

Fact Sheet for Health Professionals

Clinical Guidance for Physicians regarding patients with the Abbott Vascular Absorb Bioresorbable Vascular Scaffold (BVS) System implanted

This information is intended to provide clinical advice to general practitioners and specialists caring for patients who have had an Abbott Vascular Absorb Bioresorbable Vascular Scaffold (BVS) System [Absorb BVS System] implanted.

Background

The Absorb BVS System is an implantable medical device used as an alternative to stenting coronary arteries and is absorbed by the body over time. The Absorb BVS System has been implanted in clinical trial and non-clinical trial settings. The Absorb BVS System was approved by the TGA in September 2013 (Australian Register of Therapeutic Goods (ARTG) ID 214148).

On 21 April 2017 a Therapeutic Goods Administration (TGA) Class I Urgent Medical Device Recall and Hazard Alert notice was issued for the Absorb BVS System.¹ The Absorb BVS System has been removed from the ARTG and all unused stock is being recalled. The device will continue to be available for use in the clinical trials setting or under the TGA unapproved products pathways - Special Access Scheme and the Authorised Prescriber Scheme.

The TGA advises that Abbott Australasia Pty Ltd has contacted, by letter, physicians who have used the Absorb BVS System, to inform them of the recall procedure.

Risk

A recent analysis of research data has shown an increased risk of major adverse cardiac events, specifically myocardial infarction and scaffold thrombosis, in patients who have had an Absorb BVS System implanted when compared to patients receiving an alternate stent.²⁻³

Patient notification

Every patient who has had an Absorb BVS System implanted within a Queensland Health public hospital will be contacted about the issue by their treating physician. A Fact Sheet for Patients will also be available on the Queensland Health internet site.

Patients who have had the Absorb BVS System implanted are alerted in the Fact Sheet for Patients, to be aware of the signs and symptoms of myocardial infarction and thrombosis. Patients are advised to seek immediate medical treatment if they experience any new cardiac-related symptoms such as irregular heart rate, angina or shortness of breath.

Patient treatment

The ongoing management of patients with the Absorb BVS System may not differ to their current treatment and the Absorb BVS System does not need to be removed.

Patients are advised to follow the healthcare advice provided by their physician. This includes continuing to take medication prescribed. There may be a need to re-evaluate the appropriate anti-platelet therapy considering individual circumstances. Some patients may require an extended duration of dual anti-platelet therapy.

Safety information has also been provided by the Therapeutic Goods Administration on their website.⁴⁻⁵

If you have any further questions or concerns about this issue, contact the patient's relevant health professional.

References that may be of interest

1. Therapeutic Goods Administration Class I Urgent Medical Device Recall and Hazard Alert <http://apps.tga.gov.au/PROD/SARA/arn-detail.aspx?k=RC-2017-RN-00517-1>
2. Ellis, Stephen G; Kereiakes, Dean J; Metzger, Christopher Stone, Gregg W. (2015) Everolimus-Eluting Bioresorbable Scaffolds for Coronary Artery Disease. *The New England Journal of Medicine*. 373(20); pp 1905-1915; DOI: 10.1056/NEJMoa1509038
3. Fornell, Dave. (2017). Bioresorbable Stent Comparable to Xience at Two Year, But With Adverse Trends. *Diagnostic and Interventional Cardiology*, <https://www.dicardiology.com/article/bioresorbable-stent-comparable-xience-two-year-adverse-trends>
4. Therapeutic Goods Administration, 2 May 2017 Safety Alert. Absorb Bioresorbable Vascular Scaffold System. <https://www.tga.gov.au/alert/absorb-bioresorbable-vascular-scaffold-system>
5. Therapeutic Goods Administration 27 March 2017 Safety Alert. Abbott Vascular Absorb Bioresorbable Vascular Scaffold (BVS) <https://www.tga.gov.au/alert/abbott-vascular-absorb-bioresorbable-vascular-scaffold-bvs>