

Ideal Implant Incorporated

Dallas, TX

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General and Plastic Surgery Devices Advisory Panel

Day 1 – March 25, 2019



Why a New Technology Implant is Needed

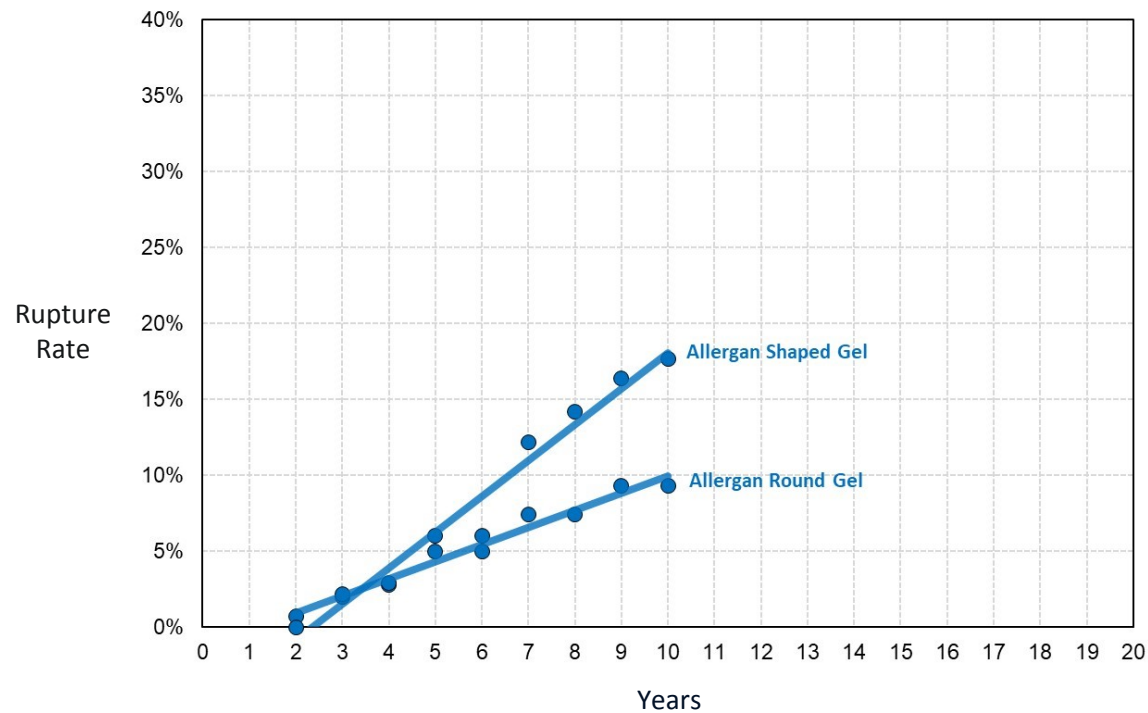
- Silicone gel implant is old technology
 - Natural look and feel
 - Cross-linked gel supports shell/tissue
 - Society trending to natural / organic / healthy products
 - Gel – some women have concerns
 - Rupture replacement – capsulectomy, sticky mess to remove
 - Ruptures are silent – detection needs an MRI scan

