Establishment Labs

41st Annual J.P. Morgan Healthcare Conference

JANUARY 12th, 2023

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ESTABLISHMENT LABS

A global medical device company dedicated to improve Women’s health and wellness.

OUR PURPOSE

Putting Women First: in health and well-being, in science and technology, and in our communities.

BREAST IMPLANT MARKET

Global breast implant market is approximately

$2.0 - $2.2B annually

Breast augmentation is the #1 aesthetic surgical procedure worldwide, with over **1.6 million** performed annually

$1.5B

Breast reconstruction represents **30%** of the global market for breast implants; **60%** of the current recon market is in US

$600M

INDUSTRY CHALLENGES

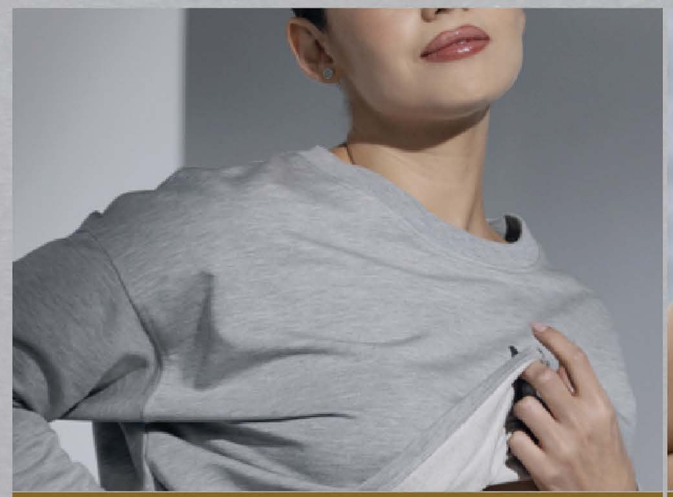
Lack of innovation

Male-centered industry

Insufficient safety

Objectification of women

GROWTH STORY



HEAL

Offer safer and innovative options for women seeking breast aesthetics

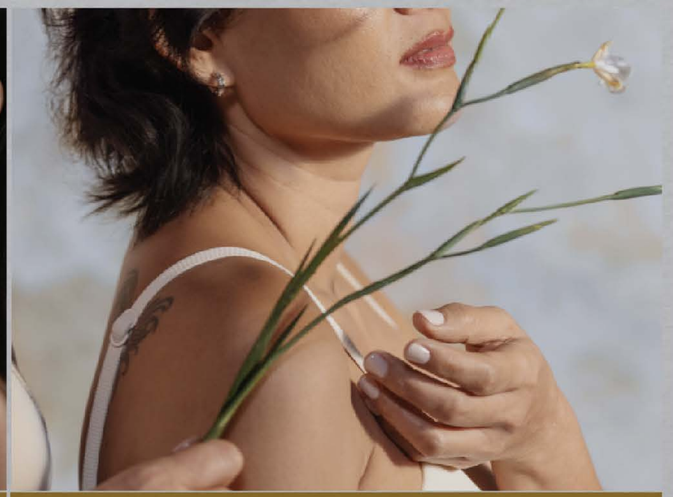
Capture market share in current and future global markets



NORMALIZE

Offer new and differentiated technologies that overcome current perceptions and behaviors in breast aesthetics

Create new categories within breast aesthetics which can expand the market opportunity



DEMOCRATIZE

Improve outcomes and expand access to breast reconstruction

Capture market share and expand market opportunity

HEALING
BREAST AESTHETICS



2004

Company founded
and research started.

2010

Product Launch
Launched Motiva Implants®.

Advanced SmoothSilk® / SilkSurface® design for a biocompatible visual barrier layer.

TrueMonobloc® Technology links the components of the shell and the filling gel to create a more cohesive structure.

2011

BluSeal® A patented barrier layer indicator minimizes risk of silicone gel diffusion.

2012

RFID Qid® an embebed RFID micro-transponder, provides a non-invasive reading of the electronic serial number associated with the implant.

2014

Ergonomix®: the world's first ergonomic breast implant.

2018

IPO ON NASDAQ:ESTA®
Motiva Implants® US IDE clinical trial begins.

2016-17

Launch of Motiva®
MinimalScar and Motiva® Hybrid designed surgeries.

2020

10 years of post-market surveillance follow up show less than 1 % of complication rate.

2021

Key launches:
Motiva Flora®
JOY®
Ergonomix2®

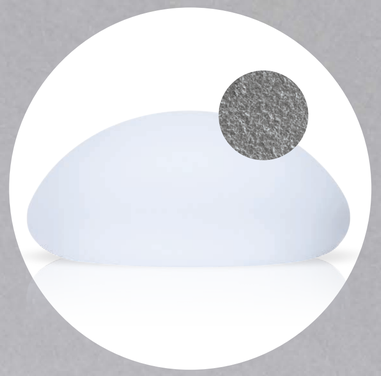
Publication of landmark surface research
nature biomedical engineering.

2 million implants in market.

2022

Presented 2 Year Data from FDA IDE trial
with modular submission progressing.

Established the Women's Health Hub in Barcelona



PIONEERING BIOCOMPATIBLE SURFACE TECHNOLOGY

SmoothSilk® patent protected technology optimizes biocompatibility and reduces the incidence of capsular contracture.



HIGH-DURABILITY SILICONE SHELL AND IMPLANT CONSTRUCTION

TrueMonobloc® This is a proprietary technology that links the components of the shell and the filling gel to create a more cohesive structure.

The interaction between the unique features of the components maximizes its bonding properties while providing the system with more flexibility and adaptability.



