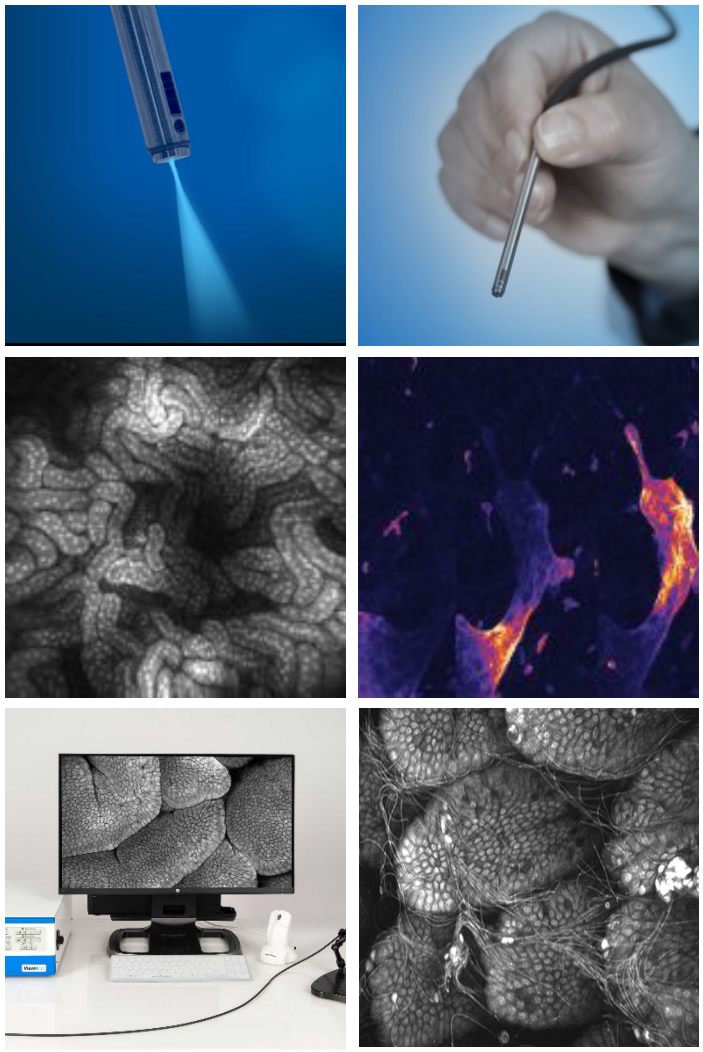
Optiscan

A Revolution in Medical Imaging

Executive Summary



Optiscan is a commercial-stage company that has developed a unique, cutting-edge technology that enables sub-cellular live microscopic imaging.

Optiscan is currently focused on driving a step change in cancer diagnostics:

- High global incidence of cancer (over 19 million new cases, and 10 million deaths, each year) poses a huge burden on society.
- Traditional diagnostic methods are inaccurate, slow, and result in poor treatment outcomes with significant healthcare system inefficiencies.

Optiscan's technology enables enhanced decision making and better surgical outcomes.

- Delivered through a diversified product range: InVivage® clinical device and ViewnVivo® research device.

Optiscan already has product-market fit in large, relevant clinical applications.

- Current focus areas include Oral/Head & Neck, Breast, Gastrointestinal – together encompassing nearly 40% of cancer cases and US$180bn of healthcare spend in the US.

Optiscan's platform technology has broad applications, and over time will expand to include:

- Real-time telepathology and online computer assisted diagnostics
- Laparoscopic and minimally invasive robotic surgery
- Veterinary medicine and precision molecular imaging

Optiscan: Who We Are

Optiscan is the global leader in real-time non-destructive digital microscopic imaging for medical applications.

Optiscan has developed biopsy-free, slide-free, non-invasive, live sub-cellular imaging technology.

