



Portable MRI For Real-Time Cancer Margin Assessment Inside The Operating Room

June 2023



The clear opportunity

> Who we are:

A device company in initial commercial-stage, bringing trusted MRI technology into the operating room to enable real-time excised tissue margin assessment in cancer surgery





Every surgical cancer treatment starts and ends with big question marks

- Is this really the target tissue?
- Have I removed enough?
- Where shall I sample for diagnosis?

**THE ANSWERS ARE WORTH \$ BILLIONS IN
AVOIDABLE HEALTHCARE COSTS.**

THE CURRENT SITUATION IN BREAST CANCER

Doctors do not know in real-time whether or not they are getting all cancerous tissue when they perform surgery, and instead take their **BEST ESTIMATE.**

- SURGEONS TAKE AN EDUCATED GUESS AT TISSUE REMOVAL
- TISSUE SAMPLE IS SENT TO PATHOLOGY
- PATHOLOGIST TAKES BEST ESTIMATE AT WHERE TO SAMPLE EXCISED TISSUE TO ASSESS MARGINS FOR CANCER
- SURGEON RECEIVES REPORT FROM PATHOLOGIST

cancer free

cancer found

Surgeon has to call patient

2nd surgery is required !

THE ANSWERS ARE WORTH \$ BILLIONS IN **AVOIDABLE** HEALTHCARE COSTS.

05

Surgeon has to
call patient

2ND SURGERY IS
REQUIRED !



Amount of 1st and 2nd Breast Conserving Surgeries per Region 2021 (K Unit)

	<u>Europe</u>	<u>USA</u>	<u>Rest of World</u>
1 st	338	190	351
2 nd	89.9	46.2	97.8
Re-excision rate	26.60%	24.32%	27.86%

Source: Globocan, SamanTree Medical, Intellectual Capital and QYResearch, 2022

THE SOLUTION

A Breakthrough for Expansion of MRI Applications

- Portable MRI on a cart
- Fully Shielded
- No contrast media
- No MD specialty needed
- No patient contact
- Workflow compatible
- Low cost = Affordable
- **FAMILIAR, TRUSTED, SIMPLE, ACCURATE & AFFORDABLE**

WE'VE TRANSFORMED
MRI FROM THIS...



...TO THIS NEW MRI
FORM FACTOR



OUR SOLUTION

Create a digital map of the tissue's surface to show the surgeon specific areas of concern - in real-time, during surgery

IMPACT

Better intra-operative decisions, fewer re-excisions, dramatically lower costs of care, enhanced quality of life, improved outcomes

CLEAR CANCER DETECTION WHEN IT'S NEEDED MOST



MRI = TRUST = CREDIBILITY

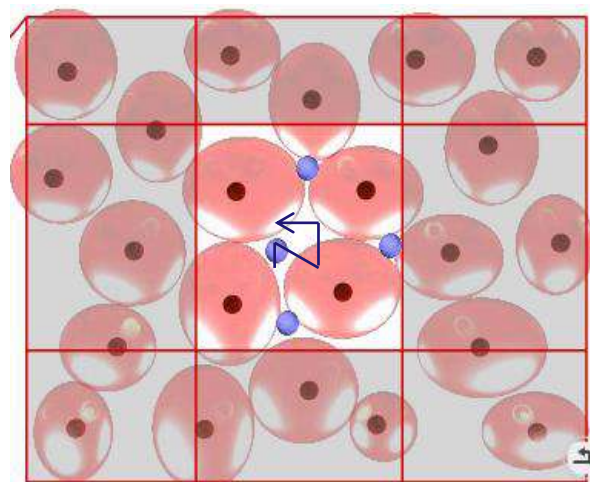
Diffusion-weighted MRI is the trusted modality for differentiating malignant vs benign tissue

* Guo et. al., Differentiation of Clinically Benign and Malignant Breast Lesions Using Diffusion-Weighted Imaging, J. MRI, 172-178, 2002.

