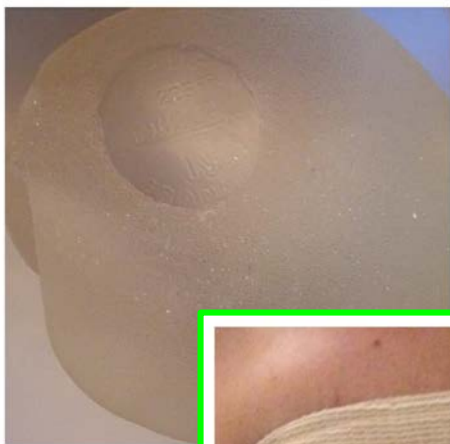


Jamee Cook - Breast Implant Victim Advocacy

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



Breast Implants

[Q&A](#)[Guides](#)[Videos](#)[Forum](#)

A: How long do breast implant last?

Most breast implants will last a lifetime.

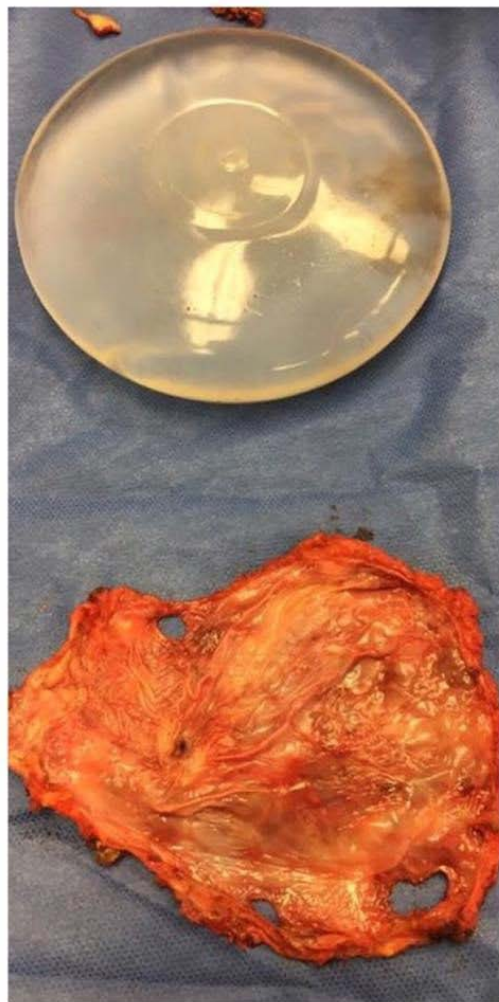
There is a common misconception that implants will only last 10 years. This is not true. If you have no problem with your implant then nothing needs to be done with them. The only reason you would change an implant is if there is a problem with them. The most common long term problem is implant rupture. 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**

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

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

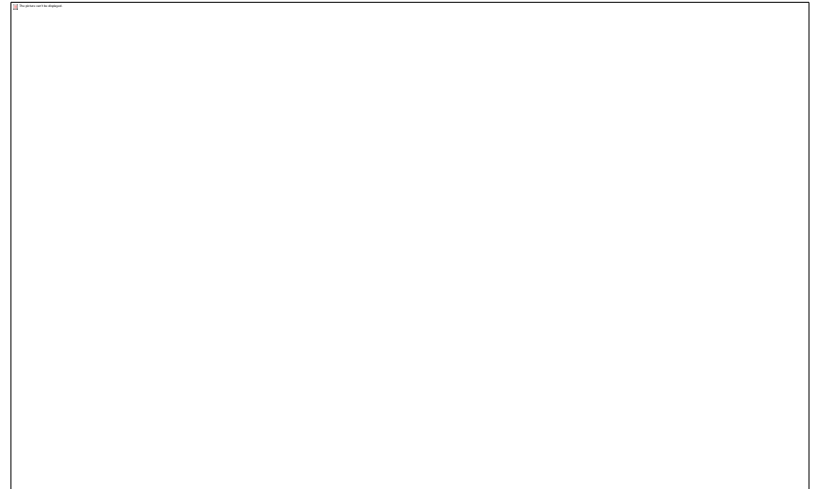
Complication	Augmentation Patients (N=551)
Reoperation	15%
Nipple Sensation Changes	11%
Capsular Contracture (Baker III or IV)	8%
Hypertrophic Scarring	6%
Implant Removal w/ or w/o Replacement	5%
Hematoma	3%
Ptosis	2%
Breast Mass	2%
Breast Sensation Changes	2%
Breast Pain	2%
Infection	2%
Miscarriage	1%
Rupture	1%