OUR PURPOSE

To enable informed decisions for optimised global healthcare

OUR VISION

To be a global leader in digital healthcare solutions

Optiscan

Optiscan Board: Experienced Leadership

Dr Camile Farah
CEO & MD

- Proven track record in organisational leadership and excellence in the healthcare industry with expertise in building successful businesses
- Dual trained physician and pathologist with strong global market linkages

Robert Cooke
Board Chair

- 40-year career in health industry
- Executive leadership roles in healthcare companies in Australia, Asia and UK

Sean Gardiner
Non-Executive Director

- Managing Director of Clermont Capital, Singapore
- 20 years' experience in equity research, with senior roles at Morgan Stanley

Karen Borg
Non-Executive Director

- Medtech leader who has held senior executive roles in private and public sector
- Formerly with Johnson & Johnson USA

Ron Song
Non-Executive Director

- Track record of developing highly profitable ventures with a network of global contacts
- Formerly managed BMW & Audi dealerships in APAC

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Improving Cancer Outcomes: A Global Challenge

	1	2	3	4
Challenge	High, growing cancer rates are a huge burden on society	Cancer treatment lacks accuracy and results in high recurrence rates	Frozen section procedure is time-consuming, costly and inaccurate	Traditional histopathology is not instantaneous
Solution	Non-invasive early detection, diagnosis and treatment	Intraoperative microscopic-guided surgery	Live, in-vivo, microscopic imaging	Real-time digital pathology

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Optiscan: A Revolution in Medical Imaging

Optiscan Has Developed Cutting-Edge Technology…

- Real-time, non-invasive, point-of-care microscopic imaging
- Opportunity to continuously image and monitor disease
- Unlimited sampling across diseased tissue
- Immediate clinical feedback and surgical workflow
- Clinician and pathologist collaboration via digital workflow
- Zero incremental cost per image

…Dramatically Improving Medical Outcomes

- Immediate, informed clinical decisions and collaboration
- Improved patient outcomes with clearly defined, targeted cancer screening and surgical margin assessment
- Near perfect concordance with frozen section biopsy
- Efficiencies within healthcare systems through reduced need for traditional histopathology and surgical revision

Melbourne, Australia

Headquarters

1994

Established

ASX

Listing Location

US$ 50m

Market Cap

US$ 2m

Revenue

200

Units Sold

Market cap as of October 2022. Revenues for fiscal year 22.

Optiscan

Customer Value Proposition

Patients & Advocates

High resolution, real-time digital microscopic imaging

Enhanced accuracy of decision making and better treatment outcomes

Clinicians & Hospital Executives

Non-invasive diagnostic imaging and better surgical outcomes

Enhanced healthcare efficiencies and better OR utilisation

Insurers & Healthcare Providers

Established CPT reimbursement codes for immediate GI applications

Cost savings on diagnostic and surgical procedures

Optiscan is setting a new standard of care in digital pathology and precision surgery

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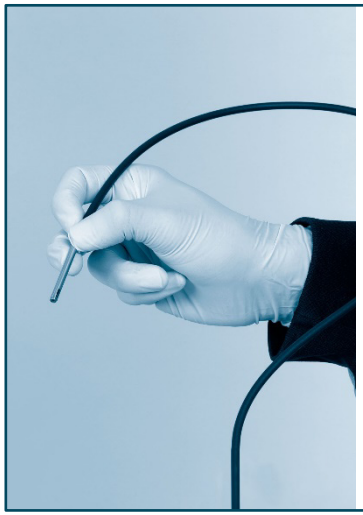
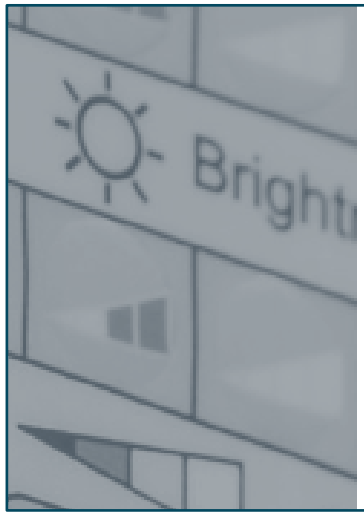
Optiscan Advantage: The Leader in Digital Microscopic Imaging



