**Fundamental Sientra Values**

- Patient Safety
- Exclusive to Board-Certified Plastic Surgeons
- Commitment to Long-Term, Real-World Data
- 20-Year Implant Warranty
- Education & Awareness

**Sientra OPUS® Portfolio**

- Silicone elastomer shell
- High-strength cohesive 5th generation silicone gel
- Implants options:
  - Smooth Round
  - Textured Round and Anatomic
- Textured surface- heat volatilization of ammonium carbonate

**Breast Cancer Non-Profit Grant Program**

ONE WOMAN’S BREAST RECONSTRUCTION CONTRIBUTES TO ANOTHER WOMAN’S CURE

**Post-Approval Status**
**Sientra Conditions of Approval**

<table>
<thead>
<tr>
<th>Study</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-Approval PMA Cohort Study (PACS)</td>
<td>10-Year – Completed</td>
</tr>
<tr>
<td>&quot;Core Study&quot;</td>
<td>Labeling under review</td>
</tr>
<tr>
<td>Post-Approval Continued Access Study (PACAS)</td>
<td>5-Year – Completed</td>
</tr>
<tr>
<td>Focus Group Study (Patient Labeling)</td>
<td>Completed</td>
</tr>
<tr>
<td>Post-Approval Case-Controlled Studies (PACCS)</td>
<td>Requirement Rescinded</td>
</tr>
<tr>
<td>U.S. Post-Approval Study (US-PAS)</td>
<td>Ongoing 10-Year Study</td>
</tr>
<tr>
<td>National Breast Implant Registry (NBIR)</td>
<td>Completed 3-Year Follow-up</td>
</tr>
</tbody>
</table>

**U.S. PAS Compliance Efforts and Challenges**

**Efforts**
- Patients & Doctors compensated
- Patient Encouragement
  - Sientra, CRO, Study Site
  - Email, personal & automated phone calls, various hardcopy communications
- Site Support
  - Proprietary search database
  - Quarterly Visit Reminders
  - Transfer participants to closer sites
- Family obligations/Childcare coverage
- Work Commitments
- Personal Commitments
- Highly mobile population
- Generally healthy population
- High mobile population
- Lost interest in participation

**Challenges**
- Sientra, CRO, Study Site
- Email, personal & automated phone calls, various hardcopy communications
- Proprietary search database
- Quarterly Visit Reminders
- Transfer participants to closer sites
- Family obligations/Childcare coverage
- Work Commitments
- Personal Commitments
- Generally healthy population
- Lost interest in participation

**Enhancements and Innovative Strategies**

**Enhancements**
- Increased financial incentives
- Increased frequency of contacts
- Expand social media searches
- On-site study support
- Customized site compliance strategies
- Personalized letters to non-compliant participants

**Innovative**
- Leverage social media and communication technologies
- Virtual follow-up visits
- Transportation
- Explore NBIR opportunities
- Seek other effective strategies

**NBIR - Strengthening Breast Implant Postmarket Surveillance**

- Active in development and implementation of NBIR
- Contributing member of NBIR Steering Committee
- Unique aspect of Device Tracking efficiencies
- Incorporates Unique Device Identification (UDI) for all enrolled breast implants
- Opportunity to expand the NBIR in the future to collect data for longitudinal outcome analyses on a variety of outcomes

**Long-Term Safety & Effectiveness**

Postapproval PMA Cohort Study (PACS/Core)
10-Year PACS (Core) Study

1,788 Patients
3,506 Implants
37 U.S. Sites

53% Smooth
47% Textured

10-Year Primary Augmentation (N=1,116)

<table>
<thead>
<tr>
<th></th>
<th>Capsular Contracture</th>
<th>Rupture (MRI Cohort)</th>
<th>Reoperation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>12.9%</td>
<td>8.5%</td>
<td>24.0%</td>
</tr>
</tbody>
</table>

10-Year Revision-Augmentation (N=363)

<table>
<thead>
<tr>
<th></th>
<th>Capsular Contracture</th>
<th>Rupture (MRI Cohort)</th>
<th>Reoperation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>13.7%</td>
<td>6.8%</td>
<td>38.8%</td>
</tr>
</tbody>
</table>

10-Year Primary Reconstruction (N=225)

<table>
<thead>
<tr>
<th></th>
<th>Capsular Contracture</th>
<th>Rupture (MRI Cohort)</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>15.8%</td>
<td>16.5%</td>
<td>48.2%</td>
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</table>

10-Year Revision-Reconstruction (N=84)

<table>
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<tr>
<th></th>
<th>Capsular Contracture</th>
<th>Rupture (MRI Cohort)</th>
<th>Reoperation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>14.3%</td>
<td>0.0%</td>
<td>56.7%</td>
</tr>
</tbody>
</table>

Signs & Symptoms: Combined Augmentation Cohorts

No significant increases were found in any of the 13 CTD categories.

