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# 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: Healthcare Professionals**

Dear Valued Abbott Vascular 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.

*CURRENT Indications on IFU for both Absorb BVS and Absorb GT1 BVS Systems :*
*The Absorb BVS is a temporary scaffold indicated for improving coronary luminal diameter that will eventually resorb and potentially facilitate normalization of vessel function in patients with ischemic heart disease due to de novo native coronary artery lesions. The treated lesion length should be less than the nominal scaffolding length (8 mm, 12 mm, 18 mm, 23 mm, 28 mm) with reference vessel diameters* ***≥ 2.0 mm and ≤ 3.8 mm.***

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.**

*NEW Indications for both Absorb BVS and Absorb GT1 BVS Systems :*
*The Absorb GT1 BVS is a temporary scaffold indicated for improving coronary luminal diameter that will eventually resorb and potentially facilitate normalization of vessel function in patients with ischemic heart disease due to de novo native coronary artery lesions. The treated lesion length should be less than the nominal scaffolding length (8 mm, 12 mm,18 mm, 23 mm, 28 mm) with reference vessel diameters* ***≥ 2.5 mm and ≤ 3.75 mm****.*

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:

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**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 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 |

**Advisory to Healthcare Professionals**

Abbott would like to reinforce the importance of following the IFU instructions (including ensuring the vessel size is ≥ 2.5 and ≤ 3.75 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.

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**Reporting of Adverse Event**

Healthcare Professionals are advised to report any adverse events and/or suspected adverse reactions associated with the use of these devices to the Abbott Vascular representative or to Abbott Laboratories (S) Pte Ltd at Tel: 6270 0760 or Fax: 6270 2920. Alternatively, healthcare professionals may report the adverse events to the Vigilance and Compliance Branch, Health Products Regulation Group at Tel: 6866 3538, Fax: 6478 9069, or report online at www.hsa.gov.sg/ae_online. Events that are reported to Abbott Laboratories (S) Pte Ltd will be investigated and subsequently reported to HSA.

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 Abbott representative.

Sincerely,

[redacted]

Marietta Nicolson
Country Manager

Abbott Laboratories (S) Pte Ltd * Co. Reg No.: 197000076Z *

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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 Abbott Vascular**

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

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