PROPRIETARY SAFETY-FOCUSED TECHNOLOGIES

Qid®, an embedded RFID micro-transponder, provides a non-invasive read of the electronic serial number associated with the implant.

BluSeal® patented barrier layer indicator minimizes risk of silicone gel diffusion.



UNIQUE SILICONE FORMULATIONS AND ERGONOMIC DESIGN

Ergonomix® proprietary silicone formulations offer differentiated elastic, viscous, and cohesive properties; implants are designed to provide a natural tactile feel and movement.



+ 2,500,000 implants sold

globally since Motiva Implants® commercial launch in 2010

+85 Countries

where Motiva Implants® have been approved

+25 Inventions

(patent families) and 218 applications globally in 21 jurisdictions

Less than 1%

device-related complications

POST-MARKET SURVEILLANCE

Adverse Events by Type Since 2010



Device-Related

Capsular Contracture	Double Capsule	BIA-ALCL	BIA-SCC	Rupture	Latrogenic Rupture	Technique-Dependent Complications*	Other**
0.022%	0.000%	0.000%	0.000%	0.000%	0.037%	0.003%	0.004%
N:535	N:0	N:0	N:0	N:0	N:918	N:71	N:71

<1 % device related complications

42 peer-reviewed studies, registry data from three independent registries with over 45,000 Motiva Implants® (Sweden, Australia, Netherlands), 290,000 women that have registered their implants in the Motiva® Registration app, the US IDE Study, all of them with the same trend

* The following were considered technique-dependent complications: implant malposition, implant displacement, asymmetry.

** Infection, wound dehiscense, hematoma, seroma.

Source: Establishment Labs®, Post-Market Surveillance Preliminary Results Q3 2022.

COMPARATIVE DATA BREAST IMPLANT INDUSTRY

3 YEAR DATA

	SIENTRA (N=1,115)	ALLERGAN (N=455)	MENTOR (N=552)
Capsular contracture III/IV	6.0%	10.7%	8.1%
Rupture MRI Cohort (Susp/ Conf)	2.5%	2.0%	0.5%
Breast Pain	0.8%	8.3%	1.7%
Infection	0.7%	<1.0%	1.5%
Implant Malposition	1.2%	5.4%	0.4%
Explantation (with/without Replacement)	4.6% with 1.2% w/out	6.1% with 0.7% w/out	4.9%
Reoperation	12.6%	19.9%	15.4%
Any Complication	20.2%	25.3%	36.6%

10 YEAR DATA

RESULTS FROM PRIMARY AUGMENTATION ONLY	SIENTRA 10-YEARS	ALLERGAN 10-YEARS	MENTOR 10-YEARS
Number of patients	1,116	455	552
Capsular contracture	12.9%	18.9%	12.1%
Ruptures	8.5%	9.3%	24.2%
Reoperation	24.0%	36.1%	25.5%

Each of these prospective studies were conducted at multiple sites in the United States and submitted by these companies as their core study supporting approval, as that term is defined in the FDA Guidance on Breast Implants. Sientra, Mentor, and Allergan studies commenced in 2002, 2000, and 1998, respectively. Kaplan-Meier risk rates were the primary method of analysis for the above data.

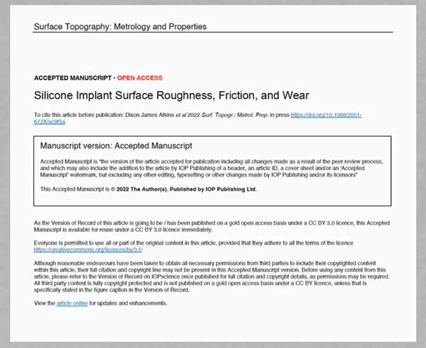
Motiva® US IDE STUDY

Motiva®KAPLAN-MEIER

2-YEAR KEY COMPLICATIONS

Primary Augmentation	2-year (N=451), 95% CI
1. Capsular Contracture (baker III/IV)	0.5%
2. Rupture, suspected or confirmed	0.3%
3. Breast Pain	0.5%
4. Infection	0.9%
5. Implant removal, with or without replacement	1.6%
6. Any reoperation*	5.7%
7. Any complication**	7.5%

*Any surgery on the breast or chest area, device or non-device related, including size change.
**Any device or non-device related event, including reoperation.
The Motiva® Core pivotal study is an ongoing US clinical trial of an investigation 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.


Surface Topography: Metrology and Properties

ACCEPTED MANUSCRIPT • OPEN ACCESS

Silicone Implant Surface Roughness, Friction, and Wear

To cite this article before publication: Dixon James Atkins *et al* 2022 *Surf. Topogr.: Metrol. Prop.* in press https://doi.org/10.1088/2051-672X/ac5f5a

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applied sciences

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Article

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

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Abstract: This study aimed to compare the dosimetric effect of traditional metallic ports and radio frequency identification (RFID) ports (Motiva Flora®) on post-mastectomy volumetric modulated arc therapy (VMAT) planning for left-sided breast cancer. Computed tomography (CT) simulation was performed on an anthropomorphic torso phantom by attaching two types of tissue expander on the left chest wall. For the comparison of CT artifacts, five points of interest were selected and compared: point A = central chest wall, B = medial chest wall, point C = lateral chest wall, point D = axilla, and point E = left anterior descending artery. VMAT planning using two partial arcs with a single isocenter was generated, and dosimetric parameters were investigated. Compared to metallic ports, RFID ports tremendously decreased distortion on CT images, with the exception of point D. The V_{42Gy}, V_{45Gy}, V_{50Gy}, V_{24Gy}, V_{30Gy}, V_{40Gy}, and D_{mean} values of the heart in RFID ports were lower than those in metallic ports. The V_{5Gy}, V_{10Gy}, V_{20Gy}, V_{30Gy}, and D_{mean} values of the ipsilateral lung in RFID ports were also lower than those in metallic ports. RFID ports showed superior dosimetric results for doses to the heart and lungs as compared to that in metallic ports.

