Surgical Best Practices: 14-Point Plan

William P. Adams, Jr., MD &
Anand K. Deva, MBBS (Hons), MS

BIA-ALCL Frequently Asked Questions

Sientra Medical Affairs
**Introduction**

The 14-Point Plan aims to reduce the number of bacteria present at the time of breast implant placement, thereby reducing the risk of associated infection. Each of these steps outlined below is backed by evidence and cumulatively have been shown to reduce the risk of capsular contracture in patients following breast implant surgery.

During breast implant placement, if bacteria attach to the surface of an implant and create a biofilm over time, the biofilm becomes almost impossible to remove. If the bacterial biofilm load reaches a certain threshold it can lead to chronic inflammation and known sequelae, including infection, capsular contracture, double capsule, and breast implant-associated ALCL (BIA-ALCL). We have performed extensive bench and clinical studies on this topic and are committed to educating plastic surgeons on proven steps that have been shown to reduce the bacterial biofilm load. These simple steps have been shown to decrease the risk of developing capsular contracture ten-fold.

Additionally, a wealth of evidence has demonstrated a link between chronic inflammation from bacterial biofilm in the pathogenesis of BIA-ALCL, especially in textured devices where the increased surface area can result in an increased amount of bacterial biofilm. A meticulous procedure will help minimize the known and likely sequelae of bacterial attachment including infection and chronic biofilm, which is implicated in the pathogenesis of both capsular contracture and BIA-ALCL.

**14-Point Plan**

Translating sound research into clinical practice results in improved outcomes for our patients by reducing post-operative complications and the need for revision surgery. These technique-focused recommendations help minimize bacterial attachment at multiple points during the operation.

1. **Use intravenous antibiotic prophylaxis at the time of anesthetic induction.**
   - It is recommended to use a cephalosporin antibiotic that specifically targets *S. epidermidis*. Many surgeons advocate for the use of vancomycin to target methicillin-resistant *S. epidermidis*.

2. **When possible use inframammary incisions shown in both laboratory and clinical studies to lead to a decreased rate of capsular contracture.**
   - Periareolar and transaxillary incisions cross ductal tissue and sweat glands that are known to harbor bacteria.

3. **Use nipple shields to cover the nipples and prevent spillage of bacteria onto the skin during the procedure as this can lead to bacterial contamination of the breast implant pocket.**

4. **Perform careful atraumatic dissection to minimize devascularized tissue.**
   - Electrocautery is recommended to develop a precise plane and assist with careful and atraumatic dissection.
Perform careful prospective hemostasis.\textsuperscript{1,12}

Avoid dissection into the breast parenchyma.\textsuperscript{8}

The use of a submuscular and/or dual-plane pocket has significant anatomic advantages because both techniques do not enter the breast parenchyma.\textsuperscript{1} This minimizes contact of the breast implant with bacteria in the breast ducts, thereby decreasing the risk of infection and chronic inflammation from bacterial biofilm. These techniques have been shown to decrease the rate of capsular contracture.\textsuperscript{13-15}

Perform irrigation of the entire breast implant pocket with precisely mixed triple antibiotic solution or 50% (1:1 dilution) or stronger betadine (povidone-iodine) solution.\textsuperscript{3,16}

- The entire surgical field should be adequately cleaned with an antibiotic solution, including:
  - Prep the skin around the incision, clean the entire breast implant pocket and all instruments that are introduced into the breast implant pocket with the antibiotic solution.
  - Do not use single agent cefazolin irrigation or bacitracin irrigation because they do not work effectively against all bacteria.\textsuperscript{14,16}

- **Recommended irrigations:** \textsuperscript{3,14,16}
  
<table>
<thead>
<tr>
<th>Triple Antibiotic Betadine Irrigation</th>
<th>50cc betadine, 1g cefazolin, 80mg gentamicin, 500cc normal saline</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>150cc per pocket, no active evacuation</td>
</tr>
<tr>
<td>Triple Antibiotic Non-Betadine Irrigation</td>
<td>50K units bacitracin, 1g cefazolin, 80mg gentamicin, 500cc normal saline</td>
</tr>
<tr>
<td></td>
<td>150cc per pocket, 5 minute contact time, no active evacuation</td>
</tr>
<tr>
<td>Betadine Irrigation</td>
<td>50% (1:1) or greater strength (out of bottle = 100%)</td>
</tr>
<tr>
<td></td>
<td>Only dilute with no more than equal volume of saline</td>
</tr>
</tbody>
</table>