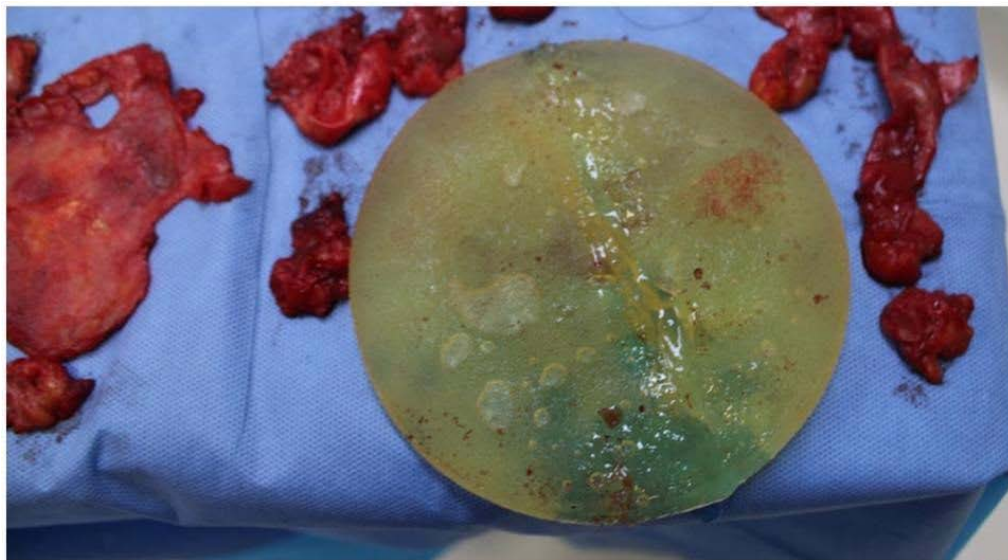




Need for MRI
follow up

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.”

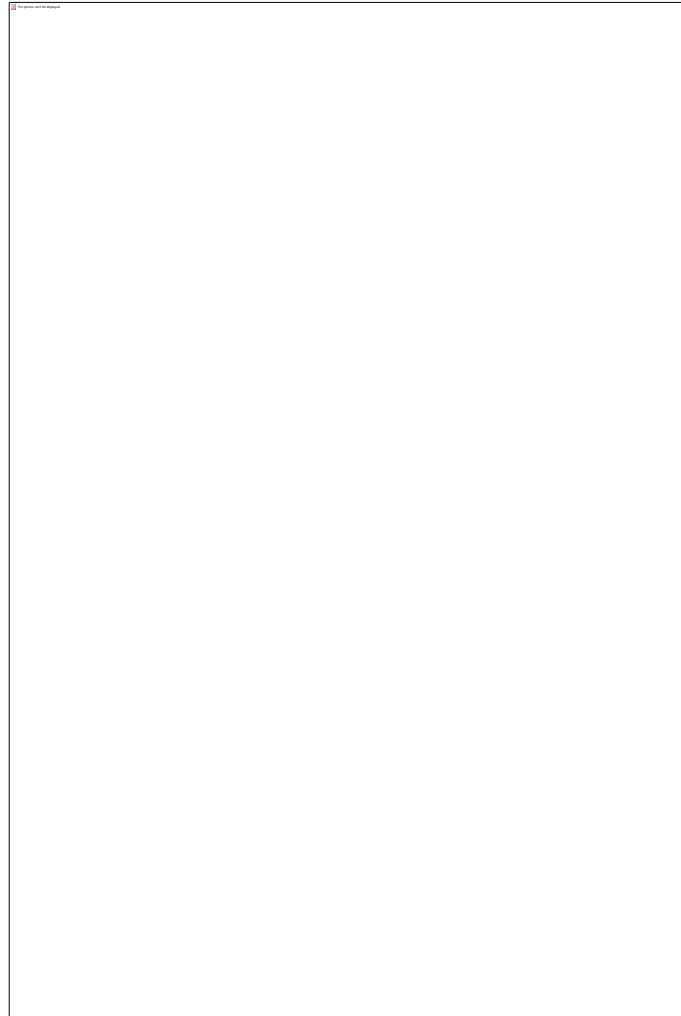
“I lost my job 4 years ago and need help to finance surgery.”

“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.”