Keywords: tissue expander; breast cancer; radiotherapy; volumetric modulated arc therapy


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


Journal of the Mechanical Behavior of Biomedical Materials

Functional biocompatibility testing of silicone breast implants and a novel classification system based on surface roughness


Aesth Plast Surg
https://doi.org/10.1007/s00266-022-02799-6

ISAPS

ORIGINAL ARTICLE BREAST SURGERY

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

Matej Patzelt[1,2] · Lucie Zarubova[1] · Michaela Veverova[1,2] · Josef Barta[3,4] · Martin Ouzky[1,2] · Andrej Sukop[1,2]

Received: 3 August 2021 / Accepted: 17 January 2022
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Abstract In patients with large breasts undergoing a subcutaneous mastectomy with immediate implant-based reconstruction, is necessary to perform a mastopexy. The combination of these procedures increases the complication rate. To reduce it, it is necessary to cover the lower pole of the implant. Our study aimed to compare the use of an autologous dermal flap and an absorbable breast mesh. A total of 64 patients without previous breast surgery were divided into 2 groups, each with 32 patients. In the 1st group, the implant was covered with an autologous caudally based dermal flap, sutured to the great pectoral muscle. In the 2nd group, the implant was covered with a fully absorbable breast mesh, fixed caudally in the inframammary fold and cranially to the great pectoral muscle. The incidence of complications, the aesthetic effect, and patient satisfaction were evaluated in a one-year follow-up. In the 1st group, there were 2 cases of seroma, 2 partial nipple-areola complex necrosis, 4 cases of dehiscence in the T-suture, and the malposition of the implant in 2 patients. In the 2nd group, there were 2 cases of seroma, 2 cases of T-junction dehiscence, and 1 case of full nipple-areola complex necrosis, which resulted in implant loss. There was no significant difference in patient satisfaction between the study groups. The dermal flap is more suitable for breasts with pronounced ptosis. The use of the synthetic mesh is suitable for smaller breasts, where the possible dermal flap would be too small to cover the implant.
Level of Evidence IV This journal requires that authors assign a level of evidence to each article. For a full description of these Evidence-Based Medicine ratings, please refer to the Table of Contents or the online Instructions to Authors www.springer.com/00266.

Keywords Fully absorbable breast mesh · Silicone breast implants · Breast reconstruction · Risk-reducing subcutaneous mastectomy · Autologous dermal flap

Introduction

A risk-reducing subcutaneous mastectomy, sometimes called prophylactic nipple-sparing mastectomy, is a procedure that involves the removal of the mammary gland without removing the skin envelope and nipple-areola complex (NAC). It was first described in 1962 by Freeman and then modified several times [1]. This procedure is suitable for women with a high lifetime risk of breast and ovarian cancers due to a mutation in BRCA 1, 2, or other genes (such as ATM, PALB2, CHECK2, etc.) [2, 3]. The procedure is growing in popularity every year, partially because of a number of celebrities who have undergone it and therefore are raising awareness among patients. It is believed that this procedure reduces the risk of breast cancer by up to 95% [4].

There are several modifications to this surgical procedure. Subcutaneous mastectomy can be performed either from an inframammary fold incision, through the Wise

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Published online: 14 February 2022

Springer


ISAPS

Bacterial Adhesion and Biofilm Formation on Textured Breast Implant Shell Materials


5/30/22, 10:00 AM Early onset of capsular contracture after breast augmentation with implant: report of two cases & review of literature

CASE REPORTS IN PLASTIC SURGERY AND HAND SURGERY
2022, VOL. 9, NO. 1, 151-157
https://doi.org/10.1080/23320885.2022.2077207

Open access

Early onset of capsular contracture after breast augmentation with implant: report of two cases & review of literature

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ABSTRACT
Capsular contracture (CC) is a local complication caused by an inflammatory reaction that leads to fibrosis. CC commonly occurs after one year of surgery. Hence, there has been no previously reported early onset of CC. Therefore, we report two unusual cases of early onset of post-breast reconstruction capsular contracture.

ARTICLE HISTORY
Received 19 October 2021
Accepted 10 May 2022

KEYWORDS
Capsular contracture, breast reconstruction, early-onset, capsulectomy, complications

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Journal of Clinical Medicine

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Review

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

Andrea Weinzierl [1,2], Daniel Schmauss [3,4], Davide Brucato [3] and Yves Harder [3,4,*]

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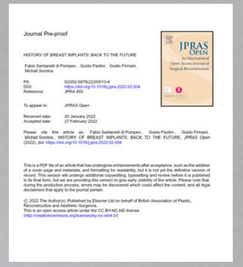
Abstract: Over the last years, prepectoral implant-based breast reconstruction has undergone a renaissance due to several technical advancements regarding mastectomy techniques and surgical approaches for the placement and soft tissue coverage of silicone implants. Initially abandoned due to the high incidence of complications, such as capsular contraction, implant extrusion, and poor aesthetic outcome, the effective prevention of these types of complications led to the prepectoral technique coming back in style for the case of implant placement and the conservation of the pectoralis muscle function. Additional advantages such as a decrease of postoperative pain, animation deformity, and operative time contribute to the steady gain in popularity. This review aims to summarize the factors influencing the trend towards prepectoral implant-based breast reconstruction and to discuss the challenges and prospects related to this operative approach.

