Discovery Session

Establishment Labs | Sulàyöm

Agenda

1. Welcome
2. The Science and Technology Behind The Motiva Standard
3. Global Clinical Evidence
4. Femtech Solutions
5. Femtech Roadmap
6. Expert panels
7. Q&A

Safe Harbor and Forward-Looking Statement

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Juan José Chacón-Quirós

Founder and CEO

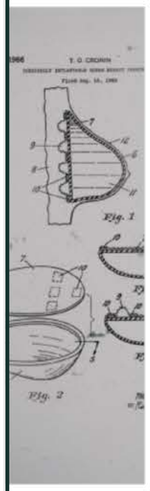
Establishment Labs

is a first-of-its-kind medical technology company focused in breast aesthetics and breast reconstruction, bringing to market Femtech innovations for women's health and wellbeing.

Establishment Labs | Sulàyöm

Lets go back to 1960's

1960s



FIRST MODERN BREAST IMPLANT, (DOW CORNING CORPORATION)

1st Generation devices using silicone, reaching US markets in 1964.

1970s



2nd GENERATION SILICONE BREAST IMPLANT.

Thinner shell, no Dacron patches, and less viscous and cohesive gel. Prone to silicone bleeding and ruptures.

1976



3rd GENERATION BREAST IMPLANTS:

Introduction of double-lumen breast implants (Heyer Schulte).

Double-lumen: silicone- filled core enclosed by a saline-filled outer shell.

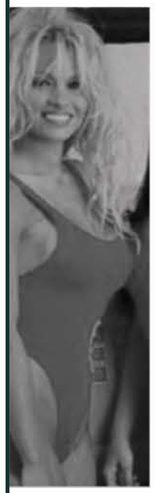
1980s



4th GENERATION BREAST IMPLANTS:

Thick outer elastomer shells, round and moderate cohesive gels. Texturization of outher shells started with different techniques: "salt-loss" and "imprint stamping" to allow integration by tissue ingrowth

1989



BAYWATCH AIRS ON TELEVISION

And ushers in a new era of implants.

1990



PLAYBOY MODEL, PAMELA ANDERSON JOINS BAYWATCH IN 1992.

Plastic surgery's popularity and implant sizes grew.

1992



FDA PLACED A TEMPORARY MORATORIUM BANNING THE USE OF SILICONE BREAST IMPLANTS IN THE USA.

(12.000 patients partook in a class-action lawsuit with evidence supporting the safety and effectiveness of breast implants was insufficient).

1993



5th GENERATION BREAST IMPLANTS: ANATOMICAL TEARDROP OR "GUMMY BEAR"

Highly cohesive form-stable gel filler and rough textured surface.

1999



ANDERSON OPTS TO HAVE HER IMPLANTS REMOVED.

2006



FDA ALLOWS THE USE OF SILICONE BREAST IMPLANTS FOR WOMEN OVER THE AGE OF 22

(Only Mentor and Allergan core studies were sufficient to be approved)



OUR HISTORY

2004 2010 2011 2012 2014 2016 2017 2018 2019 2020 2021 2022 2023

2022

Established the **Women's Health Hub** in Barcelona.

The Motiva® Standard

- **12 years** in the market.
- Post-Market Surveillance (March 2023).
- **Three-million Motiva®** devices sold.
- **3-year results** from Motiva® U.S. IDE study.
- **Less than 1%** device-related complications.
- **+85** countries where Motiva Implants® have been approved
- **+25 Inventions** (patent families) and 218 applications globally in 21 jurisdictions



THREE-YEAR
DATA FROM US
FDA STUDY



THREE MILLION
MOTIVA IMPLANTS
@12 YEARS



<1%
DEVICE-RELATED
COMPLICATIONS

Femtech Solutions

Establishment Labs | Sulàyöm

Our Femtech Solutions

Motiva Flora®



Flora Tissue Expander

SmoothSilk®/SilkSurface®
Non-Magnetic Infusion Port
TrueFixation® System

Motiva®



Motiva® Round

SmoothSilk®/SilkSurface®
ProgressiveGel® Plus
TrueMonobloc®
BluSeal®



Ergonomix®

SmoothSilk®/SilkSurface®
ProgressiveGel Ultima®
TrueMonobloc®
BluSeal®

JOY®



Ergonomix2®

SmoothSilk®/SilkSurface®
ProgressiveGel Ultima®
TrueMonobloc®
BluSeal +®
Motiva SuperSilicones®
Woman's Choice Program

Mia Femtech™



Ergonomix2®Diamond

SmoothSilk®/SilkSurface®
ProgressiveGel Ultima®TrueMonobloc +TM
BluSeal +®
Motiva SuperSilicones®
Woman's Choice Program

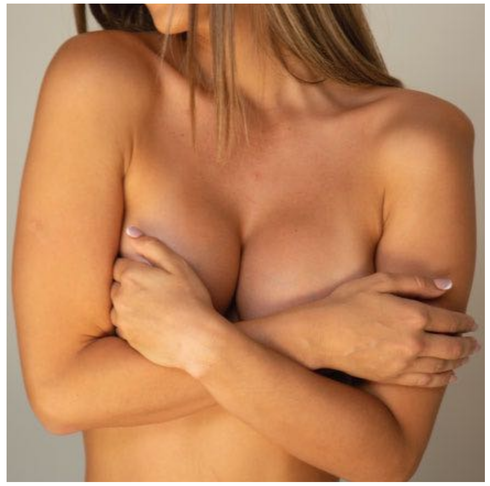
Good ● **Better** ● **Best** ● **Ultra**

Science-Based Femtech Solutions

Beyond clinical outcomes, improved aesthetic outcomes:



Concept of ergonomy



Hybrid surgery

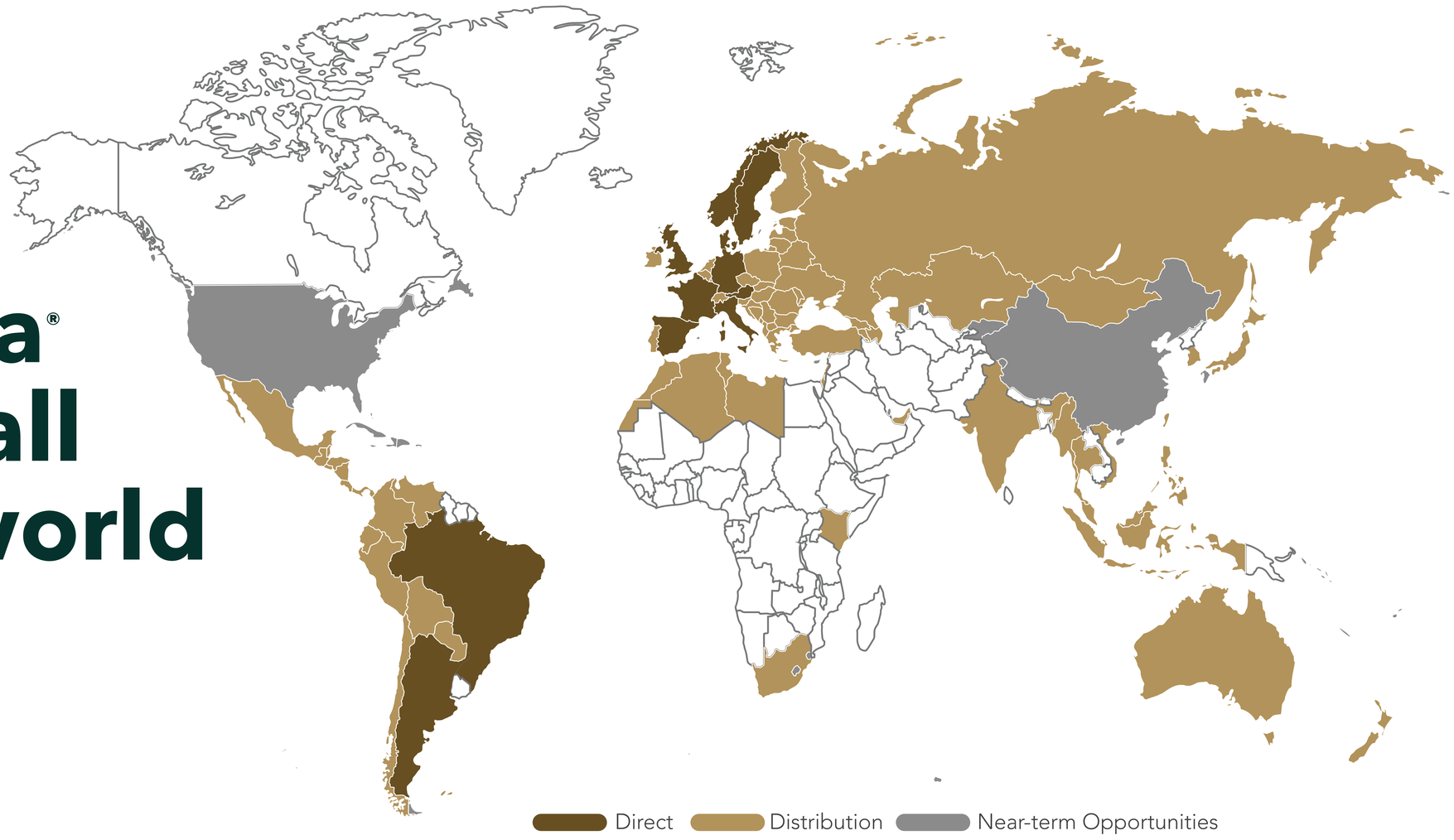


Small incisions

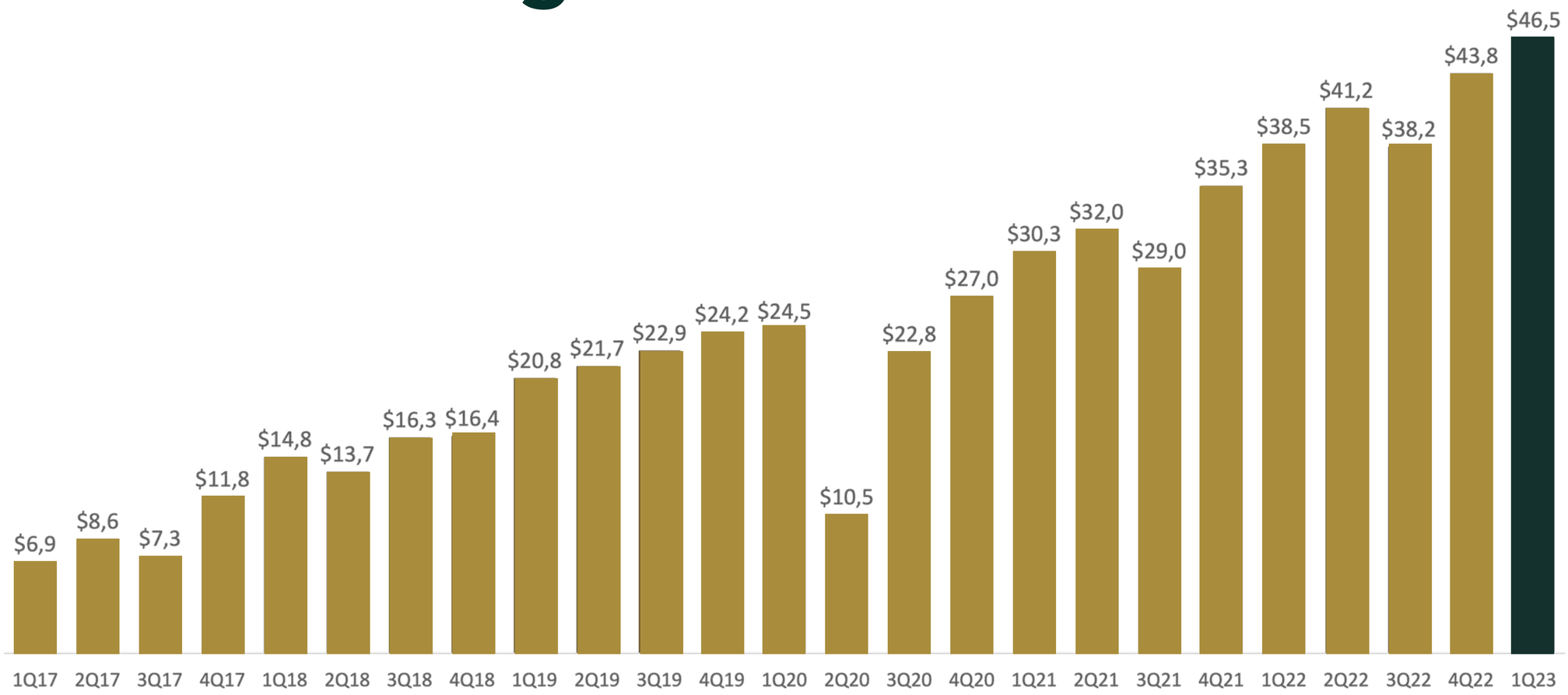
- **Breast augmentation:**
  MOTIVA®, JOY®
- **Breast harmonization:**
  Mia Femtech™
- **Breast reconstruction:**
  Aesthetic BreastRecon®, Flora® Tissue Expander
- **Custom designed procedures**
- **Safety features:**
  RFID enablement
  Ergonomic design
  Minimally invasive
  Regenerative and Advanced biomaterials

The Motiva® Standard all over the world

Motiva® implants sold in 85+ countries



Delivering Consistent Growth

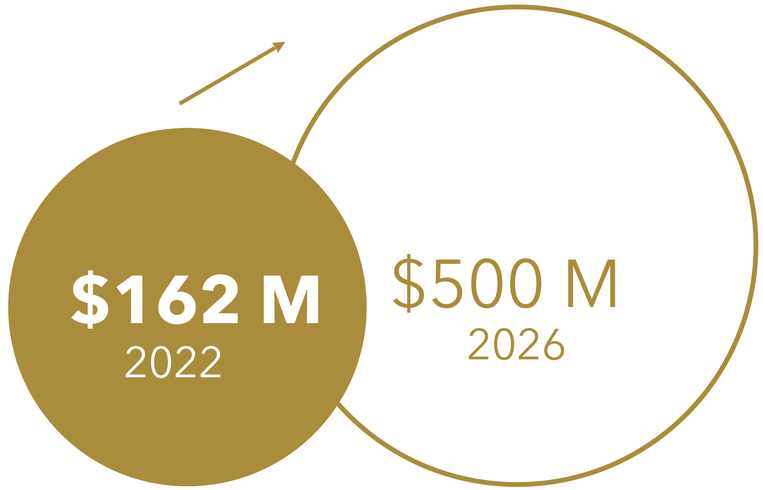


Beyond 2022

Targeting $500M in Annual Revenue in Fiscal 2026

Average rate of growth of **33%** per year over the next 4 years, and significant growth beyond

Creating positive impact and long-term social, environmental and economic value in all our products, activities and corporate efforts.



Roberto de Mezerville

Head of Research, Development and Innovation

The Science and Technology Behind The Motiva® Standard



The Science and Technology Behind The Motiva® Standard



3-year data from Motiva FDA trial further confirms our less than 1% device-related complication rate.



3 million implants in market at 12+ years data on Motiva® Implants®.



Less than 1% device-related complications supports best in class safety standard.



