Urgent Field Safety Notice/ Physician Advisory

COMMERCIAL NAME: Absorb and Absorb GT1 Bioresorbable Vascular Scaffold (BVS) Systems
Date: March 31, 2017
Type of Action: Advice regarding the use of the device
Re: Limiting Use of Absorb to Registry

Dear Valued Abbott Vascular Customer,

Abbott Vascular working jointly with the European Regulatory Agencies, (Competent Authorities and our Notified Body) and the medical expert community is pursuing the collection of additional real-world evidence for Absorb Bioresorbable Vascular Scaffold (BVS) and Absorb GT1 BVS Systems in the European market. This will be accomplished via registries in partnership with our key physician community. The registries will capture data from the implantation of all sizes of Absorb Bioresorbable Vascular Scaffold (BVS) and Absorb GT1 BVS Systems in the European market.

Effective May 31, 2017, the device will only be available for use in clinical registry setting at select sites/ institutions that will play a pivotal role in the monitoring of this technology until Summer 2018 at which time the situation will be reviewed.

Limiting use to these registries will enable systematic data collection to address questions raised from recent congresses about three-year clinical data and analysis from ABSORB II regarding the frequency of scaffold thrombosis and the duration of optimal DAPT after implantation. This will also help to demonstrate the impact on clinical outcomes following changes to implantation technique. These important containment measures are being undertaken in light of recent concerns over elevated rate of major adverse cardiac events, specifically, myocardial infarction and scaffold thrombosis, while we await further data to confirm whether improved implantation techniques will mitigate these higher event rates and for the evaluation of longer-term benefits associated with Absorb.

Continued adoption and use of the Absorb and Absorb GT1 BVS Systems over the last few years has resulted in a body of clinical evidence supporting implantation techniques that ensure optimal clinical outcomes. A key learning from this experience includes the importance of proper implantation technique, reflected by the acronym PSP (**P**repare the vessel, **S**ize appropriately, **P**ost-Dilate). Data from recent analyses such as those performed on GHOST-EU European registry[1], FOUR CITIES[2] and Abbott-sponsored studies[3] reinforce the importance of implantation technique in optimizing both short and long-term outcomes. Event rates more recently reported for Absorb across real world studies within Europe, such as those by Dr. Tanaka[4] and by Dr. Brugaletta[1] are consistent with the event rates associated with many currently approved, state of the art, metallic drug eluting stents (DES).

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1 PSP analysis on Ghost EU - Impact of Technique on Clinical Outcomes– S. Brugaletta – TCT 2016
2 Gori, T. 4 Cities Registry, EuroPCR 2015
3 PSP analysis - Impact of Procedural Technique on Long Term Adverse Outcomes in the ABSORB Trials – A First Look – S. Ellis – TCT 2016
4 Tanaka A, Latib A, Kawamoto H, Jabbour RJ, Sato K, Miyazaaki T, Naganuma T, Magieri A, Pagnesi M, Montalto C, Cheiffo A, Carlino M, Montorfano M, Colombo A. Clinical Outcomes of a real world cohort following bioresorbable vascular scaffold implantation utilizing an optimized implantation strategy. EuroIntervention 2016: Jaa-004 2016, doi10422/EIJ-D-16-00247 5 PSP analysis - Impact of Procedural Technique on Long Term Adverse Outcomes in the ABSORB Trials – A First Look – S. Ellis – TCT 2016
6 Gori, T. 4 Cities Registry, EuroPCR 2015
7 Everolimus- eluting bioresorbable vascular scaffolds in patients with coronary artery disease: The ABSORB III trial – G. Stone – TCT 2015
8 ABSORB IV Trial – G. Stone – JIM 2017

In addition, treatment of vessels with reference vessel diameter (RVD) above 2.50mm (above 2.25mm when measured with QCA) has been shown to reduce ST events to levels comparable to XIENCE.[5,6,7] Lastly, data from ABSORB IV[8], the latest randomized control trial in the ABSORB family of trials, showed preliminary ST rates (blinded pooled analysis) that were lower than those in the pooled analysis of ABSORB III both at 30 days and interim 1 year. This data also affirms the importance of avoidance in very small vessels and post-dilatation as factors that may contribute to lower ST rates.

At this time, as we continue building this real world evidence, Abbott Vascular is limiting the use of Absorb BVS in Europe to Clinical Registries to closely monitor implantation technique and vessel sizing and impact on clinical outcomes. Therefore specific next steps will be undertaken for both the registry or non-registry sites within Europe related to training and inventory. No further BVS stents will be provided to non-registry sites after 31st March 2017 and these sites are instructed to cease implants and existing inventory will be removed. For sites that are planned to be part of a registry, participation will be confirmed by May 31, 2017. An Abbott Vascular representative will be in touch with you shortly with additional information specific to your site.

Abbott Vascular is committed to providing high quality products and partnering with you to ensure the best possible clinical outcomes.

Thank you for your continued support.

For more information, please contact your sales representative or Abbott Vascular Customer Support at xxx xxx xxxx

Sincerely,
<country manager>

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TEMPLATE
Modify with country specific contact information

Effectiveness Check Form

Customer Account #_____

Account Name _____

Address _____

_____

(Information required for regulatory effectiveness check)

By checking one of the following boxes, I confirm that all users of Absorb and Absorb GT1 at this account have been informed. I understand that no further BVS stents will be provided to non-registry sites after 31st March 2017.

Option 1:

☐ My site is part of [xxx] Clinical Study/ Registry and I wish to continue to use Absorb/Absorb GT1

☐ My site is not part of a registry and I'm requesting assistance from Abbott Vascular to manage my inventory. I confirm implants have ceased.

Option 2:

☐ My site wants to be considered as a candidate for inclusion in a Registry.

_____ _____ _____

Customer Name/ Title (print) ***Signature*** ***Date***

_____ _____ _____

Abbott Representative
Name/ Title (print) ***Signature*** ***Date***

This form is to be returned to Abbott Vascular

Fax this completed form to XXX XXX XXXX or scan an e-mail to XXXXXXXXXXX