Keywords: prepectoral breast reconstruction; synthetic mesh; biologic mesh; implant-based breast reconstruction; mastectomy; hybrid breast reconstruction


Journal Pre-proof

The Key of Pocket Dissection in Transaxillary Dual-plane Breast Augmentation: How to Control Inferior Malposition of Smooth Implants

JPRAS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HISTORY OF BREAST IMPLANTS: BACK TO THE FUTURE

JPRAS Open

nature biomedical engineering

ARTICLES

https://doi.org/10.1038/s41551-021-00729-4

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

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Silicone is widely used in chronic implants and is generally perceived to be safe. However, textured breast implants have been associated with immune-related complications, including malignancies. Here, by examining for up to one year the foreign body response and capsular fibrosis triggered by miniaturized or full-scale clinically approved breast implants with different surface topography (average roughness, 0–90 μm) placed in the mammary fat pads of mice or rabbits, respectively, we show that surface topography mediates immune responses to the implants. We also show that the surface surrounding human breast implants collected during revision surgeries also differentially alters the individual's immune responses to the implant. Moreover, miniaturized implants with an average roughness of 4 μm can largely suppress the foreign body response and fibrosis (but not in T-cell-deficient mice), and that tissue surrounding these implants displayed higher levels of immunosuppressive FOXP3+ regulatory T cells. Our findings suggest that, amongst the topographies investigated, implants with an average roughness of 4 μm provoke the least amount of inflammation and foreign body response.

Poly(dimethylsiloxane) (PDMS) is one of the most widely used polymers in the fabrication of medical devices developed for chronic (long-term) implantation into the body. Many clinically approved tissue-contacting artificial devices, including intraocular lenses[1], dialysis membranes[2], finger joints[3], ventricular/portcheal shunt systems[4] and devices for plastic and reconstructive surgery[5], use a silicone elastomer, such as PDMS, as their platform material. The favourable material properties of PDMS, such as high oxygen permeability and tunable stiffness, and the initial perception of its biological inertness, have rendered it an attractive choice for the medical device industry[6]. However, over time it has become apparent that PDMS-based devices can provoke unpredictable immune responses and excessive foreign body reactions in many individuals[6–11].

For example, a majority of the 400,000 women in the United States who receive silicone breast implants every year for cosmetic or reconstructive reasons will require replacement within 10 to 20 years due to capsular contracture, which is induced by excessive foreign body response (FBR) to the implant (https://www.fda.gov/consumers/consumer-updates/what-know-about-breast-implants). These immune-driven fibrotic responses can lead to pain and discomfort for the individual as well as device failure[12–14].

To alleviate immune responses to PDMS implants, different approaches have been evaluated, including chemical modification to alter surface chemistry[15], coating with hydrogels[16], plasma treatment[17] and altering surface features such as topography and roughness[18]. Among these strategies, the alterations in surface

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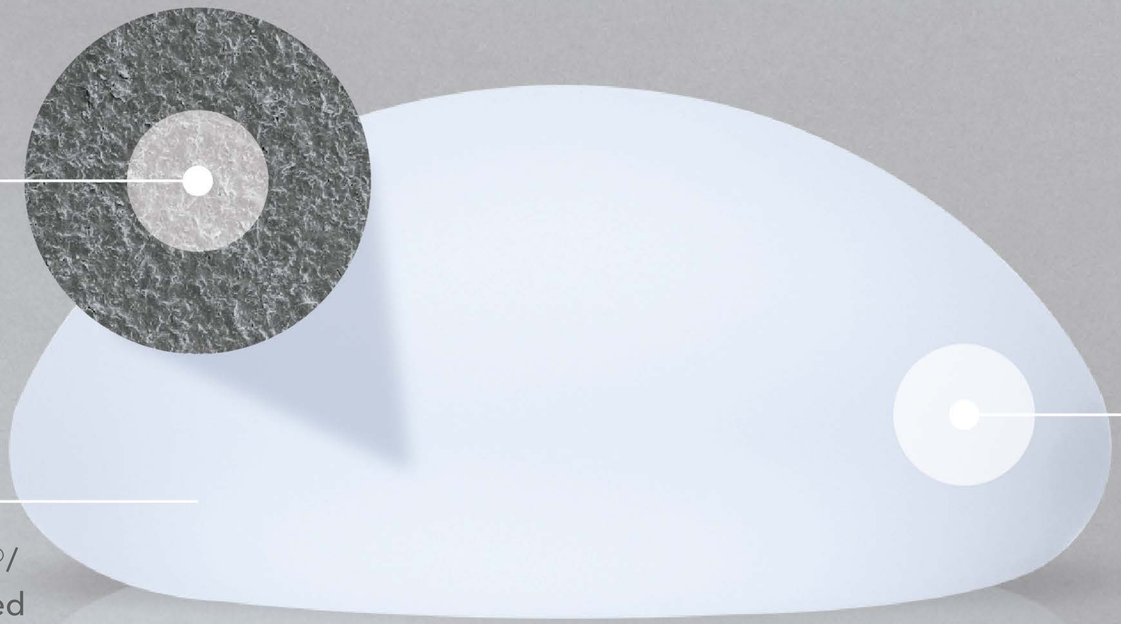
BREAST IMPLANT SURFACE RESEARCH IN NATURE BIOMEDICAL ENGINEERING





Surface architecture is an influential parameter in controlling the host's immune reactions and fibrotic encapsulation.

