MRI Considerations

**Benefits**
- Identify silent ruptures
- Potential to identify ruptures earlier

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

Potential MRI Alternatives

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

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
**PACS MRI Rates**

<table>
<thead>
<tr>
<th>Event</th>
<th>MRI Cohort (%)</th>
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<tbody>
<tr>
<td>Rupture (MRI cohort)</td>
<td>8.6%</td>
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41% of reported ruptures came from 3 sites with 16% of total subjects enrolled.

**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.

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

97% of participants felt the educational brochure (labeling) helped them understand the risks and benefits of breast implantation.

97% of participants felt that the educational brochure, in addition to discussions with their surgeons, provided the information needed to make an informed decision.

**Patient Informed Consent Process**

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

Thank You