

---

**Urgent Field Safety Notice**

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

---

**Date: 11<sup>th</sup> 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.



- Mark the checkbox on the enclosed FSCA Response Form, provide the additional information requested, and send the completed form immediately to **fax number: +41 21 804 80 01** or **email: [fieldsafetynotice@biosensors.com](mailto:fieldsafetynotice@biosensors.com)**
- On receipt of the completed FSCA Response Form, a Biosensors representative will contact you to arrange return of the affected stock.

**Actions to be taken by distributors:**

- If you are a distributor, please provide this Field Safety Notice immediately to all your customers who have received products from the affected lot numbers, as stated above. Please send your customers the following documents:
  - A copy of this Field Safety Notice
  - A copy of the FSCA Response Form
- The FSCA Response Form should be completed by your customer and returned to you. Please forward all completed FSCA Response Forms to Biosensors at **fax number: +41 21 804 80 01** or **email: [fieldsafetynotice@biosensors.com](mailto:fieldsafetynotice@biosensors.com)**
- Please also identify and quarantine any remaining stock from the affected batch numbers in your warehouse, complete the FSCA Response Form and forward it to **fax number: +41 21 804 80 01** or **email: [fieldsafetynotice@biosensors.com](mailto:fieldsafetynotice@biosensors.com)**
- On receipt of the completed FSCA Response Form, a Biosensors representative will contact you to arrange return of the affected stock.

**Transmission of this Field Safety Notice:**

This notice must be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Please transfer this notice to other organizations on which this action has an impact, if appropriate.

The undersigned confirms that this Field Safety Notice has been provided to the relevant national competent authorities.

A handwritten signature in black ink, appearing to read 'Debashis Dutta'.

Debashis Dutta  
VP Quality Assurance