Breast Implant Safety

Mentor Worldwide, LLC

Day 1: March 25, 2019

General and Plastic Surgery Devices Panel (GPSDP) Meeting
Agenda

BIA-ALCL: Risk Factors and Monitoring

Systemic Symptoms and Mentor Clinical Data

Registries for Breast Implant Surveillance

Additional Q&A Responders

Raina Dauria, MS
Vice President, Regulatory Affairs
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John Canady, MD
Michael Schwiers, MS
Laura Vellucci, PhD
Warren Foust
Roger Wixtrom, PhD
Data from Long-Term Clinical Studies Provide Support for Safety of Mentor Gel-filled Breast Implants

<table>
<thead>
<tr>
<th>Year</th>
<th>Studies</th>
<th>Patients</th>
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<td>1 - Large Post Approval Study (PAS)</td>
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<td>2016 - Ongoing</td>
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Data from Long-Term Clinical Studies Provide Support for Safety of Mentor Gel-filled Breast Implants
BIA-ALCL
Risk Factors and Monitoring
Many Factors May Contribute to Development of BIA-ALCL

- Etiology likely multifactorial
  - Bacterial contamination/biofilm
  - Particulate matter in breast implant capsule
  - Genetic predisposition
  - Surface texture

Implant Surface Texture Varies Greatly Across Manufacturers

Mentor Texture

Salt-Loss Polyurethane Gas Expansion

Barr et al., 2009; Stevens et al., 2013
Risk of BIA-ALCL with Mentor Texture Implants Remains Low Over Time

Cumulative Proportion of Patients with ALCL per 10,000 Implants

1 in 86,029 Mentor Texture
1 in 3,345 Salt-loss
1 in 2,832 Polyurethane

Multiple Studies Show Low Number of BIA-ALCL Cases with Mentor Texture Breast Implants

• Low number of BIA-ALCL cases with Mentor implants compared to total number of cases
• Mentor breast implant market share roughly equal to, or higher than, next leading manufacturer worldwide
Textured Implants Offer Important Benefits for Patients

• Reduced risk of reoperation due to
  • Capsular contracture in subglandular augmentation patients
  • Asymmetry in reconstruction patients
• Designed to reduce rotation and implant movement
• Shaped implants only available with texturing
Implant-Specific, Long-Term Clinical Data Best Reflect Implant Performance

- Breast implant classification systems designed to characterize surface properties
  - Not harmonized
  - Bench top; not clinically validated
Systemic Symptoms
Mentor Actively Monitors Systemic Symptoms

• Some women with breast implants report range of symptoms
• Symptoms may present differently in different patients
• Causes difficult to determine
• Mentor continuously monitors through clinical study data and safety surveillance activities
Likelihood of Experiencing Systemic Symptoms Did Not Increase with Longer Implant Exposure Time

MemoryGel Core (n= 1008)
MemoryShape Core (n= 955)
Registries for Breast Implant Surveillance
Registries Can Address Open Questions Related to Breast Implant Safety

- NBIR allows surgeons and manufacturers to track and trend data
- PROFILE provides number of BIA-ALCL cases and detailed case information
Recommendation for NBIR Sub-Study: Risk Factors

- Collection at baseline and ongoing
- Expanded patient factors
  - Family medical history
  - Complete breast implant history
  - Detailed medical history including allergies and medications
- Genetic marker testing
- Biofilm testing of capsule at time of explantation
Recommendation for NBIR Sub-Study: Endpoints

- Collection at baseline and ongoing
- Symptoms (immunological/ rheumatological/ neurological)
  - Captured with severity
  - Pre-implantation, following implantation and post-explantation
- Validated quality of life survey (e.g. BREAST-Q™)
Mentor Supports Data Transparency to Empower Women to Make Informed Choices