Clinical Complications Most Common User Needs



Biocompatibility Risk Assessment of Motiva® Implants

- Regulatory Requirements
- ISO 10993
- ISO 14971
- EU Directive 93/42/EEC
- Brazil ANBT NBR ISO 14949:2011
- US FDA General Guidance
- US FDA Guidance for Industry and Staff

Biocompatibility Testing:

- Leachable characterization
- Cytotoxicity
- Sensitization
- Irritation or intracutaneous reactivity
- Acute systemic toxicity
- Subacute toxicity
- Genotoxicity
- Implantation
- Biodegradation
- Carcinogenicity
- Immunocitoxicity
- Chronic toxicity
- Reproductive/developmental toxicity
- Toxicokinetics
- Other organ-specific toxicity

Patient Benefits

Bio-Tolerable

Biocompatibility Risk Assessment of Motiva® Implants

- Regulatory Requirements
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- US FDA General Guidance
- US FDA Guidance for Industry and Staff

- Patient-Focused
- Risk Assessment of
- Motiva Implants® Surfaces

Biocompatibility Testing:

- Leachable characterization
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- Reproductive/developmental toxicity
- Toxicokinetics
- Other organ-specific toxicity

Activators / Drivers:

Surface Characterization

- Roughness
- Kurtosis
- Skewness
- Density of peaks
- Hydrophobicity
- Friction coefficient
- Degradation

Surface Area

- Biofilm contamination Particles
- Debris / Particle shedding
- Coefficient of friction Gel Bleed

Process / Environment / Materials

- Heavy metals
- Chemicals and leachables
- Chemical Moieities Ergonomy
- Morphology
- Rheology

Patient Benefits

Bio-Tolerable

Patient Risks - Benefits

High Frequency – Low Risk

- Less than 1% Capsular Contracture Rate
- Less than 1% Rupture Rate

Low Frequency – High Risk

- Lower inflammation
- Historical absence of Double Capsule/ Late Seroma
- Historical absence of BIA-ALCL

Patient Satisfaction

- Healthy capsule
- Comfort Ergonomy
- Breast Dynamics / Feel
- Consistent positive feedback on patient surveys

Re-Operation

Rupture

Biofilm / Bacteria

Double Capsule

Capsular Contracture

Firm Implants Malposition

BIA-ALCL BII & SCC

“Anatomical Shaped”



Biofilm/ Bacteria

Surface Characterization

Immune Response

SmoothSilk® / Shell

Biotribology

Heavy Metals

ProgressiveGel®

Morphology

100% Filled

Rheology

TrueMonobloc®

Gel diffusion

BluSeal®

Qid™

Safety

Traceability

Ergonomix®

Ergonomy

Patient-Centric Risk vs. Benefit of Motiva® Implants

Patient Risk Benefits

High Frequency – Low Risk
Less than 1% Capsular Contracture Rate
Less than 1% Rupture Rate

Low Frequency – High Risk
Lower inflammation
Historical absence of Double Capsule / Late Seroma
Historical absence of BIA-ALCL



Patient Satisfaction

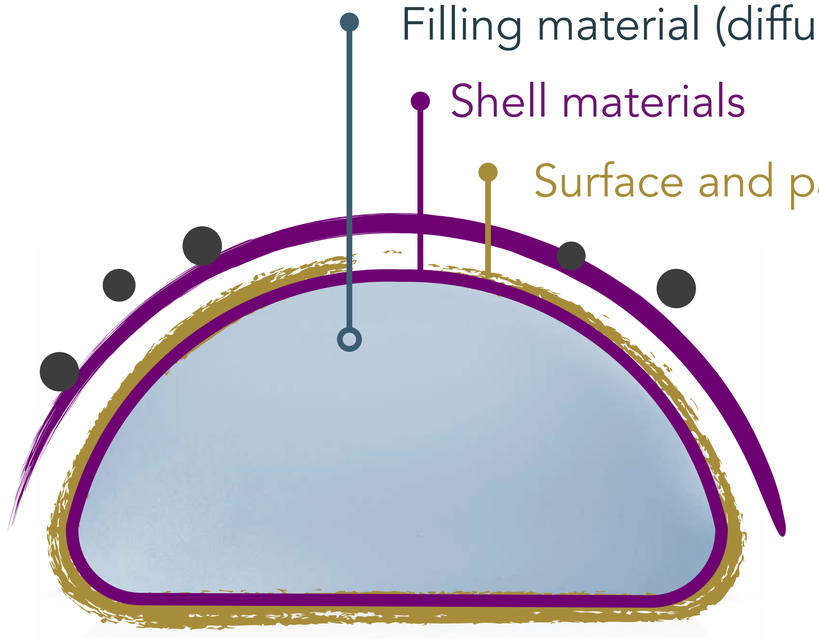
Healthy capsule
Comfort Ergonomy
Consistent positive feedback on patient surveys
Breast Dynamics / Feel

Bio-Tolerable to Bio-Compatibility

Variables that impacts

Immune Response and Capsular Contracture

Women Lifestyle

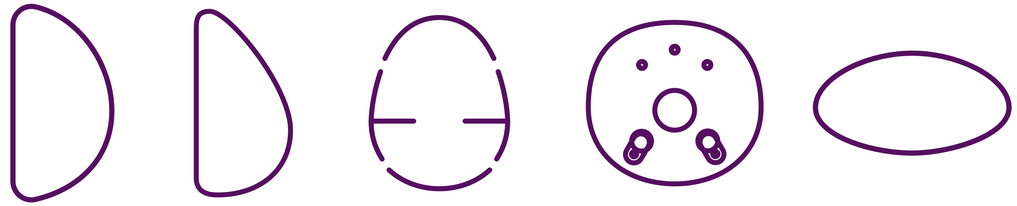


Immune response

Bacteria colonization & biofilm

Surgical techniques

Implant placement

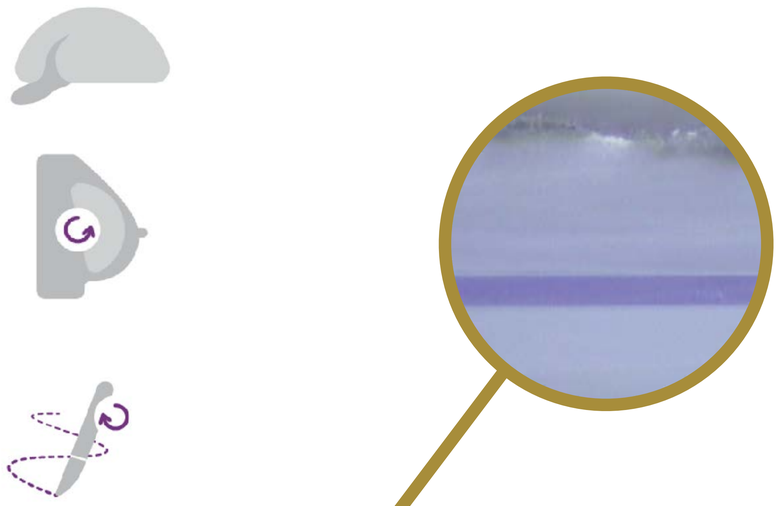


Innovative Designs



Shell: Consumer Centric Design and Engineering

Patient Risk / Benefit Analysis



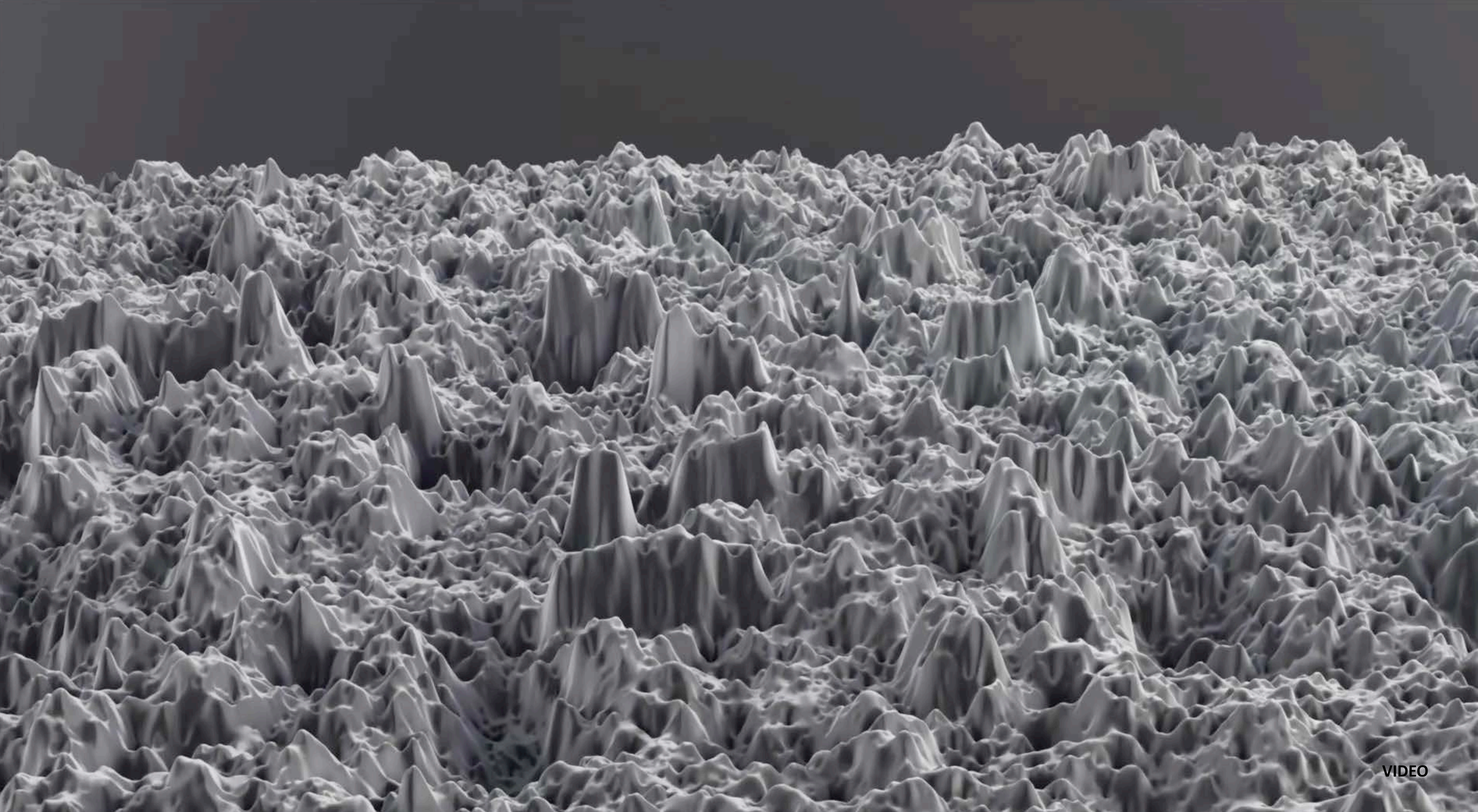
- Patient-Focused
- Risk Assessment of
- Motiva Implants® Surfaces

Minimize Ruptures — BluSeal®

Minimize Folds — 100% Filled

Minimize Gel Diffusion — Geometry

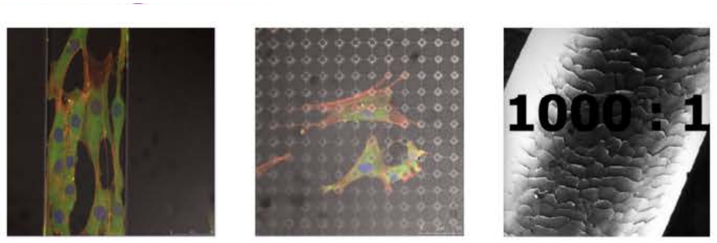



VIDEO

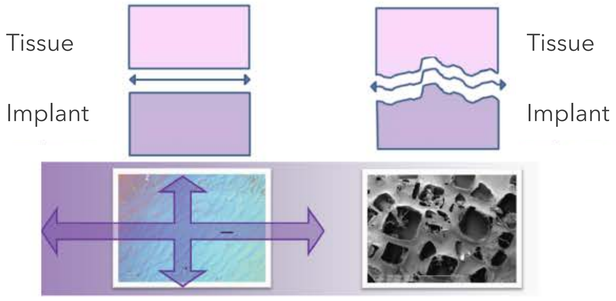
Science-Based Design

Defining Optimal Surface Architecture

Cell alignment

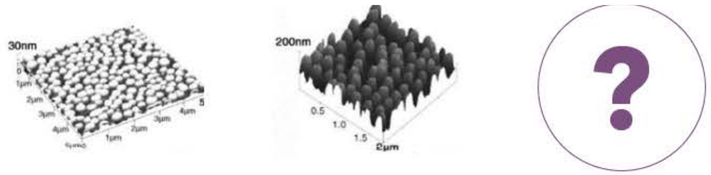


Cells align to nano-sized features

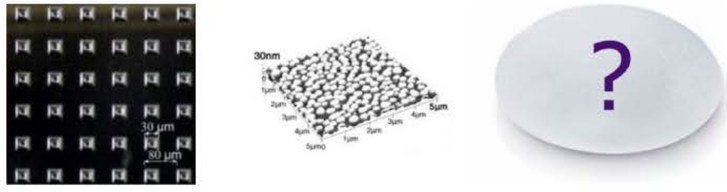


Reduces planar arrangement of tissue

Cell adhesion/ Focal adhesion formation



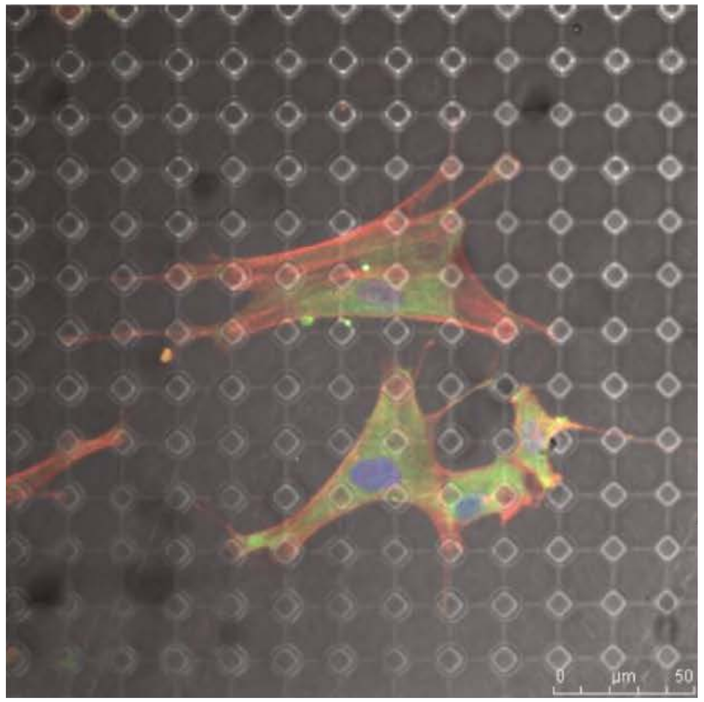
Cells preferentially adhere to small substrate heights, with MORE attachment sites



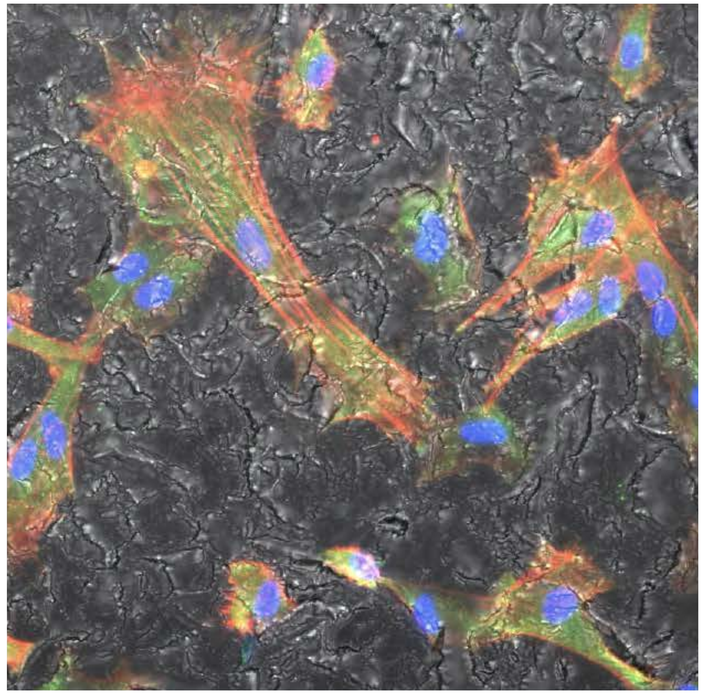
100nn width and 160nm height: endocytic reactions