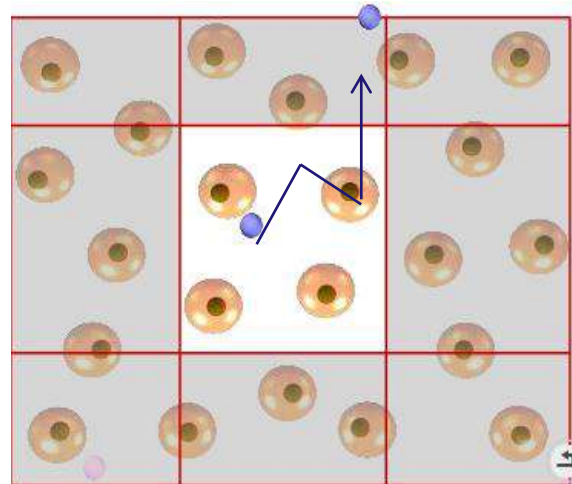
* Tsushima et al., MR Differential Diagnosis of Breast Tumors Using Apparent Diffusion Coefficient on 1.5-T, J. MRI, 249-255, 2009.

Diffusion-Weighted MRI

Cancerous tissue



Non-cancerous tissue



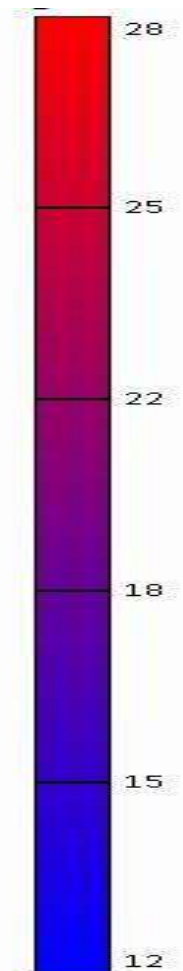
Restricted diffusion
(slower diffusion)

Lower ADC
(Apparent Diffusion Coefficient)
Higher T_2^*

Free diffusion
(faster diffusion)

Higher ADC
Lower T_2^*

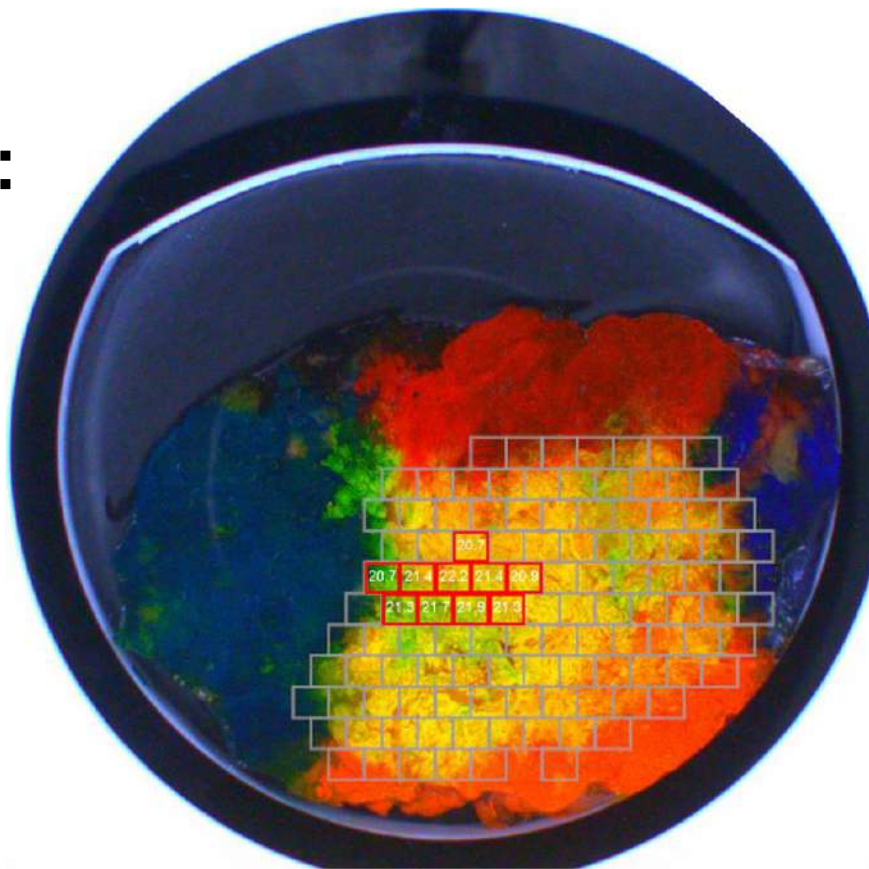
T_2^*



ONLY CLEARCUT PROVIDES REAL TIME ANSWERS THAT DO NOT REQUIRE ANY EXPERTISE !

