

# MRI for Silent Rupture, Patient Informed Consent, and Use of ADM

FDA Medical Devices Advisory Committee  
General and Plastic Surgery Devices Panel  
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Stephanie Manson Brown, MD  
Vice President, Clinical Development



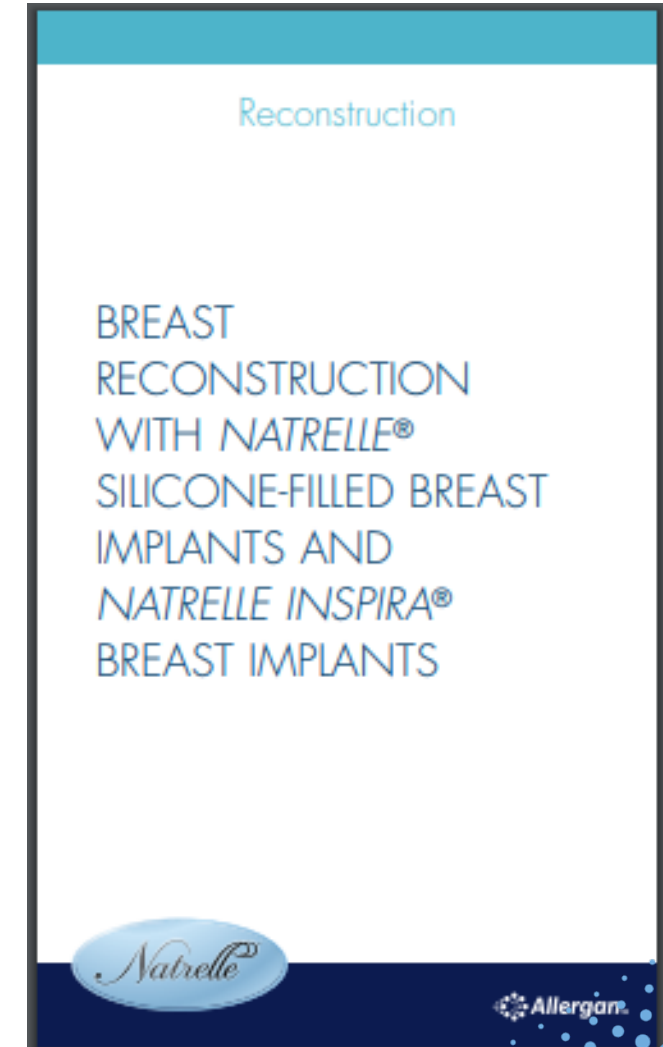
# Requested Presentation Topics

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

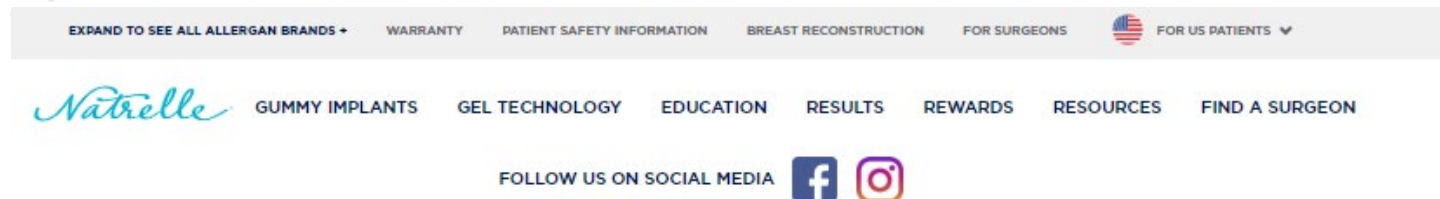
# Current Patient and Surgeon Communication



