BIOSENSORS
INTERNATIONAL™

Urgent Field Safety Notice

Device Model: Axxess™ Drug Eluting Coronary Bifurcation Stent System (AXBF-4009)
Lot numbers: W13090159 , W13080132
Field Safety Corrective Action

Date: 11th December 2013

Attention:
Interventional Cardiology departments, Interventional Cardiologists

Details on affected devices:
Biosensors has identified a potential issue with a specific subset of the Axxess™ Drug Eluting Coronary Bifurcation Stent System (**AXBF-4009**) where deployment complication may occur.

The affected product is the **4.0x9mm** model of the Axxess™ Drug Eluting Coronary Bifurcation Stent System (**AXBF-4009**). The affected lots are **W13090159** and **W13080132**.

Description of the problem:
Several cases with deployment difficulty have been reported to Biosensors International Group to date. Physicians in these cases found it either difficult or impossible to pull back the deployment actuator. In most cases, the stent was successfully deployed, resulting in a positive clinical patient outcome. In the remaining cases, deployment was aborted and patients were administered alternative treatment, with positive patient outcomes. There have been no reports of adverse patient events.

This type of issue could potentially lead to a sub-optimal deployment resulting in serious deterioration to a patient's health. This has led Biosensors to conduct a voluntary recall of the affected products while our investigation is ongoing to address the reported issue.

Actions to be taken by users:
Our records show that you have received stocks of the affected devices and Biosensors is requesting you to take the following actions:

- For all successfully implanted devices, no action is necessary and patients should continue to be managed in accordance with your standard patient management protocol.
- For the affected model AXBF-4009 (lot numbers: W13090159 and W13080132), immediately quarantine any remaining stock of products.

Biosensors Europe SA
Rue de Lausanne 29
CH – 1110 MORGES
SWITZERLAND
Tel: +41 (0) 21 804 80 00 Fax: +41 (0) 21 804 80 02
www.biosensors.com