FOR THE PATHOLOGIST:

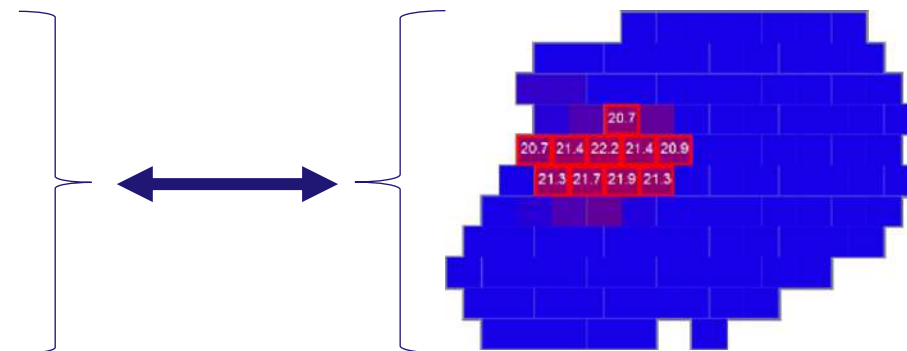
Targeted sampling reduces workload and improves diagnostic accuracy



Optical picture of the surgically excised tissue shows suspicious malignant places

FOR THE SURGEON:

Intra-operative real-time margin assessment reduces re-excision rate



ClearCoast™ MR scan shows suspicious malignancy in the tissue surface (the margin)

CLINICAL DEVELOPMENT

1. Moshe Papa, Tanir Allweis et al., An Intraoperative MRI System for Margin Assessment in Breast Conserving Surgery Initial Result From a Novel Technique_J.Surg.Oncol 2016
2. American Society of Breast Surgeons (ASBrS) 2017
3. Marc Thill, Magnetic Resonance Imaging System for Intraoperative Margin Assessment, J.Surg.Onco 2021
4. DS- Dynamic Scan

PUBLISHED 2016

P2P POINT-TO-POINT¹

POC study, 22 patients, (n=77 samples), Israel

- Scientific study to show accuracy of core technology
- High accuracy vs. pathology
- Compelling proof of concept

PUBLISHED 2017

M2M MARGIN-TO-MARGIN²

ClearSight™ 1st revision, 220 patients (n=758 aspects), USA, Europe

- First “real world” study
- High sensitivity shown for different cancer types
- Specificity better than competition, but below what’s possible with MRI

PUBLISHED 2021

M2M-II MARGIN-TO-MARGIN-II³

ClearSight™ with DS⁴, 60 patients (n=348 aspects), Europe

- Innovation of Dynamic Scan
- Sensitivity & Specificity best in class
- Improved pathology analysis to detect positive margins
- High threshold met for global commercialization

VOICES WITH EXTENSIVE CLEARCOAST™ SYSTEM EXPERIENCE



“ClearCoast™ portable, diffusion weighted MRI system delivers analytical guidance surgeons trust so they can know in real-time if there has been a complete tumor resection. This is a major advancement in the use of MRI.”

Barry Rosen, MD, Director of Breast Centers at Advocate Good Shepherd Hospital and AMITA/Alexian Brothers Medical Center, Illinois, USA and ClearCut CMO.