Take steps to minimize skin-to-implant contact,\textsuperscript{1,15} including:

- Adequate incision size
- Re-prep skin with antibiotic solution or skin prep (eg, chlorhexidine)
- Skin barrier
- Use of a sleeve

Minimize the time of implant opening, repositioning and replacement of implant or sizers.\textsuperscript{1}

- Leave the implant covered in the thermoplastic container until immediately prior to insertion. The tyvek cover can be slightly peeled back to introduce some antibiotic solution to bathe the implant while it is still covered.
- When possible avoid sizers and implant removal/replacement. Both passively increase potential bacterial contamination.
Change surgical gloves prior to handling the implant and clean all instruments with antibiotic solution or use new instruments that will come into contact with the breast implant. This helps reduce any possible transfer of bacteria from the skin to the breast implant. Only one person should handle the implant and the surgeon’s fingers should be dipped in antibiotic solution for skin de-raping maneuvers.

Avoid use of a drainage tube for primary augmentation; in revision and reconstruction cases, use proper technique when a drain is necessary.

Use a layered closure. This protects the breast implant from bacterial access via the surgical wound during the early healing process.

Recommend that your patients, who have undergone breast surgery, take antibiotic prophylaxis prior to procedures that breach skin or mucosa (i.e. tattoos, piercings, and dental procedures). This will help prevent the small risk of bacteremia that could lead to breast complications including infection and capsular contracture.

Conclusion

This paper provides a concise review of the 14-Point Plan with the aim of bringing awareness to surgeons regarding how to minimize bacteria at key points of breast implant surgery. The adoption of these standardized steps by you and your operative team is the key to optimizing their overall effectiveness. For more information on the 14-Point Plan and supporting evidence, please go to www.saferbreastimplants.org. We encourage you to take the pledge to support the use of best evidence to reduce the bacterial contamination of breast implants.

By incorporating these simple steps, it has been demonstrated that you will achieve improved surgical outcomes and a reduction in complications and reoperations. Sientra continues to drive peer-to-peer education of evidence-based medicine in order to achieve the safest outcomes for patients.

References
Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)
Frequently Asked Questions

Sientra’s highest priority is the safety and well-being of patients. The following information and FAQ is provided as a reference for plastic surgeons regarding the current known information on BIA-ALCL.

What is BIA-ALCL?
BIA-ALCL is a very rare and treatable type of non-Hodgkin T-cell lymphoma. It differs from systemic ALCL as it behaves more closely to cutaneous ALCL; is slow growing with a favorable prognosis.¹,²

BIA-ALCL is NOT breast cancer.³ To date, data suggest that BIA-ALCL occurs more frequently in women with textured implants than smooth implants⁴; however the association with smooth implants cannot be ruled out.⁵ BIA-ALCL has been diagnosed in women with silicone and saline implants.⁴

What are the symptoms of BIA-ALCL?
BIA-ALCL most commonly presents as a late occurring fluid collection or as a palpable mass adjacent to the implant.⁶ The majority of cases present, on average, eight to ten years following implantation.⁶ Patients should report delayed onset of swelling, pain and any other breast changes to their surgeon.⁴

What are the risks?
It is important to understand how rare the occurrence is and put the numbers into perspective. Through 2015 there were 173 confirmed cases of BIA-ALCL published in the Plastic and Reconstructive Surgery Journal.⁷ That same year, 364,000 women underwent breast augmentation and reconstruction with implants.⁸ Some comparative rates:

• The average woman’s risk of developing breast cancer in her lifetime is 12.5%.⁹
• The risk of developing recurrent breast cancer after mastectomy is 5-8%.¹⁰
• The risk of capsular contracture through 10-years is ~14%.¹¹
• The risk of breast implant rupture through 10-years is ~10%.¹¹
• The risk of developing ALCL from a breast implant is 0.003%.¹²

What are the reported numbers in the 2017 FDA update?
There were 359 medical device reports (MDRs) related to breast implants and ALCL submitted to FDA as of Feb. 1, 2017 (some reports may be incomplete, inaccurate, untimely, unverified).⁴ Of those reports:

• 203 were textured implants
• 28 were smooth implants
• 186 were silicone-filled implants
• 126 were saline-filled implants
• 2 were Sientra implants