The profile of SmoothSilk®/SilkSurface® is characterized by a low inflammatory cell infiltrate and anti-fibrotic gene expression.

These findings suggest that SmoothSilk®/SilkSurface® provoked the least amount of inflammation and FBR across mouse and rabbit models, and human capsules.

These results suggest that SmoothSilk®/SilkSurface® implants have improved biocompatibility and produce less pro-fibrotic inflammation compared to the other implant types evaluated.

BEYOND CLINICAL OUTCOMES:

IMPROVED AESTHETIC OUTCOMES



Concept of ergonomy



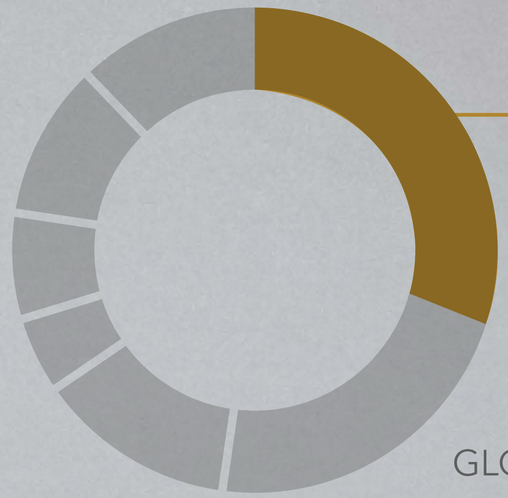
Hybrid surgery



Small incisions

TOTAL GLOBAL AESTHETIC BREAST IMPLANT MARKET ~$1.5 BILLION

ESTA COMPETES IN LESS THAN 1/2 OF THE GLOBAL MARKET WITH 33% SHARE IN THOSE MARKETS AND GROWING



33% Motiva®

GLOBAL MARKET SHARES IN TOP 14 MARKETS

ENTRY INTO REMAINING MAJOR GLOBAL MARKETS

UNITED STATES

- ~40-50% of the global aesthetic market
- Modules 1, 2 and 3 have been submitted to the FDA
- **Module 4** ready to submit. Based on collaborative discussions with the FDA, Module 4 will be submitted during Q1

CHINA

- ~10% of the global market and growing rapidly
- Among the highest ASPs globally
- Expected approval 1H 2023



mia FEMTECH

NORMALIZING
BREAST AESTHETICS

EXPANDING THE MARKET

Opportunity to create a new category that addresses unmet needs in breast aesthetics

CONSUMER INSIGHTS

76%

Of women are somewhat dissatisfied or think their bodies can have a better shape.[1]

54%

Of consumers worldwide report they will keep trying to achieve the vision they have for their body.

COMPENSATORY MECHANISMS PADDED BRA I PUSH UP BRA I CLOTHES

Daily outfit choices that adapt to their body shape and create the perception of a fuller breast	Off-label use of contraception	Make-up breast contouring techniques	Breast enlargement pumps	Breast enhancement pills and creams	Boob tape

Percentage of the Total Global Aesthetic conscious Consumers (n=14,447) who say solutions exist to address some of their body issues, who say they are concerned about unnatural results from surgical on non-surgical enhancement/treatment/procedures, and who report not being willing to give up trying to achieve the vision they have for their body.
1Source: Response to a Market Study Europe and Japan Nov 2022/937 respondents from target: Women 25-54 High Income All cups.

Mia® brings **harmony** to the woman's body with a naturally discrete proportional result



In a 15 minutes[1] procedure

+



using breakthrough minimally invasive technologies

+



and no general anesthesia

so that women can get on with their busy lives*

1.Establishment Labs®. Data on file. CLINR-001018

*Exercise is not recommended during the recovery period and always follow doctor's advice.

Ergonomix2 Diamond®
Implants

Motiva® Channel
Dissector

Motiva Injector®

Motiva® Inflatable
Balloon

Motiva® Marking Tool



"I decided to trust that the recovery process would be quick and it exceeded all my expectations.

My Big Day Was Perfect."

SHE GOT MARRIED 3 DAYS AFTER MIA FEMTECH™

Carolina - 30 years
Engineer

KEY FACTS MARKET OPPORTUNITY







11x more women would choose Mia® over other traditional breast augmentation procedures

~73% Mia® candidates are currently not considering other traditional breast augmentation procedures

