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July 29, 2019

Dear CSPS and CSAPS members:

Previously, we notified you of the decision by Health Canada to suspend the license for Allergan's BIOCELL textured breast implants.

On Wednesday, July 24, the Food and Drug Administration (FDA) issued a Safety Communication, requesting that Allergan recall its BIOCELL textured **breast implants and tissue expanders** to protect patients from the increased risk of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) associated with these implants.

In response, on Thursday, July 25, Allergan recalled all BIOCELL textured **breast implants AND tissue expanders** worldwide.

More information on these decisions can be found via the following links:

Health Canada: https://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2019/70045a-eng.php

FDA: https://www.fda.gov/medical-devices/safety-communications/fda-takes-action-protect-patients-risk-certain-textured-breast-implants-requests-allergan

And the press release of Allergan announcing their worldwide recall: https://www.allergan.com/news/news/thomson-reuters/allergan-voluntarily-recalls-biocell-textured-brea

CSPS and CSAPS advise our members to:

- Immediately stop using (implanting) the Biocell textured breast implants and tissue expanders listed in FDA and Health Canada bulletins (see links above) and work with your facility to return existing inventory.
- Take best efforts to contact your patients who have these implants and tissue expanders. Health Canada and the FDA currently do not recommend implant removal in patients with no symptoms because of the low risk of developing BIA-ALCL.
- Consider the possibility of BIA-ALCL when treating a patient with late onset, peri-implant changes, including the development of a seroma, mass, or hardening adjacent to the breast implant. If you have a patient with suspected BIA-ALCL, refer the patient's case to an expert familiar with the diagnosis and treatment of BIA-ALCL.

- Report all cases of BIA-ALCL in individuals with breast implants to the CSPS and/or CSAPS and to Dr. Peter Lennox or Dr. Mitchell Brown. This reporting should only contain de-identified data. Dr. Lennox and Dr. Brown continue to keep both societies appraised as to new cases of BIA-ALCL and their outcomes.

For more information on BIA-ALCL:

On the FDA website:

https://www.fda.gov/medical-devices/breast-implants/questions-and-answers-about-breast-implant-associated-anaplastic-large-cell-lymphoma-bia-alcl

On the ASPS website:

https://www.plasticsurgery.org/for-medical-professionals/health-policy/bia-alcl-physician-resources?utm_source=Adestra&utm_medium=email&utm_campaign=FDA%20Breast%20Implant%20Notice&utm_term=Varies&utm_content=American%20Society%20of%20Plastic%20Surgeons%20BIA-ALCL%20Physician%20Resources%20web%20page

On the CSPS website:

http://plasticsurgery.ca/medical-professionals/information-plastic-surgeons/alcl/

Sincerely,

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