Science-Based Design

Defining Optimal Surface Architecture



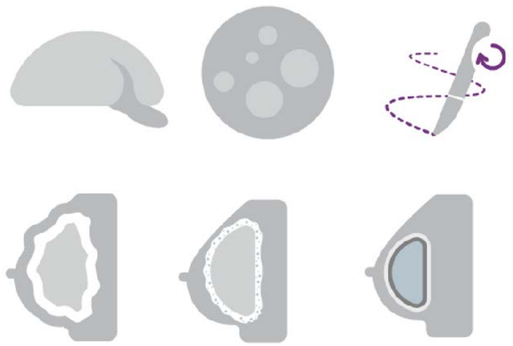
Scientific Theory



SmoothSilk®/ SilkSurface®

Shell Surface: Consumer-Centric Design & Engineering

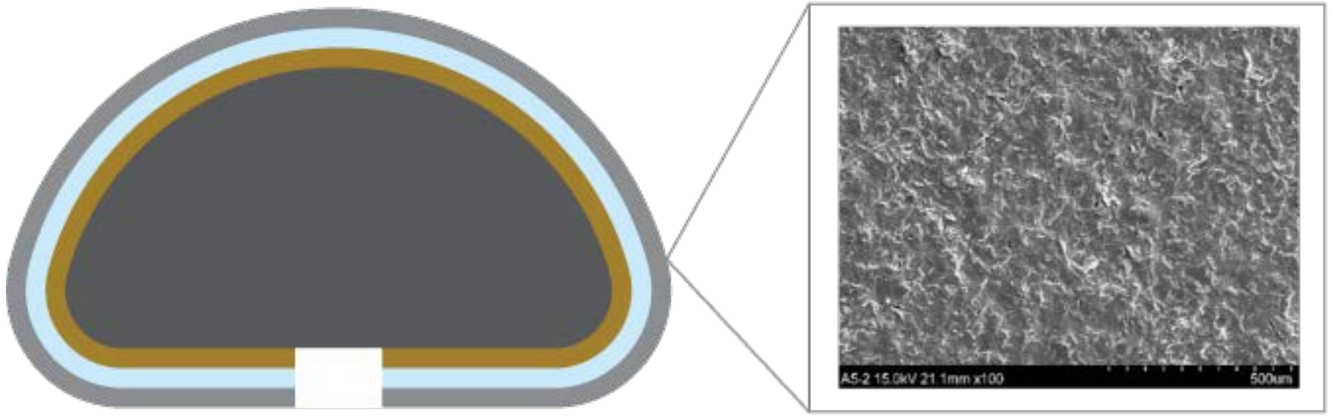
Patient Risk / Benefit Analysis



Designed and
Controlled Surface

Provokes the least amount of
inflammation and foreign body response
Less bacteria attachment
Less biofilm
Less friction
Cell friendly

SmoothSilk®

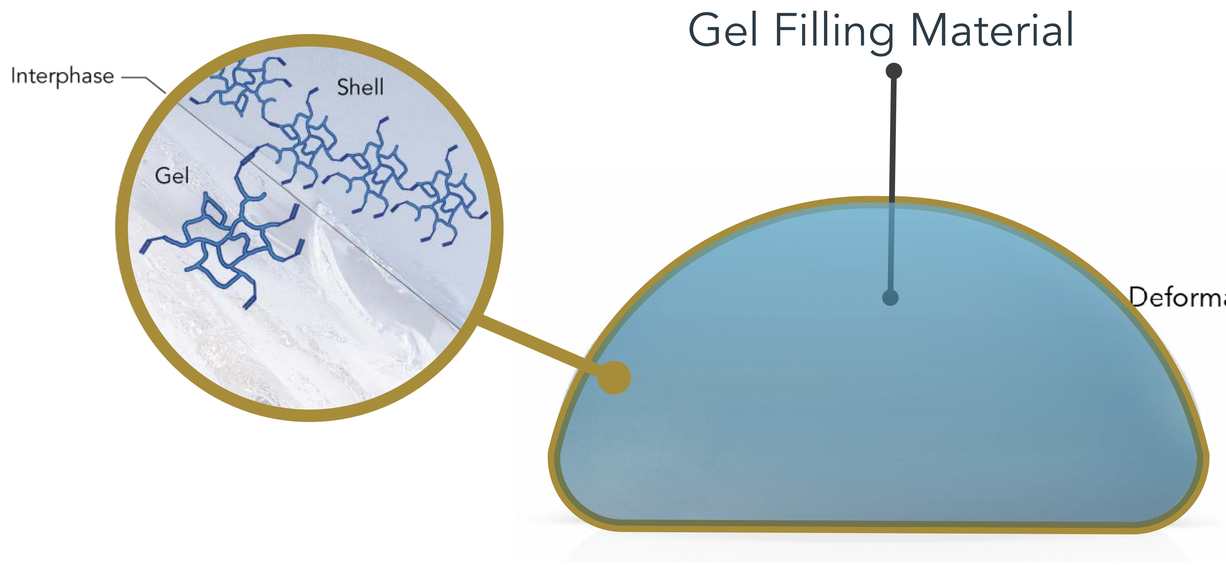


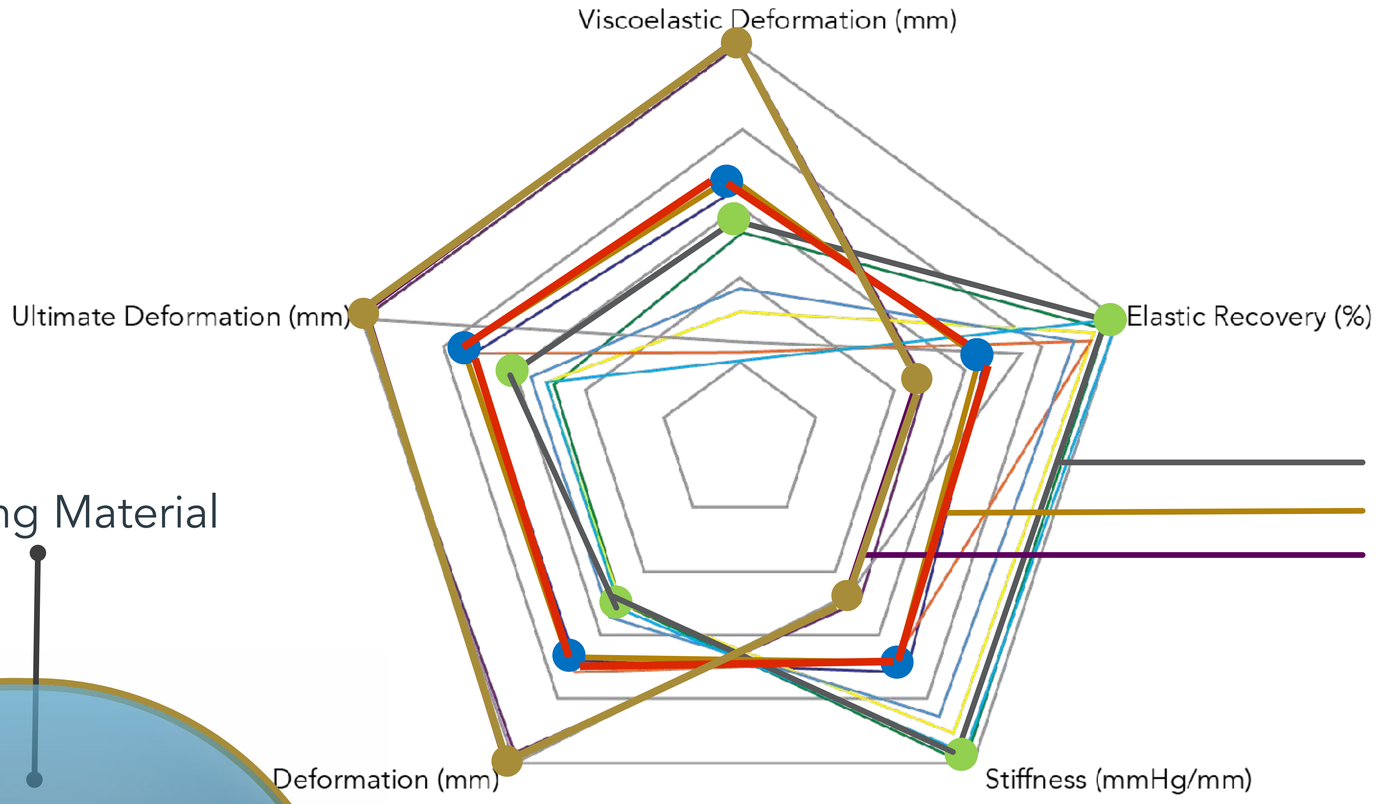
Fill Gel: Consumer-Centric Engineering

Patient Risk / Benefit Analysis

TrueMonobloc®

ProgressiveGel®

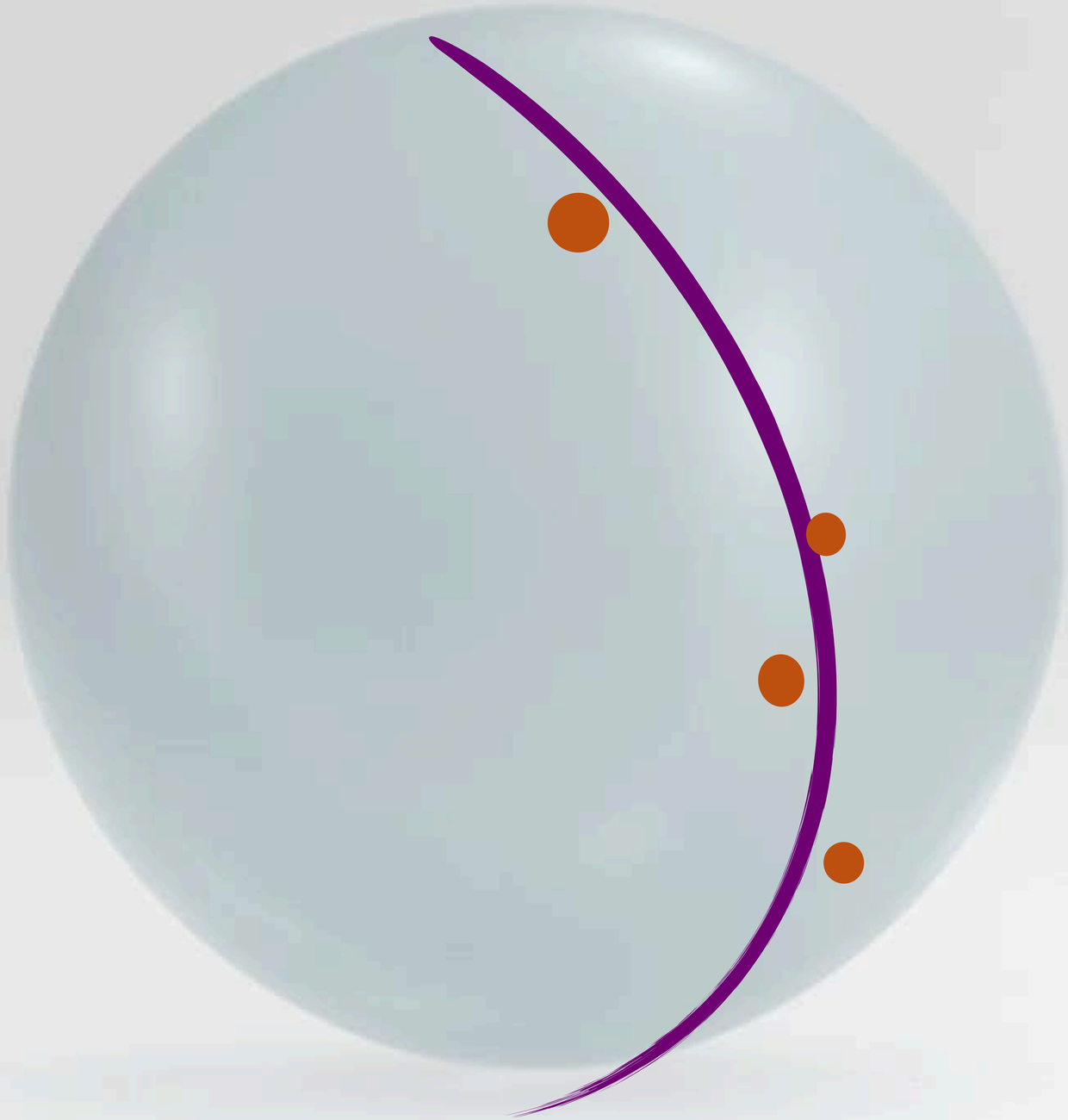





VIDEO

Ergonomix®

Women's Life-Style



Zen® Platform

New Generation for the Radio-Frequency platform:

- MR Conditional with no artifact effect outside of the implant
- Electronic Serial Number traceability feature
- Passive device with no internal battery
- Will allow Biosensing capabilities in the future



The Science Behind These Motiva® Standard

50+ peer-reviewed scientific publications



Risk Comparison Using Autologous Dermal Flap and Absorbable Breast Mesh on Patient Undergoing Subcutaneous Mastectomy with Immediate Breast Reconstruction

Implant-Based Breast Reconstruction after Mastectomy, from the Subpectoral to the Prepectoral Approach: An Evidence-Based Change of Mind?

Particulate Debris Released From Breast Implant Surfaces Is Highly Dependent on Implant Type

Silicone Implant Surface Roughness, Friction, and Wear

The surface topography of silicone breast implants mediates the foreign body response in mice, rabbits and humans

Rosalyn Cole D'Incelli

SVP, Global Clinical, Medical & US Regulatory Affairs

Global Clinical Evidence



Disclosure

The Motiva Core pivotal study is an ongoing US clinical trial of an investigational medical device under an FDA-approved Investigational Device Exemption. The Motiva device has not been approved by the Food and Drug Administration and is not commercially available in the United States.

This interim report describes preliminary data available to date and does not necessarily reflect final clinical results nor demonstrate the investigational device's safety and effectiveness. Accordingly, no conclusions should be drawn based on the information presented.


Safety Our First Priority

The Motiva® Standard



3-year data from Motiva FDA trial further confirms our less than 1% device-related complication rate.



3 million implants in market at 12+ years data on Motiva® Implants.



Less than 1% device-related complications supports best in class safety standard.

Backed by the power of Science, Technology and Clinical Evidence

US IDE Study Update 33 Study sites: US & EU

Study the Safety and Effectiveness of the Motiva® Breast Implants in Primary Breast Augmentation, Primary Breast Reconstruction, and Revision

834 Subjects • 560 Aug and Rev-Aug • 274 Recon and Rev-Recon • MRI cohort: 308	Augmentation	Office visit Follow-up rate
Augmentation: • 3-year follow-up complete, 4-5 Year visits ongoing • Reconstruction: enrollment complete	Year 3	92.4%

PMA fully submitted and accepted (Q1 2023)

DISCLOSURE: The Motiva® Core pivotal study is an ongoing US clinical trial of an investigational medical device under an FDA-approved Investigational Device Exemption.
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Motiva® Kaplan-Meier (KM)

KEY COMPLICATIONS 3-YEAR INCLUDING MRI COHORT

PRIMARY AUGMENTATION	2-YEAR (N=451), 95% CI	3-YEAR (N=451), 95% CI
Capsular contracture (Baker Grade III/IV)	0.5% (N=2)	0.5% (N=2)
Rupture, suspected or confirmed (MRI Cohort) [1]	0.6% (N=1)	0.6% (N=1)
Breast pain	0.5%	0.7%
Infection	0.9%	0.9%
Implant removal, with or without replacement	1.6%	1.6%
Any reoperation[2]	5.7%	6.1%
Any complication[3]	7.5%	8.4%

1.MRI cohort, N=176
2.Any surgery on the breast or chest area, device or non-device related, including size change
3. Any device or non-device related event, including reoperation

All data presented is preliminary 3-year follow-up data and does not reflect the final study results nor establish the ultimate safety or effectiveness of the device.

Post-Market Surveillance

Motiva® Patient Registration and Warranty

Device Registration and Warranty data provides a valuable framework for evaluating breast implant devices' long-term safety and performance, in addition to protecting surgeons and their patients.