Is the FDA update based on a study?
No, the information provided in the recent FDA update is based on the BIA-ALCL MDRs submitted to FDA’s Manufacturer and User Facility Device Experience (MAUDE) database. Importantly, the FDA notes that the 359 MDRs received “may contain incomplete, inaccurate, untimely, unverified” data⁴ and therefore, should not be interpreted as a definitive number of cases. The FDA’s update was not released with the intent to cause uncertainty, but rather to increase surgeon and patient awareness of the potential symptoms of this very rare condition and the defined diagnostic and treatment protocol.
How is BIA-ALCL diagnosed? What symptoms should patients be aware of?
If a woman develops a fluid collection more than one year after surgery (most commonly at 8 to 10 years) or a palpable mass adjacent to the implant,6,13
- Perform ultrasound scan.
- If fluid is detected, drain and test with flow cytometry, CD30 immunohistochemistry and Anaplastic Lymphoma Kinase (ALK) markers to diagnose BIA-ALCL.
- Mammograms are not useful in diagnosing BIA-ALCL.15 In confirmed cases MRI and PET/CT scans may be performed to help stage the disease.
- It is important to note that most seromas are not BIA-ALCL, but fluid testing can be used to confirm.15

How is BIA-ALCL treated?
The vast majority of patients who are diagnosed with BIA-ALCL can be cured.12,15
- Most cases are cured by the removal of the implant and the entire capsule surrounding the implant.
- The majority of patients require no additional treatment.
- Infrequently, patients will need to undergo chemotherapy or radiation therapy.

Should women with breast implants be screened for BIA-ALCL?
FDA states: “If you have breast implants, there is no need to change your routine medical care and follow-up.”4 Expert consensus advises that asymptomatic women without breast changes do not require more than routine follow-up.

Should patients have their implants removed?
FDA continues to affirm that ”BIA-ALCL is a very rare condition.”4 Neither the FDA nor any of the Plastic Surgery societies suggest additional screening or removal of implants for asymptomatic women.4,16

Why use textured breast implants?
Smooth and textured implants are both safe and effective and each has associated benefits and risks.
- Surface textures vary across manufacturers and Sientra stands behind the demonstrated safety and benefits of both its smooth and textured implants.11
- Sientra’s textured implants demonstrate a decreased risk of capsular contracture17 and a lower rupture rate.18
- Surgeons may select textured implants to better maintain implant positioning, and to reduce rotation in shaped implants.19

What causes BIA-ALCL?
The exact cause is unknown and research is ongoing to improve understanding. Current evidence supports:
- Bacterial contamination creates a long-term inflammatory response20
- Potential genetic predisposition7
- Certain geographic locations have demonstrated variable risks11 (many countries have zero cases reported)

Literature indicates that the increased association of BIA-ALCL in certain types of textured implants is not due to the textured surface itself, but to the greater surface area, which allows for a higher bacterial load.21

Have there been any deaths due to BIA-ALCL?
There have been 12 known deaths worldwide attributed to BIA-ALCL since the disease was first reported nearly 20 years ago.12 It has been estimated that worldwide 5-10 million women currently have breast implants.22 It is important to note that of these deaths, none received complete surgical excision at any point in the patient’s clinical history, none received targeted therapy, and most were significantly delayed in diagnosis or receiving any treatment (1-2 years from the onset of symptoms).7
Summary
BIA-ALCL is a condition that Sientra takes very seriously and has spent a tremendous amount of time investigating. Sientra continues to support all medical research, education and FDA initiatives to better understand BIA-ALCL and to provide women with the highest quality and safest implant options.

For any questions, please contact your Plastic Surgery Consultant or Sientra at 888.708.0808.

Important Information Sources
- ASAPS: www.surgery.org/professionals
- ASPS: www.plasticsurgery.org/alcl
- FDA: www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239995.htm

Recent Key BIA-ALCL Literature
- Understanding Rare Adverse Sequelae of Breast Implants: ALCL, Late Seromas, and Double Capsules (Clemens, et al; Gland Surg 2016): http://gs.amergroups.com/article/view/12579

Information for women regarding this potential risk is included in the Sientra Patient Informed Decision Brochure:
http://sientra.com/Content/pdfs/Patient_Educational_Brochure_Breast_Augmentation_with_Sientra_Silicone_Gel_Breast_Implants.pdf
http://sientra.com/Content/pdfs/Patient_Educational_Brochure_Breast_Reconstruction_with_Sientra_Silicone_Gel_Breast_Implants.pdf