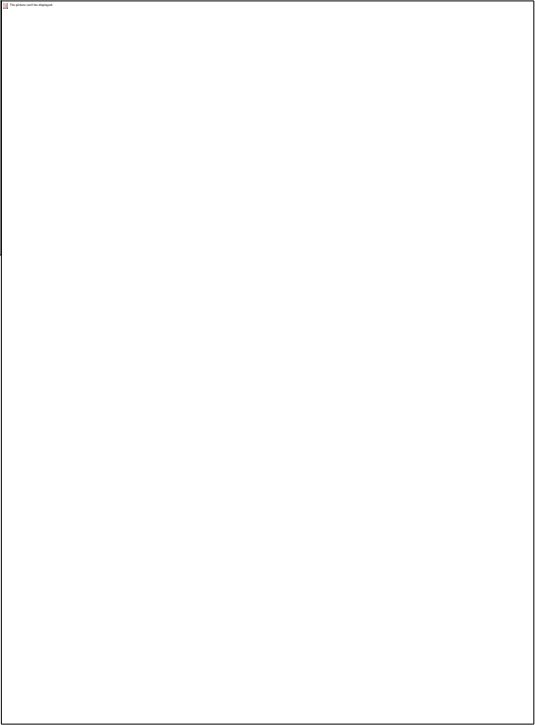
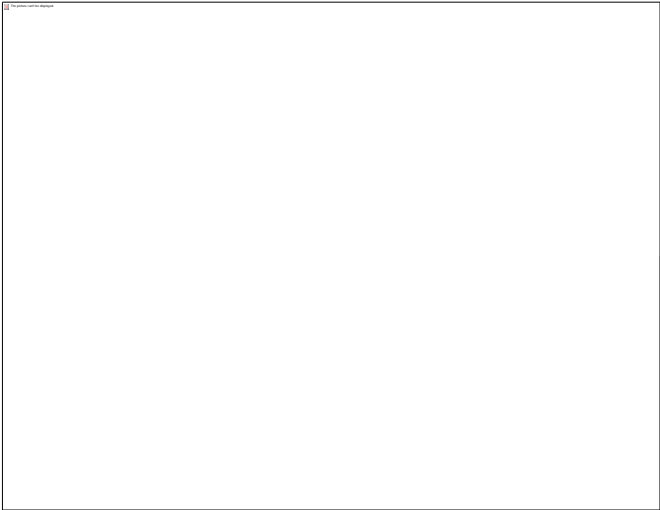
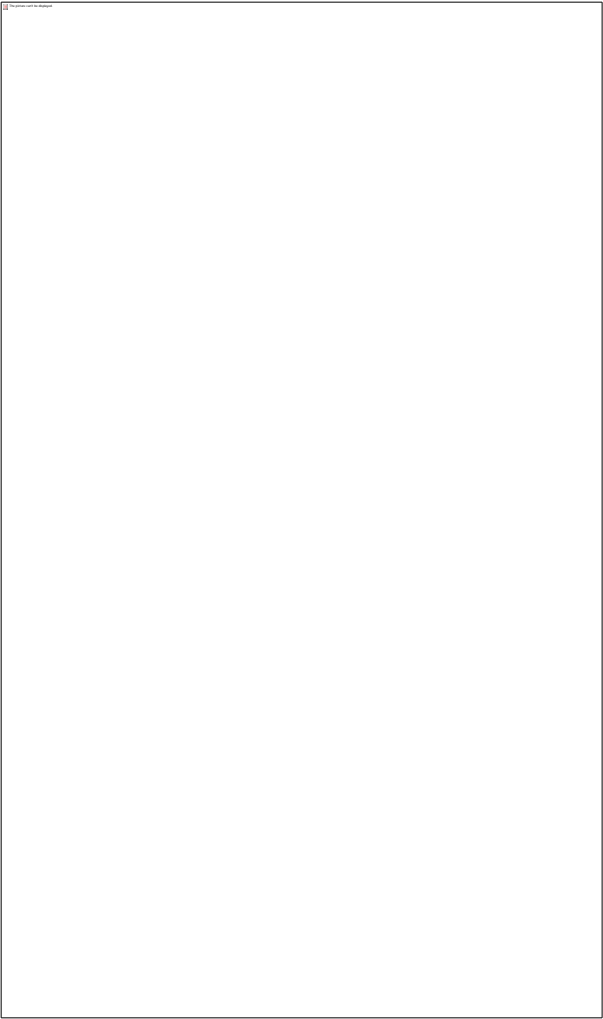
Chemical transparency -
Breast implant materials are secret





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.

Breast Implant Illness
The Adjuvant Disease
Autoimmune/inflammatory Syndrome Induced by Adjuvants (ASIA)
Silicone Autoimmune Induced Syndrome
Silicone Induced Immune Dysfunction Syndrome
Silicone Implant Disease
Silicone Immune Toxicity Syndrome
Silicone Implant Incompatibility Syndrome
Silicone-Induced Disease
Silicone Immune Dysfunction Syndrome
Silicone-Induced Immune Disorder
Silicone Sickness
Siliconosis
Silicone Toxicity Disease
Silicone Poisoning
Breast Implant Sickness
Breast Implant Toxicity Sickness
Adjuvant Breast Disease
Silicone Related Symptom Complex
Prosthetic Mammoplasty Sensitivity Syndrome
Silicone Implant Immune Dysfunction
Breast Implant Disease