326,700 women registered their implants in the MotivaImagine® App[1]

25,390 women have purchased an extended warranty[1]

344 registered women reported a device-related complication that resulted in reoperation[1]

214 have redeemed coverage[1] due to a complication

International Registries

With over 9,835 Motiva® Implants with a follow-up period of 6 years[2] Sweden national breast implant registry reports a reoperation rate of less than 1% due to device-related complications*

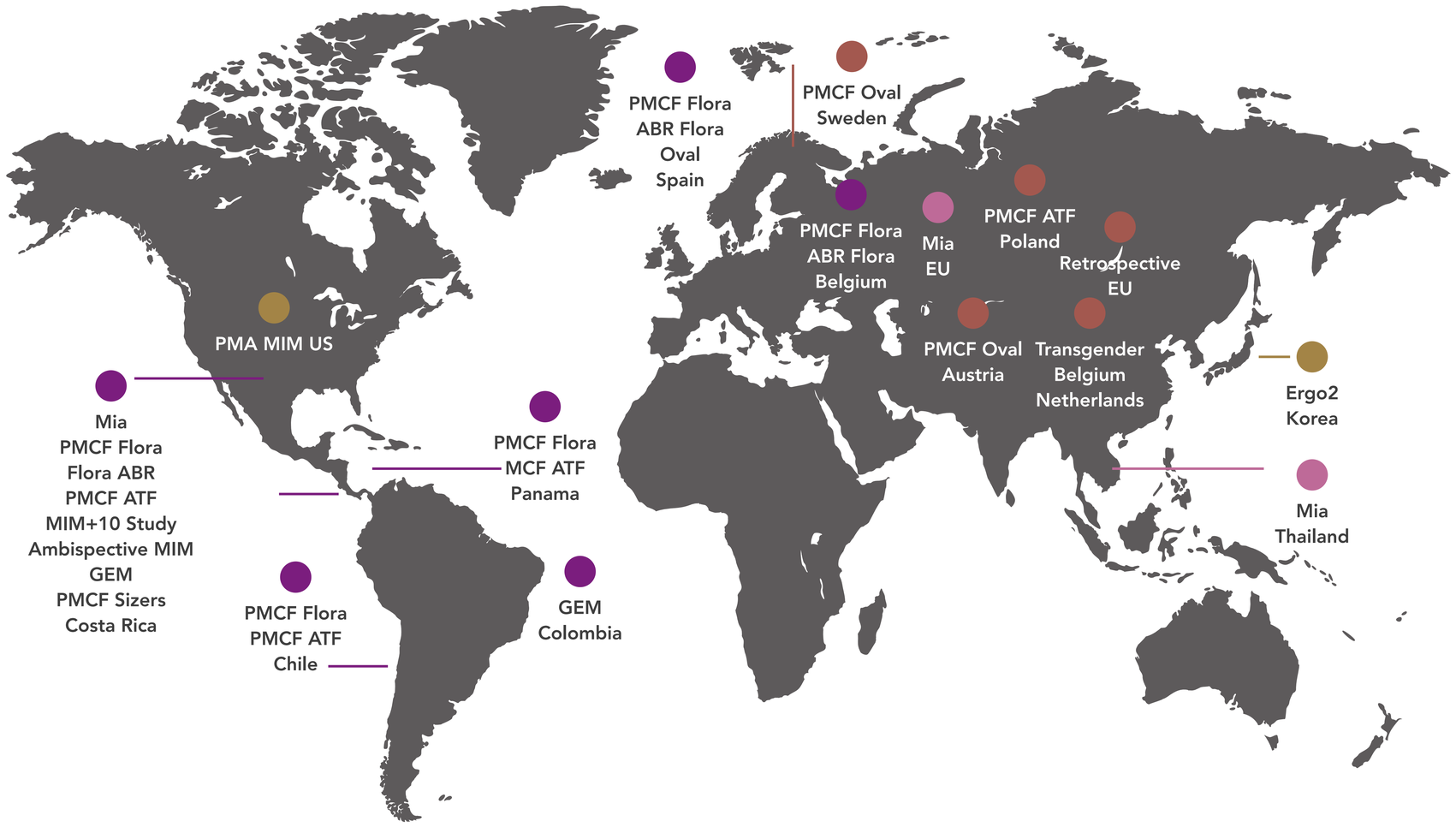
Extended Warranty

Low device-related complications

*Device-related complications are capsular contracture, device rupture, and/or BIA-ALCL.

1.Establishment Labs. Post-Market Surveillance March 2023. Establishment Labs®. Registrations via the Motiva® website and MotivaImagine® digital mobile application. 2. The Breast Implant Registry, Sweden. Report to the Establishment Labs S.A. Motiva® Implants Industry Report (2014-2020), 2021.

Global Clinical Evidence



GLOBAL MARKET EXPANSION Ergonomix2® Transgender Zen Temperature GEM



Mia® IRB Prospective Study

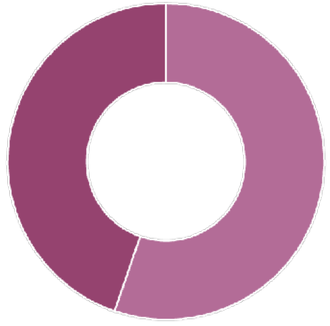
2-YEAR FOLLOW-UP

mia

Study population



100
participants



81%
Follow up compliance

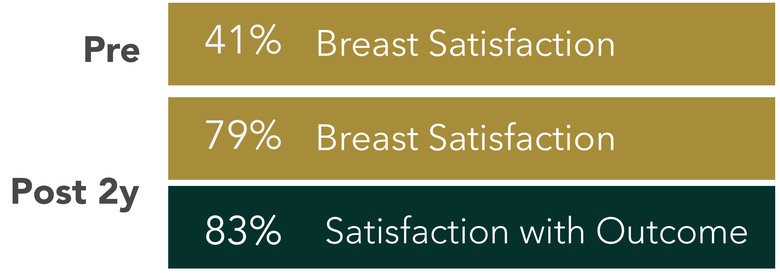
Demographics

29 age (mean)	**22** BMI (mean)
57% Professional employment	**62%** College/university graduate

Kaplan-Meier Analysis Key Events

Adverse Events by patient	2-year (N=81)95% CI
Capsular contracture (Baker Grade III/IV)	0.0%
Rupture, suspected or confirmed	0.0%
Breast pain	2.0%
Malposition	1.0%
Implant removal, with/without replacement	0.0%
Any reoperation	0.0%

BREAST-Q Scores



All data presented is preliminary 2-year follow-up data and does not reflect the final study results nor establish the ultimate safety or effectiveness of the procedure.

Study Participant

Age: 23

Height: 5.2 ft

Weight: 110 lb

BMI: 19.9

Implant: DSM 190

PRE-OP



3 MONTHS



2 YEARS

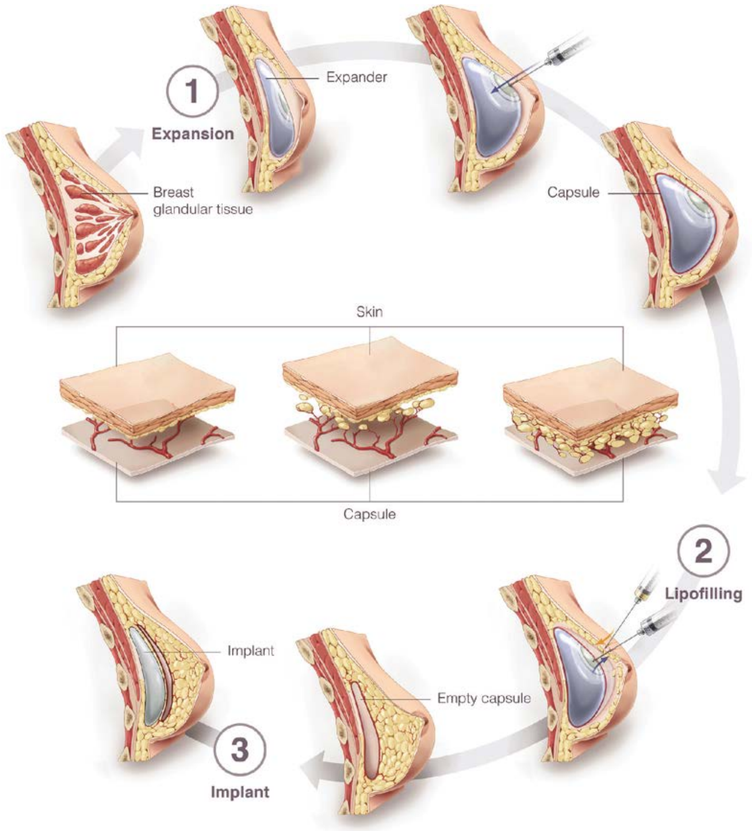


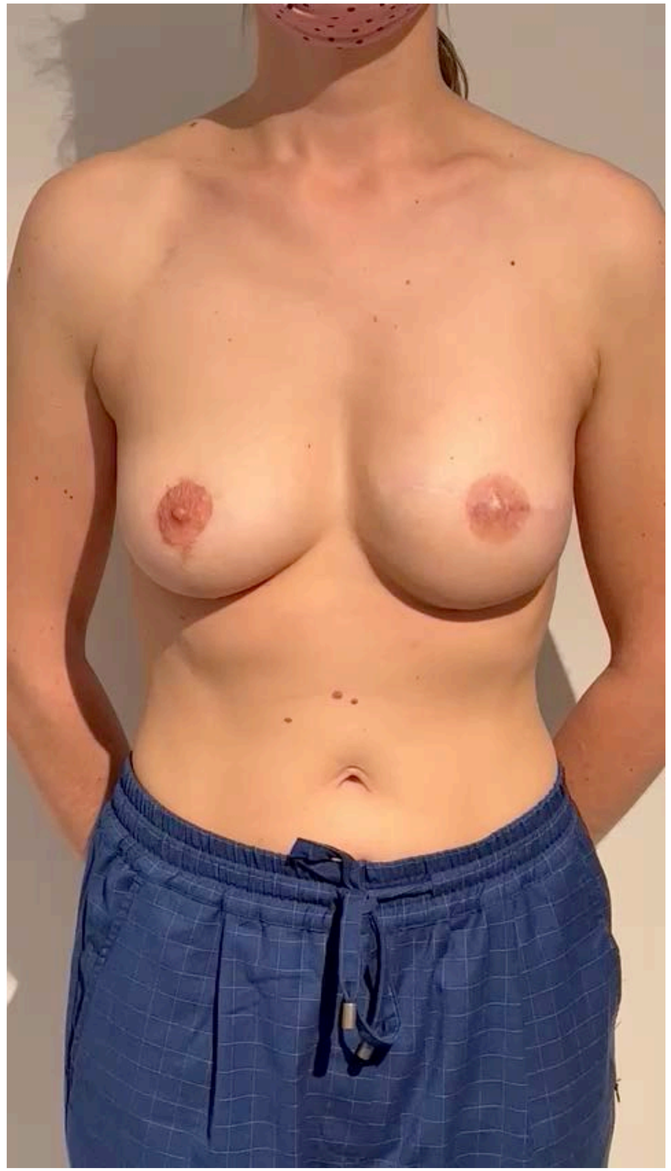

Aesthetic BreastRecon®

Flora® Studies

Flora ABR **(Reverse Expansion)**		EU, LatAm
Flora PMS		EU, LatAm
Flora PMS Retro		EU

ABR Reverse Expansion





Ergonomix2® Patient of Dr. Filip Stillaert

Flora® ABR

Peer-reviewed Studies

applied sciences
MDPI

Article

Dosimetric Effect of Injection Ports in Tissue Expanders on Post-Mastectomy Volumetric Modulated Arc Therapy (VMAT) Planning for Left-Sided Breast Cancer

Na-Hyun Hwang [1], Myungsoo Kim [2,*], Nam Kwon Lee [3], Suk Lee [3] and Jinho Hwang [2]

- In radiotherapy planning, Motiva Flora®'s RFID port showed **superior dosimetric results** to the heart and lungs vs traditional metallic ports, potentially reducing side effects to these organs.
- The RFID port material **reduces the artifact** on CT imaging than metals used in conventional expanders.

Journal of Clinical Medicine
MDPI

Article

Is It All about Surface Topography? An Intra-Individual Clinical Outcome Analysis of Two Different Implant Surfaces in Breast Reconstruction

Ines Schoberleitner [1,†], Angela Augustin [1,†], Daniel Egle [2], Christine Brunner [2], Birgit Amort [3], Bettina Zelger [4], Andrea Brunner [4] and Dolores Wolfram [1,*]

Surgeons reported:
Higher satisfaction with the **lower pole expansion** and the footprint created.*

Patients reported:
Significantly higher aesthetic and **comfort** scores.
Less breast pain, discomfort, and nipple sensitivity.*

The capsule tissue around SmoothSilk® expander devices was significantly thinner.*

The peri-prosthetic fluid was significantly lower.*

Journal of Clinical Medicine
MDPI

Article

MRI-Conditional Breast Tissue Expander: First In-Human Multi-Case Assessment of MRI-Related Complications and Image Quality

Simone Schiaffino [1,*], Andrea Cozzi [1], Barbara Pompei [2], Angela Lia Scarano [1], Carola Catanese [1], Armin Catic [2], Lorenzo Rossi [3,4], Filippo Del Grande [1,5] and Yves Harder [2,5,*]

First-in-human study confirms Flora's MRI-conditional **does not affect the image quality** of artifact-prone image sequences.

*When compared to the Mentor CPX4 Tissue Expander.

1. Hwang NH, Kim M, Lee NK, Lee S, Hwang J. Dosimetric effect of injection ports in tissue expanders on post-mastectomy volumetric modulated arc therapy (VMAT) planning for left-sided breast cancer. Applied Sciences. 2022, 12 (13), 6461. doi:10.3390/app12136461 2. Schoberleitner I, Augustin A, Egle D, Brunner C, Amort B, Zelger B, Brunner A, Wolfram D. Is it all about surface topography? An intra-individual clinical outcome analysis of two different implant surfaces in breast reconstruction. J. Clin. Med. 2023, 12, 1315. doi: 10.3390/jcm12041315 3. Schiaffino S, Cozzi A, Pompei B, et al. MRI-Conditional Breast Tissue Expander: First In-Human Multi-Case Assessment of MRI-Related Complications and Image Quality. J. Clin. Med. 2023, 12, 4410. https://doi.org/10.3390/ jcm12134410

Flora® ABR

High Satisfaction[5]



Low Device-Related Complications[1-4]

Designed by women for women.
FemTech.

1.Stillaert F, Lannau B, Van LanduytK, Blondeel P The Prepectoral, Hybrid Breast Reconstruction: The Synergy of Lipofilling and Breast Implants Plastic ReconstructiveJournalGlobal Open 2020 doi: 10.1097/GOX.0000000000002966. 2. Patzelt M, Zarubova L, Vecerova M, Barta J, Ouzky M, Sukop A. Risk comparison using autologous dermal flap and absorbable breast mesh on patient undergoing subcutaneous mastectomy with immediate breast reconstruction. Aesthetic Plastic Surgery. 2022. doi:10.1007/s00266-022-02799-6. 3. Adelson D, Singolda R, Haran O, Madah E, Barsuk D, Barnea Y. Our experience using round nano-surface ergonomix implants for breast reconstruction: A single center retrospective study. Aesth Surg Jour. 2022;, sjac264 doi: 10.1093/asj/sjac264. 5. Kaplan HM, Rysin R, Zer M, Shachar Y. A single surgeon's experience with Motiva Ergonomix Round SilkSurface silicone implants in breast reconstruction over a 5-year period. J Plast Reconstr Aesthet Surg. 2023. doi.org/10.1016/j.bjps.2023.01.047. 5. Schoberleitner I, Augustin A, Egle D, Brunner C, Amort B, Zelger B, Brunner A, Wolfram D. Is it all about surface topography? An intra-individual clinical outcome analysis of two different implant surfaces in breast reconstruction. J. Clin. Med. 2023, 12, 1315. https:// doi.org/10.3390/jcm12041315 6. Schoberleitner I, Augustin A, Egle D, Brunner C, Amort B, Zelger B, Brunner A, Wolfram D. Is it all about surface topography? An intra-individual clinical outcome analysis of two different implant surfaces in breast reconstruction. J. Clin. Med. 2023, 12, 1315. https:// doi.org/10.3390/jcm12041315

Motiva® USA

US Aesthetic Overview Market

$400m - $600m/yr
Breast augmentation market in the US

$350m/yr
Estimated breast reconstruction market in the US

~365,000
breast augmentations in 2021
(+44% from COVID decline in 2020).

