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 213 號
胡忠大廈 18 樓

THE GOVERNMENT OF
THE HONG KONG SPECIAL ADMINISTRATIVE REGION
DEPARTMENT OF HEALTH
MEDICAL DEVICE CONTROL OFFICE
18th FLOOR, WU CHUNG HOUSE,
213 QUEEN'S ROAD EAST, WAN CHAI
HONG KONG

本處檔號 OUR REF.: S/F (4) in DH/MDCO/18-25/2
來函檔號 YOUR REF.:
電 話 TEL. 29618788
傳 真 Fax: 31571286

12 April 2006

Dear Doctor,

Use of Hydrophilic Polyacrylamide Gel (PAAG) for Breast Augmentation

It has come to the notice of Department of Health (DH) that breast augmentation with injection of a material Polyacrylamide Gel (PAAG) has been done in Hong Kong. According to information provided by Consumer Council, over 50 women have received such injection and suffered from complications such as induration, infection, abscess and haematoma. The majority received the injection from Mainland China and about 10% in Hong Kong. At least 6 recipients needed mastectomy due to complications.

Polyacrylamide Gel (PAAG) is a combination of a synthetic polymer (polyacrylamide made from acrylamide monomer) and water. The material is non-biodegradable and cannot be reabsorbed into the body. However, in the manufacture of polyacrylamides, there are acrylamide monomer residues with levels ranging from 0.05 to 5%, depending on the intended use of the product. Acrylamide monomer is a known genetic, reproductive and neural toxicant. Acrylamide is also a probable carcinogen according to the International Agency for Research on Cancer (IARC).

As a medical device, PAAG has been approved as dermal fillers in European Union countries for lip augmentation, cheek and chin remodelling, treatment of wrinkles and correction of scars caused by operation, burns and trauma. As there is little evidence in literature evaluating the safety of PAAG being used for breast augmentation coupled with the adverse incidents reported in Hong Kong and elsewhere, DH does not recommend PAAG to be used for breast augmentation.

You are advised to evaluate carefully the risk of implanting materials for breast augmentation and communicate thoroughly with your clients on potential risks of such procedure. The Department of Health has launched an Adverse Incident Reporting System for users to report on significant adverse incidents in relation to use of medical devices. The soft copy of the form can be downloaded at mdco@dh.gov.hk. A copy is also attached for your easy reference. You are requested to use this form to report adverse incidents in relation to use of PAAG for breast augmentation and we will contact you for further information if necessary.

Thank you for your attention.

Yours sincerely,

(Dr Monica Wong)
for Director of Health

MEDICAL DEVICE CONTROL OFFICE

USER REPORTING FORM – MEDICAL DEVICE INCIDENTS

This is a voluntary report form for reporting suspected problem with a medical device that **may present a hazard**. Submission of this report does not constitute an admission by the reporter of liability for the event and its consequences. It is also not a conclusion that the device caused or contributed to the adverse event. Information of individual reporter and patient will be treated in strict confidence. For enquiries, please contact the MDCO at telephone no. 2961 8788.

MDCO Report No.

(Official Use Only)

I. DEVICE INFORMATION

1.	Device Description			
2.	Brand Name and Model			
3.	Serial No., Batch No., or Lot No.		4. MDCO Listing No. (if known)	

5. Is the device or its packaging available for inspection? ☐ Yes ☐ No

II. SUPPLIER INFORMATION

1.	Company Name			
2.	Name of Contact Person		3. Telephone No.	

4. Have you reported this problem to other parties?

☐ No ☐ Yes, please provide the name of the company, the name of the contact person, the telephone no. and the date:

Name of Company: _____ Name of Contact Person: _____

Telephone No.: _____ Date: _____

III. PROBLEM DESCRIPTION

1. Please give a brief description of the problem:

2. Consequence of the problem: ☐ Death ☐ Serious Injury ☐ Might lead to death or serious injury if recurs ☐ Nil

Please elaborate:

IV. REPORTER INFORMATION

1.	Name of the Organization			
2.	Name of the reporter		3. Position	
4.	Contact Telephone No.		5. Contact Fax. No.	
6.	E-mail Address		7. Date of Report	

V. SUBMISSION OF REPORT

1. By Mail:	Medical Device Control Office 18/F., Wu Chung House 213 Queen's Road East, Wan Chai, HONG KONG	2. By Fax.:	(852) 3157 1286
		3. By E-mail:	mdco_air@dh.gov.hk