

2019 FDA CDRH General and Plastic Surgery Devices Advisory Committee Meeting
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sientra OPUS

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SCIENCE SAFETY LEADERSHIP

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Fundamental Sientra Values

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

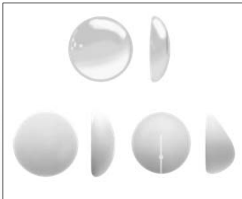
sientra FULL CIRCLE | Breast Cancer Non-Profit Grant Program

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

Keep Giving Going


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



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Post-Approval Status



Sientra Conditions of Approval

Study	Status
Post-Approval PMA Cohort Study (PACS) "Core Study"	10-Year – Completed Labeling under review
Post-Approval Continued Access Study (PACAS)	5-Year – Completed
Focus Group Study (Patient Labeling)	Completed
Post-Approval Case-Controlled Studies (PACCS)	Requirement Rescinded
U.S. Post-Approval Study (US-PAS)	Ongoing 10-Year Study Completed 3-Year Follow-up
National Breast Implant Registry (NBIR)	Ongoing

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

Challenges

- Family obligations/Childcare coverage
- Work Commitments
- Personal Commitments
- Highly mobile population
- Generally healthy population¹¹¹
- Lost interest in participation

Initial Report from an Online Breast Augmentation Follow-Up Survey. V. Leroy Young, Maria Watson, Robert F. Centeno, C.B. Boswell. Aesthetic Surgery Journal May 2004, 24 (3) 229-243.

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

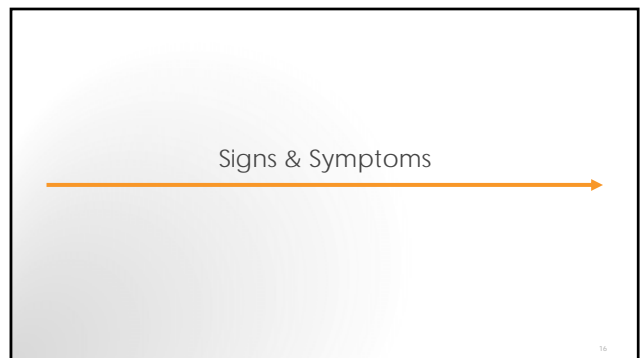
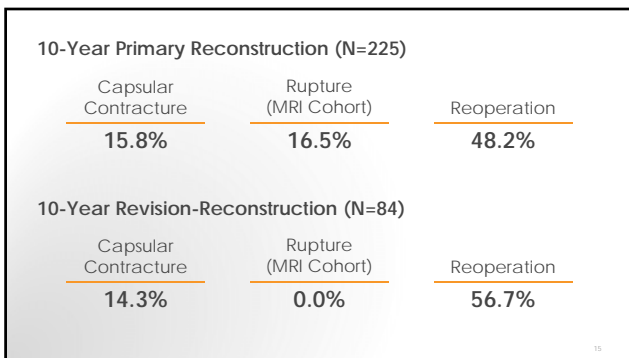
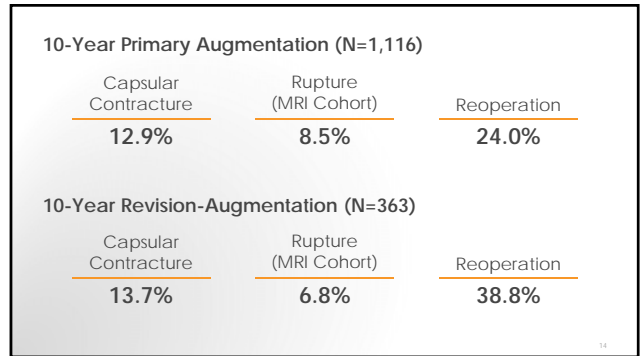
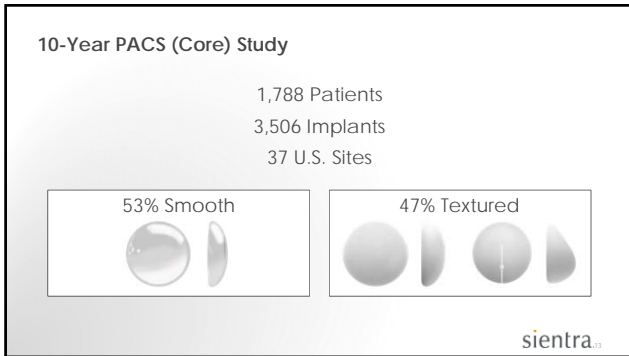
National Breast Implant Registry

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)



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

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Signs & Symptoms: **Combined Reconstruction Cohorts**

No significant **increases or decreases** were found across any of the 13 CTD categories

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Postapproval Continued Access Study
 (PACAS)

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5-Year PACAS Study

2,524 Patients
 5,042 Implants
 31 U.S. Sites

55% Smooth

45% Textured

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

Capsular Contracture	Rupture	Reoperation
10.0%	5.4%	20.2%

5-Year Revision-Augmentation (N=482)

Capsular Contracture	Rupture	Reoperation
13.3%	0.0%	31.1%

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

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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

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

Capsular Contracture	Rupture	Reoperation
1.6%	3.9%	6.0%

3-Year Revision-Augmentation (N=893)

Capsular Contracture	Rupture	Reoperation
4.1%	0.0%	11.8%

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3-Year Primary Reconstruction (N=149)

Capsular Contracture	Rupture	Reoperation
1.7%	0.0%	18.5%

3-Year Revision-Reconstruction (N=107)

Capsular Contracture	Rupture	Reoperation
3.3%	0.0%	17.3%

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- Signs & Symptoms**
Rheumatologic and Neurologic
- Participant self-reported signs and symptoms
 - Comparison between Sientra and Control participants
 - No statistically significant difference
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BIA-ALCL

Breast Implant Associated –
Anaplastic Large Cell Lymphoma

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- BIA-ALCL Reported Cases**
- | 3 Primary cases | 2 Non-Primary cases |
|---|---|
| <ul style="list-style-type: none"> • Onset 6-10 years post-operative | <ul style="list-style-type: none"> • Previous breast implants from another manufacturer • Onset 9-13 years post-operative |
- Devices removed
No further treatment
Patients disease free
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- BIA-ALCL Incidence**
- FDA Quoted Variable Rates 1:3,000 to 1:30,000
 - Calobrace et al, 2018^[1] Sientra 1:200,000
- [1] Calobrace, M.B., Schwartz, M.R., Zeidler, K.R., Pittman, T.A., Cohen, R., Stevens, W.G. (2018). Long-term safety of textured and smooth breast implants. Aesthetic surgery journal. 38(1), 38-48.
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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



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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

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Thank You



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