148,000
women reported to implant removal with replacement
(+32% from 2020)*

310,000
procedures/yr average over the past 10 years

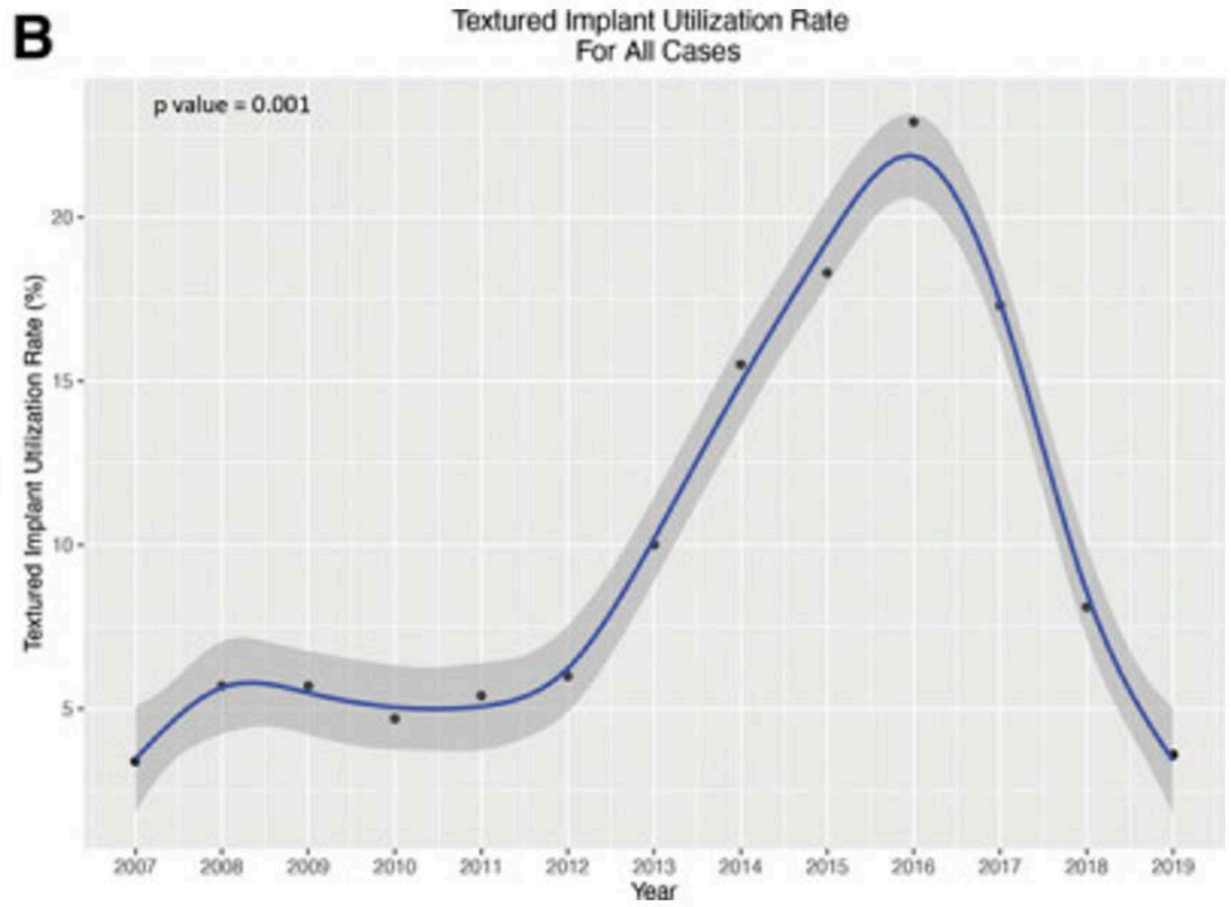
*The Aesthetic Sociaety

The US Breast Market lacks Product Differentiation

- The last PMA approval for a breast implant in the US was Sientra in **2012**
- In March 2019, the FDA hosted a General and Plastic Surgery Devices Advisory Panel.
- Allergan global textured implants recall in 2019
- FDA issues alert on SCC in 2022

In 2016 textured implants peaked at 23%

By 2019 textured implants were less than 4% of the US market



** Matros E, at al. Textured and Smooth Implant Use Reported in the Tracking Operations and Outcomes for Plastic Surgeons Database: Epidemiologic Implications for BIA-ALCL. Plast Reconstr Surg Glob Open. 2021 Mar 18.

An Opportunity to educate and differentiate in a commodity market

Market research commissioned in 2022/23 to understand US Market surgeon and patient preference

Key Patient Findings (265 interviews)

Generally unaware of implant brands

Do not come to surgeons with a pre-consult brand preference

- Top priority for their implant selection is "aesthetics" followed by "safety"

Focused on the safety benefits and aesthetics

- Patients desire improved safety, as long as aesthetics are equivalent.
- Most interested in discussing both implant-specific aesthetics and safety with their physician

Excitement to discuss Motiva Ergnonomix with their surgeons

Showed a willingness to pay a premium for Ergonomix

Key Surgeons Findings (100 interviews)

Surgeons generally view implant brands as ‘undifferentiated’ and do not identify any unmet needs

Most surgeons are interested in trialing Ergonomix when it comes to market

- Surgeons expressed excitement for a new product option

Surgeons believe Ergonomix represents a step forward in safety, pending further data

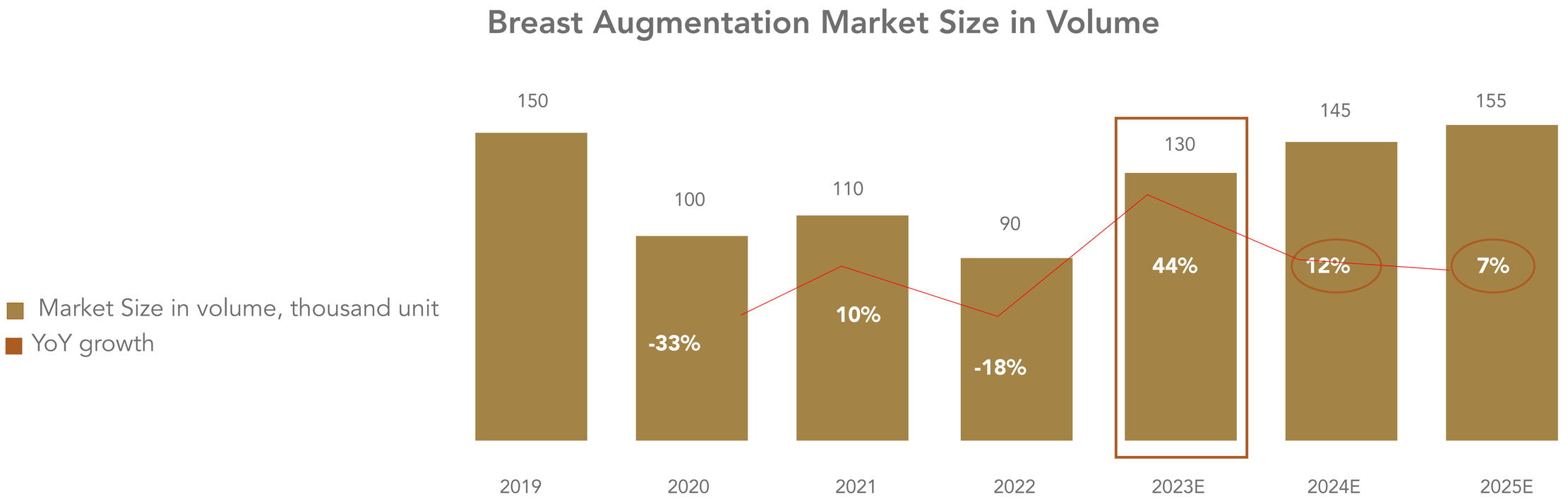
- Ergonomix is perceived as “differentiated, surgeons view it as an incremental improvement”.

IQVIA interviewed stakeholder groups to capture general insights on breast augmentation, perspectives on current implants, and reactions to a comprehensive profile of Ergonomix

IQVIA MEDTECH

Motiva® China

Breast augmentation market volume in China is recovering

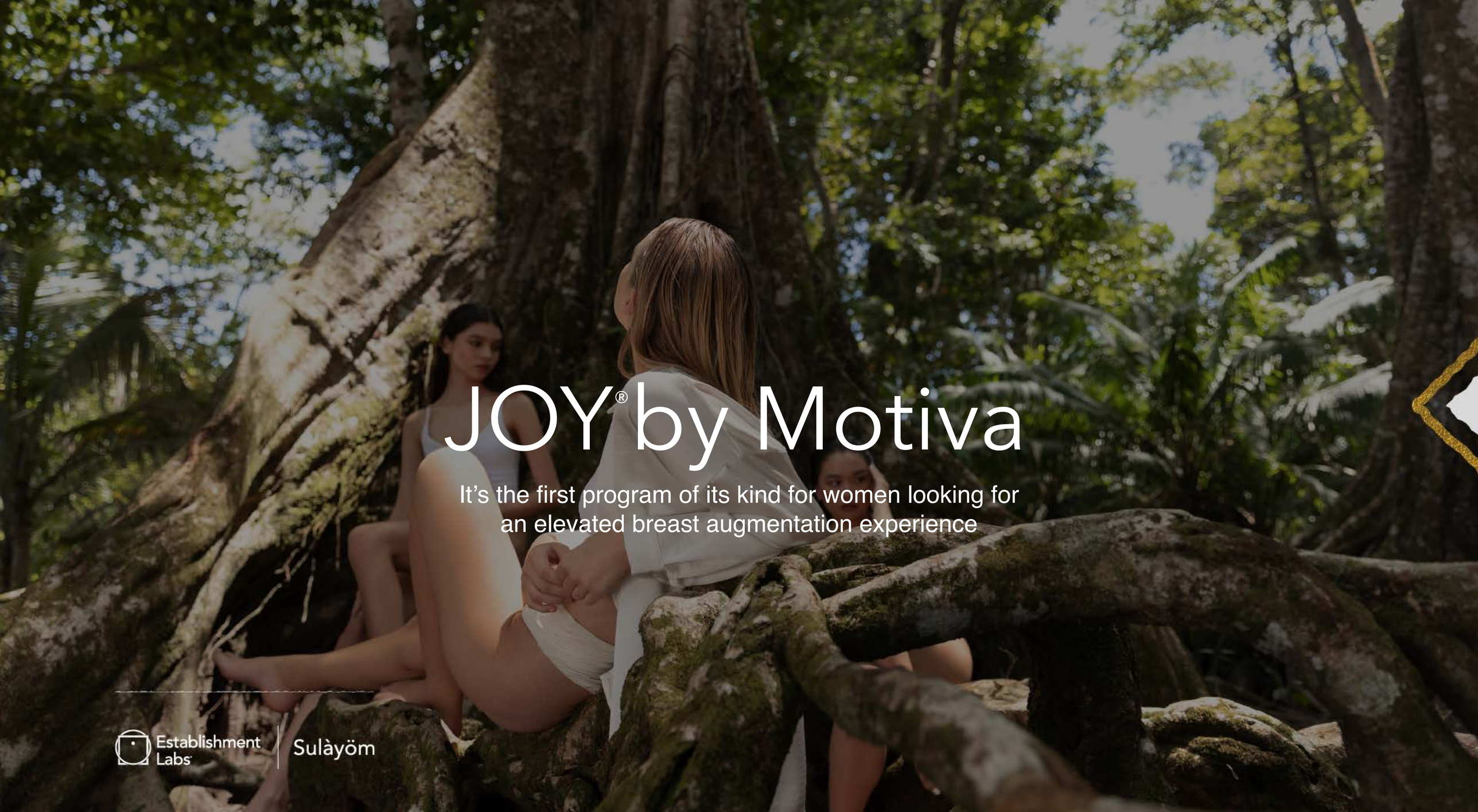


Forecast overall market will gradually recover to the pre-COVID level by 2025

Market Segment Opportunity for Motiva®

Motiva®

Patient	Economic	Mid-Low	Mid-End	Premium	Luxury
Market potential	12% (4%value)	18% (12%value)	42% (43%value)	25% (35%value)	3% (6%+value)
Patient Procedure Price (USD)	<$3,00	$3,000 -4,500	$4,500- 7,500	$7,500 - 12,500	$12,000+


JOY® by Motiva
It’s the first program of its kind for women looking for
an elevated breast augmentation experience
Establishment Labs
Sulàyöm

INNOVATION

ENHANCED SAFETY | MINIMAL SCAR | SOFTER & NATURA

Motiva®



MOTIVA® ROUND

GOOD

ERGONOMIX®

BETTER

ERGONOMIX2®

BEST

PREMIUM BREAST AUGMENTATION

+20%-30% price increase

ERGONOMIX2®

CORE PLATFORM TECHNOLOGY

RFDI ENABLED

ENHANCED ERGONOMY

MOTIVA SUPERSILICONES®

SMOOTHSILK® /SILKSURFACE®

TRUEMONOBLOC+®

+23 % ADAPTABILITY

+45 % SOFTER

+32 % HIGHER ELONGATION

BLUSEAL+®

+60 % HIGHER PERFORMANCE

Establishment Labs | Sulàyöm

Safety

wcp Woman's Choice Program

Motiva® raises the bar by offering more power of choice to the patient through the new Woman's Choice Program®.

This warranty program, unique to Motiva, provides up to USD $1.500 in financial support, in the event that women who receive Ergonomix2® implants via the JOY® program choose to reverse their augmentation, subject to additional terms and conditions.

All patients must register their implants within 90 days after surgery.



KANTAR

1800 WOMEN IN

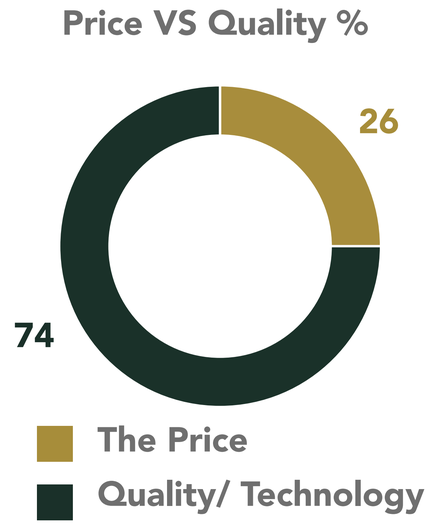
6 DIFFERENT COUNTRIES

BETWEEN AGES 20-60 YEARS

WHAT GENERATES APPEAL?

THE NATURAL RESULT I SAFETY I WARRANTY I MINIMAL SCARS

- JOY appeal: The idea is well liked in all countries and by all patients (9 out of 10 patients liked JOY)
- Women want more natural and softer results.
- 85% confirmed that our warranties are in their top things that caught their attention.
- 90% want Minimal Scars.



BREAKING THE MYTH ABOUT NEW TECHNOLOGY:
77% OF WOMEN WANT BETTER TECHNOLOGY SOLUTION; OUR ERGONOMIX2 IMPLANTS WITH RFID ARE THE MOST ADVANCED WE'VE INTRODUCED.

30 Countries

AND GROWING!

