Ideal Implant Incorporated
Dallas, TX

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Founder, CEO and President

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

<table>
<thead>
<tr>
<th>Material</th>
<th>Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allergan Gel</td>
<td>9.3%</td>
</tr>
<tr>
<td>Mentor Gel</td>
<td>24.2%</td>
</tr>
<tr>
<td>Allergan Gel (Gummy-Bear)</td>
<td>17.7%</td>
</tr>
<tr>
<td>Sientra Gel</td>
<td>8.7%</td>
</tr>
</tbody>
</table>

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**

<table>
<thead>
<tr>
<th>PRIMARY AUGMENTATION</th>
<th>8 yr</th>
<th>2.1%</th>
</tr>
</thead>
<tbody>
<tr>
<td>IDEAL IMPLANT</td>
<td>8 yr</td>
<td>2.1%</td>
</tr>
<tr>
<td>Allergan Gel</td>
<td>8 yr</td>
<td>7.4%</td>
</tr>
<tr>
<td>Mentor Gel</td>
<td>8 yr</td>
<td>13.6%</td>
</tr>
<tr>
<td>Sientra Gel</td>
<td>8 yr</td>
<td>7.2%</td>
</tr>
</tbody>
</table>

Kaplan-Meier Risk Rates of First Occurrence
## Capsule Contracture – Baker 3 & 4

### FDA Core Trial Data

<table>
<thead>
<tr>
<th>PRIMARY AUGMENTATION</th>
<th>Duration</th>
<th>Risk Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>IDEAL IMPLANT</td>
<td>8 yr</td>
<td>6.6%</td>
</tr>
<tr>
<td>Allergan Gel</td>
<td>7 yr</td>
<td>16.2%</td>
</tr>
<tr>
<td>Mentor Gel</td>
<td>8 yr</td>
<td>10.9%</td>
</tr>
<tr>
<td>Sientra Gel</td>
<td>8 yr</td>
<td>11.2%</td>
</tr>
</tbody>
</table>

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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