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May 30, 2019

Dear CSPS and CSAPS members:

## **Re: Communicating with patients about BIA-ALCL**

Many of you will have been following the issue of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). As we have shared with you previously, all known cases to date have occurred in patients with textured breast implants or textured expanders. To date there have been 30 confirmed cases in Canada. Health Canada suspended the license for the sale of Allergan's textured breast implants on May 28, 2019. Allergan responded by immediately recalling all Biocell implants in Canada. Despite this license suspension, **Health Canada does not recommend the removal of previously placed Biocell implants**.

As we have been discussing this issue with CSPS/CSAPS members and patients, it has become clear to us that many patients and plastic surgeons have found it very helpful to start a dialogue about the issue of BIA-ALCL. In particular, many surgeons have started this dialogue by communicating by letter with their patients who are known to have textured breast implants; they have additionally documented these efforts on the patients' medical records. We have heard that the majority of patients have been very appreciative of these efforts. They have been relieved to hear that the risk of BIA-ALCL is low. They have also been reassured by hearing that their surgeon is aware that they might be frightened or worried, but is willing to help and stand by them through any issues related to their implants.

Having reviewed several plastic surgeons' letters shared with us, we would like to highlight to you the following common components of these letters:

- you are being contacted because our records indicate that you have a textured breast implant (some have chosen to contact all of their breast implants patients and told them what type of implant they have and explained that smooth implants do not appear to demonstrate an association with BIA-ALCL).
- there is now known to be a rare association between textured breast implants and a type of cancer known as breast implant-associated anaplastic large cell lymphoma (BIA-ALCL)
- this is not a breast cancer but rather a type of lymphoma that develops in the fluid or tissue immediately around the breast implant
- the initial presenting symptoms of this condition are:

- o a distinct swelling or change in size of the breast
- the breast becomes tenser or more firm
- there may be a lump that can be felt on self-examination
- o usually this affects only one side but can rarely occur in both breasts
- these changes usually develop quite rapidly, over several days or weeks (not over months and years)
- BIA-ALCL is a very curable disease in most patients, but if untreated can become more serious
- because of the rarity of this condition, there is no current recommendation to have breast implants removed or replaced unless one has symptoms or a diagnosis of BIA-ALCL
- the surgeon is available at any time to discuss concerns, examine the patient provide recommendations for their particular circumstances
- steps for contacting the surgeon's office are presented
- for additional information here is a list of frequently asked questions produced by the American Society of Plastic Surgeons <a href="https://www.plasticsurgery.org/patient-safety/bia-alcl-summary/frequently-asked-questions">https://www.plasticsurgery.org/patient-safety/bia-alcl-summary/frequently-asked-questions</a>

The practical difficulty for members wishing to contact their patients is, of course, that one needs to identify who these patients are. Some members have made a practice of registering all of their patients with the manufacturer; these members may contact representatives of the manufacturer to obtain a list of the names of these patients. Others who have not registered their patients' implants may need to search through office chart records or hospital records to identify these patients. We realize this may become a laborious undertaking for some. As mentioned above though, patients have greatly appreciated these efforts.

We have attached two sample letters that can be easily modified by any physician wishing to contact his/her patients. Please feel free to use it as you see fit.

Sincerely,

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