2021

- DENMARK
- GERMANY
- ITALY
- SPAIN
- SWEDEN
- UNITED KINGDOM
- COLOMBIA
- COSTA RICA

2022

- AUSTRIA
- NORWAY
- CZECH REPUBLIC
- LATVIA
- SWITZERLAND
- TURKEY
- SINGAPORE
- FRANCE
- BELGIUM
- HUNGARY
- POLAND
- SOUTH AFRICA
- MONGOLIA
- THAILAND

2023 – to date

- IRELAND
- CROATIA
- GREECE
- DOMINICAN REPUBLIC
- ECUADOR
- PANAMA
- PERU

SEVERAL COUNTRIES

10% PENETRATION

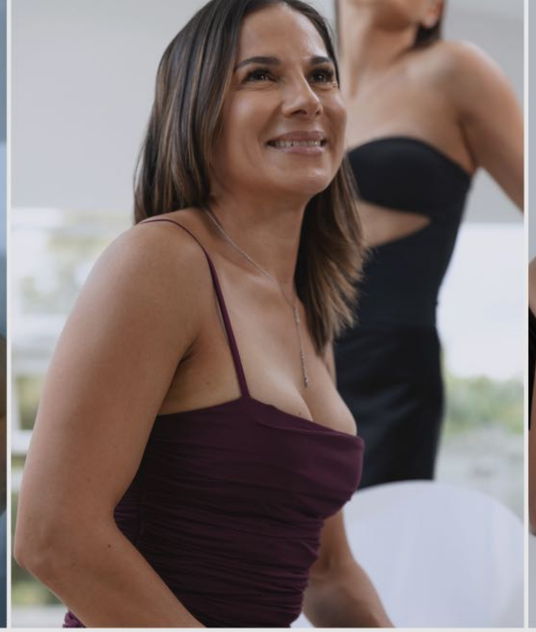

The implants that I chose fit me just right.

mia®

FEMTECH

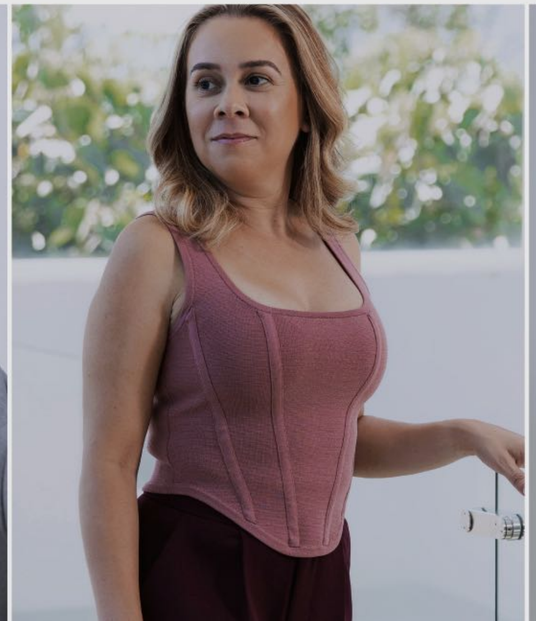
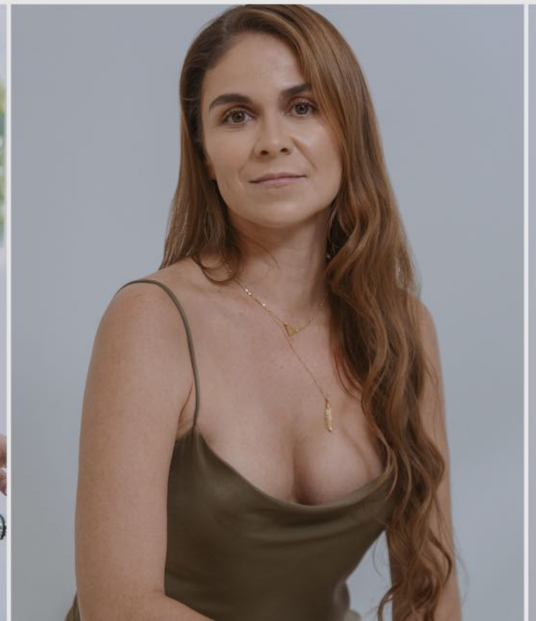





Mia® is the voice of over 16k women around the globe




Breast Harmonization

by

mia®
FEMTECH


Hundreds of satisfied
Mia® Consumers...
Get to know their stories!
mia
FEMTECH

Uniqueness of Mia®

Value proposition

1	2	3	4	5
CATEGORY AND BRAND	INNOVATION	EXPERIENCE	OUTCOME	COMMUNICATION
Breaking taboos & breaking down barriers by creating a movement.	Minimal invasive technology & technique.	Best-in-class experience in collaboration with our partners.	Align with their expectation. Natural, discreet & proportional results.	Arrive at right target and create advocates who evangelize.



mia FEMTECH

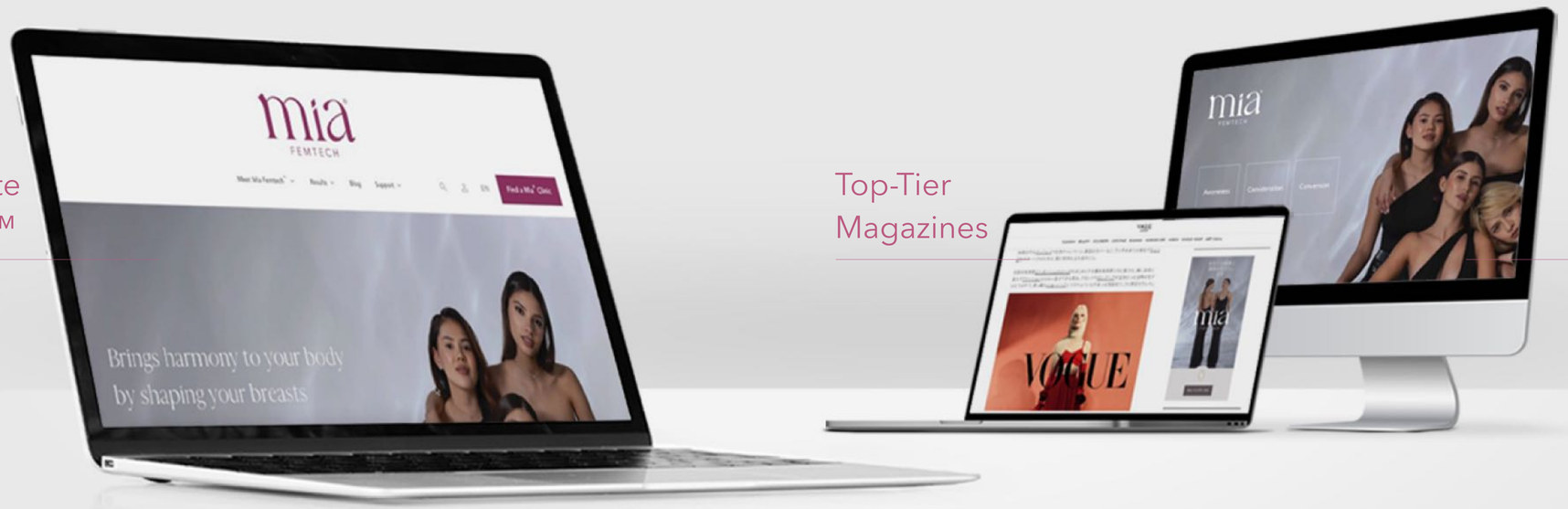

Early stage.
Building strong
brand awareness.
mia
FEMTECH

Full digital takeover

Global Website
Mia Femtech™

Top-Tier
Magazines

Local Patient
Aggregators



Local Landing Pages in each Country

JAPAN



SPAIN



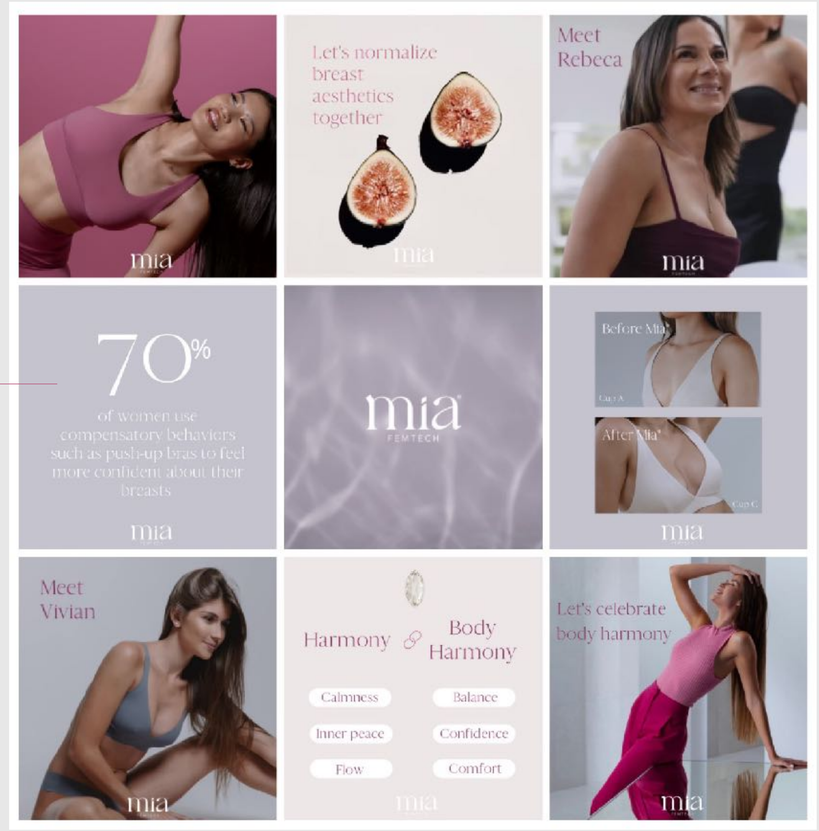
FRANCE

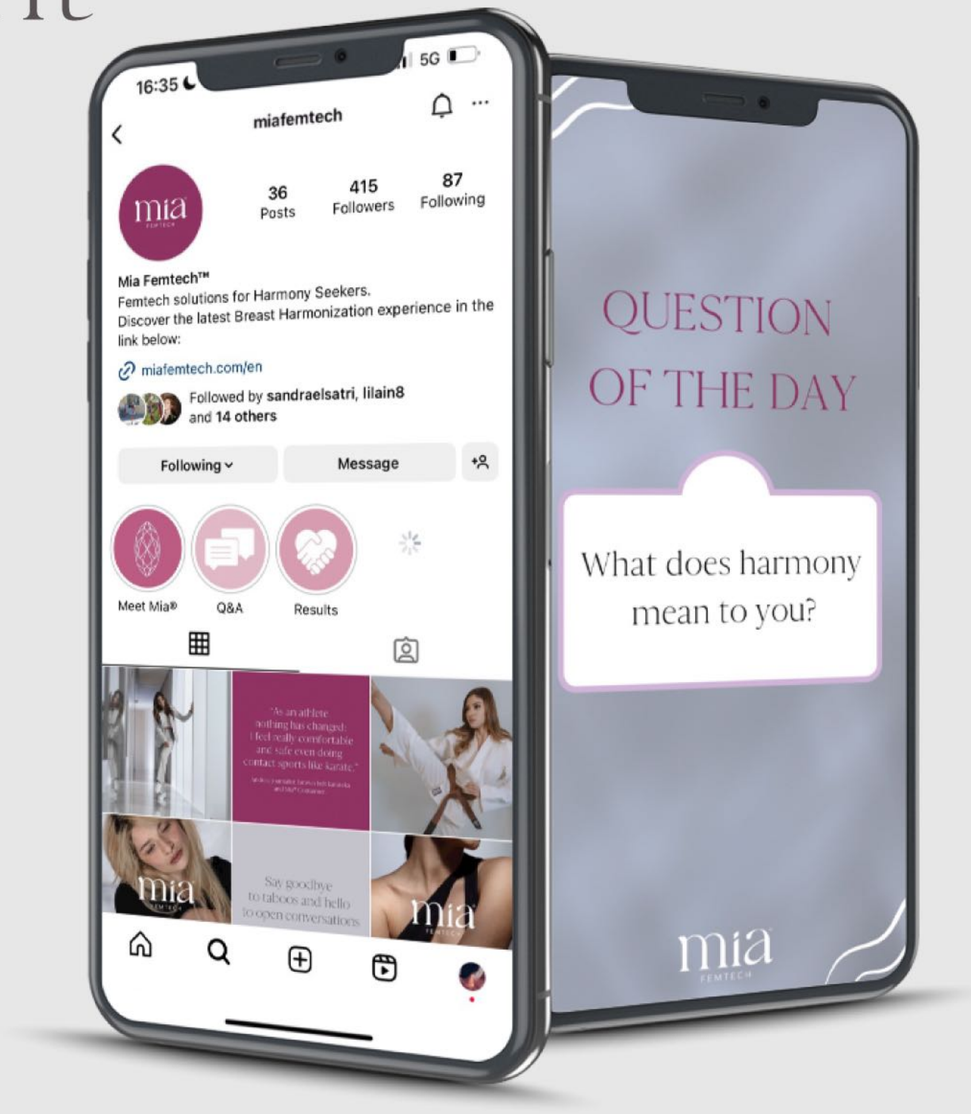


Global Instagram account

Spark conversations and build communities

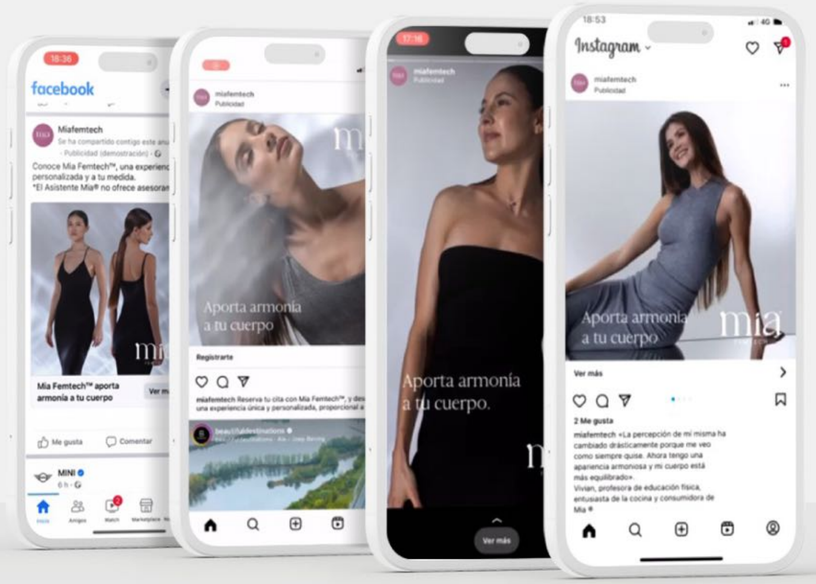
Engage, connect, influence & encourage UGC