- 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

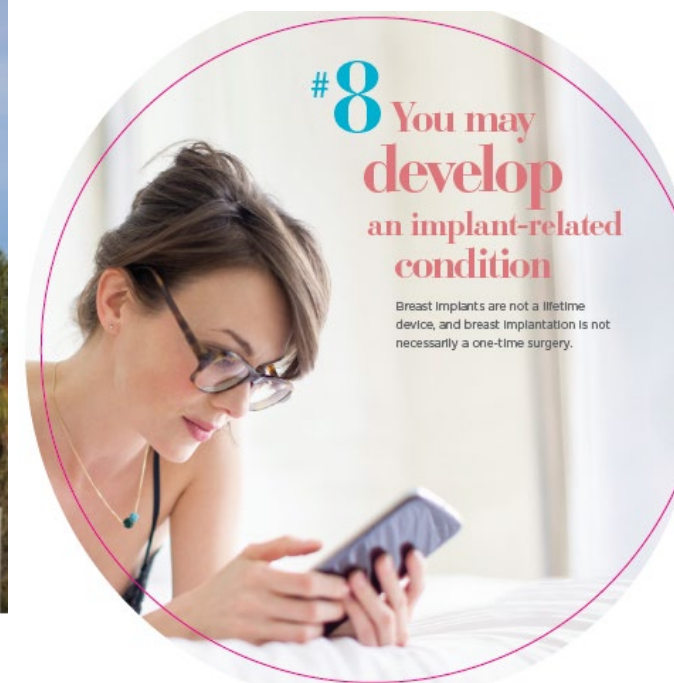


# Available Tools



BREAST IMPLANTS:  
Making the  
Best Decision  
for You

[natrelle.com/resources](https://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



Allergan Natrelle Round Post-Approval Study (N=2000)			
Indication	Year 3	Year 5	Year 7
Augmentation	2.0	2.3	2.4
Revision-augmentation	2.4	3.3	3.8
Reconstruction	13.6	13.6	12.4
Revision-reconstruction	9.1	13.6	4.5



# MRI Screening for Silent Rupture

## Observations and Recommendations



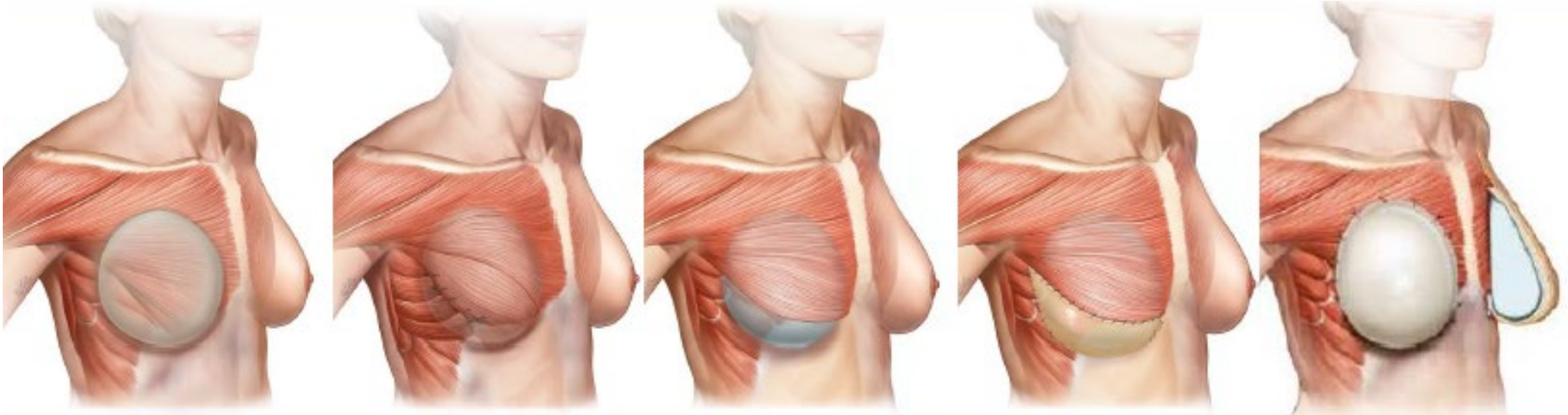
- Observations
  - Satisfied and asymptomatic patients do not return for MRI
    - High cost and low insurance coverage
    - Inconvenience
  - Majority of ruptures are silent
- Recommendations
  - Reinforce need for screening
  - Support lower-cost alternatives to MRI, such as high-resolution ultrasound



