Pennsylvania Association for Justice
Mass Torts: What's Hot and What's Not in 2020

Breast Implant Associated Anaplastic Large Cell Lymphoma
January 16, 2020

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Breast Implant Associated-Anaplastic Large Cell Lymphoma (BIA-ALCL)

What is it?

- T-cell lymphoma
- Can develop in the fluid or scar capsule surrounding a breast implant
- It is NOT breast cancer
- Australian Therapeutic Goods Administration (TGA) estimates the lifetime risk of a women with implants developing ALCL to be between 1:1,000- 1:3,000
- Positive association of ALCL in women with implants vs. those without- odds ratio of 18.2 of (95% confidence interval)

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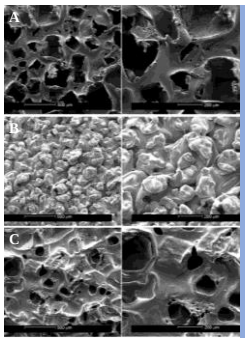

TEXTURE TYPES

A. ALLERGAN NATRELLE BIOCELL IMPLANT
Loss Salt technique
B. MENTOR MEMORY GEL IMPLANT -
Siltex
C. SIENTRA IMPLANT - *TRUE*

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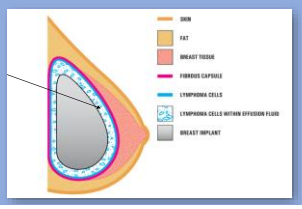
BIA-ALCL

- Long latency period
  - The median time from implant to ALCL Diagnosis is 7 years
  - However, I have seen diagnosis as early as 2 years from implant
- Only associated with textured implant surfaces



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BIA-ALCL Symptoms

- Breast enlargement
- Pain
- Asymmetry
- Lump in breast or armpit
- Skin rash
- Hardening of the breast
- Most commonly- large fluid collection

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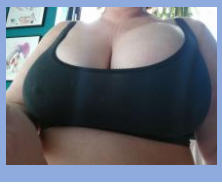
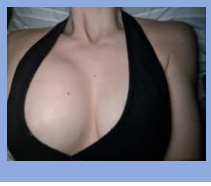
BIA-ALCL Presentation

- Most common clinical presentation→ Seroma (fluid buildup)
  - often one-sided
  - Sudden





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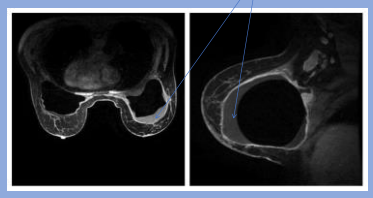
MRI showing fluid surrounding right Implant



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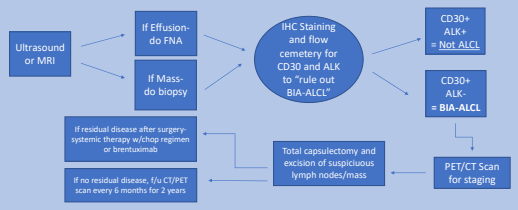
ALCL Workup and Staging



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Pathogenesis

- BIA-ALCL is a problem of textured implants. NO SMOOTH CASES!
  - **Allergan's "lost salt" process-** implant dipped in salt then dipped into a silicone elastomer and let dry (encasing every salt crystal in a layer of silicone).
    - Then the silicone layer is manually scrubbed off leaving rough surface- laden with silicone particulates.
    - Particle size influences host response-
    - **Particles shed from implant surface can infiltrate the capsule and trigger inflammatory response.**

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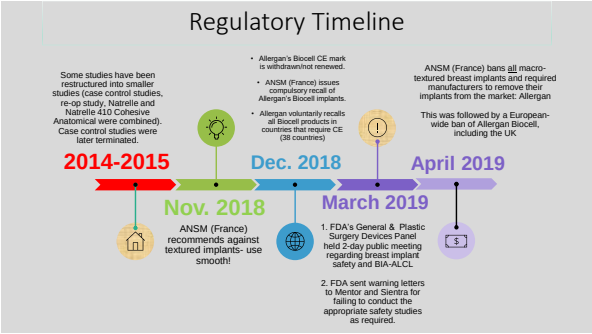

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BIOCELL BAN

- **April 4, 2019-** Health Canada announces decision to suspend the licenses for Allergan's Biocell implants
  - 28 diagnosed BIA-ALCL cases in Canada, 86% linked to Allergan Biocell
- **April 9, 2019-** TGA (Australia) does not yet ban but continues to monitor; requires manufacturers to provide additional data within 10 days of announcement.
- **May 2, 2019-** FDA releases a statement:
  - There is an opportunity to do more to protect women considering breast implants
  - Ends summary reporting of breast implant adverse event reports
  - Consider stronger warnings of BIA-ALCL and patient decision checklist
  - Consider incorporating ingredient information

"At this time, the FDA does not believe that, on the basis of all available data and information, the device meets the banning standard set forth in the Federal Food, Drug and Cosmetic Act."

