology – applicable to any field of endoscopy/surgery
- Strong clinical evidence already established in several fields

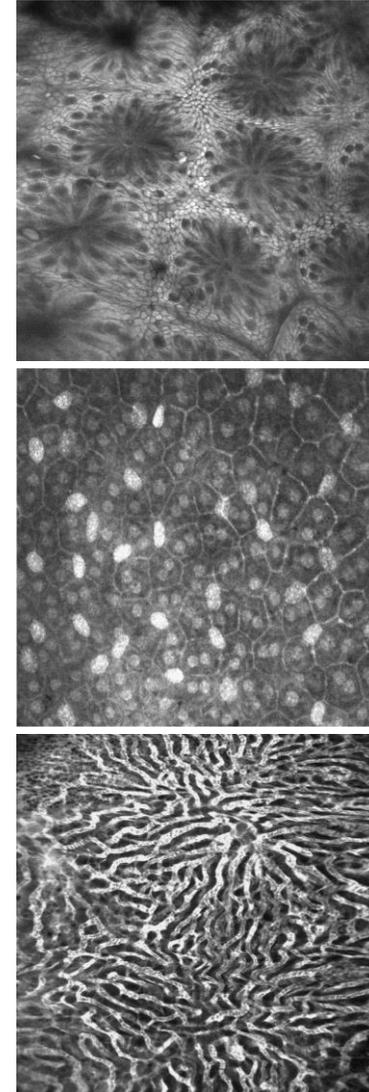


View*n*VIVO

Optiscan's next generation of
incredible imaging capability and
flexibility for Preclinical Research

Preclinical Research

- Preclinical Research is where it all starts and is the proving ground for Clinical applications
- Non-human use is the training ground for Clinical e.g. Neurosurgery
- Optiscan started its life in Preclinical Research, and remains committed to the Preclinical Research market
- Multiple Publications utilising Optiscan technology
- Broad range of biological applications enabled by numerous fluorescent dyes and only limited by Researchers imagination
- Benchtop optical systems estimated to be a US\$1.5B global market



ViewnVIVO Overview

Preclinical Research Product

- Latest Generation Imaging Platform
- Miniaturised Confocal Endomicroscope
- Low Laser Power – High Sensitivity
- Precise Optical Sectioning
- For use in Preclinical Research (Animal Models)
- Of Living Tissue within a Living Animal
- To Directly Observe ‘Systems Biology’
- In Submicron Detail

