International Confederation for Plastic Reconstructive and Aesthetic Surgery

Dear colleagues,

On January 26, 2011 the American Health Authorities have released a safety signal on Anaplastic Large Cell Lymphoma (ALCL) in women with breast implants.
Our colleagues in the American Society of Plastic Surgeons, chaired by their President Phillip Haeck, are working closely with the FDA to evaluate this issue further.

Although the number of patients who developed the disease is extremely small (34 identified cases out of an estimated number of 5 to 10 million women with breast implants), we should inform our patients and follow the recommendations of the FDA closely:

Recommended Actions for Health Care Providers and Patients

Health Care Providers:

If you have patients with breast implants, you should continue to provide them routine care and support. ALCL is a very rare condition; when it occurs, it has been identified most frequently in patients undergoing implant revision operations for late onset, persistent seroma. Because it has generally only been identified in patients with late onset of symptoms such as pain, lumps, swelling, or asymmetry, prophylactic breast implant removal in patients without symptoms or other abnormality is not recommended.

Current recommendations include the steps below. As the FDA learns more about ALCL in patients with breast implants, these recommendations may change.

Consider the possibility of ALCL when you have a patient with late onset, persistent peri-implant seroma. In some cases, patients presented with capsular contracture or masses adjacent to the breast implant. If you have a patient with suspected ALCL, refer her to an appropriate specialist for evaluation. When testing for ALCL, collect fresh seroma fluid and representative portions of the capsule and send for pathology tests to rule out ALCL. Diagnostic evaluation should include cytological evaluation of seroma fluid with Wright Giemsa stained smears and cell block immunohistochemistry testing for cluster of differentiation (CD) and Anaplastic Lymphoma Kinase (ALK) markers.

Report all confirmed cases of ALCL in women with breast implants to the FDA. In some cases, the FDA may contact you for additional information. The FDA will keep the identities of the reporter and the patient confidential.

Develop an individualized treatment plan in coordination with the patient's multi-disciplinary care team. Because of the small number of cases worldwide

and variety of available treatment options, there is no single defined consensus treatment regimen.

Patients:

If you have breast implants, there is no need to change your routine medical care and follow-up. ALCL is very rare; it has occurred in only a very small number of the millions of women who have breast implants. Although not specific to ALCL, you should follow standard medical recommendations including:

Monitoring your breast implants. If you notice any changes, contact your health care provider promptly to schedule an appointment. For more information on self breast exams, visit Medline Plus: Breast Self Exam.

Getting routine mammography screening.

If you have silicone gel-filled breast implants, getting periodic magnetic resonance imaging (MRI) to detect ruptures as recommended by your health care provider. The FDA-approved product labeling for silicone gel-filled breast implants states that the first MRI should occur three years after implant surgery and every two years thereafter.

If you do not currently have breast implants but are considering breast implant surgery, discuss the risks and benefits with your health care provider. You may also visit FDA's Breast Implants website for additional information.

Please inform us if one of your patients develops ALCL or will develop in the future. Please send the information to us first in order to avoid double reporting. We are going to forward your information to ASPS and FDA accordingly.

Please do not hesitate to approach us if you have questions or if you need our support.

For sure there is no reason to get into a panic but we need to be proactive and inform our patients and the media in a well balanced fashion.

Sincerely yours

Marita Eisenmann-Klein
IPRAS General Secretary

Zacharias Kaplanidis
IPRAS Executive Director

LINKS:

-American Society of Plastic Surgeons to MOU Partners, letter Phillip C. Haeck, President ASPS, Statement Philipp Haeck, "FDA to issue safety signal on ALCL & breast implants"

-Plastic Surgery News, Special Bulletin, January 26, 2011

-FDA Medical Device Safety Communication: Report of Anaplastic Large Cell

Lymphoma (ALCL) in Women with Breast Implants (Clean Version)

-Anaplastic Large Cell Lymphoma (ALCL) In Women with Breast Implants:"Preliminary FDA Findings and Analyses" (White Paper Clean Version)

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