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BIOCELL BAN

- **May 28, 2019-** Health Canada bans Biocell Allergan Breast Implants and expanders (following suspension of Allergan's licenses in April).
  - Allergan unable to show that the benefits outweighed the risks.
- **July 2019-** FDA publishes tens of thousands of adverse events related to breast implants previously only submitted in hidden summary reports
- **July 24, 2019-** FDA safety communication- requesting that Allergan voluntarily recall all Biocell textured implants and tissue expanders
  - Risk of BIA-ALCL with Allergan Biocell implants is 6X the risk from other manufacturers
  - Tells plastic surgeons to immediately stop implanting Allergan Biocell implants
  - The FDA analysis was attributed to "a new worldwide reported total"

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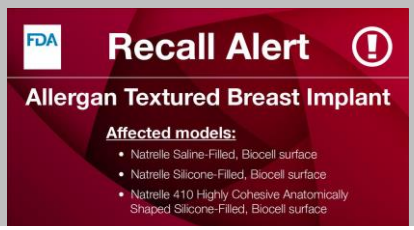
September 12, 2019

FDA identifies the Allergan recall as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

- Recall based on same number of cases



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October 24, 2019

- FDA released draft guidance document, recommending manufacturers do the following:
  - Add a black box warning on the labeling materials
  - The use of a patient decision checklist to be included at the end of a patient information booklet
  - List of chemical and heavy metal ingredients

To ensure patients have information of the risks, especially the risk of BIA-ALCL, "a boxed warning, a patient decision checklist, and a patient information booklet/brochure . . . should be provided **by manufacturers** and given to patients prior to implantation." pg. 6

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Problems for BIA-ALCL Victims

- Lack of physician awareness in other disciplines
- Uninsured
- Insured but not covering the cost of screening- biopsy/MRI
- These can cause undiagnosed cases or delays
- Diagnoses at a later stage is much more costly and dangerous
- Signing manufacturer warranty/release
  - Allergan and Mentor are asking plastic surgeons to have their diagnosed patients sign releases for $7,500 "warranty". Women who sign have no recourse.

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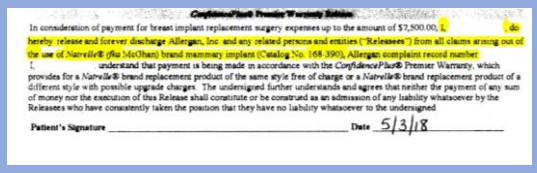
Allergan Release



ConfidencePlus® Premier Warranty Rebate

In consideration of payment for breast implant replacement surgery expenses up to the amount of $7,500.00, I, _____, do hereby release and forever discharge Allergan, Inc. and any related persons and entities ("Releasees") from all claims arising out of the use of *Natrelle®* (fka McGhan) brand mammary implant (Catalog No. 168-390), Allergan complaint record number _____. I understand that payment is being made in accordance with the *ConfidencePlus®* Premier Warranty, which provides for a *Natrelle®* brand replacement product of the same style free of charge or a *Natrelle®* brand replacement product of a different style with possible upgrade charges. The undersigned further understands and agrees that neither the payment of any sum of money nor the execution of this Release shall constitute or be construed as an admission of any liability whatsoever by the Releasees who have consistently taken the position that they have no liability whatsoever to the undersigned.

Patient's Signature _____ **Date** 5/3/18

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MDL No. 2921
IN RE: ALLERGAN BIOCELL TEXTURED BREAST IMPLANT PRODUCTS LIABILITY LITIGATION

- Dec. 2019- The U.S. Judicial Panel on Multidistrict Litigation transferred pending federal cases to the U.S District Court for the District of New Jersey
- Assigned to Judge Brian R. Martinotti and Judge Joseph A. Dickson for discovery
- Class action cases and individual injury cases
- First CMC was Monday January 13, 2019
- Leadership yet to be determined

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Thank you

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