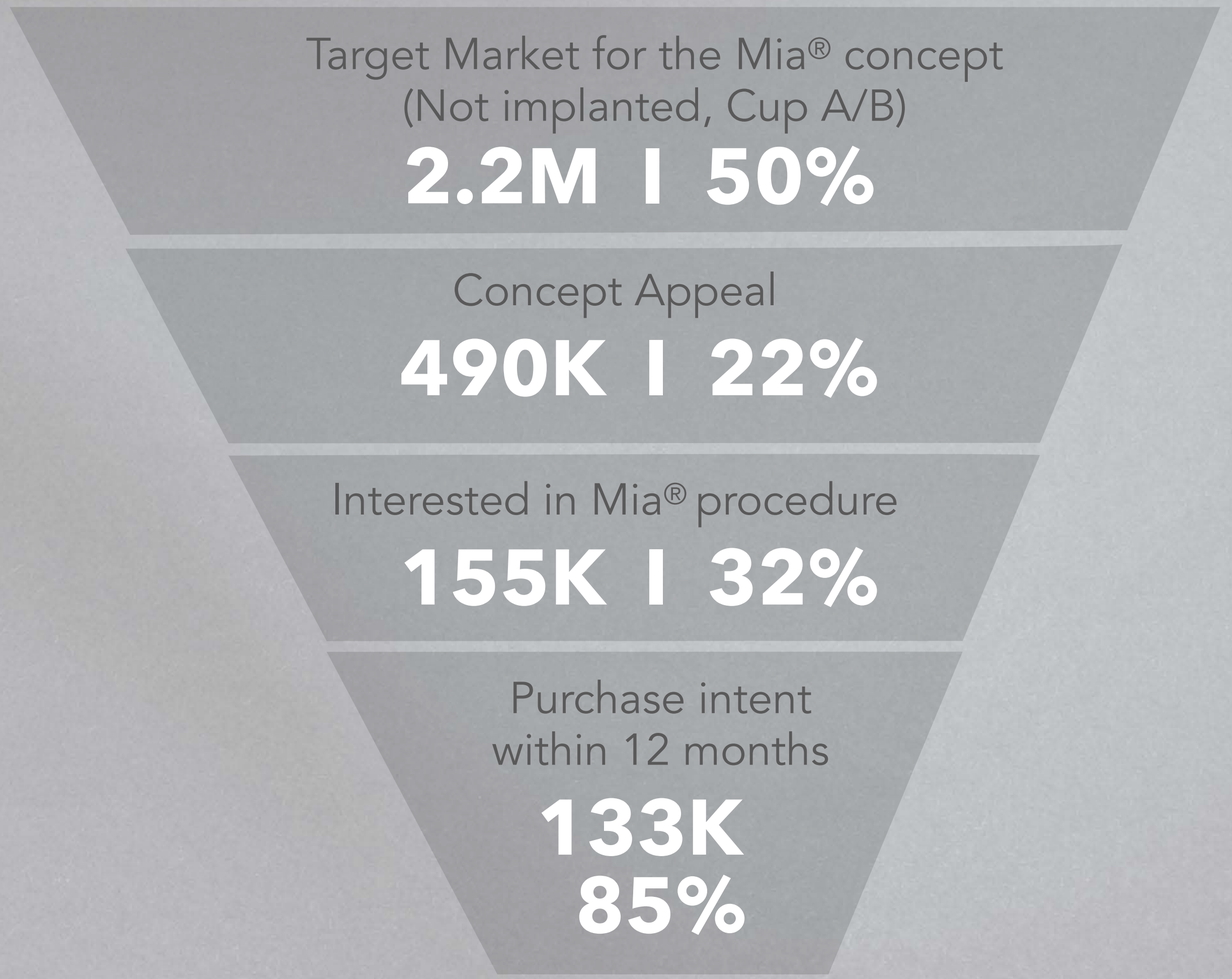
Mia® consumers are willing to pay 2x over other traditional breast augmentation procedures

*ResponseAI Study H2 2022. Target: Women 20-54 High Income.> N=937 surveys

JAPAN MARKET SIZING

Women 25-54 with income >¥6M
Represents 4.4M women in Japan

The survey yields an estimate of 155,000 women with less than C cup size who would be interested in Mia®, with 85% intending to purchase within 12 months.



Source: Market Study Japan July 2022 / 444 respondents from the target. Mia® at >¥ 1,500,000.

MIA FEMTECH™ PROOF OF CONCEPT

Case series done in early 2022 showing reality of performing 10 patients in under 5 hours

Start time	8:10 am
End time	12:48 pm
Total time 10 cases	4hr38min

10-Patient Average	27 minutes
Average discharge time	12 minutes
Average stay time per case	45 minutes

Average skin-to-skin procedure time

8

minutes

*Max time 10 min

The average time of a traditional breast augmentation procedure is 63.8 min*

Colque A, Eisemann ML. Breast augmentation and augmentation-mastopexy with local anesthesia and intravenous sedation. Aesthet Surg J. 2012 Mar;32(3):303-7. doi: 10.1177/1090820X12436601.

2021: Global total addressable Market with Mia®

Mia® I Creates $6 Billion in Annual Addressable Market

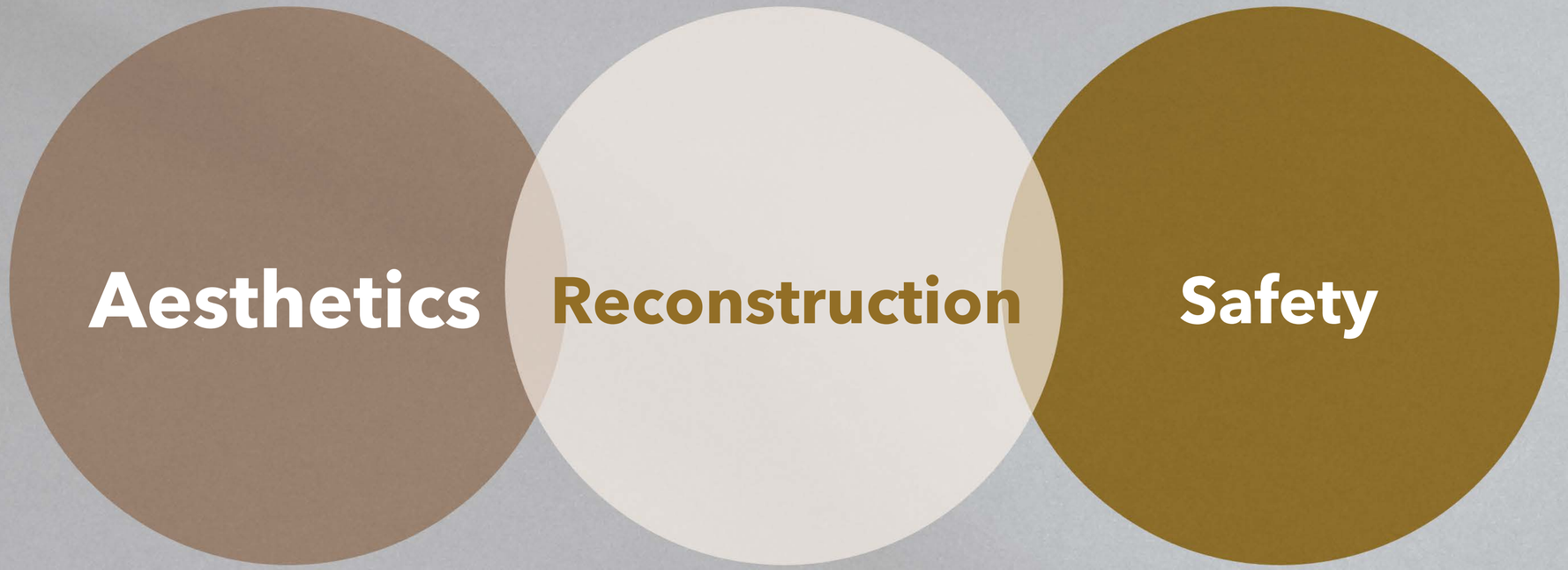
Traditional Breast Augmentation Market	New potential Market	Combined
Breast implant augmentation procederes	Mia ® procedures	Procedures
1.6M[1]	1.9M 50% NEW consumers	2.7M
Total addressable market (Breast Aug. Implants)	Total addressable market (Mia Femtech™)	Total addressable market
$1.5B[2]	$4.8-5.7B[2]	$5.6-6.5B[2]