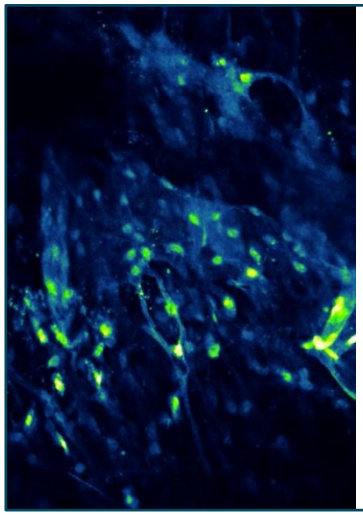
Cutting-edge Technology
Unique Miniaturised Confocal Endomicroscope

- Combination of safe low laser power and high sensitivity
- Handheld portable probe system
- Superior resolution via point scanning optical fibre



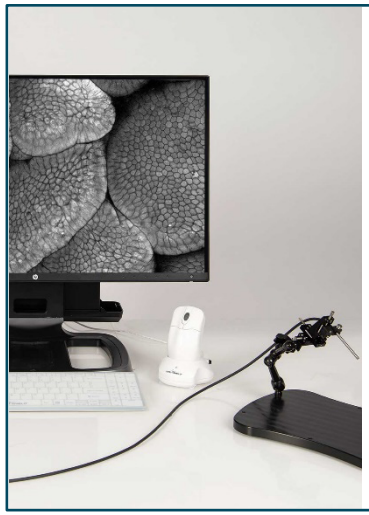
Practical, Advanced Functionality
User Control of All Key Parameters

- Completely adjustable functionality to meet user protocol needs
- Advanced software (Z-Stack, Rollback, Movie, 3D reconstructions)
- Simple and easy to use, with minimal training required



Excellent Image Quality
Superior Resolution and Sensitivity

- Unlimited image acquisition capability
- Optical sectioning – ‘virtual biopsy’
- Sub-cellular level details
- x1000 times real magnification – more powerful than any live microscope



Real-Time System
Live Imaging and Decision Making

- Observe biological systems in totality and in real-time
- Non-destructive sampling of tissue
- Repeatable – conduct longitudinal studies easily
- Live image streaming for immediate diagnosis

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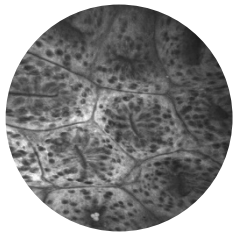
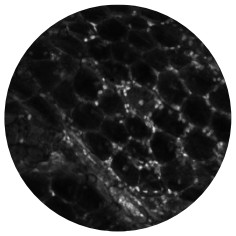
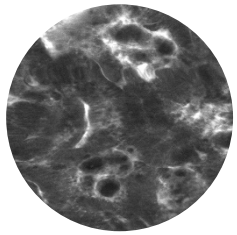
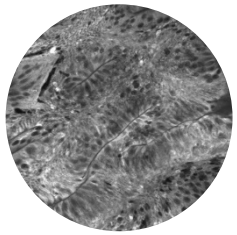
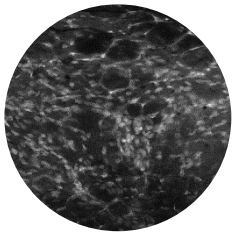
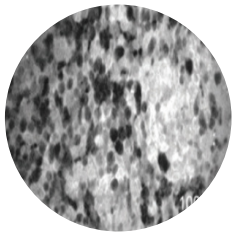
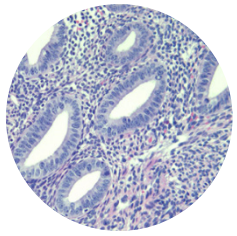
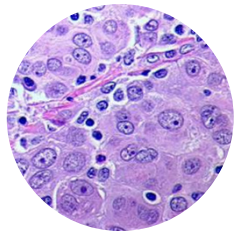
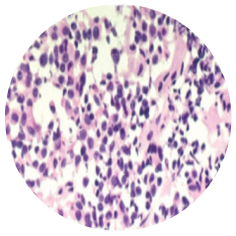
Technology: Excellent Correlation to Conventional Histopathology