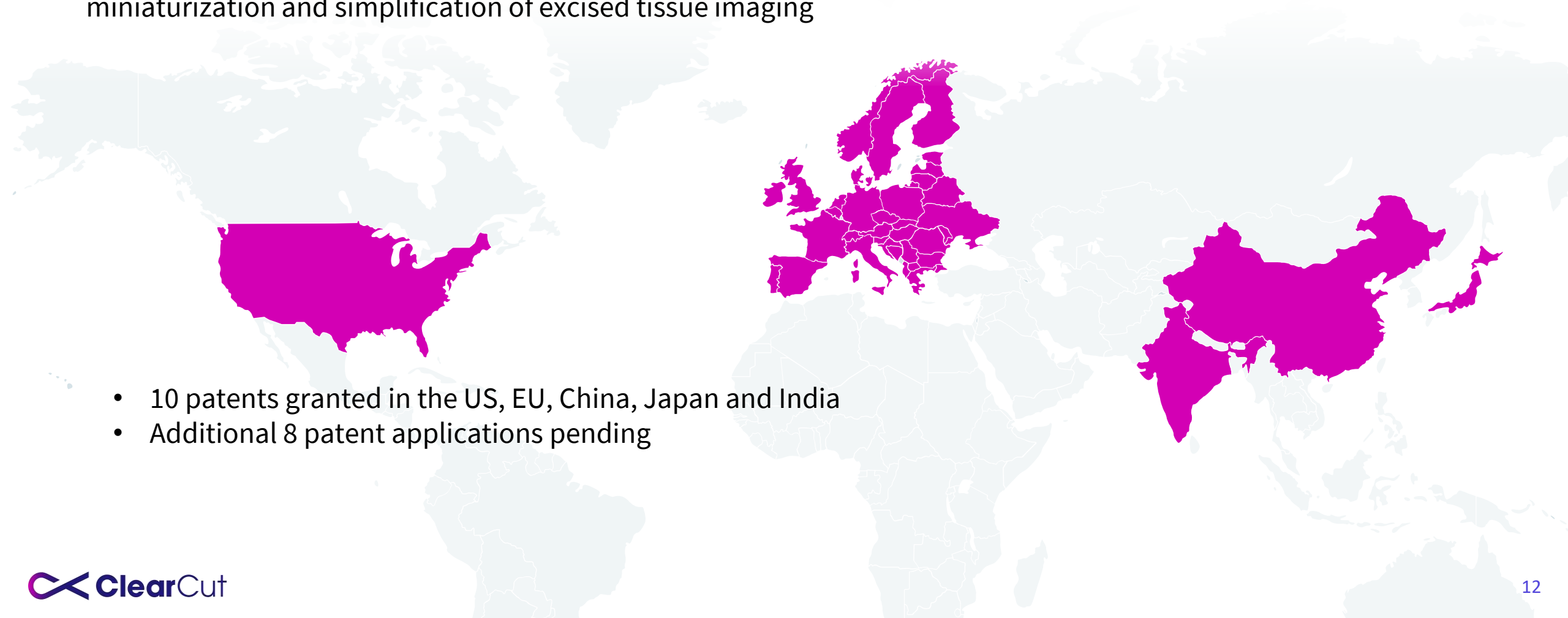
“The ClearCoast™ System is an impressive engineering feat. For the first time, surgeons have an imaging technology we know, trust and can easily use within the operating room to direct our decisions around how much, or how little, tissue that should be removed in breast cancer conservation surgeries. We were able to see for ourselves the potential of this technology to dramatically reduce the need for 2nd surgeries.”

Prof Marc Thill, MD, PhD Chief of Obstetrics and Gynecology, Agaplesion Markus Hospital, Frankfurt, Germany

INTELLECTUAL PROPERTY

Novel, proprietary MRI platform technology enabling miniaturization and simplification of excised tissue imaging

