

衛生署
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

本署檔號 Our Ref.: S/F(22) in DH/MDCO/18-25/2

來函檔號 Your Ref.:

電話 Tel.: 3107 8484

傳真 Fax No.: 3157 1286

19 May 2008

Dear Sir/Madam,

Mortality due to In-stent Thrombosis associated with Premature Termination of Dual Antiplatelet Therapy in Patient with Drug-eluting Coronary Stents (DES)

Recently, the Medical Device Control Office of the Department of Health received a report about a patient who died of subacute in-stent thrombosis after being treated with a drug-eluting coronary stent for in-stent restenosis. The patient underwent percutaneous coronary intervention to a coronary artery with a bare metal stent in early 2007 followed by a drug-eluting stent in 2008. Dual anti-platelet therapy was administered to the patient. However, aspirin was terminated due to haematuria about one month after DES implantation. A few days later, the patient developed chest pain and in-stent thrombosis was diagnosed.

Drug-eluting stents are commonly used for the treatment of coronary heart disease. DES release pharmaceutical substance slowly to block cell proliferation so as to reduce the development of restenosis. Its use has been associated with significant reduction of in-stent restenosis and the need for repeat revascularization. However, some studies suggest that the proliferation may be merely delayed. When the drug has been completely eluted, proliferation may occur. DES is associated with a small but higher risk of thrombosis after the first year (by approximately 0.5%), as compared to bare metal stents. Although the risk is still small, fatality might result in up to one-third of patients who develop late thrombosis. The risk of stent thrombosis is particularly high if antiplatelet agent is interrupted or discontinued within the first year after implantation of the stent. Most recent guidelines recommend use of dual antiplatelet therapy for at least 12 months and use of aspirin indefinitely after DES implantation.

/....

竭誠服務 顧客為本 素質為先

We are committed to providing quality client-oriented service