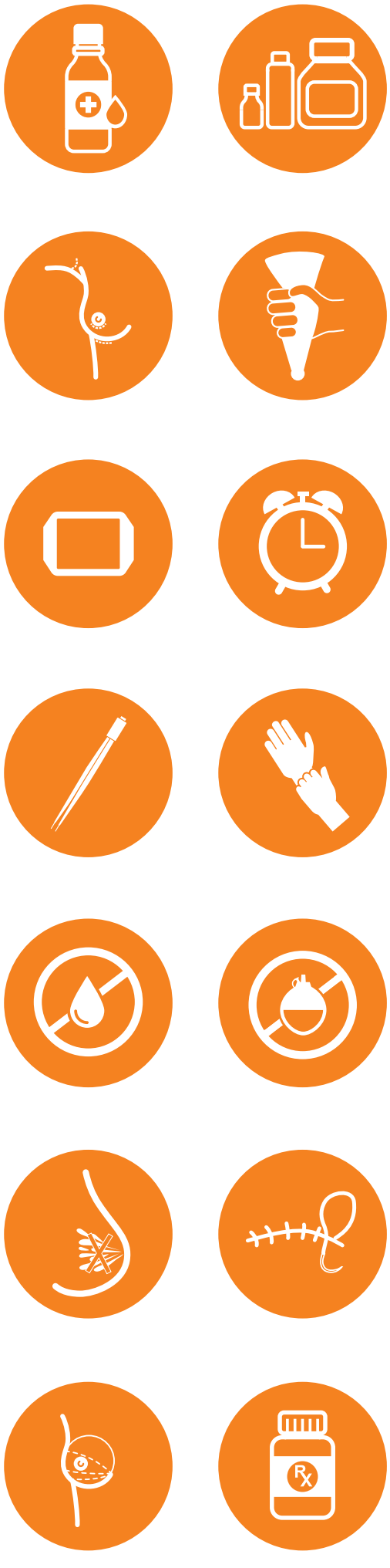

Surgical Best Practices:
14-Point Plan

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sientra®

SURGICAL BEST PRACTICES: 14-POINT PLAN

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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.[1] 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).[1, 2] 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.[1] These simple steps have been shown to decrease the risk of developing capsular contracture ten-fold.[3-5]

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.[2] 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

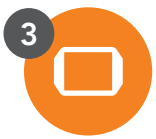
Translating sound research into clinical practice results in improved outcomes for our patients by reducing post-operative complications and the need for revision surgery. These technique-focused recommendations help minimize bacterial attachment at multiple points during the operation.

Use intravenous antibiotic prophylaxis at the time of anesthetic induction.

- It is recommended to use a cephalosporin antibiotic that specifically targets *S. epidermidis.*[6] Many surgeons advocate for the use of vancomycin to target methicillin-resistant *S. epidermidis*.

When possible use inframammary incisions shown in both laboratory and clinical studies to lead to a decreased rate of capsular contracture.[7-9]

- Periareolar and transaxillary incisions cross ductal tissue and sweat glands that are known to harbor bacteria.



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.[7-11]

Perform careful atraumatic dissection to minimize devascularized tissue.[1]

- Electrocautery is recommended to develop a precise plane and assist with careful and atraumatic dissection.

5 Perform careful prospective hemostasis.[1,12]

6 Avoid dissection into the breast parenchyma.[8]

7 The use of a submuscular and/or dual-plane pocket has significant anatomic advantages because both techniques do not enter the breast parenchyma.[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.[13-15]

8 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.[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.[14, 16]
- Recommended irrigations: [3, 14, 16]

Triple Antibiotic Betadine Irrigation	• 50cc betadine, 1g cefazolin, 80mg gentamicin, 500cc normal saline • 150cc per pocket, no active evacuation
Triple Antibiotic Non-Betadine Irrigation	• 50K units bacitracin, 1g cefazolin, 80mg gentamicin, 500cc normal saline • 150cc per pocket, 5 minute contact time, no active evacuation
Betadine Irrigation	• 50% (1:1) or greater strength (out of bottle = 100%) • Only dilute with no more than equal volume of saline

9 Take steps to minimize skin-to-implant contact,[1,15] including:

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

10 Minimize the time of implant opening, repositioning and replacement of implant or sizers.[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.[1]

- 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 re-draping maneuvers.

Avoid use of a drainage tube for primary augmentation; in revision and reconstruction cases, use proper technique when a drain is necessary.[1]

Use a layered closure.[1,6]

- 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).[1] 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.

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