Groundbreaking invention for the expanded use of MRI technology

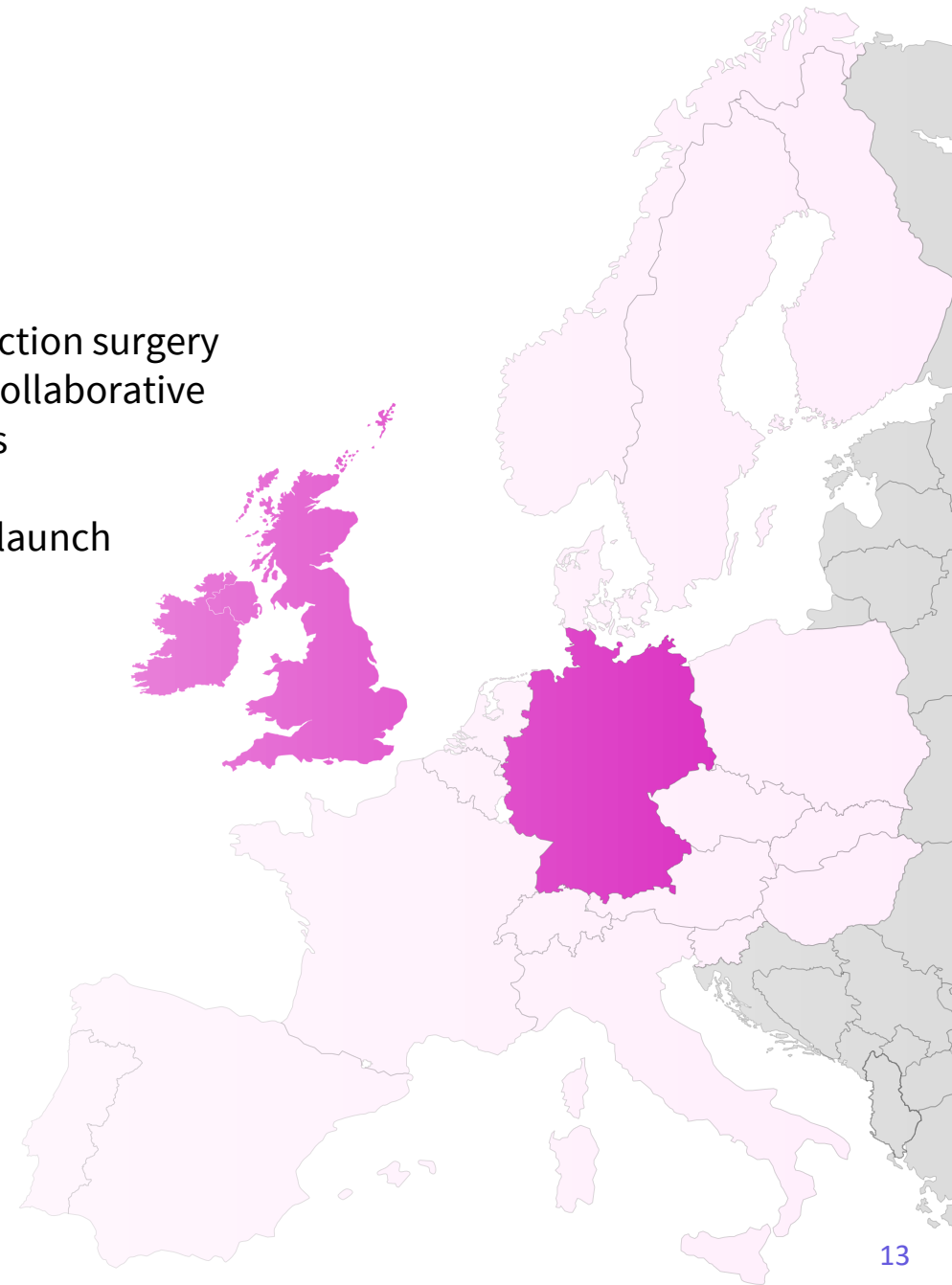
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- A light gray world map serves as a background. The United States, the European Union, China, India, and Japan are highlighted in a solid red color, indicating the regions where patents have been granted or are pending.
- 10 patents granted in the US, EU, China, Japan and India
 - Additional 8 patent applications pending



EUROPEAN LAUNCH IN 2022



- Pan-European leader in breast reconstruction surgery
- Exclusive, 3 years, minimums, clinically collaborative
- Direct and dominant in key large markets
- Large strategic investment into ClearCut
- Large internal investments in support of launch



PROJECTED MILESTONES

- > 2022 – ClearCoast™ European launch
- > Q4/2023 – Initiation of feasibility study of ClearCoast™ first additional application (outside breast cancer)
- > Q4/2023 - ClearCoast™ ROW (outside Europe and US) launch
- > 2024 - Completion of development of ClearCoast™ next generation system
- > 2025 - ClearCoast™ FDA approval and US launch

DOMINANT FEATURES AND PERFORMANCE... AND THE TRUST OF MRI

APPROACH	EASE OF USE	ACCURACY	ASSESSMENT TIME	CELL TYPE	CAPABLE OF PATHOLOGY TESTING YES=GOOD	COMMENTS
Histopathology	-	+++	Days - weeks	+++	No	Gold standard
Frozen Section	Workflow disruption	++	30-60 min	++	No	Limitations in fatty breast tissue, limited availability
RF Spectroscopy (i.e.: Dilon/Dune)	++	+	Few minutes	-	No	High rate of false positives, user dependent, expensive
OCT / Confocal Microscopy (i.e.: Perimeter Medical / SamanTree)	+	+++	Few minutes	+	No	Scant clinical data, user dependent, complex images
Fluorescent dye (i.e.: Lumicell)	++	?	Few minutes	-	No	Phase I/II drug trials, small statistics, not workflow compatible
ClearCoast™ MRI (ClearCut Medical)	+++	+++	Few minutes	-	Yes	MRI is TRUSTED High precision accuracy, user independent, pathology guidance

