Post-market Control of Medical Device

Dr Terence CHEUNG

Medical Device Control Office
Department of Health

Post-market control

Post - market

Medical Device Safety Alert Surveillance System

- DH maintains vigilance on medical device safety alerts issued by overseas authorities and follow up as appropriate

Adverse Event (AE) Reporting

- LRPs (and/or manufacturers) are required to report and investigate adverse events

Tracking of specified MDs

- Tracking of selected high-risk medical devices by LRPs and manufacturers, e.g. active cardiac implants

Post-market control – MD Safety Alert

Source of Information	● Website screening – US FDA / Health Canada / UK MHRA /TGA / Singapore HSA ● National Competent Authority Report (NCAR) ● Traders (Suppliers or manufacturers)
Contact the local supplier/ manufacturer	● Request necessary information ☐ Local distribution of the affected products ☐ Relevant field safety notice ☐ Root cause analysis and proposed corrective actions & preventive actions (CAPA)
Risk Assessment	
Risk Communication	● E-mail notification to relevant stakeholders ● Web message ● Letter to Healthcare Professionals ● Press Release ● Summary of safety alerts
Follow-up Actions (where appropriate)	● Monitor the manufacturer's / local supplier's progress of actions ☐ Notification of affected users ☐ Root cause analysis ☐ CAPA e.g. software upgrade, IFU update etc.

Actions taken by MDCO

- Contact the local supplier/ manufacturer and request the following information
  - Local distribution of the affected products
  - Relevant field safety notice
  - Root cause analysis and proposed corrective actions & preventive actions (CAPA)
- Risk assessment
- Risk communication

Risk communication

- Email notification to relevant stakeholders
- Web message
- Letter to Healthcare Professionals
- Press Release
- Summary of safety alerts

MDCO website

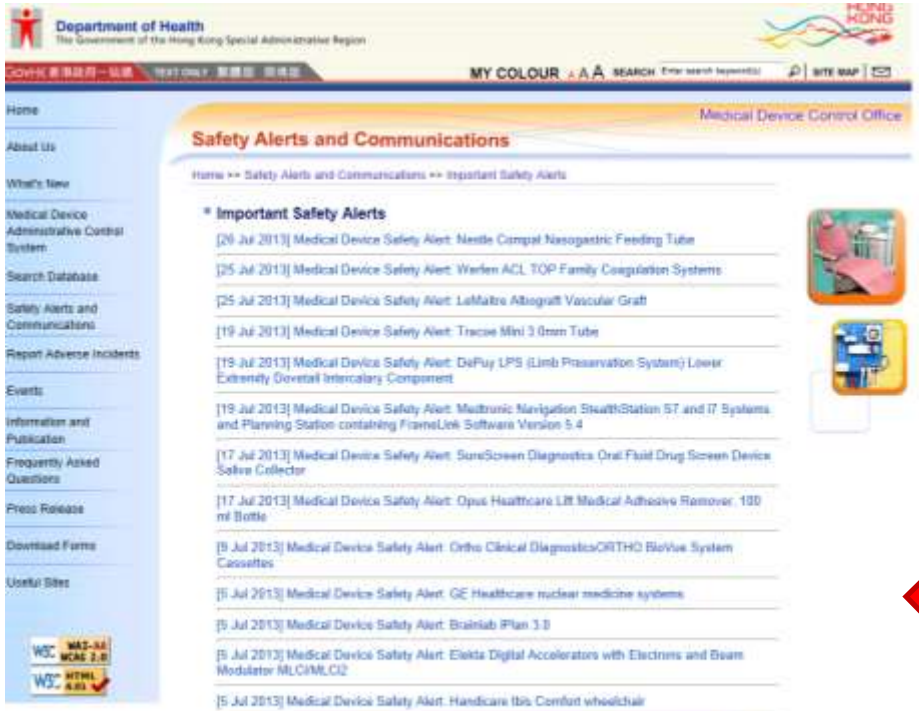
- Summary of Safety Alerts


Major Safety Alerts in July 2013

www.mdco.gov.hk

MDCO website

- Web message



MDCO website

- Letter to Healthcare Professionals

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

THE GOVERNMENTOF THE HONG KONG SPECIAL ADMINISTRATIVE REGION
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 (1) to DH/MDCO/20-10/9
來函檔號 YOUR REF.:
電話 TEL.: 3107 8484
圖文傳真 FAX: 3157 1286

18 January 2013

Dear Healthcare Professionals,

United States Food and Drug Administration's safety recommendations on metal-on-metal hip implants

Further to our letter sent to you on 3 April 2012 on the safety concerns over metal-on-metal (MoM) hip implants (The letter is available at our website: http://www.mdco.gov.hk/english/emp/emp_hp/files/hcp_mom.pdf), your attention is drawn to the safety information and recommendations over MoM hip implants recently issued by the United States Food and Drug Administration (FDA).