Cancer vs Normal

	Oesophagus	Colon	Breast
NORMAL			
CANCER			

Correlation with Histopathology

	Endometrium	Mesothelioma	Pituitary Adenoma
OPTISCAN			
HISTOPATHOLOGY			

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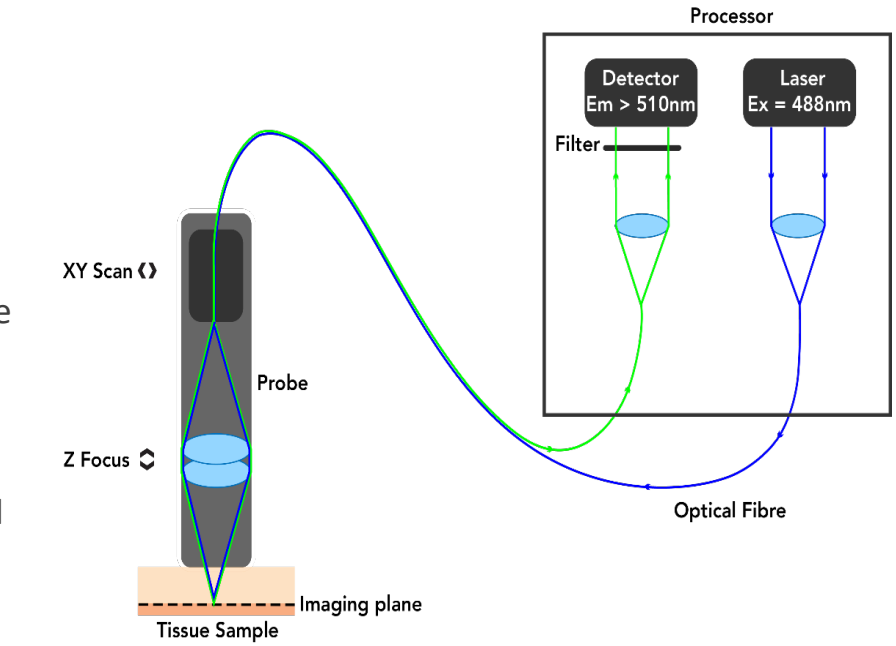
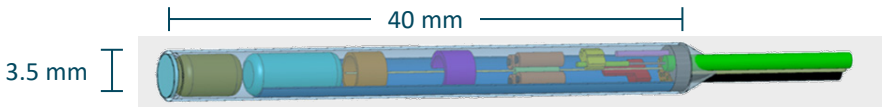
Technology: Superior to Alternatives

Process

- A single optical fibre projects a pinpoint of laser light into live tissue in a scanned raster pattern
- Fluorescence is transmitted back to the detector
- Moving lenses creates variable focal planes under operator control





Result

- Fluorescence intensity variations are mapped, creating real-time digital microscopic images
- Z-axis focus allows the ability for 3D imaging capability
- Depth of imaging up to 400 µm

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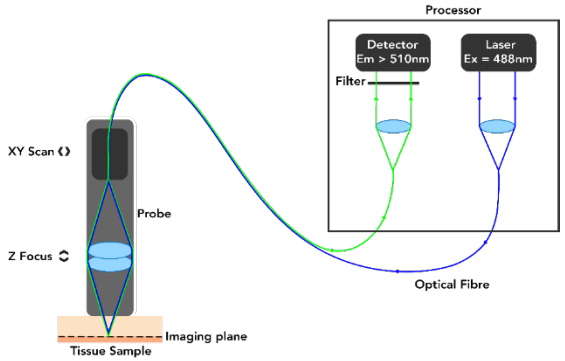
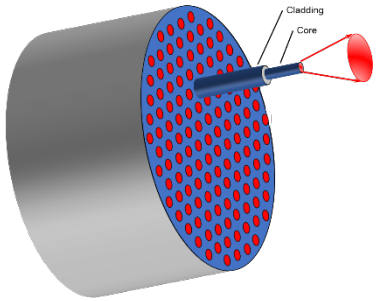
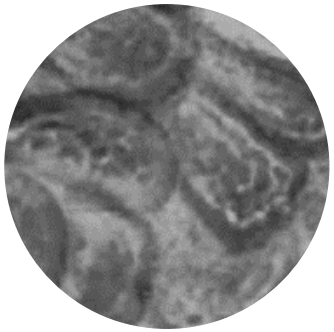
Technology: Superior to Alternatives

