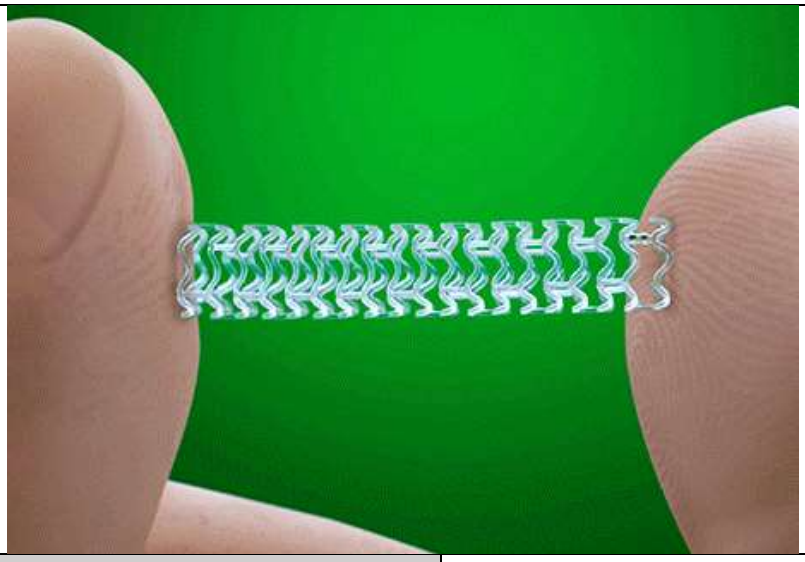
Urgent Safety Communication

Urgent Field Safety Notice of Absorb and Absorb GT1 (BVS) Systems manufactured by Abbott

Device/ Product Name:	Absorb GT1 Bioresorbable Vascular Scaffold Stents
Lot numbers/Serials:	All sizes of Absorb and Absorb GT1 (BVS) Systems
Manufacturer:	Abbott Vascular
Problem:	Saudi FDA would like to bring to your attention that Abbott Vascular issued Urgent Field Safety Notice of the Absorb and Absorb GT1 (BVS) Systems due to studies showing elevated rates of major adverse events, specifically, myocardial infraction and scaffold thrombosis when compared to patients treated with the Xience metallic drug eluting stent.
Recommendation/Actions:	• Follow the instructions for target heart vessel selection (e.g., avoiding BVS use in small heart vessels) and optimal device implantation that are included in BVS physician labeling. • 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.

Devices/Products photo:		
Authorized Representative Details	**Company name:**	**Medical supplies & Services Co.Ltd Mediserv**
	Contact Person:	**Eng. Emad El Alem**
	Phone:	**+966 11 4780555**
	Email:	**e.alem@mediserv.com.sa**

For further information, please see the Physician Advisory issued by the manufacturer. (Click Here)

You **should** be aware of the mentioned risks in the notice and **contact** the Authorized Representative for corrective action.

Healthcare Professionals should **report** any adverse events suspected to be associated with affected devices above (or other Medical Devices) to:

National Center for Medical Devices Reporting.
Medical Devices Sector
Saudi Food and Drug Authority
Postal Address: Saudi Arabia - Saudi Food and Drug Authority (3292)
North Ring Road - Al Nafal Unit (1)
Riyadh 13312 - 6288
Tel: +966 (11) 2038222 Ext: 2406, 2412
Fax: +966 (11) 2757245

For latest published Recalls/Alerts, please visit (NCMDR Website)

Sincerely,
NCMDR Team