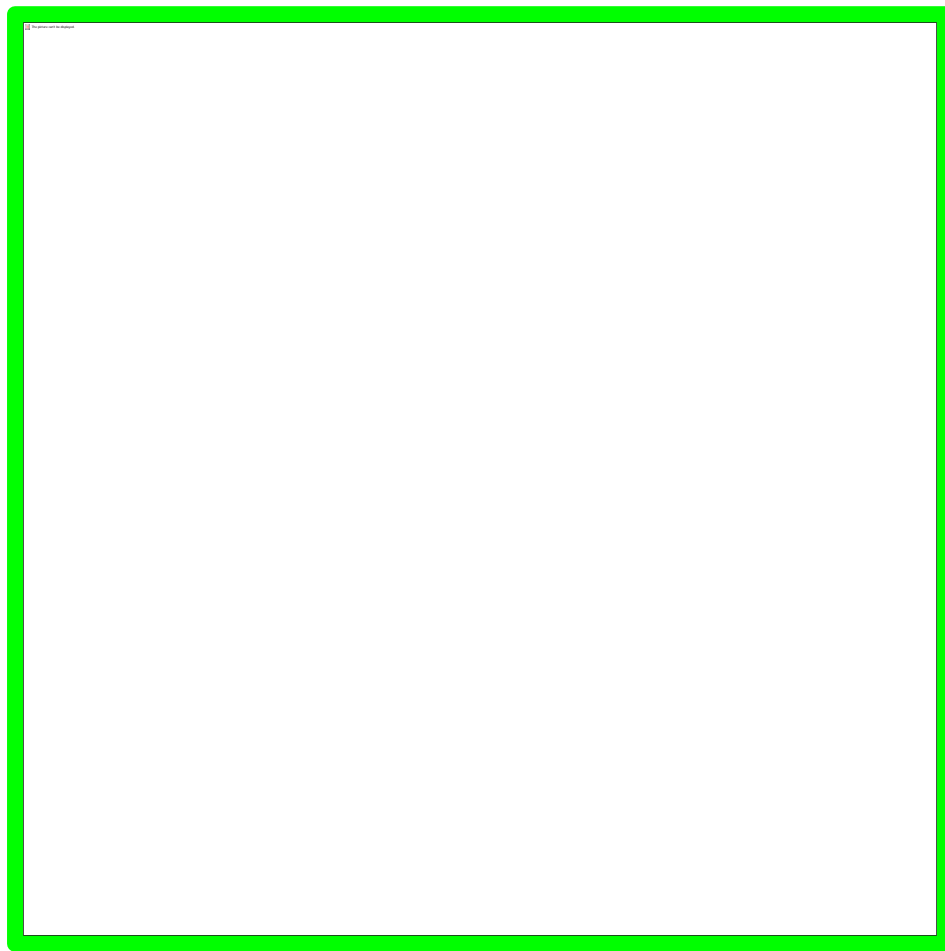
Symptoms of BII

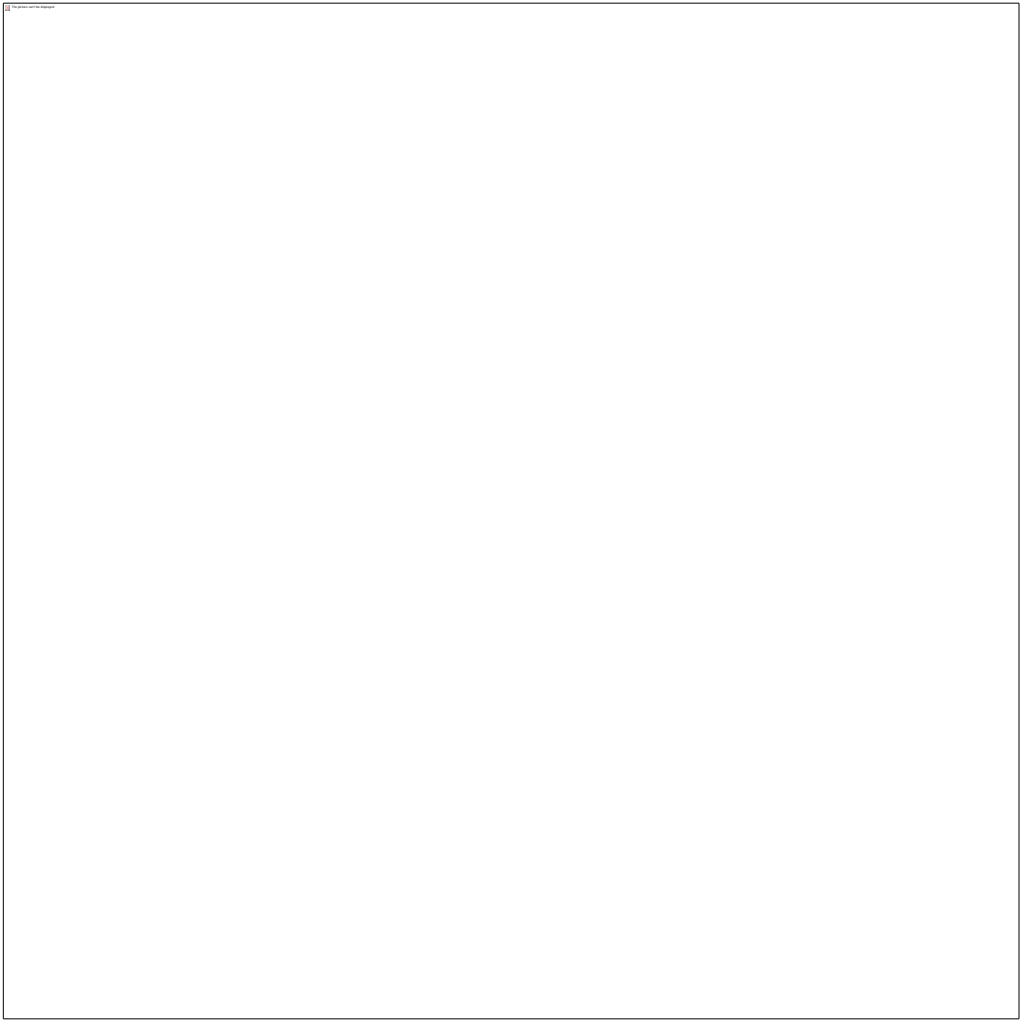
Most common:

