香港特別行政區政府
衞生署
醫療儀器管制辦公室

香港灣仔皇后大道東 183 號
合和中心 31 樓 3101 室

DEPARTMENT OF HEALTH
MEDICAL DEVICE CONTROL OFFICE

Room 3101, 31/F., Hopewell Centre,
183 Queen's Road East, Wan Chai,
Hong Kong

本處檔號 OUR REF.: L/M (1025) in DH/MDCO/20-10/8
來函檔號 YOUR REF.:
電話 TEL.: 3107 8484
圖文傳真 FAX: 3157 1286

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Dear Healthcare Professionals,

Possible association between breast implants and Anaplastic Large Cell Lymphoma (ALCL) of the breast

Your attention is drawn to the possible association between breast implants and ALCL of the breast.

The United States Food and Drug Administration (FDA) reported in January 2011 that they identified a possible association between breast implants and the development of ALCL, a rare type of non-Hodgkin's lymphoma, in the scar capsule adjacent to the implant. The FDA believed that women with breast implants may have a very low but increased risk of developing ALCL adjacent to the breast implant. In total, the agency was aware of approximately 60 cases of ALCL in women with breast implants worldwide, which was a very small number compared to the 5 to 10 million women who have received breast implants. However, it was not possible for the agency to confirm with statistical certainty that breast implants cause ALCL based on the available information, nor was it possible to identify a specific type of implant (silicone versus saline) which was associated with a lower or higher risk of ALCL. The FDA suggested that additional data is needed to fully understand the possible relationship between ALCL and breast implants; and they did not recommend prophylactic breast implant removal in patients without symptoms or other abnormalities but advised women to monitor their breast implants and contact their doctor if they notice any changes. In its June update, the FDA provided further safety data on silicone gel-filled breast implants and reiterated the need for healthcare professionals to provide routine follow-up to their patients with breast implants.

For details, please refer to the FDA website:

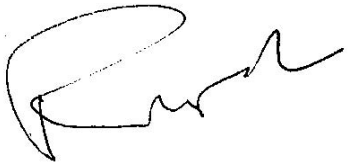
- ALCL In Women with Breast Implants: Preliminary FDA Findings and Analyses
http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239996.htm
- Update on the Safety of Silicone Gel-Filled Breast Implants (2011) - Executive Summary
http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm259866.htm

More recently, the French medical device regulatory authority (AFSSAPS) had also announced in November its first case of ALCL in a woman with silicone gel-filled breast implant and updated their follow-up recommendations for patients with breast implants.

In Hong Kong, while the Department of Health so far has not received any report of ALCL of the breast in patients with breast implants, you are advised to consider the possibility of ALCL when you encounter patients with late onset, persistent peri-implant seroma. In some cases, patients may present with capsular contracture or masses adjacent to the breast implant. In addition, please report cases of ALCL in women with breast implants to the Medical Device Control Office at mdco_alert@dh.gov.hk.

Thank you for your attention.

Yours faithfully,



(Dr. LEUNG Yiu-hong)
for Director of Health