Confocal Endomicroscope



ViewnVivo B30 Configuration

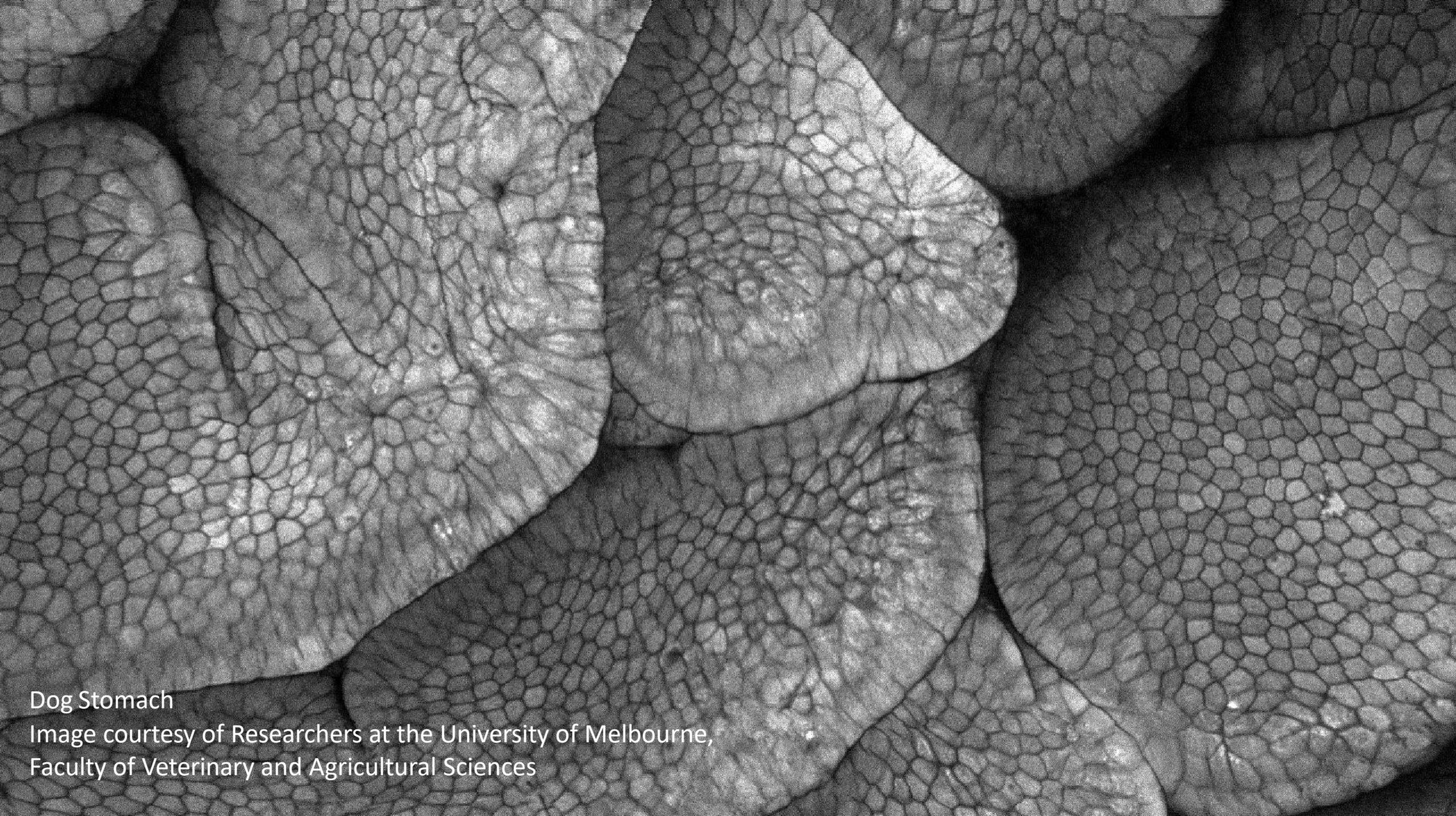


ViewnVivo Features

Take Imaging to the Model

- **Flexibility**
- Stunning Image Quality
- Enable In Vivo Imaging
- Move from Intravital to true In Vivo
- Enable Longitudinal Studies
- Reduced terminal outcomes ((of animal model)
- Small Space Requirement and No Dedicated Technician
- Ease of Use
- Time to Productivity
- Portability