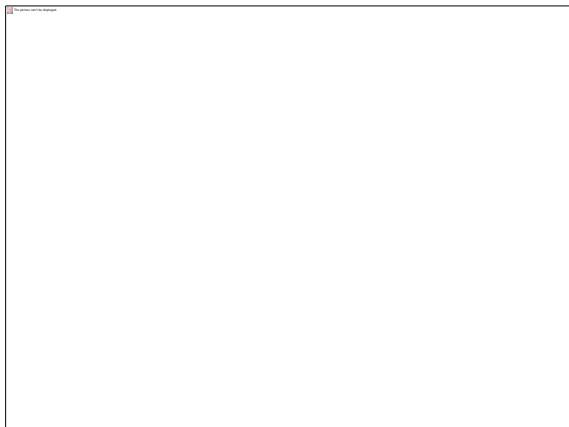
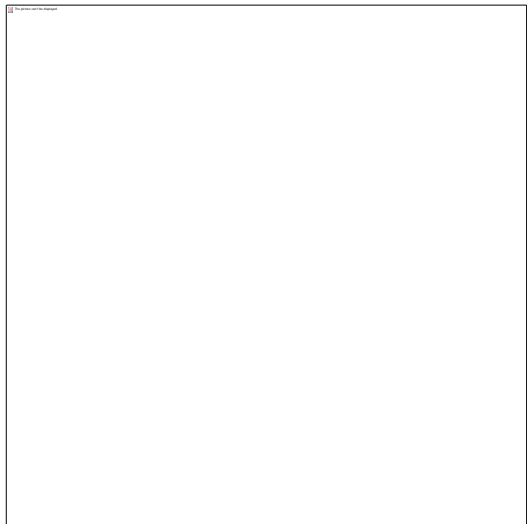
Fatigue
Joint and muscle pain
Brain fog
Neurological symptoms
Immune dysfunction
Skin manifestations
Autoimmune disease or
autoimmune symptoms

Symptoms of Implant Illness

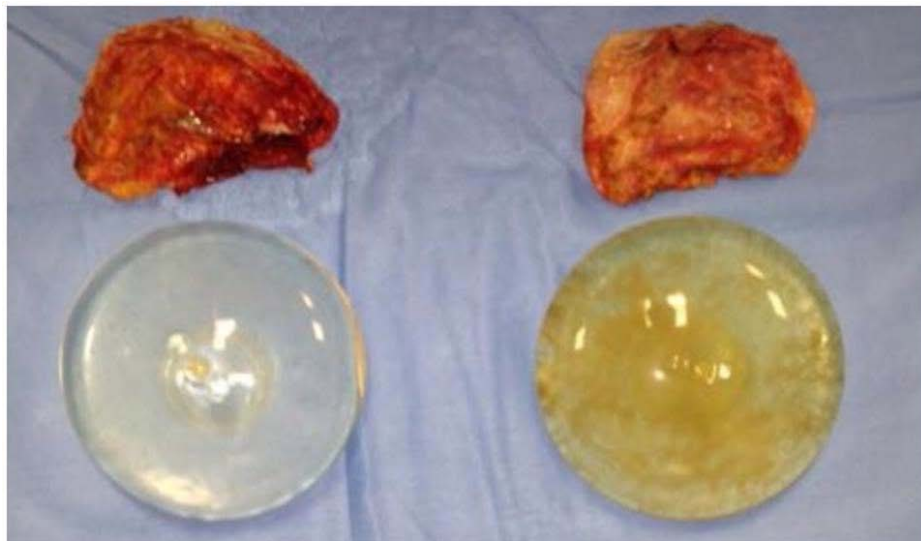
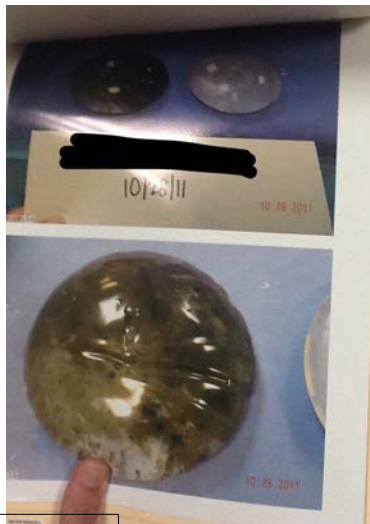
Anxiety	Candida / yeast infections
Fatigue	Skin rashes / lesions
Joint pain	Visual disturbance
Muscle pain	Choking feeling
Insomnia	Ringing in ears
Brain fog	Headaches
Difficulty concentrating	Depression
Memory loss	Decreased libido
Limb numbness / tingling	Mood swings
Vertigo	Sharp pains in breast
Fever / chills	Weight gain
Muscle weakness	Food intolerance
Temperature intolerance	Swollen / tender lymph nodes
Sensitivity to light	Autoimmune symptoms or diagnosis
Sensitivity to sound	Chronic Fatigue Syndrome symptoms
Difficulty swallowing	Fibromyalgia symptoms
Hair loss	Inflammation
Dry skin / hair	Heart palpitations
Slow healing	Irritable bowel or bladder
Sinus infections	Shortness of breath
Recurrent illness	Night sweats