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# Evolution of Breast Reconstruction Technique with ADM



Subcutaneous



Full Muscle  
Coverage (FMC)



Partial Muscle  
Coverage (PMC)



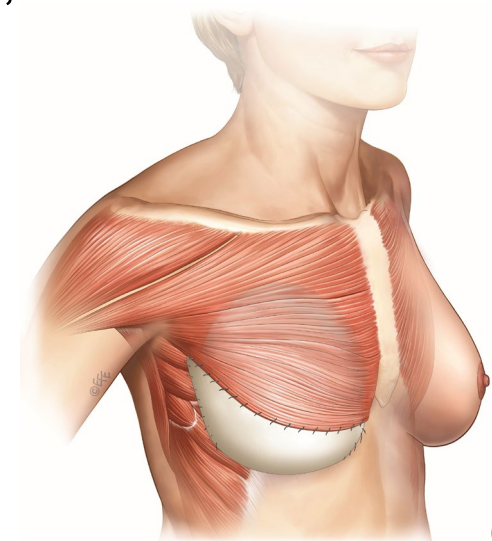
PMC  
with ADM



# Benefits for Using ADM in Partial Muscle Coverage Breast Reconstruction



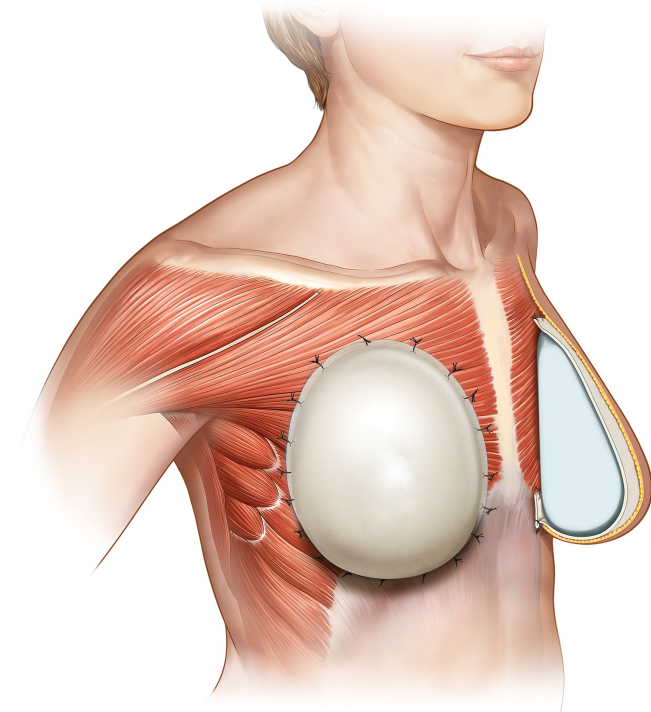
- Reinforcement of weak tissue at breast boundaries (IMF and LMF)<sup>1</sup>
- Improved aesthetic outcomes<sup>2,3</sup>
  - Improved ptosis and natural breast shape<sup>2,4</sup>
- Reduced expansion time and discomfort<sup>4</sup>
- Decreased risk of exposure or extrusion<sup>2,4,5</sup>
- Decreased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



# Potential Benefits for Prepectoral Breast Reconstruction



- Shorter surgical time<sup>1</sup>
- Decreased recovery time<sup>1</sup>
- Reduced postoperative pain<sup>1</sup>
  - Less narcotics<sup>2</sup>
- Eliminates animation deformity<sup>1,3</sup>



# Most Common Complications with ADM in Breast Reconstruction



- Seroma<sup>1</sup>
- Infection<sup>1,2</sup>
- Skin necrosis<sup>1</sup>
- Implant / expander loss<sup>1,2</sup>



# 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