FULL FOCUS TODAY IS ON BREAST CANCER

PREVALENCE

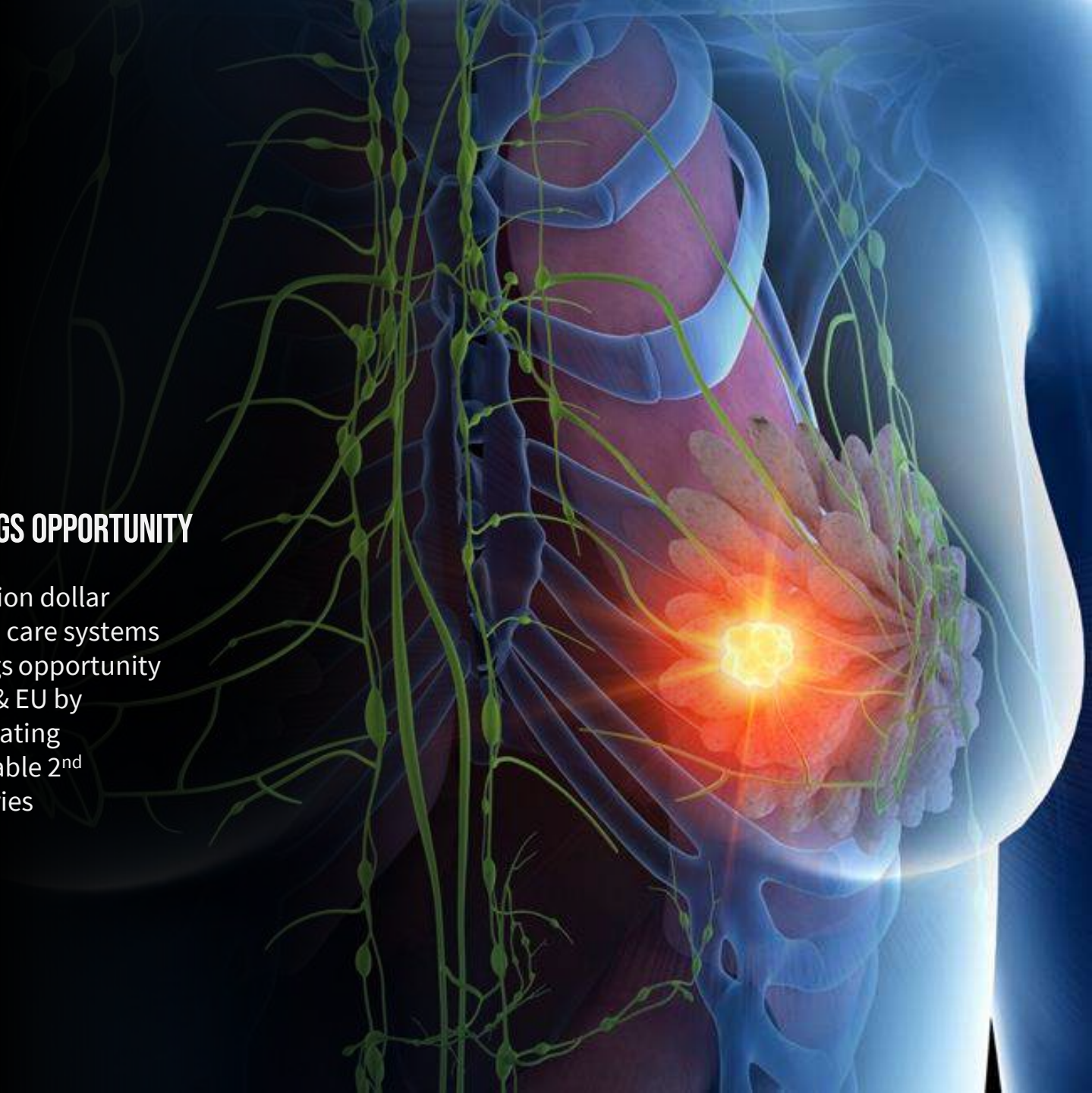
1 out of 8 women
will develop breast
cancer, with 2.1
million new cases
diagnosed annually
WW

LUMPECTOMY 1ST CHOICE

Breast conserving
surgery
(lumpectomy) is the
initial treatment of
~75% of breast
cancer cases in the
US & EU

SAVINGS OPPORTUNITY

\$2 billion dollar
health care systems
savings opportunity
in US & EU by
eliminating
avoidable 2nd
surgeries