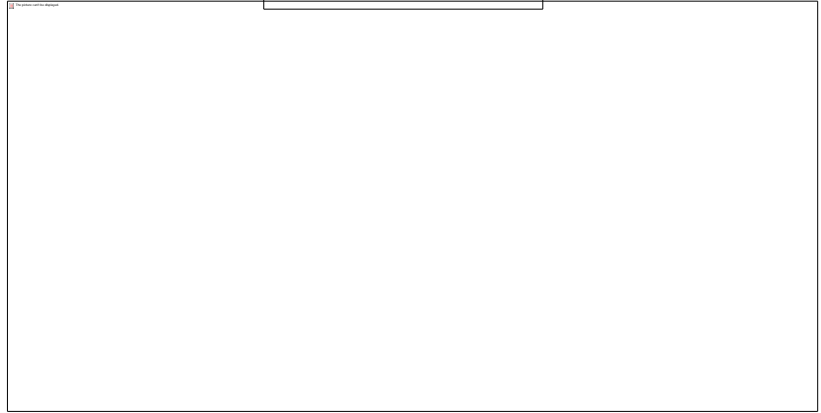
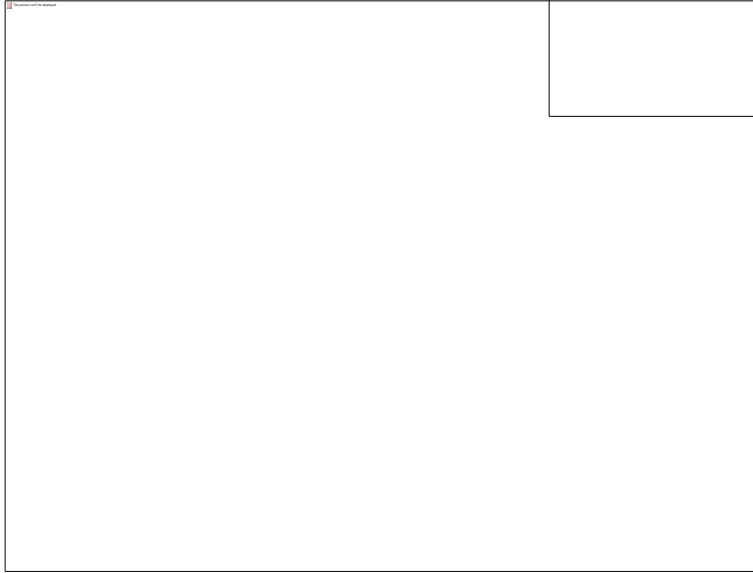
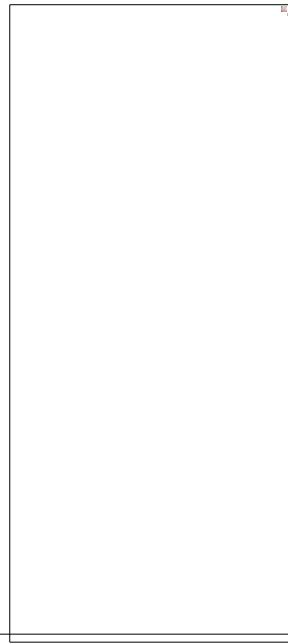
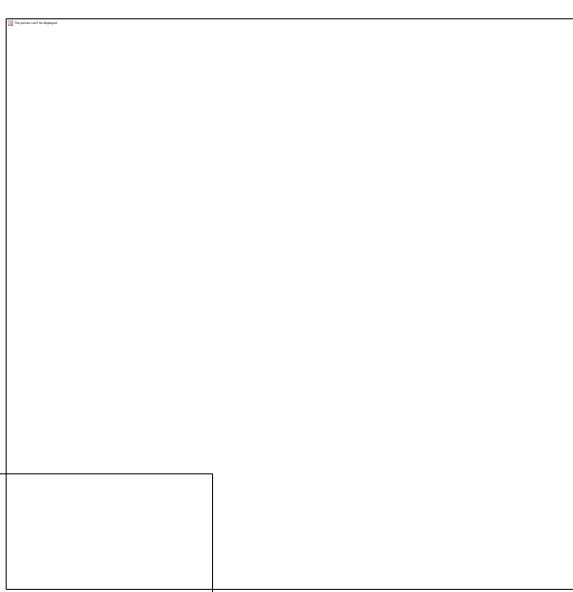
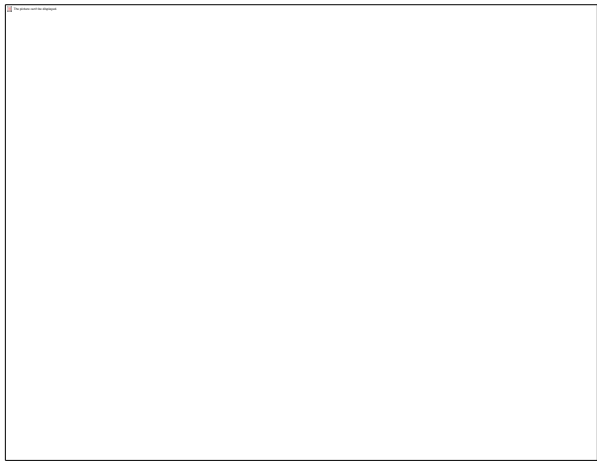












Social media awareness



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.”



