


Urgent Update – Action Required

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

Note: [This is an update of the previous Safety Communication sent on 12/6/2017 # \(SG-1712-48-H\)](#)
[Click Here](#)

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 on 03/31/2017, due to recent concerns over elevated rates of major adverse events, specifically, myocardial infraction and scaffold thrombosis.
Recommendation/Actions:	<ul style="list-style-type: none"> • Abbott Vascular after Several meeting with Saudi Food and Drug Authority (SFDA) decide to remove the Absorb Bioresorbable Vascular Scaffold (BVS) and Absorb GT1 BVS system from all healthcare facilities in KSA and is recalling all stock from the market until further notice. • 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.

	<ul style="list-style-type: none"> • 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: MR. Ma'an R. Al Bakr
	Phone: +966 11 4780555 Ext:242
	Email: m.albakr@mediserv.com.sa

For further information, please **see the Physician Advisory attached.**

Below Table is a list of affected Healthcare facilities in KSA.

For the Urgent FSN issued on 03/31/2017 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



Abbott Vascular
3200 Lakeside Dr
Santa Clara, CA 95054

Urgent Field Safety Notice/ Physician Advisory
In the Kingdom of Saudi Arabia

COMMERCIAL NAME: Absorb™ and Absorb GT1™ Bioresorbable Vascular Scaffold (BVS) Systems

Date: January 18, 2018

Type of Action: Physician Advisory

Dear Valued Customer,

Reference to Abbott Vascular release of Urgent Filed Safety Notice / Physician Advisory in March 31, 2017, advises that, effective immediately, the Absorb and Absorb GT1 Bioresorbable Vascular Scaffold (BVS) System will only be available for use in clinical registry and Special Access settings. Data from recent analyses have demonstrated that optimal implantation technique is critical to achieving good clinical outcomes. Limiting use of this device to select hospitals/institutions will enable Abbott to collect additional data and monitor implantation techniques.

In light of recent concerns over elevated rate of major adverse cardiac events, specifically, myocardial infarction and scaffold thrombosis, Abbott Vascular awaits further data to confirm whether improved implantation techniques will mitigate these higher event rates.

Instructions for health professionals

- Abbott Vascular after Several meeting with Saudi Food and Drug Authority (SFDA) decide to remove the Absorb Bioresorbable Vascular Scaffold (BVS) and Absorb GT1 BVS system from all healthcare facilities in KSA and is recalling all stock from the market until further notice.
- 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 the BVS physician labelling.
- Advise patients experiencing any new cardiac symptoms such as irregular heartbeats, chest pain, or shortness of breath to seek clinical care. For more information about risks associated with the BVS, refer to the BVS physician labelling.
- Advise BVS patients to follow the recommendations for DAPT prescribed by their health care providers.
- Report any adverse events related to the BVS.

Abbott Vascular shall cooperate with SFDA to provide additional information to National Center for Medical Device Reporting (NCMDR). If you have any questions or concerns about this issue, contact your Abbott Vascular or Mediserv sales representative.

Thank you for your continued support.

Sincerely,

Country Manager

Ehab EL Nady



Effectiveness Check Form

Customer Account # _____

Account Name _____

Address _____

(Information required for regulatory effectiveness check)

By signing the document, I confirm and acknowledge receipt of this Field Safety Notice that all users of Absorb and Absorb GT1 BVS Systems at this account have been informed of the Physician Advisory.

Customer Name/ Title (print) *Signature* *Date*

Abbott/Mediserv Representative
Name/ Title (print) *Signature* *Date*

This form is to be returned to Mediserv.

Fax this completed form to 011 479 27 25 or scan an e-mail to m.albahr@mediserv.com.sa

TOTAL ABSORB SALES 2012 - 2017

S.No	Accounts	Sold Units/2012	Sold Units/2013	Sold Units/2014	Sold Units/2015	Sold Units/2016	Sold Units/2017	Total Units Sold
1	Johns Hopkins Aram		1		2	2	3	8
2	Al Mouwasat Hospital				3	11		14
3	Al Mana General Hospital		1	16	26	11	2	56
4	Saad Specialist Hospital - Al Khobar		4	2	7			13
5	Saud Al Babtain Cardiac Center		1					1
6	King Fahd Military Medical Complex		14	33	66			113
7	Prince Sultan Cardiac Center - Al Hasa	3	23	31	30			87
8	King Fahad Univ Hospital- Khobar				5	9		14
9	King Fahd Medical City-Riyadh	5	29	60	26	3	3	126
10	Arar Cardiac Center				24	1	2	27
11	Prince Sultan Cardiac Center - Qassim			55	108	161		452
12	Prince Sultan Cardiac Center - Riyadh	4	91	84	64	4		247
13	Suliman Al Habib Al- Takhssi-Riyadh	9	72	20	23		12	136
14	King Fahad National Guard Hospital		91	43	19			153
15	Obeid Hospital Riyadh	6	30					36
16	Dallah Hospital Riyadh			12				12
17	King Khaled University Hospital Riy			30				30
18	Saudi German Hosp. - RYD			2				2
19	King Faisal Specialist Hospital Riyadh				17			17
20	Aseer Central Hospital Abha		9	18	59	20		106
21	International Medical Center			3	2	1		6
22	Al Hada Military Hospital Taif			3	38	32	10	83
23	King Abdul Aziz Military Hospital T			48	52			100
24	King Abdul Aziz University Hospital	6		40	20			66
25	Bugshan Hospital Jeddah		1	1				2
26	King Abdullah Medical City Makkah		19	19	99	32		169
27	King Abdullah Medical Complex			3				3
28	King Fahad Armed Forces Hosp. Jed.		82	117	33			232
29	King Faisal Specialist Hospital Ied Total			23	17			40
30	King Fahad General Hospital			20	63	20	1	104
31	King Khaled National Guard Hospital			2	9	29		40
32	Madinah Cardiac Center		55	70	140	38		303
33	Saudi German Hosp. - JEDDAH			1				1
34	King Khaled Najran Hospital			5	15	30	5	55
35	Ghassan N Pharaon Hospital				1	5	2	8
	TOTAL ABSORB SALES 2012 - 2017	33	523	761	968	409	168	2862