What patient who have had breast implants think that patients contemplating breast implants should know
What do patients need to know prior to breast implants for augmentation or reconstruction?
Breast implants are not lifetime devices
**A: How long do breast implant last?**

Most breast implants will last a lifetime.

There is a common misconception that implants will only last 10 years. This is not true. If you have no problem with your implant then nothing needs to be done with them. The only reason you would change an implant is if there is a problem with them. The most common long term problem is implant rupture. The risk of a rupture is 1% a year. So the risk of having a broken implant at the end of 10 years is 10%. That means that 90% of implants will be fine at 10 years. The other common misconception is that saline implants are more likely to rupture than gel. This is not true. The rupture rate is the same for saline and cohesive gel implants because the outer shell of both type of implants are virtually the same.

So most women will live their whole lives with their original implants and will never require additional surgery. **“Most breast implants will last a lifetime.”**

**“So most women will live their whole lives with their original implants and will never require additional surgery.”**
Complications
### Reconstruction Patients Cumulative Kaplan-Myer Risk Rates of Most Common Complications through 3 years

<table>
<thead>
<tr>
<th>Complication</th>
<th>Reconstruction (N=251)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reoperation</td>
<td>26%</td>
</tr>
<tr>
<td>Implant Removal w/ or w/o Replacement</td>
<td>13%</td>
</tr>
<tr>
<td>Capsular Contracture (Baker III or IV)</td>
<td>9%</td>
</tr>
<tr>
<td>Asymmetry</td>
<td>7%</td>
</tr>
<tr>
<td>Ptosis</td>
<td>7%</td>
</tr>
<tr>
<td>Hypertrophic Scarring</td>
<td>6%</td>
</tr>
<tr>
<td>Infection</td>
<td>5%</td>
</tr>
<tr>
<td>Seroma</td>
<td>5%</td>
</tr>
<tr>
<td>Breast Mass</td>
<td>4%</td>
</tr>
<tr>
<td>Nipple Sensation Changes</td>
<td>3%</td>
</tr>
<tr>
<td>Wrinkling</td>
<td>3%</td>
</tr>
<tr>
<td>Metastatic Disease</td>
<td>2%</td>
</tr>
<tr>
<td>Breast Pain</td>
<td>2%</td>
</tr>
<tr>
<td>Implant Malposition/Displacement</td>
<td>2%</td>
</tr>
<tr>
<td>Recurrent Breast Cancer</td>
<td>2%</td>
</tr>
<tr>
<td>Hematoma</td>
<td>2%</td>
</tr>
<tr>
<td>Necrosis</td>
<td>1%</td>
</tr>
<tr>
<td>Implant Extrusion</td>
<td>1%</td>
</tr>
<tr>
<td>Rupture</td>
<td>1%</td>
</tr>
</tbody>
</table>

### Augmentation Patients Cumulative Kaplan-Myer Risk rates of Most Common Complications through 3 years

<table>
<thead>
<tr>
<th>Complication</th>
<th>Augmentation Patients (N=551)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reoperation</td>
<td>15%</td>
</tr>
<tr>
<td>Nipple Sensation Changes</td>
<td>11%</td>
</tr>
<tr>
<td>Capsular Contracture (Baker III or IV)</td>
<td>8%</td>
</tr>
<tr>
<td>Hypertrophic Scarring</td>
<td>6%</td>
</tr>
<tr>
<td>Implant Removal w/ or w/o Replacement</td>
<td>5%</td>
</tr>
<tr>
<td>Hematoma</td>
<td>3%</td>
</tr>
<tr>
<td>Ptosis</td>
<td>2%</td>
</tr>
<tr>
<td>Breast Mass</td>
<td>2%</td>
</tr>
<tr>
<td>Breast Sensation Changes</td>
<td>2%</td>
</tr>
<tr>
<td>Breast Pain</td>
<td>2%</td>
</tr>
<tr>
<td>Infection</td>
<td>2%</td>
</tr>
<tr>
<td>Miscarriage</td>
<td>1%</td>
</tr>
<tr>
<td>Rupture</td>
<td>1%</td>
</tr>
</tbody>
</table>
Need for MRI follow up

Frequency and pitfalls
Health insurance often isn’t helpful
Many **health insurance policies** do not cover the cost of reoperations or explant surgery for augmentation patients with serious complications from their implants. Policies that do cover explant usually only do so for severe capsular contracture (Baker 3/4) ruptured silicone gel implants, or interference with breast cancer detection. The complications known as breast implant illness are not recognized as a medically necessary reason for explant.

