# Fact Sheet for Patients

## Important information for patients who have an Abbott Vascular Absorb Bioresorbable Vascular Scaffold (BVS) System implanted

### What is the issue?

The Abbott Vascular Absorb Bioresorbable Vascular Scaffold (BVS) System (Absorb BVS System) is an implantable medical device that opens blocked 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.

On 21 April 2017 a Therapeutic Good Administration (TGA)[1] Class I Urgent Medical Device Recall and Hazard Alert[2] notice was issued for the Absorb BVS System. This was due to research showing an increased risk of major adverse cardiac events – specifically heart attack and blood clot – in patients implanted with an Absorb BVS System compared to patients treated with an alternate stent.

The Absorb BVS System was approved by the Therapeutic Goods Administration (TGA) for use outside of a clinical trial setting in September 2013. The current recall means that the Absorb BVS System will no longer be available for use except in a clinical trials setting or under special circumstances[3].

### Am I at risk?

If you have been implanted with an Absorb BVS System in a Queensland Health public hospital, either as part of a clinical trial or outside of a clinical trial setting, you will be contacted by your treating clinician as you may be at a slightly higher risk of an adverse cardiac event.

If you have had an alternate stent to the Absorb BVS System implanted, you will not be contacted by your clinician about this issue as it is not related to your stent.

### What do I need to do next if I am at risk?

If you or someone you provide care for has an Absorb BVS System implanted, speak to your health practitioner to ensure you are receiving appropriate treatment and know the signs and symptoms of heart attack and blood clot.

If you experience any new cardiac-related symptoms, such as irregular heartbeats, chest pain, or shortness of breath, seek immediate medical attention.

If you have any further questions or concerns about this issue, talk to your health professional.

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[1] The TGA is responsible for ensuring that therapeutic goods available in Australia are of an acceptable standard and monitors the safety of therapeutic goods in Australia.
[2] Definitions of therapeutic good recall actions:
Class I - Recall action occurs when the product deficiency is potentially life-threatening or could cause a serious risk to health.
Recall - The permanent removal of an affected therapeutic good from supply or use in the market.
Hazard alert - Information issued to healthcare professionals about issues or deficiencies relating to an implanted medical device or biological product and advice about the ongoing management of patients.
[3] Namely, the TGA Special Access Scheme and Authorised Prescriber Scheme.

### Ongoing treatment

Your ongoing management following the implant of the Absorb BVS System may not differ to the current treatment that you are receiving and the Absorb BVS System does not need to be removed.

Follow the healthcare advice provided by your health professional. This includes continuing to take medicines prescribed for your condition. This will reduce the risks of heart attack and blood clot development.

## What interventional cardiology procedures are not affected by this recall?

- Percutaneous Coronary Intervention (PCI) procedures without a stent being implanted
- PCI procedures where a stent other than a Abbott Vascular Absorb Bioresorbable Vascular Scaffold (BVS) System has been implanted.