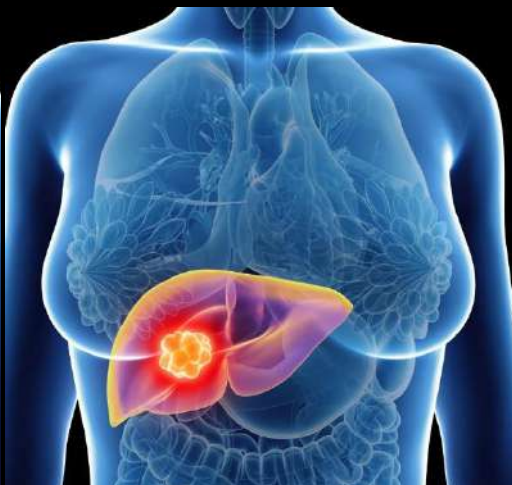


MAJOR PLATFORM OPPORTUNITY

ClearCoast™ MRI System may be valuable
in additional cancers



LUNG



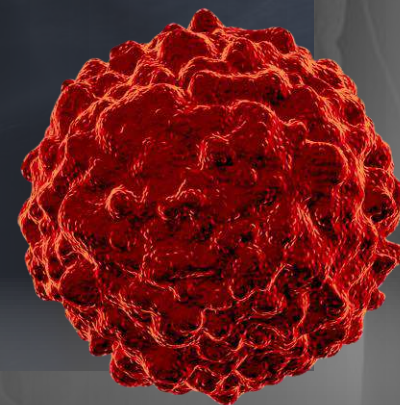
LIVER



PROSTATE



HEAD & NECK/ENT



OTHER SOLID TUMOR

DOMINANT FEATURES AND PERFORMANCE... AND THE TRUST OF MRI

APPROACH	EASE OF USE	ACCURACY	ASSESSMENT TIME	CELL TYPE	CAPABLE OF PATHOLOGY TESTING YES=GOOD	COMMENTS
Histopathology	-	+++	Days - weeks	+++	No	Gold standard

Why will ClearCoast™ MRI become the Standard of Care?
Familiar, Trusted, SIMPLE, Affordable, Highly Accurate

OCT (i.e.: Perimeter Medical)	+	+++	Few minutes	+	No	Scant clinical data, user dependent, complex images
Fluorescent dye (i.e.: Lumicell)	++	?	Few minutes	-	No	Phase I/II drug trials, small statistics, not workflow compatible
ClearCoast™ MRI (ClearCut Medical)	+++	+++	Few minutes	-	Yes	MRI is TRUSTED High precision accuracy, user independent, pathology guidance

THE LEADERSHIP TEAM



HEZI HIMELFARB

Chief Executive Officer

- Successful executive with more than 30 years of management experience in hi-tech and medical device companies
- Executive roles at InStent (sold to Medtronic), Remon (sold to Boston Scientific), IceCure (traded in TASE and Nasdaq), Microbot (traded in Nasdaq) and O2Cure
- B.Sc. In Electronic Engineering and MBA, both from Tel-Aviv University



EYAL KOLKA

Founder, Executive Director

- Serial entrepreneur. Founder and Executive Director of Pi-Cardia; Formerly founder, CFO and SVP of Bus. Dev. of TopSpin Medical
- B.Sc. in physics and mathematics in the Talpiot program; M.Sc. in physics from the Hebrew University; MBA from Tel-Aviv University



EREZ GOLAN

Founder, Executive Director

- Serial entrepreneur. Founder and CEO of Pi-Cardia (aortic valve repair); former founder and CEO of TopSpin Medical
- B.Sc. in physics and mathematics as part of the Talpiot program; M.Sc. in MRI physics from the Hebrew University



BOAZ DOVRIN

VP, R&D and Operations

- Leading programs of Multidisciplinary products for more than 30 years and Medical Device programs for more than 13 years. Played major role in product development as part of the R&D organizations at Philips Healthcare, Lumenis and Elbit Systems.
- B.Sc. Aeronautics and Space Engineering in Technion, Israel; MBA from Bar-Ilan University, Israel.



ANNA LEVIN

Director, Clinical Affairs

- Over a decade of experience managing clinical trials, regulatory pursuits and operations in a wide range of successful development activities of medical devices in addition to other accomplishments within the pharmaceutical industry
- BSc in Medical Laboratory Sciences, from Hadassah College, and a MSc in Management of Technology, from the Hebrew University



MIKE BERMAN

Chairman

- Experienced medical device entrepreneur and investor
- Previously President of Boston Scientific/Scimed

The Coast is Clear.



THANK YOU