

11 May 2009

Encik Zamanee Bin Abdul Rahman

Medical Device Bureau
Ministry of Health Malaysia
Level 5, Block E6 Complex E
Federal Government Administrative Centre
62590 Putrajaya, Malaysia

RE: Field Safety Notice to customers related to hub crack complaints of Cypher Select™ + Sirolimus-Eluting Stent

Dear Sir / Madam:

This letter is to inform you that Cordis is communicating to its customers about Cypher Select™ + stent complaints related to cracking of the hub.

Description of Event

Cordis has learnt that over last few months there was an increase in the number of complaints relating to the occurrence of cracks in the balloon inflation port hub of Cypher Select™ + Sirolimus –Eluting Coronary Stents currently in the field. Cordis is informing its customers what Cordis has learned from the investigation of these complaints, providing a description of the nature of the hub crack issue and specific directions on how to identify a hub crack prior to use. There have been no patient injuries reported to date due to this event. This is a precautionary step in line with the approach in Europe.

Communications Strategy

Field safety alerts will be sent to Hospitals / Institutions/ Distributors where the affected Cypher Select™ + lots have been distributed.

This communication is being conducted with the full knowledge of the notified body (BSI) and the relevant EU competent authorities. Other regulatory authorities in the Asia Pacific region are also being informed of this issue as required by local regulations.

Please find attached copy of the customer communication which will be sent to customers who have received the affected lots.

Yours sincerely,



Ong Yean Ting
Regulatory Affairs Manager
Johnson & Johnson Medical Malaysia

Encl: Letter to Customers