2019 FDA CDRH General and Plastic Surgery Devices Advisory Committee Meeting

March 26, 2019

sientra | OPUS

MRI Considerations

Benefits

- Identify silent ruptures
- Potential to identify ruptures earlier

Challenges

- False positives
- Costly procedure
- Limited healthcare coverage
- Optimal timeframe

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

Potential MRI Alternatives

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

sientra | OPUS

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

sientra | OPUS

PACS (Core) Study MRI →

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

7

Patient Informed Consent Process

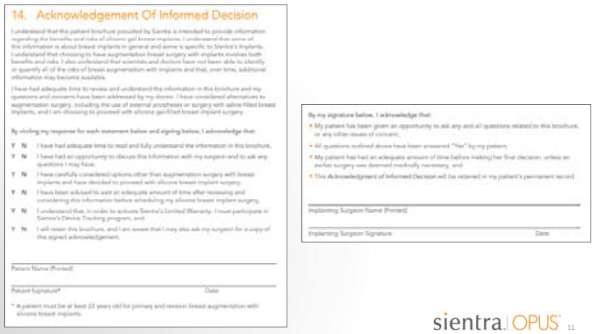
- Educational Brochures (Labeling)
- Acknowledgement of Informed Decision
- FDA-Approved Language
- Consent Prior to Surgery
- Confident in Decision

10

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

sientra OPUS 8


14. Acknowledgement Of Informed Decision

sientra OPUS 11

Patient Education and Informed Consent

9

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

sientra 12

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

19% Participants prefer the brochure had more information

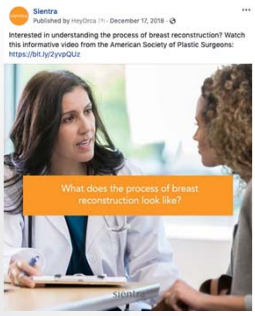
- Implant Longevity
- Reoperations
- Other Potential Complications

sientra 13

16

Sientra Safety Information Website

14



sientra | OPUS 7

Patient Education

sientra | OPUS 5

Summary and Conclusion

18

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

sientra | OPUS 19

Thank You

sientra | OPUS 20