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December 7, 2015

## **URGENT FIELD SAFETY NOTICE / PHYSICIAN ADVISORY**

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

FSNA-Identifier: December 7, 2015

Type of Action: Advice regarding the use of the device

Dear Valued Abbott Vascular Customer,

Abbott Vascular (AV) is voluntarily issuing this Field Safety Notice (FSN) for all sizes of Absorb™ Bioresorbable Vascular Scaffold (BVS) and Absorb GT1™ BVS Systems.

AV has recently published the results of ABSORB III<sup>1</sup>, a clinical trial that compared the safety and effectiveness of Absorb™ BVS to the XIENCE®, metallic drug eluting stent. Learnings from an analysis of the ABSORB III data and other published data have identified an impact on clinical outcomes following changes to procedural techniques. Implementation of these techniques is expected to facilitate optimal clinical outcomes and reduce the possibility of thrombosis. AV will be updating the Instructions for Use (IFU) with this information. Until the IFU is available, please be aware of the following key changes:

### **When Performing Lesion Sizing and Preparation:**

- In very small vessels, on-line Quantitative Coronary Angiography (QCA) or intravascular imaging is strongly recommended to accurately measure and confirm appropriate vessel sizing.
- Revised sizing instructions:

Target Vessel Diameter Ranges and BVS Diameter to be Used (Quantitative)

Target Vessel Diameter Distal and Proximal	Absorb or Absorb GT1 BVS Diameter to be used
≥ 2.0 mm and < 2.75 mm	2.5 mm
≥ 2.75 mm and < 3.25 mm	3.0 mm
≥ 3.25 mm and ≤ 3.8 mm	3.5 mm

<sup>1</sup>ABSORB III was a prospective, randomized, single-blinded, controlled clinical trial that compared the safety and effectiveness of Absorb™ BVS to the XIENCE®, metallic drug eluting stent. The trial enrolled about 2,000 people with coronary artery disease. The results showed that ABSORB III met its primary endpoint of noninferiority for target lesion failure (TLF). TLF was 7.8 percent for Absorb and 6.1 percent for XIENCE (non-inferiority p<0.007, no statistically significant difference), demonstrating that both devices are comparable in treating people with coronary artery disease CAD. Additionally, the trial found that there was no statistically significant difference in the rate of definite and/or probable stent thrombosis (ST) between the two devices.

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- Note that the use of the BVS scaffold outside the above listed ranges for target vessel diameter can result in sub-optimal apposition of the scaffold to the arterial vessel wall. The safety and efficacy has not been evaluated outside of the ranges of these target vessel diameters. Additionally, sub-optimal apposition may increase the risk of serious adverse events such as thrombosis and death as identified in the Instructions For Use.
- If visual estimation is used: Use the pre-dilatation balloon, when inflated, to assist in sizing the vessel.
- Adequate lesion preparation prior to scaffold implantation is required to ensure safe delivery of the scaffold across the target lesion. It is not recommended to treat patients having a lesion that prevents complete inflation of an angioplasty balloon. It is strongly recommended to achieve a residual stenosis between 20% and 40% after pre-dilatation to enable successful delivery and full expansion of the scaffold.

#### Scaffold Deployment and Final Result:

- Optimal expansion requires that the scaffold be in full contact with the artery wall, which can be facilitated with the use of routine angiography and post dilatation. Intravascular ultrasound (IVUS) or optical coherence tomography (OCT) can be used to confirm scaffold apposition to the artery wall.

To achieve optimal scaffold apposition, post dilatation is strongly recommended, especially for small vessels. When performed, post dilatation should be at high pressure (>16 atm)<sup>2,3</sup> with a non-compliant balloon\*.

<sup>2</sup> Enrico Fabris, MD, Gianluca Calazzo, MD, PhD, Ismail Dogu Kilic, MD, Roberta Serdoz, MD, Gioel Gabrio Secco, MD, Gianfranco Sinagra, MD, Renick Lee, BSC, Nicolas Folh, PhD, and Carlo Di Mario, MD, PhD, FSCAI. Is High Pressure Postdilatation Safe in Bioresorbable Vascular Scaffolds? Optical Coherence Tomography Observations after noncompliant Balloons Inflated at More than 24 Atmospheres. Catheterization and Cardiovascular Interventions 00:00-00 (2015) (published online)

<sup>3</sup> Charis Costopoulos, MD, Azeem Latib, MD, Toru Naganuma, MD, Tadashi Miyazaki, MD, Katsumasa Sato, MD, Filippo Figini, MD, Alessandro Sticchi, MD, Mauro Carlino, MD, Alaide Chieffo, MD, Matteo Montorfano, MD, and Antonio Colombo, MD. Comparison of Early Clinical Outcomes Between ABSORB Bioresorbable Vascular Scaffold and Everolimus-Eluting Stent Implantation in a Real-World Population. Catheterization and Cardiovascular Interventions 00:00-00 (2014) (published online)

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\*Note: Limit choice of non-compliant balloon nominal diameter to be no more than 0.5 mm above the scaffold nominal diameter to stay within the scaffold's maximum expansion limit.

AV would like to reinforce the importance of following the IFU instructions (including ensuring the vessel size is  $\geq 2.0$  and  $\leq 3.8$  mm) and the key changes in this notice to facilitate optimal clinical outcomes and reduce adverse events such as restenosis and thrombosis.

There is no need to return any product to Abbott Vascular. Patients who have had Absorb<sup>TM</sup> and GT1<sup>TM</sup> scaffolds successfully implanted are not affected by this action.

Singapore Health Sciences Authority has been made aware of this action.

Thank you for your attention to this matter. Please sign the Effectiveness Check Form and provide this FSN to those who need to be aware in your organization. For any questions, please contact your AV representative.

Yours sincerely,



Marletta Nicolson  
Country Manager

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Systems

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### Effectiveness Check Form

Customer Account # \_\_\_\_\_

Account Name \_\_\_\_\_

Address \_\_\_\_\_

Phone \_\_\_\_\_

(Information required for regulatory effectiveness check)

I acknowledge receiving and reading the December 7, 2015 Physician  
Advisory Notice

Customer Name/ Title (print) \_\_\_\_\_

Signature \_\_\_\_\_

Date \_\_\_\_\_

#### This form is to be returned to Abbott Vascular

- Return this signed form to your Abbott Vascular Representative, or
- Fax this signed form to +65 6270 2920