Technology	Image – Mouse Ilium	Comparison
		✓ Single fibre ✓ Whole imaging plane is scanned ✓ No blank spots, all critical clinical information displayed ✓ No image processing, stitching or mosaicking required ✓ Sub-micron optical resolution with optimal image sampling ✓ Z-stack capability enables optical sectioning depth actuation
Optiscan – Single Fibre	20 µm	
		X <u>Bundled fibre</u>, leaving gaps between fibre points with no image capture X Image is an array of spots, with <u>critical data missing</u> X Image is stitched and requires processing X Image is artificially ‘smeared’, transforming raw pixelated data to appear smooth; Unwanted image artifacts introduced X Sub-optimal image sampling X <u>No Z-stack capability</u> for image depth actuation
Competitor – Bundled Fibre	20 µm	

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Customer Validation: Positive, Enthusiastic Feedback

User Testimonials

Prof. Mark C. Preul

Neurosurgeon, Newsome Chair of Neurosurgery Research, Barrow Neurosurgical Institute, Arizona, USA

"This probably is the most exciting technology that I have seen in my career come through the laboratory. It is nearly a holy grail in terms of identifying malignant cells."

Prof. Bruce Mann

Breast Surgeon, Head of Breast Surgery, Royal Melbourne Hospital, Australia

"It's better for the surgeon, it's less stress for the patient, and a better outcome for the hospital and the whole health system."

Dr Tami Yap

Oral Medicine Specialist, Melbourne Dental School, Australia

"Within the next 10 years, the use of digital microscopy will be quite commonplace across many medical specialties."

Prof. Mark M. Banaszak Holl

Professor and Head, Department of Chemical Engineering, Monash University, Australia

"Optiscan's confocal laser endomicroscope delivers a crisp image of ligament and tendon fibre structure simultaneous with fluorescence imaging in a robust and easy to use package. Optiscan's CLE is a powerful tool for tissue research and medical diagnosis."

Media Coverage

Video Link:
Optiscan Technology Feature

Optiscan

Product History: Multiple Successful Device Launches

Current Product Range

1995	1999	2006	2007	2018	2018	2023
F-900 Desktop Confocal	Stratum Skin Imaging Device	Pentax ISC 1000 Pentax– Optiscan collaboration product for Gastroenterology	FIVE1 Laboratory Flexible Confocal	ViewnVivo® Laboratory Life Sciences Confocal	Zeiss CONVIVO Optiscan-Zeiss collaboration product for Neurosurgery	InVivage® Oral Cancer Screening – FDA submission completed

Optiscan has effectively transitioned from an OEM Supplier into a pure-play medical device company

Optiscan

Product Suite: Differentiated Clinical & Research Devices

InVivage® Clinical Device

FEATURES

- Push-button handpiece for easy operator use
- Advanced software user interface
- High resolution images, 1000x real magnification
- DICOM-compliant / PACS-enabled

USE CASES

- Selective virtual biopsies with higher diagnostic yield
- Multiple clinical applications including oral, cervical and breast
- For use by physicians, surgeons and pathologists

ViewnVivo® Research Device

FEATURES

- Miniaturised hand-held probe with 4 mm diameter tip
- Variable-length rigid probes for different applications
- Portable with small footprint
- Compatible with multiple dyes and contrast agents