1. Approximately 1.62 million breast augmentations were performed worldwide in 2020, according to the International Society of Aesthetic Plastic Surgery, or ISAPS.
2. Based on a range of prices in different regiones of the world for Mia® and traditional breast augmentation.



DEMOCRATIZING
Breast Reconstruction

AN EVOLUTION

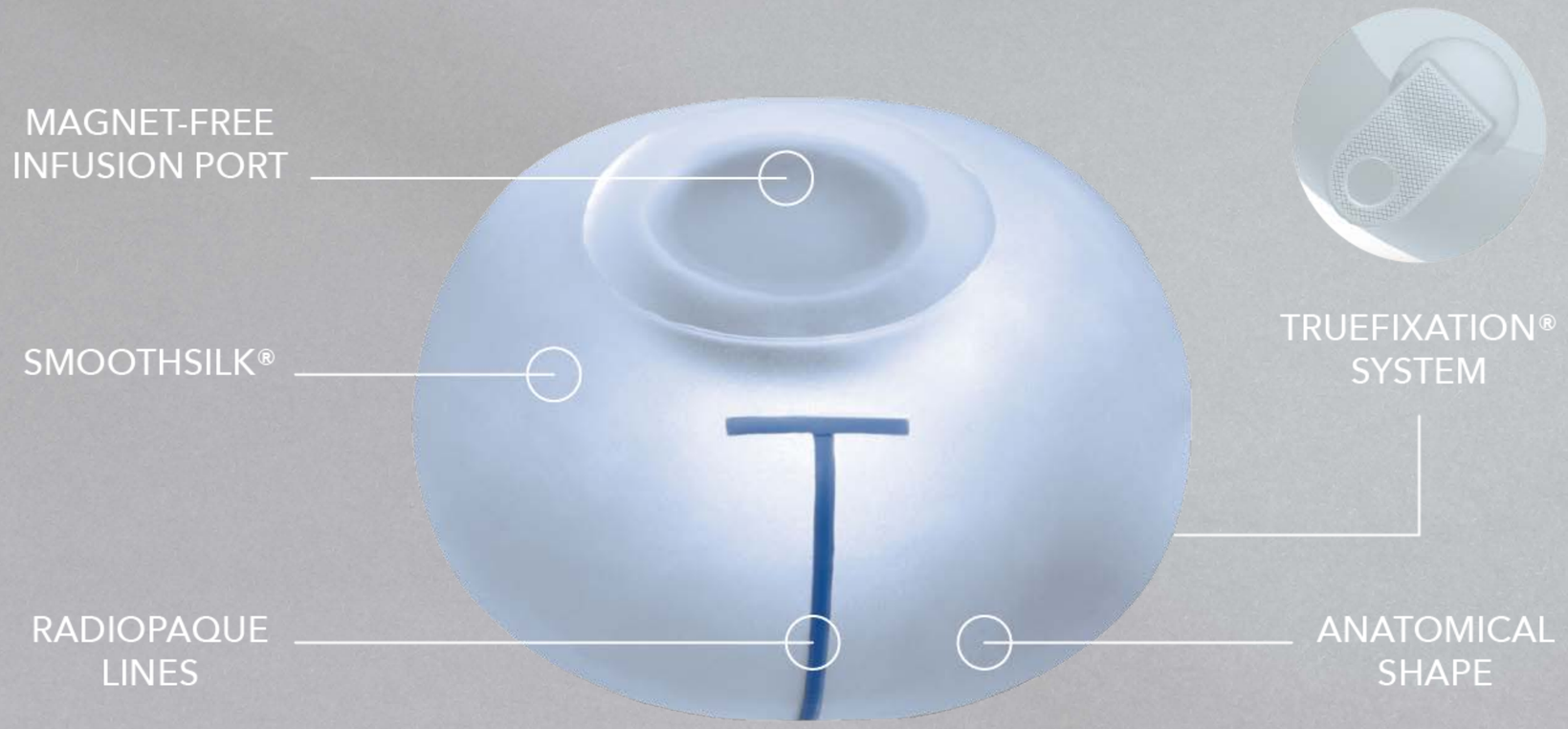


Aesthetic BreastRecon®

Enable women to receive a standard of care that achieves the aesthetic outcomes they aspire to after breast cancer.