--- *National Center for Health Research Health Insurance Project*
Statements from women:

“I am fighting my insurance for approval.”

“I am so sick and tired….so many of us are. If we had the money or insurance covered we would have our surgery dates.”

“I lost my job 4 years ago and need help to finance surgery.”

“I had these put in 3 years ago and my health has been slowly declining. I can’t understand why your insurance won’t help with a portion of the cost.”

“My only income is child support. So I am in a huge financial situation. And have ruined my credit. So I have basically lost everything from these toxic bags, and lay in bed feeling like I’m slowly dying.”
Chemical transparency - Breast implant materials are secret
Can true informed consent be given when neither the patient nor the implanting surgeon knows the full details of the device being implanted?

Could disclosure of materials potentially provide screening opportunities for future patients?
Symptoms of implant related illness are not widely recognized by the medical community.
Terms for BII

ASIA - Autoimmune/Inflammatory Syndrome Induced by Adjuvants in relation to silicone is currently the only term with diagnostic criteria. More on this will be discussed later in the meeting.
Symptoms of BII

Most common:

- Fatigue
- Joint and muscle pain
- Brain fog

Neurological symptoms

- Immune dysfunction
- Skin manifestations
- Autoimmune disease or autoimmune symptoms

Symptoms of Implant Illness

Anxiety
Fatigue
Joint pain
Muscle pain
Insomnia
Brain fog
Difficulty concentrating
Memory loss
Limb numbness / tingling
Vertigo
Fever / chills
Muscle weakness
Temperature intolerance
Sensitivity to light
Sensitivity to sound
Difficulty swallowing
Hair loss
Dry skin / hair
Slow healing
Sinus infections
Recurrent illness

Candida / yeast infections
Skin rashes / lesions
Visual disturbance
Choking feeling
Ringing in ears
Headaches
Depression
Decreased libido
Mood swings
Sharp pains in breast
Weight gain
Food intolerance
Swollen / tender lymph nodes
Autoimmune symptoms or diagnosis
Chronic Fatigue Syndrome symptoms
Fibromyalgia symptoms
Inflammation
Heart palpitations
Irritable bowel or bladder
Shortness of breath
Night sweats
Social media awareness
Preemption - Harmed patients cannot hold manufacturers accountable
Flaws in mandated studies -- were sick women excluded intentionally?
“I was never contacted by my plastic surgeon for any follow up appointments pertaining to the study or by Mentor for any information towards the study.”
“I was enrolled in the 10 year BIFS in Sept. 2009. November 2015, 6 years into the study, I received notification that “changes” were being made to the program. At this point, all follow-up appointments and questionnaires were ceased.”
“The first two surveys I filled out I wasn’t feeling the best, but, I hadn’t started feeling terrible yet; so as I recall my answers were right down the middle, not great reviews, yet not terrible reviews. About my third survey in I began to get very sick, many autoimmune problems along with terrible capsular contracture. I answered the questions honestly. ...after this particular survey I never heard from the company Allergan again.”
“10 year study but they blew me off after 3rd year. Year two I reported a little bit of fatigue, skin issues and year 3 the office no longer had a staff member assigned to the study. And year 4 they didn’t return my calls.”
“I joined the BIFS study upon implantation of my saline, smooth McGhan implants in 2008. Every year they would call me and send me mailers to complete my yearly study. They would then mail me a check for $20 for my time. The last study I did, I believe it was 2014, I told them of the inflamed lymph nodes, pain, mystery illness based on symptoms.” “That was the last time they contacted me.”
The FDA has the authority to require sponsors to perform a post-approval study (or studies) at the time of approval of a premarket approval (PMA), humanitarian device exemption (HDE), or product development protocol (PDP) application. Post-approval studies can provide patients, healthcare professionals, the device industry, the FDA and other stakeholders information on the continued safety and effectiveness (or continued probable benefit, in the case of an HDE) of approved medical devices. This database allows you to search Post-Approval Study information by applicant or device information.