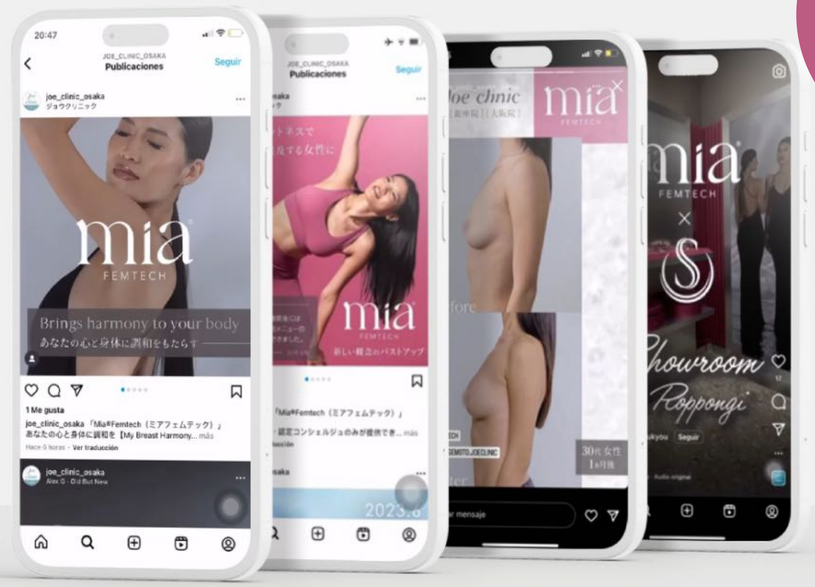


Full Social Media takeover

DTC Social Media Campaign



B2B2C Strong Communication



+50
posts & stories

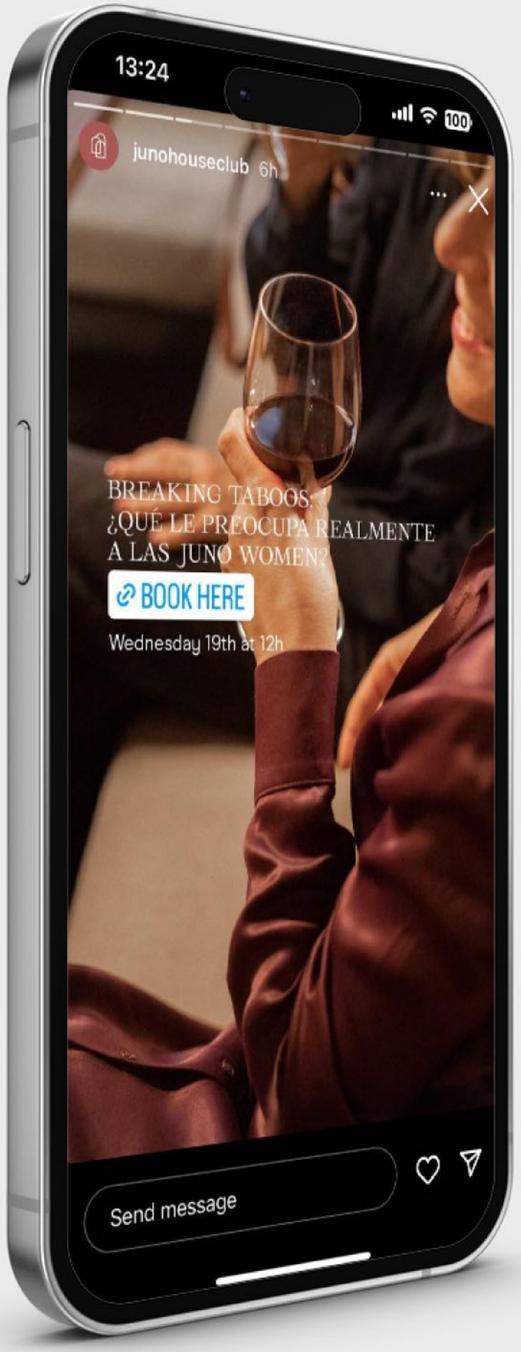
Brand Partnership

Juno (Social Club)

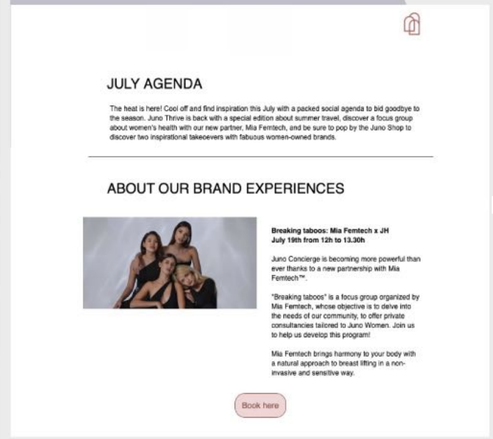
Private Consultations







Communications






“Experiences
are easy to share, but hard to copy”
mia
FEMTECH

Utoquai & LAC Clinic set-up









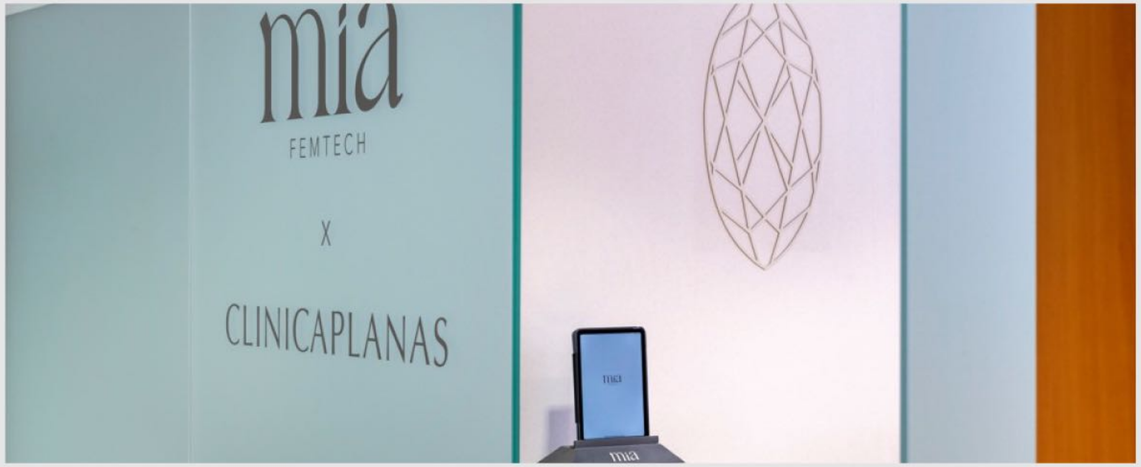


Planas Clinic set-up









Seishin Roppongi Clinic set-up







Successful launch

Demonstrated in just 13 weeks

1

EXPANDING THE MARKET

Unmet need & women´s desire

2

WILLINGNESS TO PAY PREMIUM

Minimally invasive technology & technique

3

EXCEEDING EXPECTATIONS

Innovative solution with an appealing benefit

Initial results from

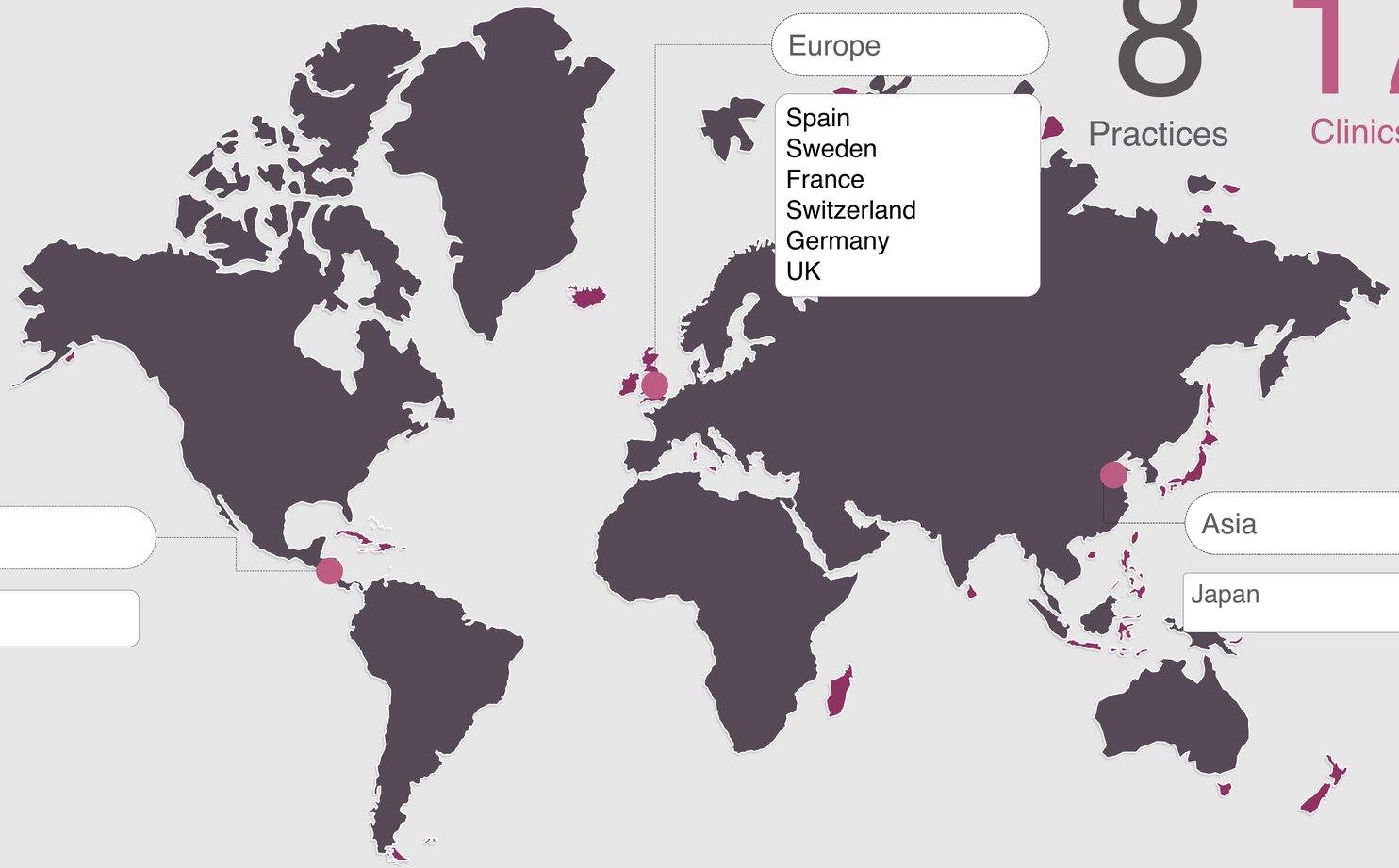
1 week launch in Spain



- The initial campaign generated over 175 leads to the clinics.
- There are ~30 women currently either awaiting a Mia appointment or have one scheduled.
- 50% of women were not considering a traditional breast augmentation.