In MoM hip implants, the metal ball and the metal cup slide against each other during mobilization causing some tiny metal particles to wear off of the device around the implant, and lead to damage to bone and/or soft tissue surrounding the implant and joint. Soft tissue damage may lead to pain, implant loosening, device failure and the need for revision surgery. Besides, some of the metal ions released may enter the bloodstream causing illnesses.

Based on its latest assessment of the issue, FDA has provided updated safety information and recommendations to patients and health care providers of MoM hip implants, including their benefits and risks, and the outcome of the June 2012 Orthopaedic and Rehabilitation Devices Advisory Panel meeting.

The safety communication provides recommendations for orthopaedic surgeons before the surgery and during patient follow-up, for imaging the implant, monitoring and assessing metal ion levels and considerations for device revision. Besides, recommendations are also given for patients considering hip implants, and those with metal-on-metal hip implants. FDA also advises all healthcare providers to watch out for metal ion adverse events that may occur in patients with MoM hip implant. These events may include general hypersensitivity reaction, cardiomyopathy, neurological changes including sensory changes, psychological status change, renal impairment and thyroid dysfunction. Patients with systemic findings should be advised to consult his or her orthopaedic surgeons for further actions.

竭誠服務客戶樽本素質為先
We are committed to providing client-oriented service

MDCO website

- Press Release

Follow up actions

- Monitor the manufacturer's / local supplier's progress of actions
  - Notification of affected users
  - Root cause analysis
  - CAPA e.g. software upgrade, IFU update etc.

Post-market control – AE Reporting (1)

- **Objectives**
  - To improve the **protection** of health and safety of patients, users and others by disseminating information that may **reduce** the likelihood of, or **prevent** repetition of adverse events associated with medical devices, or alleviated consequences of such repetition
- **Based on GHTF**
- **Types of AE**
  - Death
  - Serious Injury
  - Serious public health concern
  - Others

Post-market control – AE Reporting (2)

- **Adverse Incidents to be reported under the MDACS**
  - The LRP becomes **aware** of information regarding an incident that has occurred with his listed device(s)
  - The LRP's device is **associated** with the incident

Outcomes	Reportable
Death of a patient, user or other person	**YES**
Serious injury of a patient, user or other person	**YES**
No death or serious injury occurred but the incident might lead to death or serious injury of a patient, user or other person of the incident recurs	**YES**
Use errors meeting any of the following criteria ◆ Results in death or serious injury/serious public health concern ◆ A change in trend or a change in pattern of an issue that can potentially lead to death or serious injury or public health concern ◆When the LRP or manufacturer initiates corrective action to prevent death or serious injury or serious public health concern	**YES**

Post-market control – AE Reporting (3)

Source of Information
(LRP / MD supplier or manufacturer / Hospital or healthcare institution / Healthcare professionals, users & patients / Media)

AEs that results in
- Death
- Serious Injury
- Serious Public Health Concern

All other reportable AEs

Report within **10** elapsed calendar days

Report within **30** elapsed calendar days

Medical Device Control Office

Follow-up with the local supplier/ manufacturer
- Local and overseas incident statistics
- Investigation report with root cause analysis
- Proposed corrective actions and preventive actions (CAPA)

Actions taken When Necessary
- Request the local supplier / manufacturer to carry out field safety corrective actions, including recall
- On-site investigation
- Seek expert advice
- Press release

Thank you

Standard questions for safety alerts

1. Do you have any agencies in Hong Kong to represent you regarding the affected product?

2. Have this model (both affected and non-affected products) been distributed in Hong Kong? If affirmative, have the affected product been distributed in Hong Kong?

3. If you have supplied the affected products to Hong Kong, please provide us with the following information:

(a) The letter/information issued for the affected devices;
(b) The list of affected devices distributed in both the public and private healthcare service organizations in Hong Kong (such as public and private hospitals, clinics, health centres, laboratories, auxiliary medical service, etc.);
(c) Whether you have already notified all the affected organizations; and
(d) Your proposed rectification actions and programme, if any.

Standard questions for adverse incidents

To facilitate our investigation, we would be grateful if you could provide us with the following information:

1. Photo(s) of the broken device
2. Sales volume of _____

   - Local
   - Global

3. No. of complaints/ incidents related to_____ in the same period of time

   - Local
   - Global

4. Root cause of the incident
5. Relevant corrective and preventive actions, if applicable.