USE CASES

- Non-destructive small animal imaging
- Real-time anatomic, physiologic and metabolic research
- Accelerates drug discovery research

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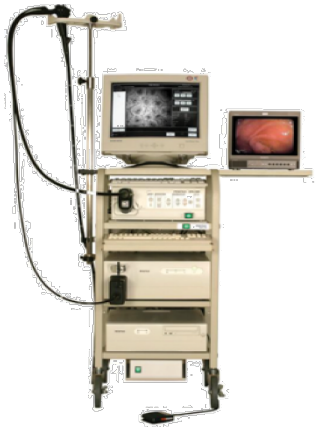
Product Partnerships: Successful Commercialisation



PENTAX

ISC-1000
Flexible Endomicroscopy
System for Gastroenterology

- Pentax is a leading Japanese brand developing medical devices and optical products
- Partnership commenced in 2002 and first generation supply agreement started in 2005; ran till 2008
- Pentax ISC-1000 embedded Optiscan scanners within a Pentax flexible endoscope
- Used in thousands of procedures, resulting in dozens of published clinical studies in the field of gastrointestinal (GI) endomicroscopy
- USA FDA 510(k) K042740 & K042741 (2004)
- Pioneering product led to the American Medical Association (US AMA) granting 3 category 1 CPT reimbursement codes for endomicroscopy
- Sold over 150 systems worldwide in only 3 years

ZEISS

CONVIVO
Rigid Endomicroscopy
System for Neurosurgery

- Zeiss is a leading German technology group operating in optics and optoelectronics
- Partnership established in 2007
- The Zeiss Convivo demonstrates how Optiscan's confocal imaging technology can be customised for specific medical applications
- Through close collaboration with Zeiss, Optiscan's technology is now being used in Neurosurgery
- USA FDA 510(k) K181116 (2018) & K211156 (2021)
- Convivo also received CE Mark (2019) and TGA approval (2021)
- Carl Zeiss continues to make sales of the Convivo in Europe and North America
- Sold circa 50 units to date

