Requested Presentation Topics

1. Patient Communication and Informed Consent
2. MRI and Silent Implant Rupture
3. Acellular Dermal Matrices (ADM)
Current Patient and Surgeon Communication

- Allergan encourages effective dialogue between patient and surgeon
  - Detailed surgeon directions for use
  - Summary patient brochure
  - Detailed patient brochure
  - Website with additional tools
- Live education sessions with surgeons
- Suggest 1-2 weeks between consult and surgery
Available Tools

BREAST IMPLANTS: Making the Best Decision for You

RESOURCES for you

natrelle.com/resources
Informed Consent is an Ongoing Process

- Use patient focus groups to evaluate
  - Content
  - Delivery methods
- Improve communication to women with existing breast implants
  - Surgeon education
  - Primary care provider education
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Current US MRI Label Recommendations

- Implant rupture is an important concern for patients
- Silent rupture
  - Occurs without signs or symptoms
- MRI screening recommendations in labeling
  - At 3 years post-implantation and every 2 years thereafter
  - If rupture is noted, surgeon should advise patient to have implant removed
## MRI Compliance is Low in Post-Market Environment

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<th>Indication</th>
<th>Allergan Natrelle Round Post-Approval Study Compliance</th>
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<td>Revision-reconstruction</td>
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MRI Screening for Silent Rupture Observations and Recommendations

- Observations
  - Satisfied and asymptomatic patients do not return for MRI
    - High cost and low insurance coverage
    - Inconvenience
  - Majority of ruptures are silent

- Recommendations
  - Reinforce need for screening
  - Support lower-cost alternatives to MRI, such as high-resolution ultrasound
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Evolution of Breast Reconstruction Technique with ADM

- Subcutaneous
- Full Muscle Coverage (FMC)
- Partial Muscle Coverage (PMC)
- PMC with ADM
Benefits for Using ADM in Partial Muscle Coverage Breast Reconstruction

- Reinforcement of weak tissue at breast boundaries (IMF and LMF)\(^1\)
- Improved aesthetic outcomes\(^2,3\)
  - Improved ptosis and natural breast shape\(^2,4\)
- Reduced expansion time and discomfort\(^4\)
- Decreased risk of exposure or extrusion\(^2,4,5\)
- Decreased risk of implant visibility and palpability\(^2,4,5\)

Potential Benefits for Prepectoral Breast Reconstruction

- Shorter surgical time\(^1\)
- Decreased recovery time\(^1\)
- Reduced postoperative pain\(^1\)
  - Less narcotics\(^2\)
- Eliminates animation deformity\(^1,3\)

1. Sbitany H et al. 2017
2. Copeland-Halperin L. et al. 2019
Most Common Complications with ADM in Breast Reconstruction

- Seroma\(^1\)
- Infection\(^1,2\)
- Skin necrosis\(^1\)
- Implant / expander loss\(^1,2\)

1. Israeli et al, 2012
2. Hallberg et al, 2018
Allergan Commitment

- Committed to generation of additional data
  - Working with FDA
  - Define clinical endpoints
  - Ensure optimal outcomes for patients
Conclusions

- Informed consent must be improved
  - Involving patients in materials development

- Continuing education of breast implant patients post-implantation

- Patient compliance with MRI screening is low
  - Evolving technology may provide a lower cost alternative that could enhance compliance

- ADMs are an important evolution in breast reconstruction
THANK YOU