Confocal Endomicroscope

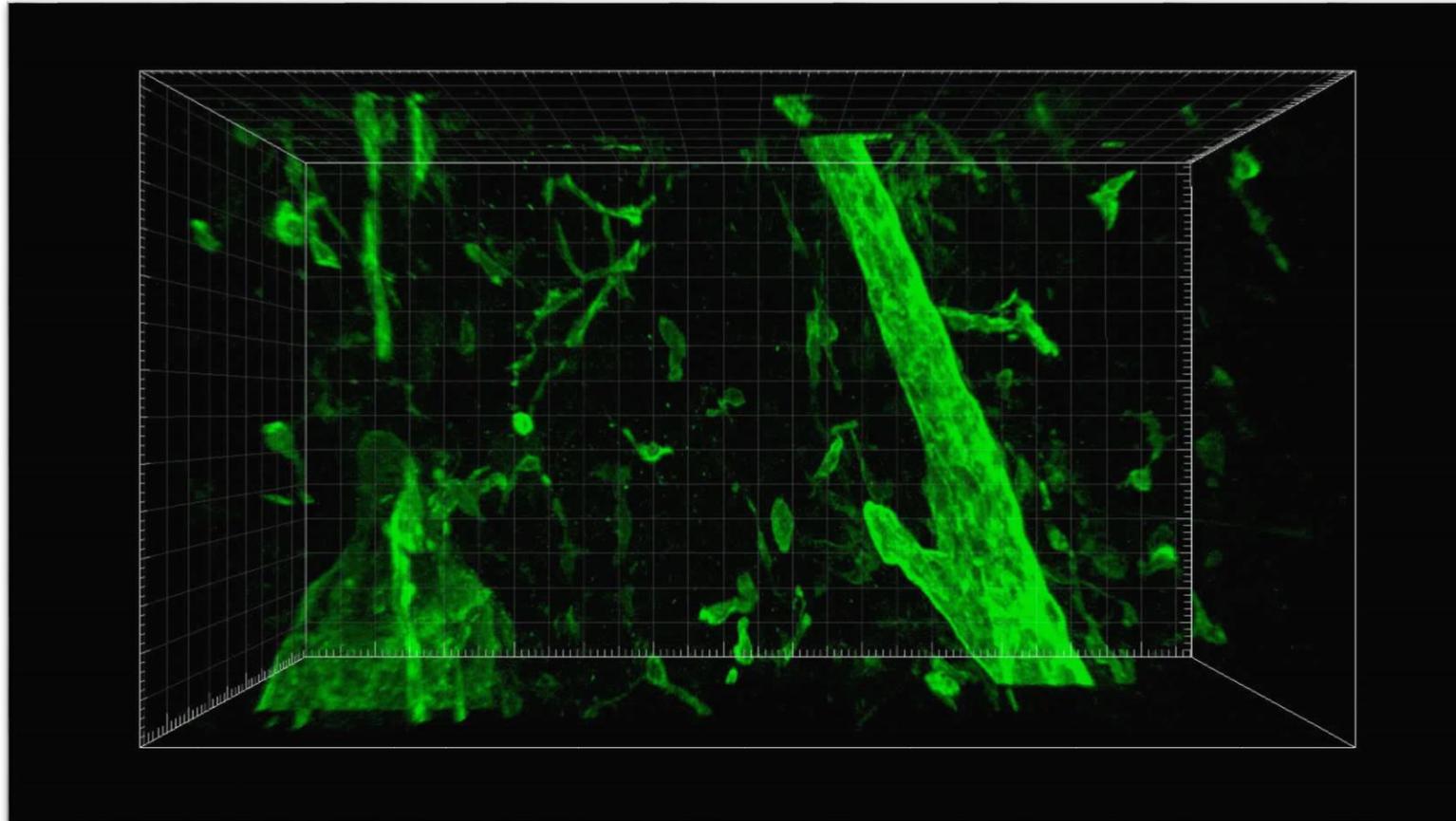


Dog Stomach

Image courtesy of Researchers at the University of Melbourne,
Faculty of Veterinary and Agricultural Sciences

Enabling Real-time Research

Whole Mount Visceral Adipose Tissue



Confocal Endomicroscope

ViewnVivo Drives CLE Adoption in Research



- ViewnVivo is Optiscan's CLE device for Preclinical Research
 - Launched in late 2016
 - Same underlying imaging technology as that used in CZM collaboration
- Current ViewnVivo product is being well received by Researchers globally
- Enables In Vivo imaging by taking the imaging to the model rather than adapting the model for imaging
- ViewnVivo exposure and related publications help Optiscan's brand
- ViewnVivo will be distributed through local specialist distribution partners in USA, China and Europe
- North America (USA & Canada) Distribution Agreement signed June 2017

Confocal Endomicroscope

ViewnVIVO

Thank You

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