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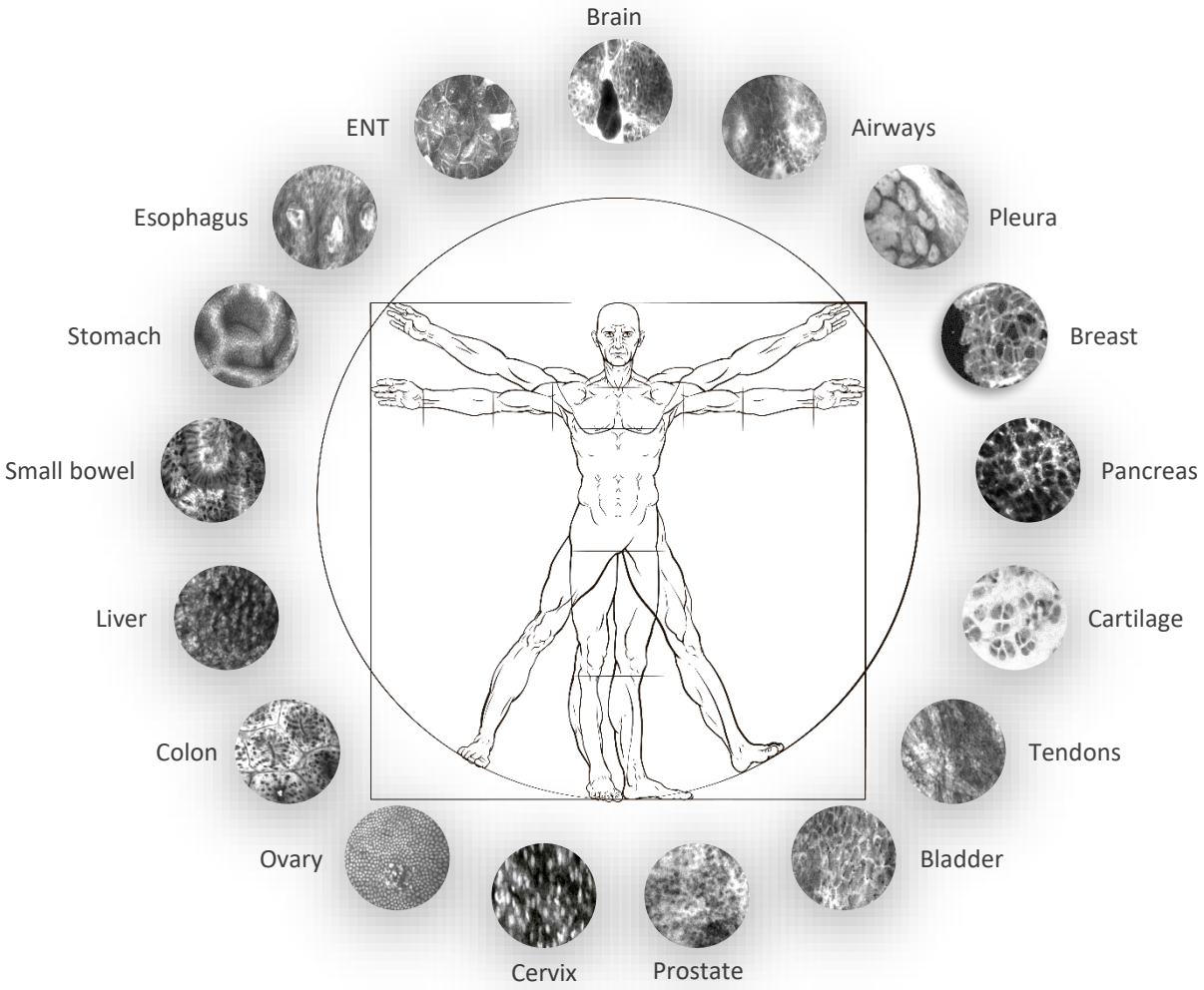
Platform Technology: Wide Range of Applications



Optiscan's platform technology has broad applications – it can be used wherever light transmittance is possible

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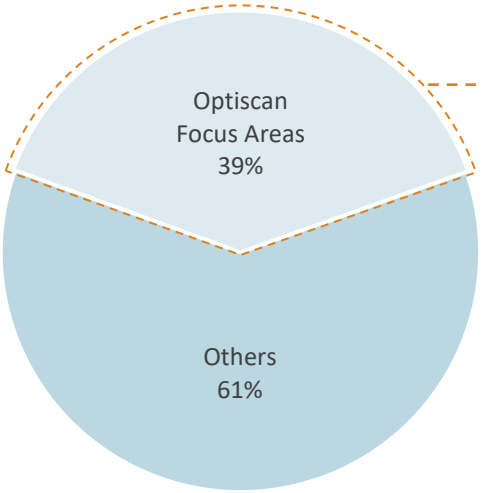
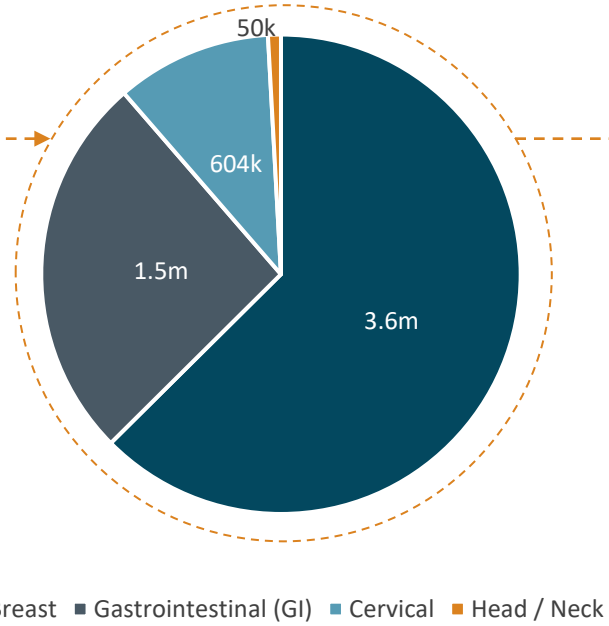
Current Clinical Applications: Large, Relevant Target Market

