

Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control

MUSCAT

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سلطنة عُمان
وزارة الصحة
المديرية العامة للصيرورة
والرقابة الدوائية
مَسْفُوط

Discontinuation of Absorb and Absorb GT1 Bioresorbable Vascular Scaffold (BVS) Systems

Please be informed that the M/s. Abbott has issued a Field Safety Notice/Physician Advisory in respect of Absorb and Absorb GT1 Bioresorbable Vascular Scaffold (BVS) Systems manufactured by Abbott in light of the recent concerns over elevated rate of major adverse cardiac events, specifically, myocardial infarction and scaffold thrombosis when compared to patients treated with the Xience metallic drug eluting stent.

Please note the following recommendations / actions:

- Withdraw any available quantities and report to the agent M/s. Waleed Pharmacy.
- Advise patients experiencing any new cardiac symptoms (e.g., irregular heartbeats, chest pain, shortness of breath) to seek clinical care.
- Refer to the BVS physician labeling for information about risks associated with affected product.
- Advise BVS patients to follow the recommendations for dual antiplatelet therapy (DAPT) prescribed by their health care providers.
- Report any adverse events associated with affected product to Abbott Vascular

Healthcare professionals are encouraged to report any adverse events suspected to be associated with the above device or any other medical device to

Director of Medical Device Control
Directorate General of Pharmaceutical Affairs & Drug Control
Ministry of Health, PO Box 393, Muscat, PC-100
Sultanate of Oman



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