FDA Safety Communication

Certain Textured Breast Implants (Allergan Biocell)

GENERAL STATEMENT/INFORMATION

- The statement was released to protect individuals from the increased risk of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL).
- The US has approximately 300,000 breast implant surgeries performed per year (All types of implants).
- The FDA requested a VOLUNTARY MANUFACTURE RECALL of Allergan Biocell textured implants.
- Biocell is a unique textured surface used by Allergan.
- Worldwide Statistics: 573 unique cases of BIA-ALCL with 33 deaths.
- Worldwide Statistics: 481 of the 573 were reported to have Biocell implants with 13 deaths. The manufacturer and/or texture for the remaining 20 deaths from BIA-ALCL is unknown.

- BIA-ALCL is a rare spectrum of disease that can range from an indolent accumulation of fluids around the breast (seroma) to a potentially metastatic lymphoma especially when there are delays in diagnosis. BIA-ACLC is not a cancer of the breast tissue itself. *Currently classified as a lymphoma*. When diagnosed early, it is readily curable. If the disease is advanced, chemotherapy or radiation may be required.

- BIA-ALCL related deaths: 33 confirmed deaths globally, 9 in the US, attributed to BIA-ALCL since the disease was first reported 20 years ago.

- Symptoms of BIA-ALCL: swelling of the breast between 2-28 years after insertion – average onset of symptoms is 8 years. Swelling is due to a collection of fluid surrounding the implant. Fluid can cause the breast to enlarge significantly over a period of days or weeks. Can also present as a lump in the breast or armpit, firmness to the breast, asymmetry, or pain. It is usually easily and completely treatable if patient sees their doctor at the first symptom.

Causes of BIA-ALCL: ASAPS, ASERF, the FDA, and implant manufacturers are intensely studying BIA-ALCL. It is felt that it is a combination of factors: 1. ***highly textured implants Allergan (Biocell)***, 2. chronic bacterial-inflammation 3. Genetic predisposition 4. Time. The source of the chronic inflammation is thought to be bacteria that have been identified around the implants in affected breasts. Evidence is accumulating that a long-term inflammatory response to the presence of these bacteria is one of the factors that may cause BIA-ALCL. Again research is ongoing and cases are being monitored.

Risk assessment based on texture grade of implants:

Grade 1 (Smooth only) – current lifetime risk is currently zero

Grade 2 (i.e.: Microtexture, Siltex and similar) – 1:82,000

Grade 3 (i.e.: Macrotexture, Biocell (Allergan) and similar) – 1:3,200

Grade 4 (i.e.: Polyurethane) – 1:2,800

- If you develop symptoms / screening for BIA-ALCL:
  1. Schedule an appointment with a physician for evaluation of symptoms.
  2. Following a physical exam and review of symptoms, an ultrasound and/or MRI may be advised to evaluate for fluid or lumps around the implant and in the lymph nodes.
  3. If fluid or a mass is found, a needle biopsy will confirm a diagnosis of BIA-ALCL.

****Early diagnosis is key in treating BIA-ALCL. It is curable in most cases.

PATIENT RECOMMENDATIONS:

- Most cases of BIA-ALCL occur many years after implant (average 8-10 years).
- If not symptomatic, implant removal is not recommended.
- Symptoms: primarily persistent swelling & pain near the implant (see page 2).
- If symptomatic: see MD for exam/evaluation, imaging via MRI, ultrasound if indicated
- Explant is recommended when positive diagnosis of BIA-ALCL is made. Additional treatment with chemo/radiation may be recommended based on advancement of the

RECOMMENDATIONS TO PHYSICIANS:

- Immediately stop using Allergan Biocell implants – return all inventory to Allergan
- If the patient is not symptomatic, implant removal is not recommended.
- Inform patients of risks and follow-up recommendations.
- MRI done 3 years after implantation, every 2 years thereafter.
- If explant is advised, send capsule to pathology to rule out BIA-ALCL. Any seroma should be sent to cytology or mass with Wright Giesmsa stained smears and cell block immunohistochemistry/flow cytometry testing for cluster of differentiation (CD-30) and Anaplastic Lymphoma Kinase (ALK) markers.
- Dominion Pathology can process the capsule.
- LabCorp or Sentara can process the seroma.
- Report cases of BIA-ALCL to MedWatch Cancer Registry.

MULTIPLE/COMBINED SOURCE INFORMATION/TALKING POINTS

- ASAPS & ASERF: both sources emphasize that the most important issue in overall breast health is to continue screening for breast cancer with self-exam, a regular physician exam, and mammography. Mammograms are not useful in diagnosing BIA-ALCL. If symptoms of BIA-ALCL are present, an ultrasound and/or MRI may be recommended.

- Treatment of BIA-ALCL:
    1. Early diagnosis is key.
    2. If diagnosed with BIA-ALCL a PET/CT scan may be ordered to look for advancement of the disease.
    3. Newly diagnosed patients will be referred to an oncologist for evaluation, staging of the disease and treatment planning.
    4. For patients with BIA-ALCL only around the implant, surgery is performed to remove the implant and the capsule.
    5. If the disease has advanced, additional testing, biopsy, and treatment may be recommended.
    6. Advanced cases may require further treatment with chemotherapy and in rare cases may include radiation therapy and/or stem cell transplant therapy.

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- Silicone or Saline: BIA-ALCL risk does not relate to the fill of the implant, it relates to the surface of the implant (textured vs smooth).

- "Remove" or "not to remove": Importantly, the FDA and other health authorities have not recommended removal or replacement of textured breast implants in asymptomatic patients.

Recommended sites for additional information:

- Food and Drug Association (FDA) – www.fda.gov/home
- American Society of Plastic Surgeons (ASPS) – www.plasticsurgery.org
- American Society of Aesthetic Plastic Surgery (ASAPS) – www.surgery.org
- The Aesthetic Surgery Education and Research Foundation (ASERF) – www.aserf.org

Thanks