

2019 FDA CDRH General and Plastic Surgery Devices Advisory Committee Meeting
 March 26, 2019

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MRI Considerations

Benefits	Challenges
<ul style="list-style-type: none"> • Identify silent ruptures • Potential to identify ruptures earlier 	<ul style="list-style-type: none"> • False positives • Costly procedure • Limited healthcare coverage • Optimal timeframe

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Rosalyn d'Incelli, CCRP VP of Clinical & Medical Affairs	JoAnn Kuhne, MSN, RAC VP of Regulatory Affairs & Quality Assurance	Bruce Van Natta, MD Medical Advisor
SCIENCE	SAFETY	LEADERSHIP

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Potential MRI Alternatives

- Alternative imaging technologies (High-resolution ultrasound)
- Follow ACR recommendations to only perform diagnostic MRIs


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Current MRI Recommendations

- Sientra Patient and Physician Labeling follows FDA recommendations:
The first MRI should be performed at 3 years postoperatively, then every 2 years, thereafter.
- American College of Radiology recommends:
MRI not appropriate for asymptomatic patients

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PACS (Core) Study MRI



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PACS MRI Rates

10-Year Kaplan-Meier, By-Patient	
Event	MRI Cohort N=571
Rupture (MRI cohort)	8.6%

41% of reported ruptures came from 3 sites with 16% of total subjects enrolled

Patient Informed Consent Process

- Educational Brochures (Labeling)
- Acknowledgement of Informed Decision
- FDA-Approved Language
- Consent Prior to Surgery
- Confident in Decision

MRI Findings

- 39% of implants with suspected silent ruptures were confirmed to be intact upon explantation or follow-up MRI
- All but 1 of the 36 explanted ruptures were found to be intracapsular

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14. Acknowledgement Of Informed Decision

I understand that this patient brochure provided by Sientra is intended to provide information regarding the benefits and risks of breast implants, the potential for silent rupture, and the importance of follow-up MRI scans to detect silent ruptures. I understand that choosing to have explantation (breast surgery with implants removed) has benefits and risks. I also understand that explantation and breast lift can be done to identify or quantify or at the time of breast augmentation with implants and that, over time, additional information may become available.

I have had adequate time to review and understand the information in this brochure and my questions and concerns have been addressed by my doctor. I have considered alternatives to augmentation surgery, including the use of prosthetic procedures or surgery with saline filled breast implants, and am willing to proceed with silicone gel-filled breast implant surgery.

By checking my responses for each statement below and signing below, I acknowledge that:

- I have had adequate time to read and fully understand the information in this brochure.
- I have had an opportunity to discuss this information with my surgeon and to ask any questions I may have.
- I have carefully considered options other than augmentation surgery with breast implants and have decided to proceed with silicone breast implant surgery.
- I have been advised to wait an adequate amount of time after receiving and considering this information before authorizing my silicone breast implant surgery.
- I understand that, in order to receive Sientra's limited lifetime breast implant warranty, I must participate in Sientra's Lifetime Tracking program, and
- I will retain this brochure and I am aware that I may also ask my surgeon for a copy of this signed acknowledgment.

By my signature below, I acknowledge that:

- My patient has been given an opportunity to ask any and all questions related to this brochure, or any other issues of concern.
- All questions related above have been answered "Yes" by my patient.
- My patient has had an adequate amount of time before making her final decision to have breast surgery was obtained (verbally, written, and).
- This acknowledgment of Informed Decision will be retained in my patient's permanent record.

Explanting Surgeon Name (Printed) _____
 Explanting Surgeon Signature _____ Date _____

Patient Name (Printed) _____
 Patient Signature* _____ Date _____

* A patient must be at least 22 years old for primary and revision breast augmentation with silicone breast implants.

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Patient Education and Informed Consent

U.S. PAS Participant Informed Decision (N=4,050)

- 97% Participants felt the educational brochure (labeling) helped them understand the risks and benefits of breast implantation
- 97% Participants felt that the educational brochure, in addition to discussions with their surgeons, provided the information needed to make an informed decision

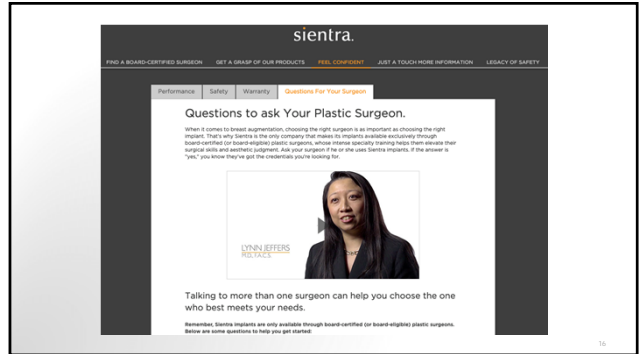
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U.S. PAS Participant Informed Decision (N=4,050)

19%

Participants prefer the brochure had more information

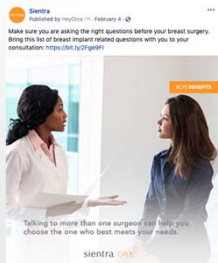
- Implant Longevity
- Reoperations
- Other Potential Complications



Sientra Safety Information Website



Patient Education



Summary and Conclusion




Sientra: Overall Summary

- ✓ PAS support long-term safety and effectiveness
- ✓ Patient labeling and informed consent emphasis
- ✓ Partner with surgeons, patients and FDA
- ✓ Patient safety and product quality
- ✓ Board-Certified Plastic Surgeons exclusively

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Thank You



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