Home

Food

Drugs

Medical Devices

Radiation-Emitting Products

Vaccines, Blood & Biologics

Animal & Veterinary

Cosmetics

Tobacco Products

Post-Approval Studies (PAS)

FDA Home Medical Devices Databases



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, health care 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.

[Learn more...](#)

Search

Search

Active Orders

Inactive Orders

All Orders

PAS FAQs

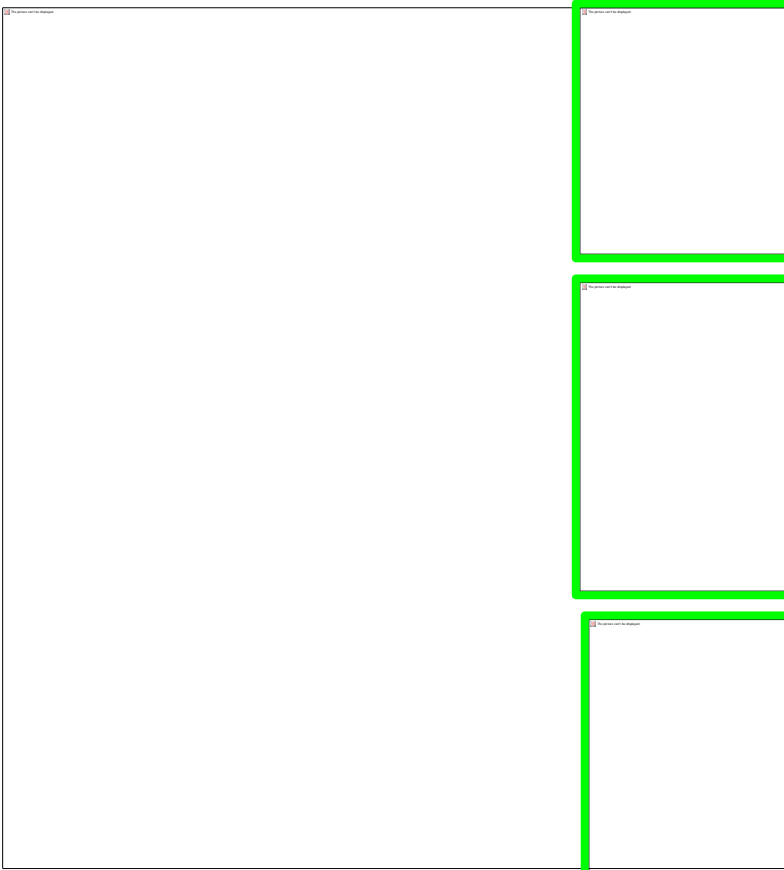
To sort by data column:

2 orders

All Orders

Suggest Enhancement / Report Issue | [Export to Excel](#)

Application Number	Application	Device Name	Medical Specialty	Date PMA Approved	Study Name	Date Original Protocol Accepted	Study Status
P040046	Allergan	NATRELLE HIGHLY COHESIVE SILICONE-FILLED BREAST IMPLANTS	General & Plastic Surgery	02/20/2013	Core Study	02/20/2013	Completed
					Continued Access Study (Natrelle 410 CAS)	02/20/2013	Completed
					Natrelle and 410 Combined	02/20/2013	Progress Adequate
					Case Control Studies	08/03/2012	Terminated
					Focus Group Study	02/20/2013	Completed









Would I have
made the
same choice?

Are we doing
enough to educate
the patients?



Adverse event data is misleading



Risk of cancer



BIA-ALCL



Breast Implant Associated Anaplastic Large Cell Lymphoma

Presented by: Jamee Cook

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

Collective voice of 20% Worldwide Patients



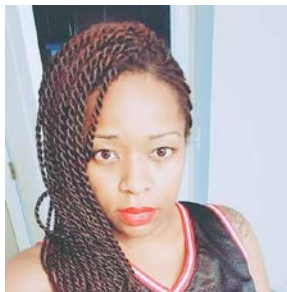
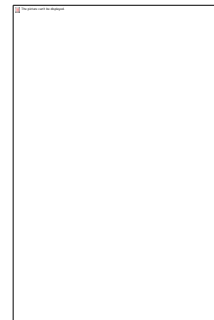
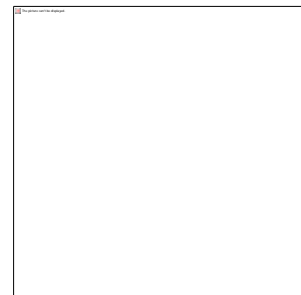
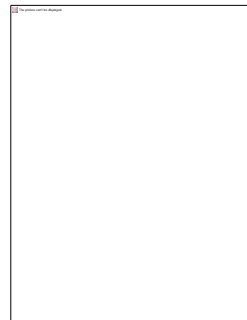
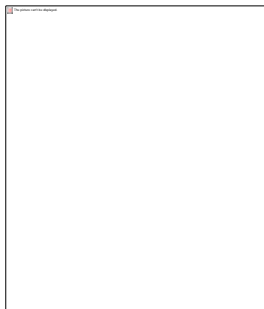
BIA-ALCL

