Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

PROPOSED FINAL DOCUMENT

Title: Guidelines for Adverse Event Reporting of Percutaneous Coronary Intervention (PCI) devices for the Medical Device Manufacturer or its Authorized Representative

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Guidelines for adverse event reporting of Percutaneous Coronary Intervention (PCI) devices[1] for the Medical Device Manufacturer or its Authorized Representative

To be read in conjunction with the AHWP adverse event reporting guidance of ref.

Reportable events[2]	Non-reportable events
• Death or heart failure that is probably or possibly device-related • Cardiac tamponade (pericardial effusion) or cardiogenic shock • Creation of distal air embolus • Difficulty deflating the balloon or other delivery system or withdrawal complications • Difficulty advancing the stent or crossing the lesion, not associated to procedural or patient factor • Acute/ sub-acute stroke/ cerebrovascular accident • Balloon rupture (if used within rated burst pressure). • Adverse reaction associated with the stent material and/ or delivery system materials, drug or polymer carrier if the reaction is not identified in the IFU • Thromotic/ calcific occlusion or stenosis (in-stent and target vessel) or myocardial infarction (suspected to be stent-related) • Incomplete stent apposition/ expansion (malapposition) or excessive recoil • Coronary or stent embolism • In vivo stent damage or deformation or device fragmentation or device fragment emboli migration • Product defect e.g. device deformation (kink, bent, flare strut, break, twisted etc.), packaging compromised, foreign material, labelling issue & etc. • Unanticipated serious injury	• Side branch occlusion[3] • Distal emboli (tissue, thrombotic/ thrombus, plaque)[3] • Acute arterial perforation/ rupture/ dissection, not associated to malfunction of the device[3] • Arrhythmias, including atrial and ventricular[3] • Angina pectoris[3] • Non-fatal bleeding complications, which may require transfusion/ haemorrhage[3] • Coronary artery spasm[3] • Premature stent dislodgement with or without migration[3] • Difficulty advancing the stent or crossing the lesion, linked to procedural or patient factor[3] • Infection – local and/ or systemic[3] • Peripheral vascular or nerve injury[3] • Death or heart failure if there is evidence that it is not device-related • Haematoma at the vascular access site • Hypotension or hypertension stated in the IFU • Fever or infection or pain at insertion site stated in the IFU • Pseudoaneurysm stated in the IFU and not due to malfunction of the device.

AHWP/WG4/F001:2015

[1] PCI (Percutaneous coronary intervention) devices – they are used in treating obstructive coronary artery disease with nonsurgical technique through percutaneous methods (commonly through femoral or radial arteries) e.g. coronary stents, balloons, guide wires

[2] Reportable adverse events must be reported to the relevant regulatory authority (ies) within the required timeframe. Please refer to the AHWP guidance document of ref. AHWP/WG4/F001:2015 for details

[3] Non-reportable events shall be reported when an adverse trend is identified