ISAPS® PATIENT SAFETY

SAFETY STATEMENT OF THE INTERNATIONAL SOCIETY OF AESTHETIC PLASTIC SURGERY

US FDA Safety Communication on Breast Implant Associated Squamous Cell Carcinoma (BIA-SCC)

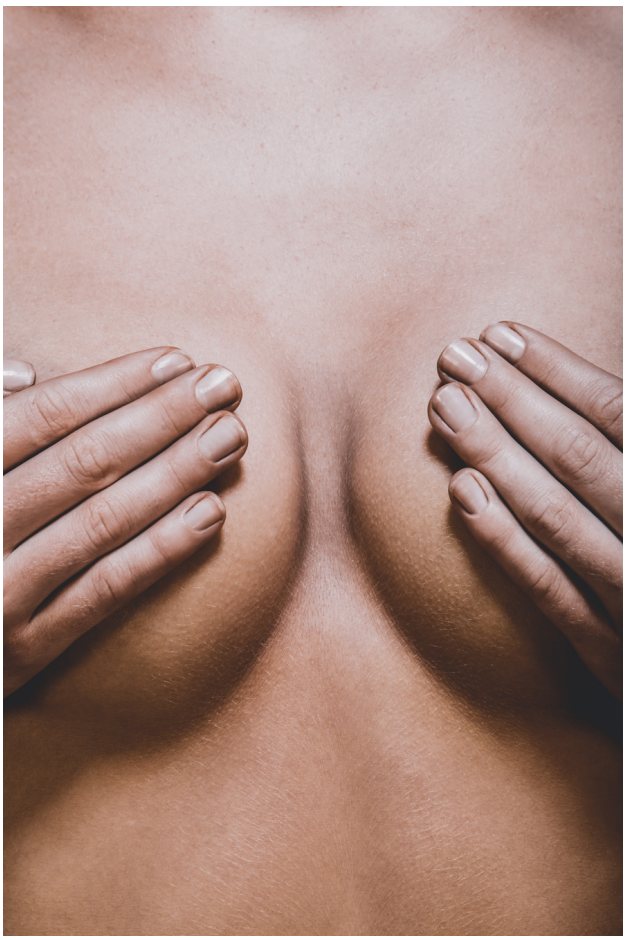
October 18, 2022

The US Food and Drug Administration (FDA) recently posted a Safety Communication informing healthcare practitioners and patients about reports of squamous cell carcinoma (SCC) and various lymphomas (not including BIA-ALCL) detected in the capsule surrounding breast implants. These reports highlight a very rare occurrence of a malignancy. We believe that developments such as this deserve attention so that you, your staff, and your patients may stay informed.

There have been literature reports of SCC and various lymphomas in the capsule around the breast implants for both textured and smooth breast implants, and for both saline and silicone breast implants. The cases were reported in patients who were diagnosed 15–42 years after having breast implants placed, and have all presented with abnormal signs and symptoms including swelling, pain, lumps, or skin changes. Awareness by breast implant patients and physicians is paramount, as well as emphasis on the need for long-term patient follow-up with their plastic surgeon.

ISAPS has identified the following talking points:

1. The FDA Safety Communication is not new information, nor is it unique to breast implants. Multiple reports of rare malignancies have been reported around several types of implanted medical devices including orthopedic implants, dental implants, pacemakers, and breast implants. The incidence of these malignancies including BIA-SCC is very rare. BIA-SCC, according to the case reports, behaves similarly to BIA-ALCL with local capsular growth followed by systemic metastasis. Primary SCC of the breast (implant-naive patients) is a known rare breast malignancy and is a separate diagnostic entity.



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2. Awareness for physicians,

their staff, and patients is key. Any abnormalities and deviation from the normal course for breast implant patients should be evaluated by a board-certified plastic surgeon. Plastic surgeons are in the best position to be knowledgeable about breast implants and potential abnormalities that can occur years after implantation.

3. Strongly continue to recommend that breast implant patients have yearly follow-ups and report any changes in their breasts to their surgeon.

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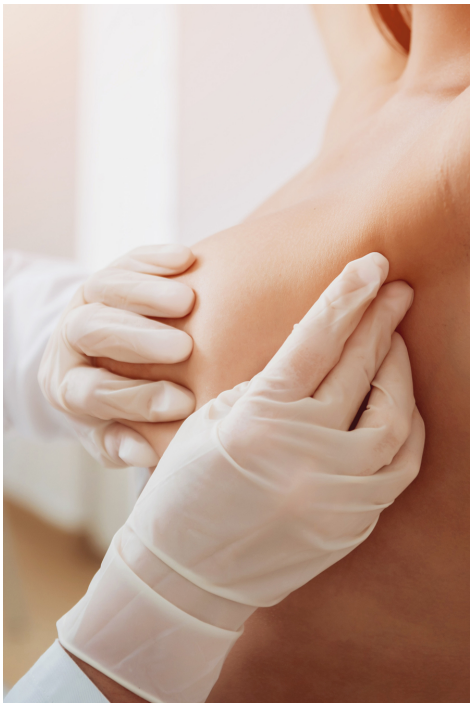
4. Breast ultrasound or MRI (approximately 5–6 years postoperatively, then every 2–3 years thereafter) is useful to monitor implant integrity and soft tissues.

5. BIA-SCC treatment recommendations will need to be based on emerging data, and we will continue to update you. There are no established guidelines for treatment.



For this initial communication, we recommend the following guidelines:

a. The presentation of BIA-SCC has included a breast/axillary mass, unilateral breast swelling, pain, and/or erythema.

b. Surgeons should be aware of BIA-ALCL, BIA-SCC, or other possible breast malignancies when evaluating implant patients for changes in their breasts and should not operate on anyone with a late-forming seroma or capsule mass without an appropriate preoperative work up.

c. If a seroma is present, the diagnostic tool of choice is an ultrasound, not mammography. The ultrasound-guided fluid aspiration procedure is used to obtain fluid for bacteriological culture and to evaluate for malignancy.

d. If your patient has a delayed seroma preoperatively, fluid should be sent for cytocentrifuge or cellblock and CD30 testing (BIA-ALCL) to rule out malignancy. Based on this evaluation, the pathologist will be able to decide if any further testing is needed. Most of these cases will have a negative evaluation as late-term seromas are typically non-malignant. Despite this, seromas are typically treated with surgical therapy.

e. The capsule should be inspected and any suspicious areas submitted for histological evaluation and, when appropriate, immunohistochemical evaluation e.g., keratin, CD5/6, p65 for suspicion of squamous cell carcinoma.

f. Suspicious abnormalities found in breast implant capsules during routine implant exchange procedures should also be sent for histologic analysis.

ISAPS Patient Safety Committee

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