mia FEMTECH

2023 Mia® clinics around the globe*



Europe

8 Practices

17 Clinics

Spain
Sweden
France
Switzerland
Germany
UK

America

1 Flagship Clinic

Costa Rica

Asia

3 Practices

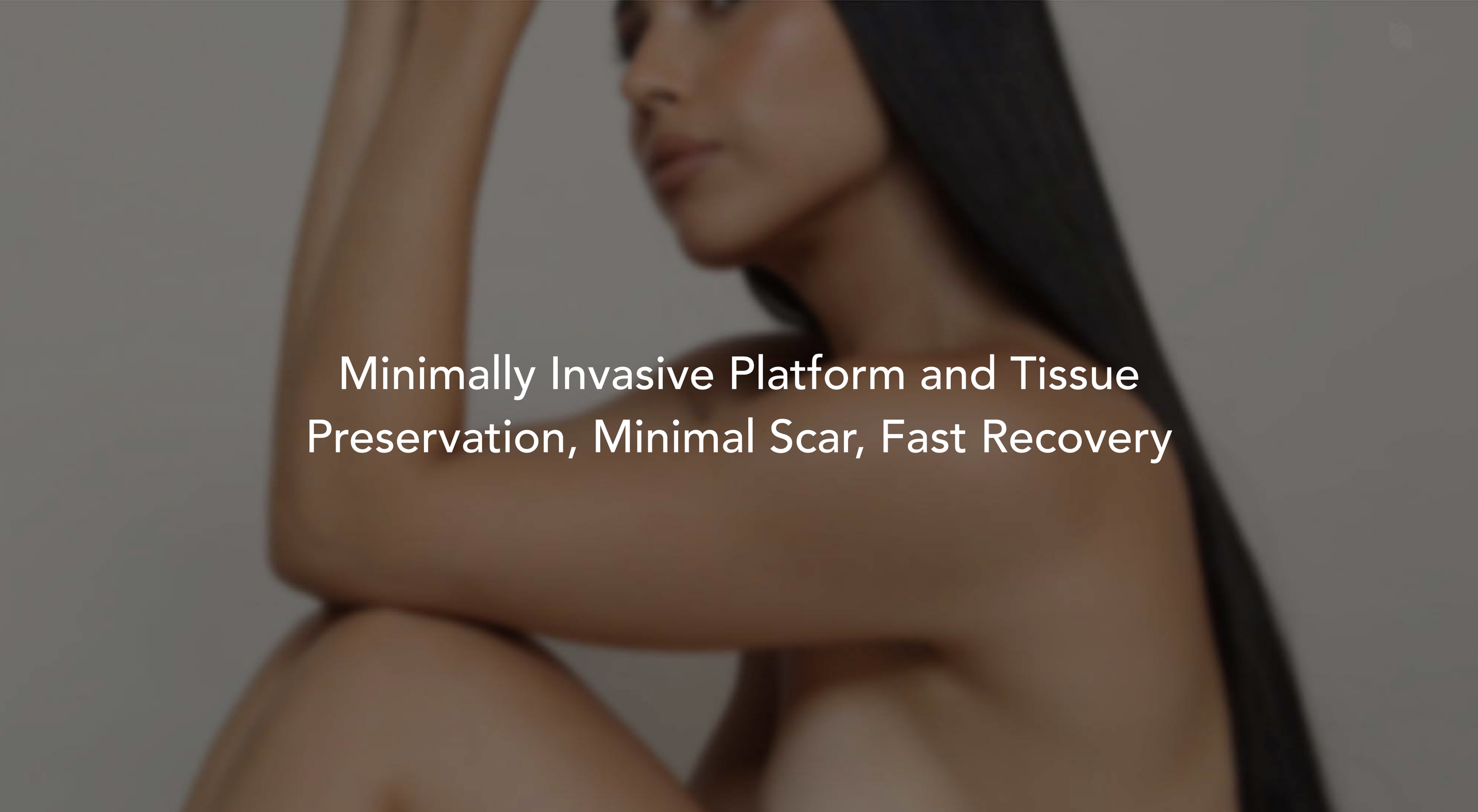
7 Clinics

Japan

*signed clinics

Femtech Roadmap

Establishment Labs | Sulàyöm


Minimally Invasive Platform and Tissue
Preservation, Minimal Scar, Fast Recovery



A SUPERIOR TECHNOLOGY PLATFORM

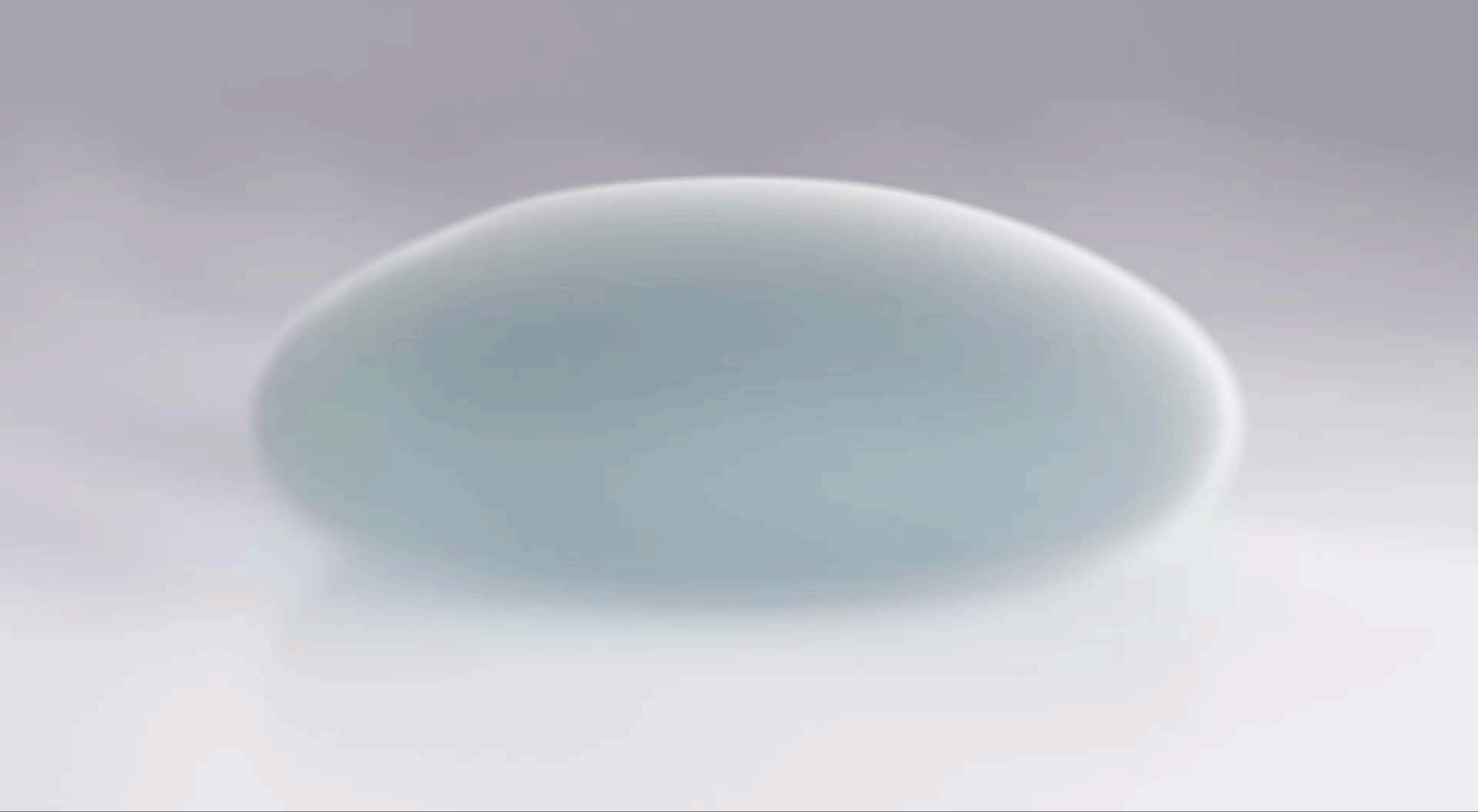
Motiva® Ergonomix2® Diamond®
Implants

Motiva® Channel
Separator

Motiva Injector ®

Motiva® Inflatable
Balloon

Motiva® Marking Tool



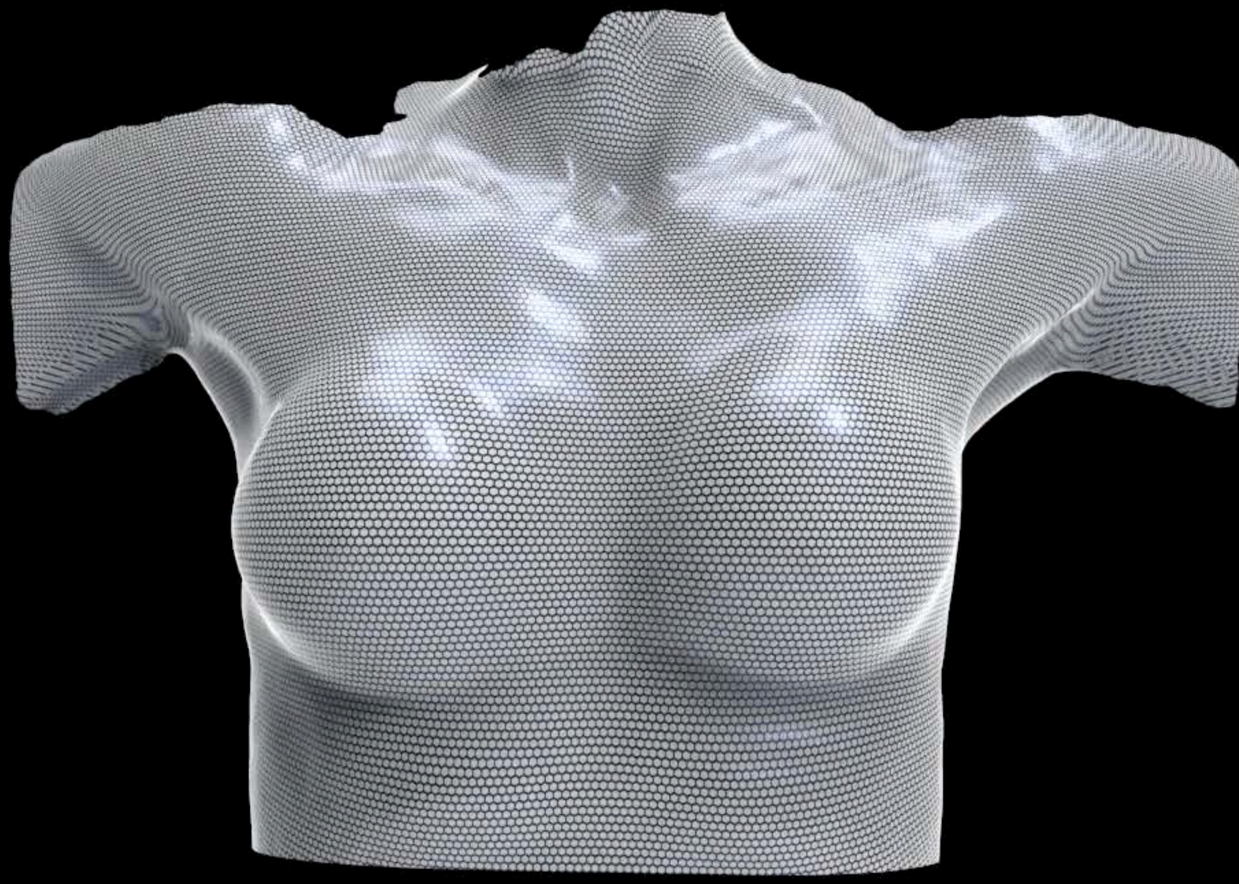
Patient "Y" Two cups size up



Pre-op Volume

Left: 326cc **Right**: 318cc

Pre-op



Post-op Volume

Left: 496cc **Right**: 473cc

Post-op

3D Scan

Mia® & Mia®+

Mia®



Mia® & Mia®+

Joy®+



GEM®


GEM®

RFID Sensor Platform

Establishment Labs | Sulàyöm

RFID Sensor Platform





3

3

<1%

RFID Sensor Platform

Motiva® launched with Qid® safety technology in 2014

Only Motiva® implants provide traceability using RFID technology

60% of Motiva® implants with Qid® in the market

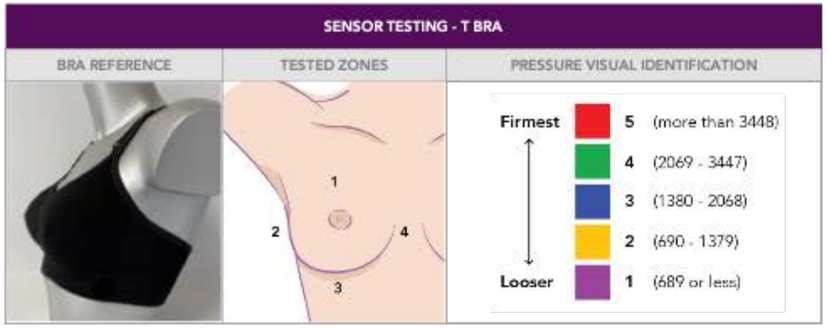
Of all registered implants, 70% are with Qid®

Vision – BioZensor Platform

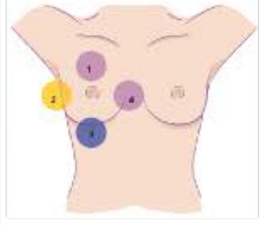


Bra development project

Pressure zones testing



- Bra development to provide the consumers a better experience and recovery results.
- Pressure testing to back-up design decisions.
- Preliminary testing before starting study with University of Portsmouth.
- Data analysis for future wearable devices development.

	NO BAND							BAND			
ZONES	Zone 1	Zone 2	Zone 3	Zone 4	Zone 5	Zone 6	Zone 7		Zone 1	Zone 2	Zone 3	Zone 4
POSITION									Upper	Axilar	Under	Inner
PRESSURE (Pa)	689.5	1,379.0	1,379.0	1,379.0	1,379.0	3,447.4	689.5		689.5	1,379.0	2,068.4	689.5
FORCE (Newton)	0.1	0.1	0.1	0.2	0.1	0.4	0.1		0.1	0.1	0.2	0.1

RFID Sensor Platform

Live Demo



Publication



MicroTransponder
Platform Sensors

www.nature.com/scientificreports

scientific reports

Check for updates

OPEN

Tumor therapeutic response monitored by telemetric temperature sensing, a preclinical study on immunotherapy and chemotherapy

Qi Shao[1✉], Mia Lundgren[2], Justin Lynch[3], Minhan Jiang[4], Mikael Mir[3], John Bischof[1,4] & Michael Nelson[2]

Temperature in the body and the tumor reflects physiological and pathological conditions. A reliable, contactless, and simplistic measurement system can be used for long-term monitoring of disease progression and therapy response. In this study, miniaturized battery-free wireless chips implanted into growing tumors on small animals were used to capture both basal and tumor temperature dynamics. Three preclinical models: melanoma (B16), breast cancer (4T1), and colon cancer (MC-38), were treated with adoptive T cell transfer, AC-T chemotherapy, and anti-PD-1 immunotherapy respectively. Each model presents a distinctive pattern of temperature history dependent on the tumor characteristic and influenced by the administered therapy. Certain features are associated with positive therapeutic response, for instance the transient reduction of body and tumor temperature following adaptive T cell transfer, the elevation of tumor temperature following chemotherapy, and a

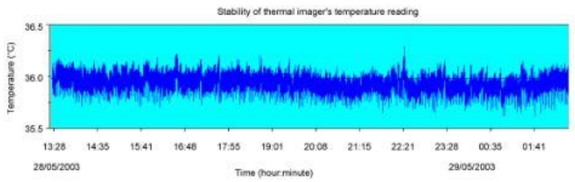


Fig. 3. An example of the stability of a typical thermal imager's temperature reading (Reproduced with permission of SPRING Singapore. Copyright remains with STR 15-1: 2003).

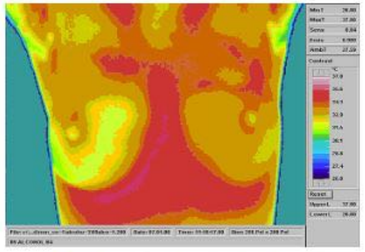


Fig. 4. Typical thermogram of an asymptomatic volunteer age 35.

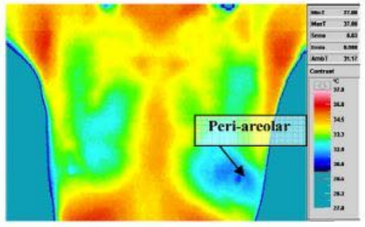


Fig. 5. Asymmetric thermogram of a 52 year old woman with left breast abnormality.

perature change: [15]). Conversely, skin surface temperature can be increased by physical exertion, the use of stimulants such as alcohol [3,45,77], topically applied nicotinate [13] and inflammation secondary to trauma [43,72] or even sunburn [25]. Heavy powdering on chest, hormone replacement therapy (HRT), pregnancy and menstruation, can also affect breast surface temperature.

Figs. 4 and 5 illustrate examples of a typical thermogram of an asymptomatic volunteer (aged 24) and a typical asymmetric thermogram of a 52 year old woman with left breast abnormality. Based on mammographic examinations in 1000 Singapore women on the eve of the breast cancer awareness month (Oct. 1998, [8,84]), the average size of a cancerous lump [54] was 1.415 cm in spheroid shape when detected in the clinic for the first time.

From the breast thermograms, temperature data are extracted from them. The thermograms consist of many colored pixels, each representing a temperature. From the thermograms, it is possible for an experienced medical practitioner to diagnose vides a reflection of functional tumor induced angiogenesis and metabolic activity rather than structurally based parameters (i.e. tumor size, architectural distortion, microcalcifications, [36]). With a direct reflection of the biological activity in the breast, IR imaging has been recommended as a significant biological risk marker for cancer [1,33].

3. Performance evaluation

A recent Health Technology Assessment from New Zealand could not find sufficient evidence for infrared thermal imaging as a screening test for breast cancer [34]. Whether thermal imaging carries the potential of a risk marker for breast disease, must be answered with adequate methodology and inclusion of all studies performed in the field.

3.1. Preparation of patient

Skin surface temperature is greatly affected by the numerous conditions such as perspiration. In order to reduce errors such

First Screenshot: Kennedy, D. A., Lee, T., & Seely, D. (2009). A comparative review of thermography as a breast cancer screening technique. Integrative cancer therapies, 8(1), 9-16.

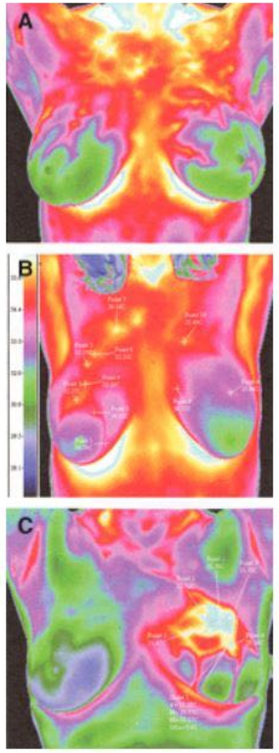


Figure 1. Thermographic breast images: (A) normal; (B) showing early stage of cancer in the right breast; (C) showing advanced cancer in the left breast

How is Thermography Performed?

Laboratory Procedure

Temperature and humidity control in the imaging room must be maintained at a stable temperature within the range of 18°C to 25°C and maintained within 1°C during the examination.[34, 36] Potential sources of additional heat generated by windows permitting sun to shine through, additional heat generated by computer equipment, and other such devices must be eliminated from the imaging room in order to reduce thermal artifacts. Drafts and air flow from air conditioners must be directed away from the patient in order or reduce the opportunity for additional physiological stress that would negatively impact the procedure.[34]

Patient Procedure

After filling out a breast history form, patients are asked to undress to the waist in a private dressing room to allow the surface of the breasts to cool to room temperature (18°C to 22°C) taking about 15 minutes. For the scan, the patient is asked to stand about 10 feet in front of the camera with her arms raised over her head while three views of the breast (anterior and two lateral views) are taken. The next step in the process is a "cold challenge" where the patient is asked to place both hands in cold water at 10°C for one minute; then these same three images are retaken.[43,44] The breasts exhibit thermal patterns that are captured by the infrared camera. It is these thermal captured image patterns that are interpreted by a trained thermographer. The necessity of the inclusion of a cold challenge as part of the imaging procedure is currently being questioned. In 2004, Amalu[45] conducted a review of the literature and found that the results of the "cold challenge" did not contribute additional information that would change the clinical follow-up of a patient.

A trained thermographer will analyze the thermogram for specific thermal features. Thermal features are divided into signs and criteria based on their established characterization of breast disease. In all instances the contra lateral breast is used as reference for some degree of control. According to Hoekstra[46] thermology signs are:

Second Screenshot: Ng, E. K. (2009). A review of thermography as promising non-invasive detection modality for breast tumor. International Journal of Thermal Sciences, 48(5), 849-859.

Expert Panel Discussion

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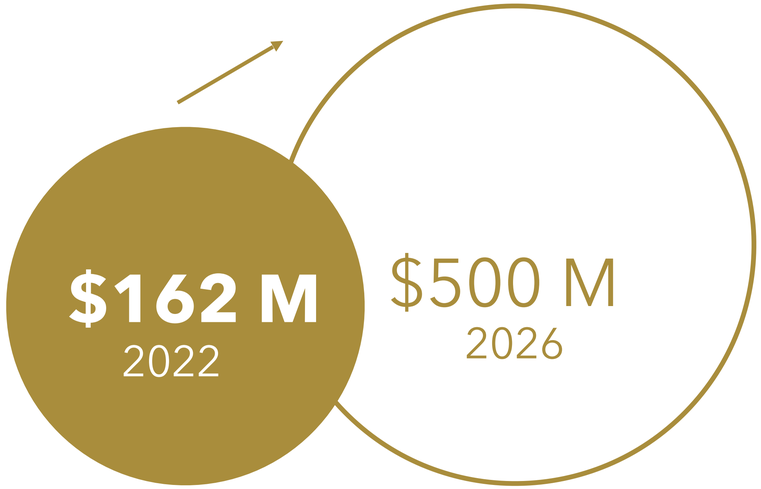

Threats to women’s health in our industry: Expert Update on BIA-ALCL and SCC and other lymphomas - Dr Mark Clemens & Dr Fabio Santanelli

Systemic Symptoms associated with breast implants: an Expert review of the evidence.

Dr Caroline Glicksman & Dr Pat McGuire

Q&A

Thank you

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