

衛生署  
醫療儀器管制辦公室  
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**DEPARTMENT OF HEALTH**  
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Dear Healthcare Professionals,

**United States Food and Drug Administration Issued a Medical Device Ban on Powdered Surgeon's Gloves, Powdered Patient Examination Gloves, and Absorbable Powder for Lubricating a Surgeon's Glove**

Your attention is drawn to the medical device ban issued by the United States Food and Drug Administration (FDA) regarding powdered medical gloves. The FDA has determined that Powdered Surgeon's Gloves, Powdered Patient Examination Gloves, and Absorbable Powder for Lubricating a Surgeon's Glove present an unreasonable and substantial risk of illness or injury and that the risk cannot be corrected or eliminated by labelling or a change in labelling. Consequently, the FDA is banning these devices with effect from 18 January 2017.

According to the FDA, a thorough review of all currently available information supports their conclusion that the risks posed by powdered gloves, including health care worker and patient sensitization to natural rubber latex (NRL) allergens, surgical complications related to peritoneal adhesions, and other adverse health events not necessarily related to surgery, such as inflammatory responses to glove powder, are important, material, and significant in relation to the benefit to public health from their continued marketing.

The level and types of risk presented by powdered gloves varies depending on the composition and intended use of the glove. In aggregate, the risks of powdered gloves include severe airway inflammation, hypersensitivity reactions, allergic reactions (including asthma), allergic rhinitis, conjunctivitis, dyspnoea, as well as granuloma and adhesion formation when exposed to internal tissue. The benefits of powdered gloves appear to only include greater ease of donning and doffing, decreased tackiness, and a degree of added comfort, which the FDA believes are nominal when compared to the risks posed by these devices.

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Please refer to the following link for more details about the ban:  
<https://www.federalregister.gov/documents/2016/12/19/2016-30382/banned-devices-powdered-surgeons-gloves-powdered-patient-examination-gloves-and-absorbable-powder>

You are advised to take note of the risks associated with the use of powdered medical gloves, and consider using non-powdered medical gloves as appropriate.

Suspected adverse events related to medical device can be reported to the Medical Device Control Office of the Department of Health. For details, please refer to the website: <http://www.mdco.gov.hk> under "Reporting Adverse Incidents".

Thank you for your attention.

Yours faithfully,

A handwritten signature in black ink, appearing to be 'T. Cheung', written in a cursive style.

(Dr. Terence CHEUNG)

for Director of Health

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