10-year Cumulative Incidence of Rupture

ALLERGAN GEL	9.3%
MENTOR GEL	24.2%
ALLERGAN GEL (GUMMY-BEAR)	17.7%
SIENTRA GEL	8.7%

FDA Core Clinical Trials - MRI Cohorts
Primary Augmentation

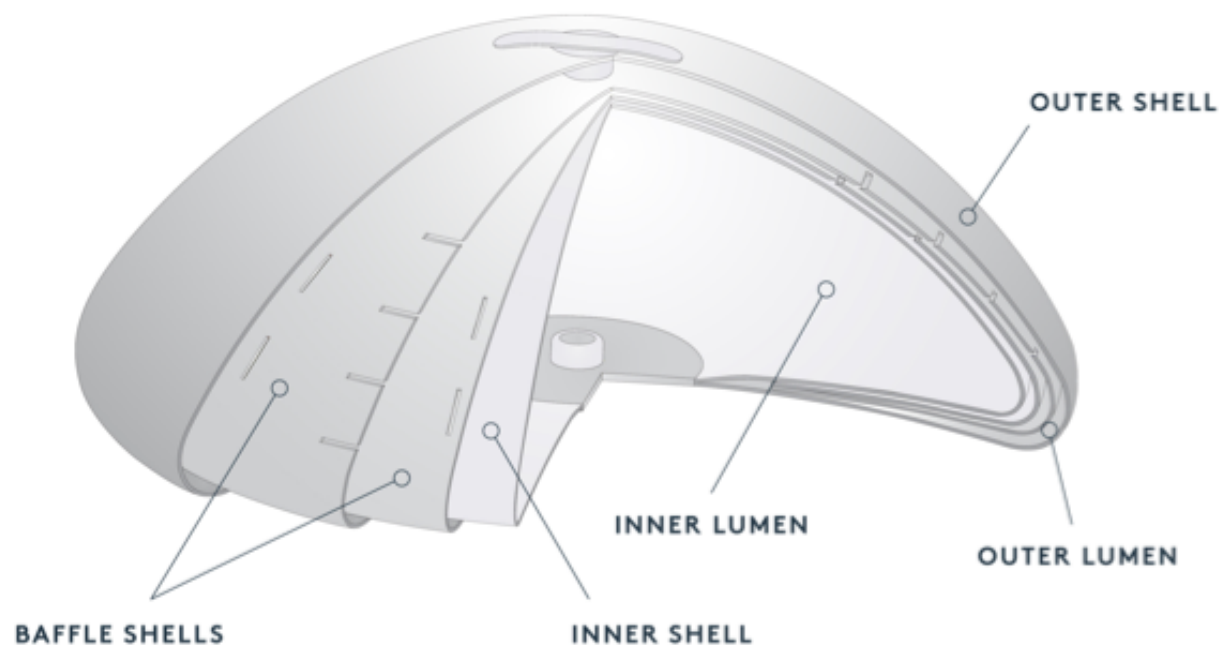
What Happens Beyond 10 Years?



How Have Women Viewed Their Choices?

- Saline implant (balloon)
 - Benefits – Perceived safety of saline & no need for MRI scans
 - Compromises – Unnatural feel & collapse
- Silicone gel implant
 - Benefits – Feels natural & looks good
 - Compromises – Silent rupture & need regular MRI scans
- Women want a third choice - “best of both”

IDEAL IMPLANT® Structured Breast Implant



Deflation / Rupture (MRI cohort)

FDA Core Trial Data

PRIMARY AUGMENTATION		
IDEAL IMPLANT	8 yr	2.1%
Allergan Gel	8 yr	7.4%
Mentor Gel	8 yr	13.6%
Sientra Gel	8 yr	7.2%

Kaplan-Meier Risk Rates of First Occurrence

Capsule Contracture – Baker 3 & 4

FDA Core Trial Data

PRIMARY AUGMENTATION		
IDEAL IMPLANT	8 yr	6.6%
Allergan Gel	7 yr	16.2%
Mentor Gel	8 yr	10.9%
Sientra Gel	8 yr	11.2%

Kaplan-Meier Risk Rates of First Occurrence

How Women View IDEAL IMPLANT

- Low rupture rate
- Low capsule contracture rate
- Look in mirror to know intact
- No risk of silent rupture
- No need for MRI scans
- Saline is natural and absorbed



Experience over 3.5 Years

- Women who choose IDEAL IMPLANT
 - Health conscious
 - Informed / online research
 - Prior implant surgery
- Surgeons are unbiased about implant choice
 - Offer women all 3 types – saline, silicone gel, structured
- No ALCL or BII

Implants for Mastectomy Reconstruction

- 5% Saline (balloon) – no support, unnatural feel
- 95% Silicone Gel – supports tissue, natural feel
- IDEAL IMPLANT – supports tissue, natural feel, saline
 - Not an FDA approved option for reconstruction
 - Women cannot be informed about this option
 - Women have no real choice – forced to silicone gel

If There Was a Reconstructive Indication

- Women would have an approved alternate to silicone gel
 - No silent ruptures, no MRIs, no capsulectomies, natural feel
- Women could be informed about IDEAL IMPLANT option
 - Could compare benefits and compromises of all 3 implant types
 - Could make an informed choice
- Women could choose option that best fits their need

The Practice of Medicine

- IDEAL IMPLANT is used for mastectomy reconstruction
 - Since 2015
 - Patient request and informed choice
 - >100 surgeons, repeated use
- Surgeons say - good outcomes / happy patients / effective
- Women say - fills unmet need for silicone gel alternative
- May be preferred option for mastectomy reconstruction

RWE Pathway to Reconstructive Indication

- Collect safety and efficacy data from medical records
- Verifiable source documentation/monitoring
- Accurate/reliable RWD & RWE with IDEAL IMPLANT
- Data quality sufficient to support regulatory decision
 - Adding reconstructive indication for an approved implant
- Planning to start a RWE study

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