Cancer Cases

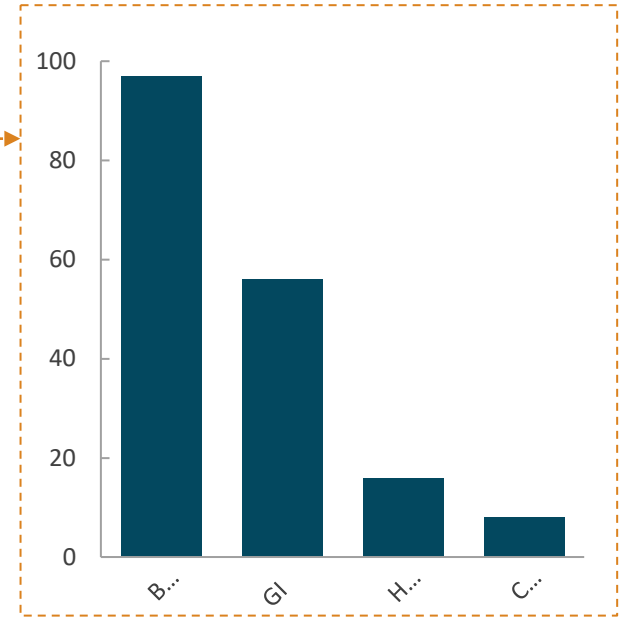




Total US Cancer Cases
(2020: 16.7m)

Optiscan Focus Areas
(2020: 5.75m)

Healthcare Spend



US Healthcare Spend
(2020: US$ 177bn)

Optiscan's focus areas encompass nearly 40% of cancer cases and US$ 177bn of healthcare spend in the US

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Current Clinical Applications: Game Changing Technology

CHALLENGE

Breast

Of women with early breast cancer, **7-11% experience local recurrence**

In the US, **30% of women who undergo lumpectomy require repeat surgery** due to remaining cancer cells after first procedure

Gastrointestinal

High recurrence rates for GI cancer (China: 60% post resection; Europe: 37%)

Among patients admitted to hospital for GI issues, **one in seven will be readmitted within 30 days**

Oral, Head and Neck

High recurrence rates, with over 50% of patients developing a loco-regional recurrence within 2 years

Of the adult population, **20% has an oral mucosal lesion requiring investigation** to avoid oral cancer development

Invasive scanning procedures and high recurrence rates

OPPORTUNITY WITH OPTISCAN

No other technology in the breast imaging space has proven ability to detect cancer at cellular level on the fly

Procedures benefit from time-saving and greater accuracy through access to reliable, real-time endomicroscopy

Virtual biopsy approach – lower patient burden, with significant opportunity in robotic minimally invasive surgery

Better patient outcomes and lower healthcare system costs

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Roadmap of Future Applications: Huge Potential

Revolutionising Healthcare

Telepathology & Remote Diagnostics

- Real-time remote clinician-pathologist communication and consultation
- Point-of-care diagnostics enabling digital pathology

Integration with Robotics Systems

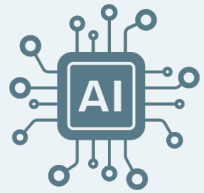
- Minimally invasive intraoperative and laparoscopic surgery
- Smaller, safer, smarter microscopic visualisation for robotic systems

Biopsy Channel Compatible Devices

- Simultaneous diagnostic and therapeutic flexible endomicroscopes
- Single procedure efficiencies and simplified workflows

Image-guided Molecular Surgery

- Biomarker-enabled, image-guided surgery
- Cell-level diagnostic and therapeutic accuracy



AI Based Identification & Diagnostics

- Computer-assisted diagnostics & data analytics
- Software as a Medical Device (SaMD)

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