FLORA® RAISING THE STANDARD OF CARE

OUR FIRST TECHNOLOGY TO TRANSFORM BREAST RECONSTRUCTION



MR

MR Conditional

Aesthetic BreastRecon®

Can expand access and acceptance of breast reconstruction worldwide

Approximately **1.67 million** new cases are diagnosed worldwide, and over 500,000 women die of the disease each year.

FDA studies show a complication rate of **30%+** in breast reconstruction procedures

In developed countries, less than **30%** of women undergo reconstruction procedures. Penetration is far less in emerging markets.

Less than **25%** of women know their reconstructive options.**

References: 1. Bennett KG, Qi J, Kim HM, et al: Comparison of 2-year complication rates among common techniques for postmastectomy breast reconstruction. JAMA Surg. June 20, 2018. 2. Morrow M, Li Y, Alderman AK. Access to breast reconstruction after mastectomy and patient perspectives on reconstruction decision making. JAMA Surg. 2014 Oct;149(10):1015-21. doi: 10.1001/jamasurg.2014.548.

** Source: American Society of Plastic Surgeons



OUR THIRD FACILITY

(Under final stage of construction)

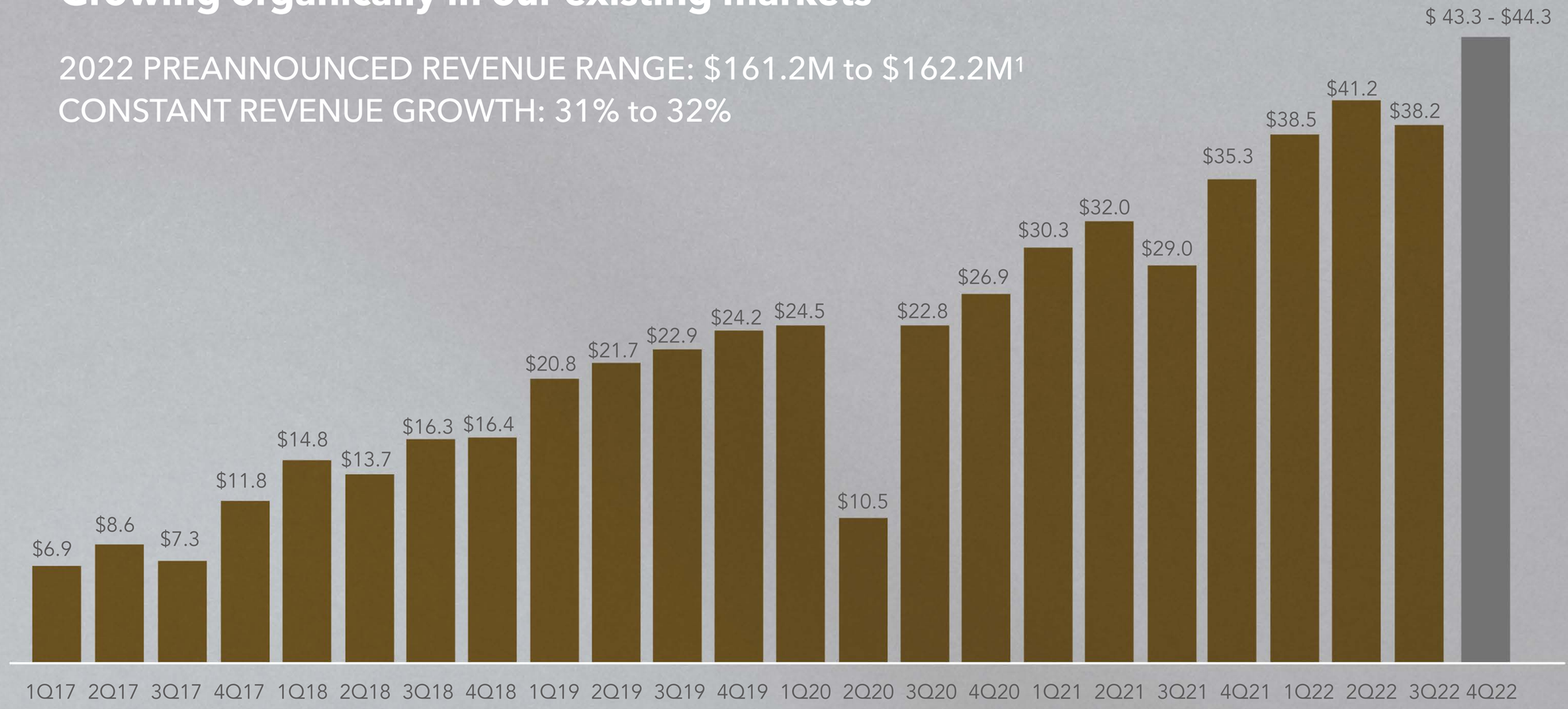
will expand our capacity by one million units per year

Expected to start operations in 2023

DELIVERING GROWTH

Growing organically in our existing markets

2022 PREANNOUNCED REVENUE RANGE: $161.2M to $162.2M[1]
CONSTANT REVENUE GROWTH: 31% to 32%



1.Fourth quarter and full year 2022 revenue results provided are preliminary and unaudited.

BEYOND 2022

Targeting $500M in Annual Revenue in Fiscal 2026

Expecting an average rate of growth of 33% per year
over the next 4 years, and significant growth beyond




Thank you