Central Drugs Standard Control Organization

Directorate General of Health Services
Ministry of Health and Family Welfare
Government of India
(Medical Devices and Diagnostics Division)

Food & Drugs Administration Bhavan,
Kotla Road, New Delhi.

File No: 31-307-MD/2017-DC (Re. Reg. 03) Date: 07 APR 2017

MEDICAL DEVICE ALERT

DEVICE

Absorb Bioresorbable Vascular Scaffold (BVS)
Absorb GT1 Bioresorbable Vascular Scaffold (BVS)

BACKGROUND

This office has approved the products viz. Absorb BVS intended to be used as a temporary scaffold indicated for improving coronary luminal diameter that will eventually resorb and potentially facilitate normalization of vessel function artery lesions. The treated lesion length (12 mm, 18 mm, 28 mm) with reference vessel diameters ≥ 2.0 mm and ≤ 3.8 and Absorb GT1 BVS intended to be used as 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 based on the documents submitted by the Indian agent/manufacturer

The Indian agent M/s Abbott Healthcare Pvt. Ltd., has informed this office that the manufacturer has initiated a Field Safety Notice in European countries to communicate that product use will be limited to established post-market registries to facilitate the collection of real-world evidence for Absorb BVS and Absorb GT1 BVS systems.

The registries will capture data from the implantation of all sizes of Absorb Bioresorbable Vascular Scaffold (BVS) and Absorb GT1 Bioresorbable Vascular Scaffold (BVS) in the European market.

PROBLEM

Based on the three years clinical data analysis from ABSORB II it has been observed that there is an over elevated rate of major adverse cardiac events, specifically, myocardial infarction and scaffold thrombosis.

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ACTION BY

- Medical Directors/Healthcare professionals
- Distributors and the Users
- Staff involved in the management of patients.

ADVERSE EFFECTS

Patients and Healthcare professionals are advised to report adverse events suspected to be associated with the use of Absorb Bioresorbable Vascular Scaffold (BVS) and Absorb GT1 Bioresorbable Vascular Scaffold (BVS) to the manufacturer, Importer and CDSCO.

CONTACTS

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