Significant decreases were found for 3 of the 13 CTD categories:
- Neurological
- Endocrine/exocrine
- Vascular

Signs & Symptoms: Combined Reconstruction Cohorts

No significant increases or decreases were found across any of the 13 CTD categories.
Postapproval Continued Access Study (PACAS)

5-Year PACAS Study
- 2,524 Patients
- 5,042 Implants
- 31 U.S. Sites

55% Smooth
45% Textured

5-Year Primary Augmentation (N=2,042)

<table>
<thead>
<tr>
<th></th>
<th>Capsular Contracture</th>
<th>Rupture</th>
<th>Reoperation</th>
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</thead>
<tbody>
<tr>
<td>10.0%</td>
<td>5.4%</td>
<td>20.2%</td>
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5-Year Revision-Augmentation (N=482)

<table>
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<th>Capsular Contracture</th>
<th>Rupture</th>
<th>Reoperation</th>
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</thead>
<tbody>
<tr>
<td>13.3%</td>
<td>0.0%</td>
<td>31.1%</td>
<td></td>
</tr>
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</table>

U.S. Postapproval Study (U.S. PAS)

U.S. PAS
- 10-year study evaluates long-term clinical performance of Sientra Implants under general conditions of use
- Overview
  - 5,197 Sientra implant participants
  - 301 control participants
  - 138 U.S. sites
- Status
  - Most patients in fourth year of follow-up
  - Continuous efforts to increase follow-up rates

3-Year Primary Augmentation (N=4,048)

<table>
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<tr>
<th></th>
<th>Capsular Contracture</th>
<th>Rupture</th>
<th>Reoperation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.6%</td>
<td></td>
<td>3.9%</td>
<td>6.0%</td>
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</table>

3-Year Revision-Augmentation (N=893)

<table>
<thead>
<tr>
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<th>Capsular Contracture</th>
<th>Rupture</th>
<th>Reoperation</th>
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</thead>
<tbody>
<tr>
<td>4.1%</td>
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<td>0.0%</td>
<td>11.8%</td>
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### 3-Year Primary Reconstruction (N=149)

<table>
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<tbody>
<tr>
<td>1.7%</td>
<td>0.0%</td>
<td>18.5%</td>
</tr>
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</table>

### 3-Year Revision-Reconstruction (N=107)

<table>
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<tr>
<th>Capsular Contracture</th>
<th>Rupture</th>
<th>Reoperation</th>
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</thead>
<tbody>
<tr>
<td>3.3%</td>
<td>0.0%</td>
<td>17.3%</td>
</tr>
</tbody>
</table>

### Signs & Symptoms
Rheumatologic and Neurologic

- Participant self-reported signs and symptoms
- Comparison between Sientra and Control participants
  - No statistically significant difference

### BIA-ALCL
Breast Implant Associated – Anaplastic Large Cell Lymphoma

### BIA-ALCL Reported Cases

**3 Primary cases**
- Onset 6-10 years post-operative

**2 Non-Primary cases**
- Previous breast implants from another manufacturer
- Onset 9-13 years post-operative

Devices removed
No further treatment
Patients disease free

### BIA-ALCL Incidence

- FDA Quoted Variable Rates 1:3,000 to 1:30,000
- Calobrace et al, 2018 [1] Sientra 1:200,000

### Professional Outreach

- Joint BIA-ALCL Statement (Societies + Industry)
- Sponsor PRS & ASJ BIA-ALCL Supplements
- BIA-ALCL Fund

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Surgeon Educational Materials

- Product Labeling
- Surgical Best Practices: 14-Point Plan & BIA-ALCL FAQ
- Partner with leading researchers

Sientra: Day 1 Summary

- Patient safety and product quality
- Board-Certified Plastic Surgeons exclusively
- PAS support long-term safety and effectiveness
- NBIR Steering Committee Participation
- Collaboration with experts to further:
  - Research
  - Awareness
  - Education

Thank You