



## Urgent FIELD SAFETY NOTICE / PHYSICIAN ADVISORY

Global Alignment of Absorb and Absorb GT1 Indication

July 27, 2016

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

FSCA-Identifier: December 7, 2015 (Update)

Purpose: Global alignment of Absorb and Absorb GT1 Indication - Increase from 2.0 mm to 2.5 mm in minimum target vessel diameter indicated for implantation of this coronary stent.

Target Vessel Diameter and Ranges and Absorb BVS / Absorb GT1 BVS Diameter to be Used  
(Quantitative Imaging)

Target Vessel Diameter Distal and Proximal	Absorb or Absorb GT1 BVS Diameter to be used
≥ 2.5 mm and < 2.75 mm	2.5 mm
≥ 2.75 mm and < 3.25 mm	3.0 mm
≥ 3.25 mm and ≤ 3.75 mm	3.5 mm

### **Attention: Hospital Representative**

Dear Valued Customer:

To align global Indications following the approval of Absorb GT1™ Bioresorbable Vascular Scaffold (BVS) System in the United States, Abbott Vascular is voluntarily updating the earlier Field Safety Notice (FSN) that was initiated on December 7, 2015 (see Attachment 1). Abbott Vascular is issuing this updated FSN for all sizes of Absorb™ BVS and Absorb GT1™ BVS Systems. One or both of these products may be approved in your country.

Abbott Vascular plans to align the Indications for Absorb and Absorb GT1 across all geographies for reference vessel diameter and as such the Indication Section and Target Vessel Diameter and Ranges Table of the IFU are being updated as reflected below. **There is no need to return any product to Abbott Vascular. Patients who have had Absorb™ and GT1™ scaffolds successfully implanted are not affected by this action.**

Until the updated IFU is available, please be aware of the following key supplemental instructions which provide more specificity to the FSN instructions issued in December:

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

##### **Indications**

- The treated lesion length should be less than the nominal scaffolding length, with reference vessel diameters ≥ 2.5 mm and ≤ 3.75 mm (previously ≥ 2.0 mm and ≤ 3.8 mm).

##### **Warnings**

- In small vessels (visually assessed reference vessel diameter ≤ 2.75 mm), on-line QCA or intravascular imaging with intravascular ultrasound or optical coherence tomography is strongly recommended to accurately measure and confirm appropriate vessel sizing (reference vessel diameter ≥ 2.5 mm).**
- If quantitative imaging determines a vessel size < 2.5 mm, do not implant the Absorb BVS / Absorb GT1 BVS. Implantation of the device in vessels < 2.5 mm may lead to an increased risk of adverse events such as scaffold thrombosis.



#### Scaffold Placement - Precautions

- Under-expansion of the scaffold may result in scaffold movement. Care must be taken to properly size the scaffold to ensure that the scaffold is in full contact with the arterial wall upon deflation of the balloon. All efforts should be made to assure that the scaffold is not under dilated. Refer to Clinician Use Information – Sections: Deployment Procedure and Further Expansion of the Deployed Scaffold.

#### Vessel and Lesion Selection

Target Vessel Diameter and Ranges and Absorb BVS / Absorb GT1 BVS Diameter to be Used  
(Quantitative Imaging)

Target Vessel Diameter Distal and	Absorb or Absorb GT1 BVS Diameter to be
$\geq 2.5 \text{ mm}$ and $< 2.75 \text{ mm}$	2.5 mm
$\geq 2.75 \text{ mm}$ and $< 3.25 \text{ mm}$	3.0 mm
$\geq 3.25 \text{ mm}$ and $\leq 3.75 \text{ mm}$	3.5 mm

Abbott would like to reinforce the importance of following the IFU instructions (including ensuring the vessel size is  $\geq 2.5$  and  $\leq 3.75 \text{ mm}$ ) and the key changes in this notice to facilitate optimal clinical outcomes and reduce adverse events such as restenosis and thrombosis.

Again, there is no need to return any product to Abbott Vascular. Patients who have had Absorb™ and GT1™ scaffolds successfully implanted are not affected by this action.

The relevant Regulatory Agencies have been made aware of this advisory.

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 local representative.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Brendan McConnell'.

Brendan McConnell

**National Sales Manager – Synapse Medical**

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ATTACHMENT 1

**URGENT FIELD SAFETY NOTICE / PHYSICIAN ADVISORY**

December 7, 2015

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

FSCA-Identifier: December 7, 2015

Type of Action: Advice regarding the use of the device

**Attention: Hospital Representative**

Dear Valued 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 < 2.5 mm	2.5 mm
≥ 2.5 mm and < 3.0 mm	3.5 mm

- 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:**

<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.

- 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\*.

\*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™ and GT1™ scaffolds successfully implanted are not affected by this action.

The relevant Regulatory Agencies have 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 local representative.

Sincerely,

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<sup>2</sup> Enrico Fabris, MD, Gianluca Caiazzo, MD, PhD, Ismail Dogu Kilic, MD, Roberta Serdoz, MD, Gioel Gabrio Secco, MD, Gianfranco Sinagra, MD, Renick Lee, BSC, Nicolas Foin, PhD, and Carlo Di Mario, MD, PhD, FSCAI. Is High Pressure Postdilation 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, Alade 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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### **Effectiveness Check Form**

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

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

Address \_\_\_\_\_  
\_\_\_\_\_

(Information required for regulatory effectiveness check)

I acknowledge receiving and reading the July 27, 2016 Physician Advisory Notice

Customer Name/ Job Title (print)

Signature

Date

#### **This form is to be returned to:**

Brendan McConnell - **National Sales Manager – Synapse Medical**

Email: [bmcconnell@synapsemedical.ie](mailto:bmcconnell@synapsemedical.ie)

or

Fax: 01 8624606