<table>
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<th>Application Number</th>
<th>Application</th>
<th>Device Name</th>
<th>Medical Specialty</th>
<th>Date PMA Approved</th>
<th>Study Name</th>
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<td>P040046</td>
<td>Allergan</td>
<td>NATRELLE HIGHLY COHESIVE SILICONE-FILLED BREAST IMPLANTS</td>
<td>General &amp; Plastic Surgery</td>
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<td>Natrelle and 410 Combined</td>
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<td>Progress Adequate</td>
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<td>Focus Group Study</td>
<td>02/20/2013</td>
<td>Completed</td>
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Would I have made the same choice?
Are we doing enough to educate the patients?
Adverse event data is misleading
Risk of cancer
Breast Implant Associated Anaplastic Large Cell Lymphoma

Presented by: Jamee Cook

On behalf of patient advocates: Terri McGregor, Raylene Hollrah, Michelle Forney, Jennifer Cook, Dawn Criss, Kim Platt, Carol Small, Larissa Torres, Roxane Vermeland

Collective voice of 20% Worldwide Patients
Patient perspective is real world evidence. 100% of these patients:
1. Were not informed of BIA-ALCL
2. Had a unique journey to diagnosis - many with resistance
3. Lives have been forever altered
Facebook: ALCL in Women with Breast Implants

- Over 20% of the world’s diagnosed patients diagnosed with BIA-ALCL
- Over 3,305 members
- Over the past 60 days
  - Generated over 456 posts related to questions about BIA-ALCL
  - 2,799 members have been actively posting and engaging
  - Group has grown over 17% in the past 60 days

www.biaalcl.com: Launched in November 2018 for Patients & Clinicians to access current, accurate and credible research for education and awareness.

These analytics represent the activity on the website from November 21, 2018 - March 1, 2019
- 10,178 Pageviews
- Highest day of pageviews was on 2/7/2019 with 422 (The day FDA announced Alert)
- 3,431 users with 4,516 total session averaging 2 minutes 16 seconds on each page
Barriers to Diagnosis this man-made cancer:

- High majority of women who have implants are not aware of BIA-ALCL
- Most symptoms: pain, change in shape or appearance are thought to be part of initial complications
- Long standing message that breast implants are the most studied device on the market so there is a presumption that they are safe
- Mammograms cannot consistently detect masses within the scar capsule, some masses are not visible
Barriers to Diagnosis this man-made cancer:

- Often labs and radiologists miss the diagnosis because it is misunderstood and considered “rare”; and errors being made by physicians and pathologists

- BIA-ALCL cannot be “seen” during surgery

- Insurance prior to diagnosis

- Recurrence Concerns:
  - 80% of diagnosed women are said to be “cured” by implant removal
  - 20% of diagnosed women require more treatment, such as chemotherapy
Thank you, FDA, for your alert to health care providers about BIA-ALCL...
Breast Implant Associated Anaplastic Large Cell Lymphoma is a man-made cancer that theoretically can be eradicated by the removal of textured breast implants and expanders from the market.
BIA-ALCL / Breast Implant Illness

Call to Action:

1. Mandatory standardized informed consent

2. Mandate that BIA-ALCL and implant related illness risk be communicated through a surgeon / patient checklist & black box warning, similar to Essure until market withdrawal can be executed

3. Request Patient Representation on the Breast Implant Advisory Team for both BIA-ALCL and BII

4. Compliance from Manufacturers reporting confirmed BIA-ALCL cases, penalty for non-compliance
Call to Action Continued:

5. Use your maximum authority towards physicians and institutions to notify patients with textured implants about BIA-ALCL

6. Mandate studies for confirmed cases of BIA-ALCL, industry funded, information public

7. Change incident narrative to: EMERGING. This man-made cancer is emerging, rather than rare

8. Ban textured implant or request a voluntary moratorium on textured implants and expanders
Call to Action Continued:

9. Increase transparency in materials used in breast implants

10. Maintain individual adverse event reporting

11. Hold the manufacturers accountable for unfinished and flawed studies
Thank You