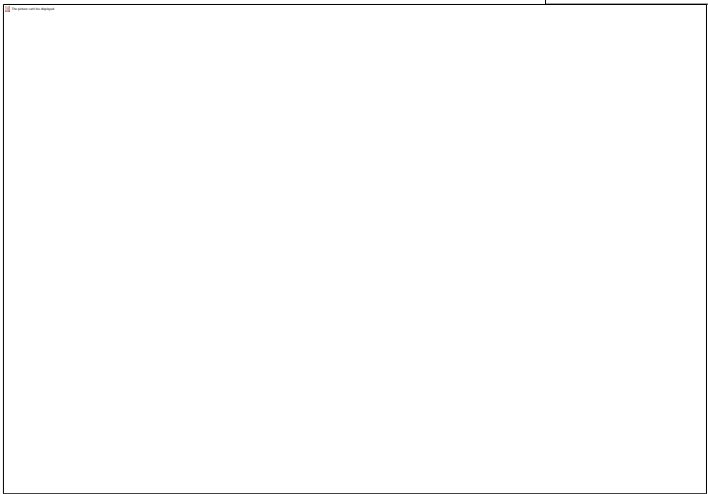
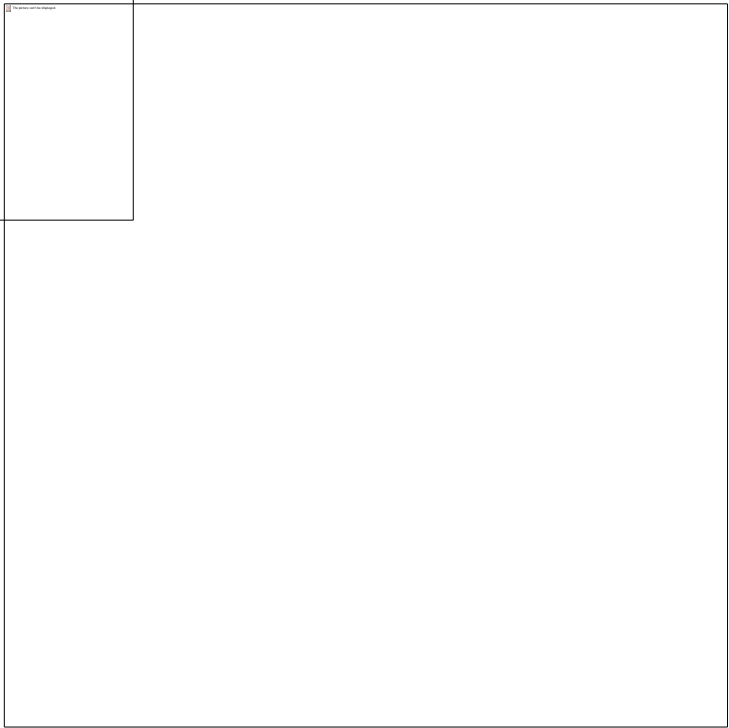
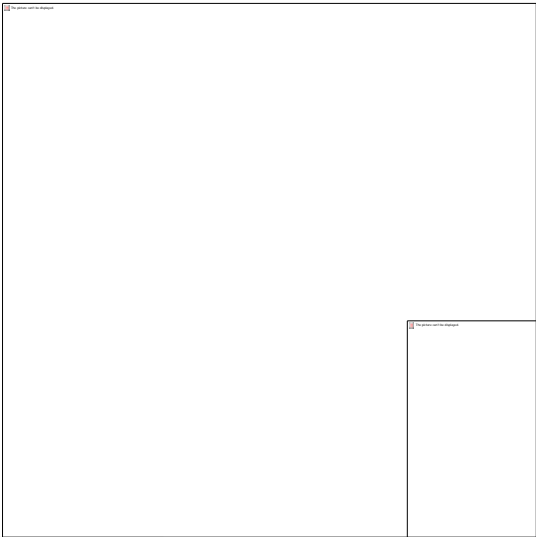
www.biaalcl.com

#patientsbeforeprofits

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







BIA-ALCL

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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



BIA-ALCL

www.biaalcl.com

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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



BIA-ALCL

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**Thank you, FDA, for your alert to
health care providers about BIA -
ALCL...**



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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



BIA-ALCL / Breast Implant Illness



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



BIA-ALCL / Breast Implant Illness



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